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Dossier zur Nutzenbewertung gemäß § 35a SGB V

Relugolix / Estradiol / Norethisteronacetat (Ryeqo®)

Gedeon Richter Pharma GmbH

Modul 4 A – Anhang 4-G

Symptomatische Therapie von Uterusmyomen

Medizinischer Nutzen und
medizinischer Zusatznutzen,
Patientengruppen mit therapeutisch
bedeutsamem Zusatznutzen

Stand: 27.08.2021

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Table EFF.RCMP24ET.MITT.Pooled.S4: Proportion of Women in the Relugolix + E2/NETA Group Versus the Placebo Group who Achieve an MBL Volume of < 80 mL and at least a 50% Reduction from Baseline MBL Volume Over the Last 35 Days of Treatment, as Measured by the Alkaline Hematin Method, by Subgroup (mITT Population)

Study: Pooled

Treatment	N	n (%)	OR[1] [95% CI]	RR[2] [95% CI]	RD[3] [95% CI]	p-value[4]	p-value (int)[5]
Maximum NRS Pain Score at Baseline							
< 4							0.0624
Relugolix+E2/NETA	73	55 (75.3)	28.24	7.80	0.66	<.0001	
Placebo	62	6 (9.7)	[10.42;76.49]	[3.60;16.90]	[0.53;0.78]		
>= 4							
Relugolix+E2/NETA	177	126 (71.2)	10.29	3.67	0.52	<.0001	
Placebo	190	37 (19.5)	[6.33;16.72]	[2.71;4.98]	[0.43;0.61]		
Missing							
Relugolix+E2/NETA	3	2 (66.7)	NC	NC	NC	NC	
Placebo	4	0	[NC;NC]	[NC;NC]	[NC;NC]		

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group.
MBL volume was calculated as the sum of MBL volume from all feminine products (validated, unauthorized and unvalidated) as assessed by the alkaline hematin method at Week 24/End of Treatment Visit.
[1] OR (95% CI) based on a logistic regression model adjusting for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates.
[2] RR (95% CI) based on a Cochran-Mantel-Haenszel approach stratified by study.
[3] RD (95% CI) based on a Mantel-Haenszel approach stratified by study. 95% CIs are based on the approximation to the normal distribution using the Sato estimator for the standard error.
[4] P-value based on a Cochran-Mantel-Haenszel test stratified by study.
[5] Interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the OR (95% CI). Missing subgroup levels are not included in estimation of the interaction p-value.
A continuity correction is applied in estimation of the OR, RR and p-value if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum. No continuity correction is applied in the estimation of the RD.
The reference group for the OR, RR and RD is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with an event; OR: Odds ratio; RR: Risk ratio; RD: Risk difference; CI: Confidence interval; int: p-value for interaction; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; NC: Not calculated.

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Table EFF.RCMP24ET.MITT.Pooled.S6: Proportion of Women in the Relugolix + E2/NETA Group Versus the Placebo Group who Achieve an MBL Volume of < 80 mL and at least a 50% Reduction from Baseline MBL Volume Over the Last 35 Days of Treatment, as Measured by the Alkaline Hematin Method, by Subgroup (mITT Population)

Study: Pooled

Treatment	**N**	**n (%)**	**OR[1] [95% CI]**	**RR[2] [95% CI]**	**RD[3] [95% CI]**	**p-value[4]**	**p-value (int)[5]**
Geographic Region I							
North America							
Relugolix+E2/NETA	191	132 (69.1)	11.37	4.19	0.53	<.0001	0.2206
Placebo	194	32 (16.5)	[6.97;18.53]	[3.01;5.83]	[0.44;0.61]		
Rest of World							
Relugolix+E2/NETA	62	51 (82.3)	21.57	4.60	0.64	<.0001	
Placebo	62	11 (17.7)	[8.57;54.24]	[2.67;7.92]	[0.51;0.78]		

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group.
MBL volume was calculated as the sum of MBL volume from all feminine products (validated, unauthorized and unvalidated) as assessed by the alkaline hematin method at Week 24/End of Treatment Visit.
[1] OR (95% CI) based on a logistic regression model adjusting for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates.
[2] RR (95% CI) based on a Cochran-Mantel-Haenszel approach stratified by study.
[3] RD (95% CI) based on a Mantel-Haenszel approach stratified by study. 95% CIs are based on the approximation to the normal distribution using the Sato estimator for the standard error.
[4] P-value based on a Cochran-Mantel-Haenszel test stratified by study.
[5] Interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the OR (95% CI). Missing subgroup levels are not included in estimation of the interaction p-value.
A continuity correction is applied in estimation of the OR, RR and p-value if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum. No continuity correction is applied in the estimation of the RD.
The reference group for the OR, RR and RD is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with an event; OR: Odds ratio; RR: Risk ratio; RD: Risk difference; CI: Confidence interval; int: p-value for interaction; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; NC: Not calculated.

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Table EFF.RCMP24ET.MITT.Pooled.S7: Proportion of Women in the Relugolix + E2/NETA Group Versus the Placebo Group who Achieve an MBL Volume of < 80 mL and at least a 50% Reduction from Baseline MBL Volume Over the Last 35 Days of Treatment, as Measured by the Alkaline Hematin Method, by Subgroup (mITT Population)

Study: Pooled

Treatment	N	n (%)	OR[1] [95% CI]	RR[2] [95% CI]	RD[3] [95% CI]	p-value[4]	p-value (int)[5]
Geographic Region II							
Europe							0.2230
Relugolix+E2/NETA	41	35 (85.4)	25.15 [7.88;80.27]	4.60 [2.37;8.92]	0.66 [0.50;0.83]	<.0001	
Placebo	42	8 (19.0)					
Rest of World (including the US)							
Relugolix+E2/NETA	212	148 (69.8)	11.83 [7.42;18.85]	4.26 [3.11;5.84]	0.53 [0.45;0.61]	<.0001	
Placebo	214	35 (16.4)					

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group.
MBL volume was calculated as the sum of MBL volume from all feminine products (validated, unauthorized and unvalidated) as assessed by the alkaline hematin method at Week 24/End of Treatment Visit.
[1] OR (95% CI) based on a logistic regression model adjusting for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates.
[2] RR (95% CI) based on a Cochran-Mantel-Haenszel approach stratified by study.
[3] RD (95% CI) based on a Mantel-Haenszel approach stratified by study. 95% CIs are based on the approximation to the normal distribution using the Sato estimator for the standard error.
[4] P-value based on a Cochran-Mantel-Haenszel test stratified by study.
[5] Interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the OR (95% CI). Missing subgroup levels are not included in estimation of the interaction p-value.
A continuity correction is applied in estimation of the OR, RR and p-value if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum. No continuity correction is applied in the estimation of the RD.
The reference group for the OR, RR and RD is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with an event; OR: Odds ratio; RR: Risk ratio; RD: Risk difference; CI: Confidence interval; int: p-value for interaction; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; NC: Not calculated.

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Table EFF.RCMP24ET.MITT.Pooled.S3: Proportion of Women in the Relugolix + E2/NETA Group Versus the Placebo Group who Achieve an MBL Volume of < 80 mL and at least a 50% Reduction from Baseline MBL Volume Over the Last 35 Days of Treatment, as Measured by the Alkaline Hematin Method, by Subgroup (mITT Population)

Study: Pooled

Treatment	N	n (%)	OR[1] [95% CI]	RR[2] [95% CI]	RD[3] [95% CI]	p-value[4]	p-value (int)[5]
Uterine Volume at Baseline (cm3)							
< 300 cm3							
Relugolix+E2/NETA	148	113 (76.4)	16.70	4.69	0.60	<.0001	0.2301
Placebo	129	21 (16.3)	[9.14;30.52]	[3.14;7.00]	[0.51;0.69]		
>= 300 cm3							
Relugolix+E2/NETA	104	70 (67.3)	9.85	3.88	0.50	<.0001	
Placebo	127	22 (17.3)	[5.32;18.25]	[2.59;5.80]	[0.39;0.61]		
Missing							
Relugolix+E2/NETA	1	0	NC	NC	NC	NC	
Placebo	0	0	[NC;NC]	[NC;NC]	[NC;NC]		

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group.
MBL volume was calculated as the sum of MBL volume from all feminine products (validated, unauthorized and unvalidated) as assessed by the alkaline hematin method at Week 24/End of Treatment Visit.
[1] OR (95% CI) based on a logistic regression model adjusting for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates.
[2] RR (95% CI) based on a Cochran-Mantel-Haenszel approach stratified by study.
[3] RD (95% CI) based on a Mantel-Haenszel approach stratified by study. 95% CIs are based on the approximation to the normal distribution using the Sato estimator for the standard error.
[4] P-value based on a Cochran-Mantel-Haenszel test stratified by study.
[5] Interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the OR (95% CI). Missing subgroup levels are not included in estimation of the interaction p-value.
A continuity correction is applied in estimation of the OR, RR and p-value if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum. No continuity correction is applied in the estimation of the RD.
The reference group for the OR, RR and RD is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with an event; OR: Odds ratio; RR: Risk ratio; RD: Risk difference; CI: Confidence interval; int: p-value for interaction; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; NC: Not calculated.

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Table EFF.RCMP24ET.MITT.Pooled.S5: Proportion of Women in the Relugolix + E2/NETA Group Versus the Placebo Group who Achieve an MBL Volume of < 80 mL and at least a 50% Reduction from Baseline MBL Volume Over the Last 35 Days of Treatment, as Measured by the Alkaline Hematin Method, by Subgroup (mITT Population)

Study: Pooled

Treatment	N	n (%)	OR[1] [95% CI]	RR[2] [95% CI]	RD[3] [95% CI]	p-value[4]	p-value (int)[5]
MBL Volume at Baseline (mL)							
< 225 mL							0.2364
Relugolix+E2/NETA	164	124 (75.6)	15.87	4.61	0.59	<.0001	
Placebo	171	28 (16.4)	[9.25;27.23]	[3.25;6.54]	[0.51;0.68]		
>= 225 mL							
Relugolix+E2/NETA	89	59 (66.3)	9.22	3.76	0.49	<.0001	
Placebo	85	15 (17.6)	[4.53;18.76]	[2.32;6.09]	[0.36;0.61]		

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group.
MBL volume was calculated as the sum of MBL volume from all feminine products (validated, unauthorized and unvalidated) as assessed by the alkaline hematin method at Week 24/End of Treatment Visit.
[1] OR (95% CI) based on a logistic regression model adjusting for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates.
[2] RR (95% CI) based on a Cochran-Mantel-Haenszel approach stratified by study.
[3] RD (95% CI) based on a Mantel-Haenszel approach stratified by study. 95% CIs are based on the approximation to the normal distribution using the Sato estimator for the standard error.
[4] P-value based on a Cochran-Mantel-Haenszel test stratified by study.
[5] Interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the OR (95% CI). Missing subgroup levels are not included in estimation of the interaction p-value.
A continuity correction is applied in estimation of the OR, RR and p-value if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum. No continuity correction is applied in the estimation of the RD.
The reference group for the OR, RR and RD is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with an event; OR: Odds ratio; RR: Risk ratio; RD: Risk difference; CI: Confidence interval; int: p-value for interaction; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; NC: Not calculated.

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Table EFF.RCMP24ET.MITT.Pooled.S8: Proportion of Women in the Relugolix + E2/NETA Group Versus the Placebo Group who Achieve an MBL Volume of < 80 mL and at least a 50% Reduction from Baseline MBL Volume Over the Last 35 Days of Treatment, as Measured by the Alkaline Hematin Method, by Subgroup (mITT Population)

Study: Pooled

Treatment	N	n (%)	OR[1] [95% CI]	RR[2] [95% CI]	RD[3] [95% CI]	p-value[4]	p-value (int)[5]
Ethnicity							
Hispanic or Latino							0.3978
Relugolix+E2/NETA	52	41 (78.8)	9.50	2.66	0.48	<.0001	
Placebo	55	15 (27.3)	[3.88;23.27]	[1.69;4.18]	[0.31;0.65]		
Not Hispanic or Latino							
Relugolix+E2/NETA	197	139 (70.6)	14.90	5.04	0.57	<.0001	
Placebo	199	28 (14.1)	[8.98;24.71]	[3.53;7.20]	[0.49;0.65]		
Not reported							
Relugolix+E2/NETA	4	3 (75.0)	NC	NC	NC	NC	
Placebo	2	0	[NC;NC]	[NC;NC]	[NC;NC]		

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group.
MBL volume was calculated as the sum of MBL volume from all feminine products (validated, unauthorized and unvalidated) as assessed by the alkaline hematin method at Week 24/End of Treatment Visit.
[1] OR (95% CI) based on a logistic regression model adjusting for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates.
[2] RR (95% CI) based on a Cochran-Mantel-Haenszel approach stratified by study.
[3] RD (95% CI) based on a Mantel-Haenszel approach stratified by study. 95% CIs are based on the approximation to the normal distribution using the Sato estimator for the standard error.
[4] P-value based on a Cochran-Mantel-Haenszel test stratified by study.
[5] Interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the OR (95% CI). Not reported subgroup levels are not included in estimation of the interaction p-value.
A continuity correction is applied in estimation of the OR, RR and p-value if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum. No continuity correction is applied in the estimation of the RD.
The reference group for the OR, RR and RD is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with an event; OR: Odds ratio; RR: Risk ratio; RD: Risk difference; CI: Confidence interval; int: p-value for interaction; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; NC: Not calculated.

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Table EFF.RCMP24ET.MITT.Pooled.S9: Proportion of Women in the Relugolix + E2/NETA Group Versus the Placebo Group who Achieve an MBL Volume of < 80 mL and at least a 50% Reduction from Baseline MBL Volume Over the Last 35 Days of Treatment, as Measured by the Alkaline Hematin Method, by Subgroup (mITT Population)

Study: Pooled

Treatment	N	n (%)	OR[1] [95% CI]	RR[2] [95% CI]	RD[3] [95% CI]	p-value[4]	p-value (int)[5]
Race							
Black/African American							0.7256
Relugolix+E2/NETA	122	77 (63.1)	11.03	4.69	0.50	<.0001	
Placebo	141	19 (13.5)	[6.00;20.26]	[3.02;7.28]	[0.39;0.60]		
White							
Relugolix+E2/NETA	122	99 (81.1)	15.47	3.72	0.59	<.0001	
Placebo	105	23 (21.9)	[8.08;29.61]	[2.57;5.38]	[0.49;0.70]		
Asian							
Relugolix+E2/NETA	1	1 (100.0)	NC	NC	NC	NC	
Placebo	3	1 (33.3)	[NC;NC]	[NC;NC]	[NC;NC]		
Others							
Relugolix+E2/NETA	5	3 (60.0)	8.74	4.41	0.69	0.0905	
Placebo	6	0	[0.66;115.36]	[0.67;29.11]	[0.33;1.00]		
Not reported							
Relugolix+E2/NETA	3	3 (100.0)	NC	NC	NC	NC	
Placebo	1	0	[NC;NC]	[NC;NC]	[NC;NC]		

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group.
MBL volume was calculated as the sum of MBL volume from all feminine products (validated, unauthorized and unvalidated) as assessed by the alkaline hematin method at Week 24/End of Treatment Visit.
[1] OR (95% CI) based on a logistic regression model adjusting for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates.
[2] RR (95% CI) based on a Cochran-Mantel-Haenszel approach stratified by study.
[3] RD (95% CI) based on a Mantel-Haenszel approach stratified by study. 95% CIs are based on the approximation to the normal distribution using the Sato estimator for the standard error.
[4] P-value based on a Cochran-Mantel-Haenszel test stratified by study.
[5] Interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the OR (95% CI). Not reported subgroup levels are not included in estimation of the interaction p-value.
A continuity correction is applied in estimation of the OR, RR and p-value if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum. No continuity correction is applied in the estimation of the RD.
The reference group for the OR, RR and RD is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with an event; OR: Odds ratio; RR: Risk ratio; RD: Risk difference; CI: Confidence interval; int: p-value for interaction; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; NC: Not calculated.

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Table EFF.RCMP24ET.MITT.Pooled.S1: Proportion of Women in the Relugolix + E2/NETA Group Versus the Placebo Group who Achieve an MBL Volume of < 80 mL and at least a 50% Reduction from Baseline MBL Volume Over the Last 35 Days of Treatment, as Measured by the Alkaline Hematin Method, by Subgroup (mITT Population)

Study: Pooled

Treatment	N	n (%)	OR[1] [95% CI]	RR[2] [95% CI]	RD[3] [95% CI]	p-value[4]	p-value (int)[5]
Age (years)							
< 40 years							0.8240
Relugolix+E2/NETA	62	41 (66.1)	11.89 [5.20;27.20]	4.67 [2.63;8.30]	0.52 [0.38;0.66]	<.0001	
Placebo	78	11 (14.1)					
>= 40 years							
Relugolix+E2/NETA	191	142 (74.3)	13.28 [8.03;21.95]	4.13 [2.99;5.72]	0.56 [0.48;0.65]	<.0001	
Placebo	178	32 (18.0)					

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group.
MBL volume was calculated as the sum of MBL volume from all feminine products (validated, unauthorized and unvalidated) as assessed by the alkaline hematin method at Week 24/End of Treatment Visit.
[1] OR (95% CI) based on a logistic regression model adjusting for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates.
[2] RR (95% CI) based on a Cochran-Mantel-Haenszel approach stratified by study.
[3] RD (95% CI) based on a Mantel-Haenszel approach stratified by study. 95% CIs are based on the approximation to the normal distribution using the Sato estimator for the standard error.
[4] P-value based on a Cochran-Mantel-Haenszel test stratified by study.
[5] Interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the OR (95% CI). Not reported subgroup levels are not included in estimation of the interaction p-value.
A continuity correction is applied in estimation of the OR, RR and p-value if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum. No continuity correction is applied in the estimation of the RD.
The reference group for the OR, RR and RD is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with an event; OR: Odds ratio; RR: Risk ratio; RD: Risk difference; CI: Confidence interval; int: p-value for interaction; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; NC: Not calculated.

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Table EFF.RCMP24ET.MITT.Pooled.S2: Proportion of Women in the Relugolix + E2/NETA Group Versus the Placebo Group who Achieve an MBL Volume of < 80 mL and at least a 50% Reduction from Baseline MBL Volume Over the Last 35 Days of Treatment, as Measured by the Alkaline Hematin Method, by Subgroup (mITT Population)

Study: Pooled

Treatment	N	n (%)	OR[1] [95% CI]	RR[2] [95% CI]	RD[3] [95% CI]	p-value[4]	p-value (int)[5]
BMI (kg/m2) at Baseline							
< 30							0.9472
Relugolix+E2/NETA	119	86 (72.3)	13.13	4.31	0.55	<.0001	
Placebo	115	19 (16.5)	[6.95;24.78]	[2.83;6.56]	[0.45;0.66]		
>= 30							
Relugolix+E2/NETA	133	96 (72.2)	12.75	4.24	0.55	<.0001	
Placebo	141	24 (17.0)	[7.13;22.81]	[2.90;6.19]	[0.45;0.65]		
Missing							
Relugolix+E2/NETA	1	1 (100.0)	NC	NC	NC	NC	
Placebo	0	0	[NC;NC]	[NC;NC]	[NC;NC]		

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group.
MBL volume was calculated as the sum of MBL volume from all feminine products (validated, unauthorized and unvalidated) as assessed by the alkaline hematin method at Week 24/End of Treatment Visit.
[1] OR (95% CI) based on a logistic regression model adjusting for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates.
[2] RR (95% CI) based on a Cochran-Mantel-Haenszel approach stratified by study.
[3] RD (95% CI) based on a Mantel-Haenszel approach stratified by study. 95% CIs are based on the approximation to the normal distribution using the Sato estimator for the standard error.
[4] P-value based on a Cochran-Mantel-Haenszel test stratified by study.
[5] Interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the OR (95% CI). Missing subgroup levels are not included in estimation of the interaction p-value.
A continuity correction is applied in estimation of the OR, RR and p-value if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum. No continuity correction is applied in the estimation of the RD.
The reference group for the OR, RR and RD is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with an event; OR: Odds ratio; RR: Risk ratio; RD: Risk difference; CI: Confidence interval; int: p-value for interaction; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; NC: Not calculated.

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1.1.1.1 Proportion of Women in the Relugolix + E2/NETA Group Versus the Placebo Group who Achieve an MBL Volume of < 80 mL Over the Last 35 Days of Treatment, as Measured by the Alkaline Hematin Method, by Subgroup (mITT Population)

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Table EFF.RL8024ET.MITT.Pooled.S7: Proportion of Women in the Relugolix + E2/NETA Group Versus the Placebo Group who Achieve an MBL Volume of < 80 mL Over the Last 35 Days of Treatment, as Measured by the Alkaline Hematin Method, by Subgroup (mITT Population)

Study: Pooled

Treatment	**N**	**n (%)**	**OR[1] [95% CI]**	**RR[2] [95% CI]**	**RD[3] [95% CI]**	**p-value[4]**	**p-value (int)[5]**
Geographic Region II							
Europe							0.2584
Relugolix+E2/NETA	41	36 (87.8)	18.40	3.11	0.59	<.0001	
Placebo	42	12 (28.6)	[5.81;58.25]	[1.88;5.15]	[0.42;0.77]		
Rest of World (including the US)							
Relugolix+E2/NETA	212	153 (72.2)	9.23	3.27	0.50	<.0001	
Placebo	214	47 (22.0)	[5.93;14.36]	[2.51;4.27]	[0.42;0.58]		

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group.
MBL volume was calculated as the sum of MBL volume from all feminine products (validated, unauthorized and unvalidated) as assessed by the alkaline hematin method at Week 24/End of Treatment Visit.
[1] OR (95% CI) based on a logistic regression model adjusting for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates.
[2] RR (95% CI) based on a Cochran-Mantel-Haenszel approach stratified by study.
[3] RD (95% CI) based on a Mantel-Haenszel approach stratified by study. 95% CIs are based on the approximation to the normal distribution using the Sato estimator for the standard error.
[4] P-value based on a Cochran-Mantel-Haenszel test stratified by study.
[5] Interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the OR (95% CI).
A continuity correction is applied in estimation of the OR, RR and p-value if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum. No continuity correction is applied in the estimation of the RD.
The reference group for the OR, RR and RD is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with an event; OR: Odds ratio; RR: Risk ratio; RD: Risk difference; CI: Confidence interval; int: p-value for interaction; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; NC: Not calculated.

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Table EFF.RL8024ET.MITT.Pooled.S4: Proportion of Women in the Relugolix + E2/NETA Group Versus the Placebo Group who Achieve an MBL Volume of < 80 mL Over the Last 35 Days of Treatment, as Measured by the Alkaline Hematin Method, by Subgroup (mITT Population)

Study: Pooled

Treatment	N	n (%)	OR[1] [95% CI]	RR[2] [95% CI]	RD[3] [95% CI]	p-value[4]	p-value (int)[5]
Maximum NRS Pain Score at Baseline							
< 4							
Relugolix+E2/NETA	73	56 (76.7)	13.55	3.92	0.57	<.0001	0.3690
Placebo	62	12 (19.4)	[5.89;31.15]	[2.33;6.60]	[0.43;0.71]		
>= 4							
Relugolix+E2/NETA	177	131 (74.0)	8.78	3.01	0.49	<.0001	
Placebo	190	47 (24.7)	[5.47;14.07]	[2.31;3.91]	[0.41;0.58]		
Missing							
Relugolix+E2/NETA	3	2 (66.7)	NC	NC	NC	NC	
Placebo	4	0	[NC;NC]	[NC;NC]	[NC;NC]		

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group.
MBL volume was calculated as the sum of MBL volume from all feminine products (validated, unauthorized and unvalidated) as assessed by the alkaline hematin method at Week 24/End of Treatment Visit.
[1] OR (95% CI) based on a logistic regression model adjusting for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates.
[2] RR (95% CI) based on a Cochran-Mantel-Haenszel approach stratified by study.
[3] RD (95% CI) based on a Mantel-Haenszel approach stratified by study. 95% CIs are based on the approximation to the normal distribution using the Sato estimator for the standard error.
[4] P-value based on a Cochran-Mantel-Haenszel test stratified by study.
[5] Interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the OR (95% CI). Missing subgroup levels are not included in estimation of the interaction p-value.
A continuity correction is applied in estimation of the OR, RR and p-value if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum. No continuity correction is applied in the estimation of the RD.
The reference group for the OR, RR and RD is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with an event; OR: Odds ratio; RR: Risk ratio; RD: Risk difference; CI: Confidence interval; int: p-value for interaction; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; NC: Not calculated.

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Table EFF.RL8024ET.MITT.Pooled.S6: Proportion of Women in the Relugolix + E2/NETA Group Versus the Placebo Group who Achieve an MBL Volume of < 80 mL Over the Last 35 Days of Treatment, as Measured by the Alkaline Hematin Method, by Subgroup (mITT Population)

Study: Pooled

Treatment	**N**	**n (%)**	**OR[1] [95% CI]**	**RR[2] [95% CI]**	**RD[3] [95% CI]**	**p-value[4]**	**p-value (int)[5]**
Geographic Region I							
North America							0.4207
Relugolix+E2/NETA	191	137 (71.7)	9.25 [5.80;14.74]	3.31 [2.50;4.39]	0.50 [0.41;0.59]	<.0001	
Placebo	194	42 (21.6)					
Rest of World							
Relugolix+E2/NETA	62	52 (83.9)	13.85 [5.75;33.36]	3.04 [2.01;4.61]	0.56 [0.42;0.71]	<.0001	
Placebo	62	17 (27.4)					

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group.
MBL volume was calculated as the sum of MBL volume from all feminine products (validated, unauthorized and unvalidated) as assessed by the alkaline hematin method at Week 24/End of Treatment Visit.
[1] OR (95% CI) based on a logistic regression model adjusting for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates.
[2] RR (95% CI) based on a Cochran-Mantel-Haenszel approach stratified by study.
[3] RD (95% CI) based on a Mantel-Haenszel approach stratified by study. 95% CIs are based on the approximation to the normal distribution using the Sato estimator for the standard error.
[4] P-value based on a Cochran-Mantel-Haenszel test stratified by study.
[5] Interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the OR (95% CI). Missing subgroup levels are not included in estimation of the interaction p-value.
A continuity correction is applied in estimation of the OR, RR and p-value if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum. No continuity correction is applied in the estimation of the RD.
The reference group for the OR, RR and RD is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with an event; OR: Odds ratio; RR: Risk ratio; RD: Risk difference; CI: Confidence interval; int: p-value for interaction; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; NC: Not calculated.

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Table EFF.RL8024ET.MITT.Pooled.S1: Proportion of Women in the Relugolix + E2/NETA Group Versus the Placebo Group who Achieve an MBL Volume of < 80 mL Over the Last 35 Days of Treatment, as Measured by the Alkaline Hematin Method, by Subgroup (mITT Population)

Study: Pooled

Treatment	**N**	**n (%)**	**OR[1] [95% CI]**	**RR[2] [95% CI]**	**RD[3] [95% CI]**	**p-value[4]**	**p-value (int)[5]**
Age (years)							
< 40 years							0.4228
Relugolix+E2/NETA	62	43 (69.4)	7.56 [3.55;16.09]	2.99 [1.93;4.63]	0.46 [0.31;0.61]	<.0001	
Placebo	78	18 (23.1)					
>= 40 years							
Relugolix+E2/NETA	191	146 (76.4)	10.93 [6.73;17.75]	3.32 [2.51;4.39]	0.53 [0.45;0.62]	<.0001	
Placebo	178	41 (23.0)					

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group.
MBL volume was calculated as the sum of MBL volume from all feminine products (validated, unauthorized and unvalidated) as assessed by the alkaline hematin method at Week 24/End of Treatment Visit.
[1] OR (95% CI) based on a logistic regression model adjusting for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates.
[2] RR (95% CI) based on a Cochran-Mantel-Haenszel approach stratified by study.
[3] RD (95% CI) based on a Mantel-Haenszel approach stratified by study. 95% CIs are based on the approximation to the normal distribution using the Sato estimator for the standard error.
[4] P-value based on a Cochran-Mantel-Haenszel test stratified by study.
[5] Interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the OR (95% CI). Missing subgroup levels are not included in estimation of the interaction p-value.
A continuity correction is applied in estimation of the OR, RR and p-value if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum. No continuity correction is applied in the estimation of the RD.
The reference group for the OR, RR and RD is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with an event; OR: Odds ratio; RR: Risk ratio; RD: Risk difference; CI: Confidence interval; int: p-value for interaction; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; NC: Not calculated.

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Table EFF.RL8024ET.MITT.Pooled.S8: Proportion of Women in the Relugolix + E2/NETA Group Versus the Placebo Group who Achieve an MBL Volume of < 80 mL Over the Last 35 Days of Treatment, as Measured by the Alkaline Hematin Method, by Subgroup (mITT Population)

Study: Pooled

Treatment	N	n (%)	OR[1] [95% CI]	RR[2] [95% CI]	RD[3] [95% CI]	p-value[4]	p-value (int)[5]
Ethnicity							
Hispanic or Latino							0.6571
Relugolix+E2/NETA	52	43 (82.7)	8.54	2.16	0.44	<.0001	
Placebo	55	19 (34.5)	[3.43;21.27]	[1.50;3.13]	[0.26;0.61]		
Not Hispanic or Latino							
Relugolix+E2/NETA	197	143 (72.6)	10.80	3.63	0.53	<.0001	
Placebo	199	40 (20.1)	[6.74;17.29]	[2.71;4.86]	[0.44;0.61]		
Not reported							
Relugolix+E2/NETA	4	3 (75.0)	NC	NC	NC	NC	
Placebo	2	0	[NC;NC]	[NC;NC]	[NC;NC]		

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group.
MBL volume was calculated as the sum of MBL volume from all feminine products (validated, unauthorized and unvalidated) as assessed by the alkaline hematin method at Week 24/End of Treatment Visit.
[1] OR (95% CI) based on a logistic regression model adjusting for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates.
[2] RR (95% CI) based on a Cochran-Mantel-Haenszel approach stratified by study.
[3] RD (95% CI) based on a Mantel-Haenszel approach stratified by study. 95% CIs are based on the approximation to the normal distribution using the Sato estimator for the standard error.
[4] P-value based on a Cochran-Mantel-Haenszel test stratified by study.
[5] Interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the OR (95% CI). Not reported subgroup levels are not included in estimation of the interaction p-value.
A continuity correction is applied in estimation of the OR, RR and p-value if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum. No continuity correction is applied in the estimation of the RD.
The reference group for the OR, RR and RD is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with an event; OR: Odds ratio; RR: Risk ratio; RD: Risk difference; CI: Confidence interval; int: p-value for interaction; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; NC: Not calculated.

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Table EFF.RL8024ET.MITT.Pooled.S5: Proportion of Women in the Relugolix + E2/NETA Group Versus the Placebo Group who Achieve an MBL Volume of < 80 mL Over the Last 35 Days of Treatment, as Measured by the Alkaline Hematin Method, by Subgroup (mITT Population)

Study: Pooled

Treatment	N	n (%)	OR[1] [95% CI]	RR[2] [95% CI]	RD[3] [95% CI]	p-value[4]	p-value (int)[5]
MBL Volume at Baseline (mL)							
< 225 mL							0.6857
Relugolix+E2/NETA	164	130 (79.3)	11.09	3.07	0.53	<.0001	
Placebo	171	44 (25.7)	[6.65;18.50]	[2.36;4.01]	[0.44;0.62]		
>= 225 mL							
Relugolix+E2/NETA	89	59 (66.3)	9.25	3.76	0.49	<.0001	
Placebo	85	15 (17.6)	[4.54;18.85]	[2.32;6.09]	[0.36;0.61]		

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group.
MBL volume was calculated as the sum of MBL volume from all feminine products (validated, unauthorized and unvalidated) as assessed by the alkaline hematin method at Week 24/End of Treatment Visit.
[1] OR (95% CI) based on a logistic regression model adjusting for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates.
[2] RR (95% CI) based on a Cochran-Mantel-Haenszel approach stratified by study.
[3] RD (95% CI) based on a Mantel-Haenszel approach stratified by study. 95% CIs are based on the approximation to the normal distribution using the Sato estimator for the standard error.
[4] P-value based on a Cochran-Mantel-Haenszel test stratified by study.
[5] Interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the OR (95% CI). Not reported subgroup levels are not included in estimation of the interaction p-value.
A continuity correction is applied in estimation of the OR, RR and p-value if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum. No continuity correction is applied in the estimation of the RD.
The reference group for the OR, RR and RD is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with an event; OR: Odds ratio; RR: Risk ratio; RD: Risk difference; CI: Confidence interval; int: p-value for interaction; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; NC: Not calculated.

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Table EFF.RL8024ET.MITT.Pooled.S3: Proportion of Women in the Relugolix + E2/NETA Group Versus the Placebo Group who Achieve an MBL Volume of < 80 mL Over the Last 35 Days of Treatment, as Measured by the Alkaline Hematin Method, by Subgroup (mITT Population)

Study: Pooled

Treatment	N	n (%)	OR[1] [95% CI]	RR[2] [95% CI]	RD[3] [95% CI]	p-value[4]	p-value (int)[5]
Uterine Volume at Baseline (cm3)							
< 300 cm3							
Relugolix+E2/NETA	148	116 (78.4)	10.22	2.97	0.52	<.0001	0.8941
Placebo	129	34 (26.4)	[5.87;17.82]	[2.20;4.01]	[0.42;0.62]		
>= 300 cm3							
Relugolix+E2/NETA	104	73 (70.2)	9.67	3.55	0.50	<.0001	
Placebo	127	25 (19.7)	[5.26;17.76]	[2.45;5.16]	[0.39;0.62]		
Missing							
Relugolix+E2/NETA	1	0	NC	NC	NC	NC	
Placebo	0	0	[NC;NC]	[NC;NC]	[NC;NC]		

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group.
MBL volume was calculated as the sum of MBL volume from all feminine products (validated, unauthorized and unvalidated) as assessed by the alkaline hematin method at Week 24/End of Treatment Visit.
[1] OR (95% CI) based on a logistic regression model adjusting for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates.
[2] RR (95% CI) based on a Cochran-Mantel-Haenszel approach stratified by study.
[3] RD (95% CI) based on a Mantel-Haenszel approach stratified by study. 95% CIs are based on the approximation to the normal distribution using the Sato estimator for the standard error.
[4] P-value based on a Cochran-Mantel-Haenszel test stratified by study.
[5] Interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the OR (95% CI). Missing subgroup levels are not included in estimation of the interaction p-value.
A continuity correction is applied in estimation of the OR, RR and p-value if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum. No continuity correction is applied in the estimation of the RD.
The reference group for the OR, RR and RD is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with an event; OR: Odds ratio; RR: Risk ratio; RD: Risk difference; CI: Confidence interval; int: p-value for interaction; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; NC: Not calculated.

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Table EFF.RL8024ET.MITT.Pooled.S9: Proportion of Women in the Relugolix + E2/NETA Group Versus the Placebo Group who Achieve an MBL Volume of < 80 mL Over the Last 35 Days of Treatment, as Measured by the Alkaline Hematin Method, by Subgroup (mITT Population)

Study: Pooled

Treatment	N	n (%)	OR[1] [95% CI]	RR[2] [95% CI]	RD[3] [95% CI]	p-value[4]	p-value (int)[5]
Race							
Black/African American							0.9098
Relugolix+E2/NETA	122	81 (66.4)	9.22 [5.20;16.38]	3.75 [2.57;5.46]	0.49 [0.38;0.59]	<.0001	
Placebo	141	25 (17.7)					
White							
Relugolix+E2/NETA	122	100 (82.0)	10.03 [5.39;18.65]	2.61 [1.95;3.51]	0.51 [0.40;0.62]	<.0001	
Placebo	105	33 (31.4)					
Asian							
Relugolix+E2/NETA	1	1 (100.0)	NC [NC;NC]	NC [NC;NC]	NC [NC;NC]	NC	
Placebo	3	1 (33.3)					
Others							
Relugolix+E2/NETA	5	4 (80.0)	16.15 [1.12;232.28]	5.24 [0.78;34.99]	0.84 [0.56;1.00]	0.0393	
Placebo	6	0					
Not reported							
Relugolix+E2/NETA	3	3 (100.0)	NC [NC;NC]	NC [NC;NC]	NC [NC;NC]	NC	
Placebo	1	0					

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group.
MBL volume was calculated as the sum of MBL volume from all feminine products (validated, unauthorized and unvalidated) as assessed by the alkaline hematin method at Week 24/End of Treatment Visit.
[1] OR (95% CI) based on a logistic regression model adjusting for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates.
[2] RR (95% CI) based on a Cochran-Mantel-Haenszel approach stratified by study.
[3] RD (95% CI) based on a Mantel-Haenszel approach stratified by study. 95% CIs are based on the approximation to the normal distribution using the Sato estimator for the standard error.
[4] P-value based on a Cochran-Mantel-Haenszel test stratified by study.
[5] Interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the OR (95% CI). Not reported subgroup levels are not included in estimation of the interaction p-value.
A continuity correction is applied in estimation of the OR, RR and p-value if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum. No continuity correction is applied in the estimation of the RD.
The reference group for the OR, RR and RD is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with an event; OR: Odds ratio; RR: Risk ratio; RD: Risk difference; CI: Confidence interval; int: p-value for interaction; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; NC: Not calculated.

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Table EFF.RL8024ET.MITT.Pooled.S2: Proportion of Women in the Relugolix + E2/NETA Group Versus the Placebo Group who Achieve an MBL Volume of < 80 mL Over the Last 35 Days of Treatment, as Measured by the Alkaline Hematin Method, by Subgroup (mITT Population)

Study: Pooled

Treatment	N	n (%)	OR[1] [95% CI]	RR[2] [95% CI]	RD[3] [95% CI]	p-value[4]	p-value (int)[5]
BMI (kg/m2) at Baseline							
< 30							
Relugolix+E2/NETA	119	89 (74.8)	9.65	3.14	0.51	<.0001	0.9218
Placebo	115	27 (23.5)	[5.30;17.56]	[2.23;4.42]	[0.40;0.62]		
>= 30							
Relugolix+E2/NETA	133	99 (74.4)	10.05	3.28	0.52	<.0001	
Placebo	141	32 (22.7)	[5.76;17.53]	[2.38;4.52]	[0.42;0.62]		
Missing							
Relugolix+E2/NETA	1	1 (100.0)	NC	NC	NC	NC	
Placebo	0	0	[NC;NC]	[NC;NC]	[NC;NC]		

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group.
MBL volume was calculated as the sum of MBL volume from all feminine products (validated, unauthorized and unvalidated) as assessed by the alkaline hematin method at Week 24/End of Treatment Visit.
[1] OR (95% CI) based on a logistic regression model adjusting for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates.
[2] RR (95% CI) based on a Cochran-Mantel-Haenszel approach stratified by study.
[3] RD (95% CI) based on a Mantel-Haenszel approach stratified by study. 95% CIs are based on the approximation to the normal distribution using the Sato estimator for the standard error.
[4] P-value based on a Cochran-Mantel-Haenszel test stratified by study.
[5] Interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the OR (95% CI). Missing subgroup levels are not included in estimation of the interaction p-value.
A continuity correction is applied in estimation of the OR, RR and p-value if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum. No continuity correction is applied in the estimation of the RD.
The reference group for the OR, RR and RD is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with an event; OR: Odds ratio; RR: Risk ratio; RD: Risk difference; CI: Confidence interval; int: p-value for interaction; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; NC: Not calculated.

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1.1.1.2 Proportion of Women in the Relugolix + E2/NETA Group Versus the Placebo Group who Achieve at least a 50% Reduction from Baseline MBL Volume Over the Last 35 Days of Treatment, as Measured by the Alkaline Hematin Method, by Subgroup (mITT Population)

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Table EFF.RG5024ET.MITT.Pooled.S5: Proportion of Women in the Relugolix + E2/NETA Group Versus the Placebo Group who Achieve at least a 50% Reduction from Baseline MBL Volume Over the Last 35 Days of Treatment, as Measured by the Alkaline Hematin Method, by Subgroup (mITT Population)

Study: Pooled

Treatment	N	n (%)	OR[1] [95% CI]	RR[2] [95% CI]	RD[3] [95% CI]	p-value[4]	p-value (int)[5]
MBL Volume at Baseline (mL)							
< 225 mL							0.2052
Relugolix+E2/NETA	164	128 (78.0)	15.44 [9.06;26.32]	4.16 [3.02;5.75]	0.59 [0.51;0.68]	<.0001	
Placebo	171	32 (18.7)					
>= 225 mL							
Relugolix+E2/NETA	89	69 (77.5)	8.77 [4.42;17.43]	2.75 [1.92;3.92]	0.49 [0.36;0.62]	<.0001	
Placebo	85	24 (28.2)					

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group.
MBL volume was calculated as the sum of MBL volume from all feminine products (validated, unauthorized and unvalidated) as assessed by the alkaline hematin method at Week 24/End of Treatment Visit.
[1] OR (95% CI) based on a logistic regression model adjusting for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates.
[2] RR (95% CI) based on a Cochran-Mantel-Haenszel approach stratified by study.
[3] RD (95% CI) based on a Mantel-Haenszel approach stratified by study. 95% CIs are based on the approximation to the normal distribution using the Sato estimator for the standard error.
[4] P-value based on a Cochran-Mantel-Haenszel test stratified by study.
[5] Interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the OR (95% CI).
A continuity correction is applied in estimation of the OR, RR and p-value if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum. No continuity correction is applied in the estimation of the RD.
The reference group for the OR, RR and RD is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with an event; OR: Odds ratio; RR: Risk ratio; RD: Risk difference; CI: Confidence interval; int: p-value for interaction; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; NC: Not calculated.

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Table EFF.RG5024ET.MITT.Pooled.S4: Proportion of Women in the Relugolix + E2/NETA Group Versus the Placebo Group who Achieve at least a 50% Reduction from Baseline MBL Volume Over the Last 35 Days of Treatment, as Measured by the Alkaline Hematin Method, by Subgroup (mITT Population)

Study: Pooled

Treatment	N	n (%)	OR[1] [95% CI]	RR[2] [95% CI]	RD[3] [95% CI]	p-value[4]	p-value (int)[5]
Maximum NRS Pain Score at Baseline							
< 4							0.2166
Relugolix+E2/NETA	73	58 (79.5)	20.04 [8.28;48.52]	5.10 [2.81;9.24]	0.64 [0.51;0.77]	<.0001	
Placebo	62	10 (16.1)					
>= 4							
Relugolix+E2/NETA	177	137 (77.4)	10.73 [6.61;17.42]	3.21 [2.46;4.18]	0.53 [0.45;0.62]	<.0001	
Placebo	190	46 (24.2)					
Missing							
Relugolix+E2/NETA	3	2 (66.7)	NC [NC;NC]	NC [NC;NC]	NC [NC;NC]	NC	
Placebo	4	0					

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group.
MBL volume was calculated as the sum of MBL volume from all feminine products (validated, unauthorized and unvalidated) as assessed by the alkaline hematin method at Week 24/End of Treatment Visit.
[1] OR (95% CI) based on a logistic regression model adjusting for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates.
[2] RR (95% CI) based on a Cochran-Mantel-Haenszel approach stratified by study.
[3] RD (95% CI) based on a Mantel-Haenszel approach stratified by study. 95% CIs are based on the approximation to the normal distribution using the Sato estimator for the standard error.
[4] P-value based on a Cochran-Mantel-Haenszel test stratified by study.
[5] Interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the OR (95% CI). Missing subgroup levels are not included in estimation of the interaction p-value.
A continuity correction is applied in estimation of the OR, RR and p-value if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum. No continuity correction is applied in the estimation of the RD.
The reference group for the OR, RR and RD is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with an event; OR: Odds ratio; RR: Risk ratio; RD: Risk difference; CI: Confidence interval; int: p-value for interaction; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; NC: Not calculated.

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Table EFF.RG5024ET.MITT.Pooled.S6: Proportion of Women in the Relugolix + E2/NETA Group Versus the Placebo Group who Achieve at least a 50% Reduction from Baseline MBL Volume Over the Last 35 Days of Treatment, as Measured by the Alkaline Hematin Method, by Subgroup (mITT Population)

Study: Pooled

Treatment	**N**	**n (%)**	**OR[1] [95% CI]**	**RR[2] [95% CI]**	**RD[3] [95% CI]**	**p-value[4]**	**p-value (int)[5]**
Geographic Region I							
North America							
Relugolix+E2/NETA	191	143 (74.9)	11.12	3.54	0.54	<.0001	0.2228
Placebo	194	41 (21.1)	[6.91;17.88]	[2.67;4.71]	[0.45;0.62]		
Rest of World							
Relugolix+E2/NETA	62	54 (87.1)	21.14	3.58	0.63	<.0001	
Placebo	62	15 (24.2)	[8.23;54.30]	[2.29;5.62]	[0.49;0.76]		

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group.
MBL volume was calculated as the sum of MBL volume from all feminine products (validated, unauthorized and unvalidated) as assessed by the alkaline hematin method at Week 24/End of Treatment Visit.
[1] OR (95% CI) based on a logistic regression model adjusting for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates.
[2] RR (95% CI) based on a Cochran-Mantel-Haenszel approach stratified by study.
[3] RD (95% CI) based on a Mantel-Haenszel approach stratified by study. 95% CIs are based on the approximation to the normal distribution using the Sato estimator for the standard error.
[4] P-value based on a Cochran-Mantel-Haenszel test stratified by study.
[5] Interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the OR (95% CI). Missing subgroup levels are not included in estimation of the interaction p-value.
A continuity correction is applied in estimation of the OR, RR and p-value if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum. No continuity correction is applied in the estimation of the RD.
The reference group for the OR, RR and RD is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with an event; OR: Odds ratio; RR: Risk ratio; RD: Risk difference; CI: Confidence interval; int: p-value for interaction; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; NC: Not calculated.

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Table EFF.RG5024ET.MITT.Pooled.S7: Proportion of Women in the Relugolix + E2/NETA Group Versus the Placebo Group who Achieve at least a 50% Reduction from Baseline MBL Volume Over the Last 35 Days of Treatment, as Measured by the Alkaline Hematin Method, by Subgroup (mITT Population)

Study: Pooled

Treatment	N	n (%)	OR[1] [95% CI]	RR[2] [95% CI]	RD[3] [95% CI]	p-value[4]	p-value (int)[5]
Geographic Region II							
Europe							0.2758
Relugolix+E2/NETA	41	37 (90.2)	22.90	3.36	0.64	<.0001	
Placebo	42	11 (26.2)	[6.97;75.17]	[2.00;5.63]	[0.47;0.80]		
Rest of World (including the US)							
Relugolix+E2/NETA	212	160 (75.5)	11.55	3.59	0.54	<.0001	
Placebo	214	45 (21.0)	[7.33;18.18]	[2.74;4.71]	[0.46;0.62]		

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group.
MBL volume was calculated as the sum of MBL volume from all feminine products (validated, unauthorized and unvalidated) as assessed by the alkaline hematin method at Week 24/End of Treatment Visit.
[1] OR (95% CI) based on a logistic regression model adjusting for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates.
[2] RR (95% CI) based on a Cochran-Mantel-Haenszel approach stratified by study.
[3] RD (95% CI) based on a Mantel-Haenszel approach stratified by study. 95% CIs are based on the approximation to the normal distribution using the Sato estimator for the standard error.
[4] P-value based on a Cochran-Mantel-Haenszel test stratified by study.
[5] Interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the OR (95% CI). Missing subgroup levels are not included in estimation of the interaction p-value.
A continuity correction is applied in estimation of the OR, RR and p-value if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum. No continuity correction is applied in the estimation of the RD.
The reference group for the OR, RR and RD is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with an event; OR: Odds ratio; RR: Risk ratio; RD: Risk difference; CI: Confidence interval; int: p-value for interaction; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; NC: Not calculated.

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Table EFF.RG5024ET.MITT.Pooled.S8: Proportion of Women in the Relugolix + E2/NETA Group Versus the Placebo Group who Achieve at least a 50% Reduction from Baseline MBL Volume Over the Last 35 Days of Treatment, as Measured by the Alkaline Hematin Method, by Subgroup (mITT Population)

Study: Pooled

Treatment	N	n (%)	OR[1] [95% CI]	RR[2] [95% CI]	RD[3] [95% CI]	p-value[4]	p-value (int)[5]
Ethnicity							
Hispanic or Latino							0.3090
Relugolix+E2/NETA	52	42 (80.8)	8.42 [3.44;20.61]	2.20 [1.51;3.22]	0.43 [0.26;0.61]	<.0001	
Placebo	55	18 (32.7)					
Not Hispanic or Latino							
Relugolix+E2/NETA	197	152 (77.2)	14.42 [8.86;23.46]	4.01 [2.99;5.39]	0.58 [0.50;0.66]	<.0001	
Placebo	199	38 (19.1)					
Not reported							
Relugolix+E2/NETA	4	3 (75.0)	NC [NC;NC]	NC [NC;NC]	NC [NC;NC]	NC	
Placebo	2	0					

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group.
MBL volume was calculated as the sum of MBL volume from all feminine products (validated, unauthorized and unvalidated) as assessed by the alkaline hematin method at Week 24/End of Treatment Visit.
[1] OR (95% CI) based on a logistic regression model adjusting for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates.
[2] RR (95% CI) based on a Cochran-Mantel-Haenszel approach stratified by study.
[3] RD (95% CI) based on a Mantel-Haenszel approach stratified by study. 95% CIs are based on the approximation to the normal distribution using the Sato estimator for the standard error.
[4] P-value based on a Cochran-Mantel-Haenszel test stratified by study.
[5] Interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the OR (95% CI). Not reported subgroup levels are not included in estimation of the interaction p-value.
A continuity correction is applied in estimation of the OR, RR and p-value if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum. No continuity correction is applied in the estimation of the RD.
The reference group for the OR, RR and RD is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with an event; OR: Odds ratio; RR: Risk ratio; RD: Risk difference; CI: Confidence interval; int: p-value for interaction; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; NC: Not calculated.

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Table EFF.RG5024ET.MITT.Pooled.S1: Proportion of Women in the Relugolix + E2/NETA Group Versus the Placebo Group who Achieve at least a 50% Reduction from Baseline MBL Volume Over the Last 35 Days of Treatment, as Measured by the Alkaline Hematin Method, by Subgroup (mITT Population)

Study: Pooled

Treatment	**N**	**n (%)**	**OR[1] [95% CI]**	**RR[2] [95% CI]**	**RD[3] [95% CI]**	**p-value[4]**	**p-value (int)[5]**
Age (years)							
< 40 years							0.4227
Relugolix+E2/NETA	62	43 (69.4)	9.50	3.62	0.50	<.0001	
Placebo	78	15 (19.2)	[4.35;20.72]	[2.23;5.88]	[0.36;0.65]		
>= 40 years							
Relugolix+E2/NETA	191	154 (80.6)	13.91	3.50	0.58	<.0001	
Placebo	178	41 (23.0)	[8.43;22.95]	[2.65;4.62]	[0.49;0.66]		

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group.
MBL volume was calculated as the sum of MBL volume from all feminine products (validated, unauthorized and unvalidated) as assessed by the alkaline hematin method at Week 24/End of Treatment Visit.
[1] OR (95% CI) based on a logistic regression model adjusting for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates.
[2] RR (95% CI) based on a Cochran-Mantel-Haenszel approach stratified by study.
[3] RD (95% CI) based on a Mantel-Haenszel approach stratified by study. 95% CIs are based on the approximation to the normal distribution using the Sato estimator for the standard error.
[4] P-value based on a Cochran-Mantel-Haenszel test stratified by study.
[5] Interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the OR (95% CI). Not reported subgroup levels are not included in estimation of the interaction p-value.
A continuity correction is applied in estimation of the OR, RR and p-value if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum. No continuity correction is applied in the estimation of the RD.
The reference group for the OR, RR and RD is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with an event; OR: Odds ratio; RR: Risk ratio; RD: Risk difference; CI: Confidence interval; int: p-value for interaction; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; NC: Not calculated.

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Table EFF.RG5024ET.MITT.Pooled.S9: Proportion of Women in the Relugolix + E2/NETA Group Versus the Placebo Group who Achieve at least a 50% Reduction from Baseline MBL Volume Over the Last 35 Days of Treatment, as Measured by the Alkaline Hematin Method, by Subgroup (mITT Population)

Study: Pooled

Treatment	N	n (%)	OR[1] [95% CI]	RR[2] [95% CI]	RD[3] [95% CI]	p-value[4]	p-value (int)[5]
Race							
Black/African American							0.6891
Relugolix+E2/NETA	122	85 (69.7)	10.66 [5.97;19.03]	3.94 [2.71;5.74]	0.52 [0.42;0.62]	<.0001	
Placebo	141	25 (17.7)					
White							
Relugolix+E2/NETA	122	105 (86.1)	15.47 [7.95;30.07]	3.02 [2.21;4.12]	0.58 [0.47;0.68]	<.0001	
Placebo	105	30 (28.6)					
Asian							
Relugolix+E2/NETA	1	1 (100.0)	NC [NC;NC]	NC [NC;NC]	NC [NC;NC]	NC	
Placebo	3	1 (33.3)					
Others							
Relugolix+E2/NETA	5	3 (60.0)	9.09 [0.69;119.82]	4.41 [0.67;29.11]	0.69 [0.33;1.00]	0.0905	
Placebo	6	0					
Not reported							
Relugolix+E2/NETA	3	3 (100.0)	NC [NC;NC]	NC [NC;NC]	NC [NC;NC]	NC	
Placebo	1	0					

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group.
MBL volume was calculated as the sum of MBL volume from all feminine products (validated, unauthorized and unvalidated) as assessed by the alkaline hematin method at Week 24/End of Treatment Visit.
[1] OR (95% CI) based on a logistic regression model adjusting for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates.
[2] RR (95% CI) based on a Cochran-Mantel-Haenszel approach stratified by study.
[3] RD (95% CI) based on a Mantel-Haenszel approach stratified by study. 95% CIs are based on the approximation to the normal distribution using the Sato estimator for the standard error.
[4] P-value based on a Cochran-Mantel-Haenszel test stratified by study.
[5] Interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the OR (95% CI). Not reported subgroup levels are not included in estimation of the interaction p-value.
A continuity correction is applied in estimation of the OR, RR and p-value if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum. No continuity correction is applied in the estimation of the RD.
The reference group for the OR, RR and RD is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with an event; OR: Odds ratio; RR: Risk ratio; RD: Risk difference; CI: Confidence interval; int: p-value for interaction; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; NC: Not calculated.

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Table EFF.RG5024ET.MITT.Pooled.S2: Proportion of Women in the Relugolix + E2/NETA Group Versus the Placebo Group who Achieve at least a 50% Reduction from Baseline MBL Volume Over the Last 35 Days of Treatment, as Measured by the Alkaline Hematin Method, by Subgroup (mITT Population)

Study: Pooled

Treatment	N	n (%)	OR[1] [95% CI]	RR[2] [95% CI]	RD[3] [95% CI]	p-value[4]	p-value (int)[5]
BMI (kg/m2) at Baseline							
< 30							
Relugolix+E2/NETA	119	94 (79.0)	11.65	3.24	0.55	<.0001	0.7574
Placebo	115	28 (24.3)	[6.31;21.51]	[2.32;4.52]	[0.44;0.65]		
>= 30							
Relugolix+E2/NETA	133	102 (76.7)	13.31	3.86	0.57	<.0001	
Placebo	141	28 (19.9)	[7.47;23.70]	[2.74;5.45]	[0.47;0.67]		
Missing							
Relugolix+E2/NETA	1	1 (100.0)	NC	NC	NC	NC	
Placebo	0	0	[NC;NC]	[NC;NC]	[NC;NC]		

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group.
MBL volume was calculated as the sum of MBL volume from all feminine products (validated, unauthorized and unvalidated) as assessed by the alkaline hematin method at Week 24/End of Treatment Visit.
[1] OR (95% CI) based on a logistic regression model adjusting for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates.
[2] RR (95% CI) based on a Cochran-Mantel-Haenszel approach stratified by study.
[3] RD (95% CI) based on a Mantel-Haenszel approach stratified by study. 95% CIs are based on the approximation to the normal distribution using the Sato estimator for the standard error.
[4] P-value based on a Cochran-Mantel-Haenszel test stratified by study.
[5] Interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the OR (95% CI). Missing subgroup levels are not included in estimation of the interaction p-value.
A continuity correction is applied in estimation of the OR, RR and p-value if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum. No continuity correction is applied in the estimation of the RD.
The reference group for the OR, RR and RD is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with an event; OR: Odds ratio; RR: Risk ratio; RD: Risk difference; CI: Confidence interval; int: p-value for interaction; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; NC: Not calculated.

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Table EFF.RG5024ET.MITT.Pooled.S3: Proportion of Women in the Relugolix + E2/NETA Group Versus the Placebo Group who Achieve at least a 50% Reduction from Baseline MBL Volume Over the Last 35 Days of Treatment, as Measured by the Alkaline Hematin Method, by Subgroup (mITT Population)

Study: Pooled

Treatment	N	n (%)	OR[1] [95% CI]	RR[2] [95% CI]	RD[3] [95% CI]	p-value[4]	p-value (int)[5]
Uterine Volume at Baseline (cm3)							
< 300 cm3							
Relugolix+E2/NETA	148	116 (78.4)	13.09	3.61	0.57	<.0001	0.9084
Placebo	129	28 (21.7)	[7.38;23.21]	[2.57;5.07]	[0.47;0.66]		
>= 300 cm3							
Relugolix+E2/NETA	104	81 (77.9)	12.45	3.53	0.56	<.0001	
Placebo	127	28 (22.0)	[6.66;23.26]	[2.51;4.97]	[0.45;0.67]		
Missing							
Relugolix+E2/NETA	1	0	NC	NC	NC	NC	
Placebo	0	0	[NC;NC]	[NC;NC]	[NC;NC]		

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group.
MBL volume was calculated as the sum of MBL volume from all feminine products (validated, unauthorized and unvalidated) as assessed by the alkaline hematin method at Week 24/End of Treatment Visit.
[1] OR (95% CI) based on a logistic regression model adjusting for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates.
[2] RR (95% CI) based on a Cochran-Mantel-Haenszel approach stratified by study.
[3] RD (95% CI) based on a Mantel-Haenszel approach stratified by study. 95% CIs are based on the approximation to the normal distribution using the Sato estimator for the standard error.
[4] P-value based on a Cochran-Mantel-Haenszel test stratified by study.
[5] Interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the OR (95% CI). Missing subgroup levels are not included in estimation of the interaction p-value.
A continuity correction is applied in estimation of the OR, RR and p-value if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum. No continuity correction is applied in the estimation of the RD.
The reference group for the OR, RR and RD is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with an event; OR: Odds ratio; RR: Risk ratio; RD: Risk difference; CI: Confidence interval; int: p-value for interaction; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; NC: Not calculated.

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1.1.2 Sustained Responder Rate (MBL volume of < 80 mL and at least a 50% Reduction from Baseline MBL Volume) by Visit, by Subgroup (mITT Population)

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Table EFF.RESPCMPS.MITT.Pooled.S1: Sustained Responder Rate (MBL volume of < 80 mL and at least a 50% Reduction from Baseline MBL Volume) by Visit, by Subgroup (mITT Population)

Study: Pooled

Subgroup: Age (years), Level: < 40 years

Treatment	N	n (%)	OR[1] [95% CI]	RR[2] [95% CI]	RD[3] [95% CI]	p-value[4]	p-value (int)[5]
Week 8							
Relugolix+E2/NETA	62	13 (21.0)	NC	NC	NC	NC	NC
Placebo	78	2 (2.6)	[NC;NC]	[NC;NC]	[NC;NC]		
Week 12							
Relugolix+E2/NETA	62	27 (43.5)	NC	NC	NC	NC	
Placebo	78	5 (6.4)	[NC;NC]	[NC;NC]	[NC;NC]		
Week 16							
Relugolix+E2/NETA	62	35 (56.5)	NC	NC	NC	NC	
Placebo	78	5 (6.4)	[NC;NC]	[NC;NC]	[NC;NC]		
Week 20							
Relugolix+E2/NETA	62	36 (58.1)	NC	NC	NC	NC	
Placebo	78	5 (6.4)	[NC;NC]	[NC;NC]	[NC;NC]		
Week 24							
Relugolix+E2/NETA	62	39 (62.9)	NC	NC	NC	NC	
Placebo	78	5 (6.4)	[NC;NC]	[NC;NC]	[NC;NC]		

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group.
Sustained response is defined as patients time to achieve and maintain response (MBL volume of < 80 mL and at least a 50% Reduction from Baseline MBL Volume) until the date of last study drug.
[1] OR (95% CI) based on a logistic regression model adjusting for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates.
[2] RR (95% CI) based on a Cochran-Mantel-Haenszel approach stratified by study.
[3] RD (95% CI) based on a Mantel-Haenszel approach stratified by study. 95% CIs are based on the approximation to the normal distribution using the Sato estimator for the standard error.
[4] P-value based on a Cochran-Mantel-Haenszel test stratified by study.
[5] Interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the OR (95% CI).
A continuity correction is applied in estimation of the OR, RR and p-value if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum. No continuity correction is applied in the estimation of the RD.
The reference group for the OR, RR and RD is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with an event; OR: Odds ratio; RR: Risk ratio; RD: Risk difference; CI: Confidence interval; int: p-value for interaction; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; NC: Not calculated.

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Table EFF.RESPCMPS.MITT.Pooled.S1: Sustained Responder Rate (MBL volume of < 80 mL and at least a 50% Reduction from Baseline MBL Volume) by Visit, by Subgroup (mITT Population)

Study: Pooled

Subgroup: Age (years), Level: >= 40 years

Treatment	N	n (%)	OR[1] [95% CI]	RR[2] [95% CI]	RD[3] [95% CI]	p-value[4]	p-value (int)[5]
Week 8							
Relugolix+E2/NETA	191	52 (27.2)	NC	NC	NC	NC	NC
Placebo	178	5 (2.8)	[NC;NC]	[NC;NC]	[NC;NC]		
Week 12							
Relugolix+E2/NETA	191	113 (59.2)	NC	NC	NC	NC	
Placebo	178	6 (3.4)	[NC;NC]	[NC;NC]	[NC;NC]		
Week 16							
Relugolix+E2/NETA	191	124 (64.9)	NC	NC	NC	NC	
Placebo	178	6 (3.4)	[NC;NC]	[NC;NC]	[NC;NC]		
Week 20							
Relugolix+E2/NETA	191	129 (67.5)	NC	NC	NC	NC	
Placebo	178	11 (6.2)	[NC;NC]	[NC;NC]	[NC;NC]		
Week 24							
Relugolix+E2/NETA	191	136 (71.2)	NC	NC	NC	NC	
Placebo	178	16 (9.0)	[NC;NC]	[NC;NC]	[NC;NC]		

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group.
Sustained response is defined as patients time to achieve and maintain response (MBL volume of < 80 mL and at least a 50% Reduction from Baseline MBL Volume) until the date of last study drug.
[1] OR (95% CI) based on a logistic regression model adjusting for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates.
[2] RR (95% CI) based on a Cochran-Mantel-Haenszel approach stratified by study.
[3] RD (95% CI) based on a Mantel-Haenszel approach stratified by study. 95% CIs are based on the approximation to the normal distribution using the Sato estimator for the standard error.
[4] P-value based on a Cochran-Mantel-Haenszel test stratified by study.
[5] Interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the OR (95% CI).
A continuity correction is applied in estimation of the OR, RR and p-value if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum. No continuity correction is applied in the estimation of the RD.
The reference group for the OR, RR and RD is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with an event; OR: Odds ratio; RR: Risk ratio; RD: Risk difference; CI: Confidence interval; int: p-value for interaction; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; NC: Not calculated.

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Table EFF.RESPCMPS.MITT.Pooled.S2: Sustained Responder Rate (MBL volume of < 80 mL and at least a 50% Reduction from Baseline MBL Volume) by Visit, by Subgroup (mITT Population)

Study: Pooled

Subgroup: BMI (kg/m2) at Baseline, Level: < 30

Treatment	N	n (%)	OR[1] [95% CI]	RR[2] [95% CI]	RD[3] [95% CI]	p-value[4]	p-value (int)[5]
Week 8							
Relugolix+E2/NETA	119	32 (26.9)	NC	NC	NC	NC	NC
Placebo	115	4 (3.5)	[NC;NC]	[NC;NC]	[NC;NC]		
Week 12							
Relugolix+E2/NETA	119	66 (55.5)	NC	NC	NC	NC	
Placebo	115	4 (3.5)	[NC;NC]	[NC;NC]	[NC;NC]		
Week 16							
Relugolix+E2/NETA	119	76 (63.9)	NC	NC	NC	NC	
Placebo	115	4 (3.5)	[NC;NC]	[NC;NC]	[NC;NC]		
Week 20							
Relugolix+E2/NETA	119	78 (65.5)	NC	NC	NC	NC	
Placebo	115	7 (6.1)	[NC;NC]	[NC;NC]	[NC;NC]		
Week 24							
Relugolix+E2/NETA	119	82 (68.9)	NC	NC	NC	NC	
Placebo	115	9 (7.8)	[NC;NC]	[NC;NC]	[NC;NC]		

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group.
Sustained response is defined as patients time to achieve and maintain response (MBL volume of < 80 mL and at least a 50% Reduction from Baseline MBL Volume) until the date of last study drug.
[1] OR (95% CI) based on a logistic regression model adjusting for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates.
[2] RR (95% CI) based on a Cochran-Mantel-Haenszel approach stratified by study.
[3] RD (95% CI) based on a Mantel-Haenszel approach stratified by study. 95% CIs are based on the approximation to the normal distribution using the Sato estimator for the standard error.
[4] P-value based on a Cochran-Mantel-Haenszel test stratified by study.
[5] Interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the OR (95% CI).
A continuity correction is applied in estimation of the OR, RR and p-value if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum. No continuity correction is applied in the estimation of the RD.
The reference group for the OR, RR and RD is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with an event; OR: Odds ratio; RR: Risk ratio; RD: Risk difference; CI: Confidence interval; int: p-value for interaction; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; NC: Not calculated.

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Table EFF.RESPCMPS.MITT.Pooled.S2: Sustained Responder Rate (MBL volume of < 80 mL and at least a 50% Reduction from Baseline MBL Volume) by Visit, by Subgroup (mITT Population)

Study: Pooled

Subgroup: BMI (kg/m2) at Baseline, Level: >= 30

Treatment	N	n (%)	OR[1] [95% CI]	RR[2] [95% CI]	RD[3] [95% CI]	p-value[4]	p-value (int)[5]
Week 8							
Relugolix+E2/NETA	133	32 (24.1)	NC	NC	NC	NC	NC
Placebo	141	3 (2.1)	[NC;NC]	[NC;NC]	[NC;NC]		
Week 12							
Relugolix+E2/NETA	133	73 (54.9)	NC	NC	NC	NC	
Placebo	141	7 (5.0)	[NC;NC]	[NC;NC]	[NC;NC]		
Week 16							
Relugolix+E2/NETA	133	82 (61.7)	NC	NC	NC	NC	
Placebo	141	7 (5.0)	[NC;NC]	[NC;NC]	[NC;NC]		
Week 20							
Relugolix+E2/NETA	133	86 (64.7)	NC	NC	NC	NC	
Placebo	141	9 (6.4)	[NC;NC]	[NC;NC]	[NC;NC]		
Week 24							
Relugolix+E2/NETA	133	92 (69.2)	NC	NC	NC	NC	
Placebo	141	12 (8.5)	[NC;NC]	[NC;NC]	[NC;NC]		

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group.
Sustained response is defined as patients time to achieve and maintain response (MBL volume of < 80 mL and at least a 50% Reduction from Baseline MBL Volume) until the date of last study drug.
[1] OR (95% CI) based on a logistic regression model adjusting for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates.
[2] RR (95% CI) based on a Cochran-Mantel-Haenszel approach stratified by study.
[3] RD (95% CI) based on a Mantel-Haenszel approach stratified by study. 95% CIs are based on the approximation to the normal distribution using the Sato estimator for the standard error.
[4] P-value based on a Cochran-Mantel-Haenszel test stratified by study.
[5] Interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the OR (95% CI).
A continuity correction is applied in estimation of the OR, RR and p-value if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum. No continuity correction is applied in the estimation of the RD.
The reference group for the OR, RR and RD is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with an event; OR: Odds ratio; RR: Risk ratio; RD: Risk difference; CI: Confidence interval; int: p-value for interaction; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; NC: Not calculated.

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Table EFF.RESPCMPS.MITT.Pooled.S2: Sustained Responder Rate (MBL volume of < 80 mL and at least a 50% Reduction from Baseline MBL Volume) by Visit, by Subgroup (mITT Population)

Study: Pooled

Subgroup: BMI (kg/m2) at Baseline, Level: Missing

Treatment	N	n (%)	OR[1] [95% CI]	RR[2] [95% CI]	RD[3] [95% CI]	p-value[4]	p-value (int)[5]
Week 8							
Relugolix+E2/NETA	1	1 (100.0)	NC	NC	NC	NC	NC
Placebo	0	0	[NC;NC]	[NC;NC]	[NC;NC]		
Week 12							
Relugolix+E2/NETA	1	1 (100.0)	NC	NC	NC	NC	
Placebo	0	0	[NC;NC]	[NC;NC]	[NC;NC]		
Week 16							
Relugolix+E2/NETA	1	1 (100.0)	NC	NC	NC	NC	
Placebo	0	0	[NC;NC]	[NC;NC]	[NC;NC]		
Week 20							
Relugolix+E2/NETA	1	1 (100.0)	NC	NC	NC	NC	
Placebo	0	0	[NC;NC]	[NC;NC]	[NC;NC]		
Week 24							
Relugolix+E2/NETA	1	1 (100.0)	NC	NC	NC	NC	
Placebo	0	0	[NC;NC]	[NC;NC]	[NC;NC]		

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group.
Sustained response is defined as patients time to achieve and maintain response (MBL volume of < 80 mL and at least a 50% Reduction from Baseline MBL Volume) until the date of last study drug.
[1] OR (95% CI) based on a logistic regression model adjusting for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates.
[2] RR (95% CI) based on a Cochran-Mantel-Haenszel approach stratified by study.
[3] RD (95% CI) based on a Mantel-Haenszel approach stratified by study. 95% CIs are based on the approximation to the normal distribution using the Sato estimator for the standard error.
[4] P-value based on a Cochran-Mantel-Haenszel test stratified by study.
[5] Interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the OR (95% CI). Missing subgroup levels are not included in estimation of the interaction p-value.
A continuity correction is applied in estimation of the OR, RR and p-value if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum. No continuity correction is applied in the estimation of the RD.
The reference group for the OR, RR and RD is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with an event; OR: Odds ratio; RR: Risk ratio; RD: Risk difference; CI: Confidence interval; int: p-value for interaction; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; NC: Not calculated.

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Table EFF.RESPCMPS.MITT.Pooled.S3: Sustained Responder Rate (MBL volume of < 80 mL and at least a 50% Reduction from Baseline MBL Volume) by Visit, by Subgroup (mITT Population)

Study: Pooled

Subgroup: Uterine Volume at Baseline (cm3), Level: < 300 cm3

Treatment	N	n (%)	OR[1] [95% CI]	RR[2] [95% CI]	RD[3] [95% CI]	p-value[4]	p-value (int)[5]
Week 8							
Relugolix+E2/NETA	148	43 (29.1)	NC	NC	NC	NC	NC
Placebo	129	5 (3.9)	[NC;NC]	[NC;NC]	[NC;NC]		
Week 12							
Relugolix+E2/NETA	148	86 (58.1)	NC	NC	NC	NC	
Placebo	129	8 (6.2)	[NC;NC]	[NC;NC]	[NC;NC]		
Week 16							
Relugolix+E2/NETA	148	100 (67.6)	NC	NC	NC	NC	
Placebo	129	8 (6.2)	[NC;NC]	[NC;NC]	[NC;NC]		
Week 20							
Relugolix+E2/NETA	148	103 (69.6)	NC	NC	NC	NC	
Placebo	129	10 (7.8)	[NC;NC]	[NC;NC]	[NC;NC]		
Week 24							
Relugolix+E2/NETA	148	110 (74.3)	NC	NC	NC	NC	
Placebo	129	12 (9.3)	[NC;NC]	[NC;NC]	[NC;NC]		

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group.
Sustained response is defined as patients time to achieve and maintain response (MBL volume of < 80 mL and at least a 50% Reduction from Baseline MBL Volume) until the date of last study drug.
[1] OR (95% CI) based on a logistic regression model adjusting for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates.
[2] RR (95% CI) based on a Cochran-Mantel-Haenszel approach stratified by study.
[3] RD (95% CI) based on a Mantel-Haenszel approach stratified by study. 95% CIs are based on the approximation to the normal distribution using the Sato estimator for the standard error.
[4] P-value based on a Cochran-Mantel-Haenszel test stratified by study.
[5] Interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the OR (95% CI). Missing subgroup levels are not included in estimation of the interaction p-value.
A continuity correction is applied in estimation of the OR, RR and p-value if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum. No continuity correction is applied in the estimation of the RD.
The reference group for the OR, RR and RD is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with an event; OR: Odds ratio; RR: Risk ratio; RD: Risk difference; CI: Confidence interval; int: p-value for interaction; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; NC: Not calculated.

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Table EFF.RESPCMPS.MITT.Pooled.S3: Sustained Responder Rate (MBL volume of < 80 mL and at least a 50% Reduction from Baseline MBL Volume) by Visit, by Subgroup (mITT Population)

Study: Pooled

Subgroup: Uterine Volume at Baseline (cm3), Level: >= 300 cm3

Treatment	N	n (%)	OR[1] [95% CI]	RR[2] [95% CI]	RD[3] [95% CI]	p-value[4]	p-value (int)[5]
Week 8							
Relugolix+E2/NETA	104	22 (21.2)	NC	NC	NC	NC	NC
Placebo	127	2 (1.6)	[NC;NC]	[NC;NC]	[NC;NC]		
Week 12							
Relugolix+E2/NETA	104	54 (51.9)	NC	NC	NC	NC	
Placebo	127	3 (2.4)	[NC;NC]	[NC;NC]	[NC;NC]		
Week 16							
Relugolix+E2/NETA	104	59 (56.7)	NC	NC	NC	NC	
Placebo	127	3 (2.4)	[NC;NC]	[NC;NC]	[NC;NC]		
Week 20							
Relugolix+E2/NETA	104	62 (59.6)	NC	NC	NC	NC	
Placebo	127	6 (4.7)	[NC;NC]	[NC;NC]	[NC;NC]		
Week 24							
Relugolix+E2/NETA	104	65 (62.5)	NC	NC	NC	NC	
Placebo	127	9 (7.1)	[NC;NC]	[NC;NC]	[NC;NC]		

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group.
Sustained response is defined as patients time to achieve and maintain response (MBL volume of < 80 mL and at least a 50% Reduction from Baseline MBL Volume) until the date of last study drug.
[1] OR (95% CI) based on a logistic regression model adjusting for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates.
[2] RR (95% CI) based on a Cochran-Mantel-Haenszel approach stratified by study.
[3] RD (95% CI) based on a Mantel-Haenszel approach stratified by study. 95% CIs are based on the approximation to the normal distribution using the Sato estimator for the standard error.
[4] P-value based on a Cochran-Mantel-Haenszel test stratified by study.
[5] Interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the OR (95% CI). Missing subgroup levels are not included in estimation of the interaction p-value.
A continuity correction is applied in estimation of the OR, RR and p-value if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum. No continuity correction is applied in the estimation of the RD.
The reference group for the OR, RR and RD is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with an event; OR: Odds ratio; RR: Risk ratio; RD: Risk difference; CI: Confidence interval; int: p-value for interaction; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; NC: Not calculated.

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Table EFF.RESPCMPS.MITT.Pooled.S3: Sustained Responder Rate (MBL volume of < 80 mL and at least a 50% Reduction from Baseline MBL Volume) by Visit, by Subgroup (mITT Population)

Study: Pooled

Subgroup: Uterine Volume at Baseline (cm3), Level: Missing

Treatment	N	n (%)	OR[1] [95% CI]	RR[2] [95% CI]	RD[3] [95% CI]	p-value[4]	p-value (int)[5]
Week 8							
Relugolix+E2/NETA	1	0	NC	NC	NC	NC	NC
Placebo	0	0	[NC;NC]	[NC;NC]	[NC;NC]		
Week 12							
Relugolix+E2/NETA	1	0	NC	NC	NC	NC	
Placebo	0	0	[NC;NC]	[NC;NC]	[NC;NC]		
Week 16							
Relugolix+E2/NETA	1	0	NC	NC	NC	NC	
Placebo	0	0	[NC;NC]	[NC;NC]	[NC;NC]		
Week 20							
Relugolix+E2/NETA	1	0	NC	NC	NC	NC	
Placebo	0	0	[NC;NC]	[NC;NC]	[NC;NC]		
Week 24							
Relugolix+E2/NETA	1	0	NC	NC	NC	NC	
Placebo	0	0	[NC;NC]	[NC;NC]	[NC;NC]		

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group.
Sustained response is defined as patients time to achieve and maintain response (MBL volume of < 80 mL and at least a 50% Reduction from Baseline MBL Volume) until the date of last study drug.
[1] OR (95% CI) based on a logistic regression model adjusting for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates.
[2] RR (95% CI) based on a Cochran-Mantel-Haenszel approach stratified by study.
[3] RD (95% CI) based on a Mantel-Haenszel approach stratified by study. 95% CIs are based on the approximation to the normal distribution using the Sato estimator for the standard error.
[4] P-value based on a Cochran-Mantel-Haenszel test stratified by study.
[5] Interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the OR (95% CI). Missing subgroup levels are not included in estimation of the interaction p-value.
A continuity correction is applied in estimation of the OR, RR and p-value if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum. No continuity correction is applied in the estimation of the RD.
The reference group for the OR, RR and RD is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with an event; OR: Odds ratio; RR: Risk ratio; RD: Risk difference; CI: Confidence interval; int: p-value for interaction; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; NC: Not calculated.

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Table EFF.RESPCMPS.MITT.Pooled.S4: Sustained Responder Rate (MBL volume of < 80 mL and at least a 50% Reduction from Baseline MBL Volume) by Visit, by Subgroup (mITT Population)

Study: Pooled

Subgroup: Maximum NRS Pain Score at Baseline, Level: < 4

Treatment	N	n (%)	OR[1] [95% CI]	RR[2] [95% CI]	RD[3] [95% CI]	p-value[4]	p-value (int)[5]
Week 8							
Relugolix+E2/NETA	73	20 (27.4)	NC	NC	NC	NC	NC
Placebo	62	0	[NC;NC]	[NC;NC]	[NC;NC]		
Week 12							
Relugolix+E2/NETA	73	45 (61.6)	NC	NC	NC	NC	
Placebo	62	1 (1.6)	[NC;NC]	[NC;NC]	[NC;NC]		
Week 16							
Relugolix+E2/NETA	73	52 (71.2)	NC	NC	NC	NC	
Placebo	62	1 (1.6)	[NC;NC]	[NC;NC]	[NC;NC]		
Week 20							
Relugolix+E2/NETA	73	53 (72.6)	NC	NC	NC	NC	
Placebo	62	1 (1.6)	[NC;NC]	[NC;NC]	[NC;NC]		
Week 24							
Relugolix+E2/NETA	73	54 (74.0)	NC	NC	NC	NC	
Placebo	62	3 (4.8)	[NC;NC]	[NC;NC]	[NC;NC]		

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group.
Sustained response is defined as patients time to achieve and maintain response (MBL volume of < 80 mL and at least a 50% Reduction from Baseline MBL Volume) until the date of last study drug.
[1] OR (95% CI) based on a logistic regression model adjusting for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates.
[2] RR (95% CI) based on a Cochran-Mantel-Haenszel approach stratified by study.
[3] RD (95% CI) based on a Mantel-Haenszel approach stratified by study. 95% CIs are based on the approximation to the normal distribution using the Sato estimator for the standard error.
[4] P-value based on a Cochran-Mantel-Haenszel test stratified by study.
[5] Interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the OR (95% CI). Missing subgroup levels are not included in estimation of the interaction p-value.
A continuity correction is applied in estimation of the OR, RR and p-value if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum. No continuity correction is applied in the estimation of the RD.
The reference group for the OR, RR and RD is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with an event; OR: Odds ratio; RR: Risk ratio; RD: Risk difference; CI: Confidence interval; int: p-value for interaction; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; NC: Not calculated.

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Table EFF.RESPCMPS.MITT.Pooled.S4: Sustained Responder Rate (MBL volume of < 80 mL and at least a 50% Reduction from Baseline MBL Volume) by Visit, by Subgroup (mITT Population)

Study: Pooled

Subgroup: Maximum NRS Pain Score at Baseline, Level: >= 4

Treatment	N	n (%)	OR[1] [95% CI]	RR[2] [95% CI]	RD[3] [95% CI]	p-value[4]	p-value (int)[5]
Week 8							
Relugolix+E2/NETA	177	45 (25.4)	NC	NC	NC	NC	NC
Placebo	190	7 (3.7)	[NC;NC]	[NC;NC]	[NC;NC]		
Week 12							
Relugolix+E2/NETA	177	94 (53.1)	NC	NC	NC	NC	
Placebo	190	10 (5.3)	[NC;NC]	[NC;NC]	[NC;NC]		
Week 16							
Relugolix+E2/NETA	177	106 (59.9)	NC	NC	NC	NC	
Placebo	190	10 (5.3)	[NC;NC]	[NC;NC]	[NC;NC]		
Week 20							
Relugolix+E2/NETA	177	111 (62.7)	NC	NC	NC	NC	
Placebo	190	15 (7.9)	[NC;NC]	[NC;NC]	[NC;NC]		
Week 24							
Relugolix+E2/NETA	177	120 (67.8)	NC	NC	NC	NC	
Placebo	190	18 (9.5)	[NC;NC]	[NC;NC]	[NC;NC]		

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group.
Sustained response is defined as patients time to achieve and maintain response (MBL volume of < 80 mL and at least a 50% Reduction from Baseline MBL Volume) until the date of last study drug.
[1] OR (95% CI) based on a logistic regression model adjusting for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates.
[2] RR (95% CI) based on a Cochran-Mantel-Haenszel approach stratified by study.
[3] RD (95% CI) based on a Mantel-Haenszel approach stratified by study. 95% CIs are based on the approximation to the normal distribution using the Sato estimator for the standard error.
[4] P-value based on a Cochran-Mantel-Haenszel test stratified by study.
[5] Interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the OR (95% CI). Missing subgroup levels are not included in estimation of the interaction p-value.
A continuity correction is applied in estimation of the OR, RR and p-value if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum. No continuity correction is applied in the estimation of the RD.
The reference group for the OR, RR and RD is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with an event; OR: Odds ratio; RR: Risk ratio; RD: Risk difference; CI: Confidence interval; int: p-value for interaction; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; NC: Not calculated.

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Table EFF.RESPCMPS.MITT.Pooled.S4: Sustained Responder Rate (MBL volume of < 80 mL and at least a 50% Reduction from Baseline MBL Volume) by Visit, by Subgroup (mITT Population)

Study: Pooled

Subgroup: Maximum NRS Pain Score at Baseline, Level: Missing

Treatment	N	n (%)	OR[1] [95% CI]	RR[2] [95% CI]	RD[3] [95% CI]	p-value[4]	p-value (int)[5]
Week 8							
Relugolix+E2/NETA	3	0	NC	NC	NC	NC	NC
Placebo	4	0	[NC;NC]	[NC;NC]	[NC;NC]		
Week 12							
Relugolix+E2/NETA	3	1 (33.3)	NC	NC	NC	NC	
Placebo	4	0	[NC;NC]	[NC;NC]	[NC;NC]		
Week 16							
Relugolix+E2/NETA	3	1 (33.3)	NC	NC	NC	NC	
Placebo	4	0	[NC;NC]	[NC;NC]	[NC;NC]		
Week 20							
Relugolix+E2/NETA	3	1 (33.3)	NC	NC	NC	NC	
Placebo	4	0	[NC;NC]	[NC;NC]	[NC;NC]		
Week 24							
Relugolix+E2/NETA	3	1 (33.3)	NC	NC	NC	NC	
Placebo	4	0	[NC;NC]	[NC;NC]	[NC;NC]		

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group.
Sustained response is defined as patients time to achieve and maintain response (MBL volume of < 80 mL and at least a 50% Reduction from Baseline MBL Volume) until the date of last study drug.
[1] OR (95% CI) based on a logistic regression model adjusting for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates.
[2] RR (95% CI) based on a Cochran-Mantel-Haenszel approach stratified by study.
[3] RD (95% CI) based on a Mantel-Haenszel approach stratified by study. 95% CIs are based on the approximation to the normal distribution using the Sato estimator for the standard error.
[4] P-value based on a Cochran-Mantel-Haenszel test stratified by study.
[5] Interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the OR (95% CI). Missing subgroup levels are not included in estimation of the interaction p-value.
A continuity correction is applied in estimation of the OR, RR and p-value if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum. No continuity correction is applied in the estimation of the RD.
The reference group for the OR, RR and RD is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with an event; OR: Odds ratio; RR: Risk ratio; RD: Risk difference; CI: Confidence interval; int: p-value for interaction; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; NC: Not calculated.

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Table EFF.RESPCMPS.MITT.Pooled.S5: Sustained Responder Rate (MBL volume of < 80 mL and at least a 50% Reduction from Baseline MBL Volume) by Visit, by Subgroup (mITT Population)

Study: Pooled

Subgroup: MBL Volume at Baseline (mL), Level: < 225 mL

Treatment	N	n (%)	OR[1] [95% CI]	RR[2] [95% CI]	RD[3] [95% CI]	p-value[4]	p-value (int)[5]
Week 8							
Relugolix+E2/NETA	164	60 (36.6)	NC	NC	NC	NC	NC
Placebo	171	7 (4.1)	[NC;NC]	[NC;NC]	[NC;NC]		
Week 12							
Relugolix+E2/NETA	164	98 (59.8)	NC	NC	NC	NC	
Placebo	171	10 (5.8)	[NC;NC]	[NC;NC]	[NC;NC]		
Week 16							
Relugolix+E2/NETA	164	107 (65.2)	NC	NC	NC	NC	
Placebo	171	10 (5.8)	[NC;NC]	[NC;NC]	[NC;NC]		
Week 20							
Relugolix+E2/NETA	164	110 (67.1)	NC	NC	NC	NC	
Placebo	171	12 (7.0)	[NC;NC]	[NC;NC]	[NC;NC]		
Week 24							
Relugolix+E2/NETA	164	118 (72.0)	NC	NC	NC	NC	
Placebo	171	15 (8.8)	[NC;NC]	[NC;NC]	[NC;NC]		

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group.
Sustained response is defined as patients time to achieve and maintain response (MBL volume of < 80 mL and at least a 50% Reduction from Baseline MBL Volume) until the date of last study drug.
[1] OR (95% CI) based on a logistic regression model adjusting for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates.
[2] RR (95% CI) based on a Cochran-Mantel-Haenszel approach stratified by study.
[3] RD (95% CI) based on a Mantel-Haenszel approach stratified by study. 95% CIs are based on the approximation to the normal distribution using the Sato estimator for the standard error.
[4] P-value based on a Cochran-Mantel-Haenszel test stratified by study.
[5] Interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the OR (95% CI). Missing subgroup levels are not included in estimation of the interaction p-value.
A continuity correction is applied in estimation of the OR, RR and p-value if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum. No continuity correction is applied in the estimation of the RD.
The reference group for the OR, RR and RD is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with an event; OR: Odds ratio; RR: Risk ratio; RD: Risk difference; CI: Confidence interval; int: p-value for interaction; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; NC: Not calculated.

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Table EFF.RESPCMPS.MITT.Pooled.S5: Sustained Responder Rate (MBL volume of < 80 mL and at least a 50% Reduction from Baseline MBL Volume) by Visit, by Subgroup (mITT Population)

Study: Pooled

Subgroup: MBL Volume at Baseline (mL), Level: >= 225 mL

Treatment	N	n (%)	OR[1] [95% CI]	RR[2] [95% CI]	RD[3] [95% CI]	p-value[4]	p-value (int)[5]
Week 8							
Relugolix+E2/NETA	89	5 (5.6)	NC	NC	NC	NC	NC
Placebo	85	0	[NC;NC]	[NC;NC]	[NC;NC]		
Week 12							
Relugolix+E2/NETA	89	42 (47.2)	NC	NC	NC	NC	
Placebo	85	1 (1.2)	[NC;NC]	[NC;NC]	[NC;NC]		
Week 16							
Relugolix+E2/NETA	89	52 (58.4)	NC	NC	NC	NC	
Placebo	85	1 (1.2)	[NC;NC]	[NC;NC]	[NC;NC]		
Week 20							
Relugolix+E2/NETA	89	55 (61.8)	NC	NC	NC	NC	
Placebo	85	4 (4.7)	[NC;NC]	[NC;NC]	[NC;NC]		
Week 24							
Relugolix+E2/NETA	89	57 (64.0)	NC	NC	NC	NC	
Placebo	85	6 (7.1)	[NC;NC]	[NC;NC]	[NC;NC]		

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group.
Sustained response is defined as patients time to achieve and maintain response (MBL volume of < 80 mL and at least a 50% Reduction from Baseline MBL Volume) until the date of last study drug.
[1] OR (95% CI) based on a logistic regression model adjusting for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates.
[2] RR (95% CI) based on a Cochran-Mantel-Haenszel approach stratified by study.
[3] RD (95% CI) based on a Mantel-Haenszel approach stratified by study. 95% CIs are based on the approximation to the normal distribution using the Sato estimator for the standard error.
[4] P-value based on a Cochran-Mantel-Haenszel test stratified by study.
[5] Interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the OR (95% CI). Missing subgroup levels are not included in estimation of the interaction p-value.
A continuity correction is applied in estimation of the OR, RR and p-value if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum. No continuity correction is applied in the estimation of the RD.
The reference group for the OR, RR and RD is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with an event; OR: Odds ratio; RR: Risk ratio; RD: Risk difference; CI: Confidence interval; int: p-value for interaction; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; NC: Not calculated.

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Table EFF.RESPCMPS.MITT.Pooled.S6: Sustained Responder Rate (MBL volume of < 80 mL and at least a 50% Reduction from Baseline MBL Volume) by Visit, by Subgroup (mITT Population)

Study: Pooled

Subgroup: Geographic Region I, Level: North America

Treatment	N	n (%)	OR[1] [95% CI]	RR[2] [95% CI]	RD[3] [95% CI]	p-value[4]	p-value (int)[5]
Week 8							
Relugolix+E2/NETA	191	41 (21.5)	NC	NC	NC	NC	NC
Placebo	194	4 (2.1)	[NC;NC]	[NC;NC]	[NC;NC]		
Week 12							
Relugolix+E2/NETA	191	96 (50.3)	NC	NC	NC	NC	
Placebo	194	7 (3.6)	[NC;NC]	[NC;NC]	[NC;NC]		
Week 16							
Relugolix+E2/NETA	191	111 (58.1)	NC	NC	NC	NC	
Placebo	194	7 (3.6)	[NC;NC]	[NC;NC]	[NC;NC]		
Week 20							
Relugolix+E2/NETA	191	116 (60.7)	NC	NC	NC	NC	
Placebo	194	12 (6.2)	[NC;NC]	[NC;NC]	[NC;NC]		
Week 24							
Relugolix+E2/NETA	191	125 (65.4)	NC	NC	NC	NC	
Placebo	194	16 (8.2)	[NC;NC]	[NC;NC]	[NC;NC]		

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group.
Sustained response is defined as patients time to achieve and maintain response (MBL volume of < 80 mL and at least a 50% Reduction from Baseline MBL Volume) until the date of last study drug.
[1] OR (95% CI) based on a logistic regression model adjusting for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates.
[2] RR (95% CI) based on a Cochran-Mantel-Haenszel approach stratified by study.
[3] RD (95% CI) based on a Mantel-Haenszel approach stratified by study. 95% CIs are based on the approximation to the normal distribution using the Sato estimator for the standard error.
[4] P-value based on a Cochran-Mantel-Haenszel test stratified by study.
[5] Interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the OR (95% CI). Missing subgroup levels are not included in estimation of the interaction p-value.
A continuity correction is applied in estimation of the OR, RR and p-value if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum. No continuity correction is applied in the estimation of the RD.
The reference group for the OR, RR and RD is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with an event; OR: Odds ratio; RR: Risk ratio; RD: Risk difference; CI: Confidence interval; int: p-value for interaction; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; NC: Not calculated.

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Table EFF.RESPCMPS.MITT.Pooled.S6: Sustained Responder Rate (MBL volume of < 80 mL and at least a 50% Reduction from Baseline MBL Volume) by Visit, by Subgroup (mITT Population)

Study: Pooled

Subgroup: Geographic Region I, Level: Rest of World

Treatment	N	n (%)	OR[1] [95% CI]	RR[2] [95% CI]	RD[3] [95% CI]	p-value[4]	p-value (int)[5]
Week 8							
Relugolix+E2/NETA	62	24 (38.7)	NC	NC	NC	NC	NC
Placebo	62	3 (4.8)	[NC;NC]	[NC;NC]	[NC;NC]		
Week 12							
Relugolix+E2/NETA	62	44 (71.0)	NC	NC	NC	NC	
Placebo	62	4 (6.5)	[NC;NC]	[NC;NC]	[NC;NC]		
Week 16							
Relugolix+E2/NETA	62	48 (77.4)	NC	NC	NC	NC	
Placebo	62	4 (6.5)	[NC;NC]	[NC;NC]	[NC;NC]		
Week 20							
Relugolix+E2/NETA	62	49 (79.0)	NC	NC	NC	NC	
Placebo	62	4 (6.5)	[NC;NC]	[NC;NC]	[NC;NC]		
Week 24							
Relugolix+E2/NETA	62	50 (80.6)	NC	NC	NC	NC	
Placebo	62	5 (8.1)	[NC;NC]	[NC;NC]	[NC;NC]		

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group.
Sustained response is defined as patients time to achieve and maintain response (MBL volume of < 80 mL and at least a 50% Reduction from Baseline MBL Volume) until the date of last study drug.
[1] OR (95% CI) based on a logistic regression model adjusting for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates.
[2] RR (95% CI) based on a Cochran-Mantel-Haenszel approach stratified by study.
[3] RD (95% CI) based on a Mantel-Haenszel approach stratified by study. 95% CIs are based on the approximation to the normal distribution using the Sato estimator for the standard error.
[4] P-value based on a Cochran-Mantel-Haenszel test stratified by study.
[5] Interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the OR (95% CI). Missing subgroup levels are not included in estimation of the interaction p-value.
A continuity correction is applied in estimation of the OR, RR and p-value if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum. No continuity correction is applied in the estimation of the RD.
The reference group for the OR, RR and RD is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with an event; OR: Odds ratio; RR: Risk ratio; RD: Risk difference; CI: Confidence interval; int: p-value for interaction; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; NC: Not calculated.

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Table EFF.RESPCMPS.MITT.Pooled.S7: Sustained Responder Rate (MBL volume of < 80 mL and at least a 50% Reduction from Baseline MBL Volume) by Visit, by Subgroup (mITT Population)

Study: Pooled

Subgroup: Geographic Region II, Level: Europe

Treatment	N	n (%)	OR[1] [95% CI]	RR[2] [95% CI]	RD[3] [95% CI]	p-value[4]	p-value (int)[5]
Week 8							
Relugolix+E2/NETA	41	15 (36.6)	NC	NC	NC	NC	NC
Placebo	42	3 (7.1)	[NC;NC]	[NC;NC]	[NC;NC]		
Week 12							
Relugolix+E2/NETA	41	31 (75.6)	NC	NC	NC	NC	
Placebo	42	3 (7.1)	[NC;NC]	[NC;NC]	[NC;NC]		
Week 16							
Relugolix+E2/NETA	41	33 (80.5)	NC	NC	NC	NC	
Placebo	42	3 (7.1)	[NC;NC]	[NC;NC]	[NC;NC]		
Week 20							
Relugolix+E2/NETA	41	34 (82.9)	NC	NC	NC	NC	
Placebo	42	3 (7.1)	[NC;NC]	[NC;NC]	[NC;NC]		
Week 24							
Relugolix+E2/NETA	41	35 (85.4)	NC	NC	NC	NC	
Placebo	42	4 (9.5)	[NC;NC]	[NC;NC]	[NC;NC]		

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group.
Sustained response is defined as patients time to achieve and maintain response (MBL volume of < 80 mL and at least a 50% Reduction from Baseline MBL Volume) until the date of last study drug.
[1] OR (95% CI) based on a logistic regression model adjusting for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates.
[2] RR (95% CI) based on a Cochran-Mantel-Haenszel approach stratified by study.
[3] RD (95% CI) based on a Mantel-Haenszel approach stratified by study. 95% CIs are based on the approximation to the normal distribution using the Sato estimator for the standard error.
[4] P-value based on a Cochran-Mantel-Haenszel test stratified by study.
[5] Interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the OR (95% CI). Missing subgroup levels are not included in estimation of the interaction p-value.
A continuity correction is applied in estimation of the OR, RR and p-value if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum. No continuity correction is applied in the estimation of the RD.
The reference group for the OR, RR and RD is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with an event; OR: Odds ratio; RR: Risk ratio; RD: Risk difference; CI: Confidence interval; int: p-value for interaction; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; NC: Not calculated.

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Table EFF.RESPCMPS.MITT.Pooled.S7: Sustained Responder Rate (MBL volume of < 80 mL and at least a 50% Reduction from Baseline MBL Volume) by Visit, by Subgroup (mITT Population)

Study: Pooled

Subgroup: Geographic Region II, Level: Rest of World (including the US)

Treatment	N	n (%)	OR[1] [95% CI]	RR[2] [95% CI]	RD[3] [95% CI]	p-value[4]	p-value (int)[5]
Week 8							
Relugolix+E2/NETA	212	50 (23.6)	NC	NC	NC	NC	NC
Placebo	214	4 (1.9)	[NC;NC]	[NC;NC]	[NC;NC]		
Week 12							
Relugolix+E2/NETA	212	109 (51.4)	NC	NC	NC	NC	
Placebo	214	8 (3.7)	[NC;NC]	[NC;NC]	[NC;NC]		
Week 16							
Relugolix+E2/NETA	212	126 (59.4)	NC	NC	NC	NC	
Placebo	214	8 (3.7)	[NC;NC]	[NC;NC]	[NC;NC]		
Week 20							
Relugolix+E2/NETA	212	131 (61.8)	NC	NC	NC	NC	
Placebo	214	13 (6.1)	[NC;NC]	[NC;NC]	[NC;NC]		
Week 24							
Relugolix+E2/NETA	212	140 (66.0)	NC	NC	NC	NC	
Placebo	214	17 (7.9)	[NC;NC]	[NC;NC]	[NC;NC]		

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group.
Sustained response is defined as patients time to achieve and maintain response (MBL volume of < 80 mL and at least a 50% Reduction from Baseline MBL Volume) until the date of last study drug.
[1] OR (95% CI) based on a logistic regression model adjusting for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates.
[2] RR (95% CI) based on a Cochran-Mantel-Haenszel approach stratified by study.
[3] RD (95% CI) based on a Mantel-Haenszel approach stratified by study. 95% CIs are based on the approximation to the normal distribution using the Sato estimator for the standard error.
[4] P-value based on a Cochran-Mantel-Haenszel test stratified by study.
[5] Interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the OR (95% CI). Missing subgroup levels are not included in estimation of the interaction p-value.
A continuity correction is applied in estimation of the OR, RR and p-value if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum. No continuity correction is applied in the estimation of the RD.
The reference group for the OR, RR and RD is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with an event; OR: Odds ratio; RR: Risk ratio; RD: Risk difference; CI: Confidence interval; int: p-value for interaction; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; NC: Not calculated.

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Table EFF.RESPCMPS.MITT.Pooled.S8: Sustained Responder Rate (MBL volume of < 80 mL and at least a 50% Reduction from Baseline MBL Volume) by Visit, by Subgroup (mITT Population)

Study: Pooled

Subgroup: Ethnicity, Level: Hispanic or Latino

Treatment	N	n (%)	OR[1] [95% CI]	RR[2] [95% CI]	RD[3] [95% CI]	p-value[4]	p-value (int)[5]
Week 8							
Relugolix+E2/NETA	52	16 (30.8)	NC	NC	NC	NC	NC
Placebo	55	3 (5.5)	[NC;NC]	[NC;NC]	[NC;NC]		
Week 12							
Relugolix+E2/NETA	52	29 (55.8)	NC	NC	NC	NC	
Placebo	55	4 (7.3)	[NC;NC]	[NC;NC]	[NC;NC]		
Week 16							
Relugolix+E2/NETA	52	36 (69.2)	NC	NC	NC	NC	
Placebo	55	4 (7.3)	[NC;NC]	[NC;NC]	[NC;NC]		
Week 20							
Relugolix+E2/NETA	52	37 (71.2)	NC	NC	NC	NC	
Placebo	55	8 (14.5)	[NC;NC]	[NC;NC]	[NC;NC]		
Week 24							
Relugolix+E2/NETA	52	39 (75.0)	NC	NC	NC	NC	
Placebo	55	8 (14.5)	[NC;NC]	[NC;NC]	[NC;NC]		

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group.
Sustained response is defined as patients time to achieve and maintain response (MBL volume of < 80 mL and at least a 50% Reduction from Baseline MBL Volume) until the date of last study drug.
[1] OR (95% CI) based on a logistic regression model adjusting for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates.
[2] RR (95% CI) based on a Cochran-Mantel-Haenszel approach stratified by study.
[3] RD (95% CI) based on a Mantel-Haenszel approach stratified by study. 95% CIs are based on the approximation to the normal distribution using the Sato estimator for the standard error.
[4] P-value based on a Cochran-Mantel-Haenszel test stratified by study.
[5] Interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the OR (95% CI). Missing subgroup levels are not included in estimation of the interaction p-value.
A continuity correction is applied in estimation of the OR, RR and p-value if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum. No continuity correction is applied in the estimation of the RD.
The reference group for the OR, RR and RD is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with an event; OR: Odds ratio; RR: Risk ratio; RD: Risk difference; CI: Confidence interval; int: p-value for interaction; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; NC: Not calculated.

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Table EFF.RESPCMPS.MITT.Pooled.S8: Sustained Responder Rate (MBL volume of < 80 mL and at least a 50% Reduction from Baseline MBL Volume) by Visit, by Subgroup (mITT Population)

Study: Pooled

Subgroup: Ethnicity, Level: Not Hispanic or Latino

Treatment	N	n (%)	OR[1] [95% CI]	RR[2] [95% CI]	RD[3] [95% CI]	p-value[4]	p-value (int)[5]
Week 8							
Relugolix+E2/NETA	197	49 (24.9)	NC	NC	NC	NC	NC
Placebo	199	4 (2.0)	[NC;NC]	[NC;NC]	[NC;NC]		
Week 12							
Relugolix+E2/NETA	197	109 (55.3)	NC	NC	NC	NC	
Placebo	199	7 (3.5)	[NC;NC]	[NC;NC]	[NC;NC]		
Week 16							
Relugolix+E2/NETA	197	120 (60.9)	NC	NC	NC	NC	
Placebo	199	7 (3.5)	[NC;NC]	[NC;NC]	[NC;NC]		
Week 20							
Relugolix+E2/NETA	197	125 (63.5)	NC	NC	NC	NC	
Placebo	199	8 (4.0)	[NC;NC]	[NC;NC]	[NC;NC]		
Week 24							
Relugolix+E2/NETA	197	133 (67.5)	NC	NC	NC	NC	
Placebo	199	13 (6.5)	[NC;NC]	[NC;NC]	[NC;NC]		

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group.
Sustained response is defined as patients time to achieve and maintain response (MBL volume of < 80 mL and at least a 50% Reduction from Baseline MBL Volume) until the date of last study drug.
[1] OR (95% CI) based on a logistic regression model adjusting for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates.
[2] RR (95% CI) based on a Cochran-Mantel-Haenszel approach stratified by study.
[3] RD (95% CI) based on a Mantel-Haenszel approach stratified by study. 95% CIs are based on the approximation to the normal distribution using the Sato estimator for the standard error.
[4] P-value based on a Cochran-Mantel-Haenszel test stratified by study.
[5] Interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the OR (95% CI). Missing subgroup levels are not included in estimation of the interaction p-value.
A continuity correction is applied in estimation of the OR, RR and p-value if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum. No continuity correction is applied in the estimation of the RD.
The reference group for the OR, RR and RD is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with an event; OR: Odds ratio; RR: Risk ratio; RD: Risk difference; CI: Confidence interval; int: p-value for interaction; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; NC: Not calculated.

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Table EFF.RESPCMPS.MITT.Pooled.S8: Sustained Responder Rate (MBL volume of < 80 mL and at least a 50% Reduction from Baseline MBL Volume) by Visit, by Subgroup (mITT Population)

Study: Pooled

Subgroup: Ethnicity, Level: Not reported

Treatment	N	n (%)	OR[1] [95% CI]	RR[2] [95% CI]	RD[3] [95% CI]	p-value[4]	p-value (int)[5]
Week 8							
Relugolix+E2/NETA	4	0	NC	NC	NC	NC	NC
Placebo	2	0	[NC;NC]	[NC;NC]	[NC;NC]		
Week 12							
Relugolix+E2/NETA	4	2 (50.0)	NC	NC	NC	NC	
Placebo	2	0	[NC;NC]	[NC;NC]	[NC;NC]		
Week 16							
Relugolix+E2/NETA	4	3 (75.0)	NC	NC	NC	NC	
Placebo	2	0	[NC;NC]	[NC;NC]	[NC;NC]		
Week 20							
Relugolix+E2/NETA	4	3 (75.0)	NC	NC	NC	NC	
Placebo	2	0	[NC;NC]	[NC;NC]	[NC;NC]		
Week 24							
Relugolix+E2/NETA	4	3 (75.0)	NC	NC	NC	NC	
Placebo	2	0	[NC;NC]	[NC;NC]	[NC;NC]		

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group.
Sustained response is defined as patients time to achieve and maintain response (MBL volume of < 80 mL and at least a 50% Reduction from Baseline MBL Volume) until the date of last study drug.
[1] OR (95% CI) based on a logistic regression model adjusting for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates.
[2] RR (95% CI) based on a Cochran-Mantel-Haenszel approach stratified by study.
[3] RD (95% CI) based on a Mantel-Haenszel approach stratified by study. 95% CIs are based on the approximation to the normal distribution using the Sato estimator for the standard error.
[4] P-value based on a Cochran-Mantel-Haenszel test stratified by study.
[5] Interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the OR (95% CI). Not reported subgroup levels are not included in estimation of the interaction p-value.
A continuity correction is applied in estimation of the OR, RR and p-value if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum. No continuity correction is applied in the estimation of the RD.
The reference group for the OR, RR and RD is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with an event; OR: Odds ratio; RR: Risk ratio; RD: Risk difference; CI: Confidence interval; int: p-value for interaction; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; NC: Not calculated.

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Table EFF.RESPCMPS.MITT.Pooled.S9: Sustained Responder Rate (MBL volume of < 80 mL and at least a 50% Reduction from Baseline MBL Volume) by Visit, by Subgroup (mITT Population)

Study: Pooled

Subgroup: Race, Level: Black/African American

Treatment	N	n (%)	OR[1] [95% CI]	RR[2] [95% CI]	RD[3] [95% CI]	p-value[4]	p-value (int)[5]
Week 8							
Relugolix+E2/NETA	122	28 (23.0)	NC	NC	NC	NC	NC
Placebo	141	3 (2.1)	[NC;NC]	[NC;NC]	[NC;NC]		
Week 12							
Relugolix+E2/NETA	122	58 (47.5)	NC	NC	NC	NC	
Placebo	141	6 (4.3)	[NC;NC]	[NC;NC]	[NC;NC]		
Week 16							
Relugolix+E2/NETA	122	64 (52.5)	NC	NC	NC	NC	
Placebo	141	6 (4.3)	[NC;NC]	[NC;NC]	[NC;NC]		
Week 20							
Relugolix+E2/NETA	122	66 (54.1)	NC	NC	NC	NC	
Placebo	141	6 (4.3)	[NC;NC]	[NC;NC]	[NC;NC]		
Week 24							
Relugolix+E2/NETA	122	71 (58.2)	NC	NC	NC	NC	
Placebo	141	8 (5.7)	[NC;NC]	[NC;NC]	[NC;NC]		

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group.
Sustained response is defined as patients time to achieve and maintain response (MBL volume of < 80 mL and at least a 50% Reduction from Baseline MBL Volume) until the date of last study drug.
[1] OR (95% CI) based on a logistic regression model adjusting for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates.
[2] RR (95% CI) based on a Cochran-Mantel-Haenszel approach stratified by study.
[3] RD (95% CI) based on a Mantel-Haenszel approach stratified by study. 95% CIs are based on the approximation to the normal distribution using the Sato estimator for the standard error.
[4] P-value based on a Cochran-Mantel-Haenszel test stratified by study.
[5] Interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the OR (95% CI). Not reported subgroup levels are not included in estimation of the interaction p-value.
A continuity correction is applied in estimation of the OR, RR and p-value if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum. No continuity correction is applied in the estimation of the RD.
The reference group for the OR, RR and RD is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with an event; OR: Odds ratio; RR: Risk ratio; RD: Risk difference; CI: Confidence interval; int: p-value for interaction; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; NC: Not calculated.

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Table EFF.RESPCMPS.MITT.Pooled.S9: Sustained Responder Rate (MBL volume of < 80 mL and at least a 50% Reduction from Baseline MBL Volume) by Visit, by Subgroup (mITT Population)

Study: Pooled

Subgroup: Race, Level: White

Treatment	N	n (%)	OR[1] [95% CI]	RR[2] [95% CI]	RD[3] [95% CI]	p-value[4]	p-value (int)[5]
Week 8							
Relugolix+E2/NETA	122	34 (27.9)	NC	NC	NC	NC	NC
Placebo	105	4 (3.8)	[NC;NC]	[NC;NC]	[NC;NC]		
Week 12							
Relugolix+E2/NETA	122	75 (61.5)	NC	NC	NC	NC	
Placebo	105	5 (4.8)	[NC;NC]	[NC;NC]	[NC;NC]		
Week 16							
Relugolix+E2/NETA	122	88 (72.1)	NC	NC	NC	NC	
Placebo	105	5 (4.8)	[NC;NC]	[NC;NC]	[NC;NC]		
Week 20							
Relugolix+E2/NETA	122	92 (75.4)	NC	NC	NC	NC	
Placebo	105	10 (9.5)	[NC;NC]	[NC;NC]	[NC;NC]		
Week 24							
Relugolix+E2/NETA	122	97 (79.5)	NC	NC	NC	NC	
Placebo	105	12 (11.4)	[NC;NC]	[NC;NC]	[NC;NC]		

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group.
Sustained response is defined as patients time to achieve and maintain response (MBL volume of < 80 mL and at least a 50% Reduction from Baseline MBL Volume) until the date of last study drug.
[1] OR (95% CI) based on a logistic regression model adjusting for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates.
[2] RR (95% CI) based on a Cochran-Mantel-Haenszel approach stratified by study.
[3] RD (95% CI) based on a Mantel-Haenszel approach stratified by study. 95% CIs are based on the approximation to the normal distribution using the Sato estimator for the standard error.
[4] P-value based on a Cochran-Mantel-Haenszel test stratified by study.
[5] Interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the OR (95% CI). Not reported subgroup levels are not included in estimation of the interaction p-value.
A continuity correction is applied in estimation of the OR, RR and p-value if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum. No continuity correction is applied in the estimation of the RD.
The reference group for the OR, RR and RD is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with an event; OR: Odds ratio; RR: Risk ratio; RD: Risk difference; CI: Confidence interval; int: p-value for interaction; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; NC: Not calculated.

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Table EFF.RESPCMPS.MITT.Pooled.S9: Sustained Responder Rate (MBL volume of < 80 mL and at least a 50% Reduction from Baseline MBL Volume) by Visit, by Subgroup (mITT Population)

Study: Pooled

Subgroup: Race, Level: Asian

Treatment	N	n (%)	OR[1] [95% CI]	RR[2] [95% CI]	RD[3] [95% CI]	p-value[4]	p-value (int)[5]
Week 8							
Relugolix+E2/NETA	1	1 (100.0)	NC	NC	NC	NC	NC
Placebo	3	0	[NC;NC]	[NC;NC]	[NC;NC]		
Week 12							
Relugolix+E2/NETA	1	1 (100.0)	NC	NC	NC	NC	
Placebo	3	0	[NC;NC]	[NC;NC]	[NC;NC]		
Week 16							
Relugolix+E2/NETA	1	1 (100.0)	NC	NC	NC	NC	
Placebo	3	0	[NC;NC]	[NC;NC]	[NC;NC]		
Week 20							
Relugolix+E2/NETA	1	1 (100.0)	NC	NC	NC	NC	
Placebo	3	0	[NC;NC]	[NC;NC]	[NC;NC]		
Week 24							
Relugolix+E2/NETA	1	1 (100.0)	NC	NC	NC	NC	
Placebo	3	1 (33.3)	[NC;NC]	[NC;NC]	[NC;NC]		

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group.
Sustained response is defined as patients time to achieve and maintain response (MBL volume of < 80 mL and at least a 50% Reduction from Baseline MBL Volume) until the date of last study drug.
[1] OR (95% CI) based on a logistic regression model adjusting for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates.
[2] RR (95% CI) based on a Cochran-Mantel-Haenszel approach stratified by study.
[3] RD (95% CI) based on a Mantel-Haenszel approach stratified by study. 95% CIs are based on the approximation to the normal distribution using the Sato estimator for the standard error.
[4] P-value based on a Cochran-Mantel-Haenszel test stratified by study.
[5] Interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the OR (95% CI). Not reported subgroup levels are not included in estimation of the interaction p-value.
A continuity correction is applied in estimation of the OR, RR and p-value if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum. No continuity correction is applied in the estimation of the RD.
The reference group for the OR, RR and RD is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with an event; OR: Odds ratio; RR: Risk ratio; RD: Risk difference; CI: Confidence interval; int: p-value for interaction; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; NC: Not calculated.

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Table EFF.RESPCMPS.MITT.Pooled.S9: Sustained Responder Rate (MBL volume of < 80 mL and at least a 50% Reduction from Baseline MBL Volume) by Visit, by Subgroup (mITT Population)

Study: Pooled

Subgroup: Race, Level: Others

Treatment	N	n (%)	OR[1] [95% CI]	RR[2] [95% CI]	RD[3] [95% CI]	p-value[4]	p-value (int)[5]
Week 8							
Relugolix+E2/NETA	5	2 (40.0)	NC	NC	NC	NC	NC
Placebo	6	0	[NC;NC]	[NC;NC]	[NC;NC]		
Week 12							
Relugolix+E2/NETA	5	3 (60.0)	NC	NC	NC	NC	
Placebo	6	0	[NC;NC]	[NC;NC]	[NC;NC]		
Week 16							
Relugolix+E2/NETA	5	3 (60.0)	NC	NC	NC	NC	
Placebo	6	0	[NC;NC]	[NC;NC]	[NC;NC]		
Week 20							
Relugolix+E2/NETA	5	3 (60.0)	NC	NC	NC	NC	
Placebo	6	0	[NC;NC]	[NC;NC]	[NC;NC]		
Week 24							
Relugolix+E2/NETA	5	3 (60.0)	NC	NC	NC	NC	
Placebo	6	0	[NC;NC]	[NC;NC]	[NC;NC]		

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group.
Sustained response is defined as patients time to achieve and maintain response (MBL volume of < 80 mL and at least a 50% Reduction from Baseline MBL Volume) until the date of last study drug.
[1] OR (95% CI) based on a logistic regression model adjusting for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates.
[2] RR (95% CI) based on a Cochran-Mantel-Haenszel approach stratified by study.
[3] RD (95% CI) based on a Mantel-Haenszel approach stratified by study. 95% CIs are based on the approximation to the normal distribution using the Sato estimator for the standard error.
[4] P-value based on a Cochran-Mantel-Haenszel test stratified by study.
[5] Interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the OR (95% CI). Not reported subgroup levels are not included in estimation of the interaction p-value.
A continuity correction is applied in estimation of the OR, RR and p-value if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum. No continuity correction is applied in the estimation of the RD.
The reference group for the OR, RR and RD is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with an event; OR: Odds ratio; RR: Risk ratio; RD: Risk difference; CI: Confidence interval; int: p-value for interaction; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; NC: Not calculated.

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Table EFF.RESPCMPS.MITT.Pooled.S9: Sustained Responder Rate (MBL volume of < 80 mL and at least a 50% Reduction from Baseline MBL Volume) by Visit, by Subgroup (mITT Population)

Study: Pooled

Subgroup: Race, Level: Not reported

Treatment	N	n (%)	OR[1] [95% CI]	RR[2] [95% CI]	RD[3] [95% CI]	p-value[4]	p-value (int)[5]
Week 8							
Relugolix+E2/NETA	3	0	NC	NC	NC	NC	NC
Placebo	1	0	[NC;NC]	[NC;NC]	[NC;NC]		
Week 12							
Relugolix+E2/NETA	3	3 (100.0)	NC	NC	NC	NC	
Placebo	1	0	[NC;NC]	[NC;NC]	[NC;NC]		
Week 16							
Relugolix+E2/NETA	3	3 (100.0)	NC	NC	NC	NC	
Placebo	1	0	[NC;NC]	[NC;NC]	[NC;NC]		
Week 20							
Relugolix+E2/NETA	3	3 (100.0)	NC	NC	NC	NC	
Placebo	1	0	[NC;NC]	[NC;NC]	[NC;NC]		
Week 24							
Relugolix+E2/NETA	3	3 (100.0)	NC	NC	NC	NC	
Placebo	1	0	[NC;NC]	[NC;NC]	[NC;NC]		

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group.
Sustained response is defined as patients time to achieve and maintain response (MBL volume of < 80 mL and at least a 50% Reduction from Baseline MBL Volume) until the date of last study drug.
[1] OR (95% CI) based on a logistic regression model adjusting for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates.
[2] RR (95% CI) based on a Cochran-Mantel-Haenszel approach stratified by study.
[3] RD (95% CI) based on a Mantel-Haenszel approach stratified by study. 95% CIs are based on the approximation to the normal distribution using the Sato estimator for the standard error.
[4] P-value based on a Cochran-Mantel-Haenszel test stratified by study.
[5] Interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the OR (95% CI). Not reported subgroup levels are not included in estimation of the interaction p-value.
A continuity correction is applied in estimation of the OR, RR and p-value if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum. No continuity correction is applied in the estimation of the RD.
The reference group for the OR, RR and RD is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with an event; OR: Odds ratio; RR: Risk ratio; RD: Risk difference; CI: Confidence interval; int: p-value for interaction; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; NC: Not calculated.

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1.1.3 Time to Achieve MBL volume of < 80 mL and at least a 50% Reduction from Baseline MBL Volume, by Subgroup (mITT Population)

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Table EFF.TTMBL.MITT.Pooled.S3: Time to Achieve MBL volume of < 80 mL and at least a 50% Reduction from Baseline MBL Volume, by Subgroup (mITT Population)

Study: Pooled

Treatment	N	n (%)	Censored patients n (%)	Median time to 1st event [95% CI][1]	Median difference[1]	HR[2] [95% CI]	p-value[3]	p-value (int)[4]
Uterine Volume at Baseline (cm3)								
< 300 cm3								
Relugolix+E2/NETA	148	126 (85.1)	22 (14.9)	8.3 [8.1;8.4]	-19.1	7.83 [5.38;11.39]	<.0001	0.2992
Placebo	129	42 (32.6)	87 (67.4)	27.4 [25.1;27.9]				
>= 300 cm3								
Relugolix+E2/NETA	104	81 (77.9)	23 (22.1)	8.7 [8.3;9.1]	-17.3	5.92 [4.00;8.77]	<.0001	
Placebo	127	39 (30.7)	88 (69.3)	26.0 [24.1;27.1]				
Missing								
Relugolix+E2/NETA	1	0	1 (100.0)	NC [NC;NC]	NC	NC [NC;NC]	NC	
Placebo	0	0	0	NC [NC;NC]				

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group.
Total menstrual blood loss volume was calculated as sum of menstrual blood loss volume from all feminine products (validated, unauthorized and unvalidated) assessed by the alkaline hematin method.
Patients without an event are censored at the last assessment date prior to their last dose of study drug.
[1] Based on Kaplan-Meier estimates. 95% CIs are calculated by log-log transformation of survivor function.
[2] Hazard Ratios (and 95% CIs) are based on a Cox proportional hazard model stratified by study and with treatment group, subgroup and a subgroup-by-treatment group as covariates. 95% CIs are based on the approximation to the normal distribution. The reference group for the HR is Placebo.
[3] Treatment P-value is based on the Wald test stratified by study.
[4] Interaction P-value is based on the subgroup-by-treatment interaction term in the proportional hazard model used to compute the Hazard Ratio and 95% CI.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with an event; HR: Hazard ratio; CI: Confidence interval; int: interaction; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; NC: Not calculated.

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Table EFF.TTMBL.MITT.Pooled.S7: Time to Achieve MBL volume of < 80 mL and at least a 50% Reduction from Baseline MBL Volume, by Subgroup (mITT Population)

Study: Pooled

Treatment	N	n (%)	Censored patients n (%)	Median time to 1st event [95% CI][1]	Median difference[1]	HR[2] [95% CI]	p-value[3]	p-value (int)[4]
Geographic Region II								
Europe								
Relugolix+E2/NETA	41	37 (90.2)	4 (9.8)	8.7 [8.1;9.0]	-16.4	5.27 [2.96;9.37]	<.0001	0.3017
Placebo	42	18 (42.9)	24 (57.1)	25.1 [16.4;NE]				
Rest of World (including the US)								
Relugolix+E2/NETA	212	170 (80.2)	42 (19.8)	8.3 [8.1;8.6]	-18.8	7.38 [5.42;10.04]	<.0001	
Placebo	214	63 (29.4)	151 (70.6)	27.1 [25.1;27.9]				

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group.
Total menstrual blood loss volume was calculated as sum of menstrual blood loss volume from all feminine products (validated, unauthorized and unvalidated) assessed by the alkaline hematin method. Patients without an event are censored at the last assessment date prior to their last dose of study drug.
[1] Based on Kaplan-Meier estimates. 95% CIs are calculated by log-log transformation of survivor function.
[2] Hazard Ratios (and 95% CIs) are based on a Cox proportional hazard model stratified by study and with treatment group, subgroup and a subgroup-by-treatment group as covariates. 95% CIs are based on the approximation to the normal distribution. The reference group for the HR is Placebo.
[3] Treatment P-value is based on the Wald test stratified by study.
[4] Interaction P-value is based on the subgroup-by-treatment interaction term in the proportional hazard model used to compute the Hazard Ratio and 95% CI.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with an event; HR: Hazard ratio; CI: Confidence interval; int: interaction; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; NE: Non-estimable.

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Table EFF.TTMBL.MITT.Pooled.S9: Time to Achieve MBL volume of < 80 mL and at least a 50% Reduction from Baseline MBL Volume, by Subgroup (mITT Population)

Study: Pooled

Treatment	N	n (%)	Censored patients n (%)	Median time to 1st event [95% CI][1]	Median difference[1]	HR[2] [95% CI]	p-value[3]	p-value (int)[4]
Race								
Black/African American								0.3133
Relugolix+E2/NETA	122	93 (76.2)	29 (23.8)	8.4 [8.1;9.0]	-18.7	8.31 [5.54;12.48]	<.0001	
Placebo	141	37 (26.2)	104 (73.8)	27.1 [26.0;30.0]				
White								
Relugolix+E2/NETA	122	106 (86.9)	16 (13.1)	8.3 [8.1;8.6]	-16.7	5.48 [3.79;7.93]	<.0001	
Placebo	105	43 (41.0)	62 (59.0)	25.0 [23.9;27.1]				
Asian								
Relugolix+E2/NETA	1	1 (100.0)	0	NC [NC;NC]	NC	NC [NC;NC]	NC	
Placebo	3	1 (33.3)	2 (66.7)	NC [NC;NC]				
Others								
Relugolix+E2/NETA	5	4 (80.0)	1 (20.0)	8.3 [3.3;NE]	NE	>99 [NC;NC]	NC	
Placebo	6	0	6 (100.0)	NR [NE;NE]				
Not reported								
Relugolix+E2/NETA	3	3 (100.0)	0	NC [NC;NC]	NC	NC [NC;NC]	NC	
Placebo	1	0	1 (100.0)	NC [NC;NC]				

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group.
Total menstrual blood loss volume was calculated as sum of menstrual blood loss volume from all feminine products (validated, unauthorized and unvalidated) assessed by the alkaline hematin method. Patients without an event are censored at the last assessment date prior to their last dose of study drug.
[1] Based on Kaplan-Meier estimates. 95% CIs are calculated by log-log transformation of survivor function.
[2] Hazard Ratios (and 95% CIs) are based on a Cox proportional hazard model stratified by study and with treatment group, subgroup and a subgroup-by-treatment group as covariates. 95% CIs are based on the approximation to the normal distribution. The reference group for the HR is Placebo.
[3] Treatment P-value is based on the Wald test stratified by study.
[4] Interaction P-value is based on the subgroup-by-treatment interaction term in the proportional hazard model used to compute the Hazard Ratio and 95% CI.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with an event; HR: Hazard ratio; CI: Confidence interval; int: interaction; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; NC: Not calculated; NE: Non-estimable; NR: Not reached.

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Table EFF.TTMBL.MITT.Pooled.S4: Time to Achieve MBL volume of < 80 mL and at least a 50% Reduction from Baseline MBL Volume, by Subgroup (mITT Population)

Study: Pooled

Treatment	N	n (%)	Censored patients n (%)	Median time to 1st event [95% CI][1]	Median difference[1]	HR[2] [95% CI]	p-value[3]	p-value (int)[4]
Maximum NRS Pain Score at Baseline								
< 4								
Relugolix+E2/NETA	73	58 (79.5)	15 (20.5)	8.6 [8.3;9.0]	NE	8.86 [4.89;16.03]	<.0001	0.3801
Placebo	62	14 (22.6)	48 (77.4)	NR [NE;NE]				
>= 4								
Relugolix+E2/NETA	177	147 (83.1)	30 (16.9)	8.3 [8.1;8.4]	-17.7	6.60 [4.85;8.98]	<.0001	
Placebo	190	67 (35.3)	123 (64.7)	26.0 [24.1;27.4]				
Missing								
Relugolix+E2/NETA	3	2 (66.7)	1 (33.3)	NC [NC;NC]	NC	NC [NC;NC]	NC	
Placebo	4	0	4 (100.0)	NC [NC;NC]				

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group.
Total menstrual blood loss volume was calculated as sum of menstrual blood loss volume from all feminine products (validated, unauthorized and unvalidated) assessed by the alkaline hematin method. Patients without an event are censored at the last assessment date prior to their last dose of study drug.
[1] Based on Kaplan-Meier estimates. 95% CIs are calculated by log-log transformation of survivor function.
[2] Hazard Ratios (and 95% CIs) are based on a Cox proportional hazard model stratified by study and with treatment group, subgroup and a subgroup-by-treatment group as covariates. 95% CIs are based on the approximation to the normal distribution. The reference group for the HR is Placebo.
[3] Treatment P-value is based on the Wald test stratified by study.
[4] Interaction P-value is based on the subgroup-by-treatment interaction term in the proportional hazard model used to compute the Hazard Ratio and 95% CI.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with an event; HR: Hazard ratio; CI: Confidence interval; int: interaction; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; NC: Not calculated; NE: Non-estimable; NR: Not reached.

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Table EFF.TTMBL.MITT.Pooled.S8: Time to Achieve MBL volume of < 80 mL and at least a 50% Reduction from Baseline MBL Volume, by Subgroup (mITT Population)

Study: Pooled

Treatment	N	n (%)	Censored patients n (%)	Median time to 1st event [95% CI][1]	Median difference[1]	HR[2] [95% CI]	p-value[3]	p-value (int)[4]
Ethnicity								
Hispanic or Latino								
Relugolix+E2/NETA	52	46 (88.5)	6 (11.5)	8.1 [8.1;8.6]	-16.9	5.70 [3.37;9.65]	<.0001	0.4567
Placebo	55	21 (38.2)	34 (61.8)	25.0 [23.9;NE]				
Not Hispanic or Latino								
Relugolix+E2/NETA	197	158 (80.2)	39 (19.8)	8.4 [8.3;8.7]	-18.7	7.18 [5.22;9.88]	<.0001	
Placebo	199	60 (30.2)	139 (69.8)	27.1 [25.1;27.4]				
Not reported								
Relugolix+E2/NETA	4	3 (75.0)	1 (25.0)	NC [NC;NC]	NC	NC [NC;NC]	NC	
Placebo	2	0	2 (100.0)	NC [NC;NC]				

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group.
Total menstrual blood loss volume was calculated as sum of menstrual blood loss volume from all feminine products (validated, unauthorized and unvalidated) assessed by the alkaline hematin method. Patients without an event are censored at the last assessment date prior to their last dose of study drug.
[1] Based on Kaplan-Meier estimates. 95% CIs are calculated by log-log transformation of survivor function.
[2] Hazard Ratios (and 95% CIs) are based on a Cox proportional hazard model stratified by study and with treatment group, subgroup and a subgroup-by-treatment group as covariates. 95% CIs are based on the approximation to the normal distribution. The reference group for the HR is Placebo.
[3] Treatment P-value is based on the Wald test stratified by study.
[4] Interaction P-value is based on the subgroup-by-treatment interaction term in the proportional hazard model used to compute the Hazard Ratio and 95% CI.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with an event; HR: Hazard ratio; CI: Confidence interval; int: interaction; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; NC: Not calculated; NE: Non-estimable.

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Table EFF.TTMBL.MITT.Pooled.S5: Time to Achieve MBL volume of < 80 mL and at least a 50% Reduction from Baseline MBL Volume, by Subgroup (mITT Population)

Study: Pooled

Treatment	N	n (%)	Censored patients n (%)	Median time to 1st event [95% CI][1]	Median difference[1]	HR[2] [95% CI]	p-value[3]	p-value (int)[4]
MBL Volume at Baseline (mL)								
< 225 mL								
Relugolix+E2/NETA	164	138 (84.1)	26 (15.9)	8.1 [8.1;8.4]	-19.0	7.79 [5.61;10.83]	<.0001	0.4979
Placebo	171	59 (34.5)	112 (65.5)	27.1 [25.0;27.9]				
>= 225 mL								
Relugolix+E2/NETA	89	69 (77.5)	20 (22.5)	9.0 [8.4;12.1]	-17.0	6.39 [3.92;10.39]	<.0001	
Placebo	85	22 (25.9)	63 (74.1)	26.0 [24.1;NE]				

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group.
Total menstrual blood loss volume was calculated as sum of menstrual blood loss volume from all feminine products (validated, unauthorized and unvalidated) assessed by the alkaline hematin method.
Patients without an event are censored at the last assessment date prior to their last dose of study drug.
[1] Based on Kaplan-Meier estimates. 95% CIs are calculated by log-log transformation of survivor function.
[2] Hazard Ratios (and 95% CIs) are based on a Cox proportional hazard model stratified by study and with treatment group, subgroup and a subgroup-by-treatment group as covariates. 95% CIs are based on the approximation to the normal distribution. The reference group for the HR is Placebo.
[3] Treatment P-value is based on the Wald test stratified by study.
[4] Interaction P-value is based on the subgroup-by-treatment interaction term in the proportional hazard model used to compute the Hazard Ratio and 95% CI.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with an event; HR: Hazard ratio; CI: Confidence interval; int: interaction; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; NE: Non-estimable.

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Table EFF.TTMBL.MITT.Pooled.S1: Time to Achieve MBL volume of < 80 mL and at least a 50% Reduction from Baseline MBL Volume, by Subgroup (mITT Population)

Study: Pooled

Treatment	N	n (%)	Censored patients n (%)	Median time to 1st event [95% CI][1]	Median difference[1]	HR[2] [95% CI]	p-value[3]	p-value (int)[4]
Age (years)								
< 40 years								0.5637
Relugolix+E2/NETA	62	49 (79.0)	13 (21.0)	8.7 [8.1;9.0]	-18.4	7.85 [4.53;13.61]	<.0001	
Placebo	78	18 (23.1)	60 (76.9)	27.1 [25.1;NE]				
>= 40 years								
Relugolix+E2/NETA	191	158 (82.7)	33 (17.3)	8.3 [8.1;8.6]	-17.7	6.55 [4.80;8.93]	<.0001	
Placebo	178	63 (35.4)	115 (64.6)	26.0 [24.1;27.4]				

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group.
Total menstrual blood loss volume was calculated as sum of menstrual blood loss volume from all feminine products (validated, unauthorized and unvalidated) assessed by the alkaline hematin method.
Patients without an event are censored at the last assessment date prior to their last dose of study drug.
[1] Based on Kaplan-Meier estimates. 95% CIs are calculated by log-log transformation of survivor function.
[2] Hazard Ratios (and 95% CIs) are based on a Cox proportional hazard model stratified by study and with treatment group, subgroup and a subgroup-by-treatment group as covariates. 95% CIs are based on the approximation to the normal distribution. The reference group for the HR is Placebo.
[3] Treatment P-value is based on the Wald test stratified by study.
[4] Interaction P-value is based on the subgroup-by-treatment interaction term in the proportional hazard model used to compute the Hazard Ratio and 95% CI.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with an event; HR: Hazard ratio; CI: Confidence interval; int: interaction; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; NE: Non-estimable.

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Table EFF.TTMBL.MITT.Pooled.S6: Time to Achieve MBL volume of < 80 mL and at least a 50% Reduction from Baseline MBL Volume, by Subgroup (mITT Population)

Study: Pooled

Treatment	N	n (%)	Censored patients n (%)	Median time to 1st event [95% CI][1]	Median difference[1]	HR[2] [95% CI]	p-value[3]	p-value (int)[4]
Geographic Region I								
North America								
Relugolix+E2/NETA	191	151 (79.1)	40 (20.9)	8.3 [8.1;8.7]	-18.8	6.86 [4.98;9.45]	<.0001	0.8704
Placebo	194	59 (30.4)	135 (69.6)	27.1 [25.1;28.1]				
Rest of World								
Relugolix+E2/NETA	62	56 (90.3)	6 (9.7)	8.3 [8.1;9.0]	-16.7	7.20 [4.34;11.94]	<.0001	
Placebo	62	22 (35.5)	40 (64.5)	25.0 [24.1;27.1]				

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group.
Total menstrual blood loss volume was calculated as sum of menstrual blood loss volume from all feminine products (validated, unauthorized and unvalidated) assessed by the alkaline hematin method.
Patients without an event are censored at the last assessment date prior to their last dose of study drug.
[1] Based on Kaplan-Meier estimates. 95% CIs are calculated by log-log transformation of survivor function.
[2] Hazard Ratios (and 95% CIs) are based on a Cox proportional hazard model stratified by study and with treatment group, subgroup and a subgroup-by-treatment group as covariates. 95% CIs are based on the approximation to the normal distribution. The reference group for the HR is Placebo.
[3] Treatment P-value is based on the Wald test stratified by study.
[4] Interaction P-value is based on the subgroup-by-treatment interaction term in the proportional hazard model used to compute the Hazard Ratio and 95% CI.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with an event; HR: Hazard ratio; CI: Confidence interval; int: interaction; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate.

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Table EFF.TTMBL.MITT.Pooled.S2: Time to Achieve MBL volume of < 80 mL and at least a 50% Reduction from Baseline MBL Volume, by Subgroup (mITT Population)

Study: Pooled

Treatment	N	n (%)	Censored patients n (%)	Median time to 1st event [95% CI][1]	Median difference[1]	HR[2] [95% CI]	p-value[3]	p-value (int)[4]
BMI (kg/m2) at Baseline								
< 30								
Relugolix+E2/NETA	119	97 (81.5)	22 (18.5)	8.3 [8.1;8.7]	-16.8	6.84 [4.62;10.13]	<.0001	0.9427
Placebo	115	37 (32.2)	78 (67.8)	25.1 [23.9;NE]				
>= 30								
Relugolix+E2/NETA	133	109 (82.0)	24 (18.0)	8.3 [8.1;9.0]	-18.8	6.98 [4.82;10.09]	<.0001	
Placebo	141	44 (31.2)	97 (68.8)	27.1 [25.0;27.9]				
Missing								
Relugolix+E2/NETA	1	1 (100.0)	0	NC [NC;NC]	NC	NC [NC;NC]	NC	
Placebo	0	0	0	NC [NC;NC]				

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group.
Total menstrual blood loss volume was calculated as sum of menstrual blood loss volume from all feminine products (validated, unauthorized and unvalidated) assessed by the alkaline hematin method. Patients without an event are censored at the last assessment date prior to their last dose of study drug.
[1] Based on Kaplan-Meier estimates. 95% CIs are calculated by log-log transformation of survivor function.
[2] Hazard Ratios (and 95% CIs) are based on a Cox proportional hazard model stratified by study and with treatment group, subgroup and a subgroup-by-treatment group as covariates. 95% CIs are based on the approximation to the normal distribution. The reference group for the HR is Placebo.
[3] Treatment P-value is based on the Wald test stratified by study.
[4] Interaction P-value is based on the subgroup-by-treatment interaction term in the proportional hazard model used to compute the Hazard Ratio and 95% CI.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with an event; HR: Hazard ratio; CI: Confidence interval; int: interaction; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; NC: Not calculated; NE: Non-estimable.

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1.1.3.1 Time to Achieve MBL Volume of < 80 mL, by Subgroup (mITT Population)

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Table EFF.TTMBLL80.MITT.Pooled.S9: Time to Achieve MBL Volume of < 80 mL, by Subgroup (mITT Population)								
Study: Pooled								
Treatment	**N**	**n (%)**	**Censored patients n (%)**	**Median time to 1st event [95% CI][1]**	**Median difference[1]**	**HR[2] [95% CI]**	**p-value[3]**	**p-value (int)[4]**
Race								
Black/African American								
Relugolix+E2/NETA	122	95 (77.9)	27 (22.1)	8.3 [8.1;8.7]	-18.8	6.79 [4.64;9.93]	<.0001	0.1310
Placebo	141	44 (31.2)	97 (68.8)	27.1 [26.0;30.0]				
White								
Relugolix+E2/NETA	122	107 (87.7)	15 (12.3)	8.3 [8.1;8.6]	-15.6	4.07 [2.89;5.73]	<.0001	
Placebo	105	53 (50.5)	52 (49.5)	23.9 [17.0;25.1]				
Asian								
Relugolix+E2/NETA	1	1 (100.0)	0	NC [NC;NC]	NC	NC [NC;NC]	NC	
Placebo	3	1 (33.3)	2 (66.7)	NC [NC;NC]				
Others								
Relugolix+E2/NETA	5	4 (80.0)	1 (20.0)	7.6 [3.3;NE]	NE	>99 [NC;NC]	NC	
Placebo	6	0	6 (100.0)	NR [NE;NE]				
Not reported								
Relugolix+E2/NETA	3	3 (100.0)	0	NC [NC;NC]	NC	NC	NC	

Placebo	1	0	1 (100.0)	NC [NC;NC]		[NC;NC]		

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group.
Total menstrual blood loss volume was calculated as sum of menstrual blood loss volume from all feminine products (validated, unauthorized and unvalidated) assessed by the alkaline hematin method.
Patients without an event are censored at the last assessment date prior to their last dose of study drug.
[1] Based on Kaplan-Meier estimates. 95% CIs are calculated by log-log transformation of survivor function.
[2] Hazard Ratios (and 95% CIs) are based on a Cox proportional hazard model stratified by study and with treatment group, subgroup and a subgroup-by-treatment group as covariates. 95% CIs are based on the approximation to the normal distribution. The reference group for the HR is Placebo.
[3] Treatment P-value is based on the Wald test stratified by study.
[4] Interaction P-value is based on the subgroup-by-treatment interaction term in the proportional hazard model used to compute the Hazard Ratio and 95% CI.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with an event; HR: Hazard ratio; CI: Confidence interval; int: interaction; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; NC: Not calculated; NE: Non-estimable; NR: Not reached.

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Table EFF.TTMBLL80.MITT.Pooled.S8: Time to Achieve MBL Volume of < 80 mL, by Subgroup (mITT Population)

Study: Pooled

Treatment	N	n (%)	Censored patients n (%)	Median time to 1st event [95% CI][1]	Median difference[1]	HR[2] [95% CI]	p-value[3]	p-value (int)[4]
Ethnicity								
Hispanic or Latino								
Relugolix+E2/NETA	52	47 (90.4)	5 (9.6)	8.1 [8.1;8.4]	-15.8	4.04 [2.49;6.56]	<.0001	0.1841
Placebo	55	27 (49.1)	28 (50.9)	23.9 [16.1;NE]				
Not Hispanic or Latino								
Relugolix+E2/NETA	197	160 (81.2)	37 (18.8)	8.3 [8.1;8.7]	-17.7	5.91 [4.38;7.97]	<.0001	
Placebo	199	71 (35.7)	128 (64.3)	26.0 [24.1;27.1]				
Not reported								
Relugolix+E2/NETA	4	3 (75.0)	1 (25.0)	NC [NC;NC]	NC	NC [NC;NC]	NC	
Placebo	2	0	2 (100.0)	NC [NC;NC]				

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group.
Total menstrual blood loss volume was calculated as sum of menstrual blood loss volume from all feminine products (validated, unauthorized and unvalidated) assessed by the alkaline hematin method. Patients without an event are censored at the last assessment date prior to their last dose of study drug.
[1] Based on Kaplan-Meier estimates. 95% CIs are calculated by log-log transformation of survivor function.
[2] Hazard Ratios (and 95% CIs) are based on a Cox proportional hazard model stratified by study and with treatment group, subgroup and a subgroup-by-treatment group as covariates. 95% CIs are based on the approximation to the normal distribution. The reference group for the HR is Placebo.
[3] Treatment P-value is based on the Wald test stratified by study.
[4] Interaction P-value is based on the subgroup-by-treatment interaction term in the proportional hazard model used to compute the Hazard Ratio and 95% CI.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with an event; HR: Hazard ratio; CI: Confidence interval; int: interaction; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; NC: Not calculated; NE: Non-estimable.

SOURCE: \Studies\MYV\MYV102\Analysis\Prod\Progs\TFLs\Tab_EFF_MBL_TTE.SAS
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Table EFF.TTMBLL80.MITT.Pooled.S7: Time to Achieve MBL Volume of < 80 mL, by Subgroup (mITT Population)

Study: Pooled

Treatment	N	n (%)	Censored patients n (%)	Median time to 1st event [95% CI][1]	Median difference[1]	HR[2] [95% CI]	p-value[3]	p-value (int)[4]
Geographic Region II								
Europe								0.4233
Relugolix+E2/NETA	41	37 (90.2)	4 (9.8)	8.7 [8.0;9.0]	-15.2	4.49 [2.59;7.76]	<.0001	
Placebo	42	21 (50.0)	21 (50.0)	23.9 [14.1;NE]				
Rest of World (including the US)								
Relugolix+E2/NETA	212	173 (81.6)	39 (18.4)	8.3 [8.1;8.4]	-17.7	5.75 [4.32;7.65]	<.0001	
Placebo	214	77 (36.0)	137 (64.0)	26.0 [24.1;27.4]				

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group.
Total menstrual blood loss volume was calculated as sum of menstrual blood loss volume from all feminine products (validated, unauthorized and unvalidated) assessed by the alkaline hematin method. Patients without an event are censored at the last assessment date prior to their last dose of study drug.
[1] Based on Kaplan-Meier estimates. 95% CIs are calculated by log-log transformation of survivor function.
[2] Hazard Ratios (and 95% CIs) are based on a Cox proportional hazard model stratified by study and with treatment group, subgroup and a subgroup-by-treatment group as covariates. 95% CIs are based on the approximation to the normal distribution. The reference group for the HR is Placebo.
[3] Treatment P-value is based on the Wald test stratified by study.
[4] Interaction P-value is based on the subgroup-by-treatment interaction term in the proportional hazard model used to compute the Hazard Ratio and 95% CI.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with an event; HR: Hazard ratio; CI: Confidence interval; int: interaction; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; NE: Non-estimable.

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Table EFF.TTMBLL80.MITT.Pooled.S4: Time to Achieve MBL Volume of < 80 mL, by Subgroup (mITT Population)

Study: Pooled

Treatment	N	n (%)	Censored patients n (%)	Median time to 1st event [95% CI][1]	Median difference[1]	HR[2] [95% CI]	p-value[3]	p-value (int)[4]
Maximum NRS Pain Score at Baseline								
< 4								
Relugolix+E2/NETA	73	59 (80.8)	14 (19.2)	8.6 [8.3;9.0]	-16.5	6.75 [3.90;11.68]	<.0001	0.4461
Placebo	62	17 (27.4)	45 (72.6)	25.1 [23.9;NE]				
>= 4								
Relugolix+E2/NETA	177	149 (84.2)	28 (15.8)	8.3 [8.1;8.3]	-16.8	5.33 [3.99;7.12]	<.0001	
Placebo	190	81 (42.6)	109 (57.4)	25.1 [23.3;27.1]				
Missing								
Relugolix+E2/NETA	3	2 (66.7)	1 (33.3)	NC [NC;NC]	NC	NC [NC;NC]	NC	
Placebo	4	0	4 (100.0)	NC [NC;NC]				

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group.
Total menstrual blood loss volume was calculated as sum of menstrual blood loss volume from all feminine products (validated, unauthorized and unvalidated) assessed by the alkaline hematin method. Patients without an event are censored at the last assessment date prior to their last dose of study drug.
[1] Based on Kaplan-Meier estimates. 95% CIs are calculated by log-log transformation of survivor function.
[2] Hazard Ratios (and 95% CIs) are based on a Cox proportional hazard model stratified by study and with treatment group, subgroup and a subgroup-by-treatment group as covariates. 95% CIs are based on the approximation to the normal distribution. The reference group for the HR is Placebo.
[3] Treatment P-value is based on the Wald test stratified by study.
[4] Interaction P-value is based on the subgroup-by-treatment interaction term in the proportional hazard model used to compute the Hazard Ratio and 95% CI.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with an event; HR: Hazard ratio; CI: Confidence interval; int: interaction; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; NC: Not calculated; NE: Non-estimable.

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Table EFF.TTMBLL80.MITT.Pooled.S1: Time to Achieve MBL Volume of < 80 mL, by Subgroup (mITT Population)

Study: Pooled

Treatment	N	n (%)	Censored patients n (%)	Median time to 1st event [95% CI][1]	Median difference[1]	HR[2] [95% CI]	p-value[3]	p-value (int)[4]
Age (years)								
< 40 years								0.5743
Relugolix+E2/NETA	62	49 (79.0)	13 (21.0)	8.7 [8.1;9.0]	-16.4	4.84 [2.99;7.81]	<.0001	
Placebo	78	27 (34.6)	51 (65.4)	25.1 [23.3;NE]				
>= 40 years								
Relugolix+E2/NETA	191	161 (84.3)	30 (15.7)	8.3 [8.1;8.4]	-17.7	5.66 [4.21;7.62]	<.0001	
Placebo	178	71 (39.9)	107 (60.1)	26.0 [24.1;27.4]				

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group.
Total menstrual blood loss volume was calculated as sum of menstrual blood loss volume from all feminine products (validated, unauthorized and unvalidated) assessed by the alkaline hematin method.
Patients without an event are censored at the last assessment date prior to their last dose of study drug.
[1] Based on Kaplan-Meier estimates. 95% CIs are calculated by log-log transformation of survivor function.
[2] Hazard Ratios (and 95% CIs) are based on a Cox proportional hazard model stratified by study and with treatment group, subgroup and a subgroup-by-treatment group as covariates. 95% CIs are based on the approximation to the normal distribution. The reference group for the HR is Placebo.
[3] Treatment P-value is based on the Wald test stratified by study.
[4] Interaction P-value is based on the subgroup-by-treatment interaction term in the proportional hazard model used to compute the Hazard Ratio and 95% CI.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with an event; HR: Hazard ratio; CI: Confidence interval; int: interaction; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; NE: Non-estimable.

SOURCE: \Studies\MYV\MYV102\Analysis\Prod\Progs\TFLs\Tab_EFF_MBL_TTE.SAS
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Table EFF.TTMBLL80.MITT.Pooled.S2: Time to Achieve MBL Volume of < 80 mL, by Subgroup (mITT Population)

Study: Pooled

Treatment	N	n (%)	Censored patients n (%)	Median time to 1st event [95% CI][1]	Median difference[1]	HR[2] [95% CI]	p-value[3]	p-value (int)[4]
BMI (kg/m2) at Baseline								
< 30								
Relugolix+E2/NETA	119	99 (83.2)	20 (16.8)	8.3 [8.1;8.7]	-15.8	5.62 [3.89;8.11]	<.0001	0.8751
Placebo	115	45 (39.1)	70 (60.9)	24.1 [21.9;27.1]				
>= 30								
Relugolix+E2/NETA	133	110 (82.7)	23 (17.3)	8.3 [8.1;8.7]	-17.7	5.40 [3.83;7.62]	<.0001	
Placebo	141	53 (37.6)	88 (62.4)	26.0 [24.1;27.4]				
Missing								
Relugolix+E2/NETA	1	1 (100.0)	0	NC [NC;NC]	NC	NC [NC;NC]	NC	
Placebo	0	0	0	NC [NC;NC]				

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group.
Total menstrual blood loss volume was calculated as sum of menstrual blood loss volume from all feminine products (validated, unauthorized and unvalidated) assessed by the alkaline hematin method.
Patients without an event are censored at the last assessment date prior to their last dose of study drug.
[1] Based on Kaplan-Meier estimates. 95% CIs are calculated by log-log transformation of survivor function.
[2] Hazard Ratios (and 95% CIs) are based on a Cox proportional hazard model stratified by study and with treatment group, subgroup and a subgroup-by-treatment group as covariates. 95% CIs are based on the approximation to the normal distribution. The reference group for the HR is Placebo.
[3] Treatment P-value is based on the Wald test stratified by study.
[4] Interaction P-value is based on the subgroup-by-treatment interaction term in the proportional hazard model used to compute the Hazard Ratio and 95% CI.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with an event; HR: Hazard ratio; CI: Confidence interval; int: interaction; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; NC: Not calculated.

SOURCE: \Studies\MYV\MYV102\Analysis\Prod\Progs\TFLs\Tab_EFF_MBL_TTE.SAS
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Table EFF.TTMBLL80.MITT.Pooled.S3: Time to Achieve MBL Volume of < 80 mL, by Subgroup (mITT Population)

Study: Pooled

Treatment	N	n (%)	Censored patients n (%)	Median time to 1st event [95% CI][1]	Median difference[1]	HR[2] [95% CI]	p-value[3]	p-value (int)[4]
Uterine Volume at Baseline (cm3)								
< 300 cm3								
Relugolix+E2/NETA	148	128 (86.5)	20 (13.5)	8.1 [8.1;8.3]	-17.0	5.56 [3.97;7.79]	<.0001	0.8943
Placebo	129	57 (44.2)	72 (55.8)	25.1 [22.6;27.4]				
>= 300 cm3								
Relugolix+E2/NETA	104	82 (78.8)	22 (21.2)	8.7 [8.3;9.1]	-17.3	5.38 [3.66;7.90]	<.0001	
Placebo	127	41 (32.3)	86 (67.7)	26.0 [24.1;28.1]				
Missing								
Relugolix+E2/NETA	1	0	1 (100.0)	NC [NC;NC]	NC	NC [NC;NC]	NC	
Placebo	0	0	0	NC [NC;NC]				

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group.
Total menstrual blood loss volume was calculated as sum of menstrual blood loss volume from all feminine products (validated, unauthorized and unvalidated) assessed by the alkaline hematin method. Patients without an event are censored at the last assessment date prior to their last dose of study drug.
[1] Based on Kaplan-Meier estimates. 95% CIs are calculated by log-log transformation of survivor function.
[2] Hazard Ratios (and 95% CIs) are based on a Cox proportional hazard model stratified by study and with treatment group, subgroup and a subgroup-by-treatment group as covariates. 95% CIs are based on the approximation to the normal distribution. The reference group for the HR is Placebo.
[3] Treatment P-value is based on the Wald test stratified by study.
[4] Interaction P-value is based on the subgroup-by-treatment interaction term in the proportional hazard model used to compute the Hazard Ratio and 95% CI.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with an event; HR: Hazard ratio; CI: Confidence interval; int: interaction; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; NC: Not calculated.

SOURCE: \Studies\MYV\MYV102\Analysis\Prod\Progs\TFLs\Tab_EFF_MBL_TTE.SAS
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Table EFF.TTMBLL80.MITT.Pooled.S6: Time to Achieve MBL Volume of < 80 mL, by Subgroup (mITT Population)

Study: Pooled

Treatment	N	n (%)	Censored patients n (%)	Median time to 1st event [95% CI][1]	Median difference[1]	HR[2] [95% CI]	p-value[3]	p-value (int)[4]
Geographic Region I								
North America								
Relugolix+E2/NETA	191	154 (80.6)	37 (19.4)	8.3 [8.1;8.6]	-17.7	5.56 [4.12;7.50]	<.0001	0.8996
Placebo	194	70 (36.1)	124 (63.9)	26.0 [24.1;27.4]				
Rest of World								
Relugolix+E2/NETA	62	56 (90.3)	6 (9.7)	8.3 [8.1;9.0]	-16.0	5.37 [3.37;8.56]	<.0001	
Placebo	62	28 (45.2)	34 (54.8)	24.3 [20.1;27.1]				

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group.
Total menstrual blood loss volume was calculated as sum of menstrual blood loss volume from all feminine products (validated, unauthorized and unvalidated) assessed by the alkaline hematin method.
Patients without an event are censored at the last assessment date prior to their last dose of study drug.
[1] Based on Kaplan-Meier estimates. 95% CIs are calculated by log-log transformation of survivor function.
[2] Hazard Ratios (and 95% CIs) are based on a Cox proportional hazard model stratified by study and with treatment group, subgroup and a subgroup-by-treatment group as covariates. 95% CIs are based on the approximation to the normal distribution. The reference group for the HR is Placebo.
[3] Treatment P-value is based on the Wald test stratified by study.
[4] Interaction P-value is based on the subgroup-by-treatment interaction term in the proportional hazard model used to compute the Hazard Ratio and 95% CI.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with an event; HR: Hazard ratio; CI: Confidence interval; int: interaction; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate.

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Table EFF.TTMBLL80.MITT.Pooled.S5: Time to Achieve MBL Volume of < 80 mL, by Subgroup (mITT Population)

Study: Pooled

Treatment	N	n (%)	Censored patients n (%)	Median time to 1st event [95% CI][1]	Median difference[1]	HR[2] [95% CI]	p-value[3]	p-value (int)[4]
MBL Volume at Baseline (mL)								
< 225 mL								
Relugolix+E2/NETA	164	141 (86.0)	23 (14.0)	8.1 [8.1;8.3]	-16.2	5.97 [4.40;8.11]	<.0001	0.9031
Placebo	171	76 (44.4)	95 (55.6)	24.3 [21.0;27.1]				
>= 225 mL								
Relugolix+E2/NETA	89	69 (77.5)	20 (22.5)	9.0 [8.4;12.1]	-17.0	6.19 [3.80;10.05]	<.0001	
Placebo	85	22 (25.9)	63 (74.1)	26.0 [24.1;NE]				

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group.
Total menstrual blood loss volume was calculated as sum of menstrual blood loss volume from all feminine products (validated, unauthorized and unvalidated) assessed by the alkaline hematin method.
Patients without an event are censored at the last assessment date prior to their last dose of study drug.
[1] Based on Kaplan-Meier estimates. 95% CIs are calculated by log-log transformation of survivor function.
[2] Hazard Ratios (and 95% CIs) are based on a Cox proportional hazard model stratified by study and with treatment group, subgroup and a subgroup-by-treatment group as covariates. 95% CIs are based on the approximation to the normal distribution. The reference group for the HR is Placebo.
[3] Treatment P-value is based on the Wald test stratified by study.
[4] Interaction P-value is based on the subgroup-by-treatment interaction term in the proportional hazard model used to compute the Hazard Ratio and 95% CI.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with an event; HR: Hazard ratio; CI: Confidence interval; int: interaction; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; NE: Non-estimable.

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1.1.3.2 Time to Achieve at least a 50% Reduction from Baseline MBL Volume, by Subgroup (mITT Population)

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Table EFF.TTMBLG50.MITT.Pooled.S5: Time to Achieve at least a 50% Reduction from Baseline MBL Volume, by Subgroup (mITT Population)

Study: Pooled

Treatment	N	n (%)	Censored patients n (%)	Median time to 1st event [95% CI][1]	Median difference[1]	HR[2] [95% CI]	p-value[3]	p-value (int)[4]
MBL Volume at Baseline (mL)								
< 225 mL								
Relugolix+E2/NETA	164	139 (84.8)	25 (15.2)	8.1 [8.1;8.3]	-17.0	7.08 [5.14;9.75]	<.0001	0.0337*
Placebo	171	62 (36.3)	109 (63.7)	25.1 [25.0;28.1]				
>= 225 mL								
Relugolix+E2/NETA	89	76 (85.4)	13 (14.6)	8.6 [8.1;9.0]	-15.5	4.11 [2.75;6.14]	<.0001	
Placebo	85	37 (43.5)	48 (56.5)	24.1 [17.7;NE]				

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group.
Total menstrual blood loss volume was calculated as sum of menstrual blood loss volume from all feminine products (validated, unauthorized and unvalidated) assessed by the alkaline hematin method. Patients without an event are censored at the last assessment date prior to their last dose of study drug.
[1] Based on Kaplan-Meier estimates. 95% CIs are calculated by log-log transformation of survivor function.
[2] Hazard Ratios (and 95% CIs) are based on a Cox proportional hazard model stratified by study and with treatment group, subgroup and a subgroup-by-treatment group as covariates. 95% CIs are based on the approximation to the normal distribution. The reference group for the HR is Placebo.
[3] Treatment P-value is based on the Wald test stratified by study.
[4] Interaction P-value is based on the subgroup-by-treatment interaction term in the proportional hazard model used to compute the Hazard Ratio and 95% CI. * Interaction P-value < 0.05.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with an event; HR: Hazard ratio; CI: Confidence interval; int: interaction; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; NE: Non-estimable.

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Table EFF.TTMBLG50.MITT.Pooled.S7: Time to Achieve at least a 50% Reduction from Baseline MBL Volume, by Subgroup (mITT Population)

Study: Pooled

Treatment	N	n (%)	Censored patients n (%)	Median time to 1st event [95% CI][1]	Median difference[1]	HR[2] [95% CI]	p-value[3]	p-value (int)[4]
Geographic Region II								
Europe								0.1275
Relugolix+E2/NETA	41	37 (90.2)	4 (9.8)	8.7 [8.1;9.0]	-8.2	3.95 [2.30;6.81]	<.0001	
Placebo	42	21 (50.0)	21 (50.0)	16.9 [12.9;NE]				
Rest of World (including the US)								
Relugolix+E2/NETA	212	178 (84.0)	34 (16.0)	8.3 [8.1;8.4]	-16.8	6.31 [4.75;8.38]	<.0001	
Placebo	214	78 (36.4)	136 (63.6)	25.1 [24.1;27.9]				

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group.
Total menstrual blood loss volume was calculated as sum of menstrual blood loss volume from all feminine products (validated, unauthorized and unvalidated) assessed by the alkaline hematin method. Patients without an event are censored at the last assessment date prior to their last dose of study drug.
[1] Based on Kaplan-Meier estimates. 95% CIs are calculated by log-log transformation of survivor function.
[2] Hazard Ratios (and 95% CIs) are based on a Cox proportional hazard model stratified by study and with treatment group, subgroup and a subgroup-by-treatment group as covariates. 95% CIs are based on the approximation to the normal distribution. The reference group for the HR is Placebo.
[3] Treatment P-value is based on the Wald test stratified by study.
[4] Interaction P-value is based on the subgroup-by-treatment interaction term in the proportional hazard model used to compute the Hazard Ratio and 95% CI.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with an event; HR: Hazard ratio; CI: Confidence interval; int: interaction; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; NE: Non-estimable.

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Table EFF.TTMBLG50.MITT.Pooled.S1: Time to Achieve at least a 50% Reduction from Baseline MBL Volume, by Subgroup (mITT Population)

Study: Pooled

Treatment	N	n (%)	Censored patients n (%)	Median time to 1st event [95% CI][1]	Median difference[1]	HR[2] [95% CI]	p-value[3]	p-value (int)[4]
Age (years)								
< 40 years								
Relugolix+E2/NETA	62	52 (83.9)	10 (16.1)	8.4 [8.1;9.0]	NE	7.38 [4.43;12.29]	<.0001	0.2589
Placebo	78	22 (28.2)	56 (71.8)	NR [NE;NE]				
>= 40 years								
Relugolix+E2/NETA	191	163 (85.3)	28 (14.7)	8.3 [8.1;8.4]	-16.7	5.31 [3.99;7.07]	<.0001	
Placebo	178	77 (43.3)	101 (56.7)	25.0 [20.9;27.4]				

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group.
Total menstrual blood loss volume was calculated as sum of menstrual blood loss volume from all feminine products (validated, unauthorized and unvalidated) assessed by the alkaline hematin method.
Patients without an event are censored at the last assessment date prior to their last dose of study drug.
[1] Based on Kaplan-Meier estimates. 95% CIs are calculated by log-log transformation of survivor function.
[2] Hazard Ratios (and 95% CIs) are based on a Cox proportional hazard model stratified by study and with treatment group, subgroup and a subgroup-by-treatment group as covariates. 95% CIs are based on the approximation to the normal distribution. The reference group for the HR is Placebo.
[3] Treatment P-value is based on the Wald test stratified by study.
[4] Interaction P-value is based on the subgroup-by-treatment interaction term in the proportional hazard model used to compute the Hazard Ratio and 95% CI.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with an event; HR: Hazard ratio; CI: Confidence interval; int: interaction; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; NE: Non-estimable; NR: Not reached.

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Table EFF.TTMBLG50.MITT.Pooled.S2: Time to Achieve at least a 50% Reduction from Baseline MBL Volume, by Subgroup (mITT Population)

Study: Pooled

Treatment	N	n (%)	Censored patients n (%)	Median time to 1st event [95% CI][1]	Median difference[1]	HR[2] [95% CI]	p-value[3]	p-value (int)[4]
BMI (kg/m2) at Baseline								
< 30								
Relugolix+E2/NETA	119	101 (84.9)	18 (15.1)	8.3 [8.1;8.6]	-14.3	5.24 [3.67;7.48]	<.0001	0.4370
Placebo	115	48 (41.7)	67 (58.3)	22.6 [16.3;NE]				
>= 30								
Relugolix+E2/NETA	133	113 (85.0)	20 (15.0)	8.3 [8.1;8.6]	-18.0	6.34 [4.48;8.98]	<.0001	
Placebo	141	51 (36.2)	90 (63.8)	26.3 [24.1;27.9]				
Missing								
Relugolix+E2/NETA	1	1 (100.0)	0	NC [NC;NC]	NC	NC [NC;NC]	NC	
Placebo	0	0	0	NC [NC;NC]				

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group.
Total menstrual blood loss volume was calculated as sum of menstrual blood loss volume from all feminine products (validated, unauthorized and unvalidated) assessed by the alkaline hematin method.
Patients without an event are censored at the last assessment date prior to their last dose of study drug.
[1] Based on Kaplan-Meier estimates. 95% CIs are calculated by log-log transformation of survivor function.
[2] Hazard Ratios (and 95% CIs) are based on a Cox proportional hazard model stratified by study and with treatment group, subgroup and a subgroup-by-treatment group as covariates. 95% CIs are based on the approximation to the normal distribution. The reference group for the HR is Placebo.
[3] Treatment P-value is based on the Wald test stratified by study.
[4] Interaction P-value is based on the subgroup-by-treatment interaction term in the proportional hazard model used to compute the Hazard Ratio and 95% CI.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with an event; HR: Hazard ratio; CI: Confidence interval; int: interaction; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; NC: Not calculated; NE: Non-estimable.

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Table EFF.TTMBLG50.MITT.Pooled.S9: Time to Achieve at least a 50% Reduction from Baseline MBL Volume, by Subgroup (mITT Population)

Study: Pooled

Treatment	N	n (%)	Censored patients n (%)	Median time to 1st event [95% CI][1]	Median difference[1]	HR[2] [95% CI]	p-value[3]	p-value (int)[4]
Race								
Black/African American								0.5391
Relugolix+E2/NETA	122	98 (80.3)	24 (19.7)	8.3 [8.1;8.7]	-18.0	6.50 [4.53;9.33]	<.0001	
Placebo	141	49 (34.8)	92 (65.2)	26.3 [24.1;28.1]				
White								
Relugolix+E2/NETA	122	109 (89.3)	13 (10.7)	8.3 [8.1;8.4]	-15.8	4.92 [3.45;7.02]	<.0001	
Placebo	105	48 (45.7)	57 (54.3)	24.1 [16.1;NE]				
Asian								
Relugolix+E2/NETA	1	1 (100.0)	0	NC [NC;NC]	NC	NC [NC;NC]	NC	
Placebo	3	1 (33.3)	2 (66.7)	NC [NC;NC]				
Others								
Relugolix+E2/NETA	5	4 (80.0)	1 (20.0)	8.3 [3.3;NE]	NE	>99 [NC;NC]	NC	
Placebo	6	0	6 (100.0)	NR [NE;NE]				
Not reported								
Relugolix+E2/NETA	3	3 (100.0)	0	NC [NC;NC]	NC	NC [NC;NC]	NC	
Placebo	1	1 (100.0)	0	NC [NC;NC]				

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group.
Total menstrual blood loss volume was calculated as sum of menstrual blood loss volume from all feminine products (validated, unauthorized and unvalidated) assessed by the alkaline hematin method. Patients without an event are censored at the last assessment date prior to their last dose of study drug.
[1] Based on Kaplan-Meier estimates. 95% CIs are calculated by log-log transformation of survivor function.
[2] Hazard Ratios (and 95% CIs) are based on a Cox proportional hazard model stratified by study and with treatment group, subgroup and a subgroup-by-treatment group as covariates. 95% CIs are based on the approximation to the normal distribution. The reference group for the HR is Placebo.
[3] Treatment P-value is based on the Wald test stratified by study.
[4] Interaction P-value is based on the subgroup-by-treatment interaction term in the proportional hazard model used to compute the Hazard Ratio and 95% CI.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with an event; HR: Hazard ratio; CI: Confidence interval; int: interaction; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; NC: Not calculated; NE: Non-estimable; NR: Not reached.

SOURCE: \Studies\MYV\MYV102\Analysis\Prod\Progs\TFLs\Tab_EFF_MBL_TTE.SAS

Table EFF.TTMBLG50.MITT.Pooled.S4: Time to Achieve at least a 50% Reduction from Baseline MBL Volume, by Subgroup (mITT Population)

Study: Pooled

Treatment	N	n (%)	Censored patients n (%)	Median time to 1st event [95% CI][1]	Median difference[1]	HR[2] [95% CI]	p-value[3]	p-value (int)[4]
Maximum NRS Pain Score at Baseline								
< 4								
Relugolix+E2/NETA	73	60 (82.2)	13 (17.8)	8.6 [8.3;9.0]	NE	6.81 [3.98;11.64]	<.0001	0.5443
Placebo	62	18 (29.0)	44 (71.0)	NR [NE;NE]				
>= 4								
Relugolix+E2/NETA	177	152 (85.9)	25 (14.1)	8.1 [8.1;8.3]	-17.0	5.66 [4.25;7.54]	<.0001	
Placebo	190	81 (42.6)	109 (57.4)	25.1 [21.9;27.4]				
Missing								
Relugolix+E2/NETA	3	3 (100.0)	0	NC [NC;NC]	NC	NC [NC;NC]	NC	
Placebo	4	0	4 (100.0)	NC [NC;NC]				

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group.
Total menstrual blood loss volume was calculated as sum of menstrual blood loss volume from all feminine products (validated, unauthorized and unvalidated) assessed by the alkaline hematin method. Patients without an event are censored at the last assessment date prior to their last dose of study drug.
[1] Based on Kaplan-Meier estimates. 95% CIs are calculated by log-log transformation of survivor function.
[2] Hazard Ratios (and 95% CIs) are based on a Cox proportional hazard model stratified by study and with treatment group, subgroup and a subgroup-by-treatment group as covariates. 95% CIs are based on the approximation to the normal distribution. The reference group for the HR is Placebo.
[3] Treatment P-value is based on the Wald test stratified by study.
[4] Interaction P-value is based on the subgroup-by-treatment interaction term in the proportional hazard model used to compute the Hazard Ratio and 95% CI.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with an event; HR: Hazard ratio; CI: Confidence interval; int: interaction; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; NC: Not calculated; NE: Non-estimable; NR: Not reached.

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Table EFF.TTMBLG50.MITT.Pooled.S3: Time to Achieve at least a 50% Reduction from Baseline MBL Volume, by Subgroup (mITT Population)

Study: Pooled

Treatment	N	n (%)	Censored patients n (%)	Median time to 1st event [95% CI][1]	Median difference[1]	HR[2] [95% CI]	p-value[3]	p-value (int)[4]
Uterine Volume at Baseline (cm3)								
< 300 cm3								
Relugolix+E2/NETA	148	128 (86.5)	20 (13.5)	8.1 [8.1;8.4]	-19.3	6.12 [4.33;8.65]	<.0001	0.5791
Placebo	129	50 (38.8)	79 (61.2)	27.4 [22.6;27.9]				
>= 300 cm3								
Relugolix+E2/NETA	104	87 (83.7)	17 (16.3)	8.3 [8.1;9.0]	-16.7	5.33 [3.71;7.65]	<.0001	
Placebo	127	49 (38.6)	78 (61.4)	25.0 [21.9;NE]				
Missing								
Relugolix+E2/NETA	1	0	1 (100.0)	NC [NC;NC]	NC	NC [NC;NC]	NC	
Placebo	0	0	0	NC [NC;NC]				

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group.
Total menstrual blood loss volume was calculated as sum of menstrual blood loss volume from all feminine products (validated, unauthorized and unvalidated) assessed by the alkaline hematin method.
Patients without an event are censored at the last assessment date prior to their last dose of study drug.
[1] Based on Kaplan-Meier estimates. 95% CIs are calculated by log-log transformation of survivor function.
[2] Hazard Ratios (and 95% CIs) are based on a Cox proportional hazard model stratified by study and with treatment group, subgroup and a subgroup-by-treatment group as covariates. 95% CIs are based on the approximation to the normal distribution. The reference group for the HR is Placebo.
[3] Treatment P-value is based on the Wald test stratified by study.
[4] Interaction P-value is based on the subgroup-by-treatment interaction term in the proportional hazard model used to compute the Hazard Ratio and 95% CI.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with an event; HR: Hazard ratio; CI: Confidence interval; int: interaction; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; NC: Not calculated; NE: Non-estimable.

SOURCE: \Studies\MYV\MYV102\Analysis\Prod\Progs\TFLs\Tab_EFF_MBL_TTE.SAS
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Table EFF.TTMBLG50.MITT.Pooled.S6: Time to Achieve at least a 50% Reduction from Baseline MBL Volume, by Subgroup (mITT Population)

Study: Pooled

Treatment	N	n (%)	Censored patients n (%)	Median time to 1st event [95% CI][1]	Median difference[1]	HR[2] [95% CI]	p-value[3]	p-value (int)[4]
Geographic Region I								
North America								
Relugolix+E2/NETA	191	158 (82.7)	33 (17.3)	8.3 [8.1;8.4]	-18.0	5.75 [4.29;7.72]	<.0001	0.8840
Placebo	194	73 (37.6)	121 (62.4)	26.3 [24.1;28.1]				
Rest of World								
Relugolix+E2/NETA	62	57 (91.9)	5 (8.1)	8.3 [8.1;9.0]	-16.7	5.99 [3.72;9.65]	<.0001	
Placebo	62	26 (41.9)	36 (58.1)	25.0 [16.9;NE]				

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group.
Total menstrual blood loss volume was calculated as sum of menstrual blood loss volume from all feminine products (validated, unauthorized and unvalidated) assessed by the alkaline hematin method.
Patients without an event are censored at the last assessment date prior to their last dose of study drug.
[1] Based on Kaplan-Meier estimates. 95% CIs are calculated by log-log transformation of survivor function.
[2] Hazard Ratios (and 95% CIs) are based on a Cox proportional hazard model stratified by study and with treatment group, subgroup and a subgroup-by-treatment group as covariates. 95% CIs are based on the approximation to the normal distribution. The reference group for the HR is Placebo.
[3] Treatment P-value is based on the Wald test stratified by study.
[4] Interaction P-value is based on the subgroup-by-treatment interaction term in the proportional hazard model used to compute the Hazard Ratio and 95% CI.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with an event; HR: Hazard ratio; CI: Confidence interval; int: interaction; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; NE: Non-estimable.

SOURCE: \Studies\MYV\MYV102\Analysis\Prod\Progs\TFLs\Tab_EFF_MBL_TTE.SAS
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Table EFF.TTMBLG50.MITT.Pooled.S8: Time to Achieve at least a 50% Reduction from Baseline MBL Volume, by Subgroup (mITT Population)

Study: Pooled

Treatment	N	n (%)	Censored patients n (%)	Median time to 1st event [95% CI][1]	Median difference[1]	HR[2] [95% CI]	p-value[3]	p-value (int)[4]
Ethnicity								
Hispanic or Latino								0.9525
Relugolix+E2/NETA	52	46 (88.5)	6 (11.5)	8.1 [7.6;8.3]	-16.9	5.66 [3.37;9.52]	<.0001	
Placebo	55	22 (40.0)	33 (60.0)	25.0 [20.1;NE]				
Not Hispanic or Latino								
Relugolix+E2/NETA	197	166 (84.3)	31 (15.7)	8.3 [8.1;8.6]	-18.0	5.77 [4.32;7.70]	<.0001	
Placebo	199	76 (38.2)	123 (61.8)	26.3 [22.6;28.1]				
Not reported								
Relugolix+E2/NETA	4	3 (75.0)	1 (25.0)	NC [NC;NC]	NC	NC [NC;NC]	NC	
Placebo	2	1 (50.0)	1 (50.0)	NC [NC;NC]				

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group.
Total menstrual blood loss volume was calculated as sum of menstrual blood loss volume from all feminine products (validated, unauthorized and unvalidated) assessed by the alkaline hematin method. Patients without an event are censored at the last assessment date prior to their last dose of study drug.
[1] Based on Kaplan-Meier estimates. 95% CIs are calculated by log-log transformation of survivor function.
[2] Hazard Ratios (and 95% CIs) are based on a Cox proportional hazard model stratified by study and with treatment group, subgroup and a subgroup-by-treatment group as covariates. 95% CIs are based on the approximation to the normal distribution. The reference group for the HR is Placebo.
[3] Treatment P-value is based on the Wald test stratified by study.
[4] Interaction P-value is based on the subgroup-by-treatment interaction term in the proportional hazard model used to compute the Hazard Ratio and 95% CI.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with an event; HR: Hazard ratio; CI: Confidence interval; int: interaction; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; NC: Not calculated; NE: Non-estimable.

SOURCE: \Studies\MYV\MYV102\Analysis\Prod\Progs\TFLs\Tab_EFF_MBL_TTE.SAS
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1.1.4 Time to Sustained Response (MBL volume of < 80 mL and at least a 50% Reduction from Baseline MBL Volume), by Subgroup (mITT Population)

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Table EFF.TTSRESP.MITT.Pooled.S8: Time to Sustained Response (MBL volume of < 80 mL and at least a 50% Reduction from Baseline MBL Volume), by Subgroup (mITT Population)

Study: Pooled

Treatment	N	n (%)	Censored patients n (%)	Median time to 1st event [95% CI][1]	Median difference[1]	HR[2] [95% CI]	p-value[3]	p-value (int)[4]
Ethnicity								
Hispanic or Latino								0.0961
Relugolix+E2/NETA	52	39 (75.0)	13 (25.0)	8.3 [7.4;12.1]	NE	9.08 [4.21;19.56]	<.0001	
Placebo	55	8 (14.5)	47 (85.5)	NR [NE;NE]				
Not Hispanic or Latino								
Relugolix+E2/NETA	197	133 (67.5)	64 (32.5)	8.3 [8.1;9.0]	NE	20.43 [11.51;36.25]	<.0001	
Placebo	199	13 (6.5)	186 (93.5)	NR [NE;NE]				
Not reported								
Relugolix+E2/NETA	4	3 (75.0)	1 (25.0)	NC [NC;NC]	NC	NC [NC;NC]	NC	
Placebo	2	0	2 (100.0)	NC [NC;NC]				

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group.
Total MBL volume was calculated as sum of MBL volume from all feminine products (validated, unauthorized and unvalidated) assessed by the alkaline hematin method. Sustained response is defined as patients time to achieve and maintain response until the date of last study drug. Patients without an event are censored at the last assessment date prior to their last dose of study drug.
[1] Based on Kaplan-Meier estimates. 95% CIs are calculated by log-log transformation of survivor function.
[2] Hazard Ratios (and 95% CIs) are based on a Cox proportional hazard model stratified by study and with treatment group, subgroup and a subgroup-by-treatment group as covariates. 95% CIs are based on the approximation to the normal distribution. The reference group for the HR is Placebo.
[3] Treatment P-value is based on the Wald test stratified by study.
[4] Interaction P-value is based on the subgroup-by-treatment interaction term in the proportional hazard model used to compute the Hazard Ratio and 95% CI.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with an event; HR: Hazard ratio; CI: Confidence interval; int: interaction; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; NC: Not calculated; NE: Non-estimable; NR: Not reached.

SOURCE: \Studies\MYV\MYV102\Analysis\Prod\Progs\TFLs\Tab_EFF_MBL_TTE.SAS
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Table EFF.TTSRESP.MITT.Pooled.S4: Time to Sustained Response (MBL volume of < 80 mL and at least a 50% Reduction from Baseline MBL Volume), by Subgroup (mITT Population)

Study: Pooled

Treatment	N	n (%)	Censored patients n (%)	Median time to 1st event [95% CI][1]	Median difference[1]	HR[2] [95% CI]	p-value[3]	p-value (int)[4]
Maximum NRS Pain Score at Baseline								
< 4								
Relugolix+E2/NETA	73	54 (74.0)	19 (26.0)	8.3 [8.1;9.0]	NE	32.48 [10.12;104.27]	<.0001	0.1846
Placebo	62	3 (4.8)	59 (95.2)	NR [NE;NE]				
>= 4								
Relugolix+E2/NETA	177	120 (67.8)	57 (32.2)	8.3 [8.1;9.6]	NE	13.80 [8.38;22.74]	<.0001	
Placebo	190	18 (9.5)	172 (90.5)	NR [NE;NE]				
Missing								
Relugolix+E2/NETA	3	1 (33.3)	2 (66.7)	NC [NC;NC]	NC	NC [NC;NC]	NC	
Placebo	4	0	4 (100.0)	NC [NC;NC]				

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group.
Total MBL volume was calculated as sum of MBL volume from all feminine products (validated, unauthorized and unvalidated) assessed by the alkaline hematin method. Sustained response is defined as patients time to achieve and maintain response until the date of last study drug.
Patients without an event are censored at the last assessment date prior to their last dose of study drug.
[1] Based on Kaplan-Meier estimates. 95% CIs are calculated by log-log transformation of survivor function.
[2] Hazard Ratios (and 95% CIs) are based on a Cox proportional hazard model stratified by study and with treatment group, subgroup and a subgroup-by-treatment group as covariates. 95% CIs are based on the approximation to the normal distribution. The reference group for the HR is Placebo.
[3] Treatment P-value is based on the Wald test stratified by study.
[4] Interaction P-value is based on the subgroup-by-treatment interaction term in the proportional hazard model used to compute the Hazard Ratio and 95% CI.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with an event; HR: Hazard ratio; CI: Confidence interval; int: interaction; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; NC: Not calculated; NE: Non-estimable; NR: Not reached.

SOURCE: \Studies\MYV\MYV102\Analysis\Prod\Progs\TFLs\Tab_EFF_MBL_TTE.SAS
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Table EFF.TTSRESP.MITT.Pooled.S6: Time to Sustained Response (MBL volume of < 80 mL and at least a 50% Reduction from Baseline MBL Volume), by Subgroup (mITT Population)

Study: Pooled

Treatment	N	n (%)	Censored patients n (%)	Median time to 1st event [95% CI][1]	Median difference[1]	HR[2] [95% CI]	p-value[3]	p-value (int)[4]
Geographic Region I								
North America								
Relugolix+E2/NETA	191	125 (65.4)	66 (34.6)	8.7 [8.3;10.7]	NE	14.65 [8.67;24.75]	<.0001	0.3368
Placebo	194	16 (8.2)	178 (91.8)	NR [NE;NE]				
Rest of World								
Relugolix+E2/NETA	62	50 (80.6)	12 (19.4)	8.1 [5.3;8.7]	NE	24.60 [9.76;62.01]	<.0001	
Placebo	62	5 (8.1)	57 (91.9)	NR [NE;NE]				

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group.
Total MBL volume was calculated as sum of MBL volume from all feminine products (validated, unauthorized and unvalidated) assessed by the alkaline hematin method. Sustained response is defined as patients time to achieve and maintain response until the date of last study drug.
Patients without an event are censored at the last assessment date prior to their last dose of study drug.
[1] Based on Kaplan-Meier estimates. 95% CIs are calculated by log-log transformation of survivor function.
[2] Hazard Ratios (and 95% CIs) are based on a Cox proportional hazard model stratified by study and with treatment group, subgroup and a subgroup-by-treatment group as covariates. 95% CIs are based on the approximation to the normal distribution. The reference group for the HR is Placebo.
[3] Treatment P-value is based on the Wald test stratified by study.
[4] Interaction P-value is based on the subgroup-by-treatment interaction term in the proportional hazard model used to compute the Hazard Ratio and 95% CI.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with an event; HR: Hazard ratio; CI: Confidence interval; int: interaction; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; NE: Non-estimable; NR: Not reached.

SOURCE: \Studies\MYV\MYV102\Analysis\Prod\Progs\TFLs\Tab_EFF_MBL_TTE.SAS
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Table EFF.TTSRESP.MITT.Pooled.S7: Time to Sustained Response (MBL volume of < 80 mL and at least a 50% Reduction from Baseline MBL Volume), by Subgroup (mITT Population)

Study: Pooled

Treatment	N	n (%)	Censored patients n (%)	Median time to 1st event [95% CI][1]	Median difference[1]	HR[2] [95% CI]	p-value[3]	p-value (int)[4]
Geographic Region II								
Europe								
Relugolix+E2/NETA	41	35 (85.4)	6 (14.6)	8.0 [5.1;8.7]	NE	23.32 [8.23;66.05]	<.0001	0.4957
Placebo	42	4 (9.5)	38 (90.5)	NR [NE;NE]				
Rest of World (including the US)								
Relugolix+E2/NETA	212	140 (66.0)	72 (34.0)	8.6 [8.3;9.7]	NE	15.62 [9.40;25.94]	<.0001	
Placebo	214	17 (7.9)	197 (92.1)	NR [NE;NE]				

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group.
Total MBL volume was calculated as sum of MBL volume from all feminine products (validated, unauthorized and unvalidated) assessed by the alkaline hematin method. Sustained response is defined as patients time to achieve and maintain response until the date of last study drug.
Patients without an event are censored at the last assessment date prior to their last dose of study drug.
[1] Based on Kaplan-Meier estimates. 95% CIs are calculated by log-log transformation of survivor function.
[2] Hazard Ratios (and 95% CIs) are based on a Cox proportional hazard model stratified by study and with treatment group, subgroup and a subgroup-by-treatment group as covariates. 95% CIs are based on the approximation to the normal distribution. The reference group for the HR is Placebo.
[3] Treatment P-value is based on the Wald test stratified by study.
[4] Interaction P-value is based on the subgroup-by-treatment interaction term in the proportional hazard model used to compute the Hazard Ratio and 95% CI.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with an event; HR: Hazard ratio; CI: Confidence interval; int: interaction; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; NE: Non-estimable; NR: Not reached.

SOURCE: \Studies\MYV\MYV102\Analysis\Prod\Progs\TFLs\Tab_EFF_MBL_TTE.SAS
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Table EFF.TTSRESP.MITT.Pooled.S5: Time to Sustained Response (MBL volume of < 80 mL and at least a 50% Reduction from Baseline MBL Volume), by Subgroup (mITT Population)

Study: Pooled

Treatment	N	n (%)	Censored patients n (%)	Median time to 1st event [95% CI][1]	Median difference[1]	HR[2] [95% CI]	p-value[3]	p-value (int)[4]
MBL Volume at Baseline (mL)								
< 225 mL								
Relugolix+E2/NETA	164	118 (72.0)	46 (28.0)	8.1 [7.1;8.3]	NE	18.25 [10.61;31.37]	<.0001	0.6548
Placebo	171	15 (8.8)	156 (91.2)	NR [NE;NE]				
>= 225 mL								
Relugolix+E2/NETA	89	57 (64.0)	32 (36.0)	10.1 [8.7;12.4]	NE	14.53 [6.25;33.78]	<.0001	
Placebo	85	6 (7.1)	79 (92.9)	NR [NE;NE]				

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group.
Total MBL volume was calculated as sum of MBL volume from all feminine products (validated, unauthorized and unvalidated) assessed by the alkaline hematin method. Sustained response is defined as patients time to achieve and maintain response until the date of last study drug.
Patients without an event are censored at the last assessment date prior to their last dose of study drug.
[1] Based on Kaplan-Meier estimates. 95% CIs are calculated by log-log transformation of survivor function.
[2] Hazard Ratios (and 95% CIs) are based on a Cox proportional hazard model stratified by study and with treatment group, subgroup and a subgroup-by-treatment group as covariates. 95% CIs are based on the approximation to the normal distribution. The reference group for the HR is Placebo.
[3] Treatment P-value is based on the Wald test stratified by study.
[4] Interaction P-value is based on the subgroup-by-treatment interaction term in the proportional hazard model used to compute the Hazard Ratio and 95% CI.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with an event; HR: Hazard ratio; CI: Confidence interval; int: interaction; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; NE: Non-estimable; NR: Not reached.

SOURCE: \Studies\MYV\MYV102\Analysis\Prod\Progs\TFLs\Tab_EFF_MBL_TTE.SAS
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Table EFF.TTSRESP.MITT.Pooled.S2: Time to Sustained Response (MBL volume of < 80 mL and at least a 50% Reduction from Baseline MBL Volume), by Subgroup (mITT Population)

Study: Pooled

Treatment	N	n (%)	Censored patients n (%)	Median time to 1st event [95% CI][1]	Median difference[1]	HR[2] [95% CI]	p-value[3]	p-value (int)[4]
BMI (kg/m2) at Baseline								
< 30								
Relugolix+E2/NETA	119	82 (68.9)	37 (31.1)	8.4 [8.1;9.0]	NE	17.67 [8.84;35.28]	<.0001	0.7654
Placebo	115	9 (7.8)	106 (92.2)	NR [NE;NE]				
>= 30								
Relugolix+E2/NETA	133	92 (69.2)	41 (30.8)	8.4 [8.1;9.9]	NE	15.37 [8.39;28.15]	<.0001	
Placebo	141	12 (8.5)	129 (91.5)	NR [NE;NE]				
Missing								
Relugolix+E2/NETA	1	1 (100.0)	0	NC [NC;NC]	NC	NC [NC;NC]	NC	
Placebo	0	0	0	NC [NC;NC]				

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group.
Total MBL volume was calculated as sum of MBL volume from all feminine products (validated, unauthorized and unvalidated) assessed by the alkaline hematin method. Sustained response is defined as patients time to achieve and maintain response until the date of last study drug.
Patients without an event are censored at the last assessment date prior to their last dose of study drug.
[1] Based on Kaplan-Meier estimates. 95% CIs are calculated by log-log transformation of survivor function.
[2] Hazard Ratios (and 95% CIs) are based on a Cox proportional hazard model stratified by study and with treatment group, subgroup and a subgroup-by-treatment group as covariates. 95% CIs are based on the approximation to the normal distribution. The reference group for the HR is Placebo.
[3] Treatment P-value is based on the Wald test stratified by study.
[4] Interaction P-value is based on the subgroup-by-treatment interaction term in the proportional hazard model used to compute the Hazard Ratio and 95% CI.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with an event; HR: Hazard ratio; CI: Confidence interval; int: interaction; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; NC: Not calculated; NE: Non-estimable; NR: Not reached.

SOURCE: \Studies\MYV\MYV102\Analysis\Prod\Progs\TFLs\Tab_EFF_MBL_TTE.SAS
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Table EFF.TTSRESP.MITT.Pooled.S9: Time to Sustained Response (MBL volume of < 80 mL and at least a 50% Reduction from Baseline MBL Volume), by Subgroup (mITT Population)

Study: Pooled

Treatment	N	n (%)	Censored patients n (%)	Median time to 1st event [95% CI][1]	Median difference[1]	HR[2] [95% CI]	p-value[3]	p-value (int)[4]
Race								
Black/African American								
Relugolix+E2/NETA	122	71 (58.2)	51 (41.8)	9.1 [8.3;12.1]	NE	18.66 [8.96;38.85]	<.0001	0.8958
Placebo	141	8 (5.7)	133 (94.3)	NR [NE;NE]				
White								
Relugolix+E2/NETA	122	97 (79.5)	25 (20.5)	8.3 [8.0;8.7]	NE	14.88 [8.12;27.28]	<.0001	
Placebo	105	12 (11.4)	93 (88.6)	NR [NE;NE]				
Asian								
Relugolix+E2/NETA	1	1 (100.0)	0	NC [NC;NC]	NC	NC [NC;NC]	NC	
Placebo	3	1 (33.3)	2 (66.7)	NC [NC;NC]				
Others								
Relugolix+E2/NETA	5	3 (60.0)	2 (40.0)	8.3 [3.3;NE]	NE	>99 [NC;NC]	NC	
Placebo	6	0	6 (100.0)	NR [NE;NE]				
Not reported								
Relugolix+E2/NETA	3	3 (100.0)	0	NC [NC;NC]	NC	NC [NC;NC]	NC	
Placebo	1	0	1 (100.0)	NC [NC;NC]				

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group.
Total MBL volume was calculated as sum of MBL volume from all feminine products (validated, unauthorized and unvalidated) assessed by the alkaline hematin method. Sustained response is defined as patients time to achieve and maintain response until the date of last study drug.
Patients without an event are censored at the last assessment date prior to their last dose of study drug.
[1] Based on Kaplan-Meier estimates. 95% CIs are calculated by log-log transformation of survivor function.
[2] Hazard Ratios (and 95% CIs) are based on a Cox proportional hazard model stratified by study and with treatment group, subgroup and a subgroup-by-treatment group as covariates. 95% CIs are based on the approximation to the normal distribution. The reference group for the HR is Placebo.
[3] Treatment P-value is based on the Wald test stratified by study.
[4] Interaction P-value is based on the subgroup-by-treatment interaction term in the proportional hazard model used to compute the Hazard Ratio and 95% CI.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with an event; HR: Hazard ratio; CI: Confidence interval; int: interaction; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; NC: Not calculated; NE: Non-estimable; NR: Not reached.

SOURCE: \Studies\MYV\MYV102\Analysis\Prod\Progs\TFLs\Tab_EFF_MBL_TTE.SAS

Table EFF.TTSRESP.MITT.Pooled.S1: Time to Sustained Response (MBL volume of < 80 mL and at least a 50% Reduction from Baseline MBL Volume), by Subgroup (mITT Population)

Study: Pooled

Treatment	N	n (%)	Censored patients n (%)	Median time to 1st event [95% CI][1]	Median difference[1]	HR[2] [95% CI]	p-value[3]	p-value (int)[4]
Age (years)								
< 40 years								
Relugolix+E2/NETA	62	39 (62.9)	23 (37.1)	11.7 [8.3;12.3]	NE	15.93 [6.27;40.48]	<.0001	0.9437
Placebo	78	5 (6.4)	73 (93.6)	NR [NE;NE]				
>= 40 years								
Relugolix+E2/NETA	191	136 (71.2)	55 (28.8)	8.3 [8.1;8.7]	NE	16.55 [9.81;27.92]	<.0001	
Placebo	178	16 (9.0)	162 (91.0)	NR [NE;NE]				

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group.
Total MBL volume was calculated as sum of MBL volume from all feminine products (validated, unauthorized and unvalidated) assessed by the alkaline hematin method. Sustained response is defined as patients time to achieve and maintain response until the date of last study drug.
Patients without an event are censored at the last assessment date prior to their last dose of study drug.
[1] Based on Kaplan-Meier estimates. 95% CIs are calculated by log-log transformation of survivor function.
[2] Hazard Ratios (and 95% CIs) are based on a Cox proportional hazard model stratified by study and with treatment group, subgroup and a subgroup-by-treatment group as covariates. 95% CIs are based on the approximation to the normal distribution. The reference group for the HR is Placebo.
[3] Treatment P-value is based on the Wald test stratified by study.
[4] Interaction P-value is based on the subgroup-by-treatment interaction term in the proportional hazard model used to compute the Hazard Ratio and 95% CI.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with an event; HR: Hazard ratio; CI: Confidence interval; int: interaction; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; NE: Non-estimable; NR: Not reached.

SOURCE: \Studies\MYV\MYV102\Analysis\Prod\Progs\TFLs\Tab_EFF_MBL_TTE.SAS
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Table EFF.TTSRESP.MITT.Pooled.S3: Time to Sustained Response (MBL volume of < 80 mL and at least a 50% Reduction from Baseline MBL Volume), by Subgroup (mITT Population)

Study: Pooled

Treatment	N	n (%)	Censored patients n (%)	Median time to 1st event [95% CI][1]	Median difference[1]	HR[2] [95% CI]	p-value[3]	p-value (int)[4]
Uterine Volume at Baseline (cm3)								
< 300 cm3								
Relugolix+E2/NETA	148	110 (74.3)	38 (25.7)	8.3 [8.1;9.0]	NE	16.09 [8.83;29.32]	<.0001	0.9852
Placebo	129	12 (9.3)	117 (90.7)	NR [NE;NE]				
>= 300 cm3								
Relugolix+E2/NETA	104	65 (62.5)	39 (37.5)	8.9 [8.3;12.1]	NE	16.23 [8.06;32.69]	<.0001	
Placebo	127	9 (7.1)	118 (92.9)	NR [NE;NE]				
Missing								
Relugolix+E2/NETA	1	0	1 (100.0)	NC [NC;NC]	NC	NC [NC;NC]	NC	
Placebo	0	0	0	NC [NC;NC]				

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group.
Total MBL volume was calculated as sum of MBL volume from all feminine products (validated, unauthorized and unvalidated) assessed by the alkaline hematin method. Sustained response is defined as patients time to achieve and maintain response until the date of last study drug.
Patients without an event are censored at the last assessment date prior to their last dose of study drug.
[1] Based on Kaplan-Meier estimates. 95% CIs are calculated by log-log transformation of survivor function.
[2] Hazard Ratios (and 95% CIs) are based on a Cox proportional hazard model stratified by study and with treatment group, subgroup and a subgroup-by-treatment group as covariates. 95% CIs are based on the approximation to the normal distribution. The reference group for the HR is Placebo.
[3] Treatment P-value is based on the Wald test stratified by study.
[4] Interaction P-value is based on the subgroup-by-treatment interaction term in the proportional hazard model used to compute the Hazard Ratio and 95% CI.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with an event; HR: Hazard ratio; CI: Confidence interval; int: interaction; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; NC: Not calculated; NE: Non-estimable; NR: Not reached.

SOURCE: \Studies\MYV\MYV102\Analysis\Prod\Progs\TFLs\Tab_EFF_MBL_TTE.SAS
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1.1.4.1 Time to Sustained Response (MBL Volume of < 80 mL), by Subgroup (mITT Population)

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Table EFF.TTSRL80.MITT.Pooled.S8: Time to Sustained Response (MBL Volume of < 80 mL), by Subgroup (mITT Population)

Study: Pooled

Treatment	N	n (%)	Censored patients n (%)	Median time to 1st event [95% CI][1]	Median difference[1]	HR[2] [95% CI]	p-value[3]	p-value (int)[4]
Ethnicity								
Hispanic or Latino								0.1334
Relugolix+E2/NETA	52	41 (78.8)	11 (21.2)	8.3 [7.4;12.1]	NE	6.68 [3.41;13.10]	<.0001	
Placebo	55	11 (20.0)	44 (80.0)	NR [NE;NE]				
Not Hispanic or Latino								
Relugolix+E2/NETA	197	137 (69.5)	60 (30.5)	8.3 [8.1;8.7]	NE	12.41 [7.88;19.56]	<.0001	
Placebo	199	22 (11.1)	177 (88.9)	NR [NE;NE]				
Not reported								
Relugolix+E2/NETA	4	3 (75.0)	1 (25.0)	NC [NC;NC]	NC	NC [NC;NC]	NC	
Placebo	2	0	2 (100.0)	NC [NC;NC]				

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group.
Total MBL volume was calculated as sum of MBL volume from all feminine products (validated, unauthorized and unvalidated) assessed by the alkaline hematin method. Sustained response is defined as patients time to achieve and maintain response until the date of last study drug.
Patients without an event are censored at the last assessment date prior to their last dose of study drug.
[1] Based on Kaplan-Meier estimates. 95% CIs are calculated by log-log transformation of survivor function.
[2] Hazard Ratios (and 95% CIs) are based on a Cox proportional hazard model stratified by study and with treatment group, subgroup and a subgroup-by-treatment group as covariates. 95% CIs are based on the approximation to the normal distribution. The reference group for the HR is Placebo.
[3] Treatment P-value is based on the Wald test stratified by study.
[4] Interaction P-value is based on the subgroup-by-treatment interaction term in the proportional hazard model used to compute the Hazard Ratio and 95% CI.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with an event; HR: Hazard ratio; CI: Confidence interval; int: interaction; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; NC: Not calculated; NE: Non-estimable; NR: Not reached.

SOURCE: \Studies\MYV\MYV102\Analysis\Prod\Progs\TFLs\Tab_EFF_MBL_TTE.SAS
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Table EFF.TTSRL80.MITT.Pooled.S5: Time to Sustained Response (MBL Volume of < 80 mL), by Subgroup (mITT Population)

Study: Pooled

Treatment	N	n (%)	Censored patients n (%)	Median time to 1st event [95% CI][1]	Median difference[1]	HR[2] [95% CI]	p-value[3]	p-value (int)[4]
MBL Volume at Baseline (mL)								
< 225 mL								
Relugolix+E2/NETA	164	124 (75.6)	40 (24.4)	7.3 [5.1;8.1]	NE	10.72 [7.03;16.35]	<.0001	0.5455
Placebo	171	27 (15.8)	144 (84.2)	NR [NE;NE]				
>= 225 mL								
Relugolix+E2/NETA	89	57 (64.0)	32 (36.0)	9.7 [8.7;12.3]	NE	14.32 [6.16;33.29]	<.0001	
Placebo	85	6 (7.1)	79 (92.9)	NR [NE;NE]				

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group.
Total MBL volume was calculated as sum of MBL volume from all feminine products (validated, unauthorized and unvalidated) assessed by the alkaline hematin method. Sustained response is defined as patients time to achieve and maintain response until the date of last study drug.
Patients without an event are censored at the last assessment date prior to their last dose of study drug.
[1] Based on Kaplan-Meier estimates. 95% CIs are calculated by log-log transformation of survivor function.
[2] Hazard Ratios (and 95% CIs) are based on a Cox proportional hazard model stratified by study and with treatment group, subgroup and a subgroup-by-treatment group as covariates. 95% CIs are based on the approximation to the normal distribution. The reference group for the HR is Placebo.
[3] Treatment P-value is based on the Wald test stratified by study.
[4] Interaction P-value is based on the subgroup-by-treatment interaction term in the proportional hazard model used to compute the Hazard Ratio and 95% CI.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with an event; HR: Hazard ratio; CI: Confidence interval; int: interaction; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; NE: Non-estimable; NR: Not reached.

SOURCE: \Studies\MYV\MYV102\Analysis\Prod\Progs\TFLs\Tab_EFF_MBL_TTE.SAS
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Table EFF.TTSRL80.MITT.Pooled.S4: Time to Sustained Response (MBL Volume of < 80 mL), by Subgroup (mITT Population)

Study: Pooled

Treatment	N	n (%)	Censored patients n (%)	Median time to 1st event [95% CI][1]	Median difference[1]	HR[2] [95% CI]	p-value[3]	p-value (int)[4]
Maximum NRS Pain Score at Baseline								
< 4								0.6060
Relugolix+E2/NETA	73	55 (75.3)	18 (24.7)	8.1 [7.1;8.7]	NE	12.72 [6.02;26.84]	<.0001	
Placebo	62	8 (12.9)	54 (87.1)	NR [NE;NE]				
>= 4								
Relugolix+E2/NETA	177	125 (70.6)	52 (29.4)	8.3 [8.1;9.3]	NE	10.15 [6.58;15.65]	<.0001	
Placebo	190	25 (13.2)	165 (86.8)	NR [NE;NE]				
Missing								
Relugolix+E2/NETA	3	1 (33.3)	2 (66.7)	NC [NC;NC]	NC	NC [NC;NC]	NC	
Placebo	4	0	4 (100.0)	NC [NC;NC]				

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group.
Total MBL volume was calculated as sum of MBL volume from all feminine products (validated, unauthorized and unvalidated) assessed by the alkaline hematin method. Sustained response is defined as patients time to achieve and maintain response until the date of last study drug.
Patients without an event are censored at the last assessment date prior to their last dose of study drug.
[1] Based on Kaplan-Meier estimates. 95% CIs are calculated by log-log transformation of survivor function.
[2] Hazard Ratios (and 95% CIs) are based on a Cox proportional hazard model stratified by study and with treatment group, subgroup and a subgroup-by-treatment group as covariates. 95% CIs are based on the approximation to the normal distribution. The reference group for the HR is Placebo.
[3] Treatment P-value is based on the Wald test stratified by study.
[4] Interaction P-value is based on the subgroup-by-treatment interaction term in the proportional hazard model used to compute the Hazard Ratio and 95% CI.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with an event; HR: Hazard ratio; CI: Confidence interval; int: interaction; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; NC: Not calculated; NE: Non-estimable; NR: Not reached.

SOURCE: \Studies\MYV\MYV102\Analysis\Prod\Progs\TFLs\Tab_EFF_MBL_TTE.SAS
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Table EFF.TTSRL80.MITT.Pooled.S1: Time to Sustained Response (MBL Volume of < 80 mL), by Subgroup (mITT Population)

Study: Pooled

Treatment	N	n (%)	Censored patients n (%)	Median time to 1st event [95% CI][1]	Median difference[1]	HR[2] [95% CI]	p-value[3]	p-value (int)[4]
Age (years)								
< 40 years								
Relugolix+E2/NETA	62	41 (66.1)	21 (33.9)	8.9 [8.1;12.1]	NE	9.24 [4.48;19.05]	<.0001	0.6458
Placebo	78	9 (11.5)	69 (88.5)	NR [NE;NE]				
>= 40 years								
Relugolix+E2/NETA	191	140 (73.3)	51 (26.7)	8.1 [8.1;8.6]	NE	11.26 [7.26;17.45]	<.0001	
Placebo	178	24 (13.5)	154 (86.5)	NR [NE;NE]				

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group.
Total MBL volume was calculated as sum of MBL volume from all feminine products (validated, unauthorized and unvalidated) assessed by the alkaline hematin method. Sustained response is defined as patients time to achieve and maintain response until the date of last study drug.
Patients without an event are censored at the last assessment date prior to their last dose of study drug.
[1] Based on Kaplan-Meier estimates. 95% CIs are calculated by log-log transformation of survivor function.
[2] Hazard Ratios (and 95% CIs) are based on a Cox proportional hazard model stratified by study and with treatment group, subgroup and a subgroup-by-treatment group as covariates. 95% CIs are based on the approximation to the normal distribution. The reference group for the HR is Placebo.
[3] Treatment P-value is based on the Wald test stratified by study.
[4] Interaction P-value is based on the subgroup-by-treatment interaction term in the proportional hazard model used to compute the Hazard Ratio and 95% CI.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with an event; HR: Hazard ratio; CI: Confidence interval; int: interaction; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; NE: Non-estimable; NR: Not reached.

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Table EFF.TTSRL80.MITT.Pooled.S3: Time to Sustained Response (MBL Volume of < 80 mL), by Subgroup (mITT Population)

Study: Pooled

Treatment	N	n (%)	Censored patients n (%)	Median time to 1st event [95% CI][1]	Median difference[1]	HR[2] [95% CI]	p-value[3]	p-value (int)[4]
Uterine Volume at Baseline (cm3)								
< 300 cm3								
Relugolix+E2/NETA	148	113 (76.4)	35 (23.6)	8.1 [7.4;8.3]	NE	10.08 [6.23;16.29]	<.0001	0.7627
Placebo	129	20 (15.5)	109 (84.5)	NR [NE;NE]				
>= 300 cm3								
Relugolix+E2/NETA	104	68 (65.4)	36 (34.6)	8.7 [8.1;10.7]	NE	11.33 [6.24;20.57]	<.0001	
Placebo	127	13 (10.2)	114 (89.8)	NR [NE;NE]				
Missing								
Relugolix+E2/NETA	1	0	1 (100.0)	NC [NC;NC]	NC	NC [NC;NC]	NC	
Placebo	0	0	0	NC [NC;NC]				

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group.
Total MBL volume was calculated as sum of MBL volume from all feminine products (validated, unauthorized and unvalidated) assessed by the alkaline hematin method. Sustained response is defined as patients time to achieve and maintain response until the date of last study drug.
Patients without an event are censored at the last assessment date prior to their last dose of study drug.
[1] Based on Kaplan-Meier estimates. 95% CIs are calculated by log-log transformation of survivor function.
[2] Hazard Ratios (and 95% CIs) are based on a Cox proportional hazard model stratified by study and with treatment group, subgroup and a subgroup-by-treatment group as covariates. 95% CIs are based on the approximation to the normal distribution. The reference group for the HR is Placebo.
[3] Treatment P-value is based on the Wald test stratified by study.
[4] Interaction P-value is based on the subgroup-by-treatment interaction term in the proportional hazard model used to compute the Hazard Ratio and 95% CI.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with an event; HR: Hazard ratio; CI: Confidence interval; int: interaction; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; NC: Not calculated; NE: Non-estimable; NR: Not reached.

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Table EFF.TTSRL80.MITT.Pooled.S7: Time to Sustained Response (MBL Volume of < 80 mL), by Subgroup (mITT Population)

Study: Pooled

Treatment	N	n (%)	Censored patients n (%)	Median time to 1st event [95% CI][1]	Median difference[1]	HR[2] [95% CI]	p-value[3]	p-value (int)[4]
Geographic Region II								
Europe								
Relugolix+E2/NETA	41	36 (87.8)	5 (12.2)	7.1 [4.9;8.7]	NE	12.39 [5.71;26.88]	<.0001	0.7655
Placebo	42	8 (19.0)	34 (81.0)	NR [NE;NE]				
Rest of World (including the US)								
Relugolix+E2/NETA	212	145 (68.4)	67 (31.6)	8.3 [8.1;9.1]	NE	10.84 [7.06;16.64]	<.0001	
Placebo	214	25 (11.7)	189 (88.3)	NR [NE;NE]				

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group.
Total MBL volume was calculated as sum of MBL volume from all feminine products (validated, unauthorized and unvalidated) assessed by the alkaline hematin method. Sustained response is defined as patients time to achieve and maintain response until the date of last study drug.
Patients without an event are censored at the last assessment date prior to their last dose of study drug.
[1] Based on Kaplan-Meier estimates. 95% CIs are calculated by log-log transformation of survivor function.
[2] Hazard Ratios (and 95% CIs) are based on a Cox proportional hazard model stratified by study and with treatment group, subgroup and a subgroup-by-treatment group as covariates. 95% CIs are based on the approximation to the normal distribution. The reference group for the HR is Placebo.
[3] Treatment P-value is based on the Wald test stratified by study.
[4] Interaction P-value is based on the subgroup-by-treatment interaction term in the proportional hazard model used to compute the Hazard Ratio and 95% CI.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with an event; HR: Hazard ratio; CI: Confidence interval; int: interaction; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; NE: Non-estimable; NR: Not reached.

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Table EFF.TTSRL80.MITT.Pooled.S6: Time to Sustained Response (MBL Volume of < 80 mL), by Subgroup (mITT Population)

Study: Pooled

Treatment	N	n (%)	Censored patients n (%)	Median time to 1st event [95% CI][1]	Median difference[1]	HR[2] [95% CI]	p-value[3]	p-value (int)[4]
Geographic Region I								
North America								
Relugolix+E2/NETA	191	130 (68.1)	61 (31.9)	8.3 [8.1;9.1]	NE	10.84 [6.87;17.10]	<.0001	0.8296
Placebo	194	22 (11.3)	172 (88.7)	NR [NE;NE]				
Rest of World								
Relugolix+E2/NETA	62	51 (82.3)	11 (17.7)	7.1 [5.0;8.3]	NE	11.82 [6.12;22.83]	<.0001	
Placebo	62	11 (17.7)	51 (82.3)	NR [NE;NE]				

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group.
Total MBL volume was calculated as sum of MBL volume from all feminine products (validated, unauthorized and unvalidated) assessed by the alkaline hematin method. Sustained response is defined as patients time to achieve and maintain response until the date of last study drug.
Patients without an event are censored at the last assessment date prior to their last dose of study drug.
[1] Based on Kaplan-Meier estimates. 95% CIs are calculated by log-log transformation of survivor function.
[2] Hazard Ratios (and 95% CIs) are based on a Cox proportional hazard model stratified by study and with treatment group, subgroup and a subgroup-by-treatment group as covariates. 95% CIs are based on the approximation to the normal distribution. The reference group for the HR is Placebo.
[3] Treatment P-value is based on the Wald test stratified by study.
[4] Interaction P-value is based on the subgroup-by-treatment interaction term in the proportional hazard model used to compute the Hazard Ratio and 95% CI.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with an event; HR: Hazard ratio; CI: Confidence interval; int: interaction; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; NE: Non-estimable; NR: Not reached.

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Table EFF.TTSRL80.MITT.Pooled.S9: Time to Sustained Response (MBL Volume of < 80 mL), by Subgroup (mITT Population)

Study: Pooled

Treatment	N	n (%)	Censored patients n (%)	Median time to 1st event [95% CI][1]	Median difference[1]	HR[2] [95% CI]	p-value[3]	p-value (int)[4]
Race								
Black/African American								
Relugolix+E2/NETA	122	75 (61.5)	47 (38.5)	8.6 [8.1;10.7]	NE	11.86 [6.56;21.43]	<.0001	0.8632
Placebo	141	13 (9.2)	128 (90.8)	NR [NE;NE]				
White								
Relugolix+E2/NETA	122	98 (80.3)	24 (19.7)	8.1 [7.4;8.4]	NE	9.59 [5.83;15.78]	<.0001	
Placebo	105	19 (18.1)	86 (81.9)	NR [NE;NE]				
Asian								
Relugolix+E2/NETA	1	1 (100.0)	0	NC [NC;NC]	NC	NC [NC;NC]	NC	
Placebo	3	1 (33.3)	2 (66.7)	NC [NC;NC]				
Others								
Relugolix+E2/NETA	5	4 (80.0)	1 (20.0)	8.3 [3.3;NE]	NE	>99 [NC;NC]	0.9674	
Placebo	6	0	6 (100.0)	NR [NE;NE]				
Not reported								
Relugolix+E2/NETA	3	3 (100.0)	0	NC [NC;NC]	NC	NC [NC;NC]	NC	
Placebo	1	0	1 (100.0)	NC [NC;NC]				

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group.
Total MBL volume was calculated as sum of MBL volume from all feminine products (validated, unauthorized and unvalidated) assessed by the alkaline hematin method. Sustained response is defined as patients time to achieve and maintain response until the date of last study drug.
Patients without an event are censored at the last assessment date prior to their last dose of study drug.
[1] Based on Kaplan-Meier estimates. 95% CIs are calculated by log-log transformation of survivor function.
[2] Hazard Ratios (and 95% CIs) are based on a Cox proportional hazard model stratified by study and with treatment group, subgroup and a subgroup-by-treatment group as covariates. 95% CIs are based on the approximation to the normal distribution. The reference group for the HR is Placebo.
[3] Treatment P-value is based on the Wald test stratified by study.
[4] Interaction P-value is based on the subgroup-by-treatment interaction term in the proportional hazard model used to compute the Hazard Ratio and 95% CI.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with an event; HR: Hazard ratio; CI: Confidence interval; int: interaction; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; NC: Not calculated; NE: Non-estimable; NR: Not reached.

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Table EFF.TTSRL80.MITT.Pooled.S2: Time to Sustained Response (MBL Volume of < 80 mL), by Subgroup (mITT Population)

Study: Pooled

Treatment	N	n (%)	Censored patients n (%)	Median time to 1st event [95% CI][1]	Median difference[1]	HR[2] [95% CI]	p-value[3]	p-value (int)[4]
BMI (kg/m2) at Baseline								
< 30								
Relugolix+E2/NETA	119	85 (71.4)	34 (28.6)	8.1 [7.4;8.9]	NE	11.04 [6.35;19.18]	<.0001	0.8706
Placebo	115	15 (13.0)	100 (87.0)	NR [NE;NE]				
>= 30								
Relugolix+E2/NETA	133	95 (71.4)	38 (28.6)	8.3 [8.1;9.1]	NE	10.37 [6.24;17.24]	<.0001	
Placebo	141	18 (12.8)	123 (87.2)	NR [NE;NE]				
Missing								
Relugolix+E2/NETA	1	1 (100.0)	0	NC [NC;NC]	NC	NC [NC;NC]	NC	
Placebo	0	0	0	NC [NC;NC]				

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group.
Total MBL volume was calculated as sum of MBL volume from all feminine products (validated, unauthorized and unvalidated) assessed by the alkaline hematin method. Sustained response is defined as patients time to achieve and maintain response until the date of last study drug.
Patients without an event are censored at the last assessment date prior to their last dose of study drug.
[1] Based on Kaplan-Meier estimates. 95% CIs are calculated by log-log transformation of survivor function.
[2] Hazard Ratios (and 95% CIs) are based on a Cox proportional hazard model stratified by study and with treatment group, subgroup and a subgroup-by-treatment group as covariates. 95% CIs are based on the approximation to the normal distribution. The reference group for the HR is Placebo.
[3] Treatment P-value is based on the Wald test stratified by study.
[4] Interaction P-value is based on the subgroup-by-treatment interaction term in the proportional hazard model used to compute the Hazard Ratio and 95% CI.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with an event; HR: Hazard ratio; CI: Confidence interval; int: interaction; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; NC: Not calculated; NE: Non-estimable; NR: Not reached.

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1.1.4.2 Time to Sustained Response (at least a 50% Reduction from Baseline MBL Volume), by Subgroup (mITT Population)

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Table EFF.TTSRG50.MITT.Pooled.S5: Time to Sustained Response (at least a 50% Reduction from Baseline MBL Volume), by Subgroup (mITT Population)

Study: Pooled

Treatment	N	n (%)	Censored patients n (%)	Median time to 1st event [95% CI][1]	Median difference[1]	HR[2] [95% CI]	p-value[3]	p-value (int)[4]
MBL Volume at Baseline (mL)								
< 225 mL								
Relugolix+E2/NETA	164	122 (74.4)	42 (25.6)	7.1 [5.1;8.1]	NE	15.72 [9.42;26.23]	<.0001	0.0145*
Placebo	171	17 (9.9)	154 (90.1)	NR [NE;NE]				
>= 225 mL								
Relugolix+E2/NETA	89	66 (74.2)	23 (25.8)	8.1 [5.0;9.1]	NE	6.40 [3.83;10.72]	<.0001	
Placebo	85	19 (22.4)	66 (77.6)	NR [NE;NE]				

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group.
Total MBL volume was calculated as sum of MBL volume from all feminine products (validated, unauthorized and unvalidated) assessed by the alkaline hematin method. Sustained response is defined as patients time to achieve and maintain response until the date of last study drug.
Patients without an event are censored at the last assessment date prior to their last dose of study drug.
[1] Based on Kaplan-Meier estimates. 95% CIs are calculated by log-log transformation of survivor function.
[2] Hazard Ratios (and 95% CIs) are based on a Cox proportional hazard model stratified by study and with treatment group, subgroup and a subgroup-by-treatment group as covariates. 95% CIs are based on the approximation to the normal distribution. The reference group for the HR is Placebo.
[3] Treatment P-value is based on the Wald test stratified by study.
[4] Interaction P-value is based on the subgroup-by-treatment interaction term in the proportional hazard model used to compute the Hazard Ratio and 95% CI. * Interaction P-value < 0.05.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with an event; HR: Hazard ratio; CI: Confidence interval; int: interaction; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; NE: Non-estimable; NR: Not reached.

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Table EFF.TTSRG50.MITT.Pooled.S8: Time to Sustained Response (at least a 50% Reduction from Baseline MBL Volume), by Subgroup (mITT Population)

Study: Pooled

Treatment	N	n (%)	Censored patients n (%)	Median time to 1st event [95% CI][1]	Median difference[1]	HR[2] [95% CI]	p-value[3]	p-value (int)[4]
Ethnicity								
Hispanic or Latino								0.1072
Relugolix+E2/NETA	52	40 (76.9)	12 (23.1)	6.3 [4.4;11.9]	NE	6.61 [3.44;12.71]	<.0001	
Placebo	55	12 (21.8)	43 (78.2)	NR [NE;NE]				
Not Hispanic or Latino								
Relugolix+E2/NETA	197	145 (73.6)	52 (26.4)	8.0 [5.3;8.3]	NE	12.58 [8.12;19.48]	<.0001	
Placebo	199	24 (12.1)	175 (87.9)	NR [NE;NE]				
Not reported								
Relugolix+E2/NETA	4	3 (75.0)	1 (25.0)	NC [NC;NC]	NC	NC [NC;NC]	NC	
Placebo	2	0	2 (100.0)	NC [NC;NC]				

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group.
Total MBL volume was calculated as sum of MBL volume from all feminine products (validated, unauthorized and unvalidated) assessed by the alkaline hematin method. Sustained response is defined as patients time to achieve and maintain response until the date of last study drug.
Patients without an event are censored at the last assessment date prior to their last dose of study drug.
[1] Based on Kaplan-Meier estimates. 95% CIs are calculated by log-log transformation of survivor function.
[2] Hazard Ratios (and 95% CIs) are based on a Cox proportional hazard model stratified by study and with treatment group, subgroup and a subgroup-by-treatment group as covariates. 95% CIs are based on the approximation to the normal distribution. The reference group for the HR is Placebo.
[3] Treatment P-value is based on the Wald test stratified by study.
[4] Interaction P-value is based on the subgroup-by-treatment interaction term in the proportional hazard model used to compute the Hazard Ratio and 95% CI.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with an event; HR: Hazard ratio; CI: Confidence interval; int: interaction; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; NC: Not calculated; NE: Non-estimable; NR: Not reached.

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Table EFF.TTSRG50.MITT.Pooled.S1: Time to Sustained Response (at least a 50% Reduction from Baseline MBL Volume), by Subgroup (mITT Population)

Study: Pooled

Treatment	N	n (%)	Censored patients n (%)	Median time to 1st event [95% CI][1]	Median difference[1]	HR[2] [95% CI]	p-value[3]	p-value (int)[4]
Age (years)								
< 40 years								
Relugolix+E2/NETA	62	41 (66.1)	21 (33.9)	8.3 [5.4;12.1]	NE	7.20 [3.78;13.73]	<.0001	0.1565
Placebo	78	12 (15.4)	66 (84.6)	NR [NE;NE]				
>= 40 years								
Relugolix+E2/NETA	191	147 (77.0)	44 (23.0)	7.3 [5.1;8.1]	NE	12.62 [8.14;19.56]	<.0001	
Placebo	178	24 (13.5)	154 (86.5)	NR [NE;NE]				

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group.
Total MBL volume was calculated as sum of MBL volume from all feminine products (validated, unauthorized and unvalidated) assessed by the alkaline hematin method. Sustained response is defined as patients time to achieve and maintain response until the date of last study drug.
Patients without an event are censored at the last assessment date prior to their last dose of study drug.
[1] Based on Kaplan-Meier estimates. 95% CIs are calculated by log-log transformation of survivor function.
[2] Hazard Ratios (and 95% CIs) are based on a Cox proportional hazard model stratified by study and with treatment group, subgroup and a subgroup-by-treatment group as covariates. 95% CIs are based on the approximation to the normal distribution. The reference group for the HR is Placebo.
[3] Treatment P-value is based on the Wald test stratified by study.
[4] Interaction P-value is based on the subgroup-by-treatment interaction term in the proportional hazard model used to compute the Hazard Ratio and 95% CI.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with an event; HR: Hazard ratio; CI: Confidence interval; int: interaction; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; NE: Non-estimable; NR: Not reached.

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Table EFF.TTSRG50.MITT.Pooled.S6: Time to Sustained Response (at least a 50% Reduction from Baseline MBL Volume), by Subgroup (mITT Population)

Study: Pooled

Treatment	N	n (%)	Censored patients n (%)	Median time to 1st event [95% CI][1]	Median difference[1]	HR[2] [95% CI]	p-value[3]	p-value (int)[4]
Geographic Region I								
North America								
Relugolix+E2/NETA	191	135 (70.7)	56 (29.3)	8.1 [7.3;8.6]	NE	9.76 [6.42;14.84]	<.0001	0.2770
Placebo	194	27 (13.9)	167 (86.1)	NR [NE;NE]				
Rest of World								
Relugolix+E2/NETA	62	53 (85.5)	9 (14.5)	5.0 [4.6;6.0]	NE	15.39 [7.54;31.38]	<.0001	
Placebo	62	9 (14.5)	53 (85.5)	NR [NE;NE]				

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group.
Total MBL volume was calculated as sum of MBL volume from all feminine products (validated, unauthorized and unvalidated) assessed by the alkaline hematin method. Sustained response is defined as patients time to achieve and maintain response until the date of last study drug.
Patients without an event are censored at the last assessment date prior to their last dose of study drug.
[1] Based on Kaplan-Meier estimates. 95% CIs are calculated by log-log transformation of survivor function.
[2] Hazard Ratios (and 95% CIs) are based on a Cox proportional hazard model stratified by study and with treatment group, subgroup and a subgroup-by-treatment group as covariates. 95% CIs are based on the approximation to the normal distribution. The reference group for the HR is Placebo.
[3] Treatment P-value is based on the Wald test stratified by study.
[4] Interaction P-value is based on the subgroup-by-treatment interaction term in the proportional hazard model used to compute the Hazard Ratio and 95% CI.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with an event; HR: Hazard ratio; CI: Confidence interval; int: interaction; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; NE: Non-estimable; NR: Not reached.

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Table EFF.TTSRG50.MITT.Pooled.S4: Time to Sustained Response (at least a 50% Reduction from Baseline MBL Volume), by Subgroup (mITT Population)

Study: Pooled

Treatment	N	n (%)	Censored patients n (%)	Median time to 1st event [95% CI][1]	Median difference[1]	HR[2] [95% CI]	p-value[3]	p-value (int)[4]
Maximum NRS Pain Score at Baseline								
< 4								
Relugolix+E2/NETA	73	57 (78.1)	16 (21.9)	7.1 [5.0;8.3]	NE	15.07 [6.84;33.20]	<.0001	0.3393
Placebo	62	7 (11.3)	55 (88.7)	NR [NE;NE]				
>= 4								
Relugolix+E2/NETA	177	130 (73.4)	47 (26.6)	8.0 [5.1;8.3]	NE	9.80 [6.52;14.73]	<.0001	
Placebo	190	29 (15.3)	161 (84.7)	NR [NE;NE]				
Missing								
Relugolix+E2/NETA	3	1 (33.3)	2 (66.7)	NC [NC;NC]	NC	NC [NC;NC]	NC	
Placebo	4	0	4 (100.0)	NC [NC;NC]				

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group.
Total MBL volume was calculated as sum of MBL volume from all feminine products (validated, unauthorized and unvalidated) assessed by the alkaline hematin method. Sustained response is defined as patients time to achieve and maintain response until the date of last study drug.
Patients without an event are censored at the last assessment date prior to their last dose of study drug.
[1] Based on Kaplan-Meier estimates. 95% CIs are calculated by log-log transformation of survivor function.
[2] Hazard Ratios (and 95% CIs) are based on a Cox proportional hazard model stratified by study and with treatment group, subgroup and a subgroup-by-treatment group as covariates. 95% CIs are based on the approximation to the normal distribution. The reference group for the HR is Placebo.
[3] Treatment P-value is based on the Wald test stratified by study.
[4] Interaction P-value is based on the subgroup-by-treatment interaction term in the proportional hazard model used to compute the Hazard Ratio and 95% CI.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with an event; HR: Hazard ratio; CI: Confidence interval; int: interaction; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; NC: Not calculated; NE: Non-estimable; NR: Not reached.

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Table EFF.TTSRG50.MITT.Pooled.S7: Time to Sustained Response (at least a 50% Reduction from Baseline MBL Volume), by Subgroup (mITT Population)

Study: Pooled

Treatment	N	n (%)	Censored patients n (%)	Median time to 1st event [95% CI][1]	Median difference[1]	HR[2] [95% CI]	p-value[3]	p-value (int)[4]
Geographic Region II								
Europe								0.4615
Relugolix+E2/NETA	41	37 (90.2)	4 (9.8)	5.0 [4.7;5.3]	NE	14.57 [6.44;32.95]	<.0001	
Placebo	42	7 (16.7)	35 (83.3)	NR [NE;NE]				
Rest of World (including the US)								
Relugolix+E2/NETA	212	151 (71.2)	61 (28.8)	8.1 [6.1;8.3]	NE	10.38 [6.94;15.53]	<.0001	
Placebo	214	29 (13.6)	185 (86.4)	NR [NE;NE]				

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group.
Total MBL volume was calculated as sum of MBL volume from all feminine products (validated, unauthorized and unvalidated) assessed by the alkaline hematin method. Sustained response is defined as patients time to achieve and maintain response until the date of last study drug.
Patients without an event are censored at the last assessment date prior to their last dose of study drug.
[1] Based on Kaplan-Meier estimates. 95% CIs are calculated by log-log transformation of survivor function.
[2] Hazard Ratios (and 95% CIs) are based on a Cox proportional hazard model stratified by study and with treatment group, subgroup and a subgroup-by-treatment group as covariates. 95% CIs are based on the approximation to the normal distribution. The reference group for the HR is Placebo.
[3] Treatment P-value is based on the Wald test stratified by study.
[4] Interaction P-value is based on the subgroup-by-treatment interaction term in the proportional hazard model used to compute the Hazard Ratio and 95% CI.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with an event; HR: Hazard ratio; CI: Confidence interval; int: interaction; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; NE: Non-estimable; NR: Not reached.

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Table EFF.TTSRG50.MITT.Pooled.S2: Time to Sustained Response (at least a 50% Reduction from Baseline MBL Volume), by Subgroup (mITT Population)

Study: Pooled

Treatment	N	n (%)	Censored patients n (%)	Median time to 1st event [95% CI][1]	Median difference[1]	HR[2] [95% CI]	p-value[3]	p-value (int)[4]
BMI (kg/m2) at Baseline								
< 30								
Relugolix+E2/NETA	119	90 (75.6)	29 (24.4)	7.1 [5.0;8.1]	NE	9.84 [5.96;16.24]	<.0001	0.6170
Placebo	115	19 (16.5)	96 (83.5)	NR [NE;NE]				
>= 30								
Relugolix+E2/NETA	133	97 (72.9)	36 (27.1)	8.1 [5.1;8.3]	NE	11.81 [7.02;19.86]	<.0001	
Placebo	141	17 (12.1)	124 (87.9)	NR [NE;NE]				
Missing								
Relugolix+E2/NETA	1	1 (100.0)	0	NC [NC;NC]	NC	NC [NC;NC]	NC	
Placebo	0	0	0	NC [NC;NC]				

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group.
Total MBL volume was calculated as sum of MBL volume from all feminine products (validated, unauthorized and unvalidated) assessed by the alkaline hematin method. Sustained response is defined as patients time to achieve and maintain response until the date of last study drug.
Patients without an event are censored at the last assessment date prior to their last dose of study drug.
[1] Based on Kaplan-Meier estimates. 95% CIs are calculated by log-log transformation of survivor function.
[2] Hazard Ratios (and 95% CIs) are based on a Cox proportional hazard model stratified by study and with treatment group, subgroup and a subgroup-by-treatment group as covariates. 95% CIs are based on the approximation to the normal distribution. The reference group for the HR is Placebo.
[3] Treatment P-value is based on the Wald test stratified by study.
[4] Interaction P-value is based on the subgroup-by-treatment interaction term in the proportional hazard model used to compute the Hazard Ratio and 95% CI.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with an event; HR: Hazard ratio; CI: Confidence interval; int: interaction; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; NC: Not calculated; NE: Non-estimable; NR: Not reached.

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Table EFF.TTSRG50.MITT.Pooled.S3: Time to Sustained Response (at least a 50% Reduction from Baseline MBL Volume), by Subgroup (mITT Population)

Study: Pooled

Treatment	N	n (%)	Censored patients n (%)	Median time to 1st event [95% CI][1]	Median difference[1]	HR[2] [95% CI]	p-value[3]	p-value (int)[4]
Uterine Volume at Baseline (cm3)								
< 300 cm3								
Relugolix+E2/NETA	148	113 (76.4)	35 (23.6)	5.3 [5.0;8.1]	NE	9.85 [6.15;15.76]	<.0001	0.6320
Placebo	129	21 (16.3)	108 (83.7)	NR [NE;NE]				
>= 300 cm3								
Relugolix+E2/NETA	104	75 (72.1)	29 (27.9)	8.3 [7.7;9.1]	NE	11.75 [6.72;20.56]	<.0001	
Placebo	127	15 (11.8)	112 (88.2)	NR [NE;NE]				
Missing								
Relugolix+E2/NETA	1	0	1 (100.0)	NC [NC;NC]	NC	NC [NC;NC]	NC	
Placebo	0	0	0	NC [NC;NC]				

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group.
Total MBL volume was calculated as sum of MBL volume from all feminine products (validated, unauthorized and unvalidated) assessed by the alkaline hematin method. Sustained response is defined as patients time to achieve and maintain response until the date of last study drug.
Patients without an event are censored at the last assessment date prior to their last dose of study drug.
[1] Based on Kaplan-Meier estimates. 95% CIs are calculated by log-log transformation of survivor function.
[2] Hazard Ratios (and 95% CIs) are based on a Cox proportional hazard model stratified by study and with treatment group, subgroup and a subgroup-by-treatment group as covariates. 95% CIs are based on the approximation to the normal distribution. The reference group for the HR is Placebo.
[3] Treatment P-value is based on the Wald test stratified by study.
[4] Interaction P-value is based on the subgroup-by-treatment interaction term in the proportional hazard model used to compute the Hazard Ratio and 95% CI.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with an event; HR: Hazard ratio; CI: Confidence interval; int: interaction; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; NC: Not calculated; NE: Non-estimable; NR: Not reached.

SOURCE: \Studies\MYV\MYV102\Analysis\Prod\Progs\TFLs\Tab_EFF_MBL_TTE.SAS
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Table EFF.TTSRG50.MITT.Pooled.S9: Time to Sustained Response (at least a 50% Reduction from Baseline MBL Volume), by Subgroup (mITT Population)

Study: Pooled

Treatment	N	n (%)	Censored patients n (%)	Median time to 1st event [95% CI][1]	Median difference[1]	HR[2] [95% CI]	p-value[3]	p-value (int)[4]
Race								
Black/African American								
Relugolix+E2/NETA	122	78 (63.9)	44 (36.1)	8.3 [6.1;9.3]	NE	12.33 [6.95;21.85]	<.0001	0.7698
Placebo	141	14 (9.9)	127 (90.1)	NR [NE;NE]				
White								
Relugolix+E2/NETA	122	103 (84.4)	19 (15.6)	5.3 [5.0;8.1]	NE	9.39 [5.83;15.12]	<.0001	
Placebo	105	21 (20.0)	84 (80.0)	NR [NE;NE]				
Asian								
Relugolix+E2/NETA	1	1 (100.0)	0	NC [NC;NC]	NC	NC [NC;NC]	NC	
Placebo	3	1 (33.3)	2 (66.7)	NC [NC;NC]				
Others								
Relugolix+E2/NETA	5	3 (60.0)	2 (40.0)	8.3 [3.3;NE]	NE	>99 [NC;NC]	0.9672	
Placebo	6	0	6 (100.0)	NR [NE;NE]				
Not reported								
Relugolix+E2/NETA	3	3 (100.0)	0	NC [NC;NC]	NC	NC [NC;NC]	NC	
Placebo	1	0	1 (100.0)	NC [NC;NC]				

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group.
Total MBL volume was calculated as sum of MBL volume from all feminine products (validated, unauthorized and unvalidated) assessed by the alkaline hematin method. Sustained response is defined as patients time to achieve and maintain response until the date of last study drug.
Patients without an event are censored at the last assessment date prior to their last dose of study drug.
[1] Based on Kaplan-Meier estimates. 95% CIs are calculated by log-log transformation of survivor function.
[2] Hazard Ratios (and 95% CIs) are based on a Cox proportional hazard model stratified by study and with treatment group, subgroup and a subgroup-by-treatment group as covariates. 95% CIs are based on the approximation to the normal distribution. The reference group for the HR is Placebo.
[3] Treatment P-value is based on the Wald test stratified by study.
[4] Interaction P-value is based on the subgroup-by-treatment interaction term in the proportional hazard model used to compute the Hazard Ratio and 95% CI.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with an event; HR: Hazard ratio; CI: Confidence interval; int: interaction; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; NC: Not calculated; NE: Non-estimable; NR: Not reached.

SOURCE: \Studies\MYV\MYV102\Analysis\Prod\Progs\TFLs\Tab_EFF_MBL_TTE.SAS

1.1.5 Summary of Percent Change from Baseline in Menstrual Blood Loss Volume (mL) by Visit and Overall, by Subgroup (mITT Population)

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Table EFF.TMBLPCHG.MITT.Pooled.S5: Summary of Percent Change from Baseline in Menstrual Blood Loss Volume (mL) by Visit and Overall, by Subgroup (mITT Population)

Study: Pooled

Treatment	Study visit	n (%)[1]	Mean (SD)[1]	Change from baseline LS-mean change (SE)[2]	Difference LS-mean change [95% CI] p-value[2]	SMD Hedges' g [95% CI][2]
MBL Volume at Baseline (mL)						
< 225 mL						
Relugolix+E2/NETA	Baseline	164 (100.0)	152.2 (39.75)	-44.19 (9.442)	-29.49	-0.29
N=164	Week 4	95 (57.9)	103.8 (285.69)		[-54.10,-4.88]	[-0.55,-0.03]
Placebo	Baseline	171 (100.0)	147.0 (39.28)	-14.70 (8.202)	0.0190	
N=171	Week 4	142 (83.0)	126.4 (79.90)			
>= 225 mL						
Relugolix+E2/NETA	Baseline	89 (100.0)	410.4 (221.57)	-63.28 (5.533)	-47.57	-1.11
N=89	Week 4	48 (53.9)	139.5 (149.76)		[-62.20,-32.94]	[-1.50,-0.71]
Placebo	Baseline	85 (100.0)	352.5 (132.44)	-15.71 (4.926)	<.0001	
N=85	Week 4	69 (81.2)	292.6 (152.08)			

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group. Total menstrual blood loss volume was calculated as sum of menstrual blood loss volume from all feminine products (validated, unauthorized and unvalidated) assessed by the alkaline hematin method.
[1] Summary statistics are based on observed data. Patients with confirmed amenorrhea are assigned as 0 mL.
[2] LS means, LS mean differences (95% CIs), p-value and Hedges' g (95% CIs) are based on a mixed-effects model with study, treatment, visit, and a treatment-by-visit interaction as fixed effects. The multiple visits for each patient are the repeated measures as a random effect within each patient with an unstructured covariance. Hedges' g is calculated using a small sample bias correction. Interaction p-value is only produced for the Overall period.
The reference group for the LS mean difference and Hedges' g is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with data; CI: Confidence interval; LS: Least squares; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; SD: Standard deviation; SE: Standard error; SMD: Standardized mean difference.

SOURCE: \Studies\MYV\MYV102\Analysis\Prod\Progs\TFLs\Tab_EFF_MBL_CON.SAS
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Table EFF.TMBLPCHG.MITT.Pooled.S5: Summary of Percent Change from Baseline in Menstrual Blood Loss Volume (mL) by Visit and Overall, by Subgroup (mITT Population)

Study: Pooled

Treatment	Study visit	n (%)[1]	Mean (SD)[1]	Change from baseline LS-mean change (SE)[2]	Difference LS-mean change [95% CI] p-value[2]	SMD Hedges' g [95% CI][2]
MBL Volume at Baseline (mL)						
< 225 mL						
Relugolix+E2/NETA	Baseline	164 (100.0)	152.2 (39.75)	-81.41 (3.859)	-74.09	-1.66
N=164	Week 8	128 (78.0)	26.4 (60.12)		[-84.54,-63.65]	[-1.94,-1.39]
Placebo	Baseline	171 (100.0)	147.0 (39.28)	-7.31 (3.641)	<.0001	
N=171	Week 8	146 (85.4)	137.5 (79.16)			
>= 225 mL						
Relugolix+E2/NETA	Baseline	89 (100.0)	410.4 (221.57)	-73.54 (6.307)	-60.39	-1.16
N=89	Week 8	65 (73.0)	100.2 (155.29)		[-77.77,-43.00]	[-1.52,-0.80]
Placebo	Baseline	85 (100.0)	352.5 (132.44)	-13.16 (6.143)	<.0001	
N=85	Week 8	72 (84.7)	289.7 (200.80)			

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group. Total menstrual blood loss volume was calculated as sum of menstrual blood loss volume from all feminine products (validated, unauthorized and unvalidated) assessed by the alkaline hematin method.
[1] Summary statistics are based on observed data. Patients with confirmed amenorrhea are assigned as 0 mL.
[2] LS means, LS mean differences (95% CIs), p-value and Hedges' g (95% CIs) are based on a mixed-effects model with study, treatment, visit, and a treatment-by-visit interaction as fixed effects. The multiple visits for each patient are the repeated measures as a random effect within each patient with an unstructured covariance. Hedges' g is calculated using a small sample bias correction. Interaction p-value is only produced for the Overall period.
The reference group for the LS mean difference and Hedges' g is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with data; CI: Confidence interval; LS: Least squares; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; SD: Standard deviation; SE: Standard error; SMD: Standardized mean difference.

SOURCE: \Studies\MYV\MYV102\Analysis\Prod\Progs\TFLs\Tab_EFF_MBL_CON.SAS
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Table EFF.TMBLPCHG.MITT.Pooled.S5: Summary of Percent Change from Baseline in Menstrual Blood Loss Volume (mL) by Visit and Overall, by Subgroup (mITT Population)

Study: Pooled

Treatment	Study visit	n (%)[1]	Mean (SD)[1]	Change from baseline LS-mean change (SE)[2]	Difference LS-mean change [95% CI] p-value[2]	SMD Hedges' g [95% CI][2]
MBL Volume at Baseline (mL)						
< 225 mL						
Relugolix+E2/NETA	Baseline	164 (100.0)	152.2 (39.75)	-83.67 (4.459)	-75.89	-1.50
N=164	Week 12	127 (77.4)	22.2 (47.30)		[-88.05,-63.73]	[-1.77,-1.23]
Placebo	Baseline	171 (100.0)	147.0 (39.28)	-7.77 (4.280)	<.0001	
N=171	Week 12	138 (80.7)	132.0 (110.20)			
>= 225 mL						
Relugolix+E2/NETA	Baseline	89 (100.0)	410.4 (221.57)	-80.91 (5.232)	-64.20	-1.46
N=89	Week 12	68 (76.4)	66.7 (123.85)		[-78.90,-49.49]	[-1.84,-1.07]
Placebo	Baseline	85 (100.0)	352.5 (132.44)	-16.71 (5.300)	<.0001	
N=85	Week 12	65 (76.5)	295.1 (196.90)			

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group. Total menstrual blood loss volume was calculated as sum of menstrual blood loss volume from all feminine products (validated, unauthorized and unvalidated) assessed by the alkaline hematin method.
[1] Summary statistics are based on observed data. Patients with confirmed amenorrhea are assigned as 0 mL.
[2] LS means, LS mean differences (95% CIs), p-value and Hedges' g (95% CIs) are based on a mixed-effects model with study, treatment, visit, and a treatment-by-visit interaction as fixed effects. The multiple visits for each patient are the repeated measures as a random effect within each patient with an unstructured covariance. Hedges' g is calculated using a small sample bias correction. Interaction p-value is only produced for the Overall period.
The reference group for the LS mean difference and Hedges' g is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with data; CI: Confidence interval; LS: Least squares; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; SD: Standard deviation; SE: Standard error; SMD: Standardized mean difference.

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Table EFF.TMBLPCHG.MITT.Pooled.S5: Summary of Percent Change from Baseline in Menstrual Blood Loss Volume (mL) by Visit and Overall, by Subgroup (mITT Population)

Study: Pooled

Treatment	Study visit	n (%)[1]	Mean (SD)[1]	Change from baseline LS-mean change (SE)[2]	Difference LS-mean change [95% CI] p-value[2]	SMD Hedges' g [95% CI][2]
MBL Volume at Baseline (mL)						
< 225 mL						
Relugolix+E2/NETA	Baseline	164 (100.0)	152.2 (39.75)	-77.89 (4.589)	-65.11	-1.20
N=164	Week 16	123 (75.0)	31.5 (101.30)		[-77.67,-52.54]	[-1.47,-0.93]
Placebo	Baseline	171 (100.0)	147.0 (39.28)	-12.78 (4.440)	<.0001	
N=171	Week 16	128 (74.9)	124.3 (85.22)			
>= 225 mL						
Relugolix+E2/NETA	Baseline	89 (100.0)	410.4 (221.57)	-87.16 (4.675)	-62.11	-1.61
N=89	Week 16	69 (77.5)	54.4 (141.93)		[-75.27,-48.95]	[-2.00,-1.22]
Placebo	Baseline	85 (100.0)	352.5 (132.44)	-25.05 (4.749)	<.0001	
N=85	Week 16	65 (76.5)	242.6 (177.26)			

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group. Total menstrual blood loss volume was calculated as sum of menstrual blood loss volume from all feminine products (validated, unauthorized and unvalidated) assessed by the alkaline hematin method.
[1] Summary statistics are based on observed data. Patients with confirmed amenorrhea are assigned as 0 mL.
[2] LS means, LS mean differences (95% CIs), p-value and Hedges' g (95% CIs) are based on a mixed-effects model with study, treatment, visit, and a treatment-by-visit interaction as fixed effects. The multiple visits for each patient are the repeated measures as a random effect within each patient with an unstructured covariance. Hedges' g is calculated using a small sample bias correction. Interaction p-value is only produced for the Overall period.
The reference group for the LS mean difference and Hedges' g is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with data; CI: Confidence interval; LS: Least squares; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; SD: Standard deviation; SE: Standard error; SMD: Standardized mean difference.

SOURCE: \Studies\MYV\MYV102\Analysis\Prod\Progs\TFLs\Tab_EFF_MBL_CON.SAS
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Table EFF.TMBLPCHG.MITT.Pooled.S5: Summary of Percent Change from Baseline in Menstrual Blood Loss Volume (mL) by Visit and Overall, by Subgroup (mITT Population)

Study: Pooled

Treatment	Study visit	n (%)[1]	Mean (SD)[1]	Change from baseline LS-mean change (SE)[2]	Difference LS-mean change [95% CI] p-value[2]	SMD Hedges' g [95% CI][2]
MBL Volume at Baseline (mL)						
< 225 mL						
Relugolix+E2/NETA	Baseline	164 (100.0)	152.2 (39.75)	-82.51 (4.290)	-73.26	-1.60
N=164	Week 20	123 (75.0)	20.9 (54.50)		[-85.04,-61.48]	[-1.89,-1.31]
Placebo	Baseline	171 (100.0)	147.0 (39.28)	-9.25 (4.177)	<.0001	
N=171	Week 20	124 (72.5)	129.5 (86.31)			
>= 225 mL						
Relugolix+E2/NETA	Baseline	89 (100.0)	410.4 (221.57)	-84.77 (4.924)	-61.73	-1.47
N=89	Week 20	70 (78.7)	71.3 (196.09)		[-75.74,-47.73]	[-1.86,-1.09]
Placebo	Baseline	85 (100.0)	352.5 (132.44)	-23.04 (5.103)	<.0001	
N=85	Week 20	61 (71.8)	255.1 (200.73)			

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group. Total menstrual blood loss volume was calculated as sum of menstrual blood loss volume from all feminine products (validated, unauthorized and unvalidated) assessed by the alkaline hematin method.
[1] Summary statistics are based on observed data. Patients with confirmed amenorrhea are assigned as 0 mL.
[2] LS means, LS mean differences (95% CIs), p-value and Hedges' g (95% CIs) are based on a mixed-effects model with study, treatment, visit, and a treatment-by-visit interaction as fixed effects. The multiple visits for each patient are the repeated measures as a random effect within each patient with an unstructured covariance. Hedges' g is calculated using a small sample bias correction. Interaction p-value is only produced for the Overall period.
The reference group for the LS mean difference and Hedges' g is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with data; CI: Confidence interval; LS: Least squares; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; SD: Standard deviation; SE: Standard error; SMD: Standardized mean difference.

SOURCE: \Studies\MYV\MYV102\Analysis\Prod\Progs\TFLs\Tab_EFF_MBL_CON.SAS
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Table EFF.TMBLPCHG.MITT.Pooled.S5: Summary of Percent Change from Baseline in Menstrual Blood Loss Volume (mL) by Visit and Overall, by Subgroup (mITT Population)

Study: Pooled

Treatment	Study visit	n (%)[1]	Mean (SD)[1]	Change from baseline LS-mean change (SE)[2]	Difference LS-mean change [95% CI] p-value[2]	SMD Hedges' g [95% CI][2]
MBL Volume at Baseline (mL)						
< 225 mL						
Relugolix+E2/NETA	Baseline	164 (100.0)	152.2 (39.75)	-83.38 (5.207)	-71.72	-1.27
N=164	Week 24	117 (71.3)	23.3 (67.32)		[-85.94,-57.50]	[-1.54,-0.99]
Placebo	Baseline	171 (100.0)	147.0 (39.28)	-11.66 (5.012)	<.0001	
N=171	Week 24	127 (74.3)	127.2 (132.04)			
>= 225 mL						
Relugolix+E2/NETA	Baseline	89 (100.0)	410.4 (221.57)	-82.30 (5.195)	-53.35	-1.22
N=89	Week 24	62 (69.7)	77.8 (216.20)		[-68.01,-38.69]	[-1.61,-0.84]
Placebo	Baseline	85 (100.0)	352.5 (132.44)	-28.95 (5.305)	<.0001	
N=85	Week 24	59 (69.4)	230.2 (178.41)			

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group. Total menstrual blood loss volume was calculated as sum of menstrual blood loss volume from all feminine products (validated, unauthorized and unvalidated) assessed by the alkaline hematin method.
[1] Summary statistics are based on observed data. Patients with confirmed amenorrhea are assigned as 0 mL.
[2] LS means, LS mean differences (95% CIs), p-value and Hedges' g (95% CIs) are based on a mixed-effects model with study, treatment, visit, and a treatment-by-visit interaction as fixed effects. The multiple visits for each patient are the repeated measures as a random effect within each patient with an unstructured covariance. Hedges' g is calculated using a small sample bias correction. Interaction p-value is only produced for the Overall period.
The reference group for the LS mean difference and Hedges' g is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with data; CI: Confidence interval; LS: Least squares; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; SD: Standard deviation; SE: Standard error; SMD: Standardized mean difference.

SOURCE: \Studies\MYV\MYV102\Analysis\Prod\Progs\TFLs\Tab_EFF_MBL_CON.SAS
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Table EFF.TMBLPCHG.MITT.Pooled.S5: Summary of Percent Change from Baseline in Menstrual Blood Loss Volume (mL) by Visit and Overall, by Subgroup (mITT Population)

Study: Pooled

Treatment	Study visit	n (%)[1]	Mean (SD)[1]	Change from baseline LS-mean change (SE)[2]	Difference LS-mean change [95% CI] p-value[2]	SMD Hedges' g [95% CI][2]	Int. p-value[2]
MBL Volume at Baseline (mL)							
< 225 mL							
Relugolix+E2/NETA	Baseline	164 (100.0)	152.2 (39.75)	-77.30 (3.369)	-67.44	-1.20	0.0987
N=164	Overall	152 (92.7)	39.5 (90.61)		[-76.59,-58.29]	[-1.44,-0.96]	
Placebo	Baseline	171 (100.0)	147.0 (39.28)	-9.87 (3.216)	<.0001		
N=171	Overall	163 (95.3)	129.2 (71.85)				
>= 225 mL							
Relugolix+E2/NETA	Baseline	89 (100.0)	410.4 (221.57)	-76.00 (4.480)	-54.85	-0.97	
N=89	Overall	82 (92.1)	85.5 (133.29)		[-67.30,-42.41]	[-1.29,-0.65]	
Placebo	Baseline	85 (100.0)	352.5 (132.44)	-21.14 (4.478)	<.0001		
N=85	Overall	81 (95.3)	270.3 (156.51)				

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group. Total menstrual blood loss volume was calculated as sum of menstrual blood loss volume from all feminine products (validated, unauthorized and unvalidated) assessed by the alkaline hematin method.
[1] Summary statistics are based on observed data. Patients with confirmed amenorrhea are assigned as 0 mL. Mean (SD) are calculated based on the mean observed value across all post-baseline visits within each patient.
[2] LS means, LS mean differences (95% CIs), p-value and Hedges' g (95% CIs) are based on a mixed-effects model with study, treatment, visit, subgroup, treatment-by-visit interaction and a subgroup-by-treatment interaction as fixed effects. The multiple visits for each patient are the repeated measures as a random effect within each patient with an unstructured covariance. Hedges' g is calculated using a small sample bias correction. The reference group for the LS mean difference and Hedges' g is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with data; CI: Confidence interval; int: Interaction; LS: Least squares; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; SD: Standard deviation; SE: Standard error; SMD: Standardized mean difference.

SOURCE: \Studies\MYV\MYV102\Analysis\Prod\Progs\TFLs\Tab_EFF_MBL_CON.SAS
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Table EFF.TMBLPCHG.MITT.Pooled.S8: Summary of Percent Change from Baseline in Menstrual Blood Loss Volume (mL) by Visit and Overall, by Subgroup (mITT Population)

Study: Pooled

Treatment	Study visit	n (%)[1]	Mean (SD)[1]	Change from baseline LS-mean change (SE)[2]	Difference LS-mean change [95% CI] p-value[2]	SMD Hedges' g [95% CI][2]
Ethnicity						
Hispanic or Latino						
Relugolix+E2/NETA	Baseline	52 (100.0)	194.4 (78.09)	-26.40 (23.794)	-13.48	-0.08
N=52	Week 4	33 (63.5)	163.8 (469.99)		[-77.62,50.65]	[-0.52,0.35]
Placebo	Baseline	55 (100.0)	220.8 (122.06)	-12.92 (21.823)	0.6775	
N=55	Week 4	49 (89.1)	166.1 (131.53)			
Not Hispanic or Latino						
Relugolix+E2/NETA	Baseline	197 (100.0)	253.9 (198.66)	-57.19 (4.021)	-45.44	-1.02
N=197	Week 4	109 (55.3)	99.7 (120.47)		[-55.83,-35.06]	[-1.28,-0.76]
Placebo	Baseline	199 (100.0)	213.2 (128.72)	-11.74 (3.425)	<.0001	
N=199	Week 4	160 (80.4)	184.9 (134.19)			
Not reported						
Relugolix+E2/NETA	Baseline	4 (100.0)	341.1 (252.99)	NC (NC)	NC	NC
N=4	Week 4	1 (25.0)	279.6 (NE)		[NC,NC]	[NC,NC]
Placebo	Baseline	2 (100.0)	267.3 (200.46)	NC (NC)	NC	
N=2	Week 4	2 (100.0)	209.9 (215.31)			

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group. Total menstrual blood loss volume was calculated as sum of menstrual blood loss volume from all feminine products (validated, unauthorized and unvalidated) assessed by the alkaline hematin method.
[1] Summary statistics are based on observed data. Patients with confirmed amenorrhea are assigned as 0 mL.
[2] LS means, LS mean differences (95% CIs), p-value and Hedges' g (95% CIs) are based on a mixed-effects model with study, treatment, visit, and a treatment-by-visit interaction as fixed effects. The multiple visits for each patient are the repeated measures as a random effect within each patient with an unstructured covariance. Hedges' g is calculated using a small sample bias correction. Interaction p-value is only produced for the Overall period.
The reference group for the LS mean difference and Hedges' g is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with data; CI: Confidence interval; LS: Least squares; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; SD: Standard deviation; SE: Standard error; SMD: Standardized mean difference; NC: Not calculated; NE: Non-estimable.

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Table EFF.TMBLPCHG.MITT.Pooled.S8: Summary of Percent Change from Baseline in Menstrual Blood Loss Volume (mL) by Visit and Overall, by Subgroup (mITT Population)

Study: Pooled

Treatment	Study visit	n (%)[1]	Mean (SD)[1]	Change from baseline LS-mean change (SE)[2]	Difference LS-mean change [95% CI] p-value[2]	SMD Hedges' g [95% CI][2]
Ethnicity						
Hispanic or Latino						
Relugolix+E2/NETA	Baseline	52 (100.0)	194.4 (78.09)	-74.89 (8.523)	-63.55	-1.15
N=52	Week 8	38 (73.1)	36.9 (63.12)		[-86.79,-40.31]	[-1.61,-0.70]
Placebo	Baseline	55 (100.0)	220.8 (122.06)	-11.34 (7.877)	<.0001	
N=55	Week 8	47 (85.5)	182.3 (137.57)			
Not Hispanic or Latino						
Relugolix+E2/NETA	Baseline	197 (100.0)	253.9 (198.66)	-79.76 (3.632)	-70.83	-1.56
N=197	Week 8	153 (77.7)	55.1 (116.91)		[-80.72,-60.94]	[-1.81,-1.31]
Placebo	Baseline	199 (100.0)	213.2 (128.72)	-8.93 (3.476)	<.0001	
N=199	Week 8	169 (84.9)	189.1 (154.31)			
Not reported						
Relugolix+E2/NETA	Baseline	4 (100.0)	341.1 (252.99)	NC (NC)	NC	NC
N=4	Week 8	2 (50.0)	28.4 (40.11)		[NC,NC]	[NC,NC]
Placebo	Baseline	2 (100.0)	267.3 (200.46)	NC (NC)	NC	
N=2	Week 8	2 (100.0)	204.0 (123.49)			

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group. Total menstrual blood loss volume was calculated as sum of menstrual blood loss volume from all feminine products (validated, unauthorized and unvalidated) assessed by the alkaline hematin method.
[1] Summary statistics are based on observed data. Patients with confirmed amenorrhea are assigned as 0 mL.
[2] LS means, LS mean differences (95% CIs), p-value and Hedges' g (95% CIs) are based on a mixed-effects model with study, treatment, visit, and a treatment-by-visit interaction as fixed effects. The multiple visits for each patient are the repeated measures as a random effect within each patient with an unstructured covariance. Hedges' g is calculated using a small sample bias correction. Interaction p-value is only produced for the Overall period.
The reference group for the LS mean difference and Hedges' g is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with data; CI: Confidence interval; LS: Least squares; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; SD: Standard deviation; SE: Standard error; SMD: Standardized mean difference; NC: Not calculated.

SOURCE: \Studies\MYV\MYV102\Analysis\Prod\Progs\TFLs\Tab_EFF_MBL_CON.SAS
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Table EFF.TMBLPCHG.MITT.Pooled.S8: Summary of Percent Change from Baseline in Menstrual Blood Loss Volume (mL) by Visit and Overall, by Subgroup (mITT Population)

Study: Pooled

Treatment	Study visit	n (%)[1]	Mean (SD)[1]	Change from baseline LS-mean change (SE)[2]	Difference LS-mean change [95% CI] p-value[2]	SMD Hedges' g [95% CI][2]
Ethnicity						
Hispanic or Latino						
Relugolix+E2/NETA	Baseline	52 (100.0)	194.4 (78.09)	-77.83 (9.498)	-74.31	-1.22
N=52	Week 12	45 (86.5)	37.8 (78.94)		[-101.12,-47.50]	[-1.67,-0.76]
Placebo	Baseline	55 (100.0)	220.8 (122.06)	-3.52 (9.472)	<.0001	
N=55	Week 12	42 (76.4)	193.8 (172.96)			
Not Hispanic or Latino						
Relugolix+E2/NETA	Baseline	197 (100.0)	253.9 (198.66)	-83.95 (3.562)	-70.92	-1.58
N=197	Week 12	148 (75.1)	38.2 (87.29)		[-80.68,-61.17]	[-1.83,-1.32]
Placebo	Baseline	199 (100.0)	213.2 (128.72)	-13.03 (3.450)	<.0001	
N=199	Week 12	159 (79.9)	181.2 (160.77)			
Not reported						
Relugolix+E2/NETA	Baseline	4 (100.0)	341.1 (252.99)	NC (NC)	NC	NC
N=4	Week 12	2 (50.0)	0.0 (0.00)		[NC,NC]	[NC,NC]
Placebo	Baseline	2 (100.0)	267.3 (200.46)	NC (NC)	NC	
N=2	Week 12	2 (100.0)	219.1 (48.98)			

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group. Total menstrual blood loss volume was calculated as sum of menstrual blood loss volume from all feminine products (validated, unauthorized and unvalidated) assessed by the alkaline hematin method.
[1] Summary statistics are based on observed data. Patients with confirmed amenorrhea are assigned as 0 mL.
[2] LS means, LS mean differences (95% CIs), p-value and Hedges' g (95% CIs) are based on a mixed-effects model with study, treatment, visit, and a treatment-by-visit interaction as fixed effects. The multiple visits for each patient are the repeated measures as a random effect within each patient with an unstructured covariance. Hedges' g is calculated using a small sample bias correction. Interaction p-value is only produced for the Overall period.
The reference group for the LS mean difference and Hedges' g is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with data; CI: Confidence interval; LS: Least squares; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; SD: Standard deviation; SE: Standard error; SMD: Standardized mean difference; NC: Not calculated.

SOURCE: \Studies\MYV\MYV102\Analysis\Prod\Progs\TFLs\Tab_EFF_MBL_CON.SAS
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Table EFF.TMBLPCHG.MITT.Pooled.S8: Summary of Percent Change from Baseline in Menstrual Blood Loss Volume (mL) by Visit and Overall, by Subgroup (mITT Population)

Study: Pooled

Treatment	Study visit	n (%)[1]	Mean (SD)[1]	Change from baseline LS-mean change (SE)[2]	Difference LS-mean change [95% CI] p-value[2]	SMD Hedges' g [95% CI][2]
Ethnicity						
Hispanic or Latino						
Relugolix+E2/NETA	Baseline	52 (100.0)	194.4 (78.09)	-74.66 (10.434)	-55.86	-0.79
N=52	Week 16	44 (84.6)	44.0 (153.85)		[-84.85,-26.87]	[-1.22,-0.36]
Placebo	Baseline	55 (100.0)	220.8 (122.06)	-18.79 (10.097)	0.0002	
N=55	Week 16	44 (80.0)	145.2 (134.87)			
Not Hispanic or Latino						
Relugolix+E2/NETA	Baseline	197 (100.0)	253.9 (198.66)	-83.47 (3.307)	-66.68	-1.61
N=197	Week 16	146 (74.1)	39.0 (105.79)		[-75.81,-57.56]	[-1.87,-1.34]
Placebo	Baseline	199 (100.0)	213.2 (128.72)	-16.78 (3.254)	<.0001	
N=199	Week 16	147 (73.9)	170.1 (136.79)			
Not reported						
Relugolix+E2/NETA	Baseline	4 (100.0)	341.1 (252.99)	NC (NC)	NC	NC
N=4	Week 16	2 (50.0)	0.0 (0.00)		[NC,NC]	[NC,NC]
Placebo	Baseline	2 (100.0)	267.3 (200.46)	NC (NC)	NC	
N=2	Week 16	2 (100.0)	144.5 (23.46)			

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group. Total menstrual blood loss volume was calculated as sum of menstrual blood loss volume from all feminine products (validated, unauthorized and unvalidated) assessed by the alkaline hematin method.
[1] Summary statistics are based on observed data. Patients with confirmed amenorrhea are assigned as 0 mL.
[2] LS means, LS mean differences (95% CIs), p-value and Hedges' g (95% CIs) are based on a mixed-effects model with study, treatment, visit, and a treatment-by-visit interaction as fixed effects. The multiple visits for each patient are the repeated measures as a random effect within each patient with an unstructured covariance. Hedges' g is calculated using a small sample bias correction. Interaction p-value is only produced for the Overall period.
The reference group for the LS mean difference and Hedges' g is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with data; CI: Confidence interval; LS: Least squares; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; SD: Standard deviation; SE: Standard error; SMD: Standardized mean difference; NC: Not calculated.

SOURCE: \Studies\MYV\MYV102\Analysis\Prod\Progs\TFLs\Tab_EFF_MBL_CON.SAS
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Table EFF.TMBLPCHG.MITT.Pooled.S8: Summary of Percent Change from Baseline in Menstrual Blood Loss Volume (mL) by Visit and Overall, by Subgroup (mITT Population)

Study: Pooled

Treatment	Study visit	n (%)[1]	Mean (SD)[1]	Change from baseline LS-mean change (SE)[2]	Difference LS-mean change [95% CI] p-value[2]	SMD Hedges' g [95% CI][2]
Ethnicity						
Hispanic or Latino						
Relugolix+E2/NETA	Baseline	52 (100.0)	194.4 (78.09)	-81.25 (8.786)	-66.15	-1.29
N=52	Week 20	43 (82.7)	22.0 (57.87)		[-90.59,-41.70]	[-1.75,-0.83]
Placebo	Baseline	55 (100.0)	220.8 (122.06)	-15.10 (8.481)	<.0001	
N=55	Week 20	44 (80.0)	149.5 (181.49)			
Not Hispanic or Latino						
Relugolix+E2/NETA	Baseline	197 (100.0)	253.9 (198.66)	-83.88 (3.620)	-70.53	-1.64
N=197	Week 20	147 (74.6)	44.7 (142.58)		[-80.59,-60.46]	[-1.90,-1.37]
Placebo	Baseline	199 (100.0)	213.2 (128.72)	-13.35 (3.614)	<.0001	
N=199	Week 20	140 (70.4)	177.5 (135.04)			
Not reported						
Relugolix+E2/NETA	Baseline	4 (100.0)	341.1 (252.99)	NC (NC)	NC	NC
N=4	Week 20	3 (75.0)	11.8 (20.46)		[NC,NC]	[NC,NC]
Placebo	Baseline	2 (100.0)	267.3 (200.46)	NC (NC)	NC	
N=2	Week 20	1 (50.0)	199.6 (NE)			

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group. Total menstrual blood loss volume was calculated as sum of menstrual blood loss volume from all feminine products (validated, unauthorized and unvalidated) assessed by the alkaline hematin method.
[1] Summary statistics are based on observed data. Patients with confirmed amenorrhea are assigned as 0 mL.
[2] LS means, LS mean differences (95% CIs), p-value and Hedges' g (95% CIs) are based on a mixed-effects model with study, treatment, visit, and a treatment-by-visit interaction as fixed effects. The multiple visits for each patient are the repeated measures as a random effect within each patient with an unstructured covariance. Hedges' g is calculated using a small sample bias correction. Interaction p-value is only produced for the Overall period.
The reference group for the LS mean difference and Hedges' g is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with data; CI: Confidence interval; LS: Least squares; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; SD: Standard deviation; SE: Standard error; SMD: Standardized mean difference; NC: Not calculated; NE: Non-estimable.

SOURCE: \Studies\MYV\MYV102\Analysis\Prod\Progs\TFLs\Tab_EFF_MBL_CON.SAS
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Table EFF.TMBLPCHG.MITT.Pooled.S8: Summary of Percent Change from Baseline in Menstrual Blood Loss Volume (mL) by Visit and Overall, by Subgroup (mITT Population)

Study: Pooled

Treatment	Study visit	n (%)[1]	Mean (SD)[1]	Change from baseline LS-mean change (SE)[2]	Difference LS-mean change [95% CI] p-value[2]	SMD Hedges' g [95% CI][2]
Ethnicity						
Hispanic or Latino						
Relugolix+E2/NETA	Baseline	52 (100.0)	194.4 (78.09)	-76.30 (8.407)	-43.04	-0.80
N=52	Week 24	39 (75.0)	46.2 (121.16)		[-66.29,-19.79]	[-1.25,-0.35]
Placebo	Baseline	55 (100.0)	220.8 (122.06)	-33.26 (8.019)	0.0004	
N=55	Week 24	42 (76.4)	126.4 (113.78)			
Not Hispanic or Latino						
Relugolix+E2/NETA	Baseline	197 (100.0)	253.9 (198.66)	-85.05 (4.419)	-72.67	-1.38
N=197	Week 24	137 (69.5)	41.6 (146.92)		[-84.87,-60.48]	[-1.64,-1.11]
Placebo	Baseline	199 (100.0)	213.2 (128.72)	-12.38 (4.350)	<.0001	
N=199	Week 24	142 (71.4)	169.1 (165.56)			
Not reported						
Relugolix+E2/NETA	Baseline	4 (100.0)	341.1 (252.99)	NC (NC)	NC	NC
N=4	Week 24	3 (75.0)	12.4 (21.48)		[NC,NC]	[NC,NC]
Placebo	Baseline	2 (100.0)	267.3 (200.46)	NC (NC)	NC	
N=2	Week 24	2 (100.0)	207.0 (102.08)			

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group. Total menstrual blood loss volume was calculated as sum of menstrual blood loss volume from all feminine products (validated, unauthorized and unvalidated) assessed by the alkaline hematin method.
[1] Summary statistics are based on observed data. Patients with confirmed amenorrhea are assigned as 0 mL.
[2] LS means, LS mean differences (95% CIs), p-value and Hedges' g (95% CIs) are based on a mixed-effects model with study, treatment, visit, and a treatment-by-visit interaction as fixed effects. The multiple visits for each patient are the repeated measures as a random effect within each patient with an unstructured covariance. Hedges' g is calculated using a small sample bias correction. Interaction p-value is only produced for the Overall period.
The reference group for the LS mean difference and Hedges' g is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with data; CI: Confidence interval; LS: Least squares; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; SD: Standard deviation; SE: Standard error; SMD: Standardized mean difference; NC: Not calculated.

SOURCE: \Studies\MYV\MYV102\Analysis\Prod\Progs\TFLs\Tab_EFF_MBL_CON.SAS
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Table EFF.TMBLPCHG.MITT.Pooled.S8: Summary of Percent Change from Baseline in Menstrual Blood Loss Volume (mL) by Visit and Overall, by Subgroup (mITT Population)

Study: Pooled

Treatment	Study visit	n (%)[1]	Mean (SD)[1]	Change from baseline LS-mean change (SE)[2]	Difference LS-mean change [95% CI] p-value[2]	SMD Hedges' g [95% CI][2]	Int. p-value[2]
Ethnicity							
Hispanic or Latino							
Relugolix+E2/NETA	Baseline	52 (100.0)	194.4 (78.09)	-71.71 (5.713)	-54.83	-0.96	0.2274
N=52	Overall	50 (96.2)	58.1 (144.69)		[-70.49,-39.17]	[-1.37,-0.56]	
Placebo	Baseline	55 (100.0)	220.8 (122.06)	-16.88 (5.527)	<.0001		
N=55	Overall	52 (94.5)	167.6 (129.99)				
Not Hispanic or Latino							
Relugolix+E2/NETA	Baseline	197 (100.0)	253.9 (198.66)	-78.25 (3.141)	-65.58	-1.16	
N=197	Overall	181 (91.9)	55.3 (98.94)		[-74.16,-57.00]	[-1.38,-0.94]	
Placebo	Baseline	199 (100.0)	213.2 (128.72)	-12.67 (3.029)	<.0001		
N=199	Overall	190 (95.5)	178.2 (125.98)				
Not reported							
Relugolix+E2/NETA	Baseline	4 (100.0)	341.1 (252.99)	NC (NC)	NC	NC	
N=4	Overall	3 (75.0)	33.0 (29.30)		[NC,NC]	[NC,NC]	
Placebo	Baseline	2 (100.0)	267.3 (200.46)	NC (NC)	NC		
N=2	Overall	2 (100.0)	191.6 (85.82)				

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group. Total menstrual blood loss volume was calculated as sum of menstrual blood loss volume from all feminine products (validated, unauthorized and unvalidated) assessed by the alkaline hematin method.
[1] Summary statistics are based on observed data. Patients with confirmed amenorrhea are assigned as 0 mL. Mean (SD) are calculated based on the mean observed value across all post-baseline visits within each patient.
[2] LS means, LS mean differences (95% CIs), p-value and Hedges' g (95% CIs) are based on a mixed-effects model with study, treatment, visit, subgroup, treatment-by-visit interaction and a subgroup-by-treatment interaction as fixed effects. The multiple visits for each patient are the repeated measures as a random effect within each patient with an unstructured covariance. Hedges' g is calculated using a small sample bias correction. Not reported subgroup levels are not included in estimation of the interaction p-value.
The reference group for the LS mean difference and Hedges' g is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with data; CI: Confidence interval; int: Interaction; LS: Least squares; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; SD: Standard deviation; SE: Standard error; SMD: Standardized mean difference; NC: Not calculated.

SOURCE: \Studies\MYV\MYV102\Analysis\Prod\Progs\TFLs\Tab_EFF_MBL_CON.SAS
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Table EFF.TMBLPCHG.MITT.Pooled.S9: Summary of Percent Change from Baseline in Menstrual Blood Loss Volume (mL) by Visit and Overall, by Subgroup (mITT Population)

Study: Pooled

Treatment	Study visit	n (%)[1]	Mean (SD)[1]	Change from baseline LS-mean change (SE)[2]	Difference LS-mean change [95% CI] p-value[2]	SMD Hedges' g [95% CI][2]
Race						
Black/African American						
Relugolix+E2/NETA	Baseline	122 (100.0)	260.1 (203.74)	-63.94 (5.641)	-57.70	-1.17
N=122	Week 4	64 (52.5)	88.1 (121.35)		[-71.91,-43.49]	[-1.50,-0.84]
Placebo	Baseline	141 (100.0)	205.6 (109.81)	-6.24 (4.498)	<.0001	
N=141	Week 4	110 (78.0)	190.6 (138.86)			
White						
Relugolix+E2/NETA	Baseline	122 (100.0)	223.8 (159.11)	-39.91 (11.681)	-20.32	-0.17
N=122	Week 4	73 (59.8)	140.6 (326.54)		[-52.63,11.98]	[-0.48,0.13]
Placebo	Baseline	105 (100.0)	224.1 (144.59)	-19.59 (11.497)	0.2163	
N=105	Week 4	92 (87.6)	162.2 (118.30)			
Asian						
Relugolix+E2/NETA	Baseline	1 (100.0)	208.4 (NE)	NC (NC)	NC	NC
N=1	Week 4	1 (100.0)	14.9 (NE)		[NC,NC]	[NC,NC]
Placebo	Baseline	3 (100.0)	257.2 (220.31)	NC (NC)	NC	
N=3	Week 4	3 (100.0)	235.1 (267.10)			
Others						
Relugolix+E2/NETA	Baseline	5 (100.0)	198.5 (91.19)	NE (NE)	NE	NE
N=5	Week 4	4 (80.0)	91.6 (98.08)		[NE,NE]	[NE,NE]
Placebo	Baseline	6 (100.0)	233.6 (146.60)	NE (NE)	NE	
N=6	Week 4	5 (83.3)	237.1 (185.09)			
Not reported						
Relugolix+E2/NETA	Baseline	3 (100.0)	417.5 (245.57)	NC (NC)	NC	NC
N=3	Week 4	1 (33.3)	279.6 (NE)		[NC,NC]	[NC,NC]
Placebo	Baseline	1 (100.0)	409.0 (NE)	NC (NC)	NC	
N=1	Week 4	1 (100.0)	362.1 (NE)			

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group. Total menstrual blood loss volume was calculated as sum of menstrual blood loss volume from all feminine products (validated, unauthorized and unvalidated) assessed by the alkaline hematin method.
[1] Summary statistics are based on observed data. Patients with confirmed amenorrhea are assigned as 0 mL.
[2] LS means, LS mean differences (95% CIs), p-value and Hedges' g (95% CIs) are based on a mixed-effects model with study, treatment, visit, and a treatment-by-visit interaction as fixed effects. The multiple visits for each patient are the repeated measures as a random effect within each patient with an unstructured covariance. Hedges' g is calculated using a small sample bias correction. Interaction p-value is only produced for the Overall period.
The reference group for the LS mean difference and Hedges' g is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with data; CI: Confidence interval; LS: Least squares; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; SD: Standard deviation; SE: Standard error; SMD: Standardized mean difference; NC: Not calculated; NE: Non-estimable.

SOURCE: \Studies\MYV\MYV102\Analysis\Prod\Progs\TFLs\Tab_EFF_MBL_CON.SAS

Table EFF.TMBLPCHG.MITT.Pooled.S9: Summary of Percent Change from Baseline in Menstrual Blood Loss Volume (mL) by Visit and Overall, by Subgroup (mITT Population)						
Study: Pooled						
Treatment	**Study visit**	**n (%)[1]**	**Mean (SD)[1]**	**Change from baseline LS-mean change (SE)[2]**	**Difference LS-mean change [95% CI] p-value[2]**	**SMD Hedges' g [95% CI][2]**
Race						
Black/African American						
Relugolix+E2/NETA	Baseline	122 (100.0)	260.1 (203.74)	-76.40 (4.759)	-69.14	-1.48
N=122	Week 8	92 (75.4)	62.5 (120.68)		[-81.71,-56.56]	[-1.79,-1.17]
Placebo	Baseline	141 (100.0)	205.6 (109.81)	-7.27 (4.258)	<.0001	
N=141	Week 8	117 (83.0)	189.2 (144.33)			
White						
Relugolix+E2/NETA	Baseline	122 (100.0)	223.8 (159.11)	-78.79 (4.940)	-63.30	-1.35
N=122	Week 8	95 (77.9)	43.3 (96.85)		[-77.29,-49.31]	[-1.66,-1.03]
Placebo	Baseline	105 (100.0)	224.1 (144.59)	-15.49 (5.099)	<.0001	
N=105	Week 8	93 (88.6)	179.9 (157.50)			
Asian						
Relugolix+E2/NETA	Baseline	1 (100.0)	208.4 (NE)	NC (NC)	NC	NC
N=1	Week 8	1 (100.0)	12.1 (NE)		[NC,NC]	[NC,NC]
Placebo	Baseline	3 (100.0)	257.2 (220.31)	NC (NC)	NC	
N=3	Week 8	3 (100.0)	199.7 (35.65)			
Others						
Relugolix+E2/NETA	Baseline	5 (100.0)	198.5 (91.19)	NE (NE)	NE	NE
N=5	Week 8	3 (60.0)	1.7 (2.89)		[NE,NE]	[NE,NE]
Placebo	Baseline	6 (100.0)	233.6 (146.60)	NE (NE)	NE	
N=6	Week 8	4 (66.7)	293.5 (204.62)			
Not reported						
Relugolix+E2/NETA	Baseline	3 (100.0)	417.5 (245.57)	NC (NC)	NC	NC
N=3	Week 8	2 (66.7)	6.8 (9.64)		[NC,NC]	[NC,NC]
Placebo	Baseline	1 (100.0)	409.0 (NE)	NC (NC)	NC	

N=1	Week 8	1 (100.0)	291.3 (NE)			

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group. Total menstrual blood loss volume was calculated as sum of menstrual blood loss volume from all feminine products (validated, unauthorized and unvalidated) assessed by the alkaline hematin method.
[1] Summary statistics are based on observed data. Patients with confirmed amenorrhea are assigned as 0 mL.
[2] LS means, LS mean differences (95% CIs), p-value and Hedges' g (95% CIs) are based on a mixed-effects model with study, treatment, visit, and a treatment-by-visit interaction as fixed effects. The multiple visits for each patient are the repeated measures as a random effect within each patient with an unstructured covariance. Hedges' g is calculated using a small sample bias correction. Interaction p-value is only produced for the Overall period.
The reference group for the LS mean difference and Hedges' g is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with data; CI: Confidence interval; LS: Least squares; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; SD: Standard deviation; SE: Standard error; SMD: Standardized mean difference; NC: Not calculated; NE: Non-estimable.

Table EFF.TMBLPCHG.MITT.Pooled.S9: Summary of Percent Change from Baseline in Menstrual Blood Loss Volume (mL) by Visit and Overall, by Subgroup (mITT Population)

Study: Pooled

Treatment	**Study visit**	**n (%)[1]**	**Mean (SD)[1]**	**Change from baseline LS-mean change (SE)[2]**	**Difference LS-mean change [95% CI] p-value[2]**	**SMD Hedges' g [95% CI][2]**
Race						
Black/African American						
Relugolix+E2/NETA	Baseline	122 (100.0)	260.1 (203.74)	-77.72 (5.771)	-75.36	-1.34
N=122	Week 12	90 (73.8)	55.1 (106.89)		[-90.69,-60.03]	[-1.64,-1.03]
Placebo	Baseline	141 (100.0)	205.6 (109.81)	-2.36 (5.221)	<.0001	
N=141	Week 12	110 (78.0)	202.0 (178.27)			
White						
Relugolix+E2/NETA	Baseline	122 (100.0)	223.8 (159.11)	-88.61 (3.611)	-65.03	-1.86
N=122	Week 12	97 (79.5)	19.4 (41.30)		[-75.41,-54.64]	[-2.20,-1.51]
Placebo	Baseline	105 (100.0)	224.1 (144.59)	-23.59 (3.841)	<.0001	
N=105	Week 12	86 (81.9)	156.4 (137.20)			
Asian						
Relugolix+E2/NETA	Baseline	1 (100.0)	208.4 (NE)	NC (NC)	NC	NC
N=1	Week 12	1 (100.0)	0.0 (NE)		[NC,NC]	[NC,NC]
Placebo	Baseline	3 (100.0)	257.2 (220.31)	NC (NC)	NC	
N=3	Week 12	2 (66.7)	166.9 (167.80)			
Others						
Relugolix+E2/NETA	Baseline	5 (100.0)	198.5 (91.19)	NE (NE)	NE	NE
N=5	Week 12	5 (100.0)	103.0 (180.93)		[NE,NE]	[NE,NE]
Placebo	Baseline	6 (100.0)	233.6 (146.60)	NE (NE)	NE	
N=6	Week 12	4 (66.7)	283.3 (165.28)			
Not reported						
Relugolix+E2/NETA	Baseline	3 (100.0)	417.5 (245.57)	NC (NC)	NC	NC

N=3	Week 12	2 (66.7)	0.0 (0.00)		[NC,NC]	[NC,NC]
Placebo	Baseline	1 (100.0)	409.0 (NE)	NC (NC)	NC	
N=1	Week 12	1 (100.0)	253.7 (NE)			

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group. Total menstrual blood loss volume was calculated as sum of menstrual blood loss volume from all feminine products (validated, unauthorized and unvalidated) assessed by the alkaline hematin method.
[1] Summary statistics are based on observed data. Patients with confirmed amenorrhea are assigned as 0 mL.
[2] LS means, LS mean differences (95% CIs), p-value and Hedges' g (95% CIs) are based on a mixed-effects model with study, treatment, visit, and a treatment-by-visit interaction as fixed effects. The multiple visits for each patient are the repeated measures as a random effect within each patient with an unstructured covariance. Hedges' g is calculated using a small sample bias correction. Interaction p-value is only produced for the Overall period.
The reference group for the LS mean difference and Hedges' g is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with data; CI: Confidence interval; LS: Least squares; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; SD: Standard deviation; SE: Standard error; SMD: Standardized mean difference; NC: Not calculated; NE: Non-estimable.

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Table EFF.TMBLPCHG.MITT.Pooled.S9: Summary of Percent Change from Baseline in Menstrual Blood Loss Volume (mL) by Visit and Overall, by Subgroup (mITT Population)

Study: Pooled

Treatment	**Study visit**	**n (%)[1]**	**Mean (SD)[1]**	**Change from baseline LS-mean change (SE)[2]**	**Difference LS-mean change [95% CI] p-value[2]**	**SMD Hedges' g [95% CI][2]**
Race						
Black/African American						
Relugolix+E2/NETA	Baseline	122 (100.0)	260.1 (203.74)	-76.33 (4.758)	-64.59	-1.40
N=122	Week 16	86 (70.5)	52.6 (117.44)		[-77.15,-52.02]	[-1.71,-1.08]
Placebo	Baseline	141 (100.0)	205.6 (109.81)	-11.74 (4.252)	<.0001	
N=141	Week 16	109 (77.3)	172.0 (133.44)			
White						
Relugolix+E2/NETA	Baseline	122 (100.0)	223.8 (159.11)	-84.63 (5.184)	-58.77	-1.08
N=122	Week 16	97 (79.5)	30.8 (122.18)		[-73.75,-43.78]	[-1.40,-0.77]
Placebo	Baseline	105 (100.0)	224.1 (144.59)	-25.86 (5.564)	<.0001	
N=105	Week 16	78 (74.3)	151.5 (139.11)			
Asian						
Relugolix+E2/NETA	Baseline	1 (100.0)	208.4 (NE)	NC (NC)	NC	NC
N=1	Week 16	1 (100.0)	0.0 (NE)		[NC,NC]	[NC,NC]
Placebo	Baseline	3 (100.0)	257.2 (220.31)	NC (NC)	NC	
N=3	Week 16	2 (66.7)	151.0 (162.50)			
Others						
Relugolix+E2/NETA	Baseline	5 (100.0)	198.5 (91.19)	NE (NE)	NE	NE
N=5	Week 16	5 (100.0)	23.8 (49.00)		[NE,NE]	[NE,NE]
Placebo	Baseline	6 (100.0)	233.6 (146.60)	NE (NE)	NE	
N=6	Week 16	3 (50.0)	227.3 (178.41)			

Not reported						
Relugolix+E2/NETA	Baseline	3 (100.0)	417.5 (245.57)	NC (NC)	NC	NC
N=3	Week 16	3 (100.0)	0.0 (0.00)		[NC,NC]	[NC,NC]
Placebo	Baseline	1 (100.0)	409.0 (NE)	NC (NC)	NC	
N=1	Week 16	1 (100.0)	127.9 (NE)			

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group. Total menstrual blood loss volume was calculated as sum of menstrual blood loss volume from all feminine products (validated, unauthorized and unvalidated) assessed by the alkaline hematin method.
[1] Summary statistics are based on observed data. Patients with confirmed amenorrhea are assigned as 0 mL.
[2] LS means, LS mean differences (95% CIs), p-value and Hedges' g (95% CIs) are based on a mixed-effects model with study, treatment, visit, and a treatment-by-visit interaction as fixed effects. The multiple visits for each patient are the repeated measures as a random effect within each patient with an unstructured covariance. Hedges' g is calculated using a small sample bias correction. Interaction p-value is only produced for the Overall period.
The reference group for the LS mean difference and Hedges' g is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with data; CI: Confidence interval; LS: Least squares; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; SD: Standard deviation; SE: Standard error; SMD: Standardized mean difference; NC: Not calculated; NE: Non-estimable.

Table EFF.TMBLPCHG.MITT.Pooled.S9: Summary of Percent Change from Baseline in Menstrual Blood Loss Volume (mL) by Visit and Overall, by Subgroup (mITT Population)

Study: Pooled

Treatment	**Study visit**	**n (%)[1]**	**Mean (SD)[1]**	**Change from baseline LS-mean change (SE)[2]**	**Difference LS-mean change [95% CI] p-value[2]**	**SMD Hedges' g [95% CI][2]**
Race						
Black/African American						
Relugolix+E2/NETA	Baseline	122 (100.0)	260.1 (203.74)	-76.97 (4.980)	-68.70	-1.44
N=122	Week 20	86 (70.5)	62.2 (176.84)		[-81.93,-55.46]	[-1.76,-1.11]
Placebo	Baseline	141 (100.0)	205.6 (109.81)	-8.27 (4.513)	<.0001	
N=141	Week 20	102 (72.3)	185.4 (137.83)			
White						
Relugolix+E2/NETA	Baseline	122 (100.0)	223.8 (159.11)	-89.48 (4.155)	-64.73	-1.72
N=122	Week 20	98 (80.3)	19.9 (60.61)		[-76.82,-52.64]	[-2.07,-1.37]
Placebo	Baseline	105 (100.0)	224.1 (144.59)	-24.76 (4.517)	<.0001	
N=105	Week 20	77 (73.3)	145.3 (155.43)			
Asian						
Relugolix+E2/NETA	Baseline	1 (100.0)	208.4 (NE)	NC (NC)	NC	NC
N=1	Week 20	1 (100.0)	0.0 (NE)		[NC,NC]	[NC,NC]
Placebo	Baseline	3 (100.0)	257.2 (220.31)	NC (NC)	NC	
N=3	Week 20	1 (33.3)	343.5 (NE)			
Others						
Relugolix+E2/NETA	Baseline	5 (100.0)	198.5 (91.19)	NE (NE)	NE	NE
N=5	Week 20	5 (100.0)	50.8 (79.80)		[NE,NE]	[NE,NE]

Placebo	Baseline	6 (100.0)	233.6 (146.60)	NE (NE)	NE	
N=6	Week 20	4 (66.7)	245.7 (181.30)			
Not reported						
Relugolix+E2/NETA	Baseline	3 (100.0)	417.5 (245.57)	NC (NC)	NC	NC
N=3	Week 20	3 (100.0)	0.0 (0.00)		[NC,NC]	[NC,NC]
Placebo	Baseline	1 (100.0)	409.0 (NE)	NC (NC)	NC	
N=1	Week 20	1 (100.0)	199.6 (NE)			

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group. Total menstrual blood loss volume was calculated as sum of menstrual blood loss volume from all feminine products (validated, unauthorized and unvalidated) assessed by the alkaline hematin method.
[1] Summary statistics are based on observed data. Patients with confirmed amenorrhea are assigned as 0 mL.
[2] LS means, LS mean differences (95% CIs), p-value and Hedges' g (95% CIs) are based on a mixed-effects model with study, treatment, visit, and a treatment-by-visit interaction as fixed effects. The multiple visits for each patient are the repeated measures as a random effect within each patient with an unstructured covariance. Hedges' g is calculated using a small sample bias correction. Interaction p-value is only produced for the Overall period.
The reference group for the LS mean difference and Hedges' g is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with data; CI: Confidence interval; LS: Least squares; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; SD: Standard deviation; SE: Standard error; SMD: Standardized mean difference; NC: Not calculated; NE: Non-estimable.

SOURCE: \Studies\MYV\MYV102\Analysis\Prod\Progs\TFLs\Tab_EFF_MBL_CON.SAS
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Table EFF.TMBLPCHG.MITT.Pooled.S9: Summary of Percent Change from Baseline in Menstrual Blood Loss Volume (mL) by Visit and Overall, by Subgroup (mITT Population)

Study: Pooled

Treatment	**Study visit**	**n (%)[1]**	**Mean (SD)[1]**	**Change from baseline LS-mean change (SE)[2]**	**Difference LS-mean change [95% CI] p-value[2]**	**SMD Hedges' g [95% CI][2]**
Race						
Black/African American						
Relugolix+E2/NETA	Baseline	122 (100.0)	260.1 (203.74)	-76.88 (4.767)	-62.09	-1.42
N=122	Week 24	80 (65.6)	64.6 (186.40)		[-74.65,-49.53]	[-1.75,-1.10]
Placebo	Baseline	141 (100.0)	205.6 (109.81)	-14.79 (4.238)	<.0001	
N=141	Week 24	102 (72.3)	166.7 (138.25)			
White						
Relugolix+E2/NETA	Baseline	122 (100.0)	223.8 (159.11)	-88.20 (6.202)	-65.07	-1.07
N=122	Week 24	91 (74.6)	22.2 (79.19)		[-83.10,-47.03]	[-1.39,-0.74]
Placebo	Baseline	105 (100.0)	224.1 (144.59)	-23.13 (6.729)	<.0001	
N=105	Week 24	77 (73.3)	145.2 (175.58)			
Asian						
Relugolix+E2/NETA	Baseline	1 (100.0)	208.4 (NE)	NC (NC)	NC	NC
N=1	Week 24	1 (100.0)	0.0 (NE)		[NC,NC]	[NC,NC]
Placebo	Baseline	3 (100.0)	257.2 (220.31)	NC (NC)	NC	
N=3	Week 24	2 (66.7)	144.2 (203.97)			
Others						

Relugolix+E2/NETA	Baseline	5 (100.0)	198.5 (91.19)	NE (NE)	NE	NE
N=5	Week 24	4 (80.0)	90.6 (177.97)		[NE,NE]	[NE,NE]
Placebo	Baseline	6 (100.0)	233.6 (146.60)	NE (NE)	NE	
N=6	Week 24	4 (66.7)	246.9 (171.72)			
Not reported						
Relugolix+E2/NETA	Baseline	3 (100.0)	417.5 (245.57)	NC (NC)	NC	NC
N=3	Week 24	3 (100.0)	0.0 (0.00)		[NC,NC]	[NC,NC]
Placebo	Baseline	1 (100.0)	409.0 (NE)	NC (NC)	NC	
N=1	Week 24	1 (100.0)	279.2 (NE)			

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group. Total menstrual blood loss volume was calculated as sum of menstrual blood loss volume from all feminine products (validated, unauthorized and unvalidated) assessed by the alkaline hematin method.
[1] Summary statistics are based on observed data. Patients with confirmed amenorrhea are assigned as 0 mL.
[2] LS means, LS mean differences (95% CIs), p-value and Hedges' g (95% CIs) are based on a mixed-effects model with study, treatment, visit, and a treatment-by-visit interaction as fixed effects. The multiple visits for each patient are the repeated measures as a random effect within each patient with an unstructured covariance. Hedges' g is calculated using a small sample bias correction. Interaction p-value is only produced for the Overall period.
The reference group for the LS mean difference and Hedges' g is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with data; CI: Confidence interval; LS: Least squares; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; SD: Standard deviation; SE: Standard error; SMD: Standardized mean difference; NC: Not calculated; NE: Non-estimable.

Table EFF.TMBLPCHG.MITT.Pooled.S9: Summary of Percent Change from Baseline in Menstrual Blood Loss Volume (mL) by Visit and Overall, by Subgroup (mITT Population)

Study: Pooled

Treatment	**Study visit**	**n (%)[1]**	**Mean (SD)[1]**	**Change from baseline LS-mean change (SE)[2]**	**Difference LS-mean change [95% CI] p-value[2]**	**SMD Hedges' g [95% CI][2]**	**Int. p-value[2]**
Race							
Black/African American							
Relugolix+E2/NETA	Baseline	122 (100.0)	260.1 (203.74)	-72.51 (3.918)	-63.87	-1.13	0.3034
N=122	Overall	111 (91.0)	66.1 (112.14)		[-74.23,-53.50]	[-1.40,-0.86]	
Placebo	Baseline	141 (100.0)	205.6 (109.81)	-8.64 (3.535)	<.0001		
N=141	Overall	133 (94.3)	183.2 (125.41)				
White							
Relugolix+E2/NETA	Baseline	122 (100.0)	223.8 (159.11)	-80.64 (3.813)	-58.80	-1.04	
N=122	Overall	114 (93.4)	46.5 (108.42)		[-69.66,-47.94]	[-1.33,-0.76]	
Placebo	Baseline	105 (100.0)	224.1 (144.59)	-21.84 (4.002)	<.0001		
N=105	Overall	102 (97.1)	158.7 (122.68)				
Asian							
Relugolix+E2/NETA	Baseline	1 (100.0)	208.4 (NE)	NC (NC)	NC	NC	
N=1	Overall	1 (100.0)	4.5 (NE)		[NC,NC]	[NC,NC]	
Placebo	Baseline	3 (100.0)	257.2 (220.31)	NC (NC)	NC		

N=3	Overall	3 (100.0)	229.4 (166.58)				
Others							
Relugolix+E2/NETA	Baseline	5 (100.0)	198.5 (91.19)	-70.10 (17.461)	-96.17	-1.54	
N=5	Overall	5 (100.0)	63.9 (110.77)		[-144.96,-47.38]	[-2.85,-0.24]	
Placebo	Baseline	6 (100.0)	233.6 (146.60)	26.07 (17.628)	0.0001		
N=6	Overall	5 (83.3)	289.5 (162.83)				
Not reported							
Relugolix+E2/NETA	Baseline	3 (100.0)	417.5 (245.57)	NC (NC)	NC	NC	
N=3	Overall	3 (100.0)	19.8 (31.35)		[NC,NC]	[NC,NC]	
Placebo	Baseline	1 (100.0)	409.0 (NE)	NC (NC)	NC		
N=1	Overall	1 (100.0)	252.3 (NE)				

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group. Total menstrual blood loss volume was calculated as sum of menstrual blood loss volume from all feminine products (validated, unauthorized and unvalidated) assessed by the alkaline hematin method.
[1] Summary statistics are based on observed data. Patients with confirmed amenorrhea are assigned as 0 mL. Mean (SD) are calculated based on the mean observed value across all post-baseline visits within each patient.
[2] LS means, LS mean differences (95% CIs), p-value and Hedges' g (95% CIs) are based on a mixed-effects model with study, treatment, visit, subgroup, treatment-by-visit interaction and a subgroup-by-treatment interaction as fixed effects. The multiple visits for each patient are the repeated measures as a random effect within each patient with an unstructured covariance. Hedges' g is calculated using a small sample bias correction. Not reported subgroup levels are not included in estimation of the interaction p-value. Subgroup levels with fewer than 10 subjects are not included in estimation of the interaction p-value. The reference group for the LS mean difference and Hedges' g is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with data; CI: Confidence interval; int: Interaction; LS: Least squares; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; SD: Standard deviation; SE: Standard error; SMD: Standardized mean difference; NC: Not calculated; NE: Non-estimable.

SOURCE: \Studies\MYV\MYV102\Analysis\Prod\Progs\TFLs\Tab_EFF_MBL_CON.SAS
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Table EFF.TMBLPCHG.MITT.Pooled.S6: Summary of Percent Change from Baseline in Menstrual Blood Loss Volume (mL) by Visit and Overall, by Subgroup (mITT Population)

Study: Pooled

Treatment	Study visit	n (%)[1]	Mean (SD)[1]	Change from baseline LS-mean change (SE)[2]	Difference LS-mean change [95% CI] p-value[2]	SMD Hedges' g [95% CI][2]
Geographic Region I						
North America						
Relugolix+E2/NETA	Baseline	191 (100.0)	250.5 (190.88)	-47.27 (8.233)	-35.05	-0.36
N=191	Week 4	108 (56.5)	127.7 (281.63)		[-56.78,-13.32]	[-0.60,-0.11]
Placebo	Baseline	194 (100.0)	221.1 (127.37)	-12.22 (7.368)	0.0016	
N=194	Week 4	155 (79.9)	187.1 (136.70)			
Rest of World						
Relugolix+E2/NETA	Baseline	62 (100.0)	220.1 (154.54)	-64.70 (6.279)	-48.05	-1.12
N=62	Week 4	35 (56.5)	78.9 (79.98)		[-64.32,-31.78]	[-1.57,-0.67]
Placebo	Baseline	62 (100.0)	197.0 (126.42)	-16.65 (5.304)	<.0001	
N=62	Week 4	56 (90.3)	163.1 (124.54)			

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group. Total menstrual blood loss volume was calculated as sum of menstrual blood loss volume from all feminine products (validated, unauthorized and unvalidated) assessed by the alkaline hematin method.
[1] Summary statistics are based on observed data. Patients with confirmed amenorrhea are assigned as 0 mL.
[2] LS means, LS mean differences (95% CIs), p-value and Hedges' g (95% CIs) are based on a mixed-effects model with study, treatment, visit, and a treatment-by-visit interaction as fixed effects. The multiple visits for each patient are the repeated measures as a random effect within each patient with an unstructured covariance. Hedges' g is calculated using a small sample bias correction. Interaction p-value is only produced for the Overall period.
The reference group for the LS mean difference and Hedges' g is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with data; CI: Confidence interval; LS: Least squares; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; SD: Standard deviation; SE: Standard error; SMD: Standardized mean difference.

SOURCE: \Studies\MYV\MYV102\Analysis\Prod\Progs\TFLs\Tab_EFF_MBL_CON.SAS
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Analysis Plan: 13JAN2021

Table EFF.TMBLPCHG.MITT.Pooled.S6: Summary of Percent Change from Baseline in Menstrual Blood Loss Volume (mL) by Visit and Overall, by Subgroup (mITT Population)

Study: Pooled

Treatment	Study visit	n (%)[1]	Mean (SD)[1]	Change from baseline LS-mean change (SE)[2]	Difference LS-mean change [95% CI] p-value[2]	SMD Hedges' g [95% CI][2]
Geographic Region I						
North America						
Relugolix+E2/NETA	Baseline	191 (100.0)	250.5 (190.88)	-75.66 (3.998)	-68.56	-1.46
N=191	Week 8	141 (73.8)	60.0 (115.70)		[-79.40,-57.73]	[-1.72,-1.21]
Placebo	Baseline	194 (100.0)	221.1 (127.37)	-7.10 (3.792)	<.0001	
N=194	Week 8	163 (84.0)	194.2 (150.49)			
Rest of World						
Relugolix+E2/NETA	Baseline	62 (100.0)	220.1 (154.54)	-85.58 (6.513)	-68.24	-1.40
N=62	Week 8	52 (83.9)	27.4 (79.58)		[-86.27,-50.22]	[-1.82,-0.98]
Placebo	Baseline	62 (100.0)	197.0 (126.42)	-17.33 (6.362)	<.0001	
N=62	Week 8	55 (88.7)	168.7 (148.61)			

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group. Total menstrual blood loss volume was calculated as sum of menstrual blood loss volume from all feminine products (validated, unauthorized and unvalidated) assessed by the alkaline hematin method.
[1] Summary statistics are based on observed data. Patients with confirmed amenorrhea are assigned as 0 mL.
[2] LS means, LS mean differences (95% CIs), p-value and Hedges' g (95% CIs) are based on a mixed-effects model with study, treatment, visit, and a treatment-by-visit interaction as fixed effects. The multiple visits for each patient are the repeated measures as a random effect within each patient with an unstructured covariance. Hedges' g is calculated using a small sample bias correction. Interaction p-value is only produced for the Overall period.
The reference group for the LS mean difference and Hedges' g is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with data; CI: Confidence interval; LS: Least squares; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; SD: Standard deviation; SE: Standard error; SMD: Standardized mean difference.

SOURCE: \Studies\MYV\MYV102\Analysis\Prod\Progs\TFLs\Tab_EFF_MBL_CON.SAS
Date/time of run: 20APR2021 15:05
Analysis Plan: 13JAN2021

Table EFF.TMBLPCHG.MITT.Pooled.S6: Summary of Percent Change from Baseline in Menstrual Blood Loss Volume (mL) by Visit and Overall, by Subgroup (mITT Population)

Study: Pooled

Treatment	Study visit	n (%)[1]	Mean (SD)[1]	Change from baseline LS-mean change (SE)[2]	Difference LS-mean change [95% CI] p-value[2]	SMD Hedges' g [95% CI][2]
Geographic Region I						
North America						
Relugolix+E2/NETA	Baseline	191 (100.0)	250.5 (190.88)	-80.07 (3.874)	-70.23	-1.48
N=191	Week 12	145 (75.9)	45.2 (95.14)		[-80.94,-59.51]	[-1.74,-1.22]
Placebo	Baseline	194 (100.0)	221.1 (127.37)	-9.85 (3.829)	<.0001	
N=194	Week 12	145 (74.7)	191.5 (160.20)			
Rest of World						
Relugolix+E2/NETA	Baseline	62 (100.0)	220.1 (154.54)	-92.34 (6.892)	-78.17	-1.52
N=62	Week 12	50 (80.6)	16.0 (35.52)		[-97.05,-59.29]	[-1.94,-1.09]
Placebo	Baseline	62 (100.0)	197.0 (126.42)	-14.16 (6.589)	<.0001	
N=62	Week 12	58 (93.5)	165.9 (167.42)			

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group. Total menstrual blood loss volume was calculated as sum of menstrual blood loss volume from all feminine products (validated, unauthorized and unvalidated) assessed by the alkaline hematin method.
[1] Summary statistics are based on observed data. Patients with confirmed amenorrhea are assigned as 0 mL.
[2] LS means, LS mean differences (95% CIs), p-value and Hedges' g (95% CIs) are based on a mixed-effects model with study, treatment, visit, and a treatment-by-visit interaction as fixed effects. The multiple visits for each patient are the repeated measures as a random effect within each patient with an unstructured covariance. Hedges' g is calculated using a small sample bias correction. Interaction p-value is only produced for the Overall period.
The reference group for the LS mean difference and Hedges' g is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with data; CI: Confidence interval; LS: Least squares; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; SD: Standard deviation; SE: Standard error; SMD: Standardized mean difference.

SOURCE: \Studies\MYV\MYV102\Analysis\Prod\Progs\TFLs\Tab_EFF_MBL_CON.SAS
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Table EFF.TMBLPCHG.MITT.Pooled.S6: Summary of Percent Change from Baseline in Menstrual Blood Loss Volume (mL) by Visit and Overall, by Subgroup (mITT Population)

Study: Pooled

Treatment	Study visit	n (%)[1]	Mean (SD)[1]	Change from baseline LS-mean change (SE)[2]	Difference LS-mean change [95% CI] p-value[2]	SMD Hedges' g [95% CI][2]
Geographic Region I						
North America						
Relugolix+E2/NETA	Baseline	191 (100.0)	250.5 (190.88)	-77.35 (4.292)	-62.81	-1.15
N=191	Week 16	140 (73.3)	50.4 (134.87)		[-74.60,-51.02]	[-1.40,-0.90]
Placebo	Baseline	194 (100.0)	221.1 (127.37)	-14.54 (4.188)	<.0001	
N=194	Week 16	146 (75.3)	167.5 (136.47)			
Rest of World						
Relugolix+E2/NETA	Baseline	62 (100.0)	220.1 (154.54)	-94.12 (4.630)	-69.71	-2.27
N=62	Week 16	52 (83.9)	11.0 (33.54)		[-82.76,-56.66]	[-2.77,-1.76]
Placebo	Baseline	62 (100.0)	197.0 (126.42)	-24.41 (4.695)	<.0001	
N=62	Week 16	47 (75.8)	153.7 (134.24)			

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group. Total menstrual blood loss volume was calculated as sum of menstrual blood loss volume from all feminine products (validated, unauthorized and unvalidated) assessed by the alkaline hematin method.
[1] Summary statistics are based on observed data. Patients with confirmed amenorrhea are assigned as 0 mL.
[2] LS means, LS mean differences (95% CIs), p-value and Hedges' g (95% CIs) are based on a mixed-effects model with study, treatment, visit, and a treatment-by-visit interaction as fixed effects. The multiple visits for each patient are the repeated measures as a random effect within each patient with an unstructured covariance. Hedges' g is calculated using a small sample bias correction. Interaction p-value is only produced for the Overall period.
The reference group for the LS mean difference and Hedges' g is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with data; CI: Confidence interval; LS: Least squares; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; SD: Standard deviation; SE: Standard error; SMD: Standardized mean difference.

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Table EFF.TMBLPCHG.MITT.Pooled.S6: Summary of Percent Change from Baseline in Menstrual Blood Loss Volume (mL) by Visit and Overall, by Subgroup (mITT Population)

Study: Pooled

Treatment	Study visit	n (%)[1]	Mean (SD)[1]	Change from baseline LS-mean change (SE)[2]	Difference LS-mean change [95% CI] p-value[2]	SMD Hedges' g [95% CI][2]
Geographic Region I						
North America						
Relugolix+E2/NETA	Baseline	191 (100.0)	250.5 (190.88)	-80.84 (4.081)	-68.26	-1.43
N=191	Week 20	140 (73.3)	46.6 (145.15)		[-79.55,-56.98]	[-1.70,-1.17]
Placebo	Baseline	194 (100.0)	221.1 (127.37)	-12.58 (4.034)	<.0001	
N=194	Week 20	136 (70.1)	176.0 (154.53)			
Rest of World						
Relugolix+E2/NETA	Baseline	62 (100.0)	220.1 (154.54)	-92.64 (6.053)	-78.00	-2.17
N=62	Week 20	53 (85.5)	19.5 (57.52)		[-94.99,-61.01]	[-2.66,-1.68]
Placebo	Baseline	62 (100.0)	197.0 (126.42)	-14.63 (6.085)	<.0001	
N=62	Week 20	49 (79.0)	157.0 (124.31)			

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group. Total menstrual blood loss volume was calculated as sum of menstrual blood loss volume from all feminine products (validated, unauthorized and unvalidated) assessed by the alkaline hematin method.
[1] Summary statistics are based on observed data. Patients with confirmed amenorrhea are assigned as 0 mL.
[2] LS means, LS mean differences (95% CIs), p-value and Hedges' g (95% CIs) are based on a mixed-effects model with study, treatment, visit, and a treatment-by-visit interaction as fixed effects. The multiple visits for each patient are the repeated measures as a random effect within each patient with an unstructured covariance. Hedges' g is calculated using a small sample bias correction. Interaction p-value is only produced for the Overall period.
The reference group for the LS mean difference and Hedges' g is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with data; CI: Confidence interval; LS: Least squares; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; SD: Standard deviation; SE: Standard error; SMD: Standardized mean difference.

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Table EFF.TMBLPCHG.MITT.Pooled.S6: Summary of Percent Change from Baseline in Menstrual Blood Loss Volume (mL) by Visit and Overall, by Subgroup (mITT Population)

Study: Pooled

Treatment	Study visit	n (%)[1]	Mean (SD)[1]	Change from baseline LS-mean change (SE)[2]	Difference LS-mean change [95% CI] p-value[2]	SMD Hedges' g [95% CI][2]
Geographic Region I						
North America						
Relugolix+E2/NETA	Baseline	191 (100.0)	250.5 (190.88)	-80.63 (3.892)	-60.40	-1.33
N=191	Week 24	127 (66.5)	49.4 (158.01)		[-71.01,-49.78]	[-1.59,-1.06]
Placebo	Baseline	194 (100.0)	221.1 (127.37)	-20.23 (3.738)	<.0001	
N=194	Week 24	140 (72.2)	159.3 (136.04)			
Rest of World						
Relugolix+E2/NETA	Baseline	62 (100.0)	220.1 (154.54)	-93.21 (9.364)	-84.70	-1.23
N=62	Week 24	52 (83.9)	24.4 (80.26)		[-111.32,-58.08]	[-1.66,-0.80]
Placebo	Baseline	62 (100.0)	197.0 (126.42)	-8.51 (9.649)	<.0001	
N=62	Week 24	46 (74.2)	161.7 (205.32)			

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group. Total menstrual blood loss volume was calculated as sum of menstrual blood loss volume from all feminine products (validated, unauthorized and unvalidated) assessed by the alkaline hematin method.
[1] Summary statistics are based on observed data. Patients with confirmed amenorrhea are assigned as 0 mL.
[2] LS means, LS mean differences (95% CIs), p-value and Hedges' g (95% CIs) are based on a mixed-effects model with study, treatment, visit, and a treatment-by-visit interaction as fixed effects. The multiple visits for each patient are the repeated measures as a random effect within each patient with an unstructured covariance. Hedges' g is calculated using a small sample bias correction. Interaction p-value is only produced for the Overall period.
The reference group for the LS mean difference and Hedges' g is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with data; CI: Confidence interval; LS: Least squares; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; SD: Standard deviation; SE: Standard error; SMD: Standardized mean difference.

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Table EFF.TMBLPCHG.MITT.Pooled.S6: Summary of Percent Change from Baseline in Menstrual Blood Loss Volume (mL) by Visit and Overall, by Subgroup (mITT Population)

Study: Pooled

Treatment	Study visit	n (%)[1]	Mean (SD)[1]	Change from baseline LS-mean change (SE)[2]	Difference LS-mean change [95% CI] p-value[2]	SMD Hedges' g [95% CI][2]	Int. p-value[2]
Geographic Region I							
North America							
Relugolix+E2/NETA	Baseline	191 (100.0)	250.5 (190.88)	-73.99 (3.174)	-61.37	-1.09	0.3875
N=191	Overall	174 (91.1)	64.9 (122.28)		[-70.04,-52.70]	[-1.31,-0.87]	
Placebo	Baseline	194 (100.0)	221.1 (127.37)	-12.62 (3.065)	<.0001		
N=194	Overall	182 (93.8)	181.4 (127.53)				
Rest of World							
Relugolix+E2/NETA	Baseline	62 (100.0)	220.1 (154.54)	-84.88 (5.147)	-68.47	-1.21	
N=62	Overall	60 (96.8)	28.7 (49.78)		[-82.64,-54.31]	[-1.60,-0.83]	
Placebo	Baseline	62 (100.0)	197.0 (126.42)	-16.41 (5.052)	<.0001		
N=62	Overall	62 (100.0)	160.2 (122.09)				

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group. Total menstrual blood loss volume was calculated as sum of menstrual blood loss volume from all feminine products (validated, unauthorized and unvalidated) assessed by the alkaline hematin method.
[1] Summary statistics are based on observed data. Patients with confirmed amenorrhea are assigned as 0 mL. Mean (SD) are calculated based on the mean observed value across all post-baseline visits within each patient.
[2] LS means, LS mean differences (95% CIs), p-value and Hedges' g (95% CIs) are based on a mixed-effects model with study, treatment, visit, subgroup, treatment-by-visit interaction and a subgroup-by-treatment interaction as fixed effects. The multiple visits for each patient are the repeated measures as a random effect within each patient with an unstructured covariance. Hedges' g is calculated using a small sample bias correction. The reference group for the LS mean difference and Hedges' g is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with data; CI: Confidence interval; int: Interaction; LS: Least squares; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; SD: Standard deviation; SE: Standard error; SMD: Standardized mean difference.

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Table EFF.TMBLPCHG.MITT.Pooled.S1: Summary of Percent Change from Baseline in Menstrual Blood Loss Volume (mL) by Visit and Overall, by Subgroup (mITT Population)

Study: Pooled

Treatment	Study visit	n (%)[1]	Mean (SD)[1]	Change from baseline LS-mean change (SE)[2]	Difference LS-mean change [95% CI] p-value[2]	SMD Hedges' g [95% CI][2]
Age (years)						
< 40 years						
Relugolix+E2/NETA	Baseline	62 (100.0)	267.1 (248.21)	-54.31 (5.567)	-36.69	-0.99
N=62	Week 4	39 (62.9)	114.5 (118.80)		[-51.03,-22.35]	[-1.41,-0.56]
Placebo	Baseline	78 (100.0)	193.1 (123.99)	-17.62 (4.649)	<.0001	
N=78	Week 4	61 (78.2)	143.1 (110.77)			
>= 40 years						
Relugolix+E2/NETA	Baseline	191 (100.0)	235.2 (155.88)	-47.88 (8.667)	-37.35	-0.37
N=191	Week 4	104 (54.5)	116.3 (282.68)		[-60.23,-14.47]	[-0.62,-0.12]
Placebo	Baseline	178 (100.0)	224.9 (127.87)	-10.53 (7.762)	0.0015	
N=178	Week 4	150 (84.3)	196.1 (139.43)			

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group. Total menstrual blood loss volume was calculated as sum of menstrual blood loss volume from all feminine products (validated, unauthorized and unvalidated) assessed by the alkaline hematin method.
[1] Summary statistics are based on observed data. Patients with confirmed amenorrhea are assigned as 0 mL.
[2] LS means, LS mean differences (95% CIs), p-value and Hedges' g (95% CIs) are based on a mixed-effects model with study, treatment, visit, and a treatment-by-visit interaction as fixed effects. The multiple visits for each patient are the repeated measures as a random effect within each patient with an unstructured covariance. Hedges' g is calculated using a small sample bias correction. Interaction p-value is only produced for the Overall period.
The reference group for the LS mean difference and Hedges' g is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with data; CI: Confidence interval; LS: Least squares; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; SD: Standard deviation; SE: Standard error; SMD: Standardized mean difference.

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Table EFF.TMBLPCHG.MITT.Pooled.S1: Summary of Percent Change from Baseline in Menstrual Blood Loss Volume (mL) by Visit and Overall, by Subgroup (mITT Population)

Study: Pooled

Treatment	Study visit	n (%)[1]	Mean (SD)[1]	Change from baseline LS-mean change (SE)[2]	Difference LS-mean change [95% CI] p-value[2]	SMD Hedges' g [95% CI][2]
Age (years)						
< 40 years						
Relugolix+E2/NETA	Baseline	62 (100.0)	267.1 (248.21)	-75.65 (6.173)	-67.40	-1.60
N=62	Week 8	45 (72.6)	62.6 (113.57)		[-83.42,-51.38]	[-2.03,-1.17]
Placebo	Baseline	78 (100.0)	193.1 (123.99)	-8.26 (5.250)	<.0001	
N=78	Week 8	65 (83.3)	164.2 (124.46)			
>= 40 years						
Relugolix+E2/NETA	Baseline	191 (100.0)	235.2 (155.88)	-78.48 (4.065)	-68.61	-1.40
N=191	Week 8	148 (77.5)	47.8 (106.35)		[-79.88,-57.34]	[-1.65,-1.15]
Placebo	Baseline	178 (100.0)	224.9 (127.87)	-9.88 (4.040)	<.0001	
N=178	Week 8	153 (86.0)	197.8 (159.06)			

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group. Total menstrual blood loss volume was calculated as sum of menstrual blood loss volume from all feminine products (validated, unauthorized and unvalidated) assessed by the alkaline hematin method.
[1] Summary statistics are based on observed data. Patients with confirmed amenorrhea are assigned as 0 mL.
[2] LS means, LS mean differences (95% CIs), p-value and Hedges' g (95% CIs) are based on a mixed-effects model with study, treatment, visit, and a treatment-by-visit interaction as fixed effects. The multiple visits for each patient are the repeated measures as a random effect within each patient with an unstructured covariance. Hedges' g is calculated using a small sample bias correction. Interaction p-value is only produced for the Overall period.
The reference group for the LS mean difference and Hedges' g is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with data; CI: Confidence interval; LS: Least squares; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; SD: Standard deviation; SE: Standard error; SMD: Standardized mean difference.

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Table EFF.TMBLPCHG.MITT.Pooled.S1: Summary of Percent Change from Baseline in Menstrual Blood Loss Volume (mL) by Visit and Overall, by Subgroup (mITT Population)

Study: Pooled

Treatment	Study visit	n (%)[1]	Mean (SD)[1]	Change from baseline LS-mean change (SE)[2]	Difference LS-mean change [95% CI] p-value[2]	SMD Hedges' g [95% CI][2]
Age (years)						
< 40 years						
Relugolix+E2/NETA	Baseline	62 (100.0)	267.1 (248.21)	-84.38 (5.407)	-70.18	-1.81
N=62	Week 12	47 (75.8)	56.7 (123.27)		[-84.51,-55.86]	[-2.26,-1.36]
Placebo	Baseline	78 (100.0)	193.1 (123.99)	-14.20 (4.821)	<.0001	
N=78	Week 12	60 (76.9)	147.8 (127.42)			
>= 40 years						
Relugolix+E2/NETA	Baseline	191 (100.0)	235.2 (155.88)	-82.69 (4.248)	-73.70	-1.42
N=191	Week 12	148 (77.5)	31.7 (67.79)		[-85.60,-61.80]	[-1.67,-1.16]
Placebo	Baseline	178 (100.0)	224.9 (127.87)	-8.99 (4.309)	<.0001	
N=178	Week 12	143 (80.3)	199.5 (173.00)			

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group. Total menstrual blood loss volume was calculated as sum of menstrual blood loss volume from all feminine products (validated, unauthorized and unvalidated) assessed by the alkaline hematin method.
[1] Summary statistics are based on observed data. Patients with confirmed amenorrhea are assigned as 0 mL.
[2] LS means, LS mean differences (95% CIs), p-value and Hedges' g (95% CIs) are based on a mixed-effects model with study, treatment, visit, and a treatment-by-visit interaction as fixed effects. The multiple visits for each patient are the repeated measures as a random effect within each patient with an unstructured covariance. Hedges' g is calculated using a small sample bias correction. Interaction p-value is only produced for the Overall period.
The reference group for the LS mean difference and Hedges' g is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with data; CI: Confidence interval; LS: Least squares; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; SD: Standard deviation; SE: Standard error; SMD: Standardized mean difference.

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Table EFF.TMBLPCHG.MITT.Pooled.S1: Summary of Percent Change from Baseline in Menstrual Blood Loss Volume (mL) by Visit and Overall, by Subgroup (mITT Population)

Study: Pooled

Treatment	Study visit	n (%)[1]	Mean (SD)[1]	Change from baseline LS-mean change (SE)[2]	Difference LS-mean change [95% CI] p-value[2]	SMD Hedges' g [95% CI][2]
Age (years)						
< 40 years						
Relugolix+E2/NETA	Baseline	62 (100.0)	267.1 (248.21)	-77.65 (5.640)	-55.14	-1.39
N=62	Week 16	47 (75.8)	51.9 (130.14)		[-70.20,-40.08]	[-1.82,-0.96]
Placebo	Baseline	78 (100.0)	193.1 (123.99)	-22.51 (5.120)	<.0001	
N=78	Week 16	55 (70.5)	147.5 (121.16)			
>= 40 years						
Relugolix+E2/NETA	Baseline	191 (100.0)	235.2 (155.88)	-82.87 (4.158)	-67.55	-1.27
N=191	Week 16	145 (75.9)	35.8 (113.54)		[-79.19,-55.92]	[-1.53,-1.02]
Placebo	Baseline	178 (100.0)	224.9 (127.87)	-15.32 (4.208)	<.0001	
N=178	Week 16	138 (77.5)	170.8 (140.96)			

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group. Total menstrual blood loss volume was calculated as sum of menstrual blood loss volume from all feminine products (validated, unauthorized and unvalidated) assessed by the alkaline hematin method.
[1] Summary statistics are based on observed data. Patients with confirmed amenorrhea are assigned as 0 mL.
[2] LS means, LS mean differences (95% CIs), p-value and Hedges' g (95% CIs) are based on a mixed-effects model with study, treatment, visit, and a treatment-by-visit interaction as fixed effects. The multiple visits for each patient are the repeated measures as a random effect within each patient with an unstructured covariance. Hedges' g is calculated using a small sample bias correction. Interaction p-value is only produced for the Overall period.
The reference group for the LS mean difference and Hedges' g is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with data; CI: Confidence interval; LS: Least squares; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; SD: Standard deviation; SE: Standard error; SMD: Standardized mean difference.

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Table EFF.TMBLPCHG.MITT.Pooled.S1: Summary of Percent Change from Baseline in Menstrual Blood Loss Volume (mL) by Visit and Overall, by Subgroup (mITT Population)

Study: Pooled

Treatment	Study visit	n (%)[1]	Mean (SD)[1]	Change from baseline LS-mean change (SE)[2]	Difference LS-mean change [95% CI] p-value[2]	SMD Hedges' g [95% CI][2]
Age (years)						
< 40 years						
Relugolix+E2/NETA	Baseline	62 (100.0)	267.1 (248.21)	-83.10 (5.594)	-67.55	-1.73
N=62	Week 20	46 (74.2)	65.3 (223.12)		[-82.45,-52.66]	[-2.19,-1.28]
Placebo	Baseline	78 (100.0)	193.1 (123.99)	-15.55 (5.043)	<.0001	
N=78	Week 20	57 (73.1)	152.2 (125.91)			
>= 40 years						
Relugolix+E2/NETA	Baseline	191 (100.0)	235.2 (155.88)	-84.44 (3.996)	-71.08	-1.51
N=191	Week 20	147 (77.0)	31.0 (76.18)		[-82.39,-59.78]	[-1.78,-1.24]
Placebo	Baseline	178 (100.0)	224.9 (127.87)	-13.35 (4.131)	<.0001	
N=178	Week 20	128 (71.9)	179.3 (155.27)			

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group. Total menstrual blood loss volume was calculated as sum of menstrual blood loss volume from all feminine products (validated, unauthorized and unvalidated) assessed by the alkaline hematin method.
[1] Summary statistics are based on observed data. Patients with confirmed amenorrhea are assigned as 0 mL.
[2] LS means, LS mean differences (95% CIs), p-value and Hedges' g (95% CIs) are based on a mixed-effects model with study, treatment, visit, and a treatment-by-visit interaction as fixed effects. The multiple visits for each patient are the repeated measures as a random effect within each patient with an unstructured covariance. Hedges' g is calculated using a small sample bias correction. Interaction p-value is only produced for the Overall period.
The reference group for the LS mean difference and Hedges' g is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with data; CI: Confidence interval; LS: Least squares; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; SD: Standard deviation; SE: Standard error; SMD: Standardized mean difference.

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Table EFF.TMBLPCHG.MITT.Pooled.S1: Summary of Percent Change from Baseline in Menstrual Blood Loss Volume (mL) by Visit and Overall, by Subgroup (mITT Population)

Study: Pooled

Treatment	Study visit	n (%)[1]	Mean (SD)[1]	Change from baseline LS-mean change (SE)[2]	Difference LS-mean change [95% CI] p-value[2]	SMD Hedges' g [95% CI][2]
Age (years)						
< 40 years						
Relugolix+E2/NETA	Baseline	62 (100.0)	267.1 (248.21)	-74.77 (6.181)	-57.51	-1.27
N=62	Week 24	44 (71.0)	91.1 (243.85)		[-73.89,-41.13]	[-1.70,-0.85]
Placebo	Baseline	78 (100.0)	193.1 (123.99)	-17.26 (5.513)	<.0001	
N=78	Week 24	57 (73.1)	146.0 (135.59)			
>= 40 years						
Relugolix+E2/NETA	Baseline	191 (100.0)	235.2 (155.88)	-86.01 (4.720)	-68.89	-1.24
N=191	Week 24	135 (70.7)	26.2 (77.32)		[-82.16,-55.62]	[-1.50,-0.97]
Placebo	Baseline	178 (100.0)	224.9 (127.87)	-17.11 (4.823)	<.0001	
N=178	Week 24	129 (72.5)	166.0 (163.56)			

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group. Total menstrual blood loss volume was calculated as sum of menstrual blood loss volume from all feminine products (validated, unauthorized and unvalidated) assessed by the alkaline hematin method.
[1] Summary statistics are based on observed data. Patients with confirmed amenorrhea are assigned as 0 mL.
[2] LS means, LS mean differences (95% CIs), p-value and Hedges' g (95% CIs) are based on a mixed-effects model with study, treatment, visit, and a treatment-by-visit interaction as fixed effects. The multiple visits for each patient are the repeated measures as a random effect within each patient with an unstructured covariance. Hedges' g is calculated using a small sample bias correction. Interaction p-value is only produced for the Overall period.
The reference group for the LS mean difference and Hedges' g is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with data; CI: Confidence interval; LS: Least squares; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; SD: Standard deviation; SE: Standard error; SMD: Standardized mean difference.

SOURCE: \Studies\MYV\MYV102\Analysis\Prod\Progs\TFLs\Tab_EFF_MBL_CON.SAS
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Table EFF.TMBLPCHG.MITT.Pooled.S1: Summary of Percent Change from Baseline in Menstrual Blood Loss Volume (mL) by Visit and Overall, by Subgroup (mITT Population)

Study: Pooled

Treatment	Study visit	n (%)[1]	Mean (SD)[1]	Change from baseline LS-mean change (SE)[2]	Difference LS-mean change [95% CI] p-value[2]	SMD Hedges' g [95% CI][2]	Int. p-value[2]
Age (years)							
< 40 years							
Relugolix+E2/NETA	Baseline	62 (100.0)	267.1 (248.21)	-74.28 (5.332)	-59.32	-1.05	0.5150
N=62	Overall	58 (93.5)	74.4 (131.71)		[-73.33,-45.30]	[-1.41,-0.68]	
Placebo	Baseline	78 (100.0)	193.1 (123.99)	-14.96 (4.742)	<.0001		
N=78	Overall	72 (92.3)	149.2 (111.16)				
>= 40 years							
Relugolix+E2/NETA	Baseline	191 (100.0)	235.2 (155.88)	-77.66 (3.162)	-64.64	-1.15	
N=191	Overall	176 (92.1)	49.5 (100.72)		[-73.42,-55.87]	[-1.37,-0.92]	
Placebo	Baseline	178 (100.0)	224.9 (127.87)	-13.02 (3.152)	<.0001		
N=178	Overall	172 (96.6)	187.2 (130.75)				

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group. Total menstrual blood loss volume was calculated as sum of menstrual blood loss volume from all feminine products (validated, unauthorized and unvalidated) assessed by the alkaline hematin method.
[1] Summary statistics are based on observed data. Patients with confirmed amenorrhea are assigned as 0 mL. Mean (SD) are calculated based on the mean observed value across all post-baseline visits within each patient.
[2] LS means, LS mean differences (95% CIs), p-value and Hedges' g (95% CIs) are based on a mixed-effects model with study, treatment, visit, subgroup, treatment-by-visit interaction and a subgroup-by-treatment interaction as fixed effects. The multiple visits for each patient are the repeated measures as a random effect within each patient with an unstructured covariance. Hedges' g is calculated using a small sample bias correction.
The reference group for the LS mean difference and Hedges' g is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with data; CI: Confidence interval; int: Interaction; LS: Least squares; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; SD: Standard deviation; SE: Standard error; SMD: Standardized mean difference.

SOURCE: \Studies\MYV\MYV102\Analysis\Prod\Progs\TFLs\Tab_EFF_MBL_CON.SAS
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Table EFF.TMBLPCHG.MITT.Pooled.S2: Summary of Percent Change from Baseline in Menstrual Blood Loss Volume (mL) by Visit and Overall, by Subgroup (mITT Population)

Study: Pooled

Treatment	Study visit	n (%)[1]	Mean (SD)[1]	Change from baseline LS-mean change (SE)[2]	Difference LS-mean change [95% CI] p-value[2]	SMD Hedges' g [95% CI][2]
BMI (kg/m2) at Baseline						
< 30						
Relugolix+E2/NETA	Baseline	119 (100.0)	231.4 (156.85)	-62.49 (4.692)	-41.18	-1.02
N=119	Week 4	66 (55.5)	87.8 (89.23)		[-53.33,-29.03]	[-1.35,-0.69]
Placebo	Baseline	115 (100.0)	218.8 (143.45)	-21.31 (4.004)	<.0001	
N=115	Week 4	96 (83.5)	170.8 (129.31)			
>= 30						
Relugolix+E2/NETA	Baseline	133 (100.0)	253.4 (203.92)	-40.65 (11.128)	-32.28	-0.29
N=133	Week 4	76 (57.1)	141.6 (329.32)		[-61.41,-3.15]	[-0.58,0.00]
Placebo	Baseline	141 (100.0)	212.3 (112.90)	-8.37 (9.746)	0.0300	
N=141	Week 4	115 (81.6)	189.0 (137.30)			
Missing						
Relugolix+E2/NETA	Baseline	1 (100.0)	243.2 (NE)	NC (NC)	NC	NC
N=1	Week 4	1 (100.0)	0.0 (NE)		[NC,NC]	[NC,NC]
Placebo	Baseline	0	NE (NE)	NC (NC)	NC	
N=0	Week 4	0	NE (NE)			

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group. Total menstrual blood loss volume was calculated as sum of menstrual blood loss volume from all feminine products (validated, unauthorized and unvalidated) assessed by the alkaline hematin method.
[1] Summary statistics are based on observed data. Patients with confirmed amenorrhea are assigned as 0 mL.
[2] LS means, LS mean differences (95% CIs), p-value and Hedges' g (95% CIs) are based on a mixed-effects model with study, treatment, visit, and a treatment-by-visit interaction as fixed effects. The multiple visits for each patient are the repeated measures as a random effect within each patient with an unstructured covariance. Hedges' g is calculated using a small sample bias correction. Interaction p-value is only produced for the Overall period.
The reference group for the LS mean difference and Hedges' g is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with data; CI: Confidence interval; LS: Least squares; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; SD: Standard deviation; SE: Standard error; SMD: Standardized mean difference; NC: Not calculated; NE: Non-estimable.

SOURCE: \Studies\MYV\MYV102\Analysis\Prod\Progs\TFLs\Tab_EFF_MBL_CON.SAS
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Table EFF.TMBLPCHG.MITT.Pooled.S2: Summary of Percent Change from Baseline in Menstrual Blood Loss Volume (mL) by Visit and Overall, by Subgroup (mITT Population)

Study: Pooled

Treatment	Study visit	n (%)[1]	Mean (SD)[1]	Change from baseline LS-mean change (SE)[2]	Difference LS-mean change [95% CI] p-value[2]	SMD Hedges' g [95% CI][2]
BMI (kg/m2) at Baseline						
< 30						
Relugolix+E2/NETA	Baseline	119 (100.0)	231.4 (156.85)	-76.54 (5.281)	-64.90	-1.25
N=119	Week 8	92 (77.3)	52.8 (102.20)		[-79.31,-50.49]	[-1.56,-0.95]
Placebo	Baseline	115 (100.0)	218.8 (143.45)	-11.64 (5.054)	<.0001	
N=115	Week 8	103 (89.6)	190.8 (167.04)			
>= 30						
Relugolix+E2/NETA	Baseline	133 (100.0)	253.4 (203.92)	-78.96 (4.445)	-70.67	-1.64
N=133	Week 8	100 (75.2)	50.4 (113.89)		[-82.72,-58.62]	[-1.95,-1.33]
Placebo	Baseline	141 (100.0)	212.3 (112.90)	-8.29 (4.209)	<.0001	
N=141	Week 8	115 (81.6)	185.0 (133.79)			
Missing						
Relugolix+E2/NETA	Baseline	1 (100.0)	243.2 (NE)	NC (NC)	NC	NC
N=1	Week 8	1 (100.0)	0.0 (NE)		[NC,NC]	[NC,NC]
Placebo	Baseline	0	NE (NE)	NC (NC)	NC	
N=0	Week 8	0	NE (NE)			

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group. Total menstrual blood loss volume was calculated as sum of menstrual blood loss volume from all feminine products (validated, unauthorized and unvalidated) assessed by the alkaline hematin method.
[1] Summary statistics are based on observed data. Patients with confirmed amenorrhea are assigned as 0 mL.
[2] LS means, LS mean differences (95% CIs), p-value and Hedges' g (95% CIs) are based on a mixed-effects model with study, treatment, visit, and a treatment-by-visit interaction as fixed effects. The multiple visits for each patient are the repeated measures as a random effect within each patient with an unstructured covariance. Hedges' g is calculated using a small sample bias correction. Interaction p-value is only produced for the Overall period.
The reference group for the LS mean difference and Hedges' g is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with data; CI: Confidence interval; LS: Least squares; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; SD: Standard deviation; SE: Standard error; SMD: Standardized mean difference; NC: Not calculated; NE: Non-estimable.

SOURCE: \Studies\MYV\MYV102\Analysis\Prod\Progs\TFLs\Tab_EFF_MBL_CON.SAS
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Table EFF.TMBLPCHG.MITT.Pooled.S2: Summary of Percent Change from Baseline in Menstrual Blood Loss Volume (mL) by Visit and Overall, by Subgroup (mITT Population)

Study: Pooled

Treatment	Study visit	n (%)[1]	Mean (SD)[1]	Change from baseline LS-mean change (SE)[2]	Difference LS-mean change [95% CI] p-value[2]	SMD Hedges' g [95% CI][2]
BMI (kg/m2) at Baseline						
< 30						
Relugolix+E2/NETA	Baseline	119 (100.0)	231.4 (156.85)	-85.65 (4.011)	-66.80	-1.78
N=119	Week 12	91 (76.5)	27.7 (63.67)		[-77.92,-55.69]	[-2.12,-1.44]
Placebo	Baseline	115 (100.0)	218.8 (143.45)	-18.84 (3.965)	<.0001	
N=115	Week 12	94 (81.7)	171.0 (140.85)			
>= 30						
Relugolix+E2/NETA	Baseline	133 (100.0)	253.4 (203.92)	-81.54 (5.352)	-78.84	-1.40
N=133	Week 12	103 (77.4)	46.9 (99.65)		[-93.51,-64.16]	[-1.70,-1.10]
Placebo	Baseline	141 (100.0)	212.3 (112.90)	-2.70 (5.186)	<.0001	
N=141	Week 12	109 (77.3)	195.6 (178.60)			
Missing						
Relugolix+E2/NETA	Baseline	1 (100.0)	243.2 (NE)	NC (NC)	NC	NC
N=1	Week 12	1 (100.0)	0.0 (NE)		[NC,NC]	[NC,NC]
Placebo	Baseline	0	NE (NE)	NC (NC)	NC	
N=0	Week 12	0	NE (NE)			

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group. Total menstrual blood loss volume was calculated as sum of menstrual blood loss volume from all feminine products (validated, unauthorized and unvalidated) assessed by the alkaline hematin method.
[1] Summary statistics are based on observed data. Patients with confirmed amenorrhea are assigned as 0 mL.
[2] LS means, LS mean differences (95% CIs), p-value and Hedges' g (95% CIs) are based on a mixed-effects model with study, treatment, visit, and a treatment-by-visit interaction as fixed effects. The multiple visits for each patient are the repeated measures as a random effect within each patient with an unstructured covariance. Hedges' g is calculated using a small sample bias correction. Interaction p-value is only produced for the Overall period.
The reference group for the LS mean difference and Hedges' g is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with data; CI: Confidence interval; LS: Least squares; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; SD: Standard deviation; SE: Standard error; SMD: Standardized mean difference; NC: Not calculated; NE: Non-estimable.

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Table EFF.TMBLPCHG.MITT.Pooled.S2: Summary of Percent Change from Baseline in Menstrual Blood Loss Volume (mL) by Visit and Overall, by Subgroup (mITT Population)

Study: Pooled

Treatment	Study visit	n (%)[1]	Mean (SD)[1]	Change from baseline LS-mean change (SE)[2]	Difference LS-mean change [95% CI] p-value[2]	SMD Hedges' g [95% CI][2]
BMI (kg/m2) at Baseline						
< 30						
Relugolix+E2/NETA	Baseline	119 (100.0)	231.4 (156.85)	-85.20 (4.397)	-61.60	-1.55
N=119	Week 16	90 (75.6)	28.9 (80.28)		[-73.90,-49.30]	[-1.89,-1.21]
Placebo	Baseline	115 (100.0)	218.8 (143.45)	-23.60 (4.427)	<.0001	
N=115	Week 16	84 (73.0)	153.6 (133.52)			
>= 30						
Relugolix+E2/NETA	Baseline	133 (100.0)	253.4 (203.92)	-79.48 (5.144)	-67.35	-1.19
N=133	Week 16	101 (75.9)	49.8 (143.13)		[-81.40,-53.31]	[-1.48,-0.90]
Placebo	Baseline	141 (100.0)	212.3 (112.90)	-12.13 (4.940)	<.0001	
N=141	Week 16	109 (77.3)	172.3 (137.44)			
Missing						
Relugolix+E2/NETA	Baseline	1 (100.0)	243.2 (NE)	NC (NC)	NC	NC
N=1	Week 16	1 (100.0)	2.5 (NE)		[NC,NC]	[NC,NC]
Placebo	Baseline	0	NE (NE)	NC (NC)	NC	
N=0	Week 16	0	NE (NE)			

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group. Total menstrual blood loss volume was calculated as sum of menstrual blood loss volume from all feminine products (validated, unauthorized and unvalidated) assessed by the alkaline hematin method.
[1] Summary statistics are based on observed data. Patients with confirmed amenorrhea are assigned as 0 mL.
[2] LS means, LS mean differences (95% CIs), p-value and Hedges' g (95% CIs) are based on a mixed-effects model with study, treatment, visit, and a treatment-by-visit interaction as fixed effects. The multiple visits for each patient are the repeated measures as a random effect within each patient with an unstructured covariance. Hedges' g is calculated using a small sample bias correction. Interaction p-value is only produced for the Overall period.
The reference group for the LS mean difference and Hedges' g is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with data; CI: Confidence interval; LS: Least squares; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; SD: Standard deviation; SE: Standard error; SMD: Standardized mean difference; NC: Not calculated; NE: Non-estimable.

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Table EFF.TMBLPCHG.MITT.Pooled.S2: Summary of Percent Change from Baseline in Menstrual Blood Loss Volume (mL) by Visit and Overall, by Subgroup (mITT Population)

Study: Pooled

Treatment	Study visit	n (%)[1]	Mean (SD)[1]	Change from baseline LS-mean change (SE)[2]	Difference LS-mean change [95% CI] p-value[2]	SMD Hedges' g [95% CI][2]
BMI (kg/m2) at Baseline						
< 30						
Relugolix+E2/NETA	Baseline	119 (100.0)	231.4 (156.85)	-86.00 (5.114)	-74.83	-1.71
N=119	Week 20	91 (76.5)	27.6 (72.22)		[-89.29,-60.38]	[-2.06,-1.36]
Placebo	Baseline	115 (100.0)	218.8 (143.45)	-11.17 (5.254)	<.0001	
N=115	Week 20	79 (68.7)	172.1 (133.82)			
>= 30						
Relugolix+E2/NETA	Baseline	133 (100.0)	253.4 (203.92)	-82.63 (4.520)	-67.59	-1.48
N=133	Week 20	101 (75.9)	49.9 (162.30)		[-79.96,-55.21]	[-1.78,-1.17]
Placebo	Baseline	141 (100.0)	212.3 (112.90)	-15.04 (4.366)	<.0001	
N=141	Week 20	106 (75.2)	170.1 (156.80)			
Missing						
Relugolix+E2/NETA	Baseline	1 (100.0)	243.2 (NE)	NC (NC)	NC	NC
N=1	Week 20	1 (100.0)	0.0 (NE)		[NC,NC]	[NC,NC]
Placebo	Baseline	0	NE (NE)	NC (NC)	NC	
N=0	Week 20	0	NE (NE)			

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group. Total menstrual blood loss volume was calculated as sum of menstrual blood loss volume from all feminine products (validated, unauthorized and unvalidated) assessed by the alkaline hematin method.
[1] Summary statistics are based on observed data. Patients with confirmed amenorrhea are assigned as 0 mL.
[2] LS means, LS mean differences (95% CIs), p-value and Hedges' g (95% CIs) are based on a mixed-effects model with study, treatment, visit, and a treatment-by-visit interaction as fixed effects. The multiple visits for each patient are the repeated measures as a random effect within each patient with an unstructured covariance. Hedges' g is calculated using a small sample bias correction. Interaction p-value is only produced for the Overall period.
The reference group for the LS mean difference and Hedges' g is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with data; CI: Confidence interval; LS: Least squares; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; SD: Standard deviation; SE: Standard error; SMD: Standardized mean difference; NC: Not calculated; NE: Non-estimable.

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Table EFF.TMBLPCHG.MITT.Pooled.S2: Summary of Percent Change from Baseline in Menstrual Blood Loss Volume (mL) by Visit and Overall, by Subgroup (mITT Population)

Study: Pooled

Treatment	Study visit	n (%)[1]	Mean (SD)[1]	Change from baseline LS-mean change (SE)[2]	Difference LS-mean change [95% CI] p-value[2]	SMD Hedges' g [95% CI][2]
BMI (kg/m2) at Baseline						
< 30						
Relugolix+E2/NETA	Baseline	119 (100.0)	231.4 (156.85)	-86.12 (6.510)	-72.15	-1.20
N=119	Week 24	80 (67.2)	29.3 (80.12)		[-90.35,-53.95]	[-1.53,-0.86]
Placebo	Baseline	115 (100.0)	218.8 (143.45)	-13.97 (6.547)	<.0001	
N=115	Week 24	81 (70.4)	167.6 (183.42)			
>= 30						
Relugolix+E2/NETA	Baseline	133 (100.0)	253.4 (203.92)	-81.06 (4.568)	-61.61	-1.33
N=133	Week 24	98 (73.7)	53.1 (174.80)		[-74.11,-49.11]	[-1.63,-1.03]
Placebo	Baseline	141 (100.0)	212.3 (112.90)	-19.45 (4.408)	<.0001	
N=141	Week 24	105 (74.5)	153.9 (130.45)			
Missing						
Relugolix+E2/NETA	Baseline	1 (100.0)	243.2 (NE)	NC (NC)	NC	NC
N=1	Week 24	1 (100.0)	0.0 (NE)		[NC,NC]	[NC,NC]
Placebo	Baseline	0	NE (NE)	NC (NC)	NC	
N=0	Week 24	0	NE (NE)			

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group. Total menstrual blood loss volume was calculated as sum of menstrual blood loss volume from all feminine products (validated, unauthorized and unvalidated) assessed by the alkaline hematin method.
[1] Summary statistics are based on observed data. Patients with confirmed amenorrhea are assigned as 0 mL.
[2] LS means, LS mean differences (95% CIs), p-value and Hedges' g (95% CIs) are based on a mixed-effects model with study, treatment, visit, and a treatment-by-visit interaction as fixed effects. The multiple visits for each patient are the repeated measures as a random effect within each patient with an unstructured covariance. Hedges' g is calculated using a small sample bias correction. Interaction p-value is only produced for the Overall period.
The reference group for the LS mean difference and Hedges' g is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with data; CI: Confidence interval; LS: Least squares; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; SD: Standard deviation; SE: Standard error; SMD: Standardized mean difference; NC: Not calculated; NE: Non-estimable.

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Table EFF.TMBLPCHG.MITT.Pooled.S2: Summary of Percent Change from Baseline in Menstrual Blood Loss Volume (mL) by Visit and Overall, by Subgroup (mITT Population)

Study: Pooled

Treatment	Study visit	n (%)[1]	Mean (SD)[1]	Change from baseline LS-mean change (SE)[2]	Difference LS-mean change [95% CI] p-value[2]	SMD Hedges' g [95% CI][2]	Int. p-value[2]
BMI (kg/m2) at Baseline							
< 30							
Relugolix+E2/NETA	Baseline	119 (100.0)	231.4 (156.85)	-77.90 (3.960)	-61.83	-1.09	0.7574
N=119	Overall	108 (90.8)	44.6 (70.99)		[-72.74,-50.91]	[-1.38,-0.81]	
Placebo	Baseline	115 (100.0)	218.8 (143.45)	-16.07 (3.895)	<.0001		
N=115	Overall	110 (95.7)	170.9 (123.57)				
>= 30							
Relugolix+E2/NETA	Baseline	133 (100.0)	253.4 (203.92)	-75.67 (3.690)	-64.08	-1.13	
N=133	Overall	125 (94.0)	65.6 (133.91)		[-74.11,-54.05]	[-1.40,-0.87]	
Placebo	Baseline	141 (100.0)	212.3 (112.90)	-11.59 (3.525)	<.0001		
N=141	Overall	134 (95.0)	180.2 (128.74)				
Missing							
Relugolix+E2/NETA	Baseline	1 (100.0)	243.2 (NE)	NC (NC)	NC	NC	
N=1	Overall	1 (100.0)	0.4 (NE)		[NC,NC]	[NC,NC]	
Placebo	Baseline	0	NE (NE)	NC (NC)	NC		
N=0	Overall	0	NE (NE)				

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group. Total menstrual blood loss volume was calculated as sum of menstrual blood loss volume from all feminine products (validated, unauthorized and unvalidated) assessed by the alkaline hematin method.
[1] Summary statistics are based on observed data. Patients with confirmed amenorrhea are assigned as 0 mL. Mean (SD) are calculated based on the mean observed value across all post-baseline visits within each patient.
[2] LS means, LS mean differences (95% CIs), p-value and Hedges' g (95% CIs) are based on a mixed-effects model with study, treatment, visit, subgroup, treatment-by-visit interaction and a subgroup-by-treatment interaction as fixed effects. The multiple visits for each patient are the repeated measures as a random effect within each patient with an unstructured covariance. Hedges' g is calculated using a small sample bias correction. Missing subgroup levels are not included in estimation of the interaction p-value.
The reference group for the LS mean difference and Hedges' g is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with data; CI: Confidence interval; int: Interaction; LS: Least squares; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; SD: Standard deviation; SE: Standard error; SMD: Standardized mean difference; NC: Not calculated; NE: Non-estimable.

SOURCE: \Studies\MYV\MYV102\Analysis\Prod\Progs\TFLs\Tab_EFF_MBL_CON.SAS
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Table EFF.TMBLPCHG.MITT.Pooled.S3: Summary of Percent Change from Baseline in Menstrual Blood Loss Volume (mL) by Visit and Overall, by Subgroup (mITT Population)

Study: Pooled

Treatment	Study visit	n (%)[1]	Mean (SD)[1]	Change from baseline LS-mean change (SE)[2]	Difference LS-mean change [95% CI] p-value[2]	SMD Hedges' g [95% CI][2]
Uterine Volume at Baseline (cm3)						
< 300 cm3						
Relugolix+E2/NETA	Baseline	148 (100.0)	209.2 (131.36)	-63.44 (4.723)	-45.36	-0.98
N=148	Week 4	79 (53.4)	69.2 (91.14)		[-57.84,-32.87]	[-1.29,-0.68]
Placebo	Baseline	129 (100.0)	195.1 (130.74)	-18.08 (4.228)	<.0001	
N=129	Week 4	109 (84.5)	151.3 (121.98)			
>= 300 cm3						
Relugolix+E2/NETA	Baseline	104 (100.0)	291.7 (230.38)	-36.39 (12.726)	-31.75	-0.27
N=104	Week 4	64 (61.5)	173.3 (350.41)		[-64.68,1.18]	[-0.58,0.04]
Placebo	Baseline	127 (100.0)	235.7 (120.84)	-4.64 (10.823)	0.0587	
N=127	Week 4	102 (80.3)	212.2 (139.02)			
Missing						
Relugolix+E2/NETA	Baseline	1 (100.0)	192.9 (NE)	NC (NC)	NC	NC
N=1	Week 4	0	NE (NE)		[NC,NC]	[NC,NC]
Placebo	Baseline	0	NE (NE)	NC (NC)	NC	
N=0	Week 4	0	NE (NE)			

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group. Total menstrual blood loss volume was calculated as sum of menstrual blood loss volume from all feminine products (validated, unauthorized and unvalidated) assessed by the alkaline hematin method.
[1] Summary statistics are based on observed data. Patients with confirmed amenorrhea are assigned as 0 mL.
[2] LS means, LS mean differences (95% CIs), p-value and Hedges' g (95% CIs) are based on a mixed-effects model with study, treatment, visit, and a treatment-by-visit interaction as fixed effects. The multiple visits for each patient are the repeated measures as a random effect within each patient with an unstructured covariance. Hedges' g is calculated using a small sample bias correction. Interaction p-value is only produced for the Overall period.
The reference group for the LS mean difference and Hedges' g is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with data; CI: Confidence interval; LS: Least squares; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; SD: Standard deviation; SE: Standard error; SMD: Standardized mean difference; NC: Not calculated; NE: Non-estimable.

SOURCE: \Studies\MYV\MYV102\Analysis\Prod\Progs\TFLs\Tab_EFF_MBL_CON.SAS
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Analysis Plan: 13JAN2021

Table EFF.TMBLPCHG.MITT.Pooled.S3: Summary of Percent Change from Baseline in Menstrual Blood Loss Volume (mL) by Visit and Overall, by Subgroup (mITT Population)

Study: Pooled

Treatment	Study visit	n (%)[1]	Mean (SD)[1]	Change from baseline LS-mean change (SE)[2]	Difference LS-mean change [95% CI] p-value[2]	SMD Hedges' g [95% CI][2]
Uterine Volume at Baseline (cm3)						
< 300 cm3						
Relugolix+E2/NETA	Baseline	148 (100.0)	209.2 (131.36)	-81.77 (3.815)	-72.00	-1.68
N=148	Week 8	120 (81.1)	40.0 (92.75)		[-82.90,-61.09]	[-1.98,-1.38]
Placebo	Baseline	129 (100.0)	195.1 (130.74)	-9.77 (4.013)	<.0001	
N=129	Week 8	109 (84.5)	168.7 (135.21)			
>= 300 cm3						
Relugolix+E2/NETA	Baseline	104 (100.0)	291.7 (230.38)	-71.47 (6.458)	-61.98	-1.18
N=104	Week 8	73 (70.2)	69.7 (127.69)		[-78.71,-45.25]	[-1.50,-0.86]
Placebo	Baseline	127 (100.0)	235.7 (120.84)	-9.49 (5.509)	<.0001	
N=127	Week 8	109 (85.8)	206.8 (162.01)			
Missing						
Relugolix+E2/NETA	Baseline	1 (100.0)	192.9 (NE)	NC (NC)	NC	NC
N=1	Week 8	0	NE (NE)		[NC,NC]	[NC,NC]
Placebo	Baseline	0	NE (NE)	NC (NC)	NC	
N=0	Week 8	0	NE (NE)			

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group. Total menstrual blood loss volume was calculated as sum of menstrual blood loss volume from all feminine products (validated, unauthorized and unvalidated) assessed by the alkaline hematin method.
[1] Summary statistics are based on observed data. Patients with confirmed amenorrhea are assigned as 0 mL.
[2] LS means, LS mean differences (95% CIs), p-value and Hedges' g (95% CIs) are based on a mixed-effects model with study, treatment, visit, and a treatment-by-visit interaction as fixed effects. The multiple visits for each patient are the repeated measures as a random effect within each patient with an unstructured covariance. Hedges' g is calculated using a small sample bias correction. Interaction p-value is only produced for the Overall period.
The reference group for the LS mean difference and Hedges' g is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with data; CI: Confidence interval; LS: Least squares; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; SD: Standard deviation; SE: Standard error; SMD: Standardized mean difference; NC: Not calculated; NE: Non-estimable.

SOURCE: \Studies\MYV\MYV102\Analysis\Prod\Progs\TFLs\Tab_EFF_MBL_CON.SAS
Date/time of run: 20APR2021 15:05
Analysis Plan: 13JAN2021

Table EFF.TMBLPCHG.MITT.Pooled.S3: Summary of Percent Change from Baseline in Menstrual Blood Loss Volume (mL) by Visit and Overall, by Subgroup (mITT Population)

Study: Pooled

Treatment	Study visit	n (%)[1]	Mean (SD)[1]	Change from baseline LS-mean change (SE)[2]	Difference LS-mean change [95% CI] p-value[2]	SMD Hedges' g [95% CI][2]
Uterine Volume at Baseline (cm3)						
< 300 cm3						
Relugolix+E2/NETA	Baseline	148 (100.0)	209.2 (131.36)	-82.60 (4.782)	-71.99	-1.38
N=148	Week 12	114 (77.0)	29.3 (67.59)		[-85.62,-58.36]	[-1.68,-1.09]
Placebo	Baseline	129 (100.0)	195.1 (130.74)	-10.61 (5.003)	<.0001	
N=129	Week 12	105 (81.4)	160.2 (147.76)			
>= 300 cm3						
Relugolix+E2/NETA	Baseline	104 (100.0)	291.7 (230.38)	-83.27 (4.908)	-71.85	-1.60
N=104	Week 12	81 (77.9)	49.6 (103.76)		[-84.85,-58.85]	[-1.94,-1.27]
Placebo	Baseline	127 (100.0)	235.7 (120.84)	-11.42 (4.405)	<.0001	
N=127	Week 12	98 (77.2)	209.9 (173.64)			
Missing						
Relugolix+E2/NETA	Baseline	1 (100.0)	192.9 (NE)	NC (NC)	NC	NC
N=1	Week 12	0	NE (NE)		[NC,NC]	[NC,NC]
Placebo	Baseline	0	NE (NE)	NC (NC)	NC	
N=0	Week 12	0	NE (NE)			

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group. Total menstrual blood loss volume was calculated as sum of menstrual blood loss volume from all feminine products (validated, unauthorized and unvalidated) assessed by the alkaline hematin method.
[1] Summary statistics are based on observed data. Patients with confirmed amenorrhea are assigned as 0 mL.
[2] LS means, LS mean differences (95% CIs), p-value and Hedges' g (95% CIs) are based on a mixed-effects model with study, treatment, visit, and a treatment-by-visit interaction as fixed effects. The multiple visits for each patient are the repeated measures as a random effect within each patient with an unstructured covariance. Hedges' g is calculated using a small sample bias correction. Interaction p-value is only produced for the Overall period.
The reference group for the LS mean difference and Hedges' g is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with data; CI: Confidence interval; LS: Least squares; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; SD: Standard deviation; SE: Standard error; SMD: Standardized mean difference; NC: Not calculated; NE: Non-estimable.

SOURCE: \Studies\MYV\MYV102\Analysis\Prod\Progs\TFLs\Tab_EFF_MBL_CON.SAS
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Table EFF.TMBLPCHG.MITT.Pooled.S3: Summary of Percent Change from Baseline in Menstrual Blood Loss Volume (mL) by Visit and Overall, by Subgroup (mITT Population)

Study: Pooled

Treatment	Study visit	n (%)[1]	Mean (SD)[1]	Change from baseline LS-mean change (SE)[2]	Difference LS-mean change [95% CI] p-value[2]	SMD Hedges' g [95% CI][2]
Uterine Volume at Baseline (cm3)						
< 300 cm3						
Relugolix+E2/NETA	Baseline	148 (100.0)	209.2 (131.36)	-83.09 (3.913)	-61.94	-1.48
N=148	Week 16	110 (74.3)	27.6 (81.75)		[-73.17,-50.72]	[-1.78,-1.17]
Placebo	Baseline	129 (100.0)	195.1 (130.74)	-21.15 (4.144)	<.0001	
N=129	Week 16	98 (76.0)	136.0 (110.55)			
>= 300 cm3						
Relugolix+E2/NETA	Baseline	104 (100.0)	291.7 (230.38)	-79.48 (5.905)	-66.03	-1.14
N=104	Week 16	82 (78.8)	56.0 (152.28)		[-81.72,-50.35]	[-1.46,-0.83]
Placebo	Baseline	127 (100.0)	235.7 (120.84)	-13.45 (5.334)	<.0001	
N=127	Week 16	95 (74.8)	193.2 (152.74)			
Missing						
Relugolix+E2/NETA	Baseline	1 (100.0)	192.9 (NE)	NC (NC)	NC	NC
N=1	Week 16	0	NE (NE)		[NC,NC]	[NC,NC]
Placebo	Baseline	0	NE (NE)	NC (NC)	NC	
N=0	Week 16	0	NE (NE)			

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group. Total menstrual blood loss volume was calculated as sum of menstrual blood loss volume from all feminine products (validated, unauthorized and unvalidated) assessed by the alkaline hematin method.
[1] Summary statistics are based on observed data. Patients with confirmed amenorrhea are assigned as 0 mL.
[2] LS means, LS mean differences (95% CIs), p-value and Hedges' g (95% CIs) are based on a mixed-effects model with study, treatment, visit, and a treatment-by-visit interaction as fixed effects. The multiple visits for each patient are the repeated measures as a random effect within each patient with an unstructured covariance. Hedges' g is calculated using a small sample bias correction. Interaction p-value is only produced for the Overall period.
The reference group for the LS mean difference and Hedges' g is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with data; CI: Confidence interval; LS: Least squares; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; SD: Standard deviation; SE: Standard error; SMD: Standardized mean difference; NC: Not calculated; NE: Non-estimable.

SOURCE: \Studies\MYV\MYV102\Analysis\Prod\Progs\TFLs\Tab_EFF_MBL_CON.SAS
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Table EFF.TMBLPCHG.MITT.Pooled.S3: Summary of Percent Change from Baseline in Menstrual Blood Loss Volume (mL) by Visit and Overall, by Subgroup (mITT Population)

Study: Pooled

Treatment	Study visit	n (%)[1]	Mean (SD)[1]	Change from baseline LS-mean change (SE)[2]	Difference LS-mean change [95% CI] p-value[2]	SMD Hedges' g [95% CI][2]
Uterine Volume at Baseline (cm3)						
< 300 cm3						
Relugolix+E2/NETA	Baseline	148 (100.0)	209.2 (131.36)	-85.92 (4.152)	-71.20	-1.54
N=148	Week 20	114 (77.0)	23.5 (62.78)		[-83.17,-59.23]	[-1.84,-1.23]
Placebo	Baseline	129 (100.0)	195.1 (130.74)	-14.71 (4.441)	<.0001	
N=129	Week 20	96 (74.4)	152.5 (149.98)			
>= 300 cm3						
Relugolix+E2/NETA	Baseline	104 (100.0)	291.7 (230.38)	-82.07 (5.217)	-68.54	-1.59
N=104	Week 20	79 (76.0)	61.7 (183.12)		[-82.45,-54.62]	[-1.94,-1.24]
Placebo	Baseline	127 (100.0)	235.7 (120.84)	-13.53 (4.757)	<.0001	
N=127	Week 20	89 (70.1)	190.8 (141.96)			
Missing						
Relugolix+E2/NETA	Baseline	1 (100.0)	192.9 (NE)	NC (NC)	NC	NC
N=1	Week 20	0	NE (NE)		[NC,NC]	[NC,NC]
Placebo	Baseline	0	NE (NE)	NC (NC)	NC	
N=0	Week 20	0	NE (NE)			

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group. Total menstrual blood loss volume was calculated as sum of menstrual blood loss volume from all feminine products (validated, unauthorized and unvalidated) assessed by the alkaline hematin method.
[1] Summary statistics are based on observed data. Patients with confirmed amenorrhea are assigned as 0 mL.
[2] LS means, LS mean differences (95% CIs), p-value and Hedges' g (95% CIs) are based on a mixed-effects model with study, treatment, visit, and a treatment-by-visit interaction as fixed effects. The multiple visits for each patient are the repeated measures as a random effect within each patient with an unstructured covariance. Hedges' g is calculated using a small sample bias correction. Interaction p-value is only produced for the Overall period.
The reference group for the LS mean difference and Hedges' g is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with data; CI: Confidence interval; LS: Least squares; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; SD: Standard deviation; SE: Standard error; SMD: Standardized mean difference; NC: Not calculated; NE: Non-estimable.

SOURCE: \Studies\MYV\MYV102\Analysis\Prod\Progs\TFLs\Tab_EFF_MBL_CON.SAS
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Table EFF.TMBLPCHG.MITT.Pooled.S3: Summary of Percent Change from Baseline in Menstrual Blood Loss Volume (mL) by Visit and Overall, by Subgroup (mITT Population)

Study: Pooled

Treatment	Study visit	n (%)[1]	Mean (SD)[1]	Change from baseline LS-mean change (SE)[2]	Difference LS-mean change [95% CI] p-value[2]	SMD Hedges' g [95% CI][2]
Uterine Volume at Baseline (cm3)						
< 300 cm3						
Relugolix+E2/NETA	Baseline	148 (100.0)	209.2 (131.36)	-83.20 (4.122)	-63.16	-1.44
N=148	Week 24	105 (70.9)	26.0 (74.99)		[-74.90,-51.42]	[-1.75,-1.13]
Placebo	Baseline	129 (100.0)	195.1 (130.74)	-20.04 (4.308)	<.0001	
N=129	Week 24	98 (76.0)	143.7 (122.97)			
>= 300 cm3						
Relugolix+E2/NETA	Baseline	104 (100.0)	291.7 (230.38)	-82.81 (7.130)	-70.05	-1.11
N=104	Week 24	74 (71.2)	65.1 (197.47)		[-89.03,-51.07]	[-1.44,-0.78]
Placebo	Baseline	127 (100.0)	235.7 (120.84)	-12.76 (6.474)	<.0001	
N=127	Week 24	88 (69.3)	177.9 (184.10)			
Missing						
Relugolix+E2/NETA	Baseline	1 (100.0)	192.9 (NE)	NC (NC)	NC	NC
N=1	Week 24	0	NE (NE)		[NC,NC]	[NC,NC]
Placebo	Baseline	0	NE (NE)	NC (NC)	NC	
N=0	Week 24	0	NE (NE)			

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group. Total menstrual blood loss volume was calculated as sum of menstrual blood loss volume from all feminine products (validated, unauthorized and unvalidated) assessed by the alkaline hematin method.
[1] Summary statistics are based on observed data. Patients with confirmed amenorrhea are assigned as 0 mL.
[2] LS means, LS mean differences (95% CIs), p-value and Hedges' g (95% CIs) are based on a mixed-effects model with study, treatment, visit, and a treatment-by-visit interaction as fixed effects. The multiple visits for each patient are the repeated measures as a random effect within each patient with an unstructured covariance. Hedges' g is calculated using a small sample bias correction. Interaction p-value is only produced for the Overall period.
The reference group for the LS mean difference and Hedges' g is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with data; CI: Confidence interval; LS: Least squares; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; SD: Standard deviation; SE: Standard error; SMD: Standardized mean difference; NC: Not calculated; NE: Non-estimable.

SOURCE: \Studies\MYV\MYV102\Analysis\Prod\Progs\TFLs\Tab_EFF_MBL_CON.SAS
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Table EFF.TMBLPCHG.MITT.Pooled.S3: Summary of Percent Change from Baseline in Menstrual Blood Loss Volume (mL) by Visit and Overall, by Subgroup (mITT Population)

Study: Pooled

Treatment	Study visit	n (%)[1]	Mean (SD)[1]	Change from baseline LS-mean change (SE)[2]	Difference LS-mean change [95% CI] p-value[2]	SMD Hedges' g [95% CI][2]	Int. p-value[2]
Uterine Volume at Baseline (cm3)							
< 300 cm3							
Relugolix+E2/NETA	Baseline	148 (100.0)	209.2 (131.36)	-78.66 (3.533)	-63.86	-1.13	0.7807
N=148	Overall	136 (91.9)	36.4 (62.96)		[-73.88,-53.83]	[-1.39,-0.87]	
Placebo	Baseline	129 (100.0)	195.1 (130.74)	-14.80 (3.680)	<.0001		
N=129	Overall	122 (94.6)	153.0 (116.54)				
>= 300 cm3							
Relugolix+E2/NETA	Baseline	104 (100.0)	291.7 (230.38)	-74.19 (4.171)	-61.82	-1.09	
N=104	Overall	98 (94.2)	82.4 (148.39)		[-72.78,-50.86]	[-1.38,-0.81]	
Placebo	Baseline	127 (100.0)	235.7 (120.84)	-12.37 (3.703)	<.0001		
N=127	Overall	122 (96.1)	199.0 (131.79)				
Missing							
Relugolix+E2/NETA	Baseline	1 (100.0)	192.9 (NE)	NC (NC)	NC	NC	
N=1	Overall	0	NE (NE)		[NC,NC]	[NC,NC]	
Placebo	Baseline	0	NE (NE)	NC (NC)	NC		
N=0	Overall	0	NE (NE)				

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group. Total menstrual blood loss volume was calculated as sum of menstrual blood loss volume from all feminine products (validated, unauthorized and unvalidated) assessed by the alkaline hematin method.
[1] Summary statistics are based on observed data. Patients with confirmed amenorrhea are assigned as 0 mL. Mean (SD) are calculated based on the mean observed value across all post-baseline visits within each patient.
[2] LS means, LS mean differences (95% CIs), p-value and Hedges' g (95% CIs) are based on a mixed-effects model with study, treatment, visit, subgroup, treatment-by-visit interaction and a subgroup-by-treatment interaction as fixed effects. The multiple visits for each patient are the repeated measures as a random effect within each patient with an unstructured covariance. Hedges' g is calculated using a small sample bias correction. Missing subgroup levels are not included in estimation of the interaction p-value.
The reference group for the LS mean difference and Hedges' g is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with data; CI: Confidence interval; int: Interaction; LS: Least squares; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; SD: Standard deviation; SE: Standard error; SMD: Standardized mean difference; NC: Not calculated; NE: Non-estimable.

SOURCE: \Studies\MYV\MYV102\Analysis\Prod\Progs\TFLs\Tab_EFF_MBL_CON.SAS
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Table EFF.TMBLPCHG.MITT.Pooled.S7: Summary of Percent Change from Baseline in Menstrual Blood Loss Volume (mL) by Visit and Overall, by Subgroup (mITT Population)

Study: Pooled

Treatment	Study visit	n (%)[1]	Mean (SD)[1]	Change from baseline LS-mean change (SE)[2]	Difference LS-mean change [95% CI] p-value[2]	SMD Hedges' g [95% CI][2]
Geographic Region II						
Europe						
Relugolix+E2/NETA	Baseline	41 (100.0)	216.0 (150.86)	-62.21 (7.039)	-36.52	-1.04
N=41	Week 4	22 (53.7)	84.4 (92.85)		[-54.56,-18.49]	[-1.59,-0.48]
Placebo	Baseline	42 (100.0)	203.7 (134.23)	-25.69 (5.729)	0.0001	
N=42	Week 4	36 (85.7)	155.8 (124.13)			
Rest of World (including the US)						
Relugolix+E2/NETA	Baseline	212 (100.0)	248.3 (188.24)	-48.18 (7.666)	-36.94	-0.39
N=212	Week 4	121 (57.1)	121.5 (267.09)		[-57.04,-16.84]	[-0.62,-0.16]
Placebo	Baseline	214 (100.0)	217.5 (126.11)	-11.24 (6.765)	0.0003	
N=214	Week 4	175 (81.8)	185.9 (135.37)			

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group. Total menstrual blood loss volume was calculated as sum of menstrual blood loss volume from all feminine products (validated, unauthorized and unvalidated) assessed by the alkaline hematin method.
[1] Summary statistics are based on observed data. Patients with confirmed amenorrhea are assigned as 0 mL.
[2] LS means, LS mean differences (95% CIs), p-value and Hedges' g (95% CIs) are based on a mixed-effects model with study, treatment, visit, and a treatment-by-visit interaction as fixed effects. The multiple visits for each patient are the repeated measures as a random effect within each patient with an unstructured covariance. Hedges' g is calculated using a small sample bias correction. Interaction p-value is only produced for the Overall period.
The reference group for the LS mean difference and Hedges' g is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with data; CI: Confidence interval; LS: Least squares; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; SD: Standard deviation; SE: Standard error; SMD: Standardized mean difference.

SOURCE: \Studies\MYV\MYV102\Analysis\Prod\Progs\TFLs\Tab_EFF_MBL_CON.SAS
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Table EFF.TMBLPCHG.MITT.Pooled.S7: Summary of Percent Change from Baseline in Menstrual Blood Loss Volume (mL) by Visit and Overall, by Subgroup (mITT Population)

Study: Pooled

Treatment	Study visit	n (%)[1]	Mean (SD)[1]	Change from baseline LS-mean change (SE)[2]	Difference LS-mean change [95% CI] p-value[2]	SMD Hedges' g [95% CI][2]
Geographic Region II						
Europe						
Relugolix+E2/NETA	Baseline	41 (100.0)	216.0 (150.86)	-88.90 (8.146)	-68.47	-1.37
N=41	Week 8	34 (82.9)	22.9 (83.88)		[-90.88,-46.05]	[-1.88,-0.86]
Placebo	Baseline	42 (100.0)	203.7 (134.23)	-20.44 (7.800)	<.0001	
N=42	Week 8	38 (90.5)	173.2 (169.56)			
Rest of World (including the US)						
Relugolix+E2/NETA	Baseline	212 (100.0)	248.3 (188.24)	-76.22 (3.730)	-69.00	-1.48
N=212	Week 8	159 (75.0)	57.3 (111.72)		[-79.13,-58.87]	[-1.72,-1.24]
Placebo	Baseline	214 (100.0)	217.5 (126.11)	-7.22 (3.558)	<.0001	
N=214	Week 8	180 (84.1)	190.8 (145.99)			

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group. Total menstrual blood loss volume was calculated as sum of menstrual blood loss volume from all feminine products (validated, unauthorized and unvalidated) assessed by the alkaline hematin method.
[1] Summary statistics are based on observed data. Patients with confirmed amenorrhea are assigned as 0 mL.
[2] LS means, LS mean differences (95% CIs), p-value and Hedges' g (95% CIs) are based on a mixed-effects model with study, treatment, visit, and a treatment-by-visit interaction as fixed effects. The multiple visits for each patient are the repeated measures as a random effect within each patient with an unstructured covariance. Hedges' g is calculated using a small sample bias correction. Interaction p-value is only produced for the Overall period.
The reference group for the LS mean difference and Hedges' g is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with data; CI: Confidence interval; LS: Least squares; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; SD: Standard deviation; SE: Standard error; SMD: Standardized mean difference.

SOURCE: \Studies\MYV\MYV102\Analysis\Prod\Progs\TFLs\Tab_EFF_MBL_CON.SAS
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Table EFF.TMBLPCHG.MITT.Pooled.S7: Summary of Percent Change from Baseline in Menstrual Blood Loss Volume (mL) by Visit and Overall, by Subgroup (mITT Population)

Study: Pooled

Treatment	Study visit	n (%)[1]	Mean (SD)[1]	Change from baseline LS-mean change (SE)[2]	Difference LS-mean change [95% CI] p-value[2]	SMD Hedges' g [95% CI][2]
Geographic Region II						
Europe						
Relugolix+E2/NETA	Baseline	41 (100.0)	216.0 (150.86)	-92.84 (5.167)	-62.20	-2.17
N=41	Week 12	33 (80.5)	7.7 (22.25)		[-76.42,-47.98]	[-2.76,-1.59]
Placebo	Baseline	42 (100.0)	203.7 (134.23)	-30.65 (4.967)	<.0001	
N=42	Week 12	38 (90.5)	143.0 (148.29)			
Rest of World (including the US)						
Relugolix+E2/NETA	Baseline	212 (100.0)	248.3 (188.24)	-81.23 (3.959)	-75.25	-1.47
N=212	Week 12	162 (76.4)	43.8 (91.41)		[-86.18,-64.31]	[-1.71,-1.22]
Placebo	Baseline	214 (100.0)	217.5 (126.11)	-5.98 (3.908)	<.0001	
N=214	Week 12	165 (77.1)	193.7 (164.31)			

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group. Total menstrual blood loss volume was calculated as sum of menstrual blood loss volume from all feminine products (validated, unauthorized and unvalidated) assessed by the alkaline hematin method.
[1] Summary statistics are based on observed data. Patients with confirmed amenorrhea are assigned as 0 mL.
[2] LS means, LS mean differences (95% CIs), p-value and Hedges' g (95% CIs) are based on a mixed-effects model with study, treatment, visit, and a treatment-by-visit interaction as fixed effects. The multiple visits for each patient are the repeated measures as a random effect within each patient with an unstructured covariance. Hedges' g is calculated using a small sample bias correction. Interaction p-value is only produced for the Overall period.
The reference group for the LS mean difference and Hedges' g is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with data; CI: Confidence interval; LS: Least squares; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; SD: Standard deviation; SE: Standard error; SMD: Standardized mean difference.

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Table EFF.TMBLPCHG.MITT.Pooled.S7: Summary of Percent Change from Baseline in Menstrual Blood Loss Volume (mL) by Visit and Overall, by Subgroup (mITT Population)

Study: Pooled

Treatment	Study visit	n (%)[1]	Mean (SD)[1]	Change from baseline LS-mean change (SE)[2]	Difference LS-mean change [95% CI] p-value[2]	SMD Hedges' g [95% CI][2]
Geographic Region II						
Europe						
Relugolix+E2/NETA	Baseline	41 (100.0)	216.0 (150.86)	-94.13 (5.558)	-63.13	-2.13
N=41	Week 16	33 (80.5)	4.0 (14.13)		[-78.77,-47.48]	[-2.74,-1.51]
Placebo	Baseline	42 (100.0)	203.7 (134.23)	-31.00 (5.591)	<.0001	
N=42	Week 16	30 (71.4)	156.7 (158.32)			
Rest of World (including the US)						
Relugolix+E2/NETA	Baseline	212 (100.0)	248.3 (188.24)	-79.01 (3.947)	-65.14	-1.24
N=212	Week 16	159 (75.0)	47.2 (127.97)		[-76.01,-54.28]	[-1.48,-1.00]
Placebo	Baseline	214 (100.0)	217.5 (126.11)	-13.87 (3.869)	<.0001	
N=214	Week 16	163 (76.2)	165.5 (131.64)			

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group. Total menstrual blood loss volume was calculated as sum of menstrual blood loss volume from all feminine products (validated, unauthorized and unvalidated) assessed by the alkaline hematin method.
[1] Summary statistics are based on observed data. Patients with confirmed amenorrhea are assigned as 0 mL.
[2] LS means, LS mean differences (95% CIs), p-value and Hedges' g (95% CIs) are based on a mixed-effects model with study, treatment, visit, and a treatment-by-visit interaction as fixed effects. The multiple visits for each patient are the repeated measures as a random effect within each patient with an unstructured covariance. Hedges' g is calculated using a small sample bias correction. Interaction p-value is only produced for the Overall period.
The reference group for the LS mean difference and Hedges' g is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with data; CI: Confidence interval; LS: Least squares; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; SD: Standard deviation; SE: Standard error; SMD: Standardized mean difference.

SOURCE: \Studies\MYV\MYV102\Analysis\Prod\Progs\TFLs\Tab_EFF_MBL_CON.SAS
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Table EFF.TMBLPCHG.MITT.Pooled.S7: Summary of Percent Change from Baseline in Menstrual Blood Loss Volume (mL) by Visit and Overall, by Subgroup (mITT Population)

Study: Pooled

Treatment	Study visit	n (%)[1]	Mean (SD)[1]	Change from baseline LS-mean change (SE)[2]	Difference LS-mean change [95% CI] p-value[2]	SMD Hedges' g [95% CI][2]
Geographic Region II						
Europe						
Relugolix+E2/NETA	Baseline	41 (100.0)	216.0 (150.86)	-97.16 (4.798)	-75.19	-2.54
N=41	Week 20	35 (85.4)	4.4 (13.41)		[-88.81,-61.57]	[-3.18,-1.90]
Placebo	Baseline	42 (100.0)	203.7 (134.23)	-21.97 (4.896)	<.0001	
N=42	Week 20	32 (76.2)	167.5 (134.48)			
Rest of World (including the US)						
Relugolix+E2/NETA	Baseline	212 (100.0)	248.3 (188.24)	-81.33 (3.824)	-69.25	-1.46
N=212	Week 20	158 (74.5)	46.9 (139.86)		[-79.83,-58.67]	[-1.71,-1.21]
Placebo	Baseline	214 (100.0)	217.5 (126.11)	-12.08 (3.788)	<.0001	
N=214	Week 20	153 (71.5)	171.7 (149.94)			

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group. Total menstrual blood loss volume was calculated as sum of menstrual blood loss volume from all feminine products (validated, unauthorized and unvalidated) assessed by the alkaline hematin method.
[1] Summary statistics are based on observed data. Patients with confirmed amenorrhea are assigned as 0 mL.
[2] LS means, LS mean differences (95% CIs), p-value and Hedges' g (95% CIs) are based on a mixed-effects model with study, treatment, visit, and a treatment-by-visit interaction as fixed effects. The multiple visits for each patient are the repeated measures as a random effect within each patient with an unstructured covariance. Hedges' g is calculated using a small sample bias correction. Interaction p-value is only produced for the Overall period.
The reference group for the LS mean difference and Hedges' g is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with data; CI: Confidence interval; LS: Least squares; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; SD: Standard deviation; SE: Standard error; SMD: Standardized mean difference.

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Table EFF.TMBLPCHG.MITT.Pooled.S7: Summary of Percent Change from Baseline in Menstrual Blood Loss Volume (mL) by Visit and Overall, by Subgroup (mITT Population)

Study: Pooled

Treatment	Study visit	n (%)[1]	Mean (SD)[1]	Change from baseline LS-mean change (SE)[2]	Difference LS-mean change [95% CI] p-value[2]	SMD Hedges' g [95% CI][2]
Geographic Region II						
Europe						
Relugolix+E2/NETA	Baseline	41 (100.0)	216.0 (150.86)	-96.91 (5.070)	-76.58	-2.79
N=41	Week 24	32 (78.0)	1.1 (4.29)		[-90.97,-62.18]	[-3.49,-2.09]
Placebo	Baseline	42 (100.0)	203.7 (134.23)	-20.33 (5.176)	<.0001	
N=42	Week 24	29 (69.0)	140.6 (112.78)			
Rest of World (including the US)						
Relugolix+E2/NETA	Baseline	212 (100.0)	248.3 (188.24)	-80.26 (4.536)	-63.57	-1.13
N=212	Week 24	147 (69.3)	51.1 (153.30)		[-76.01,-51.13]	[-1.37,-0.88]
Placebo	Baseline	214 (100.0)	217.5 (126.11)	-16.69 (4.411)	<.0001	
N=214	Week 24	157 (73.4)	163.5 (162.13)			

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group. Total menstrual blood loss volume was calculated as sum of menstrual blood loss volume from all feminine products (validated, unauthorized and unvalidated) assessed by the alkaline hematin method.
[1] Summary statistics are based on observed data. Patients with confirmed amenorrhea are assigned as 0 mL.
[2] LS means, LS mean differences (95% CIs), p-value and Hedges' g (95% CIs) are based on a mixed-effects model with study, treatment, visit, and a treatment-by-visit interaction as fixed effects. The multiple visits for each patient are the repeated measures as a random effect within each patient with an unstructured covariance. Hedges' g is calculated using a small sample bias correction. Interaction p-value is only produced for the Overall period.
The reference group for the LS mean difference and Hedges' g is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with data; CI: Confidence interval; LS: Least squares; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; SD: Standard deviation; SE: Standard error; SMD: Standardized mean difference.

SOURCE: \Studies\MYV\MYV102\Analysis\Prod\Progs\TFLs\Tab_EFF_MBL_CON.SAS
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Table EFF.TMBLPCHG.MITT.Pooled.S7: Summary of Percent Change from Baseline in Menstrual Blood Loss Volume (mL) by Visit and Overall, by Subgroup (mITT Population)

Study: Pooled

Treatment	Study visit	n (%)[1]	Mean (SD)[1]	Change from baseline LS-mean change (SE)[2]	Difference LS-mean change [95% CI] p-value[2]	SMD Hedges' g [95% CI][2]	Int. p-value[2]
Geographic Region II							
Europe							0.8779
Relugolix+E2/NETA	Baseline	41 (100.0)	216.0 (150.86)	-87.83 (6.279)	-62.05	-1.10	
N=41	Overall	40 (97.6)	21.4 (43.99)		[-79.28,-44.83]	[-1.56,-0.64]	
Placebo	Baseline	42 (100.0)	203.7 (134.23)	-25.77 (6.126)	<.0001		
N=42	Overall	42 (100.0)	152.5 (125.98)				
Rest of World (including the US)							
Relugolix+E2/NETA	Baseline	212 (100.0)	248.3 (188.24)	-74.57 (3.006)	-63.51	-1.13	
N=212	Overall	194 (91.5)	62.7 (117.38)		[-71.73,-55.30]	[-1.34,-0.92]	
Placebo	Baseline	214 (100.0)	217.5 (126.11)	-11.06 (2.909)	<.0001		
N=214	Overall	202 (94.4)	180.9 (126.08)				

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group. Total menstrual blood loss volume was calculated as sum of menstrual blood loss volume from all feminine products (validated, unauthorized and unvalidated) assessed by the alkaline hematin method.
[1] Summary statistics are based on observed data. Patients with confirmed amenorrhea are assigned as 0 mL. Mean (SD) are calculated based on the mean observed value across all post-baseline visits within each patient.
[2] LS means, LS mean differences (95% CIs), p-value and Hedges' g (95% CIs) are based on a mixed-effects model with study, treatment, visit, subgroup, treatment-by-visit interaction and a subgroup-by-treatment interaction as fixed effects. The multiple visits for each patient are the repeated measures as a random effect within each patient with an unstructured covariance. Hedges' g is calculated using a small sample bias correction. The reference group for the LS mean difference and Hedges' g is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with data; CI: Confidence interval; int: Interaction; LS: Least squares; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; SD: Standard deviation; SE: Standard error; SMD: Standardized mean difference.

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1.1.6 Proportion of Patients who Achieved Amenorrhea Over the Last 35 Days of Treatment, by Subgroup (mITT Population)

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Table EFF.AMNO24ET.MITT.Pooled.S3: Proportion of Patients who Achieved Amenorrhea Over the Last 35 Days of Treatment, by Subgroup (mITT Population)

Study: Pooled

Treatment	N	n (%)	OR[1] [95% CI]	RR[2] [95% CI]	RD[3] [95% CI]	p-value[4]	p-value (int)[5]
Uterine Volume at Baseline (cm3)							
< 300 cm3							0.0529
Relugolix+E2/NETA	148	87 (58.8)	44.73	18.95	0.56	<.0001	
Placebo	129	4 (3.1)	[15.68;127.61]	[7.15;50.20]	[0.47;0.64]		
>= 300 cm3							
Relugolix+E2/NETA	104	43 (41.3)	12.09	7.46	0.36	<.0001	
Placebo	127	7 (5.5)	[5.13;28.47]	[3.51;15.84]	[0.26;0.46]		
Missing							
Relugolix+E2/NETA	1	0	NC	NC	NC	NC	
Placebo	0	0	[NC;NC]	[NC;NC]	[NC;NC]		

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group.
Amenorrhea is defined as reported amenorrhea, spotting, or negligible bleeding (menstrual blood loss < 5 mL) with supporting eDiary compliance at 2 consecutive visits.
[1] OR (95% CI) based on a logistic regression model adjusting for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates.
[2] RR (95% CI) based on a Cochran-Mantel-Haenszel approach stratified by study.
[3] RD (95% CI) based on a Mantel-Haenszel approach stratified by study. 95% CIs are based on the approximation to the normal distribution using the Sato estimator for the standard error.
[4] P-value based on a Cochran-Mantel-Haenszel test stratified by study.
[5] Interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the OR (95% CI). Missing subgroup levels are not included in estimation of the interaction p-value. * Interaction p-value < 0.05.
A continuity correction is applied in estimation of the OR, RR and p-value if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum. No continuity correction is applied in the estimation of the RD.
The reference group for the OR, RR and RD is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with an event; OR: Odds ratio; RR: Risk ratio; RD: Risk difference; CI: Confidence interval; int: p-value for interaction; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; NC: Not calculated; NE: Non-estimable.

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Table EFF.AMNO24ET.MITT.Pooled.S9: Proportion of Patients who Achieved Amenorrhea Over the Last 35 Days of Treatment, by Subgroup (mITT Population)

Study: Pooled

Treatment	N	n (%)	OR[1] [95% CI]	RR[2] [95% CI]	RD[3] [95% CI]	p-value[4]	p-value (int)[5]
Race							
Black/African American							0.1785
Relugolix+E2/NETA	122	48 (39.3)	14.62	9.22	0.35	<.0001	
Placebo	141	6 (4.3)	[5.97;35.79]	[4.09;20.77]	[0.26;0.44]		
White							
Relugolix+E2/NETA	122	76 (62.3)	42.02	16.42	0.59	<.0001	
Placebo	105	4 (3.8)	[14.49;121.90]	[6.22;43.38]	[0.49;0.68]		
Asian							
Relugolix+E2/NETA	1	1 (100.0)	NC	NC	NC	NC	
Placebo	3	1 (33.3)	[NC;NC]	[NC;NC]	[NC;NC]		
Others							
Relugolix+E2/NETA	5	2 (40.0)	4.92	3.59	0.53	0.1712	
Placebo	6	0	[0.37;65.05]	[0.55;23.24]	[0.14;0.92]		
Not reported							
Relugolix+E2/NETA	3	3 (100.0)	NC	NC	NC	NC	
Placebo	1	0	[NC;NC]	[NC;NC]	[NC;NC]		

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group.
Amenorrhea is defined as reported amenorrhea, spotting, or negligible bleeding (menstrual blood loss < 5 mL) with supporting eDiary compliance at 2 consecutive visits.
[1] OR (95% CI) based on a logistic regression model adjusting for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates.
[2] RR (95% CI) based on a Cochran-Mantel-Haenszel approach stratified by study.
[3] RD (95% CI) based on a Mantel-Haenszel approach stratified by study. 95% CIs are based on the approximation to the normal distribution using the Sato estimator for the standard error.
[4] P-value based on a Cochran-Mantel-Haenszel test stratified by study.
[5] Interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the OR (95% CI). Not reported subgroup levels are not included in estimation of the interaction p-value.
* Interaction p-value < 0.05.
A continuity correction is applied in estimation of the OR, RR and p-value if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum. No continuity correction is applied in the estimation of the RD.
The reference group for the OR, RR and RD is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with an event; OR: Odds ratio; RR: Risk ratio; RD: Risk difference; CI: Confidence interval; int: p-value for interaction; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; NC: Not calculated; NE: Non-estimable.

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Table EFF.AMNO24ET.MITT.Pooled.S4: Proportion of Patients who Achieved Amenorrhea Over the Last 35 Days of Treatment, by Subgroup (mITT Population)

Study: Pooled

Treatment	N	n (%)	OR[1] [95% CI]	RR[2] [95% CI]	RD[3] [95% CI]	p-value[4]	p-value (int)[5]
Maximum NRS Pain Score at Baseline							
< 4							
Relugolix+E2/NETA	73	41 (56.2)	51.87	22.58	0.54	<.0001	0.2090
Placebo	62	1 (1.6)	[9.63;279.36]	[4.63;110.03]	[0.42;0.66]		
>= 4							
Relugolix+E2/NETA	177	88 (49.7)	17.89	9.49	0.44	<.0001	
Placebo	190	10 (5.3)	[8.86;36.11]	[5.08;17.70]	[0.36;0.52]		
Missing							
Relugolix+E2/NETA	3	1 (33.3)	NC	NC	NC	NC	
Placebo	4	0	[NC;NC]	[NC;NC]	[NC;NC]		

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group.
Amenorrhea is defined as reported amenorrhea, spotting, or negligible bleeding (menstrual blood loss < 5 mL) with supporting eDiary compliance at 2 consecutive visits.
[1] OR (95% CI) based on a logistic regression model adjusting for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates.
[2] RR (95% CI) based on a Cochran-Mantel-Haenszel approach stratified by study.
[3] RD (95% CI) based on a Mantel-Haenszel approach stratified by study. 95% CIs are based on the approximation to the normal distribution using the Sato estimator for the standard error.
[4] P-value based on a Cochran-Mantel-Haenszel test stratified by study.
[5] Interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the OR (95% CI). Missing subgroup levels are not included in estimation of the interaction p-value. * Interaction p-value < 0.05.
A continuity correction is applied in estimation of the OR, RR and p-value if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum. No continuity correction is applied in the estimation of the RD.
The reference group for the OR, RR and RD is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with an event; OR: Odds ratio; RR: Risk ratio; RD: Risk difference; CI: Confidence interval; int: p-value for interaction; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; NC: Not calculated; NE: Non-estimable.

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Table EFF.AMNO24ET.MITT.Pooled.S1: Proportion of Patients who Achieved Amenorrhea Over the Last 35 Days of Treatment, by Subgroup (mITT Population)

Study: Pooled

Treatment	**N**	**n (%)**	**OR[1] [95% CI]**	**RR[2] [95% CI]**	**RD[3] [95% CI]**	**p-value[4]**	**p-value (int)[5]**
Age (years)							
< 40 years							
Relugolix+E2/NETA	62	28 (45.2)	31.26	17.64	0.43	<.0001	0.6522
Placebo	78	2 (2.6)	[7.04;138.80]	[4.39;70.94]	[0.30;0.56]		
>= 40 years							
Relugolix+E2/NETA	191	102 (53.4)	21.57	10.55	0.48	<.0001	
Placebo	178	9 (5.1)	[10.41;44.69]	[5.51;20.20]	[0.41;0.56]		

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group.
Amenorrhea is defined as reported amenorrhea, spotting, or negligible bleeding (menstrual blood loss < 5 mL) with supporting eDiary compliance at 2 consecutive visits.
[1] OR (95% CI) based on a logistic regression model adjusting for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates.
[2] RR (95% CI) based on a Cochran-Mantel-Haenszel approach stratified by study.
[3] RD (95% CI) based on a Mantel-Haenszel approach stratified by study. 95% CIs are based on the approximation to the normal distribution using the Sato estimator for the standard error.
[4] P-value based on a Cochran-Mantel-Haenszel test stratified by study.
[5] Interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the OR (95% CI). Missing subgroup levels are not included in estimation of the interaction p-value. * Interaction p-value < 0.05.
A continuity correction is applied in estimation of the OR, RR and p-value if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum. No continuity correction is applied in the estimation of the RD.
The reference group for the OR, RR and RD is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with an event; OR: Odds ratio; RR: Risk ratio; RD: Risk difference; CI: Confidence interval; int: p-value for interaction; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; NC: Not calculated; NE: Non-estimable.

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Table EFF.AMNO24ET.MITT.Pooled.S8: Proportion of Patients who Achieved Amenorrhea Over the Last 35 Days of Treatment, by Subgroup (mITT Population)

Study: Pooled

Treatment	N	n (%)	OR[1] [95% CI]	RR[2] [95% CI]	RD[3] [95% CI]	p-value[4]	p-value (int)[5]
Ethnicity							
Hispanic or Latino							0.7881
Relugolix+E2/NETA	52	30 (57.7)	19.61	7.24	0.48	<.0001	
Placebo	55	3 (5.5)	[5.82;66.10]	[2.75;19.05]	[0.33;0.64]		
Not Hispanic or Latino							
Relugolix+E2/NETA	197	98 (49.7)	23.92	12.34	0.46	<.0001	
Placebo	199	8 (4.0)	[11.17;51.24]	[6.17;24.70]	[0.38;0.53]		
Not reported							
Relugolix+E2/NETA	4	2 (50.0)	NC	NC	NC	NC	
Placebo	2	0	[NC;NC]	[NC;NC]	[NC;NC]		

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group.
Amenorrhea is defined as reported amenorrhea, spotting, or negligible bleeding (menstrual blood loss < 5 mL) with supporting eDiary compliance at 2 consecutive visits.
[1] OR (95% CI) based on a logistic regression model adjusting for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates.
[2] RR (95% CI) based on a Cochran-Mantel-Haenszel approach stratified by study.
[3] RD (95% CI) based on a Mantel-Haenszel approach stratified by study. 95% CIs are based on the approximation to the normal distribution using the Sato estimator for the standard error.
[4] P-value based on a Cochran-Mantel-Haenszel test stratified by study.
[5] Interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the OR (95% CI). Not reported subgroup levels are not included in estimation of the interaction p-value.
* Interaction p-value < 0.05.
A continuity correction is applied in estimation of the OR, RR and p-value if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum. No continuity correction is applied in the estimation of the RD.
The reference group for the OR, RR and RD is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with an event; OR: Odds ratio; RR: Risk ratio; RD: Risk difference; CI: Confidence interval; int: p-value for interaction; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; NC: Not calculated; NE: Non-estimable.

SOURCE: \Studies\MYV\MYV102\Analysis\Prod\Progs\TFLs\Tab_EFF_AMN_BIN.SAS
Date/time of run: 04MAR2021 17:13
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1.1.7 Time to Achieve Amenorrhea, by Subgroup (mITT Population)

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Table EFF.TTAMENO.MITT.Pooled.S9: Time to Achieve Amenorrhea, by Subgroup (mITT Population)								
Study: Pooled								
Treatment	**N**	**n (%)**	**Censored patients n (%)**	**Median time to 1st event [95% CI][1]**	**Median difference[1]**	**HR[2] [95% CI]**	**p-value[3]**	**p-value (int)[4]**
Race								
Black/African American								0.1124
Relugolix+E2/NETA	122	59 (48.4)	63 (51.6)	9.4 [6.1;NE]	NE	7.43 [4.14;13.32]	<.0001	
Placebo	141	14 (9.9)	127 (90.1)	NR [NE;NE]				
White								
Relugolix+E2/NETA	122	83 (68.0)	39 (32.0)	5.1 [5.0;8.1]	NE	21.89 [9.53;50.24]	<.0001	
Placebo	105	6 (5.7)	99 (94.3)	NR [NE;NE]				
Asian								
Relugolix+E2/NETA	1	1 (100.0)	0	NC [NC;NC]	NC	NC [NC;NC]	NC	
Placebo	3	1 (33.3)	2 (66.7)	NC [NC;NC]				
Others								
Relugolix+E2/NETA	5	3 (60.0)	2 (40.0)	5.0 [3.3;NE]	NE	>99 [NC;NC]	NC	
Placebo	6	0	6 (100.0)	NR [NE;NE]				
Not reported								
Relugolix+E2/NETA	3	3 (100.0)	0	NC [NC;NC]	NC	NC	NC	

Placebo	1	0	1 (100.0)	NC [NC;NC]		[NC;NC]		

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group.
Amenorrhea is defined as reported amenorrhea, spotting, or negligible bleeding (menstrual blood loss < 5 mL) with supporting eDiary compliance at 2 consecutive visits.
Patients without an event are censored at the last assessment date prior to their last dose of study drug.
[1] Based on Kaplan-Meier estimates. 95% CIs are calculated by log-log transformation of survivor function.
[2] Hazard Ratios (and 95% CIs) are based on a Cox proportional hazard model stratified by study and with treatment group, subgroup and a subgroup-by-treatment group as covariates. 95% CIs are based on the approximation to the normal distribution. The reference group for the HR is Placebo.
[3] Treatment P-value is based on the Wald test stratified by study.
[4] Interaction P-value is based on the subgroup-by-treatment interaction term in the proportional hazard model used to compute the Hazard Ratio and 95% CI.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with an event; HR: Hazard ratio; CI: Confidence interval; int: interaction; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; NC: Not calculated; NE: Non-estimable; NR: Not reached.

SOURCE: \Studies\MYV\MYV102\Analysis\Prod\Progs\TFLs\Tab_EFF_AMN_TTE.SAS
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Table EFF.TTAMENO.MITT.Pooled.S3: Time to Achieve Amenorrhea, by Subgroup (mITT Population)

Study: Pooled

Treatment	N	n (%)	Censored patients n (%)	Median time to 1st event [95% CI][1]	Median difference[1]	HR[2] [95% CI]	p-value[3]	p-value (int)[4]
Uterine Volume at Baseline (cm3)								
< 300 cm3								
Relugolix+E2/NETA	148	99 (66.9)	49 (33.1)	5.4 [5.0;9.1]	NE	16.53 [8.34;32.78]	<.0001	0.1249
Placebo	129	9 (7.0)	120 (93.0)	NR [NE;NE]				
>= 300 cm3								
Relugolix+E2/NETA	104	50 (48.1)	54 (51.9)	9.0 [5.1;NE]	NE	7.99 [4.25;15.02]	<.0001	
Placebo	127	12 (9.4)	115 (90.6)	NR [NE;NE]				
Missing								
Relugolix+E2/NETA	1	0	1 (100.0)	NC [NC;NC]	NC	NC [NC;NC]	NC	
Placebo	0	0	0	NC [NC;NC]				

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group.
Amenorrhea is defined as reported amenorrhea, spotting, or negligible bleeding (menstrual blood loss < 5 mL) with supporting eDiary compliance at 2 consecutive visits.
Patients without an event are censored at the last assessment date prior to their last dose of study drug.
[1] Based on Kaplan-Meier estimates. 95% CIs are calculated by log-log transformation of survivor function.
[2] Hazard Ratios (and 95% CIs) are based on a Cox proportional hazard model stratified by study and with treatment group, subgroup and a subgroup-by-treatment group as covariates. 95% CIs are based on the approximation to the normal distribution. The reference group for the HR is Placebo.
[3] Treatment P-value is based on the Wald test stratified by study.
[4] Interaction P-value is based on the subgroup-by-treatment interaction term in the proportional hazard model used to compute the Hazard Ratio and 95% CI.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with an event; HR: Hazard ratio; CI: Confidence interval; int: interaction; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; NC: Not calculated; NE: Non-estimable; NR: Not reached.

SOURCE: \Studies\MYV\MYV102\Analysis\Prod\Progs\TFLs\Tab_EFF_AMN_TTE.SAS
Date/time of run: 06APR2021 15:51
Analysis Plan: 13JAN2021

Table EFF.TTAMENO.MITT.Pooled.S1: Time to Achieve Amenorrhea, by Subgroup (mITT Population)								
Study: Pooled								
Treatment	**N**	**n (%)**	**Censored patients n (%)**	**Median time to 1st event [95% CI][1]**	**Median difference[1]**	**HR[2] [95% CI]**	**p-value[3]**	**p-value (int)[4]**
Age (years)								
< 40 years								0.2092
Relugolix+E2/NETA	62	35 (56.5)	27 (43.5)	8.7 [5.1;17.4]	NE	22.82 [7.01;74.21]	<.0001	
Placebo	78	3 (3.8)	75 (96.2)	NR [NE;NE]				
>= 40 years								
Relugolix+E2/NETA	191	114 (59.7)	77 (40.3)	6.4 [5.1;9.4]	NE	10.05 [6.10;16.57]	<.0001	
Placebo	178	18 (10.1)	160 (89.9)	NR [NE;NE]				

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group.
Amenorrhea is defined as reported amenorrhea, spotting, or negligible bleeding (menstrual blood loss < 5 mL) with supporting eDiary compliance at 2 consecutive visits.
Patients without an event are censored at the last assessment date prior to their last dose of study drug.
[1] Based on Kaplan-Meier estimates. 95% CIs are calculated by log-log transformation of survivor function.
[2] Hazard Ratios (and 95% CIs) are based on a Cox proportional hazard model stratified by study and with treatment group, subgroup and a subgroup-by-treatment group as covariates. 95% CIs are based on the approximation to the normal distribution. The reference group for the HR is Placebo.
[3] Treatment P-value is based on the Wald test stratified by study.
[4] Interaction P-value is based on the subgroup-by-treatment interaction term in the proportional hazard model used to compute the Hazard Ratio and 95% CI.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with an event; HR: Hazard ratio; CI: Confidence interval; int: interaction; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; NE: Non-estimable; NR: Not reached.

SOURCE: \Studies\MYV\MYV102\Analysis\Prod\Progs\TFLs\Tab_EFF_AMN_TTE.SAS
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Table EFF.TTAMENO.MITT.Pooled.S5: Time to Achieve Amenorrhea, by Subgroup (mITT Population)

Study: Pooled

Treatment	N	n (%)	Censored patients n (%)	Median time to 1st event [95% CI][1]	Median difference[1]	HR[2] [95% CI]	p-value[3]	p-value (int)[4]
MBL Volume at Baseline (mL)								
< 225 mL								
Relugolix+E2/NETA	164	106 (64.6)	58 (35.4)	5.3 [5.0;8.9]	NE	13.97 [7.98;24.46]	<.0001	0.3595
Placebo	171	14 (8.2)	157 (91.8)	NR [NE;NE]				
>= 225 mL								
Relugolix+E2/NETA	89	43 (48.3)	46 (51.7)	11.3 [8.0;NE]	NE	8.86 [3.98;19.71]	<.0001	
Placebo	85	7 (8.2)	78 (91.8)	NR [NE;NE]				

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group.
Amenorrhea is defined as reported amenorrhea, spotting, or negligible bleeding (menstrual blood loss < 5 mL) with supporting eDiary compliance at 2 consecutive visits.
Patients without an event are censored at the last assessment date prior to their last dose of study drug.
[1] Based on Kaplan-Meier estimates. 95% CIs are calculated by log-log transformation of survivor function.
[2] Hazard Ratios (and 95% CIs) are based on a Cox proportional hazard model stratified by study and with treatment group, subgroup and a subgroup-by-treatment group as covariates. 95% CIs are based on the approximation to the normal distribution. The reference group for the HR is Placebo.
[3] Treatment P-value is based on the Wald test stratified by study.
[4] Interaction P-value is based on the subgroup-by-treatment interaction term in the proportional hazard model used to compute the Hazard Ratio and 95% CI.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with an event; HR: Hazard ratio; CI: Confidence interval; int: interaction; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; NE: Non-estimable; NR: Not reached.

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Table EFF.TTAMENO.MITT.Pooled.S8: Time to Achieve Amenorrhea, by Subgroup (mITT Population)								
Study: Pooled								
Treatment	**N**	**n (%)**	**Censored patients n (%)**	**Median time to 1st event [95% CI][1]**	**Median difference[1]**	**HR[2] [95% CI]**	**p-value[3]**	**p-value (int)[4]**
Ethnicity								
Hispanic or Latino								0.9023
Relugolix+E2/NETA	52	34 (65.4)	18 (34.6)	5.9 [5.0;16.1]	NE	11.23 [4.38;28.78]	<.0001	
Placebo	55	5 (9.1)	50 (90.9)	NR [NE;NE]				
Not Hispanic or Latino								
Relugolix+E2/NETA	197	113 (57.4)	84 (42.6)	8.3 [5.1;11.3]	NE	12.01 [7.10;20.33]	<.0001	
Placebo	199	16 (8.0)	183 (92.0)	NR [NE;NE]				
Not reported								
Relugolix+E2/NETA	4	2 (50.0)	2 (50.0)	NC [NC;NC]	NC	NC [NC;NC]	NC	
Placebo	2	0	2 (100.0)	NC [NC;NC]				

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group.
Amenorrhea is defined as reported amenorrhea, spotting, or negligible bleeding (menstrual blood loss < 5 mL) with supporting eDiary compliance at 2 consecutive visits.
Patients without an event are censored at the last assessment date prior to their last dose of study drug.
[1] Based on Kaplan-Meier estimates. 95% CIs are calculated by log-log transformation of survivor function.
[2] Hazard Ratios (and 95% CIs) are based on a Cox proportional hazard model stratified by study and with treatment group, subgroup and a subgroup-by-treatment group as covariates. 95% CIs are based on the approximation to the normal distribution. The reference group for the HR is Placebo.
[3] Treatment P-value is based on the Wald test stratified by study.
[4] Interaction P-value is based on the subgroup-by-treatment interaction term in the proportional hazard model used to compute the Hazard Ratio and 95% CI.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with an event; HR: Hazard ratio; CI: Confidence interval; int: interaction; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; NC: Not calculated; NE: Non-estimable; NR: Not reached.

SOURCE: \Studies\MYV\MYV102\Analysis\Prod\Progs\TFLs\Tab_EFF_AMN_TTE.SAS
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Analysis Plan: 13JAN2021

Table EFF.TTAMENO.MITT.Pooled.S4: Time to Achieve Amenorrhea, by Subgroup (mITT Population)								
Study: Pooled								
Treatment	**N**	**n (%)**	**Censored patients n (%)**	**Median time to 1st event [95% CI][1]**	**Median difference[1]**	**HR[2] [95% CI]**	**p-value[3]**	**p-value (int)[4]**
Maximum NRS Pain Score at Baseline								
< 4								0.9444
Relugolix+E2/NETA	73	44 (60.3)	29 (39.7)	8.3 [5.0;12.6]	NE	11.58 [4.58;29.27]	<.0001	
Placebo	62	5 (8.1)	57 (91.9)	NR [NE;NE]				
>= 4								
Relugolix+E2/NETA	177	104 (58.8)	73 (41.2)	8.0 [5.1;10.0]	NE	12.03 [7.09;20.40]	<.0001	
Placebo	190	16 (8.4)	174 (91.6)	NR [NE;NE]				
Missing								
Relugolix+E2/NETA	3	1 (33.3)	2 (66.7)	NC [NC;NC]	NC	NC [NC;NC]	NC	
Placebo	4	0	4 (100.0)	NC [NC;NC]				

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group.
Amenorrhea is defined as reported amenorrhea, spotting, or negligible bleeding (menstrual blood loss < 5 mL) with supporting eDiary compliance at 2 consecutive visits.
Patients without an event are censored at the last assessment date prior to their last dose of study drug.
[1] Based on Kaplan-Meier estimates. 95% CIs are calculated by log-log transformation of survivor function.
[2] Hazard Ratios (and 95% CIs) are based on a Cox proportional hazard model stratified by study and with treatment group, subgroup and a subgroup-by-treatment group as covariates. 95% CIs are based on the approximation to the normal distribution. The reference group for the HR is Placebo.
[3] Treatment P-value is based on the Wald test stratified by study.
[4] Interaction P-value is based on the subgroup-by-treatment interaction term in the proportional hazard model used to compute the Hazard Ratio and 95% CI.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with an event; HR: Hazard ratio; CI: Confidence interval; int: interaction; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; NC: Not calculated; NE: Non-estimable; NR: Not reached.

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1.1.8 Time to Achieve Sustained Amenorrhea, by Subgroup (mITT Population)

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Table EFF.TTSAMENO.MITT.Pooled.S5: Time to Achieve Sustained Amenorrhea, by Subgroup (mITT Population)

Study: Pooled

Treatment	N	n (%)	Censored patients n (%)	Median time to 1st event [95% CI][1]	Median difference[1]	HR[2] [95% CI]	p-value[3]	p-value (int)[4]
MBL Volume at Baseline (mL)								
< 225 mL								
Relugolix+E2/NETA	164	91 (55.5)	73 (44.5)	10.0 [5.4;16.7]	NE	30.47 [12.37;75.05]	<.0001	0.0524
Placebo	171	5 (2.9)	166 (97.1)	NR [NE;NE]				
>= 225 mL								
Relugolix+E2/NETA	89	39 (43.8)	50 (56.2)	NR [NE;NE]	NE	8.89 [3.76;21.02]	<.0001	
Placebo	85	6 (7.1)	79 (92.9)	NR [NE;NE]				

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group.
Amenorrhea is defined as reported amenorrhea, spotting, or negligible bleeding (menstrual blood loss < 5 mL) with supporting eDiary compliance at 2 consecutive visits. Sustained amenorrhea is defined as patients time to achieve and maintain amenorrhea until the date of last study drug.
Patients without an event are censored at the last assessment date prior to their last dose of study drug.
[1] Based on Kaplan-Meier estimates. 95% CIs are calculated by log-log transformation of survivor function.
[2] Hazard Ratios (and 95% CIs) are based on a Cox proportional hazard model stratified by study and with treatment group, subgroup and a subgroup-by-treatment group as covariates. 95% CIs are based on the approximation to the normal distribution. The reference group for the HR is Placebo.
[3] Treatment P-value is based on the Wald test stratified by study.
[4] Interaction P-value is based on the subgroup-by-treatment interaction term in the proportional hazard model used to compute the Hazard Ratio and 95% CI.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with an event; HR: Hazard ratio; CI: Confidence interval; int: interaction; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; NE: Non-estimable; NR: Not reached.

SOURCE: \Studies\MYV\MYV102\Analysis\Prod\Progs\TFLs\Tab_EFF_AMN_TTE.SAS
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Table EFF.TTSAMENO.MITT.Pooled.S2: Time to Achieve Sustained Amenorrhea, by Subgroup (mITT Population)

Study: Pooled

Treatment	N	n (%)	Censored patients n (%)	Median time to 1st event [95% CI][1]	Median difference[1]	HR[2] [95% CI]	p-value[3]	p-value (int)[4]
BMI (kg/m2) at Baseline								
< 30								0.0541
Relugolix+E2/NETA	119	65 (54.6)	54 (45.4)	8.9 [5.4;16.9]	NE	51.49 [12.60;210.44]	<.0001	
Placebo	115	2 (1.7)	113 (98.3)	NR [NE;NE]				
>= 30								
Relugolix+E2/NETA	133	64 (48.1)	69 (51.9)	16.3 [9.3;NE]	NE	11.00 [5.47;22.12]	<.0001	
Placebo	141	9 (6.4)	132 (93.6)	NR [NE;NE]				
Missing								
Relugolix+E2/NETA	1	1 (100.0)	0	NC [NC;NC]	NC	NC [NC;NC]	NC	
Placebo	0	0	0	NC [NC;NC]				

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group.
Amenorrhea is defined as reported amenorrhea, spotting, or negligible bleeding (menstrual blood loss < 5 mL) with supporting eDiary compliance at 2 consecutive visits. Sustained amenorrhea is defined as patients time to achieve and maintain amenorrhea until the date of last study drug.
Patients without an event are censored at the last assessment date prior to their last dose of study drug.
[1] Based on Kaplan-Meier estimates. 95% CIs are calculated by log-log transformation of survivor function.
[2] Hazard Ratios (and 95% CIs) are based on a Cox proportional hazard model stratified by study and with treatment group, subgroup and a subgroup-by-treatment group as covariates. 95% CIs are based on the approximation to the normal distribution. The reference group for the HR is Placebo.
[3] Treatment P-value is based on the Wald test stratified by study.
[4] Interaction P-value is based on the subgroup-by-treatment interaction term in the proportional hazard model used to compute the Hazard Ratio and 95% CI.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with an event; HR: Hazard ratio; CI: Confidence interval; int: interaction; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; NC: Not calculated; NE: Non-estimable; NR: Not reached.

SOURCE: \Studies\MYV\MYV102\Analysis\Prod\Progs\TFLs\Tab_EFF_AMN_TTE.SAS
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Table EFF.TTSAMENO.MITT.Pooled.S3: Time to Achieve Sustained Amenorrhea, by Subgroup (mITT Population)

Study: Pooled

Treatment	N	n (%)	Censored patients n (%)	Median time to 1st event [95% CI][1]	Median difference[1]	HR[2] [95% CI]	p-value[3]	p-value (int)[4]
Uterine Volume at Baseline (cm3)								
< 300 cm3								
Relugolix+E2/NETA	148	87 (58.8)	61 (41.2)	9.4 [5.3;16.1]	NE	30.33 [11.12;82.73]	<.0001	0.1175
Placebo	129	4 (3.1)	125 (96.9)	NR [NE;NE]				
>= 300 cm3								
Relugolix+E2/NETA	104	43 (41.3)	61 (58.7)	NR [NE;NE]	NE	10.90 [4.90;24.25]	<.0001	
Placebo	127	7 (5.5)	120 (94.5)	NR [NE;NE]				
Missing								
Relugolix+E2/NETA	1	0	1 (100.0)	NC [NC;NC]	NC	NC [NC;NC]	NC	
Placebo	0	0	0	NC [NC;NC]				

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group.
Amenorrhea is defined as reported amenorrhea, spotting, or negligible bleeding (menstrual blood loss < 5 mL) with supporting eDiary compliance at 2 consecutive visits. Sustained amenorrhea is defined as patients time to achieve and maintain amenorrhea until the date of last study drug.
Patients without an event are censored at the last assessment date prior to their last dose of study drug.
[1] Based on Kaplan-Meier estimates. 95% CIs are calculated by log-log transformation of survivor function.
[2] Hazard Ratios (and 95% CIs) are based on a Cox proportional hazard model stratified by study and with treatment group, subgroup and a subgroup-by-treatment group as covariates. 95% CIs are based on the approximation to the normal distribution. The reference group for the HR is Placebo.
[3] Treatment P-value is based on the Wald test stratified by study.
[4] Interaction P-value is based on the subgroup-by-treatment interaction term in the proportional hazard model used to compute the Hazard Ratio and 95% CI.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with an event; HR: Hazard ratio; CI: Confidence interval; int: interaction; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; NC: Not calculated; NE: Non-estimable; NR: Not reached.

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Table EFF.TTSAMENO.MITT.Pooled.S4: Time to Achieve Sustained Amenorrhea, by Subgroup (mITT Population)

Study: Pooled

Treatment	N	n (%)	Censored patients n (%)	Median time to 1st event [95% CI][1]	Median difference[1]	HR[2] [95% CI]	p-value[3]	p-value (int)[4]
Maximum NRS Pain Score at Baseline								
< 4								
Relugolix+E2/NETA	73	41 (56.2)	32 (43.8)	8.9 [5.1;16.1]	NE	55.70 [7.66;405.31]	<.0001	0.2069
Placebo	62	1 (1.6)	61 (98.4)	NR [NE;NE]				
>= 4								
Relugolix+E2/NETA	177	88 (49.7)	89 (50.3)	16.1 [8.3;NE]	NE	14.51 [7.54;27.94]	<.0001	
Placebo	190	10 (5.3)	180 (94.7)	NR [NE;NE]				
Missing								
Relugolix+E2/NETA	3	1 (33.3)	2 (66.7)	NC [NC;NC]	NC	NC [NC;NC]	NC	
Placebo	4	0	4 (100.0)	NC [NC;NC]				

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group.
Amenorrhea is defined as reported amenorrhea, spotting, or negligible bleeding (menstrual blood loss < 5 mL) with supporting eDiary compliance at 2 consecutive visits. Sustained amenorrhea is defined as patients time to achieve and maintain amenorrhea until the date of last study drug.
Patients without an event are censored at the last assessment date prior to their last dose of study drug.
[1] Based on Kaplan-Meier estimates. 95% CIs are calculated by log-log transformation of survivor function.
[2] Hazard Ratios (and 95% CIs) are based on a Cox proportional hazard model stratified by study and with treatment group, subgroup and a subgroup-by-treatment group as covariates. 95% CIs are based on the approximation to the normal distribution. The reference group for the HR is Placebo.
[3] Treatment P-value is based on the Wald test stratified by study.
[4] Interaction P-value is based on the subgroup-by-treatment interaction term in the proportional hazard model used to compute the Hazard Ratio and 95% CI.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with an event; HR: Hazard ratio; CI: Confidence interval; int: interaction; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; NC: Not calculated; NE: Non-estimable; NR: Not reached.

SOURCE: \Studies\MYV\MYV102\Analysis\Prod\Progs\TFLs\Tab_EFF_AMN_TTE.SAS
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Table EFF.TTSAMENO.MITT.Pooled.S9: Time to Achieve Sustained Amenorrhea, by Subgroup (mITT Population)

Study: Pooled

Treatment	N	n (%)	Censored patients n (%)	Median time to 1st event [95% CI][1]	Median difference[1]	HR[2] [95% CI]	p-value[3]	p-value (int)[4]
Race								
Black/African American								
Relugolix+E2/NETA	122	48 (39.3)	74 (60.7)	NR [NE;NE]	NE	12.90 [5.52;30.18]	<.0001	0.4940
Placebo	141	6 (4.3)	135 (95.7)	NR [NE;NE]				
White								
Relugolix+E2/NETA	122	76 (62.3)	46 (37.7)	5.4 [5.0;12.7]	NE	28.64 [10.46;78.41]	<.0001	
Placebo	105	4 (3.8)	101 (96.2)	NR [NE;NE]				
Asian								
Relugolix+E2/NETA	1	1 (100.0)	0	NC [NC;NC]	NC	NC [NC;NC]	NC	
Placebo	3	1 (33.3)	2 (66.7)	NC [NC;NC]				
Others								
Relugolix+E2/NETA	5	2 (40.0)	3 (60.0)	NR [NE;NE]	NE	>99 [NC;NC]	NC	
Placebo	6	0	6 (100.0)	NR [NE;NE]				
Not reported								
Relugolix+E2/NETA	3	3 (100.0)	0	NC [NC;NC]	NC	NC [NC;NC]	NC	
Placebo	1	0	1 (100.0)	NC [NC;NC]				

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group.
Amenorrhea is defined as reported amenorrhea, spotting, or negligible bleeding (menstrual blood loss < 5 mL) with supporting eDiary compliance at 2 consecutive visits. Sustained amenorrhea is defined as patients time to achieve and maintain amenorrhea until the date of last study drug.
Patients without an event are censored at the last assessment date prior to their last dose of study drug.
[1] Based on Kaplan-Meier estimates. 95% CIs are calculated by log-log transformation of survivor function.
[2] Hazard Ratios (and 95% CIs) are based on a Cox proportional hazard model stratified by study and with treatment group, subgroup and a subgroup-by-treatment group as covariates. 95% CIs are based on the approximation to the normal distribution. The reference group for the HR is Placebo.
[3] Treatment P-value is based on the Wald test stratified by study.
[4] Interaction P-value is based on the subgroup-by-treatment interaction term in the proportional hazard model used to compute the Hazard Ratio and 95% CI.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with an event; HR: Hazard ratio; CI: Confidence interval; int: interaction; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; NC: Not calculated; NE: Non-estimable; NR: Not reached.

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Table EFF.TTSAMENO.MITT.Pooled.S1: Time to Achieve Sustained Amenorrhea, by Subgroup (mITT Population)

Study: Pooled

Treatment	N	n (%)	Censored patients n (%)	Median time to 1st event [95% CI][1]	Median difference[1]	HR[2] [95% CI]	p-value[3]	p-value (int)[4]
Age (years)								
< 40 years								
Relugolix+E2/NETA	62	28 (45.2)	34 (54.8)	17.4 [8.1;NE]	NE	24.99 [5.96;104.84]	<.0001	0.6222
Placebo	78	2 (2.6)	76 (97.4)	NR [NE;NE]				
>= 40 years								
Relugolix+E2/NETA	191	102 (53.4)	89 (46.6)	12.6 [6.0;17.0]	NE	16.77 [8.47;33.20]	<.0001	
Placebo	178	9 (5.1)	169 (94.9)	NR [NE;NE]				

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group.
Amenorrhea is defined as reported amenorrhea, spotting, or negligible bleeding (menstrual blood loss < 5 mL) with supporting eDiary compliance at 2 consecutive visits. Sustained amenorrhea is defined as patients time to achieve and maintain amenorrhea until the date of last study drug.
Patients without an event are censored at the last assessment date prior to their last dose of study drug.
[1] Based on Kaplan-Meier estimates. 95% CIs are calculated by log-log transformation of survivor function.
[2] Hazard Ratios (and 95% CIs) are based on a Cox proportional hazard model stratified by study and with treatment group, subgroup and a subgroup-by-treatment group as covariates. 95% CIs are based on the approximation to the normal distribution. The reference group for the HR is Placebo.
[3] Treatment P-value is based on the Wald test stratified by study.
[4] Interaction P-value is based on the subgroup-by-treatment interaction term in the proportional hazard model used to compute the Hazard Ratio and 95% CI.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with an event; HR: Hazard ratio; CI: Confidence interval; int: interaction; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; NE: Non-estimable; NR: Not reached.

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Table EFF.TTSAMENO.MITT.Pooled.S8: Time to Achieve Sustained Amenorrhea, by Subgroup (mITT Population)

Study: Pooled

Treatment	N	n (%)	Censored patients n (%)	Median time to 1st event [95% CI][1]	Median difference[1]	HR[2] [95% CI]	p-value[3]	p-value (int)[4]
Ethnicity								
Hispanic or Latino								
Relugolix+E2/NETA	52	30 (57.7)	22 (42.3)	9.3 [5.0;NE]	NE	15.52 [4.72;51.00]	<.0001	0.7647
Placebo	55	3 (5.5)	52 (94.5)	NR [NE;NE]				
Not Hispanic or Latino								
Relugolix+E2/NETA	197	98 (49.7)	99 (50.3)	13.1 [8.9;NE]	NE	19.20 [9.32;39.53]	<.0001	
Placebo	199	8 (4.0)	191 (96.0)	NR [NE;NE]				
Not reported								
Relugolix+E2/NETA	4	2 (50.0)	2 (50.0)	NC [NC;NC]	NC	NC [NC;NC]	NC	
Placebo	2	0	2 (100.0)	NC [NC;NC]				

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group.
Amenorrhea is defined as reported amenorrhea, spotting, or negligible bleeding (menstrual blood loss < 5 mL) with supporting eDiary compliance at 2 consecutive visits. Sustained amenorrhea is defined as patients time to achieve and maintain amenorrhea until the date of last study drug.
Patients without an event are censored at the last assessment date prior to their last dose of study drug.
[1] Based on Kaplan-Meier estimates. 95% CIs are calculated by log-log transformation of survivor function.
[2] Hazard Ratios (and 95% CIs) are based on a Cox proportional hazard model stratified by study and with treatment group, subgroup and a subgroup-by-treatment group as covariates. 95% CIs are based on the approximation to the normal distribution. The reference group for the HR is Placebo.
[3] Treatment P-value is based on the Wald test stratified by study.
[4] Interaction P-value is based on the subgroup-by-treatment interaction term in the proportional hazard model used to compute the Hazard Ratio and 95% CI.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with an event; HR: Hazard ratio; CI: Confidence interval; int: interaction; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; NC: Not calculated; NE: Non-estimable; NR: Not reached.

SOURCE: \Studies\MYV\MYV102\Analysis\Prod\Progs\TFLs\Tab_EFF_AMN_TTE.SAS
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Table EFF.TTSAMENO.MITT.Pooled.S7: Time to Achieve Sustained Amenorrhea, by Subgroup (mITT Population)

Study: Pooled

Treatment	N	n (%)	Censored patients n (%)	Median time to 1st event [95% CI][1]	Median difference[1]	HR[2] [95% CI]	p-value[3]	p-value (int)[4]
Geographic Region II								
Europe								0.9774
Relugolix+E2/NETA	41	32 (78.0)	9 (22.0)	5.0 [4.7;8.3]	NE	>99 [NC;NC]	NC	
Placebo	42	0	42 (100.0)	NR [NE;NE]				
Rest of World (including the US)								
Relugolix+E2/NETA	212	98 (46.2)	114 (53.8)	17.0 [12.0;NE]	NE	13.24 [7.09;24.71]	<.0001	
Placebo	214	11 (5.1)	203 (94.9)	NR [NE;NE]				

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group.
Amenorrhea is defined as reported amenorrhea, spotting, or negligible bleeding (menstrual blood loss < 5 mL) with supporting eDiary compliance at 2 consecutive visits. Sustained amenorrhea is defined as patients time to achieve and maintain amenorrhea until the date of last study drug.
Patients without an event are censored at the last assessment date prior to their last dose of study drug.
[1] Based on Kaplan-Meier estimates. 95% CIs are calculated by log-log transformation of survivor function.
[2] Hazard Ratios (and 95% CIs) are based on a Cox proportional hazard model stratified by study and with treatment group, subgroup and a subgroup-by-treatment group as covariates. 95% CIs are based on the approximation to the normal distribution. The reference group for the HR is Placebo.
[3] Treatment P-value is based on the Wald test stratified by study.
[4] Interaction P-value is based on the subgroup-by-treatment interaction term in the proportional hazard model used to compute the Hazard Ratio and 95% CI.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with an event; HR: Hazard ratio; CI: Confidence interval; int: interaction; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; NC: Not calculated; NE: Non-estimable; NR: Not reached.

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Table EFF.TTSAMENO.MITT.Pooled.S6: Time to Achieve Sustained Amenorrhea, by Subgroup (mITT Population)

Study: Pooled

Treatment	N	n (%)	Censored patients n (%)	Median time to 1st event [95% CI][1]	Median difference[1]	HR[2] [95% CI]	p-value[3]	p-value (int)[4]
Geographic Region I								
North America								
Relugolix+E2/NETA	191	87 (45.5)	104 (54.5)	17.0 [12.3;NE]	NE	11.72 [6.25;21.96]	<.0001	0.9804
Placebo	194	11 (5.7)	183 (94.3)	NR [NE;NE]				
Rest of World								
Relugolix+E2/NETA	62	43 (69.4)	19 (30.6)	5.3 [4.9;9.3]	NE	>99 [NC;NC]	NC	
Placebo	62	0	62 (100.0)	NR [NE;NE]				

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group.
Amenorrhea is defined as reported amenorrhea, spotting, or negligible bleeding (menstrual blood loss < 5 mL) with supporting eDiary compliance at 2 consecutive visits. Sustained amenorrhea is defined as patients time to achieve and maintain amenorrhea until the date of last study drug.
Patients without an event are censored at the last assessment date prior to their last dose of study drug.
[1] Based on Kaplan-Meier estimates. 95% CIs are calculated by log-log transformation of survivor function.
[2] Hazard Ratios (and 95% CIs) are based on a Cox proportional hazard model stratified by study and with treatment group, subgroup and a subgroup-by-treatment group as covariates. 95% CIs are based on the approximation to the normal distribution. The reference group for the HR is Placebo.
[3] Treatment P-value is based on the Wald test stratified by study.
[4] Interaction P-value is based on the subgroup-by-treatment interaction term in the proportional hazard model used to compute the Hazard Ratio and 95% CI.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with an event; HR: Hazard ratio; CI: Confidence interval; int: interaction; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; NC: Not calculated; NE: Non-estimable; NR: Not reached.

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1.1.9 Proportion of Patients with Maximum NRS Score <= 1 During the Last 35 Days of Treatment, by Subgroup (Pain Evaluable Population)

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Table EFF.MAXNRS1.PEV.Pooled.S6: Proportion of Patients with Maximum NRS Score <= 1 During the Last 35 Days of Treatment, by Subgroup (Pain Evaluable Population)

Study: Pooled

Treatment	N	n (%)	OR[1] [95% CI]	RR[2] [95% CI]	RD[3] [95% CI]	p-value[4]	p-value (int)[5]
Geographic Region I							
North America							0.0792
Relugolix+E2/NETA	96	43 (44.8)	4.00 [2.11;7.58]	2.64 [1.66;4.20]	0.28 [0.16;0.40]	<.0001	
Placebo	112	19 (17.0)					
Rest of World							
Relugolix+E2/NETA	30	14 (46.7)	16.46 [3.34;81.18]	9.07 [2.24;36.81]	0.42 [0.22;0.61]	<.0001	
Placebo	39	2 (5.1)					

Post hoc analysis. The denominator for percentages is the number of patients in the pain evaluable population for each treatment group.
Pain evaluable population is the subset of mITT patients who had a maximum baseline NRS pain score >= 4 and who had at least 28 days [80% of the last 35 days of treatment] of pain scores recorded in their eDiary.)
[1] OR (95% CI) based on a logistic regression model adjusting for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates.
[2] RR (95% CI) based on a Cochran-Mantel-Haenszel approach stratified by study.
[3] RD (95% CI) based on a Mantel-Haenszel approach stratified by study. 95% CIs are based on the approximation to the normal distribution using the Sato estimator for the standard error.
[4] P-value based on a Cochran-Mantel-Haenszel test stratified by study.
[5] Interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the OR (95% CI). Not reported subgroup levels are not included in estimation of the interaction p-value.
* Interaction p-value < 0.05.
A continuity correction is applied in estimation of the OR, RR and p-value if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum. No continuity correction is applied in the estimation of the RD.
The reference group for the OR, RR and RD is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with an event; OR: Odds ratio; RR: Risk ratio; RD: Risk difference; CI: Confidence interval; int: p-value for interaction; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; NC: Not calculated.

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Table EFF.MAXNRS1.PEV.Pooled.S7: Proportion of Patients with Maximum NRS Score <= 1 During the Last 35 Days of Treatment, by Subgroup (Pain Evaluable Population)

Study: Pooled

Treatment	**N**	**n (%)**	**OR[1] [95% CI]**	**RR[2] [95% CI]**	**RD[3] [95% CI]**	**p-value[4]**	**p-value (int)[5]**
Geographic Region II							
Europe							0.1533
Relugolix+E2/NETA	18	9 (50.0)	16.18	8.79	0.46	0.0009	
Placebo	25	1 (4.0)	[2.47;106.05]	[1.69;45.70]	[0.21;0.70]		
Rest of World (including the US)							
Relugolix+E2/NETA	108	48 (44.4)	4.29	2.82	0.29	<.0001	
Placebo	126	20 (15.9)	[2.33;7.92]	[1.79;4.44]	[0.17;0.40]		

Post hoc analysis. The denominator for percentages is the number of patients in the pain evaluable population for each treatment group.
Pain evaluable population is the subset of mITT patients who had a maximum baseline NRS pain score >= 4 and who had at least 28 days [80% of the last 35 days of treatment] of pain scores recorded in their eDiary.)
[1] OR (95% CI) based on a logistic regression model adjusting for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates.
[2] RR (95% CI) based on a Cochran-Mantel-Haenszel approach stratified by study.
[3] RD (95% CI) based on a Mantel-Haenszel approach stratified by study. 95% CIs are based on the approximation to the normal distribution using the Sato estimator for the standard error.
[4] P-value based on a Cochran-Mantel-Haenszel test stratified by study.
[5] Interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the OR (95% CI). Not reported subgroup levels are not included in estimation of the interaction p-value.
* Interaction p-value < 0.05.
A continuity correction is applied in estimation of the OR, RR and p-value if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum. No continuity correction is applied in the estimation of the RD.
The reference group for the OR, RR and RD is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with an event; OR: Odds ratio; RR: Risk ratio; RD: Risk difference; CI: Confidence interval; int: p-value for interaction; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; NC: Not calculated.

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Table EFF.MAXNRS1.PEV.Pooled.S8: Proportion of Patients with Maximum NRS Score <= 1 During the Last 35 Days of Treatment, by Subgroup (Pain Evaluable Population)

Study: Pooled

Treatment	N	n (%)	OR[1] [95% CI]	RR[2] [95% CI]	RD[3] [95% CI]	p-value[4]	p-value (int)[5]
Ethnicity							
Hispanic or Latino							0.1568
Relugolix+E2/NETA	30	14 (46.7)	12.39	6.94	0.42	0.0010	
Placebo	32	2 (6.3)	[2.78;55.16]	[1.59;30.19]	[0.21;0.62]		
Not Hispanic or Latino							
Relugolix+E2/NETA	96	43 (44.8)	4.06	2.65	0.28	<.0001	
Placebo	117	19 (16.2)	[2.15;7.68]	[1.67;4.22]	[0.16;0.40]		
Not reported							
Relugolix+E2/NETA	0	0	NC	NC	NC	NC	
Placebo	2	0	[NC;NC]	[NC;NC]	[NC;NC]		

Post hoc analysis. The denominator for percentages is the number of patients in the pain evaluable population for each treatment group.
Pain evaluable population is the subset of mITT patients who had a maximum baseline NRS pain score >= 4 and who had at least 28 days [80% of the last 35 days of treatment] of pain scores recorded in their eDiary.)
[1] OR (95% CI) based on a logistic regression model adjusting for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates.
[2] RR (95% CI) based on a Cochran-Mantel-Haenszel approach stratified by study.
[3] RD (95% CI) based on a Mantel-Haenszel approach stratified by study. 95% CIs are based on the approximation to the normal distribution using the Sato estimator for the standard error.
[4] P-value based on a Cochran-Mantel-Haenszel test stratified by study.
[5] Interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the OR (95% CI). Not reported subgroup levels are not included in estimation of the interaction p-value.
* Interaction p-value < 0.05.
A continuity correction is applied in estimation of the OR, RR and p-value if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum. No continuity correction is applied in the estimation of the RD.
The reference group for the OR, RR and RD is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with an event; OR: Odds ratio; RR: Risk ratio; RD: Risk difference; CI: Confidence interval; int: p-value for interaction; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; NC: Not calculated.

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Table EFF.MAXNRS1.PEV.Pooled.S3: Proportion of Patients with Maximum NRS Score <= 1 During the Last 35 Days of Treatment, by Subgroup (Pain Evaluable Population)

Study: Pooled

Treatment	N	n (%)	OR[1] [95% CI]	RR[2] [95% CI]	RD[3] [95% CI]	p-value[4]	p-value (int)[5]
Uterine Volume at Baseline (cm3)							
< 300 cm3							0.2348
Relugolix+E2/NETA	73	36 (49.3)	7.20	4.05	0.37	<.0001	
Placebo	74	9 (12.2)	[3.11;16.65]	[2.11;7.79]	[0.24;0.51]		
>= 300 cm3							
Relugolix+E2/NETA	53	21 (39.6)	3.54	2.49	0.24	0.0023	
Placebo	77	12 (15.6)	[1.55;8.09]	[1.35;4.58]	[0.08;0.39]		

Post hoc analysis. The denominator for percentages is the number of patients in the pain evaluable population for each treatment group.
Pain evaluable population is the subset of mITT patients who had a maximum baseline NRS pain score >= 4 and who had at least 28 days [80% of the last 35 days of treatment] of pain scores recorded in their eDiary.)
[1] OR (95% CI) based on a logistic regression model adjusting for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates.
[2] RR (95% CI) based on a Cochran-Mantel-Haenszel approach stratified by study.
[3] RD (95% CI) based on a Mantel-Haenszel approach stratified by study. 95% CIs are based on the approximation to the normal distribution using the Sato estimator for the standard error.
[4] P-value based on a Cochran-Mantel-Haenszel test stratified by study.
[5] Interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the OR (95% CI). Not reported subgroup levels are not included in estimation of the interaction p-value.
* Interaction p-value < 0.05.
A continuity correction is applied in estimation of the OR, RR and p-value if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum. No continuity correction is applied in the estimation of the RD.
The reference group for the OR, RR and RD is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with an event; OR: Odds ratio; RR: Risk ratio; RD: Risk difference; CI: Confidence interval; int: p-value for interaction; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; NC: Not calculated.

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Table EFF.MAXNRS1.PEV.Pooled.S5: Proportion of Patients with Maximum NRS Score <= 1 During the Last 35 Days of Treatment, by Subgroup (Pain Evaluable Population)

Study: Pooled

Treatment	N	n (%)	OR[1] [95% CI]	RR[2] [95% CI]	RD[3] [95% CI]	p-value[4]	p-value (int)[5]
MBL Volume at Baseline (mL)							
< 225 mL							0.2683
Relugolix+E2/NETA	81	40 (49.4)	6.57	3.79	0.36	<.0001	
Placebo	100	13 (13.0)	[3.17;13.63]	[2.19;6.56]	[0.24;0.49]		
>= 225 mL							
Relugolix+E2/NETA	45	17 (37.8)	3.30	2.40	0.22	0.0151	
Placebo	51	8 (15.7)	[1.25;8.69]	[1.15;5.03]	[0.05;0.39]		

Post hoc analysis. The denominator for percentages is the number of patients in the pain evaluable population for each treatment group.
Pain evaluable population is the subset of mITT patients who had a maximum baseline NRS pain score >= 4 and who had at least 28 days [80% of the last 35 days of treatment] of pain scores recorded in their eDiary.)
[1] OR (95% CI) based on a logistic regression model adjusting for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates.
[2] RR (95% CI) based on a Cochran-Mantel-Haenszel approach stratified by study.
[3] RD (95% CI) based on a Mantel-Haenszel approach stratified by study. 95% CIs are based on the approximation to the normal distribution using the Sato estimator for the standard error.
[4] P-value based on a Cochran-Mantel-Haenszel test stratified by study.
[5] Interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the OR (95% CI). Not reported subgroup levels are not included in estimation of the interaction p-value.
* Interaction p-value < 0.05.
A continuity correction is applied in estimation of the OR, RR and p-value if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum. No continuity correction is applied in the estimation of the RD.
The reference group for the OR, RR and RD is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with an event; OR: Odds ratio; RR: Risk ratio; RD: Risk difference; CI: Confidence interval; int: p-value for interaction; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; NC: Not calculated.

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Table EFF.MAXNRS1.PEV.Pooled.S1: Proportion of Patients with Maximum NRS Score <= 1 During the Last 35 Days of Treatment, by Subgroup (Pain Evaluable Population)

Study: Pooled

Treatment	**N**	**n (%)**	**OR[1] [95% CI]**	**RR[2] [95% CI]**	**RD[3] [95% CI]**	**p-value[4]**	**p-value (int)[5]**
Age (years)							
< 40 years							
Relugolix+E2/NETA	28	6 (21.4)	2.62	2.35	0.13	0.1451	0.3004
Placebo	41	4 (9.8)	[0.66;10.35]	[0.73;7.55]	[-0.05;0.30]		
>= 40 years							
Relugolix+E2/NETA	98	51 (52.0)	5.93	3.34	0.36	<.0001	
Placebo	110	17 (15.5)	[3.09;11.39]	[2.08;5.36]	[0.24;0.48]		

Post hoc analysis. The denominator for percentages is the number of patients in the pain evaluable population for each treatment group.
Pain evaluable population is the subset of mITT patients who had a maximum baseline NRS pain score >= 4 and who had at least 28 days [80% of the last 35 days of treatment] of pain scores recorded in their eDiary.)
[1] OR (95% CI) based on a logistic regression model adjusting for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates.
[2] RR (95% CI) based on a Cochran-Mantel-Haenszel approach stratified by study.
[3] RD (95% CI) based on a Mantel-Haenszel approach stratified by study. 95% CIs are based on the approximation to the normal distribution using the Sato estimator for the standard error.
[4] P-value based on a Cochran-Mantel-Haenszel test stratified by study.
[5] Interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the OR (95% CI). Not reported subgroup levels are not included in estimation of the interaction p-value.
* Interaction p-value < 0.05.
A continuity correction is applied in estimation of the OR, RR and p-value if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum. No continuity correction is applied in the estimation of the RD.
The reference group for the OR, RR and RD is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with an event; OR: Odds ratio; RR: Risk ratio; RD: Risk difference; CI: Confidence interval; int: p-value for interaction; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; NC: Not calculated.

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Table EFF.MAXNRS1.PEV.Pooled.S2: Proportion of Patients with Maximum NRS Score <= 1 During the Last 35 Days of Treatment, by Subgroup (Pain Evaluable Population)

Study: Pooled

Treatment	N	n (%)	OR[1] [95% CI]	RR[2] [95% CI]	RD[3] [95% CI]	p-value[4]	p-value (int)[5]
BMI (kg/m2) at Baseline							
< 30							
Relugolix+E2/NETA	54	21 (38.9)	4.98	3.40	0.27	0.0004	0.8793
Placebo	70	8 (11.4)	[1.98;12.48]	[1.64;7.07]	[0.13;0.42]		
>= 30							
Relugolix+E2/NETA	71	36 (50.7)	5.46	3.17	0.35	<.0001	
Placebo	81	13 (16.0)	[2.56;11.63]	[1.83;5.49]	[0.21;0.49]		
Missing							
Relugolix+E2/NETA	1	0	NC	NC	NC	NC	
Placebo	0	0	[NC;NC]	[NC;NC]	[NC;NC]		

Post hoc analysis. The denominator for percentages is the number of patients in the pain evaluable population for each treatment group.
Pain evaluable population is the subset of mITT patients who had a maximum baseline NRS pain score >= 4 and who had at least 28 days [80% of the last 35 days of treatment] of pain scores recorded in their eDiary.)
[1] OR (95% CI) based on a logistic regression model adjusting for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates.
[2] RR (95% CI) based on a Cochran-Mantel-Haenszel approach stratified by study.
[3] RD (95% CI) based on a Mantel-Haenszel approach stratified by study. 95% CIs are based on the approximation to the normal distribution using the Sato estimator for the standard error.
[4] P-value based on a Cochran-Mantel-Haenszel test stratified by study.
[5] Interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the OR (95% CI). Missing subgroup levels are not included in estimation of the interaction p-value. * Interaction p-value < 0.05.
A continuity correction is applied in estimation of the OR, RR and p-value if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum. No continuity correction is applied in the estimation of the RD.
The reference group for the OR, RR and RD is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with an event; OR: Odds ratio; RR: Risk ratio; RD: Risk difference; CI: Confidence interval; int: p-value for interaction; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; NC: Not calculated.

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1.1.9.1 Proportion of Patients with Maximum NRS Score <= 1 During the Last 35 Days of Treatment, by Subgroup (mITT Population)

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Table EFF.MAXNRS1.MITT.Pooled.S9: Proportion of Patients with Maximum NRS Score <= 1 During the Last 35 Days of Treatment, by Subgroup (mITT Population)

Study: Pooled

Treatment	N	n (%)	OR[1] [95% CI]	RR[2] [95% CI]	RD[3] [95% CI]	p-value[4]	p-value (int)[5]
Race							
Black/African American							0.0585
Relugolix+E2/NETA	122	52 (42.6)	2.09	1.63	0.16	0.0049	
Placebo	141	37 (26.2)	[1.24;3.51]	[1.15;2.30]	[0.05;0.28]		
White							
Relugolix+E2/NETA	122	64 (52.5)	4.69	2.76	0.33	<.0001	
Placebo	105	20 (19.0)	[2.57;8.57]	[1.80;4.23]	[0.22;0.45]		
Asian							
Relugolix+E2/NETA	1	1 (100.0)	NC	NC	NC	NC	
Placebo	3	2 (66.7)	[NC;NC]	[NC;NC]	[NC;NC]		
Others							
Relugolix+E2/NETA	5	1 (20.0)	0.61	0.63	-0.25	0.6275	
Placebo	6	2 (33.3)	[0.05;6.87]	[0.11;3.50]	[-0.78;0.28]		
Not reported							
Relugolix+E2/NETA	3	0	NC	NC	NC	NC	
Placebo	1	0	[NC;NC]	[NC;NC]	[NC;NC]		

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group.
[1] OR (95% CI) based on a logistic regression model adjusting for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates.
[2] RR (95% CI) based on a Cochran-Mantel-Haenszel approach stratified by study.
[3] RD (95% CI) based on a Mantel-Haenszel approach stratified by study. 95% CIs are based on the approximation to the normal distribution using the Sato estimator for the standard error.
[4] P-value based on a Cochran-Mantel-Haenszel test stratified by study.
[5] Interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the OR (95% CI). Not reported subgroup levels are not included in estimation of the interaction p-value.
A continuity correction is applied in estimation of the OR, RR and p-value if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum. No continuity correction is applied in the estimation of the RD.
The reference group for the OR, RR and RD is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with an event; OR: Odds ratio; RR: Risk ratio; RD: Risk difference; CI: Confidence interval; int: p-value for interaction; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; NC: Not calculated.

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Table EFF.MAXNRS1.MITT.Pooled.S1: Proportion of Patients with Maximum NRS Score <= 1 During the Last 35 Days of Treatment, by Subgroup (mITT Population)

Study: Pooled

Treatment	N	n (%)	OR[1] [95% CI]	RR[2] [95% CI]	RD[3] [95% CI]	p-value[4]	p-value (int)[5]
Age (years)							
< 40 years							0.1000
Relugolix+E2/NETA	62	20 (32.3)	1.59	1.39	0.09	0.2315	
Placebo	78	18 (23.1)	[0.75;3.36]	[0.81;2.40]	[-0.06;0.24]		
>= 40 years							
Relugolix+E2/NETA	191	98 (51.3)	3.31	2.12	0.27	<.0001	
Placebo	178	43 (24.2)	[2.12;5.17]	[1.58;2.85]	[0.18;0.37]		

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group.
[1] OR (95% CI) based on a logistic regression model adjusting for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates.
[2] RR (95% CI) based on a Cochran-Mantel-Haenszel approach stratified by study.
[3] RD (95% CI) based on a Mantel-Haenszel approach stratified by study. 95% CIs are based on the approximation to the normal distribution using the Sato estimator for the standard error.
[4] P-value based on a Cochran-Mantel-Haenszel test stratified by study.
[5] Interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the OR (95% CI). Not reported subgroup levels are not included in estimation of the interaction p-value.
A continuity correction is applied in estimation of the OR, RR and p-value if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum. No continuity correction is applied in the estimation of the RD.
The reference group for the OR, RR and RD is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with an event; OR: Odds ratio; RR: Risk ratio; RD: Risk difference; CI: Confidence interval; int: p-value for interaction; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; NC: Not calculated.

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Table EFF.MAXNRS1.MITT.Pooled.S3: Proportion of Patients with Maximum NRS Score <= 1 During the Last 35 Days of Treatment, by Subgroup (mITT Population)

Study: Pooled

Treatment	N	n (%)	OR[1] [95% CI]	RR[2] [95% CI]	RD[3] [95% CI]	p-value[4]	p-value (int)[5]
Uterine Volume at Baseline (cm3)							
< 300 cm3							0.1564
Relugolix+E2/NETA	148	78 (52.7)	3.52	2.19	0.29	<.0001	
Placebo	129	31 (24.0)	[2.10;5.91]	[1.56;3.09]	[0.18;0.40]		
>= 300 cm3							
Relugolix+E2/NETA	104	40 (38.5)	2.02	1.63	0.15	0.0141	
Placebo	127	30 (23.6)	[1.14;3.57]	[1.10;2.43]	[0.03;0.27]		
Missing							
Relugolix+E2/NETA	1	0	NC	NC	NC	NC	
Placebo	0	0	[NC;NC]	[NC;NC]	[NC;NC]		

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group.
[1] OR (95% CI) based on a logistic regression model adjusting for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates.
[2] RR (95% CI) based on a Cochran-Mantel-Haenszel approach stratified by study.
[3] RD (95% CI) based on a Mantel-Haenszel approach stratified by study. 95% CIs are based on the approximation to the normal distribution using the Sato estimator for the standard error.
[4] P-value based on a Cochran-Mantel-Haenszel test stratified by study.
[5] Interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the OR (95% CI). Missing subgroup levels are not included in estimation of the interaction p-value.
A continuity correction is applied in estimation of the OR, RR and p-value if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum. No continuity correction is applied in the estimation of the RD.
The reference group for the OR, RR and RD is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with an event; OR: Odds ratio; RR: Risk ratio; RD: Risk difference; CI: Confidence interval; int: p-value for interaction; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; NC: Not calculated.

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Table EFF.MAXNRS1.MITT.Pooled.S4: Proportion of Patients with Maximum NRS Score <= 1 During the Last 35 Days of Treatment, by Subgroup (mITT Population)

Study: Pooled

Treatment	N	n (%)	OR[1] [95% CI]	RR[2] [95% CI]	RD[3] [95% CI]	p-value[4]	p-value (int)[5]
Maximum NRS Pain Score at Baseline							
< 4							
Relugolix+E2/NETA	73	50 (68.5)	1.93	1.29	0.16	0.0678	0.1750
Placebo	62	33 (53.2)	[0.96;3.90]	[0.98;1.71]	[-0.01;0.32]		
>= 4							
Relugolix+E2/NETA	177	67 (37.9)	3.52	2.56	0.23	<.0001	
Placebo	190	28 (14.7)	[2.13;5.82]	[1.73;3.77]	[0.14;0.32]		
Missing							
Relugolix+E2/NETA	3	1 (33.3)	NC	NC	NC	NC	
Placebo	4	0	[NC;NC]	[NC;NC]	[NC;NC]		

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group.
[1] OR (95% CI) based on a logistic regression model adjusting for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates.
[2] RR (95% CI) based on a Cochran-Mantel-Haenszel approach stratified by study.
[3] RD (95% CI) based on a Mantel-Haenszel approach stratified by study. 95% CIs are based on the approximation to the normal distribution using the Sato estimator for the standard error.
[4] P-value based on a Cochran-Mantel-Haenszel test stratified by study.
[5] Interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the OR (95% CI). Missing subgroup levels are not included in estimation of the interaction p-value.
A continuity correction is applied in estimation of the OR, RR and p-value if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum. No continuity correction is applied in the estimation of the RD.
The reference group for the OR, RR and RD is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with an event; OR: Odds ratio; RR: Risk ratio; RD: Risk difference; CI: Confidence interval; int: p-value for interaction; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; NC: Not calculated.

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Table EFF.MAXNRS1.MITT.Pooled.S2: Proportion of Patients with Maximum NRS Score <= 1 During the Last 35 Days of Treatment, by Subgroup (mITT Population)

Study: Pooled

Treatment	N	n (%)	OR[1] [95% CI]	RR[2] [95% CI]	RD[3] [95% CI]	p-value[4]	p-value (int)[5]
BMI (kg/m2) at Baseline							
< 30							
Relugolix+E2/NETA	119	57 (47.9)	2.29	1.67	0.19	0.0028	0.3016
Placebo	115	33 (28.7)	[1.33;3.93]	[1.18;2.35]	[0.07;0.31]		
>= 30							
Relugolix+E2/NETA	133	61 (45.9)	3.42	2.30	0.26	<.0001	
Placebo	141	28 (19.9)	[2.00;5.84]	[1.58;3.37]	[0.15;0.37]		
Missing							
Relugolix+E2/NETA	1	0	NC	NC	NC	NC	
Placebo	0	0	[NC;NC]	[NC;NC]	[NC;NC]		

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group.
[1] OR (95% CI) based on a logistic regression model adjusting for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates.
[2] RR (95% CI) based on a Cochran-Mantel-Haenszel approach stratified by study.
[3] RD (95% CI) based on a Mantel-Haenszel approach stratified by study. 95% CIs are based on the approximation to the normal distribution using the Sato estimator for the standard error.
[4] P-value based on a Cochran-Mantel-Haenszel test stratified by study.
[5] Interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the OR (95% CI). Missing subgroup levels are not included in estimation of the interaction p-value.
A continuity correction is applied in estimation of the OR, RR and p-value if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum. No continuity correction is applied in the estimation of the RD.
The reference group for the OR, RR and RD is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with an event; OR: Odds ratio; RR: Risk ratio; RD: Risk difference; CI: Confidence interval; int: p-value for interaction; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; NC: Not calculated.

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Table EFF.MAXNRS1.MITT.Pooled.S5: Proportion of Patients with Maximum NRS Score <= 1 During the Last 35 Days of Treatment, by Subgroup (mITT Population)

Study: Pooled

Treatment	N	n (%)	OR[1] [95% CI]	RR[2] [95% CI]	RD[3] [95% CI]	p-value[4]	p-value (int)[5]
MBL Volume at Baseline (mL)							
< 225 mL							
Relugolix+E2/NETA	164	84 (51.2)	3.23	2.09	0.27	<.0001	0.3270
Placebo	171	42 (24.6)	[2.03;5.13]	[1.54;2.83]	[0.17;0.37]		
>= 225 mL							
Relugolix+E2/NETA	89	34 (38.2)	2.15	1.71	0.16	0.0238	
Placebo	85	19 (22.4)	[1.10;4.18]	[1.06;2.75]	[0.02;0.29]		

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group.
[1] OR (95% CI) based on a logistic regression model adjusting for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates.
[2] RR (95% CI) based on a Cochran-Mantel-Haenszel approach stratified by study.
[3] RD (95% CI) based on a Mantel-Haenszel approach stratified by study. 95% CIs are based on the approximation to the normal distribution using the Sato estimator for the standard error.
[4] P-value based on a Cochran-Mantel-Haenszel test stratified by study.
[5] Interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the OR (95% CI). Missing subgroup levels are not included in estimation of the interaction p-value.
A continuity correction is applied in estimation of the OR, RR and p-value if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum. No continuity correction is applied in the estimation of the RD.
The reference group for the OR, RR and RD is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with an event; OR: Odds ratio; RR: Risk ratio; RD: Risk difference; CI: Confidence interval; int: p-value for interaction; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; NC: Not calculated.

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Table EFF.MAXNRS1.MITT.Pooled.S8: Proportion of Patients with Maximum NRS Score <= 1 During the Last 35 Days of Treatment, by Subgroup (mITT Population)

Study: Pooled

Treatment	N	n (%)	OR[1] [95% CI]	RR[2] [95% CI]	RD[3] [95% CI]	p-value[4]	p-value (int)[5]
Ethnicity							
Hispanic or Latino							0.3710
Relugolix+E2/NETA	52	27 (51.9)	3.94	2.37	0.30	0.0020	
Placebo	55	12 (21.8)	[1.69;9.18]	[1.32;4.25]	[0.12;0.48]		
Not Hispanic or Latino							
Relugolix+E2/NETA	197	90 (45.7)	2.57	1.84	0.21	<.0001	
Placebo	199	49 (24.6)	[1.67;3.93]	[1.39;2.45]	[0.12;0.30]		
Not reported							
Relugolix+E2/NETA	4	1 (25.0)	NC	NC	NC	NC	
Placebo	2	0	[NC;NC]	[NC;NC]	[NC;NC]		

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group.
[1] OR (95% CI) based on a logistic regression model adjusting for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates.
[2] RR (95% CI) based on a Cochran-Mantel-Haenszel approach stratified by study.
[3] RD (95% CI) based on a Mantel-Haenszel approach stratified by study. 95% CIs are based on the approximation to the normal distribution using the Sato estimator for the standard error.
[4] P-value based on a Cochran-Mantel-Haenszel test stratified by study.
[5] Interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the OR (95% CI). Not reported subgroup levels are not included in estimation of the interaction p-value.
A continuity correction is applied in estimation of the OR, RR and p-value if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum. No continuity correction is applied in the estimation of the RD.
The reference group for the OR, RR and RD is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with an event; OR: Odds ratio; RR: Risk ratio; RD: Risk difference; CI: Confidence interval; int: p-value for interaction; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; NC: Not calculated.

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Table EFF.MAXNRS1.MITT.Pooled.S6: Proportion of Patients with Maximum NRS Score <= 1 During the Last 35 Days of Treatment, by Subgroup (mITT Population)

Study: Pooled

Treatment	N	n (%)	OR[1] [95% CI]	RR[2] [95% CI]	RD[3] [95% CI]	p-value[4]	p-value (int)[5]
Geographic Region I							
North America							
Relugolix+E2/NETA	191	86 (45.0)	2.56	1.86	0.21	<.0001	0.4299
Placebo	194	47 (24.2)	[1.66;3.96]	[1.39;2.50]	[0.12;0.30]		
Rest of World							
Relugolix+E2/NETA	62	32 (51.6)	3.66	2.27	0.29	0.0009	
Placebo	62	14 (22.6)	[1.68;7.95]	[1.36;3.81]	[0.13;0.45]		

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group.
[1] OR (95% CI) based on a logistic regression model adjusting for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates.
[2] RR (95% CI) based on a Cochran-Mantel-Haenszel approach stratified by study.
[3] RD (95% CI) based on a Mantel-Haenszel approach stratified by study. 95% CIs are based on the approximation to the normal distribution using the Sato estimator for the standard error.
[4] P-value based on a Cochran-Mantel-Haenszel test stratified by study.
[5] Interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the OR (95% CI). Not reported subgroup levels are not included in estimation of the interaction p-value.
A continuity correction is applied in estimation of the OR, RR and p-value if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum. No continuity correction is applied in the estimation of the RD.
The reference group for the OR, RR and RD is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with an event; OR: Odds ratio; RR: Risk ratio; RD: Risk difference; CI: Confidence interval; int: p-value for interaction; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; NC: Not calculated.

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Table EFF.MAXNRS1.MITT.Pooled.S7: Proportion of Patients with Maximum NRS Score <= 1 During the Last 35 Days of Treatment, by Subgroup (mITT Population)

Study: Pooled

Treatment	**N**	**n (%)**	**OR[1] [95% CI]**	**RR[2] [95% CI]**	**RD[3] [95% CI]**	**p-value[4]**	**p-value (int)[5]**
Geographic Region II							
Europe							0.5214
Relugolix+E2/NETA	41	22 (53.7)	3.70	2.28	0.30	0.0051	
Placebo	42	10 (23.8)	[1.45;9.45]	[1.24;4.22]	[0.10;0.50]		
Rest of World (including the US)							
Relugolix+E2/NETA	212	96 (45.3)	2.65	1.91	0.22	<.0001	
Placebo	214	51 (23.8)	[1.75;4.01]	[1.44;2.53]	[0.13;0.30]		

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group.
[1] OR (95% CI) based on a logistic regression model adjusting for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates.
[2] RR (95% CI) based on a Cochran-Mantel-Haenszel approach stratified by study.
[3] RD (95% CI) based on a Mantel-Haenszel approach stratified by study. 95% CIs are based on the approximation to the normal distribution using the Sato estimator for the standard error.
[4] P-value based on a Cochran-Mantel-Haenszel test stratified by study.
[5] Interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the OR (95% CI). Not reported subgroup levels are not included in estimation of the interaction p-value.
A continuity correction is applied in estimation of the OR, RR and p-value if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum. No continuity correction is applied in the estimation of the RD.
The reference group for the OR, RR and RD is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with an event; OR: Odds ratio; RR: Risk ratio; RD: Risk difference; CI: Confidence interval; int: p-value for interaction; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; NC: Not calculated.

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1.1.10 Proportion of Patients with >= 30% Reduction in NRS Score from Baseline to Last 35 Days of Treatment, by Subgroup (Pain Evaluable Population)

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Table EFF.NRSR30.PEV.Pooled.S3: Proportion of Patients with >= 30% Reduction in NRS Score from Baseline to Last 35 Days of Treatment, by Subgroup (Pain Evaluable Population)

Study: Pooled

Treatment	N	n (%)	OR[1] [95% CI]	RR[2] [95% CI]	RD[3] [95% CI]	p-value[4]	p-value (int)[5]
Uterine Volume at Baseline (cm3)							
< 300 cm3							
Relugolix+E2/NETA	73	52 (71.2)	4.32	1.95	0.35	<.0001	0.5652
Placebo	74	27 (36.5)	[2.16;8.64]	[1.40;2.72]	[0.20;0.50]		
>= 300 cm3							
Relugolix+E2/NETA	53	38 (71.7)	3.20	1.62	0.28	0.0021	
Placebo	77	34 (44.2)	[1.51;6.76]	[1.20;2.19]	[0.11;0.44]		

Post hoc analysis. The denominator for percentages is the number of patients in the pain evaluable population for each treatment group.
Pain evaluable population is the subset of mITT patients who had a maximum baseline NRS pain score >= 4 and who had at least 28 days [80% of the last 35 days of treatment] of pain scores recorded in their eDiary.)
[1] OR (95% CI) based on a logistic regression model adjusting for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates.
[2] RR (95% CI) based on a Cochran-Mantel-Haenszel approach stratified by study.
[3] RD (95% CI) based on a Mantel-Haenszel approach stratified by study. 95% CIs are based on the approximation to the normal distribution using the Sato estimator for the standard error.
[4] P-value based on a Cochran-Mantel-Haenszel test stratified by study.
[5] Interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the OR (95% CI). Not reported subgroup levels are not included in estimation of the interaction p-value.
* Interaction p-value < 0.05.
A continuity correction is applied in estimation of the OR, RR and p-value if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum. No continuity correction is applied in the estimation of the RD.
The reference group for the OR, RR and RD is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with an event; OR: Odds ratio; RR: Risk ratio; RD: Risk difference; CI: Confidence interval; int: p-value for interaction; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; NC: Not calculated.

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Table EFF.NRSR30.PEV.Pooled.S2: Proportion of Patients with >= 30% Reduction in NRS Score from Baseline to Last 35 Days of Treatment, by Subgroup (Pain Evaluable Population)

Study: Pooled

Treatment	N	n (%)	OR[1] [95% CI]	RR[2] [95% CI]	RD[3] [95% CI]	p-value[4]	p-value (int)[5]
BMI (kg/m2) at Baseline							
< 30							
Relugolix+E2/NETA	54	36 (66.7)	4.09	2.03	0.34	0.0002	0.6956
Placebo	70	23 (32.9)	[1.92;8.69]	[1.38;2.98]	[0.17;0.51]		
>= 30							
Relugolix+E2/NETA	71	53 (74.6)	3.33	1.59	0.28	0.0005	
Placebo	81	38 (46.9)	[1.67;6.65]	[1.22;2.08]	[0.13;0.43]		
Missing							
Relugolix+E2/NETA	1	1 (100.0)	NC	NC	NC	NC	
Placebo	0	0	[NC;NC]	[NC;NC]	[NC;NC]		

Post hoc analysis. The denominator for percentages is the number of patients in the pain evaluable population for each treatment group.
Pain evaluable population is the subset of mITT patients who had a maximum baseline NRS pain score >= 4 and who had at least 28 days [80% of the last 35 days of treatment] of pain scores recorded in their eDiary.)
[1] OR (95% CI) based on a logistic regression model adjusting for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates.
[2] RR (95% CI) based on a Cochran-Mantel-Haenszel approach stratified by study.
[3] RD (95% CI) based on a Mantel-Haenszel approach stratified by study. 95% CIs are based on the approximation to the normal distribution using the Sato estimator for the standard error.
[4] P-value based on a Cochran-Mantel-Haenszel test stratified by study.
[5] Interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the OR (95% CI). Missing subgroup levels are not included in estimation of the interaction p-value. * Interaction p-value < 0.05.
A continuity correction is applied in estimation of the OR, RR and p-value if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum. No continuity correction is applied in the estimation of the RD.
The reference group for the OR, RR and RD is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with an event; OR: Odds ratio; RR: Risk ratio; RD: Risk difference; CI: Confidence interval; int: p-value for interaction; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; NC: Not calculated.

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Table EFF.NRSR30.PEV.Pooled.S5: Proportion of Patients with >= 30% Reduction in NRS Score from Baseline to Last 35 Days of Treatment, by Subgroup (Pain Evaluable Population)

Study: Pooled

Treatment	N	n (%)	OR[1] [95% CI]	RR[2] [95% CI]	RD[3] [95% CI]	p-value[4]	p-value (int)[5]
MBL Volume at Baseline (mL)							
< 225 mL							0.8056
Relugolix+E2/NETA	81	59 (72.8)	3.55	1.69	0.30	<.0001	
Placebo	100	43 (43.0)	[1.89;6.67]	[1.30;2.20]	[0.16;0.44]		
>= 225 mL							
Relugolix+E2/NETA	45	31 (68.9)	4.06	1.95	0.33	0.0012	
Placebo	51	18 (35.3)	[1.73;9.53]	[1.28;2.96]	[0.15;0.52]		

Post hoc analysis. The denominator for percentages is the number of patients in the pain evaluable population for each treatment group.
Pain evaluable population is the subset of mITT patients who had a maximum baseline NRS pain score >= 4 and who had at least 28 days [80% of the last 35 days of treatment] of pain scores recorded in their eDiary.)
[1] OR (95% CI) based on a logistic regression model adjusting for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates.
[2] RR (95% CI) based on a Cochran-Mantel-Haenszel approach stratified by study.
[3] RD (95% CI) based on a Mantel-Haenszel approach stratified by study. 95% CIs are based on the approximation to the normal distribution using the Sato estimator for the standard error.
[4] P-value based on a Cochran-Mantel-Haenszel test stratified by study.
[5] Interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the OR (95% CI). Missing subgroup levels are not included in estimation of the interaction p-value. * Interaction p-value < 0.05.
A continuity correction is applied in estimation of the OR, RR and p-value if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum. No continuity correction is applied in the estimation of the RD.
The reference group for the OR, RR and RD is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with an event; OR: Odds ratio; RR: Risk ratio; RD: Risk difference; CI: Confidence interval; int: p-value for interaction; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; NC: Not calculated.

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1.1.11 Summary of Change from Baseline in Maximum NRS Score by Visit and Overall, by Subgroup (Pain Evaluable Population)

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Table EFF.MAXNRS.PEV.Pooled.S9: Summary of Change from Baseline in Maximum NRS Score by Visit and Overall, by Subgroup (Pain Evaluable Population)						
Study: Pooled						
Treatment	**Study visit**	**n (%)[1]**	**Mean (SD)[1]**	**Change from baseline LS-mean change (SE)[2]**	**Difference LS-mean change [95% CI] p-value[2]**	**SMD Hedges' g [95% CI][2]**
Race						
Black/African American						
Relugolix+E2/NETA	Baseline	61 (100.0)	7.5 (2.09)	-2.49 (0.341)	-1.15	-0.43
N=61	Week 4	61 (100.0)	5.0 (3.13)		[-2.04,-0.25]	[-0.77,-0.10]
Placebo	Baseline	80 (100.0)	7.2 (2.01)	-1.34 (0.298)	0.0123	
N=80	Week 4	80 (100.0)	5.9 (3.00)			
White						
Relugolix+E2/NETA	Baseline	61 (100.0)	6.9 (2.00)	-2.30 (0.292)	-1.93	-0.85
N=61	Week 4	61 (100.0)	4.6 (2.81)		[-2.73,-1.12]	[-1.21,-0.48]
Placebo	Baseline	65 (100.0)	6.9 (1.87)	-0.37 (0.283)	<.0001	
N=65	Week 4	65 (100.0)	6.5 (2.04)			
Asian						
Relugolix+E2/NETA	Baseline	0	NE (NE)	NC (NC)	NC	NC
N=0	Week 4	0	NE (NE)		[NC,NC]	[NC,NC]
Placebo	Baseline	2 (100.0)	7.0 (2.83)	NC (NC)	NC	
N=2	Week 4	2 (100.0)	6.0 (1.41)			
Others						
Relugolix+E2/NETA	Baseline	4 (100.0)	8.8 (1.26)	NC (NC)	NC	NC
N=4	Week 4	4 (100.0)	6.0 (2.71)		[NC,NC]	[NC,NC]
Placebo	Baseline	3 (100.0)	6.3 (1.53)	NC (NC)	NC	
N=3	Week 4	3 (100.0)	5.7 (4.04)			
Not reported						
Relugolix+E2/NETA	Baseline	0	NE (NE)	NC (NC)	NC	NC
N=0	Week 4	0	NE (NE)		[NC,NC]	[NC,NC]
Placebo	Baseline	1 (100.0)	5.0 (NE)	NC (NC)	NC	

N=1	Week 4	1 (100.0)	8.0 (NE)			

Post hoc analysis. The denominator for percentages is the number of patients in the pain evaluable population for each treatment group.
Pain evaluable patients are defined as those who had maximum NRS score >=4 at baseline and had at least 28 days (80% of the last 35 days of treatment) of pain scores recorded in the e-Diary.
[1] Summary statistics are based on observed data.
[2] LS means, LS mean differences (95% CIs), p-value and Hedges' g (95% CIs) are based on a mixed-effects model with study, treatment, visit, and a treatment-by-visit interaction as fixed effects. The multiple visits for each patient are the repeated measures as a random effect within each patient with an unstructured covariance. Hedges' g is calculated using a small sample bias correction. Interaction p-value is only produced for the Overall period.
The reference group for the LS mean difference and Hedges' g is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with data; CI: Confidence interval; LS: Least squares; MBL: Menstrual blood loss; NETA: Norethindrone acetate; NRS: Numerical rating scale; SD: Standard deviation; SE: Standard error; SMD: Standardized mean difference; NC: Not calculated; NE: Non-estimable.

Table EFF.MAXNRS.PEV.Pooled.S9: Summary of Change from Baseline in Maximum NRS Score by Visit and Overall, by Subgroup (Pain Evaluable Population)						
Study: Pooled						
Treatment	**Study visit**	**n (%)[1]**	**Mean (SD)[1]**	**Change from baseline LS-mean change (SE)[2]**	**Difference LS-mean change [95% CI] p-value[2]**	**SMD Hedges' g [95% CI][2]**
Race						
Black/African American						
Relugolix+E2/NETA	Baseline	61 (100.0)	7.5 (2.09)	-4.40 (0.369)	-2.48	-0.87
N=61	Week 8	59 (96.7)	3.1 (2.88)		[-3.44,-1.52]	[-1.22,-0.52]
Placebo	Baseline	80 (100.0)	7.2 (2.01)	-1.92 (0.318)	<.0001	
N=80	Week 8	80 (100.0)	5.3 (3.07)			
White						
Relugolix+E2/NETA	Baseline	61 (100.0)	6.9 (2.00)	-3.72 (0.341)	-2.98	-1.13
N=61	Week 8	61 (100.0)	3.1 (2.46)		[-3.92,-2.04]	[-1.50,-0.75]
Placebo	Baseline	65 (100.0)	6.9 (1.87)	-0.74 (0.332)	<.0001	
N=65	Week 8	64 (98.5)	6.2 (2.54)			
Asian						
Relugolix+E2/NETA	Baseline	0	NE (NE)	NC (NC)	NC	NC
N=0	Week 8	0	NE (NE)		[NC,NC]	[NC,NC]
Placebo	Baseline	2 (100.0)	7.0 (2.83)	NC (NC)	NC	
N=2	Week 8	2 (100.0)	4.0 (4.24)			
Others						
Relugolix+E2/NETA	Baseline	4 (100.0)	8.8 (1.26)	NC (NC)	NC	NC
N=4	Week 8	4 (100.0)	5.8 (1.71)		[NC,NC]	[NC,NC]
Placebo	Baseline	3 (100.0)	6.3 (1.53)	NC (NC)	NC	
N=3	Week 8	3 (100.0)	5.3 (2.52)			
Not reported						
Relugolix+E2/NETA	Baseline	0	NE (NE)	NC (NC)	NC	NC
N=0	Week 8	0	NE (NE)		[NC,NC]	[NC,NC]
Placebo	Baseline	1 (100.0)	5.0 (NE)	NC (NC)	NC	

N=1	Week 8	1 (100.0)	7.0 (NE)			

Post hoc analysis. The denominator for percentages is the number of patients in the pain evaluable population for each treatment group.
Pain evaluable patients are defined as those who had maximum NRS score >=4 at baseline and had at least 28 days (80% of the last 35 days of treatment) of pain scores recorded in the e-Diary.
[1] Summary statistics are based on observed data.
[2] LS means, LS mean differences (95% CIs), p-value and Hedges' g (95% CIs) are based on a mixed-effects model with study, treatment, visit, and a treatment-by-visit interaction as fixed effects. The multiple visits for each patient are the repeated measures as a random effect within each patient with an unstructured covariance. Hedges' g is calculated using a small sample bias correction. Interaction p-value is only produced for the Overall period.
The reference group for the LS mean difference and Hedges' g is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with data; CI: Confidence interval; LS: Least squares; MBL: Menstrual blood loss; NETA: Norethindrone acetate; NRS: Numerical rating scale; SD: Standard deviation; SE: Standard error; SMD: Standardized mean difference; NC: Not calculated; NE: Non-estimable.

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Table EFF.MAXNRS.PEV.Pooled.S9: Summary of Change from Baseline in Maximum NRS Score by Visit and Overall, by Subgroup (Pain Evaluable Population)

Study: Pooled

Treatment	Study visit	n (%)[1]	Mean (SD)[1]	Change from baseline LS-mean change (SE)[2]	Difference LS-mean change [95% CI] p-value[2]	SMD Hedges' g [95% CI][2]
Race						
Black/African American						
Relugolix+E2/NETA	Baseline	61 (100.0)	7.5 (2.09)	-4.31 (0.403)	-1.52	-0.50
N=61	Week 12	56 (91.8)	3.1 (3.13)		[-2.57,-0.47]	[-0.84,-0.15]
Placebo	Baseline	80 (100.0)	7.2 (2.01)	-2.79 (0.345)	0.0048	
N=80	Week 12	78 (97.5)	4.5 (3.04)			
White						
Relugolix+E2/NETA	Baseline	61 (100.0)	6.9 (2.00)	-3.94 (0.334)	-3.20	-1.23
N=61	Week 12	61 (100.0)	2.9 (3.10)		[-4.12,-2.28]	[-1.61,-0.85]
Placebo	Baseline	65 (100.0)	6.9 (1.87)	-0.74 (0.325)	<.0001	
N=65	Week 12	64 (98.5)	6.2 (2.32)			
Asian						
Relugolix+E2/NETA	Baseline	0	NE (NE)	NC (NC)	NC	NC
N=0	Week 12	0	NE (NE)		[NC,NC]	[NC,NC]
Placebo	Baseline	2 (100.0)	7.0 (2.83)	NC (NC)	NC	
N=2	Week 12	2 (100.0)	5.5 (4.95)			
Others						
Relugolix+E2/NETA	Baseline	4 (100.0)	8.8 (1.26)	NC (NC)	NC	NC
N=4	Week 12	4 (100.0)	5.5 (3.42)		[NC,NC]	[NC,NC]
Placebo	Baseline	3 (100.0)	6.3 (1.53)	NC (NC)	NC	
N=3	Week 12	3 (100.0)	6.0 (2.00)			
Not reported						
Relugolix+E2/NETA	Baseline	0	NE (NE)	NC (NC)	NC	NC
N=0	Week 12	0	NE (NE)		[NC,NC]	[NC,NC]
Placebo	Baseline	1 (100.0)	5.0 (NE)	NC (NC)	NC	

N=1	Week 12	1 (100.0)	4.0 (NE)			

Post hoc analysis. The denominator for percentages is the number of patients in the pain evaluable population for each treatment group.
Pain evaluable patients are defined as those who had maximum NRS score >=4 at baseline and had at least 28 days (80% of the last 35 days of treatment) of pain scores recorded in the e-Diary.
[1] Summary statistics are based on observed data.
[2] LS means, LS mean differences (95% CIs), p-value and Hedges' g (95% CIs) are based on a mixed-effects model with study, treatment, visit, and a treatment-by-visit interaction as fixed effects. The multiple visits for each patient are the repeated measures as a random effect within each patient with an unstructured covariance. Hedges' g is calculated using a small sample bias correction. Interaction p-value is only produced for the Overall period.
The reference group for the LS mean difference and Hedges' g is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with data; CI: Confidence interval; LS: Least squares; MBL: Menstrual blood loss; NETA: Norethindrone acetate; NRS: Numerical rating scale; SD: Standard deviation; SE: Standard error; SMD: Standardized mean difference; NC: Not calculated; NE: Non-estimable.

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Table EFF.MAXNRS.PEV.Pooled.S9: Summary of Change from Baseline in Maximum NRS Score by Visit and Overall, by Subgroup (Pain Evaluable Population)						
Study: Pooled						
Treatment	**Study visit**	**n (%)[1]**	**Mean (SD)[1]**	**Change from baseline LS-mean change (SE)[2]**	**Difference LS-mean change [95% CI] p-value[2]**	**SMD Hedges' g [95% CI][2]**
Race						
Black/African American						
Relugolix+E2/NETA	Baseline	61 (100.0)	7.5 (2.09)	-4.27 (0.430)	-1.30	-0.40
N=61	Week 16	56 (91.8)	3.2 (3.26)		[-2.41,-0.18]	[-0.75,-0.05]
Placebo	Baseline	80 (100.0)	7.2 (2.01)	-2.97 (0.369)	0.0237	
N=80	Week 16	76 (95.0)	4.3 (3.38)			
White						
Relugolix+E2/NETA	Baseline	61 (100.0)	6.9 (2.00)	-4.38 (0.352)	-3.15	-1.15
N=61	Week 16	60 (98.4)	2.5 (2.84)		[-4.12,-2.18]	[-1.53,-0.77]
Placebo	Baseline	65 (100.0)	6.9 (1.87)	-1.23 (0.344)	<.0001	
N=65	Week 16	62 (95.4)	5.7 (2.69)			
Asian						
Relugolix+E2/NETA	Baseline	0	NE (NE)	NC (NC)	NC	NC
N=0	Week 16	0	NE (NE)		[NC,NC]	[NC,NC]
Placebo	Baseline	2 (100.0)	7.0 (2.83)	NC (NC)	NC	
N=2	Week 16	1 (50.0)	0.0 (NE)			
Others						
Relugolix+E2/NETA	Baseline	4 (100.0)	8.8 (1.26)	NC (NC)	NC	NC
N=4	Week 16	4 (100.0)	6.0 (2.94)		[NC,NC]	[NC,NC]
Placebo	Baseline	3 (100.0)	6.3 (1.53)	NC (NC)	NC	
N=3	Week 16	2 (66.7)	6.0 (1.41)			
Not reported						
Relugolix+E2/NETA	Baseline	0	NE (NE)	NC (NC)	NC	NC
N=0	Week 16	0	NE (NE)		[NC,NC]	[NC,NC]
Placebo	Baseline	1 (100.0)	5.0 (NE)	NC (NC)	NC	

N=1	Week 16	1 (100.0)	3.0 (NE)			

Post hoc analysis. The denominator for percentages is the number of patients in the pain evaluable population for each treatment group.
Pain evaluable patients are defined as those who had maximum NRS score >=4 at baseline and had at least 28 days (80% of the last 35 days of treatment) of pain scores recorded in the e-Diary.
[1] Summary statistics are based on observed data.
[2] LS means, LS mean differences (95% CIs), p-value and Hedges' g (95% CIs) are based on a mixed-effects model with study, treatment, visit, and a treatment-by-visit interaction as fixed effects. The multiple visits for each patient are the repeated measures as a random effect within each patient with an unstructured covariance. Hedges' g is calculated using a small sample bias correction. Interaction p-value is only produced for the Overall period.
The reference group for the LS mean difference and Hedges' g is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with data; CI: Confidence interval; LS: Least squares; MBL: Menstrual blood loss; NETA: Norethindrone acetate; NRS: Numerical rating scale; SD: Standard deviation; SE: Standard error; SMD: Standardized mean difference; NC: Not calculated; NE: Non-estimable.

SOURCE: \Studies\MYV\MYV102\Analysis\Prod\Progs\TFLs\Tab_EFF_NRS_CON.SAS
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Table EFF.MAXNRS.PEV.Pooled.S9: Summary of Change from Baseline in Maximum NRS Score by Visit and Overall, by Subgroup (Pain Evaluable Population)

Study: Pooled

Treatment	Study visit	n (%)[1]	Mean (SD)[1]	Change from baseline LS-mean change (SE)[2]	Difference LS-mean change [95% CI] p-value[2]	SMD Hedges' g [95% CI][2]
Race						
Black/African American						
Relugolix+E2/NETA	Baseline	61 (100.0)	7.5 (2.09)	-4.87 (0.415)	-2.17	-0.69
N=61	Week 20	55 (90.2)	2.6 (3.00)		[-3.25,-1.09]	[-1.05,-0.33]
Placebo	Baseline	80 (100.0)	7.2 (2.01)	-2.70 (0.358)	0.0001	
N=80	Week 20	74 (92.5)	4.6 (3.24)			
White						
Relugolix+E2/NETA	Baseline	61 (100.0)	6.9 (2.00)	-4.41 (0.355)	-3.06	-1.11
N=61	Week 20	58 (95.1)	2.2 (2.63)		[-4.04,-2.08]	[-1.50,-0.73]
Placebo	Baseline	65 (100.0)	6.9 (1.87)	-1.35 (0.347)	<.0001	
N=65	Week 20	60 (92.3)	5.6 (2.83)			
Asian						
Relugolix+E2/NETA	Baseline	0	NE (NE)	NC (NC)	NC	NC
N=0	Week 20	0	NE (NE)		[NC,NC]	[NC,NC]
Placebo	Baseline	2 (100.0)	7.0 (2.83)	NC (NC)	NC	
N=2	Week 20	1 (50.0)	0.0 (NE)			
Others						
Relugolix+E2/NETA	Baseline	4 (100.0)	8.8 (1.26)	NC (NC)	NC	NC
N=4	Week 20	4 (100.0)	4.8 (3.59)		[NC,NC]	[NC,NC]
Placebo	Baseline	3 (100.0)	6.3 (1.53)	NC (NC)	NC	
N=3	Week 20	2 (66.7)	4.5 (4.95)			
Not reported						
Relugolix+E2/NETA	Baseline	0	NE (NE)	NC (NC)	NC	NC
N=0	Week 20	0	NE (NE)		[NC,NC]	[NC,NC]
Placebo	Baseline	1 (100.0)	5.0 (NE)	NC (NC)	NC	

N=1	Week 20	1 (100.0)	2.0 (NE)			

Post hoc analysis. The denominator for percentages is the number of patients in the pain evaluable population for each treatment group.
Pain evaluable patients are defined as those who had maximum NRS score >=4 at baseline and had at least 28 days (80% of the last 35 days of treatment) of pain scores recorded in the e-Diary.
[1] Summary statistics are based on observed data.
[2] LS means, LS mean differences (95% CIs), p-value and Hedges' g (95% CIs) are based on a mixed-effects model with study, treatment, visit, and a treatment-by-visit interaction as fixed effects. The multiple visits for each patient are the repeated measures as a random effect within each patient with an unstructured covariance. Hedges' g is calculated using a small sample bias correction. Interaction p-value is only produced for the Overall period.
The reference group for the LS mean difference and Hedges' g is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with data; CI: Confidence interval; LS: Least squares; MBL: Menstrual blood loss; NETA: Norethindrone acetate; NRS: Numerical rating scale; SD: Standard deviation; SE: Standard error; SMD: Standardized mean difference; NC: Not calculated; NE: Non-estimable.

SOURCE: \Studies\MYV\MYV102\Analysis\Prod\Progs\TFLs\Tab_EFF_NRS_CON.SAS
Date/time of run: 20APR2021 16:04

Table EFF.MAXNRS.PEV.Pooled.S9: Summary of Change from Baseline in Maximum NRS Score by Visit and Overall, by Subgroup (Pain Evaluable Population)

Study: Pooled

Treatment	Study visit	n (%)[1]	Mean (SD)[1]	Change from baseline LS-mean change (SE)[2]	Difference LS-mean change [95% CI] p-value[2]	SMD Hedges' g [95% CI][2]
Race						
Black/African American						
Relugolix+E2/NETA	Baseline	61 (100.0)	7.5 (2.09)	-5.17 (0.411)	-1.64	-0.54
N=61	Week 24	53 (86.9)	2.2 (2.77)		[-2.71,-0.57]	[-0.89,-0.18]
Placebo	Baseline	80 (100.0)	7.2 (2.01)	-3.52 (0.352)	0.0028	
N=80	Week 24	73 (91.3)	3.8 (3.15)			
White						
Relugolix+E2/NETA	Baseline	61 (100.0)	6.9 (2.00)	-4.69 (0.384)	-2.98	-1.00
N=61	Week 24	58 (95.1)	2.0 (2.31)		[-4.04,-1.91]	[-1.39,-0.62]
Placebo	Baseline	65 (100.0)	6.9 (1.87)	-1.71 (0.377)	<.0001	
N=65	Week 24	59 (90.8)	5.2 (2.90)			
Asian						
Relugolix+E2/NETA	Baseline	0	NE (NE)	NC (NC)	NC	NC
N=0	Week 24	0	NE (NE)		[NC,NC]	[NC,NC]
Placebo	Baseline	2 (100.0)	7.0 (2.83)	NC (NC)	NC	
N=2	Week 24	1 (50.0)	0.0 (NE)			
Others						
Relugolix+E2/NETA	Baseline	4 (100.0)	8.8 (1.26)	NC (NC)	NC	NC
N=4	Week 24	4 (100.0)	4.8 (2.87)		[NC,NC]	[NC,NC]
Placebo	Baseline	3 (100.0)	6.3 (1.53)	NC (NC)	NC	
N=3	Week 24	2 (66.7)	4.0 (5.66)			
Not reported						
Relugolix+E2/NETA	Baseline	0	NE (NE)	NC (NC)	NC	NC
N=0	Week 24	0	NE (NE)		[NC,NC]	[NC,NC]
Placebo	Baseline	1 (100.0)	5.0 (NE)	NC (NC)	NC	

N=1	Week 24	1 (100.0)	6.0 (NE)			

Post hoc analysis. The denominator for percentages is the number of patients in the pain evaluable population for each treatment group.
Pain evaluable patients are defined as those who had maximum NRS score >=4 at baseline and had at least 28 days (80% of the last 35 days of treatment) of pain scores recorded in the e-Diary.
[1] Summary statistics are based on observed data.
[2] LS means, LS mean differences (95% CIs), p-value and Hedges' g (95% CIs) are based on a mixed-effects model with study, treatment, visit, and a treatment-by-visit interaction as fixed effects. The multiple visits for each patient are the repeated measures as a random effect within each patient with an unstructured covariance. Hedges' g is calculated using a small sample bias correction. Interaction p-value is only produced for the Overall period.
The reference group for the LS mean difference and Hedges' g is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with data; CI: Confidence interval; LS: Least squares; MBL: Menstrual blood loss; NETA: Norethindrone acetate; NRS: Numerical rating scale; SD: Standard deviation; SE: Standard error; SMD: Standardized mean difference; NC: Not calculated; NE: Non-estimable.

SOURCE: \Studies\MYV\MYV102\Analysis\Prod\Progs\TFLs\Tab_EFF_NRS_CON.SAS
Date/time of run: 20APR2021 16:04

Table EFF.MAXNRS.PEV.Pooled.S9: Summary of Change from Baseline in Maximum NRS Score by Visit and Overall, by Subgroup (Pain Evaluable Population)

Study: Pooled

Treatment	Study visit	n (%)[1]	Mean (SD)[1]	Change from baseline LS-mean change (SE)[2]	Difference LS-mean change [95% CI] p-value[2]	SMD Hedges' g [95% CI][2]	Int. p-value[2]
Race							
Black/African American							
Relugolix+E2/NETA	Baseline	61 (100.0)	7.5 (2.09)	-4.27 (0.287)	-1.81	-0.63	0.0721
N=61	Overall	61 (100.0)	3.4 (2.60)		[-2.56,-1.06]	[-0.97,-0.29]	
Placebo	Baseline	80 (100.0)	7.2 (2.01)	-2.46 (0.250)	<.0001		
N=80	Overall	80 (100.0)	4.7 (2.39)				
White							
Relugolix+E2/NETA	Baseline	61 (100.0)	6.9 (2.00)	-3.88 (0.285)	-2.77	-0.97	
N=61	Overall	61 (100.0)	3.0 (2.30)		[-3.55,-1.99]	[-1.34,-0.60]	
Placebo	Baseline	65 (100.0)	6.9 (1.87)	-1.11 (0.276)	<.0001		
N=65	Overall	65 (100.0)	5.9 (2.18)				
Asian							
Relugolix+E2/NETA	Baseline	0	NE (NE)	NC (NC)	NC	NC	
N=0	Overall	0	NE (NE)		[NC,NC]	[NC,NC]	
Placebo	Baseline	2 (100.0)	7.0 (2.83)	NC (NC)	NC		
N=2	Overall	2 (100.0)	4.5 (4.48)				
Others							
Relugolix+E2/NETA	Baseline	4 (100.0)	8.8 (1.26)	NC (NC)	NC	NC	
N=4	Overall	4 (100.0)	5.5 (2.25)		[NC,NC]	[NC,NC]	
Placebo	Baseline	3 (100.0)	6.3 (1.53)	NC (NC)	NC		
N=3	Overall	3 (100.0)	5.1 (2.70)				
Not reported							
Relugolix+E2/NETA	Baseline	0	NE (NE)	NC (NC)	NC	NC	
N=0	Overall	0	NE (NE)		[NC,NC]	[NC,NC]	
Placebo	Baseline	1 (100.0)	5.0 (NE)	NC (NC)	NC		

N=1	Overall	1 (100.0)	5.0 (NE)				

Post hoc analysis. The denominator for percentages is the number of patients in the pain evaluable population for each treatment group.
Pain evaluable patients are defined as those who had maximum NRS score >=4 at baseline and had at least 28 days (80% of the last 35 days of treatment) of pain scores recorded in the e-Diary.
[1] Summary statistics are based on observed data. Mean (SD) are calculated based on the mean observed value across all post-baseline visits within each patient.
[2] LS means, LS mean differences (95% CIs), p-value and Hedges' g (95% CIs) are based on a mixed-effects model with study, treatment, visit, subgroup, treatment-by-visit interaction and a subgroup-by-treatment interaction as fixed effects. The multiple visits for each patient are the repeated measures as a random effect within each patient with an unstructured covariance. Hedges' g is calculated using a small sample bias correction. Not reported subgroup levels are not included in estimation of the interaction p-value. Subgroup levels with fewer than 10 subjects are not included in estimation of the interaction p-value. The reference group for the LS mean difference and Hedges' g is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with data; CI: Confidence interval; int: Interaction; LS: Least squares; MBL: Menstrual blood loss; NETA: Norethindrone acetate; NRS: Numerical rating scale; SD: Standard deviation; SE: Standard error; SMD: Standardized mean difference; NC: Not calculated; NE: Non-estimable.

SOURCE: \Studies\MYV\MYV102\Analysis\Prod\Progs\TFLs\Tab_EFF_NRS_CON.SAS
Date/time of run: 20APR2021 16:04

Table EFF.MAXNRS.PEV.Pooled.S3: Summary of Change from Baseline in Maximum NRS Score by Visit and Overall, by Subgroup (Pain Evaluable Population)

Study: Pooled

Treatment	Study visit	n (%)[1]	Mean (SD)[1]	Change from baseline LS-mean change (SE)[2]	Difference LS-mean change [95% CI] p-value[2]	SMD Hedges' g [95% CI][2]
Uterine Volume at Baseline (cm3)						
< 300 cm3						
Relugolix+E2/NETA	Baseline	73 (100.0)	7.0 (2.12)	-2.70 (0.282)	-1.90	-0.79
N=73	Week 4	73 (100.0)	4.3 (2.95)		[-2.69,-1.12]	[-1.13,-0.46]
Placebo	Baseline	74 (100.0)	7.1 (1.98)	-0.79 (0.281)	<.0001	
N=74	Week 4	74 (100.0)	6.3 (2.48)			
>= 300 cm3						
Relugolix+E2/NETA	Baseline	53 (100.0)	7.5 (1.95)	-2.01 (0.366)	-1.06	-0.40
N=53	Week 4	53 (100.0)	5.5 (2.85)		[-2.00,-0.12]	[-0.75,-0.05]
Placebo	Baseline	77 (100.0)	7.0 (1.92)	-0.95 (0.304)	0.0275	
N=77	Week 4	77 (100.0)	6.0 (2.76)			

Post hoc analysis. The denominator for percentages is the number of patients in the pain evaluable population for each treatment group.
Pain evaluable patients are defined as those who had maximum NRS score >=4 at baseline and had at least 28 days (80% of the last 35 days of treatment) of pain scores recorded in the e-Diary.
[1] Summary statistics are based on observed data.
[2] LS means, LS mean differences (95% CIs), p-value and Hedges' g (95% CIs) are based on a mixed-effects model with study, treatment, visit, and a treatment-by-visit interaction as fixed effects. The multiple visits for each patient are the repeated measures as a random effect within each patient with an unstructured covariance. Hedges' g is calculated using a small sample bias correction. Interaction p-value is only produced for the Overall period.
The reference group for the LS mean difference and Hedges' g is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with data; CI: Confidence interval; LS: Least squares; MBL: Menstrual blood loss; NETA: Norethindrone acetate; NRS: Numerical rating scale; SD: Standard deviation; SE: Standard error; SMD: Standardized mean difference.

SOURCE: \Studies\MYV\MYV102\Analysis\Prod\Progs\TFLs\Tab_EFF_NRS_CON.SAS
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Analysis Plan: 13JAN2021

Table EFF.MAXNRS.PEV.Pooled.S3: Summary of Change from Baseline in Maximum NRS Score by Visit and Overall, by Subgroup (Pain Evaluable Population)

Study: Pooled

Treatment	Study visit	n (%)[1]	Mean (SD)[1]	Change from baseline LS-mean change (SE)[2]	Difference LS-mean change [95% CI] p-value[2]	SMD Hedges' g [95% CI][2]
Uterine Volume at Baseline (cm3)						
< 300 cm3						
Relugolix+E2/NETA	Baseline	73 (100.0)	7.0 (2.12)	-3.71 (0.306)	-2.62	-1.00
N=73	Week 8	73 (100.0)	3.3 (2.81)		[-3.47,-1.77]	[-1.35,-0.66]
Placebo	Baseline	74 (100.0)	7.1 (1.98)	-1.09 (0.305)	<.0001	
N=74	Week 8	74 (100.0)	6.0 (2.73)			
>= 300 cm3						
Relugolix+E2/NETA	Baseline	53 (100.0)	7.5 (1.95)	-4.47 (0.424)	-2.82	-0.92
N=53	Week 8	51 (96.2)	3.1 (2.49)		[-3.91,-1.73]	[-1.29,-0.55]
Placebo	Baseline	77 (100.0)	7.0 (1.92)	-1.66 (0.350)	<.0001	
N=77	Week 8	76 (98.7)	5.4 (2.97)			

Post hoc analysis. The denominator for percentages is the number of patients in the pain evaluable population for each treatment group.
Pain evaluable patients are defined as those who had maximum NRS score >=4 at baseline and had at least 28 days (80% of the last 35 days of treatment) of pain scores recorded in the e-Diary.
[1] Summary statistics are based on observed data.
[2] LS means, LS mean differences (95% CIs), p-value and Hedges' g (95% CIs) are based on a mixed-effects model with study, treatment, visit, and a treatment-by-visit interaction as fixed effects. The multiple visits for each patient are the repeated measures as a random effect within each patient with an unstructured covariance. Hedges' g is calculated using a small sample bias correction. Interaction p-value is only produced for the Overall period.
The reference group for the LS mean difference and Hedges' g is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with data; CI: Confidence interval; LS: Least squares; MBL: Menstrual blood loss; NETA: Norethindrone acetate; NRS: Numerical rating scale; SD: Standard deviation; SE: Standard error; SMD: Standardized mean difference.

SOURCE: \Studies\MYV\MYV102\Analysis\Prod\Progs\TFLs\Tab_EFF_NRS_CON.SAS
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Table EFF.MAXNRS.PEV.Pooled.S3: Summary of Change from Baseline in Maximum NRS Score by Visit and Overall, by Subgroup (Pain Evaluable Population)

Study: Pooled

Treatment	Study visit	n (%)[1]	Mean (SD)[1]	Change from baseline LS-mean change (SE)[2]	Difference LS-mean change [95% CI] p-value[2]	SMD Hedges' g [95% CI][2]
Uterine Volume at Baseline (cm3)						
< 300 cm3						
Relugolix+E2/NETA	Baseline	73 (100.0)	7.0 (2.12)	-4.08 (0.315)	-2.57	-0.96
N=73	Week 12	72 (98.6)	2.9 (3.11)		[-3.45,-1.69]	[-1.30,-0.62]
Placebo	Baseline	74 (100.0)	7.1 (1.98)	-1.51 (0.313)	<.0001	
N=74	Week 12	74 (100.0)	5.6 (2.74)			
>= 300 cm3						
Relugolix+E2/NETA	Baseline	53 (100.0)	7.5 (1.95)	-4.12 (0.459)	-1.98	-0.60
N=53	Week 12	49 (92.5)	3.4 (3.16)		[-3.16,-0.81]	[-0.97,-0.24]
Placebo	Baseline	77 (100.0)	7.0 (1.92)	-2.14 (0.377)	0.0011	
N=77	Week 12	74 (96.1)	5.0 (2.93)			

Post hoc analysis. The denominator for percentages is the number of patients in the pain evaluable population for each treatment group.
Pain evaluable patients are defined as those who had maximum NRS score >=4 at baseline and had at least 28 days (80% of the last 35 days of treatment) of pain scores recorded in the e-Diary.
[1] Summary statistics are based on observed data.
[2] LS means, LS mean differences (95% CIs), p-value and Hedges' g (95% CIs) are based on a mixed-effects model with study, treatment, visit, and a treatment-by-visit interaction as fixed effects. The multiple visits for each patient are the repeated measures as a random effect within each patient with an unstructured covariance. Hedges' g is calculated using a small sample bias correction. Interaction p-value is only produced for the Overall period.
The reference group for the LS mean difference and Hedges' g is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with data; CI: Confidence interval; LS: Least squares; MBL: Menstrual blood loss; NETA: Norethindrone acetate; NRS: Numerical rating scale; SD: Standard deviation; SE: Standard error; SMD: Standardized mean difference.

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Table EFF.MAXNRS.PEV.Pooled.S3: Summary of Change from Baseline in Maximum NRS Score by Visit and Overall, by Subgroup (Pain Evaluable Population)

Study: Pooled

Treatment	Study visit	n (%)[1]	Mean (SD)[1]	Change from baseline LS-mean change (SE)[2]	Difference LS-mean change [95% CI] p-value[2]	SMD Hedges' g [95% CI][2]
Uterine Volume at Baseline (cm3)						
< 300 cm3						
Relugolix+E2/NETA	Baseline	73 (100.0)	7.0 (2.12)	-4.27 (0.334)	-2.32	-0.82
N=73	Week 16	71 (97.3)	2.6 (3.25)		[-3.25,-1.39]	[-1.16,-0.48]
Placebo	Baseline	74 (100.0)	7.1 (1.98)	-1.96 (0.332)	<.0001	
N=74	Week 16	72 (97.3)	5.1 (3.02)			
>= 300 cm3						
Relugolix+E2/NETA	Baseline	53 (100.0)	7.5 (1.95)	-4.26 (0.475)	-1.87	-0.55
N=53	Week 16	49 (92.5)	3.3 (2.84)		[-3.09,-0.65]	[-0.92,-0.18]
Placebo	Baseline	77 (100.0)	7.0 (1.92)	-2.39 (0.395)	0.0030	
N=77	Week 16	70 (90.9)	4.7 (3.29)			

Post hoc analysis. The denominator for percentages is the number of patients in the pain evaluable population for each treatment group.
Pain evaluable patients are defined as those who had maximum NRS score >=4 at baseline and had at least 28 days (80% of the last 35 days of treatment) of pain scores recorded in the e-Diary.
[1] Summary statistics are based on observed data.
[2] LS means, LS mean differences (95% CIs), p-value and Hedges' g (95% CIs) are based on a mixed-effects model with study, treatment, visit, and a treatment-by-visit interaction as fixed effects. The multiple visits for each patient are the repeated measures as a random effect within each patient with an unstructured covariance. Hedges' g is calculated using a small sample bias correction. Interaction p-value is only produced for the Overall period.
The reference group for the LS mean difference and Hedges' g is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with data; CI: Confidence interval; LS: Least squares; MBL: Menstrual blood loss; NETA: Norethindrone acetate; NRS: Numerical rating scale; SD: Standard deviation; SE: Standard error; SMD: Standardized mean difference.

SOURCE: \Studies\MYV\MYV102\Analysis\Prod\Progs\TFLs\Tab_EFF_NRS_CON.SAS
Date/time of run: 20APR2021 16:04
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Table EFF.MAXNRS.PEV.Pooled.S3: Summary of Change from Baseline in Maximum NRS Score by Visit and Overall, by Subgroup (Pain Evaluable Population)

Study: Pooled

Treatment	Study visit	n (%)[1]	Mean (SD)[1]	Change from baseline LS-mean change (SE)[2]	Difference LS-mean change [95% CI] p-value[2]	SMD Hedges' g [95% CI][2]
Uterine Volume at Baseline (cm3)						
< 300 cm3						
Relugolix+E2/NETA	Baseline	73 (100.0)	7.0 (2.12)	-4.51 (0.336)	-2.62	-0.93
N=73	Week 20	69 (94.5)	2.4 (2.94)		[-3.56,-1.68]	[-1.27,-0.58]
Placebo	Baseline	74 (100.0)	7.1 (1.98)	-1.89 (0.336)	<.0001	
N=74	Week 20	69 (93.2)	5.2 (2.95)			
>= 300 cm3						
Relugolix+E2/NETA	Baseline	53 (100.0)	7.5 (1.95)	-4.78 (0.457)	-2.43	-0.75
N=53	Week 20	48 (90.6)	2.7 (2.75)		[-3.60,-1.25]	[-1.13,-0.37]
Placebo	Baseline	77 (100.0)	7.0 (1.92)	-2.35 (0.379)	<.0001	
N=77	Week 20	69 (89.6)	4.8 (3.29)			

Post hoc analysis. The denominator for percentages is the number of patients in the pain evaluable population for each treatment group.
Pain evaluable patients are defined as those who had maximum NRS score >=4 at baseline and had at least 28 days (80% of the last 35 days of treatment) of pain scores recorded in the e-Diary.
[1] Summary statistics are based on observed data.
[2] LS means, LS mean differences (95% CIs), p-value and Hedges' g (95% CIs) are based on a mixed-effects model with study, treatment, visit, and a treatment-by-visit interaction as fixed effects. The multiple visits for each patient are the repeated measures as a random effect within each patient with an unstructured covariance. Hedges' g is calculated using a small sample bias correction. Interaction p-value is only produced for the Overall period.
The reference group for the LS mean difference and Hedges' g is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with data; CI: Confidence interval; LS: Least squares; MBL: Menstrual blood loss; NETA: Norethindrone acetate; NRS: Numerical rating scale; SD: Standard deviation; SE: Standard error; SMD: Standardized mean difference.

SOURCE: \Studies\MYV\MYV102\Analysis\Prod\Progs\TFLs\Tab_EFF_NRS_CON.SAS
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Table EFF.MAXNRS.PEV.Pooled.S3: Summary of Change from Baseline in Maximum NRS Score by Visit and Overall, by Subgroup (Pain Evaluable Population)

Study: Pooled

Treatment	Study visit	n (%)[1]	Mean (SD)[1]	Change from baseline LS-mean change (SE)[2]	Difference LS-mean change [95% CI] p-value[2]	SMD Hedges' g [95% CI][2]
Uterine Volume at Baseline (cm3)						
< 300 cm3						
Relugolix+E2/NETA	Baseline	73 (100.0)	7.0 (2.12)	-4.75 (0.370)	-2.07	-0.67
N=73	Week 24	67 (91.8)	2.0 (2.53)		[-3.10,-1.04]	[-1.02,-0.33]
Placebo	Baseline	74 (100.0)	7.1 (1.98)	-2.68 (0.369)	0.0001	
N=74	Week 24	68 (91.9)	4.5 (3.15)			
>= 300 cm3						
Relugolix+E2/NETA	Baseline	53 (100.0)	7.5 (1.95)	-5.09 (0.445)	-2.35	-0.75
N=53	Week 24	48 (90.6)	2.4 (2.65)		[-3.50,-1.21]	[-1.13,-0.37]
Placebo	Baseline	77 (100.0)	7.0 (1.92)	-2.74 (0.370)	<.0001	
N=77	Week 24	68 (88.3)	4.4 (3.13)			

Post hoc analysis. The denominator for percentages is the number of patients in the pain evaluable population for each treatment group.
Pain evaluable patients are defined as those who had maximum NRS score >=4 at baseline and had at least 28 days (80% of the last 35 days of treatment) of pain scores recorded in the e-Diary.
[1] Summary statistics are based on observed data.
[2] LS means, LS mean differences (95% CIs), p-value and Hedges' g (95% CIs) are based on a mixed-effects model with study, treatment, visit, and a treatment-by-visit interaction as fixed effects. The multiple visits for each patient are the repeated measures as a random effect within each patient with an unstructured covariance. Hedges' g is calculated using a small sample bias correction. Interaction p-value is only produced for the Overall period.
The reference group for the LS mean difference and Hedges' g is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with data; CI: Confidence interval; LS: Least squares; MBL: Menstrual blood loss; NETA: Norethindrone acetate; NRS: Numerical rating scale; SD: Standard deviation; SE: Standard error; SMD: Standardized mean difference.

SOURCE: \Studies\MYV\MYV102\Analysis\Prod\Progs\TFLs\Tab_EFF_NRS_CON.SAS
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Table EFF.MAXNRS.PEV.Pooled.S3: Summary of Change from Baseline in Maximum NRS Score by Visit and Overall, by Subgroup (Pain Evaluable Population)

Study: Pooled

Treatment	Study visit	n (%)[1]	Mean (SD)[1]	Change from baseline LS-mean change (SE)[2]	Difference LS-mean change [95% CI] p-value[2]	SMD Hedges' g [95% CI][2]	Int. p-value[2]
Uterine Volume at Baseline (cm3)							
< 300 cm3							
Relugolix+E2/NETA	Baseline	73 (100.0)	7.0 (2.12)	-4.11 (0.271)	-2.41	-0.83	0.4262
N=73	Overall	73 (100.0)	3.0 (2.55)		[-3.16,-1.66]	[-1.16,-0.49]	
Placebo	Baseline	74 (100.0)	7.1 (1.98)	-1.70 (0.269)	<.0001		
N=74	Overall	74 (100.0)	5.4 (2.21)				
>= 300 cm3							
Relugolix+E2/NETA	Baseline	53 (100.0)	7.5 (1.95)	-3.97 (0.316)	-1.98	-0.68	
N=53	Overall	53 (100.0)	3.5 (2.35)		[-2.79,-1.17]	[-1.04,-0.32]	
Placebo	Baseline	77 (100.0)	7.0 (1.92)	-1.99 (0.264)	<.0001		
N=77	Overall	77 (100.0)	5.0 (2.50)				

Post hoc analysis. The denominator for percentages is the number of patients in the pain evaluable population for each treatment group.
Pain evaluable patients are defined as those who had maximum NRS score >=4 at baseline and had at least 28 days (80% of the last 35 days of treatment) of pain scores recorded in the e-Diary.
[1] Summary statistics are based on observed data. Mean (SD) are calculated based on the mean observed value across all post-baseline visits within each patient.
[2] LS means, LS mean differences (95% CIs), p-value and Hedges' g (95% CIs) are based on a mixed-effects model with study, treatment, visit, subgroup, treatment-by-visit interaction and a subgroup-by-treatment interaction as fixed effects. The multiple visits for each patient are the repeated measures as a random effect within each patient with an unstructured covariance. Hedges' g is calculated using a small sample bias correction.
The reference group for the LS mean difference and Hedges' g is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with data; CI: Confidence interval; int: Interaction; LS: Least squares; MBL: Menstrual blood loss; NETA: Norethindrone acetate; NRS: Numerical rating scale; SD: Standard deviation; SE: Standard error; SMD: Standardized mean difference.

SOURCE: \Studies\MYV\MYV102\Analysis\Prod\Progs\TFLs\Tab_EFF_NRS_CON.SAS
Date/time of run: 20APR2021 16:04
Analysis Plan: 13JAN2021

Table EFF.MAXNRS.PEV.Pooled.S2: Summary of Change from Baseline in Maximum NRS Score by Visit and Overall, by Subgroup (Pain Evaluable Population)

Study: Pooled

Treatment	Study visit	n (%)[1]	Mean (SD)[1]	Change from baseline LS-mean change (SE)[2]	Difference LS-mean change [95% CI] p-value[2]	SMD Hedges' g [95% CI][2]
BMI (kg/m2) at Baseline						
< 30						
Relugolix+E2/NETA	Baseline	54 (100.0)	7.1 (2.22)	-2.61 (0.342)	-1.81	-0.72
N=54	Week 4	54 (100.0)	4.4 (2.84)		[-2.71,-0.91]	[-1.09,-0.36]
Placebo	Baseline	70 (100.0)	6.8 (1.84)	-0.80 (0.301)	0.0001	
N=70	Week 4	70 (100.0)	6.0 (2.52)			
>= 30						
Relugolix+E2/NETA	Baseline	71 (100.0)	7.4 (1.94)	-2.27 (0.305)	-1.32	-0.52
N=71	Week 4	71 (100.0)	5.1 (3.05)		[-2.15,-0.50]	[-0.84,-0.19]
Placebo	Baseline	81 (100.0)	7.3 (2.01)	-0.95 (0.285)	0.0018	
N=81	Week 4	81 (100.0)	6.3 (2.71)			
Missing						
Relugolix+E2/NETA	Baseline	1 (100.0)	6.0 (NE)	NC (NC)	NC	NC
N=1	Week 4	1 (100.0)	4.0 (NE)		[NC,NC]	[NC,NC]
Placebo	Baseline	0	NE (NE)	NC (NC)	NC	
N=0	Week 4	0	NE (NE)			

Post hoc analysis. The denominator for percentages is the number of patients in the pain evaluable population for each treatment group.
Pain evaluable patients are defined as those who had maximum NRS score >=4 at baseline and had at least 28 days (80% of the last 35 days of treatment) of pain scores recorded in the e-Diary.
[1] Summary statistics are based on observed data.
[2] LS means, LS mean differences (95% CIs), p-value and Hedges' g (95% CIs) are based on a mixed-effects model with study, treatment, visit, and a treatment-by-visit interaction as fixed effects. The multiple visits for each patient are the repeated measures as a random effect within each patient with an unstructured covariance. Hedges' g is calculated using a small sample bias correction. Interaction p-value is only produced for the Overall period.
The reference group for the LS mean difference and Hedges' g is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with data; CI: Confidence interval; LS: Least squares; MBL: Menstrual blood loss; NETA: Norethindrone acetate; NRS: Numerical rating scale; SD: Standard deviation; SE: Standard error; SMD: Standardized mean difference; NC: Not calculated; NE: Non-estimable.

SOURCE: \Studies\MYV\MYV102\Analysis\Prod\Progs\TFLs\Tab_EFF_NRS_CON.SAS
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Table EFF.MAXNRS.PEV.Pooled.S2: Summary of Change from Baseline in Maximum NRS Score by Visit and Overall, by Subgroup (Pain Evaluable Population)

Study: Pooled

Treatment	Study visit	n (%)[1]	Mean (SD)[1]	Change from baseline LS-mean change (SE)[2]	Difference LS-mean change [95% CI] p-value[2]	SMD Hedges' g [95% CI][2]
BMI (kg/m2) at Baseline						
< 30						
Relugolix+E2/NETA	Baseline	54 (100.0)	7.1 (2.22)	-4.03 (0.413)	-2.87	-0.96
N=54	Week 8	53 (98.1)	3.0 (2.66)		[-3.96,-1.79]	[-1.33,-0.58]
Placebo	Baseline	70 (100.0)	6.8 (1.84)	-1.15 (0.360)	<.0001	
N=70	Week 8	70 (100.0)	5.6 (2.93)			
>= 30						
Relugolix+E2/NETA	Baseline	71 (100.0)	7.4 (1.94)	-4.05 (0.322)	-2.48	-0.92
N=71	Week 8	70 (98.6)	3.4 (2.71)		[-3.36,-1.61]	[-1.25,-0.58]
Placebo	Baseline	81 (100.0)	7.3 (2.01)	-1.57 (0.302)	<.0001	
N=81	Week 8	80 (98.8)	5.7 (2.82)			
Missing						
Relugolix+E2/NETA	Baseline	1 (100.0)	6.0 (NE)	NC (NC)	NC	NC
N=1	Week 8	1 (100.0)	4.0 (NE)		[NC,NC]	[NC,NC]
Placebo	Baseline	0	NE (NE)	NC (NC)	NC	
N=0	Week 8	0	NE (NE)			

Post hoc analysis. The denominator for percentages is the number of patients in the pain evaluable population for each treatment group.
Pain evaluable patients are defined as those who had maximum NRS score >=4 at baseline and had at least 28 days (80% of the last 35 days of treatment) of pain scores recorded in the e-Diary.
[1] Summary statistics are based on observed data.
[2] LS means, LS mean differences (95% CIs), p-value and Hedges' g (95% CIs) are based on a mixed-effects model with study, treatment, visit, and a treatment-by-visit interaction as fixed effects. The multiple visits for each patient are the repeated measures as a random effect within each patient with an unstructured covariance. Hedges' g is calculated using a small sample bias correction. Interaction p-value is only produced for the Overall period.
The reference group for the LS mean difference and Hedges' g is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with data; CI: Confidence interval; LS: Least squares; MBL: Menstrual blood loss; NETA: Norethindrone acetate; NRS: Numerical rating scale; SD: Standard deviation; SE: Standard error; SMD: Standardized mean difference; NC: Not calculated; NE: Non-estimable.

SOURCE: \Studies\MYV\MYV102\Analysis\Prod\Progs\TFLs\Tab_EFF_NRS_CON.SAS
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Table EFF.MAXNRS.PEV.Pooled.S2: Summary of Change from Baseline in Maximum NRS Score by Visit and Overall, by Subgroup (Pain Evaluable Population)

Study: Pooled

Treatment	Study visit	n (%)[1]	Mean (SD)[1]	Change from baseline LS-mean change (SE)[2]	Difference LS-mean change [95% CI] p-value[2]	SMD Hedges' g [95% CI][2]
BMI (kg/m2) at Baseline						
< 30						
Relugolix+E2/NETA	Baseline	54 (100.0)	7.1 (2.22)	-3.81 (0.431)	-2.11	-0.68
N=54	Week 12	50 (92.6)	3.1 (3.06)		[-3.24,-0.98]	[-1.05,-0.31]
Placebo	Baseline	70 (100.0)	6.8 (1.84)	-1.70 (0.375)	0.0003	
N=70	Week 12	68 (97.1)	5.1 (2.90)			
>= 30						
Relugolix+E2/NETA	Baseline	71 (100.0)	7.4 (1.94)	-4.31 (0.341)	-2.39	-0.83
N=71	Week 12	70 (98.6)	3.1 (3.22)		[-3.31,-1.46]	[-1.17,-0.50]
Placebo	Baseline	81 (100.0)	7.3 (2.01)	-1.92 (0.320)	<.0001	
N=81	Week 12	80 (98.8)	5.4 (2.81)			
Missing						
Relugolix+E2/NETA	Baseline	1 (100.0)	6.0 (NE)	NC (NC)	NC	NC
N=1	Week 12	1 (100.0)	4.0 (NE)		[NC,NC]	[NC,NC]
Placebo	Baseline	0	NE (NE)	NC (NC)	NC	
N=0	Week 12	0	NE (NE)			

Post hoc analysis. The denominator for percentages is the number of patients in the pain evaluable population for each treatment group.
Pain evaluable patients are defined as those who had maximum NRS score >=4 at baseline and had at least 28 days (80% of the last 35 days of treatment) of pain scores recorded in the e-Diary.
[1] Summary statistics are based on observed data.
[2] LS means, LS mean differences (95% CIs), p-value and Hedges' g (95% CIs) are based on a mixed-effects model with study, treatment, visit, and a treatment-by-visit interaction as fixed effects. The multiple visits for each patient are the repeated measures as a random effect within each patient with an unstructured covariance. Hedges' g is calculated using a small sample bias correction. Interaction p-value is only produced for the Overall period.
The reference group for the LS mean difference and Hedges' g is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with data; CI: Confidence interval; LS: Least squares; MBL: Menstrual blood loss; NETA: Norethindrone acetate; NRS: Numerical rating scale; SD: Standard deviation; SE: Standard error; SMD: Standardized mean difference; NC: Not calculated; NE: Non-estimable.

SOURCE: \Studies\MYV\MYV102\Analysis\Prod\Progs\TFLs\Tab_EFF_NRS_CON.SAS
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Table EFF.MAXNRS.PEV.Pooled.S2: Summary of Change from Baseline in Maximum NRS Score by Visit and Overall, by Subgroup (Pain Evaluable Population)

Study: Pooled

Treatment	Study visit	n (%)[1]	Mean (SD)[1]	Change from baseline LS-mean change (SE)[2]	Difference LS-mean change [95% CI] p-value[2]	SMD Hedges' g [95% CI][2]
BMI (kg/m2) at Baseline						
< 30						
Relugolix+E2/NETA	Baseline	54 (100.0)	7.1 (2.22)	-3.99 (0.456)	-2.00	-0.61
N=54	Week 16	50 (92.6)	2.9 (3.25)		[-3.20,-0.80]	[-0.99,-0.24]
Placebo	Baseline	70 (100.0)	6.8 (1.84)	-1.99 (0.403)	0.0013	
N=70	Week 16	63 (90.0)	4.8 (3.09)			
>= 30						
Relugolix+E2/NETA	Baseline	71 (100.0)	7.4 (1.94)	-4.50 (0.354)	-2.14	-0.73
N=71	Week 16	69 (97.2)	2.9 (3.02)		[-3.10,-1.18]	[-1.06,-0.40]
Placebo	Baseline	81 (100.0)	7.3 (2.01)	-2.36 (0.332)	<.0001	
N=81	Week 16	79 (97.5)	5.0 (3.22)			
Missing						
Relugolix+E2/NETA	Baseline	1 (100.0)	6.0 (NE)	NC (NC)	NC	NC
N=1	Week 16	1 (100.0)	4.0 (NE)		[NC,NC]	[NC,NC]
Placebo	Baseline	0	NE (NE)	NC (NC)	NC	
N=0	Week 16	0	NE (NE)			

Post hoc analysis. The denominator for percentages is the number of patients in the pain evaluable population for each treatment group.
Pain evaluable patients are defined as those who had maximum NRS score >=4 at baseline and had at least 28 days (80% of the last 35 days of treatment) of pain scores recorded in the e-Diary.
[1] Summary statistics are based on observed data.
[2] LS means, LS mean differences (95% CIs), p-value and Hedges' g (95% CIs) are based on a mixed-effects model with study, treatment, visit, and a treatment-by-visit interaction as fixed effects. The multiple visits for each patient are the repeated measures as a random effect within each patient with an unstructured covariance. Hedges' g is calculated using a small sample bias correction. Interaction p-value is only produced for the Overall period.
The reference group for the LS mean difference and Hedges' g is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with data; CI: Confidence interval; LS: Least squares; MBL: Menstrual blood loss; NETA: Norethindrone acetate; NRS: Numerical rating scale; SD: Standard deviation; SE: Standard error; SMD: Standardized mean difference; NC: Not calculated; NE: Non-estimable.

SOURCE: \Studies\MYV\MYV102\Analysis\Prod\Progs\TFLs\Tab_EFF_NRS_CON.SAS
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Table EFF.MAXNRS.PEV.Pooled.S2: Summary of Change from Baseline in Maximum NRS Score by Visit and Overall, by Subgroup (Pain Evaluable Population)

Study: Pooled

Treatment	Study visit	n (%)[1]	Mean (SD)[1]	Change from baseline LS-mean change (SE)[2]	Difference LS-mean change [95% CI] p-value[2]	SMD Hedges' g [95% CI][2]
BMI (kg/m2) at Baseline						
< 30						
Relugolix+E2/NETA	Baseline	54 (100.0)	7.1 (2.22)	-4.42 (0.443)	-2.77	-0.88
N=54	Week 20	49 (90.7)	2.6 (2.79)		[-3.94,-1.60]	[-1.27,-0.49]
Placebo	Baseline	70 (100.0)	6.8 (1.84)	-1.65 (0.392)	<.0001	
N=70	Week 20	61 (87.1)	5.1 (3.36)			
>= 30						
Relugolix+E2/NETA	Baseline	71 (100.0)	7.4 (1.94)	-4.80 (0.348)	-2.30	-0.79
N=71	Week 20	67 (94.4)	2.5 (2.94)		[-3.24,-1.36]	[-1.13,-0.45]
Placebo	Baseline	81 (100.0)	7.3 (2.01)	-2.50 (0.326)	<.0001	
N=81	Week 20	77 (95.1)	4.9 (2.94)			
Missing						
Relugolix+E2/NETA	Baseline	1 (100.0)	6.0 (NE)	NC (NC)	NC	NC
N=1	Week 20	1 (100.0)	3.0 (NE)		[NC,NC]	[NC,NC]
Placebo	Baseline	0	NE (NE)	NC (NC)	NC	
N=0	Week 20	0	NE (NE)			

Post hoc analysis. The denominator for percentages is the number of patients in the pain evaluable population for each treatment group.
Pain evaluable patients are defined as those who had maximum NRS score >=4 at baseline and had at least 28 days (80% of the last 35 days of treatment) of pain scores recorded in the e-Diary.
[1] Summary statistics are based on observed data.
[2] LS means, LS mean differences (95% CIs), p-value and Hedges' g (95% CIs) are based on a mixed-effects model with study, treatment, visit, and a treatment-by-visit interaction as fixed effects. The multiple visits for each patient are the repeated measures as a random effect within each patient with an unstructured covariance. Hedges' g is calculated using a small sample bias correction. Interaction p-value is only produced for the Overall period.
The reference group for the LS mean difference and Hedges' g is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with data; CI: Confidence interval; LS: Least squares; MBL: Menstrual blood loss; NETA: Norethindrone acetate; NRS: Numerical rating scale; SD: Standard deviation; SE: Standard error; SMD: Standardized mean difference; NC: Not calculated; NE: Non-estimable.

SOURCE: \Studies\MYV\MYV102\Analysis\Prod\Progs\TFLs\Tab_EFF_NRS_CON.SAS
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Table EFF.MAXNRS.PEV.Pooled.S2: Summary of Change from Baseline in Maximum NRS Score by Visit and Overall, by Subgroup (Pain Evaluable Population)

Study: Pooled

Treatment	Study visit	n (%)[1]	Mean (SD)[1]	Change from baseline LS-mean change (SE)[2]	Difference LS-mean change [95% CI] p-value[2]	SMD Hedges' g [95% CI][2]
BMI (kg/m2) at Baseline						
< 30						
Relugolix+E2/NETA	Baseline	54 (100.0)	7.1 (2.22)	-4.72 (0.440)	-2.58	-0.82
N=54	Week 24	48 (88.9)	2.2 (2.77)		[-3.74,-1.42]	[-1.21,-0.43]
Placebo	Baseline	70 (100.0)	6.8 (1.84)	-2.14 (0.389)	<.0001	
N=70	Week 24	60 (85.7)	4.6 (3.11)			
>= 30						
Relugolix+E2/NETA	Baseline	71 (100.0)	7.4 (1.94)	-5.07 (0.372)	-1.92	-0.63
N=71	Week 24	66 (93.0)	2.1 (2.47)		[-2.93,-0.92]	[-0.96,-0.29]
Placebo	Baseline	81 (100.0)	7.3 (2.01)	-3.15 (0.347)	0.0002	
N=81	Week 24	76 (93.8)	4.3 (3.16)			
Missing						
Relugolix+E2/NETA	Baseline	1 (100.0)	6.0 (NE)	NC (NC)	NC	NC
N=1	Week 24	1 (100.0)	4.0 (NE)		[NC,NC]	[NC,NC]
Placebo	Baseline	0	NE (NE)	NC (NC)	NC	
N=0	Week 24	0	NE (NE)			

Post hoc analysis. The denominator for percentages is the number of patients in the pain evaluable population for each treatment group.
Pain evaluable patients are defined as those who had maximum NRS score >=4 at baseline and had at least 28 days (80% of the last 35 days of treatment) of pain scores recorded in the e-Diary.
[1] Summary statistics are based on observed data.
[2] LS means, LS mean differences (95% CIs), p-value and Hedges' g (95% CIs) are based on a mixed-effects model with study, treatment, visit, and a treatment-by-visit interaction as fixed effects. The multiple visits for each patient are the repeated measures as a random effect within each patient with an unstructured covariance. Hedges' g is calculated using a small sample bias correction. Interaction p-value is only produced for the Overall period.
The reference group for the LS mean difference and Hedges' g is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with data; CI: Confidence interval; LS: Least squares; MBL: Menstrual blood loss; NETA: Norethindrone acetate; NRS: Numerical rating scale; SD: Standard deviation; SE: Standard error; SMD: Standardized mean difference; NC: Not calculated; NE: Non-estimable.

SOURCE: \Studies\MYV\MYV102\Analysis\Prod\Progs\TFLs\Tab_EFF_NRS_CON.SAS
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Table EFF.MAXNRS.PEV.Pooled.S2: Summary of Change from Baseline in Maximum NRS Score by Visit and Overall, by Subgroup (Pain Evaluable Population)

Study: Pooled

Treatment	Study visit	n (%)[1]	Mean (SD)[1]	Change from baseline LS-mean change (SE)[2]	Difference LS-mean change [95% CI] p-value[2]	SMD Hedges' g [95% CI][2]	Int. p-value[2]
BMI (kg/m2) at Baseline							
< 30							
Relugolix+E2/NETA	Baseline	54 (100.0)	7.1 (2.22)	-4.08 (0.314)	-2.45	-0.84	0.4447
N=54	Overall	54 (100.0)	3.2 (2.48)		[-3.27,-1.62]	[-1.21,-0.47]	
Placebo	Baseline	70 (100.0)	6.8 (1.84)	-1.64 (0.276)	<.0001		
N=70	Overall	70 (100.0)	5.2 (2.41)				
>= 30							
Relugolix+E2/NETA	Baseline	71 (100.0)	7.4 (1.94)	-4.06 (0.274)	-2.03	-0.70	
N=71	Overall	71 (100.0)	3.3 (2.50)		[-2.77,-1.29]	[-1.02,-0.37]	
Placebo	Baseline	81 (100.0)	7.3 (2.01)	-2.03 (0.257)	<.0001		
N=81	Overall	81 (100.0)	5.2 (2.34)				
Missing							
Relugolix+E2/NETA	Baseline	1 (100.0)	6.0 (NE)	NC (NC)	NC	NC	
N=1	Overall	1 (100.0)	3.8 (NE)		[NC,NC]	[NC,NC]	
Placebo	Baseline	0	NE (NE)	NC (NC)	NC		
N=0	Overall	0	NE (NE)				

Post hoc analysis. The denominator for percentages is the number of patients in the pain evaluable population for each treatment group.
Pain evaluable patients are defined as those who had maximum NRS score >=4 at baseline and had at least 28 days (80% of the last 35 days of treatment) of pain scores recorded in the e-Diary.
[1] Summary statistics are based on observed data. Mean (SD) are calculated based on the mean observed value across all post-baseline visits within each patient.
[2] LS means, LS mean differences (95% CIs), p-value and Hedges' g (95% CIs) are based on a mixed-effects model with study, treatment, visit, subgroup, treatment-by-visit interaction and a subgroup-by-treatment interaction as fixed effects. The multiple visits for each patient are the repeated measures as a random effect within each patient with an unstructured covariance. Hedges' g is calculated using a small sample bias correction. Missing subgroup levels are not included in estimation of the interaction p-value.
The reference group for the LS mean difference and Hedges' g is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with data; CI: Confidence interval; int: Interaction; LS: Least squares; MBL: Menstrual blood loss; NETA: Norethindrone acetate; NRS: Numerical rating scale; SD: Standard deviation; SE: Standard error; SMD: Standardized mean difference; NC: Not calculated; NE: Non-estimable.

SOURCE: \Studies\MYV\MYV102\Analysis\Prod\Progs\TFLs\Tab_EFF_NRS_CON.SAS
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Table EFF.MAXNRS.PEV.Pooled.S5: Summary of Change from Baseline in Maximum NRS Score by Visit and Overall, by Subgroup (Pain Evaluable Population)

Study: Pooled

Treatment	Study visit	n (%)[1]	Mean (SD)[1]	Change from baseline LS-mean change (SE)[2]	Difference LS-mean change [95% CI] p-value[2]	SMD Hedges' g [95% CI][2]
MBL Volume at Baseline (mL)						
< 225 mL						
Relugolix+E2/NETA	Baseline	81 (100.0)	7.4 (2.05)	-2.41 (0.265)	-1.64	-0.69
N=81	Week 4	81 (100.0)	5.0 (2.93)		[-2.34,-0.94]	[-0.99,-0.39]
Placebo	Baseline	100 (100.0)	7.1 (1.98)	-0.77 (0.238)	<.0001	
N=100	Week 4	100 (100.0)	6.3 (2.55)			
>= 225 mL						
Relugolix+E2/NETA	Baseline	45 (100.0)	6.9 (2.05)	-2.40 (0.420)	-1.32	-0.47
N=45	Week 4	45 (100.0)	4.5 (3.01)		[-2.47,-0.18]	[-0.87,-0.07]
Placebo	Baseline	51 (100.0)	6.9 (1.88)	-1.07 (0.395)	0.0238	
N=51	Week 4	51 (100.0)	5.9 (2.76)			

Post hoc analysis. The denominator for percentages is the number of patients in the pain evaluable population for each treatment group.
Pain evaluable patients are defined as those who had maximum NRS score >=4 at baseline and had at least 28 days (80% of the last 35 days of treatment) of pain scores recorded in the e-Diary.
[1] Summary statistics are based on observed data.
[2] LS means, LS mean differences (95% CIs), p-value and Hedges' g (95% CIs) are based on a mixed-effects model with study, treatment, visit, and a treatment-by-visit interaction as fixed effects. The multiple visits for each patient are the repeated measures as a random effect within each patient with an unstructured covariance. Hedges' g is calculated using a small sample bias correction. Interaction p-value is only produced for the Overall period.
The reference group for the LS mean difference and Hedges' g is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with data; CI: Confidence interval; LS: Least squares; MBL: Menstrual blood loss; NETA: Norethindrone acetate; NRS: Numerical rating scale; SD: Standard deviation; SE: Standard error; SMD: Standardized mean difference.

SOURCE: \Studies\MYV\MYV102\Analysis\Prod\Progs\TFLs\Tab_EFF_NRS_CON.SAS
Date/time of run: 20APR2021 16:04
Analysis Plan: 13JAN2021

Table EFF.MAXNRS.PEV.Pooled.S5: Summary of Change from Baseline in Maximum NRS Score by Visit and Overall, by Subgroup (Pain Evaluable Population)

Study: Pooled

Treatment	Study visit	n (%)[1]	Mean (SD)[1]	Change from baseline LS-mean change (SE)[2]	Difference LS-mean change [95% CI] p-value[2]	SMD Hedges' g [95% CI][2]
MBL Volume at Baseline (mL)						
< 225 mL						
Relugolix+E2/NETA	Baseline	81 (100.0)	7.4 (2.05)	-4.21 (0.306)	-2.87	-1.05
N=81	Week 8	80 (98.8)	3.2 (2.79)		[-3.67,-2.06]	[-1.36,-0.74]
Placebo	Baseline	100 (100.0)	7.1 (1.98)	-1.34 (0.274)	<.0001	
N=100	Week 8	100 (100.0)	5.7 (2.73)			
>= 225 mL						
Relugolix+E2/NETA	Baseline	45 (100.0)	6.9 (2.05)	-3.69 (0.454)	-2.25	-0.74
N=45	Week 8	44 (97.8)	3.3 (2.48)		[-3.49,-1.01]	[-1.16,-0.32]
Placebo	Baseline	51 (100.0)	6.9 (1.88)	-1.44 (0.428)	0.0005	
N=51	Week 8	50 (98.0)	5.5 (3.13)			

Post hoc analysis. The denominator for percentages is the number of patients in the pain evaluable population for each treatment group.
Pain evaluable patients are defined as those who had maximum NRS score >=4 at baseline and had at least 28 days (80% of the last 35 days of treatment) of pain scores recorded in the e-Diary.
[1] Summary statistics are based on observed data.
[2] LS means, LS mean differences (95% CIs), p-value and Hedges' g (95% CIs) are based on a mixed-effects model with study, treatment, visit, and a treatment-by-visit interaction as fixed effects. The multiple visits for each patient are the repeated measures as a random effect within each patient with an unstructured covariance. Hedges' g is calculated using a small sample bias correction. Interaction p-value is only produced for the Overall period.
The reference group for the LS mean difference and Hedges' g is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with data; CI: Confidence interval; LS: Least squares; MBL: Menstrual blood loss; NETA: Norethindrone acetate; NRS: Numerical rating scale; SD: Standard deviation; SE: Standard error; SMD: Standardized mean difference.

SOURCE: \Studies\MYV\MYV102\Analysis\Prod\Progs\TFLs\Tab_EFF_NRS_CON.SAS
Date/time of run: 20APR2021 16:04
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Table EFF.MAXNRS.PEV.Pooled.S5: Summary of Change from Baseline in Maximum NRS Score by Visit and Overall, by Subgroup (Pain Evaluable Population)

Study: Pooled

Treatment	Study visit	n (%)[1]	Mean (SD)[1]	Change from baseline LS-mean change (SE)[2]	Difference LS-mean change [95% CI] p-value[2]	SMD Hedges' g [95% CI][2]
MBL Volume at Baseline (mL)						
< 225 mL						
Relugolix+E2/NETA	Baseline	81 (100.0)	7.4 (2.05)	-4.07 (0.328)	-2.13	-0.74
N=81	Week 12	76 (93.8)	3.3 (3.23)		[-3.00,-1.27]	[-1.05,-0.43]
Placebo	Baseline	100 (100.0)	7.1 (1.98)	-1.93 (0.291)	<.0001	
N=100	Week 12	98 (98.0)	5.2 (2.68)			
>= 225 mL						
Relugolix+E2/NETA	Baseline	45 (100.0)	6.9 (2.05)	-4.13 (0.466)	-2.52	-0.81
N=45	Week 12	45 (100.0)	2.8 (2.97)		[-3.80,-1.25]	[-1.22,-0.39]
Placebo	Baseline	51 (100.0)	6.9 (1.88)	-1.61 (0.441)	0.0002	
N=51	Week 12	50 (98.0)	5.4 (3.16)			

Post hoc analysis. The denominator for percentages is the number of patients in the pain evaluable population for each treatment group.
Pain evaluable patients are defined as those who had maximum NRS score >=4 at baseline and had at least 28 days (80% of the last 35 days of treatment) of pain scores recorded in the e-Diary.
[1] Summary statistics are based on observed data.
[2] LS means, LS mean differences (95% CIs), p-value and Hedges' g (95% CIs) are based on a mixed-effects model with study, treatment, visit, and a treatment-by-visit interaction as fixed effects. The multiple visits for each patient are the repeated measures as a random effect within each patient with an unstructured covariance. Hedges' g is calculated using a small sample bias correction. Interaction p-value is only produced for the Overall period.
The reference group for the LS mean difference and Hedges' g is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with data; CI: Confidence interval; LS: Least squares; MBL: Menstrual blood loss; NETA: Norethindrone acetate; NRS: Numerical rating scale; SD: Standard deviation; SE: Standard error; SMD: Standardized mean difference.

SOURCE: \Studies\MYV\MYV102\Analysis\Prod\Progs\TFLs\Tab_EFF_NRS_CON.SAS
Date/time of run: 20APR2021 16:04
Analysis Plan: 13JAN2021

Table EFF.MAXNRS.PEV.Pooled.S5: Summary of Change from Baseline in Maximum NRS Score by Visit and Overall, by Subgroup (Pain Evaluable Population)

Study: Pooled

Treatment	Study visit	n (%)[1]	Mean (SD)[1]	Change from baseline LS-mean change (SE)[2]	Difference LS-mean change [95% CI] p-value[2]	SMD Hedges' g [95% CI][2]
MBL Volume at Baseline (mL)						
< 225 mL						
Relugolix+E2/NETA	Baseline	81 (100.0)	7.4 (2.05)	-4.68 (0.335)	-2.16	-0.73
N=81	Week 16	75 (92.6)	2.6 (2.93)		[-3.05,-1.27]	[-1.05,-0.42]
Placebo	Baseline	100 (100.0)	7.1 (1.98)	-2.52 (0.299)	<.0001	
N=100	Week 16	95 (95.0)	4.6 (2.93)			
>= 225 mL						
Relugolix+E2/NETA	Baseline	45 (100.0)	6.9 (2.05)	-3.58 (0.483)	-2.09	-0.65
N=45	Week 16	45 (100.0)	3.4 (3.34)		[-3.42,-0.76]	[-1.07,-0.24]
Placebo	Baseline	51 (100.0)	6.9 (1.88)	-1.49 (0.466)	0.0025	
N=51	Week 16	47 (92.2)	5.5 (3.51)			

Post hoc analysis. The denominator for percentages is the number of patients in the pain evaluable population for each treatment group.
Pain evaluable patients are defined as those who had maximum NRS score >=4 at baseline and had at least 28 days (80% of the last 35 days of treatment) of pain scores recorded in the e-Diary.
[1] Summary statistics are based on observed data.
[2] LS means, LS mean differences (95% CIs), p-value and Hedges' g (95% CIs) are based on a mixed-effects model with study, treatment, visit, and a treatment-by-visit interaction as fixed effects. The multiple visits for each patient are the repeated measures as a random effect within each patient with an unstructured covariance. Hedges' g is calculated using a small sample bias correction. Interaction p-value is only produced for the Overall period.
The reference group for the LS mean difference and Hedges' g is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with data; CI: Confidence interval; LS: Least squares; MBL: Menstrual blood loss; NETA: Norethindrone acetate; NRS: Numerical rating scale; SD: Standard deviation; SE: Standard error; SMD: Standardized mean difference.

SOURCE: \Studies\MYV\MYV102\Analysis\Prod\Progs\TFLs\Tab_EFF_NRS_CON.SAS
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Table EFF.MAXNRS.PEV.Pooled.S5: Summary of Change from Baseline in Maximum NRS Score by Visit and Overall, by Subgroup (Pain Evaluable Population)

Study: Pooled

Treatment	Study visit	n (%)[1]	Mean (SD)[1]	Change from baseline LS-mean change (SE)[2]	Difference LS-mean change [95% CI] p-value[2]	SMD Hedges' g [95% CI][2]
MBL Volume at Baseline (mL)						
< 225 mL						
Relugolix+E2/NETA	Baseline	81 (100.0)	7.4 (2.05)	-4.92 (0.338)	-2.58	-0.87
N=81	Week 20	74 (91.4)	2.5 (2.89)		[-3.47,-1.68]	[-1.19,-0.55]
Placebo	Baseline	100 (100.0)	7.1 (1.98)	-2.34 (0.303)	<.0001	
N=100	Week 20	91 (91.0)	4.8 (2.84)			
>= 225 mL						
Relugolix+E2/NETA	Baseline	45 (100.0)	6.9 (2.05)	-4.10 (0.470)	-2.42	-0.78
N=45	Week 20	43 (95.6)	2.6 (2.82)		[-3.70,-1.13]	[-1.21,-0.35]
Placebo	Baseline	51 (100.0)	6.9 (1.88)	-1.68 (0.447)	0.0003	
N=51	Week 20	47 (92.2)	5.3 (3.61)			

Post hoc analysis. The denominator for percentages is the number of patients in the pain evaluable population for each treatment group.
Pain evaluable patients are defined as those who had maximum NRS score >=4 at baseline and had at least 28 days (80% of the last 35 days of treatment) of pain scores recorded in the e-Diary.
[1] Summary statistics are based on observed data.
[2] LS means, LS mean differences (95% CIs), p-value and Hedges' g (95% CIs) are based on a mixed-effects model with study, treatment, visit, and a treatment-by-visit interaction as fixed effects. The multiple visits for each patient are the repeated measures as a random effect within each patient with an unstructured covariance. Hedges' g is calculated using a small sample bias correction. Interaction p-value is only produced for the Overall period.
The reference group for the LS mean difference and Hedges' g is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with data; CI: Confidence interval; LS: Least squares; MBL: Menstrual blood loss; NETA: Norethindrone acetate; NRS: Numerical rating scale; SD: Standard deviation; SE: Standard error; SMD: Standardized mean difference.

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Table EFF.MAXNRS.PEV.Pooled.S5: Summary of Change from Baseline in Maximum NRS Score by Visit and Overall, by Subgroup (Pain Evaluable Population)

Study: Pooled

Treatment	Study visit	n (%)[1]	Mean (SD)[1]	Change from baseline LS-mean change (SE)[2]	Difference LS-mean change [95% CI] p-value[2]	SMD Hedges' g [95% CI][2]
MBL Volume at Baseline (mL)						
< 225 mL						
Relugolix+E2/NETA	Baseline	81 (100.0)	7.4 (2.05)	-5.06 (0.346)	-2.04	-0.68
N=81	Week 24	73 (90.1)	2.2 (2.68)		[-2.96,-1.12]	[-0.99,-0.36]
Placebo	Baseline	100 (100.0)	7.1 (1.98)	-3.02 (0.310)	<.0001	
N=100	Week 24	91 (91.0)	4.2 (2.86)			
>= 225 mL						
Relugolix+E2/NETA	Baseline	45 (100.0)	6.9 (2.05)	-4.60 (0.495)	-2.53	-0.78
N=45	Week 24	42 (93.3)	2.0 (2.43)		[-3.89,-1.17]	[-1.21,-0.35]
Placebo	Baseline	51 (100.0)	6.9 (1.88)	-2.07 (0.473)	0.0004	
N=51	Week 24	45 (88.2)	5.0 (3.59)			

Post hoc analysis. The denominator for percentages is the number of patients in the pain evaluable population for each treatment group.
Pain evaluable patients are defined as those who had maximum NRS score >=4 at baseline and had at least 28 days (80% of the last 35 days of treatment) of pain scores recorded in the e-Diary.
[1] Summary statistics are based on observed data.
[2] LS means, LS mean differences (95% CIs), p-value and Hedges' g (95% CIs) are based on a mixed-effects model with study, treatment, visit, and a treatment-by-visit interaction as fixed effects. The multiple visits for each patient are the repeated measures as a random effect within each patient with an unstructured covariance. Hedges' g is calculated using a small sample bias correction. Interaction p-value is only produced for the Overall period.
The reference group for the LS mean difference and Hedges' g is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with data; CI: Confidence interval; LS: Least squares; MBL: Menstrual blood loss; NETA: Norethindrone acetate; NRS: Numerical rating scale; SD: Standard deviation; SE: Standard error; SMD: Standardized mean difference.

SOURCE: \Studies\MYV\MYV102\Analysis\Prod\Progs\TFLs\Tab_EFF_NRS_CON.SAS
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Table EFF.MAXNRS.PEV.Pooled.S5: Summary of Change from Baseline in Maximum NRS Score by Visit and Overall, by Subgroup (Pain Evaluable Population)

Study: Pooled

Treatment	Study visit	n (%)[1]	Mean (SD)[1]	Change from baseline LS-mean change (SE)[2]	Difference LS-mean change [95% CI] p-value[2]	SMD Hedges' g [95% CI][2]	Int. p-value[2]
MBL Volume at Baseline (mL)							
< 225 mL							
Relugolix+E2/NETA	Baseline	81 (100.0)	7.4 (2.05)	-4.16 (0.260)	-2.28	-0.78	0.7030
N=81	Overall	81 (100.0)	3.3 (2.52)		[-2.97,-1.60]	[-1.09,-0.48]	
Placebo	Baseline	100 (100.0)	7.1 (1.98)	-1.88 (0.233)	<.0001		
N=100	Overall	100 (100.0)	5.1 (2.18)				
>= 225 mL							
Relugolix+E2/NETA	Baseline	45 (100.0)	6.9 (2.05)	-3.86 (0.339)	-2.07	-0.71	
N=45	Overall	45 (100.0)	3.2 (2.41)		[-2.99,-1.15]	[-1.12,-0.30]	
Placebo	Baseline	51 (100.0)	6.9 (1.88)	-1.79 (0.320)	<.0001		
N=51	Overall	51 (100.0)	5.4 (2.71)				

Post hoc analysis. The denominator for percentages is the number of patients in the pain evaluable population for each treatment group.
Pain evaluable patients are defined as those who had maximum NRS score >=4 at baseline and had at least 28 days (80% of the last 35 days of treatment) of pain scores recorded in the e-Diary.
[1] Summary statistics are based on observed data. Mean (SD) are calculated based on the mean observed value across all post-baseline visits within each patient.
[2] LS means, LS mean differences (95% CIs), p-value and Hedges' g (95% CIs) are based on a mixed-effects model with study, treatment, visit, subgroup, treatment-by-visit interaction and a subgroup-by-treatment interaction as fixed effects. The multiple visits for each patient are the repeated measures as a random effect within each patient with an unstructured covariance. Hedges' g is calculated using a small sample bias correction.
The reference group for the LS mean difference and Hedges' g is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with data; CI: Confidence interval; int: Interaction; LS: Least squares; MBL: Menstrual blood loss; NETA: Norethindrone acetate; NRS: Numerical rating scale; SD: Standard deviation; SE: Standard error; SMD: Standardized mean difference.

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1.1.11.1 Summary of Change from Baseline in Maximum NRS Score by Visit and Overall, by Subgroup (mITT Population)

Table EFF.MAXNRS.MITT.Pooled.S6: Summary of Change from Baseline in Maximum NRS Score by Visit and Overall, by Subgroup (mITT Population)

Study: Pooled

Treatment	Study visit	n (%)[1]	Mean (SD)[1]	Change from baseline LS-mean change (SE)[2]	Difference LS-mean change [95% CI] p-value[2]	SMD Hedges' g [95% CI][2]
Geographic Region I						
North America						
Relugolix+E2/NETA	Baseline	188 (98.4)	5.9 (3.22)	-1.50 (0.214)	-0.80	-0.27
N=191	Week 4	189 (99.0)	4.4 (3.21)		[-1.39,-0.20]	[-0.48,-0.07]
Placebo	Baseline	192 (99.0)	6.0 (3.02)	-0.70 (0.212)	0.0086	
N=194	Week 4	192 (99.0)	5.3 (3.03)			
Rest of World						
Relugolix+E2/NETA	Baseline	62 (100.0)	4.5 (3.29)	-1.09 (0.288)	-1.11	-0.49
N=62	Week 4	62 (100.0)	3.4 (2.50)		[-1.93,-0.30]	[-0.85,-0.13]
Placebo	Baseline	60 (96.8)	4.9 (2.65)	0.02 (0.292)	0.0076	
N=62	Week 4	62 (100.0)	5.0 (2.98)			

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group.
[1] Summary statistics are based on observed data.
[2] LS means, LS mean differences (95% CIs), p-value and Hedges' g (95% CIs) are based on a mixed-effects model with study, treatment, visit, and a treatment-by-visit interaction as fixed effects. The multiple visits for each patient are the repeated measures as a random effect within each patient with an unstructured covariance. Hedges' g is calculated using a small sample bias correction. Interaction p-value is only produced for the Overall period.
The reference group for the LS mean difference and Hedges' g is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with data; CI: Confidence interval; LS: Least squares; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; NRS: Numerical rating scale; SD: Standard deviation; SE: Standard error; SMD: Standardized mean difference.

SOURCE: \Studies\MYV\MYV102\Analysis\Prod\Progs\TFLs\Tab_EFF_NRS_CON.SAS
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Table EFF.MAXNRS.MITT.Pooled.S6: Summary of Change from Baseline in Maximum NRS Score by Visit and Overall, by Subgroup (mITT Population)

Study: Pooled

Treatment	Study visit	n (%)[1]	Mean (SD)[1]	Change from baseline LS-mean change (SE)[2]	Difference LS-mean change [95% CI] p-value[2]	SMD Hedges' g [95% CI][2]
Geographic Region I						
North America						
Relugolix+E2/NETA	Baseline	188 (98.4)	5.9 (3.22)	-2.83 (0.234)	-1.42	-0.46
N=191	Week 8	174 (91.1)	3.0 (2.88)		[-2.06,-0.78]	[-0.67,-0.25]
Placebo	Baseline	192 (99.0)	6.0 (3.02)	-1.41 (0.229)	<.0001	
N=194	Week 8	182 (93.8)	4.7 (3.15)			
Rest of World						
Relugolix+E2/NETA	Baseline	62 (100.0)	4.5 (3.29)	-2.22 (0.331)	-1.80	-0.70
N=62	Week 8	59 (95.2)	2.3 (2.43)		[-2.73,-0.87]	[-1.07,-0.33]
Placebo	Baseline	60 (96.8)	4.9 (2.65)	-0.43 (0.333)	0.0002	
N=62	Week 8	61 (98.4)	4.7 (3.12)			

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group.
[1] Summary statistics are based on observed data.
[2] LS means, LS mean differences (95% CIs), p-value and Hedges' g (95% CIs) are based on a mixed-effects model with study, treatment, visit, and a treatment-by-visit interaction as fixed effects. The multiple visits for each patient are the repeated measures as a random effect within each patient with an unstructured covariance. Hedges' g is calculated using a small sample bias correction. Interaction p-value is only produced for the Overall period.
The reference group for the LS mean difference and Hedges' g is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with data; CI: Confidence interval; LS: Least squares; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; NRS: Numerical rating scale; SD: Standard deviation; SE: Standard error; SMD: Standardized mean difference.

SOURCE: \Studies\MYV\MYV102\Analysis\Prod\Progs\TFLs\Tab_EFF_NRS_CON.SAS
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Table EFF.MAXNRS.MITT.Pooled.S6: Summary of Change from Baseline in Maximum NRS Score by Visit and Overall, by Subgroup (mITT Population)

Study: Pooled

Treatment	Study visit	n (%)[1]	Mean (SD)[1]	Change from baseline LS-mean change (SE)[2]	Difference LS-mean change [95% CI] p-value[2]	SMD Hedges' g [95% CI][2]
Geographic Region I						
North America						
Relugolix+E2/NETA	Baseline	188 (98.4)	5.9 (3.22)	-2.93 (0.241)	-1.05	-0.33
N=191	Week 12	168 (88.0)	2.9 (3.09)		[-1.72,-0.39]	[-0.55,-0.12]
Placebo	Baseline	192 (99.0)	6.0 (3.02)	-1.87 (0.235)	0.0019	
N=194	Week 12	178 (91.8)	4.3 (3.02)			
Rest of World						
Relugolix+E2/NETA	Baseline	62 (100.0)	4.5 (3.29)	-2.59 (0.365)	-2.37	-0.83
N=62	Week 12	59 (95.2)	1.9 (2.62)		[-3.39,-1.34]	[-1.21,-0.46]
Placebo	Baseline	60 (96.8)	4.9 (2.65)	-0.23 (0.367)	<.0001	
N=62	Week 12	61 (98.4)	4.9 (3.00)			

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group.
[1] Summary statistics are based on observed data.
[2] LS means, LS mean differences (95% CIs), p-value and Hedges' g (95% CIs) are based on a mixed-effects model with study, treatment, visit, and a treatment-by-visit interaction as fixed effects. The multiple visits for each patient are the repeated measures as a random effect within each patient with an unstructured covariance. Hedges' g is calculated using a small sample bias correction. Interaction p-value is only produced for the Overall period.
The reference group for the LS mean difference and Hedges' g is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with data; CI: Confidence interval; LS: Least squares; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; NRS: Numerical rating scale; SD: Standard deviation; SE: Standard error; SMD: Standardized mean difference.

SOURCE: \Studies\MYV\MYV102\Analysis\Prod\Progs\TFLs\Tab_EFF_NRS_CON.SAS
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Table EFF.MAXNRS.MITT.Pooled.S6: Summary of Change from Baseline in Maximum NRS Score by Visit and Overall, by Subgroup (mITT Population)

Study: Pooled

Treatment	Study visit	n (%)[1]	Mean (SD)[1]	Change from baseline LS-mean change (SE)[2]	Difference LS-mean change [95% CI] p-value[2]	SMD Hedges' g [95% CI][2]
Geographic Region I						
North America						
Relugolix+E2/NETA	Baseline	188 (98.4)	5.9 (3.22)	-3.20 (0.253)	-1.19	-0.36
N=191	Week 16	164 (85.9)	2.6 (2.99)		[-1.88,-0.49]	[-0.58,-0.14]
Placebo	Baseline	192 (99.0)	6.0 (3.02)	-2.01 (0.247)	0.0009	
N=194	Week 16	171 (88.1)	4.1 (3.23)			
Rest of World						
Relugolix+E2/NETA	Baseline	62 (100.0)	4.5 (3.29)	-2.56 (0.358)	-1.97	-0.71
N=62	Week 16	58 (93.5)	2.0 (2.75)		[-2.98,-0.96]	[-1.08,-0.34]
Placebo	Baseline	60 (96.8)	4.9 (2.65)	-0.59 (0.360)	0.0002	
N=62	Week 16	60 (96.8)	4.5 (3.00)			

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group.
[1] Summary statistics are based on observed data.
[2] LS means, LS mean differences (95% CIs), p-value and Hedges' g (95% CIs) are based on a mixed-effects model with study, treatment, visit, and a treatment-by-visit interaction as fixed effects. The multiple visits for each patient are the repeated measures as a random effect within each patient with an unstructured covariance. Hedges' g is calculated using a small sample bias correction. Interaction p-value is only produced for the Overall period.
The reference group for the LS mean difference and Hedges' g is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with data; CI: Confidence interval; LS: Least squares; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; NRS: Numerical rating scale; SD: Standard deviation; SE: Standard error; SMD: Standardized mean difference.

SOURCE: \Studies\MYV\MYV102\Analysis\Prod\Progs\TFLs\Tab_EFF_NRS_CON.SAS
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Table EFF.MAXNRS.MITT.Pooled.S6: Summary of Change from Baseline in Maximum NRS Score by Visit and Overall, by Subgroup (mITT Population)

Study: Pooled

Treatment	Study visit	n (%)[1]	Mean (SD)[1]	Change from baseline LS-mean change (SE)[2]	Difference LS-mean change [95% CI] p-value[2]	SMD Hedges' g [95% CI][2]
Geographic Region I						
North America						
Relugolix+E2/NETA	Baseline	188 (98.4)	5.9 (3.22)	-3.39 (0.257)	-1.31	-0.39
N=191	Week 20	154 (80.6)	2.5 (2.82)		[-2.01,-0.60]	[-0.62,-0.17]
Placebo	Baseline	192 (99.0)	6.0 (3.02)	-2.08 (0.249)	0.0003	
N=194	Week 20	165 (85.1)	4.1 (3.26)			
Rest of World						
Relugolix+E2/NETA	Baseline	62 (100.0)	4.5 (3.29)	-2.94 (0.354)	-2.11	-0.76
N=62	Week 20	58 (93.5)	1.6 (2.36)		[-3.10,-1.11]	[-1.14,-0.39]
Placebo	Baseline	60 (96.8)	4.9 (2.65)	-0.84 (0.358)	<.0001	
N=62	Week 20	58 (93.5)	4.3 (3.10)			

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group.
[1] Summary statistics are based on observed data.
[2] LS means, LS mean differences (95% CIs), p-value and Hedges' g (95% CIs) are based on a mixed-effects model with study, treatment, visit, and a treatment-by-visit interaction as fixed effects. The multiple visits for each patient are the repeated measures as a random effect within each patient with an unstructured covariance. Hedges' g is calculated using a small sample bias correction. Interaction p-value is only produced for the Overall period. The reference group for the LS mean difference and Hedges' g is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with data; CI: Confidence interval; LS: Least squares; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; NRS: Numerical rating scale; SD: Standard deviation; SE: Standard error; SMD: Standardized mean difference.

SOURCE: \Studies\MYV\MYV102\Analysis\Prod\Progs\TFLs\Tab_EFF_NRS_CON.SAS
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Table EFF.MAXNRS.MITT.Pooled.S6: Summary of Change from Baseline in Maximum NRS Score by Visit and Overall, by Subgroup (mITT Population)

Study: Pooled

Treatment	Study visit	n (%)[1]	Mean (SD)[1]	Change from baseline LS-mean change (SE)[2]	Difference LS-mean change [95% CI] p-value[2]	SMD Hedges' g [95% CI][2]
Geographic Region I						
North America						
Relugolix+E2/NETA	Baseline	188 (98.4)	5.9 (3.22)	-3.76 (0.257)	-1.29	-0.40
N=191	Week 24	149 (78.0)	2.0 (2.53)		[-2.00,-0.59]	[-0.62,-0.17]
Placebo	Baseline	192 (99.0)	6.0 (3.02)	-2.47 (0.250)	0.0004	
N=194	Week 24	158 (81.4)	3.7 (3.16)			
Rest of World						
Relugolix+E2/NETA	Baseline	62 (100.0)	4.5 (3.29)	-2.89 (0.392)	-1.44	-0.48
N=62	Week 24	56 (90.3)	1.5 (1.93)		[-2.55,-0.33]	[-0.86,-0.10]
Placebo	Baseline	60 (96.8)	4.9 (2.65)	-1.45 (0.400)	0.0113	
N=62	Week 24	54 (87.1)	3.8 (3.01)			

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group.
[1] Summary statistics are based on observed data.
[2] LS means, LS mean differences (95% CIs), p-value and Hedges' g (95% CIs) are based on a mixed-effects model with study, treatment, visit, and a treatment-by-visit interaction as fixed effects. The multiple visits for each patient are the repeated measures as a random effect within each patient with an unstructured covariance. Hedges' g is calculated using a small sample bias correction. Interaction p-value is only produced for the Overall period.
The reference group for the LS mean difference and Hedges' g is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with data; CI: Confidence interval; LS: Least squares; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; NRS: Numerical rating scale; SD: Standard deviation; SE: Standard error; SMD: Standardized mean difference.

SOURCE: \Studies\MYV\MYV102\Analysis\Prod\Progs\TFLs\Tab_EFF_NRS_CON.SAS
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Table EFF.MAXNRS.MITT.Pooled.S6: Summary of Change from Baseline in Maximum NRS Score by Visit and Overall, by Subgroup (mITT Population)

Study: Pooled

Treatment	Study visit	n (%)[1]	Mean (SD)[1]	Change from baseline LS-mean change (SE)[2]	Difference LS-mean change [95% CI] p-value[2]	SMD Hedges' g [95% CI][2]	Int. p-value[2]
Geographic Region I							
North America							0.3416
Relugolix+E2/NETA	Baseline	188 (98.4)	5.9 (3.22)	-2.92 (0.192)	-1.21	-0.40	
N=191	Overall	189 (99.0)	3.1 (2.54)		[-1.74,-0.68]	[-0.60,-0.19]	
Placebo	Baseline	192 (99.0)	6.0 (3.02)	-1.71 (0.188)	<.0001		
N=194	Overall	192 (99.0)	4.4 (2.64)				
Rest of World							
Relugolix+E2/NETA	Baseline	62 (100.0)	4.5 (3.29)	-2.42 (0.321)	-1.70	-0.56	
N=62	Overall	62 (100.0)	2.2 (2.29)		[-2.60,-0.81]	[-0.92,-0.20]	
Placebo	Baseline	60 (96.8)	4.9 (2.65)	-0.72 (0.325)	0.0002		
N=62	Overall	62 (100.0)	4.5 (2.64)				

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group.
[1] Summary statistics are based on observed data. Mean (SD) are calculated based on the mean observed value across all post-baseline visits within each patient.
[2] LS means, LS mean differences (95% CIs), p-value and Hedges' g (95% CIs) are based on a mixed-effects model with study, treatment, visit, subgroup, treatment-by-visit interaction and a subgroup-by-treatment interaction as fixed effects. The multiple visits for each patient are the repeated measures as a random effect within each patient with an unstructured covariance. Hedges' g is calculated using a small sample bias correction.
The reference group for the LS mean difference and Hedges' g is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with data; CI: Confidence interval; int: Interaction; LS: Least squares; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; NRS: Numerical rating scale; SD: Standard deviation; SE: Standard error; SMD: Standardized mean difference.

SOURCE: \Studies\MYV\MYV102\Analysis\Prod\Progs\TFLs\Tab_EFF_NRS_CON.SAS
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Table EFF.MAXNRS.MITT.Pooled.S3: Summary of Change from Baseline in Maximum NRS Score by Visit and Overall, by Subgroup (mITT Population)

Study: Pooled

Treatment	Study visit	n (%)[1]	Mean (SD)[1]	Change from baseline LS-mean change (SE)[2]	Difference LS-mean change [95% CI] p-value[2]	SMD Hedges' g [95% CI][2]
Uterine Volume at Baseline (cm3)						
< 300 cm3						
Relugolix+E2/NETA	Baseline	148 (100.0)	5.3 (3.30)	-1.53 (0.230)	-1.04	-0.37
N=148	Week 4	147 (99.3)	3.8 (3.07)		[-1.70,-0.37]	[-0.61,-0.13]
Placebo	Baseline	127 (98.4)	5.7 (3.00)	-0.49 (0.248)	0.0024	
N=129	Week 4	128 (99.2)	5.2 (2.96)			
>= 300 cm3						
Relugolix+E2/NETA	Baseline	101 (97.1)	5.9 (3.27)	-1.20 (0.280)	-0.64	-0.23
N=104	Week 4	103 (99.0)	4.7 (3.00)		[-1.38,0.10]	[-0.49,0.04]
Placebo	Baseline	125 (98.4)	5.8 (2.95)	-0.56 (0.251)	0.0920	
N=127	Week 4	126 (99.2)	5.3 (3.08)			
Missing						
Relugolix+E2/NETA	Baseline	1 (100.0)	8.0 (NE)	NC (NC)	NC	NC
N=1	Week 4	1 (100.0)	7.0 (NE)		[NC,NC]	[NC,NC]
Placebo	Baseline	0	NE (NE)	NC (NC)	NC	
N=0	Week 4	0	NE (NE)			

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group.
[1] Summary statistics are based on observed data.
[2] LS means, LS mean differences (95% CIs), p-value and Hedges' g (95% CIs) are based on a mixed-effects model with study, treatment, visit, and a treatment-by-visit interaction as fixed effects. The multiple visits for each patient are the repeated measures as a random effect within each patient with an unstructured covariance. Hedges' g is calculated using a small sample bias correction. Interaction p-value is only produced for the Overall period.
The reference group for the LS mean difference and Hedges' g is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with data; CI: Confidence interval; LS: Least squares; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; NRS: Numerical rating scale; SD: Standard deviation; SE: Standard error; SMD: Standardized mean difference; NC: Not calculated; NE: Non-estimable.

SOURCE: \Studies\MYV\MYV102\Analysis\Prod\Progs\TFLs\Tab_EFF_NRS_CON.SAS
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Table EFF.MAXNRS.MITT.Pooled.S3: Summary of Change from Baseline in Maximum NRS Score by Visit and Overall, by Subgroup (mITT Population)

Study: Pooled

Treatment	Study visit	n (%)[1]	Mean (SD)[1]	Change from baseline LS-mean change (SE)[2]	Difference LS-mean change [95% CI] p-value[2]	SMD Hedges' g [95% CI][2]
Uterine Volume at Baseline (cm3)						
< 300 cm3						
Relugolix+E2/NETA	Baseline	148 (100.0)	5.3 (3.30)	-2.57 (0.231)	-1.72	-0.63
N=148	Week 8	136 (91.9)	2.7 (2.81)		[-2.38,-1.05]	[-0.88,-0.38]
Placebo	Baseline	127 (98.4)	5.7 (3.00)	-0.85 (0.247)	<.0001	
N=129	Week 8	121 (93.8)	4.9 (3.08)			
>= 300 cm3						
Relugolix+E2/NETA	Baseline	101 (97.1)	5.9 (3.27)	-2.83 (0.334)	-1.33	-0.41
N=104	Week 8	97 (93.3)	3.0 (2.75)		[-2.21,-0.45]	[-0.68,-0.14]
Placebo	Baseline	125 (98.4)	5.8 (2.95)	-1.50 (0.297)	0.0032	
N=127	Week 8	122 (96.1)	4.5 (3.19)			
Missing						
Relugolix+E2/NETA	Baseline	1 (100.0)	8.0 (NE)	NC (NC)	NC	NC
N=1	Week 8	0	NE (NE)		[NC,NC]	[NC,NC]
Placebo	Baseline	0	NE (NE)	NC (NC)	NC	
N=0	Week 8	0	NE (NE)			

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group.
[1] Summary statistics are based on observed data.
[2] LS means, LS mean differences (95% CIs), p-value and Hedges' g (95% CIs) are based on a mixed-effects model with study, treatment, visit, and a treatment-by-visit interaction as fixed effects. The multiple visits for each patient are the repeated measures as a random effect within each patient with an unstructured covariance. Hedges' g is calculated using a small sample bias correction. Interaction p-value is only produced for the Overall period.
The reference group for the LS mean difference and Hedges' g is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with data; CI: Confidence interval; LS: Least squares; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; NRS: Numerical rating scale; SD: Standard deviation; SE: Standard error; SMD: Standardized mean difference; NC: Not calculated; NE: Non-estimable.

SOURCE: \Studies\MYV\MYV102\Analysis\Prod\Progs\TFLs\Tab_EFF_NRS_CON.SAS
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Table EFF.MAXNRS.MITT.Pooled.S3: Summary of Change from Baseline in Maximum NRS Score by Visit and Overall, by Subgroup (mITT Population)

Study: Pooled

Treatment	Study visit	n (%)[1]	Mean (SD)[1]	Change from baseline LS-mean change (SE)[2]	Difference LS-mean change [95% CI] p-value[2]	SMD Hedges' g [95% CI][2]
Uterine Volume at Baseline (cm3)						
< 300 cm3						
Relugolix+E2/NETA	Baseline	148 (100.0)	5.3 (3.30)	-2.89 (0.245)	-1.70	-0.59
N=148	Week 12	134 (90.5)	2.4 (2.91)		[-2.41,-0.99]	[-0.84,-0.34]
Placebo	Baseline	127 (98.4)	5.7 (3.00)	-1.19 (0.262)	<.0001	
N=129	Week 12	121 (93.8)	4.6 (2.92)			
>= 300 cm3						
Relugolix+E2/NETA	Baseline	101 (97.1)	5.9 (3.27)	-2.77 (0.350)	-1.01	-0.30
N=104	Week 12	93 (89.4)	3.1 (3.10)		[-1.93,-0.09]	[-0.57,-0.02]
Placebo	Baseline	125 (98.4)	5.8 (2.95)	-1.76 (0.310)	0.0316	
N=127	Week 12	118 (92.9)	4.3 (3.13)			
Missing						
Relugolix+E2/NETA	Baseline	1 (100.0)	8.0 (NE)	NC (NC)	NC	NC
N=1	Week 12	0	NE (NE)		[NC,NC]	[NC,NC]
Placebo	Baseline	0	NE (NE)	NC (NC)	NC	
N=0	Week 12	0	NE (NE)			

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group.
[1] Summary statistics are based on observed data.
[2] LS means, LS mean differences (95% CIs), p-value and Hedges' g (95% CIs) are based on a mixed-effects model with study, treatment, visit, and a treatment-by-visit interaction as fixed effects. The multiple visits for each patient are the repeated measures as a random effect within each patient with an unstructured covariance. Hedges' g is calculated using a small sample bias correction. Interaction p-value is only produced for the Overall period.
The reference group for the LS mean difference and Hedges' g is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with data; CI: Confidence interval; LS: Least squares; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; NRS: Numerical rating scale; SD: Standard deviation; SE: Standard error; SMD: Standardized mean difference; NC: Not calculated; NE: Non-estimable.

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Table EFF.MAXNRS.MITT.Pooled.S3: Summary of Change from Baseline in Maximum NRS Score by Visit and Overall, by Subgroup (mITT Population)

Study: Pooled

Treatment	Study visit	n (%)[1]	Mean (SD)[1]	Change from baseline LS-mean change (SE)[2]	Difference LS-mean change [95% CI] p-value[2]	SMD Hedges' g [95% CI][2]
Uterine Volume at Baseline (cm3)						
< 300 cm3						
Relugolix+E2/NETA	Baseline	148 (100.0)	5.3 (3.30)	-3.19 (0.249)	-1.60	-0.55
N=148	Week 16	132 (89.2)	2.0 (2.84)		[-2.31,-0.88]	[-0.80,-0.29]
Placebo	Baseline	127 (98.4)	5.7 (3.00)	-1.59 (0.267)	<.0001	
N=129	Week 16	117 (90.7)	4.1 (3.15)			
>= 300 cm3						
Relugolix+E2/NETA	Baseline	101 (97.1)	5.9 (3.27)	-2.77 (0.365)	-1.05	-0.30
N=104	Week 16	90 (86.5)	3.1 (2.97)		[-2.01,-0.09]	[-0.58,-0.02]
Placebo	Baseline	125 (98.4)	5.8 (2.95)	-1.72 (0.323)	0.0326	
N=127	Week 16	114 (89.8)	4.2 (3.20)			
Missing						
Relugolix+E2/NETA	Baseline	1 (100.0)	8.0 (NE)	NC (NC)	NC	NC
N=1	Week 16	0	NE (NE)		[NC,NC]	[NC,NC]
Placebo	Baseline	0	NE (NE)	NC (NC)	NC	
N=0	Week 16	0	NE (NE)			

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group.
[1] Summary statistics are based on observed data.
[2] LS means, LS mean differences (95% CIs), p-value and Hedges' g (95% CIs) are based on a mixed-effects model with study, treatment, visit, and a treatment-by-visit interaction as fixed effects. The multiple visits for each patient are the repeated measures as a random effect within each patient with an unstructured covariance. Hedges' g is calculated using a small sample bias correction. Interaction p-value is only produced for the Overall period.
The reference group for the LS mean difference and Hedges' g is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with data; CI: Confidence interval; LS: Least squares; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; NRS: Numerical rating scale; SD: Standard deviation; SE: Standard error; SMD: Standardized mean difference; NC: Not calculated; NE: Non-estimable.

SOURCE: \Studies\MYV\MYV102\Analysis\Prod\Progs\TFLs\Tab_EFF_NRS_CON.SAS
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Table EFF.MAXNRS.MITT.Pooled.S3: Summary of Change from Baseline in Maximum NRS Score by Visit and Overall, by Subgroup (mITT Population)

Study: Pooled

Treatment	Study visit	n (%)[1]	Mean (SD)[1]	Change from baseline LS-mean change (SE)[2]	Difference LS-mean change [95% CI] p-value[2]	SMD Hedges' g [95% CI][2]
Uterine Volume at Baseline (cm3)						
< 300 cm3						
Relugolix+E2/NETA	Baseline	148 (100.0)	5.3 (3.30)	-3.27 (0.261)	-1.73	-0.57
N=148	Week 20	126 (85.1)	2.0 (2.67)		[-2.48,-0.98]	[-0.83,-0.31]
Placebo	Baseline	127 (98.4)	5.7 (3.00)	-1.54 (0.279)	<.0001	
N=129	Week 20	112 (86.8)	4.3 (3.16)			
>= 300 cm3						
Relugolix+E2/NETA	Baseline	101 (97.1)	5.9 (3.27)	-3.27 (0.354)	-1.24	-0.37
N=104	Week 20	86 (82.7)	2.6 (2.79)		[-2.17,-0.31]	[-0.65,-0.08]
Placebo	Baseline	125 (98.4)	5.8 (2.95)	-2.03 (0.313)	0.0094	
N=127	Week 20	111 (87.4)	4.0 (3.28)			
Missing						
Relugolix+E2/NETA	Baseline	1 (100.0)	8.0 (NE)	NC (NC)	NC	NC
N=1	Week 20	0	NE (NE)		[NC,NC]	[NC,NC]
Placebo	Baseline	0	NE (NE)	NC (NC)	NC	
N=0	Week 20	0	NE (NE)			

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group.
[1] Summary statistics are based on observed data.
[2] LS means, LS mean differences (95% CIs), p-value and Hedges' g (95% CIs) are based on a mixed-effects model with study, treatment, visit, and a treatment-by-visit interaction as fixed effects. The multiple visits for each patient are the repeated measures as a random effect within each patient with an unstructured covariance. Hedges' g is calculated using a small sample bias correction. Interaction p-value is only produced for the Overall period.
The reference group for the LS mean difference and Hedges' g is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with data; CI: Confidence interval; LS: Least squares; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; NRS: Numerical rating scale; SD: Standard deviation; SE: Standard error; SMD: Standardized mean difference; NC: Not calculated; NE: Non-estimable.

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Table EFF.MAXNRS.MITT.Pooled.S3: Summary of Change from Baseline in Maximum NRS Score by Visit and Overall, by Subgroup (mITT Population)

Study: Pooled

Treatment	Study visit	n (%)[1]	Mean (SD)[1]	Change from baseline LS-mean change (SE)[2]	Difference LS-mean change [95% CI] p-value[2]	SMD Hedges' g [95% CI][2]
Uterine Volume at Baseline (cm3)						
< 300 cm3						
Relugolix+E2/NETA	Baseline	148 (100.0)	5.3 (3.30)	-3.52 (0.282)	-1.44	-0.44
N=148	Week 24	121 (81.8)	1.6 (2.27)		[-2.25,-0.63]	[-0.71,-0.18]
Placebo	Baseline	127 (98.4)	5.7 (3.00)	-2.08 (0.301)	0.0006	
N=129	Week 24	108 (83.7)	3.7 (3.08)			
>= 300 cm3						
Relugolix+E2/NETA	Baseline	101 (97.1)	5.9 (3.27)	-3.55 (0.341)	-1.17	-0.36
N=104	Week 24	84 (80.8)	2.3 (2.50)		[-2.07,-0.27]	[-0.66,-0.07]
Placebo	Baseline	125 (98.4)	5.8 (2.95)	-2.38 (0.303)	0.0110	
N=127	Week 24	104 (81.9)	3.7 (3.16)			
Missing						
Relugolix+E2/NETA	Baseline	1 (100.0)	8.0 (NE)	NC (NC)	NC	NC
N=1	Week 24	0	NE (NE)		[NC,NC]	[NC,NC]
Placebo	Baseline	0	NE (NE)	NC (NC)	NC	
N=0	Week 24	0	NE (NE)			

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group.
[1] Summary statistics are based on observed data.
[2] LS means, LS mean differences (95% CIs), p-value and Hedges' g (95% CIs) are based on a mixed-effects model with study, treatment, visit, and a treatment-by-visit interaction as fixed effects. The multiple visits for each patient are the repeated measures as a random effect within each patient with an unstructured covariance. Hedges' g is calculated using a small sample bias correction. Interaction p-value is only produced for the Overall period.
The reference group for the LS mean difference and Hedges' g is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with data; CI: Confidence interval; LS: Least squares; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; NRS: Numerical rating scale; SD: Standard deviation; SE: Standard error; SMD: Standardized mean difference; NC: Not calculated; NE: Non-estimable.

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Table EFF.MAXNRS.MITT.Pooled.S3: Summary of Change from Baseline in Maximum NRS Score by Visit and Overall, by Subgroup (mITT Population)

Study: Pooled

Treatment	Study visit	n (%)[1]	Mean (SD)[1]	Change from baseline LS-mean change (SE)[2]	Difference LS-mean change [95% CI] p-value[2]	SMD Hedges' g [95% CI][2]	Int. p-value[2]
Uterine Volume at Baseline (cm3)							
< 300 cm3							
Relugolix+E2/NETA	Baseline	148 (100.0)	5.3 (3.30)	-2.85 (0.215)	-1.52	-0.50	0.3477
N=148	Overall	147 (99.3)	2.6 (2.51)		[-2.14,-0.90]	[-0.74,-0.25]	
Placebo	Baseline	127 (98.4)	5.7 (3.00)	-1.33 (0.230)	<.0001		
N=129	Overall	128 (99.2)	4.5 (2.60)				
>= 300 cm3							
Relugolix+E2/NETA	Baseline	101 (97.1)	5.9 (3.27)	-2.71 (0.258)	-1.09	-0.36	
N=104	Overall	103 (99.0)	3.3 (2.43)		[-1.78,-0.41]	[-0.62,-0.09]	
Placebo	Baseline	125 (98.4)	5.8 (2.95)	-1.62 (0.232)	0.0017		
N=127	Overall	126 (99.2)	4.3 (2.68)				
Missing							
Relugolix+E2/NETA	Baseline	1 (100.0)	8.0 (NE)	NC (NC)	NC	NC	
N=1	Overall	1 (100.0)	7.0 (NE)		[NC,NC]	[NC,NC]	
Placebo	Baseline	0	NE (NE)	NC (NC)	NC		
N=0	Overall	0	NE (NE)				

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group.
[1] Summary statistics are based on observed data. Mean (SD) are calculated based on the mean observed value across all post-baseline visits within each patient.
[2] LS means, LS mean differences (95% CIs), p-value and Hedges' g (95% CIs) are based on a mixed-effects model with study, treatment, visit, subgroup, treatment-by-visit interaction and a subgroup-by-treatment interaction as fixed effects. The multiple visits for each patient are the repeated measures as a random effect within each patient with an unstructured covariance. Hedges' g is calculated using a small sample bias correction. Missing subgroup levels are not included in estimation of the interaction p-value.
The reference group for the LS mean difference and Hedges' g is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with data; CI: Confidence interval; int: Interaction; LS: Least squares; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; NRS: Numerical rating scale; SD: Standard deviation; SE: Standard error; SMD: Standardized mean difference; NC: Not calculated; NE: Non-estimable.

SOURCE: \Studies\MYV\MYV102\Analysis\Prod\Progs\TFLs\Tab_EFF_NRS_CON.SAS
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Table EFF.MAXNRS.MITT.Pooled.S7: Summary of Change from Baseline in Maximum NRS Score by Visit and Overall, by Subgroup (mITT Population)

Study: Pooled

Treatment	Study visit	n (%)[1]	Mean (SD)[1]	Change from baseline LS-mean change (SE)[2]	Difference LS-mean change [95% CI] p-value[2]	SMD Hedges' g [95% CI][2]
Geographic Region II						
Europe						
Relugolix+E2/NETA	Baseline	41 (100.0)	4.1 (3.16)	-0.97 (0.353)	-1.18	-0.52
N=41	Week 4	41 (100.0)	3.2 (2.30)		[-2.17,-0.18]	[-0.96,-0.09]
Placebo	Baseline	41 (97.6)	4.4 (2.30)	0.21 (0.357)	0.0208	
N=42	Week 4	42 (100.0)	4.7 (2.71)			
Rest of World (including the US)						
Relugolix+E2/NETA	Baseline	209 (98.6)	5.8 (3.25)	-1.48 (0.199)	-0.81	-0.28
N=212	Week 4	210 (99.1)	4.4 (3.17)		[-1.36,-0.25]	[-0.47,-0.09]
Placebo	Baseline	211 (98.6)	6.0 (3.02)	-0.68 (0.198)	0.0043	
N=214	Week 4	212 (99.1)	5.4 (3.06)			

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group.
[1] Summary statistics are based on observed data.
[2] LS means, LS mean differences (95% CIs), p-value and Hedges' g (95% CIs) are based on a mixed-effects model with study, treatment, visit, and a treatment-by-visit interaction as fixed effects. The multiple visits for each patient are the repeated measures as a random effect within each patient with an unstructured covariance. Hedges' g is calculated using a small sample bias correction. Interaction p-value is only produced for the Overall period.
The reference group for the LS mean difference and Hedges' g is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with data; CI: Confidence interval; LS: Least squares; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; NRS: Numerical rating scale; SD: Standard deviation; SE: Standard error; SMD: Standardized mean difference.

SOURCE: \Studies\MYV\MYV102\Analysis\Prod\Progs\TFLs\Tab_EFF_NRS_CON.SAS
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Table EFF.MAXNRS.MITT.Pooled.S7: Summary of Change from Baseline in Maximum NRS Score by Visit and Overall, by Subgroup (mITT Population)

Study: Pooled

Treatment	Study visit	n (%)[1]	Mean (SD)[1]	Change from baseline LS-mean change (SE)[2]	Difference LS-mean change [95% CI] p-value[2]	SMD Hedges' g [95% CI][2]
Geographic Region II						
Europe						
Relugolix+E2/NETA	Baseline	41 (100.0)	4.1 (3.16)	-1.77 (0.358)	-1.27	-0.56
N=41	Week 8	39 (95.1)	2.3 (2.36)		[-2.27,-0.27]	[-1.01,-0.11]
Placebo	Baseline	41 (97.6)	4.4 (2.30)	-0.50 (0.360)	0.0139	
N=42	Week 8	41 (97.6)	4.1 (2.82)			
Rest of World (including the US)						
Relugolix+E2/NETA	Baseline	209 (98.6)	5.8 (3.25)	-2.86 (0.221)	-1.55	-0.50
N=212	Week 8	194 (91.5)	2.9 (2.85)		[-2.16,-0.94]	[-0.70,-0.30]
Placebo	Baseline	211 (98.6)	6.0 (3.02)	-1.31 (0.218)	<.0001	
N=214	Week 8	202 (94.4)	4.8 (3.19)			

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group.
[1] Summary statistics are based on observed data.
[2] LS means, LS mean differences (95% CIs), p-value and Hedges' g (95% CIs) are based on a mixed-effects model with study, treatment, visit, and a treatment-by-visit interaction as fixed effects. The multiple visits for each patient are the repeated measures as a random effect within each patient with an unstructured covariance. Hedges' g is calculated using a small sample bias correction. Interaction p-value is only produced for the Overall period.
The reference group for the LS mean difference and Hedges' g is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with data; CI: Confidence interval; LS: Least squares; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; NRS: Numerical rating scale; SD: Standard deviation; SE: Standard error; SMD: Standardized mean difference.

SOURCE: \Studies\MYV\MYV102\Analysis\Prod\Progs\TFLs\Tab_EFF_NRS_CON.SAS
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Table EFF.MAXNRS.MITT.Pooled.S7: Summary of Change from Baseline in Maximum NRS Score by Visit and Overall, by Subgroup (mITT Population)

Study: Pooled

Treatment	Study visit	n (%)[1]	Mean (SD)[1]	Change from baseline LS-mean change (SE)[2]	Difference LS-mean change [95% CI] p-value[2]	SMD Hedges' g [95% CI][2]
Geographic Region II						
Europe						
Relugolix+E2/NETA	Baseline	41 (100.0)	4.1 (3.16)	-2.23 (0.433)	-2.28	-0.83
N=41	Week 12	39 (95.1)	1.8 (2.56)		[-3.49,-1.07]	[-1.29,-0.38]
Placebo	Baseline	41 (97.6)	4.4 (2.30)	0.05 (0.433)	0.0003	
N=42	Week 12	41 (97.6)	4.6 (2.74)			
Rest of World (including the US)						
Relugolix+E2/NETA	Baseline	209 (98.6)	5.8 (3.25)	-2.97 (0.227)	-1.19	-0.38
N=212	Week 12	188 (88.7)	2.8 (3.06)		[-1.82,-0.57]	[-0.58,-0.18]
Placebo	Baseline	211 (98.6)	6.0 (3.02)	-1.78 (0.223)	0.0002	
N=214	Week 12	198 (92.5)	4.4 (3.08)			

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group.
[1] Summary statistics are based on observed data.
[2] LS means, LS mean differences (95% CIs), p-value and Hedges' g (95% CIs) are based on a mixed-effects model with study, treatment, visit, and a treatment-by-visit interaction as fixed effects. The multiple visits for each patient are the repeated measures as a random effect within each patient with an unstructured covariance. Hedges' g is calculated using a small sample bias correction. Interaction p-value is only produced for the Overall period.
The reference group for the LS mean difference and Hedges' g is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with data; CI: Confidence interval; LS: Least squares; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; NRS: Numerical rating scale; SD: Standard deviation; SE: Standard error; SMD: Standardized mean difference.

SOURCE: \Studies\MYV\MYV102\Analysis\Prod\Progs\TFLs\Tab_EFF_NRS_CON.SAS
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Table EFF.MAXNRS.MITT.Pooled.S7: Summary of Change from Baseline in Maximum NRS Score by Visit and Overall, by Subgroup (mITT Population)

Study: Pooled

Treatment	Study visit	n (%)[1]	Mean (SD)[1]	Change from baseline LS-mean change (SE)[2]	Difference LS-mean change [95% CI] p-value[2]	SMD Hedges' g [95% CI][2]
Geographic Region II						
Europe						
Relugolix+E2/NETA	Baseline	41 (100.0)	4.1 (3.16)	-2.36 (0.409)	-2.08	-0.81
N=41	Week 16	38 (92.7)	1.7 (2.76)		[-3.23,-0.93]	[-1.27,-0.35]
Placebo	Baseline	41 (97.6)	4.4 (2.30)	-0.28 (0.410)	0.0005	
N=42	Week 16	40 (95.2)	4.3 (2.57)			
Rest of World (including the US)						
Relugolix+E2/NETA	Baseline	209 (98.6)	5.8 (3.25)	-3.17 (0.238)	-1.23	-0.38
N=212	Week 16	184 (86.8)	2.6 (2.95)		[-1.89,-0.57]	[-0.58,-0.17]
Placebo	Baseline	211 (98.6)	6.0 (3.02)	-1.94 (0.234)	0.0003	
N=214	Week 16	191 (89.3)	4.2 (3.29)			

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group.
[1] Summary statistics are based on observed data.
[2] LS means, LS mean differences (95% CIs), p-value and Hedges' g (95% CIs) are based on a mixed-effects model with study, treatment, visit, and a treatment-by-visit interaction as fixed effects. The multiple visits for each patient are the repeated measures as a random effect within each patient with an unstructured covariance. Hedges' g is calculated using a small sample bias correction. Interaction p-value is only produced for the Overall period.
The reference group for the LS mean difference and Hedges' g is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with data; CI: Confidence interval; LS: Least squares; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; NRS: Numerical rating scale; SD: Standard deviation; SE: Standard error; SMD: Standardized mean difference.

SOURCE: \Studies\MYV\MYV102\Analysis\Prod\Progs\TFLs\Tab_EFF_NRS_CON.SAS
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Table EFF.MAXNRS.MITT.Pooled.S7: Summary of Change from Baseline in Maximum NRS Score by Visit and Overall, by Subgroup (mITT Population)

Study: Pooled

Treatment	Study visit	n (%)[1]	Mean (SD)[1]	Change from baseline LS-mean change (SE)[2]	Difference LS-mean change [95% CI] p-value[2]	SMD Hedges' g [95% CI][2]
Geographic Region II						
Europe						
Relugolix+E2/NETA	Baseline	41 (100.0)	4.1 (3.16)	-2.66 (0.388)	-2.23	-0.91
N=41	Week 20	38 (92.7)	1.4 (2.42)		[-3.33,-1.14]	[-1.38,-0.44]
Placebo	Baseline	41 (97.6)	4.4 (2.30)	-0.43 (0.393)	0.0001	
N=42	Week 20	38 (90.5)	4.2 (2.80)			
Rest of World (including the US)						
Relugolix+E2/NETA	Baseline	209 (98.6)	5.8 (3.25)	-3.40 (0.241)	-1.35	-0.41
N=212	Week 20	174 (82.1)	2.4 (2.76)		[-2.01,-0.69]	[-0.62,-0.20]
Placebo	Baseline	211 (98.6)	6.0 (3.02)	-2.05 (0.236)	<.0001	
N=214	Week 20	185 (86.4)	4.1 (3.30)			

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group.
[1] Summary statistics are based on observed data.
[2] LS means, LS mean differences (95% CIs), p-value and Hedges' g (95% CIs) are based on a mixed-effects model with study, treatment, visit, and a treatment-by-visit interaction as fixed effects. The multiple visits for each patient are the repeated measures as a random effect within each patient with an unstructured covariance. Hedges' g is calculated using a small sample bias correction. Interaction p-value is only produced for the Overall period.
The reference group for the LS mean difference and Hedges' g is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with data; CI: Confidence interval; LS: Least squares; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; NRS: Numerical rating scale; SD: Standard deviation; SE: Standard error; SMD: Standardized mean difference.

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Table EFF.MAXNRS.MITT.Pooled.S7: Summary of Change from Baseline in Maximum NRS Score by Visit and Overall, by Subgroup (mITT Population)

Study: Pooled

Treatment	Study visit	n (%)[1]	Mean (SD)[1]	Change from baseline LS-mean change (SE)[2]	Difference LS-mean change [95% CI] p-value[2]	SMD Hedges' g [95% CI][2]
Geographic Region II						
Europe						
Relugolix+E2/NETA	Baseline	41 (100.0)	4.1 (3.16)	-2.35 (0.412)	-1.51	-0.57
N=41	Week 24	36 (87.8)	1.5 (1.99)		[-2.67,-0.34]	[-1.05,-0.10]
Placebo	Baseline	41 (97.6)	4.4 (2.30)	-0.84 (0.420)	0.0120	
N=42	Week 24	35 (83.3)	4.1 (2.88)			
Rest of World (including the US)						
Relugolix+E2/NETA	Baseline	209 (98.6)	5.8 (3.25)	-3.78 (0.244)	-1.29	-0.39
N=212	Week 24	169 (79.7)	2.0 (2.46)		[-1.96,-0.61]	[-0.61,-0.18]
Placebo	Baseline	211 (98.6)	6.0 (3.02)	-2.50 (0.239)	0.0002	
N=214	Week 24	177 (82.7)	3.6 (3.16)			

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group.
[1] Summary statistics are based on observed data.
[2] LS means, LS mean differences (95% CIs), p-value and Hedges' g (95% CIs) are based on a mixed-effects model with study, treatment, visit, and a treatment-by-visit interaction as fixed effects. The multiple visits for each patient are the repeated measures as a random effect within each patient with an unstructured covariance. Hedges' g is calculated using a small sample bias correction. Interaction p-value is only produced for the Overall period.
The reference group for the LS mean difference and Hedges' g is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with data; CI: Confidence interval; LS: Least squares; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; NRS: Numerical rating scale; SD: Standard deviation; SE: Standard error; SMD: Standardized mean difference.

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Table EFF.MAXNRS.MITT.Pooled.S7: Summary of Change from Baseline in Maximum NRS Score by Visit and Overall, by Subgroup (mITT Population)

Study: Pooled

Treatment	Study visit	n (%)[1]	Mean (SD)[1]	Change from baseline LS-mean change (SE)[2]	Difference LS-mean change [95% CI] p-value[2]	SMD Hedges' g [95% CI][2]	Int. p-value[2]
Geographic Region II							
Europe							0.5407
Relugolix+E2/NETA	Baseline	41 (100.0)	4.1 (3.16)	-2.13 (0.392)	-1.63	-0.53	
N=41	Overall	41 (100.0)	2.2 (2.37)		[-2.72,-0.54]	[-0.97,-0.10]	
Placebo	Baseline	41 (97.6)	4.4 (2.30)	-0.50 (0.392)	0.0034		
N=42	Overall	42 (100.0)	4.2 (2.50)				
Rest of World (including the US)							
Relugolix+E2/NETA	Baseline	209 (98.6)	5.8 (3.25)	-2.93 (0.182)	-1.26	-0.42	
N=212	Overall	210 (99.1)	3.0 (2.51)		[-1.77,-0.76]	[-0.61,-0.22]	
Placebo	Baseline	211 (98.6)	6.0 (3.02)	-1.66 (0.180)	<.0001		
N=214	Overall	212 (99.1)	4.4 (2.66)				

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group.
[1] Summary statistics are based on observed data. Mean (SD) are calculated based on the mean observed value across all post-baseline visits within each patient.
[2] LS means, LS mean differences (95% CIs), p-value and Hedges' g (95% CIs) are based on a mixed-effects model with study, treatment, visit, subgroup, treatment-by-visit interaction and a subgroup-by-treatment interaction as fixed effects. The multiple visits for each patient are the repeated measures as a random effect within each patient with an unstructured covariance. Hedges' g is calculated using a small sample bias correction.
The reference group for the LS mean difference and Hedges' g is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with data; CI: Confidence interval; int: Interaction; LS: Least squares; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; NRS: Numerical rating scale; SD: Standard deviation; SE: Standard error; SMD: Standardized mean difference.

SOURCE: \Studies\MYV\MYV102\Analysis\Prod\Progs\TFLs\Tab_EFF_NRS_CON.SAS
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Table EFF.MAXNRS.MITT.Pooled.S5: Summary of Change from Baseline in Maximum NRS Score by Visit and Overall, by Subgroup (mITT Population)

Study: Pooled

Treatment	Study visit	n (%)[1]	Mean (SD)[1]	Change from baseline LS-mean change (SE)[2]	Difference LS-mean change [95% CI] p-value[2]	SMD Hedges' g [95% CI][2]
MBL Volume at Baseline (mL)						
< 225 mL						
Relugolix+E2/NETA	Baseline	162 (98.8)	5.8 (3.27)	-1.51 (0.212)	-0.88	-0.33
N=164	Week 4	163 (99.4)	4.3 (3.12)		[-1.47,-0.30]	[-0.55,-0.11]
Placebo	Baseline	168 (98.2)	5.7 (3.04)	-0.63 (0.209)	0.0033	
N=171	Week 4	169 (98.8)	5.2 (3.04)			
>= 225 mL						
Relugolix+E2/NETA	Baseline	88 (98.9)	5.1 (3.30)	-1.18 (0.318)	-0.86	-0.29
N=89	Week 4	88 (98.9)	3.9 (2.97)		[-1.76,0.03]	[-0.59,0.01]
Placebo	Baseline	84 (98.8)	5.7 (2.84)	-0.32 (0.324)	0.0593	
N=85	Week 4	85 (100.0)	5.4 (2.97)			

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group.
[1] Summary statistics are based on observed data.
[2] LS means, LS mean differences (95% CIs), p-value and Hedges' g (95% CIs) are based on a mixed-effects model with study, treatment, visit, and a treatment-by-visit interaction as fixed effects. The multiple visits for each patient are the repeated measures as a random effect within each patient with an unstructured covariance. Hedges' g is calculated using a small sample bias correction. Interaction p-value is only produced for the Overall period.
The reference group for the LS mean difference and Hedges' g is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with data; CI: Confidence interval; LS: Least squares; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; NRS: Numerical rating scale; SD: Standard deviation; SE: Standard error; SMD: Standardized mean difference.

SOURCE: \Studies\MYV\MYV102\Analysis\Prod\Progs\TFLs\Tab_EFF_NRS_CON.SAS
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Table EFF.MAXNRS.MITT.Pooled.S5: Summary of Change from Baseline in Maximum NRS Score by Visit and Overall, by Subgroup (mITT Population)

Study: Pooled

Treatment	Study visit	n (%)[1]	Mean (SD)[1]	Change from baseline LS-mean change (SE)[2]	Difference LS-mean change [95% CI] p-value[2]	SMD Hedges' g [95% CI][2]
MBL Volume at Baseline (mL)						
< 225 mL						
Relugolix+E2/NETA	Baseline	162 (98.8)	5.8 (3.27)	-2.91 (0.233)	-1.66	-0.58
N=164	Week 8	153 (93.3)	2.8 (2.89)		[-2.29,-1.02]	[-0.80,-0.35]
Placebo	Baseline	168 (98.2)	5.7 (3.04)	-1.26 (0.227)	<.0001	
N=171	Week 8	162 (94.7)	4.7 (3.07)			
>= 225 mL						
Relugolix+E2/NETA	Baseline	88 (98.9)	5.1 (3.30)	-2.24 (0.352)	-1.26	-0.40
N=89	Week 8	80 (89.9)	3.0 (2.58)		[-2.25,-0.28]	[-0.71,-0.08]
Placebo	Baseline	84 (98.8)	5.7 (2.84)	-0.98 (0.353)	0.0123	
N=85	Week 8	81 (95.3)	4.8 (3.29)			

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group.
[1] Summary statistics are based on observed data.
[2] LS means, LS mean differences (95% CIs), p-value and Hedges' g (95% CIs) are based on a mixed-effects model with study, treatment, visit, and a treatment-by-visit interaction as fixed effects. The multiple visits for each patient are the repeated measures as a random effect within each patient with an unstructured covariance. Hedges' g is calculated using a small sample bias correction. Interaction p-value is only produced for the Overall period.
The reference group for the LS mean difference and Hedges' g is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with data; CI: Confidence interval; LS: Least squares; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; NRS: Numerical rating scale; SD: Standard deviation; SE: Standard error; SMD: Standardized mean difference.

SOURCE: \Studies\MYV\MYV102\Analysis\Prod\Progs\TFLs\Tab_EFF_NRS_CON.SAS
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Table EFF.MAXNRS.MITT.Pooled.S5: Summary of Change from Baseline in Maximum NRS Score by Visit and Overall, by Subgroup (mITT Population)

Study: Pooled

Treatment	Study visit	n (%)[1]	Mean (SD)[1]	Change from baseline LS-mean change (SE)[2]	Difference LS-mean change [95% CI] p-value[2]	SMD Hedges' g [95% CI][2]
MBL Volume at Baseline (mL)						
< 225 mL						
Relugolix+E2/NETA	Baseline	162 (98.8)	5.8 (3.27)	-3.00 (0.247)	-1.50	-0.50
N=164	Week 12	147 (89.6)	2.6 (3.01)		[-2.17,-0.82]	[-0.72,-0.27]
Placebo	Baseline	168 (98.2)	5.7 (3.04)	-1.50 (0.240)	<.0001	
N=171	Week 12	158 (92.4)	4.4 (2.85)			
>= 225 mL						
Relugolix+E2/NETA	Baseline	88 (98.9)	5.1 (3.30)	-2.57 (0.365)	-1.16	-0.35
N=89	Week 12	80 (89.9)	2.7 (3.01)		[-2.18,-0.14]	[-0.66,-0.04]
Placebo	Baseline	84 (98.8)	5.7 (2.84)	-1.41 (0.366)	0.0264	
N=85	Week 12	81 (95.3)	4.4 (3.35)			

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group.
[1] Summary statistics are based on observed data.
[2] LS means, LS mean differences (95% CIs), p-value and Hedges' g (95% CIs) are based on a mixed-effects model with study, treatment, visit, and a treatment-by-visit interaction as fixed effects. The multiple visits for each patient are the repeated measures as a random effect within each patient with an unstructured covariance. Hedges' g is calculated using a small sample bias correction. Interaction p-value is only produced for the Overall period.
The reference group for the LS mean difference and Hedges' g is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with data; CI: Confidence interval; LS: Least squares; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; NRS: Numerical rating scale; SD: Standard deviation; SE: Standard error; SMD: Standardized mean difference.

SOURCE: \Studies\MYV\MYV102\Analysis\Prod\Progs\TFLs\Tab_EFF_NRS_CON.SAS
Date/time of run: 20APR2021 16:04
Analysis Plan: 13JAN2021

Table EFF.MAXNRS.MITT.Pooled.S5: Summary of Change from Baseline in Maximum NRS Score by Visit and Overall, by Subgroup (mITT Population)

Study: Pooled

Treatment	Study visit	n (%)[1]	Mean (SD)[1]	Change from baseline LS-mean change (SE)[2]	Difference LS-mean change [95% CI] p-value[2]	SMD Hedges' g [95% CI][2]
MBL Volume at Baseline (mL)						
< 225 mL						
Relugolix+E2/NETA	Baseline	162 (98.8)	5.8 (3.27)	-3.48 (0.261)	-1.60	-0.51
N=164	Week 16	142 (86.6)	2.2 (2.77)		[-2.32,-0.89]	[-0.74,-0.27]
Placebo	Baseline	168 (98.2)	5.7 (3.04)	-1.87 (0.253)	<.0001	
N=171	Week 16	154 (90.1)	4.0 (3.01)			
>= 225 mL						
Relugolix+E2/NETA	Baseline	88 (98.9)	5.1 (3.30)	-2.27 (0.354)	-1.02	-0.32
N=89	Week 16	80 (89.9)	3.0 (3.16)		[-2.02,-0.03]	[-0.64,-0.01]
Placebo	Baseline	84 (98.8)	5.7 (2.84)	-1.24 (0.358)	0.0435	
N=85	Week 16	77 (90.6)	4.5 (3.47)			

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group.
[1] Summary statistics are based on observed data.
[2] LS means, LS mean differences (95% CIs), p-value and Hedges' g (95% CIs) are based on a mixed-effects model with study, treatment, visit, and a treatment-by-visit interaction as fixed effects. The multiple visits for each patient are the repeated measures as a random effect within each patient with an unstructured covariance. Hedges' g is calculated using a small sample bias correction. Interaction p-value is only produced for the Overall period.
The reference group for the LS mean difference and Hedges' g is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with data; CI: Confidence interval; LS: Least squares; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; NRS: Numerical rating scale; SD: Standard deviation; SE: Standard error; SMD: Standardized mean difference.

SOURCE: \Studies\MYV\MYV102\Analysis\Prod\Progs\TFLs\Tab_EFF_NRS_CON.SAS
Date/time of run: 20APR2021 16:04
Analysis Plan: 13JAN2021

Table EFF.MAXNRS.MITT.Pooled.S5: Summary of Change from Baseline in Maximum NRS Score by Visit and Overall, by Subgroup (mITT Population)

Study: Pooled

Treatment	Study visit	n (%)[1]	Mean (SD)[1]	Change from baseline LS-mean change (SE)[2]	Difference LS-mean change [95% CI] p-value[2]	SMD Hedges' g [95% CI][2]
MBL Volume at Baseline (mL)						
< 225 mL						
Relugolix+E2/NETA	Baseline	162 (98.8)	5.8 (3.27)	-3.62 (0.259)	-1.70	-0.55
N=164	Week 20	138 (84.1)	2.1 (2.74)		[-2.41,-0.99]	[-0.78,-0.31]
Placebo	Baseline	168 (98.2)	5.7 (3.04)	-1.92 (0.251)	<.0001	
N=171	Week 20	148 (86.5)	4.0 (3.00)			
>= 225 mL						
Relugolix+E2/NETA	Baseline	88 (98.9)	5.1 (3.30)	-2.59 (0.370)	-1.07	-0.32
N=89	Week 20	74 (83.1)	2.5 (2.71)		[-2.11,-0.04]	[-0.65,0.00]
Placebo	Baseline	84 (98.8)	5.7 (2.84)	-1.51 (0.371)	0.0421	
N=85	Week 20	75 (88.2)	4.3 (3.61)			

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group.
[1] Summary statistics are based on observed data.
[2] LS means, LS mean differences (95% CIs), p-value and Hedges' g (95% CIs) are based on a mixed-effects model with study, treatment, visit, and a treatment-by-visit interaction as fixed effects. The multiple visits for each patient are the repeated measures as a random effect within each patient with an unstructured covariance. Hedges' g is calculated using a small sample bias correction. Interaction p-value is only produced for the Overall period.
The reference group for the LS mean difference and Hedges' g is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with data; CI: Confidence interval; LS: Least squares; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; NRS: Numerical rating scale; SD: Standard deviation; SE: Standard error; SMD: Standardized mean difference.

SOURCE: \Studies\MYV\MYV102\Analysis\Prod\Progs\TFLs\Tab_EFF_NRS_CON.SAS
Date/time of run: 20APR2021 16:04
Analysis Plan: 13JAN2021

Table EFF.MAXNRS.MITT.Pooled.S5: Summary of Change from Baseline in Maximum NRS Score by Visit and Overall, by Subgroup (mITT Population)

Study: Pooled

Treatment	Study visit	n (%)[1]	Mean (SD)[1]	Change from baseline LS-mean change (SE)[2]	Difference LS-mean change [95% CI] p-value[2]	SMD Hedges' g [95% CI][2]
MBL Volume at Baseline (mL)						
< 225 mL						
Relugolix+E2/NETA	Baseline	162 (98.8)	5.8 (3.27)	-3.79 (0.264)	-1.27	-0.40
N=164	Week 24	134 (81.7)	1.8 (2.45)		[-1.99,-0.55]	[-0.64,-0.16]
Placebo	Baseline	168 (98.2)	5.7 (3.04)	-2.52 (0.256)	0.0006	
N=171	Week 24	144 (84.2)	3.4 (2.84)			
>= 225 mL						
Relugolix+E2/NETA	Baseline	88 (98.9)	5.1 (3.30)	-3.03 (0.380)	-1.44	-0.43
N=89	Week 24	71 (79.8)	2.0 (2.28)		[-2.51,-0.37]	[-0.77,-0.09]
Placebo	Baseline	84 (98.8)	5.7 (2.84)	-1.59 (0.386)	0.0086	
N=85	Week 24	68 (80.0)	4.4 (3.55)			

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group.
[1] Summary statistics are based on observed data.
[2] LS means, LS mean differences (95% CIs), p-value and Hedges' g (95% CIs) are based on a mixed-effects model with study, treatment, visit, and a treatment-by-visit interaction as fixed effects. The multiple visits for each patient are the repeated measures as a random effect within each patient with an unstructured covariance. Hedges' g is calculated using a small sample bias correction. Interaction p-value is only produced for the Overall period.
The reference group for the LS mean difference and Hedges' g is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with data; CI: Confidence interval; LS: Least squares; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; NRS: Numerical rating scale; SD: Standard deviation; SE: Standard error; SMD: Standardized mean difference.

SOURCE: \Studies\MYV\MYV102\Analysis\Prod\Progs\TFLs\Tab_EFF_NRS_CON.SAS
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Table EFF.MAXNRS.MITT.Pooled.S5: Summary of Change from Baseline in Maximum NRS Score by Visit and Overall, by Subgroup (mITT Population)

Study: Pooled

Treatment	Study visit	n (%)[1]	Mean (SD)[1]	Change from baseline LS-mean change (SE)[2]	Difference LS-mean change [95% CI] p-value[2]	SMD Hedges' g [95% CI][2]	Int. p-value[2]
MBL Volume at Baseline (mL)							
< 225 mL							
Relugolix+E2/NETA	Baseline	162 (98.8)	5.8 (3.27)	-2.98 (0.206)	-1.39	-0.45	0.7124
N=164	Overall	163 (99.4)	2.9 (2.57)		[-1.95,-0.82]	[-0.67,-0.23]	
Placebo	Baseline	168 (98.2)	5.7 (3.04)	-1.59 (0.201)	<.0001		
N=171	Overall	169 (98.8)	4.2 (2.54)				
>= 225 mL							
Relugolix+E2/NETA	Baseline	88 (98.9)	5.1 (3.30)	-2.45 (0.275)	-1.21	-0.40	
N=89	Overall	88 (98.9)	2.9 (2.38)		[-1.98,-0.44]	[-0.70,-0.09]	
Placebo	Baseline	84 (98.8)	5.7 (2.84)	-1.23 (0.278)	0.0020		
N=85	Overall	85 (100.0)	4.7 (2.81)				

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group.
[1] Summary statistics are based on observed data. Mean (SD) are calculated based on the mean observed value across all post-baseline visits within each patient.
[2] LS means, LS mean differences (95% CIs), p-value and Hedges' g (95% CIs) are based on a mixed-effects model with study, treatment, visit, subgroup, treatment-by-visit interaction and a subgroup-by-treatment interaction as fixed effects. The multiple visits for each patient are the repeated measures as a random effect within each patient with an unstructured covariance. Hedges' g is calculated using a small sample bias correction.
The reference group for the LS mean difference and Hedges' g is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with data; CI: Confidence interval; int: Interaction; LS: Least squares; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; NRS: Numerical rating scale; SD: Standard deviation; SE: Standard error; SMD: Standardized mean difference.

SOURCE: \Studies\MYV\MYV102\Analysis\Prod\Progs\TFLs\Tab_EFF_NRS_CON.SAS
Date/time of run: 20APR2021 16:04
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Table EFF.MAXNRS.MITT.Pooled.S9: Summary of Change from Baseline in Maximum NRS Score by Visit and Overall, by Subgroup (mITT Population)

Study: Pooled

Treatment	Study visit	n (%)[1]	Mean (SD)[1]	Change from baseline LS-mean change (SE)[2]	Difference LS-mean change [95% CI] p-value[2]	SMD Hedges' g [95% CI][2]
Race						
Black/African American						
Relugolix+E2/NETA	Baseline	120 (98.4)	6.1 (3.26)	-1.65 (0.273)	-0.89	-0.30
N=122	Week 4	120 (98.4)	4.4 (3.27)		[-1.62,-0.16]	[-0.55,-0.05]
Placebo	Baseline	139 (98.6)	5.8 (3.11)	-0.76 (0.252)	0.0172	
N=141	Week 4	140 (99.3)	5.1 (3.20)			
White						
Relugolix+E2/NETA	Baseline	121 (99.2)	5.0 (3.23)	-1.19 (0.234)	-0.97	-0.38
N=122	Week 4	122 (100.0)	3.9 (2.90)		[-1.65,-0.29]	[-0.64,-0.11]
Placebo	Baseline	103 (98.1)	5.7 (2.78)	-0.22 (0.254)	0.0055	
N=105	Week 4	105 (100.0)	5.5 (2.72)			
Asian						
Relugolix+E2/NETA	Baseline	1 (100.0)	3.0 (NE)	NC (NC)	NC	NC
N=1	Week 4	1 (100.0)	2.0 (NE)		[NC,NC]	[NC,NC]
Placebo	Baseline	3 (100.0)	5.0 (4.00)	NC (NC)	NC	
N=3	Week 4	3 (100.0)	4.3 (3.06)			
Others						
Relugolix+E2/NETA	Baseline	5 (100.0)	7.2 (3.63)	-1.61 (1.141)	-0.95	-0.36
N=5	Week 4	5 (100.0)	5.4 (2.70)		[-4.77,2.86]	[-1.49,0.77]
Placebo	Baseline	6 (100.0)	5.7 (3.39)	-0.66 (1.141)	0.5735	
N=6	Week 4	5 (83.3)	4.2 (3.77)			
Not reported						
Relugolix+E2/NETA	Baseline	3 (100.0)	2.7 (2.08)	NC (NC)	NC	NC
N=3	Week 4	3 (100.0)	4.0 (2.65)		[NC,NC]	[NC,NC]
Placebo	Baseline	1 (100.0)	5.0 (NE)	NC (NC)	NC	
N=1	Week 4	1 (100.0)	8.0 (NE)			

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group.
[1] Summary statistics are based on observed data.
[2] LS means, LS mean differences (95% CIs), p-value and Hedges' g (95% CIs) are based on a mixed-effects model with study, treatment, visit, and a treatment-by-visit interaction as fixed effects. The multiple visits for each patient are the repeated measures as a random effect within each patient with an unstructured covariance. Hedges' g is calculated using a small sample bias correction. Interaction p-value is only produced for the Overall period.
The reference group for the LS mean difference and Hedges' g is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with data; CI: Confidence interval; LS: Least squares; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; NRS: Numerical rating scale; SD: Standard deviation; SE: Standard error; SMD: Standardized mean difference; NC: Not calculated; NE: Non-estimable.

SOURCE: \Studies\MYV\MYV102\Analysis\Prod\Progs\TFLs\Tab_EFF_NRS_CON.SAS

Table EFF.MAXNRS.MITT.Pooled.S9: Summary of Change from Baseline in Maximum NRS Score by Visit and Overall, by Subgroup (mITT Population)

Study: Pooled

Treatment	Study visit	n (%)[1]	Mean (SD)[1]	Change from baseline LS-mean change (SE)[2]	Difference LS-mean change [95% CI] p-value[2]	SMD Hedges' g [95% CI][2]
Race						
Black/African American						
Relugolix+E2/NETA	Baseline	120 (98.4)	6.1 (3.26)	-3.08 (0.301)	-1.60	-0.51
N=122	Week 8	110 (90.2)	3.0 (3.01)		[-2.40,-0.80]	[-0.76,-0.25]
Placebo	Baseline	139 (98.6)	5.8 (3.11)	-1.48 (0.273)	0.0001	
N=141	Week 8	134 (95.0)	4.5 (3.23)			
White						
Relugolix+E2/NETA	Baseline	121 (99.2)	5.0 (3.23)	-2.41 (0.251)	-1.61	-0.60
N=122	Week 8	114 (93.4)	2.6 (2.52)		[-2.34,-0.88]	[-0.87,-0.32]
Placebo	Baseline	103 (98.1)	5.7 (2.78)	-0.80 (0.271)	<.0001	
N=105	Week 8	100 (95.2)	5.0 (3.06)			
Asian						
Relugolix+E2/NETA	Baseline	1 (100.0)	3.0 (NE)	NC (NC)	NC	NC
N=1	Week 8	1 (100.0)	0.0 (NE)		[NC,NC]	[NC,NC]
Placebo	Baseline	3 (100.0)	5.0 (4.00)	NC (NC)	NC	
N=3	Week 8	3 (100.0)	4.3 (3.06)			
Others						
Relugolix+E2/NETA	Baseline	5 (100.0)	7.2 (3.63)	-2.01 (0.896)	-1.15	-0.55
N=5	Week 8	5 (100.0)	5.0 (2.24)		[-4.15,1.84]	[-1.70,0.59]
Placebo	Baseline	6 (100.0)	5.7 (3.39)	-0.86 (0.896)	0.3935	
N=6	Week 8	5 (83.3)	4.0 (2.92)			
Not reported						
Relugolix+E2/NETA	Baseline	3 (100.0)	2.7 (2.08)	NC (NC)	NC	NC
N=3	Week 8	3 (100.0)	4.3 (3.51)		[NC,NC]	[NC,NC]
Placebo	Baseline	1 (100.0)	5.0 (NE)	NC (NC)	NC	
N=1	Week 8	1 (100.0)	7.0 (NE)			

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group.
[1] Summary statistics are based on observed data.
[2] LS means, LS mean differences (95% CIs), p-value and Hedges' g (95% CIs) are based on a mixed-effects model with study, treatment, visit, and a treatment-by-visit interaction as fixed effects. The multiple visits for each patient are the repeated measures as a random effect within each patient with an unstructured covariance. Hedges' g is calculated using a small sample bias correction. Interaction p-value is only produced for the Overall period.
The reference group for the LS mean difference and Hedges' g is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with data; CI: Confidence interval; LS: Least squares; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; NRS: Numerical rating scale; SD: Standard deviation; SE: Standard error; SMD: Standardized mean difference; NC: Not calculated; NE: Non-estimable.

SOURCE: \Studies\MYV\MYV102\Analysis\Prod\Progs\TFLs\Tab_EFF_NRS_CON.SAS

Table EFF.MAXNRS.MITT.Pooled.S9: Summary of Change from Baseline in Maximum NRS Score by Visit and Overall, by Subgroup (mITT Population)						
Study: Pooled						
Treatment	**Study visit**	**n (%)[1]**	**Mean (SD)[1]**	**Change from baseline LS-mean change (SE)[2]**	**Difference LS-mean change [95% CI] p-value[2]**	**SMD Hedges' g [95% CI][2]**
Race						
Black/African American						
Relugolix+E2/NETA	Baseline	120 (98.4)	6.1 (3.26)	-3.11 (0.326)	-0.95	-0.28
N=122	Week 12	104 (85.2)	3.0 (3.07)		[-1.81,-0.08]	[-0.54,-0.02]
Placebo	Baseline	139 (98.6)	5.8 (3.11)	-2.16 (0.295)	0.0322	
N=141	Week 12	129 (91.5)	3.8 (3.13)			
White						
Relugolix+E2/NETA	Baseline	121 (99.2)	5.0 (3.23)	-2.71 (0.250)	-2.05	-0.77
N=122	Week 12	114 (93.4)	2.3 (2.86)		[-2.78,-1.33]	[-1.04,-0.49]
Placebo	Baseline	103 (98.1)	5.7 (2.78)	-0.65 (0.269)	<.0001	
N=105	Week 12	101 (96.2)	5.1 (2.77)			
Asian						
Relugolix+E2/NETA	Baseline	1 (100.0)	3.0 (NE)	NC (NC)	NC	NC
N=1	Week 12	1 (100.0)	0.0 (NE)		[NC,NC]	[NC,NC]
Placebo	Baseline	3 (100.0)	5.0 (4.00)	NC (NC)	NC	
N=3	Week 12	3 (100.0)	5.0 (3.61)			
Others						
Relugolix+E2/NETA	Baseline	5 (100.0)	7.2 (3.63)	-2.41 (0.972)	-2.15	-0.95
N=5	Week 12	5 (100.0)	4.6 (3.58)		[-5.40,1.10]	[-2.14,0.25]
Placebo	Baseline	6 (100.0)	5.7 (3.39)	-0.26 (0.972)	0.1613	
N=6	Week 12	5 (83.3)	4.6 (2.61)			
Not reported						
Relugolix+E2/NETA	Baseline	3 (100.0)	2.7 (2.08)	NC (NC)	NC	NC
N=3	Week 12	3 (100.0)	4.3 (4.04)		[NC,NC]	[NC,NC]
Placebo	Baseline	1 (100.0)	5.0 (NE)	NC (NC)	NC	

N=1	Week 12	1 (100.0)	4.0 (NE)			

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group.
[1] Summary statistics are based on observed data.
[2] LS means, LS mean differences (95% CIs), p-value and Hedges' g (95% CIs) are based on a mixed-effects model with study, treatment, visit, and a treatment-by-visit interaction as fixed effects. The multiple visits for each patient are the repeated measures as a random effect within each patient with an unstructured covariance. Hedges' g is calculated using a small sample bias correction. Interaction p-value is only produced for the Overall period.
The reference group for the LS mean difference and Hedges' g is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with data; CI: Confidence interval; LS: Least squares; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; NRS: Numerical rating scale; SD: Standard deviation; SE: Standard error; SMD: Standardized mean difference; NC: Not calculated; NE: Non-estimable.

SOURCE: \Studies\MYV\MYV102\Analysis\Prod\Progs\TFLs\Tab_EFF_NRS_CON.SAS
Date/time of run: 20APR2021 16:04

Table EFF.MAXNRS.MITT.Pooled.S9: Summary of Change from Baseline in Maximum NRS Score by Visit and Overall, by Subgroup (mITT Population)

Study: Pooled

Treatment	Study visit	n (%)[1]	Mean (SD)[1]	Change from baseline LS-mean change (SE)[2]	Difference LS-mean change [95% CI] p-value[2]	SMD Hedges' g [95% CI][2]
Race						
Black/African American						
Relugolix+E2/NETA	Baseline	120 (98.4)	6.1 (3.26)	-3.16 (0.332)	-1.02	-0.30
N=122	Week 16	102 (83.6)	2.9 (3.09)		[-1.90,-0.14]	[-0.56,-0.04]
Placebo	Baseline	139 (98.6)	5.8 (3.11)	-2.14 (0.299)	0.0232	
N=141	Week 16	127 (90.1)	3.9 (3.31)			
White						
Relugolix+E2/NETA	Baseline	121 (99.2)	5.0 (3.23)	-3.05 (0.269)	-1.99	-0.69
N=122	Week 16	111 (91.0)	1.9 (2.62)		[-2.77,-1.21]	[-0.97,-0.41]
Placebo	Baseline	103 (98.1)	5.7 (2.78)	-1.06 (0.290)	<.0001	
N=105	Week 16	97 (92.4)	4.7 (2.97)			
Asian						
Relugolix+E2/NETA	Baseline	1 (100.0)	3.0 (NE)	NC (NC)	NC	NC
N=1	Week 16	1 (100.0)	0.0 (NE)		[NC,NC]	[NC,NC]
Placebo	Baseline	3 (100.0)	5.0 (4.00)	NC (NC)	NC	
N=3	Week 16	2 (66.7)	2.0 (2.83)			
Others						
Relugolix+E2/NETA	Baseline	5 (100.0)	7.2 (3.63)	-2.01 (0.844)	-1.63	-0.79
N=5	Week 16	5 (100.0)	5.0 (3.39)		[-4.46,1.20]	[-2.01,0.43]
Placebo	Baseline	6 (100.0)	5.7 (3.39)	-0.38 (0.849)	0.2143	
N=6	Week 16	4 (66.7)	4.3 (2.99)			
Not reported						
Relugolix+E2/NETA	Baseline	3 (100.0)	2.7 (2.08)	NC (NC)	NC	NC
N=3	Week 16	3 (100.0)	4.0 (4.58)		[NC,NC]	[NC,NC]

Placebo	Baseline	1 (100.0)	5.0 (NE)	NC (NC)	NC	
N=1	Week 16	1 (100.0)	3.0 (NE)			

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group.
[1] Summary statistics are based on observed data.
[2] LS means, LS mean differences (95% CIs), p-value and Hedges' g (95% CIs) are based on a mixed-effects model with study, treatment, visit, and a treatment-by-visit interaction as fixed effects. The multiple visits for each patient are the repeated measures as a random effect within each patient with an unstructured covariance. Hedges' g is calculated using a small sample bias correction. Interaction p-value is only produced for the Overall period.
The reference group for the LS mean difference and Hedges' g is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with data; CI: Confidence interval; LS: Least squares; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; NRS: Numerical rating scale; SD: Standard deviation; SE: Standard error; SMD: Standardized mean difference; NC: Not calculated; NE: Non-estimable.

Table EFF.MAXNRS.MITT.Pooled.S9: Summary of Change from Baseline in Maximum NRS Score by Visit and Overall, by Subgroup (mITT Population)

Study: Pooled

Treatment	**Study visit**	**n (%)[1]**	**Mean (SD)[1]**	**Change from baseline LS-mean change (SE)[2]**	**Difference LS-mean change [95% CI] p-value[2]**	**SMD Hedges' g [95% CI][2]**
Race						
Black/African American						
Relugolix+E2/NETA	Baseline	120 (98.4)	6.1 (3.26)	-3.45 (0.326)	-1.27	-0.38
N=122	Week 20	96 (78.7)	2.8 (3.03)		[-2.13,-0.41]	[-0.65,-0.11]
Placebo	Baseline	139 (98.6)	5.8 (3.11)	-2.19 (0.292)	0.0041	
N=141	Week 20	123 (87.2)	3.9 (3.24)			
White						
Relugolix+E2/NETA	Baseline	121 (99.2)	5.0 (3.23)	-3.16 (0.285)	-1.98	-0.65
N=122	Week 20	107 (87.7)	1.7 (2.29)		[-2.80,-1.16]	[-0.94,-0.37]
Placebo	Baseline	103 (98.1)	5.7 (2.78)	-1.18 (0.307)	<.0001	
N=105	Week 20	93 (88.6)	4.6 (3.15)			
Asian						
Relugolix+E2/NETA	Baseline	1 (100.0)	3.0 (NE)	NC (NC)	NC	NC
N=1	Week 20	1 (100.0)	0.0 (NE)		[NC,NC]	[NC,NC]
Placebo	Baseline	3 (100.0)	5.0 (4.00)	NC (NC)	NC	
N=3	Week 20	2 (66.7)	0.5 (0.71)			
Others						
Relugolix+E2/NETA	Baseline	5 (100.0)	7.2 (3.63)	-2.81 (1.338)	-1.64	-0.51
N=5	Week 20	5 (100.0)	4.2 (3.35)		[-6.21,2.92]	[-1.71,0.68]
Placebo	Baseline	6 (100.0)	5.7 (3.39)	-1.17 (1.392)	0.4227	
N=6	Week 20	4 (66.7)	3.3 (3.59)			
Not reported						
Relugolix+E2/NETA	Baseline	3 (100.0)	2.7 (2.08)	NC (NC)	NC	NC

N=3	Week 20	3 (100.0)	2.7 (2.52)		[NC,NC]	[NC,NC]
Placebo	Baseline	1 (100.0)	5.0 (NE)	NC (NC)	NC	
N=1	Week 20	1 (100.0)	2.0 (NE)			

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group.
[1] Summary statistics are based on observed data.
[2] LS means, LS mean differences (95% CIs), p-value and Hedges' g (95% CIs) are based on a mixed-effects model with study, treatment, visit, and a treatment-by-visit interaction as fixed effects. The multiple visits for each patient are the repeated measures as a random effect within each patient with an unstructured covariance. Hedges' g is calculated using a small sample bias correction. Interaction p-value is only produced for the Overall period.
The reference group for the LS mean difference and Hedges' g is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with data; CI: Confidence interval; LS: Least squares; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; NRS: Numerical rating scale; SD: Standard deviation; SE: Standard error; SMD: Standardized mean difference; NC: Not calculated; NE: Non-estimable.

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Table EFF.MAXNRS.MITT.Pooled.S9: Summary of Change from Baseline in Maximum NRS Score by Visit and Overall, by Subgroup (mITT Population)

Study: Pooled

Treatment	**Study visit**	**n (%)[1]**	**Mean (SD)[1]**	**Change from baseline LS-mean change (SE)[2]**	**Difference LS-mean change [95% CI] p-value[2]**	**SMD Hedges' g [95% CI][2]**
Race						
Black/African American						
Relugolix+E2/NETA	Baseline	120 (98.4)	6.1 (3.26)	-3.82 (0.336)	-1.11	-0.33
N=122	Week 24	91 (74.6)	2.2 (2.64)		[-2.00,-0.23]	[-0.61,-0.06]
Placebo	Baseline	139 (98.6)	5.8 (3.11)	-2.71 (0.300)	0.0141	
N=141	Week 24	117 (83.0)	3.3 (3.03)			
White						
Relugolix+E2/NETA	Baseline	121 (99.2)	5.0 (3.23)	-3.33 (0.290)	-1.76	-0.57
N=122	Week 24	105 (86.1)	1.5 (2.06)		[-2.60,-0.91]	[-0.86,-0.28]
Placebo	Baseline	103 (98.1)	5.7 (2.78)	-1.58 (0.314)	<.0001	
N=105	Week 24	88 (83.8)	4.4 (3.13)			
Asian						
Relugolix+E2/NETA	Baseline	1 (100.0)	3.0 (NE)	NC (NC)	NC	NC
N=1	Week 24	1 (100.0)	0.0 (NE)		[NC,NC]	[NC,NC]
Placebo	Baseline	3 (100.0)	5.0 (4.00)	NC (NC)	NC	
N=3	Week 24	2 (66.7)	0.5 (0.71)			
Others						
Relugolix+E2/NETA	Baseline	5 (100.0)	7.2 (3.63)	-3.21 (1.408)	-2.60	-0.85
N=5	Week 24	5 (100.0)	3.8 (3.27)		[-7.40,2.20]	[-2.08,0.38]
Placebo	Baseline	6 (100.0)	5.7 (3.39)	-0.62 (1.462)	0.2416	
N=6	Week 24	4 (66.7)	3.3 (3.59)			
Not reported						

Relugolix+E2/NETA	Baseline	3 (100.0)	2.7 (2.08)	NC (NC)	NC	NC
N=3	Week 24	3 (100.0)	2.7 (0.58)		[NC,NC]	[NC,NC]
Placebo	Baseline	1 (100.0)	5.0 (NE)	NC (NC)	NC	
N=1	Week 24	1 (100.0)	6.0 (NE)			

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group.
[1] Summary statistics are based on observed data.
[2] LS means, LS mean differences (95% CIs), p-value and Hedges' g (95% CIs) are based on a mixed-effects model with study, treatment, visit, and a treatment-by-visit interaction as fixed effects. The multiple visits for each patient are the repeated measures as a random effect within each patient with an unstructured covariance. Hedges' g is calculated using a small sample bias correction. Interaction p-value is only produced for the Overall period.
The reference group for the LS mean difference and Hedges' g is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with data; CI: Confidence interval; LS: Least squares; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; NRS: Numerical rating scale; SD: Standard deviation; SE: Standard error; SMD: Standardized mean difference; NC: Not calculated; NE: Non-estimable.

Table EFF.MAXNRS.MITT.Pooled.S9: Summary of Change from Baseline in Maximum NRS Score by Visit and Overall, by Subgroup (mITT Population)

Study: Pooled

Treatment	**Study visit**	**n (%)[1]**	**Mean (SD)[1]**	**Change from baseline LS-mean change (SE)[2]**	**Difference LS-mean change [95% CI] p-value[2]**	**SMD Hedges' g [95% CI][2]**	**Int. p-value[2]**
Race							
Black/African American							
Relugolix+E2/NETA	Baseline	120 (98.4)	6.1 (3.26)	-3.08 (0.236)	-1.25	-0.41	0.7433
N=122	Overall	120 (98.4)	3.2 (2.58)		[-1.88,-0.62]	[-0.66,-0.16]	
Placebo	Baseline	139 (98.6)	5.8 (3.11)	-1.83 (0.217)	0.0001		
N=141	Overall	140 (99.3)	4.0 (2.59)				
White							
Relugolix+E2/NETA	Baseline	121 (99.2)	5.0 (3.23)	-2.61 (0.232)	-1.59	-0.52	
N=122	Overall	122 (100.0)	2.5 (2.37)		[-2.26,-0.92]	[-0.79,-0.26]	
Placebo	Baseline	103 (98.1)	5.7 (2.78)	-1.03 (0.249)	<.0001		
N=105	Overall	105 (100.0)	4.9 (2.63)				
Asian							
Relugolix+E2/NETA	Baseline	1 (100.0)	3.0 (NE)	NC (NC)	NC	NC	
N=1	Overall	1 (100.0)	0.3 (NE)		[NC,NC]	[NC,NC]	
Placebo	Baseline	3 (100.0)	5.0 (4.00)	NC (NC)	NC		
N=3	Overall	3 (100.0)	3.9 (3.34)				
Others							
Relugolix+E2/NETA	Baseline	5 (100.0)	7.2 (3.63)	-2.79 (1.106)	-1.73	-0.52	
N=5	Overall	5 (100.0)	4.7 (2.64)		[-4.80,1.35]	[-1.66,0.63]	
Placebo	Baseline	6 (100.0)	5.7 (3.39)	-1.06 (1.106)	0.2700		
N=6	Overall	5 (83.3)	3.9 (2.80)				

Not reported							
Relugolix+E2/NETA	Baseline	3 (100.0)	2.7 (2.08)	NC (NC)	NC	NC	
N=3	Overall	3 (100.0)	3.7 (2.62)		[NC,NC]	[NC,NC]	
Placebo	Baseline	1 (100.0)	5.0 (NE)	NC (NC)	NC		
N=1	Overall	1 (100.0)	5.0 (NE)				

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group.
[1] Summary statistics are based on observed data. Mean (SD) are calculated based on the mean observed value across all post-baseline visits within each patient.
[2] LS means, LS mean differences (95% CIs), p-value and Hedges' g (95% CIs) are based on a mixed-effects model with study, treatment, visit, subgroup, treatment-by-visit interaction and a subgroup-by-treatment interaction as fixed effects. The multiple visits for each patient are the repeated measures as a random effect within each patient with an unstructured covariance. Hedges' g is calculated using a small sample bias correction. Not reported subgroup levels are not included in estimation of the interaction p-value. Subgroup levels with fewer than 10 subjects are not included in estimation of the interaction p-value. The reference group for the LS mean difference and Hedges' g is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with data; CI: Confidence interval; int: Interaction; LS: Least squares; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; NRS: Numerical rating scale; SD: Standard deviation; SE: Standard error; SMD: Standardized mean difference; NC: Not calculated; NE: Non-estimable.

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Table EFF.MAXNRS.MITT.Pooled.S2: Summary of Change from Baseline in Maximum NRS Score by Visit and Overall, by Subgroup (mITT Population)

Study: Pooled

Treatment	Study visit	n (%)[1]	Mean (SD)[1]	Change from baseline LS-mean change (SE)[2]	Difference LS-mean change [95% CI] p-value[2]	SMD Hedges' g [95% CI][2]
BMI (kg/m2) at Baseline						
< 30						
Relugolix+E2/NETA	Baseline	118 (99.2)	5.1 (3.40)	-1.37 (0.252)	-0.80	-0.29
N=119	Week 4	118 (99.2)	3.8 (2.94)		[-1.50,-0.09]	[-0.55,-0.03]
Placebo	Baseline	114 (99.1)	5.3 (2.93)	-0.57 (0.255)	0.0274	
N=115	Week 4	115 (100.0)	4.7 (3.02)			
>= 30						
Relugolix+E2/NETA	Baseline	131 (98.5)	5.9 (3.16)	-1.42 (0.250)	-0.92	-0.32
N=133	Week 4	132 (99.2)	4.5 (3.17)		[-1.61,-0.23]	[-0.56,-0.08]
Placebo	Baseline	138 (97.9)	6.1 (2.96)	-0.50 (0.244)	0.0089	
N=141	Week 4	139 (98.6)	5.7 (2.93)			
Missing						
Relugolix+E2/NETA	Baseline	1 (100.0)	6.0 (NE)	NC (NC)	NC	NC
N=1	Week 4	1 (100.0)	4.0 (NE)		[NC,NC]	[NC,NC]
Placebo	Baseline	0	NE (NE)	NC (NC)	NC	
N=0	Week 4	0	NE (NE)			

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group.
[1] Summary statistics are based on observed data.
[2] LS means, LS mean differences (95% CIs), p-value and Hedges' g (95% CIs) are based on a mixed-effects model with study, treatment, visit, and a treatment-by-visit interaction as fixed effects. The multiple visits for each patient are the repeated measures as a random effect within each patient with an unstructured covariance. Hedges' g is calculated using a small sample bias correction. Interaction p-value is only produced for the Overall period.
The reference group for the LS mean difference and Hedges' g is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with data; CI: Confidence interval; LS: Least squares; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; NRS: Numerical rating scale; SD: Standard deviation; SE: Standard error; SMD: Standardized mean difference; NC: Not calculated; NE: Non-estimable.

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Table EFF.MAXNRS.MITT.Pooled.S2: Summary of Change from Baseline in Maximum NRS Score by Visit and Overall, by Subgroup (mITT Population)

Study: Pooled

Treatment	Study visit	n (%)[1]	Mean (SD)[1]	Change from baseline LS-mean change (SE)[2]	Difference LS-mean change [95% CI] p-value[2]	SMD Hedges' g [95% CI][2]
BMI (kg/m2) at Baseline						
< 30						
Relugolix+E2/NETA	Baseline	118 (99.2)	5.1 (3.40)	-2.46 (0.288)	-1.57	-0.52
N=119	Week 8	107 (89.9)	2.6 (2.73)		[-2.37,-0.77]	[-0.80,-0.25]
Placebo	Baseline	114 (99.1)	5.3 (2.93)	-0.89 (0.288)	0.0002	
N=115	Week 8	108 (93.9)	4.5 (3.23)			
>= 30						
Relugolix+E2/NETA	Baseline	131 (98.5)	5.9 (3.16)	-2.87 (0.266)	-1.46	-0.49
N=133	Week 8	125 (94.0)	3.1 (2.82)		[-2.19,-0.73]	[-0.74,-0.24]
Placebo	Baseline	138 (97.9)	6.1 (2.96)	-1.41 (0.258)	0.0001	
N=141	Week 8	135 (95.7)	4.8 (3.08)			
Missing						
Relugolix+E2/NETA	Baseline	1 (100.0)	6.0 (NE)	NC (NC)	NC	NC
N=1	Week 8	1 (100.0)	4.0 (NE)		[NC,NC]	[NC,NC]
Placebo	Baseline	0	NE (NE)	NC (NC)	NC	
N=0	Week 8	0	NE (NE)			

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group.
[1] Summary statistics are based on observed data.
[2] LS means, LS mean differences (95% CIs), p-value and Hedges' g (95% CIs) are based on a mixed-effects model with study, treatment, visit, and a treatment-by-visit interaction as fixed effects. The multiple visits for each patient are the repeated measures as a random effect within each patient with an unstructured covariance. Hedges' g is calculated using a small sample bias correction. Interaction p-value is only produced for the Overall period.
The reference group for the LS mean difference and Hedges' g is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with data; CI: Confidence interval; LS: Least squares; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; NRS: Numerical rating scale; SD: Standard deviation; SE: Standard error; SMD: Standardized mean difference; NC: Not calculated; NE: Non-estimable.

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Table EFF.MAXNRS.MITT.Pooled.S2: Summary of Change from Baseline in Maximum NRS Score by Visit and Overall, by Subgroup (mITT Population)

Study: Pooled

Treatment	Study visit	n (%)[1]	Mean (SD)[1]	Change from baseline LS-mean change (SE)[2]	Difference LS-mean change [95% CI] p-value[2]	SMD Hedges' g [95% CI][2]
BMI (kg/m2) at Baseline						
< 30						
Relugolix+E2/NETA	Baseline	118 (99.2)	5.1 (3.40)	-2.52 (0.296)	-1.51	-0.49
N=119	Week 12	103 (86.6)	2.4 (2.91)		[-2.33,-0.68]	[-0.77,-0.22]
Placebo	Baseline	114 (99.1)	5.3 (2.93)	-1.02 (0.295)	0.0004	
N=115	Week 12	107 (93.0)	4.4 (3.08)			
>= 30						
Relugolix+E2/NETA	Baseline	131 (98.5)	5.9 (3.16)	-3.13 (0.282)	-1.28	-0.41
N=133	Week 12	123 (92.5)	2.8 (3.09)		[-2.06,-0.51]	[-0.66,-0.16]
Placebo	Baseline	138 (97.9)	6.1 (2.96)	-1.84 (0.273)	0.0012	
N=141	Week 12	132 (93.6)	4.4 (2.99)			
Missing						
Relugolix+E2/NETA	Baseline	1 (100.0)	6.0 (NE)	NC (NC)	NC	NC
N=1	Week 12	1 (100.0)	4.0 (NE)		[NC,NC]	[NC,NC]
Placebo	Baseline	0	NE (NE)	NC (NC)	NC	
N=0	Week 12	0	NE (NE)			

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group.
[1] Summary statistics are based on observed data.
[2] LS means, LS mean differences (95% CIs), p-value and Hedges' g (95% CIs) are based on a mixed-effects model with study, treatment, visit, and a treatment-by-visit interaction as fixed effects. The multiple visits for each patient are the repeated measures as a random effect within each patient with an unstructured covariance. Hedges' g is calculated using a small sample bias correction. Interaction p-value is only produced for the Overall period.
The reference group for the LS mean difference and Hedges' g is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with data; CI: Confidence interval; LS: Least squares; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; NRS: Numerical rating scale; SD: Standard deviation; SE: Standard error; SMD: Standardized mean difference; NC: Not calculated; NE: Non-estimable.

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Table EFF.MAXNRS.MITT.Pooled.S2: Summary of Change from Baseline in Maximum NRS Score by Visit and Overall, by Subgroup (mITT Population)

Study: Pooled

Treatment	Study visit	n (%)[1]	Mean (SD)[1]	Change from baseline LS-mean change (SE)[2]	Difference LS-mean change [95% CI] p-value[2]	SMD Hedges' g [95% CI][2]
BMI (kg/m2) at Baseline						
< 30						
Relugolix+E2/NETA	Baseline	118 (99.2)	5.1 (3.40)	-2.70 (0.315)	-1.23	-0.38
N=119	Week 16	101 (84.9)	2.3 (2.99)		[-2.11,-0.35]	[-0.66,-0.10]
Placebo	Baseline	114 (99.1)	5.3 (2.93)	-1.47 (0.316)	0.0063	
N=115	Week 16	101 (87.8)	3.9 (3.20)			
>= 30						
Relugolix+E2/NETA	Baseline	131 (98.5)	5.9 (3.16)	-3.33 (0.286)	-1.49	-0.47
N=133	Week 16	120 (90.2)	2.6 (2.90)		[-2.28,-0.71]	[-0.72,-0.22]
Placebo	Baseline	138 (97.9)	6.1 (2.96)	-1.83 (0.276)	0.0002	
N=141	Week 16	130 (92.2)	4.4 (3.14)			
Missing						
Relugolix+E2/NETA	Baseline	1 (100.0)	6.0 (NE)	NC (NC)	NC	NC
N=1	Week 16	1 (100.0)	4.0 (NE)		[NC,NC]	[NC,NC]
Placebo	Baseline	0	NE (NE)	NC (NC)	NC	
N=0	Week 16	0	NE (NE)			

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group.
[1] Summary statistics are based on observed data.
[2] LS means, LS mean differences (95% CIs), p-value and Hedges' g (95% CIs) are based on a mixed-effects model with study, treatment, visit, and a treatment-by-visit interaction as fixed effects. The multiple visits for each patient are the repeated measures as a random effect within each patient with an unstructured covariance. Hedges' g is calculated using a small sample bias correction. Interaction p-value is only produced for the Overall period.
The reference group for the LS mean difference and Hedges' g is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with data; CI: Confidence interval; LS: Least squares; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; NRS: Numerical rating scale; SD: Standard deviation; SE: Standard error; SMD: Standardized mean difference; NC: Not calculated; NE: Non-estimable.

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Table EFF.MAXNRS.MITT.Pooled.S2: Summary of Change from Baseline in Maximum NRS Score by Visit and Overall, by Subgroup (mITT Population)

Study: Pooled

Treatment	Study visit	n (%)[1]	Mean (SD)[1]	Change from baseline LS-mean change (SE)[2]	Difference LS-mean change [95% CI] p-value[2]	SMD Hedges' g [95% CI][2]
BMI (kg/m2) at Baseline						
< 30						
Relugolix+E2/NETA	Baseline	118 (99.2)	5.1 (3.40)	-3.07 (0.311)	-1.68	-0.53
N=119	Week 20	98 (82.4)	2.0 (2.67)		[-2.54,-0.81]	[-0.82,-0.25]
Placebo	Baseline	114 (99.1)	5.3 (2.93)	-1.40 (0.311)	0.0002	
N=115	Week 20	98 (85.2)	3.9 (3.50)			
>= 30						
Relugolix+E2/NETA	Baseline	131 (98.5)	5.9 (3.16)	-3.44 (0.293)	-1.35	-0.42
N=133	Week 20	113 (85.0)	2.5 (2.79)		[-2.15,-0.55]	[-0.68,-0.16]
Placebo	Baseline	138 (97.9)	6.1 (2.96)	-2.10 (0.282)	0.0010	
N=141	Week 20	125 (88.7)	4.3 (2.97)			
Missing						
Relugolix+E2/NETA	Baseline	1 (100.0)	6.0 (NE)	NC (NC)	NC	NC
N=1	Week 20	1 (100.0)	3.0 (NE)		[NC,NC]	[NC,NC]
Placebo	Baseline	0	NE (NE)	NC (NC)	NC	
N=0	Week 20	0	NE (NE)			

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group.
[1] Summary statistics are based on observed data.
[2] LS means, LS mean differences (95% CIs), p-value and Hedges' g (95% CIs) are based on a mixed-effects model with study, treatment, visit, and a treatment-by-visit interaction as fixed effects. The multiple visits for each patient are the repeated measures as a random effect within each patient with an unstructured covariance. Hedges' g is calculated using a small sample bias correction. Interaction p-value is only produced for the Overall period.
The reference group for the LS mean difference and Hedges' g is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with data; CI: Confidence interval; LS: Least squares; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; NRS: Numerical rating scale; SD: Standard deviation; SE: Standard error; SMD: Standardized mean difference; NC: Not calculated; NE: Non-estimable.

SOURCE: \Studies\MYV\MYV102\Analysis\Prod\Progs\TFLs\Tab_EFF_NRS_CON.SAS
Date/time of run: 20APR2021 16:04
Analysis Plan: 13JAN2021

Table EFF.MAXNRS.MITT.Pooled.S2: Summary of Change from Baseline in Maximum NRS Score by Visit and Overall, by Subgroup (mITT Population)

Study: Pooled

Treatment	Study visit	n (%)[1]	Mean (SD)[1]	Change from baseline LS-mean change (SE)[2]	Difference LS-mean change [95% CI] p-value[2]	SMD Hedges' g [95% CI][2]
BMI (kg/m2) at Baseline						
< 30						
Relugolix+E2/NETA	Baseline	118 (99.2)	5.1 (3.40)	-3.20 (0.311)	-1.48	-0.47
N=119	Week 24	95 (79.8)	1.8 (2.54)		[-2.35,-0.61]	[-0.75,-0.18]
Placebo	Baseline	114 (99.1)	5.3 (2.93)	-1.72 (0.312)	0.0009	
N=115	Week 24	93 (80.9)	3.7 (3.25)			
>= 30						
Relugolix+E2/NETA	Baseline	131 (98.5)	5.9 (3.16)	-3.83 (0.300)	-1.20	-0.37
N=133	Week 24	109 (82.0)	1.9 (2.26)		[-2.03,-0.38]	[-0.64,-0.11]
Placebo	Baseline	138 (97.9)	6.1 (2.96)	-2.63 (0.289)	0.0042	
N=141	Week 24	119 (84.4)	3.7 (3.02)			
Missing						
Relugolix+E2/NETA	Baseline	1 (100.0)	6.0 (NE)	NC (NC)	NC	NC
N=1	Week 24	1 (100.0)	4.0 (NE)		[NC,NC]	[NC,NC]
Placebo	Baseline	0	NE (NE)	NC (NC)	NC	
N=0	Week 24	0	NE (NE)			

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group.
[1] Summary statistics are based on observed data.
[2] LS means, LS mean differences (95% CIs), p-value and Hedges' g (95% CIs) are based on a mixed-effects model with study, treatment, visit, and a treatment-by-visit interaction as fixed effects. The multiple visits for each patient are the repeated measures as a random effect within each patient with an unstructured covariance. Hedges' g is calculated using a small sample bias correction. Interaction p-value is only produced for the Overall period.
The reference group for the LS mean difference and Hedges' g is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with data; CI: Confidence interval; LS: Least squares; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; NRS: Numerical rating scale; SD: Standard deviation; SE: Standard error; SMD: Standardized mean difference; NC: Not calculated; NE: Non-estimable.

SOURCE: \Studies\MYV\MYV102\Analysis\Prod\Progs\TFLs\Tab_EFF_NRS_CON.SAS
Date/time of run: 20APR2021 16:04
Analysis Plan: 13JAN2021

Table EFF.MAXNRS.MITT.Pooled.S2: Summary of Change from Baseline in Maximum NRS Score by Visit and Overall, by Subgroup (mITT Population)

Study: Pooled

Treatment	Study visit	n (%)[1]	Mean (SD)[1]	Change from baseline LS-mean change (SE)[2]	Difference LS-mean change [95% CI] p-value[2]	SMD Hedges' g [95% CI][2]	Int. p-value[2]
BMI (kg/m2) at Baseline							
< 30							
Relugolix+E2/NETA	Baseline	118 (99.2)	5.1 (3.40)	-2.65 (0.240)	-1.34	-0.44	0.9600
N=119	Overall	118 (99.2)	2.8 (2.58)		[-2.01,-0.67]	[-0.70,-0.18]	
Placebo	Baseline	114 (99.1)	5.3 (2.93)	-1.30 (0.242)	<.0001		
N=115	Overall	115 (100.0)	4.2 (2.77)				
>= 30							
Relugolix+E2/NETA	Baseline	131 (98.5)	5.9 (3.16)	-2.93 (0.227)	-1.32	-0.43	
N=133	Overall	132 (99.2)	3.0 (2.44)		[-1.94,-0.70]	[-0.67,-0.19]	
Placebo	Baseline	138 (97.9)	6.1 (2.96)	-1.61 (0.221)	<.0001		
N=141	Overall	139 (98.6)	4.6 (2.51)				
Missing							
Relugolix+E2/NETA	Baseline	1 (100.0)	6.0 (NE)	NC (NC)	NC	NC	
N=1	Overall	1 (100.0)	3.8 (NE)		[NC,NC]	[NC,NC]	
Placebo	Baseline	0	NE (NE)	NC (NC)	NC		
N=0	Overall	0	NE (NE)				

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group.
[1] Summary statistics are based on observed data. Mean (SD) are calculated based on the mean observed value across all post-baseline visits within each patient.
[2] LS means, LS mean differences (95% CIs), p-value and Hedges' g (95% CIs) are based on a mixed-effects model with study, treatment, visit, subgroup, treatment-by-visit interaction and a subgroup-by-treatment interaction as fixed effects. The multiple visits for each patient are the repeated measures as a random effect within each patient with an unstructured covariance. Hedges' g is calculated using a small sample bias correction. Missing subgroup levels are not included in estimation of the interaction p-value.
The reference group for the LS mean difference and Hedges' g is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with data; CI: Confidence interval; int: Interaction; LS: Least squares; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; NRS: Numerical rating scale; SD: Standard deviation; SE: Standard error; SMD: Standardized mean difference; NC: Not calculated; NE: Non-estimable.

SOURCE: \Studies\MYV\MYV102\Analysis\Prod\Progs\TFLs\Tab_EFF_NRS_CON.SAS
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1.2 Gesundheitsbezogene Lebensqualität

1.2.1 Summary of Change from Baseline in UFS-QoL Symptom Severity Scale Score by Visit and Overall, by Subgroup (mITT Population)

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Table EFF.UFSSSS.MITT.Pooled.S9: Summary of Change from Baseline in UFS-QoL Symptom Severity Scale Score by Visit and Overall, by Subgroup (mITT Population)						
Study: Pooled						
Treatment	**Study visit**	**n (%)[1]**	**Mean (SD)[1]**	**Change from baseline LS-mean change (SE)[2]**	**Difference LS-mean change [95% CI] p-value[2]**	**SMD Hedges' g [95% CI][2]**
Race						
Black/African American						
Relugolix+E2/NETA	Baseline	119 (97.5)	63.9 (20.98)	-30.18 (2.531)	-18.24	-0.71
N=122	Week 12	105 (86.1)	35.5 (26.42)		[-25.01,-11.47]	[-0.99,-0.44]
Placebo	Baseline	139 (98.6)	60.0 (19.23)	-11.95 (2.324)	<.0001	
N=141	Week 12	122 (86.5)	47.5 (20.97)			
White						
Relugolix+E2/NETA	Baseline	121 (99.2)	52.7 (19.91)	-25.70 (2.115)	-16.30	-0.74
N=122	Week 12	110 (90.2)	26.6 (21.34)		[-22.38,-10.22]	[-1.02,-0.46]
Placebo	Baseline	105 (100.0)	60.1 (19.02)	-9.40 (2.245)	<.0001	
N=105	Week 12	98 (93.3)	50.7 (19.09)			
Asian						
Relugolix+E2/NETA	Baseline	1 (100.0)	56.3 (NE)	NC (NC)	NC	NC
N=1	Week 12	1 (100.0)	18.8 (NE)		[NC,NC]	[NC,NC]
Placebo	Baseline	3 (100.0)	79.2 (20.08)	NC (NC)	NC	
N=3	Week 12	3 (100.0)	68.8 (20.48)			
Others						
Relugolix+E2/NETA	Baseline	5 (100.0)	48.1 (18.30)	-24.64 (12.977)	-6.21	-0.23
N=5	Week 12	5 (100.0)	30.0 (16.89)		[-49.34,36.92]	[-1.35,0.90]
Placebo	Baseline	6 (100.0)	76.6 (16.37)	-18.44 (12.327)	0.7437	
N=6	Week 12	5 (83.3)	53.1 (36.16)			
Not reported						
Relugolix+E2/NETA	Baseline	3 (100.0)	35.4 (34.45)	NC (NC)	NC	NC
N=3	Week 12	3 (100.0)	17.7 (17.78)		[NC,NC]	[NC,NC]
Placebo	Baseline	1 (100.0)	40.6 (NE)	NC (NC)	NC	

N=1	Week 12	1 (100.0)	50.0 (NE)			

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group. Transformed score ranges from 0 to 100 based on Likert scale (Not at all, a little bit, somewhat, a great deal and a very great deal). Higher scores are indicative of greater symptom severity and lower scores indicate lower symptom severity (low score = good). For the change from baseline, negative scores indicate improvement.
[1] Summary statistics are based on observed data.
[2] LS means, LS mean differences (95% CIs), p-value and Hedges' g (95% CIs) are based on a mixed-effects model with study, treatment, visit, and a treatment-by-visit interaction as fixed effects. The multiple visits for each patient are the repeated measures as a random effect within each patient with an unstructured covariance. Hedges' g is calculated using a small sample bias correction. Interaction p-value is only produced for the Overall period. The reference group for the LS mean difference and Hedges' g is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with data; CI: Confidence interval; LS: Least squares; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; SD: Standard deviation; SE: Standard error; SMD: Standardized mean difference; UFS-QoL: Uterine Fibroid Symptom and Health-Related Quality of Life; NC: Not calculated; NE: Non-estimable.

SOURCE: \Studies\MYV\MYV102\Analysis\Prod\Progs\TFLs\Tab_QOL_UFS_CON.SAS
Date/time of run: 20APR2021 16:38

Table EFF.UFSSSS.MITT.Pooled.S9: Summary of Change from Baseline in UFS-QoL Symptom Severity Scale Score by Visit and Overall, by Subgroup (mITT Population)						
Study: Pooled						
Treatment	**Study visit**	**n (%)[1]**	**Mean (SD)[1]**	**Change from baseline LS-mean change (SE)[2]**	**Difference LS-mean change [95% CI] p-value[2]**	**SMD Hedges' g [95% CI][2]**
Race						
Black/African American						
Relugolix+E2/NETA	Baseline	119 (97.5)	63.9 (20.98)	-36.15 (2.583)	-23.68	-0.95
N=122	Week 24	87 (71.3)	26.4 (22.60)		[-30.53,-16.84]	[-1.25,-0.65]
Placebo	Baseline	139 (98.6)	60.0 (19.23)	-12.47 (2.324)	<.0001	
N=141	Week 24	108 (76.6)	47.3 (24.48)			
White						
Relugolix+E2/NETA	Baseline	121 (99.2)	52.7 (19.91)	-32.62 (2.291)	-20.12	-0.85
N=122	Week 24	100 (82.0)	18.1 (20.38)		[-26.76,-13.48]	[-1.15,-0.55]
Placebo	Baseline	105 (100.0)	60.1 (19.02)	-12.51 (2.470)	<.0001	
N=105	Week 24	84 (80.0)	47.3 (21.95)			
Asian						
Relugolix+E2/NETA	Baseline	1 (100.0)	56.3 (NE)	NC (NC)	NC	NC
N=1	Week 24	1 (100.0)	0.0 (NE)		[NC,NC]	[NC,NC]
Placebo	Baseline	3 (100.0)	79.2 (20.08)	NC (NC)	NC	
N=3	Week 24	2 (66.7)	71.9 (22.06)			
Others						
Relugolix+E2/NETA	Baseline	5 (100.0)	48.1 (18.30)	-17.78 (9.725)	-10.54	-0.55
N=5	Week 24	5 (100.0)	36.9 (25.69)		[-45.28,24.19]	[-1.74,0.65]
Placebo	Baseline	6 (100.0)	76.6 (16.37)	-7.24 (9.868)	0.4961	
N=6	Week 24	4 (66.7)	64.9 (18.79)			
Not reported						
Relugolix+E2/NETA	Baseline	3 (100.0)	35.4 (34.45)	NC (NC)	NC	NC
N=3	Week 24	3 (100.0)	11.5 (7.90)		[NC,NC]	[NC,NC]
Placebo	Baseline	1 (100.0)	40.6 (NE)	NC (NC)	NC	

N=1	Week 24	1 (100.0)	28.1 (NE)			

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group. Transformed score ranges from 0 to 100 based on Likert scale (Not at all, a little bit, somewhat, a great deal and a very great deal). Higher scores are indicative of greater symptom severity and lower scores indicate lower symptom severity (low score = good). For the change from baseline, negative scores indicate improvement.
[1] Summary statistics are based on observed data.
[2] LS means, LS mean differences (95% CIs), p-value and Hedges' g (95% CIs) are based on a mixed-effects model with study, treatment, visit, and a treatment-by-visit interaction as fixed effects. The multiple visits for each patient are the repeated measures as a random effect within each patient with an unstructured covariance. Hedges' g is calculated using a small sample bias correction. Interaction p-value is only produced for the Overall period. The reference group for the LS mean difference and Hedges' g is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with data; CI: Confidence interval; LS: Least squares; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; SD: Standard deviation; SE: Standard error; SMD: Standardized mean difference; UFS-QoL: Uterine Fibroid Symptom and Health-Related Quality of Life; NC: Not calculated; NE: Non-estimable.

SOURCE: \Studies\MYV\MYV102\Analysis\Prod\Progs\TFLs\Tab_QOL_UFS_CON.SAS
Date/time of run: 20APR2021 16:38

Table EFF.UFSSSS.MITT.Pooled.S9: Summary of Change from Baseline in UFS-QoL Symptom Severity Scale Score by Visit and Overall, by Subgroup (mITT Population)							
Study: Pooled							
Treatment	**Study visit**	**n (%)[1]**	**Mean (SD)[1]**	**Change from baseline LS-mean change (SE)[2]**	**Difference LS-mean change [95% CI] p-value[2]**	**SMD Hedges' g [95% CI][2]**	**Int. p-value[2]**
Race							
Black/African American							
Relugolix+E2/NETA	Baseline	119 (97.5)	63.9 (20.98)	-33.15 (2.196)	-20.89	-0.87	0.2623
N=122	Overall	107 (87.7)	32.5 (23.26)		[-26.73,-15.05]	[-1.14,-0.60]	
Placebo	Baseline	139 (98.6)	60.0 (19.23)	-12.26 (2.003)	<.0001		
N=141	Overall	126 (89.4)	47.3 (20.23)				
White							
Relugolix+E2/NETA	Baseline	121 (99.2)	52.7 (19.91)	-29.19 (2.110)	-18.25	-0.76	
N=122	Overall	112 (91.8)	23.4 (18.90)		[-24.31,-12.19]	[-1.04,-0.48]	
Placebo	Baseline	105 (100.0)	60.1 (19.02)	-10.94 (2.252)	<.0001		
N=105	Overall	98 (93.3)	49.6 (18.87)				
Asian							
Relugolix+E2/NETA	Baseline	1 (100.0)	56.3 (NE)	NC (NC)	NC	NC	
N=1	Overall	1 (100.0)	9.4 (NE)		[NC,NC]	[NC,NC]	
Placebo	Baseline	3 (100.0)	79.2 (20.08)	NC (NC)	NC		
N=3	Overall	3 (100.0)	70.3 (18.00)				
Others							
Relugolix+E2/NETA	Baseline	5 (100.0)	48.1 (18.30)	-15.22 (9.850)	1.96	0.07	
N=5	Overall	5 (100.0)	33.5 (19.13)		[-25.65,29.57]	[-1.05,1.19]	
Placebo	Baseline	6 (100.0)	76.6 (16.37)	-17.18 (10.000)	0.8892		
N=6	Overall	5 (83.3)	56.0 (27.26)				
Not reported							
Relugolix+E2/NETA	Baseline	3 (100.0)	35.4 (34.45)	NC (NC)	NC	NC	
N=3	Overall	3 (100.0)	14.6 (11.75)		[NC,NC]	[NC,NC]	
Placebo	Baseline	1 (100.0)	40.6 (NE)	NC (NC)	NC		

N=1	Overall	1 (100.0)	39.1 (NE)				

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group. Transformed score ranges from 0 to 100 based on Likert scale (Not at all, a little bit, somewhat, a great deal and a very great deal). Higher scores are indicative of greater symptom severity and lower scores indicate lower symptom severity (low score = good). For the change from baseline, negative scores indicate improvement.
[1] Summary statistics are based on observed data. Mean (SD) are calculated based on the mean observed value across all post-baseline visits within each patient.
[2] LS means, LS mean differences (95% CIs), p-value and Hedges' g (95% CIs) are based on a mixed-effects model with study, treatment, visit, subgroup, treatment-by-visit interaction and a subgroup-by-treatment interaction as fixed effects. The multiple visits for each patient are the repeated measures as a random effect within each patient with an unstructured covariance. Hedges' g is calculated using a small sample bias correction. Not reported subgroup levels are not included in estimation of the interaction p-value. Subgroup levels with fewer than 10 subjects are not included in estimation of the interaction p-value. The reference group for the LS mean difference and Hedges' g is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with data; CI: Confidence interval; int: Interaction; LS: Least squares; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; SD: Standard deviation; SE: Standard error; SMD: Standardized mean difference; UFS-QoL: Uterine Fibroid Symptom and Health-Related Quality of Life; NC: Not calculated; NE: Non-estimable.

SOURCE: \Studies\MYV\MYV102\Analysis\Prod\Progs\TFLs\Tab_QOL_UFS_CON.SAS
Date/time of run: 20APR2021 16:38

Table EFF.UFSSSS.MITT.Pooled.S2: Summary of Change from Baseline in UFS-QoL Symptom Severity Scale Score by Visit and Overall, by Subgroup (mITT Population)

Study: Pooled

Treatment	Study visit	n (%)[1]	Mean (SD)[1]	Change from baseline LS-mean change (SE)[2]	Difference LS-mean change [95% CI] p-value[2]	SMD Hedges' g [95% CI][2]
BMI (kg/m2) at Baseline						
< 30						
Relugolix+E2/NETA	Baseline	118 (99.2)	56.3 (23.22)	-27.52 (2.039)	-20.38	-0.98
N=119	Week 12	104 (87.4)	28.1 (22.69)		[-26.10,-14.65]	[-1.28,-0.69]
Placebo	Baseline	115 (100.0)	59.7 (19.97)	-7.14 (2.066)	<.0001	
N=115	Week 12	100 (87.0)	52.4 (20.79)			
>= 30						
Relugolix+E2/NETA	Baseline	130 (97.7)	58.9 (19.45)	-27.21 (2.409)	-13.16	-0.51
N=133	Week 12	119 (89.5)	33.1 (25.01)		[-19.73,-6.58]	[-0.76,-0.25]
Placebo	Baseline	139 (98.6)	61.2 (18.70)	-14.05 (2.310)	0.0001	
N=141	Week 12	129 (91.5)	46.9 (20.16)			
Missing						
Relugolix+E2/NETA	Baseline	1 (100.0)	81.3 (NE)	NC (NC)	NC	NC
N=1	Week 12	1 (100.0)	6.3 (NE)		[NC,NC]	[NC,NC]
Placebo	Baseline	0	NE (NE)	NC (NC)	NC	
N=0	Week 12	0	NE (NE)			

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group. Transformed score ranges from 0 to 100 based on Likert scale (Not at all, a little bit, somewhat, a great deal and a very great deal). Higher scores are indicative of greater symptom severity and lower scores indicate lower symptom severity (low score = good). For the change from baseline, negative scores indicate improvement.
[1] Summary statistics are based on observed data.
[2] LS means, LS mean differences (95% CIs), p-value and Hedges' g (95% CIs) are based on a mixed-effects model with study, treatment, visit, and a treatment-by-visit interaction as fixed effects. The multiple visits for each patient are the repeated measures as a random effect within each patient with an unstructured covariance. Hedges' g is calculated using a small sample bias correction. Interaction p-value is only produced for the Overall period. The reference group for the LS mean difference and Hedges' g is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with data; CI: Confidence interval; LS: Least squares; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; SD: Standard deviation; SE: Standard error; SMD: Standardized mean difference; UFS-QoL: Uterine Fibroid Symptom and Health-Related Quality of Life; NC: Not calculated; NE: Non-estimable.

SOURCE: \Studies\MYV\MYV102\Analysis\Prod\Progs\TFLs\Tab_QOL_UFS_CON.SAS
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Table EFF.UFSSSS.MITT.Pooled.S2: Summary of Change from Baseline in UFS-QoL Symptom Severity Scale Score by Visit and Overall, by Subgroup (mITT Population)

Study: Pooled

Treatment	Study visit	n (%)[1]	Mean (SD)[1]	Change from baseline LS-mean change (SE)[2]	Difference LS-mean change [95% CI] p-value[2]	SMD Hedges' g [95% CI][2]
BMI (kg/m2) at Baseline						
< 30						
Relugolix+E2/NETA	Baseline	118 (99.2)	56.3 (23.22)	-31.59 (2.372)	-21.06	-0.91
N=119	Week 24	89 (74.8)	21.8 (22.55)		[-27.72,-14.40]	[-1.22,-0.60]
Placebo	Baseline	115 (100.0)	59.7 (19.97)	-10.54 (2.407)	<.0001	
N=115	Week 24	86 (74.8)	48.3 (22.97)			
>= 30						
Relugolix+E2/NETA	Baseline	130 (97.7)	58.9 (19.45)	-35.25 (2.352)	-21.00	-0.85
N=133	Week 24	106 (79.7)	22.5 (21.34)		[-27.42,-14.57]	[-1.12,-0.57]
Placebo	Baseline	139 (98.6)	61.2 (18.70)	-14.25 (2.260)	<.0001	
N=141	Week 24	113 (80.1)	47.4 (23.81)			
Missing						
Relugolix+E2/NETA	Baseline	1 (100.0)	81.3 (NE)	NC (NC)	NC	NC
N=1	Week 24	1 (100.0)	3.1 (NE)		[NC,NC]	[NC,NC]
Placebo	Baseline	0	NE (NE)	NC (NC)	NC	
N=0	Week 24	0	NE (NE)			

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group. Transformed score ranges from 0 to 100 based on Likert scale (Not at all, a little bit, somewhat, a great deal and a very great deal). Higher scores are indicative of greater symptom severity and lower scores indicate lower symptom severity (low score = good). For the change from baseline, negative scores indicate improvement.
[1] Summary statistics are based on observed data.
[2] LS means, LS mean differences (95% CIs), p-value and Hedges' g (95% CIs) are based on a mixed-effects model with study, treatment, visit, and a treatment-by-visit interaction as fixed effects. The multiple visits for each patient are the repeated measures as a random effect within each patient with an unstructured covariance. Hedges' g is calculated using a small sample bias correction. Interaction p-value is only produced for the Overall period. The reference group for the LS mean difference and Hedges' g is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with data; CI: Confidence interval; LS: Least squares; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; SD: Standard deviation; SE: Standard error; SMD: Standardized mean difference; UFS-QoL: Uterine Fibroid Symptom and Health-Related Quality of Life; NC: Not calculated; NE: Non-estimable.

SOURCE: \Studies\MYV\MYV102\Analysis\Prod\Progs\TFLs\Tab_QOL_UFS_CON.SAS
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Table EFF.UFSSSS.MITT.Pooled.S2: Summary of Change from Baseline in UFS-QoL Symptom Severity Scale Score by Visit and Overall, by Subgroup (mITT Population)

Study: Pooled

Treatment	Study visit	n (%)[1]	Mean (SD)[1]	Change from baseline LS-mean change (SE)[2]	Difference LS-mean change [95% CI] p-value[2]	SMD Hedges' g [95% CI][2]	Int. p-value[2]
BMI (kg/m2) at Baseline							
< 30							
Relugolix+E2/NETA	Baseline	118 (99.2)	56.3 (23.22)	-29.69 (2.159)	-21.01	-0.88	0.3340
N=119	Overall	106 (89.1)	26.4 (21.34)		[-27.05,-14.98]	[-1.16,-0.60]	
Placebo	Baseline	115 (100.0)	59.7 (19.97)	-8.67 (2.184)	<.0001		
N=115	Overall	103 (89.6)	51.0 (19.92)				
>= 30							
Relugolix+E2/NETA	Baseline	130 (97.7)	58.9 (19.45)	-31.12 (2.031)	-16.99	-0.71	
N=133	Overall	121 (91.0)	29.0 (21.52)		[-22.52,-11.45]	[-0.97,-0.45]	
Placebo	Baseline	139 (98.6)	61.2 (18.70)	-14.14 (1.950)	<.0001		
N=141	Overall	130 (92.2)	46.9 (19.68)				
Missing							
Relugolix+E2/NETA	Baseline	1 (100.0)	81.3 (NE)	NC (NC)	NC	NC	
N=1	Overall	1 (100.0)	4.7 (NE)		[NC,NC]	[NC,NC]	
Placebo	Baseline	0	NE (NE)	NC (NC)	NC		
N=0	Overall	0	NE (NE)				

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group. Transformed score ranges from 0 to 100 based on Likert scale (Not at all, a little bit, somewhat, a great deal and a very great deal). Higher scores are indicative of greater symptom severity and lower scores indicate lower symptom severity (low score = good). For the change from baseline, negative scores indicate improvement.
[1] Summary statistics are based on observed data. Mean (SD) are calculated based on the mean observed value across all post-baseline visits within each patient.
[2] LS means, LS mean differences (95% CIs), p-value and Hedges' g (95% CIs) are based on a mixed-effects model with study, treatment, visit, subgroup, treatment-by-visit interaction and a subgroup-by-treatment interaction as fixed effects. The multiple visits for each patient are the repeated measures as a random effect within each patient with an unstructured covariance. Hedges' g is calculated using a small sample bias correction. Missing subgroup levels are not included in estimation of the interaction p-value. The reference group for the LS mean difference and Hedges' g is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with data; CI: Confidence interval; int: Interaction; LS: Least squares; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; SD: Standard deviation; SE: Standard error; SMD: Standardized mean difference; UFS-QoL: Uterine Fibroid Symptom and Health-Related Quality of Life; NC: Not calculated; NE: Non-estimable.

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Table EFF.UFSSSS.MITT.Pooled.S6: Summary of Change from Baseline in UFS-QoL Symptom Severity Scale Score by Visit and Overall, by Subgroup (mITT Population)

Study: Pooled

Treatment	Study visit	n (%)[1]	Mean (SD)[1]	Change from baseline LS-mean change (SE)[2]	Difference LS-mean change [95% CI] p-value[2]	SMD Hedges' g [95% CI][2]
Geographic Region I						
North America						
Relugolix+E2/NETA	Baseline	188 (98.4)	60.0 (21.83)	-27.38 (2.003)	-15.69	-0.62
N=191	Week 12	165 (86.4)	33.1 (24.85)		[-21.21,-10.18]	[-0.83,-0.40]
Placebo	Baseline	192 (99.0)	61.4 (19.07)	-11.69 (1.962)	<.0001	
N=194	Week 12	172 (88.7)	49.3 (21.35)			
Rest of World						
Relugolix+E2/NETA	Baseline	61 (98.4)	51.0 (18.28)	-28.03 (2.417)	-19.40	-1.05
N=62	Week 12	59 (95.2)	24.0 (20.34)		[-26.18,-12.63]	[-1.44,-0.67]
Placebo	Baseline	62 (100.0)	57.9 (19.74)	-8.63 (2.419)	<.0001	
N=62	Week 12	57 (91.9)	49.3 (18.20)			

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group. Transformed score ranges from 0 to 100 based on Likert scale (Not at all, a little bit, somewhat, a great deal and a very great deal). Higher scores are indicative of greater symptom severity and lower scores indicate lower symptom severity (low score = good). For the change from baseline, negative scores indicate improvement.
[1] Summary statistics are based on observed data.
[2] LS means, LS mean differences (95% CIs), p-value and Hedges' g (95% CIs) are based on a mixed-effects model with study, treatment, visit, and a treatment-by-visit interaction as fixed effects. The multiple visits for each patient are the repeated measures as a random effect within each patient with an unstructured covariance. Hedges' g is calculated using a small sample bias correction. Interaction p-value is only produced for the Overall period. The reference group for the LS mean difference and Hedges' g is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with data; CI: Confidence interval; LS: Least squares; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; SD: Standard deviation; SE: Standard error; SMD: Standardized mean difference; UFS-QoL: Uterine Fibroid Symptom and Health-Related Quality of Life.

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Table EFF.UFSSSS.MITT.Pooled.S6: Summary of Change from Baseline in UFS-QoL Symptom Severity Scale Score by Visit and Overall, by Subgroup (mITT Population)

Study: Pooled

Treatment	Study visit	n (%)[1]	Mean (SD)[1]	Change from baseline LS-mean change (SE)[2]	Difference LS-mean change [95% CI] p-value[2]	SMD Hedges' g [95% CI][2]
Geographic Region I						
North America						
Relugolix+E2/NETA	Baseline	188 (98.4)	60.0 (21.83)	-33.76 (2.073)	-20.75	-0.81
N=191	Week 24	139 (72.8)	24.2 (22.63)		[-26.44,-15.06]	[-1.06,-0.57]
Placebo	Baseline	192 (99.0)	61.4 (19.07)	-13.01 (2.020)	<.0001	
N=194	Week 24	146 (75.3)	47.8 (24.15)			
Rest of World						
Relugolix+E2/NETA	Baseline	61 (98.4)	51.0 (18.28)	-33.71 (2.736)	-22.72	-1.10
N=62	Week 24	57 (91.9)	17.0 (19.01)		[-30.45,-14.99]	[-1.50,-0.70]
Placebo	Baseline	62 (100.0)	57.9 (19.74)	-10.99 (2.784)	<.0001	
N=62	Week 24	53 (85.5)	47.6 (21.40)			

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group. Transformed score ranges from 0 to 100 based on Likert scale (Not at all, a little bit, somewhat, a great deal and a very great deal). Higher scores are indicative of greater symptom severity and lower scores indicate lower symptom severity (low score = good). For the change from baseline, negative scores indicate improvement.
[1] Summary statistics are based on observed data.
[2] LS means, LS mean differences (95% CIs), p-value and Hedges' g (95% CIs) are based on a mixed-effects model with study, treatment, visit, and a treatment-by-visit interaction as fixed effects. The multiple visits for each patient are the repeated measures as a random effect within each patient with an unstructured covariance. Hedges' g is calculated using a small sample bias correction. Interaction p-value is only produced for the Overall period. The reference group for the LS mean difference and Hedges' g is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with data; CI: Confidence interval; LS: Least squares; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; SD: Standard deviation; SE: Standard error; SMD: Standardized mean difference; UFS-QoL: Uterine Fibroid Symptom and Health-Related Quality of Life.

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Table EFF.UFSSSS.MITT.Pooled.S6: Summary of Change from Baseline in UFS-QoL Symptom Severity Scale Score by Visit and Overall, by Subgroup (mITT Population)

Study: Pooled

Treatment	Study visit	n (%)[1]	Mean (SD)[1]	Change from baseline LS-mean change (SE)[2]	Difference LS-mean change [95% CI] p-value[2]	SMD Hedges' g [95% CI][2]	Int. p-value[2]
Geographic Region I							
North America							
Relugolix+E2/NETA	Baseline	188 (98.4)	60.0 (21.83)	-30.55 (1.736)	-18.18	-0.76	0.5357
N=191	Overall	169 (88.5)	29.9 (21.98)		[-22.95,-13.40]	[-0.98,-0.54]	
Placebo	Baseline	192 (99.0)	61.4 (19.07)	-12.37 (1.700)	<.0001		
N=194	Overall	174 (89.7)	48.8 (20.45)				
Rest of World							
Relugolix+E2/NETA	Baseline	61 (98.4)	51.0 (18.28)	-30.93 (2.887)	-21.12	-0.88	
N=62	Overall	59 (95.2)	21.4 (18.54)		[-29.15,-13.10]	[-1.25,-0.50]	
Placebo	Baseline	62 (100.0)	57.9 (19.74)	-9.81 (2.890)	<.0001		
N=62	Overall	59 (95.2)	48.3 (18.12)				

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group. Transformed score ranges from 0 to 100 based on Likert scale (Not at all, a little bit, somewhat, a great deal and a very great deal). Higher scores are indicative of greater symptom severity and lower scores indicate lower symptom severity (low score = good). For the change from baseline, negative scores indicate improvement.
[1] Summary statistics are based on observed data. Mean (SD) are calculated based on the mean observed value across all post-baseline visits within each patient.
[2] LS means, LS mean differences (95% CIs), p-value and Hedges' g (95% CIs) are based on a mixed-effects model with study, treatment, visit, subgroup, treatment-by-visit interaction and a subgroup-by-treatment interaction as fixed effects. The multiple visits for each patient are the repeated measures as a random effect within each patient with an unstructured covariance. Hedges' g is calculated using a small sample bias correction. The reference group for the LS mean difference and Hedges' g is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with data; CI: Confidence interval; int: Interaction; LS: Least squares; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; SD: Standard deviation; SE: Standard error; SMD: Standardized mean difference; UFS-QoL: Uterine Fibroid Symptom and Health-Related Quality of Life.

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Table EFF.UFSSSS.MITT.Pooled.S8: Summary of Change from Baseline in UFS-QoL Symptom Severity Scale Score by Visit and Overall, by Subgroup (mITT Population)

Study: Pooled

Treatment	Study visit	n (%)[1]	Mean (SD)[1]	Change from baseline LS-mean change (SE)[2]	Difference LS-mean change [95% CI] p-value[2]	SMD Hedges' g [95% CI][2]
Ethnicity						
Hispanic or Latino						
Relugolix+E2/NETA	Baseline	52 (100.0)	56.4 (21.76)	-27.65 (3.604)	-17.36	-0.72
N=52	Week 12	47 (90.4)	29.7 (20.14)		[-27.39,-7.32]	[-1.13,-0.31]
Placebo	Baseline	55 (100.0)	68.8 (16.99)	-10.30 (3.479)	0.0009	
N=55	Week 12	49 (89.1)	58.8 (22.72)			
Not Hispanic or Latino						
Relugolix+E2/NETA	Baseline	193 (98.0)	58.4 (20.98)	-27.82 (1.831)	-16.53	-0.69
N=197	Week 12	174 (88.3)	31.3 (25.09)		[-21.59,-11.47]	[-0.91,-0.48]
Placebo	Baseline	197 (99.0)	58.3 (19.30)	-11.29 (1.799)	<.0001	
N=199	Week 12	178 (89.4)	46.5 (19.14)			
Not reported						
Relugolix+E2/NETA	Baseline	4 (100.0)	43.0 (32.12)	NC (NC)	NC	NC
N=4	Week 12	3 (75.0)	12.5 (9.40)		[NC,NC]	[NC,NC]
Placebo	Baseline	2 (100.0)	56.3 (22.13)	NC (NC)	NC	
N=2	Week 12	2 (100.0)	65.7 (22.13)			

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group. Transformed score ranges from 0 to 100 based on Likert scale (Not at all, a little bit, somewhat, a great deal and a very great deal). Higher scores are indicative of greater symptom severity and lower scores indicate lower symptom severity (low score = good). For the change from baseline, negative scores indicate improvement.
[1] Summary statistics are based on observed data.
[2] LS means, LS mean differences (95% CIs), p-value and Hedges' g (95% CIs) are based on a mixed-effects model with study, treatment, visit, and a treatment-by-visit interaction as fixed effects. The multiple visits for each patient are the repeated measures as a random effect within each patient with an unstructured covariance. Hedges' g is calculated using a small sample bias correction. Interaction p-value is only produced for the Overall period. The reference group for the LS mean difference and Hedges' g is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with data; CI: Confidence interval; LS: Least squares; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; SD: Standard deviation; SE: Standard error; SMD: Standardized mean difference; UFS-QoL: Uterine Fibroid Symptom and Health-Related Quality of Life; NC: Not calculated.

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Table EFF.UFSSSS.MITT.Pooled.S8: Summary of Change from Baseline in UFS-QoL Symptom Severity Scale Score by Visit and Overall, by Subgroup (mITT Population)

Study: Pooled

Treatment	Study visit	n (%)[1]	Mean (SD)[1]	Change from baseline LS-mean change (SE)[2]	Difference LS-mean change [95% CI] p-value[2]	SMD Hedges' g [95% CI][2]
Ethnicity						
Hispanic or Latino						
Relugolix+E2/NETA	Baseline	52 (100.0)	56.4 (21.76)	-32.07 (4.025)	-17.09	-0.63
N=52	Week 24	44 (84.6)	24.4 (23.54)		[-28.29,-5.89]	[-1.05,-0.21]
Placebo	Baseline	55 (100.0)	68.8 (16.99)	-14.98 (3.889)	0.0032	
N=55	Week 24	46 (83.6)	53.6 (26.94)			
Not Hispanic or Latino						
Relugolix+E2/NETA	Baseline	193 (98.0)	58.4 (20.98)	-34.52 (1.852)	-22.62	-0.97
N=197	Week 24	149 (75.6)	21.7 (21.47)		[-27.74,-17.50]	[-1.21,-0.73]
Placebo	Baseline	197 (99.0)	58.3 (19.30)	-11.90 (1.824)	<.0001	
N=199	Week 24	151 (75.9)	45.8 (21.67)			
Not reported						
Relugolix+E2/NETA	Baseline	4 (100.0)	43.0 (32.12)	NC (NC)	NC	NC
N=4	Week 24	3 (75.0)	8.3 (4.79)		[NC,NC]	[NC,NC]
Placebo	Baseline	2 (100.0)	56.3 (22.13)	NC (NC)	NC	
N=2	Week 24	2 (100.0)	64.1 (50.84)			

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group. Transformed score ranges from 0 to 100 based on Likert scale (Not at all, a little bit, somewhat, a great deal and a very great deal). Higher scores are indicative of greater symptom severity and lower scores indicate lower symptom severity (low score = good). For the change from baseline, negative scores indicate improvement.
[1] Summary statistics are based on observed data.
[2] LS means, LS mean differences (95% CIs), p-value and Hedges' g (95% CIs) are based on a mixed-effects model with study, treatment, visit, and a treatment-by-visit interaction as fixed effects. The multiple visits for each patient are the repeated measures as a random effect within each patient with an unstructured covariance. Hedges' g is calculated using a small sample bias correction. Interaction p-value is only produced for the Overall period. The reference group for the LS mean difference and Hedges' g is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with data; CI: Confidence interval; LS: Least squares; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; SD: Standard deviation; SE: Standard error; SMD: Standardized mean difference; UFS-QoL: Uterine Fibroid Symptom and Health-Related Quality of Life; NC: Not calculated.

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Table EFF.UFSSSS.MITT.Pooled.S8: Summary of Change from Baseline in UFS-QoL Symptom Severity Scale Score by Visit and Overall, by Subgroup (mITT Population)

Study: Pooled

Treatment	Study visit	n (%)[1]	Mean (SD)[1]	Change from baseline LS-mean change (SE)[2]	Difference LS-mean change [95% CI] p-value[2]	SMD Hedges' g [95% CI][2]	Int. p-value[2]
Ethnicity							
Hispanic or Latino							
Relugolix+E2/NETA	Baseline	52 (100.0)	56.4 (21.76)	-29.60 (3.187)	-16.97	-0.70	0.6302
N=52	Overall	49 (94.2)	27.5 (18.57)		[-25.74,-8.20]	[-1.10,-0.30]	
Placebo	Baseline	55 (100.0)	68.8 (16.99)	-12.63 (3.110)	0.0002		
N=55	Overall	51 (92.7)	56.8 (22.60)				
Not Hispanic or Latino							
Relugolix+E2/NETA	Baseline	193 (98.0)	58.4 (20.98)	-31.10 (1.700)	-19.42	-0.81	
N=197	Overall	176 (89.3)	28.0 (22.27)		[-24.11,-14.72]	[-1.03,-0.59]	
Placebo	Baseline	197 (99.0)	58.3 (19.30)	-11.69 (1.672)	<.0001		
N=199	Overall	180 (90.5)	46.2 (18.24)				
Not reported							
Relugolix+E2/NETA	Baseline	4 (100.0)	43.0 (32.12)	NC (NC)	NC	NC	
N=4	Overall	3 (75.0)	10.4 (4.53)		[NC,NC]	[NC,NC]	
Placebo	Baseline	2 (100.0)	56.3 (22.13)	NC (NC)	NC		
N=2	Overall	2 (100.0)	64.9 (36.49)				

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group. Transformed score ranges from 0 to 100 based on Likert scale (Not at all, a little bit, somewhat, a great deal and a very great deal). Higher scores are indicative of greater symptom severity and lower scores indicate lower symptom severity (low score = good). For the change from baseline, negative scores indicate improvement.
[1] Summary statistics are based on observed data. Mean (SD) are calculated based on the mean observed value across all post-baseline visits within each patient.
[2] LS means, LS mean differences (95% CIs), p-value and Hedges' g (95% CIs) are based on a mixed-effects model with study, treatment, visit, subgroup, treatment-by-visit interaction and a subgroup-by-treatment interaction as fixed effects. The multiple visits for each patient are the repeated measures as a random effect within each patient with an unstructured covariance. Hedges' g is calculated using a small sample bias correction. Not reported subgroup levels are not included in estimation of the interaction p-value. The reference group for the LS mean difference and Hedges' g is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with data; CI: Confidence interval; int: Interaction; LS: Least squares; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; SD: Standard deviation; SE: Standard error; SMD: Standardized mean difference; UFS-QoL: Uterine Fibroid Symptom and Health-Related Quality of Life; NC: Not calculated.

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Table EFF.UFSSSS.MITT.Pooled.S1: Summary of Change from Baseline in UFS-QoL Symptom Severity Scale Score by Visit and Overall, by Subgroup (mITT Population)

Study: Pooled

Treatment	Study visit	n (%)[1]	Mean (SD)[1]	Change from baseline LS-mean change (SE)[2]	Difference LS-mean change [95% CI] p-value[2]	SMD Hedges' g [95% CI][2]
Age (years)						
< 40 years						
Relugolix+E2/NETA	Baseline	61 (98.4)	61.4 (21.28)	-27.08 (3.080)	-15.43	-0.67
N=62	Week 12	57 (91.9)	34.4 (24.27)		[-23.65,-7.21]	[-1.03,-0.31]
Placebo	Baseline	78 (100.0)	59.5 (20.12)	-11.65 (2.789)	0.0003	
N=78	Week 12	68 (87.2)	47.5 (21.19)			
>= 40 years						
Relugolix+E2/NETA	Baseline	188 (98.4)	56.6 (21.26)	-27.72 (1.896)	-17.09	-0.70
N=191	Week 12	167 (87.4)	29.4 (23.90)		[-22.40,-11.77]	[-0.93,-0.48]
Placebo	Baseline	176 (98.9)	61.0 (18.90)	-10.63 (1.926)	<.0001	
N=178	Week 12	161 (90.4)	50.0 (20.32)			

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group. Transformed score ranges from 0 to 100 based on Likert scale (Not at all, a little bit, somewhat, a great deal and a very great deal). Higher scores are indicative of greater symptom severity and lower scores indicate lower symptom severity (low score = good). For the change from baseline, negative scores indicate improvement.
[1] Summary statistics are based on observed data.
[2] LS means, LS mean differences (95% CIs), p-value and Hedges' g (95% CIs) are based on a mixed-effects model with study, treatment, visit, and a treatment-by-visit interaction as fixed effects. The multiple visits for each patient are the repeated measures as a random effect within each patient with an unstructured covariance. Hedges' g is calculated using a small sample bias correction. Interaction p-value is only produced for the Overall period. The reference group for the LS mean difference and Hedges' g is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with data; CI: Confidence interval; LS: Least squares; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; SD: Standard deviation; SE: Standard error; SMD: Standardized mean difference; UFS-QoL: Uterine Fibroid Symptom and Health-Related Quality of Life.

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Table EFF.UFSSSS.MITT.Pooled.S1: Summary of Change from Baseline in UFS-QoL Symptom Severity Scale Score by Visit and Overall, by Subgroup (mITT Population)

Study: Pooled

Treatment	Study visit	n (%)[1]	Mean (SD)[1]	Change from baseline LS-mean change (SE)[2]	Difference LS-mean change [95% CI] p-value[2]	SMD Hedges' g [95% CI][2]
Age (years)						
< 40 years						
Relugolix+E2/NETA	Baseline	61 (98.4)	61.4 (21.28)	-32.22 (3.416)	-19.50	-0.79
N=62	Week 24	47 (75.8)	28.7 (23.52)		[-28.58,-10.42]	[-1.19,-0.40]
Placebo	Baseline	78 (100.0)	59.5 (20.12)	-12.72 (3.065)	<.0001	
N=78	Week 24	58 (74.4)	45.4 (24.28)			
>= 40 years						
Relugolix+E2/NETA	Baseline	188 (98.4)	56.6 (21.26)	-34.31 (1.929)	-21.89	-0.91
N=191	Week 24	149 (78.0)	20.0 (20.92)		[-27.31,-16.46]	[-1.15,-0.66]
Placebo	Baseline	176 (98.9)	61.0 (18.90)	-12.42 (1.971)	<.0001	
N=178	Week 24	141 (79.2)	48.7 (23.04)			

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group. Transformed score ranges from 0 to 100 based on Likert scale (Not at all, a little bit, somewhat, a great deal and a very great deal). Higher scores are indicative of greater symptom severity and lower scores indicate lower symptom severity (low score = good). For the change from baseline, negative scores indicate improvement.
[1] Summary statistics are based on observed data.
[2] LS means, LS mean differences (95% CIs), p-value and Hedges' g (95% CIs) are based on a mixed-effects model with study, treatment, visit, and a treatment-by-visit interaction as fixed effects. The multiple visits for each patient are the repeated measures as a random effect within each patient with an unstructured covariance. Hedges' g is calculated using a small sample bias correction. Interaction p-value is only produced for the Overall period. The reference group for the LS mean difference and Hedges' g is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with data; CI: Confidence interval; LS: Least squares; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; SD: Standard deviation; SE: Standard error; SMD: Standardized mean difference; UFS-QoL: Uterine Fibroid Symptom and Health-Related Quality of Life.

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Table EFF.UFSSSS.MITT.Pooled.S1: Summary of Change from Baseline in UFS-QoL Symptom Severity Scale Score by Visit and Overall, by Subgroup (mITT Population)

Study: Pooled

Treatment	Study visit	n (%)[1]	Mean (SD)[1]	Change from baseline LS-mean change (SE)[2]	Difference LS-mean change [95% CI] p-value[2]	SMD Hedges' g [95% CI][2]	Int. p-value[2]
Age (years)							
< 40 years							
Relugolix+E2/NETA	Baseline	61 (98.4)	61.4 (21.28)	-29.71 (2.982)	-17.49	-0.73	0.6757
N=62	Overall	57 (91.9)	32.3 (22.15)		[-25.39,-9.59]	[-1.09,-0.36]	
Placebo	Baseline	78 (100.0)	59.5 (20.12)	-12.21 (2.697)	<.0001		
N=78	Overall	68 (87.2)	47.1 (21.38)				
>= 40 years							
Relugolix+E2/NETA	Baseline	188 (98.4)	56.6 (21.26)	-30.97 (1.716)	-19.46	-0.81	
N=191	Overall	171 (89.5)	26.2 (21.03)		[-24.27,-14.65]	[-1.03,-0.59]	
Placebo	Baseline	176 (98.9)	61.0 (18.90)	-11.51 (1.746)	<.0001		
N=178	Overall	165 (92.7)	49.4 (19.21)				

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group. Transformed score ranges from 0 to 100 based on Likert scale (Not at all, a little bit, somewhat, a great deal and a very great deal). Higher scores are indicative of greater symptom severity and lower scores indicate lower symptom severity (low score = good). For the change from baseline, negative scores indicate improvement.
[1] Summary statistics are based on observed data. Mean (SD) are calculated based on the mean observed value across all post-baseline visits within each patient.
[2] LS means, LS mean differences (95% CIs), p-value and Hedges' g (95% CIs) are based on a mixed-effects model with study, treatment, visit, subgroup, treatment-by-visit interaction and a subgroup-by-treatment interaction as fixed effects. The multiple visits for each patient are the repeated measures as a random effect within each patient with an unstructured covariance. Hedges' g is calculated using a small sample bias correction. The reference group for the LS mean difference and Hedges' g is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with data; CI: Confidence interval; int: Interaction; LS: Least squares; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; SD: Standard deviation; SE: Standard error; SMD: Standardized mean difference; UFS-QoL: Uterine Fibroid Symptom and Health-Related Quality of Life.

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Table EFF.UFSSSS.MITT.Pooled.S7: Summary of Change from Baseline in UFS-QoL Symptom Severity Scale Score by Visit and Overall, by Subgroup (mITT Population)

Study: Pooled

Treatment	Study visit	n (%)[1]	Mean (SD)[1]	Change from baseline LS-mean change (SE)[2]	Difference LS-mean change [95% CI] p-value[2]	SMD Hedges' g [95% CI][2]
Geographic Region II						
Europe						
Relugolix+E2/NETA	Baseline	40 (97.6)	49.2 (17.05)	-26.95 (3.053)	-16.93	-0.90
N=41	Week 12	39 (95.1)	23.2 (21.27)		[-25.50,-8.35]	[-1.37,-0.44]
Placebo	Baseline	42 (100.0)	53.8 (19.06)	-10.02 (3.057)	0.0002	
N=42	Week 12	39 (92.9)	44.7 (13.69)			
Rest of World (including the US)						
Relugolix+E2/NETA	Baseline	209 (98.6)	59.4 (21.70)	-27.73 (1.838)	-16.47	-0.66
N=212	Week 12	185 (87.3)	32.3 (24.34)		[-21.54,-11.40]	[-0.87,-0.45]
Placebo	Baseline	212 (99.1)	61.9 (19.06)	-11.26 (1.810)	<.0001	
N=214	Week 12	190 (88.8)	50.2 (21.62)			

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group. Transformed score ranges from 0 to 100 based on Likert scale (Not at all, a little bit, somewhat, a great deal and a very great deal). Higher scores are indicative of greater symptom severity and lower scores indicate lower symptom severity (low score = good). For the change from baseline, negative scores indicate improvement.
[1] Summary statistics are based on observed data.
[2] LS means, LS mean differences (95% CIs), p-value and Hedges' g (95% CIs) are based on a mixed-effects model with study, treatment, visit, and a treatment-by-visit interaction as fixed effects. The multiple visits for each patient are the repeated measures as a random effect within each patient with an unstructured covariance. Hedges' g is calculated using a small sample bias correction. Interaction p-value is only produced for the Overall period. The reference group for the LS mean difference and Hedges' g is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with data; CI: Confidence interval; LS: Least squares; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; SD: Standard deviation; SE: Standard error; SMD: Standardized mean difference; UFS-QoL: Uterine Fibroid Symptom and Health-Related Quality of Life.

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Table EFF.UFSSSS.MITT.Pooled.S7: Summary of Change from Baseline in UFS-QoL Symptom Severity Scale Score by Visit and Overall, by Subgroup (mITT Population)

Study: Pooled

Treatment	Study visit	n (%)[1]	Mean (SD)[1]	Change from baseline LS-mean change (SE)[2]	Difference LS-mean change [95% CI] p-value[2]	SMD Hedges' g [95% CI][2]
Geographic Region II						
Europe						
Relugolix+E2/NETA	Baseline	40 (97.6)	49.2 (17.05)	-34.55 (3.088)	-22.92	-1.22
N=41	Week 24	37 (90.2)	13.4 (15.15)		[-31.67,-14.17]	[-1.72,-0.72]
Placebo	Baseline	42 (100.0)	53.8 (19.06)	-11.63 (3.144)	<.0001	
N=42	Week 24	35 (83.3)	43.3 (15.87)			
Rest of World (including the US)						
Relugolix+E2/NETA	Baseline	209 (98.6)	59.4 (21.70)	-33.55 (1.938)	-20.74	-0.82
N=212	Week 24	159 (75.0)	24.1 (22.68)		[-26.08,-15.40]	[-1.05,-0.59]
Placebo	Baseline	212 (99.1)	61.9 (19.06)	-12.80 (1.903)	<.0001	
N=214	Week 24	164 (76.6)	48.7 (24.64)			

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group. Transformed score ranges from 0 to 100 based on Likert scale (Not at all, a little bit, somewhat, a great deal and a very great deal). Higher scores are indicative of greater symptom severity and lower scores indicate lower symptom severity (low score = good). For the change from baseline, negative scores indicate improvement.
[1] Summary statistics are based on observed data.
[2] LS means, LS mean differences (95% CIs), p-value and Hedges' g (95% CIs) are based on a mixed-effects model with study, treatment, visit, and a treatment-by-visit interaction as fixed effects. The multiple visits for each patient are the repeated measures as a random effect within each patient with an unstructured covariance. Hedges' g is calculated using a small sample bias correction. Interaction p-value is only produced for the Overall period. The reference group for the LS mean difference and Hedges' g is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with data; CI: Confidence interval; LS: Least squares; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; SD: Standard deviation; SE: Standard error; SMD: Standardized mean difference; UFS-QoL: Uterine Fibroid Symptom and Health-Related Quality of Life.

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Table EFF.UFSSSS.MITT.Pooled.S7: Summary of Change from Baseline in UFS-QoL Symptom Severity Scale Score by Visit and Overall, by Subgroup (mITT Population)

Study: Pooled

Treatment	Study visit	n (%)[1]	Mean (SD)[1]	Change from baseline LS-mean change (SE)[2]	Difference LS-mean change [95% CI] p-value[2]	SMD Hedges' g [95% CI][2]	Int. p-value[2]
Geographic Region II							
Europe							0.7457
Relugolix+E2/NETA	Baseline	40 (97.6)	49.2 (17.05)	-30.69 (3.570)	-20.42	-0.84	
N=41	Overall	39 (95.1)	19.7 (19.16)		[-30.28,-10.56]	[-1.30,-0.39]	
Placebo	Baseline	42 (100.0)	53.8 (19.06)	-10.27 (3.530)	<.0001		
N=42	Overall	40 (95.2)	44.0 (13.22)				
Rest of World (including the US)							
Relugolix+E2/NETA	Baseline	209 (98.6)	59.4 (21.70)	-30.65 (1.637)	-18.63	-0.78	
N=212	Overall	189 (89.2)	29.3 (21.55)		[-23.14,-14.11]	[-0.99,-0.57]	
Placebo	Baseline	212 (99.1)	61.9 (19.06)	-12.02 (1.613)	<.0001		
N=214	Overall	193 (90.2)	49.7 (20.86)				

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group. Transformed score ranges from 0 to 100 based on Likert scale (Not at all, a little bit, somewhat, a great deal and a very great deal). Higher scores are indicative of greater symptom severity and lower scores indicate lower symptom severity (low score = good). For the change from baseline, negative scores indicate improvement.
[1] Summary statistics are based on observed data. Mean (SD) are calculated based on the mean observed value across all post-baseline visits within each patient.
[2] LS means, LS mean differences (95% CIs), p-value and Hedges' g (95% CIs) are based on a mixed-effects model with study, treatment, visit, subgroup, treatment-by-visit interaction and a subgroup-by-treatment interaction as fixed effects. The multiple visits for each patient are the repeated measures as a random effect within each patient with an unstructured covariance. Hedges' g is calculated using a small sample bias correction. The reference group for the LS mean difference and Hedges' g is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with data; CI: Confidence interval; int: Interaction; LS: Least squares; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; SD: Standard deviation; SE: Standard error; SMD: Standardized mean difference; UFS-QoL: Uterine Fibroid Symptom and Health-Related Quality of Life.

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Table EFF.UFSSSS.MITT.Pooled.S4: Summary of Change from Baseline in UFS-QoL Symptom Severity Scale Score by Visit and Overall, by Subgroup (mITT Population)

Study: Pooled

Treatment	Study visit	n (%)[1]	Mean (SD)[1]	Change from baseline LS-mean change (SE)[2]	Difference LS-mean change [95% CI] p-value[2]	SMD Hedges' g [95% CI][2]
Maximum NRS Pain Score at Baseline						
< 4						
Relugolix+E2/NETA	Baseline	72 (98.6)	50.4 (22.70)	-24.76 (2.633)	-17.35	-0.82
N=73	Week 12	65 (89.0)	26.3 (23.89)		[-25.14,-9.57]	[-1.20,-0.44]
Placebo	Baseline	61 (98.4)	53.1 (18.11)	-7.41 (2.931)	<.0001	
N=62	Week 12	52 (83.9)	47.3 (21.58)			
>= 4						
Relugolix+E2/NETA	Baseline	174 (98.3)	61.2 (19.83)	-29.10 (2.005)	-16.74	-0.68
N=177	Week 12	156 (88.1)	32.5 (24.04)		[-22.16,-11.33]	[-0.90,-0.45]
Placebo	Baseline	189 (99.5)	62.9 (18.93)	-12.36 (1.887)	<.0001	
N=190	Week 12	174 (91.6)	49.6 (20.18)			
Missing						
Relugolix+E2/NETA	Baseline	3 (100.0)	37.5 (21.87)	NC (NC)	NC	NC
N=3	Week 12	3 (100.0)	31.3 (21.91)		[NC,NC]	[NC,NC]
Placebo	Baseline	4 (100.0)	61.8 (27.53)	NC (NC)	NC	
N=4	Week 12	3 (75.0)	66.7 (24.29)			

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group. Transformed score ranges from 0 to 100 based on Likert scale (Not at all, a little bit, somewhat, a great deal and a very great deal). Higher scores are indicative of greater symptom severity and lower scores indicate lower symptom severity (low score = good). For the change from baseline, negative scores indicate improvement.
[1] Summary statistics are based on observed data.
[2] LS means, LS mean differences (95% CIs), p-value and Hedges' g (95% CIs) are based on a mixed-effects model with study, treatment, visit, and a treatment-by-visit interaction as fixed effects. The multiple visits for each patient are the repeated measures as a random effect within each patient with an unstructured covariance. Hedges' g is calculated using a small sample bias correction. Interaction p-value is only produced for the Overall period. The reference group for the LS mean difference and Hedges' g is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with data; CI: Confidence interval; LS: Least squares; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; SD: Standard deviation; SE: Standard error; SMD: Standardized mean difference; UFS-QoL: Uterine Fibroid Symptom and Health-Related Quality of Life; NC: Not calculated.

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Table EFF.UFSSSS.MITT.Pooled.S4: Summary of Change from Baseline in UFS-QoL Symptom Severity Scale Score by Visit and Overall, by Subgroup (mITT Population)

Study: Pooled

Treatment	Study visit	n (%)[1]	Mean (SD)[1]	Change from baseline LS-mean change (SE)[2]	Difference LS-mean change [95% CI] p-value[2]	SMD Hedges' g [95% CI][2]
Maximum NRS Pain Score at Baseline						
< 4						
Relugolix+E2/NETA	Baseline	72 (98.6)	50.4 (22.70)	-29.83 (2.734)	-22.43	-1.06
N=73	Week 24	57 (78.1)	18.2 (21.16)		[-30.54,-14.33]	[-1.48,-0.65]
Placebo	Baseline	61 (98.4)	53.1 (18.11)	-7.39 (3.053)	<.0001	
N=62	Week 24	46 (74.2)	45.3 (23.10)			
>= 4						
Relugolix+E2/NETA	Baseline	174 (98.3)	61.2 (19.83)	-36.00 (2.081)	-21.71	-0.87
N=177	Week 24	136 (76.8)	23.4 (21.85)		[-27.34,-16.09]	[-1.11,-0.62]
Placebo	Baseline	189 (99.5)	62.9 (18.93)	-14.28 (1.958)	<.0001	
N=190	Week 24	151 (79.5)	48.3 (23.44)			
Missing						
Relugolix+E2/NETA	Baseline	3 (100.0)	37.5 (21.87)	NC (NC)	NC	NC
N=3	Week 24	3 (100.0)	33.3 (31.30)		[NC,NC]	[NC,NC]
Placebo	Baseline	4 (100.0)	61.8 (27.53)	NC (NC)	NC	
N=4	Week 24	2 (50.0)	64.1 (33.16)			

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group. Transformed score ranges from 0 to 100 based on Likert scale (Not at all, a little bit, somewhat, a great deal and a very great deal). Higher scores are indicative of greater symptom severity and lower scores indicate lower symptom severity (low score = good). For the change from baseline, negative scores indicate improvement.
[1] Summary statistics are based on observed data.
[2] LS means, LS mean differences (95% CIs), p-value and Hedges' g (95% CIs) are based on a mixed-effects model with study, treatment, visit, and a treatment-by-visit interaction as fixed effects. The multiple visits for each patient are the repeated measures as a random effect within each patient with an unstructured covariance. Hedges' g is calculated using a small sample bias correction. Interaction p-value is only produced for the Overall period. The reference group for the LS mean difference and Hedges' g is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with data; CI: Confidence interval; LS: Least squares; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; SD: Standard deviation; SE: Standard error; SMD: Standardized mean difference; UFS-QoL: Uterine Fibroid Symptom and Health-Related Quality of Life; NC: Not calculated.

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Table EFF.UFSSSS.MITT.Pooled.S4: Summary of Change from Baseline in UFS-QoL Symptom Severity Scale Score by Visit and Overall, by Subgroup (mITT Population)

Study: Pooled

Treatment	Study visit	n (%)[1]	Mean (SD)[1]	Change from baseline LS-mean change (SE)[2]	Difference LS-mean change [95% CI] p-value[2]	SMD Hedges' g [95% CI][2]	Int. p-value[2]
Maximum NRS Pain Score at Baseline							
< 4							
Relugolix+E2/NETA	Baseline	72 (98.6)	50.4 (22.70)	-27.43 (2.739)	-19.89	-0.83	0.8917
N=73	Overall	66 (90.4)	24.0 (22.70)		[-27.94,-11.85]	[-1.20,-0.45]	
Placebo	Baseline	61 (98.4)	53.1 (18.11)	-7.54 (3.045)	<.0001		
N=62	Overall	54 (87.1)	47.3 (20.66)				
>= 4							
Relugolix+E2/NETA	Baseline	174 (98.3)	61.2 (19.83)	-32.53 (1.773)	-19.24	-0.81	
N=177	Overall	159 (89.8)	29.1 (20.78)		[-24.03,-14.45]	[-1.03,-0.58]	
Placebo	Baseline	189 (99.5)	62.9 (18.93)	-13.29 (1.671)	<.0001		
N=190	Overall	176 (92.6)	48.9 (19.53)				
Missing							
Relugolix+E2/NETA	Baseline	3 (100.0)	37.5 (21.87)	NC (NC)	NC	NC	
N=3	Overall	3 (100.0)	32.3 (25.41)		[NC,NC]	[NC,NC]	
Placebo	Baseline	4 (100.0)	61.8 (27.53)	NC (NC)	NC		
N=4	Overall	3 (75.0)	64.6 (23.88)				

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group. Transformed score ranges from 0 to 100 based on Likert scale (Not at all, a little bit, somewhat, a great deal and a very great deal). Higher scores are indicative of greater symptom severity and lower scores indicate lower symptom severity (low score = good). For the change from baseline, negative scores indicate improvement.
[1] Summary statistics are based on observed data. Mean (SD) are calculated based on the mean observed value across all post-baseline visits within each patient.
[2] LS means, LS mean differences (95% CIs), p-value and Hedges' g (95% CIs) are based on a mixed-effects model with study, treatment, visit, subgroup, treatment-by-visit interaction and a subgroup-by-treatment interaction as fixed effects. The multiple visits for each patient are the repeated measures as a random effect within each patient with an unstructured covariance. Hedges' g is calculated using a small sample bias correction. Missing subgroup levels are not included in estimation of the interaction p-value. The reference group for the LS mean difference and Hedges' g is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with data; CI: Confidence interval; int: Interaction; LS: Least squares; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; SD: Standard deviation; SE: Standard error; SMD: Standardized mean difference; UFS-QoL: Uterine Fibroid Symptom and Health-Related Quality of Life; NC: Not calculated.

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1.2.2 Proportion of Responders with at least 25 Points Decrease in UFS-QoL Symptom Severity Scale Score at Week 24, by Subgroup (mITT Population)

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Table QOL.UFSSSS25.MITT.Pooled.S3: Proportion of Responders with at least 25 Points Decrease in UFS-QoL Symptom Severity Scale Score at Week 24, by Subgroup (mITT Population)

Study: Pooled

Treatment	N	n (%)	OR[1] [95% CI]	RR[2] [95% CI]	RD[3] [95% CI]	p-value[4]	p-value (int)[5]
Uterine Volume at Baseline (cm3)							
< 300 cm3							
Relugolix+E2/NETA	148	81 (54.7)	5.29	2.94	0.36	<.0001	0.0811
Placebo	129	24 (18.6)	[3.05;9.16]	[1.99;4.34]	[0.26;0.47]		
>= 300 cm3							
Relugolix+E2/NETA	104	49 (47.1)	2.65	1.87	0.22	0.0005	
Placebo	127	32 (25.2)	[1.52;4.61]	[1.30;2.69]	[0.10;0.34]		
Missing							
Relugolix+E2/NETA	1	0	NC	NC	NC	NC	
Placebo	0	0	[NC;NC]	[NC;NC]	[NC;NC]		

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group.
[1] OR (95% CI) based on a logistic regression model adjusting for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates.
[2] RR (95% CI) based on a Cochran-Mantel-Haenszel approach stratified by study.
[3] RD (95% CI) based on a Mantel-Haenszel approach stratified by study. 95% CIs are based on the approximation to the normal distribution using the Sato estimator for the standard error.
[4] P-value based on a Cochran-Mantel-Haenszel test stratified by study.
[5] Interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the OR (95% CI). Missing subgroup levels are not included in estimation of the interaction p-value. * Interaction p-value < 0.05.
A continuity correction is applied in estimation of the OR, RR and p-value if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum. No continuity correction is applied in the estimation of the RD.
The reference group for the OR, RR and RD is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with an event; OR: Odds ratio; RR: Risk ratio; RD: Risk difference; CI: Confidence interval; int: p-value for interaction; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; NC: Not calculated.

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Table QOL.UFSSSS25.MITT.Pooled.S5: Proportion of Responders with at least 25 Points Decrease in UFS-QoL Symptom Severity Scale Score at Week 24, by Subgroup (mITT Population)

Study: Pooled

Treatment	N	n (%)	OR[1] [95% CI]	RR[2] [95% CI]	RD[3] [95% CI]	p-value[4]	p-value (int)[5]
MBL Volume at Baseline (mL)							
< 225 mL							
Relugolix+E2/NETA	164	85 (51.8)	3.31	2.11	0.27	<.0001	0.2927
Placebo	171	42 (24.6)	[2.08;5.26]	[1.56;2.85]	[0.17;0.37]		
>= 225 mL							
Relugolix+E2/NETA	89	45 (50.6)	5.19	3.07	0.34	<.0001	
Placebo	85	14 (16.5)	[2.56;10.53]	[1.82;5.17]	[0.21;0.47]		

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group.
[1] OR (95% CI) based on a logistic regression model adjusting for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates.
[2] RR (95% CI) based on a Cochran-Mantel-Haenszel approach stratified by study.
[3] RD (95% CI) based on a Mantel-Haenszel approach stratified by study. 95% CIs are based on the approximation to the normal distribution using the Sato estimator for the standard error.
[4] P-value based on a Cochran-Mantel-Haenszel test stratified by study.
[5] Interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the OR (95% CI). Missing subgroup levels are not included in estimation of the interaction p-value. * Interaction p-value < 0.05.
A continuity correction is applied in estimation of the OR, RR and p-value if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum. No continuity correction is applied in the estimation of the RD.
The reference group for the OR, RR and RD is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with an event; OR: Odds ratio; RR: Risk ratio; RD: Risk difference; CI: Confidence interval; int: p-value for interaction; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; NC: Not calculated.

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Table QOL.UFSSSS25.MITT.Pooled.S9: Proportion of Responders with at least 25 Points Decrease in UFS-QoL Symptom Severity Scale Score at Week 24, by Subgroup (mITT Population)

Study: Pooled

Treatment	N	n (%)	OR[1] [95% CI]	RR[2] [95% CI]	RD[3] [95% CI]	p-value[4]	p-value (int)[5]
Race							
Black/African American							0.3386
Relugolix+E2/NETA	122	56 (45.9)	2.78	1.96	0.22	0.0001	
Placebo	141	33 (23.4)	[1.64;4.71]	[1.37;2.79]	[0.11;0.34]		
White							
Relugolix+E2/NETA	122	69 (56.6)	4.91	2.70	0.36	<.0001	
Placebo	105	22 (21.0)	[2.72;8.87]	[1.80;4.04]	[0.24;0.47]		
Asian							
Relugolix+E2/NETA	1	1 (100.0)	NC	NC	NC	NC	
Placebo	3	0	[NC;NC]	[NC;NC]	[NC;NC]		
Others							
Relugolix+E2/NETA	5	2 (40.0)	2.27	2.20	0.44	0.3212	
Placebo	6	1 (16.7)	[0.25;20.36]	[0.52;9.43]	[0.07;0.81]		
Not reported							
Relugolix+E2/NETA	3	2 (66.7)	NC	NC	NC	NC	
Placebo	1	0	[NC;NC]	[NC;NC]	[NC;NC]		

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group.
[1] OR (95% CI) based on a logistic regression model adjusting for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates.
[2] RR (95% CI) based on a Cochran-Mantel-Haenszel approach stratified by study.
[3] RD (95% CI) based on a Mantel-Haenszel approach stratified by study. 95% CIs are based on the approximation to the normal distribution using the Sato estimator for the standard error.
[4] P-value based on a Cochran-Mantel-Haenszel test stratified by study.
[5] Interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the OR (95% CI). Not reported subgroup levels are not included in estimation of the interaction p-value.
* Interaction p-value < 0.05.
A continuity correction is applied in estimation of the OR, RR and p-value if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum. No continuity correction is applied in the estimation of the RD.
The reference group for the OR, RR and RD is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with an event; OR: Odds ratio; RR: Risk ratio; RD: Risk difference; CI: Confidence interval; int: p-value for interaction; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; NC: Not calculated.

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Table QOL.UFSSSS25.MITT.Pooled.S1: Proportion of Responders with at least 25 Points Decrease in UFS-QoL Symptom Severity Scale Score at Week 24, by Subgroup (mITT Population)

Study: Pooled

Treatment	N	n (%)	OR[1] [95% CI]	RR[2] [95% CI]	RD[3] [95% CI]	p-value[4]	p-value (int)[5]
Age (years)							
< 40 years							
Relugolix+E2/NETA	62	30 (48.4)	2.91	1.99	0.24	0.0032	0.4053
Placebo	78	19 (24.4)	[1.42;5.97]	[1.25;3.17]	[0.08;0.40]		
>= 40 years							
Relugolix+E2/NETA	191	100 (52.4)	4.19	2.52	0.32	<.0001	
Placebo	178	37 (20.8)	[2.64;6.63]	[1.83;3.46]	[0.22;0.41]		

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group.
[1] OR (95% CI) based on a logistic regression model adjusting for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates.
[2] RR (95% CI) based on a Cochran-Mantel-Haenszel approach stratified by study.
[3] RD (95% CI) based on a Mantel-Haenszel approach stratified by study. 95% CIs are based on the approximation to the normal distribution using the Sato estimator for the standard error.
[4] P-value based on a Cochran-Mantel-Haenszel test stratified by study.
[5] Interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the OR (95% CI). Not reported subgroup levels are not included in estimation of the interaction p-value.
* Interaction p-value < 0.05.
A continuity correction is applied in estimation of the OR, RR and p-value if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum. No continuity correction is applied in the estimation of the RD.
The reference group for the OR, RR and RD is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with an event; OR: Odds ratio; RR: Risk ratio; RD: Risk difference; CI: Confidence interval; int: p-value for interaction; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; NC: Not calculated.

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Table QOL.UFSSSS25.MITT.Pooled.S2: Proportion of Responders with at least 25 Points Decrease in UFS-QoL Symptom Severity Scale Score at Week 24, by Subgroup (mITT Population)

Study: Pooled

Treatment	N	n (%)	OR[1] [95% CI]	RR[2] [95% CI]	RD[3] [95% CI]	p-value[4]	p-value (int)[5]
BMI (kg/m2) at Baseline							
< 30							
Relugolix+E2/NETA	119	61 (51.3)	4.45	2.66	0.32	<.0001	0.4485
Placebo	115	22 (19.1)	[2.47;8.01]	[1.76;4.02]	[0.21;0.44]		
>= 30							
Relugolix+E2/NETA	133	68 (51.1)	3.29	2.12	0.27	<.0001	
Placebo	141	34 (24.1)	[1.97;5.51]	[1.51;2.97]	[0.16;0.38]		
Missing							
Relugolix+E2/NETA	1	1 (100.0)	NC	NC	NC	NC	
Placebo	0	0	[NC;NC]	[NC;NC]	[NC;NC]		

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group.
[1] OR (95% CI) based on a logistic regression model adjusting for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates.
[2] RR (95% CI) based on a Cochran-Mantel-Haenszel approach stratified by study.
[3] RD (95% CI) based on a Mantel-Haenszel approach stratified by study. 95% CIs are based on the approximation to the normal distribution using the Sato estimator for the standard error.
[4] P-value based on a Cochran-Mantel-Haenszel test stratified by study.
[5] Interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the OR (95% CI). Missing subgroup levels are not included in estimation of the interaction p-value. * Interaction p-value < 0.05.
A continuity correction is applied in estimation of the OR, RR and p-value if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum. No continuity correction is applied in the estimation of the RD.
The reference group for the OR, RR and RD is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with an event; OR: Odds ratio; RR: Risk ratio; RD: Risk difference; CI: Confidence interval; int: p-value for interaction; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; NC: Not calculated.

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Table QOL.UFSSSS25.MITT.Pooled.S4: Proportion of Responders with at least 25 Points Decrease in UFS-QoL Symptom Severity Scale Score at Week 24, by Subgroup (mITT Population)

Study: Pooled

Treatment	N	n (%)	OR[1] [95% CI]	RR[2] [95% CI]	RD[3] [95% CI]	p-value[4]	p-value (int)[5]
Maximum NRS Pain Score at Baseline							
< 4							
Relugolix+E2/NETA	73	37 (50.7)	4.77	2.97	0.34	<.0001	0.4973
Placebo	62	11 (17.7)	[2.15;10.60]	[1.65;5.32]	[0.19;0.49]		
>= 4							
Relugolix+E2/NETA	177	92 (52.0)	3.49	2.20	0.28	<.0001	
Placebo	190	45 (23.7)	[2.23;5.45]	[1.64;2.95]	[0.19;0.38]		
Missing							
Relugolix+E2/NETA	3	1 (33.3)	NC	NC	NC	NC	
Placebo	4	0	[NC;NC]	[NC;NC]	[NC;NC]		

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group.
[1] OR (95% CI) based on a logistic regression model adjusting for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates.
[2] RR (95% CI) based on a Cochran-Mantel-Haenszel approach stratified by study.
[3] RD (95% CI) based on a Mantel-Haenszel approach stratified by study. 95% CIs are based on the approximation to the normal distribution using the Sato estimator for the standard error.
[4] P-value based on a Cochran-Mantel-Haenszel test stratified by study.
[5] Interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the OR (95% CI). Missing subgroup levels are not included in estimation of the interaction p-value. * Interaction p-value < 0.05.
A continuity correction is applied in estimation of the OR, RR and p-value if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum. No continuity correction is applied in the estimation of the RD.
The reference group for the OR, RR and RD is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with an event; OR: Odds ratio; RR: Risk ratio; RD: Risk difference; CI: Confidence interval; int: p-value for interaction; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; NC: Not calculated.

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Table QOL.UFSSSS25.MITT.Pooled.S8: Proportion of Responders with at least 25 Points Decrease in UFS-QoL Symptom Severity Scale Score at Week 24, by Subgroup (mITT Population)

Study: Pooled

Treatment	N	n (%)	OR[1] [95% CI]	RR[2] [95% CI]	RD[3] [95% CI]	p-value[4]	p-value (int)[5]
Ethnicity							
Hispanic or Latino							
Relugolix+E2/NETA	52	27 (51.9)	3.17	2.17	0.29	0.0032	0.6550
Placebo	55	14 (25.5)	[1.40;7.21]	[1.27;3.71]	[0.11;0.47]		
Not Hispanic or Latino							
Relugolix+E2/NETA	197	101 (51.3)	3.93	2.44	0.30	<.0001	
Placebo	199	42 (21.1)	[2.53;6.11]	[1.80;3.31]	[0.21;0.39]		
Not reported							
Relugolix+E2/NETA	4	2 (50.0)	NC	NC	NC	NC	
Placebo	2	0	[NC;NC]	[NC;NC]	[NC;NC]		

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group.
[1] OR (95% CI) based on a logistic regression model adjusting for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates.
[2] RR (95% CI) based on a Cochran-Mantel-Haenszel approach stratified by study.
[3] RD (95% CI) based on a Mantel-Haenszel approach stratified by study. 95% CIs are based on the approximation to the normal distribution using the Sato estimator for the standard error.
[4] P-value based on a Cochran-Mantel-Haenszel test stratified by study.
[5] Interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the OR (95% CI). Not reported subgroup levels are not included in estimation of the interaction p-value.
* Interaction p-value < 0.05.
A continuity correction is applied in estimation of the OR, RR and p-value if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum. No continuity correction is applied in the estimation of the RD.
The reference group for the OR, RR and RD is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with an event; OR: Odds ratio; RR: Risk ratio; RD: Risk difference; CI: Confidence interval; int: p-value for interaction; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; NC: Not calculated.

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1.2.3 Summary of Change from Baseline in UFS-QoL Bleeding and Pelvic Discomfort Scale Score by Visit and Overall, by Subgroup (mITT Population)

Table EFF.UFSBPD.MITT.Pooled.S5: Summary of Change from Baseline in UFS-QoL Bleeding and Pelvic Discomfort Scale Score by Visit and Overall, by Subgroup (mITT Population)

Study: Pooled

Treatment	Study visit	n (%)[1]	Mean (SD)[1]	Change from baseline LS-mean change (SE)[2]	Difference LS-mean change [95% CI] p-value[2]	SMD Hedges' g [95% CI][2]
MBL Volume at Baseline (mL)						
< 225 mL						
Relugolix+E2/NETA	Baseline	163 (99.4)	66.4 (19.65)	-36.93 (2.249)	-23.63	-0.87
N=164	Week 12	147 (89.6)	29.4 (27.41)		[-29.82,-17.44]	[-1.11,-0.63]
Placebo	Baseline	170 (99.4)	70.1 (21.50)	-13.30 (2.199)	<.0001	
N=171	Week 12	153 (89.5)	57.2 (24.34)			
>= 225 mL						
Relugolix+E2/NETA	Baseline	86 (96.6)	73.1 (24.17)	-43.22 (3.363)	-30.58	-1.06
N=89	Week 12	77 (86.5)	33.2 (29.70)		[-39.98,-21.18]	[-1.40,-0.72]
Placebo	Baseline	84 (98.8)	71.9 (19.18)	-12.64 (3.357)	<.0001	
N=85	Week 12	76 (89.4)	58.0 (23.67)			

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group. Transformed score ranges from 0 to 100 based on Likert scale (Not at all, a little bit, somewhat, a great deal and a very great deal). Higher scores are indicative of greater symptom severity and lower scores indicate lower symptom severity (low score = good). For the change from baseline, negative scores indicate improvement.
[1] Summary statistics are based on observed data.
[2] LS means, LS mean differences (95% CIs), p-value and Hedges' g (95% CIs) are based on a mixed-effects model with study, treatment, visit, and a treatment-by-visit interaction as fixed effects. The multiple visits for each patient are the repeated measures as a random effect within each patient with an unstructured covariance. Hedges' g is calculated using a small sample bias correction. Interaction p-value is only produced for the Overall period. The reference group for the LS mean difference and Hedges' g is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with data; CI: Confidence interval; LS: Least squares; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; SD: Standard deviation; SE: Standard error; SMD: Standardized mean difference; UFS-QoL: Uterine Fibroid Symptom and Health-Related Quality of Life.

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Table EFF.UFSBPD.MITT.Pooled.S5: Summary of Change from Baseline in UFS-QoL Bleeding and Pelvic Discomfort Scale Score by Visit and Overall, by Subgroup (mITT Population)

Study: Pooled

Treatment	Study visit	n (%)[1]	Mean (SD)[1]	Change from baseline LS-mean change (SE)[2]	Difference LS-mean change [95% CI] p-value[2]	SMD Hedges' g [95% CI][2]
MBL Volume at Baseline (mL)						
< 225 mL						
Relugolix+E2/NETA	Baseline	163 (99.4)	66.4 (19.65)	-46.99 (2.189)	-29.51	-1.17
N=164	Week 24	126 (76.8)	17.7 (22.66)		[-35.50,-23.52]	[-1.43,-0.91]
Placebo	Baseline	170 (99.4)	70.1 (21.50)	-17.48 (2.117)	<.0001	
N=171	Week 24	137 (80.1)	52.4 (25.53)			
>= 225 mL						
Relugolix+E2/NETA	Baseline	86 (96.6)	73.1 (24.17)	-49.32 (3.344)	-34.11	-1.20
N=89	Week 24	70 (78.7)	22.9 (26.38)		[-43.59,-24.64]	[-1.57,-0.83]
Placebo	Baseline	84 (98.8)	71.9 (19.18)	-15.21 (3.434)	<.0001	
N=85	Week 24	62 (72.9)	56.3 (28.58)			

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group. Transformed score ranges from 0 to 100 based on Likert scale (Not at all, a little bit, somewhat, a great deal and a very great deal). Higher scores are indicative of greater symptom severity and lower scores indicate lower symptom severity (low score = good). For the change from baseline, negative scores indicate improvement.
[1] Summary statistics are based on observed data.
[2] LS means, LS mean differences (95% CIs), p-value and Hedges' g (95% CIs) are based on a mixed-effects model with study, treatment, visit, and a treatment-by-visit interaction as fixed effects. The multiple visits for each patient are the repeated measures as a random effect within each patient with an unstructured covariance. Hedges' g is calculated using a small sample bias correction. Interaction p-value is only produced for the Overall period. The reference group for the LS mean difference and Hedges' g is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with data; CI: Confidence interval; LS: Least squares; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; SD: Standard deviation; SE: Standard error; SMD: Standardized mean difference; UFS-QoL: Uterine Fibroid Symptom and Health-Related Quality of Life.

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Table EFF.UFSBPD.MITT.Pooled.S5: Summary of Change from Baseline in UFS-QoL Bleeding and Pelvic Discomfort Scale Score by Visit and Overall, by Subgroup (mITT Population)

Study: Pooled

Treatment	Study visit	n (%)[1]	Mean (SD)[1]	Change from baseline LS-mean change (SE)[2]	Difference LS-mean change [95% CI] p-value[2]	SMD Hedges' g [95% CI][2]	Int. p-value[2]
MBL Volume at Baseline (mL)							
< 225 mL							
Relugolix+E2/NETA	Baseline	163 (99.4)	66.4 (19.65)	-41.96 (2.051)	-26.58	-0.98	0.2644
N=164	Overall	148 (90.2)	25.4 (24.03)		[-32.20,-20.95]	[-1.22,-0.74]	
Placebo	Baseline	170 (99.4)	70.1 (21.50)	-15.38 (1.995)	<.0001		
N=171	Overall	156 (91.2)	55.2 (23.08)				
>= 225 mL							
Relugolix+E2/NETA	Baseline	86 (96.6)	73.1 (24.17)	-46.09 (2.837)	-32.10	-1.18	
N=89	Overall	80 (89.9)	28.6 (25.15)		[-40.03,-24.17]	[-1.53,-0.84]	
Placebo	Baseline	84 (98.8)	71.9 (19.18)	-13.98 (2.868)	<.0001		
N=85	Overall	77 (90.6)	57.0 (23.34)				

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group. Transformed score ranges from 0 to 100 based on Likert scale (Not at all, a little bit, somewhat, a great deal and a very great deal). Higher scores are indicative of greater symptom severity and lower scores indicate lower symptom severity (low score = good). For the change from baseline, negative scores indicate improvement.
[1] Summary statistics are based on observed data. Mean (SD) are calculated based on the mean observed value across all post-baseline visits within each patient.
[2] LS means, LS mean differences (95% CIs), p-value and Hedges' g (95% CIs) are based on a mixed-effects model with study, treatment, visit, subgroup, treatment-by-visit interaction and a subgroup-by-treatment interaction as fixed effects. The multiple visits for each patient are the repeated measures as a random effect within each patient with an unstructured covariance. Hedges' g is calculated using a small sample bias correction. The reference group for the LS mean difference and Hedges' g is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with data; CI: Confidence interval; int: Interaction; LS: Least squares; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; SD: Standard deviation; SE: Standard error; SMD: Standardized mean difference; UFS-QoL: Uterine Fibroid Symptom and Health-Related Quality of Life.

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Table EFF.UFSBPD.MITT.Pooled.S8: Summary of Change from Baseline in UFS-QoL Bleeding and Pelvic Discomfort Scale Score by Visit and Overall, by Subgroup (mITT Population)

Study: Pooled

Treatment	Study visit	n (%)[1]	Mean (SD)[1]	Change from baseline LS-mean change (SE)[2]	Difference LS-mean change [95% CI] p-value[2]	SMD Hedges' g [95% CI][2]
Ethnicity						
Hispanic or Latino						
Relugolix+E2/NETA	Baseline	52 (100.0)	65.9 (22.16)	-39.63 (4.327)	-26.46	-0.91
N=52	Week 12	47 (90.4)	27.0 (25.55)		[-38.50,-14.41]	[-1.33,-0.49]
Placebo	Baseline	55 (100.0)	79.1 (18.49)	-13.17 (4.182)	<.0001	
N=55	Week 12	49 (89.1)	65.5 (27.27)			
Not Hispanic or Latino						
Relugolix+E2/NETA	Baseline	193 (98.0)	69.9 (20.88)	-39.34 (2.107)	-25.98	-0.95
N=197	Week 12	174 (88.3)	31.9 (29.03)		[-31.79,-20.16]	[-1.17,-0.73]
Placebo	Baseline	197 (99.0)	68.3 (20.87)	-13.36 (2.070)	<.0001	
N=199	Week 12	178 (89.4)	54.9 (22.49)			
Not reported						
Relugolix+E2/NETA	Baseline	4 (100.0)	50.0 (36.00)	NC (NC)	NC	NC
N=4	Week 12	3 (75.0)	16.7 (8.35)		[NC,NC]	[NC,NC]
Placebo	Baseline	2 (100.0)	75.0 (0.00)	NC (NC)	NC	
N=2	Week 12	2 (100.0)	91.7 (11.81)			

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group. Transformed score ranges from 0 to 100 based on Likert scale (Not at all, a little bit, somewhat, a great deal and a very great deal). Higher scores are indicative of greater symptom severity and lower scores indicate lower symptom severity (low score = good). For the change from baseline, negative scores indicate improvement.
[1] Summary statistics are based on observed data.
[2] LS means, LS mean differences (95% CIs), p-value and Hedges' g (95% CIs) are based on a mixed-effects model with study, treatment, visit, and a treatment-by-visit interaction as fixed effects. The multiple visits for each patient are the repeated measures as a random effect within each patient with an unstructured covariance. Hedges' g is calculated using a small sample bias correction. Interaction p-value is only produced for the Overall period. The reference group for the LS mean difference and Hedges' g is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with data; CI: Confidence interval; LS: Least squares; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; SD: Standard deviation; SE: Standard error; SMD: Standardized mean difference; UFS-QoL: Uterine Fibroid Symptom and Health-Related Quality of Life; NC: Not calculated.

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Table EFF.UFSBPD.MITT.Pooled.S8: Summary of Change from Baseline in UFS-QoL Bleeding and Pelvic Discomfort Scale Score by Visit and Overall, by Subgroup (mITT Population)

Study: Pooled

Treatment	Study visit	n (%)[1]	Mean (SD)[1]	Change from baseline LS-mean change (SE)[2]	Difference LS-mean change [95% CI] p-value[2]	SMD Hedges' g [95% CI][2]
Ethnicity						
Hispanic or Latino						
Relugolix+E2/NETA	Baseline	52 (100.0)	65.9 (22.16)	-43.92 (4.524)	-23.23	-0.77
N=52	Week 24	44 (84.6)	22.3 (26.40)		[-35.82,-10.64]	[-1.19,-0.34]
Placebo	Baseline	55 (100.0)	79.1 (18.49)	-20.69 (4.367)	0.0004	
N=55	Week 24	46 (83.6)	57.4 (31.29)			
Not Hispanic or Latino						
Relugolix+E2/NETA	Baseline	193 (98.0)	69.9 (20.88)	-49.41 (2.000)	-33.77	-1.36
N=197	Week 24	149 (75.6)	18.9 (23.61)		[-39.31,-28.24]	[-1.61,-1.11]
Placebo	Baseline	197 (99.0)	68.3 (20.87)	-15.64 (1.971)	<.0001	
N=199	Week 24	151 (75.9)	52.2 (24.75)			
Not reported						
Relugolix+E2/NETA	Baseline	4 (100.0)	50.0 (36.00)	NC (NC)	NC	NC
N=4	Week 24	3 (75.0)	11.1 (12.73)		[NC,NC]	[NC,NC]
Placebo	Baseline	2 (100.0)	75.0 (0.00)	NC (NC)	NC	
N=2	Week 24	2 (100.0)	75.0 (35.36)			

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group. Transformed score ranges from 0 to 100 based on Likert scale (Not at all, a little bit, somewhat, a great deal and a very great deal). Higher scores are indicative of greater symptom severity and lower scores indicate lower symptom severity (low score = good). For the change from baseline, negative scores indicate improvement.
[1] Summary statistics are based on observed data.
[2] LS means, LS mean differences (95% CIs), p-value and Hedges' g (95% CIs) are based on a mixed-effects model with study, treatment, visit, and a treatment-by-visit interaction as fixed effects. The multiple visits for each patient are the repeated measures as a random effect within each patient with an unstructured covariance. Hedges' g is calculated using a small sample bias correction. Interaction p-value is only produced for the Overall period. The reference group for the LS mean difference and Hedges' g is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with data; CI: Confidence interval; LS: Least squares; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; SD: Standard deviation; SE: Standard error; SMD: Standardized mean difference; UFS-QoL: Uterine Fibroid Symptom and Health-Related Quality of Life; NC: Not calculated.

SOURCE: \Studies\MYV\MYV102\Analysis\Prod\Progs\TFLs\Tab_QOL_UFS_CON.SAS
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Table EFF.UFSBPD.MITT.Pooled.S8: Summary of Change from Baseline in UFS-QoL Bleeding and Pelvic Discomfort Scale Score by Visit and Overall, by Subgroup (mITT Population)

Study: Pooled

Treatment	Study visit	n (%)[1]	Mean (SD)[1]	Change from baseline LS-mean change (SE)[2]	Difference LS-mean change [95% CI] p-value[2]	SMD Hedges' g [95% CI][2]	Int. p-value[2]
Ethnicity							
Hispanic or Latino							
Relugolix+E2/NETA	Baseline	52 (100.0)	65.9 (22.16)	-41.16 (3.555)	-23.91	-0.88	0.2959
N=52	Overall	49 (94.2)	25.0 (22.33)		[-33.70,-14.13]	[-1.29,-0.47]	
Placebo	Baseline	55 (100.0)	79.1 (18.49)	-17.24 (3.469)	<.0001		
N=55	Overall	51 (92.7)	62.1 (26.63)				
Not Hispanic or Latino							
Relugolix+E2/NETA	Baseline	193 (98.0)	69.9 (20.88)	-44.36 (1.898)	-29.84	-1.11	
N=197	Overall	176 (89.3)	27.2 (25.14)		[-35.08,-24.60]	[-1.33,-0.88]	
Placebo	Baseline	197 (99.0)	68.3 (20.87)	-14.51 (1.867)	<.0001		
N=199	Overall	180 (90.5)	53.7 (21.64)				
Not reported							
Relugolix+E2/NETA	Baseline	4 (100.0)	50.0 (36.00)	NC (NC)	NC	NC	
N=4	Overall	3 (75.0)	13.9 (9.63)		[NC,NC]	[NC,NC]	
Placebo	Baseline	2 (100.0)	75.0 (0.00)	NC (NC)	NC		
N=2	Overall	2 (100.0)	83.3 (23.58)				

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group. Transformed score ranges from 0 to 100 based on Likert scale (Not at all, a little bit, somewhat, a great deal and a very great deal). Higher scores are indicative of greater symptom severity and lower scores indicate lower symptom severity (low score = good). For the change from baseline, negative scores indicate improvement.
[1] Summary statistics are based on observed data. Mean (SD) are calculated based on the mean observed value across all post-baseline visits within each patient.
[2] LS means, LS mean differences (95% CIs), p-value and Hedges' g (95% CIs) are based on a mixed-effects model with study, treatment, visit, subgroup, treatment-by-visit interaction and a subgroup-by-treatment interaction as fixed effects. The multiple visits for each patient are the repeated measures as a random effect within each patient with an unstructured covariance. Hedges' g is calculated using a small sample bias correction. Not reported subgroup levels are not included in estimation of the interaction p-value. The reference group for the LS mean difference and Hedges' g is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with data; CI: Confidence interval; int: Interaction; LS: Least squares; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; SD: Standard deviation; SE: Standard error; SMD: Standardized mean difference; UFS-QoL: Uterine Fibroid Symptom and Health-Related Quality of Life; NC: Not calculated.

SOURCE: \Studies\MYV\MYV102\Analysis\Prod\Progs\TFLs\Tab_QOL_UFS_CON.SAS
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Table EFF.UFSBPD.MITT.Pooled.S6: Summary of Change from Baseline in UFS-QoL Bleeding and Pelvic Discomfort Scale Score by Visit and Overall, by Subgroup (mITT Population)

Study: Pooled

Treatment	Study visit	n (%)[1]	Mean (SD)[1]	Change from baseline LS-mean change (SE)[2]	Difference LS-mean change [95% CI] p-value[2]	SMD Hedges' g [95% CI][2]
Geographic Region I						
North America						
Relugolix+E2/NETA	Baseline	188 (98.4)	70.2 (22.04)	-37.36 (2.304)	-23.76	-0.81
N=191	Week 12	165 (86.4)	33.8 (29.30)		[-30.10,-17.42]	[-1.04,-0.59]
Placebo	Baseline	192 (99.0)	70.4 (21.06)	-13.60 (2.256)	<.0001	
N=194	Week 12	172 (88.7)	56.4 (25.23)			
Rest of World						
Relugolix+E2/NETA	Baseline	61 (98.4)	64.2 (19.27)	-43.52 (2.941)	-32.09	-1.44
N=62	Week 12	59 (95.2)	21.9 (22.90)		[-40.35,-23.84]	[-1.84,-1.03]
Placebo	Baseline	62 (100.0)	71.6 (19.88)	-11.43 (2.949)	<.0001	
N=62	Week 12	57 (91.9)	60.7 (20.03)			

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group. Transformed score ranges from 0 to 100 based on Likert scale (Not at all, a little bit, somewhat, a great deal and a very great deal). Higher scores are indicative of greater symptom severity and lower scores indicate lower symptom severity (low score = good). For the change from baseline, negative scores indicate improvement.
[1] Summary statistics are based on observed data.
[2] LS means, LS mean differences (95% CIs), p-value and Hedges' g (95% CIs) are based on a mixed-effects model with study, treatment, visit, and a treatment-by-visit interaction as fixed effects. The multiple visits for each patient are the repeated measures as a random effect within each patient with an unstructured covariance. Hedges' g is calculated using a small sample bias correction. Interaction p-value is only produced for the Overall period. The reference group for the LS mean difference and Hedges' g is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with data; CI: Confidence interval; LS: Least squares; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; SD: Standard deviation; SE: Standard error; SMD: Standardized mean difference; UFS-QoL: Uterine Fibroid Symptom and Health-Related Quality of Life.

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Table EFF.UFSBPD.MITT.Pooled.S6: Summary of Change from Baseline in UFS-QoL Bleeding and Pelvic Discomfort Scale Score by Visit and Overall, by Subgroup (mITT Population)

Study: Pooled

Treatment	Study visit	n (%)[1]	Mean (SD)[1]	Change from baseline LS-mean change (SE)[2]	Difference LS-mean change [95% CI] p-value[2]	SMD Hedges' g [95% CI][2]
Geographic Region I						
North America						
Relugolix+E2/NETA	Baseline	188 (98.4)	70.2 (22.04)	-47.21 (2.288)	-30.57	-1.09
N=191	Week 24	139 (72.8)	21.5 (25.16)		[-36.85,-24.29]	[-1.34,-0.84]
Placebo	Baseline	192 (99.0)	70.4 (21.06)	-16.64 (2.229)	<.0001	
N=194	Week 24	146 (75.3)	53.1 (27.44)			
Rest of World						
Relugolix+E2/NETA	Baseline	61 (98.4)	64.2 (19.27)	-49.35 (2.897)	-32.55	-1.49
N=62	Week 24	57 (91.9)	14.9 (20.82)		[-40.76,-24.34]	[-1.91,-1.07]
Placebo	Baseline	62 (100.0)	71.6 (19.88)	-16.80 (2.963)	<.0001	
N=62	Week 24	53 (85.5)	55.0 (23.93)			

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group. Transformed score ranges from 0 to 100 based on Likert scale (Not at all, a little bit, somewhat, a great deal and a very great deal). Higher scores are indicative of greater symptom severity and lower scores indicate lower symptom severity (low score = good). For the change from baseline, negative scores indicate improvement.
[1] Summary statistics are based on observed data.
[2] LS means, LS mean differences (95% CIs), p-value and Hedges' g (95% CIs) are based on a mixed-effects model with study, treatment, visit, and a treatment-by-visit interaction as fixed effects. The multiple visits for each patient are the repeated measures as a random effect within each patient with an unstructured covariance. Hedges' g is calculated using a small sample bias correction. Interaction p-value is only produced for the Overall period. The reference group for the LS mean difference and Hedges' g is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with data; CI: Confidence interval; LS: Least squares; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; SD: Standard deviation; SE: Standard error; SMD: Standardized mean difference; UFS-QoL: Uterine Fibroid Symptom and Health-Related Quality of Life.

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Table EFF.UFSBPD.MITT.Pooled.S6: Summary of Change from Baseline in UFS-QoL Bleeding and Pelvic Discomfort Scale Score by Visit and Overall, by Subgroup (mITT Population)

Study: Pooled

Treatment	Study visit	n (%)[1]	Mean (SD)[1]	Change from baseline LS-mean change (SE)[2]	Difference LS-mean change [95% CI] p-value[2]	SMD Hedges' g [95% CI][2]	Int. p-value[2]
Geographic Region I							
North America							
Relugolix+E2/NETA	Baseline	188 (98.4)	70.2 (22.04)	-42.30 (1.942)	-27.15	-1.00	0.3571
N=191	Overall	169 (88.5)	29.1 (25.50)		[-32.49,-21.81]	[-1.23,-0.78]	
Placebo	Baseline	192 (99.0)	70.4 (21.06)	-15.15 (1.901)	<.0001		
N=194	Overall	174 (89.7)	55.2 (24.13)				
Rest of World							
Relugolix+E2/NETA	Baseline	61 (98.4)	64.2 (19.27)	-46.33 (3.220)	-32.05	-1.18	
N=62	Overall	59 (95.2)	19.2 (19.42)		[-41.01,-23.08]	[-1.57,-0.79]	
Placebo	Baseline	62 (100.0)	71.6 (19.88)	-14.29 (3.229)	<.0001		
N=62	Overall	59 (95.2)	57.6 (19.97)				

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group. Transformed score ranges from 0 to 100 based on Likert scale (Not at all, a little bit, somewhat, a great deal and a very great deal). Higher scores are indicative of greater symptom severity and lower scores indicate lower symptom severity (low score = good). For the change from baseline, negative scores indicate improvement.
[1] Summary statistics are based on observed data. Mean (SD) are calculated based on the mean observed value across all post-baseline visits within each patient.
[2] LS means, LS mean differences (95% CIs), p-value and Hedges' g (95% CIs) are based on a mixed-effects model with study, treatment, visit, subgroup, treatment-by-visit interaction and a subgroup-by-treatment interaction as fixed effects. The multiple visits for each patient are the repeated measures as a random effect within each patient with an unstructured covariance. Hedges' g is calculated using a small sample bias correction. The reference group for the LS mean difference and Hedges' g is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with data; CI: Confidence interval; int: Interaction; LS: Least squares; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; SD: Standard deviation; SE: Standard error; SMD: Standardized mean difference; UFS-QoL: Uterine Fibroid Symptom and Health-Related Quality of Life.

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Table EFF.UFSBPD.MITT.Pooled.S7: Summary of Change from Baseline in UFS-QoL Bleeding and Pelvic Discomfort Scale Score by Visit and Overall, by Subgroup (mITT Population)

Study: Pooled

Treatment	Study visit	n (%)[1]	Mean (SD)[1]	Change from baseline LS-mean change (SE)[2]	Difference LS-mean change [95% CI] p-value[2]	SMD Hedges' g [95% CI][2]
Geographic Region II						
Europe						
Relugolix+E2/NETA	Baseline	40 (97.6)	64.6 (18.47)	-42.52 (3.740)	-28.81	-1.26
N=41	Week 12	39 (95.1)	23.3 (22.72)		[-39.31,-18.30]	[-1.74,-0.77]
Placebo	Baseline	42 (100.0)	69.1 (20.36)	-13.71 (3.742)	<.0001	
N=42	Week 12	39 (92.9)	57.1 (17.15)			
Rest of World (including the US)						
Relugolix+E2/NETA	Baseline	209 (98.6)	69.5 (21.99)	-38.34 (2.123)	-25.15	-0.88
N=212	Week 12	185 (87.3)	32.3 (29.05)		[-31.01,-19.29]	[-1.09,-0.67]
Placebo	Baseline	212 (99.1)	71.0 (20.85)	-13.19 (2.092)	<.0001	
N=214	Week 12	190 (88.8)	57.5 (25.29)			

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group. Transformed score ranges from 0 to 100 based on Likert scale (Not at all, a little bit, somewhat, a great deal and a very great deal). Higher scores are indicative of greater symptom severity and lower scores indicate lower symptom severity (low score = good). For the change from baseline, negative scores indicate improvement.
[1] Summary statistics are based on observed data.
[2] LS means, LS mean differences (95% CIs), p-value and Hedges' g (95% CIs) are based on a mixed-effects model with study, treatment, visit, and a treatment-by-visit interaction as fixed effects. The multiple visits for each patient are the repeated measures as a random effect within each patient with an unstructured covariance. Hedges' g is calculated using a small sample bias correction. Interaction p-value is only produced for the Overall period. The reference group for the LS mean difference and Hedges' g is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with data; CI: Confidence interval; LS: Least squares; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; SD: Standard deviation; SE: Standard error; SMD: Standardized mean difference; UFS-QoL: Uterine Fibroid Symptom and Health-Related Quality of Life.

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Table EFF.UFSBPD.MITT.Pooled.S7: Summary of Change from Baseline in UFS-QoL Bleeding and Pelvic Discomfort Scale Score by Visit and Overall, by Subgroup (mITT Population)

Study: Pooled

Treatment	Study visit	n (%)[1]	Mean (SD)[1]	Change from baseline LS-mean change (SE)[2]	Difference LS-mean change [95% CI] p-value[2]	SMD Hedges' g [95% CI][2]
Geographic Region II						
Europe						
Relugolix+E2/NETA	Baseline	40 (97.6)	64.6 (18.47)	-53.16 (3.581)	-34.76	-1.60
N=41	Week 24	37 (90.2)	10.8 (16.77)		[-44.93,-24.58]	[-2.12,-1.07]
Placebo	Baseline	42 (100.0)	69.1 (20.36)	-18.40 (3.664)	<.0001	
N=42	Week 24	35 (83.3)	52.1 (19.11)			
Rest of World (including the US)						
Relugolix+E2/NETA	Baseline	209 (98.6)	69.5 (21.99)	-46.55 (2.101)	-29.92	-1.10
N=212	Week 24	159 (75.0)	21.6 (25.13)		[-35.71,-24.13]	[-1.34,-0.87]
Placebo	Baseline	212 (99.1)	71.0 (20.85)	-16.63 (2.062)	<.0001	
N=214	Week 24	164 (76.6)	54.0 (27.87)			

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group. Transformed score ranges from 0 to 100 based on Likert scale (Not at all, a little bit, somewhat, a great deal and a very great deal). Higher scores are indicative of greater symptom severity and lower scores indicate lower symptom severity (low score = good). For the change from baseline, negative scores indicate improvement.
[1] Summary statistics are based on observed data.
[2] LS means, LS mean differences (95% CIs), p-value and Hedges' g (95% CIs) are based on a mixed-effects model with study, treatment, visit, and a treatment-by-visit interaction as fixed effects. The multiple visits for each patient are the repeated measures as a random effect within each patient with an unstructured covariance. Hedges' g is calculated using a small sample bias correction. Interaction p-value is only produced for the Overall period. The reference group for the LS mean difference and Hedges' g is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with data; CI: Confidence interval; LS: Least squares; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; SD: Standard deviation; SE: Standard error; SMD: Standardized mean difference; UFS-QoL: Uterine Fibroid Symptom and Health-Related Quality of Life.

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Table EFF.UFSBPD.MITT.Pooled.S7: Summary of Change from Baseline in UFS-QoL Bleeding and Pelvic Discomfort Scale Score by Visit and Overall, by Subgroup (mITT Population)

Study: Pooled

Treatment	Study visit	n (%)[1]	Mean (SD)[1]	Change from baseline LS-mean change (SE)[2]	Difference LS-mean change [95% CI] p-value[2]	SMD Hedges' g [95% CI][2]	Int. p-value[2]
Geographic Region II							
Europe							
Relugolix+E2/NETA	Baseline	40 (97.6)	64.6 (18.47)	-47.88 (3.978)	-32.75	-1.20	0.3977
N=41	Overall	39 (95.1)	18.4 (19.54)		[-43.76,-21.75]	[-1.68,-0.72]	
Placebo	Baseline	42 (100.0)	69.1 (20.36)	-15.12 (3.945)	<.0001		
N=42	Overall	40 (95.2)	54.3 (16.25)				
Rest of World (including the US)							
Relugolix+E2/NETA	Baseline	209 (98.6)	69.5 (21.99)	-42.43 (1.829)	-27.54	-1.02	
N=212	Overall	189 (89.2)	28.2 (25.03)		[-32.58,-22.49]	[-1.23,-0.81]	
Placebo	Baseline	212 (99.1)	71.0 (20.85)	-14.89 (1.802)	<.0001		
N=214	Overall	193 (90.2)	56.2 (24.34)				

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group. Transformed score ranges from 0 to 100 based on Likert scale (Not at all, a little bit, somewhat, a great deal and a very great deal). Higher scores are indicative of greater symptom severity and lower scores indicate lower symptom severity (low score = good). For the change from baseline, negative scores indicate improvement.
[1] Summary statistics are based on observed data. Mean (SD) are calculated based on the mean observed value across all post-baseline visits within each patient.
[2] LS means, LS mean differences (95% CIs), p-value and Hedges' g (95% CIs) are based on a mixed-effects model with study, treatment, visit, subgroup, treatment-by-visit interaction and a subgroup-by-treatment interaction as fixed effects. The multiple visits for each patient are the repeated measures as a random effect within each patient with an unstructured covariance. Hedges' g is calculated using a small sample bias correction. The reference group for the LS mean difference and Hedges' g is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with data; CI: Confidence interval; int: Interaction; LS: Least squares; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; SD: Standard deviation; SE: Standard error; SMD: Standardized mean difference; UFS-QoL: Uterine Fibroid Symptom and Health-Related Quality of Life.

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Table EFF.UFSBPD.MITT.Pooled.S2: Summary of Change from Baseline in UFS-QoL Bleeding and Pelvic Discomfort Scale Score by Visit and Overall, by Subgroup (mITT Population)

Study: Pooled

Treatment	Study visit	n (%)[1]	Mean (SD)[1]	Change from baseline LS-mean change (SE)[2]	Difference LS-mean change [95% CI] p-value[2]	SMD Hedges' g [95% CI][2]
BMI (kg/m2) at Baseline						
< 30						
Relugolix+E2/NETA	Baseline	118 (99.2)	67.0 (23.48)	-39.40 (2.491)	-28.68	-1.14
N=119	Week 12	104 (87.4)	27.5 (26.86)		[-35.67,-21.69]	[-1.43,-0.84]
Placebo	Baseline	115 (100.0)	69.8 (21.81)	-10.72 (2.524)	<.0001	
N=115	Week 12	100 (87.0)	59.6 (24.29)			
>= 30						
Relugolix+E2/NETA	Baseline	130 (97.7)	70.1 (19.51)	-38.21 (2.754)	-23.07	-0.78
N=133	Week 12	119 (89.5)	33.7 (29.11)		[-30.59,-15.56]	[-1.04,-0.52]
Placebo	Baseline	139 (98.6)	71.5 (19.86)	-15.13 (2.640)	<.0001	
N=141	Week 12	129 (91.5)	55.8 (23.86)			
Missing						
Relugolix+E2/NETA	Baseline	1 (100.0)	91.7 (NE)	NC (NC)	NC	NC
N=1	Week 12	1 (100.0)	0.0 (NE)		[NC,NC]	[NC,NC]
Placebo	Baseline	0	NE (NE)	NC (NC)	NC	
N=0	Week 12	0	NE (NE)			

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group. Transformed score ranges from 0 to 100 based on Likert scale (Not at all, a little bit, somewhat, a great deal and a very great deal). Higher scores are indicative of greater symptom severity and lower scores indicate lower symptom severity (low score = good). For the change from baseline, negative scores indicate improvement.
[1] Summary statistics are based on observed data.
[2] LS means, LS mean differences (95% CIs), p-value and Hedges' g (95% CIs) are based on a mixed-effects model with study, treatment, visit, and a treatment-by-visit interaction as fixed effects. The multiple visits for each patient are the repeated measures as a random effect within each patient with an unstructured covariance. Hedges' g is calculated using a small sample bias correction. Interaction p-value is only produced for the Overall period. The reference group for the LS mean difference and Hedges' g is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with data; CI: Confidence interval; LS: Least squares; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; SD: Standard deviation; SE: Standard error; SMD: Standardized mean difference; UFS-QoL: Uterine Fibroid Symptom and Health-Related Quality of Life; NC: Not calculated; NE: Non-estimable.

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Table EFF.UFSBPD.MITT.Pooled.S2: Summary of Change from Baseline in UFS-QoL Bleeding and Pelvic Discomfort Scale Score by Visit and Overall, by Subgroup (mITT Population)

Study: Pooled

Treatment	Study visit	n (%)[1]	Mean (SD)[1]	Change from baseline LS-mean change (SE)[2]	Difference LS-mean change [95% CI] p-value[2]	SMD Hedges' g [95% CI][2]
BMI (kg/m2) at Baseline						
< 30						
Relugolix+E2/NETA	Baseline	118 (99.2)	67.0 (23.48)	-46.21 (2.636)	-31.79	-1.24
N=119	Week 24	89 (74.8)	19.0 (23.57)		[-39.20,-24.38]	[-1.57,-0.92]
Placebo	Baseline	115 (100.0)	69.8 (21.81)	-14.42 (2.676)	<.0001	
N=115	Week 24	86 (74.8)	54.4 (27.38)			
>= 30						
Relugolix+E2/NETA	Baseline	130 (97.7)	70.1 (19.51)	-48.73 (2.547)	-29.97	-1.13
N=133	Week 24	106 (79.7)	20.2 (24.70)		[-36.92,-23.01]	[-1.41,-0.84]
Placebo	Baseline	139 (98.6)	71.5 (19.86)	-18.76 (2.447)	<.0001	
N=141	Week 24	113 (80.1)	53.1 (25.93)			
Missing						
Relugolix+E2/NETA	Baseline	1 (100.0)	91.7 (NE)	NC (NC)	NC	NC
N=1	Week 24	1 (100.0)	0.0 (NE)		[NC,NC]	[NC,NC]
Placebo	Baseline	0	NE (NE)	NC (NC)	NC	
N=0	Week 24	0	NE (NE)			

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group. Transformed score ranges from 0 to 100 based on Likert scale (Not at all, a little bit, somewhat, a great deal and a very great deal). Higher scores are indicative of greater symptom severity and lower scores indicate lower symptom severity (low score = good). For the change from baseline, negative scores indicate improvement.
[1] Summary statistics are based on observed data.
[2] LS means, LS mean differences (95% CIs), p-value and Hedges' g (95% CIs) are based on a mixed-effects model with study, treatment, visit, and a treatment-by-visit interaction as fixed effects. The multiple visits for each patient are the repeated measures as a random effect within each patient with an unstructured covariance. Hedges' g is calculated using a small sample bias correction. Interaction p-value is only produced for the Overall period. The reference group for the LS mean difference and Hedges' g is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with data; CI: Confidence interval; LS: Least squares; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; SD: Standard deviation; SE: Standard error; SMD: Standardized mean difference; UFS-QoL: Uterine Fibroid Symptom and Health-Related Quality of Life; NC: Not calculated; NE: Non-estimable.

SOURCE: \Studies\MYV\MYV102\Analysis\Prod\Progs\TFLs\Tab_QOL_UFS_CON.SAS
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Table EFF.UFSBPD.MITT.Pooled.S2: Summary of Change from Baseline in UFS-QoL Bleeding and Pelvic Discomfort Scale Score by Visit and Overall, by Subgroup (mITT Population)

Study: Pooled

Treatment	Study visit	n (%)[1]	Mean (SD)[1]	Change from baseline LS-mean change (SE)[2]	Difference LS-mean change [95% CI] p-value[2]	SMD Hedges' g [95% CI][2]	Int. p-value[2]
BMI (kg/m2) at Baseline							
< 30							
Relugolix+E2/NETA	Baseline	118 (99.2)	67.0 (23.48)	-42.76 (2.423)	-30.23	-1.12	0.4472
N=119	Overall	106 (89.1)	24.6 (24.11)		[-37.01,-23.46]	[-1.41,-0.83]	
Placebo	Baseline	115 (100.0)	69.8 (21.81)	-12.53 (2.452)	<.0001		
N=115	Overall	103 (89.6)	57.9 (23.89)				
>= 30							
Relugolix+E2/NETA	Baseline	130 (97.7)	70.1 (19.51)	-43.51 (2.279)	-26.68	-0.99	
N=133	Overall	121 (91.0)	28.4 (24.64)		[-32.89,-20.47]	[-1.25,-0.73]	
Placebo	Baseline	139 (98.6)	71.5 (19.86)	-16.83 (2.188)	<.0001		
N=141	Overall	130 (92.2)	54.2 (22.48)				
Missing							
Relugolix+E2/NETA	Baseline	1 (100.0)	91.7 (NE)	NC (NC)	NC	NC	
N=1	Overall	1 (100.0)	0.0 (NE)		[NC,NC]	[NC,NC]	
Placebo	Baseline	0	NE (NE)	NC (NC)	NC		
N=0	Overall	0	NE (NE)				

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group. Transformed score ranges from 0 to 100 based on Likert scale (Not at all, a little bit, somewhat, a great deal and a very great deal). Higher scores are indicative of greater symptom severity and lower scores indicate lower symptom severity (low score = good). For the change from baseline, negative scores indicate improvement.
[1] Summary statistics are based on observed data. Mean (SD) are calculated based on the mean observed value across all post-baseline visits within each patient.
[2] LS means, LS mean differences (95% CIs), p-value and Hedges' g (95% CIs) are based on a mixed-effects model with study, treatment, visit, subgroup, treatment-by-visit interaction and a subgroup-by-treatment interaction as fixed effects. The multiple visits for each patient are the repeated measures as a random effect within each patient with an unstructured covariance. Hedges' g is calculated using a small sample bias correction. Missing subgroup levels are not included in estimation of the interaction p-value. The reference group for the LS mean difference and Hedges' g is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with data; CI: Confidence interval; int: Interaction; LS: Least squares; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; SD: Standard deviation; SE: Standard error; SMD: Standardized mean difference; UFS-QoL: Uterine Fibroid Symptom and Health-Related Quality of Life; NC: Not calculated; NE: Non-estimable.

SOURCE: \Studies\MYV\MYV102\Analysis\Prod\Progs\TFLs\Tab_QOL_UFS_CON.SAS
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Table EFF.UFSBPD.MITT.Pooled.S1: Summary of Change from Baseline in UFS-QoL Bleeding and Pelvic Discomfort Scale Score by Visit and Overall, by Subgroup (mITT Population)

Study: Pooled

Treatment	Study visit	n (%)[1]	Mean (SD)[1]	Change from baseline LS-mean change (SE)[2]	Difference LS-mean change [95% CI] p-value[2]	SMD Hedges' g [95% CI][2]
Age (years)						
< 40 years						
Relugolix+E2/NETA	Baseline	61 (98.4)	71.3 (21.17)	-38.34 (3.551)	-25.36	-0.96
N=62	Week 12	57 (91.9)	34.2 (29.16)		[-34.84,-15.88]	[-1.33,-0.59]
Placebo	Baseline	78 (100.0)	70.7 (21.35)	-12.98 (3.216)	<.0001	
N=78	Week 12	68 (87.2)	57.5 (25.27)			
>= 40 years						
Relugolix+E2/NETA	Baseline	188 (98.4)	67.9 (21.61)	-39.23 (2.215)	-26.07	-0.92
N=191	Week 12	167 (87.4)	29.5 (27.87)		[-32.28,-19.86]	[-1.15,-0.69]
Placebo	Baseline	176 (98.9)	70.7 (20.53)	-13.16 (2.251)	<.0001	
N=178	Week 12	161 (90.4)	57.5 (23.62)			

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group. Transformed score ranges from 0 to 100 based on Likert scale (Not at all, a little bit, somewhat, a great deal and a very great deal). Higher scores are indicative of greater symptom severity and lower scores indicate lower symptom severity (low score = good). For the change from baseline, negative scores indicate improvement.
[1] Summary statistics are based on observed data.
[2] LS means, LS mean differences (95% CIs), p-value and Hedges' g (95% CIs) are based on a mixed-effects model with study, treatment, visit, and a treatment-by-visit interaction as fixed effects. The multiple visits for each patient are the repeated measures as a random effect within each patient with an unstructured covariance. Hedges' g is calculated using a small sample bias correction. Interaction p-value is only produced for the Overall period. The reference group for the LS mean difference and Hedges' g is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with data; CI: Confidence interval; LS: Least squares; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; SD: Standard deviation; SE: Standard error; SMD: Standardized mean difference; UFS-QoL: Uterine Fibroid Symptom and Health-Related Quality of Life.

SOURCE: \Studies\MYV\MYV102\Analysis\Prod\Progs\TFLs\Tab_QOL_UFS_CON.SAS
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Table EFF.UFSBPD.MITT.Pooled.S1: Summary of Change from Baseline in UFS-QoL Bleeding and Pelvic Discomfort Scale Score by Visit and Overall, by Subgroup (mITT Population)

Study: Pooled

Treatment	Study visit	n (%)[1]	Mean (SD)[1]	Change from baseline LS-mean change (SE)[2]	Difference LS-mean change [95% CI] p-value[2]	SMD Hedges' g [95% CI][2]
Age (years)						
< 40 years						
Relugolix+E2/NETA	Baseline	61 (98.4)	71.3 (21.17)	-42.93 (3.741)	-26.47	-1.00
N=62	Week 24	47 (75.8)	28.5 (27.41)		[-36.41,-16.53]	[-1.41,-0.59]
Placebo	Baseline	78 (100.0)	70.7 (21.35)	-16.46 (3.350)	<.0001	
N=78	Week 24	58 (74.4)	52.6 (28.15)			
>= 40 years						
Relugolix+E2/NETA	Baseline	188 (98.4)	67.9 (21.61)	-49.34 (2.105)	-32.42	-1.24
N=191	Week 24	149 (78.0)	16.7 (22.34)		[-38.34,-26.50]	[-1.49,-0.99]
Placebo	Baseline	176 (98.9)	70.7 (20.53)	-16.92 (2.151)	<.0001	
N=178	Week 24	141 (79.2)	54.1 (25.89)			

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group. Transformed score ranges from 0 to 100 based on Likert scale (Not at all, a little bit, somewhat, a great deal and a very great deal). Higher scores are indicative of greater symptom severity and lower scores indicate lower symptom severity (low score = good). For the change from baseline, negative scores indicate improvement.
[1] Summary statistics are based on observed data.
[2] LS means, LS mean differences (95% CIs), p-value and Hedges' g (95% CIs) are based on a mixed-effects model with study, treatment, visit, and a treatment-by-visit interaction as fixed effects. The multiple visits for each patient are the repeated measures as a random effect within each patient with an unstructured covariance. Hedges' g is calculated using a small sample bias correction. Interaction p-value is only produced for the Overall period. The reference group for the LS mean difference and Hedges' g is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with data; CI: Confidence interval; LS: Least squares; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; SD: Standard deviation; SE: Standard error; SMD: Standardized mean difference; UFS-QoL: Uterine Fibroid Symptom and Health-Related Quality of Life.

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Table EFF.UFSBPD.MITT.Pooled.S1: Summary of Change from Baseline in UFS-QoL Bleeding and Pelvic Discomfort Scale Score by Visit and Overall, by Subgroup (mITT Population)

Study: Pooled

Treatment	Study visit	n (%)[1]	Mean (SD)[1]	Change from baseline LS-mean change (SE)[2]	Difference LS-mean change [95% CI] p-value[2]	SMD Hedges' g [95% CI][2]	Int. p-value[2]
Age (years)							
< 40 years							
Relugolix+E2/NETA	Baseline	61 (98.4)	71.3 (21.17)	-40.54 (3.339)	-25.86	-0.95	0.5154
N=62	Overall	57 (91.9)	32.2 (26.02)		[-34.70,-17.01]	[-1.32,-0.58]	
Placebo	Baseline	78 (100.0)	70.7 (21.35)	-14.68 (3.017)	<.0001		
N=78	Overall	68 (87.2)	55.9 (25.21)				
>= 40 years							
Relugolix+E2/NETA	Baseline	188 (98.4)	67.9 (21.61)	-44.31 (1.918)	-29.28	-1.08	
N=191	Overall	171 (89.5)	24.6 (23.65)		[-34.66,-23.91]	[-1.31,-0.85]	
Placebo	Baseline	176 (98.9)	70.7 (20.53)	-15.03 (1.952)	<.0001		
N=178	Overall	165 (92.7)	55.8 (22.30)				

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group. Transformed score ranges from 0 to 100 based on Likert scale (Not at all, a little bit, somewhat, a great deal and a very great deal). Higher scores are indicative of greater symptom severity and lower scores indicate lower symptom severity (low score = good). For the change from baseline, negative scores indicate improvement.
[1] Summary statistics are based on observed data. Mean (SD) are calculated based on the mean observed value across all post-baseline visits within each patient.
[2] LS means, LS mean differences (95% CIs), p-value and Hedges' g (95% CIs) are based on a mixed-effects model with study, treatment, visit, subgroup, treatment-by-visit interaction and a subgroup-by-treatment interaction as fixed effects. The multiple visits for each patient are the repeated measures as a random effect within each patient with an unstructured covariance. Hedges' g is calculated using a small sample bias correction. The reference group for the LS mean difference and Hedges' g is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with data; CI: Confidence interval; int: Interaction; LS: Least squares; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; SD: Standard deviation; SE: Standard error; SMD: Standardized mean difference; UFS-QoL: Uterine Fibroid Symptom and Health-Related Quality of Life.

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Table EFF.UFSBPD.MITT.Pooled.S4: Summary of Change from Baseline in UFS-QoL Bleeding and Pelvic Discomfort Scale Score by Visit and Overall, by Subgroup (mITT Population)

Study: Pooled

Treatment	Study visit	n (%)[1]	Mean (SD)[1]	Change from baseline LS-mean change (SE)[2]	Difference LS-mean change [95% CI] p-value[2]	SMD Hedges' g [95% CI][2]
Maximum NRS Pain Score at Baseline						
< 4						
Relugolix+E2/NETA	Baseline	72 (98.6)	60.5 (23.24)	-35.91 (3.323)	-24.63	-0.93
N=73	Week 12	65 (89.0)	25.5 (26.39)		[-34.46,-14.80]	[-1.32,-0.55]
Placebo	Baseline	61 (98.4)	62.6 (20.95)	-11.28 (3.701)	<.0001	
N=62	Week 12	52 (83.9)	53.8 (23.42)			
>= 4						
Relugolix+E2/NETA	Baseline	174 (98.3)	72.4 (19.58)	-40.83 (2.283)	-26.81	-0.95
N=177	Week 12	156 (88.1)	32.6 (28.78)		[-32.98,-20.64]	[-1.18,-0.72]
Placebo	Baseline	189 (99.5)	73.4 (20.03)	-14.02 (2.149)	<.0001	
N=190	Week 12	174 (91.6)	58.2 (24.18)			
Missing						
Relugolix+E2/NETA	Baseline	3 (100.0)	50.0 (30.02)	NC (NC)	NC	NC
N=3	Week 12	3 (100.0)	41.7 (30.08)		[NC,NC]	[NC,NC]
Placebo	Baseline	4 (100.0)	68.8 (23.94)	NC (NC)	NC	
N=4	Week 12	3 (75.0)	75.0 (25.00)			

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group. Transformed score ranges from 0 to 100 based on Likert scale (Not at all, a little bit, somewhat, a great deal and a very great deal). Higher scores are indicative of greater symptom severity and lower scores indicate lower symptom severity (low score = good). For the change from baseline, negative scores indicate improvement.
[1] Summary statistics are based on observed data.
[2] LS means, LS mean differences (95% CIs), p-value and Hedges' g (95% CIs) are based on a mixed-effects model with study, treatment, visit, and a treatment-by-visit interaction as fixed effects. The multiple visits for each patient are the repeated measures as a random effect within each patient with an unstructured covariance. Hedges' g is calculated using a small sample bias correction. Interaction p-value is only produced for the Overall period. The reference group for the LS mean difference and Hedges' g is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with data; CI: Confidence interval; LS: Least squares; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; SD: Standard deviation; SE: Standard error; SMD: Standardized mean difference; UFS-QoL: Uterine Fibroid Symptom and Health-Related Quality of Life; NC: Not calculated.

SOURCE: \Studies\MYV\MYV102\Analysis\Prod\Progs\TFLs\Tab_QOL_UFS_CON.SAS
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Table EFF.UFSBPD.MITT.Pooled.S4: Summary of Change from Baseline in UFS-QoL Bleeding and Pelvic Discomfort Scale Score by Visit and Overall, by Subgroup (mITT Population)

Study: Pooled

Treatment	Study visit	n (%)[1]	Mean (SD)[1]	Change from baseline LS-mean change (SE)[2]	Difference LS-mean change [95% CI] p-value[2]	SMD Hedges' g [95% CI][2]
Maximum NRS Pain Score at Baseline						
< 4						
Relugolix+E2/NETA	Baseline	72 (98.6)	60.5 (23.24)	-41.65 (3.299)	-28.61	-1.12
N=73	Week 24	57 (78.1)	16.7 (24.09)		[-38.40,-18.83]	[-1.54,-0.70]
Placebo	Baseline	61 (98.4)	62.6 (20.95)	-13.04 (3.685)	<.0001	
N=62	Week 24	46 (74.2)	49.4 (26.32)			
>= 4						
Relugolix+E2/NETA	Baseline	174 (98.3)	72.4 (19.58)	-50.94 (2.198)	-32.79	-1.25
N=177	Week 24	136 (76.8)	20.5 (23.96)		[-38.73,-26.86]	[-1.51,-1.00]
Placebo	Baseline	189 (99.5)	73.4 (20.03)	-18.15 (2.067)	<.0001	
N=190	Week 24	151 (79.5)	54.7 (26.59)			
Missing						
Relugolix+E2/NETA	Baseline	3 (100.0)	50.0 (30.02)	NC (NC)	NC	NC
N=3	Week 24	3 (100.0)	33.3 (33.35)		[NC,NC]	[NC,NC]
Placebo	Baseline	4 (100.0)	68.8 (23.94)	NC (NC)	NC	
N=4	Week 24	2 (50.0)	70.8 (17.68)			

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group. Transformed score ranges from 0 to 100 based on Likert scale (Not at all, a little bit, somewhat, a great deal and a very great deal). Higher scores are indicative of greater symptom severity and lower scores indicate lower symptom severity (low score = good). For the change from baseline, negative scores indicate improvement.
[1] Summary statistics are based on observed data.
[2] LS means, LS mean differences (95% CIs), p-value and Hedges' g (95% CIs) are based on a mixed-effects model with study, treatment, visit, and a treatment-by-visit interaction as fixed effects. The multiple visits for each patient are the repeated measures as a random effect within each patient with an unstructured covariance. Hedges' g is calculated using a small sample bias correction. Interaction p-value is only produced for the Overall period. The reference group for the LS mean difference and Hedges' g is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with data; CI: Confidence interval; LS: Least squares; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; SD: Standard deviation; SE: Standard error; SMD: Standardized mean difference; UFS-QoL: Uterine Fibroid Symptom and Health-Related Quality of Life; NC: Not calculated.

SOURCE: \Studies\MYV\MYV102\Analysis\Prod\Progs\TFLs\Tab_QOL_UFS_CON.SAS
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Table EFF.UFSBPD.MITT.Pooled.S4: Summary of Change from Baseline in UFS-QoL Bleeding and Pelvic Discomfort Scale Score by Visit and Overall, by Subgroup (mITT Population)

Study: Pooled

Treatment	Study visit	n (%)[1]	Mean (SD)[1]	Change from baseline LS-mean change (SE)[2]	Difference LS-mean change [95% CI] p-value[2]	SMD Hedges' g [95% CI][2]	Int. p-value[2]
Maximum NRS Pain Score at Baseline							
< 4							
Relugolix+E2/NETA	Baseline	72 (98.6)	60.5 (23.24)	-38.75 (3.058)	-26.58	-0.99	0.5391
N=73	Overall	66 (90.4)	22.7 (24.65)		[-35.57,-17.59]	[-1.37,-0.60]	
Placebo	Baseline	61 (98.4)	62.6 (20.95)	-12.17 (3.402)	<.0001		
N=62	Overall	54 (87.1)	52.6 (22.52)				
>= 4							
Relugolix+E2/NETA	Baseline	174 (98.3)	72.4 (19.58)	-45.94 (1.980)	-29.85	-1.11	
N=177	Overall	159 (89.8)	27.9 (24.26)		[-35.20,-24.50]	[-1.34,-0.88]	
Placebo	Baseline	189 (99.5)	73.4 (20.03)	-16.09 (1.866)	<.0001		
N=190	Overall	176 (92.6)	56.5 (23.29)				
Missing							
Relugolix+E2/NETA	Baseline	3 (100.0)	50.0 (30.02)	NC (NC)	NC	NC	
N=3	Overall	3 (100.0)	37.5 (25.37)		[NC,NC]	[NC,NC]	
Placebo	Baseline	4 (100.0)	68.8 (23.94)	NC (NC)	NC		
N=4	Overall	3 (75.0)	73.6 (18.79)				

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group. Transformed score ranges from 0 to 100 based on Likert scale (Not at all, a little bit, somewhat, a great deal and a very great deal). Higher scores are indicative of greater symptom severity and lower scores indicate lower symptom severity (low score = good). For the change from baseline, negative scores indicate improvement.
[1] Summary statistics are based on observed data. Mean (SD) are calculated based on the mean observed value across all post-baseline visits within each patient.
[2] LS means, LS mean differences (95% CIs), p-value and Hedges' g (95% CIs) are based on a mixed-effects model with study, treatment, visit, subgroup, treatment-by-visit interaction and a subgroup-by-treatment interaction as fixed effects. The multiple visits for each patient are the repeated measures as a random effect within each patient with an unstructured covariance. Hedges' g is calculated using a small sample bias correction. Missing subgroup levels are not included in estimation of the interaction p-value. The reference group for the LS mean difference and Hedges' g is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with data; CI: Confidence interval; int: Interaction; LS: Least squares; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; SD: Standard deviation; SE: Standard error; SMD: Standardized mean difference; UFS-QoL: Uterine Fibroid Symptom and Health-Related Quality of Life; NC: Not calculated.

SOURCE: \Studies\MYV\MYV102\Analysis\Prod\Progs\TFLs\Tab_QOL_UFS_CON.SAS
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Table EFF.UFSBPD.MITT.Pooled.S9: Summary of Change from Baseline in UFS-QoL Bleeding and Pelvic Discomfort Scale Score by Visit and Overall, by Subgroup (mITT Population)						
Study: Pooled						
Treatment	**Study visit**	**n (%)[1]**	**Mean (SD)[1]**	**Change from baseline LS-mean change (SE)[2]**	**Difference LS-mean change [95% CI] p-value[2]**	**SMD Hedges' g [95% CI][2]**
Race						
Black/African American						
Relugolix+E2/NETA	Baseline	119 (97.5)	72.8 (21.61)	-38.55 (2.868)	-24.73	-0.86
N=122	Week 12	105 (86.1)	36.7 (30.94)		[-32.40,-17.05]	[-1.13,-0.58]
Placebo	Baseline	139 (98.6)	68.0 (20.55)	-13.83 (2.635)	<.0001	
N=141	Week 12	122 (86.5)	54.2 (23.80)			
White						
Relugolix+E2/NETA	Baseline	121 (99.2)	65.6 (20.46)	-39.64 (2.579)	-27.52	-1.02
N=122	Week 12	110 (90.2)	25.8 (25.09)		[-34.92,-20.11]	[-1.31,-0.73]
Placebo	Baseline	105 (100.0)	73.1 (20.88)	-12.12 (2.734)	<.0001	
N=105	Week 12	98 (93.3)	60.6 (23.26)			
Asian						
Relugolix+E2/NETA	Baseline	1 (100.0)	75.0 (NE)	NC (NC)	NC	NC
N=1	Week 12	1 (100.0)	8.3 (NE)		[NC,NC]	[NC,NC]
Placebo	Baseline	3 (100.0)	86.1 (24.08)	NC (NC)	NC	
N=3	Week 12	3 (100.0)	77.8 (31.54)			
Others						
Relugolix+E2/NETA	Baseline	5 (100.0)	61.7 (15.13)	-37.77 (12.454)	-17.59	-0.69
N=5	Week 12	5 (100.0)	28.3 (17.29)		[-58.91,23.73]	[-1.84,0.47]
Placebo	Baseline	6 (100.0)	82.0 (14.35)	-20.18 (11.646)	0.3475	
N=6	Week 12	5 (83.3)	56.7 (35.05)			
Not reported						
Relugolix+E2/NETA	Baseline	3 (100.0)	41.7 (38.19)	NC (NC)	NC	NC
N=3	Week 12	3 (100.0)	11.1 (4.85)		[NC,NC]	[NC,NC]
Placebo	Baseline	1 (100.0)	75.0 (NE)	NC (NC)	NC	

N=1	Week 12	1 (100.0)	83.3 (NE)			

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group. Transformed score ranges from 0 to 100 based on Likert scale (Not at all, a little bit, somewhat, a great deal and a very great deal). Higher scores are indicative of greater symptom severity and lower scores indicate lower symptom severity (low score = good). For the change from baseline, negative scores indicate improvement.
[1] Summary statistics are based on observed data.
[2] LS means, LS mean differences (95% CIs), p-value and Hedges' g (95% CIs) are based on a mixed-effects model with study, treatment, visit, and a treatment-by-visit interaction as fixed effects. The multiple visits for each patient are the repeated measures as a random effect within each patient with an unstructured covariance. Hedges' g is calculated using a small sample bias correction. Interaction p-value is only produced for the Overall period. The reference group for the LS mean difference and Hedges' g is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with data; CI: Confidence interval; LS: Least squares; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; SD: Standard deviation; SE: Standard error; SMD: Standardized mean difference; UFS-QoL: Uterine Fibroid Symptom and Health-Related Quality of Life; NC: Not calculated; NE: Non-estimable.

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Table EFF.UFSBPD.MITT.Pooled.S9: Summary of Change from Baseline in UFS-QoL Bleeding and Pelvic Discomfort Scale Score by Visit and Overall, by Subgroup (mITT Population)

Study: Pooled

Treatment	Study visit	n (%)[1]	Mean (SD)[1]	Change from baseline LS-mean change (SE)[2]	Difference LS-mean change [95% CI] p-value[2]	SMD Hedges' g [95% CI][2]
Race						
Black/African American						
Relugolix+E2/NETA	Baseline	119 (97.5)	72.8 (21.61)	-47.93 (2.787)	-31.86	-1.20
N=122	Week 24	87 (71.3)	24.2 (25.69)		[-39.25,-24.47]	[-1.51,-0.89]
Placebo	Baseline	139 (98.6)	68.0 (20.55)	-16.08 (2.508)	<.0001	
N=141	Week 24	108 (76.6)	52.1 (27.27)			
White						
Relugolix+E2/NETA	Baseline	121 (99.2)	65.6 (20.46)	-48.79 (2.548)	-30.68	-1.17
N=122	Week 24	100 (82.0)	15.2 (22.04)		[-38.07,-23.30]	[-1.49,-0.86]
Placebo	Baseline	105 (100.0)	73.1 (20.88)	-18.10 (2.752)	<.0001	
N=105	Week 24	84 (80.0)	54.2 (25.56)			
Asian						
Relugolix+E2/NETA	Baseline	1 (100.0)	75.0 (NE)	NC (NC)	NC	NC
N=1	Week 24	1 (100.0)	0.0 (NE)		[NC,NC]	[NC,NC]
Placebo	Baseline	3 (100.0)	86.1 (24.08)	NC (NC)	NC	
N=3	Week 24	2 (66.7)	75.0 (35.36)			
Others						
Relugolix+E2/NETA	Baseline	5 (100.0)	61.7 (15.13)	-29.43 (11.016)	-23.06	-1.05
N=5	Week 24	5 (100.0)	36.7 (24.00)		[-61.79,15.68]	[-2.32,0.21]
Placebo	Baseline	6 (100.0)	82.0 (14.35)	-6.38 (11.048)	0.2021	
N=6	Week 24	4 (66.7)	75.0 (18.01)			
Not reported						
Relugolix+E2/NETA	Baseline	3 (100.0)	41.7 (38.19)	NC (NC)	NC	NC
N=3	Week 24	3 (100.0)	5.5 (4.79)		[NC,NC]	[NC,NC]
Placebo	Baseline	1 (100.0)	75.0 (NE)	NC (NC)	NC	

N=1	Week 24	1 (100.0)	50.0 (NE)			

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group. Transformed score ranges from 0 to 100 based on Likert scale (Not at all, a little bit, somewhat, a great deal and a very great deal). Higher scores are indicative of greater symptom severity and lower scores indicate lower symptom severity (low score = good). For the change from baseline, negative scores indicate improvement.
[1] Summary statistics are based on observed data.
[2] LS means, LS mean differences (95% CIs), p-value and Hedges' g (95% CIs) are based on a mixed-effects model with study, treatment, visit, and a treatment-by-visit interaction as fixed effects. The multiple visits for each patient are the repeated measures as a random effect within each patient with an unstructured covariance. Hedges' g is calculated using a small sample bias correction. Interaction p-value is only produced for the Overall period. The reference group for the LS mean difference and Hedges' g is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with data; CI: Confidence interval; LS: Least squares; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; SD: Standard deviation; SE: Standard error; SMD: Standardized mean difference; UFS-QoL: Uterine Fibroid Symptom and Health-Related Quality of Life; NC: Not calculated; NE: Non-estimable.

Table EFF.UFSBPD.MITT.Pooled.S9: Summary of Change from Baseline in UFS-QoL Bleeding and Pelvic Discomfort Scale Score by Visit and Overall, by Subgroup (mITT Population)

Study: Pooled

Treatment	Study visit	n (%)[1]	Mean (SD)[1]	Change from baseline LS-mean change (SE)[2]	Difference LS-mean change [95% CI] p-value[2]	SMD Hedges' g [95% CI][2]	Int. p-value[2]
Race							
Black/African American							
Relugolix+E2/NETA	Baseline	119 (97.5)	72.8 (21.61)	-43.25 (2.459)	-28.33	-1.05	0.6021
N=122	Overall	107 (87.7)	32.2 (27.23)		[-34.87,-21.80]	[-1.32,-0.77]	
Placebo	Baseline	139 (98.6)	68.0 (20.55)	-14.92 (2.241)	<.0001		
N=141	Overall	126 (89.4)	53.1 (23.25)				
White							
Relugolix+E2/NETA	Baseline	121 (99.2)	65.6 (20.46)	-44.24 (2.359)	-29.03	-1.07	
N=122	Overall	112 (91.8)	21.5 (20.70)		[-35.81,-22.25]	[-1.36,-0.78]	
Placebo	Baseline	105 (100.0)	73.1 (20.88)	-15.21 (2.520)	<.0001		
N=105	Overall	98 (93.3)	58.3 (22.20)				
Asian							
Relugolix+E2/NETA	Baseline	1 (100.0)	75.0 (NE)	NC (NC)	NC	NC	
N=1	Overall	1 (100.0)	4.2 (NE)		[NC,NC]	[NC,NC]	
Placebo	Baseline	3 (100.0)	86.1 (24.08)	NC (NC)	NC		
N=3	Overall	3 (100.0)	79.2 (29.16)				
Others							
Relugolix+E2/NETA	Baseline	5 (100.0)	61.7 (15.13)	-28.16 (10.974)	-12.82	-0.43	
N=5	Overall	5 (100.0)	32.5 (17.53)		[-43.69,18.06]	[-1.56,0.71]	
Placebo	Baseline	6 (100.0)	82.0 (14.35)	-15.35 (11.223)	0.4151		
N=6	Overall	5 (83.3)	60.8 (30.28)				
Not reported							
Relugolix+E2/NETA	Baseline	3 (100.0)	41.7 (38.19)	NC (NC)	NC	NC	
N=3	Overall	3 (100.0)	8.3 (0.03)		[NC,NC]	[NC,NC]	
Placebo	Baseline	1 (100.0)	75.0 (NE)	NC (NC)	NC		

N=1	Overall	1 (100.0)	66.7 (NE)				

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group. Transformed score ranges from 0 to 100 based on Likert scale (Not at all, a little bit, somewhat, a great deal and a very great deal). Higher scores are indicative of greater symptom severity and lower scores indicate lower symptom severity (low score = good). For the change from baseline, negative scores indicate improvement.
[1] Summary statistics are based on observed data. Mean (SD) are calculated based on the mean observed value across all post-baseline visits within each patient.
[2] LS means, LS mean differences (95% CIs), p-value and Hedges' g (95% CIs) are based on a mixed-effects model with study, treatment, visit, subgroup, treatment-by-visit interaction and a subgroup-by-treatment interaction as fixed effects. The multiple visits for each patient are the repeated measures as a random effect within each patient with an unstructured covariance. Hedges' g is calculated using a small sample bias correction. Not reported subgroup levels are not included in estimation of the interaction p-value. Subgroup levels with fewer than 10 subjects are not included in estimation of the interaction p-value. The reference group for the LS mean difference and Hedges' g is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with data; CI: Confidence interval; int: Interaction; LS: Least squares; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; SD: Standard deviation; SE: Standard error; SMD: Standardized mean difference; UFS-QoL: Uterine Fibroid Symptom and Health-Related Quality of Life; NC: Not calculated; NE: Non-estimable.

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1.2.4 Proportion of Responders with at least 20 Points Decrease in UFS-QoL Bleeding and Pelvic Discomfort Scale Score at Week 24, by Subgroup (mITT Population)

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Table QOL.UFSBPD20.MITT.Pooled.S3: Proportion of Responders with at least 20 Points Decrease in UFS-QoL Bleeding and Pelvic Discomfort Scale Score at Week 24, by Subgroup (mITT Population)

Study: Pooled

Treatment	N	n (%)	OR[1] [95% CI]	RR[2] [95% CI]	RD[3] [95% CI]	p-value[4]	p-value (int)[5]
Uterine Volume at Baseline (cm3)							
< 300 cm3							
Relugolix+E2/NETA	148	97 (65.5)	5.11	2.42	0.38	<.0001	0.3066
Placebo	129	35 (27.1)	[3.05;8.56]	[1.78;3.28]	[0.28;0.49]		
>= 300 cm3							
Relugolix+E2/NETA	104	61 (58.7)	3.45	2.01	0.29	<.0001	
Placebo	127	37 (29.1)	[2.00;5.97]	[1.47;2.76]	[0.17;0.42]		
Missing							
Relugolix+E2/NETA	1	0	NC	NC	NC	NC	
Placebo	0	0	[NC;NC]	[NC;NC]	[NC;NC]		

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group.
[1] OR (95% CI) based on a logistic regression model adjusting for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates.
[2] RR (95% CI) based on a Cochran-Mantel-Haenszel approach stratified by study.
[3] RD (95% CI) based on a Mantel-Haenszel approach stratified by study. 95% CIs are based on the approximation to the normal distribution using the Sato estimator for the standard error.
[4] P-value based on a Cochran-Mantel-Haenszel test stratified by study.
[5] Interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the OR (95% CI). Missing subgroup levels are not included in estimation of the interaction p-value. * Interaction p-value < 0.05.
A continuity correction is applied in estimation of the OR, RR and p-value if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum. No continuity correction is applied in the estimation of the RD.
The reference group for the OR, RR and RD is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with an event; OR: Odds ratio; RR: Risk ratio; RD: Risk difference; CI: Confidence interval; int: p-value for interaction; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; NC: Not calculated.

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Table QOL.UFSBPD20.MITT.Pooled.S8: Proportion of Responders with at least 20 Points Decrease in UFS-QoL Bleeding and Pelvic Discomfort Scale Score at Week 24, by Subgroup (mITT Population)

Study: Pooled

Treatment	N	n (%)	OR[1] [95% CI]	RR[2] [95% CI]	RD[3] [95% CI]	p-value[4]	p-value (int)[5]
Ethnicity							
Hispanic or Latino							
Relugolix+E2/NETA	52	33 (63.5)	3.06	1.82	0.29	0.0040	0.3280
Placebo	55	20 (36.4)	[1.39;6.76]	[1.19;2.80]	[0.10;0.47]		
Not Hispanic or Latino							
Relugolix+E2/NETA	197	123 (62.4)	4.82	2.44	0.37	<.0001	
Placebo	199	51 (25.6)	[3.13;7.40]	[1.88;3.17]	[0.28;0.46]		
Not reported							
Relugolix+E2/NETA	4	2 (50.0)	NC	NC	NC	NC	
Placebo	2	1 (50.0)	[NC;NC]	[NC;NC]	[NC;NC]		

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group.
[1] OR (95% CI) based on a logistic regression model adjusting for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates.
[2] RR (95% CI) based on a Cochran-Mantel-Haenszel approach stratified by study.
[3] RD (95% CI) based on a Mantel-Haenszel approach stratified by study. 95% CIs are based on the approximation to the normal distribution using the Sato estimator for the standard error.
[4] P-value based on a Cochran-Mantel-Haenszel test stratified by study.
[5] Interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the OR (95% CI). Not reported subgroup levels are not included in estimation of the interaction p-value.
* Interaction p-value < 0.05.
A continuity correction is applied in estimation of the OR, RR and p-value if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum. No continuity correction is applied in the estimation of the RD.
The reference group for the OR, RR and RD is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with an event; OR: Odds ratio; RR: Risk ratio; RD: Risk difference; CI: Confidence interval; int: p-value for interaction; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; NC: Not calculated.

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Table QOL.UFSBPD20.MITT.Pooled.S1: Proportion of Responders with at least 20 Points Decrease in UFS-QoL Bleeding and Pelvic Discomfort Scale Score at Week 24, by Subgroup (mITT Population)

Study: Pooled

Treatment	**N**	**n (%)**	**OR[1] [95% CI]**	**RR[2] [95% CI]**	**RD[3] [95% CI]**	**p-value[4]**	**p-value (int)[5]**
Age (years)							
< 40 years							
Relugolix+E2/NETA	62	35 (56.5)	3.31	2.01	0.28	0.0008	0.4272
Placebo	78	22 (28.2)	[1.63;6.68]	[1.32;3.05]	[0.12;0.44]		
>= 40 years							
Relugolix+E2/NETA	191	123 (64.4)	4.63	2.29	0.36	<.0001	
Placebo	178	50 (28.1)	[2.98;7.20]	[1.77;2.97]	[0.27;0.46]		

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group.
[1] OR (95% CI) based on a logistic regression model adjusting for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates.
[2] RR (95% CI) based on a Cochran-Mantel-Haenszel approach stratified by study.
[3] RD (95% CI) based on a Mantel-Haenszel approach stratified by study. 95% CIs are based on the approximation to the normal distribution using the Sato estimator for the standard error.
[4] P-value based on a Cochran-Mantel-Haenszel test stratified by study.
[5] Interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the OR (95% CI). Not reported subgroup levels are not included in estimation of the interaction p-value.
* Interaction p-value < 0.05.
A continuity correction is applied in estimation of the OR, RR and p-value if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum. No continuity correction is applied in the estimation of the RD.
The reference group for the OR, RR and RD is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with an event; OR: Odds ratio; RR: Risk ratio; RD: Risk difference; CI: Confidence interval; int: p-value for interaction; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; NC: Not calculated.

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Table QOL.UFSBPD20.MITT.Pooled.S4: Proportion of Responders with at least 20 Points Decrease in UFS-QoL Bleeding and Pelvic Discomfort Scale Score at Week 24, by Subgroup (mITT Population)

Study: Pooled

Treatment	N	n (%)	OR[1] [95% CI]	RR[2] [95% CI]	RD[3] [95% CI]	p-value[4]	p-value (int)[5]
Maximum NRS Pain Score at Baseline							
< 4							
Relugolix+E2/NETA	73	45 (61.6)	5.54	2.79	0.40	<.0001	0.4342
Placebo	62	14 (22.6)	[2.59;11.86]	[1.70;4.59]	[0.25;0.55]		
>= 4							
Relugolix+E2/NETA	177	112 (63.3)	3.92	2.07	0.33	<.0001	
Placebo	190	58 (30.5)	[2.54;6.05]	[1.63;2.64]	[0.23;0.42]		
Missing							
Relugolix+E2/NETA	3	1 (33.3)	NC	NC	NC	NC	
Placebo	4	0	[NC;NC]	[NC;NC]	[NC;NC]		

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group.
[1] OR (95% CI) based on a logistic regression model adjusting for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates.
[2] RR (95% CI) based on a Cochran-Mantel-Haenszel approach stratified by study.
[3] RD (95% CI) based on a Mantel-Haenszel approach stratified by study. 95% CIs are based on the approximation to the normal distribution using the Sato estimator for the standard error.
[4] P-value based on a Cochran-Mantel-Haenszel test stratified by study.
[5] Interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the OR (95% CI). Missing subgroup levels are not included in estimation of the interaction p-value. * Interaction p-value < 0.05.
A continuity correction is applied in estimation of the OR, RR and p-value if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum. No continuity correction is applied in the estimation of the RD.
The reference group for the OR, RR and RD is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with an event; OR: Odds ratio; RR: Risk ratio; RD: Risk difference; CI: Confidence interval; int: p-value for interaction; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; NC: Not calculated.

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Table QOL.UFSBPD20.MITT.Pooled.S2: Proportion of Responders with at least 20 Points Decrease in UFS-QoL Bleeding and Pelvic Discomfort Scale Score at Week 24, by Subgroup (mITT Population)

Study: Pooled

Treatment	N	n (%)	OR[1] [95% CI]	RR[2] [95% CI]	RD[3] [95% CI]	p-value[4]	p-value (int)[5]
BMI (kg/m2) at Baseline							
< 30							
Relugolix+E2/NETA	119	72 (60.5)	5.01	2.56	0.37	<.0001	0.4636
Placebo	115	27 (23.5)	[2.84;8.83]	[1.79;3.67]	[0.25;0.49]		
>= 30							
Relugolix+E2/NETA	133	85 (63.9)	3.78	2.00	0.32	<.0001	
Placebo	141	45 (31.9)	[2.29;6.23]	[1.52;2.62]	[0.21;0.43]		
Missing							
Relugolix+E2/NETA	1	1 (100.0)	NC	NC	NC	NC	
Placebo	0	0	[NC;NC]	[NC;NC]	[NC;NC]		

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group.
[1] OR (95% CI) based on a logistic regression model adjusting for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates.
[2] RR (95% CI) based on a Cochran-Mantel-Haenszel approach stratified by study.
[3] RD (95% CI) based on a Mantel-Haenszel approach stratified by study. 95% CIs are based on the approximation to the normal distribution using the Sato estimator for the standard error.
[4] P-value based on a Cochran-Mantel-Haenszel test stratified by study.
[5] Interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the OR (95% CI). Missing subgroup levels are not included in estimation of the interaction p-value. * Interaction p-value < 0.05.
A continuity correction is applied in estimation of the OR, RR and p-value if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum. No continuity correction is applied in the estimation of the RD.
The reference group for the OR, RR and RD is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with an event; OR: Odds ratio; RR: Risk ratio; RD: Risk difference; CI: Confidence interval; int: p-value for interaction; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; NC: Not calculated.

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Table QOL.UFSBPD20.MITT.Pooled.S5: Proportion of Responders with at least 20 Points Decrease in UFS-QoL Bleeding and Pelvic Discomfort Scale Score at Week 24, by Subgroup (mITT Population)

Study: Pooled

Treatment	N	n (%)	OR[1] [95% CI]	RR[2] [95% CI]	RD[3] [95% CI]	p-value[4]	p-value (int)[5]
MBL Volume at Baseline (mL)							
< 225 mL							
Relugolix+E2/NETA	164	106 (64.6)	4.07	2.09	0.34	<.0001	0.6577
Placebo	171	53 (31.0)	[2.58;6.43]	[1.63;2.68]	[0.24;0.44]		
>= 225 mL							
Relugolix+E2/NETA	89	52 (58.4)	4.88	2.61	0.36	<.0001	
Placebo	85	19 (22.4)	[2.52;9.47]	[1.70;4.03]	[0.23;0.50]		

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group.
[1] OR (95% CI) based on a logistic regression model adjusting for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates.
[2] RR (95% CI) based on a Cochran-Mantel-Haenszel approach stratified by study.
[3] RD (95% CI) based on a Mantel-Haenszel approach stratified by study. 95% CIs are based on the approximation to the normal distribution using the Sato estimator for the standard error.
[4] P-value based on a Cochran-Mantel-Haenszel test stratified by study.
[5] Interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the OR (95% CI). Missing subgroup levels are not included in estimation of the interaction p-value. * Interaction p-value < 0.05.
A continuity correction is applied in estimation of the OR, RR and p-value if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum. No continuity correction is applied in the estimation of the RD.
The reference group for the OR, RR and RD is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with an event; OR: Odds ratio; RR: Risk ratio; RD: Risk difference; CI: Confidence interval; int: p-value for interaction; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; NC: Not calculated.

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Table QOL.UFSBPD20.MITT.Pooled.S9: Proportion of Responders with at least 20 Points Decrease in UFS-QoL Bleeding and Pelvic Discomfort Scale Score at Week 24, by Subgroup (mITT Population)

Study: Pooled

Treatment	N	n (%)	OR[1] [95% CI]	RR[2] [95% CI]	RD[3] [95% CI]	p-value[4]	p-value (int)[5]
Race							
Black/African American							0.7511
Relugolix+E2/NETA	122	71 (58.2)	3.78	2.16	0.31	<.0001	
Placebo	141	38 (27.0)	[2.25;6.34]	[1.58;2.95]	[0.20;0.43]		
White							
Relugolix+E2/NETA	122	82 (67.2)	4.68	2.21	0.37	<.0001	
Placebo	105	32 (30.5)	[2.67;8.20]	[1.61;3.02]	[0.25;0.49]		
Asian							
Relugolix+E2/NETA	1	1 (100.0)	NC	NC	NC	NC	
Placebo	3	0	[NC;NC]	[NC;NC]	[NC;NC]		
Others							
Relugolix+E2/NETA	5	2 (40.0)	2.29	2.20	0.44	0.3212	
Placebo	6	1 (16.7)	[0.25;20.56]	[0.52;9.43]	[0.07;0.81]		
Not reported							
Relugolix+E2/NETA	3	2 (66.7)	NC	NC	NC	NC	
Placebo	1	1 (100.0)	[NC;NC]	[NC;NC]	[NC;NC]		

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group.
[1] OR (95% CI) based on a logistic regression model adjusting for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates.
[2] RR (95% CI) based on a Cochran-Mantel-Haenszel approach stratified by study.
[3] RD (95% CI) based on a Mantel-Haenszel approach stratified by study. 95% CIs are based on the approximation to the normal distribution using the Sato estimator for the standard error.
[4] P-value based on a Cochran-Mantel-Haenszel test stratified by study.
[5] Interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the OR (95% CI). Not reported subgroup levels are not included in estimation of the interaction p-value.
* Interaction p-value < 0.05.
A continuity correction is applied in estimation of the OR, RR and p-value if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum. No continuity correction is applied in the estimation of the RD.
The reference group for the OR, RR and RD is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with an event; OR: Odds ratio; RR: Risk ratio; RD: Risk difference; CI: Confidence interval; int: p-value for interaction; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; NC: Not calculated.

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1.2.4.1 Proportion of Responders with at least 25 Points Decrease in UFS-QoL Bleeding and Pelvic Discomfort Scale Score at Week 24, by Subgroup (mITT Population)

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Table QOL.UFSBPD25.MITT.Pooled.S8: Proportion of Responders with at least 25 Points Decrease in UFS-QoL Bleeding and Pelvic Discomfort Scale Score at Week 24, by Subgroup (mITT Population)

Study: Pooled

Treatment	N	n (%)	OR[1] [95% CI]	RR[2] [95% CI]	RD[3] [95% CI]	p-value[4]	p-value (int)[5]
Ethnicity							
Hispanic or Latino							
Relugolix+E2/NETA	52	31 (59.6)	2.57	1.71	0.25	0.0135	0.1686
Placebo	55	20 (36.4)	[1.17;5.64]	[1.10;2.65]	[0.06;0.44]		
Not Hispanic or Latino							
Relugolix+E2/NETA	197	122 (61.9)	4.85	2.48	0.37	<.0001	
Placebo	199	50 (25.1)	[3.15;7.47]	[1.90;3.23]	[0.28;0.46]		
Not reported							
Relugolix+E2/NETA	4	2 (50.0)	NC	NC	NC	NC	
Placebo	2	1 (50.0)	[NC;NC]	[NC;NC]	[NC;NC]		

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group.
[1] OR (95% CI) based on a logistic regression model adjusting for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates.
[2] RR (95% CI) based on a Cochran-Mantel-Haenszel approach stratified by study.
[3] RD (95% CI) based on a Mantel-Haenszel approach stratified by study. 95% CIs are based on the approximation to the normal distribution using the Sato estimator for the standard error.
[4] P-value based on a Cochran-Mantel-Haenszel test stratified by study.
[5] Interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the OR (95% CI). Not reported subgroup levels are not included in estimation of the interaction p-value.
* Interaction p-value < 0.05.
A continuity correction is applied in estimation of the OR, RR and p-value if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum. No continuity correction is applied in the estimation of the RD.
The reference group for the OR, RR and RD is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with an event; OR: Odds ratio; RR: Risk ratio; RD: Risk difference; CI: Confidence interval; int: p-value for interaction; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; NC: Not calculated.

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Table QOL.UFSBPD25.MITT.Pooled.S3: Proportion of Responders with at least 25 Points Decrease in UFS-QoL Bleeding and Pelvic Discomfort Scale Score at Week 24, by Subgroup (mITT Population)

Study: Pooled

Treatment	N	n (%)	OR[1] [95% CI]	RR[2] [95% CI]	RD[3] [95% CI]	p-value[4]	p-value (int)[5]
Uterine Volume at Baseline (cm3)							
< 300 cm3							
Relugolix+E2/NETA	148	96 (64.9)	4.96	2.39	0.38	<.0001	0.2932
Placebo	129	35 (27.1)	[2.96;8.29]	[1.76;3.25]	[0.27;0.49]		
>= 300 cm3							
Relugolix+E2/NETA	104	59 (56.7)	3.31	2.00	0.28	<.0001	
Placebo	127	36 (28.3)	[1.92;5.73]	[1.45;2.76]	[0.16;0.41]		
Missing							
Relugolix+E2/NETA	1	0	NC	NC	NC	NC	
Placebo	0	0	[NC;NC]	[NC;NC]	[NC;NC]		

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group.
[1] OR (95% CI) based on a logistic regression model adjusting for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates.
[2] RR (95% CI) based on a Cochran-Mantel-Haenszel approach stratified by study.
[3] RD (95% CI) based on a Mantel-Haenszel approach stratified by study. 95% CIs are based on the approximation to the normal distribution using the Sato estimator for the standard error.
[4] P-value based on a Cochran-Mantel-Haenszel test stratified by study.
[5] Interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the OR (95% CI). Missing subgroup levels are not included in estimation of the interaction p-value. * Interaction p-value < 0.05.
A continuity correction is applied in estimation of the OR, RR and p-value if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum. No continuity correction is applied in the estimation of the RD.
The reference group for the OR, RR and RD is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with an event; OR: Odds ratio; RR: Risk ratio; RD: Risk difference; CI: Confidence interval; int: p-value for interaction; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; NC: Not calculated.

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Table QOL.UFSBPD25.MITT.Pooled.S2: Proportion of Responders with at least 25 Points Decrease in UFS-QoL Bleeding and Pelvic Discomfort Scale Score at Week 24, by Subgroup (mITT Population)

Study: Pooled

Treatment	N	n (%)	OR[1] [95% CI]	RR[2] [95% CI]	RD[3] [95% CI]	p-value[4]	p-value (int)[5]
BMI (kg/m2) at Baseline							
< 30							
Relugolix+E2/NETA	119	70 (58.8)	4.90	2.58	0.36	<.0001	0.4493
Placebo	115	26 (22.6)	[2.77;8.65]	[1.78;3.72]	[0.24;0.48]		
>= 30							
Relugolix+E2/NETA	133	84 (63.2)	3.66	1.97	0.31	<.0001	
Placebo	141	45 (31.9)	[2.22;6.02]	[1.50;2.60]	[0.20;0.42]		
Missing							
Relugolix+E2/NETA	1	1 (100.0)	NC	NC	NC	NC	
Placebo	0	0	[NC;NC]	[NC;NC]	[NC;NC]		

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group.
[1] OR (95% CI) based on a logistic regression model adjusting for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates.
[2] RR (95% CI) based on a Cochran-Mantel-Haenszel approach stratified by study.
[3] RD (95% CI) based on a Mantel-Haenszel approach stratified by study. 95% CIs are based on the approximation to the normal distribution using the Sato estimator for the standard error.
[4] P-value based on a Cochran-Mantel-Haenszel test stratified by study.
[5] Interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the OR (95% CI). Missing subgroup levels are not included in estimation of the interaction p-value. * Interaction p-value < 0.05.
A continuity correction is applied in estimation of the OR, RR and p-value if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum. No continuity correction is applied in the estimation of the RD.
The reference group for the OR, RR and RD is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with an event; OR: Odds ratio; RR: Risk ratio; RD: Risk difference; CI: Confidence interval; int: p-value for interaction; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; NC: Not calculated.

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Table QOL.UFSBPD25.MITT.Pooled.S1: Proportion of Responders with at least 25 Points Decrease in UFS-QoL Bleeding and Pelvic Discomfort Scale Score at Week 24, by Subgroup (mITT Population)

Study: Pooled

Treatment	**N**	**n (%)**	**OR[1] [95% CI]**	**RR[2] [95% CI]**	**RD[3] [95% CI]**	**p-value[4]**	**p-value (int)[5]**
Age (years)							
< 40 years							
Relugolix+E2/NETA	62	35 (56.5)	3.30	2.01	0.28	0.0008	0.4825
Placebo	78	22 (28.2)	[1.63;6.67]	[1.32;3.05]	[0.12;0.44]		
>= 40 years							
Relugolix+E2/NETA	191	120 (62.8)	4.45	2.28	0.35	<.0001	
Placebo	178	49 (27.5)	[2.86;6.92]	[1.76;2.97]	[0.26;0.45]		

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group.
[1] OR (95% CI) based on a logistic regression model adjusting for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates.
[2] RR (95% CI) based on a Cochran-Mantel-Haenszel approach stratified by study.
[3] RD (95% CI) based on a Mantel-Haenszel approach stratified by study. 95% CIs are based on the approximation to the normal distribution using the Sato estimator for the standard error.
[4] P-value based on a Cochran-Mantel-Haenszel test stratified by study.
[5] Interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the OR (95% CI). Missing subgroup levels are not included in estimation of the interaction p-value. * Interaction p-value < 0.05.
A continuity correction is applied in estimation of the OR, RR and p-value if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum. No continuity correction is applied in the estimation of the RD.
The reference group for the OR, RR and RD is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with an event; OR: Odds ratio; RR: Risk ratio; RD: Risk difference; CI: Confidence interval; int: p-value for interaction; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; NC: Not calculated.

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Table QOL.UFSBPD25.MITT.Pooled.S4: Proportion of Responders with at least 25 Points Decrease in UFS-QoL Bleeding and Pelvic Discomfort Scale Score at Week 24, by Subgroup (mITT Population)

Study: Pooled

Treatment	N	n (%)	OR[1] [95% CI]	RR[2] [95% CI]	RD[3] [95% CI]	p-value[4]	p-value (int)[5]
Maximum NRS Pain Score at Baseline							
< 4							
Relugolix+E2/NETA	73	43 (58.9)	4.92	2.67	0.37	<.0001	0.6087
Placebo	62	14 (22.6)	[2.31;10.49]	[1.62;4.40]	[0.22;0.52]		
>= 4							
Relugolix+E2/NETA	177	111 (62.7)	3.92	2.09	0.33	<.0001	
Placebo	190	57 (30.0)	[2.54;6.06]	[1.64;2.67]	[0.23;0.42]		
Missing							
Relugolix+E2/NETA	3	1 (33.3)	NC	NC	NC	NC	
Placebo	4	0	[NC;NC]	[NC;NC]	[NC;NC]		

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group.
[1] OR (95% CI) based on a logistic regression model adjusting for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates.
[2] RR (95% CI) based on a Cochran-Mantel-Haenszel approach stratified by study.
[3] RD (95% CI) based on a Mantel-Haenszel approach stratified by study. 95% CIs are based on the approximation to the normal distribution using the Sato estimator for the standard error.
[4] P-value based on a Cochran-Mantel-Haenszel test stratified by study.
[5] Interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the OR (95% CI). Missing subgroup levels are not included in estimation of the interaction p-value. * Interaction p-value < 0.05.
A continuity correction is applied in estimation of the OR, RR and p-value if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum. No continuity correction is applied in the estimation of the RD.
The reference group for the OR, RR and RD is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with an event; OR: Odds ratio; RR: Risk ratio; RD: Risk difference; CI: Confidence interval; int: p-value for interaction; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; NC: Not calculated.

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Table QOL.UFSBPD25.MITT.Pooled.S5: Proportion of Responders with at least 25 Points Decrease in UFS-QoL Bleeding and Pelvic Discomfort Scale Score at Week 24, by Subgroup (mITT Population)

Study: Pooled

Treatment	N	n (%)	OR[1] [95% CI]	RR[2] [95% CI]	RD[3] [95% CI]	p-value[4]	p-value (int)[5]
MBL Volume at Baseline (mL)							
< 225 mL							
Relugolix+E2/NETA	164	104 (63.4)	3.97	2.09	0.33	<.0001	0.6933
Placebo	171	52 (30.4)	[2.52;6.26]	[1.62;2.69]	[0.23;0.43]		
>= 225 mL							
Relugolix+E2/NETA	89	51 (57.3)	4.66	2.56	0.35	<.0001	
Placebo	85	19 (22.4)	[2.41;9.03]	[1.66;3.96]	[0.21;0.48]		

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group.
[1] OR (95% CI) based on a logistic regression model adjusting for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates.
[2] RR (95% CI) based on a Cochran-Mantel-Haenszel approach stratified by study.
[3] RD (95% CI) based on a Mantel-Haenszel approach stratified by study. 95% CIs are based on the approximation to the normal distribution using the Sato estimator for the standard error.
[4] P-value based on a Cochran-Mantel-Haenszel test stratified by study.
[5] Interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the OR (95% CI). Missing subgroup levels are not included in estimation of the interaction p-value. * Interaction p-value < 0.05.
A continuity correction is applied in estimation of the OR, RR and p-value if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum. No continuity correction is applied in the estimation of the RD.
The reference group for the OR, RR and RD is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with an event; OR: Odds ratio; RR: Risk ratio; RD: Risk difference; CI: Confidence interval; int: p-value for interaction; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; NC: Not calculated.

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Table QOL.UFSBPD25.MITT.Pooled.S9: Proportion of Responders with at least 25 Points Decrease in UFS-QoL Bleeding and Pelvic Discomfort Scale Score at Week 24, by Subgroup (mITT Population)

Study: Pooled

Treatment	N	n (%)	OR[1] [95% CI]	RR[2] [95% CI]	RD[3] [95% CI]	p-value[4]	p-value (int)[5]
Race							
Black/African American							0.8270
Relugolix+E2/NETA	122	70 (57.4)	3.78	2.19	0.31	<.0001	
Placebo	141	37 (26.2)	[2.25;6.36]	[1.59;3.00]	[0.20;0.43]		
White							
Relugolix+E2/NETA	122	80 (65.6)	4.34	2.15	0.35	<.0001	
Placebo	105	32 (30.5)	[2.48;7.60]	[1.57;2.95]	[0.23;0.47]		
Asian							
Relugolix+E2/NETA	1	1 (100.0)	NC	NC	NC	NC	
Placebo	3	0	[NC;NC]	[NC;NC]	[NC;NC]		
Others							
Relugolix+E2/NETA	5	2 (40.0)	2.26	2.20	0.44	0.3212	
Placebo	6	1 (16.7)	[0.25;20.30]	[0.52;9.43]	[0.07;0.81]		
Not reported							
Relugolix+E2/NETA	3	2 (66.7)	NC	NC	NC	NC	
Placebo	1	1 (100.0)	[NC;NC]	[NC;NC]	[NC;NC]		

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group.
[1] OR (95% CI) based on a logistic regression model adjusting for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates.
[2] RR (95% CI) based on a Cochran-Mantel-Haenszel approach stratified by study.
[3] RD (95% CI) based on a Mantel-Haenszel approach stratified by study. 95% CIs are based on the approximation to the normal distribution using the Sato estimator for the standard error.
[4] P-value based on a Cochran-Mantel-Haenszel test stratified by study.
[5] Interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the OR (95% CI). Not reported subgroup levels are not included in estimation of the interaction p-value.
* Interaction p-value < 0.05.
A continuity correction is applied in estimation of the OR, RR and p-value if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum. No continuity correction is applied in the estimation of the RD.
The reference group for the OR, RR and RD is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with an event; OR: Odds ratio; RR: Risk ratio; RD: Risk difference; CI: Confidence interval; int: p-value for interaction; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; NC: Not calculated.

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1.2.5 Summary of Change from Baseline in UFS-QoL Concern Scale Score by Visit and Overall, by Subgroup (mITT Population)

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Table EFF.UFSCONC.MITT.Pooled.S3: Summary of Change from Baseline in UFS-QoL Concern Scale Score by Visit and Overall, by Subgroup (mITT Population)

Study: Pooled

Treatment	Study visit	n (%)[1]	Mean (SD)[1]	Change from baseline LS-mean change (SE)[2]	Difference LS-mean change [95% CI] p-value[2]	SMD Hedges' g [95% CI][2]
Uterine Volume at Baseline (cm3)						
< 300 cm3						
Relugolix+E2/NETA	Baseline	147 (99.3)	25.4 (20.76)	44.29 (2.503)	32.59	1.14
N=148	Week 12	132 (89.2)	69.8 (30.50)		[25.38,39.79]	[0.87,1.41]
Placebo	Baseline	129 (100.0)	26.2 (20.60)	11.70 (2.668)	<.0001	
N=129	Week 12	115 (89.1)	36.7 (24.62)			
>= 300 cm3						
Relugolix+E2/NETA	Baseline	101 (97.1)	21.7 (20.20)	39.12 (2.968)	22.22	0.79
N=104	Week 12	92 (88.5)	59.6 (32.35)		[14.37,30.07]	[0.50,1.08]
Placebo	Baseline	125 (98.4)	20.8 (19.04)	16.90 (2.652)	<.0001	
N=127	Week 12	114 (89.8)	36.4 (26.99)			
Missing						
Relugolix+E2/NETA	Baseline	1 (100.0)	25.0 (NE)	NC (NC)	NC	NC
N=1	Week 12	0	NE (NE)		[NC,NC]	[NC,NC]
Placebo	Baseline	0	NE (NE)	NC (NC)	NC	
N=0	Week 12	0	NE (NE)			

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group. Transformed score ranges from 0 to 100 based on Likert scale (None of the time, a little of the time, some of the time, most of the time and all of the time). Higher scores are indicative of better health-related quality of life (high score = good). For the change from baseline, positive scores indicate improvement.
[1] Summary statistics are based on observed data.
[2] LS means, LS mean differences (95% CIs), p-value and Hedges' g (95% CIs) are based on a mixed-effects model with study, treatment, visit, and a treatment-by-visit interaction as fixed effects. The multiple visits for each patient are the repeated measures as a random effect within each patient with an unstructured covariance. Hedges' g is calculated using a small sample bias correction. Interaction p-value is only produced for the Overall period. The reference group for the LS mean difference and Hedges' g is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with data; CI: Confidence interval; LS: Least squares; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; SD: Standard deviation; SE: Standard error; SMD: Standardized mean difference; UFS-QoL: Uterine Fibroid Symptom and Health-Related Quality of Life; NC: Not calculated; NE: Non-estimable.

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Table EFF.UFSCONC.MITT.Pooled.S3: Summary of Change from Baseline in UFS-QoL Concern Scale Score by Visit and Overall, by Subgroup (mITT Population)

Study: Pooled

Treatment	Study visit	n (%)[1]	Mean (SD)[1]	Change from baseline LS-mean change (SE)[2]	Difference LS-mean change [95% CI] p-value[2]	SMD Hedges' g [95% CI][2]
Uterine Volume at Baseline (cm3)						
< 300 cm3						
Relugolix+E2/NETA	Baseline	147 (99.3)	25.4 (20.76)	52.52 (2.658)	38.58	1.32
N=148	Week 24	116 (78.4)	80.2 (27.22)		[30.94,46.21]	[1.02,1.61]
Placebo	Baseline	129 (100.0)	26.2 (20.60)	13.94 (2.824)	<.0001	
N=129	Week 24	102 (79.1)	39.6 (27.12)			
>= 300 cm3						
Relugolix+E2/NETA	Baseline	101 (97.1)	21.7 (20.20)	46.55 (3.149)	29.73	1.03
N=104	Week 24	80 (76.9)	69.5 (31.59)		[21.37,38.08]	[0.72,1.35]
Placebo	Baseline	125 (98.4)	20.8 (19.04)	16.82 (2.833)	<.0001	
N=127	Week 24	97 (76.4)	35.7 (27.83)			
Missing						
Relugolix+E2/NETA	Baseline	1 (100.0)	25.0 (NE)	NC (NC)	NC	NC
N=1	Week 24	0	NE (NE)		[NC,NC]	[NC,NC]
Placebo	Baseline	0	NE (NE)	NC (NC)	NC	
N=0	Week 24	0	NE (NE)			

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group. Transformed score ranges from 0 to 100 based on Likert scale (None of the time, a little of the time, some of the time, most of the time and all of the time). Higher scores are indicative of better health-related quality of life (high score = good). For the change from baseline, positive scores indicate improvement.
[1] Summary statistics are based on observed data.
[2] LS means, LS mean differences (95% CIs), p-value and Hedges' g (95% CIs) are based on a mixed-effects model with study, treatment, visit, and a treatment-by-visit interaction as fixed effects. The multiple visits for each patient are the repeated measures as a random effect within each patient with an unstructured covariance. Hedges' g is calculated using a small sample bias correction. Interaction p-value is only produced for the Overall period. The reference group for the LS mean difference and Hedges' g is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with data; CI: Confidence interval; LS: Least squares; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; SD: Standard deviation; SE: Standard error; SMD: Standardized mean difference; UFS-QoL: Uterine Fibroid Symptom and Health-Related Quality of Life; NC: Not calculated; NE: Non-estimable.

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Table EFF.UFSCONC.MITT.Pooled.S3: Summary of Change from Baseline in UFS-QoL Concern Scale Score by Visit and Overall, by Subgroup (mITT Population)

Study: Pooled

Treatment	Study visit	n (%)[1]	Mean (SD)[1]	Change from baseline LS-mean change (SE)[2]	Difference LS-mean change [95% CI] p-value[2]	SMD Hedges' g [95% CI][2]	Int. p-value[2]
Uterine Volume at Baseline (cm3)							
< 300 cm3							
Relugolix+E2/NETA	Baseline	147 (99.3)	25.4 (20.76)	48.38 (2.290)	35.56	1.24	0.0571
N=148	Overall	134 (90.5)	73.5 (26.82)		[28.99,42.12]	[0.97,1.51]	
Placebo	Baseline	129 (100.0)	26.2 (20.60)	12.83 (2.433)	<.0001		
N=129	Overall	118 (91.5)	37.1 (23.12)				
>= 300 cm3							
Relugolix+E2/NETA	Baseline	101 (97.1)	21.7 (20.20)	42.96 (2.771)	26.03	0.91	
N=104	Overall	94 (90.4)	63.0 (30.56)		[18.71,33.34]	[0.62,1.19]	
Placebo	Baseline	125 (98.4)	20.8 (19.04)	16.93 (2.486)	<.0001		
N=127	Overall	115 (90.6)	36.4 (25.69)				
Missing							
Relugolix+E2/NETA	Baseline	1 (100.0)	25.0 (NE)	NC (NC)	NC	NC	
N=1	Overall	0	NE (NE)		[NC,NC]	[NC,NC]	
Placebo	Baseline	0	NE (NE)	NC (NC)	NC		
N=0	Overall	0	NE (NE)				

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group. Transformed score ranges from 0 to 100 based on Likert scale (None of the time, a little of the time, some of the time, most of the time and all of the time). Higher scores are indicative of better health-related quality of life (high score = good). For the change from baseline, positive scores indicate improvement.
[1] Summary statistics are based on observed data. Mean (SD) are calculated based on the mean observed value across all post-baseline visits within each patient.
[2] LS means, LS mean differences (95% CIs), p-value and Hedges' g (95% CIs) are based on a mixed-effects model with study, treatment, visit, subgroup, treatment-by-visit interaction and a subgroup-by-treatment interaction as fixed effects. The multiple visits for each patient are the repeated measures as a random effect within each patient with an unstructured covariance. Hedges' g is calculated using a small sample bias correction. Missing subgroup levels are not included in estimation of the interaction p-value. The reference group for the LS mean difference and Hedges' g is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with data; CI: Confidence interval; int: Interaction; LS: Least squares; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; SD: Standard deviation; SE: Standard error; SMD: Standardized mean difference; UFS-QoL: Uterine Fibroid Symptom and Health-Related Quality of Life; NC: Not calculated; NE: Non-estimable.

SOURCE: \Studies\MYV\MYV102\Analysis\Prod\Progs\TFLs\Tab_QOL_UFS_CON.SAS
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Table EFF.UFSCONC.MITT.Pooled.S6: Summary of Change from Baseline in UFS-QoL Concern Scale Score by Visit and Overall, by Subgroup (mITT Population)

Study: Pooled

Treatment	Study visit	n (%)[1]	Mean (SD)[1]	Change from baseline LS-mean change (SE)[2]	Difference LS-mean change [95% CI] p-value[2]	SMD Hedges' g [95% CI][2]
Geographic Region I						
North America						
Relugolix+E2/NETA	Baseline	188 (98.4)	22.7 (20.08)	41.32 (2.342)	25.54	0.85
N=191	Week 12	165 (86.4)	63.4 (33.14)		[19.10,31.99]	[0.63,1.08]
Placebo	Baseline	192 (99.0)	21.8 (18.98)	15.77 (2.293)	<.0001	
N=194	Week 12	172 (88.7)	35.9 (26.41)			
Rest of World						
Relugolix+E2/NETA	Baseline	61 (98.4)	27.6 (21.65)	44.90 (3.178)	34.96	1.44
N=62	Week 12	59 (95.2)	71.8 (26.11)		[26.05,43.87]	[1.04,1.85]
Placebo	Baseline	62 (100.0)	29.0 (22.12)	9.94 (3.182)	<.0001	
N=62	Week 12	57 (91.9)	38.4 (23.87)			

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group. Transformed score ranges from 0 to 100 based on Likert scale (None of the time, a little of the time, some of the time, most of the time and all of the time). Higher scores are indicative of better health-related quality of life (high score = good). For the change from baseline, positive scores indicate improvement.
[1] Summary statistics are based on observed data.
[2] LS means, LS mean differences (95% CIs), p-value and Hedges' g (95% CIs) are based on a mixed-effects model with study, treatment, visit, and a treatment-by-visit interaction as fixed effects. The multiple visits for each patient are the repeated measures as a random effect within each patient with an unstructured covariance. Hedges' g is calculated using a small sample bias correction. Interaction p-value is only produced for the Overall period. The reference group for the LS mean difference and Hedges' g is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with data; CI: Confidence interval; LS: Least squares; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; SD: Standard deviation; SE: Standard error; SMD: Standardized mean difference; UFS-QoL: Uterine Fibroid Symptom and Health-Related Quality of Life.

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Table EFF.UFSCONC.MITT.Pooled.S6: Summary of Change from Baseline in UFS-QoL Concern Scale Score by Visit and Overall, by Subgroup (mITT Population)

Study: Pooled

Treatment	Study visit	n (%)[1]	Mean (SD)[1]	Change from baseline LS-mean change (SE)[2]	Difference LS-mean change [95% CI] p-value[2]	SMD Hedges' g [95% CI][2]
Geographic Region I						
North America						
Relugolix+E2/NETA	Baseline	188 (98.4)	22.7 (20.08)	48.89 (2.504)	33.13	1.09
N=191	Week 24	139 (72.8)	73.4 (31.20)		[26.26,40.00]	[0.84,1.34]
Placebo	Baseline	192 (99.0)	21.8 (18.98)	15.77 (2.438)	<.0001	
N=194	Week 24	146 (75.3)	35.8 (27.49)			
Rest of World						
Relugolix+E2/NETA	Baseline	61 (98.4)	27.6 (21.65)	53.52 (3.342)	39.27	1.56
N=62	Week 24	57 (91.9)	81.8 (24.01)		[29.82,48.72]	[1.13,1.98]
Placebo	Baseline	62 (100.0)	29.0 (22.12)	14.25 (3.407)	<.0001	
N=62	Week 24	53 (85.5)	43.0 (26.95)			

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group. Transformed score ranges from 0 to 100 based on Likert scale (None of the time, a little of the time, some of the time, most of the time and all of the time). Higher scores are indicative of better health-related quality of life (high score = good). For the change from baseline, positive scores indicate improvement.
[1] Summary statistics are based on observed data.
[2] LS means, LS mean differences (95% CIs), p-value and Hedges' g (95% CIs) are based on a mixed-effects model with study, treatment, visit, and a treatment-by-visit interaction as fixed effects. The multiple visits for each patient are the repeated measures as a random effect within each patient with an unstructured covariance. Hedges' g is calculated using a small sample bias correction. Interaction p-value is only produced for the Overall period. The reference group for the LS mean difference and Hedges' g is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with data; CI: Confidence interval; LS: Least squares; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; SD: Standard deviation; SE: Standard error; SMD: Standardized mean difference; UFS-QoL: Uterine Fibroid Symptom and Health-Related Quality of Life.

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Table EFF.UFSCONC.MITT.Pooled.S6: Summary of Change from Baseline in UFS-QoL Concern Scale Score by Visit and Overall, by Subgroup (mITT Population)

Study: Pooled

Treatment	Study visit	n (%)[1]	Mean (SD)[1]	Change from baseline LS-mean change (SE)[2]	Difference LS-mean change [95% CI] p-value[2]	SMD Hedges' g [95% CI][2]	Int. p-value[2]
Geographic Region I							
North America							
Relugolix+E2/NETA	Baseline	188 (98.4)	22.7 (20.08)	45.13 (2.066)	29.28	1.02	0.1623
N=191	Overall	169 (88.5)	66.9 (30.14)		[23.60,34.96]	[0.79,1.25]	
Placebo	Baseline	192 (99.0)	21.8 (18.98)	15.84 (2.023)	<.0001		
N=194	Overall	174 (89.7)	35.6 (24.90)				
Rest of World							
Relugolix+E2/NETA	Baseline	61 (98.4)	27.6 (21.65)	49.09 (3.430)	37.19	1.29	
N=62	Overall	59 (95.2)	75.8 (23.71)		[27.64,46.73]	[0.89,1.68]	
Placebo	Baseline	62 (100.0)	29.0 (22.12)	11.91 (3.436)	<.0001		
N=62	Overall	59 (95.2)	40.1 (22.64)				

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group. Transformed score ranges from 0 to 100 based on Likert scale (None of the time, a little of the time, some of the time, most of the time and all of the time). Higher scores are indicative of better health-related quality of life (high score = good). For the change from baseline, positive scores indicate improvement.
[1] Summary statistics are based on observed data. Mean (SD) are calculated based on the mean observed value across all post-baseline visits within each patient.
[2] LS means, LS mean differences (95% CIs), p-value and Hedges' g (95% CIs) are based on a mixed-effects model with study, treatment, visit, subgroup, treatment-by-visit interaction and a subgroup-by-treatment interaction as fixed effects. The multiple visits for each patient are the repeated measures as a random effect within each patient with an unstructured covariance. Hedges' g is calculated using a small sample bias correction. The reference group for the LS mean difference and Hedges' g is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with data; CI: Confidence interval; int: Interaction; LS: Least squares; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; SD: Standard deviation; SE: Standard error; SMD: Standardized mean difference; UFS-QoL: Uterine Fibroid Symptom and Health-Related Quality of Life.

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Table EFF.UFSCONC.MITT.Pooled.S2: Summary of Change from Baseline in UFS-QoL Concern Scale Score by Visit and Overall, by Subgroup (mITT Population)

Study: Pooled

Treatment	Study visit	n (%)[1]	Mean (SD)[1]	Change from baseline LS-mean change (SE)[2]	Difference LS-mean change [95% CI] p-value[2]	SMD Hedges' g [95% CI][2]
BMI (kg/m2) at Baseline						
< 30						
Relugolix+E2/NETA	Baseline	118 (99.2)	23.9 (21.37)	43.32 (2.689)	31.97	1.17
N=119	Week 12	104 (87.4)	67.8 (30.05)		[24.43,39.52]	[0.87,1.47]
Placebo	Baseline	115 (100.0)	25.9 (20.10)	11.35 (2.724)	<.0001	
N=115	Week 12	100 (87.0)	36.3 (25.96)			
>= 30						
Relugolix+E2/NETA	Baseline	130 (97.7)	23.9 (19.91)	41.00 (2.724)	24.19	0.82
N=133	Week 12	119 (89.5)	63.4 (32.86)		[16.76,31.63]	[0.56,1.08]
Placebo	Baseline	139 (98.6)	21.6 (19.76)	16.80 (2.612)	<.0001	
N=141	Week 12	129 (91.5)	36.7 (25.72)			
Missing						
Relugolix+E2/NETA	Baseline	1 (100.0)	25.0 (NE)	NC (NC)	NC	NC
N=1	Week 12	1 (100.0)	100.0 (NE)		[NC,NC]	[NC,NC]
Placebo	Baseline	0	NE (NE)	NC (NC)	NC	
N=0	Week 12	0	NE (NE)			

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group. Transformed score ranges from 0 to 100 based on Likert scale (None of the time, a little of the time, some of the time, most of the time and all of the time). Higher scores are indicative of better health-related quality of life (high score = good). For the change from baseline, positive scores indicate improvement.
[1] Summary statistics are based on observed data.
[2] LS means, LS mean differences (95% CIs), p-value and Hedges' g (95% CIs) are based on a mixed-effects model with study, treatment, visit, and a treatment-by-visit interaction as fixed effects. The multiple visits for each patient are the repeated measures as a random effect within each patient with an unstructured covariance. Hedges' g is calculated using a small sample bias correction. Interaction p-value is only produced for the Overall period. The reference group for the LS mean difference and Hedges' g is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with data; CI: Confidence interval; LS: Least squares; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; SD: Standard deviation; SE: Standard error; SMD: Standardized mean difference; UFS-QoL: Uterine Fibroid Symptom and Health-Related Quality of Life; NC: Not calculated; NE: Non-estimable.

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Table EFF.UFSCONC.MITT.Pooled.S2: Summary of Change from Baseline in UFS-QoL Concern Scale Score by Visit and Overall, by Subgroup (mITT Population)

Study: Pooled

Treatment	Study visit	n (%)[1]	Mean (SD)[1]	Change from baseline LS-mean change (SE)[2]	Difference LS-mean change [95% CI] p-value[2]	SMD Hedges' g [95% CI][2]
BMI (kg/m2) at Baseline						
< 30						
Relugolix+E2/NETA	Baseline	118 (99.2)	23.9 (21.37)	51.28 (2.950)	37.13	1.29
N=119	Week 24	89 (74.8)	77.7 (29.30)		[28.84,45.42]	[0.96,1.61]
Placebo	Baseline	115 (100.0)	25.9 (20.10)	14.15 (2.994)	<.0001	
N=115	Week 24	86 (74.8)	39.8 (27.36)			
>= 30						
Relugolix+E2/NETA	Baseline	130 (97.7)	23.9 (19.91)	49.07 (2.819)	32.46	1.11
N=133	Week 24	106 (79.7)	74.2 (29.78)		[24.76,40.16]	[0.82,1.39]
Placebo	Baseline	139 (98.6)	21.6 (19.76)	16.61 (2.708)	<.0001	
N=141	Week 24	113 (80.1)	36.1 (27.56)			
Missing						
Relugolix+E2/NETA	Baseline	1 (100.0)	25.0 (NE)	NC (NC)	NC	NC
N=1	Week 24	1 (100.0)	90.0 (NE)		[NC,NC]	[NC,NC]
Placebo	Baseline	0	NE (NE)	NC (NC)	NC	
N=0	Week 24	0	NE (NE)			

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group. Transformed score ranges from 0 to 100 based on Likert scale (None of the time, a little of the time, some of the time, most of the time and all of the time). Higher scores are indicative of better health-related quality of life (high score = good). For the change from baseline, positive scores indicate improvement.
[1] Summary statistics are based on observed data.
[2] LS means, LS mean differences (95% CIs), p-value and Hedges' g (95% CIs) are based on a mixed-effects model with study, treatment, visit, and a treatment-by-visit interaction as fixed effects. The multiple visits for each patient are the repeated measures as a random effect within each patient with an unstructured covariance. Hedges' g is calculated using a small sample bias correction. Interaction p-value is only produced for the Overall period. The reference group for the LS mean difference and Hedges' g is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with data; CI: Confidence interval; LS: Least squares; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; SD: Standard deviation; SE: Standard error; SMD: Standardized mean difference; UFS-QoL: Uterine Fibroid Symptom and Health-Related Quality of Life; NC: Not calculated; NE: Non-estimable.

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Table EFF.UFSCONC.MITT.Pooled.S2: Summary of Change from Baseline in UFS-QoL Concern Scale Score by Visit and Overall, by Subgroup (mITT Population)

Study: Pooled

Treatment	Study visit	n (%)[1]	Mean (SD)[1]	Change from baseline LS-mean change (SE)[2]	Difference LS-mean change [95% CI] p-value[2]	SMD Hedges' g [95% CI][2]	Int. p-value[2]
BMI (kg/m2) at Baseline							
< 30							
Relugolix+E2/NETA	Baseline	118 (99.2)	23.9 (21.37)	47.28 (2.587)	34.73	1.21	0.2020
N=119	Overall	106 (89.1)	71.0 (28.34)		[27.50,41.97]	[0.91,1.50]	
Placebo	Baseline	115 (100.0)	25.9 (20.10)	12.55 (2.618)	<.0001		
N=115	Overall	103 (89.6)	37.2 (24.72)				
>= 30							
Relugolix+E2/NETA	Baseline	130 (97.7)	23.9 (19.91)	45.02 (2.434)	28.36	0.99	
N=133	Overall	121 (91.0)	67.4 (29.29)		[21.73,34.99]	[0.72,1.25]	
Placebo	Baseline	139 (98.6)	21.6 (19.76)	16.65 (2.337)	<.0001		
N=141	Overall	130 (92.2)	36.4 (24.19)				
Missing							
Relugolix+E2/NETA	Baseline	1 (100.0)	25.0 (NE)	NC (NC)	NC	NC	
N=1	Overall	1 (100.0)	95.0 (NE)		[NC,NC]	[NC,NC]	
Placebo	Baseline	0	NE (NE)	NC (NC)	NC		
N=0	Overall	0	NE (NE)				

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group. Transformed score ranges from 0 to 100 based on Likert scale (None of the time, a little of the time, some of the time, most of the time and all of the time). Higher scores are indicative of better health-related quality of life (high score = good). For the change from baseline, positive scores indicate improvement.
[1] Summary statistics are based on observed data. Mean (SD) are calculated based on the mean observed value across all post-baseline visits within each patient.
[2] LS means, LS mean differences (95% CIs), p-value and Hedges' g (95% CIs) are based on a mixed-effects model with study, treatment, visit, subgroup, treatment-by-visit interaction and a subgroup-by-treatment interaction as fixed effects. The multiple visits for each patient are the repeated measures as a random effect within each patient with an unstructured covariance. Hedges' g is calculated using a small sample bias correction. Missing subgroup levels are not included in estimation of the interaction p-value. The reference group for the LS mean difference and Hedges' g is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with data; CI: Confidence interval; int: Interaction; LS: Least squares; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; SD: Standard deviation; SE: Standard error; SMD: Standardized mean difference; UFS-QoL: Uterine Fibroid Symptom and Health-Related Quality of Life; NC: Not calculated; NE: Non-estimable.

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Table EFF.UFSCONC.MITT.Pooled.S8: Summary of Change from Baseline in UFS-QoL Concern Scale Score by Visit and Overall, by Subgroup (mITT Population)

Study: Pooled

Treatment	Study visit	n (%)[1]	Mean (SD)[1]	Change from baseline LS-mean change (SE)[2]	Difference LS-mean change [95% CI] p-value[2]	SMD Hedges' g [95% CI][2]
Ethnicity						
Hispanic or Latino						
Relugolix+E2/NETA	Baseline	52 (100.0)	25.7 (19.48)	42.69 (3.863)	23.84	0.92
N=52	Week 12	47 (90.4)	67.4 (29.58)		[13.09,34.60]	[0.50,1.33]
Placebo	Baseline	55 (100.0)	15.4 (14.90)	18.84 (3.735)	<.0001	
N=55	Week 12	49 (89.1)	32.4 (26.16)			
Not Hispanic or Latino						
Relugolix+E2/NETA	Baseline	193 (98.0)	23.0 (20.13)	42.64 (2.244)	29.58	1.01
N=197	Week 12	174 (88.3)	64.8 (32.32)		[23.38,35.78]	[0.79,1.23]
Placebo	Baseline	197 (99.0)	25.9 (20.66)	13.06 (2.205)	<.0001	
N=199	Week 12	178 (89.4)	37.8 (25.68)			
Not reported						
Relugolix+E2/NETA	Baseline	4 (100.0)	46.3 (41.31)	NC (NC)	NC	NC
N=4	Week 12	3 (75.0)	83.3 (15.28)		[NC,NC]	[NC,NC]
Placebo	Baseline	2 (100.0)	17.5 (24.75)	NC (NC)	NC	
N=2	Week 12	2 (100.0)	20.0 (14.14)			

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group. Transformed score ranges from 0 to 100 based on Likert scale (None of the time, a little of the time, some of the time, most of the time and all of the time). Higher scores are indicative of better health-related quality of life (high score = good). For the change from baseline, positive scores indicate improvement.
[1] Summary statistics are based on observed data.
[2] LS means, LS mean differences (95% CIs), p-value and Hedges' g (95% CIs) are based on a mixed-effects model with study, treatment, visit, and a treatment-by-visit interaction as fixed effects. The multiple visits for each patient are the repeated measures as a random effect within each patient with an unstructured covariance. Hedges' g is calculated using a small sample bias correction. Interaction p-value is only produced for the Overall period. The reference group for the LS mean difference and Hedges' g is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with data; CI: Confidence interval; LS: Least squares; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; SD: Standard deviation; SE: Standard error; SMD: Standardized mean difference; UFS-QoL: Uterine Fibroid Symptom and Health-Related Quality of Life; NC: Not calculated.

SOURCE: \Studies\MYV\MYV102\Analysis\Prod\Progs\TFLs\Tab_QOL_UFS_CON.SAS
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Table EFF.UFSCONC.MITT.Pooled.S8: Summary of Change from Baseline in UFS-QoL Concern Scale Score by Visit and Overall, by Subgroup (mITT Population)

Study: Pooled

Treatment	Study visit	n (%)[1]	Mean (SD)[1]	Change from baseline LS-mean change (SE)[2]	Difference LS-mean change [95% CI] p-value[2]	SMD Hedges' g [95% CI][2]
Ethnicity						
Hispanic or Latino						
Relugolix+E2/NETA	Baseline	52 (100.0)	25.7 (19.48)	49.04 (4.573)	29.25	0.97
N=52	Week 24	44 (84.6)	74.4 (28.47)		[16.52,41.97]	[0.53,1.40]
Placebo	Baseline	55 (100.0)	15.4 (14.90)	19.80 (4.426)	<.0001	
N=55	Week 24	46 (83.6)	32.9 (31.07)			
Not Hispanic or Latino						
Relugolix+E2/NETA	Baseline	193 (98.0)	23.0 (20.13)	50.96 (2.287)	36.92	1.29
N=197	Week 24	149 (75.6)	76.1 (30.07)		[30.59,43.24]	[1.04,1.54]
Placebo	Baseline	197 (99.0)	25.9 (20.66)	14.04 (2.253)	<.0001	
N=199	Week 24	151 (75.9)	39.3 (26.21)			
Not reported						
Relugolix+E2/NETA	Baseline	4 (100.0)	46.3 (41.31)	NC (NC)	NC	NC
N=4	Week 24	3 (75.0)	85.0 (15.00)		[NC,NC]	[NC,NC]
Placebo	Baseline	2 (100.0)	17.5 (24.75)	NC (NC)	NC	
N=2	Week 24	2 (100.0)	22.5 (31.82)			

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group. Transformed score ranges from 0 to 100 based on Likert scale (None of the time, a little of the time, some of the time, most of the time and all of the time). Higher scores are indicative of better health-related quality of life (high score = good). For the change from baseline, positive scores indicate improvement.
[1] Summary statistics are based on observed data.
[2] LS means, LS mean differences (95% CIs), p-value and Hedges' g (95% CIs) are based on a mixed-effects model with study, treatment, visit, and a treatment-by-visit interaction as fixed effects. The multiple visits for each patient are the repeated measures as a random effect within each patient with an unstructured covariance. Hedges' g is calculated using a small sample bias correction. Interaction p-value is only produced for the Overall period. The reference group for the LS mean difference and Hedges' g is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with data; CI: Confidence interval; LS: Least squares; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; SD: Standard deviation; SE: Standard error; SMD: Standardized mean difference; UFS-QoL: Uterine Fibroid Symptom and Health-Related Quality of Life; NC: Not calculated.

SOURCE: \Studies\MYV\MYV102\Analysis\Prod\Progs\TFLs\Tab_QOL_UFS_CON.SAS
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Table EFF.UFSCONC.MITT.Pooled.S8: Summary of Change from Baseline in UFS-QoL Concern Scale Score by Visit and Overall, by Subgroup (mITT Population)

Study: Pooled

Treatment	Study visit	n (%)[1]	Mean (SD)[1]	Change from baseline LS-mean change (SE)[2]	Difference LS-mean change [95% CI] p-value[2]	SMD Hedges' g [95% CI][2]	Int. p-value[2]
Ethnicity							
Hispanic or Latino							
Relugolix+E2/NETA	Baseline	52 (100.0)	25.7 (19.48)	45.25 (3.788)	25.74	0.89	0.2215
N=52	Overall	49 (94.2)	70.4 (24.53)		[15.31,36.16]	[0.48,1.30]	
Placebo	Baseline	55 (100.0)	15.4 (14.90)	19.52 (3.697)	<.0001		
N=55	Overall	51 (92.7)	32.8 (26.14)				
Not Hispanic or Latino							
Relugolix+E2/NETA	Baseline	193 (98.0)	23.0 (20.13)	46.74 (2.022)	33.12	1.15	
N=197	Overall	176 (89.3)	68.6 (30.11)		[27.54,38.71]	[0.93,1.38]	
Placebo	Baseline	197 (99.0)	25.9 (20.66)	13.62 (1.988)	<.0001		
N=199	Overall	180 (90.5)	38.0 (23.82)				
Not reported							
Relugolix+E2/NETA	Baseline	4 (100.0)	46.3 (41.31)	NC (NC)	NC	NC	
N=4	Overall	3 (75.0)	84.2 (13.77)		[NC,NC]	[NC,NC]	
Placebo	Baseline	2 (100.0)	17.5 (24.75)	NC (NC)	NC		
N=2	Overall	2 (100.0)	21.3 (22.98)				

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group. Transformed score ranges from 0 to 100 based on Likert scale (None of the time, a little of the time, some of the time, most of the time and all of the time). Higher scores are indicative of better health-related quality of life (high score = good). For the change from baseline, positive scores indicate improvement.
[1] Summary statistics are based on observed data. Mean (SD) are calculated based on the mean observed value across all post-baseline visits within each patient.
[2] LS means, LS mean differences (95% CIs), p-value and Hedges' g (95% CIs) are based on a mixed-effects model with study, treatment, visit, subgroup, treatment-by-visit interaction and a subgroup-by-treatment interaction as fixed effects. The multiple visits for each patient are the repeated measures as a random effect within each patient with an unstructured covariance. Hedges' g is calculated using a small sample bias correction. Not reported subgroup levels are not included in estimation of the interaction p-value. The reference group for the LS mean difference and Hedges' g is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with data; CI: Confidence interval; int: Interaction; LS: Least squares; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; SD: Standard deviation; SE: Standard error; SMD: Standardized mean difference; UFS-QoL: Uterine Fibroid Symptom and Health-Related Quality of Life; NC: Not calculated.

SOURCE: \Studies\MYV\MYV102\Analysis\Prod\Progs\TFLs\Tab_QOL_UFS_CON.SAS
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Table EFF.UFSCONC.MITT.Pooled.S1: Summary of Change from Baseline in UFS-QoL Concern Scale Score by Visit and Overall, by Subgroup (mITT Population)

Study: Pooled

Treatment	Study visit	n (%)[1]	Mean (SD)[1]	Change from baseline LS-mean change (SE)[2]	Difference LS-mean change [95% CI] p-value[2]	SMD Hedges' g [95% CI][2]
Age (years)						
< 40 years						
Relugolix+E2/NETA	Baseline	61 (98.4)	21.9 (19.48)	37.90 (3.919)	25.22	0.86
N=62	Week 12	57 (91.9)	58.6 (34.03)		[14.75,35.68]	[0.50,1.23]
Placebo	Baseline	78 (100.0)	27.1 (22.34)	12.68 (3.550)	<.0001	
N=78	Week 12	68 (87.2)	37.6 (26.80)			
>= 40 years						
Relugolix+E2/NETA	Baseline	188 (98.4)	24.6 (20.88)	43.74 (2.200)	28.71	1.02
N=191	Week 12	167 (87.4)	68.0 (30.47)		[22.55,34.88]	[0.79,1.25]
Placebo	Baseline	176 (98.9)	22.0 (18.70)	15.02 (2.235)	<.0001	
N=178	Week 12	161 (90.4)	36.1 (25.39)			

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group. Transformed score ranges from 0 to 100 based on Likert scale (None of the time, a little of the time, some of the time, most of the time and all of the time). Higher scores are indicative of better health-related quality of life (high score = good). For the change from baseline, positive scores indicate improvement.
[1] Summary statistics are based on observed data.
[2] LS means, LS mean differences (95% CIs), p-value and Hedges' g (95% CIs) are based on a mixed-effects model with study, treatment, visit, and a treatment-by-visit interaction as fixed effects. The multiple visits for each patient are the repeated measures as a random effect within each patient with an unstructured covariance. Hedges' g is calculated using a small sample bias correction. Interaction p-value is only produced for the Overall period. The reference group for the LS mean difference and Hedges' g is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with data; CI: Confidence interval; LS: Least squares; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; SD: Standard deviation; SE: Standard error; SMD: Standardized mean difference; UFS-QoL: Uterine Fibroid Symptom and Health-Related Quality of Life.

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Table EFF.UFSCONC.MITT.Pooled.S1: Summary of Change from Baseline in UFS-QoL Concern Scale Score by Visit and Overall, by Subgroup (mITT Population)

Study: Pooled

Treatment	Study visit	n (%)[1]	Mean (SD)[1]	Change from baseline LS-mean change (SE)[2]	Difference LS-mean change [95% CI] p-value[2]	SMD Hedges' g [95% CI][2]
Age (years)						
< 40 years						
Relugolix+E2/NETA	Baseline	61 (98.4)	21.9 (19.48)	44.67 (4.105)	29.87	1.03
N=62	Week 24	47 (75.8)	66.5 (32.37)		[18.98,40.76]	[0.62,1.44]
Placebo	Baseline	78 (100.0)	27.1 (22.34)	14.80 (3.670)	<.0001	
N=78	Week 24	58 (74.4)	41.8 (26.50)			
>= 40 years						
Relugolix+E2/NETA	Baseline	188 (98.4)	24.6 (20.88)	51.94 (2.341)	36.22	1.25
N=191	Week 24	149 (78.0)	78.8 (27.98)		[29.64,42.81]	[1.00,1.50]
Placebo	Baseline	176 (98.9)	22.0 (18.70)	15.71 (2.392)	<.0001	
N=178	Week 24	141 (79.2)	36.0 (27.77)			

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group. Transformed score ranges from 0 to 100 based on Likert scale (None of the time, a little of the time, some of the time, most of the time and all of the time). Higher scores are indicative of better health-related quality of life (high score = good). For the change from baseline, positive scores indicate improvement.
[1] Summary statistics are based on observed data.
[2] LS means, LS mean differences (95% CIs), p-value and Hedges' g (95% CIs) are based on a mixed-effects model with study, treatment, visit, and a treatment-by-visit interaction as fixed effects. The multiple visits for each patient are the repeated measures as a random effect within each patient with an unstructured covariance. Hedges' g is calculated using a small sample bias correction. Interaction p-value is only produced for the Overall period. The reference group for the LS mean difference and Hedges' g is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with data; CI: Confidence interval; LS: Least squares; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; SD: Standard deviation; SE: Standard error; SMD: Standardized mean difference; UFS-QoL: Uterine Fibroid Symptom and Health-Related Quality of Life.

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Table EFF.UFSCONC.MITT.Pooled.S1: Summary of Change from Baseline in UFS-QoL Concern Scale Score by Visit and Overall, by Subgroup (mITT Population)

Study: Pooled

Treatment	Study visit	n (%)[1]	Mean (SD)[1]	Change from baseline LS-mean change (SE)[2]	Difference LS-mean change [95% CI] p-value[2]	SMD Hedges' g [95% CI][2]	Int. p-value[2]
Age (years)							
< 40 years							
Relugolix+E2/NETA	Baseline	61 (98.4)	21.9 (19.48)	41.23 (3.539)	27.64	0.96	0.3884
N=62	Overall	57 (91.9)	61.4 (30.52)		[18.27,37.02]	[0.59,1.33]	
Placebo	Baseline	78 (100.0)	27.1 (22.34)	13.58 (3.200)	<.0001		
N=78	Overall	68 (87.2)	38.3 (24.06)				
>= 40 years							
Relugolix+E2/NETA	Baseline	188 (98.4)	24.6 (20.88)	47.83 (2.038)	32.46	1.13	
N=191	Overall	171 (89.5)	71.8 (27.85)		[26.75,38.17]	[0.90,1.36]	
Placebo	Baseline	176 (98.9)	22.0 (18.70)	15.36 (2.073)	<.0001		
N=178	Overall	165 (92.7)	36.1 (24.54)				

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group. Transformed score ranges from 0 to 100 based on Likert scale (None of the time, a little of the time, some of the time, most of the time and all of the time). Higher scores are indicative of better health-related quality of life (high score = good). For the change from baseline, positive scores indicate improvement.
[1] Summary statistics are based on observed data. Mean (SD) are calculated based on the mean observed value across all post-baseline visits within each patient.
[2] LS means, LS mean differences (95% CIs), p-value and Hedges' g (95% CIs) are based on a mixed-effects model with study, treatment, visit, subgroup, treatment-by-visit interaction and a subgroup-by-treatment interaction as fixed effects. The multiple visits for each patient are the repeated measures as a random effect within each patient with an unstructured covariance. Hedges' g is calculated using a small sample bias correction. The reference group for the LS mean difference and Hedges' g is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with data; CI: Confidence interval; int: Interaction; LS: Least squares; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; SD: Standard deviation; SE: Standard error; SMD: Standardized mean difference; UFS-QoL: Uterine Fibroid Symptom and Health-Related Quality of Life.

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Table EFF.UFSCONC.MITT.Pooled.S7: Summary of Change from Baseline in UFS-QoL Concern Scale Score by Visit and Overall, by Subgroup (mITT Population)

Study: Pooled

Treatment	Study visit	n (%)[1]	Mean (SD)[1]	Change from baseline LS-mean change (SE)[2]	Difference LS-mean change [95% CI] p-value[2]	SMD Hedges' g [95% CI][2]
Geographic Region II						
Europe						
Relugolix+E2/NETA	Baseline	40 (97.6)	29.6 (22.17)	41.49 (4.112)	31.85	1.26
N=41	Week 12	39 (95.1)	70.4 (29.50)		[20.29,43.41]	[0.77,1.74]
Placebo	Baseline	42 (100.0)	33.0 (22.39)	9.64 (4.125)	<.0001	
N=42	Week 12	39 (92.9)	42.6 (22.47)			
Rest of World (including the US)						
Relugolix+E2/NETA	Baseline	209 (98.6)	22.8 (20.08)	42.35 (2.160)	27.23	0.93
N=212	Week 12	185 (87.3)	64.6 (32.01)		[21.27,33.20]	[0.72,1.15]
Placebo	Baseline	212 (99.1)	21.7 (18.98)	15.12 (2.128)	<.0001	
N=214	Week 12	190 (88.8)	35.3 (26.28)			

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group. Transformed score ranges from 0 to 100 based on Likert scale (None of the time, a little of the time, some of the time, most of the time and all of the time). Higher scores are indicative of better health-related quality of life (high score = good). For the change from baseline, positive scores indicate improvement.
[1] Summary statistics are based on observed data.
[2] LS means, LS mean differences (95% CIs), p-value and Hedges' g (95% CIs) are based on a mixed-effects model with study, treatment, visit, and a treatment-by-visit interaction as fixed effects. The multiple visits for each patient are the repeated measures as a random effect within each patient with an unstructured covariance. Hedges' g is calculated using a small sample bias correction. Interaction p-value is only produced for the Overall period. The reference group for the LS mean difference and Hedges' g is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with data; CI: Confidence interval; LS: Least squares; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; SD: Standard deviation; SE: Standard error; SMD: Standardized mean difference; UFS-QoL: Uterine Fibroid Symptom and Health-Related Quality of Life.

SOURCE: \Studies\MYV\MYV102\Analysis\Prod\Progs\TFLs\Tab_QOL_UFS_CON.SAS
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Table EFF.UFSCONC.MITT.Pooled.S7: Summary of Change from Baseline in UFS-QoL Concern Scale Score by Visit and Overall, by Subgroup (mITT Population)

Study: Pooled

Treatment	Study visit	n (%)[1]	Mean (SD)[1]	Change from baseline LS-mean change (SE)[2]	Difference LS-mean change [95% CI] p-value[2]	SMD Hedges' g [95% CI][2]
Geographic Region II						
Europe						
Relugolix+E2/NETA	Baseline	40 (97.6)	29.6 (22.17)	52.52 (4.180)	39.35	1.54
N=41	Week 24	37 (90.2)	83.5 (25.30)		[27.44,51.27]	[1.02,2.06]
Placebo	Baseline	42 (100.0)	33.0 (22.39)	13.17 (4.301)	<.0001	
N=42	Week 24	35 (83.3)	47.3 (23.43)			
Rest of World (including the US)						
Relugolix+E2/NETA	Baseline	209 (98.6)	22.8 (20.08)	49.54 (2.304)	33.84	1.14
N=212	Week 24	159 (75.0)	74.1 (30.16)		[27.49,40.18]	[0.90,1.37]
Placebo	Baseline	212 (99.1)	21.7 (18.98)	15.70 (2.261)	<.0001	
N=214	Week 24	164 (76.6)	35.6 (27.89)			

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group. Transformed score ranges from 0 to 100 based on Likert scale (None of the time, a little of the time, some of the time, most of the time and all of the time). Higher scores are indicative of better health-related quality of life (high score = good). For the change from baseline, positive scores indicate improvement.
[1] Summary statistics are based on observed data.
[2] LS means, LS mean differences (95% CIs), p-value and Hedges' g (95% CIs) are based on a mixed-effects model with study, treatment, visit, and a treatment-by-visit interaction as fixed effects. The multiple visits for each patient are the repeated measures as a random effect within each patient with an unstructured covariance. Hedges' g is calculated using a small sample bias correction. Interaction p-value is only produced for the Overall period. The reference group for the LS mean difference and Hedges' g is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with data; CI: Confidence interval; LS: Least squares; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; SD: Standard deviation; SE: Standard error; SMD: Standardized mean difference; UFS-QoL: Uterine Fibroid Symptom and Health-Related Quality of Life.

SOURCE: \Studies\MYV\MYV102\Analysis\Prod\Progs\TFLs\Tab_QOL_UFS_CON.SAS
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Table EFF.UFSCONC.MITT.Pooled.S7: Summary of Change from Baseline in UFS-QoL Concern Scale Score by Visit and Overall, by Subgroup (mITT Population)

Study: Pooled

Treatment	Study visit	n (%)[1]	Mean (SD)[1]	Change from baseline LS-mean change (SE)[2]	Difference LS-mean change [95% CI] p-value[2]	SMD Hedges' g [95% CI][2]	Int. p-value[2]
Geographic Region II							
Europe							0.4861
Relugolix+E2/NETA	Baseline	40 (97.6)	29.6 (22.17)	46.95 (4.246)	35.13	1.21	
N=41	Overall	39 (95.1)	75.4 (26.32)		[23.40,46.86]	[0.73,1.69]	
Placebo	Baseline	42 (100.0)	33.0 (22.39)	11.82 (4.202)	<.0001		
N=42	Overall	40 (95.2)	44.2 (19.74)				
Rest of World (including the US)							
Relugolix+E2/NETA	Baseline	209 (98.6)	22.8 (20.08)	46.02 (1.950)	30.56	1.06	
N=212	Overall	189 (89.2)	67.9 (29.22)		[25.18,35.94]	[0.85,1.28]	
Placebo	Baseline	212 (99.1)	21.7 (18.98)	15.46 (1.921)	<.0001		
N=214	Overall	193 (90.2)	35.2 (25.00)				

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group. Transformed score ranges from 0 to 100 based on Likert scale (None of the time, a little of the time, some of the time, most of the time and all of the time). Higher scores are indicative of better health-related quality of life (high score = good). For the change from baseline, positive scores indicate improvement.
[1] Summary statistics are based on observed data. Mean (SD) are calculated based on the mean observed value across all post-baseline visits within each patient.
[2] LS means, LS mean differences (95% CIs), p-value and Hedges' g (95% CIs) are based on a mixed-effects model with study, treatment, visit, subgroup, treatment-by-visit interaction and a subgroup-by-treatment interaction as fixed effects. The multiple visits for each patient are the repeated measures as a random effect within each patient with an unstructured covariance. Hedges' g is calculated using a small sample bias correction. The reference group for the LS mean difference and Hedges' g is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with data; CI: Confidence interval; int: Interaction; LS: Least squares; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; SD: Standard deviation; SE: Standard error; SMD: Standardized mean difference; UFS-QoL: Uterine Fibroid Symptom and Health-Related Quality of Life.

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Table EFF.UFSCONC.MITT.Pooled.S9: Summary of Change from Baseline in UFS-QoL Concern Scale Score by Visit and Overall, by Subgroup (mITT Population)

Study: Pooled

Treatment	Study visit	n (%)[1]	Mean (SD)[1]	Change from baseline LS-mean change (SE)[2]	Difference LS-mean change [95% CI] p-value[2]	SMD Hedges' g [95% CI][2]
Race						
Black/African American						
Relugolix+E2/NETA	Baseline	119 (97.5)	18.9 (18.67)	43.41 (2.878)	29.24	1.00
N=122	Week 12	105 (86.1)	61.0 (33.35)		[21.54,36.94]	[0.72,1.28]
Placebo	Baseline	139 (98.6)	23.3 (20.14)	14.18 (2.643)	<.0001	
N=141	Week 12	122 (86.5)	35.7 (26.15)			
White						
Relugolix+E2/NETA	Baseline	121 (99.2)	27.6 (20.12)	41.93 (2.701)	27.81	0.99
N=122	Week 12	110 (90.2)	69.5 (30.07)		[20.06,35.57]	[0.70,1.28]
Placebo	Baseline	105 (100.0)	24.3 (20.20)	14.11 (2.862)	<.0001	
N=105	Week 12	98 (93.3)	38.0 (24.90)			
Asian						
Relugolix+E2/NETA	Baseline	1 (100.0)	35.0 (NE)	NC (NC)	NC	NC
N=1	Week 12	1 (100.0)	90.0 (NE)		[NC,NC]	[NC,NC]
Placebo	Baseline	3 (100.0)	18.3 (16.07)	NC (NC)	NC	
N=3	Week 12	3 (100.0)	25.0 (18.03)			
Others						
Relugolix+E2/NETA	Baseline	5 (100.0)	30.0 (28.50)	32.33 (16.940)	5.43	0.16
N=5	Week 12	5 (100.0)	65.0 (24.75)		[-50.71,61.58]	[-0.96,1.28]
Placebo	Baseline	6 (100.0)	16.7 (17.51)	26.89 (15.687)	0.8255	
N=6	Week 12	5 (83.3)	37.0 (42.22)			
Not reported						
Relugolix+E2/NETA	Baseline	3 (100.0)	61.7 (35.47)	NC (NC)	NC	NC
N=3	Week 12	3 (100.0)	78.3 (22.55)		[NC,NC]	[NC,NC]
Placebo	Baseline	1 (100.0)	35.0 (NE)	NC (NC)	NC	

N=1	Week 12	1 (100.0)	30.0 (NE)			

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group. Transformed score ranges from 0 to 100 based on Likert scale (None of the time, a little of the time, some of the time, most of the time and all of the time). Higher scores are indicative of better health-related quality of life (high score = good). For the change from baseline, positive scores indicate improvement.
[1] Summary statistics are based on observed data.
[2] LS means, LS mean differences (95% CIs), p-value and Hedges' g (95% CIs) are based on a mixed-effects model with study, treatment, visit, and a treatment-by-visit interaction as fixed effects. The multiple visits for each patient are the repeated measures as a random effect within each patient with an unstructured covariance. Hedges' g is calculated using a small sample bias correction. Interaction p-value is only produced for the Overall period. The reference group for the LS mean difference and Hedges' g is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with data; CI: Confidence interval; LS: Least squares; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; SD: Standard deviation; SE: Standard error; SMD: Standardized mean difference; UFS-QoL: Uterine Fibroid Symptom and Health-Related Quality of Life; NC: Not calculated; NE: Non-estimable.

Table EFF.UFSCONC.MITT.Pooled.S9: Summary of Change from Baseline in UFS-QoL Concern Scale Score by Visit and Overall, by Subgroup (mITT Population)						
Study: Pooled						
Treatment	**Study visit**	**n (%)[1]**	**Mean (SD)[1]**	**Change from baseline LS-mean change (SE)[2]**	**Difference LS-mean change [95% CI] p-value[2]**	**SMD Hedges' g [95% CI][2]**
Race						
Black/African American						
Relugolix+E2/NETA	Baseline	119 (97.5)	18.9 (18.67)	49.68 (3.078)	34.48	1.16
N=122	Week 24	87 (71.3)	70.4 (31.97)		[26.32,42.64]	[0.86,1.47]
Placebo	Baseline	139 (98.6)	23.3 (20.14)	15.20 (2.773)	<.0001	
N=141	Week 24	108 (76.6)	36.7 (27.14)			
White						
Relugolix+E2/NETA	Baseline	121 (99.2)	27.6 (20.12)	52.43 (2.771)	36.12	1.29
N=122	Week 24	100 (82.0)	81.3 (25.67)		[28.08,44.15]	[0.97,1.60]
Placebo	Baseline	105 (100.0)	24.3 (20.20)	16.31 (2.996)	<.0001	
N=105	Week 24	84 (80.0)	40.7 (27.81)			
Asian						
Relugolix+E2/NETA	Baseline	1 (100.0)	35.0 (NE)	NC (NC)	NC	NC
N=1	Week 24	1 (100.0)	100.0 (NE)		[NC,NC]	[NC,NC]
Placebo	Baseline	3 (100.0)	18.3 (16.07)	NC (NC)	NC	
N=3	Week 24	2 (66.7)	25.0 (28.28)			
Others						
Relugolix+E2/NETA	Baseline	5 (100.0)	30.0 (28.50)	21.33 (16.917)	15.87	0.46
N=5	Week 24	5 (100.0)	54.0 (42.63)		[-43.16,74.90]	[-0.73,1.64]
Placebo	Baseline	6 (100.0)	16.7 (17.51)	5.46 (17.005)	0.5452	
N=6	Week 24	4 (66.7)	5.0 (4.08)			
Not reported						
Relugolix+E2/NETA	Baseline	3 (100.0)	61.7 (35.47)	NC (NC)	NC	NC
N=3	Week 24	3 (100.0)	81.7 (16.07)		[NC,NC]	[NC,NC]
Placebo	Baseline	1 (100.0)	35.0 (NE)	NC (NC)	NC	

N=1	Week 24	1 (100.0)	45.0 (NE)			

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group. Transformed score ranges from 0 to 100 based on Likert scale (None of the time, a little of the time, some of the time, most of the time and all of the time). Higher scores are indicative of better health-related quality of life (high score = good). For the change from baseline, positive scores indicate improvement.
[1] Summary statistics are based on observed data.
[2] LS means, LS mean differences (95% CIs), p-value and Hedges' g (95% CIs) are based on a mixed-effects model with study, treatment, visit, and a treatment-by-visit interaction as fixed effects. The multiple visits for each patient are the repeated measures as a random effect within each patient with an unstructured covariance. Hedges' g is calculated using a small sample bias correction. Interaction p-value is only produced for the Overall period. The reference group for the LS mean difference and Hedges' g is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with data; CI: Confidence interval; LS: Least squares; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; SD: Standard deviation; SE: Standard error; SMD: Standardized mean difference; UFS-QoL: Uterine Fibroid Symptom and Health-Related Quality of Life; NC: Not calculated; NE: Non-estimable.

Table EFF.UFSCONC.MITT.Pooled.S9: Summary of Change from Baseline in UFS-QoL Concern Scale Score by Visit and Overall, by Subgroup (mITT Population)							
Study: Pooled							
Treatment	**Study visit**	**n (%)[1]**	**Mean (SD)[1]**	**Change from baseline LS-mean change (SE)[2]**	**Difference LS-mean change [95% CI] p-value[2]**	**SMD Hedges' g [95% CI][2]**	**Int. p-value[2]**
Race							
Black/African American							
Relugolix+E2/NETA	Baseline	119 (97.5)	18.9 (18.67)	46.80 (2.620)	32.08	1.11	0.5267
N=122	Overall	107 (87.7)	64.1 (31.27)		[25.11,39.05]	[0.83,1.39]	
Placebo	Baseline	139 (98.6)	23.3 (20.14)	14.72 (2.390)	<.0001		
N=141	Overall	126 (89.4)	35.8 (24.96)				
White							
Relugolix+E2/NETA	Baseline	121 (99.2)	27.6 (20.12)	47.03 (2.516)	31.83	1.10	
N=122	Overall	112 (91.8)	74.0 (25.70)		[24.60,39.05]	[0.81,1.39]	
Placebo	Baseline	105 (100.0)	24.3 (20.20)	15.21 (2.685)	<.0001		
N=105	Overall	98 (93.3)	38.6 (23.30)				
Asian							
Relugolix+E2/NETA	Baseline	1 (100.0)	35.0 (NE)	NC (NC)	NC	NC	
N=1	Overall	1 (100.0)	95.0 (NE)		[NC,NC]	[NC,NC]	
Placebo	Baseline	3 (100.0)	18.3 (16.07)	NC (NC)	NC		
N=3	Overall	3 (100.0)	25.8 (19.09)				
Others							
Relugolix+E2/NETA	Baseline	5 (100.0)	30.0 (28.50)	29.96 (11.735)	12.78	0.40	
N=5	Overall	5 (100.0)	59.5 (32.37)		[-20.14,45.69]	[-0.73,1.53]	
Placebo	Baseline	6 (100.0)	16.7 (17.51)	17.18 (11.927)	0.4459		
N=6	Overall	5 (83.3)	29.5 (37.10)				
Not reported							
Relugolix+E2/NETA	Baseline	3 (100.0)	61.7 (35.47)	NC (NC)	NC	NC	
N=3	Overall	3 (100.0)	80.0 (18.03)		[NC,NC]	[NC,NC]	
Placebo	Baseline	1 (100.0)	35.0 (NE)	NC (NC)	NC		

N=1	Overall	1 (100.0)	37.5 (NE)				

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group. Transformed score ranges from 0 to 100 based on Likert scale (None of the time, a little of the time, some of the time, most of the time and all of the time). Higher scores are indicative of better health-related quality of life (high score = good). For the change from baseline, positive scores indicate improvement.
[1] Summary statistics are based on observed data. Mean (SD) are calculated based on the mean observed value across all post-baseline visits within each patient.
[2] LS means, LS mean differences (95% CIs), p-value and Hedges' g (95% CIs) are based on a mixed-effects model with study, treatment, visit, subgroup, treatment-by-visit interaction and a subgroup-by-treatment interaction as fixed effects. The multiple visits for each patient are the repeated measures as a random effect within each patient with an unstructured covariance. Hedges' g is calculated using a small sample bias correction. Not reported subgroup levels are not included in estimation of the interaction p-value. Subgroup levels with fewer than 10 subjects are not included in estimation of the interaction p-value. The reference group for the LS mean difference and Hedges' g is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with data; CI: Confidence interval; int: Interaction; LS: Least squares; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; SD: Standard deviation; SE: Standard error; SMD: Standardized mean difference; UFS-QoL: Uterine Fibroid Symptom and Health-Related Quality of Life; NC: Not calculated; NE: Non-estimable.

SOURCE: \Studies\MYV\MYV102\Analysis\Prod\Progs\TFLs\Tab_QOL_UFS_CON.SAS
Date/time of run: 20APR2021 16:38

Table EFF.UFSCONC.MITT.Pooled.S4: Summary of Change from Baseline in UFS-QoL Concern Scale Score by Visit and Overall, by Subgroup (mITT Population)

Study: Pooled

Treatment	Study visit	n (%)[1]	Mean (SD)[1]	Change from baseline LS-mean change (SE)[2]	Difference LS-mean change [95% CI] p-value[2]	SMD Hedges' g [95% CI][2]
Maximum NRS Pain Score at Baseline						
< 4						
Relugolix+E2/NETA	Baseline	72 (98.6)	26.8 (20.95)	41.77 (3.359)	32.61	1.21
N=73	Week 12	65 (89.0)	68.7 (33.12)		[22.67,42.56]	[0.82,1.61]
Placebo	Baseline	61 (98.4)	29.8 (21.97)	9.16 (3.745)	<.0001	
N=62	Week 12	52 (83.9)	36.3 (24.05)			
>= 4						
Relugolix+E2/NETA	Baseline	174 (98.3)	22.8 (20.45)	42.61 (2.350)	26.99	0.93
N=177	Week 12	156 (88.1)	64.8 (31.01)		[20.64,33.34]	[0.70,1.16]
Placebo	Baseline	189 (99.5)	21.9 (19.03)	15.63 (2.212)	<.0001	
N=190	Week 12	174 (91.6)	36.7 (26.38)			
Missing						
Relugolix+E2/NETA	Baseline	3 (100.0)	18.3 (10.41)	NC (NC)	NC	NC
N=3	Week 12	3 (100.0)	38.3 (15.28)		[NC,NC]	[NC,NC]
Placebo	Baseline	4 (100.0)	7.5 (6.45)	NC (NC)	NC	
N=4	Week 12	3 (75.0)	28.3 (25.66)			

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group. Transformed score ranges from 0 to 100 based on Likert scale (None of the time, a little of the time, some of the time, most of the time and all of the time). Higher scores are indicative of better health-related quality of life (high score = good). For the change from baseline, positive scores indicate improvement.
[1] Summary statistics are based on observed data.
[2] LS means, LS mean differences (95% CIs), p-value and Hedges' g (95% CIs) are based on a mixed-effects model with study, treatment, visit, and a treatment-by-visit interaction as fixed effects. The multiple visits for each patient are the repeated measures as a random effect within each patient with an unstructured covariance. Hedges' g is calculated using a small sample bias correction. Interaction p-value is only produced for the Overall period. The reference group for the LS mean difference and Hedges' g is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with data; CI: Confidence interval; LS: Least squares; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; SD: Standard deviation; SE: Standard error; SMD: Standardized mean difference; UFS-QoL: Uterine Fibroid Symptom and Health-Related Quality of Life; NC: Not calculated.

SOURCE: \Studies\MYV\MYV102\Analysis\Prod\Progs\TFLs\Tab_QOL_UFS_CON.SAS
Date/time of run: 20APR2021 16:38
Analysis Plan: 13JAN2021

Table EFF.UFSCONC.MITT.Pooled.S4: Summary of Change from Baseline in UFS-QoL Concern Scale Score by Visit and Overall, by Subgroup (mITT Population)

Study: Pooled

Treatment	Study visit	n (%)[1]	Mean (SD)[1]	Change from baseline LS-mean change (SE)[2]	Difference LS-mean change [95% CI] p-value[2]	SMD Hedges' g [95% CI][2]
Maximum NRS Pain Score at Baseline						
< 4						
Relugolix+E2/NETA	Baseline	72 (98.6)	26.8 (20.95)	48.84 (3.701)	34.31	1.21
N=73	Week 24	57 (78.1)	78.7 (29.78)		[23.32,45.30]	[0.79,1.63]
Placebo	Baseline	61 (98.4)	29.8 (21.97)	14.53 (4.142)	<.0001	
N=62	Week 24	46 (74.2)	43.0 (26.49)			
>= 4						
Relugolix+E2/NETA	Baseline	174 (98.3)	22.8 (20.45)	51.14 (2.455)	35.56	1.21
N=177	Week 24	136 (76.8)	75.4 (28.86)		[28.93,42.19]	[0.96,1.47]
Placebo	Baseline	189 (99.5)	21.9 (19.03)	15.59 (2.309)	<.0001	
N=190	Week 24	151 (79.5)	36.3 (27.74)			
Missing						
Relugolix+E2/NETA	Baseline	3 (100.0)	18.3 (10.41)	NC (NC)	NC	NC
N=3	Week 24	3 (100.0)	40.0 (39.05)		[NC,NC]	[NC,NC]
Placebo	Baseline	4 (100.0)	7.5 (6.45)	NC (NC)	NC	
N=4	Week 24	2 (50.0)	22.5 (17.68)			

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group. Transformed score ranges from 0 to 100 based on Likert scale (None of the time, a little of the time, some of the time, most of the time and all of the time). Higher scores are indicative of better health-related quality of life (high score = good). For the change from baseline, positive scores indicate improvement.
[1] Summary statistics are based on observed data.
[2] LS means, LS mean differences (95% CIs), p-value and Hedges' g (95% CIs) are based on a mixed-effects model with study, treatment, visit, and a treatment-by-visit interaction as fixed effects. The multiple visits for each patient are the repeated measures as a random effect within each patient with an unstructured covariance. Hedges' g is calculated using a small sample bias correction. Interaction p-value is only produced for the Overall period. The reference group for the LS mean difference and Hedges' g is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with data; CI: Confidence interval; LS: Least squares; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; SD: Standard deviation; SE: Standard error; SMD: Standardized mean difference; UFS-QoL: Uterine Fibroid Symptom and Health-Related Quality of Life; NC: Not calculated.

SOURCE: \Studies\MYV\MYV102\Analysis\Prod\Progs\TFLs\Tab_QOL_UFS_CON.SAS
Date/time of run: 20APR2021 16:38
Analysis Plan: 13JAN2021

Table EFF.UFSCONC.MITT.Pooled.S4: Summary of Change from Baseline in UFS-QoL Concern Scale Score by Visit and Overall, by Subgroup (mITT Population)

Study: Pooled

Treatment	Study visit	n (%)[1]	Mean (SD)[1]	Change from baseline LS-mean change (SE)[2]	Difference LS-mean change [95% CI] p-value[2]	SMD Hedges' g [95% CI][2]	Int. p-value[2]
Maximum NRS Pain Score at Baseline							
< 4							
Relugolix+E2/NETA	Baseline	72 (98.6)	26.8 (20.95)	45.67 (3.278)	33.92	1.18	0.6406
N=73	Overall	66 (90.4)	71.8 (30.36)		[24.29,43.55]	[0.78,1.57]	
Placebo	Baseline	61 (98.4)	29.8 (21.97)	11.75 (3.646)	<.0001		
N=62	Overall	54 (87.1)	38.0 (22.64)				
>= 4							
Relugolix+E2/NETA	Baseline	174 (98.3)	22.8 (20.45)	46.91 (2.123)	31.26	1.09	
N=177	Overall	159 (89.8)	68.7 (28.03)		[25.52,36.99]	[0.86,1.32]	
Placebo	Baseline	189 (99.5)	21.9 (19.03)	15.66 (2.001)	<.0001		
N=190	Overall	176 (92.6)	36.5 (25.02)				
Missing							
Relugolix+E2/NETA	Baseline	3 (100.0)	18.3 (10.41)	NC (NC)	NC	NC	
N=3	Overall	3 (100.0)	39.2 (26.73)		[NC,NC]	[NC,NC]	
Placebo	Baseline	4 (100.0)	7.5 (6.45)	NC (NC)	NC		
N=4	Overall	3 (75.0)	27.5 (19.84)				

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group. Transformed score ranges from 0 to 100 based on Likert scale (None of the time, a little of the time, some of the time, most of the time and all of the time). Higher scores are indicative of better health-related quality of life (high score = good). For the change from baseline, positive scores indicate improvement.
[1] Summary statistics are based on observed data. Mean (SD) are calculated based on the mean observed value across all post-baseline visits within each patient.
[2] LS means, LS mean differences (95% CIs), p-value and Hedges' g (95% CIs) are based on a mixed-effects model with study, treatment, visit, subgroup, treatment-by-visit interaction and a subgroup-by-treatment interaction as fixed effects. The multiple visits for each patient are the repeated measures as a random effect within each patient with an unstructured covariance. Hedges' g is calculated using a small sample bias correction. Missing subgroup levels are not included in estimation of the interaction p-value. The reference group for the LS mean difference and Hedges' g is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with data; CI: Confidence interval; int: Interaction; LS: Least squares; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; SD: Standard deviation; SE: Standard error; SMD: Standardized mean difference; UFS-QoL: Uterine Fibroid Symptom and Health-Related Quality of Life; NC: Not calculated.

SOURCE: \Studies\MYV\MYV102\Analysis\Prod\Progs\TFLs\Tab_QOL_UFS_CON.SAS
Date/time of run: 20APR2021 16:38
Analysis Plan: 13JAN2021

Table EFF.UFSCONC.MITT.Pooled.S5: Summary of Change from Baseline in UFS-QoL Concern Scale Score by Visit and Overall, by Subgroup (mITT Population)

Study: Pooled

Treatment	Study visit	n (%)[1]	Mean (SD)[1]	Change from baseline LS-mean change (SE)[2]	Difference LS-mean change [95% CI] p-value[2]	SMD Hedges' g [95% CI][2]
MBL Volume at Baseline (mL)						
< 225 mL						
Relugolix+E2/NETA	Baseline	163 (99.4)	25.7 (19.28)	41.18 (2.357)	26.46	0.93
N=164	Week 12	147 (89.6)	67.3 (31.03)		[19.97,32.94]	[0.69,1.17]
Placebo	Baseline	170 (99.4)	24.6 (20.07)	14.72 (2.305)	<.0001	
N=171	Week 12	153 (89.5)	38.3 (26.46)			
>= 225 mL						
Relugolix+E2/NETA	Baseline	86 (96.6)	20.6 (22.46)	44.40 (3.335)	31.00	1.08
N=89	Week 12	77 (86.5)	62.4 (32.62)		[21.67,40.33]	[0.73,1.42]
Placebo	Baseline	84 (98.8)	21.5 (19.77)	13.40 (3.337)	<.0001	
N=85	Week 12	76 (89.4)	32.9 (24.09)			

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group. Transformed score ranges from 0 to 100 based on Likert scale (None of the time, a little of the time, some of the time, most of the time and all of the time). Higher scores are indicative of better health-related quality of life (high score = good). For the change from baseline, positive scores indicate improvement.
[1] Summary statistics are based on observed data.
[2] LS means, LS mean differences (95% CIs), p-value and Hedges' g (95% CIs) are based on a mixed-effects model with study, treatment, visit, and a treatment-by-visit interaction as fixed effects. The multiple visits for each patient are the repeated measures as a random effect within each patient with an unstructured covariance. Hedges' g is calculated using a small sample bias correction. Interaction p-value is only produced for the Overall period. The reference group for the LS mean difference and Hedges' g is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with data; CI: Confidence interval; LS: Least squares; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; SD: Standard deviation; SE: Standard error; SMD: Standardized mean difference; UFS-QoL: Uterine Fibroid Symptom and Health-Related Quality of Life.

SOURCE: \Studies\MYV\MYV102\Analysis\Prod\Progs\TFLs\Tab_QOL_UFS_CON.SAS
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Table EFF.UFSCONC.MITT.Pooled.S5: Summary of Change from Baseline in UFS-QoL Concern Scale Score by Visit and Overall, by Subgroup (mITT Population)

Study: Pooled

Treatment	Study visit	n (%)[1]	Mean (SD)[1]	Change from baseline LS-mean change (SE)[2]	Difference LS-mean change [95% CI] p-value[2]	SMD Hedges' g [95% CI][2]
MBL Volume at Baseline (mL)						
< 225 mL						
Relugolix+E2/NETA	Baseline	163 (99.4)	25.7 (19.28)	50.89 (2.507)	35.45	1.23
N=164	Week 24	126 (76.8)	78.4 (27.98)		[28.59,42.31]	[0.97,1.49]
Placebo	Baseline	170 (99.4)	24.6 (20.07)	15.44 (2.422)	<.0001	
N=171	Week 24	137 (80.1)	39.7 (26.33)			
>= 225 mL						
Relugolix+E2/NETA	Baseline	86 (96.6)	20.6 (22.46)	48.52 (3.496)	33.11	1.11
N=89	Week 24	70 (78.7)	71.2 (31.68)		[23.23,42.98]	[0.74,1.48]
Placebo	Baseline	84 (98.8)	21.5 (19.77)	15.42 (3.569)	<.0001	
N=85	Week 24	62 (72.9)	33.2 (29.56)			

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group. Transformed score ranges from 0 to 100 based on Likert scale (None of the time, a little of the time, some of the time, most of the time and all of the time). Higher scores are indicative of better health-related quality of life (high score = good). For the change from baseline, positive scores indicate improvement.
[1] Summary statistics are based on observed data.
[2] LS means, LS mean differences (95% CIs), p-value and Hedges' g (95% CIs) are based on a mixed-effects model with study, treatment, visit, and a treatment-by-visit interaction as fixed effects. The multiple visits for each patient are the repeated measures as a random effect within each patient with an unstructured covariance. Hedges' g is calculated using a small sample bias correction. Interaction p-value is only produced for the Overall period. The reference group for the LS mean difference and Hedges' g is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with data; CI: Confidence interval; LS: Least squares; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; SD: Standard deviation; SE: Standard error; SMD: Standardized mean difference; UFS-QoL: Uterine Fibroid Symptom and Health-Related Quality of Life.

SOURCE: \Studies\MYV\MYV102\Analysis\Prod\Progs\TFLs\Tab_QOL_UFS_CON.SAS
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Table EFF.UFSCONC.MITT.Pooled.S5: Summary of Change from Baseline in UFS-QoL Concern Scale Score by Visit and Overall, by Subgroup (mITT Population)

Study: Pooled

Treatment	Study visit	n (%)[1]	Mean (SD)[1]	Change from baseline LS-mean change (SE)[2]	Difference LS-mean change [95% CI] p-value[2]	SMD Hedges' g [95% CI][2]	Int. p-value[2]
MBL Volume at Baseline (mL)							
< 225 mL							
Relugolix+E2/NETA	Baseline	163 (99.4)	25.7 (19.28)	45.85 (2.187)	30.78	1.07	0.7469
N=164	Overall	148 (90.2)	71.1 (27.59)		[24.78,36.77]	[0.83,1.31]	
Placebo	Baseline	170 (99.4)	24.6 (20.07)	15.07 (2.127)	<.0001		
N=171	Overall	156 (91.2)	38.3 (23.89)				
>= 225 mL							
Relugolix+E2/NETA	Baseline	86 (96.6)	20.6 (22.46)	46.82 (3.024)	32.48	1.13	
N=89	Overall	80 (89.9)	65.7 (30.87)		[24.03,40.92]	[0.79,1.47]	
Placebo	Baseline	84 (98.8)	21.5 (19.77)	14.34 (3.053)	<.0001		
N=85	Overall	77 (90.6)	33.5 (25.17)				

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group. Transformed score ranges from 0 to 100 based on Likert scale (None of the time, a little of the time, some of the time, most of the time and all of the time). Higher scores are indicative of better health-related quality of life (high score = good). For the change from baseline, positive scores indicate improvement.
[1] Summary statistics are based on observed data. Mean (SD) are calculated based on the mean observed value across all post-baseline visits within each patient.
[2] LS means, LS mean differences (95% CIs), p-value and Hedges' g (95% CIs) are based on a mixed-effects model with study, treatment, visit, subgroup, treatment-by-visit interaction and a subgroup-by-treatment interaction as fixed effects. The multiple visits for each patient are the repeated measures as a random effect within each patient with an unstructured covariance. Hedges' g is calculated using a small sample bias correction. The reference group for the LS mean difference and Hedges' g is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with data; CI: Confidence interval; int: Interaction; LS: Least squares; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; SD: Standard deviation; SE: Standard error; SMD: Standardized mean difference; UFS-QoL: Uterine Fibroid Symptom and Health-Related Quality of Life.

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1.2.6 Summary of Change from Baseline in UFS-QoL Activities Scale Score by Visit and Overall, by Subgroup (mITT Population)

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Table EFF.UFSACT.MITT.Pooled.S8: Summary of Change from Baseline in UFS-QoL Activities Scale Score by Visit and Overall, by Subgroup (mITT Population)

Study: Pooled

Treatment	Study visit	n (%)[1]	Mean (SD)[1]	Change from baseline LS-mean change (SE)[2]	Difference LS-mean change [95% CI] p-value[2]	SMD Hedges' g [95% CI][2]
Ethnicity						
Hispanic or Latino						
Relugolix+E2/NETA	Baseline	52 (100.0)	40.2 (22.23)	37.58 (3.758)	19.08	0.75
N=52	Week 12	47 (90.4)	76.4 (26.61)		[8.61,29.54]	[0.34,1.16]
Placebo	Baseline	55 (100.0)	25.1 (19.28)	18.50 (3.632)	0.0005	
N=55	Week 12	49 (89.1)	43.1 (27.03)			
Not Hispanic or Latino						
Relugolix+E2/NETA	Baseline	193 (98.0)	36.3 (24.76)	38.24 (2.056)	26.14	0.98
N=197	Week 12	174 (88.3)	73.3 (28.40)		[20.47,31.82]	[0.75,1.20]
Placebo	Baseline	197 (99.0)	36.2 (22.50)	12.09 (2.020)	<.0001	
N=199	Week 12	178 (89.4)	47.8 (25.17)			
Not reported						
Relugolix+E2/NETA	Baseline	4 (100.0)	63.4 (32.27)	NC (NC)	NC	NC
N=4	Week 12	3 (75.0)	95.2 (8.26)		[NC,NC]	[NC,NC]
Placebo	Baseline	2 (100.0)	19.7 (27.79)	NC (NC)	NC	
N=2	Week 12	2 (100.0)	16.1 (17.68)			

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group. Transformed score ranges from 0 to 100 based on Likert scale (None of the time, a little of the time, some of the time, most of the time and all of the time). Higher scores are indicative of better health-related quality of life (high score = good). For the change from baseline, positive scores indicate improvement.
[1] Summary statistics are based on observed data.
[2] LS means, LS mean differences (95% CIs), p-value and Hedges' g (95% CIs) are based on a mixed-effects model with study, treatment, visit, and a treatment-by-visit interaction as fixed effects. The multiple visits for each patient are the repeated measures as a random effect within each patient with an unstructured covariance. Hedges' g is calculated using a small sample bias correction. Interaction p-value is only produced for the Overall period. The reference group for the LS mean difference and Hedges' g is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with data; CI: Confidence interval; LS: Least squares; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; SD: Standard deviation; SE: Standard error; SMD: Standardized mean difference; UFS-QoL: Uterine Fibroid Symptom and Health-Related Quality of Life; NC: Not calculated.

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Table EFF.UFSACT.MITT.Pooled.S8: Summary of Change from Baseline in UFS-QoL Activities Scale Score by Visit and Overall, by Subgroup (mITT Population)

Study: Pooled

Treatment	Study visit	n (%)[1]	Mean (SD)[1]	Change from baseline LS-mean change (SE)[2]	Difference LS-mean change [95% CI] p-value[2]	SMD Hedges' g [95% CI][2]
Ethnicity						
Hispanic or Latino						
Relugolix+E2/NETA	Baseline	52 (100.0)	40.2 (22.23)	42.79 (4.177)	23.04	0.83
N=52	Week 24	44 (84.6)	83.0 (20.01)		[11.42,34.67]	[0.40,1.25]
Placebo	Baseline	55 (100.0)	25.1 (19.28)	19.75 (4.037)	0.0002	
N=55	Week 24	46 (83.6)	44.3 (30.54)			
Not Hispanic or Latino						
Relugolix+E2/NETA	Baseline	193 (98.0)	36.3 (24.76)	43.74 (2.159)	30.01	1.10
N=197	Week 24	149 (75.6)	81.9 (24.33)		[24.04,35.98]	[0.86,1.34]
Placebo	Baseline	197 (99.0)	36.2 (22.50)	13.73 (2.127)	<.0001	
N=199	Week 24	151 (75.9)	50.0 (26.33)			
Not reported						
Relugolix+E2/NETA	Baseline	4 (100.0)	63.4 (32.27)	NC (NC)	NC	NC
N=4	Week 24	3 (75.0)	97.6 (4.10)		[NC,NC]	[NC,NC]
Placebo	Baseline	2 (100.0)	19.7 (27.79)	NC (NC)	NC	
N=2	Week 24	2 (100.0)	19.7 (27.79)			

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group. Transformed score ranges from 0 to 100 based on Likert scale (None of the time, a little of the time, some of the time, most of the time and all of the time). Higher scores are indicative of better health-related quality of life (high score = good). For the change from baseline, positive scores indicate improvement.
[1] Summary statistics are based on observed data.
[2] LS means, LS mean differences (95% CIs), p-value and Hedges' g (95% CIs) are based on a mixed-effects model with study, treatment, visit, and a treatment-by-visit interaction as fixed effects. The multiple visits for each patient are the repeated measures as a random effect within each patient with an unstructured covariance. Hedges' g is calculated using a small sample bias correction. Interaction p-value is only produced for the Overall period. The reference group for the LS mean difference and Hedges' g is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with data; CI: Confidence interval; LS: Least squares; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; SD: Standard deviation; SE: Standard error; SMD: Standardized mean difference; UFS-QoL: Uterine Fibroid Symptom and Health-Related Quality of Life; NC: Not calculated.

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Table EFF.UFSACT.MITT.Pooled.S8: Summary of Change from Baseline in UFS-QoL Activities Scale Score by Visit and Overall, by Subgroup (mITT Population)

Study: Pooled

Treatment	Study visit	n (%)[1]	Mean (SD)[1]	Change from baseline LS-mean change (SE)[2]	Difference LS-mean change [95% CI] p-value[2]	SMD Hedges' g [95% CI][2]	Int. p-value[2]
Ethnicity							
Hispanic or Latino							
Relugolix+E2/NETA	Baseline	52 (100.0)	40.2 (22.23)	39.86 (3.555)	20.62	0.76	0.1916
N=52	Overall	49 (94.2)	79.4 (20.56)		[10.83,30.41]	[0.36,1.17]	
Placebo	Baseline	55 (100.0)	25.1 (19.28)	19.24 (3.469)	<.0001		
N=55	Overall	51 (92.7)	43.3 (26.12)				
Not Hispanic or Latino							
Relugolix+E2/NETA	Baseline	193 (98.0)	36.3 (24.76)	40.98 (1.898)	28.02	1.04	
N=197	Overall	176 (89.3)	76.0 (25.37)		[22.79,33.26]	[0.82,1.27]	
Placebo	Baseline	197 (99.0)	36.2 (22.50)	12.96 (1.866)	<.0001		
N=199	Overall	180 (90.5)	48.4 (23.90)				
Not reported							
Relugolix+E2/NETA	Baseline	4 (100.0)	63.4 (32.27)	NC (NC)	NC	NC	
N=4	Overall	3 (75.0)	96.4 (3.58)		[NC,NC]	[NC,NC]	
Placebo	Baseline	2 (100.0)	19.7 (27.79)	NC (NC)	NC		
N=2	Overall	2 (100.0)	17.9 (22.73)				

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group. Transformed score ranges from 0 to 100 based on Likert scale (None of the time, a little of the time, some of the time, most of the time and all of the time). Higher scores are indicative of better health-related quality of life (high score = good). For the change from baseline, positive scores indicate improvement.
[1] Summary statistics are based on observed data. Mean (SD) are calculated based on the mean observed value across all post-baseline visits within each patient.
[2] LS means, LS mean differences (95% CIs), p-value and Hedges' g (95% CIs) are based on a mixed-effects model with study, treatment, visit, subgroup, treatment-by-visit interaction and a subgroup-by-treatment interaction as fixed effects. The multiple visits for each patient are the repeated measures as a random effect within each patient with an unstructured covariance. Hedges' g is calculated using a small sample bias correction. Not reported subgroup levels are not included in estimation of the interaction p-value. The reference group for the LS mean difference and Hedges' g is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with data; CI: Confidence interval; int: Interaction; LS: Least squares; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; SD: Standard deviation; SE: Standard error; SMD: Standardized mean difference; UFS-QoL: Uterine Fibroid Symptom and Health-Related Quality of Life; NC: Not calculated.

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Table EFF.UFSACT.MITT.Pooled.S3: Summary of Change from Baseline in UFS-QoL Activities Scale Score by Visit and Overall, by Subgroup (mITT Population)

Study: Pooled

Treatment	Study visit	n (%)[1]	Mean (SD)[1]	Change from baseline LS-mean change (SE)[2]	Difference LS-mean change [95% CI] p-value[2]	SMD Hedges' g [95% CI][2]
Uterine Volume at Baseline (cm3)						
< 300 cm3						
Relugolix+E2/NETA	Baseline	147 (99.3)	39.7 (24.45)	38.44 (2.207)	27.10	1.07
N=148	Week 12	132 (89.2)	78.0 (25.48)		[20.75,33.45]	[0.80,1.34]
Placebo	Baseline	129 (100.0)	35.5 (21.36)	11.34 (2.352)	<.0001	
N=129	Week 12	115 (89.1)	46.3 (24.83)			
>= 300 cm3						
Relugolix+E2/NETA	Baseline	101 (97.1)	34.5 (24.55)	36.57 (2.929)	21.09	0.76
N=104	Week 12	92 (88.5)	69.0 (30.47)		[13.34,28.84]	[0.47,1.05]
Placebo	Baseline	125 (98.4)	31.8 (23.15)	15.48 (2.620)	<.0001	
N=127	Week 12	114 (89.8)	46.7 (26.60)			
Missing						
Relugolix+E2/NETA	Baseline	1 (100.0)	21.4 (NE)	NC (NC)	NC	NC
N=1	Week 12	0	NE (NE)		[NC,NC]	[NC,NC]
Placebo	Baseline	0	NE (NE)	NC (NC)	NC	
N=0	Week 12	0	NE (NE)			

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group. Transformed score ranges from 0 to 100 based on Likert scale (None of the time, a little of the time, some of the time, most of the time and all of the time). Higher scores are indicative of better health-related quality of life (high score = good). For the change from baseline, positive scores indicate improvement.
[1] Summary statistics are based on observed data.
[2] LS means, LS mean differences (95% CIs), p-value and Hedges' g (95% CIs) are based on a mixed-effects model with study, treatment, visit, and a treatment-by-visit interaction as fixed effects. The multiple visits for each patient are the repeated measures as a random effect within each patient with an unstructured covariance. Hedges' g is calculated using a small sample bias correction. Interaction p-value is only produced for the Overall period. The reference group for the LS mean difference and Hedges' g is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with data; CI: Confidence interval; LS: Least squares; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; SD: Standard deviation; SE: Standard error; SMD: Standardized mean difference; UFS-QoL: Uterine Fibroid Symptom and Health-Related Quality of Life; NC: Not calculated; NE: Non-estimable.

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Table EFF.UFSACT.MITT.Pooled.S3: Summary of Change from Baseline in UFS-QoL Activities Scale Score by Visit and Overall, by Subgroup (mITT Population)

Study: Pooled

Treatment	Study visit	n (%)[1]	Mean (SD)[1]	Change from baseline LS-mean change (SE)[2]	Difference LS-mean change [95% CI] p-value[2]	SMD Hedges' g [95% CI][2]
Uterine Volume at Baseline (cm3)						
< 300 cm3						
Relugolix+E2/NETA	Baseline	147 (99.3)	39.7 (24.45)	43.28 (2.486)	30.05	1.09
N=148	Week 24	116 (78.4)	84.8 (21.62)		[22.90,37.19]	[0.80,1.37]
Placebo	Baseline	129 (100.0)	35.5 (21.36)	13.23 (2.641)	<.0001	
N=129	Week 24	102 (79.1)	48.7 (26.74)			
>= 300 cm3						
Relugolix+E2/NETA	Baseline	101 (97.1)	34.5 (24.55)	42.86 (2.946)	25.92	0.95
N=104	Week 24	80 (76.9)	78.9 (25.22)		[18.10,33.73]	[0.64,1.27]
Placebo	Baseline	125 (98.4)	31.8 (23.15)	16.94 (2.650)	<.0001	
N=127	Week 24	97 (76.4)	48.0 (28.37)			
Missing						
Relugolix+E2/NETA	Baseline	1 (100.0)	21.4 (NE)	NC (NC)	NC	NC
N=1	Week 24	0	NE (NE)		[NC,NC]	[NC,NC]
Placebo	Baseline	0	NE (NE)	NC (NC)	NC	
N=0	Week 24	0	NE (NE)			

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group. Transformed score ranges from 0 to 100 based on Likert scale (None of the time, a little of the time, some of the time, most of the time and all of the time). Higher scores are indicative of better health-related quality of life (high score = good). For the change from baseline, positive scores indicate improvement.
[1] Summary statistics are based on observed data.
[2] LS means, LS mean differences (95% CIs), p-value and Hedges' g (95% CIs) are based on a mixed-effects model with study, treatment, visit, and a treatment-by-visit interaction as fixed effects. The multiple visits for each patient are the repeated measures as a random effect within each patient with an unstructured covariance. Hedges' g is calculated using a small sample bias correction. Interaction p-value is only produced for the Overall period. The reference group for the LS mean difference and Hedges' g is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with data; CI: Confidence interval; LS: Least squares; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; SD: Standard deviation; SE: Standard error; SMD: Standardized mean difference; UFS-QoL: Uterine Fibroid Symptom and Health-Related Quality of Life; NC: Not calculated; NE: Non-estimable.

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Table EFF.UFSACT.MITT.Pooled.S3: Summary of Change from Baseline in UFS-QoL Activities Scale Score by Visit and Overall, by Subgroup (mITT Population)

Study: Pooled

Treatment	Study visit	n (%)[1]	Mean (SD)[1]	Change from baseline LS-mean change (SE)[2]	Difference LS-mean change [95% CI] p-value[2]	SMD Hedges' g [95% CI][2]	Int. p-value[2]
Uterine Volume at Baseline (cm3)							
< 300 cm3							
Relugolix+E2/NETA	Baseline	147 (99.3)	39.7 (24.45)	40.91 (2.151)	28.63	1.07	0.2715
N=148	Overall	134 (90.5)	80.4 (21.16)		[22.46,34.80]	[0.80,1.33]	
Placebo	Baseline	129 (100.0)	35.5 (21.36)	12.28 (2.286)	<.0001		
N=129	Overall	118 (91.5)	46.6 (23.03)				
>= 300 cm3							
Relugolix+E2/NETA	Baseline	101 (97.1)	34.5 (24.55)	39.71 (2.602)	23.47	0.87	
N=104	Overall	94 (90.4)	72.2 (27.69)		[16.60,30.34]	[0.59,1.16]	
Placebo	Baseline	125 (98.4)	31.8 (23.15)	16.24 (2.335)	<.0001		
N=127	Overall	115 (90.6)	47.5 (26.06)				
Missing							
Relugolix+E2/NETA	Baseline	1 (100.0)	21.4 (NE)	NC (NC)	NC	NC	
N=1	Overall	0	NE (NE)		[NC,NC]	[NC,NC]	
Placebo	Baseline	0	NE (NE)	NC (NC)	NC		
N=0	Overall	0	NE (NE)				

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group. Transformed score ranges from 0 to 100 based on Likert scale (None of the time, a little of the time, some of the time, most of the time and all of the time). Higher scores are indicative of better health-related quality of life (high score = good). For the change from baseline, positive scores indicate improvement.
[1] Summary statistics are based on observed data. Mean (SD) are calculated based on the mean observed value across all post-baseline visits within each patient.
[2] LS means, LS mean differences (95% CIs), p-value and Hedges' g (95% CIs) are based on a mixed-effects model with study, treatment, visit, subgroup, treatment-by-visit interaction and a subgroup-by-treatment interaction as fixed effects. The multiple visits for each patient are the repeated measures as a random effect within each patient with an unstructured covariance. Hedges' g is calculated using a small sample bias correction. Missing subgroup levels are not included in estimation of the interaction p-value. The reference group for the LS mean difference and Hedges' g is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with data; CI: Confidence interval; int: Interaction; LS: Least squares; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; SD: Standard deviation; SE: Standard error; SMD: Standardized mean difference; UFS-QoL: Uterine Fibroid Symptom and Health-Related Quality of Life; NC: Not calculated; NE: Non-estimable.

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Table EFF.UFSACT.MITT.Pooled.S5: Summary of Change from Baseline in UFS-QoL Activities Scale Score by Visit and Overall, by Subgroup (mITT Population)

Study: Pooled

Treatment	Study visit	n (%)[1]	Mean (SD)[1]	Change from baseline LS-mean change (SE)[2]	Difference LS-mean change [95% CI] p-value[2]	SMD Hedges' g [95% CI][2]
MBL Volume at Baseline (mL)						
< 225 mL						
Relugolix+E2/NETA	Baseline	163 (99.4)	40.1 (22.58)	35.07 (2.125)	22.26	0.86
N=164	Week 12	147 (89.6)	75.6 (27.30)		[16.41,28.11]	[0.63,1.10]
Placebo	Baseline	170 (99.4)	34.6 (21.99)	12.82 (2.078)	<.0001	
N=171	Week 12	153 (89.5)	47.2 (25.61)			
>= 225 mL						
Relugolix+E2/NETA	Baseline	86 (96.6)	32.7 (27.38)	42.90 (3.202)	28.36	1.03
N=89	Week 12	77 (86.5)	71.8 (29.12)		[19.41,37.32]	[0.69,1.37]
Placebo	Baseline	84 (98.8)	31.8 (22.92)	14.54 (3.203)	<.0001	
N=85	Week 12	76 (89.4)	45.2 (25.91)			

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group. Transformed score ranges from 0 to 100 based on Likert scale (None of the time, a little of the time, some of the time, most of the time and all of the time). Higher scores are indicative of better health-related quality of life (high score = good). For the change from baseline, positive scores indicate improvement.
[1] Summary statistics are based on observed data.
[2] LS means, LS mean differences (95% CIs), p-value and Hedges' g (95% CIs) are based on a mixed-effects model with study, treatment, visit, and a treatment-by-visit interaction as fixed effects. The multiple visits for each patient are the repeated measures as a random effect within each patient with an unstructured covariance. Hedges' g is calculated using a small sample bias correction. Interaction p-value is only produced for the Overall period. The reference group for the LS mean difference and Hedges' g is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with data; CI: Confidence interval; LS: Least squares; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; SD: Standard deviation; SE: Standard error; SMD: Standardized mean difference; UFS-QoL: Uterine Fibroid Symptom and Health-Related Quality of Life.

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Table EFF.UFSACT.MITT.Pooled.S5: Summary of Change from Baseline in UFS-QoL Activities Scale Score by Visit and Overall, by Subgroup (mITT Population)

Study: Pooled

Treatment	Study visit	n (%)[1]	Mean (SD)[1]	Change from baseline LS-mean change (SE)[2]	Difference LS-mean change [95% CI] p-value[2]	SMD Hedges' g [95% CI][2]
MBL Volume at Baseline (mL)						
< 225 mL						
Relugolix+E2/NETA	Baseline	163 (99.4)	40.1 (22.58)	42.21 (2.333)	27.31	1.01
N=164	Week 24	126 (76.8)	84.5 (21.18)		[20.92,33.69]	[0.75,1.27]
Placebo	Baseline	170 (99.4)	34.6 (21.99)	14.91 (2.255)	<.0001	
N=171	Week 24	137 (80.1)	50.1 (25.77)			
>= 225 mL						
Relugolix+E2/NETA	Baseline	86 (96.6)	32.7 (27.38)	44.91 (3.258)	29.51	1.04
N=89	Week 24	70 (78.7)	78.4 (26.34)		[20.31,38.72]	[0.68,1.41]
Placebo	Baseline	84 (98.8)	31.8 (22.92)	15.39 (3.328)	<.0001	
N=85	Week 24	62 (72.9)	44.5 (30.80)			

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group. Transformed score ranges from 0 to 100 based on Likert scale (None of the time, a little of the time, some of the time, most of the time and all of the time). Higher scores are indicative of better health-related quality of life (high score = good). For the change from baseline, positive scores indicate improvement.
[1] Summary statistics are based on observed data.
[2] LS means, LS mean differences (95% CIs), p-value and Hedges' g (95% CIs) are based on a mixed-effects model with study, treatment, visit, and a treatment-by-visit interaction as fixed effects. The multiple visits for each patient are the repeated measures as a random effect within each patient with an unstructured covariance. Hedges' g is calculated using a small sample bias correction. Interaction p-value is only produced for the Overall period. The reference group for the LS mean difference and Hedges' g is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with data; CI: Confidence interval; LS: Least squares; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; SD: Standard deviation; SE: Standard error; SMD: Standardized mean difference; UFS-QoL: Uterine Fibroid Symptom and Health-Related Quality of Life.

SOURCE: \Studies\MYV\MYV102\Analysis\Prod\Progs\TFLs\Tab_QOL_UFS_CON.SAS
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Table EFF.UFSACT.MITT.Pooled.S5: Summary of Change from Baseline in UFS-QoL Activities Scale Score by Visit and Overall, by Subgroup (mITT Population)

Study: Pooled

Treatment	Study visit	n (%)[1]	Mean (SD)[1]	Change from baseline LS-mean change (SE)[2]	Difference LS-mean change [95% CI] p-value[2]	SMD Hedges' g [95% CI][2]	Int. p-value[2]
MBL Volume at Baseline (mL)							
< 225 mL							
Relugolix+E2/NETA	Baseline	163 (99.4)	40.1 (22.58)	38.44 (2.044)	24.65	0.92	0.3622
N=164	Overall	148 (90.2)	78.4 (23.37)		[19.04,30.25]	[0.68,1.16]	
Placebo	Baseline	170 (99.4)	34.6 (21.99)	13.79 (1.989)	<.0001		
N=171	Overall	156 (91.2)	47.8 (23.66)				
>= 225 mL							
Relugolix+E2/NETA	Baseline	86 (96.6)	32.7 (27.38)	44.22 (2.826)	29.13	1.08	
N=89	Overall	80 (89.9)	74.4 (26.00)		[21.24,37.02]	[0.75,1.42]	
Placebo	Baseline	84 (98.8)	31.8 (22.92)	15.09 (2.851)	<.0001		
N=85	Overall	77 (90.6)	45.5 (26.30)				

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group. Transformed score ranges from 0 to 100 based on Likert scale (None of the time, a little of the time, some of the time, most of the time and all of the time). Higher scores are indicative of better health-related quality of life (high score = good). For the change from baseline, positive scores indicate improvement.
[1] Summary statistics are based on observed data. Mean (SD) are calculated based on the mean observed value across all post-baseline visits within each patient.
[2] LS means, LS mean differences (95% CIs), p-value and Hedges' g (95% CIs) are based on a mixed-effects model with study, treatment, visit, subgroup, treatment-by-visit interaction and a subgroup-by-treatment interaction as fixed effects. The multiple visits for each patient are the repeated measures as a random effect within each patient with an unstructured covariance. Hedges' g is calculated using a small sample bias correction. The reference group for the LS mean difference and Hedges' g is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with data; CI: Confidence interval; int: Interaction; LS: Least squares; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; SD: Standard deviation; SE: Standard error; SMD: Standardized mean difference; UFS-QoL: Uterine Fibroid Symptom and Health-Related Quality of Life.

SOURCE: \Studies\MYV\MYV102\Analysis\Prod\Progs\TFLs\Tab_QOL_UFS_CON.SAS
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Table EFF.UFSACT.MITT.Pooled.S6: Summary of Change from Baseline in UFS-QoL Activities Scale Score by Visit and Overall, by Subgroup (mITT Population)

Study: Pooled

Treatment	Study visit	n (%)[1]	Mean (SD)[1]	Change from baseline LS-mean change (SE)[2]	Difference LS-mean change [95% CI] p-value[2]	SMD Hedges' g [95% CI][2]
Geographic Region I						
North America						
Relugolix+E2/NETA	Baseline	188 (98.4)	36.1 (24.62)	37.60 (2.140)	22.91	0.84
N=191	Week 12	165 (86.4)	72.8 (28.95)		[17.02,28.80]	[0.61,1.06]
Placebo	Baseline	192 (99.0)	32.8 (22.82)	14.69 (2.096)	<.0001	
N=194	Week 12	172 (88.7)	47.0 (26.83)			
Rest of World						
Relugolix+E2/NETA	Baseline	61 (98.4)	41.9 (24.01)	38.09 (3.115)	28.59	1.21
N=62	Week 12	59 (95.2)	78.4 (24.60)		[19.86,37.32]	[0.81,1.60]
Placebo	Baseline	62 (100.0)	36.5 (20.49)	9.50 (3.117)	<.0001	
N=62	Week 12	57 (91.9)	45.1 (21.93)			

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group. Transformed score ranges from 0 to 100 based on Likert scale (None of the time, a little of the time, some of the time, most of the time and all of the time). Higher scores are indicative of better health-related quality of life (high score = good). For the change from baseline, positive scores indicate improvement.
[1] Summary statistics are based on observed data.
[2] LS means, LS mean differences (95% CIs), p-value and Hedges' g (95% CIs) are based on a mixed-effects model with study, treatment, visit, and a treatment-by-visit interaction as fixed effects. The multiple visits for each patient are the repeated measures as a random effect within each patient with an unstructured covariance. Hedges' g is calculated using a small sample bias correction. Interaction p-value is only produced for the Overall period. The reference group for the LS mean difference and Hedges' g is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with data; CI: Confidence interval; LS: Least squares; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; SD: Standard deviation; SE: Standard error; SMD: Standardized mean difference; UFS-QoL: Uterine Fibroid Symptom and Health-Related Quality of Life.

SOURCE: \Studies\MYV\MYV102\Analysis\Prod\Progs\TFLs\Tab_QOL_UFS_CON.SAS
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Table EFF.UFSACT.MITT.Pooled.S6: Summary of Change from Baseline in UFS-QoL Activities Scale Score by Visit and Overall, by Subgroup (mITT Population)

Study: Pooled

Treatment	Study visit	n (%)[1]	Mean (SD)[1]	Change from baseline LS-mean change (SE)[2]	Difference LS-mean change [95% CI] p-value[2]	SMD Hedges' g [95% CI][2]
Geographic Region I						
North America						
Relugolix+E2/NETA	Baseline	188 (98.4)	36.1 (24.62)	42.13 (2.286)	27.19	0.96
N=191	Week 24	139 (72.8)	80.5 (24.67)		[20.91,33.46]	[0.72,1.21]
Placebo	Baseline	192 (99.0)	32.8 (22.82)	14.95 (2.227)	<.0001	
N=194	Week 24	146 (75.3)	47.4 (28.59)			
Rest of World						
Relugolix+E2/NETA	Baseline	61 (98.4)	41.9 (24.01)	45.50 (3.367)	30.34	1.20
N=62	Week 24	57 (91.9)	86.8 (18.90)		[20.83,39.86]	[0.79,1.60]
Placebo	Baseline	62 (100.0)	36.5 (20.49)	15.15 (3.428)	<.0001	
N=62	Week 24	53 (85.5)	51.1 (24.20)			

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group. Transformed score ranges from 0 to 100 based on Likert scale (None of the time, a little of the time, some of the time, most of the time and all of the time). Higher scores are indicative of better health-related quality of life (high score = good). For the change from baseline, positive scores indicate improvement.
[1] Summary statistics are based on observed data.
[2] LS means, LS mean differences (95% CIs), p-value and Hedges' g (95% CIs) are based on a mixed-effects model with study, treatment, visit, and a treatment-by-visit interaction as fixed effects. The multiple visits for each patient are the repeated measures as a random effect within each patient with an unstructured covariance. Hedges' g is calculated using a small sample bias correction. Interaction p-value is only produced for the Overall period. The reference group for the LS mean difference and Hedges' g is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with data; CI: Confidence interval; LS: Least squares; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; SD: Standard deviation; SE: Standard error; SMD: Standardized mean difference; UFS-QoL: Uterine Fibroid Symptom and Health-Related Quality of Life.

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Table EFF.UFSACT.MITT.Pooled.S6: Summary of Change from Baseline in UFS-QoL Activities Scale Score by Visit and Overall, by Subgroup (mITT Population)

Study: Pooled

Treatment	Study visit	n (%)[1]	Mean (SD)[1]	Change from baseline LS-mean change (SE)[2]	Difference LS-mean change [95% CI] p-value[2]	SMD Hedges' g [95% CI][2]	Int. p-value[2]
Geographic Region I							
North America							
Relugolix+E2/NETA	Baseline	188 (98.4)	36.1 (24.62)	39.96 (1.938)	24.99	0.93	0.3797
N=191	Overall	169 (88.5)	75.4 (25.39)		[19.66,30.32]	[0.71,1.16]	
Placebo	Baseline	192 (99.0)	32.8 (22.82)	14.97 (1.898)	<.0001		
N=194	Overall	174 (89.7)	46.7 (25.93)				
Rest of World							
Relugolix+E2/NETA	Baseline	61 (98.4)	41.9 (24.01)	41.70 (3.222)	29.65	1.10	
N=62	Overall	59 (95.2)	81.8 (20.54)		[20.69,38.61]	[0.71,1.49]	
Placebo	Baseline	62 (100.0)	36.5 (20.49)	12.05 (3.225)	<.0001		
N=62	Overall	59 (95.2)	47.9 (20.00)				

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group. Transformed score ranges from 0 to 100 based on Likert scale (None of the time, a little of the time, some of the time, most of the time and all of the time). Higher scores are indicative of better health-related quality of life (high score = good). For the change from baseline, positive scores indicate improvement.
[1] Summary statistics are based on observed data. Mean (SD) are calculated based on the mean observed value across all post-baseline visits within each patient.
[2] LS means, LS mean differences (95% CIs), p-value and Hedges' g (95% CIs) are based on a mixed-effects model with study, treatment, visit, subgroup, treatment-by-visit interaction and a subgroup-by-treatment interaction as fixed effects. The multiple visits for each patient are the repeated measures as a random effect within each patient with an unstructured covariance. Hedges' g is calculated using a small sample bias correction. The reference group for the LS mean difference and Hedges' g is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with data; CI: Confidence interval; int: Interaction; LS: Least squares; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; SD: Standard deviation; SE: Standard error; SMD: Standardized mean difference; UFS-QoL: Uterine Fibroid Symptom and Health-Related Quality of Life.

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Table EFF.UFSACT.MITT.Pooled.S7: Summary of Change from Baseline in UFS-QoL Activities Scale Score by Visit and Overall, by Subgroup (mITT Population)

Study: Pooled

Treatment	Study visit	n (%)[1]	Mean (SD)[1]	Change from baseline LS-mean change (SE)[2]	Difference LS-mean change [95% CI] p-value[2]	SMD Hedges' g [95% CI][2]
Geographic Region II						
Europe						
Relugolix+E2/NETA	Baseline	40 (97.6)	41.6 (23.73)	36.14 (3.757)	27.86	1.21
N=41	Week 12	39 (95.1)	76.7 (25.63)		[17.29,38.42]	[0.72,1.69]
Placebo	Baseline	42 (100.0)	39.1 (21.20)	8.28 (3.769)	<.0001	
N=42	Week 12	39 (92.9)	46.5 (21.69)			
Rest of World (including the US)						
Relugolix+E2/NETA	Baseline	209 (98.6)	36.8 (24.68)	38.05 (2.002)	23.68	0.87
N=212	Week 12	185 (87.3)	73.8 (28.43)		[18.16,29.21]	[0.66,1.09]
Placebo	Baseline	212 (99.1)	32.6 (22.39)	14.37 (1.972)	<.0001	
N=214	Week 12	190 (88.8)	46.5 (26.46)			

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group. Transformed score ranges from 0 to 100 based on Likert scale (None of the time, a little of the time, some of the time, most of the time and all of the time). Higher scores are indicative of better health-related quality of life (high score = good). For the change from baseline, positive scores indicate improvement.
[1] Summary statistics are based on observed data.
[2] LS means, LS mean differences (95% CIs), p-value and Hedges' g (95% CIs) are based on a mixed-effects model with study, treatment, visit, and a treatment-by-visit interaction as fixed effects. The multiple visits for each patient are the repeated measures as a random effect within each patient with an unstructured covariance. Hedges' g is calculated using a small sample bias correction. Interaction p-value is only produced for the Overall period. The reference group for the LS mean difference and Hedges' g is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with data; CI: Confidence interval; LS: Least squares; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; SD: Standard deviation; SE: Standard error; SMD: Standardized mean difference; UFS-QoL: Uterine Fibroid Symptom and Health-Related Quality of Life.

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Table EFF.UFSACT.MITT.Pooled.S7: Summary of Change from Baseline in UFS-QoL Activities Scale Score by Visit and Overall, by Subgroup (mITT Population)

Study: Pooled

Treatment	Study visit	n (%)[1]	Mean (SD)[1]	Change from baseline LS-mean change (SE)[2]	Difference LS-mean change [95% CI] p-value[2]	SMD Hedges' g [95% CI][2]
Geographic Region II						
Europe						
Relugolix+E2/NETA	Baseline	40 (97.6)	41.6 (23.73)	46.76 (3.872)	33.04	1.41
N=41	Week 24	37 (90.2)	88.8 (17.07)		[22.01,44.06]	[0.90,1.92]
Placebo	Baseline	42 (100.0)	39.1 (21.20)	13.72 (3.975)	<.0001	
N=42	Week 24	35 (83.3)	52.7 (21.22)			
Rest of World (including the US)						
Relugolix+E2/NETA	Baseline	209 (98.6)	36.8 (24.68)	42.21 (2.148)	27.00	0.96
N=212	Week 24	159 (75.0)	80.9 (24.29)		[21.08,32.92]	[0.73,1.19]
Placebo	Baseline	212 (99.1)	32.6 (22.39)	15.21 (2.109)	<.0001	
N=214	Week 24	164 (76.6)	47.4 (28.61)			

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group. Transformed score ranges from 0 to 100 based on Likert scale (None of the time, a little of the time, some of the time, most of the time and all of the time). Higher scores are indicative of better health-related quality of life (high score = good). For the change from baseline, positive scores indicate improvement.
[1] Summary statistics are based on observed data.
[2] LS means, LS mean differences (95% CIs), p-value and Hedges' g (95% CIs) are based on a mixed-effects model with study, treatment, visit, and a treatment-by-visit interaction as fixed effects. The multiple visits for each patient are the repeated measures as a random effect within each patient with an unstructured covariance. Hedges' g is calculated using a small sample bias correction. Interaction p-value is only produced for the Overall period. The reference group for the LS mean difference and Hedges' g is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with data; CI: Confidence interval; LS: Least squares; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; SD: Standard deviation; SE: Standard error; SMD: Standardized mean difference; UFS-QoL: Uterine Fibroid Symptom and Health-Related Quality of Life.

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Table EFF.UFSACT.MITT.Pooled.S7: Summary of Change from Baseline in UFS-QoL Activities Scale Score by Visit and Overall, by Subgroup (mITT Population)

Study: Pooled

Treatment	Study visit	n (%)[1]	Mean (SD)[1]	Change from baseline LS-mean change (SE)[2]	Difference LS-mean change [95% CI] p-value[2]	SMD Hedges' g [95% CI][2]	Int. p-value[2]
Geographic Region II							
Europe							0.4387
Relugolix+E2/NETA	Baseline	40 (97.6)	41.6 (23.73)	41.20 (3.982)	30.15	1.11	
N=41	Overall	39 (95.1)	81.5 (20.76)		[19.15,41.14]	[0.64,1.59]	
Placebo	Baseline	42 (100.0)	39.1 (21.20)	11.05 (3.936)	<.0001		
N=42	Overall	40 (95.2)	49.5 (18.86)				
Rest of World (including the US)							
Relugolix+E2/NETA	Baseline	209 (98.6)	36.8 (24.68)	40.26 (1.827)	25.38	0.95	
N=212	Overall	189 (89.2)	76.1 (24.97)		[20.34,30.42]	[0.73,1.16]	
Placebo	Baseline	212 (99.1)	32.6 (22.39)	14.88 (1.800)	<.0001		
N=214	Overall	193 (90.2)	46.5 (25.56)				

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group. Transformed score ranges from 0 to 100 based on Likert scale (None of the time, a little of the time, some of the time, most of the time and all of the time). Higher scores are indicative of better health-related quality of life (high score = good). For the change from baseline, positive scores indicate improvement.
[1] Summary statistics are based on observed data. Mean (SD) are calculated based on the mean observed value across all post-baseline visits within each patient.
[2] LS means, LS mean differences (95% CIs), p-value and Hedges' g (95% CIs) are based on a mixed-effects model with study, treatment, visit, subgroup, treatment-by-visit interaction and a subgroup-by-treatment interaction as fixed effects. The multiple visits for each patient are the repeated measures as a random effect within each patient with an unstructured covariance. Hedges' g is calculated using a small sample bias correction. The reference group for the LS mean difference and Hedges' g is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with data; CI: Confidence interval; int: Interaction; LS: Least squares; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; SD: Standard deviation; SE: Standard error; SMD: Standardized mean difference; UFS-QoL: Uterine Fibroid Symptom and Health-Related Quality of Life.

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Table EFF.UFSACT.MITT.Pooled.S9: Summary of Change from Baseline in UFS-QoL Activities Scale Score by Visit and Overall, by Subgroup (mITT Population)

Study: Pooled

Treatment	Study visit	n (%)[1]	Mean (SD)[1]	Change from baseline LS-mean change (SE)[2]	Difference LS-mean change [95% CI] p-value[2]	SMD Hedges' g [95% CI][2]
Race						
Black/African American						
Relugolix+E2/NETA	Baseline	119 (97.5)	33.4 (25.21)	39.39 (2.748)	25.37	0.91
N=122	Week 12	105 (86.1)	71.0 (28.92)		[18.03,32.72]	[0.64,1.19]
Placebo	Baseline	139 (98.6)	34.2 (23.32)	14.01 (2.522)	<.0001	
N=141	Week 12	122 (86.5)	47.5 (26.18)			
White						
Relugolix+E2/NETA	Baseline	121 (99.2)	40.3 (23.16)	37.36 (2.393)	24.58	0.98
N=122	Week 12	110 (90.2)	77.2 (27.24)		[17.72,31.45]	[0.69,1.27]
Placebo	Baseline	105 (100.0)	33.7 (21.43)	12.77 (2.536)	<.0001	
N=105	Week 12	98 (93.3)	46.5 (24.81)			
Asian						
Relugolix+E2/NETA	Baseline	1 (100.0)	57.1 (NE)	NC (NC)	NC	NC
N=1	Week 12	1 (100.0)	100.0 (NE)		[NC,NC]	[NC,NC]
Placebo	Baseline	3 (100.0)	26.2 (22.97)	NC (NC)	NC	
N=3	Week 12	3 (100.0)	23.8 (4.16)			
Others						
Relugolix+E2/NETA	Baseline	5 (100.0)	43.6 (20.12)	25.19 (13.969)	4.03	0.14
N=5	Week 12	5 (100.0)	65.7 (19.34)		[-42.38,50.44]	[-0.98,1.26]
Placebo	Baseline	6 (100.0)	22.0 (13.06)	21.16 (13.235)	0.8432	
N=6	Week 12	5 (83.3)	41.4 (36.83)			
Not reported						
Relugolix+E2/NETA	Baseline	3 (100.0)	72.6 (25.33)	NC (NC)	NC	NC
N=3	Week 12	3 (100.0)	88.1 (20.61)		[NC,NC]	[NC,NC]
Placebo	Baseline	1 (100.0)	39.3 (NE)	NC (NC)	NC	

N=1	Week 12	1 (100.0)	28.6 (NE)			

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group. Transformed score ranges from 0 to 100 based on Likert scale (None of the time, a little of the time, some of the time, most of the time and all of the time). Higher scores are indicative of better health-related quality of life (high score = good). For the change from baseline, positive scores indicate improvement.
[1] Summary statistics are based on observed data.
[2] LS means, LS mean differences (95% CIs), p-value and Hedges' g (95% CIs) are based on a mixed-effects model with study, treatment, visit, and a treatment-by-visit interaction as fixed effects. The multiple visits for each patient are the repeated measures as a random effect within each patient with an unstructured covariance. Hedges' g is calculated using a small sample bias correction. Interaction p-value is only produced for the Overall period. The reference group for the LS mean difference and Hedges' g is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with data; CI: Confidence interval; LS: Least squares; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; SD: Standard deviation; SE: Standard error; SMD: Standardized mean difference; UFS-QoL: Uterine Fibroid Symptom and Health-Related Quality of Life; NC: Not calculated; NE: Non-estimable.

Table EFF.UFSACT.MITT.Pooled.S9: Summary of Change from Baseline in UFS-QoL Activities Scale Score by Visit and Overall, by Subgroup (mITT Population)

Study: Pooled

Treatment	Study visit	n (%)[1]	Mean (SD)[1]	Change from baseline LS-mean change (SE)[2]	Difference LS-mean change [95% CI] p-value[2]	SMD Hedges' g [95% CI][2]
Race						
Black/African American						
Relugolix+E2/NETA	Baseline	119 (97.5)	33.4 (25.21)	43.44 (3.008)	28.47	0.97
N=122	Week 24	87 (71.3)	77.9 (26.08)		[20.48,36.45]	[0.67,1.27]
Placebo	Baseline	139 (98.6)	34.2 (23.32)	14.97 (2.714)	<.0001	
N=141	Week 24	108 (76.6)	49.0 (28.50)			
White						
Relugolix+E2/NETA	Baseline	121 (99.2)	40.3 (23.16)	44.32 (2.493)	28.18	1.11
N=122	Week 24	100 (82.0)	86.5 (19.75)		[20.95,35.41]	[0.80,1.42]
Placebo	Baseline	105 (100.0)	33.7 (21.43)	16.14 (2.694)	<.0001	
N=105	Week 24	84 (80.0)	49.7 (26.14)			
Asian						
Relugolix+E2/NETA	Baseline	1 (100.0)	57.1 (NE)	NC (NC)	NC	NC
N=1	Week 24	1 (100.0)	100.0 (NE)		[NC,NC]	[NC,NC]
Placebo	Baseline	3 (100.0)	26.2 (22.97)	NC (NC)	NC	
N=3	Week 24	2 (66.7)	17.9 (20.15)			
Others						
Relugolix+E2/NETA	Baseline	5 (100.0)	43.6 (20.12)	28.05 (11.005)	23.81	1.07
N=5	Week 24	5 (100.0)	68.6 (28.73)		[-15.65,63.27]	[-0.20,2.34]
Placebo	Baseline	6 (100.0)	22.0 (13.06)	4.24 (11.303)	0.1967	
N=6	Week 24	4 (66.7)	21.4 (12.03)			
Not reported						
Relugolix+E2/NETA	Baseline	3 (100.0)	72.6 (25.33)	NC (NC)	NC	NC
N=3	Week 24	3 (100.0)	89.3 (12.88)		[NC,NC]	[NC,NC]
Placebo	Baseline	1 (100.0)	39.3 (NE)	NC (NC)	NC	

N=1	Week 24	1 (100.0)	39.3 (NE)			

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group. Transformed score ranges from 0 to 100 based on Likert scale (None of the time, a little of the time, some of the time, most of the time and all of the time). Higher scores are indicative of better health-related quality of life (high score = good). For the change from baseline, positive scores indicate improvement.
[1] Summary statistics are based on observed data.
[2] LS means, LS mean differences (95% CIs), p-value and Hedges' g (95% CIs) are based on a mixed-effects model with study, treatment, visit, and a treatment-by-visit interaction as fixed effects. The multiple visits for each patient are the repeated measures as a random effect within each patient with an unstructured covariance. Hedges' g is calculated using a small sample bias correction. Interaction p-value is only produced for the Overall period. The reference group for the LS mean difference and Hedges' g is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with data; CI: Confidence interval; LS: Least squares; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; SD: Standard deviation; SE: Standard error; SMD: Standardized mean difference; UFS-QoL: Uterine Fibroid Symptom and Health-Related Quality of Life; NC: Not calculated; NE: Non-estimable.

Table EFF.UFSACT.MITT.Pooled.S9: Summary of Change from Baseline in UFS-QoL Activities Scale Score by Visit and Overall, by Subgroup (mITT Population)

Study: Pooled

Treatment	Study visit	n (%)[1]	Mean (SD)[1]	Change from baseline LS-mean change (SE)[2]	Difference LS-mean change [95% CI] p-value[2]	SMD Hedges' g [95% CI][2]	Int. p-value[2]
Race							
Black/African American							
Relugolix+E2/NETA	Baseline	119 (97.5)	33.4 (25.21)	41.67 (2.451)	27.09	1.01	0.4664
N=122	Overall	107 (87.7)	73.1 (26.23)		[20.57,33.61]	[0.73,1.28]	
Placebo	Baseline	139 (98.6)	34.2 (23.32)	14.59 (2.236)	<.0001		
N=141	Overall	126 (89.4)	47.7 (25.83)				
White							
Relugolix+E2/NETA	Baseline	121 (99.2)	40.3 (23.16)	40.70 (2.355)	26.36	0.98	
N=122	Overall	112 (91.8)	80.7 (22.19)		[19.60,33.13]	[0.69,1.27]	
Placebo	Baseline	105 (100.0)	33.7 (21.43)	14.34 (2.513)	<.0001		
N=105	Overall	98 (93.3)	47.7 (22.81)				
Asian							
Relugolix+E2/NETA	Baseline	1 (100.0)	57.1 (NE)	NC (NC)	NC	NC	
N=1	Overall	1 (100.0)	100.0 (NE)		[NC,NC]	[NC,NC]	
Placebo	Baseline	3 (100.0)	26.2 (22.97)	NC (NC)	NC		
N=3	Overall	3 (100.0)	22.6 (8.81)				
Others							
Relugolix+E2/NETA	Baseline	5 (100.0)	43.6 (20.12)	23.86 (10.996)	7.29	0.25	
N=5	Overall	5 (100.0)	67.1 (21.16)		[-23.50,38.08]	[-0.88,1.37]	
Placebo	Baseline	6 (100.0)	22.0 (13.06)	16.57 (11.142)	0.6418		
N=6	Overall	5 (83.3)	35.7 (26.79)				
Not reported							
Relugolix+E2/NETA	Baseline	3 (100.0)	72.6 (25.33)	NC (NC)	NC	NC	
N=3	Overall	3 (100.0)	88.7 (16.59)		[NC,NC]	[NC,NC]	
Placebo	Baseline	1 (100.0)	39.3 (NE)	NC (NC)	NC		

N=1	Overall	1 (100.0)	34.0 (NE)				

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group. Transformed score ranges from 0 to 100 based on Likert scale (None of the time, a little of the time, some of the time, most of the time and all of the time). Higher scores are indicative of better health-related quality of life (high score = good). For the change from baseline, positive scores indicate improvement.
[1] Summary statistics are based on observed data. Mean (SD) are calculated based on the mean observed value across all post-baseline visits within each patient.
[2] LS means, LS mean differences (95% CIs), p-value and Hedges' g (95% CIs) are based on a mixed-effects model with study, treatment, visit, subgroup, treatment-by-visit interaction and a subgroup-by-treatment interaction as fixed effects. The multiple visits for each patient are the repeated measures as a random effect within each patient with an unstructured covariance. Hedges' g is calculated using a small sample bias correction. Not reported subgroup levels are not included in estimation of the interaction p-value. Subgroup levels with fewer than 10 subjects are not included in estimation of the interaction p-value. The reference group for the LS mean difference and Hedges' g is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with data; CI: Confidence interval; int: Interaction; LS: Least squares; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; SD: Standard deviation; SE: Standard error; SMD: Standardized mean difference; UFS-QoL: Uterine Fibroid Symptom and Health-Related Quality of Life; NC: Not calculated; NE: Non-estimable.

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Table EFF.UFSACT.MITT.Pooled.S2: Summary of Change from Baseline in UFS-QoL Activities Scale Score by Visit and Overall, by Subgroup (mITT Population)

Study: Pooled

Treatment	Study visit	n (%)[1]	Mean (SD)[1]	Change from baseline LS-mean change (SE)[2]	Difference LS-mean change [95% CI] p-value[2]	SMD Hedges' g [95% CI][2]
BMI (kg/m2) at Baseline						
< 30						
Relugolix+E2/NETA	Baseline	118 (99.2)	39.4 (25.04)	38.03 (2.413)	26.81	1.09
N=119	Week 12	104 (87.4)	77.5 (25.30)		[20.04,33.58]	[0.80,1.39]
Placebo	Baseline	115 (100.0)	35.2 (20.44)	11.22 (2.444)	<.0001	
N=115	Week 12	100 (87.0)	45.8 (25.83)			
>= 30						
Relugolix+E2/NETA	Baseline	130 (97.7)	35.9 (24.16)	37.21 (2.592)	22.06	0.79
N=133	Week 12	119 (89.5)	71.2 (29.85)		[14.98,29.13]	[0.53,1.05]
Placebo	Baseline	139 (98.6)	32.3 (23.71)	15.16 (2.486)	<.0001	
N=141	Week 12	129 (91.5)	47.1 (25.62)			
Missing						
Relugolix+E2/NETA	Baseline	1 (100.0)	35.7 (NE)	NC (NC)	NC	NC
N=1	Week 12	1 (100.0)	100.0 (NE)		[NC,NC]	[NC,NC]
Placebo	Baseline	0	NE (NE)	NC (NC)	NC	
N=0	Week 12	0	NE (NE)			

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group. Transformed score ranges from 0 to 100 based on Likert scale (None of the time, a little of the time, some of the time, most of the time and all of the time). Higher scores are indicative of better health-related quality of life (high score = good). For the change from baseline, positive scores indicate improvement.
[1] Summary statistics are based on observed data.
[2] LS means, LS mean differences (95% CIs), p-value and Hedges' g (95% CIs) are based on a mixed-effects model with study, treatment, visit, and a treatment-by-visit interaction as fixed effects. The multiple visits for each patient are the repeated measures as a random effect within each patient with an unstructured covariance. Hedges' g is calculated using a small sample bias correction. Interaction p-value is only produced for the Overall period. The reference group for the LS mean difference and Hedges' g is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with data; CI: Confidence interval; LS: Least squares; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; SD: Standard deviation; SE: Standard error; SMD: Standardized mean difference; UFS-QoL: Uterine Fibroid Symptom and Health-Related Quality of Life; NC: Not calculated; NE: Non-estimable.

SOURCE: \Studies\MYV\MYV102\Analysis\Prod\Progs\TFLs\Tab_QOL_UFS_CON.SAS
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Table EFF.UFSACT.MITT.Pooled.S2: Summary of Change from Baseline in UFS-QoL Activities Scale Score by Visit and Overall, by Subgroup (mITT Population)

Study: Pooled

Treatment	Study visit	n (%)[1]	Mean (SD)[1]	Change from baseline LS-mean change (SE)[2]	Difference LS-mean change [95% CI] p-value[2]	SMD Hedges' g [95% CI][2]
BMI (kg/m2) at Baseline						
< 30						
Relugolix+E2/NETA	Baseline	118 (99.2)	39.4 (25.04)	42.38 (2.649)	28.06	1.08
N=119	Week 24	89 (74.8)	83.6 (23.11)		[20.62,35.50]	[0.76,1.39]
Placebo	Baseline	115 (100.0)	35.2 (20.44)	14.32 (2.687)	<.0001	
N=115	Week 24	86 (74.8)	49.7 (28.05)			
>= 30						
Relugolix+E2/NETA	Baseline	130 (97.7)	35.9 (24.16)	43.67 (2.711)	27.94	0.98
N=133	Week 24	106 (79.7)	81.2 (23.56)		[20.54,35.35]	[0.70,1.26]
Placebo	Baseline	139 (98.6)	32.3 (23.71)	15.72 (2.605)	<.0001	
N=141	Week 24	113 (80.1)	47.3 (27.12)			
Missing						
Relugolix+E2/NETA	Baseline	1 (100.0)	35.7 (NE)	NC (NC)	NC	NC
N=1	Week 24	1 (100.0)	92.9 (NE)		[NC,NC]	[NC,NC]
Placebo	Baseline	0	NE (NE)	NC (NC)	NC	
N=0	Week 24	0	NE (NE)			

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group. Transformed score ranges from 0 to 100 based on Likert scale (None of the time, a little of the time, some of the time, most of the time and all of the time). Higher scores are indicative of better health-related quality of life (high score = good). For the change from baseline, positive scores indicate improvement.
[1] Summary statistics are based on observed data.
[2] LS means, LS mean differences (95% CIs), p-value and Hedges' g (95% CIs) are based on a mixed-effects model with study, treatment, visit, and a treatment-by-visit interaction as fixed effects. The multiple visits for each patient are the repeated measures as a random effect within each patient with an unstructured covariance. Hedges' g is calculated using a small sample bias correction. Interaction p-value is only produced for the Overall period. The reference group for the LS mean difference and Hedges' g is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with data; CI: Confidence interval; LS: Least squares; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; SD: Standard deviation; SE: Standard error; SMD: Standardized mean difference; UFS-QoL: Uterine Fibroid Symptom and Health-Related Quality of Life; NC: Not calculated; NE: Non-estimable.

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Table EFF.UFSACT.MITT.Pooled.S2: Summary of Change from Baseline in UFS-QoL Activities Scale Score by Visit and Overall, by Subgroup (mITT Population)

Study: Pooled

Treatment	Study visit	n (%)[1]	Mean (SD)[1]	Change from baseline LS-mean change (SE)[2]	Difference LS-mean change [95% CI] p-value[2]	SMD Hedges' g [95% CI][2]	Int. p-value[2]
BMI (kg/m2) at Baseline							
< 30							
Relugolix+E2/NETA	Baseline	118 (99.2)	39.4 (25.04)	40.31 (2.427)	27.70	1.03	0.5441
N=119	Overall	106 (89.1)	79.5 (23.06)		[20.91,34.48]	[0.74,1.32]	
Placebo	Baseline	115 (100.0)	35.2 (20.44)	12.61 (2.455)	<.0001		
N=115	Overall	103 (89.6)	47.2 (24.88)				
>= 30							
Relugolix+E2/NETA	Baseline	130 (97.7)	35.9 (24.16)	40.35 (2.284)	24.86	0.92	
N=133	Overall	121 (91.0)	74.7 (25.35)		[18.64,31.08]	[0.66,1.19]	
Placebo	Baseline	139 (98.6)	32.3 (23.71)	15.49 (2.193)	<.0001		
N=141	Overall	130 (92.2)	46.9 (24.34)				
Missing							
Relugolix+E2/NETA	Baseline	1 (100.0)	35.7 (NE)	NC (NC)	NC	NC	
N=1	Overall	1 (100.0)	96.5 (NE)		[NC,NC]	[NC,NC]	
Placebo	Baseline	0	NE (NE)	NC (NC)	NC		
N=0	Overall	0	NE (NE)				

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group. Transformed score ranges from 0 to 100 based on Likert scale (None of the time, a little of the time, some of the time, most of the time and all of the time). Higher scores are indicative of better health-related quality of life (high score = good). For the change from baseline, positive scores indicate improvement.
[1] Summary statistics are based on observed data. Mean (SD) are calculated based on the mean observed value across all post-baseline visits within each patient.
[2] LS means, LS mean differences (95% CIs), p-value and Hedges' g (95% CIs) are based on a mixed-effects model with study, treatment, visit, subgroup, treatment-by-visit interaction and a subgroup-by-treatment interaction as fixed effects. The multiple visits for each patient are the repeated measures as a random effect within each patient with an unstructured covariance. Hedges' g is calculated using a small sample bias correction. Missing subgroup levels are not included in estimation of the interaction p-value. The reference group for the LS mean difference and Hedges' g is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with data; CI: Confidence interval; int: Interaction; LS: Least squares; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; SD: Standard deviation; SE: Standard error; SMD: Standardized mean difference; UFS-QoL: Uterine Fibroid Symptom and Health-Related Quality of Life; NC: Not calculated; NE: Non-estimable.

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Table EFF.UFSACT.MITT.Pooled.S1: Summary of Change from Baseline in UFS-QoL Activities Scale Score by Visit and Overall, by Subgroup (mITT Population)

Study: Pooled

Treatment	Study visit	n (%)[1]	Mean (SD)[1]	Change from baseline LS-mean change (SE)[2]	Difference LS-mean change [95% CI] p-value[2]	SMD Hedges' g [95% CI][2]
Age (years)						
< 40 years						
Relugolix+E2/NETA	Baseline	61 (98.4)	34.8 (23.56)	34.84 (3.392)	23.40	0.93
N=62	Week 12	57 (91.9)	67.5 (29.26)		[14.35,32.45]	[0.56,1.30]
Placebo	Baseline	78 (100.0)	35.2 (23.27)	11.44 (3.072)	<.0001	
N=78	Week 12	68 (87.2)	45.9 (26.82)			
>= 40 years						
Relugolix+E2/NETA	Baseline	188 (98.4)	38.4 (24.85)	38.69 (2.093)	24.48	0.91
N=191	Week 12	167 (87.4)	76.6 (27.16)		[18.62,30.35]	[0.68,1.14]
Placebo	Baseline	176 (98.9)	33.0 (21.88)	14.20 (2.126)	<.0001	
N=178	Week 12	161 (90.4)	46.8 (25.25)			

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group. Transformed score ranges from 0 to 100 based on Likert scale (None of the time, a little of the time, some of the time, most of the time and all of the time). Higher scores are indicative of better health-related quality of life (high score = good). For the change from baseline, positive scores indicate improvement.
[1] Summary statistics are based on observed data.
[2] LS means, LS mean differences (95% CIs), p-value and Hedges' g (95% CIs) are based on a mixed-effects model with study, treatment, visit, and a treatment-by-visit interaction as fixed effects. The multiple visits for each patient are the repeated measures as a random effect within each patient with an unstructured covariance. Hedges' g is calculated using a small sample bias correction. Interaction p-value is only produced for the Overall period. The reference group for the LS mean difference and Hedges' g is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with data; CI: Confidence interval; LS: Least squares; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; SD: Standard deviation; SE: Standard error; SMD: Standardized mean difference; UFS-QoL: Uterine Fibroid Symptom and Health-Related Quality of Life.

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Table EFF.UFSACT.MITT.Pooled.S1: Summary of Change from Baseline in UFS-QoL Activities Scale Score by Visit and Overall, by Subgroup (mITT Population)

Study: Pooled

Treatment	Study visit	n (%)[1]	Mean (SD)[1]	Change from baseline LS-mean change (SE)[2]	Difference LS-mean change [95% CI] p-value[2]	SMD Hedges' g [95% CI][2]
Age (years)						
< 40 years						
Relugolix+E2/NETA	Baseline	61 (98.4)	34.8 (23.56)	40.34 (4.017)	25.50	0.90
N=62	Week 24	47 (75.8)	73.4 (28.80)		[14.83,36.16]	[0.50,1.31]
Placebo	Baseline	78 (100.0)	35.2 (23.27)	14.84 (3.596)	<.0001	
N=78	Week 24	58 (74.4)	51.0 (27.72)			
>= 40 years						
Relugolix+E2/NETA	Baseline	188 (98.4)	38.4 (24.85)	44.03 (2.151)	28.90	1.07
N=191	Week 24	149 (78.0)	85.2 (20.55)		[22.85,34.94]	[0.82,1.31]
Placebo	Baseline	176 (98.9)	33.0 (21.88)	15.14 (2.197)	<.0001	
N=178	Week 24	141 (79.2)	47.2 (27.40)			

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group. Transformed score ranges from 0 to 100 based on Likert scale (None of the time, a little of the time, some of the time, most of the time and all of the time). Higher scores are indicative of better health-related quality of life (high score = good). For the change from baseline, positive scores indicate improvement.
[1] Summary statistics are based on observed data.
[2] LS means, LS mean differences (95% CIs), p-value and Hedges' g (95% CIs) are based on a mixed-effects model with study, treatment, visit, and a treatment-by-visit interaction as fixed effects. The multiple visits for each patient are the repeated measures as a random effect within each patient with an unstructured covariance. Hedges' g is calculated using a small sample bias correction. Interaction p-value is only produced for the Overall period. The reference group for the LS mean difference and Hedges' g is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with data; CI: Confidence interval; LS: Least squares; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; SD: Standard deviation; SE: Standard error; SMD: Standardized mean difference; UFS-QoL: Uterine Fibroid Symptom and Health-Related Quality of Life.

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Table EFF.UFSACT.MITT.Pooled.S1: Summary of Change from Baseline in UFS-QoL Activities Scale Score by Visit and Overall, by Subgroup (mITT Population)

Study: Pooled

Treatment	Study visit	n (%)[1]	Mean (SD)[1]	Change from baseline LS-mean change (SE)[2]	Difference LS-mean change [95% CI] p-value[2]	SMD Hedges' g [95% CI][2]	Int. p-value[2]
Age (years)							
< 40 years							0.7023
Relugolix+E2/NETA	Baseline	61 (98.4)	34.8 (23.56)	37.60 (3.322)	24.62	0.91	
N=62	Overall	57 (91.9)	69.5 (26.58)		[15.82,33.42]	[0.54,1.28]	
Placebo	Baseline	78 (100.0)	35.2 (23.27)	12.98 (3.005)	<.0001		
N=78	Overall	68 (87.2)	47.2 (25.23)				
>= 40 years							
Relugolix+E2/NETA	Baseline	188 (98.4)	38.4 (24.85)	41.36 (1.915)	26.62	0.99	
N=191	Overall	171 (89.5)	79.5 (23.10)		[21.25,31.99]	[0.76,1.22]	
Placebo	Baseline	176 (98.9)	33.0 (21.88)	14.74 (1.948)	<.0001		
N=178	Overall	165 (92.7)	47.0 (24.31)				

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group. Transformed score ranges from 0 to 100 based on Likert scale (None of the time, a little of the time, some of the time, most of the time and all of the time). Higher scores are indicative of better health-related quality of life (high score = good). For the change from baseline, positive scores indicate improvement.
[1] Summary statistics are based on observed data. Mean (SD) are calculated based on the mean observed value across all post-baseline visits within each patient.
[2] LS means, LS mean differences (95% CIs), p-value and Hedges' g (95% CIs) are based on a mixed-effects model with study, treatment, visit, subgroup, treatment-by-visit interaction and a subgroup-by-treatment interaction as fixed effects. The multiple visits for each patient are the repeated measures as a random effect within each patient with an unstructured covariance. Hedges' g is calculated using a small sample bias correction. The reference group for the LS mean difference and Hedges' g is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with data; CI: Confidence interval; int: Interaction; LS: Least squares; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; SD: Standard deviation; SE: Standard error; SMD: Standardized mean difference; UFS-QoL: Uterine Fibroid Symptom and Health-Related Quality of Life.

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Table EFF.UFSACT.MITT.Pooled.S4: Summary of Change from Baseline in UFS-QoL Activities Scale Score by Visit and Overall, by Subgroup (mITT Population)

Study: Pooled

Treatment	Study visit	n (%)[1]	Mean (SD)[1]	Change from baseline LS-mean change (SE)[2]	Difference LS-mean change [95% CI] p-value[2]	SMD Hedges' g [95% CI][2]
Maximum NRS Pain Score at Baseline						
< 4						
Relugolix+E2/NETA	Baseline	72 (98.6)	44.0 (24.86)	33.68 (2.950)	24.39	1.03
N=73	Week 12	65 (89.0)	76.3 (28.32)		[15.66,33.12]	[0.65,1.42]
Placebo	Baseline	61 (98.4)	43.3 (22.97)	9.29 (3.287)	<.0001	
N=62	Week 12	52 (83.9)	50.1 (24.03)			
>= 4						
Relugolix+E2/NETA	Baseline	174 (98.3)	34.7 (23.95)	39.78 (2.193)	25.05	0.92
N=177	Week 12	156 (88.1)	73.8 (27.95)		[19.12,30.98]	[0.69,1.15]
Placebo	Baseline	189 (99.5)	30.8 (21.24)	14.72 (2.065)	<.0001	
N=190	Week 12	174 (91.6)	45.8 (26.15)			
Missing						
Relugolix+E2/NETA	Baseline	3 (100.0)	47.6 (27.75)	NC (NC)	NC	NC
N=3	Week 12	3 (100.0)	57.1 (14.25)		[NC,NC]	[NC,NC]
Placebo	Baseline	4 (100.0)	19.6 (20.32)	NC (NC)	NC	
N=4	Week 12	3 (75.0)	28.6 (18.59)			

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group. Transformed score ranges from 0 to 100 based on Likert scale (None of the time, a little of the time, some of the time, most of the time and all of the time). Higher scores are indicative of better health-related quality of life (high score = good). For the change from baseline, positive scores indicate improvement.
[1] Summary statistics are based on observed data.
[2] LS means, LS mean differences (95% CIs), p-value and Hedges' g (95% CIs) are based on a mixed-effects model with study, treatment, visit, and a treatment-by-visit interaction as fixed effects. The multiple visits for each patient are the repeated measures as a random effect within each patient with an unstructured covariance. Hedges' g is calculated using a small sample bias correction. Interaction p-value is only produced for the Overall period. The reference group for the LS mean difference and Hedges' g is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with data; CI: Confidence interval; LS: Least squares; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; SD: Standard deviation; SE: Standard error; SMD: Standardized mean difference; UFS-QoL: Uterine Fibroid Symptom and Health-Related Quality of Life; NC: Not calculated.

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Table EFF.UFSACT.MITT.Pooled.S4: Summary of Change from Baseline in UFS-QoL Activities Scale Score by Visit and Overall, by Subgroup (mITT Population)

Study: Pooled

Treatment	Study visit	n (%)[1]	Mean (SD)[1]	Change from baseline LS-mean change (SE)[2]	Difference LS-mean change [95% CI] p-value[2]	SMD Hedges' g [95% CI][2]
Maximum NRS Pain Score at Baseline						
< 4						
Relugolix+E2/NETA	Baseline	72 (98.6)	44.0 (24.86)	37.66 (3.284)	28.08	1.11
N=73	Week 24	57 (78.1)	83.2 (23.14)		[18.33,37.83]	[0.69,1.52]
Placebo	Baseline	61 (98.4)	43.3 (22.97)	9.58 (3.672)	<.0001	
N=62	Week 24	46 (74.2)	53.4 (24.61)			
>= 4						
Relugolix+E2/NETA	Baseline	174 (98.3)	34.7 (23.95)	45.77 (2.315)	29.11	1.04
N=177	Week 24	136 (76.8)	82.4 (23.22)		[22.85,35.37]	[0.80,1.29]
Placebo	Baseline	189 (99.5)	30.8 (21.24)	16.66 (2.178)	<.0001	
N=190	Week 24	151 (79.5)	47.0 (28.33)			
Missing						
Relugolix+E2/NETA	Baseline	3 (100.0)	47.6 (27.75)	NC (NC)	NC	NC
N=3	Week 24	3 (100.0)	66.6 (32.41)		[NC,NC]	[NC,NC]
Placebo	Baseline	4 (100.0)	19.6 (20.32)	NC (NC)	NC	
N=4	Week 24	2 (50.0)	33.9 (2.55)			

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group. Transformed score ranges from 0 to 100 based on Likert scale (None of the time, a little of the time, some of the time, most of the time and all of the time). Higher scores are indicative of better health-related quality of life (high score = good). For the change from baseline, positive scores indicate improvement.
[1] Summary statistics are based on observed data.
[2] LS means, LS mean differences (95% CIs), p-value and Hedges' g (95% CIs) are based on a mixed-effects model with study, treatment, visit, and a treatment-by-visit interaction as fixed effects. The multiple visits for each patient are the repeated measures as a random effect within each patient with an unstructured covariance. Hedges' g is calculated using a small sample bias correction. Interaction p-value is only produced for the Overall period. The reference group for the LS mean difference and Hedges' g is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with data; CI: Confidence interval; LS: Least squares; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; SD: Standard deviation; SE: Standard error; SMD: Standardized mean difference; UFS-QoL: Uterine Fibroid Symptom and Health-Related Quality of Life; NC: Not calculated.

SOURCE: \Studies\MYV\MYV102\Analysis\Prod\Progs\TFLs\Tab_QOL_UFS_CON.SAS
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Table EFF.UFSACT.MITT.Pooled.S4: Summary of Change from Baseline in UFS-QoL Activities Scale Score by Visit and Overall, by Subgroup (mITT Population)

Study: Pooled

Treatment	Study visit	n (%)[1]	Mean (SD)[1]	Change from baseline LS-mean change (SE)[2]	Difference LS-mean change [95% CI] p-value[2]	SMD Hedges' g [95% CI][2]	Int. p-value[2]
Maximum NRS Pain Score at Baseline							
< 4							
Relugolix+E2/NETA	Baseline	72 (98.6)	44.0 (24.86)	36.06 (3.058)	26.31	0.98	0.8751
N=73	Overall	66 (90.4)	78.1 (25.34)		[17.33,35.29]	[0.60,1.36]	
Placebo	Baseline	61 (98.4)	43.3 (22.97)	9.75 (3.399)	<.0001		
N=62	Overall	54 (87.1)	50.4 (22.03)				
>= 4							
Relugolix+E2/NETA	Baseline	174 (98.3)	34.7 (23.95)	42.78 (1.980)	27.15	1.02	
N=177	Overall	159 (89.8)	76.9 (24.02)		[21.80,32.50]	[0.79,1.24]	
Placebo	Baseline	189 (99.5)	30.8 (21.24)	15.63 (1.867)	<.0001		
N=190	Overall	176 (92.6)	46.3 (25.32)				
Missing							
Relugolix+E2/NETA	Baseline	3 (100.0)	47.6 (27.75)	NC (NC)	NC	NC	
N=3	Overall	3 (100.0)	61.9 (21.29)		[NC,NC]	[NC,NC]	
Placebo	Baseline	4 (100.0)	19.6 (20.32)	NC (NC)	NC		
N=4	Overall	3 (75.0)	32.1 (10.89)				

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group. Transformed score ranges from 0 to 100 based on Likert scale (None of the time, a little of the time, some of the time, most of the time and all of the time). Higher scores are indicative of better health-related quality of life (high score = good). For the change from baseline, positive scores indicate improvement.
[1] Summary statistics are based on observed data. Mean (SD) are calculated based on the mean observed value across all post-baseline visits within each patient.
[2] LS means, LS mean differences (95% CIs), p-value and Hedges' g (95% CIs) are based on a mixed-effects model with study, treatment, visit, subgroup, treatment-by-visit interaction and a subgroup-by-treatment interaction as fixed effects. The multiple visits for each patient are the repeated measures as a random effect within each patient with an unstructured covariance. Hedges' g is calculated using a small sample bias correction. Missing subgroup levels are not included in estimation of the interaction p-value. The reference group for the LS mean difference and Hedges' g is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with data; CI: Confidence interval; int: Interaction; LS: Least squares; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; SD: Standard deviation; SE: Standard error; SMD: Standardized mean difference; UFS-QoL: Uterine Fibroid Symptom and Health-Related Quality of Life; NC: Not calculated.

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1.2.7 Proportion of Responders with at least 25 Points Increase in UFS-QoL Activities Scale Score at Week 24, by Subgroup (mITT Population)

Table QOL.UFSACT25.MITT.Pooled.S1: Proportion of Responders with at least 25 Points Increase in UFS-QoL Activities Scale Score at Week 24, by Subgroup (mITT Population)

Study: Pooled

Treatment	N	n (%)	OR[1] [95% CI]	RR[2] [95% CI]	RD[3] [95% CI]	p-value[4]	p-value (int)[5]
Age (years)							
< 40 years							
Relugolix+E2/NETA	62	33 (53.2)	2.92 [1.44;5.88]	1.89 [1.24;2.89]	0.25 [0.09;0.41]	0.0026	0.1959
Placebo	78	22 (28.2)					
>= 40 years							
Relugolix+E2/NETA	191	115 (60.2)	5.07 [3.22;7.99]	2.61 [1.95;3.50]	0.37 [0.28;0.46]	<.0001	
Placebo	178	41 (23.0)					

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group.
[1] OR (95% CI) based on a logistic regression model adjusting for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates.
[2] RR (95% CI) based on a Cochran-Mantel-Haenszel approach stratified by study.
[3] RD (95% CI) based on a Mantel-Haenszel approach stratified by study. 95% CIs are based on the approximation to the normal distribution using the Sato estimator for the standard error.
[4] P-value based on a Cochran-Mantel-Haenszel test stratified by study.
[5] Interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the OR (95% CI). * Interaction p-value < 0.05.
A continuity correction is applied in estimation of the OR, RR and p-value if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum. No continuity correction is applied in the estimation of the RD.
The reference group for the OR, RR and RD is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with an event; OR: Odds ratio; RR: Risk ratio; RD: Risk difference; CI: Confidence interval; int: p-value for interaction; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate.

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Table QOL.UFSACT25.MITT.Pooled.S4: Proportion of Responders with at least 25 Points Increase in UFS-QoL Activities Scale Score at Week 24, by Subgroup (mITT Population)

Study: Pooled

Treatment	N	n (%)	OR[1] [95% CI]	RR[2] [95% CI]	RD[3] [95% CI]	p-value[4]	p-value (int)[5]
Maximum NRS Pain Score at Baseline							
< 4							
Relugolix+E2/NETA	73	42 (57.5)	6.40	3.31	0.41	<.0001	0.2996
Placebo	62	11 (17.7)	[2.87;14.26]	[1.87;5.85]	[0.26;0.55]		
>= 4							
Relugolix+E2/NETA	177	105 (59.3)	3.97	2.21	0.32	<.0001	
Placebo	190	51 (26.8)	[2.56;6.16]	[1.69;2.87]	[0.23;0.42]		
Missing							
Relugolix+E2/NETA	3	1 (33.3)	NC	NC	NC	NC	
Placebo	4	1 (25.0)	[NC;NC]	[NC;NC]	[NC;NC]		

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group.
[1] OR (95% CI) based on a logistic regression model adjusting for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates.
[2] RR (95% CI) based on a Cochran-Mantel-Haenszel approach stratified by study.
[3] RD (95% CI) based on a Mantel-Haenszel approach stratified by study. 95% CIs are based on the approximation to the normal distribution using the Sato estimator for the standard error.
[4] P-value based on a Cochran-Mantel-Haenszel test stratified by study.
[5] Interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the OR (95% CI). Missing subgroup levels are not included in estimation of the interaction p-value. * Interaction p-value < 0.05.
A continuity correction is applied in estimation of the OR, RR and p-value if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum. No continuity correction is applied in the estimation of the RD.
The reference group for the OR, RR and RD is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with an event; OR: Odds ratio; RR: Risk ratio; RD: Risk difference; CI: Confidence interval; int: p-value for interaction; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; NC: Not calculated.

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Table QOL.UFSACT25.MITT.Pooled.S5: Proportion of Responders with at least 25 Points Increase in UFS-QoL Activities Scale Score at Week 24, by Subgroup (mITT Population)

Study: Pooled

Treatment	N	n (%)	OR[1] [95% CI]	RR[2] [95% CI]	RD[3] [95% CI]	p-value[4]	p-value (int)[5]
MBL Volume at Baseline (mL)							
< 225 mL							
Relugolix+E2/NETA	164	96 (58.5)	3.98	2.22	0.32	<.0001	0.5017
Placebo	171	45 (26.3)	[2.51;6.31]	[1.68;2.95]	[0.22;0.42]		
>= 225 mL							
Relugolix+E2/NETA	89	52 (58.4)	5.25	2.76	0.37	<.0001	
Placebo	85	18 (21.2)	[2.68;10.26]	[1.77;4.31]	[0.24;0.51]		

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group.
[1] OR (95% CI) based on a logistic regression model adjusting for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates.
[2] RR (95% CI) based on a Cochran-Mantel-Haenszel approach stratified by study.
[3] RD (95% CI) based on a Mantel-Haenszel approach stratified by study. 95% CIs are based on the approximation to the normal distribution using the Sato estimator for the standard error.
[4] P-value based on a Cochran-Mantel-Haenszel test stratified by study.
[5] Interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the OR (95% CI). * Interaction p-value < 0.05.
A continuity correction is applied in estimation of the OR, RR and p-value if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum. No continuity correction is applied in the estimation of the RD.
The reference group for the OR, RR and RD is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with an event; OR: Odds ratio; RR: Risk ratio; RD: Risk difference; CI: Confidence interval; int: p-value for interaction; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; NC: Not calculated.

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Table QOL.UFSACT25.MITT.Pooled.S8: Proportion of Responders with at least 25 Points Increase in UFS-QoL Activities Scale Score at Week 24, by Subgroup (mITT Population)

Study: Pooled

Treatment	N	n (%)	OR[1] [95% CI]	RR[2] [95% CI]	RD[3] [95% CI]	p-value[4]	p-value (int)[5]
Ethnicity							
Hispanic or Latino							0.5159
Relugolix+E2/NETA	52	32 (61.5)	3.45	2.06	0.32	0.0014	
Placebo	55	18 (32.7)	[1.55;7.67]	[1.29;3.28]	[0.14;0.50]		
Not Hispanic or Latino							
Relugolix+E2/NETA	197	114 (57.9)	4.67	2.56	0.35	<.0001	
Placebo	199	45 (22.6)	[3.02;7.23]	[1.92;3.40]	[0.26;0.44]		
Not reported							
Relugolix+E2/NETA	4	2 (50.0)	NC	NC	NC	NC	
Placebo	2	0	[NC;NC]	[NC;NC]	[NC;NC]		

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group.
[1] OR (95% CI) based on a logistic regression model adjusting for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates.
[2] RR (95% CI) based on a Cochran-Mantel-Haenszel approach stratified by study.
[3] RD (95% CI) based on a Mantel-Haenszel approach stratified by study. 95% CIs are based on the approximation to the normal distribution using the Sato estimator for the standard error.
[4] P-value based on a Cochran-Mantel-Haenszel test stratified by study.
[5] Interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the OR (95% CI). Not reported subgroup levels are not included in estimation of the interaction p-value.
* Interaction p-value < 0.05.
A continuity correction is applied in estimation of the OR, RR and p-value if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum. No continuity correction is applied in the estimation of the RD.
The reference group for the OR, RR and RD is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with an event; OR: Odds ratio; RR: Risk ratio; RD: Risk difference; CI: Confidence interval; int: p-value for interaction; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; NC: Not calculated.

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Table QOL.UFSACT25.MITT.Pooled.S3: Proportion of Responders with at least 25 Points Increase in UFS-QoL Activities Scale Score at Week 24, by Subgroup (mITT Population)

Study: Pooled

Treatment	N	n (%)	OR[1] [95% CI]	RR[2] [95% CI]	RD[3] [95% CI]	p-value[4]	p-value (int)[5]
Uterine Volume at Baseline (cm3)							
< 300 cm3							
Relugolix+E2/NETA	148	87 (58.8)	4.94	2.61	0.36	<.0001	0.5461
Placebo	129	29 (22.5)	[2.91;8.37]	[1.85;3.70]	[0.26;0.47]		
>= 300 cm3							
Relugolix+E2/NETA	104	61 (58.7)	3.90	2.20	0.32	<.0001	
Placebo	127	34 (26.8)	[2.24;6.79]	[1.58;3.05]	[0.20;0.44]		
Missing							
Relugolix+E2/NETA	1	0	NC	NC	NC	NC	
Placebo	0	0	[NC;NC]	[NC;NC]	[NC;NC]		

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group.
[1] OR (95% CI) based on a logistic regression model adjusting for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates.
[2] RR (95% CI) based on a Cochran-Mantel-Haenszel approach stratified by study.
[3] RD (95% CI) based on a Mantel-Haenszel approach stratified by study. 95% CIs are based on the approximation to the normal distribution using the Sato estimator for the standard error.
[4] P-value based on a Cochran-Mantel-Haenszel test stratified by study.
[5] Interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the OR (95% CI). Missing subgroup levels are not included in estimation of the interaction p-value. * Interaction p-value < 0.05.
A continuity correction is applied in estimation of the OR, RR and p-value if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum. No continuity correction is applied in the estimation of the RD.
The reference group for the OR, RR and RD is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with an event; OR: Odds ratio; RR: Risk ratio; RD: Risk difference; CI: Confidence interval; int: p-value for interaction; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; NC: Not calculated.

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Table QOL.UFSACT25.MITT.Pooled.S9: Proportion of Responders with at least 25 Points Increase in UFS-QoL Activities Scale Score at Week 24, by Subgroup (mITT Population)

Study: Pooled

Treatment	N	n (%)	OR[1] [95% CI]	RR[2] [95% CI]	RD[3] [95% CI]	p-value[4]	p-value (int)[5]
Race							
Black/African American							0.5608
Relugolix+E2/NETA	122	64 (52.5)	3.36	2.11	0.28	<.0001	
Placebo	141	35 (24.8)	[1.99;5.66]	[1.52;2.95]	[0.16;0.39]		
White							
Relugolix+E2/NETA	122	78 (63.9)	5.13	2.48	0.38	<.0001	
Placebo	105	27 (25.7)	[2.89;9.11]	[1.75;3.53]	[0.26;0.50]		
Asian							
Relugolix+E2/NETA	1	1 (100.0)	NC	NC	NC	NC	
Placebo	3	0	[NC;NC]	[NC;NC]	[NC;NC]		
Others							
Relugolix+E2/NETA	5	3 (60.0)	4.30	2.71	0.59	0.1839	
Placebo	6	1 (16.7)	[0.48;38.75]	[0.62;11.79]	[0.23;0.96]		
Not reported							
Relugolix+E2/NETA	3	2 (66.7)	NC	NC	NC	NC	
Placebo	1	0	[NC;NC]	[NC;NC]	[NC;NC]		

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group.
[1] OR (95% CI) based on a logistic regression model adjusting for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates.
[2] RR (95% CI) based on a Cochran-Mantel-Haenszel approach stratified by study.
[3] RD (95% CI) based on a Mantel-Haenszel approach stratified by study. 95% CIs are based on the approximation to the normal distribution using the Sato estimator for the standard error.
[4] P-value based on a Cochran-Mantel-Haenszel test stratified by study.
[5] Interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the OR (95% CI). Not reported subgroup levels are not included in estimation of the interaction p-value.
* Interaction p-value < 0.05.
A continuity correction is applied in estimation of the OR, RR and p-value if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum. No continuity correction is applied in the estimation of the RD.
The reference group for the OR, RR and RD is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with an event; OR: Odds ratio; RR: Risk ratio; RD: Risk difference; CI: Confidence interval; int: p-value for interaction; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; NC: Not calculated.

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Table QOL.UFSACT25.MITT.Pooled.S2: Proportion of Responders with at least 25 Points Increase in UFS-QoL Activities Scale Score at Week 24, by Subgroup (mITT Population)

Study: Pooled

Treatment	N	n (%)	OR[1] [95% CI]	RR[2] [95% CI]	RD[3] [95% CI]	p-value[4]	p-value (int)[5]
BMI (kg/m2) at Baseline							
< 30							
Relugolix+E2/NETA	119	68 (57.1)	4.85	2.64	0.36	<.0001	0.6053
Placebo	115	25 (21.7)	[2.73;8.62]	[1.81;3.87]	[0.24;0.47]		
>= 30							
Relugolix+E2/NETA	133	79 (59.4)	3.97	2.20	0.32	<.0001	
Placebo	141	38 (27.0)	[2.39;6.60]	[1.62;2.99]	[0.21;0.44]		
Missing							
Relugolix+E2/NETA	1	1 (100.0)	NC	NC	NC	NC	
Placebo	0	0	[NC;NC]	[NC;NC]	[NC;NC]		

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group.
[1] OR (95% CI) based on a logistic regression model adjusting for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates.
[2] RR (95% CI) based on a Cochran-Mantel-Haenszel approach stratified by study.
[3] RD (95% CI) based on a Mantel-Haenszel approach stratified by study. 95% CIs are based on the approximation to the normal distribution using the Sato estimator for the standard error.
[4] P-value based on a Cochran-Mantel-Haenszel test stratified by study.
[5] Interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the OR (95% CI). Missing subgroup levels are not included in estimation of the interaction p-value. * Interaction p-value < 0.05.
A continuity correction is applied in estimation of the OR, RR and p-value if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum. No continuity correction is applied in the estimation of the RD.
The reference group for the OR, RR and RD is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with an event; OR: Odds ratio; RR: Risk ratio; RD: Risk difference; CI: Confidence interval; int: p-value for interaction; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; NC: Not calculated.

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1.2.8 Summary of Change from Baseline in UFS-QoL Revised Activities Scale Score by Visit and Overall, by Subgroup (mITT Population)

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Table EFF.UFSREVA.MITT.Pooled.S3: Summary of Change from Baseline in UFS-QoL Revised Activities Scale Score by Visit and Overall, by Subgroup (mITT Population)

Study: Pooled

Treatment	Study visit	n (%)[1]	Mean (SD)[1]	Change from baseline LS-mean change (SE)[2]	Difference LS-mean change [95% CI] p-value[2]	SMD Hedges' g [95% CI][2]
Uterine Volume at Baseline (cm3)						
< 300 cm3						
Relugolix+E2/NETA	Baseline	147 (99.3)	37.7 (25.41)	39.94 (2.312)	28.74	1.08
N=148	Week 12	132 (89.2)	77.5 (26.58)		[22.09,35.40]	[0.82,1.35]
Placebo	Baseline	129 (100.0)	33.5 (22.01)	11.20 (2.464)	<.0001	
N=129	Week 12	115 (89.1)	44.4 (25.95)			
>= 300 cm3						
Relugolix+E2/NETA	Baseline	101 (97.1)	31.8 (24.96)	37.63 (3.063)	21.02	0.72
N=104	Week 12	92 (88.5)	67.8 (31.88)		[12.91,29.12]	[0.44,1.01]
Placebo	Baseline	125 (98.4)	29.0 (23.51)	16.61 (2.739)	<.0001	
N=127	Week 12	114 (89.8)	45.1 (28.11)			
Missing						
Relugolix+E2/NETA	Baseline	1 (100.0)	20.0 (NE)	NC (NC)	NC	NC
N=1	Week 12	0	NE (NE)		[NC,NC]	[NC,NC]
Placebo	Baseline	0	NE (NE)	NC (NC)	NC	
N=0	Week 12	0	NE (NE)			

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group. Transformed score ranges from 0 to 100 based on Likert scale (None of the time, a little of the time, some of the time, most of the time and all of the time). Higher scores are indicative of better health-related quality of life (high score = good). For the change from baseline, positive scores indicate improvement.
[1] Summary statistics are based on observed data.
[2] LS means, LS mean differences (95% CIs), p-value and Hedges' g (95% CIs) are based on a mixed-effects model with study, treatment, visit, and a treatment-by-visit interaction as fixed effects. The multiple visits for each patient are the repeated measures as a random effect within each patient with an unstructured covariance. Hedges' g is calculated using a small sample bias correction. Interaction p-value is only produced for the Overall period. The reference group for the LS mean difference and Hedges' g is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with data; CI: Confidence interval; LS: Least squares; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; SD: Standard deviation; SE: Standard error; SMD: Standardized mean difference; UFS-QoL: Uterine Fibroid Symptom and Health-Related Quality of Life; NC: Not calculated; NE: Non-estimable.

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Table EFF.UFSREVA.MITT.Pooled.S3: Summary of Change from Baseline in UFS-QoL Revised Activities Scale Score by Visit and Overall, by Subgroup (mITT Population)

Study: Pooled

Treatment	Study visit	n (%)[1]	Mean (SD)[1]	Change from baseline LS-mean change (SE)[2]	Difference LS-mean change [95% CI] p-value[2]	SMD Hedges' g [95% CI][2]
Uterine Volume at Baseline (cm3)						
< 300 cm3						
Relugolix+E2/NETA	Baseline	147 (99.3)	37.7 (25.41)	44.66 (2.531)	31.96	1.14
N=148	Week 24	116 (78.4)	84.2 (22.64)		[24.69,39.23]	[0.85,1.42]
Placebo	Baseline	129 (100.0)	33.5 (22.01)	12.70 (2.688)	<.0001	
N=129	Week 24	102 (79.1)	46.1 (27.21)			
>= 300 cm3						
Relugolix+E2/NETA	Baseline	101 (97.1)	31.8 (24.96)	44.08 (3.047)	26.12	0.93
N=104	Week 24	80 (76.9)	78.1 (26.67)		[18.04,34.20]	[0.62,1.24]
Placebo	Baseline	125 (98.4)	29.0 (23.51)	17.96 (2.740)	<.0001	
N=127	Week 24	97 (76.4)	46.6 (28.39)			
Missing						
Relugolix+E2/NETA	Baseline	1 (100.0)	20.0 (NE)	NC (NC)	NC	NC
N=1	Week 24	0	NE (NE)		[NC,NC]	[NC,NC]
Placebo	Baseline	0	NE (NE)	NC (NC)	NC	
N=0	Week 24	0	NE (NE)			

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group. Transformed score ranges from 0 to 100 based on Likert scale (None of the time, a little of the time, some of the time, most of the time and all of the time). Higher scores are indicative of better health-related quality of life (high score = good). For the change from baseline, positive scores indicate improvement.
[1] Summary statistics are based on observed data.
[2] LS means, LS mean differences (95% CIs), p-value and Hedges' g (95% CIs) are based on a mixed-effects model with study, treatment, visit, and a treatment-by-visit interaction as fixed effects. The multiple visits for each patient are the repeated measures as a random effect within each patient with an unstructured covariance. Hedges' g is calculated using a small sample bias correction. Interaction p-value is only produced for the Overall period. The reference group for the LS mean difference and Hedges' g is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with data; CI: Confidence interval; LS: Least squares; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; SD: Standard deviation; SE: Standard error; SMD: Standardized mean difference; UFS-QoL: Uterine Fibroid Symptom and Health-Related Quality of Life; NC: Not calculated; NE: Non-estimable.

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Table EFF.UFSREVA.MITT.Pooled.S3: Summary of Change from Baseline in UFS-QoL Revised Activities Scale Score by Visit and Overall, by Subgroup (mITT Population)

Study: Pooled

Treatment	Study visit	n (%)[1]	Mean (SD)[1]	Change from baseline LS-mean change (SE)[2]	Difference LS-mean change [95% CI] p-value[2]	SMD Hedges' g [95% CI][2]	Int. p-value[2]
Uterine Volume at Baseline (cm3)							
< 300 cm3							
Relugolix+E2/NETA	Baseline	147 (99.3)	37.7 (25.41)	42.35 (2.225)	30.37	1.09	0.1623
N=148	Overall	134 (90.5)	79.9 (22.25)		[24.00,36.75]	[0.83,1.36]	
Placebo	Baseline	129 (100.0)	33.5 (22.01)	11.97 (2.364)	<.0001		
N=129	Overall	118 (91.5)	44.4 (23.74)				
>= 300 cm3							
Relugolix+E2/NETA	Baseline	101 (97.1)	31.8 (24.96)	40.87 (2.692)	23.58	0.85	
N=104	Overall	94 (90.4)	71.1 (28.84)		[16.47,30.69]	[0.56,1.13]	
Placebo	Baseline	125 (98.4)	29.0 (23.51)	17.29 (2.415)	<.0001		
N=127	Overall	115 (90.6)	45.9 (26.80)				
Missing							
Relugolix+E2/NETA	Baseline	1 (100.0)	20.0 (NE)	NC (NC)	NC	NC	
N=1	Overall	0	NE (NE)		[NC,NC]	[NC,NC]	
Placebo	Baseline	0	NE (NE)	NC (NC)	NC		
N=0	Overall	0	NE (NE)				

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group. Transformed score ranges from 0 to 100 based on Likert scale (None of the time, a little of the time, some of the time, most of the time and all of the time). Higher scores are indicative of better health-related quality of life (high score = good). For the change from baseline, positive scores indicate improvement.
[1] Summary statistics are based on observed data. Mean (SD) are calculated based on the mean observed value across all post-baseline visits within each patient.
[2] LS means, LS mean differences (95% CIs), p-value and Hedges' g (95% CIs) are based on a mixed-effects model with study, treatment, visit, subgroup, treatment-by-visit interaction and a subgroup-by-treatment interaction as fixed effects. The multiple visits for each patient are the repeated measures as a random effect within each patient with an unstructured covariance. Hedges' g is calculated using a small sample bias correction. Missing subgroup levels are not included in estimation of the interaction p-value. The reference group for the LS mean difference and Hedges' g is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with data; CI: Confidence interval; int: Interaction; LS: Least squares; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; SD: Standard deviation; SE: Standard error; SMD: Standardized mean difference; UFS-QoL: Uterine Fibroid Symptom and Health-Related Quality of Life; NC: Not calculated; NE: Non-estimable.

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Table EFF.UFSREVA.MITT.Pooled.S8: Summary of Change from Baseline in UFS-QoL Revised Activities Scale Score by Visit and Overall, by Subgroup (mITT Population)

Study: Pooled

Treatment	Study visit	n (%)[1]	Mean (SD)[1]	Change from baseline LS-mean change (SE)[2]	Difference LS-mean change [95% CI] p-value[2]	SMD Hedges' g [95% CI][2]
Ethnicity						
Hispanic or Latino						
Relugolix+E2/NETA	Baseline	52 (100.0)	37.4 (21.95)	39.80 (3.860)	19.97	0.76
N=52	Week 12	47 (90.4)	75.7 (28.55)		[9.22,30.71]	[0.35,1.17]
Placebo	Baseline	55 (100.0)	22.5 (20.68)	19.83 (3.733)	0.0004	
N=55	Week 12	49 (89.1)	41.7 (29.66)			
Not Hispanic or Latino						
Relugolix+E2/NETA	Baseline	193 (98.0)	34.1 (25.71)	39.29 (2.163)	26.86	0.95
N=197	Week 12	174 (88.3)	72.5 (29.50)		[20.89,32.83]	[0.73,1.18]
Placebo	Baseline	197 (99.0)	33.9 (22.82)	12.43 (2.125)	<.0001	
N=199	Week 12	178 (89.4)	46.0 (26.12)			
Not reported						
Relugolix+E2/NETA	Baseline	4 (100.0)	65.0 (33.42)	NC (NC)	NC	NC
N=4	Week 12	3 (75.0)	96.7 (5.77)		[NC,NC]	[NC,NC]
Placebo	Baseline	2 (100.0)	20.0 (28.28)	NC (NC)	NC	
N=2	Week 12	2 (100.0)	12.5 (17.68)			

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group. Transformed score ranges from 0 to 100 based on Likert scale (None of the time, a little of the time, some of the time, most of the time and all of the time). Higher scores are indicative of better health-related quality of life (high score = good). For the change from baseline, positive scores indicate improvement.
[1] Summary statistics are based on observed data.
[2] LS means, LS mean differences (95% CIs), p-value and Hedges' g (95% CIs) are based on a mixed-effects model with study, treatment, visit, and a treatment-by-visit interaction as fixed effects. The multiple visits for each patient are the repeated measures as a random effect within each patient with an unstructured covariance. Hedges' g is calculated using a small sample bias correction. Interaction p-value is only produced for the Overall period. The reference group for the LS mean difference and Hedges' g is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with data; CI: Confidence interval; LS: Least squares; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; SD: Standard deviation; SE: Standard error; SMD: Standardized mean difference; UFS-QoL: Uterine Fibroid Symptom and Health-Related Quality of Life; NC: Not calculated.

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Table EFF.UFSREVA.MITT.Pooled.S8: Summary of Change from Baseline in UFS-QoL Revised Activities Scale Score by Visit and Overall, by Subgroup (mITT Population)

Study: Pooled

Treatment	Study visit	n (%)[1]	Mean (SD)[1]	Change from baseline LS-mean change (SE)[2]	Difference LS-mean change [95% CI] p-value[2]	SMD Hedges' g [95% CI][2]
Ethnicity						
Hispanic or Latino						
Relugolix+E2/NETA	Baseline	52 (100.0)	37.4 (21.95)	44.92 (4.243)	25.12	0.89
N=52	Week 24	44 (84.6)	82.3 (22.66)		[13.31,36.93]	[0.46,1.32]
Placebo	Baseline	55 (100.0)	22.5 (20.68)	19.80 (4.102)	<.0001	
N=55	Week 24	46 (83.6)	41.8 (30.72)			
Not Hispanic or Latino						
Relugolix+E2/NETA	Baseline	193 (98.0)	34.1 (25.71)	44.85 (2.220)	30.79	1.10
N=197	Week 24	149 (75.6)	81.2 (25.21)		[24.65,36.93]	[0.85,1.34]
Placebo	Baseline	197 (99.0)	33.9 (22.82)	14.07 (2.187)	<.0001	
N=199	Week 24	151 (75.9)	48.1 (26.59)			
Not reported						
Relugolix+E2/NETA	Baseline	4 (100.0)	65.0 (33.42)	NC (NC)	NC	NC
N=4	Week 24	3 (75.0)	96.7 (5.77)		[NC,NC]	[NC,NC]
Placebo	Baseline	2 (100.0)	20.0 (28.28)	NC (NC)	NC	
N=2	Week 24	2 (100.0)	17.5 (24.75)			

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group. Transformed score ranges from 0 to 100 based on Likert scale (None of the time, a little of the time, some of the time, most of the time and all of the time). Higher scores are indicative of better health-related quality of life (high score = good). For the change from baseline, positive scores indicate improvement.
[1] Summary statistics are based on observed data.
[2] LS means, LS mean differences (95% CIs), p-value and Hedges' g (95% CIs) are based on a mixed-effects model with study, treatment, visit, and a treatment-by-visit interaction as fixed effects. The multiple visits for each patient are the repeated measures as a random effect within each patient with an unstructured covariance. Hedges' g is calculated using a small sample bias correction. Interaction p-value is only produced for the Overall period. The reference group for the LS mean difference and Hedges' g is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with data; CI: Confidence interval; LS: Least squares; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; SD: Standard deviation; SE: Standard error; SMD: Standardized mean difference; UFS-QoL: Uterine Fibroid Symptom and Health-Related Quality of Life; NC: Not calculated.

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Table EFF.UFSREVA.MITT.Pooled.S8: Summary of Change from Baseline in UFS-QoL Revised Activities Scale Score by Visit and Overall, by Subgroup (mITT Population)

Study: Pooled

Treatment	Study visit	n (%)[1]	Mean (SD)[1]	Change from baseline LS-mean change (SE)[2]	Difference LS-mean change [95% CI] p-value[2]	SMD Hedges' g [95% CI][2]	Int. p-value[2]
Ethnicity							
Hispanic or Latino							
Relugolix+E2/NETA	Baseline	52 (100.0)	37.4 (21.95)	42.17 (3.678)	22.29	0.80	0.2659
N=52	Overall	49 (94.2)	78.8 (22.33)		[12.16,32.41]	[0.39,1.20]	
Placebo	Baseline	55 (100.0)	22.5 (20.68)	19.88 (3.590)	<.0001		
N=55	Overall	51 (92.7)	41.3 (27.32)				
Not Hispanic or Latino							
Relugolix+E2/NETA	Baseline	193 (98.0)	34.1 (25.71)	42.09 (1.962)	28.82	1.04	
N=197	Overall	176 (89.3)	75.2 (26.38)		[23.40,34.23]	[0.81,1.26]	
Placebo	Baseline	197 (99.0)	33.9 (22.82)	13.27 (1.930)	<.0001		
N=199	Overall	180 (90.5)	46.6 (24.47)				
Not reported							
Relugolix+E2/NETA	Baseline	4 (100.0)	65.0 (33.42)	NC (NC)	NC	NC	
N=4	Overall	3 (75.0)	96.7 (2.89)		[NC,NC]	[NC,NC]	
Placebo	Baseline	2 (100.0)	20.0 (28.28)	NC (NC)	NC		
N=2	Overall	2 (100.0)	15.0 (21.21)				

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group. Transformed score ranges from 0 to 100 based on Likert scale (None of the time, a little of the time, some of the time, most of the time and all of the time). Higher scores are indicative of better health-related quality of life (high score = good). For the change from baseline, positive scores indicate improvement.
[1] Summary statistics are based on observed data. Mean (SD) are calculated based on the mean observed value across all post-baseline visits within each patient.
[2] LS means, LS mean differences (95% CIs), p-value and Hedges' g (95% CIs) are based on a mixed-effects model with study, treatment, visit, subgroup, treatment-by-visit interaction and a subgroup-by-treatment interaction as fixed effects. The multiple visits for each patient are the repeated measures as a random effect within each patient with an unstructured covariance. Hedges' g is calculated using a small sample bias correction. Not reported subgroup levels are not included in estimation of the interaction p-value. The reference group for the LS mean difference and Hedges' g is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with data; CI: Confidence interval; int: Interaction; LS: Least squares; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; SD: Standard deviation; SE: Standard error; SMD: Standardized mean difference; UFS-QoL: Uterine Fibroid Symptom and Health-Related Quality of Life; NC: Not calculated.

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Table EFF.UFSREVA.MITT.Pooled.S6: Summary of Change from Baseline in UFS-QoL Revised Activities Scale Score by Visit and Overall, by Subgroup (mITT Population)

Study: Pooled

Treatment	Study visit	n (%)[1]	Mean (SD)[1]	Change from baseline LS-mean change (SE)[2]	Difference LS-mean change [95% CI] p-value[2]	SMD Hedges' g [95% CI][2]
Geographic Region I						
North America						
Relugolix+E2/NETA	Baseline	188 (98.4)	33.7 (25.32)	38.90 (2.243)	23.81	0.83
N=191	Week 12	165 (86.4)	71.9 (30.27)		[17.63,29.98]	[0.61,1.05]
Placebo	Baseline	192 (99.0)	30.4 (23.43)	15.09 (2.196)	<.0001	
N=194	Week 12	172 (88.7)	45.3 (28.01)			
Rest of World						
Relugolix+E2/NETA	Baseline	61 (98.4)	40.1 (24.87)	39.45 (3.268)	29.19	1.17
N=62	Week 12	59 (95.2)	78.0 (25.70)		[20.03,38.35]	[0.78,1.57]
Placebo	Baseline	62 (100.0)	34.0 (20.79)	10.26 (3.270)	<.0001	
N=62	Week 12	57 (91.9)	43.2 (23.80)			

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group. Transformed score ranges from 0 to 100 based on Likert scale (None of the time, a little of the time, some of the time, most of the time and all of the time). Higher scores are indicative of better health-related quality of life (high score = good). For the change from baseline, positive scores indicate improvement.
[1] Summary statistics are based on observed data.
[2] LS means, LS mean differences (95% CIs), p-value and Hedges' g (95% CIs) are based on a mixed-effects model with study, treatment, visit, and a treatment-by-visit interaction as fixed effects. The multiple visits for each patient are the repeated measures as a random effect within each patient with an unstructured covariance. Hedges' g is calculated using a small sample bias correction. Interaction p-value is only produced for the Overall period. The reference group for the LS mean difference and Hedges' g is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with data; CI: Confidence interval; LS: Least squares; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; SD: Standard deviation; SE: Standard error; SMD: Standardized mean difference; UFS-QoL: Uterine Fibroid Symptom and Health-Related Quality of Life.

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Table EFF.UFSREVA.MITT.Pooled.S6: Summary of Change from Baseline in UFS-QoL Revised Activities Scale Score by Visit and Overall, by Subgroup (mITT Population)

Study: Pooled

Treatment	Study visit	n (%)[1]	Mean (SD)[1]	Change from baseline LS-mean change (SE)[2]	Difference LS-mean change [95% CI] p-value[2]	SMD Hedges' g [95% CI][2]
Geographic Region I						
North America						
Relugolix+E2/NETA	Baseline	188 (98.4)	33.7 (25.32)	43.68 (2.327)	28.46	0.99
N=191	Week 24	139 (72.8)	80.0 (25.52)		[22.07,34.85]	[0.75,1.24]
Placebo	Baseline	192 (99.0)	30.4 (23.43)	15.23 (2.268)	<.0001	
N=194	Week 24	146 (75.3)	45.6 (28.67)			
Rest of World						
Relugolix+E2/NETA	Baseline	61 (98.4)	40.1 (24.87)	46.28 (3.551)	31.04	1.16
N=62	Week 24	57 (91.9)	85.9 (21.40)		[21.00,41.07]	[0.76,1.56]
Placebo	Baseline	62 (100.0)	34.0 (20.79)	15.25 (3.614)	<.0001	
N=62	Week 24	53 (85.5)	48.5 (25.05)			

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group. Transformed score ranges from 0 to 100 based on Likert scale (None of the time, a little of the time, some of the time, most of the time and all of the time). Higher scores are indicative of better health-related quality of life (high score = good). For the change from baseline, positive scores indicate improvement.
[1] Summary statistics are based on observed data.
[2] LS means, LS mean differences (95% CIs), p-value and Hedges' g (95% CIs) are based on a mixed-effects model with study, treatment, visit, and a treatment-by-visit interaction as fixed effects. The multiple visits for each patient are the repeated measures as a random effect within each patient with an unstructured covariance. Hedges' g is calculated using a small sample bias correction. Interaction p-value is only produced for the Overall period. The reference group for the LS mean difference and Hedges' g is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with data; CI: Confidence interval; LS: Least squares; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; SD: Standard deviation; SE: Standard error; SMD: Standardized mean difference; UFS-QoL: Uterine Fibroid Symptom and Health-Related Quality of Life.

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Table EFF.UFSREVA.MITT.Pooled.S6: Summary of Change from Baseline in UFS-QoL Revised Activities Scale Score by Visit and Overall, by Subgroup (mITT Population)

Study: Pooled

Treatment	Study visit	n (%)[1]	Mean (SD)[1]	Change from baseline LS-mean change (SE)[2]	Difference LS-mean change [95% CI] p-value[2]	SMD Hedges' g [95% CI][2]	Int. p-value[2]
Geographic Region I							
North America							
Relugolix+E2/NETA	Baseline	188 (98.4)	33.7 (25.32)	41.33 (2.006)	26.08	0.94	0.4455
N=191	Overall	169 (88.5)	74.6 (26.46)		[20.56,31.60]	[0.71,1.16]	
Placebo	Baseline	192 (99.0)	30.4 (23.43)	15.25 (1.965)	<.0001		
N=194	Overall	174 (89.7)	45.0 (26.45)				
Rest of World							
Relugolix+E2/NETA	Baseline	61 (98.4)	40.1 (24.87)	42.89 (3.336)	30.28	1.08	
N=62	Overall	59 (95.2)	81.1 (21.98)		[21.00,39.55]	[0.70,1.47]	
Placebo	Baseline	62 (100.0)	34.0 (20.79)	12.62 (3.340)	<.0001		
N=62	Overall	59 (95.2)	45.8 (21.53)				

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group. Transformed score ranges from 0 to 100 based on Likert scale (None of the time, a little of the time, some of the time, most of the time and all of the time). Higher scores are indicative of better health-related quality of life (high score = good). For the change from baseline, positive scores indicate improvement.
[1] Summary statistics are based on observed data. Mean (SD) are calculated based on the mean observed value across all post-baseline visits within each patient.
[2] LS means, LS mean differences (95% CIs), p-value and Hedges' g (95% CIs) are based on a mixed-effects model with study, treatment, visit, subgroup, treatment-by-visit interaction and a subgroup-by-treatment interaction as fixed effects. The multiple visits for each patient are the repeated measures as a random effect within each patient with an unstructured covariance. Hedges' g is calculated using a small sample bias correction. The reference group for the LS mean difference and Hedges' g is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with data; CI: Confidence interval; int: Interaction; LS: Least squares; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; SD: Standard deviation; SE: Standard error; SMD: Standardized mean difference; UFS-QoL: Uterine Fibroid Symptom and Health-Related Quality of Life.

SOURCE: \Studies\MYV\MYV102\Analysis\Prod\Progs\TFLs\Tab_QOL_UFS_CON.SAS
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Analysis Plan: 13JAN2021

Table EFF.UFSREVA.MITT.Pooled.S9: Summary of Change from Baseline in UFS-QoL Revised Activities Scale Score by Visit and Overall, by Subgroup (mITT Population)

Study: Pooled

Treatment	Study visit	n (%)[1]	Mean (SD)[1]	Change from baseline LS-mean change (SE)[2]	Difference LS-mean change [95% CI] p-value[2]	SMD Hedges' g [95% CI][2]
Race						
Black/African American						
Relugolix+E2/NETA	Baseline	119 (97.5)	30.8 (26.19)	41.07 (2.838)	26.98	0.94
N=122	Week 12	105 (86.1)	70.2 (29.68)		[19.39,34.57]	[0.66,1.22]
Placebo	Baseline	139 (98.6)	31.7 (23.73)	14.09 (2.605)	<.0001	
N=141	Week 12	122 (86.5)	45.2 (27.21)			
White						
Relugolix+E2/NETA	Baseline	121 (99.2)	38.2 (23.47)	38.37 (2.551)	24.40	0.91
N=122	Week 12	110 (90.2)	76.3 (29.12)		[17.08,31.72]	[0.63,1.20]
Placebo	Baseline	105 (100.0)	31.3 (22.21)	13.97 (2.703)	<.0001	
N=105	Week 12	98 (93.3)	45.4 (26.60)			
Asian						
Relugolix+E2/NETA	Baseline	1 (100.0)	55.0 (NE)	NC (NC)	NC	NC
N=1	Week 12	1 (100.0)	100.0 (NE)		[NC,NC]	[NC,NC]
Placebo	Baseline	3 (100.0)	26.7 (23.63)	NC (NC)	NC	
N=3	Week 12	3 (100.0)	21.7 (5.77)			
Others						
Relugolix+E2/NETA	Baseline	5 (100.0)	42.0 (21.10)	27.85 (14.351)	8.13	0.27
N=5	Week 12	5 (100.0)	66.0 (20.43)		[-39.52,55.78]	[-0.85,1.40]
Placebo	Baseline	6 (100.0)	23.3 (15.06)	19.72 (13.514)	0.6986	
N=6	Week 12	5 (83.3)	40.0 (37.58)			
Not reported						
Relugolix+E2/NETA	Baseline	3 (100.0)	75.0 (25.00)	NC (NC)	NC	NC
N=3	Week 12	3 (100.0)	88.3 (20.21)		[NC,NC]	[NC,NC]
Placebo	Baseline	1 (100.0)	40.0 (NE)	NC (NC)	NC	

N=1	Week 12	1 (100.0)	25.0 (NE)			

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group. Transformed score ranges from 0 to 100 based on Likert scale (None of the time, a little of the time, some of the time, most of the time and all of the time). Higher scores are indicative of better health-related quality of life (high score = good). For the change from baseline, positive scores indicate improvement.
[1] Summary statistics are based on observed data.
[2] LS means, LS mean differences (95% CIs), p-value and Hedges' g (95% CIs) are based on a mixed-effects model with study, treatment, visit, and a treatment-by-visit interaction as fixed effects. The multiple visits for each patient are the repeated measures as a random effect within each patient with an unstructured covariance. Hedges' g is calculated using a small sample bias correction. Interaction p-value is only produced for the Overall period. The reference group for the LS mean difference and Hedges' g is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with data; CI: Confidence interval; LS: Least squares; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; SD: Standard deviation; SE: Standard error; SMD: Standardized mean difference; UFS-QoL: Uterine Fibroid Symptom and Health-Related Quality of Life; NC: Not calculated; NE: Non-estimable.

Table EFF.UFSREVA.MITT.Pooled.S9: Summary of Change from Baseline in UFS-QoL Revised Activities Scale Score by Visit and Overall, by Subgroup (mITT Population)						
Study: Pooled						
Treatment	**Study visit**	**n (%)[1]**	**Mean (SD)[1]**	**Change from baseline LS-mean change (SE)[2]**	**Difference LS-mean change [95% CI] p-value[2]**	**SMD Hedges' g [95% CI][2]**
Race						
Black/African American						
Relugolix+E2/NETA	Baseline	119 (97.5)	30.8 (26.19)	45.09 (3.048)	29.99	1.01
N=122	Week 24	87 (71.3)	77.2 (27.16)		[21.90,38.07]	[0.70,1.31]
Placebo	Baseline	139 (98.6)	31.7 (23.73)	15.10 (2.749)	<.0001	
N=141	Week 24	108 (76.6)	46.9 (29.03)			
White						
Relugolix+E2/NETA	Baseline	121 (99.2)	38.2 (23.47)	45.76 (2.568)	29.05	1.11
N=122	Week 24	100 (82.0)	86.2 (20.79)		[21.60,36.49]	[0.80,1.42]
Placebo	Baseline	105 (100.0)	31.3 (22.21)	16.72 (2.776)	<.0001	
N=105	Week 24	84 (80.0)	47.7 (26.12)			
Asian						
Relugolix+E2/NETA	Baseline	1 (100.0)	55.0 (NE)	NC (NC)	NC	NC
N=1	Week 24	1 (100.0)	100.0 (NE)		[NC,NC]	[NC,NC]
Placebo	Baseline	3 (100.0)	26.7 (23.63)	NC (NC)	NC	
N=3	Week 24	2 (66.7)	15.0 (14.14)			
Others						
Relugolix+E2/NETA	Baseline	5 (100.0)	42.0 (21.10)	26.85 (12.212)	23.92	0.96
N=5	Week 24	5 (100.0)	65.0 (33.35)		[-19.69,67.53]	[-0.29,2.21]
Placebo	Baseline	6 (100.0)	23.3 (15.06)	2.93 (12.552)	0.2358	
N=6	Week 24	4 (66.7)	22.5 (14.43)			
Not reported						
Relugolix+E2/NETA	Baseline	3 (100.0)	75.0 (25.00)	NC (NC)	NC	NC
N=3	Week 24	3 (100.0)	85.0 (18.03)		[NC,NC]	[NC,NC]
Placebo	Baseline	1 (100.0)	40.0 (NE)	NC (NC)	NC	

N=1	Week 24	1 (100.0)	35.0 (NE)			

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group. Transformed score ranges from 0 to 100 based on Likert scale (None of the time, a little of the time, some of the time, most of the time and all of the time). Higher scores are indicative of better health-related quality of life (high score = good). For the change from baseline, positive scores indicate improvement.
[1] Summary statistics are based on observed data.
[2] LS means, LS mean differences (95% CIs), p-value and Hedges' g (95% CIs) are based on a mixed-effects model with study, treatment, visit, and a treatment-by-visit interaction as fixed effects. The multiple visits for each patient are the repeated measures as a random effect within each patient with an unstructured covariance. Hedges' g is calculated using a small sample bias correction. Interaction p-value is only produced for the Overall period. The reference group for the LS mean difference and Hedges' g is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with data; CI: Confidence interval; LS: Least squares; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; SD: Standard deviation; SE: Standard error; SMD: Standardized mean difference; UFS-QoL: Uterine Fibroid Symptom and Health-Related Quality of Life; NC: Not calculated; NE: Non-estimable.

Table EFF.UFSREVA.MITT.Pooled.S9: Summary of Change from Baseline in UFS-QoL Revised Activities Scale Score by Visit and Overall, by Subgroup (mITT Population)

Study: Pooled

Treatment	Study visit	n (%)[1]	Mean (SD)[1]	Change from baseline LS-mean change (SE)[2]	Difference LS-mean change [95% CI] p-value[2]	SMD Hedges' g [95% CI][2]	Int. p-value[2]
Race							
Black/African American							
Relugolix+E2/NETA	Baseline	119 (97.5)	30.8 (26.19)	43.33 (2.531)	28.68	1.03	0.4707
N=122	Overall	107 (87.7)	72.4 (26.86)		[21.95,35.41]	[0.76,1.31]	
Placebo	Baseline	139 (98.6)	31.7 (23.73)	14.65 (2.309)	<.0001		
N=141	Overall	126 (89.4)	45.5 (26.58)				
White							
Relugolix+E2/NETA	Baseline	121 (99.2)	38.2 (23.47)	41.96 (2.431)	26.63	0.96	
N=122	Overall	112 (91.8)	80.0 (23.89)		[19.64,33.61]	[0.67,1.24]	
Placebo	Baseline	105 (100.0)	31.3 (22.21)	15.33 (2.595)	<.0001		
N=105	Overall	98 (93.3)	46.3 (23.61)				
Asian							
Relugolix+E2/NETA	Baseline	1 (100.0)	55.0 (NE)	NC (NC)	NC	NC	
N=1	Overall	1 (100.0)	100.0 (NE)		[NC,NC]	[NC,NC]	
Placebo	Baseline	3 (100.0)	26.7 (23.63)	NC (NC)	NC		
N=3	Overall	3 (100.0)	20.0 (5.00)				
Others							
Relugolix+E2/NETA	Baseline	5 (100.0)	42.0 (21.10)	23.54 (11.348)	8.75	0.29	
N=5	Overall	5 (100.0)	65.5 (24.14)		[-23.06,40.57]	[-0.84,1.41]	
Placebo	Baseline	6 (100.0)	23.3 (15.06)	14.79 (11.527)	0.5889		
N=6	Overall	5 (83.3)	34.0 (25.71)				
Not reported							
Relugolix+E2/NETA	Baseline	3 (100.0)	75.0 (25.00)	NC (NC)	NC	NC	
N=3	Overall	3 (100.0)	86.7 (18.93)		[NC,NC]	[NC,NC]	
Placebo	Baseline	1 (100.0)	40.0 (NE)	NC (NC)	NC		

N=1	Overall	1 (100.0)	30.0 (NE)				

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group. Transformed score ranges from 0 to 100 based on Likert scale (None of the time, a little of the time, some of the time, most of the time and all of the time). Higher scores are indicative of better health-related quality of life (high score = good). For the change from baseline, positive scores indicate improvement.
[1] Summary statistics are based on observed data. Mean (SD) are calculated based on the mean observed value across all post-baseline visits within each patient.
[2] LS means, LS mean differences (95% CIs), p-value and Hedges' g (95% CIs) are based on a mixed-effects model with study, treatment, visit, subgroup, treatment-by-visit interaction and a subgroup-by-treatment interaction as fixed effects. The multiple visits for each patient are the repeated measures as a random effect within each patient with an unstructured covariance. Hedges' g is calculated using a small sample bias correction. Not reported subgroup levels are not included in estimation of the interaction p-value. Subgroup levels with fewer than 10 subjects are not included in estimation of the interaction p-value. The reference group for the LS mean difference and Hedges' g is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with data; CI: Confidence interval; int: Interaction; LS: Least squares; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; SD: Standard deviation; SE: Standard error; SMD: Standardized mean difference; UFS-QoL: Uterine Fibroid Symptom and Health-Related Quality of Life; NC: Not calculated; NE: Non-estimable.

SOURCE: \Studies\MYV\MYV102\Analysis\Prod\Progs\TFLs\Tab_QOL_UFS_CON.SAS
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Table EFF.UFSREVA.MITT.Pooled.S2: Summary of Change from Baseline in UFS-QoL Revised Activities Scale Score by Visit and Overall, by Subgroup (mITT Population)

Study: Pooled

Treatment	Study visit	n (%)[1]	Mean (SD)[1]	Change from baseline LS-mean change (SE)[2]	Difference LS-mean change [95% CI] p-value[2]	SMD Hedges' g [95% CI][2]
BMI (kg/m2) at Baseline						
< 30						
Relugolix+E2/NETA	Baseline	118 (99.2)	37.5 (26.46)	39.66 (2.532)	28.33	1.10
N=119	Week 12	104 (87.4)	77.3 (26.08)		[21.23,35.44]	[0.81,1.39]
Placebo	Baseline	115 (100.0)	32.9 (20.79)	11.33 (2.564)	<.0001	
N=115	Week 12	100 (87.0)	43.7 (27.54)			
>= 30						
Relugolix+E2/NETA	Baseline	130 (97.7)	33.3 (24.25)	38.25 (2.713)	22.33	0.76
N=133	Week 12	119 (89.5)	70.0 (31.41)		[14.92,29.73]	[0.50,1.02]
Placebo	Baseline	139 (98.6)	30.0 (24.38)	15.93 (2.601)	<.0001	
N=141	Week 12	129 (91.5)	45.6 (26.63)			
Missing						
Relugolix+E2/NETA	Baseline	1 (100.0)	35.0 (NE)	NC (NC)	NC	NC
N=1	Week 12	1 (100.0)	100.0 (NE)		[NC,NC]	[NC,NC]
Placebo	Baseline	0	NE (NE)	NC (NC)	NC	
N=0	Week 12	0	NE (NE)			

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group. Transformed score ranges from 0 to 100 based on Likert scale (None of the time, a little of the time, some of the time, most of the time and all of the time). Higher scores are indicative of better health-related quality of life (high score = good). For the change from baseline, positive scores indicate improvement.
[1] Summary statistics are based on observed data.
[2] LS means, LS mean differences (95% CIs), p-value and Hedges' g (95% CIs) are based on a mixed-effects model with study, treatment, visit, and a treatment-by-visit interaction as fixed effects. The multiple visits for each patient are the repeated measures as a random effect within each patient with an unstructured covariance. Hedges' g is calculated using a small sample bias correction. Interaction p-value is only produced for the Overall period. The reference group for the LS mean difference and Hedges' g is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with data; CI: Confidence interval; LS: Least squares; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; SD: Standard deviation; SE: Standard error; SMD: Standardized mean difference; UFS-QoL: Uterine Fibroid Symptom and Health-Related Quality of Life; NC: Not calculated; NE: Non-estimable.

SOURCE: \Studies\MYV\MYV102\Analysis\Prod\Progs\TFLs\Tab_QOL_UFS_CON.SAS
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Table EFF.UFSREVA.MITT.Pooled.S2: Summary of Change from Baseline in UFS-QoL Revised Activities Scale Score by Visit and Overall, by Subgroup (mITT Population)

Study: Pooled

Treatment	Study visit	n (%)[1]	Mean (SD)[1]	Change from baseline LS-mean change (SE)[2]	Difference LS-mean change [95% CI] p-value[2]	SMD Hedges' g [95% CI][2]
BMI (kg/m2) at Baseline						
< 30						
Relugolix+E2/NETA	Baseline	118 (99.2)	37.5 (26.46)	43.58 (2.750)	28.95	1.07
N=119	Week 24	89 (74.8)	82.9 (24.56)		[21.23,36.68]	[0.75,1.38]
Placebo	Baseline	115 (100.0)	32.9 (20.79)	14.63 (2.790)	<.0001	
N=115	Week 24	86 (74.8)	47.8 (28.31)			
>= 30						
Relugolix+E2/NETA	Baseline	130 (97.7)	33.3 (24.25)	45.07 (2.758)	29.21	1.01
N=133	Week 24	106 (79.7)	80.6 (24.57)		[21.68,36.74]	[0.73,1.29]
Placebo	Baseline	139 (98.6)	30.0 (24.38)	15.86 (2.650)	<.0001	
N=141	Week 24	113 (80.1)	45.3 (27.34)			
Missing						
Relugolix+E2/NETA	Baseline	1 (100.0)	35.0 (NE)	NC (NC)	NC	NC
N=1	Week 24	1 (100.0)	95.0 (NE)		[NC,NC]	[NC,NC]
Placebo	Baseline	0	NE (NE)	NC (NC)	NC	
N=0	Week 24	0	NE (NE)			

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group. Transformed score ranges from 0 to 100 based on Likert scale (None of the time, a little of the time, some of the time, most of the time and all of the time). Higher scores are indicative of better health-related quality of life (high score = good). For the change from baseline, positive scores indicate improvement.
[1] Summary statistics are based on observed data.
[2] LS means, LS mean differences (95% CIs), p-value and Hedges' g (95% CIs) are based on a mixed-effects model with study, treatment, visit, and a treatment-by-visit interaction as fixed effects. The multiple visits for each patient are the repeated measures as a random effect within each patient with an unstructured covariance. Hedges' g is calculated using a small sample bias correction. Interaction p-value is only produced for the Overall period. The reference group for the LS mean difference and Hedges' g is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with data; CI: Confidence interval; LS: Least squares; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; SD: Standard deviation; SE: Standard error; SMD: Standardized mean difference; UFS-QoL: Uterine Fibroid Symptom and Health-Related Quality of Life; NC: Not calculated; NE: Non-estimable.

SOURCE: \Studies\MYV\MYV102\Analysis\Prod\Progs\TFLs\Tab_QOL_UFS_CON.SAS
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Analysis Plan: 13JAN2021

Table EFF.UFSREVA.MITT.Pooled.S2: Summary of Change from Baseline in UFS-QoL Revised Activities Scale Score by Visit and Overall, by Subgroup (mITT Population)

Study: Pooled

Treatment	Study visit	n (%)[1]	Mean (SD)[1]	Change from baseline LS-mean change (SE)[2]	Difference LS-mean change [95% CI] p-value[2]	SMD Hedges' g [95% CI][2]	Int. p-value[2]
BMI (kg/m2) at Baseline							
< 30							
Relugolix+E2/NETA	Baseline	118 (99.2)	37.5 (26.46)	41.74 (2.514)	28.89	1.04	0.5011
N=119	Overall	106 (89.1)	79.1 (23.98)		[21.87,35.92]	[0.75,1.32]	
Placebo	Baseline	115 (100.0)	32.9 (20.79)	12.84 (2.543)	<.0001		
N=115	Overall	103 (89.6)	45.2 (25.73)				
>= 30							
Relugolix+E2/NETA	Baseline	130 (97.7)	33.3 (24.25)	41.58 (2.365)	25.63	0.92	
N=133	Overall	121 (91.0)	73.7 (26.61)		[19.19,32.07]	[0.66,1.18]	
Placebo	Baseline	139 (98.6)	30.0 (24.38)	15.95 (2.271)	<.0001		
N=141	Overall	130 (92.2)	45.2 (24.97)				
Missing							
Relugolix+E2/NETA	Baseline	1 (100.0)	35.0 (NE)	NC (NC)	NC	NC	
N=1	Overall	1 (100.0)	97.5 (NE)		[NC,NC]	[NC,NC]	
Placebo	Baseline	0	NE (NE)	NC (NC)	NC		
N=0	Overall	0	NE (NE)				

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group. Transformed score ranges from 0 to 100 based on Likert scale (None of the time, a little of the time, some of the time, most of the time and all of the time). Higher scores are indicative of better health-related quality of life (high score = good). For the change from baseline, positive scores indicate improvement.
[1] Summary statistics are based on observed data. Mean (SD) are calculated based on the mean observed value across all post-baseline visits within each patient.
[2] LS means, LS mean differences (95% CIs), p-value and Hedges' g (95% CIs) are based on a mixed-effects model with study, treatment, visit, subgroup, treatment-by-visit interaction and a subgroup-by-treatment interaction as fixed effects. The multiple visits for each patient are the repeated measures as a random effect within each patient with an unstructured covariance. Hedges' g is calculated using a small sample bias correction. Missing subgroup levels are not included in estimation of the interaction p-value. The reference group for the LS mean difference and Hedges' g is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with data; CI: Confidence interval; int: Interaction; LS: Least squares; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; SD: Standard deviation; SE: Standard error; SMD: Standardized mean difference; UFS-QoL: Uterine Fibroid Symptom and Health-Related Quality of Life; NC: Not calculated; NE: Non-estimable.

SOURCE: \Studies\MYV\MYV102\Analysis\Prod\Progs\TFLs\Tab_QOL_UFS_CON.SAS
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Analysis Plan: 13JAN2021

Table EFF.UFSREVA.MITT.Pooled.S5: Summary of Change from Baseline in UFS-QoL Revised Activities Scale Score by Visit and Overall, by Subgroup (mITT Population)

Study: Pooled

Treatment	Study visit	n (%)[1]	Mean (SD)[1]	Change from baseline LS-mean change (SE)[2]	Difference LS-mean change [95% CI] p-value[2]	SMD Hedges' g [95% CI][2]
MBL Volume at Baseline (mL)						
< 225 mL						
Relugolix+E2/NETA	Baseline	163 (99.4)	37.3 (23.47)	36.84 (2.239)	23.61	0.87
N=164	Week 12	147 (89.6)	74.9 (28.69)		[17.45,29.77]	[0.63,1.11]
Placebo	Baseline	170 (99.4)	32.4 (22.65)	13.23 (2.189)	<.0001	
N=171	Week 12	153 (89.5)	45.4 (26.74)			
>= 225 mL						
Relugolix+E2/NETA	Baseline	86 (96.6)	31.4 (28.21)	43.33 (3.341)	28.14	0.98
N=89	Week 12	77 (86.5)	70.8 (30.17)		[18.79,37.48]	[0.64,1.32]
Placebo	Baseline	84 (98.8)	29.2 (23.17)	15.19 (3.341)	<.0001	
N=85	Week 12	76 (89.4)	43.4 (27.62)			

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group. Transformed score ranges from 0 to 100 based on Likert scale (None of the time, a little of the time, some of the time, most of the time and all of the time). Higher scores are indicative of better health-related quality of life (high score = good). For the change from baseline, positive scores indicate improvement.
[1] Summary statistics are based on observed data.
[2] LS means, LS mean differences (95% CIs), p-value and Hedges' g (95% CIs) are based on a mixed-effects model with study, treatment, visit, and a treatment-by-visit interaction as fixed effects. The multiple visits for each patient are the repeated measures as a random effect within each patient with an unstructured covariance. Hedges' g is calculated using a small sample bias correction. Interaction p-value is only produced for the Overall period. The reference group for the LS mean difference and Hedges' g is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with data; CI: Confidence interval; LS: Least squares; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; SD: Standard deviation; SE: Standard error; SMD: Standardized mean difference; UFS-QoL: Uterine Fibroid Symptom and Health-Related Quality of Life.

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Table EFF.UFSREVA.MITT.Pooled.S5: Summary of Change from Baseline in UFS-QoL Revised Activities Scale Score by Visit and Overall, by Subgroup (mITT Population)

Study: Pooled

Treatment	Study visit	n (%)[1]	Mean (SD)[1]	Change from baseline LS-mean change (SE)[2]	Difference LS-mean change [95% CI] p-value[2]	SMD Hedges' g [95% CI][2]
MBL Volume at Baseline (mL)						
< 225 mL						
Relugolix+E2/NETA	Baseline	163 (99.4)	37.3 (23.47)	43.74 (2.408)	28.69	1.03
N=164	Week 24	126 (76.8)	83.5 (23.12)		[22.10,35.28]	[0.77,1.29]
Placebo	Baseline	170 (99.4)	32.4 (22.65)	15.05 (2.328)	<.0001	
N=171	Week 24	137 (80.1)	48.1 (26.05)			
>= 225 mL						
Relugolix+E2/NETA	Baseline	86 (96.6)	31.4 (28.21)	45.83 (3.308)	30.06	1.05
N=89	Week 24	70 (78.7)	78.5 (26.64)		[20.71,39.41]	[0.69,1.42]
Placebo	Baseline	84 (98.8)	29.2 (23.17)	15.77 (3.381)	<.0001	
N=85	Week 24	62 (72.9)	42.6 (30.99)			

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group. Transformed score ranges from 0 to 100 based on Likert scale (None of the time, a little of the time, some of the time, most of the time and all of the time). Higher scores are indicative of better health-related quality of life (high score = good). For the change from baseline, positive scores indicate improvement.
[1] Summary statistics are based on observed data.
[2] LS means, LS mean differences (95% CIs), p-value and Hedges' g (95% CIs) are based on a mixed-effects model with study, treatment, visit, and a treatment-by-visit interaction as fixed effects. The multiple visits for each patient are the repeated measures as a random effect within each patient with an unstructured covariance. Hedges' g is calculated using a small sample bias correction. Interaction p-value is only produced for the Overall period. The reference group for the LS mean difference and Hedges' g is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with data; CI: Confidence interval; LS: Least squares; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; SD: Standard deviation; SE: Standard error; SMD: Standardized mean difference; UFS-QoL: Uterine Fibroid Symptom and Health-Related Quality of Life.

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Table EFF.UFSREVA.MITT.Pooled.S5: Summary of Change from Baseline in UFS-QoL Revised Activities Scale Score by Visit and Overall, by Subgroup (mITT Population)

Study: Pooled

Treatment	Study visit	n (%)[1]	Mean (SD)[1]	Change from baseline LS-mean change (SE)[2]	Difference LS-mean change [95% CI] p-value[2]	SMD Hedges' g [95% CI][2]	Int. p-value[2]
MBL Volume at Baseline (mL)							
< 225 mL							
Relugolix+E2/NETA	Baseline	163 (99.4)	37.3 (23.47)	40.16 (2.118)	26.07	0.94	0.5378
N=164	Overall	148 (90.2)	77.7 (24.62)		[20.26,31.88]	[0.70,1.17]	
Placebo	Baseline	170 (99.4)	32.4 (22.65)	14.09 (2.061)	<.0001		
N=171	Overall	156 (91.2)	45.9 (24.39)				
>= 225 mL							
Relugolix+E2/NETA	Baseline	86 (96.6)	31.4 (28.21)	44.78 (2.930)	29.22	1.05	
N=89	Overall	80 (89.9)	73.8 (27.00)		[21.03,37.40]	[0.71,1.38]	
Placebo	Baseline	84 (98.8)	29.2 (23.17)	15.57 (2.957)	<.0001		
N=85	Overall	77 (90.6)	43.6 (27.01)				

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group. Transformed score ranges from 0 to 100 based on Likert scale (None of the time, a little of the time, some of the time, most of the time and all of the time). Higher scores are indicative of better health-related quality of life (high score = good). For the change from baseline, positive scores indicate improvement.
[1] Summary statistics are based on observed data. Mean (SD) are calculated based on the mean observed value across all post-baseline visits within each patient.
[2] LS means, LS mean differences (95% CIs), p-value and Hedges' g (95% CIs) are based on a mixed-effects model with study, treatment, visit, subgroup, treatment-by-visit interaction and a subgroup-by-treatment interaction as fixed effects. The multiple visits for each patient are the repeated measures as a random effect within each patient with an unstructured covariance. Hedges' g is calculated using a small sample bias correction. The reference group for the LS mean difference and Hedges' g is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with data; CI: Confidence interval; int: Interaction; LS: Least squares; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; SD: Standard deviation; SE: Standard error; SMD: Standardized mean difference; UFS-QoL: Uterine Fibroid Symptom and Health-Related Quality of Life.

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Table EFF.UFSREVA.MITT.Pooled.S7: Summary of Change from Baseline in UFS-QoL Revised Activities Scale Score by Visit and Overall, by Subgroup (mITT Population)

Study: Pooled

Treatment	Study visit	n (%)[1]	Mean (SD)[1]	Change from baseline LS-mean change (SE)[2]	Difference LS-mean change [95% CI] p-value[2]	SMD Hedges' g [95% CI][2]
Geographic Region II						
Europe						
Relugolix+E2/NETA	Baseline	40 (97.6)	40.1 (24.17)	37.06 (3.994)	28.09	1.14
N=41	Week 12	39 (95.1)	76.4 (26.28)		[16.87,39.32]	[0.67,1.62]
Placebo	Baseline	42 (100.0)	36.8 (21.15)	8.97 (4.006)	<.0001	
N=42	Week 12	39 (92.9)	44.7 (22.77)			
Rest of World (including the US)						
Relugolix+E2/NETA	Baseline	209 (98.6)	34.3 (25.47)	39.46 (2.094)	24.62	0.87
N=212	Week 12	185 (87.3)	72.9 (29.81)		[18.84,30.39]	[0.66,1.08]
Placebo	Baseline	212 (99.1)	30.2 (23.04)	14.84 (2.063)	<.0001	
N=214	Week 12	190 (88.8)	44.8 (27.83)			

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group. Transformed score ranges from 0 to 100 based on Likert scale (None of the time, a little of the time, some of the time, most of the time and all of the time). Higher scores are indicative of better health-related quality of life (high score = good). For the change from baseline, positive scores indicate improvement.
[1] Summary statistics are based on observed data.
[2] LS means, LS mean differences (95% CIs), p-value and Hedges' g (95% CIs) are based on a mixed-effects model with study, treatment, visit, and a treatment-by-visit interaction as fixed effects. The multiple visits for each patient are the repeated measures as a random effect within each patient with an unstructured covariance. Hedges' g is calculated using a small sample bias correction. Interaction p-value is only produced for the Overall period. The reference group for the LS mean difference and Hedges' g is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with data; CI: Confidence interval; LS: Least squares; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; SD: Standard deviation; SE: Standard error; SMD: Standardized mean difference; UFS-QoL: Uterine Fibroid Symptom and Health-Related Quality of Life.

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Table EFF.UFSREVA.MITT.Pooled.S7: Summary of Change from Baseline in UFS-QoL Revised Activities Scale Score by Visit and Overall, by Subgroup (mITT Population)

Study: Pooled

Treatment	Study visit	n (%)[1]	Mean (SD)[1]	Change from baseline LS-mean change (SE)[2]	Difference LS-mean change [95% CI] p-value[2]	SMD Hedges' g [95% CI][2]
Geographic Region II						
Europe						
Relugolix+E2/NETA	Baseline	40 (97.6)	40.1 (24.17)	47.55 (4.079)	32.89	1.33
N=41	Week 24	37 (90.2)	88.4 (18.18)		[21.28,44.51]	[0.83,1.84]
Placebo	Baseline	42 (100.0)	36.8 (21.15)	14.66 (4.187)	<.0001	
N=42	Week 24	35 (83.3)	50.7 (21.56)			
Rest of World (including the US)						
Relugolix+E2/NETA	Baseline	209 (98.6)	34.3 (25.47)	43.66 (2.197)	28.34	0.99
N=212	Week 24	159 (75.0)	80.2 (25.53)		[22.29,34.40]	[0.75,1.22]
Placebo	Baseline	212 (99.1)	30.2 (23.04)	15.31 (2.157)	<.0001	
N=214	Week 24	164 (76.6)	45.4 (28.84)			

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group. Transformed score ranges from 0 to 100 based on Likert scale (None of the time, a little of the time, some of the time, most of the time and all of the time). Higher scores are indicative of better health-related quality of life (high score = good). For the change from baseline, positive scores indicate improvement.
[1] Summary statistics are based on observed data.
[2] LS means, LS mean differences (95% CIs), p-value and Hedges' g (95% CIs) are based on a mixed-effects model with study, treatment, visit, and a treatment-by-visit interaction as fixed effects. The multiple visits for each patient are the repeated measures as a random effect within each patient with an unstructured covariance. Hedges' g is calculated using a small sample bias correction. Interaction p-value is only produced for the Overall period. The reference group for the LS mean difference and Hedges' g is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with data; CI: Confidence interval; LS: Least squares; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; SD: Standard deviation; SE: Standard error; SMD: Standardized mean difference; UFS-QoL: Uterine Fibroid Symptom and Health-Related Quality of Life.

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Table EFF.UFSREVA.MITT.Pooled.S7: Summary of Change from Baseline in UFS-QoL Revised Activities Scale Score by Visit and Overall, by Subgroup (mITT Population)

Study: Pooled

Treatment	Study visit	n (%)[1]	Mean (SD)[1]	Change from baseline LS-mean change (SE)[2]	Difference LS-mean change [95% CI] p-value[2]	SMD Hedges' g [95% CI][2]	Int. p-value[2]
Geographic Region II							
Europe							0.5424
Relugolix+E2/NETA	Baseline	40 (97.6)	40.1 (24.17)	42.22 (4.124)	30.39	1.08	
N=41	Overall	39 (95.1)	81.1 (21.24)		[19.00,41.78]	[0.61,1.55]	
Placebo	Baseline	42 (100.0)	36.8 (21.15)	11.84 (4.079)	<.0001		
N=42	Overall	40 (95.2)	47.8 (19.55)				
Rest of World (including the US)							
Relugolix+E2/NETA	Baseline	209 (98.6)	34.3 (25.47)	41.65 (1.892)	26.50	0.95	
N=212	Overall	189 (89.2)	75.3 (26.22)		[21.28,31.72]	[0.74,1.17]	
Placebo	Baseline	212 (99.1)	30.2 (23.04)	15.15 (1.863)	<.0001		
N=214	Overall	193 (90.2)	44.6 (26.29)				

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group. Transformed score ranges from 0 to 100 based on Likert scale (None of the time, a little of the time, some of the time, most of the time and all of the time). Higher scores are indicative of better health-related quality of life (high score = good). For the change from baseline, positive scores indicate improvement.
[1] Summary statistics are based on observed data. Mean (SD) are calculated based on the mean observed value across all post-baseline visits within each patient.
[2] LS means, LS mean differences (95% CIs), p-value and Hedges' g (95% CIs) are based on a mixed-effects model with study, treatment, visit, subgroup, treatment-by-visit interaction and a subgroup-by-treatment interaction as fixed effects. The multiple visits for each patient are the repeated measures as a random effect within each patient with an unstructured covariance. Hedges' g is calculated using a small sample bias correction. The reference group for the LS mean difference and Hedges' g is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with data; CI: Confidence interval; int: Interaction; LS: Least squares; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; SD: Standard deviation; SE: Standard error; SMD: Standardized mean difference; UFS-QoL: Uterine Fibroid Symptom and Health-Related Quality of Life.

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Table EFF.UFSREVA.MITT.Pooled.S1: Summary of Change from Baseline in UFS-QoL Revised Activities Scale Score by Visit and Overall, by Subgroup (mITT Population)

Study: Pooled

Treatment	Study visit	n (%)[1]	Mean (SD)[1]	Change from baseline LS-mean change (SE)[2]	Difference LS-mean change [95% CI] p-value[2]	SMD Hedges' g [95% CI][2]
Age (years)						
< 40 years						
Relugolix+E2/NETA	Baseline	61 (98.4)	31.9 (25.73)	37.26 (3.560)	25.07	0.94
N=62	Week 12	57 (91.9)	67.1 (30.01)		[15.57,34.58]	[0.57,1.32]
Placebo	Baseline	78 (100.0)	32.5 (23.53)	12.19 (3.224)	<.0001	
N=78	Week 12	68 (87.2)	44.0 (28.01)			
>= 40 years						
Relugolix+E2/NETA	Baseline	188 (98.4)	36.4 (25.14)	39.62 (2.194)	25.04	0.89
N=191	Week 12	167 (87.4)	75.7 (28.69)		[18.89,31.19]	[0.66,1.12]
Placebo	Baseline	176 (98.9)	30.8 (22.55)	14.58 (2.229)	<.0001	
N=178	Week 12	161 (90.4)	45.1 (26.63)			

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group. Transformed score ranges from 0 to 100 based on Likert scale (None of the time, a little of the time, some of the time, most of the time and all of the time). Higher scores are indicative of better health-related quality of life (high score = good). For the change from baseline, positive scores indicate improvement.
[1] Summary statistics are based on observed data.
[2] LS means, LS mean differences (95% CIs), p-value and Hedges' g (95% CIs) are based on a mixed-effects model with study, treatment, visit, and a treatment-by-visit interaction as fixed effects. The multiple visits for each patient are the repeated measures as a random effect within each patient with an unstructured covariance. Hedges' g is calculated using a small sample bias correction. Interaction p-value is only produced for the Overall period. The reference group for the LS mean difference and Hedges' g is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with data; CI: Confidence interval; LS: Least squares; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; SD: Standard deviation; SE: Standard error; SMD: Standardized mean difference; UFS-QoL: Uterine Fibroid Symptom and Health-Related Quality of Life.

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Table EFF.UFSREVA.MITT.Pooled.S1: Summary of Change from Baseline in UFS-QoL Revised Activities Scale Score by Visit and Overall, by Subgroup (mITT Population)

Study: Pooled

Treatment	Study visit	n (%)[1]	Mean (SD)[1]	Change from baseline LS-mean change (SE)[2]	Difference LS-mean change [95% CI] p-value[2]	SMD Hedges' g [95% CI][2]
Age (years)						
< 40 years						
Relugolix+E2/NETA	Baseline	61 (98.4)	31.9 (25.73)	42.00 (4.124)	26.71	0.92
N=62	Week 24	47 (75.8)	72.2 (30.46)		[15.76,37.66]	[0.51,1.32]
Placebo	Baseline	78 (100.0)	32.5 (23.53)	15.29 (3.692)	<.0001	
N=78	Week 24	58 (74.4)	48.6 (28.20)			
>= 40 years						
Relugolix+E2/NETA	Baseline	188 (98.4)	36.4 (25.14)	45.23 (2.206)	29.98	1.08
N=191	Week 24	149 (78.0)	84.7 (21.54)		[23.78,36.18]	[0.83,1.33]
Placebo	Baseline	176 (98.9)	30.8 (22.55)	15.25 (2.254)	<.0001	
N=178	Week 24	141 (79.2)	45.4 (27.57)			

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group. Transformed score ranges from 0 to 100 based on Likert scale (None of the time, a little of the time, some of the time, most of the time and all of the time). Higher scores are indicative of better health-related quality of life (high score = good). For the change from baseline, positive scores indicate improvement.
[1] Summary statistics are based on observed data.
[2] LS means, LS mean differences (95% CIs), p-value and Hedges' g (95% CIs) are based on a mixed-effects model with study, treatment, visit, and a treatment-by-visit interaction as fixed effects. The multiple visits for each patient are the repeated measures as a random effect within each patient with an unstructured covariance. Hedges' g is calculated using a small sample bias correction. Interaction p-value is only produced for the Overall period. The reference group for the LS mean difference and Hedges' g is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with data; CI: Confidence interval; LS: Least squares; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; SD: Standard deviation; SE: Standard error; SMD: Standardized mean difference; UFS-QoL: Uterine Fibroid Symptom and Health-Related Quality of Life.

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Table EFF.UFSREVA.MITT.Pooled.S1: Summary of Change from Baseline in UFS-QoL Revised Activities Scale Score by Visit and Overall, by Subgroup (mITT Population)

Study: Pooled

Treatment	Study visit	n (%)[1]	Mean (SD)[1]	Change from baseline LS-mean change (SE)[2]	Difference LS-mean change [95% CI] p-value[2]	SMD Hedges' g [95% CI][2]	Int. p-value[2]
Age (years)							
< 40 years							
Relugolix+E2/NETA	Baseline	61 (98.4)	31.9 (25.73)	39.76 (3.445)	26.11	0.93	0.8060
N=62	Overall	57 (91.9)	68.9 (27.39)		[16.98,35.23]	[0.56,1.30]	
Placebo	Baseline	78 (100.0)	32.5 (23.53)	13.66 (3.116)	<.0001		
N=78	Overall	68 (87.2)	45.2 (26.29)				
>= 40 years							
Relugolix+E2/NETA	Baseline	188 (98.4)	36.4 (25.14)	42.40 (1.983)	27.44	0.99	
N=191	Overall	171 (89.5)	78.8 (24.41)		[21.89,33.00]	[0.76,1.21]	
Placebo	Baseline	176 (98.9)	30.8 (22.55)	14.96 (2.018)	<.0001		
N=178	Overall	165 (92.7)	45.2 (24.89)				

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group. Transformed score ranges from 0 to 100 based on Likert scale (None of the time, a little of the time, some of the time, most of the time and all of the time). Higher scores are indicative of better health-related quality of life (high score = good). For the change from baseline, positive scores indicate improvement.
[1] Summary statistics are based on observed data. Mean (SD) are calculated based on the mean observed value across all post-baseline visits within each patient.
[2] LS means, LS mean differences (95% CIs), p-value and Hedges' g (95% CIs) are based on a mixed-effects model with study, treatment, visit, subgroup, treatment-by-visit interaction and a subgroup-by-treatment interaction as fixed effects. The multiple visits for each patient are the repeated measures as a random effect within each patient with an unstructured covariance. Hedges' g is calculated using a small sample bias correction. The reference group for the LS mean difference and Hedges' g is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with data; CI: Confidence interval; int: Interaction; LS: Least squares; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; SD: Standard deviation; SE: Standard error; SMD: Standardized mean difference; UFS-QoL: Uterine Fibroid Symptom and Health-Related Quality of Life.

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Table EFF.UFSREVA.MITT.Pooled.S4: Summary of Change from Baseline in UFS-QoL Revised Activities Scale Score by Visit and Overall, by Subgroup (mITT Population)

Study: Pooled

Treatment	Study visit	n (%)[1]	Mean (SD)[1]	Change from baseline LS-mean change (SE)[2]	Difference LS-mean change [95% CI] p-value[2]	SMD Hedges' g [95% CI][2]
Maximum NRS Pain Score at Baseline						
< 4						
Relugolix+E2/NETA	Baseline	72 (98.6)	42.3 (26.56)	35.05 (3.113)	25.54	1.03
N=73	Week 12	65 (89.0)	75.5 (30.07)		[16.33,34.75]	[0.64,1.42]
Placebo	Baseline	61 (98.4)	42.0 (22.75)	9.51 (3.468)	<.0001	
N=62	Week 12	52 (83.9)	49.3 (25.67)			
>= 4						
Relugolix+E2/NETA	Baseline	174 (98.3)	32.1 (24.23)	41.17 (2.286)	25.79	0.91
N=177	Week 12	156 (88.1)	73.0 (29.03)		[19.61,31.97]	[0.68,1.14]
Placebo	Baseline	189 (99.5)	28.1 (21.74)	15.39 (2.152)	<.0001	
N=190	Week 12	174 (91.6)	43.7 (27.32)			
Missing						
Relugolix+E2/NETA	Baseline	3 (100.0)	50.0 (25.00)	NC (NC)	NC	NC
N=3	Week 12	3 (100.0)	55.0 (13.23)		[NC,NC]	[NC,NC]
Placebo	Baseline	4 (100.0)	21.3 (29.26)	NC (NC)	NC	
N=4	Week 12	3 (75.0)	26.7 (23.09)			

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group. Transformed score ranges from 0 to 100 based on Likert scale (None of the time, a little of the time, some of the time, most of the time and all of the time). Higher scores are indicative of better health-related quality of life (high score = good). For the change from baseline, positive scores indicate improvement.
[1] Summary statistics are based on observed data.
[2] LS means, LS mean differences (95% CIs), p-value and Hedges' g (95% CIs) are based on a mixed-effects model with study, treatment, visit, and a treatment-by-visit interaction as fixed effects. The multiple visits for each patient are the repeated measures as a random effect within each patient with an unstructured covariance. Hedges' g is calculated using a small sample bias correction. Interaction p-value is only produced for the Overall period. The reference group for the LS mean difference and Hedges' g is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with data; CI: Confidence interval; LS: Least squares; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; SD: Standard deviation; SE: Standard error; SMD: Standardized mean difference; UFS-QoL: Uterine Fibroid Symptom and Health-Related Quality of Life; NC: Not calculated.

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Table EFF.UFSREVA.MITT.Pooled.S4: Summary of Change from Baseline in UFS-QoL Revised Activities Scale Score by Visit and Overall, by Subgroup (mITT Population)

Study: Pooled

Treatment	Study visit	n (%)[1]	Mean (SD)[1]	Change from baseline LS-mean change (SE)[2]	Difference LS-mean change [95% CI] p-value[2]	SMD Hedges' g [95% CI][2]
Maximum NRS Pain Score at Baseline						
< 4						
Relugolix+E2/NETA	Baseline	72 (98.6)	42.3 (26.56)	38.47 (3.442)	30.12	1.13
N=73	Week 24	57 (78.1)	82.2 (25.02)		[19.91,40.33]	[0.72,1.55]
Placebo	Baseline	61 (98.4)	42.0 (22.75)	8.35 (3.847)	<.0001	
N=62	Week 24	46 (74.2)	51.3 (24.39)			
>= 4						
Relugolix+E2/NETA	Baseline	174 (98.3)	32.1 (24.23)	47.33 (2.355)	29.86	1.05
N=177	Week 24	136 (76.8)	81.8 (24.22)		[23.49,36.22]	[0.81,1.30]
Placebo	Baseline	189 (99.5)	28.1 (21.74)	17.47 (2.215)	<.0001	
N=190	Week 24	151 (79.5)	45.2 (28.61)			
Missing						
Relugolix+E2/NETA	Baseline	3 (100.0)	50.0 (25.00)	NC (NC)	NC	NC
N=3	Week 24	3 (100.0)	68.3 (32.53)		[NC,NC]	[NC,NC]
Placebo	Baseline	4 (100.0)	21.3 (29.26)	NC (NC)	NC	
N=4	Week 24	2 (50.0)	22.5 (10.61)			

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group. Transformed score ranges from 0 to 100 based on Likert scale (None of the time, a little of the time, some of the time, most of the time and all of the time). Higher scores are indicative of better health-related quality of life (high score = good). For the change from baseline, positive scores indicate improvement.
[1] Summary statistics are based on observed data.
[2] LS means, LS mean differences (95% CIs), p-value and Hedges' g (95% CIs) are based on a mixed-effects model with study, treatment, visit, and a treatment-by-visit interaction as fixed effects. The multiple visits for each patient are the repeated measures as a random effect within each patient with an unstructured covariance. Hedges' g is calculated using a small sample bias correction. Interaction p-value is only produced for the Overall period. The reference group for the LS mean difference and Hedges' g is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with data; CI: Confidence interval; LS: Least squares; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; SD: Standard deviation; SE: Standard error; SMD: Standardized mean difference; UFS-QoL: Uterine Fibroid Symptom and Health-Related Quality of Life; NC: Not calculated.

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Table EFF.UFSREVA.MITT.Pooled.S4: Summary of Change from Baseline in UFS-QoL Revised Activities Scale Score by Visit and Overall, by Subgroup (mITT Population)

Study: Pooled

Treatment	Study visit	n (%)[1]	Mean (SD)[1]	Change from baseline LS-mean change (SE)[2]	Difference LS-mean change [95% CI] p-value[2]	SMD Hedges' g [95% CI][2]	Int. p-value[2]
Maximum NRS Pain Score at Baseline							
< 4							
Relugolix+E2/NETA	Baseline	72 (98.6)	42.3 (26.56)	37.18 (3.160)	27.88	1.00	0.9958
N=73	Overall	66 (90.4)	77.1 (27.25)		[18.60,37.16]	[0.62,1.39]	
Placebo	Baseline	61 (98.4)	42.0 (22.75)	9.31 (3.513)	<.0001		
N=62	Overall	54 (87.1)	49.1 (22.65)				
>= 4							
Relugolix+E2/NETA	Baseline	174 (98.3)	32.1 (24.23)	44.26 (2.045)	27.91	1.01	
N=177	Overall	159 (89.8)	76.2 (24.85)		[22.38,33.43]	[0.78,1.24]	
Placebo	Baseline	189 (99.5)	28.1 (21.74)	16.35 (1.928)	<.0001		
N=190	Overall	176 (92.6)	44.3 (25.99)				
Missing							
Relugolix+E2/NETA	Baseline	3 (100.0)	50.0 (25.00)	NC (NC)	NC	NC	
N=3	Overall	3 (100.0)	61.7 (21.84)		[NC,NC]	[NC,NC]	
Placebo	Baseline	4 (100.0)	21.3 (29.26)	NC (NC)	NC		
N=4	Overall	3 (75.0)	27.5 (17.50)				

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group. Transformed score ranges from 0 to 100 based on Likert scale (None of the time, a little of the time, some of the time, most of the time and all of the time). Higher scores are indicative of better health-related quality of life (high score = good). For the change from baseline, positive scores indicate improvement.
[1] Summary statistics are based on observed data. Mean (SD) are calculated based on the mean observed value across all post-baseline visits within each patient.
[2] LS means, LS mean differences (95% CIs), p-value and Hedges' g (95% CIs) are based on a mixed-effects model with study, treatment, visit, subgroup, treatment-by-visit interaction and a subgroup-by-treatment interaction as fixed effects. The multiple visits for each patient are the repeated measures as a random effect within each patient with an unstructured covariance. Hedges' g is calculated using a small sample bias correction. Missing subgroup levels are not included in estimation of the interaction p-value. The reference group for the LS mean difference and Hedges' g is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with data; CI: Confidence interval; int: Interaction; LS: Least squares; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; SD: Standard deviation; SE: Standard error; SMD: Standardized mean difference; UFS-QoL: Uterine Fibroid Symptom and Health-Related Quality of Life; NC: Not calculated.

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1.2.9 Proportion of Responders with at least 20 Points Increase in UFS-QoL Revised Activity Scale Score at Week 24, by Subgroup (mITT Population)

Table QOL.UFSRAS20.MITT.Pooled.S1: Proportion of Responders with at least 20 Points Increase in UFS-QoL Revised Activity Scale Score at Week 24, by Subgroup (mITT Population)

Study: Pooled

Treatment	N	n (%)	OR[1] [95% CI]	RR[2] [95% CI]	RD[3] [95% CI]	p-value[4]	p-value (int)[5]
Age (years)							
< 40 years							
Relugolix+E2/NETA	62	33 (53.2)	2.15 [1.09;4.25]	1.54 [1.05;2.26]	0.19 [0.02;0.35]	0.0280	0.2219
Placebo	78	27 (34.6)					
>= 40 years							
Relugolix+E2/NETA	191	123 (64.4)	3.56 [2.32;5.46]	1.91 [1.52;2.41]	0.31 [0.21;0.40]	<.0001	
Placebo	178	60 (33.7)					

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group.
[1] OR (95% CI) based on a logistic regression model adjusting for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates.
[2] RR (95% CI) based on a Cochran-Mantel-Haenszel approach stratified by study.
[3] RD (95% CI) based on a Mantel-Haenszel approach stratified by study. 95% CIs are based on the approximation to the normal distribution using the Sato estimator for the standard error.
[4] P-value based on a Cochran-Mantel-Haenszel test stratified by study.
[5] Interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the OR (95% CI). * Interaction p-value < 0.05.
A continuity correction is applied in estimation of the OR, RR and p-value if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum. No continuity correction is applied in the estimation of the RD.
The reference group for the OR, RR and RD is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with an event; OR: Odds ratio; RR: Risk ratio; RD: Risk difference; CI: Confidence interval; int: p-value for interaction; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; NC: Not calculated.

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Table QOL.UFSRAS20.MITT.Pooled.S3: Proportion of Responders with at least 20 Points Increase in UFS-QoL Revised Activity Scale Score at Week 24, by Subgroup (mITT Population)

Study: Pooled

Treatment	N	n (%)	OR[1] [95% CI]	RR[2] [95% CI]	RD[3] [95% CI]	p-value[4]	p-value (int)[5]
Uterine Volume at Baseline (cm3)							
< 300 cm3							
Relugolix+E2/NETA	148	91 (61.5)	3.68	2.03	0.31	<.0001	0.4295
Placebo	129	39 (30.2)	[2.23;6.08]	[1.52;2.72]	[0.20;0.42]		
>= 300 cm3							
Relugolix+E2/NETA	104	65 (62.5)	2.74	1.65	0.25	0.0002	
Placebo	127	48 (37.8)	[1.61;4.68]	[1.26;2.16]	[0.12;0.37]		
Missing							
Relugolix+E2/NETA	1	0	NC	NC	NC	NC	
Placebo	0	0	[NC;NC]	[NC;NC]	[NC;NC]		

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group.
[1] OR (95% CI) based on a logistic regression model adjusting for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates.
[2] RR (95% CI) based on a Cochran-Mantel-Haenszel approach stratified by study.
[3] RD (95% CI) based on a Mantel-Haenszel approach stratified by study. 95% CIs are based on the approximation to the normal distribution using the Sato estimator for the standard error.
[4] P-value based on a Cochran-Mantel-Haenszel test stratified by study.
[5] Interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the OR (95% CI). Missing subgroup levels are not included in estimation of the interaction p-value. * Interaction p-value < 0.05.
A continuity correction is applied in estimation of the OR, RR and p-value if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum. No continuity correction is applied in the estimation of the RD.
The reference group for the OR, RR and RD is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with an event; OR: Odds ratio; RR: Risk ratio; RD: Risk difference; CI: Confidence interval; int: p-value for interaction; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; NC: Not calculated.

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Table QOL.UFSRAS20.MITT.Pooled.S4: Proportion of Responders with at least 20 Points Increase in UFS-QoL Revised Activity Scale Score at Week 24, by Subgroup (mITT Population)

Study: Pooled

Treatment	N	n (%)	OR[1] [95% CI]	RR[2] [95% CI]	RD[3] [95% CI]	p-value[4]	p-value (int)[5]
Maximum NRS Pain Score at Baseline							
< 4							
Relugolix+E2/NETA	73	43 (58.9)	4.10	2.28	0.33	0.0001	0.4487
Placebo	62	16 (25.8)	[1.96;8.57]	[1.44;3.62]	[0.18;0.49]		
>= 4							
Relugolix+E2/NETA	177	112 (63.3)	2.96	1.72	0.27	<.0001	
Placebo	190	70 (36.8)	[1.93;4.52]	[1.38;2.14]	[0.17;0.36]		
Missing							
Relugolix+E2/NETA	3	1 (33.3)	NC	NC	NC	NC	
Placebo	4	1 (25.0)	[NC;NC]	[NC;NC]	[NC;NC]		

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group.
[1] OR (95% CI) based on a logistic regression model adjusting for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates.
[2] RR (95% CI) based on a Cochran-Mantel-Haenszel approach stratified by study.
[3] RD (95% CI) based on a Mantel-Haenszel approach stratified by study. 95% CIs are based on the approximation to the normal distribution using the Sato estimator for the standard error.
[4] P-value based on a Cochran-Mantel-Haenszel test stratified by study.
[5] Interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the OR (95% CI). Missing subgroup levels are not included in estimation of the interaction p-value. * Interaction p-value < 0.05.
A continuity correction is applied in estimation of the OR, RR and p-value if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum. No continuity correction is applied in the estimation of the RD.
The reference group for the OR, RR and RD is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with an event; OR: Odds ratio; RR: Risk ratio; RD: Risk difference; CI: Confidence interval; int: p-value for interaction; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; NC: Not calculated.

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Table QOL.UFSRAS20.MITT.Pooled.S5: Proportion of Responders with at least 20 Points Increase in UFS-QoL Revised Activity Scale Score at Week 24, by Subgroup (mITT Population)

Study: Pooled

Treatment	N	n (%)	OR[1] [95% CI]	RR[2] [95% CI]	RD[3] [95% CI]	p-value[4]	p-value (int)[5]
MBL Volume at Baseline (mL)							
< 225 mL							
Relugolix+E2/NETA	164	103 (62.8)	2.97	1.73	0.27	<.0001	0.6566
Placebo	171	62 (36.3)	[1.90;4.63]	[1.37;2.18]	[0.16;0.37]		
>= 225 mL							
Relugolix+E2/NETA	89	53 (59.6)	3.53	2.02	0.30	<.0001	
Placebo	85	25 (29.4)	[1.88;6.63]	[1.40;2.94]	[0.16;0.44]		

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group.
[1] OR (95% CI) based on a logistic regression model adjusting for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates.
[2] RR (95% CI) based on a Cochran-Mantel-Haenszel approach stratified by study.
[3] RD (95% CI) based on a Mantel-Haenszel approach stratified by study. 95% CIs are based on the approximation to the normal distribution using the Sato estimator for the standard error.
[4] P-value based on a Cochran-Mantel-Haenszel test stratified by study.
[5] Interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the OR (95% CI). Missing subgroup levels are not included in estimation of the interaction p-value. * Interaction p-value < 0.05.
A continuity correction is applied in estimation of the OR, RR and p-value if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum. No continuity correction is applied in the estimation of the RD.
The reference group for the OR, RR and RD is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with an event; OR: Odds ratio; RR: Risk ratio; RD: Risk difference; CI: Confidence interval; int: p-value for interaction; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; NC: Not calculated.

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Table QOL.UFSRAS20.MITT.Pooled.S8: Proportion of Responders with at least 20 Points Increase in UFS-QoL Revised Activity Scale Score at Week 24, by Subgroup (mITT Population)

Study: Pooled

Treatment	N	n (%)	OR[1] [95% CI]	RR[2] [95% CI]	RD[3] [95% CI]	p-value[4]	p-value (int)[5]
Ethnicity							
Hispanic or Latino							0.7583
Relugolix+E2/NETA	52	35 (67.3)	2.86	1.67	0.27	0.0072	
Placebo	55	23 (41.8)	[1.29;6.32]	[1.13;2.46]	[0.08;0.46]		
Not Hispanic or Latino							
Relugolix+E2/NETA	197	120 (60.9)	3.29	1.90	0.29	<.0001	
Placebo	199	64 (32.2)	[2.18;4.97]	[1.51;2.40]	[0.19;0.38]		
Not reported							
Relugolix+E2/NETA	4	1 (25.0)	NC	NC	NC	NC	
Placebo	2	0	[NC;NC]	[NC;NC]	[NC;NC]		

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group.
[1] OR (95% CI) based on a logistic regression model adjusting for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates.
[2] RR (95% CI) based on a Cochran-Mantel-Haenszel approach stratified by study.
[3] RD (95% CI) based on a Mantel-Haenszel approach stratified by study. 95% CIs are based on the approximation to the normal distribution using the Sato estimator for the standard error.
[4] P-value based on a Cochran-Mantel-Haenszel test stratified by study.
[5] Interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the OR (95% CI). Not reported subgroup levels are not included in estimation of the interaction p-value.
* Interaction p-value < 0.05.
A continuity correction is applied in estimation of the OR, RR and p-value if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum. No continuity correction is applied in the estimation of the RD.
The reference group for the OR, RR and RD is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with an event; OR: Odds ratio; RR: Risk ratio; RD: Risk difference; CI: Confidence interval; int: p-value for interaction; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; NC: Not calculated.

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Table QOL.UFSRAS20.MITT.Pooled.S9: Proportion of Responders with at least 20 Points Increase in UFS-QoL Revised Activity Scale Score at Week 24, by Subgroup (mITT Population)

Study: Pooled

Treatment	N	n (%)	OR[1] [95% CI]	RR[2] [95% CI]	RD[3] [95% CI]	p-value[4]	p-value (int)[5]
Race							
Black/African American							0.7741
Relugolix+E2/NETA	122	70 (57.4)	2.69	1.72	0.24	<.0001	
Placebo	141	47 (33.3)	[1.63;4.45]	[1.30;2.28]	[0.12;0.36]		
White							
Relugolix+E2/NETA	122	82 (67.2)	3.47	1.81	0.30	<.0001	
Placebo	105	39 (37.1)	[2.01;6.00]	[1.37;2.39]	[0.18;0.43]		
Asian							
Relugolix+E2/NETA	1	1 (100.0)	NC	NC	NC	NC	
Placebo	3	0	[NC;NC]	[NC;NC]	[NC;NC]		
Others							
Relugolix+E2/NETA	5	3 (60.0)	4.03	2.71	0.59	0.1839	
Placebo	6	1 (16.7)	[0.45;36.18]	[0.62;11.79]	[0.23;0.96]		
Not reported							
Relugolix+E2/NETA	3	0	NC	NC	NC	NC	
Placebo	1	0	[NC;NC]	[NC;NC]	[NC;NC]		

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group.
[1] OR (95% CI) based on a logistic regression model adjusting for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates.
[2] RR (95% CI) based on a Cochran-Mantel-Haenszel approach stratified by study.
[3] RD (95% CI) based on a Mantel-Haenszel approach stratified by study. 95% CIs are based on the approximation to the normal distribution using the Sato estimator for the standard error.
[4] P-value based on a Cochran-Mantel-Haenszel test stratified by study.
[5] Interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the OR (95% CI). Not reported subgroup levels are not included in estimation of the interaction p-value.
* Interaction p-value < 0.05.
A continuity correction is applied in estimation of the OR, RR and p-value if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum. No continuity correction is applied in the estimation of the RD.
The reference group for the OR, RR and RD is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with an event; OR: Odds ratio; RR: Risk ratio; RD: Risk difference; CI: Confidence interval; int: p-value for interaction; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; NC: Not calculated.

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Table QOL.UFSRAS20.MITT.Pooled.S2: Proportion of Responders with at least 20 Points Increase in UFS-QoL Revised Activity Scale Score at Week 24, by Subgroup (mITT Population)

Study: Pooled

Treatment	N	n (%)	OR[1] [95% CI]	RR[2] [95% CI]	RD[3] [95% CI]	p-value[4]	p-value (int)[5]
BMI (kg/m2) at Baseline							
< 30							
Relugolix+E2/NETA	119	70 (58.8)	3.01	1.83	0.27	<.0001	0.8510
Placebo	115	37 (32.2)	[1.76;5.14]	[1.35;2.47]	[0.14;0.39]		
>= 30							
Relugolix+E2/NETA	133	85 (63.9)	3.22	1.80	0.28	<.0001	
Placebo	141	50 (35.5)	[1.97;5.29]	[1.39;2.33]	[0.17;0.40]		
Missing							
Relugolix+E2/NETA	1	1 (100.0)	NC	NC	NC	NC	
Placebo	0	0	[NC;NC]	[NC;NC]	[NC;NC]		

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group.
[1] OR (95% CI) based on a logistic regression model adjusting for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates.
[2] RR (95% CI) based on a Cochran-Mantel-Haenszel approach stratified by study.
[3] RD (95% CI) based on a Mantel-Haenszel approach stratified by study. 95% CIs are based on the approximation to the normal distribution using the Sato estimator for the standard error.
[4] P-value based on a Cochran-Mantel-Haenszel test stratified by study.
[5] Interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the OR (95% CI). Missing subgroup levels are not included in estimation of the interaction p-value. * Interaction p-value < 0.05.
A continuity correction is applied in estimation of the OR, RR and p-value if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum. No continuity correction is applied in the estimation of the RD.
The reference group for the OR, RR and RD is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with an event; OR: Odds ratio; RR: Risk ratio; RD: Risk difference; CI: Confidence interval; int: p-value for interaction; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; NC: Not calculated.

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1.2.9.1 Proportion of Responders with at least 25 Points Increase in UFS-QoL Revised Activity Scale Score at Week 24, by Subgroup (mITT Population)

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Table QOL.UFSRAS25.MITT.Pooled.S1: Proportion of Responders with at least 25 Points Increase in UFS-QoL Revised Activity Scale Score at Week 24, by Subgroup (mITT Population)

Study: Pooled

Treatment	N	n (%)	OR[1] [95% CI]	RR[2] [95% CI]	RD[3] [95% CI]	p-value[4]	p-value (int)[5]
Age (years)							
< 40 years							
Relugolix+E2/NETA	62	32 (51.6)	2.55	1.75	0.22	0.0080	0.1060
Placebo	78	23 (29.5)	[1.27;5.12]	[1.15;2.66]	[0.06;0.38]		
>= 40 years							
Relugolix+E2/NETA	191	118 (61.8)	5.08	2.56	0.38	<.0001	
Placebo	178	43 (24.2)	[3.23;7.96]	[1.93;3.39]	[0.28;0.47]		

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group.
[1] OR (95% CI) based on a logistic regression model adjusting for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates.
[2] RR (95% CI) based on a Cochran-Mantel-Haenszel approach stratified by study.
[3] RD (95% CI) based on a Mantel-Haenszel approach stratified by study. 95% CIs are based on the approximation to the normal distribution using the Sato estimator for the standard error.
[4] P-value based on a Cochran-Mantel-Haenszel test stratified by study.
[5] Interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the OR (95% CI). * Interaction p-value < 0.05.
A continuity correction is applied in estimation of the OR, RR and p-value if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum. No continuity correction is applied in the estimation of the RD.
The reference group for the OR, RR and RD is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with an event; OR: Odds ratio; RR: Risk ratio; RD: Risk difference; CI: Confidence interval; int: p-value for interaction; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; NC: Not calculated.

SOURCE: \Studies\MYV\MYV102\Analysis\Prod\Progs\TFLs\Tab_QOL_UFS_BIN.SAS
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Table QOL.UFSRAS25.MITT.Pooled.S4: Proportion of Responders with at least 25 Points Increase in UFS-QoL Revised Activity Scale Score at Week 24, by Subgroup (mITT Population)

Study: Pooled

Treatment	N	n (%)	OR[1] [95% CI]	RR[2] [95% CI]	RD[3] [95% CI]	p-value[4]	p-value (int)[5]
Maximum NRS Pain Score at Baseline							
< 4							
Relugolix+E2/NETA	73	42 (57.5)	5.66	3.00	0.39	<.0001	0.3958
Placebo	62	12 (19.4)	[2.58;12.38]	[1.74;5.16]	[0.24;0.54]		
>= 4							
Relugolix+E2/NETA	177	107 (60.5)	3.85	2.13	0.32	<.0001	
Placebo	190	54 (28.4)	[2.49;5.95]	[1.65;2.75]	[0.22;0.42]		
Missing							
Relugolix+E2/NETA	3	1 (33.3)	NC	NC	NC	NC	
Placebo	4	0	[NC;NC]	[NC;NC]	[NC;NC]		

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group.
[1] OR (95% CI) based on a logistic regression model adjusting for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates.
[2] RR (95% CI) based on a Cochran-Mantel-Haenszel approach stratified by study.
[3] RD (95% CI) based on a Mantel-Haenszel approach stratified by study. 95% CIs are based on the approximation to the normal distribution using the Sato estimator for the standard error.
[4] P-value based on a Cochran-Mantel-Haenszel test stratified by study.
[5] Interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the OR (95% CI). Missing subgroup levels are not included in estimation of the interaction p-value. * Interaction p-value < 0.05.
A continuity correction is applied in estimation of the OR, RR and p-value if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum. No continuity correction is applied in the estimation of the RD.
The reference group for the OR, RR and RD is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with an event; OR: Odds ratio; RR: Risk ratio; RD: Risk difference; CI: Confidence interval; int: p-value for interaction; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; NC: Not calculated.

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Table QOL.UFSRAS25.MITT.Pooled.S3: Proportion of Responders with at least 25 Points Increase in UFS-QoL Revised Activity Scale Score at Week 24, by Subgroup (mITT Population)

Study: Pooled

Treatment	N	n (%)	OR[1] [95% CI]	RR[2] [95% CI]	RD[3] [95% CI]	p-value[4]	p-value (int)[5]
Uterine Volume at Baseline (cm3)							
< 300 cm3							
Relugolix+E2/NETA	148	88 (59.5)	4.84	2.56	0.36	<.0001	0.5022
Placebo	129	30 (23.3)	[2.87;8.17]	[1.82;3.59]	[0.25;0.47]		
>= 300 cm3							
Relugolix+E2/NETA	104	62 (59.6)	3.73	2.10	0.31	<.0001	
Placebo	127	36 (28.3)	[2.15;6.47]	[1.53;2.89]	[0.19;0.44]		
Missing							
Relugolix+E2/NETA	1	0	NC	NC	NC	NC	
Placebo	0	0	[NC;NC]	[NC;NC]	[NC;NC]		

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group.
[1] OR (95% CI) based on a logistic regression model adjusting for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates.
[2] RR (95% CI) based on a Cochran-Mantel-Haenszel approach stratified by study.
[3] RD (95% CI) based on a Mantel-Haenszel approach stratified by study. 95% CIs are based on the approximation to the normal distribution using the Sato estimator for the standard error.
[4] P-value based on a Cochran-Mantel-Haenszel test stratified by study.
[5] Interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the OR (95% CI). Missing subgroup levels are not included in estimation of the interaction p-value. * Interaction p-value < 0.05.
A continuity correction is applied in estimation of the OR, RR and p-value if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum. No continuity correction is applied in the estimation of the RD.
The reference group for the OR, RR and RD is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with an event; OR: Odds ratio; RR: Risk ratio; RD: Risk difference; CI: Confidence interval; int: p-value for interaction; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; NC: Not calculated.

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Table QOL.UFSRAS25.MITT.Pooled.S9: Proportion of Responders with at least 25 Points Increase in UFS-QoL Revised Activity Scale Score at Week 24, by Subgroup (mITT Population)

Study: Pooled

Treatment	N	n (%)	OR[1] [95% CI]	RR[2] [95% CI]	RD[3] [95% CI]	p-value[4]	p-value (int)[5]
Race							
Black/African American							0.5076
Relugolix+E2/NETA	122	66 (54.1)	3.32	2.06	0.28	<.0001	
Placebo	141	37 (26.2)	[1.98;5.56]	[1.49;2.84]	[0.16;0.39]		
White							
Relugolix+E2/NETA	122	80 (65.6)	5.24	2.46	0.39	<.0001	
Placebo	105	28 (26.7)	[2.96;9.28]	[1.75;3.46]	[0.27;0.51]		
Asian							
Relugolix+E2/NETA	1	1 (100.0)	NC	NC	NC	NC	
Placebo	3	0	[NC;NC]	[NC;NC]	[NC;NC]		
Others							
Relugolix+E2/NETA	5	3 (60.0)	4.10	2.71	0.59	0.1839	
Placebo	6	1 (16.7)	[0.46;36.87]	[0.62;11.79]	[0.23;0.96]		
Not reported							
Relugolix+E2/NETA	3	0	NC	NC	NC	NC	
Placebo	1	0	[NC;NC]	[NC;NC]	[NC;NC]		

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group.
[1] OR (95% CI) based on a logistic regression model adjusting for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates.
[2] RR (95% CI) based on a Cochran-Mantel-Haenszel approach stratified by study.
[3] RD (95% CI) based on a Mantel-Haenszel approach stratified by study. 95% CIs are based on the approximation to the normal distribution using the Sato estimator for the standard error.
[4] P-value based on a Cochran-Mantel-Haenszel test stratified by study.
[5] Interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the OR (95% CI). Not reported subgroup levels are not included in estimation of the interaction p-value.
* Interaction p-value < 0.05.
A continuity correction is applied in estimation of the OR, RR and p-value if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum. No continuity correction is applied in the estimation of the RD.
The reference group for the OR, RR and RD is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with an event; OR: Odds ratio; RR: Risk ratio; RD: Risk difference; CI: Confidence interval; int: p-value for interaction; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; NC: Not calculated.

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Table QOL.UFSRAS25.MITT.Pooled.S5: Proportion of Responders with at least 25 Points Increase in UFS-QoL Revised Activity Scale Score at Week 24, by Subgroup (mITT Population)

Study: Pooled

Treatment	N	n (%)	OR[1] [95% CI]	RR[2] [95% CI]	RD[3] [95% CI]	p-value[4]	p-value (int)[5]
MBL Volume at Baseline (mL)							
< 225 mL							
Relugolix+E2/NETA	164	99 (60.4)	3.90	2.15	0.32	<.0001	0.5495
Placebo	171	48 (28.1)	[2.47;6.17]	[1.64;2.81]	[0.22;0.42]		
>= 225 mL							
Relugolix+E2/NETA	89	51 (57.3)	5.00	2.71	0.36	<.0001	
Placebo	85	18 (21.2)	[2.56;9.75]	[1.73;4.23]	[0.23;0.50]		

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group.
[1] OR (95% CI) based on a logistic regression model adjusting for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates.
[2] RR (95% CI) based on a Cochran-Mantel-Haenszel approach stratified by study.
[3] RD (95% CI) based on a Mantel-Haenszel approach stratified by study. 95% CIs are based on the approximation to the normal distribution using the Sato estimator for the standard error.
[4] P-value based on a Cochran-Mantel-Haenszel test stratified by study.
[5] Interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the OR (95% CI). Not reported subgroup levels are not included in estimation of the interaction p-value.
* Interaction p-value < 0.05.
A continuity correction is applied in estimation of the OR, RR and p-value if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum. No continuity correction is applied in the estimation of the RD.
The reference group for the OR, RR and RD is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with an event; OR: Odds ratio; RR: Risk ratio; RD: Risk difference; CI: Confidence interval; int: p-value for interaction; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; NC: Not calculated.

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Table QOL.UFSRAS25.MITT.Pooled.S2: Proportion of Responders with at least 25 Points Increase in UFS-QoL Revised Activity Scale Score at Week 24, by Subgroup (mITT Population)

Study: Pooled

Treatment	N	n (%)	OR[1] [95% CI]	RR[2] [95% CI]	RD[3] [95% CI]	p-value[4]	p-value (int)[5]
BMI (kg/m2) at Baseline							
< 30							
Relugolix+E2/NETA	119	69 (58.0)	4.73	2.57	0.35	<.0001	0.5775
Placebo	115	26 (22.6)	[2.68;8.35]	[1.77;3.72]	[0.24;0.47]		
>= 30							
Relugolix+E2/NETA	133	80 (60.2)	3.81	2.12	0.32	<.0001	
Placebo	141	40 (28.4)	[2.30;6.31]	[1.58;2.85]	[0.21;0.43]		
Missing							
Relugolix+E2/NETA	1	1 (100.0)	NC	NC	NC	NC	
Placebo	0	0	[NC;NC]	[NC;NC]	[NC;NC]		

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group.
[1] OR (95% CI) based on a logistic regression model adjusting for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates.
[2] RR (95% CI) based on a Cochran-Mantel-Haenszel approach stratified by study.
[3] RD (95% CI) based on a Mantel-Haenszel approach stratified by study. 95% CIs are based on the approximation to the normal distribution using the Sato estimator for the standard error.
[4] P-value based on a Cochran-Mantel-Haenszel test stratified by study.
[5] Interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the OR (95% CI). Missing subgroup levels are not included in estimation of the interaction p-value. * Interaction p-value < 0.05.
A continuity correction is applied in estimation of the OR, RR and p-value if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum. No continuity correction is applied in the estimation of the RD.
The reference group for the OR, RR and RD is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with an event; OR: Odds ratio; RR: Risk ratio; RD: Risk difference; CI: Confidence interval; int: p-value for interaction; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; NC: Not calculated.

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Table QOL.UFSRAS25.MITT.Pooled.S8: Proportion of Responders with at least 25 Points Increase in UFS-QoL Revised Activity Scale Score at Week 24, by Subgroup (mITT Population)

Study: Pooled

Treatment	N	n (%)	OR[1] [95% CI]	RR[2] [95% CI]	RD[3] [95% CI]	p-value[4]	p-value (int)[5]
Ethnicity							
Hispanic or Latino							
Relugolix+E2/NETA	52	33 (63.5)	3.61	2.05	0.33	0.0011	0.6369
Placebo	55	18 (32.7)	[1.62;8.05]	[1.29;3.23]	[0.14;0.51]		
Not Hispanic or Latino							
Relugolix+E2/NETA	197	116 (58.9)	4.50	2.45	0.35	<.0001	
Placebo	199	48 (24.1)	[2.92;6.92]	[1.86;3.23]	[0.26;0.44]		
Not reported							
Relugolix+E2/NETA	4	1 (25.0)	NC	NC	NC	NC	
Placebo	2	0	[NC;NC]	[NC;NC]	[NC;NC]		

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group.
[1] OR (95% CI) based on a logistic regression model adjusting for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates.
[2] RR (95% CI) based on a Cochran-Mantel-Haenszel approach stratified by study.
[3] RD (95% CI) based on a Mantel-Haenszel approach stratified by study. 95% CIs are based on the approximation to the normal distribution using the Sato estimator for the standard error.
[4] P-value based on a Cochran-Mantel-Haenszel test stratified by study.
[5] Interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the OR (95% CI). Not reported subgroup levels are not included in estimation of the interaction p-value.
* Interaction p-value < 0.05.
A continuity correction is applied in estimation of the OR, RR and p-value if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum. No continuity correction is applied in the estimation of the RD.
The reference group for the OR, RR and RD is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with an event; OR: Odds ratio; RR: Risk ratio; RD: Risk difference; CI: Confidence interval; int: p-value for interaction; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; NC: Not calculated.

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1.2.10 Summary of Change from Baseline in UFS-QoL Energy / Mood Scale Score by Visit and Overall, by Subgroup (mITT Population)

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Table EFF.UFSEMS.MITT.Pooled.S2: Summary of Change from Baseline in UFS-QoL Energy/Mood Scale Score by Visit and Overall, by Subgroup (mITT Population)

Study: Pooled

Treatment	Study visit	n (%)[1]	Mean (SD)[1]	Change from baseline LS-mean change (SE)[2]	Difference LS-mean change [95% CI] p-value[2]	SMD Hedges' g [95% CI][2]
BMI (kg/m2) at Baseline						
< 30						
Relugolix+E2/NETA	Baseline	118 (99.2)	41.5 (26.94)	29.83 (2.394)	21.37	0.88
N=119	Week 12	104 (87.4)	72.5 (25.26)		[14.66,28.09]	[0.59,1.17]
Placebo	Baseline	115 (100.0)	37.8 (23.25)	8.46 (2.424)	<.0001	
N=115	Week 12	100 (87.0)	45.6 (24.05)			
>= 30						
Relugolix+E2/NETA	Baseline	130 (97.7)	39.0 (25.08)	28.39 (2.526)	13.15	0.48
N=133	Week 12	119 (89.5)	66.7 (29.15)		[6.26,20.05]	[0.23,0.74]
Placebo	Baseline	139 (98.6)	37.1 (25.58)	15.23 (2.424)	0.0002	
N=141	Week 12	129 (91.5)	51.3 (25.51)			
Missing						
Relugolix+E2/NETA	Baseline	1 (100.0)	32.1 (NE)	NC (NC)	NC	NC
N=1	Week 12	1 (100.0)	85.7 (NE)		[NC,NC]	[NC,NC]
Placebo	Baseline	0	NE (NE)	NC (NC)	NC	
N=0	Week 12	0	NE (NE)			

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group. Transformed score ranges from 0 to 100 based on Likert scale (None of the time, a little of the time, some of the time, most of the time and all of the time). Higher scores are indicative of better health-related quality of life (high score = good). For the change from baseline, positive scores indicate improvement.
[1] Summary statistics are based on observed data.
[2] LS means, LS mean differences (95% CIs), p-value and Hedges' g (95% CIs) are based on a mixed-effects model with study, treatment, visit, and a treatment-by-visit interaction as fixed effects. The multiple visits for each patient are the repeated measures as a random effect within each patient with an unstructured covariance. Hedges' g is calculated using a small sample bias correction. Interaction p-value is only produced for the Overall period. The reference group for the LS mean difference and Hedges' g is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with data; CI: Confidence interval; LS: Least squares; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; SD: Standard deviation; SE: Standard error; SMD: Standardized mean difference; UFS-QoL: Uterine Fibroid Symptom and Health-Related Quality of Life; NC: Not calculated; NE: Non-estimable.

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Table EFF.UFSEMS.MITT.Pooled.S2: Summary of Change from Baseline in UFS-QoL Energy/Mood Scale Score by Visit and Overall, by Subgroup (mITT Population)

Study: Pooled

Treatment	Study visit	n (%)[1]	Mean (SD)[1]	Change from baseline LS-mean change (SE)[2]	Difference LS-mean change [95% CI] p-value[2]	SMD Hedges' g [95% CI][2]
BMI (kg/m2) at Baseline						
< 30						
Relugolix+E2/NETA	Baseline	118 (99.2)	41.5 (26.94)	35.71 (2.603)	22.95	0.89
N=119	Week 24	89 (74.8)	79.9 (24.61)		[15.64,30.26]	[0.58,1.20]
Placebo	Baseline	115 (100.0)	37.8 (23.25)	12.76 (2.641)	<.0001	
N=115	Week 24	86 (74.8)	49.7 (25.64)			
>= 30						
Relugolix+E2/NETA	Baseline	130 (97.7)	39.0 (25.08)	33.42 (2.592)	18.77	0.68
N=133	Week 24	106 (79.7)	75.2 (25.69)		[11.69,25.85]	[0.41,0.96]
Placebo	Baseline	139 (98.6)	37.1 (25.58)	14.65 (2.490)	<.0001	
N=141	Week 24	113 (80.1)	50.7 (28.51)			
Missing						
Relugolix+E2/NETA	Baseline	1 (100.0)	32.1 (NE)	NC (NC)	NC	NC
N=1	Week 24	1 (100.0)	96.4 (NE)		[NC,NC]	[NC,NC]
Placebo	Baseline	0	NE (NE)	NC (NC)	NC	
N=0	Week 24	0	NE (NE)			

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group. Transformed score ranges from 0 to 100 based on Likert scale (None of the time, a little of the time, some of the time, most of the time and all of the time). Higher scores are indicative of better health-related quality of life (high score = good). For the change from baseline, positive scores indicate improvement.
[1] Summary statistics are based on observed data.
[2] LS means, LS mean differences (95% CIs), p-value and Hedges' g (95% CIs) are based on a mixed-effects model with study, treatment, visit, and a treatment-by-visit interaction as fixed effects. The multiple visits for each patient are the repeated measures as a random effect within each patient with an unstructured covariance. Hedges' g is calculated using a small sample bias correction. Interaction p-value is only produced for the Overall period. The reference group for the LS mean difference and Hedges' g is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with data; CI: Confidence interval; LS: Least squares; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; SD: Standard deviation; SE: Standard error; SMD: Standardized mean difference; UFS-QoL: Uterine Fibroid Symptom and Health-Related Quality of Life; NC: Not calculated; NE: Non-estimable.

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Table EFF.UFSEMS.MITT.Pooled.S2: Summary of Change from Baseline in UFS-QoL Energy/Mood Scale Score by Visit and Overall, by Subgroup (mITT Population)

Study: Pooled

Treatment	Study visit	n (%)[1]	Mean (SD)[1]	Change from baseline LS-mean change (SE)[2]	Difference LS-mean change [95% CI] p-value[2]	SMD Hedges' g [95% CI][2]	Int. p-value[2]
BMI (kg/m2) at Baseline							
< 30							
Relugolix+E2/NETA	Baseline	118 (99.2)	41.5 (26.94)	32.72 (2.402)	22.40	0.85	0.1641
N=119	Overall	106 (89.1)	75.3 (23.83)		[15.69,29.12]	[0.57,1.13]	
Placebo	Baseline	115 (100.0)	37.8 (23.25)	10.32 (2.430)	<.0001		
N=115	Overall	103 (89.6)	47.2 (22.58)				
>= 30							
Relugolix+E2/NETA	Baseline	130 (97.7)	39.0 (25.08)	30.95 (2.262)	15.94	0.61	
N=133	Overall	121 (91.0)	69.6 (26.43)		[9.78,22.11]	[0.35,0.86]	
Placebo	Baseline	139 (98.6)	37.1 (25.58)	15.01 (2.172)	<.0001		
N=141	Overall	130 (92.2)	50.6 (25.44)				
Missing							
Relugolix+E2/NETA	Baseline	1 (100.0)	32.1 (NE)	NC (NC)	NC	NC	
N=1	Overall	1 (100.0)	91.1 (NE)		[NC,NC]	[NC,NC]	
Placebo	Baseline	0	NE (NE)	NC (NC)	NC		
N=0	Overall	0	NE (NE)				

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group. Transformed score ranges from 0 to 100 based on Likert scale (None of the time, a little of the time, some of the time, most of the time and all of the time). Higher scores are indicative of better health-related quality of life (high score = good). For the change from baseline, positive scores indicate improvement.
[1] Summary statistics are based on observed data. Mean (SD) are calculated based on the mean observed value across all post-baseline visits within each patient.
[2] LS means, LS mean differences (95% CIs), p-value and Hedges' g (95% CIs) are based on a mixed-effects model with study, treatment, visit, subgroup, treatment-by-visit interaction and a subgroup-by-treatment interaction as fixed effects. The multiple visits for each patient are the repeated measures as a random effect within each patient with an unstructured covariance. Hedges' g is calculated using a small sample bias correction. Missing subgroup levels are not included in estimation of the interaction p-value. The reference group for the LS mean difference and Hedges' g is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with data; CI: Confidence interval; int: Interaction; LS: Least squares; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; SD: Standard deviation; SE: Standard error; SMD: Standardized mean difference; UFS-QoL: Uterine Fibroid Symptom and Health-Related Quality of Life; NC: Not calculated; NE: Non-estimable.

SOURCE: \Studies\MYV\MYV102\Analysis\Prod\Progs\TFLs\Tab_QOL_UFS_CON.SAS
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Table EFF.UFSEMS.MITT.Pooled.S5: Summary of Change from Baseline in UFS-QoL Energy/Mood Scale Score by Visit and Overall, by Subgroup (mITT Population)

Study: Pooled

Treatment	Study visit	n (%)[1]	Mean (SD)[1]	Change from baseline LS-mean change (SE)[2]	Difference LS-mean change [95% CI] p-value[2]	SMD Hedges' g [95% CI][2]
MBL Volume at Baseline (mL)						
< 225 mL						
Relugolix+E2/NETA	Baseline	163 (99.4)	41.3 (24.26)	27.35 (2.202)	14.30	0.54
N=164	Week 12	147 (89.6)	70.0 (27.61)		[8.24,20.36]	[0.31,0.77]
Placebo	Baseline	170 (99.4)	37.1 (24.42)	13.05 (2.152)	<.0001	
N=171	Week 12	153 (89.5)	49.9 (24.69)			
>= 225 mL						
Relugolix+E2/NETA	Baseline	86 (96.6)	37.9 (28.81)	32.94 (2.858)	22.63	0.92
N=89	Week 12	77 (86.5)	68.5 (27.30)		[14.63,30.62]	[0.58,1.26]
Placebo	Baseline	84 (98.8)	38.0 (24.81)	10.31 (2.859)	<.0001	
N=85	Week 12	76 (89.4)	46.6 (25.62)			

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group. Transformed score ranges from 0 to 100 based on Likert scale (None of the time, a little of the time, some of the time, most of the time and all of the time). Higher scores are indicative of better health-related quality of life (high score = good). For the change from baseline, positive scores indicate improvement.
[1] Summary statistics are based on observed data.
[2] LS means, LS mean differences (95% CIs), p-value and Hedges' g (95% CIs) are based on a mixed-effects model with study, treatment, visit, and a treatment-by-visit interaction as fixed effects. The multiple visits for each patient are the repeated measures as a random effect within each patient with an unstructured covariance. Hedges' g is calculated using a small sample bias correction. Interaction p-value is only produced for the Overall period. The reference group for the LS mean difference and Hedges' g is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with data; CI: Confidence interval; LS: Least squares; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; SD: Standard deviation; SE: Standard error; SMD: Standardized mean difference; UFS-QoL: Uterine Fibroid Symptom and Health-Related Quality of Life.

SOURCE: \Studies\MYV\MYV102\Analysis\Prod\Progs\TFLs\Tab_QOL_UFS_CON.SAS
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Table EFF.UFSEMS.MITT.Pooled.S5: Summary of Change from Baseline in UFS-QoL Energy/Mood Scale Score by Visit and Overall, by Subgroup (mITT Population)

Study: Pooled

Treatment	Study visit	n (%)[1]	Mean (SD)[1]	Change from baseline LS-mean change (SE)[2]	Difference LS-mean change [95% CI] p-value[2]	SMD Hedges' g [95% CI][2]
MBL Volume at Baseline (mL)						
< 225 mL						
Relugolix+E2/NETA	Baseline	163 (99.4)	41.3 (24.26)	33.69 (2.271)	19.68	0.74
N=164	Week 24	126 (76.8)	78.2 (24.76)		[13.46,25.90]	[0.49,0.99]
Placebo	Baseline	170 (99.4)	37.1 (24.42)	14.01 (2.198)	<.0001	
N=171	Week 24	137 (80.1)	51.2 (26.12)			
>= 225 mL						
Relugolix+E2/NETA	Baseline	86 (96.6)	37.9 (28.81)	36.52 (3.132)	23.44	0.87
N=89	Week 24	70 (78.7)	76.0 (26.16)		[14.60,32.29]	[0.51,1.23]
Placebo	Baseline	84 (98.8)	38.0 (24.81)	13.08 (3.196)	<.0001	
N=85	Week 24	62 (72.9)	48.2 (29.69)			

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group. Transformed score ranges from 0 to 100 based on Likert scale (None of the time, a little of the time, some of the time, most of the time and all of the time). Higher scores are indicative of better health-related quality of life (high score = good). For the change from baseline, positive scores indicate improvement.
[1] Summary statistics are based on observed data.
[2] LS means, LS mean differences (95% CIs), p-value and Hedges' g (95% CIs) are based on a mixed-effects model with study, treatment, visit, and a treatment-by-visit interaction as fixed effects. The multiple visits for each patient are the repeated measures as a random effect within each patient with an unstructured covariance. Hedges' g is calculated using a small sample bias correction. Interaction p-value is only produced for the Overall period. The reference group for the LS mean difference and Hedges' g is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with data; CI: Confidence interval; LS: Least squares; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; SD: Standard deviation; SE: Standard error; SMD: Standardized mean difference; UFS-QoL: Uterine Fibroid Symptom and Health-Related Quality of Life.

SOURCE: \Studies\MYV\MYV102\Analysis\Prod\Progs\TFLs\Tab_QOL_UFS_CON.SAS
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Table EFF.UFSEMS.MITT.Pooled.S5: Summary of Change from Baseline in UFS-QoL Energy/Mood Scale Score by Visit and Overall, by Subgroup (mITT Population)

Study: Pooled

Treatment	Study visit	n (%)[1]	Mean (SD)[1]	Change from baseline LS-mean change (SE)[2]	Difference LS-mean change [95% CI] p-value[2]	SMD Hedges' g [95% CI][2]	Int. p-value[2]
MBL Volume at Baseline (mL)							
< 225 mL							
Relugolix+E2/NETA	Baseline	163 (99.4)	41.3 (24.26)	30.41 (2.030)	16.87	0.64	0.2030
N=164	Overall	148 (90.2)	72.7 (25.39)		[11.31,22.44]	[0.41,0.87]	
Placebo	Baseline	170 (99.4)	37.1 (24.42)	13.53 (1.975)	<.0001		
N=171	Overall	156 (91.2)	49.9 (23.40)				
>= 225 mL							
Relugolix+E2/NETA	Baseline	86 (96.6)	37.9 (28.81)	34.78 (2.806)	23.10	0.87	
N=89	Overall	80 (89.9)	71.6 (25.35)		[15.27,30.94]	[0.54,1.21]	
Placebo	Baseline	84 (98.8)	38.0 (24.81)	11.68 (2.831)	<.0001		
N=85	Overall	77 (90.6)	47.5 (25.92)				

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group. Transformed score ranges from 0 to 100 based on Likert scale (None of the time, a little of the time, some of the time, most of the time and all of the time). Higher scores are indicative of better health-related quality of life (high score = good). For the change from baseline, positive scores indicate improvement.
[1] Summary statistics are based on observed data. Mean (SD) are calculated based on the mean observed value across all post-baseline visits within each patient.
[2] LS means, LS mean differences (95% CIs), p-value and Hedges' g (95% CIs) are based on a mixed-effects model with study, treatment, visit, subgroup, treatment-by-visit interaction and a subgroup-by-treatment interaction as fixed effects. The multiple visits for each patient are the repeated measures as a random effect within each patient with an unstructured covariance. Hedges' g is calculated using a small sample bias correction. The reference group for the LS mean difference and Hedges' g is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with data; CI: Confidence interval; int: Interaction; LS: Least squares; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; SD: Standard deviation; SE: Standard error; SMD: Standardized mean difference; UFS-QoL: Uterine Fibroid Symptom and Health-Related Quality of Life.

SOURCE: \Studies\MYV\MYV102\Analysis\Prod\Progs\TFLs\Tab_QOL_UFS_CON.SAS
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Table EFF.UFSEMS.MITT.Pooled.S4: Summary of Change from Baseline in UFS-QoL Energy/Mood Scale Score by Visit and Overall, by Subgroup (mITT Population)

Study: Pooled

Treatment	Study visit	n (%)[1]	Mean (SD)[1]	Change from baseline LS-mean change (SE)[2]	Difference LS-mean change [95% CI] p-value[2]	SMD Hedges' g [95% CI][2]
Maximum NRS Pain Score at Baseline						
< 4						
Relugolix+E2/NETA	Baseline	72 (98.6)	50.4 (27.88)	22.42 (2.848)	15.46	0.68
N=73	Week 12	65 (89.0)	74.1 (26.09)		[7.04,23.89]	[0.30,1.05]
Placebo	Baseline	61 (98.4)	48.2 (23.93)	6.96 (3.171)	0.0004	
N=62	Week 12	52 (83.9)	52.7 (24.71)			
>= 4						
Relugolix+E2/NETA	Baseline	174 (98.3)	35.7 (23.95)	31.96 (2.179)	18.24	0.68
N=177	Week 12	156 (88.1)	67.5 (28.03)		[12.35,24.13]	[0.45,0.90]
Placebo	Baseline	189 (99.5)	34.2 (23.93)	13.73 (2.052)	<.0001	
N=190	Week 12	174 (91.6)	47.9 (25.11)			
Missing						
Relugolix+E2/NETA	Baseline	3 (100.0)	51.2 (19.68)	NC (NC)	NC	NC
N=3	Week 12	3 (100.0)	75.0 (18.53)		[NC,NC]	[NC,NC]
Placebo	Baseline	4 (100.0)	24.1 (5.36)	NC (NC)	NC	
N=4	Week 12	3 (75.0)	32.2 (15.58)			

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group. Transformed score ranges from 0 to 100 based on Likert scale (None of the time, a little of the time, some of the time, most of the time and all of the time). Higher scores are indicative of better health-related quality of life (high score = good). For the change from baseline, positive scores indicate improvement.
[1] Summary statistics are based on observed data.
[2] LS means, LS mean differences (95% CIs), p-value and Hedges' g (95% CIs) are based on a mixed-effects model with study, treatment, visit, and a treatment-by-visit interaction as fixed effects. The multiple visits for each patient are the repeated measures as a random effect within each patient with an unstructured covariance. Hedges' g is calculated using a small sample bias correction. Interaction p-value is only produced for the Overall period. The reference group for the LS mean difference and Hedges' g is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with data; CI: Confidence interval; LS: Least squares; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; SD: Standard deviation; SE: Standard error; SMD: Standardized mean difference; UFS-QoL: Uterine Fibroid Symptom and Health-Related Quality of Life; NC: Not calculated.

SOURCE: \Studies\MYV\MYV102\Analysis\Prod\Progs\TFLs\Tab_QOL_UFS_CON.SAS
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Table EFF.UFSEMS.MITT.Pooled.S4: Summary of Change from Baseline in UFS-QoL Energy/Mood Scale Score by Visit and Overall, by Subgroup (mITT Population)

Study: Pooled

Treatment	Study visit	n (%)[1]	Mean (SD)[1]	Change from baseline LS-mean change (SE)[2]	Difference LS-mean change [95% CI] p-value[2]	SMD Hedges' g [95% CI][2]
Maximum NRS Pain Score at Baseline						
< 4						
Relugolix+E2/NETA	Baseline	72 (98.6)	50.4 (27.88)	24.82 (3.317)	14.29	0.55
N=73	Week 24	57 (78.1)	78.9 (25.56)		[4.46,24.13]	[0.16,0.95]
Placebo	Baseline	61 (98.4)	48.2 (23.93)	10.53 (3.706)	0.0048	
N=62	Week 24	46 (74.2)	58.2 (24.09)			
>= 4						
Relugolix+E2/NETA	Baseline	174 (98.3)	35.7 (23.95)	38.84 (2.202)	24.22	0.90
N=177	Week 24	136 (76.8)	76.8 (25.31)		[18.27,30.17]	[0.66,1.15]
Placebo	Baseline	189 (99.5)	34.2 (23.93)	14.62 (2.073)	<.0001	
N=190	Week 24	151 (79.5)	48.1 (27.88)			
Missing						
Relugolix+E2/NETA	Baseline	3 (100.0)	51.2 (19.68)	NC (NC)	NC	NC
N=3	Week 24	3 (100.0)	76.2 (20.30)		[NC,NC]	[NC,NC]
Placebo	Baseline	4 (100.0)	24.1 (5.36)	NC (NC)	NC	
N=4	Week 24	2 (50.0)	34.0 (7.57)			

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group. Transformed score ranges from 0 to 100 based on Likert scale (None of the time, a little of the time, some of the time, most of the time and all of the time). Higher scores are indicative of better health-related quality of life (high score = good). For the change from baseline, positive scores indicate improvement.
[1] Summary statistics are based on observed data.
[2] LS means, LS mean differences (95% CIs), p-value and Hedges' g (95% CIs) are based on a mixed-effects model with study, treatment, visit, and a treatment-by-visit interaction as fixed effects. The multiple visits for each patient are the repeated measures as a random effect within each patient with an unstructured covariance. Hedges' g is calculated using a small sample bias correction. Interaction p-value is only produced for the Overall period. The reference group for the LS mean difference and Hedges' g is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with data; CI: Confidence interval; LS: Least squares; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; SD: Standard deviation; SE: Standard error; SMD: Standardized mean difference; UFS-QoL: Uterine Fibroid Symptom and Health-Related Quality of Life; NC: Not calculated.

SOURCE: \Studies\MYV\MYV102\Analysis\Prod\Progs\TFLs\Tab_QOL_UFS_CON.SAS
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Table EFF.UFSEMS.MITT.Pooled.S4: Summary of Change from Baseline in UFS-QoL Energy/Mood Scale Score by Visit and Overall, by Subgroup (mITT Population)

Study: Pooled

Treatment	Study visit	n (%)[1]	Mean (SD)[1]	Change from baseline LS-mean change (SE)[2]	Difference LS-mean change [95% CI] p-value[2]	SMD Hedges' g [95% CI][2]	Int. p-value[2]
Maximum NRS Pain Score at Baseline							
< 4							
Relugolix+E2/NETA	Baseline	72 (98.6)	50.4 (27.88)	24.07 (3.032)	15.27	0.58	0.2633
N=73	Overall	66 (90.4)	75.4 (24.85)		[6.37,24.17]	[0.21,0.95]	
Placebo	Baseline	61 (98.4)	48.2 (23.93)	8.80 (3.369)	0.0008		
N=62	Overall	54 (87.1)	53.8 (22.38)				
>= 4							
Relugolix+E2/NETA	Baseline	174 (98.3)	35.7 (23.95)	35.35 (1.962)	21.17	0.81	
N=177	Overall	159 (89.8)	71.0 (25.63)		[15.87,26.47]	[0.58,1.03]	
Placebo	Baseline	189 (99.5)	34.2 (23.93)	14.18 (1.850)	<.0001		
N=190	Overall	176 (92.6)	47.9 (24.76)				
Missing							
Relugolix+E2/NETA	Baseline	3 (100.0)	51.2 (19.68)	NC (NC)	NC	NC	
N=3	Overall	3 (100.0)	75.6 (19.24)		[NC,NC]	[NC,NC]	
Placebo	Baseline	4 (100.0)	24.1 (5.36)	NC (NC)	NC		
N=4	Overall	3 (75.0)	34.0 (10.86)				

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group. Transformed score ranges from 0 to 100 based on Likert scale (None of the time, a little of the time, some of the time, most of the time and all of the time). Higher scores are indicative of better health-related quality of life (high score = good). For the change from baseline, positive scores indicate improvement.
[1] Summary statistics are based on observed data. Mean (SD) are calculated based on the mean observed value across all post-baseline visits within each patient.
[2] LS means, LS mean differences (95% CIs), p-value and Hedges' g (95% CIs) are based on a mixed-effects model with study, treatment, visit, subgroup, treatment-by-visit interaction and a subgroup-by-treatment interaction as fixed effects. The multiple visits for each patient are the repeated measures as a random effect within each patient with an unstructured covariance. Hedges' g is calculated using a small sample bias correction. Missing subgroup levels are not included in estimation of the interaction p-value. The reference group for the LS mean difference and Hedges' g is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with data; CI: Confidence interval; int: Interaction; LS: Least squares; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; SD: Standard deviation; SE: Standard error; SMD: Standardized mean difference; UFS-QoL: Uterine Fibroid Symptom and Health-Related Quality of Life; NC: Not calculated.

SOURCE: \Studies\MYV\MYV102\Analysis\Prod\Progs\TFLs\Tab_QOL_UFS_CON.SAS
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Table EFF.UFSEMS.MITT.Pooled.S1: Summary of Change from Baseline in UFS-QoL Energy/Mood Scale Score by Visit and Overall, by Subgroup (mITT Population)

Study: Pooled

Treatment	Study visit	n (%)[1]	Mean (SD)[1]	Change from baseline LS-mean change (SE)[2]	Difference LS-mean change [95% CI] p-value[2]	SMD Hedges' g [95% CI][2]
Age (years)						
< 40 years						
Relugolix+E2/NETA	Baseline	61 (98.4)	36.9 (25.03)	26.46 (3.471)	13.50	0.52
N=62	Week 12	57 (91.9)	62.3 (31.33)		[4.24,22.76]	[0.16,0.88]
Placebo	Baseline	78 (100.0)	36.7 (24.45)	12.96 (3.143)	0.0046	
N=78	Week 12	68 (87.2)	48.0 (24.75)			
>= 40 years						
Relugolix+E2/NETA	Baseline	188 (98.4)	41.2 (26.17)	30.08 (2.038)	18.28	0.70
N=191	Week 12	167 (87.4)	71.9 (25.65)		[12.56,23.99]	[0.47,0.92]
Placebo	Baseline	176 (98.9)	37.7 (24.59)	11.81 (2.071)	<.0001	
N=178	Week 12	161 (90.4)	49.1 (25.17)			

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group. Transformed score ranges from 0 to 100 based on Likert scale (None of the time, a little of the time, some of the time, most of the time and all of the time). Higher scores are indicative of better health-related quality of life (high score = good). For the change from baseline, positive scores indicate improvement.
[1] Summary statistics are based on observed data.
[2] LS means, LS mean differences (95% CIs), p-value and Hedges' g (95% CIs) are based on a mixed-effects model with study, treatment, visit, and a treatment-by-visit interaction as fixed effects. The multiple visits for each patient are the repeated measures as a random effect within each patient with an unstructured covariance. Hedges' g is calculated using a small sample bias correction. Interaction p-value is only produced for the Overall period. The reference group for the LS mean difference and Hedges' g is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with data; CI: Confidence interval; LS: Least squares; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; SD: Standard deviation; SE: Standard error; SMD: Standardized mean difference; UFS-QoL: Uterine Fibroid Symptom and Health-Related Quality of Life.

SOURCE: \Studies\MYV\MYV102\Analysis\Prod\Progs\TFLs\Tab_QOL_UFS_CON.SAS
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Table EFF.UFSEMS.MITT.Pooled.S1: Summary of Change from Baseline in UFS-QoL Energy/Mood Scale Score by Visit and Overall, by Subgroup (mITT Population)

Study: Pooled

Treatment	Study visit	n (%)[1]	Mean (SD)[1]	Change from baseline LS-mean change (SE)[2]	Difference LS-mean change [95% CI] p-value[2]	SMD Hedges' g [95% CI][2]
Age (years)						
< 40 years						
Relugolix+E2/NETA	Baseline	61 (98.4)	36.9 (25.03)	31.47 (3.901)	16.69	0.60
N=62	Week 24	47 (75.8)	68.2 (29.64)		[6.32,27.05]	[0.21,0.99]
Placebo	Baseline	78 (100.0)	36.7 (24.45)	14.78 (3.496)	0.0018	
N=78	Week 24	58 (74.4)	51.6 (26.99)			
>= 40 years						
Relugolix+E2/NETA	Baseline	188 (98.4)	41.2 (26.17)	35.64 (2.078)	22.40	0.85
N=191	Week 24	149 (78.0)	80.3 (23.01)		[16.56,28.24]	[0.61,1.09]
Placebo	Baseline	176 (98.9)	37.7 (24.59)	13.23 (2.121)	<.0001	
N=178	Week 24	141 (79.2)	49.7 (27.42)			

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group. Transformed score ranges from 0 to 100 based on Likert scale (None of the time, a little of the time, some of the time, most of the time and all of the time). Higher scores are indicative of better health-related quality of life (high score = good). For the change from baseline, positive scores indicate improvement.
[1] Summary statistics are based on observed data.
[2] LS means, LS mean differences (95% CIs), p-value and Hedges' g (95% CIs) are based on a mixed-effects model with study, treatment, visit, and a treatment-by-visit interaction as fixed effects. The multiple visits for each patient are the repeated measures as a random effect within each patient with an unstructured covariance. Hedges' g is calculated using a small sample bias correction. Interaction p-value is only produced for the Overall period. The reference group for the LS mean difference and Hedges' g is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with data; CI: Confidence interval; LS: Least squares; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; SD: Standard deviation; SE: Standard error; SMD: Standardized mean difference; UFS-QoL: Uterine Fibroid Symptom and Health-Related Quality of Life.

SOURCE: \Studies\MYV\MYV102\Analysis\Prod\Progs\TFLs\Tab_QOL_UFS_CON.SAS
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Table EFF.UFSEMS.MITT.Pooled.S1: Summary of Change from Baseline in UFS-QoL Energy/Mood Scale Score by Visit and Overall, by Subgroup (mITT Population)

Study: Pooled

Treatment	Study visit	n (%)[1]	Mean (SD)[1]	Change from baseline LS-mean change (SE)[2]	Difference LS-mean change [95% CI] p-value[2]	SMD Hedges' g [95% CI][2]	Int. p-value[2]
Age (years)							
< 40 years							
Relugolix+E2/NETA	Baseline	61 (98.4)	36.9 (25.03)	29.06 (3.297)	15.20	0.57	0.3258
N=62	Overall	57 (91.9)	64.4 (29.10)		[6.46,23.93]	[0.22,0.93]	
Placebo	Baseline	78 (100.0)	36.7 (24.45)	13.86 (2.983)	0.0007		
N=78	Overall	68 (87.2)	48.8 (23.57)				
>= 40 years							
Relugolix+E2/NETA	Baseline	188 (98.4)	41.2 (26.17)	32.86 (1.899)	20.31	0.77	
N=191	Overall	171 (89.5)	75.0 (23.45)		[14.99,25.64]	[0.55,0.99]	
Placebo	Baseline	176 (98.9)	37.7 (24.59)	12.54 (1.932)	<.0001		
N=178	Overall	165 (92.7)	49.2 (24.57)				

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group. Transformed score ranges from 0 to 100 based on Likert scale (None of the time, a little of the time, some of the time, most of the time and all of the time). Higher scores are indicative of better health-related quality of life (high score = good). For the change from baseline, positive scores indicate improvement.
[1] Summary statistics are based on observed data. Mean (SD) are calculated based on the mean observed value across all post-baseline visits within each patient.
[2] LS means, LS mean differences (95% CIs), p-value and Hedges' g (95% CIs) are based on a mixed-effects model with study, treatment, visit, subgroup, treatment-by-visit interaction and a subgroup-by-treatment interaction as fixed effects. The multiple visits for each patient are the repeated measures as a random effect within each patient with an unstructured covariance. Hedges' g is calculated using a small sample bias correction. The reference group for the LS mean difference and Hedges' g is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with data; CI: Confidence interval; int: Interaction; LS: Least squares; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; SD: Standard deviation; SE: Standard error; SMD: Standardized mean difference; UFS-QoL: Uterine Fibroid Symptom and Health-Related Quality of Life.

SOURCE: \Studies\MYV\MYV102\Analysis\Prod\Progs\TFLs\Tab_QOL_UFS_CON.SAS
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Table EFF.UFSEMS.MITT.Pooled.S9: Summary of Change from Baseline in UFS-QoL Energy/Mood Scale Score by Visit and Overall, by Subgroup (mITT Population)						
Study: Pooled						
Treatment	**Study visit**	**n (%)[1]**	**Mean (SD)[1]**	**Change from baseline LS-mean change (SE)[2]**	**Difference LS-mean change [95% CI] p-value[2]**	**SMD Hedges' g [95% CI][2]**
Race						
Black/African American						
Relugolix+E2/NETA	Baseline	119 (97.5)	36.1 (26.92)	32.11 (2.583)	20.37	0.78
N=122	Week 12	105 (86.1)	67.9 (28.13)		[13.47,27.28]	[0.51,1.05]
Placebo	Baseline	139 (98.6)	39.6 (25.95)	11.74 (2.370)	<.0001	
N=141	Week 12	122 (86.5)	50.8 (25.50)			
White						
Relugolix+E2/NETA	Baseline	121 (99.2)	43.2 (24.34)	27.45 (2.515)	15.19	0.58
N=122	Week 12	110 (90.2)	71.1 (27.21)		[7.96,22.41]	[0.30,0.85]
Placebo	Baseline	105 (100.0)	35.1 (22.36)	12.26 (2.669)	<.0001	
N=105	Week 12	98 (93.3)	46.7 (24.15)			
Asian						
Relugolix+E2/NETA	Baseline	1 (100.0)	42.9 (NE)	NC (NC)	NC	NC
N=1	Week 12	1 (100.0)	85.7 (NE)		[NC,NC]	[NC,NC]
Placebo	Baseline	3 (100.0)	33.3 (30.79)	NC (NC)	NC	
N=3	Week 12	3 (100.0)	39.3 (25.77)			
Others						
Relugolix+E2/NETA	Baseline	5 (100.0)	40.0 (13.69)	23.32 (11.507)	0.40	0.02
N=5	Week 12	5 (100.0)	57.1 (17.86)		[-37.89,38.70]	[-1.10,1.14]
Placebo	Baseline	6 (100.0)	25.0 (21.45)	22.91 (11.047)	0.9808	
N=6	Week 12	5 (83.3)	45.0 (33.09)			
Not reported						
Relugolix+E2/NETA	Baseline	3 (100.0)	77.4 (30.35)	NC (NC)	NC	NC
N=3	Week 12	3 (100.0)	83.3 (28.87)		[NC,NC]	[NC,NC]
Placebo	Baseline	1 (100.0)	60.7 (NE)	NC (NC)	NC	

N=1	Week 12	1 (100.0)	60.7 (NE)			

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group. Transformed score ranges from 0 to 100 based on Likert scale (None of the time, a little of the time, some of the time, most of the time and all of the time). Higher scores are indicative of better health-related quality of life (high score = good). For the change from baseline, positive scores indicate improvement.
[1] Summary statistics are based on observed data.
[2] LS means, LS mean differences (95% CIs), p-value and Hedges' g (95% CIs) are based on a mixed-effects model with study, treatment, visit, and a treatment-by-visit interaction as fixed effects. The multiple visits for each patient are the repeated measures as a random effect within each patient with an unstructured covariance. Hedges' g is calculated using a small sample bias correction. Interaction p-value is only produced for the Overall period. The reference group for the LS mean difference and Hedges' g is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with data; CI: Confidence interval; LS: Least squares; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; SD: Standard deviation; SE: Standard error; SMD: Standardized mean difference; UFS-QoL: Uterine Fibroid Symptom and Health-Related Quality of Life; NC: Not calculated; NE: Non-estimable.

Table EFF.UFSEMS.MITT.Pooled.S9: Summary of Change from Baseline in UFS-QoL Energy/Mood Scale Score by Visit and Overall, by Subgroup (mITT Population)						
Study: Pooled						
Treatment	**Study visit**	**n (%)[1]**	**Mean (SD)[1]**	**Change from baseline LS-mean change (SE)[2]**	**Difference LS-mean change [95% CI] p-value[2]**	**SMD Hedges' g [95% CI][2]**
Race						
Black/African American						
Relugolix+E2/NETA	Baseline	119 (97.5)	36.1 (26.92)	35.58 (2.760)	22.21	0.82
N=122	Week 24	87 (71.3)	74.0 (26.88)		[14.88,29.53]	[0.53,1.12]
Placebo	Baseline	139 (98.6)	39.6 (25.95)	13.37 (2.493)	<.0001	
N=141	Week 24	108 (76.6)	52.3 (27.52)			
White						
Relugolix+E2/NETA	Baseline	121 (99.2)	43.2 (24.34)	35.63 (2.543)	20.55	0.78
N=122	Week 24	100 (82.0)	81.6 (23.06)		[13.18,27.92]	[0.48,1.08]
Placebo	Baseline	105 (100.0)	35.1 (22.36)	15.08 (2.743)	<.0001	
N=105	Week 24	84 (80.0)	49.5 (26.30)			
Asian						
Relugolix+E2/NETA	Baseline	1 (100.0)	42.9 (NE)	NC (NC)	NC	NC
N=1	Week 24	1 (100.0)	100.0 (NE)		[NC,NC]	[NC,NC]
Placebo	Baseline	3 (100.0)	33.3 (30.79)	NC (NC)	NC	
N=3	Week 24	2 (66.7)	46.4 (35.36)			
Others						
Relugolix+E2/NETA	Baseline	5 (100.0)	40.0 (13.69)	19.78 (7.499)	27.03	1.82
N=5	Week 24	5 (100.0)	53.6 (16.37)		[0.28,53.78]	[0.38,3.26]
Placebo	Baseline	6 (100.0)	25.0 (21.45)	-7.25 (7.519)	0.0482	
N=6	Week 24	4 (66.7)	10.7 (7.73)			
Not reported						
Relugolix+E2/NETA	Baseline	3 (100.0)	77.4 (30.35)	NC (NC)	NC	NC
N=3	Week 24	3 (100.0)	69.1 (30.37)		[NC,NC]	[NC,NC]
Placebo	Baseline	1 (100.0)	60.7 (NE)	NC (NC)	NC	

N=1	Week 24	1 (100.0)	67.9 (NE)			

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group. Transformed score ranges from 0 to 100 based on Likert scale (None of the time, a little of the time, some of the time, most of the time and all of the time). Higher scores are indicative of better health-related quality of life (high score = good). For the change from baseline, positive scores indicate improvement.
[1] Summary statistics are based on observed data.
[2] LS means, LS mean differences (95% CIs), p-value and Hedges' g (95% CIs) are based on a mixed-effects model with study, treatment, visit, and a treatment-by-visit interaction as fixed effects. The multiple visits for each patient are the repeated measures as a random effect within each patient with an unstructured covariance. Hedges' g is calculated using a small sample bias correction. Interaction p-value is only produced for the Overall period. The reference group for the LS mean difference and Hedges' g is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with data; CI: Confidence interval; LS: Least squares; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; SD: Standard deviation; SE: Standard error; SMD: Standardized mean difference; UFS-QoL: Uterine Fibroid Symptom and Health-Related Quality of Life; NC: Not calculated; NE: Non-estimable.

Table EFF.UFSEMS.MITT.Pooled.S9: Summary of Change from Baseline in UFS-QoL Energy/Mood Scale Score by Visit and Overall, by Subgroup (mITT Population)							
Study: Pooled							
Treatment	**Study visit**	**n (%)[1]**	**Mean (SD)[1]**	**Change from baseline LS-mean change (SE)[2]**	**Difference LS-mean change [95% CI] p-value[2]**	**SMD Hedges' g [95% CI][2]**	**Int. p-value[2]**
Race							
Black/African American							
Relugolix+E2/NETA	Baseline	119 (97.5)	36.1 (26.92)	34.09 (2.423)	21.52	0.82	0.3797
N=122	Overall	107 (87.7)	69.9 (26.58)		[15.08,27.97]	[0.55,1.09]	
Placebo	Baseline	139 (98.6)	39.6 (25.95)	12.56 (2.212)	<.0001		
N=141	Overall	126 (89.4)	50.9 (25.24)				
White							
Relugolix+E2/NETA	Baseline	121 (99.2)	43.2 (24.34)	31.43 (2.331)	17.79	0.68	
N=122	Overall	112 (91.8)	75.1 (24.13)		[11.09,24.48]	[0.40,0.95]	
Placebo	Baseline	105 (100.0)	35.1 (22.36)	13.65 (2.487)	<.0001		
N=105	Overall	98 (93.3)	47.7 (22.64)				
Asian							
Relugolix+E2/NETA	Baseline	1 (100.0)	42.9 (NE)	NC (NC)	NC	NC	
N=1	Overall	1 (100.0)	92.9 (NE)		[NC,NC]	[NC,NC]	
Placebo	Baseline	3 (100.0)	33.3 (30.79)	NC (NC)	NC		
N=3	Overall	3 (100.0)	38.1 (27.68)				
Others							
Relugolix+E2/NETA	Baseline	5 (100.0)	40.0 (13.69)	15.51 (10.899)	1.71	0.06	
N=5	Overall	5 (100.0)	55.4 (16.36)		[-28.80,32.22]	[-1.06,1.18]	
Placebo	Baseline	6 (100.0)	25.0 (21.45)	13.80 (11.036)	0.9123		
N=6	Overall	5 (83.3)	33.9 (27.43)				
Not reported							
Relugolix+E2/NETA	Baseline	3 (100.0)	77.4 (30.35)	NC (NC)	NC	NC	
N=3	Overall	3 (100.0)	76.2 (28.48)		[NC,NC]	[NC,NC]	
Placebo	Baseline	1 (100.0)	60.7 (NE)	NC (NC)	NC		

N=1	Overall	1 (100.0)	64.3 (NE)				

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group. Transformed score ranges from 0 to 100 based on Likert scale (None of the time, a little of the time, some of the time, most of the time and all of the time). Higher scores are indicative of better health-related quality of life (high score = good). For the change from baseline, positive scores indicate improvement.
[1] Summary statistics are based on observed data. Mean (SD) are calculated based on the mean observed value across all post-baseline visits within each patient.
[2] LS means, LS mean differences (95% CIs), p-value and Hedges' g (95% CIs) are based on a mixed-effects model with study, treatment, visit, subgroup, treatment-by-visit interaction and a subgroup-by-treatment interaction as fixed effects. The multiple visits for each patient are the repeated measures as a random effect within each patient with an unstructured covariance. Hedges' g is calculated using a small sample bias correction. Not reported subgroup levels are not included in estimation of the interaction p-value. Subgroup levels with fewer than 10 subjects are not included in estimation of the interaction p-value. The reference group for the LS mean difference and Hedges' g is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with data; CI: Confidence interval; int: Interaction; LS: Least squares; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; SD: Standard deviation; SE: Standard error; SMD: Standardized mean difference; UFS-QoL: Uterine Fibroid Symptom and Health-Related Quality of Life; NC: Not calculated; NE: Non-estimable.

SOURCE: \Studies\MYV\MYV102\Analysis\Prod\Progs\TFLs\Tab_QOL_UFS_CON.SAS
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Table EFF.UFSEMS.MITT.Pooled.S8: Summary of Change from Baseline in UFS-QoL Energy/Mood Scale Score by Visit and Overall, by Subgroup (mITT Population)

Study: Pooled

Treatment	Study visit	n (%)[1]	Mean (SD)[1]	Change from baseline LS-mean change (SE)[2]	Difference LS-mean change [95% CI] p-value[2]	SMD Hedges' g [95% CI][2]
Ethnicity						
Hispanic or Latino						
Relugolix+E2/NETA	Baseline	52 (100.0)	38.3 (22.15)	32.14 (3.898)	16.45	0.62
N=52	Week 12	47 (90.4)	69.9 (26.21)		[5.59,27.30]	[0.22,1.03]
Placebo	Baseline	55 (100.0)	24.3 (20.98)	15.70 (3.764)	0.0034	
N=55	Week 12	49 (89.1)	39.7 (26.16)			
Not Hispanic or Latino						
Relugolix+E2/NETA	Baseline	193 (98.0)	39.9 (26.40)	28.85 (2.002)	17.81	0.68
N=197	Week 12	174 (88.3)	68.9 (27.83)		[12.28,23.34]	[0.47,0.90]
Placebo	Baseline	197 (99.0)	41.2 (24.11)	11.05 (1.967)	<.0001	
N=199	Week 12	178 (89.4)	51.3 (24.24)			
Not reported						
Relugolix+E2/NETA	Baseline	4 (100.0)	75.9 (28.19)	NC (NC)	NC	NC
N=4	Week 12	3 (75.0)	97.6 (4.10)		[NC,NC]	[NC,NC]
Placebo	Baseline	2 (100.0)	30.4 (42.92)	NC (NC)	NC	
N=2	Week 12	2 (100.0)	46.4 (20.22)			

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group. Transformed score ranges from 0 to 100 based on Likert scale (None of the time, a little of the time, some of the time, most of the time and all of the time). Higher scores are indicative of better health-related quality of life (high score = good). For the change from baseline, positive scores indicate improvement.
[1] Summary statistics are based on observed data.
[2] LS means, LS mean differences (95% CIs), p-value and Hedges' g (95% CIs) are based on a mixed-effects model with study, treatment, visit, and a treatment-by-visit interaction as fixed effects. The multiple visits for each patient are the repeated measures as a random effect within each patient with an unstructured covariance. Hedges' g is calculated using a small sample bias correction. Interaction p-value is only produced for the Overall period. The reference group for the LS mean difference and Hedges' g is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with data; CI: Confidence interval; LS: Least squares; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; SD: Standard deviation; SE: Standard error; SMD: Standardized mean difference; UFS-QoL: Uterine Fibroid Symptom and Health-Related Quality of Life; NC: Not calculated.

SOURCE: \Studies\MYV\MYV102\Analysis\Prod\Progs\TFLs\Tab_QOL_UFS_CON.SAS
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Table EFF.UFSEMS.MITT.Pooled.S8: Summary of Change from Baseline in UFS-QoL Energy/Mood Scale Score by Visit and Overall, by Subgroup (mITT Population)

Study: Pooled

Treatment	Study visit	n (%)[1]	Mean (SD)[1]	Change from baseline LS-mean change (SE)[2]	Difference LS-mean change [95% CI] p-value[2]	SMD Hedges' g [95% CI][2]
Ethnicity						
Hispanic or Latino						
Relugolix+E2/NETA	Baseline	52 (100.0)	38.3 (22.15)	38.33 (4.313)	19.75	0.68
N=52	Week 24	44 (84.6)	77.7 (21.47)		[7.75,31.75]	[0.26,1.10]
Placebo	Baseline	55 (100.0)	24.3 (20.98)	18.58 (4.166)	0.0015	
N=55	Week 24	46 (83.6)	41.5 (31.41)			
Not Hispanic or Latino						
Relugolix+E2/NETA	Baseline	193 (98.0)	39.9 (26.40)	34.34 (2.032)	22.02	0.85
N=197	Week 24	149 (75.6)	77.1 (26.41)		[16.40,27.64]	[0.61,1.09]
Placebo	Baseline	197 (99.0)	41.2 (24.11)	12.32 (2.001)	<.0001	
N=199	Week 24	151 (75.9)	53.2 (25.15)			
Not reported						
Relugolix+E2/NETA	Baseline	4 (100.0)	75.9 (28.19)	NC (NC)	NC	NC
N=4	Week 24	3 (75.0)	88.1 (17.59)		[NC,NC]	[NC,NC]
Placebo	Baseline	2 (100.0)	30.4 (42.92)	NC (NC)	NC	
N=2	Week 24	2 (100.0)	34.0 (48.01)			

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group. Transformed score ranges from 0 to 100 based on Likert scale (None of the time, a little of the time, some of the time, most of the time and all of the time). Higher scores are indicative of better health-related quality of life (high score = good). For the change from baseline, positive scores indicate improvement.
[1] Summary statistics are based on observed data.
[2] LS means, LS mean differences (95% CIs), p-value and Hedges' g (95% CIs) are based on a mixed-effects model with study, treatment, visit, and a treatment-by-visit interaction as fixed effects. The multiple visits for each patient are the repeated measures as a random effect within each patient with an unstructured covariance. Hedges' g is calculated using a small sample bias correction. Interaction p-value is only produced for the Overall period. The reference group for the LS mean difference and Hedges' g is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with data; CI: Confidence interval; LS: Least squares; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; SD: Standard deviation; SE: Standard error; SMD: Standardized mean difference; UFS-QoL: Uterine Fibroid Symptom and Health-Related Quality of Life; NC: Not calculated.

SOURCE: \Studies\MYV\MYV102\Analysis\Prod\Progs\TFLs\Tab_QOL_UFS_CON.SAS
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Analysis Plan: 13JAN2021

Table EFF.UFSEMS.MITT.Pooled.S8: Summary of Change from Baseline in UFS-QoL Energy/Mood Scale Score by Visit and Overall, by Subgroup (mITT Population)

Study: Pooled

Treatment	Study visit	n (%)[1]	Mean (SD)[1]	Change from baseline LS-mean change (SE)[2]	Difference LS-mean change [95% CI] p-value[2]	SMD Hedges' g [95% CI][2]	Int. p-value[2]
Ethnicity							
Hispanic or Latino							
Relugolix+E2/NETA	Baseline	52 (100.0)	38.3 (22.15)	34.90 (3.525)	17.68	0.67	0.7017
N=52	Overall	49 (94.2)	73.5 (22.12)		[7.98,27.39]	[0.27,1.07]	
Placebo	Baseline	55 (100.0)	24.3 (20.98)	17.22 (3.440)	0.0004		
N=55	Overall	51 (92.7)	40.3 (26.05)				
Not Hispanic or Latino							
Relugolix+E2/NETA	Baseline	193 (98.0)	39.9 (26.40)	31.58 (1.880)	19.83	0.75	
N=197	Overall	176 (89.3)	71.7 (26.25)		[14.65,25.02]	[0.54,0.97]	
Placebo	Baseline	197 (99.0)	41.2 (24.11)	11.75 (1.848)	<.0001		
N=199	Overall	180 (90.5)	51.7 (23.13)				
Not reported							
Relugolix+E2/NETA	Baseline	4 (100.0)	75.9 (28.19)	NC (NC)	NC	NC	
N=4	Overall	3 (75.0)	92.9 (8.17)		[NC,NC]	[NC,NC]	
Placebo	Baseline	2 (100.0)	30.4 (42.92)	NC (NC)	NC		
N=2	Overall	2 (100.0)	40.2 (34.12)				

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group. Transformed score ranges from 0 to 100 based on Likert scale (None of the time, a little of the time, some of the time, most of the time and all of the time). Higher scores are indicative of better health-related quality of life (high score = good). For the change from baseline, positive scores indicate improvement.
[1] Summary statistics are based on observed data. Mean (SD) are calculated based on the mean observed value across all post-baseline visits within each patient.
[2] LS means, LS mean differences (95% CIs), p-value and Hedges' g (95% CIs) are based on a mixed-effects model with study, treatment, visit, subgroup, treatment-by-visit interaction and a subgroup-by-treatment interaction as fixed effects. The multiple visits for each patient are the repeated measures as a random effect within each patient with an unstructured covariance. Hedges' g is calculated using a small sample bias correction. Not reported subgroup levels are not included in estimation of the interaction p-value. The reference group for the LS mean difference and Hedges' g is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with data; CI: Confidence interval; int: Interaction; LS: Least squares; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; SD: Standard deviation; SE: Standard error; SMD: Standardized mean difference; UFS-QoL: Uterine Fibroid Symptom and Health-Related Quality of Life; NC: Not calculated.

SOURCE: \Studies\MYV\MYV102\Analysis\Prod\Progs\TFLs\Tab_QOL_UFS_CON.SAS
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Analysis Plan: 13JAN2021

Table EFF.UFSEMS.MITT.Pooled.S7: Summary of Change from Baseline in UFS-QoL Energy/Mood Scale Score by Visit and Overall, by Subgroup (mITT Population)

Study: Pooled

Treatment	Study visit	n (%)[1]	Mean (SD)[1]	Change from baseline LS-mean change (SE)[2]	Difference LS-mean change [95% CI] p-value[2]	SMD Hedges' g [95% CI][2]
Geographic Region II						
Europe						
Relugolix+E2/NETA	Baseline	40 (97.6)	47.5 (23.77)	25.29 (3.934)	18.85	0.78
N=41	Week 12	39 (95.1)	73.2 (25.50)		[7.79,29.90]	[0.32,1.24]
Placebo	Baseline	42 (100.0)	45.4 (20.12)	6.44 (3.942)	0.0011	
N=42	Week 12	39 (92.9)	51.2 (20.89)			
Rest of World (including the US)						
Relugolix+E2/NETA	Baseline	209 (98.6)	38.8 (26.12)	29.98 (1.952)	16.74	0.63
N=212	Week 12	185 (87.3)	68.7 (27.85)		[11.36,22.13]	[0.43,0.84]
Placebo	Baseline	212 (99.1)	35.8 (25.02)	13.24 (1.924)	<.0001	
N=214	Week 12	190 (88.8)	48.3 (25.78)			

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group. Transformed score ranges from 0 to 100 based on Likert scale (None of the time, a little of the time, some of the time, most of the time and all of the time). Higher scores are indicative of better health-related quality of life (high score = good). For the change from baseline, positive scores indicate improvement.
[1] Summary statistics are based on observed data.
[2] LS means, LS mean differences (95% CIs), p-value and Hedges' g (95% CIs) are based on a mixed-effects model with study, treatment, visit, and a treatment-by-visit interaction as fixed effects. The multiple visits for each patient are the repeated measures as a random effect within each patient with an unstructured covariance. Hedges' g is calculated using a small sample bias correction. Interaction p-value is only produced for the Overall period. The reference group for the LS mean difference and Hedges' g is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with data; CI: Confidence interval; LS: Least squares; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; SD: Standard deviation; SE: Standard error; SMD: Standardized mean difference; UFS-QoL: Uterine Fibroid Symptom and Health-Related Quality of Life.

SOURCE: \Studies\MYV\MYV102\Analysis\Prod\Progs\TFLs\Tab_QOL_UFS_CON.SAS
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Table EFF.UFSEMS.MITT.Pooled.S7: Summary of Change from Baseline in UFS-QoL Energy/Mood Scale Score by Visit and Overall, by Subgroup (mITT Population)

Study: Pooled

Treatment	Study visit	n (%)[1]	Mean (SD)[1]	Change from baseline LS-mean change (SE)[2]	Difference LS-mean change [95% CI] p-value[2]	SMD Hedges' g [95% CI][2]
Geographic Region II						
Europe						
Relugolix+E2/NETA	Baseline	40 (97.6)	47.5 (23.77)	33.10 (3.949)	23.33	0.97
N=41	Week 24	37 (90.2)	82.2 (22.04)		[12.10,34.56]	[0.48,1.45]
Placebo	Baseline	42 (100.0)	45.4 (20.12)	9.76 (4.044)	<.0001	
N=42	Week 24	35 (83.3)	55.2 (20.38)			
Rest of World (including the US)						
Relugolix+E2/NETA	Baseline	209 (98.6)	38.8 (26.12)	34.88 (2.061)	20.49	0.75
N=212	Week 24	159 (75.0)	76.3 (25.84)		[14.80,26.17]	[0.52,0.98]
Placebo	Baseline	212 (99.1)	35.8 (25.02)	14.40 (2.025)	<.0001	
N=214	Week 24	164 (76.6)	49.2 (28.44)			

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group. Transformed score ranges from 0 to 100 based on Likert scale (None of the time, a little of the time, some of the time, most of the time and all of the time). Higher scores are indicative of better health-related quality of life (high score = good). For the change from baseline, positive scores indicate improvement.
[1] Summary statistics are based on observed data.
[2] LS means, LS mean differences (95% CIs), p-value and Hedges' g (95% CIs) are based on a mixed-effects model with study, treatment, visit, and a treatment-by-visit interaction as fixed effects. The multiple visits for each patient are the repeated measures as a random effect within each patient with an unstructured covariance. Hedges' g is calculated using a small sample bias correction. Interaction p-value is only produced for the Overall period. The reference group for the LS mean difference and Hedges' g is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with data; CI: Confidence interval; LS: Least squares; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; SD: Standard deviation; SE: Standard error; SMD: Standardized mean difference; UFS-QoL: Uterine Fibroid Symptom and Health-Related Quality of Life.

SOURCE: \Studies\MYV\MYV102\Analysis\Prod\Progs\TFLs\Tab_QOL_UFS_CON.SAS
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Table EFF.UFSEMS.MITT.Pooled.S7: Summary of Change from Baseline in UFS-QoL Energy/Mood Scale Score by Visit and Overall, by Subgroup (mITT Population)

Study: Pooled

Treatment	Study visit	n (%)[1]	Mean (SD)[1]	Change from baseline LS-mean change (SE)[2]	Difference LS-mean change [95% CI] p-value[2]	SMD Hedges' g [95% CI][2]	Int. p-value[2]
Geographic Region II							
Europe							0.7385
Relugolix+E2/NETA	Baseline	40 (97.6)	47.5 (23.77)	29.15 (3.952)	20.67	0.78	
N=41	Overall	39 (95.1)	76.7 (22.78)		[9.76,31.57]	[0.32,1.24]	
Placebo	Baseline	42 (100.0)	45.4 (20.12)	8.48 (3.901)	0.0002		
N=42	Overall	40 (95.2)	52.5 (18.84)				
Rest of World (including the US)							
Relugolix+E2/NETA	Baseline	209 (98.6)	38.8 (26.12)	32.49 (1.809)	18.63	0.71	
N=212	Overall	189 (89.2)	71.4 (25.79)		[13.64,23.62]	[0.50,0.92]	
Placebo	Baseline	212 (99.1)	35.8 (25.02)	13.86 (1.782)	<.0001		
N=214	Overall	193 (90.2)	48.4 (25.19)				

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group. Transformed score ranges from 0 to 100 based on Likert scale (None of the time, a little of the time, some of the time, most of the time and all of the time). Higher scores are indicative of better health-related quality of life (high score = good). For the change from baseline, positive scores indicate improvement.
[1] Summary statistics are based on observed data. Mean (SD) are calculated based on the mean observed value across all post-baseline visits within each patient.
[2] LS means, LS mean differences (95% CIs), p-value and Hedges' g (95% CIs) are based on a mixed-effects model with study, treatment, visit, subgroup, treatment-by-visit interaction and a subgroup-by-treatment interaction as fixed effects. The multiple visits for each patient are the repeated measures as a random effect within each patient with an unstructured covariance. Hedges' g is calculated using a small sample bias correction. The reference group for the LS mean difference and Hedges' g is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with data; CI: Confidence interval; int: Interaction; LS: Least squares; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; SD: Standard deviation; SE: Standard error; SMD: Standardized mean difference; UFS-QoL: Uterine Fibroid Symptom and Health-Related Quality of Life.

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Table EFF.UFSEMS.MITT.Pooled.S6: Summary of Change from Baseline in UFS-QoL Energy/Mood Scale Score by Visit and Overall, by Subgroup (mITT Population)

Study: Pooled

Treatment	Study visit	n (%)[1]	Mean (SD)[1]	Change from baseline LS-mean change (SE)[2]	Difference LS-mean change [95% CI] p-value[2]	SMD Hedges' g [95% CI][2]
Geographic Region I						
North America						
Relugolix+E2/NETA	Baseline	188 (98.4)	38.0 (26.81)	30.32 (2.114)	16.87	0.62
N=191	Week 12	165 (86.4)	68.3 (28.39)		[11.05,22.69]	[0.40,0.84]
Placebo	Baseline	192 (99.0)	36.9 (25.01)	13.45 (2.071)	<.0001	
N=194	Week 12	172 (88.7)	49.5 (25.80)			
Rest of World						
Relugolix+E2/NETA	Baseline	61 (98.4)	46.7 (21.86)	26.03 (3.025)	17.71	0.77
N=62	Week 12	59 (95.2)	72.9 (24.57)		[9.23,26.18]	[0.39,1.15]
Placebo	Baseline	62 (100.0)	39.1 (22.98)	8.32 (3.026)	<.0001	
N=62	Week 12	57 (91.9)	46.8 (22.49)			

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group. Transformed score ranges from 0 to 100 based on Likert scale (None of the time, a little of the time, some of the time, most of the time and all of the time). Higher scores are indicative of better health-related quality of life (high score = good). For the change from baseline, positive scores indicate improvement.
[1] Summary statistics are based on observed data.
[2] LS means, LS mean differences (95% CIs), p-value and Hedges' g (95% CIs) are based on a mixed-effects model with study, treatment, visit, and a treatment-by-visit interaction as fixed effects. The multiple visits for each patient are the repeated measures as a random effect within each patient with an unstructured covariance. Hedges' g is calculated using a small sample bias correction. Interaction p-value is only produced for the Overall period. The reference group for the LS mean difference and Hedges' g is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with data; CI: Confidence interval; LS: Least squares; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; SD: Standard deviation; SE: Standard error; SMD: Standardized mean difference; UFS-QoL: Uterine Fibroid Symptom and Health-Related Quality of Life.

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Table EFF.UFSEMS.MITT.Pooled.S6: Summary of Change from Baseline in UFS-QoL Energy/Mood Scale Score by Visit and Overall, by Subgroup (mITT Population)

Study: Pooled

Treatment	Study visit	n (%)[1]	Mean (SD)[1]	Change from baseline LS-mean change (SE)[2]	Difference LS-mean change [95% CI] p-value[2]	SMD Hedges' g [95% CI][2]
Geographic Region I						
North America						
Relugolix+E2/NETA	Baseline	188 (98.4)	38.0 (26.81)	34.76 (2.218)	20.72	0.75
N=191	Week 24	139 (72.8)	75.7 (26.68)		[14.63,26.81]	[0.51,0.99]
Placebo	Baseline	192 (99.0)	36.9 (25.01)	14.04 (2.164)	<.0001	
N=194	Week 24	146 (75.3)	50.2 (28.25)			
Rest of World						
Relugolix+E2/NETA	Baseline	61 (98.4)	46.7 (21.86)	33.89 (3.221)	21.31	0.87
N=62	Week 24	57 (91.9)	81.6 (20.88)		[12.21,30.41]	[0.48,1.26]
Placebo	Baseline	62 (100.0)	39.1 (22.98)	12.59 (3.277)	<.0001	
N=62	Week 24	53 (85.5)	50.4 (24.50)			

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group. Transformed score ranges from 0 to 100 based on Likert scale (None of the time, a little of the time, some of the time, most of the time and all of the time). Higher scores are indicative of better health-related quality of life (high score = good). For the change from baseline, positive scores indicate improvement.
[1] Summary statistics are based on observed data.
[2] LS means, LS mean differences (95% CIs), p-value and Hedges' g (95% CIs) are based on a mixed-effects model with study, treatment, visit, and a treatment-by-visit interaction as fixed effects. The multiple visits for each patient are the repeated measures as a random effect within each patient with an unstructured covariance. Hedges' g is calculated using a small sample bias correction. Interaction p-value is only produced for the Overall period. The reference group for the LS mean difference and Hedges' g is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with data; CI: Confidence interval; LS: Least squares; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; SD: Standard deviation; SE: Standard error; SMD: Standardized mean difference; UFS-QoL: Uterine Fibroid Symptom and Health-Related Quality of Life.

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Table EFF.UFSEMS.MITT.Pooled.S6: Summary of Change from Baseline in UFS-QoL Energy/Mood Scale Score by Visit and Overall, by Subgroup (mITT Population)

Study: Pooled

Treatment	Study visit	n (%)[1]	Mean (SD)[1]	Change from baseline LS-mean change (SE)[2]	Difference LS-mean change [95% CI] p-value[2]	SMD Hedges' g [95% CI][2]	Int. p-value[2]
Geographic Region I							
North America							
Relugolix+E2/NETA	Baseline	188 (98.4)	38.0 (26.81)	32.64 (1.919)	18.80	0.71	0.8839
N=191	Overall	169 (88.5)	70.9 (26.42)		[13.52,24.08]	[0.49,0.93]	
Placebo	Baseline	192 (99.0)	36.9 (25.01)	13.84 (1.881)	<.0001		
N=194	Overall	174 (89.7)	49.3 (25.28)				
Rest of World							
Relugolix+E2/NETA	Baseline	61 (98.4)	46.7 (21.86)	29.87 (3.200)	19.57	0.74	
N=62	Overall	59 (95.2)	76.5 (21.55)		[10.68,28.46]	[0.37,1.11]	
Placebo	Baseline	62 (100.0)	39.1 (22.98)	10.30 (3.198)	<.0001		
N=62	Overall	59 (95.2)	48.4 (21.04)				

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group. Transformed score ranges from 0 to 100 based on Likert scale (None of the time, a little of the time, some of the time, most of the time and all of the time). Higher scores are indicative of better health-related quality of life (high score = good). For the change from baseline, positive scores indicate improvement.
[1] Summary statistics are based on observed data. Mean (SD) are calculated based on the mean observed value across all post-baseline visits within each patient.
[2] LS means, LS mean differences (95% CIs), p-value and Hedges' g (95% CIs) are based on a mixed-effects model with study, treatment, visit, subgroup, treatment-by-visit interaction and a subgroup-by-treatment interaction as fixed effects. The multiple visits for each patient are the repeated measures as a random effect within each patient with an unstructured covariance. Hedges' g is calculated using a small sample bias correction. The reference group for the LS mean difference and Hedges' g is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with data; CI: Confidence interval; int: Interaction; LS: Least squares; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; SD: Standard deviation; SE: Standard error; SMD: Standardized mean difference; UFS-QoL: Uterine Fibroid Symptom and Health-Related Quality of Life.

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Table EFF.UFSEMS.MITT.Pooled.S3: Summary of Change from Baseline in UFS-QoL Energy/Mood Scale Score by Visit and Overall, by Subgroup (mITT Population)

Study: Pooled

Treatment	Study visit	n (%)[1]	Mean (SD)[1]	Change from baseline LS-mean change (SE)[2]	Difference LS-mean change [95% CI] p-value[2]	SMD Hedges' g [95% CI][2]
Uterine Volume at Baseline (cm3)						
< 300 cm3						
Relugolix+E2/NETA	Baseline	147 (99.3)	42.6 (26.18)	28.49 (2.284)	17.75	0.68
N=148	Week 12	132 (89.2)	71.9 (25.20)		[11.18,24.33]	[0.42,0.94]
Placebo	Baseline	129 (100.0)	37.8 (23.87)	10.74 (2.433)	<.0001	
N=129	Week 12	115 (89.1)	48.1 (24.25)			
>= 300 cm3						
Relugolix+E2/NETA	Baseline	101 (97.1)	36.7 (25.36)	30.19 (2.742)	16.58	0.64
N=104	Week 12	92 (88.5)	66.0 (30.19)		[9.32,23.83]	[0.35,0.92]
Placebo	Baseline	125 (98.4)	37.1 (25.23)	13.62 (2.453)	<.0001	
N=127	Week 12	114 (89.8)	49.5 (25.81)			
Missing						
Relugolix+E2/NETA	Baseline	1 (100.0)	35.7 (NE)	NC (NC)	NC	NC
N=1	Week 12	0	NE (NE)		[NC,NC]	[NC,NC]
Placebo	Baseline	0	NE (NE)	NC (NC)	NC	
N=0	Week 12	0	NE (NE)			

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group. Transformed score ranges from 0 to 100 based on Likert scale (None of the time, a little of the time, some of the time, most of the time and all of the time). Higher scores are indicative of better health-related quality of life (high score = good). For the change from baseline, positive scores indicate improvement.
[1] Summary statistics are based on observed data.
[2] LS means, LS mean differences (95% CIs), p-value and Hedges' g (95% CIs) are based on a mixed-effects model with study, treatment, visit, and a treatment-by-visit interaction as fixed effects. The multiple visits for each patient are the repeated measures as a random effect within each patient with an unstructured covariance. Hedges' g is calculated using a small sample bias correction. Interaction p-value is only produced for the Overall period. The reference group for the LS mean difference and Hedges' g is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with data; CI: Confidence interval; LS: Least squares; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; SD: Standard deviation; SE: Standard error; SMD: Standardized mean difference; UFS-QoL: Uterine Fibroid Symptom and Health-Related Quality of Life; NC: Not calculated; NE: Non-estimable.

SOURCE: \Studies\MYV\MYV102\Analysis\Prod\Progs\TFLs\Tab_QOL_UFS_CON.SAS
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Table EFF.UFSEMS.MITT.Pooled.S3: Summary of Change from Baseline in UFS-QoL Energy/Mood Scale Score by Visit and Overall, by Subgroup (mITT Population)

Study: Pooled

Treatment	Study visit	n (%)[1]	Mean (SD)[1]	Change from baseline LS-mean change (SE)[2]	Difference LS-mean change [95% CI] p-value[2]	SMD Hedges' g [95% CI][2]
Uterine Volume at Baseline (cm3)						
< 300 cm3						
Relugolix+E2/NETA	Baseline	147 (99.3)	42.6 (26.18)	34.47 (2.483)	20.38	0.73
N=148	Week 24	116 (78.4)	79.2 (25.51)		[13.25,27.52]	[0.46,1.01]
Placebo	Baseline	129 (100.0)	37.8 (23.87)	14.09 (2.638)	<.0001	
N=129	Week 24	102 (79.1)	51.6 (27.35)			
>= 300 cm3						
Relugolix+E2/NETA	Baseline	101 (97.1)	36.7 (25.36)	34.84 (2.739)	21.60	0.85
N=104	Week 24	80 (76.9)	74.9 (24.73)		[14.34,28.86]	[0.54,1.16]
Placebo	Baseline	125 (98.4)	37.1 (25.23)	13.23 (2.463)	<.0001	
N=127	Week 24	97 (76.4)	48.8 (27.20)			
Missing						
Relugolix+E2/NETA	Baseline	1 (100.0)	35.7 (NE)	NC (NC)	NC	NC
N=1	Week 24	0	NE (NE)		[NC,NC]	[NC,NC]
Placebo	Baseline	0	NE (NE)	NC (NC)	NC	
N=0	Week 24	0	NE (NE)			

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group. Transformed score ranges from 0 to 100 based on Likert scale (None of the time, a little of the time, some of the time, most of the time and all of the time). Higher scores are indicative of better health-related quality of life (high score = good). For the change from baseline, positive scores indicate improvement.
[1] Summary statistics are based on observed data.
[2] LS means, LS mean differences (95% CIs), p-value and Hedges' g (95% CIs) are based on a mixed-effects model with study, treatment, visit, and a treatment-by-visit interaction as fixed effects. The multiple visits for each patient are the repeated measures as a random effect within each patient with an unstructured covariance. Hedges' g is calculated using a small sample bias correction. Interaction p-value is only produced for the Overall period. The reference group for the LS mean difference and Hedges' g is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with data; CI: Confidence interval; LS: Least squares; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; SD: Standard deviation; SE: Standard error; SMD: Standardized mean difference; UFS-QoL: Uterine Fibroid Symptom and Health-Related Quality of Life; NC: Not calculated; NE: Non-estimable.

SOURCE: \Studies\MYV\MYV102\Analysis\Prod\Progs\TFLs\Tab_QOL_UFS_CON.SAS
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Table EFF.UFSEMS.MITT.Pooled.S3: Summary of Change from Baseline in UFS-QoL Energy/Mood Scale Score by Visit and Overall, by Subgroup (mITT Population)

Study: Pooled

Treatment	Study visit	n (%)[1]	Mean (SD)[1]	Change from baseline LS-mean change (SE)[2]	Difference LS-mean change [95% CI] p-value[2]	SMD Hedges' g [95% CI][2]	Int. p-value[2]
Uterine Volume at Baseline (cm3)							
< 300 cm3							
Relugolix+E2/NETA	Baseline	147 (99.3)	42.6 (26.18)	31.44 (2.137)	19.15	0.73	0.9739
N=148	Overall	134 (90.5)	74.9 (22.98)		[13.02,25.28]	[0.47,0.98]	
Placebo	Baseline	129 (100.0)	37.8 (23.87)	12.29 (2.270)	<.0001		
N=129	Overall	118 (91.5)	48.9 (23.62)				
>= 300 cm3							
Relugolix+E2/NETA	Baseline	101 (97.1)	36.7 (25.36)	32.59 (2.585)	19.00	0.72	
N=104	Overall	94 (90.4)	68.7 (28.07)		[12.17,25.82]	[0.44,1.00]	
Placebo	Baseline	125 (98.4)	37.1 (25.23)	13.59 (2.319)	<.0001		
N=127	Overall	115 (90.6)	49.3 (24.95)				
Missing							
Relugolix+E2/NETA	Baseline	1 (100.0)	35.7 (NE)	NC (NC)	NC	NC	
N=1	Overall	0	NE (NE)		[NC,NC]	[NC,NC]	
Placebo	Baseline	0	NE (NE)	NC (NC)	NC		
N=0	Overall	0	NE (NE)				

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group. Transformed score ranges from 0 to 100 based on Likert scale (None of the time, a little of the time, some of the time, most of the time and all of the time). Higher scores are indicative of better health-related quality of life (high score = good). For the change from baseline, positive scores indicate improvement.
[1] Summary statistics are based on observed data. Mean (SD) are calculated based on the mean observed value across all post-baseline visits within each patient.
[2] LS means, LS mean differences (95% CIs), p-value and Hedges' g (95% CIs) are based on a mixed-effects model with study, treatment, visit, subgroup, treatment-by-visit interaction and a subgroup-by-treatment interaction as fixed effects. The multiple visits for each patient are the repeated measures as a random effect within each patient with an unstructured covariance. Hedges' g is calculated using a small sample bias correction. Missing subgroup levels are not included in estimation of the interaction p-value. The reference group for the LS mean difference and Hedges' g is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with data; CI: Confidence interval; int: Interaction; LS: Least squares; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; SD: Standard deviation; SE: Standard error; SMD: Standardized mean difference; UFS-QoL: Uterine Fibroid Symptom and Health-Related Quality of Life; NC: Not calculated; NE: Non-estimable.

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1.2.11 Summary of Change from Baseline in UFS-QoL Control Scale Score by Visit and Overall, by Subgroup (mITT Population)

Table EFF.UFSCONTR.MITT.Pooled.S5: Summary of Change from Baseline in UFS-QoL Control Scale Score by Visit and Overall, by Subgroup (mITT Population)

Study: Pooled

Treatment	Study visit	n (%)[1]	Mean (SD)[1]	Change from baseline LS-mean change (SE)[2]	Difference LS-mean change [95% CI] p-value[2]	SMD Hedges' g [95% CI][2]
MBL Volume at Baseline (mL)						
< 225 mL						
Relugolix+E2/NETA	Baseline	163 (99.4)	51.7 (26.17)	23.34 (2.192)	11.92	0.45
N=164	Week 12	147 (89.6)	75.3 (26.53)		[5.89,17.96]	[0.22,0.68]
Placebo	Baseline	170 (99.4)	43.6 (26.45)	11.41 (2.143)	0.0001	
N=171	Week 12	153 (89.5)	55.0 (27.68)			
>= 225 mL						
Relugolix+E2/NETA	Baseline	86 (96.6)	42.2 (28.95)	34.07 (3.013)	22.81	0.89
N=89	Week 12	77 (86.5)	73.8 (25.78)		[14.38,31.25]	[0.55,1.22]
Placebo	Baseline	84 (98.8)	42.0 (26.07)	11.26 (3.018)	<.0001	
N=85	Week 12	76 (89.4)	52.0 (28.11)			

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group. Transformed score ranges from 0 to 100 based on Likert scale (None of the time, a little of the time, some of the time, most of the time and all of the time). Higher scores are indicative of better health-related quality of life (high score = good). For the change from baseline, positive scores indicate improvement.
[1] Summary statistics are based on observed data.
[2] LS means, LS mean differences (95% CIs), p-value and Hedges' g (95% CIs) are based on a mixed-effects model with study, treatment, visit, and a treatment-by-visit interaction as fixed effects. The multiple visits for each patient are the repeated measures as a random effect within each patient with an unstructured covariance. Hedges' g is calculated using a small sample bias correction. Interaction p-value is only produced for the Overall period. The reference group for the LS mean difference and Hedges' g is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with data; CI: Confidence interval; LS: Least squares; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; SD: Standard deviation; SE: Standard error; SMD: Standardized mean difference; UFS-QoL: Uterine Fibroid Symptom and Health-Related Quality of Life.

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Table EFF.UFSCONTR.MITT.Pooled.S5: Summary of Change from Baseline in UFS-QoL Control Scale Score by Visit and Overall, by Subgroup (mITT Population)

Study: Pooled

Treatment	Study visit	n (%)[1]	Mean (SD)[1]	Change from baseline LS-mean change (SE)[2]	Difference LS-mean change [95% CI] p-value[2]	SMD Hedges' g [95% CI][2]
MBL Volume at Baseline (mL)						
< 225 mL						
Relugolix+E2/NETA	Baseline	163 (99.4)	51.7 (26.17)	28.25 (2.360)	16.57	0.60
N=164	Week 24	126 (76.8)	82.1 (24.29)		[10.11,23.03]	[0.35,0.85]
Placebo	Baseline	170 (99.4)	43.6 (26.45)	11.68 (2.283)	<.0001	
N=171	Week 24	137 (80.1)	55.6 (27.58)			
>= 225 mL						
Relugolix+E2/NETA	Baseline	86 (96.6)	42.2 (28.95)	33.41 (3.293)	20.08	0.70
N=89	Week 24	70 (78.7)	76.4 (26.31)		[10.79,29.37]	[0.35,1.05]
Placebo	Baseline	84 (98.8)	42.0 (26.07)	13.34 (3.352)	<.0001	
N=85	Week 24	62 (72.9)	51.7 (32.20)			

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group. Transformed score ranges from 0 to 100 based on Likert scale (None of the time, a little of the time, some of the time, most of the time and all of the time). Higher scores are indicative of better health-related quality of life (high score = good). For the change from baseline, positive scores indicate improvement.
[1] Summary statistics are based on observed data.
[2] LS means, LS mean differences (95% CIs), p-value and Hedges' g (95% CIs) are based on a mixed-effects model with study, treatment, visit, and a treatment-by-visit interaction as fixed effects. The multiple visits for each patient are the repeated measures as a random effect within each patient with an unstructured covariance. Hedges' g is calculated using a small sample bias correction. Interaction p-value is only produced for the Overall period. The reference group for the LS mean difference and Hedges' g is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with data; CI: Confidence interval; LS: Least squares; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; SD: Standard deviation; SE: Standard error; SMD: Standardized mean difference; UFS-QoL: Uterine Fibroid Symptom and Health-Related Quality of Life.

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Table EFF.UFSCONTR.MITT.Pooled.S5: Summary of Change from Baseline in UFS-QoL Control Scale Score by Visit and Overall, by Subgroup (mITT Population)

Study: Pooled

Treatment	Study visit	n (%)[1]	Mean (SD)[1]	Change from baseline LS-mean change (SE)[2]	Difference LS-mean change [95% CI] p-value[2]	SMD Hedges' g [95% CI][2]	Int. p-value[2]
MBL Volume at Baseline (mL)							
< 225 mL							
Relugolix+E2/NETA	Baseline	163 (99.4)	51.7 (26.17)	25.51 (2.080)	13.96	0.52	0.1136
N=164	Overall	148 (90.2)	77.4 (24.23)		[8.26,19.67]	[0.29,0.75]	
Placebo	Baseline	170 (99.4)	43.6 (26.45)	11.54 (2.024)	<.0001		
N=171	Overall	156 (91.2)	54.6 (25.83)				
>= 225 mL							
Relugolix+E2/NETA	Baseline	86 (96.6)	42.2 (28.95)	34.07 (2.874)	21.88	0.81	
N=89	Overall	80 (89.9)	75.1 (24.00)		[13.86,29.90]	[0.48,1.14]	
Placebo	Baseline	84 (98.8)	42.0 (26.07)	12.19 (2.897)	<.0001		
N=85	Overall	77 (90.6)	52.5 (28.47)				

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group. Transformed score ranges from 0 to 100 based on Likert scale (None of the time, a little of the time, some of the time, most of the time and all of the time). Higher scores are indicative of better health-related quality of life (high score = good). For the change from baseline, positive scores indicate improvement.
[1] Summary statistics are based on observed data. Mean (SD) are calculated based on the mean observed value across all post-baseline visits within each patient.
[2] LS means, LS mean differences (95% CIs), p-value and Hedges' g (95% CIs) are based on a mixed-effects model with study, treatment, visit, subgroup, treatment-by-visit interaction and a subgroup-by-treatment interaction as fixed effects. The multiple visits for each patient are the repeated measures as a random effect within each patient with an unstructured covariance. Hedges' g is calculated using a small sample bias correction. The reference group for the LS mean difference and Hedges' g is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with data; CI: Confidence interval; int: Interaction; LS: Least squares; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; SD: Standard deviation; SE: Standard error; SMD: Standardized mean difference; UFS-QoL: Uterine Fibroid Symptom and Health-Related Quality of Life.

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Table EFF.UFSCONTR.MITT.Pooled.S2: Summary of Change from Baseline in UFS-QoL Control Scale Score by Visit and Overall, by Subgroup (mITT Population)

Study: Pooled

Treatment	Study visit	n (%)[1]	Mean (SD)[1]	Change from baseline LS-mean change (SE)[2]	Difference LS-mean change [95% CI] p-value[2]	SMD Hedges' g [95% CI][2]
BMI (kg/m2) at Baseline						
< 30						
Relugolix+E2/NETA	Baseline	118 (99.2)	47.8 (26.81)	28.00 (2.450)	19.71	0.79
N=119	Week 12	104 (87.4)	76.5 (25.71)		[12.84,26.59]	[0.51,1.08]
Placebo	Baseline	115 (100.0)	43.2 (25.11)	8.29 (2.481)	<.0001	
N=115	Week 12	100 (87.0)	50.9 (28.86)			
>= 30						
Relugolix+E2/NETA	Baseline	130 (97.7)	49.2 (28.22)	25.63 (2.569)	11.69	0.42
N=133	Week 12	119 (89.5)	73.1 (26.71)		[4.68,18.70]	[0.17,0.67]
Placebo	Baseline	139 (98.6)	43.0 (27.30)	13.94 (2.464)	0.0012	
N=141	Week 12	129 (91.5)	56.5 (26.81)			
Missing						
Relugolix+E2/NETA	Baseline	1 (100.0)	30.0 (NE)	NC (NC)	NC	NC
N=1	Week 12	1 (100.0)	95.0 (NE)		[NC,NC]	[NC,NC]
Placebo	Baseline	0	NE (NE)	NC (NC)	NC	
N=0	Week 12	0	NE (NE)			

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group. Transformed score ranges from 0 to 100 based on Likert scale (None of the time, a little of the time, some of the time, most of the time and all of the time). Higher scores are indicative of better health-related quality of life (high score = good). For the change from baseline, positive scores indicate improvement.
[1] Summary statistics are based on observed data.
[2] LS means, LS mean differences (95% CIs), p-value and Hedges' g (95% CIs) are based on a mixed-effects model with study, treatment, visit, and a treatment-by-visit interaction as fixed effects. The multiple visits for each patient are the repeated measures as a random effect within each patient with an unstructured covariance. Hedges' g is calculated using a small sample bias correction. Interaction p-value is only produced for the Overall period. The reference group for the LS mean difference and Hedges' g is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with data; CI: Confidence interval; LS: Least squares; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; SD: Standard deviation; SE: Standard error; SMD: Standardized mean difference; UFS-QoL: Uterine Fibroid Symptom and Health-Related Quality of Life; NC: Not calculated; NE: Non-estimable.

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Table EFF.UFSCONTR.MITT.Pooled.S2: Summary of Change from Baseline in UFS-QoL Control Scale Score by Visit and Overall, by Subgroup (mITT Population)

Study: Pooled

Treatment	Study visit	n (%)[1]	Mean (SD)[1]	Change from baseline LS-mean change (SE)[2]	Difference LS-mean change [95% CI] p-value[2]	SMD Hedges' g [95% CI][2]
BMI (kg/m2) at Baseline						
< 30						
Relugolix+E2/NETA	Baseline	118 (99.2)	47.8 (26.81)	30.82 (2.728)	20.40	0.76
N=119	Week 24	89 (74.8)	80.6 (25.99)		[12.74,28.06]	[0.45,1.06]
Placebo	Baseline	115 (100.0)	43.2 (25.11)	10.42 (2.767)	<.0001	
N=115	Week 24	86 (74.8)	52.7 (29.19)			
>= 30						
Relugolix+E2/NETA	Baseline	130 (97.7)	49.2 (28.22)	28.98 (2.710)	15.36	0.54
N=133	Week 24	106 (79.7)	79.6 (24.57)		[7.96,22.76]	[0.26,0.81]
Placebo	Baseline	139 (98.6)	43.0 (27.30)	13.62 (2.603)	<.0001	
N=141	Week 24	113 (80.1)	55.7 (29.04)			
Missing						
Relugolix+E2/NETA	Baseline	1 (100.0)	30.0 (NE)	NC (NC)	NC	NC
N=1	Week 24	1 (100.0)	90.0 (NE)		[NC,NC]	[NC,NC]
Placebo	Baseline	0	NE (NE)	NC (NC)	NC	
N=0	Week 24	0	NE (NE)			

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group. Transformed score ranges from 0 to 100 based on Likert scale (None of the time, a little of the time, some of the time, most of the time and all of the time). Higher scores are indicative of better health-related quality of life (high score = good). For the change from baseline, positive scores indicate improvement.
[1] Summary statistics are based on observed data.
[2] LS means, LS mean differences (95% CIs), p-value and Hedges' g (95% CIs) are based on a mixed-effects model with study, treatment, visit, and a treatment-by-visit interaction as fixed effects. The multiple visits for each patient are the repeated measures as a random effect within each patient with an unstructured covariance. Hedges' g is calculated using a small sample bias correction. Interaction p-value is only produced for the Overall period. The reference group for the LS mean difference and Hedges' g is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with data; CI: Confidence interval; LS: Least squares; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; SD: Standard deviation; SE: Standard error; SMD: Standardized mean difference; UFS-QoL: Uterine Fibroid Symptom and Health-Related Quality of Life; NC: Not calculated; NE: Non-estimable.

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Table EFF.UFSCONTR.MITT.Pooled.S2: Summary of Change from Baseline in UFS-QoL Control Scale Score by Visit and Overall, by Subgroup (mITT Population)

Study: Pooled

Treatment	Study visit	n (%)[1]	Mean (SD)[1]	Change from baseline LS-mean change (SE)[2]	Difference LS-mean change [95% CI] p-value[2]	SMD Hedges' g [95% CI][2]	Int. p-value[2]
BMI (kg/m2) at Baseline							
< 30							
Relugolix+E2/NETA	Baseline	118 (99.2)	47.8 (26.81)	29.44 (2.468)	20.29	0.75	0.1502
N=119	Overall	106 (89.1)	77.9 (24.59)		[13.39,27.19]	[0.47,1.03]	
Placebo	Baseline	115 (100.0)	43.2 (25.11)	9.15 (2.496)	<.0001		
N=115	Overall	103 (89.6)	51.5 (27.32)				
>= 30							
Relugolix+E2/NETA	Baseline	130 (97.7)	49.2 (28.22)	27.28 (2.324)	13.44	0.50	
N=133	Overall	121 (91.0)	75.3 (23.78)		[7.11,19.77]	[0.24,0.75]	
Placebo	Baseline	139 (98.6)	43.0 (27.30)	13.84 (2.232)	<.0001		
N=141	Overall	130 (92.2)	55.8 (26.12)				
Missing							
Relugolix+E2/NETA	Baseline	1 (100.0)	30.0 (NE)	NC (NC)	NC	NC	
N=1	Overall	1 (100.0)	92.5 (NE)		[NC,NC]	[NC,NC]	
Placebo	Baseline	0	NE (NE)	NC (NC)	NC		
N=0	Overall	0	NE (NE)				

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group. Transformed score ranges from 0 to 100 based on Likert scale (None of the time, a little of the time, some of the time, most of the time and all of the time). Higher scores are indicative of better health-related quality of life (high score = good). For the change from baseline, positive scores indicate improvement.
[1] Summary statistics are based on observed data. Mean (SD) are calculated based on the mean observed value across all post-baseline visits within each patient.
[2] LS means, LS mean differences (95% CIs), p-value and Hedges' g (95% CIs) are based on a mixed-effects model with study, treatment, visit, subgroup, treatment-by-visit interaction and a subgroup-by-treatment interaction as fixed effects. The multiple visits for each patient are the repeated measures as a random effect within each patient with an unstructured covariance. Hedges' g is calculated using a small sample bias correction. Missing subgroup levels are not included in estimation of the interaction p-value. The reference group for the LS mean difference and Hedges' g is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with data; CI: Confidence interval; int: Interaction; LS: Least squares; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; SD: Standard deviation; SE: Standard error; SMD: Standardized mean difference; UFS-QoL: Uterine Fibroid Symptom and Health-Related Quality of Life; NC: Not calculated; NE: Non-estimable.

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Table EFF.UFSCONTR.MITT.Pooled.S8: Summary of Change from Baseline in UFS-QoL Control Scale Score by Visit and Overall, by Subgroup (mITT Population)

Study: Pooled

Treatment	Study visit	n (%)[1]	Mean (SD)[1]	Change from baseline LS-mean change (SE)[2]	Difference LS-mean change [95% CI] p-value[2]	SMD Hedges' g [95% CI][2]
Ethnicity						
Hispanic or Latino						
Relugolix+E2/NETA	Baseline	52 (100.0)	48.7 (25.07)	27.80 (4.130)	12.32	0.44
N=52	Week 12	47 (90.4)	75.6 (25.99)		[0.82,23.82]	[0.04,0.84]
Placebo	Baseline	55 (100.0)	31.0 (23.10)	15.48 (3.987)	0.0360	
N=55	Week 12	49 (89.1)	46.6 (29.45)			
Not Hispanic or Latino						
Relugolix+E2/NETA	Baseline	193 (98.0)	48.0 (28.01)	27.05 (2.012)	16.90	0.65
N=197	Week 12	174 (88.3)	74.2 (26.41)		[11.34,22.45]	[0.43,0.86]
Placebo	Baseline	197 (99.0)	46.4 (25.96)	10.15 (1.976)	<.0001	
N=199	Week 12	178 (89.4)	56.0 (27.20)			
Not reported						
Relugolix+E2/NETA	Baseline	4 (100.0)	68.8 (31.46)	NC (NC)	NC	NC
N=4	Week 12	3 (75.0)	96.7 (5.77)		[NC,NC]	[NC,NC]
Placebo	Baseline	2 (100.0)	47.5 (60.10)	NC (NC)	NC	
N=2	Week 12	2 (100.0)	60.0 (14.14)			

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group. Transformed score ranges from 0 to 100 based on Likert scale (None of the time, a little of the time, some of the time, most of the time and all of the time). Higher scores are indicative of better health-related quality of life (high score = good). For the change from baseline, positive scores indicate improvement.
[1] Summary statistics are based on observed data.
[2] LS means, LS mean differences (95% CIs), p-value and Hedges' g (95% CIs) are based on a mixed-effects model with study, treatment, visit, and a treatment-by-visit interaction as fixed effects. The multiple visits for each patient are the repeated measures as a random effect within each patient with an unstructured covariance. Hedges' g is calculated using a small sample bias correction. Interaction p-value is only produced for the Overall period. The reference group for the LS mean difference and Hedges' g is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with data; CI: Confidence interval; LS: Least squares; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; SD: Standard deviation; SE: Standard error; SMD: Standardized mean difference; UFS-QoL: Uterine Fibroid Symptom and Health-Related Quality of Life; NC: Not calculated.

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Table EFF.UFSCONTR.MITT.Pooled.S8: Summary of Change from Baseline in UFS-QoL Control Scale Score by Visit and Overall, by Subgroup (mITT Population)

Study: Pooled

Treatment	Study visit	n (%)[1]	Mean (SD)[1]	Change from baseline LS-mean change (SE)[2]	Difference LS-mean change [95% CI] p-value[2]	SMD Hedges' g [95% CI][2]
Ethnicity						
Hispanic or Latino						
Relugolix+E2/NETA	Baseline	52 (100.0)	48.7 (25.07)	30.99 (4.461)	14.87	0.50
N=52	Week 24	44 (84.6)	80.8 (24.49)		[2.45,27.28]	[0.08,0.91]
Placebo	Baseline	55 (100.0)	31.0 (23.10)	16.12 (4.307)	0.0195	
N=55	Week 24	46 (83.6)	45.3 (31.56)			
Not Hispanic or Latino						
Relugolix+E2/NETA	Baseline	193 (98.0)	48.0 (28.01)	30.23 (2.153)	19.15	0.70
N=197	Week 24	149 (75.6)	79.7 (25.50)		[13.19,25.10]	[0.46,0.93]
Placebo	Baseline	197 (99.0)	46.4 (25.96)	11.08 (2.120)	<.0001	
N=199	Week 24	151 (75.9)	57.3 (27.51)			
Not reported						
Relugolix+E2/NETA	Baseline	4 (100.0)	68.8 (31.46)	NC (NC)	NC	NC
N=4	Week 24	3 (75.0)	90.0 (17.32)		[NC,NC]	[NC,NC]
Placebo	Baseline	2 (100.0)	47.5 (60.10)	NC (NC)	NC	
N=2	Week 24	2 (100.0)	42.5 (60.10)			

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group. Transformed score ranges from 0 to 100 based on Likert scale (None of the time, a little of the time, some of the time, most of the time and all of the time). Higher scores are indicative of better health-related quality of life (high score = good). For the change from baseline, positive scores indicate improvement.
[1] Summary statistics are based on observed data.
[2] LS means, LS mean differences (95% CIs), p-value and Hedges' g (95% CIs) are based on a mixed-effects model with study, treatment, visit, and a treatment-by-visit interaction as fixed effects. The multiple visits for each patient are the repeated measures as a random effect within each patient with an unstructured covariance. Hedges' g is calculated using a small sample bias correction. Interaction p-value is only produced for the Overall period. The reference group for the LS mean difference and Hedges' g is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with data; CI: Confidence interval; LS: Least squares; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; SD: Standard deviation; SE: Standard error; SMD: Standardized mean difference; UFS-QoL: Uterine Fibroid Symptom and Health-Related Quality of Life; NC: Not calculated.

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Table EFF.UFSCONTR.MITT.Pooled.S8: Summary of Change from Baseline in UFS-QoL Control Scale Score by Visit and Overall, by Subgroup (mITT Population)

Study: Pooled

Treatment	Study visit	n (%)[1]	Mean (SD)[1]	Change from baseline LS-mean change (SE)[2]	Difference LS-mean change [95% CI] p-value[2]	SMD Hedges' g [95% CI][2]	Int. p-value[2]
Ethnicity							
Hispanic or Latino							
Relugolix+E2/NETA	Baseline	52 (100.0)	48.7 (25.07)	29.04 (3.635)	13.05	0.48	0.3960
N=52	Overall	49 (94.2)	77.8 (22.79)		[3.05,23.06]	[0.08,0.87]	
Placebo	Baseline	55 (100.0)	31.0 (23.10)	15.99 (3.547)	0.0107		
N=55	Overall	51 (92.7)	46.0 (28.97)				
Not Hispanic or Latino							
Relugolix+E2/NETA	Baseline	193 (98.0)	48.0 (28.01)	28.62 (1.941)	17.97	0.66	
N=197	Overall	176 (89.3)	76.0 (24.61)		[12.61,23.32]	[0.45,0.88]	
Placebo	Baseline	197 (99.0)	46.4 (25.96)	10.65 (1.908)	<.0001		
N=199	Overall	180 (90.5)	56.2 (25.65)				
Not reported							
Relugolix+E2/NETA	Baseline	4 (100.0)	68.8 (31.46)	NC (NC)	NC	NC	
N=4	Overall	3 (75.0)	93.3 (7.64)		[NC,NC]	[NC,NC]	
Placebo	Baseline	2 (100.0)	47.5 (60.10)	NC (NC)	NC		
N=2	Overall	2 (100.0)	51.3 (37.12)				

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group. Transformed score ranges from 0 to 100 based on Likert scale (None of the time, a little of the time, some of the time, most of the time and all of the time). Higher scores are indicative of better health-related quality of life (high score = good). For the change from baseline, positive scores indicate improvement.
[1] Summary statistics are based on observed data. Mean (SD) are calculated based on the mean observed value across all post-baseline visits within each patient.
[2] LS means, LS mean differences (95% CIs), p-value and Hedges' g (95% CIs) are based on a mixed-effects model with study, treatment, visit, subgroup, treatment-by-visit interaction and a subgroup-by-treatment interaction as fixed effects. The multiple visits for each patient are the repeated measures as a random effect within each patient with an unstructured covariance. Hedges' g is calculated using a small sample bias correction. Not reported subgroup levels are not included in estimation of the interaction p-value. The reference group for the LS mean difference and Hedges' g is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with data; CI: Confidence interval; int: Interaction; LS: Least squares; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; SD: Standard deviation; SE: Standard error; SMD: Standardized mean difference; UFS-QoL: Uterine Fibroid Symptom and Health-Related Quality of Life; NC: Not calculated.

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Table EFF.UFSCONTR.MITT.Pooled.S9: Summary of Change from Baseline in UFS-QoL Control Scale Score by Visit and Overall, by Subgroup (mITT Population)						
Study: Pooled						
Treatment	**Study visit**	**n (%)[1]**	**Mean (SD)[1]**	**Change from baseline LS-mean change (SE)[2]**	**Difference LS-mean change [95% CI] p-value[2]**	**SMD Hedges' g [95% CI][2]**
Race						
Black/African American						
Relugolix+E2/NETA	Baseline	119 (97.5)	44.3 (28.50)	30.12 (2.547)	18.87	0.73
N=122	Week 12	105 (86.1)	72.7 (26.74)		[12.06,25.68]	[0.46,1.01]
Placebo	Baseline	139 (98.6)	44.5 (26.74)	11.25 (2.337)	<.0001	
N=141	Week 12	122 (86.5)	55.5 (27.86)			
White						
Relugolix+E2/NETA	Baseline	121 (99.2)	52.1 (26.31)	24.33 (2.625)	13.08	0.48
N=122	Week 12	110 (90.2)	76.8 (25.96)		[5.55,20.62]	[0.20,0.75]
Placebo	Baseline	105 (100.0)	42.5 (25.37)	11.24 (2.785)	0.0007	
N=105	Week 12	98 (93.3)	53.1 (27.47)			
Asian						
Relugolix+E2/NETA	Baseline	1 (100.0)	70.0 (NE)	NC (NC)	NC	NC
N=1	Week 12	1 (100.0)	95.0 (NE)		[NC,NC]	[NC,NC]
Placebo	Baseline	3 (100.0)	33.3 (32.15)	NC (NC)	NC	
N=3	Week 12	3 (100.0)	41.7 (24.66)			
Others						
Relugolix+E2/NETA	Baseline	5 (100.0)	39.0 (10.25)	29.93 (15.670)	7.91	0.23
N=5	Week 12	5 (100.0)	63.0 (23.61)		[-44.28,60.10]	[-0.89,1.35]
Placebo	Baseline	6 (100.0)	18.3 (10.80)	22.02 (15.156)	0.7305	
N=6	Week 12	5 (83.3)	41.0 (38.63)			
Not reported						
Relugolix+E2/NETA	Baseline	3 (100.0)	75.0 (25.00)	NC (NC)	NC	NC
N=3	Week 12	3 (100.0)	88.3 (20.21)		[NC,NC]	[NC,NC]
Placebo	Baseline	1 (100.0)	90.0 (NE)	NC (NC)	NC	

N=1	Week 12	1 (100.0)	70.0 (NE)			

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group. Transformed score ranges from 0 to 100 based on Likert scale (None of the time, a little of the time, some of the time, most of the time and all of the time). Higher scores are indicative of better health-related quality of life (high score = good). For the change from baseline, positive scores indicate improvement.
[1] Summary statistics are based on observed data.
[2] LS means, LS mean differences (95% CIs), p-value and Hedges' g (95% CIs) are based on a mixed-effects model with study, treatment, visit, and a treatment-by-visit interaction as fixed effects. The multiple visits for each patient are the repeated measures as a random effect within each patient with an unstructured covariance. Hedges' g is calculated using a small sample bias correction. Interaction p-value is only produced for the Overall period. The reference group for the LS mean difference and Hedges' g is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with data; CI: Confidence interval; LS: Least squares; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; SD: Standard deviation; SE: Standard error; SMD: Standardized mean difference; UFS-QoL: Uterine Fibroid Symptom and Health-Related Quality of Life; NC: Not calculated; NE: Non-estimable.

Table EFF.UFSCONTR.MITT.Pooled.S9: Summary of Change from Baseline in UFS-QoL Control Scale Score by Visit and Overall, by Subgroup (mITT Population)

Study: Pooled

Treatment	Study visit	n (%)[1]	Mean (SD)[1]	Change from baseline LS-mean change (SE)[2]	Difference LS-mean change [95% CI] p-value[2]	SMD Hedges' g [95% CI][2]
Race						
Black/African American						
Relugolix+E2/NETA	Baseline	119 (97.5)	44.3 (28.50)	31.06 (2.956)	19.70	0.68
N=122	Week 24	87 (71.3)	76.2 (27.12)		[11.85,27.54]	[0.39,0.97]
Placebo	Baseline	139 (98.6)	44.5 (26.74)	11.36 (2.669)	<.0001	
N=141	Week 24	108 (76.6)	55.4 (29.98)			
White						
Relugolix+E2/NETA	Baseline	121 (99.2)	52.1 (26.31)	30.16 (2.635)	16.39	0.60
N=122	Week 24	100 (82.0)	84.6 (22.00)		[8.75,24.02]	[0.31,0.90]
Placebo	Baseline	105 (100.0)	42.5 (25.37)	13.78 (2.842)	<.0001	
N=105	Week 24	84 (80.0)	55.1 (27.29)			
Asian						
Relugolix+E2/NETA	Baseline	1 (100.0)	70.0 (NE)	NC (NC)	NC	NC
N=1	Week 24	1 (100.0)	100.0 (NE)		[NC,NC]	[NC,NC]
Placebo	Baseline	3 (100.0)	33.3 (32.15)	NC (NC)	NC	
N=3	Week 24	2 (66.7)	45.0 (21.21)			
Others						
Relugolix+E2/NETA	Baseline	5 (100.0)	39.0 (10.25)	19.93 (9.316)	23.32	1.31
N=5	Week 24	5 (100.0)	53.0 (31.34)		[-9.71,56.36]	[-0.00,2.63]
Placebo	Baseline	6 (100.0)	18.3 (10.80)	-3.39 (9.243)	0.1390	
N=6	Week 24	4 (66.7)	11.3 (7.50)			
Not reported						
Relugolix+E2/NETA	Baseline	3 (100.0)	75.0 (25.00)	NC (NC)	NC	NC
N=3	Week 24	3 (100.0)	81.7 (16.07)		[NC,NC]	[NC,NC]
Placebo	Baseline	1 (100.0)	90.0 (NE)	NC (NC)	NC	

N=1	Week 24	1 (100.0)	85.0 (NE)			

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group. Transformed score ranges from 0 to 100 based on Likert scale (None of the time, a little of the time, some of the time, most of the time and all of the time). Higher scores are indicative of better health-related quality of life (high score = good). For the change from baseline, positive scores indicate improvement.
[1] Summary statistics are based on observed data.
[2] LS means, LS mean differences (95% CIs), p-value and Hedges' g (95% CIs) are based on a mixed-effects model with study, treatment, visit, and a treatment-by-visit interaction as fixed effects. The multiple visits for each patient are the repeated measures as a random effect within each patient with an unstructured covariance. Hedges' g is calculated using a small sample bias correction. Interaction p-value is only produced for the Overall period. The reference group for the LS mean difference and Hedges' g is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with data; CI: Confidence interval; LS: Least squares; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; SD: Standard deviation; SE: Standard error; SMD: Standardized mean difference; UFS-QoL: Uterine Fibroid Symptom and Health-Related Quality of Life; NC: Not calculated; NE: Non-estimable.

Table EFF.UFSCONTR.MITT.Pooled.S9: Summary of Change from Baseline in UFS-QoL Control Scale Score by Visit and Overall, by Subgroup (mITT Population)

Study: Pooled

Treatment	Study visit	n (%)[1]	Mean (SD)[1]	Change from baseline LS-mean change (SE)[2]	Difference LS-mean change [95% CI] p-value[2]	SMD Hedges' g [95% CI][2]	Int. p-value[2]
Race							
Black/African American							
Relugolix+E2/NETA	Baseline	119 (97.5)	44.3 (28.50)	30.99 (2.508)	19.60	0.72	0.4145
N=122	Overall	107 (87.7)	73.5 (25.72)		[12.93,26.28]	[0.45,0.99]	
Placebo	Baseline	139 (98.6)	44.5 (26.74)	11.39 (2.291)	<.0001		
N=141	Overall	126 (89.4)	54.8 (27.57)				
White							
Relugolix+E2/NETA	Baseline	121 (99.2)	52.1 (26.31)	27.01 (2.413)	14.64	0.54	
N=122	Overall	112 (91.8)	79.9 (22.04)		[7.71,21.57]	[0.26,0.81]	
Placebo	Baseline	105 (100.0)	42.5 (25.37)	12.37 (2.574)	<.0001		
N=105	Overall	98 (93.3)	54.0 (25.21)				
Asian							
Relugolix+E2/NETA	Baseline	1 (100.0)	70.0 (NE)	NC (NC)	NC	NC	
N=1	Overall	1 (100.0)	97.5 (NE)		[NC,NC]	[NC,NC]	
Placebo	Baseline	3 (100.0)	33.3 (32.15)	NC (NC)	NC		
N=3	Overall	3 (100.0)	40.0 (21.79)				
Others							
Relugolix+E2/NETA	Baseline	5 (100.0)	39.0 (10.25)	20.02 (11.281)	3.34	0.11	
N=5	Overall	5 (100.0)	58.0 (27.12)		[-28.19,34.88]	[-1.01,1.23]	
Placebo	Baseline	6 (100.0)	18.3 (10.80)	16.67 (11.394)	0.8350		
N=6	Overall	5 (83.3)	33.5 (32.96)				
Not reported							
Relugolix+E2/NETA	Baseline	3 (100.0)	75.0 (25.00)	NC (NC)	NC	NC	
N=3	Overall	3 (100.0)	85.0 (15.00)		[NC,NC]	[NC,NC]	
Placebo	Baseline	1 (100.0)	90.0 (NE)	NC (NC)	NC		

N=1	Overall	1 (100.0)	77.5 (NE)				

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group. Transformed score ranges from 0 to 100 based on Likert scale (None of the time, a little of the time, some of the time, most of the time and all of the time). Higher scores are indicative of better health-related quality of life (high score = good). For the change from baseline, positive scores indicate improvement.
[1] Summary statistics are based on observed data. Mean (SD) are calculated based on the mean observed value across all post-baseline visits within each patient.
[2] LS means, LS mean differences (95% CIs), p-value and Hedges' g (95% CIs) are based on a mixed-effects model with study, treatment, visit, subgroup, treatment-by-visit interaction and a subgroup-by-treatment interaction as fixed effects. The multiple visits for each patient are the repeated measures as a random effect within each patient with an unstructured covariance. Hedges' g is calculated using a small sample bias correction. Not reported subgroup levels are not included in estimation of the interaction p-value. Subgroup levels with fewer than 10 subjects are not included in estimation of the interaction p-value. The reference group for the LS mean difference and Hedges' g is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with data; CI: Confidence interval; int: Interaction; LS: Least squares; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; SD: Standard deviation; SE: Standard error; SMD: Standardized mean difference; UFS-QoL: Uterine Fibroid Symptom and Health-Related Quality of Life; NC: Not calculated; NE: Non-estimable.

SOURCE: \Studies\MYV\MYV102\Analysis\Prod\Progs\TFLs\Tab_QOL_UFS_CON.SAS
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Table EFF.UFSCONTR.MITT.Pooled.S4: Summary of Change from Baseline in UFS-QoL Control Scale Score by Visit and Overall, by Subgroup (mITT Population)

Study: Pooled

Treatment	Study visit	n (%)[1]	Mean (SD)[1]	Change from baseline LS-mean change (SE)[2]	Difference LS-mean change [95% CI] p-value[2]	SMD Hedges' g [95% CI][2]
Maximum NRS Pain Score at Baseline						
< 4						
Relugolix+E2/NETA	Baseline	72 (98.6)	56.0 (27.19)	23.82 (2.990)	14.56	0.61
N=73	Week 12	65 (89.0)	79.8 (22.33)		[5.73,23.40]	[0.24,0.98]
Placebo	Baseline	61 (98.4)	53.0 (26.81)	9.26 (3.326)	0.0014	
N=62	Week 12	52 (83.9)	59.0 (27.35)			
>= 4						
Relugolix+E2/NETA	Baseline	174 (98.3)	45.0 (27.03)	28.61 (2.220)	16.76	0.61
N=177	Week 12	156 (88.1)	72.7 (27.69)		[10.76,22.76]	[0.39,0.83]
Placebo	Baseline	189 (99.5)	40.2 (25.40)	11.85 (2.091)	<.0001	
N=190	Week 12	174 (91.6)	52.4 (27.91)			
Missing						
Relugolix+E2/NETA	Baseline	3 (100.0)	66.7 (25.66)	NC (NC)	NC	NC
N=3	Week 12	3 (100.0)	73.3 (11.55)		[NC,NC]	[NC,NC]
Placebo	Baseline	4 (100.0)	27.5 (25.00)	NC (NC)	NC	
N=4	Week 12	3 (75.0)	58.3 (27.54)			

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group. Transformed score ranges from 0 to 100 based on Likert scale (None of the time, a little of the time, some of the time, most of the time and all of the time). Higher scores are indicative of better health-related quality of life (high score = good). For the change from baseline, positive scores indicate improvement.
[1] Summary statistics are based on observed data.
[2] LS means, LS mean differences (95% CIs), p-value and Hedges' g (95% CIs) are based on a mixed-effects model with study, treatment, visit, and a treatment-by-visit interaction as fixed effects. The multiple visits for each patient are the repeated measures as a random effect within each patient with an unstructured covariance. Hedges' g is calculated using a small sample bias correction. Interaction p-value is only produced for the Overall period. The reference group for the LS mean difference and Hedges' g is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with data; CI: Confidence interval; LS: Least squares; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; SD: Standard deviation; SE: Standard error; SMD: Standardized mean difference; UFS-QoL: Uterine Fibroid Symptom and Health-Related Quality of Life; NC: Not calculated.

SOURCE: \Studies\MYV\MYV102\Analysis\Prod\Progs\TFLs\Tab_QOL_UFS_CON.SAS
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Analysis Plan: 13JAN2021

Table EFF.UFSCONTR.MITT.Pooled.S4: Summary of Change from Baseline in UFS-QoL Control Scale Score by Visit and Overall, by Subgroup (mITT Population)

Study: Pooled

Treatment	Study visit	n (%)[1]	Mean (SD)[1]	Change from baseline LS-mean change (SE)[2]	Difference LS-mean change [95% CI] p-value[2]	SMD Hedges' g [95% CI][2]
Maximum NRS Pain Score at Baseline						
< 4						
Relugolix+E2/NETA	Baseline	72 (98.6)	56.0 (27.19)	23.88 (3.288)	14.94	0.58
N=73	Week 24	57 (78.1)	81.5 (24.66)		[5.19,24.69]	[0.18,0.97]
Placebo	Baseline	61 (98.4)	53.0 (26.81)	8.94 (3.670)	0.0030	
N=62	Week 24	46 (74.2)	61.3 (28.84)			
>= 4						
Relugolix+E2/NETA	Baseline	174 (98.3)	45.0 (27.03)	32.96 (2.364)	19.87	0.70
N=177	Week 24	136 (76.8)	79.6 (25.52)		[13.48,26.25]	[0.46,0.93]
Placebo	Baseline	189 (99.5)	40.2 (25.40)	13.10 (2.224)	<.0001	
N=190	Week 24	151 (79.5)	52.6 (29.01)			
Missing						
Relugolix+E2/NETA	Baseline	3 (100.0)	66.7 (25.66)	NC (NC)	NC	NC
N=3	Week 24	3 (100.0)	76.7 (20.21)		[NC,NC]	[NC,NC]
Placebo	Baseline	4 (100.0)	27.5 (25.00)	NC (NC)	NC	
N=4	Week 24	2 (50.0)	32.5 (3.54)			

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group. Transformed score ranges from 0 to 100 based on Likert scale (None of the time, a little of the time, some of the time, most of the time and all of the time). Higher scores are indicative of better health-related quality of life (high score = good). For the change from baseline, positive scores indicate improvement.
[1] Summary statistics are based on observed data.
[2] LS means, LS mean differences (95% CIs), p-value and Hedges' g (95% CIs) are based on a mixed-effects model with study, treatment, visit, and a treatment-by-visit interaction as fixed effects. The multiple visits for each patient are the repeated measures as a random effect within each patient with an unstructured covariance. Hedges' g is calculated using a small sample bias correction. Interaction p-value is only produced for the Overall period. The reference group for the LS mean difference and Hedges' g is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with data; CI: Confidence interval; LS: Least squares; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; SD: Standard deviation; SE: Standard error; SMD: Standardized mean difference; UFS-QoL: Uterine Fibroid Symptom and Health-Related Quality of Life; NC: Not calculated.

SOURCE: \Studies\MYV\MYV102\Analysis\Prod\Progs\TFLs\Tab_QOL_UFS_CON.SAS
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Table EFF.UFSCONTR.MITT.Pooled.S4: Summary of Change from Baseline in UFS-QoL Control Scale Score by Visit and Overall, by Subgroup (mITT Population)

Study: Pooled

Treatment	Study visit	n (%)[1]	Mean (SD)[1]	Change from baseline LS-mean change (SE)[2]	Difference LS-mean change [95% CI] p-value[2]	SMD Hedges' g [95% CI][2]	Int. p-value[2]
Maximum NRS Pain Score at Baseline							
< 4							
Relugolix+E2/NETA	Baseline	72 (98.6)	56.0 (27.19)	24.15 (3.135)	14.94	0.55	0.5478
N=73	Overall	66 (90.4)	80.2 (21.82)		[5.73,24.14]	[0.18,0.92]	
Placebo	Baseline	61 (98.4)	53.0 (26.81)	9.21 (3.483)	0.0015		
N=62	Overall	54 (87.1)	58.5 (26.57)				
>= 4							
Relugolix+E2/NETA	Baseline	174 (98.3)	45.0 (27.03)	30.65 (2.031)	18.21	0.67	
N=177	Overall	159 (89.8)	75.1 (25.08)		[12.72,23.70]	[0.45,0.89]	
Placebo	Baseline	189 (99.5)	40.2 (25.40)	12.44 (1.915)	<.0001		
N=190	Overall	176 (92.6)	52.5 (26.70)				
Missing							
Relugolix+E2/NETA	Baseline	3 (100.0)	66.7 (25.66)	NC (NC)	NC	NC	
N=3	Overall	3 (100.0)	75.0 (15.61)		[NC,NC]	[NC,NC]	
Placebo	Baseline	4 (100.0)	27.5 (25.00)	NC (NC)	NC		
N=4	Overall	3 (75.0)	54.2 (28.10)				

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group. Transformed score ranges from 0 to 100 based on Likert scale (None of the time, a little of the time, some of the time, most of the time and all of the time). Higher scores are indicative of better health-related quality of life (high score = good). For the change from baseline, positive scores indicate improvement.
[1] Summary statistics are based on observed data. Mean (SD) are calculated based on the mean observed value across all post-baseline visits within each patient.
[2] LS means, LS mean differences (95% CIs), p-value and Hedges' g (95% CIs) are based on a mixed-effects model with study, treatment, visit, subgroup, treatment-by-visit interaction and a subgroup-by-treatment interaction as fixed effects. The multiple visits for each patient are the repeated measures as a random effect within each patient with an unstructured covariance. Hedges' g is calculated using a small sample bias correction. Missing subgroup levels are not included in estimation of the interaction p-value. The reference group for the LS mean difference and Hedges' g is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with data; CI: Confidence interval; int: Interaction; LS: Least squares; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; SD: Standard deviation; SE: Standard error; SMD: Standardized mean difference; UFS-QoL: Uterine Fibroid Symptom and Health-Related Quality of Life; NC: Not calculated.

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Table EFF.UFSCONTR.MITT.Pooled.S1: Summary of Change from Baseline in UFS-QoL Control Scale Score by Visit and Overall, by Subgroup (mITT Population)

Study: Pooled

Treatment	Study visit	n (%)[1]	Mean (SD)[1]	Change from baseline LS-mean change (SE)[2]	Difference LS-mean change [95% CI] p-value[2]	SMD Hedges' g [95% CI][2]
Age (years)						
< 40 years						
Relugolix+E2/NETA	Baseline	61 (98.4)	43.6 (26.44)	26.38 (3.460)	13.74	0.53
N=62	Week 12	57 (91.9)	67.3 (28.93)		[4.51,22.98]	[0.18,0.89]
Placebo	Baseline	78 (100.0)	41.0 (27.02)	12.63 (3.133)	0.0039	
N=78	Week 12	68 (87.2)	53.3 (29.10)			
>= 40 years						
Relugolix+E2/NETA	Baseline	188 (98.4)	50.0 (27.70)	27.10 (2.093)	16.25	0.60
N=191	Week 12	167 (87.4)	77.4 (24.81)		[10.39,22.12]	[0.38,0.83]
Placebo	Baseline	176 (98.9)	44.0 (25.97)	10.84 (2.127)	<.0001	
N=178	Week 12	161 (90.4)	54.3 (27.32)			

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group. Transformed score ranges from 0 to 100 based on Likert scale (None of the time, a little of the time, some of the time, most of the time and all of the time). Higher scores are indicative of better health-related quality of life (high score = good). For the change from baseline, positive scores indicate improvement.
[1] Summary statistics are based on observed data.
[2] LS means, LS mean differences (95% CIs), p-value and Hedges' g (95% CIs) are based on a mixed-effects model with study, treatment, visit, and a treatment-by-visit interaction as fixed effects. The multiple visits for each patient are the repeated measures as a random effect within each patient with an unstructured covariance. Hedges' g is calculated using a small sample bias correction. Interaction p-value is only produced for the Overall period. The reference group for the LS mean difference and Hedges' g is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with data; CI: Confidence interval; LS: Least squares; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; SD: Standard deviation; SE: Standard error; SMD: Standardized mean difference; UFS-QoL: Uterine Fibroid Symptom and Health-Related Quality of Life.

SOURCE: \Studies\MYV\MYV102\Analysis\Prod\Progs\TFLs\Tab_QOL_UFS_CON.SAS
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Table EFF.UFSCONTR.MITT.Pooled.S1: Summary of Change from Baseline in UFS-QoL Control Scale Score by Visit and Overall, by Subgroup (mITT Population)

Study: Pooled

Treatment	Study visit	n (%)[1]	Mean (SD)[1]	Change from baseline LS-mean change (SE)[2]	Difference LS-mean change [95% CI] p-value[2]	SMD Hedges' g [95% CI][2]
Age (years)						
< 40 years						
Relugolix+E2/NETA	Baseline	61 (98.4)	43.6 (26.44)	30.22 (4.067)	15.59	0.54
N=62	Week 24	47 (75.8)	71.3 (31.65)		[4.79,26.39]	[0.15,0.93]
Placebo	Baseline	78 (100.0)	41.0 (27.02)	14.63 (3.642)	0.0050	
N=78	Week 24	58 (74.4)	56.5 (28.82)			
>= 40 years						
Relugolix+E2/NETA	Baseline	188 (98.4)	50.0 (27.70)	29.88 (2.181)	18.80	0.68
N=191	Week 24	149 (78.0)	82.9 (22.07)		[12.67,24.93]	[0.44,0.92]
Placebo	Baseline	176 (98.9)	44.0 (25.97)	11.08 (2.226)	<.0001	
N=178	Week 24	141 (79.2)	53.5 (29.23)			

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group. Transformed score ranges from 0 to 100 based on Likert scale (None of the time, a little of the time, some of the time, most of the time and all of the time). Higher scores are indicative of better health-related quality of life (high score = good). For the change from baseline, positive scores indicate improvement.
[1] Summary statistics are based on observed data.
[2] LS means, LS mean differences (95% CIs), p-value and Hedges' g (95% CIs) are based on a mixed-effects model with study, treatment, visit, and a treatment-by-visit interaction as fixed effects. The multiple visits for each patient are the repeated measures as a random effect within each patient with an unstructured covariance. Hedges' g is calculated using a small sample bias correction. Interaction p-value is only produced for the Overall period. The reference group for the LS mean difference and Hedges' g is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with data; CI: Confidence interval; LS: Least squares; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; SD: Standard deviation; SE: Standard error; SMD: Standardized mean difference; UFS-QoL: Uterine Fibroid Symptom and Health-Related Quality of Life.

SOURCE: \Studies\MYV\MYV102\Analysis\Prod\Progs\TFLs\Tab_QOL_UFS_CON.SAS
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Table EFF.UFSCONTR.MITT.Pooled.S1: Summary of Change from Baseline in UFS-QoL Control Scale Score by Visit and Overall, by Subgroup (mITT Population)

Study: Pooled

Treatment	Study visit	n (%)[1]	Mean (SD)[1]	Change from baseline LS-mean change (SE)[2]	Difference LS-mean change [95% CI] p-value[2]	SMD Hedges' g [95% CI][2]	Int. p-value[2]
Age (years)							
< 40 years							
Relugolix+E2/NETA	Baseline	61 (98.4)	43.6 (26.44)	28.22 (3.389)	14.74	0.54	0.6073
N=62	Overall	57 (91.9)	68.9 (27.46)		[5.76,23.72]	[0.18,0.90]	
Placebo	Baseline	78 (100.0)	41.0 (27.02)	13.49 (3.068)	0.0014		
N=78	Overall	68 (87.2)	54.1 (26.86)				
>= 40 years							
Relugolix+E2/NETA	Baseline	188 (98.4)	50.0 (27.70)	28.52 (1.956)	17.49	0.64	
N=191	Overall	171 (89.5)	79.1 (22.40)		[12.00,22.97]	[0.42,0.86]	
Placebo	Baseline	176 (98.9)	44.0 (25.97)	11.04 (1.989)	<.0001		
N=178	Overall	165 (92.7)	53.8 (26.70)				

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group. Transformed score ranges from 0 to 100 based on Likert scale (None of the time, a little of the time, some of the time, most of the time and all of the time). Higher scores are indicative of better health-related quality of life (high score = good). For the change from baseline, positive scores indicate improvement.
[1] Summary statistics are based on observed data. Mean (SD) are calculated based on the mean observed value across all post-baseline visits within each patient.
[2] LS means, LS mean differences (95% CIs), p-value and Hedges' g (95% CIs) are based on a mixed-effects model with study, treatment, visit, subgroup, treatment-by-visit interaction and a subgroup-by-treatment interaction as fixed effects. The multiple visits for each patient are the repeated measures as a random effect within each patient with an unstructured covariance. Hedges' g is calculated using a small sample bias correction. The reference group for the LS mean difference and Hedges' g is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with data; CI: Confidence interval; int: Interaction; LS: Least squares; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; SD: Standard deviation; SE: Standard error; SMD: Standardized mean difference; UFS-QoL: Uterine Fibroid Symptom and Health-Related Quality of Life.

SOURCE: \Studies\MYV\MYV102\Analysis\Prod\Progs\TFLs\Tab_QOL_UFS_CON.SAS
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Table EFF.UFSCONTR.MITT.Pooled.S6: Summary of Change from Baseline in UFS-QoL Control Scale Score by Visit and Overall, by Subgroup (mITT Population)

Study: Pooled

Treatment	Study visit	n (%)[1]	Mean (SD)[1]	Change from baseline LS-mean change (SE)[2]	Difference LS-mean change [95% CI] p-value[2]	SMD Hedges' g [95% CI][2]
Geographic Region I						
North America						
Relugolix+E2/NETA	Baseline	188 (98.4)	47.2 (28.40)	27.75 (2.139)	15.01	0.55
N=191	Week 12	165 (86.4)	74.3 (26.88)		[9.12,20.89]	[0.33,0.77]
Placebo	Baseline	192 (99.0)	42.4 (26.61)	12.74 (2.095)	<.0001	
N=194	Week 12	172 (88.7)	54.7 (28.86)			
Rest of World						
Relugolix+E2/NETA	Baseline	61 (98.4)	52.4 (24.23)	24.71 (3.170)	17.29	0.72
N=62	Week 12	59 (95.2)	76.3 (24.47)		[8.41,26.17]	[0.34,1.09]
Placebo	Baseline	62 (100.0)	45.2 (25.34)	7.42 (3.168)	0.0002	
N=62	Week 12	57 (91.9)	52.1 (24.46)			

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group. Transformed score ranges from 0 to 100 based on Likert scale (None of the time, a little of the time, some of the time, most of the time and all of the time). Higher scores are indicative of better health-related quality of life (high score = good). For the change from baseline, positive scores indicate improvement.
[1] Summary statistics are based on observed data.
[2] LS means, LS mean differences (95% CIs), p-value and Hedges' g (95% CIs) are based on a mixed-effects model with study, treatment, visit, and a treatment-by-visit interaction as fixed effects. The multiple visits for each patient are the repeated measures as a random effect within each patient with an unstructured covariance. Hedges' g is calculated using a small sample bias correction. Interaction p-value is only produced for the Overall period. The reference group for the LS mean difference and Hedges' g is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with data; CI: Confidence interval; LS: Least squares; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; SD: Standard deviation; SE: Standard error; SMD: Standardized mean difference; UFS-QoL: Uterine Fibroid Symptom and Health-Related Quality of Life.

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Table EFF.UFSCONTR.MITT.Pooled.S6: Summary of Change from Baseline in UFS-QoL Control Scale Score by Visit and Overall, by Subgroup (mITT Population)

Study: Pooled

Treatment	Study visit	n (%)[1]	Mean (SD)[1]	Change from baseline LS-mean change (SE)[2]	Difference LS-mean change [95% CI] p-value[2]	SMD Hedges' g [95% CI][2]
Geographic Region I						
North America						
Relugolix+E2/NETA	Baseline	188 (98.4)	47.2 (28.40)	29.75 (2.324)	17.51	0.61
N=191	Week 24	139 (72.8)	79.1 (26.16)		[11.13,23.90]	[0.37,0.84]
Placebo	Baseline	192 (99.0)	42.4 (26.61)	12.24 (2.267)	<.0001	
N=194	Week 24	146 (75.3)	53.8 (29.82)			
Rest of World						
Relugolix+E2/NETA	Baseline	61 (98.4)	52.4 (24.23)	30.30 (3.377)	18.56	0.73
N=62	Week 24	57 (91.9)	82.5 (22.38)		[9.04,28.09]	[0.35,1.11]
Placebo	Baseline	62 (100.0)	45.2 (25.34)	11.73 (3.425)	0.0002	
N=62	Week 24	53 (85.5)	55.9 (27.12)			

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group. Transformed score ranges from 0 to 100 based on Likert scale (None of the time, a little of the time, some of the time, most of the time and all of the time). Higher scores are indicative of better health-related quality of life (high score = good). For the change from baseline, positive scores indicate improvement.
[1] Summary statistics are based on observed data.
[2] LS means, LS mean differences (95% CIs), p-value and Hedges' g (95% CIs) are based on a mixed-effects model with study, treatment, visit, and a treatment-by-visit interaction as fixed effects. The multiple visits for each patient are the repeated measures as a random effect within each patient with an unstructured covariance. Hedges' g is calculated using a small sample bias correction. Interaction p-value is only produced for the Overall period. The reference group for the LS mean difference and Hedges' g is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with data; CI: Confidence interval; LS: Least squares; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; SD: Standard deviation; SE: Standard error; SMD: Standardized mean difference; UFS-QoL: Uterine Fibroid Symptom and Health-Related Quality of Life.

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Table EFF.UFSCONTR.MITT.Pooled.S6: Summary of Change from Baseline in UFS-QoL Control Scale Score by Visit and Overall, by Subgroup (mITT Population)

Study: Pooled

Treatment	Study visit	n (%)[1]	Mean (SD)[1]	Change from baseline LS-mean change (SE)[2]	Difference LS-mean change [95% CI] p-value[2]	SMD Hedges' g [95% CI][2]	Int. p-value[2]
Geographic Region I							
North America							
Relugolix+E2/NETA	Baseline	188 (98.4)	47.2 (28.40)	28.88 (1.977)	16.25	0.60	0.7457
N=191	Overall	169 (88.5)	75.8 (24.83)		[10.81,21.69]	[0.38,0.82]	
Placebo	Baseline	192 (99.0)	42.4 (26.61)	12.63 (1.937)	<.0001		
N=194	Overall	174 (89.7)	54.0 (27.83)				
Rest of World							
Relugolix+E2/NETA	Baseline	61 (98.4)	52.4 (24.23)	27.23 (3.292)	18.00	0.66	
N=62	Overall	59 (95.2)	78.9 (22.00)		[8.86,27.15]	[0.29,1.03]	
Placebo	Baseline	62 (100.0)	45.2 (25.34)	9.23 (3.290)	0.0001		
N=62	Overall	59 (95.2)	53.6 (23.22)				

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group. Transformed score ranges from 0 to 100 based on Likert scale (None of the time, a little of the time, some of the time, most of the time and all of the time). Higher scores are indicative of better health-related quality of life (high score = good). For the change from baseline, positive scores indicate improvement.
[1] Summary statistics are based on observed data. Mean (SD) are calculated based on the mean observed value across all post-baseline visits within each patient.
[2] LS means, LS mean differences (95% CIs), p-value and Hedges' g (95% CIs) are based on a mixed-effects model with study, treatment, visit, subgroup, treatment-by-visit interaction and a subgroup-by-treatment interaction as fixed effects. The multiple visits for each patient are the repeated measures as a random effect within each patient with an unstructured covariance. Hedges' g is calculated using a small sample bias correction. The reference group for the LS mean difference and Hedges' g is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with data; CI: Confidence interval; int: Interaction; LS: Least squares; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; SD: Standard deviation; SE: Standard error; SMD: Standardized mean difference; UFS-QoL: Uterine Fibroid Symptom and Health-Related Quality of Life.

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Table EFF.UFSCONTR.MITT.Pooled.S3: Summary of Change from Baseline in UFS-QoL Control Scale Score by Visit and Overall, by Subgroup (mITT Population)

Study: Pooled

Treatment	Study visit	n (%)[1]	Mean (SD)[1]	Change from baseline LS-mean change (SE)[2]	Difference LS-mean change [95% CI] p-value[2]	SMD Hedges' g [95% CI][2]
Uterine Volume at Baseline (cm3)						
< 300 cm3						
Relugolix+E2/NETA	Baseline	147 (99.3)	51.3 (25.97)	26.78 (2.274)	16.05	0.62
N=148	Week 12	132 (89.2)	78.2 (24.15)		[9.51,22.60]	[0.36,0.87]
Placebo	Baseline	129 (100.0)	44.6 (26.18)	10.73 (2.423)	<.0001	
N=129	Week 12	115 (89.1)	55.2 (25.92)			
>= 300 cm3						
Relugolix+E2/NETA	Baseline	101 (97.1)	44.6 (29.25)	27.09 (2.871)	15.02	0.55
N=104	Week 12	92 (88.5)	69.9 (28.36)		[7.43,22.62]	[0.27,0.83]
Placebo	Baseline	125 (98.4)	41.5 (26.40)	12.07 (2.568)	0.0001	
N=127	Week 12	114 (89.8)	52.8 (29.64)			
Missing						
Relugolix+E2/NETA	Baseline	1 (100.0)	25.0 (NE)	NC (NC)	NC	NC
N=1	Week 12	0	NE (NE)		[NC,NC]	[NC,NC]
Placebo	Baseline	0	NE (NE)	NC (NC)	NC	
N=0	Week 12	0	NE (NE)			

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group. Transformed score ranges from 0 to 100 based on Likert scale (None of the time, a little of the time, some of the time, most of the time and all of the time). Higher scores are indicative of better health-related quality of life (high score = good). For the change from baseline, positive scores indicate improvement.
[1] Summary statistics are based on observed data.
[2] LS means, LS mean differences (95% CIs), p-value and Hedges' g (95% CIs) are based on a mixed-effects model with study, treatment, visit, and a treatment-by-visit interaction as fixed effects. The multiple visits for each patient are the repeated measures as a random effect within each patient with an unstructured covariance. Hedges' g is calculated using a small sample bias correction. Interaction p-value is only produced for the Overall period. The reference group for the LS mean difference and Hedges' g is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with data; CI: Confidence interval; LS: Least squares; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; SD: Standard deviation; SE: Standard error; SMD: Standardized mean difference; UFS-QoL: Uterine Fibroid Symptom and Health-Related Quality of Life; NC: Not calculated; NE: Non-estimable.

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Table EFF.UFSCONTR.MITT.Pooled.S3: Summary of Change from Baseline in UFS-QoL Control Scale Score by Visit and Overall, by Subgroup (mITT Population)

Study: Pooled

Treatment	Study visit	n (%)[1]	Mean (SD)[1]	Change from baseline LS-mean change (SE)[2]	Difference LS-mean change [95% CI] p-value[2]	SMD Hedges' g [95% CI][2]
Uterine Volume at Baseline (cm3)						
< 300 cm3						
Relugolix+E2/NETA	Baseline	147 (99.3)	51.3 (25.97)	30.38 (2.573)	17.74	0.61
N=148	Week 24	116 (78.4)	83.0 (23.85)		[10.35,25.13]	[0.34,0.89]
Placebo	Baseline	129 (100.0)	44.6 (26.18)	12.64 (2.733)	<.0001	
N=129	Week 24	102 (79.1)	56.5 (27.96)			
>= 300 cm3						
Relugolix+E2/NETA	Baseline	101 (97.1)	44.6 (29.25)	29.37 (2.907)	17.80	0.66
N=104	Week 24	80 (76.9)	75.8 (26.41)		[10.09,25.51]	[0.36,0.97]
Placebo	Baseline	125 (98.4)	41.5 (26.40)	11.57 (2.614)	<.0001	
N=127	Week 24	97 (76.4)	52.2 (30.18)			
Missing						
Relugolix+E2/NETA	Baseline	1 (100.0)	25.0 (NE)	NC (NC)	NC	NC
N=1	Week 24	0	NE (NE)		[NC,NC]	[NC,NC]
Placebo	Baseline	0	NE (NE)	NC (NC)	NC	
N=0	Week 24	0	NE (NE)			

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group. Transformed score ranges from 0 to 100 based on Likert scale (None of the time, a little of the time, some of the time, most of the time and all of the time). Higher scores are indicative of better health-related quality of life (high score = good). For the change from baseline, positive scores indicate improvement.
[1] Summary statistics are based on observed data.
[2] LS means, LS mean differences (95% CIs), p-value and Hedges' g (95% CIs) are based on a mixed-effects model with study, treatment, visit, and a treatment-by-visit interaction as fixed effects. The multiple visits for each patient are the repeated measures as a random effect within each patient with an unstructured covariance. Hedges' g is calculated using a small sample bias correction. Interaction p-value is only produced for the Overall period. The reference group for the LS mean difference and Hedges' g is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with data; CI: Confidence interval; LS: Least squares; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; SD: Standard deviation; SE: Standard error; SMD: Standardized mean difference; UFS-QoL: Uterine Fibroid Symptom and Health-Related Quality of Life; NC: Not calculated; NE: Non-estimable.

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Table EFF.UFSCONTR.MITT.Pooled.S3: Summary of Change from Baseline in UFS-QoL Control Scale Score by Visit and Overall, by Subgroup (mITT Population)

Study: Pooled

Treatment	Study visit	n (%)[1]	Mean (SD)[1]	Change from baseline LS-mean change (SE)[2]	Difference LS-mean change [95% CI] p-value[2]	SMD Hedges' g [95% CI][2]	Int. p-value[2]
Uterine Volume at Baseline (cm3)							
< 300 cm3							
Relugolix+E2/NETA	Baseline	147 (99.3)	51.3 (25.97)	28.53 (2.199)	16.97	0.62	0.8978
N=148	Overall	134 (90.5)	80.2 (21.24)		[10.67,23.28]	[0.37,0.88]	
Placebo	Baseline	129 (100.0)	44.6 (26.18)	11.55 (2.336)	<.0001		
N=129	Overall	118 (91.5)	55.1 (24.99)				
>= 300 cm3							
Relugolix+E2/NETA	Baseline	101 (97.1)	44.6 (29.25)	28.33 (2.659)	16.36	0.60	
N=104	Overall	94 (90.4)	71.4 (27.00)		[9.34,23.38]	[0.32,0.88]	
Placebo	Baseline	125 (98.4)	41.5 (26.40)	11.97 (2.386)	<.0001		
N=127	Overall	115 (90.6)	52.7 (28.39)				
Missing							
Relugolix+E2/NETA	Baseline	1 (100.0)	25.0 (NE)	NC (NC)	NC	NC	
N=1	Overall	0	NE (NE)		[NC,NC]	[NC,NC]	
Placebo	Baseline	0	NE (NE)	NC (NC)	NC		
N=0	Overall	0	NE (NE)				

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group. Transformed score ranges from 0 to 100 based on Likert scale (None of the time, a little of the time, some of the time, most of the time and all of the time). Higher scores are indicative of better health-related quality of life (high score = good). For the change from baseline, positive scores indicate improvement.
[1] Summary statistics are based on observed data. Mean (SD) are calculated based on the mean observed value across all post-baseline visits within each patient.
[2] LS means, LS mean differences (95% CIs), p-value and Hedges' g (95% CIs) are based on a mixed-effects model with study, treatment, visit, subgroup, treatment-by-visit interaction and a subgroup-by-treatment interaction as fixed effects. The multiple visits for each patient are the repeated measures as a random effect within each patient with an unstructured covariance. Hedges' g is calculated using a small sample bias correction. Missing subgroup levels are not included in estimation of the interaction p-value. The reference group for the LS mean difference and Hedges' g is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with data; CI: Confidence interval; int: Interaction; LS: Least squares; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; SD: Standard deviation; SE: Standard error; SMD: Standardized mean difference; UFS-QoL: Uterine Fibroid Symptom and Health-Related Quality of Life; NC: Not calculated; NE: Non-estimable.

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Table EFF.UFSCONTR.MITT.Pooled.S7: Summary of Change from Baseline in UFS-QoL Control Scale Score by Visit and Overall, by Subgroup (mITT Population)

Study: Pooled

Treatment	Study visit	n (%)[1]	Mean (SD)[1]	Change from baseline LS-mean change (SE)[2]	Difference LS-mean change [95% CI] p-value[2]	SMD Hedges' g [95% CI][2]
Geographic Region II						
Europe						
Relugolix+E2/NETA	Baseline	40 (97.6)	54.8 (24.93)	22.38 (3.848)	15.30	0.65
N=41	Week 12	39 (95.1)	76.7 (24.42)		[4.48,26.11]	[0.19,1.10]
Placebo	Baseline	42 (100.0)	51.3 (24.40)	7.08 (3.858)	0.0062	
N=42	Week 12	39 (92.9)	57.6 (22.56)			
Rest of World (including the US)						
Relugolix+E2/NETA	Baseline	209 (98.6)	47.2 (27.84)	27.84 (2.002)	15.72	0.58
N=212	Week 12	185 (87.3)	74.4 (26.64)		[10.19,21.25]	[0.37,0.79]
Placebo	Baseline	212 (99.1)	41.5 (26.39)	12.12 (1.973)	<.0001	
N=214	Week 12	190 (88.8)	53.3 (28.75)			

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group. Transformed score ranges from 0 to 100 based on Likert scale (None of the time, a little of the time, some of the time, most of the time and all of the time). Higher scores are indicative of better health-related quality of life (high score = good). For the change from baseline, positive scores indicate improvement.
[1] Summary statistics are based on observed data.
[2] LS means, LS mean differences (95% CIs), p-value and Hedges' g (95% CIs) are based on a mixed-effects model with study, treatment, visit, and a treatment-by-visit interaction as fixed effects. The multiple visits for each patient are the repeated measures as a random effect within each patient with an unstructured covariance. Hedges' g is calculated using a small sample bias correction. Interaction p-value is only produced for the Overall period. The reference group for the LS mean difference and Hedges' g is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with data; CI: Confidence interval; LS: Least squares; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; SD: Standard deviation; SE: Standard error; SMD: Standardized mean difference; UFS-QoL: Uterine Fibroid Symptom and Health-Related Quality of Life.

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Table EFF.UFSCONTR.MITT.Pooled.S7: Summary of Change from Baseline in UFS-QoL Control Scale Score by Visit and Overall, by Subgroup (mITT Population)

Study: Pooled

Treatment	Study visit	n (%)[1]	Mean (SD)[1]	Change from baseline LS-mean change (SE)[2]	Difference LS-mean change [95% CI] p-value[2]	SMD Hedges' g [95% CI][2]
Geographic Region II						
Europe						
Relugolix+E2/NETA	Baseline	40 (97.6)	54.8 (24.93)	29.45 (3.972)	19.82	0.82
N=41	Week 24	37 (90.2)	84.6 (21.61)		[8.52,31.12]	[0.34,1.29]
Placebo	Baseline	42 (100.0)	51.3 (24.40)	9.63 (4.069)	0.0008	
N=42	Week 24	35 (83.3)	60.6 (23.76)			
Rest of World (including the US)						
Relugolix+E2/NETA	Baseline	209 (98.6)	47.2 (27.84)	29.96 (2.171)	17.48	0.61
N=212	Week 24	159 (75.0)	79.0 (25.81)		[11.49,23.46]	[0.39,0.83]
Placebo	Baseline	212 (99.1)	41.5 (26.39)	12.48 (2.133)	<.0001	
N=214	Week 24	164 (76.6)	53.1 (29.98)			

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group. Transformed score ranges from 0 to 100 based on Likert scale (None of the time, a little of the time, some of the time, most of the time and all of the time). Higher scores are indicative of better health-related quality of life (high score = good). For the change from baseline, positive scores indicate improvement.
[1] Summary statistics are based on observed data.
[2] LS means, LS mean differences (95% CIs), p-value and Hedges' g (95% CIs) are based on a mixed-effects model with study, treatment, visit, and a treatment-by-visit interaction as fixed effects. The multiple visits for each patient are the repeated measures as a random effect within each patient with an unstructured covariance. Hedges' g is calculated using a small sample bias correction. Interaction p-value is only produced for the Overall period. The reference group for the LS mean difference and Hedges' g is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with data; CI: Confidence interval; LS: Least squares; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; SD: Standard deviation; SE: Standard error; SMD: Standardized mean difference; UFS-QoL: Uterine Fibroid Symptom and Health-Related Quality of Life.

SOURCE: \Studies\MYV\MYV102\Analysis\Prod\Progs\TFLs\Tab_QOL_UFS_CON.SAS
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Table EFF.UFSCONTR.MITT.Pooled.S7: Summary of Change from Baseline in UFS-QoL Control Scale Score by Visit and Overall, by Subgroup (mITT Population)

Study: Pooled

Treatment	Study visit	n (%)[1]	Mean (SD)[1]	Change from baseline LS-mean change (SE)[2]	Difference LS-mean change [95% CI] p-value[2]	SMD Hedges' g [95% CI][2]	Int. p-value[2]
Geographic Region II							
Europe							0.9831
Relugolix+E2/NETA	Baseline	40 (97.6)	54.8 (24.93)	25.67 (4.067)	16.80	0.61	
N=41	Overall	39 (95.1)	79.8 (21.53)		[5.58,28.02]	[0.16,1.06]	
Placebo	Baseline	42 (100.0)	51.3 (24.40)	8.87 (4.013)	0.0034		
N=42	Overall	40 (95.2)	58.7 (20.38)				
Rest of World (including the US)							
Relugolix+E2/NETA	Baseline	209 (98.6)	47.2 (27.84)	29.03 (1.864)	16.67	0.61	
N=212	Overall	189 (89.2)	75.9 (24.62)		[11.52,21.81]	[0.41,0.82]	
Placebo	Baseline	212 (99.1)	41.5 (26.39)	12.36 (1.837)	<.0001		
N=214	Overall	193 (90.2)	52.9 (27.76)				

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group. Transformed score ranges from 0 to 100 based on Likert scale (None of the time, a little of the time, some of the time, most of the time and all of the time). Higher scores are indicative of better health-related quality of life (high score = good). For the change from baseline, positive scores indicate improvement.
[1] Summary statistics are based on observed data. Mean (SD) are calculated based on the mean observed value across all post-baseline visits within each patient.
[2] LS means, LS mean differences (95% CIs), p-value and Hedges' g (95% CIs) are based on a mixed-effects model with study, treatment, visit, subgroup, treatment-by-visit interaction and a subgroup-by-treatment interaction as fixed effects. The multiple visits for each patient are the repeated measures as a random effect within each patient with an unstructured covariance. Hedges' g is calculated using a small sample bias correction. The reference group for the LS mean difference and Hedges' g is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with data; CI: Confidence interval; int: Interaction; LS: Least squares; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; SD: Standard deviation; SE: Standard error; SMD: Standardized mean difference; UFS-QoL: Uterine Fibroid Symptom and Health-Related Quality of Life.

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1.2.12 Summary of Change from Baseline in UFS-QoL Self-Conciousness Scale Score by Visit and Overall, by Subgroup (mITT Population)

Table EFF.UFSSCONS.MITT.Pooled.S6: Summary of Change from Baseline in UFS-QoL Self-Conciousness Scale Score by Visit and Overall, by Subgroup (mITT Population)

Study: Pooled

Treatment	Study visit	n (%)[1]	Mean (SD)[1]	Change from baseline LS-mean change (SE)[2]	Difference LS-mean change [95% CI] p-value[2]	SMD Hedges' g [95% CI][2]
Geographic Region I						
North America						
Relugolix+E2/NETA	Baseline	188 (98.4)	35.6 (28.64)	26.87 (2.210)	14.05	0.50
N=191	Week 12	165 (86.4)	62.7 (30.32)		[7.97,20.13]	[0.28,0.72]
Placebo	Baseline	192 (99.0)	32.0 (28.53)	12.82 (2.164)	<.0001	
N=194	Week 12	172 (88.7)	43.4 (28.95)			
Rest of World						
Relugolix+E2/NETA	Baseline	61 (98.4)	44.9 (27.44)	29.07 (2.791)	30.54	1.44
N=62	Week 12	59 (95.2)	72.9 (24.15)		[22.72,38.37]	[1.03,1.85]
Placebo	Baseline	62 (100.0)	47.5 (26.97)	-1.47 (2.795)	<.0001	
N=62	Week 12	57 (91.9)	44.9 (27.36)			

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group. Transformed score ranges from 0 to 100 based on Likert scale (None of the time, a little of the time, some of the time, most of the time and all of the time). Higher scores are indicative of better health-related quality of life (high score = good). For the change from baseline, positive scores indicate improvement.
[1] Summary statistics are based on observed data.
[2] LS means, LS mean differences (95% CIs), p-value and Hedges' g (95% CIs) are based on a mixed-effects model with study, treatment, visit, and a treatment-by-visit interaction as fixed effects. The multiple visits for each patient are the repeated measures as a random effect within each patient with an unstructured covariance. Hedges' g is calculated using a small sample bias correction. Interaction p-value is only produced for the Overall period. The reference group for the LS mean difference and Hedges' g is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with data; CI: Confidence interval; LS: Least squares; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; SD: Standard deviation; SE: Standard error; SMD: Standardized mean difference; UFS-QoL: Uterine Fibroid Symptom and Health-Related Quality of Life.

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Table EFF.UFSSCONS.MITT.Pooled.S6: Summary of Change from Baseline in UFS-QoL Self-Conciousness Scale Score by Visit and Overall, by Subgroup (mITT Population)

Study: Pooled

Treatment	Study visit	n (%)[1]	Mean (SD)[1]	Change from baseline LS-mean change (SE)[2]	Difference LS-mean change [95% CI] p-value[2]	SMD Hedges' g [95% CI][2]
Geographic Region I						
North America						
Relugolix+E2/NETA	Baseline	188 (98.4)	35.6 (28.64)	30.87 (2.619)	21.12	0.66
N=191	Week 24	139 (72.8)	70.6 (28.88)		[13.93,28.32]	[0.42,0.90]
Placebo	Baseline	192 (99.0)	32.0 (28.53)	9.75 (2.551)	<.0001	
N=194	Week 24	146 (75.3)	40.0 (29.58)			
Rest of World						
Relugolix+E2/NETA	Baseline	61 (98.4)	44.9 (27.44)	33.52 (3.603)	26.35	0.96
N=62	Week 24	57 (91.9)	78.1 (24.94)		[16.16,36.55]	[0.57,1.36]
Placebo	Baseline	62 (100.0)	47.5 (26.97)	7.17 (3.677)	<.0001	
N=62	Week 24	53 (85.5)	53.6 (27.76)			

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group. Transformed score ranges from 0 to 100 based on Likert scale (None of the time, a little of the time, some of the time, most of the time and all of the time). Higher scores are indicative of better health-related quality of life (high score = good). For the change from baseline, positive scores indicate improvement.
[1] Summary statistics are based on observed data.
[2] LS means, LS mean differences (95% CIs), p-value and Hedges' g (95% CIs) are based on a mixed-effects model with study, treatment, visit, and a treatment-by-visit interaction as fixed effects. The multiple visits for each patient are the repeated measures as a random effect within each patient with an unstructured covariance. Hedges' g is calculated using a small sample bias correction. Interaction p-value is only produced for the Overall period. The reference group for the LS mean difference and Hedges' g is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with data; CI: Confidence interval; LS: Least squares; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; SD: Standard deviation; SE: Standard error; SMD: Standardized mean difference; UFS-QoL: Uterine Fibroid Symptom and Health-Related Quality of Life.

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Table EFF.UFSSCONS.MITT.Pooled.S6: Summary of Change from Baseline in UFS-QoL Self-Conciousness Scale Score by Visit and Overall, by Subgroup (mITT Population)

Study: Pooled

Treatment	Study visit	n (%)[1]	Mean (SD)[1]	Change from baseline LS-mean change (SE)[2]	Difference LS-mean change [95% CI] p-value[2]	SMD Hedges' g [95% CI][2]	Int. p-value[2]
Geographic Region I							
North America							
Relugolix+E2/NETA	Baseline	188 (98.4)	35.6 (28.64)	28.88 (2.061)	16.92	0.59	0.0196*
N=191	Overall	169 (88.5)	65.3 (28.12)		[11.25,22.59]	[0.37,0.81]	
Placebo	Baseline	192 (99.0)	32.0 (28.53)	11.96 (2.020)	<.0001		
N=194	Overall	174 (89.7)	41.9 (27.14)				
Rest of World							
Relugolix+E2/NETA	Baseline	61 (98.4)	44.9 (27.44)	30.95 (3.398)	29.92	1.04	
N=62	Overall	59 (95.2)	75.0 (22.61)		[20.48,39.37]	[0.65,1.42]	
Placebo	Baseline	62 (100.0)	47.5 (26.97)	1.03 (3.398)	<.0001		
N=62	Overall	59 (95.2)	48.4 (24.87)				

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group. Transformed score ranges from 0 to 100 based on Likert scale (None of the time, a little of the time, some of the time, most of the time and all of the time). Higher scores are indicative of better health-related quality of life (high score = good). For the change from baseline, positive scores indicate improvement.
[1] Summary statistics are based on observed data. Mean (SD) are calculated based on the mean observed value across all post-baseline visits within each patient.
[2] LS means, LS mean differences (95% CIs), p-value and Hedges' g (95% CIs) are based on a mixed-effects model with study, treatment, visit, subgroup, treatment-by-visit interaction and a subgroup-by-treatment interaction as fixed effects. The multiple visits for each patient are the repeated measures as a random effect within each patient with an unstructured covariance. Hedges' g is calculated using a small sample bias correction. * Interaction p-value < 0.05. The reference group for the LS mean difference and Hedges' g is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with data; CI: Confidence interval; int: Interaction; LS: Least squares; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; SD: Standard deviation; SE: Standard error; SMD: Standardized mean difference; UFS-QoL: Uterine Fibroid Symptom and Health-Related Quality of Life.

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Table EFF.UFSSCONS.MITT.Pooled.S3: Summary of Change from Baseline in UFS-QoL Self-Conciousness Scale Score by Visit and Overall, by Subgroup (mITT Population)

Study: Pooled

Treatment	Study visit	n (%)[1]	Mean (SD)[1]	Change from baseline LS-mean change (SE)[2]	Difference LS-mean change [95% CI] p-value[2]	SMD Hedges' g [95% CI][2]
Uterine Volume at Baseline (cm3)						
< 300 cm3						
Relugolix+E2/NETA	Baseline	147 (99.3)	39.9 (28.61)	29.31 (2.446)	22.57	0.81
N=148	Week 12	132 (89.2)	69.1 (27.70)		[15.53,29.61]	[0.55,1.07]
Placebo	Baseline	129 (100.0)	41.0 (30.59)	6.73 (2.607)	<.0001	
N=129	Week 12	115 (89.1)	46.9 (28.83)			
>= 300 cm3						
Relugolix+E2/NETA	Baseline	101 (97.1)	35.3 (28.36)	24.50 (2.706)	12.72	0.50
N=104	Week 12	92 (88.5)	60.1 (30.40)		[5.56,19.87]	[0.21,0.78]
Placebo	Baseline	125 (98.4)	30.4 (26.06)	11.78 (2.418)	0.0006	
N=127	Week 12	114 (89.8)	40.6 (27.95)			
Missing						
Relugolix+E2/NETA	Baseline	1 (100.0)	0.0 (NE)	NC (NC)	NC	NC
N=1	Week 12	0	NE (NE)		[NC,NC]	[NC,NC]
Placebo	Baseline	0	NE (NE)	NC (NC)	NC	
N=0	Week 12	0	NE (NE)			

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group. Transformed score ranges from 0 to 100 based on Likert scale (None of the time, a little of the time, some of the time, most of the time and all of the time). Higher scores are indicative of better health-related quality of life (high score = good). For the change from baseline, positive scores indicate improvement.
[1] Summary statistics are based on observed data.
[2] LS means, LS mean differences (95% CIs), p-value and Hedges' g (95% CIs) are based on a mixed-effects model with study, treatment, visit, and a treatment-by-visit interaction as fixed effects. The multiple visits for each patient are the repeated measures as a random effect within each patient with an unstructured covariance. Hedges' g is calculated using a small sample bias correction. Interaction p-value is only produced for the Overall period. The reference group for the LS mean difference and Hedges' g is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with data; CI: Confidence interval; LS: Least squares; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; SD: Standard deviation; SE: Standard error; SMD: Standardized mean difference; UFS-QoL: Uterine Fibroid Symptom and Health-Related Quality of Life; NC: Not calculated; NE: Non-estimable.

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Table EFF.UFSSCONS.MITT.Pooled.S3: Summary of Change from Baseline in UFS-QoL Self-Conciousness Scale Score by Visit and Overall, by Subgroup (mITT Population)

Study: Pooled

Treatment	Study visit	n (%)[1]	Mean (SD)[1]	Change from baseline LS-mean change (SE)[2]	Difference LS-mean change [95% CI] p-value[2]	SMD Hedges' g [95% CI][2]
Uterine Volume at Baseline (cm3)						
< 300 cm3						
Relugolix+E2/NETA	Baseline	147 (99.3)	39.9 (28.61)	33.46 (2.903)	27.92	0.87
N=148	Week 24	116 (78.4)	76.1 (26.89)		[19.58,36.26]	[0.59,1.15]
Placebo	Baseline	129 (100.0)	41.0 (30.59)	5.54 (3.083)	<.0001	
N=129	Week 24	102 (79.1)	46.6 (29.70)			
>= 300 cm3						
Relugolix+E2/NETA	Baseline	101 (97.1)	35.3 (28.36)	28.59 (3.189)	15.74	0.54
N=104	Week 24	80 (76.9)	68.0 (28.88)		[7.28,24.20]	[0.24,0.85]
Placebo	Baseline	125 (98.4)	30.4 (26.06)	12.85 (2.869)	0.0003	
N=127	Week 24	97 (76.4)	40.6 (29.46)			
Missing						
Relugolix+E2/NETA	Baseline	1 (100.0)	0.0 (NE)	NC (NC)	NC	NC
N=1	Week 24	0	NE (NE)		[NC,NC]	[NC,NC]
Placebo	Baseline	0	NE (NE)	NC (NC)	NC	
N=0	Week 24	0	NE (NE)			

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group. Transformed score ranges from 0 to 100 based on Likert scale (None of the time, a little of the time, some of the time, most of the time and all of the time). Higher scores are indicative of better health-related quality of life (high score = good). For the change from baseline, positive scores indicate improvement.
[1] Summary statistics are based on observed data.
[2] LS means, LS mean differences (95% CIs), p-value and Hedges' g (95% CIs) are based on a mixed-effects model with study, treatment, visit, and a treatment-by-visit interaction as fixed effects. The multiple visits for each patient are the repeated measures as a random effect within each patient with an unstructured covariance. Hedges' g is calculated using a small sample bias correction. Interaction p-value is only produced for the Overall period. The reference group for the LS mean difference and Hedges' g is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with data; CI: Confidence interval; LS: Least squares; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; SD: Standard deviation; SE: Standard error; SMD: Standardized mean difference; UFS-QoL: Uterine Fibroid Symptom and Health-Related Quality of Life; NC: Not calculated; NE: Non-estimable.

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Table EFF.UFSSCONS.MITT.Pooled.S3: Summary of Change from Baseline in UFS-QoL Self-Conciousness Scale Score by Visit and Overall, by Subgroup (mITT Population)

Study: Pooled

Treatment	Study visit	n (%)[1]	Mean (SD)[1]	Change from baseline LS-mean change (SE)[2]	Difference LS-mean change [95% CI] p-value[2]	SMD Hedges' g [95% CI][2]	Int. p-value[2]
Uterine Volume at Baseline (cm3)							
< 300 cm3							
Relugolix+E2/NETA	Baseline	147 (99.3)	39.9 (28.61)	31.38 (2.287)	25.00	0.87	0.0340*
N=148	Overall	134 (90.5)	71.5 (25.42)		[18.45,31.56]	[0.61,1.13]	
Placebo	Baseline	129 (100.0)	41.0 (30.59)	6.38 (2.426)	<.0001		
N=129	Overall	118 (91.5)	45.8 (26.41)				
>= 300 cm3							
Relugolix+E2/NETA	Baseline	101 (97.1)	35.3 (28.36)	26.57 (2.757)	14.52	0.50	
N=104	Overall	94 (90.4)	62.5 (28.64)		[7.24,21.80]	[0.23,0.78]	
Placebo	Baseline	125 (98.4)	30.4 (26.06)	12.05 (2.476)	0.0001		
N=127	Overall	115 (90.6)	41.2 (26.88)				
Missing							
Relugolix+E2/NETA	Baseline	1 (100.0)	0.0 (NE)	NC (NC)	NC	NC	
N=1	Overall	0	NE (NE)		[NC,NC]	[NC,NC]	
Placebo	Baseline	0	NE (NE)	NC (NC)	NC		
N=0	Overall	0	NE (NE)				

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group. Transformed score ranges from 0 to 100 based on Likert scale (None of the time, a little of the time, some of the time, most of the time and all of the time). Higher scores are indicative of better health-related quality of life (high score = good). For the change from baseline, positive scores indicate improvement.
[1] Summary statistics are based on observed data. Mean (SD) are calculated based on the mean observed value across all post-baseline visits within each patient.
[2] LS means, LS mean differences (95% CIs), p-value and Hedges' g (95% CIs) are based on a mixed-effects model with study, treatment, visit, subgroup, treatment-by-visit interaction and a subgroup-by-treatment interaction as fixed effects. The multiple visits for each patient are the repeated measures as a random effect within each patient with an unstructured covariance. Hedges' g is calculated using a small sample bias correction. * Interaction p-value < 0.05. Missing subgroup levels are not included in estimation of the interaction p-value. The reference group for the LS mean difference and Hedges' g is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with data; CI: Confidence interval; int: Interaction; LS: Least squares; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; SD: Standard deviation; SE: Standard error; SMD: Standardized mean difference; UFS-QoL: Uterine Fibroid Symptom and Health-Related Quality of Life; NC: Not calculated; NE: Non-estimable.

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Table EFF.UFSSCONS.MITT.Pooled.S2: Summary of Change from Baseline in UFS-QoL Self-Conciousness Scale Score by Visit and Overall, by Subgroup (mITT Population)

Study: Pooled

Treatment	Study visit	n (%)[1]	Mean (SD)[1]	Change from baseline LS-mean change (SE)[2]	Difference LS-mean change [95% CI] p-value[2]	SMD Hedges' g [95% CI][2]
BMI (kg/m2) at Baseline						
< 30						
Relugolix+E2/NETA	Baseline	118 (99.2)	39.3 (29.05)	31.46 (2.415)	24.92	1.01
N=119	Week 12	104 (87.4)	72.3 (25.13)		[18.14,31.70]	[0.72,1.31]
Placebo	Baseline	115 (100.0)	40.0 (28.58)	6.53 (2.446)	<.0001	
N=115	Week 12	100 (87.0)	45.2 (28.48)			
>= 30						
Relugolix+E2/NETA	Baseline	130 (97.7)	36.6 (28.31)	23.48 (2.655)	12.12	0.42
N=133	Week 12	119 (89.5)	59.2 (31.06)		[4.87,19.37]	[0.17,0.68]
Placebo	Baseline	139 (98.6)	32.3 (28.76)	11.36 (2.546)	0.0011	
N=141	Week 12	129 (91.5)	42.6 (28.60)			
Missing						
Relugolix+E2/NETA	Baseline	1 (100.0)	33.3 (NE)	NC (NC)	NC	NC
N=1	Week 12	1 (100.0)	91.7 (NE)		[NC,NC]	[NC,NC]
Placebo	Baseline	0	NE (NE)	NC (NC)	NC	
N=0	Week 12	0	NE (NE)			

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group. Transformed score ranges from 0 to 100 based on Likert scale (None of the time, a little of the time, some of the time, most of the time and all of the time). Higher scores are indicative of better health-related quality of life (high score = good). For the change from baseline, positive scores indicate improvement.
[1] Summary statistics are based on observed data.
[2] LS means, LS mean differences (95% CIs), p-value and Hedges' g (95% CIs) are based on a mixed-effects model with study, treatment, visit, and a treatment-by-visit interaction as fixed effects. The multiple visits for each patient are the repeated measures as a random effect within each patient with an unstructured covariance. Hedges' g is calculated using a small sample bias correction. Interaction p-value is only produced for the Overall period. The reference group for the LS mean difference and Hedges' g is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with data; CI: Confidence interval; LS: Least squares; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; SD: Standard deviation; SE: Standard error; SMD: Standardized mean difference; UFS-QoL: Uterine Fibroid Symptom and Health-Related Quality of Life; NC: Not calculated; NE: Non-estimable.

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Table EFF.UFSSCONS.MITT.Pooled.S2: Summary of Change from Baseline in UFS-QoL Self-Conciousness Scale Score by Visit and Overall, by Subgroup (mITT Population)

Study: Pooled

Treatment	Study visit	n (%)[1]	Mean (SD)[1]	Change from baseline LS-mean change (SE)[2]	Difference LS-mean change [95% CI] p-value[2]	SMD Hedges' g [95% CI][2]
BMI (kg/m2) at Baseline						
< 30						
Relugolix+E2/NETA	Baseline	118 (99.2)	39.3 (29.05)	32.70 (2.980)	21.41	0.74
N=119	Week 24	89 (74.8)	76.0 (26.62)		[13.04,29.78]	[0.44,1.05]
Placebo	Baseline	115 (100.0)	40.0 (28.58)	11.29 (3.023)	<.0001	
N=115	Week 24	86 (74.8)	49.1 (28.84)			
>= 30						
Relugolix+E2/NETA	Baseline	130 (97.7)	36.6 (28.31)	30.18 (3.089)	22.58	0.70
N=133	Week 24	106 (79.7)	69.9 (28.89)		[14.14,31.01]	[0.42,0.97]
Placebo	Baseline	139 (98.6)	32.3 (28.76)	7.60 (2.967)	<.0001	
N=141	Week 24	113 (80.1)	39.5 (29.71)			
Missing						
Relugolix+E2/NETA	Baseline	1 (100.0)	33.3 (NE)	NC (NC)	NC	NC
N=1	Week 24	1 (100.0)	91.7 (NE)		[NC,NC]	[NC,NC]
Placebo	Baseline	0	NE (NE)	NC (NC)	NC	
N=0	Week 24	0	NE (NE)			

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group. Transformed score ranges from 0 to 100 based on Likert scale (None of the time, a little of the time, some of the time, most of the time and all of the time). Higher scores are indicative of better health-related quality of life (high score = good). For the change from baseline, positive scores indicate improvement.
[1] Summary statistics are based on observed data.
[2] LS means, LS mean differences (95% CIs), p-value and Hedges' g (95% CIs) are based on a mixed-effects model with study, treatment, visit, and a treatment-by-visit interaction as fixed effects. The multiple visits for each patient are the repeated measures as a random effect within each patient with an unstructured covariance. Hedges' g is calculated using a small sample bias correction. Interaction p-value is only produced for the Overall period. The reference group for the LS mean difference and Hedges' g is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with data; CI: Confidence interval; LS: Least squares; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; SD: Standard deviation; SE: Standard error; SMD: Standardized mean difference; UFS-QoL: Uterine Fibroid Symptom and Health-Related Quality of Life; NC: Not calculated; NE: Non-estimable.

SOURCE: \Studies\MYV\MYV102\Analysis\Prod\Progs\TFLs\Tab_QOL_UFS_CON.SAS
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Table EFF.UFSSCONS.MITT.Pooled.S2: Summary of Change from Baseline in UFS-QoL Self-Conciousness Scale Score by Visit and Overall, by Subgroup (mITT Population)

Study: Pooled

Treatment	Study visit	n (%)[1]	Mean (SD)[1]	Change from baseline LS-mean change (SE)[2]	Difference LS-mean change [95% CI] p-value[2]	SMD Hedges' g [95% CI][2]	Int. p-value[2]
BMI (kg/m2) at Baseline							
< 30							
Relugolix+E2/NETA	Baseline	118 (99.2)	39.3 (29.05)	32.73 (2.575)	24.94	0.87	0.0701
N=119	Overall	106 (89.1)	73.2 (24.52)		[17.74,32.14]	[0.58,1.15]	
Placebo	Baseline	115 (100.0)	40.0 (28.58)	7.79 (2.604)	<.0001		
N=115	Overall	103 (89.6)	47.1 (26.24)				
>= 30							
Relugolix+E2/NETA	Baseline	130 (97.7)	36.6 (28.31)	26.27 (2.428)	16.02	0.56	
N=133	Overall	121 (91.0)	62.8 (28.42)		[9.41,22.64]	[0.30,0.81]	
Placebo	Baseline	139 (98.6)	32.3 (28.76)	10.24 (2.332)	<.0001		
N=141	Overall	130 (92.2)	40.8 (26.81)				
Missing							
Relugolix+E2/NETA	Baseline	1 (100.0)	33.3 (NE)	NC (NC)	NC	NC	
N=1	Overall	1 (100.0)	91.7 (NE)		[NC,NC]	[NC,NC]	
Placebo	Baseline	0	NE (NE)	NC (NC)	NC		
N=0	Overall	0	NE (NE)				

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group. Transformed score ranges from 0 to 100 based on Likert scale (None of the time, a little of the time, some of the time, most of the time and all of the time). Higher scores are indicative of better health-related quality of life (high score = good). For the change from baseline, positive scores indicate improvement.
[1] Summary statistics are based on observed data. Mean (SD) are calculated based on the mean observed value across all post-baseline visits within each patient.
[2] LS means, LS mean differences (95% CIs), p-value and Hedges' g (95% CIs) are based on a mixed-effects model with study, treatment, visit, subgroup, treatment-by-visit interaction and a subgroup-by-treatment interaction as fixed effects. The multiple visits for each patient are the repeated measures as a random effect within each patient with an unstructured covariance. Hedges' g is calculated using a small sample bias correction. Missing subgroup levels are not included in estimation of the interaction p-value. The reference group for the LS mean difference and Hedges' g is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with data; CI: Confidence interval; int: Interaction; LS: Least squares; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; SD: Standard deviation; SE: Standard error; SMD: Standardized mean difference; UFS-QoL: Uterine Fibroid Symptom and Health-Related Quality of Life; NC: Not calculated; NE: Non-estimable.

SOURCE: \Studies\MYV\MYV102\Analysis\Prod\Progs\TFLs\Tab_QOL_UFS_CON.SAS
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Table EFF.UFSSCONS.MITT.Pooled.S7: Summary of Change from Baseline in UFS-QoL Self-Conciousness Scale Score by Visit and Overall, by Subgroup (mITT Population)

Study: Pooled

Treatment	Study visit	n (%)[1]	Mean (SD)[1]	Change from baseline LS-mean change (SE)[2]	Difference LS-mean change [95% CI] p-value[2]	SMD Hedges' g [95% CI][2]
Geographic Region II						
Europe						
Relugolix+E2/NETA	Baseline	40 (97.6)	46.7 (28.61)	28.54 (3.346)	31.22	1.52
N=41	Week 12	39 (95.1)	75.0 (24.93)		[21.80,40.64]	[1.02,2.03]
Placebo	Baseline	42 (100.0)	51.4 (26.40)	-2.68 (3.371)	<.0001	
N=42	Week 12	39 (92.9)	48.3 (26.09)			
Rest of World (including the US)						
Relugolix+E2/NETA	Baseline	209 (98.6)	36.2 (28.34)	27.06 (2.061)	15.75	0.57
N=212	Week 12	185 (87.3)	63.4 (29.59)		[10.06,21.44]	[0.36,0.77]
Placebo	Baseline	212 (99.1)	32.7 (28.40)	11.31 (2.031)	<.0001	
N=214	Week 12	190 (88.8)	42.8 (28.96)			

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group. Transformed score ranges from 0 to 100 based on Likert scale (None of the time, a little of the time, some of the time, most of the time and all of the time). Higher scores are indicative of better health-related quality of life (high score = good). For the change from baseline, positive scores indicate improvement.
[1] Summary statistics are based on observed data.
[2] LS means, LS mean differences (95% CIs), p-value and Hedges' g (95% CIs) are based on a mixed-effects model with study, treatment, visit, and a treatment-by-visit interaction as fixed effects. The multiple visits for each patient are the repeated measures as a random effect within each patient with an unstructured covariance. Hedges' g is calculated using a small sample bias correction. Interaction p-value is only produced for the Overall period. The reference group for the LS mean difference and Hedges' g is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with data; CI: Confidence interval; LS: Least squares; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; SD: Standard deviation; SE: Standard error; SMD: Standardized mean difference; UFS-QoL: Uterine Fibroid Symptom and Health-Related Quality of Life.

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Table EFF.UFSSCONS.MITT.Pooled.S7: Summary of Change from Baseline in UFS-QoL Self-Conciousness Scale Score by Visit and Overall, by Subgroup (mITT Population)

Study: Pooled

Treatment	Study visit	n (%)[1]	Mean (SD)[1]	Change from baseline LS-mean change (SE)[2]	Difference LS-mean change [95% CI] p-value[2]	SMD Hedges' g [95% CI][2]
Geographic Region II						
Europe						
Relugolix+E2/NETA	Baseline	40 (97.6)	46.7 (28.61)	32.94 (4.421)	25.21	0.93
N=41	Week 24	37 (90.2)	80.6 (25.32)		[12.63,37.79]	[0.45,1.41]
Placebo	Baseline	42 (100.0)	51.4 (26.40)	7.73 (4.529)	0.0002	
N=42	Week 24	35 (83.3)	59.5 (23.50)			
Rest of World (including the US)						
Relugolix+E2/NETA	Baseline	209 (98.6)	36.2 (28.34)	31.13 (2.428)	22.08	0.70
N=212	Week 24	159 (75.0)	71.0 (28.27)		[15.39,28.77]	[0.48,0.93]
Placebo	Baseline	212 (99.1)	32.7 (28.40)	9.04 (2.384)	<.0001	
N=214	Week 24	164 (76.6)	40.2 (29.79)			

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group. Transformed score ranges from 0 to 100 based on Likert scale (None of the time, a little of the time, some of the time, most of the time and all of the time). Higher scores are indicative of better health-related quality of life (high score = good). For the change from baseline, positive scores indicate improvement.
[1] Summary statistics are based on observed data.
[2] LS means, LS mean differences (95% CIs), p-value and Hedges' g (95% CIs) are based on a mixed-effects model with study, treatment, visit, and a treatment-by-visit interaction as fixed effects. The multiple visits for each patient are the repeated measures as a random effect within each patient with an unstructured covariance. Hedges' g is calculated using a small sample bias correction. Interaction p-value is only produced for the Overall period. The reference group for the LS mean difference and Hedges' g is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with data; CI: Confidence interval; LS: Least squares; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; SD: Standard deviation; SE: Standard error; SMD: Standardized mean difference; UFS-QoL: Uterine Fibroid Symptom and Health-Related Quality of Life.

SOURCE: \Studies\MYV\MYV102\Analysis\Prod\Progs\TFLs\Tab_QOL_UFS_CON.SAS
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Table EFF.UFSSCONS.MITT.Pooled.S7: Summary of Change from Baseline in UFS-QoL Self-Conciousness Scale Score by Visit and Overall, by Subgroup (mITT Population)

Study: Pooled

Treatment	Study visit	n (%)[1]	Mean (SD)[1]	Change from baseline LS-mean change (SE)[2]	Difference LS-mean change [95% CI] p-value[2]	SMD Hedges' g [95% CI][2]	Int. p-value[2]
Geographic Region II							
Europe							0.0966
Relugolix+E2/NETA	Baseline	40 (97.6)	46.7 (28.61)	30.91 (4.208)	29.19	1.01	
N=41	Overall	39 (95.1)	77.0 (23.28)		[17.58,40.80]	[0.54,1.47]	
Placebo	Baseline	42 (100.0)	51.4 (26.40)	1.72 (4.153)	<.0001		
N=42	Overall	40 (95.2)	53.0 (22.17)				
Rest of World (including the US)							
Relugolix+E2/NETA	Baseline	209 (98.6)	36.2 (28.34)	29.12 (1.954)	18.41	0.64	
N=212	Overall	189 (89.2)	65.9 (27.49)		[13.02,23.81]	[0.43,0.85]	
Placebo	Baseline	212 (99.1)	32.7 (28.40)	10.71 (1.925)	<.0001		
N=214	Overall	193 (90.2)	41.6 (27.17)				

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group. Transformed score ranges from 0 to 100 based on Likert scale (None of the time, a little of the time, some of the time, most of the time and all of the time). Higher scores are indicative of better health-related quality of life (high score = good). For the change from baseline, positive scores indicate improvement.
[1] Summary statistics are based on observed data. Mean (SD) are calculated based on the mean observed value across all post-baseline visits within each patient.
[2] LS means, LS mean differences (95% CIs), p-value and Hedges' g (95% CIs) are based on a mixed-effects model with study, treatment, visit, subgroup, treatment-by-visit interaction and a subgroup-by-treatment interaction as fixed effects. The multiple visits for each patient are the repeated measures as a random effect within each patient with an unstructured covariance. Hedges' g is calculated using a small sample bias correction. The reference group for the LS mean difference and Hedges' g is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with data; CI: Confidence interval; int: Interaction; LS: Least squares; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; SD: Standard deviation; SE: Standard error; SMD: Standardized mean difference; UFS-QoL: Uterine Fibroid Symptom and Health-Related Quality of Life.

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Table EFF.UFSSCONS.MITT.Pooled.S9: Summary of Change from Baseline in UFS-QoL Self-Conciousness Scale Score by Visit and Overall, by Subgroup (mITT Population)						
Study: Pooled						
Treatment	**Study visit**	**n (%)[1]**	**Mean (SD)[1]**	**Change from baseline LS-mean change (SE)[2]**	**Difference LS-mean change [95% CI] p-value[2]**	**SMD Hedges' g [95% CI][2]**
Race						
Black/African American						
Relugolix+E2/NETA	Baseline	119 (97.5)	33.6 (28.41)	26.41 (2.605)	14.28	0.54
N=122	Week 12	105 (86.1)	60.4 (29.71)		[7.31,21.24]	[0.28,0.81]
Placebo	Baseline	139 (98.6)	33.2 (29.41)	12.13 (2.391)	<.0001	
N=141	Week 12	122 (86.5)	43.0 (29.46)			
White						
Relugolix+E2/NETA	Baseline	121 (99.2)	42.3 (28.28)	28.04 (2.670)	21.95	0.78
N=122	Week 12	110 (90.2)	70.4 (28.44)		[14.28,29.62]	[0.50,1.07]
Placebo	Baseline	105 (100.0)	39.5 (27.85)	6.09 (2.831)	<.0001	
N=105	Week 12	98 (93.3)	45.2 (27.18)			
Asian						
Relugolix+E2/NETA	Baseline	1 (100.0)	33.3 (NE)	NC (NC)	NC	NC
N=1	Week 12	1 (100.0)	66.7 (NE)		[NC,NC]	[NC,NC]
Placebo	Baseline	3 (100.0)	36.1 (37.58)	NC (NC)	NC	
N=3	Week 12	3 (100.0)	30.6 (26.79)			
Others						
Relugolix+E2/NETA	Baseline	5 (100.0)	21.7 (20.07)	43.28 (12.542)	34.91	1.31
N=5	Week 12	5 (100.0)	60.0 (21.60)		[-6.77,76.59]	[0.05,2.57]
Placebo	Baseline	6 (100.0)	22.2 (21.51)	8.37 (11.900)	0.0881	
N=6	Week 12	5 (83.3)	36.7 (37.54)			
Not reported						
Relugolix+E2/NETA	Baseline	3 (100.0)	58.3 (36.33)	NC (NC)	NC	NC
N=3	Week 12	3 (100.0)	66.7 (30.04)		[NC,NC]	[NC,NC]
Placebo	Baseline	1 (100.0)	83.3 (NE)	NC (NC)	NC	

N=1	Week 12	1 (100.0)	66.7 (NE)			

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group. Transformed score ranges from 0 to 100 based on Likert scale (None of the time, a little of the time, some of the time, most of the time and all of the time). Higher scores are indicative of better health-related quality of life (high score = good). For the change from baseline, positive scores indicate improvement.
[1] Summary statistics are based on observed data.
[2] LS means, LS mean differences (95% CIs), p-value and Hedges' g (95% CIs) are based on a mixed-effects model with study, treatment, visit, and a treatment-by-visit interaction as fixed effects. The multiple visits for each patient are the repeated measures as a random effect within each patient with an unstructured covariance. Hedges' g is calculated using a small sample bias correction. Interaction p-value is only produced for the Overall period. The reference group for the LS mean difference and Hedges' g is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with data; CI: Confidence interval; LS: Least squares; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; SD: Standard deviation; SE: Standard error; SMD: Standardized mean difference; UFS-QoL: Uterine Fibroid Symptom and Health-Related Quality of Life; NC: Not calculated; NE: Non-estimable.

Table EFF.UFSSCONS.MITT.Pooled.S9: Summary of Change from Baseline in UFS-QoL Self-Conciousness Scale Score by Visit and Overall, by Subgroup (mITT Population)

Study: Pooled

Treatment	Study visit	n (%)[1]	Mean (SD)[1]	Change from baseline LS-mean change (SE)[2]	Difference LS-mean change [95% CI] p-value[2]	SMD Hedges' g [95% CI][2]
Race						
Black/African American						
Relugolix+E2/NETA	Baseline	119 (97.5)	33.6 (28.41)	30.89 (3.214)	20.87	0.68
N=122	Week 24	87 (71.3)	68.0 (29.99)		[12.35,29.39]	[0.39,0.97]
Placebo	Baseline	139 (98.6)	33.2 (29.41)	10.02 (2.895)	<.0001	
N=141	Week 24	108 (76.6)	41.3 (29.52)			
White						
Relugolix+E2/NETA	Baseline	121 (99.2)	42.3 (28.28)	32.58 (3.075)	23.69	0.75
N=122	Week 24	100 (82.0)	78.1 (25.12)		[14.78,32.61]	[0.45,1.05]
Placebo	Baseline	105 (100.0)	39.5 (27.85)	8.89 (3.321)	<.0001	
N=105	Week 24	84 (80.0)	48.3 (29.44)			
Asian						
Relugolix+E2/NETA	Baseline	1 (100.0)	33.3 (NE)	NC (NC)	NC	NC
N=1	Week 24	1 (100.0)	100.0 (NE)		[NC,NC]	[NC,NC]
Placebo	Baseline	3 (100.0)	36.1 (37.58)	NC (NC)	NC	
N=3	Week 24	2 (66.7)	29.2 (41.22)			
Others						
Relugolix+E2/NETA	Baseline	5 (100.0)	21.7 (20.07)	29.96 (10.050)	32.84	1.83
N=5	Week 24	5 (100.0)	46.7 (21.71)		[-1.24,66.92]	[0.39,3.27]
Placebo	Baseline	6 (100.0)	22.2 (21.51)	-2.88 (9.487)	0.0567	
N=6	Week 24	4 (66.7)	12.5 (10.77)			
Not reported						
Relugolix+E2/NETA	Baseline	3 (100.0)	58.3 (36.33)	NC (NC)	NC	NC
N=3	Week 24	3 (100.0)	69.4 (26.79)		[NC,NC]	[NC,NC]
Placebo	Baseline	1 (100.0)	83.3 (NE)	NC (NC)	NC	

N=1	Week 24	1 (100.0)	58.3 (NE)			

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group. Transformed score ranges from 0 to 100 based on Likert scale (None of the time, a little of the time, some of the time, most of the time and all of the time). Higher scores are indicative of better health-related quality of life (high score = good). For the change from baseline, positive scores indicate improvement.
[1] Summary statistics are based on observed data.
[2] LS means, LS mean differences (95% CIs), p-value and Hedges' g (95% CIs) are based on a mixed-effects model with study, treatment, visit, and a treatment-by-visit interaction as fixed effects. The multiple visits for each patient are the repeated measures as a random effect within each patient with an unstructured covariance. Hedges' g is calculated using a small sample bias correction. Interaction p-value is only produced for the Overall period. The reference group for the LS mean difference and Hedges' g is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with data; CI: Confidence interval; LS: Least squares; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; SD: Standard deviation; SE: Standard error; SMD: Standardized mean difference; UFS-QoL: Uterine Fibroid Symptom and Health-Related Quality of Life; NC: Not calculated; NE: Non-estimable.

Table EFF.UFSSCONS.MITT.Pooled.S9: Summary of Change from Baseline in UFS-QoL Self-Conciousness Scale Score by Visit and Overall, by Subgroup (mITT Population)

Study: Pooled

Treatment	Study visit	n (%)[1]	Mean (SD)[1]	Change from baseline LS-mean change (SE)[2]	Difference LS-mean change [95% CI] p-value[2]	SMD Hedges' g [95% CI][2]	Int. p-value[2]
Race							
Black/African American							
Relugolix+E2/NETA	Baseline	119 (97.5)	33.6 (28.41)	28.64 (2.610)	17.15	0.59	0.4194
N=122	Overall	107 (87.7)	63.0 (28.15)		[10.20,24.10]	[0.33,0.86]	
Placebo	Baseline	139 (98.6)	33.2 (29.41)	11.49 (2.388)	<.0001		
N=141	Overall	126 (89.4)	42.0 (27.97)				
White							
Relugolix+E2/NETA	Baseline	121 (99.2)	42.3 (28.28)	30.24 (2.513)	23.26	0.80	
N=122	Overall	112 (91.8)	72.9 (25.57)		[16.05,30.47]	[0.52,1.09]	
Placebo	Baseline	105 (100.0)	39.5 (27.85)	6.97 (2.675)	<.0001		
N=105	Overall	98 (93.3)	46.2 (24.39)				
Asian							
Relugolix+E2/NETA	Baseline	1 (100.0)	33.3 (NE)	NC (NC)	NC	NC	
N=1	Overall	1 (100.0)	83.4 (NE)		[NC,NC]	[NC,NC]	
Placebo	Baseline	3 (100.0)	36.1 (37.58)	NC (NC)	NC		
N=3	Overall	3 (100.0)	33.3 (28.87)				
Others							
Relugolix+E2/NETA	Baseline	5 (100.0)	21.7 (20.07)	35.71 (11.655)	28.73	0.90	
N=5	Overall	5 (100.0)	53.3 (21.53)		[-3.80,61.26]	[-0.29,2.09]	
Placebo	Baseline	6 (100.0)	22.2 (21.51)	6.97 (11.735)	0.0833		
N=6	Overall	5 (83.3)	33.3 (38.42)				
Not reported							
Relugolix+E2/NETA	Baseline	3 (100.0)	58.3 (36.33)	NC (NC)	NC	NC	
N=3	Overall	3 (100.0)	68.1 (27.75)		[NC,NC]	[NC,NC]	
Placebo	Baseline	1 (100.0)	83.3 (NE)	NC (NC)	NC		

N=1	Overall	1 (100.0)	62.5 (NE)				

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group. Transformed score ranges from 0 to 100 based on Likert scale (None of the time, a little of the time, some of the time, most of the time and all of the time). Higher scores are indicative of better health-related quality of life (high score = good). For the change from baseline, positive scores indicate improvement.
[1] Summary statistics are based on observed data. Mean (SD) are calculated based on the mean observed value across all post-baseline visits within each patient.
[2] LS means, LS mean differences (95% CIs), p-value and Hedges' g (95% CIs) are based on a mixed-effects model with study, treatment, visit, subgroup, treatment-by-visit interaction and a subgroup-by-treatment interaction as fixed effects. The multiple visits for each patient are the repeated measures as a random effect within each patient with an unstructured covariance. Hedges' g is calculated using a small sample bias correction. Not reported subgroup levels are not included in estimation of the interaction p-value. Subgroup levels with fewer than 10 subjects are not included in estimation of the interaction p-value. The reference group for the LS mean difference and Hedges' g is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with data; CI: Confidence interval; int: Interaction; LS: Least squares; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; SD: Standard deviation; SE: Standard error; SMD: Standardized mean difference; UFS-QoL: Uterine Fibroid Symptom and Health-Related Quality of Life; NC: Not calculated; NE: Non-estimable.

SOURCE: \Studies\MYV\MYV102\Analysis\Prod\Progs\TFLs\Tab_QOL_UFS_CON.SAS
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Table EFF.UFSSCONS.MITT.Pooled.S4: Summary of Change from Baseline in UFS-QoL Self-Conciousness Scale Score by Visit and Overall, by Subgroup (mITT Population)

Study: Pooled

Treatment	Study visit	n (%)[1]	Mean (SD)[1]	Change from baseline LS-mean change (SE)[2]	Difference LS-mean change [95% CI] p-value[2]	SMD Hedges' g [95% CI][2]
Maximum NRS Pain Score at Baseline						
< 4						
Relugolix+E2/NETA	Baseline	72 (98.6)	44.8 (29.98)	24.40 (3.153)	17.25	0.69
N=73	Week 12	65 (89.0)	69.0 (28.17)		[7.92,26.58]	[0.31,1.06]
Placebo	Baseline	61 (98.4)	44.4 (27.42)	7.14 (3.514)	0.0004	
N=62	Week 12	52 (83.9)	47.9 (26.70)			
>= 4						
Relugolix+E2/NETA	Baseline	174 (98.3)	34.8 (27.34)	28.79 (2.244)	18.81	0.68
N=177	Week 12	156 (88.1)	63.8 (29.49)		[12.74,24.87]	[0.45,0.90]
Placebo	Baseline	189 (99.5)	32.5 (28.66)	9.98 (2.113)	<.0001	
N=190	Week 12	174 (91.6)	42.1 (28.84)			
Missing						
Relugolix+E2/NETA	Baseline	3 (100.0)	52.8 (42.74)	NC (NC)	NC	NC
N=3	Week 12	3 (100.0)	69.4 (33.70)		[NC,NC]	[NC,NC]
Placebo	Baseline	4 (100.0)	56.3 (32.86)	NC (NC)	NC	
N=4	Week 12	3 (75.0)	69.5 (29.25)			

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group. Transformed score ranges from 0 to 100 based on Likert scale (None of the time, a little of the time, some of the time, most of the time and all of the time). Higher scores are indicative of better health-related quality of life (high score = good). For the change from baseline, positive scores indicate improvement.
[1] Summary statistics are based on observed data.
[2] LS means, LS mean differences (95% CIs), p-value and Hedges' g (95% CIs) are based on a mixed-effects model with study, treatment, visit, and a treatment-by-visit interaction as fixed effects. The multiple visits for each patient are the repeated measures as a random effect within each patient with an unstructured covariance. Hedges' g is calculated using a small sample bias correction. Interaction p-value is only produced for the Overall period. The reference group for the LS mean difference and Hedges' g is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with data; CI: Confidence interval; LS: Least squares; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; SD: Standard deviation; SE: Standard error; SMD: Standardized mean difference; UFS-QoL: Uterine Fibroid Symptom and Health-Related Quality of Life; NC: Not calculated.

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Table EFF.UFSSCONS.MITT.Pooled.S4: Summary of Change from Baseline in UFS-QoL Self-Conciousness Scale Score by Visit and Overall, by Subgroup (mITT Population)

Study: Pooled

Treatment	Study visit	n (%)[1]	Mean (SD)[1]	Change from baseline LS-mean change (SE)[2]	Difference LS-mean change [95% CI] p-value[2]	SMD Hedges' g [95% CI][2]
Maximum NRS Pain Score at Baseline						
< 4						
Relugolix+E2/NETA	Baseline	72 (98.6)	44.8 (29.98)	25.71 (3.854)	17.89	0.60
N=73	Week 24	57 (78.1)	73.7 (28.73)		[6.45,29.33]	[0.20,1.00]
Placebo	Baseline	61 (98.4)	44.4 (27.42)	7.82 (4.313)	0.0025	
N=62	Week 24	46 (74.2)	49.8 (28.90)			
>= 4						
Relugolix+E2/NETA	Baseline	174 (98.3)	34.8 (27.34)	34.42 (2.607)	24.53	0.79
N=177	Week 24	136 (76.8)	72.7 (27.57)		[17.49,31.58]	[0.55,1.03]
Placebo	Baseline	189 (99.5)	32.5 (28.66)	9.89 (2.452)	<.0001	
N=190	Week 24	151 (79.5)	41.4 (29.78)			
Missing						
Relugolix+E2/NETA	Baseline	3 (100.0)	52.8 (42.74)	NC (NC)	NC	NC
N=3	Week 24	3 (100.0)	61.1 (37.58)		[NC,NC]	[NC,NC]
Placebo	Baseline	4 (100.0)	56.3 (32.86)	NC (NC)	NC	
N=4	Week 24	2 (50.0)	66.7 (0.00)			

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group. Transformed score ranges from 0 to 100 based on Likert scale (None of the time, a little of the time, some of the time, most of the time and all of the time). Higher scores are indicative of better health-related quality of life (high score = good). For the change from baseline, positive scores indicate improvement.
[1] Summary statistics are based on observed data.
[2] LS means, LS mean differences (95% CIs), p-value and Hedges' g (95% CIs) are based on a mixed-effects model with study, treatment, visit, and a treatment-by-visit interaction as fixed effects. The multiple visits for each patient are the repeated measures as a random effect within each patient with an unstructured covariance. Hedges' g is calculated using a small sample bias correction. Interaction p-value is only produced for the Overall period. The reference group for the LS mean difference and Hedges' g is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with data; CI: Confidence interval; LS: Least squares; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; SD: Standard deviation; SE: Standard error; SMD: Standardized mean difference; UFS-QoL: Uterine Fibroid Symptom and Health-Related Quality of Life; NC: Not calculated.

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Table EFF.UFSSCONS.MITT.Pooled.S4: Summary of Change from Baseline in UFS-QoL Self-Conciousness Scale Score by Visit and Overall, by Subgroup (mITT Population)

Study: Pooled

Treatment	Study visit	n (%)[1]	Mean (SD)[1]	Change from baseline LS-mean change (SE)[2]	Difference LS-mean change [95% CI] p-value[2]	SMD Hedges' g [95% CI][2]	Int. p-value[2]
Maximum NRS Pain Score at Baseline							
< 4							
Relugolix+E2/NETA	Baseline	72 (98.6)	44.8 (29.98)	25.72 (3.265)	18.34	0.63	0.5911
N=73	Overall	66 (90.4)	69.9 (27.38)		[8.75,27.92]	[0.27,1.00]	
Placebo	Baseline	61 (98.4)	44.4 (27.42)	7.38 (3.626)	0.0002		
N=62	Overall	54 (87.1)	48.2 (24.24)				
>= 4							
Relugolix+E2/NETA	Baseline	174 (98.3)	34.8 (27.34)	31.35 (2.130)	21.37	0.74	
N=177	Overall	159 (89.8)	66.9 (27.05)		[15.62,27.13]	[0.52,0.97]	
Placebo	Baseline	189 (99.5)	32.5 (28.66)	9.97 (2.010)	<.0001		
N=190	Overall	176 (92.6)	41.8 (27.28)				
Missing							
Relugolix+E2/NETA	Baseline	3 (100.0)	52.8 (42.74)	NC (NC)	NC	NC	
N=3	Overall	3 (100.0)	65.3 (30.15)		[NC,NC]	[NC,NC]	
Placebo	Baseline	4 (100.0)	56.3 (32.86)	NC (NC)	NC		
N=4	Overall	3 (75.0)	63.9 (20.96)				

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group. Transformed score ranges from 0 to 100 based on Likert scale (None of the time, a little of the time, some of the time, most of the time and all of the time). Higher scores are indicative of better health-related quality of life (high score = good). For the change from baseline, positive scores indicate improvement.
[1] Summary statistics are based on observed data. Mean (SD) are calculated based on the mean observed value across all post-baseline visits within each patient.
[2] LS means, LS mean differences (95% CIs), p-value and Hedges' g (95% CIs) are based on a mixed-effects model with study, treatment, visit, subgroup, treatment-by-visit interaction and a subgroup-by-treatment interaction as fixed effects. The multiple visits for each patient are the repeated measures as a random effect within each patient with an unstructured covariance. Hedges' g is calculated using a small sample bias correction. Missing subgroup levels are not included in estimation of the interaction p-value. The reference group for the LS mean difference and Hedges' g is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with data; CI: Confidence interval; int: Interaction; LS: Least squares; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; SD: Standard deviation; SE: Standard error; SMD: Standardized mean difference; UFS-QoL: Uterine Fibroid Symptom and Health-Related Quality of Life; NC: Not calculated.

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Table EFF.UFSSCONS.MITT.Pooled.S5: Summary of Change from Baseline in UFS-QoL Self-Conciousness Scale Score by Visit and Overall, by Subgroup (mITT Population)

Study: Pooled

Treatment	Study visit	n (%)[1]	Mean (SD)[1]	Change from baseline LS-mean change (SE)[2]	Difference LS-mean change [95% CI] p-value[2]	SMD Hedges' g [95% CI][2]
MBL Volume at Baseline (mL)						
< 225 mL						
Relugolix+E2/NETA	Baseline	163 (99.4)	37.5 (27.61)	28.03 (2.211)	18.81	0.71
N=164	Week 12	147 (89.6)	66.4 (28.89)		[12.73,24.90]	[0.47,0.94]
Placebo	Baseline	170 (99.4)	34.6 (28.53)	9.22 (2.162)	<.0001	
N=171	Week 12	153 (89.5)	42.4 (27.38)			
>= 225 mL						
Relugolix+E2/NETA	Baseline	86 (96.6)	38.6 (30.49)	26.28 (3.205)	17.14	0.62
N=89	Week 12	77 (86.5)	63.5 (29.65)		[8.18,26.10]	[0.29,0.94]
Placebo	Baseline	84 (98.8)	38.2 (29.59)	9.14 (3.206)	0.0002	
N=85	Week 12	76 (89.4)	46.4 (30.68)			

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group. Transformed score ranges from 0 to 100 based on Likert scale (None of the time, a little of the time, some of the time, most of the time and all of the time). Higher scores are indicative of better health-related quality of life (high score = good). For the change from baseline, positive scores indicate improvement.
[1] Summary statistics are based on observed data.
[2] LS means, LS mean differences (95% CIs), p-value and Hedges' g (95% CIs) are based on a mixed-effects model with study, treatment, visit, and a treatment-by-visit interaction as fixed effects. The multiple visits for each patient are the repeated measures as a random effect within each patient with an unstructured covariance. Hedges' g is calculated using a small sample bias correction. Interaction p-value is only produced for the Overall period. The reference group for the LS mean difference and Hedges' g is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with data; CI: Confidence interval; LS: Least squares; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; SD: Standard deviation; SE: Standard error; SMD: Standardized mean difference; UFS-QoL: Uterine Fibroid Symptom and Health-Related Quality of Life.

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Table EFF.UFSSCONS.MITT.Pooled.S5: Summary of Change from Baseline in UFS-QoL Self-Conciousness Scale Score by Visit and Overall, by Subgroup (mITT Population)

Study: Pooled

Treatment	Study visit	n (%)[1]	Mean (SD)[1]	Change from baseline LS-mean change (SE)[2]	Difference LS-mean change [95% CI] p-value[2]	SMD Hedges' g [95% CI][2]
MBL Volume at Baseline (mL)						
< 225 mL						
Relugolix+E2/NETA	Baseline	163 (99.4)	37.5 (27.61)	32.74 (2.684)	23.34	0.76
N=164	Week 24	126 (76.8)	73.2 (29.25)		[16.00,30.69]	[0.51,1.01]
Placebo	Baseline	170 (99.4)	34.6 (28.53)	9.39 (2.593)	<.0001	
N=171	Week 24	137 (80.1)	43.4 (28.05)			
>= 225 mL						
Relugolix+E2/NETA	Baseline	86 (96.6)	38.6 (30.49)	29.25 (3.603)	20.73	0.67
N=89	Week 24	70 (78.7)	72.1 (25.57)		[10.55,30.91]	[0.32,1.02]
Placebo	Baseline	84 (98.8)	38.2 (29.59)	8.53 (3.680)	<.0001	
N=85	Week 24	62 (72.9)	44.1 (33.18)			

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group. Transformed score ranges from 0 to 100 based on Likert scale (None of the time, a little of the time, some of the time, most of the time and all of the time). Higher scores are indicative of better health-related quality of life (high score = good). For the change from baseline, positive scores indicate improvement.
[1] Summary statistics are based on observed data.
[2] LS means, LS mean differences (95% CIs), p-value and Hedges' g (95% CIs) are based on a mixed-effects model with study, treatment, visit, and a treatment-by-visit interaction as fixed effects. The multiple visits for each patient are the repeated measures as a random effect within each patient with an unstructured covariance. Hedges' g is calculated using a small sample bias correction. Interaction p-value is only produced for the Overall period. The reference group for the LS mean difference and Hedges' g is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with data; CI: Confidence interval; LS: Least squares; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; SD: Standard deviation; SE: Standard error; SMD: Standardized mean difference; UFS-QoL: Uterine Fibroid Symptom and Health-Related Quality of Life.

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Table EFF.UFSSCONS.MITT.Pooled.S5: Summary of Change from Baseline in UFS-QoL Self-Conciousness Scale Score by Visit and Overall, by Subgroup (mITT Population)

Study: Pooled

Treatment	Study visit	n (%)[1]	Mean (SD)[1]	Change from baseline LS-mean change (SE)[2]	Difference LS-mean change [95% CI] p-value[2]	SMD Hedges' g [95% CI][2]	Int. p-value[2]
MBL Volume at Baseline (mL)							
< 225 mL							
Relugolix+E2/NETA	Baseline	163 (99.4)	37.5 (27.61)	30.24 (2.187)	21.02	0.73	0.6767
N=164	Overall	148 (90.2)	68.4 (27.11)		[15.02,27.02]	[0.50,0.96]	
Placebo	Baseline	170 (99.4)	34.6 (28.53)	9.22 (2.130)	<.0001		
N=171	Overall	156 (91.2)	42.3 (25.18)				
>= 225 mL							
Relugolix+E2/NETA	Baseline	86 (96.6)	38.6 (30.49)	27.89 (3.009)	18.85	0.65	
N=89	Overall	80 (89.9)	66.6 (27.20)		[10.46,27.25]	[0.33,0.98]	
Placebo	Baseline	84 (98.8)	38.2 (29.59)	9.03 (3.029)	<.0001		
N=85	Overall	77 (90.6)	46.0 (29.52)				

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group. Transformed score ranges from 0 to 100 based on Likert scale (None of the time, a little of the time, some of the time, most of the time and all of the time). Higher scores are indicative of better health-related quality of life (high score = good). For the change from baseline, positive scores indicate improvement.
[1] Summary statistics are based on observed data. Mean (SD) are calculated based on the mean observed value across all post-baseline visits within each patient.
[2] LS means, LS mean differences (95% CIs), p-value and Hedges' g (95% CIs) are based on a mixed-effects model with study, treatment, visit, subgroup, treatment-by-visit interaction and a subgroup-by-treatment interaction as fixed effects. The multiple visits for each patient are the repeated measures as a random effect within each patient with an unstructured covariance. Hedges' g is calculated using a small sample bias correction. The reference group for the LS mean difference and Hedges' g is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with data; CI: Confidence interval; int: Interaction; LS: Least squares; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; SD: Standard deviation; SE: Standard error; SMD: Standardized mean difference; UFS-QoL: Uterine Fibroid Symptom and Health-Related Quality of Life.

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Table EFF.UFSSCONS.MITT.Pooled.S1: Summary of Change from Baseline in UFS-QoL Self-Conciousness Scale Score by Visit and Overall, by Subgroup (mITT Population)

Study: Pooled

Treatment	Study visit	n (%)[1]	Mean (SD)[1]	Change from baseline LS-mean change (SE)[2]	Difference LS-mean change [95% CI] p-value[2]	SMD Hedges' g [95% CI][2]
Age (years)						
< 40 years						
Relugolix+E2/NETA	Baseline	61 (98.4)	33.7 (27.15)	28.01 (3.608)	19.79	0.74
N=62	Week 12	57 (91.9)	61.7 (29.29)		[10.16,29.42]	[0.37,1.10]
Placebo	Baseline	78 (100.0)	34.3 (27.91)	8.22 (3.267)	<.0001	
N=78	Week 12	68 (87.2)	41.5 (26.68)			
>= 40 years						
Relugolix+E2/NETA	Baseline	188 (98.4)	39.2 (28.97)	27.21 (2.110)	17.52	0.65
N=191	Week 12	167 (87.4)	66.7 (29.05)		[11.61,23.44]	[0.42,0.87]
Placebo	Baseline	176 (98.9)	36.4 (29.35)	9.69 (2.144)	<.0001	
N=178	Week 12	161 (90.4)	44.7 (29.28)			

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group. Transformed score ranges from 0 to 100 based on Likert scale (None of the time, a little of the time, some of the time, most of the time and all of the time). Higher scores are indicative of better health-related quality of life (high score = good). For the change from baseline, positive scores indicate improvement.
[1] Summary statistics are based on observed data.
[2] LS means, LS mean differences (95% CIs), p-value and Hedges' g (95% CIs) are based on a mixed-effects model with study, treatment, visit, and a treatment-by-visit interaction as fixed effects. The multiple visits for each patient are the repeated measures as a random effect within each patient with an unstructured covariance. Hedges' g is calculated using a small sample bias correction. Interaction p-value is only produced for the Overall period. The reference group for the LS mean difference and Hedges' g is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with data; CI: Confidence interval; LS: Least squares; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; SD: Standard deviation; SE: Standard error; SMD: Standardized mean difference; UFS-QoL: Uterine Fibroid Symptom and Health-Related Quality of Life.

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Table EFF.UFSSCONS.MITT.Pooled.S1: Summary of Change from Baseline in UFS-QoL Self-Conciousness Scale Score by Visit and Overall, by Subgroup (mITT Population)

Study: Pooled

Treatment	Study visit	n (%)[1]	Mean (SD)[1]	Change from baseline LS-mean change (SE)[2]	Difference LS-mean change [95% CI] p-value[2]	SMD Hedges' g [95% CI][2]
Age (years)						
< 40 years						
Relugolix+E2/NETA	Baseline	61 (98.4)	33.7 (27.15)	34.23 (4.233)	23.59	0.78
N=62	Week 24	47 (75.8)	69.0 (30.09)		[12.35,34.84]	[0.39,1.18]
Placebo	Baseline	78 (100.0)	34.3 (27.91)	10.64 (3.791)	<.0001	
N=78	Week 24	58 (74.4)	46.0 (26.55)			
>= 40 years						
Relugolix+E2/NETA	Baseline	188 (98.4)	39.2 (28.97)	30.70 (2.511)	22.19	0.71
N=191	Week 24	149 (78.0)	74.0 (27.21)		[15.13,29.25]	[0.47,0.95]
Placebo	Baseline	176 (98.9)	36.4 (29.35)	8.52 (2.565)	<.0001	
N=178	Week 24	141 (79.2)	42.7 (30.89)			

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group. Transformed score ranges from 0 to 100 based on Likert scale (None of the time, a little of the time, some of the time, most of the time and all of the time). Higher scores are indicative of better health-related quality of life (high score = good). For the change from baseline, positive scores indicate improvement.
[1] Summary statistics are based on observed data.
[2] LS means, LS mean differences (95% CIs), p-value and Hedges' g (95% CIs) are based on a mixed-effects model with study, treatment, visit, and a treatment-by-visit interaction as fixed effects. The multiple visits for each patient are the repeated measures as a random effect within each patient with an unstructured covariance. Hedges' g is calculated using a small sample bias correction. Interaction p-value is only produced for the Overall period. The reference group for the LS mean difference and Hedges' g is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with data; CI: Confidence interval; LS: Least squares; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; SD: Standard deviation; SE: Standard error; SMD: Standardized mean difference; UFS-QoL: Uterine Fibroid Symptom and Health-Related Quality of Life.

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Table EFF.UFSSCONS.MITT.Pooled.S1: Summary of Change from Baseline in UFS-QoL Self-Conciousness Scale Score by Visit and Overall, by Subgroup (mITT Population)

Study: Pooled

Treatment	Study visit	n (%)[1]	Mean (SD)[1]	Change from baseline LS-mean change (SE)[2]	Difference LS-mean change [95% CI] p-value[2]	SMD Hedges' g [95% CI][2]	Int. p-value[2]
Age (years)							
< 40 years							
Relugolix+E2/NETA	Baseline	61 (98.4)	33.7 (27.15)	30.48 (3.518)	21.65	0.75	0.7359
N=62	Overall	57 (91.9)	64.3 (26.78)		[12.33,30.98]	[0.38,1.11]	
Placebo	Baseline	78 (100.0)	34.3 (27.91)	8.83 (3.188)	<.0001		
N=78	Overall	68 (87.2)	42.7 (24.45)				
>= 40 years							
Relugolix+E2/NETA	Baseline	188 (98.4)	39.2 (28.97)	29.08 (2.051)	19.79	0.69	
N=191	Overall	171 (89.5)	68.9 (27.18)		[14.05,25.54]	[0.47,0.91]	
Placebo	Baseline	176 (98.9)	36.4 (29.35)	9.29 (2.084)	<.0001		
N=178	Overall	165 (92.7)	43.9 (27.62)				

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group. Transformed score ranges from 0 to 100 based on Likert scale (None of the time, a little of the time, some of the time, most of the time and all of the time). Higher scores are indicative of better health-related quality of life (high score = good). For the change from baseline, positive scores indicate improvement.
[1] Summary statistics are based on observed data. Mean (SD) are calculated based on the mean observed value across all post-baseline visits within each patient.
[2] LS means, LS mean differences (95% CIs), p-value and Hedges' g (95% CIs) are based on a mixed-effects model with study, treatment, visit, subgroup, treatment-by-visit interaction and a subgroup-by-treatment interaction as fixed effects. The multiple visits for each patient are the repeated measures as a random effect within each patient with an unstructured covariance. Hedges' g is calculated using a small sample bias correction. The reference group for the LS mean difference and Hedges' g is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with data; CI: Confidence interval; int: Interaction; LS: Least squares; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; SD: Standard deviation; SE: Standard error; SMD: Standardized mean difference; UFS-QoL: Uterine Fibroid Symptom and Health-Related Quality of Life.

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Table EFF.UFSSCONS.MITT.Pooled.S8: Summary of Change from Baseline in UFS-QoL Self-Conciousness Scale Score by Visit and Overall, by Subgroup (mITT Population)

Study: Pooled

Treatment	Study visit	n (%)[1]	Mean (SD)[1]	Change from baseline LS-mean change (SE)[2]	Difference LS-mean change [95% CI] p-value[2]	SMD Hedges' g [95% CI][2]
Ethnicity						
Hispanic or Latino						
Relugolix+E2/NETA	Baseline	52 (100.0)	34.5 (25.62)	33.32 (4.298)	18.60	0.64
N=52	Week 12	47 (90.4)	65.4 (27.85)		[6.63,30.56]	[0.23,1.05]
Placebo	Baseline	55 (100.0)	28.2 (25.93)	14.72 (4.154)	0.0027	
N=55	Week 12	49 (89.1)	43.9 (30.08)			
Not Hispanic or Latino						
Relugolix+E2/NETA	Baseline	193 (98.0)	38.5 (29.03)	26.31 (2.024)	18.53	0.70
N=197	Week 12	174 (88.3)	65.2 (29.65)		[12.94,24.12]	[0.49,0.92]
Placebo	Baseline	197 (99.0)	37.8 (29.25)	7.78 (1.989)	<.0001	
N=199	Week 12	178 (89.4)	43.8 (28.13)			
Not reported						
Relugolix+E2/NETA	Baseline	4 (100.0)	52.1 (44.30)	NC (NC)	NC	NC
N=4	Week 12	3 (75.0)	77.8 (20.99)		[NC,NC]	[NC,NC]
Placebo	Baseline	2 (100.0)	45.8 (53.03)	NC (NC)	NC	
N=2	Week 12	2 (100.0)	37.5 (41.30)			

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group. Transformed score ranges from 0 to 100 based on Likert scale (None of the time, a little of the time, some of the time, most of the time and all of the time). Higher scores are indicative of better health-related quality of life (high score = good). For the change from baseline, positive scores indicate improvement.
[1] Summary statistics are based on observed data.
[2] LS means, LS mean differences (95% CIs), p-value and Hedges' g (95% CIs) are based on a mixed-effects model with study, treatment, visit, and a treatment-by-visit interaction as fixed effects. The multiple visits for each patient are the repeated measures as a random effect within each patient with an unstructured covariance. Hedges' g is calculated using a small sample bias correction. Interaction p-value is only produced for the Overall period. The reference group for the LS mean difference and Hedges' g is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with data; CI: Confidence interval; LS: Least squares; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; SD: Standard deviation; SE: Standard error; SMD: Standardized mean difference; UFS-QoL: Uterine Fibroid Symptom and Health-Related Quality of Life; NC: Not calculated.

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Table EFF.UFSSCONS.MITT.Pooled.S8: Summary of Change from Baseline in UFS-QoL Self-Conciousness Scale Score by Visit and Overall, by Subgroup (mITT Population)

Study: Pooled

Treatment	Study visit	n (%)[1]	Mean (SD)[1]	Change from baseline LS-mean change (SE)[2]	Difference LS-mean change [95% CI] p-value[2]	SMD Hedges' g [95% CI][2]
Ethnicity						
Hispanic or Latino						
Relugolix+E2/NETA	Baseline	52 (100.0)	34.5 (25.62)	35.72 (4.920)	24.14	0.74
N=52	Week 24	44 (84.6)	70.8 (26.76)		[10.45,37.83]	[0.32,1.16]
Placebo	Baseline	55 (100.0)	28.2 (25.93)	11.58 (4.759)	0.0007	
N=55	Week 24	46 (83.6)	40.4 (32.16)			
Not Hispanic or Latino						
Relugolix+E2/NETA	Baseline	193 (98.0)	38.5 (29.03)	31.08 (2.419)	22.50	0.74
N=197	Week 24	149 (75.6)	73.4 (28.46)		[15.81,29.19]	[0.51,0.98]
Placebo	Baseline	197 (99.0)	37.8 (29.25)	8.58 (2.382)	<.0001	
N=199	Week 24	151 (75.9)	44.8 (28.85)			
Not reported						
Relugolix+E2/NETA	Baseline	4 (100.0)	52.1 (44.30)	NC (NC)	NC	NC
N=4	Week 24	3 (75.0)	72.2 (25.46)		[NC,NC]	[NC,NC]
Placebo	Baseline	2 (100.0)	45.8 (53.03)	NC (NC)	NC	
N=2	Week 24	2 (100.0)	29.2 (41.22)			

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group. Transformed score ranges from 0 to 100 based on Likert scale (None of the time, a little of the time, some of the time, most of the time and all of the time). Higher scores are indicative of better health-related quality of life (high score = good). For the change from baseline, positive scores indicate improvement.
[1] Summary statistics are based on observed data.
[2] LS means, LS mean differences (95% CIs), p-value and Hedges' g (95% CIs) are based on a mixed-effects model with study, treatment, visit, and a treatment-by-visit interaction as fixed effects. The multiple visits for each patient are the repeated measures as a random effect within each patient with an unstructured covariance. Hedges' g is calculated using a small sample bias correction. Interaction p-value is only produced for the Overall period. The reference group for the LS mean difference and Hedges' g is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with data; CI: Confidence interval; LS: Least squares; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; SD: Standard deviation; SE: Standard error; SMD: Standardized mean difference; UFS-QoL: Uterine Fibroid Symptom and Health-Related Quality of Life; NC: Not calculated.

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Table EFF.UFSSCONS.MITT.Pooled.S8: Summary of Change from Baseline in UFS-QoL Self-Conciousness Scale Score by Visit and Overall, by Subgroup (mITT Population)

Study: Pooled

Treatment	Study visit	n (%)[1]	Mean (SD)[1]	Change from baseline LS-mean change (SE)[2]	Difference LS-mean change [95% CI] p-value[2]	SMD Hedges' g [95% CI][2]	Int. p-value[2]
Ethnicity							
Hispanic or Latino							0.9595
Relugolix+E2/NETA	Baseline	52 (100.0)	34.5 (25.62)	34.13 (3.763)	20.19	0.70	
N=52	Overall	49 (94.2)	67.6 (25.09)		[9.83,30.55]	[0.30,1.10]	
Placebo	Baseline	55 (100.0)	28.2 (25.93)	13.94 (3.673)	0.0001		
N=55	Overall	51 (92.7)	41.7 (27.72)				
Not Hispanic or Latino							
Relugolix+E2/NETA	Baseline	193 (98.0)	38.5 (29.03)	28.53 (2.028)	20.49	0.71	
N=197	Overall	176 (89.3)	67.7 (27.79)		[14.90,26.09]	[0.50,0.93]	
Placebo	Baseline	197 (99.0)	37.8 (29.25)	8.04 (1.994)	<.0001		
N=199	Overall	180 (90.5)	44.2 (26.39)				
Not reported							
Relugolix+E2/NETA	Baseline	4 (100.0)	52.1 (44.30)	NC (NC)	NC	NC	
N=4	Overall	3 (75.0)	75.0 (23.21)		[NC,NC]	[NC,NC]	
Placebo	Baseline	2 (100.0)	45.8 (53.03)	NC (NC)	NC		
N=2	Overall	2 (100.0)	33.3 (41.26)				

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group. Transformed score ranges from 0 to 100 based on Likert scale (None of the time, a little of the time, some of the time, most of the time and all of the time). Higher scores are indicative of better health-related quality of life (high score = good). For the change from baseline, positive scores indicate improvement.
[1] Summary statistics are based on observed data. Mean (SD) are calculated based on the mean observed value across all post-baseline visits within each patient.
[2] LS means, LS mean differences (95% CIs), p-value and Hedges' g (95% CIs) are based on a mixed-effects model with study, treatment, visit, subgroup, treatment-by-visit interaction and a subgroup-by-treatment interaction as fixed effects. The multiple visits for each patient are the repeated measures as a random effect within each patient with an unstructured covariance. Hedges' g is calculated using a small sample bias correction. Not reported subgroup levels are not included in estimation of the interaction p-value. The reference group for the LS mean difference and Hedges' g is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with data; CI: Confidence interval; int: Interaction; LS: Least squares; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; SD: Standard deviation; SE: Standard error; SMD: Standardized mean difference; UFS-QoL: Uterine Fibroid Symptom and Health-Related Quality of Life; NC: Not calculated.

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1.2.13 Summary of Change from Baseline in UFS-QoL Symptom Severity Scale Score by Visit and Overall, by Subgroup (mITT Population)

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Table EFF.UFSSSS.MITT.Pooled.S9: Summary of Change from Baseline in UFS-QoL Symptom Severity Scale Score by Visit and Overall, by Subgroup (mITT Population)						
Study: Pooled						
Treatment	**Study visit**	**n (%)[1]**	**Mean (SD)[1]**	**Change from baseline LS-mean change (SE)[2]**	**Difference LS-mean change [95% CI] p-value[2]**	**SMD Hedges' g [95% CI][2]**
Race						
Black/African American						
Relugolix+E2/NETA	Baseline	119 (97.5)	63.9 (20.98)	-30.18 (2.531)	-18.24	-0.71
N=122	Week 12	105 (86.1)	35.5 (26.42)		[-25.01,-11.47]	[-0.99,-0.44]
Placebo	Baseline	139 (98.6)	60.0 (19.23)	-11.95 (2.324)	<.0001	
N=141	Week 12	122 (86.5)	47.5 (20.97)			
White						
Relugolix+E2/NETA	Baseline	121 (99.2)	52.7 (19.91)	-25.70 (2.115)	-16.30	-0.74
N=122	Week 12	110 (90.2)	26.6 (21.34)		[-22.38,-10.22]	[-1.02,-0.46]
Placebo	Baseline	105 (100.0)	60.1 (19.02)	-9.40 (2.245)	<.0001	
N=105	Week 12	98 (93.3)	50.7 (19.09)			
Asian						
Relugolix+E2/NETA	Baseline	1 (100.0)	56.3 (NE)	NC (NC)	NC	NC
N=1	Week 12	1 (100.0)	18.8 (NE)		[NC,NC]	[NC,NC]
Placebo	Baseline	3 (100.0)	79.2 (20.08)	NC (NC)	NC	
N=3	Week 12	3 (100.0)	68.8 (20.48)			
Others						
Relugolix+E2/NETA	Baseline	5 (100.0)	48.1 (18.30)	-24.64 (12.977)	-6.21	-0.23
N=5	Week 12	5 (100.0)	30.0 (16.89)		[-49.34,36.92]	[-1.35,0.90]
Placebo	Baseline	6 (100.0)	76.6 (16.37)	-18.44 (12.327)	0.7437	
N=6	Week 12	5 (83.3)	53.1 (36.16)			
Not reported						
Relugolix+E2/NETA	Baseline	3 (100.0)	35.4 (34.45)	NC (NC)	NC	NC
N=3	Week 12	3 (100.0)	17.7 (17.78)		[NC,NC]	[NC,NC]
Placebo	Baseline	1 (100.0)	40.6 (NE)	NC (NC)	NC	

N=1	Week 12	1 (100.0)	50.0 (NE)			

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group. Transformed score ranges from 0 to 100 based on Likert scale (Not at all, a little bit, somewhat, a great deal and a very great deal). Higher scores are indicative of greater symptom severity and lower scores indicate lower symptom severity (low score = good). For the change from baseline, negative scores indicate improvement.
[1] Summary statistics are based on observed data.
[2] LS means, LS mean differences (95% CIs), p-value and Hedges' g (95% CIs) are based on a mixed-effects model with study, treatment, visit, and a treatment-by-visit interaction as fixed effects. The multiple visits for each patient are the repeated measures as a random effect within each patient with an unstructured covariance. Hedges' g is calculated using a small sample bias correction. Interaction p-value is only produced for the Overall period. The reference group for the LS mean difference and Hedges' g is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with data; CI: Confidence interval; LS: Least squares; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; SD: Standard deviation; SE: Standard error; SMD: Standardized mean difference; UFS-QoL: Uterine Fibroid Symptom and Health-Related Quality of Life; NC: Not calculated; NE: Non-estimable.

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Table EFF.UFSSSS.MITT.Pooled.S9: Summary of Change from Baseline in UFS-QoL Symptom Severity Scale Score by Visit and Overall, by Subgroup (mITT Population)						
Study: Pooled						
Treatment	**Study visit**	**n (%)[1]**	**Mean (SD)[1]**	**Change from baseline LS-mean change (SE)[2]**	**Difference LS-mean change [95% CI] p-value[2]**	**SMD Hedges' g [95% CI][2]**
Race						
Black/African American						
Relugolix+E2/NETA	Baseline	119 (97.5)	63.9 (20.98)	-36.15 (2.583)	-23.68	-0.95
N=122	Week 24	87 (71.3)	26.4 (22.60)		[-30.53,-16.84]	[-1.25,-0.65]
Placebo	Baseline	139 (98.6)	60.0 (19.23)	-12.47 (2.324)	<.0001	
N=141	Week 24	108 (76.6)	47.3 (24.48)			
White						
Relugolix+E2/NETA	Baseline	121 (99.2)	52.7 (19.91)	-32.62 (2.291)	-20.12	-0.85
N=122	Week 24	100 (82.0)	18.1 (20.38)		[-26.76,-13.48]	[-1.15,-0.55]
Placebo	Baseline	105 (100.0)	60.1 (19.02)	-12.51 (2.470)	<.0001	
N=105	Week 24	84 (80.0)	47.3 (21.95)			
Asian						
Relugolix+E2/NETA	Baseline	1 (100.0)	56.3 (NE)	NC (NC)	NC	NC
N=1	Week 24	1 (100.0)	0.0 (NE)		[NC,NC]	[NC,NC]
Placebo	Baseline	3 (100.0)	79.2 (20.08)	NC (NC)	NC	
N=3	Week 24	2 (66.7)	71.9 (22.06)			
Others						
Relugolix+E2/NETA	Baseline	5 (100.0)	48.1 (18.30)	-17.78 (9.725)	-10.54	-0.55
N=5	Week 24	5 (100.0)	36.9 (25.69)		[-45.28,24.19]	[-1.74,0.65]
Placebo	Baseline	6 (100.0)	76.6 (16.37)	-7.24 (9.868)	0.4961	
N=6	Week 24	4 (66.7)	64.9 (18.79)			
Not reported						
Relugolix+E2/NETA	Baseline	3 (100.0)	35.4 (34.45)	NC (NC)	NC	NC
N=3	Week 24	3 (100.0)	11.5 (7.90)		[NC,NC]	[NC,NC]
Placebo	Baseline	1 (100.0)	40.6 (NE)	NC (NC)	NC	

N=1	Week 24	1 (100.0)	28.1 (NE)			

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group. Transformed score ranges from 0 to 100 based on Likert scale (Not at all, a little bit, somewhat, a great deal and a very great deal). Higher scores are indicative of greater symptom severity and lower scores indicate lower symptom severity (low score = good). For the change from baseline, negative scores indicate improvement.
[1] Summary statistics are based on observed data.
[2] LS means, LS mean differences (95% CIs), p-value and Hedges' g (95% CIs) are based on a mixed-effects model with study, treatment, visit, and a treatment-by-visit interaction as fixed effects. The multiple visits for each patient are the repeated measures as a random effect within each patient with an unstructured covariance. Hedges' g is calculated using a small sample bias correction. Interaction p-value is only produced for the Overall period. The reference group for the LS mean difference and Hedges' g is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with data; CI: Confidence interval; LS: Least squares; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; SD: Standard deviation; SE: Standard error; SMD: Standardized mean difference; UFS-QoL: Uterine Fibroid Symptom and Health-Related Quality of Life; NC: Not calculated; NE: Non-estimable.

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Table EFF.UFSSSS.MITT.Pooled.S9: Summary of Change from Baseline in UFS-QoL Symptom Severity Scale Score by Visit and Overall, by Subgroup (mITT Population)							
Study: Pooled							
Treatment	**Study visit**	**n (%)[1]**	**Mean (SD)[1]**	**Change from baseline LS-mean change (SE)[2]**	**Difference LS-mean change [95% CI] p-value[2]**	**SMD Hedges' g [95% CI][2]**	**Int. p-value[2]**
Race							
Black/African American							
Relugolix+E2/NETA	Baseline	119 (97.5)	63.9 (20.98)	-33.15 (2.196)	-20.89	-0.87	0.2623
N=122	Overall	107 (87.7)	32.5 (23.26)		[-26.73,-15.05]	[-1.14,-0.60]	
Placebo	Baseline	139 (98.6)	60.0 (19.23)	-12.26 (2.003)	<.0001		
N=141	Overall	126 (89.4)	47.3 (20.23)				
White							
Relugolix+E2/NETA	Baseline	121 (99.2)	52.7 (19.91)	-29.19 (2.110)	-18.25	-0.76	
N=122	Overall	112 (91.8)	23.4 (18.90)		[-24.31,-12.19]	[-1.04,-0.48]	
Placebo	Baseline	105 (100.0)	60.1 (19.02)	-10.94 (2.252)	<.0001		
N=105	Overall	98 (93.3)	49.6 (18.87)				
Asian							
Relugolix+E2/NETA	Baseline	1 (100.0)	56.3 (NE)	NC (NC)	NC	NC	
N=1	Overall	1 (100.0)	9.4 (NE)		[NC,NC]	[NC,NC]	
Placebo	Baseline	3 (100.0)	79.2 (20.08)	NC (NC)	NC		
N=3	Overall	3 (100.0)	70.3 (18.00)				
Others							
Relugolix+E2/NETA	Baseline	5 (100.0)	48.1 (18.30)	-15.22 (9.850)	1.96	0.07	
N=5	Overall	5 (100.0)	33.5 (19.13)		[-25.65,29.57]	[-1.05,1.19]	
Placebo	Baseline	6 (100.0)	76.6 (16.37)	-17.18 (10.000)	0.8892		
N=6	Overall	5 (83.3)	56.0 (27.26)				
Not reported							
Relugolix+E2/NETA	Baseline	3 (100.0)	35.4 (34.45)	NC (NC)	NC	NC	
N=3	Overall	3 (100.0)	14.6 (11.75)		[NC,NC]	[NC,NC]	
Placebo	Baseline	1 (100.0)	40.6 (NE)	NC (NC)	NC		

N=1	Overall	1 (100.0)	39.1 (NE)				

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group. Transformed score ranges from 0 to 100 based on Likert scale (Not at all, a little bit, somewhat, a great deal and a very great deal). Higher scores are indicative of greater symptom severity and lower scores indicate lower symptom severity (low score = good). For the change from baseline, negative scores indicate improvement.
[1] Summary statistics are based on observed data. Mean (SD) are calculated based on the mean observed value across all post-baseline visits within each patient.
[2] LS means, LS mean differences (95% CIs), p-value and Hedges' g (95% CIs) are based on a mixed-effects model with study, treatment, visit, subgroup, treatment-by-visit interaction and a subgroup-by-treatment interaction as fixed effects. The multiple visits for each patient are the repeated measures as a random effect within each patient with an unstructured covariance. Hedges' g is calculated using a small sample bias correction. Not reported subgroup levels are not included in estimation of the interaction p-value. Subgroup levels with fewer than 10 subjects are not included in estimation of the interaction p-value. The reference group for the LS mean difference and Hedges' g is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with data; CI: Confidence interval; int: Interaction; LS: Least squares; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; SD: Standard deviation; SE: Standard error; SMD: Standardized mean difference; UFS-QoL: Uterine Fibroid Symptom and Health-Related Quality of Life; NC: Not calculated; NE: Non-estimable.

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Table EFF.UFSSSS.MITT.Pooled.S2: Summary of Change from Baseline in UFS-QoL Symptom Severity Scale Score by Visit and Overall, by Subgroup (mITT Population)

Study: Pooled

Treatment	Study visit	n (%)[1]	Mean (SD)[1]	Change from baseline LS-mean change (SE)[2]	Difference LS-mean change [95% CI] p-value[2]	SMD Hedges' g [95% CI][2]
BMI (kg/m2) at Baseline						
< 30						
Relugolix+E2/NETA	Baseline	118 (99.2)	56.3 (23.22)	-27.52 (2.039)	-20.38	-0.98
N=119	Week 12	104 (87.4)	28.1 (22.69)		[-26.10,-14.65]	[-1.28,-0.69]
Placebo	Baseline	115 (100.0)	59.7 (19.97)	-7.14 (2.066)	<.0001	
N=115	Week 12	100 (87.0)	52.4 (20.79)			
>= 30						
Relugolix+E2/NETA	Baseline	130 (97.7)	58.9 (19.45)	-27.21 (2.409)	-13.16	-0.51
N=133	Week 12	119 (89.5)	33.1 (25.01)		[-19.73,-6.58]	[-0.76,-0.25]
Placebo	Baseline	139 (98.6)	61.2 (18.70)	-14.05 (2.310)	0.0001	
N=141	Week 12	129 (91.5)	46.9 (20.16)			
Missing						
Relugolix+E2/NETA	Baseline	1 (100.0)	81.3 (NE)	NC (NC)	NC	NC
N=1	Week 12	1 (100.0)	6.3 (NE)		[NC,NC]	[NC,NC]
Placebo	Baseline	0	NE (NE)	NC (NC)	NC	
N=0	Week 12	0	NE (NE)			

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group. Transformed score ranges from 0 to 100 based on Likert scale (Not at all, a little bit, somewhat, a great deal and a very great deal). Higher scores are indicative of greater symptom severity and lower scores indicate lower symptom severity (low score = good). For the change from baseline, negative scores indicate improvement.
[1] Summary statistics are based on observed data.
[2] LS means, LS mean differences (95% CIs), p-value and Hedges' g (95% CIs) are based on a mixed-effects model with study, treatment, visit, and a treatment-by-visit interaction as fixed effects. The multiple visits for each patient are the repeated measures as a random effect within each patient with an unstructured covariance. Hedges' g is calculated using a small sample bias correction. Interaction p-value is only produced for the Overall period. The reference group for the LS mean difference and Hedges' g is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with data; CI: Confidence interval; LS: Least squares; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; SD: Standard deviation; SE: Standard error; SMD: Standardized mean difference; UFS-QoL: Uterine Fibroid Symptom and Health-Related Quality of Life; NC: Not calculated; NE: Non-estimable.

SOURCE: \Studies\MYV\MYV102\Analysis\Prod\Progs\TFLs\Tab_QOL_UFS_CON.SAS
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Table EFF.UFSSSS.MITT.Pooled.S2: Summary of Change from Baseline in UFS-QoL Symptom Severity Scale Score by Visit and Overall, by Subgroup (mITT Population)

Study: Pooled

Treatment	Study visit	n (%)[1]	Mean (SD)[1]	Change from baseline LS-mean change (SE)[2]	Difference LS-mean change [95% CI] p-value[2]	SMD Hedges' g [95% CI][2]
BMI (kg/m2) at Baseline						
< 30						
Relugolix+E2/NETA	Baseline	118 (99.2)	56.3 (23.22)	-31.59 (2.372)	-21.06	-0.91
N=119	Week 24	89 (74.8)	21.8 (22.55)		[-27.72,-14.40]	[-1.22,-0.60]
Placebo	Baseline	115 (100.0)	59.7 (19.97)	-10.54 (2.407)	<.0001	
N=115	Week 24	86 (74.8)	48.3 (22.97)			
>= 30						
Relugolix+E2/NETA	Baseline	130 (97.7)	58.9 (19.45)	-35.25 (2.352)	-21.00	-0.85
N=133	Week 24	106 (79.7)	22.5 (21.34)		[-27.42,-14.57]	[-1.12,-0.57]
Placebo	Baseline	139 (98.6)	61.2 (18.70)	-14.25 (2.260)	<.0001	
N=141	Week 24	113 (80.1)	47.4 (23.81)			
Missing						
Relugolix+E2/NETA	Baseline	1 (100.0)	81.3 (NE)	NC (NC)	NC	NC
N=1	Week 24	1 (100.0)	3.1 (NE)		[NC,NC]	[NC,NC]
Placebo	Baseline	0	NE (NE)	NC (NC)	NC	
N=0	Week 24	0	NE (NE)			

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group. Transformed score ranges from 0 to 100 based on Likert scale (Not at all, a little bit, somewhat, a great deal and a very great deal). Higher scores are indicative of greater symptom severity and lower scores indicate lower symptom severity (low score = good). For the change from baseline, negative scores indicate improvement.
[1] Summary statistics are based on observed data.
[2] LS means, LS mean differences (95% CIs), p-value and Hedges' g (95% CIs) are based on a mixed-effects model with study, treatment, visit, and a treatment-by-visit interaction as fixed effects. The multiple visits for each patient are the repeated measures as a random effect within each patient with an unstructured covariance. Hedges' g is calculated using a small sample bias correction. Interaction p-value is only produced for the Overall period. The reference group for the LS mean difference and Hedges' g is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with data; CI: Confidence interval; LS: Least squares; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; SD: Standard deviation; SE: Standard error; SMD: Standardized mean difference; UFS-QoL: Uterine Fibroid Symptom and Health-Related Quality of Life; NC: Not calculated; NE: Non-estimable.

SOURCE: \Studies\MYV\MYV102\Analysis\Prod\Progs\TFLs\Tab_QOL_UFS_CON.SAS
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Table EFF.UFSSSS.MITT.Pooled.S2: Summary of Change from Baseline in UFS-QoL Symptom Severity Scale Score by Visit and Overall, by Subgroup (mITT Population)

Study: Pooled

Treatment	Study visit	n (%)[1]	Mean (SD)[1]	Change from baseline LS-mean change (SE)[2]	Difference LS-mean change [95% CI] p-value[2]	SMD Hedges' g [95% CI][2]	Int. p-value[2]
BMI (kg/m2) at Baseline							
< 30							
Relugolix+E2/NETA	Baseline	118 (99.2)	56.3 (23.22)	-29.69 (2.159)	-21.01	-0.88	0.3340
N=119	Overall	106 (89.1)	26.4 (21.34)		[-27.05,-14.98]	[-1.16,-0.60]	
Placebo	Baseline	115 (100.0)	59.7 (19.97)	-8.67 (2.184)	<.0001		
N=115	Overall	103 (89.6)	51.0 (19.92)				
>= 30							
Relugolix+E2/NETA	Baseline	130 (97.7)	58.9 (19.45)	-31.12 (2.031)	-16.99	-0.71	
N=133	Overall	121 (91.0)	29.0 (21.52)		[-22.52,-11.45]	[-0.97,-0.45]	
Placebo	Baseline	139 (98.6)	61.2 (18.70)	-14.14 (1.950)	<.0001		
N=141	Overall	130 (92.2)	46.9 (19.68)				
Missing							
Relugolix+E2/NETA	Baseline	1 (100.0)	81.3 (NE)	NC (NC)	NC	NC	
N=1	Overall	1 (100.0)	4.7 (NE)		[NC,NC]	[NC,NC]	
Placebo	Baseline	0	NE (NE)	NC (NC)	NC		
N=0	Overall	0	NE (NE)				

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group. Transformed score ranges from 0 to 100 based on Likert scale (Not at all, a little bit, somewhat, a great deal and a very great deal). Higher scores are indicative of greater symptom severity and lower scores indicate lower symptom severity (low score = good). For the change from baseline, negative scores indicate improvement.
[1] Summary statistics are based on observed data. Mean (SD) are calculated based on the mean observed value across all post-baseline visits within each patient.
[2] LS means, LS mean differences (95% CIs), p-value and Hedges' g (95% CIs) are based on a mixed-effects model with study, treatment, visit, subgroup, treatment-by-visit interaction and a subgroup-by-treatment interaction as fixed effects. The multiple visits for each patient are the repeated measures as a random effect within each patient with an unstructured covariance. Hedges' g is calculated using a small sample bias correction. Missing subgroup levels are not included in estimation of the interaction p-value. The reference group for the LS mean difference and Hedges' g is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with data; CI: Confidence interval; int: Interaction; LS: Least squares; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; SD: Standard deviation; SE: Standard error; SMD: Standardized mean difference; UFS-QoL: Uterine Fibroid Symptom and Health-Related Quality of Life; NC: Not calculated; NE: Non-estimable.

SOURCE: \Studies\MYV\MYV102\Analysis\Prod\Progs\TFLs\Tab_QOL_UFS_CON.SAS
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Table EFF.UFSSSS.MITT.Pooled.S6: Summary of Change from Baseline in UFS-QoL Symptom Severity Scale Score by Visit and Overall, by Subgroup (mITT Population)

Study: Pooled

Treatment	Study visit	n (%)[1]	Mean (SD)[1]	Change from baseline LS-mean change (SE)[2]	Difference LS-mean change [95% CI] p-value[2]	SMD Hedges' g [95% CI][2]
Geographic Region I						
North America						
Relugolix+E2/NETA	Baseline	188 (98.4)	60.0 (21.83)	-27.38 (2.003)	-15.69	-0.62
N=191	Week 12	165 (86.4)	33.1 (24.85)		[-21.21,-10.18]	[-0.83,-0.40]
Placebo	Baseline	192 (99.0)	61.4 (19.07)	-11.69 (1.962)	<.0001	
N=194	Week 12	172 (88.7)	49.3 (21.35)			
Rest of World						
Relugolix+E2/NETA	Baseline	61 (98.4)	51.0 (18.28)	-28.03 (2.417)	-19.40	-1.05
N=62	Week 12	59 (95.2)	24.0 (20.34)		[-26.18,-12.63]	[-1.44,-0.67]
Placebo	Baseline	62 (100.0)	57.9 (19.74)	-8.63 (2.419)	<.0001	
N=62	Week 12	57 (91.9)	49.3 (18.20)			

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group. Transformed score ranges from 0 to 100 based on Likert scale (Not at all, a little bit, somewhat, a great deal and a very great deal). Higher scores are indicative of greater symptom severity and lower scores indicate lower symptom severity (low score = good). For the change from baseline, negative scores indicate improvement.
[1] Summary statistics are based on observed data.
[2] LS means, LS mean differences (95% CIs), p-value and Hedges' g (95% CIs) are based on a mixed-effects model with study, treatment, visit, and a treatment-by-visit interaction as fixed effects. The multiple visits for each patient are the repeated measures as a random effect within each patient with an unstructured covariance. Hedges' g is calculated using a small sample bias correction. Interaction p-value is only produced for the Overall period. The reference group for the LS mean difference and Hedges' g is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with data; CI: Confidence interval; LS: Least squares; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; SD: Standard deviation; SE: Standard error; SMD: Standardized mean difference; UFS-QoL: Uterine Fibroid Symptom and Health-Related Quality of Life.

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Table EFF.UFSSSS.MITT.Pooled.S6: Summary of Change from Baseline in UFS-QoL Symptom Severity Scale Score by Visit and Overall, by Subgroup (mITT Population)

Study: Pooled

Treatment	Study visit	n (%)[1]	Mean (SD)[1]	Change from baseline LS-mean change (SE)[2]	Difference LS-mean change [95% CI] p-value[2]	SMD Hedges' g [95% CI][2]
Geographic Region I						
North America						
Relugolix+E2/NETA	Baseline	188 (98.4)	60.0 (21.83)	-33.76 (2.073)	-20.75	-0.81
N=191	Week 24	139 (72.8)	24.2 (22.63)		[-26.44,-15.06]	[-1.06,-0.57]
Placebo	Baseline	192 (99.0)	61.4 (19.07)	-13.01 (2.020)	<.0001	
N=194	Week 24	146 (75.3)	47.8 (24.15)			
Rest of World						
Relugolix+E2/NETA	Baseline	61 (98.4)	51.0 (18.28)	-33.71 (2.736)	-22.72	-1.10
N=62	Week 24	57 (91.9)	17.0 (19.01)		[-30.45,-14.99]	[-1.50,-0.70]
Placebo	Baseline	62 (100.0)	57.9 (19.74)	-10.99 (2.784)	<.0001	
N=62	Week 24	53 (85.5)	47.6 (21.40)			

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group. Transformed score ranges from 0 to 100 based on Likert scale (Not at all, a little bit, somewhat, a great deal and a very great deal). Higher scores are indicative of greater symptom severity and lower scores indicate lower symptom severity (low score = good). For the change from baseline, negative scores indicate improvement.
[1] Summary statistics are based on observed data.
[2] LS means, LS mean differences (95% CIs), p-value and Hedges' g (95% CIs) are based on a mixed-effects model with study, treatment, visit, and a treatment-by-visit interaction as fixed effects. The multiple visits for each patient are the repeated measures as a random effect within each patient with an unstructured covariance. Hedges' g is calculated using a small sample bias correction. Interaction p-value is only produced for the Overall period. The reference group for the LS mean difference and Hedges' g is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with data; CI: Confidence interval; LS: Least squares; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; SD: Standard deviation; SE: Standard error; SMD: Standardized mean difference; UFS-QoL: Uterine Fibroid Symptom and Health-Related Quality of Life.

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Table EFF.UFSSSS.MITT.Pooled.S6: Summary of Change from Baseline in UFS-QoL Symptom Severity Scale Score by Visit and Overall, by Subgroup (mITT Population)

Study: Pooled

Treatment	Study visit	n (%)[1]	Mean (SD)[1]	Change from baseline LS-mean change (SE)[2]	Difference LS-mean change [95% CI] p-value[2]	SMD Hedges' g [95% CI][2]	Int. p-value[2]
Geographic Region I							
North America							
Relugolix+E2/NETA	Baseline	188 (98.4)	60.0 (21.83)	-30.55 (1.736)	-18.18	-0.76	0.5357
N=191	Overall	169 (88.5)	29.9 (21.98)		[-22.95,-13.40]	[-0.98,-0.54]	
Placebo	Baseline	192 (99.0)	61.4 (19.07)	-12.37 (1.700)	<.0001		
N=194	Overall	174 (89.7)	48.8 (20.45)				
Rest of World							
Relugolix+E2/NETA	Baseline	61 (98.4)	51.0 (18.28)	-30.93 (2.887)	-21.12	-0.88	
N=62	Overall	59 (95.2)	21.4 (18.54)		[-29.15,-13.10]	[-1.25,-0.50]	
Placebo	Baseline	62 (100.0)	57.9 (19.74)	-9.81 (2.890)	<.0001		
N=62	Overall	59 (95.2)	48.3 (18.12)				

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group. Transformed score ranges from 0 to 100 based on Likert scale (Not at all, a little bit, somewhat, a great deal and a very great deal). Higher scores are indicative of greater symptom severity and lower scores indicate lower symptom severity (low score = good). For the change from baseline, negative scores indicate improvement.
[1] Summary statistics are based on observed data. Mean (SD) are calculated based on the mean observed value across all post-baseline visits within each patient.
[2] LS means, LS mean differences (95% CIs), p-value and Hedges' g (95% CIs) are based on a mixed-effects model with study, treatment, visit, subgroup, treatment-by-visit interaction and a subgroup-by-treatment interaction as fixed effects. The multiple visits for each patient are the repeated measures as a random effect within each patient with an unstructured covariance. Hedges' g is calculated using a small sample bias correction. The reference group for the LS mean difference and Hedges' g is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with data; CI: Confidence interval; int: Interaction; LS: Least squares; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; SD: Standard deviation; SE: Standard error; SMD: Standardized mean difference; UFS-QoL: Uterine Fibroid Symptom and Health-Related Quality of Life.

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Table EFF.UFSSSS.MITT.Pooled.S8: Summary of Change from Baseline in UFS-QoL Symptom Severity Scale Score by Visit and Overall, by Subgroup (mITT Population)

Study: Pooled

Treatment	Study visit	n (%)[1]	Mean (SD)[1]	Change from baseline LS-mean change (SE)[2]	Difference LS-mean change [95% CI] p-value[2]	SMD Hedges' g [95% CI][2]
Ethnicity						
Hispanic or Latino						
Relugolix+E2/NETA	Baseline	52 (100.0)	56.4 (21.76)	-27.65 (3.604)	-17.36	-0.72
N=52	Week 12	47 (90.4)	29.7 (20.14)		[-27.39,-7.32]	[-1.13,-0.31]
Placebo	Baseline	55 (100.0)	68.8 (16.99)	-10.30 (3.479)	0.0009	
N=55	Week 12	49 (89.1)	58.8 (22.72)			
Not Hispanic or Latino						
Relugolix+E2/NETA	Baseline	193 (98.0)	58.4 (20.98)	-27.82 (1.831)	-16.53	-0.69
N=197	Week 12	174 (88.3)	31.3 (25.09)		[-21.59,-11.47]	[-0.91,-0.48]
Placebo	Baseline	197 (99.0)	58.3 (19.30)	-11.29 (1.799)	<.0001	
N=199	Week 12	178 (89.4)	46.5 (19.14)			
Not reported						
Relugolix+E2/NETA	Baseline	4 (100.0)	43.0 (32.12)	NC (NC)	NC	NC
N=4	Week 12	3 (75.0)	12.5 (9.40)		[NC,NC]	[NC,NC]
Placebo	Baseline	2 (100.0)	56.3 (22.13)	NC (NC)	NC	
N=2	Week 12	2 (100.0)	65.7 (22.13)			

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group. Transformed score ranges from 0 to 100 based on Likert scale (Not at all, a little bit, somewhat, a great deal and a very great deal). Higher scores are indicative of greater symptom severity and lower scores indicate lower symptom severity (low score = good). For the change from baseline, negative scores indicate improvement.
[1] Summary statistics are based on observed data.
[2] LS means, LS mean differences (95% CIs), p-value and Hedges' g (95% CIs) are based on a mixed-effects model with study, treatment, visit, and a treatment-by-visit interaction as fixed effects. The multiple visits for each patient are the repeated measures as a random effect within each patient with an unstructured covariance. Hedges' g is calculated using a small sample bias correction. Interaction p-value is only produced for the Overall period. The reference group for the LS mean difference and Hedges' g is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with data; CI: Confidence interval; LS: Least squares; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; SD: Standard deviation; SE: Standard error; SMD: Standardized mean difference; UFS-QoL: Uterine Fibroid Symptom and Health-Related Quality of Life; NC: Not calculated.

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Table EFF.UFSSSS.MITT.Pooled.S8: Summary of Change from Baseline in UFS-QoL Symptom Severity Scale Score by Visit and Overall, by Subgroup (mITT Population)

Study: Pooled

Treatment	Study visit	n (%)[1]	Mean (SD)[1]	Change from baseline LS-mean change (SE)[2]	Difference LS-mean change [95% CI] p-value[2]	SMD Hedges' g [95% CI][2]
Ethnicity						
Hispanic or Latino						
Relugolix+E2/NETA	Baseline	52 (100.0)	56.4 (21.76)	-32.07 (4.025)	-17.09	-0.63
N=52	Week 24	44 (84.6)	24.4 (23.54)		[-28.29,-5.89]	[-1.05,-0.21]
Placebo	Baseline	55 (100.0)	68.8 (16.99)	-14.98 (3.889)	0.0032	
N=55	Week 24	46 (83.6)	53.6 (26.94)			
Not Hispanic or Latino						
Relugolix+E2/NETA	Baseline	193 (98.0)	58.4 (20.98)	-34.52 (1.852)	-22.62	-0.97
N=197	Week 24	149 (75.6)	21.7 (21.47)		[-27.74,-17.50]	[-1.21,-0.73]
Placebo	Baseline	197 (99.0)	58.3 (19.30)	-11.90 (1.824)	<.0001	
N=199	Week 24	151 (75.9)	45.8 (21.67)			
Not reported						
Relugolix+E2/NETA	Baseline	4 (100.0)	43.0 (32.12)	NC (NC)	NC	NC
N=4	Week 24	3 (75.0)	8.3 (4.79)		[NC,NC]	[NC,NC]
Placebo	Baseline	2 (100.0)	56.3 (22.13)	NC (NC)	NC	
N=2	Week 24	2 (100.0)	64.1 (50.84)			

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group. Transformed score ranges from 0 to 100 based on Likert scale (Not at all, a little bit, somewhat, a great deal and a very great deal). Higher scores are indicative of greater symptom severity and lower scores indicate lower symptom severity (low score = good). For the change from baseline, negative scores indicate improvement.
[1] Summary statistics are based on observed data.
[2] LS means, LS mean differences (95% CIs), p-value and Hedges' g (95% CIs) are based on a mixed-effects model with study, treatment, visit, and a treatment-by-visit interaction as fixed effects. The multiple visits for each patient are the repeated measures as a random effect within each patient with an unstructured covariance. Hedges' g is calculated using a small sample bias correction. Interaction p-value is only produced for the Overall period. The reference group for the LS mean difference and Hedges' g is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with data; CI: Confidence interval; LS: Least squares; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; SD: Standard deviation; SE: Standard error; SMD: Standardized mean difference; UFS-QoL: Uterine Fibroid Symptom and Health-Related Quality of Life; NC: Not calculated.

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Table EFF.UFSSSS.MITT.Pooled.S8: Summary of Change from Baseline in UFS-QoL Symptom Severity Scale Score by Visit and Overall, by Subgroup (mITT Population)

Study: Pooled

Treatment	Study visit	n (%)[1]	Mean (SD)[1]	Change from baseline LS-mean change (SE)[2]	Difference LS-mean change [95% CI] p-value[2]	SMD Hedges' g [95% CI][2]	Int. p-value[2]
Ethnicity							
Hispanic or Latino							
Relugolix+E2/NETA	Baseline	52 (100.0)	56.4 (21.76)	-29.60 (3.187)	-16.97	-0.70	0.6302
N=52	Overall	49 (94.2)	27.5 (18.57)		[-25.74,-8.20]	[-1.10,-0.30]	
Placebo	Baseline	55 (100.0)	68.8 (16.99)	-12.63 (3.110)	0.0002		
N=55	Overall	51 (92.7)	56.8 (22.60)				
Not Hispanic or Latino							
Relugolix+E2/NETA	Baseline	193 (98.0)	58.4 (20.98)	-31.10 (1.700)	-19.42	-0.81	
N=197	Overall	176 (89.3)	28.0 (22.27)		[-24.11,-14.72]	[-1.03,-0.59]	
Placebo	Baseline	197 (99.0)	58.3 (19.30)	-11.69 (1.672)	<.0001		
N=199	Overall	180 (90.5)	46.2 (18.24)				
Not reported							
Relugolix+E2/NETA	Baseline	4 (100.0)	43.0 (32.12)	NC (NC)	NC	NC	
N=4	Overall	3 (75.0)	10.4 (4.53)		[NC,NC]	[NC,NC]	
Placebo	Baseline	2 (100.0)	56.3 (22.13)	NC (NC)	NC		
N=2	Overall	2 (100.0)	64.9 (36.49)				

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group. Transformed score ranges from 0 to 100 based on Likert scale (Not at all, a little bit, somewhat, a great deal and a very great deal). Higher scores are indicative of greater symptom severity and lower scores indicate lower symptom severity (low score = good). For the change from baseline, negative scores indicate improvement.
[1] Summary statistics are based on observed data. Mean (SD) are calculated based on the mean observed value across all post-baseline visits within each patient.
[2] LS means, LS mean differences (95% CIs), p-value and Hedges' g (95% CIs) are based on a mixed-effects model with study, treatment, visit, subgroup, treatment-by-visit interaction and a subgroup-by-treatment interaction as fixed effects. The multiple visits for each patient are the repeated measures as a random effect within each patient with an unstructured covariance. Hedges' g is calculated using a small sample bias correction. Not reported subgroup levels are not included in estimation of the interaction p-value. The reference group for the LS mean difference and Hedges' g is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with data; CI: Confidence interval; int: Interaction; LS: Least squares; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; SD: Standard deviation; SE: Standard error; SMD: Standardized mean difference; UFS-QoL: Uterine Fibroid Symptom and Health-Related Quality of Life; NC: Not calculated.

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Table EFF.UFSSSS.MITT.Pooled.S1: Summary of Change from Baseline in UFS-QoL Symptom Severity Scale Score by Visit and Overall, by Subgroup (mITT Population)

Study: Pooled

Treatment	Study visit	n (%)[1]	Mean (SD)[1]	Change from baseline LS-mean change (SE)[2]	Difference LS-mean change [95% CI] p-value[2]	SMD Hedges' g [95% CI][2]
Age (years)						
< 40 years						
Relugolix+E2/NETA	Baseline	61 (98.4)	61.4 (21.28)	-27.08 (3.080)	-15.43	-0.67
N=62	Week 12	57 (91.9)	34.4 (24.27)		[-23.65,-7.21]	[-1.03,-0.31]
Placebo	Baseline	78 (100.0)	59.5 (20.12)	-11.65 (2.789)	0.0003	
N=78	Week 12	68 (87.2)	47.5 (21.19)			
>= 40 years						
Relugolix+E2/NETA	Baseline	188 (98.4)	56.6 (21.26)	-27.72 (1.896)	-17.09	-0.70
N=191	Week 12	167 (87.4)	29.4 (23.90)		[-22.40,-11.77]	[-0.93,-0.48]
Placebo	Baseline	176 (98.9)	61.0 (18.90)	-10.63 (1.926)	<.0001	
N=178	Week 12	161 (90.4)	50.0 (20.32)			

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group. Transformed score ranges from 0 to 100 based on Likert scale (Not at all, a little bit, somewhat, a great deal and a very great deal). Higher scores are indicative of greater symptom severity and lower scores indicate lower symptom severity (low score = good). For the change from baseline, negative scores indicate improvement.
[1] Summary statistics are based on observed data.
[2] LS means, LS mean differences (95% CIs), p-value and Hedges' g (95% CIs) are based on a mixed-effects model with study, treatment, visit, and a treatment-by-visit interaction as fixed effects. The multiple visits for each patient are the repeated measures as a random effect within each patient with an unstructured covariance. Hedges' g is calculated using a small sample bias correction. Interaction p-value is only produced for the Overall period. The reference group for the LS mean difference and Hedges' g is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with data; CI: Confidence interval; LS: Least squares; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; SD: Standard deviation; SE: Standard error; SMD: Standardized mean difference; UFS-QoL: Uterine Fibroid Symptom and Health-Related Quality of Life.

SOURCE: \Studies\MYV\MYV102\Analysis\Prod\Progs\TFLs\Tab_QOL_UFS_CON.SAS
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Table EFF.UFSSSS.MITT.Pooled.S1: Summary of Change from Baseline in UFS-QoL Symptom Severity Scale Score by Visit and Overall, by Subgroup (mITT Population)

Study: Pooled

Treatment	Study visit	n (%)[1]	Mean (SD)[1]	Change from baseline LS-mean change (SE)[2]	Difference LS-mean change [95% CI] p-value[2]	SMD Hedges' g [95% CI][2]
Age (years)						
< 40 years						
Relugolix+E2/NETA	Baseline	61 (98.4)	61.4 (21.28)	-32.22 (3.416)	-19.50	-0.79
N=62	Week 24	47 (75.8)	28.7 (23.52)		[-28.58,-10.42]	[-1.19,-0.40]
Placebo	Baseline	78 (100.0)	59.5 (20.12)	-12.72 (3.065)	<.0001	
N=78	Week 24	58 (74.4)	45.4 (24.28)			
>= 40 years						
Relugolix+E2/NETA	Baseline	188 (98.4)	56.6 (21.26)	-34.31 (1.929)	-21.89	-0.91
N=191	Week 24	149 (78.0)	20.0 (20.92)		[-27.31,-16.46]	[-1.15,-0.66]
Placebo	Baseline	176 (98.9)	61.0 (18.90)	-12.42 (1.971)	<.0001	
N=178	Week 24	141 (79.2)	48.7 (23.04)			

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group. Transformed score ranges from 0 to 100 based on Likert scale (Not at all, a little bit, somewhat, a great deal and a very great deal). Higher scores are indicative of greater symptom severity and lower scores indicate lower symptom severity (low score = good). For the change from baseline, negative scores indicate improvement.
[1] Summary statistics are based on observed data.
[2] LS means, LS mean differences (95% CIs), p-value and Hedges' g (95% CIs) are based on a mixed-effects model with study, treatment, visit, and a treatment-by-visit interaction as fixed effects. The multiple visits for each patient are the repeated measures as a random effect within each patient with an unstructured covariance. Hedges' g is calculated using a small sample bias correction. Interaction p-value is only produced for the Overall period. The reference group for the LS mean difference and Hedges' g is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with data; CI: Confidence interval; LS: Least squares; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; SD: Standard deviation; SE: Standard error; SMD: Standardized mean difference; UFS-QoL: Uterine Fibroid Symptom and Health-Related Quality of Life.

SOURCE: \Studies\MYV\MYV102\Analysis\Prod\Progs\TFLs\Tab_QOL_UFS_CON.SAS
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Table EFF.UFSSSS.MITT.Pooled.S1: Summary of Change from Baseline in UFS-QoL Symptom Severity Scale Score by Visit and Overall, by Subgroup (mITT Population)

Study: Pooled

Treatment	Study visit	n (%)[1]	Mean (SD)[1]	Change from baseline LS-mean change (SE)[2]	Difference LS-mean change [95% CI] p-value[2]	SMD Hedges' g [95% CI][2]	Int. p-value[2]
Age (years)							
< 40 years							
Relugolix+E2/NETA	Baseline	61 (98.4)	61.4 (21.28)	-29.71 (2.982)	-17.49	-0.73	0.6757
N=62	Overall	57 (91.9)	32.3 (22.15)		[-25.39,-9.59]	[-1.09,-0.36]	
Placebo	Baseline	78 (100.0)	59.5 (20.12)	-12.21 (2.697)	<.0001		
N=78	Overall	68 (87.2)	47.1 (21.38)				
>= 40 years							
Relugolix+E2/NETA	Baseline	188 (98.4)	56.6 (21.26)	-30.97 (1.716)	-19.46	-0.81	
N=191	Overall	171 (89.5)	26.2 (21.03)		[-24.27,-14.65]	[-1.03,-0.59]	
Placebo	Baseline	176 (98.9)	61.0 (18.90)	-11.51 (1.746)	<.0001		
N=178	Overall	165 (92.7)	49.4 (19.21)				

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group. Transformed score ranges from 0 to 100 based on Likert scale (Not at all, a little bit, somewhat, a great deal and a very great deal). Higher scores are indicative of greater symptom severity and lower scores indicate lower symptom severity (low score = good). For the change from baseline, negative scores indicate improvement.
[1] Summary statistics are based on observed data. Mean (SD) are calculated based on the mean observed value across all post-baseline visits within each patient.
[2] LS means, LS mean differences (95% CIs), p-value and Hedges' g (95% CIs) are based on a mixed-effects model with study, treatment, visit, subgroup, treatment-by-visit interaction and a subgroup-by-treatment interaction as fixed effects. The multiple visits for each patient are the repeated measures as a random effect within each patient with an unstructured covariance. Hedges' g is calculated using a small sample bias correction. The reference group for the LS mean difference and Hedges' g is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with data; CI: Confidence interval; int: Interaction; LS: Least squares; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; SD: Standard deviation; SE: Standard error; SMD: Standardized mean difference; UFS-QoL: Uterine Fibroid Symptom and Health-Related Quality of Life.

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Table EFF.UFSSSS.MITT.Pooled.S7: Summary of Change from Baseline in UFS-QoL Symptom Severity Scale Score by Visit and Overall, by Subgroup (mITT Population)

Study: Pooled

Treatment	Study visit	n (%)[1]	Mean (SD)[1]	Change from baseline LS-mean change (SE)[2]	Difference LS-mean change [95% CI] p-value[2]	SMD Hedges' g [95% CI][2]
Geographic Region II						
Europe						
Relugolix+E2/NETA	Baseline	40 (97.6)	49.2 (17.05)	-26.95 (3.053)	-16.93	-0.90
N=41	Week 12	39 (95.1)	23.2 (21.27)		[-25.50,-8.35]	[-1.37,-0.44]
Placebo	Baseline	42 (100.0)	53.8 (19.06)	-10.02 (3.057)	0.0002	
N=42	Week 12	39 (92.9)	44.7 (13.69)			
Rest of World (including the US)						
Relugolix+E2/NETA	Baseline	209 (98.6)	59.4 (21.70)	-27.73 (1.838)	-16.47	-0.66
N=212	Week 12	185 (87.3)	32.3 (24.34)		[-21.54,-11.40]	[-0.87,-0.45]
Placebo	Baseline	212 (99.1)	61.9 (19.06)	-11.26 (1.810)	<.0001	
N=214	Week 12	190 (88.8)	50.2 (21.62)			

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group. Transformed score ranges from 0 to 100 based on Likert scale (Not at all, a little bit, somewhat, a great deal and a very great deal). Higher scores are indicative of greater symptom severity and lower scores indicate lower symptom severity (low score = good). For the change from baseline, negative scores indicate improvement.
[1] Summary statistics are based on observed data.
[2] LS means, LS mean differences (95% CIs), p-value and Hedges' g (95% CIs) are based on a mixed-effects model with study, treatment, visit, and a treatment-by-visit interaction as fixed effects. The multiple visits for each patient are the repeated measures as a random effect within each patient with an unstructured covariance. Hedges' g is calculated using a small sample bias correction. Interaction p-value is only produced for the Overall period. The reference group for the LS mean difference and Hedges' g is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with data; CI: Confidence interval; LS: Least squares; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; SD: Standard deviation; SE: Standard error; SMD: Standardized mean difference; UFS-QoL: Uterine Fibroid Symptom and Health-Related Quality of Life.

SOURCE: \Studies\MYV\MYV102\Analysis\Prod\Progs\TFLs\Tab_QOL_UFS_CON.SAS
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Table EFF.UFSSSS.MITT.Pooled.S7: Summary of Change from Baseline in UFS-QoL Symptom Severity Scale Score by Visit and Overall, by Subgroup (mITT Population)

Study: Pooled

Treatment	Study visit	n (%)[1]	Mean (SD)[1]	Change from baseline LS-mean change (SE)[2]	Difference LS-mean change [95% CI] p-value[2]	SMD Hedges' g [95% CI][2]
Geographic Region II						
Europe						
Relugolix+E2/NETA	Baseline	40 (97.6)	49.2 (17.05)	-34.55 (3.088)	-22.92	-1.22
N=41	Week 24	37 (90.2)	13.4 (15.15)		[-31.67,-14.17]	[-1.72,-0.72]
Placebo	Baseline	42 (100.0)	53.8 (19.06)	-11.63 (3.144)	<.0001	
N=42	Week 24	35 (83.3)	43.3 (15.87)			
Rest of World (including the US)						
Relugolix+E2/NETA	Baseline	209 (98.6)	59.4 (21.70)	-33.55 (1.938)	-20.74	-0.82
N=212	Week 24	159 (75.0)	24.1 (22.68)		[-26.08,-15.40]	[-1.05,-0.59]
Placebo	Baseline	212 (99.1)	61.9 (19.06)	-12.80 (1.903)	<.0001	
N=214	Week 24	164 (76.6)	48.7 (24.64)			

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group. Transformed score ranges from 0 to 100 based on Likert scale (Not at all, a little bit, somewhat, a great deal and a very great deal). Higher scores are indicative of greater symptom severity and lower scores indicate lower symptom severity (low score = good). For the change from baseline, negative scores indicate improvement.
[1] Summary statistics are based on observed data.
[2] LS means, LS mean differences (95% CIs), p-value and Hedges' g (95% CIs) are based on a mixed-effects model with study, treatment, visit, and a treatment-by-visit interaction as fixed effects. The multiple visits for each patient are the repeated measures as a random effect within each patient with an unstructured covariance. Hedges' g is calculated using a small sample bias correction. Interaction p-value is only produced for the Overall period. The reference group for the LS mean difference and Hedges' g is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with data; CI: Confidence interval; LS: Least squares; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; SD: Standard deviation; SE: Standard error; SMD: Standardized mean difference; UFS-QoL: Uterine Fibroid Symptom and Health-Related Quality of Life.

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Table EFF.UFSSSS.MITT.Pooled.S7: Summary of Change from Baseline in UFS-QoL Symptom Severity Scale Score by Visit and Overall, by Subgroup (mITT Population)

Study: Pooled

Treatment	Study visit	n (%)[1]	Mean (SD)[1]	Change from baseline LS-mean change (SE)[2]	Difference LS-mean change [95% CI] p-value[2]	SMD Hedges' g [95% CI][2]	Int. p-value[2]
Geographic Region II							
Europe							0.7457
Relugolix+E2/NETA	Baseline	40 (97.6)	49.2 (17.05)	-30.69 (3.570)	-20.42	-0.84	
N=41	Overall	39 (95.1)	19.7 (19.16)		[-30.28,-10.56]	[-1.30,-0.39]	
Placebo	Baseline	42 (100.0)	53.8 (19.06)	-10.27 (3.530)	<.0001		
N=42	Overall	40 (95.2)	44.0 (13.22)				
Rest of World (including the US)							
Relugolix+E2/NETA	Baseline	209 (98.6)	59.4 (21.70)	-30.65 (1.637)	-18.63	-0.78	
N=212	Overall	189 (89.2)	29.3 (21.55)		[-23.14,-14.11]	[-0.99,-0.57]	
Placebo	Baseline	212 (99.1)	61.9 (19.06)	-12.02 (1.613)	<.0001		
N=214	Overall	193 (90.2)	49.7 (20.86)				

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group. Transformed score ranges from 0 to 100 based on Likert scale (Not at all, a little bit, somewhat, a great deal and a very great deal). Higher scores are indicative of greater symptom severity and lower scores indicate lower symptom severity (low score = good). For the change from baseline, negative scores indicate improvement.
[1] Summary statistics are based on observed data. Mean (SD) are calculated based on the mean observed value across all post-baseline visits within each patient.
[2] LS means, LS mean differences (95% CIs), p-value and Hedges' g (95% CIs) are based on a mixed-effects model with study, treatment, visit, subgroup, treatment-by-visit interaction and a subgroup-by-treatment interaction as fixed effects. The multiple visits for each patient are the repeated measures as a random effect within each patient with an unstructured covariance. Hedges' g is calculated using a small sample bias correction. The reference group for the LS mean difference and Hedges' g is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with data; CI: Confidence interval; int: Interaction; LS: Least squares; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; SD: Standard deviation; SE: Standard error; SMD: Standardized mean difference; UFS-QoL: Uterine Fibroid Symptom and Health-Related Quality of Life.

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Table EFF.UFSSSS.MITT.Pooled.S4: Summary of Change from Baseline in UFS-QoL Symptom Severity Scale Score by Visit and Overall, by Subgroup (mITT Population)

Study: Pooled

Treatment	Study visit	n (%)[1]	Mean (SD)[1]	Change from baseline LS-mean change (SE)[2]	Difference LS-mean change [95% CI] p-value[2]	SMD Hedges' g [95% CI][2]
Maximum NRS Pain Score at Baseline						
< 4						
Relugolix+E2/NETA	Baseline	72 (98.6)	50.4 (22.70)	-24.76 (2.633)	-17.35	-0.82
N=73	Week 12	65 (89.0)	26.3 (23.89)		[-25.14,-9.57]	[-1.20,-0.44]
Placebo	Baseline	61 (98.4)	53.1 (18.11)	-7.41 (2.931)	<.0001	
N=62	Week 12	52 (83.9)	47.3 (21.58)			
>= 4						
Relugolix+E2/NETA	Baseline	174 (98.3)	61.2 (19.83)	-29.10 (2.005)	-16.74	-0.68
N=177	Week 12	156 (88.1)	32.5 (24.04)		[-22.16,-11.33]	[-0.90,-0.45]
Placebo	Baseline	189 (99.5)	62.9 (18.93)	-12.36 (1.887)	<.0001	
N=190	Week 12	174 (91.6)	49.6 (20.18)			
Missing						
Relugolix+E2/NETA	Baseline	3 (100.0)	37.5 (21.87)	NC (NC)	NC	NC
N=3	Week 12	3 (100.0)	31.3 (21.91)		[NC,NC]	[NC,NC]
Placebo	Baseline	4 (100.0)	61.8 (27.53)	NC (NC)	NC	
N=4	Week 12	3 (75.0)	66.7 (24.29)			

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group. Transformed score ranges from 0 to 100 based on Likert scale (Not at all, a little bit, somewhat, a great deal and a very great deal). Higher scores are indicative of greater symptom severity and lower scores indicate lower symptom severity (low score = good). For the change from baseline, negative scores indicate improvement.
[1] Summary statistics are based on observed data.
[2] LS means, LS mean differences (95% CIs), p-value and Hedges' g (95% CIs) are based on a mixed-effects model with study, treatment, visit, and a treatment-by-visit interaction as fixed effects. The multiple visits for each patient are the repeated measures as a random effect within each patient with an unstructured covariance. Hedges' g is calculated using a small sample bias correction. Interaction p-value is only produced for the Overall period. The reference group for the LS mean difference and Hedges' g is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with data; CI: Confidence interval; LS: Least squares; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; SD: Standard deviation; SE: Standard error; SMD: Standardized mean difference; UFS-QoL: Uterine Fibroid Symptom and Health-Related Quality of Life; NC: Not calculated.

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Table EFF.UFSSSS.MITT.Pooled.S4: Summary of Change from Baseline in UFS-QoL Symptom Severity Scale Score by Visit and Overall, by Subgroup (mITT Population)

Study: Pooled

Treatment	Study visit	n (%)[1]	Mean (SD)[1]	Change from baseline LS-mean change (SE)[2]	Difference LS-mean change [95% CI] p-value[2]	SMD Hedges' g [95% CI][2]
Maximum NRS Pain Score at Baseline						
< 4						
Relugolix+E2/NETA	Baseline	72 (98.6)	50.4 (22.70)	-29.83 (2.734)	-22.43	-1.06
N=73	Week 24	57 (78.1)	18.2 (21.16)		[-30.54,-14.33]	[-1.48,-0.65]
Placebo	Baseline	61 (98.4)	53.1 (18.11)	-7.39 (3.053)	<.0001	
N=62	Week 24	46 (74.2)	45.3 (23.10)			
>= 4						
Relugolix+E2/NETA	Baseline	174 (98.3)	61.2 (19.83)	-36.00 (2.081)	-21.71	-0.87
N=177	Week 24	136 (76.8)	23.4 (21.85)		[-27.34,-16.09]	[-1.11,-0.62]
Placebo	Baseline	189 (99.5)	62.9 (18.93)	-14.28 (1.958)	<.0001	
N=190	Week 24	151 (79.5)	48.3 (23.44)			
Missing						
Relugolix+E2/NETA	Baseline	3 (100.0)	37.5 (21.87)	NC (NC)	NC	NC
N=3	Week 24	3 (100.0)	33.3 (31.30)		[NC,NC]	[NC,NC]
Placebo	Baseline	4 (100.0)	61.8 (27.53)	NC (NC)	NC	
N=4	Week 24	2 (50.0)	64.1 (33.16)			

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group. Transformed score ranges from 0 to 100 based on Likert scale (Not at all, a little bit, somewhat, a great deal and a very great deal). Higher scores are indicative of greater symptom severity and lower scores indicate lower symptom severity (low score = good). For the change from baseline, negative scores indicate improvement.
[1] Summary statistics are based on observed data.
[2] LS means, LS mean differences (95% CIs), p-value and Hedges' g (95% CIs) are based on a mixed-effects model with study, treatment, visit, and a treatment-by-visit interaction as fixed effects. The multiple visits for each patient are the repeated measures as a random effect within each patient with an unstructured covariance. Hedges' g is calculated using a small sample bias correction. Interaction p-value is only produced for the Overall period. The reference group for the LS mean difference and Hedges' g is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with data; CI: Confidence interval; LS: Least squares; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; SD: Standard deviation; SE: Standard error; SMD: Standardized mean difference; UFS-QoL: Uterine Fibroid Symptom and Health-Related Quality of Life; NC: Not calculated.

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Table EFF.UFSSSS.MITT.Pooled.S4: Summary of Change from Baseline in UFS-QoL Symptom Severity Scale Score by Visit and Overall, by Subgroup (mITT Population)

Study: Pooled

Treatment	Study visit	n (%)[1]	Mean (SD)[1]	Change from baseline LS-mean change (SE)[2]	Difference LS-mean change [95% CI] p-value[2]	SMD Hedges' g [95% CI][2]	Int. p-value[2]
Maximum NRS Pain Score at Baseline							
< 4							
Relugolix+E2/NETA	Baseline	72 (98.6)	50.4 (22.70)	-27.43 (2.739)	-19.89	-0.83	0.8917
N=73	Overall	66 (90.4)	24.0 (22.70)		[-27.94,-11.85]	[-1.20,-0.45]	
Placebo	Baseline	61 (98.4)	53.1 (18.11)	-7.54 (3.045)	<.0001		
N=62	Overall	54 (87.1)	47.3 (20.66)				
>= 4							
Relugolix+E2/NETA	Baseline	174 (98.3)	61.2 (19.83)	-32.53 (1.773)	-19.24	-0.81	
N=177	Overall	159 (89.8)	29.1 (20.78)		[-24.03,-14.45]	[-1.03,-0.58]	
Placebo	Baseline	189 (99.5)	62.9 (18.93)	-13.29 (1.671)	<.0001		
N=190	Overall	176 (92.6)	48.9 (19.53)				
Missing							
Relugolix+E2/NETA	Baseline	3 (100.0)	37.5 (21.87)	NC (NC)	NC	NC	
N=3	Overall	3 (100.0)	32.3 (25.41)		[NC,NC]	[NC,NC]	
Placebo	Baseline	4 (100.0)	61.8 (27.53)	NC (NC)	NC		
N=4	Overall	3 (75.0)	64.6 (23.88)				

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group. Transformed score ranges from 0 to 100 based on Likert scale (Not at all, a little bit, somewhat, a great deal and a very great deal). Higher scores are indicative of greater symptom severity and lower scores indicate lower symptom severity (low score = good). For the change from baseline, negative scores indicate improvement.
[1] Summary statistics are based on observed data. Mean (SD) are calculated based on the mean observed value across all post-baseline visits within each patient.
[2] LS means, LS mean differences (95% CIs), p-value and Hedges' g (95% CIs) are based on a mixed-effects model with study, treatment, visit, subgroup, treatment-by-visit interaction and a subgroup-by-treatment interaction as fixed effects. The multiple visits for each patient are the repeated measures as a random effect within each patient with an unstructured covariance. Hedges' g is calculated using a small sample bias correction. Missing subgroup levels are not included in estimation of the interaction p-value. The reference group for the LS mean difference and Hedges' g is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with data; CI: Confidence interval; int: Interaction; LS: Least squares; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; SD: Standard deviation; SE: Standard error; SMD: Standardized mean difference; UFS-QoL: Uterine Fibroid Symptom and Health-Related Quality of Life; NC: Not calculated.

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1.2.14 Summary of Change from Baseline in UFS-QoL Total Score by Visit and Overall, by Subgroup (mITT Population)

Table EFF.HRQLTOT.MITT.Pooled.S2: Summary of Change from Baseline in UFS-QoL Total Score by Visit and Overall, by Subgroup (mITT Population)

Study: Pooled

Treatment	Study visit	n (%)[1]	Mean (SD)[1]	Change from baseline LS-mean change (SE)[2]	Difference LS-mean change [95% CI] p-value[2]	SMD Hedges' g [95% CI][2]
BMI (kg/m2) at Baseline						
< 30						
Relugolix+E2/NETA	Baseline	118 (99.2)	39.1 (22.13)	33.21 (2.121)	24.29	1.13
N=119	Week 12	104 (87.4)	73.1 (23.73)		[18.33,30.24]	[0.83,1.42]
Placebo	Baseline	115 (100.0)	36.8 (19.35)	8.92 (2.148)	<.0001	
N=115	Week 12	100 (87.0)	45.0 (22.71)			
>= 30						
Relugolix+E2/NETA	Baseline	130 (97.7)	37.3 (21.72)	31.17 (2.293)	16.89	0.68
N=133	Week 12	119 (89.5)	67.2 (27.69)		[10.63,23.15]	[0.42,0.94]
Placebo	Baseline	139 (98.6)	34.2 (21.48)	14.28 (2.200)	<.0001	
N=141	Week 12	129 (91.5)	47.5 (22.90)			
Missing						
Relugolix+E2/NETA	Baseline	1 (100.0)	31.0 (NE)	NC (NC)	NC	NC
N=1	Week 12	1 (100.0)	93.1 (NE)		[NC,NC]	[NC,NC]
Placebo	Baseline	0	NE (NE)	NC (NC)	NC	
N=0	Week 12	0	NE (NE)			

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group. Transformed score ranges from 0 to 100 based on Likert scale (None of the time, a little of the time, some of the time, most of the time and all of the time). Higher scores are indicative of better health-related quality of life (high score = good). For the change from baseline, positive scores indicate improvement. HRQL Total includes following scales: concern, activities, energy/mood, control, self-conscious, and sexual function.
[1] Summary statistics are based on observed data.
[2] LS means, LS mean differences (95% CIs), p-value and Hedges' g (95% CIs) are based on a mixed-effects model with study, treatment, visit, and a treatment-by-visit interaction as fixed effects. The multiple visits for each patient are the repeated measures as a random effect within each patient with an unstructured covariance. Hedges' g is calculated using a small sample bias correction. Interaction p-value is only produced for the Overall period. The reference group for the LS mean difference and Hedges' g is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with data; CI: Confidence interval; LS: Least squares; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; SD: Standard deviation; SE: Standard error; SMD: Standardized mean difference; UFS-QoL: Uterine Fibroid Symptom and Health-Related Quality of Life; NC: Not calculated; NE: Non-estimable.

SOURCE: \Studies\MYV\MYV102\Analysis\Prod\Progs\TFLs\Tab_QOL_UFS_CON.SAS
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Table EFF.HRQLTOT.MITT.Pooled.S2: Summary of Change from Baseline in UFS-QoL Total Score by Visit and Overall, by Subgroup (mITT Population)

Study: Pooled

Treatment	Study visit	n (%)[1]	Mean (SD)[1]	Change from baseline LS-mean change (SE)[2]	Difference LS-mean change [95% CI] p-value[2]	SMD Hedges' g [95% CI][2]
BMI (kg/m2) at Baseline						
< 30						
Relugolix+E2/NETA	Baseline	118 (99.2)	39.1 (22.13)	38.03 (2.411)	25.93	1.09
N=119	Week 24	89 (74.8)	79.5 (23.74)		[19.16,32.70]	[0.77,1.41]
Placebo	Baseline	115 (100.0)	36.8 (19.35)	12.10 (2.446)	<.0001	
N=115	Week 24	86 (74.8)	48.2 (24.67)			
>= 30						
Relugolix+E2/NETA	Baseline	130 (97.7)	37.3 (21.72)	36.65 (2.459)	22.73	0.88
N=133	Week 24	106 (79.7)	76.1 (23.70)		[16.01,29.44]	[0.60,1.16]
Placebo	Baseline	139 (98.6)	34.2 (21.48)	13.92 (2.362)	<.0001	
N=141	Week 24	113 (80.1)	47.0 (25.76)			
Missing						
Relugolix+E2/NETA	Baseline	1 (100.0)	31.0 (NE)	NC (NC)	NC	NC
N=1	Week 24	1 (100.0)	91.4 (NE)		[NC,NC]	[NC,NC]
Placebo	Baseline	0	NE (NE)	NC (NC)	NC	
N=0	Week 24	0	NE (NE)			

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group. Transformed score ranges from 0 to 100 based on Likert scale (None of the time, a little of the time, some of the time, most of the time and all of the time). Higher scores are indicative of better health-related quality of life (high score = good). For the change from baseline, positive scores indicate improvement. HRQL Total includes following scales: concern, activities, energy/mood, control, self-conscious, and sexual function.
[1] Summary statistics are based on observed data.
[2] LS means, LS mean differences (95% CIs), p-value and Hedges' g (95% CIs) are based on a mixed-effects model with study, treatment, visit, and a treatment-by-visit interaction as fixed effects. The multiple visits for each patient are the repeated measures as a random effect within each patient with an unstructured covariance. Hedges' g is calculated using a small sample bias correction. Interaction p-value is only produced for the Overall period. The reference group for the LS mean difference and Hedges' g is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with data; CI: Confidence interval; LS: Least squares; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; SD: Standard deviation; SE: Standard error; SMD: Standardized mean difference; UFS-QoL: Uterine Fibroid Symptom and Health-Related Quality of Life; NC: Not calculated; NE: Non-estimable.

SOURCE: \Studies\MYV\MYV102\Analysis\Prod\Progs\TFLs\Tab_QOL_UFS_CON.SAS
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Table EFF.HRQLTOT.MITT.Pooled.S2: Summary of Change from Baseline in UFS-QoL Total Score by Visit and Overall, by Subgroup (mITT Population)

Study: Pooled

Treatment	Study visit	n (%)[1]	Mean (SD)[1]	Change from baseline LS-mean change (SE)[2]	Difference LS-mean change [95% CI] p-value[2]	SMD Hedges' g [95% CI][2]	Int. p-value[2]
BMI (kg/m2) at Baseline							
< 30							
Relugolix+E2/NETA	Baseline	118 (99.2)	39.1 (22.13)	35.66 (2.184)	25.47	1.06	0.1670
N=119	Overall	106 (89.1)	75.3 (22.58)		[19.37,31.58]	[0.77,1.34]	
Placebo	Baseline	115 (100.0)	36.8 (19.35)	10.18 (2.209)	<.0001		
N=115	Overall	103 (89.6)	46.1 (21.89)				
>= 30							
Relugolix+E2/NETA	Baseline	130 (97.7)	37.3 (21.72)	33.88 (2.057)	19.66	0.81	
N=133	Overall	121 (91.0)	70.3 (24.54)		[14.06,25.26]	[0.56,1.07]	
Placebo	Baseline	139 (98.6)	34.2 (21.48)	14.22 (1.975)	<.0001		
N=141	Overall	130 (92.2)	47.0 (22.72)				
Missing							
Relugolix+E2/NETA	Baseline	1 (100.0)	31.0 (NE)	NC (NC)	NC	NC	
N=1	Overall	1 (100.0)	92.3 (NE)		[NC,NC]	[NC,NC]	
Placebo	Baseline	0	NE (NE)	NC (NC)	NC		
N=0	Overall	0	NE (NE)				

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group. Transformed score ranges from 0 to 100 based on Likert scale (None of the time, a little of the time, some of the time, most of the time and all of the time). Higher scores are indicative of better health-related quality of life (high score = good). For the change from baseline, positive scores indicate improvement. HRQL Total includes following scales: concern, activities, energy/mood, control, self-conscious, and sexual function.
[1] Summary statistics are based on observed data. Mean (SD) are calculated based on the mean observed value across all post-baseline visits within each patient.
[2] LS means, LS mean differences (95% CIs), p-value and Hedges' g (95% CIs) are based on a mixed-effects model with study, treatment, visit, subgroup, treatment-by-visit interaction and a subgroup-by-treatment interaction as fixed effects. The multiple visits for each patient are the repeated measures as a random effect within each patient with an unstructured covariance. Hedges' g is calculated using a small sample bias correction. Missing subgroup levels are not included in estimation of the interaction p-value. The reference group for the LS mean difference and Hedges' g is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with data; CI: Confidence interval; int: Interaction; LS: Least squares; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; SD: Standard deviation; SE: Standard error; SMD: Standardized mean difference; UFS-QoL: Uterine Fibroid Symptom and Health-Related Quality of Life; NC: Not calculated; NE: Non-estimable.

SOURCE: \Studies\MYV\MYV102\Analysis\Prod\Progs\TFLs\Tab_QOL_UFS_CON.SAS
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Table EFF.HRQLTOT.MITT.Pooled.S3: Summary of Change from Baseline in UFS-QoL Total Score by Visit and Overall, by Subgroup (mITT Population)

Study: Pooled

Treatment	Study visit	n (%)[1]	Mean (SD)[1]	Change from baseline LS-mean change (SE)[2]	Difference LS-mean change [95% CI] p-value[2]	SMD Hedges' g [95% CI][2]
Uterine Volume at Baseline (cm3)						
< 300 cm3						
Relugolix+E2/NETA	Baseline	147 (99.3)	40.3 (21.41)	32.71 (2.020)	22.65	0.98
N=148	Week 12	132 (89.2)	73.3 (24.31)		[16.84,28.47]	[0.72,1.24]
Placebo	Baseline	129 (100.0)	37.0 (20.40)	10.05 (2.152)	<.0001	
N=129	Week 12	115 (89.1)	46.6 (21.92)			
>= 300 cm3						
Relugolix+E2/NETA	Baseline	101 (97.1)	35.0 (22.27)	31.56 (2.504)	17.88	0.75
N=104	Week 12	92 (88.5)	65.4 (27.76)		[11.25,24.50]	[0.46,1.04]
Placebo	Baseline	125 (98.4)	33.6 (20.63)	13.69 (2.240)	<.0001	
N=127	Week 12	114 (89.8)	46.3 (23.76)			
Missing						
Relugolix+E2/NETA	Baseline	1 (100.0)	25.0 (NE)	NC (NC)	NC	NC
N=1	Week 12	0	NE (NE)		[NC,NC]	[NC,NC]
Placebo	Baseline	0	NE (NE)	NC (NC)	NC	
N=0	Week 12	0	NE (NE)			

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group. Transformed score ranges from 0 to 100 based on Likert scale (None of the time, a little of the time, some of the time, most of the time and all of the time). Higher scores are indicative of better health-related quality of life (high score = good). For the change from baseline, positive scores indicate improvement. HRQL Total includes following scales: concern, activities, energy/mood, control, self-conscious, and sexual function.
[1] Summary statistics are based on observed data.
[2] LS means, LS mean differences (95% CIs), p-value and Hedges' g (95% CIs) are based on a mixed-effects model with study, treatment, visit, and a treatment-by-visit interaction as fixed effects. The multiple visits for each patient are the repeated measures as a random effect within each patient with an unstructured covariance. Hedges' g is calculated using a small sample bias correction. Interaction p-value is only produced for the Overall period. The reference group for the LS mean difference and Hedges' g is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with data; CI: Confidence interval; LS: Least squares; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; SD: Standard deviation; SE: Standard error; SMD: Standardized mean difference; UFS-QoL: Uterine Fibroid Symptom and Health-Related Quality of Life; NC: Not calculated; NE: Non-estimable.

SOURCE: \Studies\MYV\MYV102\Analysis\Prod\Progs\TFLs\Tab_QOL_UFS_CON.SAS
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Table EFF.HRQLTOT.MITT.Pooled.S3: Summary of Change from Baseline in UFS-QoL Total Score by Visit and Overall, by Subgroup (mITT Population)

Study: Pooled

Treatment	Study visit	n (%)[1]	Mean (SD)[1]	Change from baseline LS-mean change (SE)[2]	Difference LS-mean change [95% CI] p-value[2]	SMD Hedges' g [95% CI][2]
Uterine Volume at Baseline (cm3)						
< 300 cm3						
Relugolix+E2/NETA	Baseline	147 (99.3)	40.3 (21.41)	38.07 (2.319)	26.10	1.01
N=148	Week 24	116 (78.4)	80.5 (22.93)		[19.44,32.77]	[0.73,1.29]
Placebo	Baseline	129 (100.0)	37.0 (20.40)	11.96 (2.464)	<.0001	
N=129	Week 24	102 (79.1)	48.6 (25.04)			
>= 300 cm3						
Relugolix+E2/NETA	Baseline	101 (97.1)	35.0 (22.27)	36.37 (2.591)	22.30	0.93
N=104	Week 24	80 (76.9)	73.7 (24.32)		[15.43,29.17]	[0.62,1.24]
Placebo	Baseline	125 (98.4)	33.6 (20.63)	14.07 (2.329)	<.0001	
N=127	Week 24	97 (76.4)	46.4 (25.53)			
Missing						
Relugolix+E2/NETA	Baseline	1 (100.0)	25.0 (NE)	NC (NC)	NC	NC
N=1	Week 24	0	NE (NE)		[NC,NC]	[NC,NC]
Placebo	Baseline	0	NE (NE)	NC (NC)	NC	
N=0	Week 24	0	NE (NE)			

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group. Transformed score ranges from 0 to 100 based on Likert scale (None of the time, a little of the time, some of the time, most of the time and all of the time). Higher scores are indicative of better health-related quality of life (high score = good). For the change from baseline, positive scores indicate improvement. HRQL Total includes following scales: concern, activities, energy/mood, control, self-conscious, and sexual function.
[1] Summary statistics are based on observed data.
[2] LS means, LS mean differences (95% CIs), p-value and Hedges' g (95% CIs) are based on a mixed-effects model with study, treatment, visit, and a treatment-by-visit interaction as fixed effects. The multiple visits for each patient are the repeated measures as a random effect within each patient with an unstructured covariance. Hedges' g is calculated using a small sample bias correction. Interaction p-value is only produced for the Overall period. The reference group for the LS mean difference and Hedges' g is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with data; CI: Confidence interval; LS: Least squares; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; SD: Standard deviation; SE: Standard error; SMD: Standardized mean difference; UFS-QoL: Uterine Fibroid Symptom and Health-Related Quality of Life; NC: Not calculated; NE: Non-estimable.

SOURCE: \Studies\MYV\MYV102\Analysis\Prod\Progs\TFLs\Tab_QOL_UFS_CON.SAS
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Table EFF.HRQLTOT.MITT.Pooled.S3: Summary of Change from Baseline in UFS-QoL Total Score by Visit and Overall, by Subgroup (mITT Population)

Study: Pooled

Treatment	Study visit	n (%)[1]	Mean (SD)[1]	Change from baseline LS-mean change (SE)[2]	Difference LS-mean change [95% CI] p-value[2]	SMD Hedges' g [95% CI][2]	Int. p-value[2]
Uterine Volume at Baseline (cm3)							
< 300 cm3							
Relugolix+E2/NETA	Baseline	147 (99.3)	40.3 (21.41)	35.36 (1.942)	24.43	1.01	0.3027
N=148	Overall	134 (90.5)	75.9 (21.39)		[18.86,29.99]	[0.75,1.27]	
Placebo	Baseline	129 (100.0)	37.0 (20.40)	10.94 (2.063)	<.0001		
N=129	Overall	118 (91.5)	46.8 (21.38)				
>= 300 cm3							
Relugolix+E2/NETA	Baseline	101 (97.1)	35.0 (22.27)	34.05 (2.347)	20.07	0.83	
N=104	Overall	94 (90.4)	68.1 (26.09)		[13.87,26.27]	[0.54,1.12]	
Placebo	Baseline	125 (98.4)	33.6 (20.63)	13.99 (2.107)	<.0001		
N=127	Overall	115 (90.6)	46.5 (23.33)				
Missing							
Relugolix+E2/NETA	Baseline	1 (100.0)	25.0 (NE)	NC (NC)	NC	NC	
N=1	Overall	0	NE (NE)		[NC,NC]	[NC,NC]	
Placebo	Baseline	0	NE (NE)	NC (NC)	NC		
N=0	Overall	0	NE (NE)				

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group. Transformed score ranges from 0 to 100 based on Likert scale (None of the time, a little of the time, some of the time, most of the time and all of the time). Higher scores are indicative of better health-related quality of life (high score = good). For the change from baseline, positive scores indicate improvement. HRQL Total includes following scales: concern, activities, energy/mood, control, self-conscious, and sexual function.
[1] Summary statistics are based on observed data. Mean (SD) are calculated based on the mean observed value across all post-baseline visits within each patient.
[2] LS means, LS mean differences (95% CIs), p-value and Hedges' g (95% CIs) are based on a mixed-effects model with study, treatment, visit, subgroup, treatment-by-visit interaction and a subgroup-by-treatment interaction as fixed effects. The multiple visits for each patient are the repeated measures as a random effect within each patient with an unstructured covariance. Hedges' g is calculated using a small sample bias correction. Missing subgroup levels are not included in estimation of the interaction p-value. The reference group for the LS mean difference and Hedges' g is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with data; CI: Confidence interval; int: Interaction; LS: Least squares; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; SD: Standard deviation; SE: Standard error; SMD: Standardized mean difference; UFS-QoL: Uterine Fibroid Symptom and Health-Related Quality of Life; NC: Not calculated; NE: Non-estimable.

SOURCE: \Studies\MYV\MYV102\Analysis\Prod\Progs\TFLs\Tab_QOL_UFS_CON.SAS
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Table EFF.HRQLTOT.MITT.Pooled.S8: Summary of Change from Baseline in UFS-QoL Total Score by Visit and Overall, by Subgroup (mITT Population)

Study: Pooled

Treatment	Study visit	n (%)[1]	Mean (SD)[1]	Change from baseline LS-mean change (SE)[2]	Difference LS-mean change [95% CI] p-value[2]	SMD Hedges' g [95% CI][2]
Ethnicity						
Hispanic or Latino						
Relugolix+E2/NETA	Baseline	52 (100.0)	38.6 (19.64)	33.49 (3.426)	17.29	0.75
N=52	Week 12	47 (90.4)	71.2 (24.89)		[7.75,26.83]	[0.33,1.16]
Placebo	Baseline	55 (100.0)	25.0 (16.56)	16.20 (3.309)	0.0005	
N=55	Week 12	49 (89.1)	41.0 (23.76)			
Not Hispanic or Latino						
Relugolix+E2/NETA	Baseline	193 (98.0)	37.4 (22.02)	32.41 (1.810)	21.78	0.92
N=197	Week 12	174 (88.3)	69.4 (26.42)		[16.78,26.78]	[0.70,1.15]
Placebo	Baseline	197 (99.0)	38.3 (20.56)	10.63 (1.778)	<.0001	
N=199	Week 12	178 (89.4)	48.1 (22.40)			
Not reported						
Relugolix+E2/NETA	Baseline	4 (100.0)	63.6 (31.04)	NC (NC)	NC	NC
N=4	Week 12	3 (75.0)	91.4 (9.08)		[NC,NC]	[NC,NC]
Placebo	Baseline	2 (100.0)	28.9 (38.40)	NC (NC)	NC	
N=2	Week 12	2 (100.0)	34.9 (21.35)			

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group. Transformed score ranges from 0 to 100 based on Likert scale (None of the time, a little of the time, some of the time, most of the time and all of the time). Higher scores are indicative of better health-related quality of life (high score = good). For the change from baseline, positive scores indicate improvement. HRQL Total includes following scales: concern, activities, energy/mood, control, self-conscious, and sexual function.
[1] Summary statistics are based on observed data.
[2] LS means, LS mean differences (95% CIs), p-value and Hedges' g (95% CIs) are based on a mixed-effects model with study, treatment, visit, and a treatment-by-visit interaction as fixed effects. The multiple visits for each patient are the repeated measures as a random effect within each patient with an unstructured covariance. Hedges' g is calculated using a small sample bias correction. Interaction p-value is only produced for the Overall period. The reference group for the LS mean difference and Hedges' g is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with data; CI: Confidence interval; LS: Least squares; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; SD: Standard deviation; SE: Standard error; SMD: Standardized mean difference; UFS-QoL: Uterine Fibroid Symptom and Health-Related Quality of Life; NC: Not calculated.

SOURCE: \Studies\MYV\MYV102\Analysis\Prod\Progs\TFLs\Tab_QOL_UFS_CON.SAS
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Table EFF.HRQLTOT.MITT.Pooled.S8: Summary of Change from Baseline in UFS-QoL Total Score by Visit and Overall, by Subgroup (mITT Population)

Study: Pooled

Treatment	Study visit	n (%)[1]	Mean (SD)[1]	Change from baseline LS-mean change (SE)[2]	Difference LS-mean change [95% CI] p-value[2]	SMD Hedges' g [95% CI][2]
Ethnicity						
Hispanic or Latino						
Relugolix+E2/NETA	Baseline	52 (100.0)	38.6 (19.64)	38.05 (4.031)	20.77	0.77
N=52	Week 24	44 (84.6)	77.4 (21.40)		[9.55,31.99]	[0.34,1.19]
Placebo	Baseline	55 (100.0)	25.0 (16.56)	17.28 (3.899)	0.0004	
N=55	Week 24	46 (83.6)	41.2 (28.94)			
Not Hispanic or Latino						
Relugolix+E2/NETA	Baseline	193 (98.0)	37.4 (22.02)	37.81 (1.918)	25.99	1.07
N=197	Week 24	149 (75.6)	77.6 (24.52)		[20.69,31.29]	[0.82,1.31]
Placebo	Baseline	197 (99.0)	38.3 (20.56)	11.82 (1.889)	<.0001	
N=199	Week 24	151 (75.9)	49.7 (23.59)			
Not reported						
Relugolix+E2/NETA	Baseline	4 (100.0)	63.6 (31.04)	NC (NC)	NC	NC
N=4	Week 24	3 (75.0)	88.2 (13.36)		[NC,NC]	[NC,NC]
Placebo	Baseline	2 (100.0)	28.9 (38.40)	NC (NC)	NC	
N=2	Week 24	2 (100.0)	28.9 (40.87)			

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group. Transformed score ranges from 0 to 100 based on Likert scale (None of the time, a little of the time, some of the time, most of the time and all of the time). Higher scores are indicative of better health-related quality of life (high score = good). For the change from baseline, positive scores indicate improvement. HRQL Total includes following scales: concern, activities, energy/mood, control, self-conscious, and sexual function.
[1] Summary statistics are based on observed data.
[2] LS means, LS mean differences (95% CIs), p-value and Hedges' g (95% CIs) are based on a mixed-effects model with study, treatment, visit, and a treatment-by-visit interaction as fixed effects. The multiple visits for each patient are the repeated measures as a random effect within each patient with an unstructured covariance. Hedges' g is calculated using a small sample bias correction. Interaction p-value is only produced for the Overall period. The reference group for the LS mean difference and Hedges' g is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with data; CI: Confidence interval; LS: Least squares; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; SD: Standard deviation; SE: Standard error; SMD: Standardized mean difference; UFS-QoL: Uterine Fibroid Symptom and Health-Related Quality of Life; NC: Not calculated.

SOURCE: \Studies\MYV\MYV102\Analysis\Prod\Progs\TFLs\Tab_QOL_UFS_CON.SAS
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Table EFF.HRQLTOT.MITT.Pooled.S8: Summary of Change from Baseline in UFS-QoL Total Score by Visit and Overall, by Subgroup (mITT Population)

Study: Pooled

Treatment	Study visit	n (%)[1]	Mean (SD)[1]	Change from baseline LS-mean change (SE)[2]	Difference LS-mean change [95% CI] p-value[2]	SMD Hedges' g [95% CI][2]	Int. p-value[2]
Ethnicity							
Hispanic or Latino							
Relugolix+E2/NETA	Baseline	52 (100.0)	38.6 (19.64)	35.43 (3.205)	18.57	0.77	0.3068
N=52	Overall	49 (94.2)	73.9 (20.72)		[9.75,27.39]	[0.36,1.17]	
Placebo	Baseline	55 (100.0)	25.0 (16.56)	16.86 (3.128)	<.0001		
N=55	Overall	51 (92.7)	40.8 (24.21)				
Not Hispanic or Latino							
Relugolix+E2/NETA	Baseline	193 (98.0)	37.4 (22.02)	35.06 (1.713)	23.79	0.99	
N=197	Overall	176 (89.3)	72.1 (24.59)		[19.06,28.52]	[0.76,1.21]	
Placebo	Baseline	197 (99.0)	38.3 (20.56)	11.27 (1.685)	<.0001		
N=199	Overall	180 (90.5)	48.4 (21.47)				
Not reported							
Relugolix+E2/NETA	Baseline	4 (100.0)	63.6 (31.04)	NC (NC)	NC	NC	
N=4	Overall	3 (75.0)	89.8 (8.73)		[NC,NC]	[NC,NC]	
Placebo	Baseline	2 (100.0)	28.9 (38.40)	NC (NC)	NC		
N=2	Overall	2 (100.0)	31.9 (31.11)				

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group. Transformed score ranges from 0 to 100 based on Likert scale (None of the time, a little of the time, some of the time, most of the time and all of the time). Higher scores are indicative of better health-related quality of life (high score = good). For the change from baseline, positive scores indicate improvement. HRQL Total includes following scales: concern, activities, energy/mood, control, self-conscious, and sexual function.
[1] Summary statistics are based on observed data. Mean (SD) are calculated based on the mean observed value across all post-baseline visits within each patient.
[2] LS means, LS mean differences (95% CIs), p-value and Hedges' g (95% CIs) are based on a mixed-effects model with study, treatment, visit, subgroup, treatment-by-visit interaction and a subgroup-by-treatment interaction as fixed effects. The multiple visits for each patient are the repeated measures as a random effect within each patient with an unstructured covariance. Hedges' g is calculated using a small sample bias correction. Not reported subgroup levels are not included in estimation of the interaction p-value. The reference group for the LS mean difference and Hedges' g is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with data; CI: Confidence interval; int: Interaction; LS: Least squares; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; SD: Standard deviation; SE: Standard error; SMD: Standardized mean difference; UFS-QoL: Uterine Fibroid Symptom and Health-Related Quality of Life; NC: Not calculated.

SOURCE: \Studies\MYV\MYV102\Analysis\Prod\Progs\TFLs\Tab_QOL_UFS_CON.SAS
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Table EFF.HRQLTOT.MITT.Pooled.S6: Summary of Change from Baseline in UFS-QoL Total Score by Visit and Overall, by Subgroup (mITT Population)

Study: Pooled

Treatment	Study visit	n (%)[1]	Mean (SD)[1]	Change from baseline LS-mean change (SE)[2]	Difference LS-mean change [95% CI] p-value[2]	SMD Hedges' g [95% CI][2]
Geographic Region I						
North America						
Relugolix+E2/NETA	Baseline	188 (98.4)	36.4 (22.38)	32.50 (1.915)	19.09	0.78
N=191	Week 12	165 (86.4)	68.5 (27.22)		[13.81,24.36]	[0.56,1.00]
Placebo	Baseline	192 (99.0)	34.1 (20.62)	13.41 (1.876)	<.0001	
N=194	Week 12	172 (88.7)	46.6 (23.84)			
Rest of World						
Relugolix+E2/NETA	Baseline	61 (98.4)	43.4 (19.37)	31.72 (2.633)	24.49	1.22
N=62	Week 12	59 (95.2)	74.3 (21.95)		[17.11,31.86]	[0.82,1.62]
Placebo	Baseline	62 (100.0)	39.2 (19.99)	7.23 (2.633)	<.0001	
N=62	Week 12	57 (91.9)	45.9 (19.54)			

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group. Transformed score ranges from 0 to 100 based on Likert scale (None of the time, a little of the time, some of the time, most of the time and all of the time). Higher scores are indicative of better health-related quality of life (high score = good). For the change from baseline, positive scores indicate improvement. HRQL Total includes following scales: concern, activities, energy/mood, control, self-conscious, and sexual function.
[1] Summary statistics are based on observed data.
[2] LS means, LS mean differences (95% CIs), p-value and Hedges' g (95% CIs) are based on a mixed-effects model with study, treatment, visit, and a treatment-by-visit interaction as fixed effects. The multiple visits for each patient are the repeated measures as a random effect within each patient with an unstructured covariance. Hedges' g is calculated using a small sample bias correction. Interaction p-value is only produced for the Overall period. The reference group for the LS mean difference and Hedges' g is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with data; CI: Confidence interval; LS: Least squares; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; SD: Standard deviation; SE: Standard error; SMD: Standardized mean difference; UFS-QoL: Uterine Fibroid Symptom and Health-Related Quality of Life.

SOURCE: \Studies\MYV\MYV102\Analysis\Prod\Progs\TFLs\Tab_QOL_UFS_CON.SAS
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Table EFF.HRQLTOT.MITT.Pooled.S6: Summary of Change from Baseline in UFS-QoL Total Score by Visit and Overall, by Subgroup (mITT Population)

Study: Pooled

Treatment	Study visit	n (%)[1]	Mean (SD)[1]	Change from baseline LS-mean change (SE)[2]	Difference LS-mean change [95% CI] p-value[2]	SMD Hedges' g [95% CI][2]
Geographic Region I						
North America						
Relugolix+E2/NETA	Baseline	188 (98.4)	36.4 (22.38)	36.96 (2.105)	23.65	0.91
N=191	Week 24	139 (72.8)	76.0 (24.98)		[17.87,29.44]	[0.66,1.15]
Placebo	Baseline	192 (99.0)	34.1 (20.62)	13.30 (2.052)	<.0001	
N=194	Week 24	146 (75.3)	46.4 (25.94)			
Rest of World						
Relugolix+E2/NETA	Baseline	61 (98.4)	43.4 (19.37)	38.43 (2.932)	26.34	1.19
N=62	Week 24	57 (91.9)	82.0 (19.72)		[18.06,34.62]	[0.79,1.59]
Placebo	Baseline	62 (100.0)	39.2 (19.99)	12.09 (2.980)	<.0001	
N=62	Week 24	53 (85.5)	50.6 (23.15)			

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group. Transformed score ranges from 0 to 100 based on Likert scale (None of the time, a little of the time, some of the time, most of the time and all of the time). Higher scores are indicative of better health-related quality of life (high score = good). For the change from baseline, positive scores indicate improvement. HRQL Total includes following scales: concern, activities, energy/mood, control, self-conscious, and sexual function.
[1] Summary statistics are based on observed data.
[2] LS means, LS mean differences (95% CIs), p-value and Hedges' g (95% CIs) are based on a mixed-effects model with study, treatment, visit, and a treatment-by-visit interaction as fixed effects. The multiple visits for each patient are the repeated measures as a random effect within each patient with an unstructured covariance. Hedges' g is calculated using a small sample bias correction. Interaction p-value is only produced for the Overall period. The reference group for the LS mean difference and Hedges' g is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with data; CI: Confidence interval; LS: Least squares; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; SD: Standard deviation; SE: Standard error; SMD: Standardized mean difference; UFS-QoL: Uterine Fibroid Symptom and Health-Related Quality of Life.

SOURCE: \Studies\MYV\MYV102\Analysis\Prod\Progs\TFLs\Tab_QOL_UFS_CON.SAS
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Table EFF.HRQLTOT.MITT.Pooled.S6: Summary of Change from Baseline in UFS-QoL Total Score by Visit and Overall, by Subgroup (mITT Population)

Study: Pooled

Treatment	Study visit	n (%)[1]	Mean (SD)[1]	Change from baseline LS-mean change (SE)[2]	Difference LS-mean change [95% CI] p-value[2]	SMD Hedges' g [95% CI][2]	Int. p-value[2]
Geographic Region I							
North America							
Relugolix+E2/NETA	Baseline	188 (98.4)	36.4 (22.38)	34.82 (1.748)	21.29	0.88	0.3644
N=191	Overall	169 (88.5)	71.0 (24.77)		[16.48,26.10]	[0.66,1.11]	
Placebo	Baseline	192 (99.0)	34.1 (20.62)	13.53 (1.713)	<.0001		
N=194	Overall	174 (89.7)	46.2 (23.34)				
Rest of World							
Relugolix+E2/NETA	Baseline	61 (98.4)	43.4 (19.37)	34.86 (2.906)	25.62	1.06	
N=62	Overall	59 (95.2)	77.4 (19.80)		[17.55,33.70]	[0.67,1.44]	
Placebo	Baseline	62 (100.0)	39.2 (19.99)	9.24 (2.906)	<.0001		
N=62	Overall	59 (95.2)	47.9 (19.08)				

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group. Transformed score ranges from 0 to 100 based on Likert scale (None of the time, a little of the time, some of the time, most of the time and all of the time). Higher scores are indicative of better health-related quality of life (high score = good). For the change from baseline, positive scores indicate improvement. HRQL Total includes following scales: concern, activities, energy/mood, control, self-conscious, and sexual function.
[1] Summary statistics are based on observed data. Mean (SD) are calculated based on the mean observed value across all post-baseline visits within each patient.
[2] LS means, LS mean differences (95% CIs), p-value and Hedges' g (95% CIs) are based on a mixed-effects model with study, treatment, visit, subgroup, treatment-by-visit interaction and a subgroup-by-treatment interaction as fixed effects. The multiple visits for each patient are the repeated measures as a random effect within each patient with an unstructured covariance. Hedges' g is calculated using a small sample bias correction. The reference group for the LS mean difference and Hedges' g is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with data; CI: Confidence interval; int: Interaction; LS: Least squares; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; SD: Standard deviation; SE: Standard error; SMD: Standardized mean difference; UFS-QoL: Uterine Fibroid Symptom and Health-Related Quality of Life.

SOURCE: \Studies\MYV\MYV102\Analysis\Prod\Progs\TFLs\Tab_QOL_UFS_CON.SAS
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Analysis Plan: 13JAN2021

Table EFF.HRQLTOT.MITT.Pooled.S5: Summary of Change from Baseline in UFS-QoL Total Score by Visit and Overall, by Subgroup (mITT Population)

Study: Pooled

Treatment	Study visit	n (%)[1]	Mean (SD)[1]	Change from baseline LS-mean change (SE)[2]	Difference LS-mean change [95% CI] p-value[2]	SMD Hedges' g [95% CI][2]
MBL Volume at Baseline (mL)						
< 225 mL						
Relugolix+E2/NETA	Baseline	163 (99.4)	39.7 (20.48)	30.45 (1.927)	18.47	0.79
N=164	Week 12	147 (89.6)	70.9 (25.97)		[13.17,23.78]	[0.56,1.03]
Placebo	Baseline	170 (99.4)	35.7 (20.41)	11.98 (1.884)	<.0001	
N=171	Week 12	153 (89.5)	47.3 (22.57)			
>= 225 mL						
Relugolix+E2/NETA	Baseline	86 (96.6)	35.0 (24.05)	35.94 (2.733)	24.41	1.04
N=89	Week 12	77 (86.5)	68.4 (26.19)		[16.76,32.06]	[0.70,1.38]
Placebo	Baseline	84 (98.8)	34.7 (20.93)	11.52 (2.736)	<.0001	
N=85	Week 12	76 (89.4)	44.7 (23.33)			

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group. Transformed score ranges from 0 to 100 based on Likert scale (None of the time, a little of the time, some of the time, most of the time and all of the time). Higher scores are indicative of better health-related quality of life (high score = good). For the change from baseline, positive scores indicate improvement. HRQL Total includes following scales: concern, activities, energy/mood, control, self-conscious, and sexual function.
[1] Summary statistics are based on observed data.
[2] LS means, LS mean differences (95% CIs), p-value and Hedges' g (95% CIs) are based on a mixed-effects model with study, treatment, visit, and a treatment-by-visit interaction as fixed effects. The multiple visits for each patient are the repeated measures as a random effect within each patient with an unstructured covariance. Hedges' g is calculated using a small sample bias correction. Interaction p-value is only produced for the Overall period. The reference group for the LS mean difference and Hedges' g is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with data; CI: Confidence interval; LS: Least squares; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; SD: Standard deviation; SE: Standard error; SMD: Standardized mean difference; UFS-QoL: Uterine Fibroid Symptom and Health-Related Quality of Life.

SOURCE: \Studies\MYV\MYV102\Analysis\Prod\Progs\TFLs\Tab_QOL_UFS_CON.SAS
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Table EFF.HRQLTOT.MITT.Pooled.S5: Summary of Change from Baseline in UFS-QoL Total Score by Visit and Overall, by Subgroup (mITT Population)

Study: Pooled

Treatment	Study visit	n (%)[1]	Mean (SD)[1]	Change from baseline LS-mean change (SE)[2]	Difference LS-mean change [95% CI] p-value[2]	SMD Hedges' g [95% CI][2]
MBL Volume at Baseline (mL)						
< 225 mL						
Relugolix+E2/NETA	Baseline	163 (99.4)	39.7 (20.48)	36.98 (2.139)	24.13	0.97
N=164	Week 24	126 (76.8)	79.3 (22.98)		[18.28,29.99]	[0.71,1.22]
Placebo	Baseline	170 (99.4)	35.7 (20.41)	12.85 (2.068)	<.0001	
N=171	Week 24	137 (80.1)	48.7 (23.75)			
>= 225 mL						
Relugolix+E2/NETA	Baseline	86 (96.6)	35.0 (24.05)	38.26 (2.925)	24.81	0.98
N=89	Week 24	70 (78.7)	74.9 (24.80)		[16.55,33.07]	[0.61,1.34]
Placebo	Baseline	84 (98.8)	34.7 (20.93)	13.45 (2.983)	<.0001	
N=85	Week 24	62 (72.9)	45.0 (28.29)			

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group. Transformed score ranges from 0 to 100 based on Likert scale (None of the time, a little of the time, some of the time, most of the time and all of the time). Higher scores are indicative of better health-related quality of life (high score = good). For the change from baseline, positive scores indicate improvement. HRQL Total includes following scales: concern, activities, energy/mood, control, self-conscious, and sexual function.
[1] Summary statistics are based on observed data.
[2] LS means, LS mean differences (95% CIs), p-value and Hedges' g (95% CIs) are based on a mixed-effects model with study, treatment, visit, and a treatment-by-visit interaction as fixed effects. The multiple visits for each patient are the repeated measures as a random effect within each patient with an unstructured covariance. Hedges' g is calculated using a small sample bias correction. Interaction p-value is only produced for the Overall period. The reference group for the LS mean difference and Hedges' g is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with data; CI: Confidence interval; LS: Least squares; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; SD: Standard deviation; SE: Standard error; SMD: Standardized mean difference; UFS-QoL: Uterine Fibroid Symptom and Health-Related Quality of Life.

SOURCE: \Studies\MYV\MYV102\Analysis\Prod\Progs\TFLs\Tab_QOL_UFS_CON.SAS
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Table EFF.HRQLTOT.MITT.Pooled.S5: Summary of Change from Baseline in UFS-QoL Total Score by Visit and Overall, by Subgroup (mITT Population)

Study: Pooled

Treatment	Study visit	n (%)[1]	Mean (SD)[1]	Change from baseline LS-mean change (SE)[2]	Difference LS-mean change [95% CI] p-value[2]	SMD Hedges' g [95% CI][2]	Int. p-value[2]
MBL Volume at Baseline (mL)							
< 225 mL							
Relugolix+E2/NETA	Baseline	163 (99.4)	39.7 (20.48)	33.48 (1.848)	21.07	0.87	0.3812
N=164	Overall	148 (90.2)	73.6 (23.55)		[16.00,26.14]	[0.64,1.11]	
Placebo	Baseline	170 (99.4)	35.7 (20.41)	12.41 (1.798)	<.0001		
N=171	Overall	156 (91.2)	47.3 (21.34)				
>= 225 mL							
Relugolix+E2/NETA	Baseline	86 (96.6)	35.0 (24.05)	37.41 (2.552)	24.95	1.03	
N=89	Overall	80 (89.9)	71.0 (24.06)		[17.83,32.08]	[0.70,1.37]	
Placebo	Baseline	84 (98.8)	34.7 (20.93)	12.45 (2.572)	<.0001		
N=85	Overall	77 (90.6)	45.3 (24.26)				

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group. Transformed score ranges from 0 to 100 based on Likert scale (None of the time, a little of the time, some of the time, most of the time and all of the time). Higher scores are indicative of better health-related quality of life (high score = good). For the change from baseline, positive scores indicate improvement. HRQL Total includes following scales: concern, activities, energy/mood, control, self-conscious, and sexual function.
[1] Summary statistics are based on observed data. Mean (SD) are calculated based on the mean observed value across all post-baseline visits within each patient.
[2] LS means, LS mean differences (95% CIs), p-value and Hedges' g (95% CIs) are based on a mixed-effects model with study, treatment, visit, subgroup, treatment-by-visit interaction and a subgroup-by-treatment interaction as fixed effects. The multiple visits for each patient are the repeated measures as a random effect within each patient with an unstructured covariance. Hedges' g is calculated using a small sample bias correction. The reference group for the LS mean difference and Hedges' g is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with data; CI: Confidence interval; int: Interaction; LS: Least squares; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; SD: Standard deviation; SE: Standard error; SMD: Standardized mean difference; UFS-QoL: Uterine Fibroid Symptom and Health-Related Quality of Life.

SOURCE: \Studies\MYV\MYV102\Analysis\Prod\Progs\TFLs\Tab_QOL_UFS_CON.SAS
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Table EFF.HRQLTOT.MITT.Pooled.S9: Summary of Change from Baseline in UFS-QoL Total Score by Visit and Overall, by Subgroup (mITT Population)

Study: Pooled

Treatment	Study visit	n (%)[1]	Mean (SD)[1]	Change from baseline LS-mean change (SE)[2]	Difference LS-mean change [95% CI] p-value[2]	SMD Hedges' g [95% CI][2]
Race						
Black/African American						
Relugolix+E2/NETA	Baseline	119 (97.5)	33.8 (22.13)	34.25 (2.330)	22.05	0.94
N=122	Week 12	105 (86.1)	67.1 (26.78)		[15.82,28.28]	[0.66,1.21]
Placebo	Baseline	139 (98.6)	36.0 (21.28)	12.19 (2.138)	<.0001	
N=141	Week 12	122 (86.5)	47.3 (23.32)			
White						
Relugolix+E2/NETA	Baseline	121 (99.2)	41.5 (20.62)	31.20 (2.240)	19.89	0.85
N=122	Week 12	110 (90.2)	72.7 (25.47)		[13.46,26.32]	[0.56,1.13]
Placebo	Baseline	105 (100.0)	35.1 (19.76)	11.31 (2.376)	<.0001	
N=105	Week 12	98 (93.3)	46.0 (22.01)			
Asian						
Relugolix+E2/NETA	Baseline	1 (100.0)	49.1 (NE)	NC (NC)	NC	NC
N=1	Week 12	1 (100.0)	90.5 (NE)		[NC,NC]	[NC,NC]
Placebo	Baseline	3 (100.0)	30.2 (24.75)	NC (NC)	NC	
N=3	Week 12	3 (100.0)	32.5 (14.26)			
Others						
Relugolix+E2/NETA	Baseline	5 (100.0)	36.7 (15.58)	27.75 (12.860)	8.21	0.29
N=5	Week 12	5 (100.0)	60.5 (19.02)		[-34.58,51.01]	[-0.83,1.42]
Placebo	Baseline	6 (100.0)	23.0 (13.89)	19.54 (12.350)	0.6637	
N=6	Week 12	5 (83.3)	41.7 (33.75)			
Not reported						
Relugolix+E2/NETA	Baseline	3 (100.0)	71.6 (28.01)	NC (NC)	NC	NC
N=3	Week 12	3 (100.0)	83.0 (22.97)		[NC,NC]	[NC,NC]
Placebo	Baseline	1 (100.0)	56.0 (NE)	NC (NC)	NC	

N=1	Week 12	1 (100.0)	50.0 (NE)			

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group. Transformed score ranges from 0 to 100 based on Likert scale (None of the time, a little of the time, some of the time, most of the time and all of the time). Higher scores are indicative of better health-related quality of life (high score = good). For the change from baseline, positive scores indicate improvement. HRQL Total includes following scales: concern, activities, energy/mood, control, self-conscious, and sexual function.
[1] Summary statistics are based on observed data.
[2] LS means, LS mean differences (95% CIs), p-value and Hedges' g (95% CIs) are based on a mixed-effects model with study, treatment, visit, and a treatment-by-visit interaction as fixed effects. The multiple visits for each patient are the repeated measures as a random effect within each patient with an unstructured covariance. Hedges' g is calculated using a small sample bias correction. Interaction p-value is only produced for the Overall period. The reference group for the LS mean difference and Hedges' g is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with data; CI: Confidence interval; LS: Least squares; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; SD: Standard deviation; SE: Standard error; SMD: Standardized mean difference; UFS-QoL: Uterine Fibroid Symptom and Health-Related Quality of Life; NC: Not calculated; NE: Non-estimable.

SOURCE: \Studies\MYV\MYV102\Analysis\Prod\Progs\TFLs\Tab_QOL_UFS_CON.SAS
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Table EFF.HRQLTOT.MITT.Pooled.S9: Summary of Change from Baseline in UFS-QoL Total Score by Visit and Overall, by Subgroup (mITT Population)

Study: Pooled

Treatment	Study visit	n (%)[1]	Mean (SD)[1]	Change from baseline LS-mean change (SE)[2]	Difference LS-mean change [95% CI] p-value[2]	SMD Hedges' g [95% CI][2]
Race						
Black/African American						
Relugolix+E2/NETA	Baseline	119 (97.5)	33.8 (22.13)	37.93 (2.633)	25.08	0.97
N=122	Week 24	87 (71.3)	73.6 (25.58)		[18.09,32.07]	[0.67,1.27]
Placebo	Baseline	139 (98.6)	36.0 (21.28)	12.86 (2.377)	<.0001	
N=141	Week 24	108 (76.6)	48.0 (25.63)			
White						
Relugolix+E2/NETA	Baseline	121 (99.2)	41.5 (20.62)	38.45 (2.363)	24.36	1.01
N=122	Week 24	100 (82.0)	82.2 (20.93)		[17.51,31.21]	[0.70,1.31]
Placebo	Baseline	105 (100.0)	35.1 (19.76)	14.09 (2.551)	<.0001	
N=105	Week 24	84 (80.0)	48.7 (24.45)			
Asian						
Relugolix+E2/NETA	Baseline	1 (100.0)	49.1 (NE)	NC (NC)	NC	NC
N=1	Week 24	1 (100.0)	100.0 (NE)		[NC,NC]	[NC,NC]
Placebo	Baseline	3 (100.0)	30.2 (24.75)	NC (NC)	NC	
N=3	Week 24	2 (66.7)	34.1 (28.64)			
Others						
Relugolix+E2/NETA	Baseline	5 (100.0)	36.7 (15.58)	21.55 (8.396)	24.78	1.51
N=5	Week 24	5 (100.0)	54.3 (24.00)		[-4.85,54.42]	[0.15,2.87]
Placebo	Baseline	6 (100.0)	23.0 (13.89)	-3.23 (8.288)	0.0885	
N=6	Week 24	4 (66.7)	13.4 (5.73)			
Not reported						
Relugolix+E2/NETA	Baseline	3 (100.0)	71.6 (28.01)	NC (NC)	NC	NC
N=3	Week 24	3 (100.0)	78.7 (18.27)		[NC,NC]	[NC,NC]
Placebo	Baseline	1 (100.0)	56.0 (NE)	NC (NC)	NC	

N=1	Week 24	1 (100.0)	57.8 (NE)			

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group. Transformed score ranges from 0 to 100 based on Likert scale (None of the time, a little of the time, some of the time, most of the time and all of the time). Higher scores are indicative of better health-related quality of life (high score = good). For the change from baseline, positive scores indicate improvement. HRQL Total includes following scales: concern, activities, energy/mood, control, self-conscious, and sexual function.
[1] Summary statistics are based on observed data.
[2] LS means, LS mean differences (95% CIs), p-value and Hedges' g (95% CIs) are based on a mixed-effects model with study, treatment, visit, and a treatment-by-visit interaction as fixed effects. The multiple visits for each patient are the repeated measures as a random effect within each patient with an unstructured covariance. Hedges' g is calculated using a small sample bias correction. Interaction p-value is only produced for the Overall period. The reference group for the LS mean difference and Hedges' g is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with data; CI: Confidence interval; LS: Least squares; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; SD: Standard deviation; SE: Standard error; SMD: Standardized mean difference; UFS-QoL: Uterine Fibroid Symptom and Health-Related Quality of Life; NC: Not calculated; NE: Non-estimable.

Table EFF.HRQLTOT.MITT.Pooled.S9: Summary of Change from Baseline in UFS-QoL Total Score by Visit and Overall, by Subgroup (mITT Population)

Study: Pooled

Treatment	Study visit	n (%)[1]	Mean (SD)[1]	Change from baseline LS-mean change (SE)[2]	Difference LS-mean change [95% CI] p-value[2]	SMD Hedges' g [95% CI][2]	Int. p-value[2]
Race							
Black/African American							
Relugolix+E2/NETA	Baseline	119 (97.5)	33.8 (22.13)	36.40 (2.211)	23.80	0.98	0.5261
N=122	Overall	107 (87.7)	69.2 (25.19)		[17.92,29.69]	[0.71,1.26]	
Placebo	Baseline	139 (98.6)	36.0 (21.28)	12.60 (2.019)	<.0001		
N=141	Overall	126 (89.4)	47.2 (23.30)				
White							
Relugolix+E2/NETA	Baseline	121 (99.2)	41.5 (20.62)	34.60 (2.127)	22.05	0.91	
N=122	Overall	112 (91.8)	76.3 (21.88)		[15.94,28.15]	[0.63,1.20]	
Placebo	Baseline	105 (100.0)	35.1 (19.76)	12.55 (2.268)	<.0001		
N=105	Overall	98 (93.3)	47.0 (20.85)				
Asian							
Relugolix+E2/NETA	Baseline	1 (100.0)	49.1 (NE)	NC (NC)	NC	NC	
N=1	Overall	1 (100.0)	95.3 (NE)		[NC,NC]	[NC,NC]	
Placebo	Baseline	3 (100.0)	30.2 (24.75)	NC (NC)	NC		
N=3	Overall	3 (100.0)	32.8 (17.29)				
Others							
Relugolix+E2/NETA	Baseline	5 (100.0)	36.7 (15.58)	21.79 (9.930)	7.83	0.29	
N=5	Overall	5 (100.0)	57.4 (21.01)		[-19.93,35.60]	[-0.83,1.42]	
Placebo	Baseline	6 (100.0)	23.0 (13.89)	13.95 (10.033)	0.5795		
N=6	Overall	5 (83.3)	34.1 (29.32)				
Not reported							
Relugolix+E2/NETA	Baseline	3 (100.0)	71.6 (28.01)	NC (NC)	NC	NC	
N=3	Overall	3 (100.0)	80.9 (19.67)		[NC,NC]	[NC,NC]	
Placebo	Baseline	1 (100.0)	56.0 (NE)	NC (NC)	NC		

N=1	Overall	1 (100.0)	53.9 (NE)				

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group. Transformed score ranges from 0 to 100 based on Likert scale (None of the time, a little of the time, some of the time, most of the time and all of the time). Higher scores are indicative of better health-related quality of life (high score = good). For the change from baseline, positive scores indicate improvement. HRQL Total includes following scales: concern, activities, energy/mood, control, self-conscious, and sexual function.
[1] Summary statistics are based on observed data. Mean (SD) are calculated based on the mean observed value across all post-baseline visits within each patient.
[2] LS means, LS mean differences (95% CIs), p-value and Hedges' g (95% CIs) are based on a mixed-effects model with study, treatment, visit, subgroup, treatment-by-visit interaction and a subgroup-by-treatment interaction as fixed effects. The multiple visits for each patient are the repeated measures as a random effect within each patient with an unstructured covariance. Hedges' g is calculated using a small sample bias correction. Not reported subgroup levels are not included in estimation of the interaction p-value. Subgroup levels with fewer than 10 subjects are not included in estimation of the interaction p-value. The reference group for the LS mean difference and Hedges' g is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with data; CI: Confidence interval; int: Interaction; LS: Least squares; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; SD: Standard deviation; SE: Standard error; SMD: Standardized mean difference; UFS-QoL: Uterine Fibroid Symptom and Health-Related Quality of Life; NC: Not calculated; NE: Non-estimable.

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Table EFF.HRQLTOT.MITT.Pooled.S7: Summary of Change from Baseline in UFS-QoL Total Score by Visit and Overall, by Subgroup (mITT Population)

Study: Pooled

Treatment	Study visit	n (%)[1]	Mean (SD)[1]	Change from baseline LS-mean change (SE)[2]	Difference LS-mean change [95% CI] p-value[2]	SMD Hedges' g [95% CI][2]
Geographic Region II						
Europe						
Relugolix+E2/NETA	Baseline	40 (97.6)	44.5 (20.76)	29.90 (3.319)	23.52	1.15
N=41	Week 12	39 (95.1)	74.0 (23.23)		[14.19,32.85]	[0.67,1.63]
Placebo	Baseline	42 (100.0)	43.5 (19.49)	6.38 (3.331)	<.0001	
N=42	Week 12	39 (92.9)	49.4 (18.55)			
Rest of World (including the US)						
Relugolix+E2/NETA	Baseline	209 (98.6)	36.9 (21.89)	32.74 (1.773)	19.90	0.83
N=212	Week 12	185 (87.3)	69.2 (26.55)		[15.00,24.79]	[0.62,1.04]
Placebo	Baseline	212 (99.1)	33.8 (20.41)	12.84 (1.747)	<.0001	
N=214	Week 12	190 (88.8)	45.8 (23.58)			

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group. Transformed score ranges from 0 to 100 based on Likert scale (None of the time, a little of the time, some of the time, most of the time and all of the time). Higher scores are indicative of better health-related quality of life (high score = good). For the change from baseline, positive scores indicate improvement. HRQL Total includes following scales: concern, activities, energy/mood, control, self-conscious, and sexual function.
[1] Summary statistics are based on observed data.
[2] LS means, LS mean differences (95% CIs), p-value and Hedges' g (95% CIs) are based on a mixed-effects model with study, treatment, visit, and a treatment-by-visit interaction as fixed effects. The multiple visits for each patient are the repeated measures as a random effect within each patient with an unstructured covariance. Hedges' g is calculated using a small sample bias correction. Interaction p-value is only produced for the Overall period. The reference group for the LS mean difference and Hedges' g is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with data; CI: Confidence interval; LS: Least squares; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; SD: Standard deviation; SE: Standard error; SMD: Standardized mean difference; UFS-QoL: Uterine Fibroid Symptom and Health-Related Quality of Life.

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Table EFF.HRQLTOT.MITT.Pooled.S7: Summary of Change from Baseline in UFS-QoL Total Score by Visit and Overall, by Subgroup (mITT Population)

Study: Pooled

Treatment	Study visit	n (%)[1]	Mean (SD)[1]	Change from baseline LS-mean change (SE)[2]	Difference LS-mean change [95% CI] p-value[2]	SMD Hedges' g [95% CI][2]
Geographic Region II						
Europe						
Relugolix+E2/NETA	Baseline	40 (97.6)	44.5 (20.76)	38.10 (3.545)	27.26	1.26
N=41	Week 24	37 (90.2)	83.6 (19.87)		[17.18,37.34]	[0.76,1.76]
Placebo	Baseline	42 (100.0)	43.5 (19.49)	10.84 (3.629)	<.0001	
N=42	Week 24	35 (83.3)	54.4 (19.38)			
Rest of World (including the US)						
Relugolix+E2/NETA	Baseline	209 (98.6)	36.9 (21.89)	37.15 (1.952)	23.83	0.93
N=212	Week 24	159 (75.0)	76.4 (24.33)		[18.45,29.21]	[0.70,1.16]
Placebo	Baseline	212 (99.1)	33.8 (20.41)	13.32 (1.917)	<.0001	
N=214	Week 24	164 (76.6)	46.1 (26.14)			

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group. Transformed score ranges from 0 to 100 based on Likert scale (None of the time, a little of the time, some of the time, most of the time and all of the time). Higher scores are indicative of better health-related quality of life (high score = good). For the change from baseline, positive scores indicate improvement. HRQL Total includes following scales: concern, activities, energy/mood, control, self-conscious, and sexual function.
[1] Summary statistics are based on observed data.
[2] LS means, LS mean differences (95% CIs), p-value and Hedges' g (95% CIs) are based on a mixed-effects model with study, treatment, visit, and a treatment-by-visit interaction as fixed effects. The multiple visits for each patient are the repeated measures as a random effect within each patient with an unstructured covariance. Hedges' g is calculated using a small sample bias correction. Interaction p-value is only produced for the Overall period. The reference group for the LS mean difference and Hedges' g is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with data; CI: Confidence interval; LS: Least squares; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; SD: Standard deviation; SE: Standard error; SMD: Standardized mean difference; UFS-QoL: Uterine Fibroid Symptom and Health-Related Quality of Life.

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Table EFF.HRQLTOT.MITT.Pooled.S7: Summary of Change from Baseline in UFS-QoL Total Score by Visit and Overall, by Subgroup (mITT Population)

Study: Pooled

Treatment	Study visit	n (%)[1]	Mean (SD)[1]	Change from baseline LS-mean change (SE)[2]	Difference LS-mean change [95% CI] p-value[2]	SMD Hedges' g [95% CI][2]	Int. p-value[2]
Geographic Region II							
Europe							0.5748
Relugolix+E2/NETA	Baseline	40 (97.6)	44.5 (20.76)	33.77 (3.591)	24.98	1.03	
N=41	Overall	39 (95.1)	77.7 (20.67)		[15.07,34.89]	[0.56,1.50]	
Placebo	Baseline	42 (100.0)	43.5 (19.49)	8.80 (3.545)	<.0001		
N=42	Overall	40 (95.2)	51.4 (16.86)				
Rest of World (including the US)							
Relugolix+E2/NETA	Baseline	209 (98.6)	36.9 (21.89)	35.05 (1.649)	21.87	0.91	
N=212	Overall	189 (89.2)	71.7 (24.21)		[17.32,26.42]	[0.69,1.12]	
Placebo	Baseline	212 (99.1)	33.8 (20.41)	13.19 (1.625)	<.0001		
N=214	Overall	193 (90.2)	45.6 (23.20)				

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group. Transformed score ranges from 0 to 100 based on Likert scale (None of the time, a little of the time, some of the time, most of the time and all of the time). Higher scores are indicative of better health-related quality of life (high score = good). For the change from baseline, positive scores indicate improvement. HRQL Total includes following scales: concern, activities, energy/mood, control, self-conscious, and sexual function.
[1] Summary statistics are based on observed data. Mean (SD) are calculated based on the mean observed value across all post-baseline visits within each patient.
[2] LS means, LS mean differences (95% CIs), p-value and Hedges' g (95% CIs) are based on a mixed-effects model with study, treatment, visit, subgroup, treatment-by-visit interaction and a subgroup-by-treatment interaction as fixed effects. The multiple visits for each patient are the repeated measures as a random effect within each patient with an unstructured covariance. Hedges' g is calculated using a small sample bias correction. The reference group for the LS mean difference and Hedges' g is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with data; CI: Confidence interval; int: Interaction; LS: Least squares; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; SD: Standard deviation; SE: Standard error; SMD: Standardized mean difference; UFS-QoL: Uterine Fibroid Symptom and Health-Related Quality of Life.

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Table EFF.HRQLTOT.MITT.Pooled.S1: Summary of Change from Baseline in UFS-QoL Total Score by Visit and Overall, by Subgroup (mITT Population)

Study: Pooled

Treatment	Study visit	n (%)[1]	Mean (SD)[1]	Change from baseline LS-mean change (SE)[2]	Difference LS-mean change [95% CI] p-value[2]	SMD Hedges' g [95% CI][2]
Age (years)						
< 40 years						
Relugolix+E2/NETA	Baseline	61 (98.4)	34.7 (20.61)	30.08 (3.076)	18.92	0.83
N=62	Week 12	57 (91.9)	63.4 (28.15)		[10.72,27.13]	[0.46,1.19]
Placebo	Baseline	78 (100.0)	36.0 (21.19)	11.16 (2.785)	<.0001	
N=78	Week 12	68 (87.2)	46.0 (23.39)			
>= 40 years						
Relugolix+E2/NETA	Baseline	188 (98.4)	39.2 (22.18)	33.02 (1.841)	20.88	0.88
N=191	Week 12	167 (87.4)	72.3 (24.93)		[15.71,26.04]	[0.65,1.11]
Placebo	Baseline	176 (98.9)	35.1 (20.31)	12.14 (1.871)	<.0001	
N=178	Week 12	161 (90.4)	46.6 (22.63)			

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group. Transformed score ranges from 0 to 100 based on Likert scale (None of the time, a little of the time, some of the time, most of the time and all of the time). Higher scores are indicative of better health-related quality of life (high score = good). For the change from baseline, positive scores indicate improvement. HRQL Total includes following scales: concern, activities, energy/mood, control, self-conscious, and sexual function.
[1] Summary statistics are based on observed data.
[2] LS means, LS mean differences (95% CIs), p-value and Hedges' g (95% CIs) are based on a mixed-effects model with study, treatment, visit, and a treatment-by-visit interaction as fixed effects. The multiple visits for each patient are the repeated measures as a random effect within each patient with an unstructured covariance. Hedges' g is calculated using a small sample bias correction. Interaction p-value is only produced for the Overall period. The reference group for the LS mean difference and Hedges' g is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with data; CI: Confidence interval; LS: Least squares; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; SD: Standard deviation; SE: Standard error; SMD: Standardized mean difference; UFS-QoL: Uterine Fibroid Symptom and Health-Related Quality of Life.

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Table EFF.HRQLTOT.MITT.Pooled.S1: Summary of Change from Baseline in UFS-QoL Total Score by Visit and Overall, by Subgroup (mITT Population)

Study: Pooled

Treatment	Study visit	n (%)[1]	Mean (SD)[1]	Change from baseline LS-mean change (SE)[2]	Difference LS-mean change [95% CI] p-value[2]	SMD Hedges' g [95% CI][2]
Age (years)						
< 40 years						
Relugolix+E2/NETA	Baseline	61 (98.4)	34.7 (20.61)	35.56 (3.612)	21.98	0.86
N=62	Week 24	47 (75.8)	69.5 (28.06)		[12.39,31.57]	[0.46,1.26]
Placebo	Baseline	78 (100.0)	36.0 (21.19)	13.58 (3.234)	<.0001	
N=78	Week 24	58 (74.4)	50.1 (24.51)			
>= 40 years						
Relugolix+E2/NETA	Baseline	188 (98.4)	39.2 (22.18)	38.02 (1.967)	25.22	1.02
N=191	Week 24	149 (78.0)	80.3 (21.58)		[19.70,30.75]	[0.77,1.26]
Placebo	Baseline	176 (98.9)	35.1 (20.31)	12.79 (2.008)	<.0001	
N=178	Week 24	141 (79.2)	46.5 (25.54)			

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group. Transformed score ranges from 0 to 100 based on Likert scale (None of the time, a little of the time, some of the time, most of the time and all of the time). Higher scores are indicative of better health-related quality of life (high score = good). For the change from baseline, positive scores indicate improvement. HRQL Total includes following scales: concern, activities, energy/mood, control, self-conscious, and sexual function.
[1] Summary statistics are based on observed data.
[2] LS means, LS mean differences (95% CIs), p-value and Hedges' g (95% CIs) are based on a mixed-effects model with study, treatment, visit, and a treatment-by-visit interaction as fixed effects. The multiple visits for each patient are the repeated measures as a random effect within each patient with an unstructured covariance. Hedges' g is calculated using a small sample bias correction. Interaction p-value is only produced for the Overall period. The reference group for the LS mean difference and Hedges' g is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with data; CI: Confidence interval; LS: Least squares; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; SD: Standard deviation; SE: Standard error; SMD: Standardized mean difference; UFS-QoL: Uterine Fibroid Symptom and Health-Related Quality of Life.

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Table EFF.HRQLTOT.MITT.Pooled.S1: Summary of Change from Baseline in UFS-QoL Total Score by Visit and Overall, by Subgroup (mITT Population)

Study: Pooled

Treatment	Study visit	n (%)[1]	Mean (SD)[1]	Change from baseline LS-mean change (SE)[2]	Difference LS-mean change [95% CI] p-value[2]	SMD Hedges' g [95% CI][2]	Int. p-value[2]
Age (years)							
< 40 years							
Relugolix+E2/NETA	Baseline	61 (98.4)	34.7 (20.61)	32.72 (2.993)	20.54	0.85	0.6035
N=62	Overall	57 (91.9)	65.6 (25.94)		[12.61,28.48]	[0.48,1.21]	
Placebo	Baseline	78 (100.0)	36.0 (21.19)	12.18 (2.710)	<.0001		
N=78	Overall	68 (87.2)	47.1 (22.06)				
>= 40 years							
Relugolix+E2/NETA	Baseline	188 (98.4)	39.2 (22.18)	35.53 (1.730)	23.00	0.95	
N=191	Overall	171 (89.5)	75.0 (22.51)		[18.15,27.84]	[0.73,1.18]	
Placebo	Baseline	176 (98.9)	35.1 (20.31)	12.53 (1.759)	<.0001		
N=178	Overall	165 (92.7)	46.5 (22.48)				

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group. Transformed score ranges from 0 to 100 based on Likert scale (None of the time, a little of the time, some of the time, most of the time and all of the time). Higher scores are indicative of better health-related quality of life (high score = good). For the change from baseline, positive scores indicate improvement. HRQL Total includes following scales: concern, activities, energy/mood, control, self-conscious, and sexual function.
[1] Summary statistics are based on observed data. Mean (SD) are calculated based on the mean observed value across all post-baseline visits within each patient.
[2] LS means, LS mean differences (95% CIs), p-value and Hedges' g (95% CIs) are based on a mixed-effects model with study, treatment, visit, subgroup, treatment-by-visit interaction and a subgroup-by-treatment interaction as fixed effects. The multiple visits for each patient are the repeated measures as a random effect within each patient with an unstructured covariance. Hedges' g is calculated using a small sample bias correction. The reference group for the LS mean difference and Hedges' g is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with data; CI: Confidence interval; int: Interaction; LS: Least squares; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; SD: Standard deviation; SE: Standard error; SMD: Standardized mean difference; UFS-QoL: Uterine Fibroid Symptom and Health-Related Quality of Life.

SOURCE: \Studies\MYV\MYV102\Analysis\Prod\Progs\TFLs\Tab_QOL_UFS_CON.SAS
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Table EFF.HRQLTOT.MITT.Pooled.S4: Summary of Change from Baseline in UFS-QoL Total Score by Visit and Overall, by Subgroup (mITT Population)

Study: Pooled

Treatment	Study visit	n (%)[1]	Mean (SD)[1]	Change from baseline LS-mean change (SE)[2]	Difference LS-mean change [95% CI] p-value[2]	SMD Hedges' g [95% CI][2]
Maximum NRS Pain Score at Baseline						
< 4						
Relugolix+E2/NETA	Baseline	72 (98.6)	45.2 (22.69)	28.55 (2.593)	20.45	0.98
N=73	Week 12	65 (89.0)	73.7 (25.42)		[12.78,28.12]	[0.60,1.37]
Placebo	Baseline	61 (98.4)	44.4 (20.71)	8.10 (2.888)	<.0001	
N=62	Week 12	52 (83.9)	49.9 (21.47)			
>= 4						
Relugolix+E2/NETA	Baseline	174 (98.3)	35.0 (20.92)	33.99 (1.960)	21.03	0.87
N=177	Week 12	156 (88.1)	68.6 (26.36)		[15.73,26.33]	[0.64,1.09]
Placebo	Baseline	189 (99.5)	32.6 (19.82)	12.96 (1.846)	<.0001	
N=190	Week 12	174 (91.6)	45.5 (23.24)			
Missing						
Relugolix+E2/NETA	Baseline	3 (100.0)	46.6 (18.95)	NC (NC)	NC	NC
N=3	Week 12	3 (100.0)	62.9 (15.76)		[NC,NC]	[NC,NC]
Placebo	Baseline	4 (100.0)	25.2 (11.26)	NC (NC)	NC	
N=4	Week 12	3 (75.0)	38.5 (18.53)			

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group. Transformed score ranges from 0 to 100 based on Likert scale (None of the time, a little of the time, some of the time, most of the time and all of the time). Higher scores are indicative of better health-related quality of life (high score = good). For the change from baseline, positive scores indicate improvement. HRQL Total includes following scales: concern, activities, energy/mood, control, self-conscious, and sexual function.
[1] Summary statistics are based on observed data.
[2] LS means, LS mean differences (95% CIs), p-value and Hedges' g (95% CIs) are based on a mixed-effects model with study, treatment, visit, and a treatment-by-visit interaction as fixed effects. The multiple visits for each patient are the repeated measures as a random effect within each patient with an unstructured covariance. Hedges' g is calculated using a small sample bias correction. Interaction p-value is only produced for the Overall period. The reference group for the LS mean difference and Hedges' g is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with data; CI: Confidence interval; LS: Least squares; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; SD: Standard deviation; SE: Standard error; SMD: Standardized mean difference; UFS-QoL: Uterine Fibroid Symptom and Health-Related Quality of Life; NC: Not calculated.

SOURCE: \Studies\MYV\MYV102\Analysis\Prod\Progs\TFLs\Tab_QOL_UFS_CON.SAS
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Table EFF.HRQLTOT.MITT.Pooled.S4: Summary of Change from Baseline in UFS-QoL Total Score by Visit and Overall, by Subgroup (mITT Population)

Study: Pooled

Treatment	Study visit	n (%)[1]	Mean (SD)[1]	Change from baseline LS-mean change (SE)[2]	Difference LS-mean change [95% CI] p-value[2]	SMD Hedges' g [95% CI][2]
Maximum NRS Pain Score at Baseline						
< 4						
Relugolix+E2/NETA	Baseline	72 (98.6)	45.2 (22.69)	31.46 (3.020)	21.50	0.92
N=73	Week 24	57 (78.1)	79.3 (23.83)		[12.53,30.46]	[0.51,1.33]
Placebo	Baseline	61 (98.4)	44.4 (20.71)	9.97 (3.376)	<.0001	
N=62	Week 24	46 (74.2)	54.0 (22.97)			
>= 4						
Relugolix+E2/NETA	Baseline	174 (98.3)	35.0 (20.92)	40.18 (2.103)	26.24	1.03
N=177	Week 24	136 (76.8)	77.4 (23.68)		[20.56,31.93]	[0.78,1.28]
Placebo	Baseline	189 (99.5)	32.6 (19.82)	13.94 (1.979)	<.0001	
N=190	Week 24	151 (79.5)	45.7 (25.78)			
Missing						
Relugolix+E2/NETA	Baseline	3 (100.0)	46.6 (18.95)	NC (NC)	NC	NC
N=3	Week 24	3 (100.0)	65.2 (24.38)		[NC,NC]	[NC,NC]
Placebo	Baseline	4 (100.0)	25.2 (11.26)	NC (NC)	NC	
N=4	Week 24	2 (50.0)	35.3 (4.88)			

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group. Transformed score ranges from 0 to 100 based on Likert scale (None of the time, a little of the time, some of the time, most of the time and all of the time). Higher scores are indicative of better health-related quality of life (high score = good). For the change from baseline, positive scores indicate improvement. HRQL Total includes following scales: concern, activities, energy/mood, control, self-conscious, and sexual function.
[1] Summary statistics are based on observed data.
[2] LS means, LS mean differences (95% CIs), p-value and Hedges' g (95% CIs) are based on a mixed-effects model with study, treatment, visit, and a treatment-by-visit interaction as fixed effects. The multiple visits for each patient are the repeated measures as a random effect within each patient with an unstructured covariance. Hedges' g is calculated using a small sample bias correction. Interaction p-value is only produced for the Overall period. The reference group for the LS mean difference and Hedges' g is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with data; CI: Confidence interval; LS: Least squares; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; SD: Standard deviation; SE: Standard error; SMD: Standardized mean difference; UFS-QoL: Uterine Fibroid Symptom and Health-Related Quality of Life; NC: Not calculated.

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Table EFF.HRQLTOT.MITT.Pooled.S4: Summary of Change from Baseline in UFS-QoL Total Score by Visit and Overall, by Subgroup (mITT Population)

Study: Pooled

Treatment	Study visit	n (%)[1]	Mean (SD)[1]	Change from baseline LS-mean change (SE)[2]	Difference LS-mean change [95% CI] p-value[2]	SMD Hedges' g [95% CI][2]	Int. p-value[2]
Maximum NRS Pain Score at Baseline							
< 4							
Relugolix+E2/NETA	Baseline	72 (98.6)	45.2 (22.69)	30.49 (2.765)	21.39	0.88	0.6522
N=73	Overall	66 (90.4)	75.3 (23.87)		[13.27,29.50]	[0.51,1.26]	
Placebo	Baseline	61 (98.4)	44.4 (20.71)	9.10 (3.072)	<.0001		
N=62	Overall	54 (87.1)	50.5 (20.40)				
>= 4							
Relugolix+E2/NETA	Baseline	174 (98.3)	35.0 (20.92)	37.00 (1.793)	23.55	0.98	
N=177	Overall	159 (89.8)	71.8 (23.74)		[18.71,28.39]	[0.75,1.21]	
Placebo	Baseline	189 (99.5)	32.6 (19.82)	13.45 (1.691)	<.0001		
N=190	Overall	176 (92.6)	45.6 (22.93)				
Missing							
Relugolix+E2/NETA	Baseline	3 (100.0)	46.6 (18.95)	NC (NC)	NC	NC	
N=3	Overall	3 (100.0)	64.1 (18.98)		[NC,NC]	[NC,NC]	
Placebo	Baseline	4 (100.0)	25.2 (11.26)	NC (NC)	NC		
N=4	Overall	3 (75.0)	38.9 (12.52)				

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group. Transformed score ranges from 0 to 100 based on Likert scale (None of the time, a little of the time, some of the time, most of the time and all of the time). Higher scores are indicative of better health-related quality of life (high score = good). For the change from baseline, positive scores indicate improvement. HRQL Total includes following scales: concern, activities, energy/mood, control, self-conscious, and sexual function.
[1] Summary statistics are based on observed data. Mean (SD) are calculated based on the mean observed value across all post-baseline visits within each patient.
[2] LS means, LS mean differences (95% CIs), p-value and Hedges' g (95% CIs) are based on a mixed-effects model with study, treatment, visit, subgroup, treatment-by-visit interaction and a subgroup-by-treatment interaction as fixed effects. The multiple visits for each patient are the repeated measures as a random effect within each patient with an unstructured covariance. Hedges' g is calculated using a small sample bias correction. Missing subgroup levels are not included in estimation of the interaction p-value. The reference group for the LS mean difference and Hedges' g is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with data; CI: Confidence interval; int: Interaction; LS: Least squares; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; SD: Standard deviation; SE: Standard error; SMD: Standardized mean difference; UFS-QoL: Uterine Fibroid Symptom and Health-Related Quality of Life; NC: Not calculated.

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1.2.15 Summary of Change from Baseline in European Quality of Life Five Dimension Five Level Scale (VAS Score) at Week 24, by Subgroup (mITT Population)

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Table EFF.EQ5D0206.MITT.Pooled.S5: Summary of Change from Baseline in European Quality of Life Five Dimension Five Level Scale (VAS Score) at Week 24, by Subgroup (mITT Population)

Study: Pooled

Treatment	Study visit	n (%)[1]	Mean (SD)[1]	Change from baseline LS-mean change (SE)[2]	Difference LS-mean change [95% CI] p-value[2]	SMD Hedges' g [95% CI][2]	Int. p-value[2]
MBL Volume at Baseline (mL)							
< 225 mL							
Relugolix+E2/NETA	Baseline	163 (99.4)	75.3 (17.89)	5.86 (1.740)	0.46	0.02	0.1921
N=164	Week 24	126 (76.8)	80.9 (18.95)		[-4.29,5.21]	[-0.22,0.26]	
Placebo	Baseline	169 (98.8)	73.1 (19.05)	5.40 (1.676)	0.8502		
N=171	Week 24	138 (80.7)	78.6 (17.66)				
>= 225 mL							
Relugolix+E2/NETA	Baseline	86 (96.6)	74.2 (19.28)	7.53 (2.335)	5.90	0.30	
N=89	Week 24	73 (82.0)	81.0 (14.34)		[-0.77,12.57]	[-0.04,0.64]	
Placebo	Baseline	84 (98.8)	77.9 (18.58)	1.63 (2.461)	0.0829		
N=85	Week 24	63 (74.1)	78.8 (17.26)				

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group.
[1] Summary statistics are based on observed data.
[2] LS means, LS mean differences (95% CIs), p-value and Hedges' g (95% CIs) are based on an Analysis of Variance (ANOVA) model with study, treatment, subgroup and a subgroup-by-treatment interaction as covariates. Hedges' g is calculated using a small sample bias correction.
The reference group for the LS mean difference and Hedges' g is Placebo.
Interaction p-value is based on the subgroup-by-treatment interaction term in the ANOVA model used to compute the LS means, mean differences and 95% CIs.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with data; CI: Confidence interval; int: Interaction; LS: Least squares; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; SD: Standard deviation; SE: Standard error; SMD: Standardized mean difference; VAS: Visual analogue scale.

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Table EFF.EQ5D0206.MITT.Pooled.S3: Summary of Change from Baseline in European Quality of Life Five Dimension Five Level Scale (VAS Score) at Week 24, by Subgroup (mITT Population)

Study: Pooled

Treatment	Study visit	n (%)[1]	Mean (SD)[1]	Change from baseline LS-mean change (SE)[2]	Difference LS-mean change [95% CI] p-value[2]	SMD Hedges' g [95% CI][2]	Int. p-value[2]
Uterine Volume at Baseline (cm3)							
< 300 cm3							
Relugolix+E2/NETA	Baseline	147 (99.3)	75.0 (18.53)	7.46 (1.799)	4.32	0.22	0.2350
N=148	Week 24	119 (80.4)	81.9 (18.22)		[-0.87,9.50]	[-0.04,0.48]	
Placebo	Baseline	129 (100.0)	74.9 (18.33)	3.14 (1.926)	0.1023		
N=129	Week 24	103 (79.8)	76.9 (19.85)				
>= 300 cm3							
Relugolix+E2/NETA	Baseline	101 (97.1)	74.9 (18.15)	4.94 (2.213)	-0.41	-0.02	
N=104	Week 24	80 (76.9)	79.6 (16.02)		[-6.27,5.44]	[-0.32,0.28]	
Placebo	Baseline	124 (97.6)	74.4 (19.73)	5.35 (1.995)	0.8895		
N=127	Week 24	98 (77.2)	80.4 (14.49)				
Missing							
Relugolix+E2/NETA	Baseline	1 (100.0)	54.0 (NE)	NC (NC)	NC	NC	
N=1	Week 24	0	NE (NE)		[NC,NC]	[NC,NC]	
Placebo	Baseline	0	NE (NE)	NC (NC)	NC		
N=0	Week 24	0	NE (NE)				

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group.
[1] Summary statistics are based on observed data.
[2] LS means, LS mean differences (95% CIs), p-value and Hedges' g (95% CIs) are based on an Analysis of Variance (ANOVA) model with study, treatment, subgroup and a subgroup-by-treatment interaction as covariates. Hedges' g is calculated using a small sample bias correction. Missing subgroup levels are not included in estimation of the interaction p-value. The reference group for the LS mean difference and Hedges' g is Placebo. Interaction p-value is based on the subgroup-by-treatment interaction term in the ANOVA model used to compute the LS means, mean differences and 95% CIs.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with data; CI: Confidence interval; int: Interaction; LS: Least squares; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; SD: Standard deviation; SE: Standard error; SMD: Standardized mean difference; VAS: Visual analogue scale; NC: Not calculated; NE: Non-estimable.

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Table EFF.EQ5D0206.MITT.Pooled.S2: Summary of Change from Baseline in European Quality of Life Five Dimension Five Level Scale (VAS Score) at Week 24, by Subgroup (mITT Population)

Study: Pooled

Treatment	Study visit	n (%)[1]	Mean (SD)[1]	Change from baseline LS-mean change (SE)[2]	Difference LS-mean change [95% CI] p-value[2]	SMD Hedges' g [95% CI][2]	Int. p-value[2]
BMI (kg/m2) at Baseline							
< 30							
Relugolix+E2/NETA	Baseline	118 (99.2)	75.4 (17.17)	8.25 (2.062)	4.83	0.25	0.2411
N=119	Week 24	90 (75.6)	82.4 (17.23)		[-0.95,10.61]	[-0.05,0.54]	
Placebo	Baseline	115 (100.0)	75.1 (19.33)	3.42 (2.097)	0.1014		
N=115	Week 24	87 (75.7)	80.2 (15.72)				
>= 30							
Relugolix+E2/NETA	Baseline	130 (97.7)	74.4 (19.46)	5.00 (1.909)	0.18	0.01	
N=133	Week 24	108 (81.2)	79.8 (17.54)		[-5.05,5.40]	[-0.26,0.27]	
Placebo	Baseline	138 (97.9)	74.3 (18.77)	4.82 (1.851)	0.9474		
N=141	Week 24	114 (80.9)	77.4 (18.72)				
Missing							
Relugolix+E2/NETA	Baseline	1 (100.0)	86.0 (NE)	NC (NC)	NC	NC	
N=1	Week 24	1 (100.0)	85.0 (NE)		[NC,NC]	[NC,NC]	
Placebo	Baseline	0	NE (NE)	NC (NC)	NC		
N=0	Week 24	0	NE (NE)				

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group.
[1] Summary statistics are based on observed data.
[2] LS means, LS mean differences (95% CIs), p-value and Hedges' g (95% CIs) are based on an Analysis of Variance (ANOVA) model with study, treatment, subgroup and a subgroup-by-treatment interaction as covariates. Hedges' g is calculated using a small sample bias correction. Missing subgroup levels are not included in estimation of the interaction p-value. The reference group for the LS mean difference and Hedges' g is Placebo. Interaction p-value is based on the subgroup-by-treatment interaction term in the ANOVA model used to compute the LS means, mean differences and 95% CIs.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with data; CI: Confidence interval; int: Interaction; LS: Least squares; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; SD: Standard deviation; SE: Standard error; SMD: Standardized mean difference; VAS: Visual analogue scale; NC: Not calculated; NE: Non-estimable.

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Table EFF.EQ5D0206.MITT.Pooled.S6: Summary of Change from Baseline in European Quality of Life Five Dimension Five Level Scale (VAS Score) at Week 24, by Subgroup (mITT Population)

Study: Pooled

Treatment	Study visit	n (%)[1]	Mean (SD)[1]	Change from baseline LS-mean change (SE)[2]	Difference LS-mean change [95% CI] p-value[2]	SMD Hedges' g [95% CI][2]	Int. p-value[2]
Geographic Region I							
North America							
Relugolix+E2/NETA	Baseline	188 (98.4)	75.4 (17.92)	5.80 (1.659)	0.98	0.05	0.3039
N=191	Week 24	142 (74.3)	80.9 (17.24)		[-3.58,5.54]	[-0.18,0.28]	
Placebo	Baseline	191 (98.5)	76.2 (18.87)	4.82 (1.625)	0.6728		
N=194	Week 24	147 (75.8)	81.3 (15.42)				
Rest of World							
Relugolix+E2/NETA	Baseline	61 (98.4)	73.4 (19.71)	8.05 (2.591)	5.49	0.28	
N=62	Week 24	57 (91.9)	81.2 (17.82)		[-1.81,12.79]	[-0.09,0.65]	
Placebo	Baseline	62 (100.0)	69.9 (18.76)	2.56 (2.661)	0.1402		
N=62	Week 24	54 (87.1)	71.3 (20.62)				

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group.
[1] Summary statistics are based on observed data.
[2] LS means, LS mean differences (95% CIs), p-value and Hedges' g (95% CIs) are based on an Analysis of Variance (ANOVA) model with study, treatment, subgroup and a subgroup-by-treatment interaction as covariates. Hedges' g is calculated using a small sample bias correction.
The reference group for the LS mean difference and Hedges' g is Placebo.
Interaction p-value is based on the subgroup-by-treatment interaction term in the ANOVA model used to compute the LS means, mean differences and 95% CIs.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with data; CI: Confidence interval; int: Interaction; LS: Least squares; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; SD: Standard deviation; SE: Standard error; SMD: Standardized mean difference; VAS: Visual analogue scale.

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Table EFF.EQ5D0206.MITT.Pooled.S9: Summary of Change from Baseline in European Quality of Life Five Dimension Five Level Scale (VAS Score) at Week 24, by Subgroup (mITT Population)							
Study: Pooled							
Treatment	**Study visit**	**n (%)[1]**	**Mean (SD)[1]**	**Change from baseline LS-mean change (SE)[2]**	**Difference LS-mean change [95% CI] p-value[2]**	**SMD Hedges' g [95% CI][2]**	**Int. p-value[2]**
Race							
Black/African American							
Relugolix+E2/NETA	Baseline	119 (97.5)	74.3 (18.04)	6.32 (2.105)	0.73	0.04	0.3229
N=122	Week 24	89 (73.0)	80.0 (18.37)		[-4.84,6.30]	[-0.24,0.32]	
Placebo	Baseline	139 (98.6)	77.3 (18.56)	5.58 (1.898)	0.7965		
N=141	Week 24	108 (76.6)	83.6 (12.72)				
White							
Relugolix+E2/NETA	Baseline	121 (99.2)	75.1 (18.88)	6.87 (1.963)	4.74	0.24	
N=122	Week 24	101 (82.8)	81.7 (16.46)		[-0.96,10.45]	[-0.05,0.53]	
Placebo	Baseline	104 (99.0)	72.1 (18.00)	2.13 (2.135)	0.1026		
N=105	Week 24	86 (81.9)	73.1 (20.56)				
Asian							
Relugolix+E2/NETA	Baseline	1 (100.0)	91.0 (NE)	NC (NC)	NC	NC	
N=1	Week 24	1 (100.0)	100.0 (NE)		[NC,NC]	[NC,NC]	
Placebo	Baseline	3 (100.0)	75.3 (30.75)	NC (NC)	NC		
N=3	Week 24	2 (66.7)	90.5 (0.71)				
Others							
Relugolix+E2/NETA	Baseline	5 (100.0)	76.0 (15.17)	NC (NC)	NC	NC	
N=5	Week 24	5 (100.0)	73.6 (20.12)		[NC,NC]	[NC,NC]	
Placebo	Baseline	6 (100.0)	56.7 (29.98)	NC (NC)	NC		
N=6	Week 24	4 (66.7)	58.0 (14.90)				
Not reported							
Relugolix+E2/NETA	Baseline	3 (100.0)	83.0 (21.38)	NC (NC)	NC	NC	
N=3	Week 24	3 (100.0)	93.3 (4.04)		[NC,NC]	[NC,NC]	
Placebo	Baseline	1 (100.0)	70.0 (NE)	NC (NC)	NC		

N=1	Week 24	1 (100.0)	81.0 (NE)				

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group.
[1] Summary statistics are based on observed data.
[2] LS means, LS mean differences (95% CIs), p-value and Hedges' g (95% CIs) are based on an Analysis of Variance (ANOVA) model with study, treatment, subgroup and a subgroup-by-treatment interaction as covariates. Hedges' g is calculated using a small sample bias correction. Not reported subgroup levels are not included in estimation of the interaction p-value. Subgroup levels with fewer than 10 subjects are not included in estimation of the interaction p-value.
The reference group for the LS mean difference and Hedges' g is Placebo.
Interaction p-value is based on the subgroup-by-treatment interaction term in the ANOVA model used to compute the LS means, mean differences and 95% CIs.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with data; CI: Confidence interval; int: Interaction; LS: Least squares; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; SD: Standard deviation; SE: Standard error; SMD: Standardized mean difference; VAS: Visual analogue scale; NC: Not calculated; NE: Non-estimable.

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Table EFF.EQ5D0206.MITT.Pooled.S1: Summary of Change from Baseline in European Quality of Life Five Dimension Five Level Scale (VAS Score) at Week 24, by Subgroup (mITT Population)

Study: Pooled

Treatment	Study visit	n (%)[1]	Mean (SD)[1]	Change from baseline LS-mean change (SE)[2]	Difference LS-mean change [95% CI] p-value[2]	SMD Hedges' g [95% CI][2]	Int. p-value[2]
Age (years)							
< 40 years							
Relugolix+E2/NETA	Baseline	61 (98.4)	74.8 (18.48)	7.57 (2.800)	3.82	0.19	0.6313
N=62	Week 24	50 (80.6)	81.5 (16.05)		[-3.65,11.29]	[-0.18,0.57]	
Placebo	Baseline	78 (100.0)	75.3 (16.77)	3.75 (2.570)	0.3150		
N=78	Week 24	58 (74.4)	80.3 (15.18)				
>= 40 years							
Relugolix+E2/NETA	Baseline	188 (98.4)	75.0 (18.36)	6.08 (1.615)	1.69	0.09	
N=191	Week 24	149 (78.0)	80.8 (17.83)		[-2.85,6.22]	[-0.14,0.32]	
Placebo	Baseline	175 (98.3)	74.4 (19.95)	4.40 (1.650)	0.4650		
N=178	Week 24	143 (80.3)	77.9 (18.35)				

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group.
[1] Summary statistics are based on observed data.
[2] LS means, LS mean differences (95% CIs), p-value and Hedges' g (95% CIs) are based on an Analysis of Variance (ANOVA) model with study, treatment, subgroup and a subgroup-by-treatment interaction as covariates. Hedges' g is calculated using a small sample bias correction.
The reference group for the LS mean difference and Hedges' g is Placebo.
Interaction p-value is based on the subgroup-by-treatment interaction term in the ANOVA model used to compute the LS means, mean differences and 95% CIs.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with data; CI: Confidence interval; int: Interaction; LS: Least squares; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; SD: Standard deviation; SE: Standard error; SMD: Standardized mean difference; VAS: Visual analogue scale.

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Table EFF.EQ5D0206.MITT.Pooled.S7: Summary of Change from Baseline in European Quality of Life Five Dimension Five Level Scale (VAS Score) at Week 24, by Subgroup (mITT Population)

Study: Pooled

Treatment	Study visit	n (%)[1]	Mean (SD)[1]	Change from baseline LS-mean change (SE)[2]	Difference LS-mean change [95% CI] p-value[2]	SMD Hedges' g [95% CI][2]	Int. p-value[2]
Geographic Region II							
Europe							0.8325
Relugolix+E2/NETA	Baseline	40 (97.6)	74.2 (18.54)	7.73 (3.218)	3.12	0.16	
N=41	Week 24	37 (90.2)	81.1 (18.53)		[-5.91,12.15]	[-0.30,0.61]	
Placebo	Baseline	42 (100.0)	69.9 (18.48)	4.61 (3.279)	0.4979		
N=42	Week 24	36 (85.7)	73.3 (16.59)				
Rest of World (including the US)							
Relugolix+E2/NETA	Baseline	209 (98.6)	75.1 (18.36)	6.16 (1.552)	2.04	0.10	
N=212	Week 24	162 (76.4)	80.9 (17.15)		[-2.25,6.33]	[-0.11,0.32]	
Placebo	Baseline	211 (98.6)	75.6 (19.00)	4.12 (1.533)	0.3505		
N=214	Week 24	165 (77.1)	79.8 (17.52)				

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group.
[1] Summary statistics are based on observed data.
[2] LS means, LS mean differences (95% CIs), p-value and Hedges' g (95% CIs) are based on an Analysis of Variance (ANOVA) model with study, treatment, subgroup and a subgroup-by-treatment interaction as covariates. Hedges' g is calculated using a small sample bias correction.
The reference group for the LS mean difference and Hedges' g is Placebo.
Interaction p-value is based on the subgroup-by-treatment interaction term in the ANOVA model used to compute the LS means, mean differences and 95% CIs.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with data; CI: Confidence interval; int: Interaction; LS: Least squares; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; SD: Standard deviation; SE: Standard error; SMD: Standardized mean difference; VAS: Visual analogue scale.

SOURCE: \Studies\MYV\MYV102\Analysis\Prod\Progs\TFLs\Tab_QOL_UFS_CON.SAS
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Table EFF.EQ5D0206.MITT.Pooled.S4: Summary of Change from Baseline in European Quality of Life Five Dimension Five Level Scale (VAS Score) at Week 24, by Subgroup (mITT Population)

Study: Pooled

Treatment	Study visit	n (%)[1]	Mean (SD)[1]	Change from baseline LS-mean change (SE)[2]	Difference LS-mean change [95% CI] p-value[2]	SMD Hedges' g [95% CI][2]	Int. p-value[2]
Maximum NRS Pain Score at Baseline							
< 4							
Relugolix+E2/NETA	Baseline	72 (98.6)	78.8 (17.71)	3.75 (2.581)	2.51	0.13	0.9771
N=73	Week 24	57 (78.1)	82.6 (14.92)		[-5.13,10.14]	[-0.26,0.52]	
Placebo	Baseline	60 (96.8)	81.0 (13.11)	1.24 (2.904)	0.5189		
N=62	Week 24	47 (75.8)	81.0 (13.00)				
>= 4							
Relugolix+E2/NETA	Baseline	174 (98.3)	73.4 (18.58)	7.66 (1.670)	2.38	0.12	
N=177	Week 24	139 (78.5)	80.4 (18.42)		[-2.15,6.91]	[-0.11,0.35]	
Placebo	Baseline	189 (99.5)	72.6 (20.23)	5.28 (1.586)	0.3027		
N=190	Week 24	151 (79.5)	78.0 (18.65)				
Missing							
Relugolix+E2/NETA	Baseline	3 (100.0)	71.7 (2.89)	NC (NC)	NC	NC	
N=3	Week 24	3 (100.0)	75.3 (8.08)		[NC,NC]	[NC,NC]	
Placebo	Baseline	4 (100.0)	79.0 (13.83)	NC (NC)	NC		
N=4	Week 24	3 (75.0)	74.0 (20.66)				

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group.
[1] Summary statistics are based on observed data.
[2] LS means, LS mean differences (95% CIs), p-value and Hedges' g (95% CIs) are based on an Analysis of Variance (ANOVA) model with study, treatment, subgroup and a subgroup-by-treatment interaction as covariates. Hedges' g is calculated using a small sample bias correction. Missing subgroup levels are not included in estimation of the interaction p-value. The reference group for the LS mean difference and Hedges' g is Placebo. Interaction p-value is based on the subgroup-by-treatment interaction term in the ANOVA model used to compute the LS means, mean differences and 95% CIs.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with data; CI: Confidence interval; int: Interaction; LS: Least squares; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; SD: Standard deviation; SE: Standard error; SMD: Standardized mean difference; VAS: Visual analogue scale; NC: Not calculated.

SOURCE: \Studies\MYV\MYV102\Analysis\Prod\Progs\TFLs\Tab_QOL_UFS_CON.SAS
Date/time of run: 20APR2021 16:38
Analysis Plan: 13JAN2021

Table EFF.EQ5D0206.MITT.Pooled.S8: Summary of Change from Baseline in European Quality of Life Five Dimension Five Level Scale (VAS Score) at Week 24, by Subgroup (mITT Population)

Study: Pooled

Treatment	Study visit	n (%)[1]	Mean (SD)[1]	Change from baseline LS-mean change (SE)[2]	Difference LS-mean change [95% CI] p-value[2]	SMD Hedges' g [95% CI][2]	Int. p-value[2]
Ethnicity							
Hispanic or Latino							0.9880
Relugolix+E2/NETA	Baseline	52 (100.0)	73.8 (21.50)	6.17 (2.892)	2.50	0.13	
N=52	Week 24	45 (86.5)	80.5 (20.19)		[-5.50,10.51]	[-0.28,0.54]	
Placebo	Baseline	55 (100.0)	73.5 (20.04)	3.67 (2.852)	0.5390		
N=55	Week 24	46 (83.6)	76.0 (24.70)				
Not Hispanic or Latino							
Relugolix+E2/NETA	Baseline	193 (98.0)	75.3 (17.46)	6.33 (1.589)	2.43	0.13	
N=197	Week 24	151 (76.6)	80.9 (16.59)		[-1.97,6.84]	[-0.10,0.35]	
Placebo	Baseline	196 (98.5)	75.2 (18.55)	3.90 (1.575)	0.2781		
N=199	Week 24	153 (76.9)	79.3 (14.71)				
Not reported							
Relugolix+E2/NETA	Baseline	4 (100.0)	70.8 (20.61)	NC (NC)	NC	NC	
N=4	Week 24	3 (75.0)	93.3 (4.04)		[NC,NC]	[NC,NC]	
Placebo	Baseline	2 (100.0)	50.0 (28.28)	NC (NC)	NC		
N=2	Week 24	2 (100.0)	90.5 (13.44)				

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group.
[1] Summary statistics are based on observed data.
[2] LS means, LS mean differences (95% CIs), p-value and Hedges' g (95% CIs) are based on an Analysis of Variance (ANOVA) model with study, treatment, subgroup and a subgroup-by-treatment interaction as covariates. Hedges' g is calculated using a small sample bias correction. Not reported subgroup levels are not included in estimation of the interaction p-value. The reference group for the LS mean difference and Hedges' g is Placebo. Interaction p-value is based on the subgroup-by-treatment interaction term in the ANOVA model used to compute the LS means, mean differences and 95% CIs.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with data; CI: Confidence interval; int: Interaction; LS: Least squares; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; SD: Standard deviation; SE: Standard error; SMD: Standardized mean difference; VAS: Visual analogue scale; NC: Not calculated.

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1.2.16 Proportion of Patients with >= 7 Points Increase in the EQ-5D-5L VAS Scale at Week 24, by Subgroup (mITT Population)

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Table QOL.EQVAS7.MITT.Pooled.S1: Proportion of Patients with >= 7 Points Increase in the EQ-5D-5L VAS Scale at Week 24, by Subgroup (mITT Population)

Study: Pooled

Treatment	N	n (%)	OR[1] [95% CI]	RR[2] [95% CI]	RD[3] [95% CI]	p-value[4]	p-value (int)[5]
Age (years)							
< 40 years							
Relugolix+E2/NETA	62	26 (41.9)	2.24 [1.09;4.61]	1.72 [1.06;2.80]	0.18 [0.02;0.33]	0.0279	0.2052
Placebo	78	19 (24.4)					
>= 40 years							
Relugolix+E2/NETA	191	75 (39.3)	1.30 [0.85;2.00]	1.18 [0.90;1.56]	0.06 [-0.04;0.16]	0.2232	
Placebo	178	59 (33.1)					

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group.
[1] OR (95% CI) based on a logistic regression model adjusting for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates.
[2] RR (95% CI) based on a Cochran-Mantel-Haenszel approach stratified by study.
[3] RD (95% CI) based on a Mantel-Haenszel approach stratified by study. 95% CIs are based on the approximation to the normal distribution using the Sato estimator for the standard error.
[4] P-value based on a Cochran-Mantel-Haenszel test stratified by study.
[5] Interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the OR (95% CI).
A continuity correction is applied in estimation of the OR, RR and p-value if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum. No continuity correction is applied in the estimation of the RD.
The reference group for the OR, RR and RD is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with an event; OR: Odds ratio; RR: Risk ratio; RD: Risk difference; CI: Confidence interval; int: p-value for interaction; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; NC: Not calculated.

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Table QOL.EQVAS7.MITT.Pooled.S5: Proportion of Patients with >= 7 Points Increase in the EQ-5D-5L VAS Scale at Week 24, by Subgroup (mITT Population)

Study: Pooled

Treatment	N	n (%)	OR[1] [95% CI]	RR[2] [95% CI]	RD[3] [95% CI]	p-value[4]	p-value (int)[5]
MBL Volume at Baseline (mL)							
< 225 mL							
Relugolix+E2/NETA	164	62 (37.8)	1.28	1.18	0.06	0.2787	0.2098
Placebo	171	55 (32.2)	[0.82;2.01]	[0.88;1.58]	[-0.05;0.16]		
>= 225 mL							
Relugolix+E2/NETA	89	39 (43.8)	2.10	1.62	0.17	0.0211	
Placebo	85	23 (27.1)	[1.11;3.97]	[1.07;2.46]	[0.03;0.31]		

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group.
[1] OR (95% CI) based on a logistic regression model adjusting for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates.
[2] RR (95% CI) based on a Cochran-Mantel-Haenszel approach stratified by study.
[3] RD (95% CI) based on a Mantel-Haenszel approach stratified by study. 95% CIs are based on the approximation to the normal distribution using the Sato estimator for the standard error.
[4] P-value based on a Cochran-Mantel-Haenszel test stratified by study.
[5] Interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the OR (95% CI).
A continuity correction is applied in estimation of the OR, RR and p-value if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum. No continuity correction is applied in the estimation of the RD.
The reference group for the OR, RR and RD is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with an event; OR: Odds ratio; RR: Risk ratio; RD: Risk difference; CI: Confidence interval; int: p-value for interaction; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; NC: Not calculated.

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Table QOL.EQVAS7.MITT.Pooled.S2: Proportion of Patients with >= 7 Points Increase in the EQ-5D-5L VAS Scale at Week 24, by Subgroup (mITT Population)

Study: Pooled

Treatment	N	n (%)	OR[1] [95% CI]	RR[2] [95% CI]	RD[3] [95% CI]	p-value[4]	p-value (int)[5]
BMI (kg/m2) at Baseline							
< 30							
Relugolix+E2/NETA	119	46 (38.7)	1.86	1.53	0.13	0.0283	0.3705
Placebo	115	29 (25.2)	[1.06;3.26]	[1.04;2.25]	[0.02;0.25]		
>= 30							
Relugolix+E2/NETA	133	55 (41.4)	1.33	1.19	0.07	0.2575	
Placebo	141	49 (34.8)	[0.81;2.16]	[0.88;1.62]	[-0.05;0.18]		
Missing							
Relugolix+E2/NETA	1	0	NC	NC	NC	NC	
Placebo	0	0	[NC;NC]	[NC;NC]	[NC;NC]		

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group.
[1] OR (95% CI) based on a logistic regression model adjusting for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates.
[2] RR (95% CI) based on a Cochran-Mantel-Haenszel approach stratified by study.
[3] RD (95% CI) based on a Mantel-Haenszel approach stratified by study. 95% CIs are based on the approximation to the normal distribution using the Sato estimator for the standard error.
[4] P-value based on a Cochran-Mantel-Haenszel test stratified by study.
[5] Interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the OR (95% CI). Missing subgroup levels are not included in estimation of the interaction p-value.
A continuity correction is applied in estimation of the OR, RR and p-value if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum. No continuity correction is applied in the estimation of the RD.
The reference group for the OR, RR and RD is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with an event; OR: Odds ratio; RR: Risk ratio; RD: Risk difference; CI: Confidence interval; int: p-value for interaction; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; NC: Not calculated.

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Table QOL.EQVAS7.MITT.Pooled.S6: Proportion of Patients with >= 7 Points Increase in the EQ-5D-5L VAS Scale at Week 24, by Subgroup (mITT Population)

Study: Pooled

Treatment	N	n (%)	OR[1] [95% CI]	RR[2] [95% CI]	RD[3] [95% CI]	p-value[4]	p-value (int)[5]
Geographic Region I							
North America							
Relugolix+E2/NETA	191	72 (37.7)	1.42	1.26	0.08	0.1072	0.5420
Placebo	194	58 (29.9)	[0.93;2.17]	[0.95;1.67]	[-0.02;0.17]		
Rest of World							
Relugolix+E2/NETA	62	29 (46.8)	1.84	1.45	0.14	0.1026	
Placebo	62	20 (32.3)	[0.89;3.82]	[0.92;2.26]	[-0.03;0.31]		

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group.
[1] OR (95% CI) based on a logistic regression model adjusting for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates.
[2] RR (95% CI) based on a Cochran-Mantel-Haenszel approach stratified by study.
[3] RD (95% CI) based on a Mantel-Haenszel approach stratified by study. 95% CIs are based on the approximation to the normal distribution using the Sato estimator for the standard error.
[4] P-value based on a Cochran-Mantel-Haenszel test stratified by study.
[5] Interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the OR (95% CI). Missing subgroup levels are not included in estimation of the interaction p-value.
A continuity correction is applied in estimation of the OR, RR and p-value if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum. No continuity correction is applied in the estimation of the RD.
The reference group for the OR, RR and RD is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with an event; OR: Odds ratio; RR: Risk ratio; RD: Risk difference; CI: Confidence interval; int: p-value for interaction; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; NC: Not calculated.

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Table QOL.EQVAS7.MITT.Pooled.S8: Proportion of Patients with >= 7 Points Increase in the EQ-5D-5L VAS Scale at Week 24, by Subgroup (mITT Population)

Study: Pooled

Treatment	N	n (%)	OR[1] [95% CI]	RR[2] [95% CI]	RD[3] [95% CI]	p-value[4]	p-value (int)[5]
Ethnicity							
Hispanic or Latino							
Relugolix+E2/NETA	52	22 (42.3)	1.35	1.27	0.09	0.3561	0.7042
Placebo	55	19 (34.5)	[0.62;2.97]	[0.77;2.10]	[-0.10;0.28]		
Not Hispanic or Latino							
Relugolix+E2/NETA	197	77 (39.1)	1.61	1.38	0.11	0.0252	
Placebo	199	57 (28.6)	[1.06;2.45]	[1.04;1.83]	[0.01;0.20]		
Not reported							
Relugolix+E2/NETA	4	2 (50.0)	NC	NC	NC	NC	
Placebo	2	2 (100.0)	[NC;NC]	[NC;NC]	[NC;NC]		

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group.
[1] OR (95% CI) based on a logistic regression model adjusting for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates.
[2] RR (95% CI) based on a Cochran-Mantel-Haenszel approach stratified by study.
[3] RD (95% CI) based on a Mantel-Haenszel approach stratified by study. 95% CIs are based on the approximation to the normal distribution using the Sato estimator for the standard error.
[4] P-value based on a Cochran-Mantel-Haenszel test stratified by study.
[5] Interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the OR (95% CI). Not reported subgroup levels are not included in estimation of the interaction p-value.
A continuity correction is applied in estimation of the OR, RR and p-value if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum. No continuity correction is applied in the estimation of the RD.
The reference group for the OR, RR and RD is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with an event; OR: Odds ratio; RR: Risk ratio; RD: Risk difference; CI: Confidence interval; int: p-value for interaction; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; NC: Not calculated.

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Table QOL.EQVAS7.MITT.Pooled.S4: Proportion of Patients with >= 7 Points Increase in the EQ-5D-5L VAS Scale at Week 24, by Subgroup (mITT Population)

Study: Pooled

Treatment	N	n (%)	OR[1] [95% CI]	RR[2] [95% CI]	RD[3] [95% CI]	p-value[4]	p-value (int)[5]
Maximum NRS Pain Score at Baseline							
< 4							
Relugolix+E2/NETA	73	23 (31.5)	1.71	1.48	0.10	0.1826	0.7986
Placebo	62	13 (21.0)	[0.78;3.76]	[0.83;2.63]	[-0.05;0.25]		
>= 4							
Relugolix+E2/NETA	177	77 (43.5)	1.52	1.29	0.10	0.0516	
Placebo	190	64 (33.7)	[1.00;2.33]	[1.00;1.68]	[-0.00;0.20]		
Missing							
Relugolix+E2/NETA	3	1 (33.3)	NC	NC	NC	NC	
Placebo	4	1 (25.0)	[NC;NC]	[NC;NC]	[NC;NC]		

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group.
[1] OR (95% CI) based on a logistic regression model adjusting for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates.
[2] RR (95% CI) based on a Cochran-Mantel-Haenszel approach stratified by study.
[3] RD (95% CI) based on a Mantel-Haenszel approach stratified by study. 95% CIs are based on the approximation to the normal distribution using the Sato estimator for the standard error.
[4] P-value based on a Cochran-Mantel-Haenszel test stratified by study.
[5] Interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the OR (95% CI). Missing subgroup levels are not included in estimation of the interaction p-value.
A continuity correction is applied in estimation of the OR, RR and p-value if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum. No continuity correction is applied in the estimation of the RD.
The reference group for the OR, RR and RD is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with an event; OR: Odds ratio; RR: Risk ratio; RD: Risk difference; CI: Confidence interval; int: p-value for interaction; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; NC: Not calculated.

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Table QOL.EQVAS7.MITT.Pooled.S3: Proportion of Patients with >= 7 Points Increase in the EQ-5D-5L VAS Scale at Week 24, by Subgroup (mITT Population)

Study: Pooled

Treatment	N	n (%)	OR[1] [95% CI]	RR[2] [95% CI]	RD[3] [95% CI]	p-value[4]	p-value (int)[5]
Uterine Volume at Baseline (cm3)							
< 300 cm3							
Relugolix+E2/NETA	148	61 (41.2)	1.56	1.33	0.10	0.0795	0.8635
Placebo	129	40 (31.0)	[0.95;2.56]	[0.96;1.83]	[-0.01;0.21]		
>= 300 cm3							
Relugolix+E2/NETA	104	40 (38.5)	1.46	1.29	0.09	0.1737	
Placebo	127	38 (29.9)	[0.84;2.53]	[0.90;1.84]	[-0.04;0.21]		
Missing							
Relugolix+E2/NETA	1	0	NC	NC	NC	NC	
Placebo	0	0	[NC;NC]	[NC;NC]	[NC;NC]		

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group.
[1] OR (95% CI) based on a logistic regression model adjusting for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates.
[2] RR (95% CI) based on a Cochran-Mantel-Haenszel approach stratified by study.
[3] RD (95% CI) based on a Mantel-Haenszel approach stratified by study. 95% CIs are based on the approximation to the normal distribution using the Sato estimator for the standard error.
[4] P-value based on a Cochran-Mantel-Haenszel test stratified by study.
[5] Interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the OR (95% CI). Missing subgroup levels are not included in estimation of the interaction p-value.
A continuity correction is applied in estimation of the OR, RR and p-value if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum. No continuity correction is applied in the estimation of the RD.
The reference group for the OR, RR and RD is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with an event; OR: Odds ratio; RR: Risk ratio; RD: Risk difference; CI: Confidence interval; int: p-value for interaction; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; NC: Not calculated.

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Table QOL.EQVAS7.MITT.Pooled.S7: Proportion of Patients with >= 7 Points Increase in the EQ-5D-5L VAS Scale at Week 24, by Subgroup (mITT Population)

Study: Pooled

Treatment	N	n (%)	OR[1] [95% CI]	RR[2] [95% CI]	RD[3] [95% CI]	p-value[4]	p-value (int)[5]
Geographic Region II							
Europe							
Relugolix+E2/NETA	41	18 (43.9)	1.57	1.34	0.11	0.2977	0.9271
Placebo	42	14 (33.3)	[0.65;3.84]	[0.77;2.35]	[-0.10;0.32]		
Rest of World (including the US)							
Relugolix+E2/NETA	212	83 (39.2)	1.50	1.31	0.09	0.0457	
Placebo	214	64 (29.9)	[1.01;2.25]	[1.00;1.70]	[0.00;0.18]		

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group.
[1] OR (95% CI) based on a logistic regression model adjusting for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates.
[2] RR (95% CI) based on a Cochran-Mantel-Haenszel approach stratified by study.
[3] RD (95% CI) based on a Mantel-Haenszel approach stratified by study. 95% CIs are based on the approximation to the normal distribution using the Sato estimator for the standard error.
[4] P-value based on a Cochran-Mantel-Haenszel test stratified by study.
[5] Interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the OR (95% CI). Missing subgroup levels are not included in estimation of the interaction p-value.
A continuity correction is applied in estimation of the OR, RR and p-value if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum. No continuity correction is applied in the estimation of the RD.
The reference group for the OR, RR and RD is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with an event; OR: Odds ratio; RR: Risk ratio; RD: Risk difference; CI: Confidence interval; int: p-value for interaction; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; NC: Not calculated.

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Table QOL.EQVAS7.MITT.Pooled.S9: Proportion of Patients with >= 7 Points Increase in the EQ-5D-5L VAS Scale at Week 24, by Subgroup (mITT Population)

Study: Pooled

Treatment	N	n (%)	OR[1] [95% CI]	RR[2] [95% CI]	RD[3] [95% CI]	p-value[4]	p-value (int)[5]
Race							
Black/African American							0.9449
Relugolix+E2/NETA	122	50 (41.0)	1.58	1.34	0.10	0.0770	
Placebo	141	43 (30.5)	[0.95;2.63]	[0.97;1.87]	[-0.01;0.22]		
White							
Relugolix+E2/NETA	122	47 (38.5)	1.43	1.27	0.08	0.1997	
Placebo	105	32 (30.5)	[0.82;2.49]	[0.88;1.83]	[-0.04;0.20]		
Asian							
Relugolix+E2/NETA	1	1 (100.0)	NC	NC	NC	NC	
Placebo	3	0	[NC;NC]	[NC;NC]	[NC;NC]		
Others							
Relugolix+E2/NETA	5	2 (40.0)	1.20	1.59	0.34	0.4999	
Placebo	6	2 (33.3)	[0.15;9.57]	[0.47;5.42]	[-0.00;0.69]		
Not reported							
Relugolix+E2/NETA	3	1 (33.3)	NC	NC	NC	NC	
Placebo	1	1 (100.0)	[NC;NC]	[NC;NC]	[NC;NC]		

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group.
[1] OR (95% CI) based on a logistic regression model adjusting for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates.
[2] RR (95% CI) based on a Cochran-Mantel-Haenszel approach stratified by study.
[3] RD (95% CI) based on a Mantel-Haenszel approach stratified by study. 95% CIs are based on the approximation to the normal distribution using the Sato estimator for the standard error.
[4] P-value based on a Cochran-Mantel-Haenszel test stratified by study.
[5] Interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the OR (95% CI). Not reported subgroup levels are not included in estimation of the interaction p-value.
A continuity correction is applied in estimation of the OR, RR and p-value if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum. No continuity correction is applied in the estimation of the RD.
The reference group for the OR, RR and RD is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with an event; OR: Odds ratio; RR: Risk ratio; RD: Risk difference; CI: Confidence interval; int: p-value for interaction; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; NC: Not calculated.

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1.2.17 Proportion of Patients with >= 10 Points Increase in the EQ-5D-5L VAS Scale at Week 24, by Subgroup (mITT Population)

Table QOL.EQVAS10.MITT.Pooled.S5: Proportion of Patients with >= 10 Points Increase in the EQ-5D-5L VAS Scale at Week 24, by Subgroup (mITT Population)

Study: Pooled

Treatment	N	n (%)	OR[1] [95% CI]	RR[2] [95% CI]	RD[3] [95% CI]	p-value[4]	p-value (int)[5]
MBL Volume at Baseline (mL)							
< 225 mL							0.1318
Relugolix+E2/NETA	164	51 (31.1)	1.15 [0.72;1.85]	1.11 [0.79;1.54]	0.03 [-0.07;0.13]	0.5520	
Placebo	171	48 (28.1)					
>= 225 mL							
Relugolix+E2/NETA	89	34 (38.2)	2.15 [1.10;4.19]	1.71 [1.06;2.75]	0.16 [0.02;0.29]	0.0236	
Placebo	85	19 (22.4)					

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group.
[1] OR (95% CI) based on a logistic regression model adjusting for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates.
[2] RR (95% CI) based on a Cochran-Mantel-Haenszel approach stratified by study.
[3] RD (95% CI) based on a Mantel-Haenszel approach stratified by study. 95% CIs are based on the approximation to the normal distribution using the Sato estimator for the standard error.
[4] P-value based on a Cochran-Mantel-Haenszel test stratified by study.
[5] Interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the OR (95% CI).
A continuity correction is applied in estimation of the OR, RR and p-value if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum. No continuity correction is applied in the estimation of the RD.
The reference group for the OR, RR and RD is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with an event; OR: Odds ratio; RR: Risk ratio; RD: Risk difference; CI: Confidence interval; int: p-value for interaction; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; NC: Not calculated.

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Table QOL.EQVAS10.MITT.Pooled.S2: Proportion of Patients with >= 10 Points Increase in the EQ-5D-5L VAS Scale at Week 24, by Subgroup (mITT Population)

Study: Pooled

Treatment	N	n (%)	OR[1] [95% CI]	RR[2] [95% CI]	RD[3] [95% CI]	p-value[4]	p-value (int)[5]
BMI (kg/m2) at Baseline							
< 30							
Relugolix+E2/NETA	119	41 (34.5)	1.98	1.64	0.13	0.0222	0.1571
Placebo	115	24 (20.9)	[1.10;3.56]	[1.06;2.52]	[0.02;0.25]		
>= 30							
Relugolix+E2/NETA	133	44 (33.1)	1.13	1.09	0.03	0.6373	
Placebo	141	43 (30.5)	[0.68;1.88]	[0.77;1.54]	[-0.08;0.14]		
Missing							
Relugolix+E2/NETA	1	0	NC	NC	NC	NC	
Placebo	0	0	[NC;NC]	[NC;NC]	[NC;NC]		

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group.
[1] OR (95% CI) based on a logistic regression model adjusting for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates.
[2] RR (95% CI) based on a Cochran-Mantel-Haenszel approach stratified by study.
[3] RD (95% CI) based on a Mantel-Haenszel approach stratified by study. 95% CIs are based on the approximation to the normal distribution using the Sato estimator for the standard error.
[4] P-value based on a Cochran-Mantel-Haenszel test stratified by study.
[5] Interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the OR (95% CI). Missing subgroup levels are not included in estimation of the interaction p-value.
A continuity correction is applied in estimation of the OR, RR and p-value if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum. No continuity correction is applied in the estimation of the RD.
The reference group for the OR, RR and RD is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with an event; OR: Odds ratio; RR: Risk ratio; RD: Risk difference; CI: Confidence interval; int: p-value for interaction; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; NC: Not calculated.

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Table QOL.EQVAS10.MITT.Pooled.S1: Proportion of Patients with >= 10 Points Increase in the EQ-5D-5L VAS Scale at Week 24, by Subgroup (mITT Population)

Study: Pooled

Treatment	N	n (%)	OR[1] [95% CI]	RR[2] [95% CI]	RD[3] [95% CI]	p-value[4]	p-value (int)[5]
Age (years)							
< 40 years							0.3101
Relugolix+E2/NETA	62	21 (33.9)	1.98	1.64	0.13	0.0789	
Placebo	78	16 (20.5)	[0.92;4.24]	[0.94;2.87]	[-0.02;0.28]		
>= 40 years							
Relugolix+E2/NETA	191	64 (33.5)	1.26	1.17	0.05	0.3158	
Placebo	178	51 (28.7)	[0.81;1.95]	[0.86;1.59]	[-0.05;0.14]		

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group.
[1] OR (95% CI) based on a logistic regression model adjusting for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates.
[2] RR (95% CI) based on a Cochran-Mantel-Haenszel approach stratified by study.
[3] RD (95% CI) based on a Mantel-Haenszel approach stratified by study. 95% CIs are based on the approximation to the normal distribution using the Sato estimator for the standard error.
[4] P-value based on a Cochran-Mantel-Haenszel test stratified by study.
[5] Interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the OR (95% CI). Missing subgroup levels are not included in estimation of the interaction p-value.
A continuity correction is applied in estimation of the OR, RR and p-value if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum. No continuity correction is applied in the estimation of the RD.
The reference group for the OR, RR and RD is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with an event; OR: Odds ratio; RR: Risk ratio; RD: Risk difference; CI: Confidence interval; int: p-value for interaction; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; NC: Not calculated.

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Table QOL.EQVAS10.MITT.Pooled.S6: Proportion of Patients with >= 10 Points Increase in the EQ-5D-5L VAS Scale at Week 24, by Subgroup (mITT Population)

Study: Pooled

Treatment	N	n (%)	OR[1] [95% CI]	RR[2] [95% CI]	RD[3] [95% CI]	p-value[4]	p-value (int)[5]
Geographic Region I							
North America							
Relugolix+E2/NETA	191	60 (31.4)	1.39	1.27	0.07	0.1478	0.8356
Placebo	194	48 (24.7)	[0.89;2.18]	[0.92;1.75]	[-0.02;0.16]		
Rest of World							
Relugolix+E2/NETA	62	25 (40.3)	1.53	1.31	0.10	0.2681	
Placebo	62	19 (30.6)	[0.73;3.20]	[0.81;2.12]	[-0.07;0.26]		

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group.
[1] OR (95% CI) based on a logistic regression model adjusting for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates.
[2] RR (95% CI) based on a Cochran-Mantel-Haenszel approach stratified by study.
[3] RD (95% CI) based on a Mantel-Haenszel approach stratified by study. 95% CIs are based on the approximation to the normal distribution using the Sato estimator for the standard error.
[4] P-value based on a Cochran-Mantel-Haenszel test stratified by study.
[5] Interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the OR (95% CI). Missing subgroup levels are not included in estimation of the interaction p-value.
A continuity correction is applied in estimation of the OR, RR and p-value if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum. No continuity correction is applied in the estimation of the RD.
The reference group for the OR, RR and RD is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with an event; OR: Odds ratio; RR: Risk ratio; RD: Risk difference; CI: Confidence interval; int: p-value for interaction; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; NC: Not calculated.

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Table QOL.EQVAS10.MITT.Pooled.S3: Proportion of Patients with >= 10 Points Increase in the EQ-5D-5L VAS Scale at Week 24, by Subgroup (mITT Population)

Study: Pooled

Treatment	N	n (%)	OR[1] [95% CI]	RR[2] [95% CI]	RD[3] [95% CI]	p-value[4]	p-value (int)[5]
Uterine Volume at Baseline (cm3)							
< 300 cm3							0.8886
Relugolix+E2/NETA	148	52 (35.1)	1.45	1.29	0.08	0.1535	
Placebo	129	35 (27.1)	[0.87;2.44]	[0.91;1.85]	[-0.03;0.19]		
>= 300 cm3							
Relugolix+E2/NETA	104	33 (31.7)	1.38	1.26	0.07	0.2728	
Placebo	127	32 (25.2)	[0.77;2.45]	[0.83;1.90]	[-0.05;0.18]		
Missing							
Relugolix+E2/NETA	1	0	NC	NC	NC	NC	
Placebo	0	0	[NC;NC]	[NC;NC]	[NC;NC]		

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group.
[1] OR (95% CI) based on a logistic regression model adjusting for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates.
[2] RR (95% CI) based on a Cochran-Mantel-Haenszel approach stratified by study.
[3] RD (95% CI) based on a Mantel-Haenszel approach stratified by study. 95% CIs are based on the approximation to the normal distribution using the Sato estimator for the standard error.
[4] P-value based on a Cochran-Mantel-Haenszel test stratified by study.
[5] Interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the OR (95% CI). Missing subgroup levels are not included in estimation of the interaction p-value.
A continuity correction is applied in estimation of the OR, RR and p-value if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum. No continuity correction is applied in the estimation of the RD.
The reference group for the OR, RR and RD is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with an event; OR: Odds ratio; RR: Risk ratio; RD: Risk difference; CI: Confidence interval; int: p-value for interaction; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; NC: Not calculated.

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Table QOL.EQVAS10.MITT.Pooled.S9: Proportion of Patients with >= 10 Points Increase in the EQ-5D-5L VAS Scale at Week 24, by Subgroup (mITT Population)

Study: Pooled

Treatment	N	n (%)	OR[1] [95% CI]	RR[2] [95% CI]	RD[3] [95% CI]	p-value[4]	p-value (int)[5]
Race							
Black/African American							0.9207
Relugolix+E2/NETA	122	41 (33.6)	1.53	1.35	0.09	0.1188	
Placebo	141	35 (24.8)	[0.90;2.62]	[0.92;1.98]	[-0.02;0.20]		
White							
Relugolix+E2/NETA	122	41 (33.6)	1.33	1.22	0.06	0.3192	
Placebo	105	29 (27.6)	[0.75;2.35]	[0.82;1.81]	[-0.06;0.18]		
Asian							
Relugolix+E2/NETA	1	0	NC	NC	NC	NC	
Placebo	3	0	[NC;NC]	[NC;NC]	[NC;NC]		
Others							
Relugolix+E2/NETA	5	2 (40.0)	1.15	1.59	0.34	0.4999	
Placebo	6	2 (33.3)	[0.14;9.21]	[0.47;5.42]	[-0.00;0.69]		
Not reported							
Relugolix+E2/NETA	3	1 (33.3)	NC	NC	NC	NC	
Placebo	1	1 (100.0)	[NC;NC]	[NC;NC]	[NC;NC]		

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group.
[1] OR (95% CI) based on a logistic regression model adjusting for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates.
[2] RR (95% CI) based on a Cochran-Mantel-Haenszel approach stratified by study.
[3] RD (95% CI) based on a Mantel-Haenszel approach stratified by study. 95% CIs are based on the approximation to the normal distribution using the Sato estimator for the standard error.
[4] P-value based on a Cochran-Mantel-Haenszel test stratified by study.
[5] Interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the OR (95% CI). Not reported subgroup levels are not included in estimation of the interaction p-value.
A continuity correction is applied in estimation of the OR, RR and p-value if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum. No continuity correction is applied in the estimation of the RD.
The reference group for the OR, RR and RD is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with an event; OR: Odds ratio; RR: Risk ratio; RD: Risk difference; CI: Confidence interval; int: p-value for interaction; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; NC: Not calculated.

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Table QOL.EQVAS10.MITT.Pooled.S4: Proportion of Patients with >= 10 Points Increase in the EQ-5D-5L VAS Scale at Week 24, by Subgroup (mITT Population)

Study: Pooled

Treatment	N	n (%)	OR[1] [95% CI]	RR[2] [95% CI]	RD[3] [95% CI]	p-value[4]	p-value (int)[5]
Maximum NRS Pain Score at Baseline							
< 4							
Relugolix+E2/NETA	73	19 (26.0)	1.43	1.31	0.06	0.3982	0.9526
Placebo	62	12 (19.4)	[0.63;3.26]	[0.70;2.46]	[-0.08;0.20]		
>= 4							
Relugolix+E2/NETA	177	65 (36.7)	1.47	1.30	0.08	0.0846	
Placebo	190	54 (28.4)	[0.95;2.29]	[0.96;1.75]	[-0.01;0.18]		
Missing							
Relugolix+E2/NETA	3	1 (33.3)	NC	NC	NC	NC	
Placebo	4	1 (25.0)	[NC;NC]	[NC;NC]	[NC;NC]		

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group.
[1] OR (95% CI) based on a logistic regression model adjusting for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates.
[2] RR (95% CI) based on a Cochran-Mantel-Haenszel approach stratified by study.
[3] RD (95% CI) based on a Mantel-Haenszel approach stratified by study. 95% CIs are based on the approximation to the normal distribution using the Sato estimator for the standard error.
[4] P-value based on a Cochran-Mantel-Haenszel test stratified by study.
[5] Interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the OR (95% CI). Missing subgroup levels are not included in estimation of the interaction p-value.
A continuity correction is applied in estimation of the OR, RR and p-value if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum. No continuity correction is applied in the estimation of the RD.
The reference group for the OR, RR and RD is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with an event; OR: Odds ratio; RR: Risk ratio; RD: Risk difference; CI: Confidence interval; int: p-value for interaction; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; NC: Not calculated.

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Table QOL.EQVAS10.MITT.Pooled.S8: Proportion of Patients with >= 10 Points Increase in the EQ-5D-5L VAS Scale at Week 24, by Subgroup (mITT Population)

Study: Pooled

Treatment	N	n (%)	OR[1] [95% CI]	RR[2] [95% CI]	RD[3] [95% CI]	p-value[4]	p-value (int)[5]
Ethnicity							
Hispanic or Latino							
Relugolix+E2/NETA	52	20 (38.5)	1.45	1.37	0.10	0.2878	0.9927
Placebo	55	16 (29.1)	[0.64;3.27]	[0.76;2.46]	[-0.08;0.28]		
Not Hispanic or Latino							
Relugolix+E2/NETA	197	63 (32.0)	1.46	1.32	0.08	0.0905	
Placebo	199	49 (24.6)	[0.94;2.26]	[0.95;1.81]	[-0.01;0.17]		
Not reported							
Relugolix+E2/NETA	4	2 (50.0)	NC	NC	NC	NC	
Placebo	2	2 (100.0)	[NC;NC]	[NC;NC]	[NC;NC]		

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group.
[1] OR (95% CI) based on a logistic regression model adjusting for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates.
[2] RR (95% CI) based on a Cochran-Mantel-Haenszel approach stratified by study.
[3] RD (95% CI) based on a Mantel-Haenszel approach stratified by study. 95% CIs are based on the approximation to the normal distribution using the Sato estimator for the standard error.
[4] P-value based on a Cochran-Mantel-Haenszel test stratified by study.
[5] Interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the OR (95% CI). Not reported subgroup levels are not included in estimation of the interaction p-value.
A continuity correction is applied in estimation of the OR, RR and p-value if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum. No continuity correction is applied in the estimation of the RD.
The reference group for the OR, RR and RD is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with an event; OR: Odds ratio; RR: Risk ratio; RD: Risk difference; CI: Confidence interval; int: p-value for interaction; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; NC: Not calculated.

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Table QOL.EQVAS10.MITT.Pooled.S7: Proportion of Patients with >= 10 Points Increase in the EQ-5D-5L VAS Scale at Week 24, by Subgroup (mITT Population)

Study: Pooled

Treatment	N	n (%)	OR[1] [95% CI]	RR[2] [95% CI]	RD[3] [95% CI]	p-value[4]	p-value (int)[5]
Geographic Region II							
Europe							
Relugolix+E2/NETA	41	17 (41.5)	1.43	1.27	0.09	0.4018	0.9946
Placebo	42	14 (33.3)	[0.59;3.51]	[0.72;2.25]	[-0.12;0.30]		
Rest of World (including the US)							
Relugolix+E2/NETA	212	68 (32.1)	1.43	1.29	0.07	0.0975	
Placebo	214	53 (24.8)	[0.94;2.18]	[0.95;1.75]	[-0.01;0.16]		

Post hoc analysis. The denominator for percentages is the number of patients in the mITT population for each treatment group.
[1] OR (95% CI) based on a logistic regression model adjusting for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates.
[2] RR (95% CI) based on a Cochran-Mantel-Haenszel approach stratified by study.
[3] RD (95% CI) based on a Mantel-Haenszel approach stratified by study. 95% CIs are based on the approximation to the normal distribution using the Sato estimator for the standard error.
[4] P-value based on a Cochran-Mantel-Haenszel test stratified by study.
[5] Interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the OR (95% CI). Not reported subgroup levels are not included in estimation of the interaction p-value.
A continuity correction is applied in estimation of the OR, RR and p-value if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum. No continuity correction is applied in the estimation of the RD.
The reference group for the OR, RR and RD is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with an event; OR: Odds ratio; RR: Risk ratio; RD: Risk difference; CI: Confidence interval; int: p-value for interaction; MBL: Menstrual blood loss; mITT: Modified intent-to-treat; NETA: Norethindrone acetate; NC: Not calculated.

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1.3 Sicherheit

1.3.1 Proportion of Patients With at Least One Treatment Emergent Adverse Event by Subgroup (Safety Population)

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Table SAF.TEAE.SAF.POOL.S7: Proportion of Patients With at Least One Treatment Emergent Adverse Event by Subgroup (Safety Population)

Study: Pooled

Treatment	N	n (%)	OR[1] [95% CI]	RR[2] [95% CI]	RD[3] [95% CI]	p-value[4]	p-value (int)[5]
Geographic Region II							
Europe							
Relugolix+E2/NETA	41	29 (70.7)	1.50	1.14	0.08	0.4217	0.2717
Placebo	42	26 (61.9)	[0.60;3.77]	[0.83;1.56]	[-0.12;0.29]		
Rest of World (including the US)							
Relugolix+E2/NETA	213	126 (59.2)	0.86	0.94	-0.04	0.4471	
Placebo	214	134 (62.6)	[0.58;1.27]	[0.81;1.10]	[-0.13;0.06]		

Post hoc analysis. The denominator for percentages is the number of patients in the safety population for each treatment group. Patients with multiple events are counted only once.
[1] OR (95% CI) based on a logistic regression model adjusting for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates.
[2] RR (95% CI) based on a Cochran-Mantel-Haenszel approach stratified by study.
[3] RD (95% CI) based on a Mantel-Haenszel approach stratified by study. 95% CIs are based on the approximation to the normal distribution using the Sato estimator for the standard error.
[4] P-value based on a Cochran-Mantel-Haenszel test stratified by study.
[5] Interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the OR (95% CI).
A continuity correction is applied in estimation of the OR, RR and p-value if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum. No continuity correction is applied in the estimation of the RD.
The reference group for the OR, RR and RD is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with >= 1 event; OR: Odds ratio; RR: Risk ratio; RD: Risk difference; CI: Confidence interval; int: p-value for interaction; NETA: Norethindrone acetate.

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Table SAF.TEAE.SAF.POOL.S3: Proportion of Patients With at Least One Treatment Emergent Adverse Event by Subgroup (Safety Population)

Study: Pooled

Treatment	N	n (%)	OR[1] [95% CI]	RR[2] [95% CI]	RD[3] [95% CI]	p-value[4]	p-value (int)[5]
Uterine Volume at Baseline (cm3)							
< 300 cm3							
Relugolix+E2/NETA	148	95 (64.2)	1.10	1.03	0.02	0.7116	0.3036
Placebo	129	80 (62.0)	[0.67;1.79]	[0.86;1.24]	[-0.09;0.14]		
>= 300 cm3							
Relugolix+E2/NETA	105	59 (56.2)	0.75	0.89	-0.07	0.2930	
Placebo	127	80 (63.0)	[0.44;1.28]	[0.72;1.11]	[-0.20;0.06]		
Missing							
Relugolix+E2/NETA	1	1 (100.0)	NC	NC	NC	NC	
Placebo	0	0	[NC;NC]	[NC;NC]	[NC;NC]		

Post hoc analysis. The denominator for percentages is the number of patients in the safety population for each treatment group. Patients with multiple events are counted only once.
[1] OR (95% CI) based on a logistic regression model adjusting for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates.
[2] RR (95% CI) based on a Cochran-Mantel-Haenszel approach stratified by study.
[3] RD (95% CI) based on a Mantel-Haenszel approach stratified by study. 95% CIs are based on the approximation to the normal distribution using the Sato estimator for the standard error.
[4] P-value based on a Cochran-Mantel-Haenszel test stratified by study.
[5] Interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the OR (95% CI). Missing subgroup levels are not included in estimation of the interaction p-value.
A continuity correction is applied in estimation of the OR, RR and p-value if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum. No continuity correction is applied in the estimation of the RD.
The reference group for the OR, RR and RD is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with >= 1 event; OR: Odds ratio; RR: Risk ratio; RD: Risk difference; CI: Confidence interval; int: p-value for interaction; NETA: Norethindrone acetate; NC: Not calculated.

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Table SAF.TEAE.SAF.POOL.S5: Proportion of Patients With at Least One Treatment Emergent Adverse Event by Subgroup (Safety Population)

Study: Pooled

Treatment	N	n (%)	OR[1] [95% CI]	RR[2] [95% CI]	RD[3] [95% CI]	p-value[4]	p-value (int)[5]
MBL Volume at Baseline (mL)							
< 225 mL							
Relugolix+E2/NETA	164	103 (62.8)	1.01	1.00	0.00	0.9924	0.6063
Placebo	171	107 (62.6)	[0.65;1.57]	[0.85;1.18]	[-0.10;0.10]		
>= 225 mL							
Relugolix+E2/NETA	90	52 (57.8)	0.83	0.93	-0.05	0.5320	
Placebo	85	53 (62.4)	[0.45;1.52]	[0.73;1.18]	[-0.19;0.10]		

Post hoc analysis. The denominator for percentages is the number of patients in the safety population for each treatment group. Patients with multiple events are counted only once.
[1] OR (95% CI) based on a logistic regression model adjusting for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates.
[2] RR (95% CI) based on a Cochran-Mantel-Haenszel approach stratified by study.
[3] RD (95% CI) based on a Mantel-Haenszel approach stratified by study. 95% CIs are based on the approximation to the normal distribution using the Sato estimator for the standard error.
[4] P-value based on a Cochran-Mantel-Haenszel test stratified by study.
[5] Interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the OR (95% CI).
A continuity correction is applied in estimation of the OR, RR and p-value if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum. No continuity correction is applied in the estimation of the RD.
The reference group for the OR, RR and RD is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with >= 1 event; OR: Odds ratio; RR: Risk ratio; RD: Risk difference; CI: Confidence interval; int: p-value for interaction; NETA: Norethindrone acetate.

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Table SAF.TEAE.SAF.POOL.S4: Proportion of Patients With at Least One Treatment Emergent Adverse Event by Subgroup (Safety Population)

Study: Pooled

Treatment	N	n (%)	OR[1] [95% CI]	RR[2] [95% CI]	RD[3] [95% CI]	p-value[4]	p-value (int)[5]
Maximum NRS Pain Score at Baseline							
< 4							
Relugolix+E2/NETA	73	40 (54.8)	0.80	0.91	-0.06	0.5105	0.6386
Placebo	62	37 (59.7)	[0.40;1.60]	[0.68;1.21]	[-0.23;0.11]		
>= 4							
Relugolix+E2/NETA	178	112 (62.9)	0.97	0.99	-0.01	0.8971	
Placebo	190	121 (63.7)	[0.64;1.49]	[0.85;1.16]	[-0.11;0.09]		
Missing							
Relugolix+E2/NETA	3	3 (100.0)	NC	NC	NC	NC	
Placebo	4	2 (50.0)	[NC;NC]	[NC;NC]	[NC;NC]		

Post hoc analysis. The denominator for percentages is the number of patients in the safety population for each treatment group. Patients with multiple events are counted only once.
[1] OR (95% CI) based on a logistic regression model adjusting for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates.
[2] RR (95% CI) based on a Cochran-Mantel-Haenszel approach stratified by study.
[3] RD (95% CI) based on a Mantel-Haenszel approach stratified by study. 95% CIs are based on the approximation to the normal distribution using the Sato estimator for the standard error.
[4] P-value based on a Cochran-Mantel-Haenszel test stratified by study.
[5] Interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the OR (95% CI). Missing subgroup levels are not included in estimation of the interaction p-value.
A continuity correction is applied in estimation of the OR, RR and p-value if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum. No continuity correction is applied in the estimation of the RD.
The reference group for the OR, RR and RD is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with >= 1 event; OR: Odds ratio; RR: Risk ratio; RD: Risk difference; CI: Confidence interval; int: p-value for interaction; NETA: Norethindrone acetate; NC: Not calculated.

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Table SAF.TEAE.SAF.POOL.S8: Proportion of Patients With at Least One Treatment Emergent Adverse Event by Subgroup (Safety Population)

Study: Pooled

Treatment	N	n (%)	OR[1] [95% CI]	RR[2] [95% CI]	RD[3] [95% CI]	p-value[4]	p-value (int)[5]
Ethnicity							
Hispanic or Latino							
Relugolix+E2/NETA	53	36 (67.9)	1.08	1.07	0.04	0.6428	0.6847
Placebo	55	36 (65.5)	[0.48;2.41]	[0.81;1.40]	[-0.14;0.22]		
Not Hispanic or Latino							
Relugolix+E2/NETA	197	115 (58.4)	0.89	0.96	-0.03	0.6030	
Placebo	199	122 (61.3)	[0.60;1.34]	[0.81;1.13]	[-0.12;0.07]		
Not reported							
Relugolix+E2/NETA	4	4 (100.0)	NC	NC	NC	NC	
Placebo	2	2 (100.0)	[NC;NC]	[NC;NC]	[NC;NC]		

Post hoc analysis. The denominator for percentages is the number of patients in the safety population for each treatment group. Patients with multiple events are counted only once.
[1] OR (95% CI) based on a logistic regression model adjusting for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates.
[2] RR (95% CI) based on a Cochran-Mantel-Haenszel approach stratified by study.
[3] RD (95% CI) based on a Mantel-Haenszel approach stratified by study. 95% CIs are based on the approximation to the normal distribution using the Sato estimator for the standard error.
[4] P-value based on a Cochran-Mantel-Haenszel test stratified by study.
[5] Interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the OR (95% CI). Not reported subgroup levels are not included in estimation of the interaction p-value.
A continuity correction is applied in estimation of the OR, RR and p-value if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum. No continuity correction is applied in the estimation of the RD.
The reference group for the OR, RR and RD is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with >= 1 event; OR: Odds ratio; RR: Risk ratio; RD: Risk difference; CI: Confidence interval; int: p-value for interaction; NETA: Norethindrone acetate; NC: Not calculated.

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Table SAF.TEAE.SAF.POOL.S6: Proportion of Patients With at Least One Treatment Emergent Adverse Event by Subgroup (Safety Population)

Study: Pooled

Treatment	N	n (%)	OR[1] [95% CI]	RR[2] [95% CI]	RD[3] [95% CI]	p-value[4]	p-value (int)[5]
Geographic Region I							
North America							
Relugolix+E2/NETA	192	111 (57.8)	0.92	0.97	-0.02	0.6861	0.8582
Placebo	194	116 (59.8)	[0.61;1.38]	[0.82;1.14]	[-0.12;0.08]		
Rest of World							
Relugolix+E2/NETA	62	44 (71.0)	1.00	1.00	0.00	0.9905	
Placebo	62	44 (71.0)	[0.46;2.17]	[0.80;1.25]	[-0.16;0.16]		

Post hoc analysis. The denominator for percentages is the number of patients in the safety population for each treatment group. Patients with multiple events are counted only once.
[1] OR (95% CI) based on a logistic regression model adjusting for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates.
[2] RR (95% CI) based on a Cochran-Mantel-Haenszel approach stratified by study.
[3] RD (95% CI) based on a Mantel-Haenszel approach stratified by study. 95% CIs are based on the approximation to the normal distribution using the Sato estimator for the standard error.
[4] P-value based on a Cochran-Mantel-Haenszel test stratified by study.
[5] Interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the OR (95% CI).
A continuity correction is applied in estimation of the OR, RR and p-value if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum. No continuity correction is applied in the estimation of the RD.
The reference group for the OR, RR and RD is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with >= 1 event; OR: Odds ratio; RR: Risk ratio; RD: Risk difference; CI: Confidence interval; int: p-value for interaction; NETA: Norethindrone acetate.

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Table SAF.TEAE.SAF.POOL.S9: Proportion of Patients With at Least One Treatment Emergent Adverse Event by Subgroup (Safety Population)

Study: Pooled

Treatment	N	n (%)	OR[1] [95% CI]	RR[2] [95% CI]	RD[3] [95% CI]	p-value[4]	p-value (int)[5]
Race							
Black/African American							0.9226
Relugolix+E2/NETA	122	69 (56.6)	0.86	0.94	-0.04	0.5317	
Placebo	141	85 (60.3)	[0.52;1.40]	[0.76;1.15]	[-0.16;0.08]		
White							
Relugolix+E2/NETA	123	78 (63.4)	0.99	0.99	-0.00	0.9472	
Placebo	105	67 (63.8)	[0.57;1.69]	[0.82;1.21]	[-0.13;0.12]		
Asian							
Relugolix+E2/NETA	1	1 (100.0)	NC	NC	NC	NC	
Placebo	3	2 (66.7)	[NC;NC]	[NC;NC]	[NC;NC]		
Others							
Relugolix+E2/NETA	5	4 (80.0)	0.78	0.80	-0.28	0.5183	
Placebo	6	5 (83.3)	[0.08;7.72]	[0.37;1.72]	[-0.62;0.06]		
Not reported							
Relugolix+E2/NETA	3	3 (100.0)	NC	NC	NC	NC	
Placebo	1	1 (100.0)	[NC;NC]	[NC;NC]	[NC;NC]		

Post hoc analysis. The denominator for percentages is the number of patients in the safety population for each treatment group. Patients with multiple events are counted only once.
[1] OR (95% CI) based on a logistic regression model adjusting for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates.
[2] RR (95% CI) based on a Cochran-Mantel-Haenszel approach stratified by study.
[3] RD (95% CI) based on a Mantel-Haenszel approach stratified by study. 95% CIs are based on the approximation to the normal distribution using the Sato estimator for the standard error.
[4] P-value based on a Cochran-Mantel-Haenszel test stratified by study.
[5] Interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the OR (95% CI). Not reported subgroup levels are not included in estimation of the interaction p-value.
A continuity correction is applied in estimation of the OR, RR and p-value if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum. No continuity correction is applied in the estimation of the RD.
The reference group for the OR, RR and RD is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with >= 1 event; OR: Odds ratio; RR: Risk ratio; RD: Risk difference; CI: Confidence interval; int: p-value for interaction; NETA: Norethindrone acetate; NC: Not calculated.

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Table SAF.TEAE.SAF.POOL.S2: Proportion of Patients With at Least One Treatment Emergent Adverse Event by Subgroup (Safety Population)

Study: Pooled

Treatment	**N**	**n (%)**	**OR[1] [95% CI]**	**RR[2] [95% CI]**	**RD[3] [95% CI]**	**p-value[4]**	**p-value (int)[5]**
BMI (kg/m2) at Baseline							
< 30							0.9581
Relugolix+E2/NETA	119	71 (59.7)	0.94	0.97	-0.02	0.8084	
Placebo	115	70 (60.9)	[0.56;1.59]	[0.79;1.20]	[-0.14;0.11]		
>= 30							
Relugolix+E2/NETA	134	83 (61.9)	0.93	0.97	-0.02	0.7497	
Placebo	141	90 (63.8)	[0.57;1.51]	[0.81;1.16]	[-0.13;0.10]		
Missing							
Relugolix+E2/NETA	1	1 (100.0)	NC	NC	NC	NC	
Placebo	0	0	[NC;NC]	[NC;NC]	[NC;NC]		

Post hoc analysis. The denominator for percentages is the number of patients in the safety population for each treatment group. Patients with multiple events are counted only once.
[1] OR (95% CI) based on a logistic regression model adjusting for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates.
[2] RR (95% CI) based on a Cochran-Mantel-Haenszel approach stratified by study.
[3] RD (95% CI) based on a Mantel-Haenszel approach stratified by study. 95% CIs are based on the approximation to the normal distribution using the Sato estimator for the standard error.
[4] P-value based on a Cochran-Mantel-Haenszel test stratified by study.
[5] Interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the OR (95% CI). Missing subgroup levels are not included in estimation of the interaction p-value.
A continuity correction is applied in estimation of the OR, RR and p-value if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum. No continuity correction is applied in the estimation of the RD.
The reference group for the OR, RR and RD is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with >= 1 event; OR: Odds ratio; RR: Risk ratio; RD: Risk difference; CI: Confidence interval; int: p-value for interaction; NETA: Norethindrone acetate; NC: Not calculated.

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Table SAF.TEAE.SAF.POOL.S1: Proportion of Patients With at Least One Treatment Emergent Adverse Event by Subgroup (Safety Population)

Study: Pooled

Treatment	N	n (%)	OR[1] [95% CI]	RR[2] [95% CI]	RD[3] [95% CI]	p-value[4]	p-value (int)[5]
Age (years)							
< 40 years							
Relugolix+E2/NETA	62	38 (61.3)	0.93	0.97	-0.02	0.8219	0.9823
Placebo	78	49 (62.8)	[0.47;1.86]	[0.75;1.26]	[-0.18;0.14]		
>= 40 years							
Relugolix+E2/NETA	192	117 (60.9)	0.94	0.98	-0.01	0.7793	
Placebo	178	111 (62.4)	[0.62;1.43]	[0.83;1.15]	[-0.11;0.08]		

Post hoc analysis. The denominator for percentages is the number of patients in the safety population for each treatment group. Patients with multiple events are counted only once.
[1] OR (95% CI) based on a logistic regression model adjusting for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates.
[2] RR (95% CI) based on a Cochran-Mantel-Haenszel approach stratified by study.
[3] RD (95% CI) based on a Mantel-Haenszel approach stratified by study. 95% CIs are based on the approximation to the normal distribution using the Sato estimator for the standard error.
[4] P-value based on a Cochran-Mantel-Haenszel test stratified by study.
[5] Interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the OR (95% CI).
A continuity correction is applied in estimation of the OR, RR and p-value if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum. No continuity correction is applied in the estimation of the RD.
The reference group for the OR, RR and RD is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with >= 1 event; OR: Odds ratio; RR: Risk ratio; RD: Risk difference; CI: Confidence interval; int: p-value for interaction; NETA: Norethindrone acetate.

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1.3.2 Proportion of Patients With at Least One Grade 3 or Above Treatment Emergent Adverse Event by Subgroup (Safety Population)

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Table SAF.G34TEAE.SAF.POOL.S7: Proportion of Patients With at Least One Grade 3 or Above Treatment Emergent Adverse Event by Subgroup (Safety Population)

Study: Pooled

Treatment	N	n (%)	OR[1] [95% CI]	RR[2] [95% CI]	RD[3] [95% CI]	p-value[4]	p-value (int)[5]
Geographic Region II							
Europe							
Relugolix+E2/NETA	41	0	0.15	0.17	-0.12	0.0592	0.1007
Placebo	42	5 (11.9)	[0.02;1.33]	[0.02;1.41]	[-0.21;-0.02]		
Rest of World (including the US)							
Relugolix+E2/NETA	213	12 (5.6)	0.85	0.86	-0.01	0.6861	
Placebo	214	14 (6.5)	[0.38;1.88]	[0.41;1.81]	[-0.05;0.04]		

Post hoc analysis. The denominator for percentages is the number of patients in the safety population for each treatment group. Patients with multiple events are counted only once. Adverse event grades are evaluated based on National Cancer Institute Common Terminology Criteria for Adverse Events version 5.0.
[1] OR (95% CI) based on a logistic regression model adjusting for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates.
[2] RR (95% CI) based on a Cochran-Mantel-Haenszel approach stratified by study.
[3] RD (95% CI) based on a Mantel-Haenszel approach stratified by study. 95% CIs are based on the approximation to the normal distribution using the Sato estimator for the standard error.
[4] P-value based on a Cochran-Mantel-Haenszel test stratified by study.
[5] Interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the OR (95% CI).
A continuity correction is applied in estimation of the OR, RR and p-value if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum. No continuity correction is applied in the estimation of the RD.
The reference group for the OR, RR and RD is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with >= 1 event; OR: Odds ratio; RR: Risk ratio; RD: Risk difference; CI: Confidence interval; int: p-value for interaction; NETA: Norethindrone acetate.

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Table SAF.G34TEAE.SAF.POOL.S4: Proportion of Patients With at Least One Grade 3 or Above Treatment Emergent Adverse Event by Subgroup (Safety Population)

Study: Pooled

Treatment	**N**	**n (%)**	**OR[1] [95% CI]**	**RR[2] [95% CI]**	**RD[3] [95% CI]**	**p-value[4]**	**p-value (int)[5]**
Maximum NRS Pain Score at Baseline							
< 4							
Relugolix+E2/NETA	73	2 (2.7)	0.31	0.33	-0.06	0.1404	0.2492
Placebo	62	5 (8.1)	[0.06;1.64]	[0.07;1.56]	[-0.14;0.02]		
>= 4							
Relugolix+E2/NETA	178	10 (5.6)	0.90	0.90	-0.01	0.7998	
Placebo	190	12 (6.3)	[0.38;2.13]	[0.40;2.03]	[-0.05;0.04]		
Missing							
Relugolix+E2/NETA	3	0	NC	NC	NC	NC	
Placebo	4	2 (50.0)	[NC;NC]	[NC;NC]	[NC;NC]		

Post hoc analysis. The denominator for percentages is the number of patients in the safety population for each treatment group. Patients with multiple events are counted only once. Adverse event grades are evaluated based on National Cancer Institute Common Terminology Criteria for Adverse Events version 5.0.
[1] OR (95% CI) based on a logistic regression model adjusting for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates.
[2] RR (95% CI) based on a Cochran-Mantel-Haenszel approach stratified by study.
[3] RD (95% CI) based on a Mantel-Haenszel approach stratified by study. 95% CIs are based on the approximation to the normal distribution using the Sato estimator for the standard error.
[4] P-value based on a Cochran-Mantel-Haenszel test stratified by study.
[5] Interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the OR (95% CI). Missing subgroup levels are not included in estimation of the interaction p-value.
A continuity correction is applied in estimation of the OR, RR and p-value if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum. No continuity correction is applied in the estimation of the RD.
The reference group for the OR, RR and RD is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with >= 1 event; OR: Odds ratio; RR: Risk ratio; RD: Risk difference; CI: Confidence interval; int: p-value for interaction; NETA: Norethindrone acetate; NC: Not calculated.

SOURCE: \Studies\MYV\MYV102\Analysis\Prod\Progs\TFLs\Tab_SAF_AE_BIN.SAS
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Table SAF.G34TEAE.SAF.POOL.S2: Proportion of Patients With at Least One Grade 3 or Above Treatment Emergent Adverse Event by Subgroup (Safety Population)

Study: Pooled

Treatment	N	n (%)	OR[1] [95% CI]	RR[2] [95% CI]	RD[3] [95% CI]	p-value[4]	p-value (int)[5]
BMI (kg/m2) at Baseline							
< 30							
Relugolix+E2/NETA	119	3 (2.5)	0.34	0.35	-0.05	0.0938	0.2576
Placebo	115	8 (7.0)	[0.09;1.32]	[0.10;1.27]	[-0.10;0.01]		
>= 30							
Relugolix+E2/NETA	134	9 (6.7)	0.86	0.86	-0.01	0.7289	
Placebo	141	11 (7.8)	[0.34;2.14]	[0.37;2.01]	[-0.07;0.05]		
Missing							
Relugolix+E2/NETA	1	0	NC	NC	NC	NC	
Placebo	0	0	[NC;NC]	[NC;NC]	[NC;NC]		

Post hoc analysis. The denominator for percentages is the number of patients in the safety population for each treatment group. Patients with multiple events are counted only once. Adverse event grades are evaluated based on National Cancer Institute Common Terminology Criteria for Adverse Events version 5.0.
[1] OR (95% CI) based on a logistic regression model adjusting for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates.
[2] RR (95% CI) based on a Cochran-Mantel-Haenszel approach stratified by study.
[3] RD (95% CI) based on a Mantel-Haenszel approach stratified by study. 95% CIs are based on the approximation to the normal distribution using the Sato estimator for the standard error.
[4] P-value based on a Cochran-Mantel-Haenszel test stratified by study.
[5] Interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the OR (95% CI). Missing subgroup levels are not included in estimation of the interaction p-value.
A continuity correction is applied in estimation of the OR, RR and p-value if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum. No continuity correction is applied in the estimation of the RD.
The reference group for the OR, RR and RD is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with >= 1 event; OR: Odds ratio; RR: Risk ratio; RD: Risk difference; CI: Confidence interval; int: p-value for interaction; NETA: Norethindrone acetate; NC: Not calculated.

SOURCE: \Studies\MYV\MYV102\Analysis\Prod\Progs\TFLs\Tab_SAF_AE_BIN.SAS
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Table SAF.G34TEAE.SAF.POOL.S3: Proportion of Patients With at Least One Grade 3 or Above Treatment Emergent Adverse Event by Subgroup (Safety Population)

Study: Pooled

Treatment	**N**	**n (%)**	**OR[1] [95% CI]**	**RR[2] [95% CI]**	**RD[3] [95% CI]**	**p-value[4]**	**p-value (int)[5]**
Uterine Volume at Baseline (cm3)							
< 300 cm3							
Relugolix+E2/NETA	148	6 (4.1)	0.45	0.47	-0.04	0.1209	0.3686
Placebo	129	11 (8.5)	[0.16;1.26]	[0.18;1.25]	[-0.10;0.01]		
>= 300 cm3							
Relugolix+E2/NETA	105	6 (5.7)	0.90	0.91	-0.01	0.8529	
Placebo	127	8 (6.3)	[0.30;2.68]	[0.32;2.54]	[-0.07;0.06]		
Missing							
Relugolix+E2/NETA	1	0	NC	NC	NC	NC	
Placebo	0	0	[NC;NC]	[NC;NC]	[NC;NC]		

Post hoc analysis. The denominator for percentages is the number of patients in the safety population for each treatment group. Patients with multiple events are counted only once. Adverse event grades are evaluated based on National Cancer Institute Common Terminology Criteria for Adverse Events version 5.0.
[1] OR (95% CI) based on a logistic regression model adjusting for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates.
[2] RR (95% CI) based on a Cochran-Mantel-Haenszel approach stratified by study.
[3] RD (95% CI) based on a Mantel-Haenszel approach stratified by study. 95% CIs are based on the approximation to the normal distribution using the Sato estimator for the standard error.
[4] P-value based on a Cochran-Mantel-Haenszel test stratified by study.
[5] Interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the OR (95% CI). Missing subgroup levels are not included in estimation of the interaction p-value.
A continuity correction is applied in estimation of the OR, RR and p-value if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum. No continuity correction is applied in the estimation of the RD.
The reference group for the OR, RR and RD is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with >= 1 event; OR: Odds ratio; RR: Risk ratio; RD: Risk difference; CI: Confidence interval; int: p-value for interaction; NETA: Norethindrone acetate; NC: Not calculated.

SOURCE: \Studies\MYV\MYV102\Analysis\Prod\Progs\TFLs\Tab_SAF_AE_BIN.SAS
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Table SAF.G34TEAE.SAF.POOL.S1: Proportion of Patients With at Least One Grade 3 or Above Treatment Emergent Adverse Event by Subgroup (Safety Population)

Study: Pooled

Treatment	**N**	**n (%)**	**OR[1] [95% CI]**	**RR[2] [95% CI]**	**RD[3] [95% CI]**	**p-value[4]**	**p-value (int)[5]**
Age (years)							
< 40 years							
Relugolix+E2/NETA	62	1 (1.6)	0.32	0.34	-0.05	0.2088	0.4232
Placebo	78	5 (6.4)	[0.05;2.03]	[0.06;2.00]	[-0.11;0.01]		
>= 40 years							
Relugolix+E2/NETA	192	11 (5.7)	0.71	0.73	-0.02	0.4148	
Placebo	178	14 (7.9)	[0.31;1.61]	[0.34;1.56]	[-0.07;0.03]		

Post hoc analysis. The denominator for percentages is the number of patients in the safety population for each treatment group. Patients with multiple events are counted only once.
Adverse event grades are evaluated based on National Cancer Institute Common Terminology Criteria for Adverse Events version 5.0.
[1] OR (95% CI) based on a logistic regression model adjusting for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates.
[2] RR (95% CI) based on a Cochran-Mantel-Haenszel approach stratified by study.
[3] RD (95% CI) based on a Mantel-Haenszel approach stratified by study. 95% CIs are based on the approximation to the normal distribution using the Sato estimator for the standard error.
[4] P-value based on a Cochran-Mantel-Haenszel test stratified by study.
[5] Interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the OR (95% CI).
A continuity correction is applied in estimation of the OR, RR and p-value if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum. No continuity correction is applied in the estimation of the RD.
The reference group for the OR, RR and RD is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with >= 1 event; OR: Odds ratio; RR: Risk ratio; RD: Risk difference; CI: Confidence interval; int: p-value for interaction; NETA: Norethindrone acetate.

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Table SAF.G34TEAE.SAF.POOL.S8: Proportion of Patients With at Least One Grade 3 or Above Treatment Emergent Adverse Event by Subgroup (Safety Population)

Study: Pooled

Treatment	N	n (%)	OR[1] [95% CI]	RR[2] [95% CI]	RD[3] [95% CI]	p-value[4]	p-value (int)[5]
Ethnicity							
Hispanic or Latino							0.7909
Relugolix+E2/NETA	53	4 (7.5)	0.77	0.80	-0.02	0.7380	
Placebo	55	5 (9.1)	[0.19;3.06]	[0.21;3.03]	[-0.12;0.09]		
Not Hispanic or Latino							
Relugolix+E2/NETA	197	8 (4.1)	0.61	0.63	-0.02	0.2895	
Placebo	199	13 (6.5)	[0.25;1.52]	[0.27;1.49]	[-0.07;0.02]		
Not reported							
Relugolix+E2/NETA	4	0	NC	NC	NC	NC	
Placebo	2	1 (50.0)	[NC;NC]	[NC;NC]	[NC;NC]		

Post hoc analysis. The denominator for percentages is the number of patients in the safety population for each treatment group. Patients with multiple events are counted only once. Adverse event grades are evaluated based on National Cancer Institute Common Terminology Criteria for Adverse Events version 5.0.
[1] OR (95% CI) based on a logistic regression model adjusting for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates.
[2] RR (95% CI) based on a Cochran-Mantel-Haenszel approach stratified by study.
[3] RD (95% CI) based on a Mantel-Haenszel approach stratified by study. 95% CIs are based on the approximation to the normal distribution using the Sato estimator for the standard error.
[4] P-value based on a Cochran-Mantel-Haenszel test stratified by study.
[5] Interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the OR (95% CI). Not reported subgroup levels are not included in estimation of the interaction p-value.
A continuity correction is applied in estimation of the OR, RR and p-value if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum. No continuity correction is applied in the estimation of the RD.
The reference group for the OR, RR and RD is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with >= 1 event; OR: Odds ratio; RR: Risk ratio; RD: Risk difference; CI: Confidence interval; int: p-value for interaction; NETA: Norethindrone acetate; NC: Not calculated.

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Table SAF.G34TEAE.SAF.POOL.S9: Proportion of Patients With at Least One Grade 3 or Above Treatment Emergent Adverse Event by Subgroup (Safety Population)

Study: Pooled

Treatment	N	n (%)	OR[1] [95% CI]	RR[2] [95% CI]	RD[3] [95% CI]	p-value[4]	p-value (int)[5]
Race							
Black/African American							
Relugolix+E2/NETA	122	6 (4.9)	0.68	0.69	-0.02	0.4628	0.8567
Placebo	141	10 (7.1)	[0.24;1.92]	[0.26;1.86]	[-0.08;0.04]		
White							
Relugolix+E2/NETA	123	5 (4.1)	0.52	0.53	-0.04	0.2539	
Placebo	105	8 (7.6)	[0.16;1.63]	[0.18;1.60]	[-0.10;0.03]		
Asian							
Relugolix+E2/NETA	1	0	NC	NC	NC	NC	
Placebo	3	0	[NC;NC]	[NC;NC]	[NC;NC]		
Others							
Relugolix+E2/NETA	5	1 (20.0)	1.10	0.85	-0.16	0.8736	
Placebo	6	1 (16.7)	[0.08;14.81]	[0.15;4.91]	[-0.64;0.33]		
Not reported							
Relugolix+E2/NETA	3	0	NC	NC	NC	NC	
Placebo	1	0	[NC;NC]	[NC;NC]	[NC;NC]		

Post hoc analysis. The denominator for percentages is the number of patients in the safety population for each treatment group. Patients with multiple events are counted only once.
Adverse event grades are evaluated based on National Cancer Institute Common Terminology Criteria for Adverse Events version 5.0.
[1] OR (95% CI) based on a logistic regression model adjusting for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates.
[2] RR (95% CI) based on a Cochran-Mantel-Haenszel approach stratified by study.
[3] RD (95% CI) based on a Mantel-Haenszel approach stratified by study. 95% CIs are based on the approximation to the normal distribution using the Sato estimator for the standard error.
[4] P-value based on a Cochran-Mantel-Haenszel test stratified by study.
[5] Interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the OR (95% CI). Not reported subgroup levels are not included in estimation of the interaction p-value.
A continuity correction is applied in estimation of the OR, RR and p-value if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum. No continuity correction is applied in the estimation of the RD.
The reference group for the OR, RR and RD is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with >= 1 event; OR: Odds ratio; RR: Risk ratio; RD: Risk difference; CI: Confidence interval; int: p-value for interaction; NETA: Norethindrone acetate; NC: Not calculated.

SOURCE: \Studies\MYV\MYV102\Analysis\Prod\Progs\TFLs\Tab_SAF_AE_BIN.SAS
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Table SAF.G34TEAE.SAF.POOL.S5: Proportion of Patients With at Least One Grade 3 or Above Treatment Emergent Adverse Event by Subgroup (Safety Population)

Study: Pooled

Treatment	**N**	**n (%)**	**OR[1] [95% CI]**	**RR[2] [95% CI]**	**RD[3] [95% CI]**	**p-value[4]**	**p-value (int)[5]**
MBL Volume at Baseline (mL)							
< 225 mL							
Relugolix+E2/NETA	164	9 (5.5)	0.60	0.62	-0.03	0.2400	0.8645
Placebo	171	15 (8.8)	[0.25;1.41]	[0.28;1.38]	[-0.09;0.02]		
>= 225 mL							
Relugolix+E2/NETA	90	3 (3.3)	0.70	0.71	-0.01	0.6466	
Placebo	85	4 (4.7)	[0.15;3.22]	[0.16;3.07]	[-0.07;0.04]		

Post hoc analysis. The denominator for percentages is the number of patients in the safety population for each treatment group. Patients with multiple events are counted only once.
Adverse event grades are evaluated based on National Cancer Institute Common Terminology Criteria for Adverse Events version 5.0.
[1] OR (95% CI) based on a logistic regression model adjusting for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates.
[2] RR (95% CI) based on a Cochran-Mantel-Haenszel approach stratified by study.
[3] RD (95% CI) based on a Mantel-Haenszel approach stratified by study. 95% CIs are based on the approximation to the normal distribution using the Sato estimator for the standard error.
[4] P-value based on a Cochran-Mantel-Haenszel test stratified by study.
[5] Interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the OR (95% CI).
A continuity correction is applied in estimation of the OR, RR and p-value if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum. No continuity correction is applied in the estimation of the RD.
The reference group for the OR, RR and RD is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with >= 1 event; OR: Odds ratio; RR: Risk ratio; RD: Risk difference; CI: Confidence interval; int: p-value for interaction; NETA: Norethindrone acetate.

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Table SAF.TEAE.SPT.POOL.1.1.S7: Frequent Treatment Emergent Adverse Events by System Organ Class and Preferred Term, by Subgroup (Safety Population)

Study: Pooled

System Organ Class: Any, Preferred Term: Any

Treatment	**N**	**n (%)**	**OR[1] [95% CI]**	**RR[2] [95% CI]**	**RD[3] [95% CI]**	**p-value[4]**	**p-value (int)[5]**
Geographic Region II							
Europe							0.2717
Relugolix+E2/NETA	41	29 (70.7)	1.50	1.14	0.08	0.4217	
Placebo	42	26 (61.9)	[0.60;3.77]	[0.83;1.56]	[-0.12;0.29]		
Rest of World (including the US)							
Relugolix+E2/NETA	213	126 (59.2)	0.86	0.94	-0.04	0.4471	
Placebo	214	134 (62.6)	[0.58;1.27]	[0.81;1.10]	[-0.13;0.06]		

Post hoc analysis. The denominator for percentages is the number of patients in the safety population for each treatment group. Patients with multiple events for a given PT or SOC are counted only once for each PT and SOC. Only SOCs or PTs for which there are at least 10% of patients with an event in at least one treatment group OR at least 10 patients with an event overall and at least 1% of patients with an event in at least one treatment group in the overall safety population are considered. Further, only SOCs and PTs for which there is a significant treatment effect (p-value <0.05) in the overall safety population are presented. Events are sorted alphabetically by SOC and PT and then by ascending subgroup-by-treatment interaction p-value within each. MedDRA (version 22.0).
[1] OR (95% CI) based on a logistic regression model adjusting for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates.
[2] RR (95% CI) based on a Cochran-Mantel-Haenszel approach stratified by study.
[3] RD (95% CI) based on a Mantel-Haenszel approach stratified by study. 95% CIs are based on the approximation to the normal distribution using the Sato estimator for the standard error.
[4] P-value based on a Cochran-Mantel-Haenszel test stratified by study.
[5] Interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the OR (95% CI).
A continuity correction is applied in estimation of the OR, RR and p-value if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum. No continuity correction is applied in the estimation of the RD.
The reference group for the OR, RR and RD is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with >= 1 event; OR: Odds ratio; RR: Risk ratio; RD: Risk difference; CI: Confidence interval; NETA: Norethindrone acetate; SOC: System organ class; PT: Preferred term.

SOURCE: \Studies\MYV\MYV102\Analysis\Prod\Progs\TFLs\Tab_SAF_AE_SOC_PT_S_BIN.SAS
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Table SAF.TEAE.SPT.POOL.1.1.S3: Frequent Treatment Emergent Adverse Events by System Organ Class and Preferred Term, by Subgroup (Safety Population)

Study: Pooled

System Organ Class: Any, Preferred Term: Any

Treatment	N	n (%)	OR[1] [95% CI]	RR[2] [95% CI]	RD[3] [95% CI]	p-value[4]	p-value (int)[5]
Uterine Volume at Baseline (cm3)							
< 300 cm3							
Relugolix+E2/NETA	148	95 (64.2)	1.10	1.03	0.02	0.7116	0.3036
Placebo	129	80 (62.0)	[0.67;1.79]	[0.86;1.24]	[-0.09;0.14]		
>= 300 cm3							
Relugolix+E2/NETA	105	59 (56.2)	0.75	0.89	-0.07	0.2930	
Placebo	127	80 (63.0)	[0.44;1.28]	[0.72;1.11]	[-0.20;0.06]		
Missing							
Relugolix+E2/NETA	1	1 (100.0)	NC	NC	NC	NC	
Placebo	0	0	[NC;NC]	[NC;NC]	[NC;NC]		

Post hoc analysis. The denominator for percentages is the number of patients in the safety population for each treatment group. Patients with multiple events for a given PT or SOC are counted only once for each PT and SOC. Only SOCs or PTs for which there are at least 10% of patients with an event in at least one treatment group OR at least 10 patients with an event overall and at least 1% of patients with an event in at least one treatment group in the overall safety population are considered. Further, only SOCs and PTs for which there is a significant treatment effect (p-value <0.05) in the overall safety population are presented. Events are sorted alphabetically by SOC and PT and then by ascending subgroup-by-treatment interaction p-value within each. MedDRA (version 22.0).
[1] OR (95% CI) based on a logistic regression model adjusting for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates.
[2] RR (95% CI) based on a Cochran-Mantel-Haenszel approach stratified by study.
[3] RD (95% CI) based on a Mantel-Haenszel approach stratified by study. 95% CIs are based on the approximation to the normal distribution using the Sato estimator for the standard error.
[4] P-value based on a Cochran-Mantel-Haenszel test stratified by study.
[5] Interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the OR (95% CI). Missing subgroup levels are not included in estimation of the interaction p-value.
A continuity correction is applied in estimation of the OR, RR and p-value if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum. No continuity correction is applied in the estimation of the RD.
The reference group for the OR, RR and RD is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with >= 1 event; OR: Odds ratio; RR: Risk ratio; RD: Risk difference; CI: Confidence interval; NETA: Norethindrone acetate; SOC: System organ class; PT: Preferred term; NC: Not calculated.

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Table SAF.TEAE.SPT.POOL.1.1.S5: Frequent Treatment Emergent Adverse Events by System Organ Class and Preferred Term, by Subgroup (Safety Population)

Study: Pooled

System Organ Class: Any, Preferred Term: Any

Treatment	N	n (%)	OR[1] [95% CI]	RR[2] [95% CI]	RD[3] [95% CI]	p-value[4]	p-value (int)[5]
MBL Volume at Baseline (mL)							
< 225 mL							
Relugolix+E2/NETA	164	103 (62.8)	1.01	1.00	0.00	0.9924	0.6063
Placebo	171	107 (62.6)	[0.65;1.57]	[0.85;1.18]	[-0.10;0.10]		
>= 225 mL							
Relugolix+E2/NETA	90	52 (57.8)	0.83	0.93	-0.05	0.5320	
Placebo	85	53 (62.4)	[0.45;1.52]	[0.73;1.18]	[-0.19;0.10]		

Post hoc analysis. The denominator for percentages is the number of patients in the safety population for each treatment group. Patients with multiple events for a given PT or SOC are counted only once for each PT and SOC. Only SOCs or PTs for which there are at least 10% of patients with an event in at least one treatment group OR at least 10 patients with an event overall and at least 1% of patients with an event in at least one treatment group in the overall safety population are considered. Further, only SOCs and PTs for which there is a significant treatment effect (p-value <0.05) in the overall safety population are presented. Events are sorted alphabetically by SOC and PT and then by ascending subgroup-by-treatment interaction p-value within each. MedDRA (version 22.0).
[1] OR (95% CI) based on a logistic regression model adjusting for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates.
[2] RR (95% CI) based on a Cochran-Mantel-Haenszel approach stratified by study.
[3] RD (95% CI) based on a Mantel-Haenszel approach stratified by study. 95% CIs are based on the approximation to the normal distribution using the Sato estimator for the standard error.
[4] P-value based on a Cochran-Mantel-Haenszel test stratified by study.
[5] Interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the OR (95% CI).
A continuity correction is applied in estimation of the OR, RR and p-value if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum. No continuity correction is applied in the estimation of the RD.
The reference group for the OR, RR and RD is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with >= 1 event; OR: Odds ratio; RR: Risk ratio; RD: Risk difference; CI: Confidence interval; NETA: Norethindrone acetate; SOC: System organ class; PT: Preferred term.

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Table SAF.TEAE.SPT.POOL.1.1.S4: Frequent Treatment Emergent Adverse Events by System Organ Class and Preferred Term, by Subgroup (Safety Population)

Study: Pooled

System Organ Class: Any, Preferred Term: Any

Treatment	N	n (%)	OR[1] [95% CI]	RR[2] [95% CI]	RD[3] [95% CI]	p-value[4]	p-value (int)[5]
Maximum NRS Pain Score at Baseline							
< 4							
Relugolix+E2/NETA	73	40 (54.8)	0.80	0.91	-0.06	0.5105	0.6386
Placebo	62	37 (59.7)	[0.40;1.60]	[0.68;1.21]	[-0.23;0.11]		
>= 4							
Relugolix+E2/NETA	178	112 (62.9)	0.97	0.99	-0.01	0.8971	
Placebo	190	121 (63.7)	[0.64;1.49]	[0.85;1.16]	[-0.11;0.09]		
Missing							
Relugolix+E2/NETA	3	3 (100.0)	NC	NC	NC	NC	
Placebo	4	2 (50.0)	[NC;NC]	[NC;NC]	[NC;NC]		

Post hoc analysis. The denominator for percentages is the number of patients in the safety population for each treatment group. Patients with multiple events for a given PT or SOC are counted only once for each PT and SOC. Only SOCs or PTs for which there are at least 10% of patients with an event in at least one treatment group OR at least 10 patients with an event overall and at least 1% of patients with an event in at least one treatment group in the overall safety population are considered. Further, only SOCs and PTs for which there is a significant treatment effect (p-value <0.05) in the overall safety population are presented. Events are sorted alphabetically by SOC and PT and then by ascending subgroup-by-treatment interaction p-value within each. MedDRA (version 22.0).
[1] OR (95% CI) based on a logistic regression model adjusting for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates.
[2] RR (95% CI) based on a Cochran-Mantel-Haenszel approach stratified by study.
[3] RD (95% CI) based on a Mantel-Haenszel approach stratified by study. 95% CIs are based on the approximation to the normal distribution using the Sato estimator for the standard error.
[4] P-value based on a Cochran-Mantel-Haenszel test stratified by study.
[5] Interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the OR (95% CI). Missing subgroup levels are not included in estimation of the interaction p-value.
A continuity correction is applied in estimation of the OR, RR and p-value if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum. No continuity correction is applied in the estimation of the RD.
The reference group for the OR, RR and RD is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with >= 1 event; OR: Odds ratio; RR: Risk ratio; RD: Risk difference; CI: Confidence interval; NETA: Norethindrone acetate; SOC: System organ class; PT: Preferred term; NC: Not calculated.

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Table SAF.TEAE.SPT.POOL.1.1.S8: Frequent Treatment Emergent Adverse Events by System Organ Class and Preferred Term, by Subgroup (Safety Population)

Study: Pooled

System Organ Class: Any, Preferred Term: Any

Treatment	**N**	**n (%)**	**OR[1] [95% CI]**	**RR[2] [95% CI]**	**RD[3] [95% CI]**	**p-value[4]**	**p-value (int)[5]**
Ethnicity							
Hispanic or Latino							
Relugolix+E2/NETA	53	36 (67.9)	1.08	1.07	0.04	0.6428	0.6847
Placebo	55	36 (65.5)	[0.48;2.41]	[0.81;1.40]	[-0.14;0.22]		
Not Hispanic or Latino							
Relugolix+E2/NETA	197	115 (58.4)	0.89	0.96	-0.03	0.6030	
Placebo	199	122 (61.3)	[0.60;1.34]	[0.81;1.13]	[-0.12;0.07]		
Not reported							
Relugolix+E2/NETA	4	4 (100.0)	NC	NC	NC	NC	
Placebo	2	2 (100.0)	[NC;NC]	[NC;NC]	[NC;NC]		

Post hoc analysis. The denominator for percentages is the number of patients in the safety population for each treatment group. Patients with multiple events for a given PT or SOC are counted only once for each PT and SOC. Only SOCs or PTs for which there are at least 10% of patients with an event in at least one treatment group OR at least 10 patients with an event overall and at least 1% of patients with an event in at least one treatment group in the overall safety population are considered. Further, only SOCs and PTs for which there is a significant treatment effect (p-value <0.05) in the overall safety population are presented. Events are sorted alphabetically by SOC and PT and then by ascending subgroup-by-treatment interaction p-value within each. MedDRA (version 22.0).
[1] OR (95% CI) based on a logistic regression model adjusting for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates.
[2] RR (95% CI) based on a Cochran-Mantel-Haenszel approach stratified by study.
[3] RD (95% CI) based on a Mantel-Haenszel approach stratified by study. 95% CIs are based on the approximation to the normal distribution using the Sato estimator for the standard error.
[4] P-value based on a Cochran-Mantel-Haenszel test stratified by study.
[5] Interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the OR (95% CI). Not reported subgroup levels are not included in estimation of the interaction p-value.
A continuity correction is applied in estimation of the OR, RR and p-value if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum. No continuity correction is applied in the estimation of the RD.
The reference group for the OR, RR and RD is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with >= 1 event; OR: Odds ratio; RR: Risk ratio; RD: Risk difference; CI: Confidence interval; NETA: Norethindrone acetate; SOC: System organ class; PT: Preferred term; NC: Not calculated.

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Table SAF.TEAE.SPT.POOL.1.1.S6: Frequent Treatment Emergent Adverse Events by System Organ Class and Preferred Term, by Subgroup (Safety Population)

Study: Pooled

System Organ Class: Any, Preferred Term: Any

Treatment	N	n (%)	OR[1] [95% CI]	RR[2] [95% CI]	RD[3] [95% CI]	p-value[4]	p-value (int)[5]
Geographic Region I							
North America							
Relugolix+E2/NETA	192	111 (57.8)	0.92	0.97	-0.02	0.6861	0.8582
Placebo	194	116 (59.8)	[0.61;1.38]	[0.82;1.14]	[-0.12;0.08]		
Rest of World							
Relugolix+E2/NETA	62	44 (71.0)	1.00	1.00	0.00	0.9905	
Placebo	62	44 (71.0)	[0.46;2.17]	[0.80;1.25]	[-0.16;0.16]		

Post hoc analysis. The denominator for percentages is the number of patients in the safety population for each treatment group. Patients with multiple events for a given PT or SOC are counted only once for each PT and SOC. Only SOCs or PTs for which there are at least 10% of patients with an event in at least one treatment group OR at least 10 patients with an event overall and at least 1% of patients with an event in at least one treatment group in the overall safety population are considered. Further, only SOCs and PTs for which there is a significant treatment effect (p-value <0.05) in the overall safety population are presented. Events are sorted alphabetically by SOC and PT and then by ascending subgroup-by-treatment interaction p-value within each. MedDRA (version 22.0).
[1] OR (95% CI) based on a logistic regression model adjusting for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates.
[2] RR (95% CI) based on a Cochran-Mantel-Haenszel approach stratified by study.
[3] RD (95% CI) based on a Mantel-Haenszel approach stratified by study. 95% CIs are based on the approximation to the normal distribution using the Sato estimator for the standard error.
[4] P-value based on a Cochran-Mantel-Haenszel test stratified by study.
[5] Interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the OR (95% CI).
A continuity correction is applied in estimation of the OR, RR and p-value if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum. No continuity correction is applied in the estimation of the RD.
The reference group for the OR, RR and RD is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with >= 1 event; OR: Odds ratio; RR: Risk ratio; RD: Risk difference; CI: Confidence interval; NETA: Norethindrone acetate; SOC: System organ class; PT: Preferred term.

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Table SAF.TEAE.SPT.POOL.1.1.S9: Frequent Treatment Emergent Adverse Events by System Organ Class and Preferred Term, by Subgroup (Safety Population)

Study: Pooled

System Organ Class: Any, Preferred Term: Any

Treatment	N	n (%)	OR[1] [95% CI]	RR[2] [95% CI]	RD[3] [95% CI]	p-value[4]	p-value (int)[5]
Race							
Black/African American							0.9226
Relugolix+E2/NETA	122	69 (56.6)	0.86	0.94	-0.04	0.5317	
Placebo	141	85 (60.3)	[0.52;1.40]	[0.76;1.15]	[-0.16;0.08]		
White							
Relugolix+E2/NETA	123	78 (63.4)	0.99	0.99	-0.00	0.9472	
Placebo	105	67 (63.8)	[0.57;1.69]	[0.82;1.21]	[-0.13;0.12]		
Asian							
Relugolix+E2/NETA	1	1 (100.0)	NC	NC	NC	NC	
Placebo	3	2 (66.7)	[NC;NC]	[NC;NC]	[NC;NC]		
Others							
Relugolix+E2/NETA	5	4 (80.0)	0.78	0.80	-0.28	0.5183	
Placebo	6	5 (83.3)	[0.08;7.72]	[0.37;1.72]	[-0.62;0.06]		
Not reported							
Relugolix+E2/NETA	3	3 (100.0)	NC	NC	NC	NC	
Placebo	1	1 (100.0)	[NC;NC]	[NC;NC]	[NC;NC]		

Post hoc analysis. The denominator for percentages is the number of patients in the safety population for each treatment group. Patients with multiple events for a given PT or SOC are counted only once for each PT and SOC. Only SOCs or PTs for which there are at least 10% of patients with an event in at least one treatment group OR at least 10 patients with an event overall and at least 1% of patients with an event in at least one treatment group in the overall safety population are considered. Further, only SOCs and PTs for which there is a significant treatment effect (p-value <0.05) in the overall safety population are presented. Events are sorted alphabetically by SOC and PT and then by ascending subgroup-by-treatment interaction p-value within each. MedDRA (version 22.0).
[1] OR (95% CI) based on a logistic regression model adjusting for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates.
[2] RR (95% CI) based on a Cochran-Mantel-Haenszel approach stratified by study.
[3] RD (95% CI) based on a Mantel-Haenszel approach stratified by study. 95% CIs are based on the approximation to the normal distribution using the Sato estimator for the standard error.
[4] P-value based on a Cochran-Mantel-Haenszel test stratified by study.
[5] Interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the OR (95% CI). Not reported subgroup levels are not included in estimation of the interaction p-value.
A continuity correction is applied in estimation of the OR, RR and p-value if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum. No continuity correction is applied in the estimation of the RD.
The reference group for the OR, RR and RD is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with >= 1 event; OR: Odds ratio; RR: Risk ratio; RD: Risk difference; CI: Confidence interval; NETA: Norethindrone acetate; SOC: System organ class; PT: Preferred term; NC: Not calculated.

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Table SAF.TEAE.SPT.POOL.1.1.S2: Frequent Treatment Emergent Adverse Events by System Organ Class and Preferred Term, by Subgroup (Safety Population)

Study: Pooled

System Organ Class: Any, Preferred Term: Any

Treatment	N	n (%)	OR[1] [95% CI]	RR[2] [95% CI]	RD[3] [95% CI]	p-value[4]	p-value (int)[5]
BMI (kg/m2) at Baseline							
< 30							
Relugolix+E2/NETA	119	71 (59.7)	0.94	0.97	-0.02	0.8084	0.9581
Placebo	115	70 (60.9)	[0.56;1.59]	[0.79;1.20]	[-0.14;0.11]		
>= 30							
Relugolix+E2/NETA	134	83 (61.9)	0.93	0.97	-0.02	0.7497	
Placebo	141	90 (63.8)	[0.57;1.51]	[0.81;1.16]	[-0.13;0.10]		
Missing							
Relugolix+E2/NETA	1	1 (100.0)	NC	NC	NC	NC	
Placebo	0	0	[NC;NC]	[NC;NC]	[NC;NC]		

Post hoc analysis. The denominator for percentages is the number of patients in the safety population for each treatment group. Patients with multiple events for a given PT or SOC are counted only once for each PT and SOC. Only SOCs or PTs for which there are at least 10% of patients with an event in at least one treatment group OR at least 10 patients with an event overall and at least 1% of patients with an event in at least one treatment group in the overall safety population are considered. Further, only SOCs and PTs for which there is a significant treatment effect (p-value <0.05) in the overall safety population are presented. Events are sorted alphabetically by SOC and PT and then by ascending subgroup-by-treatment interaction p-value within each. MedDRA (version 22.0).
[1] OR (95% CI) based on a logistic regression model adjusting for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates.
[2] RR (95% CI) based on a Cochran-Mantel-Haenszel approach stratified by study.
[3] RD (95% CI) based on a Mantel-Haenszel approach stratified by study. 95% CIs are based on the approximation to the normal distribution using the Sato estimator for the standard error.
[4] P-value based on a Cochran-Mantel-Haenszel test stratified by study.
[5] Interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the OR (95% CI). Missing subgroup levels are not included in estimation of the interaction p-value.
A continuity correction is applied in estimation of the OR, RR and p-value if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum. No continuity correction is applied in the estimation of the RD.
The reference group for the OR, RR and RD is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with >= 1 event; OR: Odds ratio; RR: Risk ratio; RD: Risk difference; CI: Confidence interval; NETA: Norethindrone acetate; SOC: System organ class; PT: Preferred term; NC: Not calculated.

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Table SAF.TEAE.SPT.POOL.1.1.S1: Frequent Treatment Emergent Adverse Events by System Organ Class and Preferred Term, by Subgroup (Safety Population)

Study: Pooled

System Organ Class: Any, Preferred Term: Any

Treatment	N	n (%)	OR[1] [95% CI]	RR[2] [95% CI]	RD[3] [95% CI]	p-value[4]	p-value (int)[5]
Age (years)							
< 40 years							
Relugolix+E2/NETA	62	38 (61.3)	0.93	0.97	-0.02	0.8219	0.9823
Placebo	78	49 (62.8)	[0.47;1.86]	[0.75;1.26]	[-0.18;0.14]		
>= 40 years							
Relugolix+E2/NETA	192	117 (60.9)	0.94	0.98	-0.01	0.7793	
Placebo	178	111 (62.4)	[0.62;1.43]	[0.83;1.15]	[-0.11;0.08]		

Post hoc analysis. The denominator for percentages is the number of patients in the safety population for each treatment group. Patients with multiple events for a given PT or SOC are counted only once for each PT and SOC. Only SOCs or PTs for which there are at least 10% of patients with an event in at least one treatment group OR at least 10 patients with an event overall and at least 1% of patients with an event in at least one treatment group in the overall safety population are considered. Further, only SOCs and PTs for which there is a significant treatment effect (p-value <0.05) in the overall safety population are presented. Events are sorted alphabetically by SOC and PT and then by ascending subgroup-by-treatment interaction p-value within each. MedDRA (version 22.0).
[1] OR (95% CI) based on a logistic regression model adjusting for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates.
[2] RR (95% CI) based on a Cochran-Mantel-Haenszel approach stratified by study.
[3] RD (95% CI) based on a Mantel-Haenszel approach stratified by study. 95% CIs are based on the approximation to the normal distribution using the Sato estimator for the standard error.
[4] P-value based on a Cochran-Mantel-Haenszel test stratified by study.
[5] Interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the OR (95% CI).
A continuity correction is applied in estimation of the OR, RR and p-value if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum. No continuity correction is applied in the estimation of the RD.
The reference group for the OR, RR and RD is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with >= 1 event; OR: Odds ratio; RR: Risk ratio; RD: Risk difference; CI: Confidence interval; NETA: Norethindrone acetate; SOC: System organ class; PT: Preferred term.

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Table SAF.TEAE.SPT.POOL.2.1.S6: Frequent Treatment Emergent Adverse Events by System Organ Class and Preferred Term, by Subgroup (Safety Population)

Study: Pooled

System Organ Class: Blood and lymphatic system disorders, Preferred Term: Any

Treatment	N	n (%)	OR[1] [95% CI]	RR[2] [95% CI]	RD[3] [95% CI]	p-value[4]	p-value (int)[5]
Geographic Region I							
North America							
Relugolix+E2/NETA	192	6 (3.1)	0.86	0.87	-0.00	0.7964	0.0623
Placebo	194	7 (3.6)	[0.28;2.62]	[0.30;2.54]	[-0.04;0.03]		
Rest of World							
Relugolix+E2/NETA	62	2 (3.2)	0.15	0.18	-0.15	0.0089	
Placebo	62	11 (17.7)	[0.03;0.73]	[0.04;0.79]	[-0.25;-0.04]		

Post hoc analysis. The denominator for percentages is the number of patients in the safety population for each treatment group. Patients with multiple events for a given PT or SOC are counted only once for each PT and SOC. Only SOCs or PTs for which there are at least 10% of patients with an event in at least one treatment group OR at least 10 patients with an event overall and at least 1% of patients with an event in at least one treatment group in the overall safety population are considered. Further, only SOCs and PTs for which there is a significant treatment effect (p-value <0.05) in the overall safety population are presented. Events are sorted alphabetically by SOC and PT and then by ascending subgroup-by-treatment interaction p-value within each. MedDRA (version 22.0).
[1] OR (95% CI) based on a logistic regression model adjusting for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates.
[2] RR (95% CI) based on a Cochran-Mantel-Haenszel approach stratified by study.
[3] RD (95% CI) based on a Mantel-Haenszel approach stratified by study. 95% CIs are based on the approximation to the normal distribution using the Sato estimator for the standard error.
[4] P-value based on a Cochran-Mantel-Haenszel test stratified by study.
[5] Interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the OR (95% CI).
A continuity correction is applied in estimation of the OR, RR and p-value if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum. No continuity correction is applied in the estimation of the RD.
The reference group for the OR, RR and RD is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with >= 1 event; OR: Odds ratio; RR: Risk ratio; RD: Risk difference; CI: Confidence interval; NETA: Norethindrone acetate; SOC: System organ class; PT: Preferred term.

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Table SAF.TEAE.SPT.POOL.2.1.S8: Frequent Treatment Emergent Adverse Events by System Organ Class and Preferred Term, by Subgroup (Safety Population)

Study: Pooled

System Organ Class: Blood and lymphatic system disorders, Preferred Term: Any

Treatment	**N**	**n (%)**	**OR[1] [95% CI]**	**RR[2] [95% CI]**	**RD[3] [95% CI]**	**p-value[4]**	**p-value (int)[5]**
Ethnicity							
Hispanic or Latino							
Relugolix+E2/NETA	53	4 (7.5)	1.10	1.27	0.02	0.7291	0.1445
Placebo	55	4 (7.3)	[0.28;4.35]	[0.33;4.94]	[-0.07;0.12]		
Not Hispanic or Latino							
Relugolix+E2/NETA	197	4 (2.0)	0.29	0.31	-0.04	0.0284	
Placebo	199	13 (6.5)	[0.09;0.92]	[0.10;0.94]	[-0.08;-0.01]		
Not reported							
Relugolix+E2/NETA	4	0	NC	NC	NC	NC	
Placebo	2	1 (50.0)	[NC;NC]	[NC;NC]	[NC;NC]		

Post hoc analysis. The denominator for percentages is the number of patients in the safety population for each treatment group. Patients with multiple events for a given PT or SOC are counted only once for each PT and SOC. Only SOCs or PTs for which there are at least 10% of patients with an event in at least one treatment group OR at least 10 patients with an event overall and at least 1% of patients with an event in at least one treatment group in the overall safety population are considered. Further, only SOCs and PTs for which there is a significant treatment effect (p-value <0.05) in the overall safety population are presented. Events are sorted alphabetically by SOC and PT and then by ascending subgroup-by-treatment interaction p-value within each. MedDRA (version 22.0).
[1] OR (95% CI) based on a logistic regression model adjusting for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates.
[2] RR (95% CI) based on a Cochran-Mantel-Haenszel approach stratified by study.
[3] RD (95% CI) based on a Mantel-Haenszel approach stratified by study. 95% CIs are based on the approximation to the normal distribution using the Sato estimator for the standard error.
[4] P-value based on a Cochran-Mantel-Haenszel test stratified by study.
[5] Interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the OR (95% CI). Not reported subgroup levels are not included in estimation of the interaction p-value.
A continuity correction is applied in estimation of the OR, RR and p-value if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum. No continuity correction is applied in the estimation of the RD.
The reference group for the OR, RR and RD is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with >= 1 event; OR: Odds ratio; RR: Risk ratio; RD: Risk difference; CI: Confidence interval; NETA: Norethindrone acetate; SOC: System organ class; PT: Preferred term; NC: Not calculated.

SOURCE: \Studies\MYV\MYV102\Analysis\Prod\Progs\TFLs\Tab_SAF_AE_SOC_PT_S_BIN.SAS
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Table SAF.TEAE.SPT.POOL.2.1.S7: Frequent Treatment Emergent Adverse Events by System Organ Class and Preferred Term, by Subgroup (Safety Population)

Study: Pooled

System Organ Class: Blood and lymphatic system disorders, Preferred Term: Any

Treatment	N	n (%)	OR[1] [95% CI]	RR[2] [95% CI]	RD[3] [95% CI]	p-value[4]	p-value (int)[5]
Geographic Region II							
Europe							0.2943
Relugolix+E2/NETA	41	1 (2.4)	0.20 [0.03;1.26]	0.24 [0.04;1.37]	-0.11 [-0.23;0.00]	0.0790	
Placebo	42	6 (14.3)					
Rest of World (including the US)							
Relugolix+E2/NETA	213	7 (3.3)	0.58 [0.22;1.50]	0.60 [0.24;1.49]	-0.02 [-0.06;0.02]	0.2607	
Placebo	214	12 (5.6)					

Post hoc analysis. The denominator for percentages is the number of patients in the safety population for each treatment group. Patients with multiple events for a given PT or SOC are counted only once for each PT and SOC. Only SOCs or PTs for which there are at least 10% of patients with an event in at least one treatment group OR at least 10 patients with an event overall and at least 1% of patients with an event in at least one treatment group in the overall safety population are considered. Further, only SOCs and PTs for which there is a significant treatment effect (p-value <0.05) in the overall safety population are presented. Events are sorted alphabetically by SOC and PT and then by ascending subgroup-by-treatment interaction p-value within each. MedDRA (version 22.0).
[1] OR (95% CI) based on a logistic regression model adjusting for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates.
[2] RR (95% CI) based on a Cochran-Mantel-Haenszel approach stratified by study.
[3] RD (95% CI) based on a Mantel-Haenszel approach stratified by study. 95% CIs are based on the approximation to the normal distribution using the Sato estimator for the standard error.
[4] P-value based on a Cochran-Mantel-Haenszel test stratified by study.
[5] Interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the OR (95% CI).
A continuity correction is applied in estimation of the OR, RR and p-value if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum. No continuity correction is applied in the estimation of the RD.
The reference group for the OR, RR and RD is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with >= 1 event; OR: Odds ratio; RR: Risk ratio; RD: Risk difference; CI: Confidence interval; NETA: Norethindrone acetate; SOC: System organ class; PT: Preferred term.

SOURCE: \Studies\MYV\MYV102\Analysis\Prod\Progs\TFLs\Tab_SAF_AE_SOC_PT_S_BIN.SAS
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Table SAF.TEAE.SPT.POOL.2.1.S9: Frequent Treatment Emergent Adverse Events by System Organ Class and Preferred Term, by Subgroup (Safety Population)

Study: Pooled

System Organ Class: Blood and lymphatic system disorders, Preferred Term: Any

Treatment	N	n (%)	OR[1] [95% CI]	RR[2] [95% CI]	RD[3] [95% CI]	p-value[4]	p-value (int)[5]
Race							
Black/African American							0.3972
Relugolix+E2/NETA	122	2 (1.6)	0.24	0.26	-0.05	0.0568	
Placebo	141	9 (6.4)	[0.05;1.16]	[0.06;1.18]	[-0.09;-0.00]		
White							
Relugolix+E2/NETA	123	6 (4.9)	0.84	0.86	-0.01	0.7885	
Placebo	105	6 (5.7)	[0.26;2.70]	[0.28;2.60]	[-0.07;0.05]		
Asian							
Relugolix+E2/NETA	1	0	NC	NC	NC	NC	
Placebo	3	0	[NC;NC]	[NC;NC]	[NC;NC]		
Others							
Relugolix+E2/NETA	5	0	0.30	0.53	-0.19	0.5475	
Placebo	6	2 (33.3)	[0.02;3.92]	[0.07;4.29]	[-0.58;0.20]		
Not reported							
Relugolix+E2/NETA	3	0	NC	NC	NC	NC	
Placebo	1	1 (100.0)	[NC;NC]	[NC;NC]	[NC;NC]		

Post hoc analysis. The denominator for percentages is the number of patients in the safety population for each treatment group. Patients with multiple events for a given PT or SOC are counted only once for each PT and SOC. Only SOCs or PTs for which there are at least 10% of patients with an event in at least one treatment group OR at least 10 patients with an event overall and at least 1% of patients with an event in at least one treatment group in the overall safety population are considered. Further, only SOCs and PTs for which there is a significant treatment effect (p-value <0.05) in the overall safety population are presented. Events are sorted alphabetically by SOC and PT and then by ascending subgroup-by-treatment interaction p-value within each. MedDRA (version 22.0).
[1] OR (95% CI) based on a logistic regression model adjusting for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates.
[2] RR (95% CI) based on a Cochran-Mantel-Haenszel approach stratified by study.
[3] RD (95% CI) based on a Mantel-Haenszel approach stratified by study. 95% CIs are based on the approximation to the normal distribution using the Sato estimator for the standard error.
[4] P-value based on a Cochran-Mantel-Haenszel test stratified by study.
[5] Interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the OR (95% CI). Not reported subgroup levels are not included in estimation of the interaction p-value.
A continuity correction is applied in estimation of the OR, RR and p-value if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum. No continuity correction is applied in the estimation of the RD.
The reference group for the OR, RR and RD is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with >= 1 event; OR: Odds ratio; RR: Risk ratio; RD: Risk difference; CI: Confidence interval; NETA: Norethindrone acetate; SOC: System organ class; PT: Preferred term; NC: Not calculated.

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Table SAF.TEAE.SPT.POOL.2.1.S4: Frequent Treatment Emergent Adverse Events by System Organ Class and Preferred Term, by Subgroup (Safety Population)

Study: Pooled

System Organ Class: Blood and lymphatic system disorders, Preferred Term: Any

Treatment	N	n (%)	OR[1] [95% CI]	RR[2] [95% CI]	RD[3] [95% CI]	p-value[4]	p-value (int)[5]
Maximum NRS Pain Score at Baseline							
< 4							
Relugolix+E2/NETA	73	3 (4.1)	0.63 [0.14;2.95]	0.67 [0.16;2.79]	-0.02 [-0.10;0.06]	0.5813	0.4687
Placebo	62	4 (6.5)					
>= 4							
Relugolix+E2/NETA	178	4 (2.2)	0.31 [0.10;0.97]	0.33 [0.11;0.99]	-0.05 [-0.09;-0.00]	0.0360	
Placebo	190	13 (6.8)					
Missing							
Relugolix+E2/NETA	3	1 (33.3)	NC [NC;NC]	NC [NC;NC]	NC [NC;NC]	NC	
Placebo	4	1 (25.0)					

Post hoc analysis. The denominator for percentages is the number of patients in the safety population for each treatment group. Patients with multiple events for a given PT or SOC are counted only once for each PT and SOC. Only SOCs or PTs for which there are at least 10% of patients with an event in at least one treatment group OR at least 10 patients with an event overall and at least 1% of patients with an event in at least one treatment group in the overall safety population are considered. Further, only SOCs and PTs for which there is a significant treatment effect (p-value <0.05) in the overall safety population are presented. Events are sorted alphabetically by SOC and PT and then by ascending subgroup-by-treatment interaction p-value within each. MedDRA (version 22.0).
[1] OR (95% CI) based on a logistic regression model adjusting for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates.
[2] RR (95% CI) based on a Cochran-Mantel-Haenszel approach stratified by study.
[3] RD (95% CI) based on a Mantel-Haenszel approach stratified by study. 95% CIs are based on the approximation to the normal distribution using the Sato estimator for the standard error.
[4] P-value based on a Cochran-Mantel-Haenszel test stratified by study.
[5] Interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the OR (95% CI). Missing subgroup levels are not included in estimation of the interaction p-value.
A continuity correction is applied in estimation of the OR, RR and p-value if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum. No continuity correction is applied in the estimation of the RD.
The reference group for the OR, RR and RD is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with >= 1 event; OR: Odds ratio; RR: Risk ratio; RD: Risk difference; CI: Confidence interval; NETA: Norethindrone acetate; SOC: System organ class; PT: Preferred term; NC: Not calculated.

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Table SAF.TEAE.SPT.POOL.2.1.S2: Frequent Treatment Emergent Adverse Events by System Organ Class and Preferred Term, by Subgroup (Safety Population)

Study: Pooled

System Organ Class: Blood and lymphatic system disorders, Preferred Term: Any

Treatment	N	n (%)	OR[1] [95% CI]	RR[2] [95% CI]	RD[3] [95% CI]	p-value[4]	p-value (int)[5]
BMI (kg/m2) at Baseline							
< 30							0.4919
Relugolix+E2/NETA	119	3 (2.5)	0.31 [0.08;1.17]	0.32 [0.09;1.14]	-0.05 [-0.11;0.00]	0.0624	
Placebo	115	9 (7.8)					
>= 30							
Relugolix+E2/NETA	134	5 (3.7)	0.56 [0.18;1.73]	0.58 [0.20;1.66]	-0.03 [-0.08;0.02]	0.3020	
Placebo	141	9 (6.4)					
Missing							
Relugolix+E2/NETA	1	0	NC [NC;NC]	NC [NC;NC]	NC [NC;NC]	NC	
Placebo	0	0					

Post hoc analysis. The denominator for percentages is the number of patients in the safety population for each treatment group. Patients with multiple events for a given PT or SOC are counted only once for each PT and SOC. Only SOCs or PTs for which there are at least 10% of patients with an event in at least one treatment group OR at least 10 patients with an event overall and at least 1% of patients with an event in at least one treatment group in the overall safety population are considered. Further, only SOCs and PTs for which there is a significant treatment effect (p-value <0.05) in the overall safety population are presented. Events are sorted alphabetically by SOC and PT and then by ascending subgroup-by-treatment interaction p-value within each. MedDRA (version 22.0).
[1] OR (95% CI) based on a logistic regression model adjusting for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates.
[2] RR (95% CI) based on a Cochran-Mantel-Haenszel approach stratified by study.
[3] RD (95% CI) based on a Mantel-Haenszel approach stratified by study. 95% CIs are based on the approximation to the normal distribution using the Sato estimator for the standard error.
[4] P-value based on a Cochran-Mantel-Haenszel test stratified by study.
[5] Interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the OR (95% CI). Missing subgroup levels are not included in estimation of the interaction p-value.
A continuity correction is applied in estimation of the OR, RR and p-value if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum. No continuity correction is applied in the estimation of the RD.
The reference group for the OR, RR and RD is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with >= 1 event; OR: Odds ratio; RR: Risk ratio; RD: Risk difference; CI: Confidence interval; NETA: Norethindrone acetate; SOC: System organ class; PT: Preferred term; NC: Not calculated.

SOURCE: \Studies\MYV\MYV102\Analysis\Prod\Progs\TFLs\Tab_SAF_AE_SOC_PT_S_BIN.SAS
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Table SAF.TEAE.SPT.POOL.2.1.S3: Frequent Treatment Emergent Adverse Events by System Organ Class and Preferred Term, by Subgroup (Safety Population)

Study: Pooled

System Organ Class: Blood and lymphatic system disorders, Preferred Term: Any

Treatment	N	n (%)	OR[1] [95% CI]	RR[2] [95% CI]	RD[3] [95% CI]	p-value[4]	p-value (int)[5]
Uterine Volume at Baseline (cm3)							
< 300 cm3							
Relugolix+E2/NETA	148	3 (2.0)	0.36	0.37	-0.03	0.1319	0.6686
Placebo	129	7 (5.4)	[0.09;1.43]	[0.10;1.43]	[-0.08;0.01]		
>= 300 cm3							
Relugolix+E2/NETA	105	5 (4.8)	0.53	0.55	-0.04	0.2454	
Placebo	127	11 (8.7)	[0.18;1.57]	[0.20;1.53]	[-0.10;0.02]		
Missing							
Relugolix+E2/NETA	1	0	NC	NC	NC	NC	
Placebo	0	0	[NC;NC]	[NC;NC]	[NC;NC]		

Post hoc analysis. The denominator for percentages is the number of patients in the safety population for each treatment group. Patients with multiple events for a given PT or SOC are counted only once for each PT and SOC. Only SOCs or PTs for which there are at least 10% of patients with an event in at least one treatment group OR at least 10 patients with an event overall and at least 1% of patients with an event in at least one treatment group in the overall safety population are considered. Further, only SOCs and PTs for which there is a significant treatment effect (p-value <0.05) in the overall safety population are presented. Events are sorted alphabetically by SOC and PT and then by ascending subgroup-by-treatment interaction p-value within each. MedDRA (version 22.0).
[1] OR (95% CI) based on a logistic regression model adjusting for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates.
[2] RR (95% CI) based on a Cochran-Mantel-Haenszel approach stratified by study.
[3] RD (95% CI) based on a Mantel-Haenszel approach stratified by study. 95% CIs are based on the approximation to the normal distribution using the Sato estimator for the standard error.
[4] P-value based on a Cochran-Mantel-Haenszel test stratified by study.
[5] Interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the OR (95% CI). Missing subgroup levels are not included in estimation of the interaction p-value.
A continuity correction is applied in estimation of the OR, RR and p-value if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum. No continuity correction is applied in the estimation of the RD.
The reference group for the OR, RR and RD is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with >= 1 event; OR: Odds ratio; RR: Risk ratio; RD: Risk difference; CI: Confidence interval; NETA: Norethindrone acetate; SOC: System organ class; PT: Preferred term; NC: Not calculated.

SOURCE: \Studies\MYV\MYV102\Analysis\Prod\Progs\TFLs\Tab_SAF_AE_SOC_PT_S_BIN.SAS
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Table SAF.TEAE.SPT.POOL.2.1.S1: Frequent Treatment Emergent Adverse Events by System Organ Class and Preferred Term, by Subgroup (Safety Population)

Study: Pooled

System Organ Class: Blood and lymphatic system disorders, Preferred Term: Any

Treatment	N	n (%)	OR[1] [95% CI]	RR[2] [95% CI]	RD[3] [95% CI]	p-value[4]	p-value (int)[5]
Age (years)							
< 40 years							
Relugolix+E2/NETA	62	1 (1.6)	0.53 [0.08;3.69]	0.54 [0.08;3.55]	-0.02 [-0.07;0.03]	0.5183	0.8194
Placebo	78	3 (3.8)					
>= 40 years							
Relugolix+E2/NETA	192	7 (3.6)	0.41 [0.16;1.03]	0.43 [0.18;1.04]	-0.05 [-0.10;0.00]	0.0525	
Placebo	178	15 (8.4)					

Post hoc analysis. The denominator for percentages is the number of patients in the safety population for each treatment group. Patients with multiple events for a given PT or SOC are counted only once for each PT and SOC. Only SOCs or PTs for which there are at least 10% of patients with an event in at least one treatment group OR at least 10 patients with an event overall and at least 1% of patients with an event in at least one treatment group in the overall safety population are considered. Further, only SOCs and PTs for which there is a significant treatment effect (p-value <0.05) in the overall safety population are presented. Events are sorted alphabetically by SOC and PT and then by ascending subgroup-by-treatment interaction p-value within each. MedDRA (version 22.0).
[1] OR (95% CI) based on a logistic regression model adjusting for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates.
[2] RR (95% CI) based on a Cochran-Mantel-Haenszel approach stratified by study.
[3] RD (95% CI) based on a Mantel-Haenszel approach stratified by study. 95% CIs are based on the approximation to the normal distribution using the Sato estimator for the standard error.
[4] P-value based on a Cochran-Mantel-Haenszel test stratified by study.
[5] Interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the OR (95% CI).
A continuity correction is applied in estimation of the OR, RR and p-value if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum. No continuity correction is applied in the estimation of the RD.
The reference group for the OR, RR and RD is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with >= 1 event; OR: Odds ratio; RR: Risk ratio; RD: Risk difference; CI: Confidence interval; NETA: Norethindrone acetate; SOC: System organ class; PT: Preferred term.

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Table SAF.TEAE.SPT.POOL.2.1.S5: Frequent Treatment Emergent Adverse Events by System Organ Class and Preferred Term, by Subgroup (Safety Population)

Study: Pooled

System Organ Class: Blood and lymphatic system disorders, Preferred Term: Any

Treatment	N	n (%)	OR[1] [95% CI]	RR[2] [95% CI]	RD[3] [95% CI]	p-value[4]	p-value (int)[5]
MBL Volume at Baseline (mL)							
< 225 mL							
Relugolix+E2/NETA	164	5 (3.0)	0.46 [0.16;1.35]	0.48 [0.17;1.34]	-0.03 [-0.08;0.01]	0.1515	0.8395
Placebo	171	11 (6.4)					
>= 225 mL							
Relugolix+E2/NETA	90	3 (3.3)	0.38 [0.10;1.53]	0.41 [0.11;1.52]	-0.05 [-0.12;0.02]	0.1651	
Placebo	85	7 (8.2)					

Post hoc analysis. The denominator for percentages is the number of patients in the safety population for each treatment group. Patients with multiple events for a given PT or SOC are counted only once for each PT and SOC. Only SOCs or PTs for which there are at least 10% of patients with an event in at least one treatment group OR at least 10 patients with an event overall and at least 1% of patients with an event in at least one treatment group in the overall safety population are considered. Further, only SOCs and PTs for which there is a significant treatment effect (p-value <0.05) in the overall safety population are presented. Events are sorted alphabetically by SOC and PT and then by ascending subgroup-by-treatment interaction p-value within each. MedDRA (version 22.0).
[1] OR (95% CI) based on a logistic regression model adjusting for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates.
[2] RR (95% CI) based on a Cochran-Mantel-Haenszel approach stratified by study.
[3] RD (95% CI) based on a Mantel-Haenszel approach stratified by study. 95% CIs are based on the approximation to the normal distribution using the Sato estimator for the standard error.
[4] P-value based on a Cochran-Mantel-Haenszel test stratified by study.
[5] Interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the OR (95% CI).
A continuity correction is applied in estimation of the OR, RR and p-value if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum. No continuity correction is applied in the estimation of the RD.
The reference group for the OR, RR and RD is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with >= 1 event; OR: Odds ratio; RR: Risk ratio; RD: Risk difference; CI: Confidence interval; NETA: Norethindrone acetate; SOC: System organ class; PT: Preferred term.

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Table SAF.TEAE.SPT.POOL.3.1.S2: Frequent Treatment Emergent Adverse Events by System Organ Class and Preferred Term, by Subgroup (Safety Population)

Study: Pooled

System Organ Class: Nervous system disorders, Preferred Term: Any

Treatment	N	n (%)	OR[1] [95% CI]	RR[2] [95% CI]	RD[3] [95% CI]	p-value[4]	p-value (int)[5]
BMI (kg/m2) at Baseline							
< 30							
Relugolix+E2/NETA	119	9 (7.6)	0.32	0.37	-0.13	0.0048	0.1129
Placebo	115	23 (20.0)	[0.14;0.74]	[0.18;0.77]	[-0.21;-0.04]		
>= 30							
Relugolix+E2/NETA	134	20 (14.9)	0.74	0.78	-0.04	0.3513	
Placebo	141	27 (19.1)	[0.39;1.40]	[0.46;1.32]	[-0.13;0.05]		
Missing							
Relugolix+E2/NETA	1	0	NC	NC	NC	NC	
Placebo	0	0	[NC;NC]	[NC;NC]	[NC;NC]		

Post hoc analysis. The denominator for percentages is the number of patients in the safety population for each treatment group. Patients with multiple events for a given PT or SOC are counted only once for each PT and SOC. Only SOCs or PTs for which there are at least 10% of patients with an event in at least one treatment group OR at least 10 patients with an event overall and at least 1% of patients with an event in at least one treatment group in the overall safety population are considered. Further, only SOCs and PTs for which there is a significant treatment effect (p-value <0.05) in the overall safety population are presented. Events are sorted alphabetically by SOC and PT and then by ascending subgroup-by-treatment interaction p-value within each. MedDRA (version 22.0).
[1] OR (95% CI) based on a logistic regression model adjusting for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates.
[2] RR (95% CI) based on a Cochran-Mantel-Haenszel approach stratified by study.
[3] RD (95% CI) based on a Mantel-Haenszel approach stratified by study. 95% CIs are based on the approximation to the normal distribution using the Sato estimator for the standard error.
[4] P-value based on a Cochran-Mantel-Haenszel test stratified by study.
[5] Interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the OR (95% CI). Missing subgroup levels are not included in estimation of the interaction p-value.
A continuity correction is applied in estimation of the OR, RR and p-value if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum. No continuity correction is applied in the estimation of the RD.
The reference group for the OR, RR and RD is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with >= 1 event; OR: Odds ratio; RR: Risk ratio; RD: Risk difference; CI: Confidence interval; NETA: Norethindrone acetate; SOC: System organ class; PT: Preferred term; NC: Not calculated.

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Table SAF.TEAE.SPT.POOL.3.1.S8: Frequent Treatment Emergent Adverse Events by System Organ Class and Preferred Term, by Subgroup (Safety Population)

Study: Pooled

System Organ Class: Nervous system disorders, Preferred Term: Any

Treatment	**N**	**n (%)**	**OR[1] [95% CI]**	**RR[2] [95% CI]**	**RD[3] [95% CI]**	**p-value[4]**	**p-value (int)[5]**
Ethnicity							
Hispanic or Latino							
Relugolix+E2/NETA	53	8 (15.1)	0.30	0.47	-0.19	0.0267	0.1266
Placebo	55	20 (36.4)	[0.12;0.76]	[0.24;0.94]	[-0.36;-0.02]		
Not Hispanic or Latino							
Relugolix+E2/NETA	197	21 (10.7)	0.71	0.75	-0.04	0.2748	
Placebo	199	29 (14.6)	[0.39;1.29]	[0.44;1.26]	[-0.10;0.03]		
Not reported							
Relugolix+E2/NETA	4	0	NC	NC	NC	NC	
Placebo	2	1 (50.0)	[NC;NC]	[NC;NC]	[NC;NC]		

Post hoc analysis. The denominator for percentages is the number of patients in the safety population for each treatment group. Patients with multiple events for a given PT or SOC are counted only once for each PT and SOC. Only SOCs or PTs for which there are at least 10% of patients with an event in at least one treatment group OR at least 10 patients with an event overall and at least 1% of patients with an event in at least one treatment group in the overall safety population are considered. Further, only SOCs and PTs for which there is a significant treatment effect (p-value <0.05) in the overall safety population are presented. Events are sorted alphabetically by SOC and PT and then by ascending subgroup-by-treatment interaction p-value within each. MedDRA (version 22.0).
[1] OR (95% CI) based on a logistic regression model adjusting for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates.
[2] RR (95% CI) based on a Cochran-Mantel-Haenszel approach stratified by study.
[3] RD (95% CI) based on a Mantel-Haenszel approach stratified by study. 95% CIs are based on the approximation to the normal distribution using the Sato estimator for the standard error.
[4] P-value based on a Cochran-Mantel-Haenszel test stratified by study.
[5] Interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the OR (95% CI). Not reported subgroup levels are not included in estimation of the interaction p-value.
A continuity correction is applied in estimation of the OR, RR and p-value if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum. No continuity correction is applied in the estimation of the RD.
The reference group for the OR, RR and RD is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with >= 1 event; OR: Odds ratio; RR: Risk ratio; RD: Risk difference; CI: Confidence interval; NETA: Norethindrone acetate; SOC: System organ class; PT: Preferred term; NC: Not calculated.

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Table SAF.TEAE.SPT.POOL.3.1.S4: Frequent Treatment Emergent Adverse Events by System Organ Class and Preferred Term, by Subgroup (Safety Population)

Study: Pooled

System Organ Class: Nervous system disorders, Preferred Term: Any

Treatment	N	n (%)	OR[1] [95% CI]	RR[2] [95% CI]	RD[3] [95% CI]	p-value[4]	p-value (int)[5]
Maximum NRS Pain Score at Baseline							
< 4							
Relugolix+E2/NETA	73	7 (9.6)	0.33	0.39	-0.15	0.0201	0.2650
Placebo	62	15 (24.2)	[0.12;0.86]	[0.17;0.89]	[-0.28;-0.02]		
>= 4							
Relugolix+E2/NETA	178	21 (11.8)	0.62	0.66	-0.06	0.1056	
Placebo	190	34 (17.9)	[0.34;1.11]	[0.40;1.10]	[-0.13;0.01]		
Missing							
Relugolix+E2/NETA	3	1 (33.3)	NC	NC	NC	NC	
Placebo	4	1 (25.0)	[NC;NC]	[NC;NC]	[NC;NC]		

Post hoc analysis. The denominator for percentages is the number of patients in the safety population for each treatment group. Patients with multiple events for a given PT or SOC are counted only once for each PT and SOC. Only SOCs or PTs for which there are at least 10% of patients with an event in at least one treatment group OR at least 10 patients with an event overall and at least 1% of patients with an event in at least one treatment group in the overall safety population are considered. Further, only SOCs and PTs for which there is a significant treatment effect (p-value <0.05) in the overall safety population are presented. Events are sorted alphabetically by SOC and PT and then by ascending subgroup-by-treatment interaction p-value within each. MedDRA (version 22.0).
[1] OR (95% CI) based on a logistic regression model adjusting for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates.
[2] RR (95% CI) based on a Cochran-Mantel-Haenszel approach stratified by study.
[3] RD (95% CI) based on a Mantel-Haenszel approach stratified by study. 95% CIs are based on the approximation to the normal distribution using the Sato estimator for the standard error.
[4] P-value based on a Cochran-Mantel-Haenszel test stratified by study.
[5] Interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the OR (95% CI). Missing subgroup levels are not included in estimation of the interaction p-value.
A continuity correction is applied in estimation of the OR, RR and p-value if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum. No continuity correction is applied in the estimation of the RD.
The reference group for the OR, RR and RD is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with >= 1 event; OR: Odds ratio; RR: Risk ratio; RD: Risk difference; CI: Confidence interval; NETA: Norethindrone acetate; SOC: System organ class; PT: Preferred term; NC: Not calculated.

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Table SAF.TEAE.SPT.POOL.3.1.S7: Frequent Treatment Emergent Adverse Events by System Organ Class and Preferred Term, by Subgroup (Safety Population)

Study: Pooled

System Organ Class: Nervous system disorders, Preferred Term: Any

Treatment	N	n (%)	OR[1] [95% CI]	RR[2] [95% CI]	RD[3] [95% CI]	p-value[4]	p-value (int)[5]
Geographic Region II							
Europe							0.3790
Relugolix+E2/NETA	41	6 (14.6)	0.87 [0.26;2.84]	0.92 [0.34;2.45]	-0.01 [-0.17;0.14]	0.8643	
Placebo	42	7 (16.7)					
Rest of World (including the US)							
Relugolix+E2/NETA	213	23 (10.8)	0.48 [0.28;0.83]	0.54 [0.34;0.86]	-0.09 [-0.16;-0.03]	0.0080	
Placebo	214	43 (20.1)					

Post hoc analysis. The denominator for percentages is the number of patients in the safety population for each treatment group. Patients with multiple events for a given PT or SOC are counted only once for each PT and SOC. Only SOCs or PTs for which there are at least 10% of patients with an event in at least one treatment group OR at least 10 patients with an event overall and at least 1% of patients with an event in at least one treatment group in the overall safety population are considered. Further, only SOCs and PTs for which there is a significant treatment effect (p-value <0.05) in the overall safety population are presented. Events are sorted alphabetically by SOC and PT and then by ascending subgroup-by-treatment interaction p-value within each. MedDRA (version 22.0).
[1] OR (95% CI) based on a logistic regression model adjusting for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates.
[2] RR (95% CI) based on a Cochran-Mantel-Haenszel approach stratified by study.
[3] RD (95% CI) based on a Mantel-Haenszel approach stratified by study. 95% CIs are based on the approximation to the normal distribution using the Sato estimator for the standard error.
[4] P-value based on a Cochran-Mantel-Haenszel test stratified by study.
[5] Interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the OR (95% CI).
A continuity correction is applied in estimation of the OR, RR and p-value if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum. No continuity correction is applied in the estimation of the RD.
The reference group for the OR, RR and RD is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with >= 1 event; OR: Odds ratio; RR: Risk ratio; RD: Risk difference; CI: Confidence interval; NETA: Norethindrone acetate; SOC: System organ class; PT: Preferred term.

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Table SAF.TEAE.SPT.POOL.3.1.S3: Frequent Treatment Emergent Adverse Events by System Organ Class and Preferred Term, by Subgroup (Safety Population)

Study: Pooled

System Organ Class: Nervous system disorders, Preferred Term: Any

Treatment	**N**	**n (%)**	**OR[1] [95% CI]**	**RR[2] [95% CI]**	**RD[3] [95% CI]**	**p-value[4]**	**p-value (int)[5]**
Uterine Volume at Baseline (cm3)							
< 300 cm3							0.4362
Relugolix+E2/NETA	148	21 (14.2)	0.60	0.65	-0.08	0.1021	
Placebo	129	28 (21.7)	[0.32;1.11]	[0.39;1.09]	[-0.17;0.02]		
>= 300 cm3							
Relugolix+E2/NETA	105	8 (7.6)	0.39	0.44	-0.10	0.0290	
Placebo	127	22 (17.3)	[0.17;0.92]	[0.20;0.95]	[-0.18;-0.01]		
Missing							
Relugolix+E2/NETA	1	0	NC	NC	NC	NC	
Placebo	0	0	[NC;NC]	[NC;NC]	[NC;NC]		

Post hoc analysis. The denominator for percentages is the number of patients in the safety population for each treatment group. Patients with multiple events for a given PT or SOC are counted only once for each PT and SOC. Only SOCs or PTs for which there are at least 10% of patients with an event in at least one treatment group OR at least 10 patients with an event overall and at least 1% of patients with an event in at least one treatment group in the overall safety population are considered. Further, only SOCs and PTs for which there is a significant treatment effect (p-value <0.05) in the overall safety population are presented. Events are sorted alphabetically by SOC and PT and then by ascending subgroup-by-treatment interaction p-value within each. MedDRA (version 22.0).
[1] OR (95% CI) based on a logistic regression model adjusting for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates.
[2] RR (95% CI) based on a Cochran-Mantel-Haenszel approach stratified by study.
[3] RD (95% CI) based on a Mantel-Haenszel approach stratified by study. 95% CIs are based on the approximation to the normal distribution using the Sato estimator for the standard error.
[4] P-value based on a Cochran-Mantel-Haenszel test stratified by study.
[5] Interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the OR (95% CI). Missing subgroup levels are not included in estimation of the interaction p-value.
A continuity correction is applied in estimation of the OR, RR and p-value if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum. No continuity correction is applied in the estimation of the RD.
The reference group for the OR, RR and RD is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with >= 1 event; OR: Odds ratio; RR: Risk ratio; RD: Risk difference; CI: Confidence interval; NETA: Norethindrone acetate; SOC: System organ class; PT: Preferred term; NC: Not calculated.

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Table SAF.TEAE.SPT.POOL.3.1.S9: Frequent Treatment Emergent Adverse Events by System Organ Class and Preferred Term, by Subgroup (Safety Population)

Study: Pooled

System Organ Class: Nervous system disorders, Preferred Term: Any

Treatment	N	n (%)	OR[1] [95% CI]	RR[2] [95% CI]	RD[3] [95% CI]	p-value[4]	p-value (int)[5]
Race							
Black/African American							0.4419
Relugolix+E2/NETA	122	13 (10.7)	0.61 [0.29;1.27]	0.65 [0.35;1.23]	-0.06 [-0.14;0.02]	0.1814	
Placebo	141	23 (16.3)					
White							
Relugolix+E2/NETA	123	12 (9.8)	0.37 [0.17;0.77]	0.43 [0.22;0.81]	-0.13 [-0.23;-0.04]	0.0068	
Placebo	105	24 (22.9)					
Asian							
Relugolix+E2/NETA	1	1 (100.0)	NC [NC;NC]	NC [NC;NC]	NC [NC;NC]	NC	
Placebo	3	1 (33.3)					
Others							
Relugolix+E2/NETA	5	2 (40.0)	1.19 [0.15;9.48]	0.76 [0.28;2.04]	-0.31 [-0.63;0.01]	0.6251	
Placebo	6	2 (33.3)					
Not reported							
Relugolix+E2/NETA	3	1 (33.3)	NC [NC;NC]	NC [NC;NC]	NC [NC;NC]	NC	
Placebo	1	0					

Post hoc analysis. The denominator for percentages is the number of patients in the safety population for each treatment group. Patients with multiple events for a given PT or SOC are counted only once for each PT and SOC. Only SOCs or PTs for which there are at least 10% of patients with an event in at least one treatment group OR at least 10 patients with an event overall and at least 1% of patients with an event in at least one treatment group in the overall safety population are considered. Further, only SOCs and PTs for which there is a significant treatment effect (p-value <0.05) in the overall safety population are presented. Events are sorted alphabetically by SOC and PT and then by ascending subgroup-by-treatment interaction p-value within each. MedDRA (version 22.0).
[1] OR (95% CI) based on a logistic regression model adjusting for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates.
[2] RR (95% CI) based on a Cochran-Mantel-Haenszel approach stratified by study.
[3] RD (95% CI) based on a Mantel-Haenszel approach stratified by study. 95% CIs are based on the approximation to the normal distribution using the Sato estimator for the standard error.
[4] P-value based on a Cochran-Mantel-Haenszel test stratified by study.
[5] Interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the OR (95% CI). Not reported subgroup levels are not included in estimation of the interaction p-value.
A continuity correction is applied in estimation of the OR, RR and p-value if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum. No continuity correction is applied in the estimation of the RD.
The reference group for the OR, RR and RD is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with >= 1 event; OR: Odds ratio; RR: Risk ratio; RD: Risk difference; CI: Confidence interval; NETA: Norethindrone acetate; SOC: System organ class; PT: Preferred term; NC: Not calculated.

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Table SAF.TEAE.SPT.POOL.3.1.S1: Frequent Treatment Emergent Adverse Events by System Organ Class and Preferred Term, by Subgroup (Safety Population)

Study: Pooled

System Organ Class: Nervous system disorders, Preferred Term: Any

Treatment	N	n (%)	OR[1] [95% CI]	RR[2] [95% CI]	RD[3] [95% CI]	p-value[4]	p-value (int)[5]
Age (years)							
< 40 years							
Relugolix+E2/NETA	62	7 (11.3)	0.45	0.52	-0.11	0.0997	0.6939
Placebo	78	17 (21.8)	[0.18;1.18]	[0.23;1.16]	[-0.23;0.02]		
>= 40 years							
Relugolix+E2/NETA	192	22 (11.5)	0.57	0.62	-0.07	0.0564	
Placebo	178	33 (18.5)	[0.32;1.02]	[0.37;1.02]	[-0.14;0.00]		

Post hoc analysis. The denominator for percentages is the number of patients in the safety population for each treatment group. Patients with multiple events for a given PT or SOC are counted only once for each PT and SOC. Only SOCs or PTs for which there are at least 10% of patients with an event in at least one treatment group OR at least 10 patients with an event overall and at least 1% of patients with an event in at least one treatment group in the overall safety population are considered. Further, only SOCs and PTs for which there is a significant treatment effect (p-value <0.05) in the overall safety population are presented. Events are sorted alphabetically by SOC and PT and then by ascending subgroup-by-treatment interaction p-value within each. MedDRA (version 22.0).
[1] OR (95% CI) based on a logistic regression model adjusting for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates.
[2] RR (95% CI) based on a Cochran-Mantel-Haenszel approach stratified by study.
[3] RD (95% CI) based on a Mantel-Haenszel approach stratified by study. 95% CIs are based on the approximation to the normal distribution using the Sato estimator for the standard error.
[4] P-value based on a Cochran-Mantel-Haenszel test stratified by study.
[5] Interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the OR (95% CI).
A continuity correction is applied in estimation of the OR, RR and p-value if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum. No continuity correction is applied in the estimation of the RD.
The reference group for the OR, RR and RD is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with >= 1 event; OR: Odds ratio; RR: Risk ratio; RD: Risk difference; CI: Confidence interval; NETA: Norethindrone acetate; SOC: System organ class; PT: Preferred term.

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Table SAF.TEAE.SPT.POOL.3.1.S6: Frequent Treatment Emergent Adverse Events by System Organ Class and Preferred Term, by Subgroup (Safety Population)

Study: Pooled

System Organ Class: Nervous system disorders, Preferred Term: Any

Treatment	N	n (%)	OR[1] [95% CI]	RR[2] [95% CI]	RD[3] [95% CI]	p-value[4]	p-value (int)[5]
Geographic Region I							
North America							
Relugolix+E2/NETA	192	19 (9.9)	0.56 [0.30;1.02]	0.60 [0.35;1.02]	-0.07 [-0.13;0.00]	0.0557	0.7530
Placebo	194	32 (16.5)					
Rest of World							
Relugolix+E2/NETA	62	10 (16.1)	0.47 [0.20;1.12]	0.55 [0.28;1.11]	-0.13 [-0.27;0.02]	0.0873	
Placebo	62	18 (29.0)					

Post hoc analysis. The denominator for percentages is the number of patients in the safety population for each treatment group. Patients with multiple events for a given PT or SOC are counted only once for each PT and SOC. Only SOCs or PTs for which there are at least 10% of patients with an event in at least one treatment group OR at least 10 patients with an event overall and at least 1% of patients with an event in at least one treatment group in the overall safety population are considered. Further, only SOCs and PTs for which there is a significant treatment effect (p-value <0.05) in the overall safety population are presented. Events are sorted alphabetically by SOC and PT and then by ascending subgroup-by-treatment interaction p-value within each. MedDRA (version 22.0).
[1] OR (95% CI) based on a logistic regression model adjusting for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates.
[2] RR (95% CI) based on a Cochran-Mantel-Haenszel approach stratified by study.
[3] RD (95% CI) based on a Mantel-Haenszel approach stratified by study. 95% CIs are based on the approximation to the normal distribution using the Sato estimator for the standard error.
[4] P-value based on a Cochran-Mantel-Haenszel test stratified by study.
[5] Interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the OR (95% CI).
A continuity correction is applied in estimation of the OR, RR and p-value if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum. No continuity correction is applied in the estimation of the RD.
The reference group for the OR, RR and RD is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with >= 1 event; OR: Odds ratio; RR: Risk ratio; RD: Risk difference; CI: Confidence interval; NETA: Norethindrone acetate; SOC: System organ class; PT: Preferred term.

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Table SAF.TEAE.SPT.POOL.3.1.S5: Frequent Treatment Emergent Adverse Events by System Organ Class and Preferred Term, by Subgroup (Safety Population)

Study: Pooled

System Organ Class: Nervous system disorders, Preferred Term: Any

Treatment	N	n (%)	OR[1] [95% CI]	RR[2] [95% CI]	RD[3] [95% CI]	p-value[4]	p-value (int)[5]
MBL Volume at Baseline (mL)							
< 225 mL							0.7540
Relugolix+E2/NETA	164	22 (13.4)	0.56 [0.31;1.00]	0.62 [0.38;1.00]	-0.08 [-0.16;-0.00]	0.0477	
Placebo	171	37 (21.6)					
>= 225 mL							
Relugolix+E2/NETA	90	7 (7.8)	0.47 [0.18;1.23]	0.51 [0.21;1.21]	-0.08 [-0.17;0.02]	0.1205	
Placebo	85	13 (15.3)					

Post hoc analysis. The denominator for percentages is the number of patients in the safety population for each treatment group. Patients with multiple events for a given PT or SOC are counted only once for each PT and SOC. Only SOCs or PTs for which there are at least 10% of patients with an event in at least one treatment group OR at least 10 patients with an event overall and at least 1% of patients with an event in at least one treatment group in the overall safety population are considered. Further, only SOCs and PTs for which there is a significant treatment effect (p-value <0.05) in the overall safety population are presented. Events are sorted alphabetically by SOC and PT and then by ascending subgroup-by-treatment interaction p-value within each. MedDRA (version 22.0).
[1] OR (95% CI) based on a logistic regression model adjusting for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates.
[2] RR (95% CI) based on a Cochran-Mantel-Haenszel approach stratified by study.
[3] RD (95% CI) based on a Mantel-Haenszel approach stratified by study. 95% CIs are based on the approximation to the normal distribution using the Sato estimator for the standard error.
[4] P-value based on a Cochran-Mantel-Haenszel test stratified by study.
[5] Interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the OR (95% CI).
A continuity correction is applied in estimation of the OR, RR and p-value if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum. No continuity correction is applied in the estimation of the RD.
The reference group for the OR, RR and RD is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with >= 1 event; OR: Odds ratio; RR: Risk ratio; RD: Risk difference; CI: Confidence interval; NETA: Norethindrone acetate; SOC: System organ class; PT: Preferred term.

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Table SAF.TEAE.SPT.POOL.4.1.S2: Frequent Treatment Emergent Adverse Events by System Organ Class and Preferred Term, by Subgroup (Safety Population)

Study: Pooled

System Organ Class: Psychiatric disorders, Preferred Term: Any

Treatment	N	n (%)	OR[1] [95% CI]	RR[2] [95% CI]	RD[3] [95% CI]	p-value[4]	p-value (int)[5]
BMI (kg/m2) at Baseline							
< 30							
Relugolix+E2/NETA	119	14 (11.8)	7.42	6.75	0.10	0.0025	0.0144*
Placebo	115	2 (1.7)	[1.64;33.46]	[1.57;29.02]	[0.04;0.16]		
>= 30							
Relugolix+E2/NETA	134	7 (5.2)	0.93	0.94	-0.00	0.9060	
Placebo	141	8 (5.7)	[0.34;2.57]	[0.36;2.46]	[-0.06;0.05]		
Missing							
Relugolix+E2/NETA	1	0	NC	NC	NC	NC	
Placebo	0	0	[NC;NC]	[NC;NC]	[NC;NC]		

Post hoc analysis. The denominator for percentages is the number of patients in the safety population for each treatment group. Patients with multiple events for a given PT or SOC are counted only once for each PT and SOC. Only SOCs or PTs for which there are at least 10% of patients with an event in at least one treatment group OR at least 10 patients with an event overall and at least 1% of patients with an event in at least one treatment group in the overall safety population are considered. Further, only SOCs and PTs for which there is a significant treatment effect (p-value <0.05) in the overall safety population are presented. Events are sorted alphabetically by SOC and PT and then by ascending subgroup-by-treatment interaction p-value within each. MedDRA (version 22.0).
[1] OR (95% CI) based on a logistic regression model adjusting for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates.
[2] RR (95% CI) based on a Cochran-Mantel-Haenszel approach stratified by study.
[3] RD (95% CI) based on a Mantel-Haenszel approach stratified by study. 95% CIs are based on the approximation to the normal distribution using the Sato estimator for the standard error.
[4] P-value based on a Cochran-Mantel-Haenszel test stratified by study.
[5] Interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the OR (95% CI). Missing subgroup levels are not included in estimation of the interaction p-value. * Interaction p-value < 0.05.
A continuity correction is applied in estimation of the OR, RR and p-value if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum. No continuity correction is applied in the estimation of the RD.
The reference group for the OR, RR and RD is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with >= 1 event; OR: Odds ratio; RR: Risk ratio; RD: Risk difference; CI: Confidence interval; NETA: Norethindrone acetate; SOC: System organ class; PT: Preferred term; NC: Not calculated.

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Table SAF.TEAE.SPT.POOL.4.1.S6: Frequent Treatment Emergent Adverse Events by System Organ Class and Preferred Term, by Subgroup (Safety Population)

Study: Pooled

System Organ Class: Psychiatric disorders, Preferred Term: Any

Treatment	**N**	**n (%)**	**OR[1] [95% CI]**	**RR[2] [95% CI]**	**RD[3] [95% CI]**	**p-value[4]**	**p-value (int)[5]**
Geographic Region I							
North America							
Relugolix+E2/NETA	192	11 (5.7)	1.41	1.38	0.02	0.4708	0.1406
Placebo	194	8 (4.1)	[0.55;3.59]	[0.57;3.35]	[-0.03;0.06]		
Rest of World							
Relugolix+E2/NETA	62	10 (16.1)	4.85	4.16	0.13	0.0204	
Placebo	62	2 (3.2)	[1.16;20.29]	[1.10;15.66]	[0.03;0.23]		

Post hoc analysis. The denominator for percentages is the number of patients in the safety population for each treatment group. Patients with multiple events for a given PT or SOC are counted only once for each PT and SOC. Only SOCs or PTs for which there are at least 10% of patients with an event in at least one treatment group OR at least 10 patients with an event overall and at least 1% of patients with an event in at least one treatment group in the overall safety population are considered. Further, only SOCs and PTs for which there is a significant treatment effect (p-value <0.05) in the overall safety population are presented. Events are sorted alphabetically by SOC and PT and then by ascending subgroup-by-treatment interaction p-value within each. MedDRA (version 22.0).
[1] OR (95% CI) based on a logistic regression model adjusting for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates.
[2] RR (95% CI) based on a Cochran-Mantel-Haenszel approach stratified by study.
[3] RD (95% CI) based on a Mantel-Haenszel approach stratified by study. 95% CIs are based on the approximation to the normal distribution using the Sato estimator for the standard error.
[4] P-value based on a Cochran-Mantel-Haenszel test stratified by study.
[5] Interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the OR (95% CI).
A continuity correction is applied in estimation of the OR, RR and p-value if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum. No continuity correction is applied in the estimation of the RD.
The reference group for the OR, RR and RD is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with >= 1 event; OR: Odds ratio; RR: Risk ratio; RD: Risk difference; CI: Confidence interval; NETA: Norethindrone acetate; SOC: System organ class; PT: Preferred term.

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Table SAF.TEAE.SPT.POOL.4.1.S7: Frequent Treatment Emergent Adverse Events by System Organ Class and Preferred Term, by Subgroup (Safety Population)

Study: Pooled

System Organ Class: Psychiatric disorders, Preferred Term: Any

Treatment	N	n (%)	OR[1] [95% CI]	RR[2] [95% CI]	RD[3] [95% CI]	p-value[4]	p-value (int)[5]
Geographic Region II							
Europe							
Relugolix+E2/NETA	41	6 (14.6)	5.26	4.35	0.12	0.0690	0.2489
Placebo	42	1 (2.4)	[0.84;32.95]	[0.75;25.33]	[0.00;0.24]		
Rest of World (including the US)							
Relugolix+E2/NETA	213	15 (7.0)	1.71	1.64	0.03	0.2189	
Placebo	214	9 (4.2)	[0.73;4.00]	[0.74;3.63]	[-0.02;0.07]		

Post hoc analysis. The denominator for percentages is the number of patients in the safety population for each treatment group. Patients with multiple events for a given PT or SOC are counted only once for each PT and SOC. Only SOCs or PTs for which there are at least 10% of patients with an event in at least one treatment group OR at least 10 patients with an event overall and at least 1% of patients with an event in at least one treatment group in the overall safety population are considered. Further, only SOCs and PTs for which there is a significant treatment effect (p-value <0.05) in the overall safety population are presented. Events are sorted alphabetically by SOC and PT and then by ascending subgroup-by-treatment interaction p-value within each. MedDRA (version 22.0).
[1] OR (95% CI) based on a logistic regression model adjusting for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates.
[2] RR (95% CI) based on a Cochran-Mantel-Haenszel approach stratified by study.
[3] RD (95% CI) based on a Mantel-Haenszel approach stratified by study. 95% CIs are based on the approximation to the normal distribution using the Sato estimator for the standard error.
[4] P-value based on a Cochran-Mantel-Haenszel test stratified by study.
[5] Interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the OR (95% CI).
A continuity correction is applied in estimation of the OR, RR and p-value if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum. No continuity correction is applied in the estimation of the RD.
The reference group for the OR, RR and RD is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with >= 1 event; OR: Odds ratio; RR: Risk ratio; RD: Risk difference; CI: Confidence interval; NETA: Norethindrone acetate; SOC: System organ class; PT: Preferred term.

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Table SAF.TEAE.SPT.POOL.4.1.S3: Frequent Treatment Emergent Adverse Events by System Organ Class and Preferred Term, by Subgroup (Safety Population)

Study: Pooled

System Organ Class: Psychiatric disorders, Preferred Term: Any

Treatment	**N**	**n (%)**	**OR[1] [95% CI]**	**RR[2] [95% CI]**	**RD[3] [95% CI]**	**p-value[4]**	**p-value (int)[5]**
Uterine Volume at Baseline (cm3)							
< 300 cm3							0.5937
Relugolix+E2/NETA	148	15 (10.1)	1.71	1.63	0.04	0.2389	
Placebo	129	8 (6.2)	[0.70;4.18]	[0.71;3.72]	[-0.02;0.10]		
>= 300 cm3							
Relugolix+E2/NETA	105	5 (4.8)	2.74	2.64	0.03	0.1784	
Placebo	127	2 (1.6)	[0.60;12.53]	[0.61;11.47]	[-0.01;0.08]		
Missing							
Relugolix+E2/NETA	1	1 (100.0)	NC	NC	NC	NC	
Placebo	0	0	[NC;NC]	[NC;NC]	[NC;NC]		

Post hoc analysis. The denominator for percentages is the number of patients in the safety population for each treatment group. Patients with multiple events for a given PT or SOC are counted only once for each PT and SOC. Only SOCs or PTs for which there are at least 10% of patients with an event in at least one treatment group OR at least 10 patients with an event overall and at least 1% of patients with an event in at least one treatment group in the overall safety population are considered. Further, only SOCs and PTs for which there is a significant treatment effect (p-value <0.05) in the overall safety population are presented. Events are sorted alphabetically by SOC and PT and then by ascending subgroup-by-treatment interaction p-value within each. MedDRA (version 22.0).
[1] OR (95% CI) based on a logistic regression model adjusting for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates.
[2] RR (95% CI) based on a Cochran-Mantel-Haenszel approach stratified by study.
[3] RD (95% CI) based on a Mantel-Haenszel approach stratified by study. 95% CIs are based on the approximation to the normal distribution using the Sato estimator for the standard error.
[4] P-value based on a Cochran-Mantel-Haenszel test stratified by study.
[5] Interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the OR (95% CI). Missing subgroup levels are not included in estimation of the interaction p-value.
A continuity correction is applied in estimation of the OR, RR and p-value if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum. No continuity correction is applied in the estimation of the RD.
The reference group for the OR, RR and RD is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with >= 1 event; OR: Odds ratio; RR: Risk ratio; RD: Risk difference; CI: Confidence interval; NETA: Norethindrone acetate; SOC: System organ class; PT: Preferred term; NC: Not calculated.

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Table SAF.TEAE.SPT.POOL.4.1.S8: Frequent Treatment Emergent Adverse Events by System Organ Class and Preferred Term, by Subgroup (Safety Population)

Study: Pooled

System Organ Class: Psychiatric disorders, Preferred Term: Any

Treatment	**N**	**n (%)**	**OR[1] [95% CI]**	**RR[2] [95% CI]**	**RD[3] [95% CI]**	**p-value[4]**	**p-value (int)[5]**
Ethnicity							
Hispanic or Latino							
Relugolix+E2/NETA	53	3 (5.7)	1.30	1.26	0.01	0.7590	0.5974
Placebo	55	2 (3.6)	[0.24;6.99]	[0.29;5.47]	[-0.08;0.09]		
Not Hispanic or Latino							
Relugolix+E2/NETA	197	16 (8.1)	2.18	2.10	0.04	0.0751	
Placebo	199	8 (4.0)	[0.91;5.24]	[0.91;4.87]	[-0.00;0.09]		
Not reported							
Relugolix+E2/NETA	4	2 (50.0)	NC	NC	NC	NC	
Placebo	2	0	[NC;NC]	[NC;NC]	[NC;NC]		

Post hoc analysis. The denominator for percentages is the number of patients in the safety population for each treatment group. Patients with multiple events for a given PT or SOC are counted only once for each PT and SOC. Only SOCs or PTs for which there are at least 10% of patients with an event in at least one treatment group OR at least 10 patients with an event overall and at least 1% of patients with an event in at least one treatment group in the overall safety population are considered. Further, only SOCs and PTs for which there is a significant treatment effect (p-value <0.05) in the overall safety population are presented. Events are sorted alphabetically by SOC and PT and then by ascending subgroup-by-treatment interaction p-value within each. MedDRA (version 22.0).
[1] OR (95% CI) based on a logistic regression model adjusting for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates.
[2] RR (95% CI) based on a Cochran-Mantel-Haenszel approach stratified by study.
[3] RD (95% CI) based on a Mantel-Haenszel approach stratified by study. 95% CIs are based on the approximation to the normal distribution using the Sato estimator for the standard error.
[4] P-value based on a Cochran-Mantel-Haenszel test stratified by study.
[5] Interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the OR (95% CI). Not reported subgroup levels are not included in estimation of the interaction p-value.
A continuity correction is applied in estimation of the OR, RR and p-value if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum. No continuity correction is applied in the estimation of the RD.
The reference group for the OR, RR and RD is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with >= 1 event; OR: Odds ratio; RR: Risk ratio; RD: Risk difference; CI: Confidence interval; NETA: Norethindrone acetate; SOC: System organ class; PT: Preferred term; NC: Not calculated.

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Table SAF.TEAE.SPT.POOL.4.1.S5: Frequent Treatment Emergent Adverse Events by System Organ Class and Preferred Term, by Subgroup (Safety Population)

Study: Pooled

System Organ Class: Psychiatric disorders, Preferred Term: Any

Treatment	N	n (%)	OR[1] [95% CI]	RR[2] [95% CI]	RD[3] [95% CI]	p-value[4]	p-value (int)[5]
MBL Volume at Baseline (mL)							
< 225 mL							
Relugolix+E2/NETA	164	15 (9.1)	2.35 [0.93;5.93]	2.20 [0.93;5.21]	0.05 [-0.00;0.10]	0.0656	0.7608
Placebo	171	7 (4.1)					
>= 225 mL							
Relugolix+E2/NETA	90	6 (6.7)	1.82 [0.48;6.94]	1.76 [0.48;6.36]	0.03 [-0.03;0.10]	0.3798	
Placebo	85	3 (3.5)					

Post hoc analysis. The denominator for percentages is the number of patients in the safety population for each treatment group. Patients with multiple events for a given PT or SOC are counted only once for each PT and SOC. Only SOCs or PTs for which there are at least 10% of patients with an event in at least one treatment group OR at least 10 patients with an event overall and at least 1% of patients with an event in at least one treatment group in the overall safety population are considered. Further, only SOCs and PTs for which there is a significant treatment effect (p-value <0.05) in the overall safety population are presented. Events are sorted alphabetically by SOC and PT and then by ascending subgroup-by-treatment interaction p-value within each. MedDRA (version 22.0).
[1] OR (95% CI) based on a logistic regression model adjusting for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates.
[2] RR (95% CI) based on a Cochran-Mantel-Haenszel approach stratified by study.
[3] RD (95% CI) based on a Mantel-Haenszel approach stratified by study. 95% CIs are based on the approximation to the normal distribution using the Sato estimator for the standard error.
[4] P-value based on a Cochran-Mantel-Haenszel test stratified by study.
[5] Interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the OR (95% CI).
A continuity correction is applied in estimation of the OR, RR and p-value if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum. No continuity correction is applied in the estimation of the RD.
The reference group for the OR, RR and RD is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with >= 1 event; OR: Odds ratio; RR: Risk ratio; RD: Risk difference; CI: Confidence interval; NETA: Norethindrone acetate; SOC: System organ class; PT: Preferred term.

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Table SAF.TEAE.SPT.POOL.4.1.S9: Frequent Treatment Emergent Adverse Events by System Organ Class and Preferred Term, by Subgroup (Safety Population)

Study: Pooled

System Organ Class: Psychiatric disorders, Preferred Term: Any

Treatment	**N**	**n (%)**	**OR[1] [95% CI]**	**RR[2] [95% CI]**	**RD[3] [95% CI]**	**p-value[4]**	**p-value (int)[5]**
Race							
Black/African American							0.8434
Relugolix+E2/NETA	122	7 (5.7)	1.61	1.56	0.02	0.4105	
Placebo	141	5 (3.5)	[0.52;4.98]	[0.54;4.51]	[-0.03;0.07]		
White							
Relugolix+E2/NETA	123	12 (9.8)	2.56	2.39	0.06	0.0930	
Placebo	105	4 (3.8)	[0.84;7.78]	[0.83;6.87]	[-0.00;0.12]		
Asian							
Relugolix+E2/NETA	1	0	NC	NC	NC	NC	
Placebo	3	1 (33.3)	[NC;NC]	[NC;NC]	[NC;NC]		
Others							
Relugolix+E2/NETA	5	1 (20.0)	2.34	2.02	0.16	0.5509	
Placebo	6	0	[0.16;34.22]	[0.22;18.83]	[-0.20;0.51]		
Not reported							
Relugolix+E2/NETA	3	1 (33.3)	NC	NC	NC	NC	
Placebo	1	0	[NC;NC]	[NC;NC]	[NC;NC]		

Post hoc analysis. The denominator for percentages is the number of patients in the safety population for each treatment group. Patients with multiple events for a given PT or SOC are counted only once for each PT and SOC. Only SOCs or PTs for which there are at least 10% of patients with an event in at least one treatment group OR at least 10 patients with an event overall and at least 1% of patients with an event in at least one treatment group in the overall safety population are considered. Further, only SOCs and PTs for which there is a significant treatment effect (p-value <0.05) in the overall safety population are presented. Events are sorted alphabetically by SOC and PT and then by ascending subgroup-by-treatment interaction p-value within each. MedDRA (version 22.0).
[1] OR (95% CI) based on a logistic regression model adjusting for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates.
[2] RR (95% CI) based on a Cochran-Mantel-Haenszel approach stratified by study.
[3] RD (95% CI) based on a Mantel-Haenszel approach stratified by study. 95% CIs are based on the approximation to the normal distribution using the Sato estimator for the standard error.
[4] P-value based on a Cochran-Mantel-Haenszel test stratified by study.
[5] Interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the OR (95% CI). Not reported subgroup levels are not included in estimation of the interaction p-value.
A continuity correction is applied in estimation of the OR, RR and p-value if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum. No continuity correction is applied in the estimation of the RD.
The reference group for the OR, RR and RD is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with >= 1 event; OR: Odds ratio; RR: Risk ratio; RD: Risk difference; CI: Confidence interval; NETA: Norethindrone acetate; SOC: System organ class; PT: Preferred term; NC: Not calculated.

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Table SAF.TEAE.SPT.POOL.4.1.S4: Frequent Treatment Emergent Adverse Events by System Organ Class and Preferred Term, by Subgroup (Safety Population)

Study: Pooled

System Organ Class: Psychiatric disorders, Preferred Term: Any

Treatment	N	n (%)	OR[1] [95% CI]	RR[2] [95% CI]	RD[3] [95% CI]	p-value[4]	p-value (int)[5]
Maximum NRS Pain Score at Baseline							
< 4							
Relugolix+E2/NETA	73	4 (5.5)	2.54	2.66	0.04	0.2523	0.8801
Placebo	62	1 (1.6)	[0.39;16.65]	[0.46;15.25]	[-0.02;0.10]		
>= 4							
Relugolix+E2/NETA	178	17 (9.6)	2.17	2.08	0.05	0.0614	
Placebo	190	9 (4.7)	[0.94;5.01]	[0.95;4.55]	[-0.00;0.10]		
Missing							
Relugolix+E2/NETA	3	0	NC	NC	NC	NC	
Placebo	4	0	[NC;NC]	[NC;NC]	[NC;NC]		

Post hoc analysis. The denominator for percentages is the number of patients in the safety population for each treatment group. Patients with multiple events for a given PT or SOC are counted only once for each PT and SOC. Only SOCs or PTs for which there are at least 10% of patients with an event in at least one treatment group OR at least 10 patients with an event overall and at least 1% of patients with an event in at least one treatment group in the overall safety population are considered. Further, only SOCs and PTs for which there is a significant treatment effect (p-value <0.05) in the overall safety population are presented. Events are sorted alphabetically by SOC and PT and then by ascending subgroup-by-treatment interaction p-value within each. MedDRA (version 22.0).
[1] OR (95% CI) based on a logistic regression model adjusting for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates.
[2] RR (95% CI) based on a Cochran-Mantel-Haenszel approach stratified by study.
[3] RD (95% CI) based on a Mantel-Haenszel approach stratified by study. 95% CIs are based on the approximation to the normal distribution using the Sato estimator for the standard error.
[4] P-value based on a Cochran-Mantel-Haenszel test stratified by study.
[5] Interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the OR (95% CI). Missing subgroup levels are not included in estimation of the interaction p-value.
A continuity correction is applied in estimation of the OR, RR and p-value if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum. No continuity correction is applied in the estimation of the RD.
The reference group for the OR, RR and RD is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with >= 1 event; OR: Odds ratio; RR: Risk ratio; RD: Risk difference; CI: Confidence interval; NETA: Norethindrone acetate; SOC: System organ class; PT: Preferred term; NC: Not calculated.

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Table SAF.TEAE.SPT.POOL.4.1.S1: Frequent Treatment Emergent Adverse Events by System Organ Class and Preferred Term, by Subgroup (Safety Population)

Study: Pooled

System Organ Class: Psychiatric disorders, Preferred Term: Any

Treatment	**N**	**n (%)**	**OR[1] [95% CI]**	**RR[2] [95% CI]**	**RD[3] [95% CI]**	**p-value[4]**	**p-value (int)[5]**
Age (years)							
< 40 years							
Relugolix+E2/NETA	62	5 (8.1)	2.05	1.93	0.04	0.3093	0.9199
Placebo	78	3 (3.8)	[0.51;8.19]	[0.53;6.97]	[-0.04;0.12]		
>= 40 years							
Relugolix+E2/NETA	192	16 (8.3)	2.23	2.12	0.04	0.0801	
Placebo	178	7 (3.9)	[0.89;5.56]	[0.89;5.04]	[-0.00;0.09]		

Post hoc analysis. The denominator for percentages is the number of patients in the safety population for each treatment group. Patients with multiple events for a given PT or SOC are counted only once for each PT and SOC. Only SOCs or PTs for which there are at least 10% of patients with an event in at least one treatment group OR at least 10 patients with an event overall and at least 1% of patients with an event in at least one treatment group in the overall safety population are considered. Further, only SOCs and PTs for which there is a significant treatment effect (p-value <0.05) in the overall safety population are presented. Events are sorted alphabetically by SOC and PT and then by ascending subgroup-by-treatment interaction p-value within each. MedDRA (version 22.0).
[1] OR (95% CI) based on a logistic regression model adjusting for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates.
[2] RR (95% CI) based on a Cochran-Mantel-Haenszel approach stratified by study.
[3] RD (95% CI) based on a Mantel-Haenszel approach stratified by study. 95% CIs are based on the approximation to the normal distribution using the Sato estimator for the standard error.
[4] P-value based on a Cochran-Mantel-Haenszel test stratified by study.
[5] Interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the OR (95% CI).
A continuity correction is applied in estimation of the OR, RR and p-value if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum. No continuity correction is applied in the estimation of the RD.
The reference group for the OR, RR and RD is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with >= 1 event; OR: Odds ratio; RR: Risk ratio; RD: Risk difference; CI: Confidence interval; NETA: Norethindrone acetate; SOC: System organ class; PT: Preferred term.

SOURCE: \Studies\MYV\MYV102\Analysis\Prod\Progs\TFLs\Tab_SAF_AE_SOC_PT_S_BIN.SAS
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Table SAF.TEAE.SPT.POOL.5.1.S2: Frequent Treatment Emergent Adverse Events by System Organ Class and Preferred Term, by Subgroup (Safety Population)

Study: Pooled

System Organ Class: Respiratory, thoracic and mediastinal disorders, Preferred Term: Any

Treatment	**N**	**n (%)**	**OR[1] [95% CI]**	**RR[2] [95% CI]**	**RD[3] [95% CI]**	**p-value[4]**	**p-value (int)[5]**
BMI (kg/m2) at Baseline							
< 30							
Relugolix+E2/NETA	119	2 (1.7)	1.60	1.60	0.01	0.6409	0.0450*
Placebo	115	1 (0.9)	[0.21;12.35]	[0.22;11.64]	[-0.02;0.04]		
>= 30							
Relugolix+E2/NETA	134	3 (2.2)	0.15	0.17	-0.11	0.0006	
Placebo	141	19 (13.5)	[0.04;0.51]	[0.05;0.55]	[-0.17;-0.05]		
Missing							
Relugolix+E2/NETA	1	0	NC	NC	NC	NC	
Placebo	0	0	[NC;NC]	[NC;NC]	[NC;NC]		

Post hoc analysis. The denominator for percentages is the number of patients in the safety population for each treatment group. Patients with multiple events for a given PT or SOC are counted only once for each PT and SOC. Only SOCs or PTs for which there are at least 10% of patients with an event in at least one treatment group OR at least 10 patients with an event overall and at least 1% of patients with an event in at least one treatment group in the overall safety population are considered. Further, only SOCs and PTs for which there is a significant treatment effect (p-value <0.05) in the overall safety population are presented. Events are sorted alphabetically by SOC and PT and then by ascending subgroup-by-treatment interaction p-value within each. MedDRA (version 22.0).
[1] OR (95% CI) based on a logistic regression model adjusting for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates.
[2] RR (95% CI) based on a Cochran-Mantel-Haenszel approach stratified by study.
[3] RD (95% CI) based on a Mantel-Haenszel approach stratified by study. 95% CIs are based on the approximation to the normal distribution using the Sato estimator for the standard error.
[4] P-value based on a Cochran-Mantel-Haenszel test stratified by study.
[5] Interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the OR (95% CI). Missing subgroup levels are not included in estimation of the interaction p-value. * Interaction p-value < 0.05.
A continuity correction is applied in estimation of the OR, RR and p-value if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum. No continuity correction is applied in the estimation of the RD.
The reference group for the OR, RR and RD is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with >= 1 event; OR: Odds ratio; RR: Risk ratio; RD: Risk difference; CI: Confidence interval; NETA: Norethindrone acetate; SOC: System organ class; PT: Preferred term; NC: Not calculated.

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Table SAF.TEAE.SPT.POOL.5.1.S8: Frequent Treatment Emergent Adverse Events by System Organ Class and Preferred Term, by Subgroup (Safety Population)

Study: Pooled

System Organ Class: Respiratory, thoracic and mediastinal disorders, Preferred Term: Any

Treatment	**N**	**n (%)**	**OR[1] [95% CI]**	**RR[2] [95% CI]**	**RD[3] [95% CI]**	**p-value[4]**	**p-value (int)[5]**
Ethnicity							
Hispanic or Latino							
Relugolix+E2/NETA	53	3 (5.7)	0.55	0.57	-0.04	0.4110	0.1715
Placebo	55	5 (9.1)	[0.12;2.45]	[0.14;2.21]	[-0.15;0.06]		
Not Hispanic or Latino							
Relugolix+E2/NETA	197	2 (1.0)	0.13	0.14	-0.06	0.0016	
Placebo	199	15 (7.5)	[0.03;0.57]	[0.03;0.59]	[-0.10;-0.03]		
Not reported							
Relugolix+E2/NETA	4	0	NC	NC	NC	NC	
Placebo	2	0	[NC;NC]	[NC;NC]	[NC;NC]		

Post hoc analysis. The denominator for percentages is the number of patients in the safety population for each treatment group. Patients with multiple events for a given PT or SOC are counted only once for each PT and SOC. Only SOCs or PTs for which there are at least 10% of patients with an event in at least one treatment group OR at least 10 patients with an event overall and at least 1% of patients with an event in at least one treatment group in the overall safety population are considered. Further, only SOCs and PTs for which there is a significant treatment effect (p-value <0.05) in the overall safety population are presented. Events are sorted alphabetically by SOC and PT and then by ascending subgroup-by-treatment interaction p-value within each. MedDRA (version 22.0).
[1] OR (95% CI) based on a logistic regression model adjusting for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates.
[2] RR (95% CI) based on a Cochran-Mantel-Haenszel approach stratified by study.
[3] RD (95% CI) based on a Mantel-Haenszel approach stratified by study. 95% CIs are based on the approximation to the normal distribution using the Sato estimator for the standard error.
[4] P-value based on a Cochran-Mantel-Haenszel test stratified by study.
[5] Interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the OR (95% CI). Not reported subgroup levels are not included in estimation of the interaction p-value.
A continuity correction is applied in estimation of the OR, RR and p-value if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum. No continuity correction is applied in the estimation of the RD.
The reference group for the OR, RR and RD is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with >= 1 event; OR: Odds ratio; RR: Risk ratio; RD: Risk difference; CI: Confidence interval; NETA: Norethindrone acetate; SOC: System organ class; PT: Preferred term; NC: Not calculated.

SOURCE: \Studies\MYV\MYV102\Analysis\Prod\Progs\TFLs\Tab_SAF_AE_SOC_PT_S_BIN.SAS
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Table SAF.TEAE.SPT.POOL.5.1.S1: Frequent Treatment Emergent Adverse Events by System Organ Class and Preferred Term, by Subgroup (Safety Population)

Study: Pooled

System Organ Class: Respiratory, thoracic and mediastinal disorders, Preferred Term: Any

Treatment	**N**	**n (%)**	**OR[1] [95% CI]**	**RR[2] [95% CI]**	**RD[3] [95% CI]**	**p-value[4]**	**p-value (int)[5]**
Age (years)							
< 40 years							
Relugolix+E2/NETA	62	2 (3.2)	0.40	0.42	-0.04	0.2659	0.4813
Placebo	78	6 (7.7)	[0.08;2.03]	[0.09;2.03]	[-0.12;0.03]		
>= 40 years							
Relugolix+E2/NETA	192	3 (1.6)	0.19	0.20	-0.06	0.0038	
Placebo	178	14 (7.9)	[0.05;0.66]	[0.06;0.68]	[-0.11;-0.02]		

Post hoc analysis. The denominator for percentages is the number of patients in the safety population for each treatment group. Patients with multiple events for a given PT or SOC are counted only once for each PT and SOC. Only SOCs or PTs for which there are at least 10% of patients with an event in at least one treatment group OR at least 10 patients with an event overall and at least 1% of patients with an event in at least one treatment group in the overall safety population are considered. Further, only SOCs and PTs for which there is a significant treatment effect (p-value <0.05) in the overall safety population are presented. Events are sorted alphabetically by SOC and PT and then by ascending subgroup-by-treatment interaction p-value within each. MedDRA (version 22.0).
[1] OR (95% CI) based on a logistic regression model adjusting for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates.
[2] RR (95% CI) based on a Cochran-Mantel-Haenszel approach stratified by study.
[3] RD (95% CI) based on a Mantel-Haenszel approach stratified by study. 95% CIs are based on the approximation to the normal distribution using the Sato estimator for the standard error.
[4] P-value based on a Cochran-Mantel-Haenszel test stratified by study.
[5] Interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the OR (95% CI).
A continuity correction is applied in estimation of the OR, RR and p-value if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum. No continuity correction is applied in the estimation of the RD.
The reference group for the OR, RR and RD is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with >= 1 event; OR: Odds ratio; RR: Risk ratio; RD: Risk difference; CI: Confidence interval; NETA: Norethindrone acetate; SOC: System organ class; PT: Preferred term.

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Table SAF.TEAE.SPT.POOL.5.1.S4: Frequent Treatment Emergent Adverse Events by System Organ Class and Preferred Term, by Subgroup (Safety Population)

Study: Pooled

System Organ Class: Respiratory, thoracic and mediastinal disorders, Preferred Term: Any

Treatment	N	n (%)	OR[1] [95% CI]	RR[2] [95% CI]	RD[3] [95% CI]	p-value[4]	p-value (int)[5]
Maximum NRS Pain Score at Baseline							
< 4							
Relugolix+E2/NETA	73	1 (1.4)	0.49	0.48	-0.02	0.4530	0.5176
Placebo	62	2 (3.2)	[0.06;3.79]	[0.07;3.40]	[-0.07;0.03]		
>= 4							
Relugolix+E2/NETA	178	4 (2.2)	0.22	0.24	-0.07	0.0037	
Placebo	190	18 (9.5)	[0.07;0.67]	[0.08;0.69]	[-0.12;-0.02]		
Missing							
Relugolix+E2/NETA	3	0	NC	NC	NC	NC	
Placebo	4	0	[NC;NC]	[NC;NC]	[NC;NC]		

Post hoc analysis. The denominator for percentages is the number of patients in the safety population for each treatment group. Patients with multiple events for a given PT or SOC are counted only once for each PT and SOC. Only SOCs or PTs for which there are at least 10% of patients with an event in at least one treatment group OR at least 10 patients with an event overall and at least 1% of patients with an event in at least one treatment group in the overall safety population are considered. Further, only SOCs and PTs for which there is a significant treatment effect (p-value <0.05) in the overall safety population are presented. Events are sorted alphabetically by SOC and PT and then by ascending subgroup-by-treatment interaction p-value within each. MedDRA (version 22.0).
[1] OR (95% CI) based on a logistic regression model adjusting for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates.
[2] RR (95% CI) based on a Cochran-Mantel-Haenszel approach stratified by study.
[3] RD (95% CI) based on a Mantel-Haenszel approach stratified by study. 95% CIs are based on the approximation to the normal distribution using the Sato estimator for the standard error.
[4] P-value based on a Cochran-Mantel-Haenszel test stratified by study.
[5] Interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the OR (95% CI). Missing subgroup levels are not included in estimation of the interaction p-value.
A continuity correction is applied in estimation of the OR, RR and p-value if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum. No continuity correction is applied in the estimation of the RD.
The reference group for the OR, RR and RD is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with >= 1 event; OR: Odds ratio; RR: Risk ratio; RD: Risk difference; CI: Confidence interval; NETA: Norethindrone acetate; SOC: System organ class; PT: Preferred term; NC: Not calculated.

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Table SAF.TEAE.SPT.POOL.5.1.S3: Frequent Treatment Emergent Adverse Events by System Organ Class and Preferred Term, by Subgroup (Safety Population)

Study: Pooled

System Organ Class: Respiratory, thoracic and mediastinal disorders, Preferred Term: Any

Treatment	N	n (%)	OR[1] [95% CI]	RR[2] [95% CI]	RD[3] [95% CI]	p-value[4]	p-value (int)[5]
Uterine Volume at Baseline (cm3)							
< 300 cm3							
Relugolix+E2/NETA	148	3 (2.0)	0.20	0.22	-0.07	0.0077	0.5994
Placebo	129	12 (9.3)	[0.06;0.73]	[0.06;0.76]	[-0.13;-0.02]		
>= 300 cm3							
Relugolix+E2/NETA	105	2 (1.9)	0.34	0.35	-0.04	0.1243	
Placebo	127	8 (6.3)	[0.08;1.42]	[0.09;1.42]	[-0.09;0.01]		
Missing							
Relugolix+E2/NETA	1	0	NC	NC	NC	NC	
Placebo	0	0	[NC;NC]	[NC;NC]	[NC;NC]		

Post hoc analysis. The denominator for percentages is the number of patients in the safety population for each treatment group. Patients with multiple events for a given PT or SOC are counted only once for each PT and SOC. Only SOCs or PTs for which there are at least 10% of patients with an event in at least one treatment group OR at least 10 patients with an event overall and at least 1% of patients with an event in at least one treatment group in the overall safety population are considered. Further, only SOCs and PTs for which there is a significant treatment effect (p-value <0.05) in the overall safety population are presented. Events are sorted alphabetically by SOC and PT and then by ascending subgroup-by-treatment interaction p-value within each. MedDRA (version 22.0).
[1] OR (95% CI) based on a logistic regression model adjusting for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates.
[2] RR (95% CI) based on a Cochran-Mantel-Haenszel approach stratified by study.
[3] RD (95% CI) based on a Mantel-Haenszel approach stratified by study. 95% CIs are based on the approximation to the normal distribution using the Sato estimator for the standard error.
[4] P-value based on a Cochran-Mantel-Haenszel test stratified by study.
[5] Interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the OR (95% CI). Missing subgroup levels are not included in estimation of the interaction p-value.
A continuity correction is applied in estimation of the OR, RR and p-value if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum. No continuity correction is applied in the estimation of the RD.
The reference group for the OR, RR and RD is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with >= 1 event; OR: Odds ratio; RR: Risk ratio; RD: Risk difference; CI: Confidence interval; NETA: Norethindrone acetate; SOC: System organ class; PT: Preferred term; NC: Not calculated.

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Table SAF.TEAE.SPT.POOL.5.1.S5: Frequent Treatment Emergent Adverse Events by System Organ Class and Preferred Term, by Subgroup (Safety Population)

Study: Pooled

System Organ Class: Respiratory, thoracic and mediastinal disorders, Preferred Term: Any

Treatment	N	n (%)	OR[1] [95% CI]	RR[2] [95% CI]	RD[3] [95% CI]	p-value[4]	p-value (int)[5]
MBL Volume at Baseline (mL)							
< 225 mL							
Relugolix+E2/NETA	164	4 (2.4)	0.30 [0.10;0.95]	0.32 [0.11;0.96]	-0.05 [-0.10;-0.01]	0.0301	0.6070
Placebo	171	13 (7.6)					
>= 225 mL							
Relugolix+E2/NETA	90	1 (1.1)	0.18 [0.03;1.04]	0.19 [0.03;1.06]	-0.07 [-0.13;-0.01]	0.0331	
Placebo	85	7 (8.2)					

Post hoc analysis. The denominator for percentages is the number of patients in the safety population for each treatment group. Patients with multiple events for a given PT or SOC are counted only once for each PT and SOC. Only SOCs or PTs for which there are at least 10% of patients with an event in at least one treatment group OR at least 10 patients with an event overall and at least 1% of patients with an event in at least one treatment group in the overall safety population are considered. Further, only SOCs and PTs for which there is a significant treatment effect (p-value <0.05) in the overall safety population are presented. Events are sorted alphabetically by SOC and PT and then by ascending subgroup-by-treatment interaction p-value within each. MedDRA (version 22.0).
[1] OR (95% CI) based on a logistic regression model adjusting for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates.
[2] RR (95% CI) based on a Cochran-Mantel-Haenszel approach stratified by study.
[3] RD (95% CI) based on a Mantel-Haenszel approach stratified by study. 95% CIs are based on the approximation to the normal distribution using the Sato estimator for the standard error.
[4] P-value based on a Cochran-Mantel-Haenszel test stratified by study.
[5] Interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the OR (95% CI).
A continuity correction is applied in estimation of the OR, RR and p-value if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum. No continuity correction is applied in the estimation of the RD.
The reference group for the OR, RR and RD is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with >= 1 event; OR: Odds ratio; RR: Risk ratio; RD: Risk difference; CI: Confidence interval; NETA: Norethindrone acetate; SOC: System organ class; PT: Preferred term.

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Table SAF.TEAE.SPT.POOL.5.1.S6: Frequent Treatment Emergent Adverse Events by System Organ Class and Preferred Term, by Subgroup (Safety Population)

Study: Pooled

System Organ Class: Respiratory, thoracic and mediastinal disorders, Preferred Term: Any

Treatment	N	n (%)	OR[1] [95% CI]	RR[2] [95% CI]	RD[3] [95% CI]	p-value[4]	p-value (int)[5]
Geographic Region I							
North America							0.6509
Relugolix+E2/NETA	192	4 (2.1)	0.24	0.25	-0.06	0.0064	
Placebo	194	16 (8.2)	[0.08;0.72]	[0.09;0.74]	[-0.11;-0.02]		
Rest of World							
Relugolix+E2/NETA	62	1 (1.6)	0.38	0.40	-0.05	0.2360	
Placebo	62	4 (6.5)	[0.07;2.02]	[0.08;1.97]	[-0.12;0.02]		

Post hoc analysis. The denominator for percentages is the number of patients in the safety population for each treatment group. Patients with multiple events for a given PT or SOC are counted only once for each PT and SOC. Only SOCs or PTs for which there are at least 10% of patients with an event in at least one treatment group OR at least 10 patients with an event overall and at least 1% of patients with an event in at least one treatment group in the overall safety population are considered. Further, only SOCs and PTs for which there is a significant treatment effect (p-value <0.05) in the overall safety population are presented. Events are sorted alphabetically by SOC and PT and then by ascending subgroup-by-treatment interaction p-value within each. MedDRA (version 22.0).
[1] OR (95% CI) based on a logistic regression model adjusting for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates.
[2] RR (95% CI) based on a Cochran-Mantel-Haenszel approach stratified by study.
[3] RD (95% CI) based on a Mantel-Haenszel approach stratified by study. 95% CIs are based on the approximation to the normal distribution using the Sato estimator for the standard error.
[4] P-value based on a Cochran-Mantel-Haenszel test stratified by study.
[5] Interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the OR (95% CI).
A continuity correction is applied in estimation of the OR, RR and p-value if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum. No continuity correction is applied in the estimation of the RD.
The reference group for the OR, RR and RD is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with >= 1 event; OR: Odds ratio; RR: Risk ratio; RD: Risk difference; CI: Confidence interval; NETA: Norethindrone acetate; SOC: System organ class; PT: Preferred term.

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Table SAF.TEAE.SPT.POOL.5.1.S7: Frequent Treatment Emergent Adverse Events by System Organ Class and Preferred Term, by Subgroup (Safety Population)

Study: Pooled

System Organ Class: Respiratory, thoracic and mediastinal disorders, Preferred Term: Any

Treatment	N	n (%)	OR[1] [95% CI]	RR[2] [95% CI]	RD[3] [95% CI]	p-value[4]	p-value (int)[5]
Geographic Region II							
Europe							0.8476
Relugolix+E2/NETA	41	0	0.33	0.35	-0.05	0.3393	
Placebo	42	2 (4.8)	[0.03;3.33]	[0.04;3.36]	[-0.11;0.02]		
Rest of World (including the US)							
Relugolix+E2/NETA	213	5 (2.3)	0.26	0.28	-0.06	0.0053	
Placebo	214	18 (8.4)	[0.09;0.71]	[0.10;0.73]	[-0.10;-0.02]		

Post hoc analysis. The denominator for percentages is the number of patients in the safety population for each treatment group. Patients with multiple events for a given PT or SOC are counted only once for each PT and SOC. Only SOCs or PTs for which there are at least 10% of patients with an event in at least one treatment group OR at least 10 patients with an event overall and at least 1% of patients with an event in at least one treatment group in the overall safety population are considered. Further, only SOCs and PTs for which there is a significant treatment effect (p-value <0.05) in the overall safety population are presented. Events are sorted alphabetically by SOC and PT and then by ascending subgroup-by-treatment interaction p-value within each. MedDRA (version 22.0).
[1] OR (95% CI) based on a logistic regression model adjusting for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates.
[2] RR (95% CI) based on a Cochran-Mantel-Haenszel approach stratified by study.
[3] RD (95% CI) based on a Mantel-Haenszel approach stratified by study. 95% CIs are based on the approximation to the normal distribution using the Sato estimator for the standard error.
[4] P-value based on a Cochran-Mantel-Haenszel test stratified by study.
[5] Interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the OR (95% CI).
A continuity correction is applied in estimation of the OR, RR and p-value if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum. No continuity correction is applied in the estimation of the RD.
The reference group for the OR, RR and RD is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with >= 1 event; OR: Odds ratio; RR: Risk ratio; RD: Risk difference; CI: Confidence interval; NETA: Norethindrone acetate; SOC: System organ class; PT: Preferred term.

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Table SAF.TEAE.SPT.POOL.5.1.S9: Frequent Treatment Emergent Adverse Events by System Organ Class and Preferred Term, by Subgroup (Safety Population)

Study: Pooled

System Organ Class: Respiratory, thoracic and mediastinal disorders, Preferred Term: Any

Treatment	**N**	**n (%)**	**OR[1] [95% CI]**	**RR[2] [95% CI]**	**RD[3] [95% CI]**	**p-value[4]**	**p-value (int)[5]**
Race							
Black/African American							0.9328
Relugolix+E2/NETA	122	2 (1.6)	0.32	0.33	-0.03	0.1394	
Placebo	141	7 (5.0)	[0.06;1.56]	[0.07;1.56]	[-0.08;0.01]		
White							
Relugolix+E2/NETA	123	3 (2.4)	0.21	0.23	-0.08	0.0124	
Placebo	105	11 (10.5)	[0.06;0.79]	[0.07;0.82]	[-0.14;-0.02]		
Asian							
Relugolix+E2/NETA	1	0	NC	NC	NC	NC	
Placebo	3	0	[NC;NC]	[NC;NC]	[NC;NC]		
Others							
Relugolix+E2/NETA	5	0	0.24	0.53	-0.19	0.5475	
Placebo	6	2 (33.3)	[0.02;3.16]	[0.07;4.29]	[-0.58;0.20]		
Not reported							
Relugolix+E2/NETA	3	0	NC	NC	NC	NC	
Placebo	1	0	[NC;NC]	[NC;NC]	[NC;NC]		

Post hoc analysis. The denominator for percentages is the number of patients in the safety population for each treatment group. Patients with multiple events for a given PT or SOC are counted only once for each PT and SOC. Only SOCs or PTs for which there are at least 10% of patients with an event in at least one treatment group OR at least 10 patients with an event overall and at least 1% of patients with an event in at least one treatment group in the overall safety population are considered. Further, only SOCs and PTs for which there is a significant treatment effect (p-value <0.05) in the overall safety population are presented. Events are sorted alphabetically by SOC and PT and then by ascending subgroup-by-treatment interaction p-value within each. MedDRA (version 22.0).
[1] OR (95% CI) based on a logistic regression model adjusting for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates.
[2] RR (95% CI) based on a Cochran-Mantel-Haenszel approach stratified by study.
[3] RD (95% CI) based on a Mantel-Haenszel approach stratified by study. 95% CIs are based on the approximation to the normal distribution using the Sato estimator for the standard error.
[4] P-value based on a Cochran-Mantel-Haenszel test stratified by study.
[5] Interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the OR (95% CI). Not reported subgroup levels are not included in estimation of the interaction p-value.
A continuity correction is applied in estimation of the OR, RR and p-value if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum. No continuity correction is applied in the estimation of the RD.
The reference group for the OR, RR and RD is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with >= 1 event; OR: Odds ratio; RR: Risk ratio; RD: Risk difference; CI: Confidence interval; NETA: Norethindrone acetate; SOC: System organ class; PT: Preferred term; NC: Not calculated.

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Table SAF.TEAE.SPT.POOL.5.2.S4: Frequent Treatment Emergent Adverse Events by System Organ Class and Preferred Term, by Subgroup (Safety Population)

Study: Pooled

System Organ Class: Respiratory, thoracic and mediastinal disorders, Preferred Term: Cough

Treatment	N	n (%)	OR[1] [95% CI]	RR[2] [95% CI]	RD[3] [95% CI]	p-value[4]	p-value (int)[5]
Maximum NRS Pain Score at Baseline							
< 4							
Relugolix+E2/NETA	73	1 (1.4)	0.82	0.81	-0.00	0.8568	0.1560
Placebo	62	1 (1.6)	[0.08;8.10]	[0.09;7.55]	[-0.05;0.04]		
>= 4							
Relugolix+E2/NETA	178	0	0.09	0.10	-0.05	0.0051	
Placebo	190	10 (5.3)	[0.01;0.73]	[0.01;0.75]	[-0.08;-0.02]		
Missing							
Relugolix+E2/NETA	3	0	NC	NC	NC	NC	
Placebo	4	0	[NC;NC]	[NC;NC]	[NC;NC]		

Post hoc analysis. The denominator for percentages is the number of patients in the safety population for each treatment group. Patients with multiple events for a given PT or SOC are counted only once for each PT and SOC. Only SOCs or PTs for which there are at least 10% of patients with an event in at least one treatment group OR at least 10 patients with an event overall and at least 1% of patients with an event in at least one treatment group in the overall safety population are considered. Further, only SOCs and PTs for which there is a significant treatment effect (p-value <0.05) in the overall safety population are presented. Events are sorted alphabetically by SOC and PT and then by ascending subgroup-by-treatment interaction p-value within each. MedDRA (version 22.0).
[1] OR (95% CI) based on a logistic regression model adjusting for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates.
[2] RR (95% CI) based on a Cochran-Mantel-Haenszel approach stratified by study.
[3] RD (95% CI) based on a Mantel-Haenszel approach stratified by study. 95% CIs are based on the approximation to the normal distribution using the Sato estimator for the standard error.
[4] P-value based on a Cochran-Mantel-Haenszel test stratified by study.
[5] Interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the OR (95% CI). Missing subgroup levels are not included in estimation of the interaction p-value.
A continuity correction is applied in estimation of the OR, RR and p-value if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum. No continuity correction is applied in the estimation of the RD.
The reference group for the OR, RR and RD is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with >= 1 event; OR: Odds ratio; RR: Risk ratio; RD: Risk difference; CI: Confidence interval; NETA: Norethindrone acetate; SOC: System organ class; PT: Preferred term; NC: Not calculated.

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Table SAF.TEAE.SPT.POOL.5.2.S7: Frequent Treatment Emergent Adverse Events by System Organ Class and Preferred Term, by Subgroup (Safety Population)

Study: Pooled

System Organ Class: Respiratory, thoracic and mediastinal disorders, Preferred Term: Cough

Treatment	**N**	**n (%)**	**OR[1] [95% CI]**	**RR[2] [95% CI]**	**RD[3] [95% CI]**	**p-value[4]**	**p-value (int)[5]**
Geographic Region II							
Europe							
Relugolix+E2/NETA	41	0	1.05	1.00	0.00	0.9982	0.2118
Placebo	42	0	[0.06;17.38]	[0.07;15.45]			
Rest of World (including the US)							
Relugolix+E2/NETA	213	1 (0.5)	0.12	0.13	-0.05	0.0047	
Placebo	214	11 (5.1)	[0.02;0.68]	[0.02;0.70]	[-0.08;-0.02]		

Post hoc analysis. The denominator for percentages is the number of patients in the safety population for each treatment group. Patients with multiple events for a given PT or SOC are counted only once for each PT and SOC. Only SOCs or PTs for which there are at least 10% of patients with an event in at least one treatment group OR at least 10 patients with an event overall and at least 1% of patients with an event in at least one treatment group in the overall safety population are considered. Further, only SOCs and PTs for which there is a significant treatment effect (p-value <0.05) in the overall safety population are presented. Events are sorted alphabetically by SOC and PT and then by ascending subgroup-by-treatment interaction p-value within each. MedDRA (version 22.0).
[1] OR (95% CI) based on a logistic regression model adjusting for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates.
[2] RR (95% CI) based on a Cochran-Mantel-Haenszel approach stratified by study.
[3] RD (95% CI) based on a Mantel-Haenszel approach stratified by study. 95% CIs are based on the approximation to the normal distribution using the Sato estimator for the standard error.
[4] P-value based on a Cochran-Mantel-Haenszel test stratified by study.
[5] Interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the OR (95% CI).
A continuity correction is applied in estimation of the OR, RR and p-value if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum. No continuity correction is applied in the estimation of the RD.
The reference group for the OR, RR and RD is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with >= 1 event; OR: Odds ratio; RR: Risk ratio; RD: Risk difference; CI: Confidence interval; NETA: Norethindrone acetate; SOC: System organ class; PT: Preferred term.

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Table SAF.TEAE.SPT.POOL.5.2.S2: Frequent Treatment Emergent Adverse Events by System Organ Class and Preferred Term, by Subgroup (Safety Population)

Study: Pooled

System Organ Class: Respiratory, thoracic and mediastinal disorders, Preferred Term: Cough

Treatment	N	n (%)	OR[1] [95% CI]	RR[2] [95% CI]	RD[3] [95% CI]	p-value[4]	p-value (int)[5]
BMI (kg/m2) at Baseline							
< 30							
Relugolix+E2/NETA	119	0	0.47	0.47	-0.01	0.5256	0.4390
Placebo	115	1 (0.9)	[0.04;5.27]	[0.04;5.01]	[-0.03;0.01]		
>= 30							
Relugolix+E2/NETA	134	1 (0.7)	0.14	0.15	-0.06	0.0108	
Placebo	141	10 (7.1)	[0.03;0.80]	[0.03;0.82]	[-0.11;-0.02]		
Missing							
Relugolix+E2/NETA	1	0	NC	NC	NC	NC	
Placebo	0	0	[NC;NC]	[NC;NC]	[NC;NC]		

Post hoc analysis. The denominator for percentages is the number of patients in the safety population for each treatment group. Patients with multiple events for a given PT or SOC are counted only once for each PT and SOC. Only SOCs or PTs for which there are at least 10% of patients with an event in at least one treatment group OR at least 10 patients with an event overall and at least 1% of patients with an event in at least one treatment group in the overall safety population are considered. Further, only SOCs and PTs for which there is a significant treatment effect (p-value <0.05) in the overall safety population are presented. Events are sorted alphabetically by SOC and PT and then by ascending subgroup-by-treatment interaction p-value within each. MedDRA (version 22.0).
[1] OR (95% CI) based on a logistic regression model adjusting for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates.
[2] RR (95% CI) based on a Cochran-Mantel-Haenszel approach stratified by study.
[3] RD (95% CI) based on a Mantel-Haenszel approach stratified by study. 95% CIs are based on the approximation to the normal distribution using the Sato estimator for the standard error.
[4] P-value based on a Cochran-Mantel-Haenszel test stratified by study.
[5] Interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the OR (95% CI). Missing subgroup levels are not included in estimation of the interaction p-value.
A continuity correction is applied in estimation of the OR, RR and p-value if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum. No continuity correction is applied in the estimation of the RD.
The reference group for the OR, RR and RD is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with >= 1 event; OR: Odds ratio; RR: Risk ratio; RD: Risk difference; CI: Confidence interval; NETA: Norethindrone acetate; SOC: System organ class; PT: Preferred term; NC: Not calculated.

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Table SAF.TEAE.SPT.POOL.5.2.S6: Frequent Treatment Emergent Adverse Events by System Organ Class and Preferred Term, by Subgroup (Safety Population)

Study: Pooled

System Organ Class: Respiratory, thoracic and mediastinal disorders, Preferred Term: Cough

Treatment	**N**	**n (%)**	**OR[1] [95% CI]**	**RR[2] [95% CI]**	**RD[3] [95% CI]**	**p-value[4]**	**p-value (int)[5]**
Geographic Region I							
North America							
Relugolix+E2/NETA	192	1 (0.5)	0.15	0.16	-0.04	0.0153	0.6189
Placebo	194	9 (4.6)	[0.03;0.86]	[0.03;0.88]	[-0.07;-0.01]		
Rest of World							
Relugolix+E2/NETA	62	0	0.32	0.33	-0.03	0.3029	
Placebo	62	2 (3.2)	[0.03;3.17]	[0.04;3.04]	[-0.08;0.01]		

Post hoc analysis. The denominator for percentages is the number of patients in the safety population for each treatment group. Patients with multiple events for a given PT or SOC are counted only once for each PT and SOC. Only SOCs or PTs for which there are at least 10% of patients with an event in at least one treatment group OR at least 10 patients with an event overall and at least 1% of patients with an event in at least one treatment group in the overall safety population are considered. Further, only SOCs and PTs for which there is a significant treatment effect (p-value <0.05) in the overall safety population are presented. Events are sorted alphabetically by SOC and PT and then by ascending subgroup-by-treatment interaction p-value within each. MedDRA (version 22.0).
[1] OR (95% CI) based on a logistic regression model adjusting for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates.
[2] RR (95% CI) based on a Cochran-Mantel-Haenszel approach stratified by study.
[3] RD (95% CI) based on a Mantel-Haenszel approach stratified by study. 95% CIs are based on the approximation to the normal distribution using the Sato estimator for the standard error.
[4] P-value based on a Cochran-Mantel-Haenszel test stratified by study.
[5] Interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the OR (95% CI).
A continuity correction is applied in estimation of the OR, RR and p-value if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum. No continuity correction is applied in the estimation of the RD.
The reference group for the OR, RR and RD is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with >= 1 event; OR: Odds ratio; RR: Risk ratio; RD: Risk difference; CI: Confidence interval; NETA: Norethindrone acetate; SOC: System organ class; PT: Preferred term.

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Table SAF.TEAE.SPT.POOL.5.2.S1: Frequent Treatment Emergent Adverse Events by System Organ Class and Preferred Term, by Subgroup (Safety Population)

Study: Pooled

System Organ Class: Respiratory, thoracic and mediastinal disorders, Preferred Term: Cough

Treatment	**N**	**n (%)**	**OR[1] [95% CI]**	**RR[2] [95% CI]**	**RD[3] [95% CI]**	**p-value[4]**	**p-value (int)[5]**
Age (years)							
< 40 years							NC
Relugolix+E2/NETA	62	1 (1.6)	NC [NC;NC]	NC [NC;NC]	NC [NC;NC]	NC	
Placebo	78	3 (3.8)					
>= 40 years							
Relugolix+E2/NETA	192	0	NC [NC;NC]	NC [NC;NC]	NC [NC;NC]	NC	
Placebo	178	8 (4.5)					

Post hoc analysis. The denominator for percentages is the number of patients in the safety population for each treatment group. Patients with multiple events for a given PT or SOC are counted only once for each PT and SOC. Only SOCs or PTs for which there are at least 10% of patients with an event in at least one treatment group OR at least 10 patients with an event overall and at least 1% of patients with an event in at least one treatment group in the overall safety population are considered. Further, only SOCs and PTs for which there is a significant treatment effect (p-value <0.05) in the overall safety population are presented. Events are sorted alphabetically by SOC and PT and then by ascending subgroup-by-treatment interaction p-value within each. MedDRA (version 22.0).
[1] OR (95% CI) based on a logistic regression model adjusting for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates.
[2] RR (95% CI) based on a Cochran-Mantel-Haenszel approach stratified by study.
[3] RD (95% CI) based on a Mantel-Haenszel approach stratified by study. 95% CIs are based on the approximation to the normal distribution using the Sato estimator for the standard error.
[4] P-value based on a Cochran-Mantel-Haenszel test stratified by study.
[5] Interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the OR (95% CI).
A continuity correction is applied in estimation of the OR, RR and p-value if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum. No continuity correction is applied in the estimation of the RD.
The reference group for the OR, RR and RD is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with >= 1 event; OR: Odds ratio; RR: Risk ratio; RD: Risk difference; CI: Confidence interval; NETA: Norethindrone acetate; SOC: System organ class; PT: Preferred term; NC: Not calculated.

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Table SAF.TEAE.SPT.POOL.5.2.S3: Frequent Treatment Emergent Adverse Events by System Organ Class and Preferred Term, by Subgroup (Safety Population)

Study: Pooled

System Organ Class: Respiratory, thoracic and mediastinal disorders, Preferred Term: Cough

Treatment	N	n (%)	OR[1] [95% CI]	RR[2] [95% CI]	RD[3] [95% CI]	p-value[4]	p-value (int)[5]
Uterine Volume at Baseline (cm3)							
< 300 cm3							NC
Relugolix+E2/NETA	148	0	NC	NC	NC	NC	
Placebo	129	7 (5.4)	[NC;NC]	[NC;NC]	[NC;NC]		
>= 300 cm3							
Relugolix+E2/NETA	105	1 (1.0)	NC	NC	NC	NC	
Placebo	127	4 (3.1)	[NC;NC]	[NC;NC]	[NC;NC]		
Missing							
Relugolix+E2/NETA	1	0	NC	NC	NC	NC	
Placebo	0	0	[NC;NC]	[NC;NC]	[NC;NC]		

Post hoc analysis. The denominator for percentages is the number of patients in the safety population for each treatment group. Patients with multiple events for a given PT or SOC are counted only once for each PT and SOC. Only SOCs or PTs for which there are at least 10% of patients with an event in at least one treatment group OR at least 10 patients with an event overall and at least 1% of patients with an event in at least one treatment group in the overall safety population are considered. Further, only SOCs and PTs for which there is a significant treatment effect (p-value <0.05) in the overall safety population are presented. Events are sorted alphabetically by SOC and PT and then by ascending subgroup-by-treatment interaction p-value within each. MedDRA (version 22.0).
[1] OR (95% CI) based on a logistic regression model adjusting for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates.
[2] RR (95% CI) based on a Cochran-Mantel-Haenszel approach stratified by study.
[3] RD (95% CI) based on a Mantel-Haenszel approach stratified by study. 95% CIs are based on the approximation to the normal distribution using the Sato estimator for the standard error.
[4] P-value based on a Cochran-Mantel-Haenszel test stratified by study.
[5] Interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the OR (95% CI). Missing subgroup levels are not included in estimation of the interaction p-value.
A continuity correction is applied in estimation of the OR, RR and p-value if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum. No continuity correction is applied in the estimation of the RD.
The reference group for the OR, RR and RD is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with >= 1 event; OR: Odds ratio; RR: Risk ratio; RD: Risk difference; CI: Confidence interval; NETA: Norethindrone acetate; SOC: System organ class; PT: Preferred term; NC: Not calculated.

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Table SAF.TEAE.SPT.POOL.5.2.S5: Frequent Treatment Emergent Adverse Events by System Organ Class and Preferred Term, by Subgroup (Safety Population)

Study: Pooled

System Organ Class: Respiratory, thoracic and mediastinal disorders, Preferred Term: Cough

Treatment	N	n (%)	OR[1] [95% CI]	RR[2] [95% CI]	RD[3] [95% CI]	p-value[4]	p-value (int)[5]
MBL Volume at Baseline (mL)							
< 225 mL							NC
Relugolix+E2/NETA	164	0	NC [NC;NC]	NC [NC;NC]	NC [NC;NC]	NC	
Placebo	171	9 (5.3)					
>= 225 mL							
Relugolix+E2/NETA	90	1 (1.1)	NC [NC;NC]	NC [NC;NC]	NC [NC;NC]	NC	
Placebo	85	2 (2.4)					

Post hoc analysis. The denominator for percentages is the number of patients in the safety population for each treatment group. Patients with multiple events for a given PT or SOC are counted only once for each PT and SOC. Only SOCs or PTs for which there are at least 10% of patients with an event in at least one treatment group OR at least 10 patients with an event overall and at least 1% of patients with an event in at least one treatment group in the overall safety population are considered. Further, only SOCs and PTs for which there is a significant treatment effect (p-value <0.05) in the overall safety population are presented. Events are sorted alphabetically by SOC and PT and then by ascending subgroup-by-treatment interaction p-value within each. MedDRA (version 22.0).
[1] OR (95% CI) based on a logistic regression model adjusting for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates.
[2] RR (95% CI) based on a Cochran-Mantel-Haenszel approach stratified by study.
[3] RD (95% CI) based on a Mantel-Haenszel approach stratified by study. 95% CIs are based on the approximation to the normal distribution using the Sato estimator for the standard error.
[4] P-value based on a Cochran-Mantel-Haenszel test stratified by study.
[5] Interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the OR (95% CI).
A continuity correction is applied in estimation of the OR, RR and p-value if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum. No continuity correction is applied in the estimation of the RD.
The reference group for the OR, RR and RD is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with >= 1 event; OR: Odds ratio; RR: Risk ratio; RD: Risk difference; CI: Confidence interval; NETA: Norethindrone acetate; SOC: System organ class; PT: Preferred term; NC: Not calculated.

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Table SAF.TEAE.SPT.POOL.5.2.S8: Frequent Treatment Emergent Adverse Events by System Organ Class and Preferred Term, by Subgroup (Safety Population)

Study: Pooled

System Organ Class: Respiratory, thoracic and mediastinal disorders, Preferred Term: Cough

Treatment	**N**	**n (%)**	**OR[1] [95% CI]**	**RR[2] [95% CI]**	**RD[3] [95% CI]**	**p-value[4]**	**p-value (int)[5]**
Ethnicity							
Hispanic or Latino							NC
Relugolix+E2/NETA	53	0	NC [NC;NC]	NC [NC;NC]	NC [NC;NC]	NC	
Placebo	55	5 (9.1)					
Not Hispanic or Latino							
Relugolix+E2/NETA	197	1 (0.5)	NC [NC;NC]	NC [NC;NC]	NC [NC;NC]	NC	
Placebo	199	6 (3.0)					
Not reported							
Relugolix+E2/NETA	4	0	NC [NC;NC]	NC [NC;NC]	NC [NC;NC]	NC	
Placebo	2	0					

Post hoc analysis. The denominator for percentages is the number of patients in the safety population for each treatment group. Patients with multiple events for a given PT or SOC are counted only once for each PT and SOC. Only SOCs or PTs for which there are at least 10% of patients with an event in at least one treatment group OR at least 10 patients with an event overall and at least 1% of patients with an event in at least one treatment group in the overall safety population are considered. Further, only SOCs and PTs for which there is a significant treatment effect (p-value <0.05) in the overall safety population are presented. Events are sorted alphabetically by SOC and PT and then by ascending subgroup-by-treatment interaction p-value within each. MedDRA (version 22.0).
[1] OR (95% CI) based on a logistic regression model adjusting for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates.
[2] RR (95% CI) based on a Cochran-Mantel-Haenszel approach stratified by study.
[3] RD (95% CI) based on a Mantel-Haenszel approach stratified by study. 95% CIs are based on the approximation to the normal distribution using the Sato estimator for the standard error.
[4] P-value based on a Cochran-Mantel-Haenszel test stratified by study.
[5] Interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the OR (95% CI). Not reported subgroup levels are not included in estimation of the interaction p-value.
A continuity correction is applied in estimation of the OR, RR and p-value if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum. No continuity correction is applied in the estimation of the RD.
The reference group for the OR, RR and RD is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with >= 1 event; OR: Odds ratio; RR: Risk ratio; RD: Risk difference; CI: Confidence interval; NETA: Norethindrone acetate; SOC: System organ class; PT: Preferred term; NC: Not calculated.

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Table SAF.TEAE.SPT.POOL.5.2.S9: Frequent Treatment Emergent Adverse Events by System Organ Class and Preferred Term, by Subgroup (Safety Population)

Study: Pooled

System Organ Class: Respiratory, thoracic and mediastinal disorders, Preferred Term: Cough

Treatment	**N**	**n (%)**	**OR[1] [95% CI]**	**RR[2] [95% CI]**	**RD[3] [95% CI]**	**p-value[4]**	**p-value (int)[5]**
Race							
Black/African American							NC
Relugolix+E2/NETA	122	1 (0.8)	NC [NC;NC]	NC [NC;NC]	NC [NC;NC]	NC	
Placebo	141	3 (2.1)					
White							
Relugolix+E2/NETA	123	0	NC [NC;NC]	NC [NC;NC]	NC [NC;NC]	NC	
Placebo	105	7 (6.7)					
Asian							
Relugolix+E2/NETA	1	0	NC [NC;NC]	NC [NC;NC]	NC [NC;NC]	NC	
Placebo	3	0					
Others							
Relugolix+E2/NETA	5	0	NC [NC;NC]	NC [NC;NC]	NC [NC;NC]	NC	
Placebo	6	1 (16.7)					
Not reported							
Relugolix+E2/NETA	3	0	NC [NC;NC]	NC [NC;NC]	NC [NC;NC]	NC	
Placebo	1	0					

Post hoc analysis. The denominator for percentages is the number of patients in the safety population for each treatment group. Patients with multiple events for a given PT or SOC are counted only once for each PT and SOC. Only SOCs or PTs for which there are at least 10% of patients with an event in at least one treatment group OR at least 10 patients with an event overall and at least 1% of patients with an event in at least one treatment group in the overall safety population are considered. Further, only SOCs and PTs for which there is a significant treatment effect (p-value <0.05) in the overall safety population are presented. Events are sorted alphabetically by SOC and PT and then by ascending subgroup-by-treatment interaction p-value within each. MedDRA (version 22.0).
[1] OR (95% CI) based on a logistic regression model adjusting for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates.
[2] RR (95% CI) based on a Cochran-Mantel-Haenszel approach stratified by study.
[3] RD (95% CI) based on a Mantel-Haenszel approach stratified by study. 95% CIs are based on the approximation to the normal distribution using the Sato estimator for the standard error.
[4] P-value based on a Cochran-Mantel-Haenszel test stratified by study.
[5] Interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the OR (95% CI). Not reported subgroup levels are not included in estimation of the interaction p-value.
A continuity correction is applied in estimation of the OR, RR and p-value if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum. No continuity correction is applied in the estimation of the RD.
The reference group for the OR, RR and RD is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with >= 1 event; OR: Odds ratio; RR: Risk ratio; RD: Risk difference; CI: Confidence interval; NETA: Norethindrone acetate; SOC: System organ class; PT: Preferred term; NC: Not calculated.

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Table SAF.TEAE.SPT.POOL.6.1.S4: Frequent Treatment Emergent Adverse Events by System Organ Class and Preferred Term, by Subgroup (Safety Population)

Study: Pooled

System Organ Class: Skin and subcutaneous tissue disorders, Preferred Term: Any

Treatment	N	n (%)	OR[1] [95% CI]	RR[2] [95% CI]	RD[3] [95% CI]	p-value[4]	p-value (int)[5]
Maximum NRS Pain Score at Baseline							
< 4							
Relugolix+E2/NETA	73	6 (8.2)	1.30 [0.35;4.84]	1.34 [0.41;4.42]	0.02 [-0.07;0.11]	0.6333	0.2424
Placebo	62	4 (6.5)					
>= 4							
Relugolix+E2/NETA	178	18 (10.1)	3.45 [1.34;8.90]	3.22 [1.31;7.91]	0.07 [0.02;0.12]	0.0067	
Placebo	190	6 (3.2)					
Missing							
Relugolix+E2/NETA	3	0	NC [NC;NC]	NC [NC;NC]	NC [NC;NC]	NC	
Placebo	4	0					

Post hoc analysis. The denominator for percentages is the number of patients in the safety population for each treatment group. Patients with multiple events for a given PT or SOC are counted only once for each PT and SOC. Only SOCs or PTs for which there are at least 10% of patients with an event in at least one treatment group OR at least 10 patients with an event overall and at least 1% of patients with an event in at least one treatment group in the overall safety population are considered. Further, only SOCs and PTs for which there is a significant treatment effect (p-value <0.05) in the overall safety population are presented. Events are sorted alphabetically by SOC and PT and then by ascending subgroup-by-treatment interaction p-value within each. MedDRA (version 22.0).
[1] OR (95% CI) based on a logistic regression model adjusting for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates.
[2] RR (95% CI) based on a Cochran-Mantel-Haenszel approach stratified by study.
[3] RD (95% CI) based on a Mantel-Haenszel approach stratified by study. 95% CIs are based on the approximation to the normal distribution using the Sato estimator for the standard error.
[4] P-value based on a Cochran-Mantel-Haenszel test stratified by study.
[5] Interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the OR (95% CI). Missing subgroup levels are not included in estimation of the interaction p-value.
A continuity correction is applied in estimation of the OR, RR and p-value if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum. No continuity correction is applied in the estimation of the RD.
The reference group for the OR, RR and RD is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with >= 1 event; OR: Odds ratio; RR: Risk ratio; RD: Risk difference; CI: Confidence interval; NETA: Norethindrone acetate; SOC: System organ class; PT: Preferred term; NC: Not calculated.

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Table SAF.TEAE.SPT.POOL.6.1.S7: Frequent Treatment Emergent Adverse Events by System Organ Class and Preferred Term, by Subgroup (Safety Population)

Study: Pooled

System Organ Class: Skin and subcutaneous tissue disorders, Preferred Term: Any

Treatment	N	n (%)	OR[1] [95% CI]	RR[2] [95% CI]	RD[3] [95% CI]	p-value[4]	p-value (int)[5]
Geographic Region II							
Europe							0.2467
Relugolix+E2/NETA	41	7 (17.1)	5.99	4.99	0.14	0.0385	
Placebo	42	1 (2.4)	[0.98;36.62]	[0.87;28.55]	[0.02;0.27]		
Rest of World (including the US)							
Relugolix+E2/NETA	213	17 (8.0)	1.98	1.89	0.04	0.1061	
Placebo	214	9 (4.2)	[0.86;4.55]	[0.86;4.16]	[-0.01;0.08]		

Post hoc analysis. The denominator for percentages is the number of patients in the safety population for each treatment group. Patients with multiple events for a given PT or SOC are counted only once for each PT and SOC. Only SOCs or PTs for which there are at least 10% of patients with an event in at least one treatment group OR at least 10 patients with an event overall and at least 1% of patients with an event in at least one treatment group in the overall safety population are considered. Further, only SOCs and PTs for which there is a significant treatment effect (p-value <0.05) in the overall safety population are presented. Events are sorted alphabetically by SOC and PT and then by ascending subgroup-by-treatment interaction p-value within each. MedDRA (version 22.0).
[1] OR (95% CI) based on a logistic regression model adjusting for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates.
[2] RR (95% CI) based on a Cochran-Mantel-Haenszel approach stratified by study.
[3] RD (95% CI) based on a Mantel-Haenszel approach stratified by study. 95% CIs are based on the approximation to the normal distribution using the Sato estimator for the standard error.
[4] P-value based on a Cochran-Mantel-Haenszel test stratified by study.
[5] Interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the OR (95% CI).
A continuity correction is applied in estimation of the OR, RR and p-value if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum. No continuity correction is applied in the estimation of the RD.
The reference group for the OR, RR and RD is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with >= 1 event; OR: Odds ratio; RR: Risk ratio; RD: Risk difference; CI: Confidence interval; NETA: Norethindrone acetate; SOC: System organ class; PT: Preferred term.

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Table SAF.TEAE.SPT.POOL.6.1.S6: Frequent Treatment Emergent Adverse Events by System Organ Class and Preferred Term, by Subgroup (Safety Population)

Study: Pooled

System Organ Class: Skin and subcutaneous tissue disorders, Preferred Term: Any

Treatment	N	n (%)	OR[1] [95% CI]	RR[2] [95% CI]	RD[3] [95% CI]	p-value[4]	p-value (int)[5]
Geographic Region I							
North America							0.3374
Relugolix+E2/NETA	192	13 (6.8)	1.94	1.87	0.03	0.1632	
Placebo	194	7 (3.6)	[0.76;4.97]	[0.76;4.59]	[-0.01;0.08]		
Rest of World							
Relugolix+E2/NETA	62	11 (17.7)	4.24	3.71	0.13	0.0216	
Placebo	62	3 (4.8)	[1.12;16.04]	[1.09;12.56]	[0.02;0.24]		

Post hoc analysis. The denominator for percentages is the number of patients in the safety population for each treatment group. Patients with multiple events for a given PT or SOC are counted only once for each PT and SOC. Only SOCs or PTs for which there are at least 10% of patients with an event in at least one treatment group OR at least 10 patients with an event overall and at least 1% of patients with an event in at least one treatment group in the overall safety population are considered. Further, only SOCs and PTs for which there is a significant treatment effect (p-value <0.05) in the overall safety population are presented. Events are sorted alphabetically by SOC and PT and then by ascending subgroup-by-treatment interaction p-value within each. MedDRA (version 22.0).
[1] OR (95% CI) based on a logistic regression model adjusting for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates.
[2] RR (95% CI) based on a Cochran-Mantel-Haenszel approach stratified by study.
[3] RD (95% CI) based on a Mantel-Haenszel approach stratified by study. 95% CIs are based on the approximation to the normal distribution using the Sato estimator for the standard error.
[4] P-value based on a Cochran-Mantel-Haenszel test stratified by study.
[5] Interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the OR (95% CI).
A continuity correction is applied in estimation of the OR, RR and p-value if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum. No continuity correction is applied in the estimation of the RD.
The reference group for the OR, RR and RD is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with >= 1 event; OR: Odds ratio; RR: Risk ratio; RD: Risk difference; CI: Confidence interval; NETA: Norethindrone acetate; SOC: System organ class; PT: Preferred term.

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Table SAF.TEAE.SPT.POOL.6.1.S2: Frequent Treatment Emergent Adverse Events by System Organ Class and Preferred Term, by Subgroup (Safety Population)

Study: Pooled

System Organ Class: Skin and subcutaneous tissue disorders, Preferred Term: Any

Treatment	N	n (%)	OR[1] [95% CI]	RR[2] [95% CI]	RD[3] [95% CI]	p-value[4]	p-value (int)[5]
BMI (kg/m2) at Baseline							
< 30							0.3786
Relugolix+E2/NETA	119	11 (9.2)	1.85 [0.66;5.18]	1.80 [0.69;4.73]	0.04 [-0.02;0.11]	0.2253	
Placebo	115	6 (5.2)					
>= 30							
Relugolix+E2/NETA	134	13 (9.7)	3.68 [1.17;11.59]	3.45 [1.15;10.36]	0.07 [0.01;0.13]	0.0179	
Placebo	141	4 (2.8)					
Missing							
Relugolix+E2/NETA	1	0	NC [NC;NC]	NC [NC;NC]	NC [NC;NC]	NC	
Placebo	0	0					

Post hoc analysis. The denominator for percentages is the number of patients in the safety population for each treatment group. Patients with multiple events for a given PT or SOC are counted only once for each PT and SOC. Only SOCs or PTs for which there are at least 10% of patients with an event in at least one treatment group OR at least 10 patients with an event overall and at least 1% of patients with an event in at least one treatment group in the overall safety population are considered. Further, only SOCs and PTs for which there is a significant treatment effect (p-value <0.05) in the overall safety population are presented. Events are sorted alphabetically by SOC and PT and then by ascending subgroup-by-treatment interaction p-value within each. MedDRA (version 22.0).
[1] OR (95% CI) based on a logistic regression model adjusting for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates.
[2] RR (95% CI) based on a Cochran-Mantel-Haenszel approach stratified by study.
[3] RD (95% CI) based on a Mantel-Haenszel approach stratified by study. 95% CIs are based on the approximation to the normal distribution using the Sato estimator for the standard error.
[4] P-value based on a Cochran-Mantel-Haenszel test stratified by study.
[5] Interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the OR (95% CI). Missing subgroup levels are not included in estimation of the interaction p-value.
A continuity correction is applied in estimation of the OR, RR and p-value if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum. No continuity correction is applied in the estimation of the RD.
The reference group for the OR, RR and RD is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with >= 1 event; OR: Odds ratio; RR: Risk ratio; RD: Risk difference; CI: Confidence interval; NETA: Norethindrone acetate; SOC: System organ class; PT: Preferred term; NC: Not calculated.

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Table SAF.TEAE.SPT.POOL.6.1.S9: Frequent Treatment Emergent Adverse Events by System Organ Class and Preferred Term, by Subgroup (Safety Population)

Study: Pooled

System Organ Class: Skin and subcutaneous tissue disorders, Preferred Term: Any

Treatment	N	n (%)	OR[1] [95% CI]	RR[2] [95% CI]	RD[3] [95% CI]	p-value[4]	p-value (int)[5]
Race							
Black/African American							0.4005
Relugolix+E2/NETA	122	7 (5.7)	1.66	1.62	0.02	0.3981	
Placebo	141	5 (3.5)	[0.51;5.36]	[0.53;4.98]	[-0.03;0.07]		
White							
Relugolix+E2/NETA	123	13 (10.6)	4.02	3.69	0.08	0.0242	
Placebo	105	3 (2.9)	[1.11;14.50]	[1.07;12.71]	[0.01;0.14]		
Asian							
Relugolix+E2/NETA	1	0	NC	NC	NC	NC	
Placebo	3	1 (33.3)	[NC;NC]	[NC;NC]	[NC;NC]		
Others							
Relugolix+E2/NETA	5	4 (80.0)	7.66	1.89	0.31	0.2154	
Placebo	6	1 (16.7)	[0.76;76.91]	[0.61;5.84]	[-0.22;0.85]		
Not reported							
Relugolix+E2/NETA	3	0	NC	NC	NC	NC	
Placebo	1	0	[NC;NC]	[NC;NC]	[NC;NC]		

Post hoc analysis. The denominator for percentages is the number of patients in the safety population for each treatment group. Patients with multiple events for a given PT or SOC are counted only once for each PT and SOC. Only SOCs or PTs for which there are at least 10% of patients with an event in at least one treatment group OR at least 10 patients with an event overall and at least 1% of patients with an event in at least one treatment group in the overall safety population are considered. Further, only SOCs and PTs for which there is a significant treatment effect (p-value <0.05) in the overall safety population are presented. Events are sorted alphabetically by SOC and PT and then by ascending subgroup-by-treatment interaction p-value within each. MedDRA (version 22.0).
[1] OR (95% CI) based on a logistic regression model adjusting for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates.
[2] RR (95% CI) based on a Cochran-Mantel-Haenszel approach stratified by study.
[3] RD (95% CI) based on a Mantel-Haenszel approach stratified by study. 95% CIs are based on the approximation to the normal distribution using the Sato estimator for the standard error.
[4] P-value based on a Cochran-Mantel-Haenszel test stratified by study.
[5] Interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the OR (95% CI). Not reported subgroup levels are not included in estimation of the interaction p-value.
A continuity correction is applied in estimation of the OR, RR and p-value if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum. No continuity correction is applied in the estimation of the RD.
The reference group for the OR, RR and RD is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with >= 1 event; OR: Odds ratio; RR: Risk ratio; RD: Risk difference; CI: Confidence interval; NETA: Norethindrone acetate; SOC: System organ class; PT: Preferred term; NC: Not calculated.

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Table SAF.TEAE.SPT.POOL.6.1.S1: Frequent Treatment Emergent Adverse Events by System Organ Class and Preferred Term, by Subgroup (Safety Population)

Study: Pooled

System Organ Class: Skin and subcutaneous tissue disorders, Preferred Term: Any

Treatment	**N**	**n (%)**	**OR[1] [95% CI]**	**RR[2] [95% CI]**	**RD[3] [95% CI]**	**p-value[4]**	**p-value (int)[5]**
Age (years)							
< 40 years							
Relugolix+E2/NETA	62	4 (6.5)	3.97	3.78	0.05	0.1260	0.5558
Placebo	78	1 (1.3)	[0.61;26.00]	[0.61;23.53]	[-0.01;0.12]		
>= 40 years							
Relugolix+E2/NETA	192	20 (10.4)	2.18	2.06	0.05	0.0559	
Placebo	178	9 (5.1)	[0.97;4.93]	[0.96;4.41]	[-0.00;0.11]		

Post hoc analysis. The denominator for percentages is the number of patients in the safety population for each treatment group. Patients with multiple events for a given PT or SOC are counted only once for each PT and SOC. Only SOCs or PTs for which there are at least 10% of patients with an event in at least one treatment group OR at least 10 patients with an event overall and at least 1% of patients with an event in at least one treatment group in the overall safety population are considered. Further, only SOCs and PTs for which there is a significant treatment effect (p-value <0.05) in the overall safety population are presented. Events are sorted alphabetically by SOC and PT and then by ascending subgroup-by-treatment interaction p-value within each. MedDRA (version 22.0).
[1] OR (95% CI) based on a logistic regression model adjusting for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates.
[2] RR (95% CI) based on a Cochran-Mantel-Haenszel approach stratified by study.
[3] RD (95% CI) based on a Mantel-Haenszel approach stratified by study. 95% CIs are based on the approximation to the normal distribution using the Sato estimator for the standard error.
[4] P-value based on a Cochran-Mantel-Haenszel test stratified by study.
[5] Interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the OR (95% CI).
A continuity correction is applied in estimation of the OR, RR and p-value if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum. No continuity correction is applied in the estimation of the RD.
The reference group for the OR, RR and RD is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with >= 1 event; OR: Odds ratio; RR: Risk ratio; RD: Risk difference; CI: Confidence interval; NETA: Norethindrone acetate; SOC: System organ class; PT: Preferred term.

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Table SAF.TEAE.SPT.POOL.6.1.S8: Frequent Treatment Emergent Adverse Events by System Organ Class and Preferred Term, by Subgroup (Safety Population)

Study: Pooled

System Organ Class: Skin and subcutaneous tissue disorders, Preferred Term: Any

Treatment	**N**	**n (%)**	**OR[1] [95% CI]**	**RR[2] [95% CI]**	**RD[3] [95% CI]**	**p-value[4]**	**p-value (int)[5]**
Ethnicity							
Hispanic or Latino							
Relugolix+E2/NETA	53	9 (17.0)	3.62	2.89	0.12	0.0652	0.5713
Placebo	55	3 (5.5)	[0.91;14.33]	[0.88;9.48]	[-0.01;0.24]		
Not Hispanic or Latino							
Relugolix+E2/NETA	197	15 (7.6)	2.25	2.15	0.04	0.0786	
Placebo	199	7 (3.5)	[0.90;5.65]	[0.90;5.13]	[-0.00;0.09]		
Not reported							
Relugolix+E2/NETA	4	0	NC	NC	NC	NC	
Placebo	2	0	[NC;NC]	[NC;NC]	[NC;NC]		

Post hoc analysis. The denominator for percentages is the number of patients in the safety population for each treatment group. Patients with multiple events for a given PT or SOC are counted only once for each PT and SOC. Only SOCs or PTs for which there are at least 10% of patients with an event in at least one treatment group OR at least 10 patients with an event overall and at least 1% of patients with an event in at least one treatment group in the overall safety population are considered. Further, only SOCs and PTs for which there is a significant treatment effect (p-value <0.05) in the overall safety population are presented. Events are sorted alphabetically by SOC and PT and then by ascending subgroup-by-treatment interaction p-value within each. MedDRA (version 22.0).
[1] OR (95% CI) based on a logistic regression model adjusting for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates.
[2] RR (95% CI) based on a Cochran-Mantel-Haenszel approach stratified by study.
[3] RD (95% CI) based on a Mantel-Haenszel approach stratified by study. 95% CIs are based on the approximation to the normal distribution using the Sato estimator for the standard error.
[4] P-value based on a Cochran-Mantel-Haenszel test stratified by study.
[5] Interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the OR (95% CI). Not reported subgroup levels are not included in estimation of the interaction p-value.
A continuity correction is applied in estimation of the OR, RR and p-value if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum. No continuity correction is applied in the estimation of the RD.
The reference group for the OR, RR and RD is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with >= 1 event; OR: Odds ratio; RR: Risk ratio; RD: Risk difference; CI: Confidence interval; NETA: Norethindrone acetate; SOC: System organ class; PT: Preferred term; NC: Not calculated.

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Table SAF.TEAE.SPT.POOL.6.1.S3: Frequent Treatment Emergent Adverse Events by System Organ Class and Preferred Term, by Subgroup (Safety Population)

Study: Pooled

System Organ Class: Skin and subcutaneous tissue disorders, Preferred Term: Any

Treatment	N	n (%)	OR[1] [95% CI]	RR[2] [95% CI]	RD[3] [95% CI]	p-value[4]	p-value (int)[5]
Uterine Volume at Baseline (cm3)							
< 300 cm3							
Relugolix+E2/NETA	148	16 (10.8)	3.01	2.79	0.07	0.0299	0.6104
Placebo	129	5 (3.9)	[1.07;8.45]	[1.05;7.41]	[0.01;0.13]		
>= 300 cm3							
Relugolix+E2/NETA	105	8 (7.6)	2.01	1.93	0.04	0.2290	
Placebo	127	5 (3.9)	[0.64;6.35]	[0.65;5.71]	[-0.02;0.10]		
Missing							
Relugolix+E2/NETA	1	0	NC	NC	NC	NC	
Placebo	0	0	[NC;NC]	[NC;NC]	[NC;NC]		

Post hoc analysis. The denominator for percentages is the number of patients in the safety population for each treatment group. Patients with multiple events for a given PT or SOC are counted only once for each PT and SOC. Only SOCs or PTs for which there are at least 10% of patients with an event in at least one treatment group OR at least 10 patients with an event overall and at least 1% of patients with an event in at least one treatment group in the overall safety population are considered. Further, only SOCs and PTs for which there is a significant treatment effect (p-value <0.05) in the overall safety population are presented. Events are sorted alphabetically by SOC and PT and then by ascending subgroup-by-treatment interaction p-value within each. MedDRA (version 22.0).
[1] OR (95% CI) based on a logistic regression model adjusting for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates.
[2] RR (95% CI) based on a Cochran-Mantel-Haenszel approach stratified by study.
[3] RD (95% CI) based on a Mantel-Haenszel approach stratified by study. 95% CIs are based on the approximation to the normal distribution using the Sato estimator for the standard error.
[4] P-value based on a Cochran-Mantel-Haenszel test stratified by study.
[5] Interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the OR (95% CI). Missing subgroup levels are not included in estimation of the interaction p-value.
A continuity correction is applied in estimation of the OR, RR and p-value if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum. No continuity correction is applied in the estimation of the RD.
The reference group for the OR, RR and RD is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with >= 1 event; OR: Odds ratio; RR: Risk ratio; RD: Risk difference; CI: Confidence interval; NETA: Norethindrone acetate; SOC: System organ class; PT: Preferred term; NC: Not calculated.

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Table SAF.TEAE.SPT.POOL.6.1.S5: Frequent Treatment Emergent Adverse Events by System Organ Class and Preferred Term, by Subgroup (Safety Population)

Study: Pooled

System Organ Class: Skin and subcutaneous tissue disorders, Preferred Term: Any

Treatment	N	n (%)	OR[1] [95% CI]	RR[2] [95% CI]	RD[3] [95% CI]	p-value[4]	p-value (int)[5]
MBL Volume at Baseline (mL)							
< 225 mL							0.7596
Relugolix+E2/NETA	164	15 (9.1)	2.36	2.23	0.05	0.0635	
Placebo	171	7 (4.1)	[0.94;5.94]	[0.93;5.35]	[-0.00;0.10]		
>= 225 mL							
Relugolix+E2/NETA	90	9 (10.0)	3.04	2.83	0.06	0.0926	
Placebo	85	3 (3.5)	[0.79;11.62]	[0.79;10.18]	[-0.01;0.14]		

Post hoc analysis. The denominator for percentages is the number of patients in the safety population for each treatment group. Patients with multiple events for a given PT or SOC are counted only once for each PT and SOC. Only SOCs or PTs for which there are at least 10% of patients with an event in at least one treatment group OR at least 10 patients with an event overall and at least 1% of patients with an event in at least one treatment group in the overall safety population are considered. Further, only SOCs and PTs for which there is a significant treatment effect (p-value <0.05) in the overall safety population are presented. Events are sorted alphabetically by SOC and PT and then by ascending subgroup-by-treatment interaction p-value within each. MedDRA (version 22.0).
[1] OR (95% CI) based on a logistic regression model adjusting for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates.
[2] RR (95% CI) based on a Cochran-Mantel-Haenszel approach stratified by study.
[3] RD (95% CI) based on a Mantel-Haenszel approach stratified by study. 95% CIs are based on the approximation to the normal distribution using the Sato estimator for the standard error.
[4] P-value based on a Cochran-Mantel-Haenszel test stratified by study.
[5] Interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the OR (95% CI).
A continuity correction is applied in estimation of the OR, RR and p-value if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum. No continuity correction is applied in the estimation of the RD.
The reference group for the OR, RR and RD is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with >= 1 event; OR: Odds ratio; RR: Risk ratio; RD: Risk difference; CI: Confidence interval; NETA: Norethindrone acetate; SOC: System organ class; PT: Preferred term.

SOURCE: \Studies\MYV\MYV102\Analysis\Prod\Progs\TFLs\Tab_SAF_AE_SOC_PT_S_BIN.SAS
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Table SAF.TEAE.SPT.POOL.6.2.S1: Frequent Treatment Emergent Adverse Events by System Organ Class and Preferred Term, by Subgroup (Safety Population)

Study: Pooled

System Organ Class: Skin and subcutaneous tissue disorders, Preferred Term: Alopecia

Treatment	**N**	**n (%)**	**OR[1] [95% CI]**	**RR[2] [95% CI]**	**RD[3] [95% CI]**	**p-value[4]**	**p-value (int)[5]**
Age (years)							
< 40 years							0.5060
Relugolix+E2/NETA	62	0	1.25 [0.08;20.45]	1.25 [0.08;19.54]	0.00	0.8757	
Placebo	78	0					
>= 40 years							
Relugolix+E2/NETA	192	9 (4.7)	3.66 [0.89;14.95]	3.53 [0.89;14.01]	0.04 [0.00;0.07]	0.0551	
Placebo	178	2 (1.1)					

Post hoc analysis. The denominator for percentages is the number of patients in the safety population for each treatment group. Patients with multiple events for a given PT or SOC are counted only once for each PT and SOC. Only SOCs or PTs for which there are at least 10% of patients with an event in at least one treatment group OR at least 10 patients with an event overall and at least 1% of patients with an event in at least one treatment group in the overall safety population are considered. Further, only SOCs and PTs for which there is a significant treatment effect (p-value <0.05) in the overall safety population are presented. Events are sorted alphabetically by SOC and PT and then by ascending subgroup-by-treatment interaction p-value within each. MedDRA (version 22.0).
[1] OR (95% CI) based on a logistic regression model adjusting for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates.
[2] RR (95% CI) based on a Cochran-Mantel-Haenszel approach stratified by study.
[3] RD (95% CI) based on a Mantel-Haenszel approach stratified by study. 95% CIs are based on the approximation to the normal distribution using the Sato estimator for the standard error.
[4] P-value based on a Cochran-Mantel-Haenszel test stratified by study.
[5] Interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the OR (95% CI).
A continuity correction is applied in estimation of the OR, RR and p-value if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum. No continuity correction is applied in the estimation of the RD.
The reference group for the OR, RR and RD is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with >= 1 event; OR: Odds ratio; RR: Risk ratio; RD: Risk difference; CI: Confidence interval; NETA: Norethindrone acetate; SOC: System organ class; PT: Preferred term.

SOURCE: \Studies\MYV\MYV102\Analysis\Prod\Progs\TFLs\Tab_SAF_AE_SOC_PT_S_BIN.SAS
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Table SAF.TEAE.SPT.POOL.6.2.S2: Frequent Treatment Emergent Adverse Events by System Organ Class and Preferred Term, by Subgroup (Safety Population)

Study: Pooled

System Organ Class: Skin and subcutaneous tissue disorders, Preferred Term: Alopecia

Treatment	N	n (%)	OR[1] [95% CI]	RR[2] [95% CI]	RD[3] [95% CI]	p-value[4]	p-value (int)[5]
BMI (kg/m2) at Baseline							
< 30							NC
Relugolix+E2/NETA	119	4 (3.4)	NC [NC;NC]	NC [NC;NC]	NC [NC;NC]	NC	
Placebo	115	1 (0.9)					
>= 30							
Relugolix+E2/NETA	134	5 (3.7)	NC [NC;NC]	NC [NC;NC]	NC [NC;NC]	NC	
Placebo	141	1 (0.7)					
Missing							
Relugolix+E2/NETA	1	0	NC [NC;NC]	NC [NC;NC]	NC [NC;NC]	NC	
Placebo	0	0					

Post hoc analysis. The denominator for percentages is the number of patients in the safety population for each treatment group. Patients with multiple events for a given PT or SOC are counted only once for each PT and SOC. Only SOCs or PTs for which there are at least 10% of patients with an event in at least one treatment group OR at least 10 patients with an event overall and at least 1% of patients with an event in at least one treatment group in the overall safety population are considered. Further, only SOCs and PTs for which there is a significant treatment effect (p-value <0.05) in the overall safety population are presented. Events are sorted alphabetically by SOC and PT and then by ascending subgroup-by-treatment interaction p-value within each. MedDRA (version 22.0).
[1] OR (95% CI) based on a logistic regression model adjusting for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates.
[2] RR (95% CI) based on a Cochran-Mantel-Haenszel approach stratified by study.
[3] RD (95% CI) based on a Mantel-Haenszel approach stratified by study. 95% CIs are based on the approximation to the normal distribution using the Sato estimator for the standard error.
[4] P-value based on a Cochran-Mantel-Haenszel test stratified by study.
[5] Interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the OR (95% CI). Missing subgroup levels are not included in estimation of the interaction p-value.
A continuity correction is applied in estimation of the OR, RR and p-value if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum. No continuity correction is applied in the estimation of the RD.
The reference group for the OR, RR and RD is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with >= 1 event; OR: Odds ratio; RR: Risk ratio; RD: Risk difference; CI: Confidence interval; NETA: Norethindrone acetate; SOC: System organ class; PT: Preferred term; NC: Not calculated.

SOURCE: \Studies\MYV\MYV102\Analysis\Prod\Progs\TFLs\Tab_SAF_AE_SOC_PT_S_BIN.SAS
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Table SAF.TEAE.SPT.POOL.6.2.S3: Frequent Treatment Emergent Adverse Events by System Organ Class and Preferred Term, by Subgroup (Safety Population)

Study: Pooled

System Organ Class: Skin and subcutaneous tissue disorders, Preferred Term: Alopecia

Treatment	N	n (%)	OR[1] [95% CI]	RR[2] [95% CI]	RD[3] [95% CI]	p-value[4]	p-value (int)[5]
Uterine Volume at Baseline (cm3)							
< 300 cm3							
Relugolix+E2/NETA	148	4 (2.7)	NC	NC	NC	NC	NC
Placebo	129	1 (0.8)	[NC;NC]	[NC;NC]	[NC;NC]		
>= 300 cm3							
Relugolix+E2/NETA	105	5 (4.8)	NC	NC	NC	NC	
Placebo	127	1 (0.8)	[NC;NC]	[NC;NC]	[NC;NC]		
Missing							
Relugolix+E2/NETA	1	0	NC	NC	NC	NC	
Placebo	0	0	[NC;NC]	[NC;NC]	[NC;NC]		

Post hoc analysis. The denominator for percentages is the number of patients in the safety population for each treatment group. Patients with multiple events for a given PT or SOC are counted only once for each PT and SOC. Only SOCs or PTs for which there are at least 10% of patients with an event in at least one treatment group OR at least 10 patients with an event overall and at least 1% of patients with an event in at least one treatment group in the overall safety population are considered. Further, only SOCs and PTs for which there is a significant treatment effect (p-value <0.05) in the overall safety population are presented. Events are sorted alphabetically by SOC and PT and then by ascending subgroup-by-treatment interaction p-value within each. MedDRA (version 22.0).
[1] OR (95% CI) based on a logistic regression model adjusting for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates.
[2] RR (95% CI) based on a Cochran-Mantel-Haenszel approach stratified by study.
[3] RD (95% CI) based on a Mantel-Haenszel approach stratified by study. 95% CIs are based on the approximation to the normal distribution using the Sato estimator for the standard error.
[4] P-value based on a Cochran-Mantel-Haenszel test stratified by study.
[5] Interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the OR (95% CI). Missing subgroup levels are not included in estimation of the interaction p-value.
A continuity correction is applied in estimation of the OR, RR and p-value if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum. No continuity correction is applied in the estimation of the RD.
The reference group for the OR, RR and RD is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with >= 1 event; OR: Odds ratio; RR: Risk ratio; RD: Risk difference; CI: Confidence interval; NETA: Norethindrone acetate; SOC: System organ class; PT: Preferred term; NC: Not calculated.

SOURCE: \Studies\MYV\MYV102\Analysis\Prod\Progs\TFLs\Tab_SAF_AE_SOC_PT_S_BIN.SAS
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Table SAF.TEAE.SPT.POOL.6.2.S4: Frequent Treatment Emergent Adverse Events by System Organ Class and Preferred Term, by Subgroup (Safety Population)

Study: Pooled

System Organ Class: Skin and subcutaneous tissue disorders, Preferred Term: Alopecia

Treatment	**N**	**n (%)**	**OR[1] [95% CI]**	**RR[2] [95% CI]**	**RD[3] [95% CI]**	**p-value[4]**	**p-value (int)[5]**
Maximum NRS Pain Score at Baseline							
< 4							
Relugolix+E2/NETA	73	3 (4.1)	NC	NC	NC	NC	NC
Placebo	62	1 (1.6)	[NC;NC]	[NC;NC]	[NC;NC]		
>= 4							
Relugolix+E2/NETA	178	6 (3.4)	NC	NC	NC	NC	
Placebo	190	1 (0.5)	[NC;NC]	[NC;NC]	[NC;NC]		
Missing							
Relugolix+E2/NETA	3	0	NC	NC	NC	NC	
Placebo	4	0	[NC;NC]	[NC;NC]	[NC;NC]		

Post hoc analysis. The denominator for percentages is the number of patients in the safety population for each treatment group. Patients with multiple events for a given PT or SOC are counted only once for each PT and SOC. Only SOCs or PTs for which there are at least 10% of patients with an event in at least one treatment group OR at least 10 patients with an event overall and at least 1% of patients with an event in at least one treatment group in the overall safety population are considered. Further, only SOCs and PTs for which there is a significant treatment effect (p-value <0.05) in the overall safety population are presented. Events are sorted alphabetically by SOC and PT and then by ascending subgroup-by-treatment interaction p-value within each. MedDRA (version 22.0).
[1] OR (95% CI) based on a logistic regression model adjusting for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates.
[2] RR (95% CI) based on a Cochran-Mantel-Haenszel approach stratified by study.
[3] RD (95% CI) based on a Mantel-Haenszel approach stratified by study. 95% CIs are based on the approximation to the normal distribution using the Sato estimator for the standard error.
[4] P-value based on a Cochran-Mantel-Haenszel test stratified by study.
[5] Interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the OR (95% CI). Missing subgroup levels are not included in estimation of the interaction p-value.
A continuity correction is applied in estimation of the OR, RR and p-value if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum. No continuity correction is applied in the estimation of the RD.
The reference group for the OR, RR and RD is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with >= 1 event; OR: Odds ratio; RR: Risk ratio; RD: Risk difference; CI: Confidence interval; NETA: Norethindrone acetate; SOC: System organ class; PT: Preferred term; NC: Not calculated.

SOURCE: \Studies\MYV\MYV102\Analysis\Prod\Progs\TFLs\Tab_SAF_AE_SOC_PT_S_BIN.SAS
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Table SAF.TEAE.SPT.POOL.6.2.S5: Frequent Treatment Emergent Adverse Events by System Organ Class and Preferred Term, by Subgroup (Safety Population)

Study: Pooled

System Organ Class: Skin and subcutaneous tissue disorders, Preferred Term: Alopecia

Treatment	**N**	**n (%)**	**OR[1] [95% CI]**	**RR[2] [95% CI]**	**RD[3] [95% CI]**	**p-value[4]**	**p-value (int)[5]**
MBL Volume at Baseline (mL)							
< 225 mL							
Relugolix+E2/NETA	164	4 (2.4)	NC [NC;NC]	NC [NC;NC]	NC [NC;NC]	NC	NC
Placebo	171	1 (0.6)					
>= 225 mL							
Relugolix+E2/NETA	90	5 (5.6)	NC [NC;NC]	NC [NC;NC]	NC [NC;NC]	NC	
Placebo	85	1 (1.2)					

Post hoc analysis. The denominator for percentages is the number of patients in the safety population for each treatment group. Patients with multiple events for a given PT or SOC are counted only once for each PT and SOC. Only SOCs or PTs for which there are at least 10% of patients with an event in at least one treatment group OR at least 10 patients with an event overall and at least 1% of patients with an event in at least one treatment group in the overall safety population are considered. Further, only SOCs and PTs for which there is a significant treatment effect (p-value <0.05) in the overall safety population are presented. Events are sorted alphabetically by SOC and PT and then by ascending subgroup-by-treatment interaction p-value within each. MedDRA (version 22.0).
[1] OR (95% CI) based on a logistic regression model adjusting for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates.
[2] RR (95% CI) based on a Cochran-Mantel-Haenszel approach stratified by study.
[3] RD (95% CI) based on a Mantel-Haenszel approach stratified by study. 95% CIs are based on the approximation to the normal distribution using the Sato estimator for the standard error.
[4] P-value based on a Cochran-Mantel-Haenszel test stratified by study.
[5] Interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the OR (95% CI).
A continuity correction is applied in estimation of the OR, RR and p-value if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum. No continuity correction is applied in the estimation of the RD.
The reference group for the OR, RR and RD is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with >= 1 event; OR: Odds ratio; RR: Risk ratio; RD: Risk difference; CI: Confidence interval; NETA: Norethindrone acetate; SOC: System organ class; PT: Preferred term; NC: Not calculated.

SOURCE: \Studies\MYV\MYV102\Analysis\Prod\Progs\TFLs\Tab_SAF_AE_SOC_PT_S_BIN.SAS
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Table SAF.TEAE.SPT.POOL.6.2.S6: Frequent Treatment Emergent Adverse Events by System Organ Class and Preferred Term, by Subgroup (Safety Population)

Study: Pooled

System Organ Class: Skin and subcutaneous tissue disorders, Preferred Term: Alopecia

Treatment	**N**	**n (%)**	**OR[1] [95% CI]**	**RR[2] [95% CI]**	**RD[3] [95% CI]**	**p-value[4]**	**p-value (int)[5]**
Geographic Region I							
North America							
Relugolix+E2/NETA	192	5 (2.6)	NC	NC	NC	NC	NC
Placebo	194	2 (1.0)	[NC;NC]	[NC;NC]	[NC;NC]		
Rest of World							
Relugolix+E2/NETA	62	4 (6.5)	NC	NC	NC	NC	
Placebo	62	0	[NC;NC]	[NC;NC]	[NC;NC]		

Post hoc analysis. The denominator for percentages is the number of patients in the safety population for each treatment group. Patients with multiple events for a given PT or SOC are counted only once for each PT and SOC. Only SOCs or PTs for which there are at least 10% of patients with an event in at least one treatment group OR at least 10 patients with an event overall and at least 1% of patients with an event in at least one treatment group in the overall safety population are considered. Further, only SOCs and PTs for which there is a significant treatment effect (p-value <0.05) in the overall safety population are presented. Events are sorted alphabetically by SOC and PT and then by ascending subgroup-by-treatment interaction p-value within each. MedDRA (version 22.0).
[1] OR (95% CI) based on a logistic regression model adjusting for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates.
[2] RR (95% CI) based on a Cochran-Mantel-Haenszel approach stratified by study.
[3] RD (95% CI) based on a Mantel-Haenszel approach stratified by study. 95% CIs are based on the approximation to the normal distribution using the Sato estimator for the standard error.
[4] P-value based on a Cochran-Mantel-Haenszel test stratified by study.
[5] Interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the OR (95% CI).
A continuity correction is applied in estimation of the OR, RR and p-value if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum. No continuity correction is applied in the estimation of the RD.
The reference group for the OR, RR and RD is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with >= 1 event; OR: Odds ratio; RR: Risk ratio; RD: Risk difference; CI: Confidence interval; NETA: Norethindrone acetate; SOC: System organ class; PT: Preferred term; NC: Not calculated.

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Table SAF.TEAE.SPT.POOL.6.2.S7: Frequent Treatment Emergent Adverse Events by System Organ Class and Preferred Term, by Subgroup (Safety Population)

Study: Pooled

System Organ Class: Skin and subcutaneous tissue disorders, Preferred Term: Alopecia

Treatment	N	n (%)	OR[1] [95% CI]	RR[2] [95% CI]	RD[3] [95% CI]	p-value[4]	p-value (int)[5]
Geographic Region II							
Europe							
Relugolix+E2/NETA	41	3 (7.3)	NC	NC	NC	NC	NC
Placebo	42	0	[NC;NC]	[NC;NC]	[NC;NC]		
Rest of World (including the US)							
Relugolix+E2/NETA	213	6 (2.8)	NC	NC	NC	NC	
Placebo	214	2 (0.9)	[NC;NC]	[NC;NC]	[NC;NC]		

Post hoc analysis. The denominator for percentages is the number of patients in the safety population for each treatment group. Patients with multiple events for a given PT or SOC are counted only once for each PT and SOC. Only SOCs or PTs for which there are at least 10% of patients with an event in at least one treatment group OR at least 10 patients with an event overall and at least 1% of patients with an event in at least one treatment group in the overall safety population are considered. Further, only SOCs and PTs for which there is a significant treatment effect (p-value <0.05) in the overall safety population are presented. Events are sorted alphabetically by SOC and PT and then by ascending subgroup-by-treatment interaction p-value within each. MedDRA (version 22.0).
[1] OR (95% CI) based on a logistic regression model adjusting for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates.
[2] RR (95% CI) based on a Cochran-Mantel-Haenszel approach stratified by study.
[3] RD (95% CI) based on a Mantel-Haenszel approach stratified by study. 95% CIs are based on the approximation to the normal distribution using the Sato estimator for the standard error.
[4] P-value based on a Cochran-Mantel-Haenszel test stratified by study.
[5] Interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the OR (95% CI).
A continuity correction is applied in estimation of the OR, RR and p-value if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum. No continuity correction is applied in the estimation of the RD.
The reference group for the OR, RR and RD is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with >= 1 event; OR: Odds ratio; RR: Risk ratio; RD: Risk difference; CI: Confidence interval; NETA: Norethindrone acetate; SOC: System organ class; PT: Preferred term; NC: Not calculated.

SOURCE: \Studies\MYV\MYV102\Analysis\Prod\Progs\TFLs\Tab_SAF_AE_SOC_PT_S_BIN.SAS
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Table SAF.TEAE.SPT.POOL.6.2.S8: Frequent Treatment Emergent Adverse Events by System Organ Class and Preferred Term, by Subgroup (Safety Population)

Study: Pooled

System Organ Class: Skin and subcutaneous tissue disorders, Preferred Term: Alopecia

Treatment	**N**	**n (%)**	**OR[1] [95% CI]**	**RR[2] [95% CI]**	**RD[3] [95% CI]**	**p-value[4]**	**p-value (int)[5]**
Ethnicity							
Hispanic or Latino							NC
Relugolix+E2/NETA	53	4 (7.5)	NC	NC	NC	NC	
Placebo	55	2 (3.6)	[NC;NC]	[NC;NC]	[NC;NC]		
Not Hispanic or Latino							
Relugolix+E2/NETA	197	5 (2.5)	NC	NC	NC	NC	
Placebo	199	0	[NC;NC]	[NC;NC]	[NC;NC]		
Not reported							
Relugolix+E2/NETA	4	0	NC	NC	NC	NC	
Placebo	2	0	[NC;NC]	[NC;NC]	[NC;NC]		

Post hoc analysis. The denominator for percentages is the number of patients in the safety population for each treatment group. Patients with multiple events for a given PT or SOC are counted only once for each PT and SOC. Only SOCs or PTs for which there are at least 10% of patients with an event in at least one treatment group OR at least 10 patients with an event overall and at least 1% of patients with an event in at least one treatment group in the overall safety population are considered. Further, only SOCs and PTs for which there is a significant treatment effect (p-value <0.05) in the overall safety population are presented. Events are sorted alphabetically by SOC and PT and then by ascending subgroup-by-treatment interaction p-value within each. MedDRA (version 22.0).
[1] OR (95% CI) based on a logistic regression model adjusting for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates.
[2] RR (95% CI) based on a Cochran-Mantel-Haenszel approach stratified by study.
[3] RD (95% CI) based on a Mantel-Haenszel approach stratified by study. 95% CIs are based on the approximation to the normal distribution using the Sato estimator for the standard error.
[4] P-value based on a Cochran-Mantel-Haenszel test stratified by study.
[5] Interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the OR (95% CI). Not reported subgroup levels are not included in estimation of the interaction p-value.
A continuity correction is applied in estimation of the OR, RR and p-value if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum. No continuity correction is applied in the estimation of the RD.
The reference group for the OR, RR and RD is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with >= 1 event; OR: Odds ratio; RR: Risk ratio; RD: Risk difference; CI: Confidence interval; NETA: Norethindrone acetate; SOC: System organ class; PT: Preferred term; NC: Not calculated.

SOURCE: \Studies\MYV\MYV102\Analysis\Prod\Progs\TFLs\Tab_SAF_AE_SOC_PT_S_BIN.SAS
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Table SAF.TEAE.SPT.POOL.6.2.S9: Frequent Treatment Emergent Adverse Events by System Organ Class and Preferred Term, by Subgroup (Safety Population)

Study: Pooled

System Organ Class: Skin and subcutaneous tissue disorders, Preferred Term: Alopecia

Treatment	N	n (%)	OR[1] [95% CI]	RR[2] [95% CI]	RD[3] [95% CI]	p-value[4]	p-value (int)[5]
Race							
Black/African American							NC
Relugolix+E2/NETA	122	2 (1.6)	NC	NC	NC	NC	
Placebo	141	0	[NC;NC]	[NC;NC]	[NC;NC]		
White							
Relugolix+E2/NETA	123	5 (4.1)	NC	NC	NC	NC	
Placebo	105	1 (1.0)	[NC;NC]	[NC;NC]	[NC;NC]		
Asian							
Relugolix+E2/NETA	1	0	NC	NC	NC	NC	
Placebo	3	0	[NC;NC]	[NC;NC]	[NC;NC]		
Others							
Relugolix+E2/NETA	5	2 (40.0)	NC	NC	NC	NC	
Placebo	6	1 (16.7)	[NC;NC]	[NC;NC]	[NC;NC]		
Not reported							
Relugolix+E2/NETA	3	0	NC	NC	NC	NC	
Placebo	1	0	[NC;NC]	[NC;NC]	[NC;NC]		

Post hoc analysis. The denominator for percentages is the number of patients in the safety population for each treatment group. Patients with multiple events for a given PT or SOC are counted only once for each PT and SOC. Only SOCs or PTs for which there are at least 10% of patients with an event in at least one treatment group OR at least 10 patients with an event overall and at least 1% of patients with an event in at least one treatment group in the overall safety population are considered. Further, only SOCs and PTs for which there is a significant treatment effect (p-value <0.05) in the overall safety population are presented. Events are sorted alphabetically by SOC and PT and then by ascending subgroup-by-treatment interaction p-value within each. MedDRA (version 22.0).
[1] OR (95% CI) based on a logistic regression model adjusting for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates.
[2] RR (95% CI) based on a Cochran-Mantel-Haenszel approach stratified by study.
[3] RD (95% CI) based on a Mantel-Haenszel approach stratified by study. 95% CIs are based on the approximation to the normal distribution using the Sato estimator for the standard error.
[4] P-value based on a Cochran-Mantel-Haenszel test stratified by study.
[5] Interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the OR (95% CI). Not reported subgroup levels are not included in estimation of the interaction p-value.
A continuity correction is applied in estimation of the OR, RR and p-value if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum. No continuity correction is applied in the estimation of the RD.
The reference group for the OR, RR and RD is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with >= 1 event; OR: Odds ratio; RR: Risk ratio; RD: Risk difference; CI: Confidence interval; NETA: Norethindrone acetate; SOC: System organ class; PT: Preferred term; NC: Not calculated.

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1.3.3 Frequent Treatment Emergent Adverse Events by System Organ Class and Preferred Term, by Subgroup (Safety Population)

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Table SAF.TEAE.SPT.POOL.7.1.S2: Frequent Treatment Emergent Adverse Events by System Organ Class and Preferred Term, by Subgroup (Safety Population)

Study: Pooled

System Organ Class: Vascular disorders, Preferred Term: Hypertension

Treatment	N	n (%)	OR[1] [95% CI]	RR[2] [95% CI]	RD[3] [95% CI]	p-value[4]	p-value (int)[5]
BMI (kg/m2) at Baseline							
< 30							
Relugolix+E2/NETA	119	4 (3.4)	5.03	4.74	0.03	0.1156	0.4518
Placebo	115	0	[0.58;43.76]	[0.55;40.65]	[0.00;0.07]		
>= 30							
Relugolix+E2/NETA	134	8 (6.0)	2.05	1.96	0.03	0.2258	
Placebo	141	4 (2.8)	[0.64;6.59]	[0.65;5.95]	[-0.02;0.08]		
Missing							
Relugolix+E2/NETA	1	0	NC	NC	NC	NC	
Placebo	0	0	[NC;NC]	[NC;NC]	[NC;NC]		

Post hoc analysis. The denominator for percentages is the number of patients in the safety population for each treatment group. Patients with multiple events for a given PT or SOC are counted only once for each PT and SOC. Only SOCs or PTs for which there are at least 10% of patients with an event in at least one treatment group OR at least 10 patients with an event overall and at least 1% of patients with an event in at least one treatment group in the overall safety population are considered. Further, only SOCs and PTs for which there is a significant treatment effect (p-value <0.05) in the overall safety population are presented. Events are sorted alphabetically by SOC and PT and then by ascending subgroup-by-treatment interaction p-value within each. MedDRA (version 22.0).
[1] OR (95% CI) based on a logistic regression model adjusting for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates.
[2] RR (95% CI) based on a Cochran-Mantel-Haenszel approach stratified by study.
[3] RD (95% CI) based on a Mantel-Haenszel approach stratified by study. 95% CIs are based on the approximation to the normal distribution using the Sato estimator for the standard error.
[4] P-value based on a Cochran-Mantel-Haenszel test stratified by study.
[5] Interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the OR (95% CI). Missing subgroup levels are not included in estimation of the interaction p-value.
A continuity correction is applied in estimation of the OR, RR and p-value if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum. No continuity correction is applied in the estimation of the RD.
The reference group for the OR, RR and RD is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with >= 1 event; OR: Odds ratio; RR: Risk ratio; RD: Risk difference; CI: Confidence interval; NETA: Norethindrone acetate; SOC: System organ class; PT: Preferred term; NC: Not calculated.

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Table SAF.TEAE.SPT.POOL.7.1.S4: Frequent Treatment Emergent Adverse Events by System Organ Class and Preferred Term, by Subgroup (Safety Population)

Study: Pooled

System Organ Class: Vascular disorders, Preferred Term: Hypertension

Treatment	**N**	**n (%)**	**OR[1] [95% CI]**	**RR[2] [95% CI]**	**RD[3] [95% CI]**	**p-value[4]**	**p-value (int)[5]**
Maximum NRS Pain Score at Baseline							
< 4							
Relugolix+E2/NETA	73	1 (1.4)	1.74	1.65	0.01	0.6822	0.7241
Placebo	62	0	[0.15;19.67]	[0.15;18.62]	[-0.01;0.04]		
>= 4							
Relugolix+E2/NETA	178	11 (6.2)	2.84	2.68	0.04	0.0565	
Placebo	190	4 (2.1)	[0.94;8.61]	[0.93;7.73]	[-0.00;0.08]		
Missing							
Relugolix+E2/NETA	3	0	NC	NC	NC	NC	
Placebo	4	0	[NC;NC]	[NC;NC]	[NC;NC]		

Post hoc analysis. The denominator for percentages is the number of patients in the safety population for each treatment group. Patients with multiple events for a given PT or SOC are counted only once for each PT and SOC. Only SOCs or PTs for which there are at least 10% of patients with an event in at least one treatment group OR at least 10 patients with an event overall and at least 1% of patients with an event in at least one treatment group in the overall safety population are considered. Further, only SOCs and PTs for which there is a significant treatment effect (p-value <0.05) in the overall safety population are presented. Events are sorted alphabetically by SOC and PT and then by ascending subgroup-by-treatment interaction p-value within each. MedDRA (version 22.0).
[1] OR (95% CI) based on a logistic regression model adjusting for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates.
[2] RR (95% CI) based on a Cochran-Mantel-Haenszel approach stratified by study.
[3] RD (95% CI) based on a Mantel-Haenszel approach stratified by study. 95% CIs are based on the approximation to the normal distribution using the Sato estimator for the standard error.
[4] P-value based on a Cochran-Mantel-Haenszel test stratified by study.
[5] Interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the OR (95% CI). Missing subgroup levels are not included in estimation of the interaction p-value.
A continuity correction is applied in estimation of the OR, RR and p-value if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum. No continuity correction is applied in the estimation of the RD.
The reference group for the OR, RR and RD is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with >= 1 event; OR: Odds ratio; RR: Risk ratio; RD: Risk difference; CI: Confidence interval; NETA: Norethindrone acetate; SOC: System organ class; PT: Preferred term; NC: Not calculated.

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Table SAF.TEAE.SPT.POOL.7.1.S8: Frequent Treatment Emergent Adverse Events by System Organ Class and Preferred Term, by Subgroup (Safety Population)

Study: Pooled

System Organ Class: Vascular disorders, Preferred Term: Hypertension

Treatment	**N**	**n (%)**	**OR[1] [95% CI]**	**RR[2] [95% CI]**	**RD[3] [95% CI]**	**p-value[4]**	**p-value (int)[5]**
Ethnicity							
Hispanic or Latino							
Relugolix+E2/NETA	53	3 (5.7)	2.23	2.01	0.03	0.4571	0.8338
Placebo	55	1 (1.8)	[0.39;12.85]	[0.30;13.31]	[-0.04;0.10]		
Not Hispanic or Latino							
Relugolix+E2/NETA	197	9 (4.6)	2.81	2.64	0.03	0.0951	
Placebo	199	3 (1.5)	[0.81;9.73]	[0.81;8.67]	[-0.00;0.06]		
Not reported							
Relugolix+E2/NETA	4	0	NC	NC	NC	NC	
Placebo	2	0	[NC;NC]	[NC;NC]	[NC;NC]		

Post hoc analysis. The denominator for percentages is the number of patients in the safety population for each treatment group. Patients with multiple events for a given PT or SOC are counted only once for each PT and SOC. Only SOCs or PTs for which there are at least 10% of patients with an event in at least one treatment group OR at least 10 patients with an event overall and at least 1% of patients with an event in at least one treatment group in the overall safety population are considered. Further, only SOCs and PTs for which there is a significant treatment effect (p-value <0.05) in the overall safety population are presented. Events are sorted alphabetically by SOC and PT and then by ascending subgroup-by-treatment interaction p-value within each. MedDRA (version 22.0).
[1] OR (95% CI) based on a logistic regression model adjusting for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates.
[2] RR (95% CI) based on a Cochran-Mantel-Haenszel approach stratified by study.
[3] RD (95% CI) based on a Mantel-Haenszel approach stratified by study. 95% CIs are based on the approximation to the normal distribution using the Sato estimator for the standard error.
[4] P-value based on a Cochran-Mantel-Haenszel test stratified by study.
[5] Interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the OR (95% CI). Not reported subgroup levels are not included in estimation of the interaction p-value.
A continuity correction is applied in estimation of the OR, RR and p-value if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum. No continuity correction is applied in the estimation of the RD.
The reference group for the OR, RR and RD is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with >= 1 event; OR: Odds ratio; RR: Risk ratio; RD: Risk difference; CI: Confidence interval; NETA: Norethindrone acetate; SOC: System organ class; PT: Preferred term; NC: Not calculated.

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Table SAF.TEAE.SPT.POOL.7.1.S6: Frequent Treatment Emergent Adverse Events by System Organ Class and Preferred Term, by Subgroup (Safety Population)

Study: Pooled

System Organ Class: Vascular disorders, Preferred Term: Hypertension

Treatment	**N**	**n (%)**	**OR[1] [95% CI]**	**RR[2] [95% CI]**	**RD[3] [95% CI]**	**p-value[4]**	**p-value (int)[5]**
Geographic Region I							
North America							
Relugolix+E2/NETA	192	8 (4.2)	2.52	2.46	0.03	0.1376	0.8452
Placebo	194	3 (1.5)	[0.71;8.90]	[0.72;8.44]	[-0.01;0.06]		
Rest of World							
Relugolix+E2/NETA	62	4 (6.5)	3.15	2.99	0.05	0.2169	
Placebo	62	1 (1.6)	[0.48;20.72]	[0.48;18.68]	[-0.02;0.12]		

Post hoc analysis. The denominator for percentages is the number of patients in the safety population for each treatment group. Patients with multiple events for a given PT or SOC are counted only once for each PT and SOC. Only SOCs or PTs for which there are at least 10% of patients with an event in at least one treatment group OR at least 10 patients with an event overall and at least 1% of patients with an event in at least one treatment group in the overall safety population are considered. Further, only SOCs and PTs for which there is a significant treatment effect (p-value <0.05) in the overall safety population are presented. Events are sorted alphabetically by SOC and PT and then by ascending subgroup-by-treatment interaction p-value within each. MedDRA (version 22.0).
[1] OR (95% CI) based on a logistic regression model adjusting for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates.
[2] RR (95% CI) based on a Cochran-Mantel-Haenszel approach stratified by study.
[3] RD (95% CI) based on a Mantel-Haenszel approach stratified by study. 95% CIs are based on the approximation to the normal distribution using the Sato estimator for the standard error.
[4] P-value based on a Cochran-Mantel-Haenszel test stratified by study.
[5] Interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the OR (95% CI).
A continuity correction is applied in estimation of the OR, RR and p-value if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum. No continuity correction is applied in the estimation of the RD.
The reference group for the OR, RR and RD is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with >= 1 event; OR: Odds ratio; RR: Risk ratio; RD: Risk difference; CI: Confidence interval; NETA: Norethindrone acetate; SOC: System organ class; PT: Preferred term.

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Table SAF.TEAE.SPT.POOL.7.1.S1: Frequent Treatment Emergent Adverse Events by System Organ Class and Preferred Term, by Subgroup (Safety Population)

Study: Pooled

System Organ Class: Vascular disorders, Preferred Term: Hypertension

Treatment	**N**	**n (%)**	**OR[1] [95% CI]**	**RR[2] [95% CI]**	**RD[3] [95% CI]**	**p-value[4]**	**p-value (int)[5]**
Age (years)							
< 40 years							
Relugolix+E2/NETA	62	3 (4.8)	3.04	2.92	0.04	0.2484	0.8926
Placebo	78	1 (1.3)	[0.44;21.21]	[0.43;19.62]	[-0.02;0.09]		
>= 40 years							
Relugolix+E2/NETA	192	9 (4.7)	2.60	2.52	0.03	0.1205	
Placebo	178	3 (1.7)	[0.75;9.00]	[0.75;8.43]	[-0.01;0.07]		

Post hoc analysis. The denominator for percentages is the number of patients in the safety population for each treatment group. Patients with multiple events for a given PT or SOC are counted only once for each PT and SOC. Only SOCs or PTs for which there are at least 10% of patients with an event in at least one treatment group OR at least 10 patients with an event overall and at least 1% of patients with an event in at least one treatment group in the overall safety population are considered. Further, only SOCs and PTs for which there is a significant treatment effect (p-value <0.05) in the overall safety population are presented. Events are sorted alphabetically by SOC and PT and then by ascending subgroup-by-treatment interaction p-value within each. MedDRA (version 22.0).
[1] OR (95% CI) based on a logistic regression model adjusting for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates.
[2] RR (95% CI) based on a Cochran-Mantel-Haenszel approach stratified by study.
[3] RD (95% CI) based on a Mantel-Haenszel approach stratified by study. 95% CIs are based on the approximation to the normal distribution using the Sato estimator for the standard error.
[4] P-value based on a Cochran-Mantel-Haenszel test stratified by study.
[5] Interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the OR (95% CI).
A continuity correction is applied in estimation of the OR, RR and p-value if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum. No continuity correction is applied in the estimation of the RD.
The reference group for the OR, RR and RD is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with >= 1 event; OR: Odds ratio; RR: Risk ratio; RD: Risk difference; CI: Confidence interval; NETA: Norethindrone acetate; SOC: System organ class; PT: Preferred term.

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Table SAF.TEAE.SPT.POOL.7.1.S7: Frequent Treatment Emergent Adverse Events by System Organ Class and Preferred Term, by Subgroup (Safety Population)

Study: Pooled

System Organ Class: Vascular disorders, Preferred Term: Hypertension

Treatment	**N**	**n (%)**	**OR[1] [95% CI]**	**RR[2] [95% CI]**	**RD[3] [95% CI]**	**p-value[4]**	**p-value (int)[5]**
Geographic Region II							
Europe							
Relugolix+E2/NETA	41	3 (7.3)	2.50 [0.35;17.84]	2.35 [0.38;14.58]	0.05 [-0.05;0.14]	0.3475	0.9226
Placebo	42	1 (2.4)					
Rest of World (including the US)							
Relugolix+E2/NETA	213	9 (4.2)	2.81 [0.81;9.72]	2.76 [0.81;9.37]	0.03 [-0.00;0.06]	0.0894	
Placebo	214	3 (1.4)					

Post hoc analysis. The denominator for percentages is the number of patients in the safety population for each treatment group. Patients with multiple events for a given PT or SOC are counted only once for each PT and SOC. Only SOCs or PTs for which there are at least 10% of patients with an event in at least one treatment group OR at least 10 patients with an event overall and at least 1% of patients with an event in at least one treatment group in the overall safety population are considered. Further, only SOCs and PTs for which there is a significant treatment effect (p-value <0.05) in the overall safety population are presented. Events are sorted alphabetically by SOC and PT and then by ascending subgroup-by-treatment interaction p-value within each. MedDRA (version 22.0).
[1] OR (95% CI) based on a logistic regression model adjusting for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates.
[2] RR (95% CI) based on a Cochran-Mantel-Haenszel approach stratified by study.
[3] RD (95% CI) based on a Mantel-Haenszel approach stratified by study. 95% CIs are based on the approximation to the normal distribution using the Sato estimator for the standard error.
[4] P-value based on a Cochran-Mantel-Haenszel test stratified by study.
[5] Interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the OR (95% CI).
A continuity correction is applied in estimation of the OR, RR and p-value if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum. No continuity correction is applied in the estimation of the RD.
The reference group for the OR, RR and RD is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with >= 1 event; OR: Odds ratio; RR: Risk ratio; RD: Risk difference; CI: Confidence interval; NETA: Norethindrone acetate; SOC: System organ class; PT: Preferred term.

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Table SAF.TEAE.SPT.POOL.7.1.S9: Frequent Treatment Emergent Adverse Events by System Organ Class and Preferred Term, by Subgroup (Safety Population)

Study: Pooled

System Organ Class: Vascular disorders, Preferred Term: Hypertension

Treatment	N	n (%)	OR[1] [95% CI]	RR[2] [95% CI]	RD[3] [95% CI]	p-value[4]	p-value (int)[5]
Race							
Black/African American							
Relugolix+E2/NETA	122	7 (5.7)	2.57	2.49	0.04	0.1383	0.9975
Placebo	141	3 (2.1)	[0.71;9.37]	[0.71;8.68]	[-0.01;0.08]		
White							
Relugolix+E2/NETA	123	4 (3.3)	2.62	2.57	0.02	0.2912	
Placebo	105	1 (1.0)	[0.41;16.95]	[0.42;15.90]	[-0.01;0.06]		
Asian							
Relugolix+E2/NETA	1	0	NC	NC	NC	NC	
Placebo	3	0	[NC;NC]	[NC;NC]	[NC;NC]		
Others							
Relugolix+E2/NETA	5	1 (20.0)	2.86	2.02	0.16	0.5509	
Placebo	6	0	[0.20;41.77]	[0.22;18.83]	[-0.20;0.51]		
Not reported							
Relugolix+E2/NETA	3	0	NC	NC	NC	NC	
Placebo	1	0	[NC;NC]	[NC;NC]	[NC;NC]		

Post hoc analysis. The denominator for percentages is the number of patients in the safety population for each treatment group. Patients with multiple events for a given PT or SOC are counted only once for each PT and SOC. Only SOCs or PTs for which there are at least 10% of patients with an event in at least one treatment group OR at least 10 patients with an event overall and at least 1% of patients with an event in at least one treatment group in the overall safety population are considered. Further, only SOCs and PTs for which there is a significant treatment effect (p-value <0.05) in the overall safety population are presented. Events are sorted alphabetically by SOC and PT and then by ascending subgroup-by-treatment interaction p-value within each. MedDRA (version 22.0).
[1] OR (95% CI) based on a logistic regression model adjusting for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates.
[2] RR (95% CI) based on a Cochran-Mantel-Haenszel approach stratified by study.
[3] RD (95% CI) based on a Mantel-Haenszel approach stratified by study. 95% CIs are based on the approximation to the normal distribution using the Sato estimator for the standard error.
[4] P-value based on a Cochran-Mantel-Haenszel test stratified by study.
[5] Interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the OR (95% CI). Not reported subgroup levels are not included in estimation of the interaction p-value.
A continuity correction is applied in estimation of the OR, RR and p-value if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum. No continuity correction is applied in the estimation of the RD.
The reference group for the OR, RR and RD is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with >= 1 event; OR: Odds ratio; RR: Risk ratio; RD: Risk difference; CI: Confidence interval; NETA: Norethindrone acetate; SOC: System organ class; PT: Preferred term; NC: Not calculated.

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Table SAF.TEAE.SPT.POOL.7.1.S3: Frequent Treatment Emergent Adverse Events by System Organ Class and Preferred Term, by Subgroup (Safety Population)

Study: Pooled

System Organ Class: Vascular disorders, Preferred Term: Hypertension

Treatment	N	n (%)	OR[1] [95% CI]	RR[2] [95% CI]	RD[3] [95% CI]	p-value[4]	p-value (int)[5]
Uterine Volume at Baseline (cm3)							
< 300 cm3							
Relugolix+E2/NETA	148	5 (3.4)	NC	NC	NC	NC	NC
Placebo	129	2 (1.6)	[NC;NC]	[NC;NC]	[NC;NC]		
>= 300 cm3							
Relugolix+E2/NETA	105	7 (6.7)	NC	NC	NC	NC	
Placebo	127	2 (1.6)	[NC;NC]	[NC;NC]	[NC;NC]		
Missing							
Relugolix+E2/NETA	1	0	NC	NC	NC	NC	
Placebo	0	0	[NC;NC]	[NC;NC]	[NC;NC]		

Post hoc analysis. The denominator for percentages is the number of patients in the safety population for each treatment group. Patients with multiple events for a given PT or SOC are counted only once for each PT and SOC. Only SOCs or PTs for which there are at least 10% of patients with an event in at least one treatment group OR at least 10 patients with an event overall and at least 1% of patients with an event in at least one treatment group in the overall safety population are considered. Further, only SOCs and PTs for which there is a significant treatment effect (p-value <0.05) in the overall safety population are presented. Events are sorted alphabetically by SOC and PT and then by ascending subgroup-by-treatment interaction p-value within each. MedDRA (version 22.0).
[1] OR (95% CI) based on a logistic regression model adjusting for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates.
[2] RR (95% CI) based on a Cochran-Mantel-Haenszel approach stratified by study.
[3] RD (95% CI) based on a Mantel-Haenszel approach stratified by study. 95% CIs are based on the approximation to the normal distribution using the Sato estimator for the standard error.
[4] P-value based on a Cochran-Mantel-Haenszel test stratified by study.
[5] Interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the OR (95% CI). Missing subgroup levels are not included in estimation of the interaction p-value.
A continuity correction is applied in estimation of the OR, RR and p-value if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum. No continuity correction is applied in the estimation of the RD.
The reference group for the OR, RR and RD is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with >= 1 event; OR: Odds ratio; RR: Risk ratio; RD: Risk difference; CI: Confidence interval; NETA: Norethindrone acetate; SOC: System organ class; PT: Preferred term; NC: Not calculated.

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Table SAF.TEAE.SPT.POOL.7.1.S5: Frequent Treatment Emergent Adverse Events by System Organ Class and Preferred Term, by Subgroup (Safety Population)

Study: Pooled

System Organ Class: Vascular disorders, Preferred Term: Hypertension

Treatment	**N**	**n (%)**	**OR[1] [95% CI]**	**RR[2] [95% CI]**	**RD[3] [95% CI]**	**p-value[4]**	**p-value (int)[5]**
MBL Volume at Baseline (mL)							
< 225 mL							
Relugolix+E2/NETA	164	6 (3.7)	NC [NC;NC]	NC [NC;NC]	NC [NC;NC]	NC	NC
Placebo	171	2 (1.2)					
>= 225 mL							
Relugolix+E2/NETA	90	6 (6.7)	NC [NC;NC]	NC [NC;NC]	NC [NC;NC]	NC	
Placebo	85	2 (2.4)					

Post hoc analysis. The denominator for percentages is the number of patients in the safety population for each treatment group. Patients with multiple events for a given PT or SOC are counted only once for each PT and SOC. Only SOCs or PTs for which there are at least 10% of patients with an event in at least one treatment group OR at least 10 patients with an event overall and at least 1% of patients with an event in at least one treatment group in the overall safety population are considered. Further, only SOCs and PTs for which there is a significant treatment effect (p-value <0.05) in the overall safety population are presented. Events are sorted alphabetically by SOC and PT and then by ascending subgroup-by-treatment interaction p-value within each. MedDRA (version 22.0).
[1] OR (95% CI) based on a logistic regression model adjusting for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates.
[2] RR (95% CI) based on a Cochran-Mantel-Haenszel approach stratified by study.
[3] RD (95% CI) based on a Mantel-Haenszel approach stratified by study. 95% CIs are based on the approximation to the normal distribution using the Sato estimator for the standard error.
[4] P-value based on a Cochran-Mantel-Haenszel test stratified by study.
[5] Interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the OR (95% CI).
A continuity correction is applied in estimation of the OR, RR and p-value if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum. No continuity correction is applied in the estimation of the RD.
The reference group for the OR, RR and RD is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with >= 1 event; OR: Odds ratio; RR: Risk ratio; RD: Risk difference; CI: Confidence interval; NETA: Norethindrone acetate; SOC: System organ class; PT: Preferred term; NC: Not calculated.

SOURCE: \Studies\MYV\MYV102\Analysis\Prod\Progs\TFLs\Tab_SAF_AE_SOC_PT_S_BIN.SAS
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1.3.4 Proportion of Patients With at Least One Serious Treatment Emergent Adverse Event by Subgroup (Safety Population)

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Table SAF.STEAE.SAF.POOL.S2: Proportion of Patients With at Least One Serious Treatment Emergent Adverse Event by Subgroup (Safety Population)

Study: Pooled

Treatment	N	n (%)	OR[1] [95% CI]	RR[2] [95% CI]	RD[3] [95% CI]	p-value[4]	p-value (int)[5]
BMI (kg/m2) at Baseline							
< 30							
Relugolix+E2/NETA	119	1 (0.8)	0.56	0.58	-0.01	0.5899	0.3110
Placebo	115	2 (1.7)	[0.07;4.35]	[0.08;4.38]	[-0.04;0.02]		
>= 30							
Relugolix+E2/NETA	134	7 (5.2)	1.90	1.85	0.02	0.3064	
Placebo	141	4 (2.8)	[0.54;6.67]	[0.56;6.13]	[-0.02;0.07]		
Missing							
Relugolix+E2/NETA	1	0	NC	NC	NC	NC	
Placebo	0	0	[NC;NC]	[NC;NC]	[NC;NC]		

Post hoc analysis. The denominator for percentages is the number of patients in the safety population for each treatment group. Patients with multiple events are counted only once.
[1] OR (95% CI) based on a logistic regression model adjusting for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates.
[2] RR (95% CI) based on a Cochran-Mantel-Haenszel approach stratified by study.
[3] RD (95% CI) based on a Mantel-Haenszel approach stratified by study. 95% CIs are based on the approximation to the normal distribution using the Sato estimator for the standard error.
[4] P-value based on a Cochran-Mantel-Haenszel test stratified by study.
[5] Interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the OR (95% CI). Missing subgroup levels are not included in estimation of the interaction p-value.
A continuity correction is applied in estimation of the OR, RR and p-value if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum. No continuity correction is applied in the estimation of the RD.
The reference group for the OR, RR and RD is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with >= 1 event; OR: Odds ratio; RR: Risk ratio; RD: Risk difference; CI: Confidence interval; int: p-value for interaction; NETA: Norethindrone acetate; NC: Not calculated.

SOURCE: \Studies\MYV\MYV102\Analysis\Prod\Progs\TFLs\Tab_SAF_AE_BIN.SAS
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Table SAF.STEAE.SAF.POOL.S5: Proportion of Patients With at Least One Serious Treatment Emergent Adverse Event by Subgroup (Safety Population)

Study: Pooled

Treatment	N	n (%)	OR[1] [95% CI]	RR[2] [95% CI]	RD[3] [95% CI]	p-value[4]	p-value (int)[5]
MBL Volume at Baseline (mL)							
< 225 mL							
Relugolix+E2/NETA	164	5 (3.0)	1.04	1.04	0.00	0.9540	0.5605
Placebo	171	5 (2.9)	[0.29;3.65]	[0.30;3.55]	[-0.04;0.04]		
>= 225 mL							
Relugolix+E2/NETA	90	3 (3.3)	1.94	1.89	0.02	0.4455	
Placebo	85	1 (1.2)	[0.35;10.89]	[0.35;10.12]	[-0.02;0.07]		

Post hoc analysis. The denominator for percentages is the number of patients in the safety population for each treatment group. Patients with multiple events are counted only once.
[1] OR (95% CI) based on a logistic regression model adjusting for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates.
[2] RR (95% CI) based on a Cochran-Mantel-Haenszel approach stratified by study.
[3] RD (95% CI) based on a Mantel-Haenszel approach stratified by study. 95% CIs are based on the approximation to the normal distribution using the Sato estimator for the standard error.
[4] P-value based on a Cochran-Mantel-Haenszel test stratified by study.
[5] Interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the OR (95% CI).
A continuity correction is applied in estimation of the OR, RR and p-value if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum. No continuity correction is applied in the estimation of the RD.
The reference group for the OR, RR and RD is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with >= 1 event; OR: Odds ratio; RR: Risk ratio; RD: Risk difference; CI: Confidence interval; int: p-value for interaction; NETA: Norethindrone acetate.

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Table SAF.STEAE.SAF.POOL.S8: Proportion of Patients With at Least One Serious Treatment Emergent Adverse Event by Subgroup (Safety Population)

Study: Pooled

Treatment	N	n (%)	OR[1] [95% CI]	RR[2] [95% CI]	RD[3] [95% CI]	p-value[4]	p-value (int)[5]
Ethnicity							
Hispanic or Latino							
Relugolix+E2/NETA	53	2 (3.8)	0.93	1.07	0.00	0.9400	0.6238
Placebo	55	2 (3.6)	[0.18;4.89]	[0.18;6.46]	[-0.06;0.07]		
Not Hispanic or Latino							
Relugolix+E2/NETA	197	6 (3.0)	1.57	1.57	0.01	0.4685	
Placebo	199	4 (2.0)	[0.44;5.68]	[0.46;5.35]	[-0.02;0.04]		
Not reported							
Relugolix+E2/NETA	4	0	NC	NC	NC	NC	
Placebo	2	0	[NC;NC]	[NC;NC]	[NC;NC]		

Post hoc analysis. The denominator for percentages is the number of patients in the safety population for each treatment group. Patients with multiple events are counted only once.
[1] OR (95% CI) based on a logistic regression model adjusting for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates.
[2] RR (95% CI) based on a Cochran-Mantel-Haenszel approach stratified by study.
[3] RD (95% CI) based on a Mantel-Haenszel approach stratified by study. 95% CIs are based on the approximation to the normal distribution using the Sato estimator for the standard error.
[4] P-value based on a Cochran-Mantel-Haenszel test stratified by study.
[5] Interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the OR (95% CI). Not reported subgroup levels are not included in estimation of the interaction p-value.
A continuity correction is applied in estimation of the OR, RR and p-value if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum. No continuity correction is applied in the estimation of the RD.
The reference group for the OR, RR and RD is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with >= 1 event; OR: Odds ratio; RR: Risk ratio; RD: Risk difference; CI: Confidence interval; int: p-value for interaction; NETA: Norethindrone acetate; NC: Not calculated.

SOURCE: \Studies\MYV\MYV102\Analysis\Prod\Progs\TFLs\Tab_SAF_AE_BIN.SAS
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Table SAF.STEAE.SAF.POOL.S4: Proportion of Patients With at Least One Serious Treatment Emergent Adverse Event by Subgroup (Safety Population)

Study: Pooled

Treatment	N	n (%)	OR[1] [95% CI]	RR[2] [95% CI]	RD[3] [95% CI]	p-value[4]	p-value (int)[5]
Maximum NRS Pain Score at Baseline							
< 4							
Relugolix+E2/NETA	73	2 (2.7)	2.45	2.44	0.03	0.4317	0.7704
Placebo	62	0	[0.25;24.29]	[0.25;24.26]	[-0.01;0.06]		
>= 4							
Relugolix+E2/NETA	178	6 (3.4)	1.67	1.63	0.01	0.4324	
Placebo	190	4 (2.1)	[0.46;6.03]	[0.47;5.62]	[-0.02;0.05]		
Missing							
Relugolix+E2/NETA	3	0	NC	NC	NC	NC	
Placebo	4	2 (50.0)	[NC;NC]	[NC;NC]	[NC;NC]		

Post hoc analysis. The denominator for percentages is the number of patients in the safety population for each treatment group. Patients with multiple events are counted only once.
[1] OR (95% CI) based on a logistic regression model adjusting for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates.
[2] RR (95% CI) based on a Cochran-Mantel-Haenszel approach stratified by study.
[3] RD (95% CI) based on a Mantel-Haenszel approach stratified by study. 95% CIs are based on the approximation to the normal distribution using the Sato estimator for the standard error.
[4] P-value based on a Cochran-Mantel-Haenszel test stratified by study.
[5] Interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the OR (95% CI). Missing subgroup levels are not included in estimation of the interaction p-value.
A continuity correction is applied in estimation of the OR, RR and p-value if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum. No continuity correction is applied in the estimation of the RD.
The reference group for the OR, RR and RD is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with >= 1 event; OR: Odds ratio; RR: Risk ratio; RD: Risk difference; CI: Confidence interval; int: p-value for interaction; NETA: Norethindrone acetate; NC: Not calculated.

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Table SAF.STEAE.SAF.POOL.S7: Proportion of Patients With at Least One Serious Treatment Emergent Adverse Event by Subgroup (Safety Population)

Study: Pooled

Treatment	N	n (%)	OR[1] [95% CI]	RR[2] [95% CI]	RD[3] [95% CI]	p-value[4]	p-value (int)[5]
Geographic Region II							
Europe							
Relugolix+E2/NETA	41	2 (4.9)	1.62	1.52	0.03	0.6270	0.7899
Placebo	42	1 (2.4)	[0.26;10.22]	[0.28;8.29]	[-0.06;0.11]		
Rest of World (including the US)							
Relugolix+E2/NETA	213	6 (2.8)	1.20	1.19	0.00	0.7708	
Placebo	214	5 (2.3)	[0.36;4.00]	[0.36;3.89]	[-0.03;0.03]		

Post hoc analysis. The denominator for percentages is the number of patients in the safety population for each treatment group. Patients with multiple events are counted only once.
[1] OR (95% CI) based on a logistic regression model adjusting for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates.
[2] RR (95% CI) based on a Cochran-Mantel-Haenszel approach stratified by study.
[3] RD (95% CI) based on a Mantel-Haenszel approach stratified by study. 95% CIs are based on the approximation to the normal distribution using the Sato estimator for the standard error.
[4] P-value based on a Cochran-Mantel-Haenszel test stratified by study.
[5] Interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the OR (95% CI).
A continuity correction is applied in estimation of the OR, RR and p-value if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum. No continuity correction is applied in the estimation of the RD.
The reference group for the OR, RR and RD is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with >= 1 event; OR: Odds ratio; RR: Risk ratio; RD: Risk difference; CI: Confidence interval; int: p-value for interaction; NETA: Norethindrone acetate.

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Table SAF.STEAE.SAF.POOL.S1: Proportion of Patients With at Least One Serious Treatment Emergent Adverse Event by Subgroup (Safety Population)

Study: Pooled

Treatment	N	n (%)	OR[1] [95% CI]	RR[2] [95% CI]	RD[3] [95% CI]	p-value[4]	p-value (int)[5]
Age (years)							
< 40 years							
Relugolix+E2/NETA	62	1 (1.6)	1.24	1.25	0.00	0.8237	0.9649
Placebo	78	1 (1.3)	[0.17;9.10]	[0.18;8.88]	[-0.04;0.04]		
>= 40 years							
Relugolix+E2/NETA	192	7 (3.6)	1.31	1.30	0.01	0.6495	
Placebo	178	5 (2.8)	[0.41;4.21]	[0.42;4.03]	[-0.03;0.04]		

Post hoc analysis. The denominator for percentages is the number of patients in the safety population for each treatment group. Patients with multiple events are counted only once.
[1] OR (95% CI) based on a logistic regression model adjusting for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates.
[2] RR (95% CI) based on a Cochran-Mantel-Haenszel approach stratified by study.
[3] RD (95% CI) based on a Mantel-Haenszel approach stratified by study. 95% CIs are based on the approximation to the normal distribution using the Sato estimator for the standard error.
[4] P-value based on a Cochran-Mantel-Haenszel test stratified by study.
[5] Interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the OR (95% CI).
A continuity correction is applied in estimation of the OR, RR and p-value if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum. No continuity correction is applied in the estimation of the RD.
The reference group for the OR, RR and RD is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with >= 1 event; OR: Odds ratio; RR: Risk ratio; RD: Risk difference; CI: Confidence interval; int: p-value for interaction; NETA: Norethindrone acetate.

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Table SAF.STEAE.SAF.POOL.S3: Proportion of Patients With at Least One Serious Treatment Emergent Adverse Event by Subgroup (Safety Population)

Study: Pooled

Treatment	N	n (%)	OR[1] [95% CI]	RR[2] [95% CI]	RD[3] [95% CI]	p-value[4]	p-value (int)[5]
Uterine Volume at Baseline (cm3)							
< 300 cm3							NC
Relugolix+E2/NETA	148	5 (3.4)	NC [NC;NC]	NC [NC;NC]	NC [NC;NC]	NC	
Placebo	129	3 (2.3)					
>= 300 cm3							
Relugolix+E2/NETA	105	3 (2.9)	NC [NC;NC]	NC [NC;NC]	NC [NC;NC]	NC	
Placebo	127	3 (2.4)					
Missing							
Relugolix+E2/NETA	1	0	NC [NC;NC]	NC [NC;NC]	NC [NC;NC]	NC	
Placebo	0	0					

Post hoc analysis. The denominator for percentages is the number of patients in the safety population for each treatment group. Patients with multiple events are counted only once.
[1] OR (95% CI) based on a logistic regression model adjusting for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates.
[2] RR (95% CI) based on a Cochran-Mantel-Haenszel approach stratified by study.
[3] RD (95% CI) based on a Mantel-Haenszel approach stratified by study. 95% CIs are based on the approximation to the normal distribution using the Sato estimator for the standard error.
[4] P-value based on a Cochran-Mantel-Haenszel test stratified by study.
[5] Interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the OR (95% CI). Missing subgroup levels are not included in estimation of the interaction p-value.
A continuity correction is applied in estimation of the OR, RR and p-value if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum. No continuity correction is applied in the estimation of the RD.
The reference group for the OR, RR and RD is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with >= 1 event; OR: Odds ratio; RR: Risk ratio; RD: Risk difference; CI: Confidence interval; int: p-value for interaction; NETA: Norethindrone acetate; NC: Not calculated.

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Table SAF.STEAE.SAF.POOL.S6: Proportion of Patients With at Least One Serious Treatment Emergent Adverse Event by Subgroup (Safety Population)

Study: Pooled

Treatment	N	n (%)	OR[1] [95% CI]	RR[2] [95% CI]	RD[3] [95% CI]	p-value[4]	p-value (int)[5]
Geographic Region I							
North America							
Relugolix+E2/NETA	192	6 (3.1)	NC [NC;NC]	NC [NC;NC]	NC [NC;NC]	NC	NC
Placebo	194	3 (1.5)					
Rest of World							
Relugolix+E2/NETA	62	2 (3.2)	NC [NC;NC]	NC [NC;NC]	NC [NC;NC]	NC	
Placebo	62	3 (4.8)					

Post hoc analysis. The denominator for percentages is the number of patients in the safety population for each treatment group. Patients with multiple events are counted only once.
[1] OR (95% CI) based on a logistic regression model adjusting for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates.
[2] RR (95% CI) based on a Cochran-Mantel-Haenszel approach stratified by study.
[3] RD (95% CI) based on a Mantel-Haenszel approach stratified by study. 95% CIs are based on the approximation to the normal distribution using the Sato estimator for the standard error.
[4] P-value based on a Cochran-Mantel-Haenszel test stratified by study.
[5] Interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the OR (95% CI).
A continuity correction is applied in estimation of the OR, RR and p-value if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum. No continuity correction is applied in the estimation of the RD.
The reference group for the OR, RR and RD is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with >= 1 event; OR: Odds ratio; RR: Risk ratio; RD: Risk difference; CI: Confidence interval; int: p-value for interaction; NETA: Norethindrone acetate; NC: Not calculated.

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Table SAF.STEAE.SAF.POOL.S9: Proportion of Patients With at Least One Serious Treatment Emergent Adverse Event by Subgroup (Safety Population)

Study: Pooled

Treatment	N	n (%)	OR[1] [95% CI]	RR[2] [95% CI]	RD[3] [95% CI]	p-value[4]	p-value (int)[5]
Race							
Black/African American							NC
Relugolix+E2/NETA	122	3 (2.5)	NC [NC;NC]	NC [NC;NC]	NC [NC;NC]	NC	
Placebo	141	4 (2.8)					
White							
Relugolix+E2/NETA	123	5 (4.1)	NC [NC;NC]	NC [NC;NC]	NC [NC;NC]	NC	
Placebo	105	2 (1.9)					
Asian							
Relugolix+E2/NETA	1	0	NC [NC;NC]	NC [NC;NC]	NC [NC;NC]	NC	
Placebo	3	0					
Others							
Relugolix+E2/NETA	5	0	NC [NC;NC]	NC [NC;NC]	NC [NC;NC]	NC	
Placebo	6	0					
Not reported							
Relugolix+E2/NETA	3	0	NC [NC;NC]	NC [NC;NC]	NC [NC;NC]	NC	
Placebo	1	0					

Post hoc analysis. The denominator for percentages is the number of patients in the safety population for each treatment group. Patients with multiple events are counted only once.
[1] OR (95% CI) based on a logistic regression model adjusting for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates.
[2] RR (95% CI) based on a Cochran-Mantel-Haenszel approach stratified by study.
[3] RD (95% CI) based on a Mantel-Haenszel approach stratified by study. 95% CIs are based on the approximation to the normal distribution using the Sato estimator for the standard error.
[4] P-value based on a Cochran-Mantel-Haenszel test stratified by study.
[5] Interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the OR (95% CI). Not reported subgroup levels are not included in estimation of the interaction p-value.
A continuity correction is applied in estimation of the OR, RR and p-value if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum. No continuity correction is applied in the estimation of the RD.
The reference group for the OR, RR and RD is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with >= 1 event; OR: Odds ratio; RR: Risk ratio; RD: Risk difference; CI: Confidence interval; int: p-value for interaction; NETA: Norethindrone acetate; NC: Not calculated.

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1.3.5 Proportion of Patients With at Least One Treatment Emergent Adverse Event with Action Taken of Study Treatment Discontinuation by Subgroup (Safety Population)

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Table SAF.TEAED.SAF.POOL.S3: Proportion of Patients With at Least One Treatment Emergent Adverse Event with Action Taken of Study Treatment Discontinuation by Subgroup (Safety Population)

Study: Pooled

Treatment	N	n (%)	OR[1] [95% CI]	RR[2] [95% CI]	RD[3] [95% CI]	p-value[4]	p-value (int)[5]
Uterine Volume at Baseline (cm3)							
< 300 cm3							
Relugolix+E2/NETA	148	6 (4.1)	2.68	2.61	0.02	0.2165	0.0531
Placebo	129	2 (1.6)	[0.53;13.53]	[0.53;12.72]	[-0.01;0.06]		
>= 300 cm3							
Relugolix+E2/NETA	105	3 (2.9)	0.38	0.40	-0.04	0.1505	
Placebo	127	9 (7.1)	[0.10;1.46]	[0.11;1.45]	[-0.10;0.01]		
Missing							
Relugolix+E2/NETA	1	1 (100.0)	NC	NC	NC	NC	
Placebo	0	0	[NC;NC]	[NC;NC]	[NC;NC]		

Post hoc analysis. The denominator for percentages is the number of patients in the safety population for each treatment group. Patients with multiple events are counted only once. Adverse events with action taken of permanent discontinuation are taken from the AE case report form.
[1] OR (95% CI) based on a logistic regression model adjusting for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates.
[2] RR (95% CI) based on a Cochran-Mantel-Haenszel approach stratified by study.
[3] RD (95% CI) based on a Mantel-Haenszel approach stratified by study. 95% CIs are based on the approximation to the normal distribution using the Sato estimator for the standard error.
[4] P-value based on a Cochran-Mantel-Haenszel test stratified by study.
[5] Interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the OR (95% CI). Missing subgroup levels are not included in estimation of the interaction p-value.
A continuity correction is applied in estimation of the OR, RR and p-value if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum. No continuity correction is applied in the estimation of the RD.
The reference group for the OR, RR and RD is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with >= 1 event; OR: Odds ratio; RR: Risk ratio; RD: Risk difference; CI: Confidence interval; int: p-value for interaction; NETA: Norethindrone acetate; NC: Not calculated.

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Table SAF.TEAED.SAF.POOL.S6: Proportion of Patients With at Least One Treatment Emergent Adverse Event with Action Taken of Study Treatment Discontinuation by Subgroup (Safety Population)

Study: Pooled

Treatment	N	n (%)	OR[1] [95% CI]	RR[2] [95% CI]	RD[3] [95% CI]	p-value[4]	p-value (int)[5]
Geographic Region I							
North America							
Relugolix+E2/NETA	192	9 (4.7)	1.31	1.30	0.01	0.5973	0.1686
Placebo	194	7 (3.6)	[0.48;3.60]	[0.49;3.42]	[-0.03;0.05]		
Rest of World							
Relugolix+E2/NETA	62	1 (1.6)	0.32	0.33	-0.05	0.2121	
Placebo	62	4 (6.5)	[0.05;2.08]	[0.05;2.05]	[-0.12;0.02]		

Post hoc analysis. The denominator for percentages is the number of patients in the safety population for each treatment group. Patients with multiple events are counted only once.
Adverse events with action taken of permanent discontinuation are taken from the AE case report form.
[1] OR (95% CI) based on a logistic regression model adjusting for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates.
[2] RR (95% CI) based on a Cochran-Mantel-Haenszel approach stratified by study.
[3] RD (95% CI) based on a Mantel-Haenszel approach stratified by study. 95% CIs are based on the approximation to the normal distribution using the Sato estimator for the standard error.
[4] P-value based on a Cochran-Mantel-Haenszel test stratified by study.
[5] Interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the OR (95% CI).
A continuity correction is applied in estimation of the OR, RR and p-value if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum. No continuity correction is applied in the estimation of the RD.
The reference group for the OR, RR and RD is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with >= 1 event; OR: Odds ratio; RR: Risk ratio; RD: Risk difference; CI: Confidence interval; int: p-value for interaction; NETA: Norethindrone acetate.

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Table SAF.TEAED.SAF.POOL.S7: Proportion of Patients With at Least One Treatment Emergent Adverse Event with Action Taken of Study Treatment Discontinuation by Subgroup (Safety Population)

Study: Pooled

Treatment	N	n (%)	OR[1] [95% CI]	RR[2] [95% CI]	RD[3] [95% CI]	p-value[4]	p-value (int)[5]
Geographic Region II							
Europe							0.1784
Relugolix+E2/NETA	41	1 (2.4)	0.32 [0.05;2.14]	0.34 [0.06;2.00]	-0.07 [-0.17;0.03]	0.2109	
Placebo	42	4 (9.5)					
Rest of World (including the US)							
Relugolix+E2/NETA	213	9 (4.2)	1.30 [0.48;3.56]	1.28 [0.48;3.41]	0.01 [-0.03;0.05]	0.6138	
Placebo	214	7 (3.3)					

Post hoc analysis. The denominator for percentages is the number of patients in the safety population for each treatment group. Patients with multiple events are counted only once. Adverse events with action taken of permanent discontinuation are taken from the AE case report form.
[1] OR (95% CI) based on a logistic regression model adjusting for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates.
[2] RR (95% CI) based on a Cochran-Mantel-Haenszel approach stratified by study.
[3] RD (95% CI) based on a Mantel-Haenszel approach stratified by study. 95% CIs are based on the approximation to the normal distribution using the Sato estimator for the standard error.
[4] P-value based on a Cochran-Mantel-Haenszel test stratified by study.
[5] Interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the OR (95% CI).
A continuity correction is applied in estimation of the OR, RR and p-value if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum. No continuity correction is applied in the estimation of the RD.
The reference group for the OR, RR and RD is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with >= 1 event; OR: Odds ratio; RR: Risk ratio; RD: Risk difference; CI: Confidence interval; int: p-value for interaction; NETA: Norethindrone acetate.

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Table SAF.TEAED.SAF.POOL.S4: Proportion of Patients With at Least One Treatment Emergent Adverse Event with Action Taken of Study Treatment Discontinuation by Subgroup (Safety Population)

Study: Pooled

Treatment	N	n (%)	OR[1] [95% CI]	RR[2] [95% CI]	RD[3] [95% CI]	p-value[4]	p-value (int)[5]
Maximum NRS Pain Score at Baseline							
< 4							
Relugolix+E2/NETA	73	1 (1.4)	0.34	0.37	-0.03	0.2659	0.2308
Placebo	62	3 (4.8)	[0.05;2.38]	[0.06;2.28]	[-0.10;0.03]		
>= 4							
Relugolix+E2/NETA	178	9 (5.1)	1.23	1.21	0.01	0.6819	
Placebo	190	8 (4.2)	[0.46;3.25]	[0.48;3.05]	[-0.03;0.05]		
Missing							
Relugolix+E2/NETA	3	0	NC	NC	NC	NC	
Placebo	4	0	[NC;NC]	[NC;NC]	[NC;NC]		

Post hoc analysis. The denominator for percentages is the number of patients in the safety population for each treatment group. Patients with multiple events are counted only once. Adverse events with action taken of permanent discontinuation are taken from the AE case report form.
[1] OR (95% CI) based on a logistic regression model adjusting for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates.
[2] RR (95% CI) based on a Cochran-Mantel-Haenszel approach stratified by study.
[3] RD (95% CI) based on a Mantel-Haenszel approach stratified by study. 95% CIs are based on the approximation to the normal distribution using the Sato estimator for the standard error.
[4] P-value based on a Cochran-Mantel-Haenszel test stratified by study.
[5] Interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the OR (95% CI). Missing subgroup levels are not included in estimation of the interaction p-value.
A continuity correction is applied in estimation of the OR, RR and p-value if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum. No continuity correction is applied in the estimation of the RD.
The reference group for the OR, RR and RD is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with >= 1 event; OR: Odds ratio; RR: Risk ratio; RD: Risk difference; CI: Confidence interval; int: p-value for interaction; NETA: Norethindrone acetate; NC: Not calculated.

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Table SAF.TEAED.SAF.POOL.S5: Proportion of Patients With at Least One Treatment Emergent Adverse Event with Action Taken of Study Treatment Discontinuation by Subgroup (Safety Population)

Study: Pooled

Treatment	N	n (%)	OR[1] [95% CI]	RR[2] [95% CI]	RD[3] [95% CI]	p-value[4]	p-value (int)[5]
MBL Volume at Baseline (mL)							
< 225 mL							
Relugolix+E2/NETA	164	7 (4.3)	1.22	1.21	0.01	0.7287	0.3931
Placebo	171	6 (3.5)	[0.40;3.71]	[0.41;3.57]	[-0.03;0.05]		
>= 225 mL							
Relugolix+E2/NETA	90	3 (3.3)	0.55	0.57	-0.03	0.4225	
Placebo	85	5 (5.9)	[0.13;2.39]	[0.14;2.31]	[-0.09;0.04]		

Post hoc analysis. The denominator for percentages is the number of patients in the safety population for each treatment group. Patients with multiple events are counted only once. Adverse events with action taken of permanent discontinuation are taken from the AE case report form.
[1] OR (95% CI) based on a logistic regression model adjusting for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates.
[2] RR (95% CI) based on a Cochran-Mantel-Haenszel approach stratified by study.
[3] RD (95% CI) based on a Mantel-Haenszel approach stratified by study. 95% CIs are based on the approximation to the normal distribution using the Sato estimator for the standard error.
[4] P-value based on a Cochran-Mantel-Haenszel test stratified by study.
[5] Interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the OR (95% CI).
A continuity correction is applied in estimation of the OR, RR and p-value if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum. No continuity correction is applied in the estimation of the RD.
The reference group for the OR, RR and RD is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with >= 1 event; OR: Odds ratio; RR: Risk ratio; RD: Risk difference; CI: Confidence interval; int: p-value for interaction; NETA: Norethindrone acetate.

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Table SAF.TEAED.SAF.POOL.S8: Proportion of Patients With at Least One Treatment Emergent Adverse Event with Action Taken of Study Treatment Discontinuation by Subgroup (Safety Population)

Study: Pooled

Treatment	N	n (%)	OR[1] [95% CI]	RR[2] [95% CI]	RD[3] [95% CI]	p-value[4]	p-value (int)[5]
Ethnicity							
Hispanic or Latino							0.4302
Relugolix+E2/NETA	53	2 (3.8)	1.74	1.70	0.02	0.5676	
Placebo	55	1 (1.8)	[0.22;13.74]	[0.27;10.66]	[-0.05;0.09]		
Not Hispanic or Latino							
Relugolix+E2/NETA	197	7 (3.6)	0.70	0.72	-0.01	0.4802	
Placebo	199	10 (5.0)	[0.26;1.88]	[0.28;1.82]	[-0.05;0.03]		
Not reported							
Relugolix+E2/NETA	4	1 (25.0)	NC	NC	NC	NC	
Placebo	2	0	[NC;NC]	[NC;NC]	[NC;NC]		

Post hoc analysis. The denominator for percentages is the number of patients in the safety population for each treatment group. Patients with multiple events are counted only once. Adverse events with action taken of permanent discontinuation are taken from the AE case report form.
[1] OR (95% CI) based on a logistic regression model adjusting for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates.
[2] RR (95% CI) based on a Cochran-Mantel-Haenszel approach stratified by study.
[3] RD (95% CI) based on a Mantel-Haenszel approach stratified by study. 95% CIs are based on the approximation to the normal distribution using the Sato estimator for the standard error.
[4] P-value based on a Cochran-Mantel-Haenszel test stratified by study.
[5] Interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the OR (95% CI). Not reported subgroup levels are not included in estimation of the interaction p-value.
A continuity correction is applied in estimation of the OR, RR and p-value if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum. No continuity correction is applied in the estimation of the RD.
The reference group for the OR, RR and RD is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with >= 1 event; OR: Odds ratio; RR: Risk ratio; RD: Risk difference; CI: Confidence interval; int: p-value for interaction; NETA: Norethindrone acetate; NC: Not calculated.

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Table SAF.TEAED.SAF.POOL.S9: Proportion of Patients With at Least One Treatment Emergent Adverse Event with Action Taken of Study Treatment Discontinuation by Subgroup (Safety Population)

Study: Pooled

Treatment	N	n (%)	OR[1] [95% CI]	RR[2] [95% CI]	RD[3] [95% CI]	p-value[4]	p-value (int)[5]
Race							
Black/African American							0.8449
Relugolix+E2/NETA	122	5 (4.1)	0.96	0.96	-0.00	0.9466	
Placebo	141	6 (4.3)	[0.29;3.23]	[0.30;3.10]	[-0.05;0.05]		
White							
Relugolix+E2/NETA	123	5 (4.1)	1.07	1.07	0.00	0.9198	
Placebo	105	4 (3.8)	[0.28;4.11]	[0.29;3.87]	[-0.05;0.05]		
Asian							
Relugolix+E2/NETA	1	0	NC	NC	NC	NC	
Placebo	3	0	[NC;NC]	[NC;NC]	[NC;NC]		
Others							
Relugolix+E2/NETA	5	0	0.45	0.50	-0.31	0.4913	
Placebo	6	1 (16.7)	[0.03;6.56]	[0.08;3.32]	[-0.71;0.09]		
Not reported							
Relugolix+E2/NETA	3	0	NC	NC	NC	NC	
Placebo	1	0	[NC;NC]	[NC;NC]	[NC;NC]		

Post hoc analysis. The denominator for percentages is the number of patients in the safety population for each treatment group. Patients with multiple events are counted only once. Adverse events with action taken of permanent discontinuation are taken from the AE case report form.
[1] OR (95% CI) based on a logistic regression model adjusting for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates.
[2] RR (95% CI) based on a Cochran-Mantel-Haenszel approach stratified by study.
[3] RD (95% CI) based on a Mantel-Haenszel approach stratified by study. 95% CIs are based on the approximation to the normal distribution using the Sato estimator for the standard error.
[4] P-value based on a Cochran-Mantel-Haenszel test stratified by study.
[5] Interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the OR (95% CI). Not reported subgroup levels are not included in estimation of the interaction p-value.
A continuity correction is applied in estimation of the OR, RR and p-value if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum. No continuity correction is applied in the estimation of the RD.
The reference group for the OR, RR and RD is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with >= 1 event; OR: Odds ratio; RR: Risk ratio; RD: Risk difference; CI: Confidence interval; int: p-value for interaction; NETA: Norethindrone acetate; NC: Not calculated.

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Table SAF.TEAED.SAF.POOL.S2: Proportion of Patients With at Least One Treatment Emergent Adverse Event with Action Taken of Study Treatment Discontinuation by Subgroup (Safety Population)

Study: Pooled

Treatment	N	n (%)	OR[1] [95% CI]	RR[2] [95% CI]	RD[3] [95% CI]	p-value[4]	p-value (int)[5]
BMI (kg/m2) at Baseline							
< 30							
Relugolix+E2/NETA	119	6 (5.0)	0.95	0.95	-0.00	0.9293	0.8912
Placebo	115	6 (5.2)	[0.30;3.05]	[0.31;2.88]	[-0.06;0.05]		
>= 30							
Relugolix+E2/NETA	134	4 (3.0)	0.84	0.85	-0.01	0.7983	
Placebo	141	5 (3.5)	[0.22;3.20]	[0.23;3.06]	[-0.05;0.04]		
Missing							
Relugolix+E2/NETA	1	0	NC	NC	NC	NC	
Placebo	0	0	[NC;NC]	[NC;NC]	[NC;NC]		

Post hoc analysis. The denominator for percentages is the number of patients in the safety population for each treatment group. Patients with multiple events are counted only once. Adverse events with action taken of permanent discontinuation are taken from the AE case report form.
[1] OR (95% CI) based on a logistic regression model adjusting for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates.
[2] RR (95% CI) based on a Cochran-Mantel-Haenszel approach stratified by study.
[3] RD (95% CI) based on a Mantel-Haenszel approach stratified by study. 95% CIs are based on the approximation to the normal distribution using the Sato estimator for the standard error.
[4] P-value based on a Cochran-Mantel-Haenszel test stratified by study.
[5] Interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the OR (95% CI). Missing subgroup levels are not included in estimation of the interaction p-value.
A continuity correction is applied in estimation of the OR, RR and p-value if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum. No continuity correction is applied in the estimation of the RD.
The reference group for the OR, RR and RD is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with >= 1 event; OR: Odds ratio; RR: Risk ratio; RD: Risk difference; CI: Confidence interval; int: p-value for interaction; NETA: Norethindrone acetate; NC: Not calculated.

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Table SAF.TEAED.SAF.POOL.S1: Proportion of Patients With at Least One Treatment Emergent Adverse Event with Action Taken of Study Treatment Discontinuation by Subgroup (Safety Population)

Study: Pooled

Treatment	N	n (%)	OR[1] [95% CI]	RR[2] [95% CI]	RD[3] [95% CI]	p-value[4]	p-value (int)[5]
Age (years)							
< 40 years							0.9122
Relugolix+E2/NETA	62	1 (1.6)	0.82 [0.13;5.08]	0.84 [0.14;5.02]	-0.01 [-0.06;0.04]	0.8452	
Placebo	78	2 (2.6)					
>= 40 years							
Relugolix+E2/NETA	192	9 (4.7)	0.92 [0.36;2.38]	0.93 [0.38;2.28]	-0.00 [-0.05;0.04]	0.8700	
Placebo	178	9 (5.1)					

Post hoc analysis. The denominator for percentages is the number of patients in the safety population for each treatment group. Patients with multiple events are counted only once.
Adverse events with action taken of permanent discontinuation are taken from the AE case report form.
[1] OR (95% CI) based on a logistic regression model adjusting for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates.
[2] RR (95% CI) based on a Cochran-Mantel-Haenszel approach stratified by study.
[3] RD (95% CI) based on a Mantel-Haenszel approach stratified by study. 95% CIs are based on the approximation to the normal distribution using the Sato estimator for the standard error.
[4] P-value based on a Cochran-Mantel-Haenszel test stratified by study.
[5] Interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the OR (95% CI).
A continuity correction is applied in estimation of the OR, RR and p-value if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum. No continuity correction is applied in the estimation of the RD.
The reference group for the OR, RR and RD is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with >= 1 event; OR: Odds ratio; RR: Risk ratio; RD: Risk difference; CI: Confidence interval; int: p-value for interaction; NETA: Norethindrone acetate.

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1.3.6 Adverse Event Category: Vasomotor Symptoms by System Organ Class and Preferred Term, by Subgroup (Safety Population)

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Table SAF.VASOANY.SPT.POOL.1.1.S5: Adverse Event Category: Vasomotor Symptoms by System Organ Class and Preferred Term, by Subgroup (Safety Population)

Study: Pooled

System Organ Class: Any, Preferred Term: Any

Treatment	N	n (%)	OR[1] [95% CI]	RR[2] [95% CI]	RD[3] [95% CI]	p-value[4]	p-value (int)[5]
MBL Volume at Baseline (mL)							
< 225 mL							
Relugolix+E2/NETA	164	18 (11.0)	2.21	2.06	0.06	0.0582	0.2804
Placebo	171	9 (5.3)	[0.96;5.11]	[0.96;4.43]	[-0.00;0.11]		
>= 225 mL							
Relugolix+E2/NETA	90	9 (10.0)	1.08	1.07	0.01	0.8900	
Placebo	85	8 (9.4)	[0.39;2.96]	[0.43;2.63]	[-0.08;0.09]		

Post hoc analysis. The denominator for percentages is the number of patients in the safety population for each treatment group. Patients with multiple events for a given PT or SOC are counted only once for each PT and SOC. Events are sorted alphabetically by SOC and PT and then by ascending subgroup-by-treatment interaction p-value within each. MedDRA (version 22.0).
Vasomotor symptoms include preferred term of Hyperhidrosis, Feeling hot, Hot flush, Night sweats and Flushing.
[1] OR (95% CI) based on a logistic regression model adjusting for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates.
[2] RR (95% CI) based on a Cochran-Mantel-Haenszel approach stratified by study.
[3] RD (95% CI) based on a Mantel-Haenszel approach stratified by study. 95% CIs are based on the approximation to the normal distribution using the Sato estimator for the standard error.
[4] P-value based on a Cochran-Mantel-Haenszel test stratified by study.
[5] Interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the OR (95% CI).
A continuity correction is applied in estimation of the OR, RR and p-value if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum. No continuity correction is applied in the estimation of the RD.
The reference group for the OR, RR and RD is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with >= 1 event; OR: Odds ratio; RR: Risk ratio; RD: Risk difference; CI: Confidence interval; int: p-value for interaction; NETA: Norethindrone acetate; SOC: System organ class; PT: Preferred term.

SOURCE: \Studies\MYV\MYV102\Analysis\Prod\Progs\TFLs\Tab_SAF_AESI_SOC_PT_S_BIN.SAS
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Table SAF.VASOANY.SPT.POOL.1.1.S3: Adverse Event Category: Vasomotor Symptoms by System Organ Class and Preferred Term, by Subgroup (Safety Population)

Study: Pooled

System Organ Class: Any, Preferred Term: Any

Treatment	N	n (%)	OR[1] [95% CI]	RR[2] [95% CI]	RD[3] [95% CI]	p-value[4]	p-value (int)[5]
Uterine Volume at Baseline (cm3)							
< 300 cm3							
Relugolix+E2/NETA	148	15 (10.1)	2.33	2.17	0.05	0.0847	0.4164
Placebo	129	6 (4.7)	[0.87;6.23]	[0.88;5.37]	[-0.01;0.11]		
>= 300 cm3							
Relugolix+E2/NETA	105	12 (11.4)	1.36	1.31	0.03	0.4908	
Placebo	127	11 (8.7)	[0.57;3.24]	[0.61;2.84]	[-0.05;0.10]		
Missing							
Relugolix+E2/NETA	1	0	NC	NC	NC	NC	
Placebo	0	0	[NC;NC]	[NC;NC]	[NC;NC]		

Post hoc analysis. The denominator for percentages is the number of patients in the safety population for each treatment group. Patients with multiple events for a given PT or SOC are counted only once for each PT and SOC. Events are sorted alphabetically by SOC and PT and then by ascending subgroup-by-treatment interaction p-value within each. MedDRA (version 22.0).
Vasomotor symptoms include preferred term of Hyperhidrosis, Feeling hot, Hot flush, Night sweats and Flushing.
[1] OR (95% CI) based on a logistic regression model adjusting for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates.
[2] RR (95% CI) based on a Cochran-Mantel-Haenszel approach stratified by study.
[3] RD (95% CI) based on a Mantel-Haenszel approach stratified by study. 95% CIs are based on the approximation to the normal distribution using the Sato estimator for the standard error.
[4] P-value based on a Cochran-Mantel-Haenszel test stratified by study.
[5] Interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the OR (95% CI). Missing subgroup levels are not included in estimation of the interaction p-value.
A continuity correction is applied in estimation of the OR, RR and p-value if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum. No continuity correction is applied in the estimation of the RD.
The reference group for the OR, RR and RD is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with >= 1 event; OR: Odds ratio; RR: Risk ratio; RD: Risk difference; CI: Confidence interval; int: p-value for interaction; NETA: Norethindrone acetate; SOC: System organ class; PT: Preferred term; NC: Not calculated.

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Table SAF.VASOANY.SPT.POOL.1.1.S7: Adverse Event Category: Vasomotor Symptoms by System Organ Class and Preferred Term, by Subgroup (Safety Population)

Study: Pooled

System Organ Class: Any, Preferred Term: Any

Treatment	**N**	**n (%)**	**OR[1] [95% CI]**	**RR[2] [95% CI]**	**RD[3] [95% CI]**	**p-value[4]**	**p-value (int)[5]**
Geographic Region II							
Europe							0.5094
Relugolix+E2/NETA	41	8 (19.5)	2.46	2.10	0.10	0.1877	
Placebo	42	4 (9.5)	[0.67;9.04]	[0.68;6.46]	[-0.05;0.25]		
Rest of World (including the US)							
Relugolix+E2/NETA	213	19 (8.9)	1.49	1.44	0.03	0.2866	
Placebo	214	13 (6.1)	[0.71;3.12]	[0.73;2.83]	[-0.02;0.08]		

Post hoc analysis. The denominator for percentages is the number of patients in the safety population for each treatment group. Patients with multiple events for a given PT or SOC are counted only once for each PT and SOC. Events are sorted alphabetically by SOC and PT and then by ascending subgroup-by-treatment interaction p-value within each. MedDRA (version 22.0).
Vasomotor symptoms include preferred term of Hyperhidrosis, Feeling hot, Hot flush, Night sweats and Flushing.
[1] OR (95% CI) based on a logistic regression model adjusting for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates.
[2] RR (95% CI) based on a Cochran-Mantel-Haenszel approach stratified by study.
[3] RD (95% CI) based on a Mantel-Haenszel approach stratified by study. 95% CIs are based on the approximation to the normal distribution using the Sato estimator for the standard error.
[4] P-value based on a Cochran-Mantel-Haenszel test stratified by study.
[5] Interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the OR (95% CI).
A continuity correction is applied in estimation of the OR, RR and p-value if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum. No continuity correction is applied in the estimation of the RD.
The reference group for the OR, RR and RD is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with >= 1 event; OR: Odds ratio; RR: Risk ratio; RD: Risk difference; CI: Confidence interval; int: p-value for interaction; NETA: Norethindrone acetate; SOC: System organ class; PT: Preferred term.

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Table SAF.VASOANY.SPT.POOL.1.1.S2: Adverse Event Category: Vasomotor Symptoms by System Organ Class and Preferred Term, by Subgroup (Safety Population)

Study: Pooled

System Organ Class: Any, Preferred Term: Any

Treatment	N	n (%)	OR[1] [95% CI]	RR[2] [95% CI]	RD[3] [95% CI]	p-value[4]	p-value (int)[5]
BMI (kg/m2) at Baseline							
< 30							
Relugolix+E2/NETA	119	14 (11.8)	2.00	1.86	0.05	0.1508	0.5275
Placebo	115	7 (6.1)	[0.77;5.19]	[0.79;4.40]	[-0.02;0.13]		
>= 30							
Relugolix+E2/NETA	134	12 (9.0)	1.32	1.28	0.02	0.5418	
Placebo	141	10 (7.1)	[0.54;3.18]	[0.58;2.85]	[-0.04;0.08]		
Missing							
Relugolix+E2/NETA	1	1 (100.0)	NC	NC	NC	NC	
Placebo	0	0	[NC;NC]	[NC;NC]	[NC;NC]		

Post hoc analysis. The denominator for percentages is the number of patients in the safety population for each treatment group. Patients with multiple events for a given PT or SOC are counted only once for each PT and SOC. Events are sorted alphabetically by SOC and PT and then by ascending subgroup-by-treatment interaction p-value within each. MedDRA (version 22.0).
Vasomotor symptoms include preferred term of Hyperhidrosis, Feeling hot, Hot flush, Night sweats and Flushing.
[1] OR (95% CI) based on a logistic regression model adjusting for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates.
[2] RR (95% CI) based on a Cochran-Mantel-Haenszel approach stratified by study.
[3] RD (95% CI) based on a Mantel-Haenszel approach stratified by study. 95% CIs are based on the approximation to the normal distribution using the Sato estimator for the standard error.
[4] P-value based on a Cochran-Mantel-Haenszel test stratified by study.
[5] Interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the OR (95% CI). Missing subgroup levels are not included in estimation of the interaction p-value.
A continuity correction is applied in estimation of the OR, RR and p-value if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum. No continuity correction is applied in the estimation of the RD.
The reference group for the OR, RR and RD is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with >= 1 event; OR: Odds ratio; RR: Risk ratio; RD: Risk difference; CI: Confidence interval; int: p-value for interaction; NETA: Norethindrone acetate; SOC: System organ class; PT: Preferred term; NC: Not calculated.

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Table SAF.VASOANY.SPT.POOL.1.1.S1: Adverse Event Category: Vasomotor Symptoms by System Organ Class and Preferred Term, by Subgroup (Safety Population)

Study: Pooled

System Organ Class: Any, Preferred Term: Any

Treatment	**N**	**n (%)**	**OR[1] [95% CI]**	**RR[2] [95% CI]**	**RD[3] [95% CI]**	**p-value[4]**	**p-value (int)[5]**
Age (years)							
< 40 years							
Relugolix+E2/NETA	62	7 (11.3)	2.22	2.03	0.06	0.1977	0.5783
Placebo	78	4 (5.1)	[0.65;7.59]	[0.68;6.11]	[-0.03;0.15]		
>= 40 years							
Relugolix+E2/NETA	192	20 (10.4)	1.48	1.43	0.03	0.2921	
Placebo	178	13 (7.3)	[0.71;3.10]	[0.73;2.78]	[-0.03;0.09]		

Post hoc analysis. The denominator for percentages is the number of patients in the safety population for each treatment group. Patients with multiple events for a given PT or SOC are counted only once for each PT and SOC. Events are sorted alphabetically by SOC and PT and then by ascending subgroup-by-treatment interaction p-value within each. MedDRA (version 22.0).
Vasomotor symptoms include preferred term of Hyperhidrosis, Feeling hot, Hot flush, Night sweats and Flushing.
[1] OR (95% CI) based on a logistic regression model adjusting for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates.
[2] RR (95% CI) based on a Cochran-Mantel-Haenszel approach stratified by study.
[3] RD (95% CI) based on a Mantel-Haenszel approach stratified by study. 95% CIs are based on the approximation to the normal distribution using the Sato estimator for the standard error.
[4] P-value based on a Cochran-Mantel-Haenszel test stratified by study.
[5] Interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the OR (95% CI).
A continuity correction is applied in estimation of the OR, RR and p-value if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum. No continuity correction is applied in the estimation of the RD.
The reference group for the OR, RR and RD is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with >= 1 event; OR: Odds ratio; RR: Risk ratio; RD: Risk difference; CI: Confidence interval; int: p-value for interaction; NETA: Norethindrone acetate; SOC: System organ class; PT: Preferred term.

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Table SAF.VASOANY.SPT.POOL.1.1.S6: Adverse Event Category: Vasomotor Symptoms by System Organ Class and Preferred Term, by Subgroup (Safety Population)

Study: Pooled

System Organ Class: Any, Preferred Term: Any

Treatment	N	n (%)	OR[1] [95% CI]	RR[2] [95% CI]	RD[3] [95% CI]	p-value[4]	p-value (int)[5]
Geographic Region I							
North America							
Relugolix+E2/NETA	192	18 (9.4)	1.57	1.51	0.03	0.2448	0.7703
Placebo	194	12 (6.2)	[0.73;3.38]	[0.75;3.04]	[-0.02;0.08]		
Rest of World							
Relugolix+E2/NETA	62	9 (14.5)	1.93	1.77	0.06	0.2663	
Placebo	62	5 (8.1)	[0.60;6.21]	[0.64;4.90]	[-0.05;0.17]		

Post hoc analysis. The denominator for percentages is the number of patients in the safety population for each treatment group. Patients with multiple events for a given PT or SOC are counted only once for each PT and SOC. Events are sorted alphabetically by SOC and PT and then by ascending subgroup-by-treatment interaction p-value within each. MedDRA (version 22.0).
Vasomotor symptoms include preferred term of Hyperhidrosis, Feeling hot, Hot flush, Night sweats and Flushing.
[1] OR (95% CI) based on a logistic regression model adjusting for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates.
[2] RR (95% CI) based on a Cochran-Mantel-Haenszel approach stratified by study.
[3] RD (95% CI) based on a Mantel-Haenszel approach stratified by study. 95% CIs are based on the approximation to the normal distribution using the Sato estimator for the standard error.
[4] P-value based on a Cochran-Mantel-Haenszel test stratified by study.
[5] Interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the OR (95% CI).
A continuity correction is applied in estimation of the OR, RR and p-value if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum. No continuity correction is applied in the estimation of the RD.
The reference group for the OR, RR and RD is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with >= 1 event; OR: Odds ratio; RR: Risk ratio; RD: Risk difference; CI: Confidence interval; int: p-value for interaction; NETA: Norethindrone acetate; SOC: System organ class; PT: Preferred term.

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Table SAF.VASOANY.SPT.POOL.1.1.S9: Adverse Event Category: Vasomotor Symptoms by System Organ Class and Preferred Term, by Subgroup (Safety Population)

Study: Pooled

System Organ Class: Any, Preferred Term: Any

Treatment	N	n (%)	OR[1] [95% CI]	RR[2] [95% CI]	RD[3] [95% CI]	p-value[4]	p-value (int)[5]
Race							
Black/African American							
Relugolix+E2/NETA	122	11 (9.0)	1.65	1.58	0.03	0.3025	0.7867
Placebo	141	8 (5.7)	[0.64;4.26]	[0.66;3.77]	[-0.03;0.10]		
White							
Relugolix+E2/NETA	123	14 (11.4)	1.59	1.51	0.04	0.3272	
Placebo	105	8 (7.6)	[0.63;3.97]	[0.66;3.46]	[-0.04;0.11]		
Asian							
Relugolix+E2/NETA	1	0	NC	NC	NC	NC	
Placebo	3	1 (33.3)	[NC;NC]	[NC;NC]	[NC;NC]		
Others							
Relugolix+E2/NETA	5	2 (40.0)	4.05	2.84	0.31	0.3180	
Placebo	6	0	[0.30;55.60]	[0.33;24.63]	[-0.16;0.79]		
Not reported							
Relugolix+E2/NETA	3	0	NC	NC	NC	NC	
Placebo	1	0	[NC;NC]	[NC;NC]	[NC;NC]		

Post hoc analysis. The denominator for percentages is the number of patients in the safety population for each treatment group. Patients with multiple events for a given PT or SOC are counted only once for each PT and SOC. Events are sorted alphabetically by SOC and PT and then by ascending subgroup-by-treatment interaction p-value within each. MedDRA (version 22.0).
Vasomotor symptoms include preferred term of Hyperhidrosis, Feeling hot, Hot flush, Night sweats and Flushing.
[1] OR (95% CI) based on a logistic regression model adjusting for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates.
[2] RR (95% CI) based on a Cochran-Mantel-Haenszel approach stratified by study.
[3] RD (95% CI) based on a Mantel-Haenszel approach stratified by study. 95% CIs are based on the approximation to the normal distribution using the Sato estimator for the standard error.
[4] P-value based on a Cochran-Mantel-Haenszel test stratified by study.
[5] Interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the OR (95% CI). Not reported subgroup levels are not included in estimation of the interaction p-value.
A continuity correction is applied in estimation of the OR, RR and p-value if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum. No continuity correction is applied in the estimation of the RD.
The reference group for the OR, RR and RD is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with >= 1 event; OR: Odds ratio; RR: Risk ratio; RD: Risk difference; CI: Confidence interval; int: p-value for interaction; NETA: Norethindrone acetate; SOC: System organ class; PT: Preferred term; NC: Not calculated.

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Table SAF.VASOANY.SPT.POOL.1.1.S8: Adverse Event Category: Vasomotor Symptoms by System Organ Class and Preferred Term, by Subgroup (Safety Population)

Study: Pooled

System Organ Class: Any, Preferred Term: Any

Treatment	N	n (%)	OR[1] [95% CI]	RR[2] [95% CI]	RD[3] [95% CI]	p-value[4]	p-value (int)[5]
Ethnicity							
Hispanic or Latino							
Relugolix+E2/NETA	53	5 (9.4)	1.42	1.29	0.02	0.6844	0.7981
Placebo	55	3 (5.5)	[0.35;5.82]	[0.38;4.33]	[-0.09;0.12]		
Not Hispanic or Latino							
Relugolix+E2/NETA	197	22 (11.2)	1.75	1.64	0.04	0.1214	
Placebo	199	14 (7.0)	[0.86;3.55]	[0.87;3.10]	[-0.01;0.10]		
Not reported							
Relugolix+E2/NETA	4	0	NC	NC	NC	NC	
Placebo	2	0	[NC;NC]	[NC;NC]	[NC;NC]		

Post hoc analysis. The denominator for percentages is the number of patients in the safety population for each treatment group. Patients with multiple events for a given PT or SOC are counted only once for each PT and SOC. Events are sorted alphabetically by SOC and PT and then by ascending subgroup-by-treatment interaction p-value within each. MedDRA (version 22.0).
Vasomotor symptoms include preferred term of Hyperhidrosis, Feeling hot, Hot flush, Night sweats and Flushing.
[1] OR (95% CI) based on a logistic regression model adjusting for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates.
[2] RR (95% CI) based on a Cochran-Mantel-Haenszel approach stratified by study.
[3] RD (95% CI) based on a Mantel-Haenszel approach stratified by study. 95% CIs are based on the approximation to the normal distribution using the Sato estimator for the standard error.
[4] P-value based on a Cochran-Mantel-Haenszel test stratified by study.
[5] Interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the OR (95% CI). Not reported subgroup levels are not included in estimation of the interaction p-value.
A continuity correction is applied in estimation of the OR, RR and p-value if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum. No continuity correction is applied in the estimation of the RD.
The reference group for the OR, RR and RD is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with >= 1 event; OR: Odds ratio; RR: Risk ratio; RD: Risk difference; CI: Confidence interval; int: p-value for interaction; NETA: Norethindrone acetate; SOC: System organ class; PT: Preferred term; NC: Not calculated.

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Table SAF.VASOANY.SPT.POOL.1.1.S4: Adverse Event Category: Vasomotor Symptoms by System Organ Class and Preferred Term, by Subgroup (Safety Population)

Study: Pooled

System Organ Class: Any, Preferred Term: Any

Treatment	N	n (%)	OR[1] [95% CI]	RR[2] [95% CI]	RD[3] [95% CI]	p-value[4]	p-value (int)[5]
Maximum NRS Pain Score at Baseline							
< 4							
Relugolix+E2/NETA	73	9 (12.3)	1.80	1.67	0.05	0.3272	0.8544
Placebo	62	4 (6.5)	[0.55;5.88]	[0.59;4.70]	[-0.05;0.15]		
>= 4							
Relugolix+E2/NETA	178	18 (10.1)	1.58	1.51	0.03	0.2314	
Placebo	190	13 (6.8)	[0.74;3.34]	[0.77;2.97]	[-0.02;0.09]		
Missing							
Relugolix+E2/NETA	3	0	NC	NC	NC	NC	
Placebo	4	0	[NC;NC]	[NC;NC]	[NC;NC]		

Post hoc analysis. The denominator for percentages is the number of patients in the safety population for each treatment group. Patients with multiple events for a given PT or SOC are counted only once for each PT and SOC. Events are sorted alphabetically by SOC and PT and then by ascending subgroup-by-treatment interaction p-value within each. MedDRA (version 22.0).
Vasomotor symptoms include preferred term of Hyperhidrosis, Feeling hot, Hot flush, Night sweats and Flushing.
[1] OR (95% CI) based on a logistic regression model adjusting for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates.
[2] RR (95% CI) based on a Cochran-Mantel-Haenszel approach stratified by study.
[3] RD (95% CI) based on a Mantel-Haenszel approach stratified by study. 95% CIs are based on the approximation to the normal distribution using the Sato estimator for the standard error.
[4] P-value based on a Cochran-Mantel-Haenszel test stratified by study.
[5] Interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the OR (95% CI). Missing subgroup levels are not included in estimation of the interaction p-value.
A continuity correction is applied in estimation of the OR, RR and p-value if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum. No continuity correction is applied in the estimation of the RD.
The reference group for the OR, RR and RD is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with >= 1 event; OR: Odds ratio; RR: Risk ratio; RD: Risk difference; CI: Confidence interval; int: p-value for interaction; NETA: Norethindrone acetate; SOC: System organ class; PT: Preferred term; NC: Not calculated.

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Table SAF.VASOANY.SPT.POOL.2.1.S1: Adverse Event Category: Vasomotor Symptoms by System Organ Class and Preferred Term, by Subgroup (Safety Population)

Study: Pooled

System Organ Class: Skin and subcutaneous tissue disorders, Preferred Term: Any

Treatment	**N**	**n (%)**	**OR[1] [95% CI]**	**RR[2] [95% CI]**	**RD[3] [95% CI]**	**p-value[4]**	**p-value (int)[5]**
Age (years)							
< 40 years							
Relugolix+E2/NETA	62	3 (4.8)	NC [NC;NC]	NC [NC;NC]	NC [NC;NC]	NC	NC
Placebo	78	0					
>= 40 years							
Relugolix+E2/NETA	192	5 (2.6)	NC [NC;NC]	NC [NC;NC]	NC [NC;NC]	NC	
Placebo	178	2 (1.1)					

Post hoc analysis. The denominator for percentages is the number of patients in the safety population for each treatment group. Patients with multiple events for a given PT or SOC are counted only once for each PT and SOC. Events are sorted alphabetically by SOC and PT and then by ascending subgroup-by-treatment interaction p-value within each. MedDRA (version 22.0).
Vasomotor symptoms include preferred term of Hyperhidrosis, Feeling hot, Hot flush, Night sweats and Flushing.
[1] OR (95% CI) based on a logistic regression model adjusting for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates.
[2] RR (95% CI) based on a Cochran-Mantel-Haenszel approach stratified by study.
[3] RD (95% CI) based on a Mantel-Haenszel approach stratified by study. 95% CIs are based on the approximation to the normal distribution using the Sato estimator for the standard error.
[4] P-value based on a Cochran-Mantel-Haenszel test stratified by study.
[5] Interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the OR (95% CI).
A continuity correction is applied in estimation of the OR, RR and p-value if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum. No continuity correction is applied in the estimation of the RD.
The reference group for the OR, RR and RD is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with >= 1 event; OR: Odds ratio; RR: Risk ratio; RD: Risk difference; CI: Confidence interval; int: p-value for interaction; NETA: Norethindrone acetate; SOC: System organ class; PT: Preferred term; NC: Not calculated.

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Table SAF.VASOANY.SPT.POOL.2.1.S2: Adverse Event Category: Vasomotor Symptoms by System Organ Class and Preferred Term, by Subgroup (Safety Population)

Study: Pooled

System Organ Class: Skin and subcutaneous tissue disorders, Preferred Term: Any

Treatment	N	n (%)	OR[1] [95% CI]	RR[2] [95% CI]	RD[3] [95% CI]	p-value[4]	p-value (int)[5]
BMI (kg/m2) at Baseline							
< 30							
Relugolix+E2/NETA	119	6 (5.0)	NC	NC	NC	NC	NC
Placebo	115	0	[NC;NC]	[NC;NC]	[NC;NC]		
>= 30							
Relugolix+E2/NETA	134	2 (1.5)	NC	NC	NC	NC	
Placebo	141	2 (1.4)	[NC;NC]	[NC;NC]	[NC;NC]		
Missing							
Relugolix+E2/NETA	1	0	NC	NC	NC	NC	
Placebo	0	0	[NC;NC]	[NC;NC]	[NC;NC]		

Post hoc analysis. The denominator for percentages is the number of patients in the safety population for each treatment group. Patients with multiple events for a given PT or SOC are counted only once for each PT and SOC. Events are sorted alphabetically by SOC and PT and then by ascending subgroup-by-treatment interaction p-value within each. MedDRA (version 22.0).
Vasomotor symptoms include preferred term of Hyperhidrosis, Feeling hot, Hot flush, Night sweats and Flushing.
[1] OR (95% CI) based on a logistic regression model adjusting for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates.
[2] RR (95% CI) based on a Cochran-Mantel-Haenszel approach stratified by study.
[3] RD (95% CI) based on a Mantel-Haenszel approach stratified by study. 95% CIs are based on the approximation to the normal distribution using the Sato estimator for the standard error.
[4] P-value based on a Cochran-Mantel-Haenszel test stratified by study.
[5] Interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the OR (95% CI). Missing subgroup levels are not included in estimation of the interaction p-value.
A continuity correction is applied in estimation of the OR, RR and p-value if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum. No continuity correction is applied in the estimation of the RD.
The reference group for the OR, RR and RD is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with >= 1 event; OR: Odds ratio; RR: Risk ratio; RD: Risk difference; CI: Confidence interval; int: p-value for interaction; NETA: Norethindrone acetate; SOC: System organ class; PT: Preferred term; NC: Not calculated.

SOURCE: \Studies\MYV\MYV102\Analysis\Prod\Progs\TFLs\Tab_SAF_AESI_SOC_PT_S_BIN.SAS
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Table SAF.VASOANY.SPT.POOL.2.1.S3: Adverse Event Category: Vasomotor Symptoms by System Organ Class and Preferred Term, by Subgroup (Safety Population)

Study: Pooled

System Organ Class: Skin and subcutaneous tissue disorders, Preferred Term: Any

Treatment	**N**	**n (%)**	**OR[1] [95% CI]**	**RR[2] [95% CI]**	**RD[3] [95% CI]**	**p-value[4]**	**p-value (int)[5]**
Uterine Volume at Baseline (cm3)							
< 300 cm3							
Relugolix+E2/NETA	148	6 (4.1)	NC	NC	NC	NC	NC
Placebo	129	1 (0.8)	[NC;NC]	[NC;NC]	[NC;NC]		
>= 300 cm3							
Relugolix+E2/NETA	105	2 (1.9)	NC	NC	NC	NC	
Placebo	127	1 (0.8)	[NC;NC]	[NC;NC]	[NC;NC]		
Missing							
Relugolix+E2/NETA	1	0	NC	NC	NC	NC	
Placebo	0	0	[NC;NC]	[NC;NC]	[NC;NC]		

Post hoc analysis. The denominator for percentages is the number of patients in the safety population for each treatment group. Patients with multiple events for a given PT or SOC are counted only once for each PT and SOC. Events are sorted alphabetically by SOC and PT and then by ascending subgroup-by-treatment interaction p-value within each. MedDRA (version 22.0).
Vasomotor symptoms include preferred term of Hyperhidrosis, Feeling hot, Hot flush, Night sweats and Flushing.
[1] OR (95% CI) based on a logistic regression model adjusting for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates.
[2] RR (95% CI) based on a Cochran-Mantel-Haenszel approach stratified by study.
[3] RD (95% CI) based on a Mantel-Haenszel approach stratified by study. 95% CIs are based on the approximation to the normal distribution using the Sato estimator for the standard error.
[4] P-value based on a Cochran-Mantel-Haenszel test stratified by study.
[5] Interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the OR (95% CI). Missing subgroup levels are not included in estimation of the interaction p-value.
A continuity correction is applied in estimation of the OR, RR and p-value if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum. No continuity correction is applied in the estimation of the RD.
The reference group for the OR, RR and RD is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with >= 1 event; OR: Odds ratio; RR: Risk ratio; RD: Risk difference; CI: Confidence interval; int: p-value for interaction; NETA: Norethindrone acetate; SOC: System organ class; PT: Preferred term; NC: Not calculated.

SOURCE: \Studies\MYV\MYV102\Analysis\Prod\Progs\TFLs\Tab_SAF_AESI_SOC_PT_S_BIN.SAS
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Table SAF.VASOANY.SPT.POOL.2.1.S4: Adverse Event Category: Vasomotor Symptoms by System Organ Class and Preferred Term, by Subgroup (Safety Population)

Study: Pooled

System Organ Class: Skin and subcutaneous tissue disorders, Preferred Term: Any

Treatment	N	n (%)	OR[1] [95% CI]	RR[2] [95% CI]	RD[3] [95% CI]	p-value[4]	p-value (int)[5]
Maximum NRS Pain Score at Baseline							
< 4							
Relugolix+E2/NETA	73	3 (4.1)	NC	NC	NC	NC	NC
Placebo	62	2 (3.2)	[NC;NC]	[NC;NC]	[NC;NC]		
>= 4							
Relugolix+E2/NETA	178	5 (2.8)	NC	NC	NC	NC	
Placebo	190	0	[NC;NC]	[NC;NC]	[NC;NC]		
Missing							
Relugolix+E2/NETA	3	0	NC	NC	NC	NC	
Placebo	4	0	[NC;NC]	[NC;NC]	[NC;NC]		

Post hoc analysis. The denominator for percentages is the number of patients in the safety population for each treatment group. Patients with multiple events for a given PT or SOC are counted only once for each PT and SOC. Events are sorted alphabetically by SOC and PT and then by ascending subgroup-by-treatment interaction p-value within each. MedDRA (version 22.0).
Vasomotor symptoms include preferred term of Hyperhidrosis, Feeling hot, Hot flush, Night sweats and Flushing.
[1] OR (95% CI) based on a logistic regression model adjusting for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates.
[2] RR (95% CI) based on a Cochran-Mantel-Haenszel approach stratified by study.
[3] RD (95% CI) based on a Mantel-Haenszel approach stratified by study. 95% CIs are based on the approximation to the normal distribution using the Sato estimator for the standard error.
[4] P-value based on a Cochran-Mantel-Haenszel test stratified by study.
[5] Interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the OR (95% CI). Missing subgroup levels are not included in estimation of the interaction p-value.
A continuity correction is applied in estimation of the OR, RR and p-value if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum. No continuity correction is applied in the estimation of the RD.
The reference group for the OR, RR and RD is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with >= 1 event; OR: Odds ratio; RR: Risk ratio; RD: Risk difference; CI: Confidence interval; int: p-value for interaction; NETA: Norethindrone acetate; SOC: System organ class; PT: Preferred term; NC: Not calculated.

SOURCE: \Studies\MYV\MYV102\Analysis\Prod\Progs\TFLs\Tab_SAF_AESI_SOC_PT_S_BIN.SAS
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Table SAF.VASOANY.SPT.POOL.2.1.S5: Adverse Event Category: Vasomotor Symptoms by System Organ Class and Preferred Term, by Subgroup (Safety Population)

Study: Pooled

System Organ Class: Skin and subcutaneous tissue disorders, Preferred Term: Any

Treatment	**N**	**n (%)**	**OR[1] [95% CI]**	**RR[2] [95% CI]**	**RD[3] [95% CI]**	**p-value[4]**	**p-value (int)[5]**
MBL Volume at Baseline (mL)							
< 225 mL							
Relugolix+E2/NETA	164	8 (4.9)	NC [NC;NC]	NC [NC;NC]	NC [NC;NC]	NC	NC
Placebo	171	1 (0.6)					
>= 225 mL							
Relugolix+E2/NETA	90	0	NC [NC;NC]	NC [NC;NC]	NC [NC;NC]	NC	
Placebo	85	1 (1.2)					

Post hoc analysis. The denominator for percentages is the number of patients in the safety population for each treatment group. Patients with multiple events for a given PT or SOC are counted only once for each PT and SOC. Events are sorted alphabetically by SOC and PT and then by ascending subgroup-by-treatment interaction p-value within each. MedDRA (version 22.0).
Vasomotor symptoms include preferred term of Hyperhidrosis, Feeling hot, Hot flush, Night sweats and Flushing.
[1] OR (95% CI) based on a logistic regression model adjusting for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates.
[2] RR (95% CI) based on a Cochran-Mantel-Haenszel approach stratified by study.
[3] RD (95% CI) based on a Mantel-Haenszel approach stratified by study. 95% CIs are based on the approximation to the normal distribution using the Sato estimator for the standard error.
[4] P-value based on a Cochran-Mantel-Haenszel test stratified by study.
[5] Interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the OR (95% CI).
A continuity correction is applied in estimation of the OR, RR and p-value if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum. No continuity correction is applied in the estimation of the RD.
The reference group for the OR, RR and RD is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with >= 1 event; OR: Odds ratio; RR: Risk ratio; RD: Risk difference; CI: Confidence interval; int: p-value for interaction; NETA: Norethindrone acetate; SOC: System organ class; PT: Preferred term; NC: Not calculated.

SOURCE: \Studies\MYV\MYV102\Analysis\Prod\Progs\TFLs\Tab_SAF_AESI_SOC_PT_S_BIN.SAS
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Table SAF.VASOANY.SPT.POOL.2.1.S6: Adverse Event Category: Vasomotor Symptoms by System Organ Class and Preferred Term, by Subgroup (Safety Population)

Study: Pooled

System Organ Class: Skin and subcutaneous tissue disorders, Preferred Term: Any

Treatment	**N**	**n (%)**	**OR[1] [95% CI]**	**RR[2] [95% CI]**	**RD[3] [95% CI]**	**p-value[4]**	**p-value (int)[5]**
Geographic Region I							
North America							
Relugolix+E2/NETA	192	3 (1.6)	NC	NC	NC	NC	NC
Placebo	194	1 (0.5)	[NC;NC]	[NC;NC]	[NC;NC]		
Rest of World							
Relugolix+E2/NETA	62	5 (8.1)	NC	NC	NC	NC	
Placebo	62	1 (1.6)	[NC;NC]	[NC;NC]	[NC;NC]		

Post hoc analysis. The denominator for percentages is the number of patients in the safety population for each treatment group. Patients with multiple events for a given PT or SOC are counted only once for each PT and SOC. Events are sorted alphabetically by SOC and PT and then by ascending subgroup-by-treatment interaction p-value within each. MedDRA (version 22.0).
Vasomotor symptoms include preferred term of Hyperhidrosis, Feeling hot, Hot flush, Night sweats and Flushing.
[1] OR (95% CI) based on a logistic regression model adjusting for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates.
[2] RR (95% CI) based on a Cochran-Mantel-Haenszel approach stratified by study.
[3] RD (95% CI) based on a Mantel-Haenszel approach stratified by study. 95% CIs are based on the approximation to the normal distribution using the Sato estimator for the standard error.
[4] P-value based on a Cochran-Mantel-Haenszel test stratified by study.
[5] Interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the OR (95% CI).
A continuity correction is applied in estimation of the OR, RR and p-value if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum. No continuity correction is applied in the estimation of the RD.
The reference group for the OR, RR and RD is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with >= 1 event; OR: Odds ratio; RR: Risk ratio; RD: Risk difference; CI: Confidence interval; int: p-value for interaction; NETA: Norethindrone acetate; SOC: System organ class; PT: Preferred term; NC: Not calculated.

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Table SAF.VASOANY.SPT.POOL.2.1.S7: Adverse Event Category: Vasomotor Symptoms by System Organ Class and Preferred Term, by Subgroup (Safety Population)

Study: Pooled

System Organ Class: Skin and subcutaneous tissue disorders, Preferred Term: Any

Treatment	**N**	**n (%)**	**OR[1] [95% CI]**	**RR[2] [95% CI]**	**RD[3] [95% CI]**	**p-value[4]**	**p-value (int)[5]**
Geographic Region II							
Europe							
Relugolix+E2/NETA	41	4 (9.8)	NC [NC;NC]	NC [NC;NC]	NC [NC;NC]	NC	NC
Placebo	42	1 (2.4)					
Rest of World (including the US)							
Relugolix+E2/NETA	213	4 (1.9)	NC [NC;NC]	NC [NC;NC]	NC [NC;NC]	NC	
Placebo	214	1 (0.5)					

Post hoc analysis. The denominator for percentages is the number of patients in the safety population for each treatment group. Patients with multiple events for a given PT or SOC are counted only once for each PT and SOC. Events are sorted alphabetically by SOC and PT and then by ascending subgroup-by-treatment interaction p-value within each. MedDRA (version 22.0).
Vasomotor symptoms include preferred term of Hyperhidrosis, Feeling hot, Hot flush, Night sweats and Flushing.
[1] OR (95% CI) based on a logistic regression model adjusting for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates.
[2] RR (95% CI) based on a Cochran-Mantel-Haenszel approach stratified by study.
[3] RD (95% CI) based on a Mantel-Haenszel approach stratified by study. 95% CIs are based on the approximation to the normal distribution using the Sato estimator for the standard error.
[4] P-value based on a Cochran-Mantel-Haenszel test stratified by study.
[5] Interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the OR (95% CI).
A continuity correction is applied in estimation of the OR, RR and p-value if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum. No continuity correction is applied in the estimation of the RD.
The reference group for the OR, RR and RD is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with >= 1 event; OR: Odds ratio; RR: Risk ratio; RD: Risk difference; CI: Confidence interval; int: p-value for interaction; NETA: Norethindrone acetate; SOC: System organ class; PT: Preferred term; NC: Not calculated.

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Table SAF.VASOANY.SPT.POOL.2.1.S8: Adverse Event Category: Vasomotor Symptoms by System Organ Class and Preferred Term, by Subgroup (Safety Population)

Study: Pooled

System Organ Class: Skin and subcutaneous tissue disorders, Preferred Term: Any

Treatment	N	n (%)	OR[1] [95% CI]	RR[2] [95% CI]	RD[3] [95% CI]	p-value[4]	p-value (int)[5]
Ethnicity							
Hispanic or Latino							
Relugolix+E2/NETA	53	2 (3.8)	NC	NC	NC	NC	NC
Placebo	55	1 (1.8)	[NC;NC]	[NC;NC]	[NC;NC]		
Not Hispanic or Latino							
Relugolix+E2/NETA	197	6 (3.0)	NC	NC	NC	NC	
Placebo	199	1 (0.5)	[NC;NC]	[NC;NC]	[NC;NC]		
Not reported							
Relugolix+E2/NETA	4	0	NC	NC	NC	NC	
Placebo	2	0	[NC;NC]	[NC;NC]	[NC;NC]		

Post hoc analysis. The denominator for percentages is the number of patients in the safety population for each treatment group. Patients with multiple events for a given PT or SOC are counted only once for each PT and SOC. Events are sorted alphabetically by SOC and PT and then by ascending subgroup-by-treatment interaction p-value within each. MedDRA (version 22.0).
Vasomotor symptoms include preferred term of Hyperhidrosis, Feeling hot, Hot flush, Night sweats and Flushing.
[1] OR (95% CI) based on a logistic regression model adjusting for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates.
[2] RR (95% CI) based on a Cochran-Mantel-Haenszel approach stratified by study.
[3] RD (95% CI) based on a Mantel-Haenszel approach stratified by study. 95% CIs are based on the approximation to the normal distribution using the Sato estimator for the standard error.
[4] P-value based on a Cochran-Mantel-Haenszel test stratified by study.
[5] Interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the OR (95% CI). Not reported subgroup levels are not included in estimation of the interaction p-value.
A continuity correction is applied in estimation of the OR, RR and p-value if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum. No continuity correction is applied in the estimation of the RD.
The reference group for the OR, RR and RD is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with >= 1 event; OR: Odds ratio; RR: Risk ratio; RD: Risk difference; CI: Confidence interval; int: p-value for interaction; NETA: Norethindrone acetate; SOC: System organ class; PT: Preferred term; NC: Not calculated.

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Table SAF.VASOANY.SPT.POOL.2.1.S9: Adverse Event Category: Vasomotor Symptoms by System Organ Class and Preferred Term, by Subgroup (Safety Population)

Study: Pooled

System Organ Class: Skin and subcutaneous tissue disorders, Preferred Term: Any

Treatment	N	n (%)	OR[1] [95% CI]	RR[2] [95% CI]	RD[3] [95% CI]	p-value[4]	p-value (int)[5]
Race							
Black/African American							
Relugolix+E2/NETA	122	1 (0.8)	NC	NC	NC	NC	NC
Placebo	141	0	[NC;NC]	[NC;NC]	[NC;NC]		
White							
Relugolix+E2/NETA	123	5 (4.1)	NC	NC	NC	NC	
Placebo	105	2 (1.9)	[NC;NC]	[NC;NC]	[NC;NC]		
Asian							
Relugolix+E2/NETA	1	0	NC	NC	NC	NC	
Placebo	3	0	[NC;NC]	[NC;NC]	[NC;NC]		
Others							
Relugolix+E2/NETA	5	2 (40.0)	NC	NC	NC	NC	
Placebo	6	0	[NC;NC]	[NC;NC]	[NC;NC]		
Not reported							
Relugolix+E2/NETA	3	0	NC	NC	NC	NC	
Placebo	1	0	[NC;NC]	[NC;NC]	[NC;NC]		

Post hoc analysis. The denominator for percentages is the number of patients in the safety population for each treatment group. Patients with multiple events for a given PT or SOC are counted only once for each PT and SOC. Events are sorted alphabetically by SOC and PT and then by ascending subgroup-by-treatment interaction p-value within each. MedDRA (version 22.0).
Vasomotor symptoms include preferred term of Hyperhidrosis, Feeling hot, Hot flush, Night sweats and Flushing.
[1] OR (95% CI) based on a logistic regression model adjusting for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates.
[2] RR (95% CI) based on a Cochran-Mantel-Haenszel approach stratified by study.
[3] RD (95% CI) based on a Mantel-Haenszel approach stratified by study. 95% CIs are based on the approximation to the normal distribution using the Sato estimator for the standard error.
[4] P-value based on a Cochran-Mantel-Haenszel test stratified by study.
[5] Interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the OR (95% CI). Not reported subgroup levels are not included in estimation of the interaction p-value.
A continuity correction is applied in estimation of the OR, RR and p-value if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum. No continuity correction is applied in the estimation of the RD.
The reference group for the OR, RR and RD is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with >= 1 event; OR: Odds ratio; RR: Risk ratio; RD: Risk difference; CI: Confidence interval; int: p-value for interaction; NETA: Norethindrone acetate; SOC: System organ class; PT: Preferred term; NC: Not calculated.

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Table SAF.VASOANY.SPT.POOL.2.2.S1: Adverse Event Category: Vasomotor Symptoms by System Organ Class and Preferred Term, by Subgroup (Safety Population)

Study: Pooled

System Organ Class: Skin and subcutaneous tissue disorders, Preferred Term: Hyperhidrosis

Treatment	**N**	**n (%)**	**OR[1] [95% CI]**	**RR[2] [95% CI]**	**RD[3] [95% CI]**	**p-value[4]**	**p-value (int)[5]**
Age (years)							
< 40 years							
Relugolix+E2/NETA	62	2 (3.2)	NC [NC;NC]	NC [NC;NC]	NC [NC;NC]	NC	NC
Placebo	78	0					
>= 40 years							
Relugolix+E2/NETA	192	3 (1.6)	NC [NC;NC]	NC [NC;NC]	NC [NC;NC]	NC	
Placebo	178	2 (1.1)					

Post hoc analysis. The denominator for percentages is the number of patients in the safety population for each treatment group. Patients with multiple events for a given PT or SOC are counted only once for each PT and SOC. Events are sorted alphabetically by SOC and PT and then by ascending subgroup-by-treatment interaction p-value within each. MedDRA (version 22.0).
Vasomotor symptoms include preferred term of Hyperhidrosis, Feeling hot, Hot flush, Night sweats and Flushing.
[1] OR (95% CI) based on a logistic regression model adjusting for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates.
[2] RR (95% CI) based on a Cochran-Mantel-Haenszel approach stratified by study.
[3] RD (95% CI) based on a Mantel-Haenszel approach stratified by study. 95% CIs are based on the approximation to the normal distribution using the Sato estimator for the standard error.
[4] P-value based on a Cochran-Mantel-Haenszel test stratified by study.
[5] Interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the OR (95% CI).
A continuity correction is applied in estimation of the OR, RR and p-value if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum. No continuity correction is applied in the estimation of the RD.
The reference group for the OR, RR and RD is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with >= 1 event; OR: Odds ratio; RR: Risk ratio; RD: Risk difference; CI: Confidence interval; int: p-value for interaction; NETA: Norethindrone acetate; SOC: System organ class; PT: Preferred term; NC: Not calculated.

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Table SAF.VASOANY.SPT.POOL.2.2.S2: Adverse Event Category: Vasomotor Symptoms by System Organ Class and Preferred Term, by Subgroup (Safety Population)

Study: Pooled

System Organ Class: Skin and subcutaneous tissue disorders, Preferred Term: Hyperhidrosis

Treatment	N	n (%)	OR[1] [95% CI]	RR[2] [95% CI]	RD[3] [95% CI]	p-value[4]	p-value (int)[5]
BMI (kg/m2) at Baseline							
< 30							
Relugolix+E2/NETA	119	4 (3.4)	NC	NC	NC	NC	NC
Placebo	115	0	[NC;NC]	[NC;NC]	[NC;NC]		
>= 30							
Relugolix+E2/NETA	134	1 (0.7)	NC	NC	NC	NC	
Placebo	141	2 (1.4)	[NC;NC]	[NC;NC]	[NC;NC]		
Missing							
Relugolix+E2/NETA	1	0	NC	NC	NC	NC	
Placebo	0	0	[NC;NC]	[NC;NC]	[NC;NC]		

Post hoc analysis. The denominator for percentages is the number of patients in the safety population for each treatment group. Patients with multiple events for a given PT or SOC are counted only once for each PT and SOC. Events are sorted alphabetically by SOC and PT and then by ascending subgroup-by-treatment interaction p-value within each. MedDRA (version 22.0).
Vasomotor symptoms include preferred term of Hyperhidrosis, Feeling hot, Hot flush, Night sweats and Flushing.
[1] OR (95% CI) based on a logistic regression model adjusting for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates.
[2] RR (95% CI) based on a Cochran-Mantel-Haenszel approach stratified by study.
[3] RD (95% CI) based on a Mantel-Haenszel approach stratified by study. 95% CIs are based on the approximation to the normal distribution using the Sato estimator for the standard error.
[4] P-value based on a Cochran-Mantel-Haenszel test stratified by study.
[5] Interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the OR (95% CI). Missing subgroup levels are not included in estimation of the interaction p-value.
A continuity correction is applied in estimation of the OR, RR and p-value if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum. No continuity correction is applied in the estimation of the RD.
The reference group for the OR, RR and RD is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with >= 1 event; OR: Odds ratio; RR: Risk ratio; RD: Risk difference; CI: Confidence interval; int: p-value for interaction; NETA: Norethindrone acetate; SOC: System organ class; PT: Preferred term; NC: Not calculated.

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Table SAF.VASOANY.SPT.POOL.2.2.S3: Adverse Event Category: Vasomotor Symptoms by System Organ Class and Preferred Term, by Subgroup (Safety Population)

Study: Pooled

System Organ Class: Skin and subcutaneous tissue disorders, Preferred Term: Hyperhidrosis

Treatment	**N**	**n (%)**	**OR[1] [95% CI]**	**RR[2] [95% CI]**	**RD[3] [95% CI]**	**p-value[4]**	**p-value (int)[5]**
Uterine Volume at Baseline (cm3)							
< 300 cm3							
Relugolix+E2/NETA	148	4 (2.7)	NC	NC	NC	NC	NC
Placebo	129	1 (0.8)	[NC;NC]	[NC;NC]	[NC;NC]		
>= 300 cm3							
Relugolix+E2/NETA	105	1 (1.0)	NC	NC	NC	NC	
Placebo	127	1 (0.8)	[NC;NC]	[NC;NC]	[NC;NC]		
Missing							
Relugolix+E2/NETA	1	0	NC	NC	NC	NC	
Placebo	0	0	[NC;NC]	[NC;NC]	[NC;NC]		

Post hoc analysis. The denominator for percentages is the number of patients in the safety population for each treatment group. Patients with multiple events for a given PT or SOC are counted only once for each PT and SOC. Events are sorted alphabetically by SOC and PT and then by ascending subgroup-by-treatment interaction p-value within each. MedDRA (version 22.0).
Vasomotor symptoms include preferred term of Hyperhidrosis, Feeling hot, Hot flush, Night sweats and Flushing.
[1] OR (95% CI) based on a logistic regression model adjusting for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates.
[2] RR (95% CI) based on a Cochran-Mantel-Haenszel approach stratified by study.
[3] RD (95% CI) based on a Mantel-Haenszel approach stratified by study. 95% CIs are based on the approximation to the normal distribution using the Sato estimator for the standard error.
[4] P-value based on a Cochran-Mantel-Haenszel test stratified by study.
[5] Interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the OR (95% CI). Missing subgroup levels are not included in estimation of the interaction p-value.
A continuity correction is applied in estimation of the OR, RR and p-value if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum. No continuity correction is applied in the estimation of the RD.
The reference group for the OR, RR and RD is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with >= 1 event; OR: Odds ratio; RR: Risk ratio; RD: Risk difference; CI: Confidence interval; int: p-value for interaction; NETA: Norethindrone acetate; SOC: System organ class; PT: Preferred term; NC: Not calculated.

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Table SAF.VASOANY.SPT.POOL.2.2.S4: Adverse Event Category: Vasomotor Symptoms by System Organ Class and Preferred Term, by Subgroup (Safety Population)

Study: Pooled

System Organ Class: Skin and subcutaneous tissue disorders, Preferred Term: Hyperhidrosis

Treatment	N	n (%)	OR[1] [95% CI]	RR[2] [95% CI]	RD[3] [95% CI]	p-value[4]	p-value (int)[5]
Maximum NRS Pain Score at Baseline							
< 4							
Relugolix+E2/NETA	73	2 (2.7)	NC	NC	NC	NC	NC
Placebo	62	2 (3.2)	[NC;NC]	[NC;NC]	[NC;NC]		
>= 4							
Relugolix+E2/NETA	178	3 (1.7)	NC	NC	NC	NC	
Placebo	190	0	[NC;NC]	[NC;NC]	[NC;NC]		
Missing							
Relugolix+E2/NETA	3	0	NC	NC	NC	NC	
Placebo	4	0	[NC;NC]	[NC;NC]	[NC;NC]		

Post hoc analysis. The denominator for percentages is the number of patients in the safety population for each treatment group. Patients with multiple events for a given PT or SOC are counted only once for each PT and SOC. Events are sorted alphabetically by SOC and PT and then by ascending subgroup-by-treatment interaction p-value within each. MedDRA (version 22.0).
Vasomotor symptoms include preferred term of Hyperhidrosis, Feeling hot, Hot flush, Night sweats and Flushing.
[1] OR (95% CI) based on a logistic regression model adjusting for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates.
[2] RR (95% CI) based on a Cochran-Mantel-Haenszel approach stratified by study.
[3] RD (95% CI) based on a Mantel-Haenszel approach stratified by study. 95% CIs are based on the approximation to the normal distribution using the Sato estimator for the standard error.
[4] P-value based on a Cochran-Mantel-Haenszel test stratified by study.
[5] Interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the OR (95% CI). Missing subgroup levels are not included in estimation of the interaction p-value.
A continuity correction is applied in estimation of the OR, RR and p-value if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum. No continuity correction is applied in the estimation of the RD.
The reference group for the OR, RR and RD is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with >= 1 event; OR: Odds ratio; RR: Risk ratio; RD: Risk difference; CI: Confidence interval; int: p-value for interaction; NETA: Norethindrone acetate; SOC: System organ class; PT: Preferred term; NC: Not calculated.

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Table SAF.VASOANY.SPT.POOL.2.2.S5: Adverse Event Category: Vasomotor Symptoms by System Organ Class and Preferred Term, by Subgroup (Safety Population)

Study: Pooled

System Organ Class: Skin and subcutaneous tissue disorders, Preferred Term: Hyperhidrosis

Treatment	N	n (%)	OR[1] [95% CI]	RR[2] [95% CI]	RD[3] [95% CI]	p-value[4]	p-value (int)[5]
MBL Volume at Baseline (mL)							
< 225 mL							
Relugolix+E2/NETA	164	5 (3.0)	NC	NC	NC	NC	NC
Placebo	171	1 (0.6)	[NC;NC]	[NC;NC]	[NC;NC]		
>= 225 mL							
Relugolix+E2/NETA	90	0	NC	NC	NC	NC	
Placebo	85	1 (1.2)	[NC;NC]	[NC;NC]	[NC;NC]		

Post hoc analysis. The denominator for percentages is the number of patients in the safety population for each treatment group. Patients with multiple events for a given PT or SOC are counted only once for each PT and SOC. Events are sorted alphabetically by SOC and PT and then by ascending subgroup-by-treatment interaction p-value within each. MedDRA (version 22.0).
Vasomotor symptoms include preferred term of Hyperhidrosis, Feeling hot, Hot flush, Night sweats and Flushing.
[1] OR (95% CI) based on a logistic regression model adjusting for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates.
[2] RR (95% CI) based on a Cochran-Mantel-Haenszel approach stratified by study.
[3] RD (95% CI) based on a Mantel-Haenszel approach stratified by study. 95% CIs are based on the approximation to the normal distribution using the Sato estimator for the standard error.
[4] P-value based on a Cochran-Mantel-Haenszel test stratified by study.
[5] Interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the OR (95% CI).
A continuity correction is applied in estimation of the OR, RR and p-value if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum. No continuity correction is applied in the estimation of the RD.
The reference group for the OR, RR and RD is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with >= 1 event; OR: Odds ratio; RR: Risk ratio; RD: Risk difference; CI: Confidence interval; int: p-value for interaction; NETA: Norethindrone acetate; SOC: System organ class; PT: Preferred term; NC: Not calculated.

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Table SAF.VASOANY.SPT.POOL.2.2.S6: Adverse Event Category: Vasomotor Symptoms by System Organ Class and Preferred Term, by Subgroup (Safety Population)

Study: Pooled

System Organ Class: Skin and subcutaneous tissue disorders, Preferred Term: Hyperhidrosis

Treatment	**N**	**n (%)**	**OR[1] [95% CI]**	**RR[2] [95% CI]**	**RD[3] [95% CI]**	**p-value[4]**	**p-value (int)[5]**
Geographic Region I							
North America							
Relugolix+E2/NETA	192	1 (0.5)	NC	NC	NC	NC	NC
Placebo	194	1 (0.5)	[NC;NC]	[NC;NC]	[NC;NC]		
Rest of World							
Relugolix+E2/NETA	62	4 (6.5)	NC	NC	NC	NC	
Placebo	62	1 (1.6)	[NC;NC]	[NC;NC]	[NC;NC]		

Post hoc analysis. The denominator for percentages is the number of patients in the safety population for each treatment group. Patients with multiple events for a given PT or SOC are counted only once for each PT and SOC. Events are sorted alphabetically by SOC and PT and then by ascending subgroup-by-treatment interaction p-value within each. MedDRA (version 22.0).
Vasomotor symptoms include preferred term of Hyperhidrosis, Feeling hot, Hot flush, Night sweats and Flushing.
[1] OR (95% CI) based on a logistic regression model adjusting for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates.
[2] RR (95% CI) based on a Cochran-Mantel-Haenszel approach stratified by study.
[3] RD (95% CI) based on a Mantel-Haenszel approach stratified by study. 95% CIs are based on the approximation to the normal distribution using the Sato estimator for the standard error.
[4] P-value based on a Cochran-Mantel-Haenszel test stratified by study.
[5] Interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the OR (95% CI).
A continuity correction is applied in estimation of the OR, RR and p-value if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum. No continuity correction is applied in the estimation of the RD.
The reference group for the OR, RR and RD is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with >= 1 event; OR: Odds ratio; RR: Risk ratio; RD: Risk difference; CI: Confidence interval; int: p-value for interaction; NETA: Norethindrone acetate; SOC: System organ class; PT: Preferred term; NC: Not calculated.

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Table SAF.VASOANY.SPT.POOL.2.2.S7: Adverse Event Category: Vasomotor Symptoms by System Organ Class and Preferred Term, by Subgroup (Safety Population)

Study: Pooled

System Organ Class: Skin and subcutaneous tissue disorders, Preferred Term: Hyperhidrosis

Treatment	**N**	**n (%)**	**OR[1] [95% CI]**	**RR[2] [95% CI]**	**RD[3] [95% CI]**	**p-value[4]**	**p-value (int)[5]**
Geographic Region II							
Europe							
Relugolix+E2/NETA	41	4 (9.8)	NC [NC;NC]	NC [NC;NC]	NC [NC;NC]	NC	NC
Placebo	42	1 (2.4)					
Rest of World (including the US)							
Relugolix+E2/NETA	213	1 (0.5)	NC [NC;NC]	NC [NC;NC]	NC [NC;NC]	NC	
Placebo	214	1 (0.5)					

Post hoc analysis. The denominator for percentages is the number of patients in the safety population for each treatment group. Patients with multiple events for a given PT or SOC are counted only once for each PT and SOC. Events are sorted alphabetically by SOC and PT and then by ascending subgroup-by-treatment interaction p-value within each. MedDRA (version 22.0).
Vasomotor symptoms include preferred term of Hyperhidrosis, Feeling hot, Hot flush, Night sweats and Flushing.
[1] OR (95% CI) based on a logistic regression model adjusting for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates.
[2] RR (95% CI) based on a Cochran-Mantel-Haenszel approach stratified by study.
[3] RD (95% CI) based on a Mantel-Haenszel approach stratified by study. 95% CIs are based on the approximation to the normal distribution using the Sato estimator for the standard error.
[4] P-value based on a Cochran-Mantel-Haenszel test stratified by study.
[5] Interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the OR (95% CI).
A continuity correction is applied in estimation of the OR, RR and p-value if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum. No continuity correction is applied in the estimation of the RD.
The reference group for the OR, RR and RD is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with >= 1 event; OR: Odds ratio; RR: Risk ratio; RD: Risk difference; CI: Confidence interval; int: p-value for interaction; NETA: Norethindrone acetate; SOC: System organ class; PT: Preferred term; NC: Not calculated.

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Table SAF.VASOANY.SPT.POOL.2.2.S8: Adverse Event Category: Vasomotor Symptoms by System Organ Class and Preferred Term, by Subgroup (Safety Population)

Study: Pooled

System Organ Class: Skin and subcutaneous tissue disorders, Preferred Term: Hyperhidrosis

Treatment	**N**	**n (%)**	**OR[1] [95% CI]**	**RR[2] [95% CI]**	**RD[3] [95% CI]**	**p-value[4]**	**p-value (int)[5]**
Ethnicity							
Hispanic or Latino							
Relugolix+E2/NETA	53	1 (1.9)	NC	NC	NC	NC	NC
Placebo	55	1 (1.8)	[NC;NC]	[NC;NC]	[NC;NC]		
Not Hispanic or Latino							
Relugolix+E2/NETA	197	4 (2.0)	NC	NC	NC	NC	
Placebo	199	1 (0.5)	[NC;NC]	[NC;NC]	[NC;NC]		
Not reported							
Relugolix+E2/NETA	4	0	NC	NC	NC	NC	
Placebo	2	0	[NC;NC]	[NC;NC]	[NC;NC]		

Post hoc analysis. The denominator for percentages is the number of patients in the safety population for each treatment group. Patients with multiple events for a given PT or SOC are counted only once for each PT and SOC. Events are sorted alphabetically by SOC and PT and then by ascending subgroup-by-treatment interaction p-value within each. MedDRA (version 22.0).
Vasomotor symptoms include preferred term of Hyperhidrosis, Feeling hot, Hot flush, Night sweats and Flushing.
[1] OR (95% CI) based on a logistic regression model adjusting for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates.
[2] RR (95% CI) based on a Cochran-Mantel-Haenszel approach stratified by study.
[3] RD (95% CI) based on a Mantel-Haenszel approach stratified by study. 95% CIs are based on the approximation to the normal distribution using the Sato estimator for the standard error.
[4] P-value based on a Cochran-Mantel-Haenszel test stratified by study.
[5] Interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the OR (95% CI). Not reported subgroup levels are not included in estimation of the interaction p-value.
A continuity correction is applied in estimation of the OR, RR and p-value if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum. No continuity correction is applied in the estimation of the RD.
The reference group for the OR, RR and RD is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with >= 1 event; OR: Odds ratio; RR: Risk ratio; RD: Risk difference; CI: Confidence interval; int: p-value for interaction; NETA: Norethindrone acetate; SOC: System organ class; PT: Preferred term; NC: Not calculated.

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Table SAF.VASOANY.SPT.POOL.2.2.S9: Adverse Event Category: Vasomotor Symptoms by System Organ Class and Preferred Term, by Subgroup (Safety Population)

Study: Pooled

System Organ Class: Skin and subcutaneous tissue disorders, Preferred Term: Hyperhidrosis

Treatment	N	n (%)	OR[1] [95% CI]	RR[2] [95% CI]	RD[3] [95% CI]	p-value[4]	p-value (int)[5]
Race							
Black/African American							
Relugolix+E2/NETA	122	0	NC	NC	NC	NC	NC
Placebo	141	0	[NC;NC]	[NC;NC]	[NC;NC]		
White							
Relugolix+E2/NETA	123	4 (3.3)	NC	NC	NC	NC	
Placebo	105	2 (1.9)	[NC;NC]	[NC;NC]	[NC;NC]		
Asian							
Relugolix+E2/NETA	1	0	NC	NC	NC	NC	
Placebo	3	0	[NC;NC]	[NC;NC]	[NC;NC]		
Others							
Relugolix+E2/NETA	5	1 (20.0)	NC	NC	NC	NC	
Placebo	6	0	[NC;NC]	[NC;NC]	[NC;NC]		
Not reported							
Relugolix+E2/NETA	3	0	NC	NC	NC	NC	
Placebo	1	0	[NC;NC]	[NC;NC]	[NC;NC]		

Post hoc analysis. The denominator for percentages is the number of patients in the safety population for each treatment group. Patients with multiple events for a given PT or SOC are counted only once for each PT and SOC. Events are sorted alphabetically by SOC and PT and then by ascending subgroup-by-treatment interaction p-value within each. MedDRA (version 22.0).
Vasomotor symptoms include preferred term of Hyperhidrosis, Feeling hot, Hot flush, Night sweats and Flushing.
[1] OR (95% CI) based on a logistic regression model adjusting for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates.
[2] RR (95% CI) based on a Cochran-Mantel-Haenszel approach stratified by study.
[3] RD (95% CI) based on a Mantel-Haenszel approach stratified by study. 95% CIs are based on the approximation to the normal distribution using the Sato estimator for the standard error.
[4] P-value based on a Cochran-Mantel-Haenszel test stratified by study.
[5] Interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the OR (95% CI). Not reported subgroup levels are not included in estimation of the interaction p-value.
A continuity correction is applied in estimation of the OR, RR and p-value if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum. No continuity correction is applied in the estimation of the RD.
The reference group for the OR, RR and RD is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with >= 1 event; OR: Odds ratio; RR: Risk ratio; RD: Risk difference; CI: Confidence interval; int: p-value for interaction; NETA: Norethindrone acetate; SOC: System organ class; PT: Preferred term; NC: Not calculated.

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Table SAF.VASOANY.SPT.POOL.2.3.S1: Adverse Event Category: Vasomotor Symptoms by System Organ Class and Preferred Term, by Subgroup (Safety Population)

Study: Pooled

System Organ Class: Skin and subcutaneous tissue disorders, Preferred Term: Night sweats

Treatment	**N**	**n (%)**	**OR[1] [95% CI]**	**RR[2] [95% CI]**	**RD[3] [95% CI]**	**p-value[4]**	**p-value (int)[5]**
Age (years)							
< 40 years							NC
Relugolix+E2/NETA	62	1 (1.6)	NC [NC;NC]	NC [NC;NC]	NC [NC;NC]	NC	
Placebo	78	0					
>= 40 years							
Relugolix+E2/NETA	192	2 (1.0)	NC [NC;NC]	NC [NC;NC]	NC [NC;NC]	NC	
Placebo	178	0					

Post hoc analysis. The denominator for percentages is the number of patients in the safety population for each treatment group. Patients with multiple events for a given PT or SOC are counted only once for each PT and SOC. Events are sorted alphabetically by SOC and PT and then by ascending subgroup-by-treatment interaction p-value within each. MedDRA (version 22.0).
Vasomotor symptoms include preferred term of Hyperhidrosis, Feeling hot, Hot flush, Night sweats and Flushing.
[1] OR (95% CI) based on a logistic regression model adjusting for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates.
[2] RR (95% CI) based on a Cochran-Mantel-Haenszel approach stratified by study.
[3] RD (95% CI) based on a Mantel-Haenszel approach stratified by study. 95% CIs are based on the approximation to the normal distribution using the Sato estimator for the standard error.
[4] P-value based on a Cochran-Mantel-Haenszel test stratified by study.
[5] Interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the OR (95% CI).
A continuity correction is applied in estimation of the OR, RR and p-value if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum. No continuity correction is applied in the estimation of the RD.
The reference group for the OR, RR and RD is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with >= 1 event; OR: Odds ratio; RR: Risk ratio; RD: Risk difference; CI: Confidence interval; int: p-value for interaction; NETA: Norethindrone acetate; SOC: System organ class; PT: Preferred term; NC: Not calculated.

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Table SAF.VASOANY.SPT.POOL.2.3.S2: Adverse Event Category: Vasomotor Symptoms by System Organ Class and Preferred Term, by Subgroup (Safety Population)

Study: Pooled

System Organ Class: Skin and subcutaneous tissue disorders, Preferred Term: Night sweats

Treatment	N	n (%)	OR[1] [95% CI]	RR[2] [95% CI]	RD[3] [95% CI]	p-value[4]	p-value (int)[5]
BMI (kg/m2) at Baseline							
< 30							
Relugolix+E2/NETA	119	2 (1.7)	NC	NC	NC	NC	NC
Placebo	115	0	[NC;NC]	[NC;NC]	[NC;NC]		
>= 30							
Relugolix+E2/NETA	134	1 (0.7)	NC	NC	NC	NC	
Placebo	141	0	[NC;NC]	[NC;NC]	[NC;NC]		
Missing							
Relugolix+E2/NETA	1	0	NC	NC	NC	NC	
Placebo	0	0	[NC;NC]	[NC;NC]	[NC;NC]		

Post hoc analysis. The denominator for percentages is the number of patients in the safety population for each treatment group. Patients with multiple events for a given PT or SOC are counted only once for each PT and SOC. Events are sorted alphabetically by SOC and PT and then by ascending subgroup-by-treatment interaction p-value within each. MedDRA (version 22.0).
Vasomotor symptoms include preferred term of Hyperhidrosis, Feeling hot, Hot flush, Night sweats and Flushing.
[1] OR (95% CI) based on a logistic regression model adjusting for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates.
[2] RR (95% CI) based on a Cochran-Mantel-Haenszel approach stratified by study.
[3] RD (95% CI) based on a Mantel-Haenszel approach stratified by study. 95% CIs are based on the approximation to the normal distribution using the Sato estimator for the standard error.
[4] P-value based on a Cochran-Mantel-Haenszel test stratified by study.
[5] Interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the OR (95% CI). Missing subgroup levels are not included in estimation of the interaction p-value.
A continuity correction is applied in estimation of the OR, RR and p-value if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum. No continuity correction is applied in the estimation of the RD.
The reference group for the OR, RR and RD is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with >= 1 event; OR: Odds ratio; RR: Risk ratio; RD: Risk difference; CI: Confidence interval; int: p-value for interaction; NETA: Norethindrone acetate; SOC: System organ class; PT: Preferred term; NC: Not calculated.

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Table SAF.VASOANY.SPT.POOL.2.3.S3: Adverse Event Category: Vasomotor Symptoms by System Organ Class and Preferred Term, by Subgroup (Safety Population)

Study: Pooled

System Organ Class: Skin and subcutaneous tissue disorders, Preferred Term: Night sweats

Treatment	N	n (%)	OR[1] [95% CI]	RR[2] [95% CI]	RD[3] [95% CI]	p-value[4]	p-value (int)[5]
Uterine Volume at Baseline (cm3)							
< 300 cm3							
Relugolix+E2/NETA	148	2 (1.4)	NC	NC	NC	NC	NC
Placebo	129	0	[NC;NC]	[NC;NC]	[NC;NC]		
>= 300 cm3							
Relugolix+E2/NETA	105	1 (1.0)	NC	NC	NC	NC	
Placebo	127	0	[NC;NC]	[NC;NC]	[NC;NC]		
Missing							
Relugolix+E2/NETA	1	0	NC	NC	NC	NC	
Placebo	0	0	[NC;NC]	[NC;NC]	[NC;NC]		

Post hoc analysis. The denominator for percentages is the number of patients in the safety population for each treatment group. Patients with multiple events for a given PT or SOC are counted only once for each PT and SOC. Events are sorted alphabetically by SOC and PT and then by ascending subgroup-by-treatment interaction p-value within each. MedDRA (version 22.0).
Vasomotor symptoms include preferred term of Hyperhidrosis, Feeling hot, Hot flush, Night sweats and Flushing.
[1] OR (95% CI) based on a logistic regression model adjusting for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates.
[2] RR (95% CI) based on a Cochran-Mantel-Haenszel approach stratified by study.
[3] RD (95% CI) based on a Mantel-Haenszel approach stratified by study. 95% CIs are based on the approximation to the normal distribution using the Sato estimator for the standard error.
[4] P-value based on a Cochran-Mantel-Haenszel test stratified by study.
[5] Interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the OR (95% CI). Missing subgroup levels are not included in estimation of the interaction p-value.
A continuity correction is applied in estimation of the OR, RR and p-value if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum. No continuity correction is applied in the estimation of the RD.
The reference group for the OR, RR and RD is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with >= 1 event; OR: Odds ratio; RR: Risk ratio; RD: Risk difference; CI: Confidence interval; int: p-value for interaction; NETA: Norethindrone acetate; SOC: System organ class; PT: Preferred term; NC: Not calculated.

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Table SAF.VASOANY.SPT.POOL.2.3.S4: Adverse Event Category: Vasomotor Symptoms by System Organ Class and Preferred Term, by Subgroup (Safety Population)

Study: Pooled

System Organ Class: Skin and subcutaneous tissue disorders, Preferred Term: Night sweats

Treatment	N	n (%)	OR[1] [95% CI]	RR[2] [95% CI]	RD[3] [95% CI]	p-value[4]	p-value (int)[5]
Maximum NRS Pain Score at Baseline							
< 4							
Relugolix+E2/NETA	73	1 (1.4)	NC	NC	NC	NC	NC
Placebo	62	0	[NC;NC]	[NC;NC]	[NC;NC]		
>= 4							
Relugolix+E2/NETA	178	2 (1.1)	NC	NC	NC	NC	
Placebo	190	0	[NC;NC]	[NC;NC]	[NC;NC]		
Missing							
Relugolix+E2/NETA	3	0	NC	NC	NC	NC	
Placebo	4	0	[NC;NC]	[NC;NC]	[NC;NC]		

Post hoc analysis. The denominator for percentages is the number of patients in the safety population for each treatment group. Patients with multiple events for a given PT or SOC are counted only once for each PT and SOC. Events are sorted alphabetically by SOC and PT and then by ascending subgroup-by-treatment interaction p-value within each. MedDRA (version 22.0).
Vasomotor symptoms include preferred term of Hyperhidrosis, Feeling hot, Hot flush, Night sweats and Flushing.
[1] OR (95% CI) based on a logistic regression model adjusting for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates.
[2] RR (95% CI) based on a Cochran-Mantel-Haenszel approach stratified by study.
[3] RD (95% CI) based on a Mantel-Haenszel approach stratified by study. 95% CIs are based on the approximation to the normal distribution using the Sato estimator for the standard error.
[4] P-value based on a Cochran-Mantel-Haenszel test stratified by study.
[5] Interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the OR (95% CI). Missing subgroup levels are not included in estimation of the interaction p-value.
A continuity correction is applied in estimation of the OR, RR and p-value if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum. No continuity correction is applied in the estimation of the RD.
The reference group for the OR, RR and RD is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with >= 1 event; OR: Odds ratio; RR: Risk ratio; RD: Risk difference; CI: Confidence interval; int: p-value for interaction; NETA: Norethindrone acetate; SOC: System organ class; PT: Preferred term; NC: Not calculated.

SOURCE: \Studies\MYV\MYV102\Analysis\Prod\Progs\TFLs\Tab_SAF_AESI_SOC_PT_S_BIN.SAS
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Table SAF.VASOANY.SPT.POOL.2.3.S5: Adverse Event Category: Vasomotor Symptoms by System Organ Class and Preferred Term, by Subgroup (Safety Population)

Study: Pooled

System Organ Class: Skin and subcutaneous tissue disorders, Preferred Term: Night sweats

Treatment	**N**	**n (%)**	**OR[1] [95% CI]**	**RR[2] [95% CI]**	**RD[3] [95% CI]**	**p-value[4]**	**p-value (int)[5]**
MBL Volume at Baseline (mL)							
< 225 mL							
Relugolix+E2/NETA	164	3 (1.8)	NC [NC;NC]	NC [NC;NC]	NC [NC;NC]	NC	NC
Placebo	171	0					
>= 225 mL							
Relugolix+E2/NETA	90	0	NC [NC;NC]	NC [NC;NC]	NC [NC;NC]	NC	
Placebo	85	0					

Post hoc analysis. The denominator for percentages is the number of patients in the safety population for each treatment group. Patients with multiple events for a given PT or SOC are counted only once for each PT and SOC. Events are sorted alphabetically by SOC and PT and then by ascending subgroup-by-treatment interaction p-value within each. MedDRA (version 22.0).
Vasomotor symptoms include preferred term of Hyperhidrosis, Feeling hot, Hot flush, Night sweats and Flushing.
[1] OR (95% CI) based on a logistic regression model adjusting for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates.
[2] RR (95% CI) based on a Cochran-Mantel-Haenszel approach stratified by study.
[3] RD (95% CI) based on a Mantel-Haenszel approach stratified by study. 95% CIs are based on the approximation to the normal distribution using the Sato estimator for the standard error.
[4] P-value based on a Cochran-Mantel-Haenszel test stratified by study.
[5] Interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the OR (95% CI).
A continuity correction is applied in estimation of the OR, RR and p-value if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum. No continuity correction is applied in the estimation of the RD.
The reference group for the OR, RR and RD is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with >= 1 event; OR: Odds ratio; RR: Risk ratio; RD: Risk difference; CI: Confidence interval; int: p-value for interaction; NETA: Norethindrone acetate; SOC: System organ class; PT: Preferred term; NC: Not calculated.

SOURCE: \Studies\MYV\MYV102\Analysis\Prod\Progs\TFLs\Tab_SAF_AESI_SOC_PT_S_BIN.SAS
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Table SAF.VASOANY.SPT.POOL.2.3.S6: Adverse Event Category: Vasomotor Symptoms by System Organ Class and Preferred Term, by Subgroup (Safety Population)

Study: Pooled

System Organ Class: Skin and subcutaneous tissue disorders, Preferred Term: Night sweats

Treatment	**N**	**n (%)**	**OR[1] [95% CI]**	**RR[2] [95% CI]**	**RD[3] [95% CI]**	**p-value[4]**	**p-value (int)[5]**
Geographic Region I							
North America							
Relugolix+E2/NETA	192	2 (1.0)	NC	NC	NC	NC	NC
Placebo	194	0	[NC;NC]	[NC;NC]	[NC;NC]		
Rest of World							
Relugolix+E2/NETA	62	1 (1.6)	NC	NC	NC	NC	
Placebo	62	0	[NC;NC]	[NC;NC]	[NC;NC]		

Post hoc analysis. The denominator for percentages is the number of patients in the safety population for each treatment group. Patients with multiple events for a given PT or SOC are counted only once for each PT and SOC. Events are sorted alphabetically by SOC and PT and then by ascending subgroup-by-treatment interaction p-value within each. MedDRA (version 22.0).
Vasomotor symptoms include preferred term of Hyperhidrosis, Feeling hot, Hot flush, Night sweats and Flushing.
[1] OR (95% CI) based on a logistic regression model adjusting for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates.
[2] RR (95% CI) based on a Cochran-Mantel-Haenszel approach stratified by study.
[3] RD (95% CI) based on a Mantel-Haenszel approach stratified by study. 95% CIs are based on the approximation to the normal distribution using the Sato estimator for the standard error.
[4] P-value based on a Cochran-Mantel-Haenszel test stratified by study.
[5] Interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the OR (95% CI).
A continuity correction is applied in estimation of the OR, RR and p-value if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum. No continuity correction is applied in the estimation of the RD.
The reference group for the OR, RR and RD is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with >= 1 event; OR: Odds ratio; RR: Risk ratio; RD: Risk difference; CI: Confidence interval; int: p-value for interaction; NETA: Norethindrone acetate; SOC: System organ class; PT: Preferred term; NC: Not calculated.

SOURCE: \Studies\MYV\MYV102\Analysis\Prod\Progs\TFLs\Tab_SAF_AESI_SOC_PT_S_BIN.SAS
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Table SAF.VASOANY.SPT.POOL.2.3.S7: Adverse Event Category: Vasomotor Symptoms by System Organ Class and Preferred Term, by Subgroup (Safety Population)

Study: Pooled

System Organ Class: Skin and subcutaneous tissue disorders, Preferred Term: Night sweats

Treatment	**N**	**n (%)**	**OR[1] [95% CI]**	**RR[2] [95% CI]**	**RD[3] [95% CI]**	**p-value[4]**	**p-value (int)[5]**
Geographic Region II							
Europe							
Relugolix+E2/NETA	41	0	NC	NC	NC	NC	NC
Placebo	42	0	[NC;NC]	[NC;NC]	[NC;NC]		
Rest of World (including the US)							
Relugolix+E2/NETA	213	3 (1.4)	NC	NC	NC	NC	
Placebo	214	0	[NC;NC]	[NC;NC]	[NC;NC]		

Post hoc analysis. The denominator for percentages is the number of patients in the safety population for each treatment group. Patients with multiple events for a given PT or SOC are counted only once for each PT and SOC. Events are sorted alphabetically by SOC and PT and then by ascending subgroup-by-treatment interaction p-value within each. MedDRA (version 22.0).
Vasomotor symptoms include preferred term of Hyperhidrosis, Feeling hot, Hot flush, Night sweats and Flushing.
[1] OR (95% CI) based on a logistic regression model adjusting for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates.
[2] RR (95% CI) based on a Cochran-Mantel-Haenszel approach stratified by study.
[3] RD (95% CI) based on a Mantel-Haenszel approach stratified by study. 95% CIs are based on the approximation to the normal distribution using the Sato estimator for the standard error.
[4] P-value based on a Cochran-Mantel-Haenszel test stratified by study.
[5] Interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the OR (95% CI).
A continuity correction is applied in estimation of the OR, RR and p-value if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum. No continuity correction is applied in the estimation of the RD.
The reference group for the OR, RR and RD is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with >= 1 event; OR: Odds ratio; RR: Risk ratio; RD: Risk difference; CI: Confidence interval; int: p-value for interaction; NETA: Norethindrone acetate; SOC: System organ class; PT: Preferred term; NC: Not calculated.

SOURCE: \Studies\MYV\MYV102\Analysis\Prod\Progs\TFLs\Tab_SAF_AESI_SOC_PT_S_BIN.SAS
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Table SAF.VASOANY.SPT.POOL.2.3.S8: Adverse Event Category: Vasomotor Symptoms by System Organ Class and Preferred Term, by Subgroup (Safety Population)

Study: Pooled

System Organ Class: Skin and subcutaneous tissue disorders, Preferred Term: Night sweats

Treatment	N	n (%)	OR[1] [95% CI]	RR[2] [95% CI]	RD[3] [95% CI]	p-value[4]	p-value (int)[5]
Ethnicity							
Hispanic or Latino							
Relugolix+E2/NETA	53	1 (1.9)	NC	NC	NC	NC	NC
Placebo	55	0	[NC;NC]	[NC;NC]	[NC;NC]		
Not Hispanic or Latino							
Relugolix+E2/NETA	197	2 (1.0)	NC	NC	NC	NC	
Placebo	199	0	[NC;NC]	[NC;NC]	[NC;NC]		
Not reported							
Relugolix+E2/NETA	4	0	NC	NC	NC	NC	
Placebo	2	0	[NC;NC]	[NC;NC]	[NC;NC]		

Post hoc analysis. The denominator for percentages is the number of patients in the safety population for each treatment group. Patients with multiple events for a given PT or SOC are counted only once for each PT and SOC. Events are sorted alphabetically by SOC and PT and then by ascending subgroup-by-treatment interaction p-value within each. MedDRA (version 22.0).
Vasomotor symptoms include preferred term of Hyperhidrosis, Feeling hot, Hot flush, Night sweats and Flushing.
[1] OR (95% CI) based on a logistic regression model adjusting for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates.
[2] RR (95% CI) based on a Cochran-Mantel-Haenszel approach stratified by study.
[3] RD (95% CI) based on a Mantel-Haenszel approach stratified by study. 95% CIs are based on the approximation to the normal distribution using the Sato estimator for the standard error.
[4] P-value based on a Cochran-Mantel-Haenszel test stratified by study.
[5] Interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the OR (95% CI). Not reported subgroup levels are not included in estimation of the interaction p-value.
A continuity correction is applied in estimation of the OR, RR and p-value if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum. No continuity correction is applied in the estimation of the RD.
The reference group for the OR, RR and RD is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with >= 1 event; OR: Odds ratio; RR: Risk ratio; RD: Risk difference; CI: Confidence interval; int: p-value for interaction; NETA: Norethindrone acetate; SOC: System organ class; PT: Preferred term; NC: Not calculated.

SOURCE: \Studies\MYV\MYV102\Analysis\Prod\Progs\TFLs\Tab_SAF_AESI_SOC_PT_S_BIN.SAS
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Table SAF.VASOANY.SPT.POOL.2.3.S9: Adverse Event Category: Vasomotor Symptoms by System Organ Class and Preferred Term, by Subgroup (Safety Population)

Study: Pooled

System Organ Class: Skin and subcutaneous tissue disorders, Preferred Term: Night sweats

Treatment	N	n (%)	OR[1] [95% CI]	RR[2] [95% CI]	RD[3] [95% CI]	p-value[4]	p-value (int)[5]
Race							
Black/African American							
Relugolix+E2/NETA	122	1 (0.8)	NC	NC	NC	NC	NC
Placebo	141	0	[NC;NC]	[NC;NC]	[NC;NC]		
White							
Relugolix+E2/NETA	123	1 (0.8)	NC	NC	NC	NC	
Placebo	105	0	[NC;NC]	[NC;NC]	[NC;NC]		
Asian							
Relugolix+E2/NETA	1	0	NC	NC	NC	NC	
Placebo	3	0	[NC;NC]	[NC;NC]	[NC;NC]		
Others							
Relugolix+E2/NETA	5	1 (20.0)	NC	NC	NC	NC	
Placebo	6	0	[NC;NC]	[NC;NC]	[NC;NC]		
Not reported							
Relugolix+E2/NETA	3	0	NC	NC	NC	NC	
Placebo	1	0	[NC;NC]	[NC;NC]	[NC;NC]		

Post hoc analysis. The denominator for percentages is the number of patients in the safety population for each treatment group. Patients with multiple events for a given PT or SOC are counted only once for each PT and SOC. Events are sorted alphabetically by SOC and PT and then by ascending subgroup-by-treatment interaction p-value within each. MedDRA (version 22.0).
Vasomotor symptoms include preferred term of Hyperhidrosis, Feeling hot, Hot flush, Night sweats and Flushing.
[1] OR (95% CI) based on a logistic regression model adjusting for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates.
[2] RR (95% CI) based on a Cochran-Mantel-Haenszel approach stratified by study.
[3] RD (95% CI) based on a Mantel-Haenszel approach stratified by study. 95% CIs are based on the approximation to the normal distribution using the Sato estimator for the standard error.
[4] P-value based on a Cochran-Mantel-Haenszel test stratified by study.
[5] Interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the OR (95% CI). Not reported subgroup levels are not included in estimation of the interaction p-value.
A continuity correction is applied in estimation of the OR, RR and p-value if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum. No continuity correction is applied in the estimation of the RD.
The reference group for the OR, RR and RD is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with >= 1 event; OR: Odds ratio; RR: Risk ratio; RD: Risk difference; CI: Confidence interval; int: p-value for interaction; NETA: Norethindrone acetate; SOC: System organ class; PT: Preferred term; NC: Not calculated.

SOURCE: \Studies\MYV\MYV102\Analysis\Prod\Progs\TFLs\Tab_SAF_AESI_SOC_PT_S_BIN.SAS
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Table SAF.VASOANY.SPT.POOL.3.1.S4: Adverse Event Category: Vasomotor Symptoms by System Organ Class and Preferred Term, by Subgroup (Safety Population)

Study: Pooled

System Organ Class: Vascular disorders, Preferred Term: Any

Treatment	N	n (%)	OR[1] [95% CI]	RR[2] [95% CI]	RD[3] [95% CI]	p-value[4]	p-value (int)[5]
Maximum NRS Pain Score at Baseline							
< 4							
Relugolix+E2/NETA	73	7 (9.6)	2.60	2.39	0.06	0.1961	0.3435
Placebo	62	2 (3.2)	[0.59;11.38]	[0.61;9.36]	[-0.02;0.14]		
>= 4							
Relugolix+E2/NETA	178	14 (7.9)	1.18	1.17	0.01	0.6744	
Placebo	190	13 (6.8)	[0.54;2.60]	[0.57;2.41]	[-0.04;0.06]		
Missing							
Relugolix+E2/NETA	3	0	NC	NC	NC	NC	
Placebo	4	0	[NC;NC]	[NC;NC]	[NC;NC]		

Post hoc analysis. The denominator for percentages is the number of patients in the safety population for each treatment group. Patients with multiple events for a given PT or SOC are counted only once for each PT and SOC. Events are sorted alphabetically by SOC and PT and then by ascending subgroup-by-treatment interaction p-value within each. MedDRA (version 22.0).
Vasomotor symptoms include preferred term of Hyperhidrosis, Feeling hot, Hot flush, Night sweats and Flushing.
[1] OR (95% CI) based on a logistic regression model adjusting for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates.
[2] RR (95% CI) based on a Cochran-Mantel-Haenszel approach stratified by study.
[3] RD (95% CI) based on a Mantel-Haenszel approach stratified by study. 95% CIs are based on the approximation to the normal distribution using the Sato estimator for the standard error.
[4] P-value based on a Cochran-Mantel-Haenszel test stratified by study.
[5] Interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the OR (95% CI). Missing subgroup levels are not included in estimation of the interaction p-value.
A continuity correction is applied in estimation of the OR, RR and p-value if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum. No continuity correction is applied in the estimation of the RD.
The reference group for the OR, RR and RD is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with >= 1 event; OR: Odds ratio; RR: Risk ratio; RD: Risk difference; CI: Confidence interval; int: p-value for interaction; NETA: Norethindrone acetate; SOC: System organ class; PT: Preferred term; NC: Not calculated.

SOURCE: \Studies\MYV\MYV102\Analysis\Prod\Progs\TFLs\Tab_SAF_AESI_SOC_PT_S_BIN.SAS
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Table SAF.VASOANY.SPT.POOL.3.1.S3: Adverse Event Category: Vasomotor Symptoms by System Organ Class and Preferred Term, by Subgroup (Safety Population)

Study: Pooled

System Organ Class: Vascular disorders, Preferred Term: Any

Treatment	N	n (%)	OR[1] [95% CI]	RR[2] [95% CI]	RD[3] [95% CI]	p-value[4]	p-value (int)[5]
Uterine Volume at Baseline (cm3)							
< 300 cm3							
Relugolix+E2/NETA	148	11 (7.4)	1.99	1.91	0.04	0.2074	0.5004
Placebo	129	5 (3.9)	[0.67;5.92]	[0.69;5.33]	[-0.02;0.09]		
>= 300 cm3							
Relugolix+E2/NETA	105	10 (9.5)	1.23	1.20	0.02	0.6647	
Placebo	127	10 (7.9)	[0.49;3.08]	[0.52;2.77]	[-0.06;0.09]		
Missing							
Relugolix+E2/NETA	1	0	NC	NC	NC	NC	
Placebo	0	0	[NC;NC]	[NC;NC]	[NC;NC]		

Post hoc analysis. The denominator for percentages is the number of patients in the safety population for each treatment group. Patients with multiple events for a given PT or SOC are counted only once for each PT and SOC. Events are sorted alphabetically by SOC and PT and then by ascending subgroup-by-treatment interaction p-value within each. MedDRA (version 22.0).
Vasomotor symptoms include preferred term of Hyperhidrosis, Feeling hot, Hot flush, Night sweats and Flushing.
[1] OR (95% CI) based on a logistic regression model adjusting for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates.
[2] RR (95% CI) based on a Cochran-Mantel-Haenszel approach stratified by study.
[3] RD (95% CI) based on a Mantel-Haenszel approach stratified by study. 95% CIs are based on the approximation to the normal distribution using the Sato estimator for the standard error.
[4] P-value based on a Cochran-Mantel-Haenszel test stratified by study.
[5] Interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the OR (95% CI). Missing subgroup levels are not included in estimation of the interaction p-value.
A continuity correction is applied in estimation of the OR, RR and p-value if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum. No continuity correction is applied in the estimation of the RD.
The reference group for the OR, RR and RD is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with >= 1 event; OR: Odds ratio; RR: Risk ratio; RD: Risk difference; CI: Confidence interval; int: p-value for interaction; NETA: Norethindrone acetate; SOC: System organ class; PT: Preferred term; NC: Not calculated.

SOURCE: \Studies\MYV\MYV102\Analysis\Prod\Progs\TFLs\Tab_SAF_AESI_SOC_PT_S_BIN.SAS
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Table SAF.VASOANY.SPT.POOL.3.1.S7: Adverse Event Category: Vasomotor Symptoms by System Organ Class and Preferred Term, by Subgroup (Safety Population)

Study: Pooled

System Organ Class: Vascular disorders, Preferred Term: Any

Treatment	**N**	**n (%)**	**OR[1] [95% CI]**	**RR[2] [95% CI]**	**RD[3] [95% CI]**	**p-value[4]**	**p-value (int)[5]**
Geographic Region II							
Europe							
Relugolix+E2/NETA	41	5 (12.2)	1.89 [0.42;8.54]	1.73 [0.44;6.78]	0.05 [-0.08;0.18]	0.4329	0.6968
Placebo	42	3 (7.1)					
Rest of World (including the US)							
Relugolix+E2/NETA	213	16 (7.5)	1.35 [0.62;2.94]	1.32 [0.64;2.71]	0.02 [-0.03;0.06]	0.4520	
Placebo	214	12 (5.6)					

Post hoc analysis. The denominator for percentages is the number of patients in the safety population for each treatment group. Patients with multiple events for a given PT or SOC are counted only once for each PT and SOC. Events are sorted alphabetically by SOC and PT and then by ascending subgroup-by-treatment interaction p-value within each. MedDRA (version 22.0).
Vasomotor symptoms include preferred term of Hyperhidrosis, Feeling hot, Hot flush, Night sweats and Flushing.
[1] OR (95% CI) based on a logistic regression model adjusting for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates.
[2] RR (95% CI) based on a Cochran-Mantel-Haenszel approach stratified by study.
[3] RD (95% CI) based on a Mantel-Haenszel approach stratified by study. 95% CIs are based on the approximation to the normal distribution using the Sato estimator for the standard error.
[4] P-value based on a Cochran-Mantel-Haenszel test stratified by study.
[5] Interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the OR (95% CI).
A continuity correction is applied in estimation of the OR, RR and p-value if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum. No continuity correction is applied in the estimation of the RD.
The reference group for the OR, RR and RD is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with >= 1 event; OR: Odds ratio; RR: Risk ratio; RD: Risk difference; CI: Confidence interval; int: p-value for interaction; NETA: Norethindrone acetate; SOC: System organ class; PT: Preferred term.

SOURCE: \Studies\MYV\MYV102\Analysis\Prod\Progs\TFLs\Tab_SAF_AESI_SOC_PT_S_BIN.SAS
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Table SAF.VASOANY.SPT.POOL.3.1.S5: Adverse Event Category: Vasomotor Symptoms by System Organ Class and Preferred Term, by Subgroup (Safety Population)

Study: Pooled

System Organ Class: Vascular disorders, Preferred Term: Any

Treatment	**N**	**n (%)**	**OR[1] [95% CI]**	**RR[2] [95% CI]**	**RD[3] [95% CI]**	**p-value[4]**	**p-value (int)[5]**
MBL Volume at Baseline (mL)							
< 225 mL							
Relugolix+E2/NETA	164	12 (7.3)	1.60	1.55	0.03	0.3204	0.7271
Placebo	171	8 (4.7)	[0.63;4.03]	[0.65;3.68]	[-0.02;0.08]		
>= 225 mL							
Relugolix+E2/NETA	90	9 (10.0)	1.25	1.22	0.02	0.6820	
Placebo	85	7 (8.2)	[0.44;3.53]	[0.48;3.12]	[-0.07;0.10]		

Post hoc analysis. The denominator for percentages is the number of patients in the safety population for each treatment group. Patients with multiple events for a given PT or SOC are counted only once for each PT and SOC. Events are sorted alphabetically by SOC and PT and then by ascending subgroup-by-treatment interaction p-value within each. MedDRA (version 22.0).
Vasomotor symptoms include preferred term of Hyperhidrosis, Feeling hot, Hot flush, Night sweats and Flushing.
[1] OR (95% CI) based on a logistic regression model adjusting for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates.
[2] RR (95% CI) based on a Cochran-Mantel-Haenszel approach stratified by study.
[3] RD (95% CI) based on a Mantel-Haenszel approach stratified by study. 95% CIs are based on the approximation to the normal distribution using the Sato estimator for the standard error.
[4] P-value based on a Cochran-Mantel-Haenszel test stratified by study.
[5] Interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the OR (95% CI).
A continuity correction is applied in estimation of the OR, RR and p-value if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum. No continuity correction is applied in the estimation of the RD.
The reference group for the OR, RR and RD is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with >= 1 event; OR: Odds ratio; RR: Risk ratio; RD: Risk difference; CI: Confidence interval; int: p-value for interaction; NETA: Norethindrone acetate; SOC: System organ class; PT: Preferred term.

SOURCE: \Studies\MYV\MYV102\Analysis\Prod\Progs\TFLs\Tab_SAF_AESI_SOC_PT_S_BIN.SAS
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Table SAF.VASOANY.SPT.POOL.3.1.S2: Adverse Event Category: Vasomotor Symptoms by System Organ Class and Preferred Term, by Subgroup (Safety Population)

Study: Pooled

System Organ Class: Vascular disorders, Preferred Term: Any

Treatment	N	n (%)	OR[1] [95% CI]	RR[2] [95% CI]	RD[3] [95% CI]	p-value[4]	p-value (int)[5]
BMI (kg/m2) at Baseline							
< 30							
Relugolix+E2/NETA	119	9 (7.6)	1.22	1.20	0.01	0.7052	0.7641
Placebo	115	7 (6.1)	[0.44;3.42]	[0.47;3.09]	[-0.05;0.08]		
>= 30							
Relugolix+E2/NETA	134	11 (8.2)	1.51	1.46	0.03	0.3910	
Placebo	141	8 (5.7)	[0.59;3.91]	[0.61;3.51]	[-0.03;0.09]		
Missing							
Relugolix+E2/NETA	1	1 (100.0)	NC	NC	NC	NC	
Placebo	0	0	[NC;NC]	[NC;NC]	[NC;NC]		

Post hoc analysis. The denominator for percentages is the number of patients in the safety population for each treatment group. Patients with multiple events for a given PT or SOC are counted only once for each PT and SOC. Events are sorted alphabetically by SOC and PT and then by ascending subgroup-by-treatment interaction p-value within each. MedDRA (version 22.0).
Vasomotor symptoms include preferred term of Hyperhidrosis, Feeling hot, Hot flush, Night sweats and Flushing.
[1] OR (95% CI) based on a logistic regression model adjusting for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates.
[2] RR (95% CI) based on a Cochran-Mantel-Haenszel approach stratified by study.
[3] RD (95% CI) based on a Mantel-Haenszel approach stratified by study. 95% CIs are based on the approximation to the normal distribution using the Sato estimator for the standard error.
[4] P-value based on a Cochran-Mantel-Haenszel test stratified by study.
[5] Interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the OR (95% CI). Missing subgroup levels are not included in estimation of the interaction p-value.
A continuity correction is applied in estimation of the OR, RR and p-value if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum. No continuity correction is applied in the estimation of the RD.
The reference group for the OR, RR and RD is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with >= 1 event; OR: Odds ratio; RR: Risk ratio; RD: Risk difference; CI: Confidence interval; int: p-value for interaction; NETA: Norethindrone acetate; SOC: System organ class; PT: Preferred term; NC: Not calculated.

SOURCE: \Studies\MYV\MYV102\Analysis\Prod\Progs\TFLs\Tab_SAF_AESI_SOC_PT_S_BIN.SAS
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Table SAF.VASOANY.SPT.POOL.3.1.S6: Adverse Event Category: Vasomotor Symptoms by System Organ Class and Preferred Term, by Subgroup (Safety Population)

Study: Pooled

System Organ Class: Vascular disorders, Preferred Term: Any

Treatment	**N**	**n (%)**	**OR[1] [95% CI]**	**RR[2] [95% CI]**	**RD[3] [95% CI]**	**p-value[4]**	**p-value (int)[5]**
Geographic Region I							
North America							
Relugolix+E2/NETA	192	16 (8.3)	1.51	1.46	0.03	0.3087	0.8219
Placebo	194	11 (5.7)	[0.68;3.36]	[0.70;3.07]	[-0.02;0.08]		
Rest of World							
Relugolix+E2/NETA	62	5 (8.1)	1.26	1.23	0.02	0.7443	
Placebo	62	4 (6.5)	[0.32;4.96]	[0.35;4.34]	[-0.08;0.11]		

Post hoc analysis. The denominator for percentages is the number of patients in the safety population for each treatment group. Patients with multiple events for a given PT or SOC are counted only once for each PT and SOC. Events are sorted alphabetically by SOC and PT and then by ascending subgroup-by-treatment interaction p-value within each. MedDRA (version 22.0).
Vasomotor symptoms include preferred term of Hyperhidrosis, Feeling hot, Hot flush, Night sweats and Flushing.
[1] OR (95% CI) based on a logistic regression model adjusting for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates.
[2] RR (95% CI) based on a Cochran-Mantel-Haenszel approach stratified by study.
[3] RD (95% CI) based on a Mantel-Haenszel approach stratified by study. 95% CIs are based on the approximation to the normal distribution using the Sato estimator for the standard error.
[4] P-value based on a Cochran-Mantel-Haenszel test stratified by study.
[5] Interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the OR (95% CI).
A continuity correction is applied in estimation of the OR, RR and p-value if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum. No continuity correction is applied in the estimation of the RD.
The reference group for the OR, RR and RD is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with >= 1 event; OR: Odds ratio; RR: Risk ratio; RD: Risk difference; CI: Confidence interval; int: p-value for interaction; NETA: Norethindrone acetate; SOC: System organ class; PT: Preferred term.

SOURCE: \Studies\MYV\MYV102\Analysis\Prod\Progs\TFLs\Tab_SAF_AESI_SOC_PT_S_BIN.SAS
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Table SAF.VASOANY.SPT.POOL.3.1.S1: Adverse Event Category: Vasomotor Symptoms by System Organ Class and Preferred Term, by Subgroup (Safety Population)

Study: Pooled

System Organ Class: Vascular disorders, Preferred Term: Any

Treatment	**N**	**n (%)**	**OR[1] [95% CI]**	**RR[2] [95% CI]**	**RD[3] [95% CI]**	**p-value[4]**	**p-value (int)[5]**
Age (years)							
< 40 years							
Relugolix+E2/NETA	62	5 (8.1)	1.57	1.50	0.03	0.5024	0.8728
Placebo	78	4 (5.1)	[0.43;5.73]	[0.46;4.91]	[-0.06;0.11]		
>= 40 years							
Relugolix+E2/NETA	192	16 (8.3)	1.38	1.35	0.02	0.4258	
Placebo	178	11 (6.2)	[0.62;3.08]	[0.64;2.83]	[-0.03;0.07]		

Post hoc analysis. The denominator for percentages is the number of patients in the safety population for each treatment group. Patients with multiple events for a given PT or SOC are counted only once for each PT and SOC. Events are sorted alphabetically by SOC and PT and then by ascending subgroup-by-treatment interaction p-value within each. MedDRA (version 22.0).
Vasomotor symptoms include preferred term of Hyperhidrosis, Feeling hot, Hot flush, Night sweats and Flushing.
[1] OR (95% CI) based on a logistic regression model adjusting for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates.
[2] RR (95% CI) based on a Cochran-Mantel-Haenszel approach stratified by study.
[3] RD (95% CI) based on a Mantel-Haenszel approach stratified by study. 95% CIs are based on the approximation to the normal distribution using the Sato estimator for the standard error.
[4] P-value based on a Cochran-Mantel-Haenszel test stratified by study.
[5] Interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the OR (95% CI).
A continuity correction is applied in estimation of the OR, RR and p-value if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum. No continuity correction is applied in the estimation of the RD.
The reference group for the OR, RR and RD is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with >= 1 event; OR: Odds ratio; RR: Risk ratio; RD: Risk difference; CI: Confidence interval; int: p-value for interaction; NETA: Norethindrone acetate; SOC: System organ class; PT: Preferred term.

SOURCE: \Studies\MYV\MYV102\Analysis\Prod\Progs\TFLs\Tab_SAF_AESI_SOC_PT_S_BIN.SAS
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Table SAF.VASOANY.SPT.POOL.3.1.S8: Adverse Event Category: Vasomotor Symptoms by System Organ Class and Preferred Term, by Subgroup (Safety Population)

Study: Pooled

System Organ Class: Vascular disorders, Preferred Term: Any

Treatment	N	n (%)	OR[1] [95% CI]	RR[2] [95% CI]	RD[3] [95% CI]	p-value[4]	p-value (int)[5]
Ethnicity							
Hispanic or Latino							
Relugolix+E2/NETA	53	3 (5.7)	1.29	1.26	0.01	0.7590	0.8741
Placebo	55	2 (3.6)	[0.24;6.89]	[0.29;5.47]	[-0.08;0.09]		
Not Hispanic or Latino							
Relugolix+E2/NETA	197	18 (9.1)	1.49	1.44	0.03	0.2904	
Placebo	199	13 (6.5)	[0.71;3.15]	[0.73;2.85]	[-0.02;0.08]		
Not reported							
Relugolix+E2/NETA	4	0	NC	NC	NC	NC	
Placebo	2	0	[NC;NC]	[NC;NC]	[NC;NC]		

Post hoc analysis. The denominator for percentages is the number of patients in the safety population for each treatment group. Patients with multiple events for a given PT or SOC are counted only once for each PT and SOC. Events are sorted alphabetically by SOC and PT and then by ascending subgroup-by-treatment interaction p-value within each. MedDRA (version 22.0).
Vasomotor symptoms include preferred term of Hyperhidrosis, Feeling hot, Hot flush, Night sweats and Flushing.
[1] OR (95% CI) based on a logistic regression model adjusting for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates.
[2] RR (95% CI) based on a Cochran-Mantel-Haenszel approach stratified by study.
[3] RD (95% CI) based on a Mantel-Haenszel approach stratified by study. 95% CIs are based on the approximation to the normal distribution using the Sato estimator for the standard error.
[4] P-value based on a Cochran-Mantel-Haenszel test stratified by study.
[5] Interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the OR (95% CI). Not reported subgroup levels are not included in estimation of the interaction p-value.
A continuity correction is applied in estimation of the OR, RR and p-value if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum. No continuity correction is applied in the estimation of the RD.
The reference group for the OR, RR and RD is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with >= 1 event; OR: Odds ratio; RR: Risk ratio; RD: Risk difference; CI: Confidence interval; int: p-value for interaction; NETA: Norethindrone acetate; SOC: System organ class; PT: Preferred term; NC: Not calculated.

SOURCE: \Studies\MYV\MYV102\Analysis\Prod\Progs\TFLs\Tab_SAF_AESI_SOC_PT_S_BIN.SAS
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Table SAF.VASOANY.SPT.POOL.3.1.S9: Adverse Event Category: Vasomotor Symptoms by System Organ Class and Preferred Term, by Subgroup (Safety Population)

Study: Pooled

System Organ Class: Vascular disorders, Preferred Term: Any

Treatment	N	n (%)	OR[1] [95% CI]	RR[2] [95% CI]	RD[3] [95% CI]	p-value[4]	p-value (int)[5]
Race							
Black/African American							
Relugolix+E2/NETA	122	11 (9.0)	1.64	1.58	0.03	0.3025	0.9312
Placebo	141	8 (5.7)	[0.64;4.25]	[0.66;3.77]	[-0.03;0.10]		
White							
Relugolix+E2/NETA	123	10 (8.1)	1.48	1.43	0.02	0.4714	
Placebo	105	6 (5.7)	[0.52;4.24]	[0.54;3.83]	[-0.04;0.09]		
Asian							
Relugolix+E2/NETA	1	0	NC	NC	NC	NC	
Placebo	3	1 (33.3)	[NC;NC]	[NC;NC]	[NC;NC]		
Others							
Relugolix+E2/NETA	5	0	0.91	1.20	0.00	0.8927	
Placebo	6	0	[0.04;18.32]	[0.11;13.17]	[NE;NE]		
Not reported							
Relugolix+E2/NETA	3	0	NC	NC	NC	NC	
Placebo	1	0	[NC;NC]	[NC;NC]	[NC;NC]		

Post hoc analysis. The denominator for percentages is the number of patients in the safety population for each treatment group. Patients with multiple events for a given PT or SOC are counted only once for each PT and SOC. Events are sorted alphabetically by SOC and PT and then by ascending subgroup-by-treatment interaction p-value within each. MedDRA (version 22.0).
Vasomotor symptoms include preferred term of Hyperhidrosis, Feeling hot, Hot flush, Night sweats and Flushing.
[1] OR (95% CI) based on a logistic regression model adjusting for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates.
[2] RR (95% CI) based on a Cochran-Mantel-Haenszel approach stratified by study.
[3] RD (95% CI) based on a Mantel-Haenszel approach stratified by study. 95% CIs are based on the approximation to the normal distribution using the Sato estimator for the standard error.
[4] P-value based on a Cochran-Mantel-Haenszel test stratified by study.
[5] Interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the OR (95% CI). Not reported subgroup levels are not included in estimation of the interaction p-value.
A continuity correction is applied in estimation of the OR, RR and p-value if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum. No continuity correction is applied in the estimation of the RD.
The reference group for the OR, RR and RD is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with >= 1 event; OR: Odds ratio; RR: Risk ratio; RD: Risk difference; CI: Confidence interval; int: p-value for interaction; NETA: Norethindrone acetate; SOC: System organ class; PT: Preferred term; NC: Not calculated; NE: Non-estimable.

SOURCE: \Studies\MYV\MYV102\Analysis\Prod\Progs\TFLs\Tab_SAF_AESI_SOC_PT_S_BIN.SAS
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Table SAF.VASOANY.SPT.POOL.3.2.S4: Adverse Event Category: Vasomotor Symptoms by System Organ Class and Preferred Term, by Subgroup (Safety Population)

Study: Pooled

System Organ Class: Vascular disorders, Preferred Term: Hot flush

Treatment	N	n (%)	OR[1] [95% CI]	RR[2] [95% CI]	RD[3] [95% CI]	p-value[4]	p-value (int)[5]
Maximum NRS Pain Score at Baseline							
< 4							
Relugolix+E2/NETA	73	7 (9.6)	2.60	2.39	0.06	0.1961	0.3435
Placebo	62	2 (3.2)	[0.59;11.38]	[0.61;9.36]	[-0.02;0.14]		
>= 4							
Relugolix+E2/NETA	178	14 (7.9)	1.18	1.17	0.01	0.6744	
Placebo	190	13 (6.8)	[0.54;2.60]	[0.57;2.41]	[-0.04;0.06]		
Missing							
Relugolix+E2/NETA	3	0	NC	NC	NC	NC	
Placebo	4	0	[NC;NC]	[NC;NC]	[NC;NC]		

Post hoc analysis. The denominator for percentages is the number of patients in the safety population for each treatment group. Patients with multiple events for a given PT or SOC are counted only once for each PT and SOC. Events are sorted alphabetically by SOC and PT and then by ascending subgroup-by-treatment interaction p-value within each. MedDRA (version 22.0).
Vasomotor symptoms include preferred term of Hyperhidrosis, Feeling hot, Hot flush, Night sweats and Flushing.
[1] OR (95% CI) based on a logistic regression model adjusting for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates.
[2] RR (95% CI) based on a Cochran-Mantel-Haenszel approach stratified by study.
[3] RD (95% CI) based on a Mantel-Haenszel approach stratified by study. 95% CIs are based on the approximation to the normal distribution using the Sato estimator for the standard error.
[4] P-value based on a Cochran-Mantel-Haenszel test stratified by study.
[5] Interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the OR (95% CI). Missing subgroup levels are not included in estimation of the interaction p-value.
A continuity correction is applied in estimation of the OR, RR and p-value if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum. No continuity correction is applied in the estimation of the RD.
The reference group for the OR, RR and RD is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with >= 1 event; OR: Odds ratio; RR: Risk ratio; RD: Risk difference; CI: Confidence interval; int: p-value for interaction; NETA: Norethindrone acetate; SOC: System organ class; PT: Preferred term; NC: Not calculated.

SOURCE: \Studies\MYV\MYV102\Analysis\Prod\Progs\TFLs\Tab_SAF_AESI_SOC_PT_S_BIN.SAS
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Table SAF.VASOANY.SPT.POOL.3.2.S3: Adverse Event Category: Vasomotor Symptoms by System Organ Class and Preferred Term, by Subgroup (Safety Population)

Study: Pooled

System Organ Class: Vascular disorders, Preferred Term: Hot flush

Treatment	**N**	**n (%)**	**OR[1] [95% CI]**	**RR[2] [95% CI]**	**RD[3] [95% CI]**	**p-value[4]**	**p-value (int)[5]**
Uterine Volume at Baseline (cm3)							
< 300 cm3							
Relugolix+E2/NETA	148	11 (7.4)	1.99	1.91	0.04	0.2074	0.5004
Placebo	129	5 (3.9)	[0.67;5.92]	[0.69;5.33]	[-0.02;0.09]		
>= 300 cm3							
Relugolix+E2/NETA	105	10 (9.5)	1.23	1.20	0.02	0.6647	
Placebo	127	10 (7.9)	[0.49;3.08]	[0.52;2.77]	[-0.06;0.09]		
Missing							
Relugolix+E2/NETA	1	0	NC	NC	NC	NC	
Placebo	0	0	[NC;NC]	[NC;NC]	[NC;NC]		

Post hoc analysis. The denominator for percentages is the number of patients in the safety population for each treatment group. Patients with multiple events for a given PT or SOC are counted only once for each PT and SOC. Events are sorted alphabetically by SOC and PT and then by ascending subgroup-by-treatment interaction p-value within each. MedDRA (version 22.0).
Vasomotor symptoms include preferred term of Hyperhidrosis, Feeling hot, Hot flush, Night sweats and Flushing.
[1] OR (95% CI) based on a logistic regression model adjusting for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates.
[2] RR (95% CI) based on a Cochran-Mantel-Haenszel approach stratified by study.
[3] RD (95% CI) based on a Mantel-Haenszel approach stratified by study. 95% CIs are based on the approximation to the normal distribution using the Sato estimator for the standard error.
[4] P-value based on a Cochran-Mantel-Haenszel test stratified by study.
[5] Interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the OR (95% CI). Missing subgroup levels are not included in estimation of the interaction p-value.
A continuity correction is applied in estimation of the OR, RR and p-value if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum. No continuity correction is applied in the estimation of the RD.
The reference group for the OR, RR and RD is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with >= 1 event; OR: Odds ratio; RR: Risk ratio; RD: Risk difference; CI: Confidence interval; int: p-value for interaction; NETA: Norethindrone acetate; SOC: System organ class; PT: Preferred term; NC: Not calculated.

SOURCE: \Studies\MYV\MYV102\Analysis\Prod\Progs\TFLs\Tab_SAF_AESI_SOC_PT_S_BIN.SAS
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Table SAF.VASOANY.SPT.POOL.3.2.S7: Adverse Event Category: Vasomotor Symptoms by System Organ Class and Preferred Term, by Subgroup (Safety Population)

Study: Pooled

System Organ Class: Vascular disorders, Preferred Term: Hot flush

Treatment	**N**	**n (%)**	**OR[1] [95% CI]**	**RR[2] [95% CI]**	**RD[3] [95% CI]**	**p-value[4]**	**p-value (int)[5]**
Geographic Region II							
Europe							
Relugolix+E2/NETA	41	5 (12.2)	1.89	1.73	0.05	0.4329	0.6968
Placebo	42	3 (7.1)	[0.42;8.54]	[0.44;6.78]	[-0.08;0.18]		
Rest of World (including the US)							
Relugolix+E2/NETA	213	16 (7.5)	1.35	1.32	0.02	0.4520	
Placebo	214	12 (5.6)	[0.62;2.94]	[0.64;2.71]	[-0.03;0.06]		

Post hoc analysis. The denominator for percentages is the number of patients in the safety population for each treatment group. Patients with multiple events for a given PT or SOC are counted only once for each PT and SOC. Events are sorted alphabetically by SOC and PT and then by ascending subgroup-by-treatment interaction p-value within each. MedDRA (version 22.0).
Vasomotor symptoms include preferred term of Hyperhidrosis, Feeling hot, Hot flush, Night sweats and Flushing.
[1] OR (95% CI) based on a logistic regression model adjusting for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates.
[2] RR (95% CI) based on a Cochran-Mantel-Haenszel approach stratified by study.
[3] RD (95% CI) based on a Mantel-Haenszel approach stratified by study. 95% CIs are based on the approximation to the normal distribution using the Sato estimator for the standard error.
[4] P-value based on a Cochran-Mantel-Haenszel test stratified by study.
[5] Interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the OR (95% CI).
A continuity correction is applied in estimation of the OR, RR and p-value if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum. No continuity correction is applied in the estimation of the RD.
The reference group for the OR, RR and RD is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with >= 1 event; OR: Odds ratio; RR: Risk ratio; RD: Risk difference; CI: Confidence interval; int: p-value for interaction; NETA: Norethindrone acetate; SOC: System organ class; PT: Preferred term.

SOURCE: \Studies\MYV\MYV102\Analysis\Prod\Progs\TFLs\Tab_SAF_AESI_SOC_PT_S_BIN.SAS
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Table SAF.VASOANY.SPT.POOL.3.2.S5: Adverse Event Category: Vasomotor Symptoms by System Organ Class and Preferred Term, by Subgroup (Safety Population)

Study: Pooled

System Organ Class: Vascular disorders, Preferred Term: Hot flush

Treatment	**N**	**n (%)**	**OR[1] [95% CI]**	**RR[2] [95% CI]**	**RD[3] [95% CI]**	**p-value[4]**	**p-value (int)[5]**
MBL Volume at Baseline (mL)							
< 225 mL							
Relugolix+E2/NETA	164	12 (7.3)	1.60	1.55	0.03	0.3204	0.7271
Placebo	171	8 (4.7)	[0.63;4.03]	[0.65;3.68]	[-0.02;0.08]		
>= 225 mL							
Relugolix+E2/NETA	90	9 (10.0)	1.25	1.22	0.02	0.6820	
Placebo	85	7 (8.2)	[0.44;3.53]	[0.48;3.12]	[-0.07;0.10]		

Post hoc analysis. The denominator for percentages is the number of patients in the safety population for each treatment group. Patients with multiple events for a given PT or SOC are counted only once for each PT and SOC. Events are sorted alphabetically by SOC and PT and then by ascending subgroup-by-treatment interaction p-value within each. MedDRA (version 22.0).
Vasomotor symptoms include preferred term of Hyperhidrosis, Feeling hot, Hot flush, Night sweats and Flushing.
[1] OR (95% CI) based on a logistic regression model adjusting for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates.
[2] RR (95% CI) based on a Cochran-Mantel-Haenszel approach stratified by study.
[3] RD (95% CI) based on a Mantel-Haenszel approach stratified by study. 95% CIs are based on the approximation to the normal distribution using the Sato estimator for the standard error.
[4] P-value based on a Cochran-Mantel-Haenszel test stratified by study.
[5] Interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the OR (95% CI).
A continuity correction is applied in estimation of the OR, RR and p-value if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum. No continuity correction is applied in the estimation of the RD.
The reference group for the OR, RR and RD is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with >= 1 event; OR: Odds ratio; RR: Risk ratio; RD: Risk difference; CI: Confidence interval; int: p-value for interaction; NETA: Norethindrone acetate; SOC: System organ class; PT: Preferred term.

SOURCE: \Studies\MYV\MYV102\Analysis\Prod\Progs\TFLs\Tab_SAF_AESI_SOC_PT_S_BIN.SAS
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Table SAF.VASOANY.SPT.POOL.3.2.S2: Adverse Event Category: Vasomotor Symptoms by System Organ Class and Preferred Term, by Subgroup (Safety Population)

Study: Pooled

System Organ Class: Vascular disorders, Preferred Term: Hot flush

Treatment	**N**	**n (%)**	**OR[1] [95% CI]**	**RR[2] [95% CI]**	**RD[3] [95% CI]**	**p-value[4]**	**p-value (int)[5]**
BMI (kg/m2) at Baseline							
< 30							
Relugolix+E2/NETA	119	9 (7.6)	1.22	1.20	0.01	0.7052	0.7641
Placebo	115	7 (6.1)	[0.44;3.42]	[0.47;3.09]	[-0.05;0.08]		
>= 30							
Relugolix+E2/NETA	134	11 (8.2)	1.51	1.46	0.03	0.3910	
Placebo	141	8 (5.7)	[0.59;3.91]	[0.61;3.51]	[-0.03;0.09]		
Missing							
Relugolix+E2/NETA	1	1 (100.0)	NC	NC	NC	NC	
Placebo	0	0	[NC;NC]	[NC;NC]	[NC;NC]		

Post hoc analysis. The denominator for percentages is the number of patients in the safety population for each treatment group. Patients with multiple events for a given PT or SOC are counted only once for each PT and SOC. Events are sorted alphabetically by SOC and PT and then by ascending subgroup-by-treatment interaction p-value within each. MedDRA (version 22.0).
Vasomotor symptoms include preferred term of Hyperhidrosis, Feeling hot, Hot flush, Night sweats and Flushing.
[1] OR (95% CI) based on a logistic regression model adjusting for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates.
[2] RR (95% CI) based on a Cochran-Mantel-Haenszel approach stratified by study.
[3] RD (95% CI) based on a Mantel-Haenszel approach stratified by study. 95% CIs are based on the approximation to the normal distribution using the Sato estimator for the standard error.
[4] P-value based on a Cochran-Mantel-Haenszel test stratified by study.
[5] Interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the OR (95% CI). Missing subgroup levels are not included in estimation of the interaction p-value.
A continuity correction is applied in estimation of the OR, RR and p-value if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum. No continuity correction is applied in the estimation of the RD.
The reference group for the OR, RR and RD is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with >= 1 event; OR: Odds ratio; RR: Risk ratio; RD: Risk difference; CI: Confidence interval; int: p-value for interaction; NETA: Norethindrone acetate; SOC: System organ class; PT: Preferred term; NC: Not calculated.

SOURCE: \Studies\MYV\MYV102\Analysis\Prod\Progs\TFLs\Tab_SAF_AESI_SOC_PT_S_BIN.SAS
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Table SAF.VASOANY.SPT.POOL.3.2.S6: Adverse Event Category: Vasomotor Symptoms by System Organ Class and Preferred Term, by Subgroup (Safety Population)

Study: Pooled

System Organ Class: Vascular disorders, Preferred Term: Hot flush

Treatment	**N**	**n (%)**	**OR[1] [95% CI]**	**RR[2] [95% CI]**	**RD[3] [95% CI]**	**p-value[4]**	**p-value (int)[5]**
Geographic Region I							
North America							
Relugolix+E2/NETA	192	16 (8.3)	1.51	1.46	0.03	0.3087	0.8219
Placebo	194	11 (5.7)	[0.68;3.36]	[0.70;3.07]	[-0.02;0.08]		
Rest of World							
Relugolix+E2/NETA	62	5 (8.1)	1.26	1.23	0.02	0.7443	
Placebo	62	4 (6.5)	[0.32;4.96]	[0.35;4.34]	[-0.08;0.11]		

Post hoc analysis. The denominator for percentages is the number of patients in the safety population for each treatment group. Patients with multiple events for a given PT or SOC are counted only once for each PT and SOC. Events are sorted alphabetically by SOC and PT and then by ascending subgroup-by-treatment interaction p-value within each. MedDRA (version 22.0).
Vasomotor symptoms include preferred term of Hyperhidrosis, Feeling hot, Hot flush, Night sweats and Flushing.
[1] OR (95% CI) based on a logistic regression model adjusting for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates.
[2] RR (95% CI) based on a Cochran-Mantel-Haenszel approach stratified by study.
[3] RD (95% CI) based on a Mantel-Haenszel approach stratified by study. 95% CIs are based on the approximation to the normal distribution using the Sato estimator for the standard error.
[4] P-value based on a Cochran-Mantel-Haenszel test stratified by study.
[5] Interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the OR (95% CI).
A continuity correction is applied in estimation of the OR, RR and p-value if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum. No continuity correction is applied in the estimation of the RD.
The reference group for the OR, RR and RD is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with >= 1 event; OR: Odds ratio; RR: Risk ratio; RD: Risk difference; CI: Confidence interval; int: p-value for interaction; NETA: Norethindrone acetate; SOC: System organ class; PT: Preferred term.

SOURCE: \Studies\MYV\MYV102\Analysis\Prod\Progs\TFLs\Tab_SAF_AESI_SOC_PT_S_BIN.SAS
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Table SAF.VASOANY.SPT.POOL.3.2.S1: Adverse Event Category: Vasomotor Symptoms by System Organ Class and Preferred Term, by Subgroup (Safety Population)

Study: Pooled

System Organ Class: Vascular disorders, Preferred Term: Hot flush

Treatment	**N**	**n (%)**	**OR[1] [95% CI]**	**RR[2] [95% CI]**	**RD[3] [95% CI]**	**p-value[4]**	**p-value (int)[5]**
Age (years)							
< 40 years							
Relugolix+E2/NETA	62	5 (8.1)	1.57 [0.43;5.73]	1.50 [0.46;4.91]	0.03 [-0.06;0.11]	0.5024	0.8728
Placebo	78	4 (5.1)					
>= 40 years							
Relugolix+E2/NETA	192	16 (8.3)	1.38 [0.62;3.08]	1.35 [0.64;2.83]	0.02 [-0.03;0.07]	0.4258	
Placebo	178	11 (6.2)					

Post hoc analysis. The denominator for percentages is the number of patients in the safety population for each treatment group. Patients with multiple events for a given PT or SOC are counted only once for each PT and SOC. Events are sorted alphabetically by SOC and PT and then by ascending subgroup-by-treatment interaction p-value within each. MedDRA (version 22.0).
Vasomotor symptoms include preferred term of Hyperhidrosis, Feeling hot, Hot flush, Night sweats and Flushing.
[1] OR (95% CI) based on a logistic regression model adjusting for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates.
[2] RR (95% CI) based on a Cochran-Mantel-Haenszel approach stratified by study.
[3] RD (95% CI) based on a Mantel-Haenszel approach stratified by study. 95% CIs are based on the approximation to the normal distribution using the Sato estimator for the standard error.
[4] P-value based on a Cochran-Mantel-Haenszel test stratified by study.
[5] Interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the OR (95% CI).
A continuity correction is applied in estimation of the OR, RR and p-value if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum. No continuity correction is applied in the estimation of the RD.
The reference group for the OR, RR and RD is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with >= 1 event; OR: Odds ratio; RR: Risk ratio; RD: Risk difference; CI: Confidence interval; int: p-value for interaction; NETA: Norethindrone acetate; SOC: System organ class; PT: Preferred term.

SOURCE: \Studies\MYV\MYV102\Analysis\Prod\Progs\TFLs\Tab_SAF_AESI_SOC_PT_S_BIN.SAS
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Table SAF.VASOANY.SPT.POOL.3.2.S8: Adverse Event Category: Vasomotor Symptoms by System Organ Class and Preferred Term, by Subgroup (Safety Population)

Study: Pooled

System Organ Class: Vascular disorders, Preferred Term: Hot flush

Treatment	N	n (%)	OR[1] [95% CI]	RR[2] [95% CI]	RD[3] [95% CI]	p-value[4]	p-value (int)[5]
Ethnicity							
Hispanic or Latino							
Relugolix+E2/NETA	53	3 (5.7)	1.29	1.26	0.01	0.7590	0.8741
Placebo	55	2 (3.6)	[0.24;6.89]	[0.29;5.47]	[-0.08;0.09]		
Not Hispanic or Latino							
Relugolix+E2/NETA	197	18 (9.1)	1.49	1.44	0.03	0.2904	
Placebo	199	13 (6.5)	[0.71;3.15]	[0.73;2.85]	[-0.02;0.08]		
Not reported							
Relugolix+E2/NETA	4	0	NC	NC	NC	NC	
Placebo	2	0	[NC;NC]	[NC;NC]	[NC;NC]		

Post hoc analysis. The denominator for percentages is the number of patients in the safety population for each treatment group. Patients with multiple events for a given PT or SOC are counted only once for each PT and SOC. Events are sorted alphabetically by SOC and PT and then by ascending subgroup-by-treatment interaction p-value within each. MedDRA (version 22.0).
Vasomotor symptoms include preferred term of Hyperhidrosis, Feeling hot, Hot flush, Night sweats and Flushing.
[1] OR (95% CI) based on a logistic regression model adjusting for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates.
[2] RR (95% CI) based on a Cochran-Mantel-Haenszel approach stratified by study.
[3] RD (95% CI) based on a Mantel-Haenszel approach stratified by study. 95% CIs are based on the approximation to the normal distribution using the Sato estimator for the standard error.
[4] P-value based on a Cochran-Mantel-Haenszel test stratified by study.
[5] Interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the OR (95% CI). Not reported subgroup levels are not included in estimation of the interaction p-value.
A continuity correction is applied in estimation of the OR, RR and p-value if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum. No continuity correction is applied in the estimation of the RD.
The reference group for the OR, RR and RD is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with >= 1 event; OR: Odds ratio; RR: Risk ratio; RD: Risk difference; CI: Confidence interval; int: p-value for interaction; NETA: Norethindrone acetate; SOC: System organ class; PT: Preferred term; NC: Not calculated.

SOURCE: \Studies\MYV\MYV102\Analysis\Prod\Progs\TFLs\Tab_SAF_AESI_SOC_PT_S_BIN.SAS
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Table SAF.VASOANY.SPT.POOL.3.2.S9: Adverse Event Category: Vasomotor Symptoms by System Organ Class and Preferred Term, by Subgroup (Safety Population)

Study: Pooled

System Organ Class: Vascular disorders, Preferred Term: Hot flush

Treatment	**N**	**n (%)**	**OR[1] [95% CI]**	**RR[2] [95% CI]**	**RD[3] [95% CI]**	**p-value[4]**	**p-value (int)[5]**
Race							
Black/African American							
Relugolix+E2/NETA	122	11 (9.0)	1.64	1.58	0.03	0.3025	0.9312
Placebo	141	8 (5.7)	[0.64;4.25]	[0.66;3.77]	[-0.03;0.10]		
White							
Relugolix+E2/NETA	123	10 (8.1)	1.48	1.43	0.02	0.4714	
Placebo	105	6 (5.7)	[0.52;4.24]	[0.54;3.83]	[-0.04;0.09]		
Asian							
Relugolix+E2/NETA	1	0	NC	NC	NC	NC	
Placebo	3	1 (33.3)	[NC;NC]	[NC;NC]	[NC;NC]		
Others							
Relugolix+E2/NETA	5	0	0.91	1.20	0.00	0.8927	
Placebo	6	0	[0.04;18.32]	[0.11;13.17]	[NE;NE]		
Not reported							
Relugolix+E2/NETA	3	0	NC	NC	NC	NC	
Placebo	1	0	[NC;NC]	[NC;NC]	[NC;NC]		

Post hoc analysis. The denominator for percentages is the number of patients in the safety population for each treatment group. Patients with multiple events for a given PT or SOC are counted only once for each PT and SOC. Events are sorted alphabetically by SOC and PT and then by ascending subgroup-by-treatment interaction p-value within each. MedDRA (version 22.0).
Vasomotor symptoms include preferred term of Hyperhidrosis, Feeling hot, Hot flush, Night sweats and Flushing.
[1] OR (95% CI) based on a logistic regression model adjusting for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates.
[2] RR (95% CI) based on a Cochran-Mantel-Haenszel approach stratified by study.
[3] RD (95% CI) based on a Mantel-Haenszel approach stratified by study. 95% CIs are based on the approximation to the normal distribution using the Sato estimator for the standard error.
[4] P-value based on a Cochran-Mantel-Haenszel test stratified by study.
[5] Interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the OR (95% CI). Not reported subgroup levels are not included in estimation of the interaction p-value.
A continuity correction is applied in estimation of the OR, RR and p-value if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum. No continuity correction is applied in the estimation of the RD.
The reference group for the OR, RR and RD is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with >= 1 event; OR: Odds ratio; RR: Risk ratio; RD: Risk difference; CI: Confidence interval; int: p-value for interaction; NETA: Norethindrone acetate; SOC: System organ class; PT: Preferred term; NC: Not calculated; NE: Non-estimable.

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1.3.7 Adverse Event Category: Mood Disorders by System Organ Class and Preferred Term, by Subgroup (Safety Population)

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Table SAF.MOODANY.SPT.POOL.1.1.S1: Adverse Event Category: Mood Disorders by System Organ Class and Preferred Term, by Subgroup (Safety Population)

Study: Pooled

System Organ Class: Any, Preferred Term: Any

Treatment	N	n (%)	OR[1] [95% CI]	RR[2] [95% CI]	RD[3] [95% CI]	p-value[4]	p-value (int)[5]
Age (years)							
< 40 years							NC
Relugolix+E2/NETA	62	1 (1.6)	NC [NC;NC]	NC [NC;NC]	NC [NC;NC]	NC	
Placebo	78	0					
>= 40 years							
Relugolix+E2/NETA	192	5 (2.6)	NC [NC;NC]	NC [NC;NC]	NC [NC;NC]	NC	
Placebo	178	4 (2.2)					

Post hoc analysis. The denominator for percentages is the number of patients in the safety population for each treatment group. Patients with multiple events for a given PT or SOC are counted only once for each PT and SOC. Events are sorted alphabetically by SOC and PT and then by ascending subgroup-by-treatment interaction p-value within each. MedDRA (version 22.0).
Mood disorders include depression and suicide/self injury (broad) standardized MedDRA query.
[1] OR (95% CI) based on a logistic regression model adjusting for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates.
[2] RR (95% CI) based on a Cochran-Mantel-Haenszel approach stratified by study.
[3] RD (95% CI) based on a Mantel-Haenszel approach stratified by study. 95% CIs are based on the approximation to the normal distribution using the Sato estimator for the standard error.
[4] P-value based on a Cochran-Mantel-Haenszel test stratified by study.
[5] Interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the OR (95% CI).
A continuity correction is applied in estimation of the OR, RR and p-value if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum. No continuity correction is applied in the estimation of the RD.
The reference group for the OR, RR and RD is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with >= 1 event; OR: Odds ratio; RR: Risk ratio; RD: Risk difference; CI: Confidence interval; int: p-value for interaction; NETA: Norethindrone acetate; SOC: System organ class; PT: Preferred term; NC: Not calculated.

SOURCE: \Studies\MYV\MYV102\Analysis\Prod\Progs\TFLs\Tab_SAF_AESI_SOC_PT_S_BIN.SAS
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Table SAF.MOODANY.SPT.POOL.1.1.S2: Adverse Event Category: Mood Disorders by System Organ Class and Preferred Term, by Subgroup (Safety Population)

Study: Pooled

System Organ Class: Any, Preferred Term: Any

Treatment	N	n (%)	OR[1] [95% CI]	RR[2] [95% CI]	RD[3] [95% CI]	p-value[4]	p-value (int)[5]
BMI (kg/m2) at Baseline							
< 30							
Relugolix+E2/NETA	119	3 (2.5)	NC [NC;NC]	NC [NC;NC]	NC [NC;NC]	NC	NC
Placebo	115	1 (0.9)					
>= 30							
Relugolix+E2/NETA	134	3 (2.2)	NC [NC;NC]	NC [NC;NC]	NC [NC;NC]	NC	
Placebo	141	3 (2.1)					
Missing							
Relugolix+E2/NETA	1	0	NC [NC;NC]	NC [NC;NC]	NC [NC;NC]	NC	
Placebo	0	0					

Post hoc analysis. The denominator for percentages is the number of patients in the safety population for each treatment group. Patients with multiple events for a given PT or SOC are counted only once for each PT and SOC. Events are sorted alphabetically by SOC and PT and then by ascending subgroup-by-treatment interaction p-value within each. MedDRA (version 22.0).
Mood disorders include depression and suicide/self injury (broad) standardized MedDRA query.
[1] OR (95% CI) based on a logistic regression model adjusting for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates.
[2] RR (95% CI) based on a Cochran-Mantel-Haenszel approach stratified by study.
[3] RD (95% CI) based on a Mantel-Haenszel approach stratified by study. 95% CIs are based on the approximation to the normal distribution using the Sato estimator for the standard error.
[4] P-value based on a Cochran-Mantel-Haenszel test stratified by study.
[5] Interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the OR (95% CI). Missing subgroup levels are not included in estimation of the interaction p-value.
A continuity correction is applied in estimation of the OR, RR and p-value if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum. No continuity correction is applied in the estimation of the RD.
The reference group for the OR, RR and RD is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with >= 1 event; OR: Odds ratio; RR: Risk ratio; RD: Risk difference; CI: Confidence interval; int: p-value for interaction; NETA: Norethindrone acetate; SOC: System organ class; PT: Preferred term; NC: Not calculated.

SOURCE: \Studies\MYV\MYV102\Analysis\Prod\Progs\TFLs\Tab_SAF_AESI_SOC_PT_S_BIN.SAS
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Table SAF.MOODANY.SPT.POOL.1.1.S3: Adverse Event Category: Mood Disorders by System Organ Class and Preferred Term, by Subgroup (Safety Population)

Study: Pooled

System Organ Class: Any, Preferred Term: Any

Treatment	N	n (%)	OR[1] [95% CI]	RR[2] [95% CI]	RD[3] [95% CI]	p-value[4]	p-value (int)[5]
Uterine Volume at Baseline (cm3)							
< 300 cm3							
Relugolix+E2/NETA	148	5 (3.4)	NC	NC	NC	NC	NC
Placebo	129	2 (1.6)	[NC;NC]	[NC;NC]	[NC;NC]		
>= 300 cm3							
Relugolix+E2/NETA	105	1 (1.0)	NC	NC	NC	NC	
Placebo	127	2 (1.6)	[NC;NC]	[NC;NC]	[NC;NC]		
Missing							
Relugolix+E2/NETA	1	0	NC	NC	NC	NC	
Placebo	0	0	[NC;NC]	[NC;NC]	[NC;NC]		

Post hoc analysis. The denominator for percentages is the number of patients in the safety population for each treatment group. Patients with multiple events for a given PT or SOC are counted only once for each PT and SOC. Events are sorted alphabetically by SOC and PT and then by ascending subgroup-by-treatment interaction p-value within each. MedDRA (version 22.0).
Mood disorders include depression and suicide/self injury (broad) standardized MedDRA query.
[1] OR (95% CI) based on a logistic regression model adjusting for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates.
[2] RR (95% CI) based on a Cochran-Mantel-Haenszel approach stratified by study.
[3] RD (95% CI) based on a Mantel-Haenszel approach stratified by study. 95% CIs are based on the approximation to the normal distribution using the Sato estimator for the standard error.
[4] P-value based on a Cochran-Mantel-Haenszel test stratified by study.
[5] Interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the OR (95% CI). Missing subgroup levels are not included in estimation of the interaction p-value.
A continuity correction is applied in estimation of the OR, RR and p-value if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum. No continuity correction is applied in the estimation of the RD.
The reference group for the OR, RR and RD is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with >= 1 event; OR: Odds ratio; RR: Risk ratio; RD: Risk difference; CI: Confidence interval; int: p-value for interaction; NETA: Norethindrone acetate; SOC: System organ class; PT: Preferred term; NC: Not calculated.

SOURCE: \Studies\MYV\MYV102\Analysis\Prod\Progs\TFLs\Tab_SAF_AESI_SOC_PT_S_BIN.SAS
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Table SAF.MOODANY.SPT.POOL.1.1.S4: Adverse Event Category: Mood Disorders by System Organ Class and Preferred Term, by Subgroup (Safety Population)

Study: Pooled

System Organ Class: Any, Preferred Term: Any

Treatment	N	n (%)	OR[1] [95% CI]	RR[2] [95% CI]	RD[3] [95% CI]	p-value[4]	p-value (int)[5]
Maximum NRS Pain Score at Baseline							
< 4							
Relugolix+E2/NETA	73	3 (4.1)	NC	NC	NC	NC	NC
Placebo	62	1 (1.6)	[NC;NC]	[NC;NC]	[NC;NC]		
>= 4							
Relugolix+E2/NETA	178	3 (1.7)	NC	NC	NC	NC	
Placebo	190	3 (1.6)	[NC;NC]	[NC;NC]	[NC;NC]		
Missing							
Relugolix+E2/NETA	3	0	NC	NC	NC	NC	
Placebo	4	0	[NC;NC]	[NC;NC]	[NC;NC]		

Post hoc analysis. The denominator for percentages is the number of patients in the safety population for each treatment group. Patients with multiple events for a given PT or SOC are counted only once for each PT and SOC. Events are sorted alphabetically by SOC and PT and then by ascending subgroup-by-treatment interaction p-value within each. MedDRA (version 22.0).
Mood disorders include depression and suicide/self injury (broad) standardized MedDRA query.
[1] OR (95% CI) based on a logistic regression model adjusting for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates.
[2] RR (95% CI) based on a Cochran-Mantel-Haenszel approach stratified by study.
[3] RD (95% CI) based on a Mantel-Haenszel approach stratified by study. 95% CIs are based on the approximation to the normal distribution using the Sato estimator for the standard error.
[4] P-value based on a Cochran-Mantel-Haenszel test stratified by study.
[5] Interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the OR (95% CI). Missing subgroup levels are not included in estimation of the interaction p-value.
A continuity correction is applied in estimation of the OR, RR and p-value if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum. No continuity correction is applied in the estimation of the RD.
The reference group for the OR, RR and RD is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with >= 1 event; OR: Odds ratio; RR: Risk ratio; RD: Risk difference; CI: Confidence interval; int: p-value for interaction; NETA: Norethindrone acetate; SOC: System organ class; PT: Preferred term; NC: Not calculated.

SOURCE: \Studies\MYV\MYV102\Analysis\Prod\Progs\TFLs\Tab_SAF_AESI_SOC_PT_S_BIN.SAS
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Table SAF.MOODANY.SPT.POOL.1.1.S5: Adverse Event Category: Mood Disorders by System Organ Class and Preferred Term, by Subgroup (Safety Population)

Study: Pooled

System Organ Class: Any, Preferred Term: Any

Treatment	N	n (%)	OR[1] [95% CI]	RR[2] [95% CI]	RD[3] [95% CI]	p-value[4]	p-value (int)[5]
MBL Volume at Baseline (mL)							
< 225 mL							
Relugolix+E2/NETA	164	4 (2.4)	NC [NC;NC]	NC [NC;NC]	NC [NC;NC]	NC	NC
Placebo	171	3 (1.8)					
>= 225 mL							
Relugolix+E2/NETA	90	2 (2.2)	NC [NC;NC]	NC [NC;NC]	NC [NC;NC]	NC	
Placebo	85	1 (1.2)					

Post hoc analysis. The denominator for percentages is the number of patients in the safety population for each treatment group. Patients with multiple events for a given PT or SOC are counted only once for each PT and SOC. Events are sorted alphabetically by SOC and PT and then by ascending subgroup-by-treatment interaction p-value within each. MedDRA (version 22.0).
Mood disorders include depression and suicide/self injury (broad) standardized MedDRA query.
[1] OR (95% CI) based on a logistic regression model adjusting for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates.
[2] RR (95% CI) based on a Cochran-Mantel-Haenszel approach stratified by study.
[3] RD (95% CI) based on a Mantel-Haenszel approach stratified by study. 95% CIs are based on the approximation to the normal distribution using the Sato estimator for the standard error.
[4] P-value based on a Cochran-Mantel-Haenszel test stratified by study.
[5] Interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the OR (95% CI).
A continuity correction is applied in estimation of the OR, RR and p-value if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum. No continuity correction is applied in the estimation of the RD.
The reference group for the OR, RR and RD is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with >= 1 event; OR: Odds ratio; RR: Risk ratio; RD: Risk difference; CI: Confidence interval; int: p-value for interaction; NETA: Norethindrone acetate; SOC: System organ class; PT: Preferred term; NC: Not calculated.

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Table SAF.MOODANY.SPT.POOL.1.1.S6: Adverse Event Category: Mood Disorders by System Organ Class and Preferred Term, by Subgroup (Safety Population)

Study: Pooled

System Organ Class: Any, Preferred Term: Any

Treatment	N	n (%)	OR[1] [95% CI]	RR[2] [95% CI]	RD[3] [95% CI]	p-value[4]	p-value (int)[5]
Geographic Region I							
North America							
Relugolix+E2/NETA	192	3 (1.6)	NC	NC	NC	NC	NC
Placebo	194	3 (1.5)	[NC;NC]	[NC;NC]	[NC;NC]		
Rest of World							
Relugolix+E2/NETA	62	3 (4.8)	NC	NC	NC	NC	
Placebo	62	1 (1.6)	[NC;NC]	[NC;NC]	[NC;NC]		

Post hoc analysis. The denominator for percentages is the number of patients in the safety population for each treatment group. Patients with multiple events for a given PT or SOC are counted only once for each PT and SOC. Events are sorted alphabetically by SOC and PT and then by ascending subgroup-by-treatment interaction p-value within each. MedDRA (version 22.0).
Mood disorders include depression and suicide/self injury (broad) standardized MedDRA query.
[1] OR (95% CI) based on a logistic regression model adjusting for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates.
[2] RR (95% CI) based on a Cochran-Mantel-Haenszel approach stratified by study.
[3] RD (95% CI) based on a Mantel-Haenszel approach stratified by study. 95% CIs are based on the approximation to the normal distribution using the Sato estimator for the standard error.
[4] P-value based on a Cochran-Mantel-Haenszel test stratified by study.
[5] Interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the OR (95% CI).
A continuity correction is applied in estimation of the OR, RR and p-value if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum. No continuity correction is applied in the estimation of the RD.
The reference group for the OR, RR and RD is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with >= 1 event; OR: Odds ratio; RR: Risk ratio; RD: Risk difference; CI: Confidence interval; int: p-value for interaction; NETA: Norethindrone acetate; SOC: System organ class; PT: Preferred term; NC: Not calculated.

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Table SAF.MOODANY.SPT.POOL.1.1.S7: Adverse Event Category: Mood Disorders by System Organ Class and Preferred Term, by Subgroup (Safety Population)

Study: Pooled

System Organ Class: Any, Preferred Term: Any

Treatment	N	n (%)	OR[1] [95% CI]	RR[2] [95% CI]	RD[3] [95% CI]	p-value[4]	p-value (int)[5]
Geographic Region II							
Europe							
Relugolix+E2/NETA	41	2 (4.9)	NC	NC	NC	NC	NC
Placebo	42	1 (2.4)	[NC;NC]	[NC;NC]	[NC;NC]		
Rest of World (including the US)							
Relugolix+E2/NETA	213	4 (1.9)	NC	NC	NC	NC	
Placebo	214	3 (1.4)	[NC;NC]	[NC;NC]	[NC;NC]		

Post hoc analysis. The denominator for percentages is the number of patients in the safety population for each treatment group. Patients with multiple events for a given PT or SOC are counted only once for each PT and SOC. Events are sorted alphabetically by SOC and PT and then by ascending subgroup-by-treatment interaction p-value within each. MedDRA (version 22.0).
Mood disorders include depression and suicide/self injury (broad) standardized MedDRA query.
[1] OR (95% CI) based on a logistic regression model adjusting for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates.
[2] RR (95% CI) based on a Cochran-Mantel-Haenszel approach stratified by study.
[3] RD (95% CI) based on a Mantel-Haenszel approach stratified by study. 95% CIs are based on the approximation to the normal distribution using the Sato estimator for the standard error.
[4] P-value based on a Cochran-Mantel-Haenszel test stratified by study.
[5] Interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the OR (95% CI).
A continuity correction is applied in estimation of the OR, RR and p-value if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum. No continuity correction is applied in the estimation of the RD.
The reference group for the OR, RR and RD is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with >= 1 event; OR: Odds ratio; RR: Risk ratio; RD: Risk difference; CI: Confidence interval; int: p-value for interaction; NETA: Norethindrone acetate; SOC: System organ class; PT: Preferred term; NC: Not calculated.

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Table SAF.MOODANY.SPT.POOL.1.1.S8: Adverse Event Category: Mood Disorders by System Organ Class and Preferred Term, by Subgroup (Safety Population)

Study: Pooled

System Organ Class: Any, Preferred Term: Any

Treatment	N	n (%)	OR[1] [95% CI]	RR[2] [95% CI]	RD[3] [95% CI]	p-value[4]	p-value (int)[5]
Ethnicity							
Hispanic or Latino							
Relugolix+E2/NETA	53	1 (1.9)	NC	NC	NC	NC	NC
Placebo	55	0	[NC;NC]	[NC;NC]	[NC;NC]		
Not Hispanic or Latino							
Relugolix+E2/NETA	197	5 (2.5)	NC	NC	NC	NC	
Placebo	199	4 (2.0)	[NC;NC]	[NC;NC]	[NC;NC]		
Not reported							
Relugolix+E2/NETA	4	0	NC	NC	NC	NC	
Placebo	2	0	[NC;NC]	[NC;NC]	[NC;NC]		

Post hoc analysis. The denominator for percentages is the number of patients in the safety population for each treatment group. Patients with multiple events for a given PT or SOC are counted only once for each PT and SOC. Events are sorted alphabetically by SOC and PT and then by ascending subgroup-by-treatment interaction p-value within each. MedDRA (version 22.0).
Mood disorders include depression and suicide/self injury (broad) standardized MedDRA query.
[1] OR (95% CI) based on a logistic regression model adjusting for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates.
[2] RR (95% CI) based on a Cochran-Mantel-Haenszel approach stratified by study.
[3] RD (95% CI) based on a Mantel-Haenszel approach stratified by study. 95% CIs are based on the approximation to the normal distribution using the Sato estimator for the standard error.
[4] P-value based on a Cochran-Mantel-Haenszel test stratified by study.
[5] Interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the OR (95% CI). Not reported subgroup levels are not included in estimation of the interaction p-value.
A continuity correction is applied in estimation of the OR, RR and p-value if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum. No continuity correction is applied in the estimation of the RD.
The reference group for the OR, RR and RD is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with >= 1 event; OR: Odds ratio; RR: Risk ratio; RD: Risk difference; CI: Confidence interval; int: p-value for interaction; NETA: Norethindrone acetate; SOC: System organ class; PT: Preferred term; NC: Not calculated.

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Table SAF.MOODANY.SPT.POOL.1.1.S9: Adverse Event Category: Mood Disorders by System Organ Class and Preferred Term, by Subgroup (Safety Population)

Study: Pooled

System Organ Class: Any, Preferred Term: Any

Treatment	N	n (%)	OR[1] [95% CI]	RR[2] [95% CI]	RD[3] [95% CI]	p-value[4]	p-value (int)[5]
Race							
Black/African American							NC
Relugolix+E2/NETA	122	2 (1.6)	NC [NC;NC]	NC [NC;NC]	NC [NC;NC]	NC	
Placebo	141	2 (1.4)					
White							
Relugolix+E2/NETA	123	4 (3.3)	NC [NC;NC]	NC [NC;NC]	NC [NC;NC]	NC	
Placebo	105	2 (1.9)					
Asian							
Relugolix+E2/NETA	1	0	NC [NC;NC]	NC [NC;NC]	NC [NC;NC]	NC	
Placebo	3	0					
Others							
Relugolix+E2/NETA	5	0	NC [NC;NC]	NC [NC;NC]	NC [NC;NC]	NC	
Placebo	6	0					
Not reported							
Relugolix+E2/NETA	3	0	NC [NC;NC]	NC [NC;NC]	NC [NC;NC]	NC	
Placebo	1	0					

Post hoc analysis. The denominator for percentages is the number of patients in the safety population for each treatment group. Patients with multiple events for a given PT or SOC are counted only once for each PT and SOC. Events are sorted alphabetically by SOC and PT and then by ascending subgroup-by-treatment interaction p-value within each. MedDRA (version 22.0).
Mood disorders include depression and suicide/self injury (broad) standardized MedDRA query.
[1] OR (95% CI) based on a logistic regression model adjusting for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates.
[2] RR (95% CI) based on a Cochran-Mantel-Haenszel approach stratified by study.
[3] RD (95% CI) based on a Mantel-Haenszel approach stratified by study. 95% CIs are based on the approximation to the normal distribution using the Sato estimator for the standard error.
[4] P-value based on a Cochran-Mantel-Haenszel test stratified by study.
[5] Interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the OR (95% CI). Not reported subgroup levels are not included in estimation of the interaction p-value.
A continuity correction is applied in estimation of the OR, RR and p-value if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum. No continuity correction is applied in the estimation of the RD.
The reference group for the OR, RR and RD is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with >= 1 event; OR: Odds ratio; RR: Risk ratio; RD: Risk difference; CI: Confidence interval; int: p-value for interaction; NETA: Norethindrone acetate; SOC: System organ class; PT: Preferred term; NC: Not calculated.

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Table SAF.MOODANY.SPT.POOL.2.1.S1: Adverse Event Category: Mood Disorders by System Organ Class and Preferred Term, by Subgroup (Safety Population)

Study: Pooled

System Organ Class: Psychiatric disorders, Preferred Term: Any

Treatment	N	n (%)	OR[1] [95% CI]	RR[2] [95% CI]	RD[3] [95% CI]	p-value[4]	p-value (int)[5]
Age (years)							
< 40 years							
Relugolix+E2/NETA	62	1 (1.6)	NC	NC	NC	NC	NC
Placebo	78	0	[NC;NC]	[NC;NC]	[NC;NC]		
>= 40 years							
Relugolix+E2/NETA	192	5 (2.6)	NC	NC	NC	NC	
Placebo	178	4 (2.2)	[NC;NC]	[NC;NC]	[NC;NC]		

Post hoc analysis. The denominator for percentages is the number of patients in the safety population for each treatment group. Patients with multiple events for a given PT or SOC are counted only once for each PT and SOC. Events are sorted alphabetically by SOC and PT and then by ascending subgroup-by-treatment interaction p-value within each. MedDRA (version 22.0).
Mood disorders include depression and suicide/self injury (broad) standardized MedDRA query.
[1] OR (95% CI) based on a logistic regression model adjusting for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates.
[2] RR (95% CI) based on a Cochran-Mantel-Haenszel approach stratified by study.
[3] RD (95% CI) based on a Mantel-Haenszel approach stratified by study. 95% CIs are based on the approximation to the normal distribution using the Sato estimator for the standard error.
[4] P-value based on a Cochran-Mantel-Haenszel test stratified by study.
[5] Interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the OR (95% CI).
A continuity correction is applied in estimation of the OR, RR and p-value if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum. No continuity correction is applied in the estimation of the RD.
The reference group for the OR, RR and RD is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with >= 1 event; OR: Odds ratio; RR: Risk ratio; RD: Risk difference; CI: Confidence interval; int: p-value for interaction; NETA: Norethindrone acetate; SOC: System organ class; PT: Preferred term; NC: Not calculated.

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Table SAF.MOODANY.SPT.POOL.2.1.S2: Adverse Event Category: Mood Disorders by System Organ Class and Preferred Term, by Subgroup (Safety Population)

Study: Pooled

System Organ Class: Psychiatric disorders, Preferred Term: Any

Treatment	N	n (%)	OR[1] [95% CI]	RR[2] [95% CI]	RD[3] [95% CI]	p-value[4]	p-value (int)[5]
BMI (kg/m2) at Baseline							
< 30							
Relugolix+E2/NETA	119	3 (2.5)	NC	NC	NC	NC	NC
Placebo	115	1 (0.9)	[NC;NC]	[NC;NC]	[NC;NC]		
>= 30							
Relugolix+E2/NETA	134	3 (2.2)	NC	NC	NC	NC	
Placebo	141	3 (2.1)	[NC;NC]	[NC;NC]	[NC;NC]		
Missing							
Relugolix+E2/NETA	1	0	NC	NC	NC	NC	
Placebo	0	0	[NC;NC]	[NC;NC]	[NC;NC]		

Post hoc analysis. The denominator for percentages is the number of patients in the safety population for each treatment group. Patients with multiple events for a given PT or SOC are counted only once for each PT and SOC. Events are sorted alphabetically by SOC and PT and then by ascending subgroup-by-treatment interaction p-value within each. MedDRA (version 22.0).
Mood disorders include depression and suicide/self injury (broad) standardized MedDRA query.
[1] OR (95% CI) based on a logistic regression model adjusting for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates.
[2] RR (95% CI) based on a Cochran-Mantel-Haenszel approach stratified by study.
[3] RD (95% CI) based on a Mantel-Haenszel approach stratified by study. 95% CIs are based on the approximation to the normal distribution using the Sato estimator for the standard error.
[4] P-value based on a Cochran-Mantel-Haenszel test stratified by study.
[5] Interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the OR (95% CI). Missing subgroup levels are not included in estimation of the interaction p-value.
A continuity correction is applied in estimation of the OR, RR and p-value if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum. No continuity correction is applied in the estimation of the RD.
The reference group for the OR, RR and RD is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with >= 1 event; OR: Odds ratio; RR: Risk ratio; RD: Risk difference; CI: Confidence interval; int: p-value for interaction; NETA: Norethindrone acetate; SOC: System organ class; PT: Preferred term; NC: Not calculated.

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Table SAF.MOODANY.SPT.POOL.2.1.S3: Adverse Event Category: Mood Disorders by System Organ Class and Preferred Term, by Subgroup (Safety Population)

Study: Pooled

System Organ Class: Psychiatric disorders, Preferred Term: Any

Treatment	N	n (%)	OR[1] [95% CI]	RR[2] [95% CI]	RD[3] [95% CI]	p-value[4]	p-value (int)[5]
Uterine Volume at Baseline (cm3)							
< 300 cm3							
Relugolix+E2/NETA	148	5 (3.4)	NC	NC	NC	NC	NC
Placebo	129	2 (1.6)	[NC;NC]	[NC;NC]	[NC;NC]		
>= 300 cm3							
Relugolix+E2/NETA	105	1 (1.0)	NC	NC	NC	NC	
Placebo	127	2 (1.6)	[NC;NC]	[NC;NC]	[NC;NC]		
Missing							
Relugolix+E2/NETA	1	0	NC	NC	NC	NC	
Placebo	0	0	[NC;NC]	[NC;NC]	[NC;NC]		

Post hoc analysis. The denominator for percentages is the number of patients in the safety population for each treatment group. Patients with multiple events for a given PT or SOC are counted only once for each PT and SOC. Events are sorted alphabetically by SOC and PT and then by ascending subgroup-by-treatment interaction p-value within each. MedDRA (version 22.0).
Mood disorders include depression and suicide/self injury (broad) standardized MedDRA query.
[1] OR (95% CI) based on a logistic regression model adjusting for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates.
[2] RR (95% CI) based on a Cochran-Mantel-Haenszel approach stratified by study.
[3] RD (95% CI) based on a Mantel-Haenszel approach stratified by study. 95% CIs are based on the approximation to the normal distribution using the Sato estimator for the standard error.
[4] P-value based on a Cochran-Mantel-Haenszel test stratified by study.
[5] Interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the OR (95% CI). Missing subgroup levels are not included in estimation of the interaction p-value.
A continuity correction is applied in estimation of the OR, RR and p-value if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum. No continuity correction is applied in the estimation of the RD.
The reference group for the OR, RR and RD is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with >= 1 event; OR: Odds ratio; RR: Risk ratio; RD: Risk difference; CI: Confidence interval; int: p-value for interaction; NETA: Norethindrone acetate; SOC: System organ class; PT: Preferred term; NC: Not calculated.

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Table SAF.MOODANY.SPT.POOL.2.1.S4: Adverse Event Category: Mood Disorders by System Organ Class and Preferred Term, by Subgroup (Safety Population)

Study: Pooled

System Organ Class: Psychiatric disorders, Preferred Term: Any

Treatment	N	n (%)	OR[1] [95% CI]	RR[2] [95% CI]	RD[3] [95% CI]	p-value[4]	p-value (int)[5]
Maximum NRS Pain Score at Baseline							
< 4							
Relugolix+E2/NETA	73	3 (4.1)	NC	NC	NC	NC	NC
Placebo	62	1 (1.6)	[NC;NC]	[NC;NC]	[NC;NC]		
>= 4							
Relugolix+E2/NETA	178	3 (1.7)	NC	NC	NC	NC	
Placebo	190	3 (1.6)	[NC;NC]	[NC;NC]	[NC;NC]		
Missing							
Relugolix+E2/NETA	3	0	NC	NC	NC	NC	
Placebo	4	0	[NC;NC]	[NC;NC]	[NC;NC]		

Post hoc analysis. The denominator for percentages is the number of patients in the safety population for each treatment group. Patients with multiple events for a given PT or SOC are counted only once for each PT and SOC. Events are sorted alphabetically by SOC and PT and then by ascending subgroup-by-treatment interaction p-value within each. MedDRA (version 22.0).
Mood disorders include depression and suicide/self injury (broad) standardized MedDRA query.
[1] OR (95% CI) based on a logistic regression model adjusting for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates.
[2] RR (95% CI) based on a Cochran-Mantel-Haenszel approach stratified by study.
[3] RD (95% CI) based on a Mantel-Haenszel approach stratified by study. 95% CIs are based on the approximation to the normal distribution using the Sato estimator for the standard error.
[4] P-value based on a Cochran-Mantel-Haenszel test stratified by study.
[5] Interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the OR (95% CI). Missing subgroup levels are not included in estimation of the interaction p-value.
A continuity correction is applied in estimation of the OR, RR and p-value if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum. No continuity correction is applied in the estimation of the RD.
The reference group for the OR, RR and RD is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with >= 1 event; OR: Odds ratio; RR: Risk ratio; RD: Risk difference; CI: Confidence interval; int: p-value for interaction; NETA: Norethindrone acetate; SOC: System organ class; PT: Preferred term; NC: Not calculated.

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Table SAF.MOODANY.SPT.POOL.2.1.S5: Adverse Event Category: Mood Disorders by System Organ Class and Preferred Term, by Subgroup (Safety Population)

Study: Pooled

System Organ Class: Psychiatric disorders, Preferred Term: Any

Treatment	N	n (%)	OR[1] [95% CI]	RR[2] [95% CI]	RD[3] [95% CI]	p-value[4]	p-value (int)[5]
MBL Volume at Baseline (mL)							
< 225 mL							
Relugolix+E2/NETA	164	4 (2.4)	NC	NC	NC	NC	NC
Placebo	171	3 (1.8)	[NC;NC]	[NC;NC]	[NC;NC]		
>= 225 mL							
Relugolix+E2/NETA	90	2 (2.2)	NC	NC	NC	NC	
Placebo	85	1 (1.2)	[NC;NC]	[NC;NC]	[NC;NC]		

Post hoc analysis. The denominator for percentages is the number of patients in the safety population for each treatment group. Patients with multiple events for a given PT or SOC are counted only once for each PT and SOC. Events are sorted alphabetically by SOC and PT and then by ascending subgroup-by-treatment interaction p-value within each. MedDRA (version 22.0).
Mood disorders include depression and suicide/self injury (broad) standardized MedDRA query.
[1] OR (95% CI) based on a logistic regression model adjusting for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates.
[2] RR (95% CI) based on a Cochran-Mantel-Haenszel approach stratified by study.
[3] RD (95% CI) based on a Mantel-Haenszel approach stratified by study. 95% CIs are based on the approximation to the normal distribution using the Sato estimator for the standard error.
[4] P-value based on a Cochran-Mantel-Haenszel test stratified by study.
[5] Interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the OR (95% CI).
A continuity correction is applied in estimation of the OR, RR and p-value if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum. No continuity correction is applied in the estimation of the RD.
The reference group for the OR, RR and RD is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with >= 1 event; OR: Odds ratio; RR: Risk ratio; RD: Risk difference; CI: Confidence interval; int: p-value for interaction; NETA: Norethindrone acetate; SOC: System organ class; PT: Preferred term; NC: Not calculated.

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Table SAF.MOODANY.SPT.POOL.2.1.S6: Adverse Event Category: Mood Disorders by System Organ Class and Preferred Term, by Subgroup (Safety Population)

Study: Pooled

System Organ Class: Psychiatric disorders, Preferred Term: Any

Treatment	**N**	**n (%)**	**OR[1] [95% CI]**	**RR[2] [95% CI]**	**RD[3] [95% CI]**	**p-value[4]**	**p-value (int)[5]**
Geographic Region I							
North America							
Relugolix+E2/NETA	192	3 (1.6)	NC	NC	NC	NC	NC
Placebo	194	3 (1.5)	[NC;NC]	[NC;NC]	[NC;NC]		
Rest of World							
Relugolix+E2/NETA	62	3 (4.8)	NC	NC	NC	NC	
Placebo	62	1 (1.6)	[NC;NC]	[NC;NC]	[NC;NC]		

Post hoc analysis. The denominator for percentages is the number of patients in the safety population for each treatment group. Patients with multiple events for a given PT or SOC are counted only once for each PT and SOC. Events are sorted alphabetically by SOC and PT and then by ascending subgroup-by-treatment interaction p-value within each. MedDRA (version 22.0).
Mood disorders include depression and suicide/self injury (broad) standardized MedDRA query.
[1] OR (95% CI) based on a logistic regression model adjusting for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates.
[2] RR (95% CI) based on a Cochran-Mantel-Haenszel approach stratified by study.
[3] RD (95% CI) based on a Mantel-Haenszel approach stratified by study. 95% CIs are based on the approximation to the normal distribution using the Sato estimator for the standard error.
[4] P-value based on a Cochran-Mantel-Haenszel test stratified by study.
[5] Interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the OR (95% CI).
A continuity correction is applied in estimation of the OR, RR and p-value if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum. No continuity correction is applied in the estimation of the RD.
The reference group for the OR, RR and RD is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with >= 1 event; OR: Odds ratio; RR: Risk ratio; RD: Risk difference; CI: Confidence interval; int: p-value for interaction; NETA: Norethindrone acetate; SOC: System organ class; PT: Preferred term; NC: Not calculated.

SOURCE: \Studies\MYV\MYV102\Analysis\Prod\Progs\TFLs\Tab_SAF_AESI_SOC_PT_S_BIN.SAS
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Table SAF.MOODANY.SPT.POOL.2.1.S7: Adverse Event Category: Mood Disorders by System Organ Class and Preferred Term, by Subgroup (Safety Population)

Study: Pooled

System Organ Class: Psychiatric disorders, Preferred Term: Any

Treatment	N	n (%)	OR[1] [95% CI]	RR[2] [95% CI]	RD[3] [95% CI]	p-value[4]	p-value (int)[5]
Geographic Region II							
Europe							
Relugolix+E2/NETA	41	2 (4.9)	NC	NC	NC	NC	NC
Placebo	42	1 (2.4)	[NC;NC]	[NC;NC]	[NC;NC]		
Rest of World (including the US)							
Relugolix+E2/NETA	213	4 (1.9)	NC	NC	NC	NC	
Placebo	214	3 (1.4)	[NC;NC]	[NC;NC]	[NC;NC]		

Post hoc analysis. The denominator for percentages is the number of patients in the safety population for each treatment group. Patients with multiple events for a given PT or SOC are counted only once for each PT and SOC. Events are sorted alphabetically by SOC and PT and then by ascending subgroup-by-treatment interaction p-value within each. MedDRA (version 22.0).
Mood disorders include depression and suicide/self injury (broad) standardized MedDRA query.
[1] OR (95% CI) based on a logistic regression model adjusting for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates.
[2] RR (95% CI) based on a Cochran-Mantel-Haenszel approach stratified by study.
[3] RD (95% CI) based on a Mantel-Haenszel approach stratified by study. 95% CIs are based on the approximation to the normal distribution using the Sato estimator for the standard error.
[4] P-value based on a Cochran-Mantel-Haenszel test stratified by study.
[5] Interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the OR (95% CI).
A continuity correction is applied in estimation of the OR, RR and p-value if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum. No continuity correction is applied in the estimation of the RD.
The reference group for the OR, RR and RD is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with >= 1 event; OR: Odds ratio; RR: Risk ratio; RD: Risk difference; CI: Confidence interval; int: p-value for interaction; NETA: Norethindrone acetate; SOC: System organ class; PT: Preferred term; NC: Not calculated.

SOURCE: \Studies\MYV\MYV102\Analysis\Prod\Progs\TFLs\Tab_SAF_AESI_SOC_PT_S_BIN.SAS
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Table SAF.MOODANY.SPT.POOL.2.1.S8: Adverse Event Category: Mood Disorders by System Organ Class and Preferred Term, by Subgroup (Safety Population)

Study: Pooled

System Organ Class: Psychiatric disorders, Preferred Term: Any

Treatment	N	n (%)	OR[1] [95% CI]	RR[2] [95% CI]	RD[3] [95% CI]	p-value[4]	p-value (int)[5]
Ethnicity							
Hispanic or Latino							
Relugolix+E2/NETA	53	1 (1.9)	NC	NC	NC	NC	NC
Placebo	55	0	[NC;NC]	[NC;NC]	[NC;NC]		
Not Hispanic or Latino							
Relugolix+E2/NETA	197	5 (2.5)	NC	NC	NC	NC	
Placebo	199	4 (2.0)	[NC;NC]	[NC;NC]	[NC;NC]		
Not reported							
Relugolix+E2/NETA	4	0	NC	NC	NC	NC	
Placebo	2	0	[NC;NC]	[NC;NC]	[NC;NC]		

Post hoc analysis. The denominator for percentages is the number of patients in the safety population for each treatment group. Patients with multiple events for a given PT or SOC are counted only once for each PT and SOC. Events are sorted alphabetically by SOC and PT and then by ascending subgroup-by-treatment interaction p-value within each. MedDRA (version 22.0).
Mood disorders include depression and suicide/self injury (broad) standardized MedDRA query.
[1] OR (95% CI) based on a logistic regression model adjusting for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates.
[2] RR (95% CI) based on a Cochran-Mantel-Haenszel approach stratified by study.
[3] RD (95% CI) based on a Mantel-Haenszel approach stratified by study. 95% CIs are based on the approximation to the normal distribution using the Sato estimator for the standard error.
[4] P-value based on a Cochran-Mantel-Haenszel test stratified by study.
[5] Interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the OR (95% CI). Not reported subgroup levels are not included in estimation of the interaction p-value.
A continuity correction is applied in estimation of the OR, RR and p-value if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum. No continuity correction is applied in the estimation of the RD.
The reference group for the OR, RR and RD is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with >= 1 event; OR: Odds ratio; RR: Risk ratio; RD: Risk difference; CI: Confidence interval; int: p-value for interaction; NETA: Norethindrone acetate; SOC: System organ class; PT: Preferred term; NC: Not calculated.

SOURCE: \Studies\MYV\MYV102\Analysis\Prod\Progs\TFLs\Tab_SAF_AESI_SOC_PT_S_BIN.SAS
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Table SAF.MOODANY.SPT.POOL.2.1.S9: Adverse Event Category: Mood Disorders by System Organ Class and Preferred Term, by Subgroup (Safety Population)

Study: Pooled

System Organ Class: Psychiatric disorders, Preferred Term: Any

Treatment	N	n (%)	OR[1] [95% CI]	RR[2] [95% CI]	RD[3] [95% CI]	p-value[4]	p-value (int)[5]
Race							
Black/African American							NC
Relugolix+E2/NETA	122	2 (1.6)	NC	NC	NC	NC	
Placebo	141	2 (1.4)	[NC;NC]	[NC;NC]	[NC;NC]		
White							
Relugolix+E2/NETA	123	4 (3.3)	NC	NC	NC	NC	
Placebo	105	2 (1.9)	[NC;NC]	[NC;NC]	[NC;NC]		
Asian							
Relugolix+E2/NETA	1	0	NC	NC	NC	NC	
Placebo	3	0	[NC;NC]	[NC;NC]	[NC;NC]		
Others							
Relugolix+E2/NETA	5	0	NC	NC	NC	NC	
Placebo	6	0	[NC;NC]	[NC;NC]	[NC;NC]		
Not reported							
Relugolix+E2/NETA	3	0	NC	NC	NC	NC	
Placebo	1	0	[NC;NC]	[NC;NC]	[NC;NC]		

Post hoc analysis. The denominator for percentages is the number of patients in the safety population for each treatment group. Patients with multiple events for a given PT or SOC are counted only once for each PT and SOC. Events are sorted alphabetically by SOC and PT and then by ascending subgroup-by-treatment interaction p-value within each. MedDRA (version 22.0).
Mood disorders include depression and suicide/self injury (broad) standardized MedDRA query.
[1] OR (95% CI) based on a logistic regression model adjusting for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates.
[2] RR (95% CI) based on a Cochran-Mantel-Haenszel approach stratified by study.
[3] RD (95% CI) based on a Mantel-Haenszel approach stratified by study. 95% CIs are based on the approximation to the normal distribution using the Sato estimator for the standard error.
[4] P-value based on a Cochran-Mantel-Haenszel test stratified by study.
[5] Interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the OR (95% CI). Not reported subgroup levels are not included in estimation of the interaction p-value.
A continuity correction is applied in estimation of the OR, RR and p-value if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum. No continuity correction is applied in the estimation of the RD.
The reference group for the OR, RR and RD is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with >= 1 event; OR: Odds ratio; RR: Risk ratio; RD: Risk difference; CI: Confidence interval; int: p-value for interaction; NETA: Norethindrone acetate; SOC: System organ class; PT: Preferred term; NC: Not calculated.

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Table SAF.MOODANY.SPT.POOL.2.2.S1: Adverse Event Category: Mood Disorders by System Organ Class and Preferred Term, by Subgroup (Safety Population)

Study: Pooled

System Organ Class: Psychiatric disorders, Preferred Term: Affect lability

Treatment	**N**	**n (%)**	**OR[1] [95% CI]**	**RR[2] [95% CI]**	**RD[3] [95% CI]**	**p-value[4]**	**p-value (int)[5]**
Age (years)							
< 40 years							
Relugolix+E2/NETA	62	0	NC [NC;NC]	NC [NC;NC]	NC [NC;NC]	NC	NC
Placebo	78	0					
>= 40 years							
Relugolix+E2/NETA	192	0	NC [NC;NC]	NC [NC;NC]	NC [NC;NC]	NC	
Placebo	178	2 (1.1)					

Post hoc analysis. The denominator for percentages is the number of patients in the safety population for each treatment group. Patients with multiple events for a given PT or SOC are counted only once for each PT and SOC. Events are sorted alphabetically by SOC and PT and then by ascending subgroup-by-treatment interaction p-value within each. MedDRA (version 22.0).
Mood disorders include depression and suicide/self injury (broad) standardized MedDRA query.
[1] OR (95% CI) based on a logistic regression model adjusting for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates.
[2] RR (95% CI) based on a Cochran-Mantel-Haenszel approach stratified by study.
[3] RD (95% CI) based on a Mantel-Haenszel approach stratified by study. 95% CIs are based on the approximation to the normal distribution using the Sato estimator for the standard error.
[4] P-value based on a Cochran-Mantel-Haenszel test stratified by study.
[5] Interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the OR (95% CI).
A continuity correction is applied in estimation of the OR, RR and p-value if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum. No continuity correction is applied in the estimation of the RD.
The reference group for the OR, RR and RD is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with >= 1 event; OR: Odds ratio; RR: Risk ratio; RD: Risk difference; CI: Confidence interval; int: p-value for interaction; NETA: Norethindrone acetate; SOC: System organ class; PT: Preferred term; NC: Not calculated.

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Table SAF.MOODANY.SPT.POOL.2.2.S2: Adverse Event Category: Mood Disorders by System Organ Class and Preferred Term, by Subgroup (Safety Population)

Study: Pooled

System Organ Class: Psychiatric disorders, Preferred Term: Affect lability

Treatment	N	n (%)	OR[1] [95% CI]	RR[2] [95% CI]	RD[3] [95% CI]	p-value[4]	p-value (int)[5]
BMI (kg/m2) at Baseline							
< 30							
Relugolix+E2/NETA	119	0	NC	NC	NC	NC	NC
Placebo	115	0	[NC;NC]	[NC;NC]	[NC;NC]		
>= 30							
Relugolix+E2/NETA	134	0	NC	NC	NC	NC	
Placebo	141	2 (1.4)	[NC;NC]	[NC;NC]	[NC;NC]		
Missing							
Relugolix+E2/NETA	1	0	NC	NC	NC	NC	
Placebo	0	0	[NC;NC]	[NC;NC]	[NC;NC]		

Post hoc analysis. The denominator for percentages is the number of patients in the safety population for each treatment group. Patients with multiple events for a given PT or SOC are counted only once for each PT and SOC. Events are sorted alphabetically by SOC and PT and then by ascending subgroup-by-treatment interaction p-value within each. MedDRA (version 22.0).
Mood disorders include depression and suicide/self injury (broad) standardized MedDRA query.
[1] OR (95% CI) based on a logistic regression model adjusting for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates.
[2] RR (95% CI) based on a Cochran-Mantel-Haenszel approach stratified by study.
[3] RD (95% CI) based on a Mantel-Haenszel approach stratified by study. 95% CIs are based on the approximation to the normal distribution using the Sato estimator for the standard error.
[4] P-value based on a Cochran-Mantel-Haenszel test stratified by study.
[5] Interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the OR (95% CI). Missing subgroup levels are not included in estimation of the interaction p-value.
A continuity correction is applied in estimation of the OR, RR and p-value if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum. No continuity correction is applied in the estimation of the RD.
The reference group for the OR, RR and RD is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with >= 1 event; OR: Odds ratio; RR: Risk ratio; RD: Risk difference; CI: Confidence interval; int: p-value for interaction; NETA: Norethindrone acetate; SOC: System organ class; PT: Preferred term; NC: Not calculated.

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Table SAF.MOODANY.SPT.POOL.2.2.S3: Adverse Event Category: Mood Disorders by System Organ Class and Preferred Term, by Subgroup (Safety Population)

Study: Pooled

System Organ Class: Psychiatric disorders, Preferred Term: Affect lability

Treatment	N	n (%)	OR[1] [95% CI]	RR[2] [95% CI]	RD[3] [95% CI]	p-value[4]	p-value (int)[5]
Uterine Volume at Baseline (cm3)							
< 300 cm3							
Relugolix+E2/NETA	148	0	NC	NC	NC	NC	NC
Placebo	129	2 (1.6)	[NC;NC]	[NC;NC]	[NC;NC]		
>= 300 cm3							
Relugolix+E2/NETA	105	0	NC	NC	NC	NC	
Placebo	127	0	[NC;NC]	[NC;NC]	[NC;NC]		
Missing							
Relugolix+E2/NETA	1	0	NC	NC	NC	NC	
Placebo	0	0	[NC;NC]	[NC;NC]	[NC;NC]		

Post hoc analysis. The denominator for percentages is the number of patients in the safety population for each treatment group. Patients with multiple events for a given PT or SOC are counted only once for each PT and SOC. Events are sorted alphabetically by SOC and PT and then by ascending subgroup-by-treatment interaction p-value within each. MedDRA (version 22.0).
Mood disorders include depression and suicide/self injury (broad) standardized MedDRA query.
[1] OR (95% CI) based on a logistic regression model adjusting for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates.
[2] RR (95% CI) based on a Cochran-Mantel-Haenszel approach stratified by study.
[3] RD (95% CI) based on a Mantel-Haenszel approach stratified by study. 95% CIs are based on the approximation to the normal distribution using the Sato estimator for the standard error.
[4] P-value based on a Cochran-Mantel-Haenszel test stratified by study.
[5] Interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the OR (95% CI). Missing subgroup levels are not included in estimation of the interaction p-value.
A continuity correction is applied in estimation of the OR, RR and p-value if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum. No continuity correction is applied in the estimation of the RD.
The reference group for the OR, RR and RD is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with >= 1 event; OR: Odds ratio; RR: Risk ratio; RD: Risk difference; CI: Confidence interval; int: p-value for interaction; NETA: Norethindrone acetate; SOC: System organ class; PT: Preferred term; NC: Not calculated.

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Table SAF.MOODANY.SPT.POOL.2.2.S4: Adverse Event Category: Mood Disorders by System Organ Class and Preferred Term, by Subgroup (Safety Population)

Study: Pooled

System Organ Class: Psychiatric disorders, Preferred Term: Affect lability

Treatment	N	n (%)	OR[1] [95% CI]	RR[2] [95% CI]	RD[3] [95% CI]	p-value[4]	p-value (int)[5]
Maximum NRS Pain Score at Baseline							
< 4							
Relugolix+E2/NETA	73	0	NC	NC	NC	NC	NC
Placebo	62	0	[NC;NC]	[NC;NC]	[NC;NC]		
>= 4							
Relugolix+E2/NETA	178	0	NC	NC	NC	NC	
Placebo	190	2 (1.1)	[NC;NC]	[NC;NC]	[NC;NC]		
Missing							
Relugolix+E2/NETA	3	0	NC	NC	NC	NC	
Placebo	4	0	[NC;NC]	[NC;NC]	[NC;NC]		

Post hoc analysis. The denominator for percentages is the number of patients in the safety population for each treatment group. Patients with multiple events for a given PT or SOC are counted only once for each PT and SOC. Events are sorted alphabetically by SOC and PT and then by ascending subgroup-by-treatment interaction p-value within each. MedDRA (version 22.0).
Mood disorders include depression and suicide/self injury (broad) standardized MedDRA query.
[1] OR (95% CI) based on a logistic regression model adjusting for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates.
[2] RR (95% CI) based on a Cochran-Mantel-Haenszel approach stratified by study.
[3] RD (95% CI) based on a Mantel-Haenszel approach stratified by study. 95% CIs are based on the approximation to the normal distribution using the Sato estimator for the standard error.
[4] P-value based on a Cochran-Mantel-Haenszel test stratified by study.
[5] Interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the OR (95% CI). Missing subgroup levels are not included in estimation of the interaction p-value.
A continuity correction is applied in estimation of the OR, RR and p-value if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum. No continuity correction is applied in the estimation of the RD.
The reference group for the OR, RR and RD is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with >= 1 event; OR: Odds ratio; RR: Risk ratio; RD: Risk difference; CI: Confidence interval; int: p-value for interaction; NETA: Norethindrone acetate; SOC: System organ class; PT: Preferred term; NC: Not calculated.

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Table SAF.MOODANY.SPT.POOL.2.2.S5: Adverse Event Category: Mood Disorders by System Organ Class and Preferred Term, by Subgroup (Safety Population)

Study: Pooled

System Organ Class: Psychiatric disorders, Preferred Term: Affect lability

Treatment	**N**	**n (%)**	**OR[1] [95% CI]**	**RR[2] [95% CI]**	**RD[3] [95% CI]**	**p-value[4]**	**p-value (int)[5]**
MBL Volume at Baseline (mL)							
< 225 mL							
Relugolix+E2/NETA	164	0	NC [NC;NC]	NC [NC;NC]	NC [NC;NC]	NC	NC
Placebo	171	2 (1.2)					
>= 225 mL							
Relugolix+E2/NETA	90	0	NC [NC;NC]	NC [NC;NC]	NC [NC;NC]	NC	
Placebo	85	0					

Post hoc analysis. The denominator for percentages is the number of patients in the safety population for each treatment group. Patients with multiple events for a given PT or SOC are counted only once for each PT and SOC. Events are sorted alphabetically by SOC and PT and then by ascending subgroup-by-treatment interaction p-value within each. MedDRA (version 22.0).
Mood disorders include depression and suicide/self injury (broad) standardized MedDRA query.
[1] OR (95% CI) based on a logistic regression model adjusting for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates.
[2] RR (95% CI) based on a Cochran-Mantel-Haenszel approach stratified by study.
[3] RD (95% CI) based on a Mantel-Haenszel approach stratified by study. 95% CIs are based on the approximation to the normal distribution using the Sato estimator for the standard error.
[4] P-value based on a Cochran-Mantel-Haenszel test stratified by study.
[5] Interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the OR (95% CI).
A continuity correction is applied in estimation of the OR, RR and p-value if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum. No continuity correction is applied in the estimation of the RD.
The reference group for the OR, RR and RD is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with >= 1 event; OR: Odds ratio; RR: Risk ratio; RD: Risk difference; CI: Confidence interval; int: p-value for interaction; NETA: Norethindrone acetate; SOC: System organ class; PT: Preferred term; NC: Not calculated.

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Table SAF.MOODANY.SPT.POOL.2.2.S6: Adverse Event Category: Mood Disorders by System Organ Class and Preferred Term, by Subgroup (Safety Population)

Study: Pooled

System Organ Class: Psychiatric disorders, Preferred Term: Affect lability

Treatment	**N**	**n (%)**	**OR[1] [95% CI]**	**RR[2] [95% CI]**	**RD[3] [95% CI]**	**p-value[4]**	**p-value (int)[5]**
Geographic Region I							
North America							
Relugolix+E2/NETA	192	0	NC	NC	NC	NC	NC
Placebo	194	2 (1.0)	[NC;NC]	[NC;NC]	[NC;NC]		
Rest of World							
Relugolix+E2/NETA	62	0	NC	NC	NC	NC	
Placebo	62	0	[NC;NC]	[NC;NC]	[NC;NC]		

Post hoc analysis. The denominator for percentages is the number of patients in the safety population for each treatment group. Patients with multiple events for a given PT or SOC are counted only once for each PT and SOC. Events are sorted alphabetically by SOC and PT and then by ascending subgroup-by-treatment interaction p-value within each. MedDRA (version 22.0).
Mood disorders include depression and suicide/self injury (broad) standardized MedDRA query.
[1] OR (95% CI) based on a logistic regression model adjusting for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates.
[2] RR (95% CI) based on a Cochran-Mantel-Haenszel approach stratified by study.
[3] RD (95% CI) based on a Mantel-Haenszel approach stratified by study. 95% CIs are based on the approximation to the normal distribution using the Sato estimator for the standard error.
[4] P-value based on a Cochran-Mantel-Haenszel test stratified by study.
[5] Interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the OR (95% CI).
A continuity correction is applied in estimation of the OR, RR and p-value if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum. No continuity correction is applied in the estimation of the RD.
The reference group for the OR, RR and RD is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with >= 1 event; OR: Odds ratio; RR: Risk ratio; RD: Risk difference; CI: Confidence interval; int: p-value for interaction; NETA: Norethindrone acetate; SOC: System organ class; PT: Preferred term; NC: Not calculated.

SOURCE: \Studies\MYV\MYV102\Analysis\Prod\Progs\TFLs\Tab_SAF_AESI_SOC_PT_S_BIN.SAS
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Table SAF.MOODANY.SPT.POOL.2.2.S7: Adverse Event Category: Mood Disorders by System Organ Class and Preferred Term, by Subgroup (Safety Population)

Study: Pooled

System Organ Class: Psychiatric disorders, Preferred Term: Affect lability

Treatment	**N**	**n (%)**	**OR[1] [95% CI]**	**RR[2] [95% CI]**	**RD[3] [95% CI]**	**p-value[4]**	**p-value (int)[5]**
Geographic Region II							
Europe							
Relugolix+E2/NETA	41	0	NC	NC	NC	NC	NC
Placebo	42	0	[NC;NC]	[NC;NC]	[NC;NC]		
Rest of World (including the US)							
Relugolix+E2/NETA	213	0	NC	NC	NC	NC	
Placebo	214	2 (0.9)	[NC;NC]	[NC;NC]	[NC;NC]		

Post hoc analysis. The denominator for percentages is the number of patients in the safety population for each treatment group. Patients with multiple events for a given PT or SOC are counted only once for each PT and SOC. Events are sorted alphabetically by SOC and PT and then by ascending subgroup-by-treatment interaction p-value within each. MedDRA (version 22.0).
Mood disorders include depression and suicide/self injury (broad) standardized MedDRA query.
[1] OR (95% CI) based on a logistic regression model adjusting for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates.
[2] RR (95% CI) based on a Cochran-Mantel-Haenszel approach stratified by study.
[3] RD (95% CI) based on a Mantel-Haenszel approach stratified by study. 95% CIs are based on the approximation to the normal distribution using the Sato estimator for the standard error.
[4] P-value based on a Cochran-Mantel-Haenszel test stratified by study.
[5] Interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the OR (95% CI).
A continuity correction is applied in estimation of the OR, RR and p-value if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum. No continuity correction is applied in the estimation of the RD.
The reference group for the OR, RR and RD is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with >= 1 event; OR: Odds ratio; RR: Risk ratio; RD: Risk difference; CI: Confidence interval; int: p-value for interaction; NETA: Norethindrone acetate; SOC: System organ class; PT: Preferred term; NC: Not calculated.

SOURCE: \Studies\MYV\MYV102\Analysis\Prod\Progs\TFLs\Tab_SAF_AESI_SOC_PT_S_BIN.SAS
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Table SAF.MOODANY.SPT.POOL.2.2.S8: Adverse Event Category: Mood Disorders by System Organ Class and Preferred Term, by Subgroup (Safety Population)

Study: Pooled

System Organ Class: Psychiatric disorders, Preferred Term: Affect lability

Treatment	N	n (%)	OR[1] [95% CI]	RR[2] [95% CI]	RD[3] [95% CI]	p-value[4]	p-value (int)[5]
Ethnicity							
Hispanic or Latino							
Relugolix+E2/NETA	53	0	NC	NC	NC	NC	NC
Placebo	55	0	[NC;NC]	[NC;NC]	[NC;NC]		
Not Hispanic or Latino							
Relugolix+E2/NETA	197	0	NC	NC	NC	NC	
Placebo	199	2 (1.0)	[NC;NC]	[NC;NC]	[NC;NC]		
Not reported							
Relugolix+E2/NETA	4	0	NC	NC	NC	NC	
Placebo	2	0	[NC;NC]	[NC;NC]	[NC;NC]		

Post hoc analysis. The denominator for percentages is the number of patients in the safety population for each treatment group. Patients with multiple events for a given PT or SOC are counted only once for each PT and SOC. Events are sorted alphabetically by SOC and PT and then by ascending subgroup-by-treatment interaction p-value within each. MedDRA (version 22.0).
Mood disorders include depression and suicide/self injury (broad) standardized MedDRA query.
[1] OR (95% CI) based on a logistic regression model adjusting for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates.
[2] RR (95% CI) based on a Cochran-Mantel-Haenszel approach stratified by study.
[3] RD (95% CI) based on a Mantel-Haenszel approach stratified by study. 95% CIs are based on the approximation to the normal distribution using the Sato estimator for the standard error.
[4] P-value based on a Cochran-Mantel-Haenszel test stratified by study.
[5] Interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the OR (95% CI). Not reported subgroup levels are not included in estimation of the interaction p-value.
A continuity correction is applied in estimation of the OR, RR and p-value if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum. No continuity correction is applied in the estimation of the RD.
The reference group for the OR, RR and RD is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with >= 1 event; OR: Odds ratio; RR: Risk ratio; RD: Risk difference; CI: Confidence interval; int: p-value for interaction; NETA: Norethindrone acetate; SOC: System organ class; PT: Preferred term; NC: Not calculated.

SOURCE: \Studies\MYV\MYV102\Analysis\Prod\Progs\TFLs\Tab_SAF_AESI_SOC_PT_S_BIN.SAS
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Table SAF.MOODANY.SPT.POOL.2.2.S9: Adverse Event Category: Mood Disorders by System Organ Class and Preferred Term, by Subgroup (Safety Population)

Study: Pooled

System Organ Class: Psychiatric disorders, Preferred Term: Affect lability

Treatment	**N**	**n (%)**	**OR[1] [95% CI]**	**RR[2] [95% CI]**	**RD[3] [95% CI]**	**p-value[4]**	**p-value (int)[5]**
Race							
Black/African American							NC
Relugolix+E2/NETA	122	0	NC	NC	NC	NC	
Placebo	141	1 (0.7)	[NC;NC]	[NC;NC]	[NC;NC]		
White							
Relugolix+E2/NETA	123	0	NC	NC	NC	NC	
Placebo	105	1 (1.0)	[NC;NC]	[NC;NC]	[NC;NC]		
Asian							
Relugolix+E2/NETA	1	0	NC	NC	NC	NC	
Placebo	3	0	[NC;NC]	[NC;NC]	[NC;NC]		
Others							
Relugolix+E2/NETA	5	0	NC	NC	NC	NC	
Placebo	6	0	[NC;NC]	[NC;NC]	[NC;NC]		
Not reported							
Relugolix+E2/NETA	3	0	NC	NC	NC	NC	
Placebo	1	0	[NC;NC]	[NC;NC]	[NC;NC]		

Post hoc analysis. The denominator for percentages is the number of patients in the safety population for each treatment group. Patients with multiple events for a given PT or SOC are counted only once for each PT and SOC. Events are sorted alphabetically by SOC and PT and then by ascending subgroup-by-treatment interaction p-value within each. MedDRA (version 22.0).
Mood disorders include depression and suicide/self injury (broad) standardized MedDRA query.
[1] OR (95% CI) based on a logistic regression model adjusting for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates.
[2] RR (95% CI) based on a Cochran-Mantel-Haenszel approach stratified by study.
[3] RD (95% CI) based on a Mantel-Haenszel approach stratified by study. 95% CIs are based on the approximation to the normal distribution using the Sato estimator for the standard error.
[4] P-value based on a Cochran-Mantel-Haenszel test stratified by study.
[5] Interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the OR (95% CI). Not reported subgroup levels are not included in estimation of the interaction p-value.
A continuity correction is applied in estimation of the OR, RR and p-value if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum. No continuity correction is applied in the estimation of the RD.
The reference group for the OR, RR and RD is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with >= 1 event; OR: Odds ratio; RR: Risk ratio; RD: Risk difference; CI: Confidence interval; int: p-value for interaction; NETA: Norethindrone acetate; SOC: System organ class; PT: Preferred term; NC: Not calculated.

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Table SAF.MOODANY.SPT.POOL.2.3.S1: Adverse Event Category: Mood Disorders by System Organ Class and Preferred Term, by Subgroup (Safety Population)

Study: Pooled

System Organ Class: Psychiatric disorders, Preferred Term: Depressed mood

Treatment	**N**	**n (%)**	**OR[1] [95% CI]**	**RR[2] [95% CI]**	**RD[3] [95% CI]**	**p-value[4]**	**p-value (int)[5]**
Age (years)							
< 40 years							
Relugolix+E2/NETA	62	1 (1.6)	NC	NC	NC	NC	NC
Placebo	78	0	[NC;NC]	[NC;NC]	[NC;NC]		
>= 40 years							
Relugolix+E2/NETA	192	0	NC	NC	NC	NC	
Placebo	178	1 (0.6)	[NC;NC]	[NC;NC]	[NC;NC]		

Post hoc analysis. The denominator for percentages is the number of patients in the safety population for each treatment group. Patients with multiple events for a given PT or SOC are counted only once for each PT and SOC. Events are sorted alphabetically by SOC and PT and then by ascending subgroup-by-treatment interaction p-value within each. MedDRA (version 22.0).
Mood disorders include depression and suicide/self injury (broad) standardized MedDRA query.
[1] OR (95% CI) based on a logistic regression model adjusting for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates.
[2] RR (95% CI) based on a Cochran-Mantel-Haenszel approach stratified by study.
[3] RD (95% CI) based on a Mantel-Haenszel approach stratified by study. 95% CIs are based on the approximation to the normal distribution using the Sato estimator for the standard error.
[4] P-value based on a Cochran-Mantel-Haenszel test stratified by study.
[5] Interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the OR (95% CI).
A continuity correction is applied in estimation of the OR, RR and p-value if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum. No continuity correction is applied in the estimation of the RD.
The reference group for the OR, RR and RD is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with >= 1 event; OR: Odds ratio; RR: Risk ratio; RD: Risk difference; CI: Confidence interval; int: p-value for interaction; NETA: Norethindrone acetate; SOC: System organ class; PT: Preferred term; NC: Not calculated.

SOURCE: \Studies\MYV\MYV102\Analysis\Prod\Progs\TFLs\Tab_SAF_AESI_SOC_PT_S_BIN.SAS
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Table SAF.MOODANY.SPT.POOL.2.3.S2: Adverse Event Category: Mood Disorders by System Organ Class and Preferred Term, by Subgroup (Safety Population)

Study: Pooled

System Organ Class: Psychiatric disorders, Preferred Term: Depressed mood

Treatment	N	n (%)	OR[1] [95% CI]	RR[2] [95% CI]	RD[3] [95% CI]	p-value[4]	p-value (int)[5]
BMI (kg/m2) at Baseline							
< 30							
Relugolix+E2/NETA	119	1 (0.8)	NC	NC	NC	NC	NC
Placebo	115	0	[NC;NC]	[NC;NC]	[NC;NC]		
>= 30							
Relugolix+E2/NETA	134	0	NC	NC	NC	NC	
Placebo	141	1 (0.7)	[NC;NC]	[NC;NC]	[NC;NC]		
Missing							
Relugolix+E2/NETA	1	0	NC	NC	NC	NC	
Placebo	0	0	[NC;NC]	[NC;NC]	[NC;NC]		

Post hoc analysis. The denominator for percentages is the number of patients in the safety population for each treatment group. Patients with multiple events for a given PT or SOC are counted only once for each PT and SOC. Events are sorted alphabetically by SOC and PT and then by ascending subgroup-by-treatment interaction p-value within each. MedDRA (version 22.0).
Mood disorders include depression and suicide/self injury (broad) standardized MedDRA query.
[1] OR (95% CI) based on a logistic regression model adjusting for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates.
[2] RR (95% CI) based on a Cochran-Mantel-Haenszel approach stratified by study.
[3] RD (95% CI) based on a Mantel-Haenszel approach stratified by study. 95% CIs are based on the approximation to the normal distribution using the Sato estimator for the standard error.
[4] P-value based on a Cochran-Mantel-Haenszel test stratified by study.
[5] Interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the OR (95% CI). Missing subgroup levels are not included in estimation of the interaction p-value.
A continuity correction is applied in estimation of the OR, RR and p-value if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum. No continuity correction is applied in the estimation of the RD.
The reference group for the OR, RR and RD is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with >= 1 event; OR: Odds ratio; RR: Risk ratio; RD: Risk difference; CI: Confidence interval; int: p-value for interaction; NETA: Norethindrone acetate; SOC: System organ class; PT: Preferred term; NC: Not calculated.

SOURCE: \Studies\MYV\MYV102\Analysis\Prod\Progs\TFLs\Tab_SAF_AESI_SOC_PT_S_BIN.SAS
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Table SAF.MOODANY.SPT.POOL.2.3.S3: Adverse Event Category: Mood Disorders by System Organ Class and Preferred Term, by Subgroup (Safety Population)

Study: Pooled

System Organ Class: Psychiatric disorders, Preferred Term: Depressed mood

Treatment	N	n (%)	OR[1] [95% CI]	RR[2] [95% CI]	RD[3] [95% CI]	p-value[4]	p-value (int)[5]
Uterine Volume at Baseline (cm3)							
< 300 cm3							
Relugolix+E2/NETA	148	1 (0.7)	NC	NC	NC	NC	NC
Placebo	129	0	[NC;NC]	[NC;NC]	[NC;NC]		
>= 300 cm3							
Relugolix+E2/NETA	105	0	NC	NC	NC	NC	
Placebo	127	1 (0.8)	[NC;NC]	[NC;NC]	[NC;NC]		
Missing							
Relugolix+E2/NETA	1	0	NC	NC	NC	NC	
Placebo	0	0	[NC;NC]	[NC;NC]	[NC;NC]		

Post hoc analysis. The denominator for percentages is the number of patients in the safety population for each treatment group. Patients with multiple events for a given PT or SOC are counted only once for each PT and SOC. Events are sorted alphabetically by SOC and PT and then by ascending subgroup-by-treatment interaction p-value within each. MedDRA (version 22.0).
Mood disorders include depression and suicide/self injury (broad) standardized MedDRA query.
[1] OR (95% CI) based on a logistic regression model adjusting for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates.
[2] RR (95% CI) based on a Cochran-Mantel-Haenszel approach stratified by study.
[3] RD (95% CI) based on a Mantel-Haenszel approach stratified by study. 95% CIs are based on the approximation to the normal distribution using the Sato estimator for the standard error.
[4] P-value based on a Cochran-Mantel-Haenszel test stratified by study.
[5] Interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the OR (95% CI). Missing subgroup levels are not included in estimation of the interaction p-value.
A continuity correction is applied in estimation of the OR, RR and p-value if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum. No continuity correction is applied in the estimation of the RD.
The reference group for the OR, RR and RD is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with >= 1 event; OR: Odds ratio; RR: Risk ratio; RD: Risk difference; CI: Confidence interval; int: p-value for interaction; NETA: Norethindrone acetate; SOC: System organ class; PT: Preferred term; NC: Not calculated.

SOURCE: \Studies\MYV\MYV102\Analysis\Prod\Progs\TFLs\Tab_SAF_AESI_SOC_PT_S_BIN.SAS
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Table SAF.MOODANY.SPT.POOL.2.3.S4: Adverse Event Category: Mood Disorders by System Organ Class and Preferred Term, by Subgroup (Safety Population)

Study: Pooled

System Organ Class: Psychiatric disorders, Preferred Term: Depressed mood

Treatment	N	n (%)	OR[1] [95% CI]	RR[2] [95% CI]	RD[3] [95% CI]	p-value[4]	p-value (int)[5]
Maximum NRS Pain Score at Baseline							
< 4							
Relugolix+E2/NETA	73	0	NC	NC	NC	NC	NC
Placebo	62	1 (1.6)	[NC;NC]	[NC;NC]	[NC;NC]		
>= 4							
Relugolix+E2/NETA	178	1 (0.6)	NC	NC	NC	NC	
Placebo	190	0	[NC;NC]	[NC;NC]	[NC;NC]		
Missing							
Relugolix+E2/NETA	3	0	NC	NC	NC	NC	
Placebo	4	0	[NC;NC]	[NC;NC]	[NC;NC]		

Post hoc analysis. The denominator for percentages is the number of patients in the safety population for each treatment group. Patients with multiple events for a given PT or SOC are counted only once for each PT and SOC. Events are sorted alphabetically by SOC and PT and then by ascending subgroup-by-treatment interaction p-value within each. MedDRA (version 22.0).
Mood disorders include depression and suicide/self injury (broad) standardized MedDRA query.
[1] OR (95% CI) based on a logistic regression model adjusting for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates.
[2] RR (95% CI) based on a Cochran-Mantel-Haenszel approach stratified by study.
[3] RD (95% CI) based on a Mantel-Haenszel approach stratified by study. 95% CIs are based on the approximation to the normal distribution using the Sato estimator for the standard error.
[4] P-value based on a Cochran-Mantel-Haenszel test stratified by study.
[5] Interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the OR (95% CI). Missing subgroup levels are not included in estimation of the interaction p-value.
A continuity correction is applied in estimation of the OR, RR and p-value if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum. No continuity correction is applied in the estimation of the RD.
The reference group for the OR, RR and RD is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with >= 1 event; OR: Odds ratio; RR: Risk ratio; RD: Risk difference; CI: Confidence interval; int: p-value for interaction; NETA: Norethindrone acetate; SOC: System organ class; PT: Preferred term; NC: Not calculated.

SOURCE: \Studies\MYV\MYV102\Analysis\Prod\Progs\TFLs\Tab_SAF_AESI_SOC_PT_S_BIN.SAS
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Table SAF.MOODANY.SPT.POOL.2.3.S5: Adverse Event Category: Mood Disorders by System Organ Class and Preferred Term, by Subgroup (Safety Population)

Study: Pooled

System Organ Class: Psychiatric disorders, Preferred Term: Depressed mood

Treatment	**N**	**n (%)**	**OR[1] [95% CI]**	**RR[2] [95% CI]**	**RD[3] [95% CI]**	**p-value[4]**	**p-value (int)[5]**
MBL Volume at Baseline (mL)							
< 225 mL							
Relugolix+E2/NETA	164	1 (0.6)	NC [NC;NC]	NC [NC;NC]	NC [NC;NC]	NC	NC
Placebo	171	0					
>= 225 mL							
Relugolix+E2/NETA	90	0	NC [NC;NC]	NC [NC;NC]	NC [NC;NC]	NC	
Placebo	85	1 (1.2)					

Post hoc analysis. The denominator for percentages is the number of patients in the safety population for each treatment group. Patients with multiple events for a given PT or SOC are counted only once for each PT and SOC. Events are sorted alphabetically by SOC and PT and then by ascending subgroup-by-treatment interaction p-value within each. MedDRA (version 22.0).
Mood disorders include depression and suicide/self injury (broad) standardized MedDRA query.
[1] OR (95% CI) based on a logistic regression model adjusting for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates.
[2] RR (95% CI) based on a Cochran-Mantel-Haenszel approach stratified by study.
[3] RD (95% CI) based on a Mantel-Haenszel approach stratified by study. 95% CIs are based on the approximation to the normal distribution using the Sato estimator for the standard error.
[4] P-value based on a Cochran-Mantel-Haenszel test stratified by study.
[5] Interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the OR (95% CI).
A continuity correction is applied in estimation of the OR, RR and p-value if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum. No continuity correction is applied in the estimation of the RD.
The reference group for the OR, RR and RD is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with >= 1 event; OR: Odds ratio; RR: Risk ratio; RD: Risk difference; CI: Confidence interval; int: p-value for interaction; NETA: Norethindrone acetate; SOC: System organ class; PT: Preferred term; NC: Not calculated.

SOURCE: \Studies\MYV\MYV102\Analysis\Prod\Progs\TFLs\Tab_SAF_AESI_SOC_PT_S_BIN.SAS
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Table SAF.MOODANY.SPT.POOL.2.3.S6: Adverse Event Category: Mood Disorders by System Organ Class and Preferred Term, by Subgroup (Safety Population)

Study: Pooled

System Organ Class: Psychiatric disorders, Preferred Term: Depressed mood

Treatment	**N**	**n (%)**	**OR[1] [95% CI]**	**RR[2] [95% CI]**	**RD[3] [95% CI]**	**p-value[4]**	**p-value (int)[5]**
Geographic Region I							
North America							
Relugolix+E2/NETA	192	0	NC	NC	NC	NC	NC
Placebo	194	0	[NC;NC]	[NC;NC]	[NC;NC]		
Rest of World							
Relugolix+E2/NETA	62	1 (1.6)	NC	NC	NC	NC	
Placebo	62	1 (1.6)	[NC;NC]	[NC;NC]	[NC;NC]		

Post hoc analysis. The denominator for percentages is the number of patients in the safety population for each treatment group. Patients with multiple events for a given PT or SOC are counted only once for each PT and SOC. Events are sorted alphabetically by SOC and PT and then by ascending subgroup-by-treatment interaction p-value within each. MedDRA (version 22.0).
Mood disorders include depression and suicide/self injury (broad) standardized MedDRA query.
[1] OR (95% CI) based on a logistic regression model adjusting for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates.
[2] RR (95% CI) based on a Cochran-Mantel-Haenszel approach stratified by study.
[3] RD (95% CI) based on a Mantel-Haenszel approach stratified by study. 95% CIs are based on the approximation to the normal distribution using the Sato estimator for the standard error.
[4] P-value based on a Cochran-Mantel-Haenszel test stratified by study.
[5] Interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the OR (95% CI).
A continuity correction is applied in estimation of the OR, RR and p-value if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum. No continuity correction is applied in the estimation of the RD.
The reference group for the OR, RR and RD is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with >= 1 event; OR: Odds ratio; RR: Risk ratio; RD: Risk difference; CI: Confidence interval; int: p-value for interaction; NETA: Norethindrone acetate; SOC: System organ class; PT: Preferred term; NC: Not calculated.

SOURCE: \Studies\MYV\MYV102\Analysis\Prod\Progs\TFLs\Tab_SAF_AESI_SOC_PT_S_BIN.SAS
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Table SAF.MOODANY.SPT.POOL.2.3.S7: Adverse Event Category: Mood Disorders by System Organ Class and Preferred Term, by Subgroup (Safety Population)

Study: Pooled

System Organ Class: Psychiatric disorders, Preferred Term: Depressed mood

Treatment	**N**	**n (%)**	**OR[1] [95% CI]**	**RR[2] [95% CI]**	**RD[3] [95% CI]**	**p-value[4]**	**p-value (int)[5]**
Geographic Region II							
Europe							NC
Relugolix+E2/NETA	41	1 (2.4)	NC [NC;NC]	NC [NC;NC]	NC [NC;NC]	NC	
Placebo	42	1 (2.4)					
Rest of World (including the US)							
Relugolix+E2/NETA	213	0	NC [NC;NC]	NC [NC;NC]	NC [NC;NC]	NC	
Placebo	214	0					

Post hoc analysis. The denominator for percentages is the number of patients in the safety population for each treatment group. Patients with multiple events for a given PT or SOC are counted only once for each PT and SOC. Events are sorted alphabetically by SOC and PT and then by ascending subgroup-by-treatment interaction p-value within each. MedDRA (version 22.0).
Mood disorders include depression and suicide/self injury (broad) standardized MedDRA query.
[1] OR (95% CI) based on a logistic regression model adjusting for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates.
[2] RR (95% CI) based on a Cochran-Mantel-Haenszel approach stratified by study.
[3] RD (95% CI) based on a Mantel-Haenszel approach stratified by study. 95% CIs are based on the approximation to the normal distribution using the Sato estimator for the standard error.
[4] P-value based on a Cochran-Mantel-Haenszel test stratified by study.
[5] Interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the OR (95% CI).
A continuity correction is applied in estimation of the OR, RR and p-value if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum. No continuity correction is applied in the estimation of the RD.
The reference group for the OR, RR and RD is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with >= 1 event; OR: Odds ratio; RR: Risk ratio; RD: Risk difference; CI: Confidence interval; int: p-value for interaction; NETA: Norethindrone acetate; SOC: System organ class; PT: Preferred term; NC: Not calculated.

SOURCE: \Studies\MYV\MYV102\Analysis\Prod\Progs\TFLs\Tab_SAF_AESI_SOC_PT_S_BIN.SAS
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Table SAF.MOODANY.SPT.POOL.2.3.S8: Adverse Event Category: Mood Disorders by System Organ Class and Preferred Term, by Subgroup (Safety Population)

Study: Pooled

System Organ Class: Psychiatric disorders, Preferred Term: Depressed mood

Treatment	**N**	**n (%)**	**OR[1] [95% CI]**	**RR[2] [95% CI]**	**RD[3] [95% CI]**	**p-value[4]**	**p-value (int)[5]**
Ethnicity							
Hispanic or Latino							
Relugolix+E2/NETA	53	0	NC	NC	NC	NC	NC
Placebo	55	0	[NC;NC]	[NC;NC]	[NC;NC]		
Not Hispanic or Latino							
Relugolix+E2/NETA	197	1 (0.5)	NC	NC	NC	NC	
Placebo	199	1 (0.5)	[NC;NC]	[NC;NC]	[NC;NC]		
Not reported							
Relugolix+E2/NETA	4	0	NC	NC	NC	NC	
Placebo	2	0	[NC;NC]	[NC;NC]	[NC;NC]		

Post hoc analysis. The denominator for percentages is the number of patients in the safety population for each treatment group. Patients with multiple events for a given PT or SOC are counted only once for each PT and SOC. Events are sorted alphabetically by SOC and PT and then by ascending subgroup-by-treatment interaction p-value within each. MedDRA (version 22.0).
Mood disorders include depression and suicide/self injury (broad) standardized MedDRA query.
[1] OR (95% CI) based on a logistic regression model adjusting for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates.
[2] RR (95% CI) based on a Cochran-Mantel-Haenszel approach stratified by study.
[3] RD (95% CI) based on a Mantel-Haenszel approach stratified by study. 95% CIs are based on the approximation to the normal distribution using the Sato estimator for the standard error.
[4] P-value based on a Cochran-Mantel-Haenszel test stratified by study.
[5] Interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the OR (95% CI). Not reported subgroup levels are not included in estimation of the interaction p-value.
A continuity correction is applied in estimation of the OR, RR and p-value if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum. No continuity correction is applied in the estimation of the RD.
The reference group for the OR, RR and RD is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with >= 1 event; OR: Odds ratio; RR: Risk ratio; RD: Risk difference; CI: Confidence interval; int: p-value for interaction; NETA: Norethindrone acetate; SOC: System organ class; PT: Preferred term; NC: Not calculated.

SOURCE: \Studies\MYV\MYV102\Analysis\Prod\Progs\TFLs\Tab_SAF_AESI_SOC_PT_S_BIN.SAS
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Table SAF.MOODANY.SPT.POOL.2.3.S9: Adverse Event Category: Mood Disorders by System Organ Class and Preferred Term, by Subgroup (Safety Population)

Study: Pooled

System Organ Class: Psychiatric disorders, Preferred Term: Depressed mood

Treatment	N	n (%)	OR[1] [95% CI]	RR[2] [95% CI]	RD[3] [95% CI]	p-value[4]	p-value (int)[5]
Race							
Black/African American							
Relugolix+E2/NETA	122	0	NC	NC	NC	NC	NC
Placebo	141	0	[NC;NC]	[NC;NC]	[NC;NC]		
White							
Relugolix+E2/NETA	123	1 (0.8)	NC	NC	NC	NC	
Placebo	105	1 (1.0)	[NC;NC]	[NC;NC]	[NC;NC]		
Asian							
Relugolix+E2/NETA	1	0	NC	NC	NC	NC	
Placebo	3	0	[NC;NC]	[NC;NC]	[NC;NC]		
Others							
Relugolix+E2/NETA	5	0	NC	NC	NC	NC	
Placebo	6	0	[NC;NC]	[NC;NC]	[NC;NC]		
Not reported							
Relugolix+E2/NETA	3	0	NC	NC	NC	NC	
Placebo	1	0	[NC;NC]	[NC;NC]	[NC;NC]		

Post hoc analysis. The denominator for percentages is the number of patients in the safety population for each treatment group. Patients with multiple events for a given PT or SOC are counted only once for each PT and SOC. Events are sorted alphabetically by SOC and PT and then by ascending subgroup-by-treatment interaction p-value within each. MedDRA (version 22.0).
Mood disorders include depression and suicide/self injury (broad) standardized MedDRA query.
[1] OR (95% CI) based on a logistic regression model adjusting for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates.
[2] RR (95% CI) based on a Cochran-Mantel-Haenszel approach stratified by study.
[3] RD (95% CI) based on a Mantel-Haenszel approach stratified by study. 95% CIs are based on the approximation to the normal distribution using the Sato estimator for the standard error.
[4] P-value based on a Cochran-Mantel-Haenszel test stratified by study.
[5] Interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the OR (95% CI). Not reported subgroup levels are not included in estimation of the interaction p-value.
A continuity correction is applied in estimation of the OR, RR and p-value if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum. No continuity correction is applied in the estimation of the RD.
The reference group for the OR, RR and RD is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with >= 1 event; OR: Odds ratio; RR: Risk ratio; RD: Risk difference; CI: Confidence interval; int: p-value for interaction; NETA: Norethindrone acetate; SOC: System organ class; PT: Preferred term; NC: Not calculated.

SOURCE: \Studies\MYV\MYV102\Analysis\Prod\Progs\TFLs\Tab_SAF_AESI_SOC_PT_S_BIN.SAS
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Table SAF.MOODANY.SPT.POOL.2.4.S1: Adverse Event Category: Mood Disorders by System Organ Class and Preferred Term, by Subgroup (Safety Population)

Study: Pooled

System Organ Class: Psychiatric disorders, Preferred Term: Depression

Treatment	**N**	**n (%)**	**OR[1] [95% CI]**	**RR[2] [95% CI]**	**RD[3] [95% CI]**	**p-value[4]**	**p-value (int)[5]**
Age (years)							
< 40 years							
Relugolix+E2/NETA	62	0	NC [NC;NC]	NC [NC;NC]	NC [NC;NC]	NC	NC
Placebo	78	0					
>= 40 years							
Relugolix+E2/NETA	192	2 (1.0)	NC [NC;NC]	NC [NC;NC]	NC [NC;NC]	NC	
Placebo	178	1 (0.6)					

Post hoc analysis. The denominator for percentages is the number of patients in the safety population for each treatment group. Patients with multiple events for a given PT or SOC are counted only once for each PT and SOC. Events are sorted alphabetically by SOC and PT and then by ascending subgroup-by-treatment interaction p-value within each. MedDRA (version 22.0).
Mood disorders include depression and suicide/self injury (broad) standardized MedDRA query.
[1] OR (95% CI) based on a logistic regression model adjusting for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates.
[2] RR (95% CI) based on a Cochran-Mantel-Haenszel approach stratified by study.
[3] RD (95% CI) based on a Mantel-Haenszel approach stratified by study. 95% CIs are based on the approximation to the normal distribution using the Sato estimator for the standard error.
[4] P-value based on a Cochran-Mantel-Haenszel test stratified by study.
[5] Interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the OR (95% CI).
A continuity correction is applied in estimation of the OR, RR and p-value if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum. No continuity correction is applied in the estimation of the RD.
The reference group for the OR, RR and RD is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with >= 1 event; OR: Odds ratio; RR: Risk ratio; RD: Risk difference; CI: Confidence interval; int: p-value for interaction; NETA: Norethindrone acetate; SOC: System organ class; PT: Preferred term; NC: Not calculated.

SOURCE: \Studies\MYV\MYV102\Analysis\Prod\Progs\TFLs\Tab_SAF_AESI_SOC_PT_S_BIN.SAS
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Table SAF.MOODANY.SPT.POOL.2.4.S2: Adverse Event Category: Mood Disorders by System Organ Class and Preferred Term, by Subgroup (Safety Population)

Study: Pooled

System Organ Class: Psychiatric disorders, Preferred Term: Depression

Treatment	N	n (%)	OR[1] [95% CI]	RR[2] [95% CI]	RD[3] [95% CI]	p-value[4]	p-value (int)[5]
BMI (kg/m2) at Baseline							
< 30							
Relugolix+E2/NETA	119	1 (0.8)	NC	NC	NC	NC	NC
Placebo	115	1 (0.9)	[NC;NC]	[NC;NC]	[NC;NC]		
>= 30							
Relugolix+E2/NETA	134	1 (0.7)	NC	NC	NC	NC	
Placebo	141	0	[NC;NC]	[NC;NC]	[NC;NC]		
Missing							
Relugolix+E2/NETA	1	0	NC	NC	NC	NC	
Placebo	0	0	[NC;NC]	[NC;NC]	[NC;NC]		

Post hoc analysis. The denominator for percentages is the number of patients in the safety population for each treatment group. Patients with multiple events for a given PT or SOC are counted only once for each PT and SOC. Events are sorted alphabetically by SOC and PT and then by ascending subgroup-by-treatment interaction p-value within each. MedDRA (version 22.0).
Mood disorders include depression and suicide/self injury (broad) standardized MedDRA query.
[1] OR (95% CI) based on a logistic regression model adjusting for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates.
[2] RR (95% CI) based on a Cochran-Mantel-Haenszel approach stratified by study.
[3] RD (95% CI) based on a Mantel-Haenszel approach stratified by study. 95% CIs are based on the approximation to the normal distribution using the Sato estimator for the standard error.
[4] P-value based on a Cochran-Mantel-Haenszel test stratified by study.
[5] Interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the OR (95% CI). Missing subgroup levels are not included in estimation of the interaction p-value.
A continuity correction is applied in estimation of the OR, RR and p-value if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum. No continuity correction is applied in the estimation of the RD.
The reference group for the OR, RR and RD is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with >= 1 event; OR: Odds ratio; RR: Risk ratio; RD: Risk difference; CI: Confidence interval; int: p-value for interaction; NETA: Norethindrone acetate; SOC: System organ class; PT: Preferred term; NC: Not calculated.

SOURCE: \Studies\MYV\MYV102\Analysis\Prod\Progs\TFLs\Tab_SAF_AESI_SOC_PT_S_BIN.SAS
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Table SAF.MOODANY.SPT.POOL.2.4.S3: Adverse Event Category: Mood Disorders by System Organ Class and Preferred Term, by Subgroup (Safety Population)

Study: Pooled

System Organ Class: Psychiatric disorders, Preferred Term: Depression

Treatment	N	n (%)	OR[1] [95% CI]	RR[2] [95% CI]	RD[3] [95% CI]	p-value[4]	p-value (int)[5]
Uterine Volume at Baseline (cm3)							
< 300 cm3							
Relugolix+E2/NETA	148	2 (1.4)	NC	NC	NC	NC	NC
Placebo	129	0	[NC;NC]	[NC;NC]	[NC;NC]		
>= 300 cm3							
Relugolix+E2/NETA	105	0	NC	NC	NC	NC	
Placebo	127	1 (0.8)	[NC;NC]	[NC;NC]	[NC;NC]		
Missing							
Relugolix+E2/NETA	1	0	NC	NC	NC	NC	
Placebo	0	0	[NC;NC]	[NC;NC]	[NC;NC]		

Post hoc analysis. The denominator for percentages is the number of patients in the safety population for each treatment group. Patients with multiple events for a given PT or SOC are counted only once for each PT and SOC. Events are sorted alphabetically by SOC and PT and then by ascending subgroup-by-treatment interaction p-value within each. MedDRA (version 22.0).
Mood disorders include depression and suicide/self injury (broad) standardized MedDRA query.
[1] OR (95% CI) based on a logistic regression model adjusting for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates.
[2] RR (95% CI) based on a Cochran-Mantel-Haenszel approach stratified by study.
[3] RD (95% CI) based on a Mantel-Haenszel approach stratified by study. 95% CIs are based on the approximation to the normal distribution using the Sato estimator for the standard error.
[4] P-value based on a Cochran-Mantel-Haenszel test stratified by study.
[5] Interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the OR (95% CI). Missing subgroup levels are not included in estimation of the interaction p-value.
A continuity correction is applied in estimation of the OR, RR and p-value if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum. No continuity correction is applied in the estimation of the RD.
The reference group for the OR, RR and RD is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with >= 1 event; OR: Odds ratio; RR: Risk ratio; RD: Risk difference; CI: Confidence interval; int: p-value for interaction; NETA: Norethindrone acetate; SOC: System organ class; PT: Preferred term; NC: Not calculated.

SOURCE: \Studies\MYV\MYV102\Analysis\Prod\Progs\TFLs\Tab_SAF_AESI_SOC_PT_S_BIN.SAS
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Table SAF.MOODANY.SPT.POOL.2.4.S4: Adverse Event Category: Mood Disorders by System Organ Class and Preferred Term, by Subgroup (Safety Population)

Study: Pooled

System Organ Class: Psychiatric disorders, Preferred Term: Depression

Treatment	N	n (%)	OR[1] [95% CI]	RR[2] [95% CI]	RD[3] [95% CI]	p-value[4]	p-value (int)[5]
Maximum NRS Pain Score at Baseline							
< 4							
Relugolix+E2/NETA	73	2 (2.7)	NC	NC	NC	NC	NC
Placebo	62	0	[NC;NC]	[NC;NC]	[NC;NC]		
>= 4							
Relugolix+E2/NETA	178	0	NC	NC	NC	NC	
Placebo	190	1 (0.5)	[NC;NC]	[NC;NC]	[NC;NC]		
Missing							
Relugolix+E2/NETA	3	0	NC	NC	NC	NC	
Placebo	4	0	[NC;NC]	[NC;NC]	[NC;NC]		

Post hoc analysis. The denominator for percentages is the number of patients in the safety population for each treatment group. Patients with multiple events for a given PT or SOC are counted only once for each PT and SOC. Events are sorted alphabetically by SOC and PT and then by ascending subgroup-by-treatment interaction p-value within each. MedDRA (version 22.0).
Mood disorders include depression and suicide/self injury (broad) standardized MedDRA query.
[1] OR (95% CI) based on a logistic regression model adjusting for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates.
[2] RR (95% CI) based on a Cochran-Mantel-Haenszel approach stratified by study.
[3] RD (95% CI) based on a Mantel-Haenszel approach stratified by study. 95% CIs are based on the approximation to the normal distribution using the Sato estimator for the standard error.
[4] P-value based on a Cochran-Mantel-Haenszel test stratified by study.
[5] Interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the OR (95% CI). Missing subgroup levels are not included in estimation of the interaction p-value.
A continuity correction is applied in estimation of the OR, RR and p-value if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum. No continuity correction is applied in the estimation of the RD.
The reference group for the OR, RR and RD is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with >= 1 event; OR: Odds ratio; RR: Risk ratio; RD: Risk difference; CI: Confidence interval; int: p-value for interaction; NETA: Norethindrone acetate; SOC: System organ class; PT: Preferred term; NC: Not calculated.

SOURCE: \Studies\MYV\MYV102\Analysis\Prod\Progs\TFLs\Tab_SAF_AESI_SOC_PT_S_BIN.SAS
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Table SAF.MOODANY.SPT.POOL.2.4.S5: Adverse Event Category: Mood Disorders by System Organ Class and Preferred Term, by Subgroup (Safety Population)

Study: Pooled

System Organ Class: Psychiatric disorders, Preferred Term: Depression

Treatment	**N**	**n (%)**	**OR[1] [95% CI]**	**RR[2] [95% CI]**	**RD[3] [95% CI]**	**p-value[4]**	**p-value (int)[5]**
MBL Volume at Baseline (mL)							
< 225 mL							
Relugolix+E2/NETA	164	2 (1.2)	NC [NC;NC]	NC [NC;NC]	NC [NC;NC]	NC	NC
Placebo	171	1 (0.6)					
>= 225 mL							
Relugolix+E2/NETA	90	0	NC [NC;NC]	NC [NC;NC]	NC [NC;NC]	NC	
Placebo	85	0					

Post hoc analysis. The denominator for percentages is the number of patients in the safety population for each treatment group. Patients with multiple events for a given PT or SOC are counted only once for each PT and SOC. Events are sorted alphabetically by SOC and PT and then by ascending subgroup-by-treatment interaction p-value within each. MedDRA (version 22.0).
Mood disorders include depression and suicide/self injury (broad) standardized MedDRA query.
[1] OR (95% CI) based on a logistic regression model adjusting for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates.
[2] RR (95% CI) based on a Cochran-Mantel-Haenszel approach stratified by study.
[3] RD (95% CI) based on a Mantel-Haenszel approach stratified by study. 95% CIs are based on the approximation to the normal distribution using the Sato estimator for the standard error.
[4] P-value based on a Cochran-Mantel-Haenszel test stratified by study.
[5] Interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the OR (95% CI).
A continuity correction is applied in estimation of the OR, RR and p-value if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum. No continuity correction is applied in the estimation of the RD.
The reference group for the OR, RR and RD is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with >= 1 event; OR: Odds ratio; RR: Risk ratio; RD: Risk difference; CI: Confidence interval; int: p-value for interaction; NETA: Norethindrone acetate; SOC: System organ class; PT: Preferred term; NC: Not calculated.

SOURCE: \Studies\MYV\MYV102\Analysis\Prod\Progs\TFLs\Tab_SAF_AESI_SOC_PT_S_BIN.SAS
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Table SAF.MOODANY.SPT.POOL.2.4.S6: Adverse Event Category: Mood Disorders by System Organ Class and Preferred Term, by Subgroup (Safety Population)

Study: Pooled

System Organ Class: Psychiatric disorders, Preferred Term: Depression

Treatment	**N**	**n (%)**	**OR[1] [95% CI]**	**RR[2] [95% CI]**	**RD[3] [95% CI]**	**p-value[4]**	**p-value (int)[5]**
Geographic Region I							
North America							
Relugolix+E2/NETA	192	0	NC [NC;NC]	NC [NC;NC]	NC [NC;NC]	NC	NC
Placebo	194	1 (0.5)					
Rest of World							
Relugolix+E2/NETA	62	2 (3.2)	NC [NC;NC]	NC [NC;NC]	NC [NC;NC]	NC	
Placebo	62	0					

Post hoc analysis. The denominator for percentages is the number of patients in the safety population for each treatment group. Patients with multiple events for a given PT or SOC are counted only once for each PT and SOC. Events are sorted alphabetically by SOC and PT and then by ascending subgroup-by-treatment interaction p-value within each. MedDRA (version 22.0).
Mood disorders include depression and suicide/self injury (broad) standardized MedDRA query.
[1] OR (95% CI) based on a logistic regression model adjusting for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates.
[2] RR (95% CI) based on a Cochran-Mantel-Haenszel approach stratified by study.
[3] RD (95% CI) based on a Mantel-Haenszel approach stratified by study. 95% CIs are based on the approximation to the normal distribution using the Sato estimator for the standard error.
[4] P-value based on a Cochran-Mantel-Haenszel test stratified by study.
[5] Interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the OR (95% CI).
A continuity correction is applied in estimation of the OR, RR and p-value if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum. No continuity correction is applied in the estimation of the RD.
The reference group for the OR, RR and RD is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with >= 1 event; OR: Odds ratio; RR: Risk ratio; RD: Risk difference; CI: Confidence interval; int: p-value for interaction; NETA: Norethindrone acetate; SOC: System organ class; PT: Preferred term; NC: Not calculated.

SOURCE: \Studies\MYV\MYV102\Analysis\Prod\Progs\TFLs\Tab_SAF_AESI_SOC_PT_S_BIN.SAS
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Table SAF.MOODANY.SPT.POOL.2.4.S7: Adverse Event Category: Mood Disorders by System Organ Class and Preferred Term, by Subgroup (Safety Population)

Study: Pooled

System Organ Class: Psychiatric disorders, Preferred Term: Depression

Treatment	**N**	**n (%)**	**OR[1] [95% CI]**	**RR[2] [95% CI]**	**RD[3] [95% CI]**	**p-value[4]**	**p-value (int)[5]**
Geographic Region II							
Europe							NC
Relugolix+E2/NETA	41	1 (2.4)	NC [NC;NC]	NC [NC;NC]	NC [NC;NC]	NC	
Placebo	42	0					
Rest of World (including the US)							
Relugolix+E2/NETA	213	1 (0.5)	NC [NC;NC]	NC [NC;NC]	NC [NC;NC]	NC	
Placebo	214	1 (0.5)					

Post hoc analysis. The denominator for percentages is the number of patients in the safety population for each treatment group. Patients with multiple events for a given PT or SOC are counted only once for each PT and SOC. Events are sorted alphabetically by SOC and PT and then by ascending subgroup-by-treatment interaction p-value within each. MedDRA (version 22.0).
Mood disorders include depression and suicide/self injury (broad) standardized MedDRA query.
[1] OR (95% CI) based on a logistic regression model adjusting for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates.
[2] RR (95% CI) based on a Cochran-Mantel-Haenszel approach stratified by study.
[3] RD (95% CI) based on a Mantel-Haenszel approach stratified by study. 95% CIs are based on the approximation to the normal distribution using the Sato estimator for the standard error.
[4] P-value based on a Cochran-Mantel-Haenszel test stratified by study.
[5] Interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the OR (95% CI).
A continuity correction is applied in estimation of the OR, RR and p-value if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum. No continuity correction is applied in the estimation of the RD.
The reference group for the OR, RR and RD is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with >= 1 event; OR: Odds ratio; RR: Risk ratio; RD: Risk difference; CI: Confidence interval; int: p-value for interaction; NETA: Norethindrone acetate; SOC: System organ class; PT: Preferred term; NC: Not calculated.

SOURCE: \Studies\MYV\MYV102\Analysis\Prod\Progs\TFLs\Tab_SAF_AESI_SOC_PT_S_BIN.SAS
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Table SAF.MOODANY.SPT.POOL.2.4.S8: Adverse Event Category: Mood Disorders by System Organ Class and Preferred Term, by Subgroup (Safety Population)

Study: Pooled

System Organ Class: Psychiatric disorders, Preferred Term: Depression

Treatment	**N**	**n (%)**	**OR[1] [95% CI]**	**RR[2] [95% CI]**	**RD[3] [95% CI]**	**p-value[4]**	**p-value (int)[5]**
Ethnicity							
Hispanic or Latino							
Relugolix+E2/NETA	53	1 (1.9)	NC	NC	NC	NC	NC
Placebo	55	0	[NC;NC]	[NC;NC]	[NC;NC]		
Not Hispanic or Latino							
Relugolix+E2/NETA	197	1 (0.5)	NC	NC	NC	NC	
Placebo	199	1 (0.5)	[NC;NC]	[NC;NC]	[NC;NC]		
Not reported							
Relugolix+E2/NETA	4	0	NC	NC	NC	NC	
Placebo	2	0	[NC;NC]	[NC;NC]	[NC;NC]		

Post hoc analysis. The denominator for percentages is the number of patients in the safety population for each treatment group. Patients with multiple events for a given PT or SOC are counted only once for each PT and SOC. Events are sorted alphabetically by SOC and PT and then by ascending subgroup-by-treatment interaction p-value within each. MedDRA (version 22.0).
Mood disorders include depression and suicide/self injury (broad) standardized MedDRA query.
[1] OR (95% CI) based on a logistic regression model adjusting for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates.
[2] RR (95% CI) based on a Cochran-Mantel-Haenszel approach stratified by study.
[3] RD (95% CI) based on a Mantel-Haenszel approach stratified by study. 95% CIs are based on the approximation to the normal distribution using the Sato estimator for the standard error.
[4] P-value based on a Cochran-Mantel-Haenszel test stratified by study.
[5] Interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the OR (95% CI). Not reported subgroup levels are not included in estimation of the interaction p-value.
A continuity correction is applied in estimation of the OR, RR and p-value if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum. No continuity correction is applied in the estimation of the RD.
The reference group for the OR, RR and RD is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with >= 1 event; OR: Odds ratio; RR: Risk ratio; RD: Risk difference; CI: Confidence interval; int: p-value for interaction; NETA: Norethindrone acetate; SOC: System organ class; PT: Preferred term; NC: Not calculated.

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Table SAF.MOODANY.SPT.POOL.2.4.S9: Adverse Event Category: Mood Disorders by System Organ Class and Preferred Term, by Subgroup (Safety Population)

Study: Pooled

System Organ Class: Psychiatric disorders, Preferred Term: Depression

Treatment	N	n (%)	OR[1] [95% CI]	RR[2] [95% CI]	RD[3] [95% CI]	p-value[4]	p-value (int)[5]
Race							
Black/African American							NC
Relugolix+E2/NETA	122	0	NC [NC;NC]	NC [NC;NC]	NC [NC;NC]	NC	
Placebo	141	1 (0.7)					
White							
Relugolix+E2/NETA	123	2 (1.6)	NC [NC;NC]	NC [NC;NC]	NC [NC;NC]	NC	
Placebo	105	0					
Asian							
Relugolix+E2/NETA	1	0	NC [NC;NC]	NC [NC;NC]	NC [NC;NC]	NC	
Placebo	3	0					
Others							
Relugolix+E2/NETA	5	0	NC [NC;NC]	NC [NC;NC]	NC [NC;NC]	NC	
Placebo	6	0					
Not reported							
Relugolix+E2/NETA	3	0	NC [NC;NC]	NC [NC;NC]	NC [NC;NC]	NC	
Placebo	1	0					

Post hoc analysis. The denominator for percentages is the number of patients in the safety population for each treatment group. Patients with multiple events for a given PT or SOC are counted only once for each PT and SOC. Events are sorted alphabetically by SOC and PT and then by ascending subgroup-by-treatment interaction p-value within each. MedDRA (version 22.0).
Mood disorders include depression and suicide/self injury (broad) standardized MedDRA query.
[1] OR (95% CI) based on a logistic regression model adjusting for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates.
[2] RR (95% CI) based on a Cochran-Mantel-Haenszel approach stratified by study.
[3] RD (95% CI) based on a Mantel-Haenszel approach stratified by study. 95% CIs are based on the approximation to the normal distribution using the Sato estimator for the standard error.
[4] P-value based on a Cochran-Mantel-Haenszel test stratified by study.
[5] Interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the OR (95% CI). Not reported subgroup levels are not included in estimation of the interaction p-value.
A continuity correction is applied in estimation of the OR, RR and p-value if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum. No continuity correction is applied in the estimation of the RD.
The reference group for the OR, RR and RD is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with >= 1 event; OR: Odds ratio; RR: Risk ratio; RD: Risk difference; CI: Confidence interval; int: p-value for interaction; NETA: Norethindrone acetate; SOC: System organ class; PT: Preferred term; NC: Not calculated.

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Table SAF.MOODANY.SPT.POOL.2.5.S1: Adverse Event Category: Mood Disorders by System Organ Class and Preferred Term, by Subgroup (Safety Population)

Study: Pooled

System Organ Class: Psychiatric disorders, Preferred Term: Mood swings

Treatment	**N**	**n (%)**	**OR[1] [95% CI]**	**RR[2] [95% CI]**	**RD[3] [95% CI]**	**p-value[4]**	**p-value (int)[5]**
Age (years)							
< 40 years							
Relugolix+E2/NETA	62	0	NC [NC;NC]	NC [NC;NC]	NC [NC;NC]	NC	NC
Placebo	78	0					
>= 40 years							
Relugolix+E2/NETA	192	3 (1.6)	NC [NC;NC]	NC [NC;NC]	NC [NC;NC]	NC	
Placebo	178	0					

Post hoc analysis. The denominator for percentages is the number of patients in the safety population for each treatment group. Patients with multiple events for a given PT or SOC are counted only once for each PT and SOC. Events are sorted alphabetically by SOC and PT and then by ascending subgroup-by-treatment interaction p-value within each. MedDRA (version 22.0).
Mood disorders include depression and suicide/self injury (broad) standardized MedDRA query.
[1] OR (95% CI) based on a logistic regression model adjusting for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates.
[2] RR (95% CI) based on a Cochran-Mantel-Haenszel approach stratified by study.
[3] RD (95% CI) based on a Mantel-Haenszel approach stratified by study. 95% CIs are based on the approximation to the normal distribution using the Sato estimator for the standard error.
[4] P-value based on a Cochran-Mantel-Haenszel test stratified by study.
[5] Interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the OR (95% CI).
A continuity correction is applied in estimation of the OR, RR and p-value if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum. No continuity correction is applied in the estimation of the RD.
The reference group for the OR, RR and RD is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with >= 1 event; OR: Odds ratio; RR: Risk ratio; RD: Risk difference; CI: Confidence interval; int: p-value for interaction; NETA: Norethindrone acetate; SOC: System organ class; PT: Preferred term; NC: Not calculated.

SOURCE: \Studies\MYV\MYV102\Analysis\Prod\Progs\TFLs\Tab_SAF_AESI_SOC_PT_S_BIN.SAS
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Table SAF.MOODANY.SPT.POOL.2.5.S2: Adverse Event Category: Mood Disorders by System Organ Class and Preferred Term, by Subgroup (Safety Population)

Study: Pooled

System Organ Class: Psychiatric disorders, Preferred Term: Mood swings

Treatment	**N**	**n (%)**	**OR[1] [95% CI]**	**RR[2] [95% CI]**	**RD[3] [95% CI]**	**p-value[4]**	**p-value (int)[5]**
BMI (kg/m2) at Baseline							
< 30							
Relugolix+E2/NETA	119	1 (0.8)	NC	NC	NC	NC	NC
Placebo	115	0	[NC;NC]	[NC;NC]	[NC;NC]		
>= 30							
Relugolix+E2/NETA	134	2 (1.5)	NC	NC	NC	NC	
Placebo	141	0	[NC;NC]	[NC;NC]	[NC;NC]		
Missing							
Relugolix+E2/NETA	1	0	NC	NC	NC	NC	
Placebo	0	0	[NC;NC]	[NC;NC]	[NC;NC]		

Post hoc analysis. The denominator for percentages is the number of patients in the safety population for each treatment group. Patients with multiple events for a given PT or SOC are counted only once for each PT and SOC. Events are sorted alphabetically by SOC and PT and then by ascending subgroup-by-treatment interaction p-value within each. MedDRA (version 22.0).
Mood disorders include depression and suicide/self injury (broad) standardized MedDRA query.
[1] OR (95% CI) based on a logistic regression model adjusting for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates.
[2] RR (95% CI) based on a Cochran-Mantel-Haenszel approach stratified by study.
[3] RD (95% CI) based on a Mantel-Haenszel approach stratified by study. 95% CIs are based on the approximation to the normal distribution using the Sato estimator for the standard error.
[4] P-value based on a Cochran-Mantel-Haenszel test stratified by study.
[5] Interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the OR (95% CI). Missing subgroup levels are not included in estimation of the interaction p-value.
A continuity correction is applied in estimation of the OR, RR and p-value if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum. No continuity correction is applied in the estimation of the RD.
The reference group for the OR, RR and RD is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with >= 1 event; OR: Odds ratio; RR: Risk ratio; RD: Risk difference; CI: Confidence interval; int: p-value for interaction; NETA: Norethindrone acetate; SOC: System organ class; PT: Preferred term; NC: Not calculated.

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Table SAF.MOODANY.SPT.POOL.2.5.S3: Adverse Event Category: Mood Disorders by System Organ Class and Preferred Term, by Subgroup (Safety Population)

Study: Pooled

System Organ Class: Psychiatric disorders, Preferred Term: Mood swings

Treatment	**N**	**n (%)**	**OR[1] [95% CI]**	**RR[2] [95% CI]**	**RD[3] [95% CI]**	**p-value[4]**	**p-value (int)[5]**
Uterine Volume at Baseline (cm3)							
< 300 cm3							
Relugolix+E2/NETA	148	2 (1.4)	NC	NC	NC	NC	NC
Placebo	129	0	[NC;NC]	[NC;NC]	[NC;NC]		
>= 300 cm3							
Relugolix+E2/NETA	105	1 (1.0)	NC	NC	NC	NC	
Placebo	127	0	[NC;NC]	[NC;NC]	[NC;NC]		
Missing							
Relugolix+E2/NETA	1	0	NC	NC	NC	NC	
Placebo	0	0	[NC;NC]	[NC;NC]	[NC;NC]		

Post hoc analysis. The denominator for percentages is the number of patients in the safety population for each treatment group. Patients with multiple events for a given PT or SOC are counted only once for each PT and SOC. Events are sorted alphabetically by SOC and PT and then by ascending subgroup-by-treatment interaction p-value within each. MedDRA (version 22.0).
Mood disorders include depression and suicide/self injury (broad) standardized MedDRA query.
[1] OR (95% CI) based on a logistic regression model adjusting for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates.
[2] RR (95% CI) based on a Cochran-Mantel-Haenszel approach stratified by study.
[3] RD (95% CI) based on a Mantel-Haenszel approach stratified by study. 95% CIs are based on the approximation to the normal distribution using the Sato estimator for the standard error.
[4] P-value based on a Cochran-Mantel-Haenszel test stratified by study.
[5] Interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the OR (95% CI). Missing subgroup levels are not included in estimation of the interaction p-value.
A continuity correction is applied in estimation of the OR, RR and p-value if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum. No continuity correction is applied in the estimation of the RD.
The reference group for the OR, RR and RD is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with >= 1 event; OR: Odds ratio; RR: Risk ratio; RD: Risk difference; CI: Confidence interval; int: p-value for interaction; NETA: Norethindrone acetate; SOC: System organ class; PT: Preferred term; NC: Not calculated.

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Table SAF.MOODANY.SPT.POOL.2.5.S4: Adverse Event Category: Mood Disorders by System Organ Class and Preferred Term, by Subgroup (Safety Population)

Study: Pooled

System Organ Class: Psychiatric disorders, Preferred Term: Mood swings

Treatment	N	n (%)	OR[1] [95% CI]	RR[2] [95% CI]	RD[3] [95% CI]	p-value[4]	p-value (int)[5]
Maximum NRS Pain Score at Baseline							
< 4							
Relugolix+E2/NETA	73	1 (1.4)	NC	NC	NC	NC	NC
Placebo	62	0	[NC;NC]	[NC;NC]	[NC;NC]		
>= 4							
Relugolix+E2/NETA	178	2 (1.1)	NC	NC	NC	NC	
Placebo	190	0	[NC;NC]	[NC;NC]	[NC;NC]		
Missing							
Relugolix+E2/NETA	3	0	NC	NC	NC	NC	
Placebo	4	0	[NC;NC]	[NC;NC]	[NC;NC]		

Post hoc analysis. The denominator for percentages is the number of patients in the safety population for each treatment group. Patients with multiple events for a given PT or SOC are counted only once for each PT and SOC. Events are sorted alphabetically by SOC and PT and then by ascending subgroup-by-treatment interaction p-value within each. MedDRA (version 22.0).
Mood disorders include depression and suicide/self injury (broad) standardized MedDRA query.
[1] OR (95% CI) based on a logistic regression model adjusting for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates.
[2] RR (95% CI) based on a Cochran-Mantel-Haenszel approach stratified by study.
[3] RD (95% CI) based on a Mantel-Haenszel approach stratified by study. 95% CIs are based on the approximation to the normal distribution using the Sato estimator for the standard error.
[4] P-value based on a Cochran-Mantel-Haenszel test stratified by study.
[5] Interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the OR (95% CI). Missing subgroup levels are not included in estimation of the interaction p-value.
A continuity correction is applied in estimation of the OR, RR and p-value if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum. No continuity correction is applied in the estimation of the RD.
The reference group for the OR, RR and RD is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with >= 1 event; OR: Odds ratio; RR: Risk ratio; RD: Risk difference; CI: Confidence interval; int: p-value for interaction; NETA: Norethindrone acetate; SOC: System organ class; PT: Preferred term; NC: Not calculated.

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Table SAF.MOODANY.SPT.POOL.2.5.S5: Adverse Event Category: Mood Disorders by System Organ Class and Preferred Term, by Subgroup (Safety Population)

Study: Pooled

System Organ Class: Psychiatric disorders, Preferred Term: Mood swings

Treatment	**N**	**n (%)**	**OR[1] [95% CI]**	**RR[2] [95% CI]**	**RD[3] [95% CI]**	**p-value[4]**	**p-value (int)[5]**
MBL Volume at Baseline (mL)							
< 225 mL							
Relugolix+E2/NETA	164	1 (0.6)	NC [NC;NC]	NC [NC;NC]	NC [NC;NC]	NC	NC
Placebo	171	0					
>= 225 mL							
Relugolix+E2/NETA	90	2 (2.2)	NC [NC;NC]	NC [NC;NC]	NC [NC;NC]	NC	
Placebo	85	0					

Post hoc analysis. The denominator for percentages is the number of patients in the safety population for each treatment group. Patients with multiple events for a given PT or SOC are counted only once for each PT and SOC. Events are sorted alphabetically by SOC and PT and then by ascending subgroup-by-treatment interaction p-value within each. MedDRA (version 22.0).
Mood disorders include depression and suicide/self injury (broad) standardized MedDRA query.
[1] OR (95% CI) based on a logistic regression model adjusting for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates.
[2] RR (95% CI) based on a Cochran-Mantel-Haenszel approach stratified by study.
[3] RD (95% CI) based on a Mantel-Haenszel approach stratified by study. 95% CIs are based on the approximation to the normal distribution using the Sato estimator for the standard error.
[4] P-value based on a Cochran-Mantel-Haenszel test stratified by study.
[5] Interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the OR (95% CI).
A continuity correction is applied in estimation of the OR, RR and p-value if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum. No continuity correction is applied in the estimation of the RD.
The reference group for the OR, RR and RD is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with >= 1 event; OR: Odds ratio; RR: Risk ratio; RD: Risk difference; CI: Confidence interval; int: p-value for interaction; NETA: Norethindrone acetate; SOC: System organ class; PT: Preferred term; NC: Not calculated.

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Table SAF.MOODANY.SPT.POOL.2.5.S6: Adverse Event Category: Mood Disorders by System Organ Class and Preferred Term, by Subgroup (Safety Population)

Study: Pooled

System Organ Class: Psychiatric disorders, Preferred Term: Mood swings

Treatment	**N**	**n (%)**	**OR[1] [95% CI]**	**RR[2] [95% CI]**	**RD[3] [95% CI]**	**p-value[4]**	**p-value (int)[5]**
Geographic Region I							
North America							
Relugolix+E2/NETA	192	3 (1.6)	NC [NC;NC]	NC [NC;NC]	NC [NC;NC]	NC	NC
Placebo	194	0					
Rest of World							
Relugolix+E2/NETA	62	0	NC [NC;NC]	NC [NC;NC]	NC [NC;NC]	NC	
Placebo	62	0					

Post hoc analysis. The denominator for percentages is the number of patients in the safety population for each treatment group. Patients with multiple events for a given PT or SOC are counted only once for each PT and SOC. Events are sorted alphabetically by SOC and PT and then by ascending subgroup-by-treatment interaction p-value within each. MedDRA (version 22.0).
Mood disorders include depression and suicide/self injury (broad) standardized MedDRA query.
[1] OR (95% CI) based on a logistic regression model adjusting for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates.
[2] RR (95% CI) based on a Cochran-Mantel-Haenszel approach stratified by study.
[3] RD (95% CI) based on a Mantel-Haenszel approach stratified by study. 95% CIs are based on the approximation to the normal distribution using the Sato estimator for the standard error.
[4] P-value based on a Cochran-Mantel-Haenszel test stratified by study.
[5] Interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the OR (95% CI).
A continuity correction is applied in estimation of the OR, RR and p-value if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum. No continuity correction is applied in the estimation of the RD.
The reference group for the OR, RR and RD is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with >= 1 event; OR: Odds ratio; RR: Risk ratio; RD: Risk difference; CI: Confidence interval; int: p-value for interaction; NETA: Norethindrone acetate; SOC: System organ class; PT: Preferred term; NC: Not calculated.

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Table SAF.MOODANY.SPT.POOL.2.5.S7: Adverse Event Category: Mood Disorders by System Organ Class and Preferred Term, by Subgroup (Safety Population)

Study: Pooled

System Organ Class: Psychiatric disorders, Preferred Term: Mood swings

Treatment	**N**	**n (%)**	**OR[1] [95% CI]**	**RR[2] [95% CI]**	**RD[3] [95% CI]**	**p-value[4]**	**p-value (int)[5]**
Geographic Region II							
Europe							
Relugolix+E2/NETA	41	0	NC	NC	NC	NC	NC
Placebo	42	0	[NC;NC]	[NC;NC]	[NC;NC]		
Rest of World (including the US)							
Relugolix+E2/NETA	213	3 (1.4)	NC	NC	NC	NC	
Placebo	214	0	[NC;NC]	[NC;NC]	[NC;NC]		

Post hoc analysis. The denominator for percentages is the number of patients in the safety population for each treatment group. Patients with multiple events for a given PT or SOC are counted only once for each PT and SOC. Events are sorted alphabetically by SOC and PT and then by ascending subgroup-by-treatment interaction p-value within each. MedDRA (version 22.0).
Mood disorders include depression and suicide/self injury (broad) standardized MedDRA query.
[1] OR (95% CI) based on a logistic regression model adjusting for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates.
[2] RR (95% CI) based on a Cochran-Mantel-Haenszel approach stratified by study.
[3] RD (95% CI) based on a Mantel-Haenszel approach stratified by study. 95% CIs are based on the approximation to the normal distribution using the Sato estimator for the standard error.
[4] P-value based on a Cochran-Mantel-Haenszel test stratified by study.
[5] Interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the OR (95% CI).
A continuity correction is applied in estimation of the OR, RR and p-value if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum. No continuity correction is applied in the estimation of the RD.
The reference group for the OR, RR and RD is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with >= 1 event; OR: Odds ratio; RR: Risk ratio; RD: Risk difference; CI: Confidence interval; int: p-value for interaction; NETA: Norethindrone acetate; SOC: System organ class; PT: Preferred term; NC: Not calculated.

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Table SAF.MOODANY.SPT.POOL.2.5.S8: Adverse Event Category: Mood Disorders by System Organ Class and Preferred Term, by Subgroup (Safety Population)

Study: Pooled

System Organ Class: Psychiatric disorders, Preferred Term: Mood swings

Treatment	**N**	**n (%)**	**OR[1] [95% CI]**	**RR[2] [95% CI]**	**RD[3] [95% CI]**	**p-value[4]**	**p-value (int)[5]**
Ethnicity							
Hispanic or Latino							
Relugolix+E2/NETA	53	0	NC	NC	NC	NC	NC
Placebo	55	0	[NC;NC]	[NC;NC]	[NC;NC]		
Not Hispanic or Latino							
Relugolix+E2/NETA	197	3 (1.5)	NC	NC	NC	NC	
Placebo	199	0	[NC;NC]	[NC;NC]	[NC;NC]		
Not reported							
Relugolix+E2/NETA	4	0	NC	NC	NC	NC	
Placebo	2	0	[NC;NC]	[NC;NC]	[NC;NC]		

Post hoc analysis. The denominator for percentages is the number of patients in the safety population for each treatment group. Patients with multiple events for a given PT or SOC are counted only once for each PT and SOC. Events are sorted alphabetically by SOC and PT and then by ascending subgroup-by-treatment interaction p-value within each. MedDRA (version 22.0).
Mood disorders include depression and suicide/self injury (broad) standardized MedDRA query.
[1] OR (95% CI) based on a logistic regression model adjusting for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates.
[2] RR (95% CI) based on a Cochran-Mantel-Haenszel approach stratified by study.
[3] RD (95% CI) based on a Mantel-Haenszel approach stratified by study. 95% CIs are based on the approximation to the normal distribution using the Sato estimator for the standard error.
[4] P-value based on a Cochran-Mantel-Haenszel test stratified by study.
[5] Interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the OR (95% CI). Not reported subgroup levels are not included in estimation of the interaction p-value.
A continuity correction is applied in estimation of the OR, RR and p-value if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum. No continuity correction is applied in the estimation of the RD.
The reference group for the OR, RR and RD is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with >= 1 event; OR: Odds ratio; RR: Risk ratio; RD: Risk difference; CI: Confidence interval; int: p-value for interaction; NETA: Norethindrone acetate; SOC: System organ class; PT: Preferred term; NC: Not calculated.

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Table SAF.MOODANY.SPT.POOL.2.5.S9: Adverse Event Category: Mood Disorders by System Organ Class and Preferred Term, by Subgroup (Safety Population)

Study: Pooled

System Organ Class: Psychiatric disorders, Preferred Term: Mood swings

Treatment	**N**	**n (%)**	**OR[1] [95% CI]**	**RR[2] [95% CI]**	**RD[3] [95% CI]**	**p-value[4]**	**p-value (int)[5]**
Race							
Black/African American							
Relugolix+E2/NETA	122	2 (1.6)	NC	NC	NC	NC	NC
Placebo	141	0	[NC;NC]	[NC;NC]	[NC;NC]		
White							
Relugolix+E2/NETA	123	1 (0.8)	NC	NC	NC	NC	
Placebo	105	0	[NC;NC]	[NC;NC]	[NC;NC]		
Asian							
Relugolix+E2/NETA	1	0	NC	NC	NC	NC	
Placebo	3	0	[NC;NC]	[NC;NC]	[NC;NC]		
Others							
Relugolix+E2/NETA	5	0	NC	NC	NC	NC	
Placebo	6	0	[NC;NC]	[NC;NC]	[NC;NC]		
Not reported							
Relugolix+E2/NETA	3	0	NC	NC	NC	NC	
Placebo	1	0	[NC;NC]	[NC;NC]	[NC;NC]		

Post hoc analysis. The denominator for percentages is the number of patients in the safety population for each treatment group. Patients with multiple events for a given PT or SOC are counted only once for each PT and SOC. Events are sorted alphabetically by SOC and PT and then by ascending subgroup-by-treatment interaction p-value within each. MedDRA (version 22.0).
Mood disorders include depression and suicide/self injury (broad) standardized MedDRA query.
[1] OR (95% CI) based on a logistic regression model adjusting for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates.
[2] RR (95% CI) based on a Cochran-Mantel-Haenszel approach stratified by study.
[3] RD (95% CI) based on a Mantel-Haenszel approach stratified by study. 95% CIs are based on the approximation to the normal distribution using the Sato estimator for the standard error.
[4] P-value based on a Cochran-Mantel-Haenszel test stratified by study.
[5] Interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the OR (95% CI). Not reported subgroup levels are not included in estimation of the interaction p-value.
A continuity correction is applied in estimation of the OR, RR and p-value if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum. No continuity correction is applied in the estimation of the RD.
The reference group for the OR, RR and RD is Placebo.
Abbreviations: N: Number of patients in treatment group; n: Number of patients with >= 1 event; OR: Odds ratio; RR: Risk ratio; RD: Risk difference; CI: Confidence interval; int: p-value for interaction; NETA: Norethindrone acetate; SOC: System organ class; PT: Preferred term; NC: Not calculated.

SOURCE: \Studies\MYV\MYV102\Analysis\Prod\Progs\TFLs\Tab_SAF_AESI_SOC_PT_S_BIN.SAS
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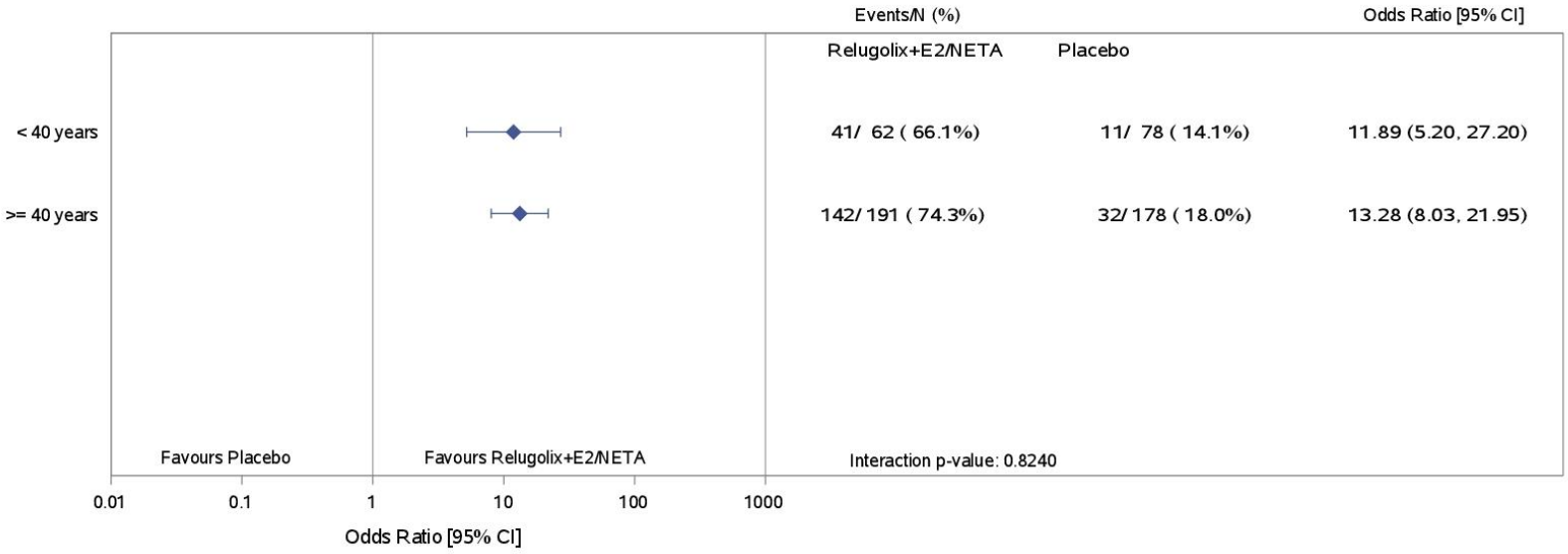
2 Subgruppenanalysen mit nicht signifikantem Interaktionsterm – Forest Plots

2.1 Morbidität

2.1.1 Proportion of Women in the Relugolix + E2/NETA Group Versus the Placebo Group who Achieve an MBL Volume of < 80 mL and at Least a 50% Reduction from Baseline MBL Volume Over the Last 35 Days of Treatment, as Measured by the Alkaline Hematin Method, by Subgroup (mITT Population)

Nachfolgend sind zunächst alle Forest Plots für das *Odds Ratio* dargestellt; gefolgt von den entsprechenden Forest Plots für *Risk Ratio* und *Risk Difference*.

Figure EFF.RCMP24ET.MITT.S1.BIN.FP: Proportion of Women in the Relugolix + E2/NETA Group Versus the Placebo Group who Achieve an MBL Volume of < 80 mL and at Least a 50% Reduction from Baseline MBL Volume Over the Last 35 Days of Treatment, as Measured by the Alkaline Hematin Method, by Subgroup (mITT Population)
Study: Pooled
Subgroup: Age (years)



Results are based on a logistic regression model adjusted for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates using a one-stage fixed-effects IPD meta-analysis approach. A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
The interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the Odds Ratio and 95% CI. Missing subgroup levels are not included in estimation of the interaction p-value. The reference group is Placebo.
N: Number of patients in treatment group; NETA: Norethindrone acetate; mITT: Modified intent-to-treat; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

SOURCE: X:\Numerus\Studies\MYV\MYV102\Analysis\Prod\Progs\TFLs\Fig_EFF_MBL_S_BIN_FP.SAS Date/time of run: 30JUN21 10:23
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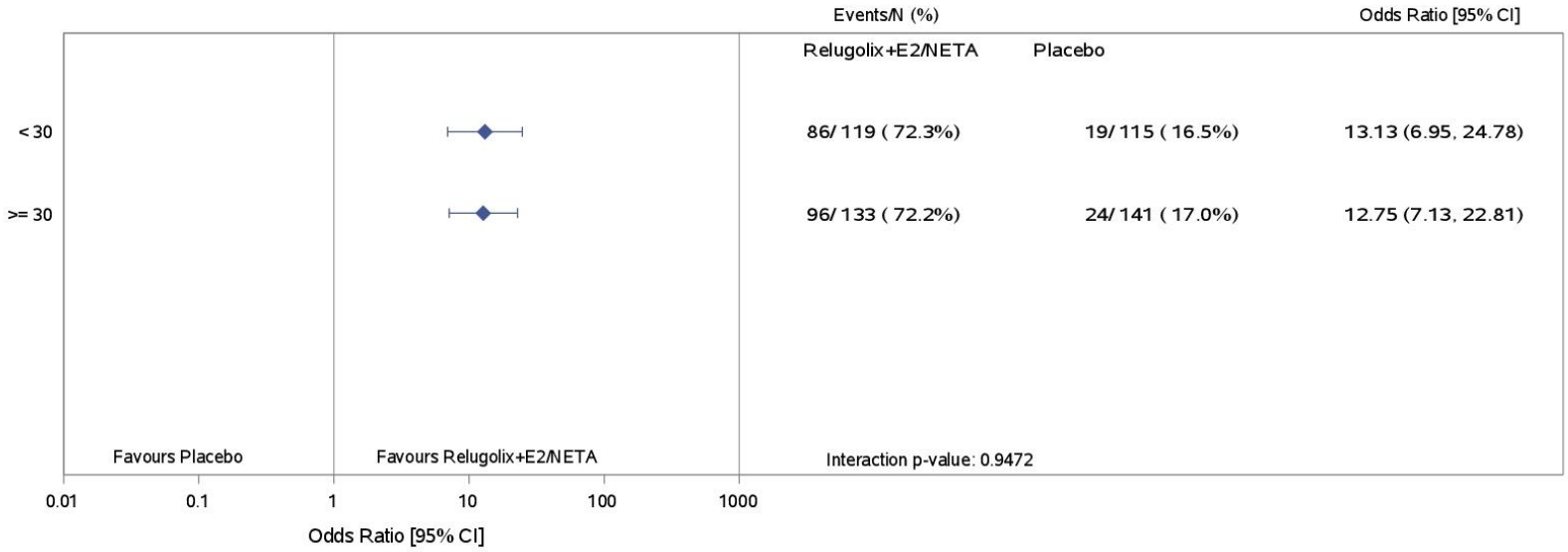
Figure EFF.RCMP24ET.MITT.S2.BIN.FP: Proportion of Women in the Relugolix + E2/NETA Group Versus the Placebo Group who Achieve an MBL Volume of < 80 mL and at Least a 50% Reduction from Baseline MBL Volume Over the Last 35 Days of Treatment, as Measured by the Alkaline Hematin Method, by Subgroup (mITT Population)
Study: Pooled
Subgroup: BMI (kg/m2) at Baseline



Results are based on a logistic regression model adjusted for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates using a one-stage fixed-effects IPD meta-analysis approach. A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
The interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the Odds Ratio and 95% CI. Missing subgroup levels are not included in estimation of the interaction p-value. The reference group is Placebo.
N: Number of patients in treatment group; NETA: Norethindrone acetate; mITT: Modified intent-to-treat; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

SOURCE: X:\Numerus\Studies\MYV\MYV102\Analysis\Prod\Progs\TFLs\Fig_EFF_MBL_S_BIN_FP.SAS Date/time of run: 30JUN21 10:23
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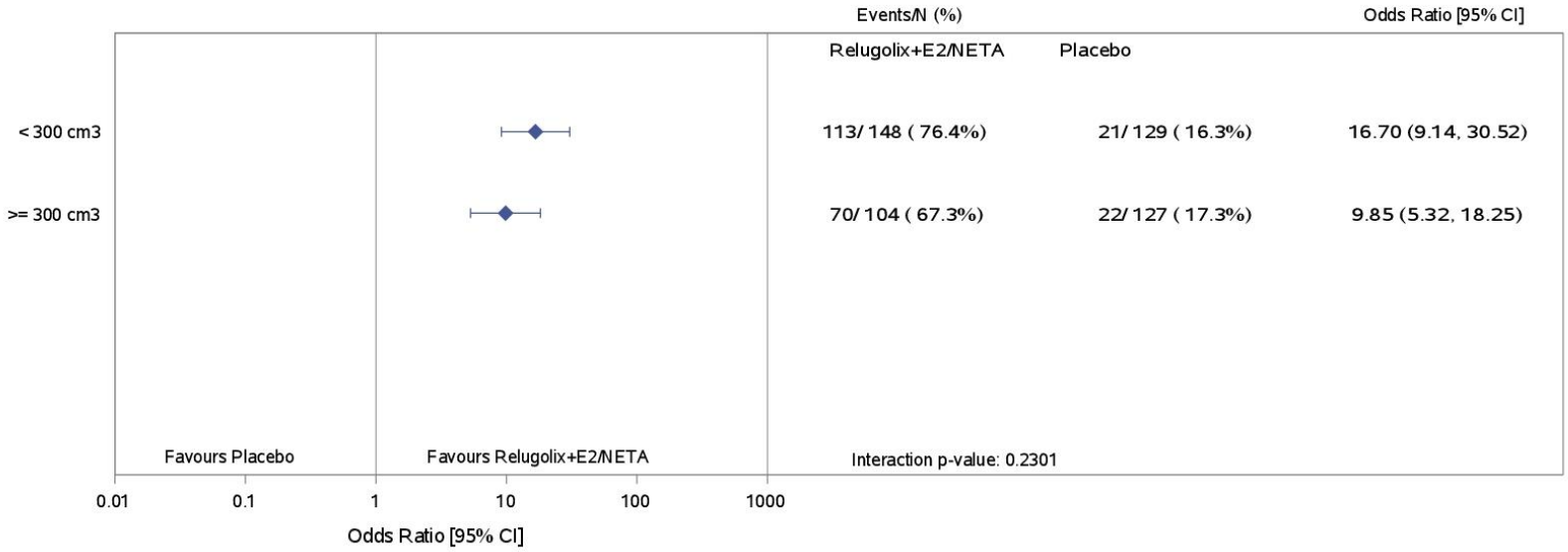
Figure EFF.RCMP24ET.MITT.S3.BIN.FP: Proportion of Women in the Relugolix + E2/NETA Group Versus the Placebo Group who Achieve an MBL Volume of < 80 mL and at Least a 50% Reduction from Baseline MBL Volume Over the Last 35 Days of Treatment, as Measured by the Alkaline Hematin Method, by Subgroup (mITT Population)
Study: Pooled
Subgroup: Uterine Volume at Baseline (cm3)



Results are based on a logistic regression model adjusted for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates using a one-stage fixed-effects IPD meta-analysis approach. A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
The interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the Odds Ratio and 95% CI. Missing subgroup levels are not included in estimation of the interaction p-value. The reference group is Placebo.
N: Number of patients in treatment group; NETA: Norethindrone acetate; mITT: Modified intent-to-treat; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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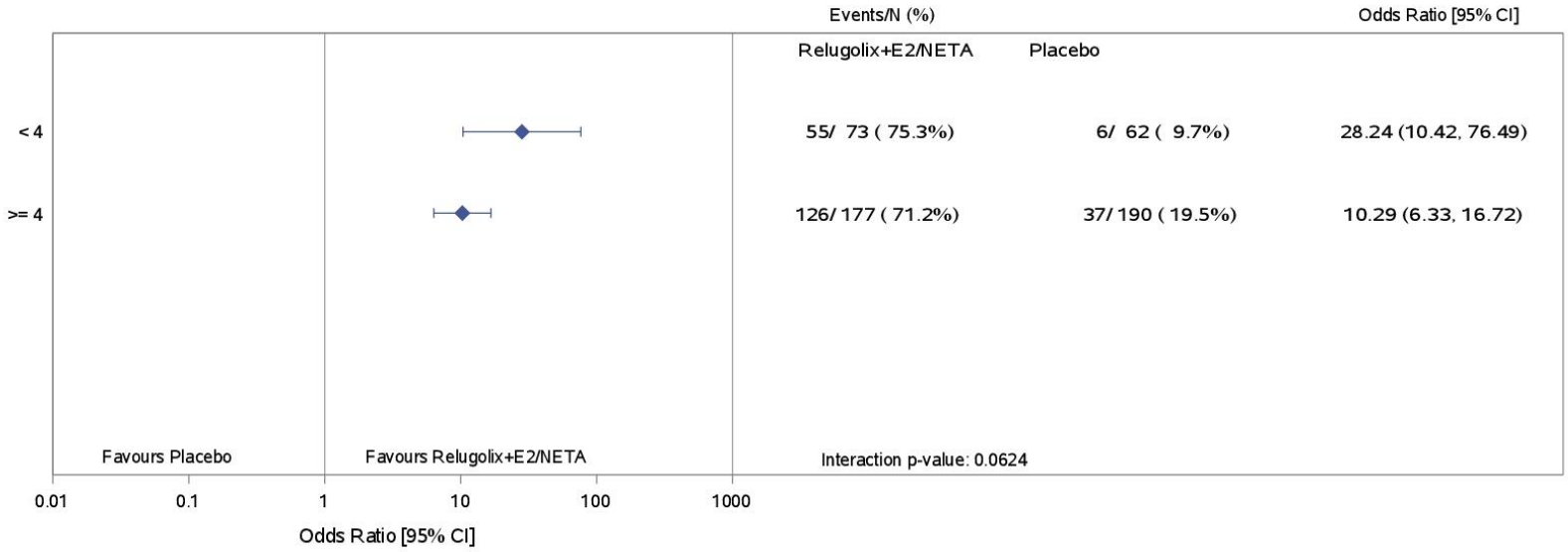
Figure EFF.RCMP24ET.MITT.S4.BIN.FP: Proportion of Women in the Relugolix + E2/NETA Group Versus the Placebo Group who Achieve an MBL Volume of < 80 mL and at Least a 50% Reduction from Baseline MBL Volume Over the Last 35 Days of Treatment, as Measured by the Alkaline Hematin Method, by Subgroup (mITT Population)
Study: Pooled
Subgroup: Maximum NRS Pain Score at Baseline



Results are based on a logistic regression model adjusted for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates using a one-stage fixed-effects IPD meta-analysis approach. A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
The interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the Odds Ratio and 95% CI. Missing subgroup levels are not included in estimation of the interaction p-value. The reference group is Placebo.
N: Number of patients in treatment group; NETA: Norethindrone acetate; mITT: Modified intent-to-treat; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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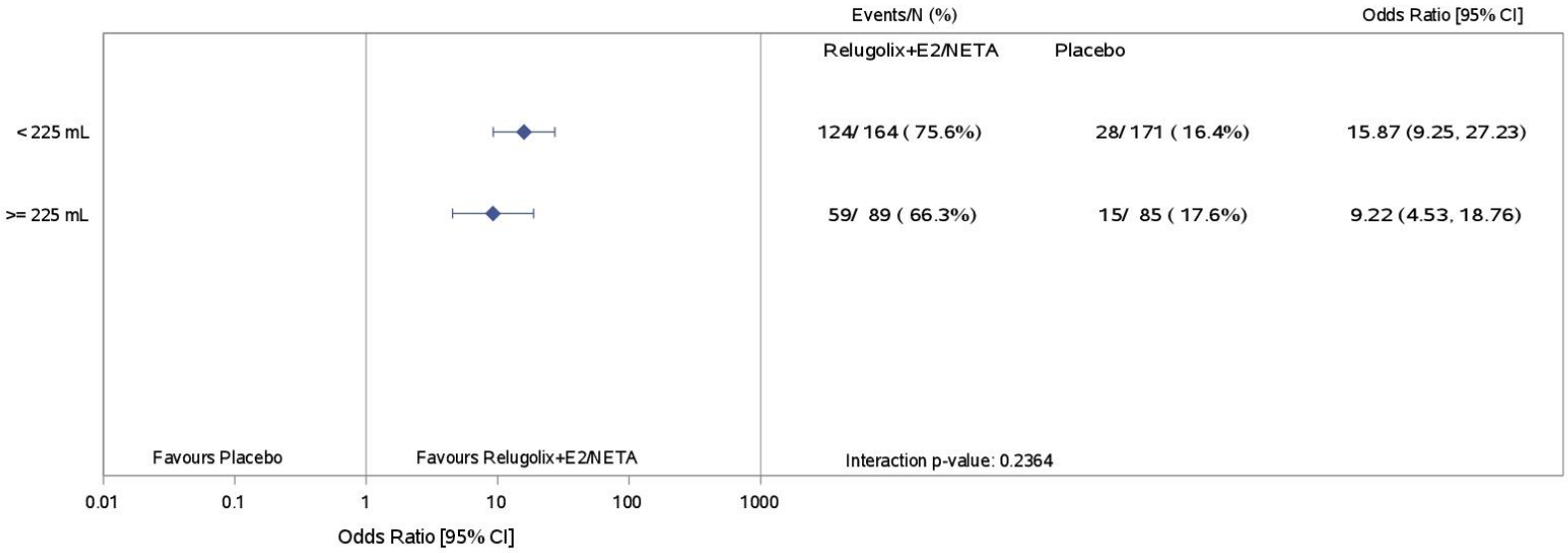
Figure EFF.RCMP24ET.MITT.S5.BIN.FP: Proportion of Women in the Relugolix + E2/NETA Group Versus the Placebo Group who Achieve an MBL Volume of < 80 mL and at Least a 50% Reduction from Baseline MBL Volume Over the Last 35 Days of Treatment, as Measured by the Alkaline Hematin Method, by Subgroup (mITT Population)
Study: Pooled
Subgroup: MBL Volume at Baseline (mL)



Results are based on a logistic regression model adjusted for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates using a one-stage fixed-effects IPD meta-analysis approach. A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
The interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the Odds Ratio and 95% CI. Missing subgroup levels are not included in estimation of the interaction p-value. The reference group is Placebo.
N: Number of patients in treatment group; NETA: Norethindrone acetate; mITT: Modified intent-to-treat; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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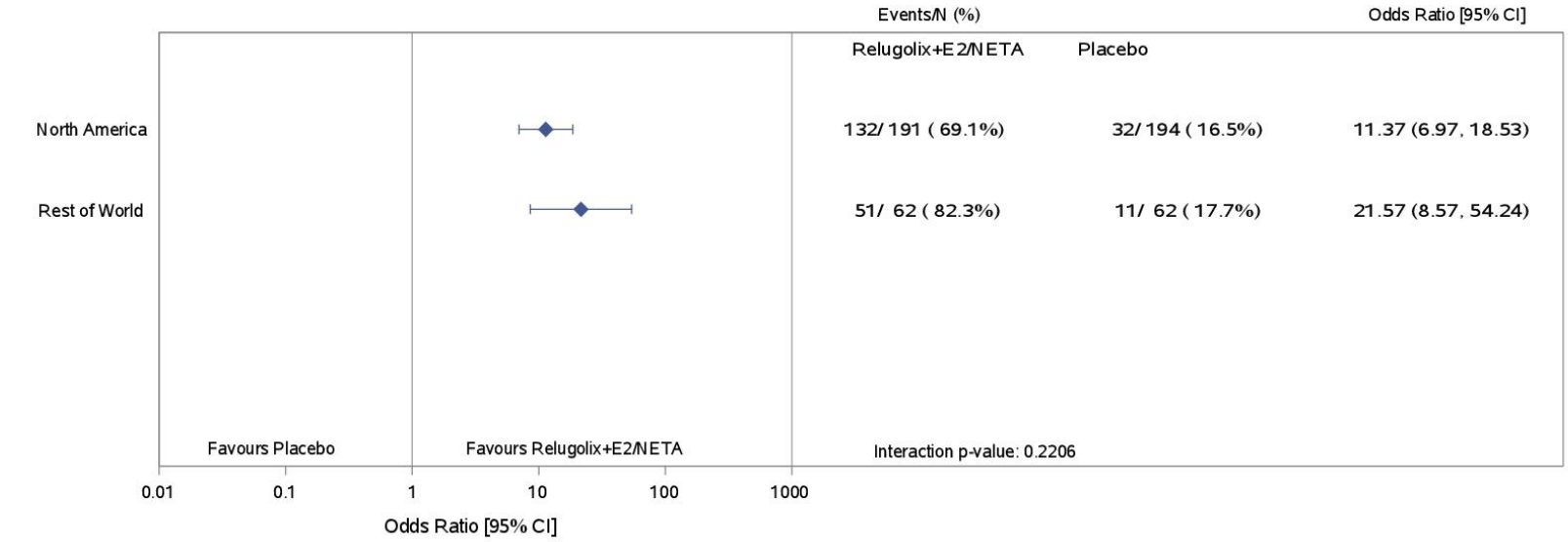
Figure EFF.RCMP24ET.MITT.S6.BIN.FP: Proportion of Women in the Relugolix + E2/NETA Group Versus the Placebo Group who Achieve an MBL Volume of < 80 mL and at Least a 50% Reduction from Baseline MBL Volume Over the Last 35 Days of Treatment, as Measured by the Alkaline Hematin Method, by Subgroup (mITT Population)
Study: Pooled
Subgroup: Geographic Region I



Results are based on a logistic regression model adjusted for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates using a one-stage fixed-effects IPD meta-analysis approach. A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
The interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the Odds Ratio and 95% CI. Missing subgroup levels are not included in estimation of the interaction p-value. The reference group is Placebo.
N: Number of patients in treatment group; NETA: Norethindrone acetate; mITT: Modified intent-to-treat; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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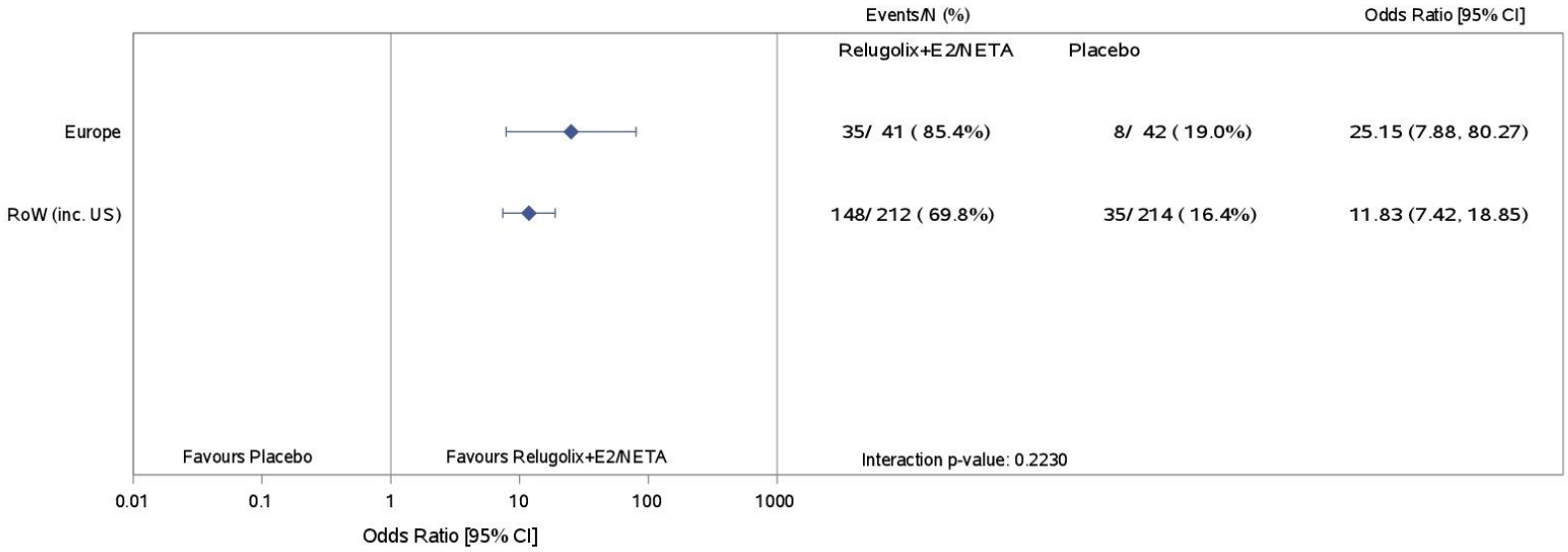
Figure EFF.RCMP24ET.MITT.S7.BIN.FP: Proportion of Women in the Relugolix + E2/NETA Group Versus the Placebo Group who Achieve an MBL Volume of < 80 mL and at Least a 50% Reduction from Baseline MBL Volume Over the Last 35 Days of Treatment, as Measured by the Alkaline Hematin Method, by Subgroup (mITT Population)
Study: Pooled
Subgroup: Geographic Region II



Results are based on a logistic regression model adjusted for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates using a one-stage fixed-effects IPD meta-analysis approach. A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
The interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the Odds Ratio and 95% CI. Missing subgroup levels are not included in estimation of the interaction p-value. The reference group is Placebo.
N: Number of patients in treatment group; NETA: Norethindrone acetate; mITT: Modified intent-to-treat; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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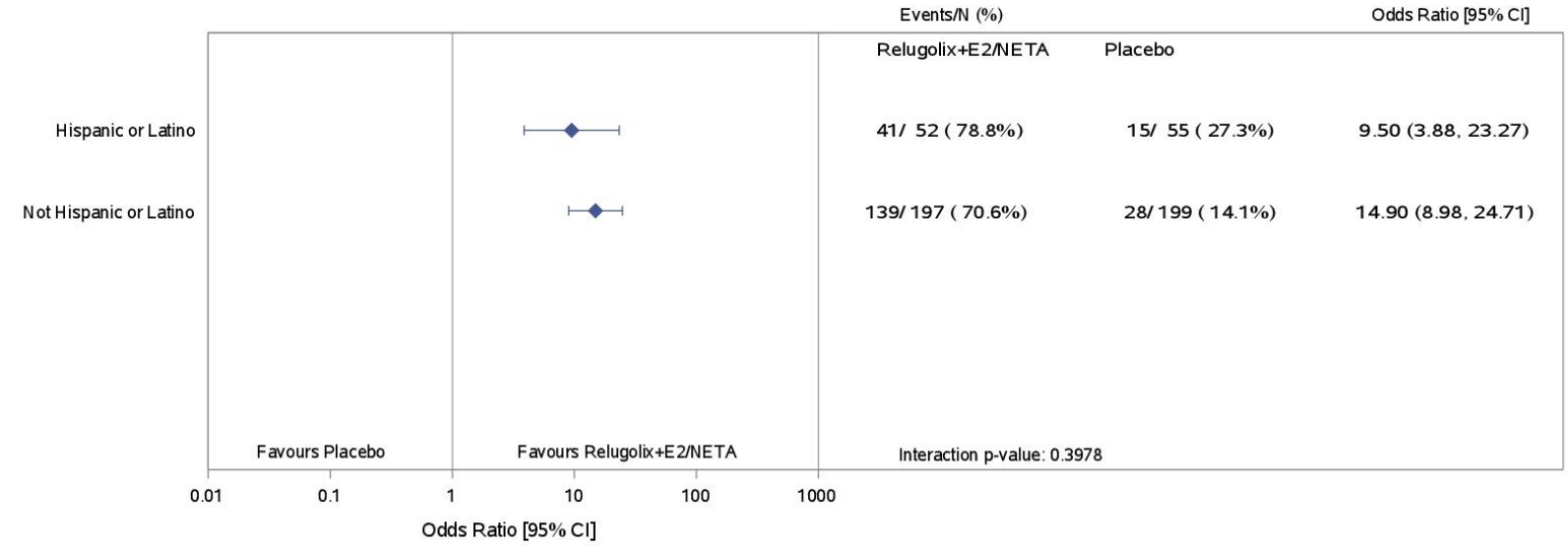
Figure EFF.RCMP24ET.MITT.S8.BIN.FP: Proportion of Women in the Relugolix + E2/NETA Group Versus the Placebo Group who Achieve an MBL Volume of < 80 mL and at Least a 50% Reduction from Baseline MBL Volume Over the Last 35 Days of Treatment, as Measured by the Alkaline Hematin Method, by Subgroup (mITT Population)
Study: Pooled
Subgroup: Ethnicity



Results are based on a logistic regression model adjusted for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates using a one-stage fixed-effects IPD meta-analysis approach. A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
The interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the Odds Ratio and 95% CI. Missing subgroup levels are not included in estimation of the interaction p-value. The reference group is Placebo.
N: Number of patients in treatment group; NETA: Norethindrone acetate; mITT: Modified intent-to-treat; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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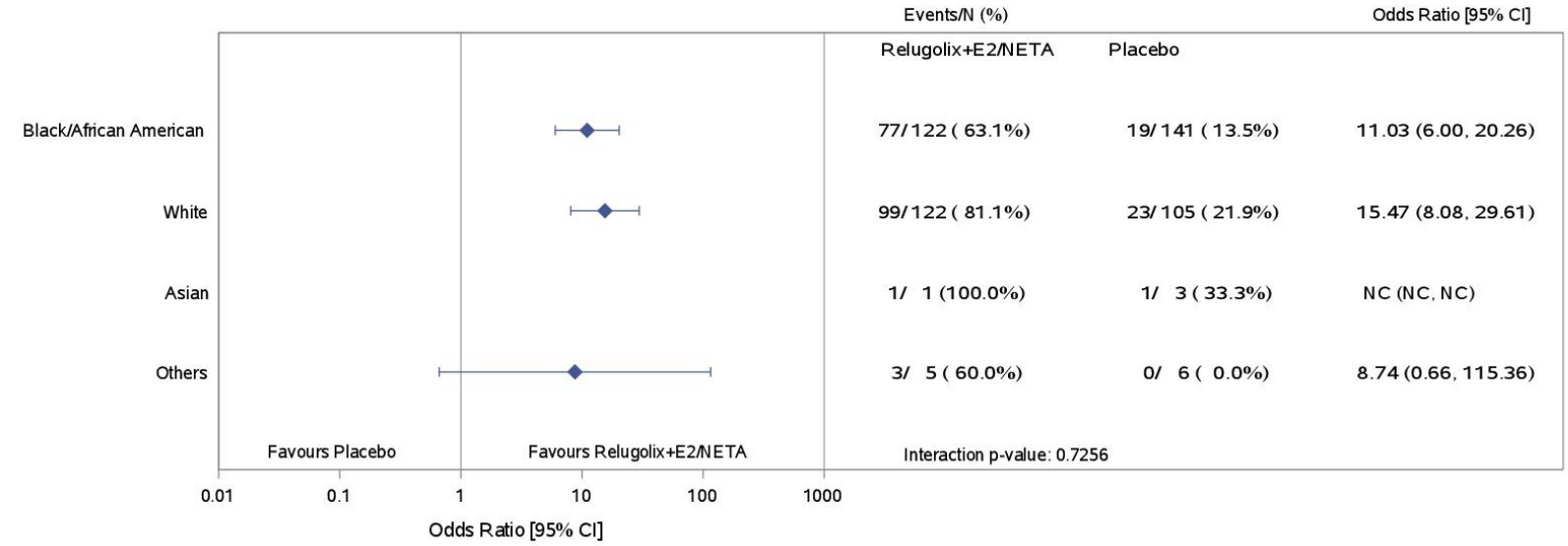
Figure EFF.RCMP24ET.MITT.S9.BIN.FP: Proportion of Women in the Relugolix + E2/NETA Group Versus the Placebo Group who Achieve an MBL Volume of < 80 mL and at Least a 50% Reduction from Baseline MBL Volume Over the Last 35 Days of Treatment, as Measured by the Alkaline Hematin Method, by Subgroup (mITT Population)
Study: Pooled
Subgroup: Race



Results are based on a logistic regression model adjusted for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates using a one-stage fixed-effects IPD meta-analysis approach. A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
The interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the Odds Ratio and 95% CI. Missing subgroup levels are not included in estimation of the interaction p-value. The reference group is Placebo.
N: Number of patients in treatment group; NETA: Norethindrone acetate; mITT: Modified intent-to-treat; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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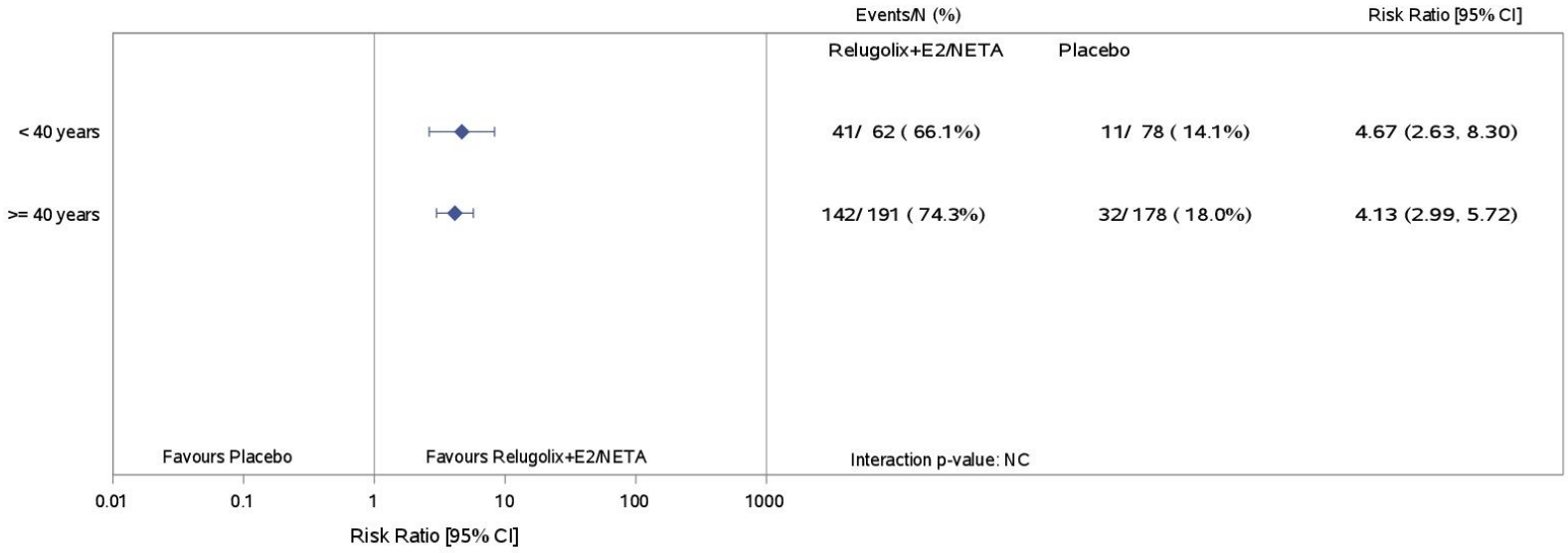
Figure EFF.RCMP24ET.MITT.S1.BIN.FP.RR: Proportion of Women in the Relugolix + E2/NETA Group Versus the Placebo Group who Achieve an MBL Volume of < 80 mL and at Least a 50% Reduction from Baseline MBL Volume Over the Last 35 Days of Treatment, as Measured by the Alkaline Hematin Method, by Subgroup (mITT Population) - Risk Ratio
Study: Pooled
Subgroup: Age (years)



Results are based on a Cochran-Mantel-Haenszel approach stratified by study using a one-stage fixed-effects IPD meta-analysis. A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
The reference group is Placebo.
N: Number of patients in treatment group; NETA: Norethindrone acetate; mITT: Modified intent-to-treat; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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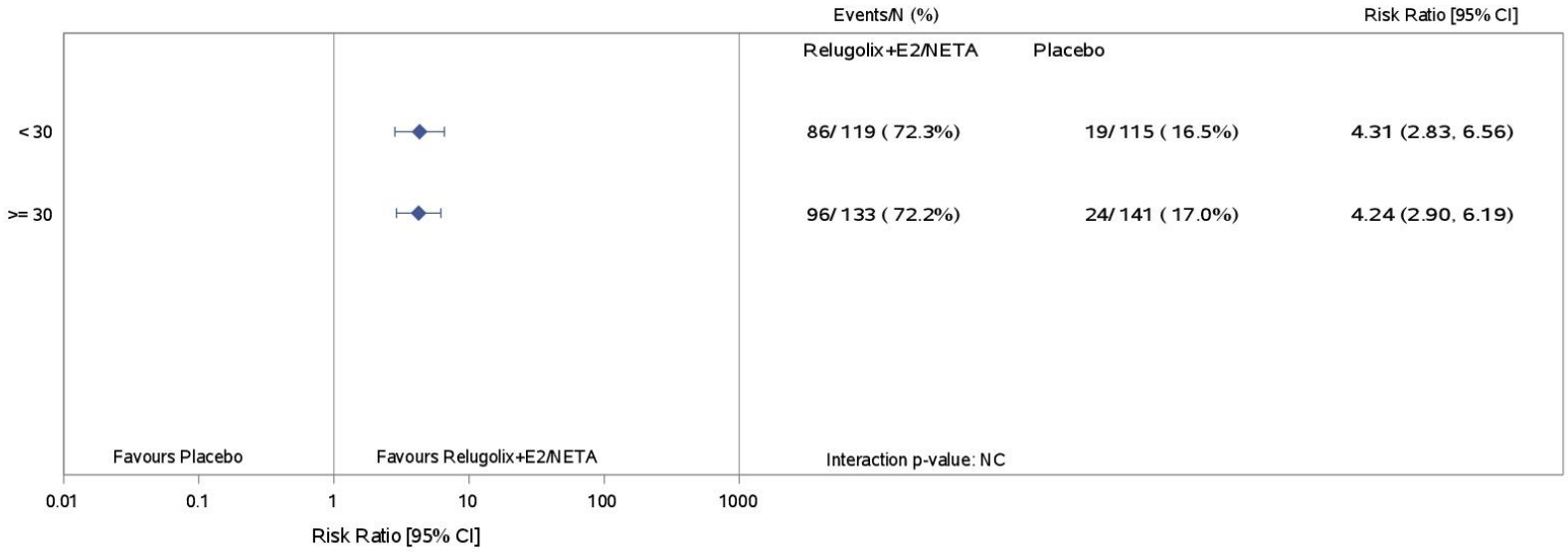
Figure EFF.RCMP24ET.MITT.S2.BIN.FP.RR: Proportion of Women in the Relugolix + E2/NETA Group Versus the Placebo Group who Achieve an MBL Volume of < 80 mL and at Least a 50% Reduction from Baseline MBL Volume Over the Last 35 Days of Treatment, as Measured by the Alkaline Hematin Method, by Subgroup (mITT Population) - Risk Ratio
Study: Pooled
Subgroup: BMI (kg/m2) at Baseline



Results are based on a Cochran-Mantel-Haenszel approach stratified by study using a one-stage fixed-effects IPD meta-analysis. A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
The reference group is Placebo.
N: Number of patients in treatment group; NETA: Norethindrone acetate; mITT: Modified intent-to-treat; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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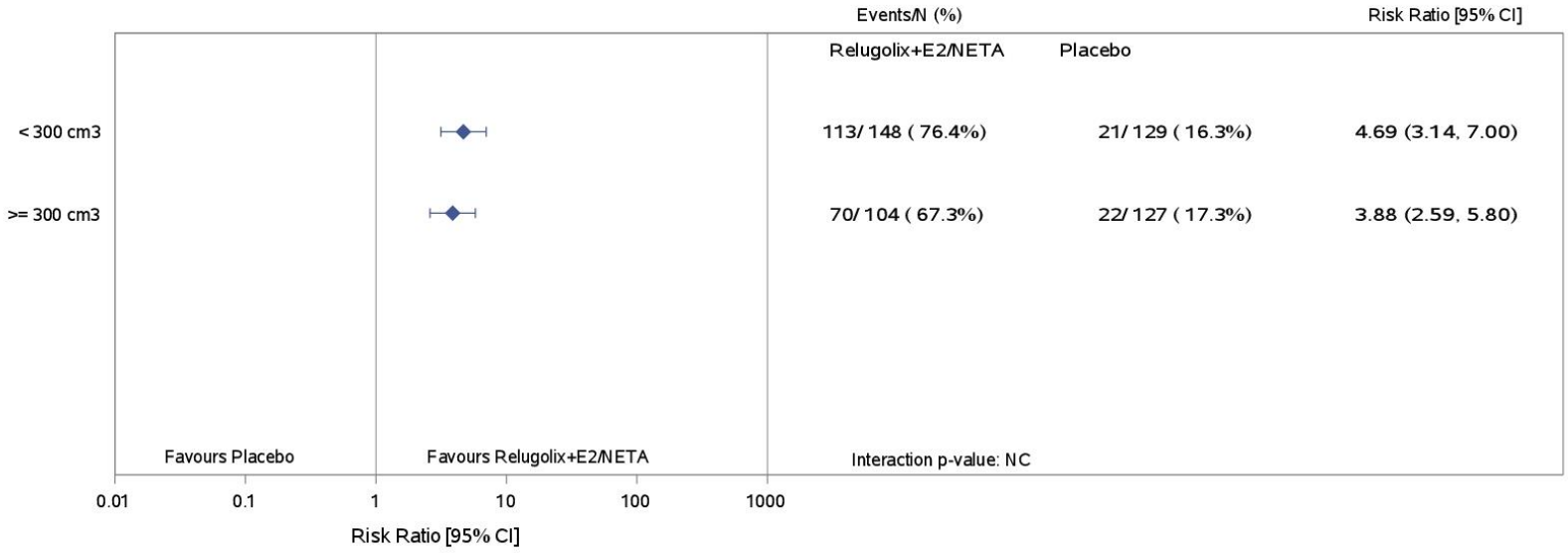
Figure EFF.RCMP24ET.MITT.S3.BIN.FP.RR: Proportion of Women in the Relugolix + E2/NETA Group Versus the Placebo Group who Achieve an MBL Volume of < 80 mL and at Least a 50% Reduction from Baseline MBL Volume Over the Last 35 Days of Treatment, as Measured by the Alkaline Hematin Method, by Subgroup (mITT Population) - Risk Ratio
Study: Pooled
Subgroup: Uterine Volume at Baseline (cm3)



Results are based on a Cochran-Mantel-Haenszel approach stratified by study using a one-stage fixed-effects IPD meta-analysis. A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
The reference group is Placebo.
N: Number of patients in treatment group; NETA: Norethindrone acetate; mITT: Modified intent-to-treat; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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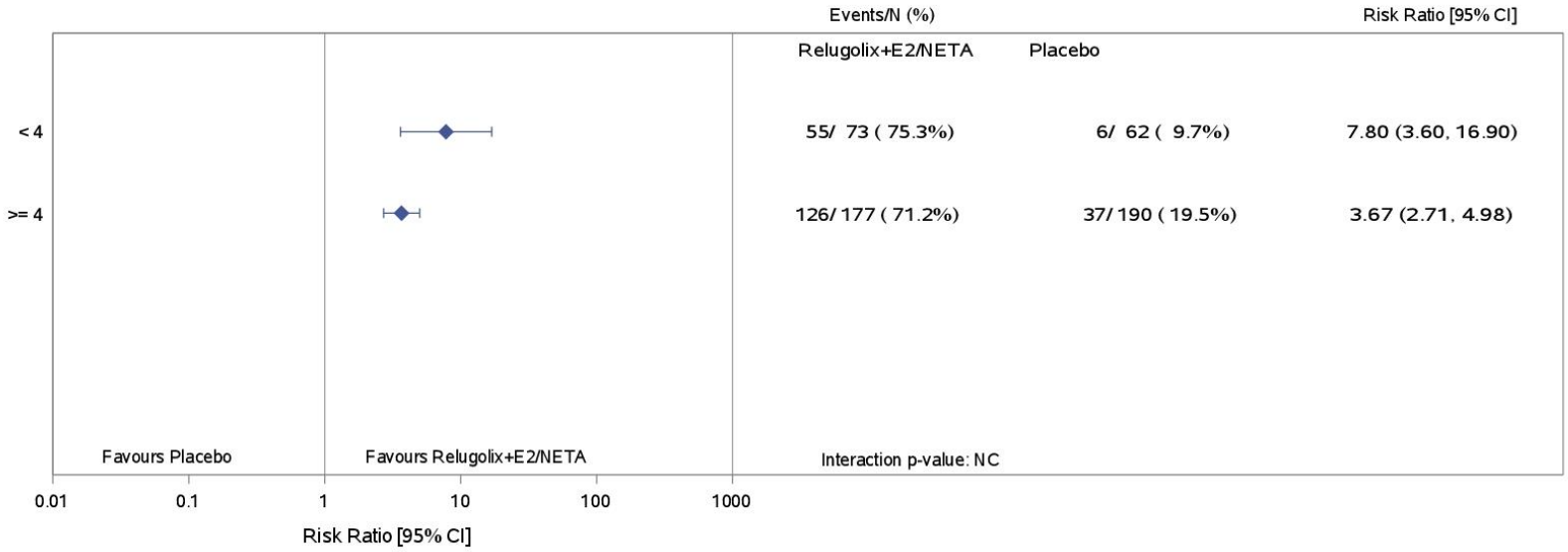
Figure EFF.RCMP24ET.MITT.S4.BIN.FP.RR: Proportion of Women in the Relugolix + E2/NETA Group Versus the Placebo Group who Achieve an MBL Volume of < 80 mL and at Least a 50% Reduction from Baseline MBL Volume Over the Last 35 Days of Treatment, as Measured by the Alkaline Hematin Method, by Subgroup (mITT Population) - Risk Ratio
Study: Pooled
Subgroup: Maximum NRS Pain Score at Baseline



Results are based on a Cochran-Mantel-Haenszel approach stratified by study using a one-stage fixed-effects IPD meta-analysis. A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
The reference group is Placebo.
N: Number of patients in treatment group; NETA: Norethindrone acetate; mITT: Modified intent-to-treat; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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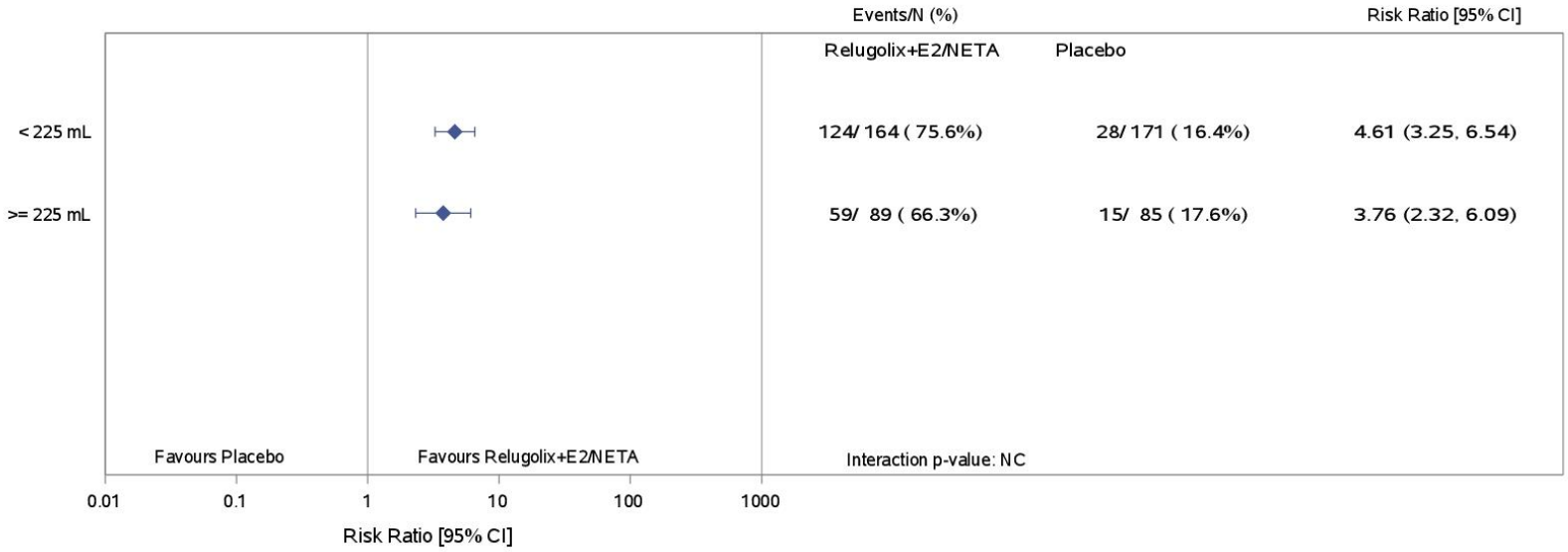
Figure EFF.RCMP24ET.MITT.S5.BIN.FP.RR: Proportion of Women in the Relugolix + E2/NETA Group Versus the Placebo Group who Achieve an MBL Volume of < 80 mL and at Least a 50% Reduction from Baseline MBL Volume Over the Last 35 Days of Treatment, as Measured by the Alkaline Hematin Method, by Subgroup (mITT Population) - Risk Ratio
Study: Pooled
Subgroup: MBL Volume at Baseline (mL)



Results are based on a Cochran-Mantel-Haenszel approach stratified by study using a one-stage fixed-effects IPD meta-analysis. A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
The reference group is Placebo.
N: Number of patients in treatment group; NETA: Norethindrone acetate; mITT: Modified intent-to-treat; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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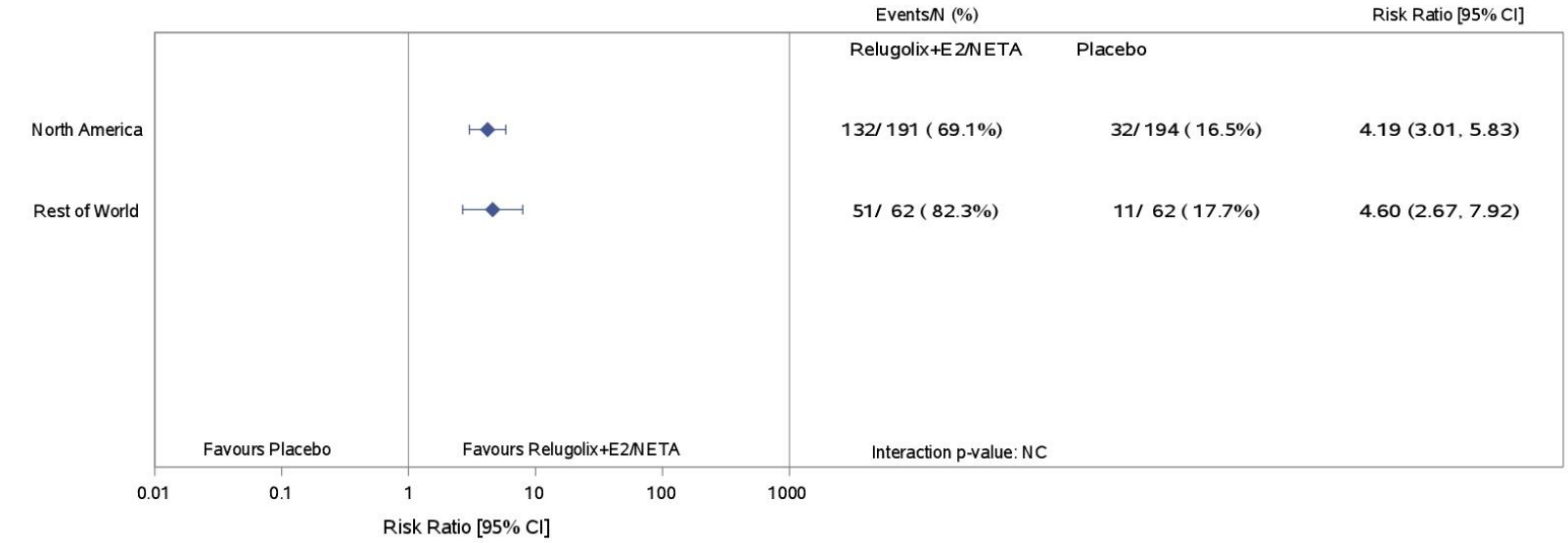
Figure EFF.RCMP24ET.MITT.S6.BIN.FP.RR: Proportion of Women in the Relugolix + E2/NETA Group Versus the Placebo Group who Achieve an MBL Volume of < 80 mL and at Least a 50% Reduction from Baseline MBL Volume Over the Last 35 Days of Treatment, as Measured by the Alkaline Hematin Method, by Subgroup (mITT Population) - Risk Ratio
Study: Pooled
Subgroup: Geographic Region I



Results are based on a Cochran-Mantel-Haenszel approach stratified by study using a one-stage fixed-effects IPD meta-analysis. A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
The reference group is Placebo.
N: Number of patients in treatment group; NETA: Norethindrone acetate; mITT: Modified intent-to-treat; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

SOURCE: X:\Numerus\Studies\MYV\MYV102\Analysis\Prod\Progs\TFLs\Fig_EFF_MBL_S_BIN_FP.SAS Date/time of run: 30JUN21 10:23
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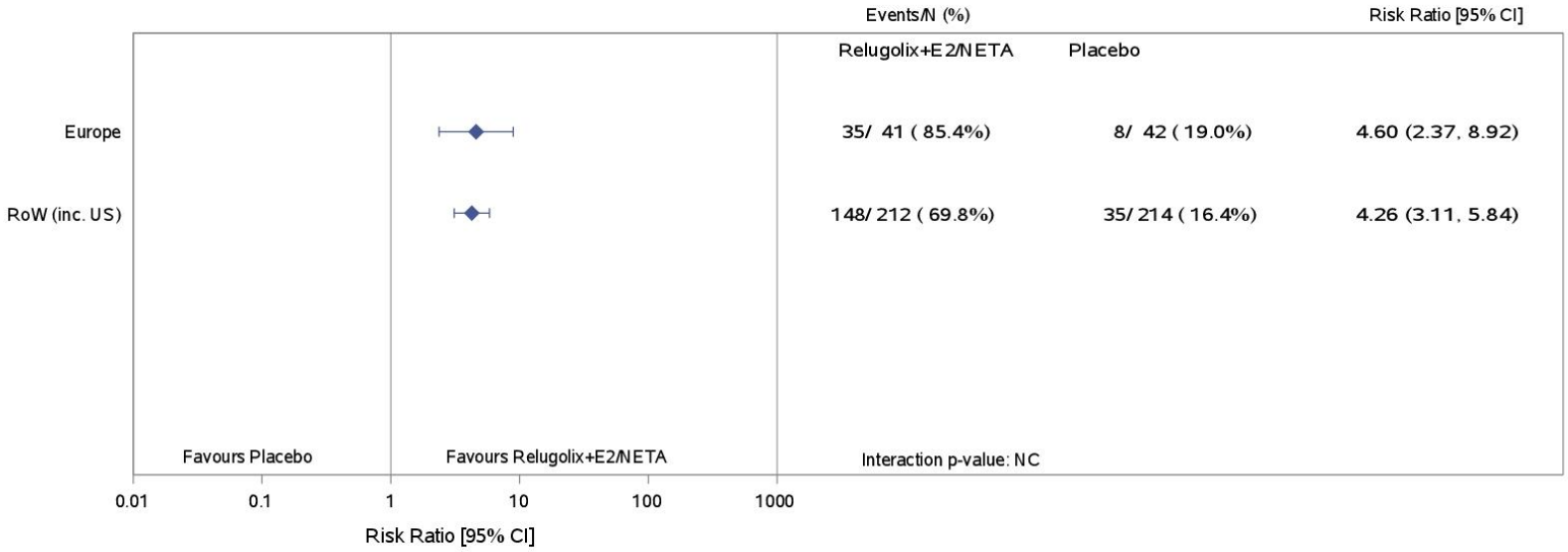
Figure EFF.RCMP24ET.MITT.S7.BIN.FP.RR: Proportion of Women in the Relugolix + E2/NETA Group Versus the Placebo Group who Achieve an MBL Volume of < 80 mL and at Least a 50% Reduction from Baseline MBL Volume Over the Last 35 Days of Treatment, as Measured by the Alkaline Hematin Method, by Subgroup (mITT Population) - Risk Ratio
Study: Pooled
Subgroup: Geographic Region II



Results are based on a Cochran-Mantel-Haenszel approach stratified by study using a one-stage fixed-effects IPD meta-analysis. A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
The reference group is Placebo.
N: Number of patients in treatment group; NETA: Norethindrone acetate; mITT: Modified intent-to-treat; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

SOURCE: X:\Numerus\Studies\MYV\MYV102\Analysis\Prod\Progs\TFLs\Fig_EFF_MBL_S_BIN_FP.SAS Date/time of run: 30JUN21 10:23
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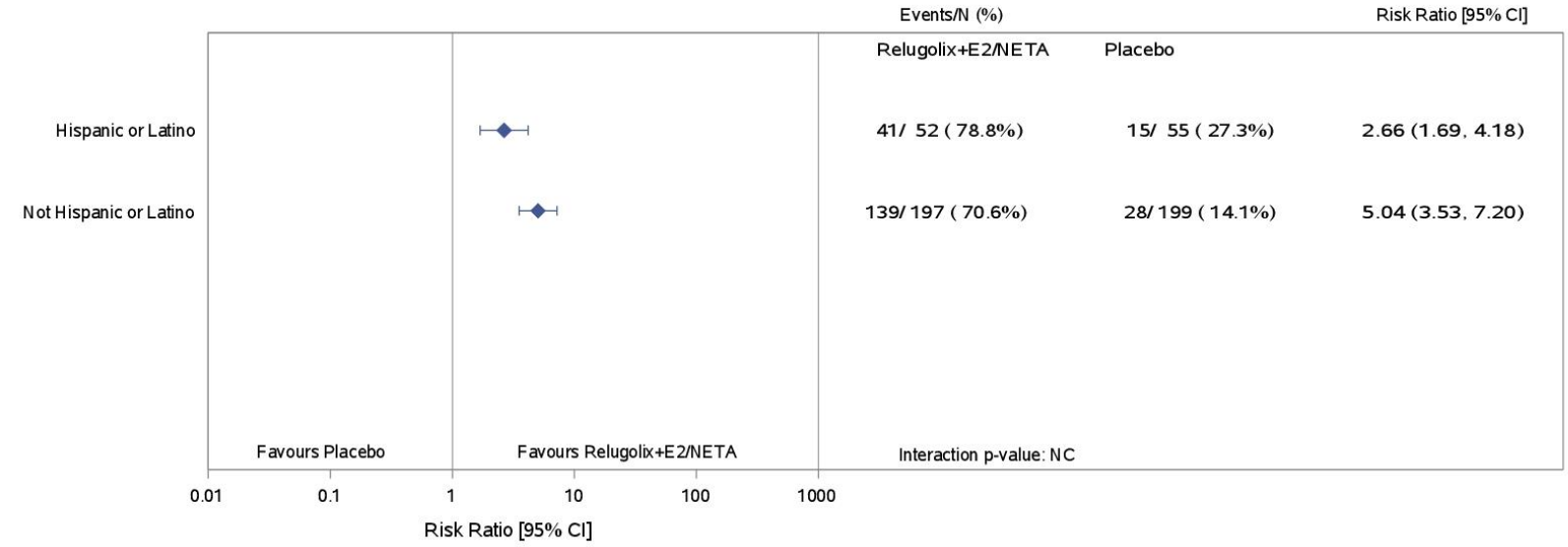
Figure EFF.RCMP24ET.MITT.S8.BIN.FP.RR: Proportion of Women in the Relugolix + E2/NETA Group Versus the Placebo Group who Achieve an MBL Volume of < 80 mL and at Least a 50% Reduction from Baseline MBL Volume Over the Last 35 Days of Treatment, as Measured by the Alkaline Hematin Method, by Subgroup (mITT Population) - Risk Ratio
Study: Pooled
Subgroup: Ethnicity



Results are based on a Cochran-Mantel-Haenszel approach stratified by study using a one-stage fixed-effects IPD meta-analysis. A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
The reference group is Placebo.
N: Number of patients in treatment group; NETA: Norethindrone acetate; mITT: Modified intent-to-treat; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

SOURCE: X:\Numerus\Studies\MYV\MYV102\Analysis\Prod\Progs\TFLs\Fig_EFF_MBL_S_BIN_FP.SAS Date/time of run: 30JUN21 10:23
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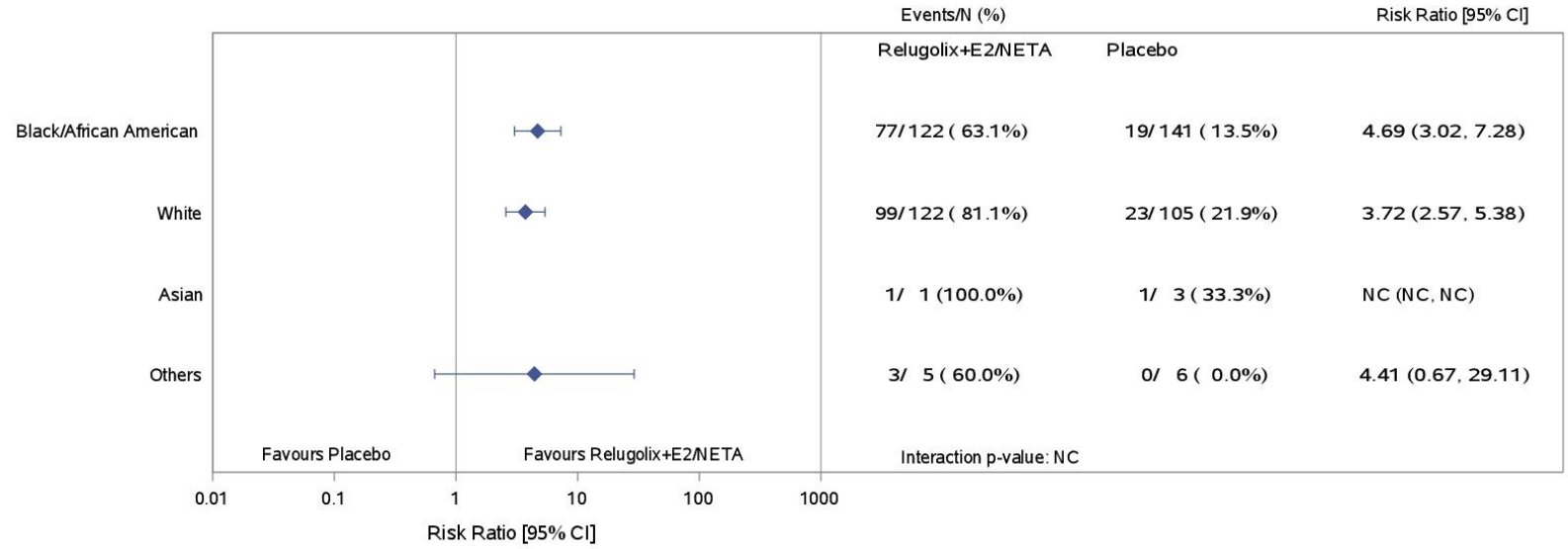
Figure EFF.RCMP24ET.MITT.S9.BIN.FP.RR: Proportion of Women in the Relugolix + E2/NETA Group Versus the Placebo Group who Achieve an MBL Volume of < 80 mL and at Least a 50% Reduction from Baseline MBL Volume Over the Last 35 Days of Treatment, as Measured by the Alkaline Hematin Method, by Subgroup (mITT Population) - Risk Ratio
Study: Pooled
Subgroup: Race



Results are based on a Cochran-Mantel-Haenszel approach stratified by study using a one-stage fixed-effects IPD meta-analysis. A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
The reference group is Placebo.
N: Number of patients in treatment group; NETA: Norethindrone acetate; mITT: Modified intent-to-treat; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

SOURCE: X:\Numerus\Studies\MYV\MYV102\Analysis\Prod\Progs\TFLs\Fig_EFF_MBL_S_BIN_FP.SAS Date/time of run: 30JUN21 10:23
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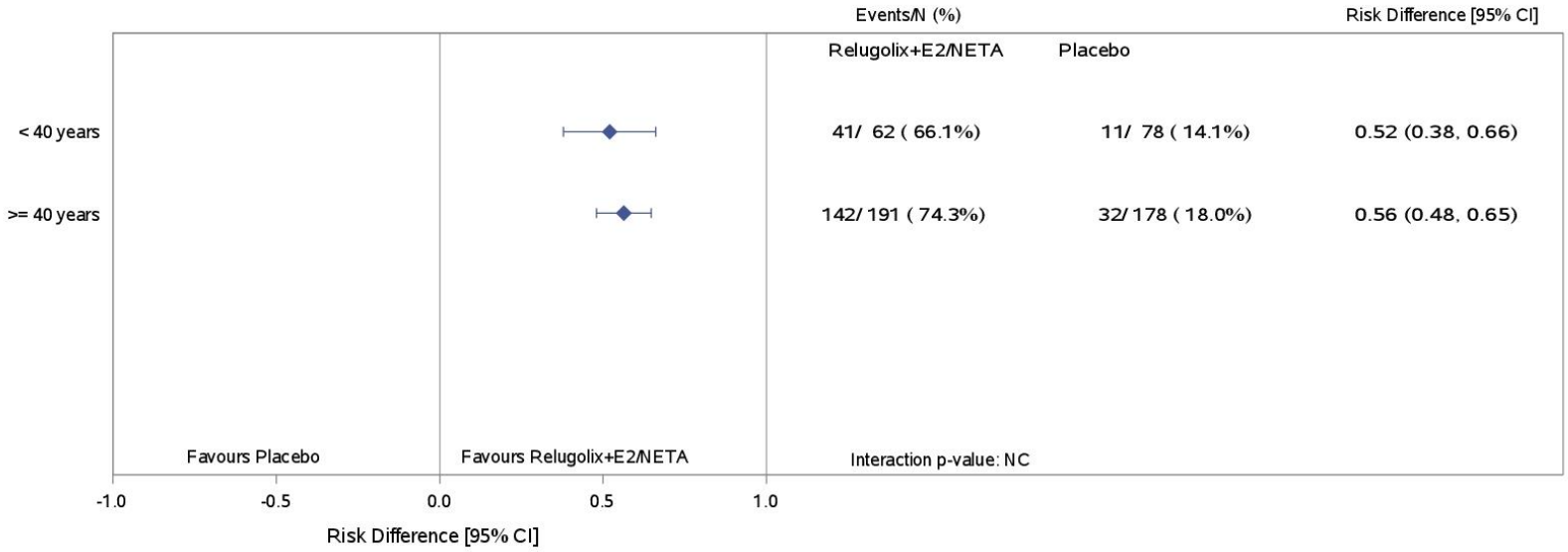
Figure EFF.RCMP24ET.MITT.S1.BIN.FP.RD: Proportion of Women in the Relugolix + E2/NETA Group Versus the Placebo Group who Achieve an MBL Volume of < 80 mL and at Least a 50% Reduction from Baseline MBL Volume Over the Last 35 Days of Treatment, as Measured by the Alkaline Hematin Method, by Subgroup (mITT Population) - Risk Difference
Study: Pooled
Subgroup: Age (years)



Results are based on a Mantel-Haenszel approach stratified by study using a one-stage fixed-effects IPD meta-analysis.
The reference group is Placebo.
N: Number of patients in treatment group; NETA: Norethindrone acetate; mITT: Modified intent-to-treat; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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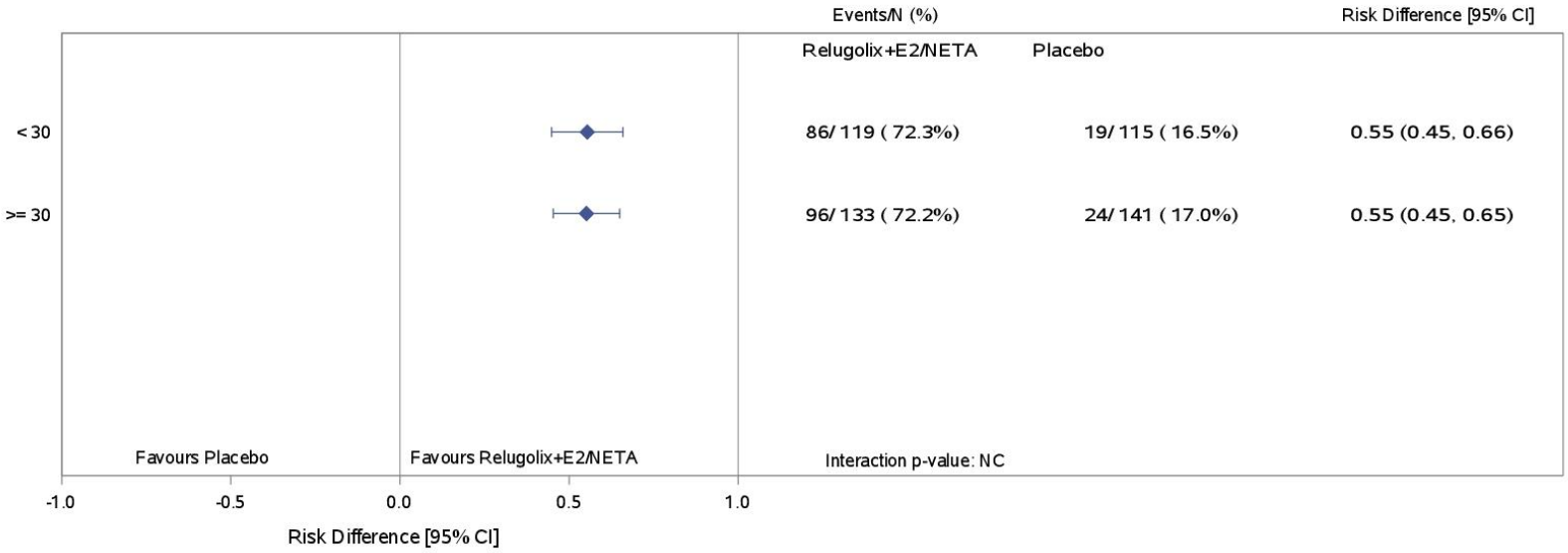
Figure EFF.RCMP24ET.MITT.S2.BIN.FP.RD: Proportion of Women in the Relugolix + E2/NETA Group Versus the Placebo Group who Achieve an MBL Volume of < 80 mL and at Least a 50% Reduction from Baseline MBL Volume Over the Last 35 Days of Treatment, as Measured by the Alkaline Hematin Method, by Subgroup (mITT Population) - Risk Difference
Study: Pooled
Subgroup: BMI (kg/m2) at Baseline



Results are based on a Mantel-Haenszel approach stratified by study using a one-stage fixed-effects IPD meta-analysis.
The reference group is Placebo.
N: Number of patients in treatment group; NETA: Norethindrone acetate; mITT: Modified intent-to-treat; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

SOURCE: X:\Numerus\Studies\MYV\MYV102\Analysis\Prod\Progs\TFLs\Fig_EFF_MBL_S_BIN_FP.SAS Date/time of run: 30JUN21 10:23
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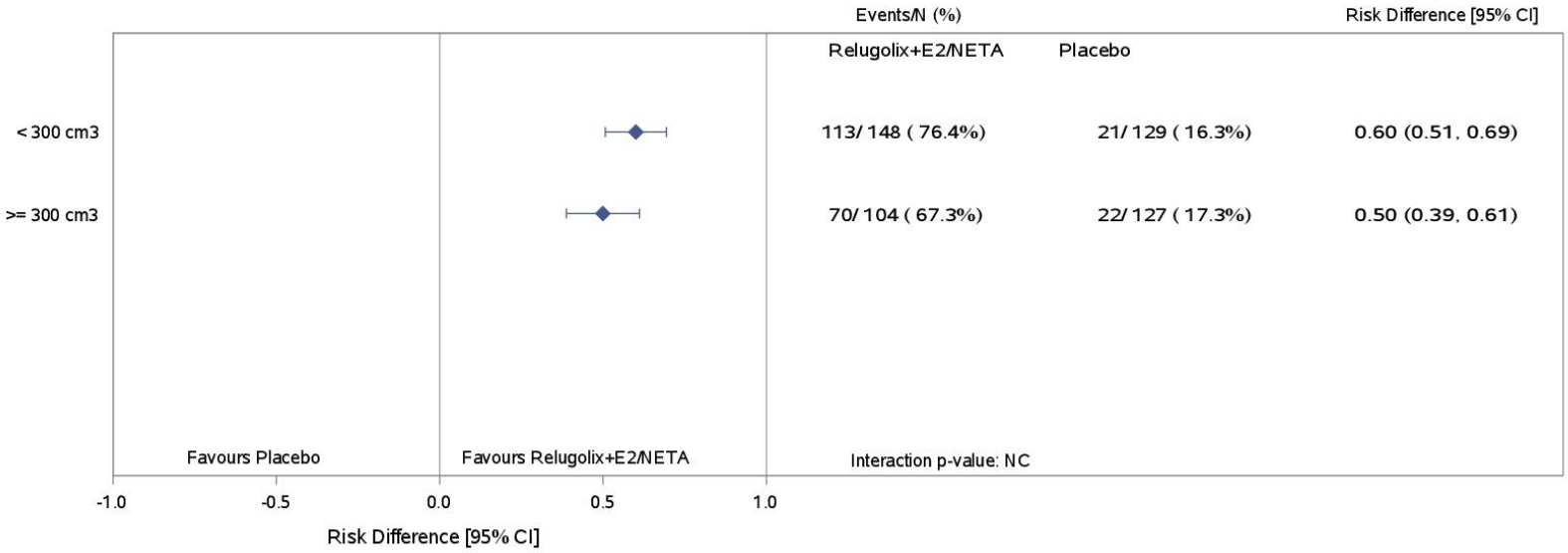
Figure EFF.RCMP24ET.MITT.S3.BIN.FP.RD: Proportion of Women in the Relugolix + E2/NETA Group Versus the Placebo Group who Achieve an MBL Volume of < 80 mL and at Least a 50% Reduction from Baseline MBL Volume Over the Last 35 Days of Treatment, as Measured by the Alkaline Hematin Method, by Subgroup (mITT Population) - Risk Difference
Study: Pooled
Subgroup: Uterine Volume at Baseline (cm3)



Results are based on a Mantel-Haenszel approach stratified by study using a one-stage fixed-effects IPD meta-analysis.
The reference group is Placebo.
N: Number of patients in treatment group; NETA: Norethindrone acetate; mITT: Modified intent-to-treat; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

SOURCE: X:\Numerus\Studies\MYV\MYV102\Analysis\Prod\Progs\TFLs\Fig_EFF_MBL_S_BIN_FP.SAS Date/time of run: 30JUN21 10:23
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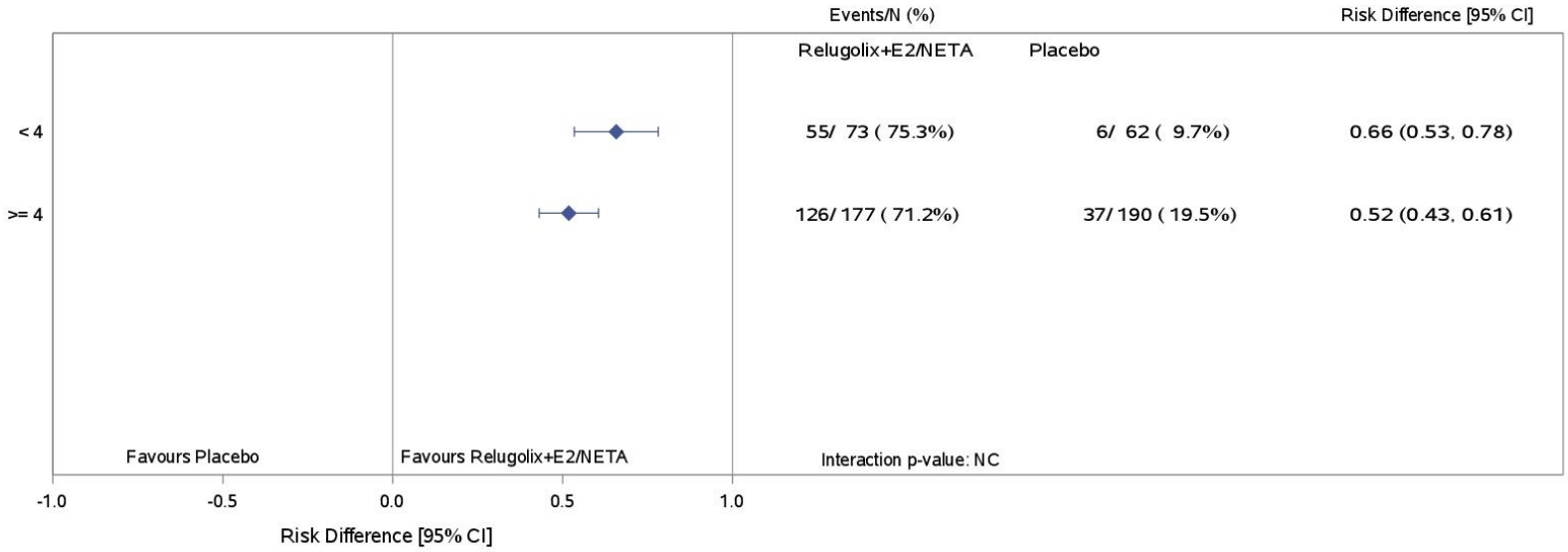
Figure EFF.RCMP24ET.MITT.S4.BIN.FP.RD: Proportion of Women in the Relugolix + E2/NETA Group Versus the Placebo Group who Achieve an MBL Volume of < 80 mL and at Least a 50% Reduction from Baseline MBL Volume Over the Last 35 Days of Treatment, as Measured by the Alkaline Hematin Method, by Subgroup (mITT Population) - Risk Difference
Study: Pooled
Subgroup: Maximum NRS Pain Score at Baseline



Results are based on a Mantel-Haenszel approach stratified by study using a one-stage fixed-effects IPD meta-analysis.
The reference group is Placebo.
N: Number of patients in treatment group; NETA: Norethindrone acetate; mITT: Modified intent-to-treat; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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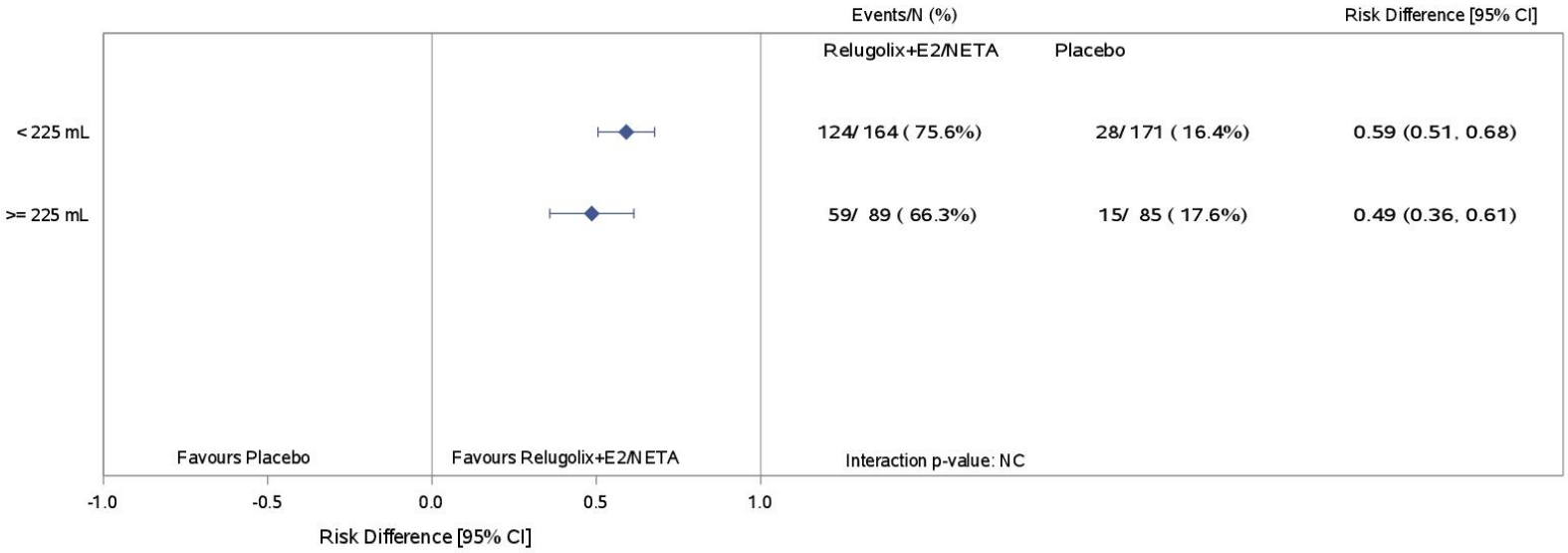
Figure EFF.RCMP24ET.MITT.S5.BIN.FP.RD: Proportion of Women in the Relugolix + E2/NETA Group Versus the Placebo Group who Achieve an MBL Volume of < 80 mL and at Least a 50% Reduction from Baseline MBL Volume Over the Last 35 Days of Treatment, as Measured by the Alkaline Hematin Method, by Subgroup (mITT Population) - Risk Difference
Study: Pooled
Subgroup: MBL Volume at Baseline (mL)



Results are based on a Mantel-Haenszel approach stratified by study using a one-stage fixed-effects IPD meta-analysis.
The reference group is Placebo.
N: Number of patients in treatment group; NETA: Norethindrone acetate; mITT: Modified intent-to-treat; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

SOURCE: X:\Numerus\Studies\MYV\MYV102\Analysis\Prod\Progs\TFLs\Fig_EFF_MBL_S_BIN_FP.SAS Date/time of run: 30JUN21 10:23
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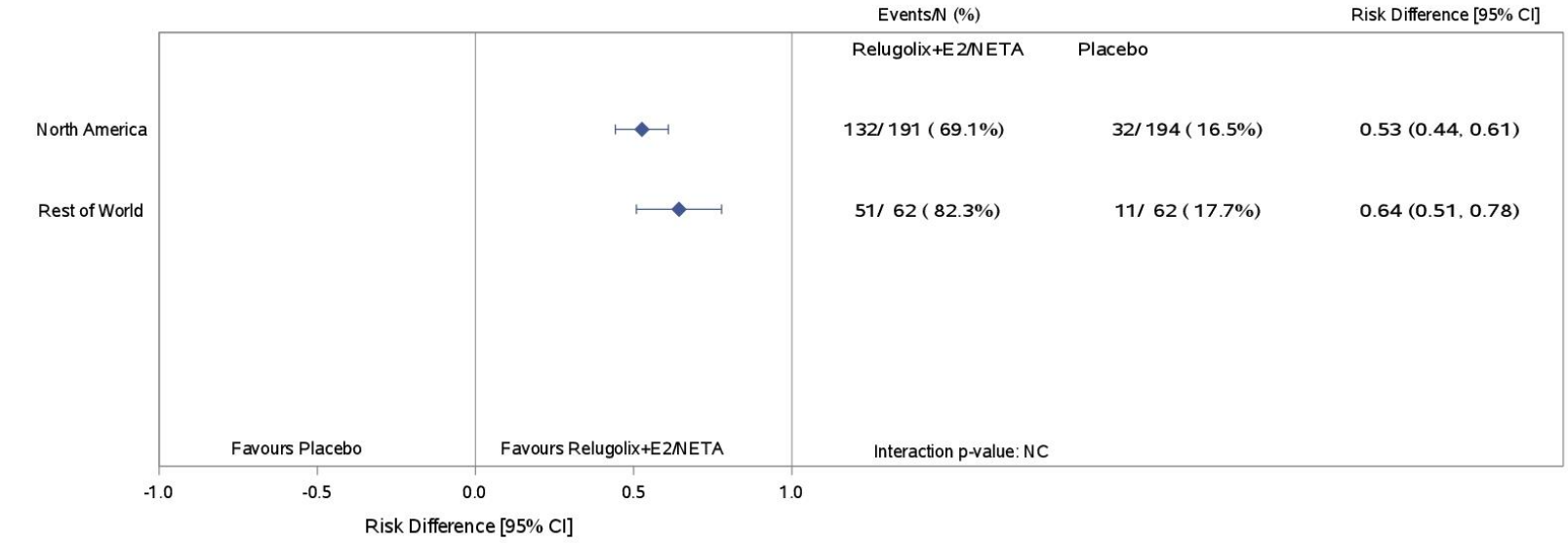
Figure EFF.RCMP24ET.MITT.S6.BIN.FP.RD: Proportion of Women in the Relugolix + E2/NETA Group Versus the Placebo Group who Achieve an MBL Volume of < 80 mL and at Least a 50% Reduction from Baseline MBL Volume Over the Last 35 Days of Treatment, as Measured by the Alkaline Hematin Method, by Subgroup (mITT Population) - Risk Difference
Study: Pooled
Subgroup: Geographic Region I



Results are based on a Mantel-Haenszel approach stratified by study using a one-stage fixed-effects IPD meta-analysis.
The reference group is Placebo.
N: Number of patients in treatment group; NETA: Norethindrone acetate; mITT: Modified intent-to-treat; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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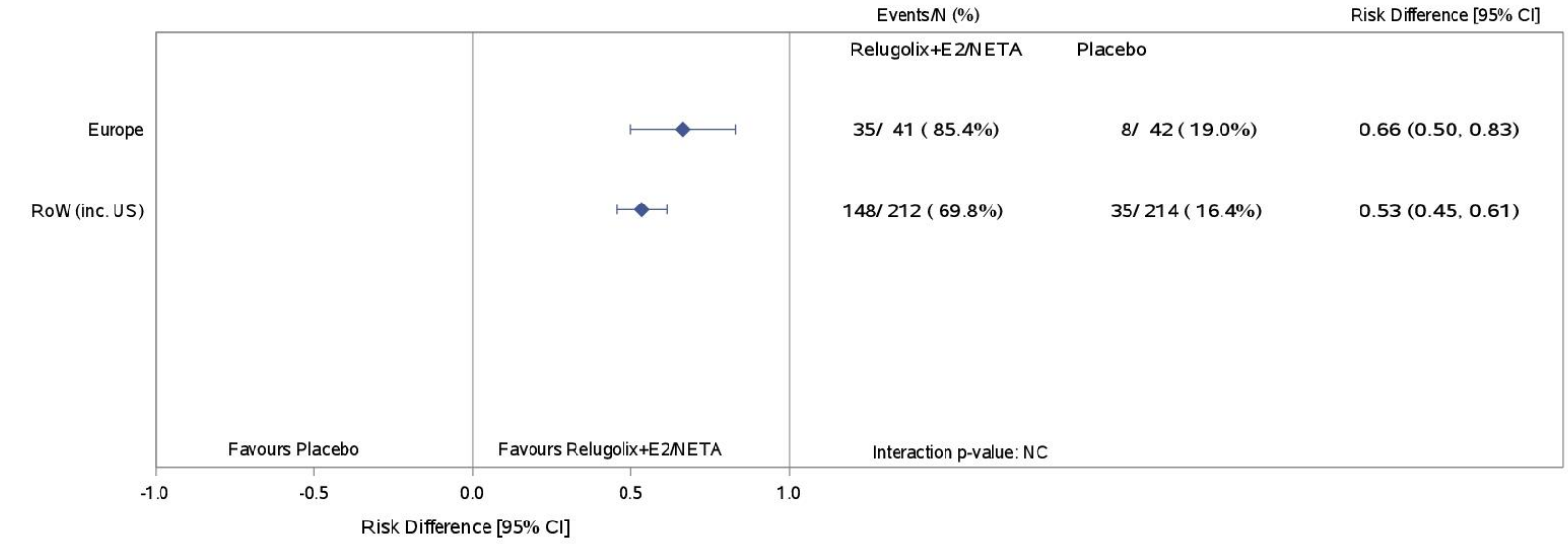
Figure EFF.RCMP24ET.MITT.S7.BIN.FP.RD: Proportion of Women in the Relugolix + E2/NETA Group Versus the Placebo Group who Achieve an MBL Volume of < 80 mL and at Least a 50% Reduction from Baseline MBL Volume Over the Last 35 Days of Treatment, as Measured by the Alkaline Hematin Method, by Subgroup (mITT Population) - Risk Difference
Study: Pooled
Subgroup: Geographic Region II



Results are based on a Mantel-Haenszel approach stratified by study using a one-stage fixed-effects IPD meta-analysis.
The reference group is Placebo.
N: Number of patients in treatment group; NETA: Norethindrone acetate; mITT: Modified intent-to-treat; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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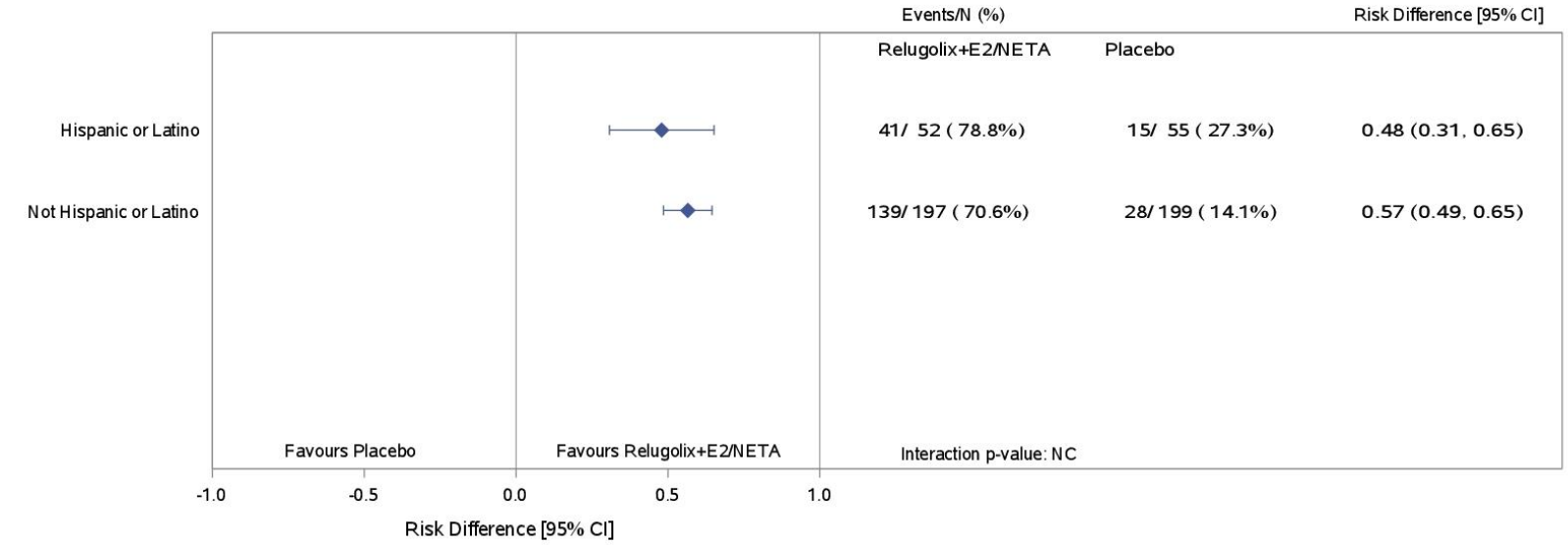
Figure EFF.RCMP24ET.MITT.S8.BIN.FP.RD: Proportion of Women in the Relugolix + E2/NETA Group Versus the Placebo Group who Achieve an MBL Volume of < 80 mL and at Least a 50% Reduction from Baseline MBL Volume Over the Last 35 Days of Treatment, as Measured by the Alkaline Hematin Method, by Subgroup (mITT Population) - Risk Difference
Study: Pooled
Subgroup: Ethnicity



Results are based on a Mantel-Haenszel approach stratified by study using a one-stage fixed-effects IPD meta-analysis.
The reference group is Placebo.
N: Number of patients in treatment group; NETA: Norethindrone acetate; mITT: Modified intent-to-treat; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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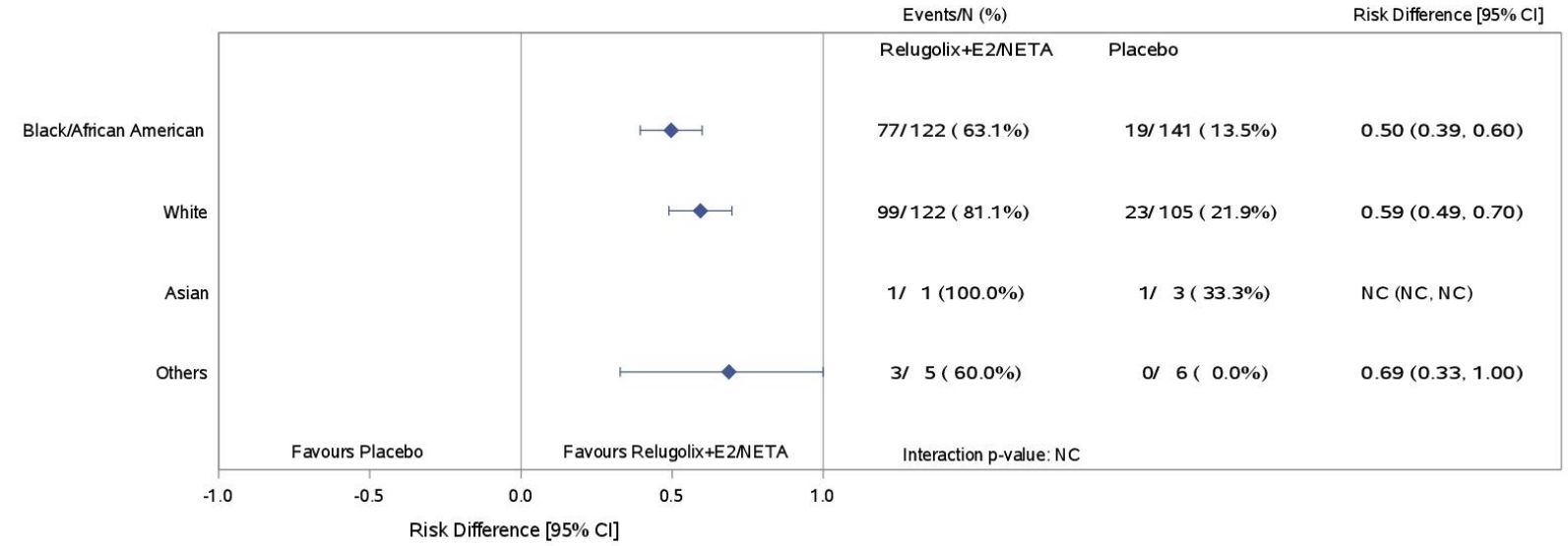
Figure EFF.RCMP24ET.MITT.S9.BIN.FP.RD: Proportion of Women in the Relugolix + E2/NETA Group Versus the Placebo Group who Achieve an MBL Volume of < 80 mL and at Least a 50% Reduction from Baseline MBL Volume Over the Last 35 Days of Treatment, as Measured by the Alkaline Hematin Method, by Subgroup (mITT Population) - Risk Difference
Study: Pooled
Subgroup: Race



Results are based on a Mantel-Haenszel approach stratified by study using a one-stage fixed-effects IPD meta-analysis.
The reference group is Placebo.
N: Number of patients in treatment group; NETA: Norethindrone acetate; mITT: Modified intent-to-treat; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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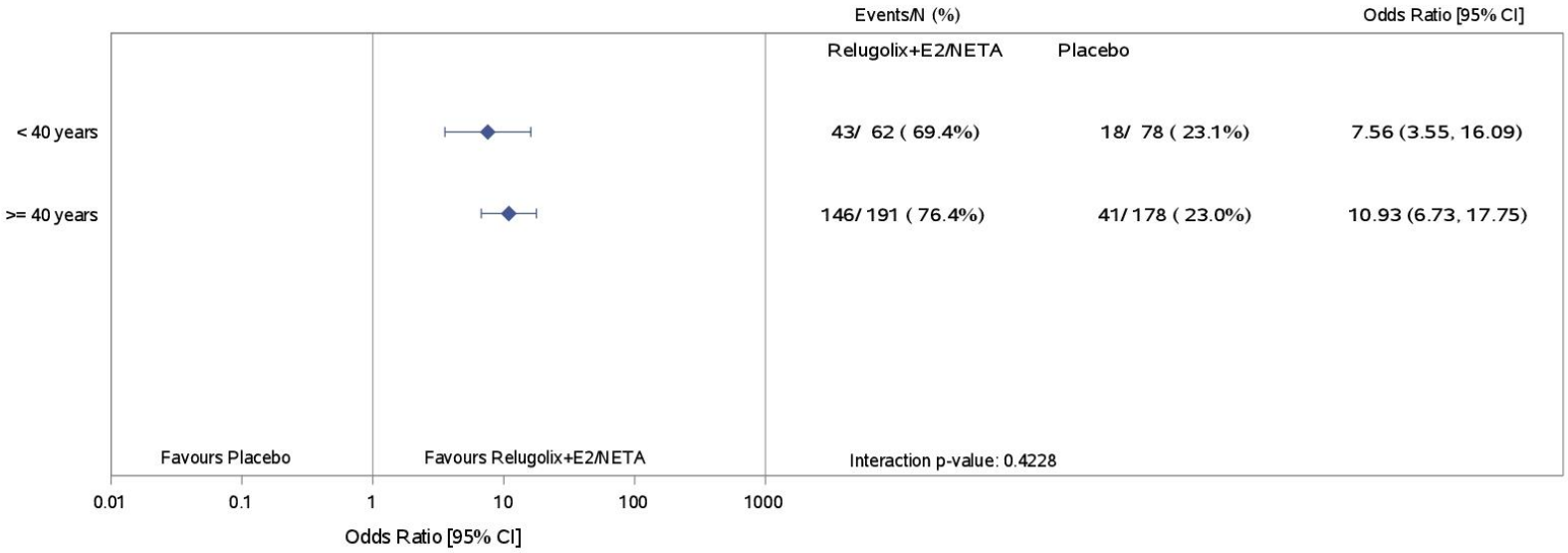
2.1.2 Proportion of Women in the Relugolix + E2/NETA Group Versus the Placebo Group who Achieve an MBL Volume of < 80 mL Over the Last 35 Days of Treatment, as Measured by the Alkaline Hematin Method, by Subgroup (mITT Population)

Nachfolgend sind zunächst alle Forest Plots für das *Odds Ratio* dargestellt; gefolgt von den entsprechenden Forest Plots für *Risk Ratio* und *Risk Difference*.

Figure EFF.RL8024ET.MITT.S1.BIN.FP: Proportion of Women in the Relugolix + E2/NETA Group Versus the Placebo Group who Achieve an MBL Volume of < 80 mL Over the Last 35 Days of Treatment, as Measured by the Alkaline Hematin Method, by Subgroup (mITT Population)
Study: Pooled
Subgroup: Age (years)



Results are based on a logistic regression model adjusted for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates using a one-stage fixed-effects IPD meta-analysis approach. A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
The interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the Odds Ratio and 95% CI. Missing subgroup levels are not included in estimation of the interaction p-value. The reference group is Placebo.
N: Number of patients in treatment group; NETA: Norethindrone acetate; mITT: Modified intent-to-treat; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

SOURCE: X:\Numerus\Studies\MYV\MYV102\Analysis\Prod\Progs\TFLs\Fig_EFF_MBL_S_BIN_FP.SAS Date/time of run: 30JUN21 10:23
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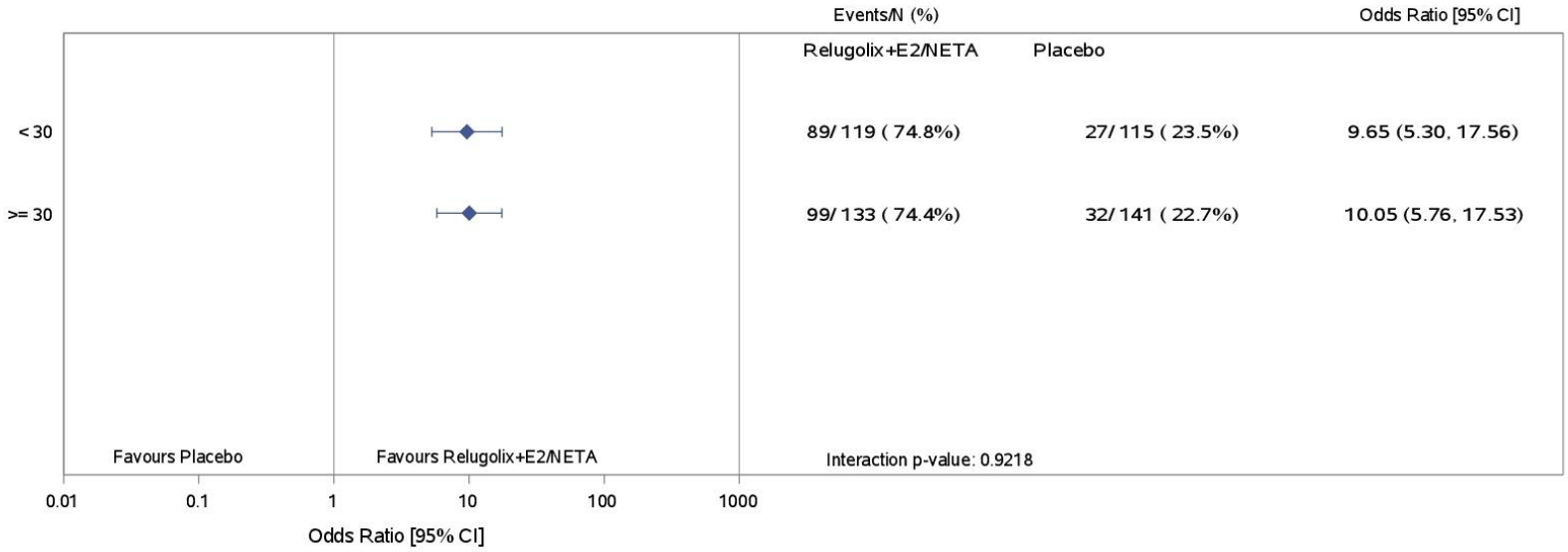
Figure EFF.RL8024ET.MITT.S2.BIN.FP: Proportion of Women in the Relugolix + E2/NETA Group Versus the Placebo Group who Achieve an MBL Volume of < 80 mL Over the Last 35 Days of Treatment, as Measured by the Alkaline Hematin Method, by Subgroup (mITT Population)
Study: Pooled
Subgroup: BMI (kg/m2) at Baseline



Results are based on a logistic regression model adjusted for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates using a one-stage fixed-effects IPD meta-analysis approach. A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
The interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the Odds Ratio and 95% CI. Missing subgroup levels are not included in estimation of the interaction p-value. The reference group is Placebo.
N: Number of patients in treatment group; NETA: Norethindrone acetate; mITT: Modified intent-to-treat; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

SOURCE: X:\Numerus\Studies\MYV\MYV102\Analysis\Prod\Progs\TFLs\Fig_EFF_MBL_S_BIN_FP.SAS Date/time of run: 30JUN21 10:23
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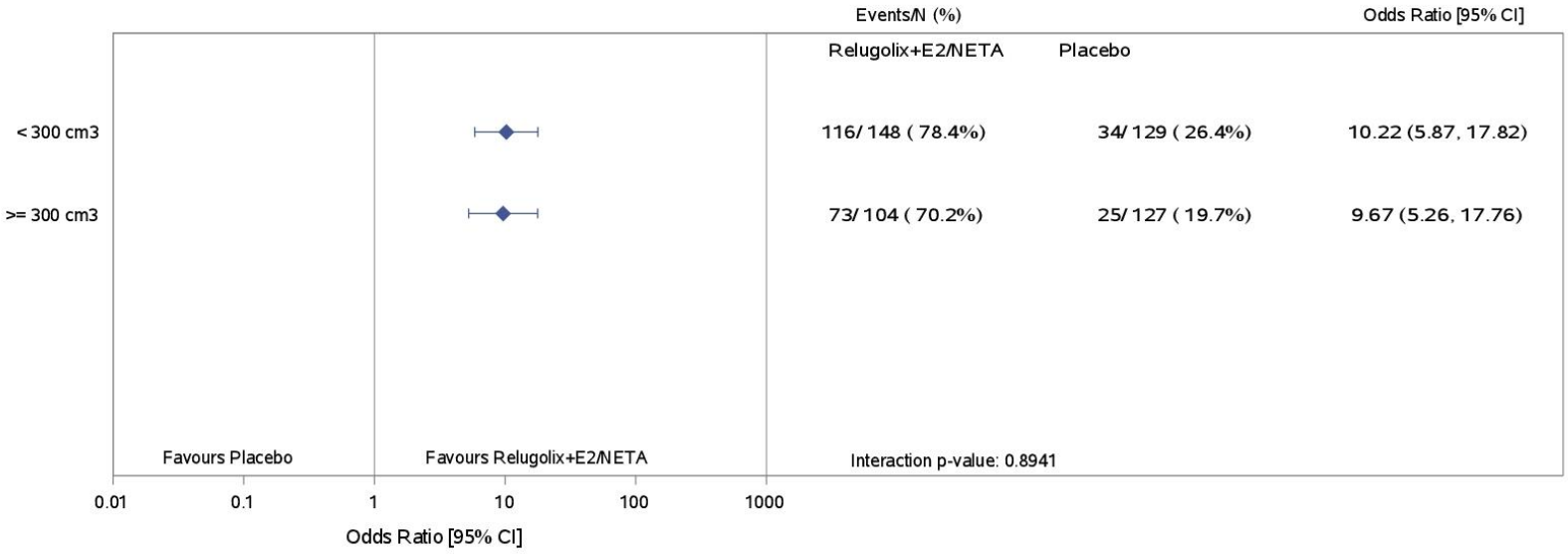
Figure EFF.RL8024ET.MITT.S3.BIN.FP: Proportion of Women in the Relugolix + E2/NETA Group Versus the Placebo Group who Achieve an MBL Volume of < 80 mL Over the Last 35 Days of Treatment, as Measured by the Alkaline Hematin Method, by Subgroup (mITT Population)
Study: Pooled
Subgroup: Uterine Volume at Baseline (cm3)



Results are based on a logistic regression model adjusted for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates using a one-stage fixed-effects IPD meta-analysis approach. A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
The interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the Odds Ratio and 95% CI. Missing subgroup levels are not included in estimation of the interaction p-value. The reference group is Placebo.
N: Number of patients in treatment group; NETA: Norethindrone acetate; mITT: Modified intent-to-treat; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

SOURCE: X:\Numerus\Studies\MYV\MYV102\Analysis\Prod\Progs\TFLs\Fig_EFF_MBL_S_BIN_FP.SAS Date/time of run: 30JUN21 10:23
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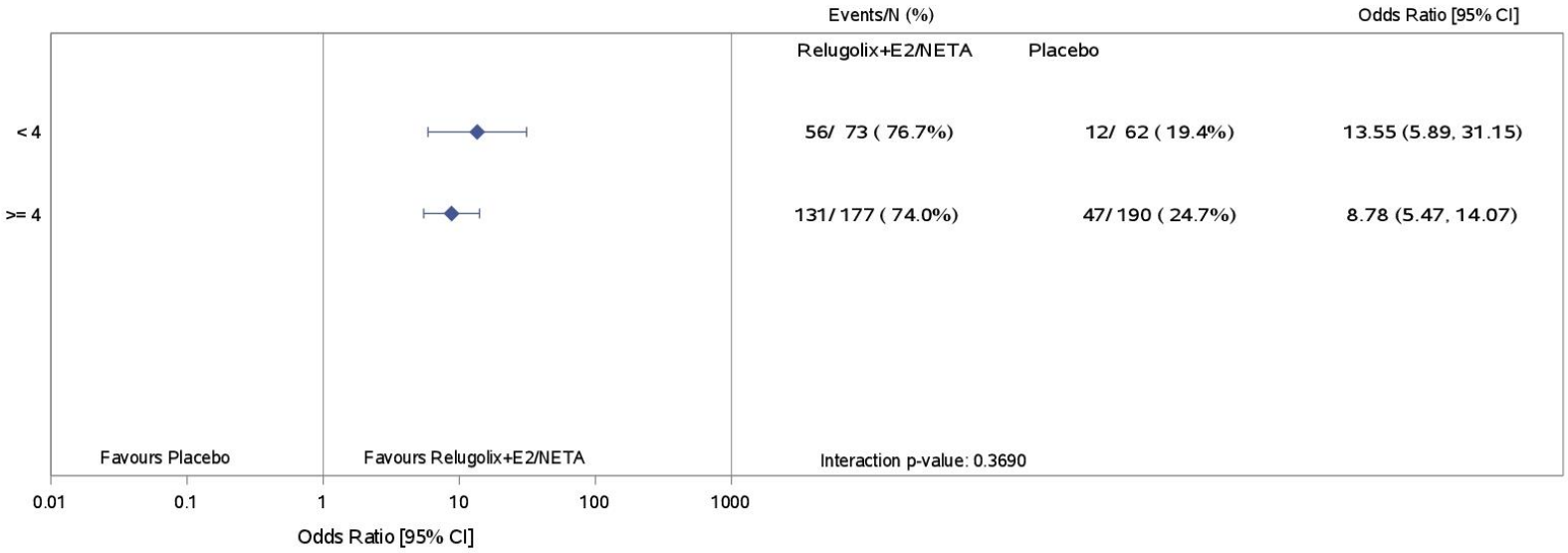
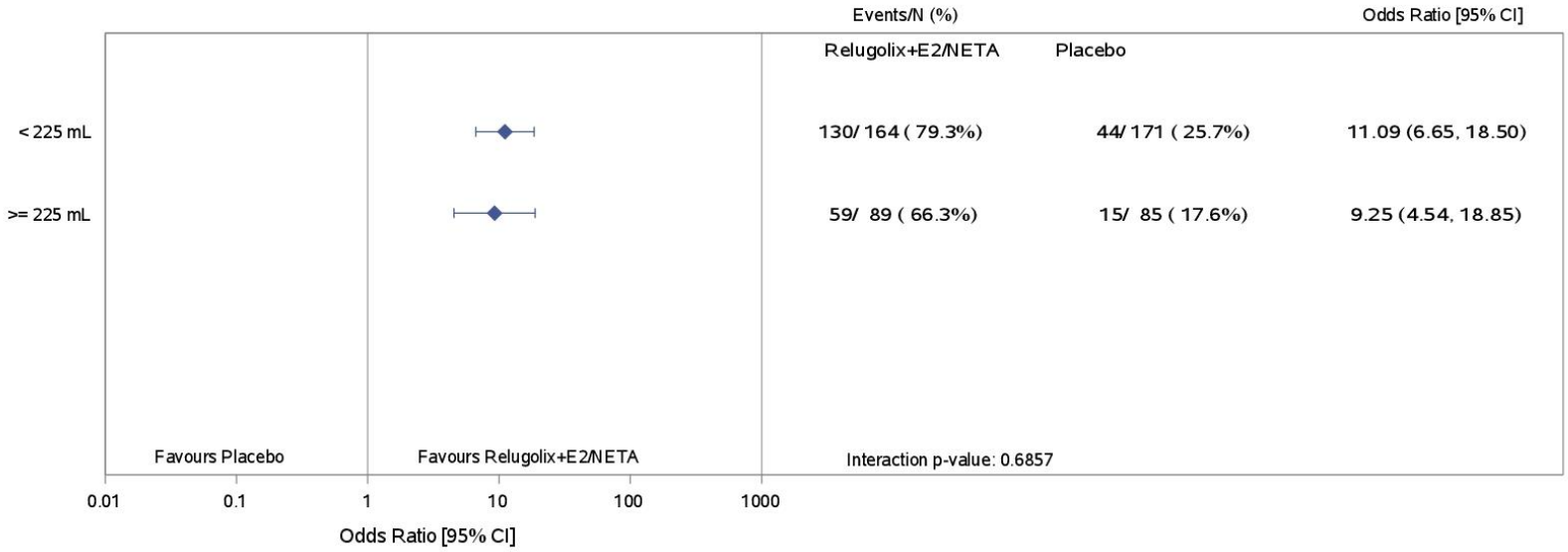
Figure EFF.RL8024ET.MITT.S4.BIN.FP: Proportion of Women in the Relugolix + E2/NETA Group Versus the Placebo Group who Achieve an MBL Volume of < 80 mL Over the Last 35 Days of Treatment, as Measured by the Alkaline Hematin Method, by Subgroup (mITT Population)
Study: Pooled
Subgroup: Maximum NRS Pain Score at Baseline



Results are based on a logistic regression model adjusted for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates using a one-stage fixed-effects IPD meta-analysis approach. A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
The interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the Odds Ratio and 95% CI. Missing subgroup levels are not included in estimation of the interaction p-value. The reference group is Placebo.
N: Number of patients in treatment group; NETA: Norethindrone acetate; mITT: Modified intent-to-treat; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

SOURCE: X:\Numerus\Studies\MYV\MYV102\Analysis\Prod\Progs\TFLs\Fig_EFF_MBL_S_BIN_FP.SAS Date/time of run: 30JUN21 10:23

Figure EFF.RL8024ET.MITT.S5.BIN.FP: Proportion of Women in the Relugolix + E2/NETA Group Versus the Placebo Group who Achieve an MBL Volume of < 80 mL Over the Last 35 Days of Treatment, as Measured by the Alkaline Hematin Method, by Subgroup (mITT Population)
Study: Pooled
Subgroup: MBL Volume at Baseline (mL)



Results are based on a logistic regression model adjusted for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates using a one-stage fixed-effects IPD meta-analysis approach. A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
The interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the Odds Ratio and 95% CI. Missing subgroup levels are not included in estimation of the interaction p-value. The reference group is Placebo.
N: Number of patients in treatment group; NETA: Norethindrone acetate; mITT: Modified intent-to-treat; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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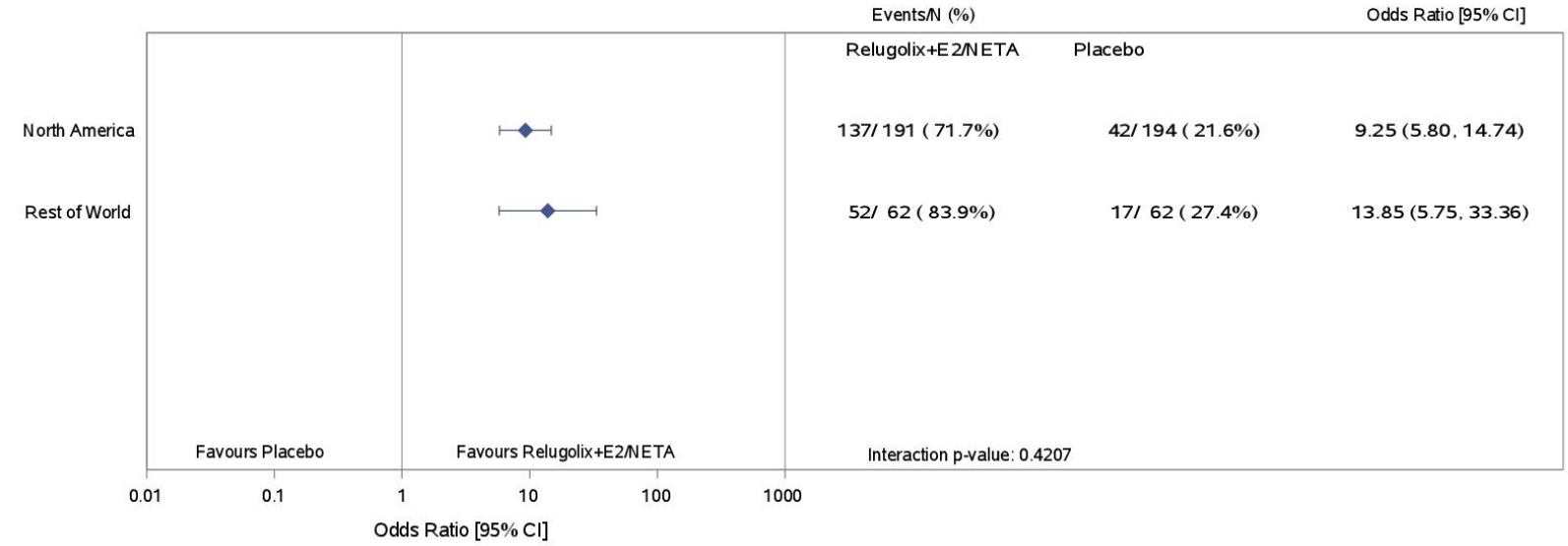
Figure EFF.RL8024ET.MITT.S6.BIN.FP: Proportion of Women in the Relugolix + E2/NETA Group Versus the Placebo Group who Achieve an MBL Volume of < 80 mL Over the Last 35 Days of Treatment, as Measured by the Alkaline Hematin Method, by Subgroup (mITT Population)
Study: Pooled
Subgroup: Geographic Region I



Results are based on a logistic regression model adjusted for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates using a one-stage fixed-effects IPD meta-analysis approach. A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
The interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the Odds Ratio and 95% CI. Missing subgroup levels are not included in estimation of the interaction p-value. The reference group is Placebo.
N: Number of patients in treatment group; NETA: Norethindrone acetate; mITT: Modified intent-to-treat; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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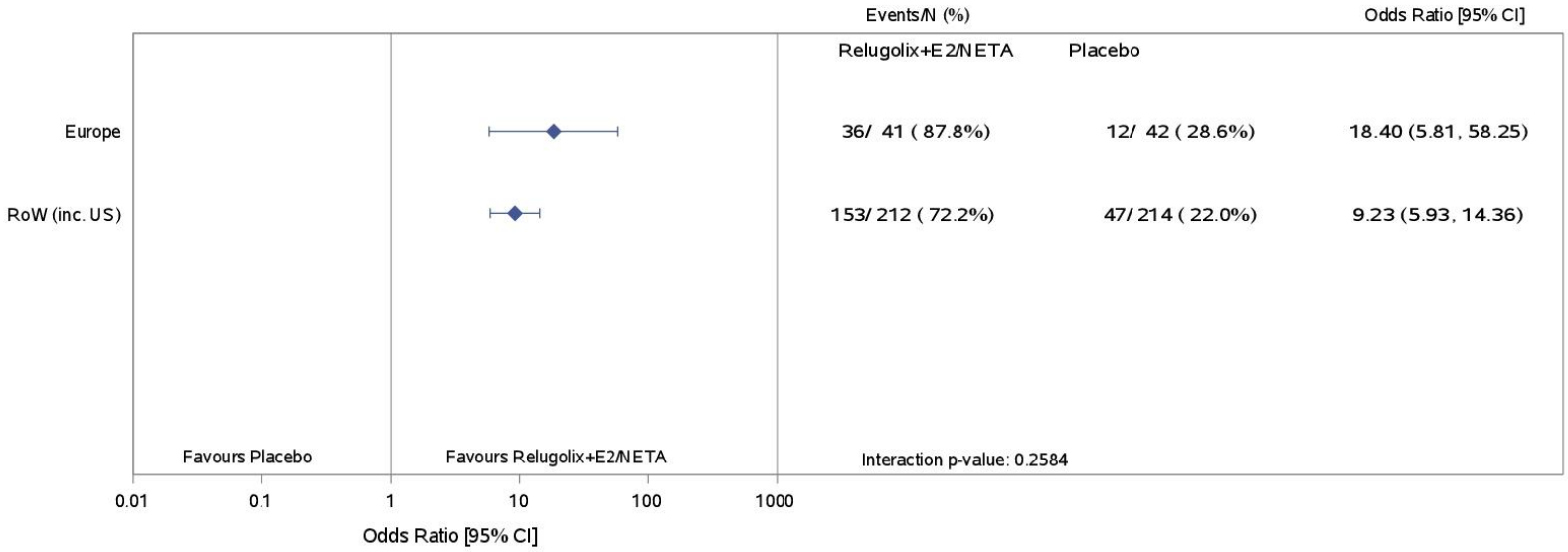
Figure EFF.RL8024ET.MITT.S7.BIN.FP: Proportion of Women in the Relugolix + E2/NETA Group Versus the Placebo Group who Achieve an MBL Volume of < 80 mL Over the Last 35 Days of Treatment, as Measured by the Alkaline Hematin Method, by Subgroup (mITT Population)
Study: Pooled
Subgroup: Geographic Region II



Results are based on a logistic regression model adjusted for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates using a one-stage fixed-effects IPD meta-analysis approach. A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
The interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the Odds Ratio and 95% CI. Missing subgroup levels are not included in estimation of the interaction p-value. The reference group is Placebo.
N: Number of patients in treatment group; NETA: Norethindrone acetate; mITT: Modified intent-to-treat; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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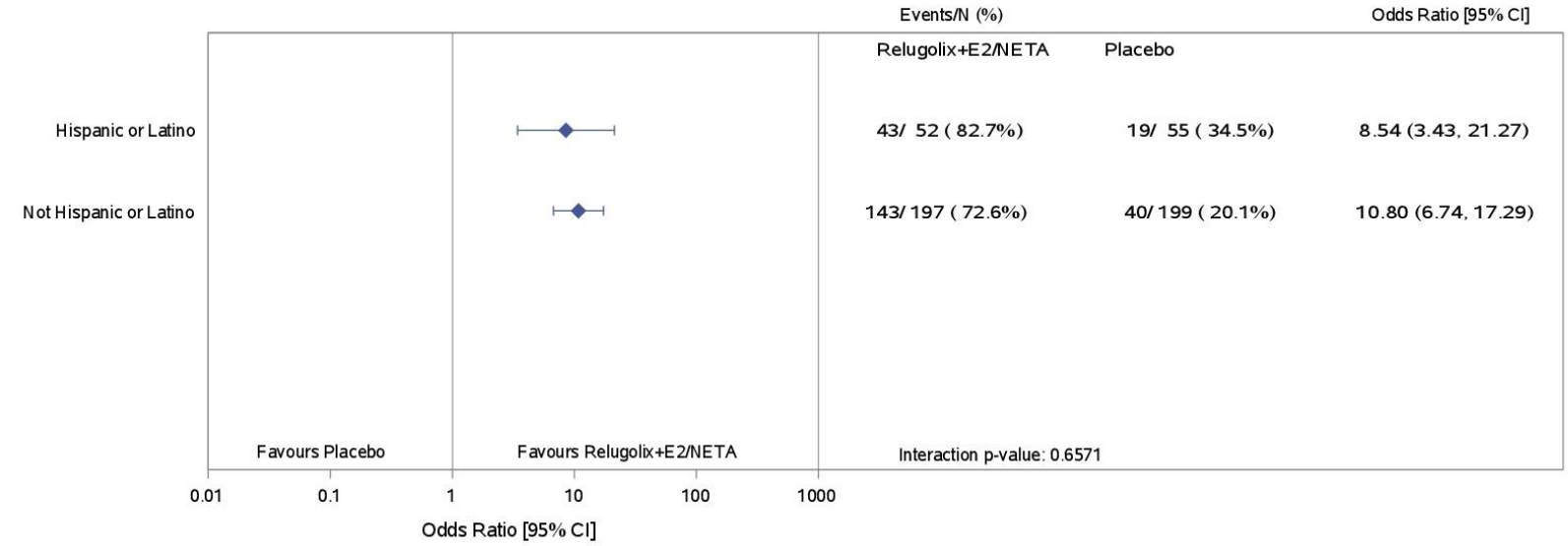
Figure EFF.RL8024ET.MITT.S8.BIN.FP: Proportion of Women in the Relugolix + E2/NETA Group Versus the Placebo Group who Achieve an MBL Volume of < 80 mL Over the Last 35 Days of Treatment, as Measured by the Alkaline Hematin Method, by Subgroup (mITT Population)
Study: Pooled
Subgroup: Ethnicity



Results are based on a logistic regression model adjusted for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates using a one-stage fixed-effects IPD meta-analysis approach. A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
The interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the Odds Ratio and 95% CI. Missing subgroup levels are not included in estimation of the interaction p-value. The reference group is Placebo.
N: Number of patients in treatment group; NETA: Norethindrone acetate; mITT: Modified intent-to-treat; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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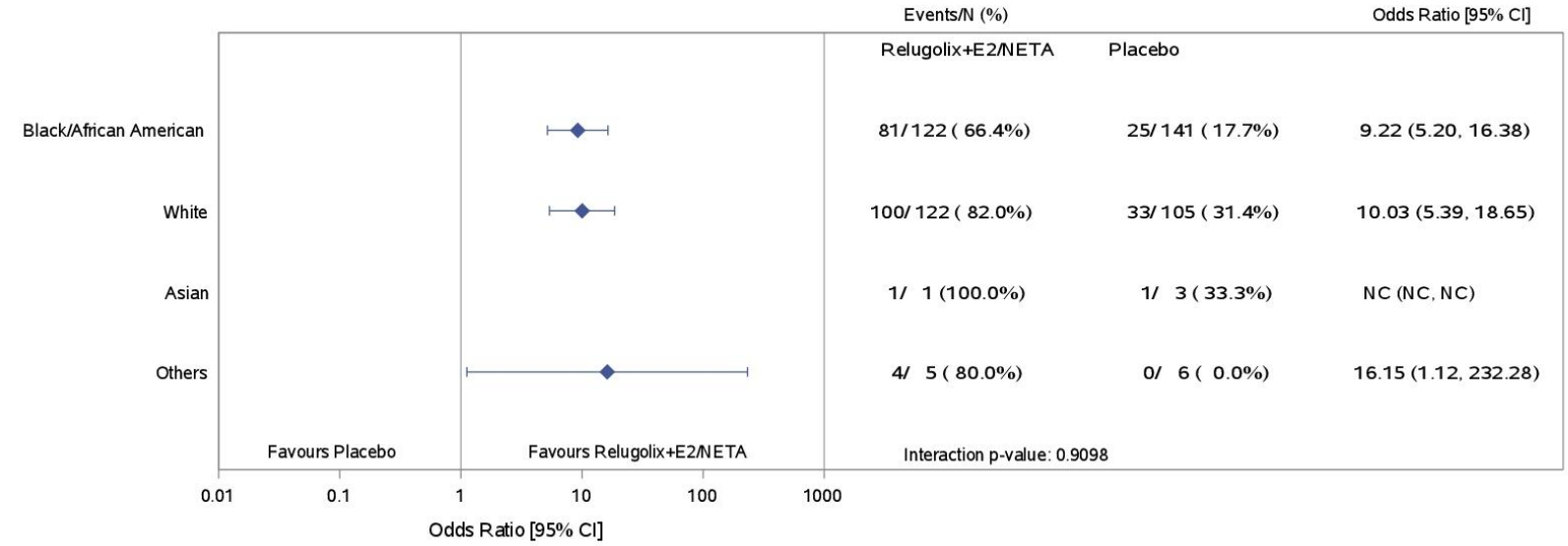
Figure EFF.RL8024ET.MITT.S9.BIN.FP: Proportion of Women in the Relugolix + E2/NETA Group Versus the Placebo Group who Achieve an MBL Volume of < 80 mL Over the Last 35 Days of Treatment, as Measured by the Alkaline Hematin Method, by Subgroup (mITT Population)
Study: Pooled
Subgroup: Race



Results are based on a logistic regression model adjusted for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates using a one-stage fixed-effects IPD meta-analysis approach. A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
The interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the Odds Ratio and 95% CI. Missing subgroup levels are not included in estimation of the interaction p-value. The reference group is Placebo.
N: Number of patients in treatment group; NETA: Norethindrone acetate; mITT: Modified intent-to-treat; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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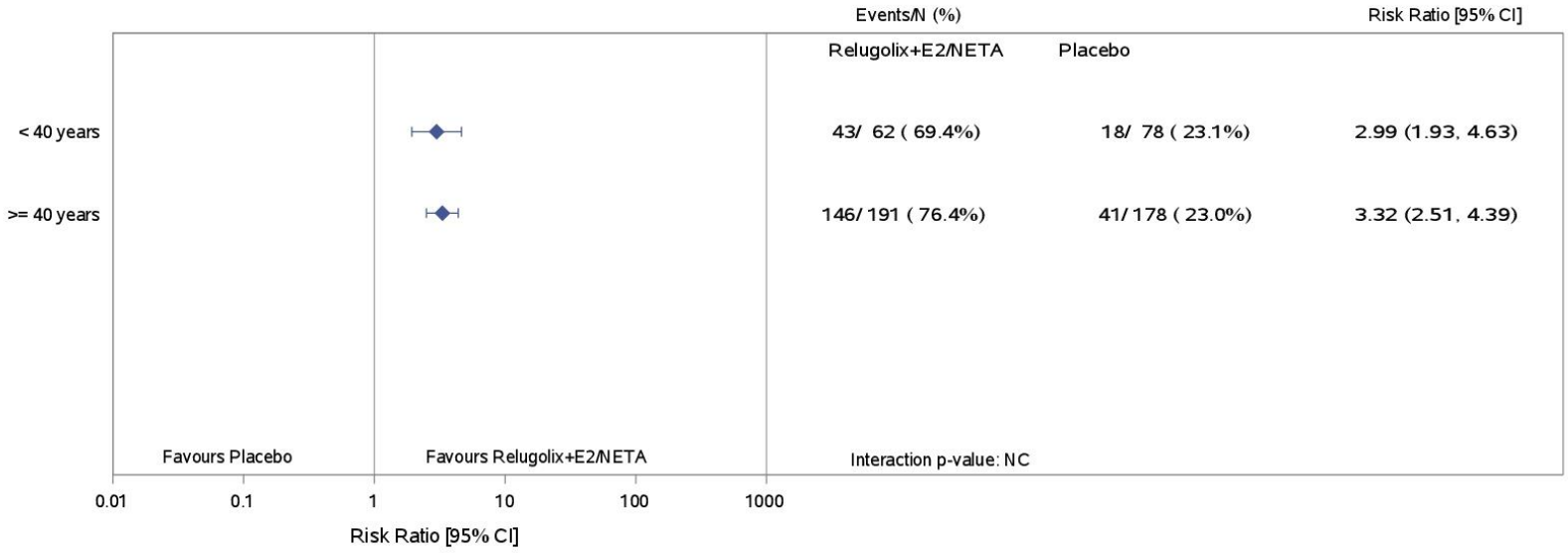
Figure EFF.RL8024ET.MITT.S1.BIN.FP.RR: Proportion of Women in the Relugolix + E2/NETA Group Versus the Placebo Group who Achieve an MBL Volume of < 80 mL Over the Last 35 Days of Treatment, as Measured by the Alkaline Hematin Method, by Subgroup (mITT Population) - Risk Ratio
Study: Pooled
Subgroup: Age (years)



Results are based on a Cochran-Mantel-Haenszel approach stratified by study using a one-stage fixed-effects IPD meta-analysis. A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
The reference group is Placebo.
N: Number of patients in treatment group; NETA: Norethindrone acetate; mITT: Modified intent-to-treat; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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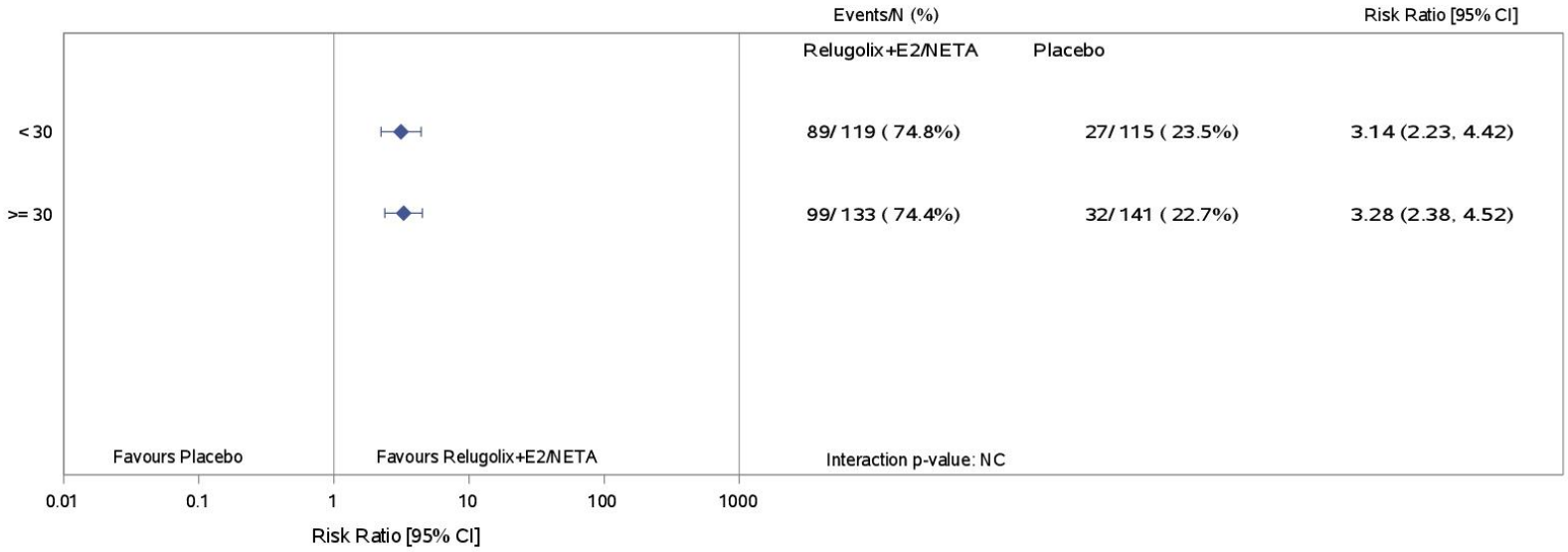
Figure EFF.RL8024ET.MITT.S2.BIN.FP.RR: Proportion of Women in the Relugolix + E2/NETA Group Versus the Placebo Group who Achieve an MBL Volume of < 80 mL Over the Last 35 Days of Treatment, as Measured by the Alkaline Hematin Method, by Subgroup (mITT Population) - Risk Ratio
Study: Pooled
Subgroup: BMI (kg/m2) at Baseline



Results are based on a Cochran-Mantel-Haenszel approach stratified by study using a one-stage fixed-effects IPD meta-analysis. A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
The reference group is Placebo.
N: Number of patients in treatment group; NETA: Norethindrone acetate; mITT: Modified intent-to-treat; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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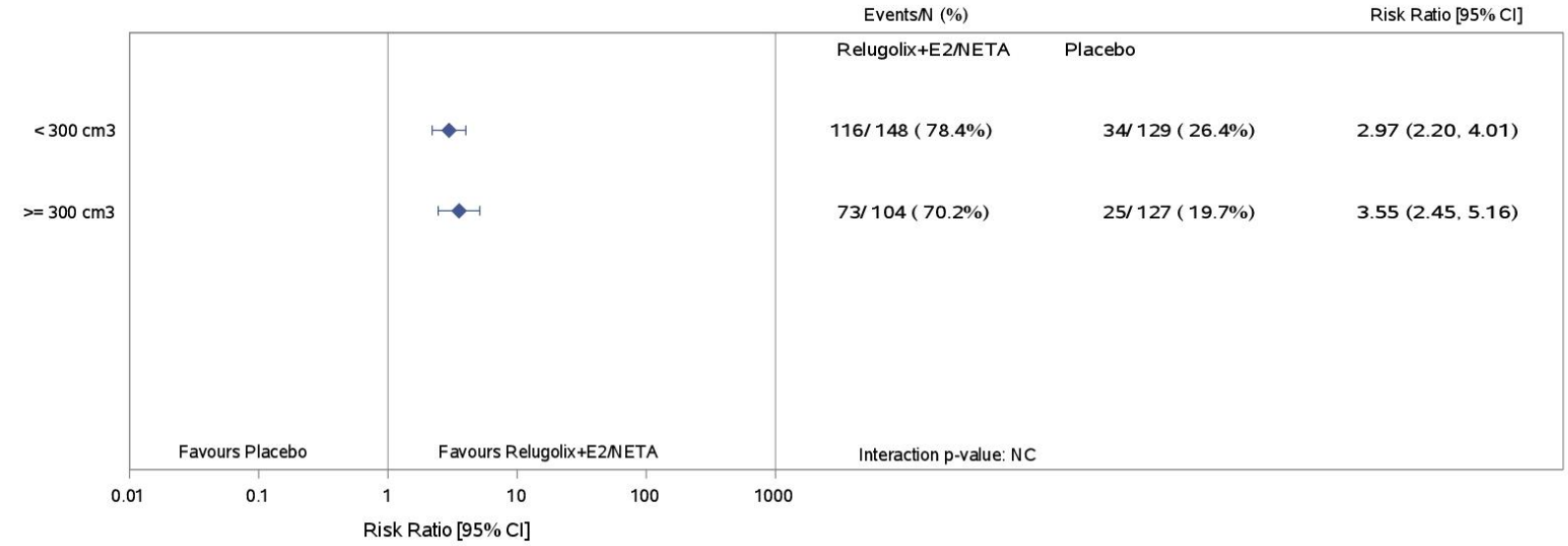
Figure EFF.RL8024ET.MITT.S3.BIN.FP.RR: Proportion of Women in the Relugolix + E2/NETA Group Versus the Placebo Group who Achieve an MBL Volume of < 80 mL Over the Last 35 Days of Treatment, as Measured by the Alkaline Hematin Method, by Subgroup (mITT Population) - Risk Ratio
Study: Pooled
Subgroup: Uterine Volume at Baseline (cm3)



Results are based on a Cochran-Mantel-Haenszel approach stratified by study using a one-stage fixed-effects IPD meta-analysis. A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
The reference group is Placebo.
N: Number of patients in treatment group; NETA: Norethindrone acetate; mITT: Modified intent-to-treat; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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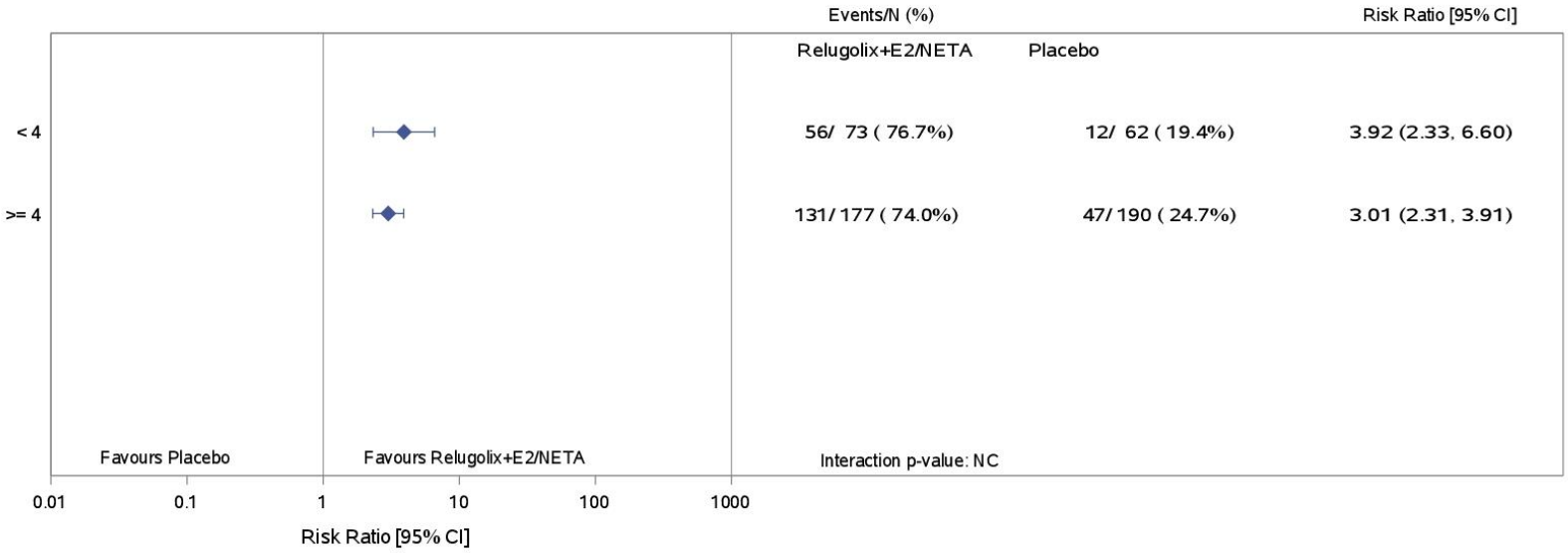
Figure EFF.RL8024ET.MITT.S4.BIN.FP.RR: Proportion of Women in the Relugolix + E2/NETA Group Versus the Placebo Group who Achieve an MBL Volume of < 80 mL Over the Last 35 Days of Treatment, as Measured by the Alkaline Hematin Method, by Subgroup (mITT Population) - Risk Ratio
Study: Pooled
Subgroup: Maximum NRS Pain Score at Baseline



Results are based on a Cochran-Mantel-Haenszel approach stratified by study using a one-stage fixed-effects IPD meta-analysis. A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
The reference group is Placebo.
N: Number of patients in treatment group; NETA: Norethindrone acetate; mITT: Modified intent-to-treat; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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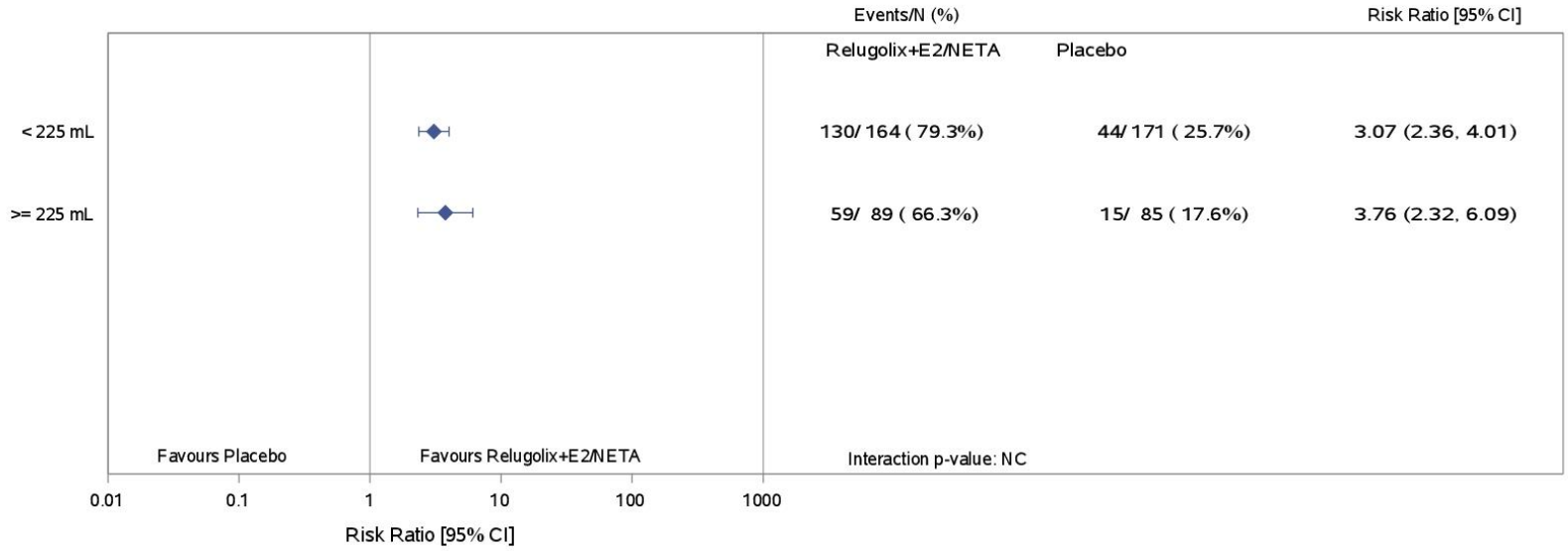
Figure EFF.RL8024ET.MITT.S5.BIN.FP.RR: Proportion of Women in the Relugolix + E2/NETA Group Versus the Placebo Group who Achieve an MBL Volume of < 80 mL Over the Last 35 Days of Treatment, as Measured by the Alkaline Hematin Method, by Subgroup (mITT Population) - Risk Ratio
Study: Pooled
Subgroup: MBL Volume at Baseline (mL)



Results are based on a Cochran-Mantel-Haenszel approach stratified by study using a one-stage fixed-effects IPD meta-analysis. A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
The reference group is Placebo.
N: Number of patients in treatment group; NETA: Norethindrone acetate; mITT: Modified intent-to-treat; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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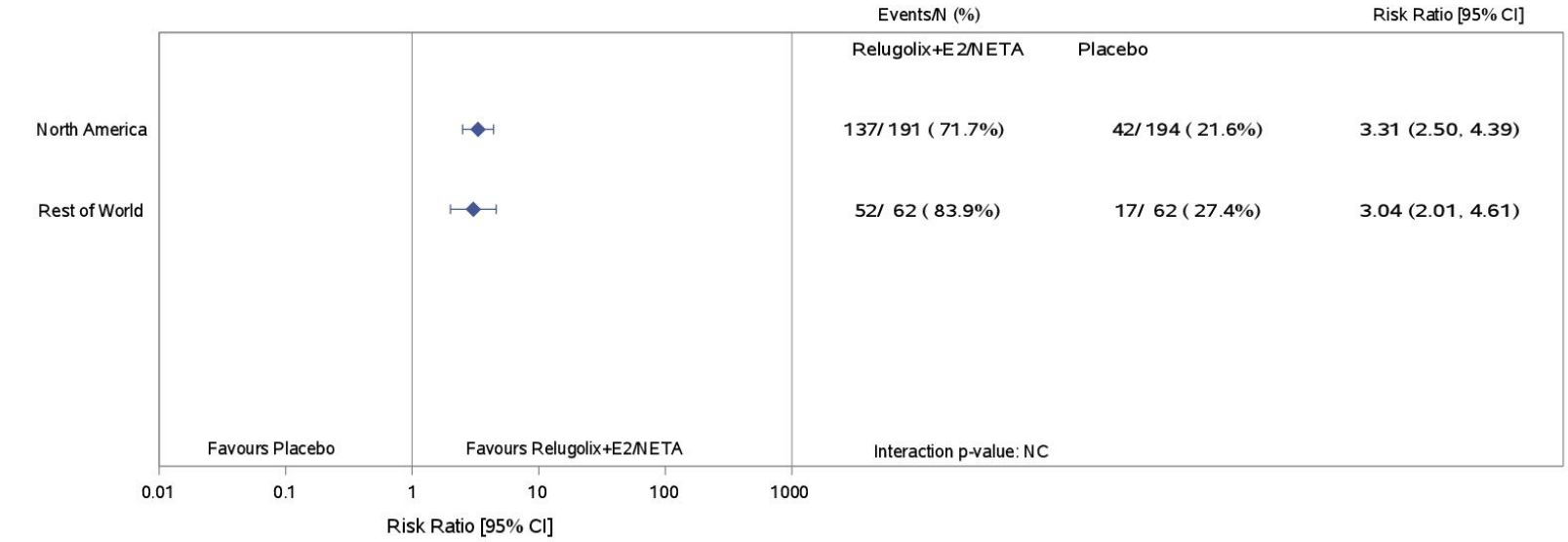
Figure EFF.RL8024ET.MITT.S6.BIN.FP.RR: Proportion of Women in the Relugolix + E2/NETA Group Versus the Placebo Group who Achieve an MBL Volume of < 80 mL Over the Last 35 Days of Treatment, as Measured by the Alkaline Hematin Method, by Subgroup (mITT Population) - Risk Ratio
Study: Pooled
Subgroup: Geographic Region I



Results are based on a Cochran-Mantel-Haenszel approach stratified by study using a one-stage fixed-effects IPD meta-analysis. A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
The reference group is Placebo.
N: Number of patients in treatment group; NETA: Norethindrone acetate; mITT: Modified intent-to-treat; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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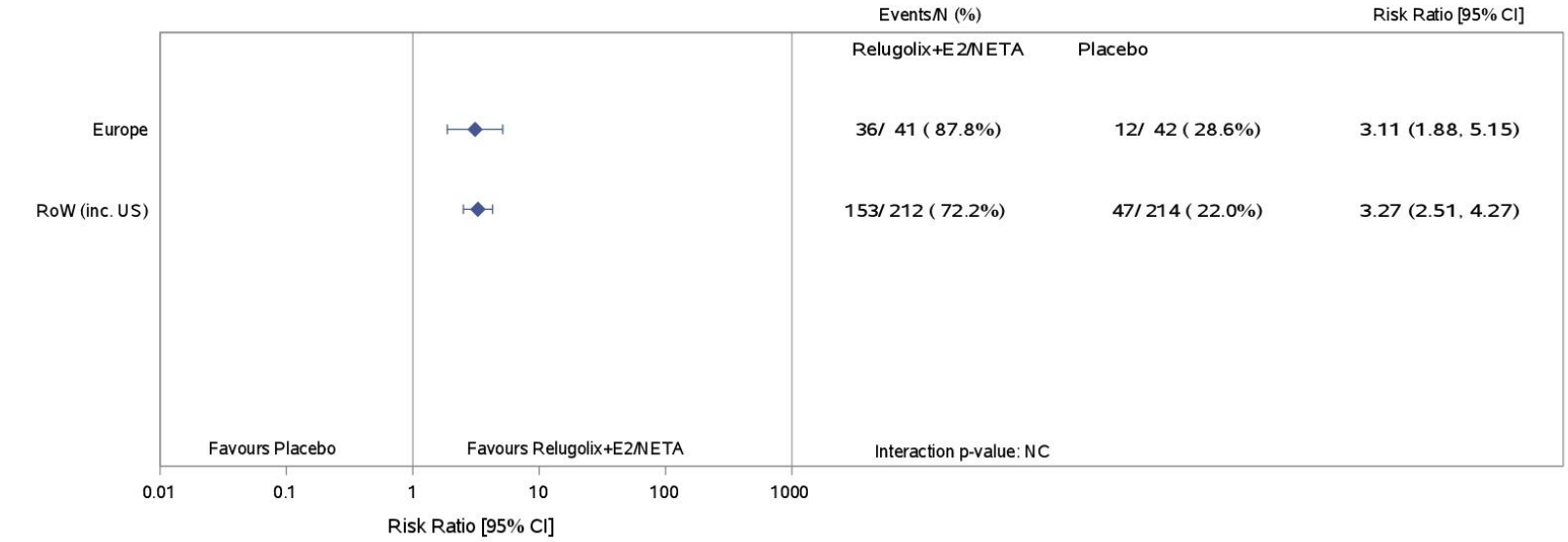
Figure EFF.RL8024ET.MITT.S7.BIN.FP.RR: Proportion of Women in the Relugolix + E2/NETA Group Versus the Placebo Group who Achieve an MBL Volume of < 80 mL Over the Last 35 Days of Treatment, as Measured by the Alkaline Hematin Method, by Subgroup (mITT Population) - Risk Ratio
Study: Pooled
Subgroup: Geographic Region II



Results are based on a Cochran-Mantel-Haenszel approach stratified by study using a one-stage fixed-effects IPD meta-analysis. A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
The reference group is Placebo.
N: Number of patients in treatment group; NETA: Norethindrone acetate; mITT: Modified intent-to-treat; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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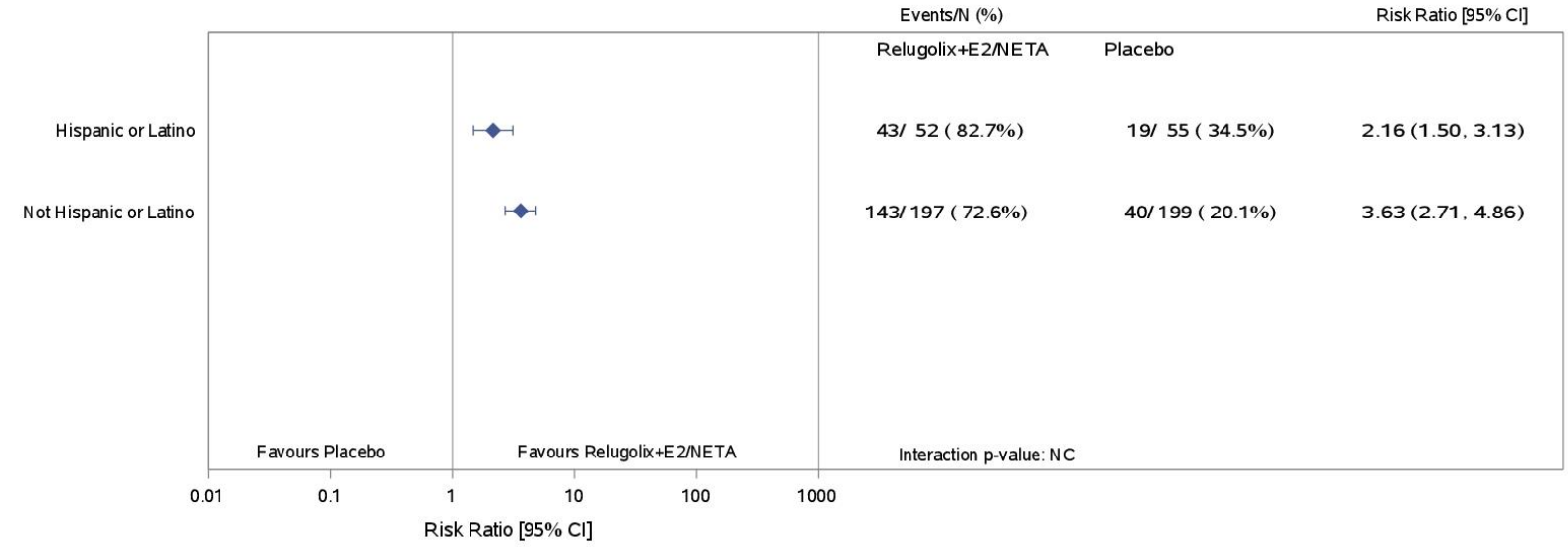
Figure EFF.RL8024ET.MITT.S8.BIN.FP.RR: Proportion of Women in the Relugolix + E2/NETA Group Versus the Placebo Group who Achieve an MBL Volume of < 80 mL Over the Last 35 Days of Treatment, as Measured by the Alkaline Hematin Method, by Subgroup (mITT Population) - Risk Ratio
Study: Pooled
Subgroup: Ethnicity



Results are based on a Cochran-Mantel-Haenszel approach stratified by study using a one-stage fixed-effects IPD meta-analysis. A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
The reference group is Placebo.
N: Number of patients in treatment group; NETA: Norethindrone acetate; mITT: Modified intent-to-treat; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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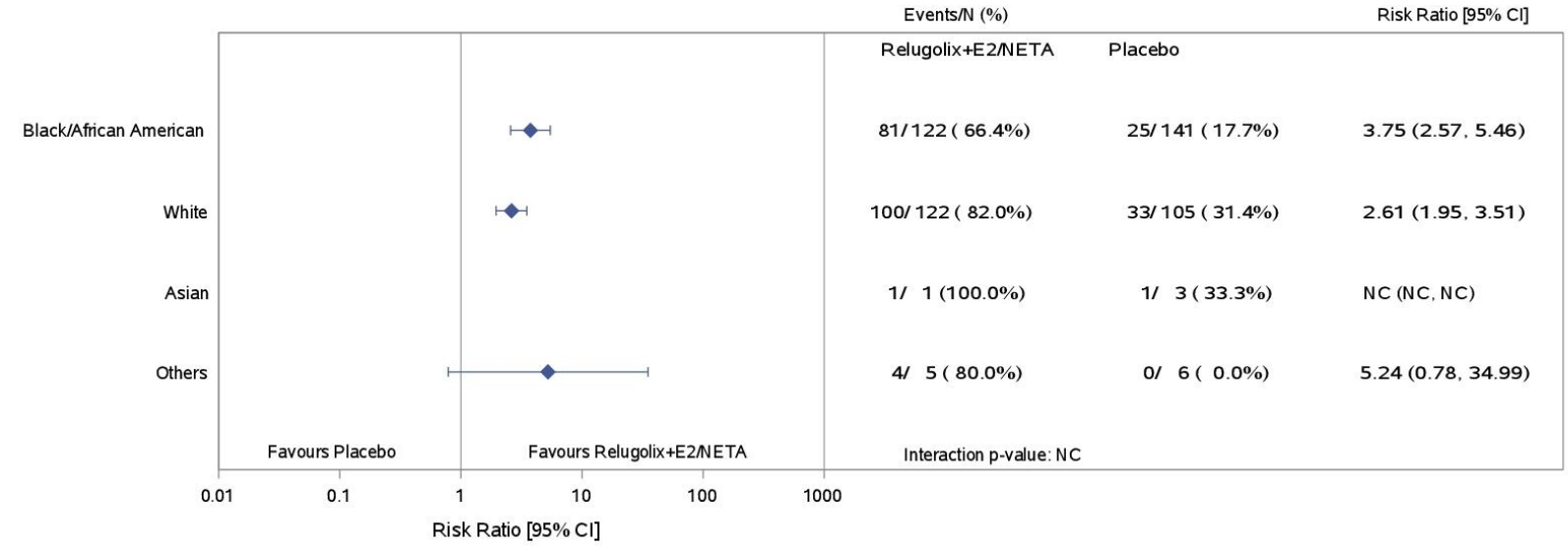
Figure EFF.RL8024ET.MITT.S9.BIN.FP.RR: Proportion of Women in the Relugolix + E2/NETA Group Versus the Placebo Group who Achieve an MBL Volume of < 80 mL Over the Last 35 Days of Treatment, as Measured by the Alkaline Hematin Method, by Subgroup (mITT Population) - Risk Ratio
Study: Pooled
Subgroup: Race



Results are based on a Cochran-Mantel-Haenszel approach stratified by study using a one-stage fixed-effects IPD meta-analysis. A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
The reference group is Placebo.
N: Number of patients in treatment group; NETA: Norethindrone acetate; mITT: Modified intent-to-treat; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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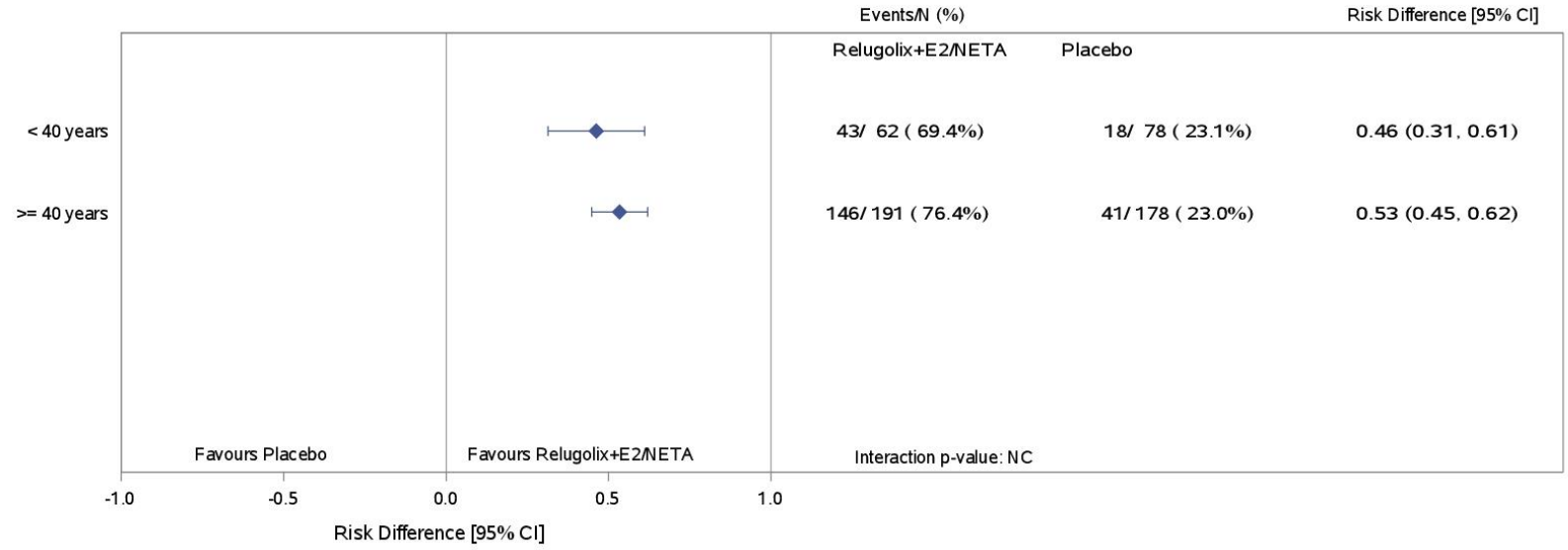
Figure EFF.RL8024ET.MITT.S1.BIN.FP.RD: Proportion of Women in the Relugolix + E2/NETA Group Versus the Placebo Group who Achieve an MBL Volume of < 80 mL Over the Last 35 Days of Treatment, as Measured by the Alkaline Hematin Method, by Subgroup (mITT Population) - Risk Difference
Study: Pooled
Subgroup: Age (years)



Results are based on a Mantel-Haenszel approach stratified by study using a one-stage fixed-effects IPD meta-analysis.
The reference group is Placebo.
N: Number of patients in treatment group; NETA: Norethindrone acetate; mITT: Modified intent-to-treat; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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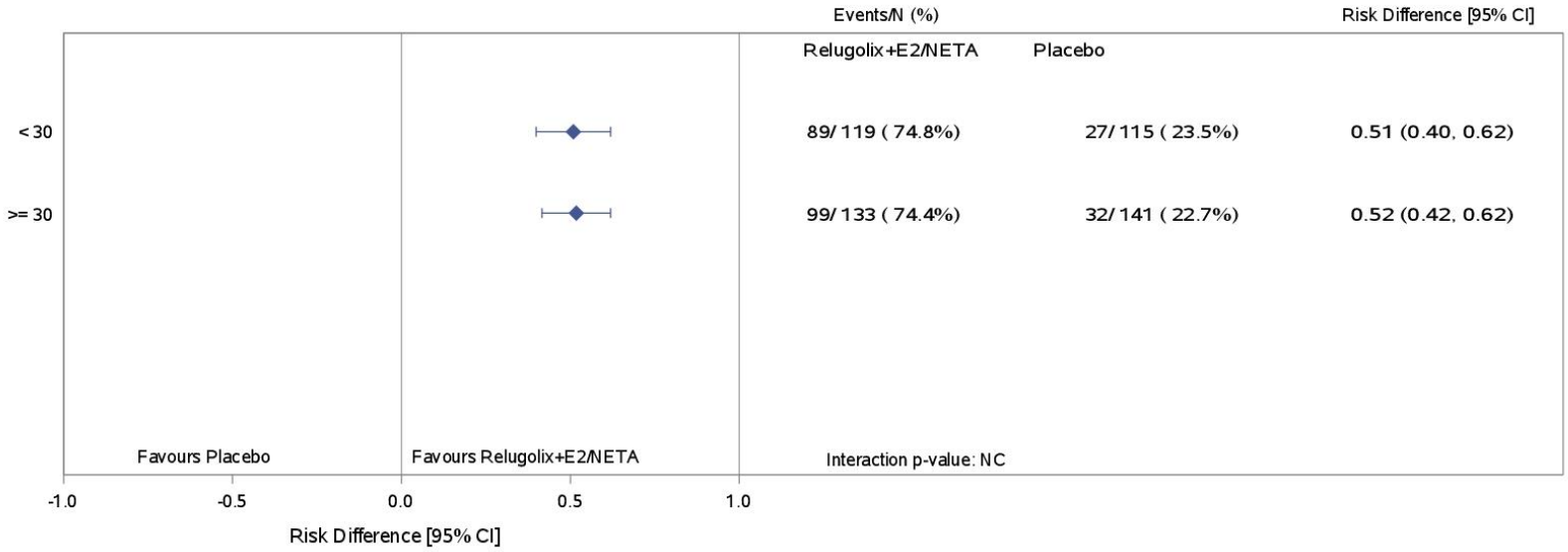
Figure EFF.RL8024ET.MITT.S2.BIN.FP.RD: Proportion of Women in the Relugolix + E2/NETA Group Versus the Placebo Group who Achieve an MBL Volume of < 80 mL Over the Last 35 Days of Treatment, as Measured by the Alkaline Hematin Method, by Subgroup (mITT Population) - Risk Difference
Study: Pooled
Subgroup: BMI (kg/m2) at Baseline



Results are based on a Mantel-Haenszel approach stratified by study using a one-stage fixed-effects IPD meta-analysis.
The reference group is Placebo.
N: Number of patients in treatment group; NETA: Norethindrone acetate; mITT: Modified intent-to-treat; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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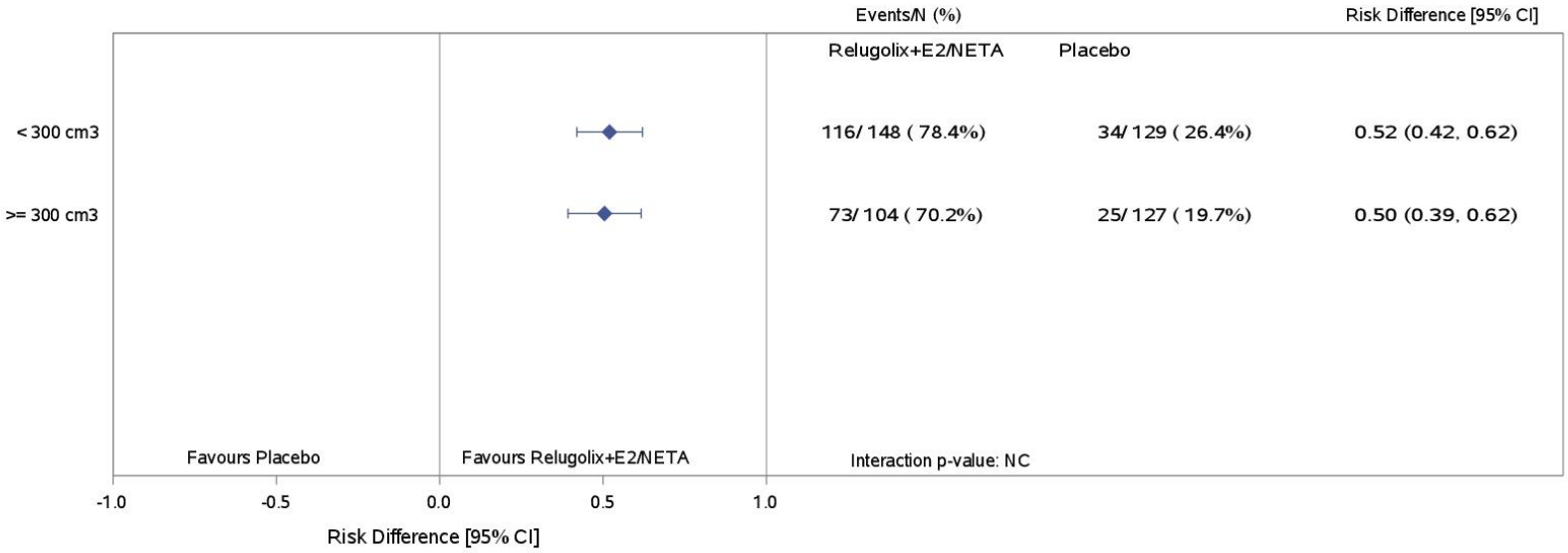
Figure EFF.RL8024ET.MITT.S3.BIN.FP.RD: Proportion of Women in the Relugolix + E2/NETA Group Versus the Placebo Group who Achieve an MBL Volume of < 80 mL Over the Last 35 Days of Treatment, as Measured by the Alkaline Hematin Method, by Subgroup (mITT Population) - Risk Difference
Study: Pooled
Subgroup: Uterine Volume at Baseline (cm3)



Results are based on a Mantel-Haenszel approach stratified by study using a one-stage fixed-effects IPD meta-analysis.
The reference group is Placebo.
N: Number of patients in treatment group; NETA: Norethindrone acetate; mITT: Modified intent-to-treat; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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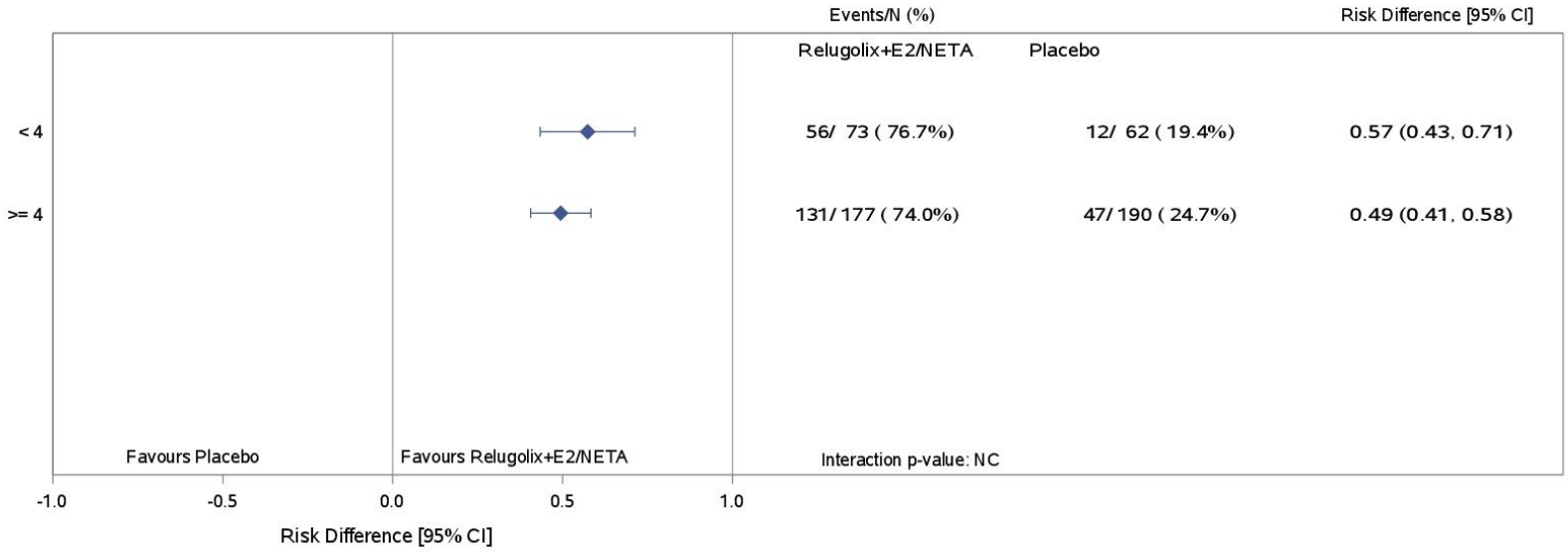
Figure EFF.RL8024ET.MITT.S4.BIN.FP.RD: Proportion of Women in the Relugolix + E2/NETA Group Versus the Placebo Group who Achieve an MBL Volume of < 80 mL Over the Last 35 Days of Treatment, as Measured by the Alkaline Hematin Method, by Subgroup (mITT Population) - Risk Difference
Study: Pooled
Subgroup: Maximum NRS Pain Score at Baseline



Results are based on a Mantel-Haenszel approach stratified by study using a one-stage fixed-effects IPD meta-analysis.
The reference group is Placebo.
N: Number of patients in treatment group; NETA: Norethindrone acetate; mITT: Modified intent-to-treat; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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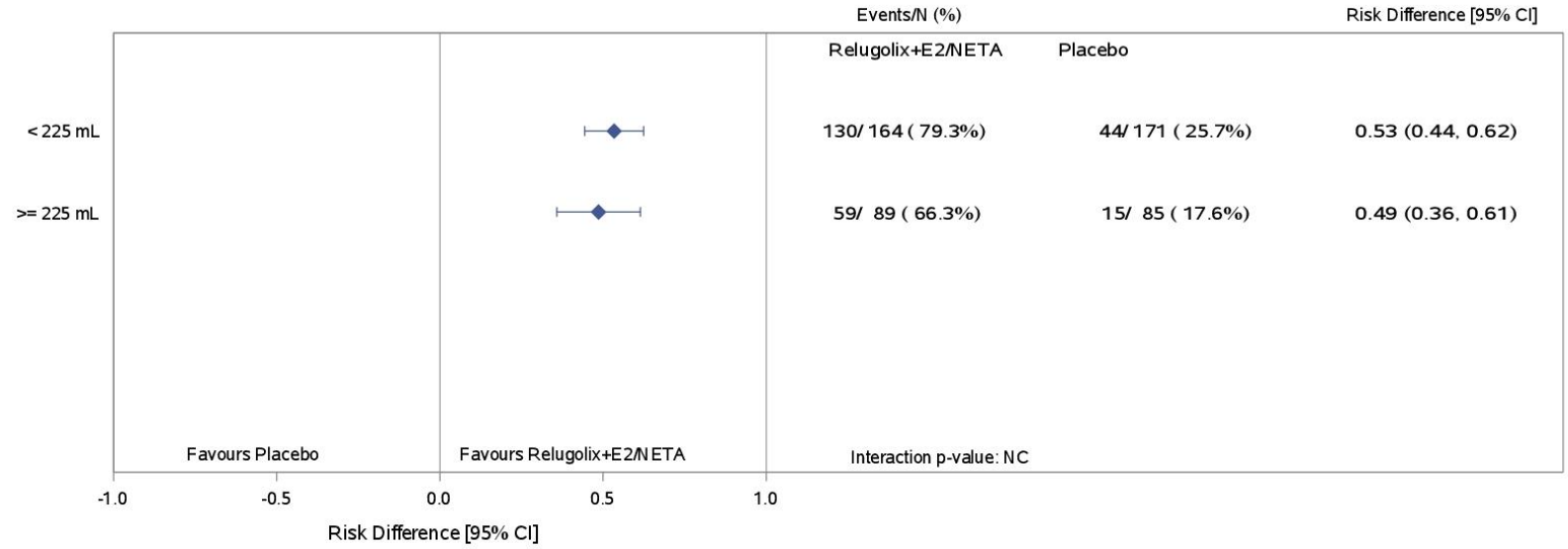
Figure EFF.RL8024ET.MITT.S5.BIN.FP.RD: Proportion of Women in the Relugolix + E2/NETA Group Versus the Placebo Group who Achieve an MBL Volume of < 80 mL Over the Last 35 Days of Treatment, as Measured by the Alkaline Hematin Method, by Subgroup (mITT Population) - Risk Difference
Study: Pooled
Subgroup: MBL Volume at Baseline (mL)



Results are based on a Mantel-Haenszel approach stratified by study using a one-stage fixed-effects IPD meta-analysis.
The reference group is Placebo.
N: Number of patients in treatment group; NETA: Norethindrone acetate; mITT: Modified intent-to-treat; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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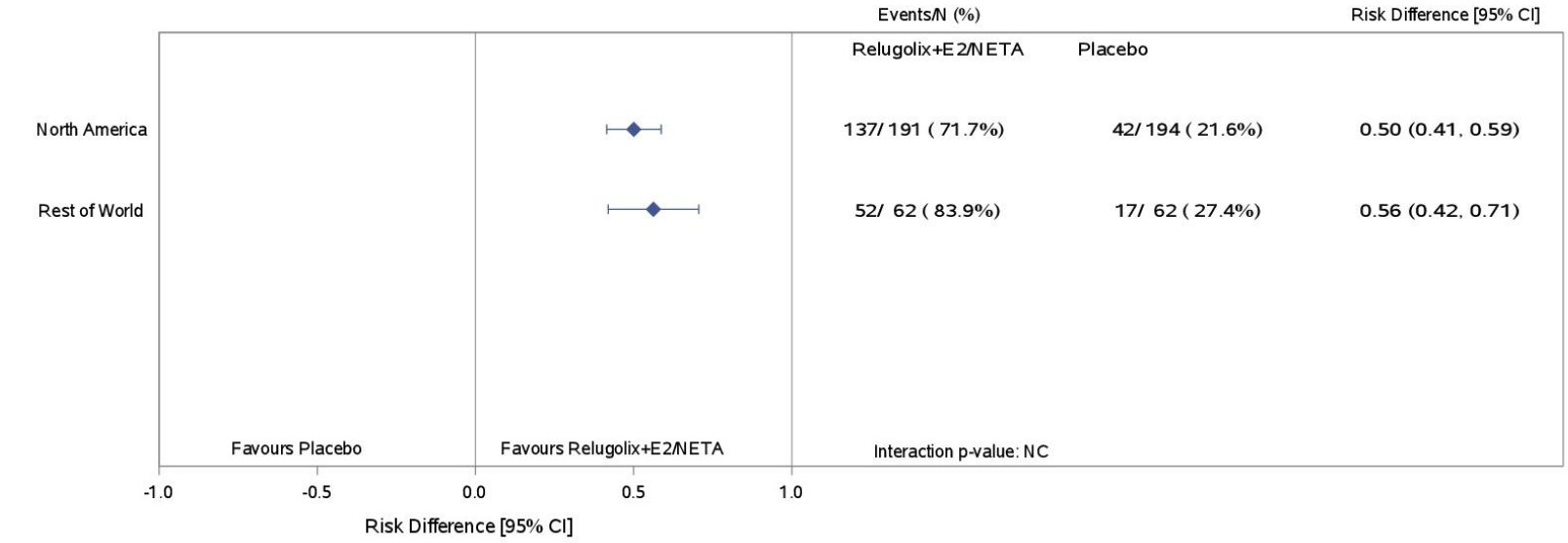
Figure EFF.RL8024ET.MITT.S6.BIN.FP.RD: Proportion of Women in the Relugolix + E2/NETA Group Versus the Placebo Group who Achieve an MBL Volume of < 80 mL Over the Last 35 Days of Treatment, as Measured by the Alkaline Hematin Method, by Subgroup (mITT Population) - Risk Difference
Study: Pooled
Subgroup: Geographic Region I



Results are based on a Mantel-Haenszel approach stratified by study using a one-stage fixed-effects IPD meta-analysis.
The reference group is Placebo.
N: Number of patients in treatment group; NETA: Norethindrone acetate; mITT: Modified intent-to-treat; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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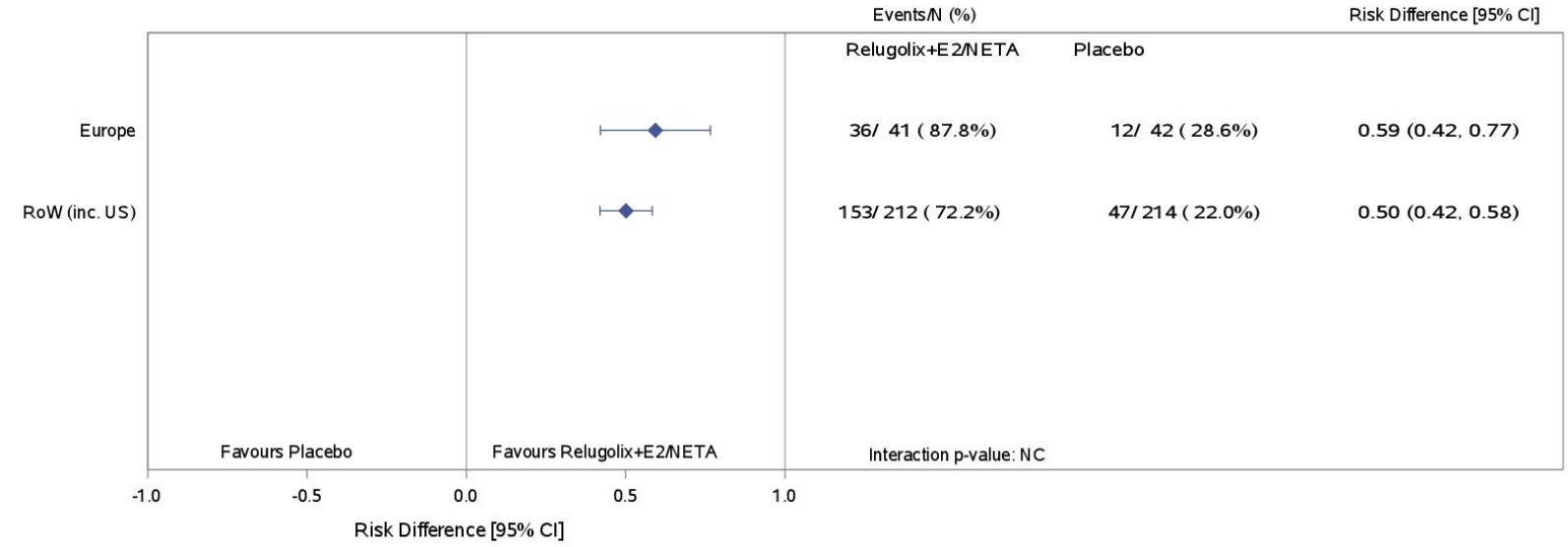
Figure EFF.RL8024ET.MITT.S7.BIN.FP.RD: Proportion of Women in the Relugolix + E2/NETA Group Versus the Placebo Group who Achieve an MBL Volume of < 80 mL Over the Last 35 Days of Treatment, as Measured by the Alkaline Hematin Method, by Subgroup (mITT Population) - Risk Difference
Study: Pooled
Subgroup: Geographic Region II



Results are based on a Mantel-Haenszel approach stratified by study using a one-stage fixed-effects IPD meta-analysis.
The reference group is Placebo.
N: Number of patients in treatment group; NETA: Norethindrone acetate; mITT: Modified intent-to-treat; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

SOURCE: X:\Numerus\Studies\MYV\MYV102\Analysis\Prod\Progs\TFLs\Fig_EFF_MBL_S_BIN_FP.SAS Date/time of run: 30JUN21 10:23
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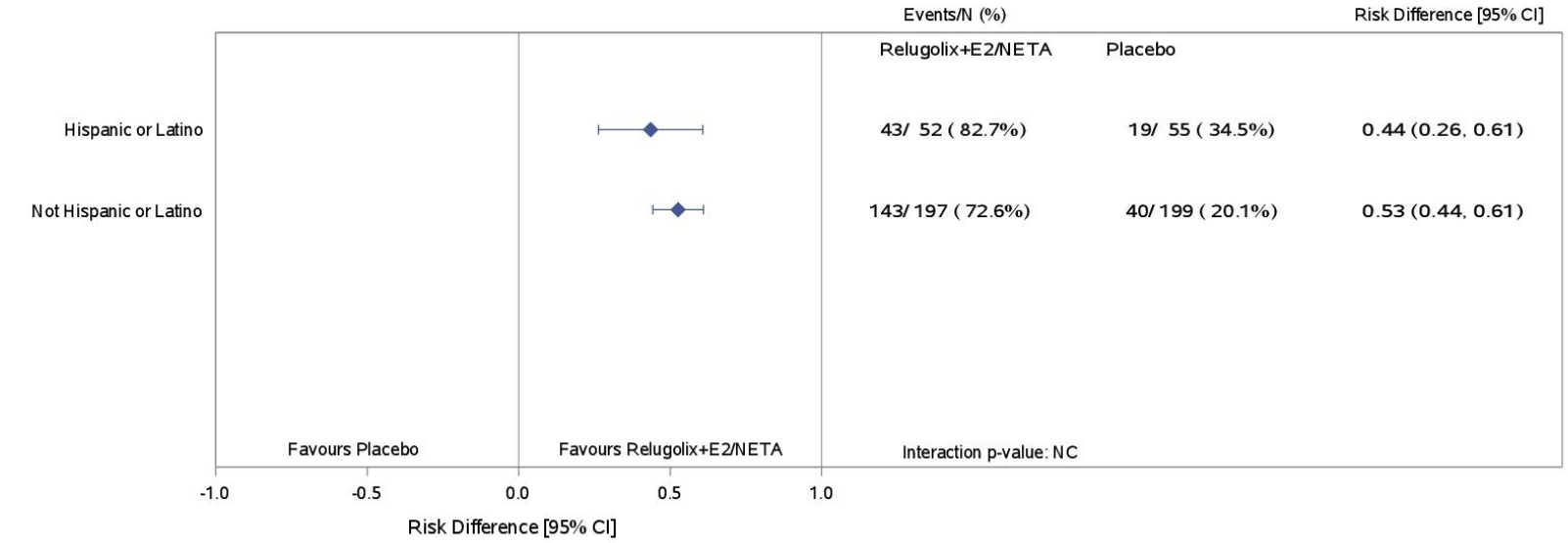
Figure EFF.RL8024ET.MITT.S8.BIN.FP.RD: Proportion of Women in the Relugolix + E2/NETA Group Versus the Placebo Group who Achieve an MBL Volume of < 80 mL Over the Last 35 Days of Treatment, as Measured by the Alkaline Hematin Method, by Subgroup (mITT Population) - Risk Difference
Study: Pooled
Subgroup: Ethnicity



Results are based on a Mantel-Haenszel approach stratified by study using a one-stage fixed-effects IPD meta-analysis.
The reference group is Placebo.
N: Number of patients in treatment group; NETA: Norethindrone acetate; mITT: Modified intent-to-treat; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

SOURCE: X:\Numerus\Studies\MYV\MYV102\Analysis\Prod\Progs\TFLs\Fig_EFF_MBL_S_BIN_FP.SAS Date/time of run: 30JUN21 10:23
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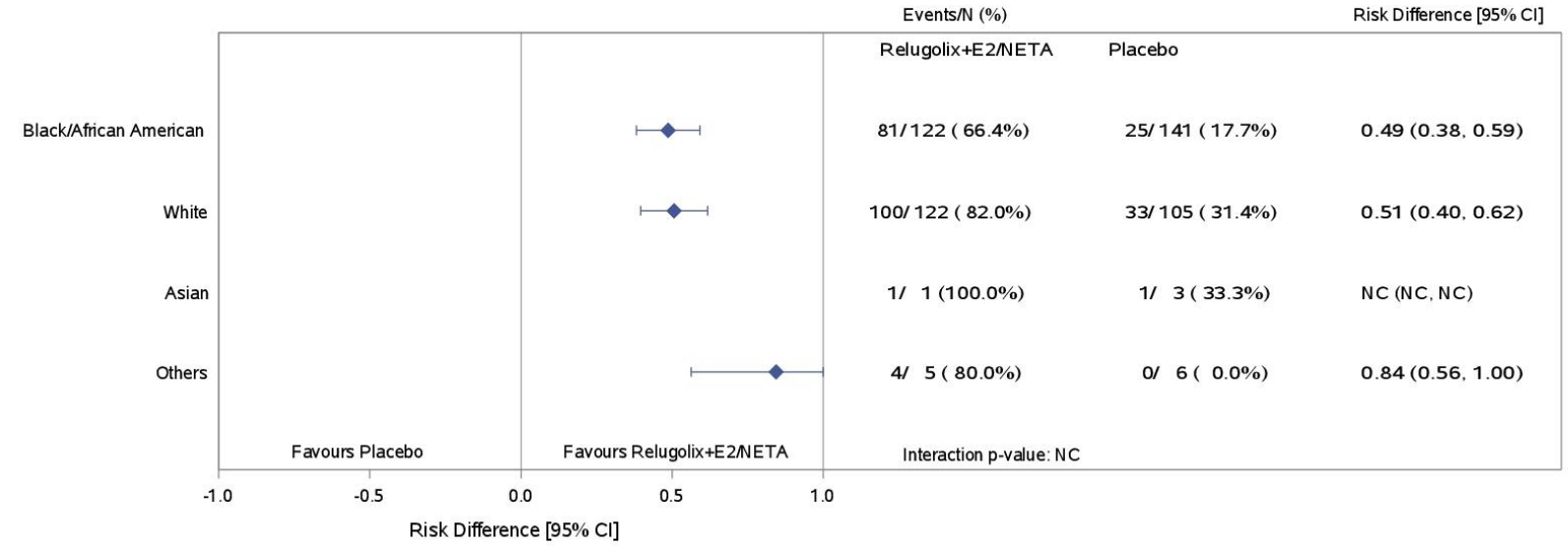
Figure EFF.RL8024ET.MITT.S9.BIN.FP.RD: Proportion of Women in the Relugolix + E2/NETA Group Versus the Placebo Group who Achieve an MBL Volume of < 80 mL Over the Last 35 Days of Treatment, as Measured by the Alkaline Hematin Method, by Subgroup (mITT Population) - Risk Difference
Study: Pooled
Subgroup: Race



Results are based on a Mantel-Haenszel approach stratified by study using a one-stage fixed-effects IPD meta-analysis.
The reference group is Placebo.
N: Number of patients in treatment group; NETA: Norethindrone acetate; mITT: Modified intent-to-treat; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

SOURCE: X:\Numerus\Studies\MYV\MYV102\Analysis\Prod\Progs\TFLs\Fig_EFF_MBL_S_BIN_FP.SAS Date/time of run: 30JUN21 10:23
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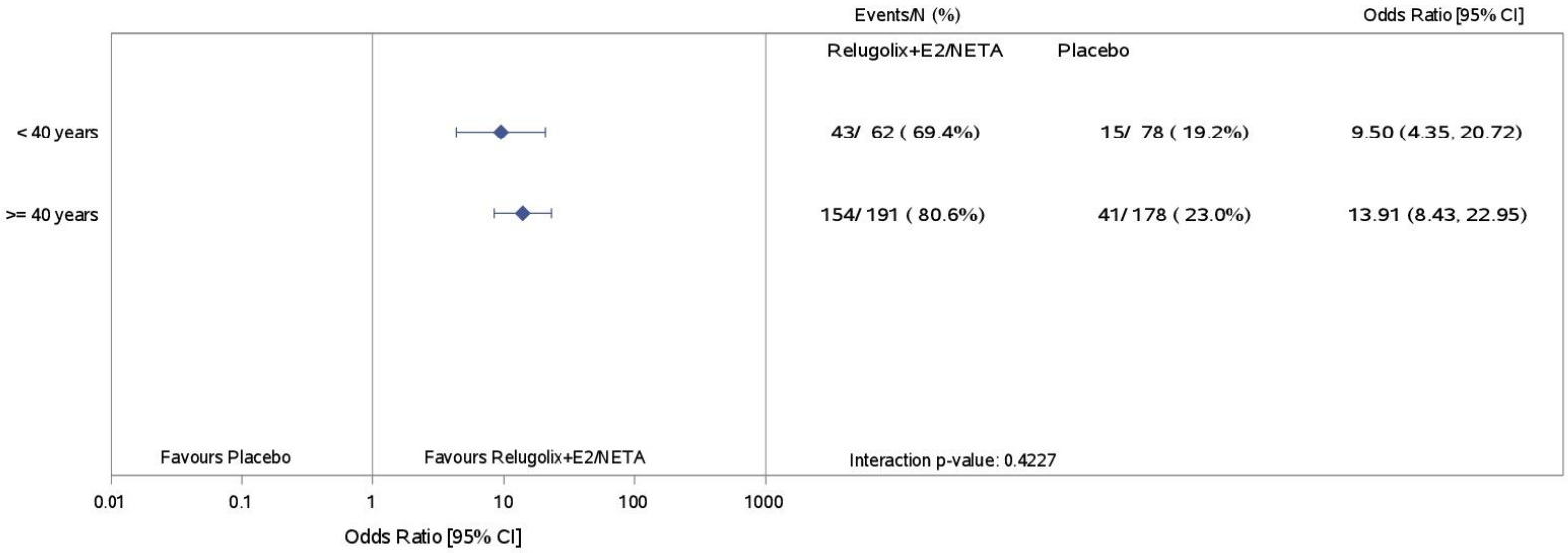
2.1.3 Proportion of Women in the Relugolix + E2/NETA Group Versus the Placebo Group who Achieve at Least a 50% Reduction from Baseline MBL Volume Over the Last 35 Days of Treatment, as Measured by the Alkaline Hematin Method, by Subgroup (mITT Population)

Nachfolgend sind zunächst alle Forest Plots für das *Odds Ratio* dargestellt; gefolgt von den entsprechenden Forest Plots für *Risk Ratio* und *Risk Difference*.

Figure EFF.RG5024ET.MITT.S1.BIN.FP: Proportion of Women in the Relugolix + E2/NETA Group Versus the Placebo Group who Achieve at Least a 50% Reduction from Baseline MBL Volume Over the Last 35 Days of Treatment, as Measured by the Alkaline Hematin Method, by Subgroup (mITT Population)
Study: Pooled
Subgroup: Age (years)



Results are based on a logistic regression model adjusted for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates using a one-stage fixed-effects IPD meta-analysis approach. A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
The interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the Odds Ratio and 95% CI. Missing subgroup levels are not included in estimation of the interaction p-value. The reference group is Placebo.
N: Number of patients in treatment group; NETA: Norethindrone acetate; mITT: Modified intent-to-treat; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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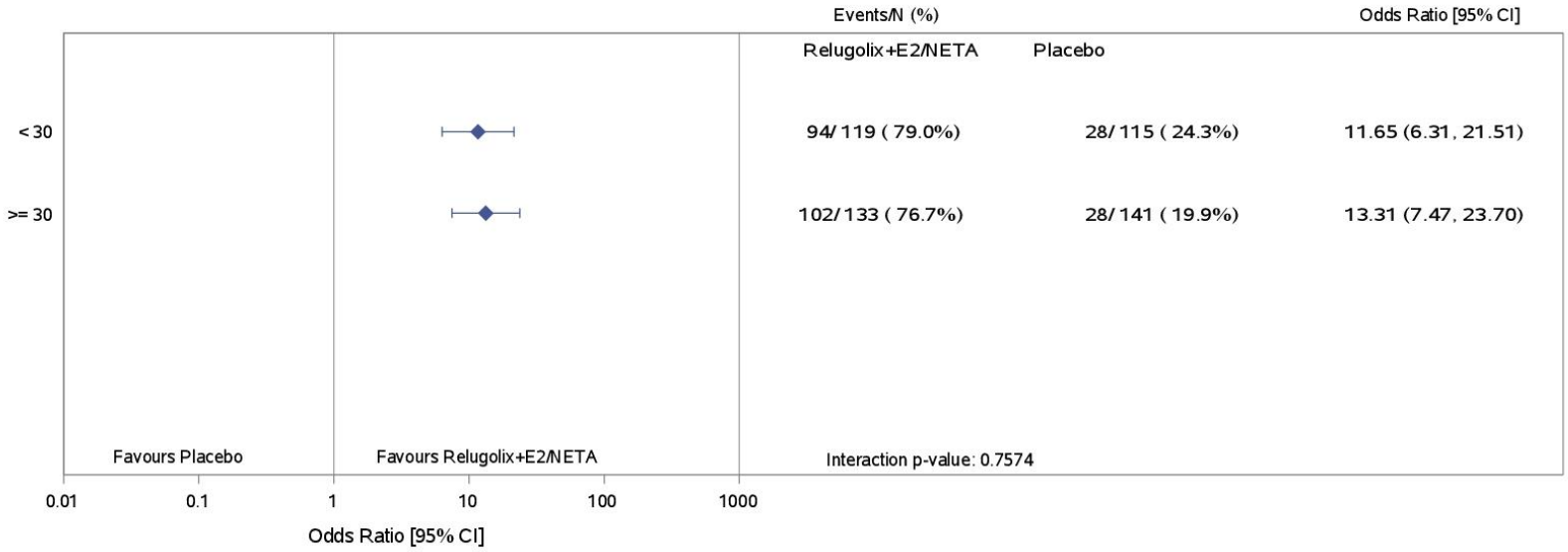
Figure EFF.RG5024ET.MITT.S2.BIN.FP: Proportion of Women in the Relugolix + E2/NETA Group Versus the Placebo Group who Achieve at Least a 50% Reduction from Baseline MBL Volume Over the Last 35 Days of Treatment, as Measured by the Alkaline Hematin Method, by Subgroup (mITT Population)
Study: Pooled
Subgroup: BMI (kg/m2) at Baseline



Results are based on a logistic regression model adjusted for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates using a one-stage fixed-effects IPD meta-analysis approach. A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
The interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the Odds Ratio and 95% CI. Missing subgroup levels are not included in estimation of the interaction p-value. The reference group is Placebo.
N: Number of patients in treatment group; NETA: Norethindrone acetate; mITT: Modified intent-to-treat; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

SOURCE: X:\Numerus\Studies\MYV\MYV102\Analysis\Prod\Progs\TFLs\Fig_EFF_MBL_S_BIN_FP.SAS Date/time of run: 30JUN21 10:23
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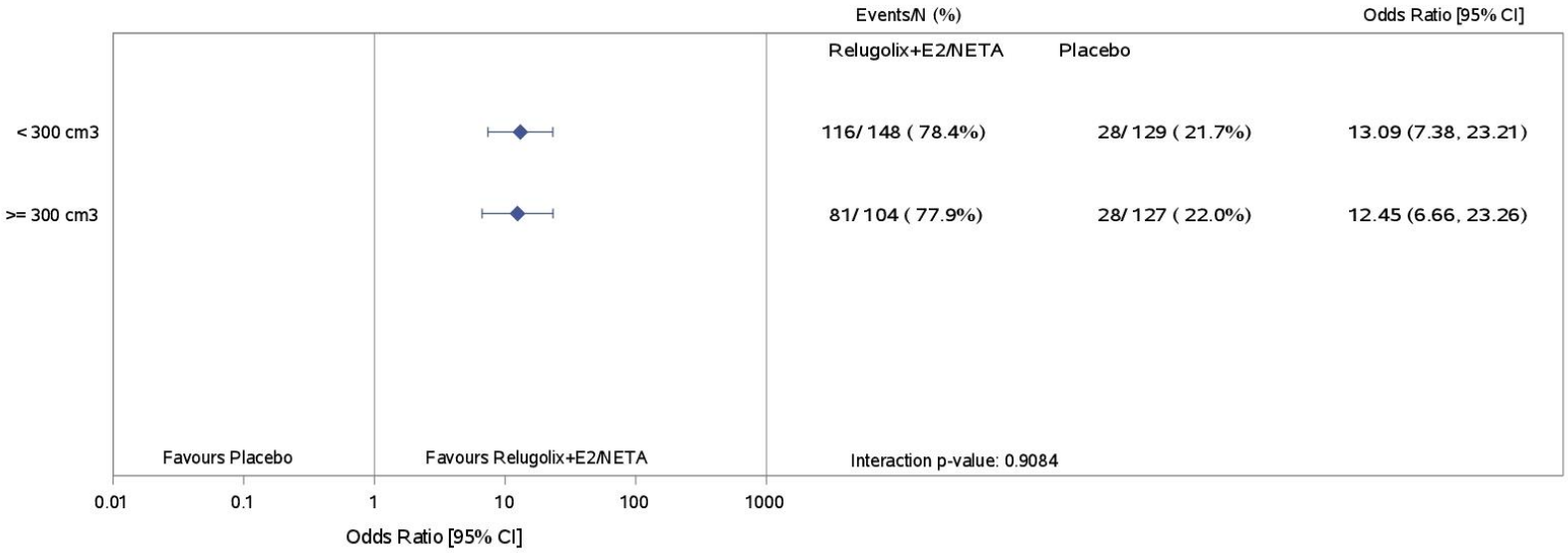
Figure EFF.RG5024ET.MITT.S3.BIN.FP: Proportion of Women in the Relugolix + E2/NETA Group Versus the Placebo Group who Achieve at Least a 50% Reduction from Baseline MBL Volume Over the Last 35 Days of Treatment, as Measured by the Alkaline Hematin Method, by Subgroup (mITT Population)
Study: Pooled
Subgroup: Uterine Volume at Baseline (cm3)



Results are based on a logistic regression model adjusted for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates using a one-stage fixed-effects IPD meta-analysis approach. A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
The interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the Odds Ratio and 95% CI. Missing subgroup levels are not included in estimation of the interaction p-value. The reference group is Placebo.
N: Number of patients in treatment group; NETA: Norethindrone acetate; mITT: Modified intent-to-treat; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

SOURCE: X:\Numerus\Studies\MYV\MYV102\Analysis\Prod\Progs\TFLs\Fig_EFF_MBL_S_BIN_FP.SAS Date/time of run: 30JUN21 10:23
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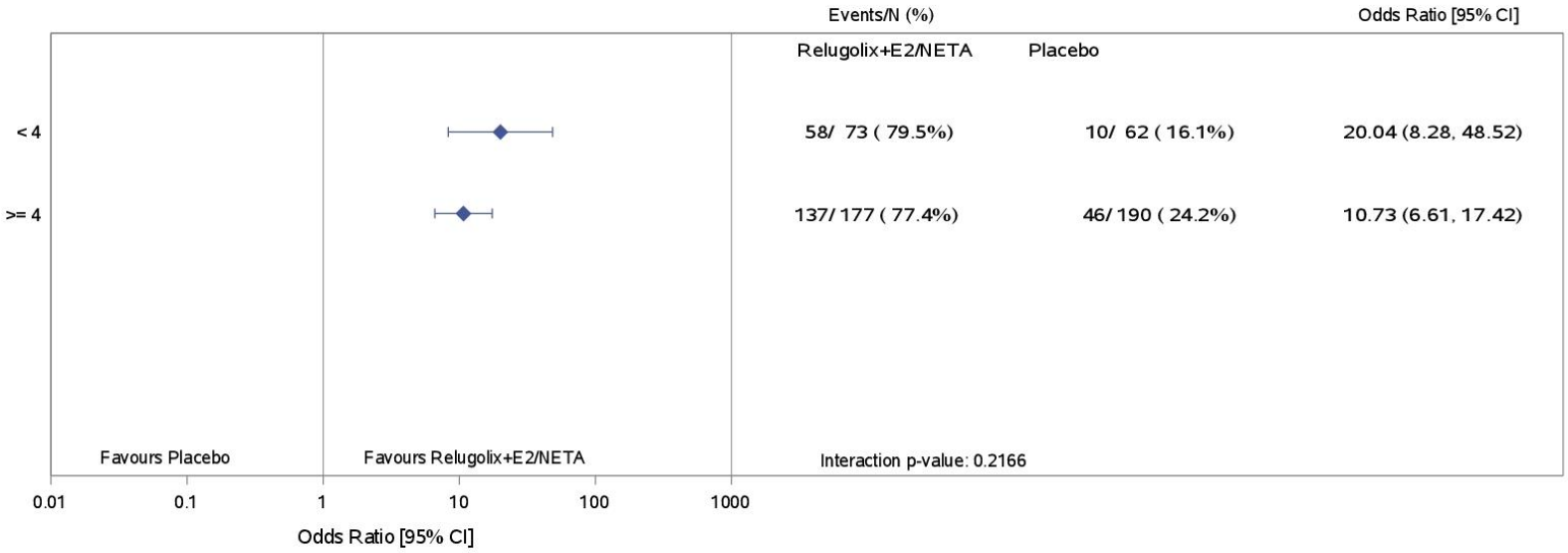
Figure EFF.RG5024ET.MITT.S4.BIN.FP: Proportion of Women in the Relugolix + E2/NETA Group Versus the Placebo Group who Achieve at Least a 50% Reduction from Baseline MBL Volume Over the Last 35 Days of Treatment, as Measured by the Alkaline Hematin Method, by Subgroup (mITT Population)
Study: Pooled
Subgroup: Maximum NRS Pain Score at Baseline



Results are based on a logistic regression model adjusted for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates using a one-stage fixed-effects IPD meta-analysis approach. A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
The interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the Odds Ratio and 95% CI. Missing subgroup levels are not included in estimation of the interaction p-value. The reference group is Placebo.
N: Number of patients in treatment group; NETA: Norethindrone acetate; mITT: Modified intent-to-treat; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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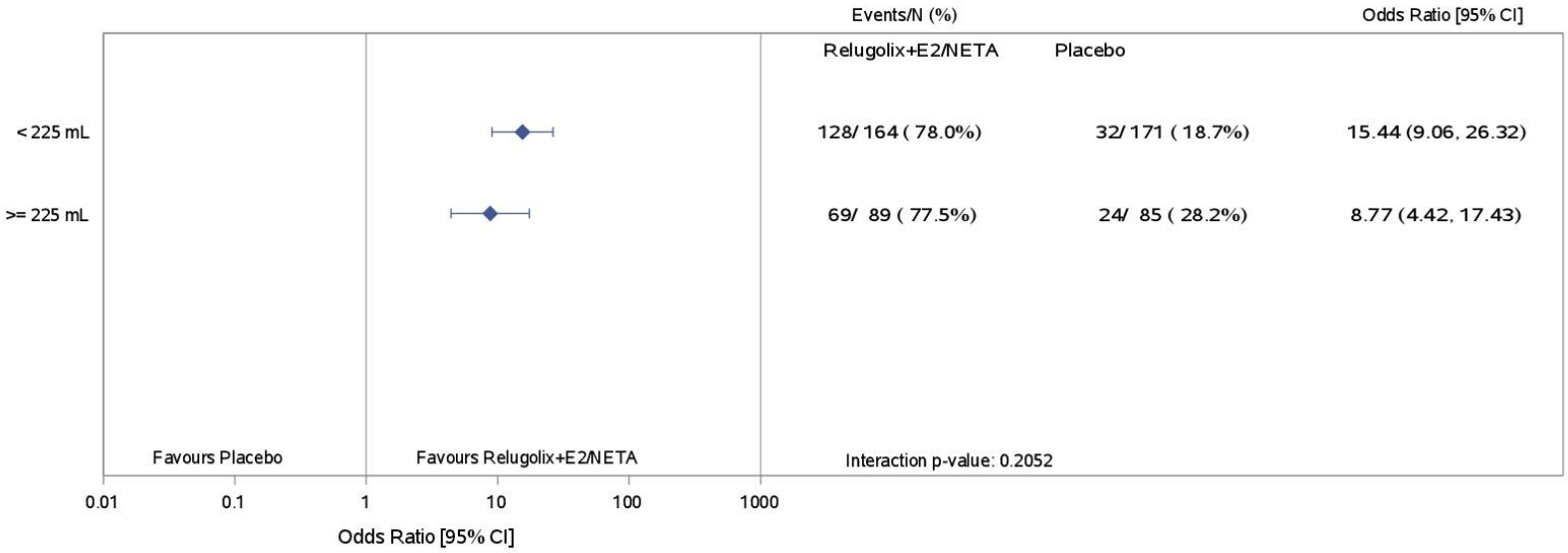
Figure EFF.RG5024ET.MITT.S5.BIN.FP: Proportion of Women in the Relugolix + E2/NETA Group Versus the Placebo Group who Achieve at Least a 50% Reduction from Baseline MBL Volume Over the Last 35 Days of Treatment, as Measured by the Alkaline Hematin Method, by Subgroup (mITT Population)
Study: Pooled
Subgroup: MBL Volume at Baseline (mL)



Results are based on a logistic regression model adjusted for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates using a one-stage fixed-effects IPD meta-analysis approach. A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
The interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the Odds Ratio and 95% CI. Missing subgroup levels are not included in estimation of the interaction p-value. The reference group is Placebo.
N: Number of patients in treatment group; NETA: Norethindrone acetate; mITT: Modified intent-to-treat; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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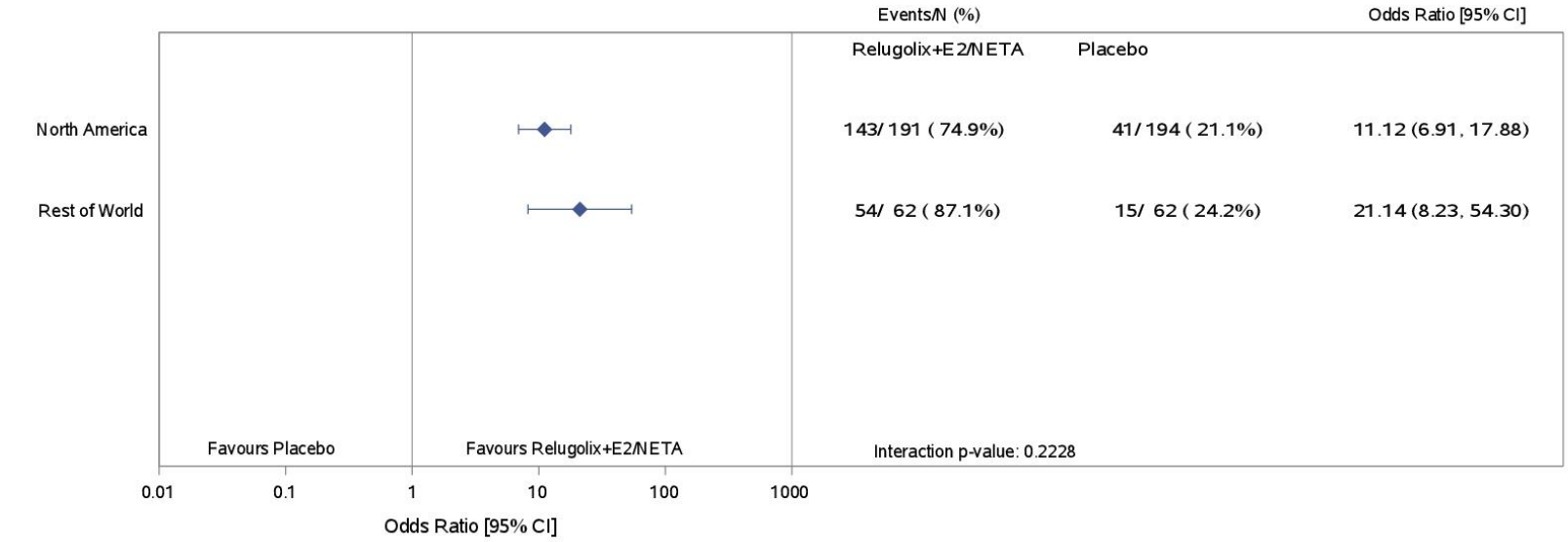
Figure EFF.RG5024ET.MITT.S6.BIN.FP: Proportion of Women in the Relugolix + E2/NETA Group Versus the Placebo Group who Achieve at Least a 50% Reduction from Baseline MBL Volume Over the Last 35 Days of Treatment, as Measured by the Alkaline Hematin Method, by Subgroup (mITT Population)
Study: Pooled
Subgroup: Geographic Region I



Results are based on a logistic regression model adjusted for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates using a one-stage fixed-effects IPD meta-analysis approach. A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
The interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the Odds Ratio and 95% CI. Missing subgroup levels are not included in estimation of the interaction p-value. The reference group is Placebo.
N: Number of patients in treatment group; NETA: Norethindrone acetate; mITT: Modified intent-to-treat; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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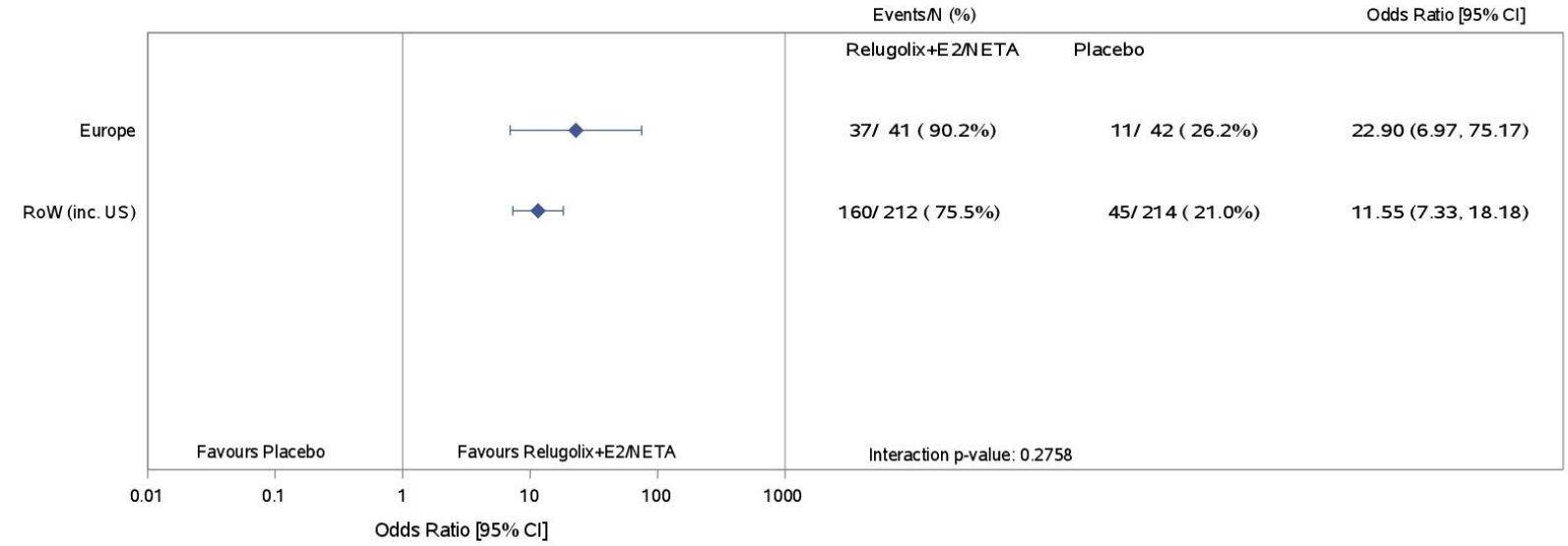
Figure EFF.RG5024ET.MITT.S7.BIN.FP: Proportion of Women in the Relugolix + E2/NETA Group Versus the Placebo Group who Achieve at Least a 50% Reduction from Baseline MBL Volume Over the Last 35 Days of Treatment, as Measured by the Alkaline Hematin Method, by Subgroup (mITT Population)
Study: Pooled
Subgroup: Geographic Region II



Results are based on a logistic regression model adjusted for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates using a one-stage fixed-effects IPD meta-analysis approach. A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
The interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the Odds Ratio and 95% CI. Missing subgroup levels are not included in estimation of the interaction p-value. The reference group is Placebo.
N: Number of patients in treatment group; NETA: Norethindrone acetate; mITT: Modified intent-to-treat; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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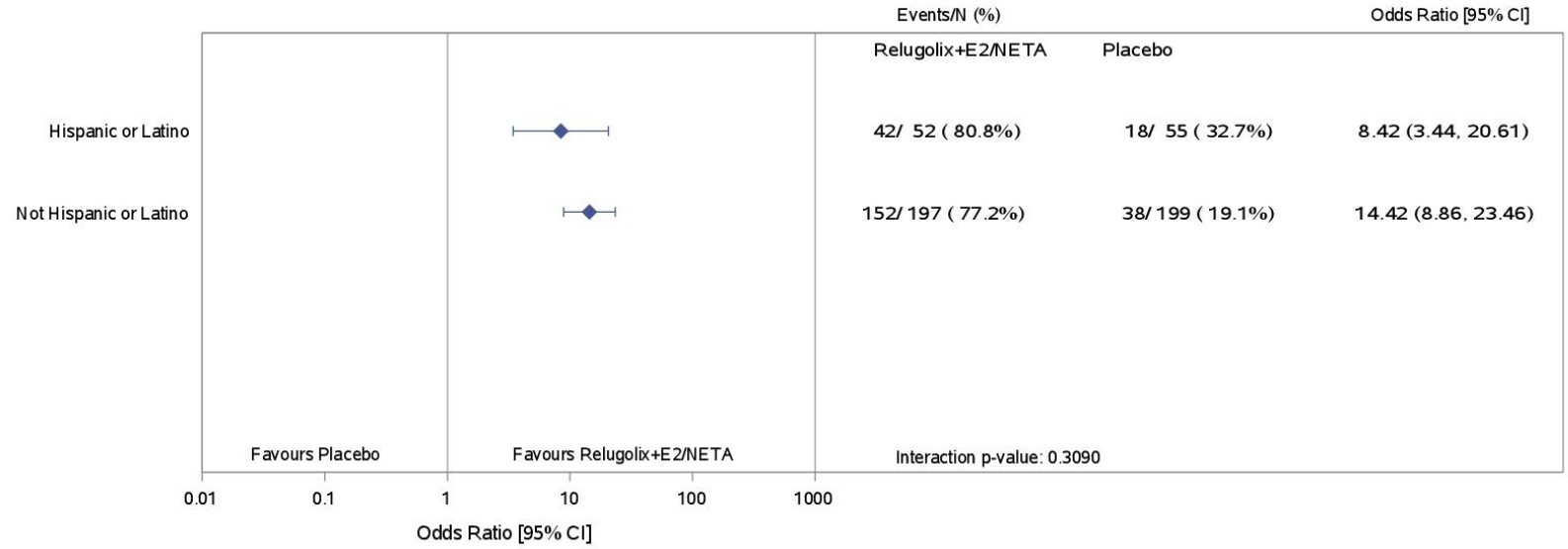
Figure EFF.RG5024ET.MITT.S8.BIN.FP: Proportion of Women in the Relugolix + E2/NETA Group Versus the Placebo Group who Achieve at Least a 50% Reduction from Baseline MBL Volume Over the Last 35 Days of Treatment, as Measured by the Alkaline Hematin Method, by Subgroup (mITT Population)
Study: Pooled
Subgroup: Ethnicity



Results are based on a logistic regression model adjusted for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates using a one-stage fixed-effects IPD meta-analysis approach. A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
The interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the Odds Ratio and 95% CI. Missing subgroup levels are not included in estimation of the interaction p-value. The reference group is Placebo.
N: Number of patients in treatment group; NETA: Norethindrone acetate; mITT: Modified intent-to-treat; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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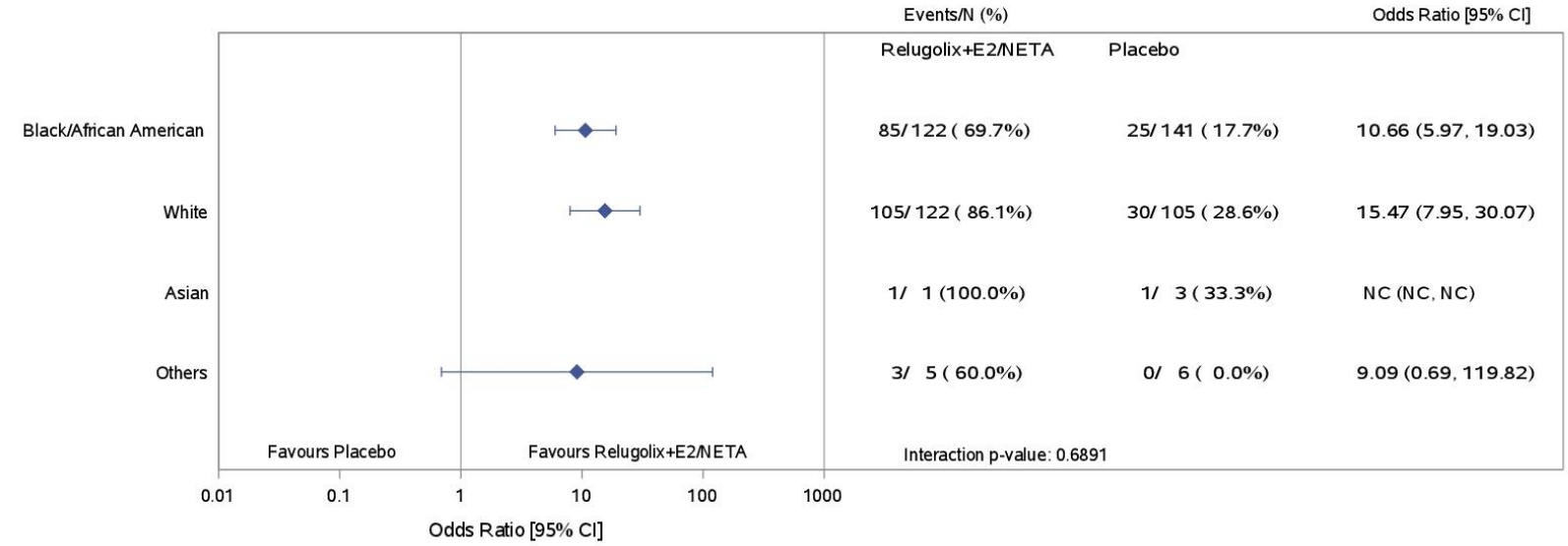
Figure EFF.RG5024ET.MITT.S9.BIN.FP: Proportion of Women in the Relugolix + E2/NETA Group Versus the Placebo Group who Achieve at Least a 50% Reduction from Baseline MBL Volume Over the Last 35 Days of Treatment, as Measured by the Alkaline Hematin Method, by Subgroup (mITT Population)
Study: Pooled
Subgroup: Race



Results are based on a logistic regression model adjusted for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates using a one-stage fixed-effects IPD meta-analysis approach. A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
The interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the Odds Ratio and 95% CI. Missing subgroup levels are not included in estimation of the interaction p-value. The reference group is Placebo.
N: Number of patients in treatment group; NETA: Norethindrone acetate; mITT: Modified intent-to-treat; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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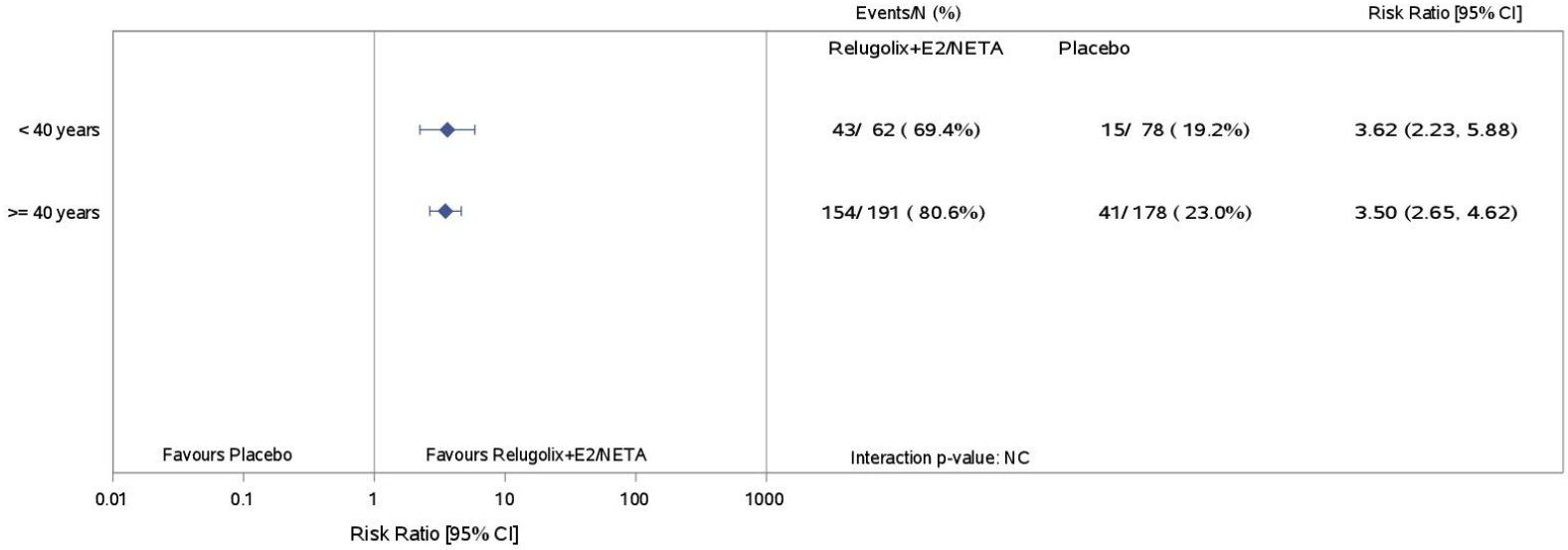
Figure EFF.RG5024ET.MITT.S1.BIN.FP.RR: Proportion of Women in the Relugolix + E2/NETA Group Versus the Placebo Group who Achieve at Least a 50% Reduction from Baseline MBL Volume Over the Last 35 Days of Treatment, as Measured by the Alkaline Hematin Method, by Subgroup (mITT Population) - Risk Ratio
Study: Pooled
Subgroup: Age (years)



Results are based on a Cochran-Mantel-Haenszel approach stratified by study using a one-stage fixed-effects IPD meta-analysis. A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
The reference group is Placebo.
N: Number of patients in treatment group; NETA: Norethindrone acetate; mITT: Modified intent-to-treat; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

SOURCE: X:\Numerus\Studies\MYV\MYV102\Analysis\Prod\Progs\TFLs\Fig_EFF_MBL_S_BIN_FP.SAS Date/time of run: 30JUN21 10:23
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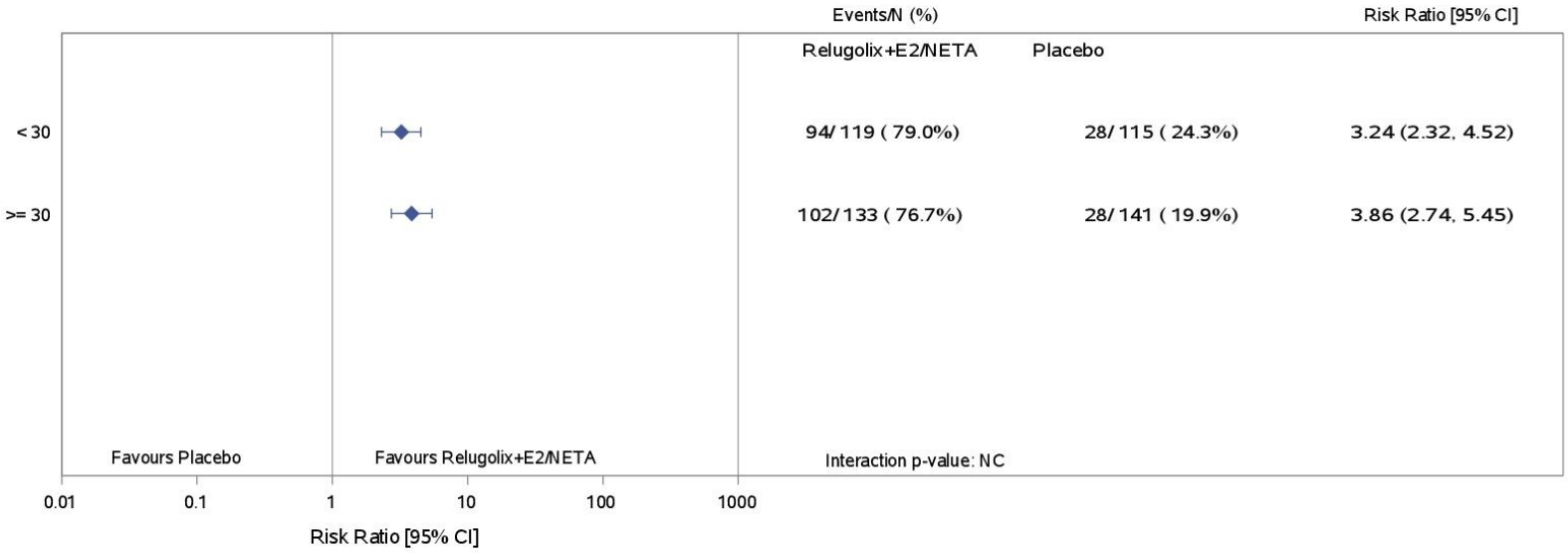
Figure EFF.RG5024ET.MITT.S2.BIN.FP.RR: Proportion of Women in the Relugolix + E2/NETA Group Versus the Placebo Group who Achieve at Least a 50% Reduction from Baseline MBL Volume Over the Last 35 Days of Treatment, as Measured by the Alkaline Hematin Method, by Subgroup (mITT Population) - Risk Ratio
Study: Pooled
Subgroup: BMI (kg/m2) at Baseline



Results are based on a Cochran-Mantel-Haenszel approach stratified by study using a one-stage fixed-effects IPD meta-analysis. A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
The reference group is Placebo.
N: Number of patients in treatment group; NETA: Norethindrone acetate; mITT: Modified intent-to-treat; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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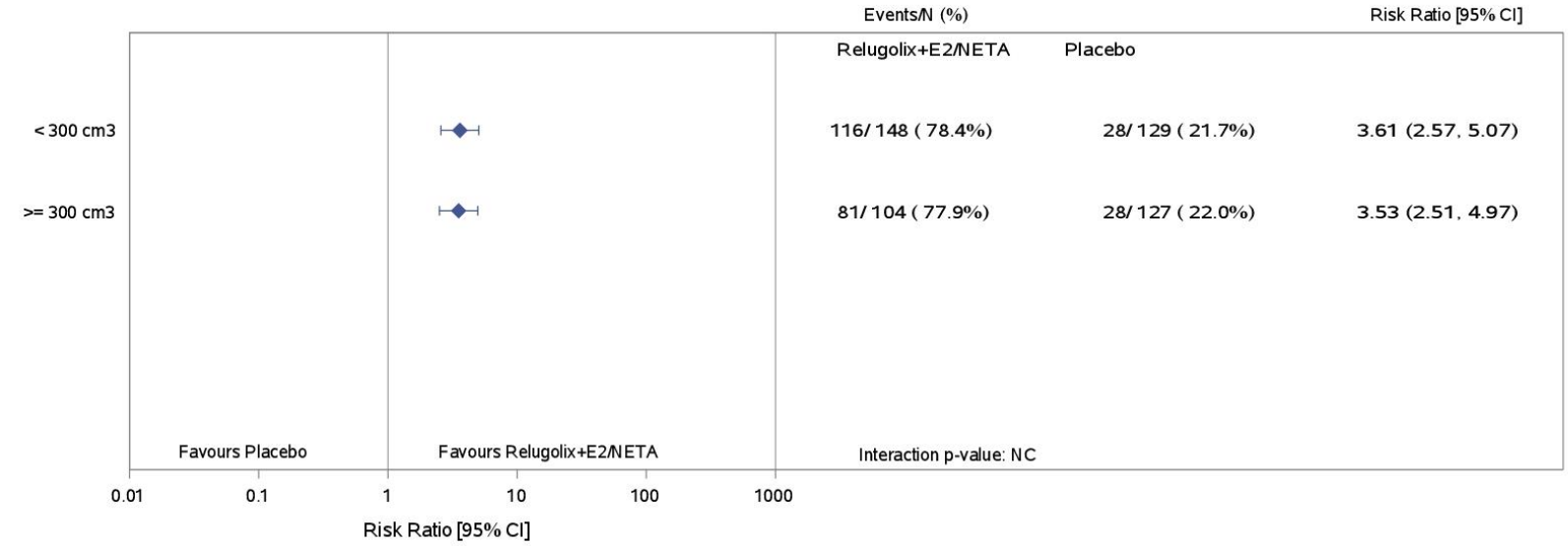
Figure EFF.RG5024ET.MITT.S3.BIN.FP.RR: Proportion of Women in the Relugolix + E2/NETA Group Versus the Placebo Group who Achieve at Least a 50% Reduction from Baseline MBL Volume Over the Last 35 Days of Treatment, as Measured by the Alkaline Hematin Method, by Subgroup (mITT Population) - Risk Ratio
Study: Pooled
Subgroup: Uterine Volume at Baseline (cm3)



Results are based on a Cochran-Mantel-Haenszel approach stratified by study using a one-stage fixed-effects IPD meta-analysis. A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
The reference group is Placebo.
N: Number of patients in treatment group; NETA: Norethindrone acetate; mITT: Modified intent-to-treat; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

SOURCE: X:\Numerus\Studies\MYV\MYV102\Analysis\Prod\Progs\TFLs\Fig_EFF_MBL_S_BIN_FP.SAS Date/time of run: 30JUN21 10:23
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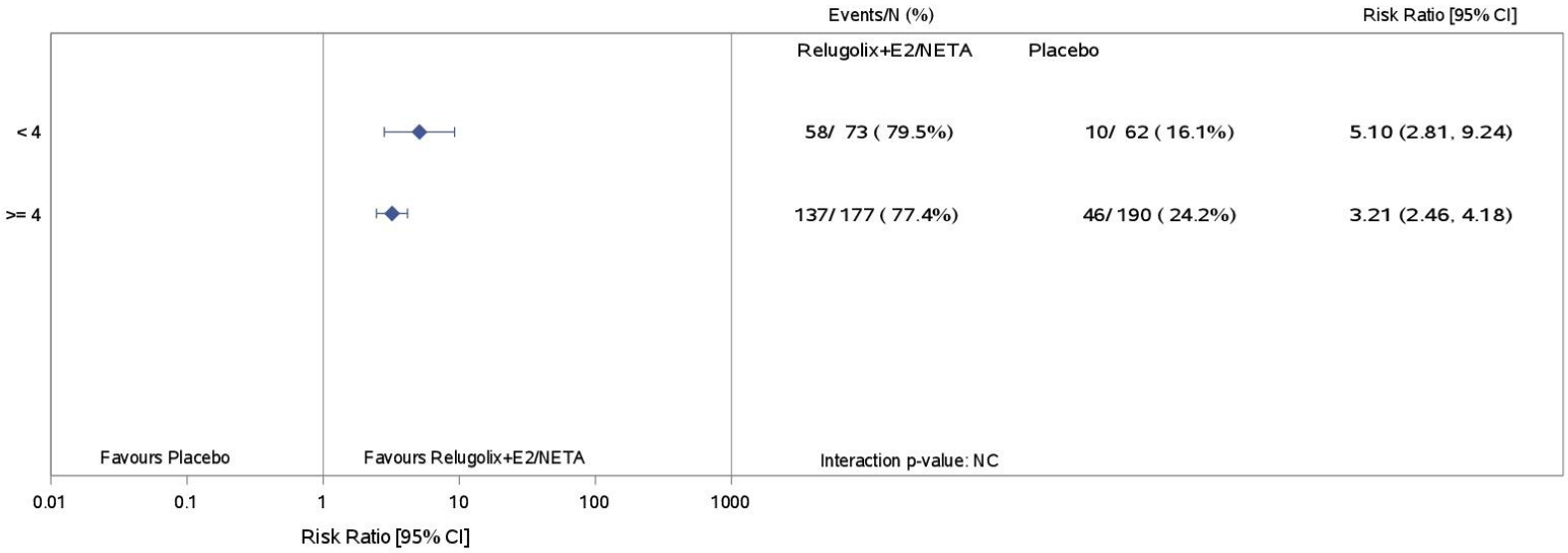
Figure EFF.RG5024ET.MITT.S4.BIN.FP.RR: Proportion of Women in the Relugolix + E2/NETA Group Versus the Placebo Group who Achieve at Least a 50% Reduction from Baseline MBL Volume Over the Last 35 Days of Treatment, as Measured by the Alkaline Hematin Method, by Subgroup (mITT Population) - Risk Ratio
Study: Pooled
Subgroup: Maximum NRS Pain Score at Baseline



Results are based on a Cochran-Mantel-Haenszel approach stratified by study using a one-stage fixed-effects IPD meta-analysis. A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
The reference group is Placebo.
N: Number of patients in treatment group; NETA: Norethindrone acetate; mITT: Modified intent-to-treat; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

SOURCE: X:\Numerus\Studies\MYV\MYV102\Analysis\Prod\Progs\TFLs\Fig_EFF_MBL_S_BIN_FP.SAS Date/time of run: 30JUN21 10:23
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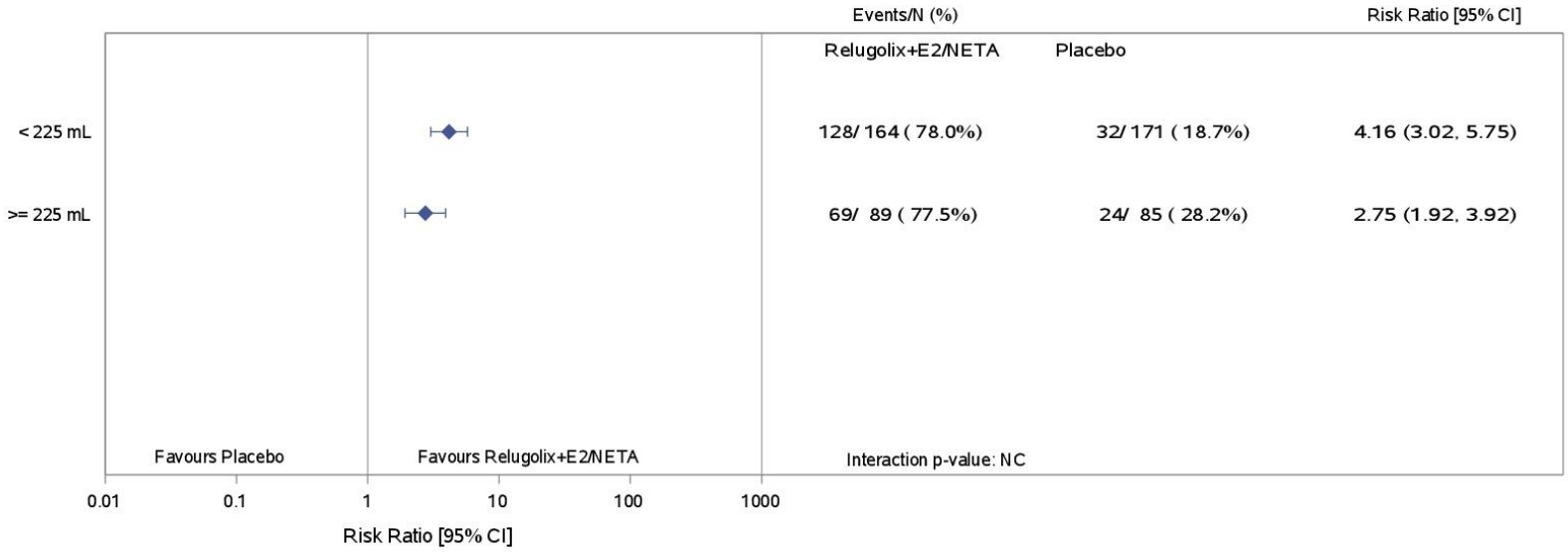
Figure EFF.RG5024ET.MITT.S5.BIN.FP.RR: Proportion of Women in the Relugolix + E2/NETA Group Versus the Placebo Group who Achieve at Least a 50% Reduction from Baseline MBL Volume Over the Last 35 Days of Treatment, as Measured by the Alkaline Hematin Method, by Subgroup (mITT Population) - Risk Ratio
Study: Pooled
Subgroup: MBL Volume at Baseline (mL)



Results are based on a Cochran-Mantel-Haenszel approach stratified by study using a one-stage fixed-effects IPD meta-analysis. A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
The reference group is Placebo.
N: Number of patients in treatment group; NETA: Norethindrone acetate; mITT: Modified intent-to-treat; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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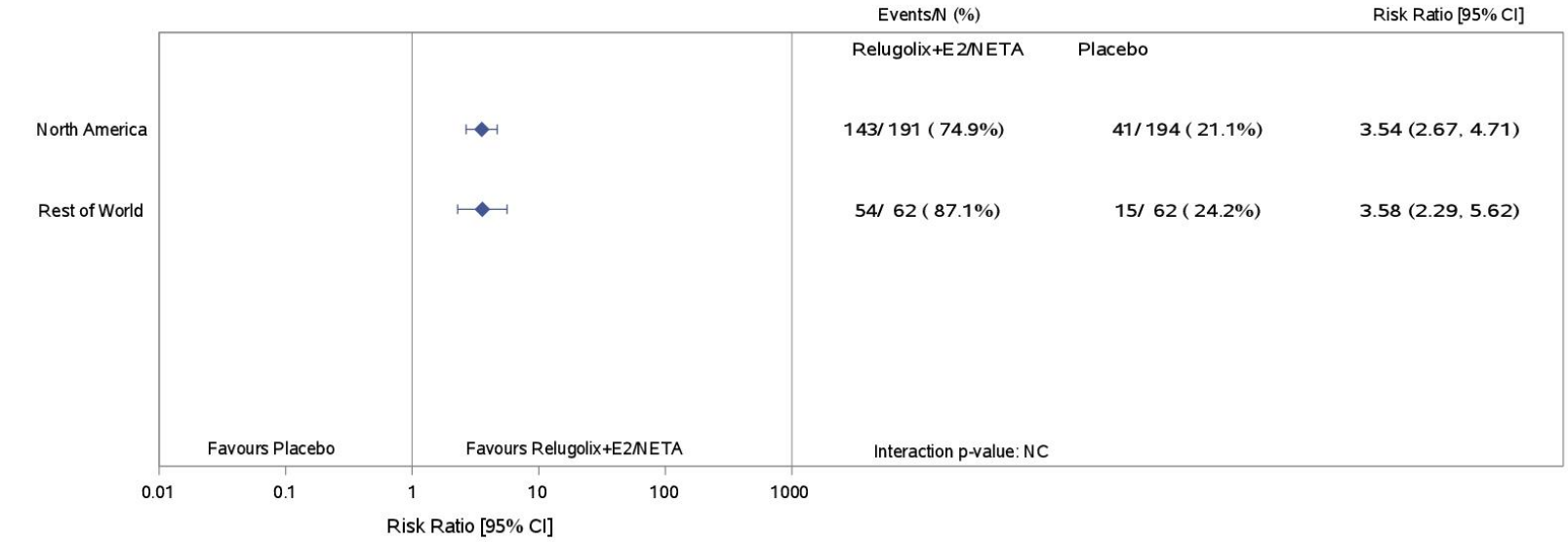
Figure EFF.RG5024ET.MITT.S6.BIN.FP.RR: Proportion of Women in the Relugolix + E2/NETA Group Versus the Placebo Group who Achieve at Least a 50% Reduction from Baseline MBL Volume Over the Last 35 Days of Treatment, as Measured by the Alkaline Hematin Method, by Subgroup (mITT Population) - Risk Ratio
Study: Pooled
Subgroup: Geographic Region I



Results are based on a Cochran-Mantel-Haenszel approach stratified by study using a one-stage fixed-effects IPD meta-analysis. A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
The reference group is Placebo.
N: Number of patients in treatment group; NETA: Norethindrone acetate; mITT: Modified intent-to-treat; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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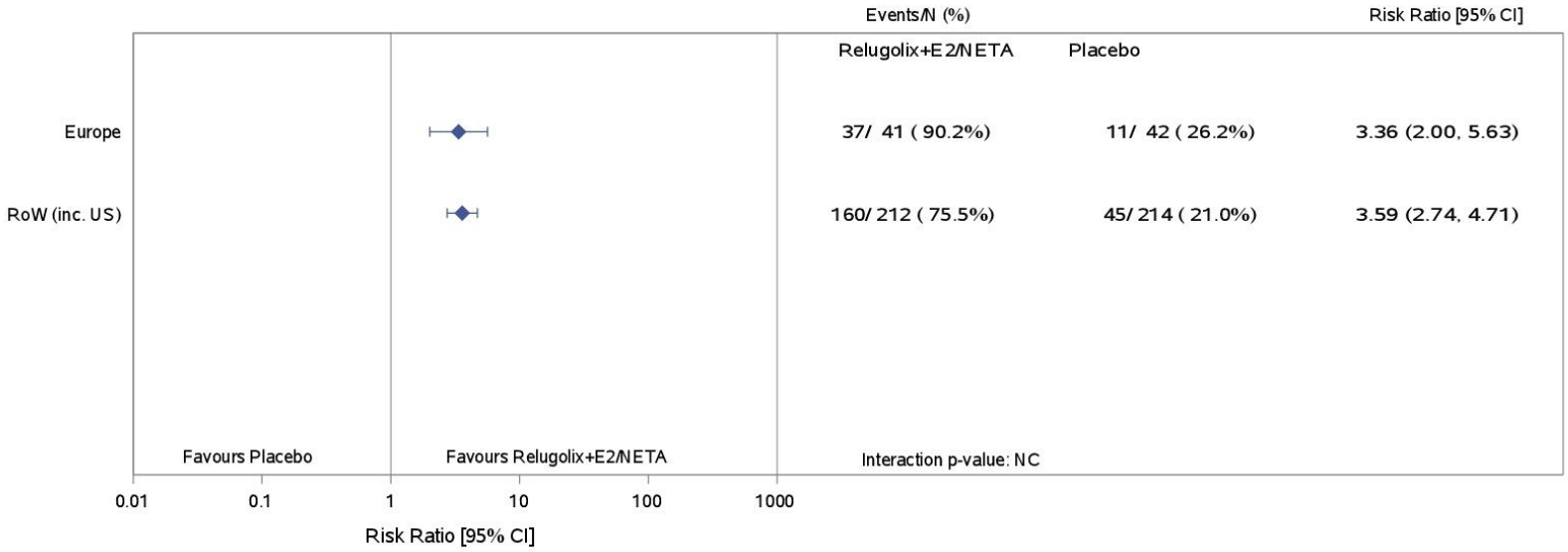
Figure EFF.RG5024ET.MITT.S7.BIN.FP.RR: Proportion of Women in the Relugolix + E2/NETA Group Versus the Placebo Group who Achieve at Least a 50% Reduction from Baseline MBL Volume Over the Last 35 Days of Treatment, as Measured by the Alkaline Hematin Method, by Subgroup (mITT Population) - Risk Ratio
Study: Pooled
Subgroup: Geographic Region II



Results are based on a Cochran-Mantel-Haenszel approach stratified by study using a one-stage fixed-effects IPD meta-analysis. A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
The reference group is Placebo.
N: Number of patients in treatment group; NETA: Norethindrone acetate; mITT: Modified intent-to-treat; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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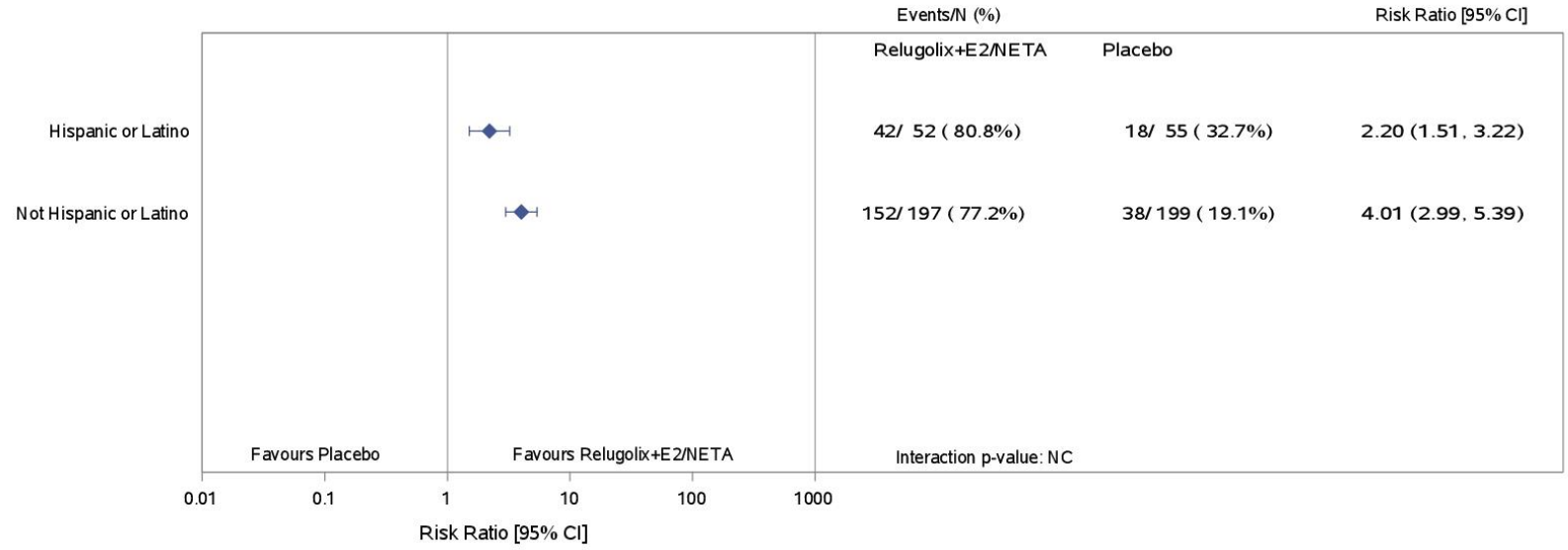
Figure EFF.RG5024ET.MITT.S8.BIN.FP.RR: Proportion of Women in the Relugolix + E2/NETA Group Versus the Placebo Group who Achieve at Least a 50% Reduction from Baseline MBL Volume Over the Last 35 Days of Treatment, as Measured by the Alkaline Hematin Method, by Subgroup (mITT Population) - Risk Ratio
Study: Pooled
Subgroup: Ethnicity



Results are based on a Cochran-Mantel-Haenszel approach stratified by study using a one-stage fixed-effects IPD meta-analysis. A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
The reference group is Placebo.
N: Number of patients in treatment group; NETA: Norethindrone acetate; mITT: Modified intent-to-treat; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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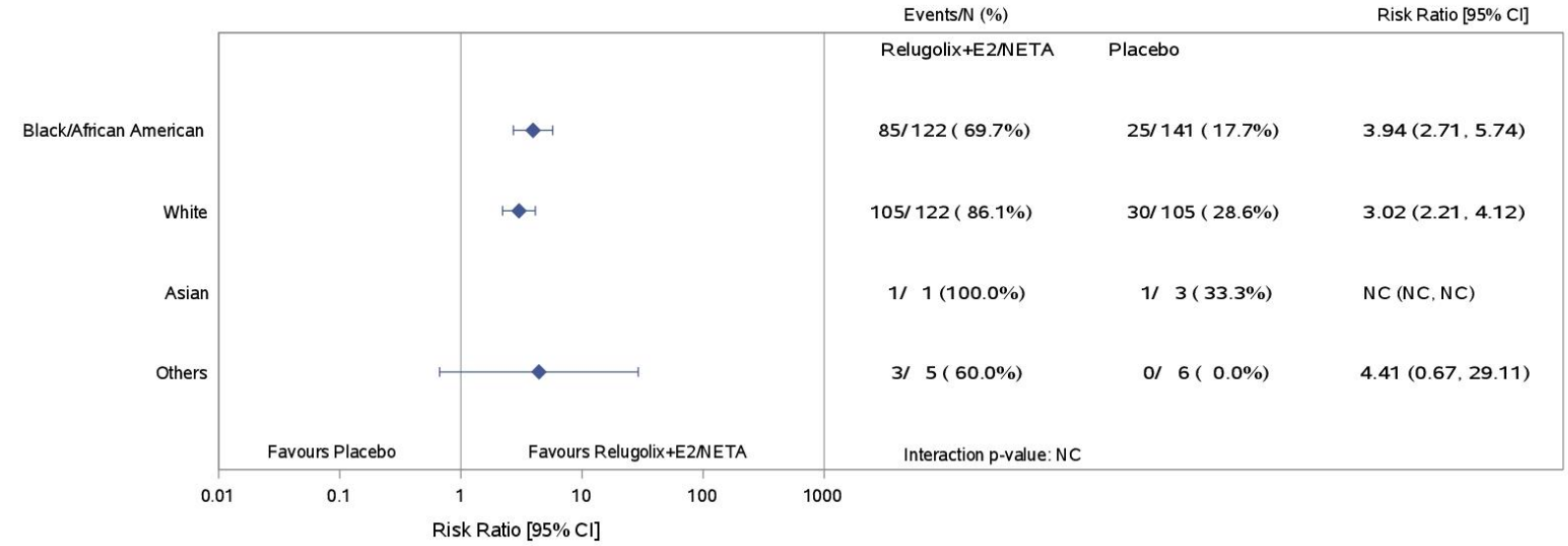
Figure EFF.RG5024ET.MITT.S9.BIN.FP.RR: Proportion of Women in the Relugolix + E2/NETA Group Versus the Placebo Group who Achieve at Least a 50% Reduction from Baseline MBL Volume Over the Last 35 Days of Treatment, as Measured by the Alkaline Hematin Method, by Subgroup (mITT Population) - Risk Ratio
Study: Pooled
Subgroup: Race



Results are based on a Cochran-Mantel-Haenszel approach stratified by study using a one-stage fixed-effects IPD meta-analysis. A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
The reference group is Placebo.
N: Number of patients in treatment group; NETA: Norethindrone acetate; mITT: Modified intent-to-treat; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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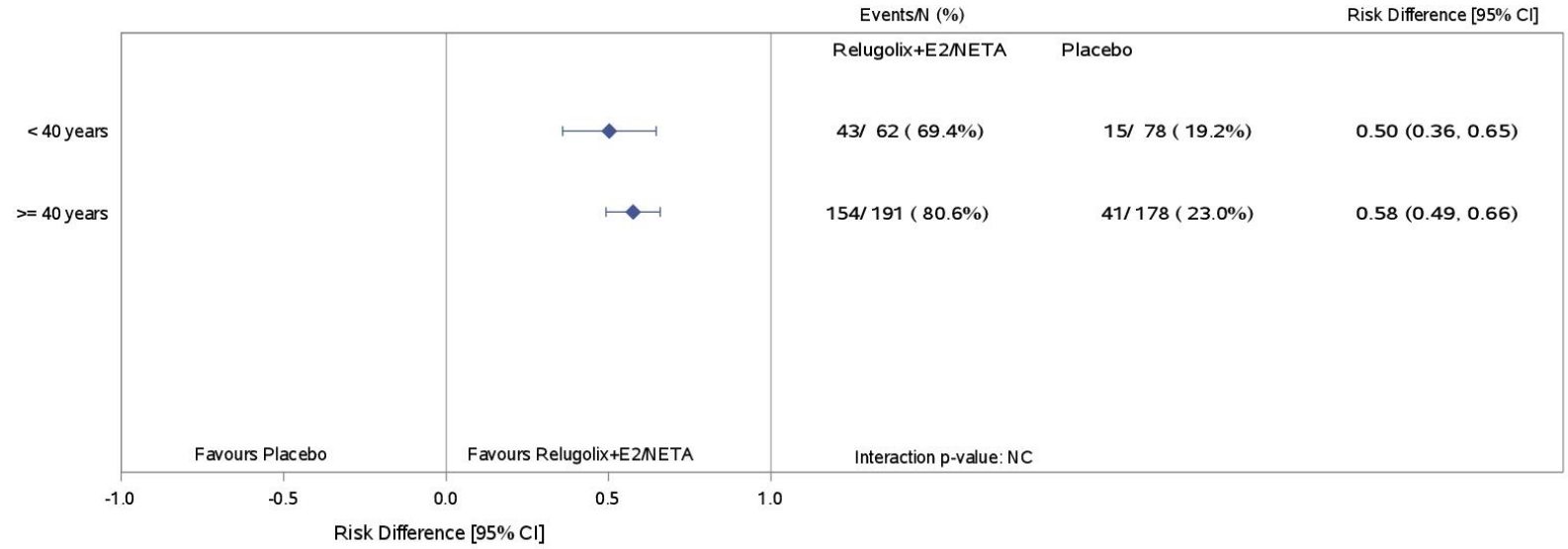
Figure EFF.RG5024ET.MITT.S1.BIN.FP.RD: Proportion of Women in the Relugolix + E2/NETA Group Versus the Placebo Group who Achieve at Least a 50% Reduction from Baseline MBL Volume Over the Last 35 Days of Treatment, as Measured by the Alkaline Hematin Method, by Subgroup (mITT Population) - Risk Difference
Study: Pooled
Subgroup: Age (years)



Results are based on a Mantel-Haenszel approach stratified by study using a one-stage fixed-effects IPD meta-analysis.
The reference group is Placebo.
N: Number of patients in treatment group; NETA: Norethindrone acetate; mITT: Modified intent-to-treat; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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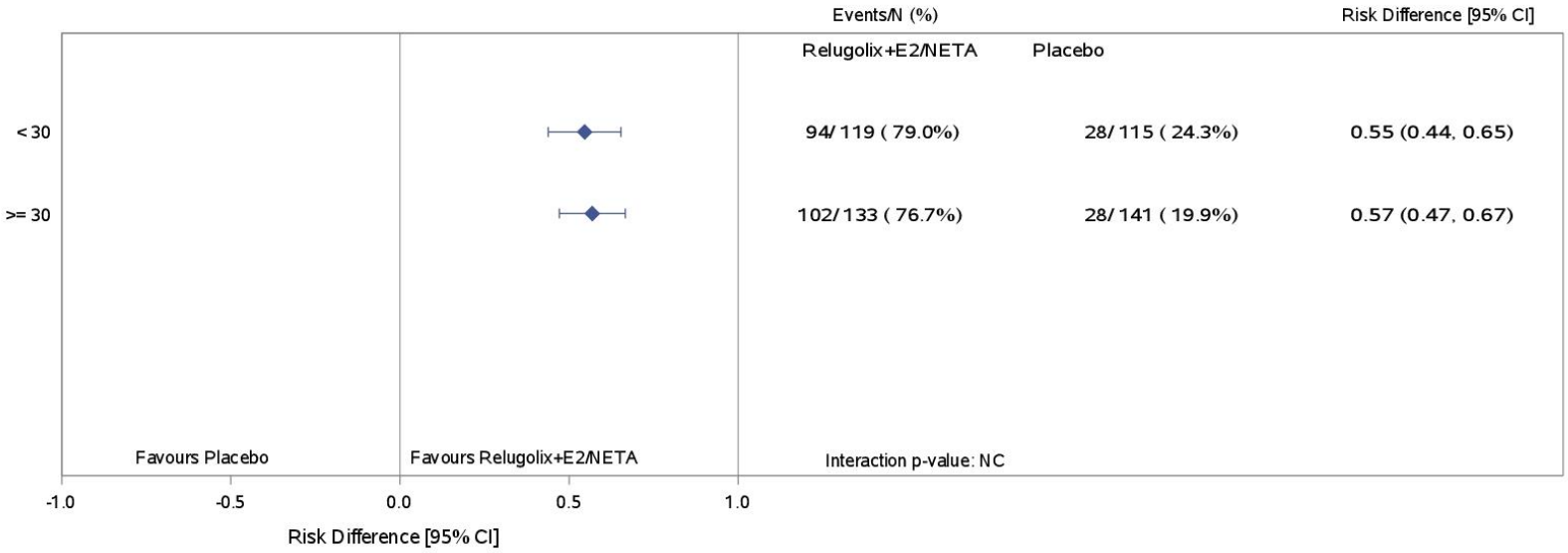
Figure EFF.RG5024ET.MITT.S2.BIN.FP.RD: Proportion of Women in the Relugolix + E2/NETA Group Versus the Placebo Group who Achieve at Least a 50% Reduction from Baseline MBL Volume Over the Last 35 Days of Treatment, as Measured by the Alkaline Hematin Method, by Subgroup (mITT Population) - Risk Difference
Study: Pooled
Subgroup: BMI (kg/m2) at Baseline



Results are based on a Mantel-Haenszel approach stratified by study using a one-stage fixed-effects IPD meta-analysis.
The reference group is Placebo.
N: Number of patients in treatment group; NETA: Norethindrone acetate; mITT: Modified intent-to-treat; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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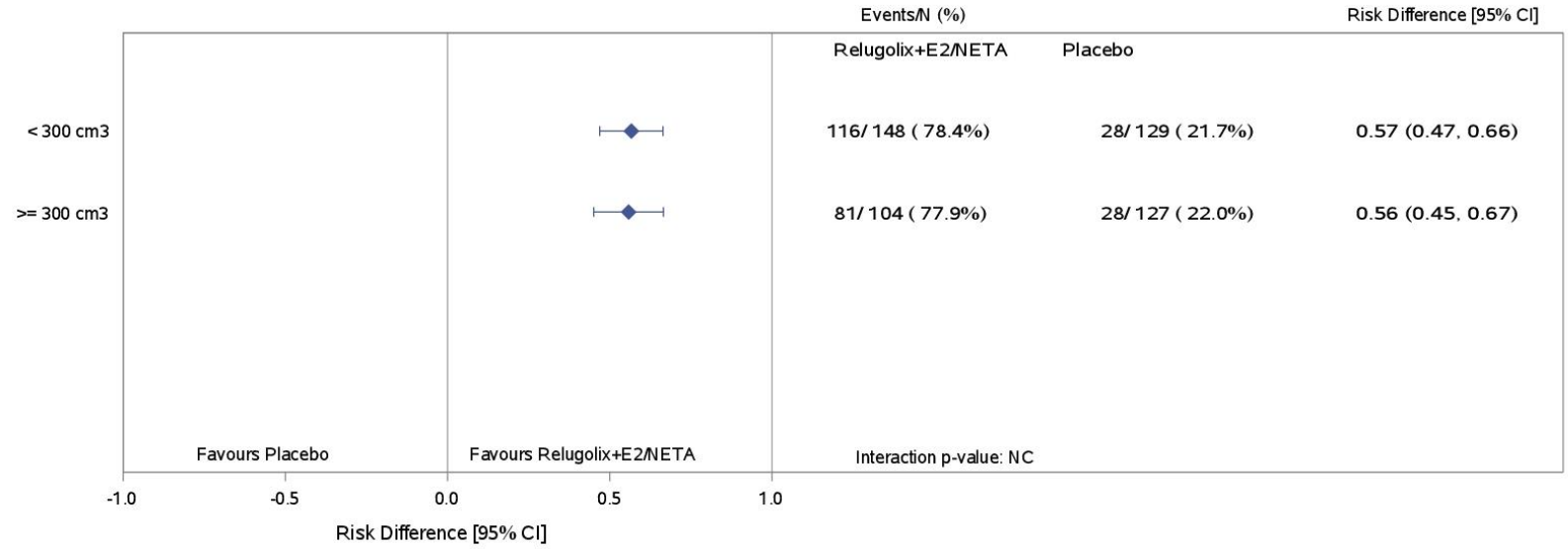
Figure EFF.RG5024ET.MITT.S3.BIN.FP.RD: Proportion of Women in the Relugolix + E2/NETA Group Versus the Placebo Group who Achieve at Least a 50% Reduction from Baseline MBL Volume Over the Last 35 Days of Treatment, as Measured by the Alkaline Hematin Method, by Subgroup (mITT Population) - Risk Difference
Study: Pooled
Subgroup: Uterine Volume at Baseline (cm3)



Results are based on a Mantel-Haenszel approach stratified by study using a one-stage fixed-effects IPD meta-analysis.
The reference group is Placebo.
N: Number of patients in treatment group; NETA: Norethindrone acetate; mITT: Modified intent-to-treat; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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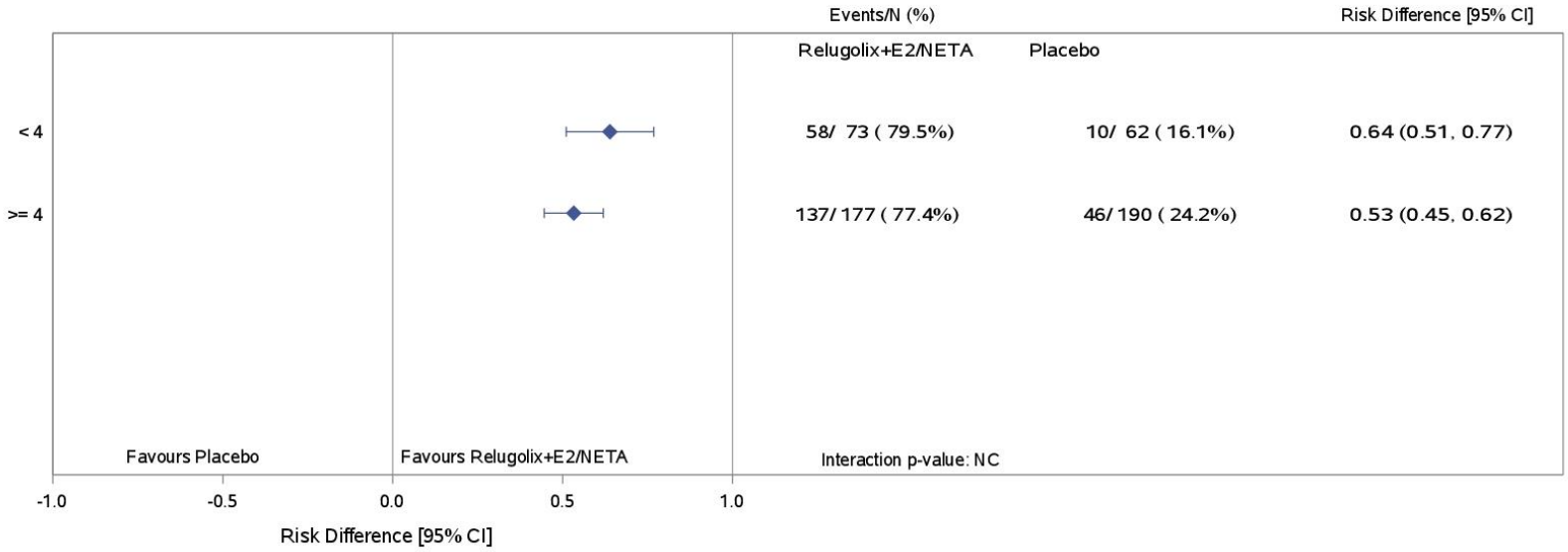
Figure EFF.RG5024ET.MITT.S4.BIN.FP.RD: Proportion of Women in the Relugolix + E2/NETA Group Versus the Placebo Group who Achieve at Least a 50% Reduction from Baseline MBL Volume Over the Last 35 Days of Treatment, as Measured by the Alkaline Hematin Method, by Subgroup (mITT Population) - Risk Difference
Study: Pooled
Subgroup: Maximum NRS Pain Score at Baseline



Results are based on a Mantel-Haenszel approach stratified by study using a one-stage fixed-effects IPD meta-analysis.
The reference group is Placebo.
N: Number of patients in treatment group; NETA: Norethindrone acetate; mITT: Modified intent-to-treat; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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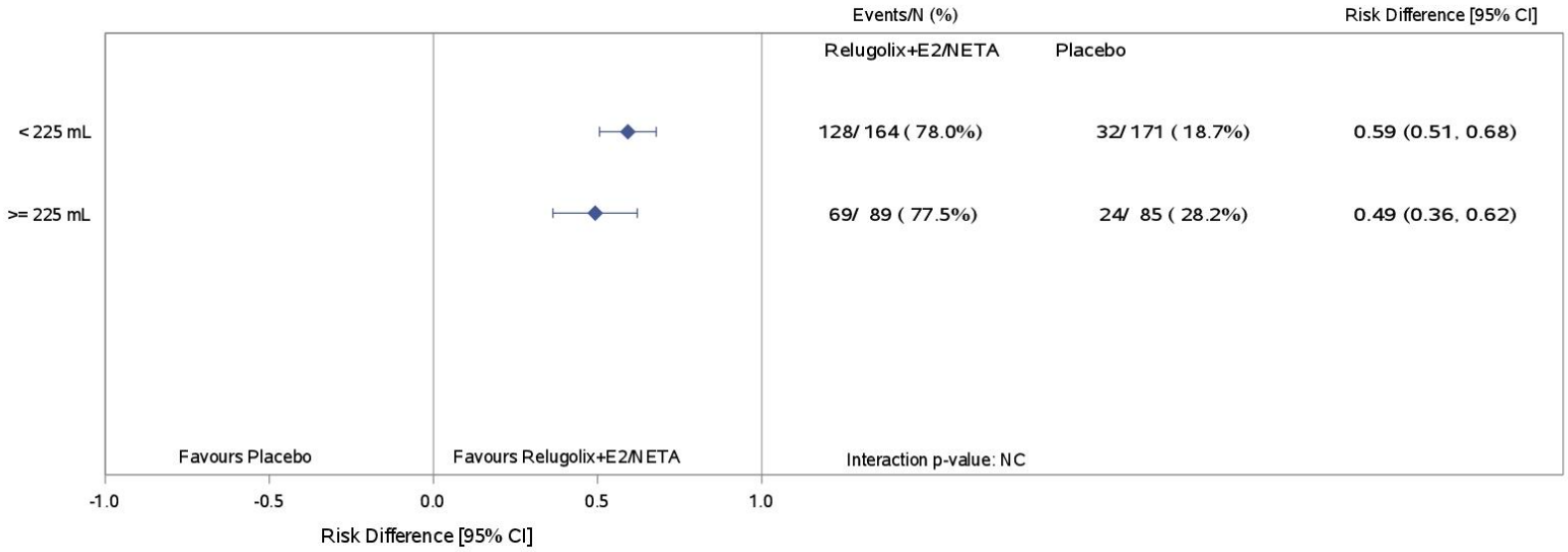
Figure EFF.RG5024ET.MITT.S5.BIN.FP.RD: Proportion of Women in the Relugolix + E2/NETA Group Versus the Placebo Group who Achieve at Least a 50% Reduction from Baseline MBL Volume Over the Last 35 Days of Treatment, as Measured by the Alkaline Hematin Method, by Subgroup (mITT Population) - Risk Difference
Study: Pooled
Subgroup: MBL Volume at Baseline (mL)



Results are based on a Mantel-Haenszel approach stratified by study using a one-stage fixed-effects IPD meta-analysis.
The reference group is Placebo.
N: Number of patients in treatment group; NETA: Norethindrone acetate; mITT: Modified intent-to-treat; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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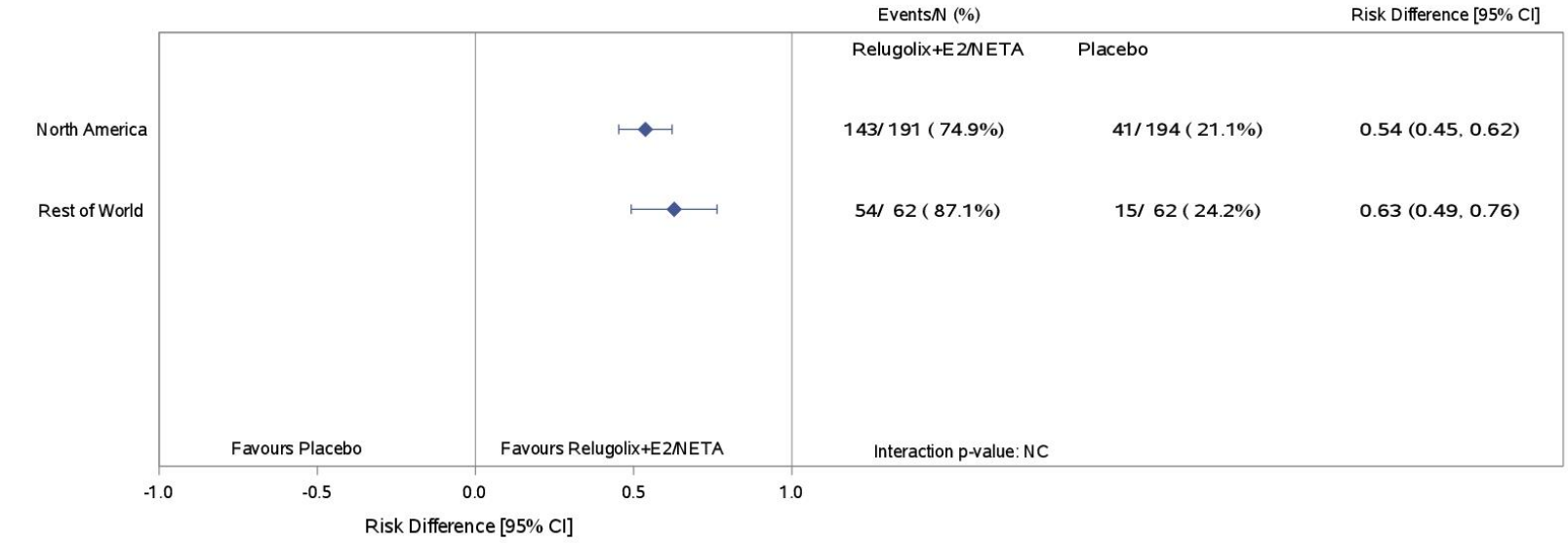
Figure EFF.RG5024ET.MITT.S6.BIN.FP.RD: Proportion of Women in the Relugolix + E2/NETA Group Versus the Placebo Group who Achieve at Least a 50% Reduction from Baseline MBL Volume Over the Last 35 Days of Treatment, as Measured by the Alkaline Hematin Method, by Subgroup (mITT Population) - Risk Difference
Study: Pooled
Subgroup: Geographic Region I



Results are based on a Mantel-Haenszel approach stratified by study using a one-stage fixed-effects IPD meta-analysis.
The reference group is Placebo.
N: Number of patients in treatment group; NETA: Norethindrone acetate; mITT: Modified intent-to-treat; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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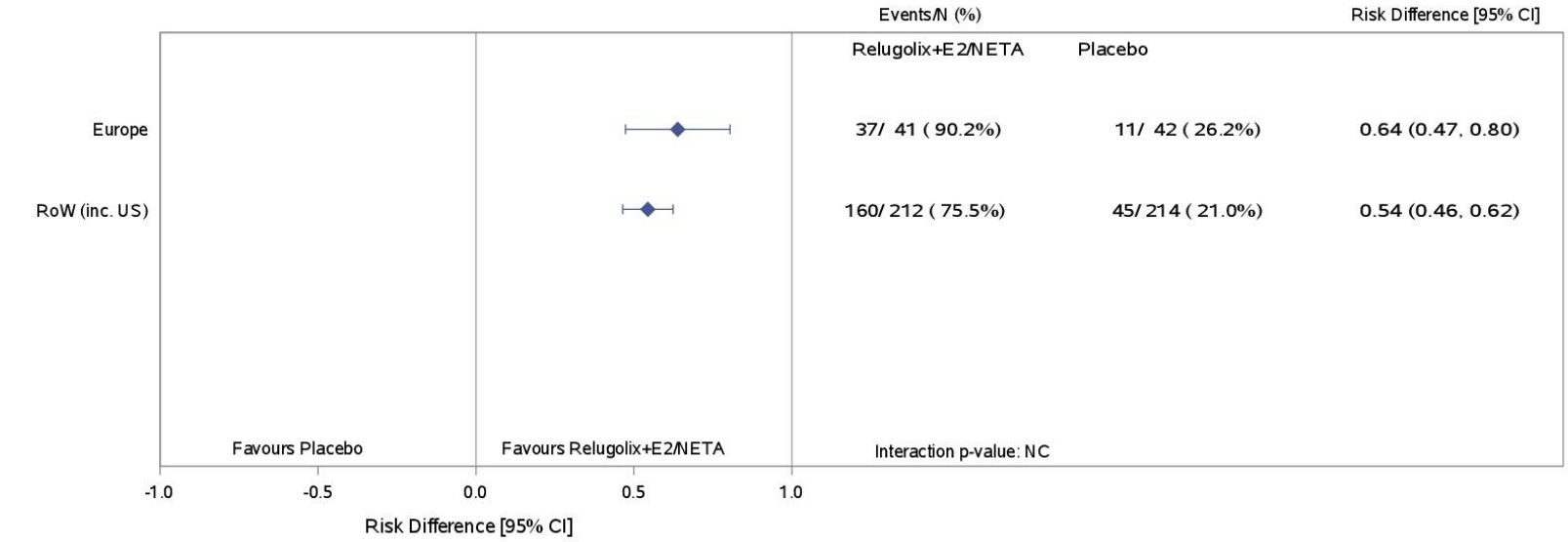
Figure EFF.RG5024ET.MITT.S7.BIN.FP.RD: Proportion of Women in the Relugolix + E2/NETA Group Versus the Placebo Group who Achieve at Least a 50% Reduction from Baseline MBL Volume Over the Last 35 Days of Treatment, as Measured by the Alkaline Hematin Method, by Subgroup (mITT Population) - Risk Difference
Study: Pooled
Subgroup: Geographic Region II



Results are based on a Mantel-Haenszel approach stratified by study using a one-stage fixed-effects IPD meta-analysis.
The reference group is Placebo.
N: Number of patients in treatment group; NETA: Norethindrone acetate; mITT: Modified intent-to-treat; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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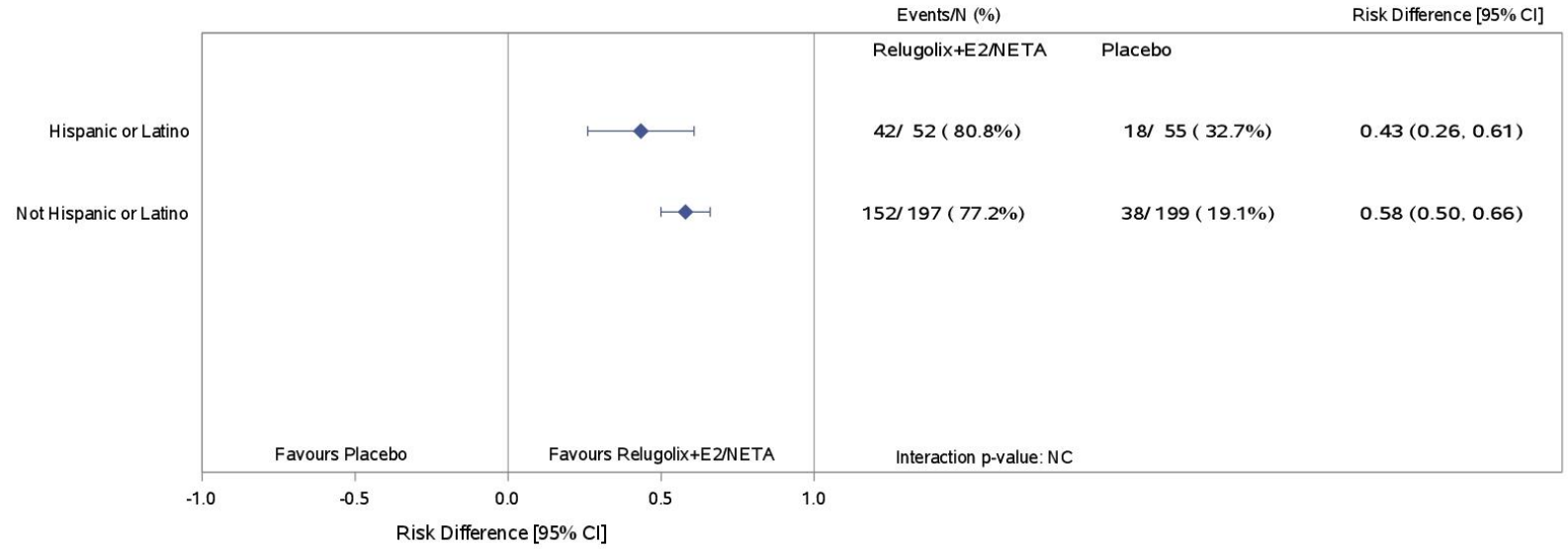
Figure EFF.RG5024ET.MITT.S8.BIN.FP.RD: Proportion of Women in the Relugolix + E2/NETA Group Versus the Placebo Group who Achieve at Least a 50% Reduction from Baseline MBL Volume Over the Last 35 Days of Treatment, as Measured by the Alkaline Hematin Method, by Subgroup (mITT Population) - Risk Difference
Study: Pooled
Subgroup: Ethnicity



Results are based on a Mantel-Haenszel approach stratified by study using a one-stage fixed-effects IPD meta-analysis.
The reference group is Placebo.
N: Number of patients in treatment group; NETA: Norethindrone acetate; mITT: Modified intent-to-treat; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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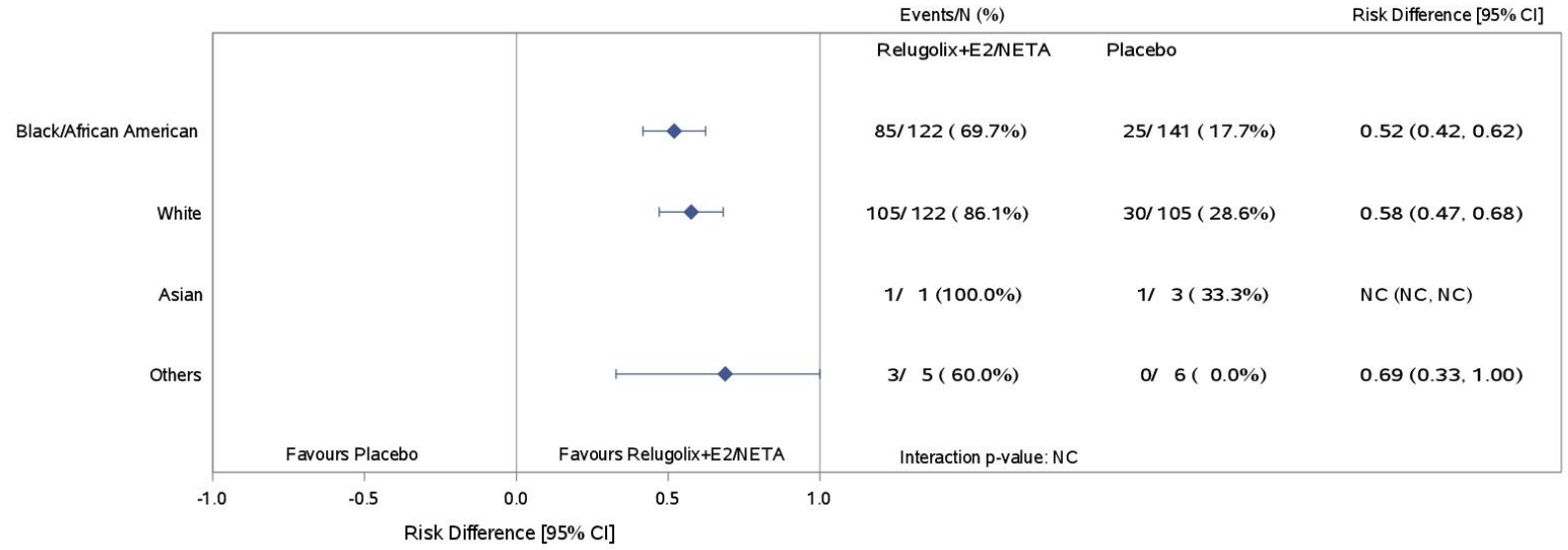
Figure EFF.RG5024ET.MITT.S9.BIN.FP.RD: Proportion of Women in the Relugolix + E2/NETA Group Versus the Placebo Group who Achieve at Least a 50% Reduction from Baseline MBL Volume Over the Last 35 Days of Treatment, as Measured by the Alkaline Hematin Method, by Subgroup (mITT Population) - Risk Difference
Study: Pooled
Subgroup: Race



Results are based on a Mantel-Haenszel approach stratified by study using a one-stage fixed-effects IPD meta-analysis.
The reference group is Placebo.
N: Number of patients in treatment group; NETA: Norethindrone acetate; mITT: Modified intent-to-treat; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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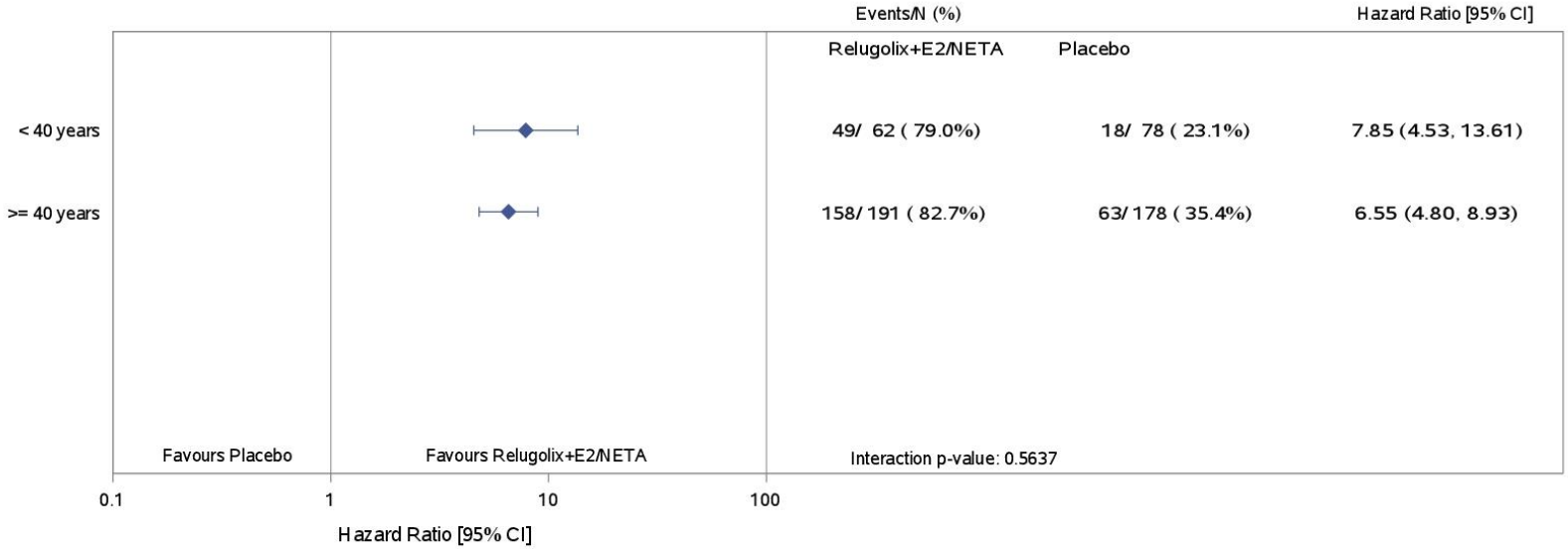
2.1.4 Time to Achieve MBL Volume < 80 mL and >= 50 % Reduction from Baseline, by Subgroup (mITT Population)

Figure EFF.TTMBL.MITT.S1.TTE.FP: Time to Achieve MBL Volume < 80 mL and >= 50 % Reduction from Baseline, by Subgroup (mITT Population)
Study: Pooled
Subgroup: Age (years)



Results are based on a Cox proportional hazard model stratified by study and with treatment group, subgroup and a subgroup-by-treatment group interaction as covariates using a one-stage fixed-effects IPD meta-analysis approach.
The interaction p-value is based on the subgroup-by-treatment interaction term in the proportional hazard model used to compute the Hazard Ratio and 95% CI. Missing subgroup levels are not included in estimation of the interaction p-value. The reference group is Placebo.
N: Number of patients in treatment group; NETA: Norethindrone acetate; mITT: Modified intent-to-treat; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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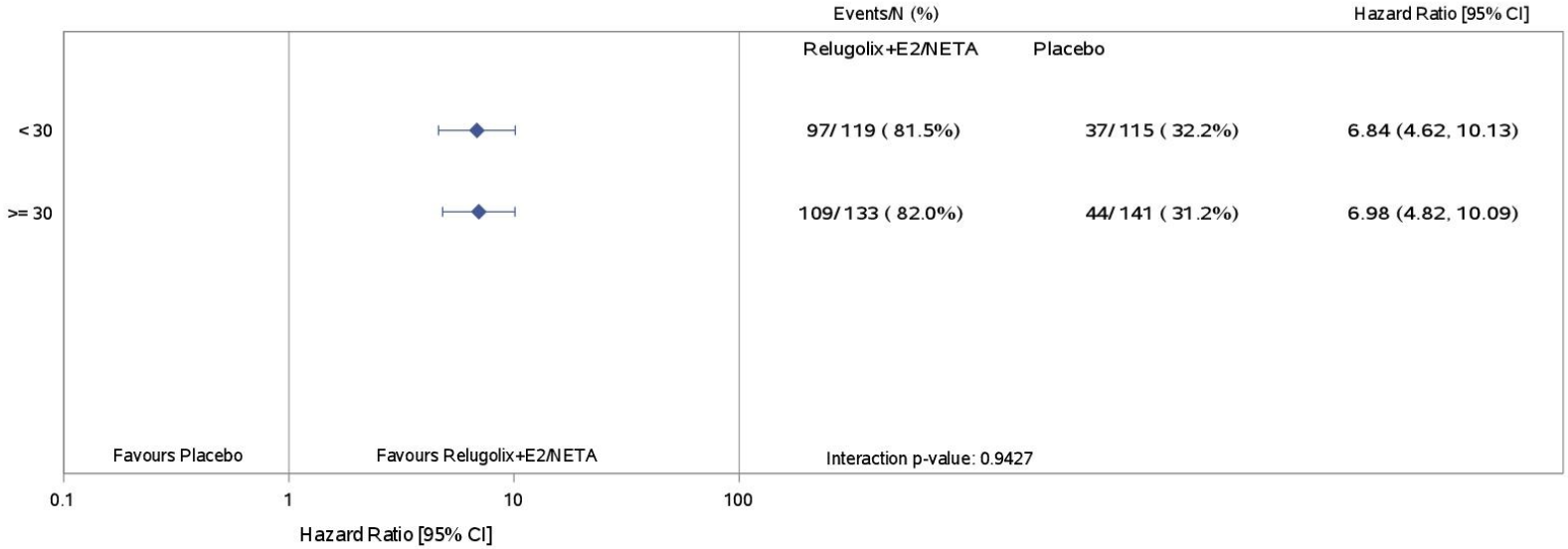
Figure EFF.TTMBL.MITT.S2.TTE.FP: Time to Achieve MBL Volume < 80 mL and >= 50 % Reduction from Baseline, by Subgroup (mITT Population)
Study: Pooled
Subgroup: BMI (kg/m2) at Baseline



Results are based on a Cox proportional hazard model stratified by study and with treatment group, subgroup and a subgroup-by-treatment group interaction as covariates using a one-stage fixed-effects IPD meta-analysis approach.
The interaction p-value is based on the subgroup-by-treatment interaction term in the proportional hazard model used to compute the Hazard Ratio and 95% CI. Missing subgroup levels are not included in estimation of the interaction p-value. The reference group is Placebo.
N: Number of patients in treatment group; NETA: Norethindrone acetate; mITT: Modified intent-to-treat; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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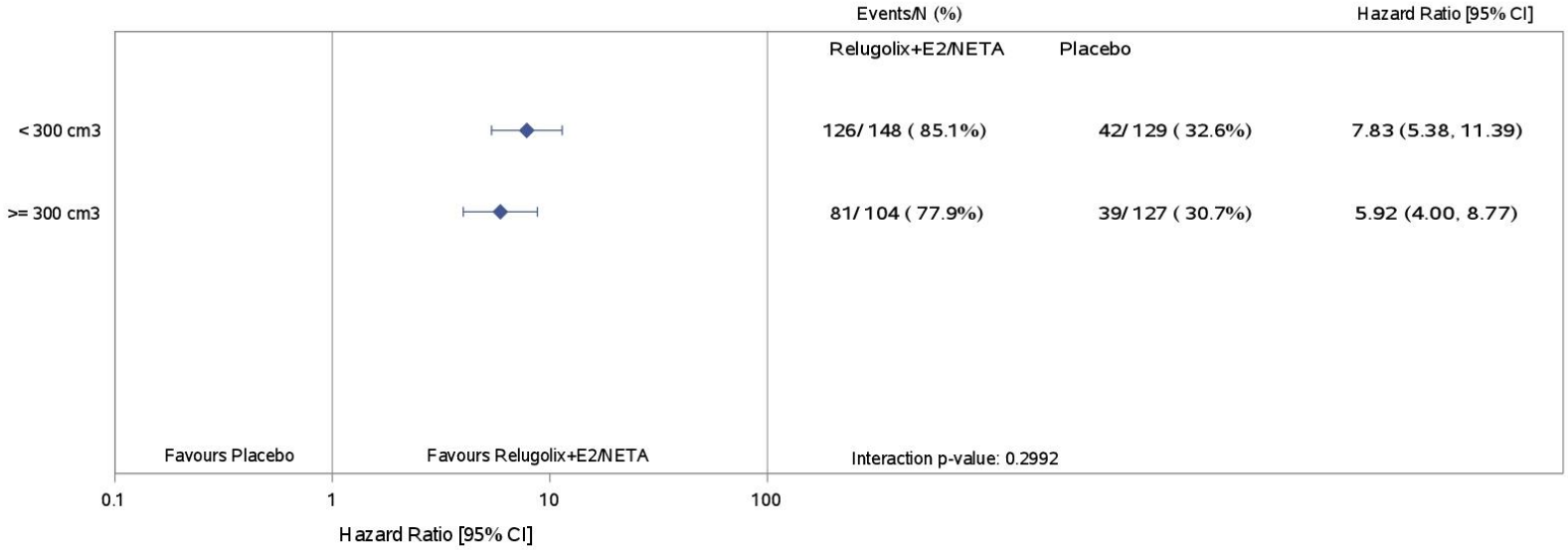
Figure EFF.TTMBL.MITT.S3.TTE.FP: Time to Achieve MBL Volume < 80 mL and >= 50 % Reduction from Baseline, by Subgroup (mITT Population)
Study: Pooled
Subgroup: Uterine Volume at Baseline (cm3)



Results are based on a Cox proportional hazard model stratified by study and with treatment group, subgroup and a subgroup-by-treatment group interaction as covariates using a one-stage fixed-effects IPD meta-analysis approach.
The interaction p-value is based on the subgroup-by-treatment interaction term in the proportional hazard model used to compute the Hazard Ratio and 95% CI. Missing subgroup levels are not included in estimation of the interaction p-value. The reference group is Placebo.
N: Number of patients in treatment group; NETA: Norethindrone acetate; mITT: Modified intent-to-treat; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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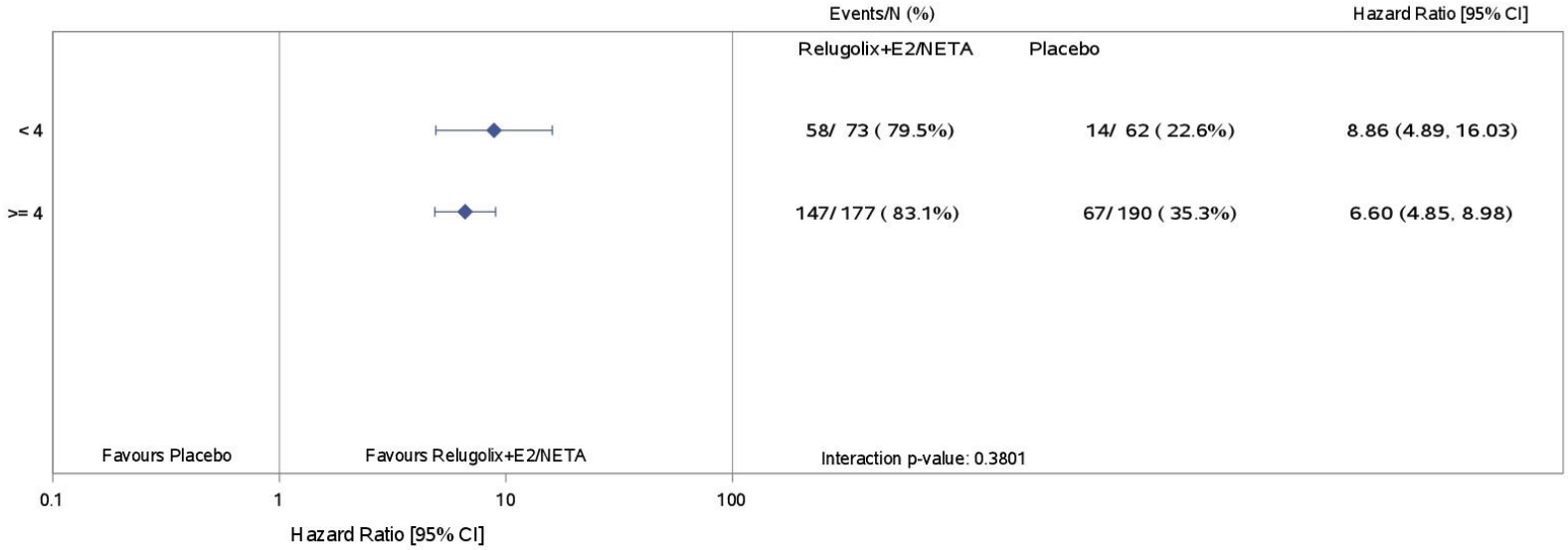
Figure EFF.TTMBL.MITT.S4.TTE.FP: Time to Achieve MBL Volume < 80 mL and >= 50 % Reduction from Baseline, by Subgroup (mITT Population)
Study: Pooled
Subgroup: Maximum NRS Pain Score at Baseline



Results are based on a Cox proportional hazard model stratified by study and with treatment group, subgroup and a subgroup-by-treatment group interaction as covariates using a one-stage fixed-effects IPD meta-analysis approach.
The interaction p-value is based on the subgroup-by-treatment interaction term in the proportional hazard model used to compute the Hazard Ratio and 95% CI. Missing subgroup levels are not included in estimation of the interaction p-value. The reference group is Placebo.
N: Number of patients in treatment group; NETA: Norethindrone acetate; mITT: Modified intent-to-treat; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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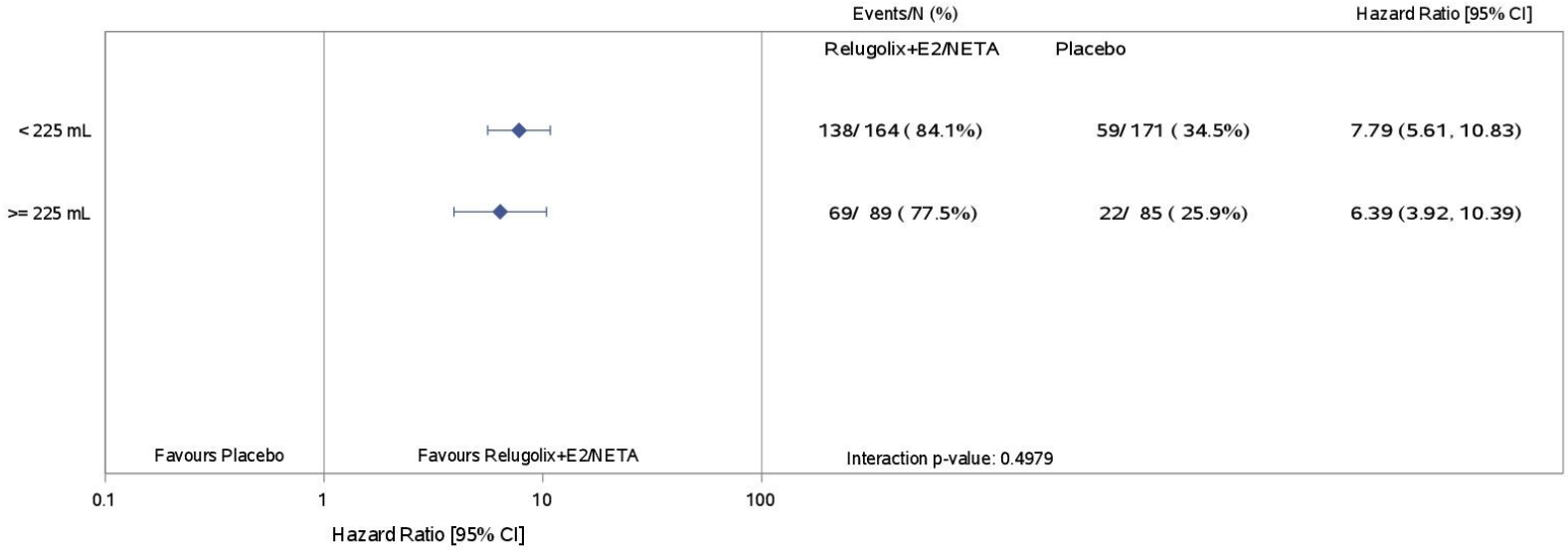
Figure EFF.TTMBL.MITT.S5.TTE.FP: Time to Achieve MBL Volume < 80 mL and >= 50 % Reduction from Baseline, by Subgroup (mITT Population)
Study: Pooled
Subgroup: MBL Volume at Baseline (mL)



Results are based on a Cox proportional hazard model stratified by study and with treatment group, subgroup and a subgroup-by-treatment group interaction as covariates using a one-stage fixed-effects IPD meta-analysis approach.
The interaction p-value is based on the subgroup-by-treatment interaction term in the proportional hazard model used to compute the Hazard Ratio and 95% CI. Missing subgroup levels are not included in estimation of the interaction p-value. The reference group is Placebo.
N: Number of patients in treatment group; NETA: Norethindrone acetate; mITT: Modified intent-to-treat; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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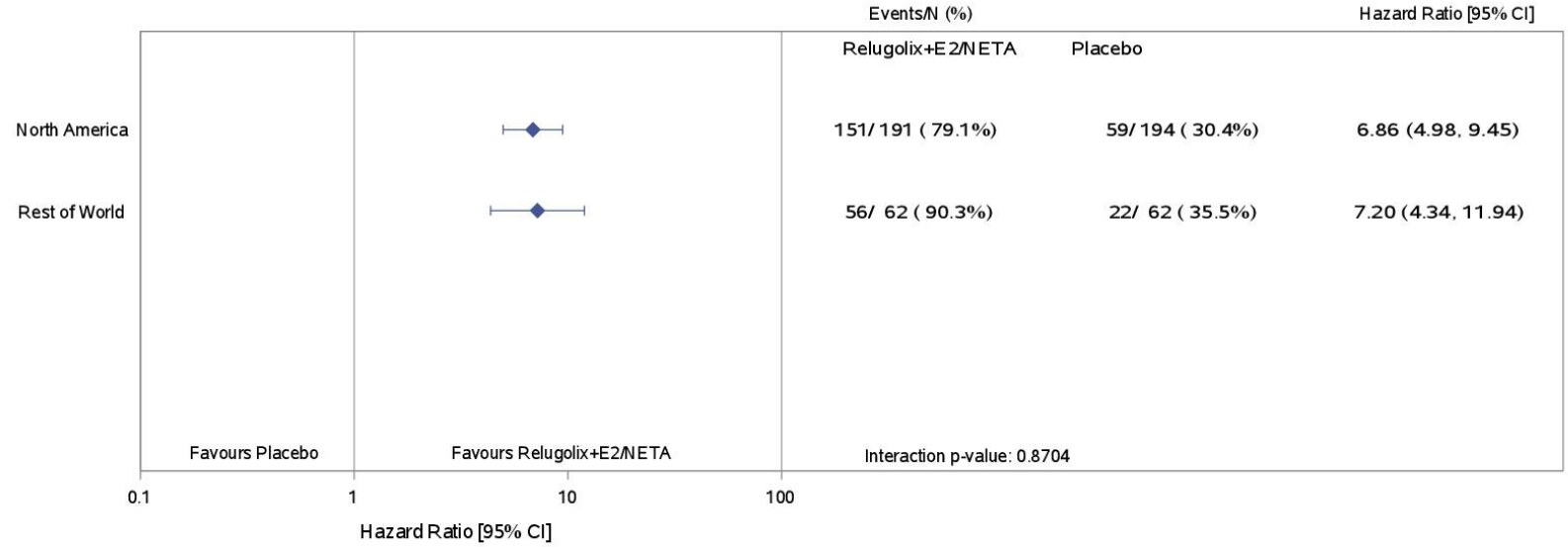
Figure EFF.TTMBL.MITT.S6.TTE.FP: Time to Achieve MBL Volume < 80 mL and >= 50 % Reduction from Baseline, by Subgroup (mITT Population)
Study: Pooled
Subgroup: Geographic Region I



Results are based on a Cox proportional hazard model stratified by study and with treatment group, subgroup and a subgroup-by-treatment group interaction as covariates using a one-stage fixed-effects IPD meta-analysis approach.
The interaction p-value is based on the subgroup-by-treatment interaction term in the proportional hazard model used to compute the Hazard Ratio and 95% CI. Missing subgroup levels are not included in estimation of the interaction p-value. The reference group is Placebo.
N: Number of patients in treatment group; NETA: Norethindrone acetate; mITT: Modified intent-to-treat; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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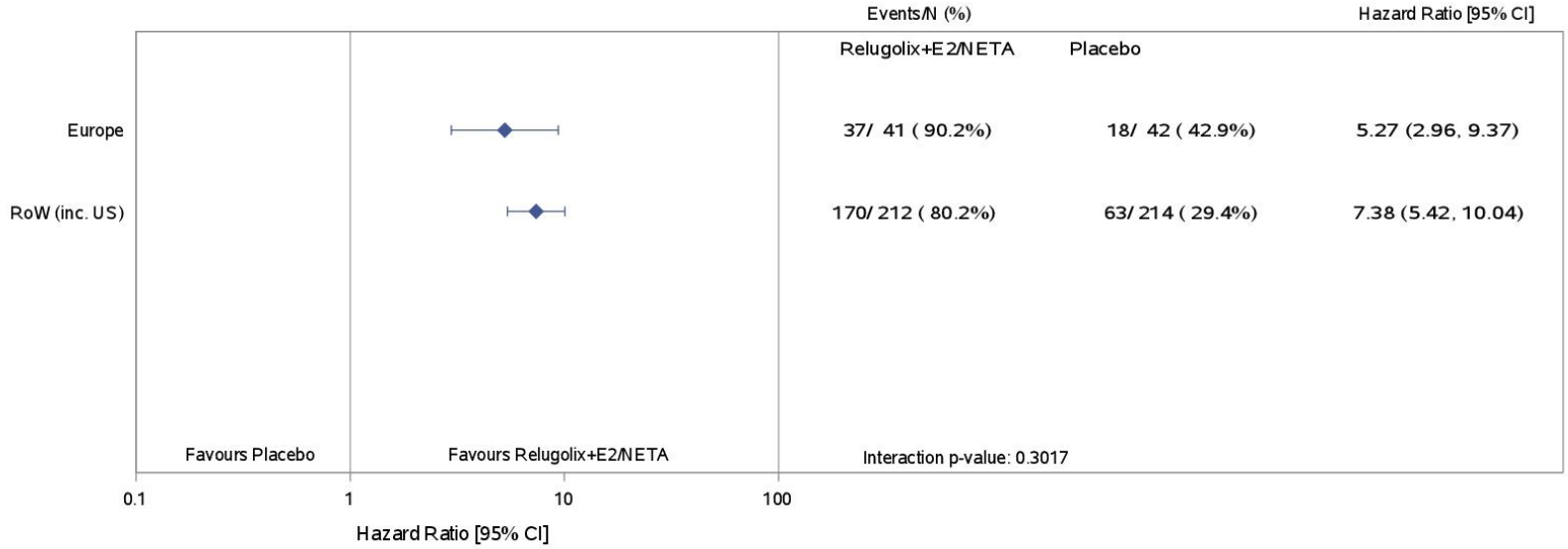
Figure EFF.TTMBL.MITT.S7.TTE.FP: Time to Achieve MBL Volume < 80 mL and >= 50 % Reduction from Baseline, by Subgroup (mITT Population)
Study: Pooled
Subgroup: Geographic Region II



Results are based on a Cox proportional hazard model stratified by study and with treatment group, subgroup and a subgroup-by-treatment group interaction as covariates using a one-stage fixed-effects IPD meta-analysis approach.
The interaction p-value is based on the subgroup-by-treatment interaction term in the proportional hazard model used to compute the Hazard Ratio and 95% CI. Missing subgroup levels are not included in estimation of the interaction p-value. The reference group is Placebo.
N: Number of patients in treatment group; NETA: Norethindrone acetate; mITT: Modified intent-to-treat; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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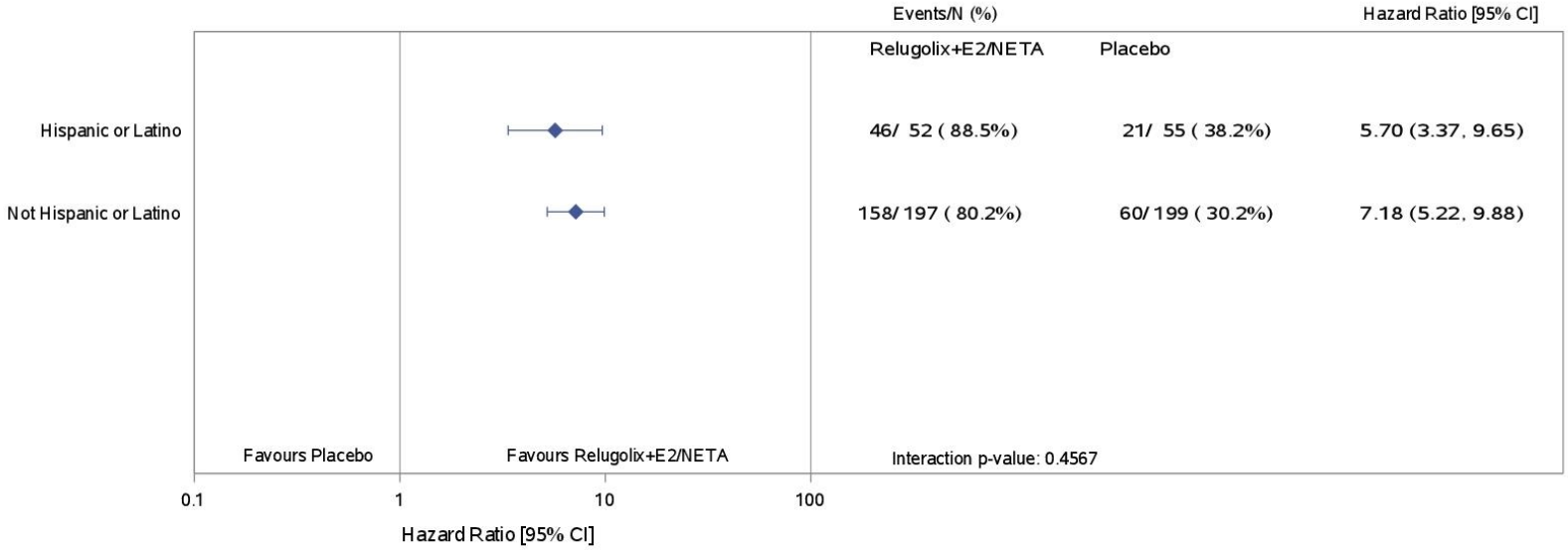
Figure EFF.TTMBL.MITT.S8.TTE.FP: Time to Achieve MBL Volume < 80 mL and >= 50 % Reduction from Baseline, by Subgroup (mITT Population)
Study: Pooled
Subgroup: Ethnicity



Results are based on a Cox proportional hazard model stratified by study and with treatment group, subgroup and a subgroup-by-treatment group interaction as covariates using a one-stage fixed-effects IPD meta-analysis approach.
The interaction p-value is based on the subgroup-by-treatment interaction term in the proportional hazard model used to compute the Hazard Ratio and 95% CI. Missing subgroup levels are not included in estimation of the interaction p-value. The reference group is Placebo.
N: Number of patients in treatment group; NETA: Norethindrone acetate; mITT: Modified intent-to-treat; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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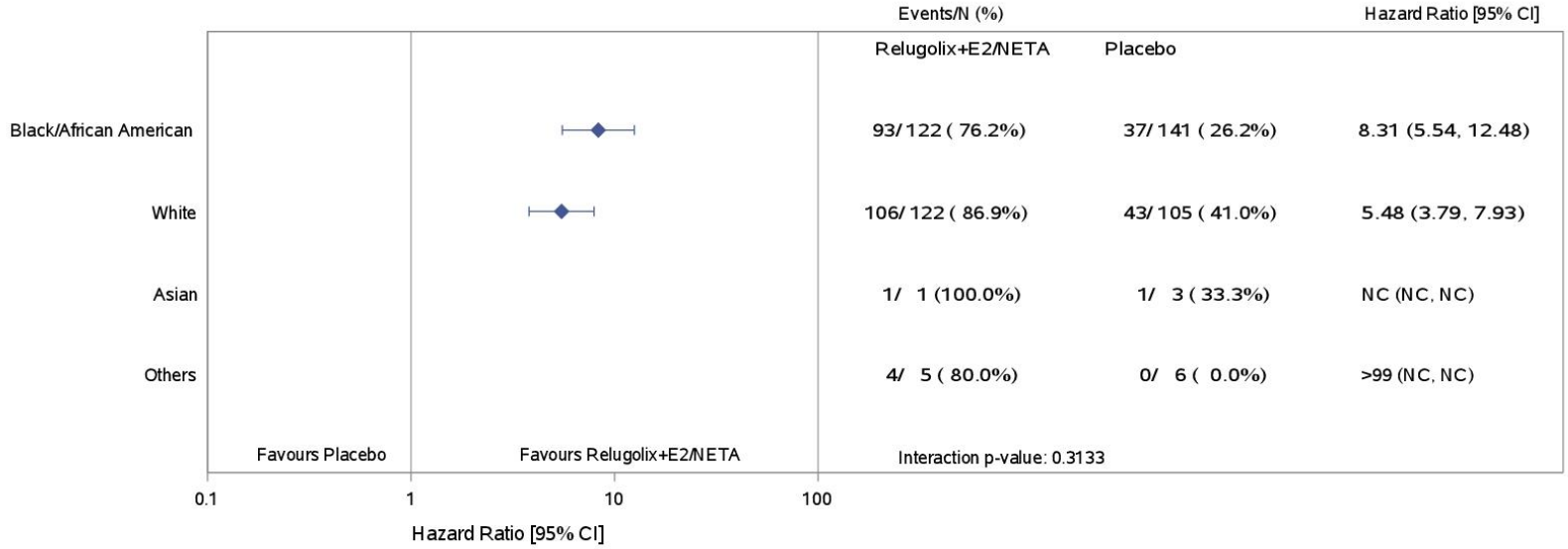
Figure EFF.TTMBL.MITT.S9.TTE.FP: Time to Achieve MBL Volume < 80 mL and >= 50 % Reduction from Baseline, by Subgroup (mITT Population)
Study: Pooled
Subgroup: Race



Results are based on a Cox proportional hazard model stratified by study and with treatment group, subgroup and a subgroup-by-treatment group interaction as covariates using a one-stage fixed-effects IPD meta-analysis approach.
The interaction p-value is based on the subgroup-by-treatment interaction term in the proportional hazard model used to compute the Hazard Ratio and 95% CI. Missing subgroup levels are not included in estimation of the interaction p-value. The reference group is Placebo.
N: Number of patients in treatment group; NETA: Norethindrone acetate; mITT: Modified intent-to-treat; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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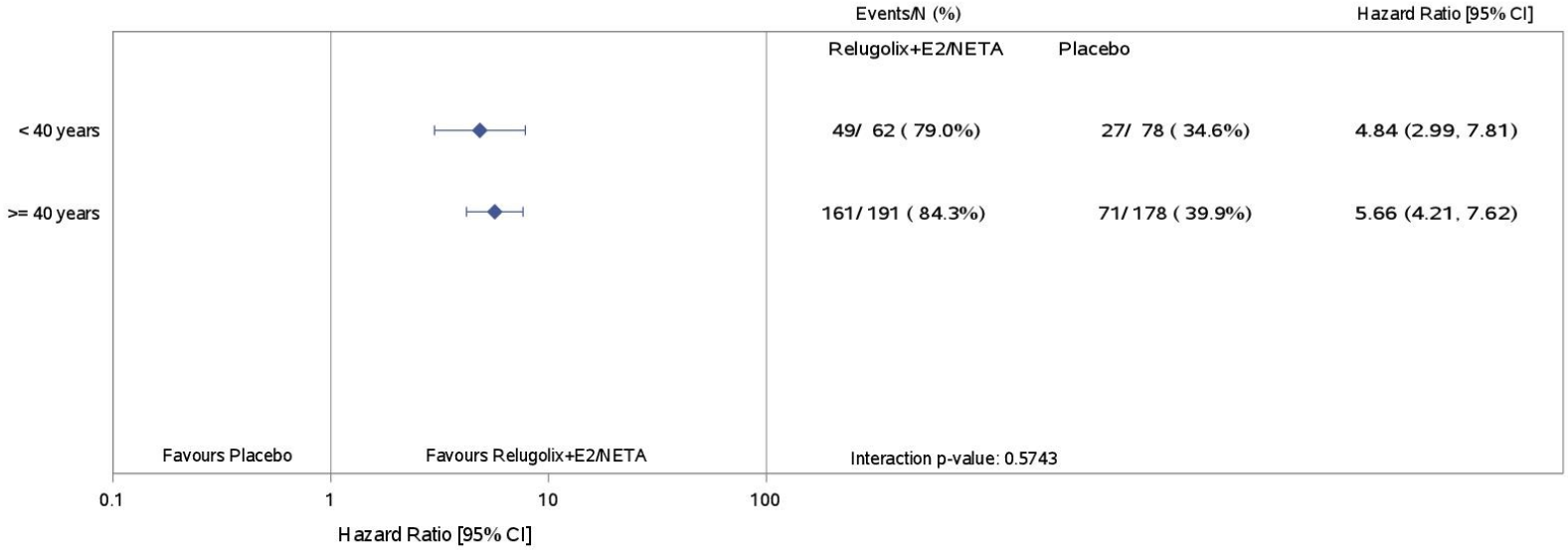
2.1.5 Time to Achieve MBL Volume < 80 mL, by Subgroup (mITT Population)

Figure EFF.TTMBLL80.MITT.S1.TTE.FP: Time to Achieve MBL Volume < 80 mL, by Subgroup (mITT Population)
Study: Pooled
Subgroup: Age (years)



Results are based on a Cox proportional hazard model stratified by study and with treatment group, subgroup and a subgroup-by-treatment group interaction as covariates using a one-stage fixed-effects IPD meta-analysis approach.
The interaction p-value is based on the subgroup-by-treatment interaction term in the proportional hazard model used to compute the Hazard Ratio and 95% CI. Missing subgroup levels are not included in estimation of the interaction p-value. The reference group is Placebo.
N: Number of patients in treatment group; NETA: Norethindrone acetate; mITT: Modified intent-to-treat; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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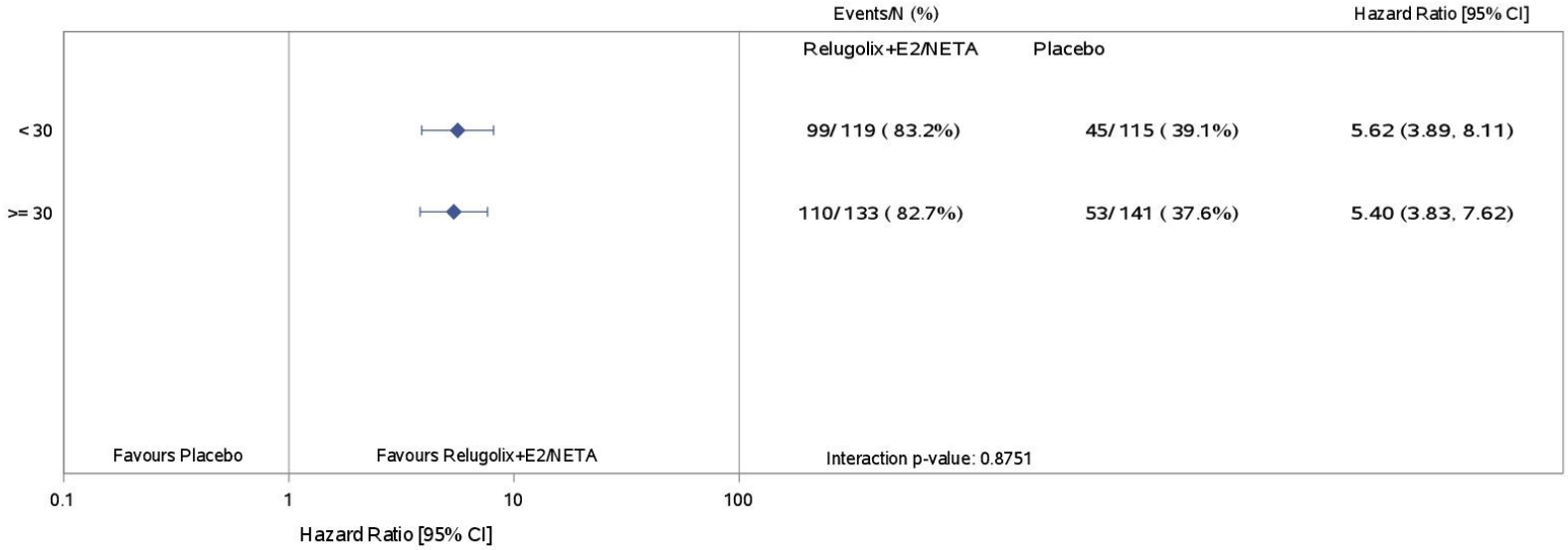
Figure EFF.TTMBLL80.MITT.S2.TTE.FP: Time to Achieve MBL Volume < 80 mL, by Subgroup (mITT Population)
Study: Pooled
Subgroup: BMI (kg/m2) at Baseline



Results are based on a Cox proportional hazard model stratified by study and with treatment group, subgroup and a subgroup-by-treatment group interaction as covariates using a one-stage fixed-effects IPD meta-analysis approach.
The interaction p-value is based on the subgroup-by-treatment interaction term in the proportional hazard model used to compute the Hazard Ratio and 95% CI. Missing subgroup levels are not included in estimation of the interaction p-value. The reference group is Placebo.
N: Number of patients in treatment group; NETA: Norethindrone acetate; mITT: Modified intent-to-treat; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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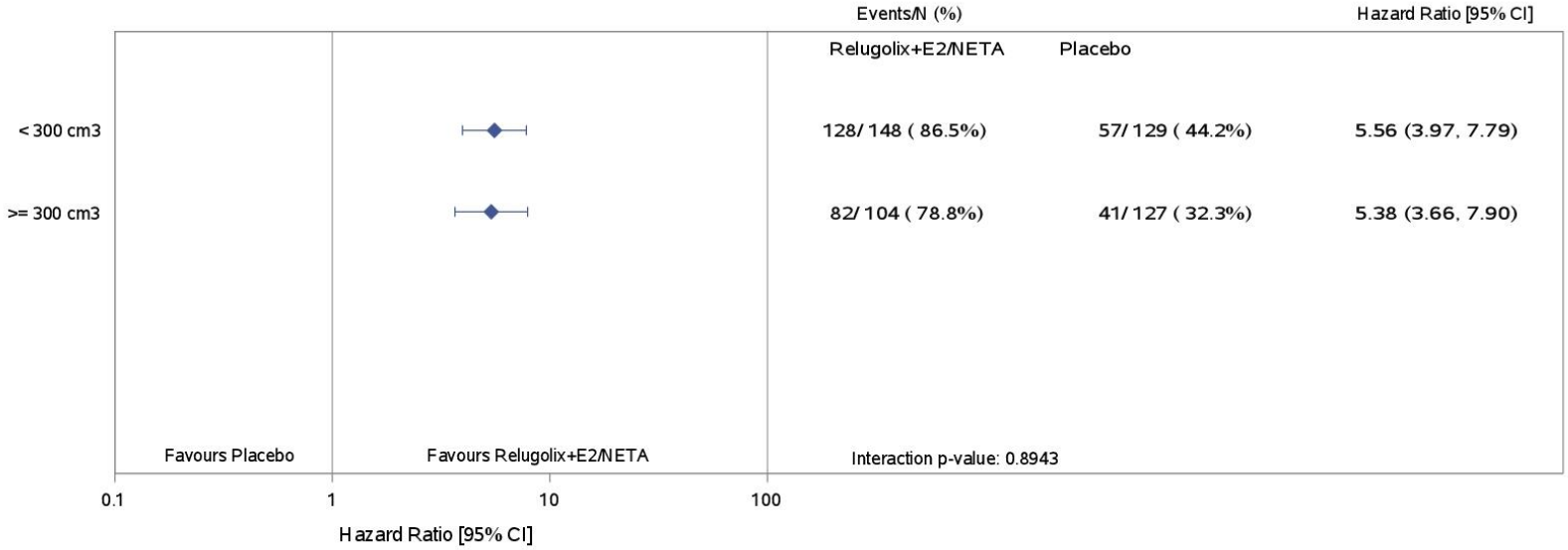
Figure EFF.TTMBLL80.MITT.S3.TTE.FP: Time to Achieve MBL Volume < 80 mL, by Subgroup (mITT Population)
Study: Pooled
Subgroup: Uterine Volume at Baseline (cm3)



Results are based on a Cox proportional hazard model stratified by study and with treatment group, subgroup and a subgroup-by-treatment group interaction as covariates using a one-stage fixed-effects IPD meta-analysis approach.
The interaction p-value is based on the subgroup-by-treatment interaction term in the proportional hazard model used to compute the Hazard Ratio and 95% CI. Missing subgroup levels are not included in estimation of the interaction p-value. The reference group is Placebo.
N: Number of patients in treatment group; NETA: Norethindrone acetate; mITT: Modified intent-to-treat; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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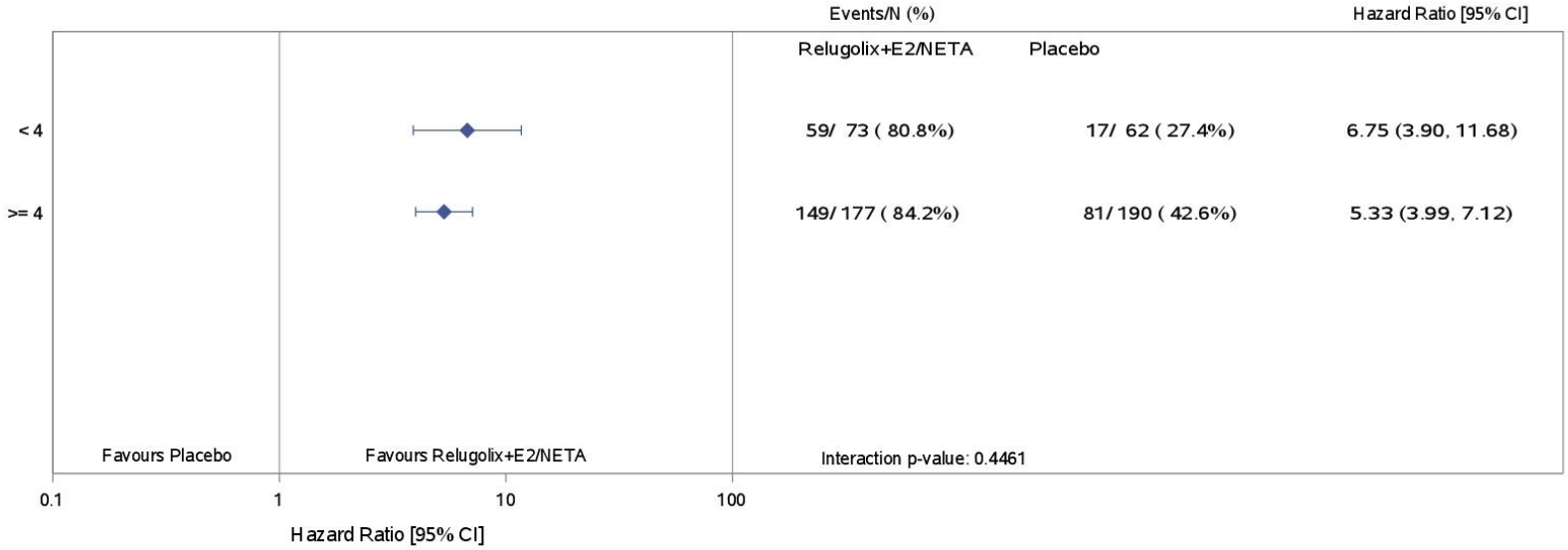
Figure EFF.TTMBLL80.MITT.S4.TTE.FP: Time to Achieve MBL Volume < 80 mL, by Subgroup (mITT Population)
Study: Pooled
Subgroup: Maximum NRS Pain Score at Baseline



Results are based on a Cox proportional hazard model stratified by study and with treatment group, subgroup and a subgroup-by-treatment group interaction as covariates using a one-stage fixed-effects IPD meta-analysis approach.
The interaction p-value is based on the subgroup-by-treatment interaction term in the proportional hazard model used to compute the Hazard Ratio and 95% CI. Missing subgroup levels are not included in estimation of the interaction p-value. The reference group is Placebo.
N: Number of patients in treatment group; NETA: Norethindrone acetate; mITT: Modified intent-to-treat; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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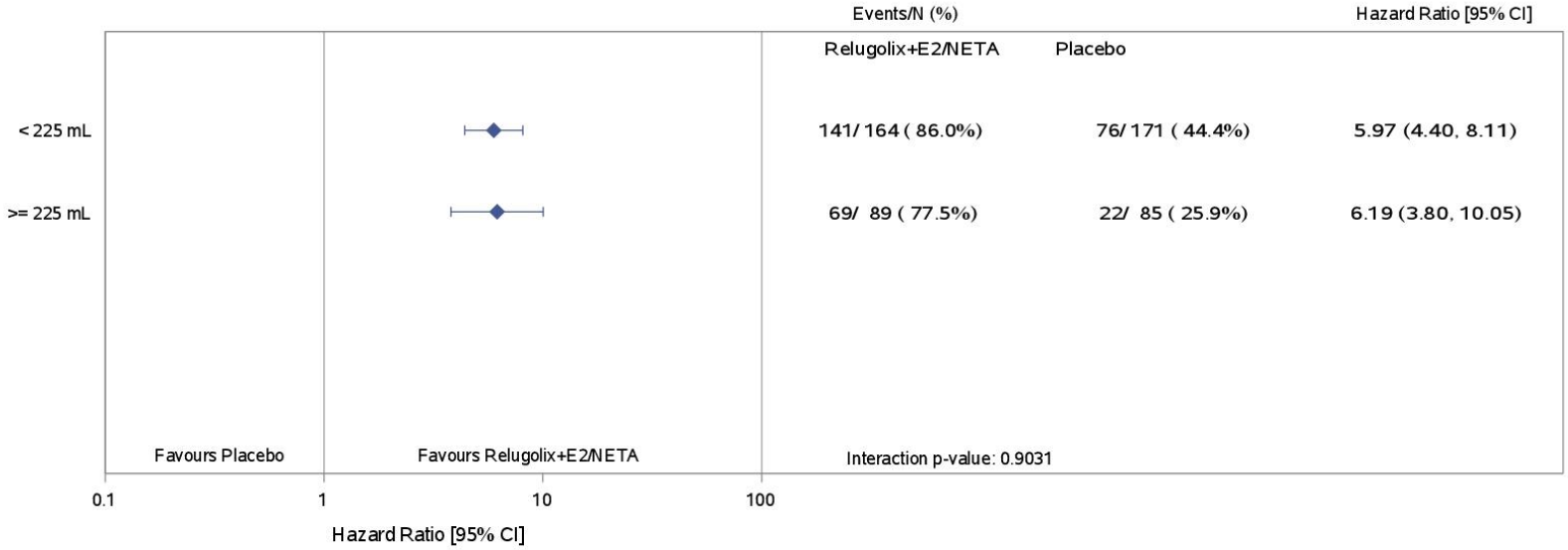
Figure EFF.TTMBLL80.MITT.S5.TTE.FP: Time to Achieve MBL Volume < 80 mL, by Subgroup (mITT Population)
Study: Pooled
Subgroup: MBL Volume at Baseline (mL)



Results are based on a Cox proportional hazard model stratified by study and with treatment group, subgroup and a subgroup-by-treatment group interaction as covariates using a one-stage fixed-effects IPD meta-analysis approach.
The interaction p-value is based on the subgroup-by-treatment interaction term in the proportional hazard model used to compute the Hazard Ratio and 95% CI. Missing subgroup levels are not included in estimation of the interaction p-value. The reference group is Placebo.
N: Number of patients in treatment group; NETA: Norethindrone acetate; mITT: Modified intent-to-treat; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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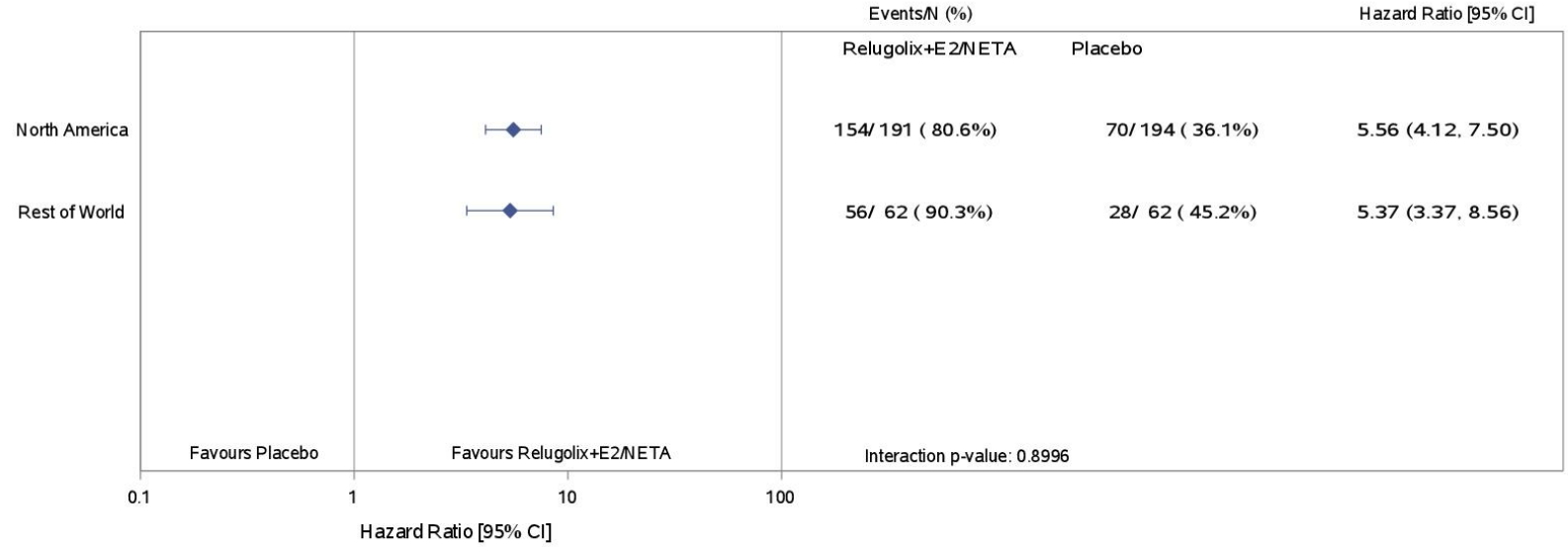
Figure EFF.TTMBLL80.MITT.S6.TTE.FP: Time to Achieve MBL Volume < 80 mL, by Subgroup (mITT Population)
Study: Pooled
Subgroup: Geographic Region I



Results are based on a Cox proportional hazard model stratified by study and with treatment group, subgroup and a subgroup-by-treatment group interaction as covariates using a one-stage fixed-effects IPD meta-analysis approach.
The interaction p-value is based on the subgroup-by-treatment interaction term in the proportional hazard model used to compute the Hazard Ratio and 95% CI. Missing subgroup levels are not included in estimation of the interaction p-value. The reference group is Placebo.
N: Number of patients in treatment group; NETA: Norethindrone acetate; mITT: Modified intent-to-treat; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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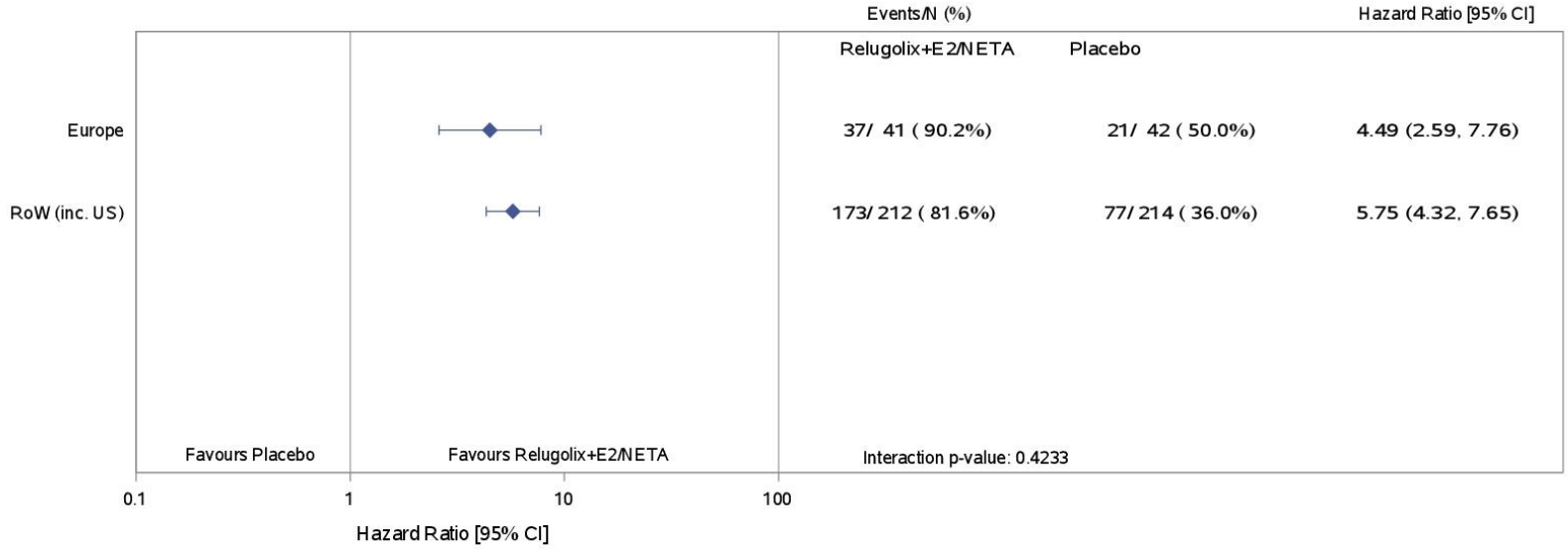
Figure EFF.TTMBLL80.MITT.S7.TTE.FP: Time to Achieve MBL Volume < 80 mL, by Subgroup (mITT Population)
Study: Pooled
Subgroup: Geographic Region II



Results are based on a Cox proportional hazard model stratified by study and with treatment group, subgroup and a subgroup-by-treatment group interaction as covariates using a one-stage fixed-effects IPD meta-analysis approach.
The interaction p-value is based on the subgroup-by-treatment interaction term in the proportional hazard model used to compute the Hazard Ratio and 95% CI. Missing subgroup levels are not included in estimation of the interaction p-value. The reference group is Placebo.
N: Number of patients in treatment group; NETA: Norethindrone acetate; mITT: Modified intent-to-treat; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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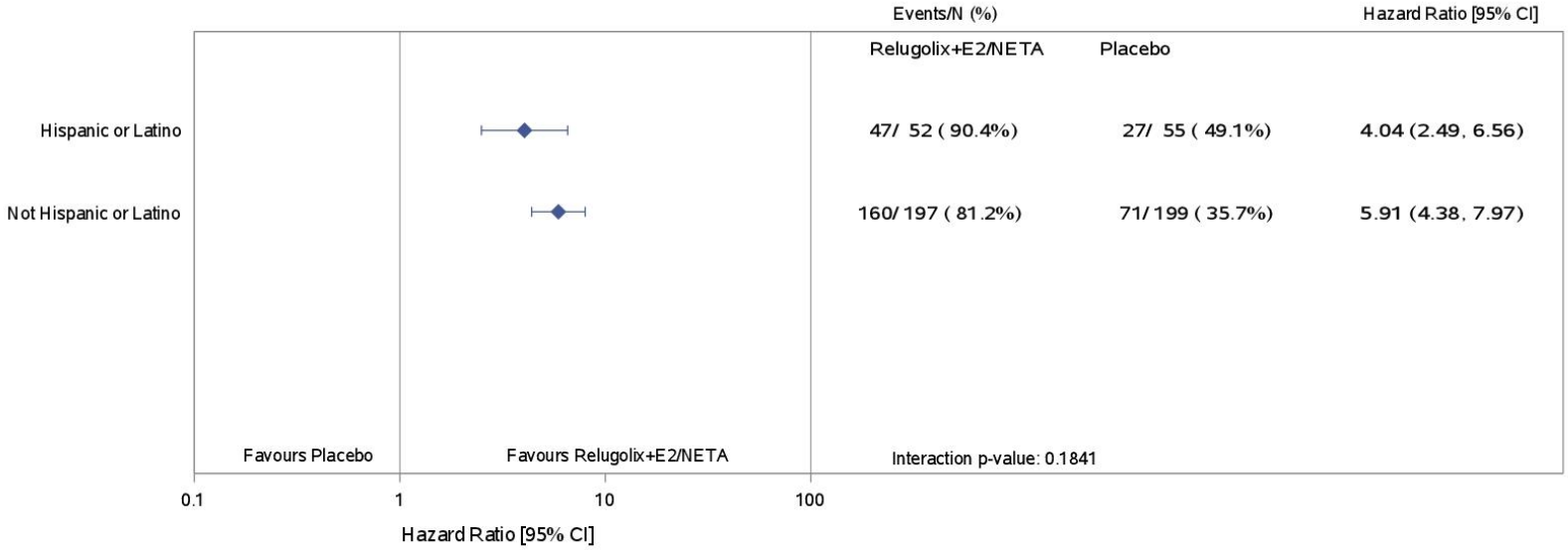
Figure EFF.TTMBLL80.MITT.S8.TTE.FP: Time to Achieve MBL Volume < 80 mL, by Subgroup (mITT Population)
Study: Pooled
Subgroup: Ethnicity



Results are based on a Cox proportional hazard model stratified by study and with treatment group, subgroup and a subgroup-by-treatment group interaction as covariates using a one-stage fixed-effects IPD meta-analysis approach.
The interaction p-value is based on the subgroup-by-treatment interaction term in the proportional hazard model used to compute the Hazard Ratio and 95% CI. Missing subgroup levels are not included in estimation of the interaction p-value. The reference group is Placebo.
N: Number of patients in treatment group; NETA: Norethindrone acetate; mITT: Modified intent-to-treat; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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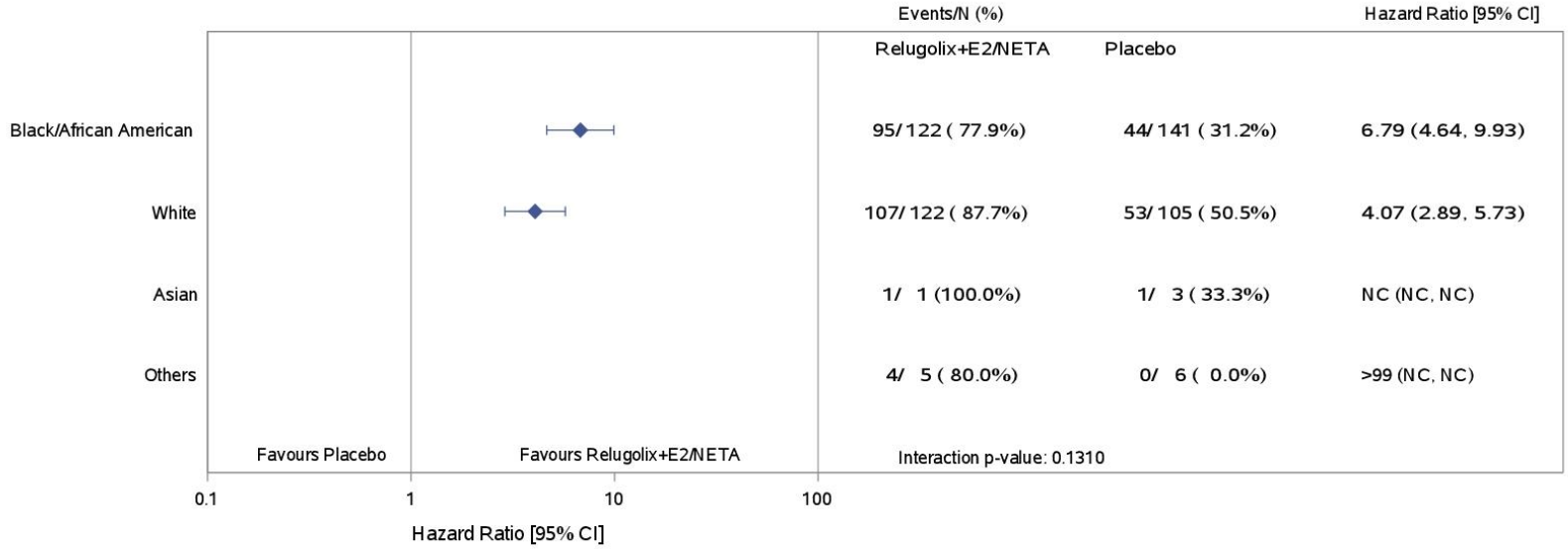
Figure EFF.TTMBLL80.MITT.S9.TTE.FP: Time to Achieve MBL Volume < 80 mL, by Subgroup (mITT Population)
Study: Pooled
Subgroup: Race



Results are based on a Cox proportional hazard model stratified by study and with treatment group, subgroup and a subgroup-by-treatment group interaction as covariates using a one-stage fixed-effects IPD meta-analysis approach.
The interaction p-value is based on the subgroup-by-treatment interaction term in the proportional hazard model used to compute the Hazard Ratio and 95% CI. Missing subgroup levels are not included in estimation of the interaction p-value. The reference group is Placebo.
N: Number of patients in treatment group; NETA: Norethindrone acetate; mITT: Modified intent-to-treat; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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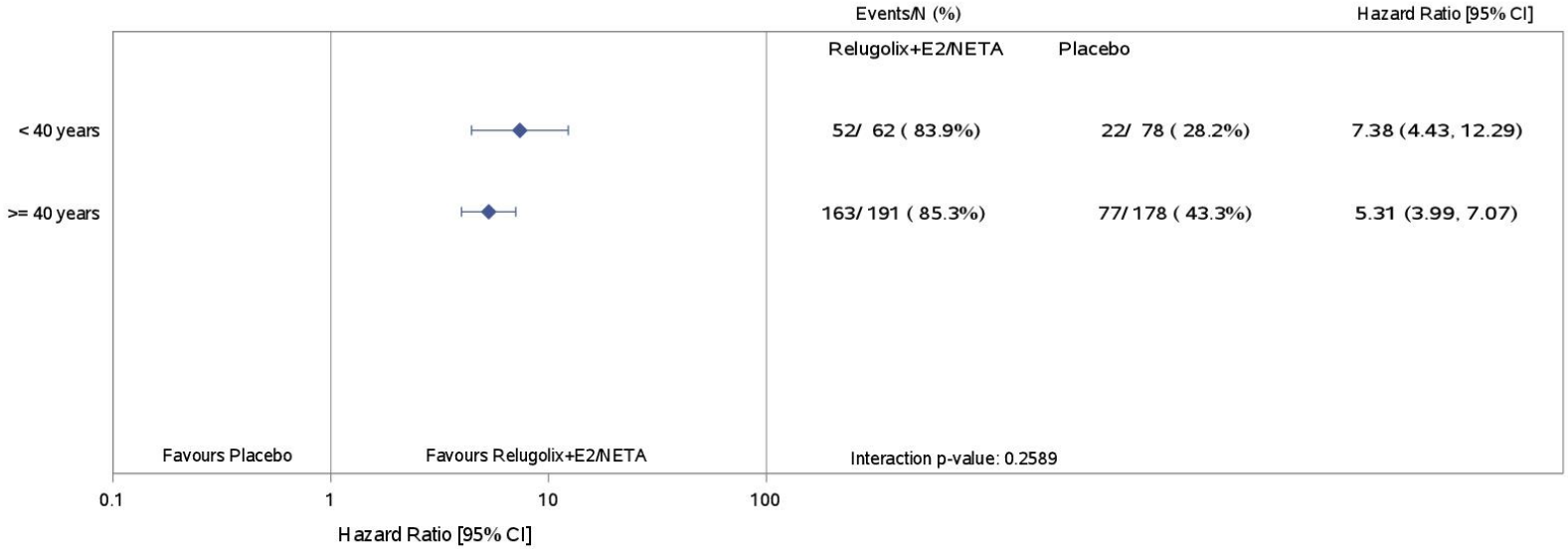
2.1.6 Time to Achieve >= 50% Reduction in Menstrual Blood Loss Volume from Baseline, by Subgroup (mITT Population)

Figure EFF.TTMBLG50.MITT.S1.TTE.FP: Time to Achieve >= 50% Reduction in Menstrual Blood Loss Volume from Baseline, by Subgroup (mITT Population)
Study: Pooled
Subgroup: Age (years)



Results are based on a Cox proportional hazard model stratified by study and with treatment group, subgroup and a subgroup-by-treatment group interaction as covariates using a one-stage fixed-effects IPD meta-analysis approach.
The interaction p-value is based on the subgroup-by-treatment interaction term in the proportional hazard model used to compute the Hazard Ratio and 95% CI. Missing subgroup levels are not included in estimation of the interaction p-value. The reference group is Placebo.
N: Number of patients in treatment group; NETA: Norethindrone acetate; mITT: Modified intent-to-treat; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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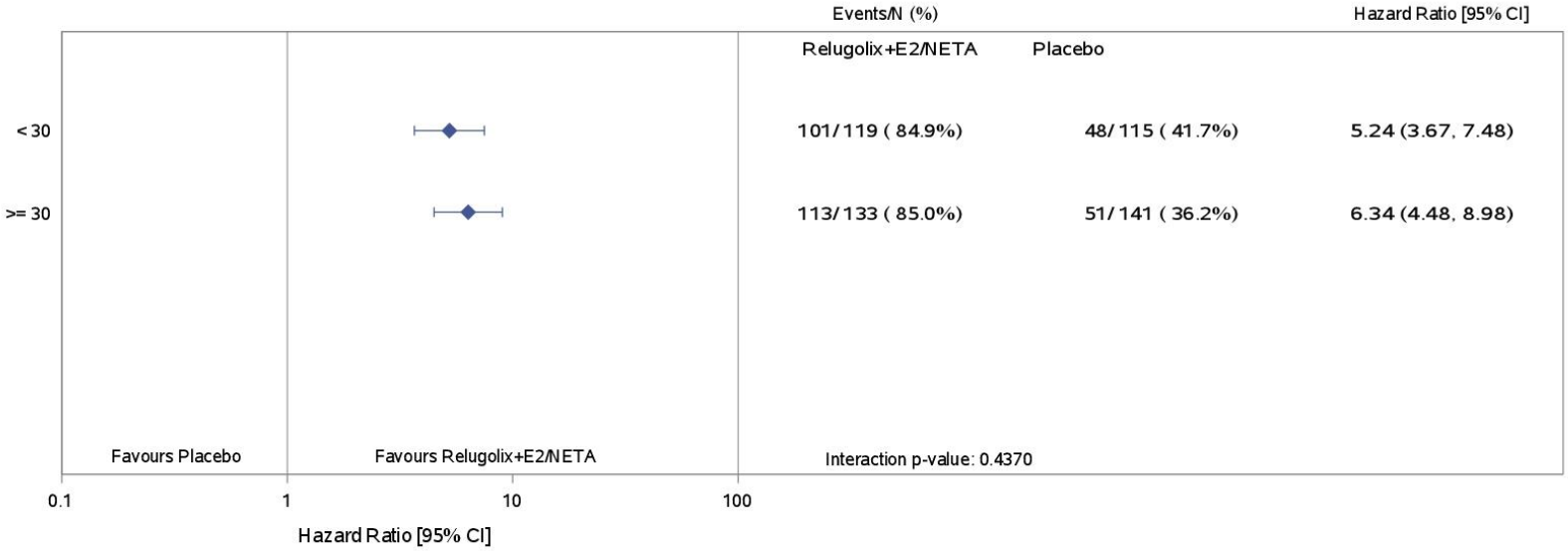
Figure EFF.TTMBLG50.MITT.S2.TTE.FP: Time to Achieve >= 50% Reduction in Menstrual Blood Loss Volume from Baseline, by Subgroup (mITT Population)
Study: Pooled
Subgroup: BMI (kg/m2) at Baseline



Results are based on a Cox proportional hazard model stratified by study and with treatment group, subgroup and a subgroup-by-treatment group interaction as covariates using a one-stage fixed-effects IPD meta-analysis approach.
The interaction p-value is based on the subgroup-by-treatment interaction term in the proportional hazard model used to compute the Hazard Ratio and 95% CI. Missing subgroup levels are not included in estimation of the interaction p-value. The reference group is Placebo.
N: Number of patients in treatment group; NETA: Norethindrone acetate; mITT: Modified intent-to-treat; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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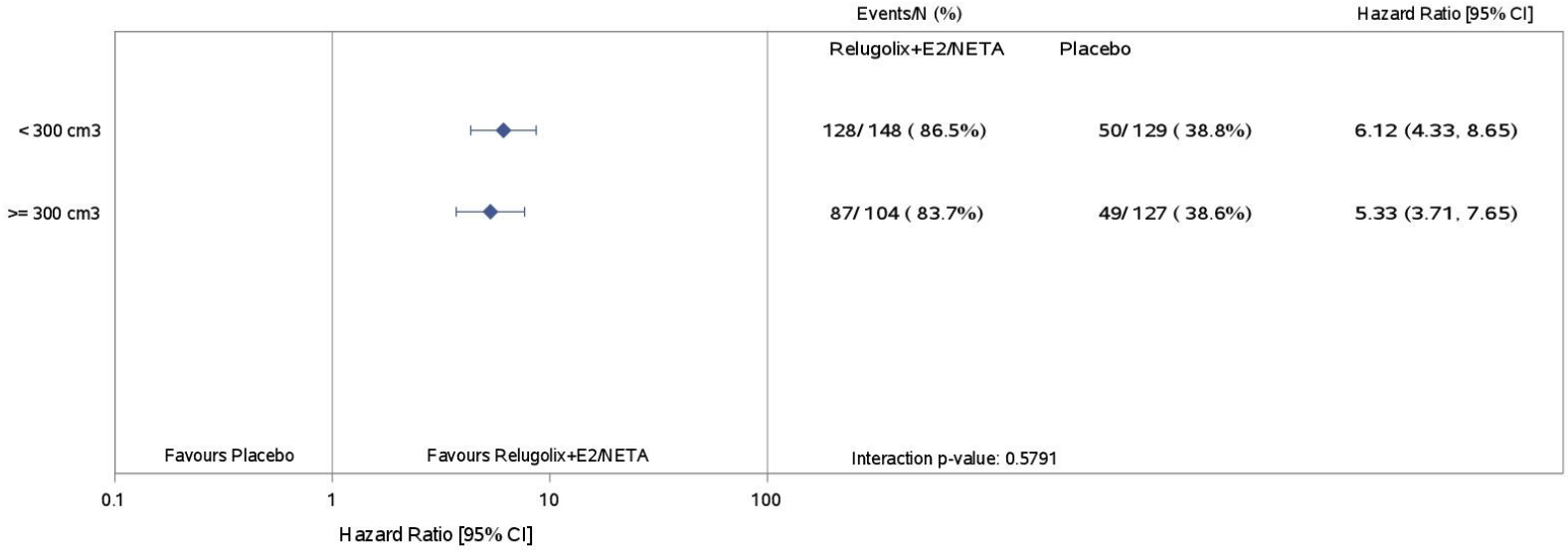
Figure EFF.TTMBLG50.MITT.S3.TTE.FP: Time to Achieve >= 50% Reduction in Menstrual Blood Loss Volume from Baseline, by Subgroup (mITT Population)
Study: Pooled
Subgroup: Uterine Volume at Baseline (cm3)



Results are based on a Cox proportional hazard model stratified by study and with treatment group, subgroup and a subgroup-by-treatment group interaction as covariates using a one-stage fixed-effects IPD meta-analysis approach.
The interaction p-value is based on the subgroup-by-treatment interaction term in the proportional hazard model used to compute the Hazard Ratio and 95% CI. Missing subgroup levels are not included in estimation of the interaction p-value. The reference group is Placebo.
N: Number of patients in treatment group; NETA: Norethindrone acetate; mITT: Modified intent-to-treat; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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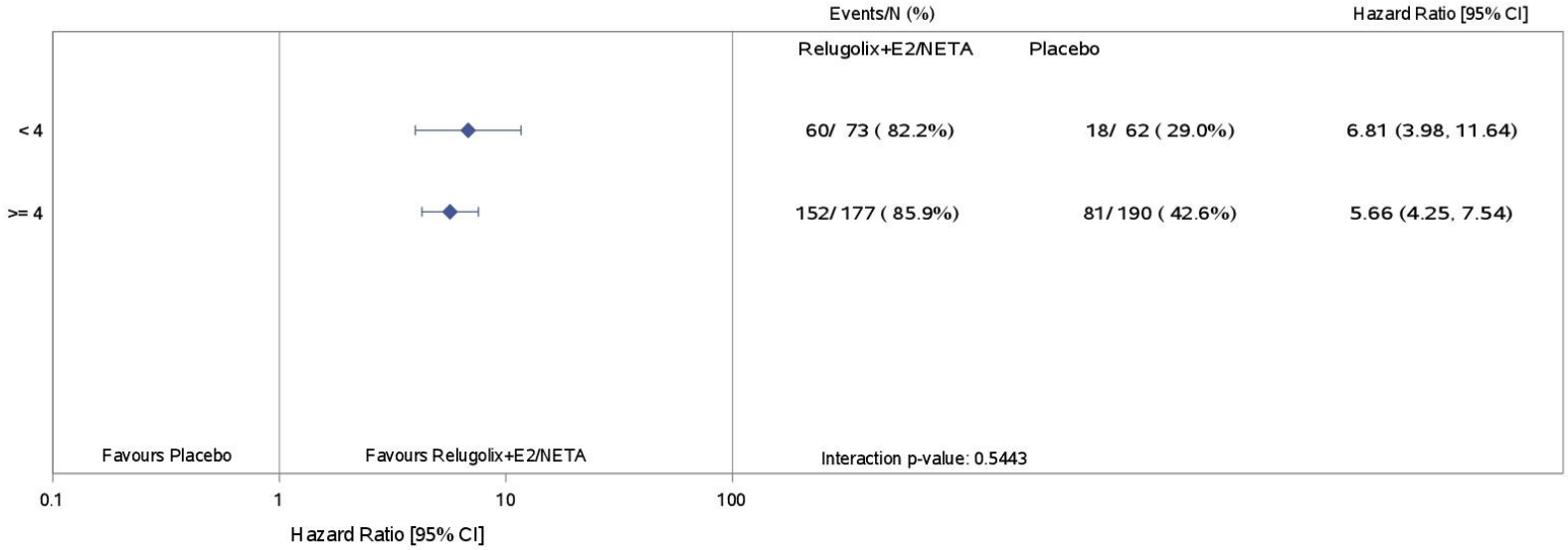
Figure EFF.TTMBLG50.MITT.S4.TTE.FP: Time to Achieve >= 50% Reduction in Menstrual Blood Loss Volume from Baseline, by Subgroup (mITT Population)
Study: Pooled
Subgroup: Maximum NRS Pain Score at Baseline



Results are based on a Cox proportional hazard model stratified by study and with treatment group, subgroup and a subgroup-by-treatment group interaction as covariates using a one-stage fixed-effects IPD meta-analysis approach.
The interaction p-value is based on the subgroup-by-treatment interaction term in the proportional hazard model used to compute the Hazard Ratio and 95% CI. Missing subgroup levels are not included in estimation of the interaction p-value. The reference group is Placebo.
N: Number of patients in treatment group; NETA: Norethindrone acetate; mITT: Modified intent-to-treat; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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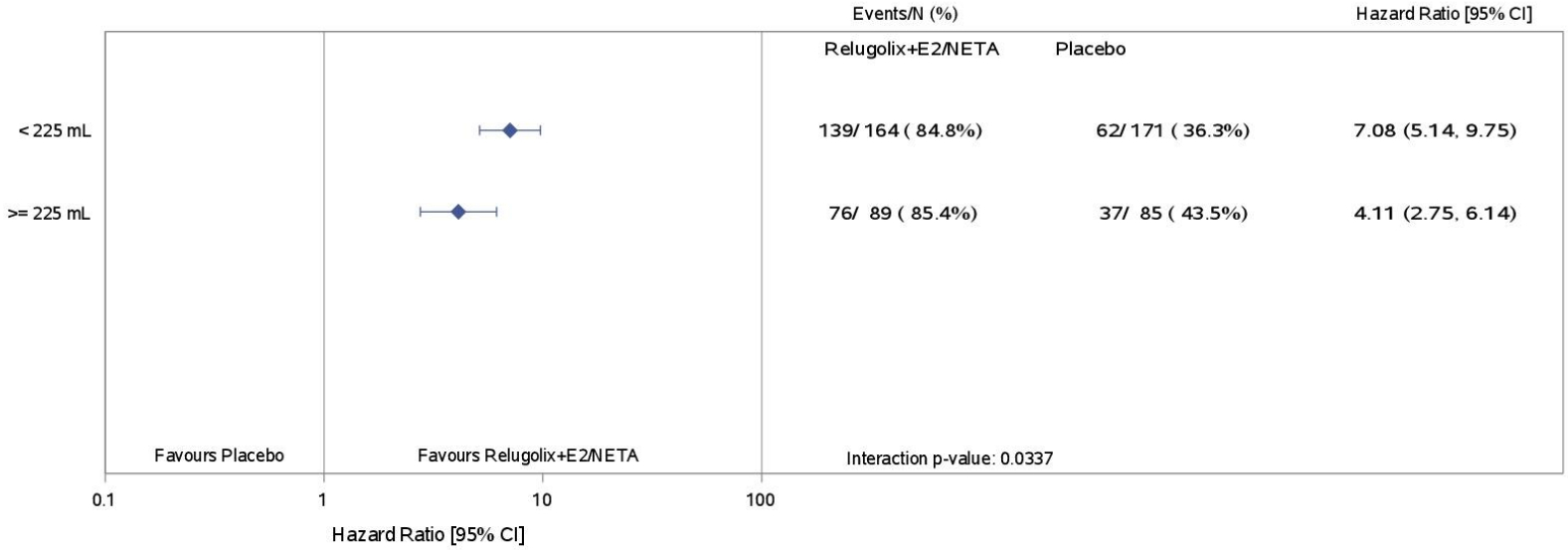
Figure EFF.TTMBLG50.MITT.S5.TTE.FP: Time to Achieve >= 50% Reduction in Menstrual Blood Loss Volume from Baseline, by Subgroup (mITT Population)
Study: Pooled
Subgroup: MBL Volume at Baseline (mL)



Results are based on a Cox proportional hazard model stratified by study and with treatment group, subgroup and a subgroup-by-treatment group interaction as covariates using a one-stage fixed-effects IPD meta-analysis approach.
The interaction p-value is based on the subgroup-by-treatment interaction term in the proportional hazard model used to compute the Hazard Ratio and 95% CI. Missing subgroup levels are not included in estimation of the interaction p-value. The reference group is Placebo.
N: Number of patients in treatment group; NETA: Norethindrone acetate; mITT: Modified intent-to-treat; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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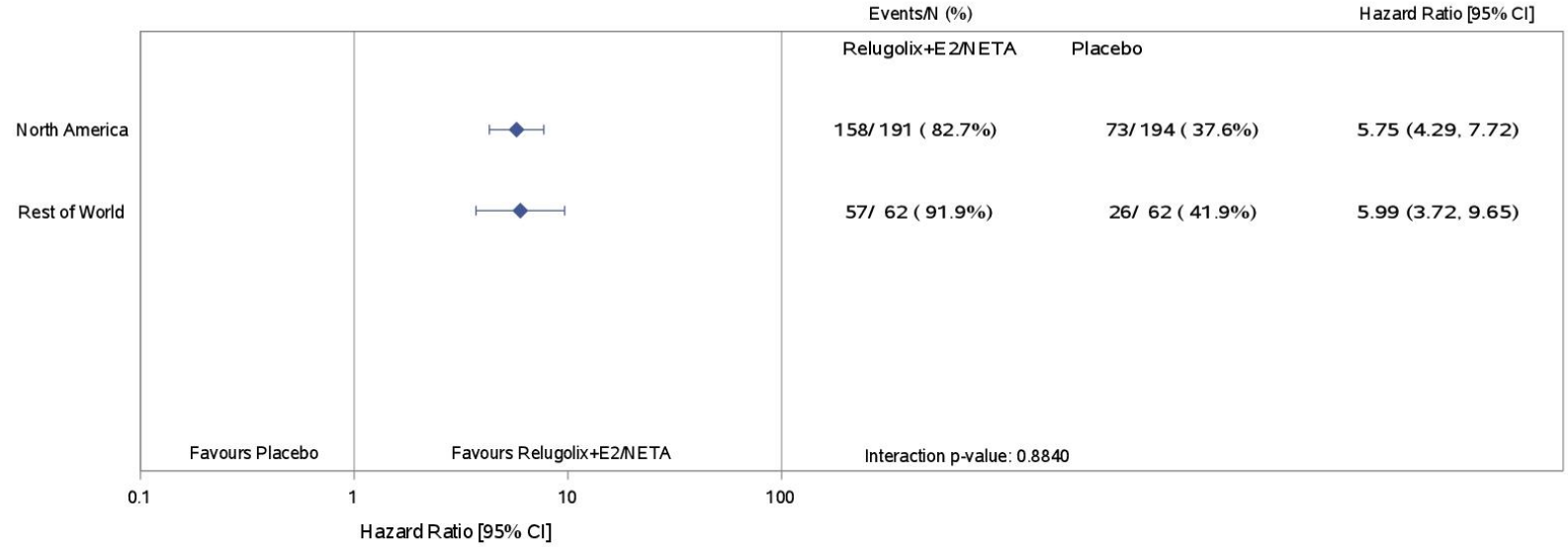
Figure EFF.TTMBLG50.MITT.S6.TTE.FP: Time to Achieve >= 50% Reduction in Menstrual Blood Loss Volume from Baseline, by Subgroup (mITT Population)
Study: Pooled
Subgroup: Geographic Region I



Results are based on a Cox proportional hazard model stratified by study and with treatment group, subgroup and a subgroup-by-treatment group interaction as covariates using a one-stage fixed-effects IPD meta-analysis approach.
The interaction p-value is based on the subgroup-by-treatment interaction term in the proportional hazard model used to compute the Hazard Ratio and 95% CI. Missing subgroup levels are not included in estimation of the interaction p-value. The reference group is Placebo.
N: Number of patients in treatment group; NETA: Norethindrone acetate; mITT: Modified intent-to-treat; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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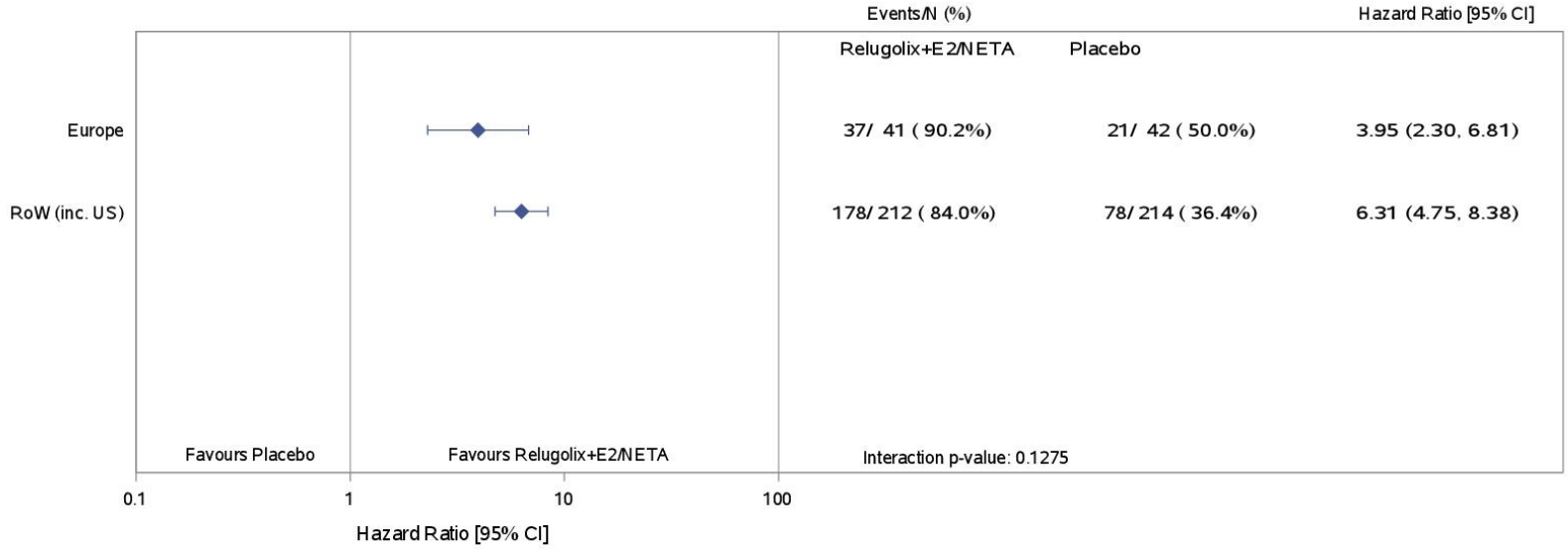
Figure EFF.TTMBLG50.MITT.S7.TTE.FP: Time to Achieve >= 50% Reduction in Menstrual Blood Loss Volume from Baseline, by Subgroup (mITT Population)
Study: Pooled
Subgroup: Geographic Region II



Results are based on a Cox proportional hazard model stratified by study and with treatment group, subgroup and a subgroup-by-treatment group interaction as covariates using a one-stage fixed-effects IPD meta-analysis approach.
The interaction p-value is based on the subgroup-by-treatment interaction term in the proportional hazard model used to compute the Hazard Ratio and 95% CI. Missing subgroup levels are not included in estimation of the interaction p-value. The reference group is Placebo.
N: Number of patients in treatment group; NETA: Norethindrone acetate; mITT: Modified intent-to-treat; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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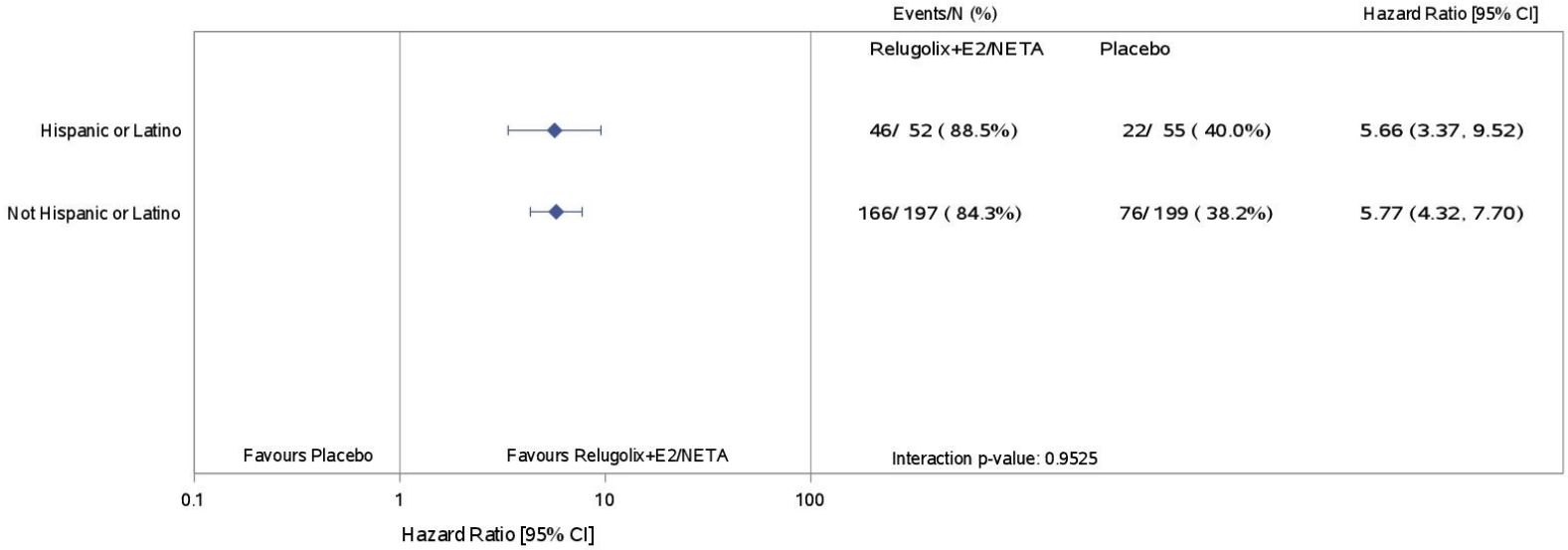
Figure EFF.TTMBLG50.MITT.S8.TTE.FP: Time to Achieve >= 50% Reduction in Menstrual Blood Loss Volume from Baseline, by Subgroup (mITT Population)
Study: Pooled
Subgroup: Ethnicity



Results are based on a Cox proportional hazard model stratified by study and with treatment group, subgroup and a subgroup-by-treatment group interaction as covariates using a one-stage fixed-effects IPD meta-analysis approach.
The interaction p-value is based on the subgroup-by-treatment interaction term in the proportional hazard model used to compute the Hazard Ratio and 95% CI. Missing subgroup levels are not included in estimation of the interaction p-value. The reference group is Placebo.
N: Number of patients in treatment group; NETA: Norethindrone acetate; mITT: Modified intent-to-treat; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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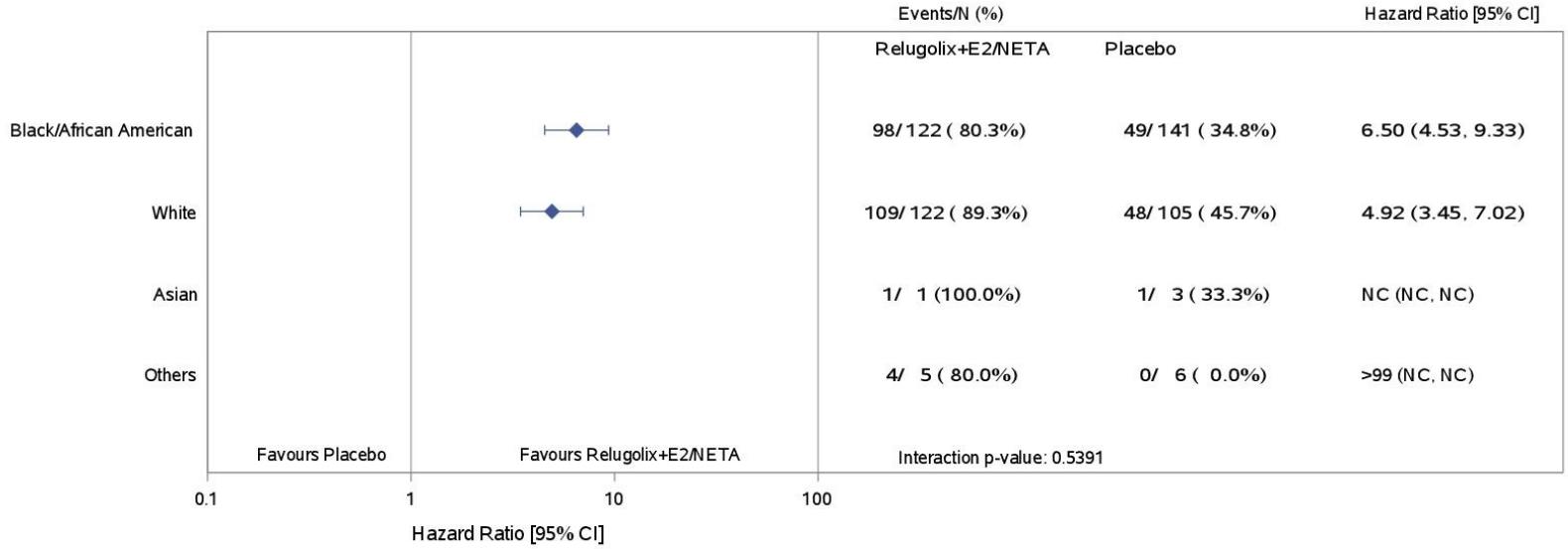
Figure EFF.TTMBLG50.MITT.S9.TTE.FP: Time to Achieve >= 50% Reduction in Menstrual Blood Loss Volume from Baseline, by Subgroup (mITT Population)
Study: Pooled
Subgroup: Race



Results are based on a Cox proportional hazard model stratified by study and with treatment group, subgroup and a subgroup-by-treatment group interaction as covariates using a one-stage fixed-effects IPD meta-analysis approach.
The interaction p-value is based on the subgroup-by-treatment interaction term in the proportional hazard model used to compute the Hazard Ratio and 95% CI. Missing subgroup levels are not included in estimation of the interaction p-value. The reference group is Placebo.
N: Number of patients in treatment group; NETA: Norethindrone acetate; mITT: Modified intent-to-treat; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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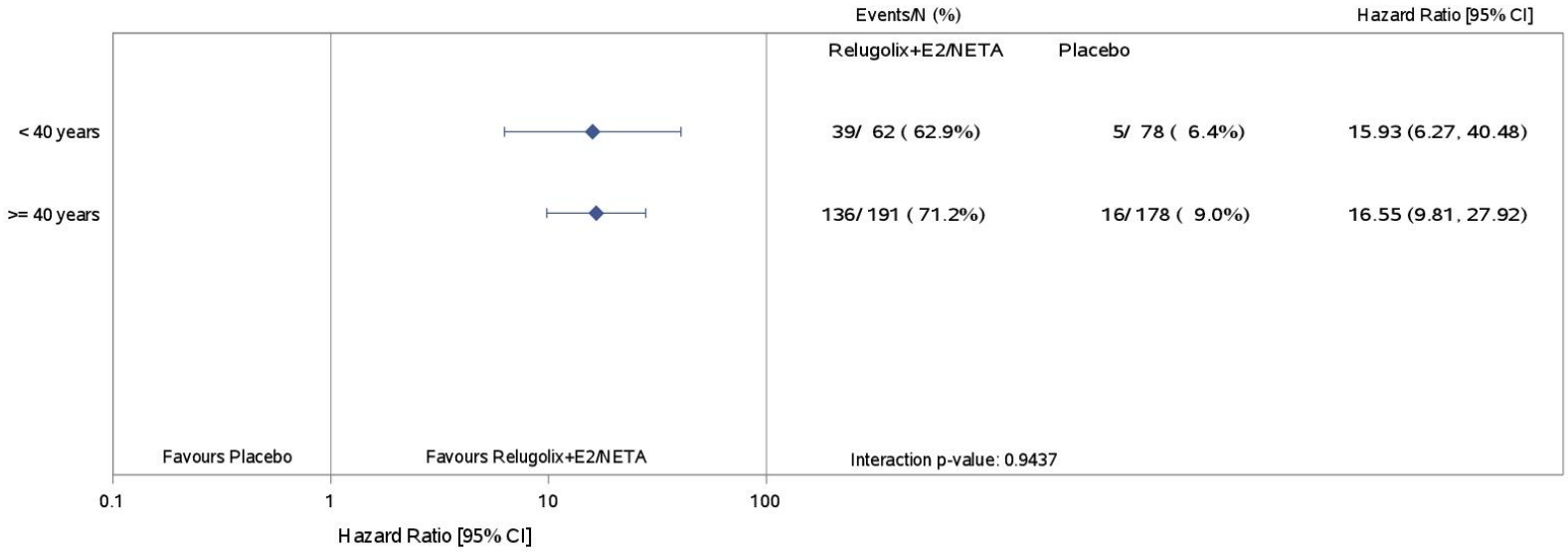
2.1.7 Time to Sustained Response (MBL volume of < 80 mL and at Least a 50% Reduction from Baseline MBL Volume), by Subgroup (mITT Population)

Figure EFF.TTSRESP.MITT.TTE.FP.S1.TTE.FP: Time to Sustained Response (MBL volume of < 80 mL and at Least a 50% Reduction from Baseline MBL Volume), by Subgroup (mITT Population)
Study: Pooled
Subgroup: Age (years)



Results are based on a Cox proportional hazard model stratified by study and with treatment group, subgroup and a subgroup-by-treatment group interaction as covariates using a one-stage fixed-effects IPD meta-analysis approach.
The interaction p-value is based on the subgroup-by-treatment interaction term in the proportional hazard model used to compute the Hazard Ratio and 95% CI. Missing subgroup levels are not included in estimation of the interaction p-value. The reference group is Placebo.
N: Number of patients in treatment group; NETA: Norethindrone acetate; mITT: Modified intent-to-treat; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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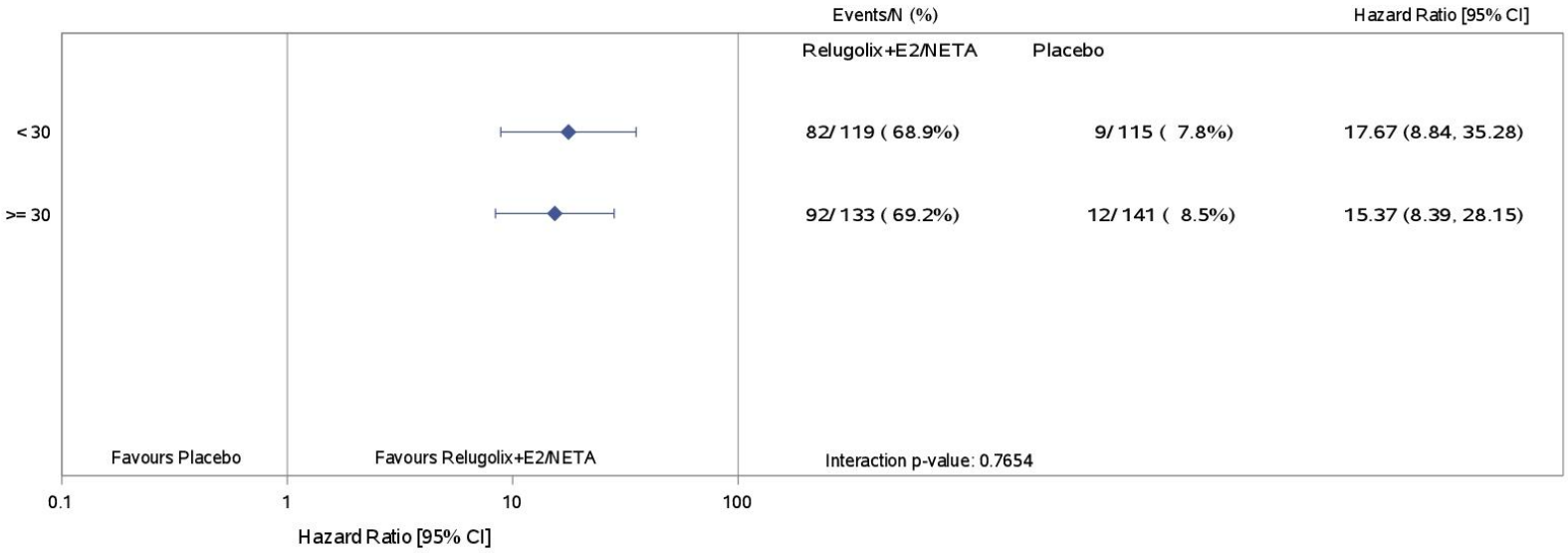
Figure EFF.TTSRESP.MITT.TTE.FP.S2.TTE.FP: Time to Sustained Response (MBL volume of < 80 mL and at Least a 50% Reduction from Baseline MBL Volume), by Subgroup (mITT Population)
Study: Pooled
Subgroup: BMI (kg/m2) at Baseline



Results are based on a Cox proportional hazard model stratified by study and with treatment group, subgroup and a subgroup-by-treatment group interaction as covariates using a one-stage fixed-effects IPD meta-analysis approach.
The interaction p-value is based on the subgroup-by-treatment interaction term in the proportional hazard model used to compute the Hazard Ratio and 95% CI. Missing subgroup levels are not included in estimation of the interaction p-value. The reference group is Placebo.
N: Number of patients in treatment group; NETA: Norethindrone acetate; mITT: Modified intent-to-treat; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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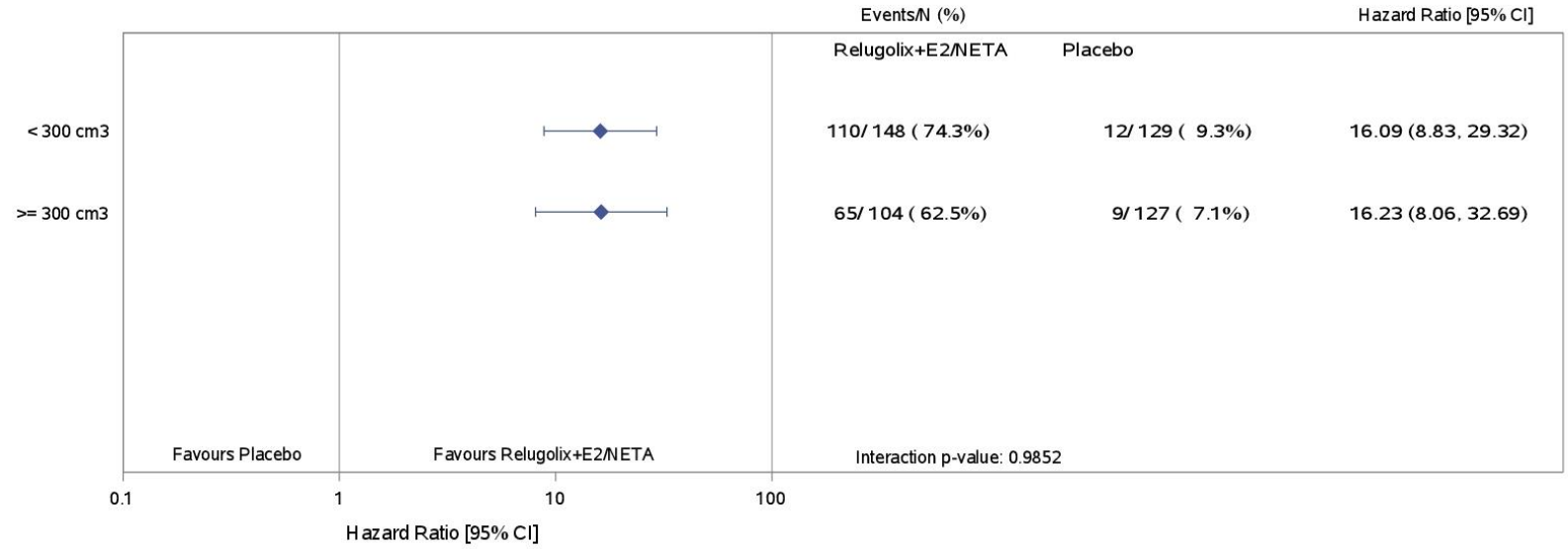
Figure EFF.TTSRESP.MITT.TTE.FP.S3.TTE.FP: Time to Sustained Response (MBL volume of < 80 mL and at Least a 50% Reduction from Baseline MBL Volume), by Subgroup (mITT Population)
Study: Pooled
Subgroup: Uterine Volume at Baseline (cm3)



Results are based on a Cox proportional hazard model stratified by study and with treatment group, subgroup and a subgroup-by-treatment group interaction as covariates using a one-stage fixed-effects IPD meta-analysis approach.
The interaction p-value is based on the subgroup-by-treatment interaction term in the proportional hazard model used to compute the Hazard Ratio and 95% CI. Missing subgroup levels are not included in estimation of the interaction p-value. The reference group is Placebo.
N: Number of patients in treatment group; NETA: Norethindrone acetate; mITT: Modified intent-to-treat; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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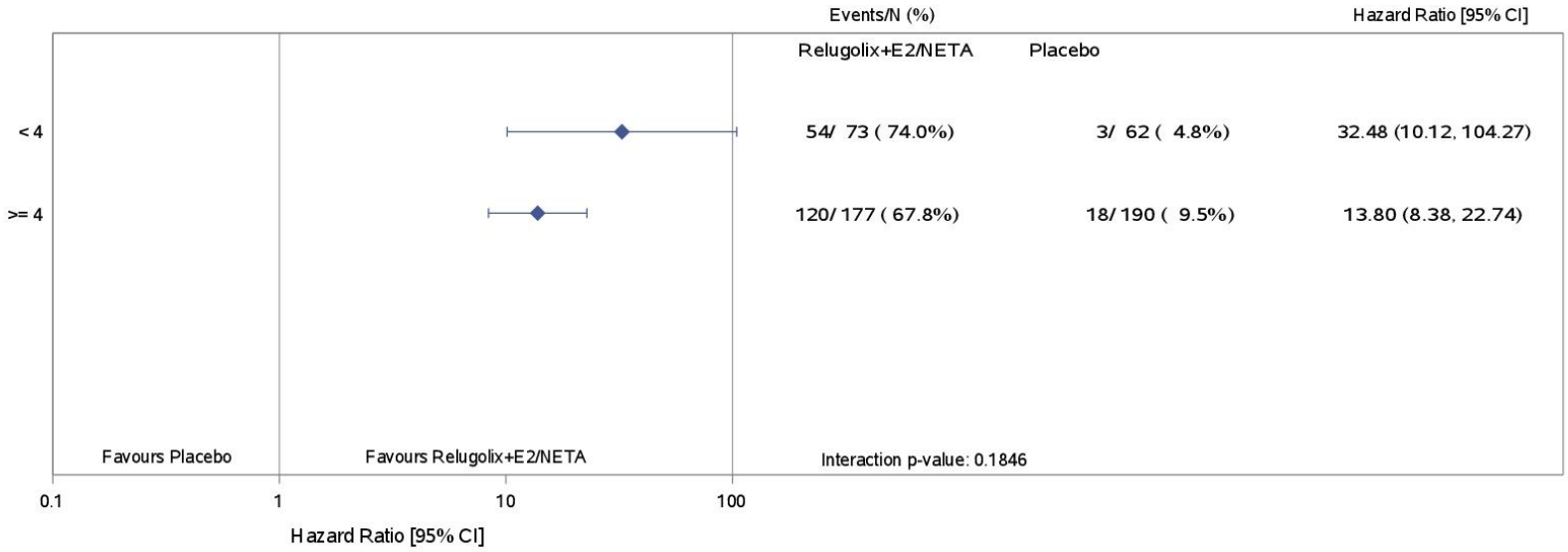
Figure EFF.TTSRESP.MITT.TTE.FP.S4.TTE.FP: Time to Sustained Response (MBL volume of < 80 mL and at Least a 50% Reduction from Baseline MBL Volume), by Subgroup (mITT Population)
Study: Pooled
Subgroup: Maximum NRS Pain Score at Baseline



Results are based on a Cox proportional hazard model stratified by study and with treatment group, subgroup and a subgroup-by-treatment group interaction as covariates using a one-stage fixed-effects IPD meta-analysis approach.
The interaction p-value is based on the subgroup-by-treatment interaction term in the proportional hazard model used to compute the Hazard Ratio and 95% CI. Missing subgroup levels are not included in estimation of the interaction p-value. The reference group is Placebo.
N: Number of patients in treatment group; NETA: Norethindrone acetate; mITT: Modified intent-to-treat; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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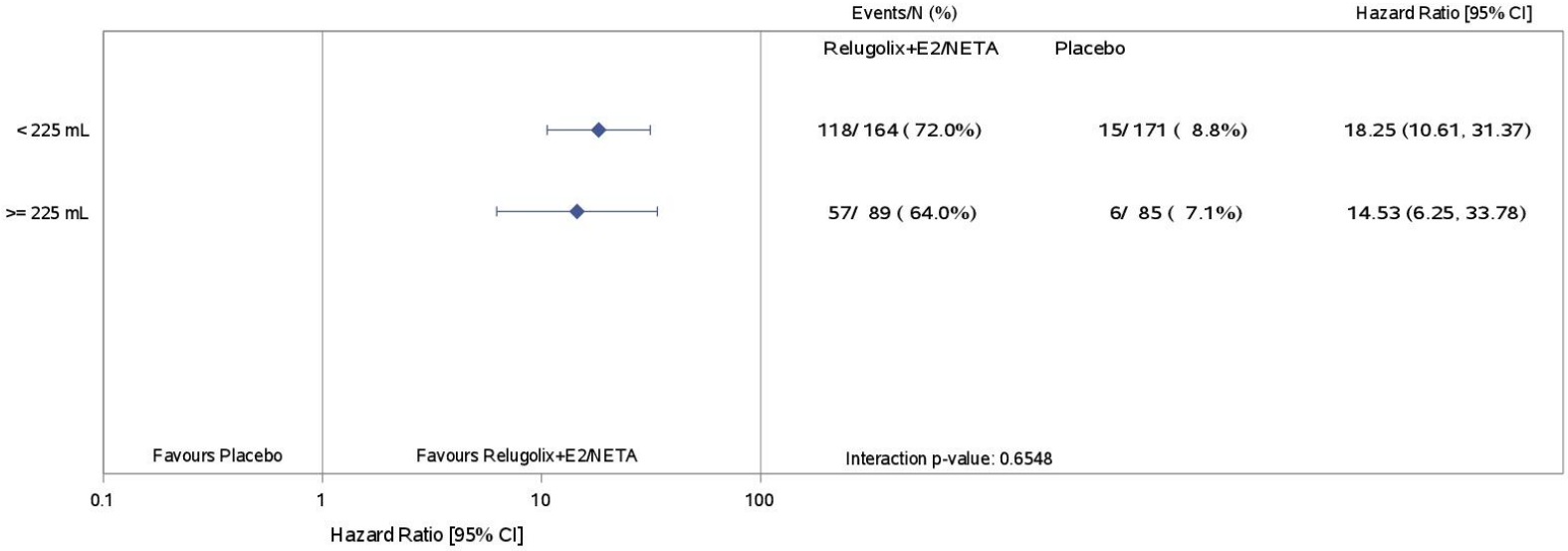
Figure EFF.TTSRESP.MITT.TTE.FP.S5.TTE.FP: Time to Sustained Response (MBL volume of < 80 mL and at Least a 50% Reduction from Baseline MBL Volume), by Subgroup (mITT Population)
Study: Pooled
Subgroup: MBL Volume at Baseline (mL)



Results are based on a Cox proportional hazard model stratified by study and with treatment group, subgroup and a subgroup-by-treatment group interaction as covariates using a one-stage fixed-effects IPD meta-analysis approach.
The interaction p-value is based on the subgroup-by-treatment interaction term in the proportional hazard model used to compute the Hazard Ratio and 95% CI. Missing subgroup levels are not included in estimation of the interaction p-value. The reference group is Placebo.
N: Number of patients in treatment group; NETA: Norethindrone acetate; mITT: Modified intent-to-treat; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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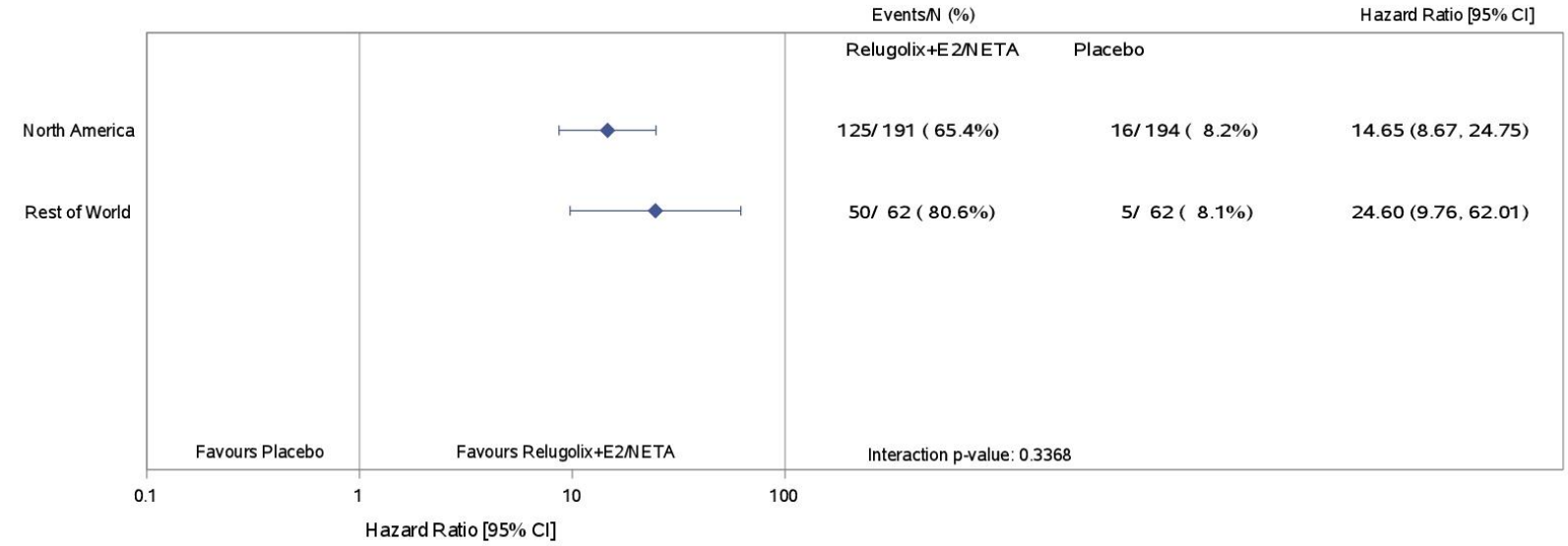
Figure EFF.TTSRESP.MITT.TTE.FP.S6.TTE.FP: Time to Sustained Response (MBL volume of < 80 mL and at Least a 50% Reduction from Baseline MBL Volume), by Subgroup (mITT Population)
Study: Pooled
Subgroup: Geographic Region I



Results are based on a Cox proportional hazard model stratified by study and with treatment group, subgroup and a subgroup-by-treatment group interaction as covariates using a one-stage fixed-effects IPD meta-analysis approach.
The interaction p-value is based on the subgroup-by-treatment interaction term in the proportional hazard model used to compute the Hazard Ratio and 95% CI. Missing subgroup levels are not included in estimation of the interaction p-value. The reference group is Placebo.
N: Number of patients in treatment group; NETA: Norethindrone acetate; mITT: Modified intent-to-treat; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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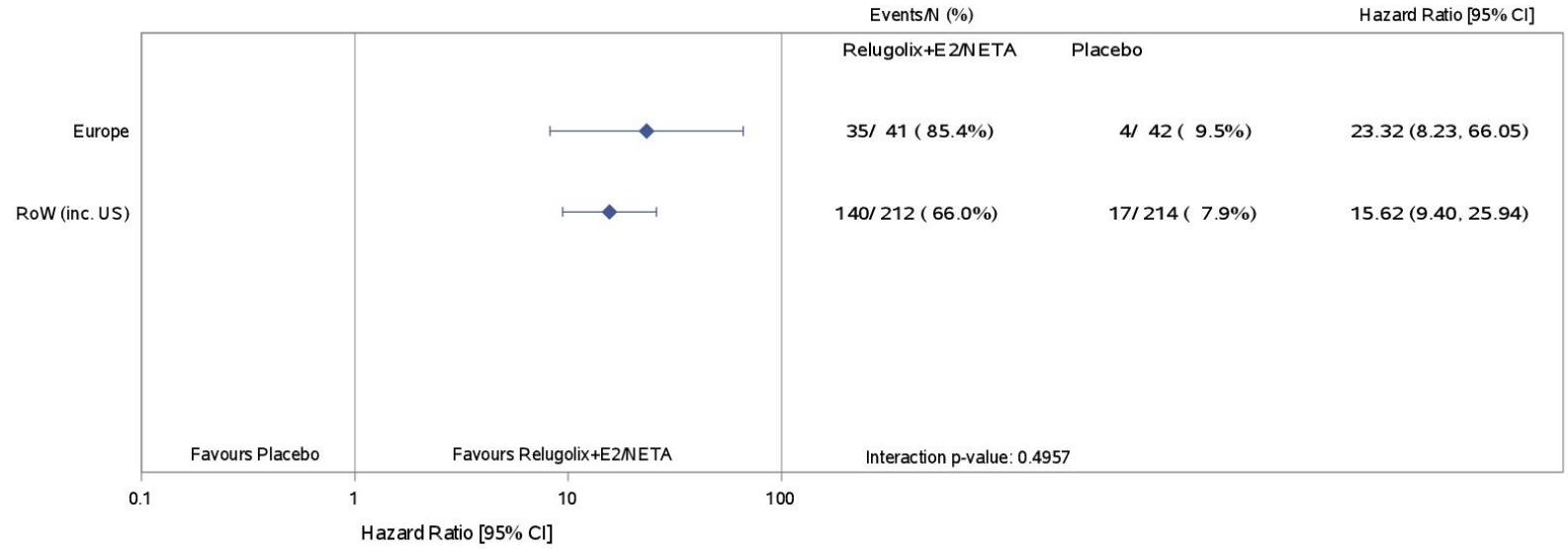
Figure EFF.TTSRESP.MITT.TTE.FP.S7.TTE.FP: Time to Sustained Response (MBL volume of < 80 mL and at Least a 50% Reduction from Baseline MBL Volume), by Subgroup (mITT Population)
Study: Pooled
Subgroup: Geographic Region II



Results are based on a Cox proportional hazard model stratified by study and with treatment group, subgroup and a subgroup-by-treatment group interaction as covariates using a one-stage fixed-effects IPD meta-analysis approach.
The interaction p-value is based on the subgroup-by-treatment interaction term in the proportional hazard model used to compute the Hazard Ratio and 95% CI. Missing subgroup levels are not included in estimation of the interaction p-value. The reference group is Placebo.
N: Number of patients in treatment group; NETA: Norethindrone acetate; mITT: Modified intent-to-treat; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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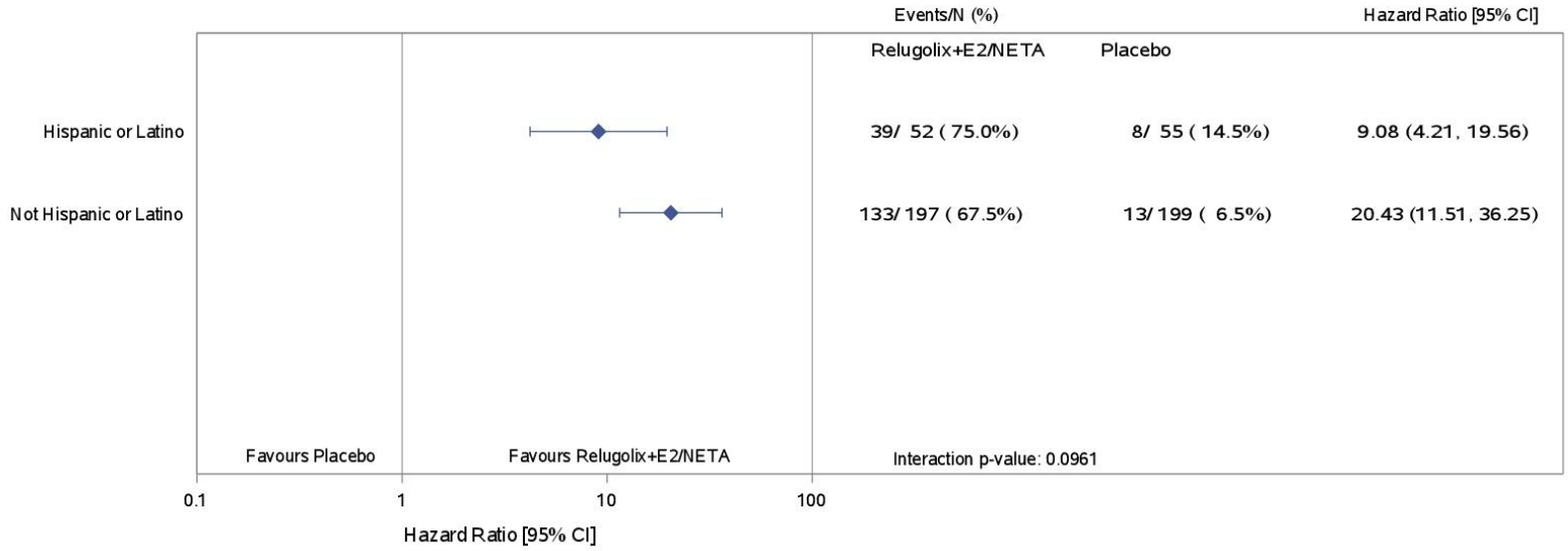
Figure EFF.TTSRESP.MITT.TTE.FP.S8.TTE.FP: Time to Sustained Response (MBL volume of < 80 mL and at Least a 50% Reduction from Baseline MBL Volume), by Subgroup (mITT Population)
Study: Pooled
Subgroup: Ethnicity



Results are based on a Cox proportional hazard model stratified by study and with treatment group, subgroup and a subgroup-by-treatment group interaction as covariates using a one-stage fixed-effects IPD meta-analysis approach.
The interaction p-value is based on the subgroup-by-treatment interaction term in the proportional hazard model used to compute the Hazard Ratio and 95% CI. Missing subgroup levels are not included in estimation of the interaction p-value. The reference group is Placebo.
N: Number of patients in treatment group; NETA: Norethindrone acetate; mITT: Modified intent-to-treat; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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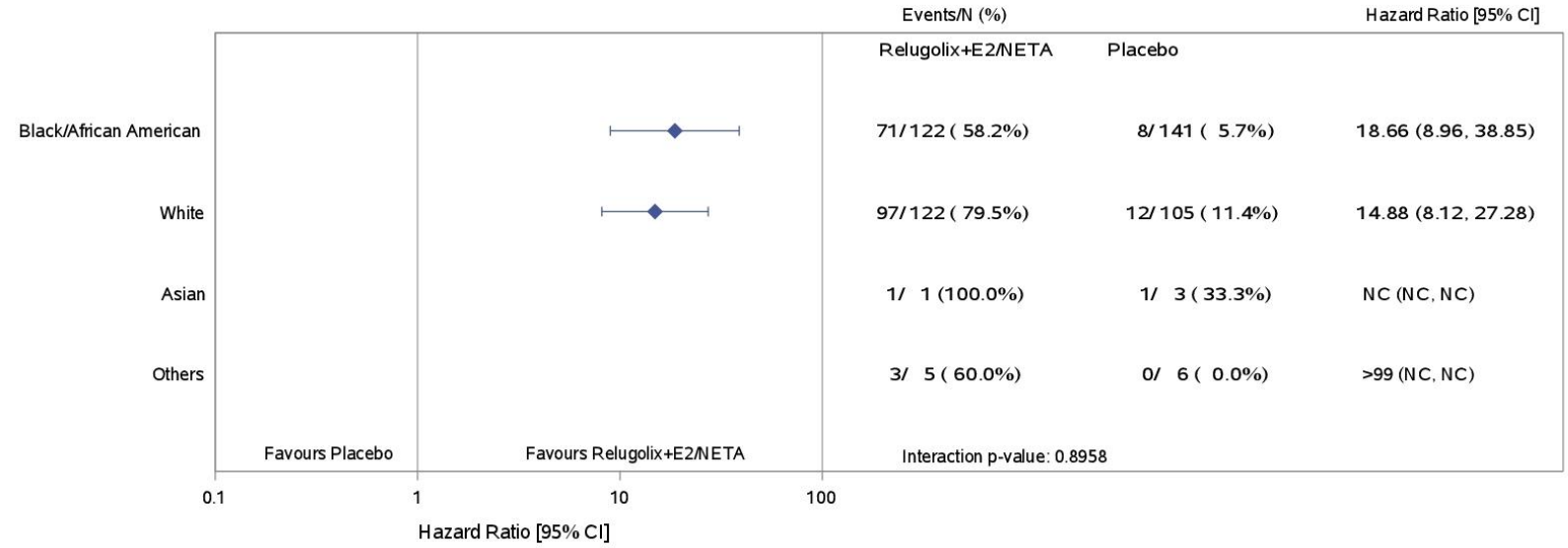
Figure EFF.TTSRESP.MITT.TTE.FP.S9.TTE.FP: Time to Sustained Response (MBL volume of < 80 mL and at Least a 50% Reduction from Baseline MBL Volume), by Subgroup (mITT Population)
Study: Pooled
Subgroup: Race



Results are based on a Cox proportional hazard model stratified by study and with treatment group, subgroup and a subgroup-by-treatment group interaction as covariates using a one-stage fixed-effects IPD meta-analysis approach.
The interaction p-value is based on the subgroup-by-treatment interaction term in the proportional hazard model used to compute the Hazard Ratio and 95% CI. Missing subgroup levels are not included in estimation of the interaction p-value. The reference group is Placebo.
N: Number of patients in treatment group; NETA: Norethindrone acetate; mITT: Modified intent-to-treat; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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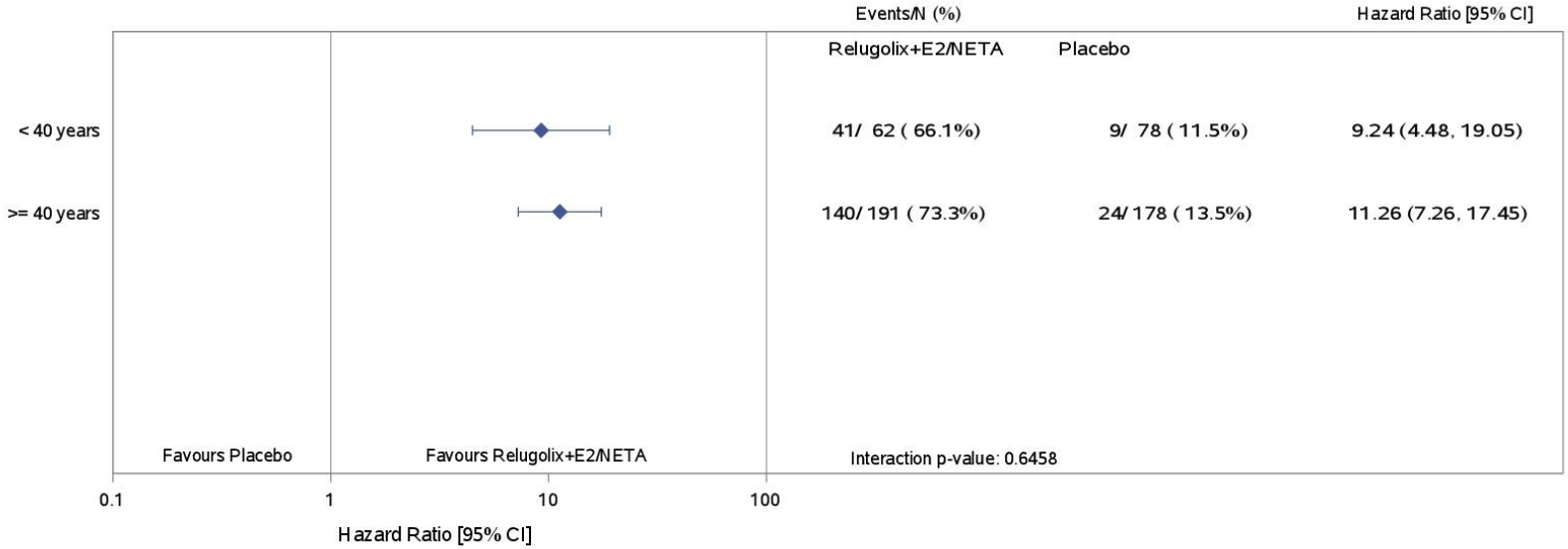
2.1.8 Time to Sustained Response (MBL volume of < 80 mL), by Subgroup (mITT Population)

Figure EFF.TTSRL80.MITT.S1.TTE.FP: Time to Sustained Response (MBL volume of < 80 mL), by Subgroup (mITT Population)
Study: Pooled
Subgroup: Age (years)



Results are based on a Cox proportional hazard model stratified by study and with treatment group, subgroup and a subgroup-by-treatment group interaction as covariates using a one-stage fixed-effects IPD meta-analysis approach.
The interaction p-value is based on the subgroup-by-treatment interaction term in the proportional hazard model used to compute the Hazard Ratio and 95% CI. Missing subgroup levels are not included in estimation of the interaction p-value. The reference group is Placebo.
N: Number of patients in treatment group; NETA: Norethindrone acetate; mITT: Modified intent-to-treat; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

SOURCE: X:\Numerus\Studies\MYV\MYV102\Analysis\Prod\Progs\TFLs\Fig_EFF_MBL_S_TTE_FP.SAS Date/time of run: 30JUN21 10:25
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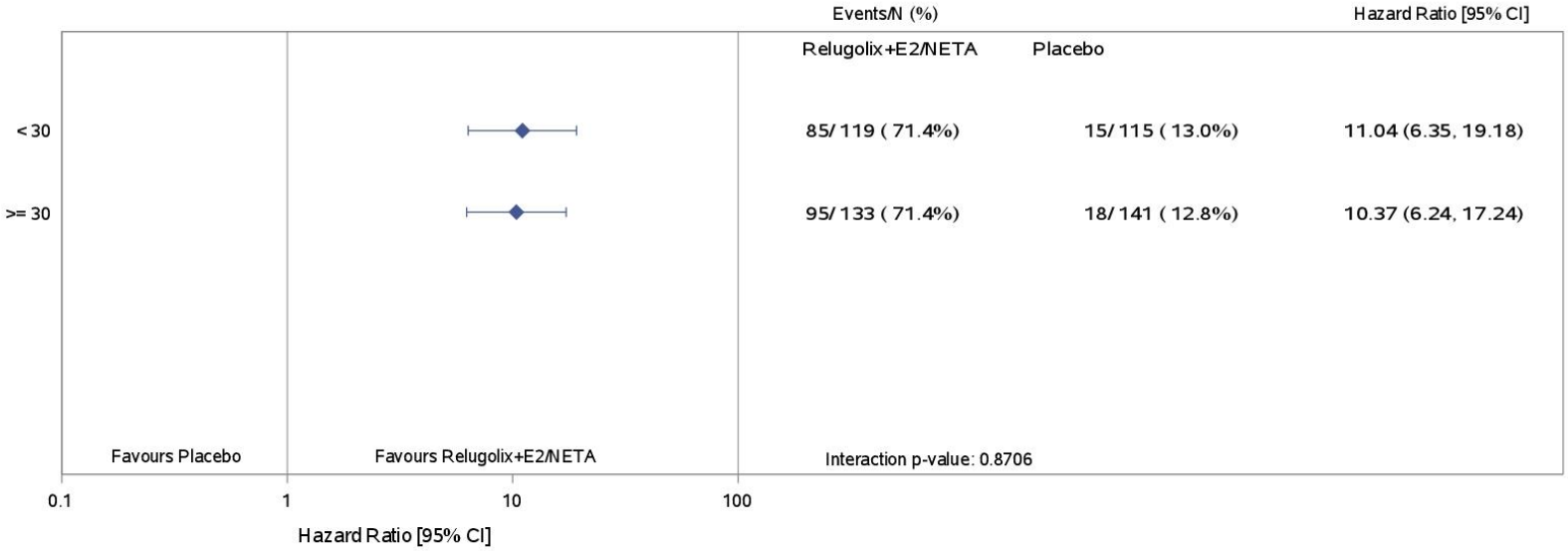
Figure EFF.TTSRL80.MITT.S2.TTE.FP: Time to Sustained Response (MBL volume of < 80 mL), by Subgroup (mITT Population)
Study: Pooled
Subgroup: BMI (kg/m2) at Baseline



Results are based on a Cox proportional hazard model stratified by study and with treatment group, subgroup and a subgroup-by-treatment group interaction as covariates using a one-stage fixed-effects IPD meta-analysis approach.
The interaction p-value is based on the subgroup-by-treatment interaction term in the proportional hazard model used to compute the Hazard Ratio and 95% CI. Missing subgroup levels are not included in estimation of the interaction p-value. The reference group is Placebo.
N: Number of patients in treatment group; NETA: Norethindrone acetate; mITT: Modified intent-to-treat; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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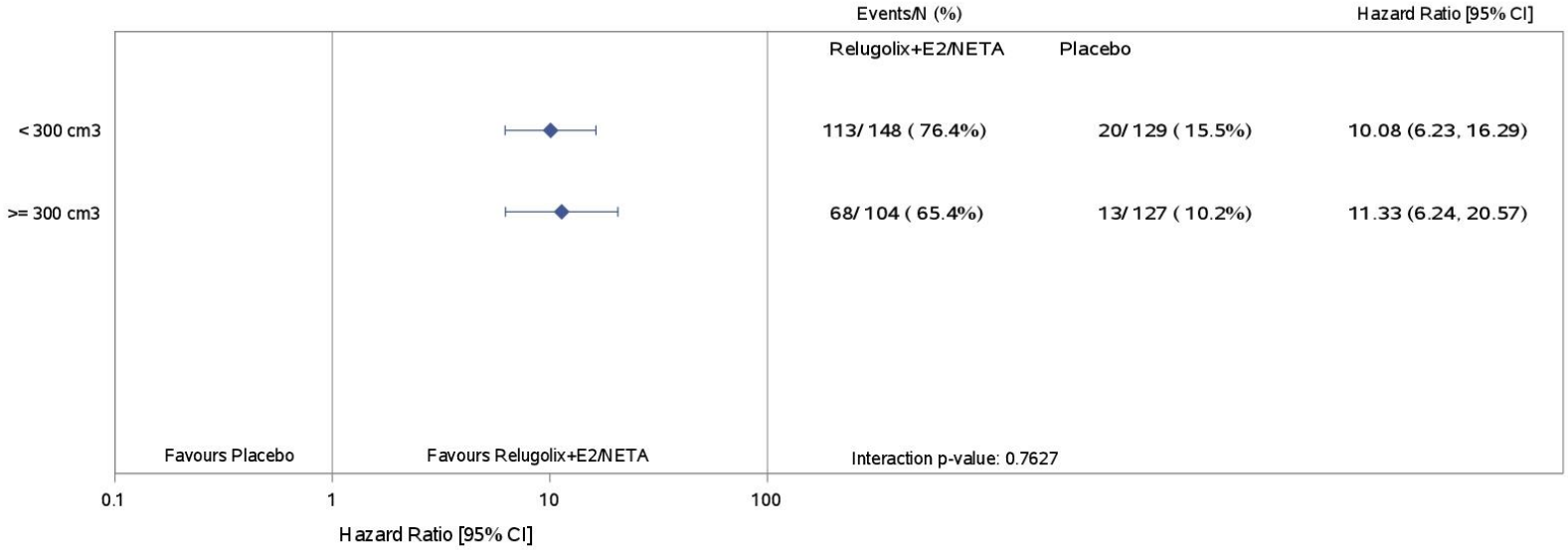
Figure EFF.TTSRL80.MITT.S3.TTE.FP: Time to Sustained Response (MBL volume of < 80 mL), by Subgroup (mITT Population)
Study: Pooled
Subgroup: Uterine Volume at Baseline (cm3)



Results are based on a Cox proportional hazard model stratified by study and with treatment group, subgroup and a subgroup-by-treatment group interaction as covariates using a one-stage fixed-effects IPD meta-analysis approach.
The interaction p-value is based on the subgroup-by-treatment interaction term in the proportional hazard model used to compute the Hazard Ratio and 95% CI. Missing subgroup levels are not included in estimation of the interaction p-value. The reference group is Placebo.
N: Number of patients in treatment group; NETA: Norethindrone acetate; mITT: Modified intent-to-treat; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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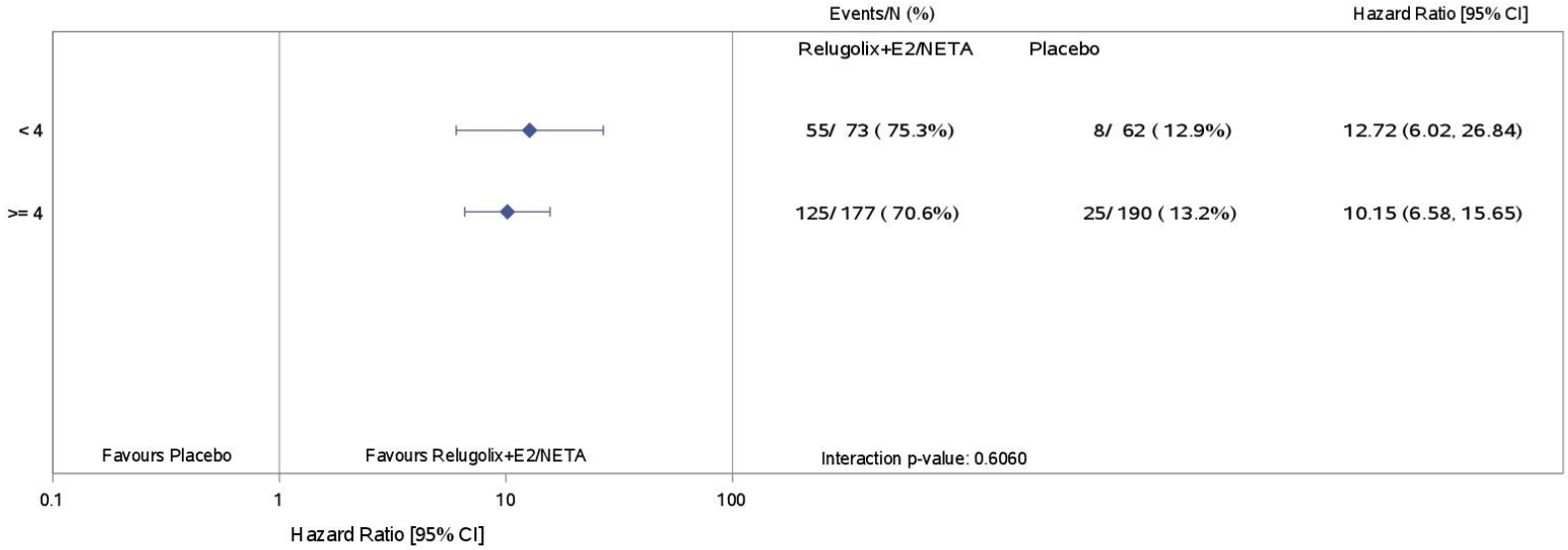
Figure EFF.TTSRL80.MITT.S4.TTE.FP: Time to Sustained Response (MBL volume of < 80 mL), by Subgroup (mITT Population)
Study: Pooled
Subgroup: Maximum NRS Pain Score at Baseline



Results are based on a Cox proportional hazard model stratified by study and with treatment group, subgroup and a subgroup-by-treatment group interaction as covariates using a one-stage fixed-effects IPD meta-analysis approach.
The interaction p-value is based on the subgroup-by-treatment interaction term in the proportional hazard model used to compute the Hazard Ratio and 95% CI. Missing subgroup levels are not included in estimation of the interaction p-value. The reference group is Placebo.
N: Number of patients in treatment group; NETA: Norethindrone acetate; mITT: Modified intent-to-treat; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

SOURCE: X:\Numerus\Studies\MYV\MYV102\Analysis\Prod\Progs\TFLs\Fig_EFF_MBL_S_TTE_FP.SAS Date/time of run: 30JUN21 10:25
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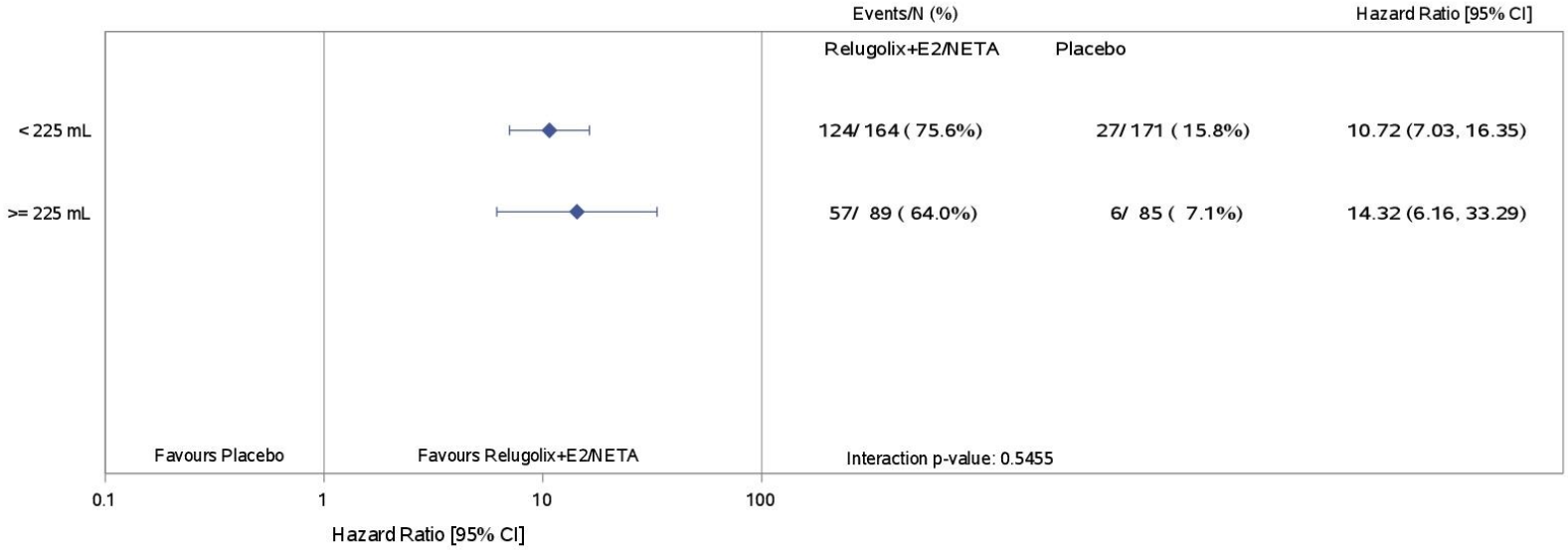
Figure EFF.TTSRL80.MITT.S5.TTE.FP: Time to Sustained Response (MBL volume of < 80 mL), by Subgroup (mITT Population)
Study: Pooled
Subgroup: MBL Volume at Baseline (mL)



Results are based on a Cox proportional hazard model stratified by study and with treatment group, subgroup and a subgroup-by-treatment group interaction as covariates using a one-stage fixed-effects IPD meta-analysis approach.
The interaction p-value is based on the subgroup-by-treatment interaction term in the proportional hazard model used to compute the Hazard Ratio and 95% CI. Missing subgroup levels are not included in estimation of the interaction p-value. The reference group is Placebo.
N: Number of patients in treatment group; NETA: Norethindrone acetate; mITT: Modified intent-to-treat; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

SOURCE: X:\Numerus\Studies\MYV\MYV102\Analysis\Prod\Progs\TFLs\Fig_EFF_MBL_S_TTE_FP.SAS Date/time of run: 30JUN21 10:25
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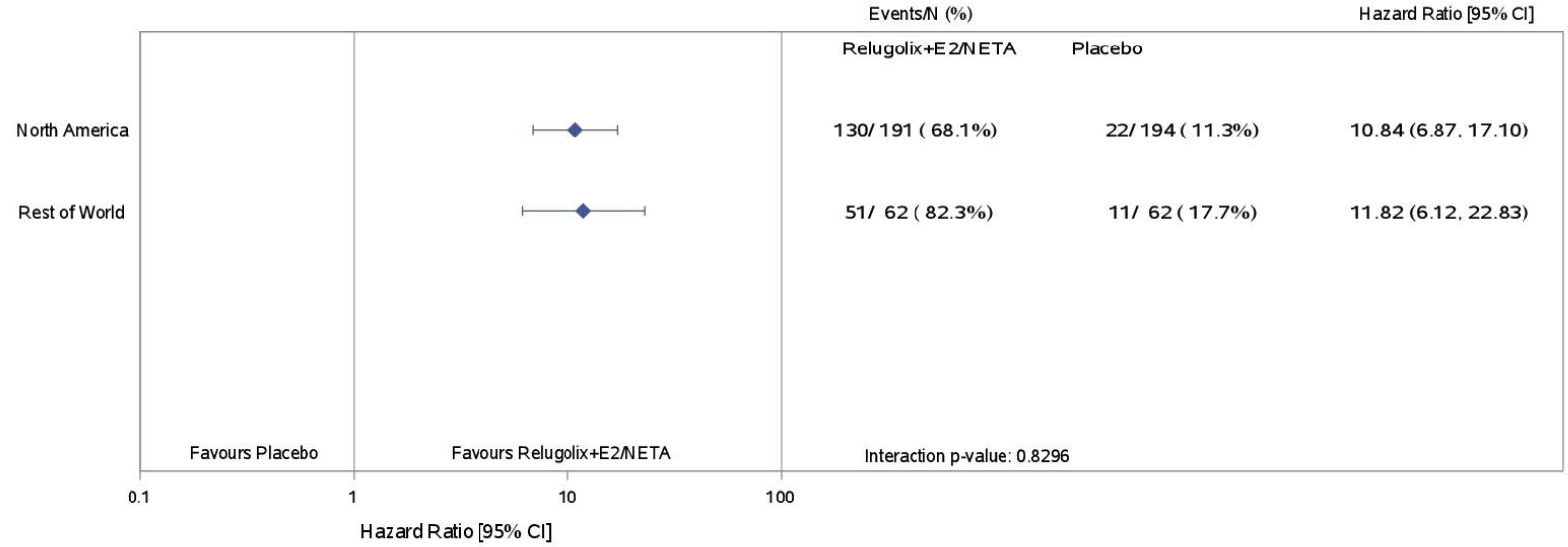
Figure EFF.TTSRL80.MITT.S6.TTE.FP: Time to Sustained Response (MBL volume of < 80 mL), by Subgroup (mITT Population)
Study: Pooled
Subgroup: Geographic Region I



Results are based on a Cox proportional hazard model stratified by study and with treatment group, subgroup and a subgroup-by-treatment group interaction as covariates using a one-stage fixed-effects IPD meta-analysis approach.
The interaction p-value is based on the subgroup-by-treatment interaction term in the proportional hazard model used to compute the Hazard Ratio and 95% CI. Missing subgroup levels are not included in estimation of the interaction p-value. The reference group is Placebo.
N: Number of patients in treatment group; NETA: Norethindrone acetate; mITT: Modified intent-to-treat; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

SOURCE: X:\Numerus\Studies\MYV\MYV102\Analysis\Prod\Progs\TFLs\Fig_EFF_MBL_S_TTE_FP.SAS Date/time of run: 30JUN21 10:25
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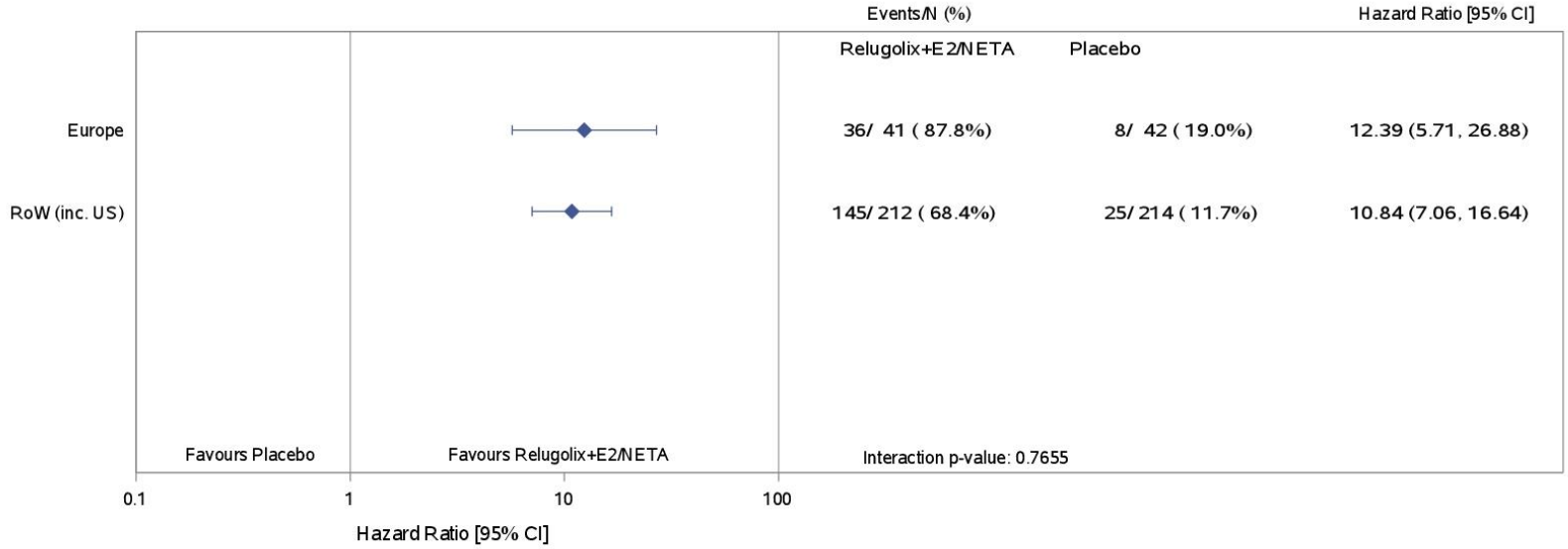
Figure EFF.TTSRL80.MITT.S7.TTE.FP: Time to Sustained Response (MBL volume of < 80 mL), by Subgroup (mITT Population)
Study: Pooled
Subgroup: Geographic Region II



Results are based on a Cox proportional hazard model stratified by study and with treatment group, subgroup and a subgroup-by-treatment group interaction as covariates using a one-stage fixed-effects IPD meta-analysis approach.
The interaction p-value is based on the subgroup-by-treatment interaction term in the proportional hazard model used to compute the Hazard Ratio and 95% CI. Missing subgroup levels are not included in estimation of the interaction p-value. The reference group is Placebo.
N: Number of patients in treatment group; NETA: Norethindrone acetate; mITT: Modified intent-to-treat; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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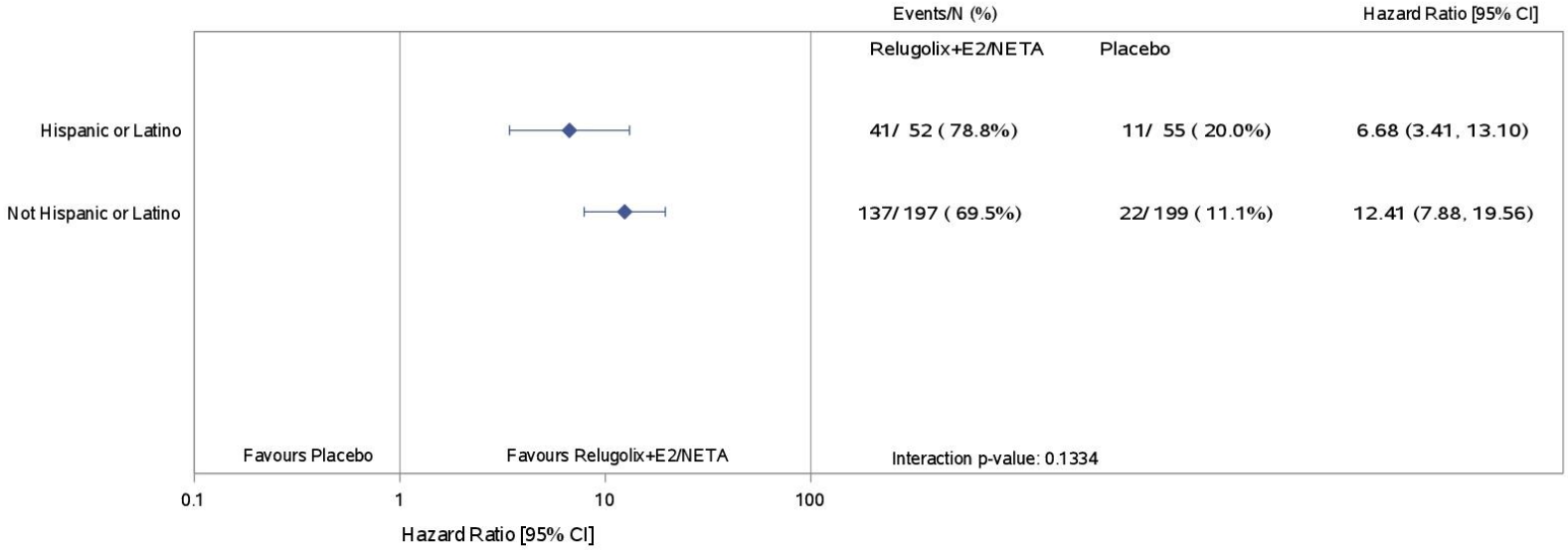
Figure EFF.TTSRL80.MITT.S8.TTE.FP: Time to Sustained Response (MBL volume of < 80 mL), by Subgroup (mITT Population)
Study: Pooled
Subgroup: Ethnicity



Results are based on a Cox proportional hazard model stratified by study and with treatment group, subgroup and a subgroup-by-treatment group interaction as covariates using a one-stage fixed-effects IPD meta-analysis approach.
The interaction p-value is based on the subgroup-by-treatment interaction term in the proportional hazard model used to compute the Hazard Ratio and 95% CI. Missing subgroup levels are not included in estimation of the interaction p-value. The reference group is Placebo.
N: Number of patients in treatment group; NETA: Norethindrone acetate; mITT: Modified intent-to-treat; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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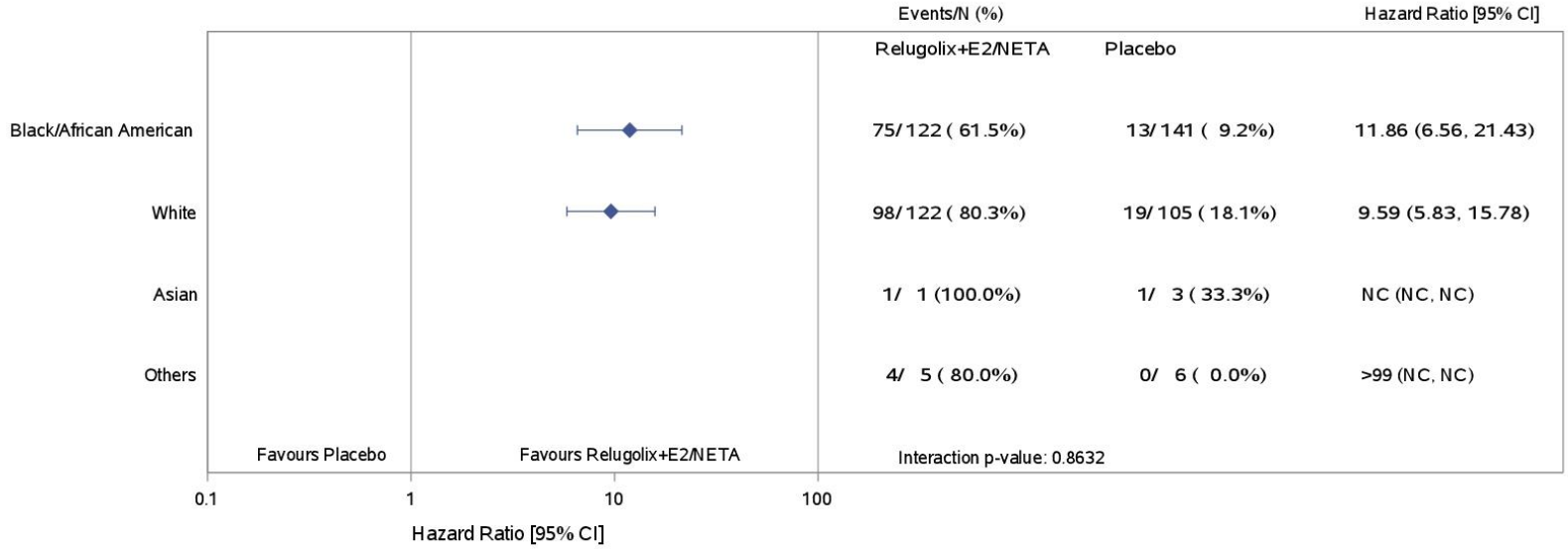
Figure EFF.TTSRL80.MITT.S9.TTE.FP: Time to Sustained Response (MBL volume of < 80 mL), by Subgroup (mITT Population)
Study: Pooled
Subgroup: Race



Results are based on a Cox proportional hazard model stratified by study and with treatment group, subgroup and a subgroup-by-treatment group interaction as covariates using a one-stage fixed-effects IPD meta-analysis approach.
The interaction p-value is based on the subgroup-by-treatment interaction term in the proportional hazard model used to compute the Hazard Ratio and 95% CI. Missing subgroup levels are not included in estimation of the interaction p-value. The reference group is Placebo.
N: Number of patients in treatment group; NETA: Norethindrone acetate; mITT: Modified intent-to-treat; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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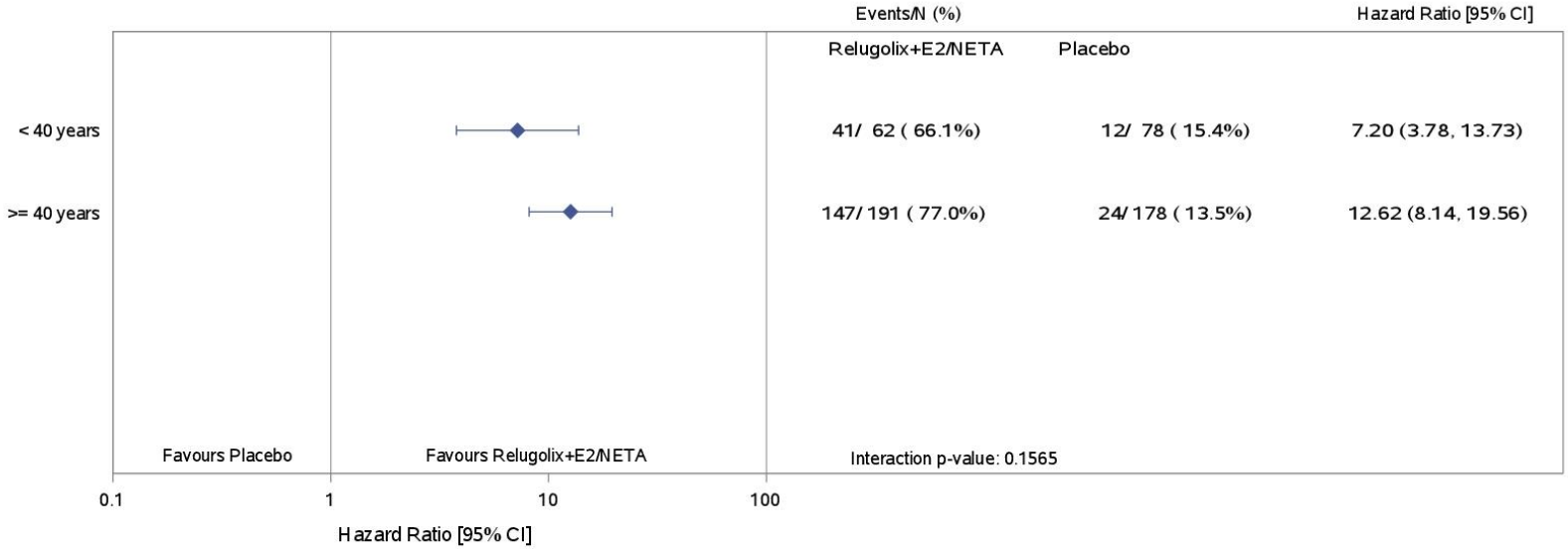
2.1.9 Time to Sustained Response (at Least a 50% Reduction from Baseline MBL Volume), by Subgroup (mITT Population)

Figure EFF.TTSRG50.MITT.S1.TTE.FP: Time to Sustained Response (at Least a 50% Reduction from Baseline MBL Volume), by Subgroup (mITT Population)
Study: Pooled
Subgroup: Age (years)



Results are based on a Cox proportional hazard model stratified by study and with treatment group, subgroup and a subgroup-by-treatment group interaction as covariates using a one-stage fixed-effects IPD meta-analysis approach.
The interaction p-value is based on the subgroup-by-treatment interaction term in the proportional hazard model used to compute the Hazard Ratio and 95% CI. Missing subgroup levels are not included in estimation of the interaction p-value. The reference group is Placebo.
N: Number of patients in treatment group; NETA: Norethindrone acetate; mITT: Modified intent-to-treat; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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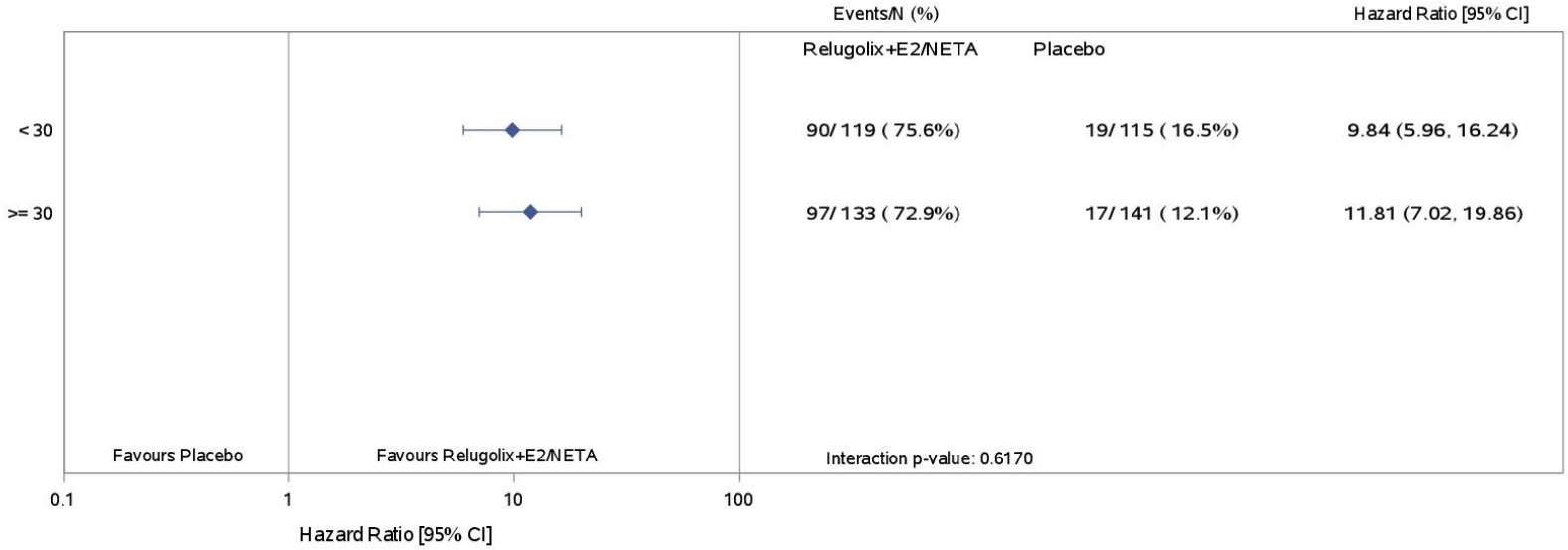
Figure EFF.TTSRG50.MITT.S2.TTE.FP: Time to Sustained Response (at Least a 50% Reduction from Baseline MBL Volume), by Subgroup (mITT Population)
Study: Pooled
Subgroup: BMI (kg/m2) at Baseline



Results are based on a Cox proportional hazard model stratified by study and with treatment group, subgroup and a subgroup-by-treatment group interaction as covariates using a one-stage fixed-effects IPD meta-analysis approach.
The interaction p-value is based on the subgroup-by-treatment interaction term in the proportional hazard model used to compute the Hazard Ratio and 95% CI. Missing subgroup levels are not included in estimation of the interaction p-value. The reference group is Placebo.
N: Number of patients in treatment group; NETA: Norethindrone acetate; mITT: Modified intent-to-treat; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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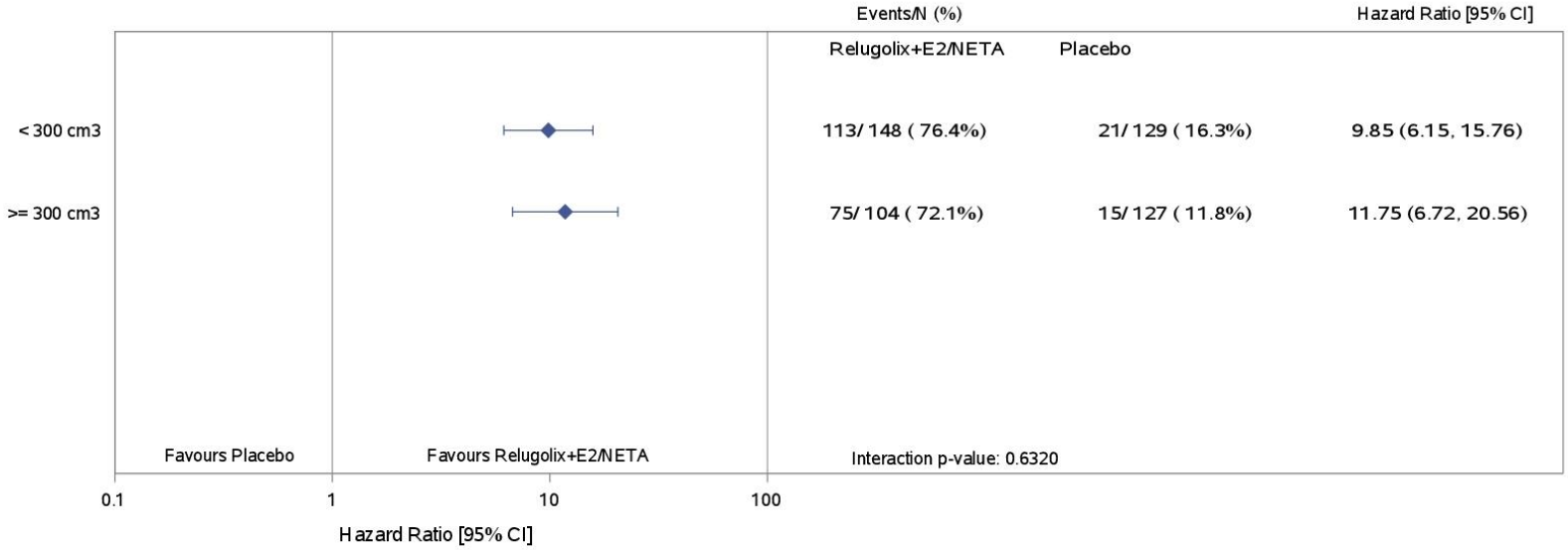
Figure EFF.TTSRG50.MITT.S3.TTE.FP: Time to Sustained Response (at Least a 50% Reduction from Baseline MBL Volume), by Subgroup (mITT Population)
Study: Pooled
Subgroup: Uterine Volume at Baseline (cm3)



Results are based on a Cox proportional hazard model stratified by study and with treatment group, subgroup and a subgroup-by-treatment group interaction as covariates using a one-stage fixed-effects IPD meta-analysis approach.
The interaction p-value is based on the subgroup-by-treatment interaction term in the proportional hazard model used to compute the Hazard Ratio and 95% CI. Missing subgroup levels are not included in estimation of the interaction p-value. The reference group is Placebo.
N: Number of patients in treatment group; NETA: Norethindrone acetate; mITT: Modified intent-to-treat; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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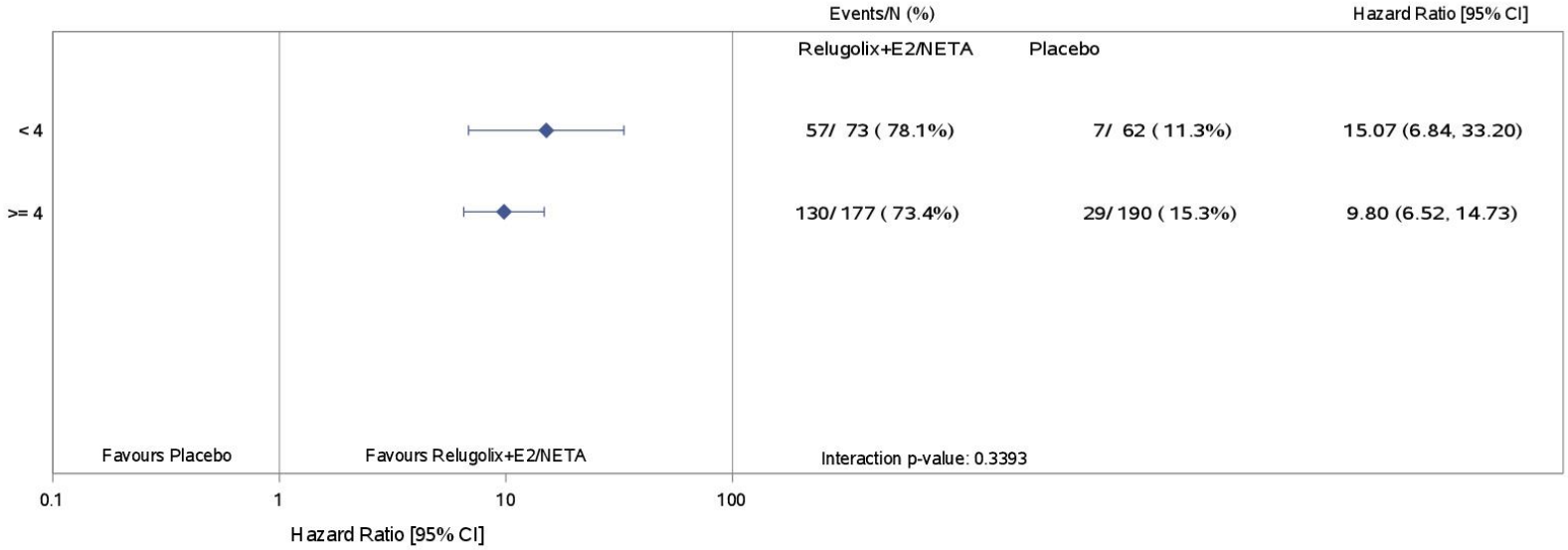
Figure EFF.TTSRG50.MITT.S4.TTE.FP: Time to Sustained Response (at Least a 50% Reduction from Baseline MBL Volume), by Subgroup (mITT Population)
Study: Pooled
Subgroup: Maximum NRS Pain Score at Baseline



Results are based on a Cox proportional hazard model stratified by study and with treatment group, subgroup and a subgroup-by-treatment group interaction as covariates using a one-stage fixed-effects IPD meta-analysis approach.
The interaction p-value is based on the subgroup-by-treatment interaction term in the proportional hazard model used to compute the Hazard Ratio and 95% CI. Missing subgroup levels are not included in estimation of the interaction p-value. The reference group is Placebo.
N: Number of patients in treatment group; NETA: Norethindrone acetate; mITT: Modified intent-to-treat; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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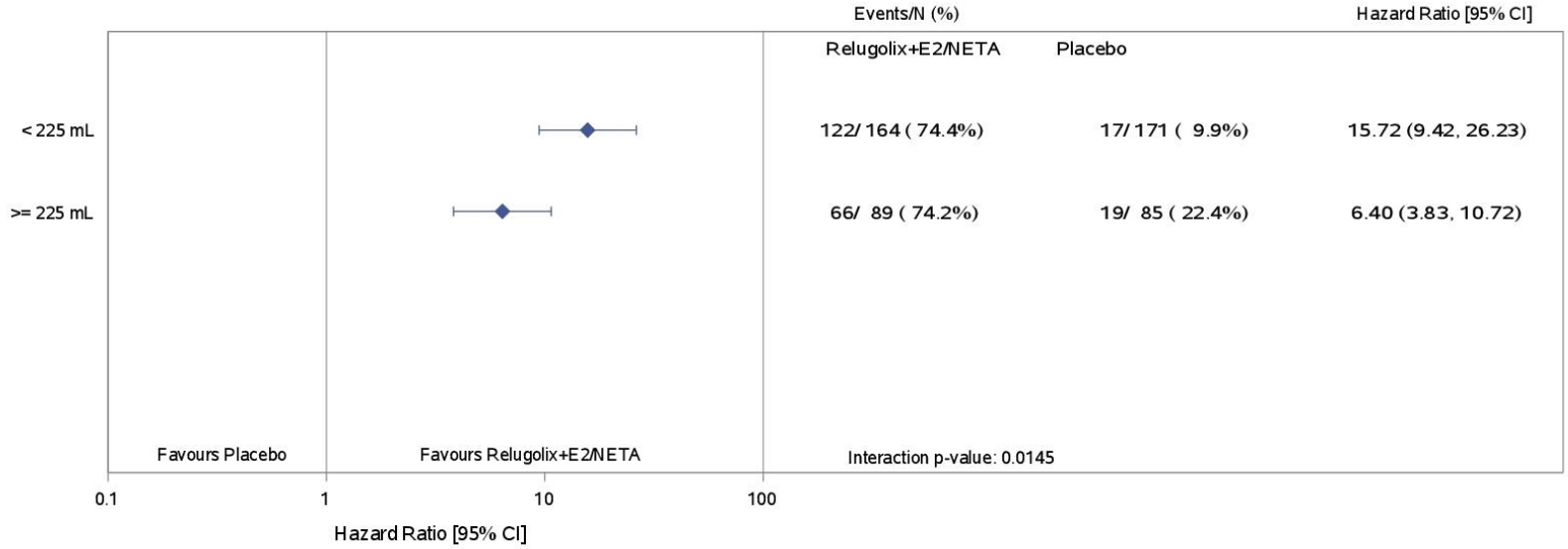
Figure EFF.TTSRG50.MITT.S5.TTE.FP: Time to Sustained Response (at Least a 50% Reduction from Baseline MBL Volume), by Subgroup (mITT Population)
Study: Pooled
Subgroup: MBL Volume at Baseline (mL)



Results are based on a Cox proportional hazard model stratified by study and with treatment group, subgroup and a subgroup-by-treatment group interaction as covariates using a one-stage fixed-effects IPD meta-analysis approach.
The interaction p-value is based on the subgroup-by-treatment interaction term in the proportional hazard model used to compute the Hazard Ratio and 95% CI. Missing subgroup levels are not included in estimation of the interaction p-value. The reference group is Placebo.
N: Number of patients in treatment group; NETA: Norethindrone acetate; mITT: Modified intent-to-treat; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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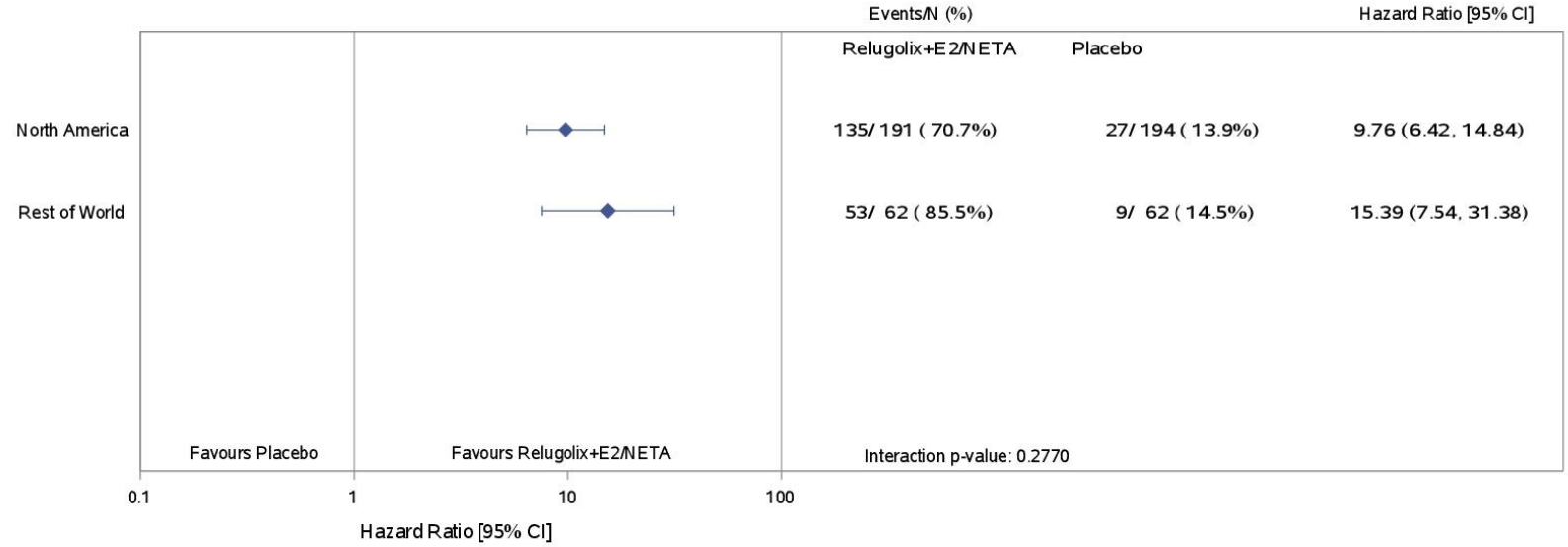
Figure EFF.TTSRG50.MITT.S6.TTE.FP: Time to Sustained Response (at Least a 50% Reduction from Baseline MBL Volume), by Subgroup (mITT Population)
Study: Pooled
Subgroup: Geographic Region I



Results are based on a Cox proportional hazard model stratified by study and with treatment group, subgroup and a subgroup-by-treatment group interaction as covariates using a one-stage fixed-effects IPD meta-analysis approach.
The interaction p-value is based on the subgroup-by-treatment interaction term in the proportional hazard model used to compute the Hazard Ratio and 95% CI. Missing subgroup levels are not included in estimation of the interaction p-value. The reference group is Placebo.
N: Number of patients in treatment group; NETA: Norethindrone acetate; mITT: Modified intent-to-treat; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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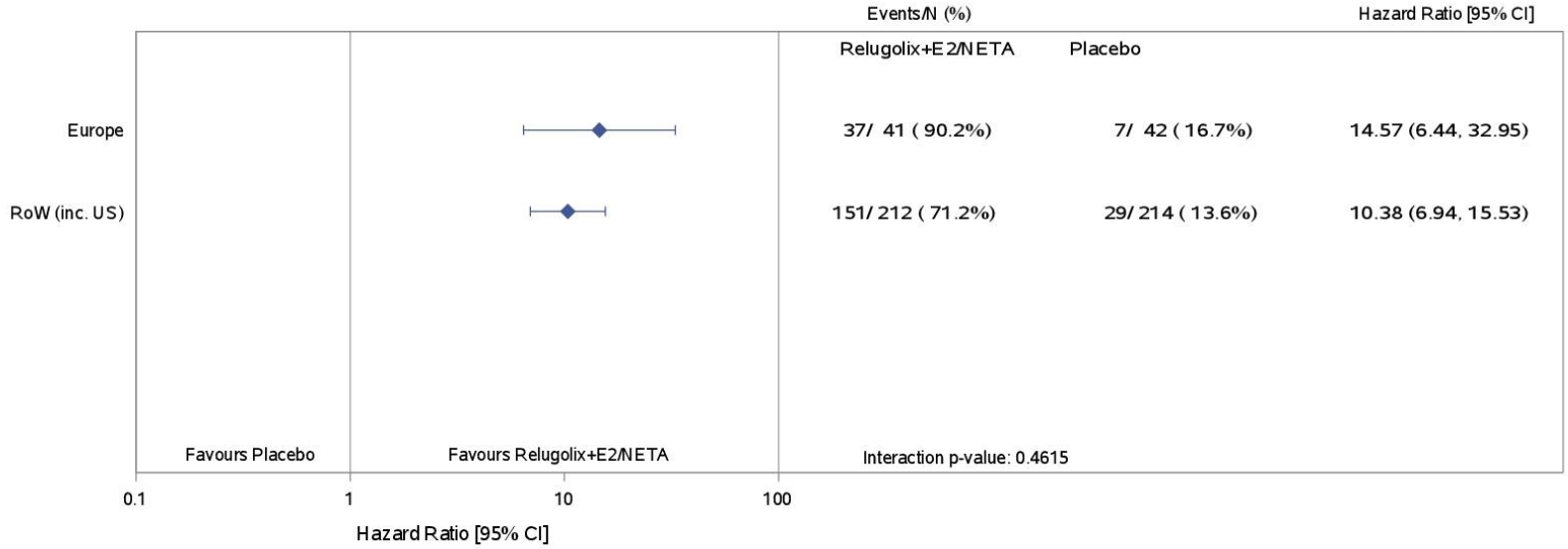
Figure EFF.TTSRG50.MITT.S7.TTE.FP: Time to Sustained Response (at Least a 50% Reduction from Baseline MBL Volume), by Subgroup (mITT Population)
Study: Pooled
Subgroup: Geographic Region II



Results are based on a Cox proportional hazard model stratified by study and with treatment group, subgroup and a subgroup-by-treatment group interaction as covariates using a one-stage fixed-effects IPD meta-analysis approach.
The interaction p-value is based on the subgroup-by-treatment interaction term in the proportional hazard model used to compute the Hazard Ratio and 95% CI. Missing subgroup levels are not included in estimation of the interaction p-value. The reference group is Placebo.
N: Number of patients in treatment group; NETA: Norethindrone acetate; mITT: Modified intent-to-treat; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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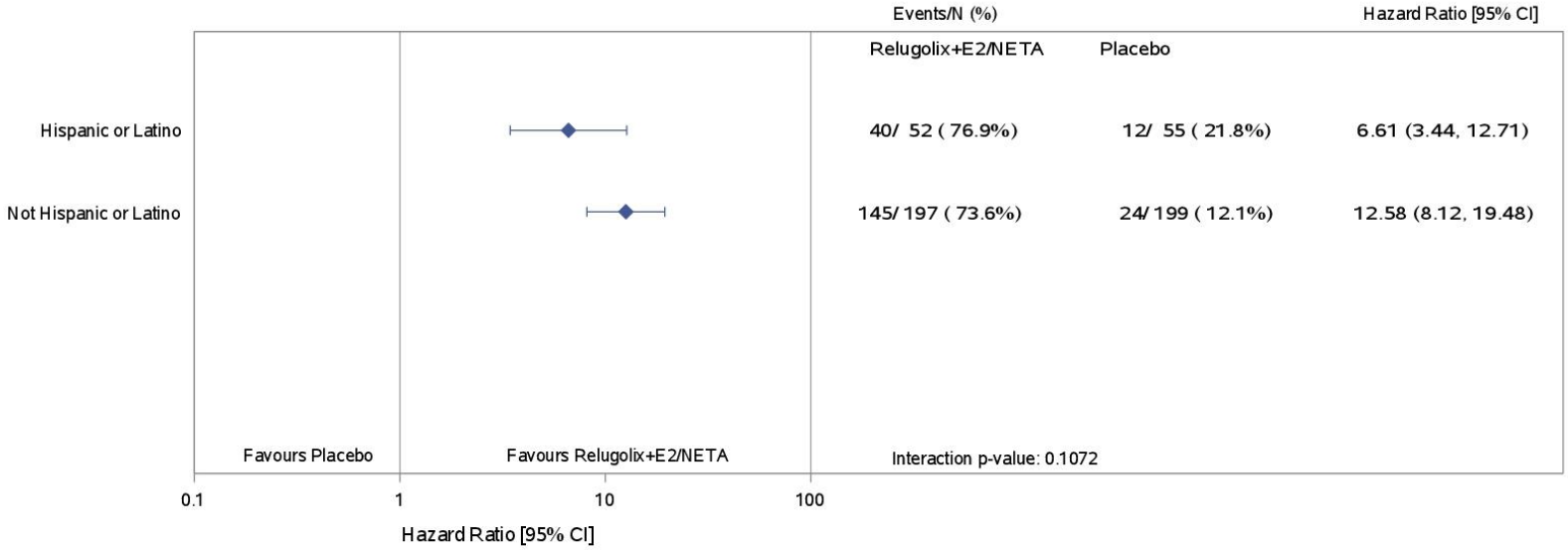
Figure EFF.TTSRG50.MITT.S8.TTE.FP: Time to Sustained Response (at Least a 50% Reduction from Baseline MBL Volume), by Subgroup (mITT Population)
Study: Pooled
Subgroup: Ethnicity



Results are based on a Cox proportional hazard model stratified by study and with treatment group, subgroup and a subgroup-by-treatment group interaction as covariates using a one-stage fixed-effects IPD meta-analysis approach.
The interaction p-value is based on the subgroup-by-treatment interaction term in the proportional hazard model used to compute the Hazard Ratio and 95% CI. Missing subgroup levels are not included in estimation of the interaction p-value. The reference group is Placebo.
N: Number of patients in treatment group; NETA: Norethindrone acetate; mITT: Modified intent-to-treat; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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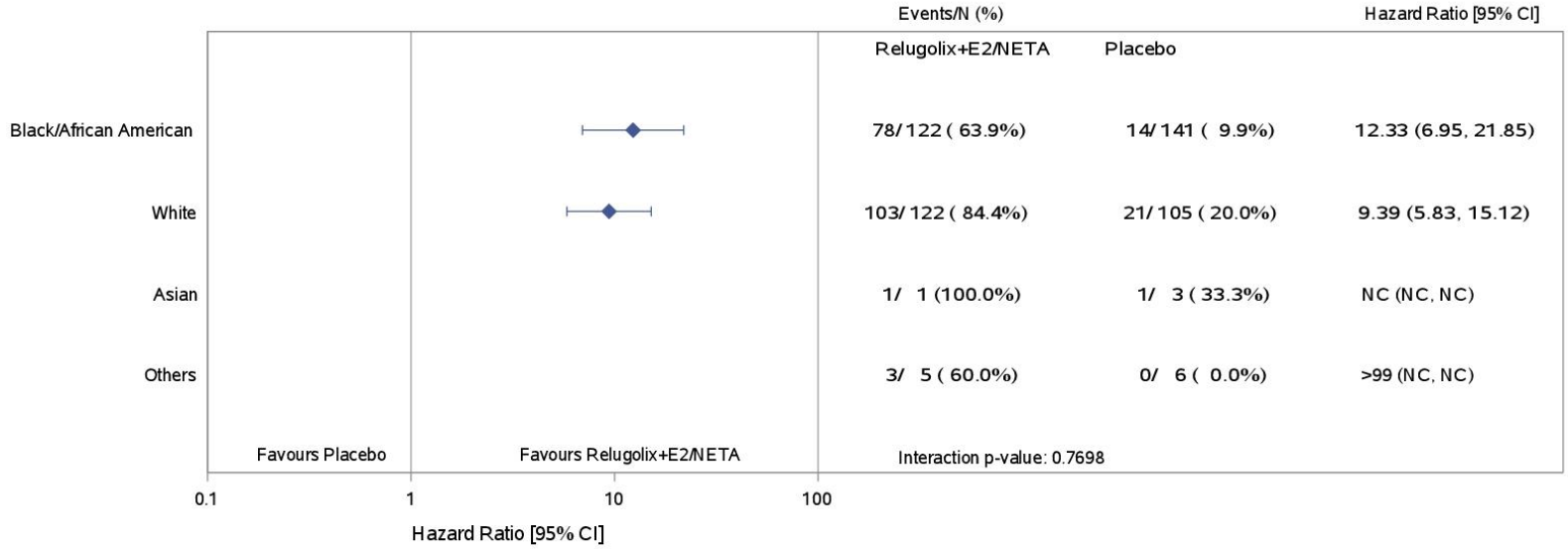
Figure EFF.TTSRG50.MITT.S9.TTE.FP: Time to Sustained Response (at Least a 50% Reduction from Baseline MBL Volume), by Subgroup (mITT Population)
Study: Pooled
Subgroup: Race



Results are based on a Cox proportional hazard model stratified by study and with treatment group, subgroup and a subgroup-by-treatment group interaction as covariates using a one-stage fixed-effects IPD meta-analysis approach.
The interaction p-value is based on the subgroup-by-treatment interaction term in the proportional hazard model used to compute the Hazard Ratio and 95% CI. Missing subgroup levels are not included in estimation of the interaction p-value. The reference group is Placebo.
N: Number of patients in treatment group; NETA: Norethindrone acetate; mITT: Modified intent-to-treat; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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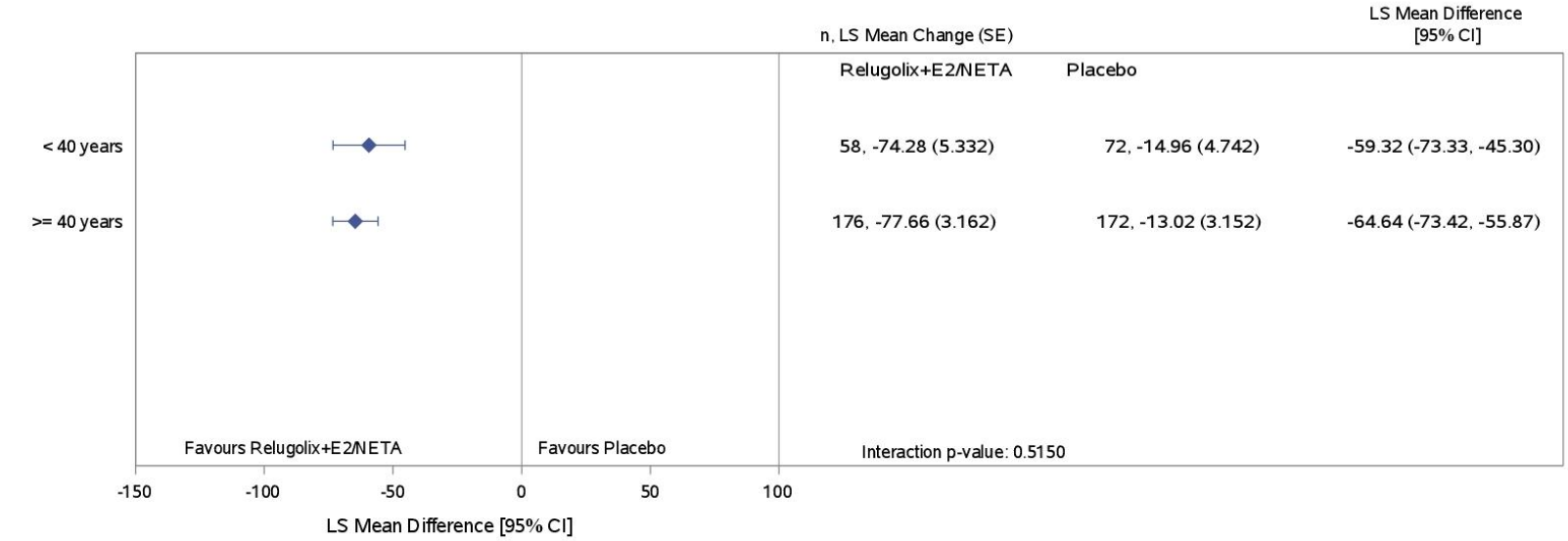
2.1.10 Summary of Average Percent Change from Baseline in Menstrual Blood Loss Volume (mL) Over 24 Weeks, by Subgroup (mITT Population)

Figure EFF.TMBLPCHG.MITT.S1.CON.FP: Summary of Average Percent Change from Baseline in Menstrual Blood Loss Volume (mL) Over 24 Weeks, by Subgroup (mITT Population)
Study: Pooled
Subgroup: Age (years)



Results are based on a mixed-effects model with study, treatment, visit, subgroup, treatment-by-visit interaction, and a subgroup-by-treatment interaction as fixed effects using a one-stage IPD meta-analysis approach. The multiple visits for each patient are the repeated measures as a random effect within each patient with an unstructured covariance.
The interaction p-value is based on the subgroup-by-treatment interaction term in the mixed-effects model used to compute the LS means, mean differences and 95% CIs. Missing subgroup levels are not included in estimation of the interaction p-value. The reference group is Placebo.
n: Number of patients with data; NETA: Norethindrone acetate; mITT: Modified intent-to-treat; LS: Least squares; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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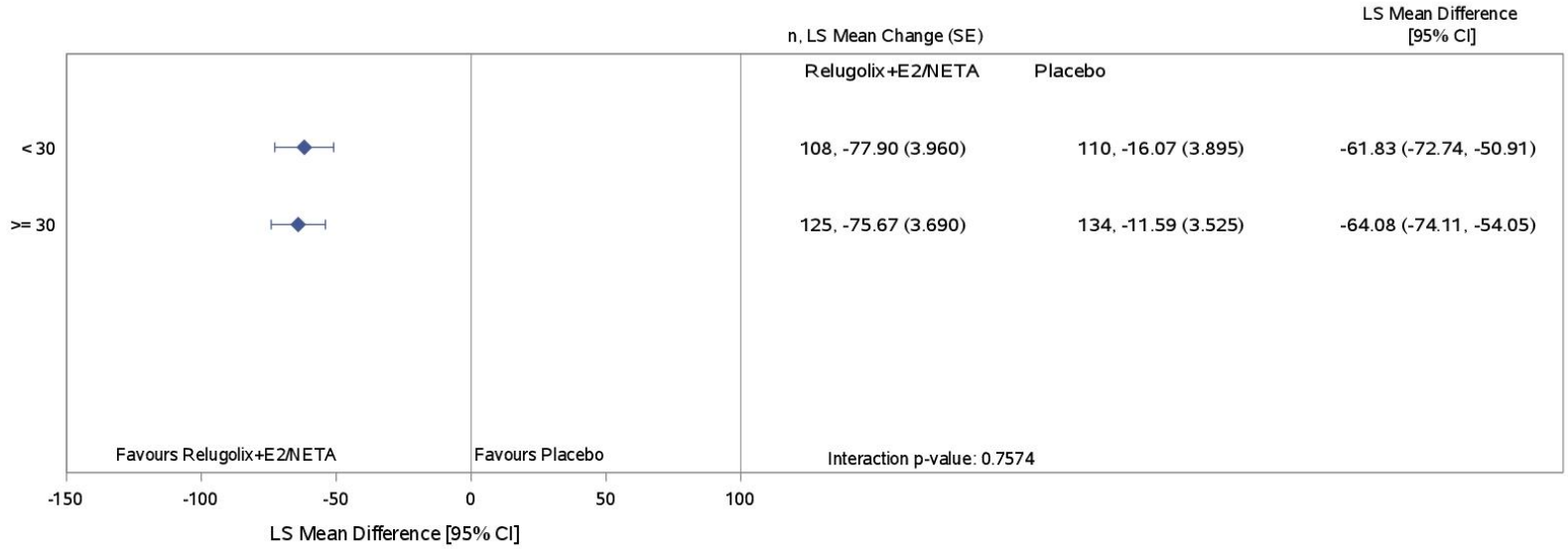
Figure EFF.TMBLPCHG.MITT.S2.CON.FP: Summary of Average Percent Change from Baseline in Menstrual Blood Loss Volume (mL) Over 24 Weeks, by Subgroup (mITT Population)
Study: Pooled
Subgroup: BMI (kg/m2) at Baseline



Results are based on a mixed-effects model with study, treatment, visit, subgroup, treatment-by-visit interaction, and a subgroup-by-treatment interaction as fixed effects using a one-stage IPD meta-analysis approach. The multiple visits for each patient are the repeated measures as a random effect within each patient with an unstructured covariance.
The interaction p-value is based on the subgroup-by-treatment interaction term in the mixed-effects model used to compute the LS means, mean differences and 95% CIs. Missing subgroup levels are not included in estimation of the interaction p-value. The reference group is Placebo.
n: Number of patients with data; NETA: Norethindrone acetate; mITT: Modified intent-to-treat; LS: Least squares; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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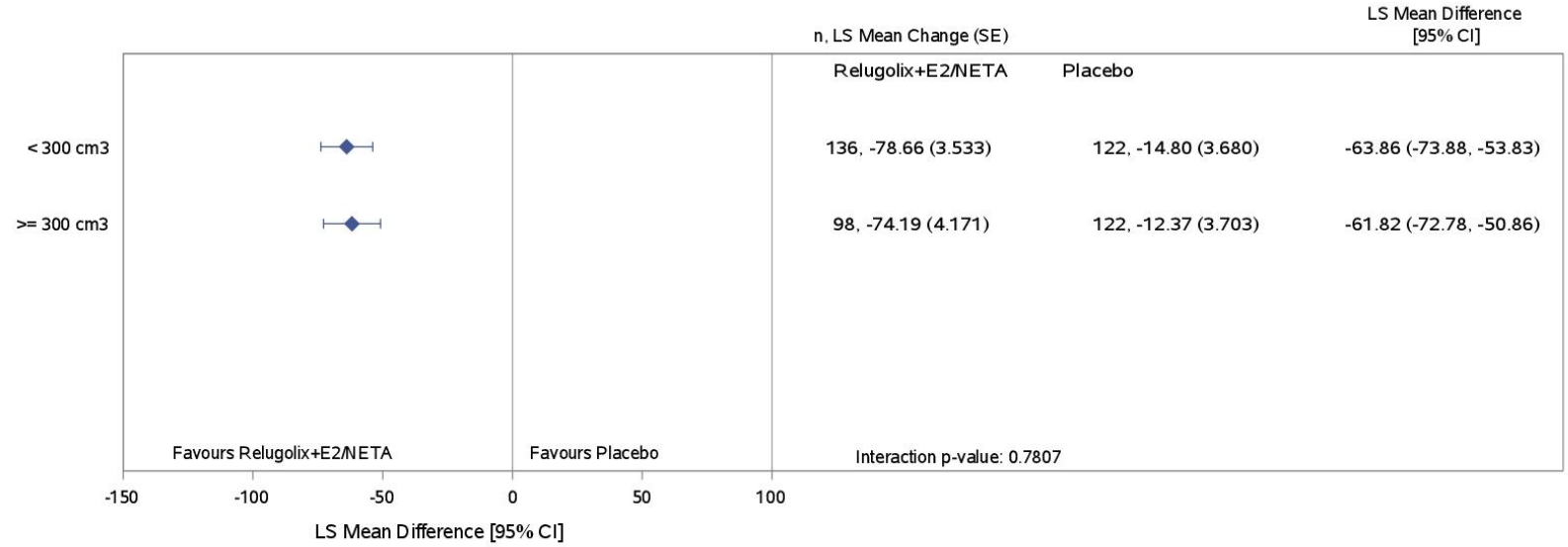
Figure EFF.TMBLPCHG.MITT.S3.CON.FP: Summary of Average Percent Change from Baseline in Menstrual Blood Loss Volume (mL) Over 24 Weeks, by Subgroup (mITT Population)
Study: Pooled
Subgroup: Uterine Volume at Baseline (cm3)



Results are based on a mixed-effects model with study, treatment, visit, subgroup, treatment-by-visit interaction, and a subgroup-by-treatment interaction as fixed effects using a one-stage IPD meta-analysis approach. The multiple visits for each patient are the repeated measures as a random effect within each patient with an unstructured covariance.
The interaction p-value is based on the subgroup-by-treatment interaction term in the mixed-effects model used to compute the LS means, mean differences and 95% CIs. Missing subgroup levels are not included in estimation of the interaction p-value. The reference group is Placebo.
n: Number of patients with data; NETA: Norethindrone acetate; mITT: Modified intent-to-treat; LS: Least squares; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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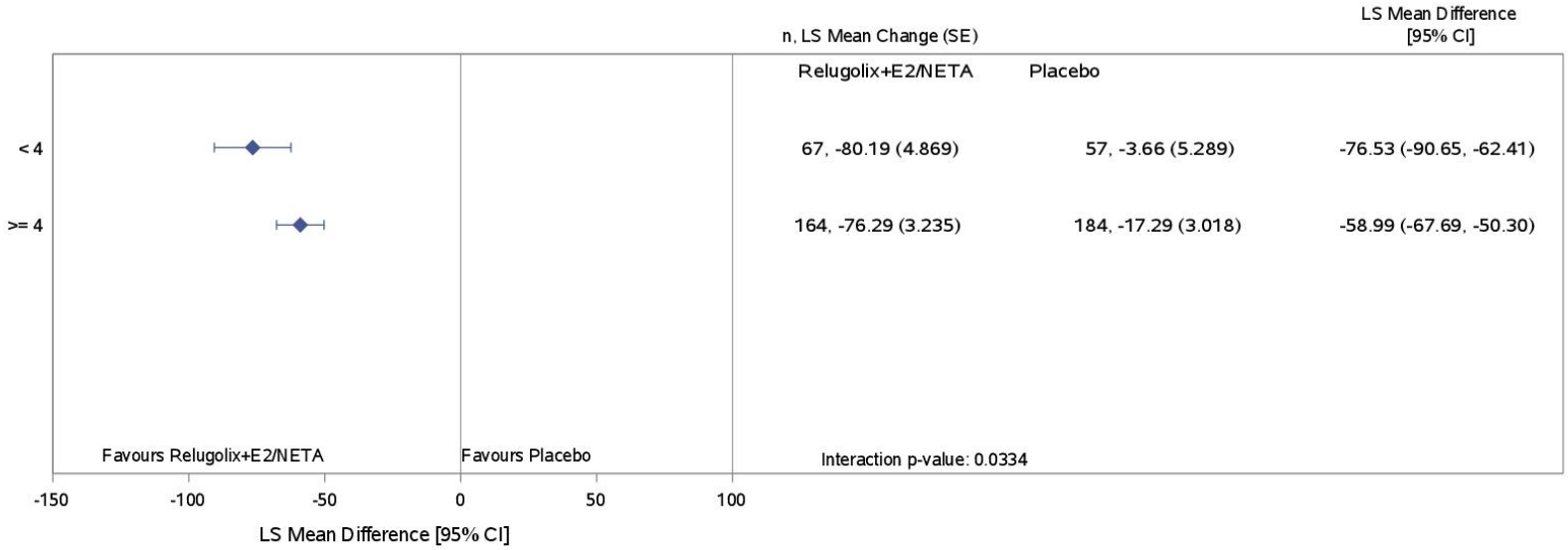
Figure EFF.TMBLPCHG.MITT.S4.CON.FP: Summary of Average Percent Change from Baseline in Menstrual Blood Loss Volume (mL) Over 24 Weeks, by Subgroup (mITT Population)
Study: Pooled
Subgroup: Maximum NRS Pain Score at Baseline



Results are based on a mixed-effects model with study, treatment, visit, subgroup, treatment-by-visit interaction, and a subgroup-by-treatment interaction as fixed effects using a one-stage IPD meta-analysis approach. The multiple visits for each patient are the repeated measures as a random effect within each patient with an unstructured covariance.
The interaction p-value is based on the subgroup-by-treatment interaction term in the mixed-effects model used to compute the LS means, mean differences and 95% CIs. Missing subgroup levels are not included in estimation of the interaction p-value. The reference group is Placebo.
n: Number of patients with data; NETA: Norethindrone acetate; mITT: Modified intent-to-treat; LS: Least squares; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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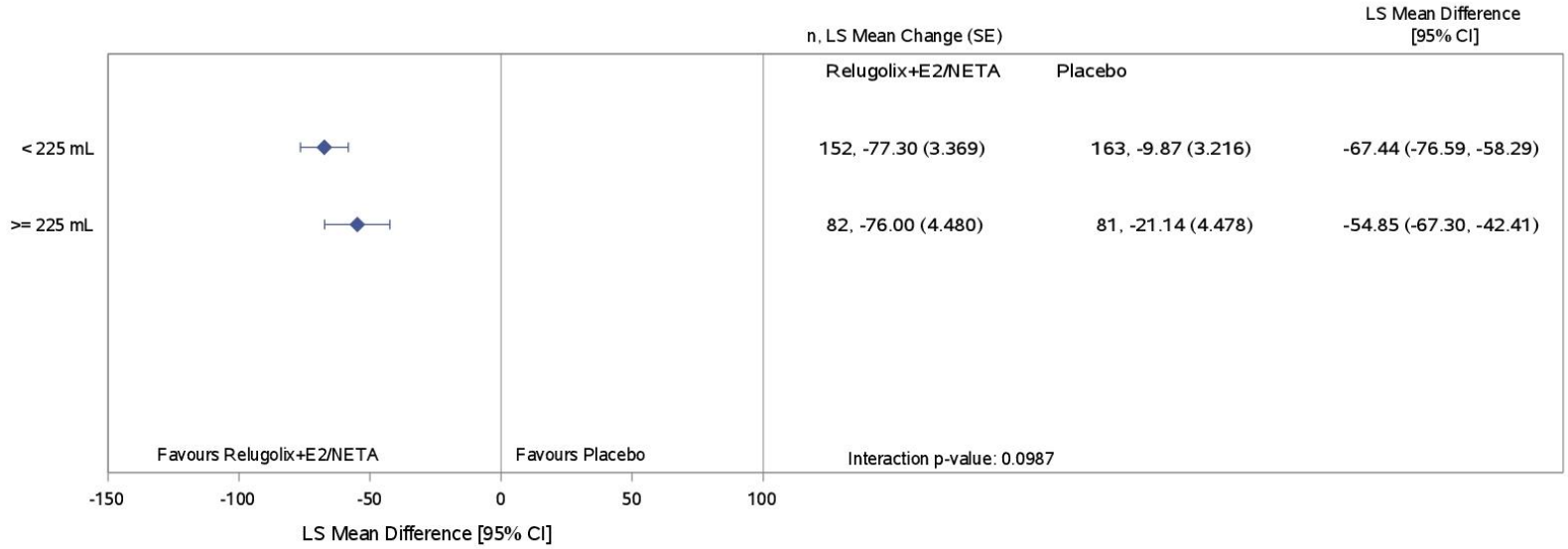
Figure EFF.TMBLPCHG.MITT.S5.CON.FP: Summary of Average Percent Change from Baseline in Menstrual Blood Loss Volume (mL) Over 24 Weeks, by Subgroup (mITT Population)
Study: Pooled
Subgroup: MBL Volume at Baseline (mL)



Results are based on a mixed-effects model with study, treatment, visit, subgroup, treatment-by-visit interaction, and a subgroup-by-treatment interaction as fixed effects using a one-stage IPD meta-analysis approach. The multiple visits for each patient are the repeated measures as a random effect within each patient with an unstructured covariance.
The interaction p-value is based on the subgroup-by-treatment interaction term in the mixed-effects model used to compute the LS means, mean differences and 95% CIs. Missing subgroup levels are not included in estimation of the interaction p-value. The reference group is Placebo.
n: Number of patients with data; NETA: Norethindrone acetate; mITT: Modified intent-to-treat; LS: Least squares; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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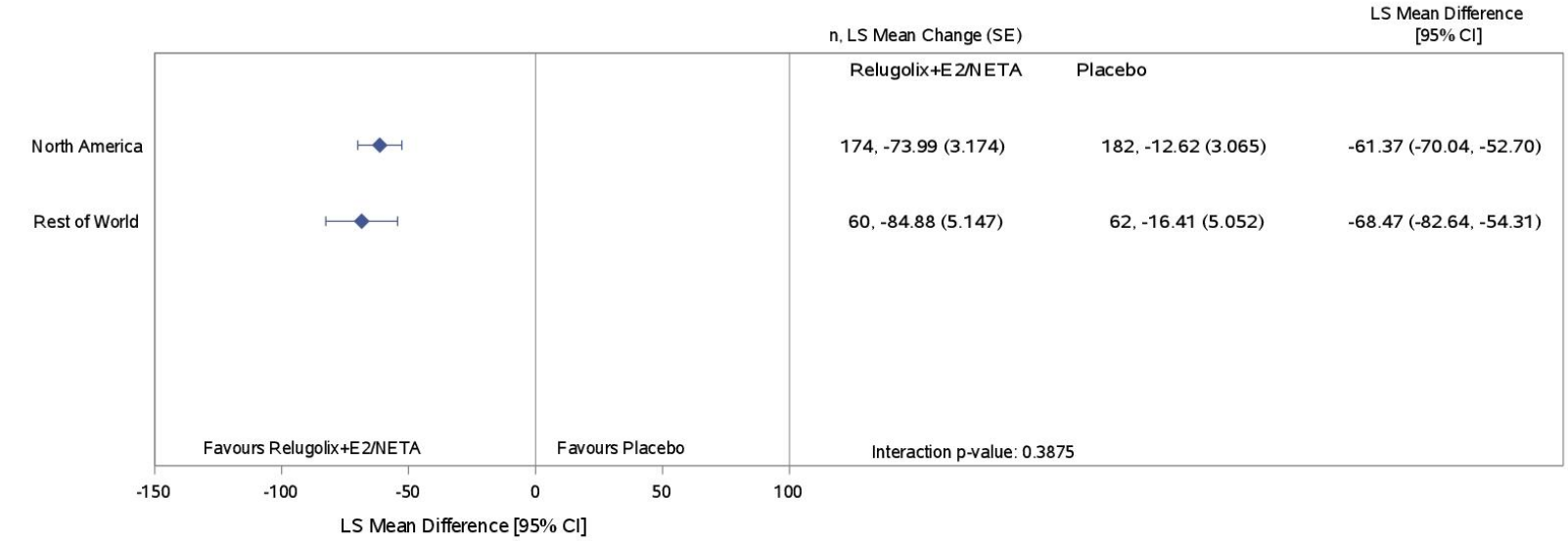
Figure EFF.TMBLPCHG.MITT.S6.CON.FP: Summary of Average Percent Change from Baseline in Menstrual Blood Loss Volume (mL) Over 24 Weeks, by Subgroup (mITT Population)
Study: Pooled
Subgroup: Geographic Region I



Results are based on a mixed-effects model with study, treatment, visit, subgroup, treatment-by-visit interaction, and a subgroup-by-treatment interaction as fixed effects using a one-stage IPD meta-analysis approach. The multiple visits for each patient are the repeated measures as a random effect within each patient with an unstructured covariance.
The interaction p-value is based on the subgroup-by-treatment interaction term in the mixed-effects model used to compute the LS means, mean differences and 95% CIs. Missing subgroup levels are not included in estimation of the interaction p-value. The reference group is Placebo.
n: Number of patients with data; NETA: Norethindrone acetate; mITT: Modified intent-to-treat; LS: Least squares; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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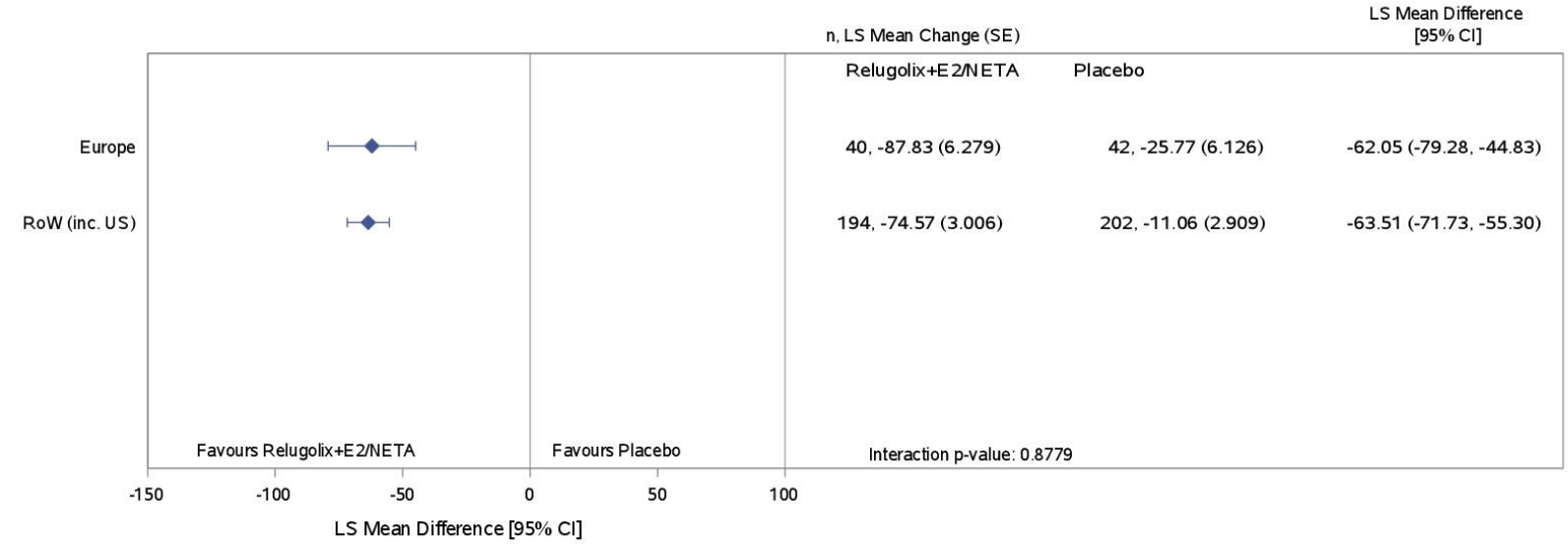
Figure EFF.TMBLPCHG.MITT.S7.CON.FP: Summary of Average Percent Change from Baseline in Menstrual Blood Loss Volume (mL) Over 24 Weeks, by Subgroup (mITT Population)
Study: Pooled
Subgroup: Geographic Region II



Results are based on a mixed-effects model with study, treatment, visit, subgroup, treatment-by-visit interaction, and a subgroup-by-treatment interaction as fixed effects using a one-stage IPD meta-analysis approach. The multiple visits for each patient are the repeated measures as a random effect within each patient with an unstructured covariance.
The interaction p-value is based on the subgroup-by-treatment interaction term in the mixed-effects model used to compute the LS means, mean differences and 95% CIs. Missing subgroup levels are not included in estimation of the interaction p-value. The reference group is Placebo.
n: Number of patients with data; NETA: Norethindrone acetate; mITT: Modified intent-to-treat; LS: Least squares; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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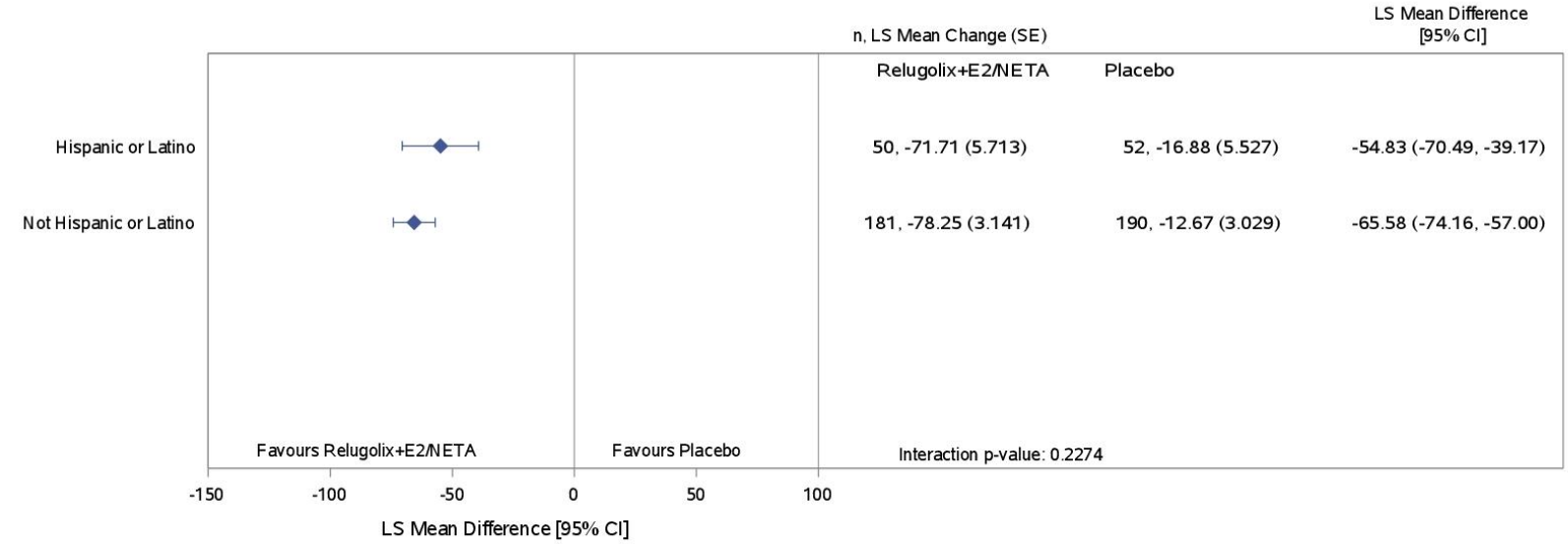
Figure EFF.TMBLPCHG.MITT.S8.CON.FP: Summary of Average Percent Change from Baseline in Menstrual Blood Loss Volume (mL) Over 24 Weeks, by Subgroup (mITT Population)
Study: Pooled
Subgroup: Ethnicity



Results are based on a mixed-effects model with study, treatment, visit, subgroup, treatment-by-visit interaction, and a subgroup-by-treatment interaction as fixed effects using a one-stage IPD meta-analysis approach. The multiple visits for each patient are the repeated measures as a random effect within each patient with an unstructured covariance.
The interaction p-value is based on the subgroup-by-treatment interaction term in the mixed-effects model used to compute the LS means, mean differences and 95% CIs. Missing subgroup levels are not included in estimation of the interaction p-value. The reference group is Placebo.
n: Number of patients with data; NETA: Norethindrone acetate; mITT: Modified intent-to-treat; LS: Least squares; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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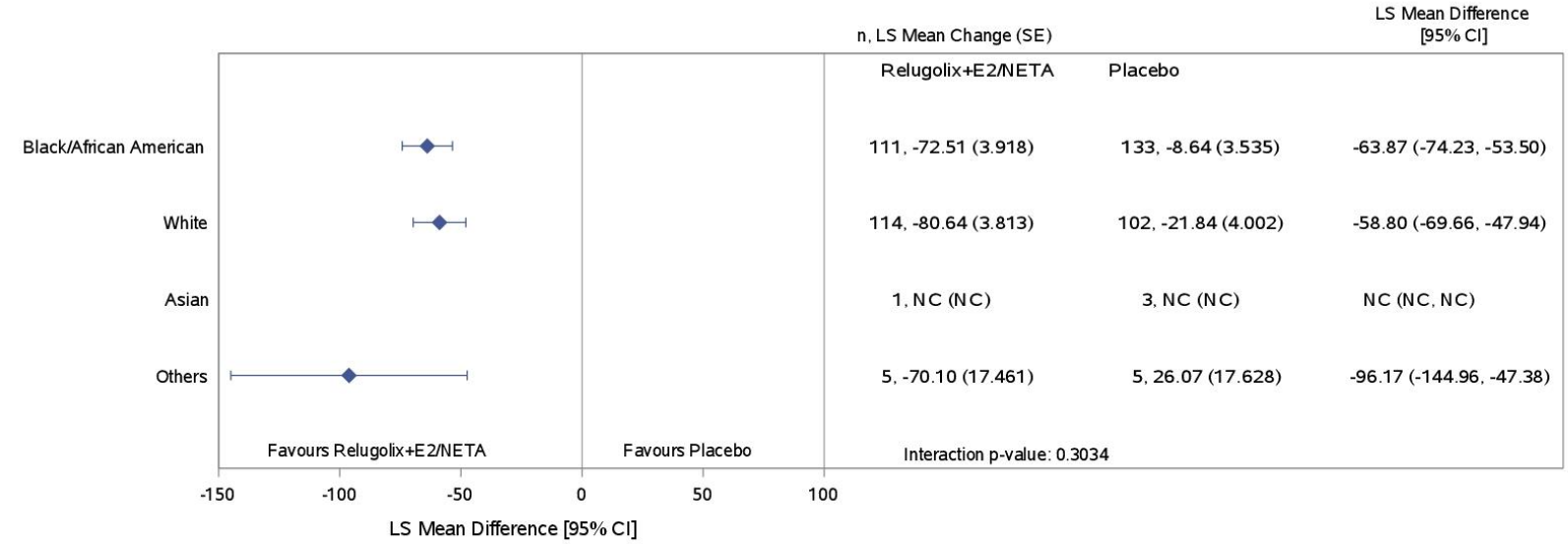
Figure EFF.TMBLPCHG.MITT.S9.CON.FP: Summary of Average Percent Change from Baseline in Menstrual Blood Loss Volume (mL) Over 24 Weeks, by Subgroup (mITT Population)
Study: Pooled
Subgroup: Race



Results are based on a mixed-effects model with study, treatment, visit, subgroup, treatment-by-visit interaction, and a subgroup-by-treatment interaction as fixed effects using a one-stage IPD meta-analysis approach. The multiple visits for each patient are the repeated measures as a random effect within each patient with an unstructured covariance.
The interaction p-value is based on the subgroup-by-treatment interaction term in the mixed-effects model used to compute the LS means, mean differences and 95% CIs. Missing subgroup levels are not included in estimation of the interaction p-value. The reference group is Placebo.
n: Number of patients with data; NETA: Norethindrone acetate; mITT: Modified intent-to-treat; LS: Least squares; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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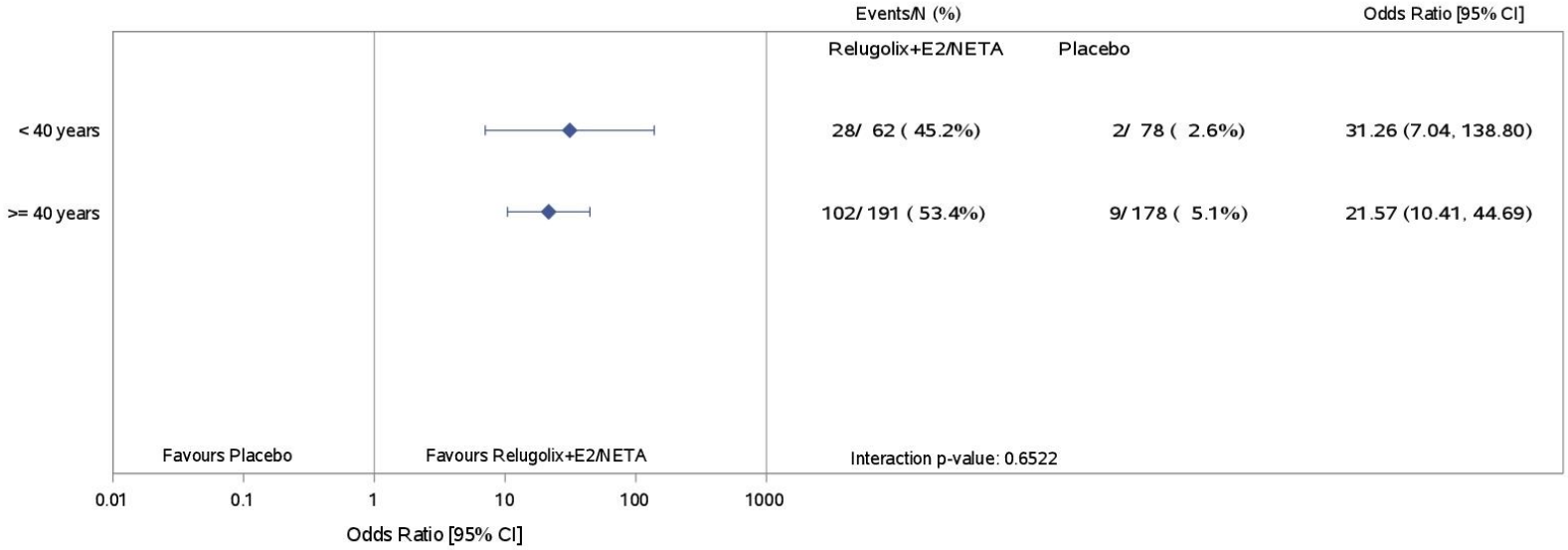
2.1.11 Proportion of Patients who Achieved Amenorrhea Over the Last 35 Days of Treatment, by Subgroup (mITT Population)

Nachfolgend sind zunächst alle Forest Plots für das *Odds Ratio* dargestellt; gefolgt von den entsprechenden Forest Plots für *Risk Ratio* und *Risk Difference*.

Figure EFF.AMNO24ET.MITT.S1.BIN.FP: Proportion of Patients who Achieved Amenorrhea Over the Last 35 Days of Treatment, by Subgroup (mITT Population)
Study: Pooled
Subgroup: Age (years)



Results are based on a logistic regression model adjusted for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates using a one-stage fixed-effects IPD meta-analysis approach. A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
The interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the Odds Ratio and 95% CI. Missing subgroup levels are not included in estimation of the interaction p-value. The reference group is Placebo.
N: Number of patients in treatment group; NETA: Norethindrone acetate; mITT: Modified intent-to-treat; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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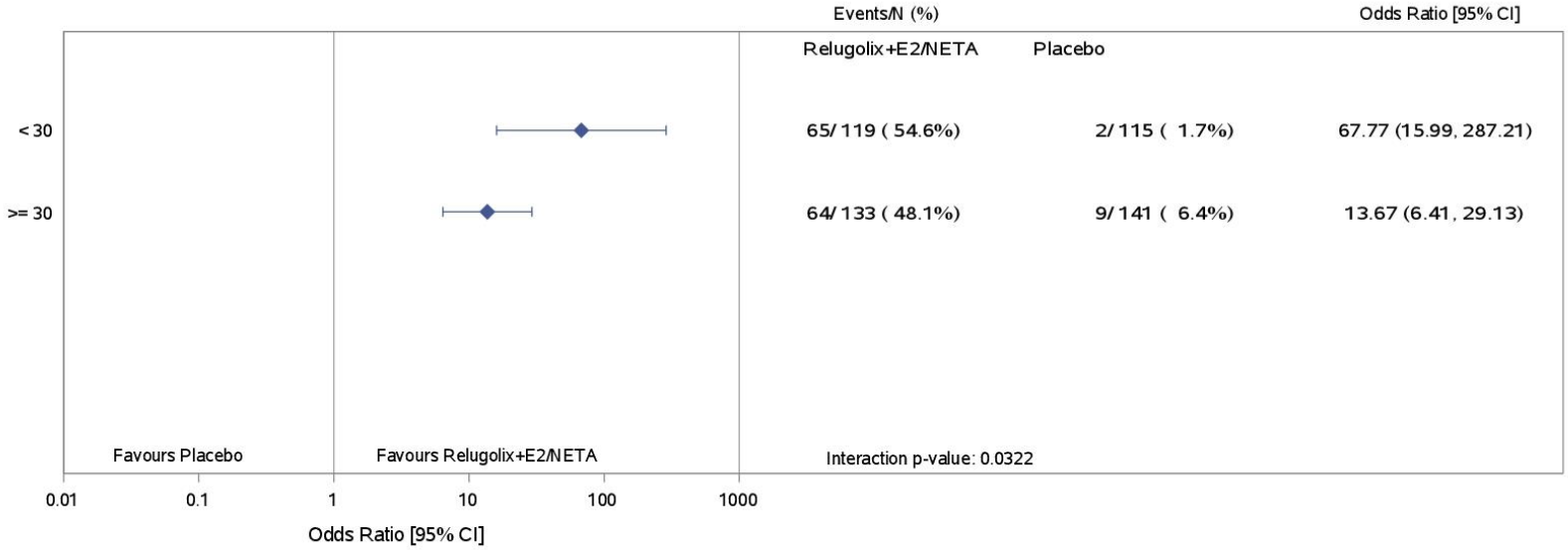
Figure EFF.AMNO24ET.MITT.S2.BIN.FP: Proportion of Patients who Achieved Amenorrhea Over the Last 35 Days of Treatment, by Subgroup (mITT Population)
Study: Pooled
Subgroup: BMI (kg/m2) at Baseline



Results are based on a logistic regression model adjusted for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates using a one-stage fixed-effects IPD meta-analysis approach. A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
The interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the Odds Ratio and 95% CI. Missing subgroup levels are not included in estimation of the interaction p-value. The reference group is Placebo.
N: Number of patients in treatment group; NETA: Norethindrone acetate; mITT: Modified intent-to-treat; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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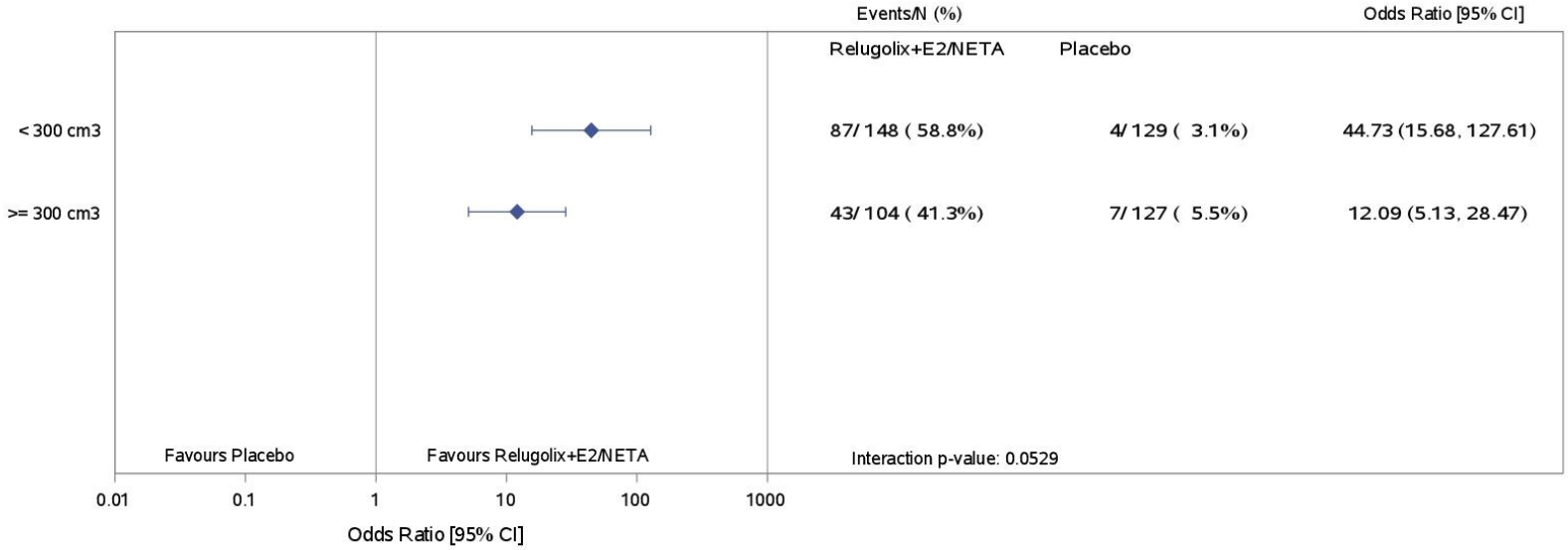
Figure EFF.AMNO24ET.MITT.S3.BIN.FP: Proportion of Patients who Achieved Amenorrhea Over the Last 35 Days of Treatment, by Subgroup (mITT Population)
Study: Pooled
Subgroup: Uterine Volume at Baseline (cm3)



Results are based on a logistic regression model adjusted for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates using a one-stage fixed-effects IPD meta-analysis approach. A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
The interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the Odds Ratio and 95% CI. Missing subgroup levels are not included in estimation of the interaction p-value. The reference group is Placebo.
N: Number of patients in treatment group; NETA: Norethindrone acetate; mITT: Modified intent-to-treat; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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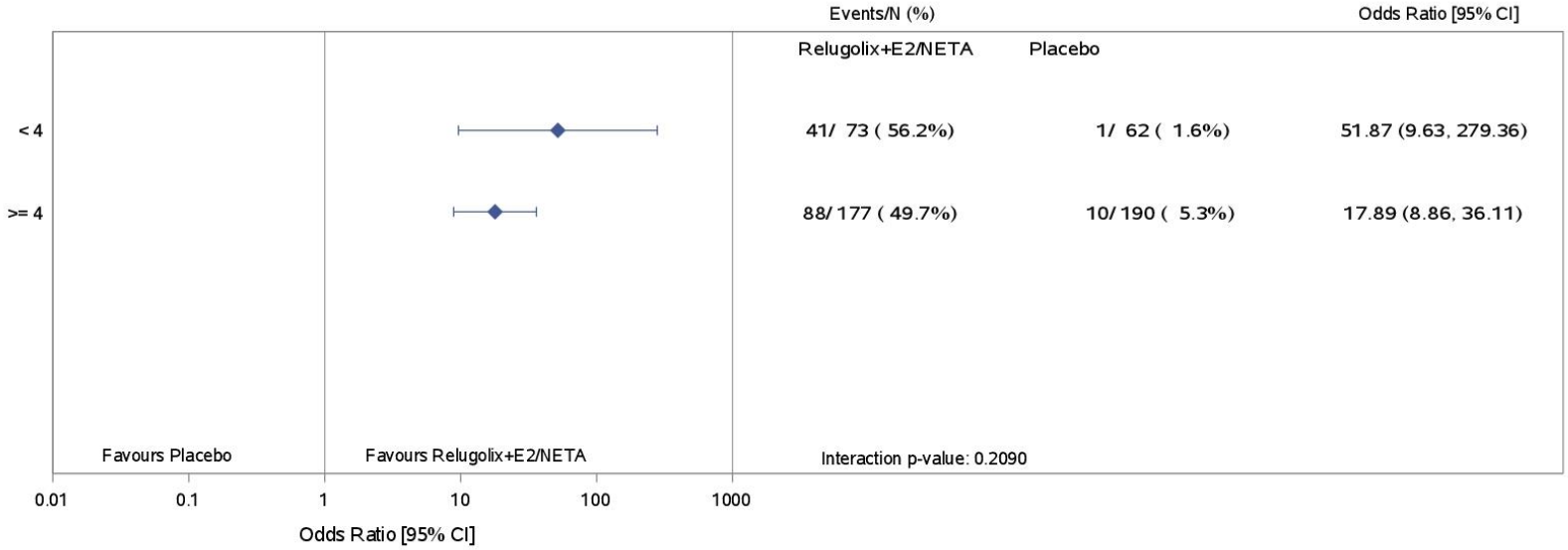
Figure EFF.AMNO24ET.MITT.S4.BIN.FP: Proportion of Patients who Achieved Amenorrhea Over the Last 35 Days of Treatment, by Subgroup (mITT Population)
Study: Pooled
Subgroup: Maximum NRS Pain Score at Baseline



Results are based on a logistic regression model adjusted for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates using a one-stage fixed-effects IPD meta-analysis approach. A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
The interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the Odds Ratio and 95% CI. Missing subgroup levels are not included in estimation of the interaction p-value. The reference group is Placebo.
N: Number of patients in treatment group; NETA: Norethindrone acetate; mITT: Modified intent-to-treat; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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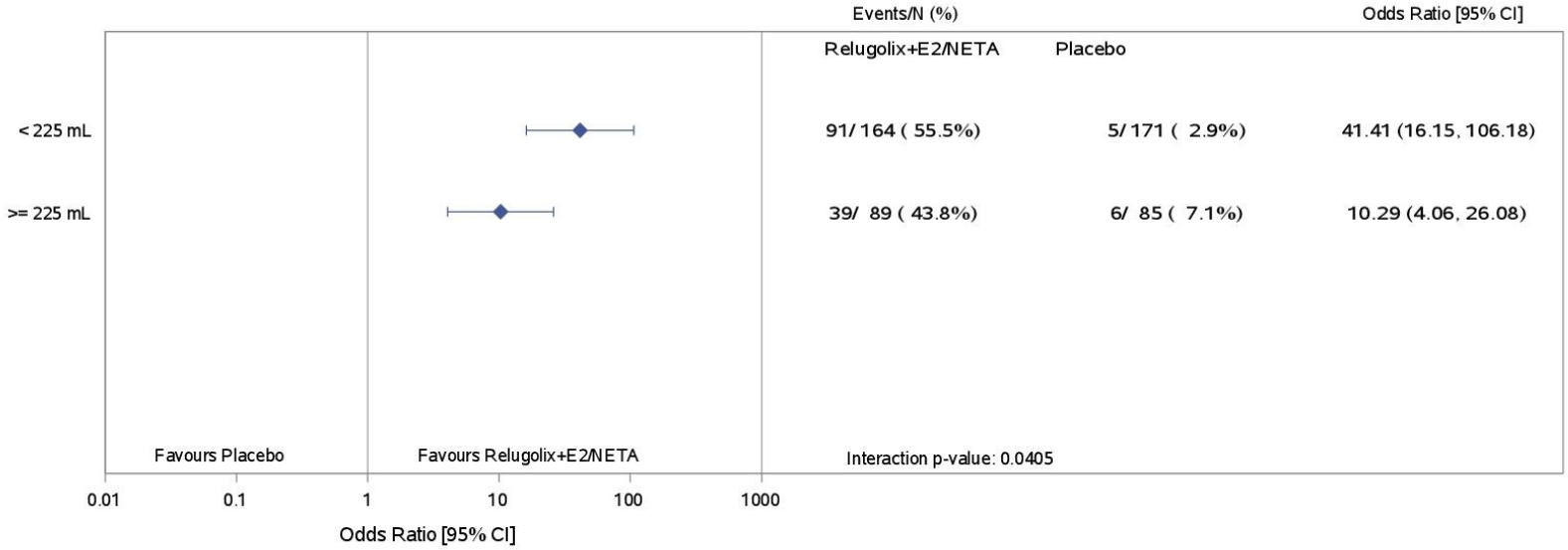
Figure EFF.AMNO24ET.MITT.S5.BIN.FP: Proportion of Patients who Achieved Amenorrhea Over the Last 35 Days of Treatment, by Subgroup (mITT Population)
Study: Pooled
Subgroup: MBL Volume at Baseline (mL)



Results are based on a logistic regression model adjusted for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates using a one-stage fixed-effects IPD meta-analysis approach. A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
The interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the Odds Ratio and 95% CI. Missing subgroup levels are not included in estimation of the interaction p-value. The reference group is Placebo.
N: Number of patients in treatment group; NETA: Norethindrone acetate; mITT: Modified intent-to-treat; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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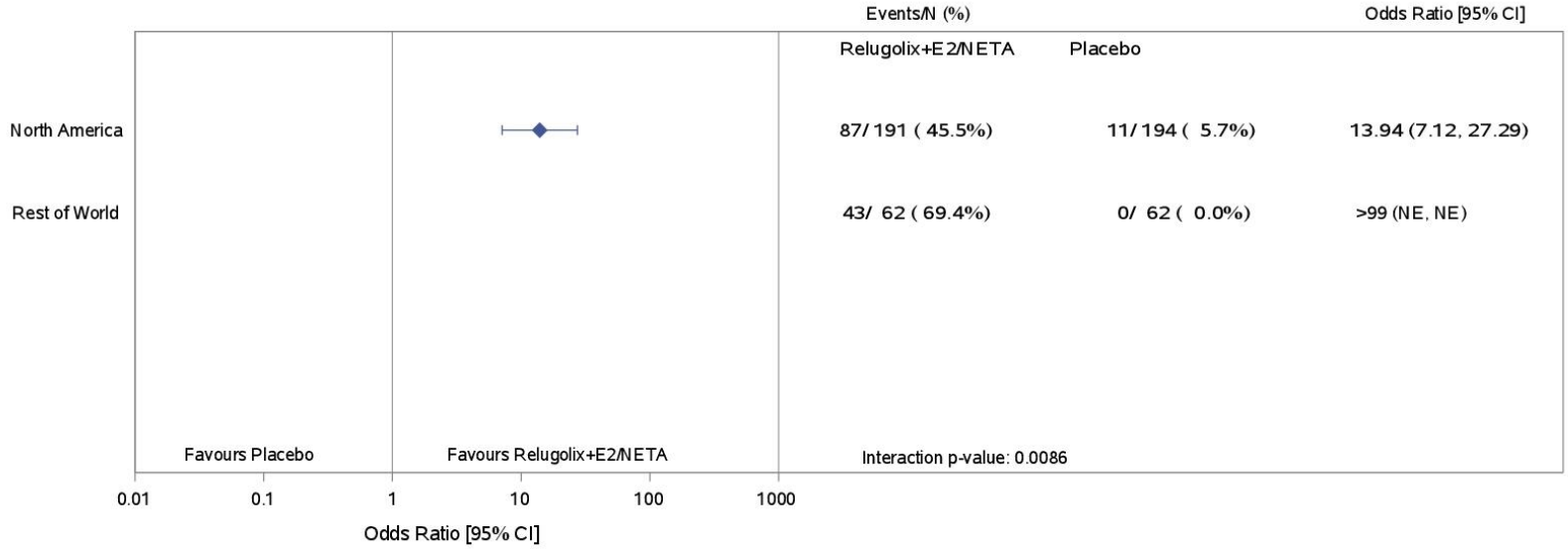
Figure EFF.AMNO24ET.MITT.S6.BIN.FP: Proportion of Patients who Achieved Amenorrhea Over the Last 35 Days of Treatment, by Subgroup (mITT Population)
Study: Pooled
Subgroup: Geographic Region I



Results are based on a logistic regression model adjusted for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates using a one-stage fixed-effects IPD meta-analysis approach. A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
The interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the Odds Ratio and 95% CI. Missing subgroup levels are not included in estimation of the interaction p-value. The reference group is Placebo.
N: Number of patients in treatment group; NETA: Norethindrone acetate; mITT: Modified intent-to-treat; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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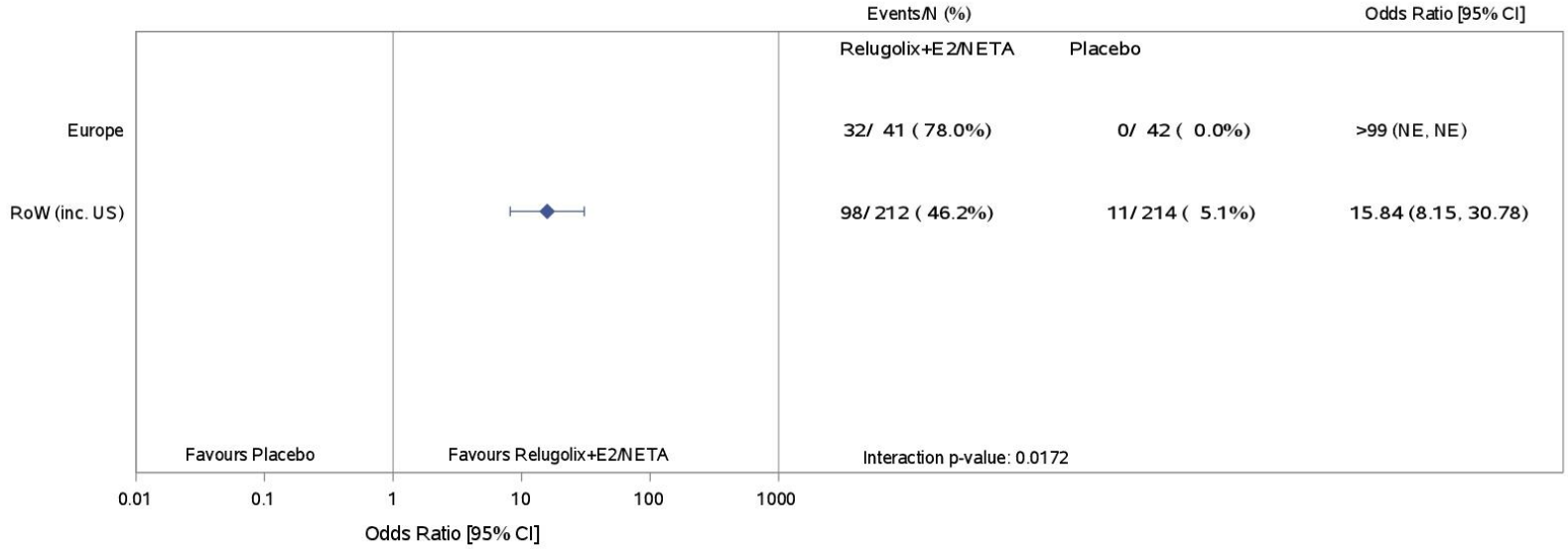
Figure EFF.AMNO24ET.MITT.S7.BIN.FP: Proportion of Patients who Achieved Amenorrhea Over the Last 35 Days of Treatment, by Subgroup (mITT Population)
Study: Pooled
Subgroup: Geographic Region II



Results are based on a logistic regression model adjusted for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates using a one-stage fixed-effects IPD meta-analysis approach. A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
The interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the Odds Ratio and 95% CI. Missing subgroup levels are not included in estimation of the interaction p-value. The reference group is Placebo.
N: Number of patients in treatment group; NETA: Norethindrone acetate; mITT: Modified intent-to-treat; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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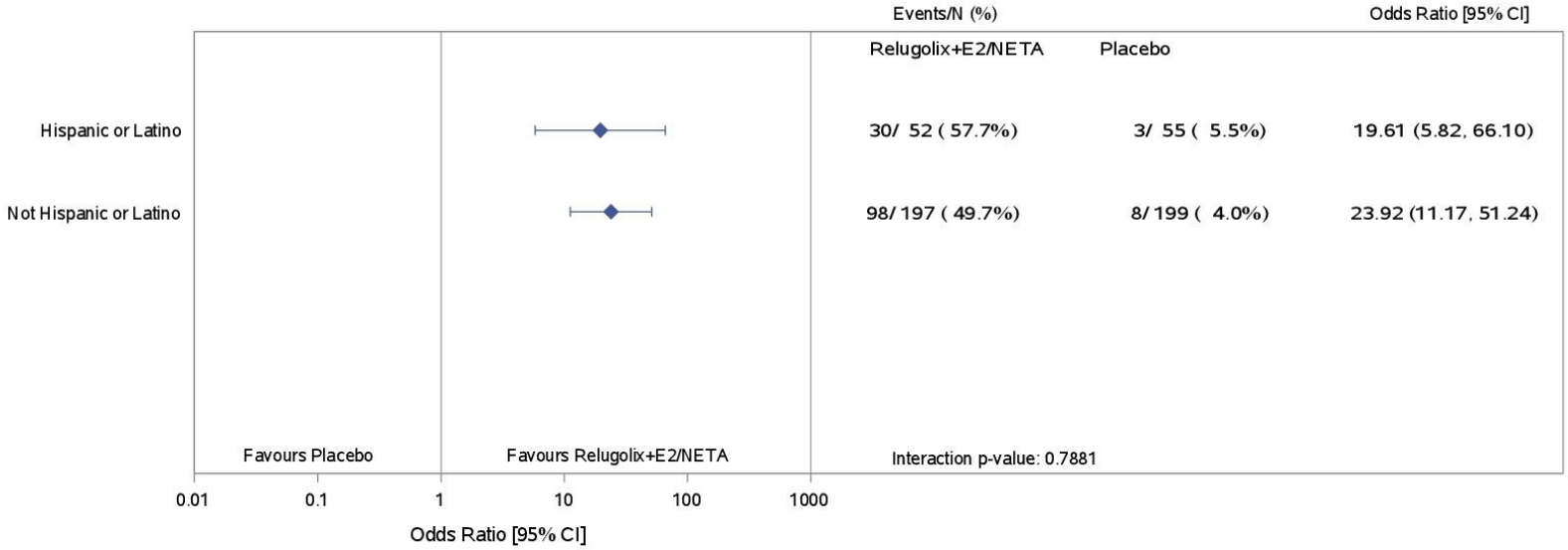
Figure EFF.AMNO24ET.MITT.S8.BIN.FP: Proportion of Patients who Achieved Amenorrhea Over the Last 35 Days of Treatment, by Subgroup (mITT Population)
Study: Pooled
Subgroup: Ethnicity



Results are based on a logistic regression model adjusted for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates using a one-stage fixed-effects IPD meta-analysis approach. A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
The interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the Odds Ratio and 95% CI. Missing subgroup levels are not included in estimation of the interaction p-value. The reference group is Placebo.
N: Number of patients in treatment group; NETA: Norethindrone acetate; mITT: Modified intent-to-treat; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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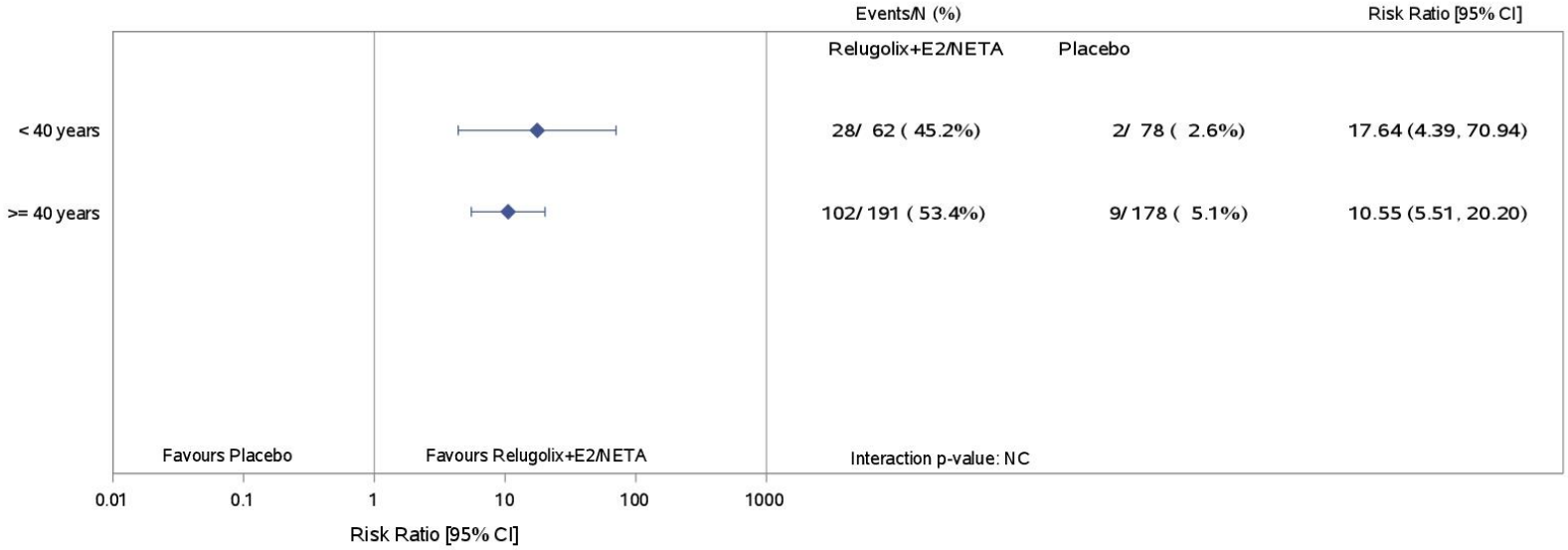
Figure EFF.AMNO24ET.MITT.S1.BIN.FP.RR: Proportion of Patients who Achieved Amenorrhea Over the Last 35 Days of Treatment, by Subgroup (mITT Population) - Risk Ratio
Study: Pooled
Subgroup: Age (years)



Results are based on a Cochran-Mantel-Haenszel approach stratified by study using a one-stage fixed-effects IPD meta-analysis. A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
The reference group is Placebo.
N: Number of patients in treatment group; NETA: Norethindrone acetate; mITT: Modified intent-to-treat; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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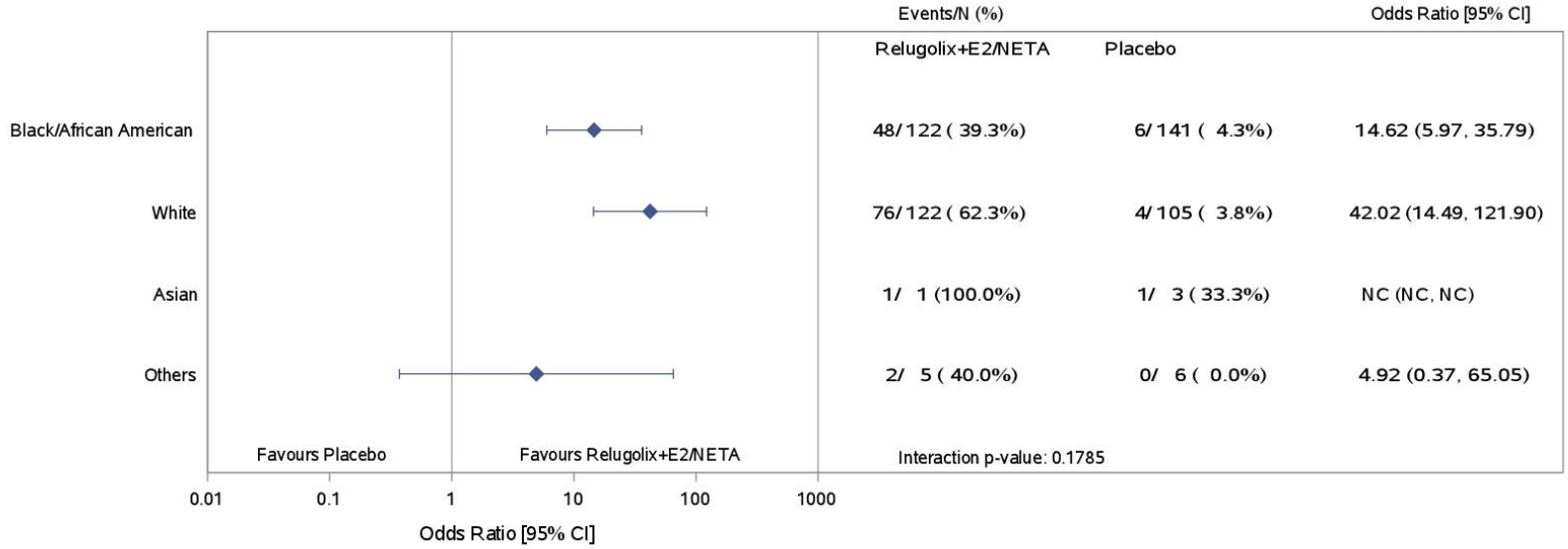
Figure EFF.AMNO24ET.MITT.S9.BIN.FP: Proportion of Patients who Achieved Amenorrhea Over the Last 35 Days of Treatment, by Subgroup (mITT Population)
Study: Pooled
Subgroup: Race



Results are based on a logistic regression model adjusted for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates using a one-stage fixed-effects IPD meta-analysis approach. A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
The interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the Odds Ratio and 95% CI. Missing subgroup levels are not included in estimation of the interaction p-value. The reference group is Placebo.
N: Number of patients in treatment group; NETA: Norethindrone acetate; mITT: Modified intent-to-treat; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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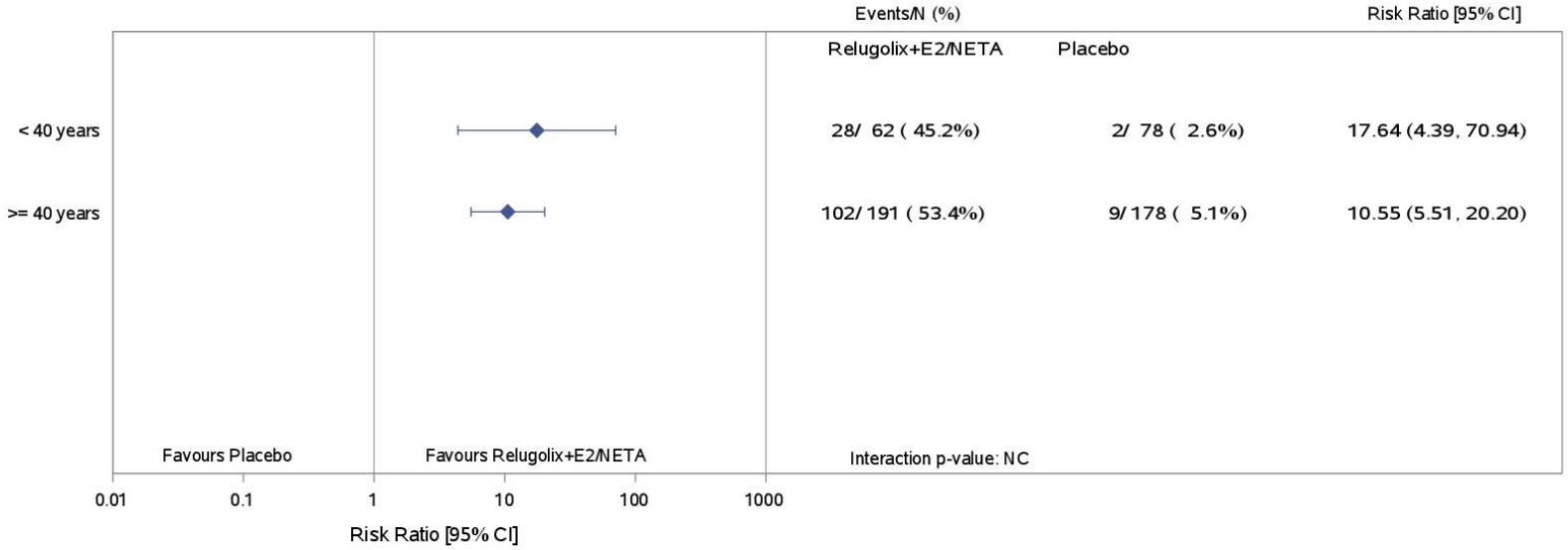
Figure EFF.AMNO24ET.MITT.S1.BIN.FP.RR: Proportion of Patients who Achieved Amenorrhea Over the Last 35 Days of Treatment, by Subgroup (mITT Population) - Risk Ratio
Study: Pooled
Subgroup: Age (years)



Results are based on a Cochran-Mantel-Haenszel approach stratified by study using a one-stage fixed-effects IPD meta-analysis. A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
The reference group is Placebo.
N: Number of patients in treatment group; NETA: Norethindrone acetate; mITT: Modified intent-to-treat; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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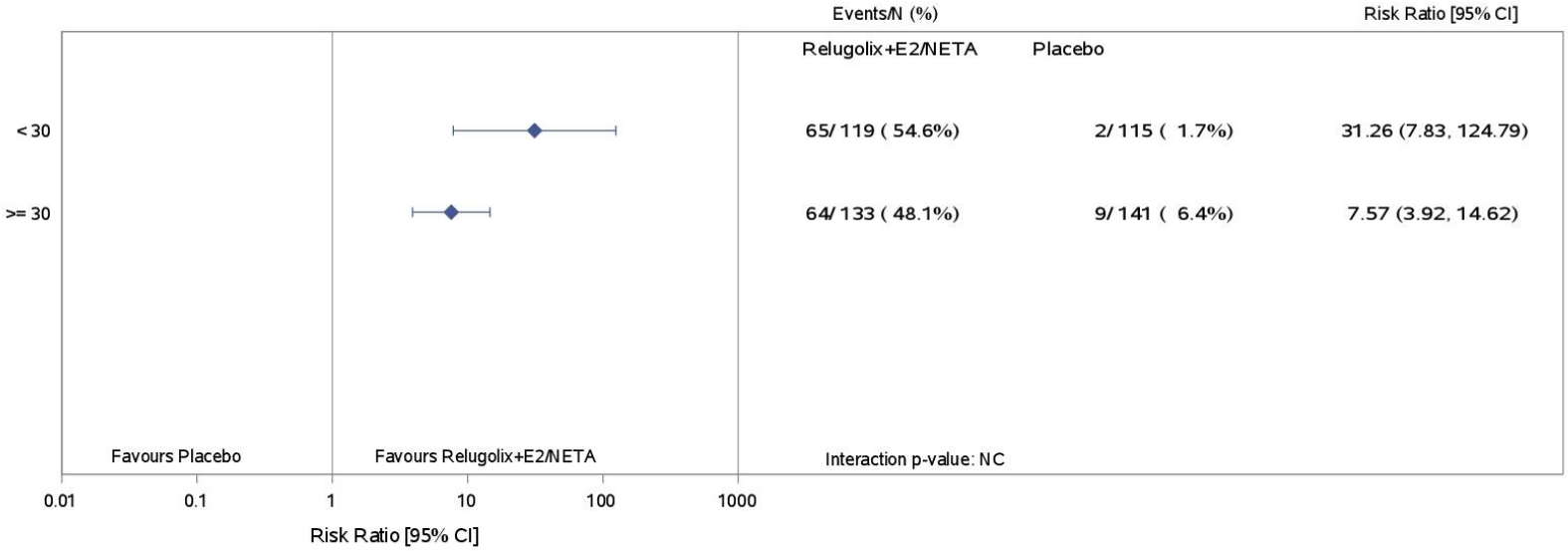
Figure EFF.AMNO24ET.MITT.S2.BIN.FP.RR: Proportion of Patients who Achieved Amenorrhea Over the Last 35 Days of Treatment, by Subgroup (mITT Population) - Risk Ratio
Study: Pooled
Subgroup: BMI (kg/m2) at Baseline



Results are based on a Cochran-Mantel-Haenszel approach stratified by study using a one-stage fixed-effects IPD meta-analysis. A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
The reference group is Placebo.
N: Number of patients in treatment group; NETA: Norethindrone acetate; mITT: Modified intent-to-treat; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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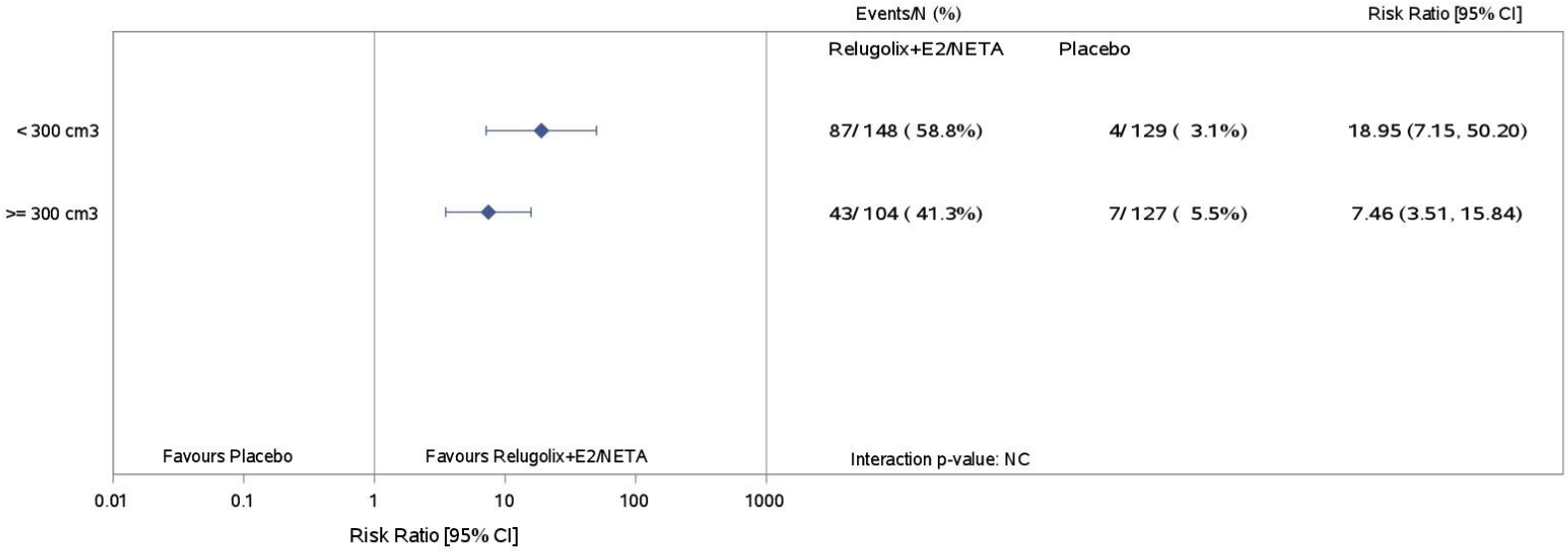
Figure EFF.AMNO24ET.MITT.S3.BIN.FP.RR: Proportion of Patients who Achieved Amenorrhea Over the Last 35 Days of Treatment, by Subgroup (mITT Population) - Risk Ratio
Study: Pooled
Subgroup: Uterine Volume at Baseline (cm3)



Results are based on a Cochran-Mantel-Haenszel approach stratified by study using a one-stage fixed-effects IPD meta-analysis. A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
The reference group is Placebo.
N: Number of patients in treatment group; NETA: Norethindrone acetate; mITT: Modified intent-to-treat; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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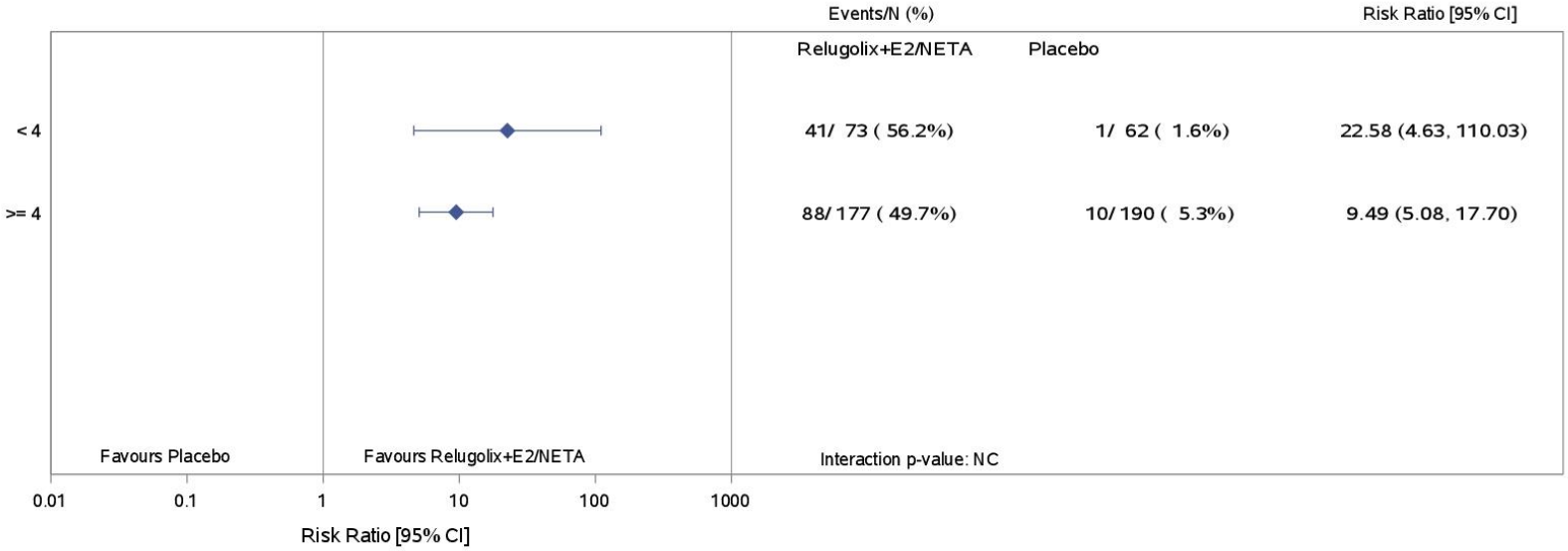
Figure EFF.AMNO24ET.MITT.S4.BIN.FP.RR: Proportion of Patients who Achieved Amenorrhea Over the Last 35 Days of Treatment, by Subgroup (mITT Population) - Risk Ratio
Study: Pooled
Subgroup: Maximum NRS Pain Score at Baseline



Results are based on a Cochran-Mantel-Haenszel approach stratified by study using a one-stage fixed-effects IPD meta-analysis. A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
The reference group is Placebo.
N: Number of patients in treatment group; NETA: Norethindrone acetate; mITT: Modified intent-to-treat; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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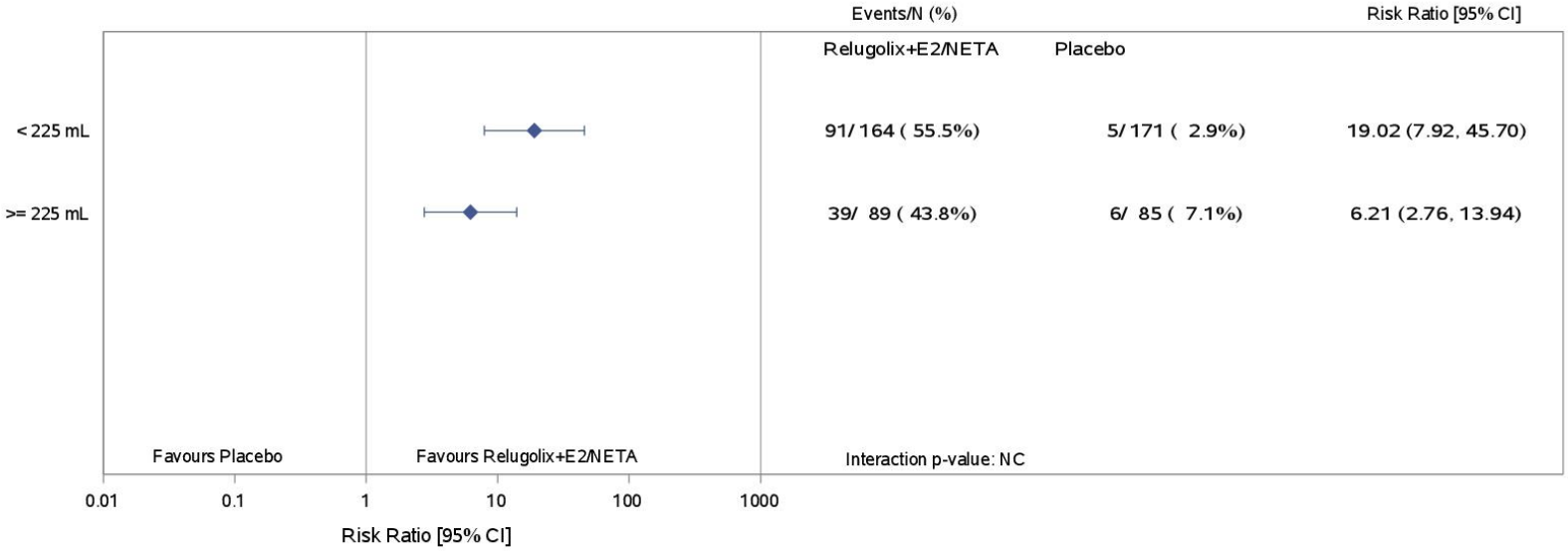
Figure EFF.AMNO24ET.MITT.S5.BIN.FP.RR: Proportion of Patients who Achieved Amenorrhea Over the Last 35 Days of Treatment, by Subgroup (mITT Population) - Risk Ratio
Study: Pooled
Subgroup: MBL Volume at Baseline (mL)



Results are based on a Cochran-Mantel-Haenszel approach stratified by study using a one-stage fixed-effects IPD meta-analysis. A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
The reference group is Placebo.
N: Number of patients in treatment group; NETA: Norethindrone acetate; mITT: Modified intent-to-treat; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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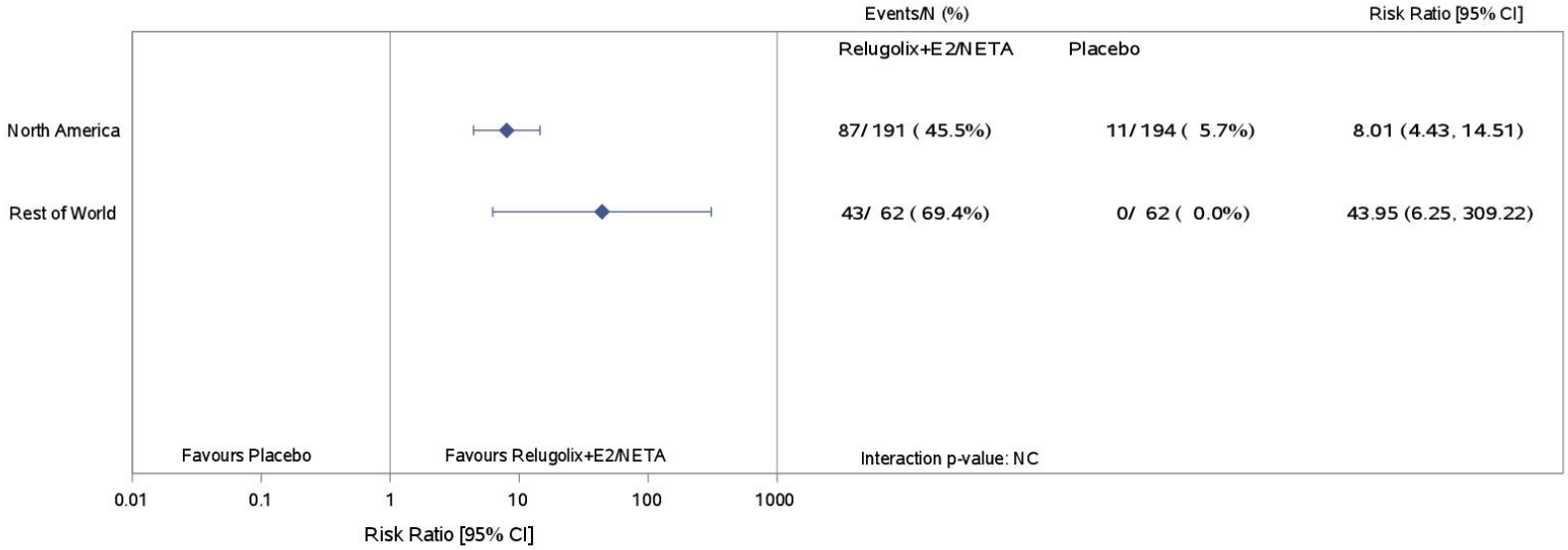
Figure EFF.AMNO24ET.MITT.S6.BIN.FP.RR: Proportion of Patients who Achieved Amenorrhea Over the Last 35 Days of Treatment, by Subgroup (mITT Population) - Risk Ratio
Study: Pooled
Subgroup: Geographic Region I



Results are based on a Cochran-Mantel-Haenszel approach stratified by study using a one-stage fixed-effects IPD meta-analysis. A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
The reference group is Placebo.
N: Number of patients in treatment group; NETA: Norethindrone acetate; mITT: Modified intent-to-treat; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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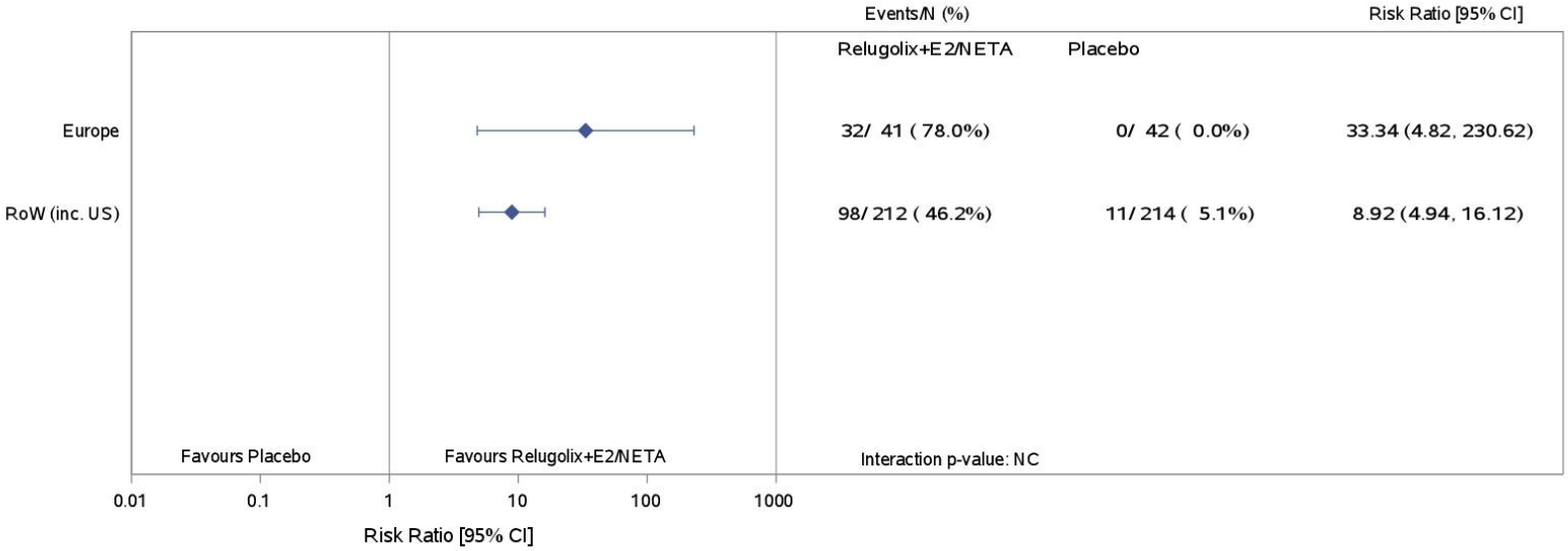
Figure EFF.AMNO24ET.MITT.S7.BIN.FP.RR: Proportion of Patients who Achieved Amenorrhea Over the Last 35 Days of Treatment, by Subgroup (mITT Population) - Risk Ratio
Study: Pooled
Subgroup: Geographic Region II



Results are based on a Cochran-Mantel-Haenszel approach stratified by study using a one-stage fixed-effects IPD meta-analysis. A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
The reference group is Placebo.
N: Number of patients in treatment group; NETA: Norethindrone acetate; mITT: Modified intent-to-treat; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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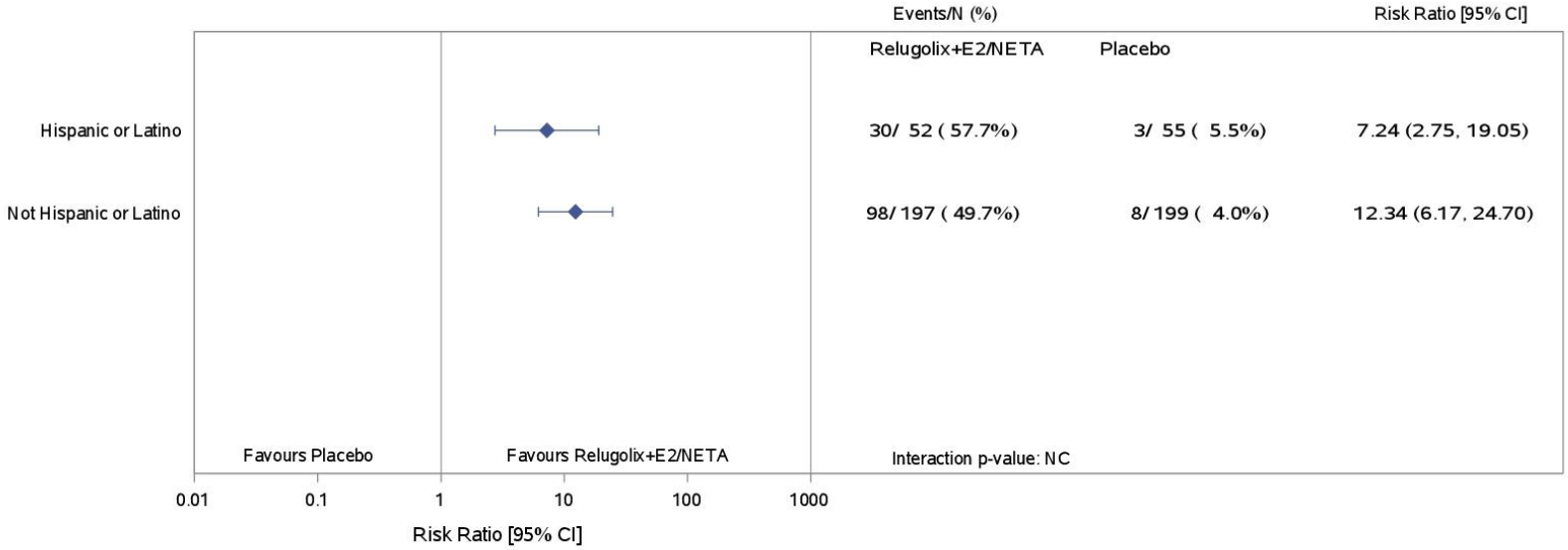
Figure EFF.AMNO24ET.MITT.S8.BIN.FP.RR: Proportion of Patients who Achieved Amenorrhea Over the Last 35 Days of Treatment, by Subgroup (mITT Population) - Risk Ratio
Study: Pooled
Subgroup: Ethnicity



Results are based on a Cochran-Mantel-Haenszel approach stratified by study using a one-stage fixed-effects IPD meta-analysis. A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
The reference group is Placebo.
N: Number of patients in treatment group; NETA: Norethindrone acetate; mITT: Modified intent-to-treat; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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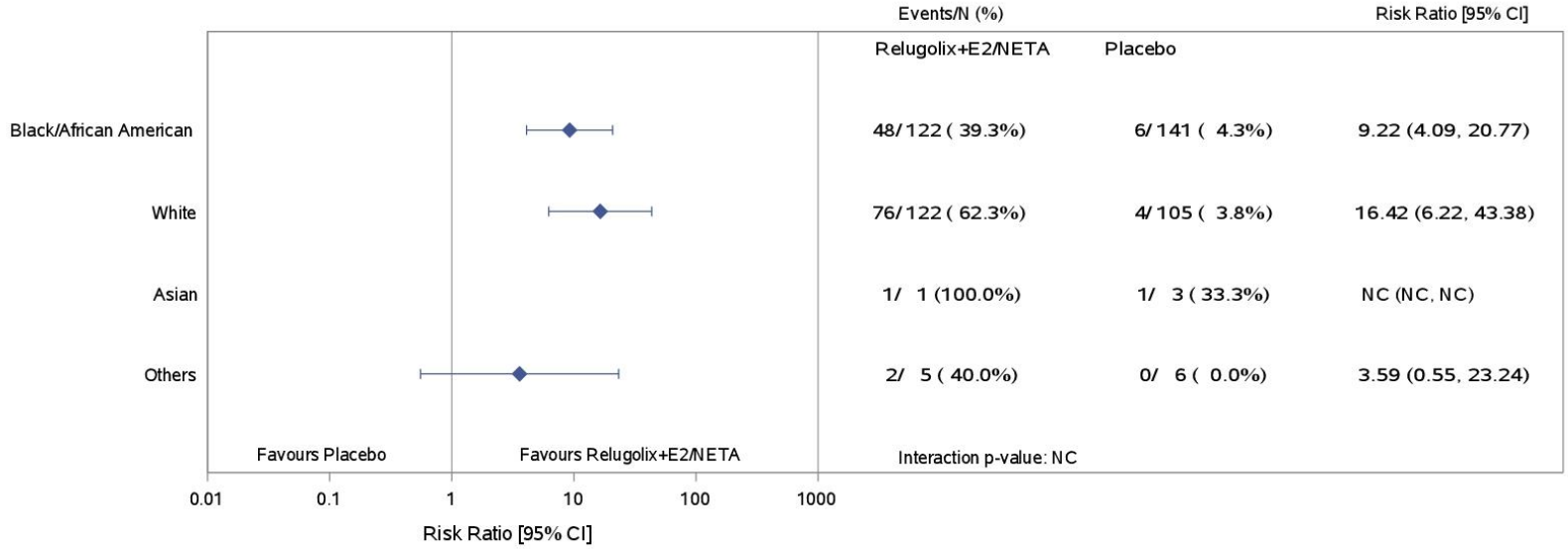
Figure EFF.AMNO24ET.MITT.S9.BIN.FP.RR: Proportion of Patients who Achieved Amenorrhea Over the Last 35 Days of Treatment, by Subgroup (mITT Population) - Risk Ratio
Study: Pooled
Subgroup: Race



Results are based on a Cochran-Mantel-Haenszel approach stratified by study using a one-stage fixed-effects IPD meta-analysis. A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
The reference group is Placebo.
N: Number of patients in treatment group; NETA: Norethindrone acetate; mITT: Modified intent-to-treat; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

SOURCE: X:\Numerus\Studies\MYV\MYV102\Analysis\Prod\Progs\TFLs\Fig_EFF_AMN_S_BIN_FP.SAS Date/time of run: 30JUN21 10:22
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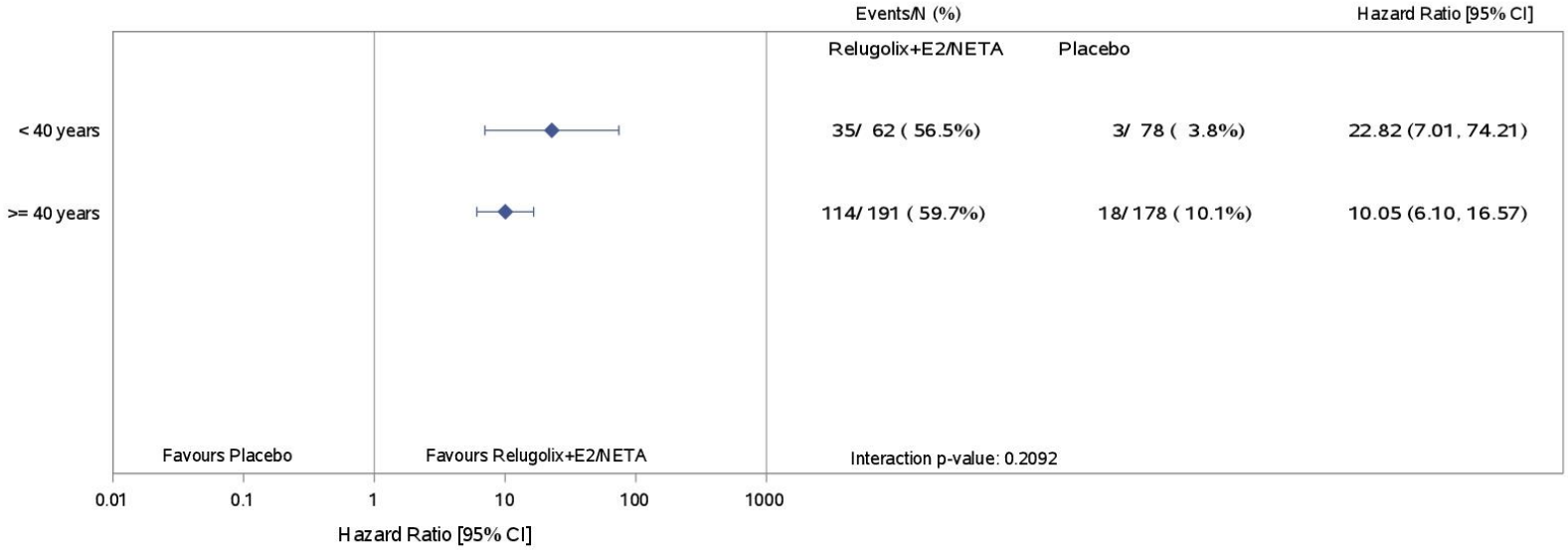
2.1.12 Time to Achieve Amenorrhea, by Subgroup (mITT Population)

Figure EFF.TTAMENO.MITT.S1.TTE.FP: Time to Achieve Amenorrhea, by Subgroup (mITT Population)
Study: Pooled
Subgroup: Age (years)



Results are based on a Cox proportional hazard model stratified by study and with treatment group, subgroup and a subgroup-by-treatment group interaction as covariates using a one-stage fixed-effects IPD meta-analysis approach.
The interaction p-value is based on the subgroup-by-treatment interaction term in the proportional hazard model used to compute the Hazard Ratio and 95% CI. Missing subgroup levels are not included in estimation of the interaction p-value. The reference group is Placebo.
N: Number of patients in treatment group; NETA: Norethindrone acetate; mITT: Modified intent-to-treat; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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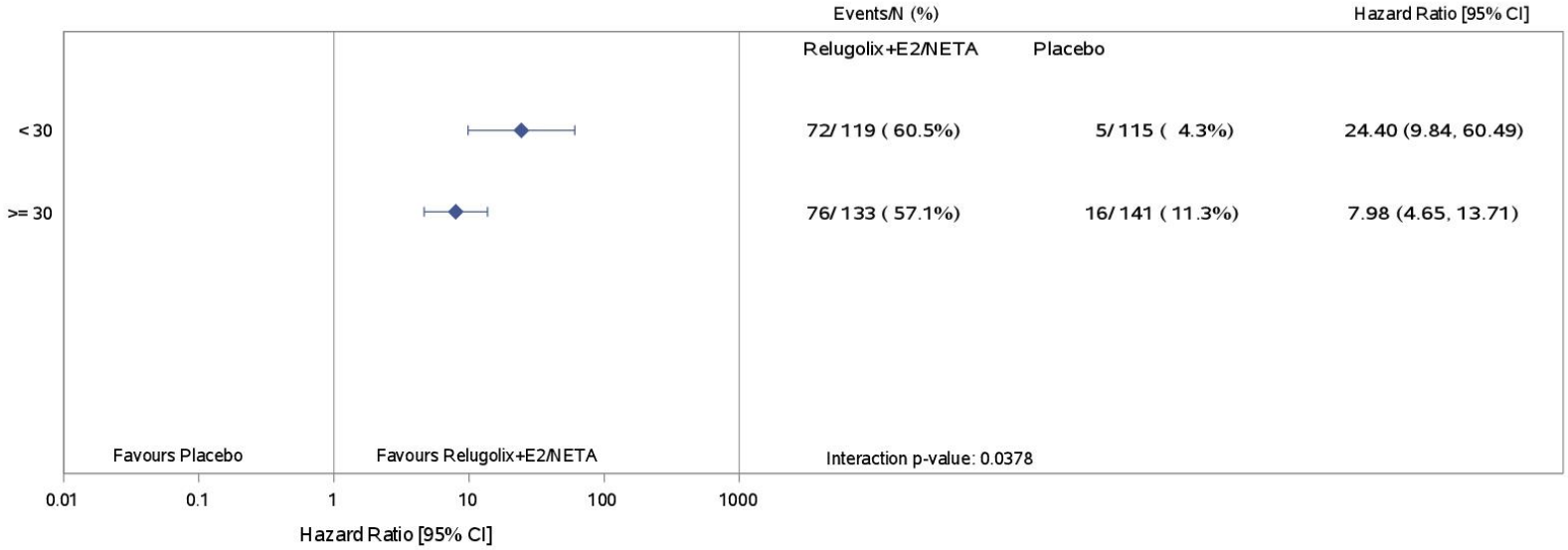
Figure EFF.TTAMENO.MITT.S2.TTE.FP: Time to Achieve Amenorrhea, by Subgroup (mITT Population)
Study: Pooled
Subgroup: BMI (kg/m2) at Baseline



Results are based on a Cox proportional hazard model stratified by study and with treatment group, subgroup and a subgroup-by-treatment group interaction as covariates using a one-stage fixed-effects IPD meta-analysis approach.
The interaction p-value is based on the subgroup-by-treatment interaction term in the proportional hazard model used to compute the Hazard Ratio and 95% CI. Missing subgroup levels are not included in estimation of the interaction p-value. The reference group is Placebo.
N: Number of patients in treatment group; NETA: Norethindrone acetate; mITT: Modified intent-to-treat; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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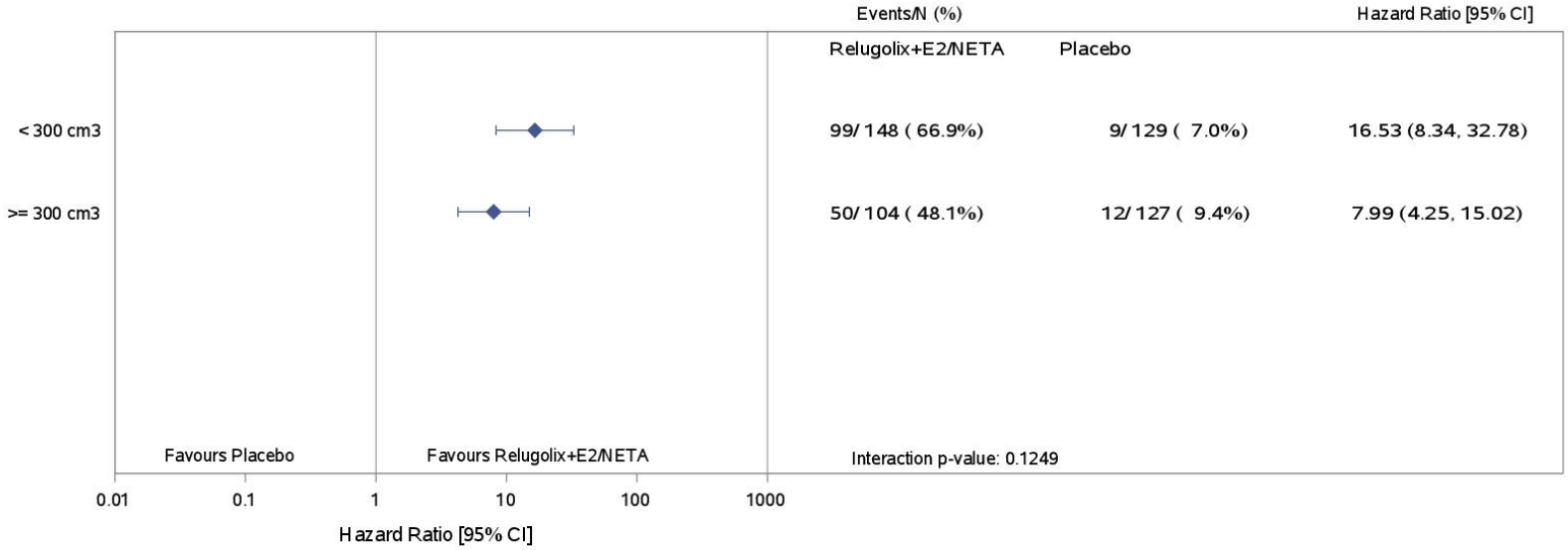
Figure EFF.TTAMENO.MITT.S3.TTE.FP: Time to Achieve Amenorrhea, by Subgroup (mITT Population)
Study: Pooled
Subgroup: Uterine Volume at Baseline (cm3)



Results are based on a Cox proportional hazard model stratified by study and with treatment group, subgroup and a subgroup-by-treatment group interaction as covariates using a one-stage fixed-effects IPD meta-analysis approach.
The interaction p-value is based on the subgroup-by-treatment interaction term in the proportional hazard model used to compute the Hazard Ratio and 95% CI. Missing subgroup levels are not included in estimation of the interaction p-value. The reference group is Placebo.
N: Number of patients in treatment group; NETA: Norethindrone acetate; mITT: Modified intent-to-treat; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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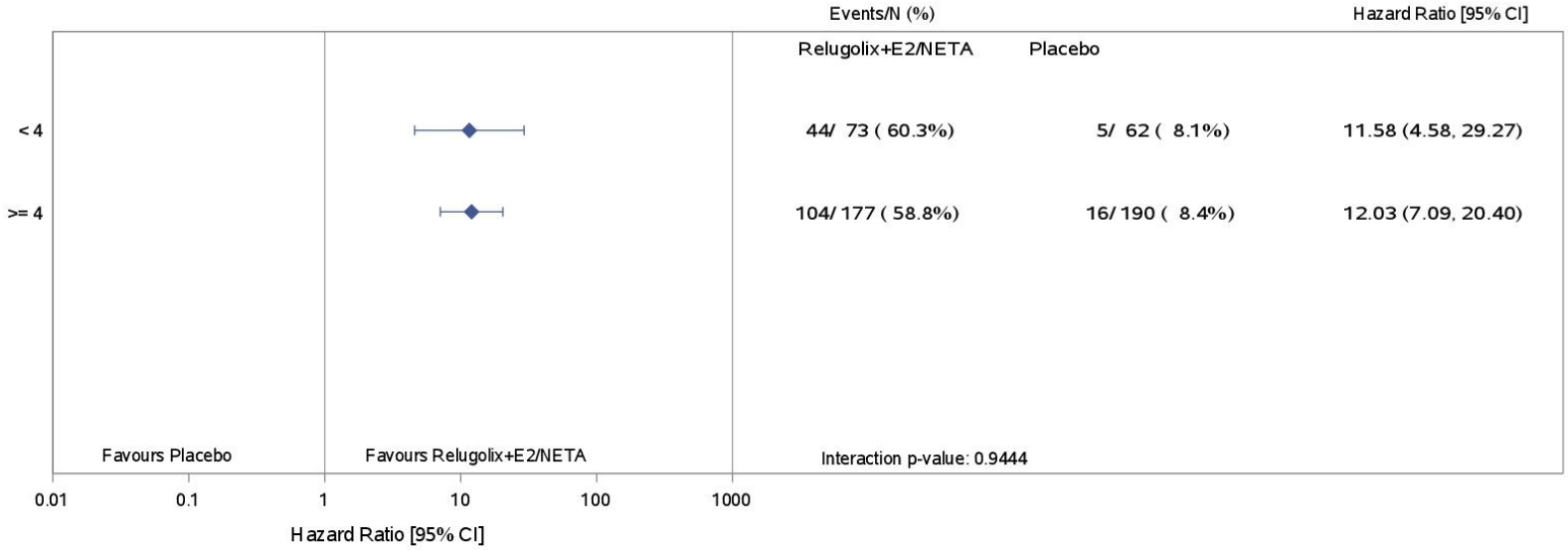
Figure EFF.TTAMENO.MITT.S4.TTE.FP: Time to Achieve Amenorrhea, by Subgroup (mITT Population)
Study: Pooled
Subgroup: Maximum NRS Pain Score at Baseline



Results are based on a Cox proportional hazard model stratified by study and with treatment group, subgroup and a subgroup-by-treatment group interaction as covariates using a one-stage fixed-effects IPD meta-analysis approach.
The interaction p-value is based on the subgroup-by-treatment interaction term in the proportional hazard model used to compute the Hazard Ratio and 95% CI. Missing subgroup levels are not included in estimation of the interaction p-value. The reference group is Placebo.
N: Number of patients in treatment group; NETA: Norethindrone acetate; mITT: Modified intent-to-treat; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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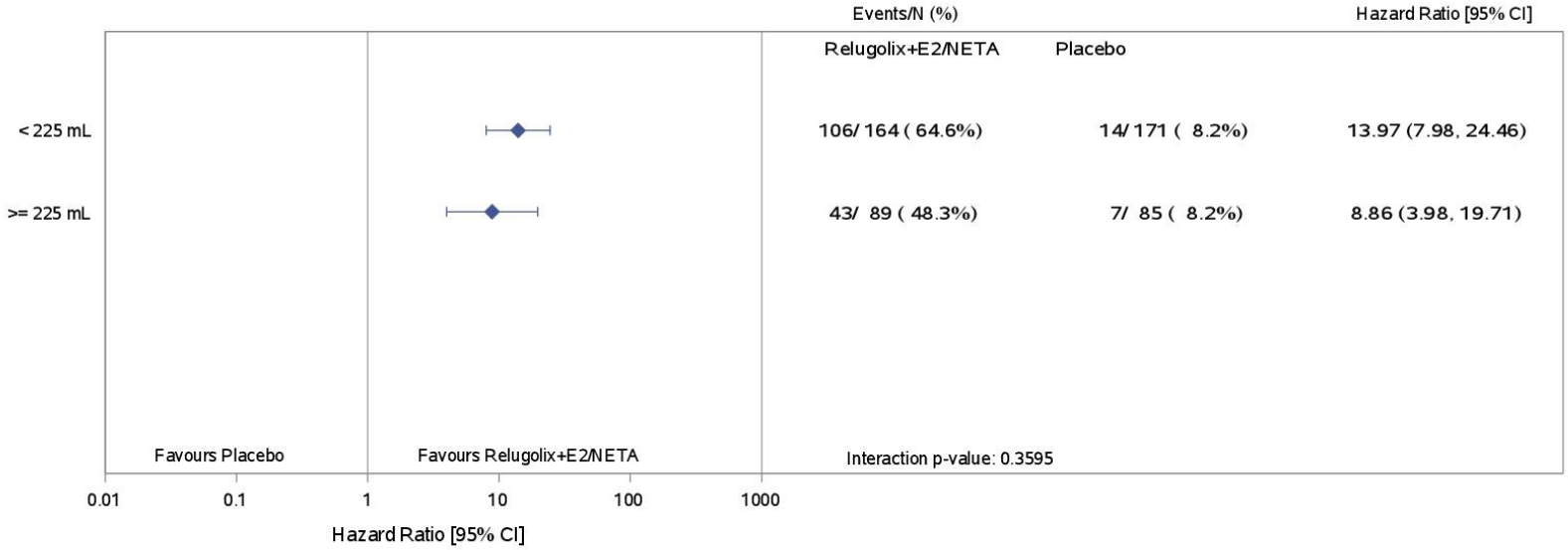
Figure EFF.TTAMENO.MITT.S5.TTE.FP: Time to Achieve Amenorrhea, by Subgroup (mITT Population)
Study: Pooled
Subgroup: MBL Volume at Baseline (mL)



Results are based on a Cox proportional hazard model stratified by study and with treatment group, subgroup and a subgroup-by-treatment group interaction as covariates using a one-stage fixed-effects IPD meta-analysis approach.
The interaction p-value is based on the subgroup-by-treatment interaction term in the proportional hazard model used to compute the Hazard Ratio and 95% CI. Missing subgroup levels are not included in estimation of the interaction p-value. The reference group is Placebo.
N: Number of patients in treatment group; NETA: Norethindrone acetate; mITT: Modified intent-to-treat; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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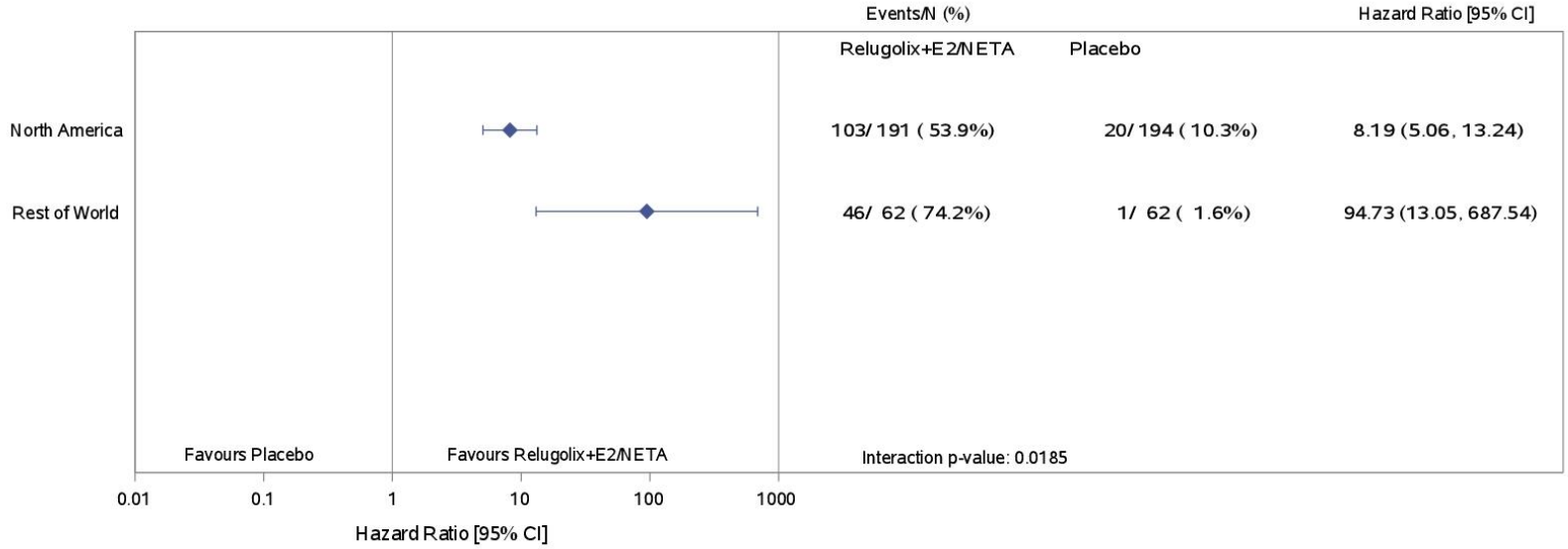
Figure EFF.TTAMENO.MITT.S6.TTE.FP: Time to Achieve Amenorrhea, by Subgroup (mITT Population)
Study: Pooled
Subgroup: Geographic Region I



Results are based on a Cox proportional hazard model stratified by study and with treatment group, subgroup and a subgroup-by-treatment group interaction as covariates using a one-stage fixed-effects IPD meta-analysis approach.
The interaction p-value is based on the subgroup-by-treatment interaction term in the proportional hazard model used to compute the Hazard Ratio and 95% CI. Missing subgroup levels are not included in estimation of the interaction p-value. The reference group is Placebo.
N: Number of patients in treatment group; NETA: Norethindrone acetate; mITT: Modified intent-to-treat; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

SOURCE: X:\Numerus\Studies\MYV\MYV102\Analysis\Prod\Progs\TFLs\Fig_EFF_AMN_S_TTE_FP.SAS Date/time of run: 30JUN21 10:22
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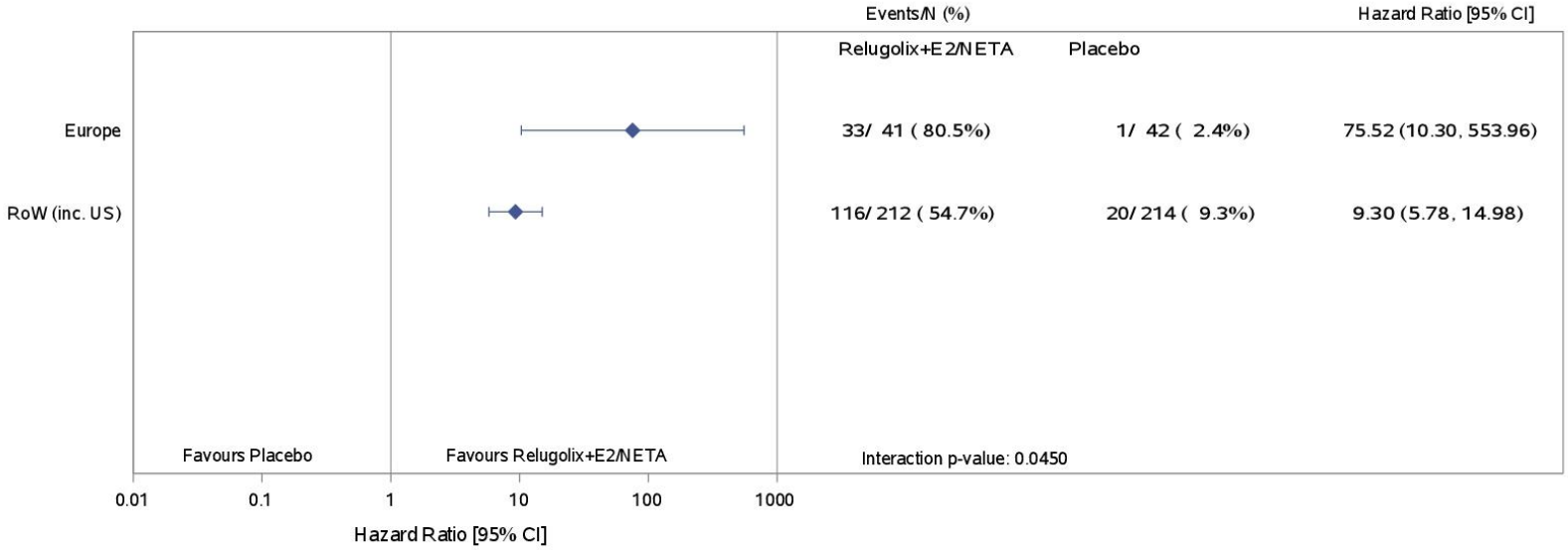
Figure EFF.TTAMENO.MITT.S7.TTE.FP: Time to Achieve Amenorrhea, by Subgroup (mITT Population)
Study: Pooled
Subgroup: Geographic Region II



Results are based on a Cox proportional hazard model stratified by study and with treatment group, subgroup and a subgroup-by-treatment group interaction as covariates using a one-stage fixed-effects IPD meta-analysis approach.
The interaction p-value is based on the subgroup-by-treatment interaction term in the proportional hazard model used to compute the Hazard Ratio and 95% CI. Missing subgroup levels are not included in estimation of the interaction p-value. The reference group is Placebo.
N: Number of patients in treatment group; NETA: Norethindrone acetate; mITT: Modified intent-to-treat; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

SOURCE: X:\Numerus\Studies\MYV\MYV102\Analysis\Prod\Progs\TFLs\Fig_EFF_AMN_S_TTE_FP.SAS Date/time of run: 30JUN21 10:22
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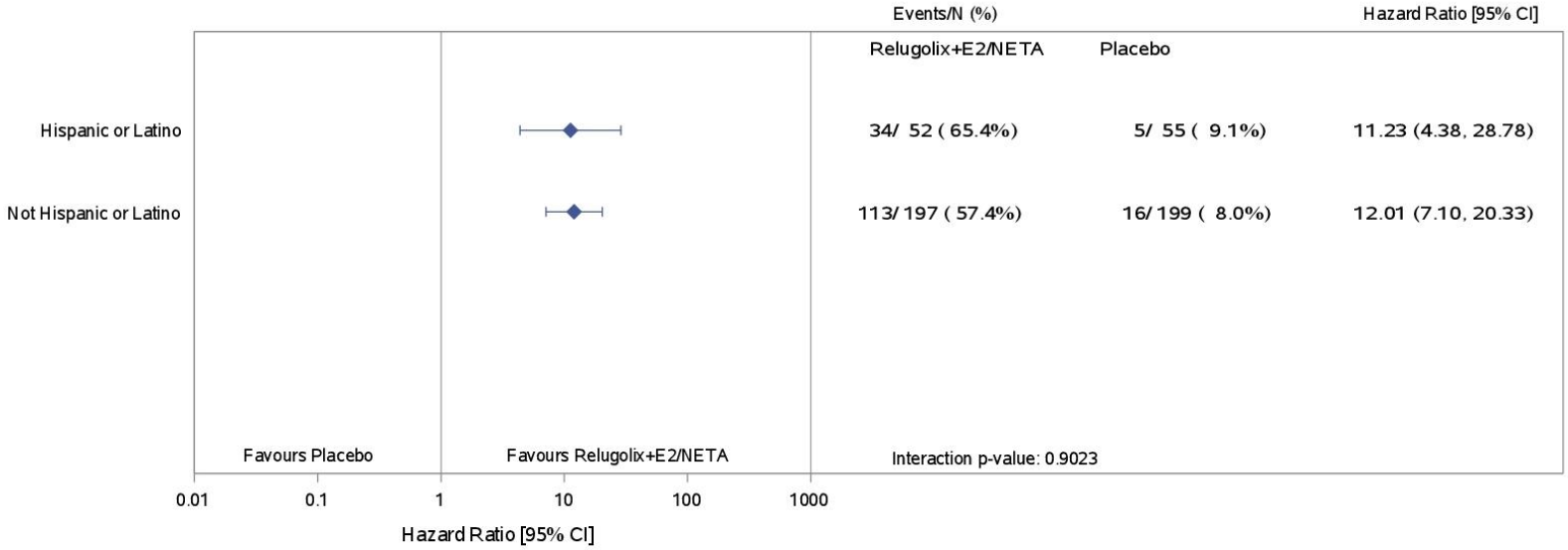
Figure EFF.TTAMENO.MITT.S8.TTE.FP: Time to Achieve Amenorrhea, by Subgroup (mITT Population)
Study: Pooled
Subgroup: Ethnicity



Results are based on a Cox proportional hazard model stratified by study and with treatment group, subgroup and a subgroup-by-treatment group interaction as covariates using a one-stage fixed-effects IPD meta-analysis approach.
The interaction p-value is based on the subgroup-by-treatment interaction term in the proportional hazard model used to compute the Hazard Ratio and 95% CI. Missing subgroup levels are not included in estimation of the interaction p-value. The reference group is Placebo.
N: Number of patients in treatment group; NETA: Norethindrone acetate; mITT: Modified intent-to-treat; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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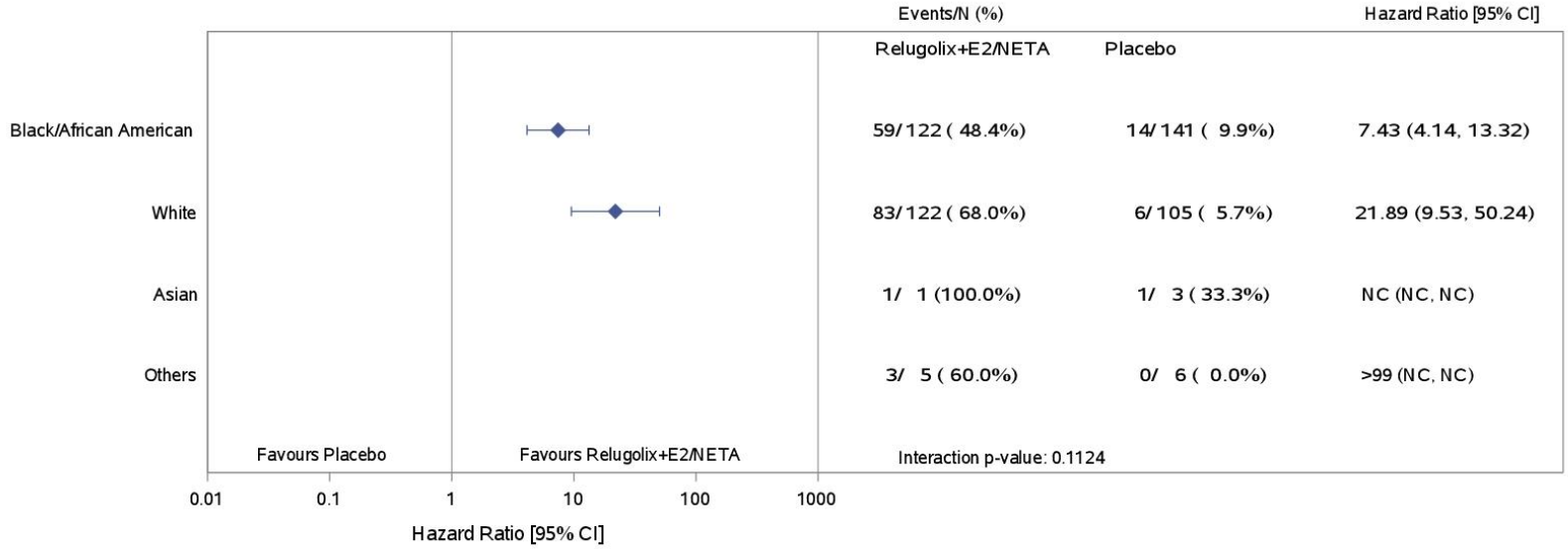
Figure EFF.TTAMENO.MITT.S9.TTE.FP: Time to Achieve Amenorrhea, by Subgroup (mITT Population)
Study: Pooled
Subgroup: Race



Results are based on a Cox proportional hazard model stratified by study and with treatment group, subgroup and a subgroup-by-treatment group interaction as covariates using a one-stage fixed-effects IPD meta-analysis approach.
The interaction p-value is based on the subgroup-by-treatment interaction term in the proportional hazard model used to compute the Hazard Ratio and 95% CI. Missing subgroup levels are not included in estimation of the interaction p-value. The reference group is Placebo.
N: Number of patients in treatment group; NETA: Norethindrone acetate; mITT: Modified intent-to-treat; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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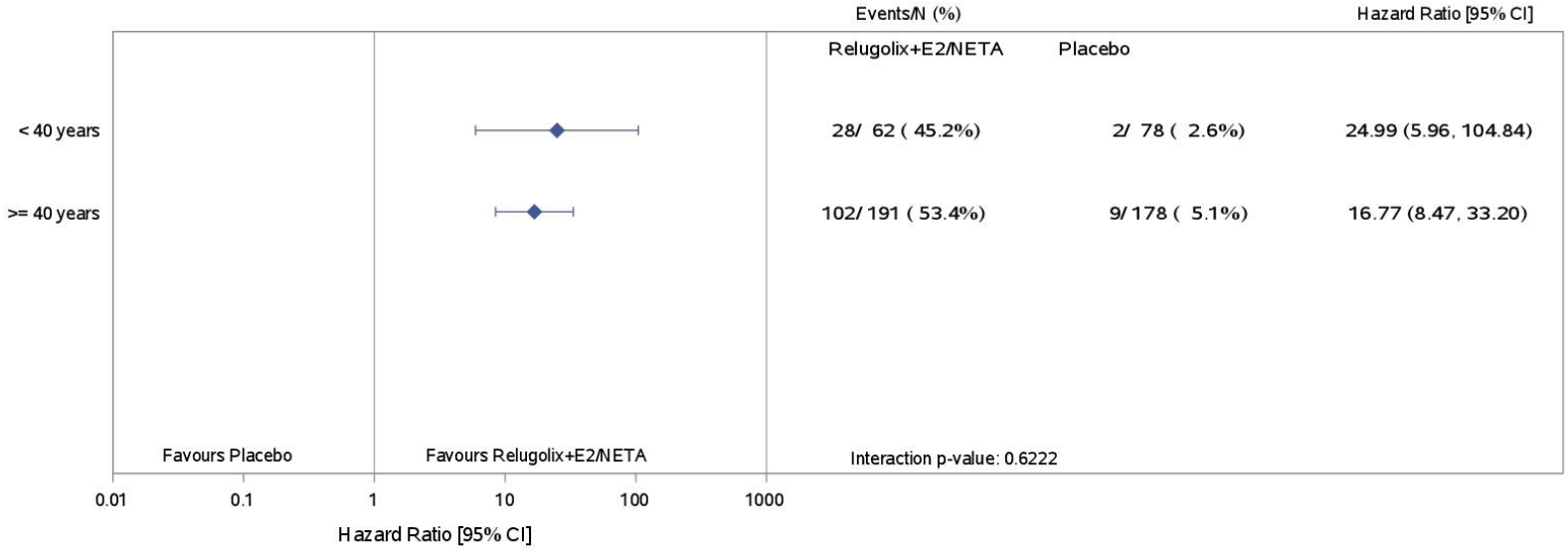
2.1.13 Time to Achieve Sustained Amenorrhea, by Subgroup (mITT Population)

Figure EFF.TTSAMENO.MITT.S1.TTE.FP: Time to Achieve Sustained Amenorrhea, by Subgroup (mITT Population)
Study: Pooled
Subgroup: Age (years)



Results are based on a Cox proportional hazard model stratified by study and with treatment group, subgroup and a subgroup-by-treatment group interaction as covariates using a one-stage fixed-effects IPD meta-analysis approach.
The interaction p-value is based on the subgroup-by-treatment interaction term in the proportional hazard model used to compute the Hazard Ratio and 95% CI. Missing subgroup levels are not included in estimation of the interaction p-value. The reference group is Placebo.
N: Number of patients in treatment group; NETA: Norethindrone acetate; mITT: Modified intent-to-treat; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

SOURCE: X:\Numerus\Studies\MYV\MYV102\Analysis\Prod\Progs\TFLs\Fig_EFF_AMN_S_TTE_FP.SAS Date/time of run: 30JUN21 10:22
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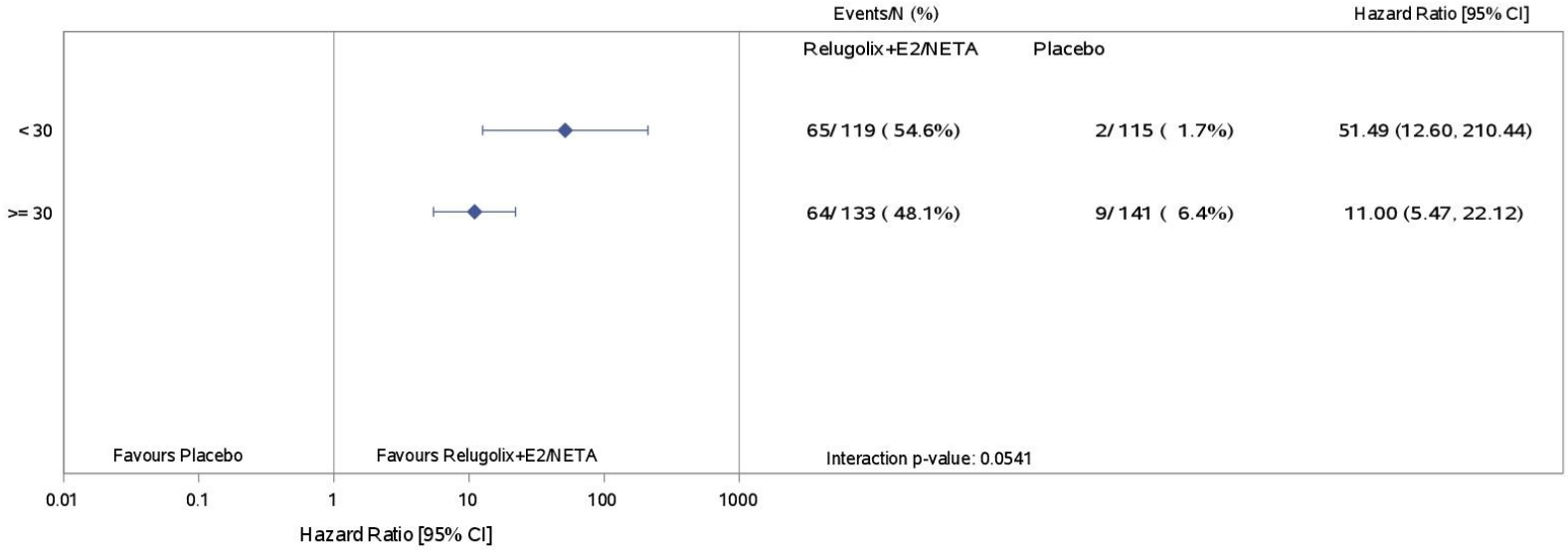
Figure EFF.TTSAMENO.MITT.S2.TTE.FP: Time to Achieve Sustained Amenorrhea, by Subgroup (mITT Population)
Study: Pooled
Subgroup: BMI (kg/m2) at Baseline



Results are based on a Cox proportional hazard model stratified by study and with treatment group, subgroup and a subgroup-by-treatment group interaction as covariates using a one-stage fixed-effects IPD meta-analysis approach.
The interaction p-value is based on the subgroup-by-treatment interaction term in the proportional hazard model used to compute the Hazard Ratio and 95% CI. Missing subgroup levels are not included in estimation of the interaction p-value. The reference group is Placebo.
N: Number of patients in treatment group; NETA: Norethindrone acetate; mITT: Modified intent-to-treat; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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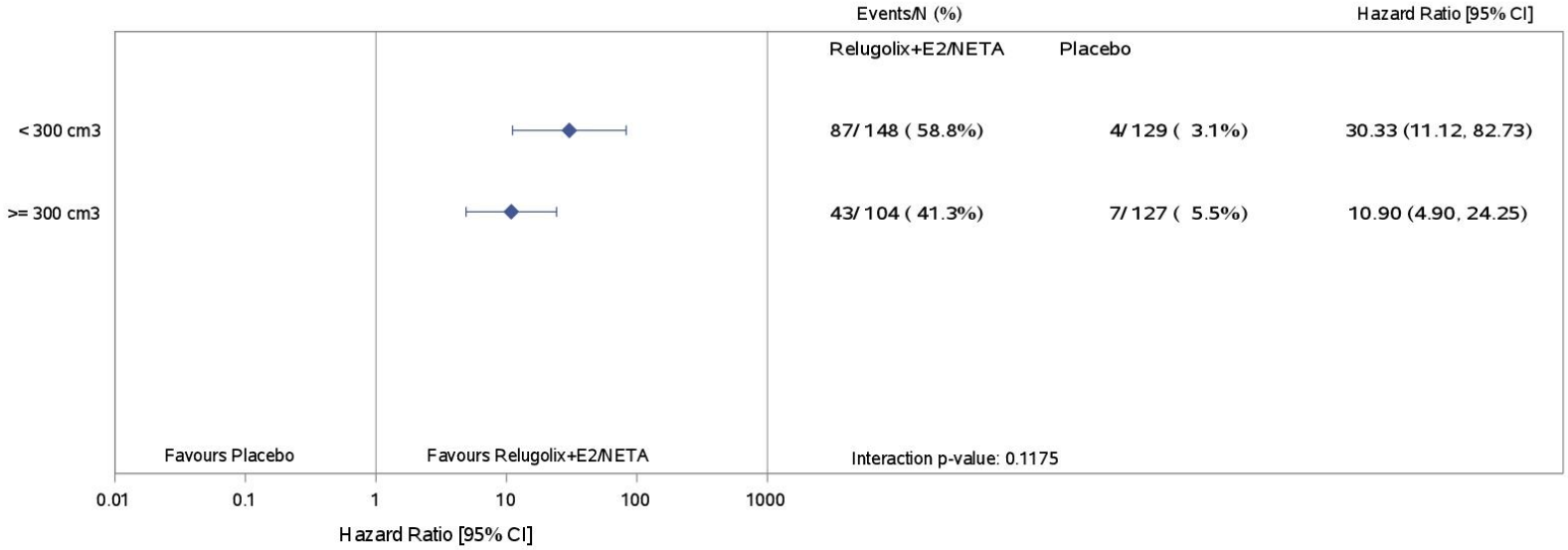
Figure EFF.TTSAMENO.MITT.S3.TTE.FP: Time to Achieve Sustained Amenorrhea, by Subgroup (mITT Population)
Study: Pooled
Subgroup: Uterine Volume at Baseline (cm3)



Results are based on a Cox proportional hazard model stratified by study and with treatment group, subgroup and a subgroup-by-treatment group interaction as covariates using a one-stage fixed-effects IPD meta-analysis approach.
The interaction p-value is based on the subgroup-by-treatment interaction term in the proportional hazard model used to compute the Hazard Ratio and 95% CI. Missing subgroup levels are not included in estimation of the interaction p-value. The reference group is Placebo.
N: Number of patients in treatment group; NETA: Norethindrone acetate; mITT: Modified intent-to-treat; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

SOURCE: X:\Numerus\Studies\MYV\MYV102\Analysis\Prod\Progs\TFLs\Fig_EFF_AMN_S_TTE_FP.SAS Date/time of run: 30JUN21 10:22
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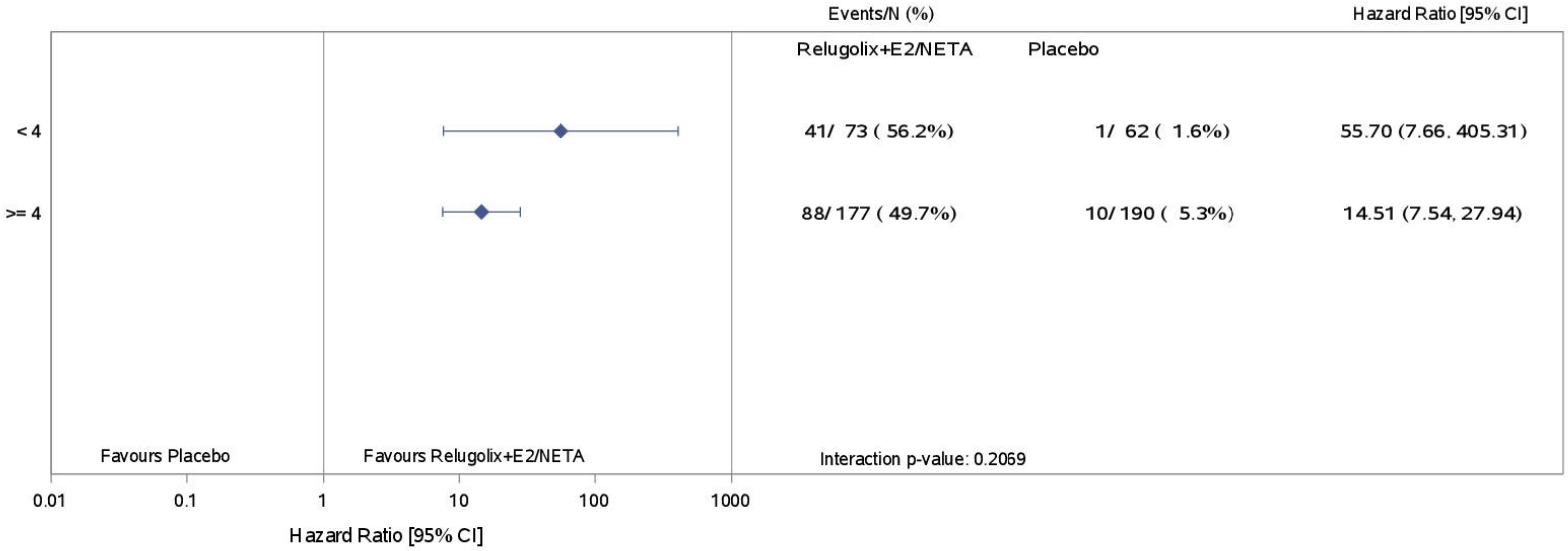
Figure EFF.TTSAMENO.MITT.S4.TTE.FP: Time to Achieve Sustained Amenorrhea, by Subgroup (mITT Population)
Study: Pooled
Subgroup: Maximum NRS Pain Score at Baseline



Results are based on a Cox proportional hazard model stratified by study and with treatment group, subgroup and a subgroup-by-treatment group interaction as covariates using a one-stage fixed-effects IPD meta-analysis approach.
The interaction p-value is based on the subgroup-by-treatment interaction term in the proportional hazard model used to compute the Hazard Ratio and 95% CI. Missing subgroup levels are not included in estimation of the interaction p-value. The reference group is Placebo.
N: Number of patients in treatment group; NETA: Norethindrone acetate; mITT: Modified intent-to-treat; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

SOURCE: X:\Numerus\Studies\MYV\MYV102\Analysis\Prod\Progs\TFLs\Fig_EFF_AMN_S_TTE_FP.SAS Date/time of run: 30JUN21 10:22
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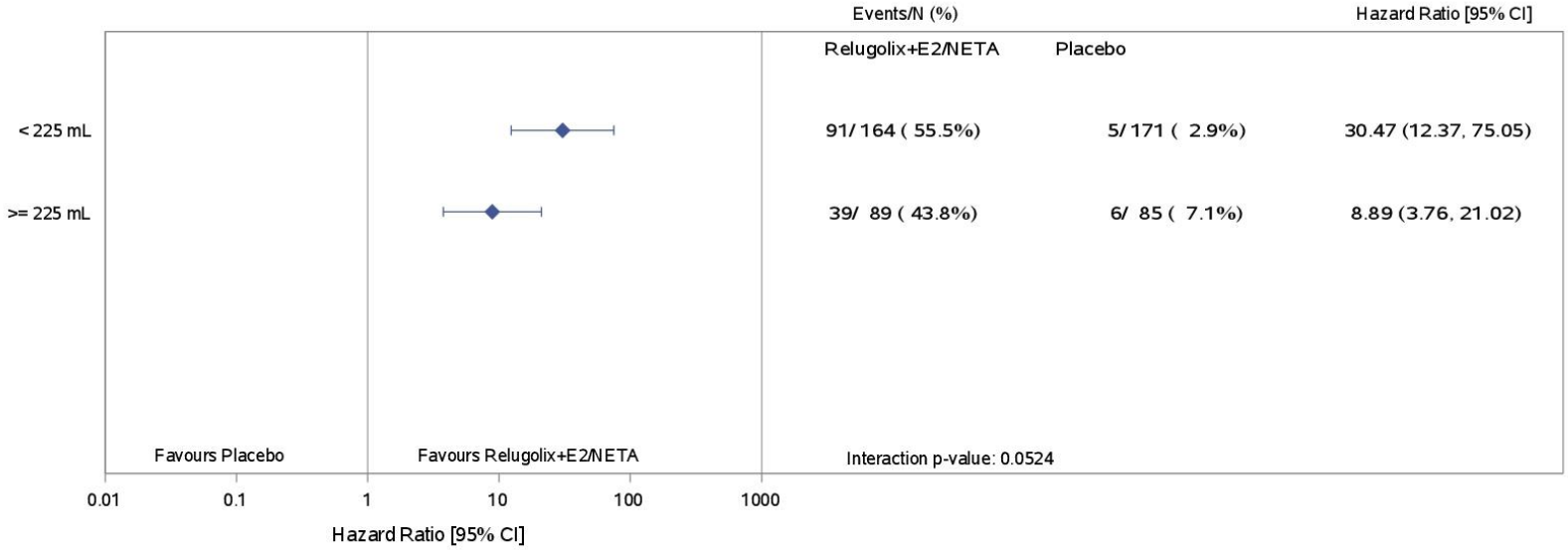
Figure EFF.TTSAMENO.MITT.S5.TTE.FP: Time to Achieve Sustained Amenorrhea, by Subgroup (mITT Population)
Study: Pooled
Subgroup: MBL Volume at Baseline (mL)



Results are based on a Cox proportional hazard model stratified by study and with treatment group, subgroup and a subgroup-by-treatment group interaction as covariates using a one-stage fixed-effects IPD meta-analysis approach.
The interaction p-value is based on the subgroup-by-treatment interaction term in the proportional hazard model used to compute the Hazard Ratio and 95% CI. Missing subgroup levels are not included in estimation of the interaction p-value. The reference group is Placebo.
N: Number of patients in treatment group; NETA: Norethindrone acetate; mITT: Modified intent-to-treat; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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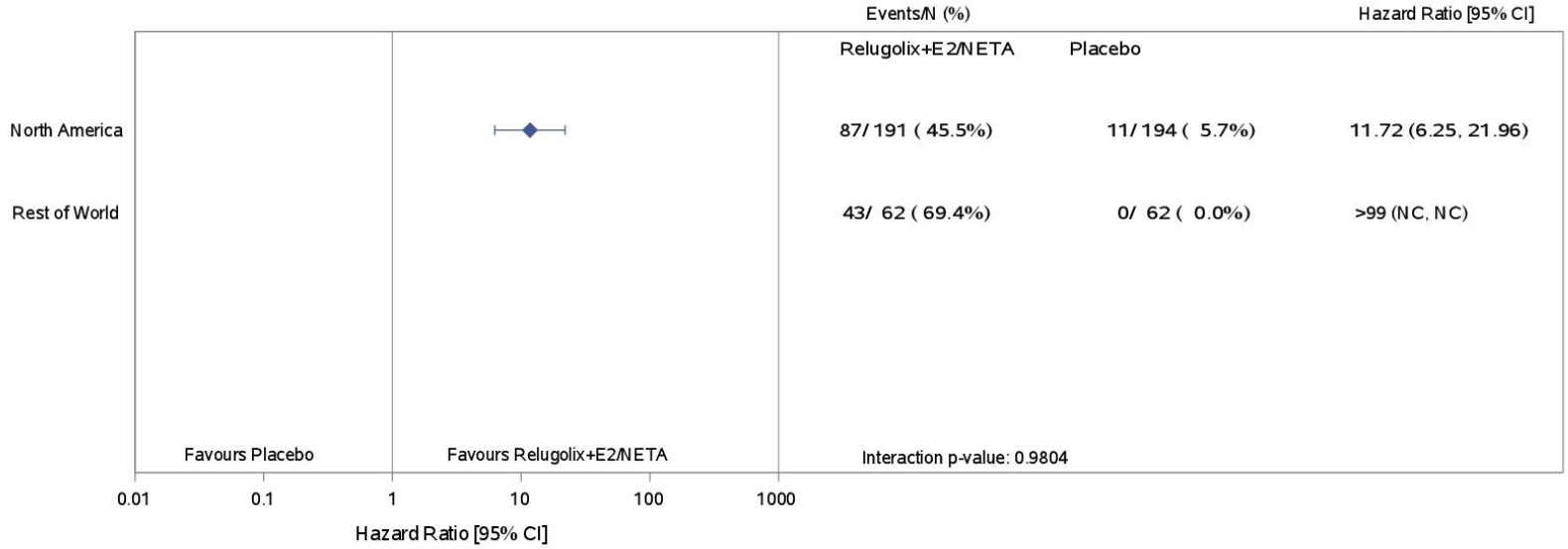
Figure EFF.TTSAMENO.MITT.S6.TTE.FP: Time to Achieve Sustained Amenorrhea, by Subgroup (mITT Population)
Study: Pooled
Subgroup: Geographic Region I



Results are based on a Cox proportional hazard model stratified by study and with treatment group, subgroup and a subgroup-by-treatment group interaction as covariates using a one-stage fixed-effects IPD meta-analysis approach.
The interaction p-value is based on the subgroup-by-treatment interaction term in the proportional hazard model used to compute the Hazard Ratio and 95% CI. Missing subgroup levels are not included in estimation of the interaction p-value. The reference group is Placebo.
N: Number of patients in treatment group; NETA: Norethindrone acetate; mITT: Modified intent-to-treat; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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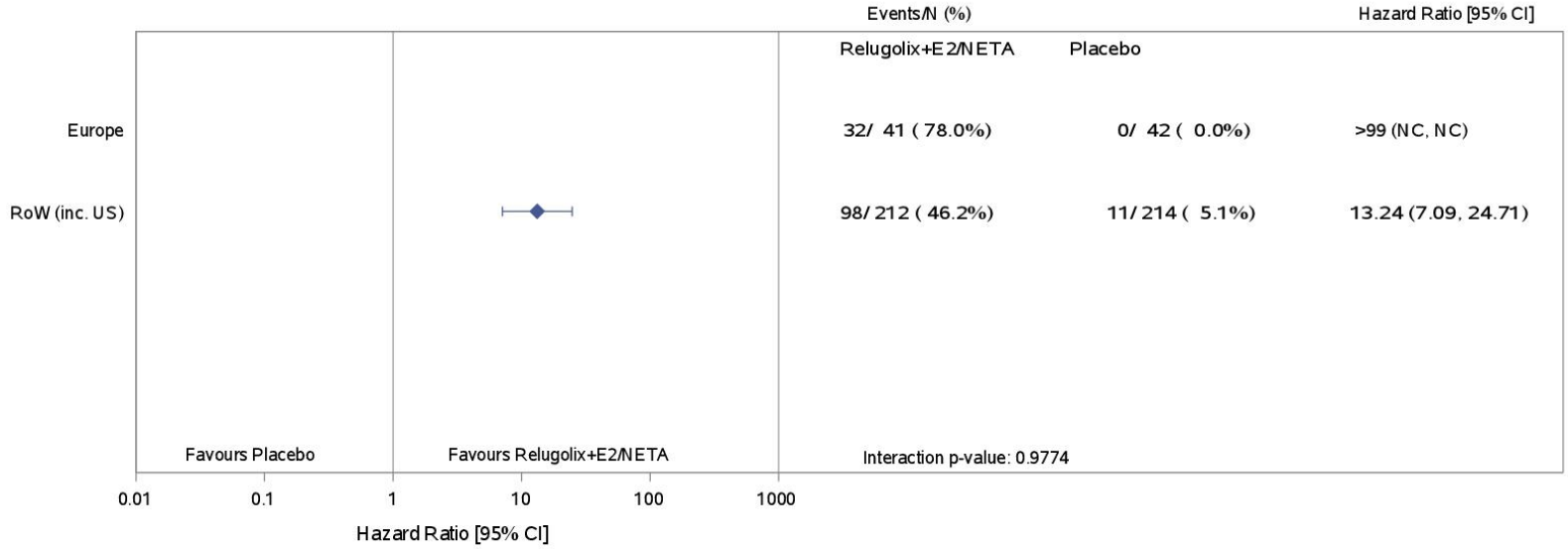
Figure EFF.TTSAMENO.MITT.S7.TTE.FP: Time to Achieve Sustained Amenorrhea, by Subgroup (mITT Population)
Study: Pooled
Subgroup: Geographic Region II



Results are based on a Cox proportional hazard model stratified by study and with treatment group, subgroup and a subgroup-by-treatment group interaction as covariates using a one-stage fixed-effects IPD meta-analysis approach.
The interaction p-value is based on the subgroup-by-treatment interaction term in the proportional hazard model used to compute the Hazard Ratio and 95% CI. Missing subgroup levels are not included in estimation of the interaction p-value. The reference group is Placebo.
N: Number of patients in treatment group; NETA: Norethindrone acetate; mITT: Modified intent-to-treat; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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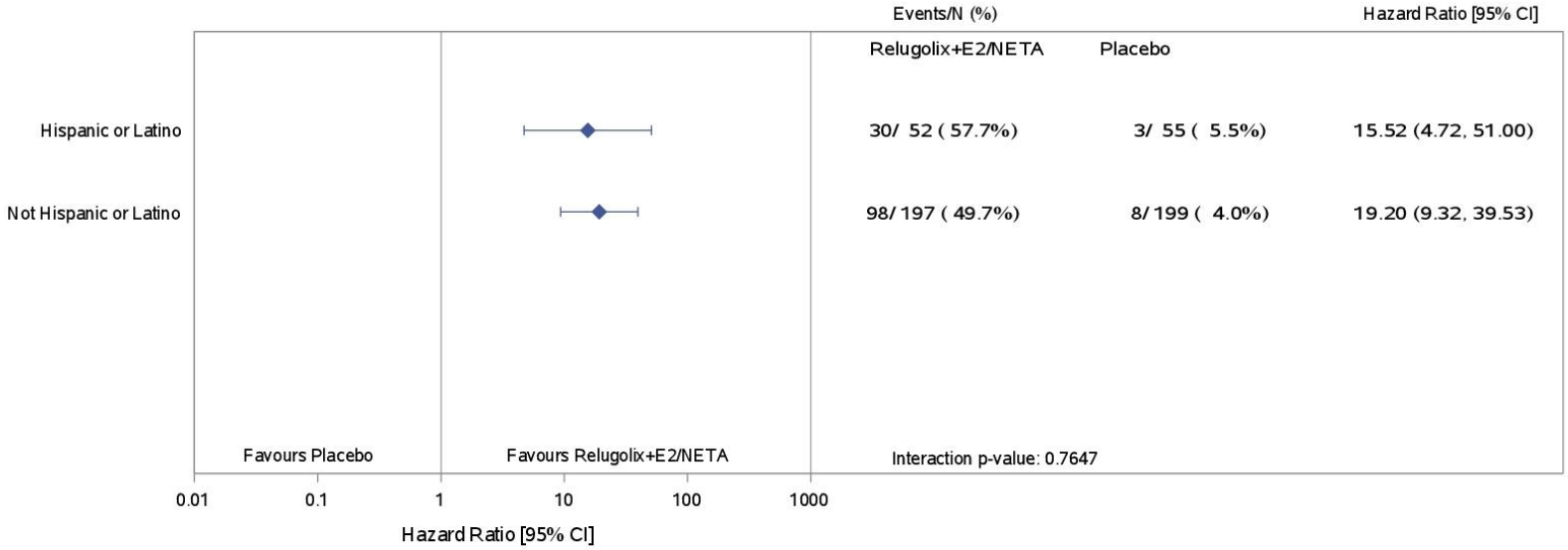
Figure EFF.TTSAMENO.MITT.S8.TTE.FP: Time to Achieve Sustained Amenorrhea, by Subgroup (mITT Population)
Study: Pooled
Subgroup: Ethnicity



Results are based on a Cox proportional hazard model stratified by study and with treatment group, subgroup and a subgroup-by-treatment group interaction as covariates using a one-stage fixed-effects IPD meta-analysis approach.
The interaction p-value is based on the subgroup-by-treatment interaction term in the proportional hazard model used to compute the Hazard Ratio and 95% CI. Missing subgroup levels are not included in estimation of the interaction p-value. The reference group is Placebo.
N: Number of patients in treatment group; NETA: Norethindrone acetate; mITT: Modified intent-to-treat; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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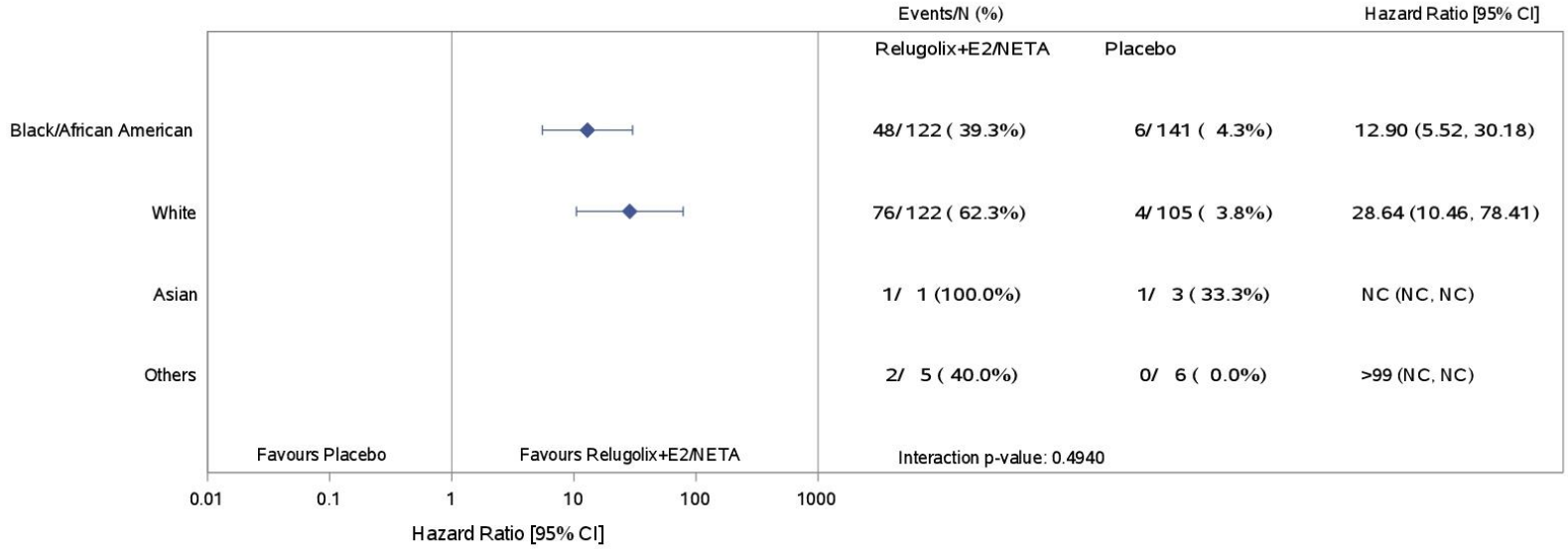
Figure EFF.TTSAMENO.MITT.S9.TTE.FP: Time to Achieve Sustained Amenorrhea, by Subgroup (mITT Population)
Study: Pooled
Subgroup: Race



Results are based on a Cox proportional hazard model stratified by study and with treatment group, subgroup and a subgroup-by-treatment group interaction as covariates using a one-stage fixed-effects IPD meta-analysis approach.
The interaction p-value is based on the subgroup-by-treatment interaction term in the proportional hazard model used to compute the Hazard Ratio and 95% CI. Missing subgroup levels are not included in estimation of the interaction p-value. The reference group is Placebo.
N: Number of patients in treatment group; NETA: Norethindrone acetate; mITT: Modified intent-to-treat; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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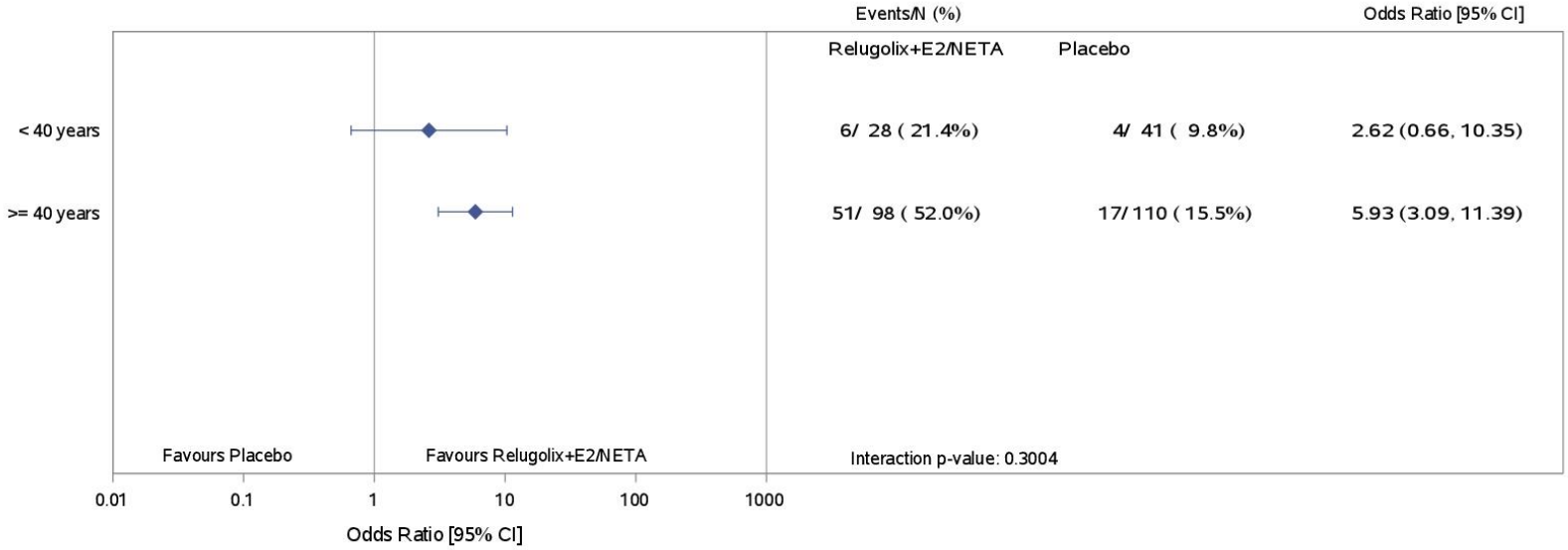
2.1.14 Proportion of Patients with Maximum NRS Score <= 1 During the Last 35 Days of Treatment, by Subgroup (Pain Evaluable Population)

Nachfolgend sind zunächst alle Forest Plots für das *Odds Ratio* dargestellt; gefolgt von den entsprechenden Forest Plots für *Risk Ratio* und *Risk Difference*.

Figure EFF.MAXNRS1.PEV.S1.BIN.FP: Proportion of Patients with Maximum NRS Score <= 1 During the Last 35 Days of Treatment, by Subgroup (Pain Evaluable Population)
Study: Pooled
Subgroup: Age (years)



Results are based on a logistic regression model adjusted for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates using a one-stage fixed-effects IPD meta-analysis approach. A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
The interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the Odds Ratio and 95% CI. Missing subgroup levels are not included in estimation of the interaction p-value. The reference group is Placebo.
N: Number of patients in treatment group; NETA: Norethindrone acetate; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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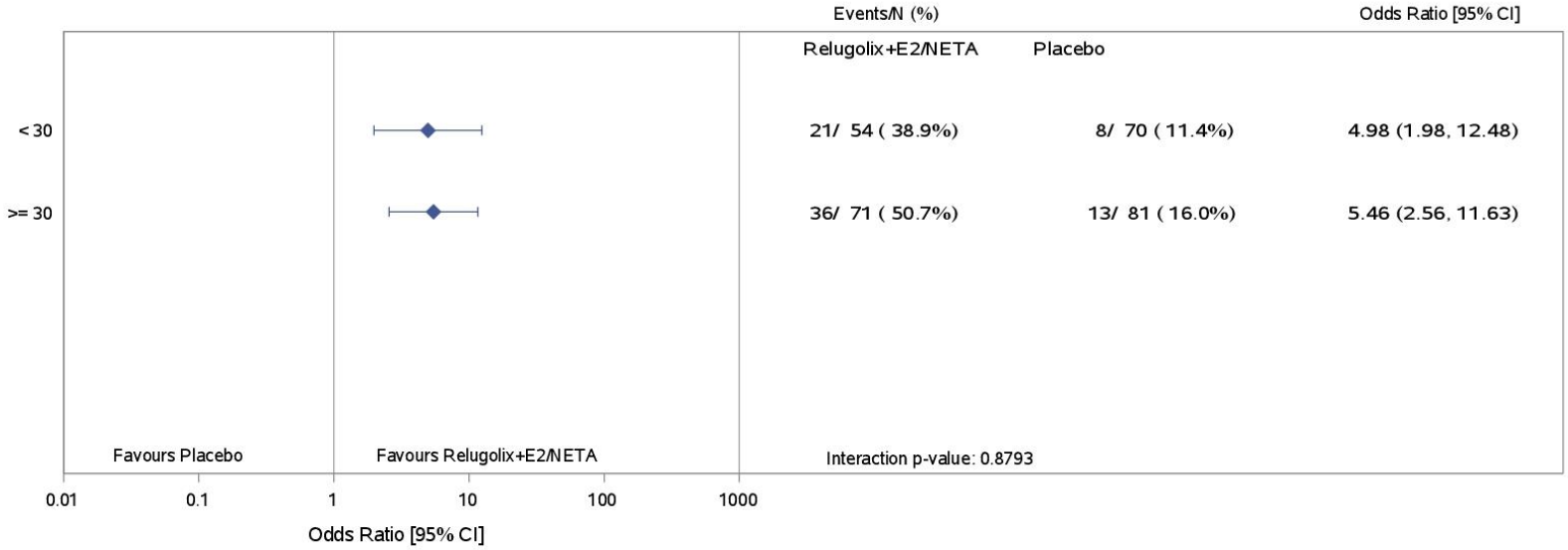
Figure EFF.MAXNRS1.PEV.S2.BIN.FP: Proportion of Patients with Maximum NRS Score <= 1 During the Last 35 Days of Treatment, by Subgroup (Pain Evaluable Population)
Study: Pooled
Subgroup: BMI (kg/m2) at Baseline



Results are based on a logistic regression model adjusted for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates using a one-stage fixed-effects IPD meta-analysis approach. A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
The interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the Odds Ratio and 95% CI. Missing subgroup levels are not included in estimation of the interaction p-value. The reference group is Placebo.
N: Number of patients in treatment group; NETA: Norethindrone acetate; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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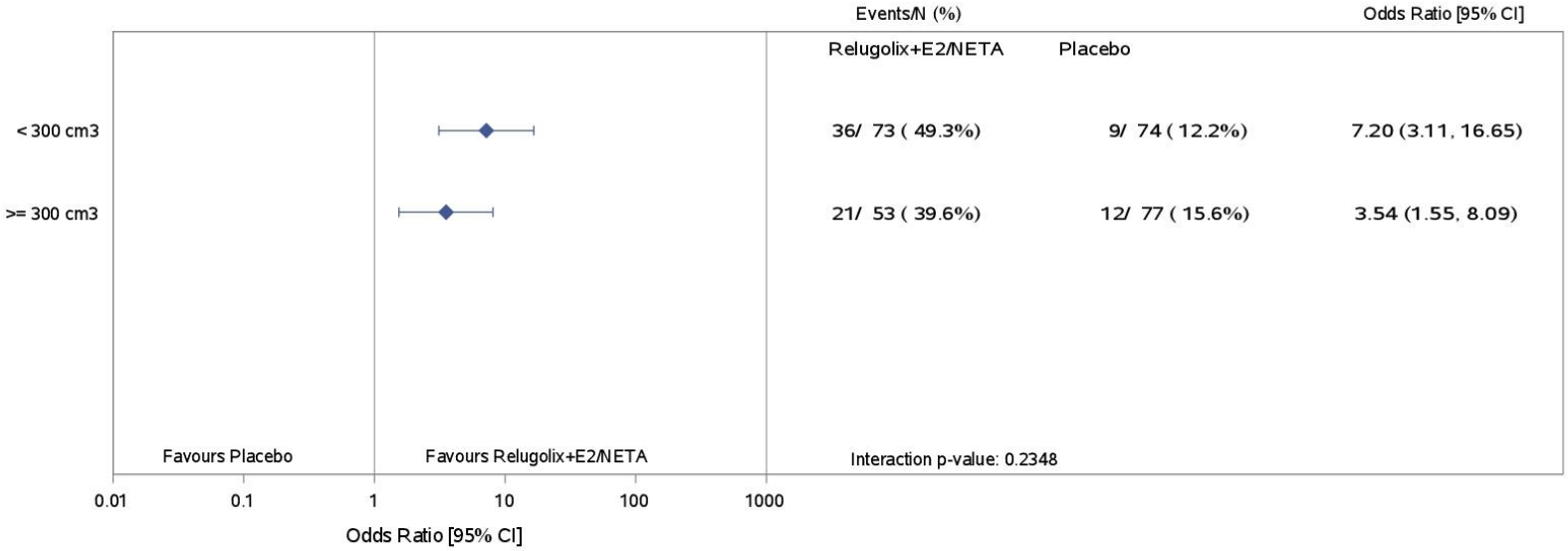
Figure EFF.MAXNRS1.PEV.S3.BIN.FP: Proportion of Patients with Maximum NRS Score <= 1 During the Last 35 Days of Treatment, by Subgroup (Pain Evaluable Population)
Study: Pooled
Subgroup: Uterine Volume at Baseline (cm3)



Results are based on a logistic regression model adjusted for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates using a one-stage fixed-effects IPD meta-analysis approach. A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
The interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the Odds Ratio and 95% CI. Missing subgroup levels are not included in estimation of the interaction p-value. The reference group is Placebo.
N: Number of patients in treatment group; NETA: Norethindrone acetate; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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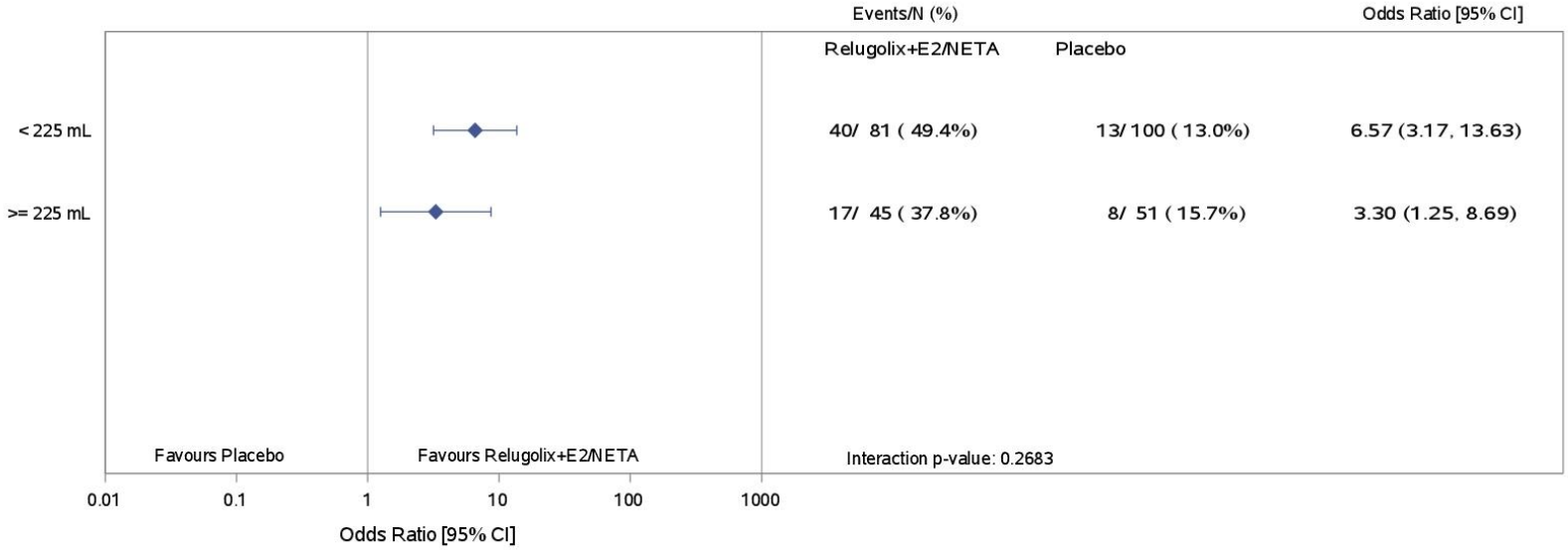
Figure EFF.MAXNRS1.PEV.S5.BIN.FP: Proportion of Patients with Maximum NRS Score <= 1 During the Last 35 Days of Treatment, by Subgroup (Pain Evaluable Population)
Study: Pooled
Subgroup: MBL Volume at Baseline (mL)



Results are based on a logistic regression model adjusted for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates using a one-stage fixed-effects IPD meta-analysis approach. A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
The interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the Odds Ratio and 95% CI. Missing subgroup levels are not included in estimation of the interaction p-value. The reference group is Placebo.
N: Number of patients in treatment group; NETA: Norethindrone acetate; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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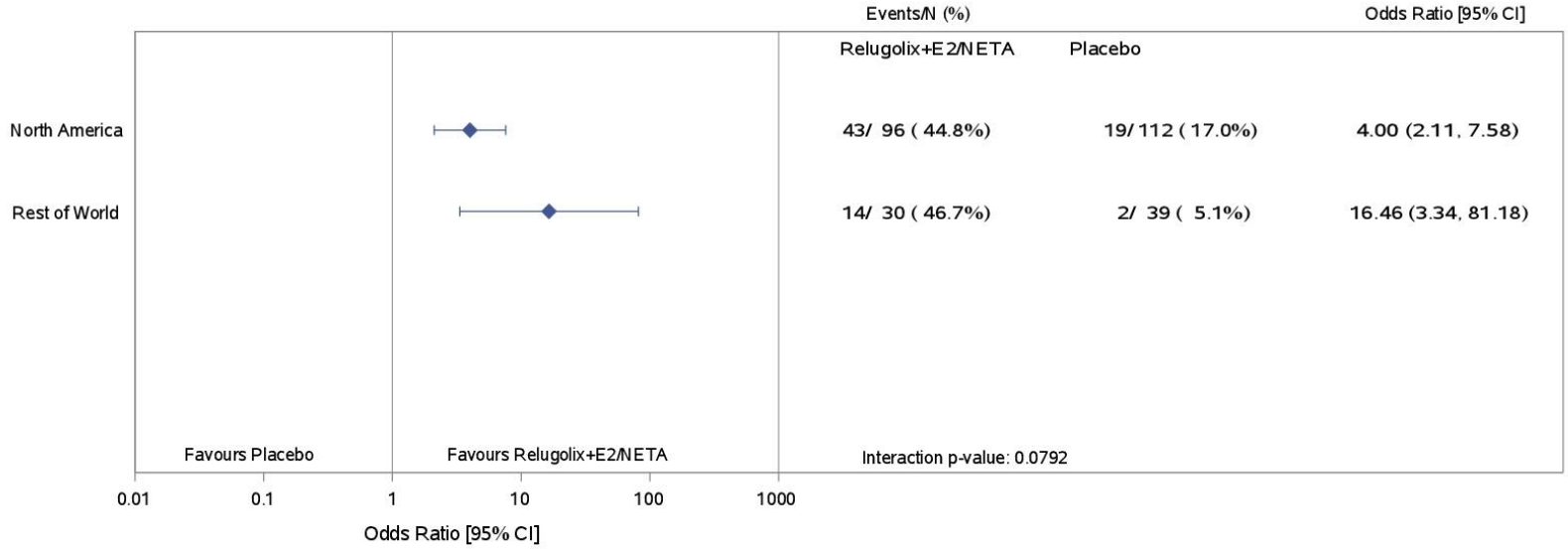
Figure EFF.MAXNRS1.PEV.S6.BIN.FP: Proportion of Patients with Maximum NRS Score <= 1 During the Last 35 Days of Treatment, by Subgroup (Pain Evaluable Population)
Study: Pooled
Subgroup: Geographic Region I



Results are based on a logistic regression model adjusted for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates using a one-stage fixed-effects IPD meta-analysis approach. A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
The interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the Odds Ratio and 95% CI. Missing subgroup levels are not included in estimation of the interaction p-value. The reference group is Placebo.
N: Number of patients in treatment group; NETA: Norethindrone acetate; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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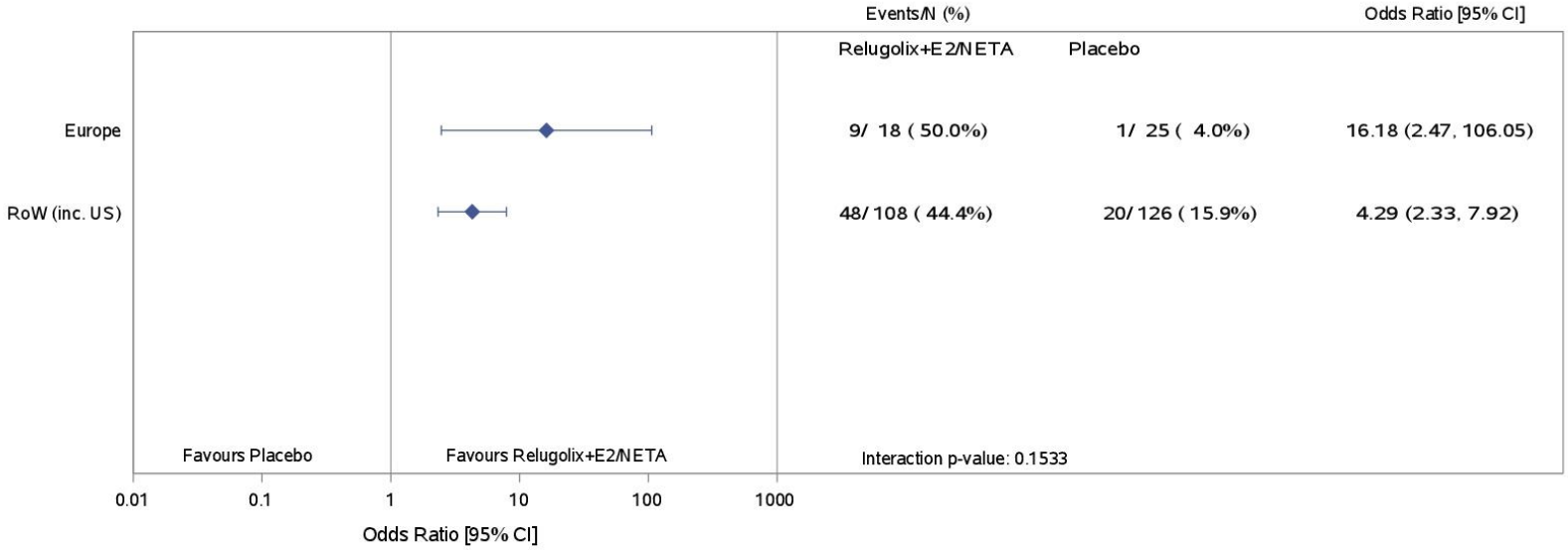
Figure EFF.MAXNRS1.PEV.S7.BIN.FP: Proportion of Patients with Maximum NRS Score <= 1 During the Last 35 Days of Treatment, by Subgroup (Pain Evaluable Population)
Study: Pooled
Subgroup: Geographic Region II



Results are based on a logistic regression model adjusted for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates using a one-stage fixed-effects IPD meta-analysis approach. A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
The interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the Odds Ratio and 95% CI. Missing subgroup levels are not included in estimation of the interaction p-value. The reference group is Placebo.
N: Number of patients in treatment group; NETA: Norethindrone acetate; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

SOURCE: X:\Numerus\Studies\MYV\MYV102\Analysis\Prod\Progs\TFLs\Fig_EFF_NRS_S_BIN_FP.SAS Date/time of run: 30JUN21 10:26
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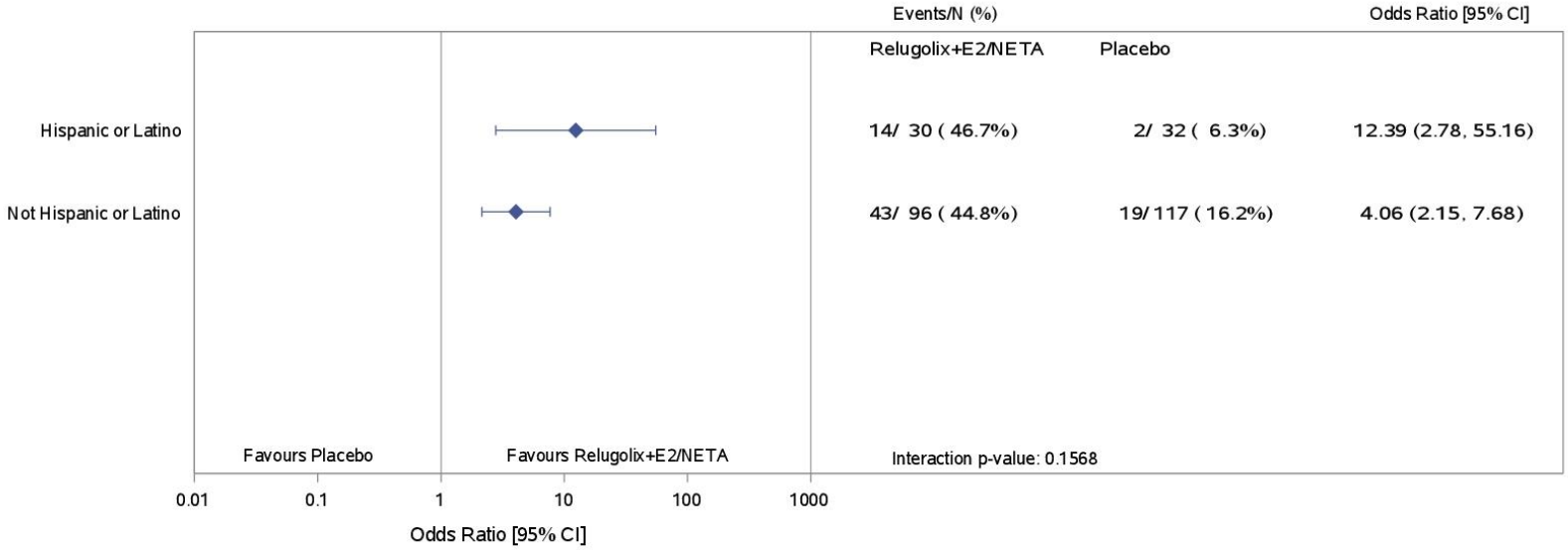
Figure EFF.MAXNRS1.PEV.S8.BIN.FP: Proportion of Patients with Maximum NRS Score <= 1 During the Last 35 Days of Treatment, by Subgroup (Pain Evaluable Population)
Study: Pooled
Subgroup: Ethnicity



Results are based on a logistic regression model adjusted for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates using a one-stage fixed-effects IPD meta-analysis approach. A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
The interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the Odds Ratio and 95% CI. Missing subgroup levels are not included in estimation of the interaction p-value. The reference group is Placebo.
N: Number of patients in treatment group; NETA: Norethindrone acetate; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

SOURCE: X:\Numerus\Studies\MYV\MYV102\Analysis\Prod\Progs\TFLs\Fig_EFF_NRS_S_BIN_FP.SAS Date/time of run: 30JUN21 10:26
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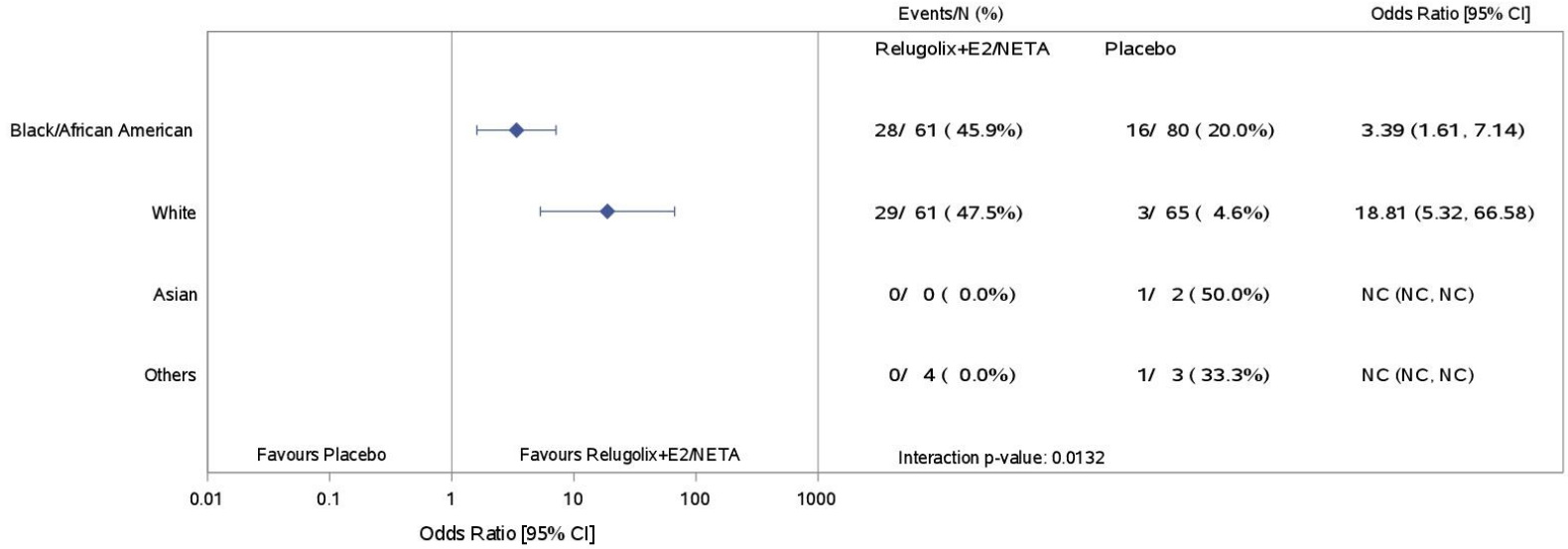
Figure EFF.MAXNRS1.PEV.S9.BIN.FP: Proportion of Patients with Maximum NRS Score <= 1 During the Last 35 Days of Treatment, by Subgroup (Pain Evaluable Population)
Study: Pooled
Subgroup: Race



Results are based on a logistic regression model adjusted for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates using a one-stage fixed-effects IPD meta-analysis approach. A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
The interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the Odds Ratio and 95% CI. Missing subgroup levels are not included in estimation of the interaction p-value. The reference group is Placebo.
N: Number of patients in treatment group; NETA: Norethindrone acetate; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

SOURCE: X:\Numerus\Studies\MYV\MYV102\Analysis\Prod\Progs\TFLs\Fig_EFF_NRS_S_BIN_FP.SAS Date/time of run: 30JUN21 10:26
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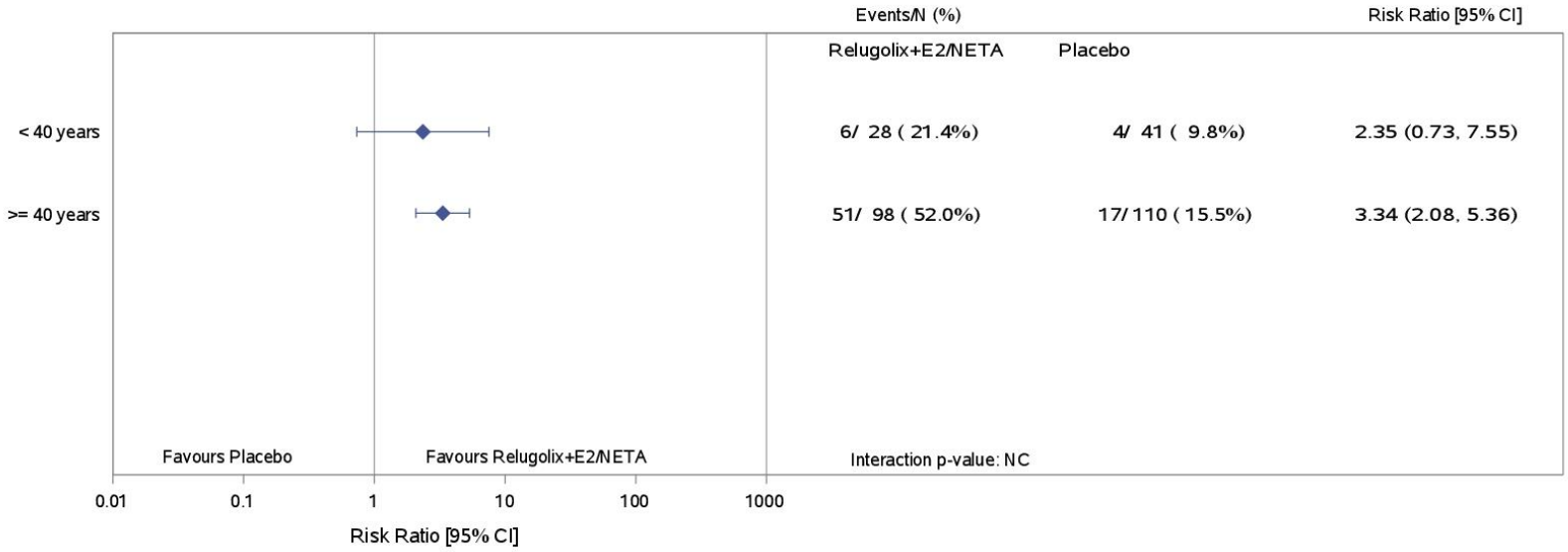
Figure EFF.MAXNRS1.PEV.S1.BIN.FP.RR: Proportion of Patients with Maximum NRS Score <= 1 During the Last 35 Days of Treatment, by Subgroup (Pain Evaluable Population) - Risk Ratio
Study: Pooled
Subgroup: Age (years)



Results are based on a Cochran-Mantel-Haenszel approach stratified by study using a one-stage fixed-effects IPD meta-analysis. A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
The reference group is Placebo.
N: Number of patients in treatment group; NETA: Norethindrone acetate; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

SOURCE: X:\Numerus\Studies\MYV\MYV102\Analysis\Prod\Progs\TFLs\Fig_EFF_NRS_S_BIN_FP.SAS Date/time of run: 30JUN21 10:26
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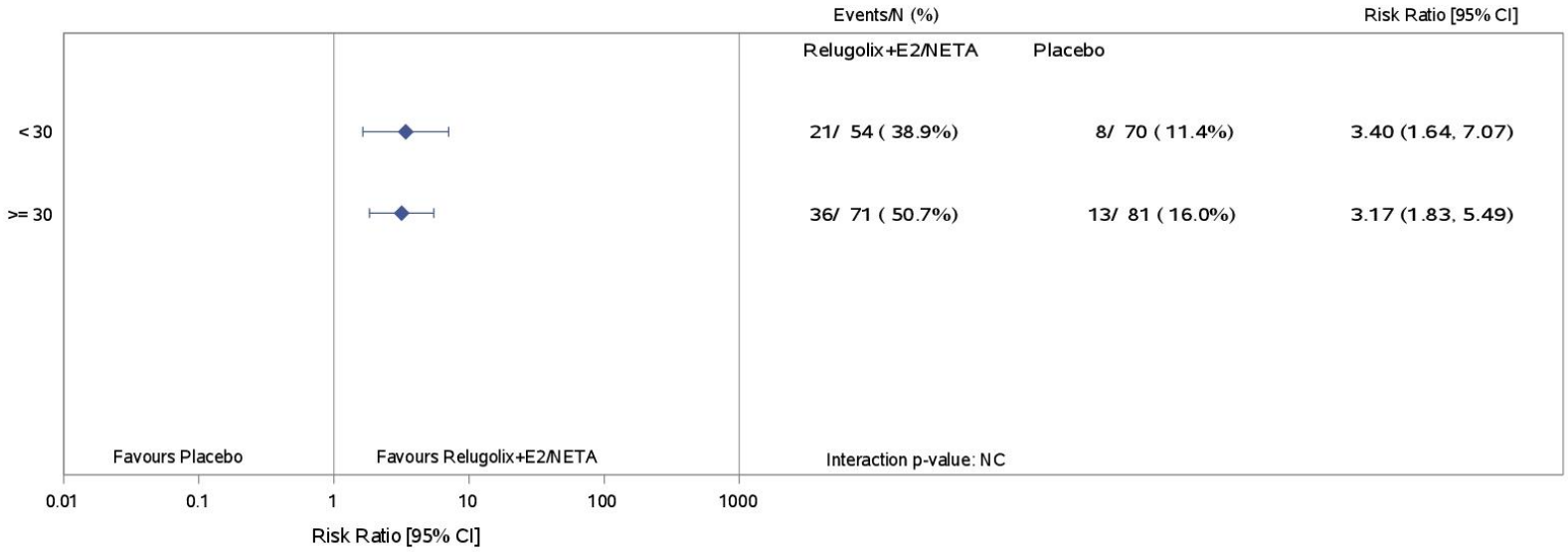
Figure EFF.MAXNRS1.PEV.S2.BIN.FP.RR: Proportion of Patients with Maximum NRS Score <= 1 During the Last 35 Days of Treatment, by Subgroup (Pain Evaluable Population) - Risk Ratio
Study: Pooled
Subgroup: BMI (kg/m2) at Baseline



Results are based on a Cochran-Mantel-Haenszel approach stratified by study using a one-stage fixed-effects IPD meta-analysis. A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
The reference group is Placebo.
N: Number of patients in treatment group; NETA: Norethindrone acetate; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

SOURCE: X:\Numerus\Studies\MYV\MYV102\Analysis\Prod\Progs\TFLs\Fig_EFF_NRS_S_BIN_FP.SAS Date/time of run: 30JUN21 10:26
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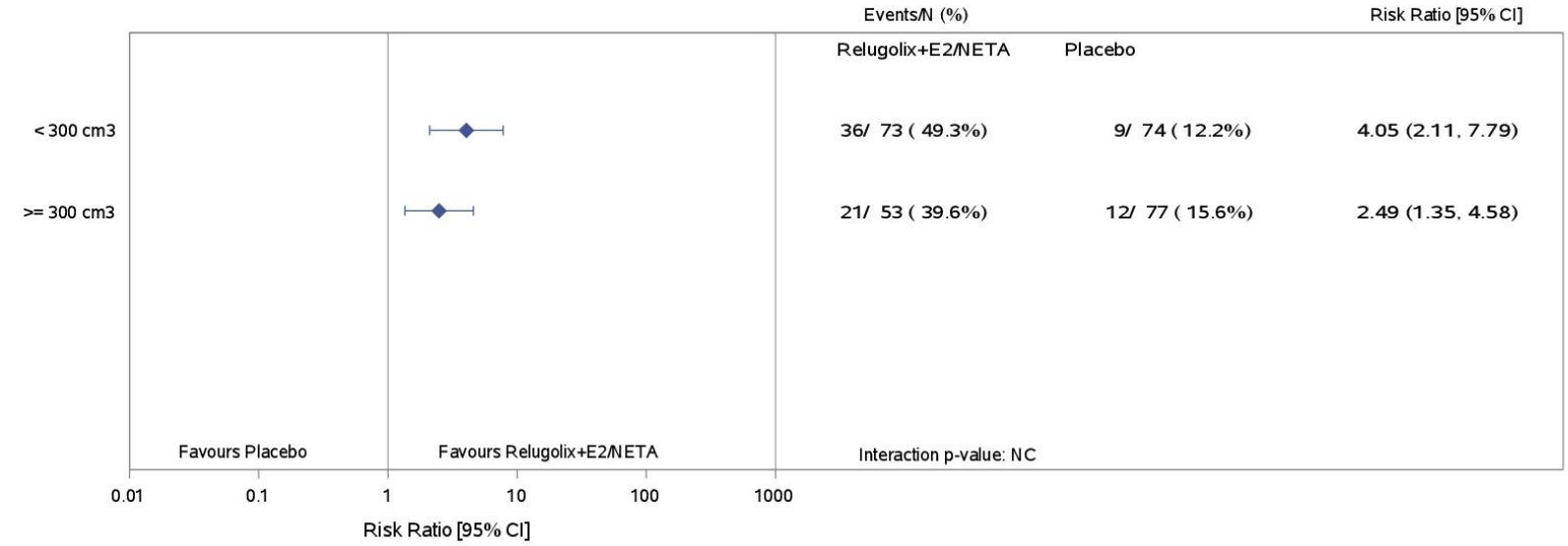
Figure EFF.MAXNRS1.PEV.S3.BIN.FP.RR: Proportion of Patients with Maximum NRS Score <= 1 During the Last 35 Days of Treatment, by Subgroup (Pain Evaluable Population) - Risk Ratio
Study: Pooled
Subgroup: Uterine Volume at Baseline (cm3)



Results are based on a Cochran-Mantel-Haenszel approach stratified by study using a one-stage fixed-effects IPD meta-analysis. A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
The reference group is Placebo.
N: Number of patients in treatment group; NETA: Norethindrone acetate; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

SOURCE: X:\Numerus\Studies\MYV\MYV102\Analysis\Prod\Progs\TFLs\Fig_EFF_NRS_S_BIN_FP.SAS Date/time of run: 30JUN21 10:26
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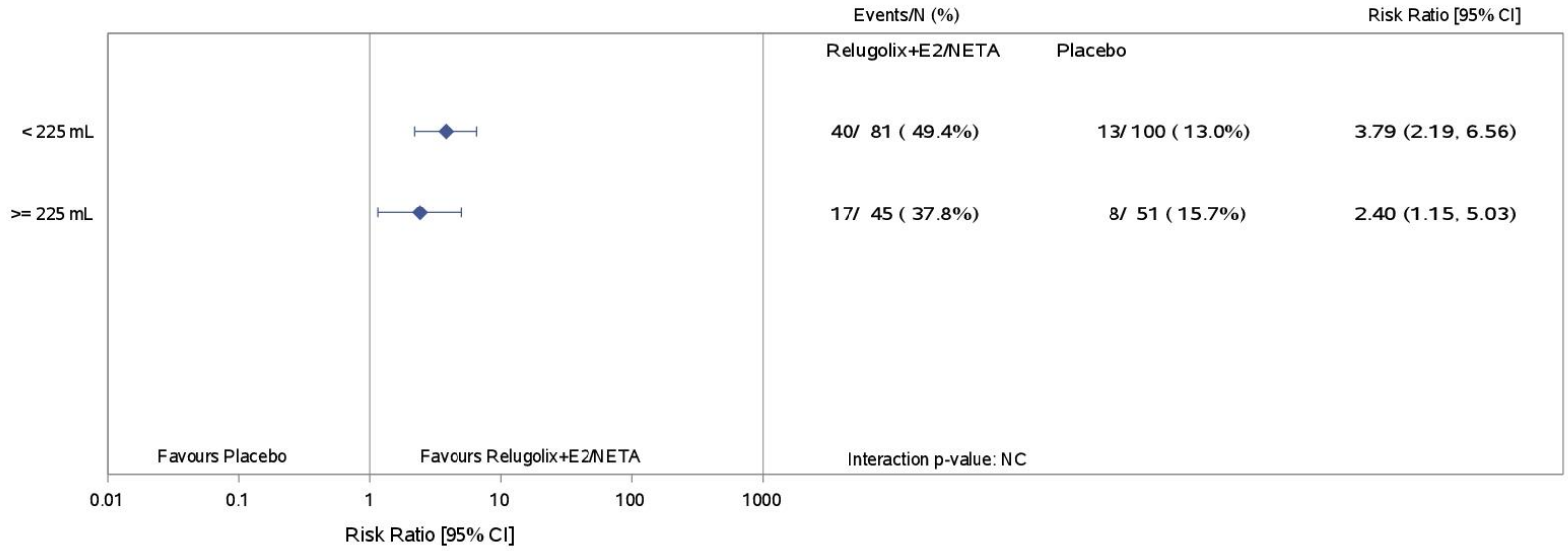
Figure EFF.MAXNRS1.PEV.S5.BIN.FP.RR: Proportion of Patients with Maximum NRS Score <= 1 During the Last 35 Days of Treatment, by Subgroup (Pain Evaluable Population) - Risk Ratio
Study: Pooled
Subgroup: MBL Volume at Baseline (mL)



Results are based on a Cochran-Mantel-Haenszel approach stratified by study using a one-stage fixed-effects IPD meta-analysis. A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
The reference group is Placebo.
N: Number of patients in treatment group; NETA: Norethindrone acetate; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

SOURCE: X:\Numerus\Studies\MYV\MYV102\Analysis\Prod\Progs\TFLs\Fig_EFF_NRS_S_BIN_FP.SAS Date/time of run: 30JUN21 10:26
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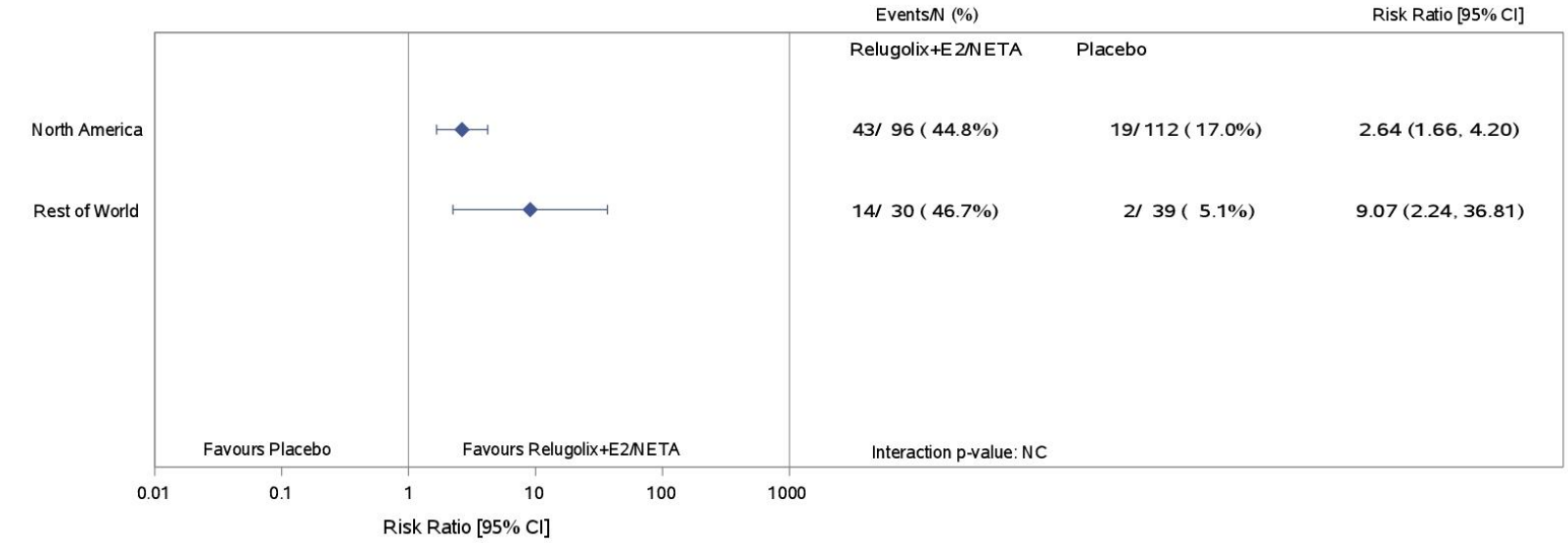
Figure EFF.MAXNRS1.PEV.S6.BIN.FP.RR: Proportion of Patients with Maximum NRS Score <= 1 During the Last 35 Days of Treatment, by Subgroup (Pain Evaluable Population) - Risk Ratio
Study: Pooled
Subgroup: Geographic Region I



Results are based on a Cochran-Mantel-Haenszel approach stratified by study using a one-stage fixed-effects IPD meta-analysis. A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
The reference group is Placebo.
N: Number of patients in treatment group; NETA: Norethindrone acetate; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

SOURCE: X:\Numerus\Studies\MYV\MYV102\Analysis\Prod\Progs\TFLs\Fig_EFF_NRS_S_BIN_FP.SAS Date/time of run: 30JUN21 10:26
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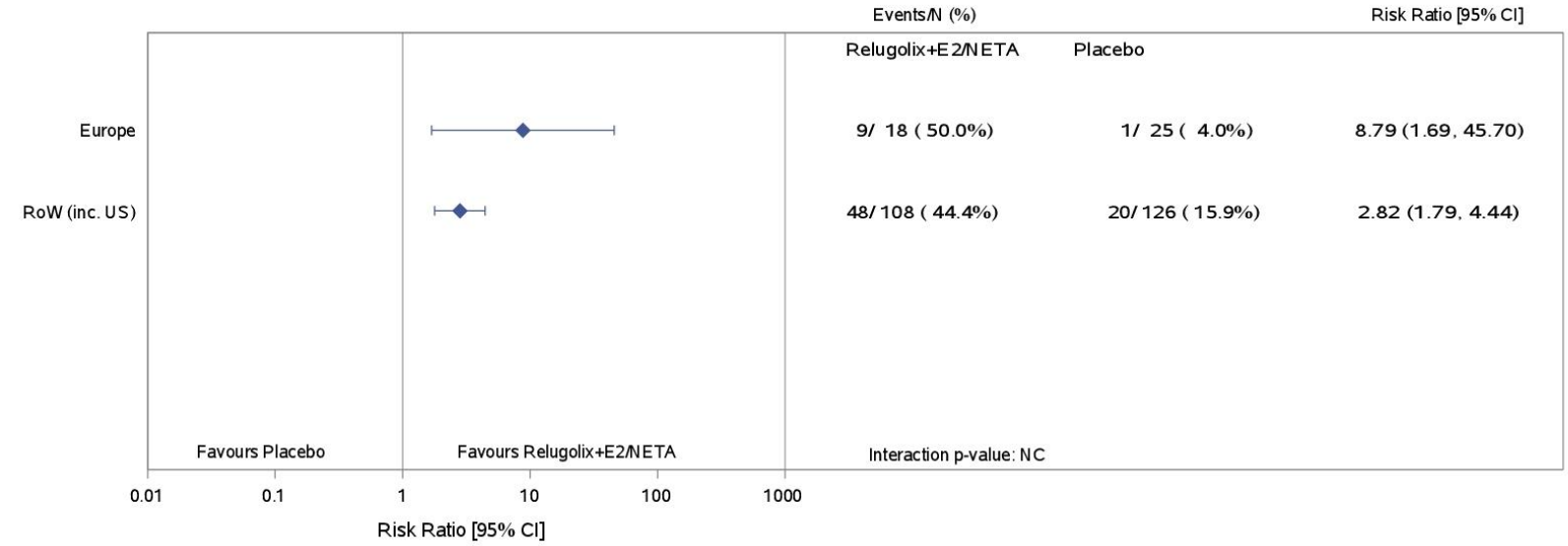
Figure EFF.MAXNRS1.PEV.S7.BIN.FP.RR: Proportion of Patients with Maximum NRS Score <= 1 During the Last 35 Days of Treatment, by Subgroup (Pain Evaluable Population) - Risk Ratio
Study: Pooled
Subgroup: Geographic Region II



Results are based on a Cochran-Mantel-Haenszel approach stratified by study using a one-stage fixed-effects IPD meta-analysis. A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
The reference group is Placebo.
N: Number of patients in treatment group; NETA: Norethindrone acetate; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

SOURCE: X:\Numerus\Studies\MYV\MYV102\Analysis\Prod\Progs\TFLs\Fig_EFF_NRS_S_BIN_FP.SAS Date/time of run: 30JUN21 10:26
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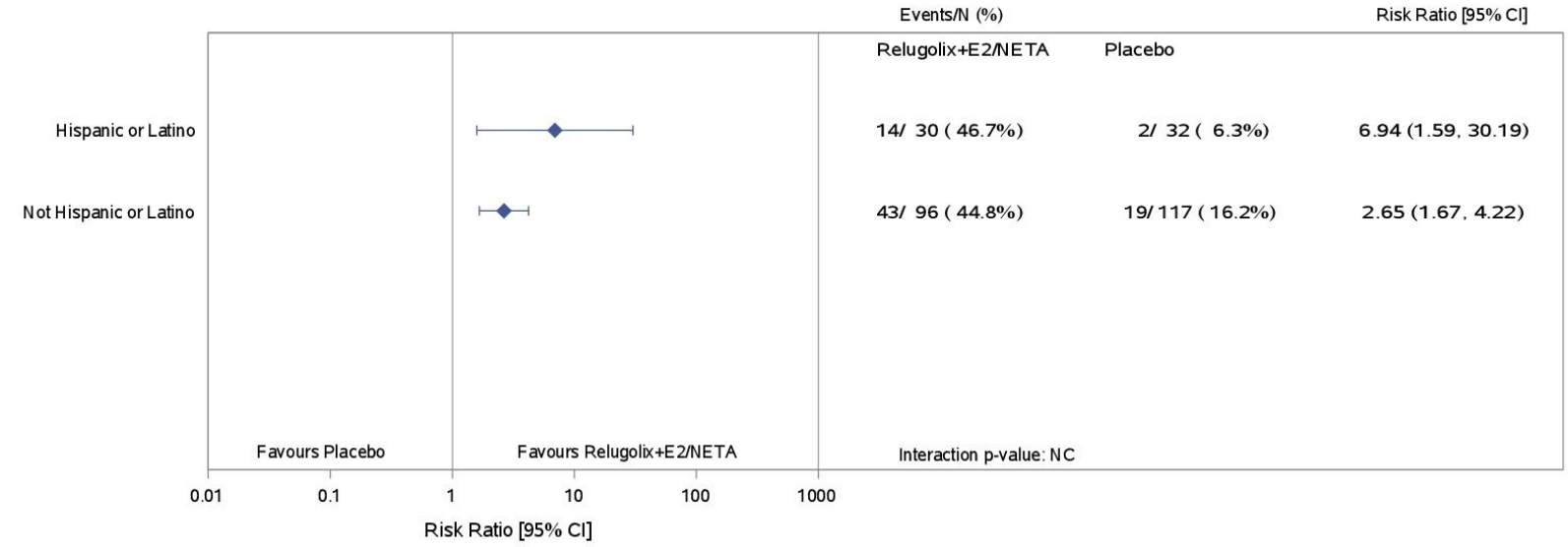
Figure EFF.MAXNRS1.PEV.S8.BIN.FP.RR: Proportion of Patients with Maximum NRS Score <= 1 During the Last 35 Days of Treatment, by Subgroup (Pain Evaluable Population) - Risk Ratio
Study: Pooled
Subgroup: Ethnicity



Results are based on a Cochran-Mantel-Haenszel approach stratified by study using a one-stage fixed-effects IPD meta-analysis. A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
The reference group is Placebo.
N: Number of patients in treatment group; NETA: Norethindrone acetate; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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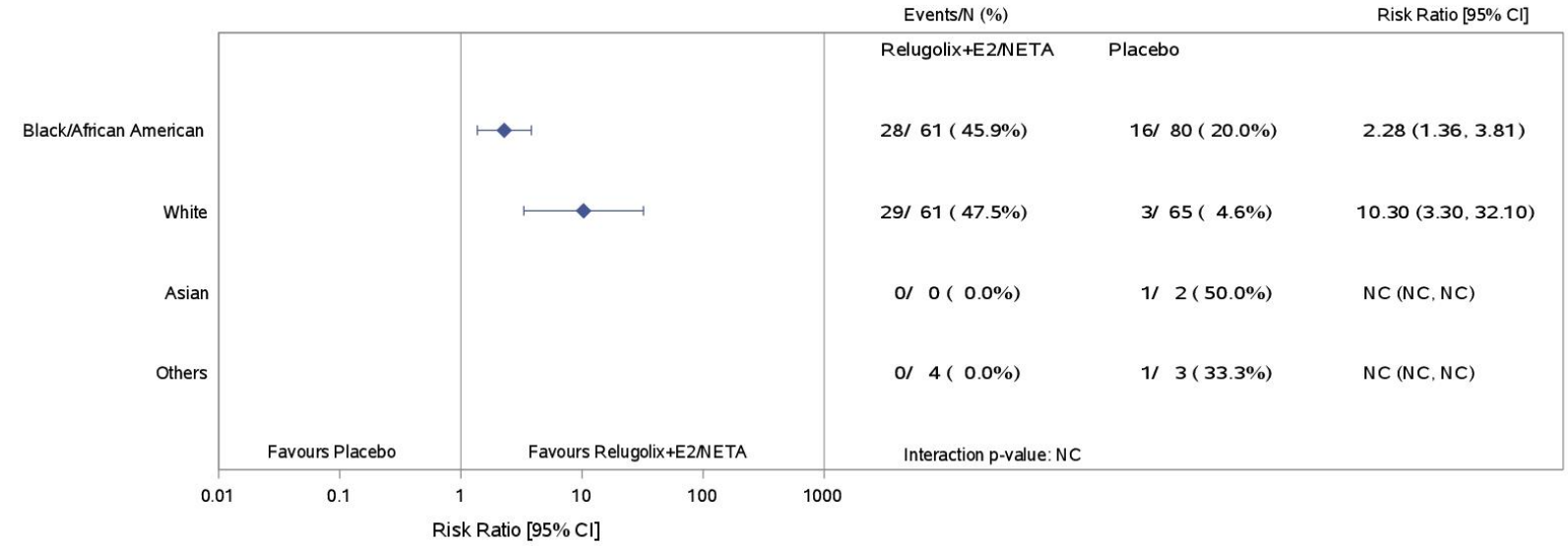
Figure EFF.MAXNRS1.PEV.S9.BIN.FP.RR: Proportion of Patients with Maximum NRS Score <= 1 During the Last 35 Days of Treatment, by Subgroup (Pain Evaluable Population) - Risk Ratio
Study: Pooled
Subgroup: Race



Results are based on a Cochran-Mantel-Haenszel approach stratified by study using a one-stage fixed-effects IPD meta-analysis. A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
The reference group is Placebo.
N: Number of patients in treatment group; NETA: Norethindrone acetate; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

SOURCE: X:\Numerus\Studies\MYV\MYV102\Analysis\Prod\Progs\TFLs\Fig_EFF_NRS_S_BIN_FP.SAS Date/time of run: 30JUN21 10:26
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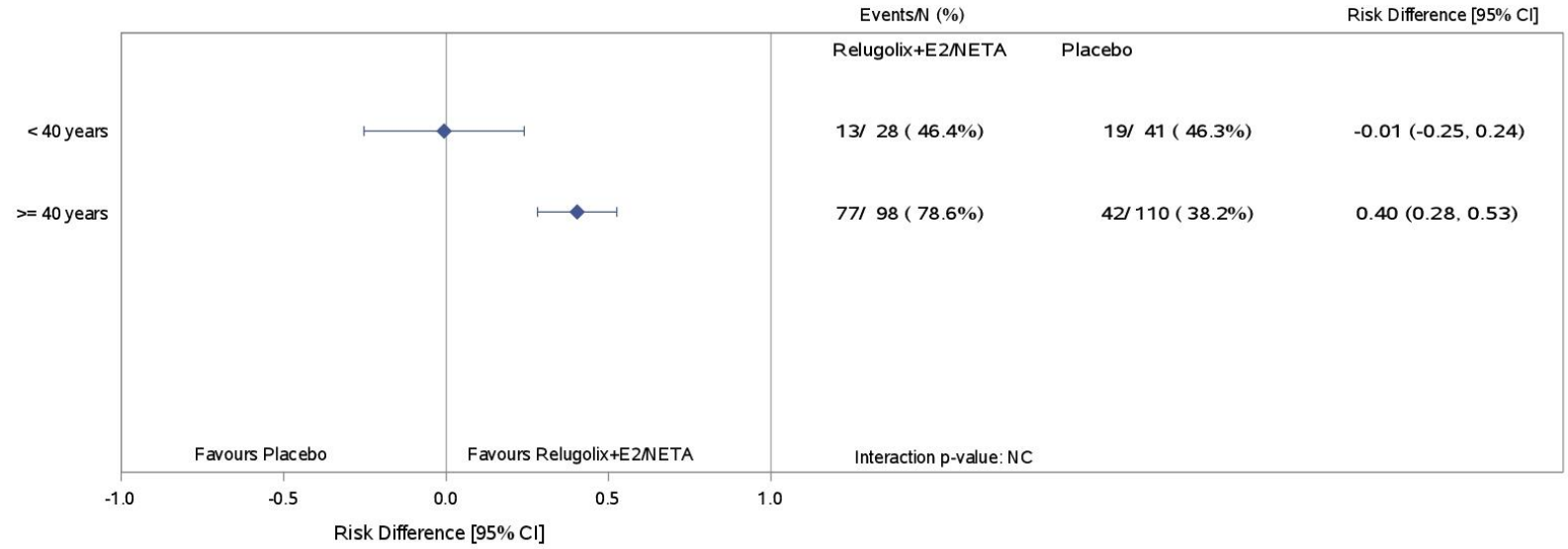
Figure EFF.NRSR30.PEV.S1.BIN.FP.RD: Proportion of Patients with >= 30% Reduction in NRS Score from Baseline to Last 35 Days of Treatment, by Subgroup (Pain Evaluable Population)
- Risk Difference
Study: Pooled
Subgroup: Age (years)



Results are based on a Mantel-Haenszel approach stratified by study using a one-stage fixed-effects IPD meta-analysis.
The reference group is Placebo.
N: Number of patients in treatment group; NETA: Norethindrone acetate; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

SOURCE: X:\Numerus\Studies\MYV\MYV102\Analysis\Prod\Progs\TFLs\Fig_EFF_NRS_S_BIN_FP.SAS Date/time of run: 30JUN21 10:26
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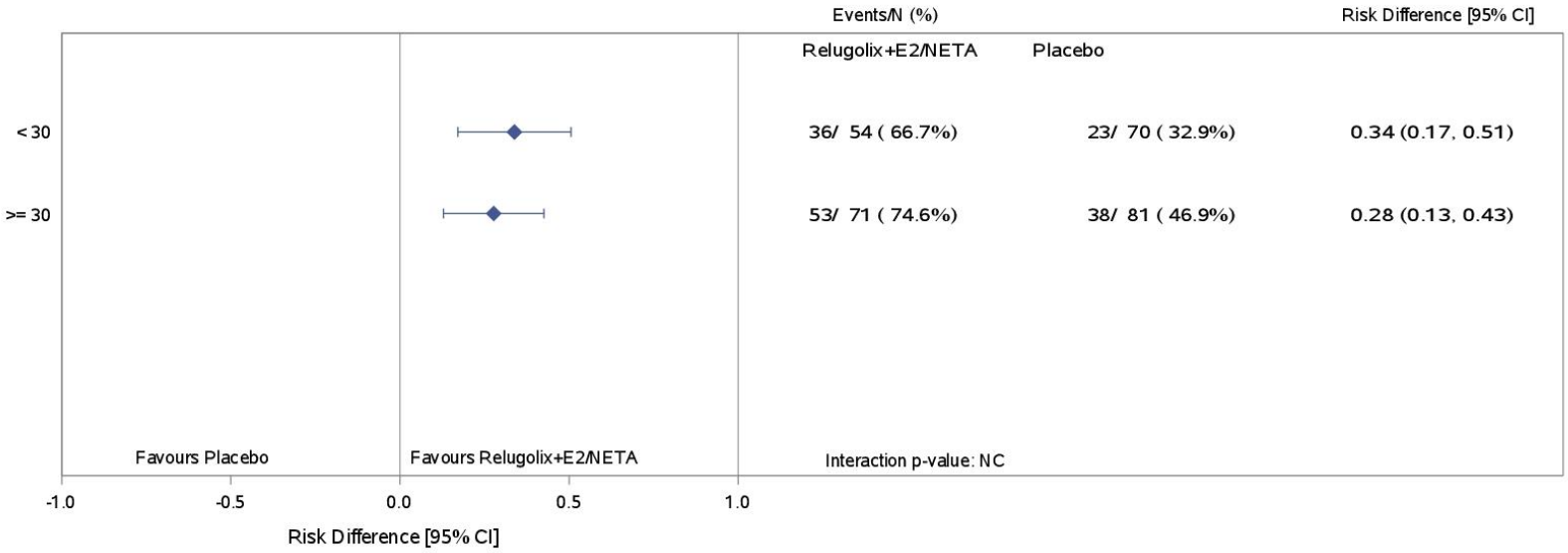
Figure EFF.NRSR30.PEV.S2.BIN.FP.RD: Proportion of Patients with >= 30% Reduction in NRS Score from Baseline to Last 35 Days of Treatment, by Subgroup (Pain Evaluable Population)
- Risk Difference
Study: Pooled
Subgroup: BMI (kg/m2) at Baseline



Results are based on a Mantel-Haenszel approach stratified by study using a one-stage fixed-effects IPD meta-analysis.
The reference group is Placebo.
N: Number of patients in treatment group; NETA: Norethindrone acetate; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

SOURCE: X:\Numerus\Studies\MYV\MYV102\Analysis\Prod\Progs\TFLs\Fig_EFF_NRS_S_BIN_FP.SAS Date/time of run: 30JUN21 10:26
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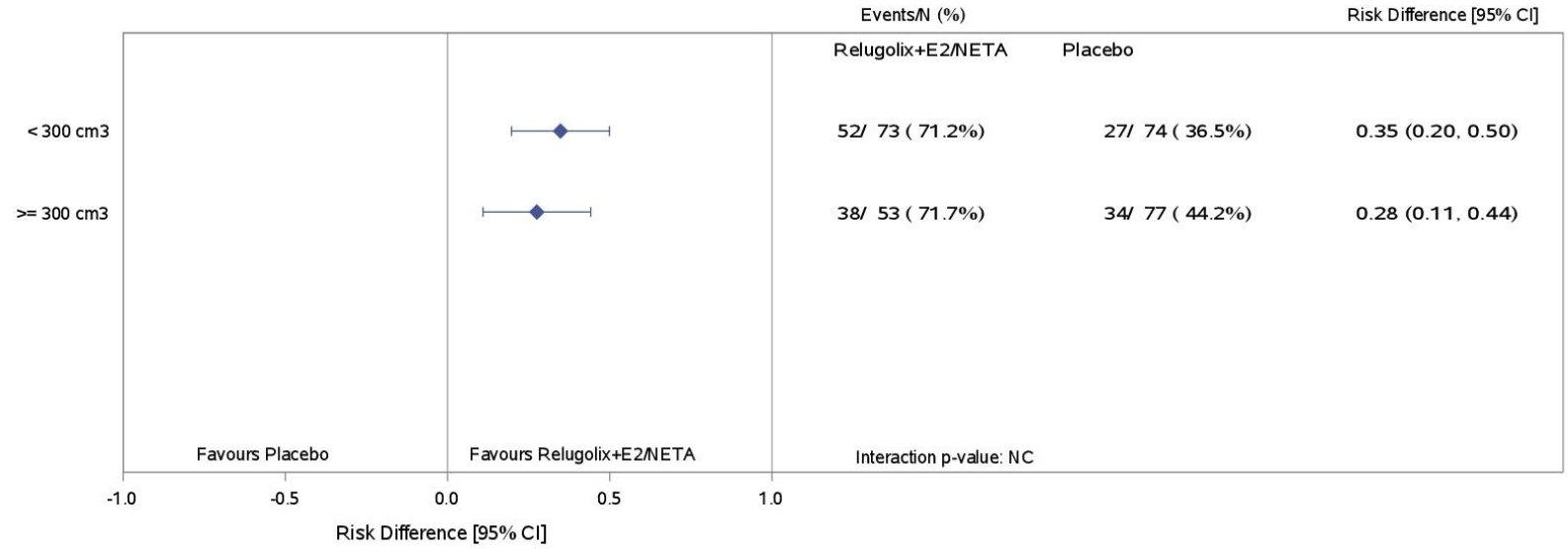
Figure EFF.NRSR30.PEV.S3.BIN.FP.RD: Proportion of Patients with >= 30% Reduction in NRS Score from Baseline to Last 35 Days of Treatment, by Subgroup (Pain Evaluable Population)
- Risk Difference
Study: Pooled
Subgroup: Uterine Volume at Baseline (cm3)



Results are based on a Mantel-Haenszel approach stratified by study using a one-stage fixed-effects IPD meta-analysis.
The reference group is Placebo.
N: Number of patients in treatment group; NETA: Norethindrone acetate; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

SOURCE: X:\Numerus\Studies\MYV\MYV102\Analysis\Prod\Progs\TFLs\Fig_EFF_NRS_S_BIN_FP.SAS Date/time of run: 30JUN21 10:26
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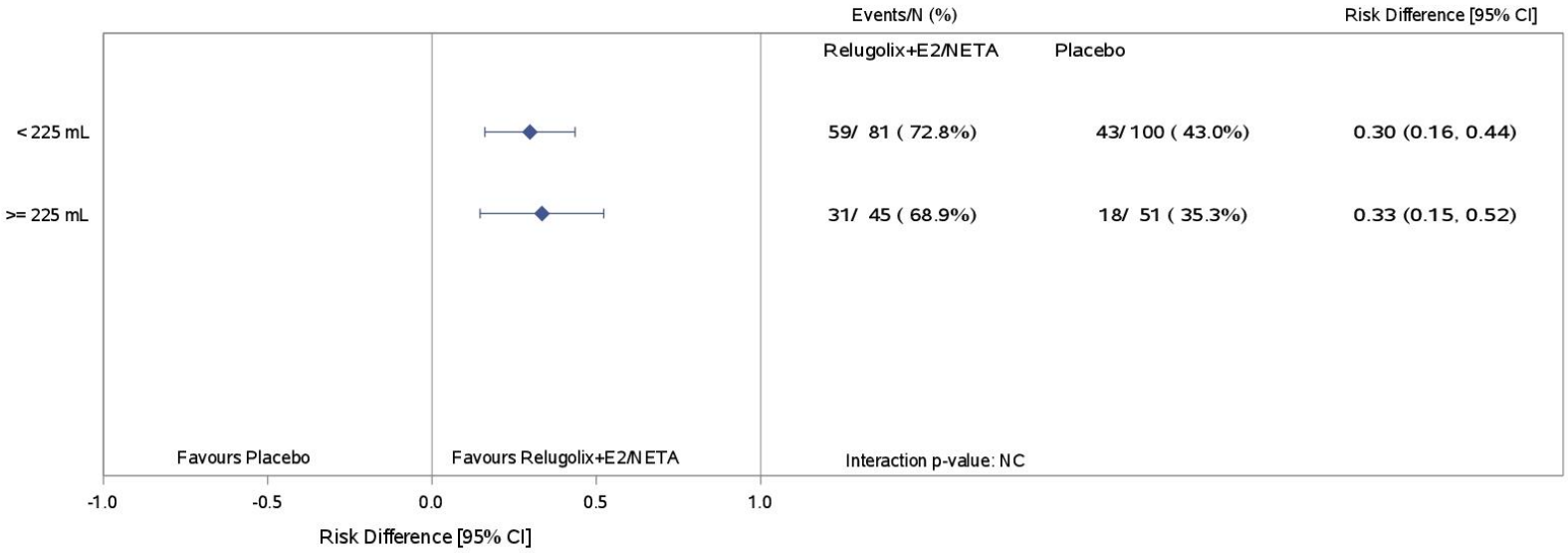
Figure EFF.NRSR30.PEV.S5.BIN.FP.RD: Proportion of Patients with >= 30% Reduction in NRS Score from Baseline to Last 35 Days of Treatment, by Subgroup (Pain Evaluable Population)
- Risk Difference
Study: Pooled
Subgroup: MBL Volume at Baseline (mL)



Results are based on a Mantel-Haenszel approach stratified by study using a one-stage fixed-effects IPD meta-analysis.
The reference group is Placebo.
N: Number of patients in treatment group; NETA: Norethindrone acetate; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

SOURCE: X:\Numerus\Studies\MYV\MYV102\Analysis\Prod\Progs\TFLs\Fig_EFF_NRS_S_BIN_FP.SAS Date/time of run: 30JUN21 10:26
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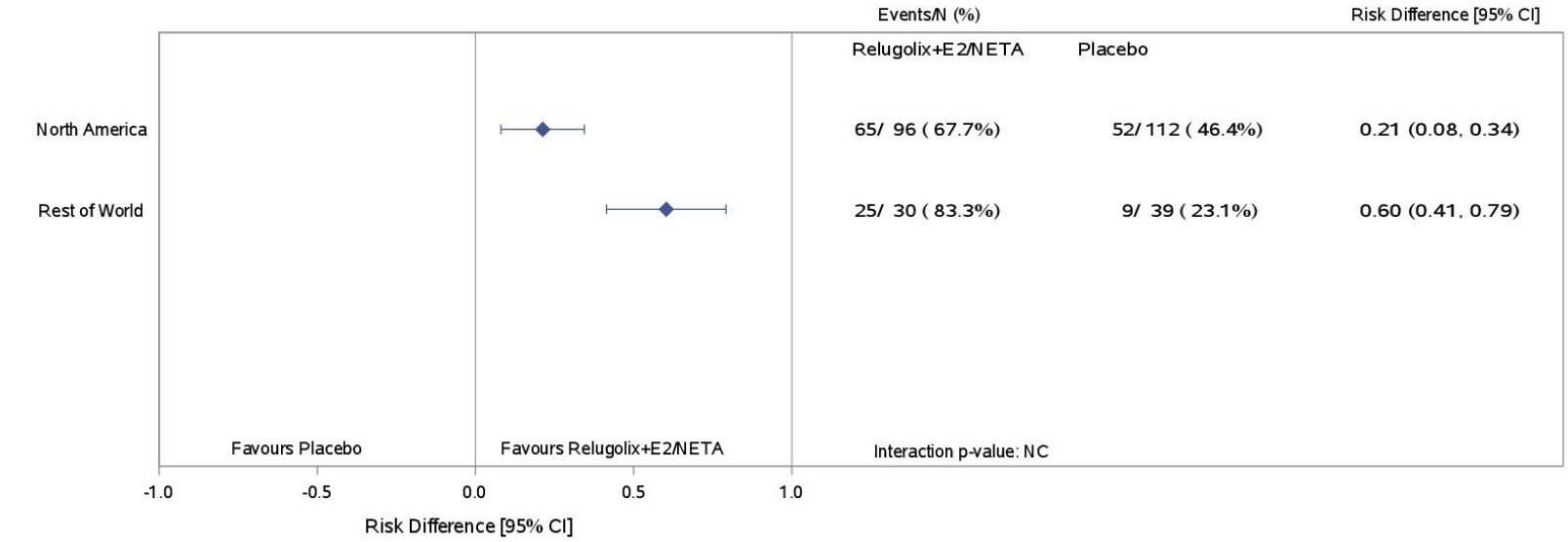
Figure EFF.NRSR30.PEV.S6.BIN.FP.RD: Proportion of Patients with >= 30% Reduction in NRS Score from Baseline to Last 35 Days of Treatment, by Subgroup (Pain Evaluable Population)
- Risk Difference
Study: Pooled
Subgroup: Geographic Region I



Results are based on a Mantel-Haenszel approach stratified by study using a one-stage fixed-effects IPD meta-analysis.
The reference group is Placebo.
N: Number of patients in treatment group; NETA: Norethindrone acetate; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

SOURCE: X:\Numerus\Studies\MYV\MYV102\Analysis\Prod\Progs\TFLs\Fig_EFF_NRS_S_BIN_FP.SAS Date/time of run: 30JUN21 10:26
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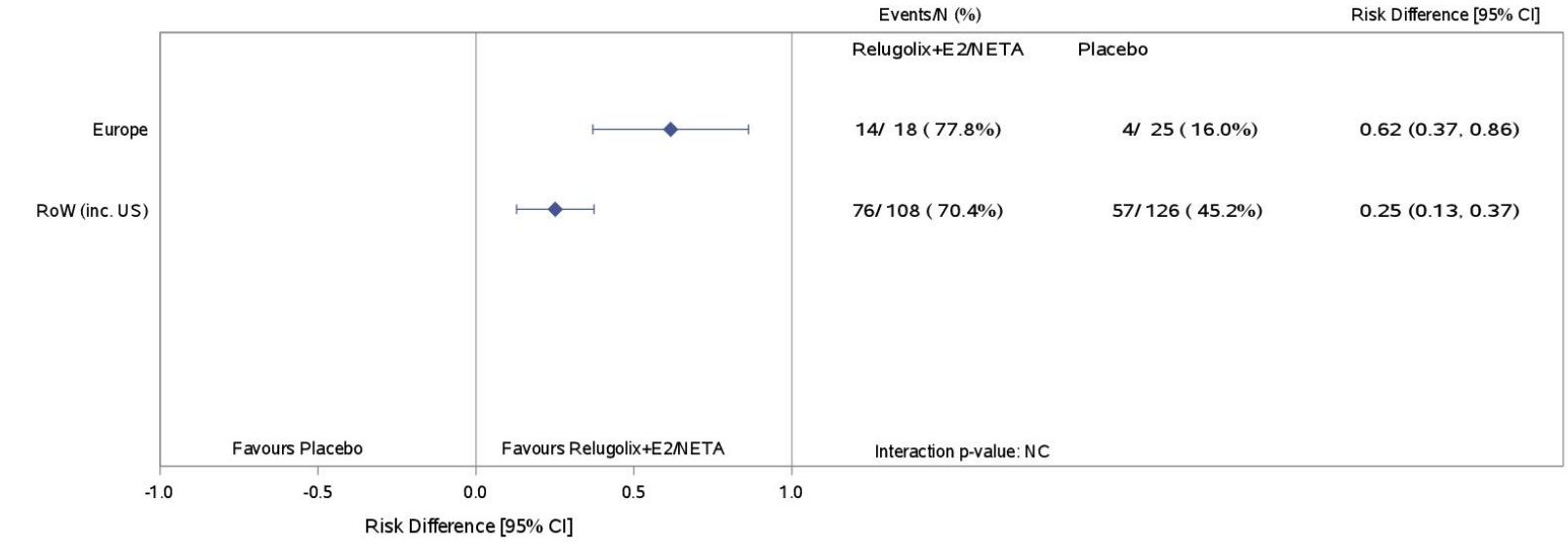
Figure EFF.NRSR30.PEV.S7.BIN.FP.RD: Proportion of Patients with >= 30% Reduction in NRS Score from Baseline to Last 35 Days of Treatment, by Subgroup (Pain Evaluable Population)
- Risk Difference
Study: Pooled
Subgroup: Geographic Region II



Results are based on a Mantel-Haenszel approach stratified by study using a one-stage fixed-effects IPD meta-analysis.
The reference group is Placebo.
N: Number of patients in treatment group; NETA: Norethindrone acetate; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

SOURCE: X:\Numerus\Studies\MYV\MYV102\Analysis\Prod\Progs\TFLs\Fig_EFF_NRS_S_BIN_FP.SAS Date/time of run: 30JUN21 10:26
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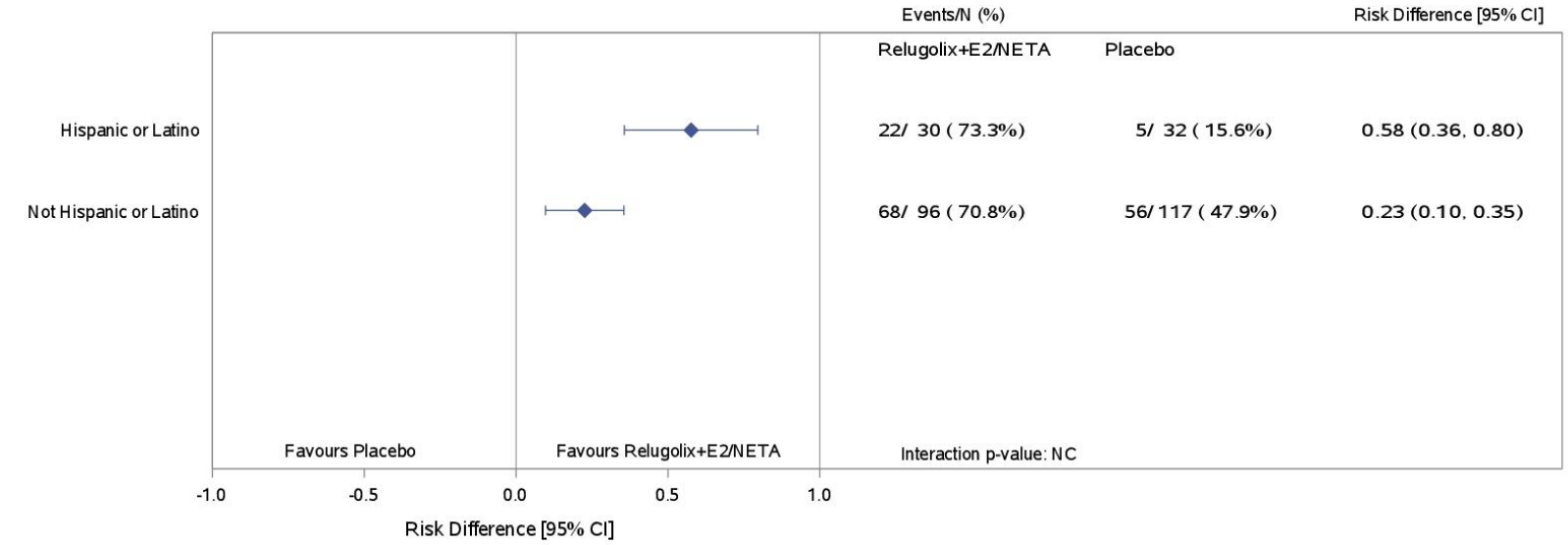
Figure EFF.NRSR30.PEV.S8.BIN.FP.RD: Proportion of Patients with >= 30% Reduction in NRS Score from Baseline to Last 35 Days of Treatment, by Subgroup (Pain Evaluable Population) - Risk Difference
Study: Pooled
Subgroup: Ethnicity



Results are based on a Mantel-Haenszel approach stratified by study using a one-stage fixed-effects IPD meta-analysis.
The reference group is Placebo.
N: Number of patients in treatment group; NETA: Norethindrone acetate; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

SOURCE: X:\Numerus\Studies\MYV\MYV102\Analysis\Prod\Progs\TFLs\Fig_EFF_NRS_S_BIN_FP.SAS Date/time of run: 30JUN21 10:26
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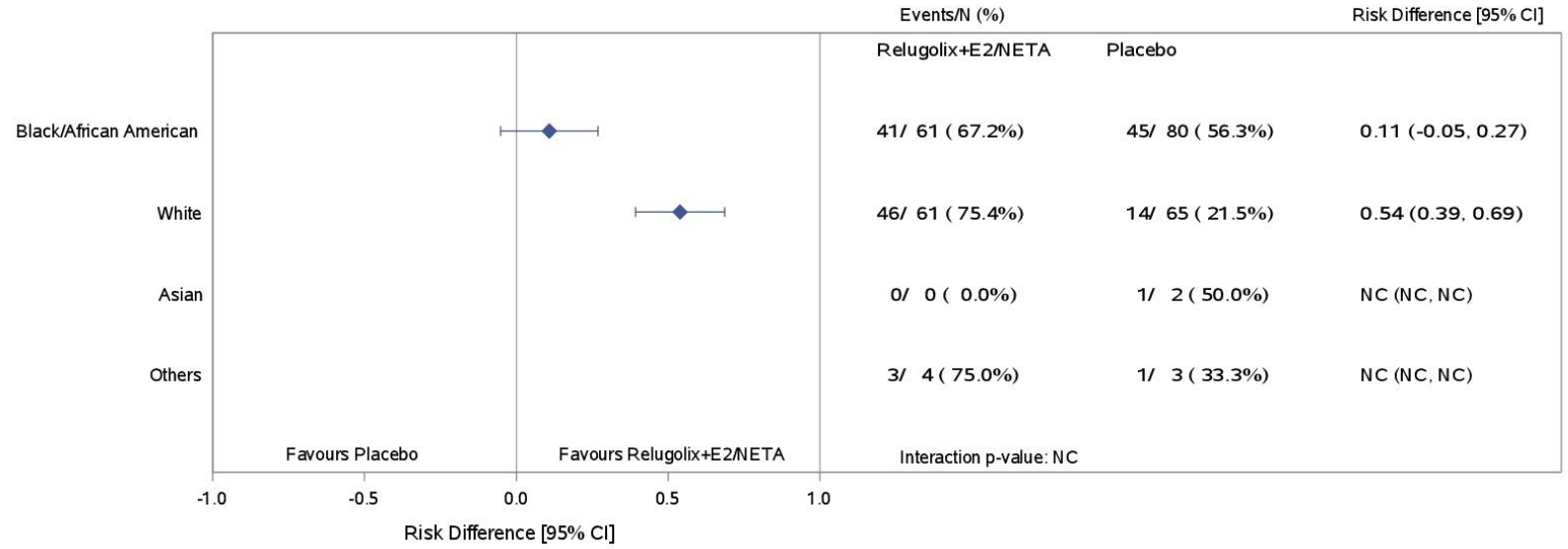
Figure EFF.NRSR30.PEV.S9.BIN.FP.RD: Proportion of Patients with >= 30% Reduction in NRS Score from Baseline to Last 35 Days of Treatment, by Subgroup (Pain Evaluable Population)
- Risk Difference
Study: Pooled
Subgroup: Race



Results are based on a Mantel-Haenszel approach stratified by study using a one-stage fixed-effects IPD meta-analysis.
The reference group is Placebo.
N: Number of patients in treatment group; NETA: Norethindrone acetate; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

SOURCE: X:\Numerus\Studies\MYV\MYV102\Analysis\Prod\Progs\TFLs\Fig_EFF_NRS_S_BIN_FP.SAS Date/time of run: 30JUN21 10:26
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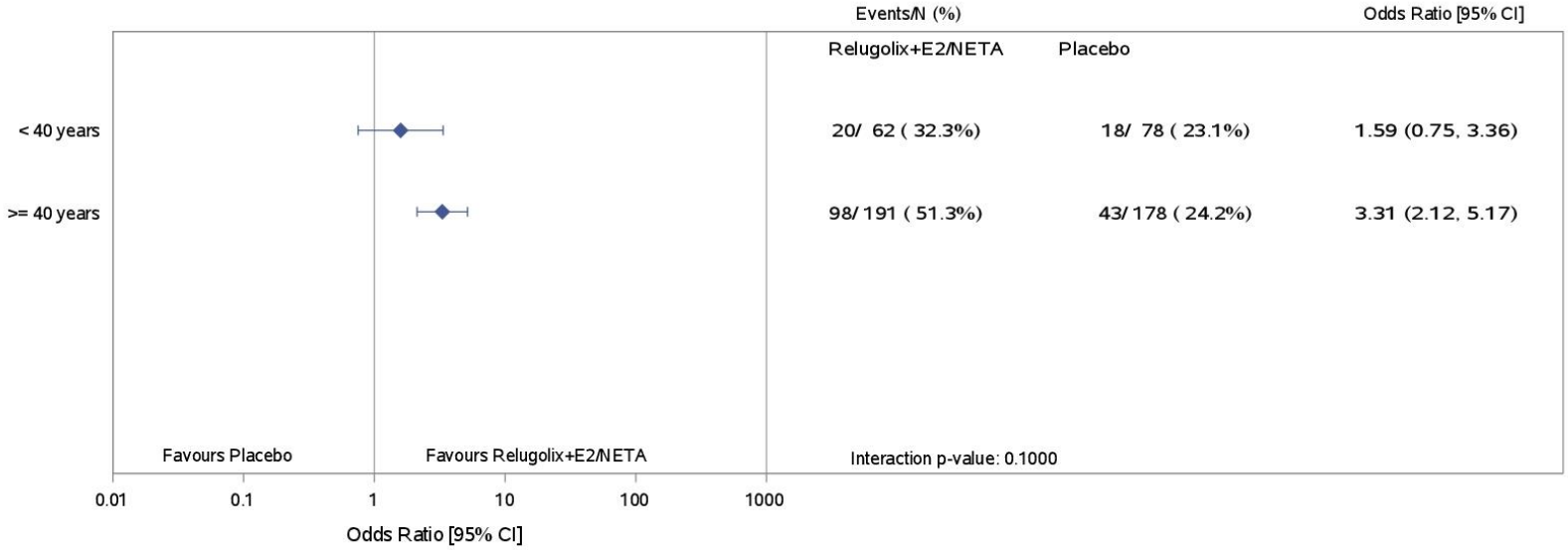
2.1.15 Proportion of Patients with Maximum NRS Score <= 1 During the Last 35 Days of Treatment, by Subgroup (mITT Population)

Nachfolgend sind zunächst alle Forest Plots für das *Odds Ratio* dargestellt; gefolgt von den entsprechenden Forest Plots für *Risk Ratio* und *Risk Difference*.

Figure EFF.MAXNRS1.MITT.S1.BIN.FP: Proportion of Patients with Maximum NRS Score <= 1 During the Last 35 Days of Treatment, by Subgroup (mITT Population)
Study: Pooled
Subgroup: Age (years)



Results are based on a logistic regression model adjusted for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates using a one-stage fixed-effects IPD meta-analysis approach. A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
The interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the Odds Ratio and 95% CI. Missing subgroup levels are not included in estimation of the interaction p-value. The reference group is Placebo.
N: Number of patients in treatment group; NETA: Norethindrone acetate; mITT: Modified intent-to-treat; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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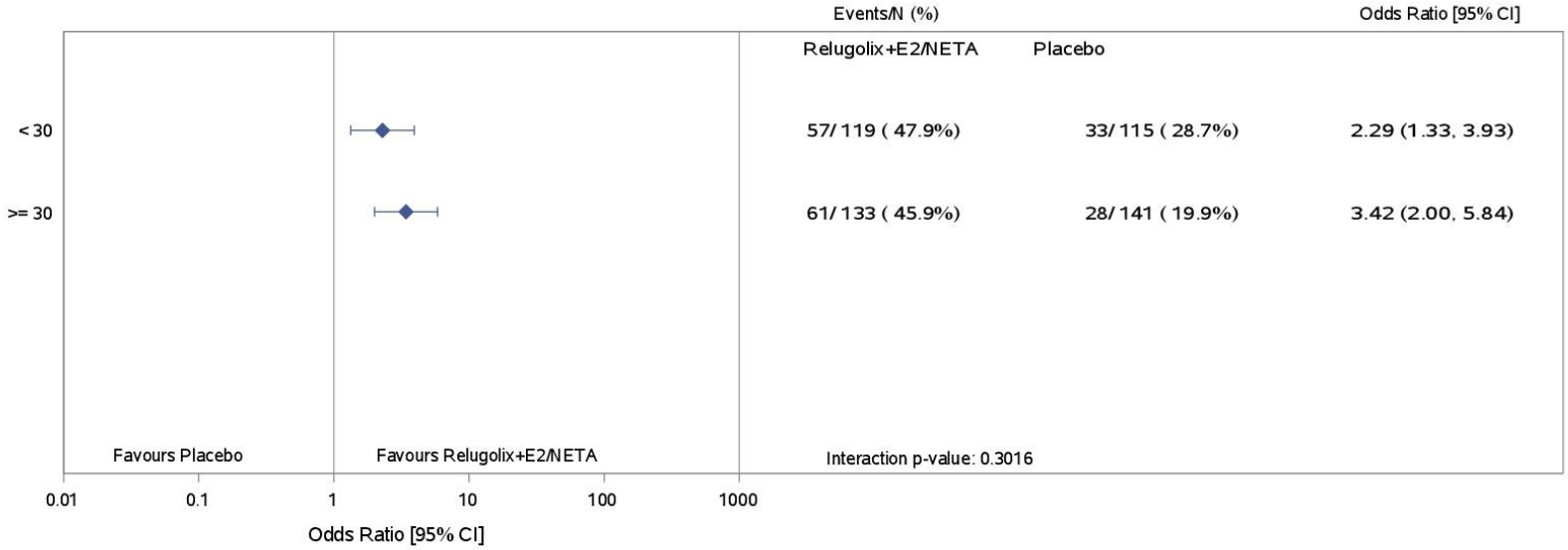
Figure EFF.MAXNRS1.MITT.S2.BIN.FP: Proportion of Patients with Maximum NRS Score <= 1 During the Last 35 Days of Treatment, by Subgroup (mITT Population)
Study: Pooled
Subgroup: BMI (kg/m2) at Baseline



Results are based on a logistic regression model adjusted for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates using a one-stage fixed-effects IPD meta-analysis approach. A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
The interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the Odds Ratio and 95% CI. Missing subgroup levels are not included in estimation of the interaction p-value. The reference group is Placebo.
N: Number of patients in treatment group; NETA: Norethindrone acetate; mITT: Modified intent-to-treat; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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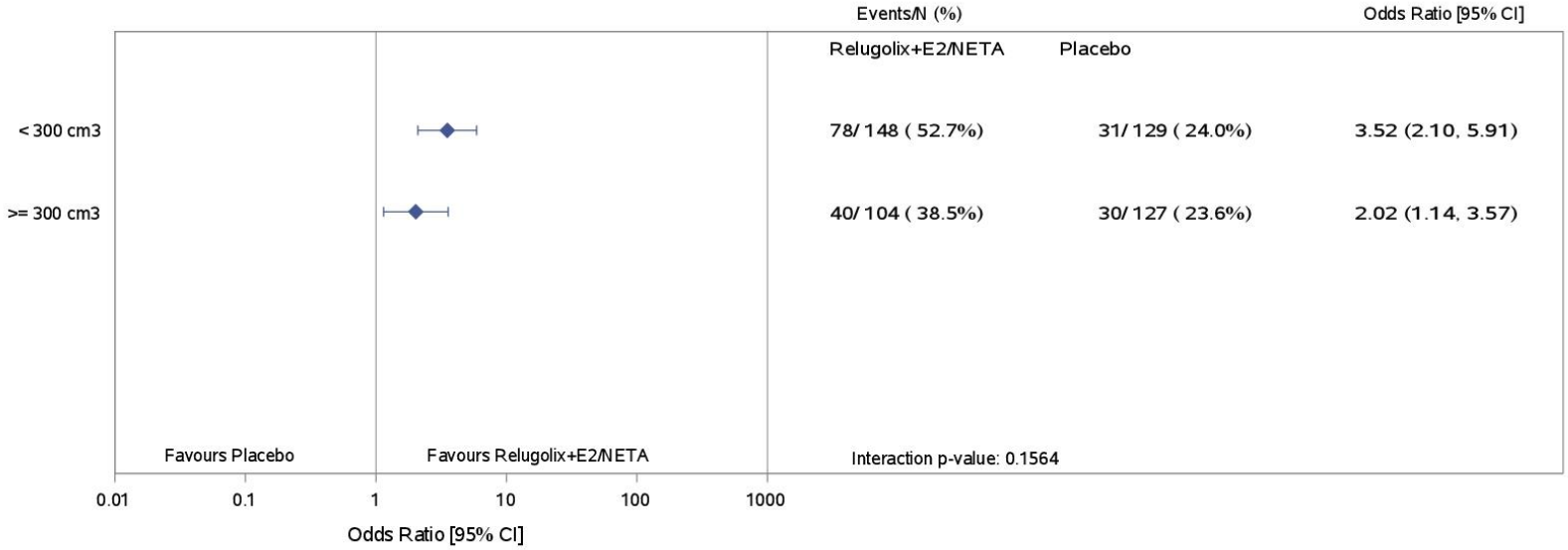
Figure EFF.MAXNRS1.MITT.S3.BIN.FP: Proportion of Patients with Maximum NRS Score <= 1 During the Last 35 Days of Treatment, by Subgroup (mITT Population)
Study: Pooled
Subgroup: Uterine Volume at Baseline (cm3)



Results are based on a logistic regression model adjusted for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates using a one-stage fixed-effects IPD meta-analysis approach. A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
The interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the Odds Ratio and 95% CI. Missing subgroup levels are not included in estimation of the interaction p-value. The reference group is Placebo.
N: Number of patients in treatment group; NETA: Norethindrone acetate; mITT: Modified intent-to-treat; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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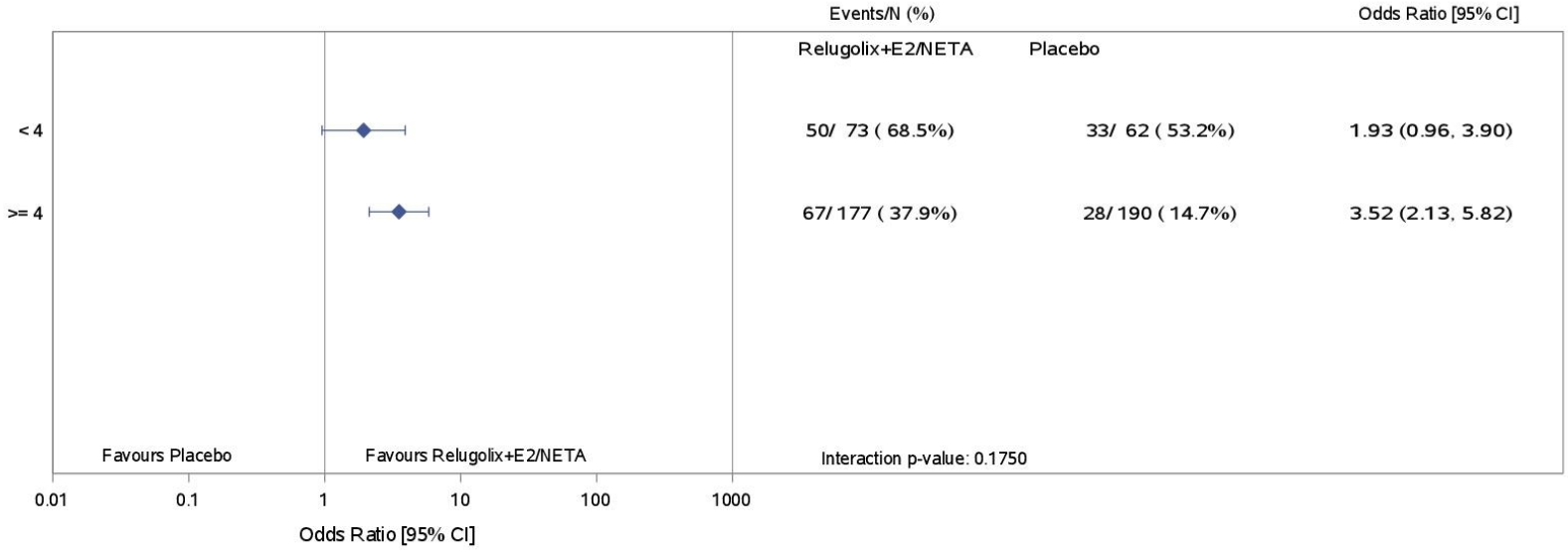
Figure EFF.MAXNRS1.MITT.S4.BIN.FP: Proportion of Patients with Maximum NRS Score <= 1 During the Last 35 Days of Treatment, by Subgroup (mITT Population)
Study: Pooled
Subgroup: Maximum NRS Pain Score at Baseline



Results are based on a logistic regression model adjusted for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates using a one-stage fixed-effects IPD meta-analysis approach. A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
The interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the Odds Ratio and 95% CI. Missing subgroup levels are not included in estimation of the interaction p-value. The reference group is Placebo.
N: Number of patients in treatment group; NETA: Norethindrone acetate; mITT: Modified intent-to-treat; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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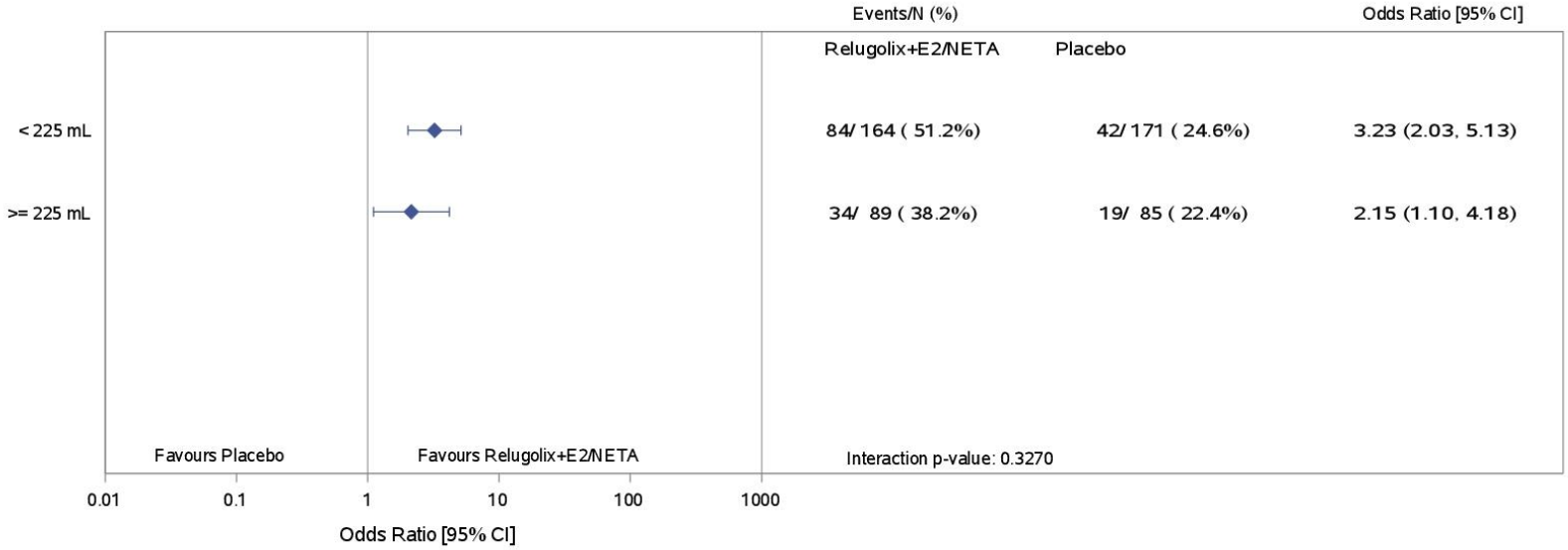
Figure EFF.MAXNRS1.MITT.S5.BIN.FP: Proportion of Patients with Maximum NRS Score <= 1 During the Last 35 Days of Treatment, by Subgroup (mITT Population)
Study: Pooled
Subgroup: MBL Volume at Baseline (mL)



Results are based on a logistic regression model adjusted for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates using a one-stage fixed-effects IPD meta-analysis approach. A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
The interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the Odds Ratio and 95% CI. Missing subgroup levels are not included in estimation of the interaction p-value. The reference group is Placebo.
N: Number of patients in treatment group; NETA: Norethindrone acetate; mITT: Modified intent-to-treat; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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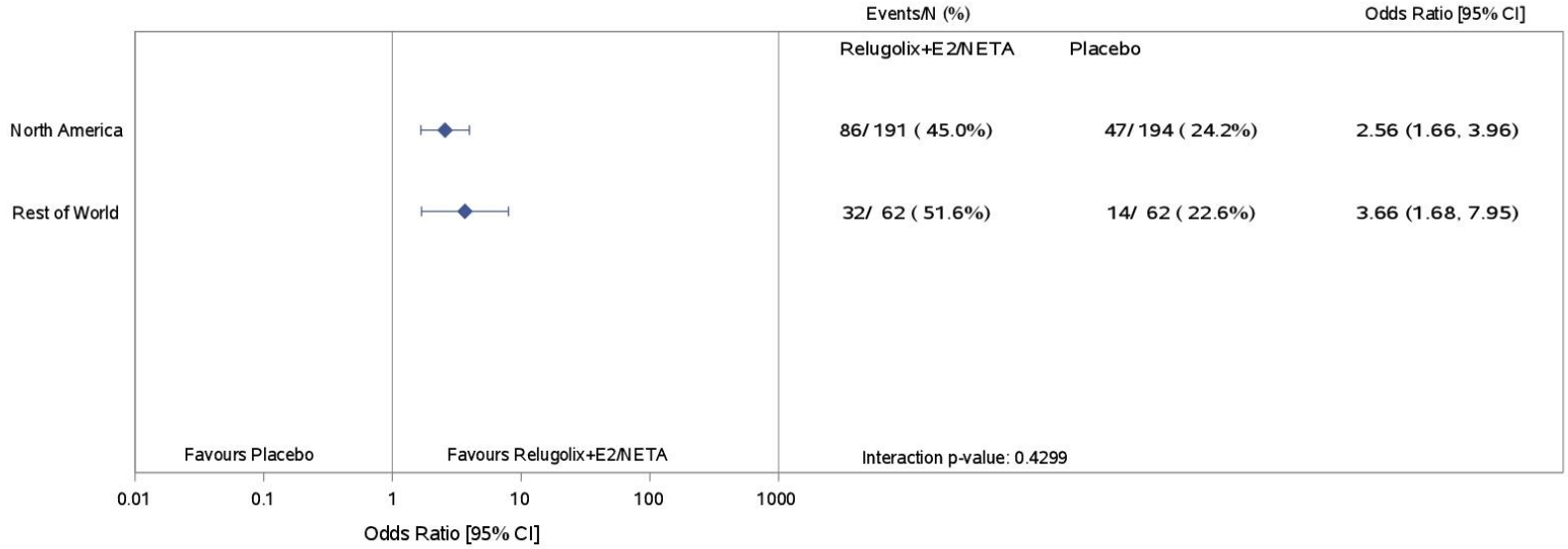
Figure EFF.MAXNRS1.MITT.S6.BIN.FP: Proportion of Patients with Maximum NRS Score <= 1 During the Last 35 Days of Treatment, by Subgroup (mITT Population)
Study: Pooled
Subgroup: Geographic Region I



Results are based on a logistic regression model adjusted for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates using a one-stage fixed-effects IPD meta-analysis approach. A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
The interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the Odds Ratio and 95% CI. Missing subgroup levels are not included in estimation of the interaction p-value. The reference group is Placebo.
N: Number of patients in treatment group; NETA: Norethindrone acetate; mITT: Modified intent-to-treat; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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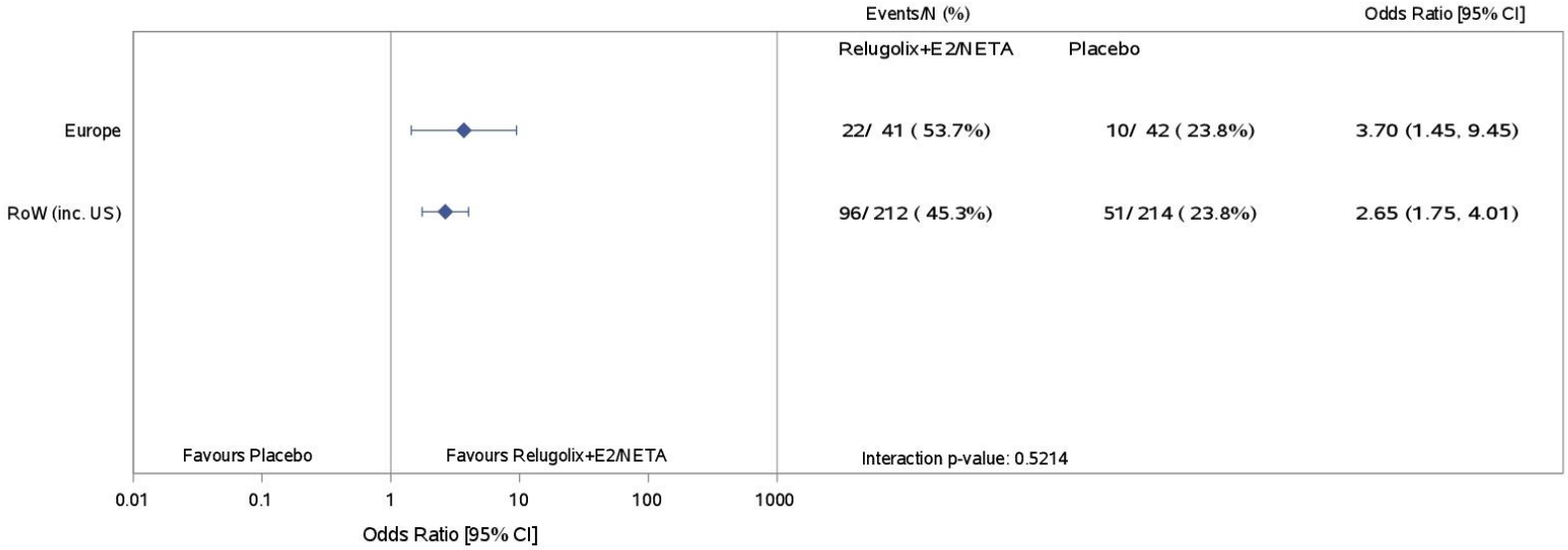
Figure EFF.MAXNRS1.MITT.S7.BIN.FP: Proportion of Patients with Maximum NRS Score <= 1 During the Last 35 Days of Treatment, by Subgroup (mITT Population)
Study: Pooled
Subgroup: Geographic Region II



Results are based on a logistic regression model adjusted for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates using a one-stage fixed-effects IPD meta-analysis approach. A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
The interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the Odds Ratio and 95% CI. Missing subgroup levels are not included in estimation of the interaction p-value. The reference group is Placebo.
N: Number of patients in treatment group; NETA: Norethindrone acetate; mITT: Modified intent-to-treat; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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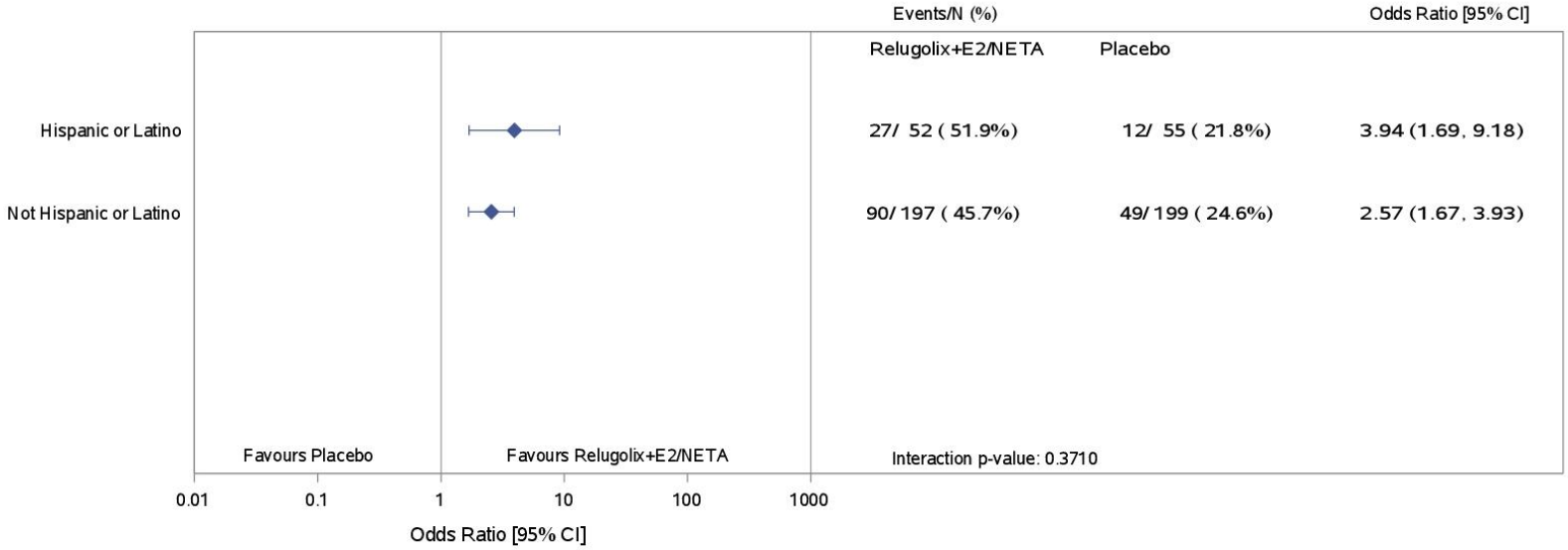
Figure EFF.MAXNRS1.MITT.S8.BIN.FP: Proportion of Patients with Maximum NRS Score <= 1 During the Last 35 Days of Treatment, by Subgroup (mITT Population)
Study: Pooled
Subgroup: Ethnicity



Results are based on a logistic regression model adjusted for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates using a one-stage fixed-effects IPD meta-analysis approach. A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
The interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the Odds Ratio and 95% CI. Missing subgroup levels are not included in estimation of the interaction p-value. The reference group is Placebo.
N: Number of patients in treatment group; NETA: Norethindrone acetate; mITT: Modified intent-to-treat; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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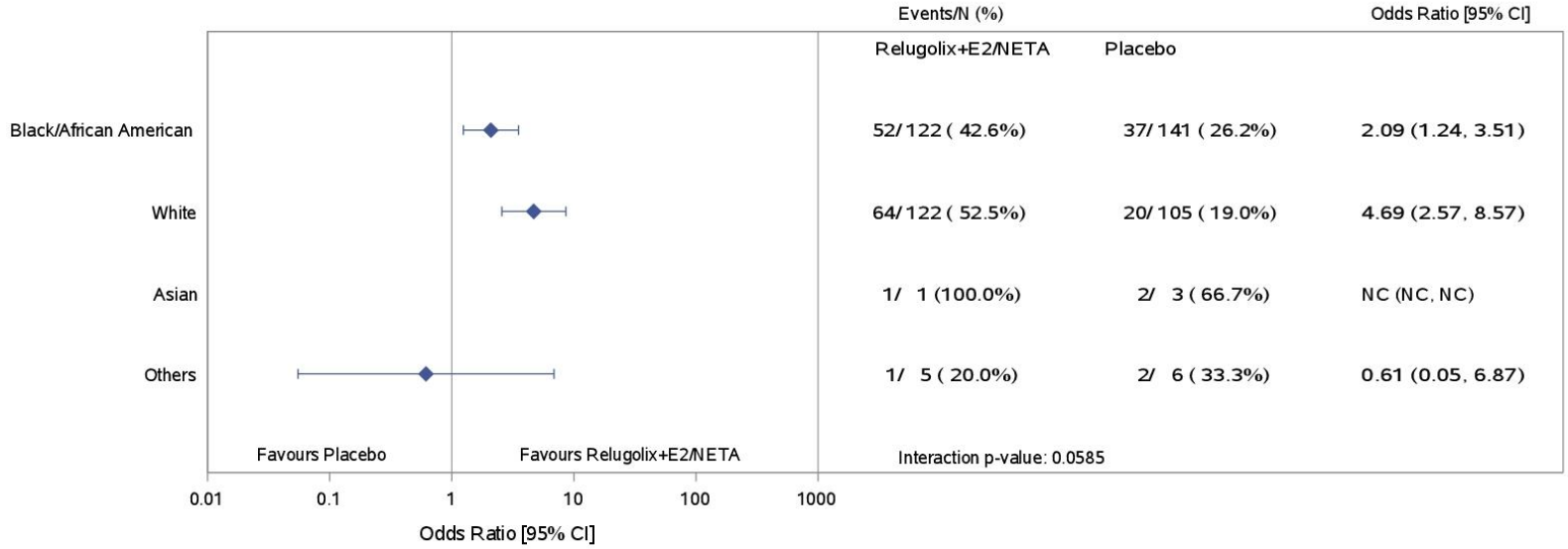
Figure EFF.MAXNRS1.MITT.S9.BIN.FP: Proportion of Patients with Maximum NRS Score <= 1 During the Last 35 Days of Treatment, by Subgroup (mITT Population)
Study: Pooled
Subgroup: Race



Results are based on a logistic regression model adjusted for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates using a one-stage fixed-effects IPD meta-analysis approach. A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
The interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the Odds Ratio and 95% CI. Missing subgroup levels are not included in estimation of the interaction p-value. The reference group is Placebo.
N: Number of patients in treatment group; NETA: Norethindrone acetate; mITT: Modified intent-to-treat; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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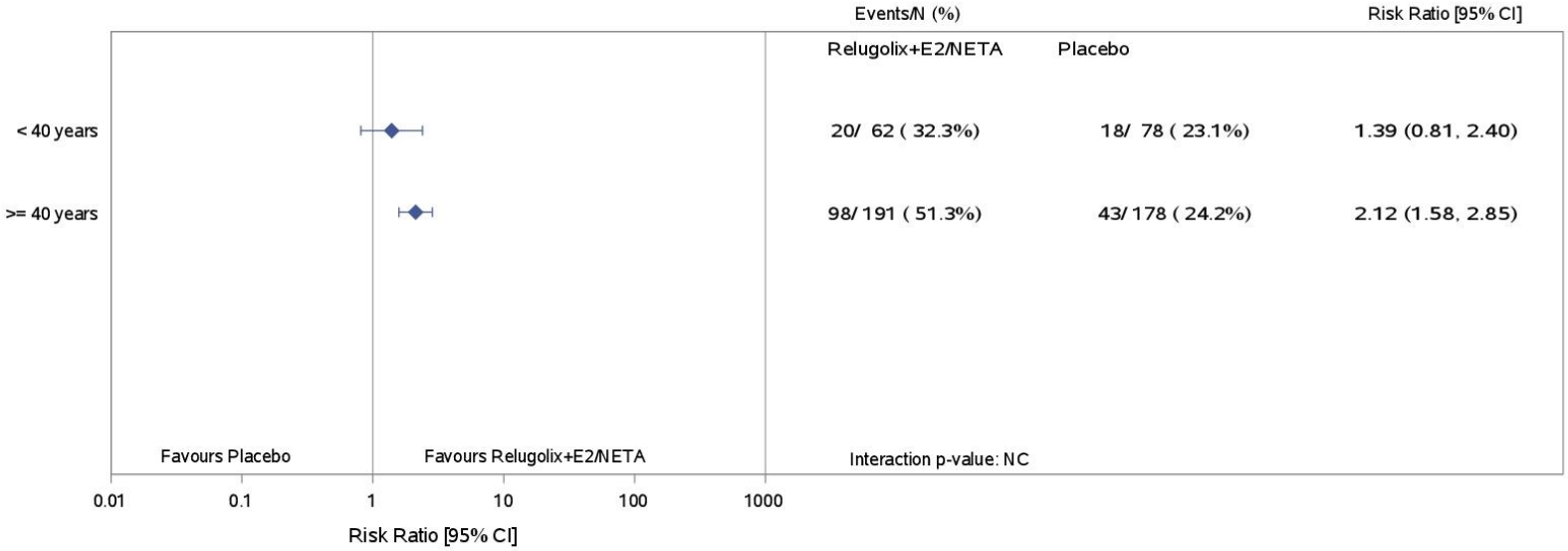
Figure EFF.MAXNRS1.MITT.S1.BIN.FP.RR: Proportion of Patients with Maximum NRS Score <= 1 During the Last 35 Days of Treatment, by Subgroup (mITT Population) - Risk Ratio
Study: Pooled
Subgroup: Age (years)



Results are based on a Cochran-Mantel-Haenszel approach stratified by study using a one-stage fixed-effects IPD meta-analysis. A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
The reference group is Placebo.
N: Number of patients in treatment group; NETA: Norethindrone acetate; mITT: Modified intent-to-treat; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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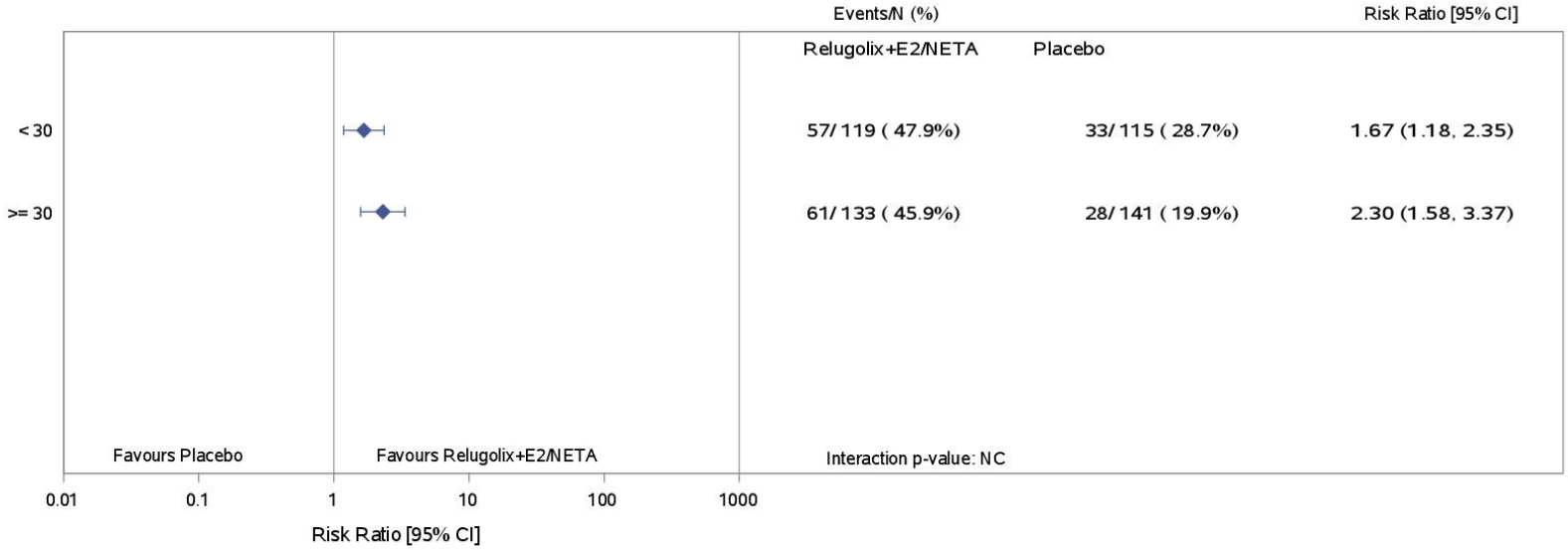
Figure EFF.MAXNRS1.MITT.S2.BIN.FP.RR: Proportion of Patients with Maximum NRS Score <= 1 During the Last 35 Days of Treatment, by Subgroup (mITT Population) - Risk Ratio
Study: Pooled
Subgroup: BMI (kg/m2) at Baseline



Results are based on a Cochran-Mantel-Haenszel approach stratified by study using a one-stage fixed-effects IPD meta-analysis. A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
The reference group is Placebo.
N: Number of patients in treatment group; NETA: Norethindrone acetate; mITT: Modified intent-to-treat; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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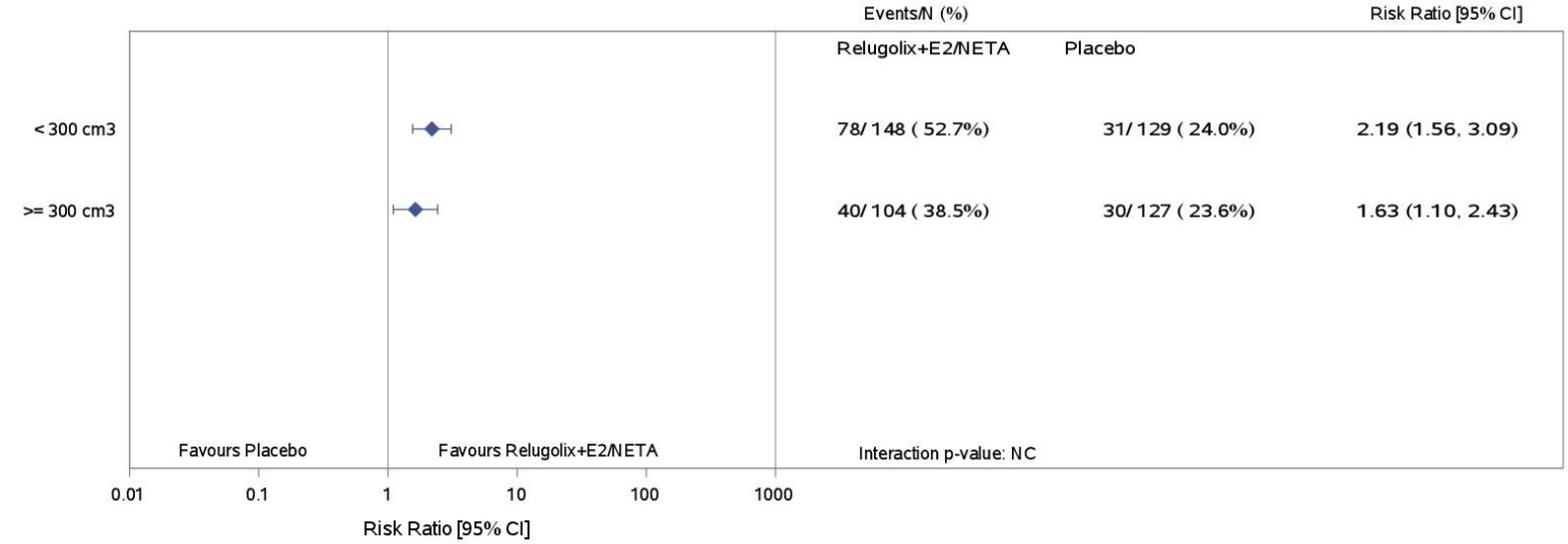
Figure EFF.MAXNRS1.MITT.S3.BIN.FP.RR: Proportion of Patients with Maximum NRS Score <= 1 During the Last 35 Days of Treatment, by Subgroup (mITT Population) - Risk Ratio
Study: Pooled
Subgroup: Uterine Volume at Baseline (cm3)



Results are based on a Cochran-Mantel-Haenszel approach stratified by study using a one-stage fixed-effects IPD meta-analysis. A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
The reference group is Placebo.
N: Number of patients in treatment group; NETA: Norethindrone acetate; mITT: Modified intent-to-treat; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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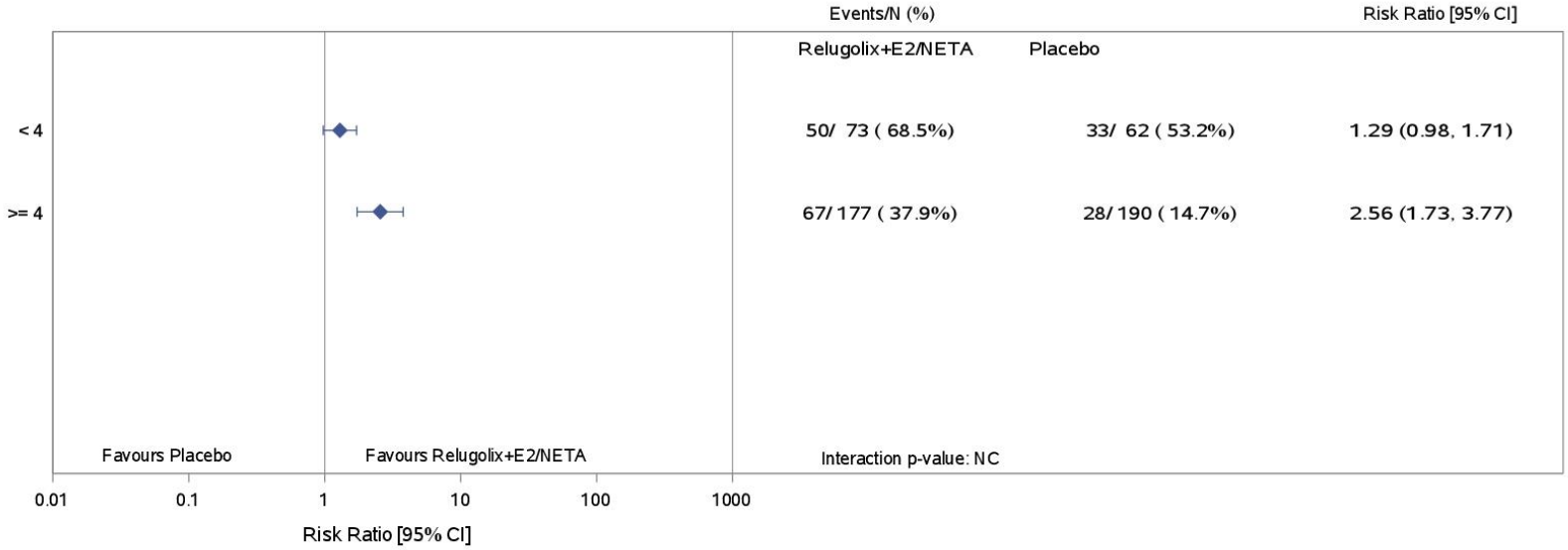
Figure EFF.MAXNRS1.MITT.S4.BIN.FP.RR: Proportion of Patients with Maximum NRS Score <= 1 During the Last 35 Days of Treatment, by Subgroup (mITT Population) - Risk Ratio
Study: Pooled
Subgroup: Maximum NRS Pain Score at Baseline



Results are based on a Cochran-Mantel-Haenszel approach stratified by study using a one-stage fixed-effects IPD meta-analysis. A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
The reference group is Placebo.
N: Number of patients in treatment group; NETA: Norethindrone acetate; mITT: Modified intent-to-treat; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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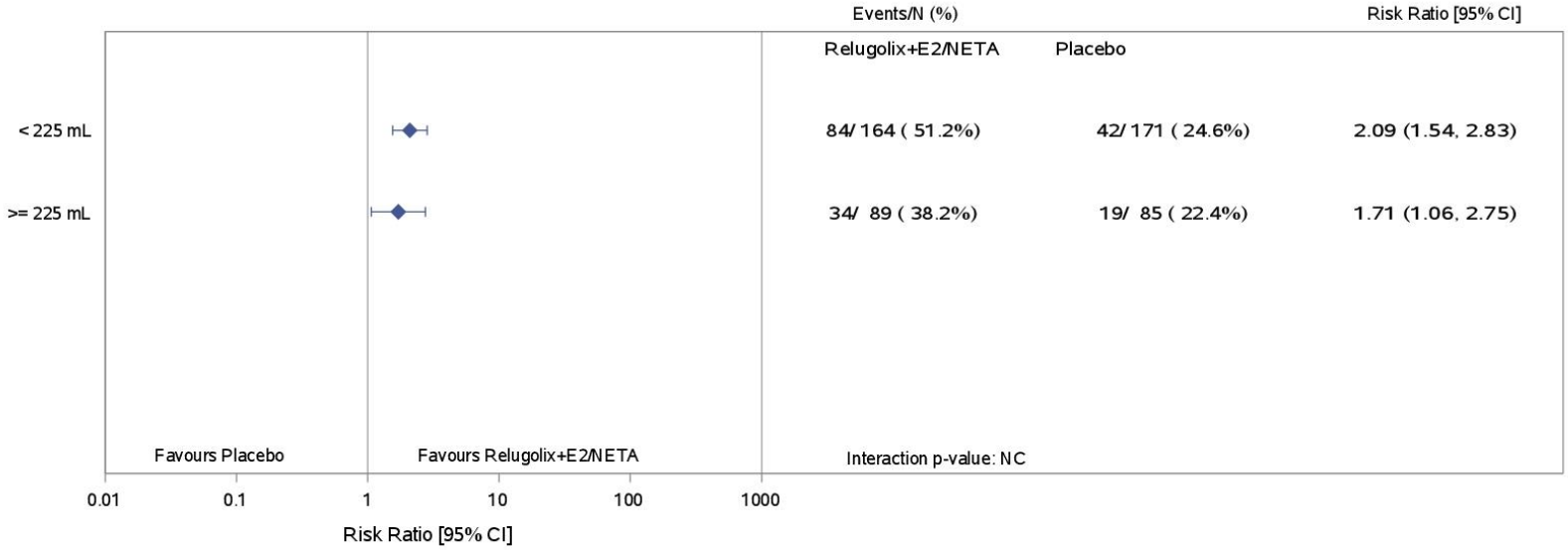
Figure EFF.MAXNRS1.MITT.S5.BIN.FP.RR: Proportion of Patients with Maximum NRS Score <= 1 During the Last 35 Days of Treatment, by Subgroup (mITT Population) - Risk Ratio
Study: Pooled
Subgroup: MBL Volume at Baseline (mL)



Results are based on a Cochran-Mantel-Haenszel approach stratified by study using a one-stage fixed-effects IPD meta-analysis. A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
The reference group is Placebo.
N: Number of patients in treatment group; NETA: Norethindrone acetate; mITT: Modified intent-to-treat; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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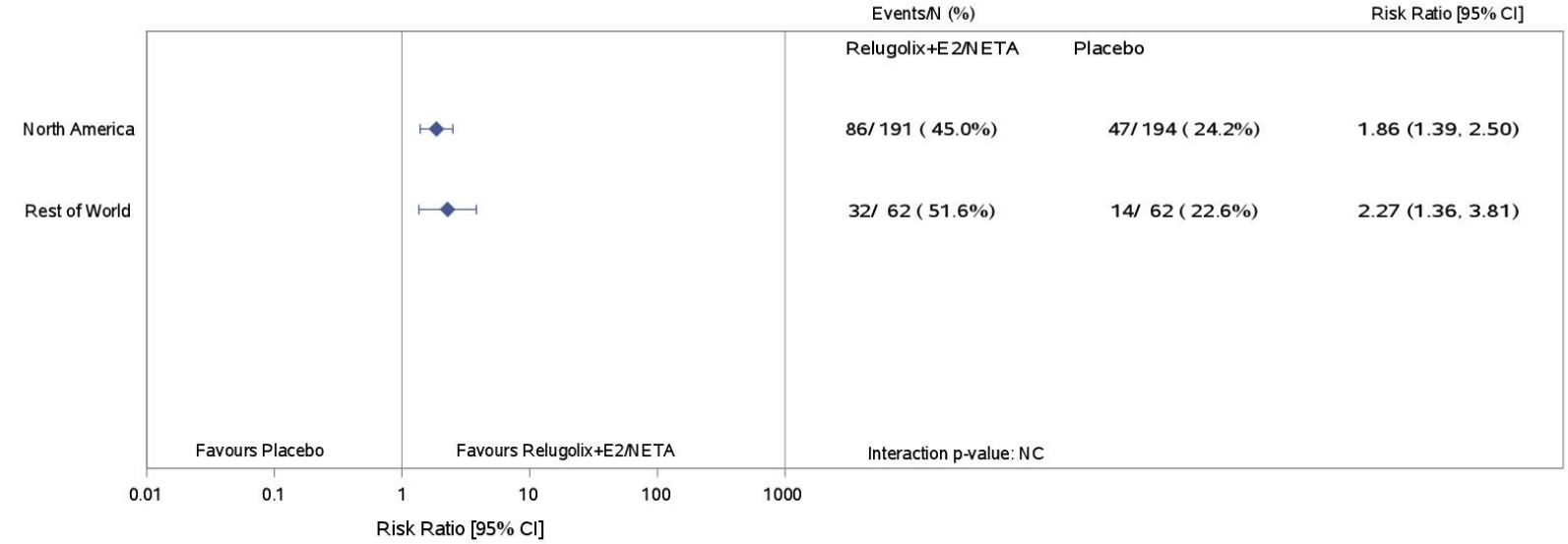
Figure EFF.MAXNRS1.MITT.S6.BIN.FP.RR: Proportion of Patients with Maximum NRS Score <= 1 During the Last 35 Days of Treatment, by Subgroup (mITT Population) - Risk Ratio
Study: Pooled
Subgroup: Geographic Region I



Results are based on a Cochran-Mantel-Haenszel approach stratified by study using a one-stage fixed-effects IPD meta-analysis. A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
The reference group is Placebo.
N: Number of patients in treatment group; NETA: Norethindrone acetate; mITT: Modified intent-to-treat; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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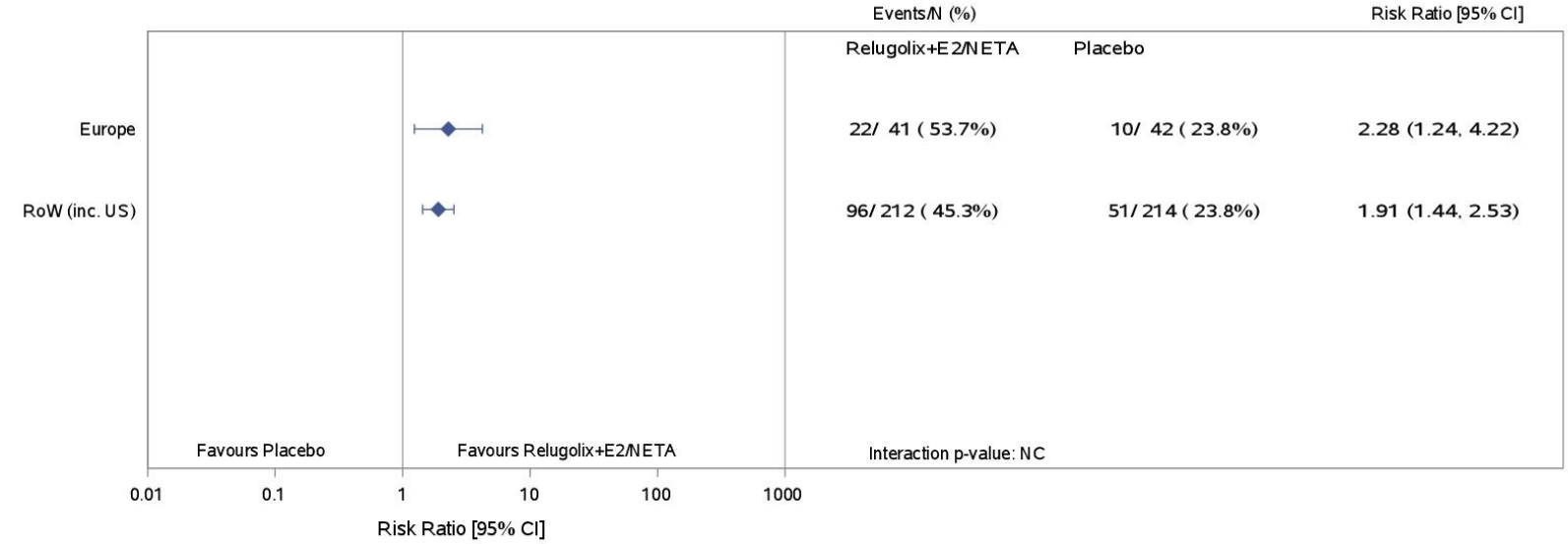
Figure EFF.MAXNRS1.MITT.S7.BIN.FP.RR: Proportion of Patients with Maximum NRS Score <= 1 During the Last 35 Days of Treatment, by Subgroup (mITT Population) - Risk Ratio
Study: Pooled
Subgroup: Geographic Region II



Results are based on a Cochran-Mantel-Haenszel approach stratified by study using a one-stage fixed-effects IPD meta-analysis. A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
The reference group is Placebo.
N: Number of patients in treatment group; NETA: Norethindrone acetate; mITT: Modified intent-to-treat; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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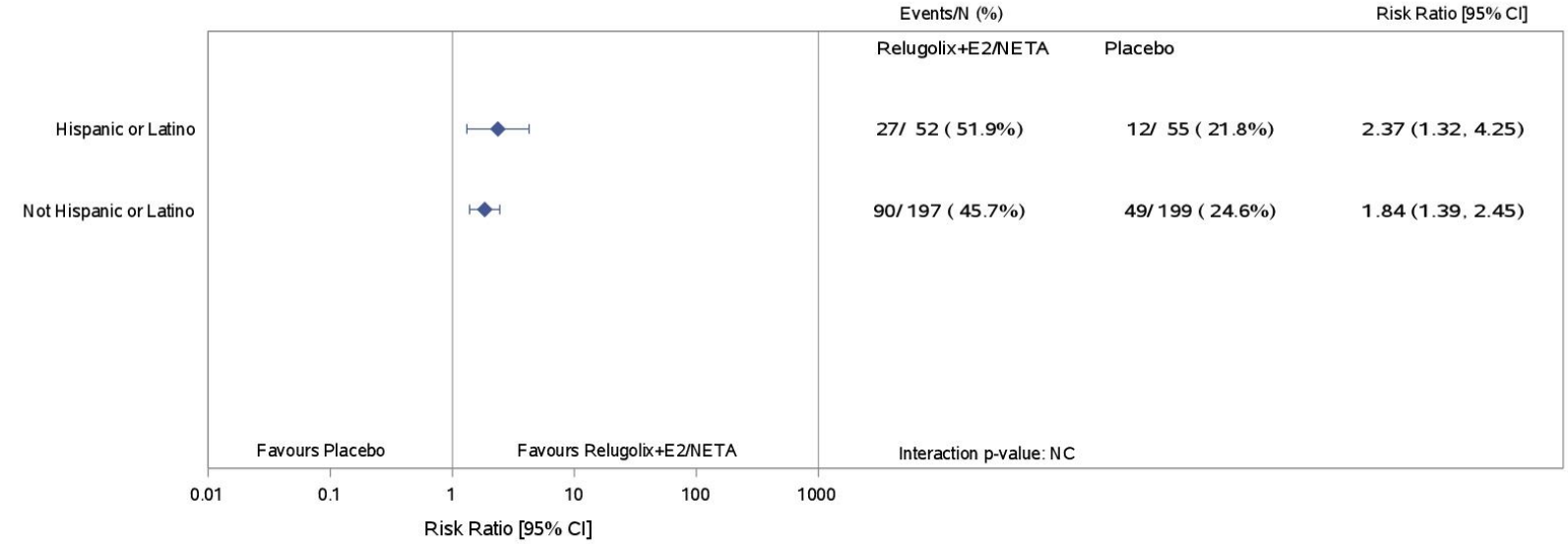
Figure EFF.MAXNRS1.MITT.S8.BIN.FP.RR: Proportion of Patients with Maximum NRS Score <= 1 During the Last 35 Days of Treatment, by Subgroup (mITT Population) - Risk Ratio
Study: Pooled
Subgroup: Ethnicity



Results are based on a Cochran-Mantel-Haenszel approach stratified by study using a one-stage fixed-effects IPD meta-analysis. A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
The reference group is Placebo.
N: Number of patients in treatment group; NETA: Norethindrone acetate; mITT: Modified intent-to-treat; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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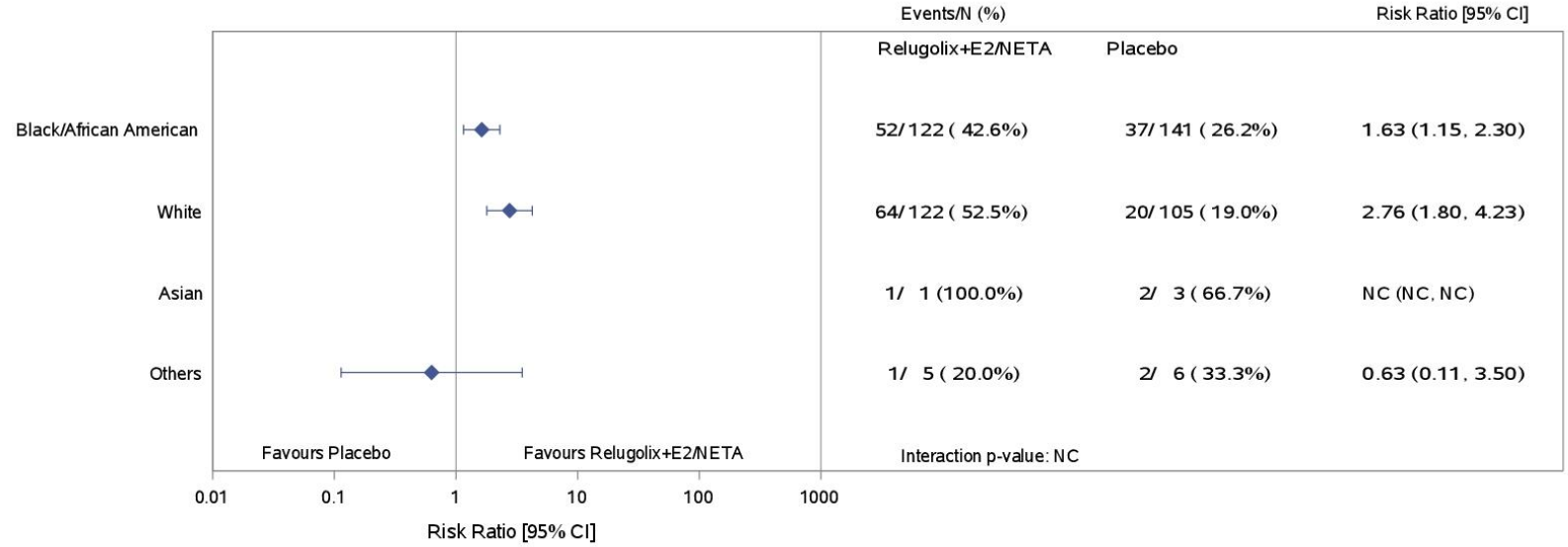
Figure EFF.MAXNRS1.MITT.S9.BIN.FP.RR: Proportion of Patients with Maximum NRS Score <= 1 During the Last 35 Days of Treatment, by Subgroup (mITT Population) - Risk Ratio
Study: Pooled
Subgroup: Race



Results are based on a Cochran-Mantel-Haenszel approach stratified by study using a one-stage fixed-effects IPD meta-analysis. A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
The reference group is Placebo.
N: Number of patients in treatment group; NETA: Norethindrone acetate; mITT: Modified intent-to-treat; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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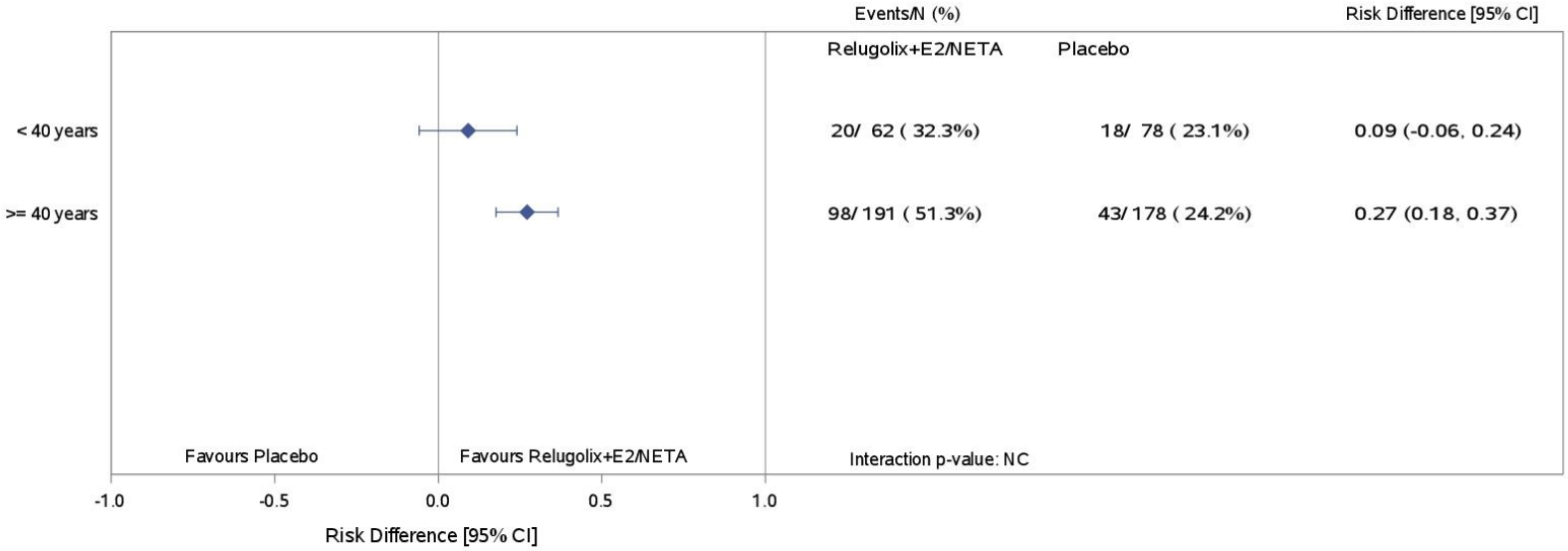
Figure EFF.MAXNRS1.MITT.S1.BIN.FP.RD: Proportion of Patients with Maximum NRS Score <= 1 During the Last 35 Days of Treatment, by Subgroup (mITT Population) - Risk Difference
Study: Pooled
Subgroup: Age (years)



Results are based on a Mantel-Haenszel approach stratified by study using a one-stage fixed-effects IPD meta-analysis.
The reference group is Placebo.
N: Number of patients in treatment group; NETA: Norethindrone acetate; mITT: Modified intent-to-treat; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

SOURCE: X:\Numerus\Studies\MYV\MYV102\Analysis\Prod\Progs\TFLs\Fig_EFF_NRS_S_BIN_FP.SAS Date/time of run: 30JUN21 10:26
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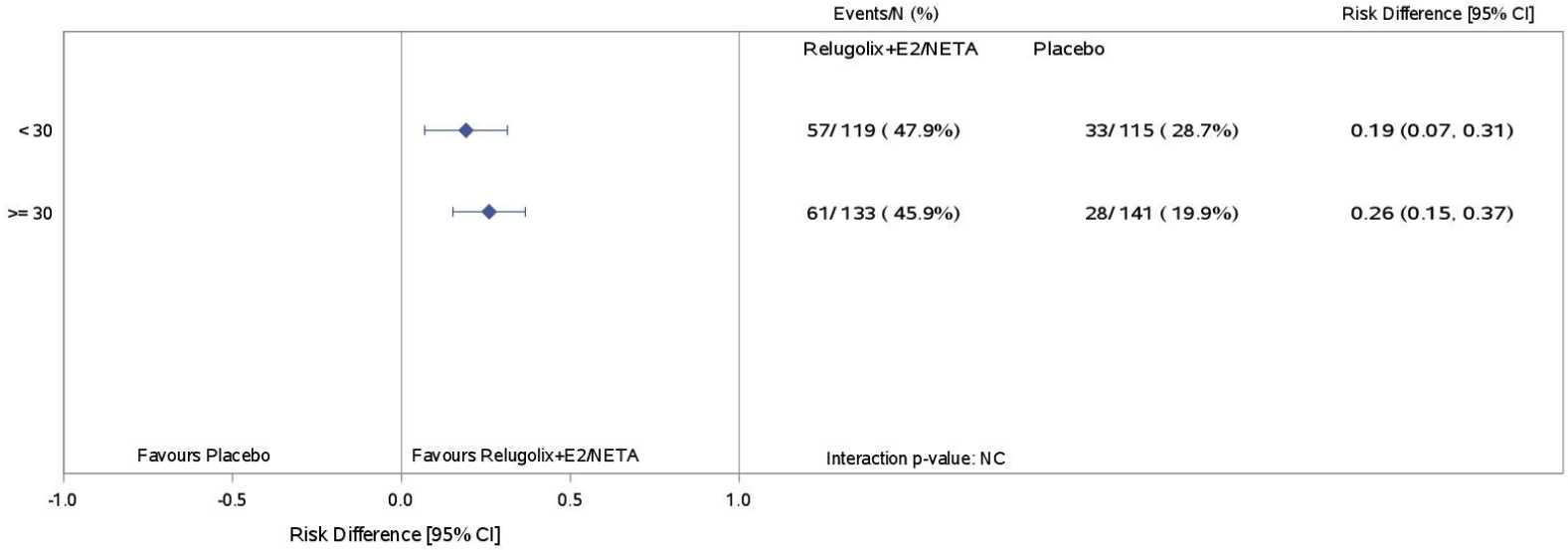
Figure EFF.MAXNRS1.MITT.S2.BIN.FP.RD: Proportion of Patients with Maximum NRS Score <= 1 During the Last 35 Days of Treatment, by Subgroup (mITT Population) - Risk Difference
Study: Pooled
Subgroup: BMI (kg/m2) at Baseline



Results are based on a Mantel-Haenszel approach stratified by study using a one-stage fixed-effects IPD meta-analysis.
The reference group is Placebo.
N: Number of patients in treatment group; NETA: Norethindrone acetate; mITT: Modified intent-to-treat; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

SOURCE: X:\Numerus\Studies\MYV\MYV102\Analysis\Prod\Progs\TFLs\Fig_EFF_NRS_S_BIN_FP.SAS Date/time of run: 30JUN21 10:26
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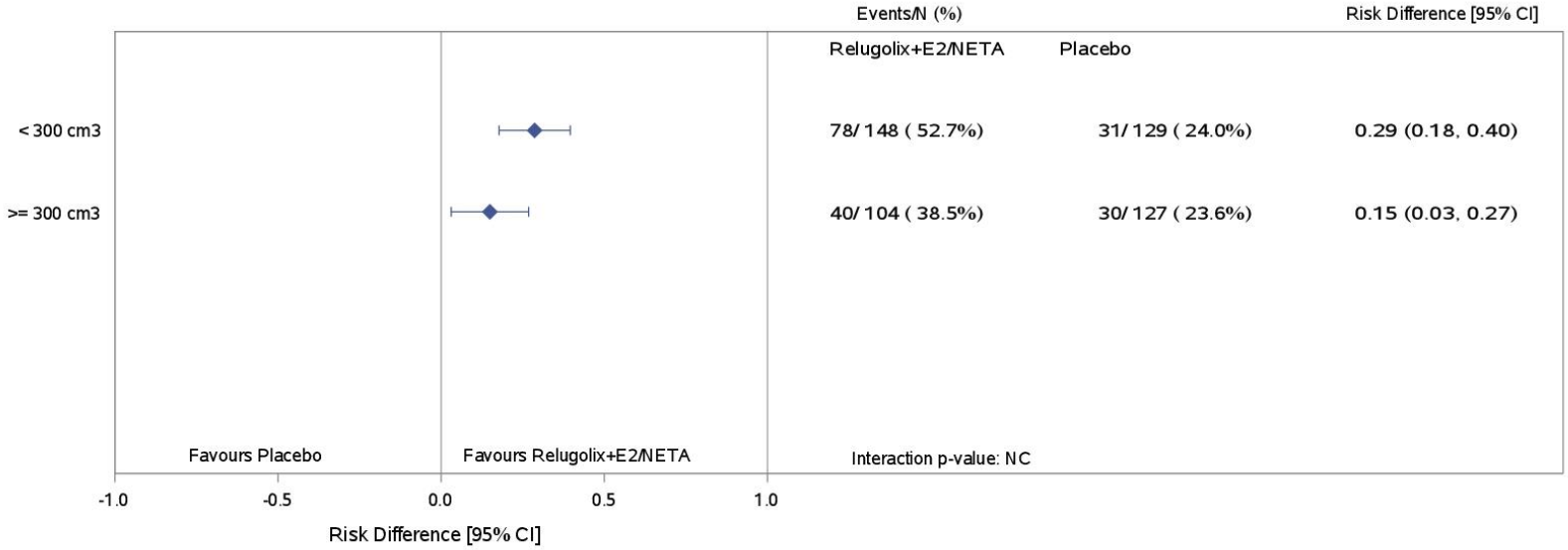
Figure EFF.MAXNRS1.MITT.S3.BIN.FP.RD: Proportion of Patients with Maximum NRS Score <= 1 During the Last 35 Days of Treatment, by Subgroup (mITT Population) - Risk Difference
Study: Pooled
Subgroup: Uterine Volume at Baseline (cm3)



Results are based on a Mantel-Haenszel approach stratified by study using a one-stage fixed-effects IPD meta-analysis.
The reference group is Placebo.
N: Number of patients in treatment group; NETA: Norethindrone acetate; mITT: Modified intent-to-treat; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

SOURCE: X:\Numerus\Studies\MYV\MYV102\Analysis\Prod\Progs\TFLs\Fig_EFF_NRS_S_BIN_FP.SAS Date/time of run: 30JUN21 10:26
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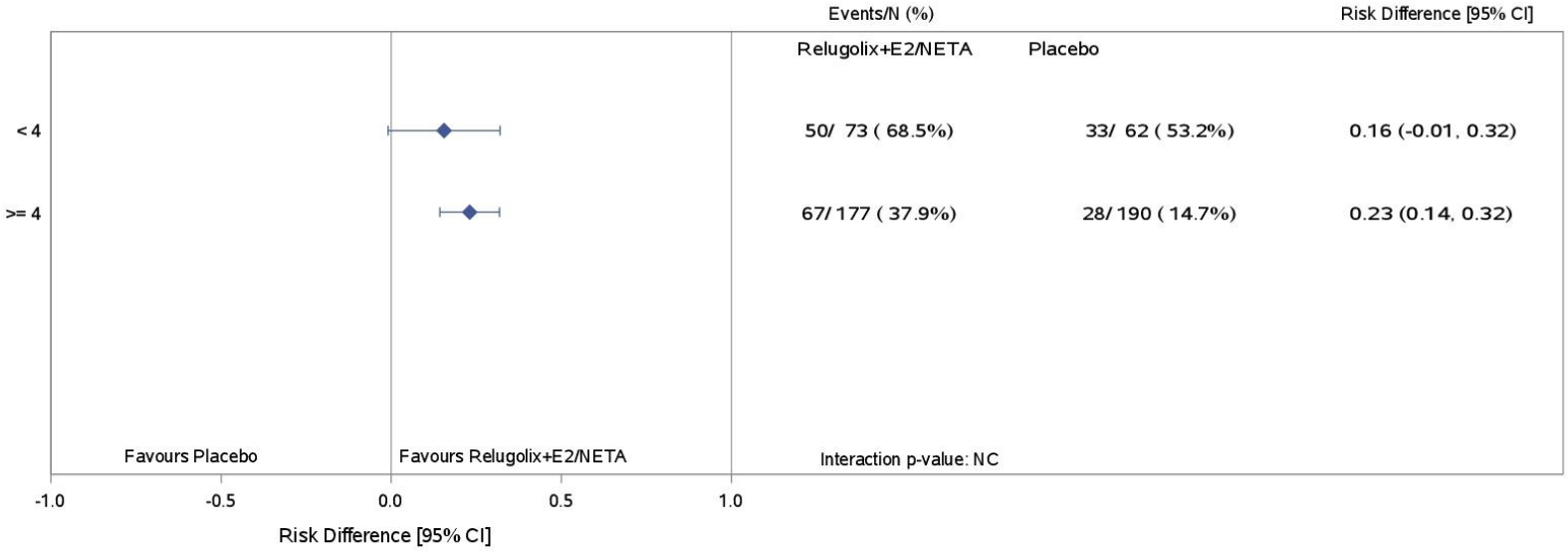
Figure EFF.MAXNRS1.MITT.S4.BIN.FP.RD: Proportion of Patients with Maximum NRS Score <= 1 During the Last 35 Days of Treatment, by Subgroup (mITT Population) - Risk Difference
Study: Pooled
Subgroup: Maximum NRS Pain Score at Baseline



Results are based on a Mantel-Haenszel approach stratified by study using a one-stage fixed-effects IPD meta-analysis.
The reference group is Placebo.
N: Number of patients in treatment group; NETA: Norethindrone acetate; mITT: Modified intent-to-treat; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

SOURCE: X:\Numerus\Studies\MYV\MYV102\Analysis\Prod\Progs\TFLs\Fig_EFF_NRS_S_BIN_FP.SAS Date/time of run: 30JUN21 10:26
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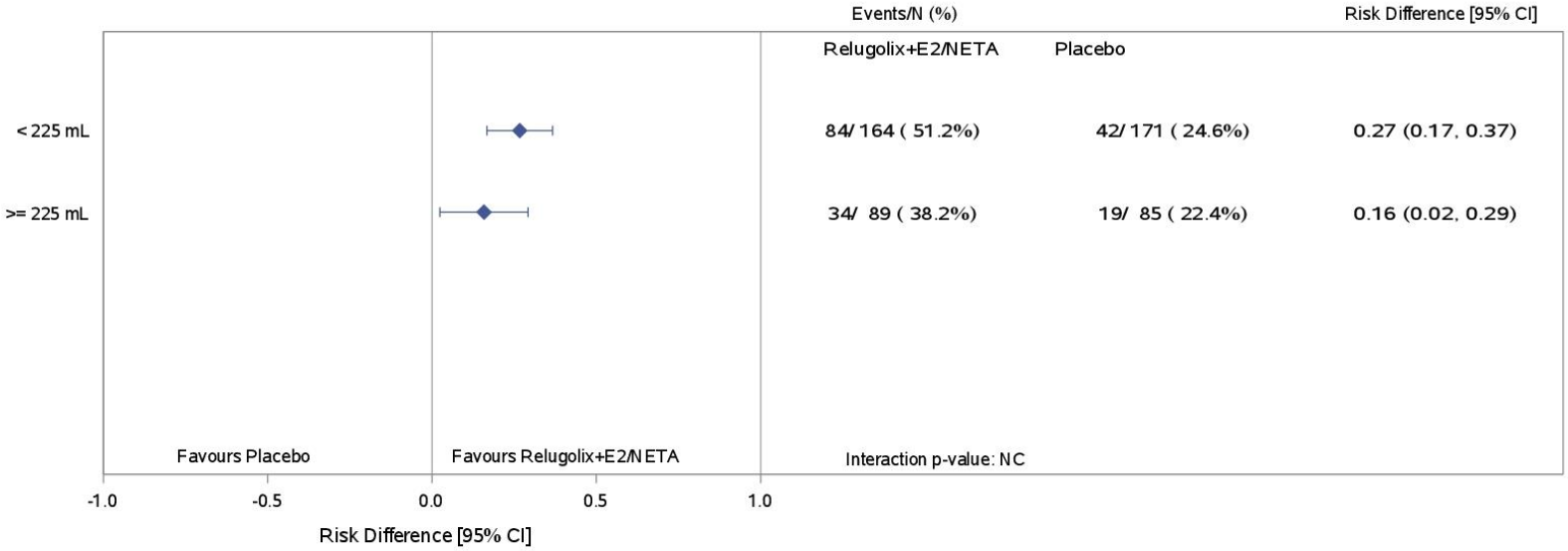
Figure EFF.MAXNRS1.MITT.S5.BIN.FP.RD: Proportion of Patients with Maximum NRS Score <= 1 During the Last 35 Days of Treatment, by Subgroup (mITT Population) - Risk Difference
Study: Pooled
Subgroup: MBL Volume at Baseline (mL)



Results are based on a Mantel-Haenszel approach stratified by study using a one-stage fixed-effects IPD meta-analysis.
The reference group is Placebo.
N: Number of patients in treatment group; NETA: Norethindrone acetate; mITT: Modified intent-to-treat; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

SOURCE: X:\Numerus\Studies\MYV\MYV102\Analysis\Prod\Progs\TFLs\Fig_EFF_NRS_S_BIN_FP.SAS Date/time of run: 30JUN21 10:26
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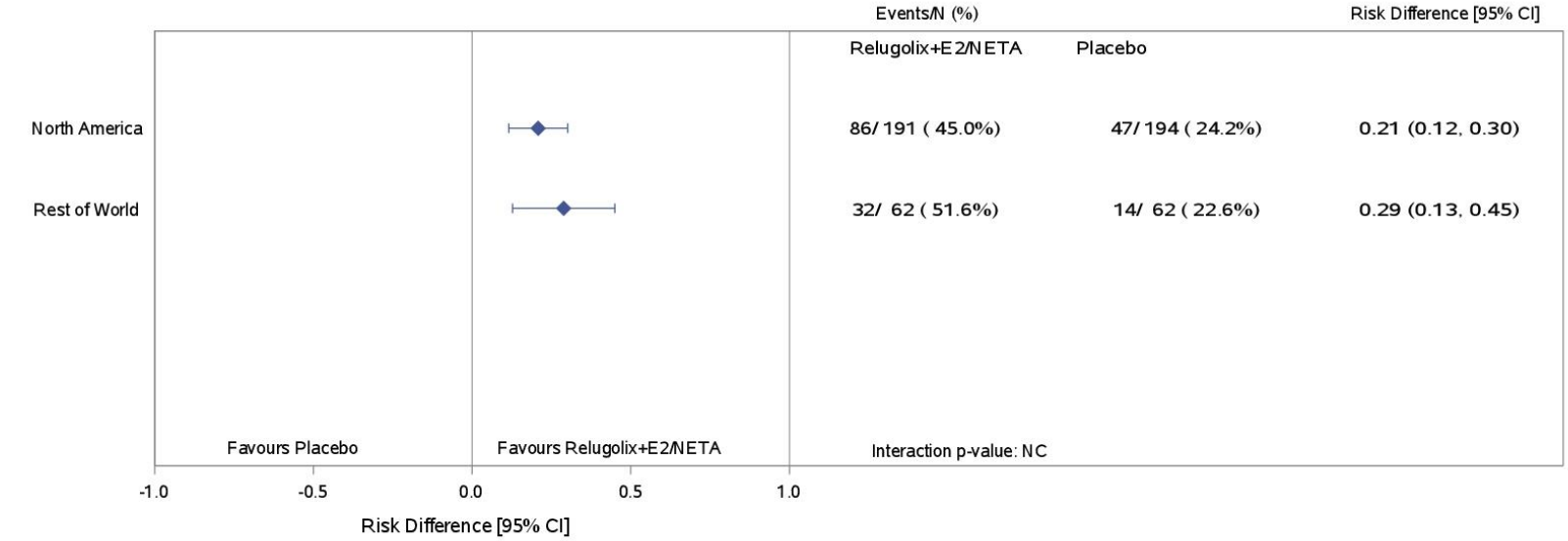
Figure EFF.MAXNRS1.MITT.S6.BIN.FP.RD: Proportion of Patients with Maximum NRS Score <= 1 During the Last 35 Days of Treatment, by Subgroup (mITT Population) - Risk Difference
Study: Pooled
Subgroup: Geographic Region I



Results are based on a Mantel-Haenszel approach stratified by study using a one-stage fixed-effects IPD meta-analysis.
The reference group is Placebo.
N: Number of patients in treatment group; NETA: Norethindrone acetate; mITT: Modified intent-to-treat; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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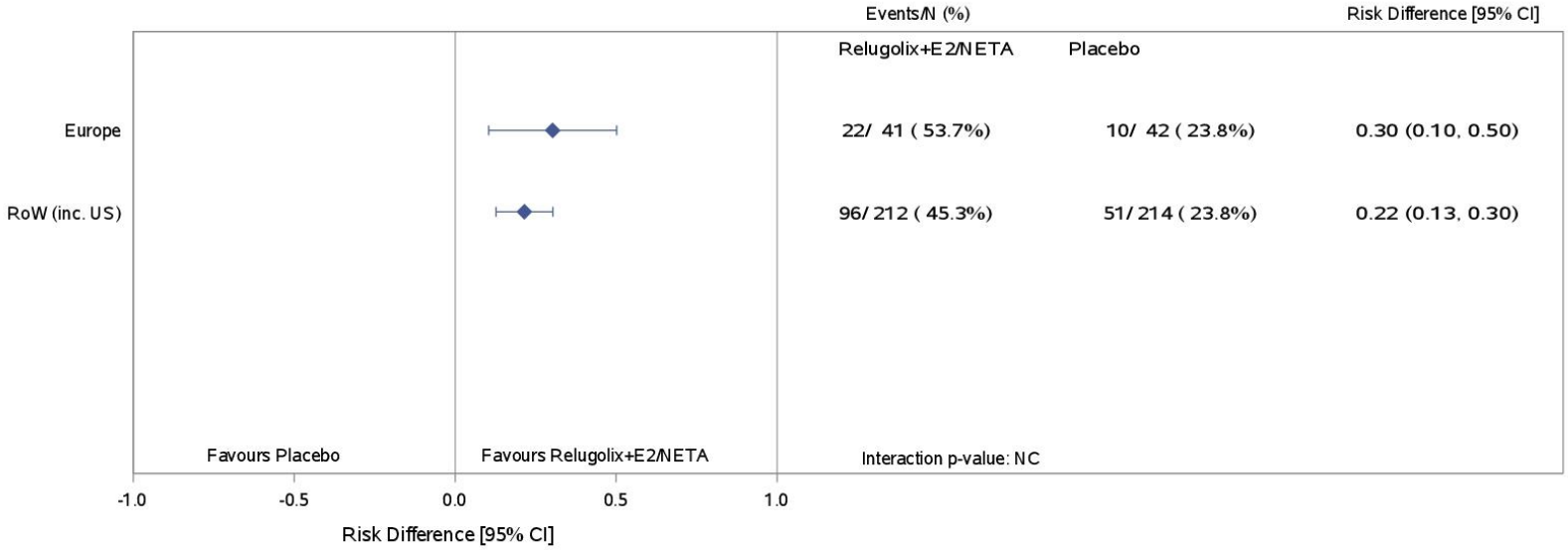
Figure EFF.MAXNRS1.MITT.S7.BIN.FP.RD: Proportion of Patients with Maximum NRS Score <= 1 During the Last 35 Days of Treatment, by Subgroup (mITT Population) - Risk Difference
Study: Pooled
Subgroup: Geographic Region II



Results are based on a Mantel-Haenszel approach stratified by study using a one-stage fixed-effects IPD meta-analysis.
The reference group is Placebo.
N: Number of patients in treatment group; NETA: Norethindrone acetate; mITT: Modified intent-to-treat; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

SOURCE: X:\Numerus\Studies\MYV\MYV102\Analysis\Prod\Progs\TFLs\Fig_EFF_NRS_S_BIN_FP.SAS Date/time of run: 30JUN21 10:26
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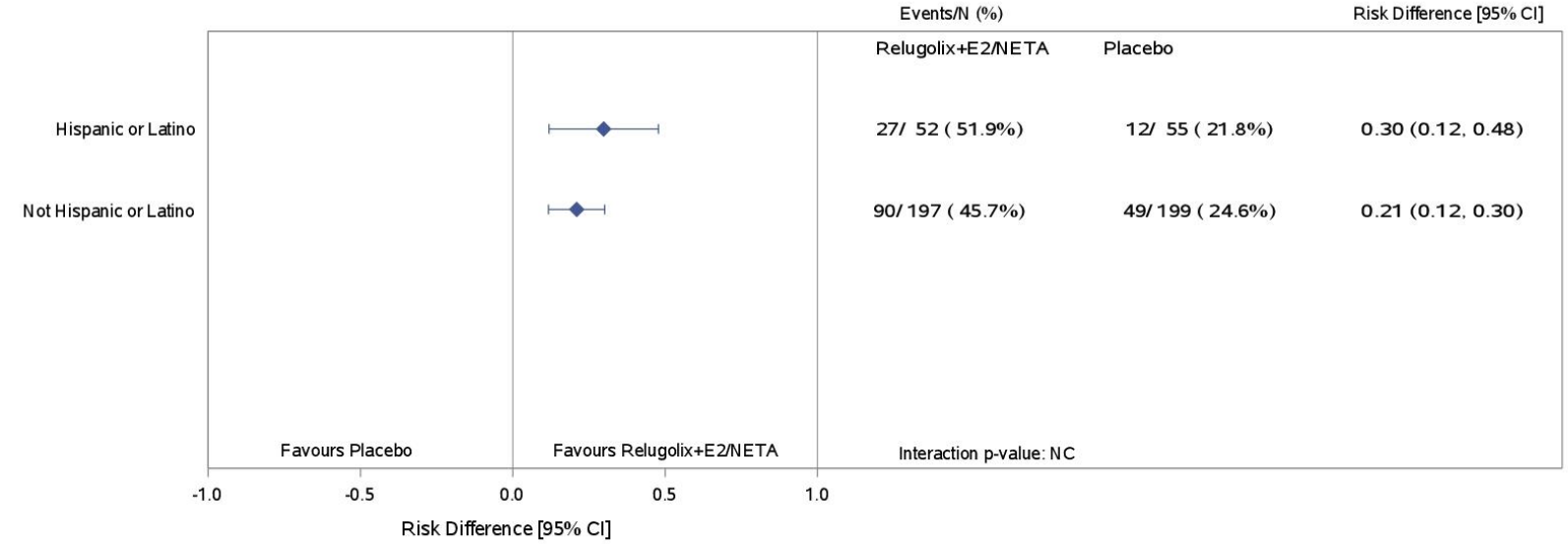
Figure EFF.MAXNRS1.MITT.S8.BIN.FP.RD: Proportion of Patients with Maximum NRS Score <= 1 During the Last 35 Days of Treatment, by Subgroup (mITT Population) - Risk Difference
Study: Pooled
Subgroup: Ethnicity



Results are based on a Mantel-Haenszel approach stratified by study using a one-stage fixed-effects IPD meta-analysis.
The reference group is Placebo.
N: Number of patients in treatment group; NETA: Norethindrone acetate; mITT: Modified intent-to-treat; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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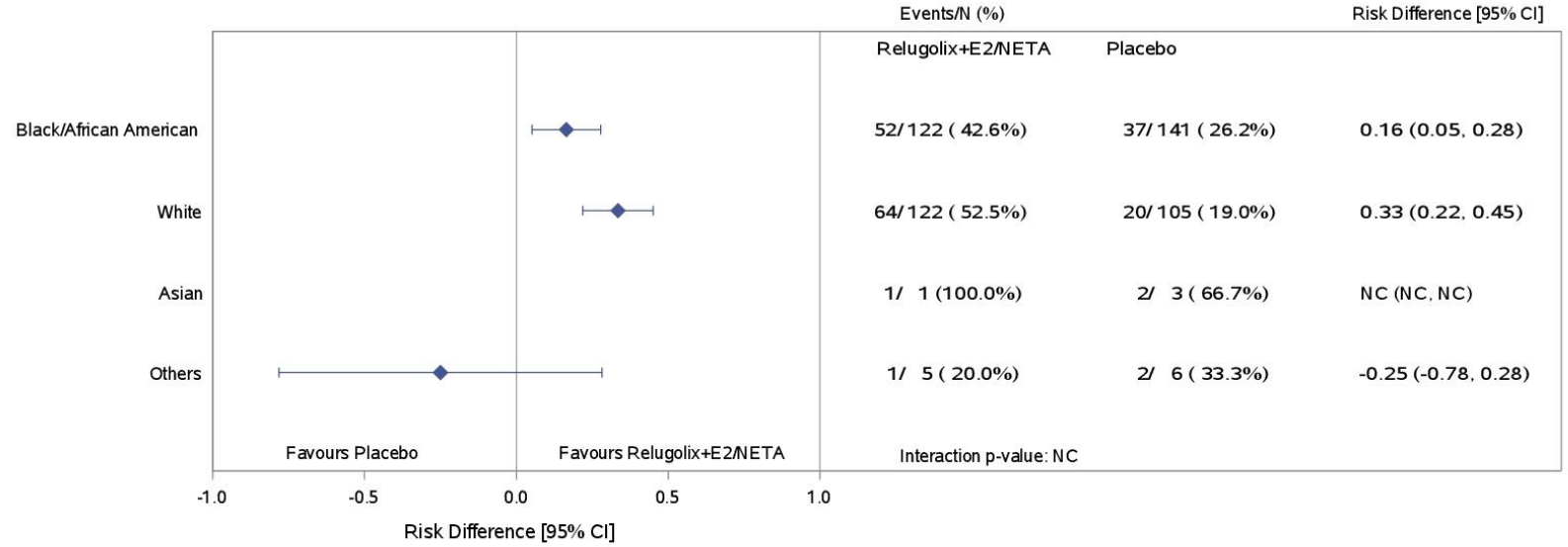
Figure EFF.MAXNRS1.MITT.S9.BIN.FP.RD: Proportion of Patients with Maximum NRS Score <= 1 During the Last 35 Days of Treatment, by Subgroup (mITT Population) - Risk Difference
Study: Pooled
Subgroup: Race



Results are based on a Mantel-Haenszel approach stratified by study using a one-stage fixed-effects IPD meta-analysis.
The reference group is Placebo.
N: Number of patients in treatment group; NETA: Norethindrone acetate; mITT: Modified intent-to-treat; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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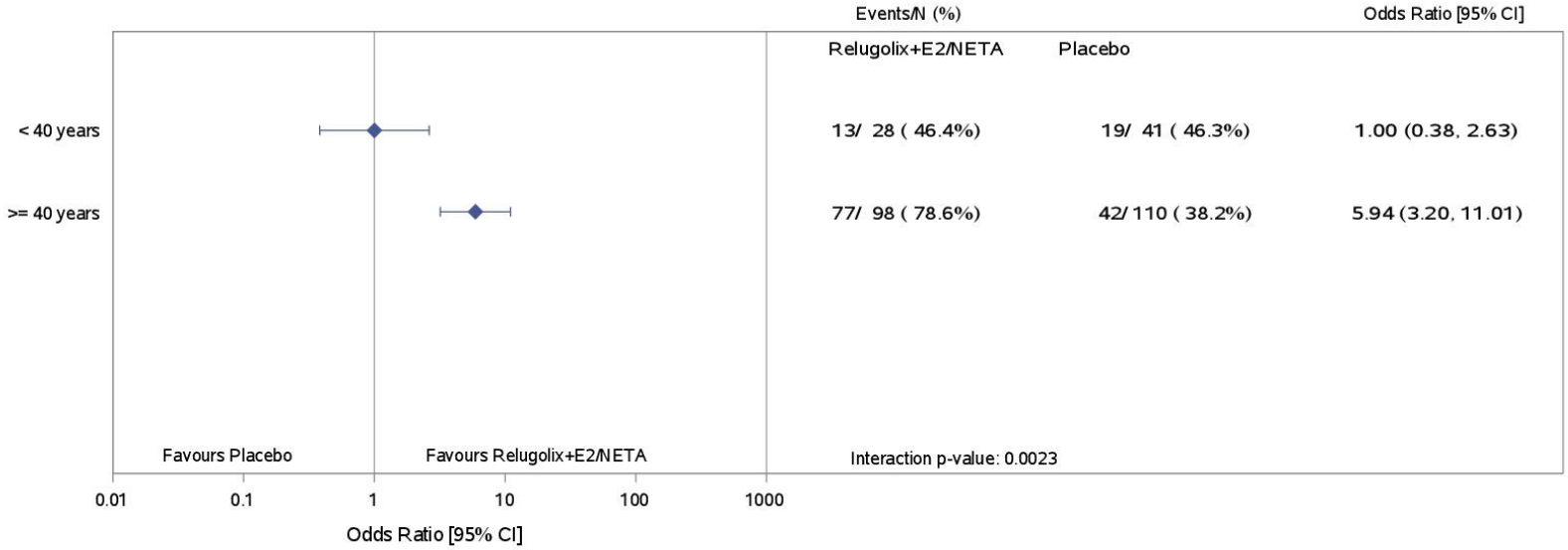
2.1.16 Proportion of Patients with >= 30% Reduction in NRS Score from Baseline to Last 35 Days of Treatment, by Subgroup (Pain Evaluable Population)

Nachfolgend sind zunächst alle Forest Plots für das *Odds Ratio* dargestellt; gefolgt von den entsprechenden Forest Plots für *Risk Ratio* und *Risk Difference*.

Figure EFF.NRSR30.PEV.S1.BIN.FP: Proportion of Patients with >= 30% Reduction in NRS Score from Baseline to Last 35 Days of Treatment, by Subgroup (Pain Evaluable Population)
Study: Pooled
Subgroup: Age (years)



Results are based on a logistic regression model adjusted for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates using a one-stage fixed-effects IPD meta-analysis approach. A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
The interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the Odds Ratio and 95% CI. Missing subgroup levels are not included in estimation of the interaction p-value. The reference group is Placebo.
N: Number of patients in treatment group; NETA: Norethindrone acetate; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

SOURCE: X:\Numerus\Studies\MYV\MYV102\Analysis\Prod\Progs\TFLs\Fig_EFF_NRS_S_BIN_FP.SAS Date/time of run: 30JUN21 10:26
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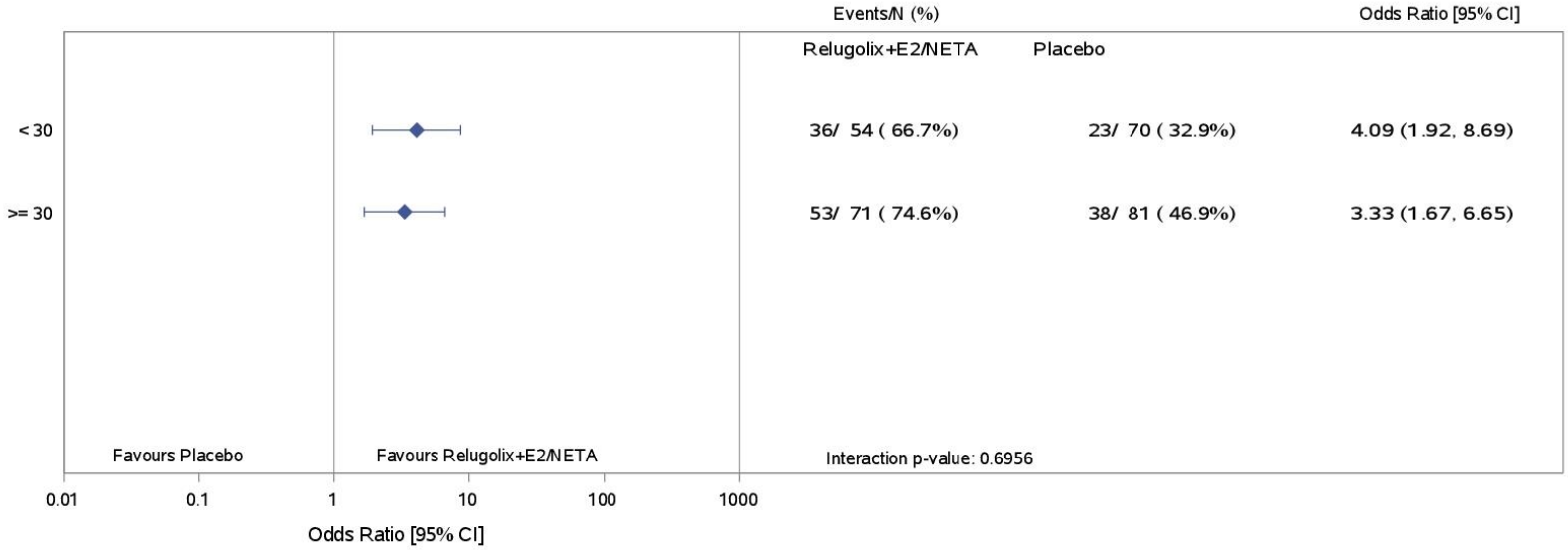
Figure EFF.NRSR30.PEV.S2.BIN.FP: Proportion of Patients with >= 30% Reduction in NRS Score from Baseline to Last 35 Days of Treatment, by Subgroup (Pain Evaluable Population)
Study: Pooled
Subgroup: BMI (kg/m2) at Baseline



Results are based on a logistic regression model adjusted for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates using a one-stage fixed-effects IPD meta-analysis approach. A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
The interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the Odds Ratio and 95% CI. Missing subgroup levels are not included in estimation of the interaction p-value. The reference group is Placebo.
N: Number of patients in treatment group; NETA: Norethindrone acetate; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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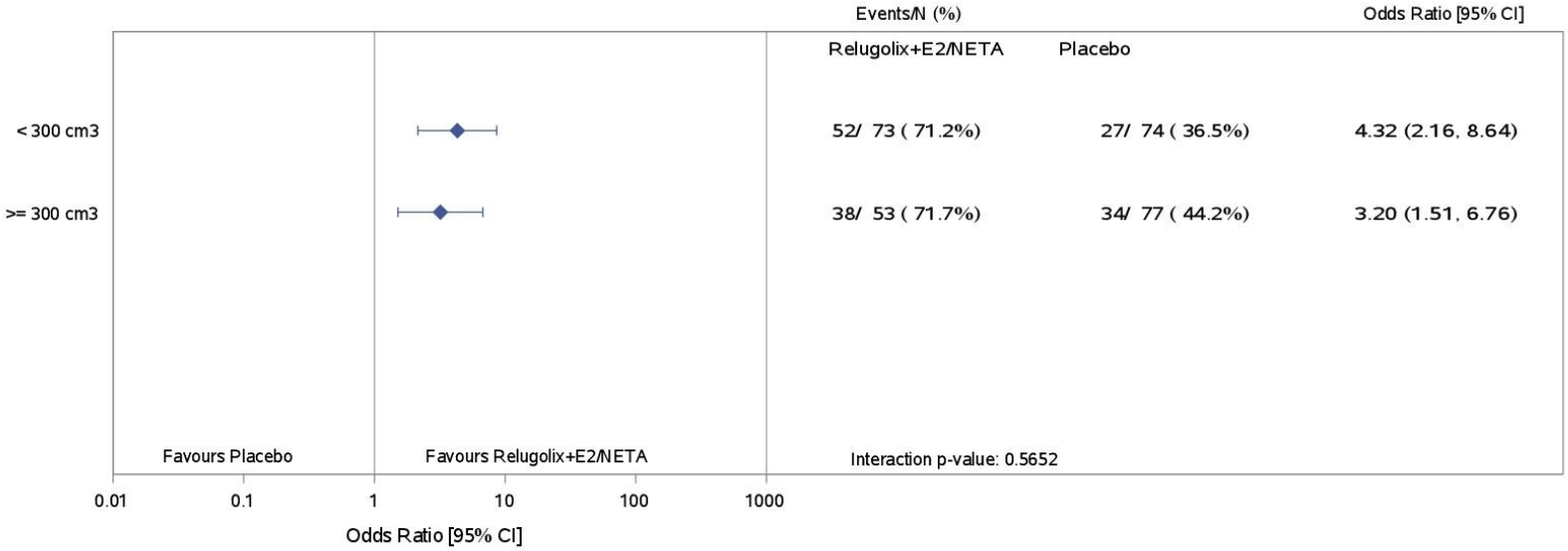
Figure EFF.NRSR30.PEV.S3.BIN.FP: Proportion of Patients with >= 30% Reduction in NRS Score from Baseline to Last 35 Days of Treatment, by Subgroup (Pain Evaluable Population)
Study: Pooled
Subgroup: Uterine Volume at Baseline (cm3)



Results are based on a logistic regression model adjusted for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates using a one-stage fixed-effects IPD meta-analysis approach. A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
The interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the Odds Ratio and 95% CI. Missing subgroup levels are not included in estimation of the interaction p-value. The reference group is Placebo.
N: Number of patients in treatment group; NETA: Norethindrone acetate; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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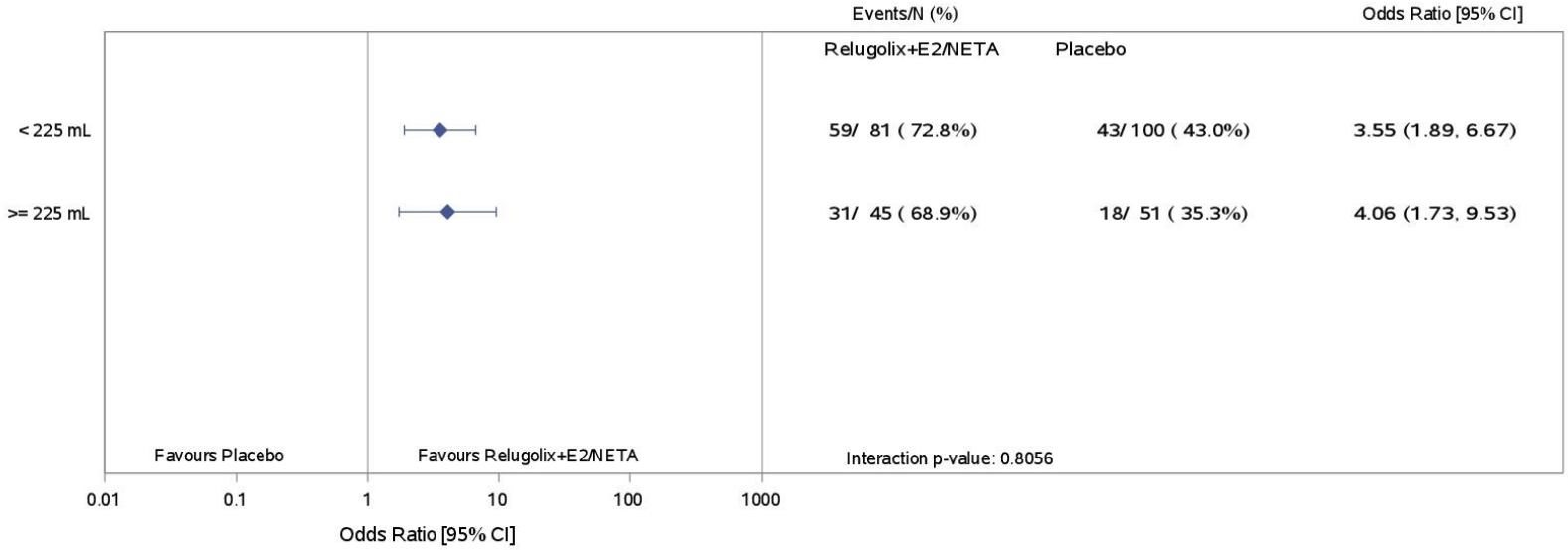
Figure EFF.NRSR30.PEV.S5.BIN.FP: Proportion of Patients with >= 30% Reduction in NRS Score from Baseline to Last 35 Days of Treatment, by Subgroup (Pain Evaluable Population)
Study: Pooled
Subgroup: MBL Volume at Baseline (mL)



Results are based on a logistic regression model adjusted for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates using a one-stage fixed-effects IPD meta-analysis approach. A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
The interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the Odds Ratio and 95% CI. Missing subgroup levels are not included in estimation of the interaction p-value. The reference group is Placebo.
N: Number of patients in treatment group; NETA: Norethindrone acetate; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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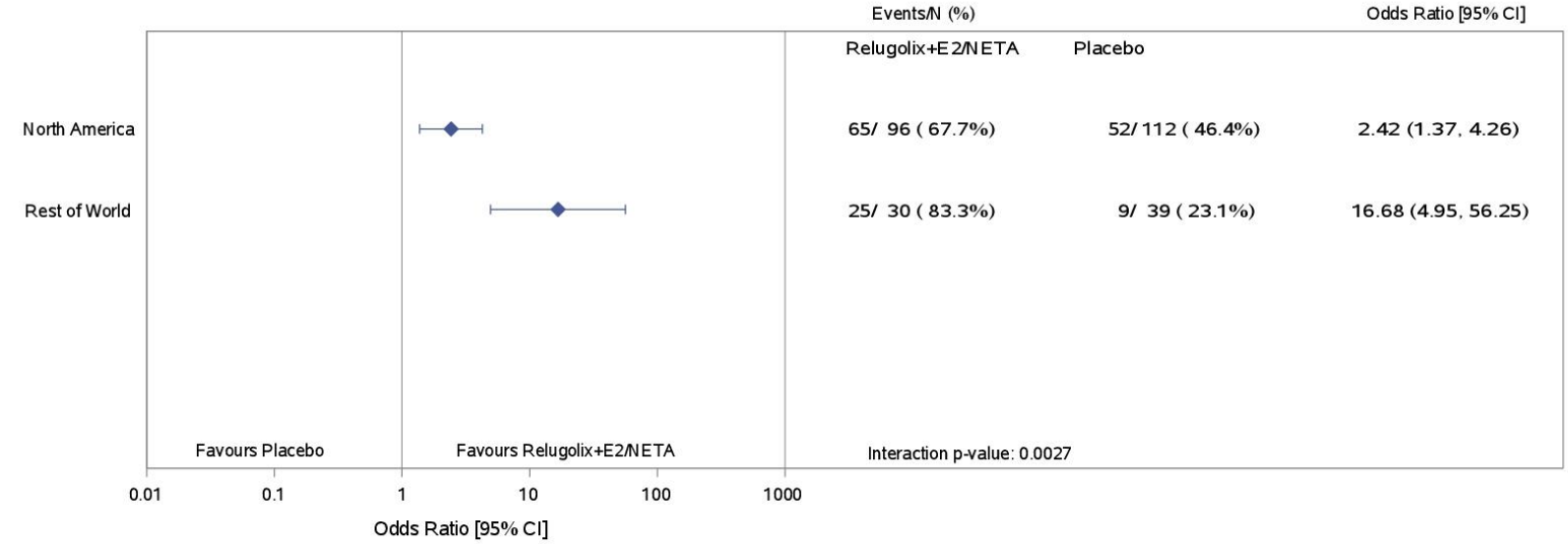
Figure EFF.NRSR30.PEV.S6.BIN.FP: Proportion of Patients with >= 30% Reduction in NRS Score from Baseline to Last 35 Days of Treatment, by Subgroup (Pain Evaluable Population)
Study: Pooled
Subgroup: Geographic Region I



Results are based on a logistic regression model adjusted for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates using a one-stage fixed-effects IPD meta-analysis approach. A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
The interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the Odds Ratio and 95% CI. Missing subgroup levels are not included in estimation of the interaction p-value. The reference group is Placebo.
N: Number of patients in treatment group; NETA: Norethindrone acetate; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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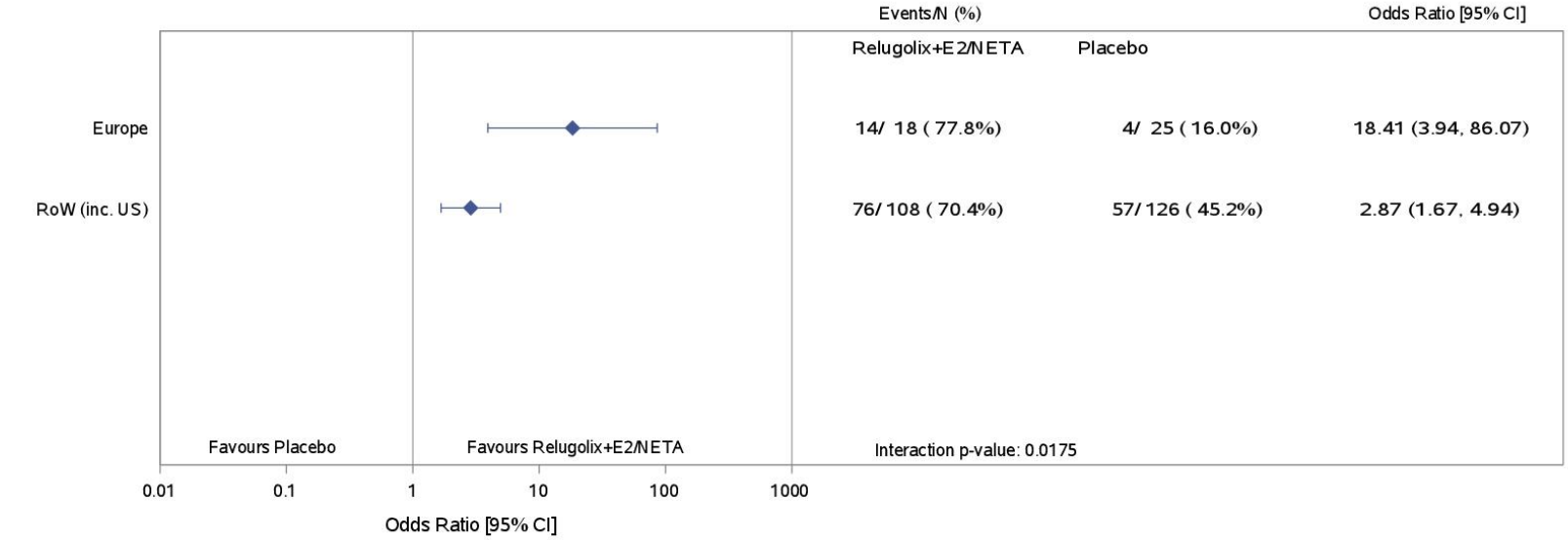
Figure EFF.NRSR30.PEV.S7.BIN.FP: Proportion of Patients with >= 30% Reduction in NRS Score from Baseline to Last 35 Days of Treatment, by Subgroup (Pain Evaluable Population)
Study: Pooled
Subgroup: Geographic Region II



Results are based on a logistic regression model adjusted for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates using a one-stage fixed-effects IPD meta-analysis approach. A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
The interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the Odds Ratio and 95% CI. Missing subgroup levels are not included in estimation of the interaction p-value. The reference group is Placebo.
N: Number of patients in treatment group; NETA: Norethindrone acetate; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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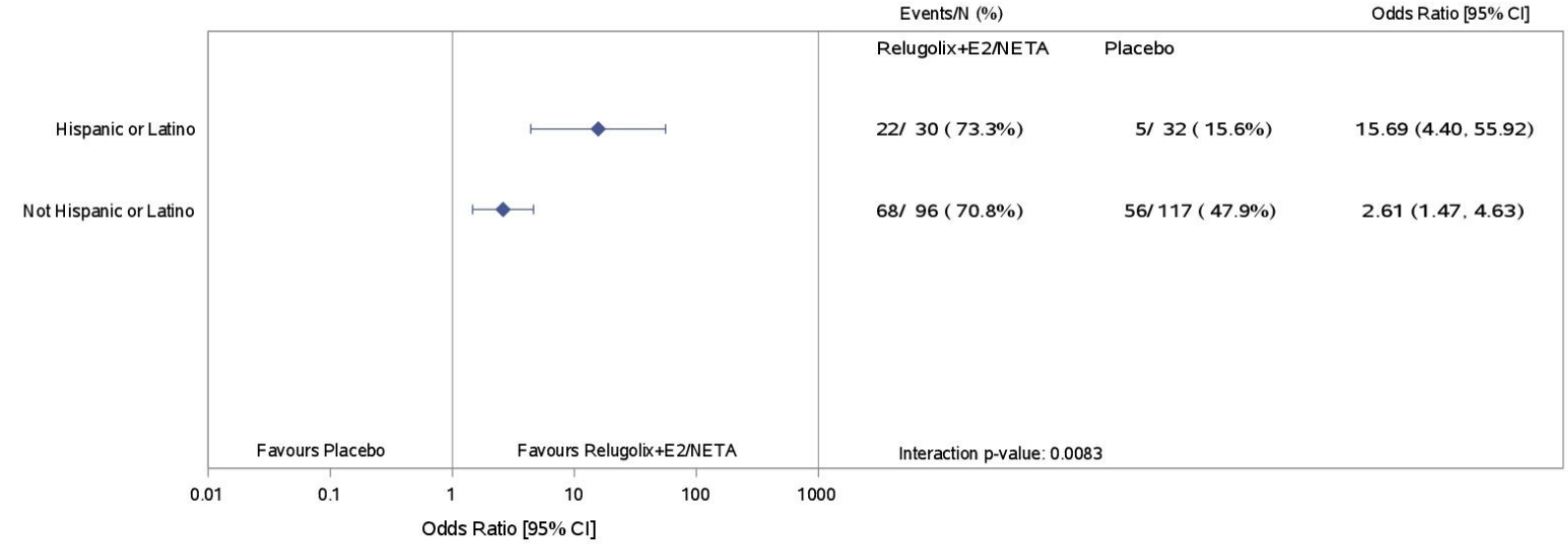
Figure EFF.NRSR30.PEV.S8.BIN.FP: Proportion of Patients with >= 30% Reduction in NRS Score from Baseline to Last 35 Days of Treatment, by Subgroup (Pain Evaluable Population)
Study: Pooled
Subgroup: Ethnicity



Results are based on a logistic regression model adjusted for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates using a one-stage fixed-effects IPD meta-analysis approach. A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
The interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the Odds Ratio and 95% CI. Missing subgroup levels are not included in estimation of the interaction p-value. The reference group is Placebo.
N: Number of patients in treatment group; NETA: Norethindrone acetate; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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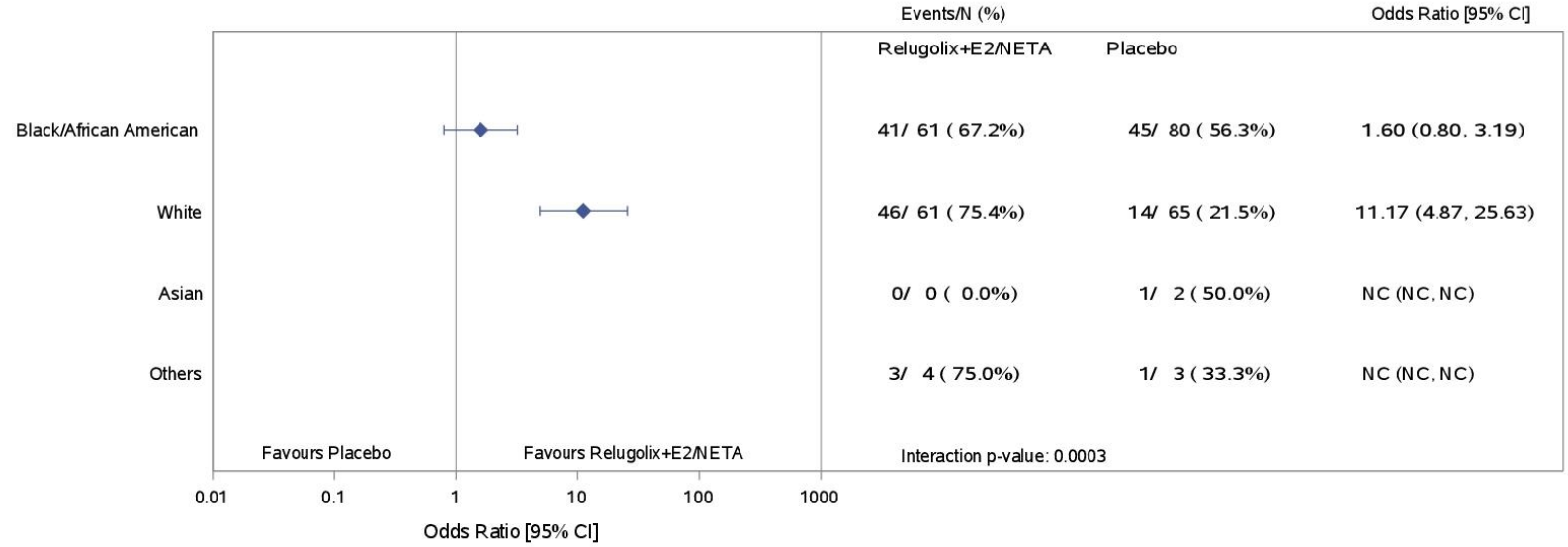
Figure EFF.NRSR30.PEV.S9.BIN.FP: Proportion of Patients with >= 30% Reduction in NRS Score from Baseline to Last 35 Days of Treatment, by Subgroup (Pain Evaluable Population)
Study: Pooled
Subgroup: Race



Results are based on a logistic regression model adjusted for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates using a one-stage fixed-effects IPD meta-analysis approach. A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
The interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the Odds Ratio and 95% CI. Missing subgroup levels are not included in estimation of the interaction p-value. The reference group is Placebo.
N: Number of patients in treatment group; NETA: Norethindrone acetate; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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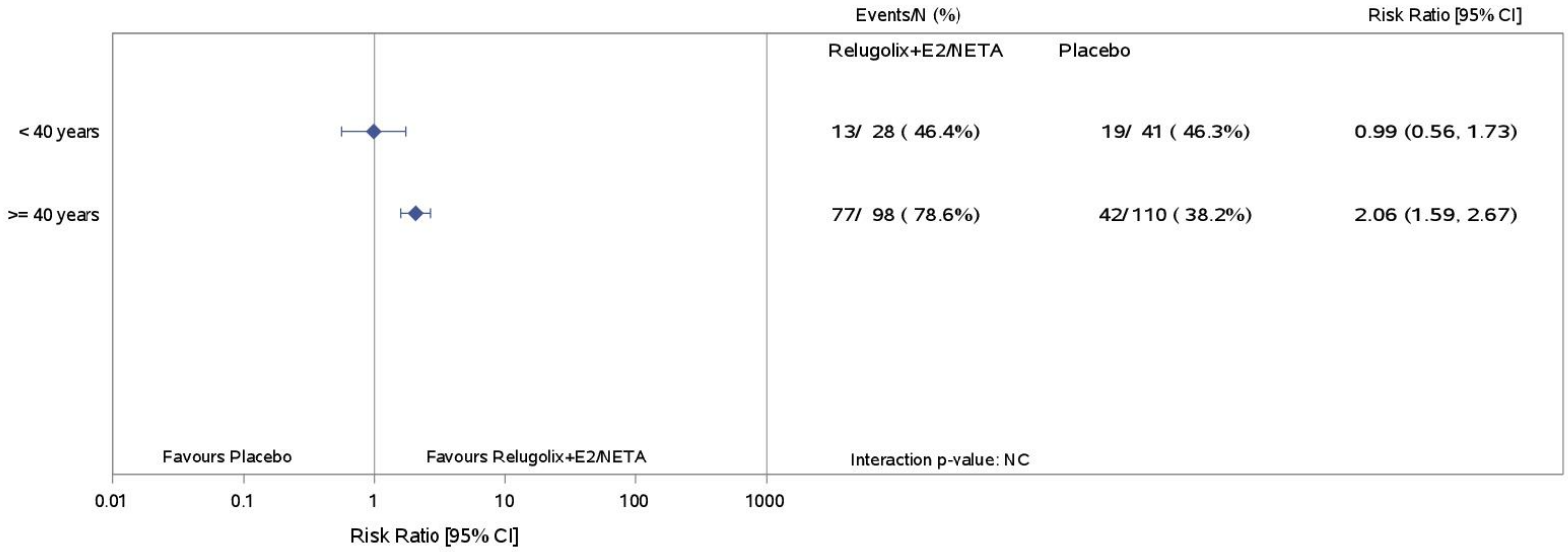
Figure EFF.NRSR30.PEV.S1.BIN.FP.RR: Proportion of Patients with >= 30% Reduction in NRS Score from Baseline to Last 35 Days of Treatment, by Subgroup (Pain Evaluable Population)
- Risk Ratio
Study: Pooled
Subgroup: Age (years)



Results are based on a Cochran-Mantel-Haenszel approach stratified by study using a one-stage fixed-effects IPD meta-analysis. A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
The reference group is Placebo.
N: Number of patients in treatment group; NETA: Norethindrone acetate; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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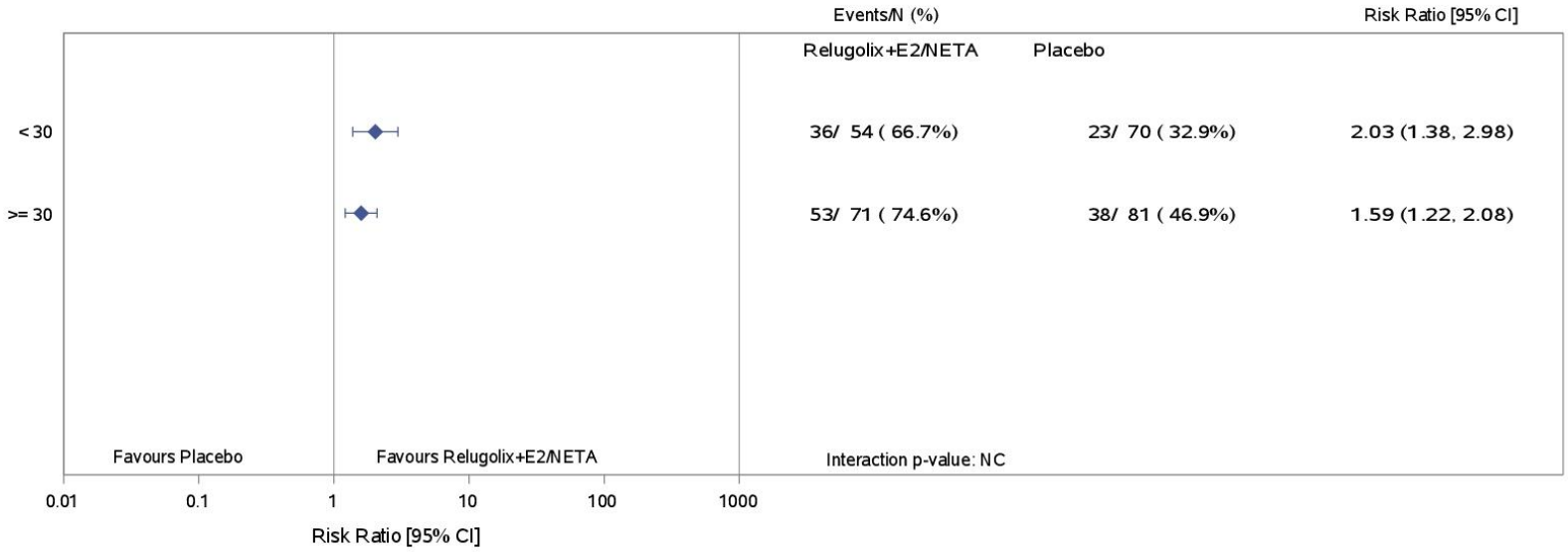
Figure EFF.NRSR30.PEV.S2.BIN.FP.RR: Proportion of Patients with >= 30% Reduction in NRS Score from Baseline to Last 35 Days of Treatment, by Subgroup (Pain Evaluable Population)
- Risk Ratio
Study: Pooled
Subgroup: BMI (kg/m2) at Baseline



Results are based on a Cochran-Mantel-Haenszel approach stratified by study using a one-stage fixed-effects IPD meta-analysis. A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
The reference group is Placebo.
N: Number of patients in treatment group; NETA: Norethindrone acetate; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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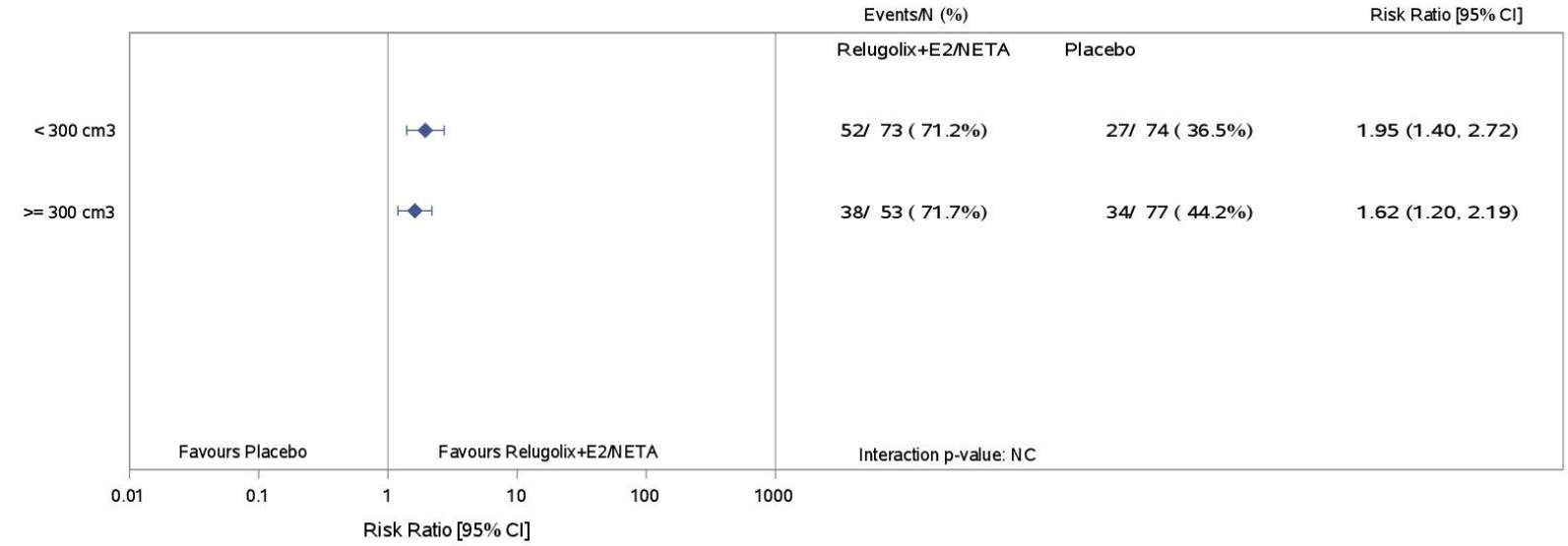
Figure EFF.NRSR30.PEV.S3.BIN.FP.RR: Proportion of Patients with >= 30% Reduction in NRS Score from Baseline to Last 35 Days of Treatment, by Subgroup (Pain Evaluable Population)
- Risk Ratio
Study: Pooled
Subgroup: Uterine Volume at Baseline (cm3)



Results are based on a Cochran-Mantel-Haenszel approach stratified by study using a one-stage fixed-effects IPD meta-analysis. A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
The reference group is Placebo.
N: Number of patients in treatment group; NETA: Norethindrone acetate; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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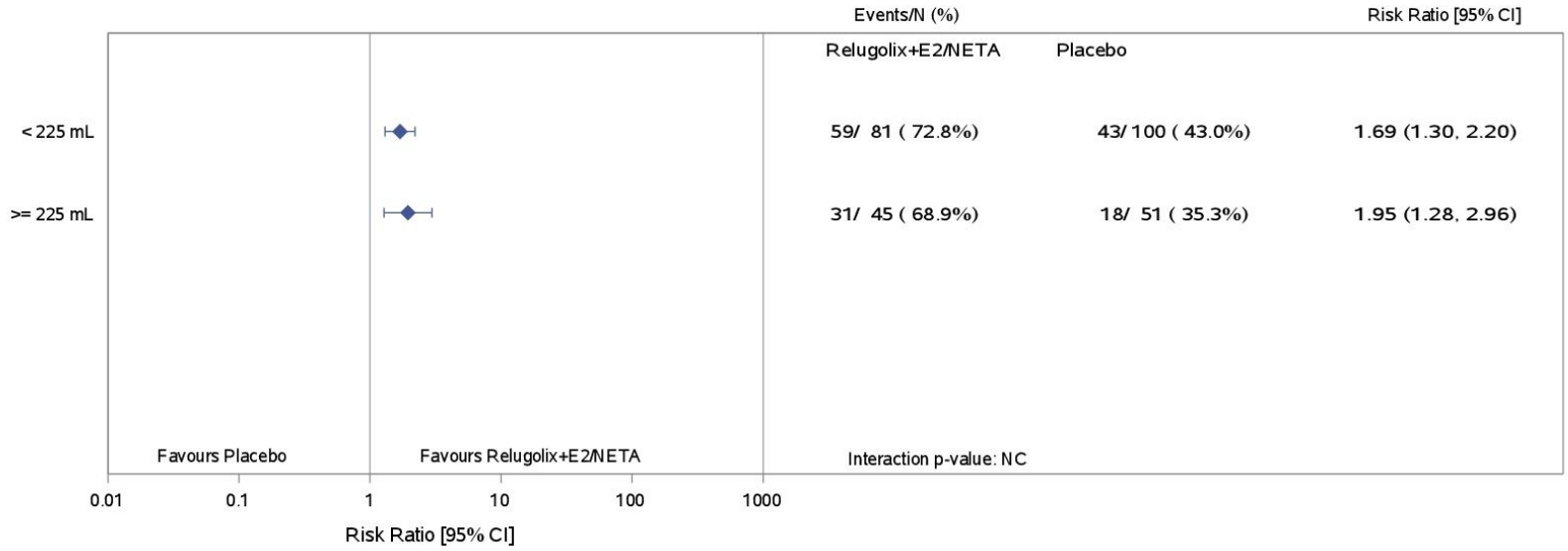
Figure EFF.NRSR30.PEV.S5.BIN.FP.RR: Proportion of Patients with >= 30% Reduction in NRS Score from Baseline to Last 35 Days of Treatment, by Subgroup (Pain Evaluable Population)
- Risk Ratio
Study: Pooled
Subgroup: MBL Volume at Baseline (mL)



Results are based on a Cochran-Mantel-Haenszel approach stratified by study using a one-stage fixed-effects IPD meta-analysis. A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
The reference group is Placebo.
N: Number of patients in treatment group; NETA: Norethindrone acetate; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

SOURCE: X:\Numerus\Studies\MYV\MYV102\Analysis\Prod\Progs\TFLs\Fig_EFF_NRS_S_BIN_FP.SAS Date/time of run: 30JUN21 10:26
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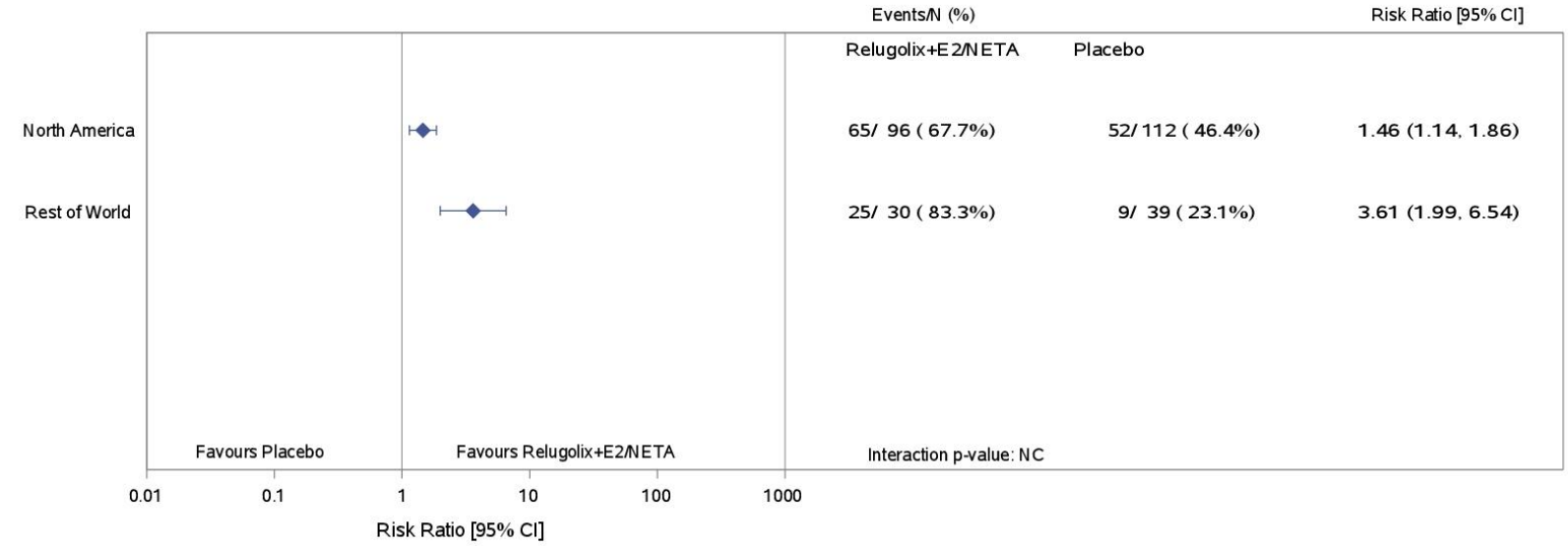
Figure EFF.NRSR30.PEV.S6.BIN.FP.RR: Proportion of Patients with >= 30% Reduction in NRS Score from Baseline to Last 35 Days of Treatment, by Subgroup (Pain Evaluable Population)
- Risk Ratio
Study: Pooled
Subgroup: Geographic Region I



Results are based on a Cochran-Mantel-Haenszel approach stratified by study using a one-stage fixed-effects IPD meta-analysis. A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
The reference group is Placebo.
N: Number of patients in treatment group; NETA: Norethindrone acetate; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

SOURCE: X:\Numerus\Studies\MYV\MYV102\Analysis\Prod\Progs\TFLs\Fig_EFF_NRS_S_BIN_FP.SAS Date/time of run: 30JUN21 10:26
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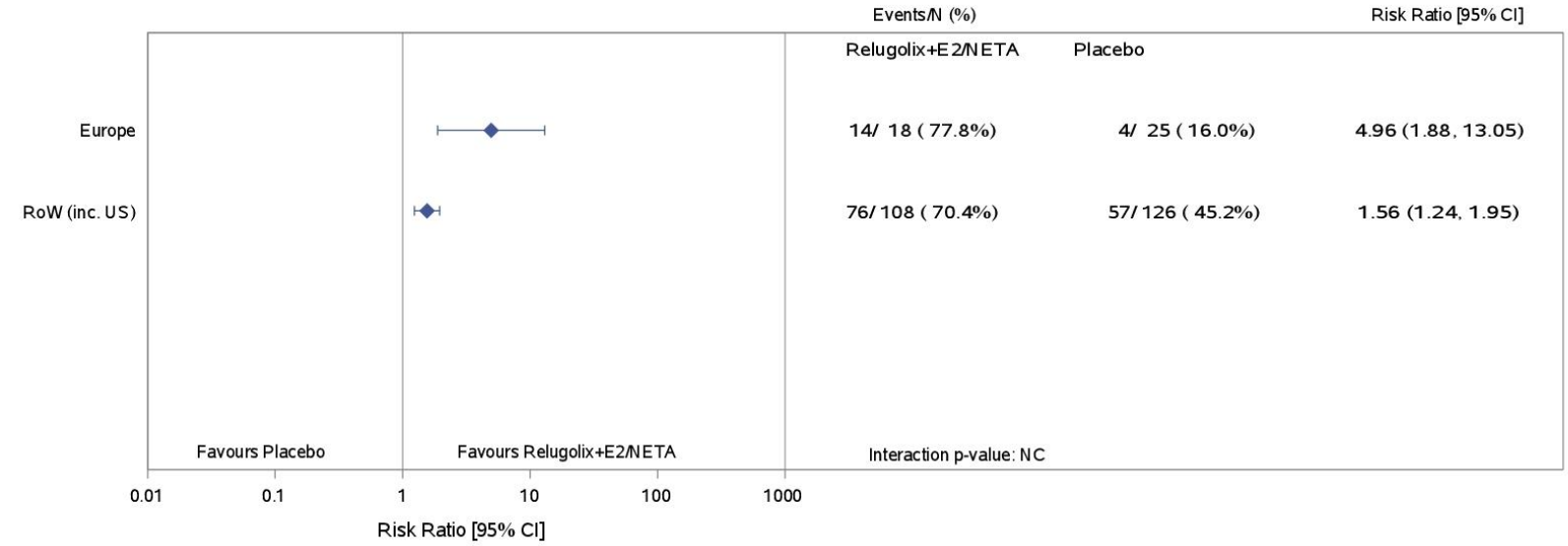
Figure EFF.NRSR30.PEV.S7.BIN.FP.RR: Proportion of Patients with >= 30% Reduction in NRS Score from Baseline to Last 35 Days of Treatment, by Subgroup (Pain Evaluable Population)
- Risk Ratio
Study: Pooled
Subgroup: Geographic Region II



Results are based on a Cochran-Mantel-Haenszel approach stratified by study using a one-stage fixed-effects IPD meta-analysis. A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
The reference group is Placebo.
N: Number of patients in treatment group; NETA: Norethindrone acetate; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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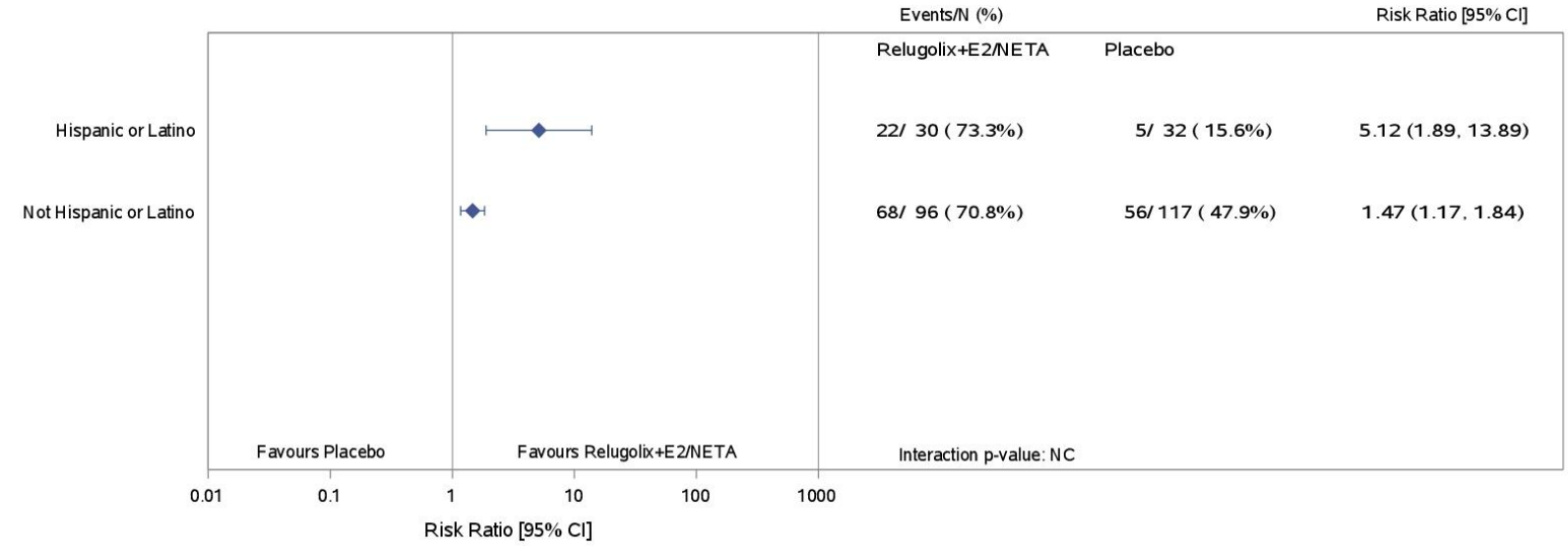
Figure EFF.NRSR30.PEV.S8.BIN.FP.RR: Proportion of Patients with >= 30% Reduction in NRS Score from Baseline to Last 35 Days of Treatment, by Subgroup (Pain Evaluable Population)
- Risk Ratio
Study: Pooled
Subgroup: Ethnicity



Results are based on a Cochran-Mantel-Haenszel approach stratified by study using a one-stage fixed-effects IPD meta-analysis. A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
The reference group is Placebo.
N: Number of patients in treatment group; NETA: Norethindrone acetate; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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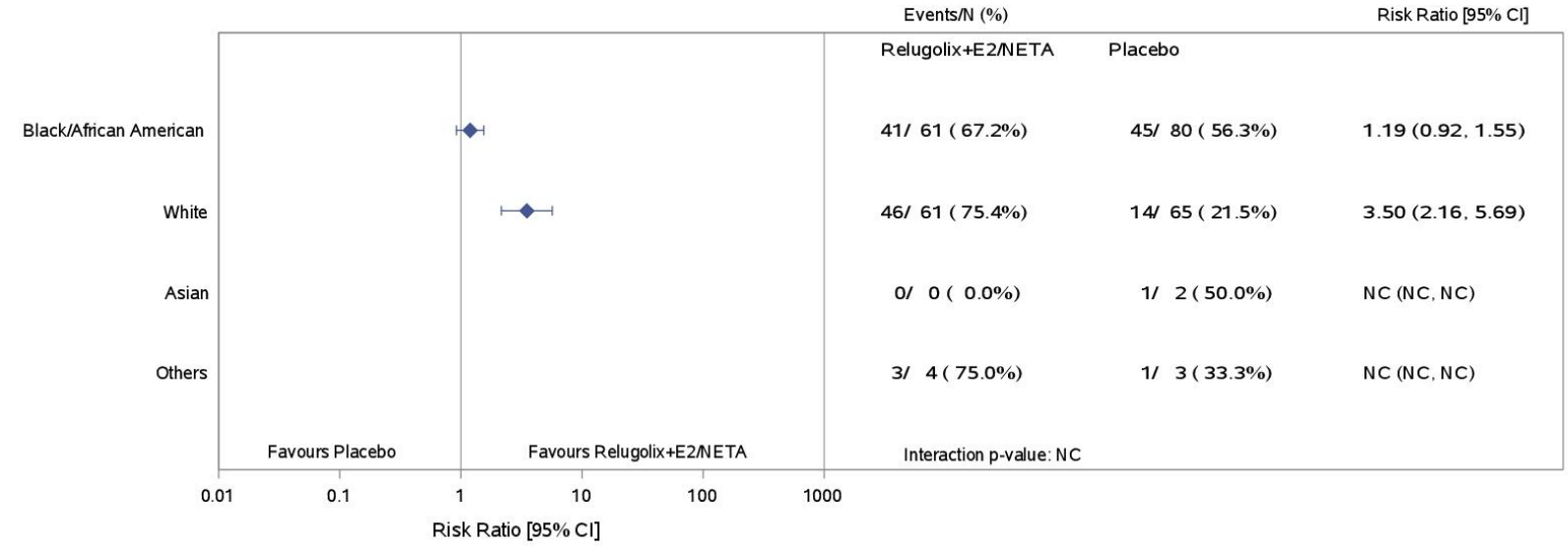
Figure EFF.NRSR30.PEV.S9.BIN.FP.RR: Proportion of Patients with >= 30% Reduction in NRS Score from Baseline to Last 35 Days of Treatment, by Subgroup (Pain Evaluable Population)
- Risk Ratio
Study: Pooled
Subgroup: Race



Results are based on a Cochran-Mantel-Haenszel approach stratified by study using a one-stage fixed-effects IPD meta-analysis. A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
The reference group is Placebo.
N: Number of patients in treatment group; NETA: Norethindrone acetate; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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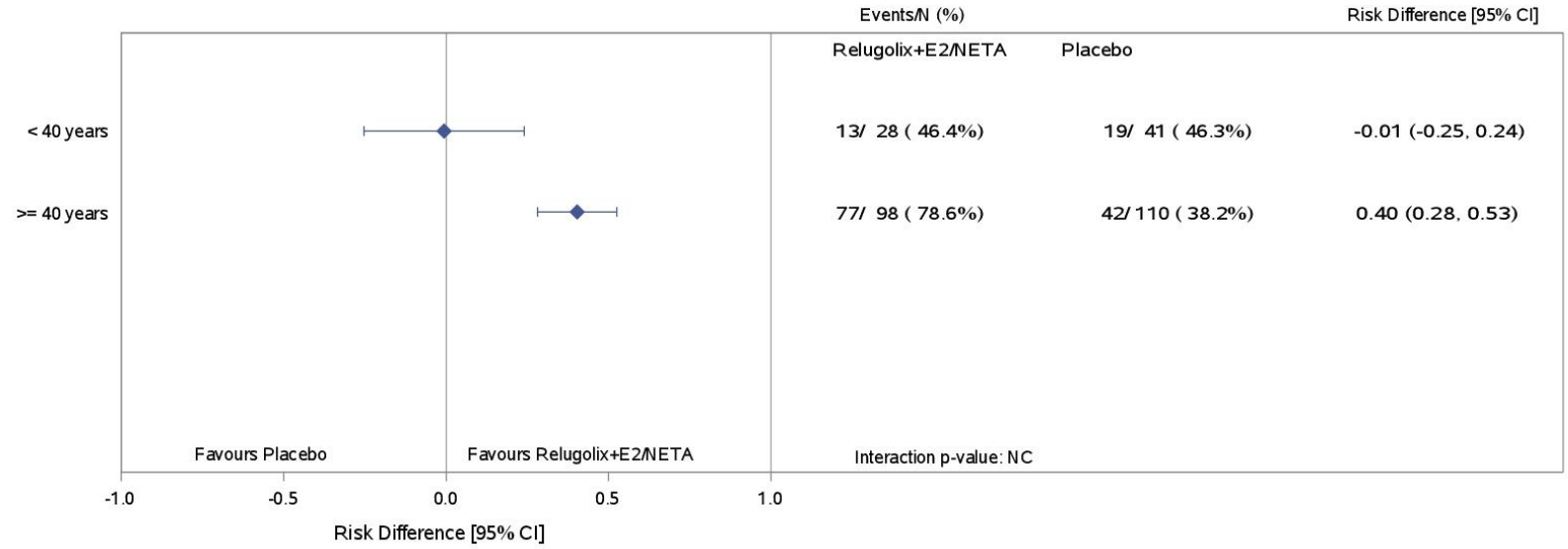
Figure EFF.NRSR30.PEV.S1.BIN.FP.RD: Proportion of Patients with >= 30% Reduction in NRS Score from Baseline to Last 35 Days of Treatment, by Subgroup (Pain Evaluable Population)
- Risk Difference
Study: Pooled
Subgroup: Age (years)



Results are based on a Mantel-Haenszel approach stratified by study using a one-stage fixed-effects IPD meta-analysis.
The reference group is Placebo.
N: Number of patients in treatment group; NETA: Norethindrone acetate; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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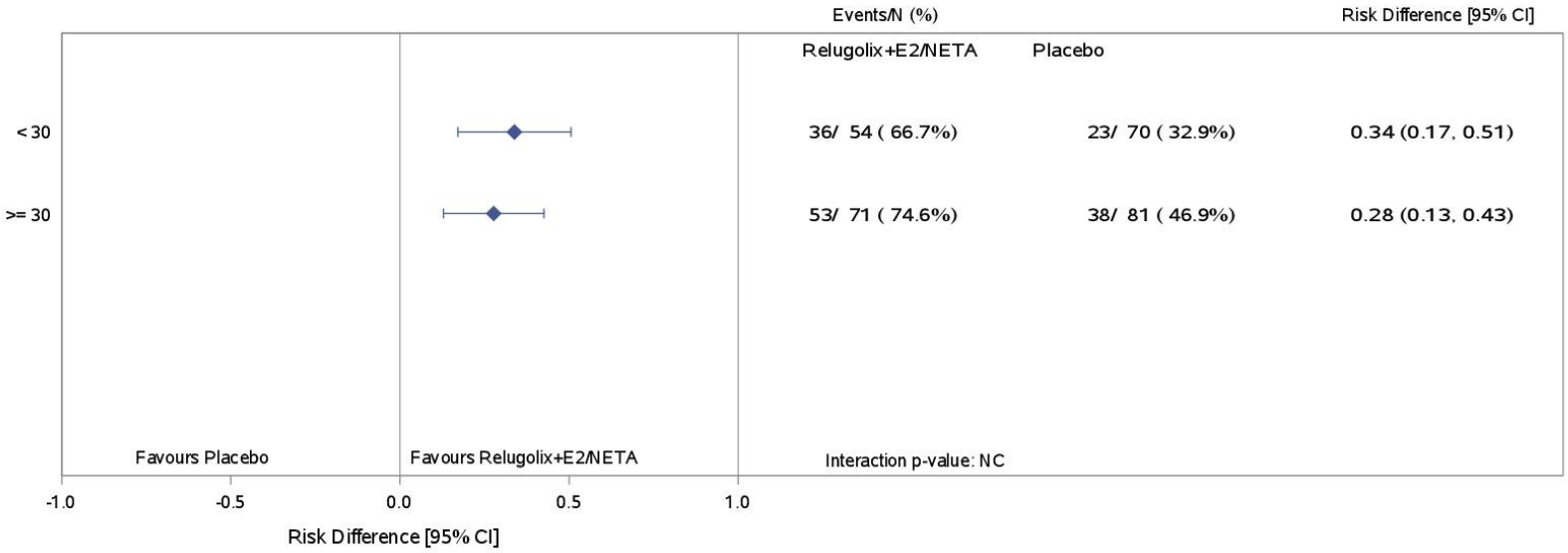
Figure EFF.NRSR30.PEV.S2.BIN.FP.RD: Proportion of Patients with >= 30% Reduction in NRS Score from Baseline to Last 35 Days of Treatment, by Subgroup (Pain Evaluable Population)
- Risk Difference
Study: Pooled
Subgroup: BMI (kg/m2) at Baseline



Results are based on a Mantel-Haenszel approach stratified by study using a one-stage fixed-effects IPD meta-analysis.
The reference group is Placebo.
N: Number of patients in treatment group; NETA: Norethindrone acetate; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

SOURCE: X:\Numerus\Studies\MYV\MYV102\Analysis\Prod\Progs\TFLs\Fig_EFF_NRS_S_BIN_FP.SAS Date/time of run: 30JUN21 10:26
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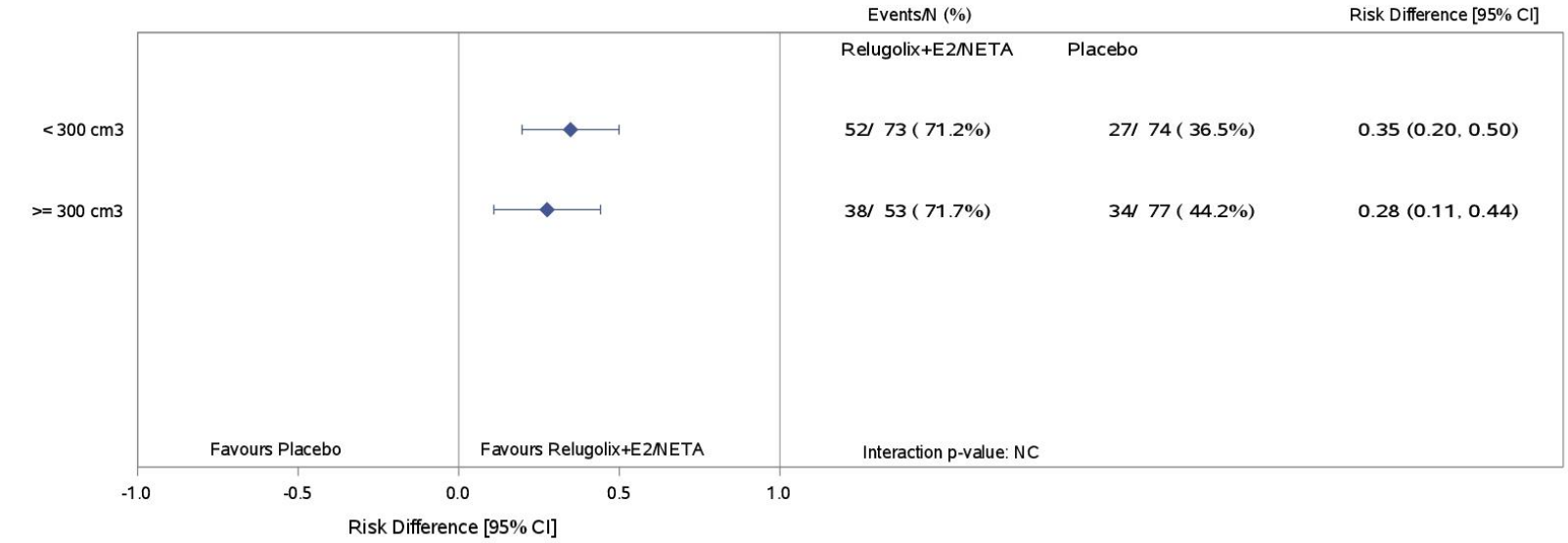
Figure EFF.NRSR30.PEV.S3.BIN.FP.RD: Proportion of Patients with >= 30% Reduction in NRS Score from Baseline to Last 35 Days of Treatment, by Subgroup (Pain Evaluable Population) - Risk Difference
Study: Pooled
Subgroup: Uterine Volume at Baseline (cm3)



Results are based on a Mantel-Haenszel approach stratified by study using a one-stage fixed-effects IPD meta-analysis.
The reference group is Placebo.
N: Number of patients in treatment group; NETA: Norethindrone acetate; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

SOURCE: X:\Numerus\Studies\MYV\MYV102\Analysis\Prod\Progs\TFLs\Fig_EFF_NRS_S_BIN_FP.SAS Date/time of run: 30JUN21 10:26
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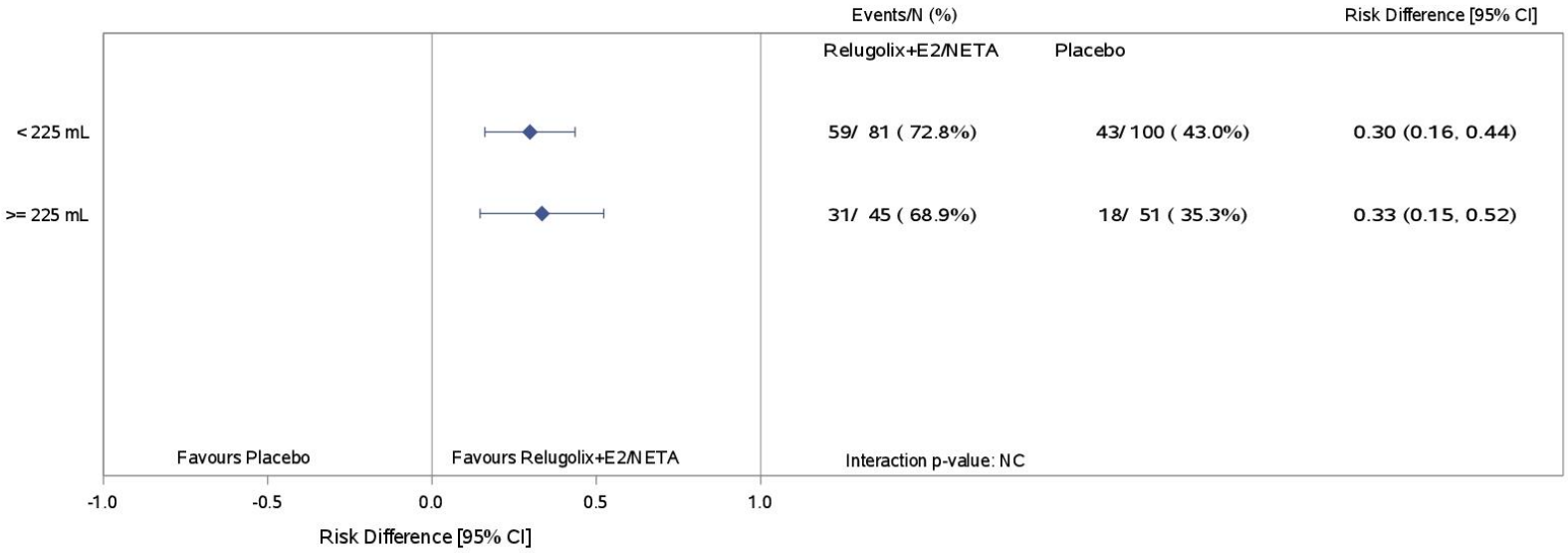
Figure EFF.NRSR30.PEV.S5.BIN.FP.RD: Proportion of Patients with >= 30% Reduction in NRS Score from Baseline to Last 35 Days of Treatment, by Subgroup (Pain Evaluable Population)
- Risk Difference
Study: Pooled
Subgroup: MBL Volume at Baseline (mL)



Results are based on a Mantel-Haenszel approach stratified by study using a one-stage fixed-effects IPD meta-analysis.
The reference group is Placebo.
N: Number of patients in treatment group; NETA: Norethindrone acetate; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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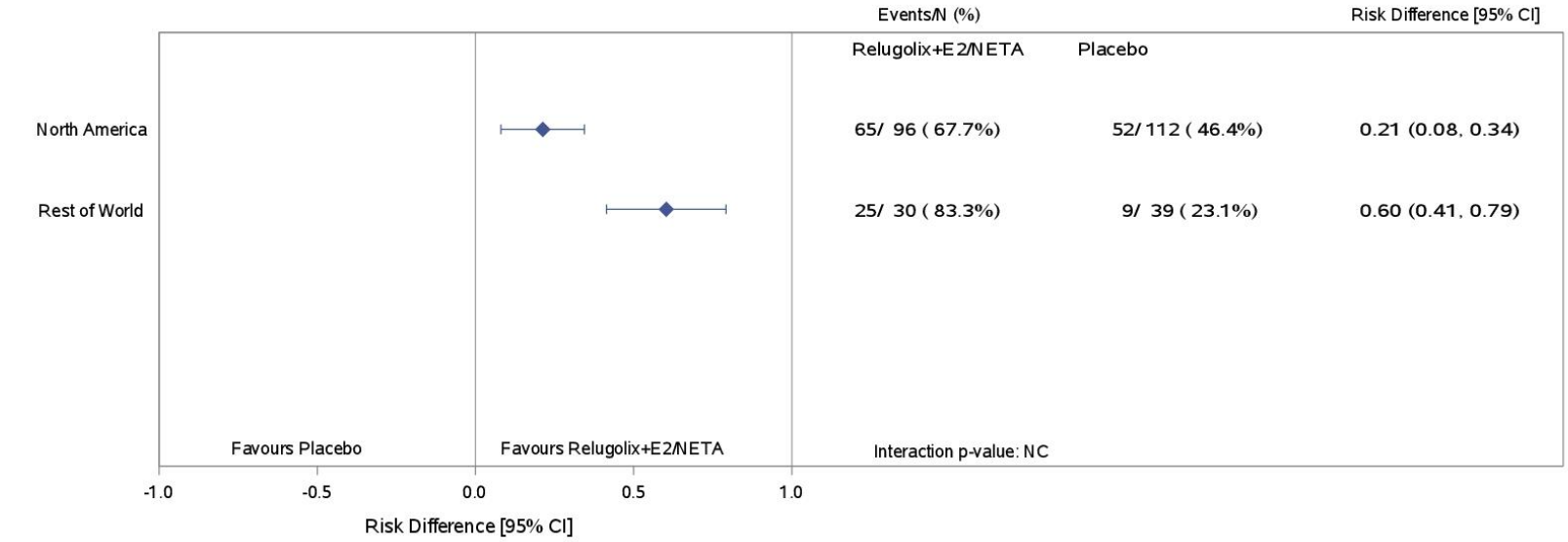
Figure EFF.NRSR30.PEV.S6.BIN.FP.RD: Proportion of Patients with >= 30% Reduction in NRS Score from Baseline to Last 35 Days of Treatment, by Subgroup (Pain Evaluable Population)
- Risk Difference
Study: Pooled
Subgroup: Geographic Region I



Results are based on a Mantel-Haenszel approach stratified by study using a one-stage fixed-effects IPD meta-analysis.
The reference group is Placebo.
N: Number of patients in treatment group; NETA: Norethindrone acetate; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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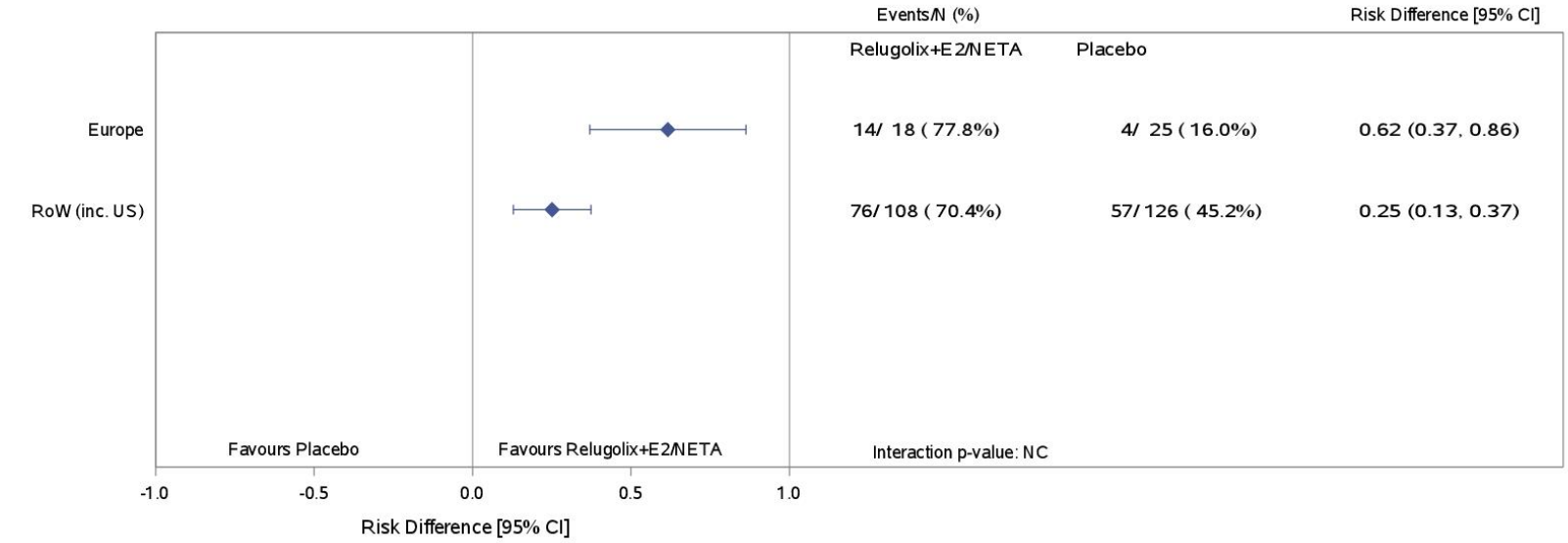
Figure EFF.NRSR30.PEV.S7.BIN.FP.RD: Proportion of Patients with >= 30% Reduction in NRS Score from Baseline to Last 35 Days of Treatment, by Subgroup (Pain Evaluable Population)
- Risk Difference
Study: Pooled
Subgroup: Geographic Region II



Results are based on a Mantel-Haenszel approach stratified by study using a one-stage fixed-effects IPD meta-analysis.
The reference group is Placebo.
N: Number of patients in treatment group; NETA: Norethindrone acetate; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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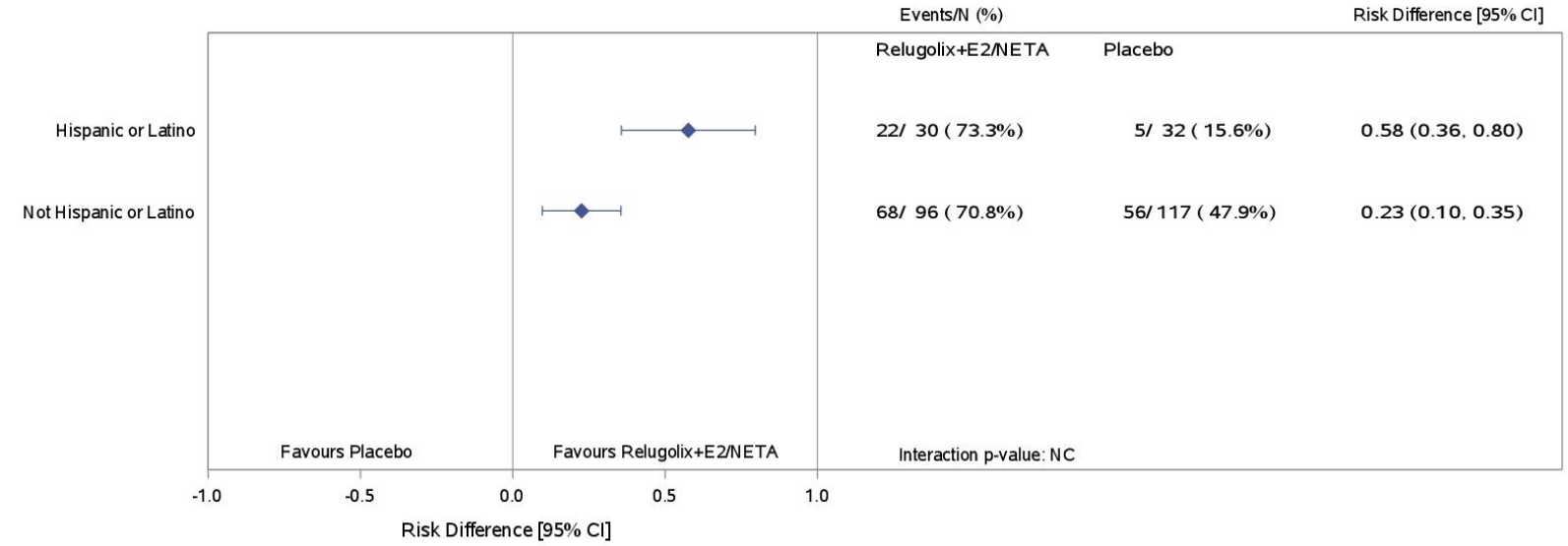
Figure EFF.NRSR30.PEV.S8.BIN.FP.RD: Proportion of Patients with >= 30% Reduction in NRS Score from Baseline to Last 35 Days of Treatment, by Subgroup (Pain Evaluable Population) - Risk Difference
Study: Pooled
Subgroup: Ethnicity



Results are based on a Mantel-Haenszel approach stratified by study using a one-stage fixed-effects IPD meta-analysis.
The reference group is Placebo.
N: Number of patients in treatment group; NETA: Norethindrone acetate; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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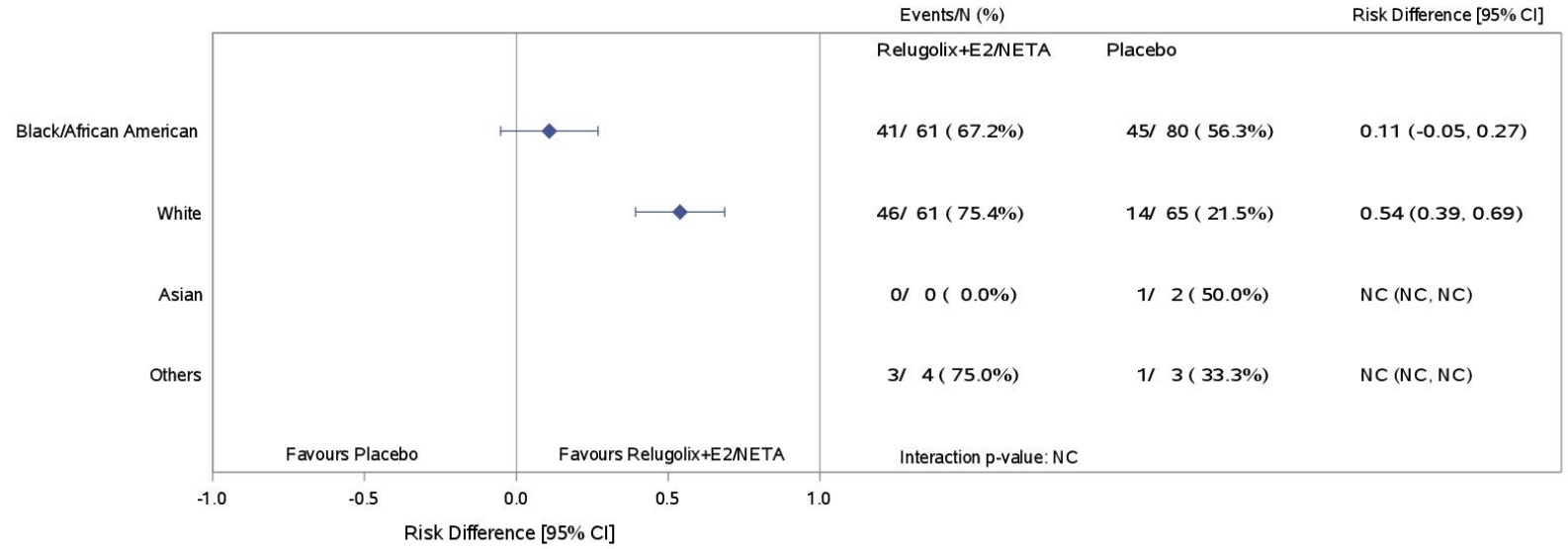
Figure EFF.NRSR30.PEV.S9.BIN.FP.RD: Proportion of Patients with >= 30% Reduction in NRS Score from Baseline to Last 35 Days of Treatment, by Subgroup (Pain Evaluable Population)
- Risk Difference
Study: Pooled
Subgroup: Race



Results are based on a Mantel-Haenszel approach stratified by study using a one-stage fixed-effects IPD meta-analysis.
The reference group is Placebo.
N: Number of patients in treatment group; NETA: Norethindrone acetate; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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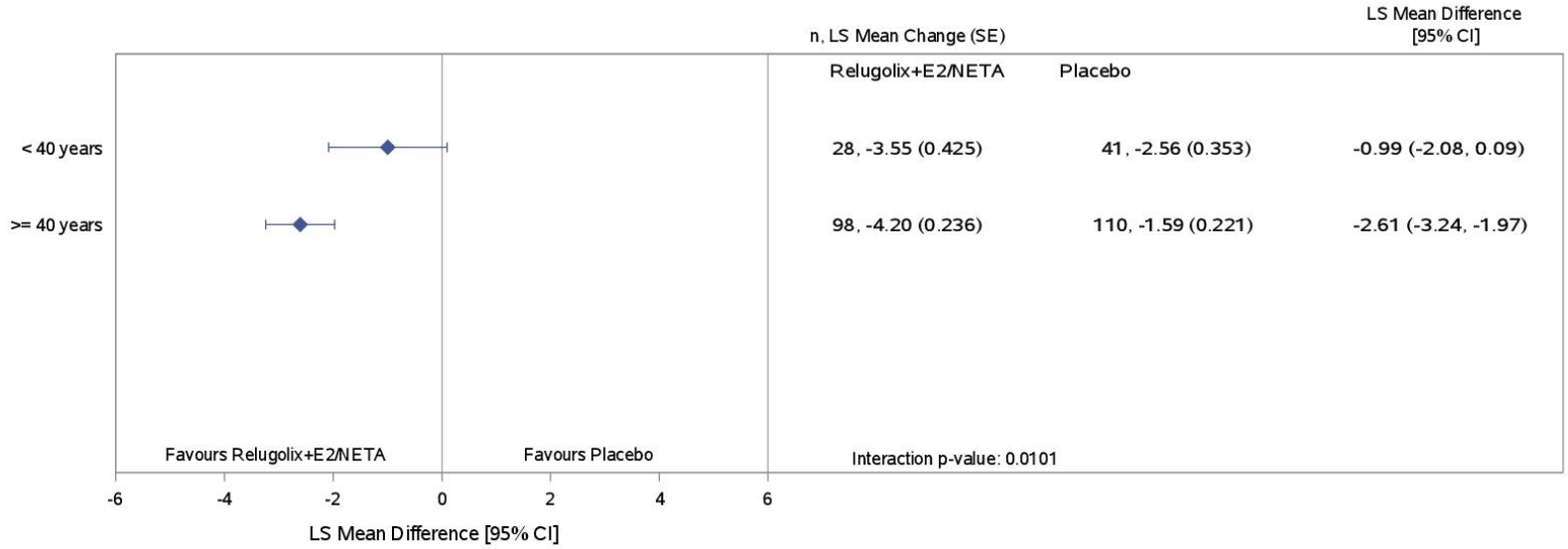
2.1.17 Summary of Average Change from Baseline in Maximum NRS Score Over 24 Weeks, by Subgroup (Pain Evaluable Population)

Figure EFF.MAXNRS.PEV.S1.CON.FP: Summary of Average Change from Baseline in Maximum NRS Score Over 24 Weeks, by Subgroup (Pain Evaluable Population)
Study: Pooled
Subgroup: Age (years)



Results are based on a mixed-effects model with study, treatment, visit, subgroup, treatment-by-visit interaction, and a subgroup-by-treatment interaction as fixed effects using a one-stage IPD meta-analysis approach. The multiple visits for each patient are the repeated measures as a random effect within each patient with an unstructured covariance.
The interaction p-value is based on the subgroup-by-treatment interaction term in the mixed-effects model used to compute the LS means, mean differences and 95% CIs. Missing subgroup levels are not included in estimation of the interaction p-value. The reference group is Placebo.
n: Number of patients with data; NETA: Norethindrone acetate; LS: Least squares; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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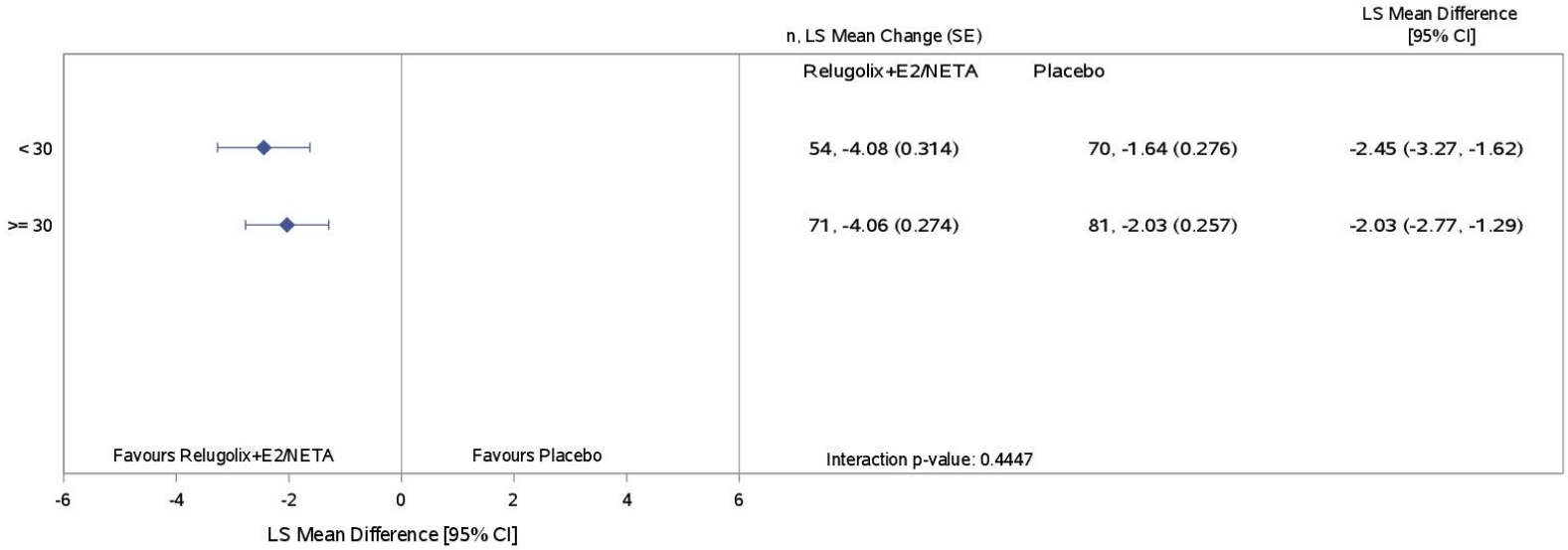
Figure EFF.MAXNRS.PEV.S2.CON.FP: Summary of Average Change from Baseline in Maximum NRS Score Over 24 Weeks, by Subgroup (Pain Evaluable Population)
Study: Pooled
Subgroup: BMI (kg/m2) at Baseline



Results are based on a mixed-effects model with study, treatment, visit, subgroup, treatment-by-visit interaction, and a subgroup-by-treatment interaction as fixed effects using a one-stage IPD meta-analysis approach. The multiple visits for each patient are the repeated measures as a random effect within each patient with an unstructured covariance.
The interaction p-value is based on the subgroup-by-treatment interaction term in the mixed-effects model used to compute the LS means, mean differences and 95% CIs. Missing subgroup levels are not included in estimation of the interaction p-value. The reference group is Placebo.
n: Number of patients with data; NETA: Norethindrone acetate; LS: Least squares; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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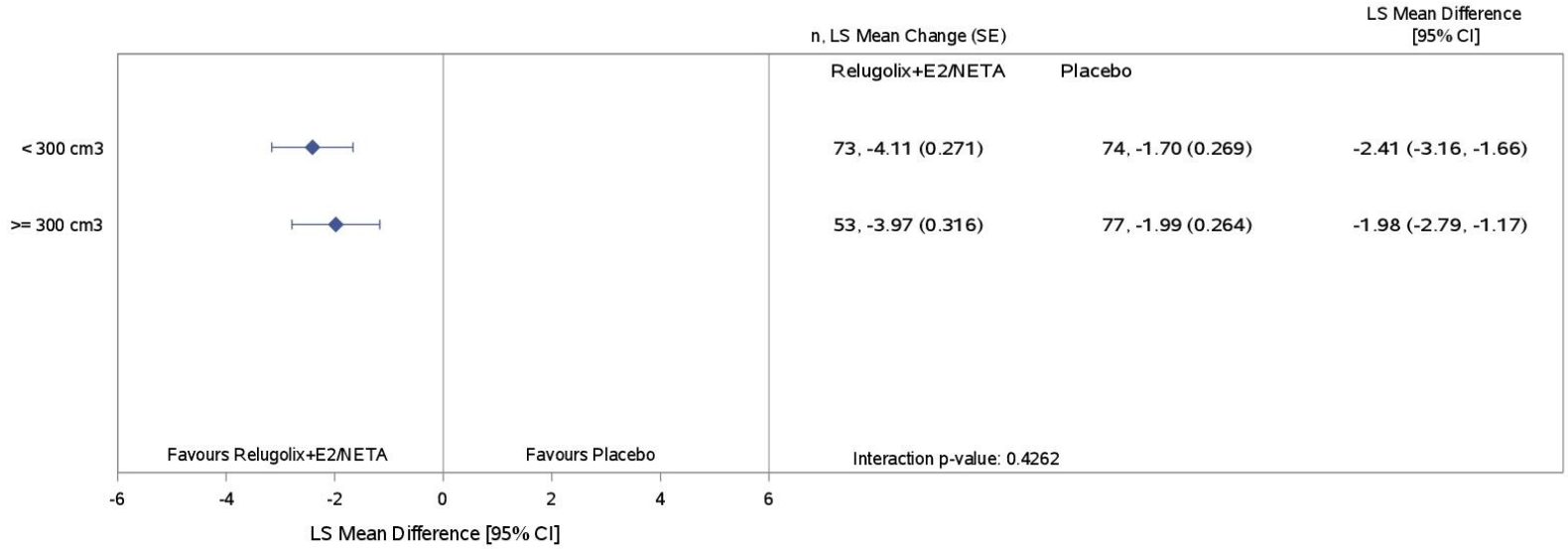
Figure EFF.MAXNRS.PEV.S3.CON.FP: Summary of Average Change from Baseline in Maximum NRS Score Over 24 Weeks, by Subgroup (Pain Evaluable Population)
Study: Pooled
Subgroup: Uterine Volume at Baseline (cm3)



Results are based on a mixed-effects model with study, treatment, visit, subgroup, treatment-by-visit interaction, and a subgroup-by-treatment interaction as fixed effects using a one-stage IPD meta-analysis approach. The multiple visits for each patient are the repeated measures as a random effect within each patient with an unstructured covariance.
The interaction p-value is based on the subgroup-by-treatment interaction term in the mixed-effects model used to compute the LS means, mean differences and 95% CIs. Missing subgroup levels are not included in estimation of the interaction p-value. The reference group is Placebo.
n: Number of patients with data; NETA: Norethindrone acetate; LS: Least squares; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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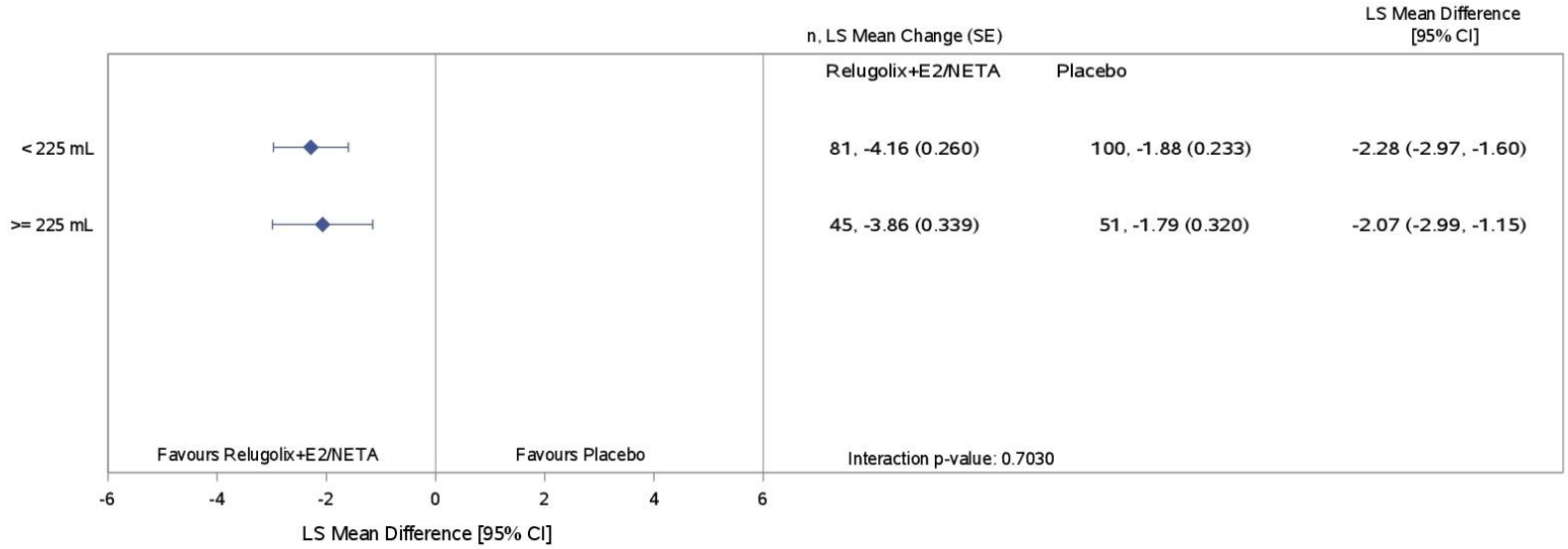
Figure EFF.MAXNRS.PEV.S5.CON.FP: Summary of Average Change from Baseline in Maximum NRS Score Over 24 Weeks, by Subgroup (Pain Evaluable Population)
Study: Pooled
Subgroup: MBL Volume at Baseline (mL)



Results are based on a mixed-effects model with study, treatment, visit, subgroup, treatment-by-visit interaction, and a subgroup-by-treatment interaction as fixed effects using a one-stage IPD meta-analysis approach. The multiple visits for each patient are the repeated measures as a random effect within each patient with an unstructured covariance.
The interaction p-value is based on the subgroup-by-treatment interaction term in the mixed-effects model used to compute the LS means, mean differences and 95% CIs. Missing subgroup levels are not included in estimation of the interaction p-value. The reference group is Placebo.
n: Number of patients with data; NETA: Norethindrone acetate; LS: Least squares; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

SOURCE: X:\Numerus\Studies\MYV\MYV102\Analysis\Prod\Progs\TFLs\FIG_EFF_NRS_S_CON_FP.SAS Date/time of run: 30JUN21 10:27
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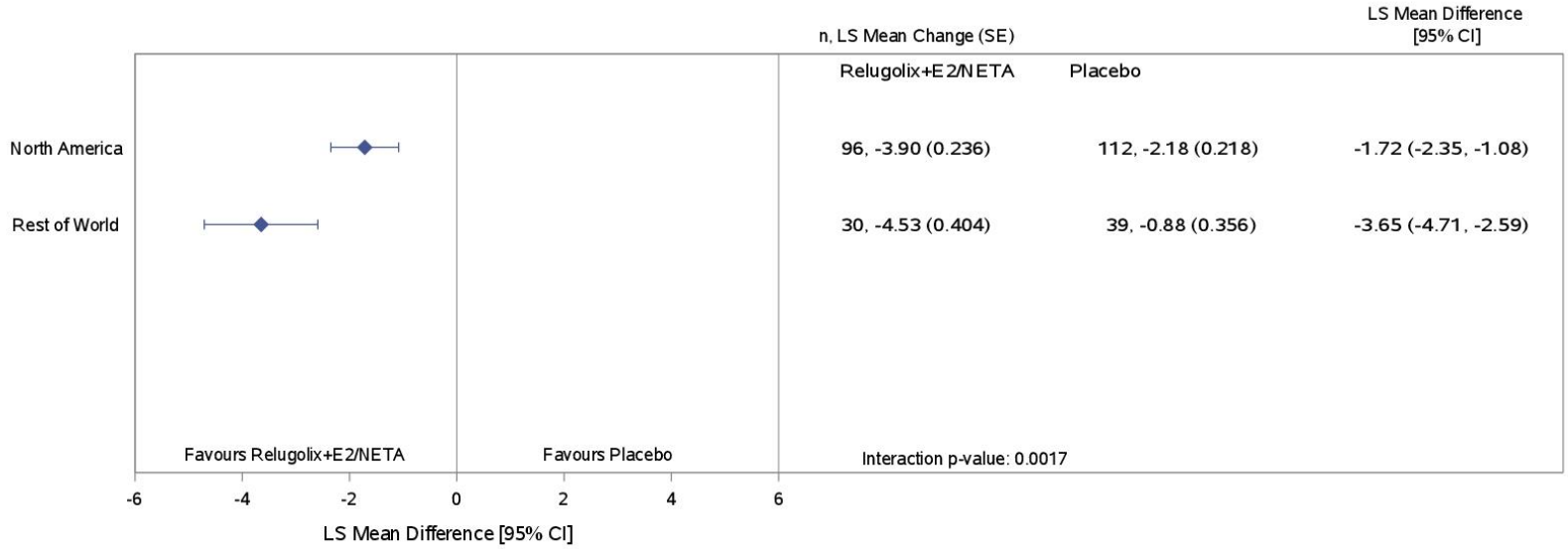
Figure EFF.MAXNRS.PEV.S6.CON.FP: Summary of Average Change from Baseline in Maximum NRS Score Over 24 Weeks, by Subgroup (Pain Evaluable Population)
Study: Pooled
Subgroup: Geographic Region I



Results are based on a mixed-effects model with study, treatment, visit, subgroup, treatment-by-visit interaction, and a subgroup-by-treatment interaction as fixed effects using a one-stage IPD meta-analysis approach. The multiple visits for each patient are the repeated measures as a random effect within each patient with an unstructured covariance.
The interaction p-value is based on the subgroup-by-treatment interaction term in the mixed-effects model used to compute the LS means, mean differences and 95% CIs. Missing subgroup levels are not included in estimation of the interaction p-value. The reference group is Placebo.
n: Number of patients with data; NETA: Norethindrone acetate; LS: Least squares; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

SOURCE: X:\Numerus\Studies\MYV\MYV102\Analysis\Prod\Progs\TFLs\FIG_EFF_NRS_S_CON_FP.SAS Date/time of run: 30JUN21 10:27
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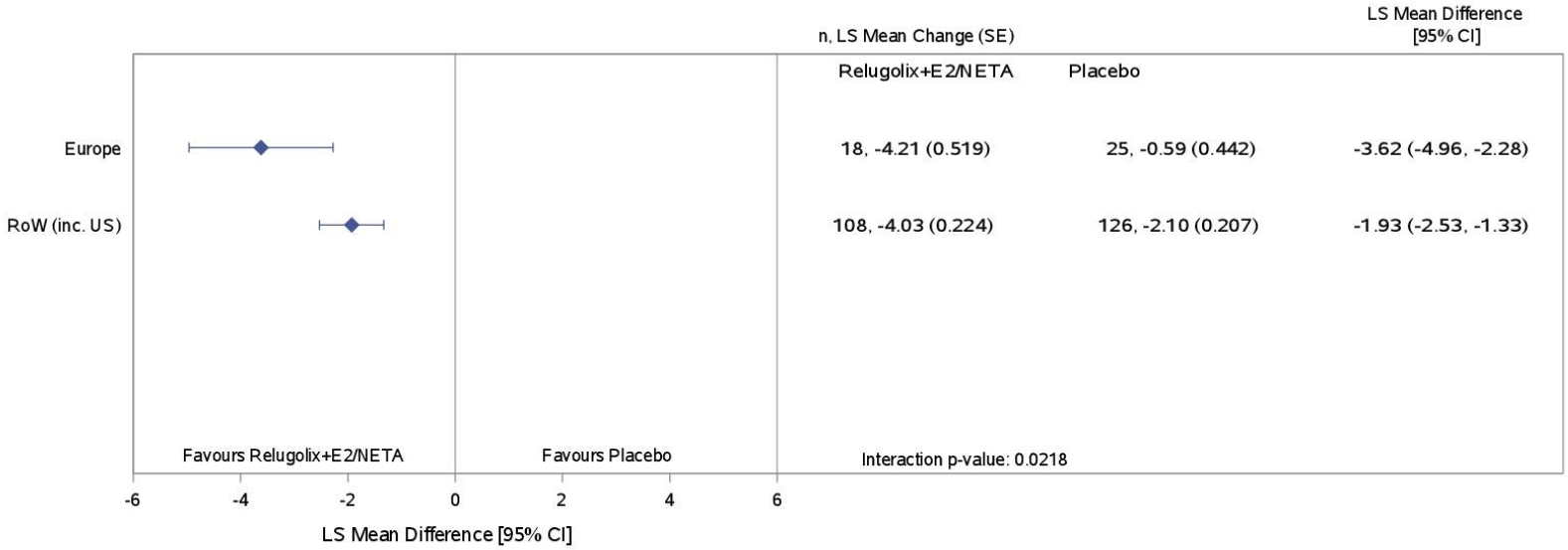
Figure EFF.MAXNRS.PEV.S7.CON.FP: Summary of Average Change from Baseline in Maximum NRS Score Over 24 Weeks, by Subgroup (Pain Evaluable Population)
Study: Pooled
Subgroup: Geographic Region II



Results are based on a mixed-effects model with study, treatment, visit, subgroup, treatment-by-visit interaction, and a subgroup-by-treatment interaction as fixed effects using a one-stage IPD meta-analysis approach. The multiple visits for each patient are the repeated measures as a random effect within each patient with an unstructured covariance.
The interaction p-value is based on the subgroup-by-treatment interaction term in the mixed-effects model used to compute the LS means, mean differences and 95% CIs. Missing subgroup levels are not included in estimation of the interaction p-value. The reference group is Placebo.
n: Number of patients with data; NETA: Norethindrone acetate; LS: Least squares; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

SOURCE: X:\Numerus\Studies\MYV\MYV102\Analysis\Prod\Progs\TFLs\FIG_EFF_NRS_S_CON_FP.SAS Date/time of run: 30JUN21 10:27
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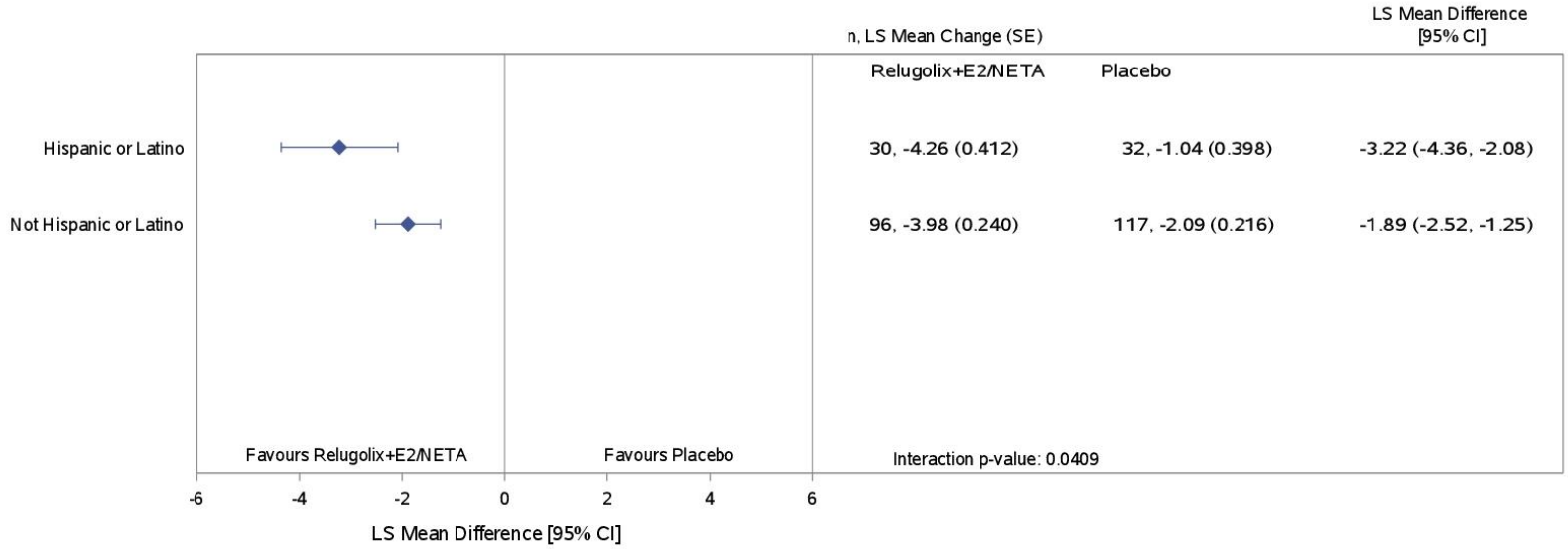
Figure EFF.MAXNRS.PEV.S8.CON.FP: Summary of Average Change from Baseline in Maximum NRS Score Over 24 Weeks, by Subgroup (Pain Evaluable Population)
Study: Pooled
Subgroup: Ethnicity



Results are based on a mixed-effects model with study, treatment, visit, subgroup, treatment-by-visit interaction, and a subgroup-by-treatment interaction as fixed effects using a one-stage IPD meta-analysis approach. The multiple visits for each patient are the repeated measures as a random effect within each patient with an unstructured covariance.
The interaction p-value is based on the subgroup-by-treatment interaction term in the mixed-effects model used to compute the LS means, mean differences and 95% CIs. Missing subgroup levels are not included in estimation of the interaction p-value. The reference group is Placebo.
n: Number of patients with data; NETA: Norethindrone acetate; LS: Least squares; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

SOURCE: X:\Numerus\Studies\MYV\MYV102\Analysis\Prod\Progs\TFLs\FIG_EFF_NRS_S_CON_FP.SAS Date/time of run: 30JUN21 10:27
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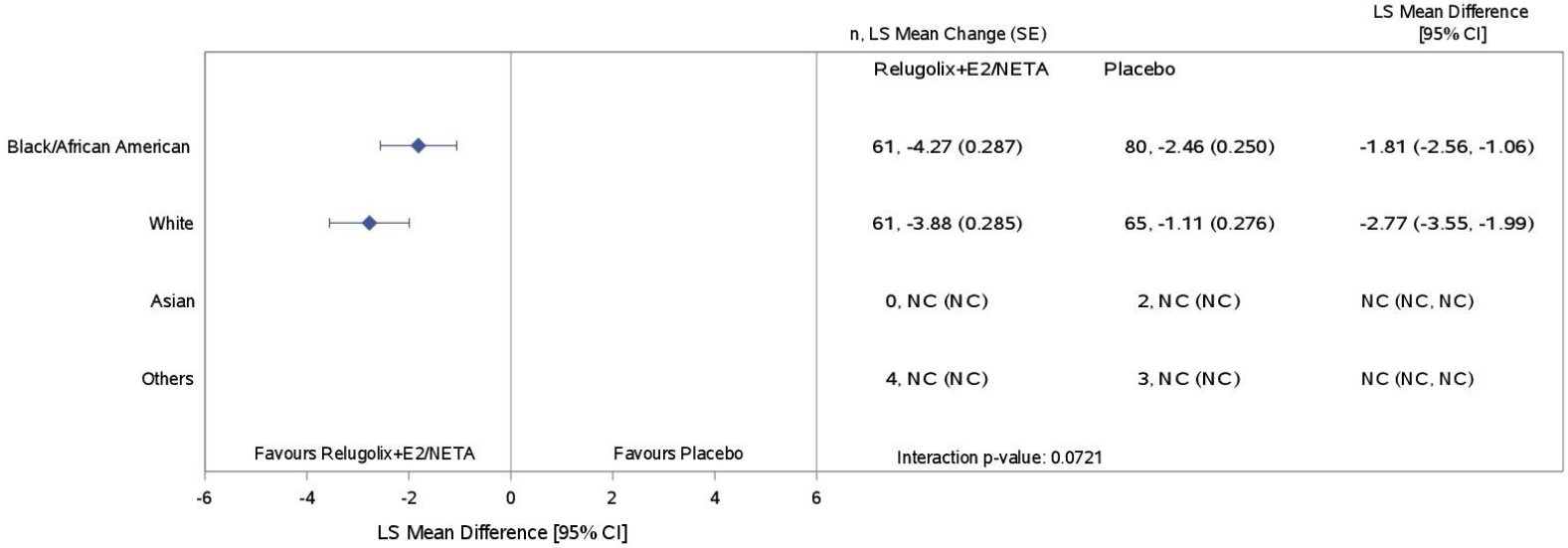
Figure EFF.MAXNRS.PEV.S9.CON.FP: Summary of Average Change from Baseline in Maximum NRS Score Over 24 Weeks, by Subgroup (Pain Evaluable Population)
Study: Pooled
Subgroup: Race



Results are based on a mixed-effects model with study, treatment, visit, subgroup, treatment-by-visit interaction, and a subgroup-by-treatment interaction as fixed effects using a one-stage IPD meta-analysis approach. The multiple visits for each patient are the repeated measures as a random effect within each patient with an unstructured covariance.
The interaction p-value is based on the subgroup-by-treatment interaction term in the mixed-effects model used to compute the LS means, mean differences and 95% CIs. Missing subgroup levels are not included in estimation of the interaction p-value. The reference group is Placebo.
n: Number of patients with data; NETA: Norethindrone acetate; LS: Least squares; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

SOURCE: X:\Numerus\Studies\MYV\MYV102\Analysis\Prod\Progs\TFLs\FIG_EFF_NRS_S_CON_FP.SAS Date/time of run: 30JUN21 10:27
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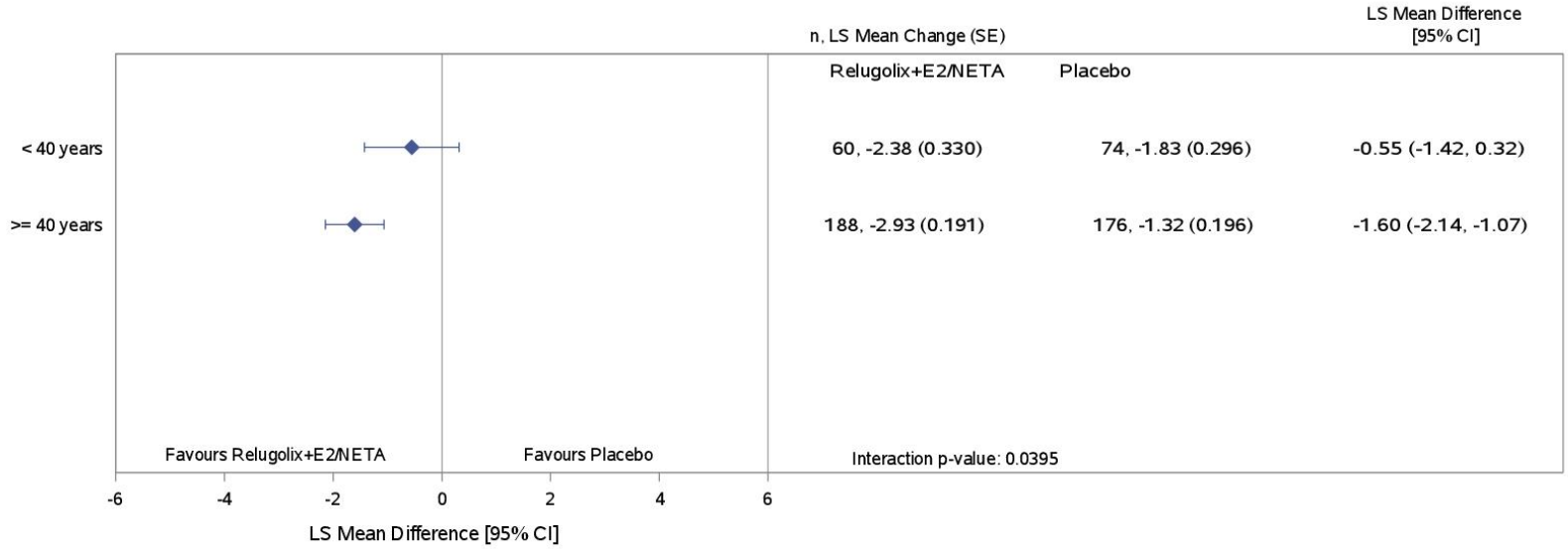
2.1.18 Summary of Average Change from Baseline in Maximum NRS Score Over 24 Weeks, by Subgroup (mITT Population)

Figure EFF.MAXNRS.MITT.S1.CON.FP: Summary of Average Change from Baseline in Maximum NRS Score Over 24 Weeks, by Subgroup (mITT Population)
Study: Pooled
Subgroup: Age (years)



Results are based on a mixed-effects model with study, treatment, visit, subgroup, treatment-by-visit interaction, and a subgroup-by-treatment interaction as fixed effects using a one-stage IPD meta-analysis approach. The multiple visits for each patient are the repeated measures as a random effect within each patient with an unstructured covariance.
The interaction p-value is based on the subgroup-by-treatment interaction term in the mixed-effects model used to compute the LS means, mean differences and 95% CIs. Missing subgroup levels are not included in estimation of the interaction p-value. The reference group is Placebo.
n: Number of patients with data; NETA: Norethindrone acetate; mITT: Modified intent-to-treat; LS: Least squares; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

SOURCE: X:\Numerus\Studies\MYV\MYV102\Analysis\Prod\Progs\TFLs\FIG_EFF_NRS_S_CON_FP.SAS Date/time of run: 30JUN21 10:27
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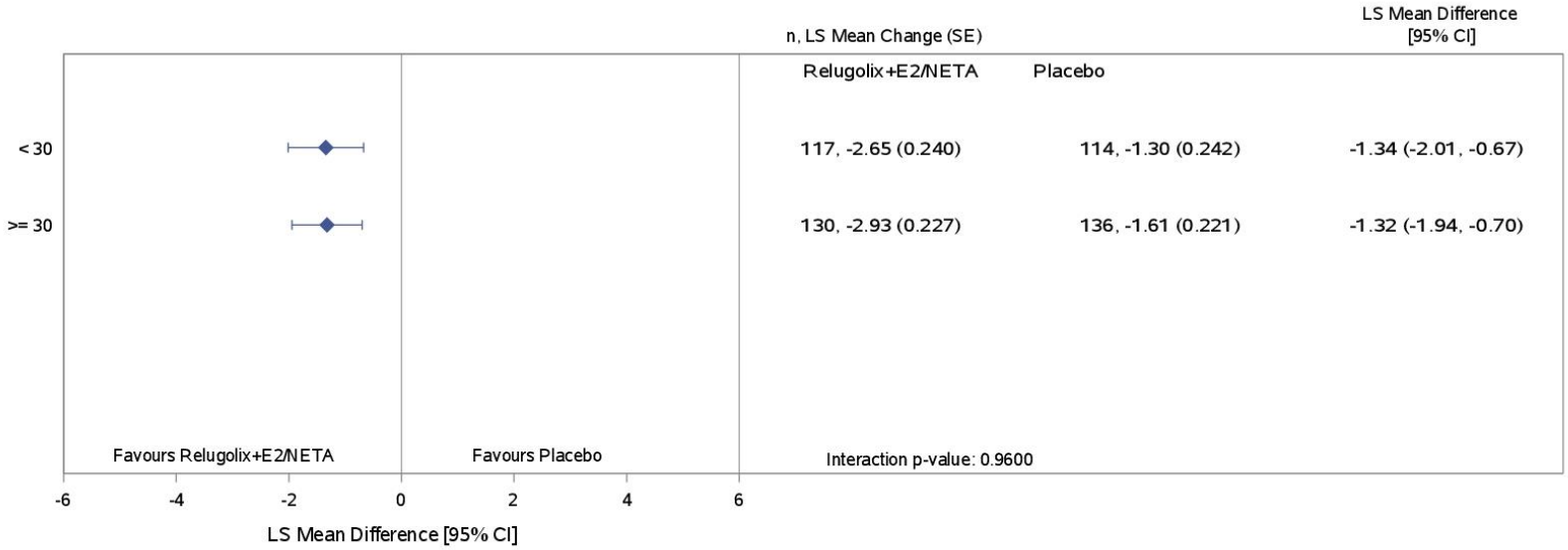
Figure EFF.MAXNRS.MITT.S2.CON.FP: Summary of Average Change from Baseline in Maximum NRS Score Over 24 Weeks, by Subgroup (mITT Population)
Study: Pooled
Subgroup: BMI (kg/m2) at Baseline



Results are based on a mixed-effects model with study, treatment, visit, subgroup, treatment-by-visit interaction, and a subgroup-by-treatment interaction as fixed effects using a one-stage IPD meta-analysis approach. The multiple visits for each patient are the repeated measures as a random effect within each patient with an unstructured covariance.
The interaction p-value is based on the subgroup-by-treatment interaction term in the mixed-effects model used to compute the LS means, mean differences and 95% CIs. Missing subgroup levels are not included in estimation of the interaction p-value. The reference group is Placebo.
n: Number of patients with data; NETA: Norethindrone acetate; mITT: Modified intent-to-treat; LS: Least squares; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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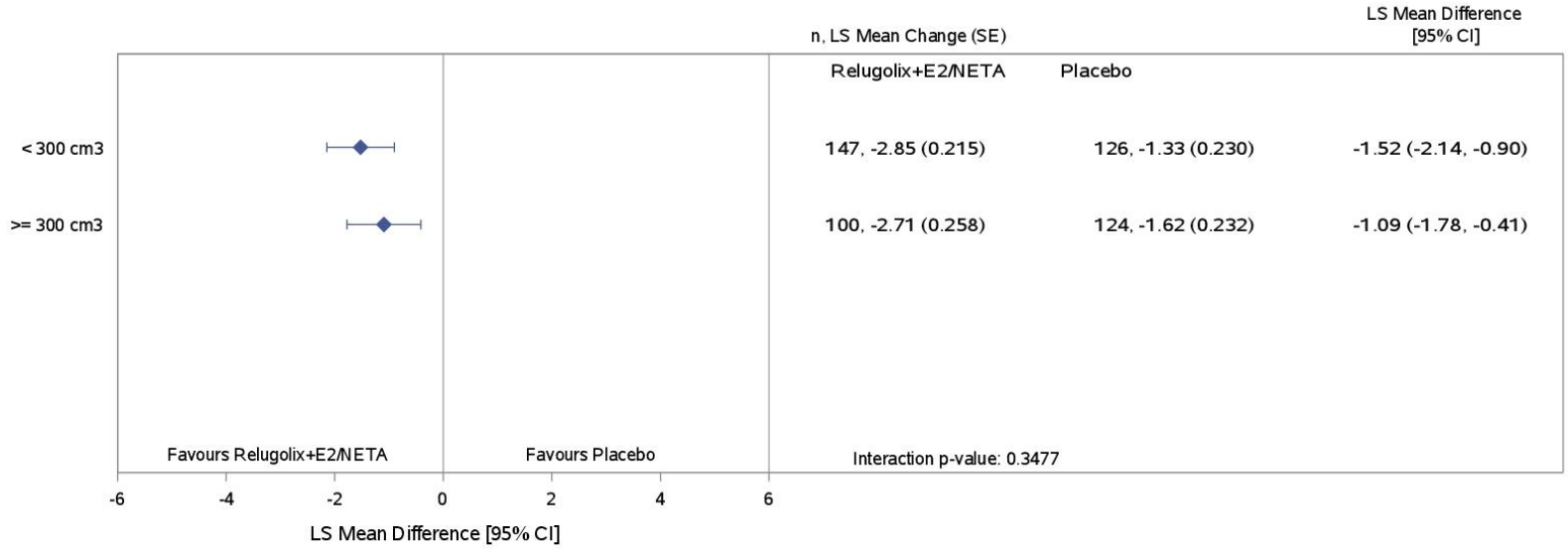
Figure EFF.MAXNRS.MITT.S3.CON.FP: Summary of Average Change from Baseline in Maximum NRS Score Over 24 Weeks, by Subgroup (mITT Population)
Study: Pooled
Subgroup: Uterine Volume at Baseline (cm3)



Results are based on a mixed-effects model with study, treatment, visit, subgroup, treatment-by-visit interaction, and a subgroup-by-treatment interaction as fixed effects using a one-stage IPD meta-analysis approach. The multiple visits for each patient are the repeated measures as a random effect within each patient with an unstructured covariance.
The interaction p-value is based on the subgroup-by-treatment interaction term in the mixed-effects model used to compute the LS means, mean differences and 95% CIs. Missing subgroup levels are not included in estimation of the interaction p-value. The reference group is Placebo.
n: Number of patients with data; NETA: Norethindrone acetate; mITT: Modified intent-to-treat; LS: Least squares; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

SOURCE: X:\Numerus\Studies\MYV\MYV102\Analysis\Prod\Progs\TFLs\FIG_EFF_NRS_S_CON_FP.SAS Date/time of run: 30JUN21 10:27
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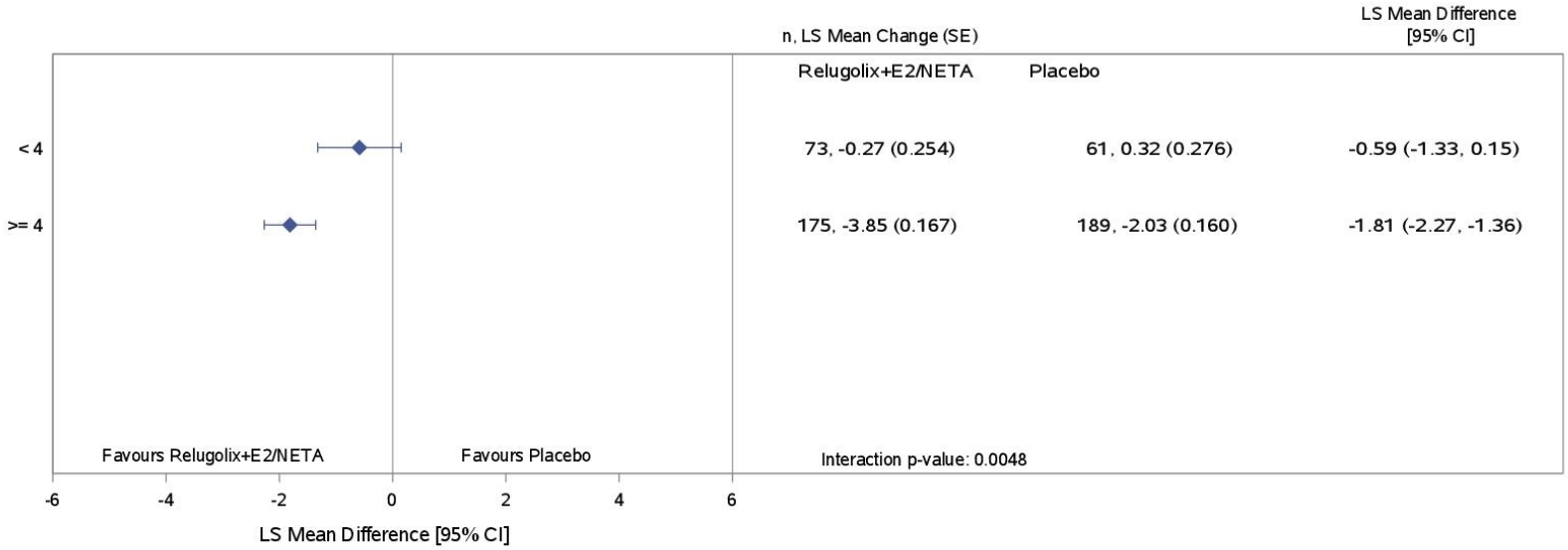
Figure EFF.MAXNRS.MITT.S4.CON.FP: Summary of Average Change from Baseline in Maximum NRS Score Over 24 Weeks, by Subgroup (mITT Population)
Study: Pooled
Subgroup: Maximum NRS Pain Score at Baseline



Results are based on a mixed-effects model with study, treatment, visit, subgroup, treatment-by-visit interaction, and a subgroup-by-treatment interaction as fixed effects using a one-stage IPD meta-analysis approach. The multiple visits for each patient are the repeated measures as a random effect within each patient with an unstructured covariance.
The interaction p-value is based on the subgroup-by-treatment interaction term in the mixed-effects model used to compute the LS means, mean differences and 95% CIs. Missing subgroup levels are not included in estimation of the interaction p-value. The reference group is Placebo.
n: Number of patients with data; NETA: Norethindrone acetate; mITT: Modified intent-to-treat; LS: Least squares; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

SOURCE: X:\Numerus\Studies\MYV\MYV102\Analysis\Prod\Progs\TFLs\FIG_EFF_NRS_S_CON_FP.SAS Date/time of run: 30JUN21 10:27
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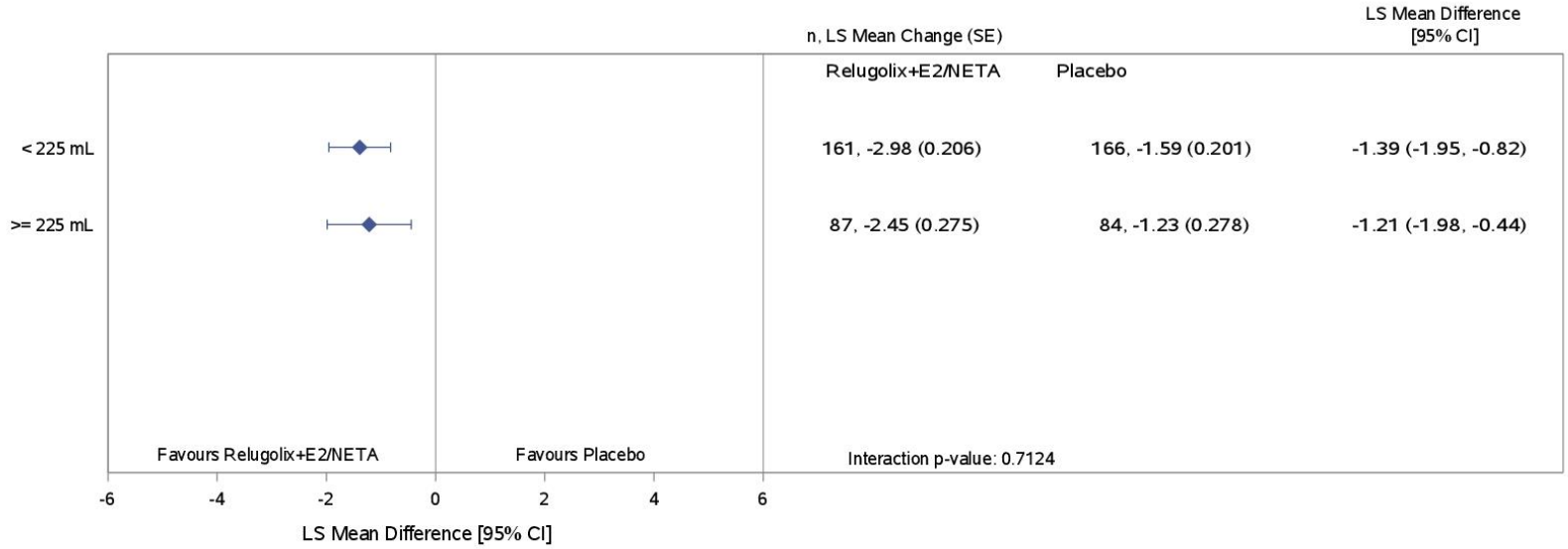
Figure EFF.MAXNRS.MITT.S5.CON.FP: Summary of Average Change from Baseline in Maximum NRS Score Over 24 Weeks, by Subgroup (mITT Population)
Study: Pooled
Subgroup: MBL Volume at Baseline (mL)



Results are based on a mixed-effects model with study, treatment, visit, subgroup, treatment-by-visit interaction, and a subgroup-by-treatment interaction as fixed effects using a one-stage IPD meta-analysis approach. The multiple visits for each patient are the repeated measures as a random effect within each patient with an unstructured covariance.
The interaction p-value is based on the subgroup-by-treatment interaction term in the mixed-effects model used to compute the LS means, mean differences and 95% CIs. Missing subgroup levels are not included in estimation of the interaction p-value. The reference group is Placebo.
n: Number of patients with data; NETA: Norethindrone acetate; mITT: Modified intent-to-treat; LS: Least squares; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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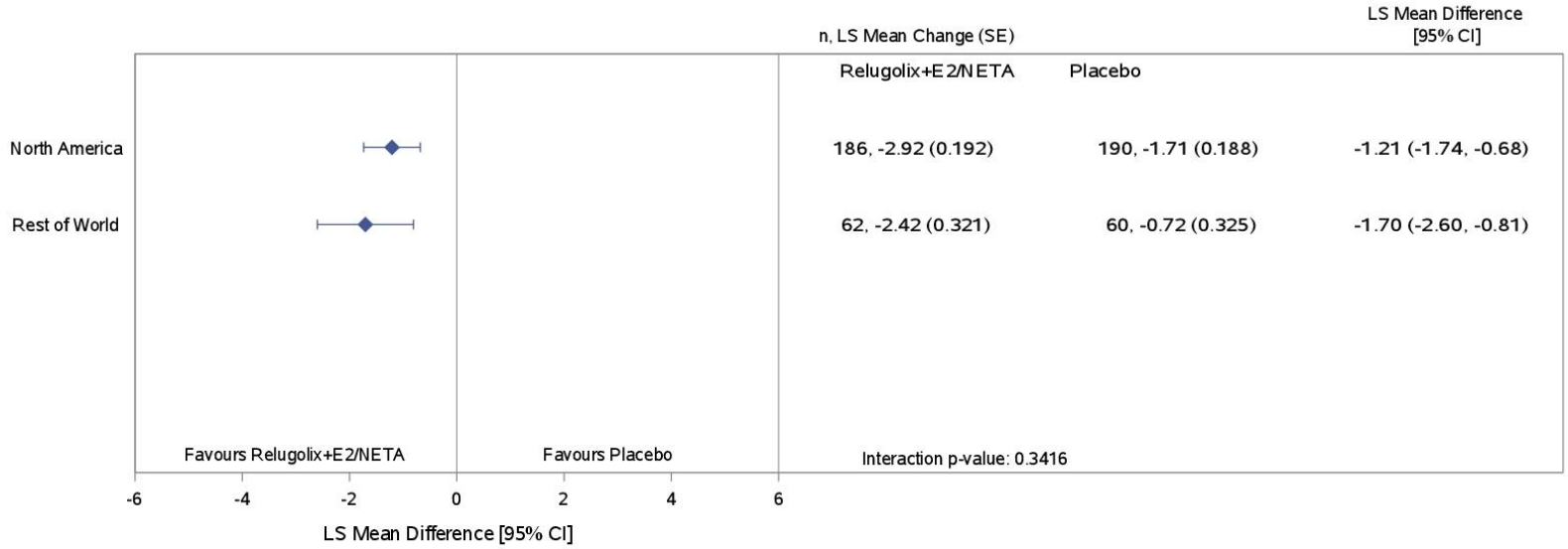
Figure EFF.MAXNRS.MITT.S6.CON.FP: Summary of Average Change from Baseline in Maximum NRS Score Over 24 Weeks, by Subgroup (mITT Population)
Study: Pooled
Subgroup: Geographic Region I



Results are based on a mixed-effects model with study, treatment, visit, subgroup, treatment-by-visit interaction, and a subgroup-by-treatment interaction as fixed effects using a one-stage IPD meta-analysis approach. The multiple visits for each patient are the repeated measures as a random effect within each patient with an unstructured covariance.
The interaction p-value is based on the subgroup-by-treatment interaction term in the mixed-effects model used to compute the LS means, mean differences and 95% CIs. Missing subgroup levels are not included in estimation of the interaction p-value. The reference group is Placebo.
n: Number of patients with data; NETA: Norethindrone acetate; mITT: Modified intent-to-treat; LS: Least squares; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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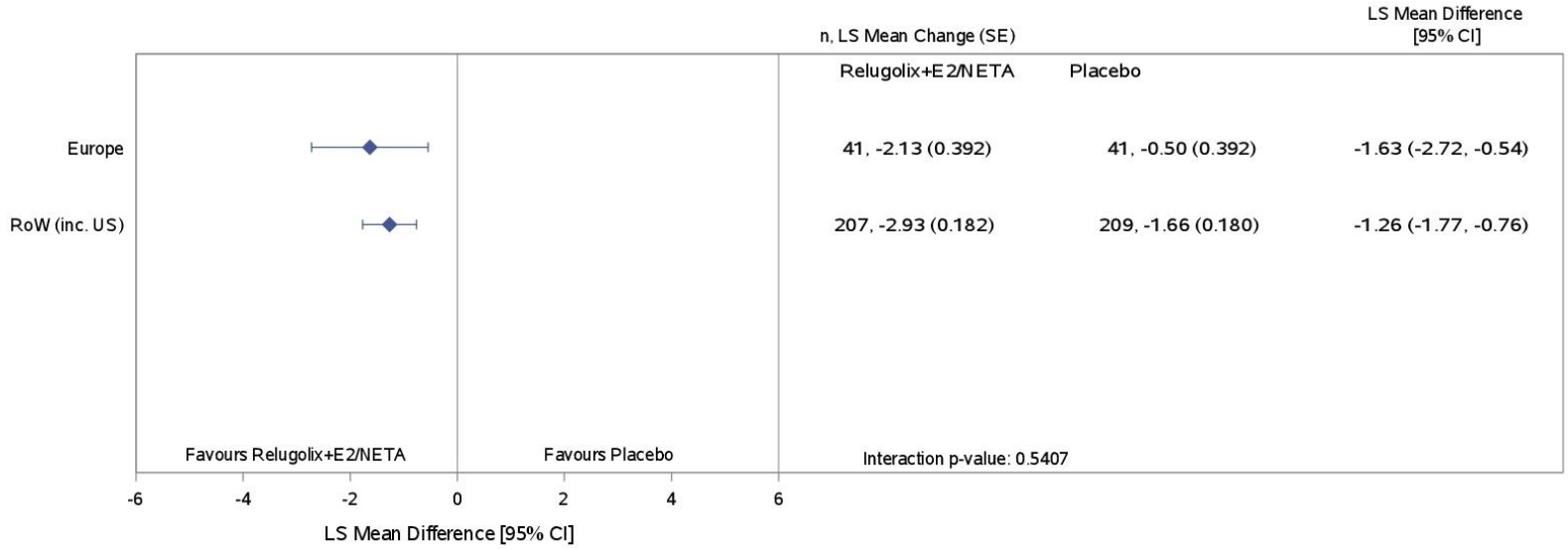
Figure EFF.MAXNRS.MITT.S7.CON.FP: Summary of Average Change from Baseline in Maximum NRS Score Over 24 Weeks, by Subgroup (mITT Population)
Study: Pooled
Subgroup: Geographic Region II



Results are based on a mixed-effects model with study, treatment, visit, subgroup, treatment-by-visit interaction, and a subgroup-by-treatment interaction as fixed effects using a one-stage IPD meta-analysis approach. The multiple visits for each patient are the repeated measures as a random effect within each patient with an unstructured covariance.
The interaction p-value is based on the subgroup-by-treatment interaction term in the mixed-effects model used to compute the LS means, mean differences and 95% CIs. Missing subgroup levels are not included in estimation of the interaction p-value. The reference group is Placebo.
n: Number of patients with data; NETA: Norethindrone acetate; mITT: Modified intent-to-treat; LS: Least squares; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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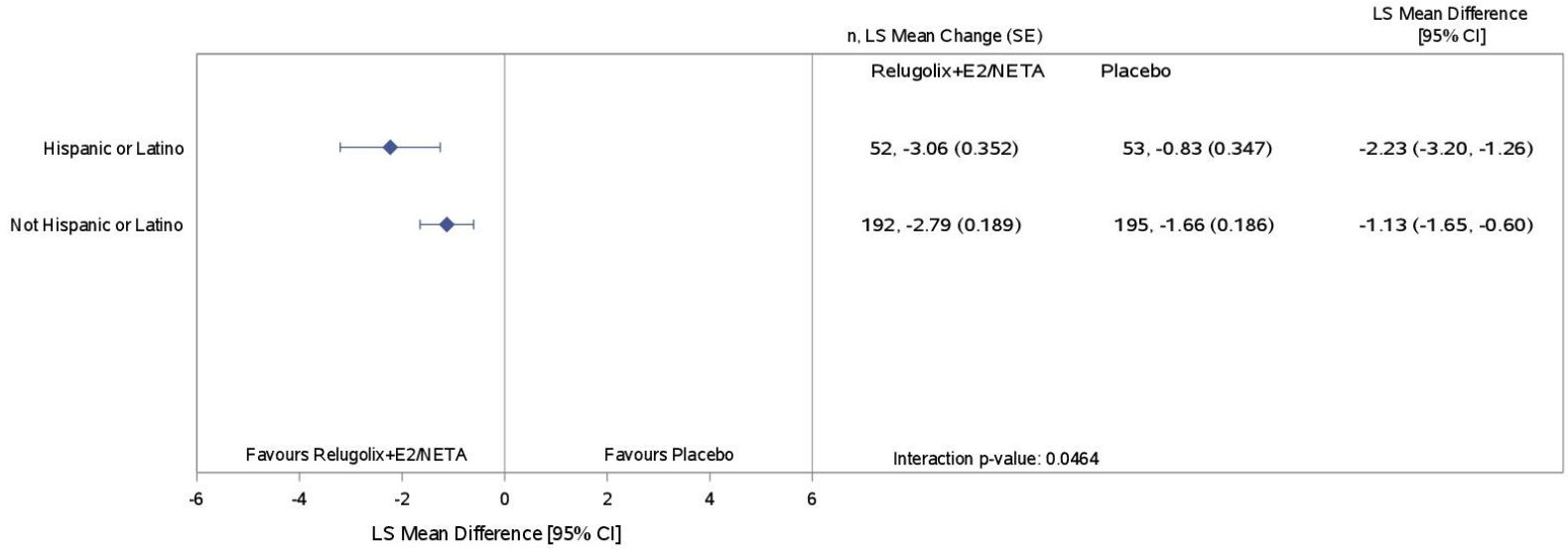
Figure EFF.MAXNRS.MITT.S8.CON.FP: Summary of Average Change from Baseline in Maximum NRS Score Over 24 Weeks, by Subgroup (mITT Population)
Study: Pooled
Subgroup: Ethnicity



Results are based on a mixed-effects model with study, treatment, visit, subgroup, treatment-by-visit interaction, and a subgroup-by-treatment interaction as fixed effects using a one-stage IPD meta-analysis approach. The multiple visits for each patient are the repeated measures as a random effect within each patient with an unstructured covariance.
The interaction p-value is based on the subgroup-by-treatment interaction term in the mixed-effects model used to compute the LS means, mean differences and 95% CIs. Missing subgroup levels are not included in estimation of the interaction p-value. The reference group is Placebo.
n: Number of patients with data; NETA: Norethindrone acetate; mITT: Modified intent-to-treat; LS: Least squares; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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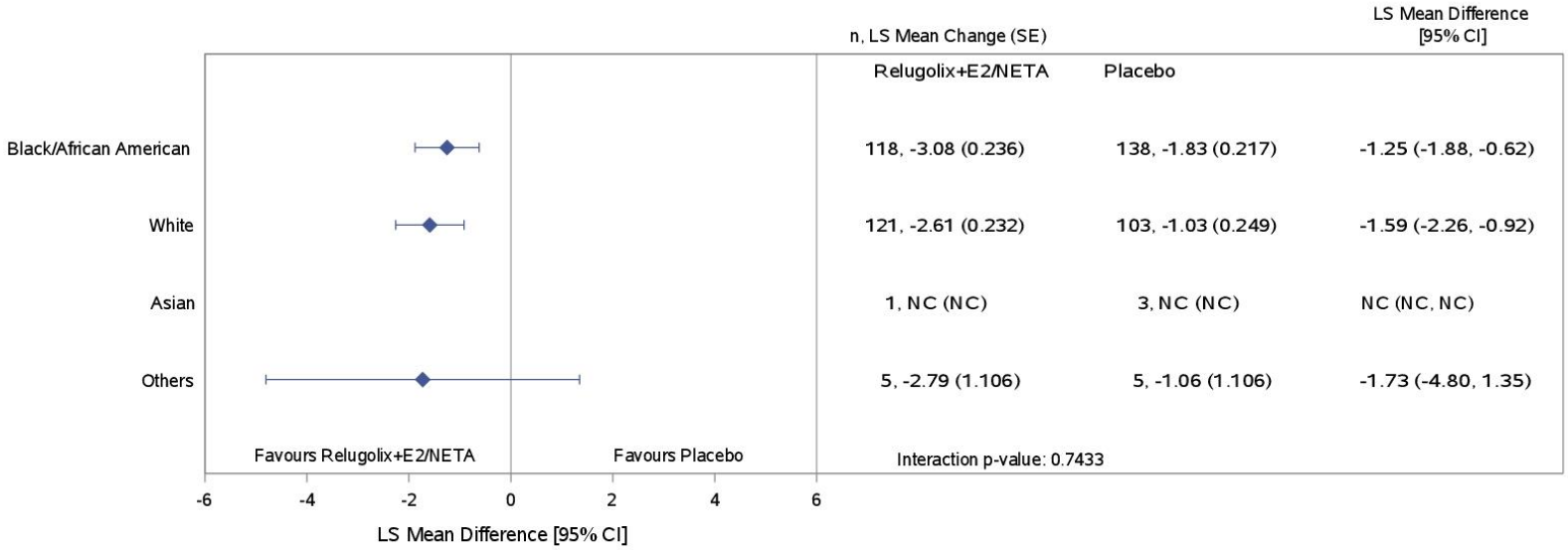
Figure EFF.MAXNRS.MITT.S9.CON.FP: Summary of Average Change from Baseline in Maximum NRS Score Over 24 Weeks, by Subgroup (mITT Population)
Study: Pooled
Subgroup: Race



Results are based on a mixed-effects model with study, treatment, visit, subgroup, treatment-by-visit interaction, and a subgroup-by-treatment interaction as fixed effects using a one-stage IPD meta-analysis approach. The multiple visits for each patient are the repeated measures as a random effect within each patient with an unstructured covariance.
The interaction p-value is based on the subgroup-by-treatment interaction term in the mixed-effects model used to compute the LS means, mean differences and 95% CIs. Missing subgroup levels are not included in estimation of the interaction p-value. The reference group is Placebo.
n: Number of patients with data; NETA: Norethindrone acetate; mITT: Modified intent-to-treat; LS: Least squares; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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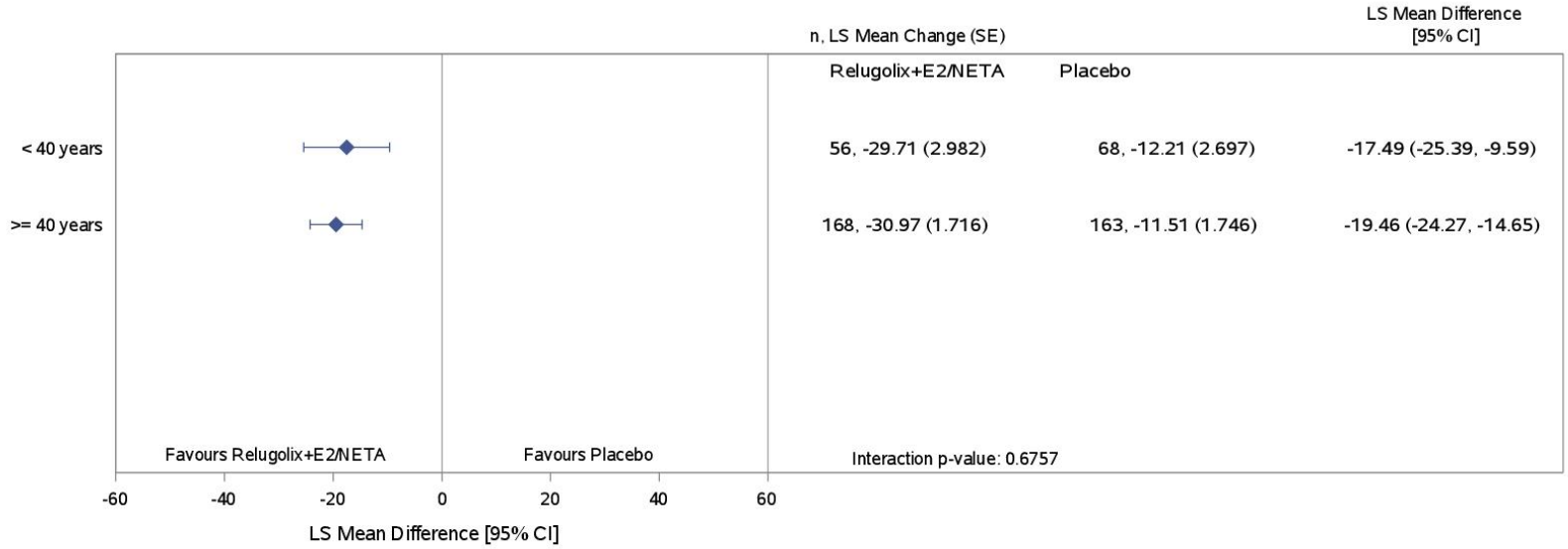
2.2 Gesundheitsbezogene Lebensqualität

2.2.1 Summary of Average Change from Baseline in UFS-QoL Symptom Severity Scale Score Over 24 Weeks, by Subgroup (mITT Population)

Figure QOL.UFSSSS.MITT.S1.CON.FP: Summary of Average Change from Baseline in UFS-QoL Symptom Severity Scale Score Over 24 Weeks, by Subgroup (mITT Population)
Study: Pooled
Subgroup: Age (years)



Results are based on a mixed-effects model with study, treatment, visit, subgroup, treatment-by-visit interaction, and a subgroup-by-treatment interaction as fixed effects using a one-stage IPD meta-analysis approach. The multiple visits for each patient are the repeated measures as a random effect within each patient with an unstructured covariance.
The interaction p-value is based on the subgroup-by-treatment interaction term in the mixed-effects model used to compute the LS means, mean differences and 95% CIs. Missing subgroup levels are not included in estimation of the interaction p-value. The reference group is Placebo.
n: Number of patients with data; NETA: Norethindrone acetate; mITT: Modified intent-to-treat; LS: Least squares; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

SOURCE: X:\Numerus\Studies\MYV\MYV102\Analysis\Prod\Progs\TFLs\FIG_QOL_QS_S_CON_FP.SAS Date/time of run: 30JUN21 10:30
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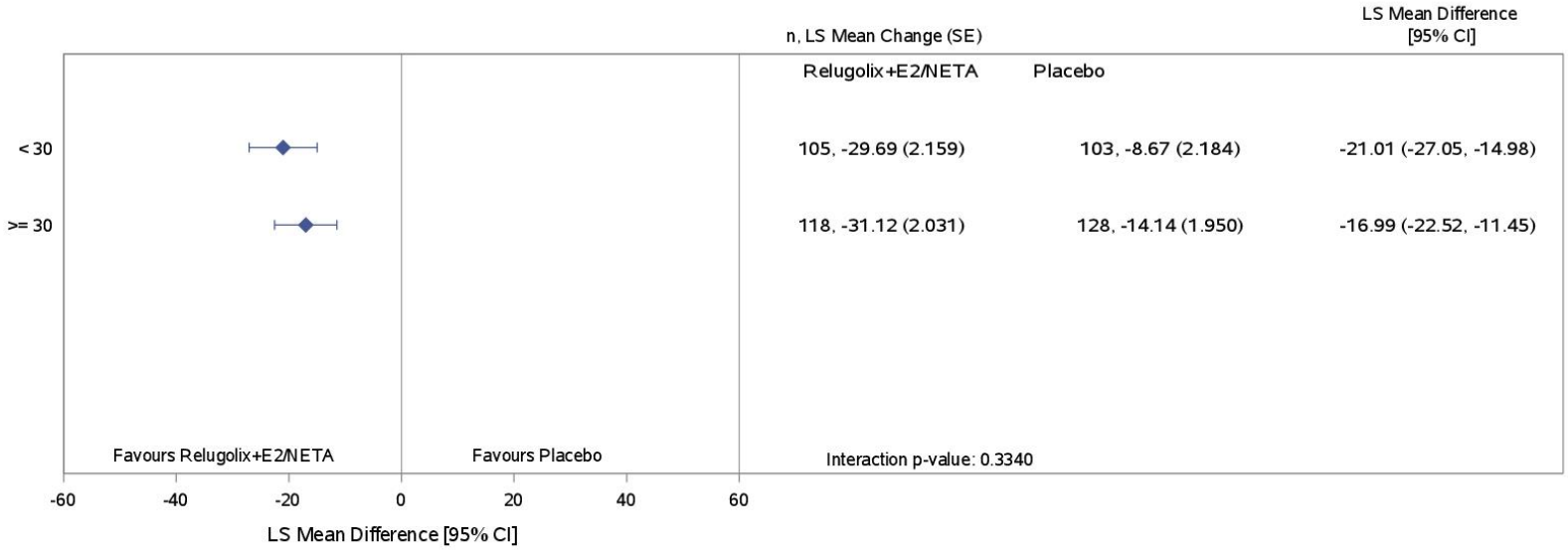
Figure QOL.UFSSSS.MITT.S2.CON.FP: Summary of Average Change from Baseline in UFS-QoL Symptom Severity Scale Score Over 24 Weeks, by Subgroup (mITT Population)
Study: Pooled
Subgroup: BMI (kg/m2) at Baseline



Results are based on a mixed-effects model with study, treatment, visit, subgroup, treatment-by-visit interaction, and a subgroup-by-treatment interaction as fixed effects using a one-stage IPD meta-analysis approach. The multiple visits for each patient are the repeated measures as a random effect within each patient with an unstructured covariance.
The interaction p-value is based on the subgroup-by-treatment interaction term in the mixed-effects model used to compute the LS means, mean differences and 95% CIs. Missing subgroup levels are not included in estimation of the interaction p-value. The reference group is Placebo.
n: Number of patients with data; NETA: Norethindrone acetate; mITT: Modified intent-to-treat; LS: Least squares; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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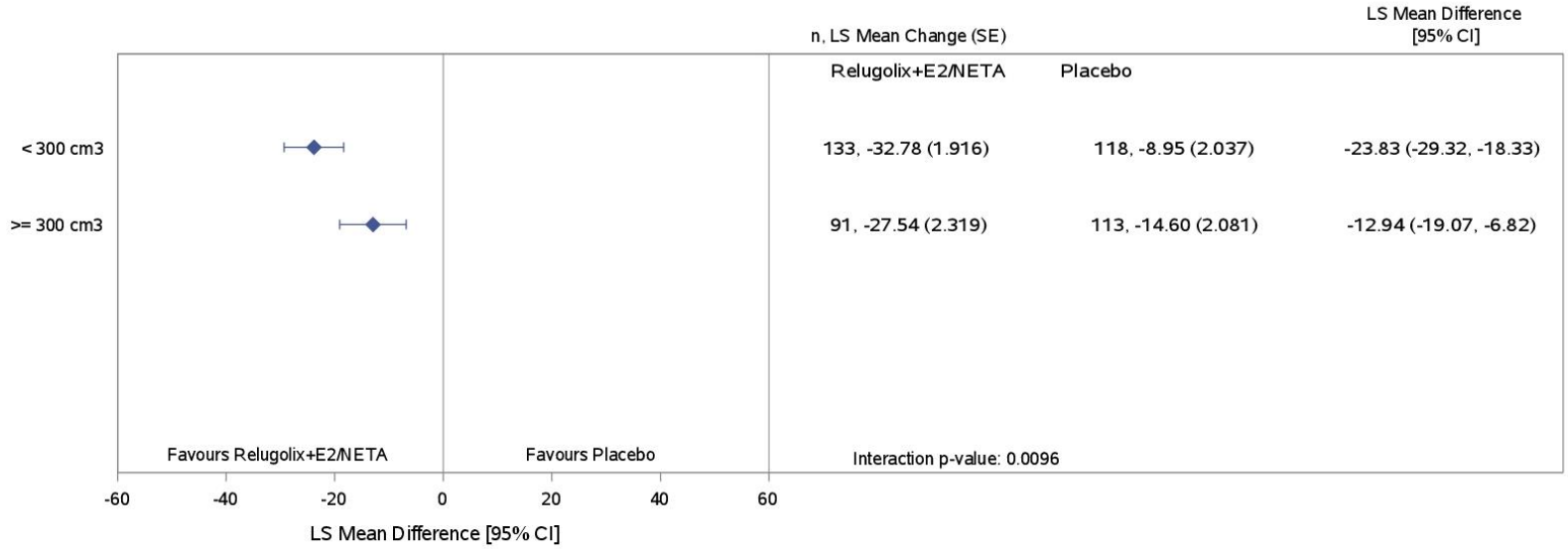
Figure QOL.UFSSSS.MITT.S3.CON.FP: Summary of Average Change from Baseline in UFS-QoL Symptom Severity Scale Score Over 24 Weeks, by Subgroup (mITT Population)
Study: Pooled
Subgroup: Uterine Volume at Baseline (cm3)



Results are based on a mixed-effects model with study, treatment, visit, subgroup, treatment-by-visit interaction, and a subgroup-by-treatment interaction as fixed effects using a one-stage IPD meta-analysis approach. The multiple visits for each patient are the repeated measures as a random effect within each patient with an unstructured covariance.
The interaction p-value is based on the subgroup-by-treatment interaction term in the mixed-effects model used to compute the LS means, mean differences and 95% CIs. Missing subgroup levels are not included in estimation of the interaction p-value. The reference group is Placebo.
n: Number of patients with data; NETA: Norethindrone acetate; mITT: Modified intent-to-treat; LS: Least squares; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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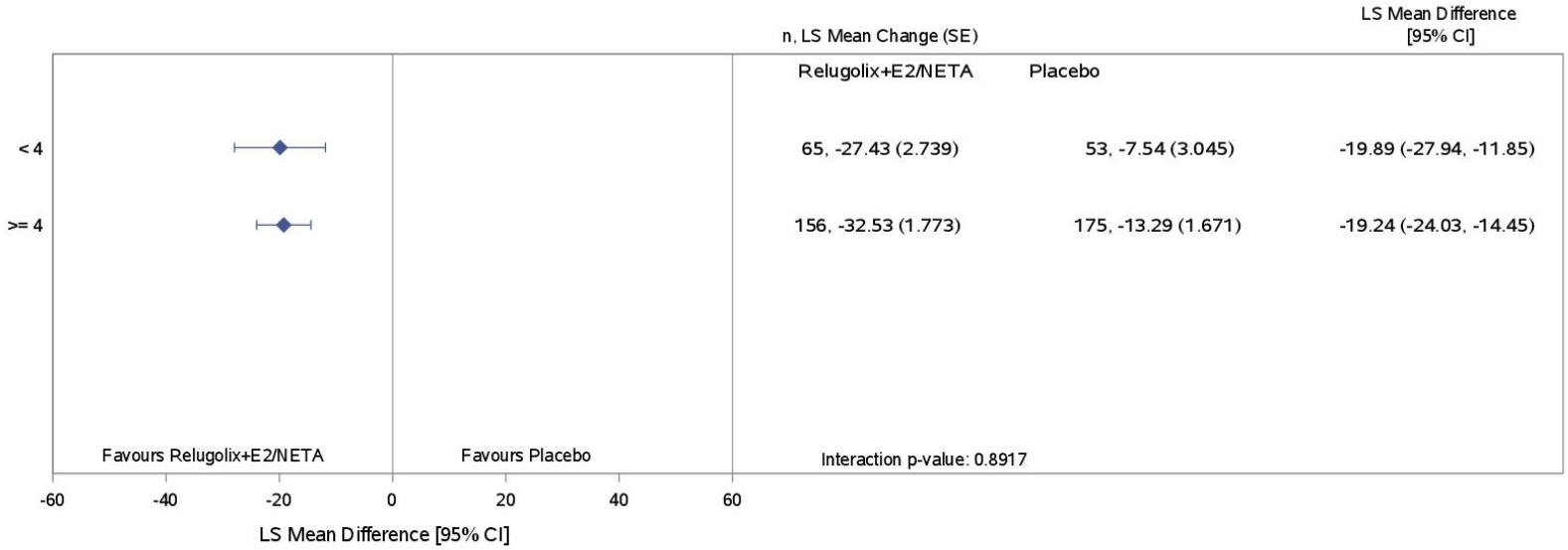
Figure QOL.UFSSSS.MITT.S4.CON.FP: Summary of Average Change from Baseline in UFS-QoL Symptom Severity Scale Score Over 24 Weeks, by Subgroup (mITT Population)
Study: Pooled
Subgroup: Maximum NRS Pain Score at Baseline



Results are based on a mixed-effects model with study, treatment, visit, subgroup, treatment-by-visit interaction, and a subgroup-by-treatment interaction as fixed effects using a one-stage IPD meta-analysis approach. The multiple visits for each patient are the repeated measures as a random effect within each patient with an unstructured covariance.
The interaction p-value is based on the subgroup-by-treatment interaction term in the mixed-effects model used to compute the LS means, mean differences and 95% CIs. Missing subgroup levels are not included in estimation of the interaction p-value. The reference group is Placebo.
n: Number of patients with data; NETA: Norethindrone acetate; mITT: Modified intent-to-treat; LS: Least squares; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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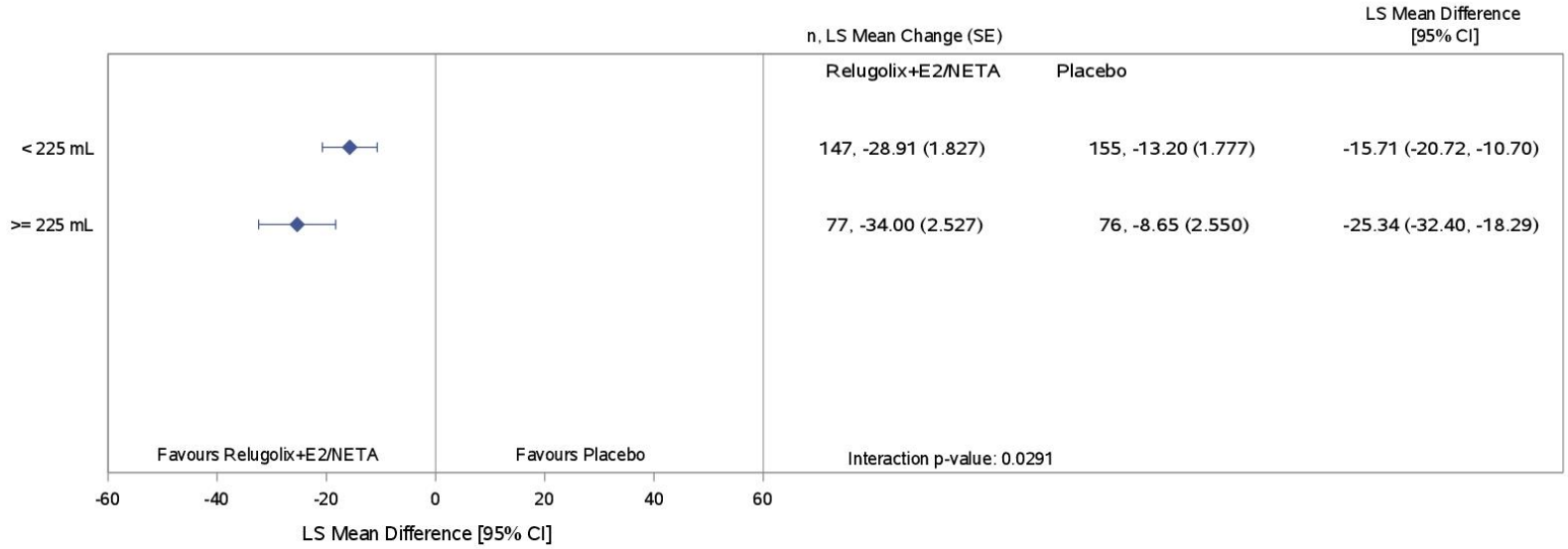
Figure QOL.UFSSSS.MITT.S5.CON.FP: Summary of Average Change from Baseline in UFS-QoL Symptom Severity Scale Score Over 24 Weeks, by Subgroup (mITT Population)
Study: Pooled
Subgroup: MBL Volume at Baseline (mL)



Results are based on a mixed-effects model with study, treatment, visit, subgroup, treatment-by-visit interaction, and a subgroup-by-treatment interaction as fixed effects using a one-stage IPD meta-analysis approach. The multiple visits for each patient are the repeated measures as a random effect within each patient with an unstructured covariance.
The interaction p-value is based on the subgroup-by-treatment interaction term in the mixed-effects model used to compute the LS means, mean differences and 95% CIs. Missing subgroup levels are not included in estimation of the interaction p-value. The reference group is Placebo.
n: Number of patients with data; NETA: Norethindrone acetate; mITT: Modified intent-to-treat; LS: Least squares; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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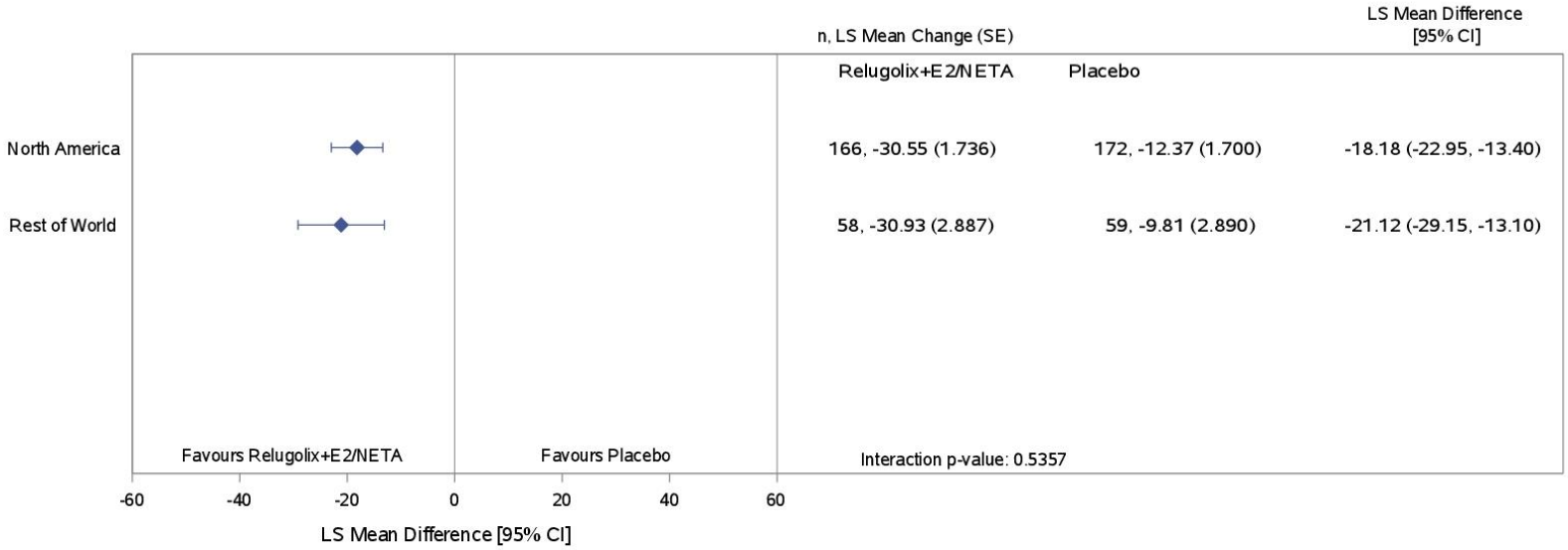
Figure QOL.UFSSSS.MITT.S6.CON.FP: Summary of Average Change from Baseline in UFS-QoL Symptom Severity Scale Score Over 24 Weeks, by Subgroup (mITT Population)
Study: Pooled
Subgroup: Geographic Region I



Results are based on a mixed-effects model with study, treatment, visit, subgroup, treatment-by-visit interaction, and a subgroup-by-treatment interaction as fixed effects using a one-stage IPD meta-analysis approach. The multiple visits for each patient are the repeated measures as a random effect within each patient with an unstructured covariance.
The interaction p-value is based on the subgroup-by-treatment interaction term in the mixed-effects model used to compute the LS means, mean differences and 95% CIs. Missing subgroup levels are not included in estimation of the interaction p-value. The reference group is Placebo.
n: Number of patients with data; NETA: Norethindrone acetate; mITT: Modified intent-to-treat; LS: Least squares; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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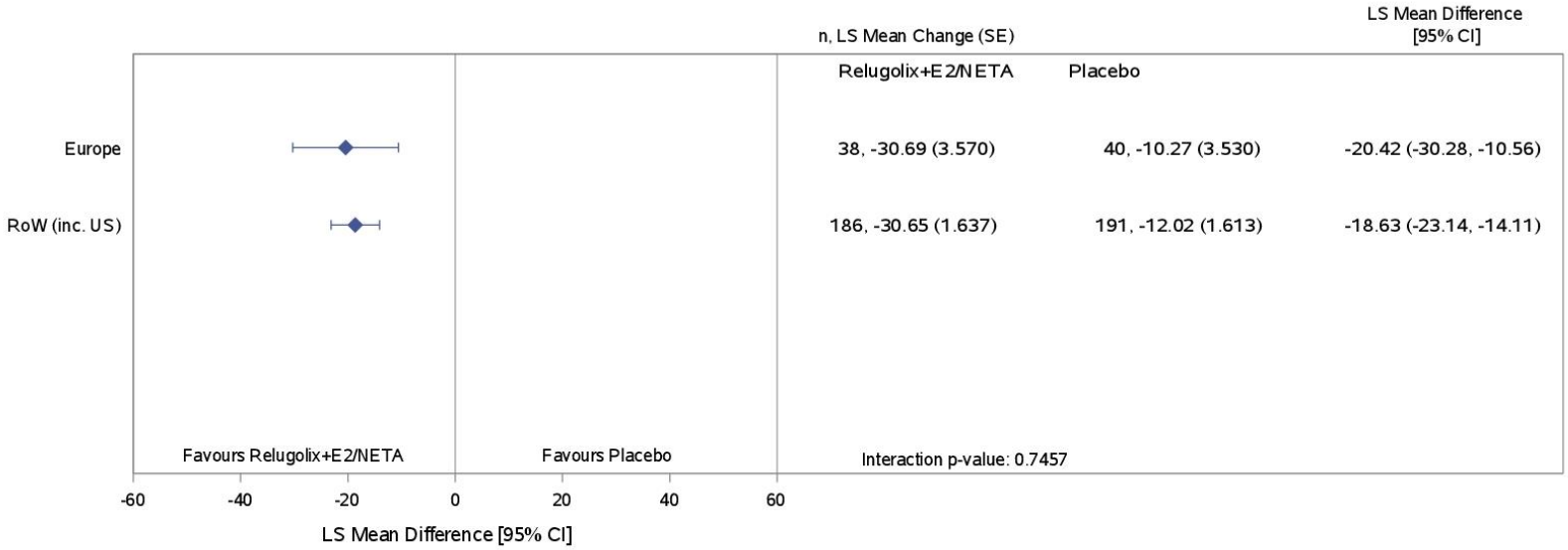
Figure QOL.UFSSSS.MITT.S7.CON.FP: Summary of Average Change from Baseline in UFS-QoL Symptom Severity Scale Score Over 24 Weeks, by Subgroup (mITT Population)
Study: Pooled
Subgroup: Geographic Region II



Results are based on a mixed-effects model with study, treatment, visit, subgroup, treatment-by-visit interaction, and a subgroup-by-treatment interaction as fixed effects using a one-stage IPD meta-analysis approach. The multiple visits for each patient are the repeated measures as a random effect within each patient with an unstructured covariance.
The interaction p-value is based on the subgroup-by-treatment interaction term in the mixed-effects model used to compute the LS means, mean differences and 95% CIs. Missing subgroup levels are not included in estimation of the interaction p-value. The reference group is Placebo.
n: Number of patients with data; NETA: Norethindrone acetate; mITT: Modified intent-to-treat; LS: Least squares; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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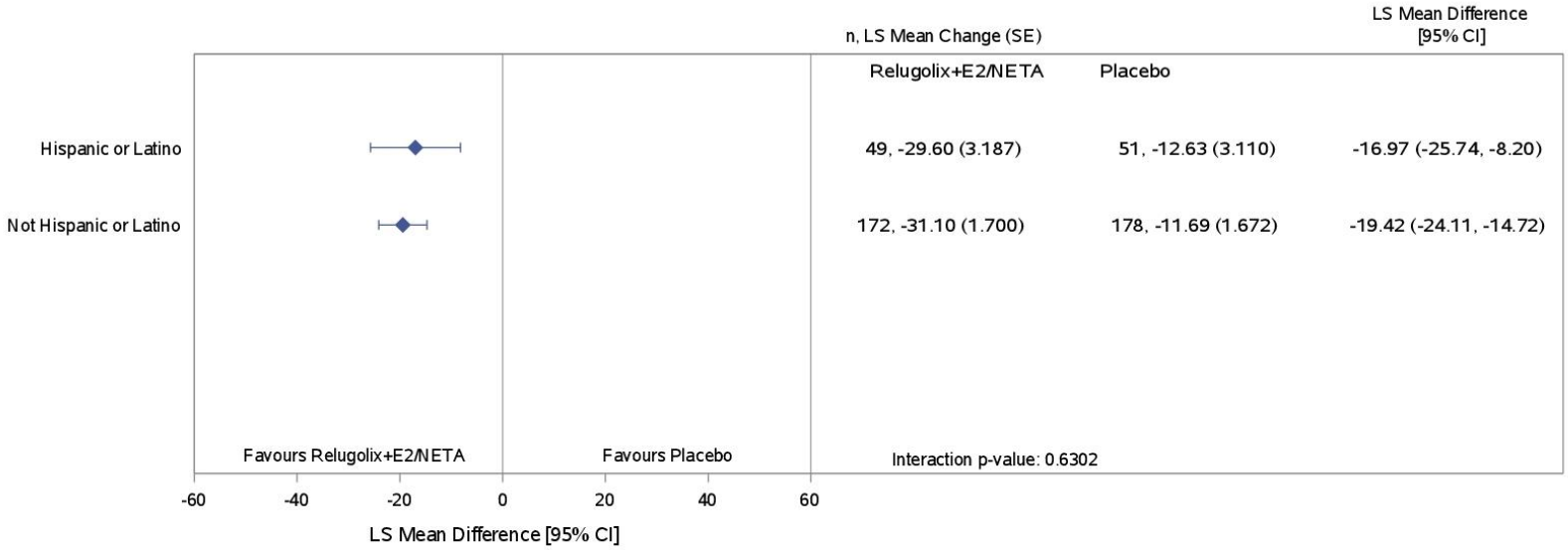
Figure QOL.UFSSSS.MITT.S8.CON.FP: Summary of Average Change from Baseline in UFS-QoL Symptom Severity Scale Score Over 24 Weeks, by Subgroup (mITT Population)
Study: Pooled
Subgroup: Ethnicity



Results are based on a mixed-effects model with study, treatment, visit, subgroup, treatment-by-visit interaction, and a subgroup-by-treatment interaction as fixed effects using a one-stage IPD meta-analysis approach. The multiple visits for each patient are the repeated measures as a random effect within each patient with an unstructured covariance.
The interaction p-value is based on the subgroup-by-treatment interaction term in the mixed-effects model used to compute the LS means, mean differences and 95% CIs. Missing subgroup levels are not included in estimation of the interaction p-value. The reference group is Placebo.
n: Number of patients with data; NETA: Norethindrone acetate; mITT: Modified intent-to-treat; LS: Least squares; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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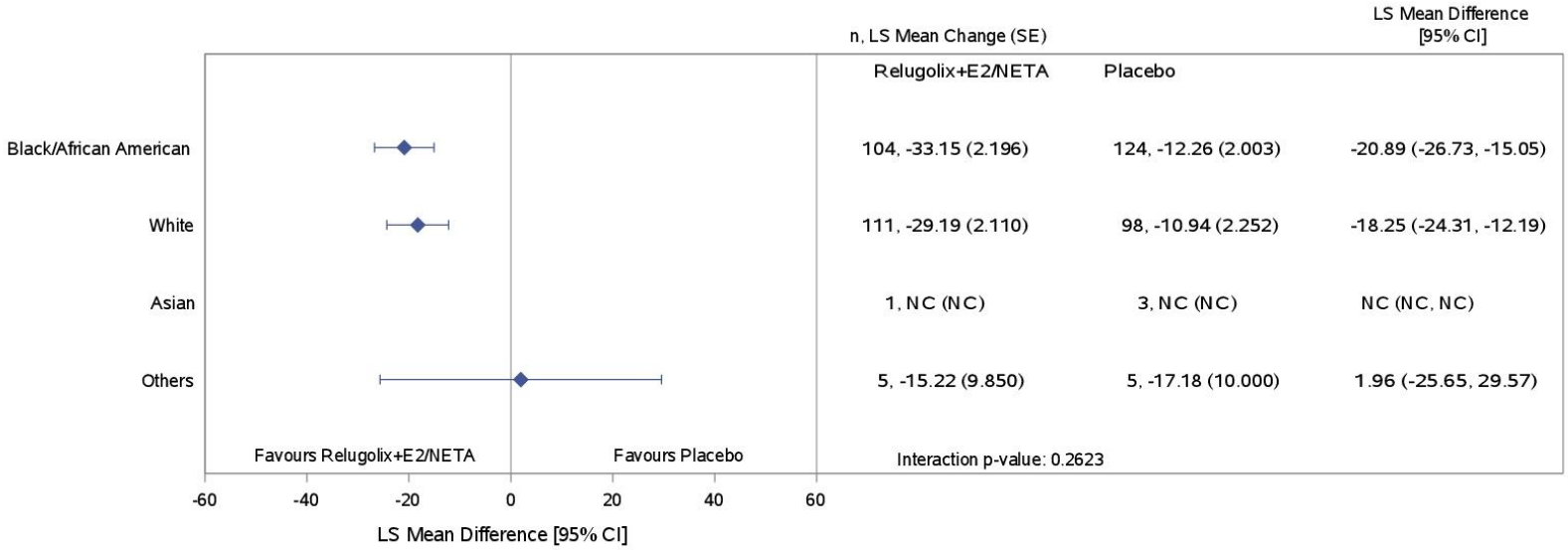
Figure QOL.UFSSSS.MITT.S9.CON.FP: Summary of Average Change from Baseline in UFS-QoL Symptom Severity Scale Score Over 24 Weeks, by Subgroup (mITT Population)
Study: Pooled
Subgroup: Race



Results are based on a mixed-effects model with study, treatment, visit, subgroup, treatment-by-visit interaction, and a subgroup-by-treatment interaction as fixed effects using a one-stage IPD meta-analysis approach. The multiple visits for each patient are the repeated measures as a random effect within each patient with an unstructured covariance.
The interaction p-value is based on the subgroup-by-treatment interaction term in the mixed-effects model used to compute the LS means, mean differences and 95% CIs. Missing subgroup levels are not included in estimation of the interaction p-value. The reference group is Placebo.
n: Number of patients with data; NETA: Norethindrone acetate; mITT: Modified intent-to-treat; LS: Least squares; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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2.2.2 Proportion of Responders with at Least 25 Points Decrease in UFS-QoL Symptom Severity Scale Score at Week 24, by Subgroup (mITT Population)

Nachfolgend sind zunächst alle Forest Plots für das *Odds Ratio* dargestellt; gefolgt von den entsprechenden Forest Plots für *Risk Ratio* und *Risk Difference*.

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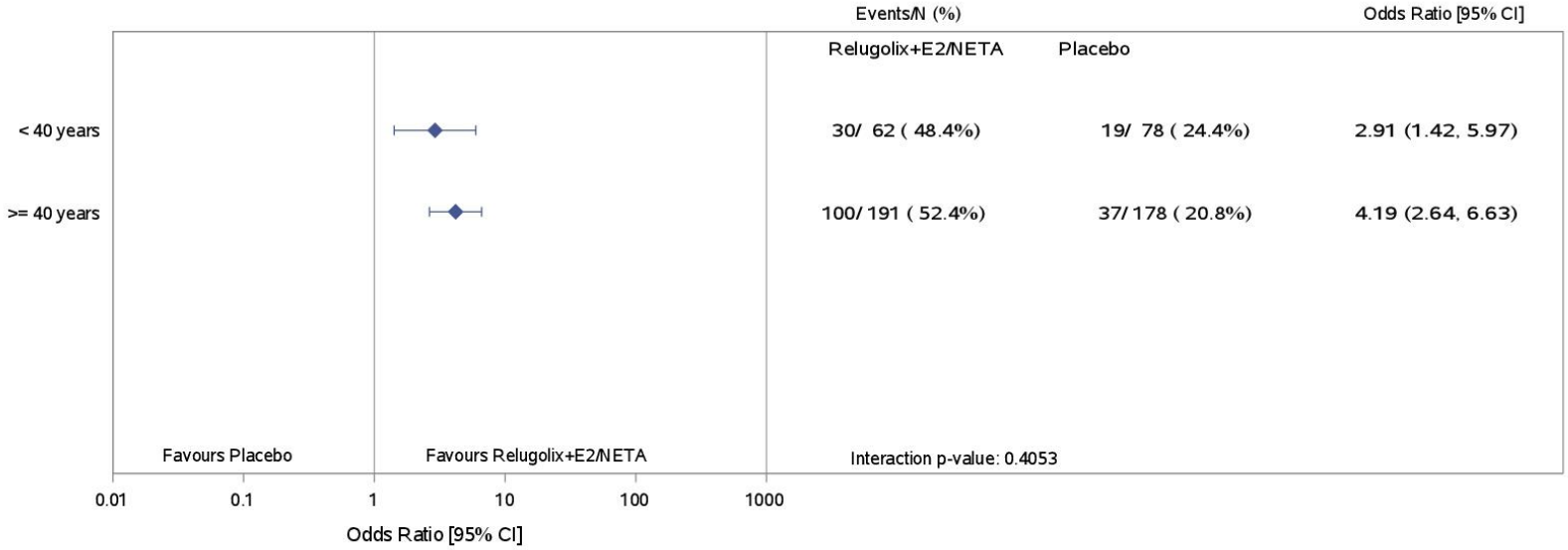
Figure QOL.UFSSSS25.MITT.S1.BIN.FP: Proportion of Responders with at Least 25 Points Decrease in UFS-QoL Symptom Severity Scale Score at Week 24, by Subgroup (mITT Population)
Study: Pooled
Subgroup: Age (years)



Results are based on a logistic regression model adjusted for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates using a one-stage fixed-effects IPD meta-analysis approach. A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
The interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the Odds Ratio and 95% CI. Missing subgroup levels are not included in estimation of the interaction p-value. The reference group is Placebo.
N: Number of patients in treatment group; NETA: Norethindrone acetate; mITT: Modified intent-to-treat; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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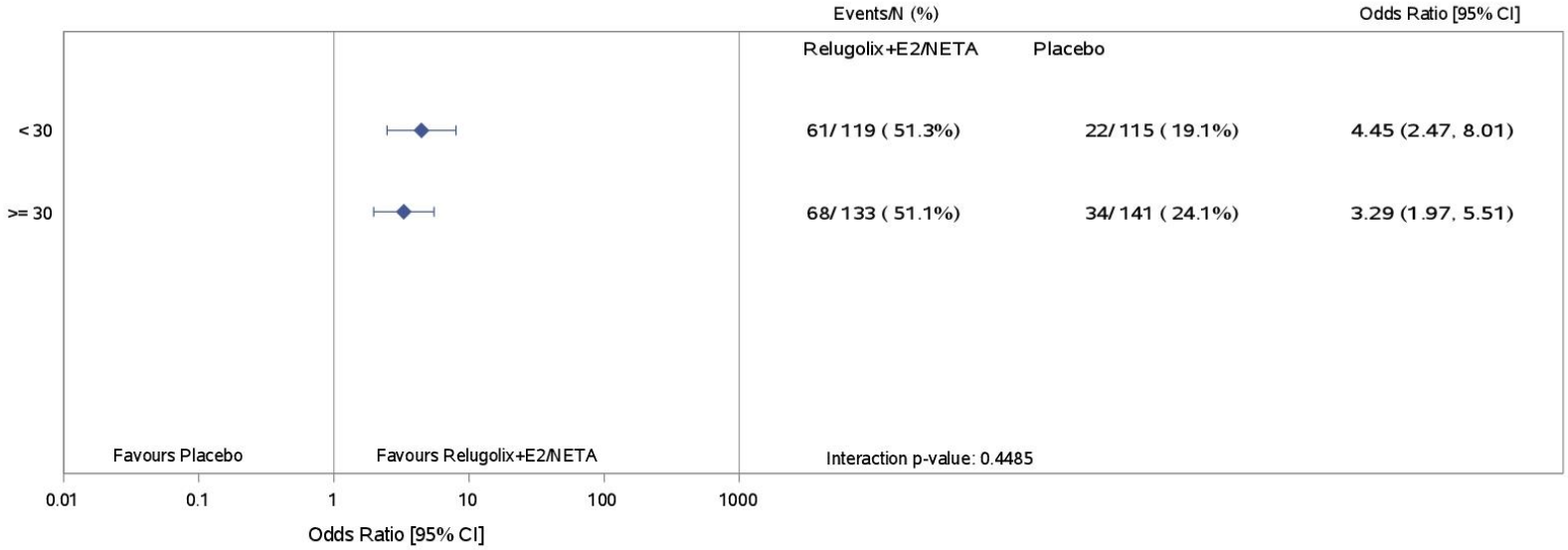
Figure QOL.UFSSSS25.MITT.S2.BIN.FP: Proportion of Responders with at Least 25 Points Decrease in UFS-QoL Symptom Severity Scale Score at Week 24, by Subgroup (mITT Population)
Study: Pooled
Subgroup: BMI (kg/m2) at Baseline



Results are based on a logistic regression model adjusted for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates using a one-stage fixed-effects IPD meta-analysis approach. A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
The interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the Odds Ratio and 95% CI. Missing subgroup levels are not included in estimation of the interaction p-value. The reference group is Placebo.
N: Number of patients in treatment group; NETA: Norethindrone acetate; mITT: Modified intent-to-treat; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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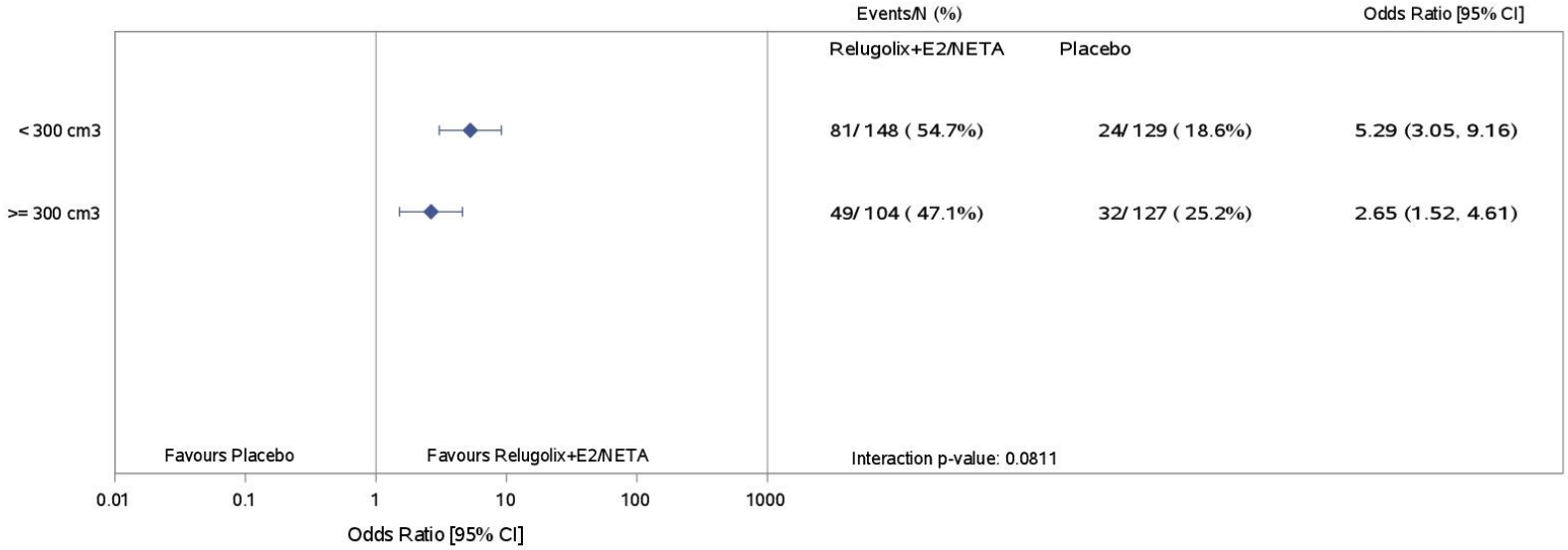
Figure QOL.UFSSSS25.MITT.S3.BIN.FP: Proportion of Responders with at Least 25 Points Decrease in UFS-QoL Symptom Severity Scale Score at Week 24, by Subgroup (mITT Population)
Study: Pooled
Subgroup: Uterine Volume at Baseline (cm3)



Results are based on a logistic regression model adjusted for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates using a one-stage fixed-effects IPD meta-analysis approach. A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
The interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the Odds Ratio and 95% CI. Missing subgroup levels are not included in estimation of the interaction p-value. The reference group is Placebo.
N: Number of patients in treatment group; NETA: Norethindrone acetate; mITT: Modified intent-to-treat; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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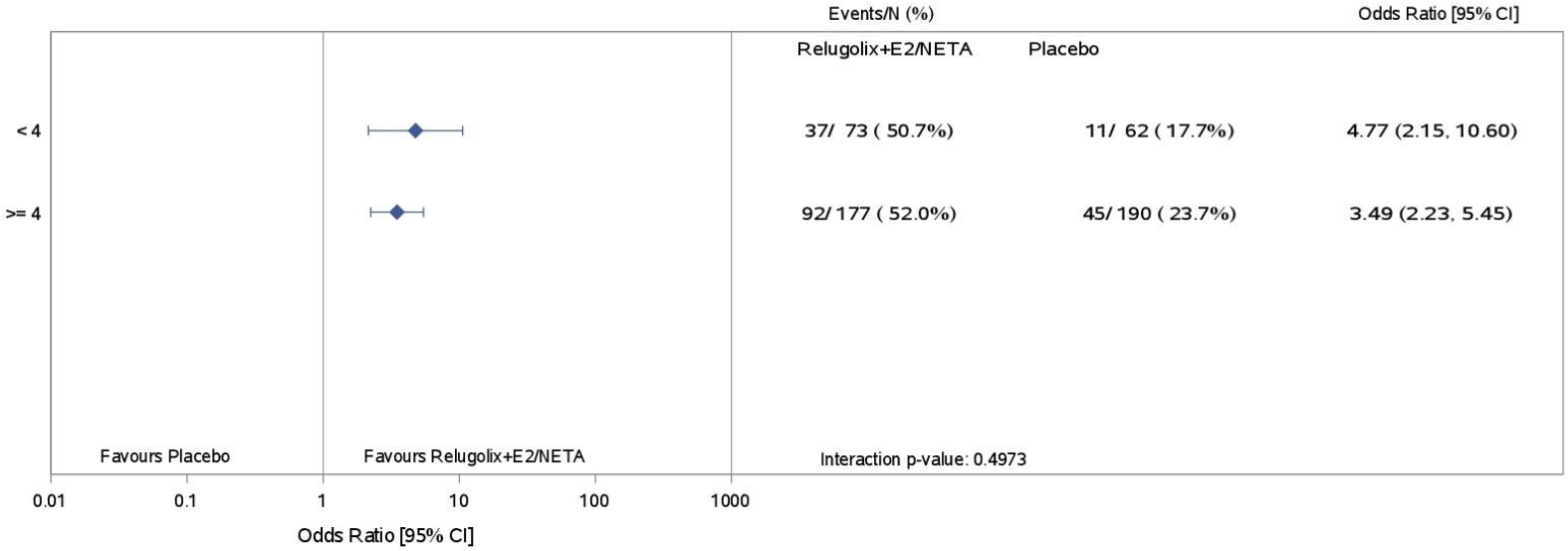
Figure QOL.UFSSSS25.MITT.S4.BIN.FP: Proportion of Responders with at Least 25 Points Decrease in UFS-QoL Symptom Severity Scale Score at Week 24, by Subgroup (mITT Population)
Study: Pooled
Subgroup: Maximum NRS Pain Score at Baseline



Results are based on a logistic regression model adjusted for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates using a one-stage fixed-effects IPD meta-analysis approach. A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
The interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the Odds Ratio and 95% CI. Missing subgroup levels are not included in estimation of the interaction p-value. The reference group is Placebo.
N: Number of patients in treatment group; NETA: Norethindrone acetate; mITT: Modified intent-to-treat; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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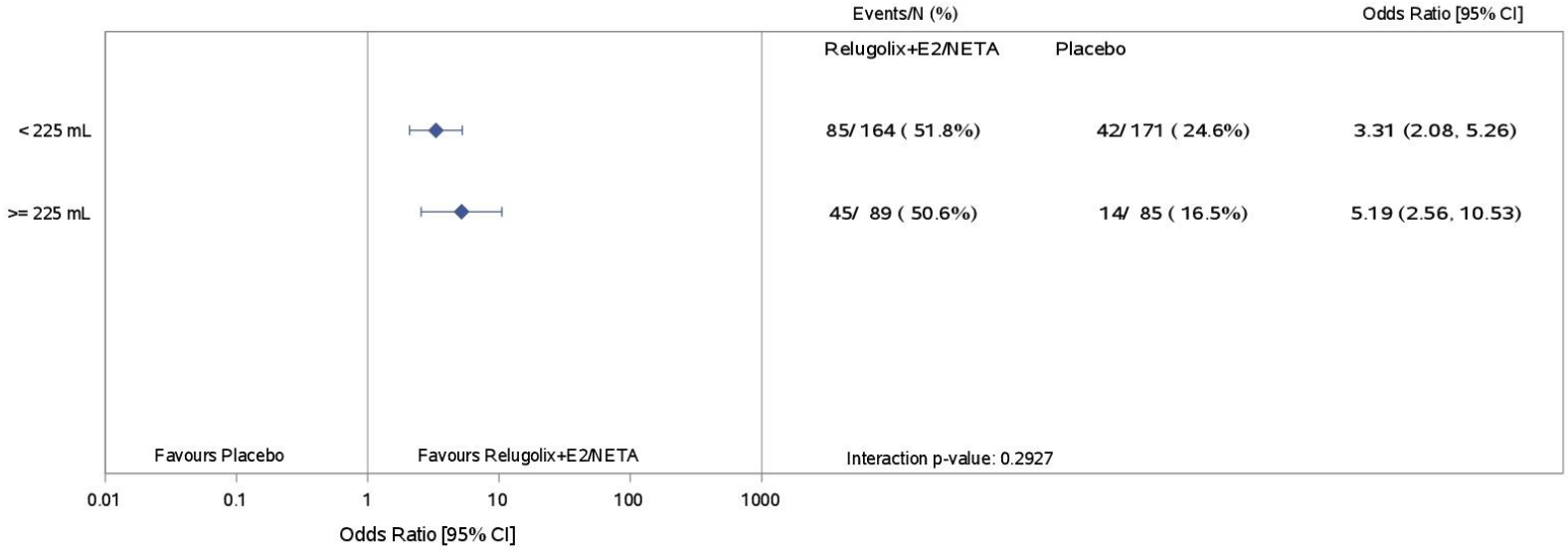
Figure QOL.UFSSSS25.MITT.S5.BIN.FP: Proportion of Responders with at Least 25 Points Decrease in UFS-QoL Symptom Severity Scale Score at Week 24, by Subgroup (mITT Population)
Study: Pooled
Subgroup: MBL Volume at Baseline (mL)



Results are based on a logistic regression model adjusted for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates using a one-stage fixed-effects IPD meta-analysis approach. A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
The interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the Odds Ratio and 95% CI. Missing subgroup levels are not included in estimation of the interaction p-value. The reference group is Placebo.
N: Number of patients in treatment group; NETA: Norethindrone acetate; mITT: Modified intent-to-treat; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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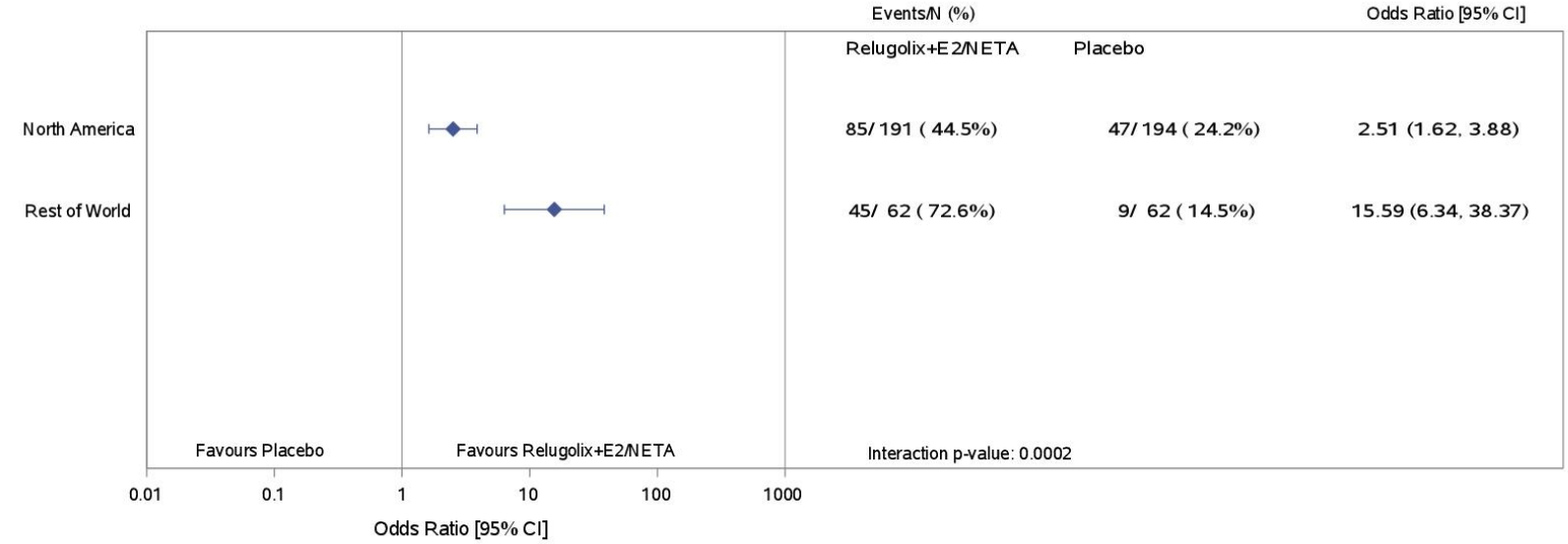
Figure QOL.UFSSSS25.MITT.S6.BIN.FP: Proportion of Responders with at Least 25 Points Decrease in UFS-QoL Symptom Severity Scale Score at Week 24, by Subgroup (mITT Population)
Study: Pooled
Subgroup: Geographic Region I



Results are based on a logistic regression model adjusted for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates using a one-stage fixed-effects IPD meta-analysis approach. A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
The interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the Odds Ratio and 95% CI. Missing subgroup levels are not included in estimation of the interaction p-value. The reference group is Placebo.
N: Number of patients in treatment group; NETA: Norethindrone acetate; mITT: Modified intent-to-treat; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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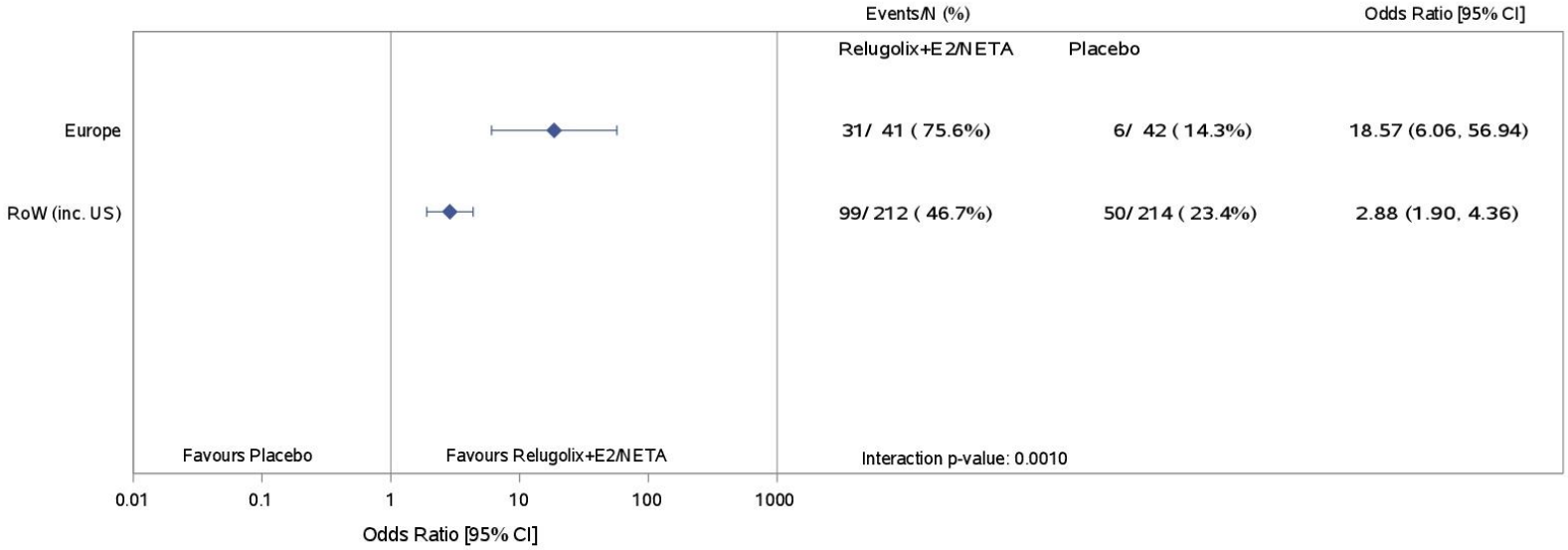
Figure QOL.UFSSSS25.MITT.S7.BIN.FP: Proportion of Responders with at Least 25 Points Decrease in UFS-QoL Symptom Severity Scale Score at Week 24, by Subgroup (mITT Population)
Study: Pooled
Subgroup: Geographic Region II



Results are based on a logistic regression model adjusted for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates using a one-stage fixed-effects IPD meta-analysis approach. A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
The interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the Odds Ratio and 95% CI. Missing subgroup levels are not included in estimation of the interaction p-value. The reference group is Placebo.
N: Number of patients in treatment group; NETA: Norethindrone acetate; mITT: Modified intent-to-treat; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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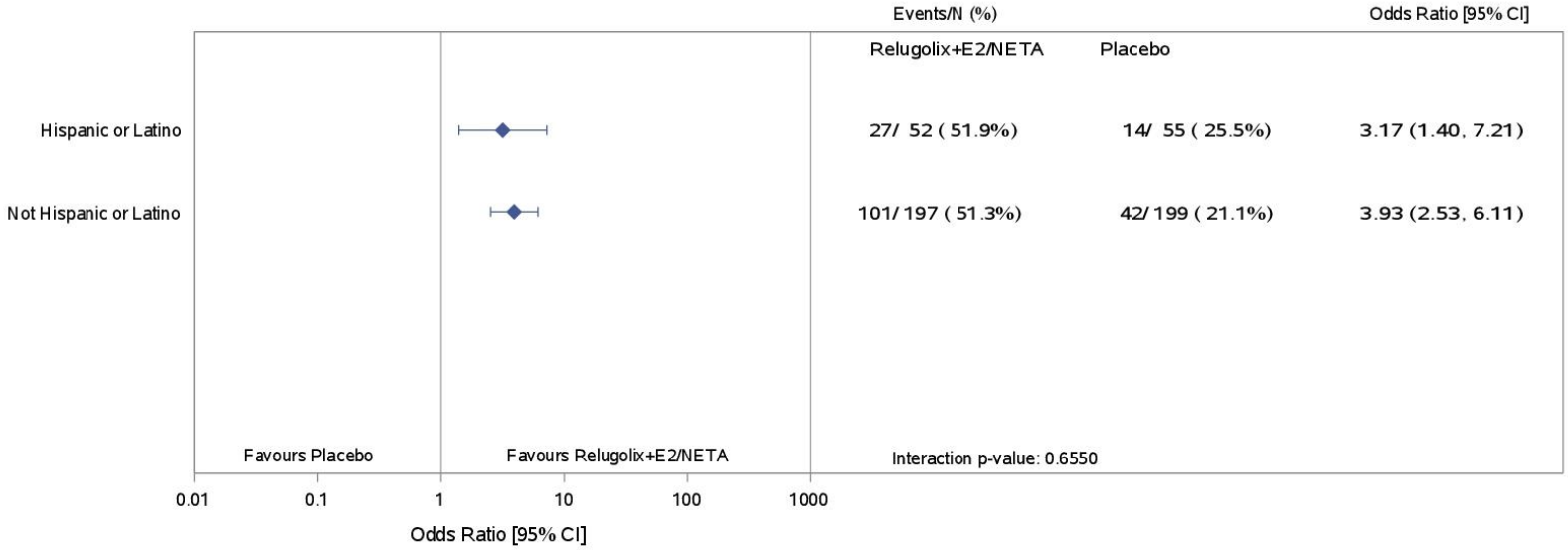
Figure QOL.UFSSSS25.MITT.S8.BIN.FP: Proportion of Responders with at Least 25 Points Decrease in UFS-QoL Symptom Severity Scale Score at Week 24, by Subgroup (mITT Population)
Study: Pooled
Subgroup: Ethnicity



Results are based on a logistic regression model adjusted for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates using a one-stage fixed-effects IPD meta-analysis approach. A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
The interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the Odds Ratio and 95% CI. Missing subgroup levels are not included in estimation of the interaction p-value. The reference group is Placebo.
N: Number of patients in treatment group; NETA: Norethindrone acetate; mITT: Modified intent-to-treat; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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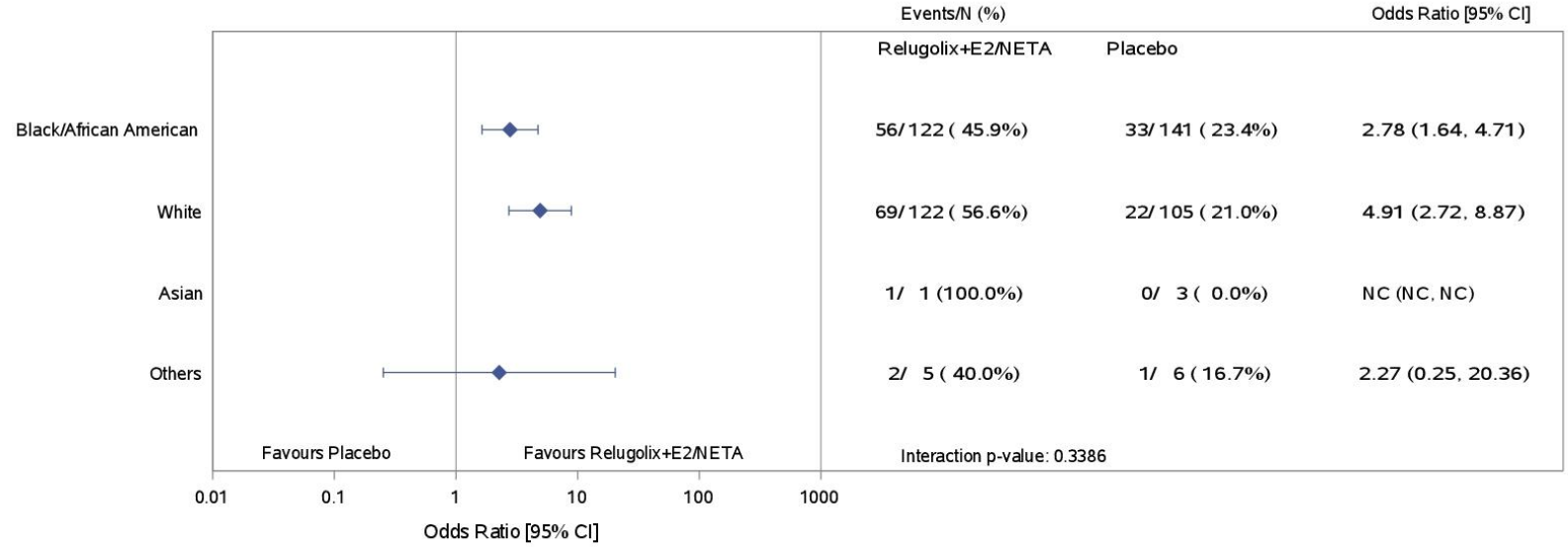
Figure QOL.UFSSSS25.MITT.S9.BIN.FP: Proportion of Responders with at Least 25 Points Decrease in UFS-QoL Symptom Severity Scale Score at Week 24, by Subgroup (mITT Population)
Study: Pooled
Subgroup: Race



Results are based on a logistic regression model adjusted for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates using a one-stage fixed-effects IPD meta-analysis approach. A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
The interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the Odds Ratio and 95% CI. Missing subgroup levels are not included in estimation of the interaction p-value. The reference group is Placebo.
N: Number of patients in treatment group; NETA: Norethindrone acetate; mITT: Modified intent-to-treat; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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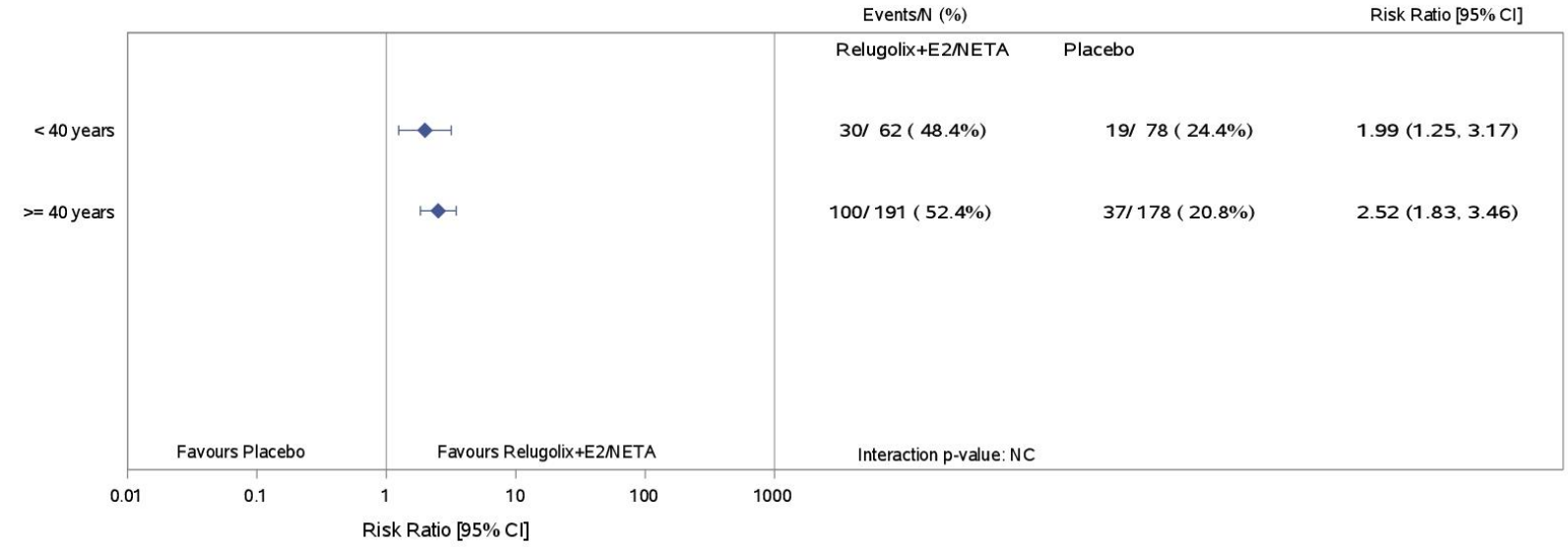
Figure QOL.UFSSSS25.MITT.S1.BIN.FP.RR: Proportion of Responders with at Least 25 Points Decrease in UFS-QoL Symptom Severity Scale Score at Week 24, by Subgroup (mITT Population) - Risk Ratio
Study: Pooled
Subgroup: Age (years)



Results are based on a Cochran-Mantel-Haenszel approach stratified by study using a one-stage fixed-effects IPD meta-analysis. A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
The reference group is Placebo.
N: Number of patients in treatment group; NETA: Norethindrone acetate; mITT: Modified intent-to-treat; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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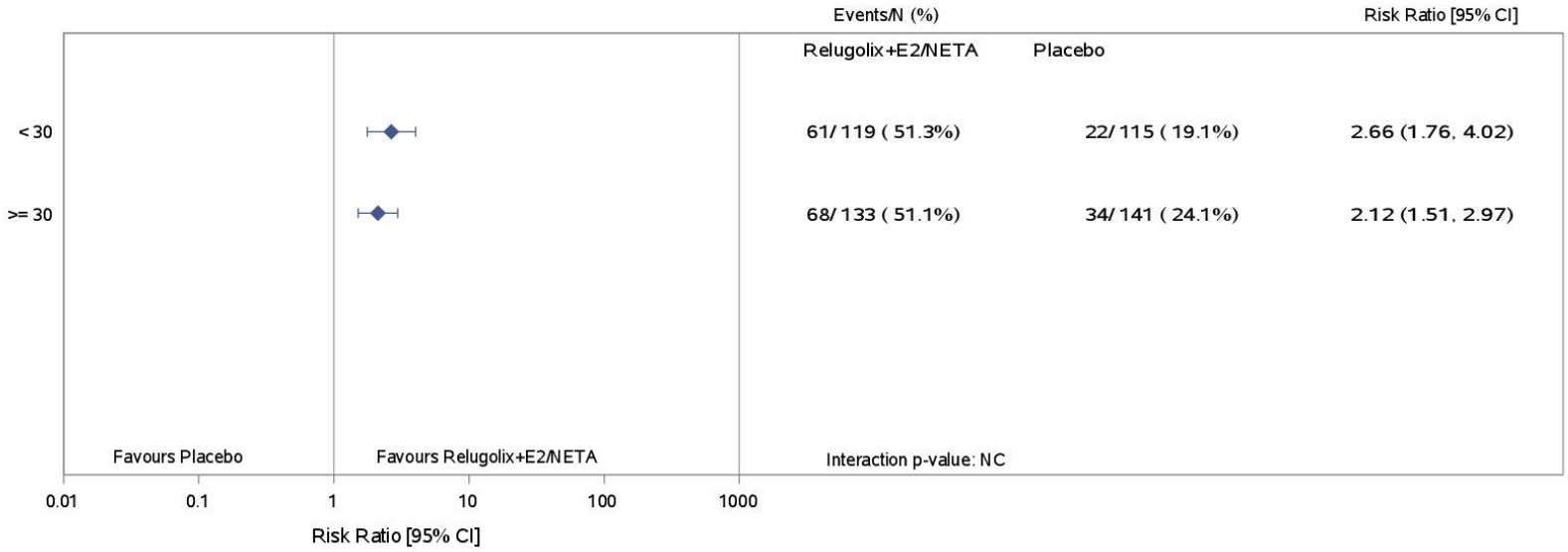
Figure QOL.UFSSSS25.MITT.S2.BIN.FP.RR: Proportion of Responders with at Least 25 Points Decrease in UFS-QoL Symptom Severity Scale Score at Week 24, by Subgroup (mITT Population) - Risk Ratio
Study: Pooled
Subgroup: BMI (kg/m2) at Baseline



Results are based on a Cochran-Mantel-Haenszel approach stratified by study using a one-stage fixed-effects IPD meta-analysis. A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
The reference group is Placebo.
N: Number of patients in treatment group; NETA: Norethindrone acetate; mITT: Modified intent-to-treat; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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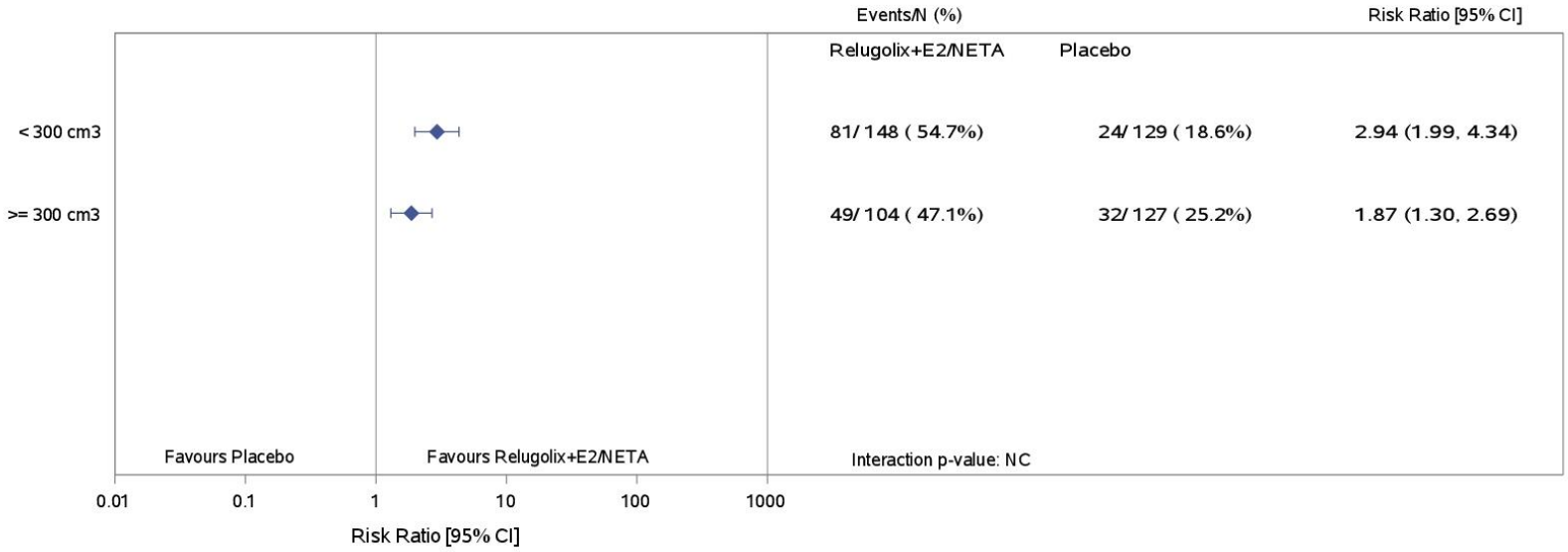
Figure QOL.UFSSSS25.MITT.S3.BIN.FP.RR: Proportion of Responders with at Least 25 Points Decrease in UFS-QoL Symptom Severity Scale Score at Week 24, by Subgroup (mITT Population) - Risk Ratio
Study: Pooled
Subgroup: Uterine Volume at Baseline (cm3)



Results are based on a Cochran-Mantel-Haenszel approach stratified by study using a one-stage fixed-effects IPD meta-analysis. A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
The reference group is Placebo.
N: Number of patients in treatment group; NETA: Norethindrone acetate; mITT: Modified intent-to-treat; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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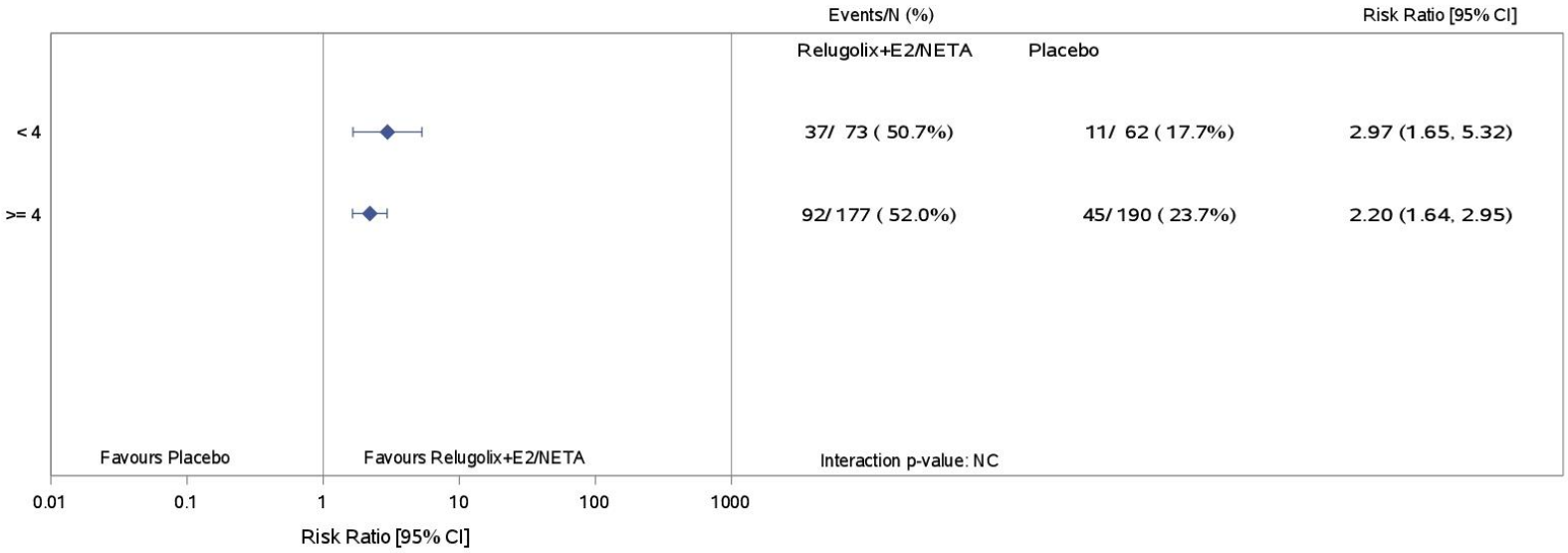
Figure QOL.UFSSSS25.MITT.S4.BIN.FP.RR: Proportion of Responders with at Least 25 Points Decrease in UFS-QoL Symptom Severity Scale Score at Week 24, by Subgroup (mITT Population) - Risk Ratio
Study: Pooled
Subgroup: Maximum NRS Pain Score at Baseline



Results are based on a Cochran-Mantel-Haenszel approach stratified by study using a one-stage fixed-effects IPD meta-analysis. A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
The reference group is Placebo.
N: Number of patients in treatment group; NETA: Norethindrone acetate; mITT: Modified intent-to-treat; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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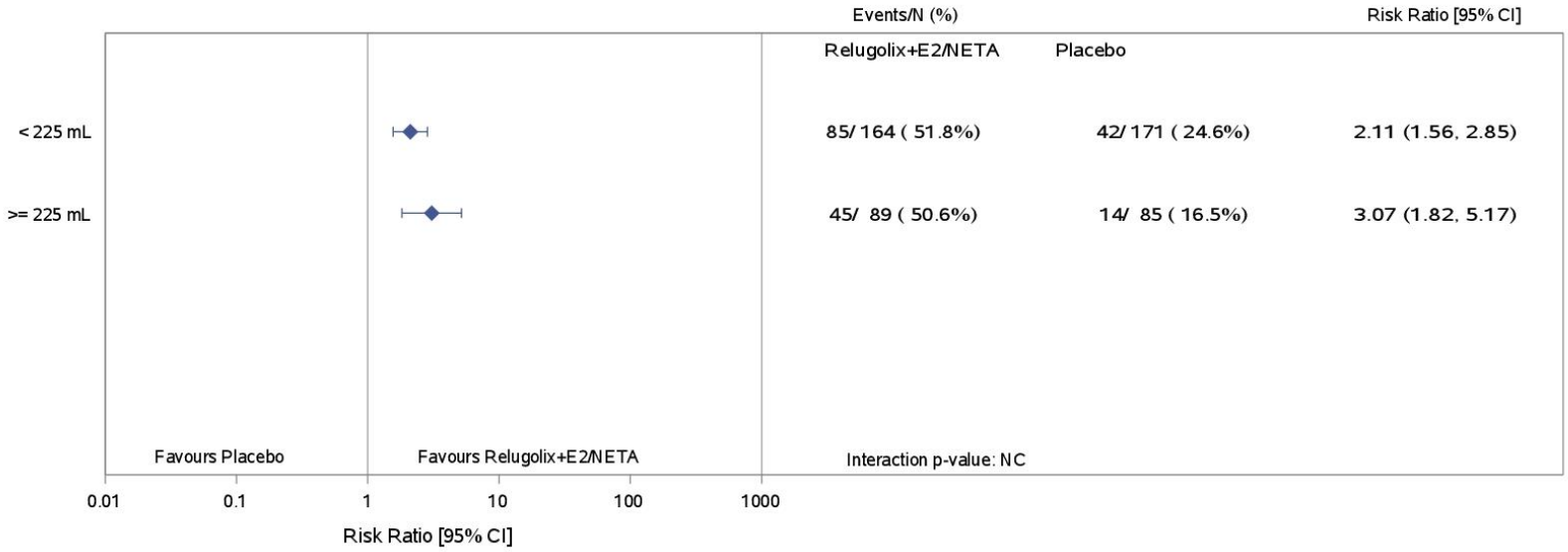
Figure QOL.UFSSSS25.MITT.S5.BIN.FP.RR: Proportion of Responders with at Least 25 Points Decrease in UFS-QoL Symptom Severity Scale Score at Week 24, by Subgroup (mITT Population) - Risk Ratio
Study: Pooled
Subgroup: MBL Volume at Baseline (mL)



Results are based on a Cochran-Mantel-Haenszel approach stratified by study using a one-stage fixed-effects IPD meta-analysis. A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
The reference group is Placebo.
N: Number of patients in treatment group; NETA: Norethindrone acetate; mITT: Modified intent-to-treat; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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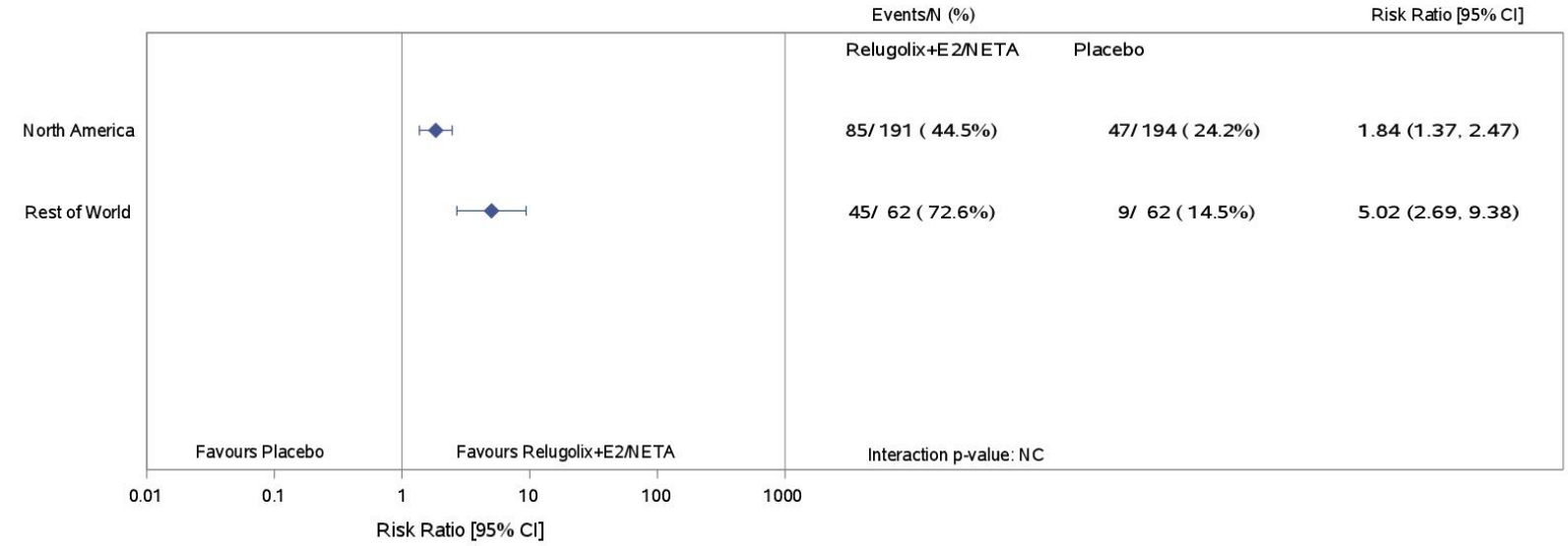
Figure QOL.UFSSSS25.MITT.S6.BIN.FP.RR: Proportion of Responders with at Least 25 Points Decrease in UFS-QoL Symptom Severity Scale Score at Week 24, by Subgroup (mITT Population) - Risk Ratio
Study: Pooled
Subgroup: Geographic Region I



Results are based on a Cochran-Mantel-Haenszel approach stratified by study using a one-stage fixed-effects IPD meta-analysis. A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
The reference group is Placebo.
N: Number of patients in treatment group; NETA: Norethindrone acetate; mITT: Modified intent-to-treat; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

SOURCE: X:\Numerus\Studies\MYV\MYV102\Analysis\Prod\Progs\TFLs\Fig_QOL_QS_S_BIN_FP.SAS Date/time of run: 30JUN21 10:27
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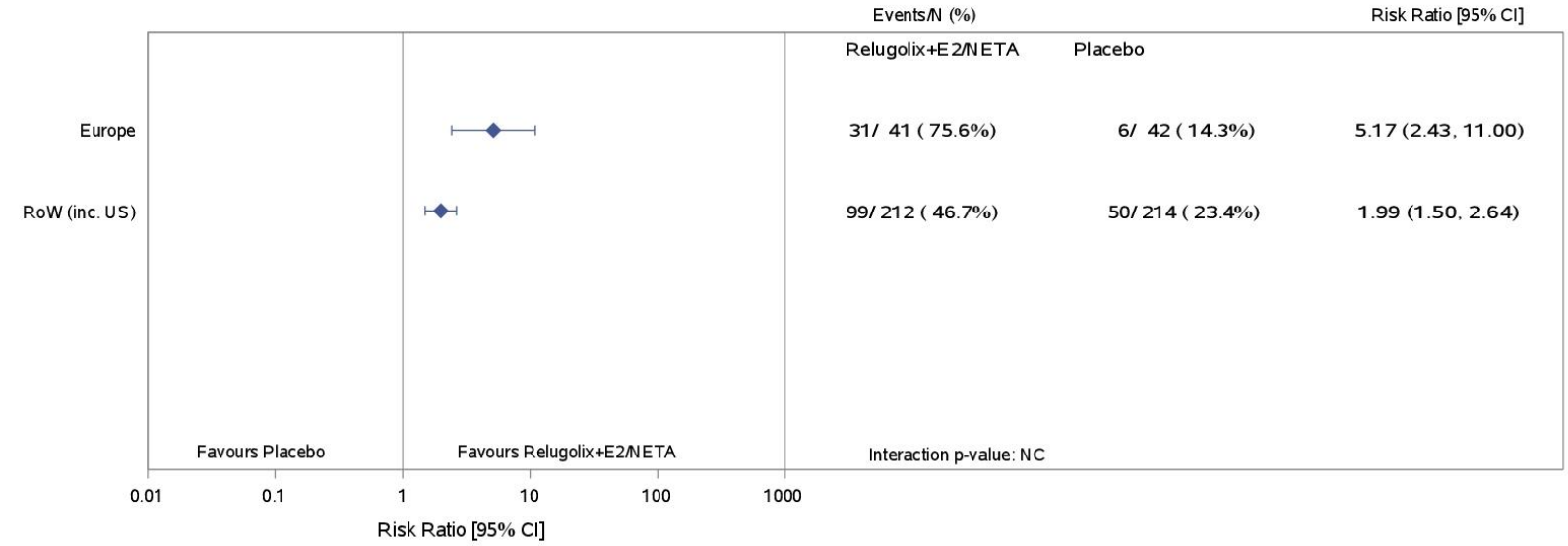
Figure QOL.UFSSSS25.MITT.S7.BIN.FP.RR: Proportion of Responders with at Least 25 Points Decrease in UFS-QoL Symptom Severity Scale Score at Week 24, by Subgroup (mITT Population) - Risk Ratio
Study: Pooled
Subgroup: Geographic Region II



Results are based on a Cochran-Mantel-Haenszel approach stratified by study using a one-stage fixed-effects IPD meta-analysis. A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
The reference group is Placebo.
N: Number of patients in treatment group; NETA: Norethindrone acetate; mITT: Modified intent-to-treat; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

SOURCE: X:\Numerus\Studies\MYV\MYV102\Analysis\Prod\Progs\TFLs\Fig_QOL_QS_S_BIN_FP.SAS Date/time of run: 30JUN21 10:27
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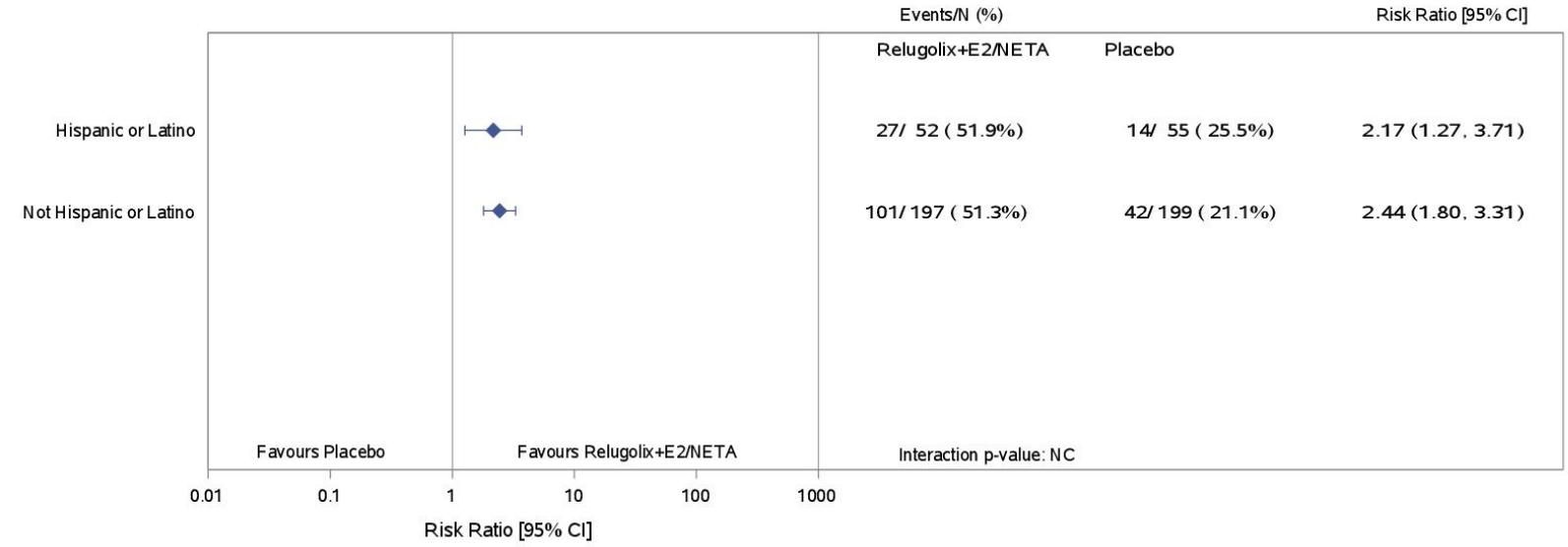
Figure QOL.UFSSSS25.MITT.S8.BIN.FP.RR: Proportion of Responders with at Least 25 Points Decrease in UFS-QoL Symptom Severity Scale Score at Week 24, by Subgroup (mITT Population) - Risk Ratio
Study: Pooled
Subgroup: Ethnicity



Results are based on a Cochran-Mantel-Haenszel approach stratified by study using a one-stage fixed-effects IPD meta-analysis. A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
The reference group is Placebo.
N: Number of patients in treatment group; NETA: Norethindrone acetate; mITT: Modified intent-to-treat; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

SOURCE: X:\Numerus\Studies\MYV\MYV102\Analysis\Prod\Progs\TFLs\Fig_QOL_QS_S_BIN_FP.SAS Date/time of run: 30JUN21 10:27
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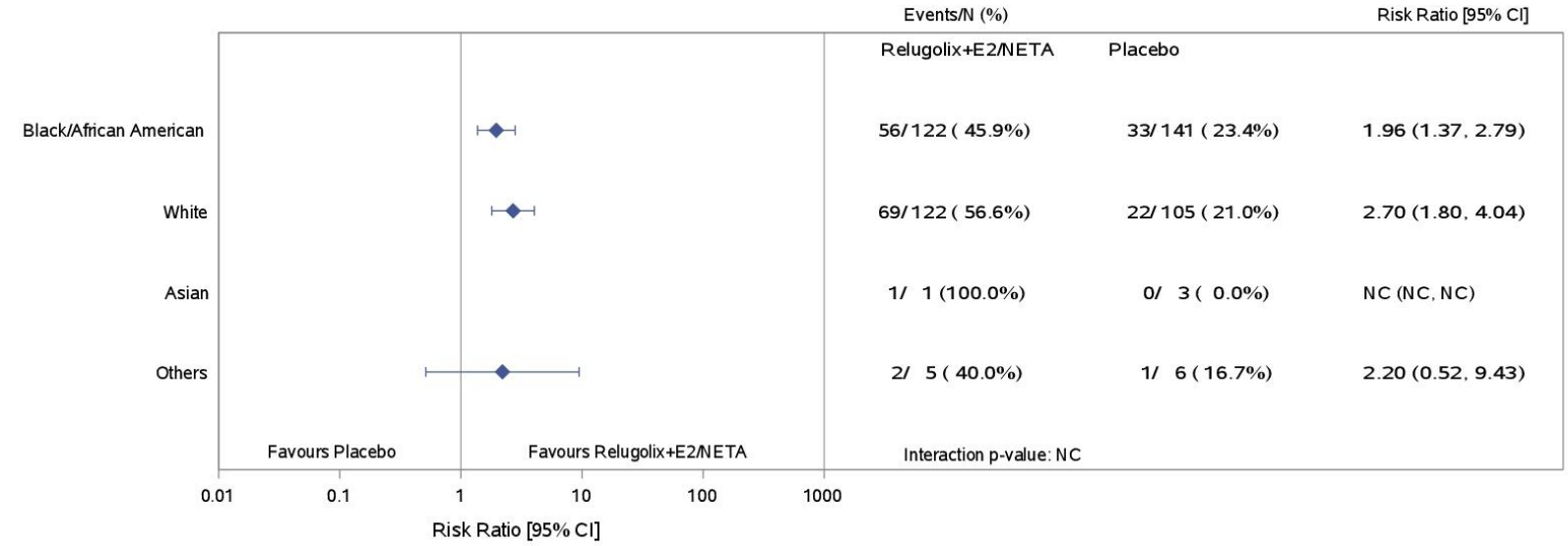
Figure QOL.UFSSSS25.MITT.S9.BIN.FP.RR: Proportion of Responders with at Least 25 Points Decrease in UFS-QoL Symptom Severity Scale Score at Week 24, by Subgroup (mITT Population) - Risk Ratio
Study: Pooled
Subgroup: Race



Results are based on a Cochran-Mantel-Haenszel approach stratified by study using a one-stage fixed-effects IPD meta-analysis. A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
The reference group is Placebo.
N: Number of patients in treatment group; NETA: Norethindrone acetate; mITT: Modified intent-to-treat; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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2.2.3 Summary of Average Change from Baseline in UFS-QoL Bleeding and Pelvic Discomfort Scale Score Over 24 Weeks, by Subgroup (mITT Population)

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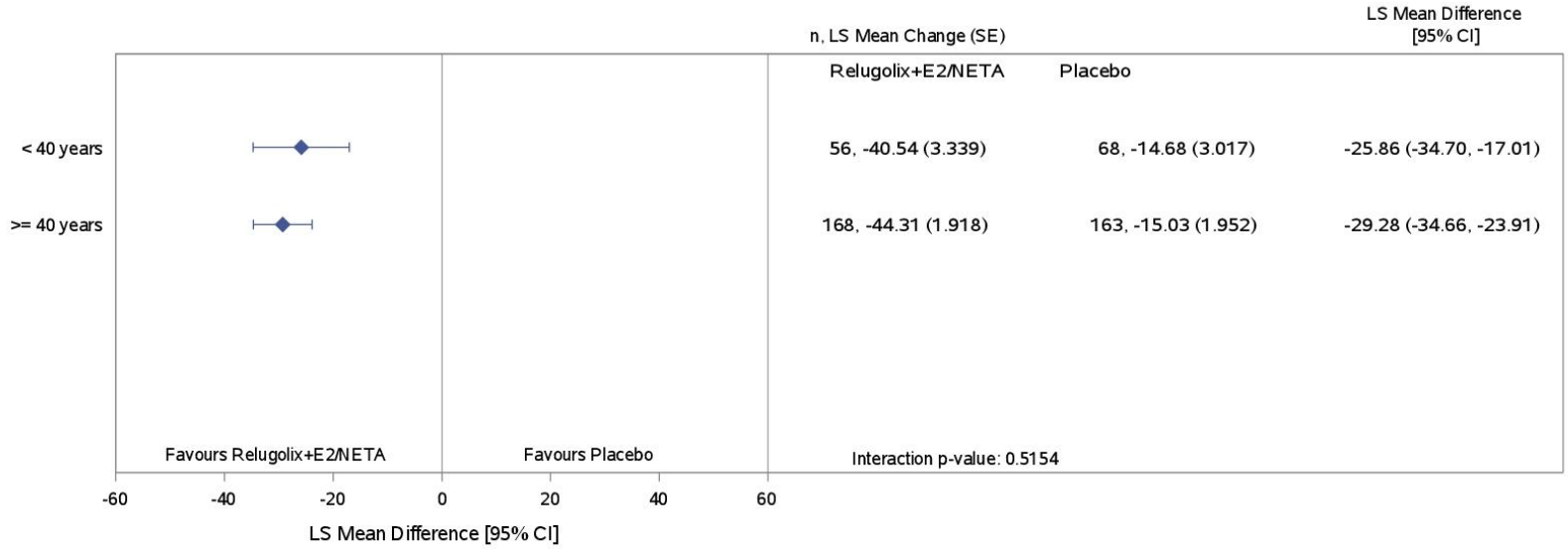
Figure QOL.UFSBPD.MITT.S1.CON.FP: Summary of Average Change from Baseline in UFS-QoL Bleeding and Pelvic Discomfort Scale Score Over 24 Weeks, by Subgroup (mITT Population)
Study: Pooled
Subgroup: Age (years)



Results are based on a mixed-effects model with study, treatment, visit, subgroup, treatment-by-visit interaction, and a subgroup-by-treatment interaction as fixed effects using a one-stage IPD meta-analysis approach. The multiple visits for each patient are the repeated measures as a random effect within each patient with an unstructured covariance.
The interaction p-value is based on the subgroup-by-treatment interaction term in the mixed-effects model used to compute the LS means, mean differences and 95% CIs. Missing subgroup levels are not included in estimation of the interaction p-value. The reference group is Placebo.
n: Number of patients with data; NETA: Norethindrone acetate; mITT: Modified intent-to-treat; LS: Least squares; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

SOURCE: X:\Numerus\Studies\MYV\MYV102\Analysis\Prod\Progs\TFLs\FIG_QOL_QS_S_CON_FP.SAS Date/time of run: 30JUN21 10:30
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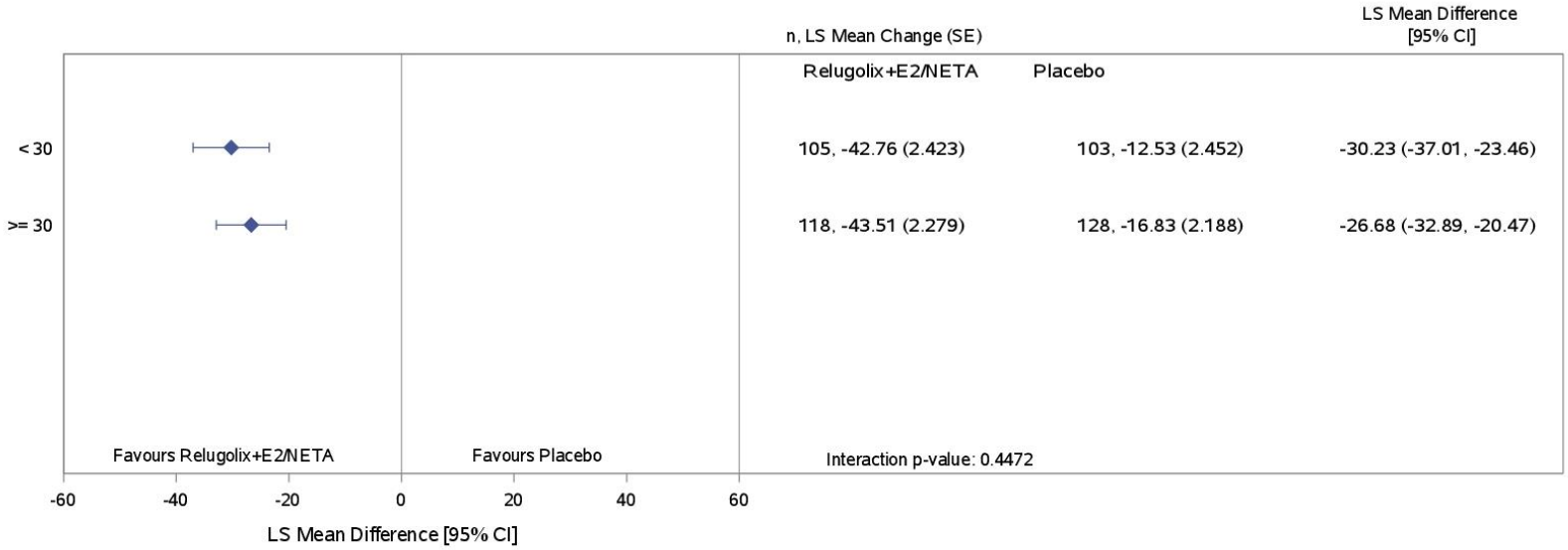
Figure QOL.UFSBPD.MITT.S2.CON.FP: Summary of Average Change from Baseline in UFS-QoL Bleeding and Pelvic Discomfort Scale Score Over 24 Weeks, by Subgroup (mITT Population)
Study: Pooled
Subgroup: BMI (kg/m2) at Baseline



Results are based on a mixed-effects model with study, treatment, visit, subgroup, treatment-by-visit interaction, and a subgroup-by-treatment interaction as fixed effects using a one-stage IPD meta-analysis approach. The multiple visits for each patient are the repeated measures as a random effect within each patient with an unstructured covariance.
The interaction p-value is based on the subgroup-by-treatment interaction term in the mixed-effects model used to compute the LS means, mean differences and 95% CIs. Missing subgroup levels are not included in estimation of the interaction p-value. The reference group is Placebo.
n: Number of patients with data; NETA: Norethindrone acetate; mITT: Modified intent-to-treat; LS: Least squares; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

SOURCE: X:\Numerus\Studies\MYV\MYV102\Analysis\Prod\Progs\TFLs\FIG_QOL_QS_S_CON_FP.SAS Date/time of run: 30JUN21 10:30
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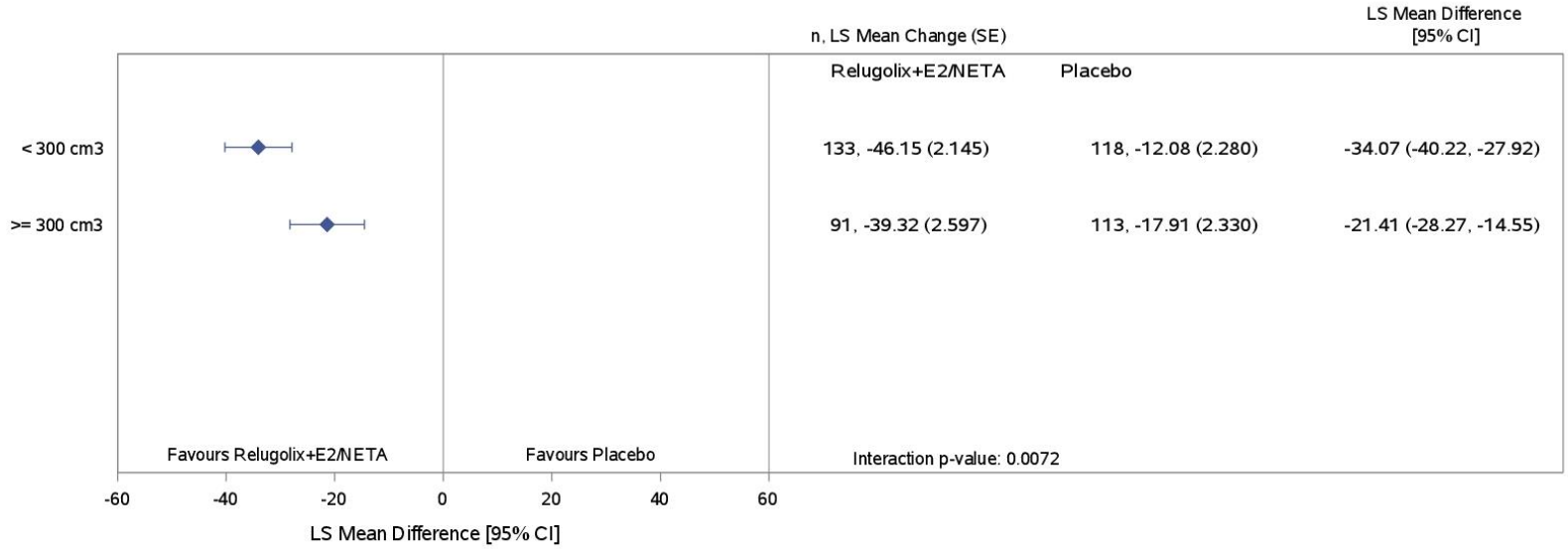
Figure QOL.UFSBPD.MITT.S3.CON.FP: Summary of Average Change from Baseline in UFS-QoL Bleeding and Pelvic Discomfort Scale Score Over 24 Weeks, by Subgroup (mITT Population)
Study: Pooled
Subgroup: Uterine Volume at Baseline (cm3)



Results are based on a mixed-effects model with study, treatment, visit, subgroup, treatment-by-visit interaction, and a subgroup-by-treatment interaction as fixed effects using a one-stage IPD meta-analysis approach. The multiple visits for each patient are the repeated measures as a random effect within each patient with an unstructured covariance.
The interaction p-value is based on the subgroup-by-treatment interaction term in the mixed-effects model used to compute the LS means, mean differences and 95% CIs. Missing subgroup levels are not included in estimation of the interaction p-value. The reference group is Placebo.
n: Number of patients with data; NETA: Norethindrone acetate; mITT: Modified intent-to-treat; LS: Least squares; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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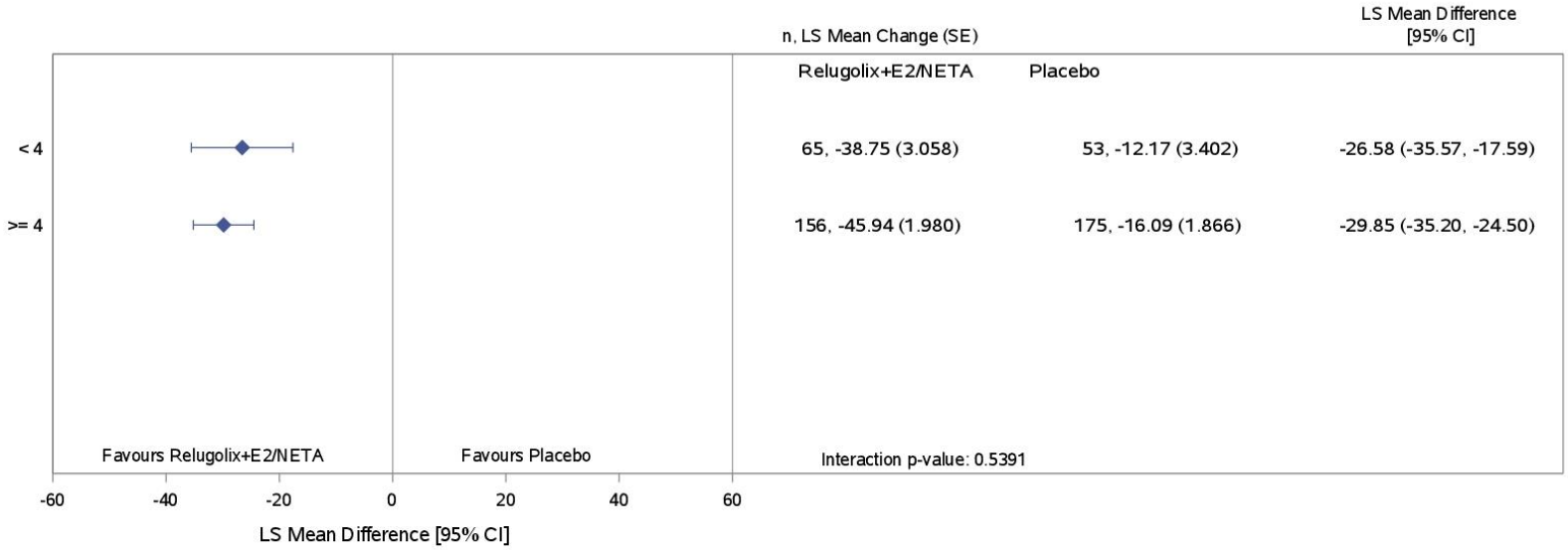
Figure QOL.UFSBPD.MITT.S4.CON.FP: Summary of Average Change from Baseline in UFS-QoL Bleeding and Pelvic Discomfort Scale Score Over 24 Weeks, by Subgroup (mITT Population)
Study: Pooled
Subgroup: Maximum NRS Pain Score at Baseline



Results are based on a mixed-effects model with study, treatment, visit, subgroup, treatment-by-visit interaction, and a subgroup-by-treatment interaction as fixed effects using a one-stage IPD meta-analysis approach. The multiple visits for each patient are the repeated measures as a random effect within each patient with an unstructured covariance.
The interaction p-value is based on the subgroup-by-treatment interaction term in the mixed-effects model used to compute the LS means, mean differences and 95% CIs. Missing subgroup levels are not included in estimation of the interaction p-value. The reference group is Placebo.
n: Number of patients with data; NETA: Norethindrone acetate; mITT: Modified intent-to-treat; LS: Least squares; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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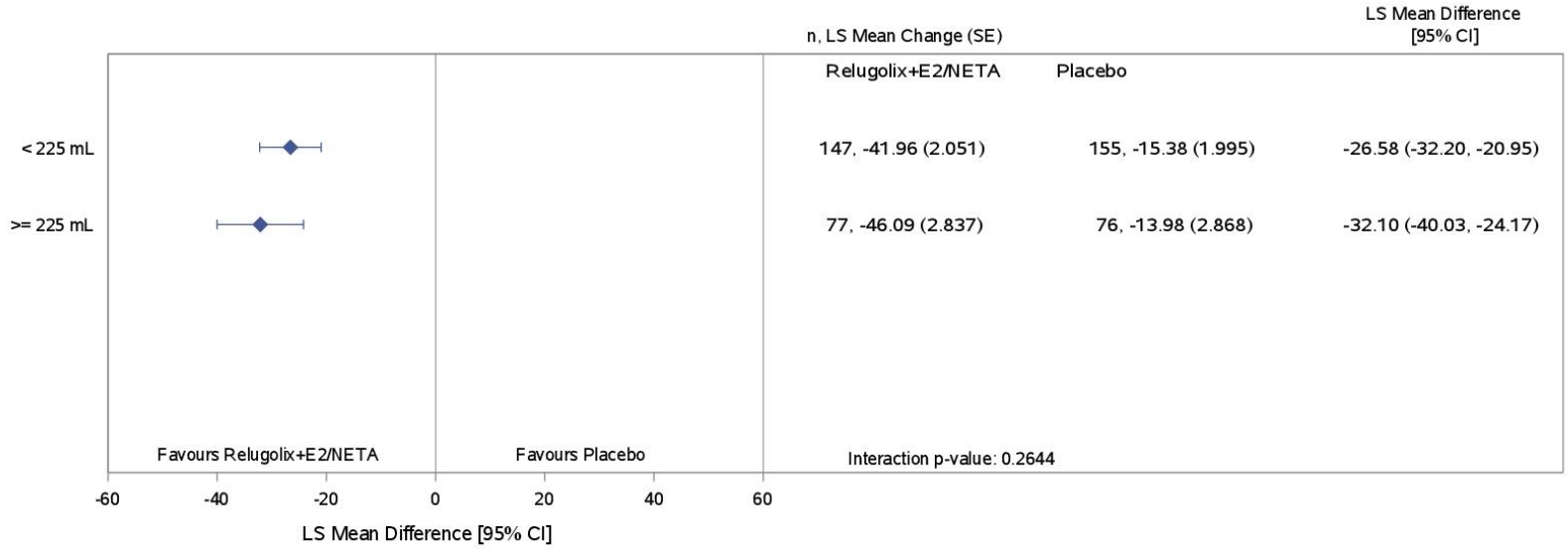
Figure QOL.UFSBPD.MITT.S5.CON.FP: Summary of Average Change from Baseline in UFS-QoL Bleeding and Pelvic Discomfort Scale Score Over 24 Weeks, by Subgroup (mITT Population)
Study: Pooled
Subgroup: MBL Volume at Baseline (mL)



Results are based on a mixed-effects model with study, treatment, visit, subgroup, treatment-by-visit interaction, and a subgroup-by-treatment interaction as fixed effects using a one-stage IPD meta-analysis approach. The multiple visits for each patient are the repeated measures as a random effect within each patient with an unstructured covariance.
The interaction p-value is based on the subgroup-by-treatment interaction term in the mixed-effects model used to compute the LS means, mean differences and 95% CIs. Missing subgroup levels are not included in estimation of the interaction p-value. The reference group is Placebo.
n: Number of patients with data; NETA: Norethindrone acetate; mITT: Modified intent-to-treat; LS: Least squares; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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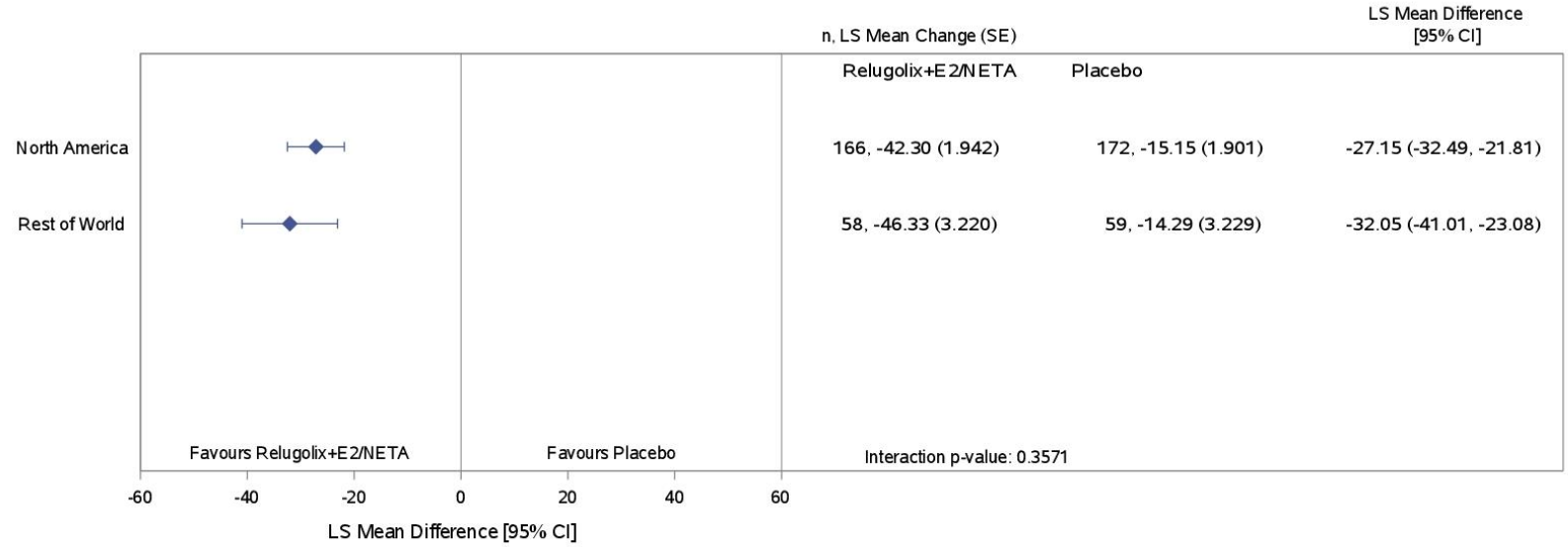
Figure QOL.UFSBPD.MITT.S6.CON.FP: Summary of Average Change from Baseline in UFS-QoL Bleeding and Pelvic Discomfort Scale Score Over 24 Weeks, by Subgroup (mITT Population)
Study: Pooled
Subgroup: Geographic Region I



Results are based on a mixed-effects model with study, treatment, visit, subgroup, treatment-by-visit interaction, and a subgroup-by-treatment interaction as fixed effects using a one-stage IPD meta-analysis approach. The multiple visits for each patient are the repeated measures as a random effect within each patient with an unstructured covariance.
The interaction p-value is based on the subgroup-by-treatment interaction term in the mixed-effects model used to compute the LS means, mean differences and 95% CIs. Missing subgroup levels are not included in estimation of the interaction p-value. The reference group is Placebo.
n: Number of patients with data; NETA: Norethindrone acetate; mITT: Modified intent-to-treat; LS: Least squares; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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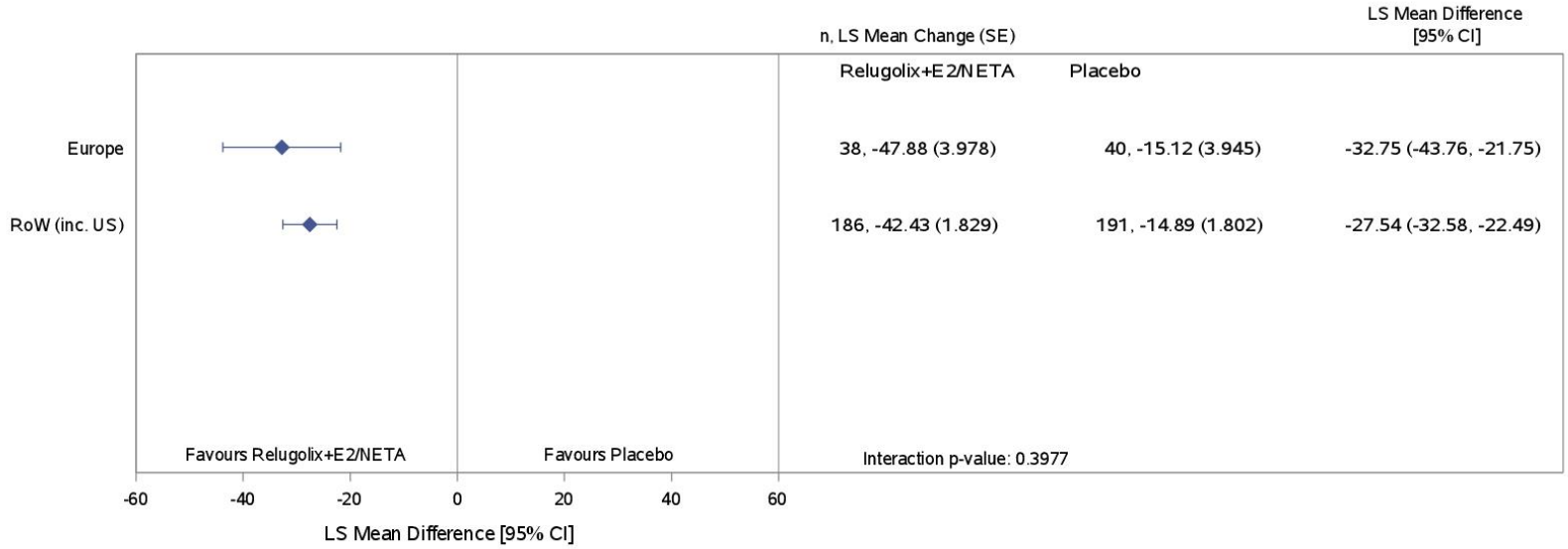
Figure QOL.UFSBPD.MITT.S7.CON.FP: Summary of Average Change from Baseline in UFS-QoL Bleeding and Pelvic Discomfort Scale Score Over 24 Weeks, by Subgroup (mITT Population)
Study: Pooled
Subgroup: Geographic Region II



Results are based on a mixed-effects model with study, treatment, visit, subgroup, treatment-by-visit interaction, and a subgroup-by-treatment interaction as fixed effects using a one-stage IPD meta-analysis approach. The multiple visits for each patient are the repeated measures as a random effect within each patient with an unstructured covariance.
The interaction p-value is based on the subgroup-by-treatment interaction term in the mixed-effects model used to compute the LS means, mean differences and 95% CIs. Missing subgroup levels are not included in estimation of the interaction p-value. The reference group is Placebo.
n: Number of patients with data; NETA: Norethindrone acetate; mITT: Modified intent-to-treat; LS: Least squares; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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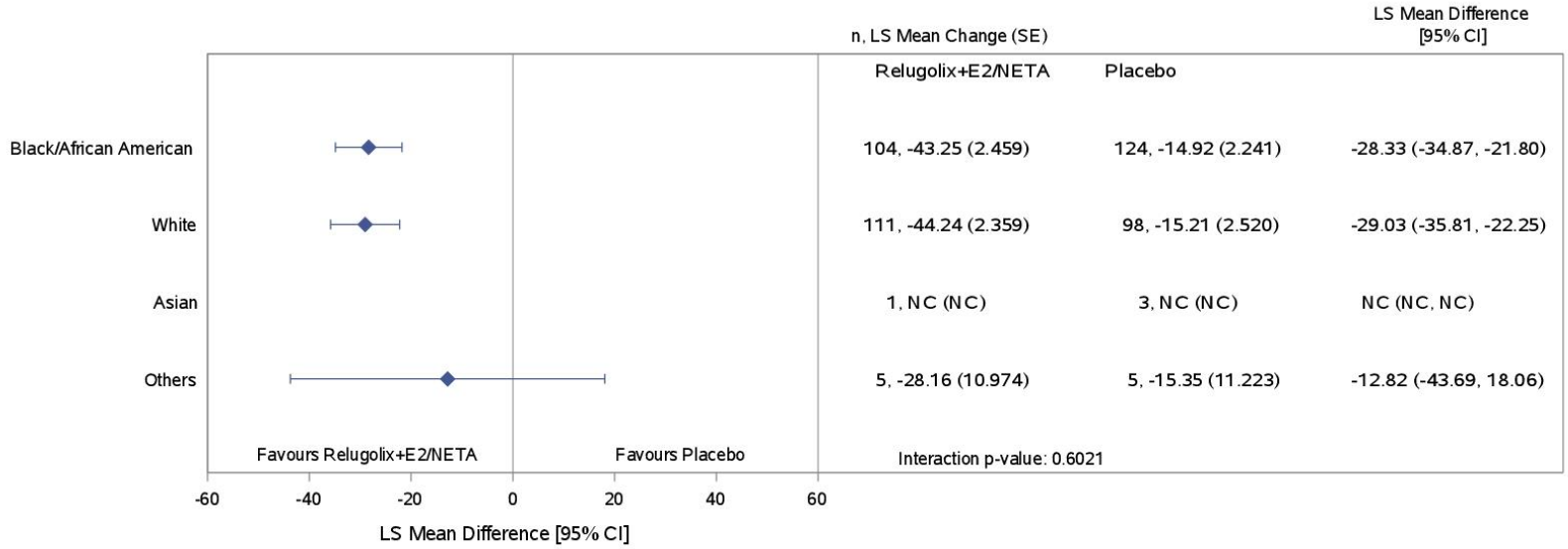
Figure QOL.UFSBPD.MITT.S9.CON.FP: Summary of Average Change from Baseline in UFS-QoL Bleeding and Pelvic Discomfort Scale Score Over 24 Weeks, by Subgroup (mITT Population)
Study: Pooled
Subgroup: Race



Results are based on a mixed-effects model with study, treatment, visit, subgroup, treatment-by-visit interaction, and a subgroup-by-treatment interaction as fixed effects using a one-stage IPD meta-analysis approach. The multiple visits for each patient are the repeated measures as a random effect within each patient with an unstructured covariance.
The interaction p-value is based on the subgroup-by-treatment interaction term in the mixed-effects model used to compute the LS means, mean differences and 95% CIs. Missing subgroup levels are not included in estimation of the interaction p-value. The reference group is Placebo.
n: Number of patients with data; NETA: Norethindrone acetate; mITT: Modified intent-to-treat; LS: Least squares; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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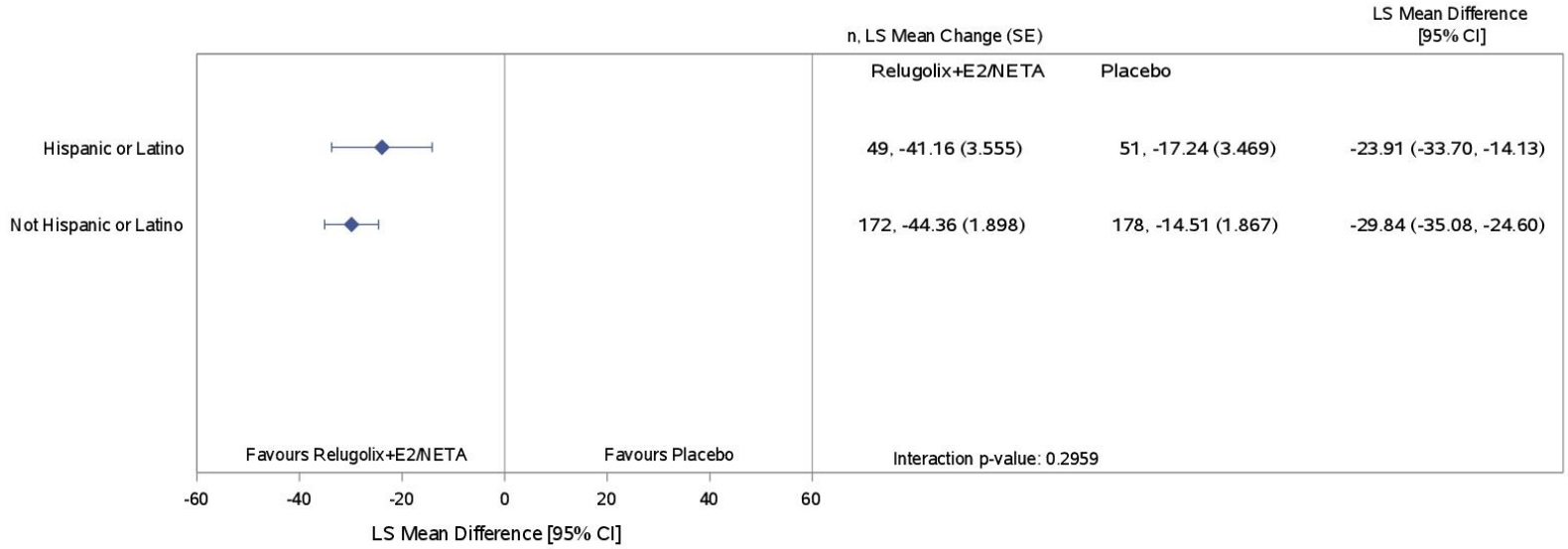
Figure QOL.UFSBPD.MITT.S8.CON.FP: Summary of Average Change from Baseline in UFS-QoL Bleeding and Pelvic Discomfort Scale Score Over 24 Weeks, by Subgroup (mITT Population)
Study: Pooled
Subgroup: Ethnicity



Results are based on a mixed-effects model with study, treatment, visit, subgroup, treatment-by-visit interaction, and a subgroup-by-treatment interaction as fixed effects using a one-stage IPD meta-analysis approach. The multiple visits for each patient are the repeated measures as a random effect within each patient with an unstructured covariance.
The interaction p-value is based on the subgroup-by-treatment interaction term in the mixed-effects model used to compute the LS means, mean differences and 95% CIs. Missing subgroup levels are not included in estimation of the interaction p-value. The reference group is Placebo.
n: Number of patients with data; NETA: Norethindrone acetate; mITT: Modified intent-to-treat; LS: Least squares; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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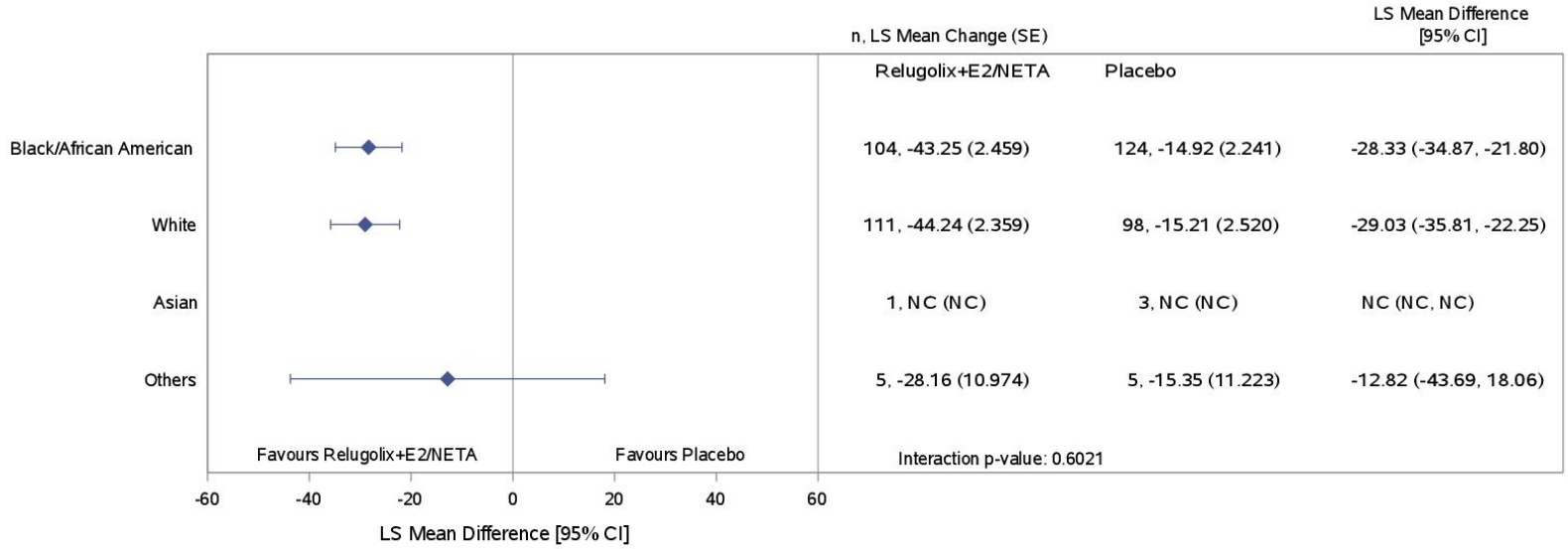
Figure QOL.UFSBPD.MITT.S9.CON.FP: Summary of Average Change from Baseline in UFS-QoL Bleeding and Pelvic Discomfort Scale Score Over 24 Weeks, by Subgroup (mITT Population)
Study: Pooled
Subgroup: Race



Results are based on a mixed-effects model with study, treatment, visit, subgroup, treatment-by-visit interaction, and a subgroup-by-treatment interaction as fixed effects using a one-stage IPD meta-analysis approach. The multiple visits for each patient are the repeated measures as a random effect within each patient with an unstructured covariance.
The interaction p-value is based on the subgroup-by-treatment interaction term in the mixed-effects model used to compute the LS means, mean differences and 95% CIs. Missing subgroup levels are not included in estimation of the interaction p-value. The reference group is Placebo.
n: Number of patients with data; NETA: Norethindrone acetate; mITT: Modified intent-to-treat; LS: Least squares; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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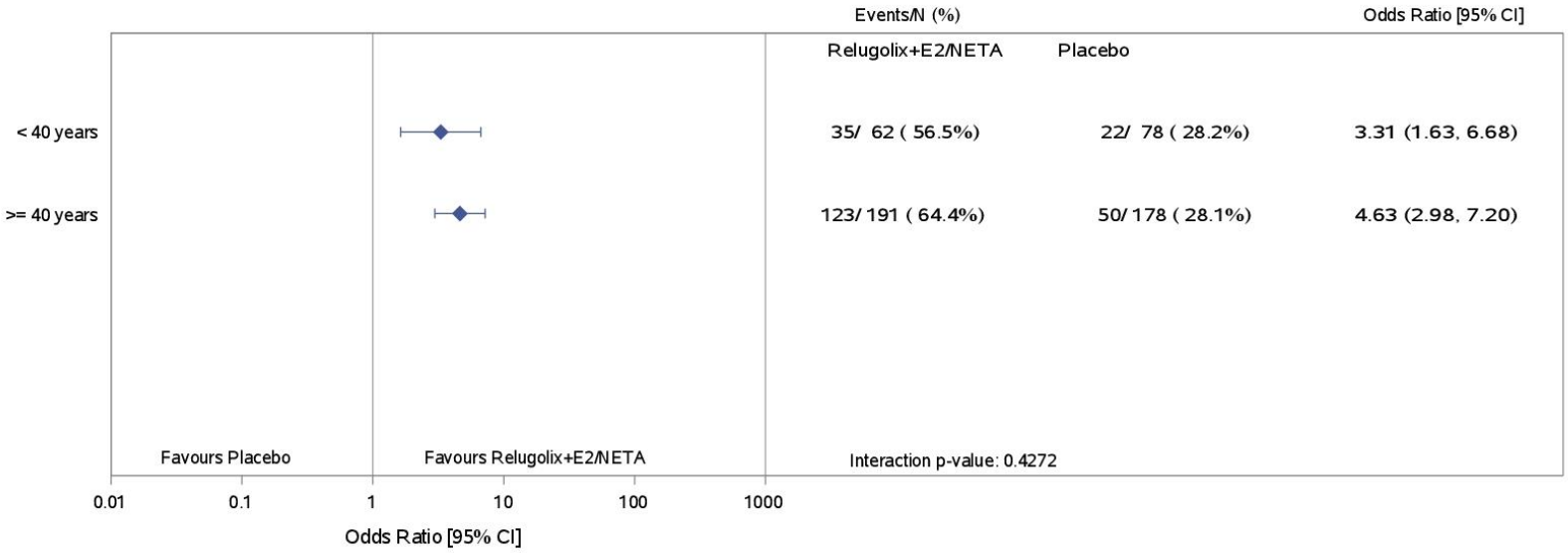
2.2.4 Proportion of Responders with at Least 20 Points Decrease in UFS-QoL Bleeding and Pelvic Discomfort Scale Score at Week 24, by Subgroup (mITT Population)

Nachfolgend sind zunächst alle Forest Plots für das *Odds Ratio* dargestellt; gefolgt von den entsprechenden Forest Plots für *Risk Ratio* und *Risk Difference*.

Figure QOL.UFSBPD20.MITT.S1.BIN.FP: Proportion of Responders with at Least 20 Points Decrease in UFS-QoL Bleeding and Pelvic Discomfort Scale Score at Week 24, by Subgroup
(mITT Population)
Study: Pooled
Subgroup: Age (years)



Results are based on a logistic regression model adjusted for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates using a one-stage fixed-effects IPD meta-analysis approach. A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
The interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the Odds Ratio and 95% CI. Missing subgroup levels are not included in estimation of the interaction p-value. The reference group is Placebo.
N: Number of patients in treatment group; NETA: Norethindrone acetate; mITT: Modified intent-to-treat; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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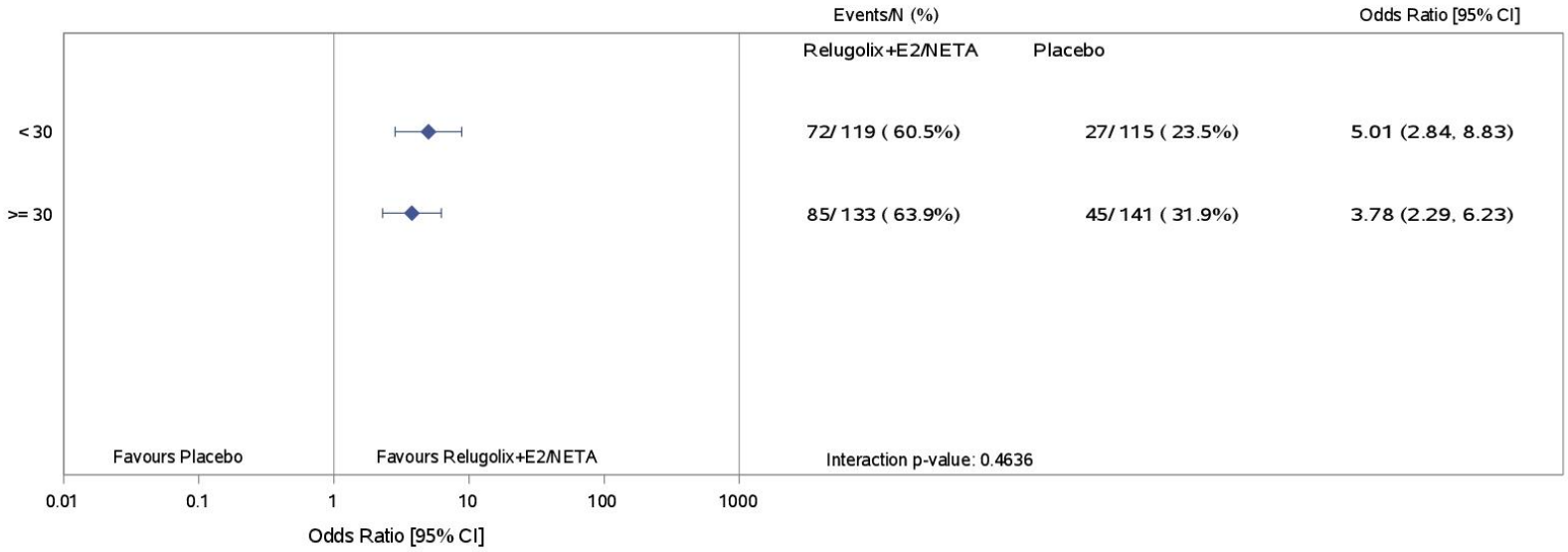
Figure QOL.UFSBPD20.MITT.S2.BIN.FP: Proportion of Responders with at Least 20 Points Decrease in UFS-QoL Bleeding and Pelvic Discomfort Scale Score at Week 24, by Subgroup (mITT Population)
Study: Pooled
Subgroup: BMI (kg/m2) at Baseline



Results are based on a logistic regression model adjusted for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates using a one-stage fixed-effects IPD meta-analysis approach. A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
The interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the Odds Ratio and 95% CI. Missing subgroup levels are not included in estimation of the interaction p-value. The reference group is Placebo.
N: Number of patients in treatment group; NETA: Norethindrone acetate; mITT: Modified intent-to-treat; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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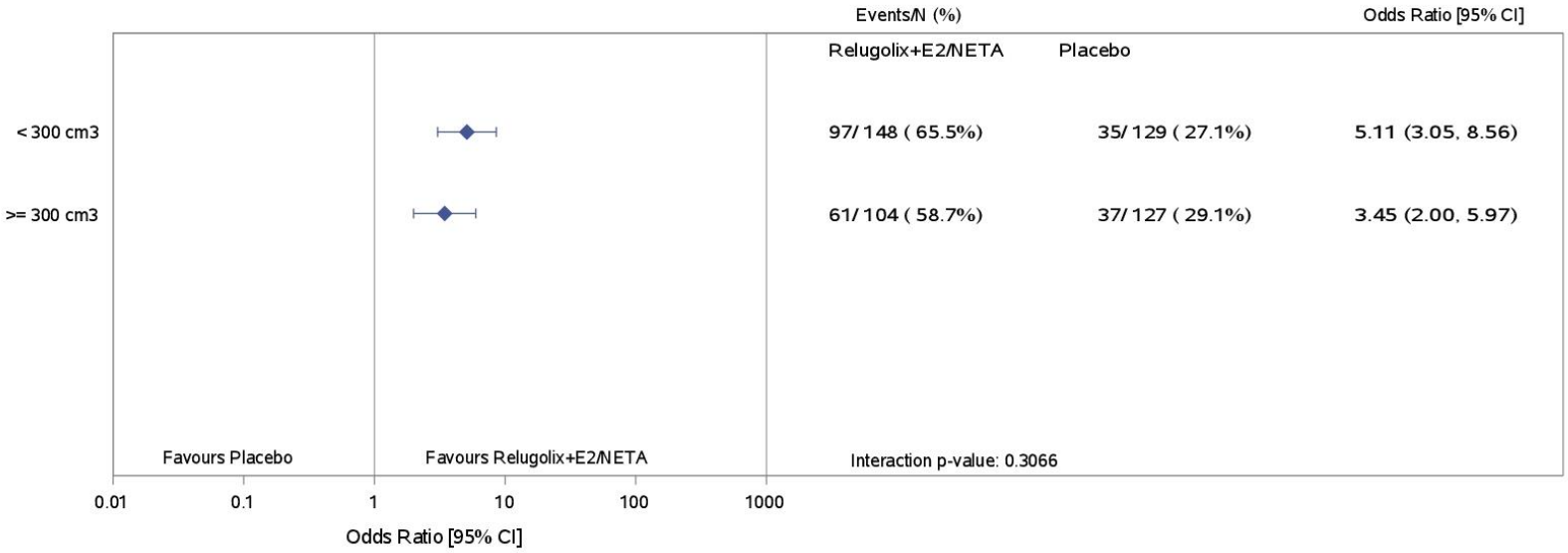
Figure QOL.UFSBPD20.MITT.S3.BIN.FP: Proportion of Responders with at Least 20 Points Decrease in UFS-QoL Bleeding and Pelvic Discomfort Scale Score at Week 24, by Subgroup (mITT Population)
Study: Pooled
Subgroup: Uterine Volume at Baseline (cm3)



Results are based on a logistic regression model adjusted for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates using a one-stage fixed-effects IPD meta-analysis approach. A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
The interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the Odds Ratio and 95% CI. Missing subgroup levels are not included in estimation of the interaction p-value. The reference group is Placebo.
N: Number of patients in treatment group; NETA: Norethindrone acetate; mITT: Modified intent-to-treat; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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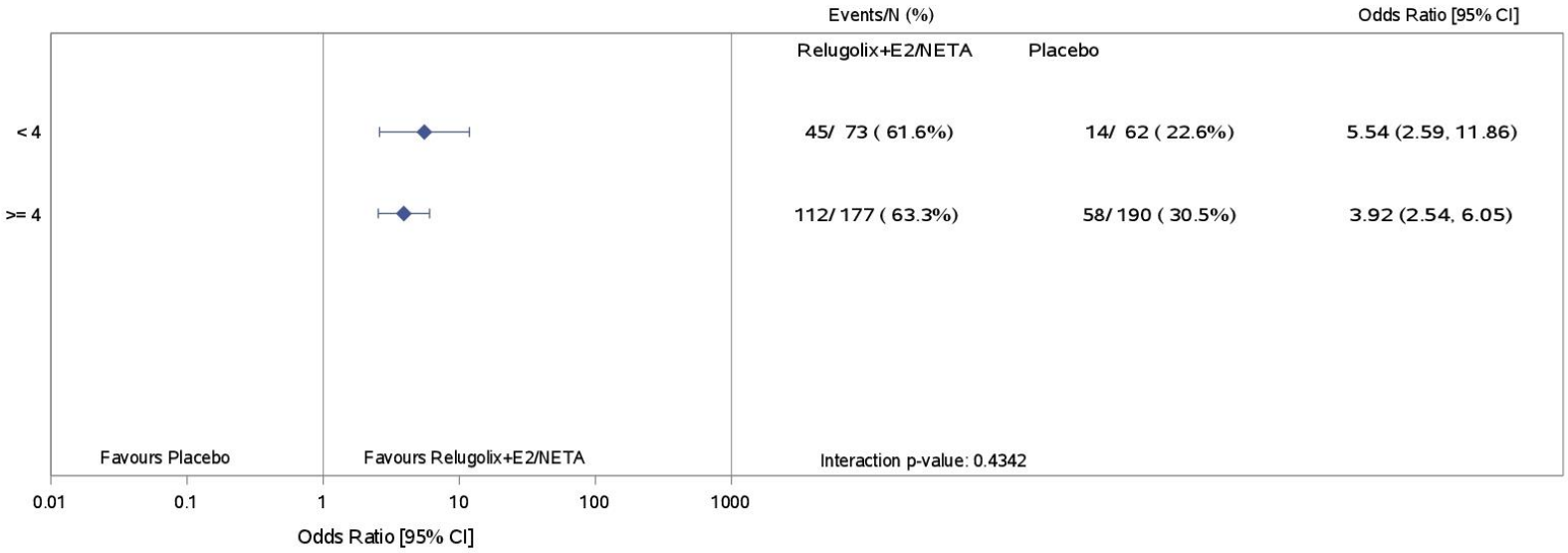
Figure QOL.UFSBPD20.MITT.S4.BIN.FP: Proportion of Responders with at Least 20 Points Decrease in UFS-QoL Bleeding and Pelvic Discomfort Scale Score at Week 24, by Subgroup (mITT Population)
Study: Pooled
Subgroup: Maximum NRS Pain Score at Baseline



Results are based on a logistic regression model adjusted for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates using a one-stage fixed-effects IPD meta-analysis approach. A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
The interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the Odds Ratio and 95% CI. Missing subgroup levels are not included in estimation of the interaction p-value. The reference group is Placebo.
N: Number of patients in treatment group; NETA: Norethindrone acetate; mITT: Modified intent-to-treat; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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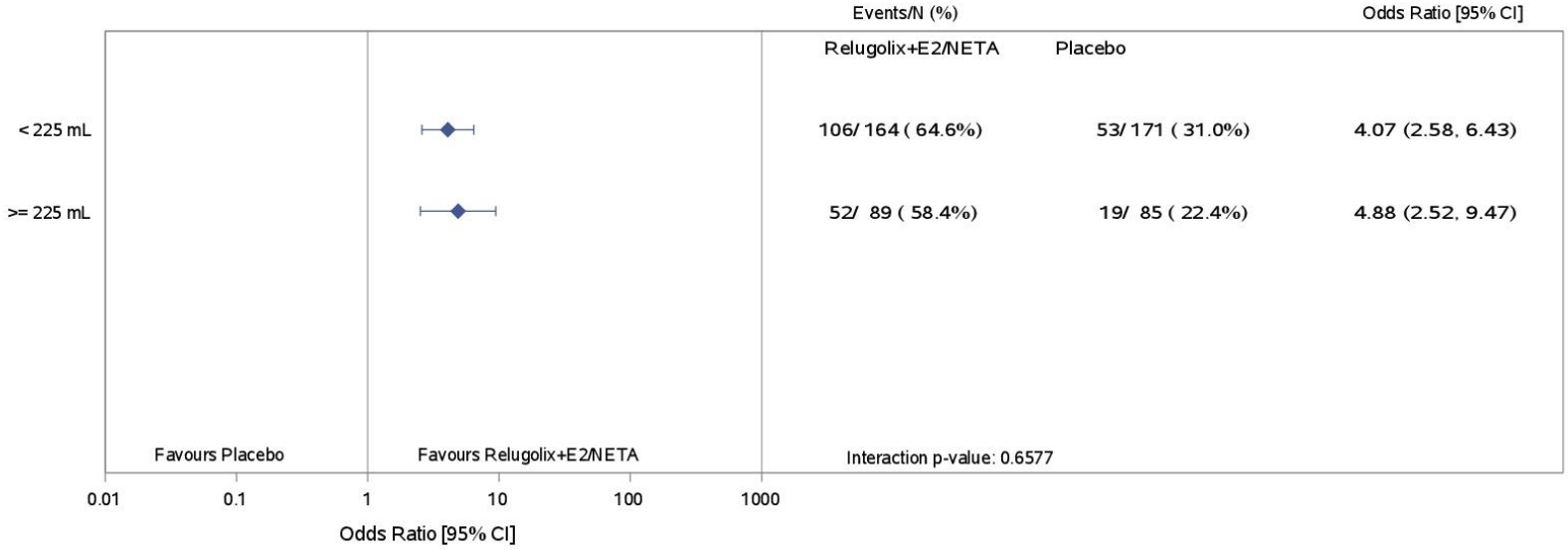
Figure QOL.UFSBPD20.MITT.S5.BIN.FP: Proportion of Responders with at Least 20 Points Decrease in UFS-QoL Bleeding and Pelvic Discomfort Scale Score at Week 24, by Subgroup (mITT Population)
Study: Pooled
Subgroup: MBL Volume at Baseline (mL)



Results are based on a logistic regression model adjusted for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates using a one-stage fixed-effects IPD meta-analysis approach. A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
The interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the Odds Ratio and 95% CI. Missing subgroup levels are not included in estimation of the interaction p-value. The reference group is Placebo.
N: Number of patients in treatment group; NETA: Norethindrone acetate; mITT: Modified intent-to-treat; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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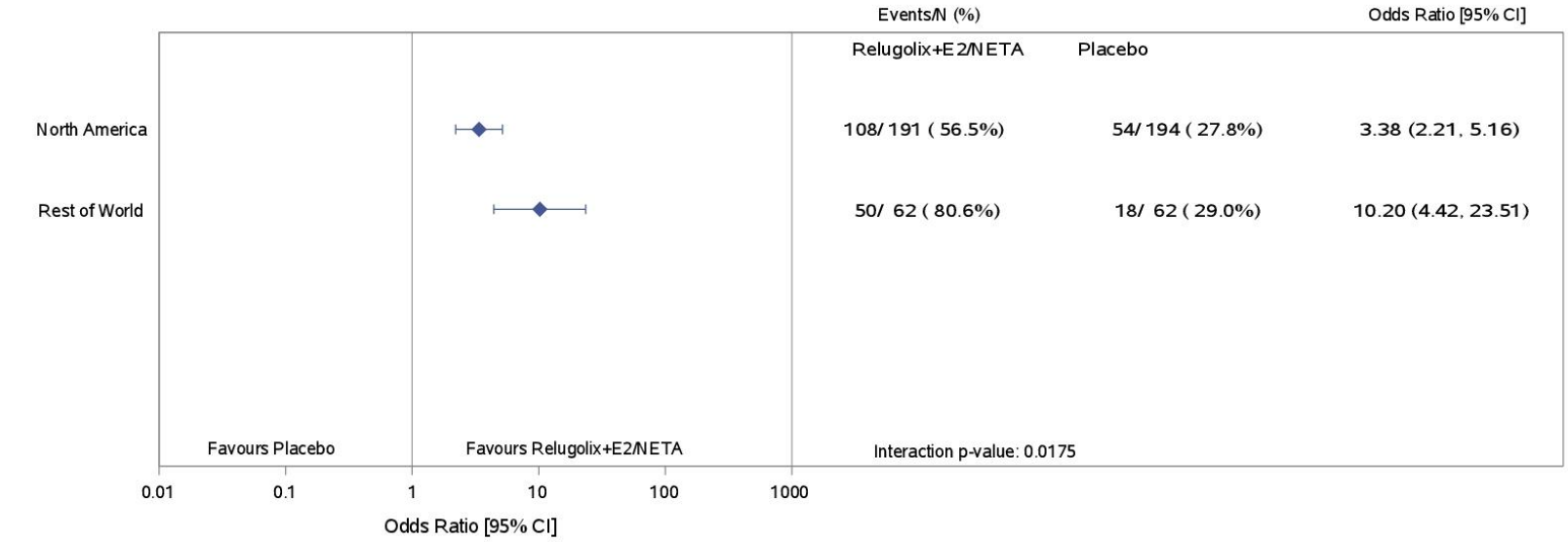
Figure QOL.UFSBPD20.MITT.S6.BIN.FP: Proportion of Responders with at Least 20 Points Decrease in UFS-QoL Bleeding and Pelvic Discomfort Scale Score at Week 24, by Subgroup (mITT Population)
Study: Pooled
Subgroup: Geographic Region I



Results are based on a logistic regression model adjusted for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates using a one-stage fixed-effects IPD meta-analysis approach. A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
The interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the Odds Ratio and 95% CI. Missing subgroup levels are not included in estimation of the interaction p-value. The reference group is Placebo.
N: Number of patients in treatment group; NETA: Norethindrone acetate; mITT: Modified intent-to-treat; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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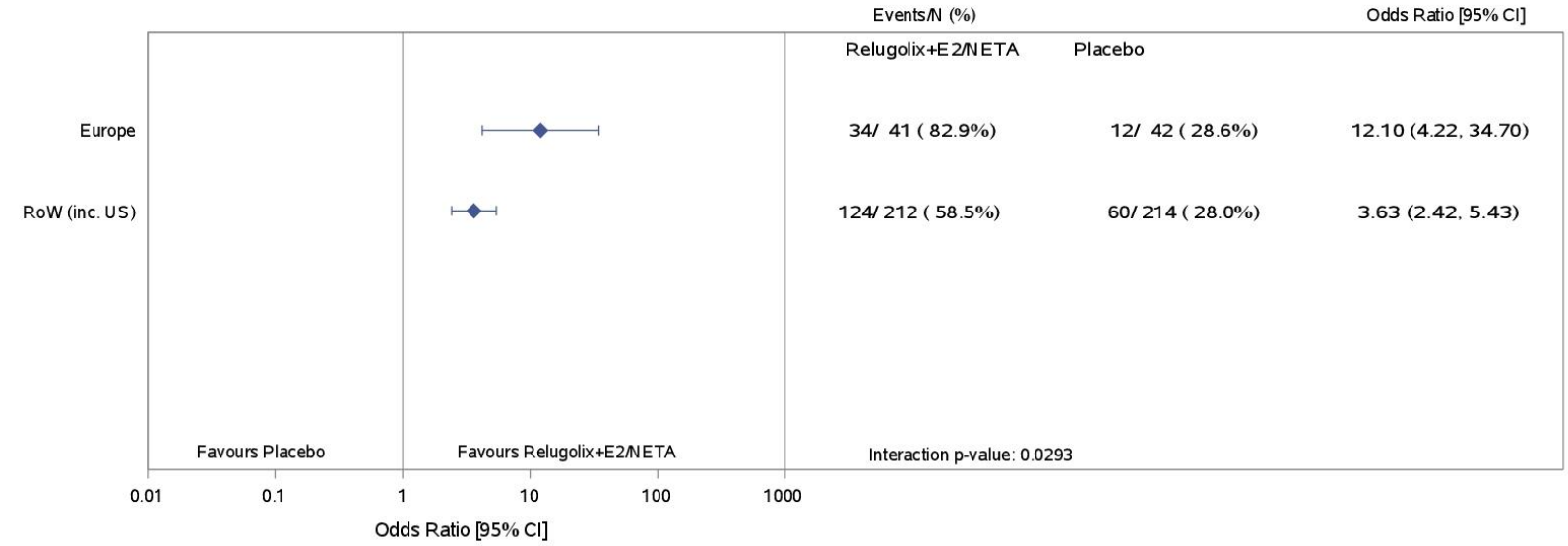
Figure QOL.UFSBPD20.MITT.S7.BIN.FP: Proportion of Responders with at Least 20 Points Decrease in UFS-QoL Bleeding and Pelvic Discomfort Scale Score at Week 24, by Subgroup (mITT Population)
Study: Pooled
Subgroup: Geographic Region II



Results are based on a logistic regression model adjusted for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates using a one-stage fixed-effects IPD meta-analysis approach. A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
The interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the Odds Ratio and 95% CI. Missing subgroup levels are not included in estimation of the interaction p-value. The reference group is Placebo.
N: Number of patients in treatment group; NETA: Norethindrone acetate; mITT: Modified intent-to-treat; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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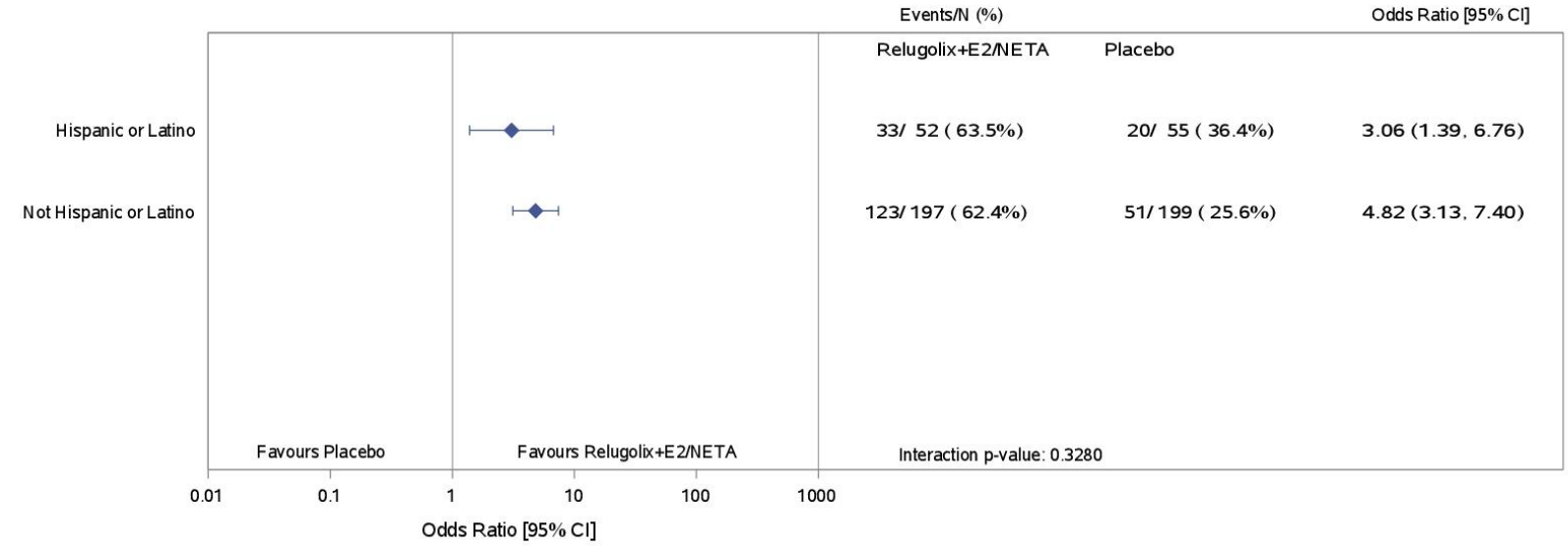
Figure QOL.UFSBPD20.MITT.S8.BIN.FP: Proportion of Responders with at Least 20 Points Decrease in UFS-QoL Bleeding and Pelvic Discomfort Scale Score at Week 24, by Subgroup
(mITT Population)
Study: Pooled
Subgroup: Ethnicity



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The interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the Odds Ratio and 95% CI. Missing subgroup levels are not included in estimation of the interaction p-value. The reference group is Placebo.
N: Number of patients in treatment group; NETA: Norethindrone acetate; mITT: Modified intent-to-treat; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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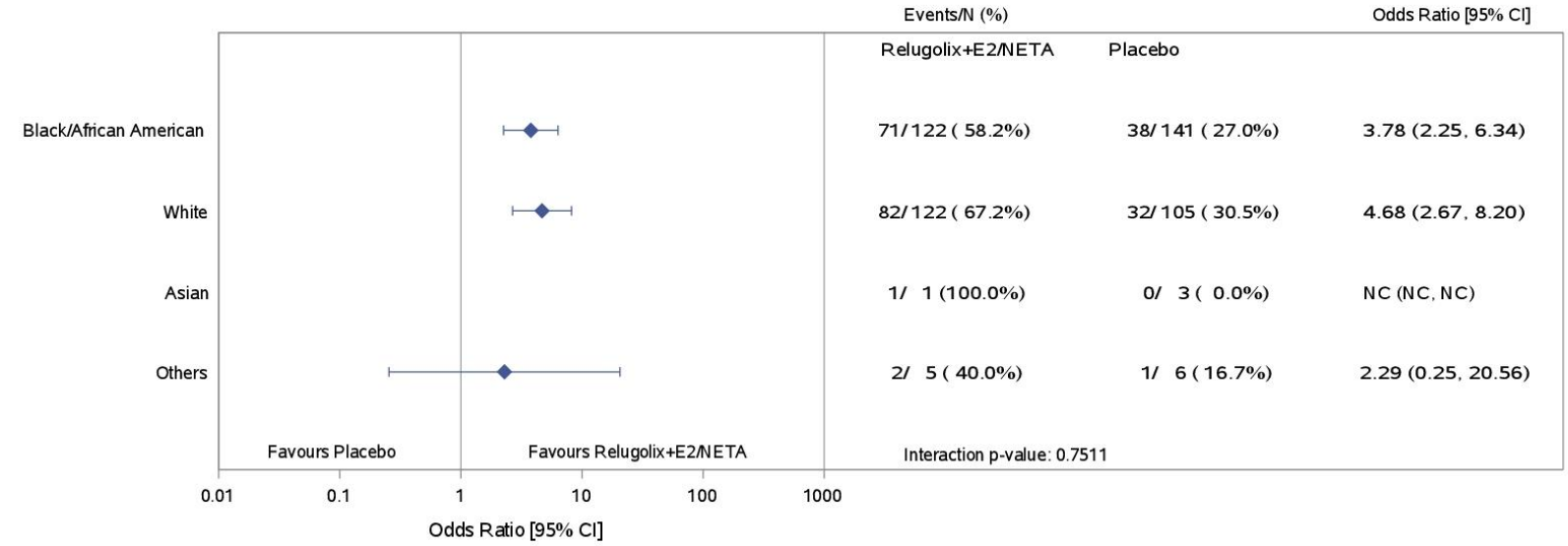
Figure QOL.UFSBPD20.MITT.S9.BIN.FP: Proportion of Responders with at Least 20 Points Decrease in UFS-QoL Bleeding and Pelvic Discomfort Scale Score at Week 24, by Subgroup (mITT Population)
Study: Pooled
Subgroup: Race



Results are based on a logistic regression model adjusted for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates using a one-stage fixed-effects IPD meta-analysis approach. A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
The interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the Odds Ratio and 95% CI. Missing subgroup levels are not included in estimation of the interaction p-value. The reference group is Placebo.
N: Number of patients in treatment group; NETA: Norethindrone acetate; mITT: Modified intent-to-treat; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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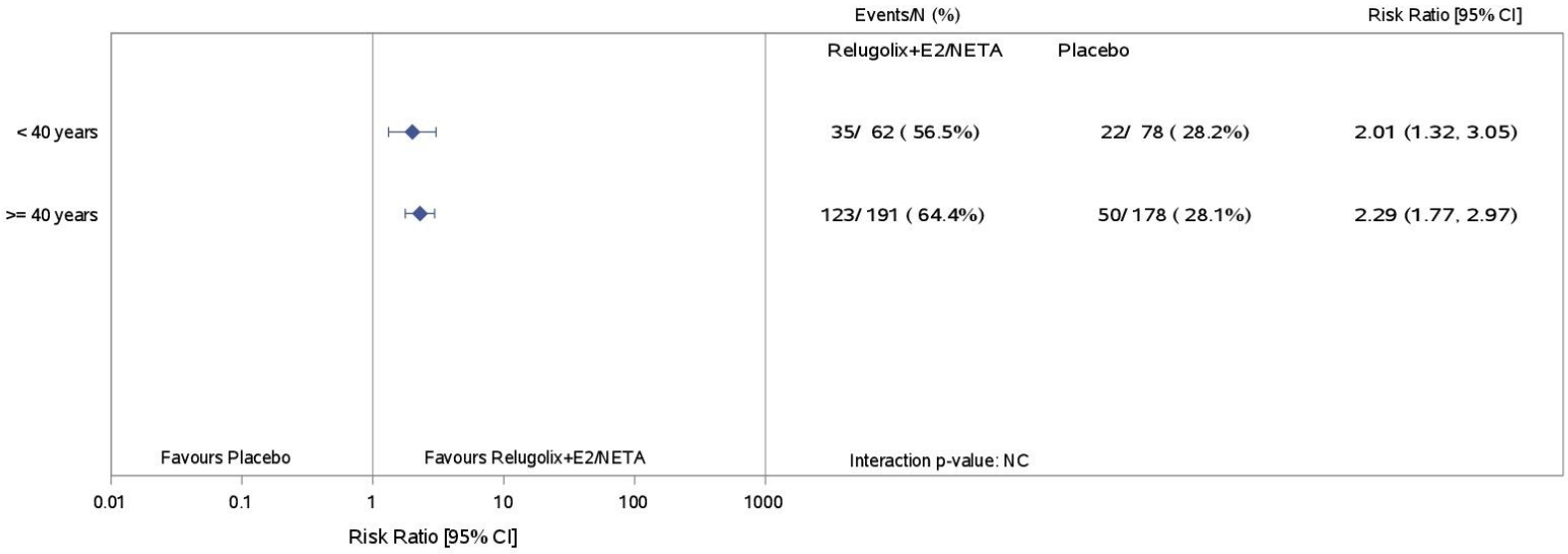
Figure QOL.UFSBPD20.MITT.S1.BIN.FP.RR: Proportion of Responders with at Least 20 Points Decrease in UFS-QoL Bleeding and Pelvic Discomfort Scale Score at Week 24, by Subgroup (mITT Population) - Risk Ratio
Study: Pooled
Subgroup: Age (years)



Results are based on a Cochran-Mantel-Haenszel approach stratified by study using a one-stage fixed-effects IPD meta-analysis. A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
The reference group is Placebo.
N: Number of patients in treatment group; NETA: Norethindrone acetate; mITT: Modified intent-to-treat; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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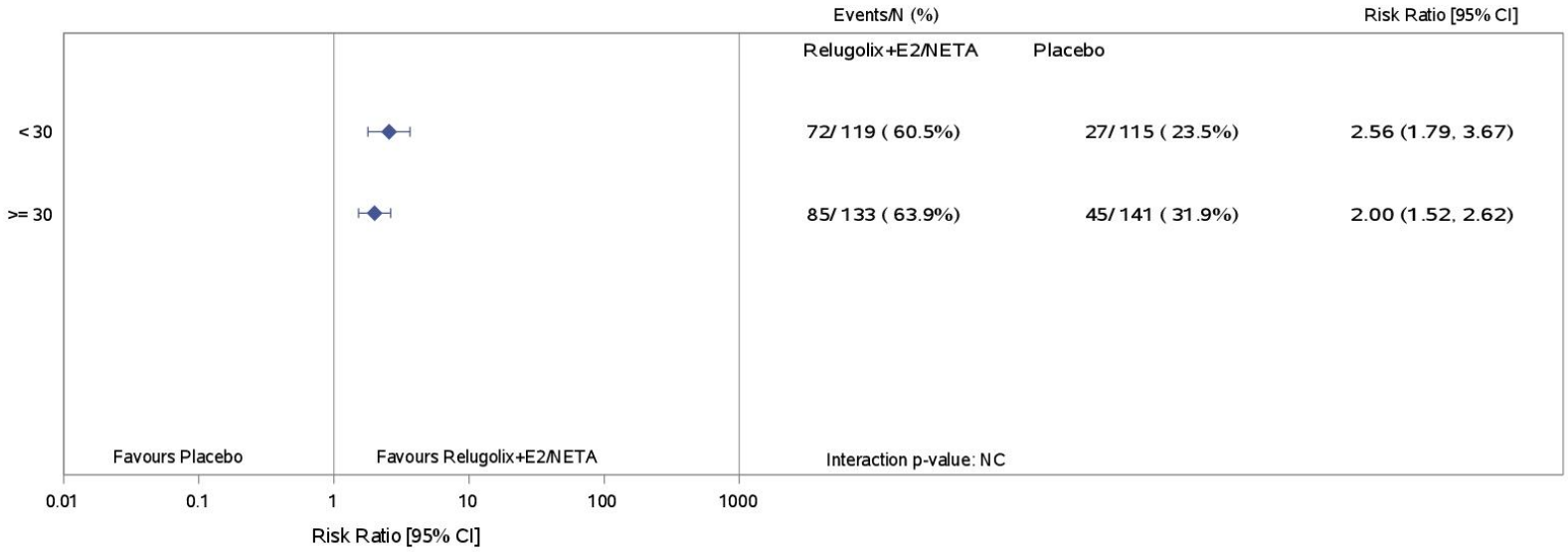
Figure QOL.UFSBPD20.MITT.S2.BIN.FP.RR: Proportion of Responders with at Least 20 Points Decrease in UFS-QoL Bleeding and Pelvic Discomfort Scale Score at Week 24, by Subgroup (mITT Population) - Risk Ratio
Study: Pooled
Subgroup: BMI (kg/m2) at Baseline



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The reference group is Placebo.
N: Number of patients in treatment group; NETA: Norethindrone acetate; mITT: Modified intent-to-treat; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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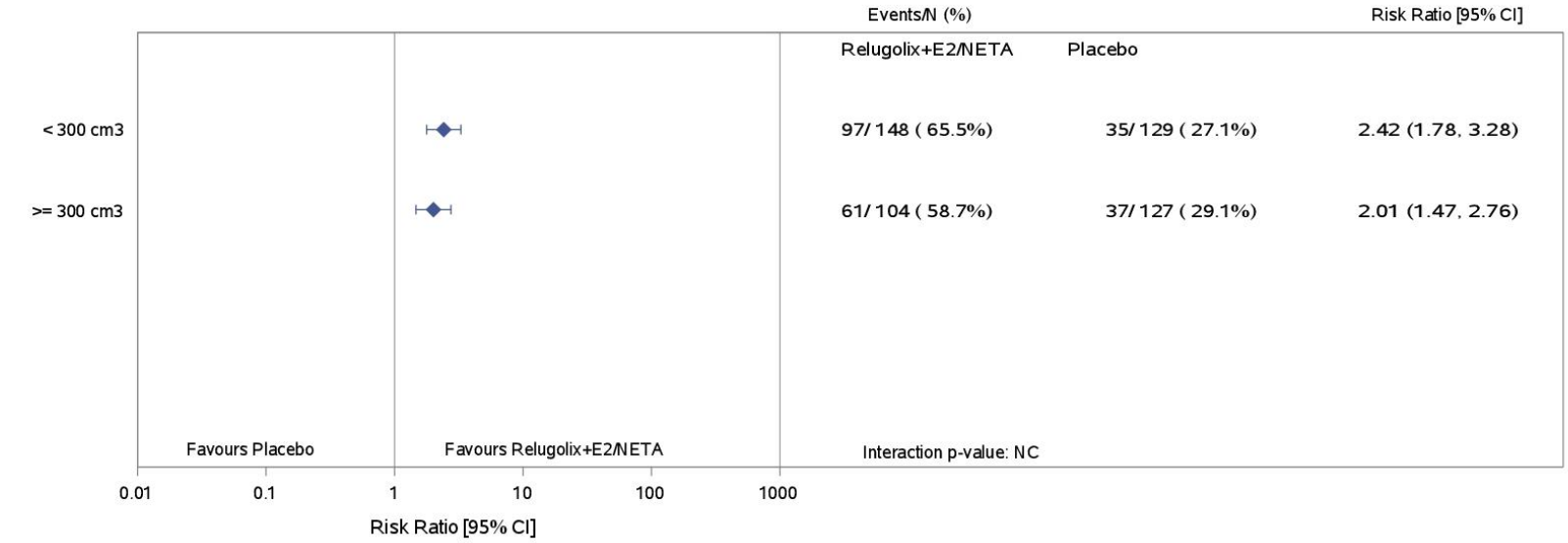
Figure QOL.UFSBPD20.MITT.S3.BIN.FP.RR: Proportion of Responders with at Least 20 Points Decrease in UFS-QoL Bleeding and Pelvic Discomfort Scale Score at Week 24, by Subgroup (mITT Population) - Risk Ratio
Study: Pooled
Subgroup: Uterine Volume at Baseline (cm3)



Results are based on a Cochran-Mantel-Haenszel approach stratified by study using a one-stage fixed-effects IPD meta-analysis. A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
The reference group is Placebo.
N: Number of patients in treatment group; NETA: Norethindrone acetate; mITT: Modified intent-to-treat; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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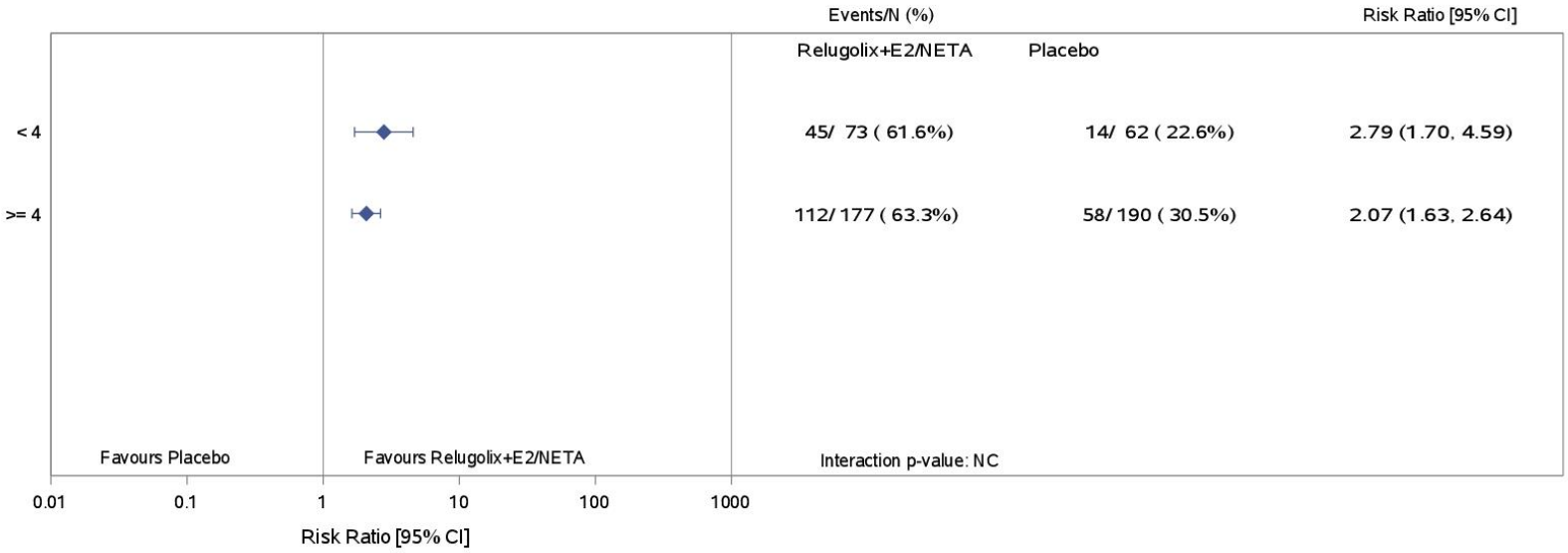
Figure QOL.UFSBPD20.MITT.S4.BIN.FP.RR: Proportion of Responders with at Least 20 Points Decrease in UFS-QoL Bleeding and Pelvic Discomfort Scale Score at Week 24, by Subgroup (mITT Population) - Risk Ratio
Study: Pooled
Subgroup: Maximum NRS Pain Score at Baseline



Results are based on a Cochran-Mantel-Haenszel approach stratified by study using a one-stage fixed-effects IPD meta-analysis. A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
The reference group is Placebo.
N: Number of patients in treatment group; NETA: Norethindrone acetate; mITT: Modified intent-to-treat; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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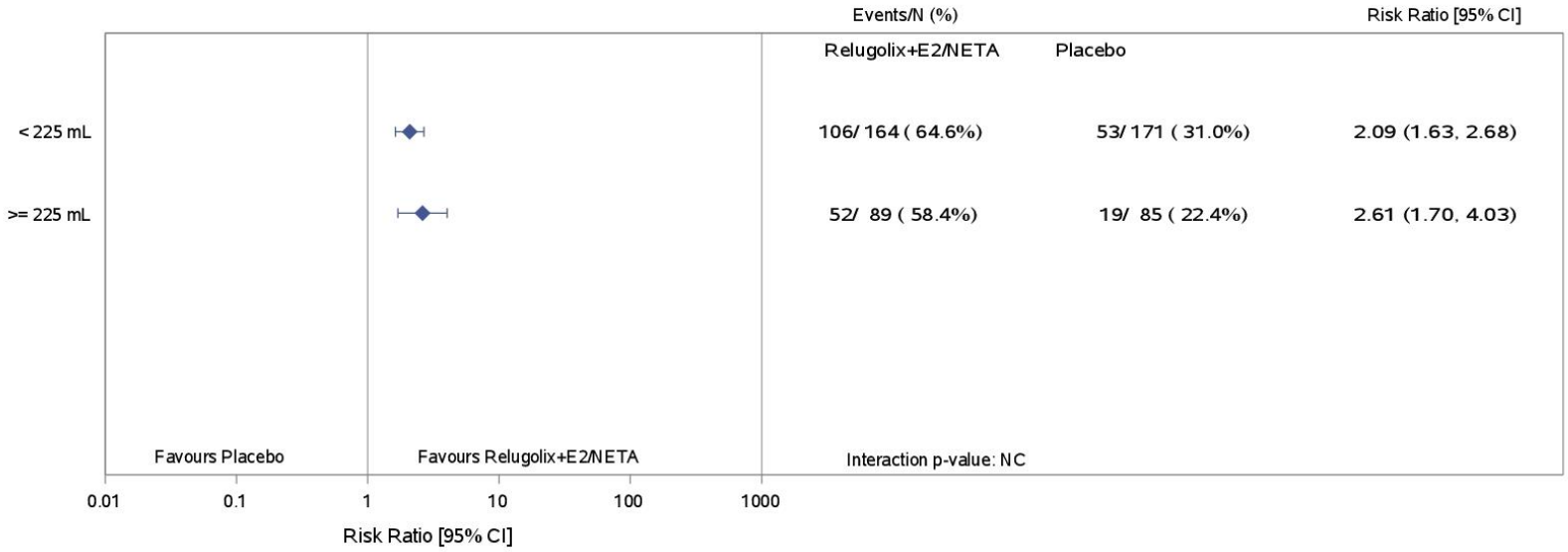
Figure QOL.UFSBPD20.MITT.S5.BIN.FP.RR: Proportion of Responders with at Least 20 Points Decrease in UFS-QoL Bleeding and Pelvic Discomfort Scale Score at Week 24, by Subgroup (mITT Population) - Risk Ratio
Study: Pooled
Subgroup: MBL Volume at Baseline (mL)



Results are based on a Cochran-Mantel-Haenszel approach stratified by study using a one-stage fixed-effects IPD meta-analysis. A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
The reference group is Placebo.
N: Number of patients in treatment group; NETA: Norethindrone acetate; mITT: Modified intent-to-treat; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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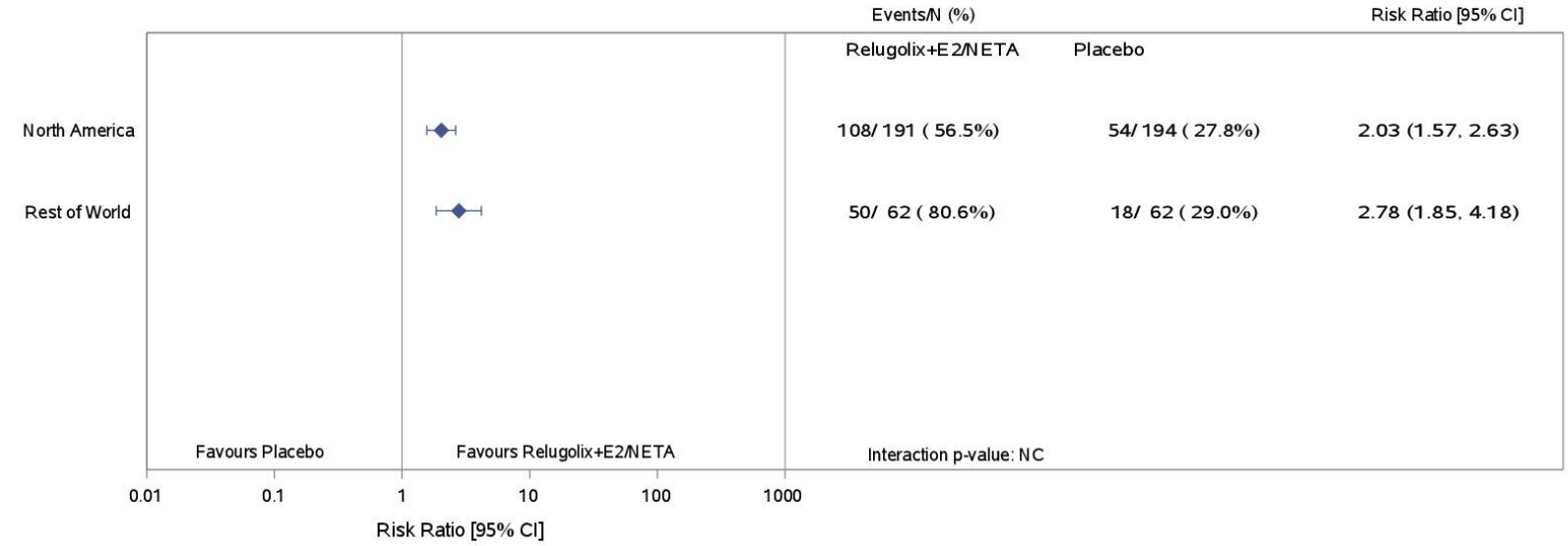
Figure QOL.UFSBPD20.MITT.S6.BIN.FP.RR: Proportion of Responders with at Least 20 Points Decrease in UFS-QoL Bleeding and Pelvic Discomfort Scale Score at Week 24, by Subgroup (mITT Population) - Risk Ratio
Study: Pooled
Subgroup: Geographic Region I



Results are based on a Cochran-Mantel-Haenszel approach stratified by study using a one-stage fixed-effects IPD meta-analysis. A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
The reference group is Placebo.
N: Number of patients in treatment group; NETA: Norethindrone acetate; mITT: Modified intent-to-treat; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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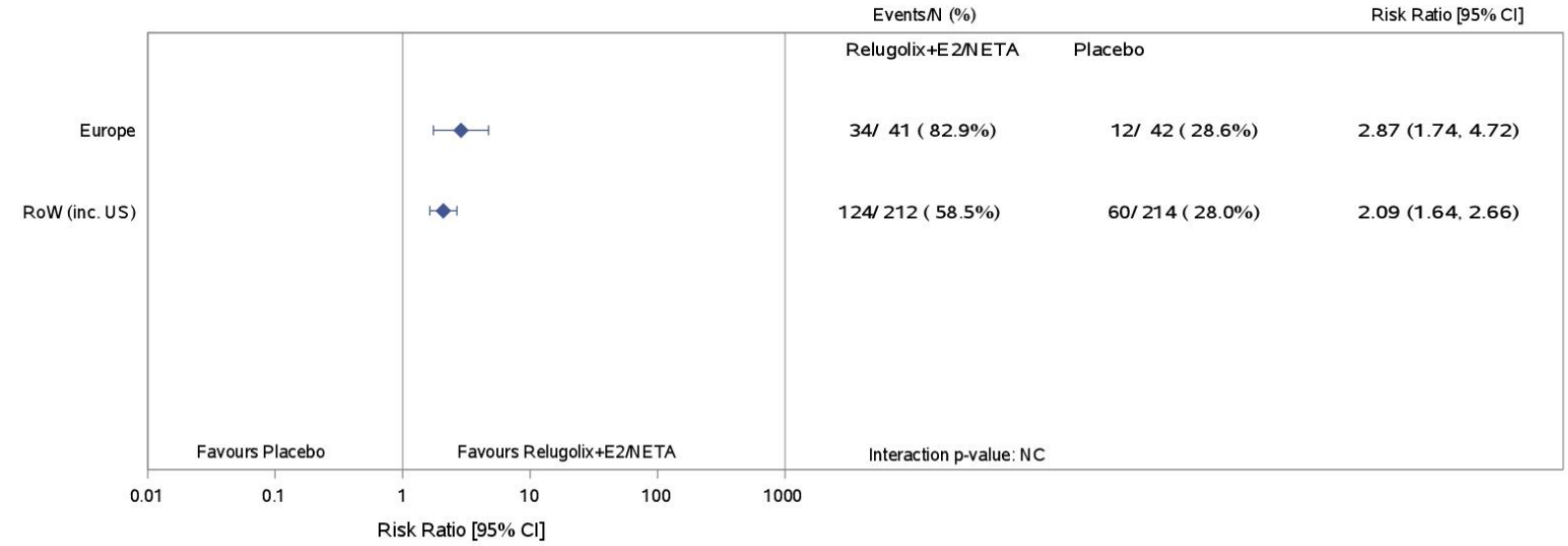
Figure QOL.UFSBPD20.MITT.S7.BIN.FP.RR: Proportion of Responders with at Least 20 Points Decrease in UFS-QoL Bleeding and Pelvic Discomfort Scale Score at Week 24, by Subgroup (mITT Population) - Risk Ratio
Study: Pooled
Subgroup: Geographic Region II



Results are based on a Cochran-Mantel-Haenszel approach stratified by study using a one-stage fixed-effects IPD meta-analysis. A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
The reference group is Placebo.
N: Number of patients in treatment group; NETA: Norethindrone acetate; mITT: Modified intent-to-treat; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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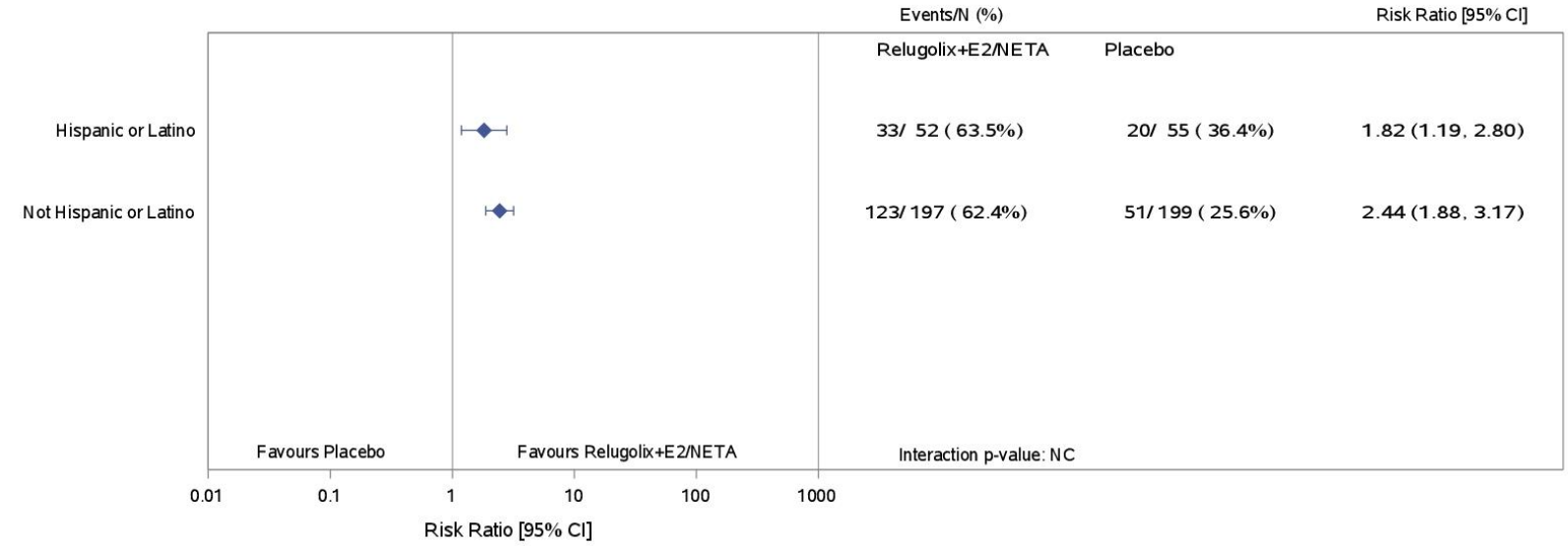
Figure QOL.UFSBPD20.MITT.S8.BIN.FP.RR: Proportion of Responders with at Least 20 Points Decrease in UFS-QoL Bleeding and Pelvic Discomfort Scale Score at Week 24, by Subgroup (mITT Population) - Risk Ratio
Study: Pooled
Subgroup: Ethnicity



Results are based on a Cochran-Mantel-Haenszel approach stratified by study using a one-stage fixed-effects IPD meta-analysis. A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
The reference group is Placebo.
N: Number of patients in treatment group; NETA: Norethindrone acetate; mITT: Modified intent-to-treat; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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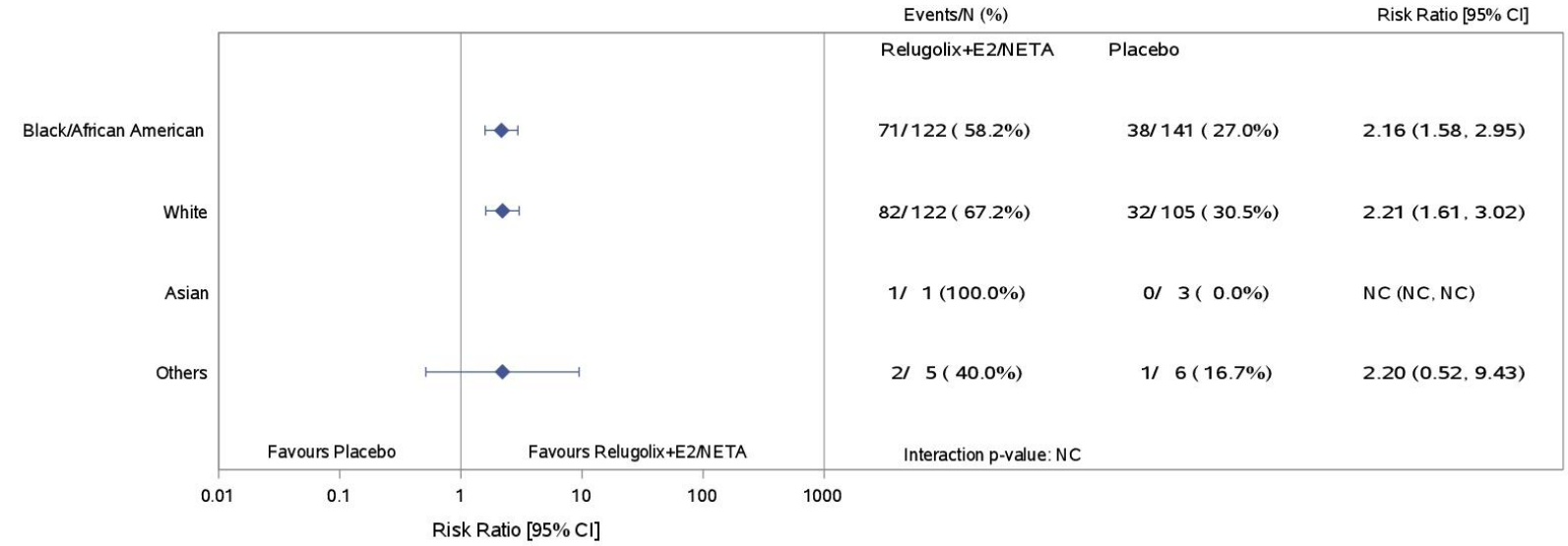
Figure QOL.UFSBPD20.MITT.S9.BIN.FP.RR: Proportion of Responders with at Least 20 Points Decrease in UFS-QoL Bleeding and Pelvic Discomfort Scale Score at Week 24, by Subgroup (mITT Population) - Risk Ratio
Study: Pooled
Subgroup: Race



Results are based on a Cochran-Mantel-Haenszel approach stratified by study using a one-stage fixed-effects IPD meta-analysis. A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
The reference group is Placebo.
N: Number of patients in treatment group; NETA: Norethindrone acetate; mITT: Modified intent-to-treat; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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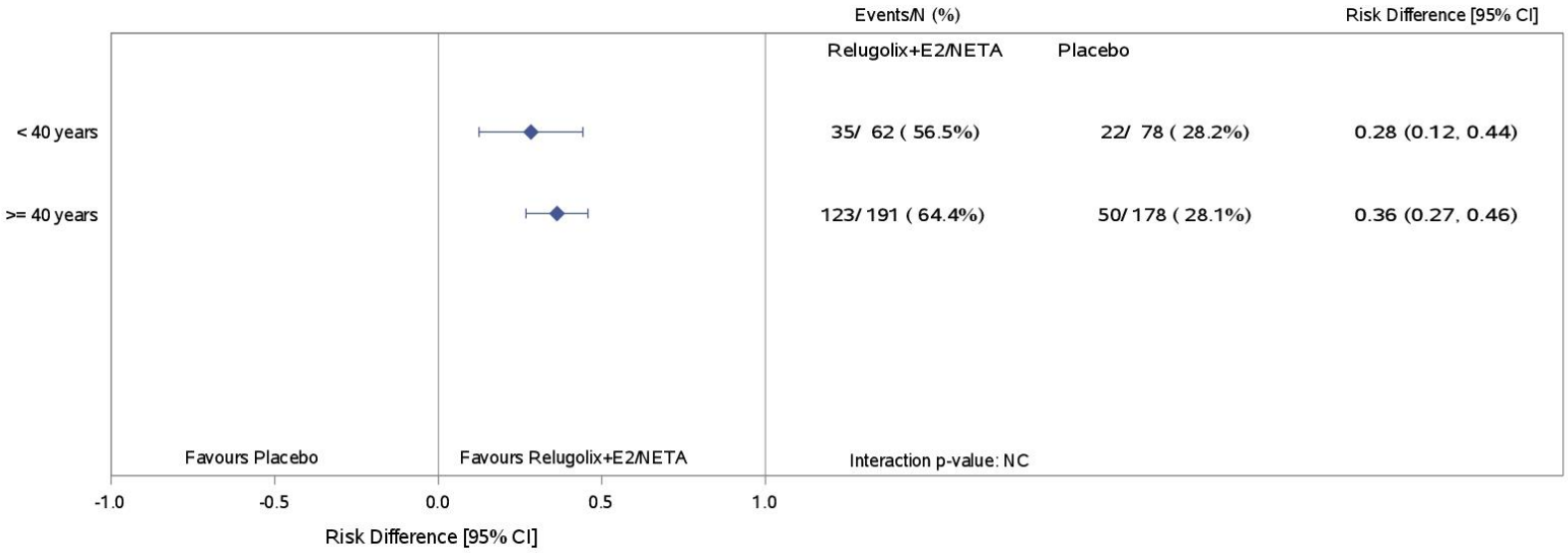
Figure QOL.UFSBPD20.MITT.S1.BIN.FP.RD: Proportion of Responders with at Least 20 Points Decrease in UFS-QoL Bleeding and Pelvic Discomfort Scale Score at Week 24, by Subgroup (mITT Population) - Risk Difference
Study: Pooled
Subgroup: Age (years)



Results are based on a Mantel-Haenszel approach stratified by study using a one-stage fixed-effects IPD meta-analysis.
The reference group is Placebo.
N: Number of patients in treatment group; NETA: Norethindrone acetate; mITT: Modified intent-to-treat; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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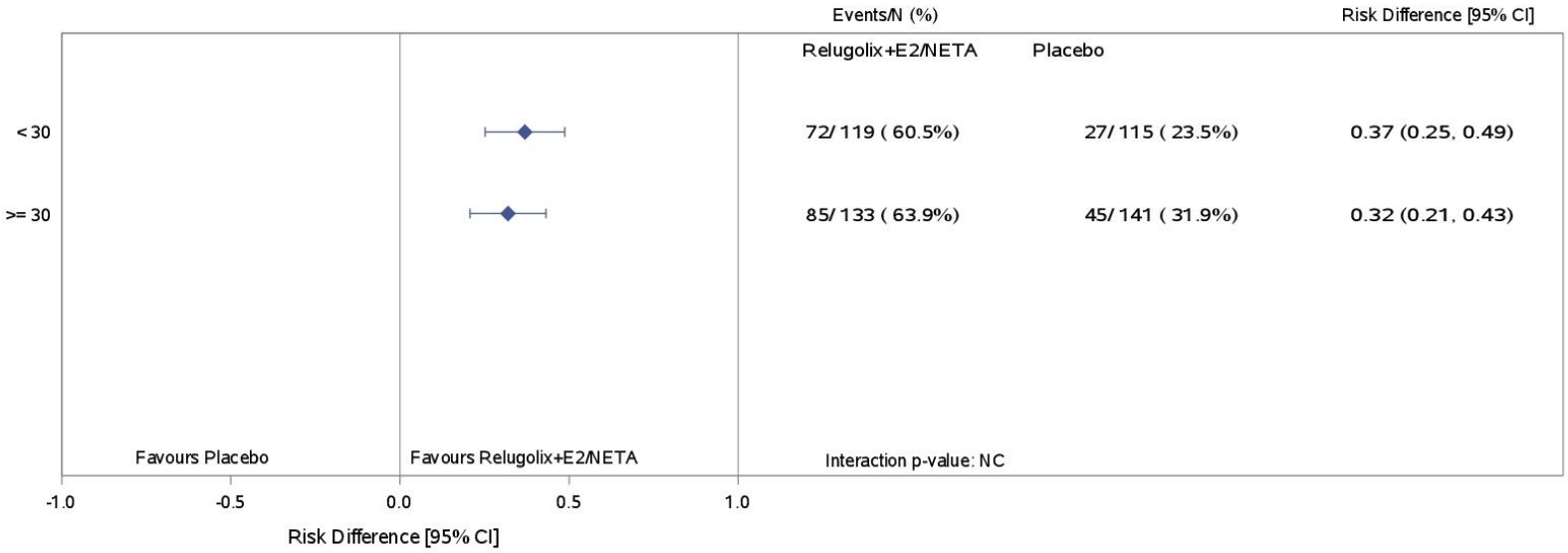
Figure QOL.UFSBPD20.MITT.S2.BIN.FP.RD: Proportion of Responders with at Least 20 Points Decrease in UFS-QoL Bleeding and Pelvic Discomfort Scale Score at Week 24, by Subgroup (mITT Population) - Risk Difference
Study: Pooled
Subgroup: BMI (kg/m2) at Baseline



Results are based on a Mantel-Haenszel approach stratified by study using a one-stage fixed-effects IPD meta-analysis.
The reference group is Placebo.
N: Number of patients in treatment group; NETA: Norethindrone acetate; mITT: Modified intent-to-treat; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

SOURCE: X:\Numerus\Studies\MYV\MYV102\Analysis\Prod\Progs\TFLs\Fig_QOL_QS_S_BIN_FP.SAS Date/time of run: 30JUN21 10:27
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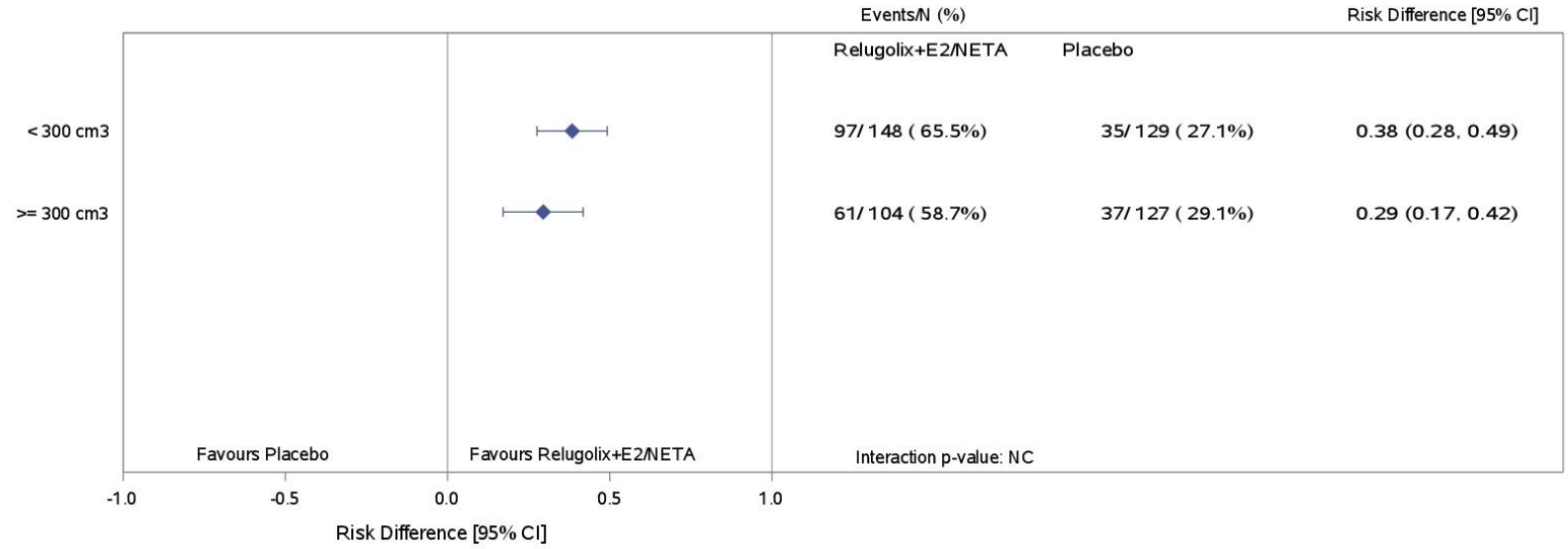
Figure QOL.UFSBPD20.MITT.S3.BIN.FP.RD: Proportion of Responders with at Least 20 Points Decrease in UFS-QoL Bleeding and Pelvic Discomfort Scale Score at Week 24, by Subgroup (mITT Population) - Risk Difference
Study: Pooled
Subgroup: Uterine Volume at Baseline (cm3)



Results are based on a Mantel-Haenszel approach stratified by study using a one-stage fixed-effects IPD meta-analysis.
The reference group is Placebo.
N: Number of patients in treatment group; NETA: Norethindrone acetate; mITT: Modified intent-to-treat; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

SOURCE: X:\Numerus\Studies\MYV\MYV102\Analysis\Prod\Progs\TFLs\Fig_QOL_QS_S_BIN_FP.SAS Date/time of run: 30JUN21 10:27
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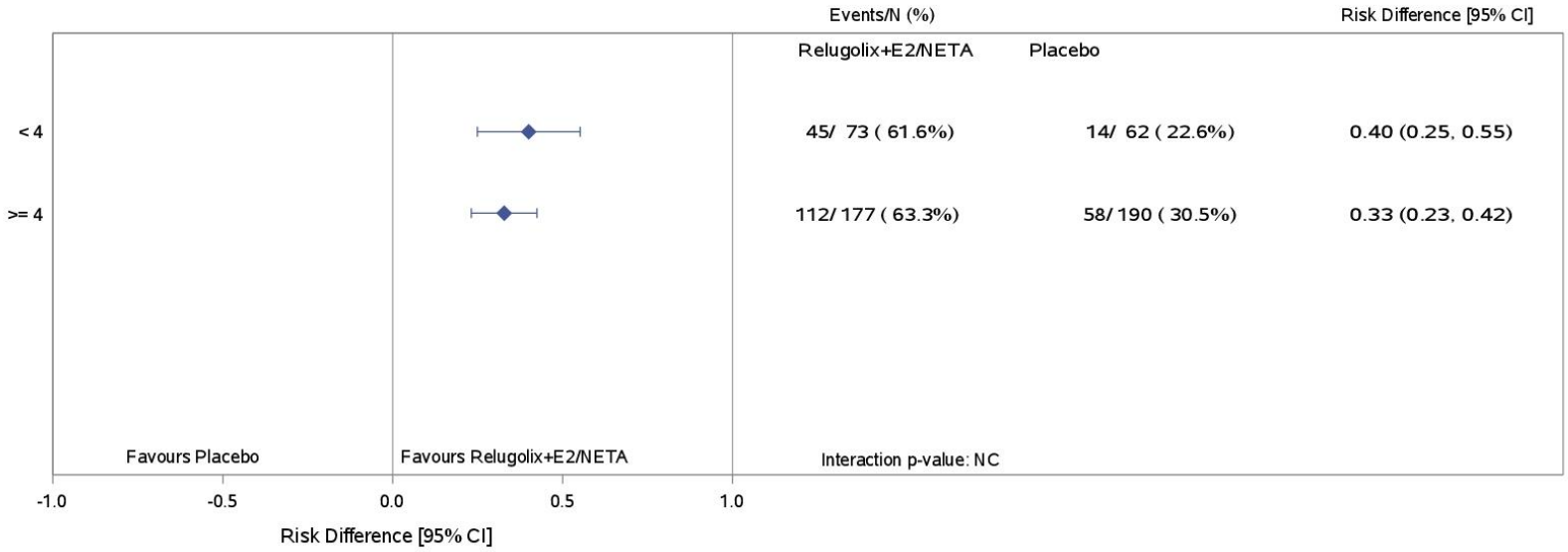
Figure QOL.UFSBPD20.MITT.S4.BIN.FP.RD: Proportion of Responders with at Least 20 Points Decrease in UFS-QoL Bleeding and Pelvic Discomfort Scale Score at Week 24, by Subgroup (mITT Population) - Risk Difference
Study: Pooled
Subgroup: Maximum NRS Pain Score at Baseline



Results are based on a Mantel-Haenszel approach stratified by study using a one-stage fixed-effects IPD meta-analysis.
The reference group is Placebo.
N: Number of patients in treatment group; NETA: Norethindrone acetate; mITT: Modified intent-to-treat; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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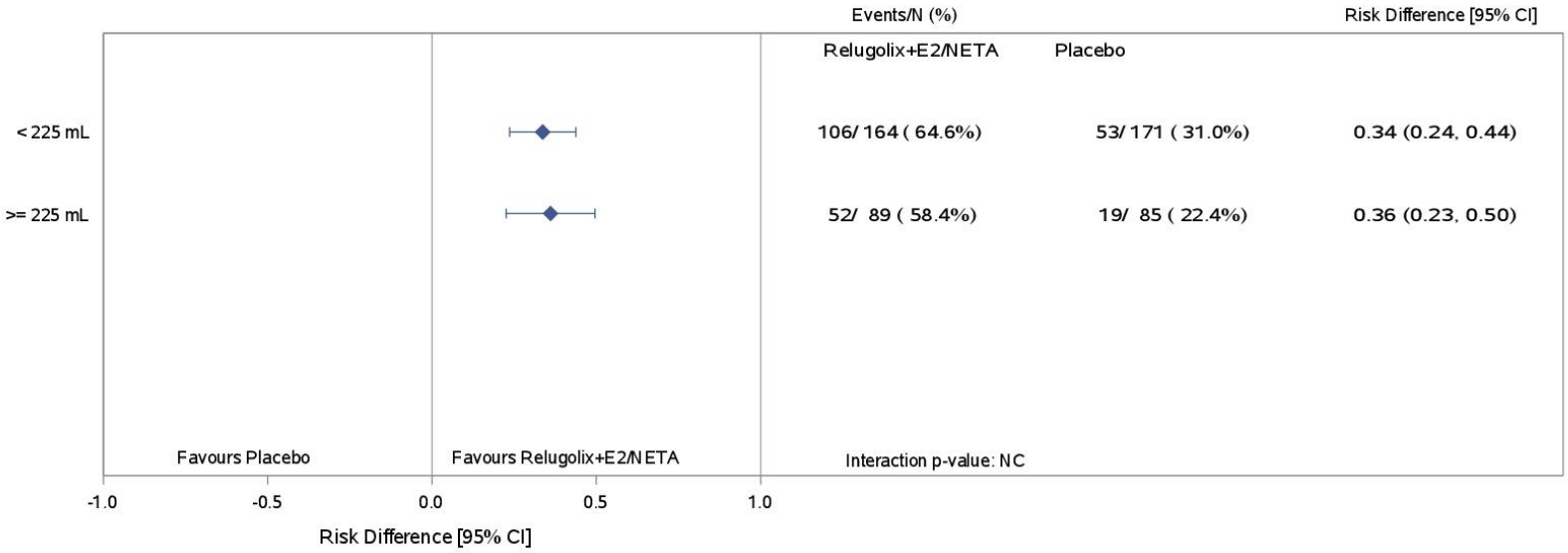
Figure QOL.UFSBPD20.MITT.S5.BIN.FP.RD: Proportion of Responders with at Least 20 Points Decrease in UFS-QoL Bleeding and Pelvic Discomfort Scale Score at Week 24, by Subgroup (mITT Population) - Risk Difference
Study: Pooled
Subgroup: MBL Volume at Baseline (mL)



Results are based on a Mantel-Haenszel approach stratified by study using a one-stage fixed-effects IPD meta-analysis.
The reference group is Placebo.
N: Number of patients in treatment group; NETA: Norethindrone acetate; mITT: Modified intent-to-treat; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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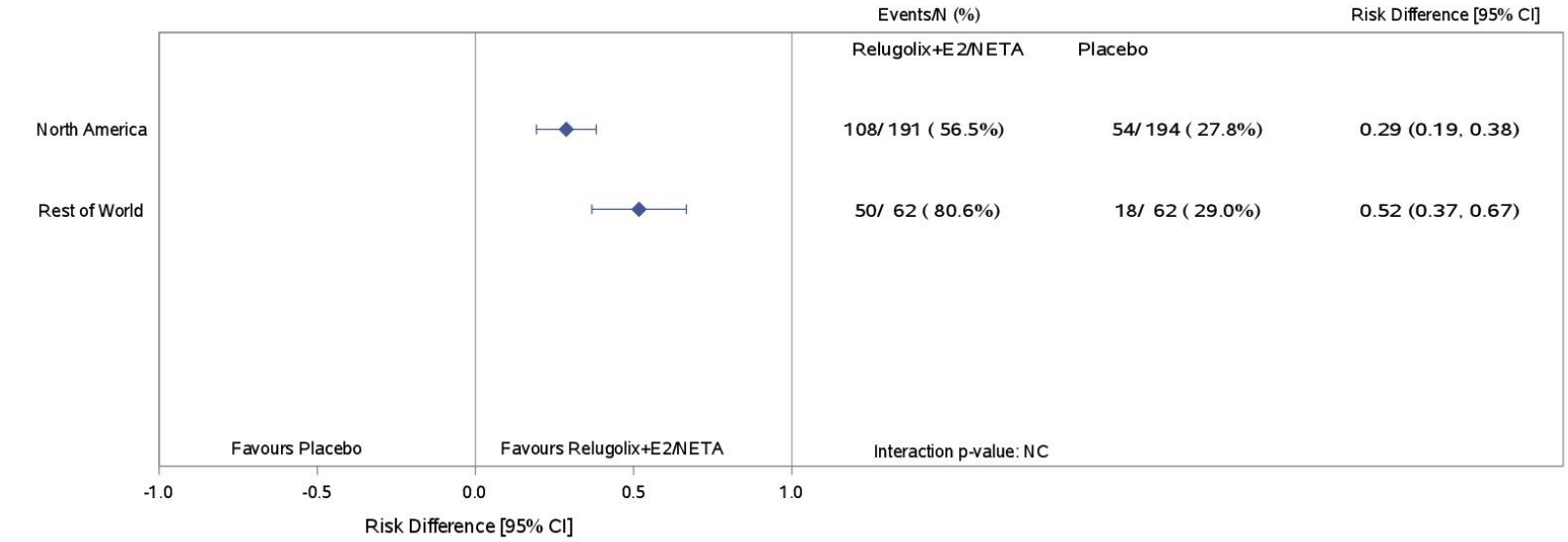
Figure QOL.UFSBPD20.MITT.S6.BIN.FP.RD: Proportion of Responders with at Least 20 Points Decrease in UFS-QoL Bleeding and Pelvic Discomfort Scale Score at Week 24, by Subgroup (mITT Population) - Risk Difference
Study: Pooled
Subgroup: Geographic Region I



Results are based on a Mantel-Haenszel approach stratified by study using a one-stage fixed-effects IPD meta-analysis.
The reference group is Placebo.
N: Number of patients in treatment group; NETA: Norethindrone acetate; mITT: Modified intent-to-treat; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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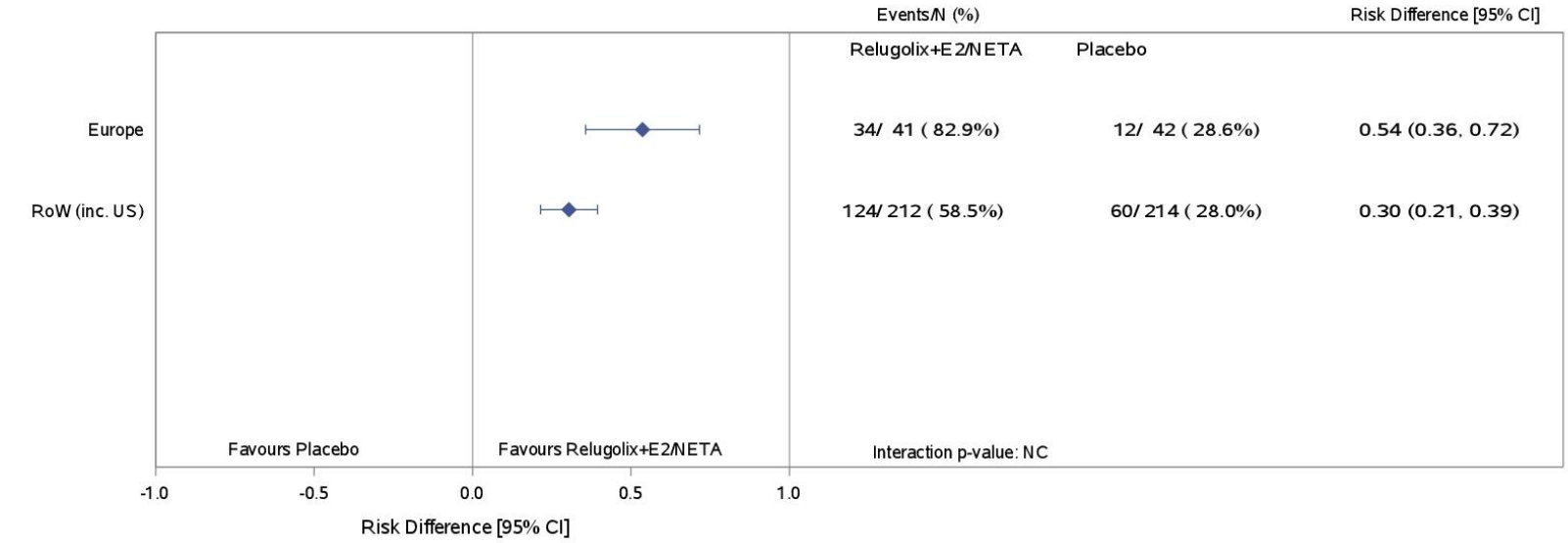
Figure QOL.UFSBPD20.MITT.S7.BIN.FP.RD: Proportion of Responders with at Least 20 Points Decrease in UFS-QoL Bleeding and Pelvic Discomfort Scale Score at Week 24, by Subgroup (mITT Population) - Risk Difference
Study: Pooled
Subgroup: Geographic Region II



Results are based on a Mantel-Haenszel approach stratified by study using a one-stage fixed-effects IPD meta-analysis.
The reference group is Placebo.
N: Number of patients in treatment group; NETA: Norethindrone acetate; mITT: Modified intent-to-treat; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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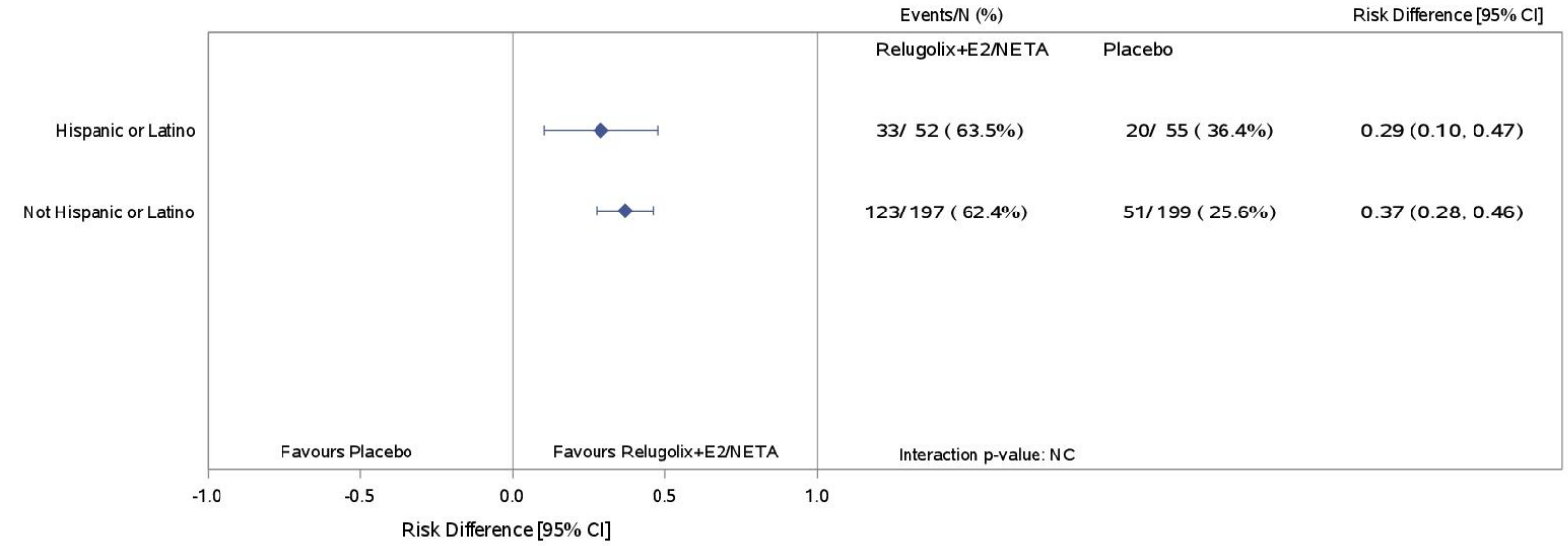
Figure QOL.UFSBPD20.MITT.S8.BIN.FP.RD: Proportion of Responders with at Least 20 Points Decrease in UFS-QoL Bleeding and Pelvic Discomfort Scale Score at Week 24, by Subgroup (mITT Population) - Risk Difference
Study: Pooled
Subgroup: Ethnicity



Results are based on a Mantel-Haenszel approach stratified by study using a one-stage fixed-effects IPD meta-analysis.
The reference group is Placebo.
N: Number of patients in treatment group; NETA: Norethindrone acetate; mITT: Modified intent-to-treat; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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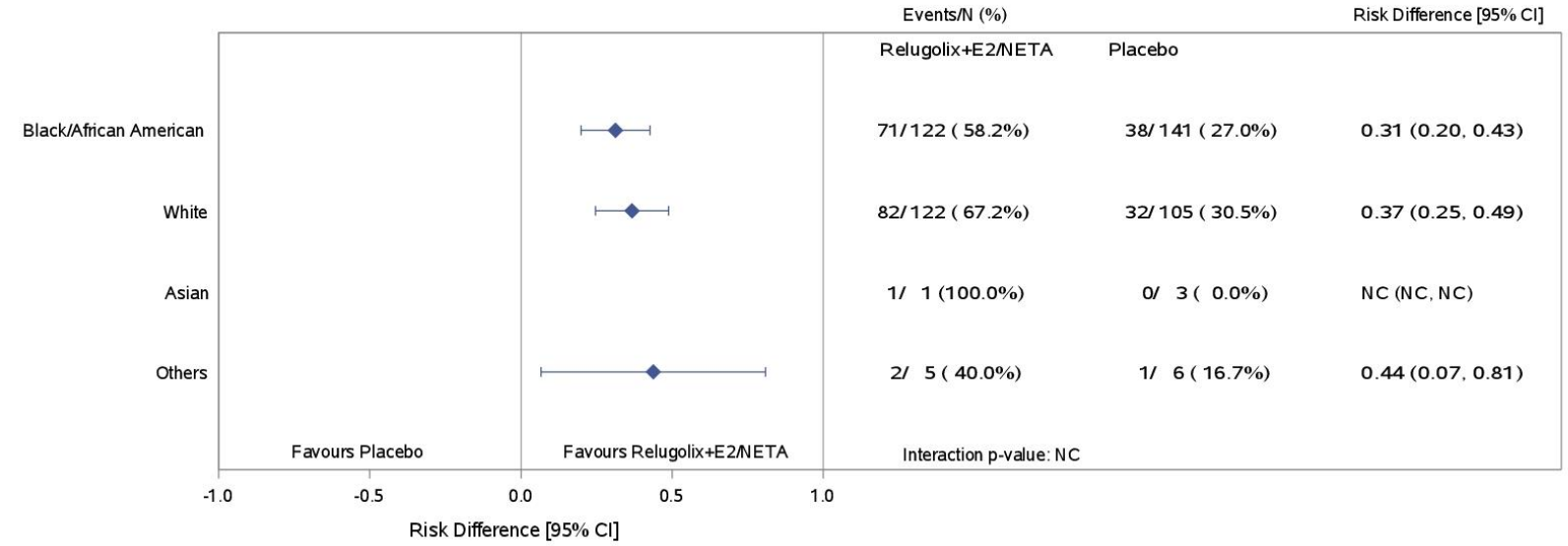
Figure QOL.UFSBPD20.MITT.S9.BIN.FP.RD: Proportion of Responders with at Least 20 Points Decrease in UFS-QoL Bleeding and Pelvic Discomfort Scale Score at Week 24, by Subgroup (mITT Population) - Risk Difference
Study: Pooled
Subgroup: Race



Results are based on a Mantel-Haenszel approach stratified by study using a one-stage fixed-effects IPD meta-analysis.
The reference group is Placebo.
N: Number of patients in treatment group; NETA: Norethindrone acetate; mITT: Modified intent-to-treat; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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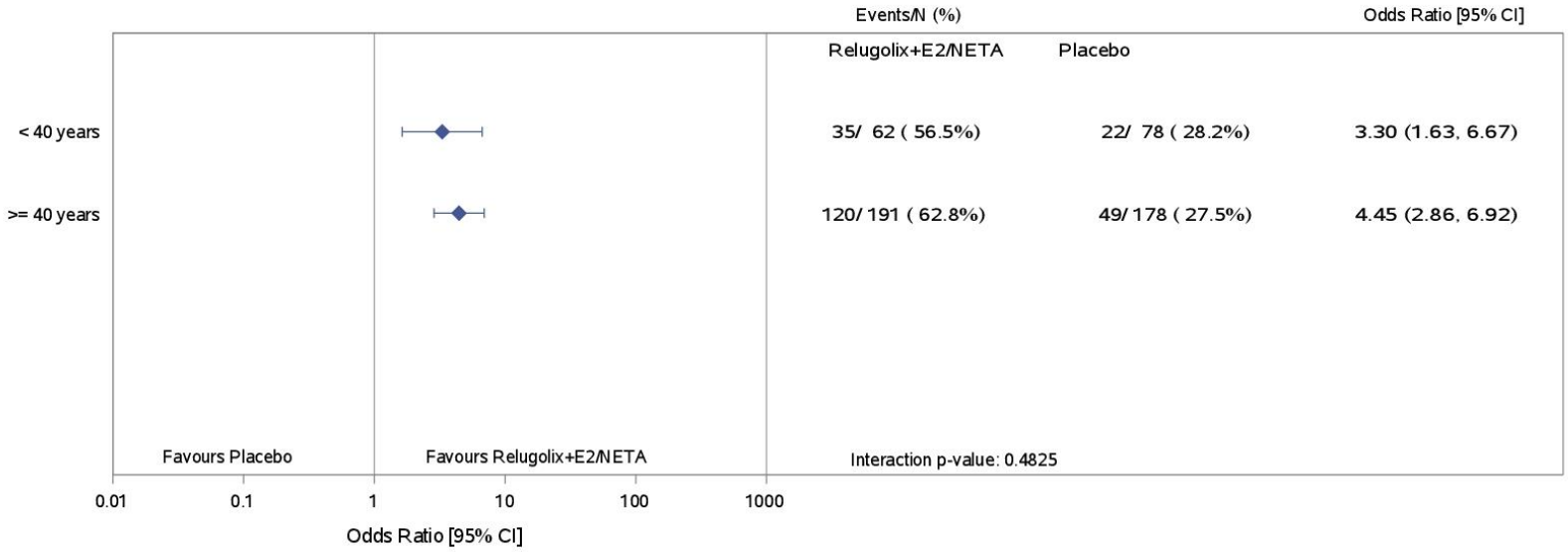
2.2.5 Proportion of Responders with at Least 25 Points Decrease in UFS-QoL Bleeding and Pelvic Discomfort Scale Score at Week 24, by Subgroup (mITT Population)

Nachfolgend sind zunächst alle Forest Plots für das *Odds Ratio* dargestellt; gefolgt von den entsprechenden Forest Plots für *Risk Ratio* und *Risk Difference*.

Figure QOL.UFSBPD25.MITT.S1.BIN.FP: Proportion of Responders with at Least 25 Points Decrease in UFS-QoL Bleeding and Pelvic Discomfort Scale Score at Week 24, by Subgroup
(mITT Population)
Study: Pooled
Subgroup: Age (years)



Results are based on a logistic regression model adjusted for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates using a one-stage fixed-effects IPD meta-analysis approach. A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
The interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the Odds Ratio and 95% CI. Missing subgroup levels are not included in estimation of the interaction p-value. The reference group is Placebo.
N: Number of patients in treatment group; NETA: Norethindrone acetate; mITT: Modified intent-to-treat; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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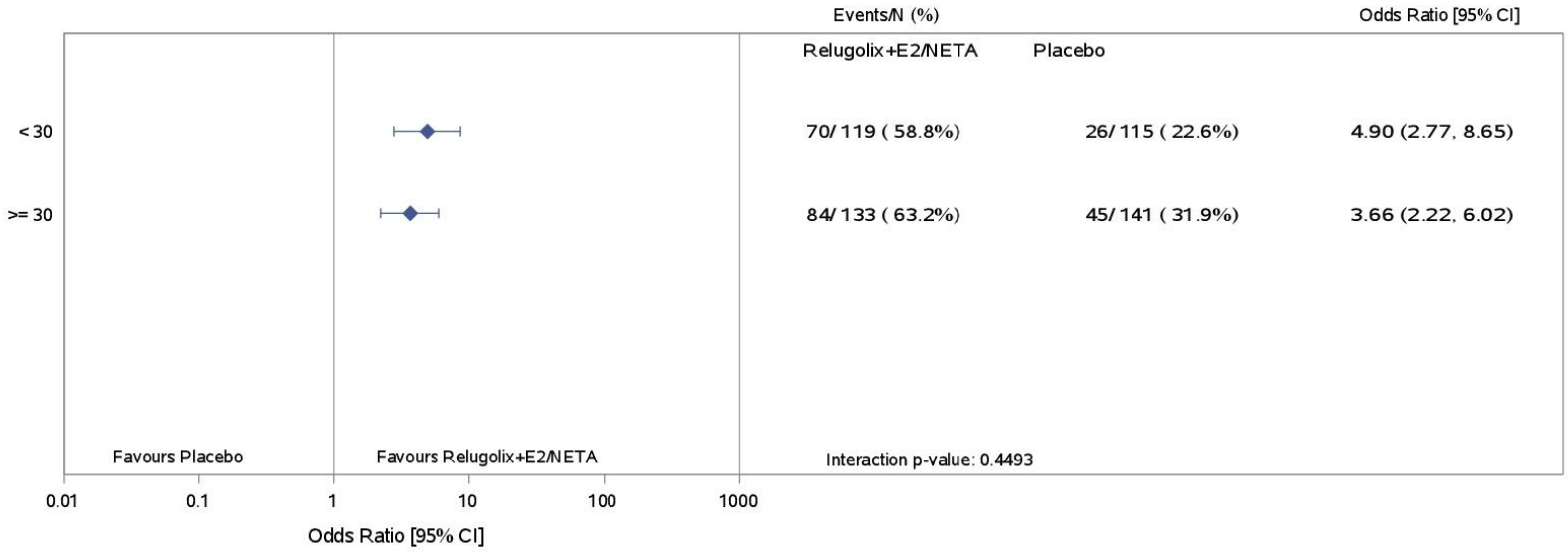
Figure QOL.UFSBPD25.MITT.S2.BIN.FP: Proportion of Responders with at Least 25 Points Decrease in UFS-QoL Bleeding and Pelvic Discomfort Scale Score at Week 24, by Subgroup (mITT Population)
Study: Pooled
Subgroup: BMI (kg/m2) at Baseline



Results are based on a logistic regression model adjusted for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates using a one-stage fixed-effects IPD meta-analysis approach. A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
The interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the Odds Ratio and 95% CI. Missing subgroup levels are not included in estimation of the interaction p-value. The reference group is Placebo.
N: Number of patients in treatment group; NETA: Norethindrone acetate; mITT: Modified intent-to-treat; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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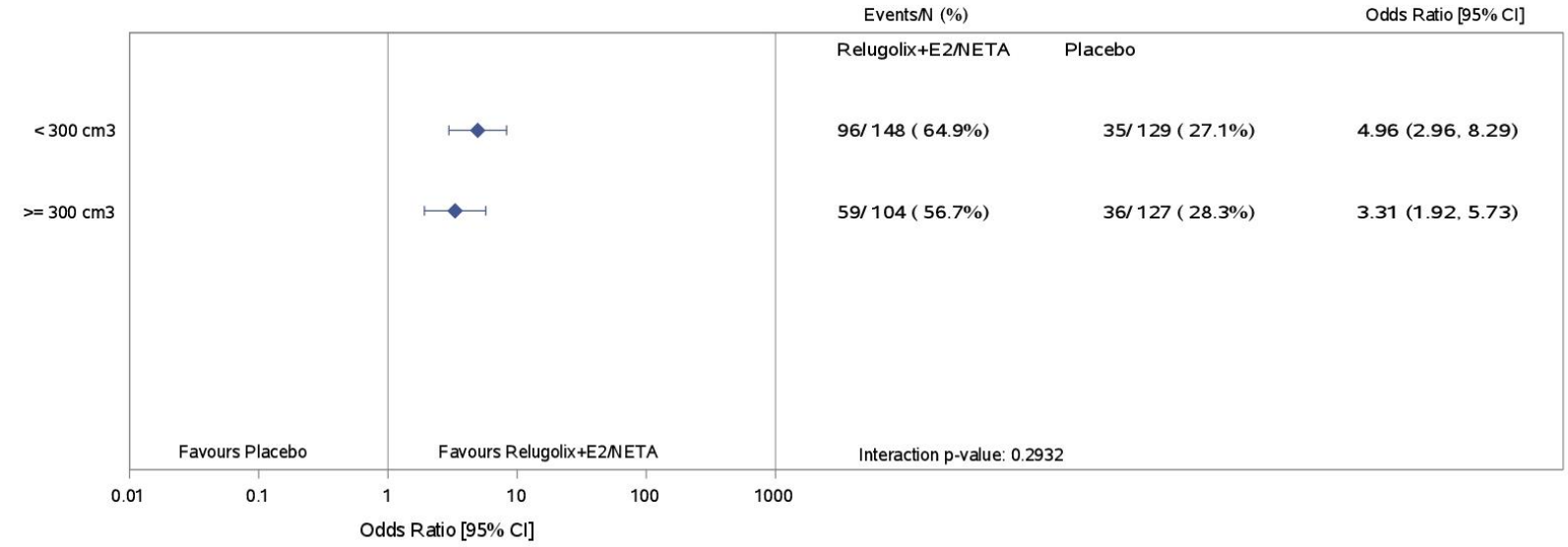
Figure QOL.UFSBPD25.MITT.S3.BIN.FP: Proportion of Responders with at Least 25 Points Decrease in UFS-QoL Bleeding and Pelvic Discomfort Scale Score at Week 24, by Subgroup (mITT Population)
Study: Pooled
Subgroup: Uterine Volume at Baseline (cm3)



Results are based on a logistic regression model adjusted for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates using a one-stage fixed-effects IPD meta-analysis approach. A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
The interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the Odds Ratio and 95% CI. Missing subgroup levels are not included in estimation of the interaction p-value. The reference group is Placebo.
N: Number of patients in treatment group; NETA: Norethindrone acetate; mITT: Modified intent-to-treat; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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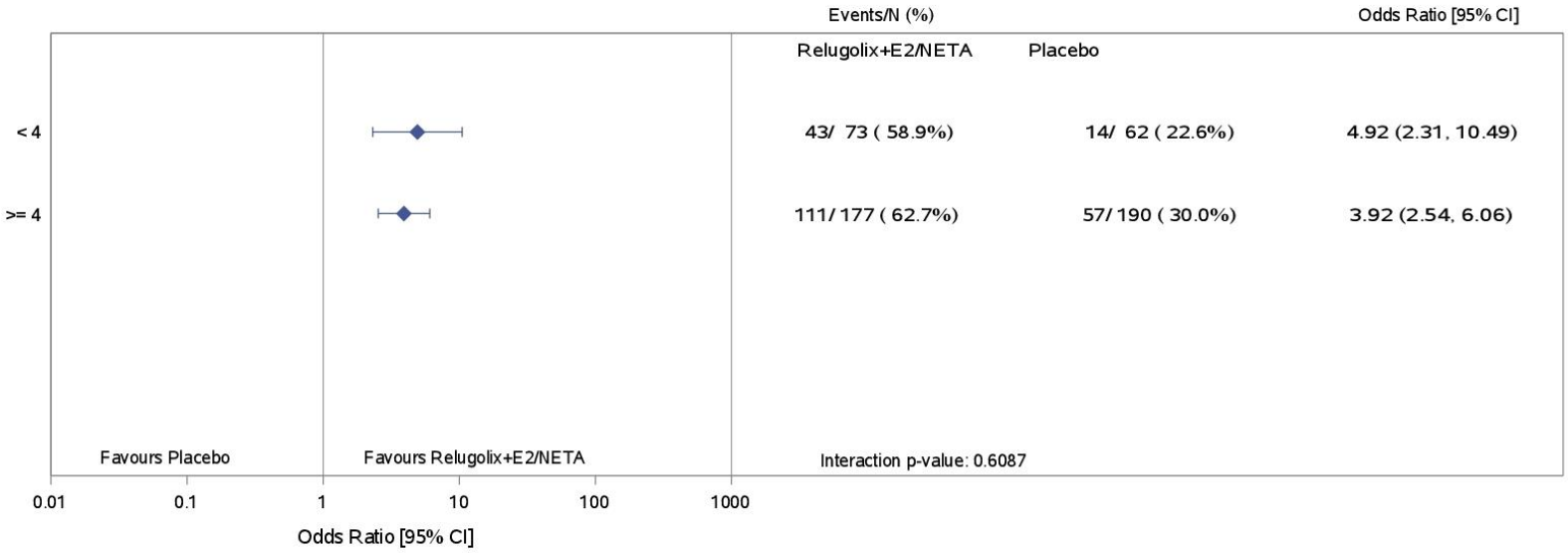
Figure QOL.UFSBPD25.MITT.S4.BIN.FP: Proportion of Responders with at Least 25 Points Decrease in UFS-QoL Bleeding and Pelvic Discomfort Scale Score at Week 24, by Subgroup (mITT Population)
Study: Pooled
Subgroup: Maximum NRS Pain Score at Baseline



Results are based on a logistic regression model adjusted for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates using a one-stage fixed-effects IPD meta-analysis approach. A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
The interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the Odds Ratio and 95% CI. Missing subgroup levels are not included in estimation of the interaction p-value. The reference group is Placebo.
N: Number of patients in treatment group; NETA: Norethindrone acetate; mITT: Modified intent-to-treat; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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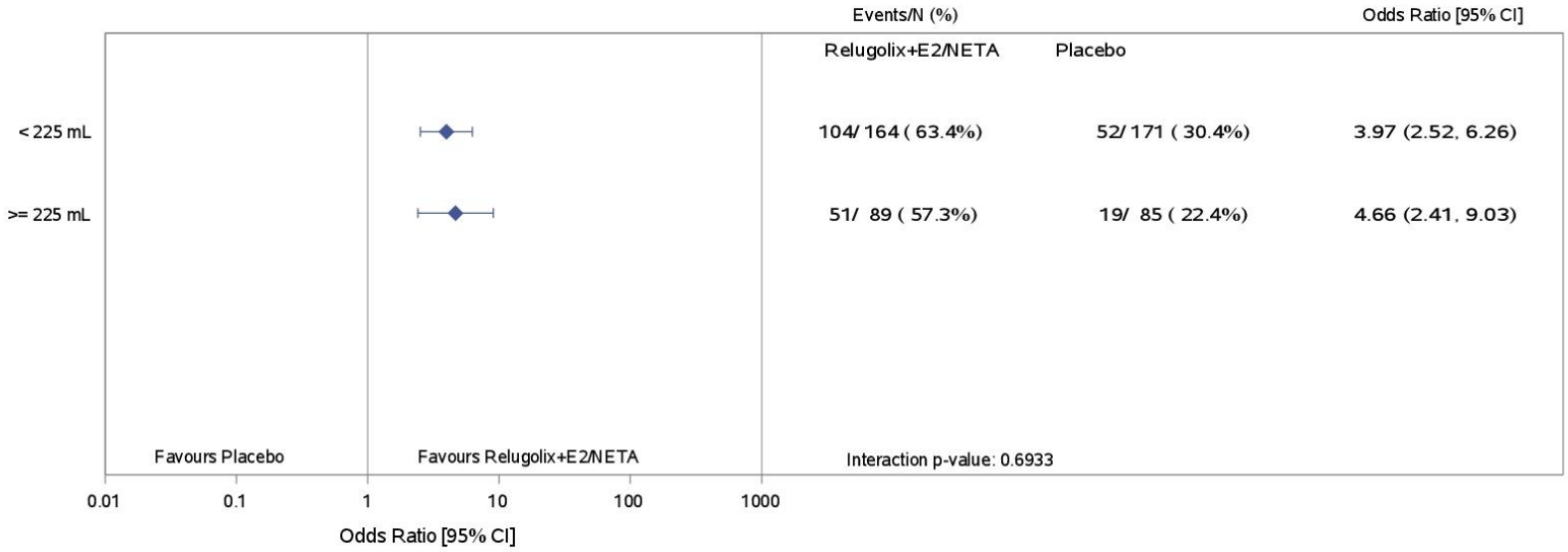
Figure QOL.UFSBPD25.MITT.S5.BIN.FP: Proportion of Responders with at Least 25 Points Decrease in UFS-QoL Bleeding and Pelvic Discomfort Scale Score at Week 24, by Subgroup (mITT Population)
Study: Pooled
Subgroup: MBL Volume at Baseline (mL)



Results are based on a logistic regression model adjusted for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates using a one-stage fixed-effects IPD meta-analysis approach. A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
The interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the Odds Ratio and 95% CI. Missing subgroup levels are not included in estimation of the interaction p-value. The reference group is Placebo.
N: Number of patients in treatment group; NETA: Norethindrone acetate; mITT: Modified intent-to-treat; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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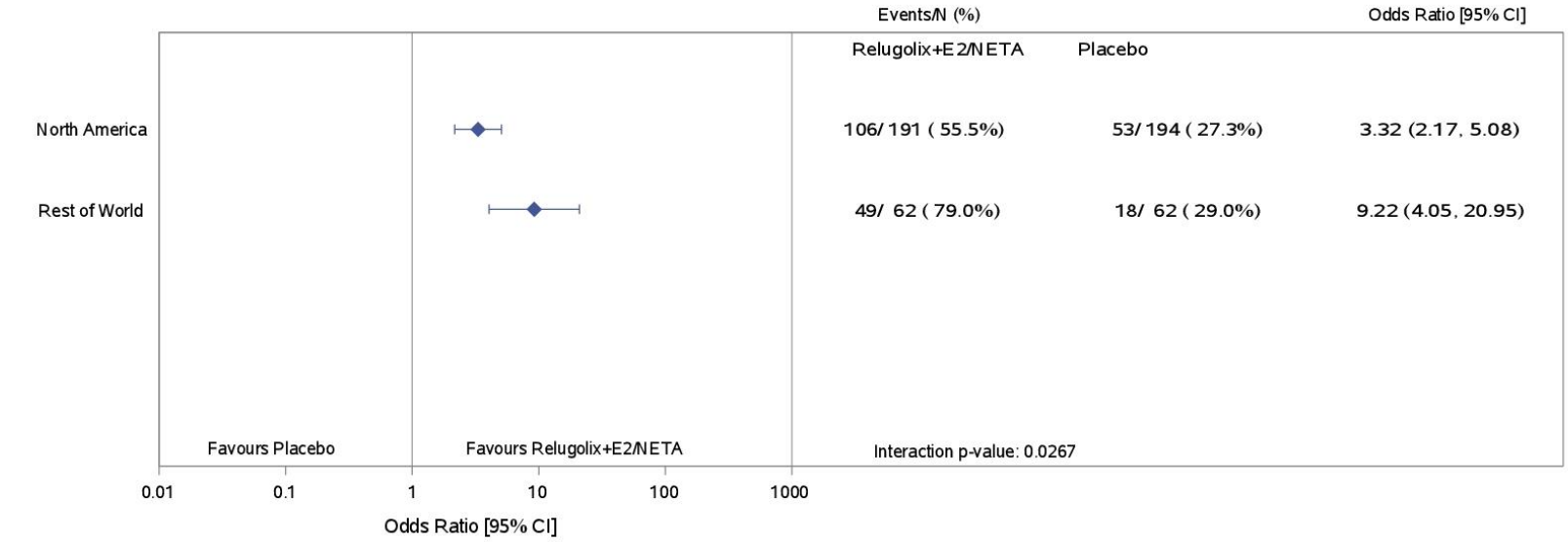
Figure QOL.UFSBPD25.MITT.S6.BIN.FP: Proportion of Responders with at Least 25 Points Decrease in UFS-QoL Bleeding and Pelvic Discomfort Scale Score at Week 24, by Subgroup (mITT Population)
Study: Pooled
Subgroup: Geographic Region I



Results are based on a logistic regression model adjusted for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates using a one-stage fixed-effects IPD meta-analysis approach. A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
The interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the Odds Ratio and 95% CI. Missing subgroup levels are not included in estimation of the interaction p-value. The reference group is Placebo.
N: Number of patients in treatment group; NETA: Norethindrone acetate; mITT: Modified intent-to-treat; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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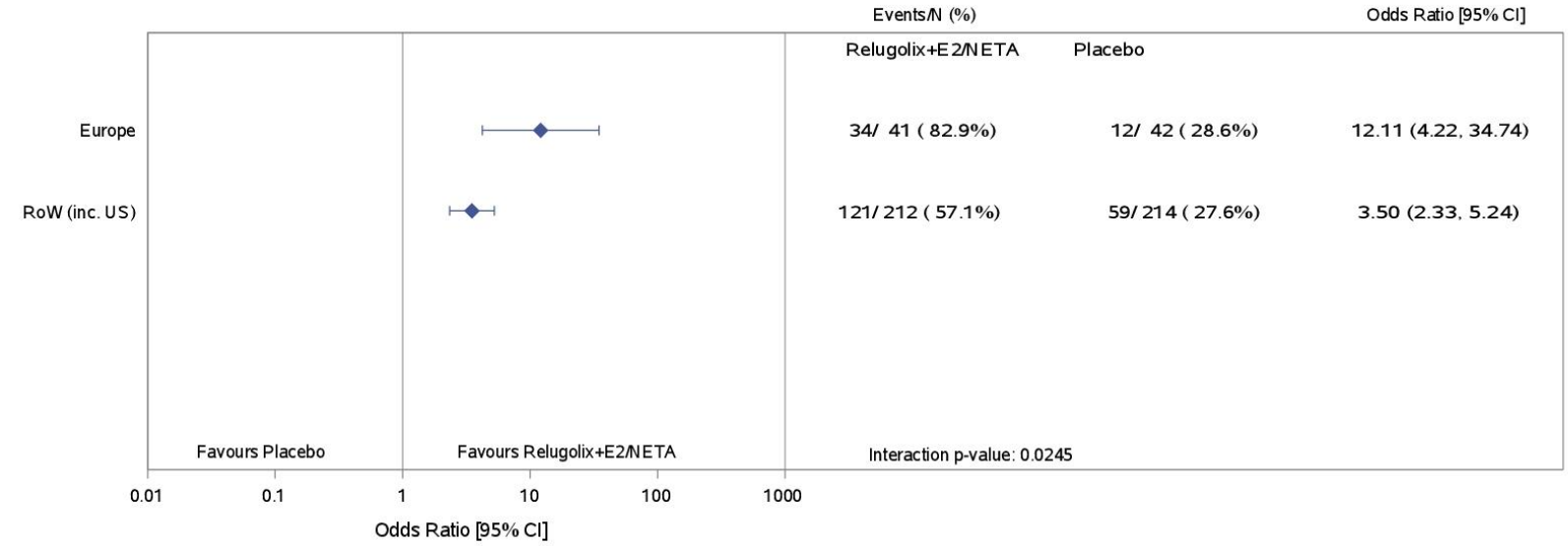
Figure QOL.UFSBPD25.MITT.S7.BIN.FP: Proportion of Responders with at Least 25 Points Decrease in UFS-QoL Bleeding and Pelvic Discomfort Scale Score at Week 24, by Subgroup (mITT Population)
Study: Pooled
Subgroup: Geographic Region II



Results are based on a logistic regression model adjusted for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates using a one-stage fixed-effects IPD meta-analysis approach. A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
The interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the Odds Ratio and 95% CI. Missing subgroup levels are not included in estimation of the interaction p-value. The reference group is Placebo.
N: Number of patients in treatment group; NETA: Norethindrone acetate; mITT: Modified intent-to-treat; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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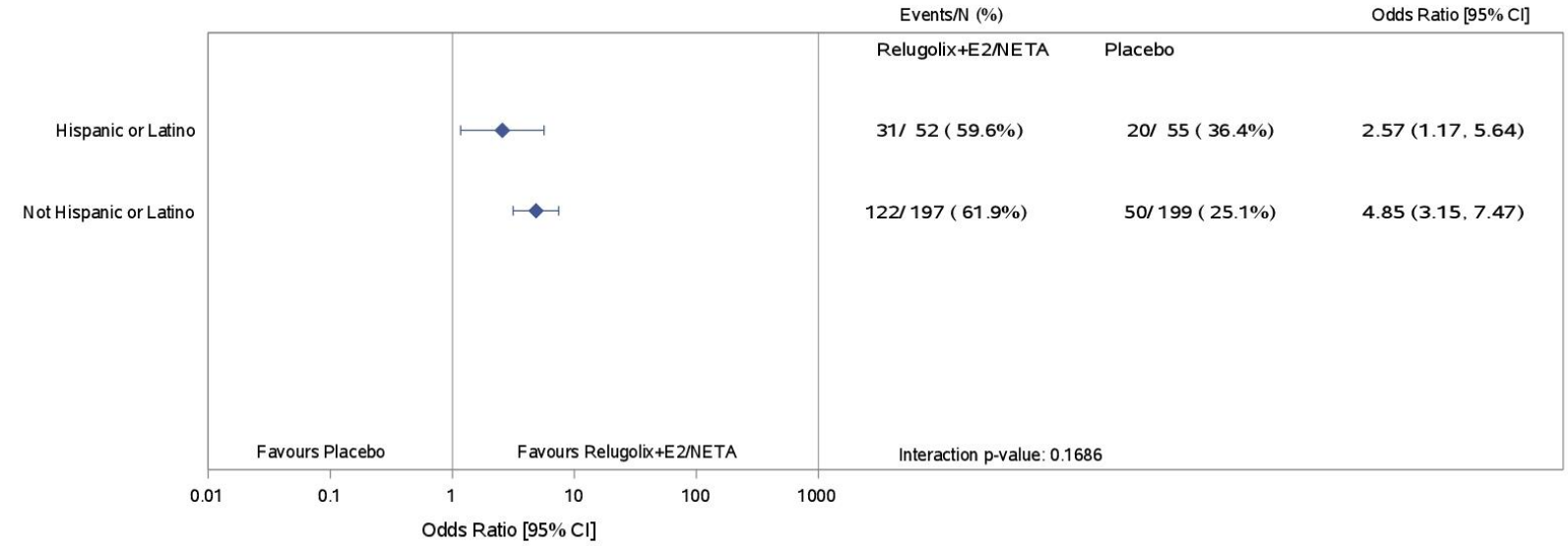
Figure QOL.UFSBPD25.MITT.S8.BIN.FP: Proportion of Responders with at Least 25 Points Decrease in UFS-QoL Bleeding and Pelvic Discomfort Scale Score at Week 24, by Subgroup (mITT Population)
Study: Pooled
Subgroup: Ethnicity



Results are based on a logistic regression model adjusted for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates using a one-stage fixed-effects IPD meta-analysis approach. A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
The interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the Odds Ratio and 95% CI. Missing subgroup levels are not included in estimation of the interaction p-value. The reference group is Placebo.
N: Number of patients in treatment group; NETA: Norethindrone acetate; mITT: Modified intent-to-treat; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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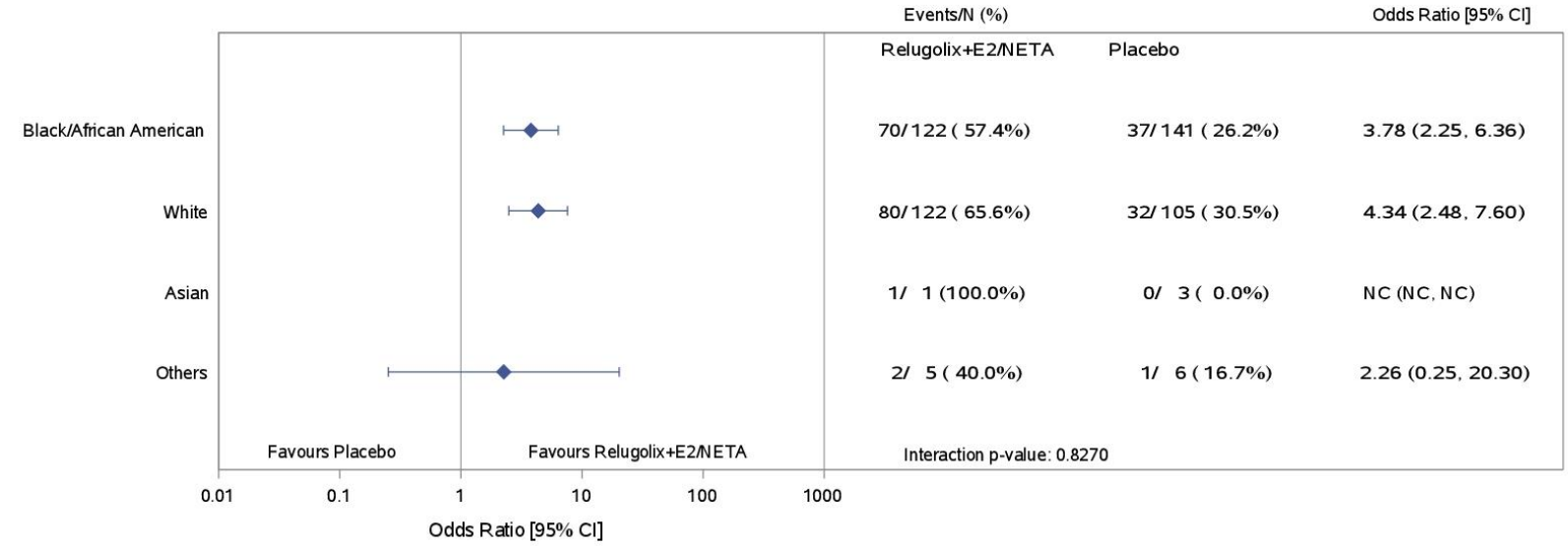
Figure QOL.UFSBPD25.MITT.S9.BIN.FP: Proportion of Responders with at Least 25 Points Decrease in UFS-QoL Bleeding and Pelvic Discomfort Scale Score at Week 24, by Subgroup (mITT Population)
Study: Pooled
Subgroup: Race



Results are based on a logistic regression model adjusted for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates using a one-stage fixed-effects IPD meta-analysis approach. A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
The interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the Odds Ratio and 95% CI. Missing subgroup levels are not included in estimation of the interaction p-value. The reference group is Placebo.
N: Number of patients in treatment group; NETA: Norethindrone acetate; mITT: Modified intent-to-treat; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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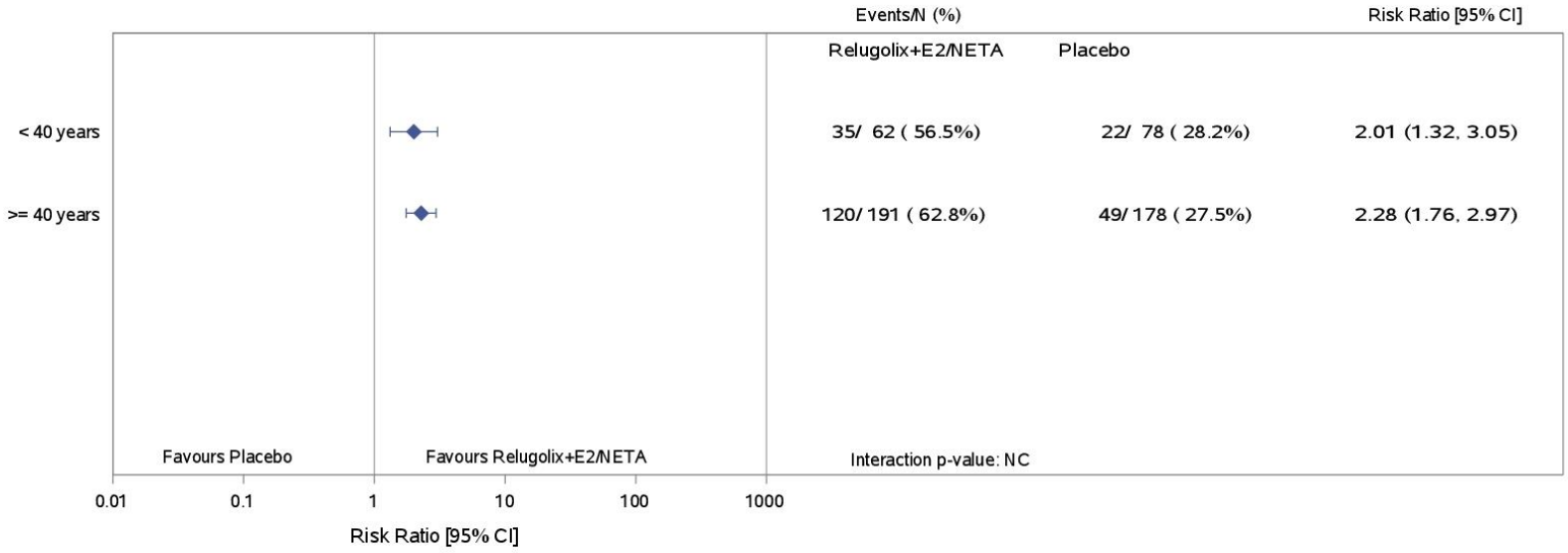
Figure QOL.UFSBPD25.MITT.S1.BIN.FP.RR: Proportion of Responders with at Least 25 Points Decrease in UFS-QoL Bleeding and Pelvic Discomfort Scale Score at Week 24, by Subgroup (mITT Population) - Risk Ratio
Study: Pooled
Subgroup: Age (years)



Results are based on a Cochran-Mantel-Haenszel approach stratified by study using a one-stage fixed-effects IPD meta-analysis. A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
The reference group is Placebo.
N: Number of patients in treatment group; NETA: Norethindrone acetate; mITT: Modified intent-to-treat; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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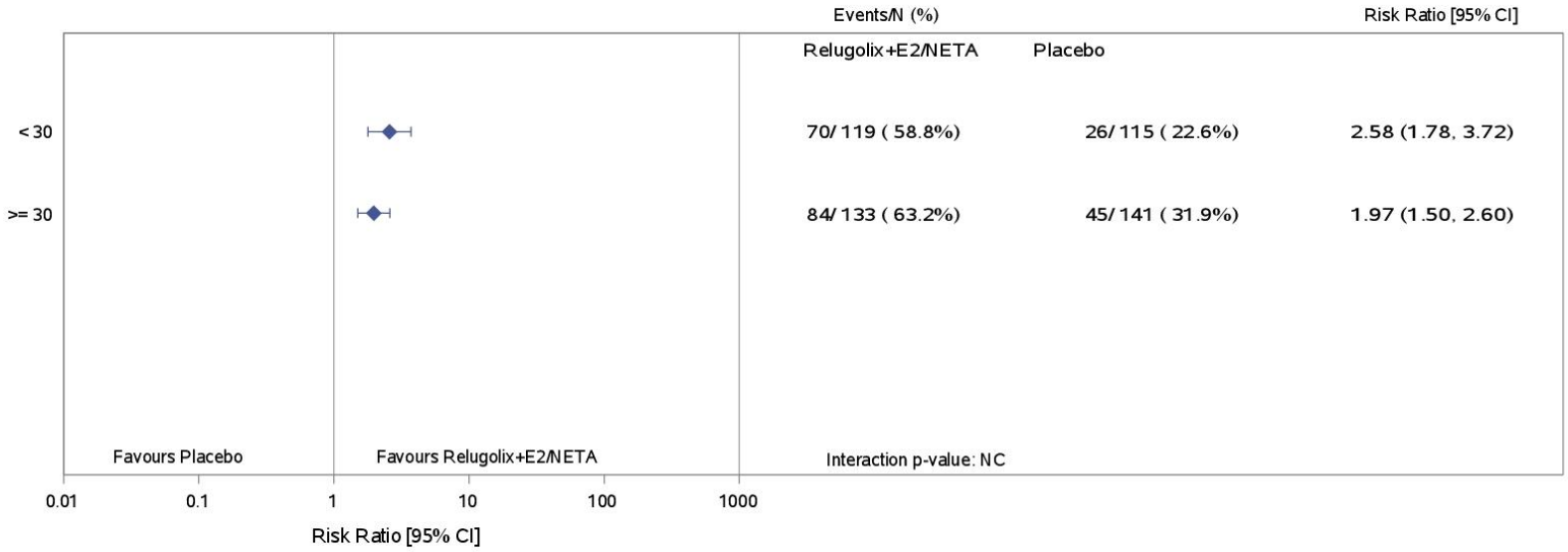
Figure QOL.UFSBPD25.MITT.S2.BIN.FP.RR: Proportion of Responders with at Least 25 Points Decrease in UFS-QoL Bleeding and Pelvic Discomfort Scale Score at Week 24, by Subgroup (mITT Population) - Risk Ratio
Study: Pooled
Subgroup: BMI (kg/m2) at Baseline



Results are based on a Cochran-Mantel-Haenszel approach stratified by study using a one-stage fixed-effects IPD meta-analysis. A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
The reference group is Placebo.
N: Number of patients in treatment group; NETA: Norethindrone acetate; mITT: Modified intent-to-treat; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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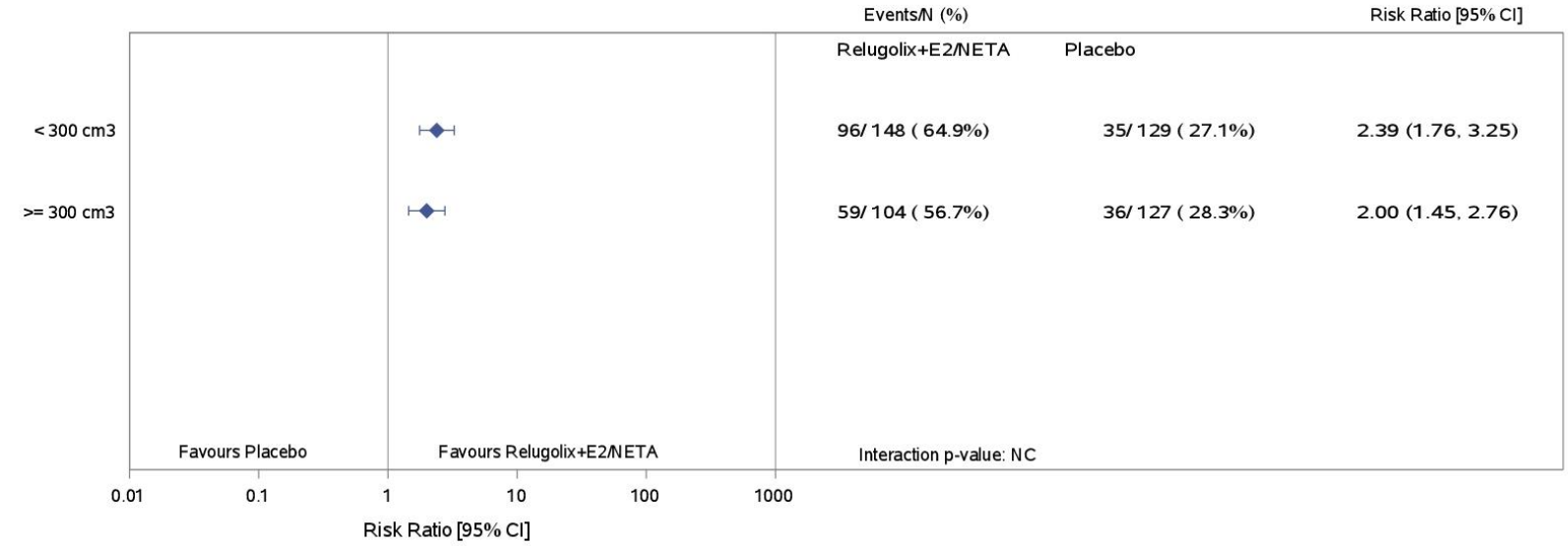
Figure QOL.UFSBPD25.MITT.S3.BIN.FP.RR: Proportion of Responders with at Least 25 Points Decrease in UFS-QoL Bleeding and Pelvic Discomfort Scale Score at Week 24, by Subgroup (mITT Population) - Risk Ratio
Study: Pooled
Subgroup: Uterine Volume at Baseline (cm3)



Results are based on a Cochran-Mantel-Haenszel approach stratified by study using a one-stage fixed-effects IPD meta-analysis. A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
The reference group is Placebo.
N: Number of patients in treatment group; NETA: Norethindrone acetate; mITT: Modified intent-to-treat; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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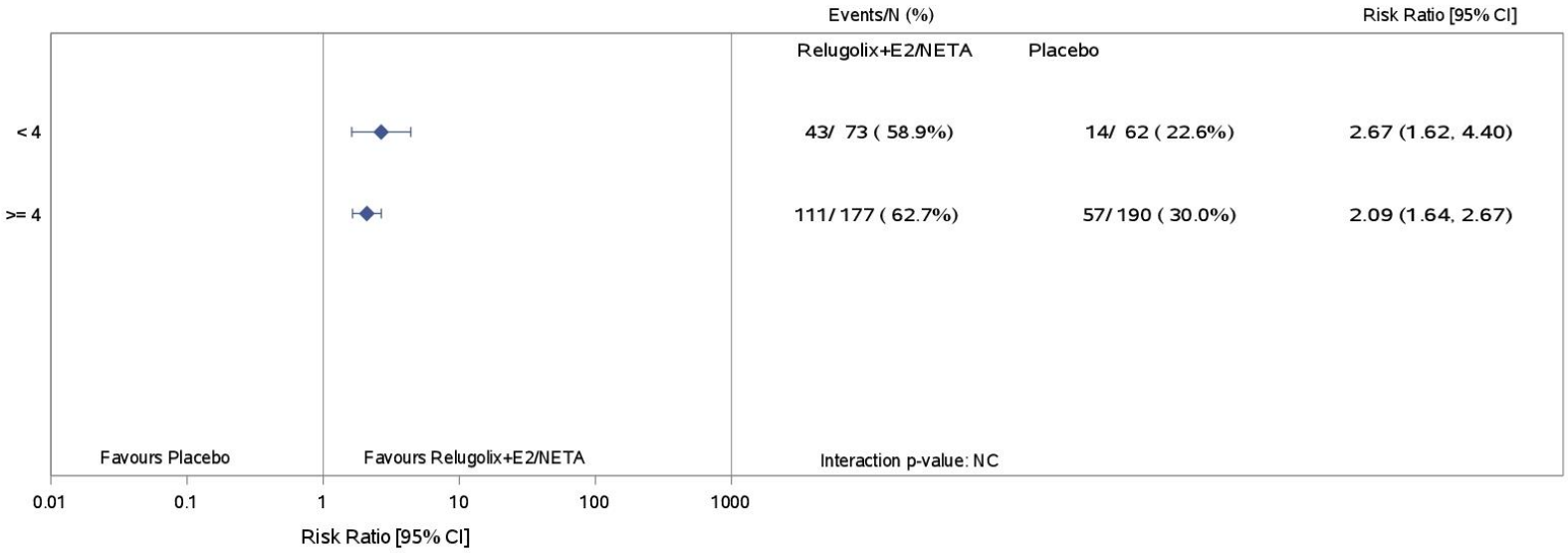
Figure QOL.UFSBPD25.MITT.S4.BIN.FP.RR: Proportion of Responders with at Least 25 Points Decrease in UFS-QoL Bleeding and Pelvic Discomfort Scale Score at Week 24, by Subgroup (mITT Population) - Risk Ratio
Study: Pooled
Subgroup: Maximum NRS Pain Score at Baseline



Results are based on a Cochran-Mantel-Haenszel approach stratified by study using a one-stage fixed-effects IPD meta-analysis. A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
The reference group is Placebo.
N: Number of patients in treatment group; NETA: Norethindrone acetate; mITT: Modified intent-to-treat; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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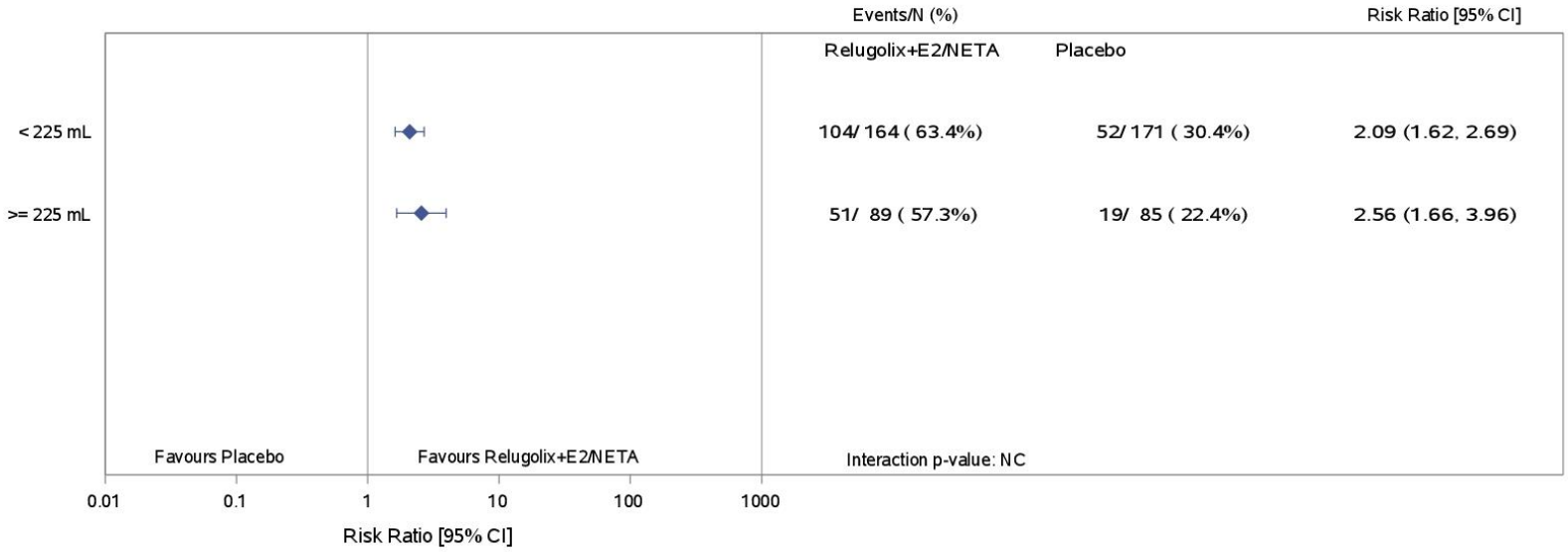
Figure QOL.UFSBPD25.MITT.S5.BIN.FP.RR: Proportion of Responders with at Least 25 Points Decrease in UFS-QoL Bleeding and Pelvic Discomfort Scale Score at Week 24, by Subgroup (mITT Population) - Risk Ratio
Study: Pooled
Subgroup: MBL Volume at Baseline (mL)



Results are based on a Cochran-Mantel-Haenszel approach stratified by study using a one-stage fixed-effects IPD meta-analysis. A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
The reference group is Placebo.
N: Number of patients in treatment group; NETA: Norethindrone acetate; mITT: Modified intent-to-treat; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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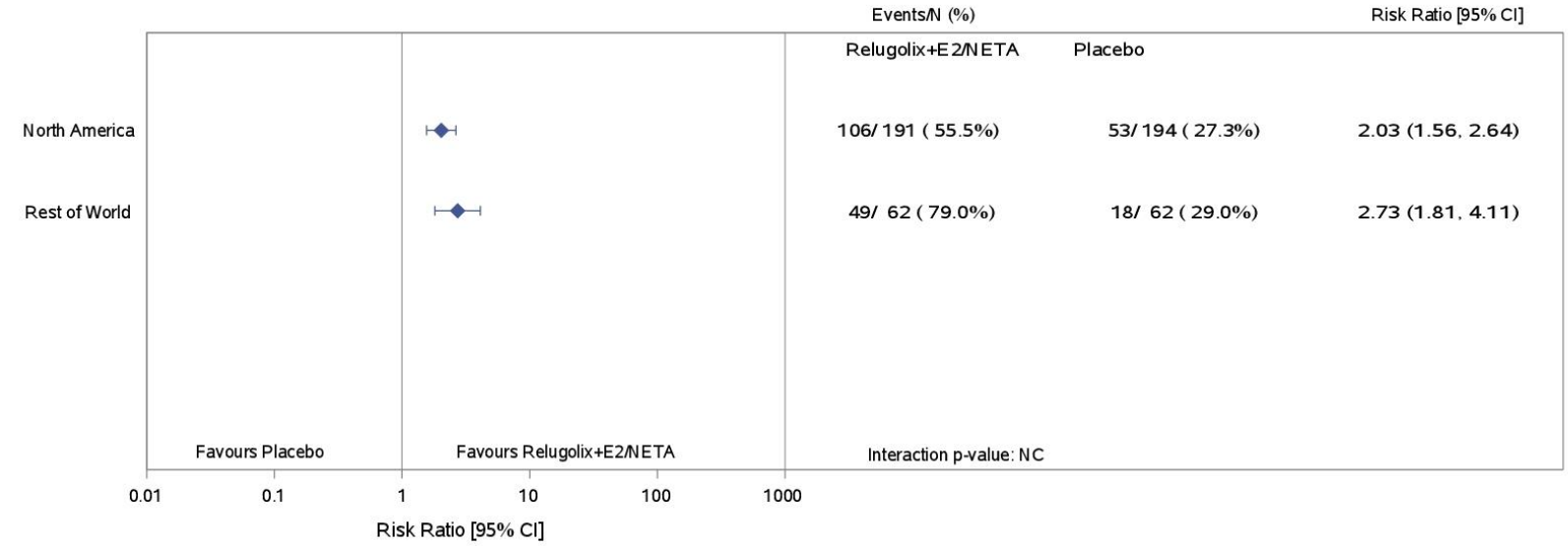
Figure QOL.UFSBPD25.MITT.S6.BIN.FP.RR: Proportion of Responders with at Least 25 Points Decrease in UFS-QoL Bleeding and Pelvic Discomfort Scale Score at Week 24, by Subgroup (mITT Population) - Risk Ratio
Study: Pooled
Subgroup: Geographic Region I



Results are based on a Cochran-Mantel-Haenszel approach stratified by study using a one-stage fixed-effects IPD meta-analysis. A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
The reference group is Placebo.
N: Number of patients in treatment group; NETA: Norethindrone acetate; mITT: Modified intent-to-treat; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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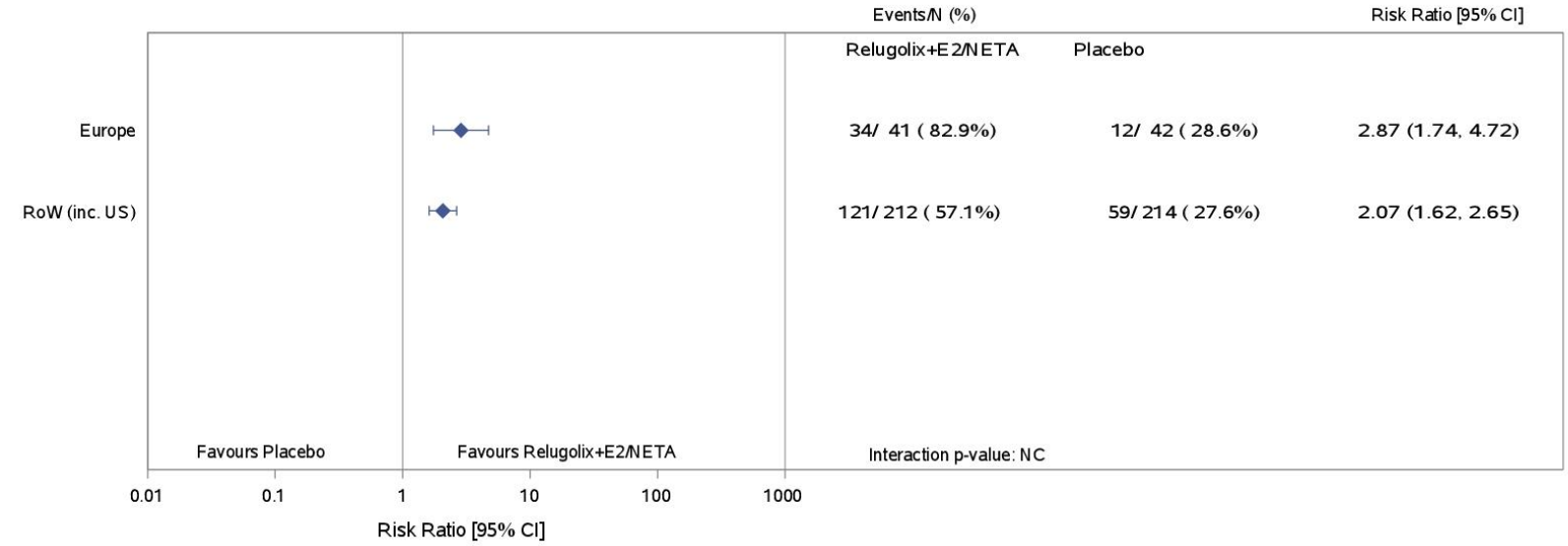
Figure QOL.UFSBPD25.MITT.S7.BIN.FP.RR: Proportion of Responders with at Least 25 Points Decrease in UFS-QoL Bleeding and Pelvic Discomfort Scale Score at Week 24, by Subgroup (mITT Population) - Risk Ratio
Study: Pooled
Subgroup: Geographic Region II



Results are based on a Cochran-Mantel-Haenszel approach stratified by study using a one-stage fixed-effects IPD meta-analysis. A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
The reference group is Placebo.
N: Number of patients in treatment group; NETA: Norethindrone acetate; mITT: Modified intent-to-treat; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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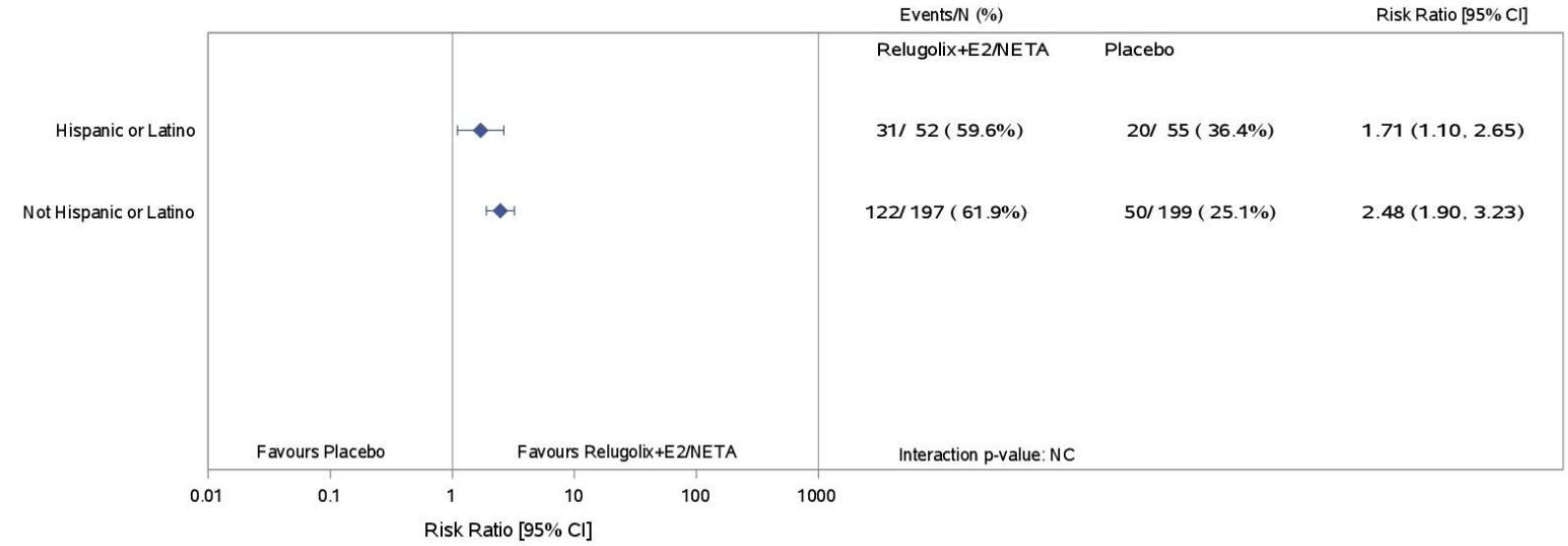
Figure QOL.UFSBPD25.MITT.S8.BIN.FP.RR: Proportion of Responders with at Least 25 Points Decrease in UFS-QoL Bleeding and Pelvic Discomfort Scale Score at Week 24, by Subgroup (mITT Population) - Risk Ratio
Study: Pooled
Subgroup: Ethnicity



Results are based on a Cochran-Mantel-Haenszel approach stratified by study using a one-stage fixed-effects IPD meta-analysis. A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
The reference group is Placebo.
N: Number of patients in treatment group; NETA: Norethindrone acetate; mITT: Modified intent-to-treat; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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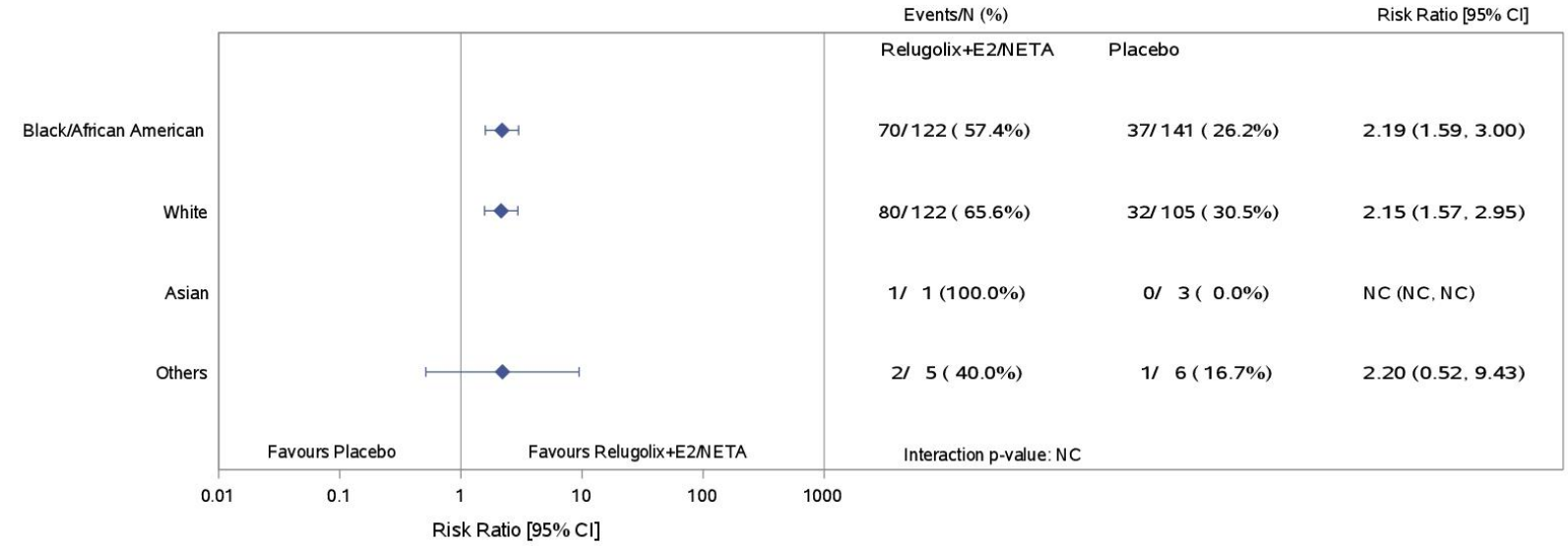
Figure QOL.UFSBPD25.MITT.S9.BIN.FP.RR: Proportion of Responders with at Least 25 Points Decrease in UFS-QoL Bleeding and Pelvic Discomfort Scale Score at Week 24, by Subgroup (mITT Population) - Risk Ratio
Study: Pooled
Subgroup: Race



Results are based on a Cochran-Mantel-Haenszel approach stratified by study using a one-stage fixed-effects IPD meta-analysis. A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
The reference group is Placebo.
N: Number of patients in treatment group; NETA: Norethindrone acetate; mITT: Modified intent-to-treat; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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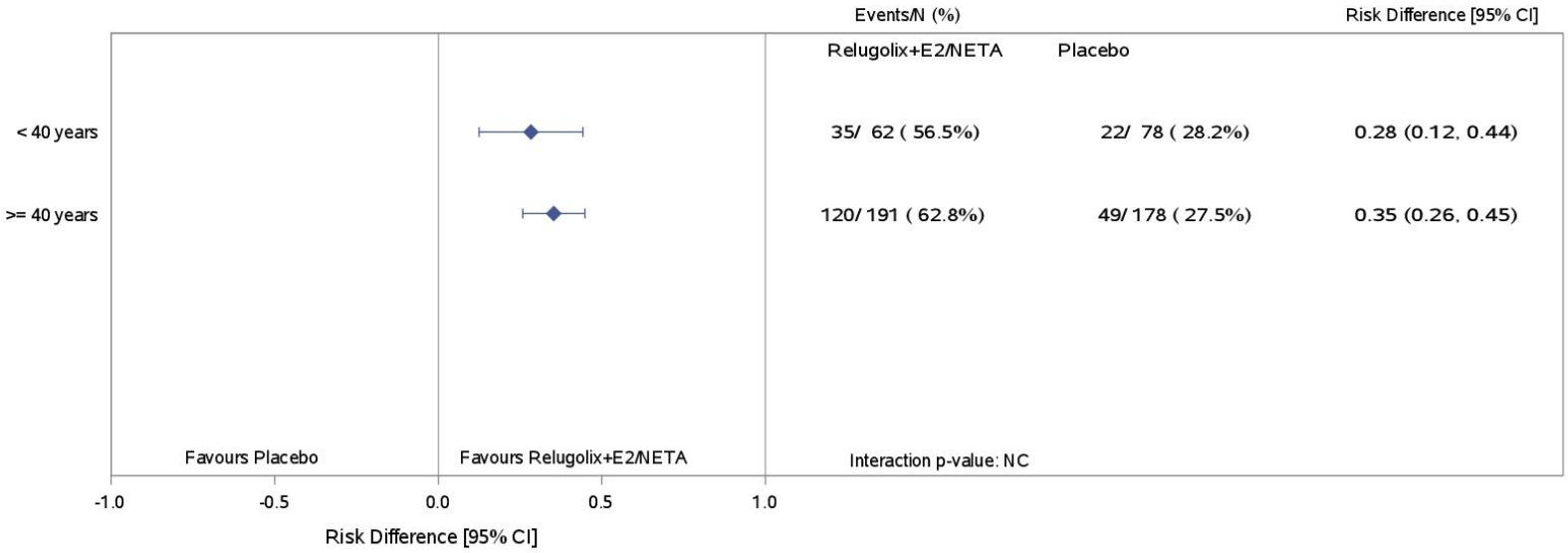
Figure QOL.UFSBPD25.MITT.S1.BIN.FP.RD: Proportion of Responders with at Least 25 Points Decrease in UFS-QoL Bleeding and Pelvic Discomfort Scale Score at Week 24, by Subgroup (mITT Population) - Risk Difference
Study: Pooled
Subgroup: Age (years)



Results are based on a Mantel-Haenszel approach stratified by study using a one-stage fixed-effects IPD meta-analysis.
The reference group is Placebo.
N: Number of patients in treatment group; NETA: Norethindrone acetate; mITT: Modified intent-to-treat; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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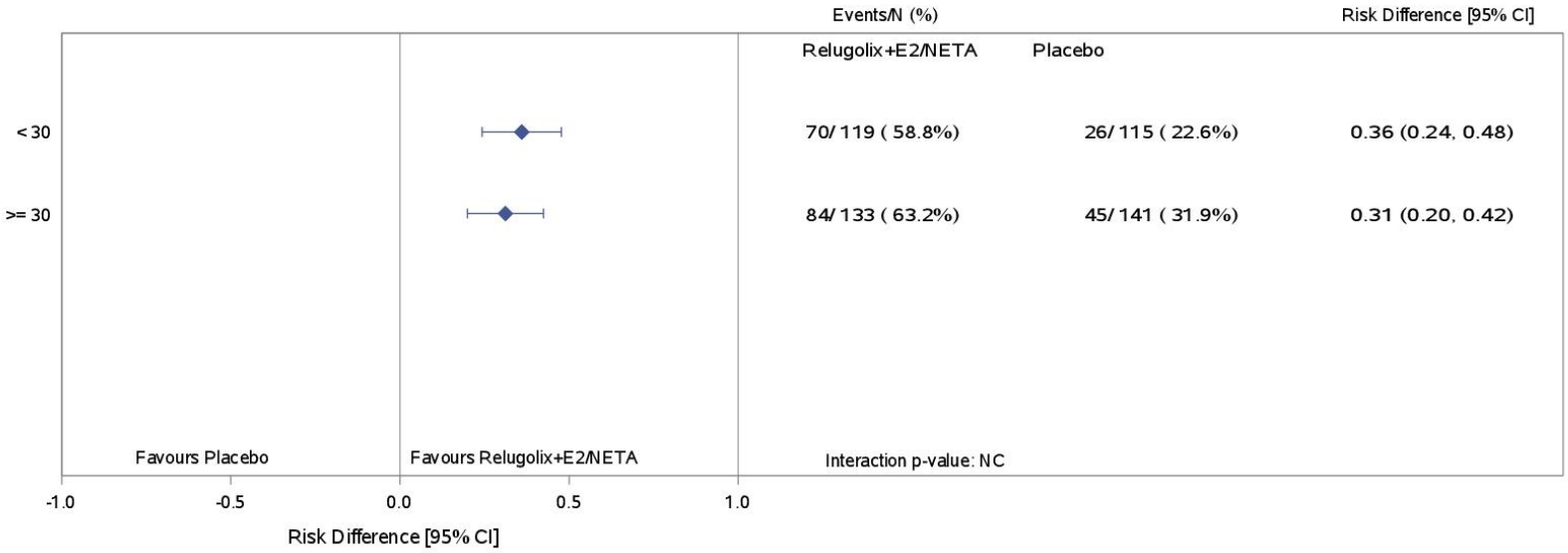
Figure QOL.UFSBPD25.MITT.S2.BIN.FP.RD: Proportion of Responders with at Least 25 Points Decrease in UFS-QoL Bleeding and Pelvic Discomfort Scale Score at Week 24, by Subgroup (mITT Population) - Risk Difference
Study: Pooled
Subgroup: BMI (kg/m2) at Baseline



Results are based on a Mantel-Haenszel approach stratified by study using a one-stage fixed-effects IPD meta-analysis.
The reference group is Placebo.
N: Number of patients in treatment group; NETA: Norethindrone acetate; mITT: Modified intent-to-treat; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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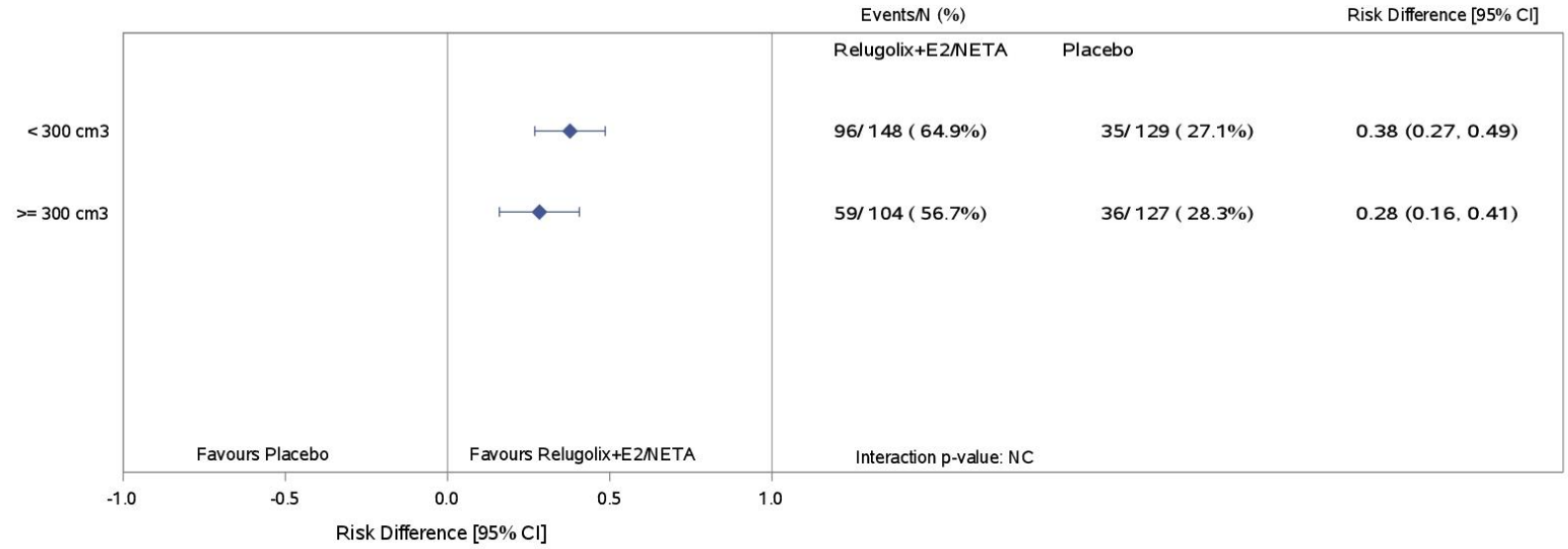
Figure QOL.UFSBPD25.MITT.S3.BIN.FP.RD: Proportion of Responders with at Least 25 Points Decrease in UFS-QoL Bleeding and Pelvic Discomfort Scale Score at Week 24, by Subgroup (mITT Population) - Risk Difference
Study: Pooled
Subgroup: Uterine Volume at Baseline (cm3)



Results are based on a Mantel-Haenszel approach stratified by study using a one-stage fixed-effects IPD meta-analysis.
The reference group is Placebo.
N: Number of patients in treatment group; NETA: Norethindrone acetate; mITT: Modified intent-to-treat; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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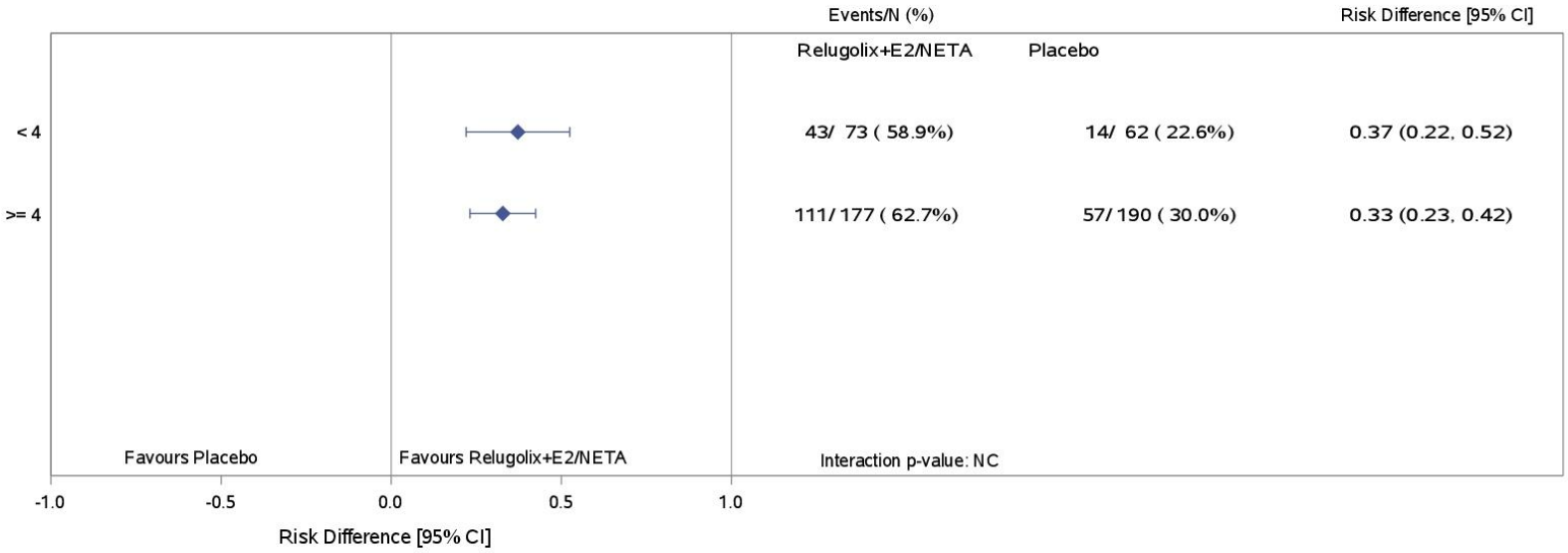
Figure QOL.UFSBPD25.MITT.S4.BIN.FP.RD: Proportion of Responders with at Least 25 Points Decrease in UFS-QoL Bleeding and Pelvic Discomfort Scale Score at Week 24, by Subgroup (mITT Population) - Risk Difference
Study: Pooled
Subgroup: Maximum NRS Pain Score at Baseline



Results are based on a Mantel-Haenszel approach stratified by study using a one-stage fixed-effects IPD meta-analysis.
The reference group is Placebo.
N: Number of patients in treatment group; NETA: Norethindrone acetate; mITT: Modified intent-to-treat; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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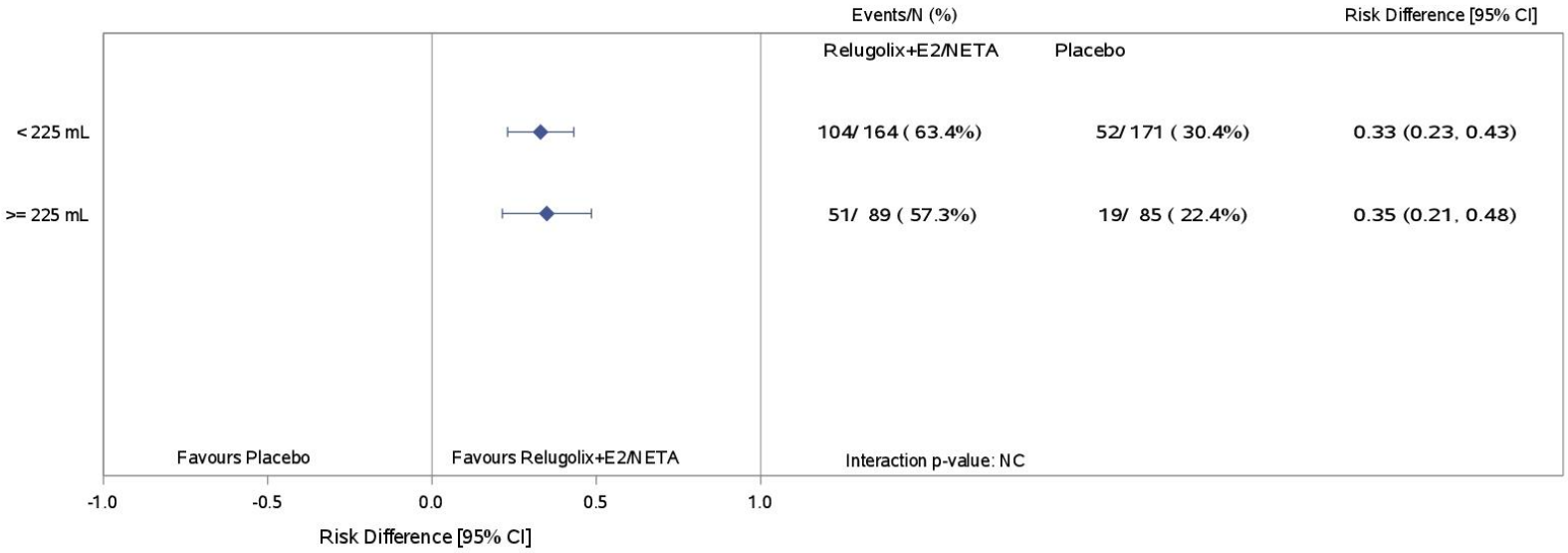
Figure QOL.UFSBPD25.MITT.S5.BIN.FP.RD: Proportion of Responders with at Least 25 Points Decrease in UFS-QoL Bleeding and Pelvic Discomfort Scale Score at Week 24, by Subgroup (mITT Population) - Risk Difference
Study: Pooled
Subgroup: MBL Volume at Baseline (mL)



Results are based on a Mantel-Haenszel approach stratified by study using a one-stage fixed-effects IPD meta-analysis.
The reference group is Placebo.
N: Number of patients in treatment group; NETA: Norethindrone acetate; mITT: Modified intent-to-treat; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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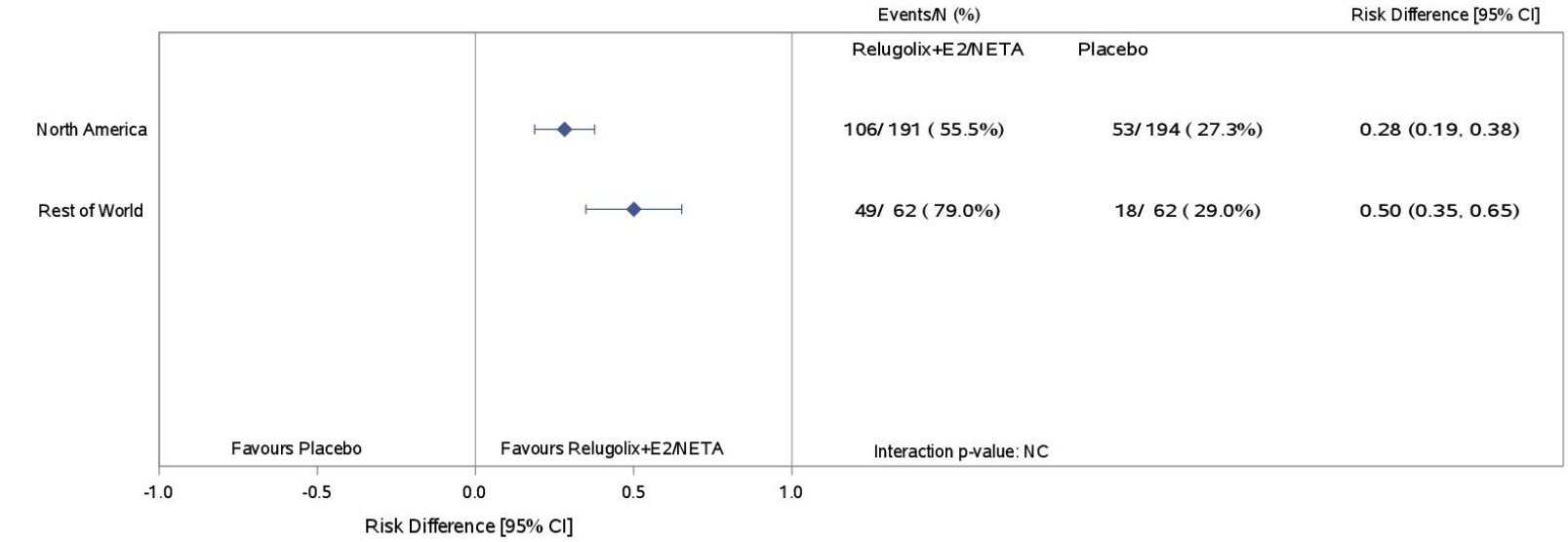
Figure QOL.UFSBPD25.MITT.S6.BIN.FP.RD: Proportion of Responders with at Least 25 Points Decrease in UFS-QoL Bleeding and Pelvic Discomfort Scale Score at Week 24, by Subgroup (mITT Population) - Risk Difference
Study: Pooled
Subgroup: Geographic Region I



Results are based on a Mantel-Haenszel approach stratified by study using a one-stage fixed-effects IPD meta-analysis.
The reference group is Placebo.
N: Number of patients in treatment group; NETA: Norethindrone acetate; mITT: Modified intent-to-treat; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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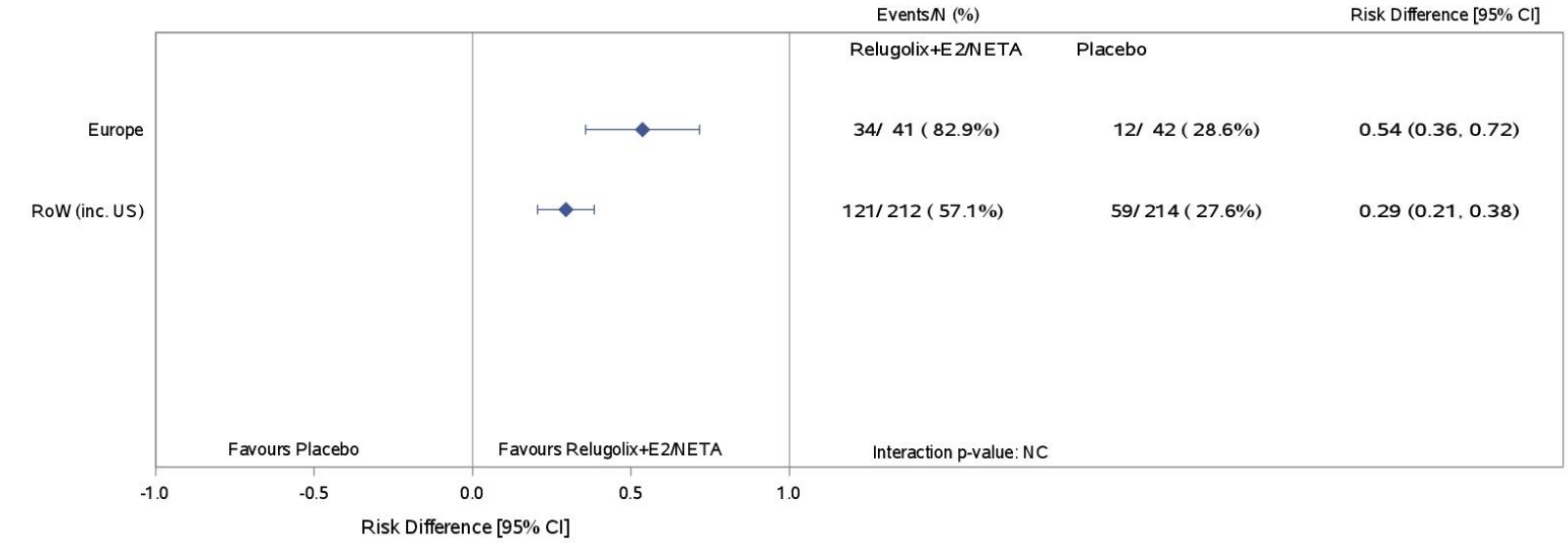
Figure QOL.UFSBPD25.MITT.S7.BIN.FP.RD: Proportion of Responders with at Least 25 Points Decrease in UFS-QoL Bleeding and Pelvic Discomfort Scale Score at Week 24, by Subgroup (mITT Population) - Risk Difference
Study: Pooled
Subgroup: Geographic Region II



Results are based on a Mantel-Haenszel approach stratified by study using a one-stage fixed-effects IPD meta-analysis.
The reference group is Placebo.
N: Number of patients in treatment group; NETA: Norethindrone acetate; mITT: Modified intent-to-treat; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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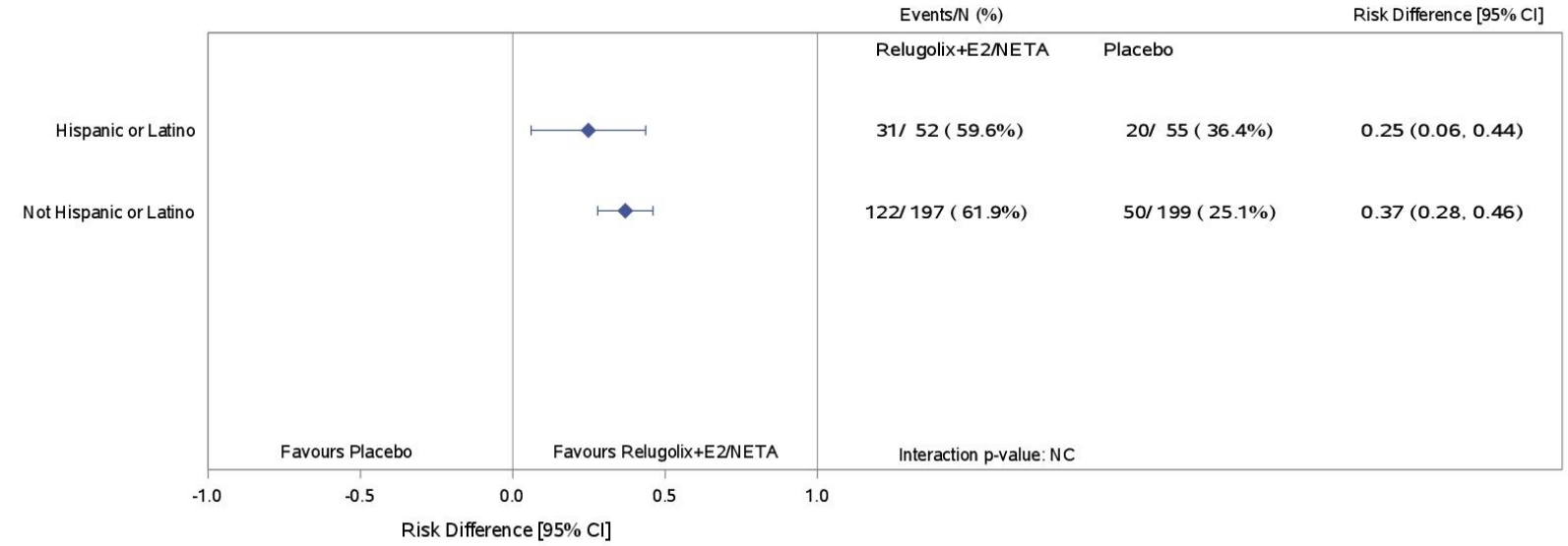
Figure QOL.UFSBPD25.MITT.S8.BIN.FP.RD: Proportion of Responders with at Least 25 Points Decrease in UFS-QoL Bleeding and Pelvic Discomfort Scale Score at Week 24, by Subgroup (mITT Population) - Risk Difference
Study: Pooled
Subgroup: Ethnicity



Results are based on a Mantel-Haenszel approach stratified by study using a one-stage fixed-effects IPD meta-analysis.
The reference group is Placebo.
N: Number of patients in treatment group; NETA: Norethindrone acetate; mITT: Modified intent-to-treat; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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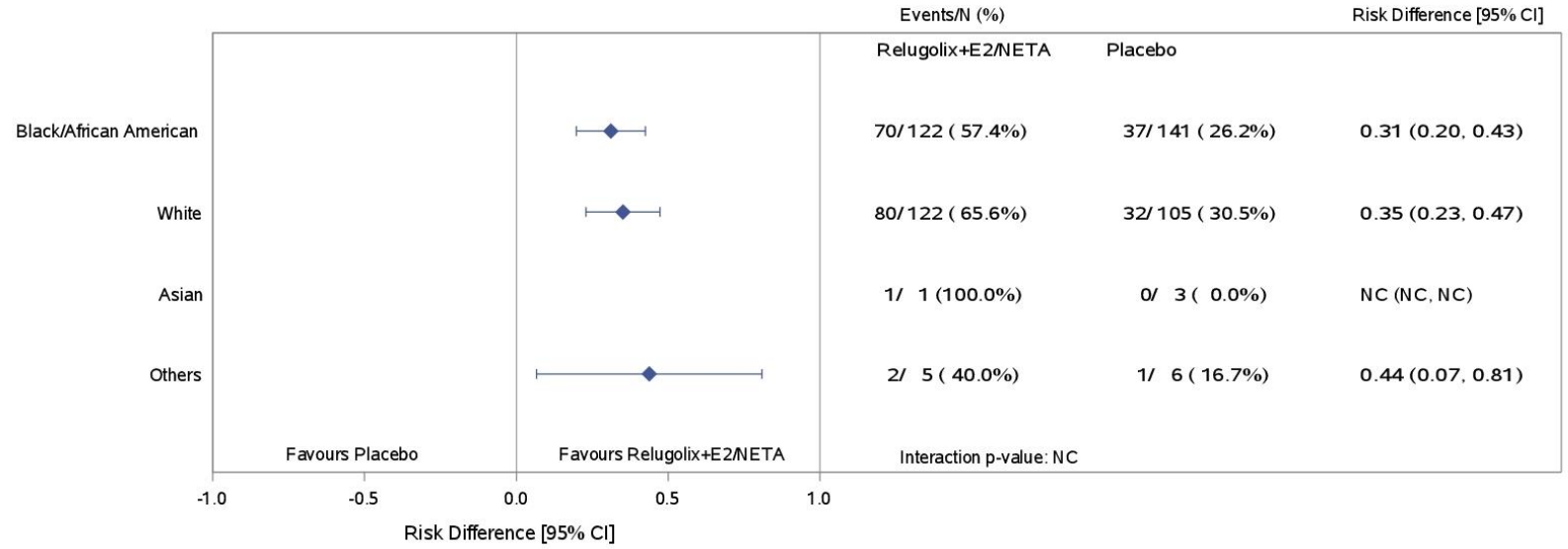
Figure QOL.UFSBPD25.MITT.S9.BIN.FP.RD: Proportion of Responders with at Least 25 Points Decrease in UFS-QoL Bleeding and Pelvic Discomfort Scale Score at Week 24, by Subgroup (mITT Population) - Risk Difference
Study: Pooled
Subgroup: Race



Results are based on a Mantel-Haenszel approach stratified by study using a one-stage fixed-effects IPD meta-analysis.
The reference group is Placebo.
N: Number of patients in treatment group; NETA: Norethindrone acetate; mITT: Modified intent-to-treat; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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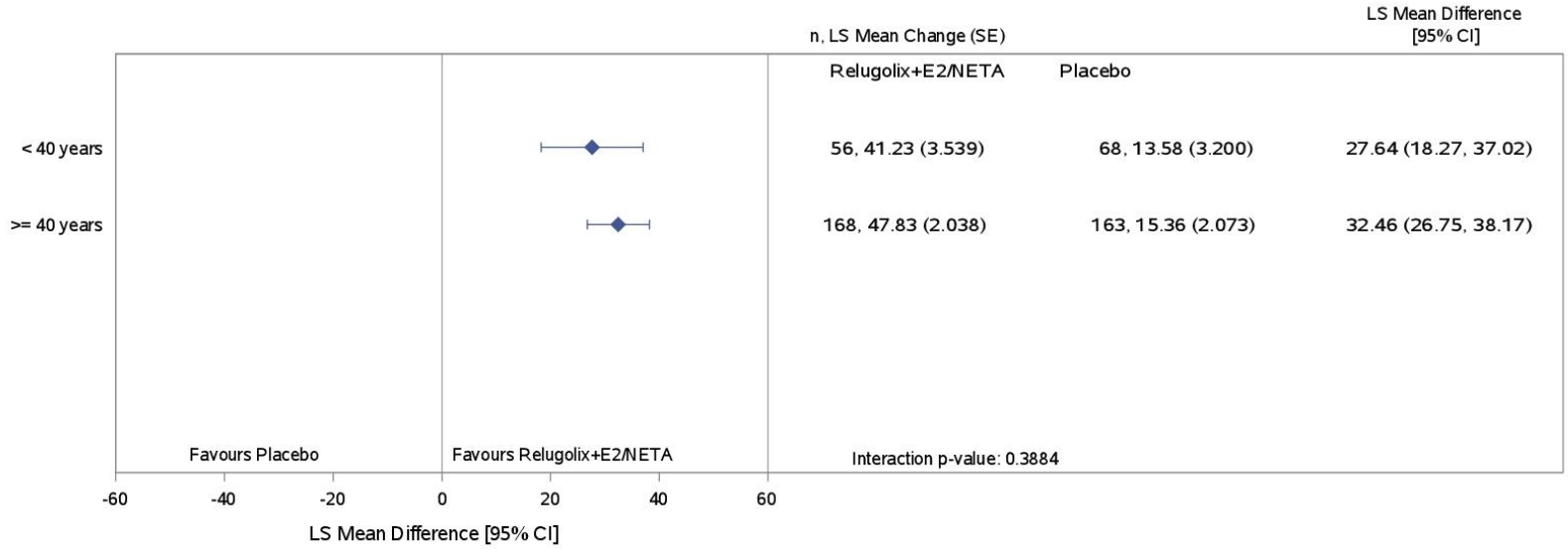
2.2.6 Summary of Average Change from Baseline in UFS-QoL Concern Scale Score Over 24 Weeks, by Subgroup (mITT Population)

Figure QOL.UFSCONC.MITT.S1.CON.FP: Summary of Average Change from Baseline in UFS-QoL Concern Scale Score Over 24 Weeks, by Subgroup (mITT Population)
Study: Pooled
Subgroup: Age (years)



Results are based on a mixed-effects model with study, treatment, visit, subgroup, treatment-by-visit interaction, and a subgroup-by-treatment interaction as fixed effects using a one-stage IPD meta-analysis approach. The multiple visits for each patient are the repeated measures as a random effect within each patient with an unstructured covariance.
The interaction p-value is based on the subgroup-by-treatment interaction term in the mixed-effects model used to compute the LS means, mean differences and 95% CIs. Missing subgroup levels are not included in estimation of the interaction p-value. The reference group is Placebo.
n: Number of patients with data; NETA: Norethindrone acetate; mITT: Modified intent-to-treat; LS: Least squares; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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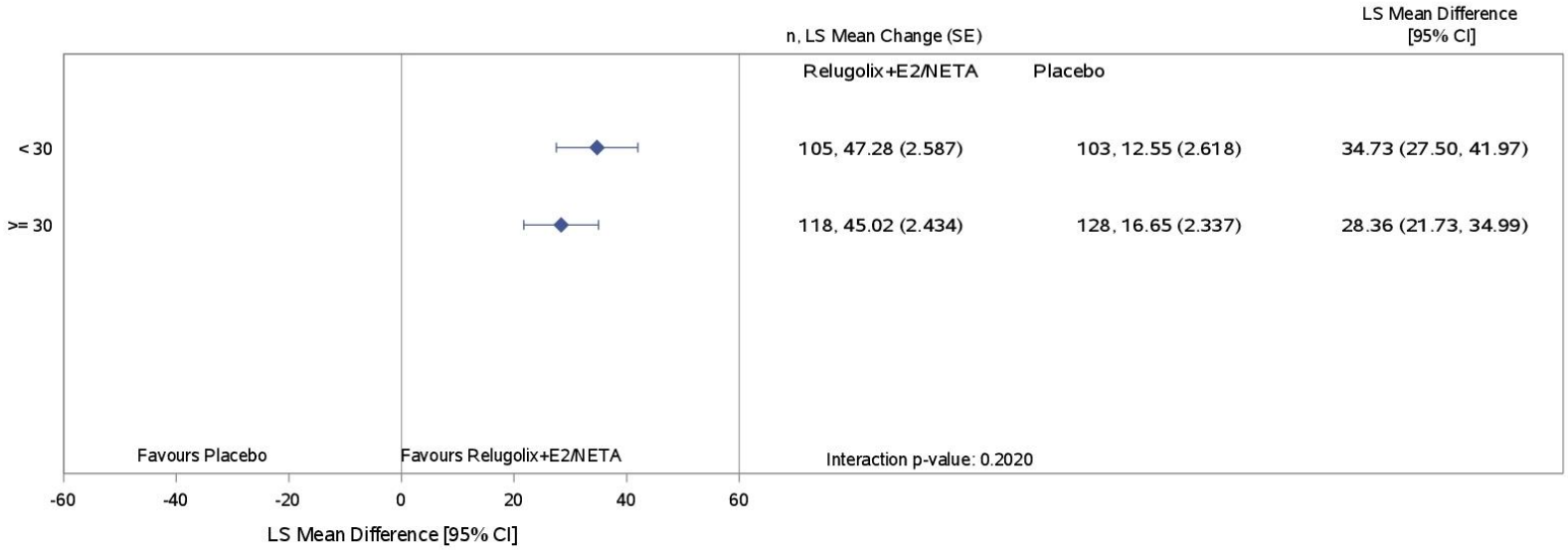
Figure QOL.UFSCONC.MITT.S2.CON.FP: Summary of Average Change from Baseline in UFS-QoL Concern Scale Score Over 24 Weeks, by Subgroup (mITT Population)
Study: Pooled
Subgroup: BMI (kg/m2) at Baseline



Results are based on a mixed-effects model with study, treatment, visit, subgroup, treatment-by-visit interaction, and a subgroup-by-treatment interaction as fixed effects using a one-stage IPD meta-analysis approach. The multiple visits for each patient are the repeated measures as a random effect within each patient with an unstructured covariance.
The interaction p-value is based on the subgroup-by-treatment interaction term in the mixed-effects model used to compute the LS means, mean differences and 95% CIs. Missing subgroup levels are not included in estimation of the interaction p-value. The reference group is Placebo.
n: Number of patients with data; NETA: Norethindrone acetate; mITT: Modified intent-to-treat; LS: Least squares; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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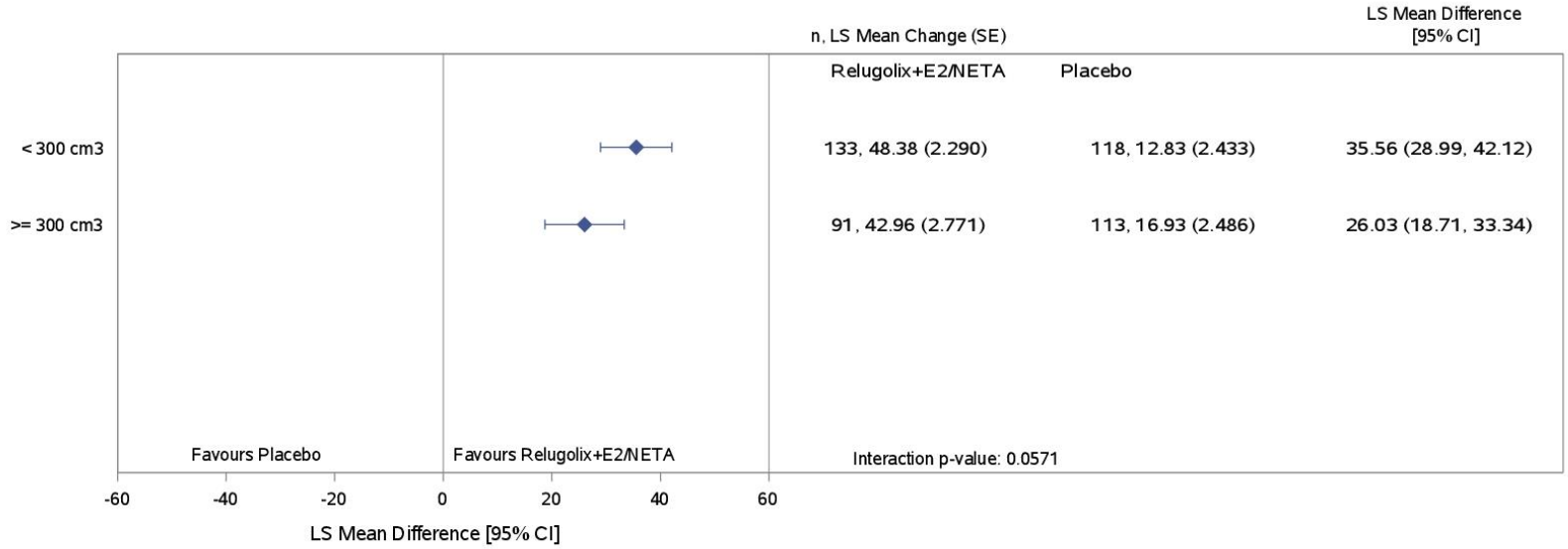
Figure QOL.UFSCONC.MITT.S3.CON.FP: Summary of Average Change from Baseline in UFS-QoL Concern Scale Score Over 24 Weeks, by Subgroup (mITT Population)
Study: Pooled
Subgroup: Uterine Volume at Baseline (cm3)



Results are based on a mixed-effects model with study, treatment, visit, subgroup, treatment-by-visit interaction, and a subgroup-by-treatment interaction as fixed effects using a one-stage IPD meta-analysis approach. The multiple visits for each patient are the repeated measures as a random effect within each patient with an unstructured covariance.
The interaction p-value is based on the subgroup-by-treatment interaction term in the mixed-effects model used to compute the LS means, mean differences and 95% CIs. Missing subgroup levels are not included in estimation of the interaction p-value. The reference group is Placebo.
n: Number of patients with data; NETA: Norethindrone acetate; mITT: Modified intent-to-treat; LS: Least squares; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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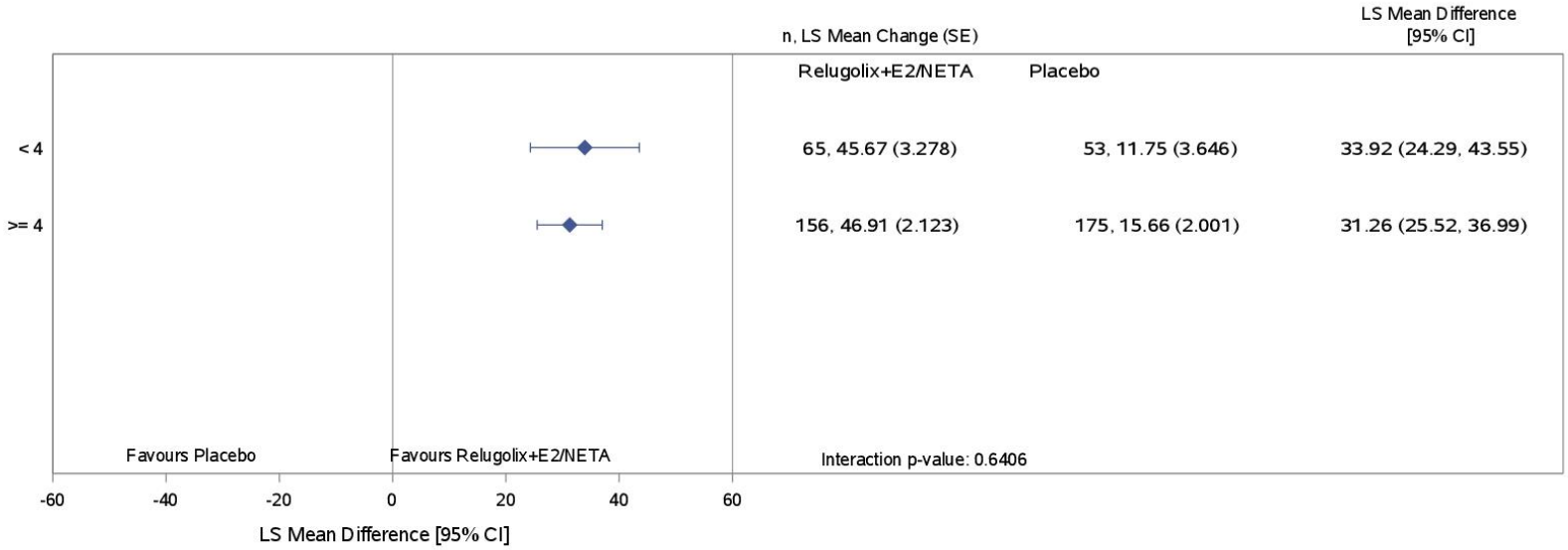
Figure QOL.UFSCONC.MITT.S4.CON.FP: Summary of Average Change from Baseline in UFS-QoL Concern Scale Score Over 24 Weeks, by Subgroup (mITT Population)
Study: Pooled
Subgroup: Maximum NRS Pain Score at Baseline



Results are based on a mixed-effects model with study, treatment, visit, subgroup, treatment-by-visit interaction, and a subgroup-by-treatment interaction as fixed effects using a one-stage IPD meta-analysis approach. The multiple visits for each patient are the repeated measures as a random effect within each patient with an unstructured covariance.
The interaction p-value is based on the subgroup-by-treatment interaction term in the mixed-effects model used to compute the LS means, mean differences and 95% CIs. Missing subgroup levels are not included in estimation of the interaction p-value. The reference group is Placebo.
n: Number of patients with data; NETA: Norethindrone acetate; mITT: Modified intent-to-treat; LS: Least squares; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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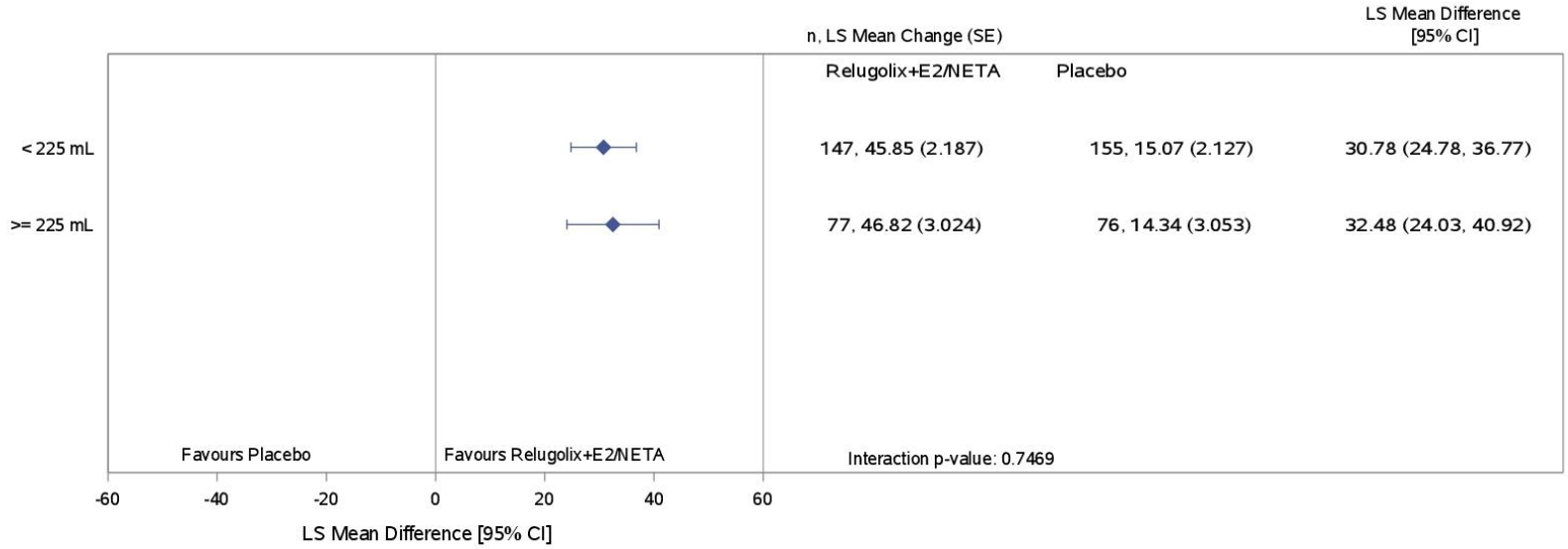
Figure QOL.UFSCONC.MITT.S5.CON.FP: Summary of Average Change from Baseline in UFS-QoL Concern Scale Score Over 24 Weeks, by Subgroup (mITT Population)
Study: Pooled
Subgroup: MBL Volume at Baseline (mL)



Results are based on a mixed-effects model with study, treatment, visit, subgroup, treatment-by-visit interaction, and a subgroup-by-treatment interaction as fixed effects using a one-stage IPD meta-analysis approach. The multiple visits for each patient are the repeated measures as a random effect within each patient with an unstructured covariance.
The interaction p-value is based on the subgroup-by-treatment interaction term in the mixed-effects model used to compute the LS means, mean differences and 95% CIs. Missing subgroup levels are not included in estimation of the interaction p-value. The reference group is Placebo.
n: Number of patients with data; NETA: Norethindrone acetate; mITT: Modified intent-to-treat; LS: Least squares; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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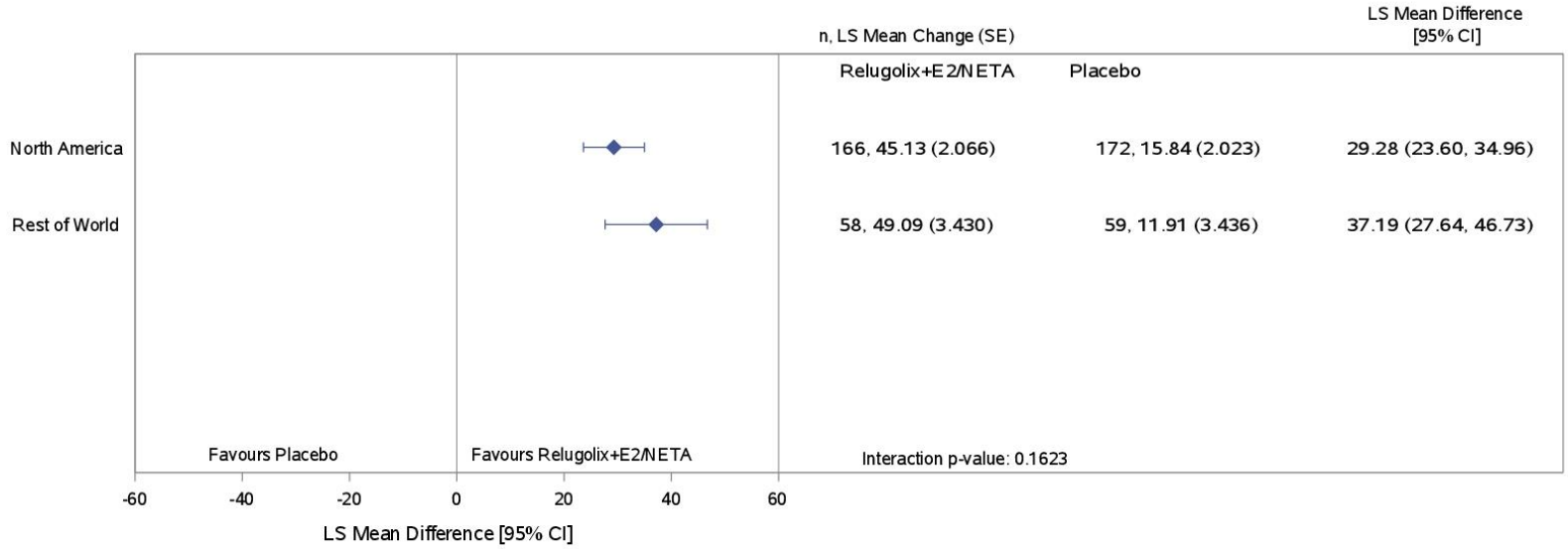
Figure QOL.UFSCONC.MITT.S6.CON.FP: Summary of Average Change from Baseline in UFS-QoL Concern Scale Score Over 24 Weeks, by Subgroup (mITT Population)
Study: Pooled
Subgroup: Geographic Region I



Results are based on a mixed-effects model with study, treatment, visit, subgroup, treatment-by-visit interaction, and a subgroup-by-treatment interaction as fixed effects using a one-stage IPD meta-analysis approach. The multiple visits for each patient are the repeated measures as a random effect within each patient with an unstructured covariance.
The interaction p-value is based on the subgroup-by-treatment interaction term in the mixed-effects model used to compute the LS means, mean differences and 95% CIs. Missing subgroup levels are not included in estimation of the interaction p-value. The reference group is Placebo.
n: Number of patients with data; NETA: Norethindrone acetate; mITT: Modified intent-to-treat; LS: Least squares; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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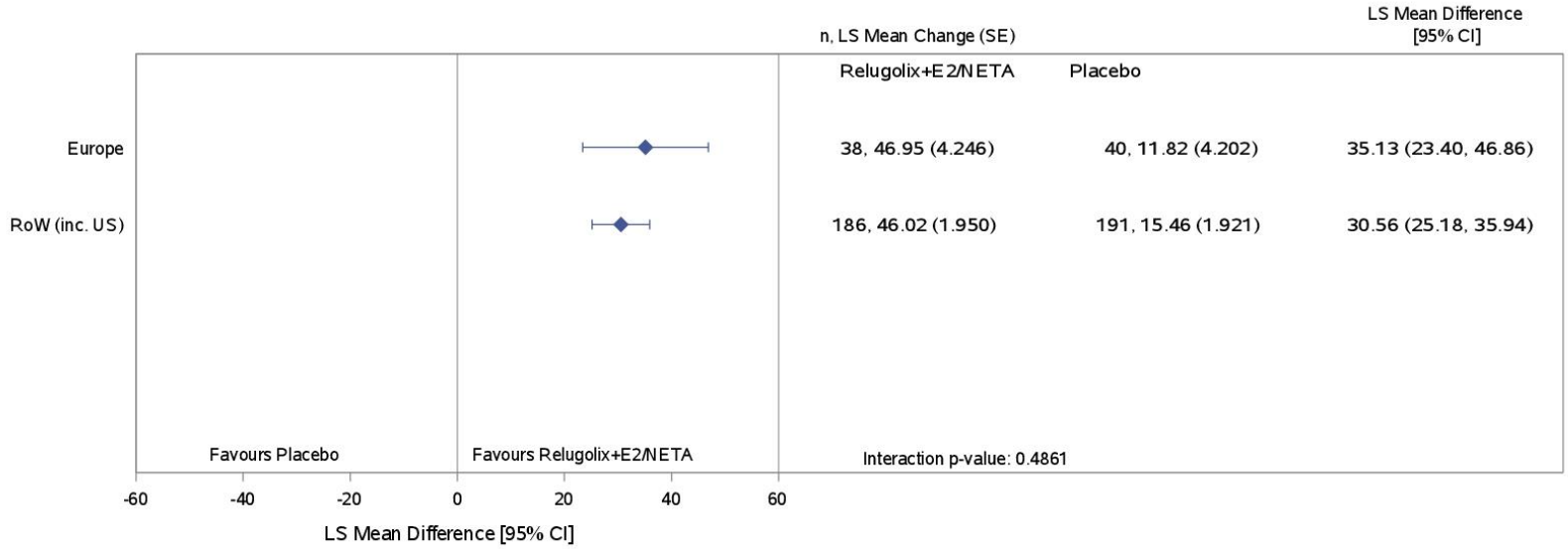
Figure QOL.UFSCONC.MITT.S7.CON.FP: Summary of Average Change from Baseline in UFS-QoL Concern Scale Score Over 24 Weeks, by Subgroup (mITT Population)
Study: Pooled
Subgroup: Geographic Region II



Results are based on a mixed-effects model with study, treatment, visit, subgroup, treatment-by-visit interaction, and a subgroup-by-treatment interaction as fixed effects using a one-stage IPD meta-analysis approach. The multiple visits for each patient are the repeated measures as a random effect within each patient with an unstructured covariance.
The interaction p-value is based on the subgroup-by-treatment interaction term in the mixed-effects model used to compute the LS means, mean differences and 95% CIs. Missing subgroup levels are not included in estimation of the interaction p-value. The reference group is Placebo.
n: Number of patients with data; NETA: Norethindrone acetate; mITT: Modified intent-to-treat; LS: Least squares; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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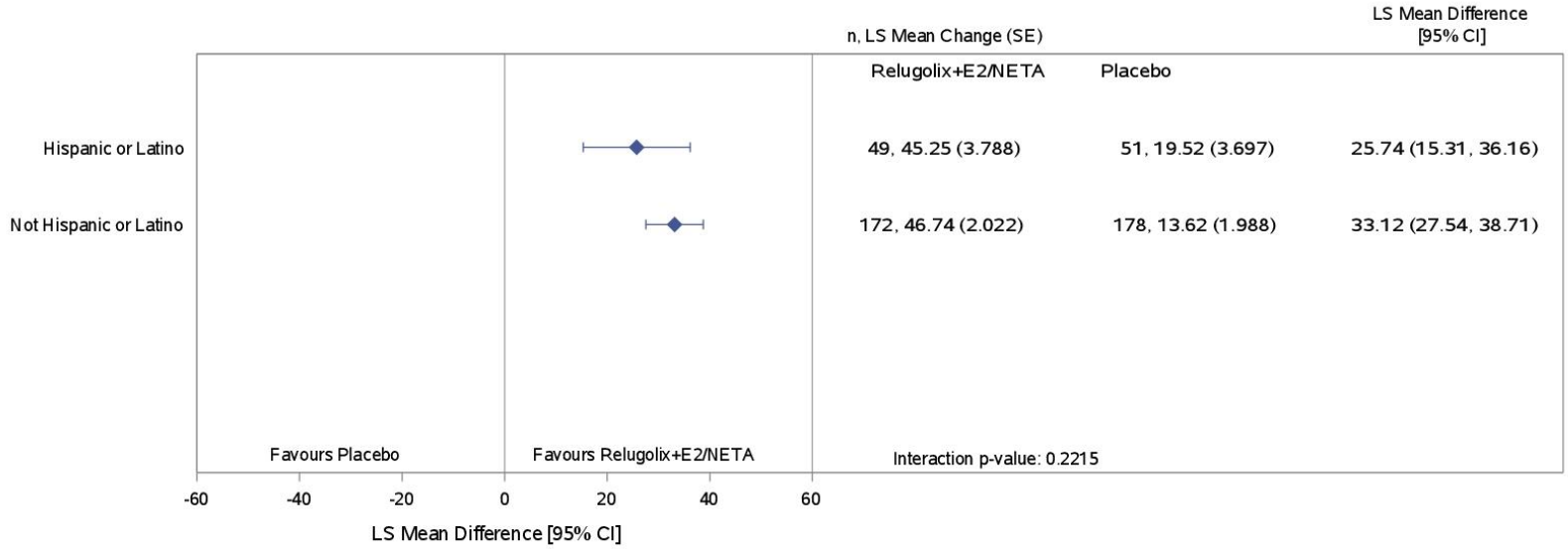
Figure QOL.UFSCONC.MITT.S8.CON.FP: Summary of Average Change from Baseline in UFS-QoL Concern Scale Score Over 24 Weeks, by Subgroup (mITT Population)
Study: Pooled
Subgroup: Ethnicity



Results are based on a mixed-effects model with study, treatment, visit, subgroup, treatment-by-visit interaction, and a subgroup-by-treatment interaction as fixed effects using a one-stage IPD meta-analysis approach. The multiple visits for each patient are the repeated measures as a random effect within each patient with an unstructured covariance.
The interaction p-value is based on the subgroup-by-treatment interaction term in the mixed-effects model used to compute the LS means, mean differences and 95% CIs. Missing subgroup levels are not included in estimation of the interaction p-value. The reference group is Placebo.
n: Number of patients with data; NETA: Norethindrone acetate; mITT: Modified intent-to-treat; LS: Least squares; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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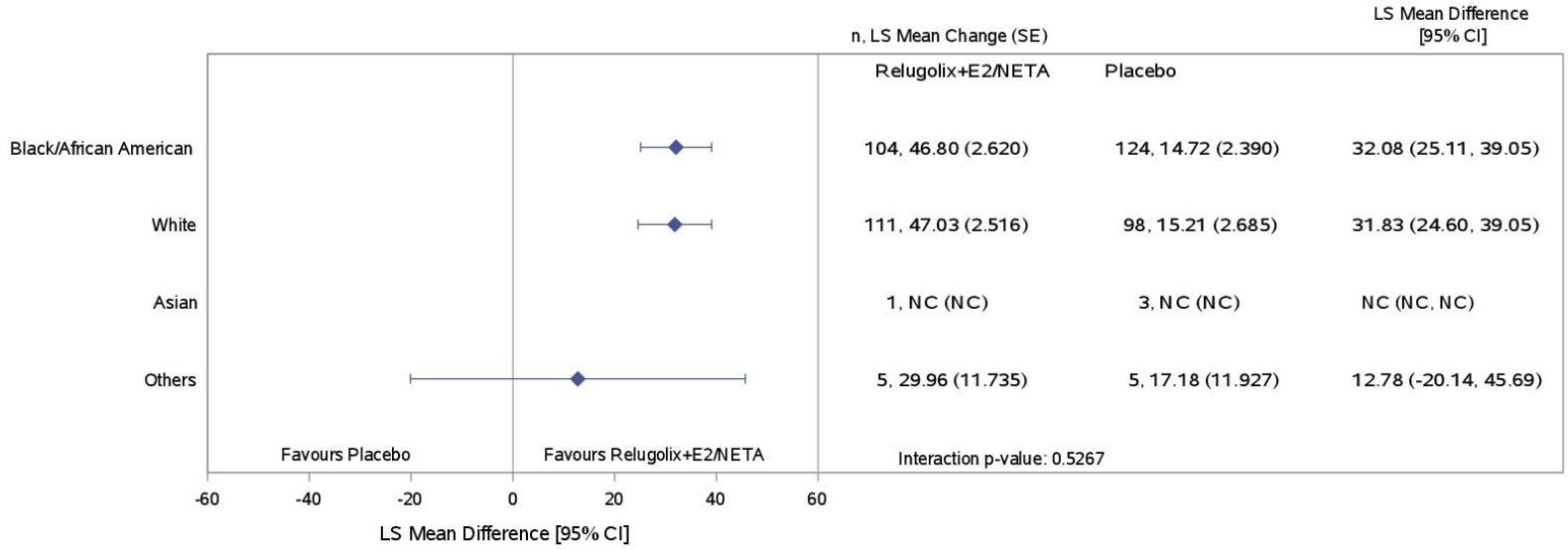
Figure QOL.UFSCONC.MITT.S9.CON.FP: Summary of Average Change from Baseline in UFS-QoL Concern Scale Score Over 24 Weeks, by Subgroup (mITT Population)
Study: Pooled
Subgroup: Race



Results are based on a mixed-effects model with study, treatment, visit, subgroup, treatment-by-visit interaction, and a subgroup-by-treatment interaction as fixed effects using a one-stage IPD meta-analysis approach. The multiple visits for each patient are the repeated measures as a random effect within each patient with an unstructured covariance.
The interaction p-value is based on the subgroup-by-treatment interaction term in the mixed-effects model used to compute the LS means, mean differences and 95% CIs. Missing subgroup levels are not included in estimation of the interaction p-value. The reference group is Placebo.
n: Number of patients with data; NETA: Norethindrone acetate; mITT: Modified intent-to-treat; LS: Least squares; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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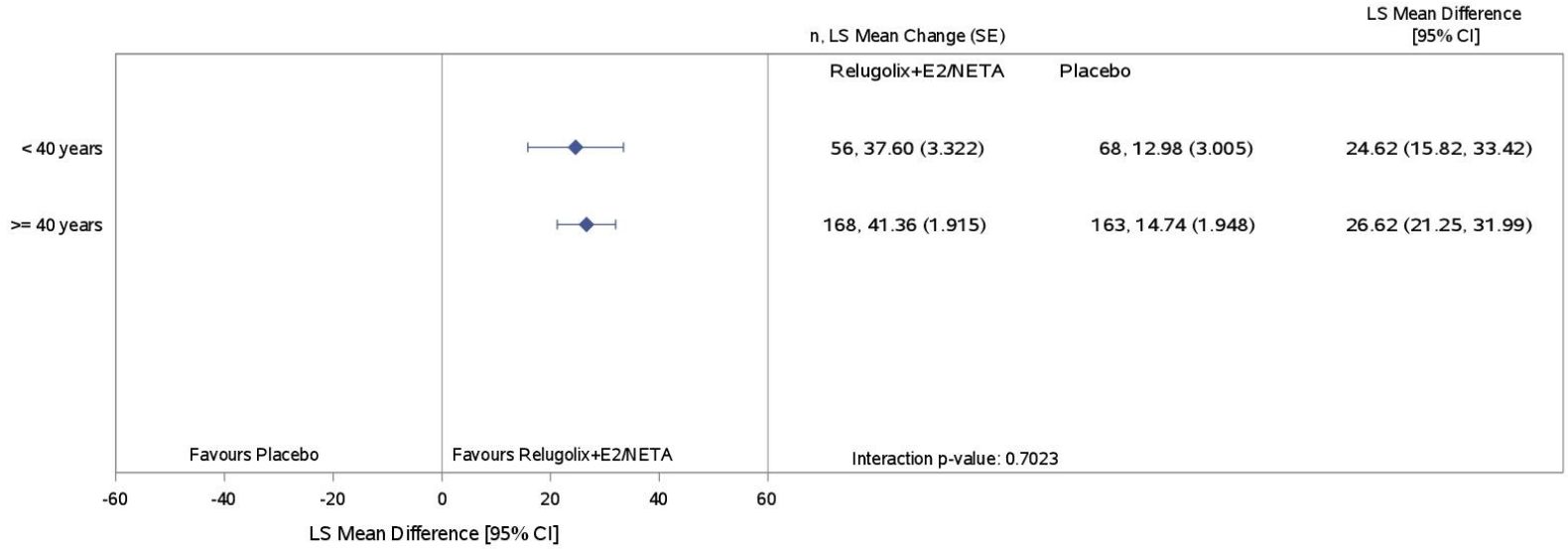
2.2.7 Summary of Average Change from Baseline in UFS-QoL Activities Scale Score Over 24 Weeks, by Subgroup (mITT Population)

Figure QOL.UFSACT.MITT.S1.CON.FP: Summary of Average Change from Baseline in UFS-QoL Activities Scale Score Over 24 Weeks, by Subgroup (mITT Population)
Study: Pooled
Subgroup: Age (years)



Results are based on a mixed-effects model with study, treatment, visit, subgroup, treatment-by-visit interaction, and a subgroup-by-treatment interaction as fixed effects using a one-stage IPD meta-analysis approach. The multiple visits for each patient are the repeated measures as a random effect within each patient with an unstructured covariance.
The interaction p-value is based on the subgroup-by-treatment interaction term in the mixed-effects model used to compute the LS means, mean differences and 95% CIs. Missing subgroup levels are not included in estimation of the interaction p-value. The reference group is Placebo.
n: Number of patients with data; NETA: Norethindrone acetate; mITT: Modified intent-to-treat; LS: Least squares; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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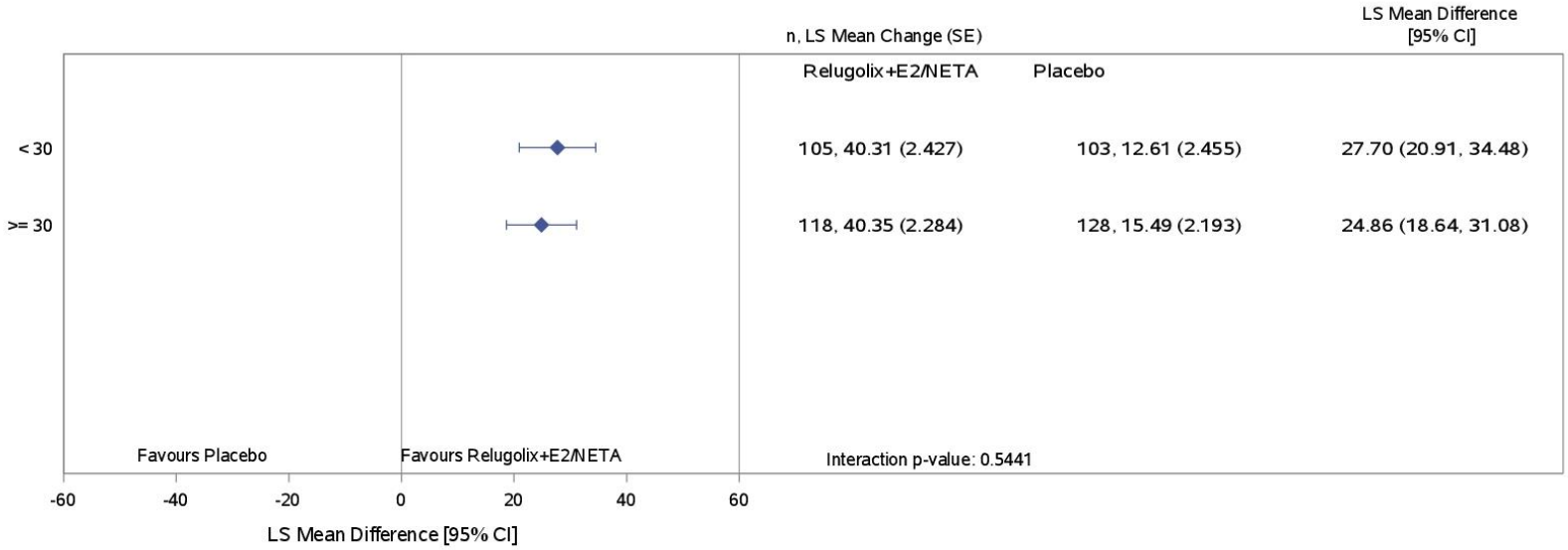
Figure QOL.UFSACT.MITT.S2.CON.FP: Summary of Average Change from Baseline in UFS-QoL Activities Scale Score Over 24 Weeks, by Subgroup (mITT Population)
Study: Pooled
Subgroup: BMI (kg/m2) at Baseline



Results are based on a mixed-effects model with study, treatment, visit, subgroup, treatment-by-visit interaction, and a subgroup-by-treatment interaction as fixed effects using a one-stage IPD meta-analysis approach. The multiple visits for each patient are the repeated measures as a random effect within each patient with an unstructured covariance.
The interaction p-value is based on the subgroup-by-treatment interaction term in the mixed-effects model used to compute the LS means, mean differences and 95% CIs. Missing subgroup levels are not included in estimation of the interaction p-value. The reference group is Placebo.
n: Number of patients with data; NETA: Norethindrone acetate; mITT: Modified intent-to-treat; LS: Least squares; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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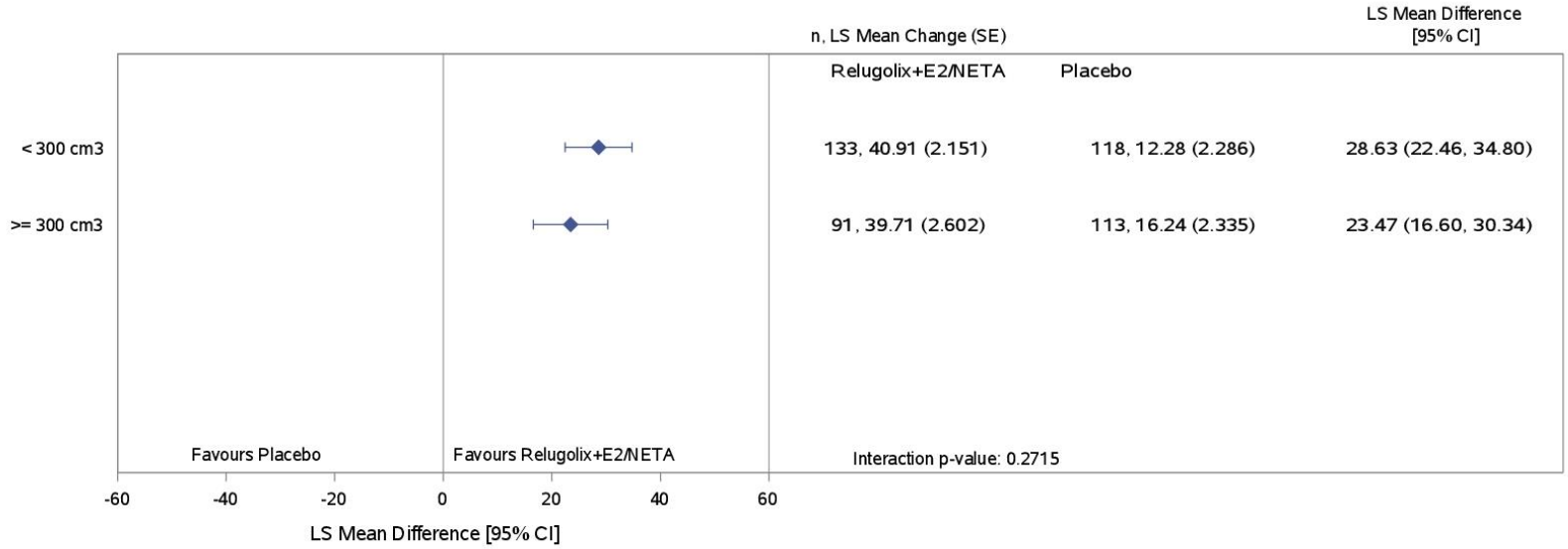
Figure QOL.UFSACT.MITT.S3.CON.FP: Summary of Average Change from Baseline in UFS-QoL Activities Scale Score Over 24 Weeks, by Subgroup (mITT Population)
Study: Pooled
Subgroup: Uterine Volume at Baseline (cm3)



Results are based on a mixed-effects model with study, treatment, visit, subgroup, treatment-by-visit interaction, and a subgroup-by-treatment interaction as fixed effects using a one-stage IPD meta-analysis approach. The multiple visits for each patient are the repeated measures as a random effect within each patient with an unstructured covariance.
The interaction p-value is based on the subgroup-by-treatment interaction term in the mixed-effects model used to compute the LS means, mean differences and 95% CIs. Missing subgroup levels are not included in estimation of the interaction p-value. The reference group is Placebo.
n: Number of patients with data; NETA: Norethindrone acetate; mITT: Modified intent-to-treat; LS: Least squares; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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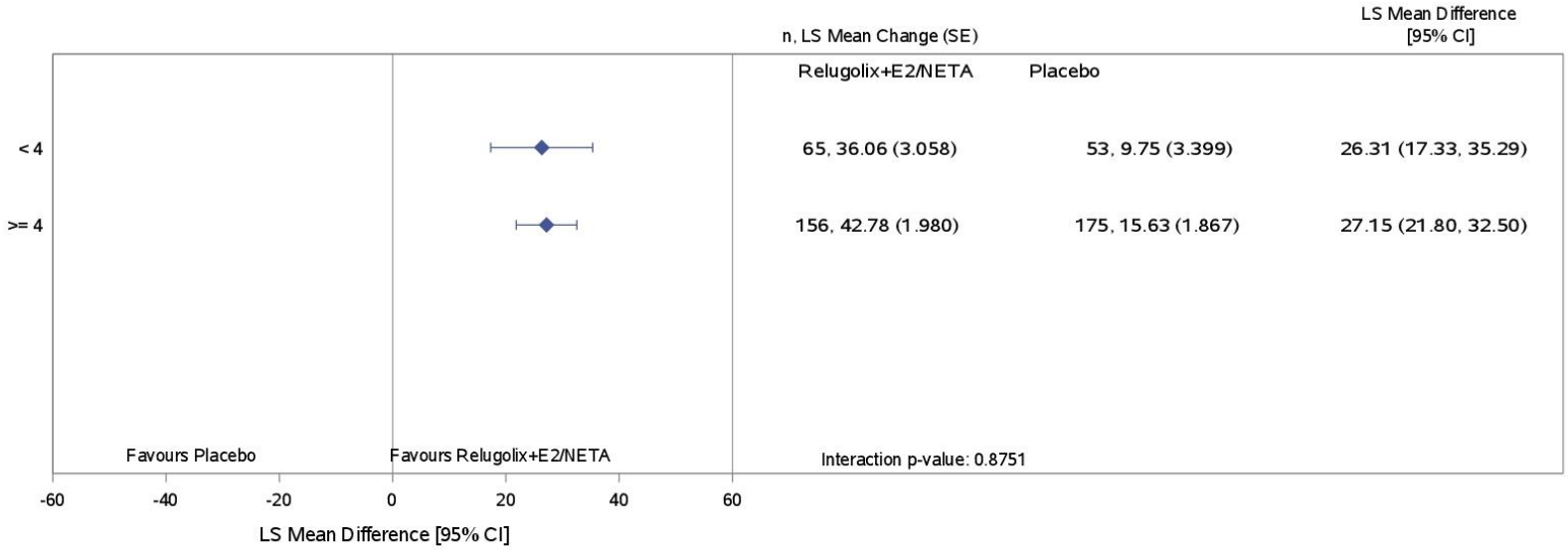
Figure QOL.UFSACT.MITT.S4.CON.FP: Summary of Average Change from Baseline in UFS-QoL Activities Scale Score Over 24 Weeks, by Subgroup (mITT Population)
Study: Pooled
Subgroup: Maximum NRS Pain Score at Baseline



Results are based on a mixed-effects model with study, treatment, visit, subgroup, treatment-by-visit interaction, and a subgroup-by-treatment interaction as fixed effects using a one-stage IPD meta-analysis approach. The multiple visits for each patient are the repeated measures as a random effect within each patient with an unstructured covariance.
The interaction p-value is based on the subgroup-by-treatment interaction term in the mixed-effects model used to compute the LS means, mean differences and 95% CIs. Missing subgroup levels are not included in estimation of the interaction p-value. The reference group is Placebo.
n: Number of patients with data; NETA: Norethindrone acetate; mITT: Modified intent-to-treat; LS: Least squares; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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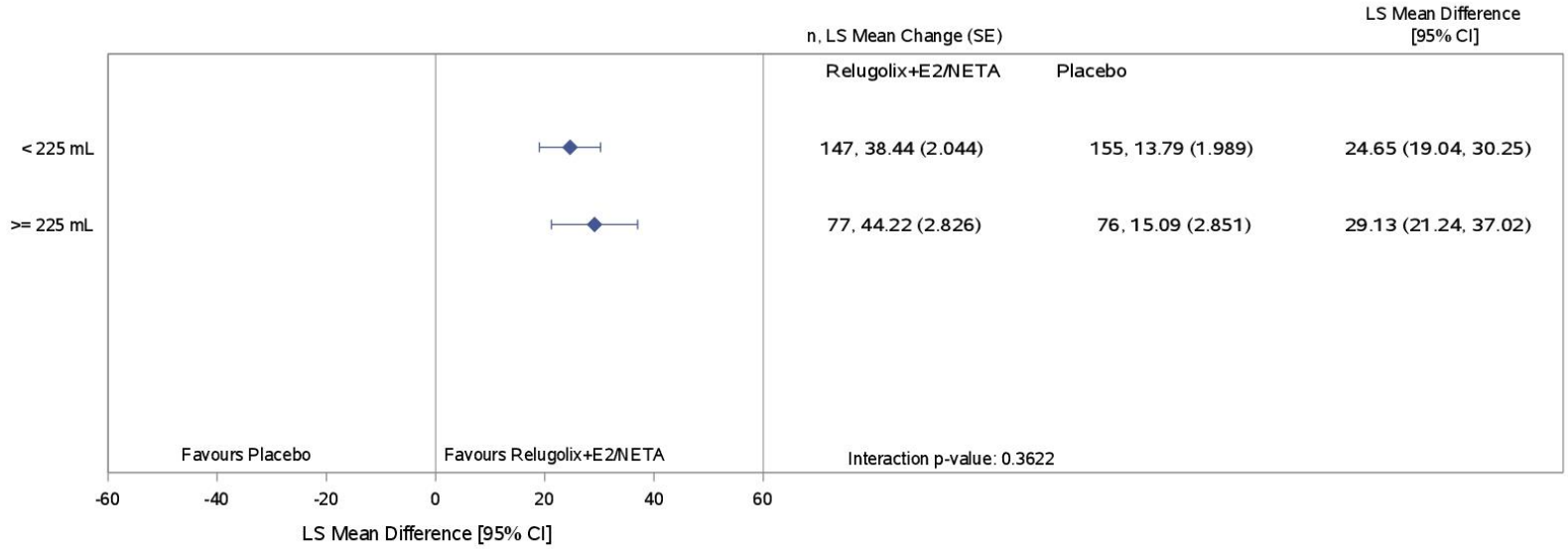
Figure QOL.UFSACT.MITT.S5.CON.FP: Summary of Average Change from Baseline in UFS-QoL Activities Scale Score Over 24 Weeks, by Subgroup (mITT Population)
Study: Pooled
Subgroup: MBL Volume at Baseline (mL)



Results are based on a mixed-effects model with study, treatment, visit, subgroup, treatment-by-visit interaction, and a subgroup-by-treatment interaction as fixed effects using a one-stage IPD meta-analysis approach. The multiple visits for each patient are the repeated measures as a random effect within each patient with an unstructured covariance.
The interaction p-value is based on the subgroup-by-treatment interaction term in the mixed-effects model used to compute the LS means, mean differences and 95% CIs. Missing subgroup levels are not included in estimation of the interaction p-value. The reference group is Placebo.
n: Number of patients with data; NETA: Norethindrone acetate; mITT: Modified intent-to-treat; LS: Least squares; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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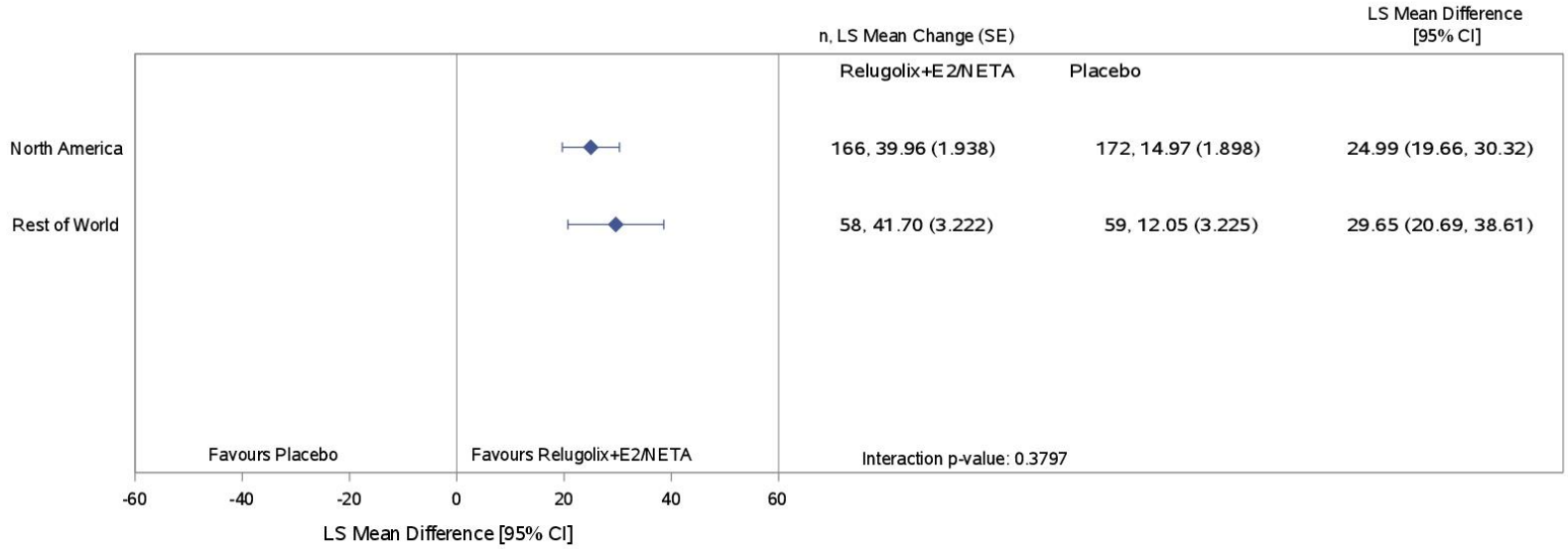
Figure QOL.UFSACT.MITT.S6.CON.FP: Summary of Average Change from Baseline in UFS-QoL Activities Scale Score Over 24 Weeks, by Subgroup (mITT Population)
Study: Pooled
Subgroup: Geographic Region I



Results are based on a mixed-effects model with study, treatment, visit, subgroup, treatment-by-visit interaction, and a subgroup-by-treatment interaction as fixed effects using a one-stage IPD meta-analysis approach. The multiple visits for each patient are the repeated measures as a random effect within each patient with an unstructured covariance.
The interaction p-value is based on the subgroup-by-treatment interaction term in the mixed-effects model used to compute the LS means, mean differences and 95% CIs. Missing subgroup levels are not included in estimation of the interaction p-value. The reference group is Placebo.
n: Number of patients with data; NETA: Norethindrone acetate; mITT: Modified intent-to-treat; LS: Least squares; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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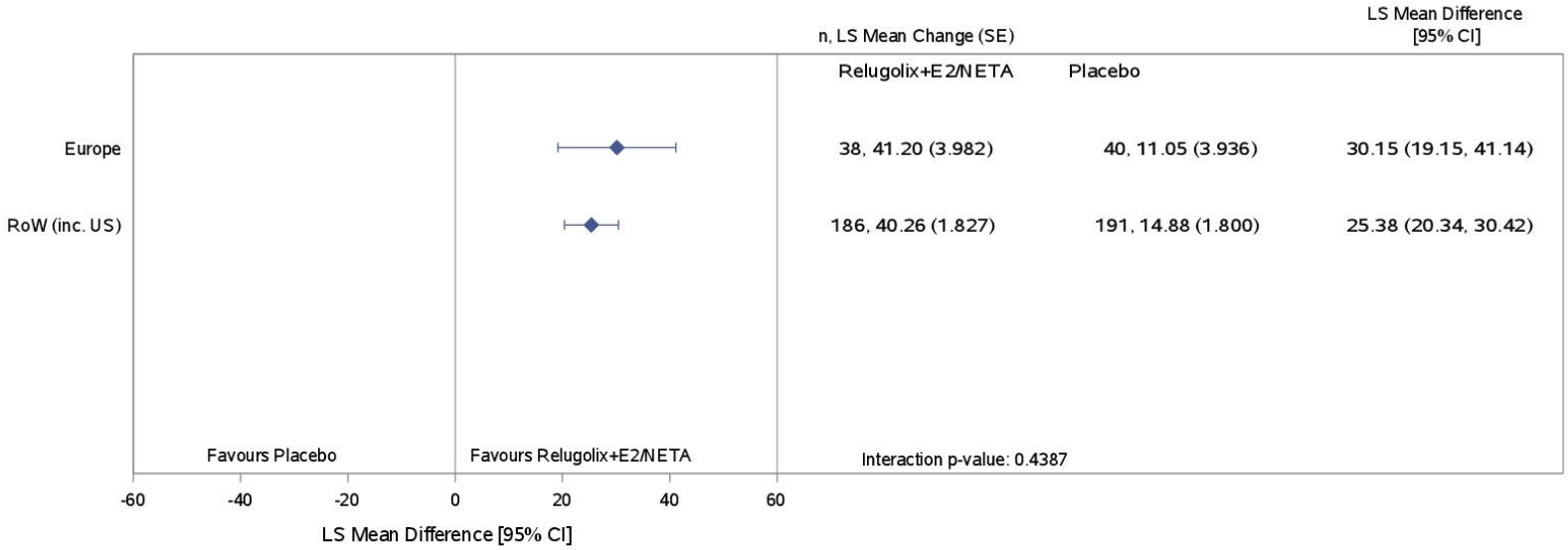
Figure QOL.UFSACT.MITT.S7.CON.FP: Summary of Average Change from Baseline in UFS-QoL Activities Scale Score Over 24 Weeks, by Subgroup (mITT Population)
Study: Pooled
Subgroup: Geographic Region II



Results are based on a mixed-effects model with study, treatment, visit, subgroup, treatment-by-visit interaction, and a subgroup-by-treatment interaction as fixed effects using a one-stage IPD meta-analysis approach. The multiple visits for each patient are the repeated measures as a random effect within each patient with an unstructured covariance.
The interaction p-value is based on the subgroup-by-treatment interaction term in the mixed-effects model used to compute the LS means, mean differences and 95% CIs. Missing subgroup levels are not included in estimation of the interaction p-value. The reference group is Placebo.
n: Number of patients with data; NETA: Norethindrone acetate; mITT: Modified intent-to-treat; LS: Least squares; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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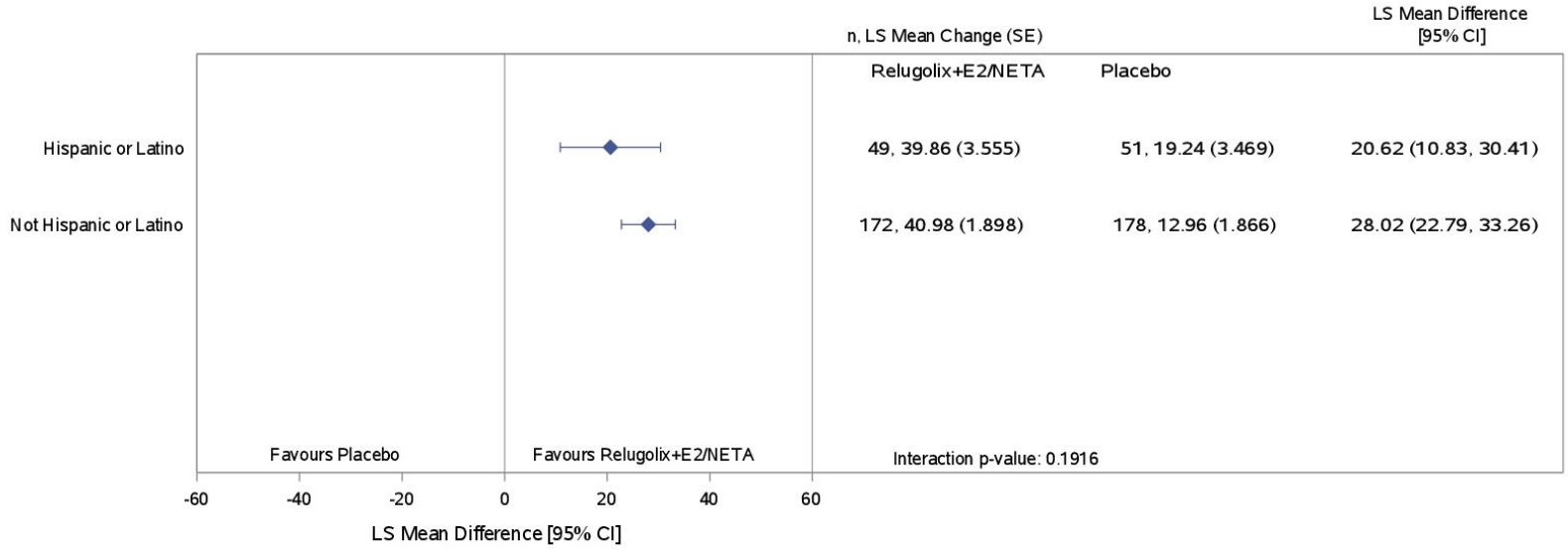
Figure QOL.UFSACT.MITT.S8.CON.FP: Summary of Average Change from Baseline in UFS-QoL Activities Scale Score Over 24 Weeks, by Subgroup (mITT Population)
Study: Pooled
Subgroup: Ethnicity



Results are based on a mixed-effects model with study, treatment, visit, subgroup, treatment-by-visit interaction, and a subgroup-by-treatment interaction as fixed effects using a one-stage IPD meta-analysis approach. The multiple visits for each patient are the repeated measures as a random effect within each patient with an unstructured covariance.
The interaction p-value is based on the subgroup-by-treatment interaction term in the mixed-effects model used to compute the LS means, mean differences and 95% CIs. Missing subgroup levels are not included in estimation of the interaction p-value. The reference group is Placebo.
n: Number of patients with data; NETA: Norethindrone acetate; mITT: Modified intent-to-treat; LS: Least squares; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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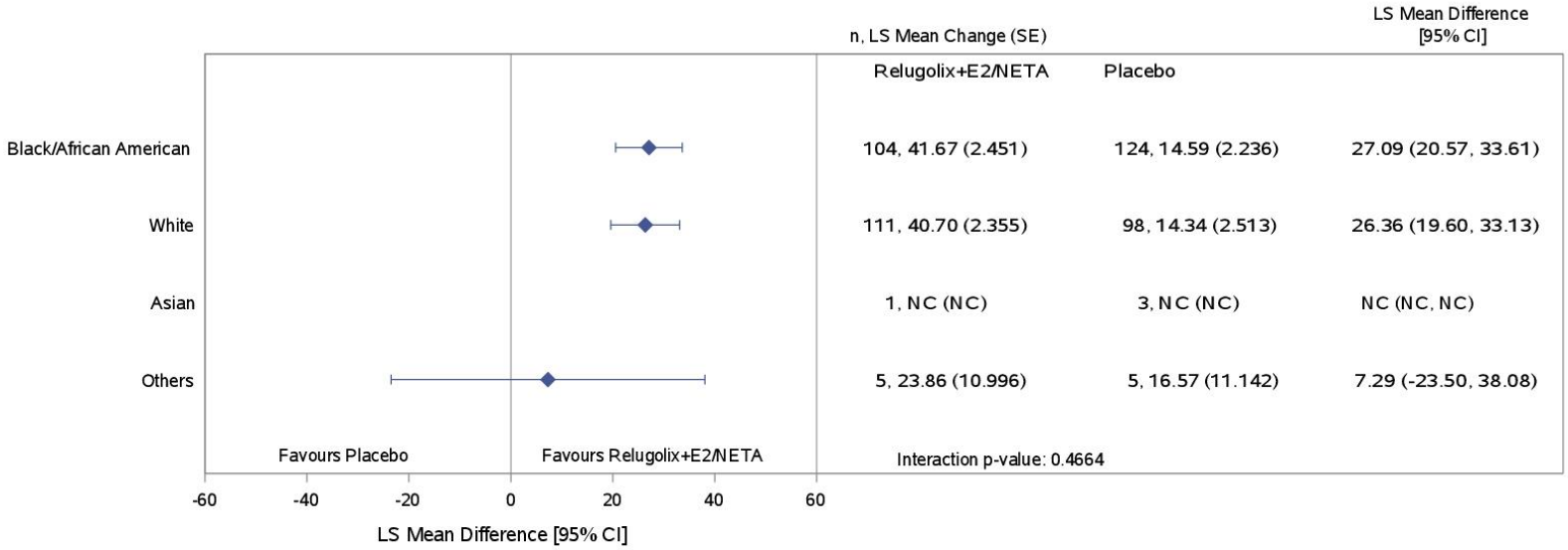
Figure QOL.UFSACT.MITT.S9.CON.FP: Summary of Average Change from Baseline in UFS-QoL Activities Scale Score Over 24 Weeks, by Subgroup (mITT Population)
Study: Pooled
Subgroup: Race



Results are based on a mixed-effects model with study, treatment, visit, subgroup, treatment-by-visit interaction, and a subgroup-by-treatment interaction as fixed effects using a one-stage IPD meta-analysis approach. The multiple visits for each patient are the repeated measures as a random effect within each patient with an unstructured covariance.
The interaction p-value is based on the subgroup-by-treatment interaction term in the mixed-effects model used to compute the LS means, mean differences and 95% CIs. Missing subgroup levels are not included in estimation of the interaction p-value. The reference group is Placebo.
n: Number of patients with data; NETA: Norethindrone acetate; mITT: Modified intent-to-treat; LS: Least squares; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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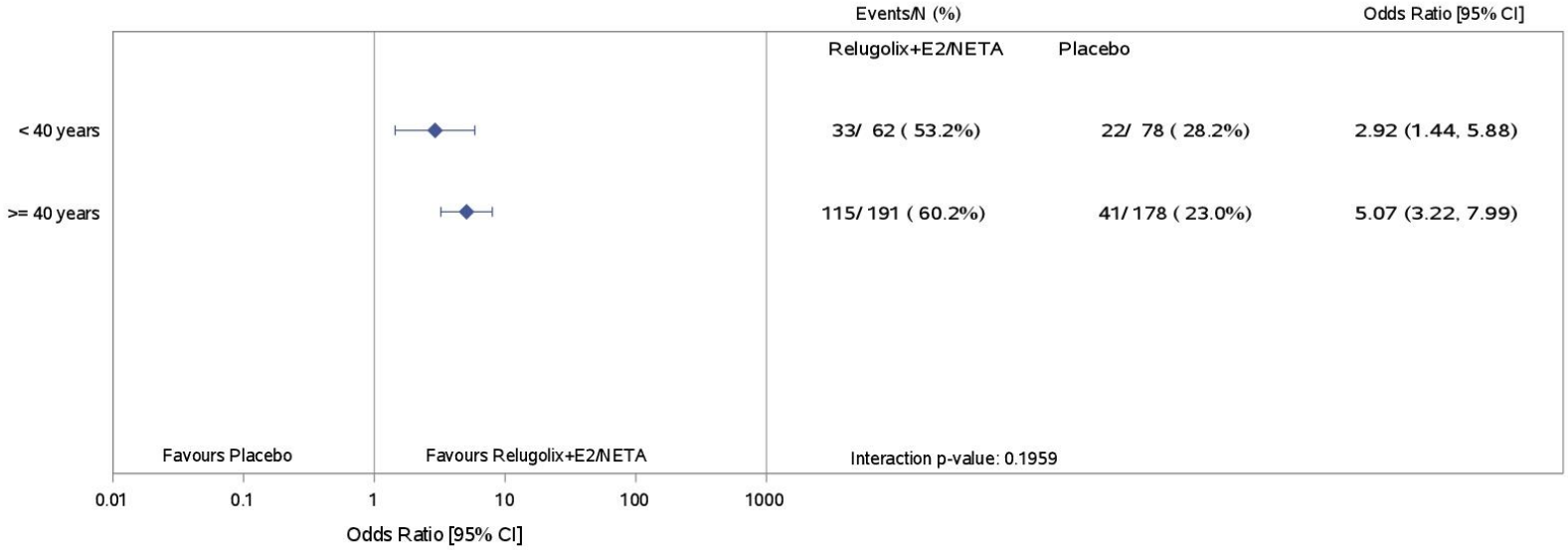
2.2.8 Proportion of Responders with at Least 25 Points Increase in UFS-QoL Activity Scale Score at Week 24, by Subgroup (mITT Population)

Nachfolgend sind zunächst alle Forest Plots für das *Odds Ratio* dargestellt; gefolgt von den entsprechenden Forest Plots für *Risk Ratio* und *Risk Difference*.

Figure QOL.UFSACT25.MITT.S1.BIN.FP: Proportion of Responders with at Least 25 Points Increase in UFS-QoL Activity Scale Score at Week 24, by Subgroup (mITT Population)
Study: Pooled
Subgroup: Age (years)



Results are based on a logistic regression model adjusted for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates using a one-stage fixed-effects IPD meta-analysis approach. A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
The interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the Odds Ratio and 95% CI. Missing subgroup levels are not included in estimation of the interaction p-value. The reference group is Placebo.
N: Number of patients in treatment group; NETA: Norethindrone acetate; mITT: Modified intent-to-treat; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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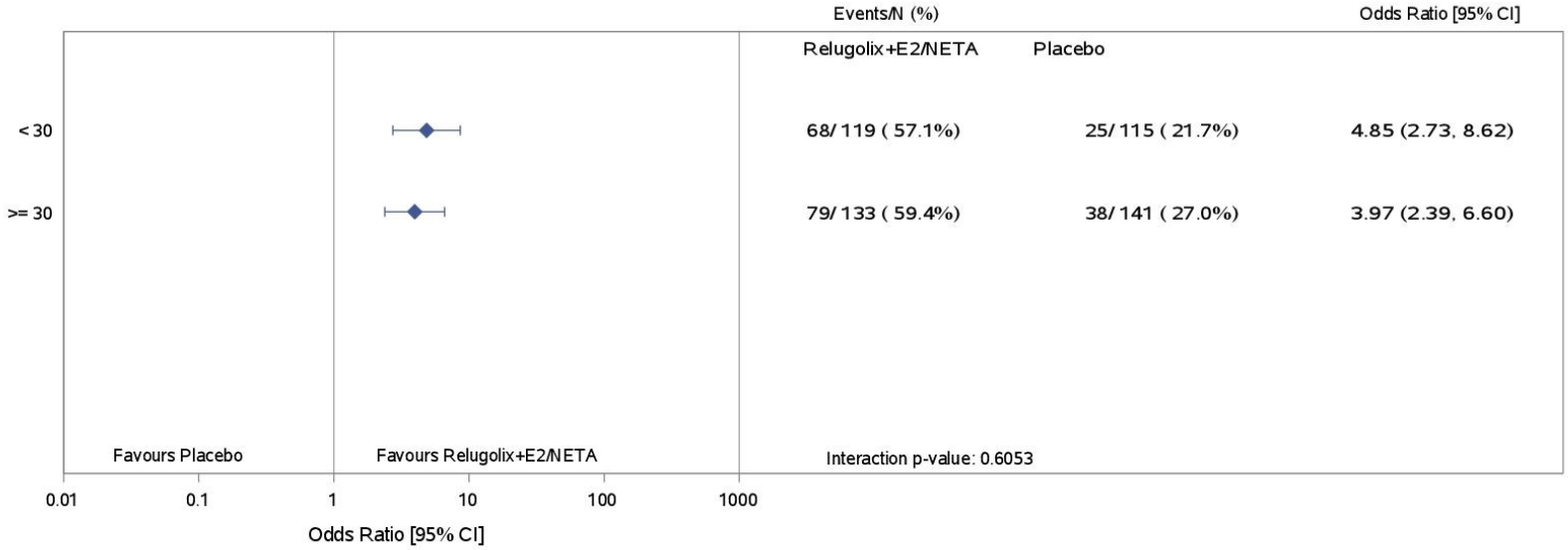
Figure QOL.UFSACT25.MITT.S2.BIN.FP: Proportion of Responders with at Least 25 Points Increase in UFS-QoL Activity Scale Score at Week 24, by Subgroup (mITT Population)
Study: Pooled
Subgroup: BMI (kg/m2) at Baseline



Results are based on a logistic regression model adjusted for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates using a one-stage fixed-effects IPD meta-analysis approach. A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
The interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the Odds Ratio and 95% CI. Missing subgroup levels are not included in estimation of the interaction p-value. The reference group is Placebo.
N: Number of patients in treatment group; NETA: Norethindrone acetate; mITT: Modified intent-to-treat; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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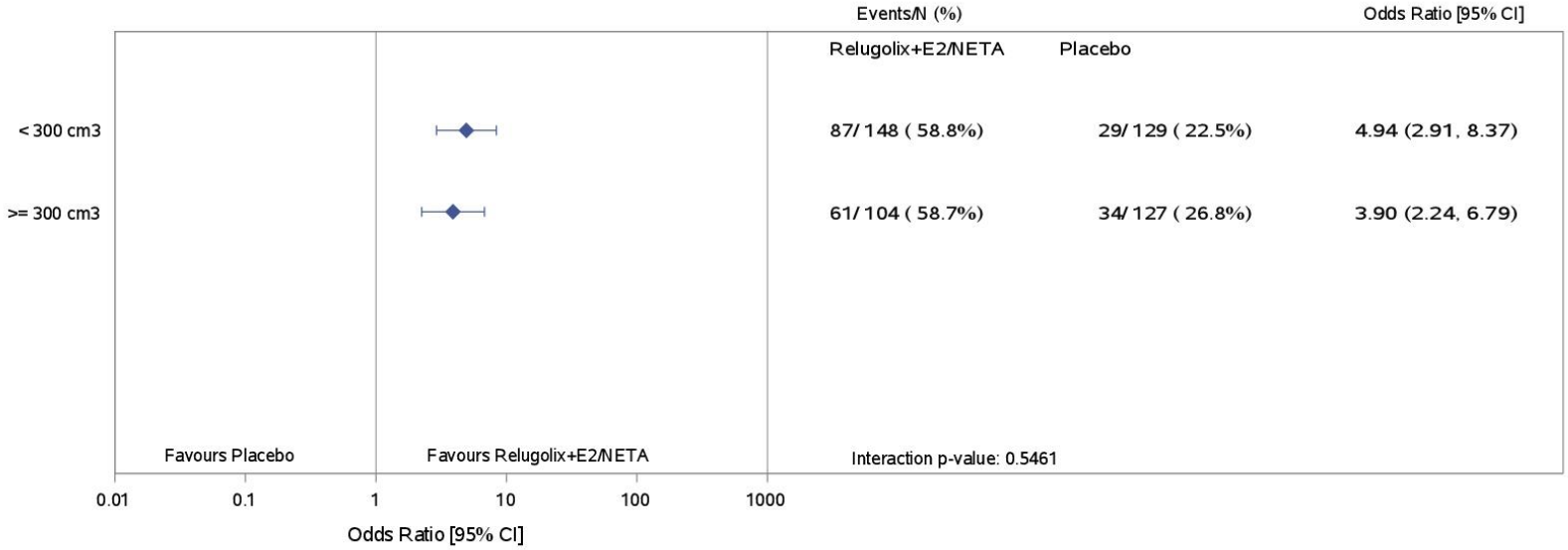
Figure QOL.UFSACT25.MITT.S3.BIN.FP: Proportion of Responders with at Least 25 Points Increase in UFS-QoL Activity Scale Score at Week 24, by Subgroup (mITT Population)
Study: Pooled
Subgroup: Uterine Volume at Baseline (cm3)



Results are based on a logistic regression model adjusted for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates using a one-stage fixed-effects IPD meta-analysis approach. A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
The interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the Odds Ratio and 95% CI. Missing subgroup levels are not included in estimation of the interaction p-value. The reference group is Placebo.
N: Number of patients in treatment group; NETA: Norethindrone acetate; mITT: Modified intent-to-treat; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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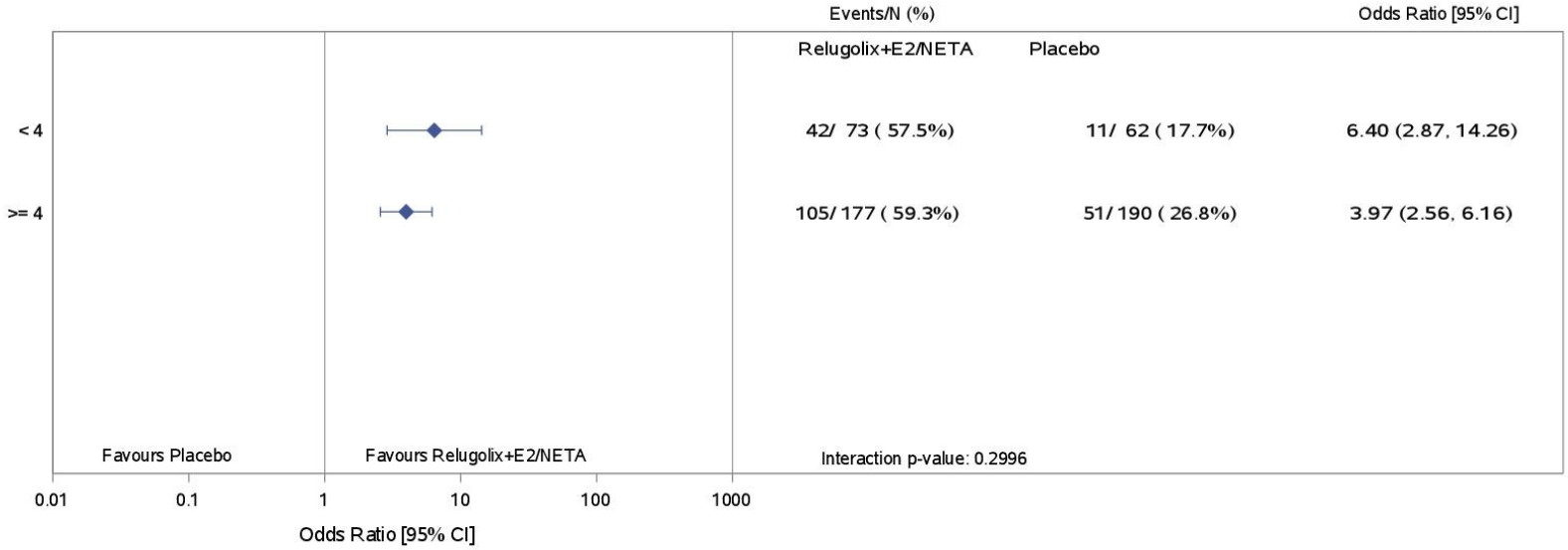
Figure QOL.UFSACT25.MITT.S4.BIN.FP: Proportion of Responders with at Least 25 Points Increase in UFS-QoL Activity Scale Score at Week 24, by Subgroup (mITT Population)
Study: Pooled
Subgroup: Maximum NRS Pain Score at Baseline



Results are based on a logistic regression model adjusted for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates using a one-stage fixed-effects IPD meta-analysis approach. A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
The interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the Odds Ratio and 95% CI. Missing subgroup levels are not included in estimation of the interaction p-value. The reference group is Placebo.
N: Number of patients in treatment group; NETA: Norethindrone acetate; mITT: Modified intent-to-treat; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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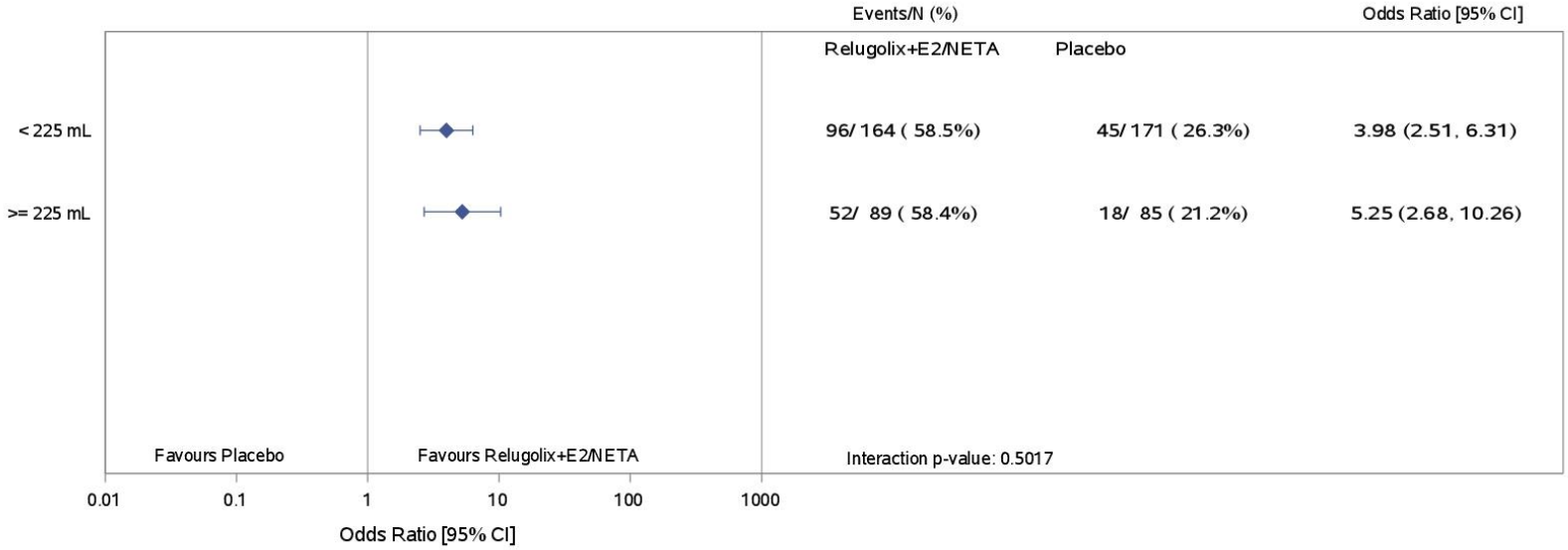
Figure QOL.UFSACT25.MITT.S5.BIN.FP: Proportion of Responders with at Least 25 Points Increase in UFS-QoL Activity Scale Score at Week 24, by Subgroup (mITT Population)
Study: Pooled
Subgroup: MBL Volume at Baseline (mL)



Results are based on a logistic regression model adjusted for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates using a one-stage fixed-effects IPD meta-analysis approach. A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
The interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the Odds Ratio and 95% CI. Missing subgroup levels are not included in estimation of the interaction p-value. The reference group is Placebo.
N: Number of patients in treatment group; NETA: Norethindrone acetate; mITT: Modified intent-to-treat; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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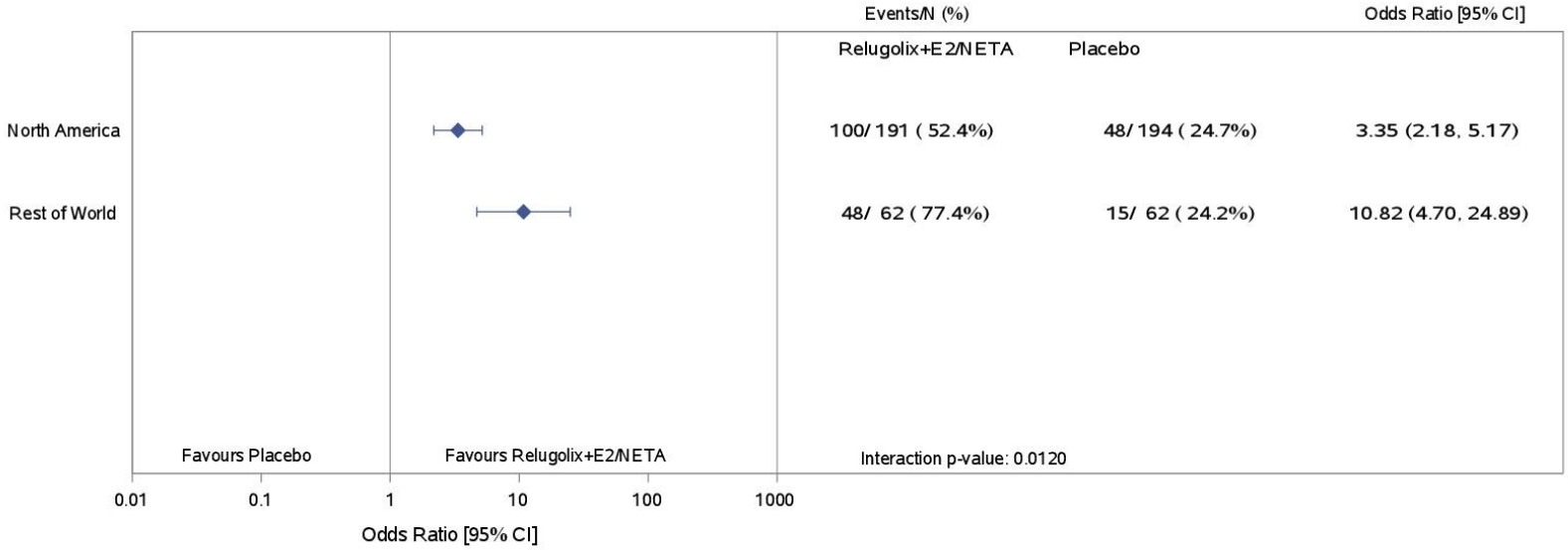
Figure QOL.UFSACT25.MITT.S6.BIN.FP: Proportion of Responders with at Least 25 Points Increase in UFS-QoL Activity Scale Score at Week 24, by Subgroup (mITT Population)
Study: Pooled
Subgroup: Geographic Region I



Results are based on a logistic regression model adjusted for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates using a one-stage fixed-effects IPD meta-analysis approach. A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
The interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the Odds Ratio and 95% CI. Missing subgroup levels are not included in estimation of the interaction p-value. The reference group is Placebo.
N: Number of patients in treatment group; NETA: Norethindrone acetate; mITT: Modified intent-to-treat; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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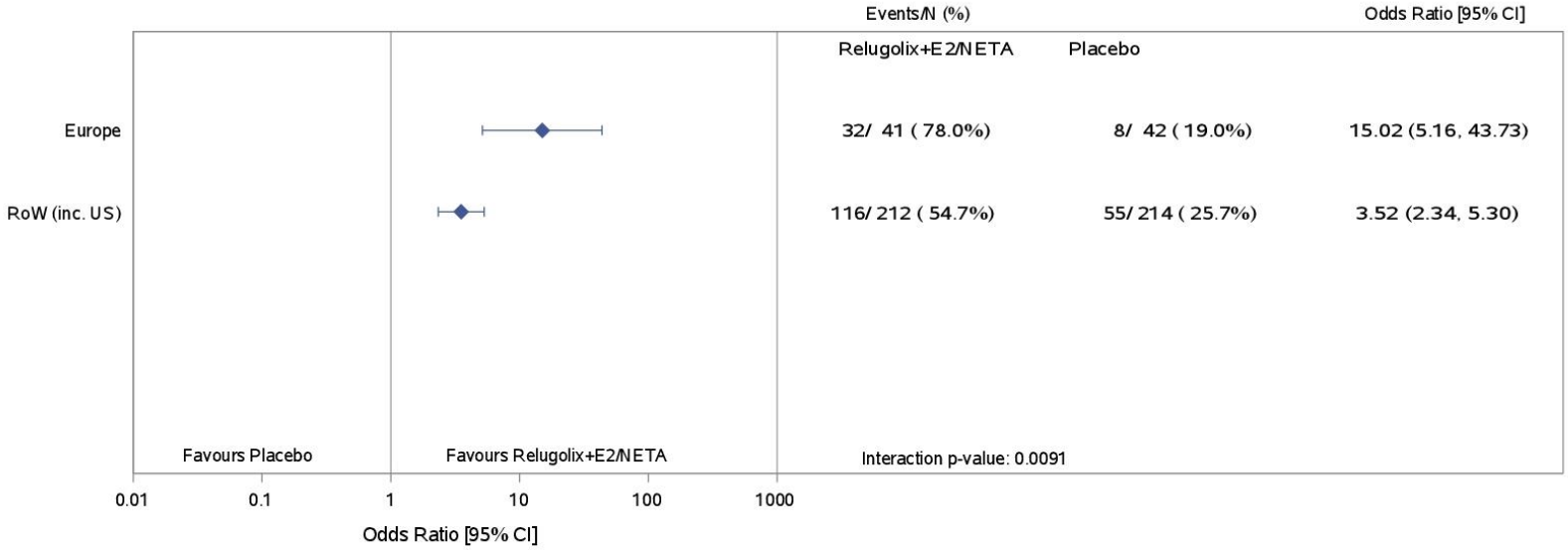
Figure QOL.UFSACT25.MITT.S7.BIN.FP: Proportion of Responders with at Least 25 Points Increase in UFS-QoL Activity Scale Score at Week 24, by Subgroup (mITT Population)
Study: Pooled
Subgroup: Geographic Region II



Results are based on a logistic regression model adjusted for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates using a one-stage fixed-effects IPD meta-analysis approach. A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
The interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the Odds Ratio and 95% CI. Missing subgroup levels are not included in estimation of the interaction p-value. The reference group is Placebo.
N: Number of patients in treatment group; NETA: Norethindrone acetate; mITT: Modified intent-to-treat; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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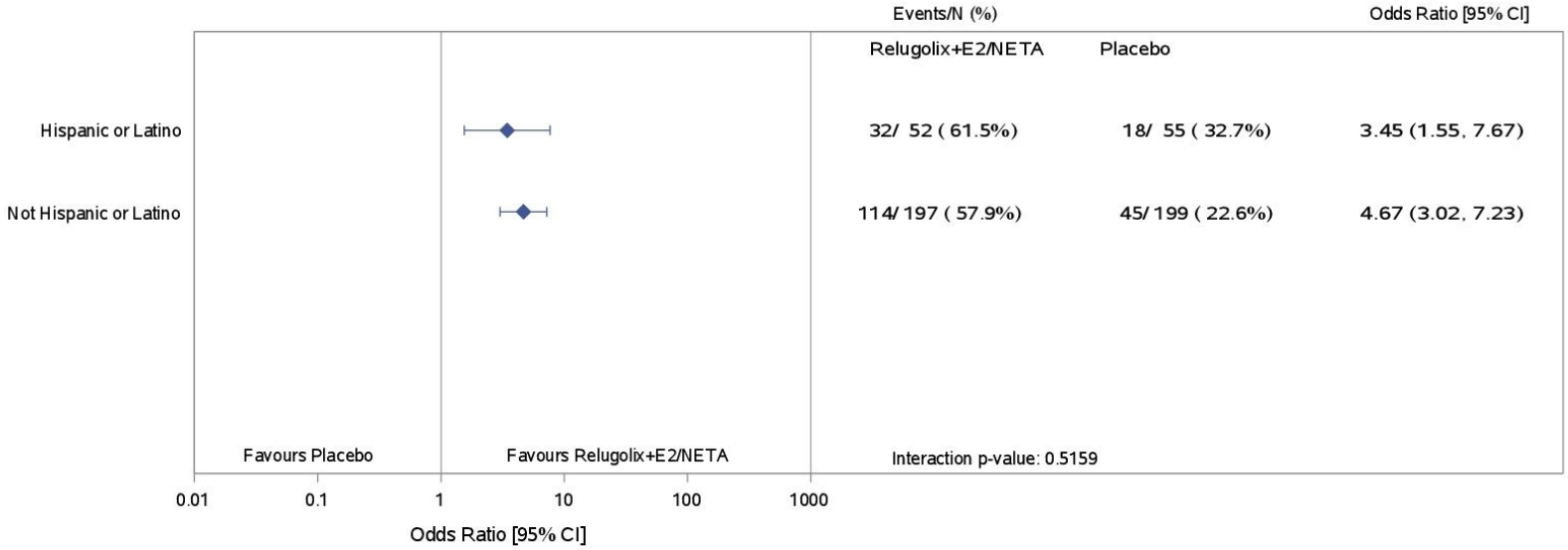
Figure QOL.UFSACT25.MITT.S8.BIN.FP: Proportion of Responders with at Least 25 Points Increase in UFS-QoL Activity Scale Score at Week 24, by Subgroup (mITT Population)
Study: Pooled
Subgroup: Ethnicity



Results are based on a logistic regression model adjusted for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates using a one-stage fixed-effects IPD meta-analysis approach. A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
The interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the Odds Ratio and 95% CI. Missing subgroup levels are not included in estimation of the interaction p-value. The reference group is Placebo.
N: Number of patients in treatment group; NETA: Norethindrone acetate; mITT: Modified intent-to-treat; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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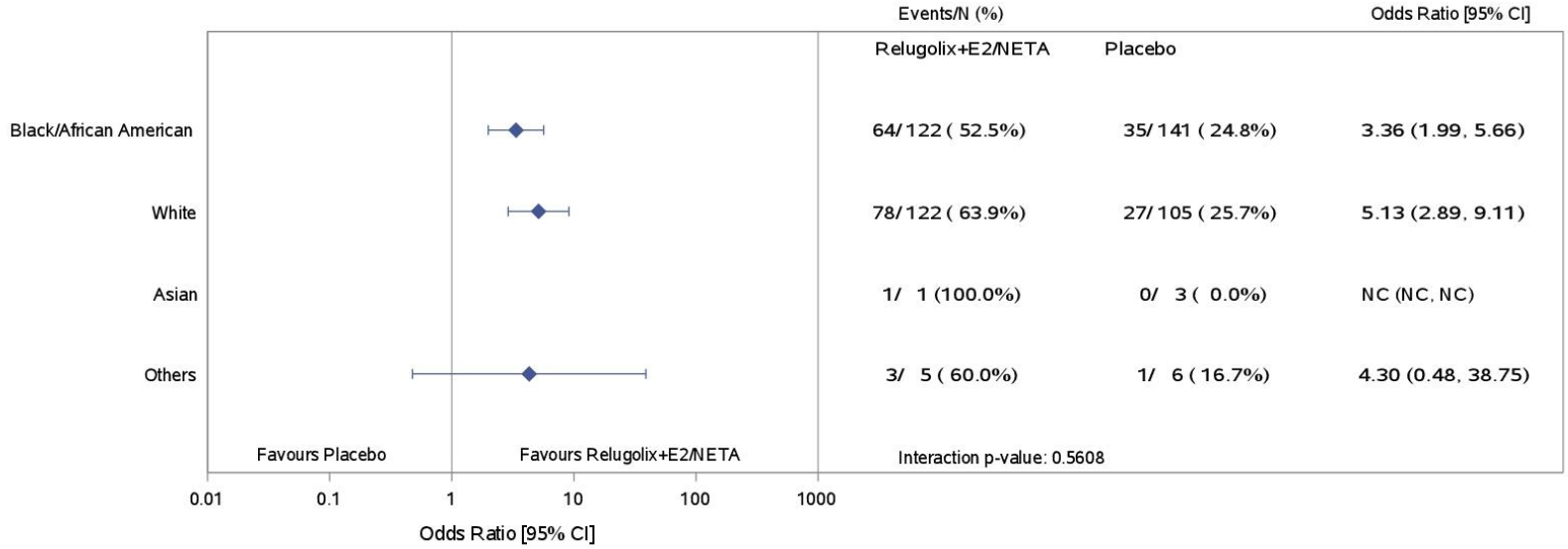
Figure QOL.UFSACT25.MITT.S9.BIN.FP: Proportion of Responders with at Least 25 Points Increase in UFS-QoL Activity Scale Score at Week 24, by Subgroup (mITT Population)
Study: Pooled
Subgroup: Race



Results are based on a logistic regression model adjusted for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates using a one-stage fixed-effects IPD meta-analysis approach. A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
The interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the Odds Ratio and 95% CI. Missing subgroup levels are not included in estimation of the interaction p-value. The reference group is Placebo.
N: Number of patients in treatment group; NETA: Norethindrone acetate; mITT: Modified intent-to-treat; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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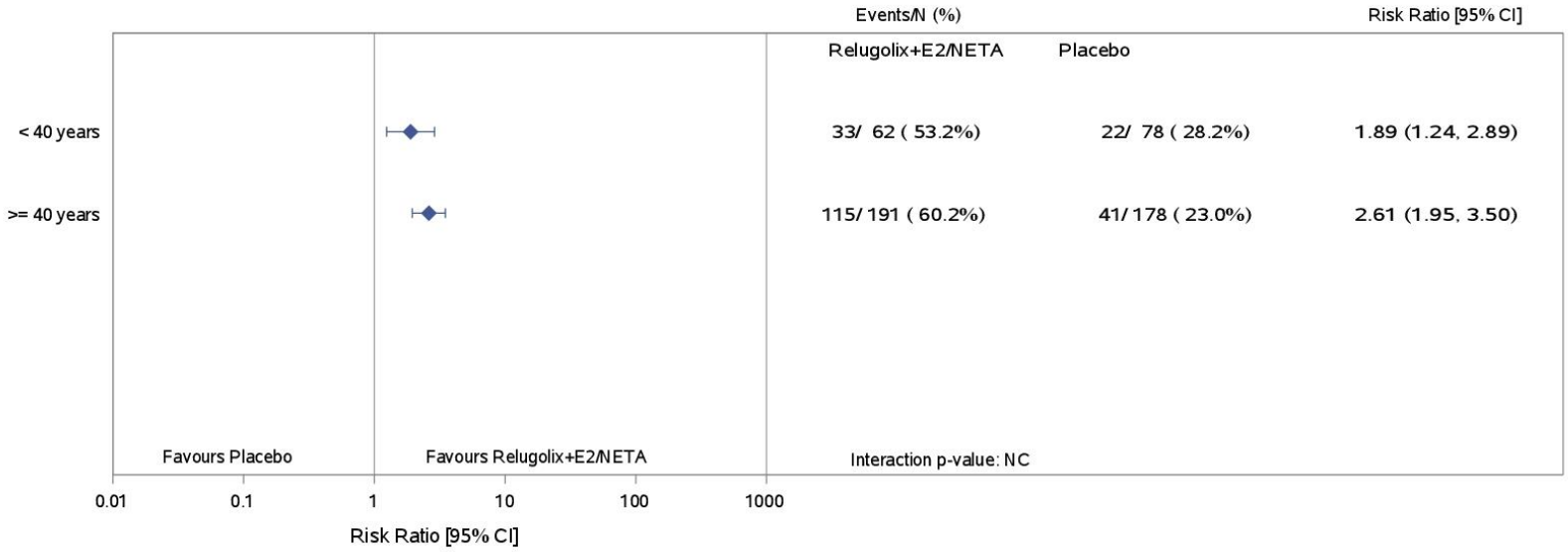
Figure QOL.UFSACT25.MITT.S1.BIN.FP.RR: Proportion of Responders with at Least 25 Points Increase in UFS-QoL Activity Scale Score at Week 24, by Subgroup (mITT Population) - Risk Ratio
Study: Pooled
Subgroup: Age (years)



Results are based on a Cochran-Mantel-Haenszel approach stratified by study using a one-stage fixed-effects IPD meta-analysis. A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
The reference group is Placebo.
N: Number of patients in treatment group; NETA: Norethindrone acetate; mITT: Modified intent-to-treat; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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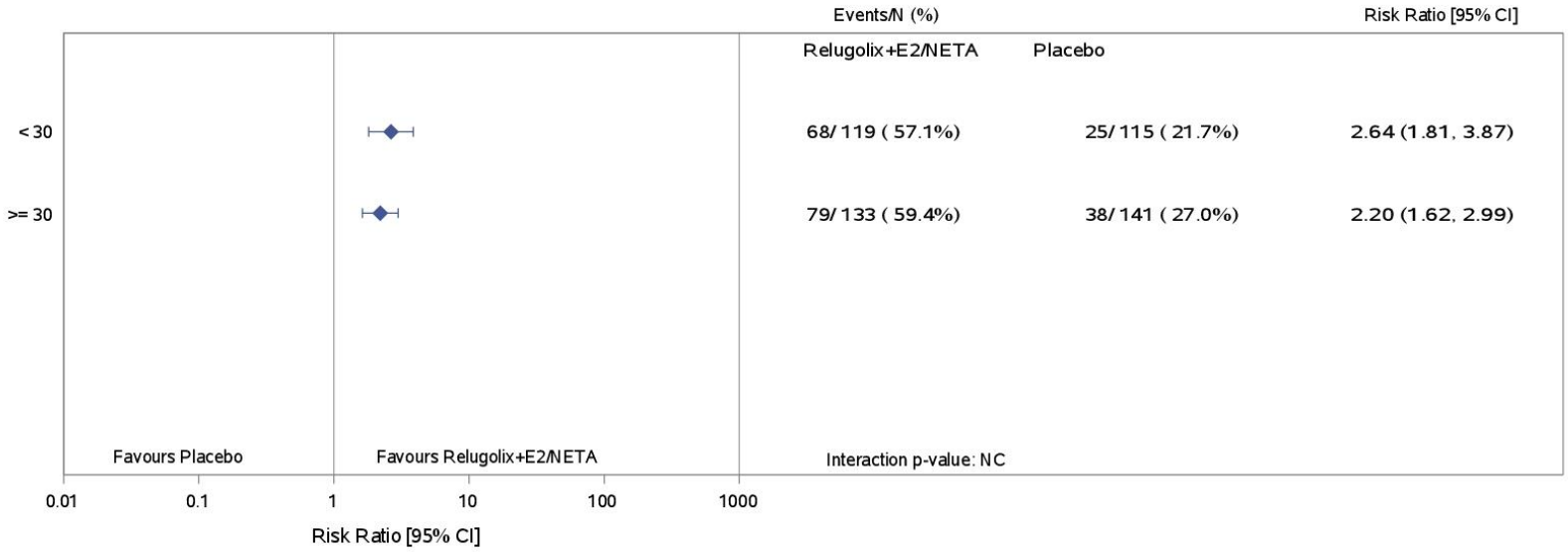
Figure QOL.UFSACT25.MITT.S2.BIN.FP.RR: Proportion of Responders with at Least 25 Points Increase in UFS-QoL Activity Scale Score at Week 24, by Subgroup (mITT Population) - Risk Ratio
Study: Pooled
Subgroup: BMI (kg/m2) at Baseline



Results are based on a Cochran-Mantel-Haenszel approach stratified by study using a one-stage fixed-effects IPD meta-analysis. A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
The reference group is Placebo.
N: Number of patients in treatment group; NETA: Norethindrone acetate; mITT: Modified intent-to-treat; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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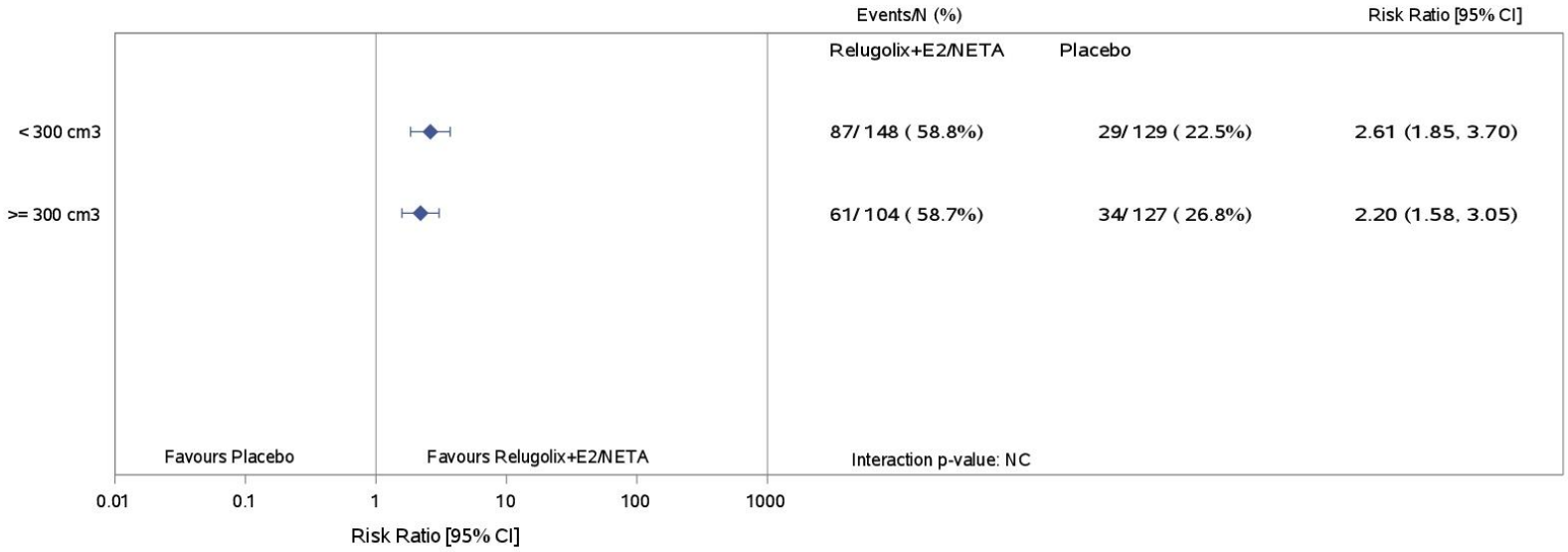
Figure QOL.UFSACT25.MITT.S3.BIN.FP.RR: Proportion of Responders with at Least 25 Points Increase in UFS-QoL Activity Scale Score at Week 24, by Subgroup (mITT Population) - Risk Ratio
Study: Pooled
Subgroup: Uterine Volume at Baseline (cm3)



Results are based on a Cochran-Mantel-Haenszel approach stratified by study using a one-stage fixed-effects IPD meta-analysis. A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
The reference group is Placebo.
N: Number of patients in treatment group; NETA: Norethindrone acetate; mITT: Modified intent-to-treat; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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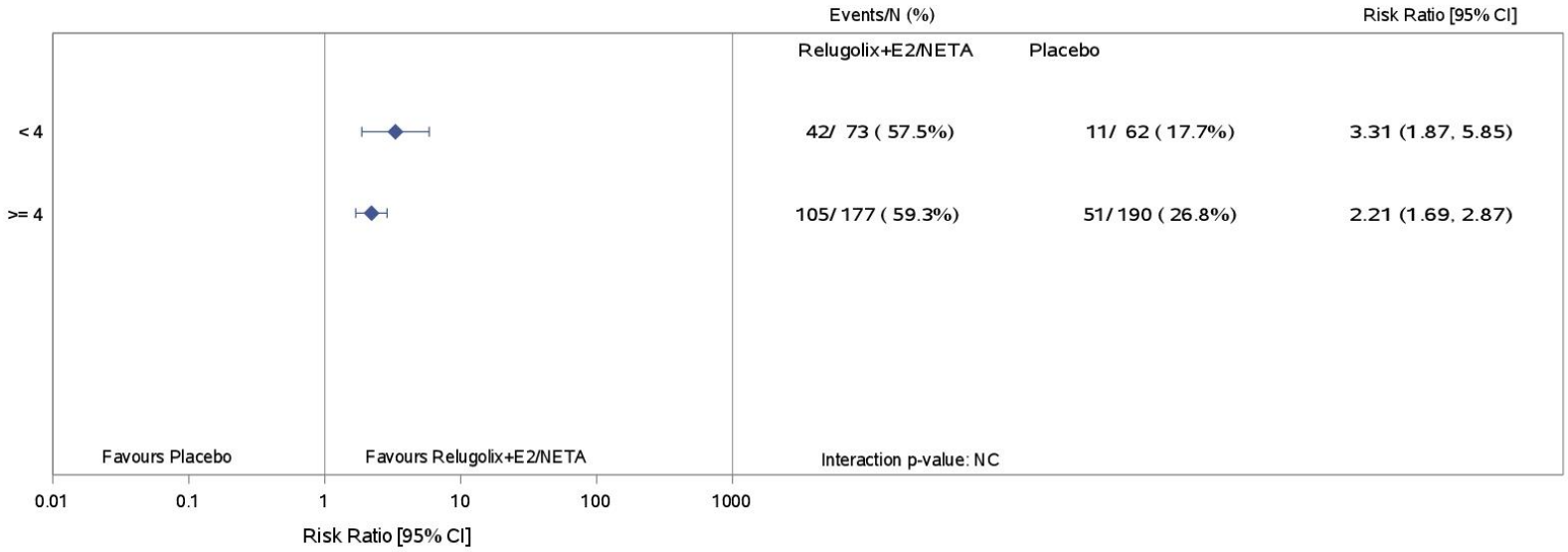
Figure QOL.UFSACT25.MITT.S4.BIN.FP.RR: Proportion of Responders with at Least 25 Points Increase in UFS-QoL Activity Scale Score at Week 24, by Subgroup (mITT Population) - Risk Ratio
Study: Pooled
Subgroup: Maximum NRS Pain Score at Baseline



Results are based on a Cochran-Mantel-Haenszel approach stratified by study using a one-stage fixed-effects IPD meta-analysis. A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
The reference group is Placebo.
N: Number of patients in treatment group; NETA: Norethindrone acetate; mITT: Modified intent-to-treat; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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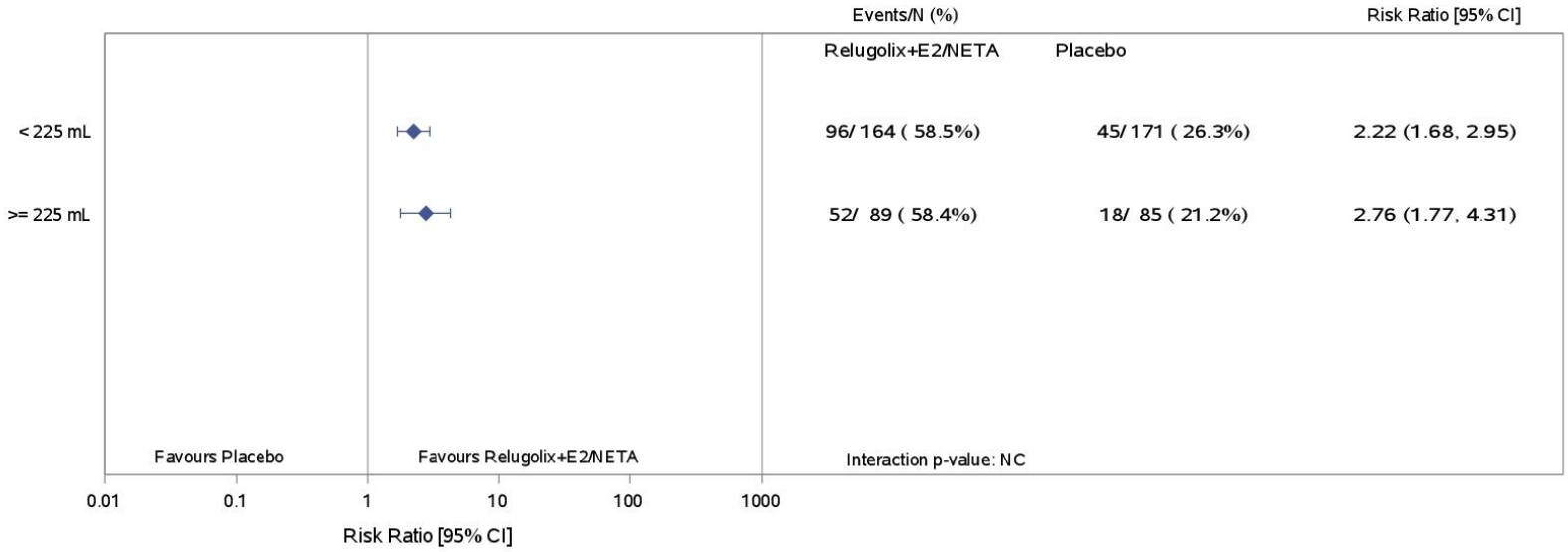
Figure QOL.UFSACT25.MITT.S5.BIN.FP.RR: Proportion of Responders with at Least 25 Points Increase in UFS-QoL Activity Scale Score at Week 24, by Subgroup (mITT Population) - Risk Ratio
Study: Pooled
Subgroup: MBL Volume at Baseline (mL)



Results are based on a Cochran-Mantel-Haenszel approach stratified by study using a one-stage fixed-effects IPD meta-analysis. A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
The reference group is Placebo.
N: Number of patients in treatment group; NETA: Norethindrone acetate; mITT: Modified intent-to-treat; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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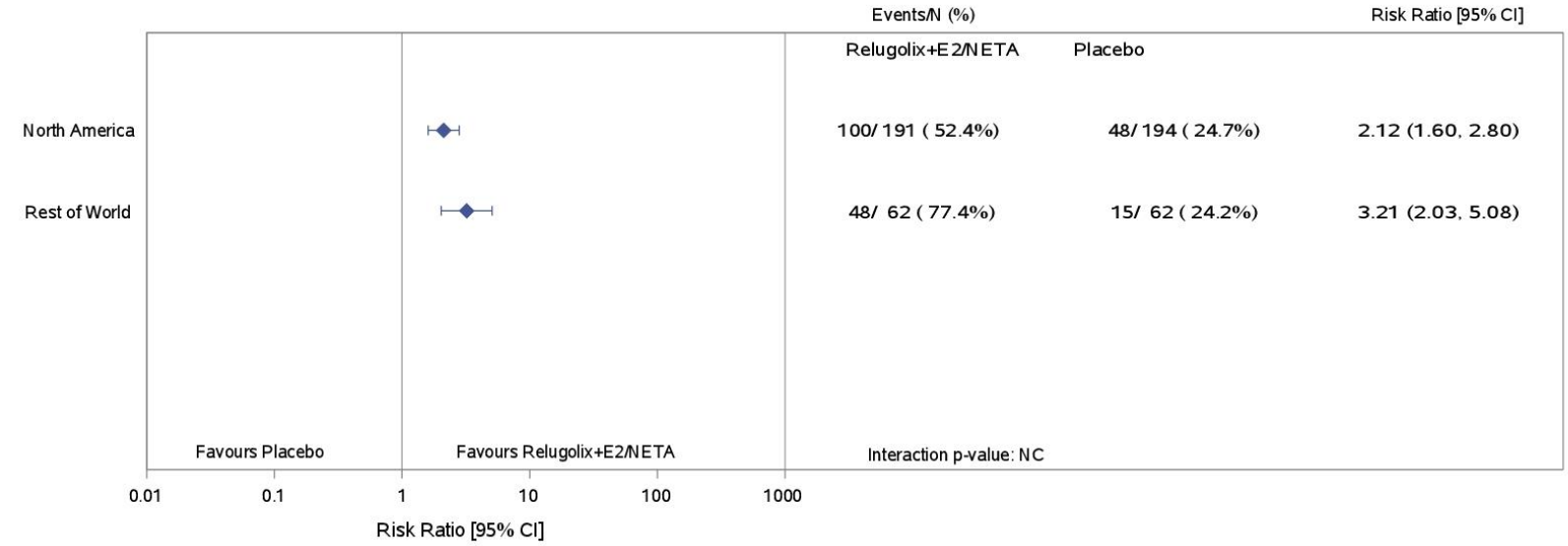
Figure QOL.UFSACT25.MITT.S6.BIN.FP.RR: Proportion of Responders with at Least 25 Points Increase in UFS-QoL Activity Scale Score at Week 24, by Subgroup (mITT Population) - Risk Ratio
Study: Pooled
Subgroup: Geographic Region I



Results are based on a Cochran-Mantel-Haenszel approach stratified by study using a one-stage fixed-effects IPD meta-analysis. A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
The reference group is Placebo.
N: Number of patients in treatment group; NETA: Norethindrone acetate; mITT: Modified intent-to-treat; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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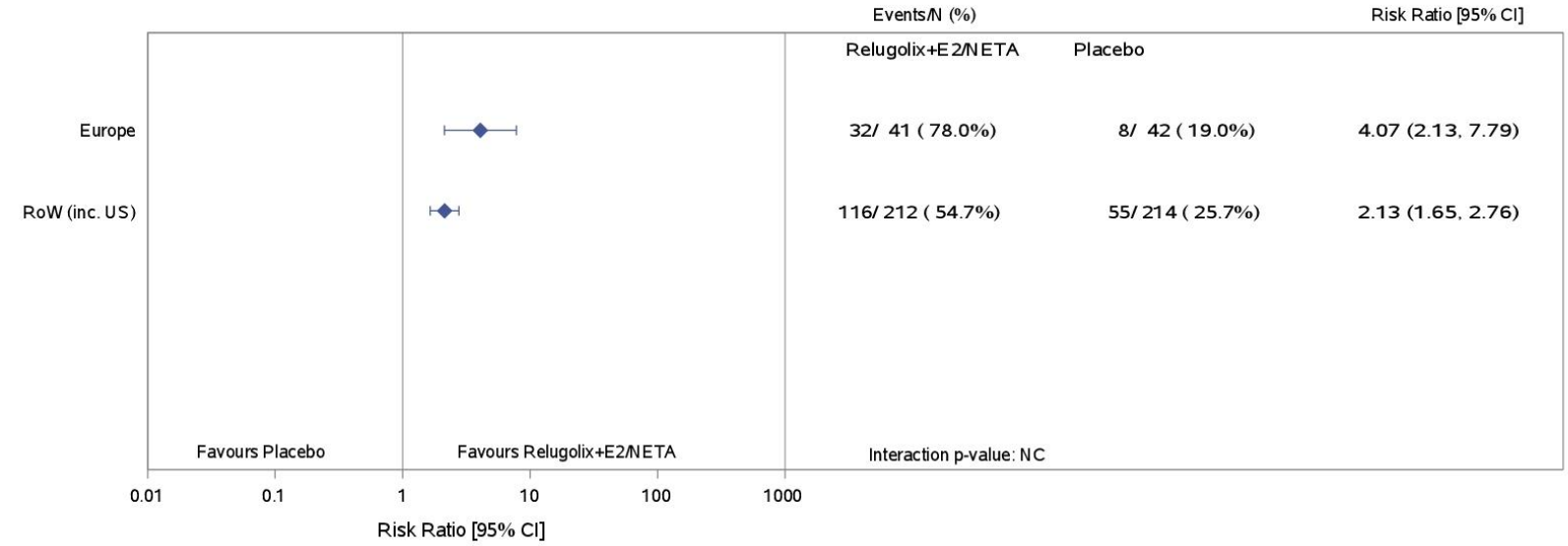
Figure QOL.UFSACT25.MITT.S7.BIN.FP.RR: Proportion of Responders with at Least 25 Points Increase in UFS-QoL Activity Scale Score at Week 24, by Subgroup (mITT Population) - Risk Ratio
Study: Pooled
Subgroup: Geographic Region II



Results are based on a Cochran-Mantel-Haenszel approach stratified by study using a one-stage fixed-effects IPD meta-analysis. A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
The reference group is Placebo.
N: Number of patients in treatment group; NETA: Norethindrone acetate; mITT: Modified intent-to-treat; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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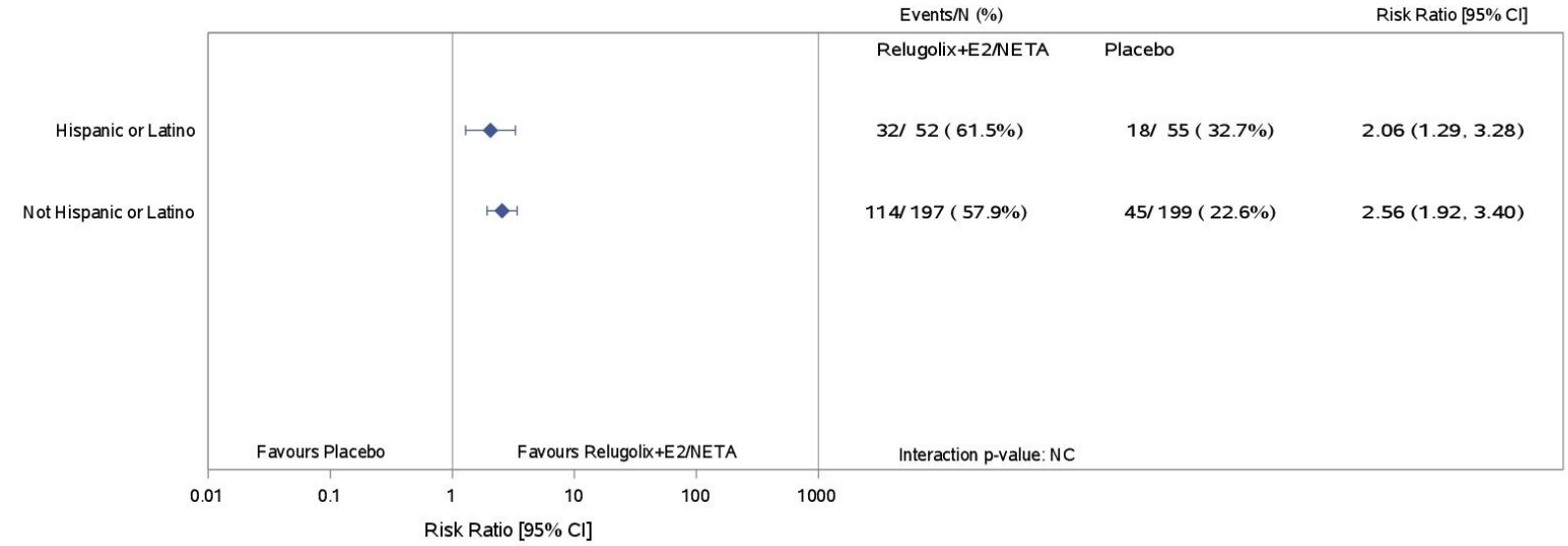
Figure QOL.UFSACT25.MITT.S8.BIN.FP.RR: Proportion of Responders with at Least 25 Points Increase in UFS-QoL Activity Scale Score at Week 24, by Subgroup (mITT Population) - Risk Ratio
Study: Pooled
Subgroup: Ethnicity



Results are based on a Cochran-Mantel-Haenszel approach stratified by study using a one-stage fixed-effects IPD meta-analysis. A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
The reference group is Placebo.
N: Number of patients in treatment group; NETA: Norethindrone acetate; mITT: Modified intent-to-treat; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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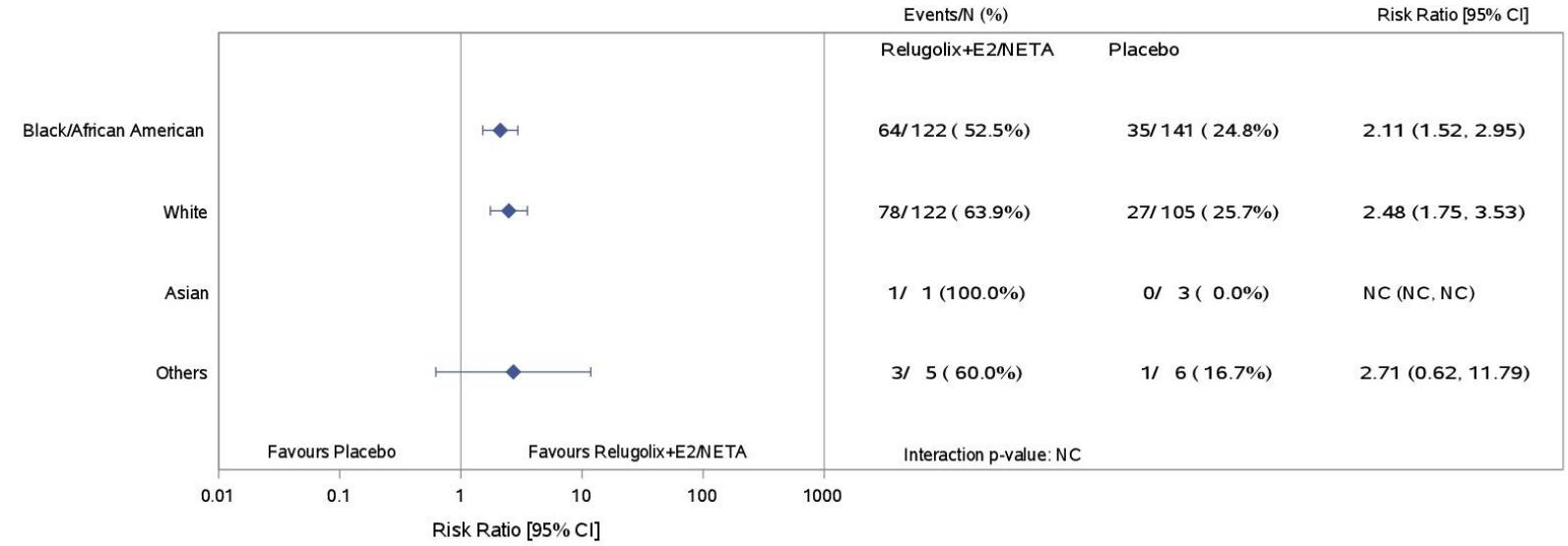
Figure QOL.UFSACT25.MITT.S9.BIN.FP.RR: Proportion of Responders with at Least 25 Points Increase in UFS-QoL Activity Scale Score at Week 24, by Subgroup (mITT Population) - Risk Ratio
Study: Pooled
Subgroup: Race



Results are based on a Cochran-Mantel-Haenszel approach stratified by study using a one-stage fixed-effects IPD meta-analysis. A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
The reference group is Placebo.
N: Number of patients in treatment group; NETA: Norethindrone acetate; mITT: Modified intent-to-treat; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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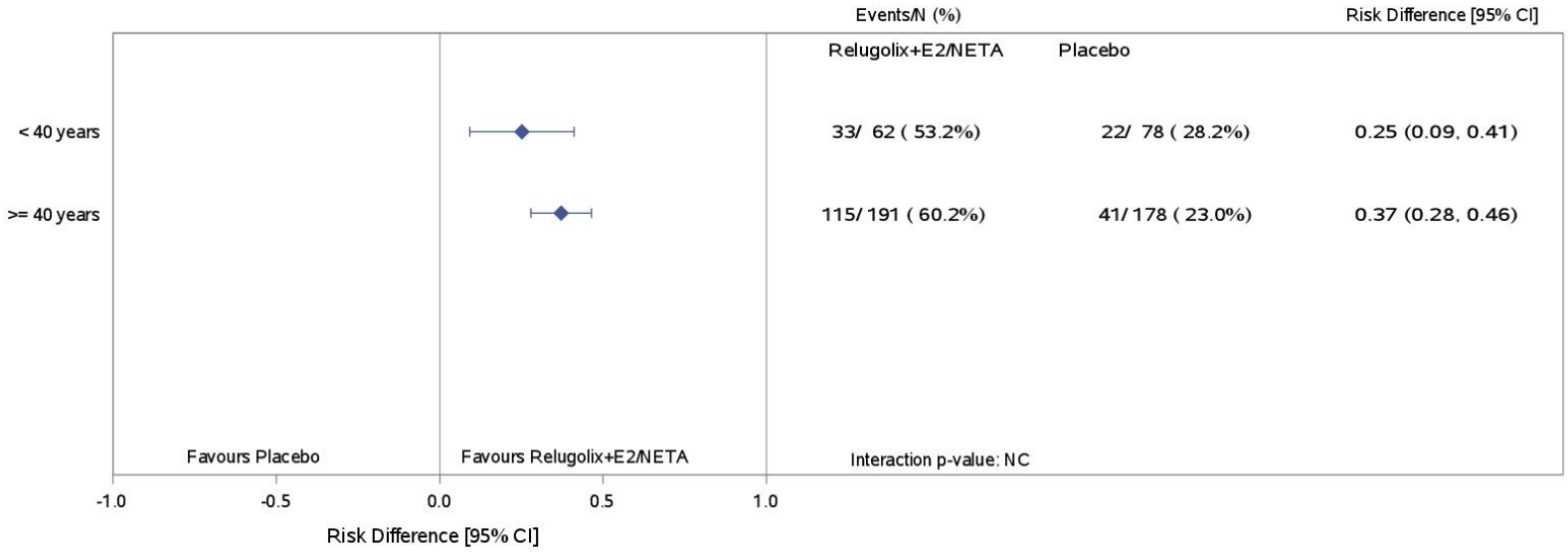
Figure QOL.UFSACT25.MITT.S1.BIN.FP.RD: Proportion of Responders with at Least 25 Points Increase in UFS-QoL Activity Scale Score at Week 24, by Subgroup (mITT Population) - Risk Difference
Study: Pooled
Subgroup: Age (years)



Results are based on a Mantel-Haenszel approach stratified by study using a one-stage fixed-effects IPD meta-analysis.
The reference group is Placebo.
N: Number of patients in treatment group; NETA: Norethindrone acetate; mITT: Modified intent-to-treat; NC: Not Calculated; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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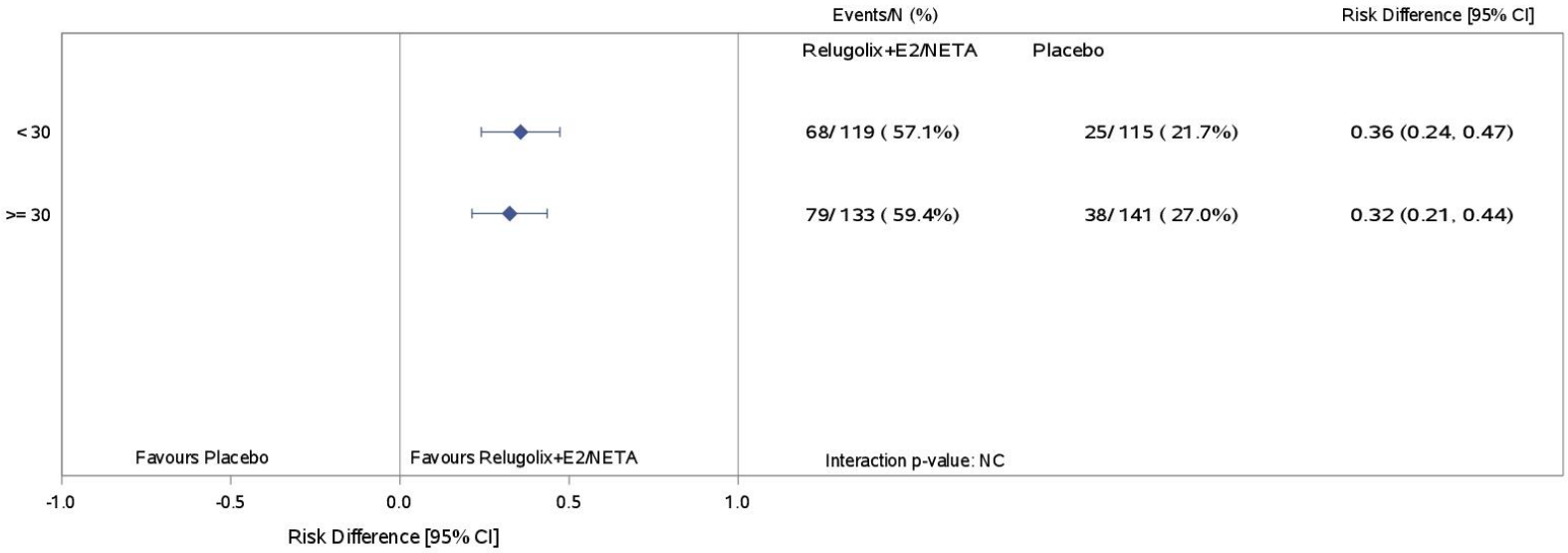
Figure QOL.UFSACT25.MITT.S2.BIN.FP.RD: Proportion of Responders with at Least 25 Points Increase in UFS-QoL Activity Scale Score at Week 24, by Subgroup (mITT Population) - Risk Difference
Study: Pooled
Subgroup: BMI (kg/m2) at Baseline



Results are based on a Mantel-Haenszel approach stratified by study using a one-stage fixed-effects IPD meta-analysis.
The reference group is Placebo.
N: Number of patients in treatment group; NETA: Norethindrone acetate; mITT: Modified intent-to-treat; NC: Not Calculated; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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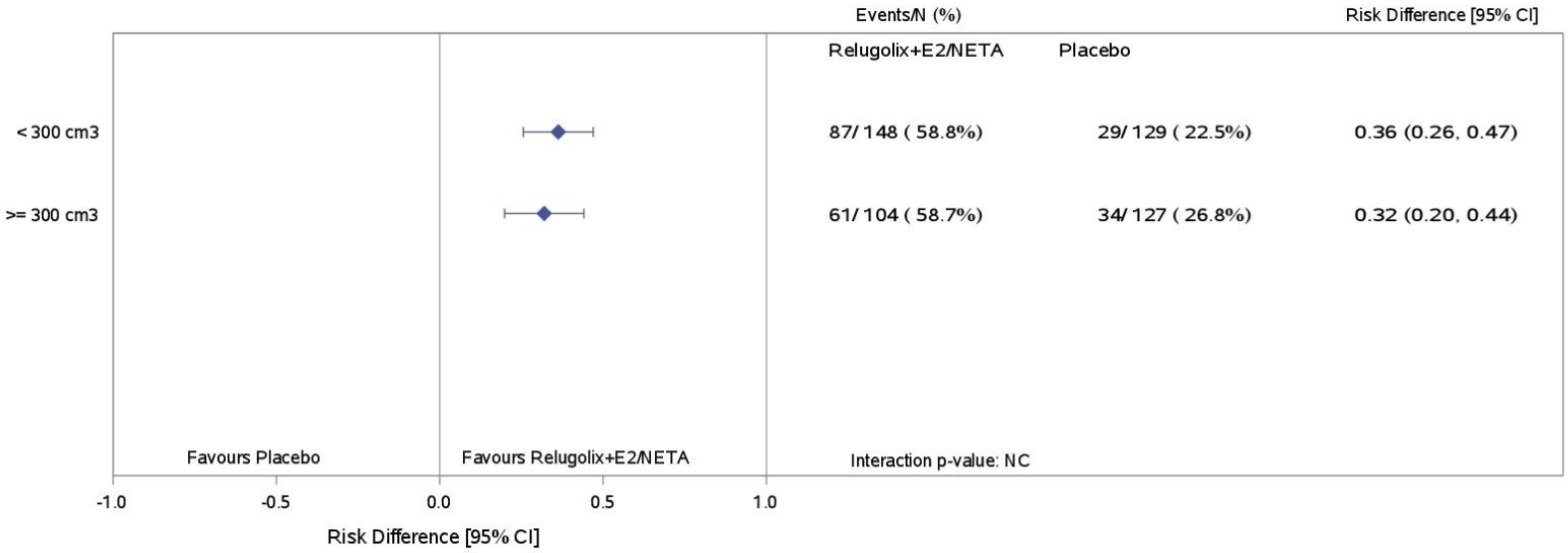
Figure QOL.UFSACT25.MITT.S3.BIN.FP.RD: Proportion of Responders with at Least 25 Points Increase in UFS-QoL Activity Scale Score at Week 24, by Subgroup (mITT Population) - Risk Difference
Study: Pooled
Subgroup: Uterine Volume at Baseline (cm3)



Results are based on a Mantel-Haenszel approach stratified by study using a one-stage fixed-effects IPD meta-analysis.
The reference group is Placebo.
N: Number of patients in treatment group; NETA: Norethindrone acetate; mITT: Modified intent-to-treat; NC: Not Calculated; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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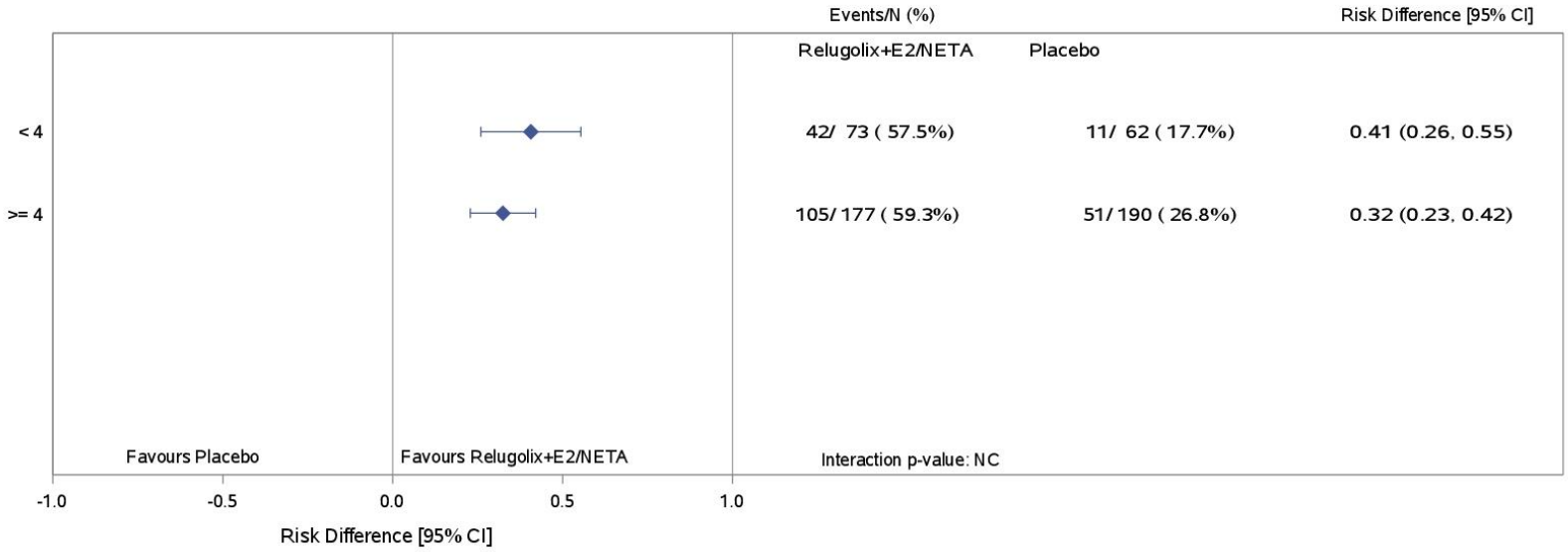
Figure QOL.UFSACT25.MITT.S4.BIN.FP.RD: Proportion of Responders with at Least 25 Points Increase in UFS-QoL Activity Scale Score at Week 24, by Subgroup (mITT Population) - Risk Difference
Study: Pooled
Subgroup: Maximum NRS Pain Score at Baseline



Results are based on a Mantel-Haenszel approach stratified by study using a one-stage fixed-effects IPD meta-analysis.
The reference group is Placebo.
N: Number of patients in treatment group; NETA: Norethindrone acetate; mITT: Modified intent-to-treat; NC: Not Calculated; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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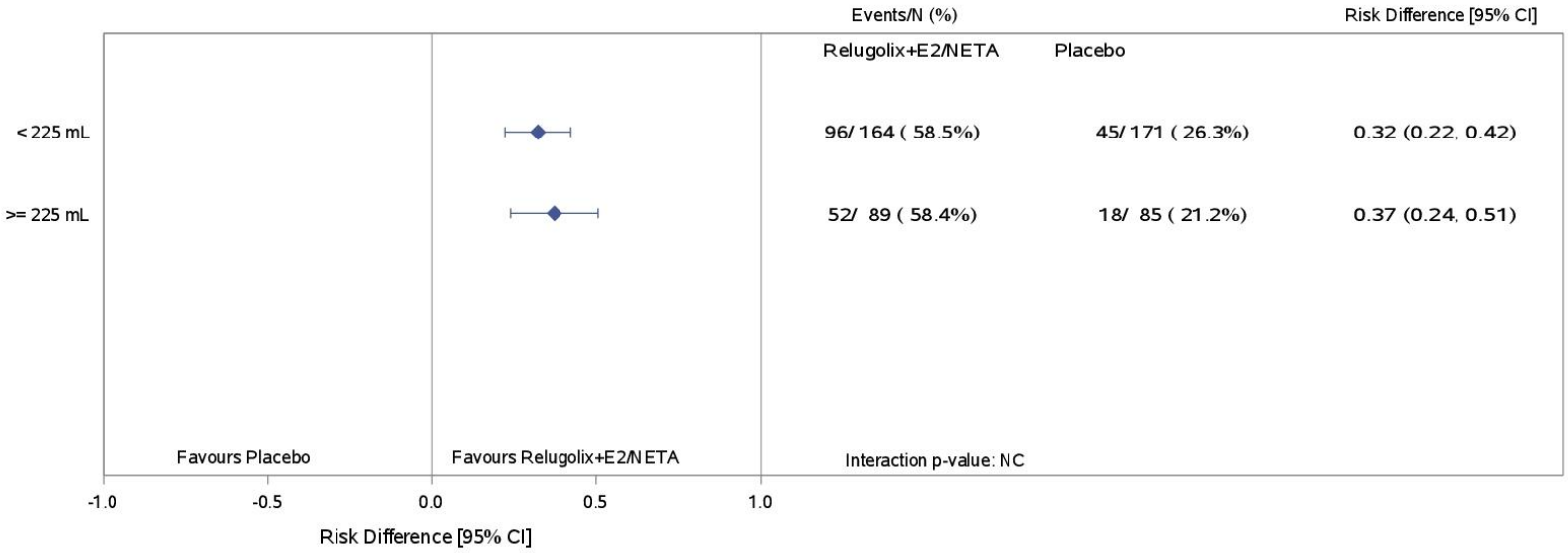
Figure QOL.UFSACT25.MITT.S5.BIN.FP.RD: Proportion of Responders with at Least 25 Points Increase in UFS-QoL Activity Scale Score at Week 24, by Subgroup (mITT Population) - Risk Difference
Study: Pooled
Subgroup: MBL Volume at Baseline (mL)



Results are based on a Mantel-Haenszel approach stratified by study using a one-stage fixed-effects IPD meta-analysis.
The reference group is Placebo.
N: Number of patients in treatment group; NETA: Norethindrone acetate; mITT: Modified intent-to-treat; NC: Not Calculated; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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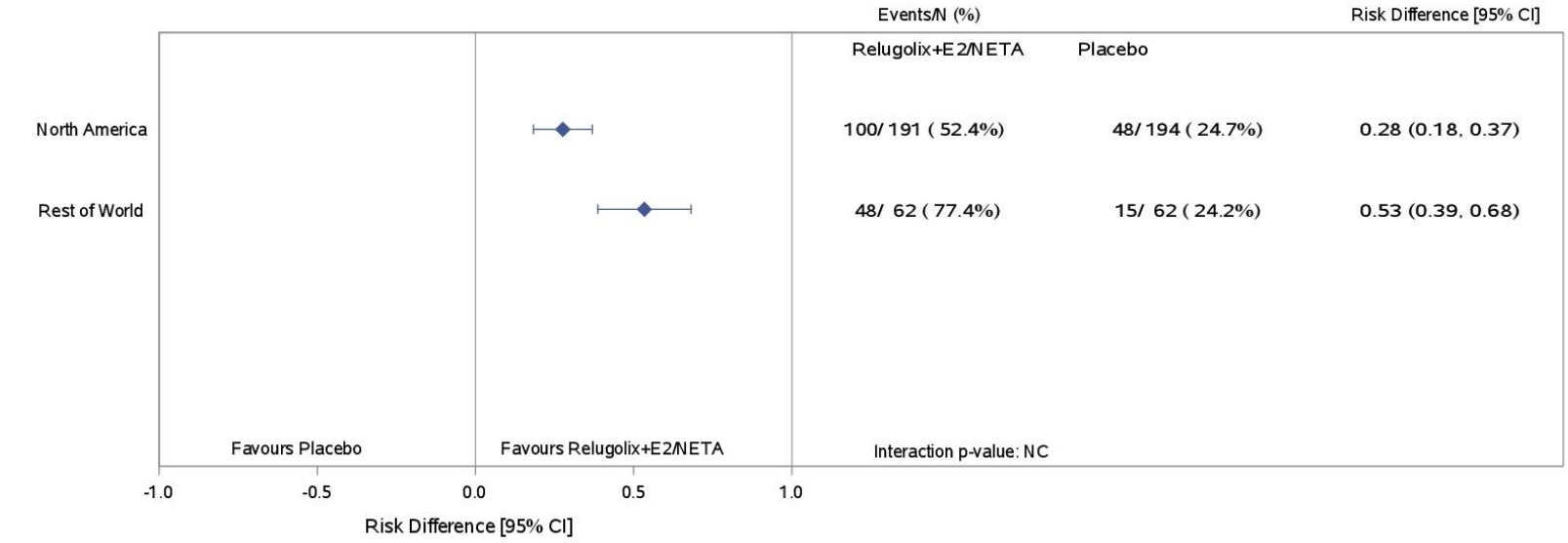
Figure QOL.UFSACT25.MITT.S6.BIN.FP.RD: Proportion of Responders with at Least 25 Points Increase in UFS-QoL Activity Scale Score at Week 24, by Subgroup (mITT Population) - Risk Difference
Study: Pooled
Subgroup: Geographic Region I



Results are based on a Mantel-Haenszel approach stratified by study using a one-stage fixed-effects IPD meta-analysis.
The reference group is Placebo.
N: Number of patients in treatment group; NETA: Norethindrone acetate; mITT: Modified intent-to-treat; NC: Not Calculated; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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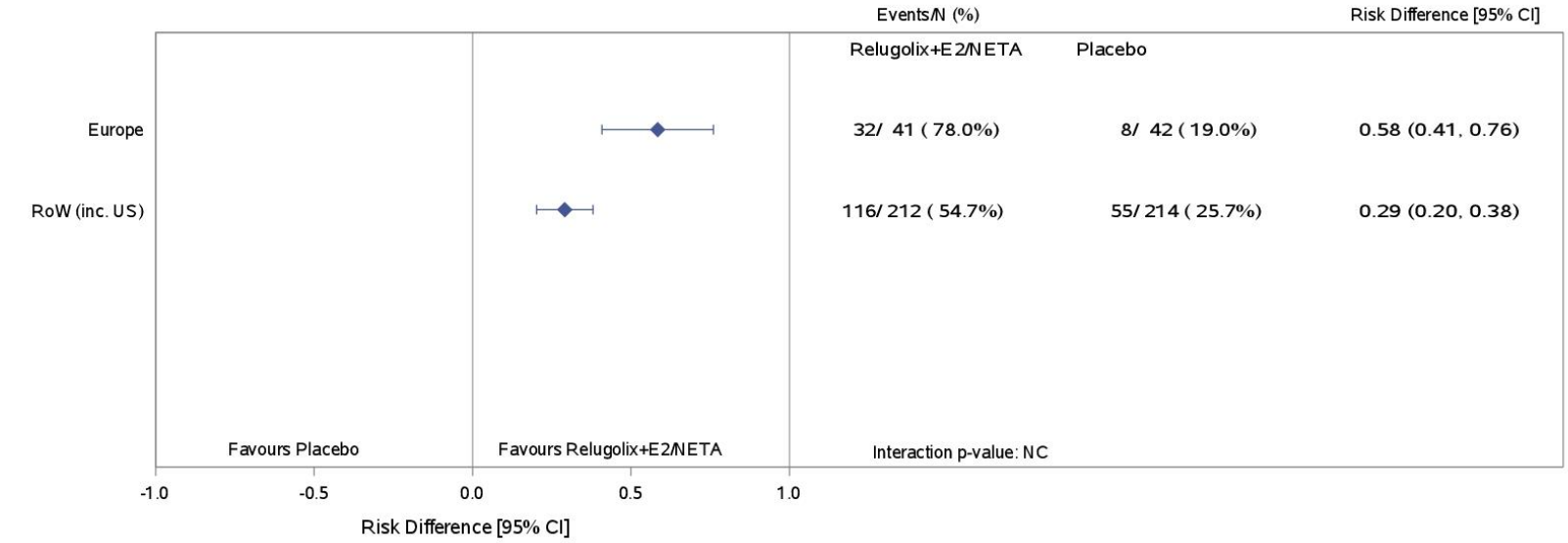
Figure QOL.UFSACT25.MITT.S7.BIN.FP.RD: Proportion of Responders with at Least 25 Points Increase in UFS-QoL Activity Scale Score at Week 24, by Subgroup (mITT Population) - Risk Difference
Study: Pooled
Subgroup: Geographic Region II



Results are based on a Mantel-Haenszel approach stratified by study using a one-stage fixed-effects IPD meta-analysis.
The reference group is Placebo.
N: Number of patients in treatment group; NETA: Norethindrone acetate; mITT: Modified intent-to-treat; NC: Not Calculated; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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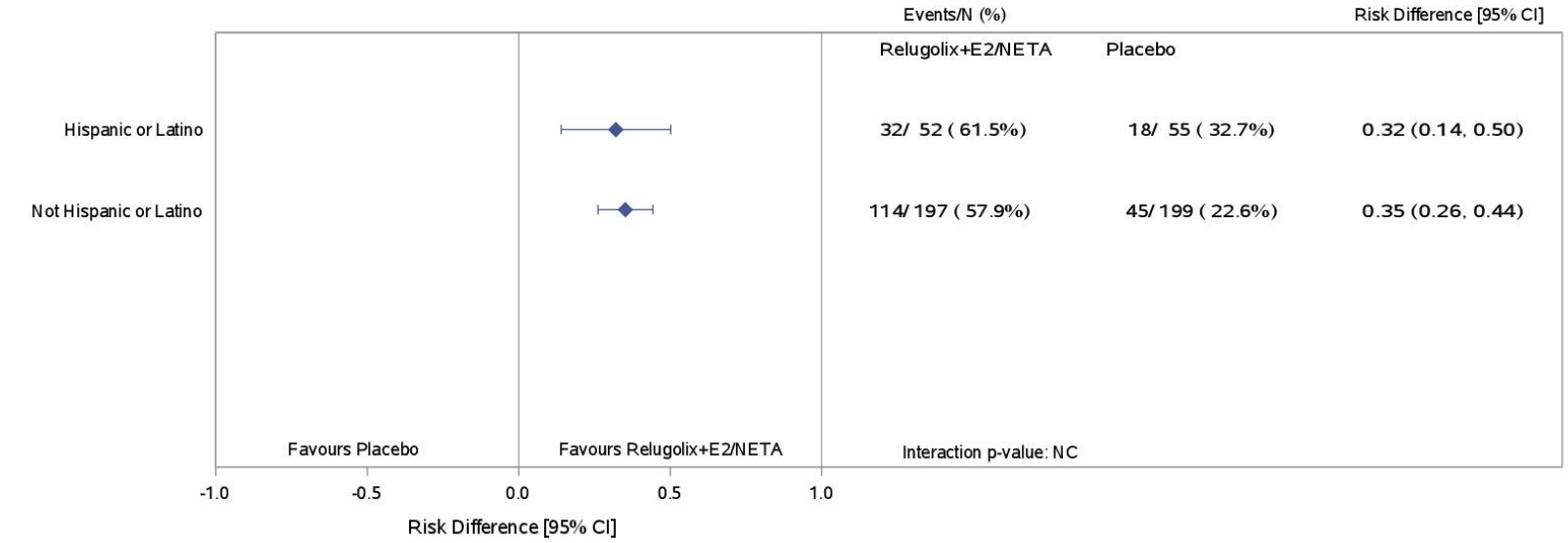
Figure QOL.UFSACT25.MITT.S8.BIN.FP.RD: Proportion of Responders with at Least 25 Points Increase in UFS-QoL Activity Scale Score at Week 24, by Subgroup (mITT Population) - Risk Difference
Study: Pooled
Subgroup: Ethnicity



Results are based on a Mantel-Haenszel approach stratified by study using a one-stage fixed-effects IPD meta-analysis.
The reference group is Placebo.
N: Number of patients in treatment group; NETA: Norethindrone acetate; mITT: Modified intent-to-treat; NC: Not Calculated; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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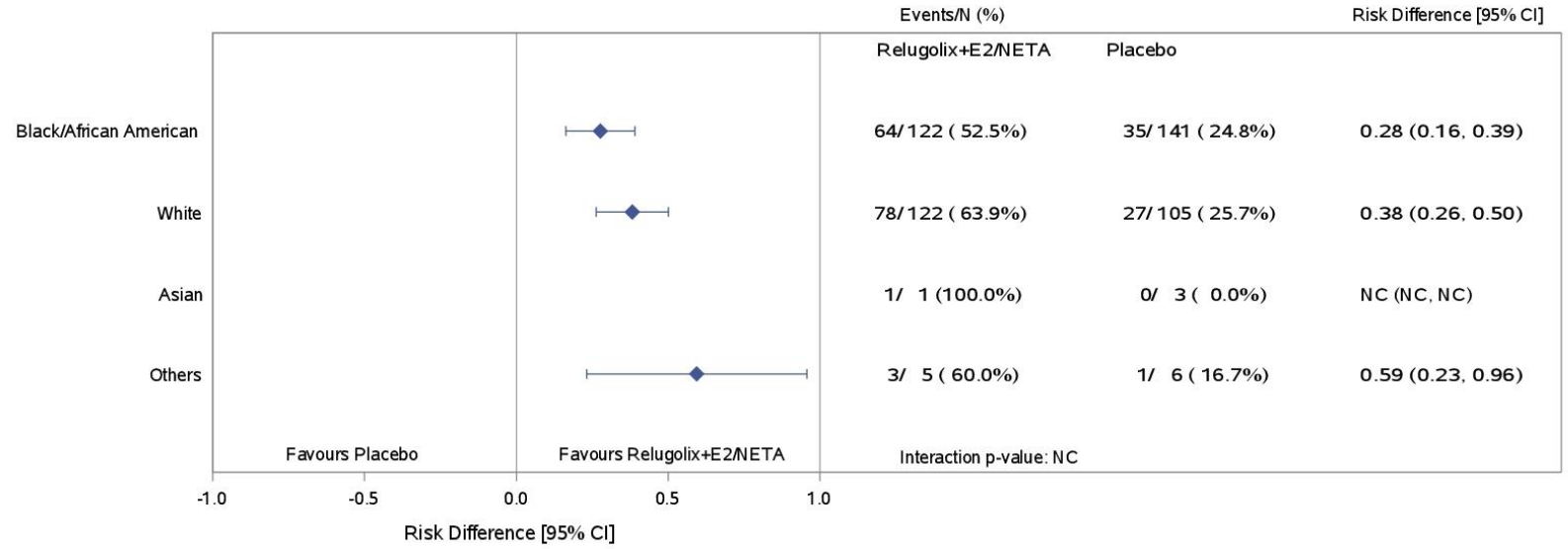
Figure QOL.UFSACT25.MITT.S9.BIN.FP.RD: Proportion of Responders with at Least 25 Points Increase in UFS-QoL Activity Scale Score at Week 24, by Subgroup (mITT Population) - Risk Difference
Study: Pooled
Subgroup: Race



Results are based on a Mantel-Haenszel approach stratified by study using a one-stage fixed-effects IPD meta-analysis.
The reference group is Placebo.
N: Number of patients in treatment group; NETA: Norethindrone acetate; mITT: Modified intent-to-treat; NC: Not Calculated; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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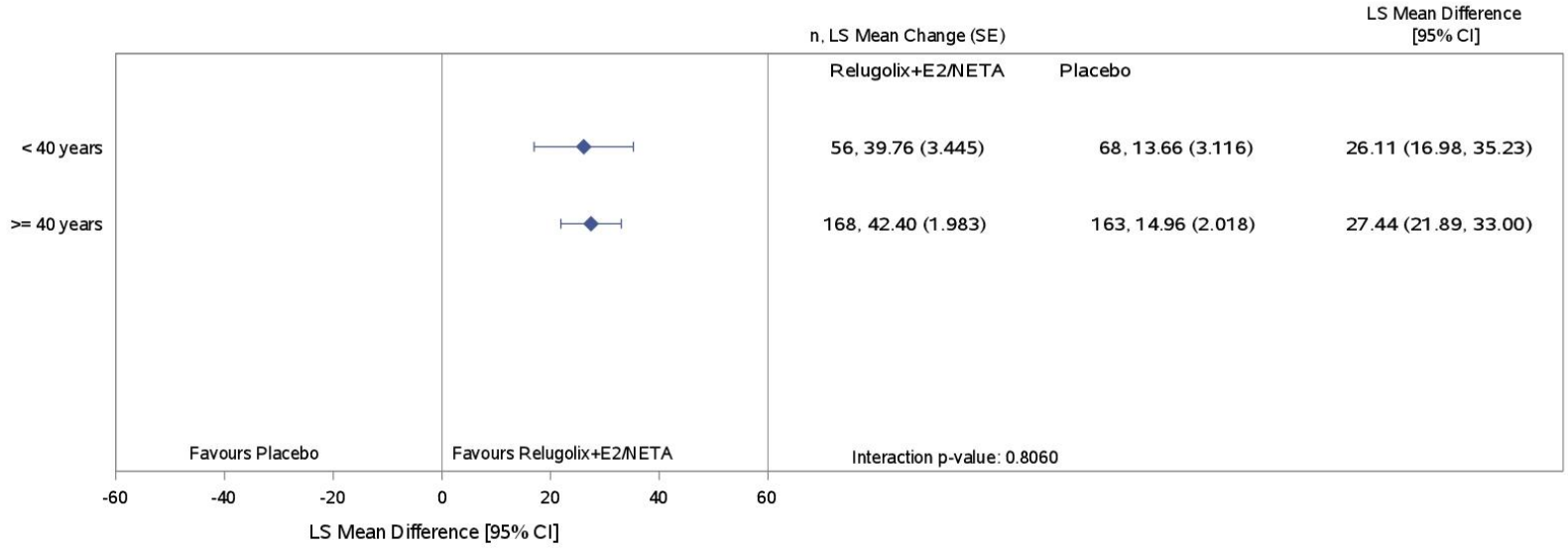
2.2.9 Summary of Average Change from Baseline in UFS-QoL Revised Activities Scale Score Over 24 Weeks, by Subgroup (mITT Population)

Figure QOL.UFSREVA.MITT.S1.CON.FP: Summary of Average Change from Baseline in UFS-QoL Revised Activities Scale Score Over 24 Weeks, by Subgroup (mITT Population)
Study: Pooled
Subgroup: Age (years)



Results are based on a mixed-effects model with study, treatment, visit, subgroup, treatment-by-visit interaction, and a subgroup-by-treatment interaction as fixed effects using a one-stage IPD meta-analysis approach. The multiple visits for each patient are the repeated measures as a random effect within each patient with an unstructured covariance.
The interaction p-value is based on the subgroup-by-treatment interaction term in the mixed-effects model used to compute the LS means, mean differences and 95% CIs. Missing subgroup levels are not included in estimation of the interaction p-value. The reference group is Placebo.
n: Number of patients with data; NETA: Norethindrone acetate; mITT: Modified intent-to-treat; LS: Least squares; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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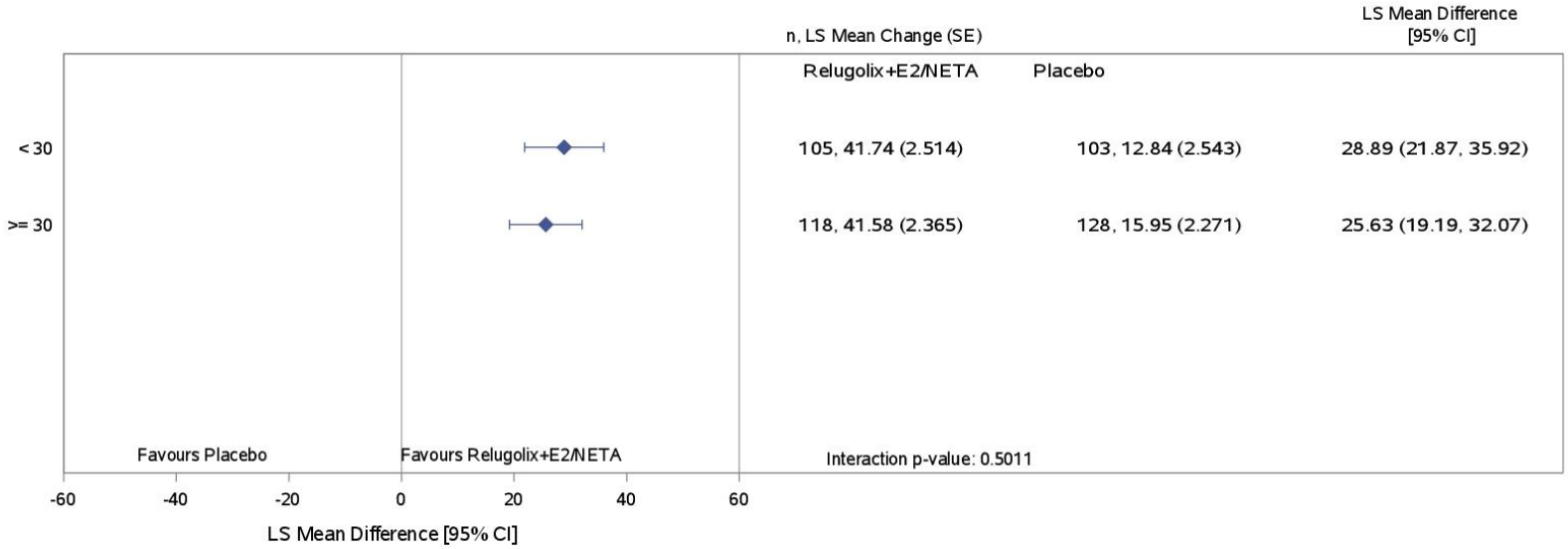
Figure QOL.UFSREVA.MITT.S2.CON.FP: Summary of Average Change from Baseline in UFS-QoL Revised Activities Scale Score Over 24 Weeks, by Subgroup (mITT Population)
Study: Pooled
Subgroup: BMI (kg/m2) at Baseline



Results are based on a mixed-effects model with study, treatment, visit, subgroup, treatment-by-visit interaction, and a subgroup-by-treatment interaction as fixed effects using a one-stage IPD meta-analysis approach. The multiple visits for each patient are the repeated measures as a random effect within each patient with an unstructured covariance.
The interaction p-value is based on the subgroup-by-treatment interaction term in the mixed-effects model used to compute the LS means, mean differences and 95% CIs. Missing subgroup levels are not included in estimation of the interaction p-value. The reference group is Placebo.
n: Number of patients with data; NETA: Norethindrone acetate; mITT: Modified intent-to-treat; LS: Least squares; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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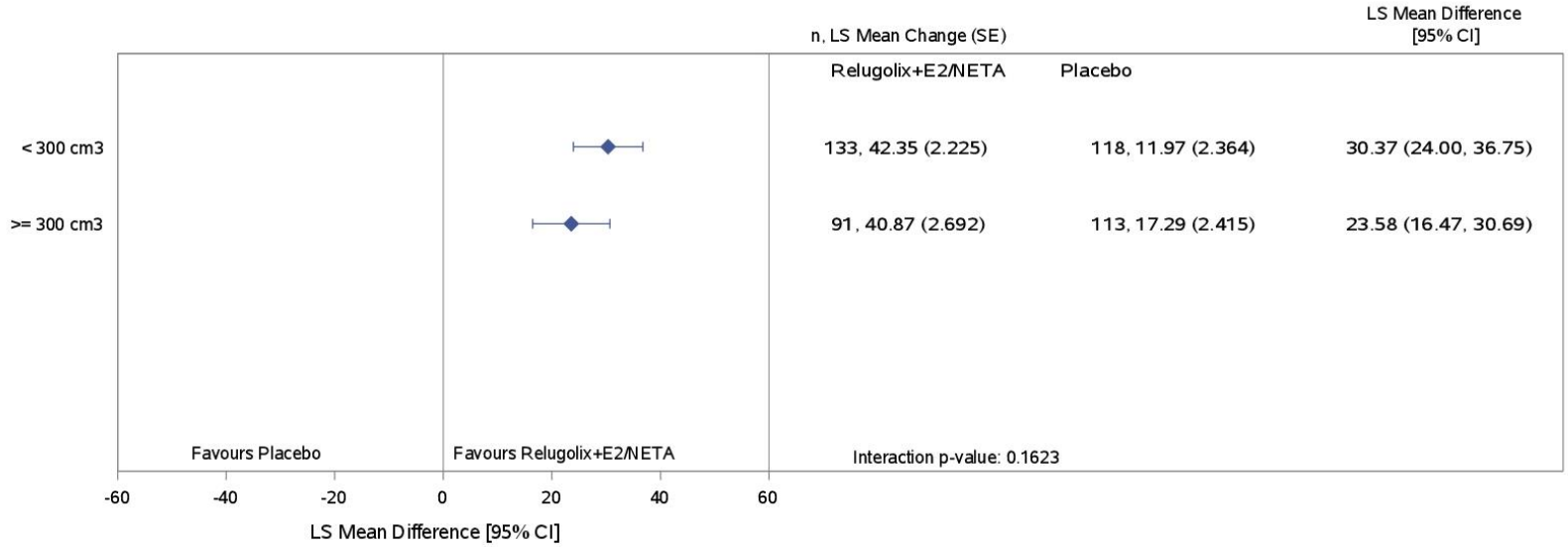
Figure QOL.UFSREVA.MITT.S3.CON.FP: Summary of Average Change from Baseline in UFS-QoL Revised Activities Scale Score Over 24 Weeks, by Subgroup (mITT Population)
Study: Pooled
Subgroup: Uterine Volume at Baseline (cm3)



Results are based on a mixed-effects model with study, treatment, visit, subgroup, treatment-by-visit interaction, and a subgroup-by-treatment interaction as fixed effects using a one-stage IPD meta-analysis approach. The multiple visits for each patient are the repeated measures as a random effect within each patient with an unstructured covariance.
The interaction p-value is based on the subgroup-by-treatment interaction term in the mixed-effects model used to compute the LS means, mean differences and 95% CIs. Missing subgroup levels are not included in estimation of the interaction p-value. The reference group is Placebo.
n: Number of patients with data; NETA: Norethindrone acetate; mITT: Modified intent-to-treat; LS: Least squares; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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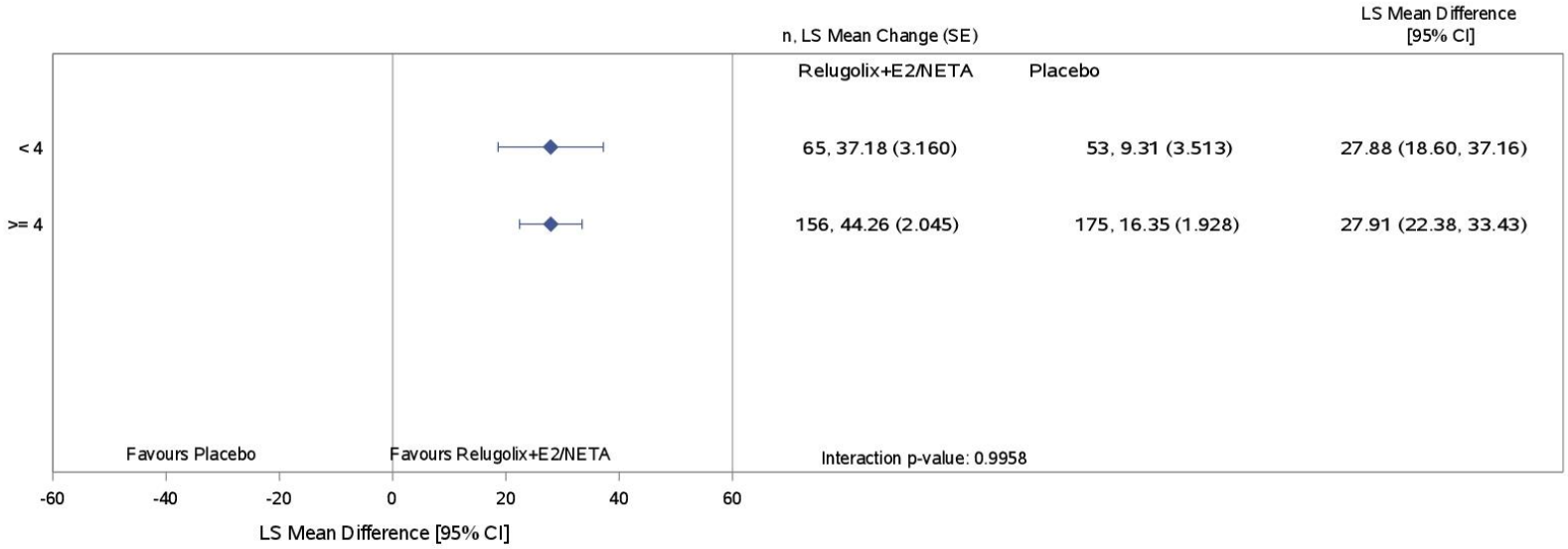
Figure QOL.UFSREVA.MITT.S4.CON.FP: Summary of Average Change from Baseline in UFS-QoL Revised Activities Scale Score Over 24 Weeks, by Subgroup (mITT Population)
Study: Pooled
Subgroup: Maximum NRS Pain Score at Baseline



Results are based on a mixed-effects model with study, treatment, visit, subgroup, treatment-by-visit interaction, and a subgroup-by-treatment interaction as fixed effects using a one-stage IPD meta-analysis approach. The multiple visits for each patient are the repeated measures as a random effect within each patient with an unstructured covariance.
The interaction p-value is based on the subgroup-by-treatment interaction term in the mixed-effects model used to compute the LS means, mean differences and 95% CIs. Missing subgroup levels are not included in estimation of the interaction p-value. The reference group is Placebo.
n: Number of patients with data; NETA: Norethindrone acetate; mITT: Modified intent-to-treat; LS: Least squares; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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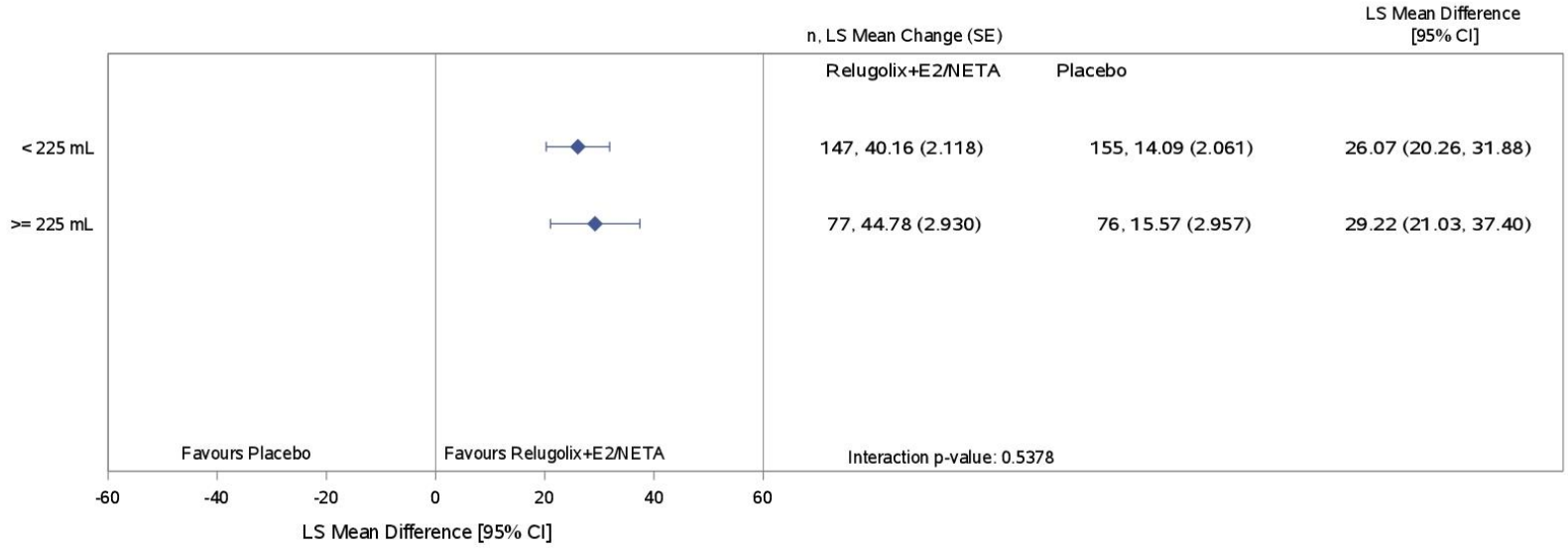
Figure QOL.UFSREVA.MITT.S5.CON.FP: Summary of Average Change from Baseline in UFS-QoL Revised Activities Scale Score Over 24 Weeks, by Subgroup (mITT Population)
Study: Pooled
Subgroup: MBL Volume at Baseline (mL)



Results are based on a mixed-effects model with study, treatment, visit, subgroup, treatment-by-visit interaction, and a subgroup-by-treatment interaction as fixed effects using a one-stage IPD meta-analysis approach. The multiple visits for each patient are the repeated measures as a random effect within each patient with an unstructured covariance.
The interaction p-value is based on the subgroup-by-treatment interaction term in the mixed-effects model used to compute the LS means, mean differences and 95% CIs. Missing subgroup levels are not included in estimation of the interaction p-value. The reference group is Placebo.
n: Number of patients with data; NETA: Norethindrone acetate; mITT: Modified intent-to-treat; LS: Least squares; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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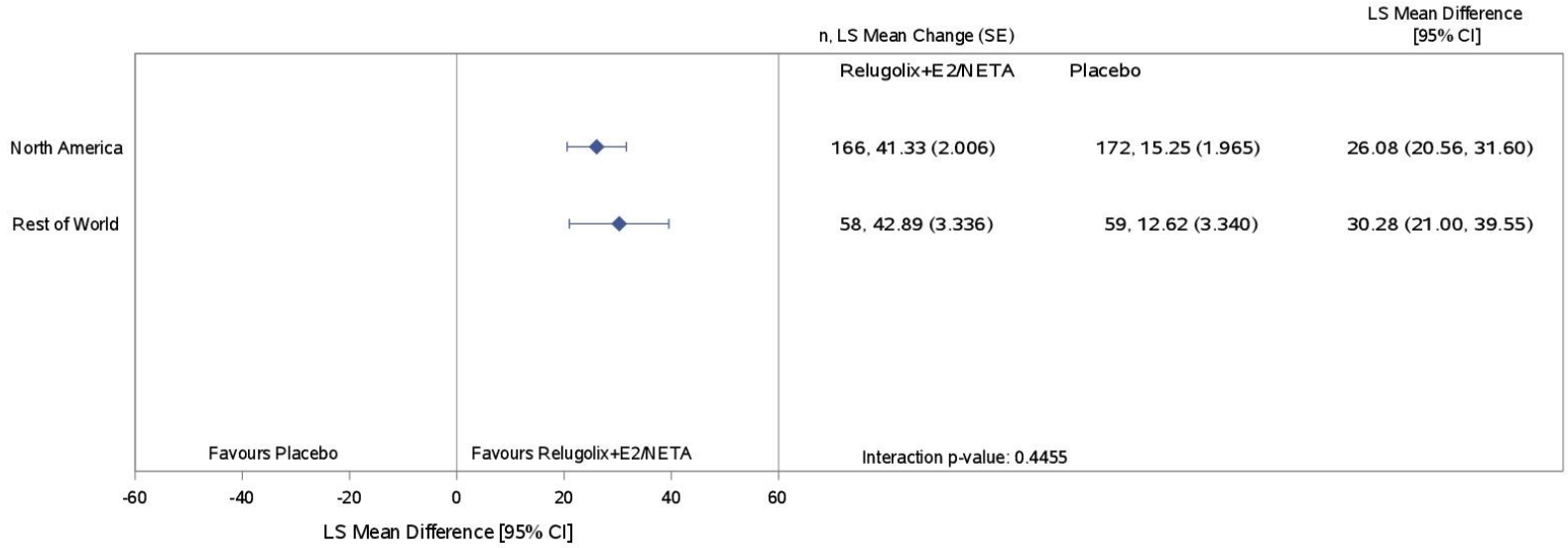
Figure QOL.UFSREVA.MITT.S6.CON.FP: Summary of Average Change from Baseline in UFS-QoL Revised Activities Scale Score Over 24 Weeks, by Subgroup (mITT Population)
Study: Pooled
Subgroup: Geographic Region I



Results are based on a mixed-effects model with study, treatment, visit, subgroup, treatment-by-visit interaction, and a subgroup-by-treatment interaction as fixed effects using a one-stage IPD meta-analysis approach. The multiple visits for each patient are the repeated measures as a random effect within each patient with an unstructured covariance.
The interaction p-value is based on the subgroup-by-treatment interaction term in the mixed-effects model used to compute the LS means, mean differences and 95% CIs. Missing subgroup levels are not included in estimation of the interaction p-value. The reference group is Placebo.
n: Number of patients with data; NETA: Norethindrone acetate; mITT: Modified intent-to-treat; LS: Least squares; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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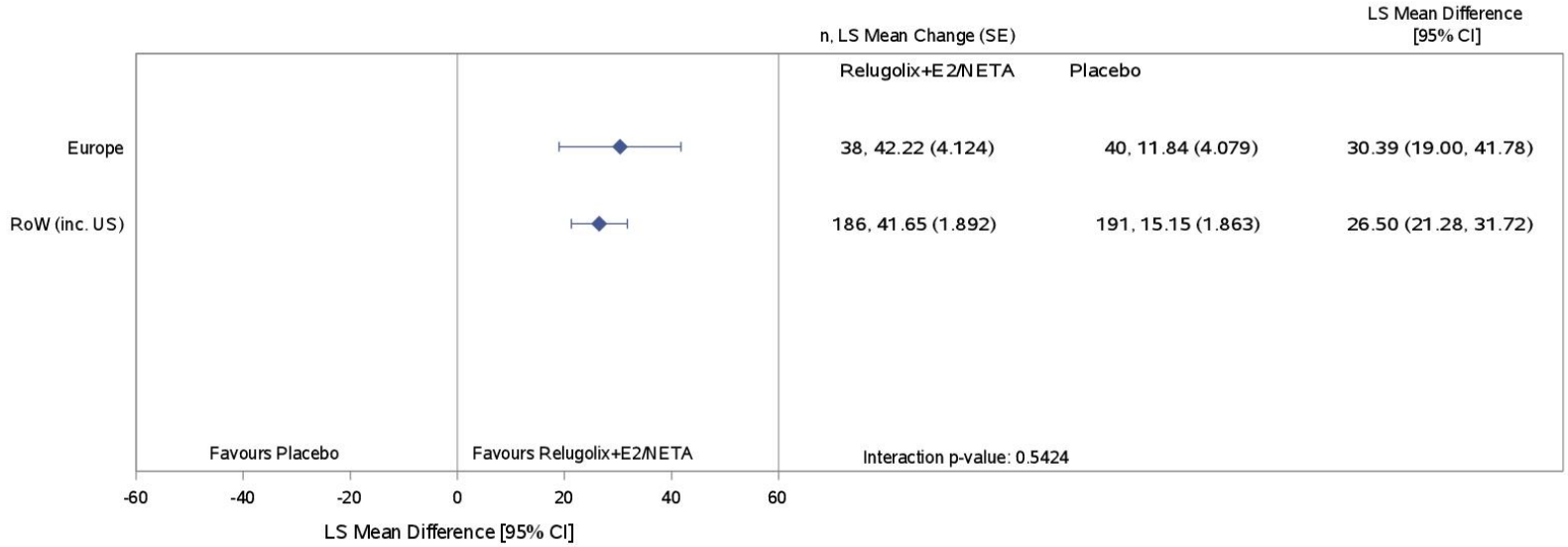
Figure QOL.UFSREVA.MITT.S7.CON.FP: Summary of Average Change from Baseline in UFS-QoL Revised Activities Scale Score Over 24 Weeks, by Subgroup (mITT Population)
Study: Pooled
Subgroup: Geographic Region II



Results are based on a mixed-effects model with study, treatment, visit, subgroup, treatment-by-visit interaction, and a subgroup-by-treatment interaction as fixed effects using a one-stage IPD meta-analysis approach. The multiple visits for each patient are the repeated measures as a random effect within each patient with an unstructured covariance.
The interaction p-value is based on the subgroup-by-treatment interaction term in the mixed-effects model used to compute the LS means, mean differences and 95% CIs. Missing subgroup levels are not included in estimation of the interaction p-value. The reference group is Placebo.
n: Number of patients with data; NETA: Norethindrone acetate; mITT: Modified intent-to-treat; LS: Least squares; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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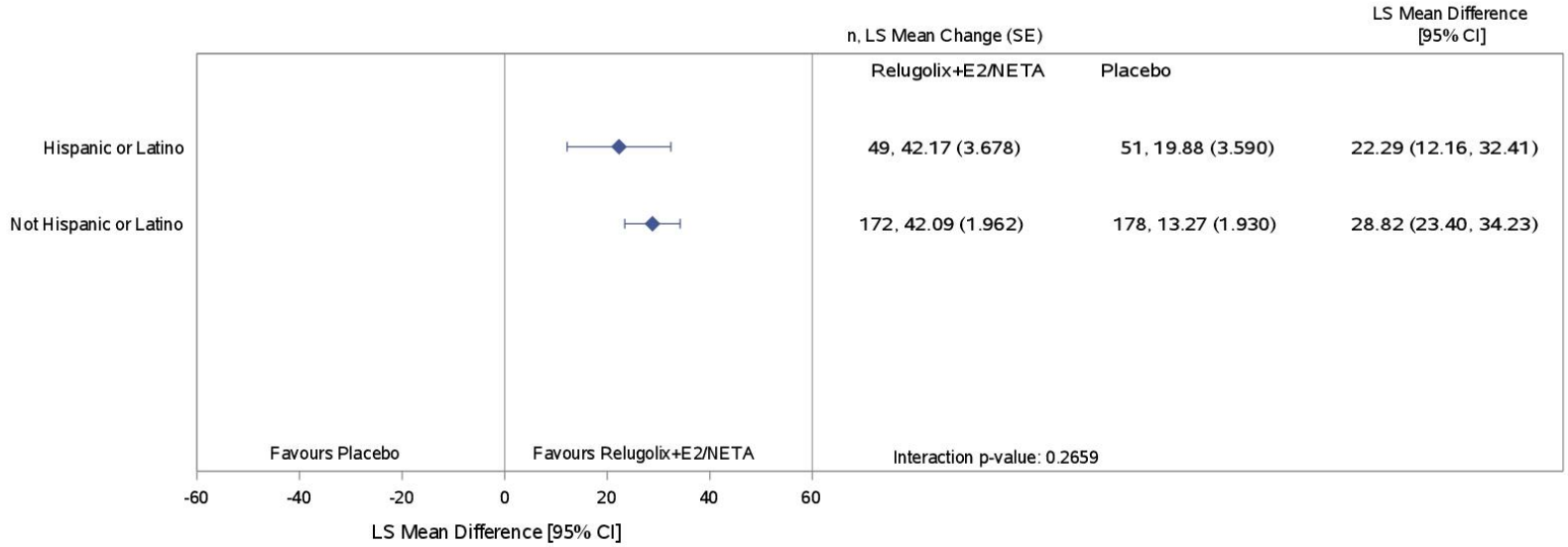
Figure QOL.UFSREVA.MITT.S8.CON.FP: Summary of Average Change from Baseline in UFS-QoL Revised Activities Scale Score Over 24 Weeks, by Subgroup (mITT Population)
Study: Pooled
Subgroup: Ethnicity



Results are based on a mixed-effects model with study, treatment, visit, subgroup, treatment-by-visit interaction, and a subgroup-by-treatment interaction as fixed effects using a one-stage IPD meta-analysis approach. The multiple visits for each patient are the repeated measures as a random effect within each patient with an unstructured covariance.
The interaction p-value is based on the subgroup-by-treatment interaction term in the mixed-effects model used to compute the LS means, mean differences and 95% CIs. Missing subgroup levels are not included in estimation of the interaction p-value. The reference group is Placebo.
n: Number of patients with data; NETA: Norethindrone acetate; mITT: Modified intent-to-treat; LS: Least squares; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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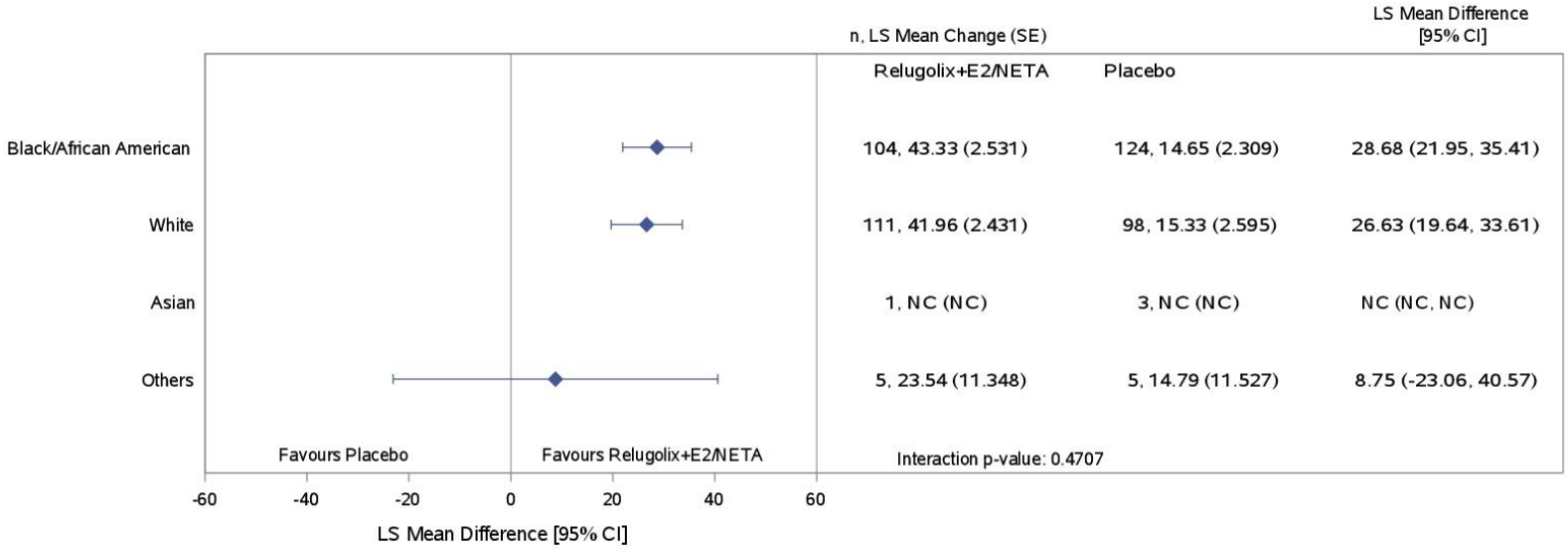
Figure QOL.UFSREVA.MITT.S9.CON.FP: Summary of Average Change from Baseline in UFS-QoL Revised Activities Scale Score Over 24 Weeks, by Subgroup (mITT Population)
Study: Pooled
Subgroup: Race



Results are based on a mixed-effects model with study, treatment, visit, subgroup, treatment-by-visit interaction, and a subgroup-by-treatment interaction as fixed effects using a one-stage IPD meta-analysis approach. The multiple visits for each patient are the repeated measures as a random effect within each patient with an unstructured covariance.
The interaction p-value is based on the subgroup-by-treatment interaction term in the mixed-effects model used to compute the LS means, mean differences and 95% CIs. Missing subgroup levels are not included in estimation of the interaction p-value. The reference group is Placebo.
n: Number of patients with data; NETA: Norethindrone acetate; mITT: Modified intent-to-treat; LS: Least squares; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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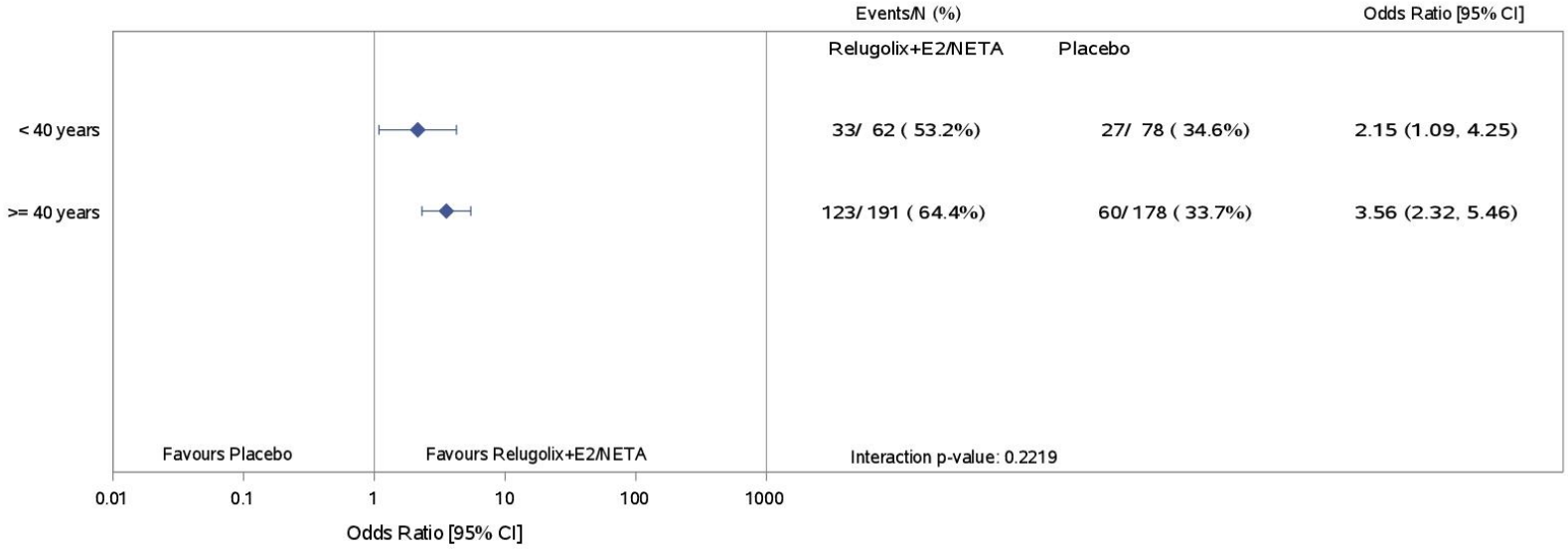
2.2.10 Proportion of Responders with at Least 20 Points Increase in UFS-QoL Revised Activity Scale Score at Week 24, by Subgroup (mITT Population)

Nachfolgend sind zunächst alle Forest Plots für das *Odds Ratio* dargestellt; gefolgt von den entsprechenden Forest Plots für *Risk Ratio* und *Risk Difference*.

Figure QOL.UFSRAS20.MITT.S1.BIN.FP: Proportion of Responders with at Least 20 Points Increase in UFS-QoL Revised Activity Scale Score at Week 24, by Subgroup (mITT Population)
Study: Pooled
Subgroup: Age (years)



Results are based on a logistic regression model adjusted for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates using a one-stage fixed-effects IPD meta-analysis approach. A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
The interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the Odds Ratio and 95% CI. Missing subgroup levels are not included in estimation of the interaction p-value. The reference group is Placebo.
N: Number of patients in treatment group; NETA: Norethindrone acetate; mITT: Modified intent-to-treat; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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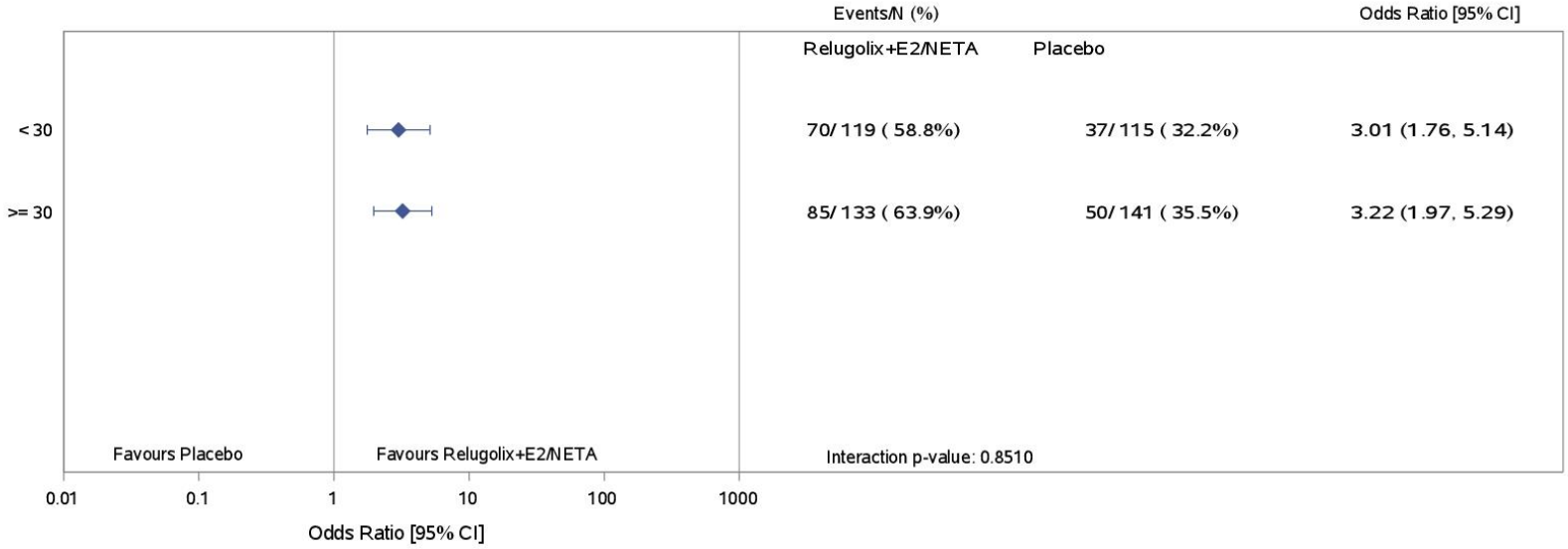
Figure QOL.UFSRAS20.MITT.S2.BIN.FP: Proportion of Responders with at Least 20 Points Increase in UFS-QoL Revised Activity Scale Score at Week 24, by Subgroup (mITT Population)
Study: Pooled
Subgroup: BMI (kg/m2) at Baseline



Results are based on a logistic regression model adjusted for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates using a one-stage fixed-effects IPD meta-analysis approach. A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
The interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the Odds Ratio and 95% CI. Missing subgroup levels are not included in estimation of the interaction p-value. The reference group is Placebo.
N: Number of patients in treatment group; NETA: Norethindrone acetate; mITT: Modified intent-to-treat; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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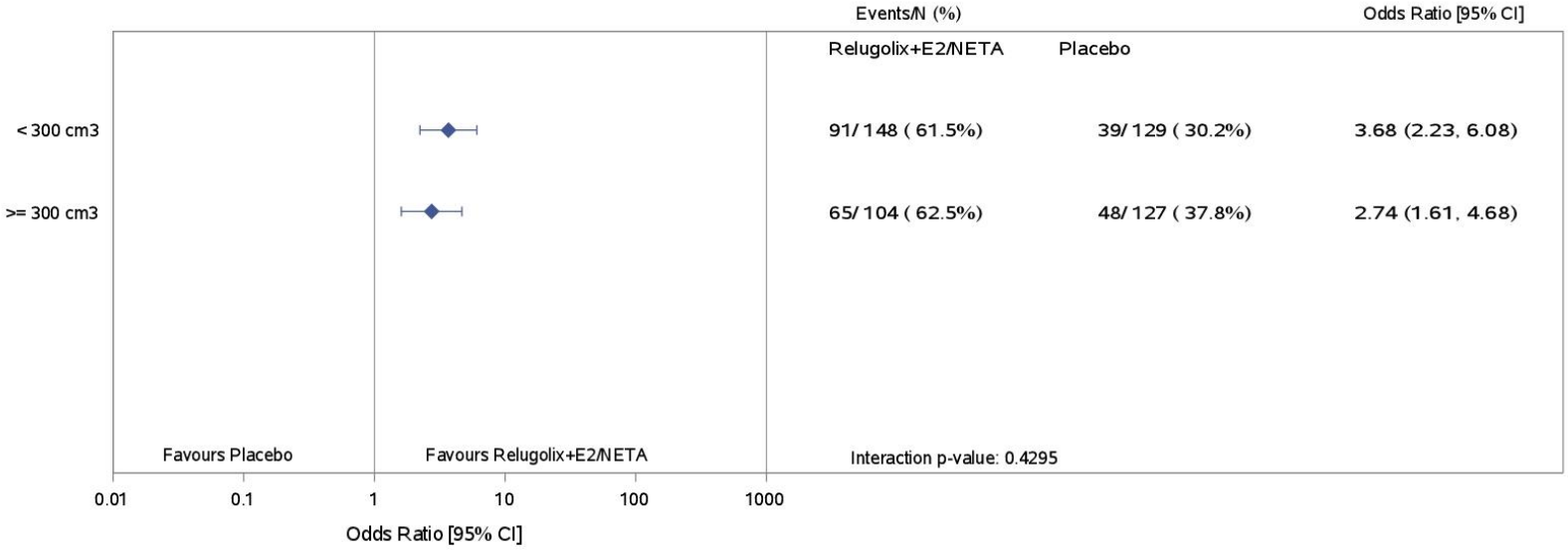
Figure QOL.UFSRAS20.MITT.S3.BIN.FP: Proportion of Responders with at Least 20 Points Increase in UFS-QoL Revised Activity Scale Score at Week 24, by Subgroup (mITT Population)
Study: Pooled
Subgroup: Uterine Volume at Baseline (cm3)



Results are based on a logistic regression model adjusted for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates using a one-stage fixed-effects IPD meta-analysis approach. A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
The interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the Odds Ratio and 95% CI. Missing subgroup levels are not included in estimation of the interaction p-value. The reference group is Placebo.
N: Number of patients in treatment group; NETA: Norethindrone acetate; mITT: Modified intent-to-treat; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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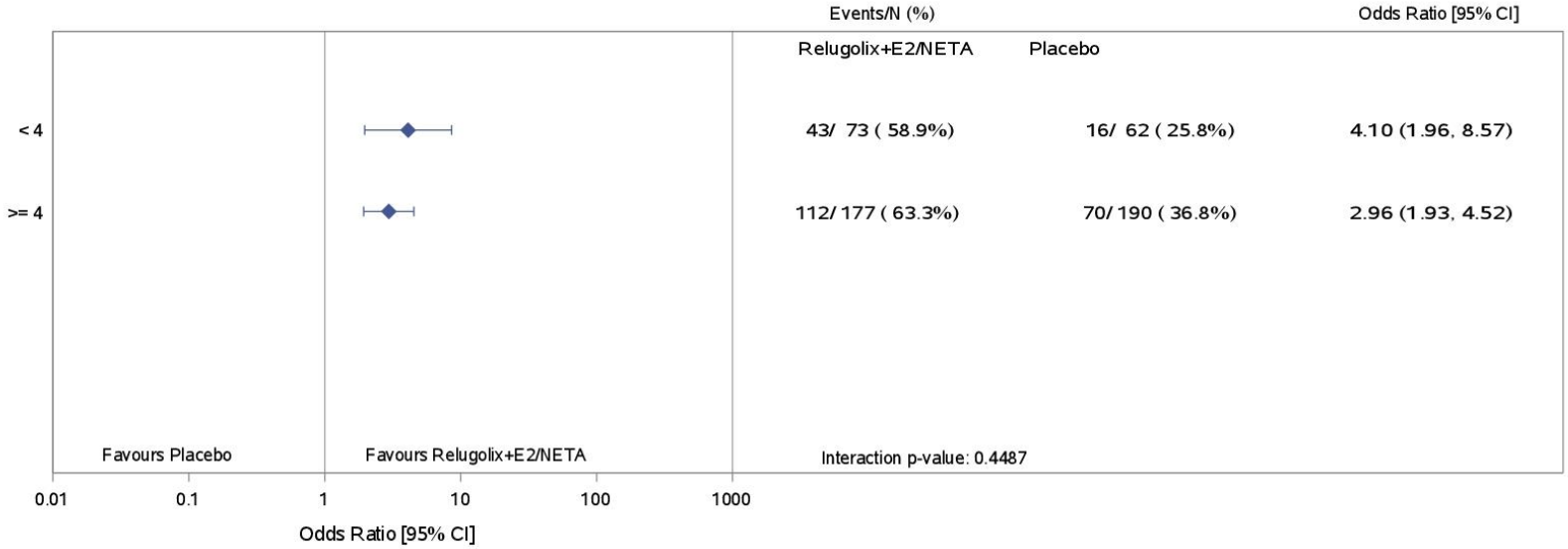
Figure QOL.UFSRAS20.MITT.S4.BIN.FP: Proportion of Responders with at Least 20 Points Increase in UFS-QoL Revised Activity Scale Score at Week 24, by Subgroup (mITT Population)
Study: Pooled
Subgroup: Maximum NRS Pain Score at Baseline



Results are based on a logistic regression model adjusted for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates using a one-stage fixed-effects IPD meta-analysis approach. A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
The interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the Odds Ratio and 95% CI. Missing subgroup levels are not included in estimation of the interaction p-value. The reference group is Placebo.
N: Number of patients in treatment group; NETA: Norethindrone acetate; mITT: Modified intent-to-treat; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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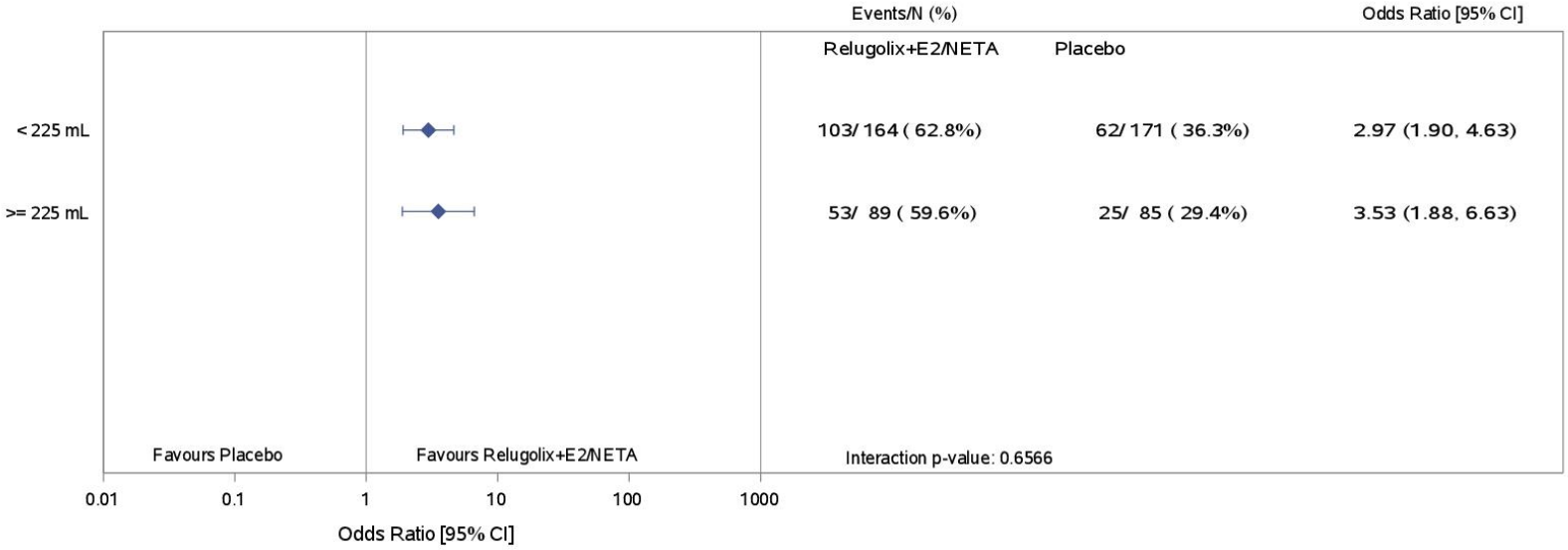
Figure QOL.UFSRAS20.MITT.S5.BIN.FP: Proportion of Responders with at Least 20 Points Increase in UFS-QoL Revised Activity Scale Score at Week 24, by Subgroup (mITT Population)
Study: Pooled
Subgroup: MBL Volume at Baseline (mL)



Results are based on a logistic regression model adjusted for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates using a one-stage fixed-effects IPD meta-analysis approach. A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
The interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the Odds Ratio and 95% CI. Missing subgroup levels are not included in estimation of the interaction p-value. The reference group is Placebo.
N: Number of patients in treatment group; NETA: Norethindrone acetate; mITT: Modified intent-to-treat; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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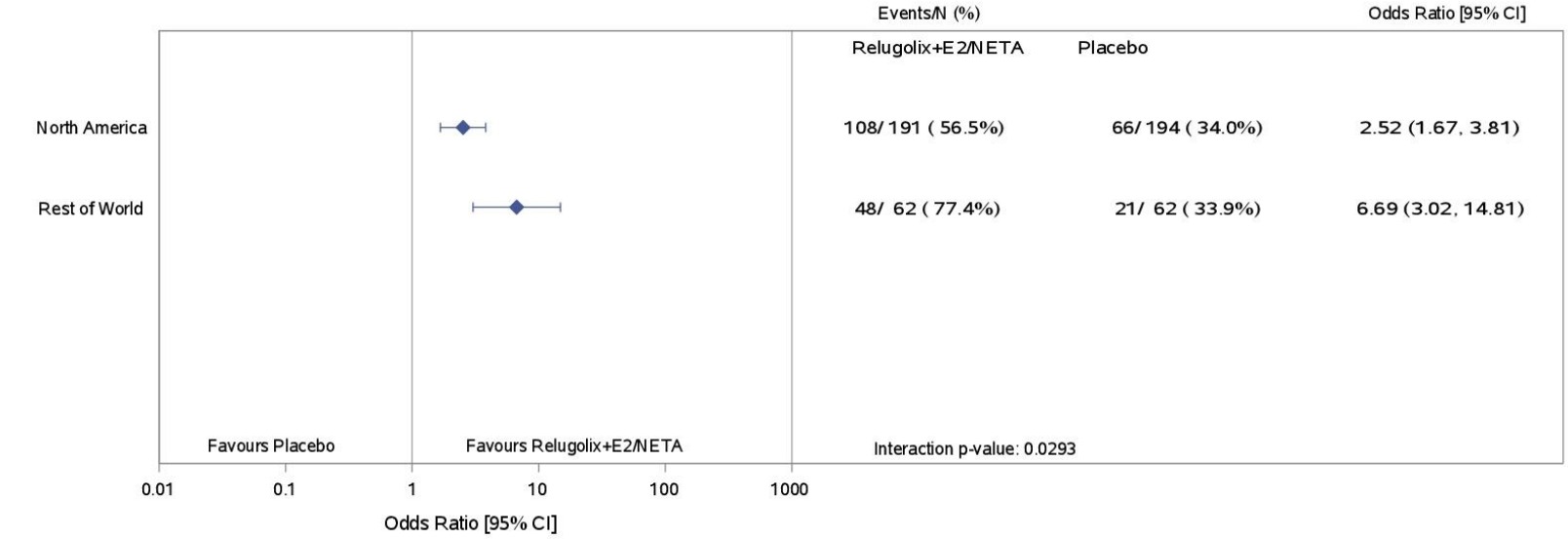
Figure QOL.UFSRAS20.MITT.S6.BIN.FP: Proportion of Responders with at Least 20 Points Increase in UFS-QoL Revised Activity Scale Score at Week 24, by Subgroup (mITT Population)
Study: Pooled
Subgroup: Geographic Region I



Results are based on a logistic regression model adjusted for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates using a one-stage fixed-effects IPD meta-analysis approach. A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
The interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the Odds Ratio and 95% CI. Missing subgroup levels are not included in estimation of the interaction p-value. The reference group is Placebo.
N: Number of patients in treatment group; NETA: Norethindrone acetate; mITT: Modified intent-to-treat; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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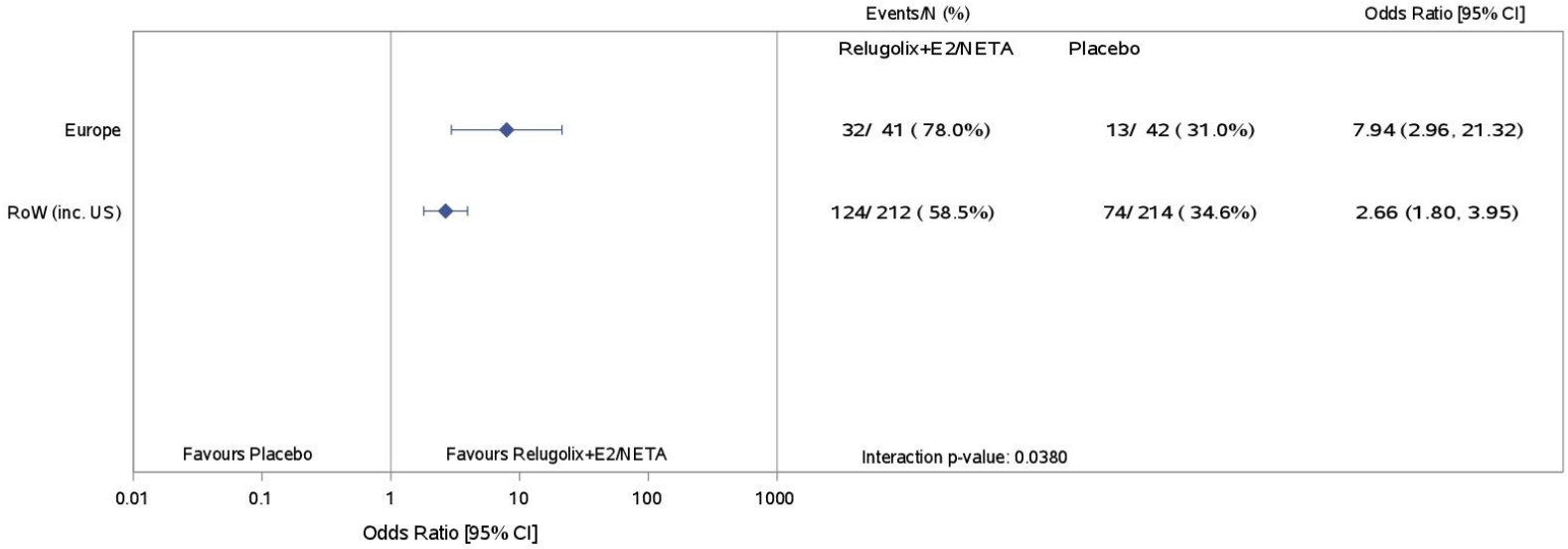
Figure QOL.UFSRAS20.MITT.S7.BIN.FP: Proportion of Responders with at Least 20 Points Increase in UFS-QoL Revised Activity Scale Score at Week 24, by Subgroup (mITT Population)
Study: Pooled
Subgroup: Geographic Region II



Results are based on a logistic regression model adjusted for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates using a one-stage fixed-effects IPD meta-analysis approach. A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
The interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the Odds Ratio and 95% CI. Missing subgroup levels are not included in estimation of the interaction p-value. The reference group is Placebo.
N: Number of patients in treatment group; NETA: Norethindrone acetate; mITT: Modified intent-to-treat; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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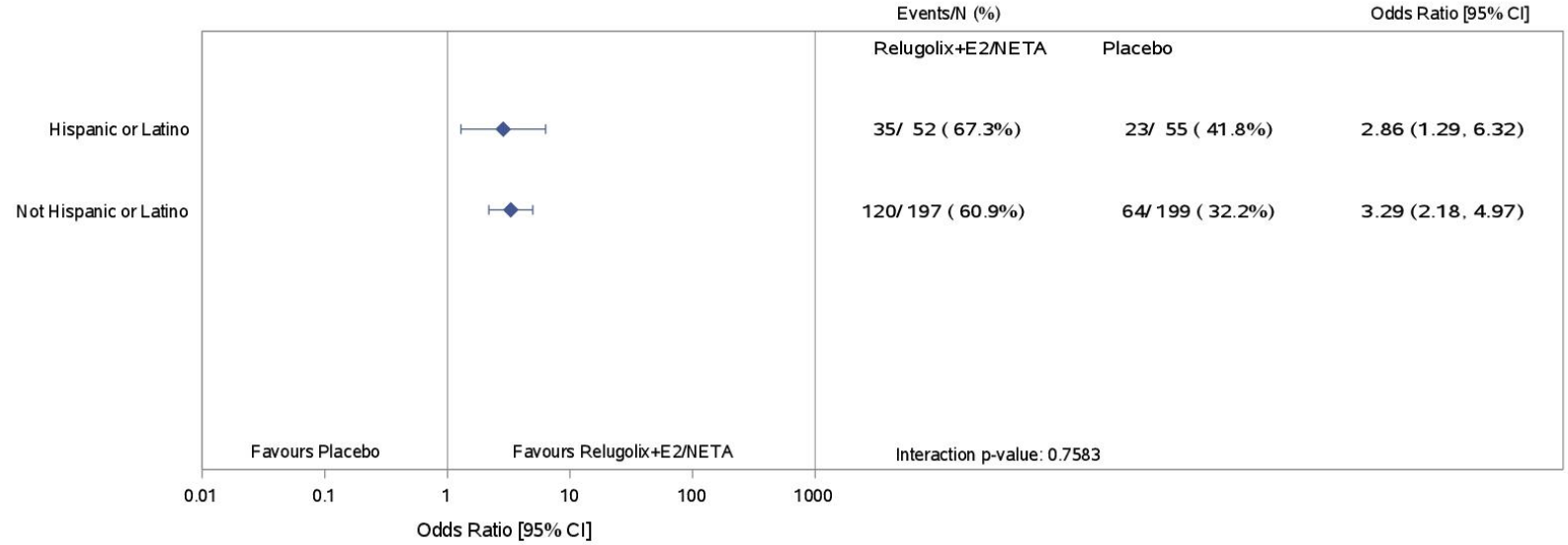
Figure QOL.UFSRAS20.MITT.S8.BIN.FP: Proportion of Responders with at Least 20 Points Increase in UFS-QoL Revised Activity Scale Score at Week 24, by Subgroup (mITT Population)
Study: Pooled
Subgroup: Ethnicity



Results are based on a logistic regression model adjusted for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates using a one-stage fixed-effects IPD meta-analysis approach. A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
The interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the Odds Ratio and 95% CI. Missing subgroup levels are not included in estimation of the interaction p-value. The reference group is Placebo.
N: Number of patients in treatment group; NETA: Norethindrone acetate; mITT: Modified intent-to-treat; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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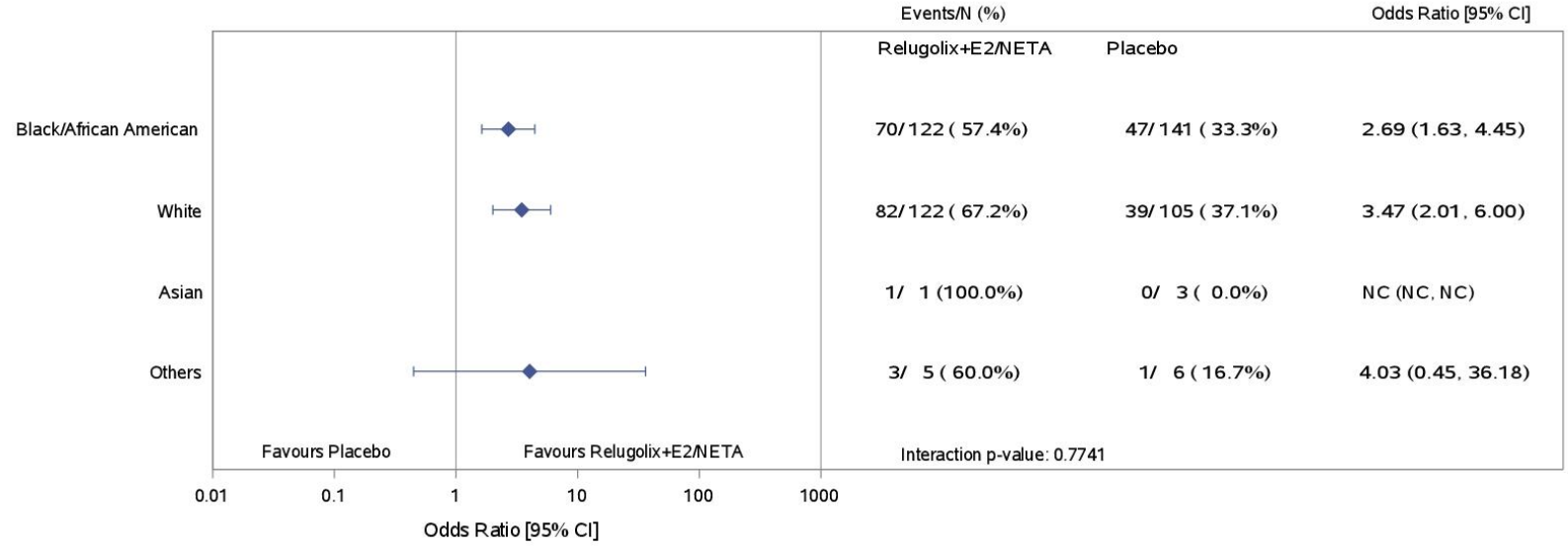
Figure QOL.UFSRAS20.MITT.S9.BIN.FP: Proportion of Responders with at Least 20 Points Increase in UFS-QoL Revised Activity Scale Score at Week 24, by Subgroup (mITT Population)
Study: Pooled
Subgroup: Race



Results are based on a logistic regression model adjusted for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates using a one-stage fixed-effects IPD meta-analysis approach. A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
The interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the Odds Ratio and 95% CI. Missing subgroup levels are not included in estimation of the interaction p-value. The reference group is Placebo.
N: Number of patients in treatment group; NETA: Norethindrone acetate; mITT: Modified intent-to-treat; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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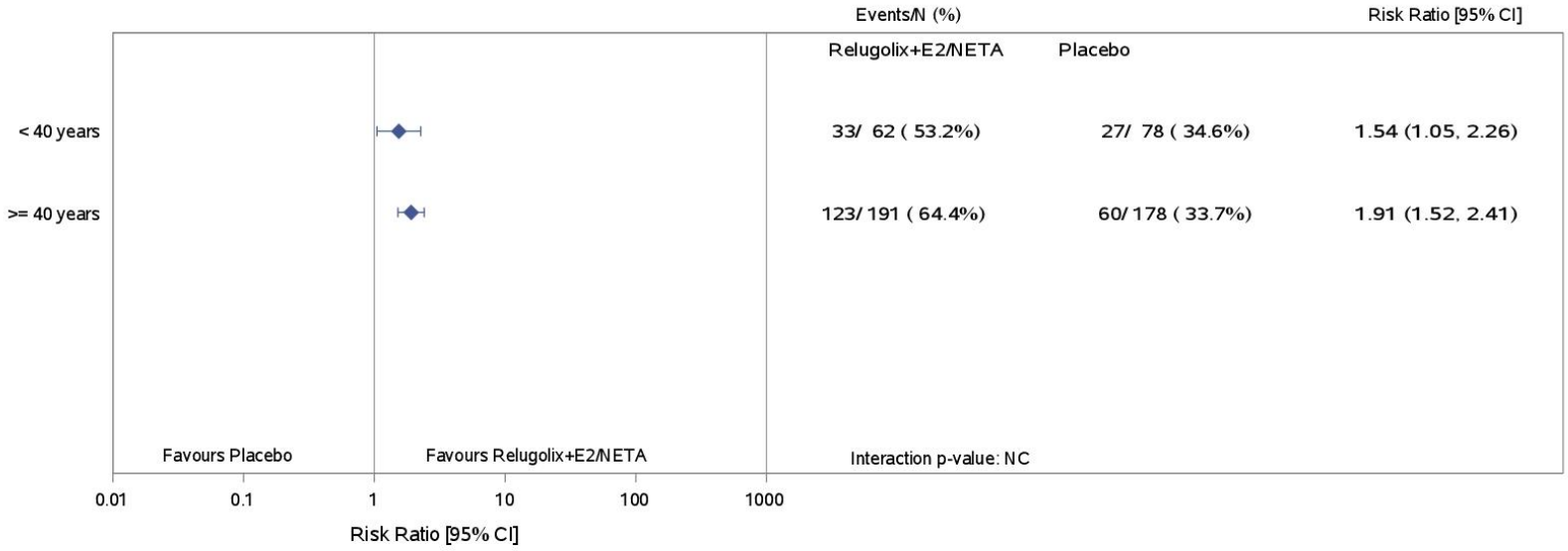
Figure QOL.UFSRAS20.MITT.S1.BIN.FP.RR: Proportion of Responders with at Least 20 Points Increase in UFS-QoL Revised Activity Scale Score at Week 24, by Subgroup (mITT Population) - Risk Ratio
Study: Pooled
Subgroup: Age (years)



Results are based on a Cochran-Mantel-Haenszel approach stratified by study using a one-stage fixed-effects IPD meta-analysis. A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
The reference group is Placebo.
N: Number of patients in treatment group; NETA: Norethindrone acetate; mITT: Modified intent-to-treat; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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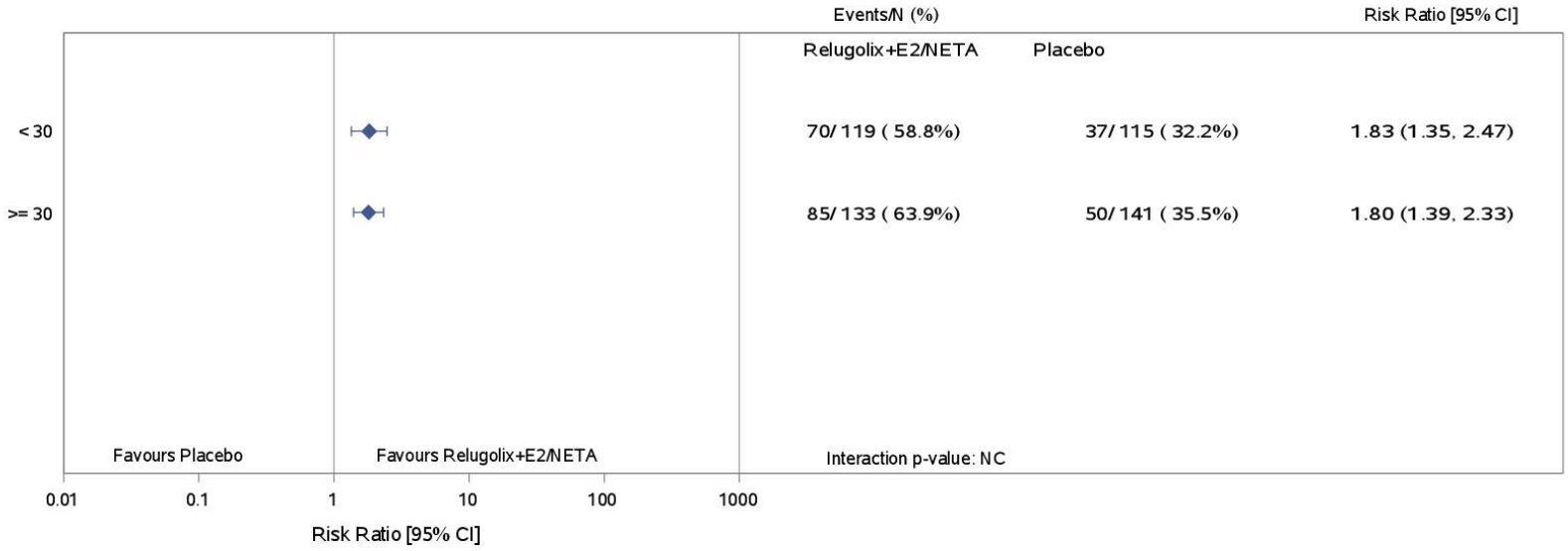
Figure QOL.UFSRAS20.MITT.S2.BIN.FP.RR: Proportion of Responders with at Least 20 Points Increase in UFS-QoL Revised Activity Scale Score at Week 24, by Subgroup (mITT Population) - Risk Ratio
Study: Pooled
Subgroup: BMI (kg/m2) at Baseline



Results are based on a Cochran-Mantel-Haenszel approach stratified by study using a one-stage fixed-effects IPD meta-analysis. A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
The reference group is Placebo.
N: Number of patients in treatment group; NETA: Norethindrone acetate; mITT: Modified intent-to-treat; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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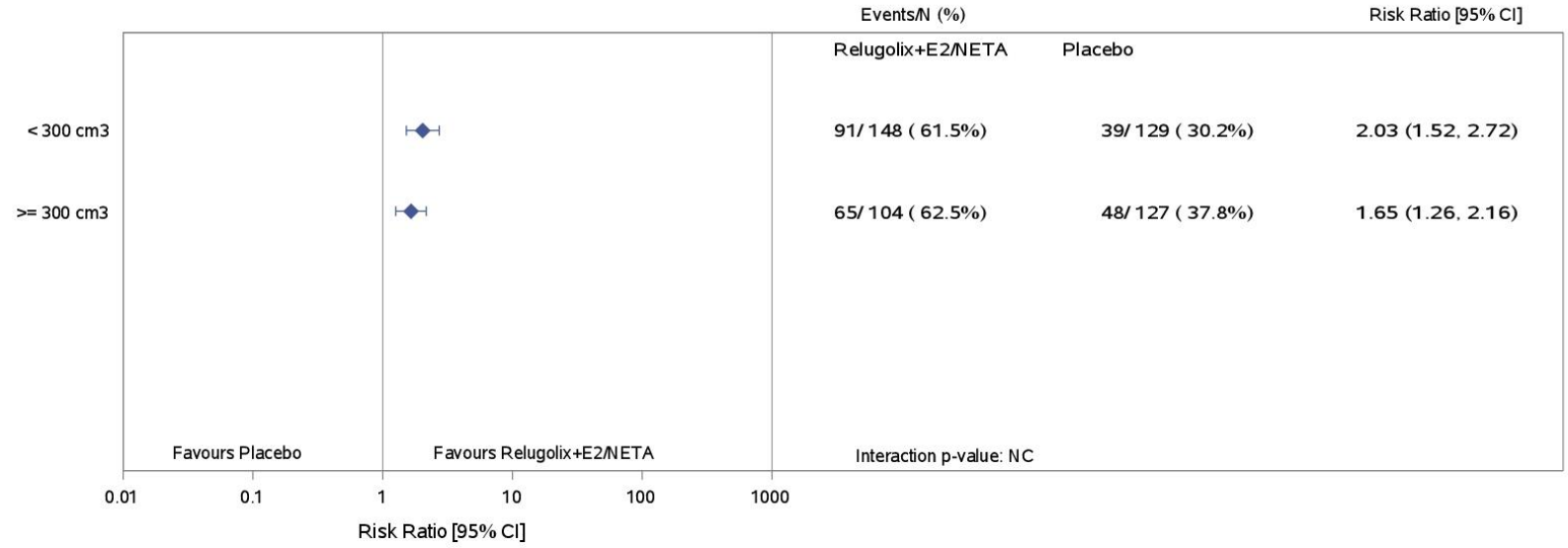
Figure QOL.UFSRAS20.MITT.S3.BIN.FP.RR: Proportion of Responders with at Least 20 Points Increase in UFS-QoL Revised Activity Scale Score at Week 24, by Subgroup (mITT Population) - Risk Ratio
Study: Pooled
Subgroup: Uterine Volume at Baseline (cm3)



Results are based on a Cochran-Mantel-Haenszel approach stratified by study using a one-stage fixed-effects IPD meta-analysis. A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
The reference group is Placebo.
N: Number of patients in treatment group; NETA: Norethindrone acetate; mITT: Modified intent-to-treat; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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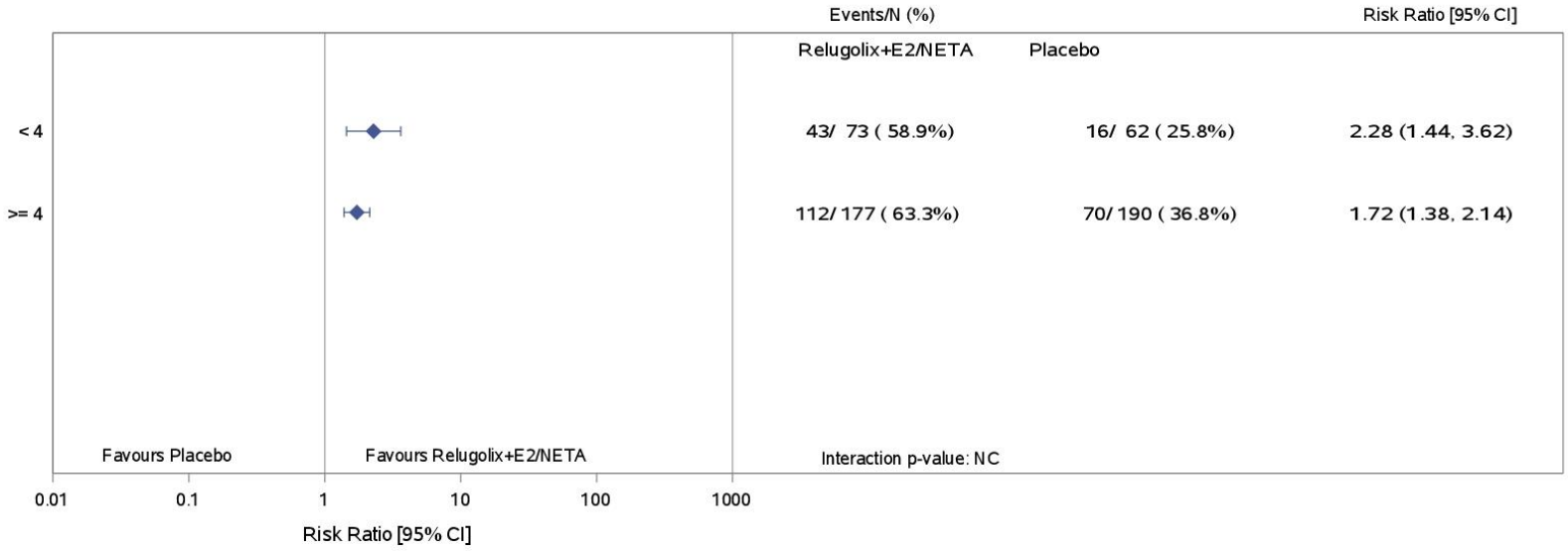
Figure QOL.UFSRAS20.MITT.S4.BIN.FP.RR: Proportion of Responders with at Least 20 Points Increase in UFS-QoL Revised Activity Scale Score at Week 24, by Subgroup (mITT Population) - Risk Ratio
Study: Pooled
Subgroup: Maximum NRS Pain Score at Baseline



Results are based on a Cochran-Mantel-Haenszel approach stratified by study using a one-stage fixed-effects IPD meta-analysis. A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
The reference group is Placebo.
N: Number of patients in treatment group; NETA: Norethindrone acetate; mITT: Modified intent-to-treat; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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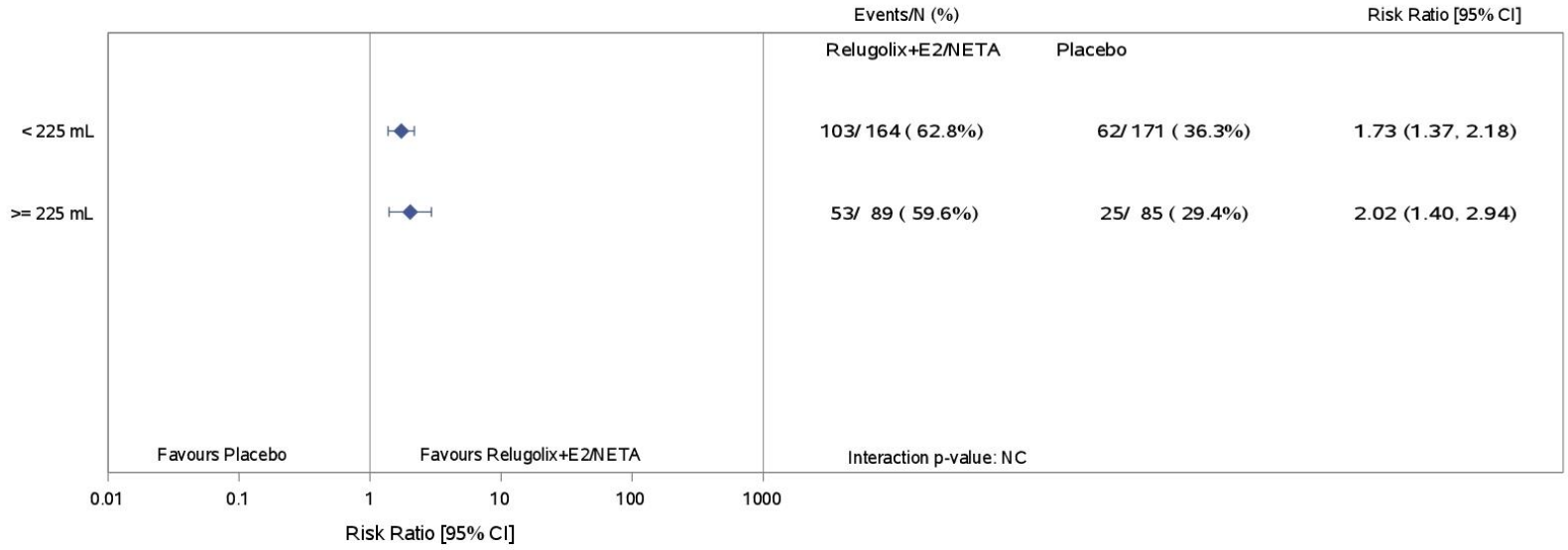
Figure QOL.UFSRAS20.MITT.S5.BIN.FP.RR: Proportion of Responders with at Least 20 Points Increase in UFS-QoL Revised Activity Scale Score at Week 24, by Subgroup (mITT Population) - Risk Ratio
Study: Pooled
Subgroup: MBL Volume at Baseline (mL)



Results are based on a Cochran-Mantel-Haenszel approach stratified by study using a one-stage fixed-effects IPD meta-analysis. A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
The reference group is Placebo.
N: Number of patients in treatment group; NETA: Norethindrone acetate; mITT: Modified intent-to-treat; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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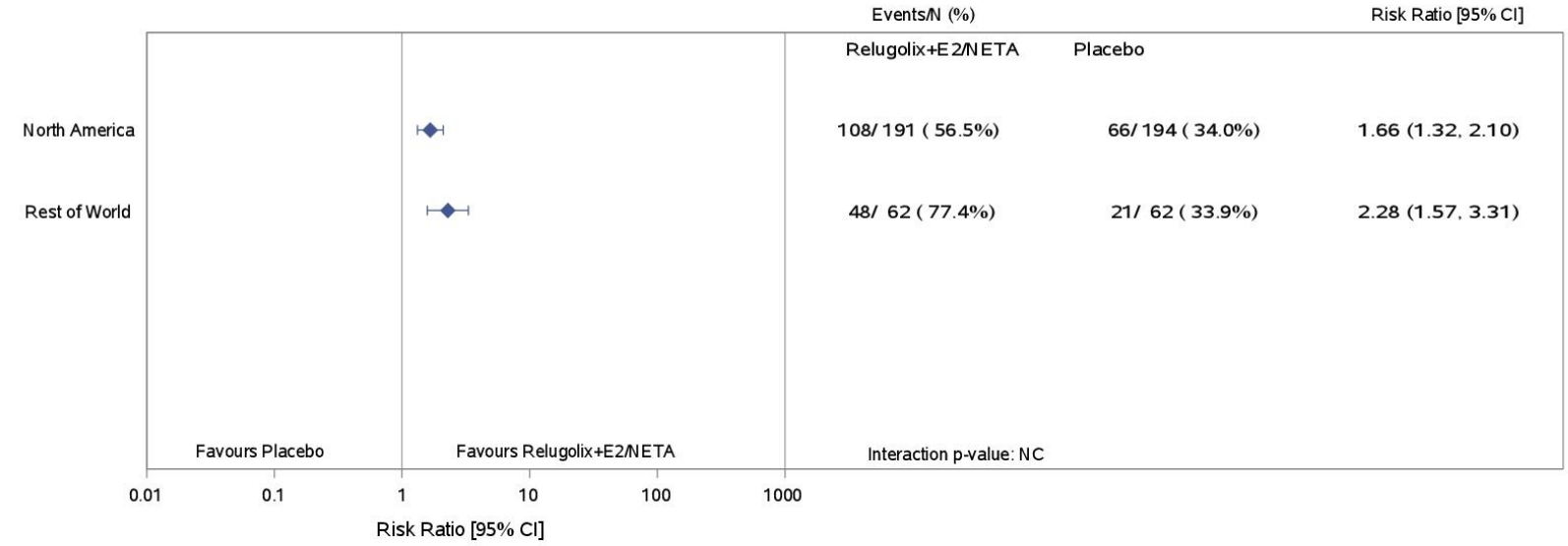
Figure QOL.UFSRAS20.MITT.S6.BIN.FP.RR: Proportion of Responders with at Least 20 Points Increase in UFS-QoL Revised Activity Scale Score at Week 24, by Subgroup (mITT Population) - Risk Ratio
Study: Pooled
Subgroup: Geographic Region I



Results are based on a Cochran-Mantel-Haenszel approach stratified by study using a one-stage fixed-effects IPD meta-analysis. A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
The reference group is Placebo.
N: Number of patients in treatment group; NETA: Norethindrone acetate; mITT: Modified intent-to-treat; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

SOURCE: X:\Numerus\Studies\MYV\MYV102\Analysis\Prod\Progs\TFLs\Fig_QOL_QS_S_BIN_FP.SAS Date/time of run: 30JUN21 10:27
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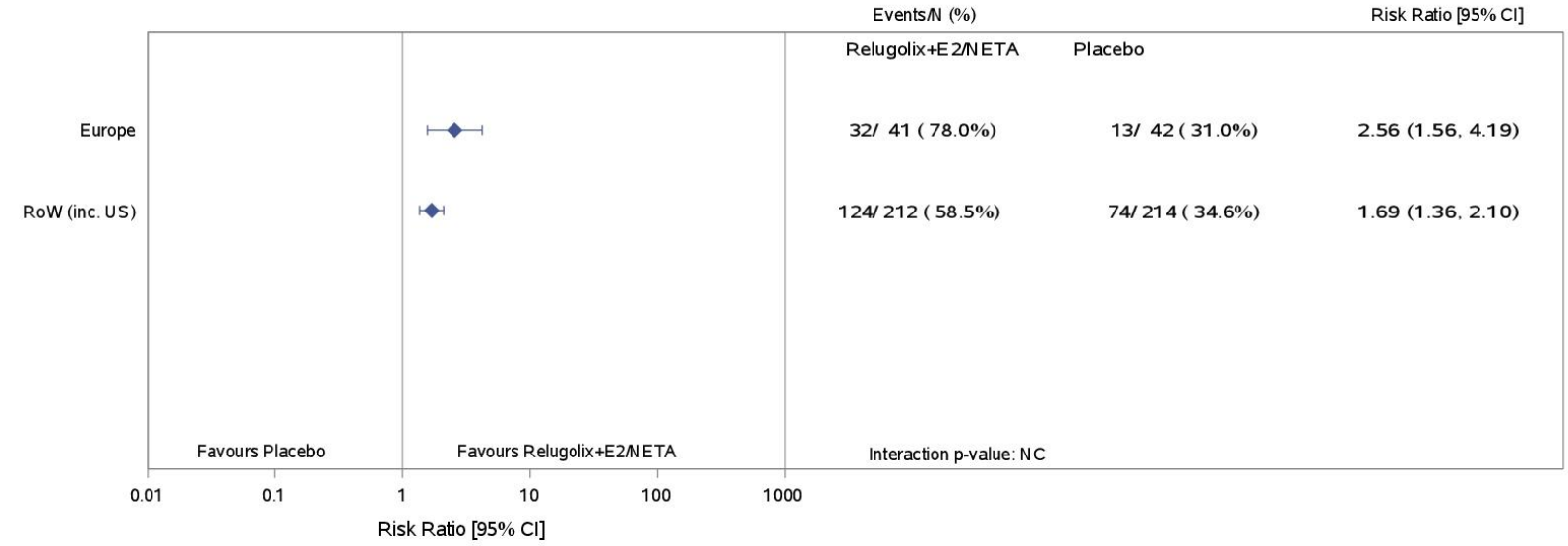
Figure QOL.UFSRAS20.MITT.S7.BIN.FP.RR: Proportion of Responders with at Least 20 Points Increase in UFS-QoL Revised Activity Scale Score at Week 24, by Subgroup (mITT Population) - Risk Ratio
Study: Pooled
Subgroup: Geographic Region II



Results are based on a Cochran-Mantel-Haenszel approach stratified by study using a one-stage fixed-effects IPD meta-analysis. A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
The reference group is Placebo.
N: Number of patients in treatment group; NETA: Norethindrone acetate; mITT: Modified intent-to-treat; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

SOURCE: X:\Numerus\Studies\MYV\MYV102\Analysis\Prod\Progs\TFLs\Fig_QOL_QS_S_BIN_FP.SAS Date/time of run: 30JUN21 10:27
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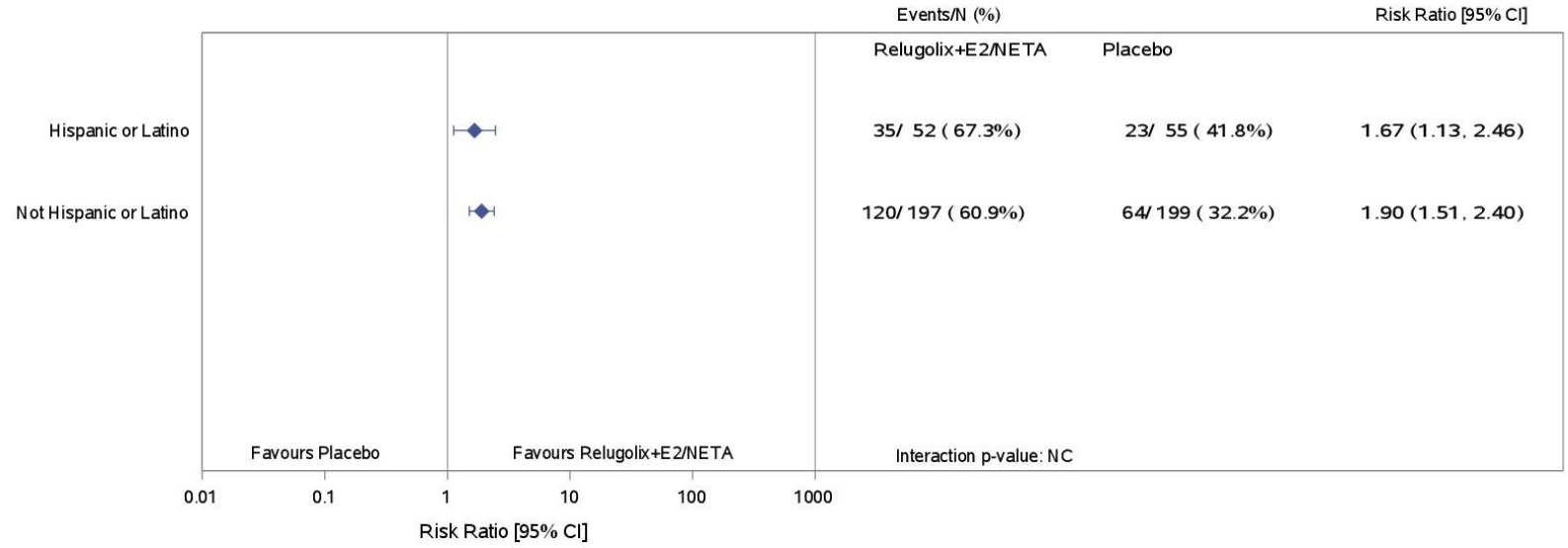
Figure QOL.UFSRAS20.MITT.S8.BIN.FP.RR: Proportion of Responders with at Least 20 Points Increase in UFS-QoL Revised Activity Scale Score at Week 24, by Subgroup (mITT Population) - Risk Ratio
Study: Pooled
Subgroup: Ethnicity



Results are based on a Cochran-Mantel-Haenszel approach stratified by study using a one-stage fixed-effects IPD meta-analysis. A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
The reference group is Placebo.
N: Number of patients in treatment group; NETA: Norethindrone acetate; mITT: Modified intent-to-treat; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

SOURCE: X:\Numerus\Studies\MYV\MYV102\Analysis\Prod\Progs\TFLs\Fig_QOL_QS_S_BIN_FP.SAS Date/time of run: 30JUN21 10:27
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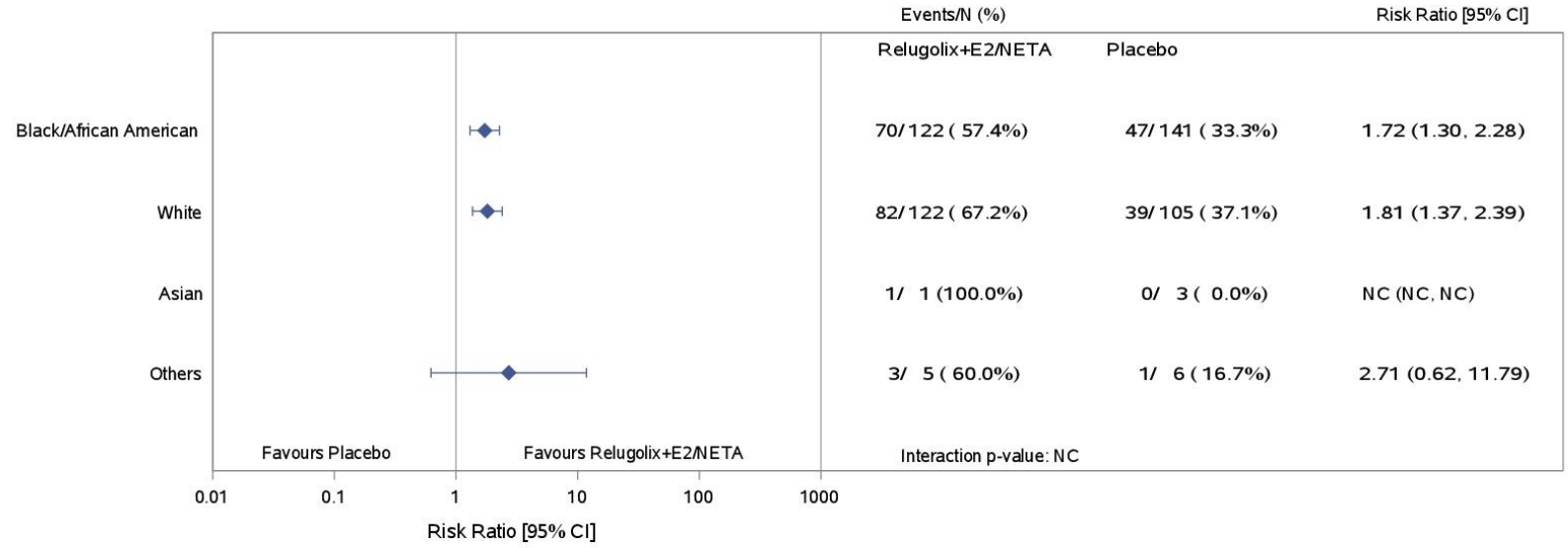
Figure QOL.UFSRAS20.MITT.S9.BIN.FP.RR: Proportion of Responders with at Least 20 Points Increase in UFS-QoL Revised Activity Scale Score at Week 24, by Subgroup (mITT Population) - Risk Ratio
Study: Pooled
Subgroup: Race



Results are based on a Cochran-Mantel-Haenszel approach stratified by study using a one-stage fixed-effects IPD meta-analysis. A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
The reference group is Placebo.
N: Number of patients in treatment group; NETA: Norethindrone acetate; mITT: Modified intent-to-treat; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

SOURCE: X:\Numerus\Studies\MYV\MYV102\Analysis\Prod\Progs\TFLs\Fig_QOL_QS_S_BIN_FP.SAS Date/time of run: 30JUN21 10:27
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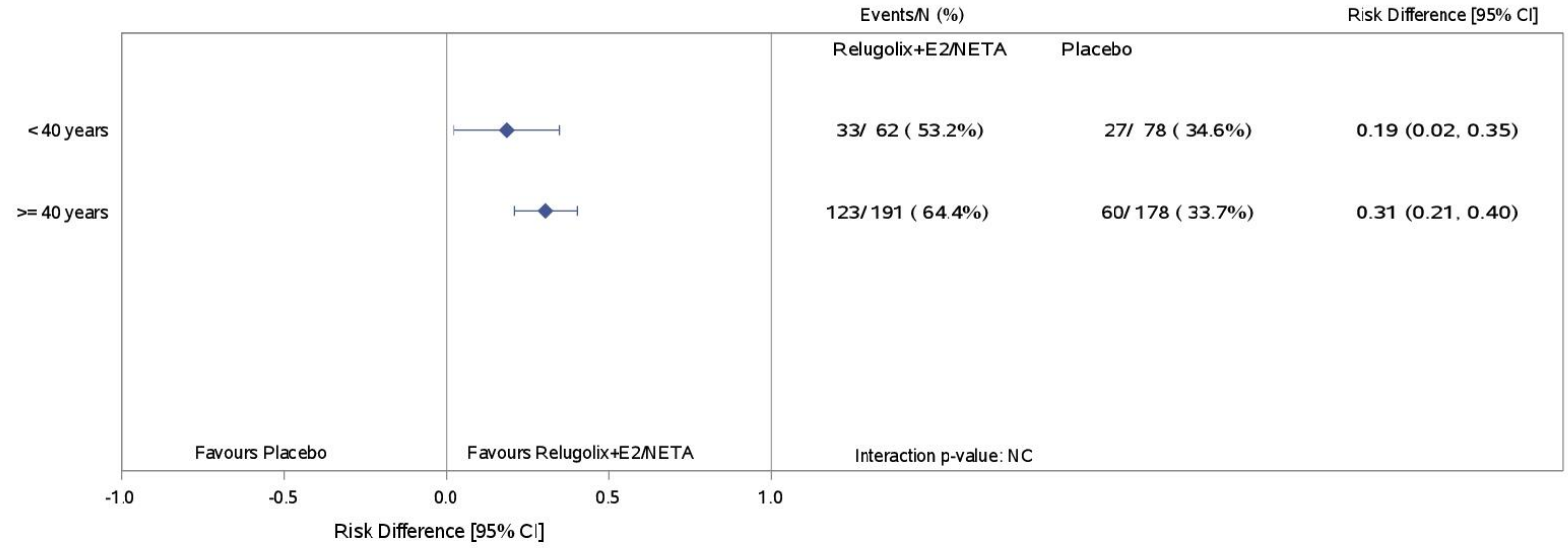
Figure QOL.UFSRAS20.MITT.S1.BIN.FP.RD: Proportion of Responders with at Least 20 Points Increase in UFS-QoL Revised Activity Scale Score at Week 24, by Subgroup (mITT Population) - Risk Difference
Study: Pooled
Subgroup: Age (years)



Results are based on a Mantel-Haenszel approach stratified by study using a one-stage fixed-effects IPD meta-analysis.
The reference group is Placebo.
N: Number of patients in treatment group; NETA: Norethindrone acetate; mITT: Modified intent-to-treat; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

SOURCE: X:\Numerus\Studies\MYV\MYV102\Analysis\Prod\Progs\TFLs\Fig_QOL_QS_S_BIN_FP.SAS Date/time of run: 30JUN21 10:27
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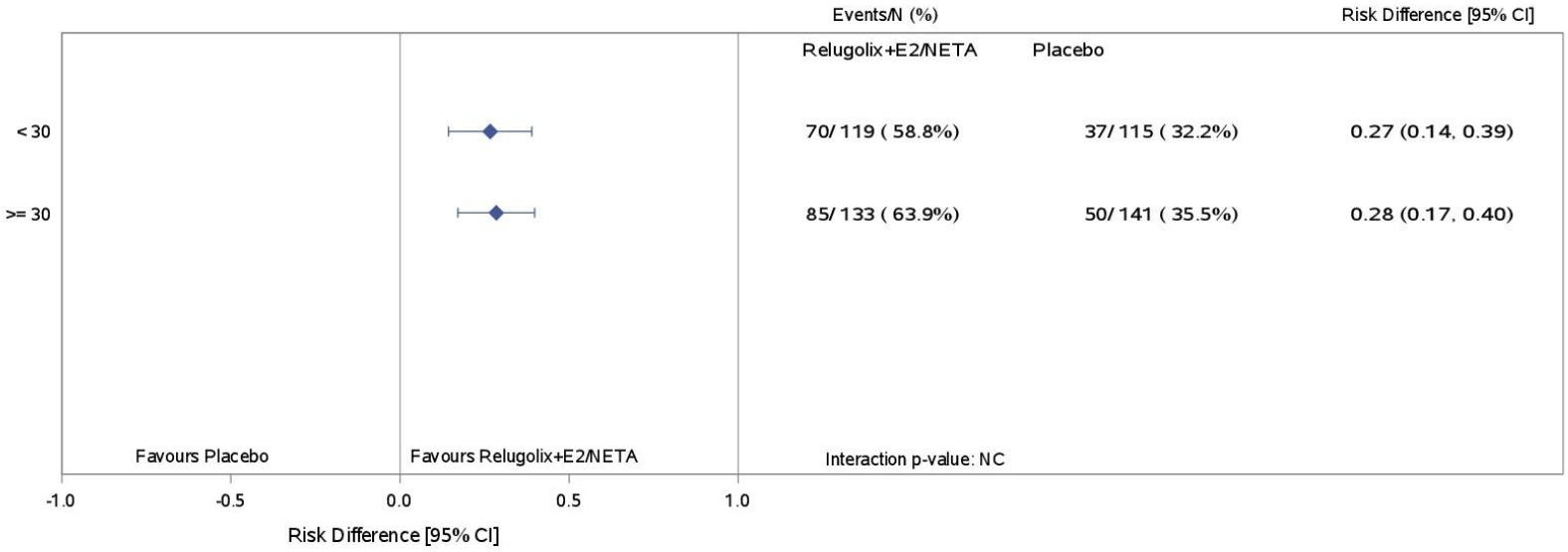
Figure QOL.UFSRAS20.MITT.S2.BIN.FP.RD: Proportion of Responders with at Least 20 Points Increase in UFS-QoL Revised Activity Scale Score at Week 24, by Subgroup (mITT Population) - Risk Difference
Study: Pooled
Subgroup: BMI (kg/m2) at Baseline



Results are based on a Mantel-Haenszel approach stratified by study using a one-stage fixed-effects IPD meta-analysis.
The reference group is Placebo.
N: Number of patients in treatment group; NETA: Norethindrone acetate; mITT: Modified intent-to-treat; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

SOURCE: X:\Numerus\Studies\MYV\MYV102\Analysis\Prod\Progs\TFLs\Fig_QOL_QS_S_BIN_FP.SAS Date/time of run: 30JUN21 10:27
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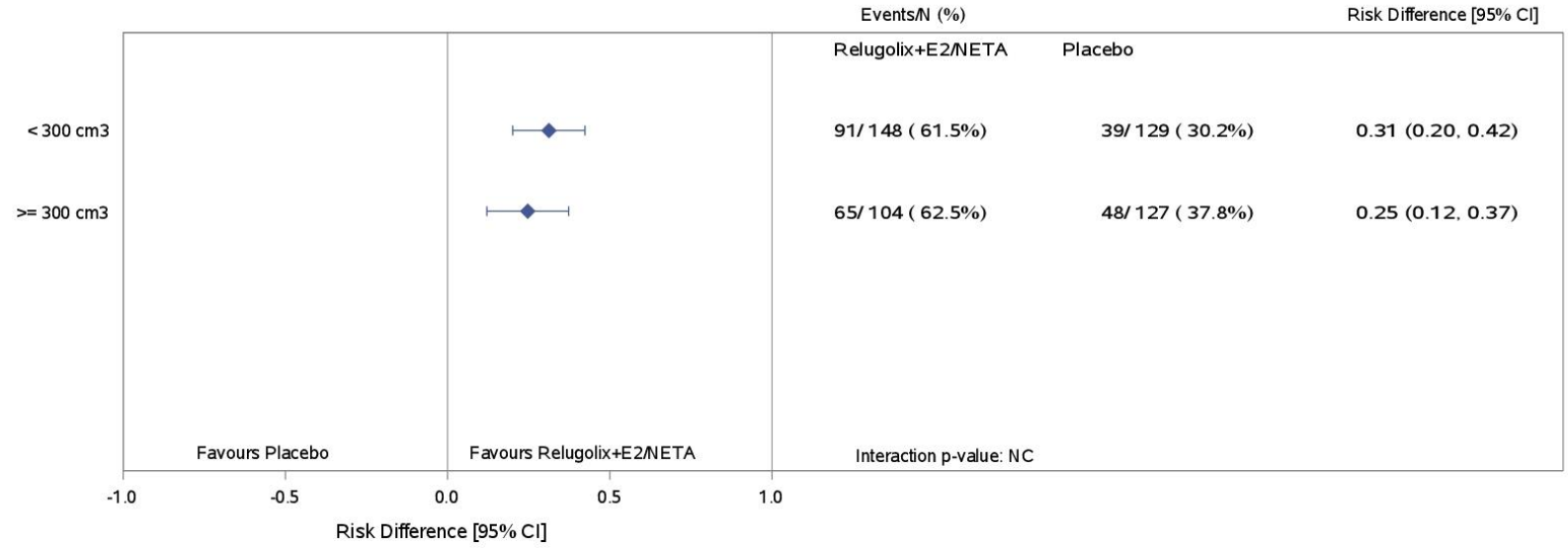
Figure QOL.UFSRAS20.MITT.S3.BIN.FP.RD: Proportion of Responders with at Least 20 Points Increase in UFS-QoL Revised Activity Scale Score at Week 24, by Subgroup (mITT Population) - Risk Difference
Study: Pooled
Subgroup: Uterine Volume at Baseline (cm3)



Results are based on a Mantel-Haenszel approach stratified by study using a one-stage fixed-effects IPD meta-analysis.
The reference group is Placebo.
N: Number of patients in treatment group; NETA: Norethindrone acetate; mITT: Modified intent-to-treat; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

SOURCE: X:\Numerus\Studies\MYV\MYV102\Analysis\Prod\Progs\TFLs\Fig_QOL_QS_S_BIN_FP.SAS Date/time of run: 30JUN21 10:27
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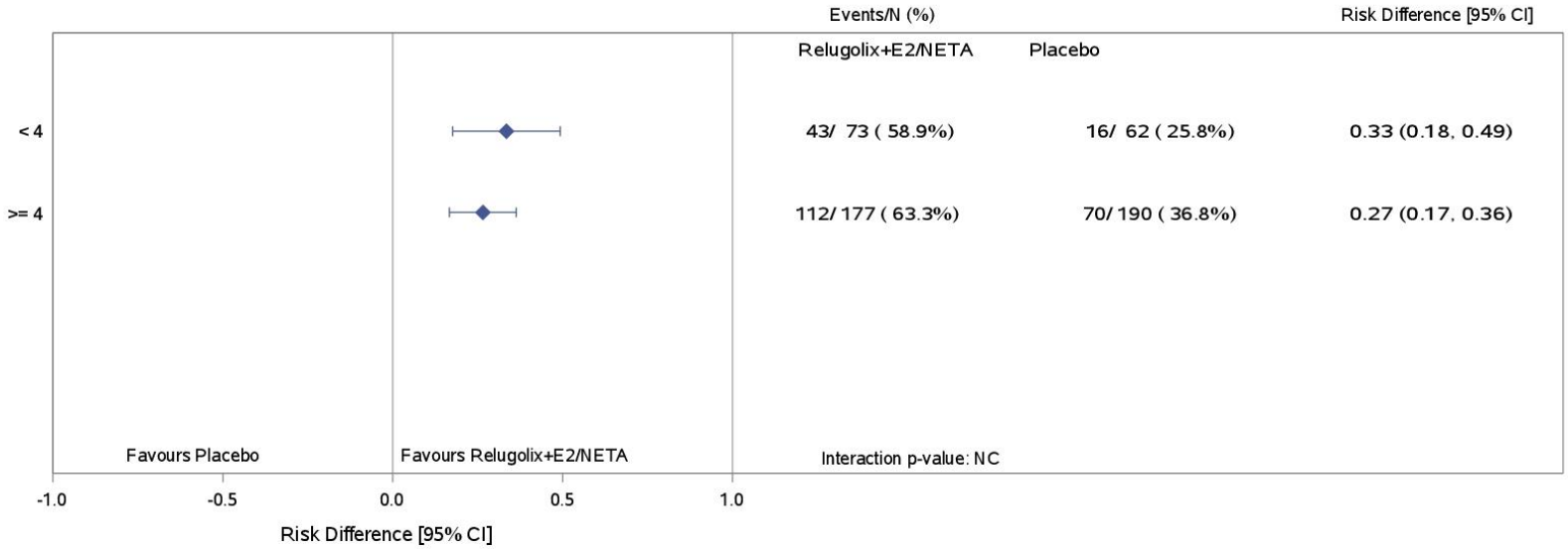
Figure QOL.UFSRAS20.MITT.S4.BIN.FP.RD: Proportion of Responders with at Least 20 Points Increase in UFS-QoL Revised Activity Scale Score at Week 24, by Subgroup (mITT Population) - Risk Difference
Study: Pooled
Subgroup: Maximum NRS Pain Score at Baseline



Results are based on a Mantel-Haenszel approach stratified by study using a one-stage fixed-effects IPD meta-analysis.
The reference group is Placebo.
N: Number of patients in treatment group; NETA: Norethindrone acetate; mITT: Modified intent-to-treat; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

SOURCE: X:\Numerus\Studies\MYV\MYV102\Analysis\Prod\Progs\TFLs\Fig_QOL_QS_S_BIN_FP.SAS Date/time of run: 30JUN21 10:27
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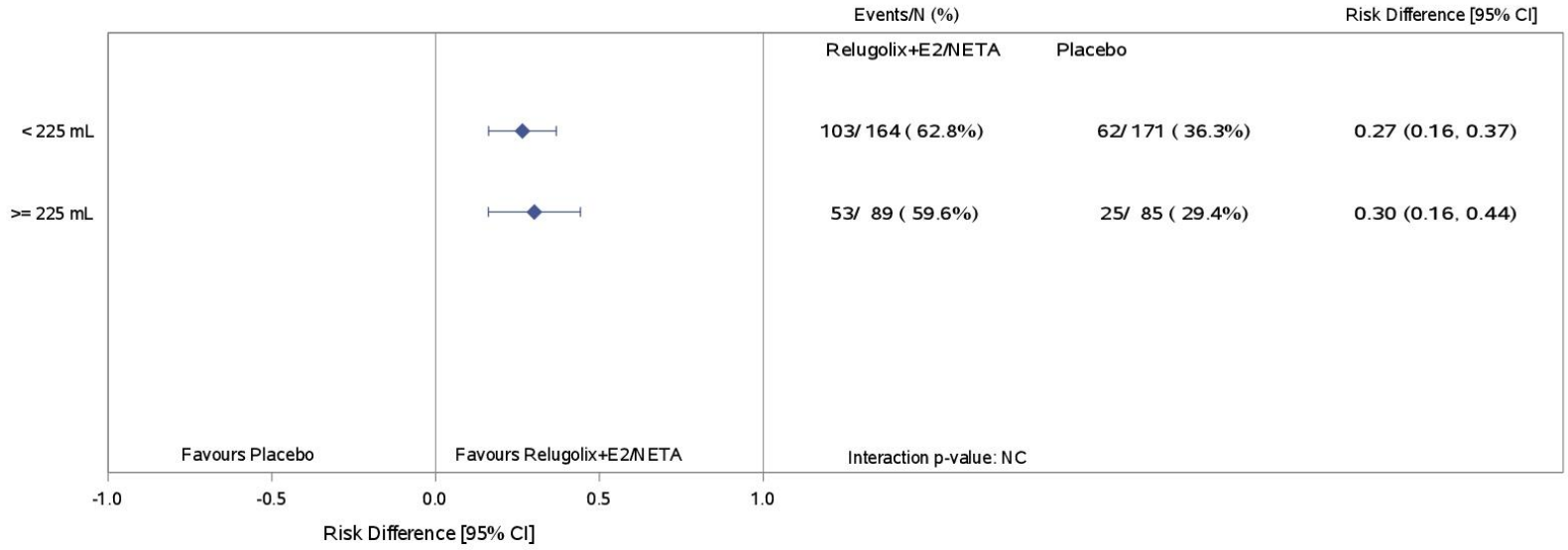
Figure QOL.UFSRAS20.MITT.S5.BIN.FP.RD: Proportion of Responders with at Least 20 Points Increase in UFS-QoL Revised Activity Scale Score at Week 24, by Subgroup (mITT Population) - Risk Difference
Study: Pooled
Subgroup: MBL Volume at Baseline (mL)



Results are based on a Mantel-Haenszel approach stratified by study using a one-stage fixed-effects IPD meta-analysis.
The reference group is Placebo.
N: Number of patients in treatment group; NETA: Norethindrone acetate; mITT: Modified intent-to-treat; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

SOURCE: X:\Numerus\Studies\MYV\MYV102\Analysis\Prod\Progs\TFLs\Fig_QOL_QS_S_BIN_FP.SAS Date/time of run: 30JUN21 10:27
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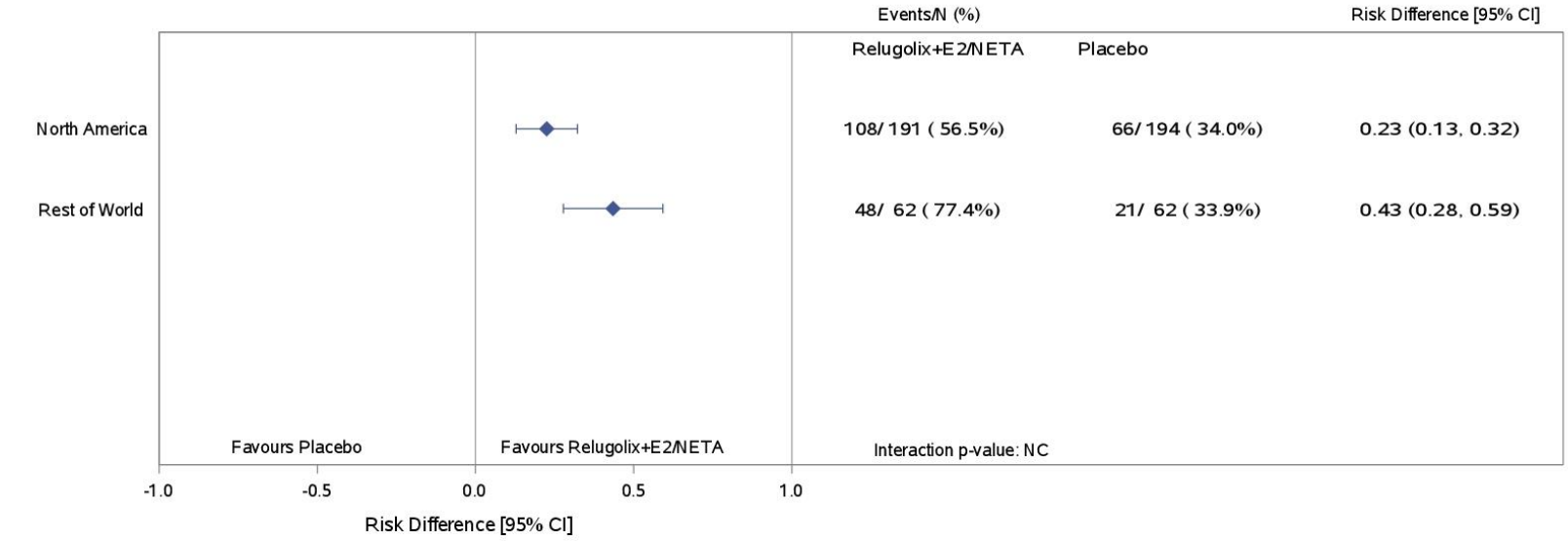
Figure QOL.UFSRAS20.MITT.S6.BIN.FP.RD: Proportion of Responders with at Least 20 Points Increase in UFS-QoL Revised Activity Scale Score at Week 24, by Subgroup (mITT Population) - Risk Difference
Study: Pooled
Subgroup: Geographic Region I



Results are based on a Mantel-Haenszel approach stratified by study using a one-stage fixed-effects IPD meta-analysis.
The reference group is Placebo.
N: Number of patients in treatment group; NETA: Norethindrone acetate; mITT: Modified intent-to-treat; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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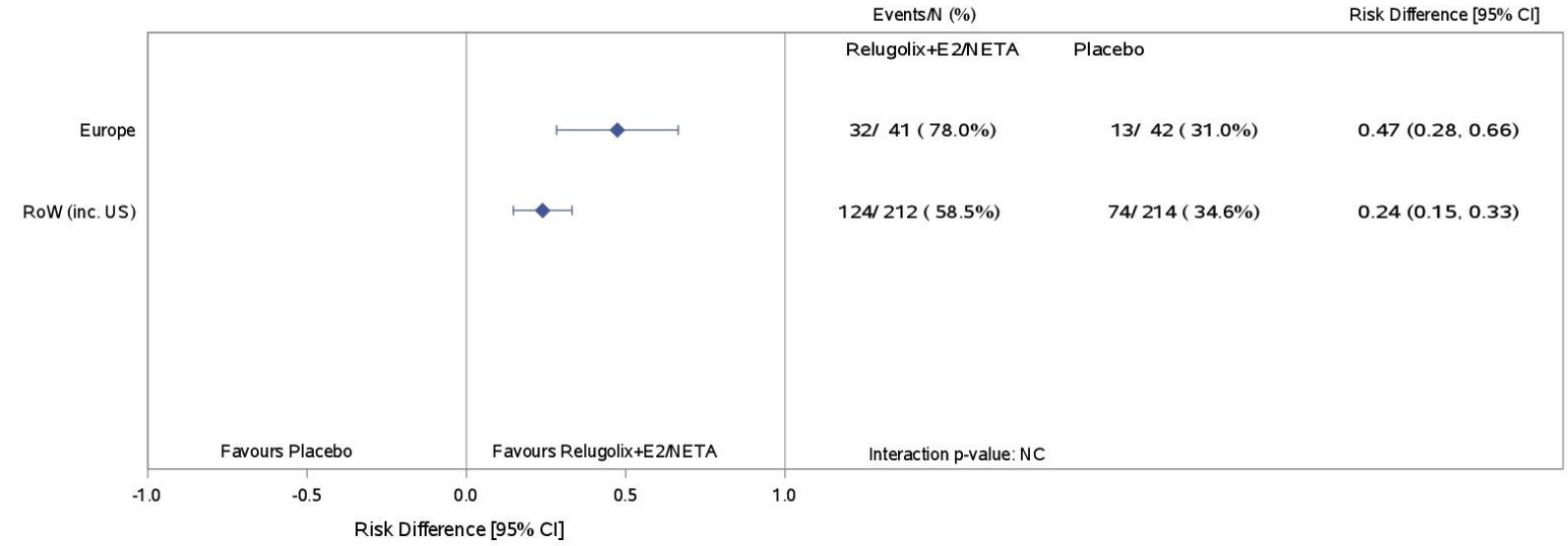
Figure QOL.UFSRAS20.MITT.S7.BIN.FP.RD: Proportion of Responders with at Least 20 Points Increase in UFS-QoL Revised Activity Scale Score at Week 24, by Subgroup (mITT Population) - Risk Difference
Study: Pooled
Subgroup: Geographic Region II



Results are based on a Mantel-Haenszel approach stratified by study using a one-stage fixed-effects IPD meta-analysis.
The reference group is Placebo.
N: Number of patients in treatment group; NETA: Norethindrone acetate; mITT: Modified intent-to-treat; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

SOURCE: X:\Numerus\Studies\MYV\MYV102\Analysis\Prod\Progs\TFLs\Fig_QOL_QS_S_BIN_FP.SAS Date/time of run: 30JUN21 10:27
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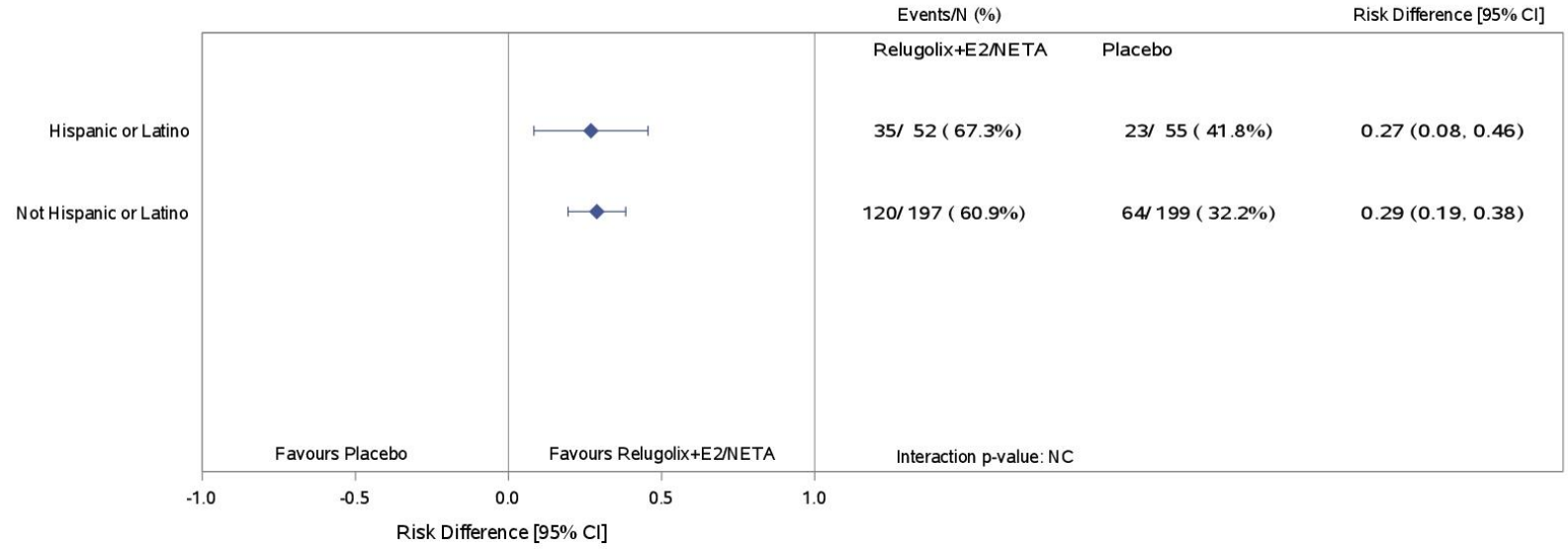
Figure QOL.UFSRAS20.MITT.S8.BIN.FP.RD: Proportion of Responders with at Least 20 Points Increase in UFS-QoL Revised Activity Scale Score at Week 24, by Subgroup (mITT Population) - Risk Difference
Study: Pooled
Subgroup: Ethnicity



Results are based on a Mantel-Haenszel approach stratified by study using a one-stage fixed-effects IPD meta-analysis.
The reference group is Placebo.
N: Number of patients in treatment group; NETA: Norethindrone acetate; mITT: Modified intent-to-treat; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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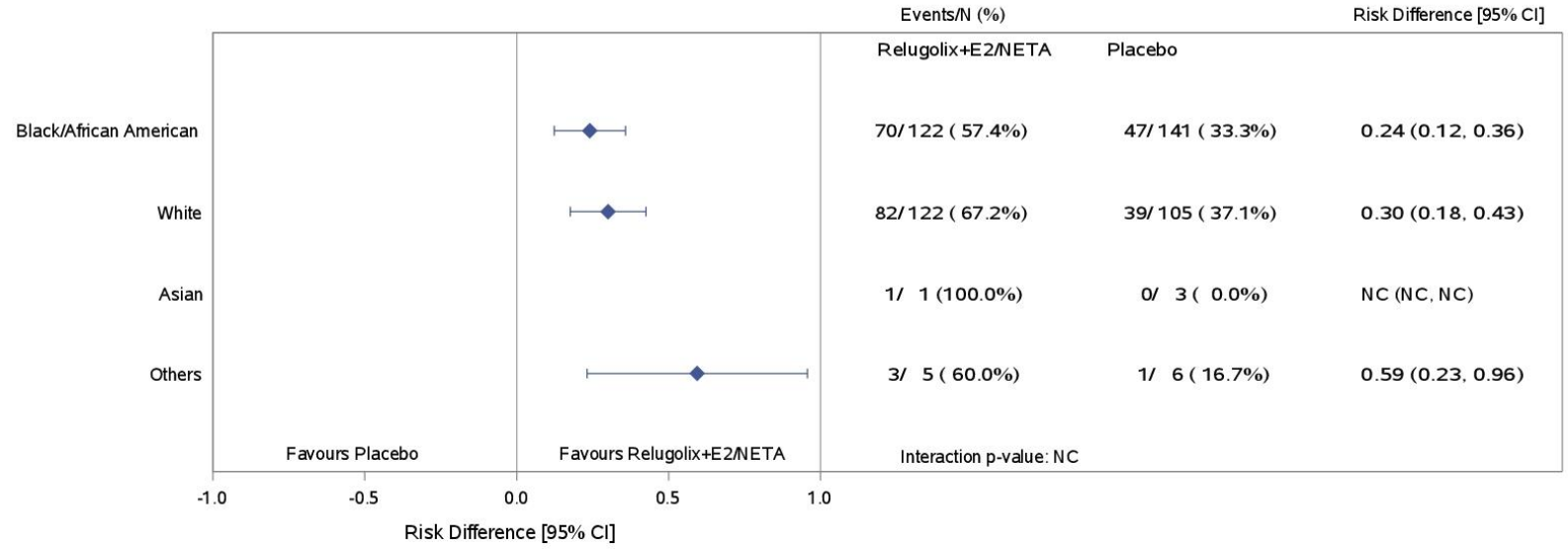
Figure QOL.UFSRAS20.MITT.S9.BIN.FP.RD: Proportion of Responders with at Least 20 Points Increase in UFS-QoL Revised Activity Scale Score at Week 24, by Subgroup (mITT Population) - Risk Difference
Study: Pooled
Subgroup: Race



Results are based on a Mantel-Haenszel approach stratified by study using a one-stage fixed-effects IPD meta-analysis.
The reference group is Placebo.
N: Number of patients in treatment group; NETA: Norethindrone acetate; mITT: Modified intent-to-treat; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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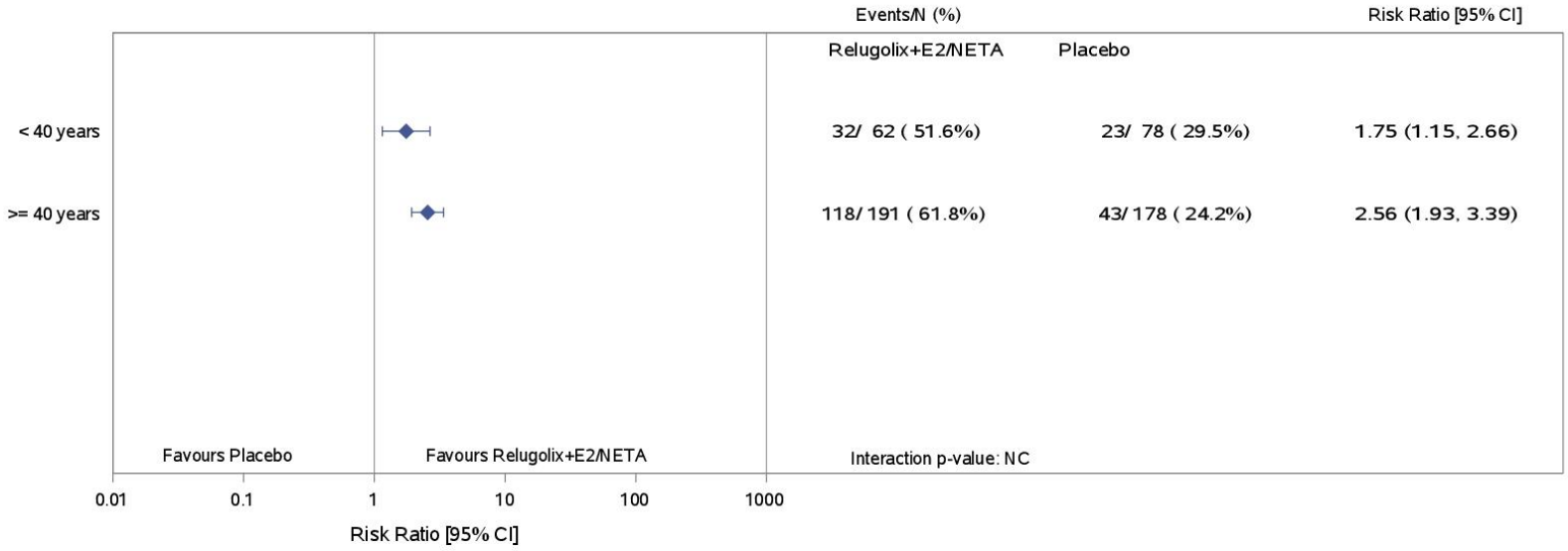
2.2.11 Proportion of Responders with at Least 25 Points Increase in UFS-QoL Revised Activity Scale Score at Week 24, by Subgroup (mITT Population)

Nachfolgend sind zunächst alle Forest Plots für das *Odds Ratio* dargestellt; gefolgt von den entsprechenden Forest Plots für *Risk Ratio* und *Risk Difference*.

Figure QOL.UFSRAS25.MITT.S1.BIN.FP.RR: Proportion of Responders with at Least 25 Points Increase in UFS-QoL Revised Activity Scale Score at Week 24, by Subgroup (mITT Population) - Risk Ratio
Study: Pooled
Subgroup: Age (years)



Results are based on a Cochran-Mantel-Haenszel approach stratified by study using a one-stage fixed-effects IPD meta-analysis. A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
The reference group is Placebo.
N: Number of patients in treatment group; NETA: Norethindrone acetate; mITT: Modified intent-to-treat; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

SOURCE: X:\Numerus\Studies\MYV\MYV102\Analysis\Prod\Progs\TFLs\Fig_QOL_QS_S_BIN_FP.SAS Date/time of run: 30JUN21 10:27
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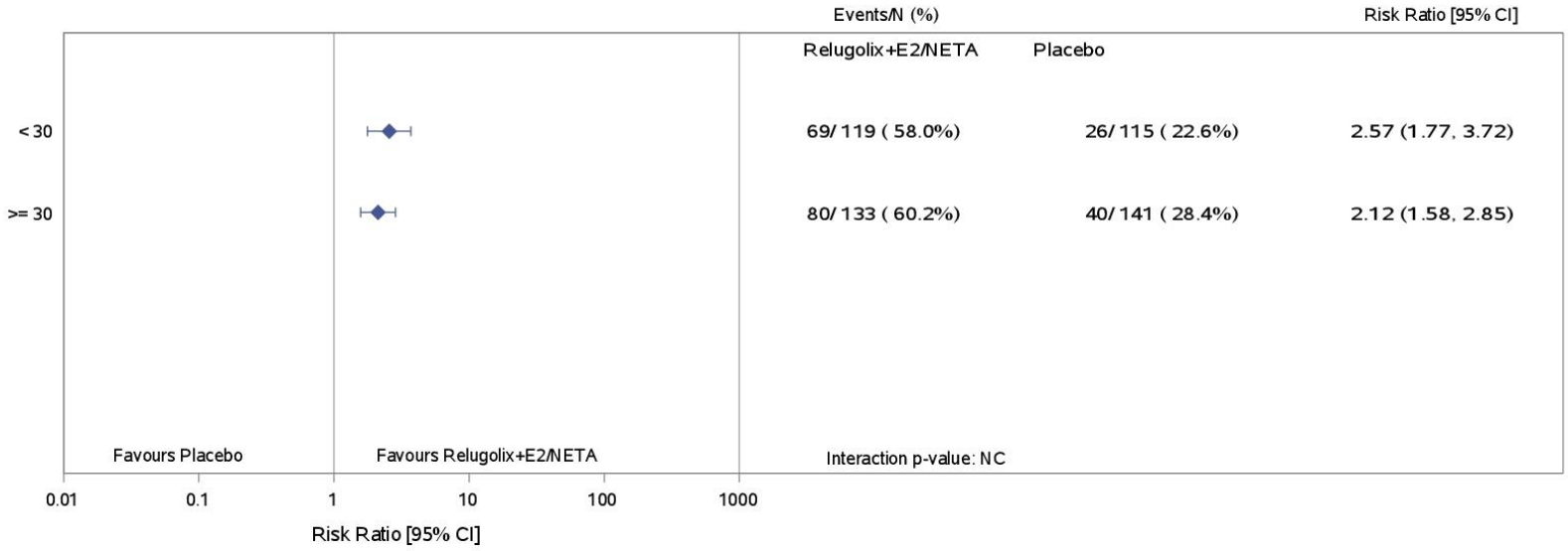
Figure QOL.UFSRAS25.MITT.S2.BIN.FP.RR: Proportion of Responders with at Least 25 Points Increase in UFS-QoL Revised Activity Scale Score at Week 24, by Subgroup (mITT Population) - Risk Ratio
Study: Pooled
Subgroup: BMI (kg/m2) at Baseline



Results are based on a Cochran-Mantel-Haenszel approach stratified by study using a one-stage fixed-effects IPD meta-analysis. A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
The reference group is Placebo.
N: Number of patients in treatment group; NETA: Norethindrone acetate; mITT: Modified intent-to-treat; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

SOURCE: X:\Numerus\Studies\MYV\MYV102\Analysis\Prod\Progs\TFLs\Fig_QOL_QS_S_BIN_FP.SAS Date/time of run: 30JUN21 10:27
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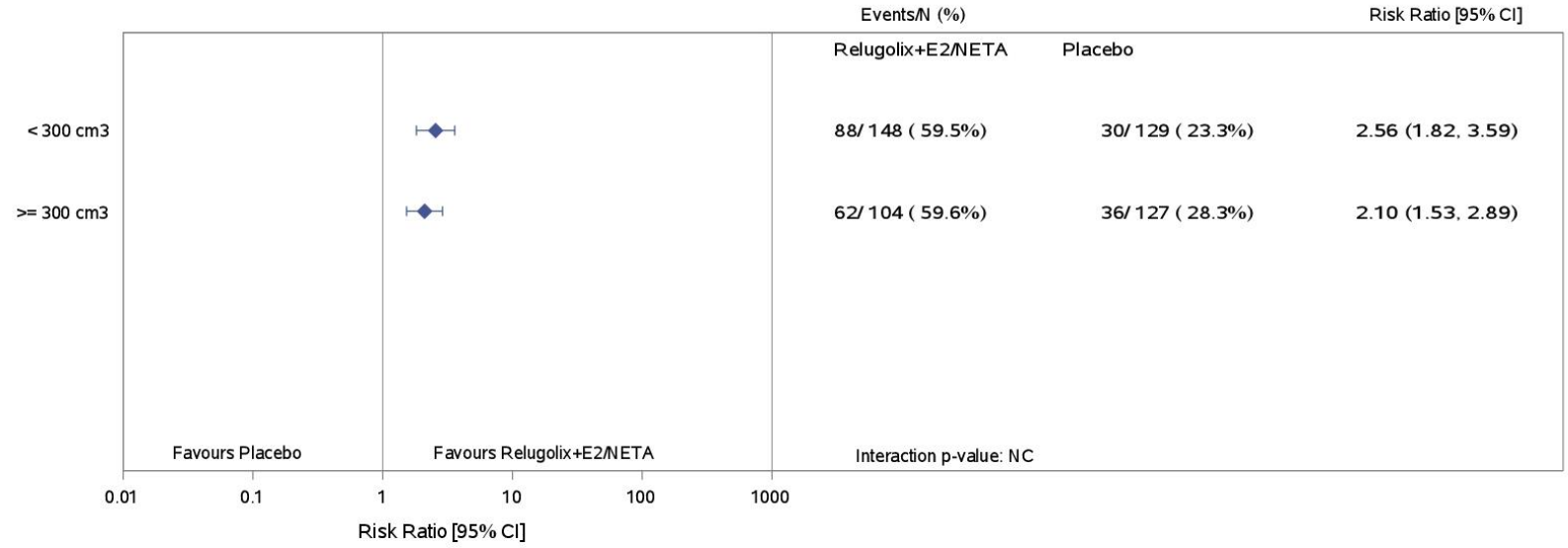
Figure QOL.UFSRAS25.MITT.S3.BIN.FP.RR: Proportion of Responders with at Least 25 Points Increase in UFS-QoL Revised Activity Scale Score at Week 24, by Subgroup (mITT Population) - Risk Ratio
Study: Pooled
Subgroup: Uterine Volume at Baseline (cm3)



Results are based on a Cochran-Mantel-Haenszel approach stratified by study using a one-stage fixed-effects IPD meta-analysis. A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
The reference group is Placebo.
N: Number of patients in treatment group; NETA: Norethindrone acetate; mITT: Modified intent-to-treat; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

SOURCE: X:\Numerus\Studies\MYV\MYV102\Analysis\Prod\Progs\TFLs\Fig_QOL_QS_S_BIN_FP.SAS Date/time of run: 30JUN21 10:27
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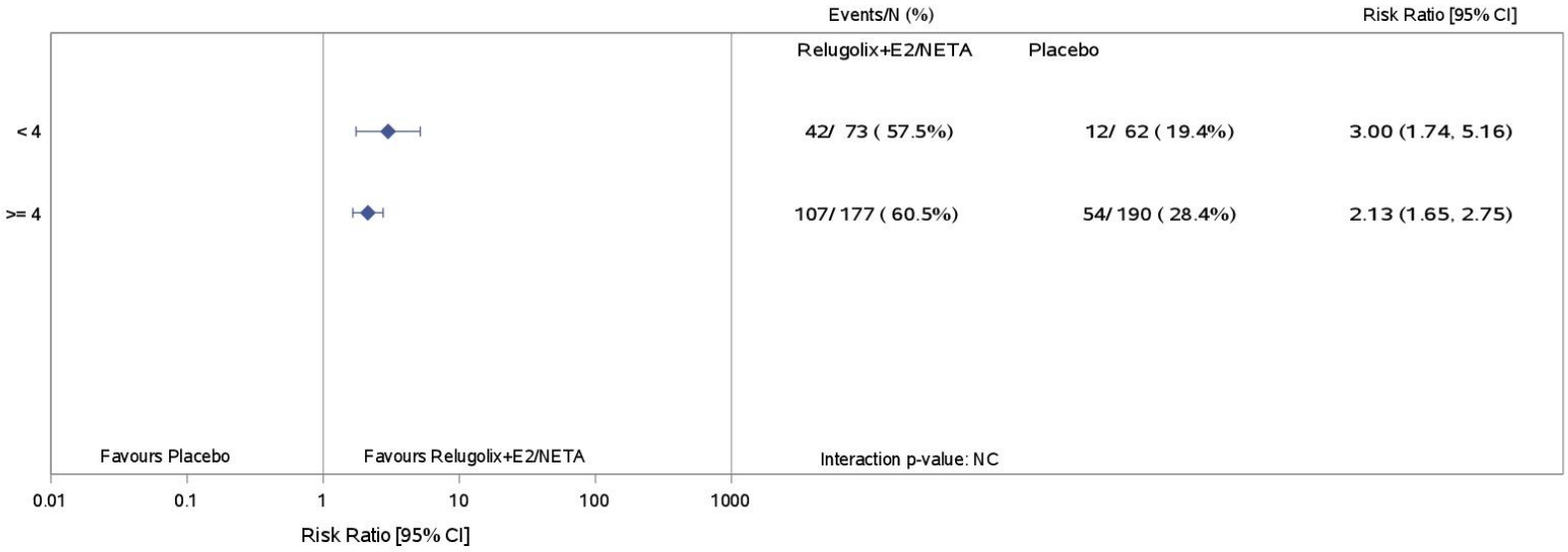
Figure QOL.UFSRAS25.MITT.S4.BIN.FP.RR: Proportion of Responders with at Least 25 Points Increase in UFS-QoL Revised Activity Scale Score at Week 24, by Subgroup (mITT Population) - Risk Ratio
Study: Pooled
Subgroup: Maximum NRS Pain Score at Baseline



Results are based on a Cochran-Mantel-Haenszel approach stratified by study using a one-stage fixed-effects IPD meta-analysis. A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
The reference group is Placebo.
N: Number of patients in treatment group; NETA: Norethindrone acetate; mITT: Modified intent-to-treat; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

SOURCE: X:\Numerus\Studies\MYV\MYV102\Analysis\Prod\Progs\TFLs\Fig_QOL_QS_S_BIN_FP.SAS Date/time of run: 30JUN21 10:27
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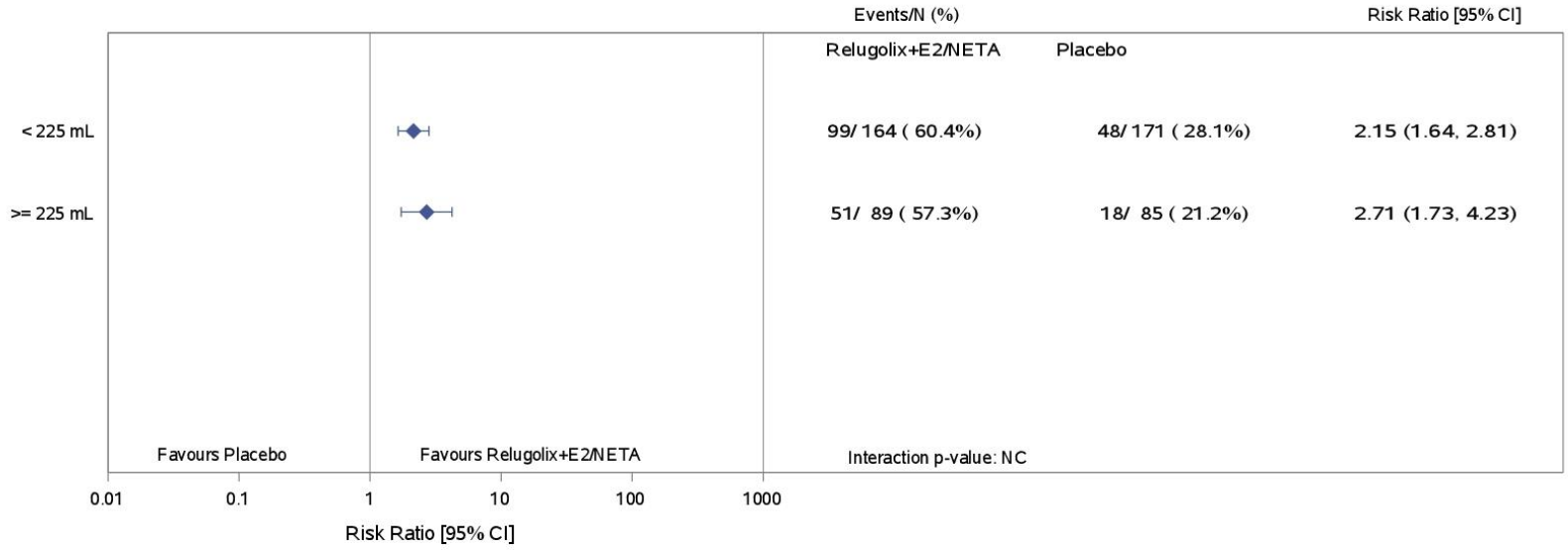
Figure QOL.UFSRAS25.MITT.S5.BIN.FP.RR: Proportion of Responders with at Least 25 Points Increase in UFS-QoL Revised Activity Scale Score at Week 24, by Subgroup (mITT Population) - Risk Ratio
Study: Pooled
Subgroup: MBL Volume at Baseline (mL)



Results are based on a Cochran-Mantel-Haenszel approach stratified by study using a one-stage fixed-effects IPD meta-analysis. A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
The reference group is Placebo.
N: Number of patients in treatment group; NETA: Norethindrone acetate; mITT: Modified intent-to-treat; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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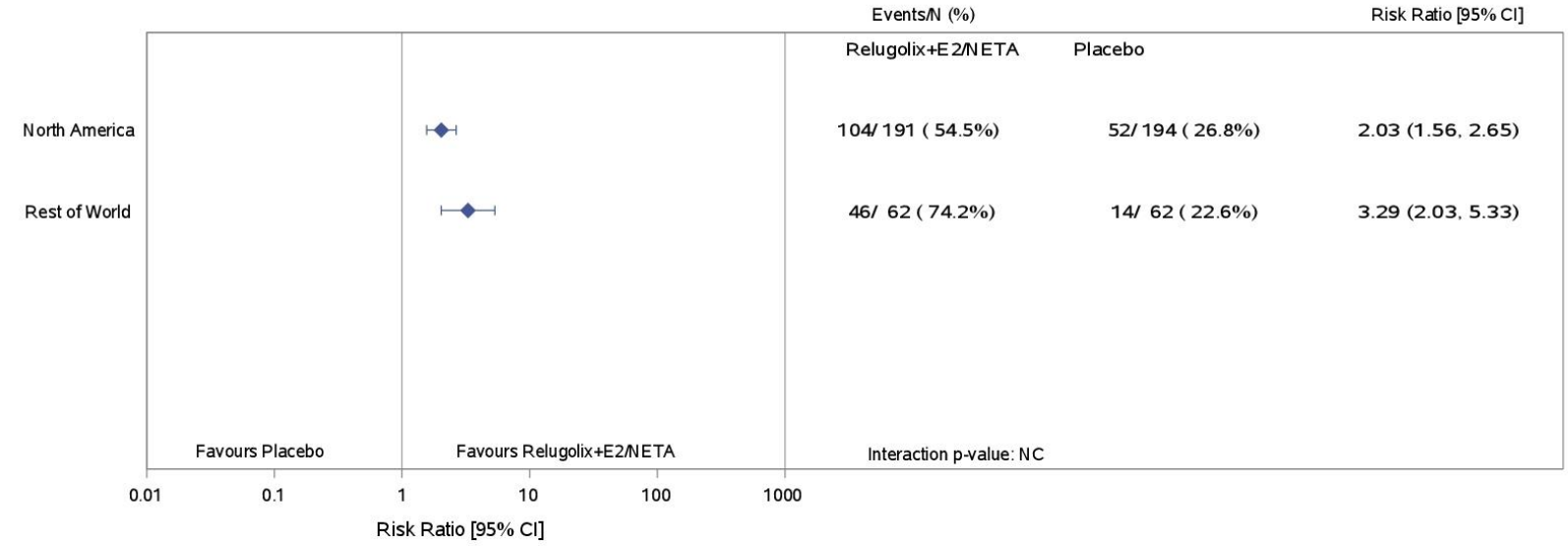
Figure QOL.UFSRAS25.MITT.S6.BIN.FP.RR: Proportion of Responders with at Least 25 Points Increase in UFS-QoL Revised Activity Scale Score at Week 24, by Subgroup (mITT Population) - Risk Ratio
Study: Pooled
Subgroup: Geographic Region I



Results are based on a Cochran-Mantel-Haenszel approach stratified by study using a one-stage fixed-effects IPD meta-analysis. A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
The reference group is Placebo.
N: Number of patients in treatment group; NETA: Norethindrone acetate; mITT: Modified intent-to-treat; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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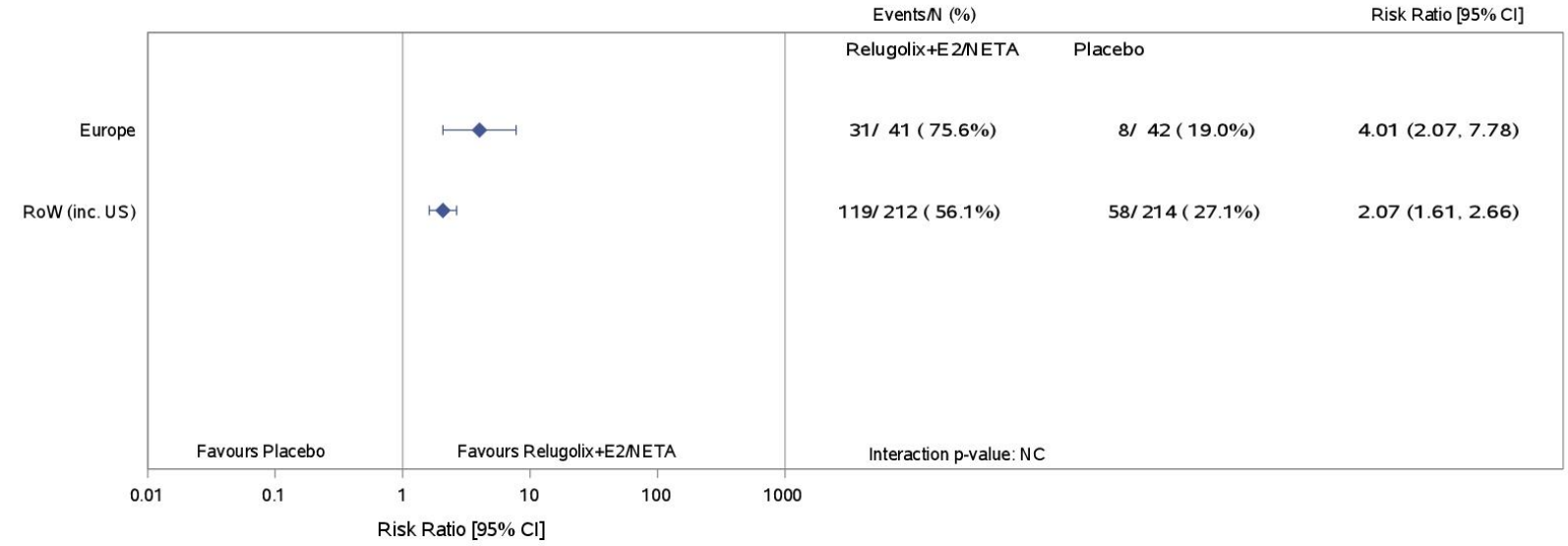
Figure QOL.UFSRAS25.MITT.S7.BIN.FP.RR: Proportion of Responders with at Least 25 Points Increase in UFS-QoL Revised Activity Scale Score at Week 24, by Subgroup (mITT Population) - Risk Ratio
Study: Pooled
Subgroup: Geographic Region II



Results are based on a Cochran-Mantel-Haenszel approach stratified by study using a one-stage fixed-effects IPD meta-analysis. A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
The reference group is Placebo.
N: Number of patients in treatment group; NETA: Norethindrone acetate; mITT: Modified intent-to-treat; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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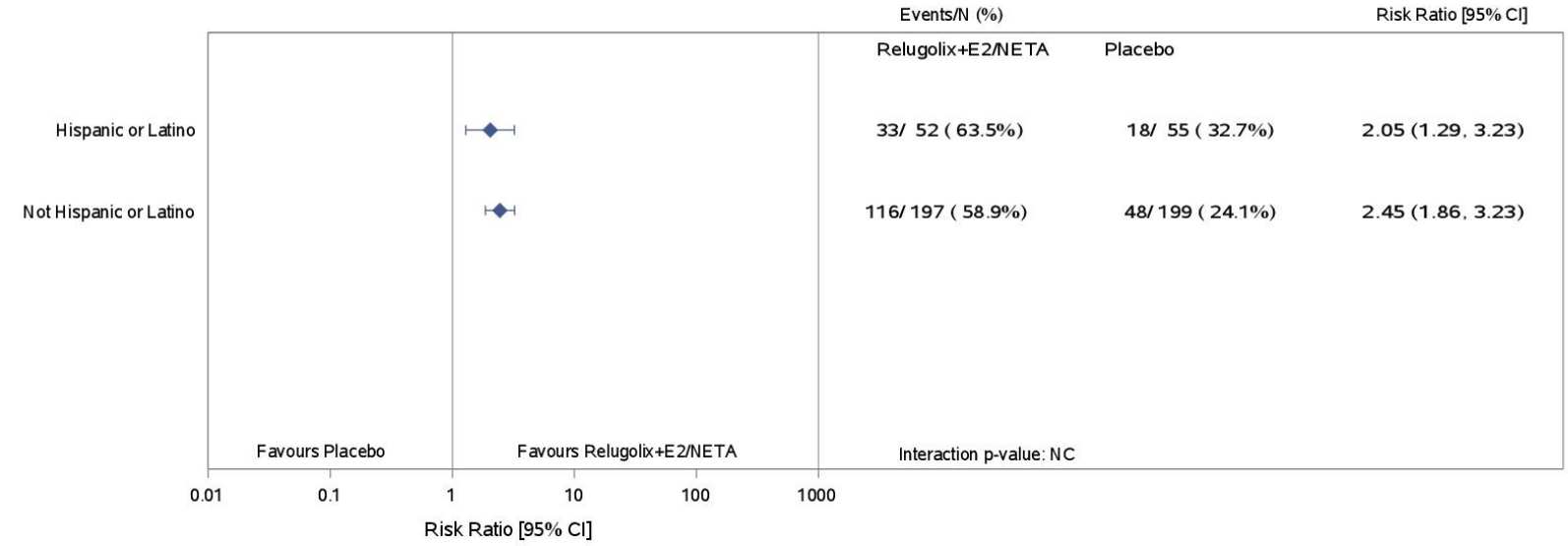
Figure QOL.UFSRAS25.MITT.S8.BIN.FP.RR: Proportion of Responders with at Least 25 Points Increase in UFS-QoL Revised Activity Scale Score at Week 24, by Subgroup (mITT Population) - Risk Ratio
Study: Pooled
Subgroup: Ethnicity



Results are based on a Cochran-Mantel-Haenszel approach stratified by study using a one-stage fixed-effects IPD meta-analysis. A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
The reference group is Placebo.
N: Number of patients in treatment group; NETA: Norethindrone acetate; mITT: Modified intent-to-treat; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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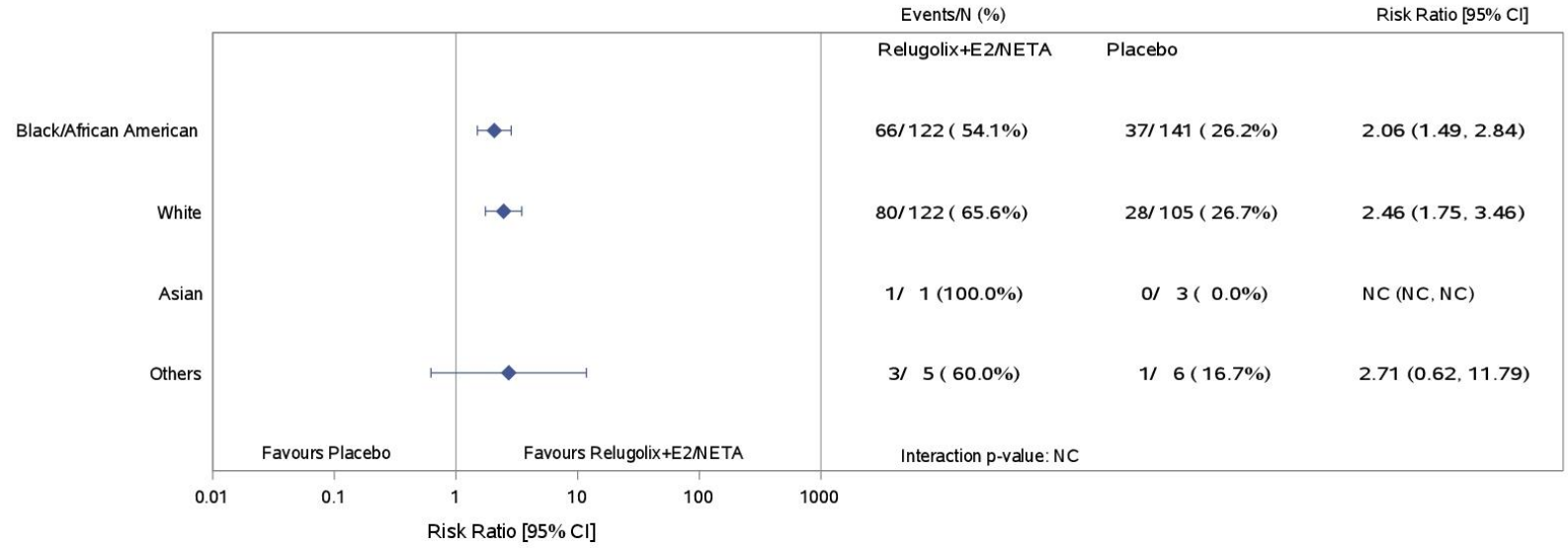
Figure QOL.UFSRAS25.MITT.S9.BIN.FP.RR: Proportion of Responders with at Least 25 Points Increase in UFS-QoL Revised Activity Scale Score at Week 24, by Subgroup (mITT Population) - Risk Ratio
Study: Pooled
Subgroup: Race



Results are based on a Cochran-Mantel-Haenszel approach stratified by study using a one-stage fixed-effects IPD meta-analysis. A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
The reference group is Placebo.
N: Number of patients in treatment group; NETA: Norethindrone acetate; mITT: Modified intent-to-treat; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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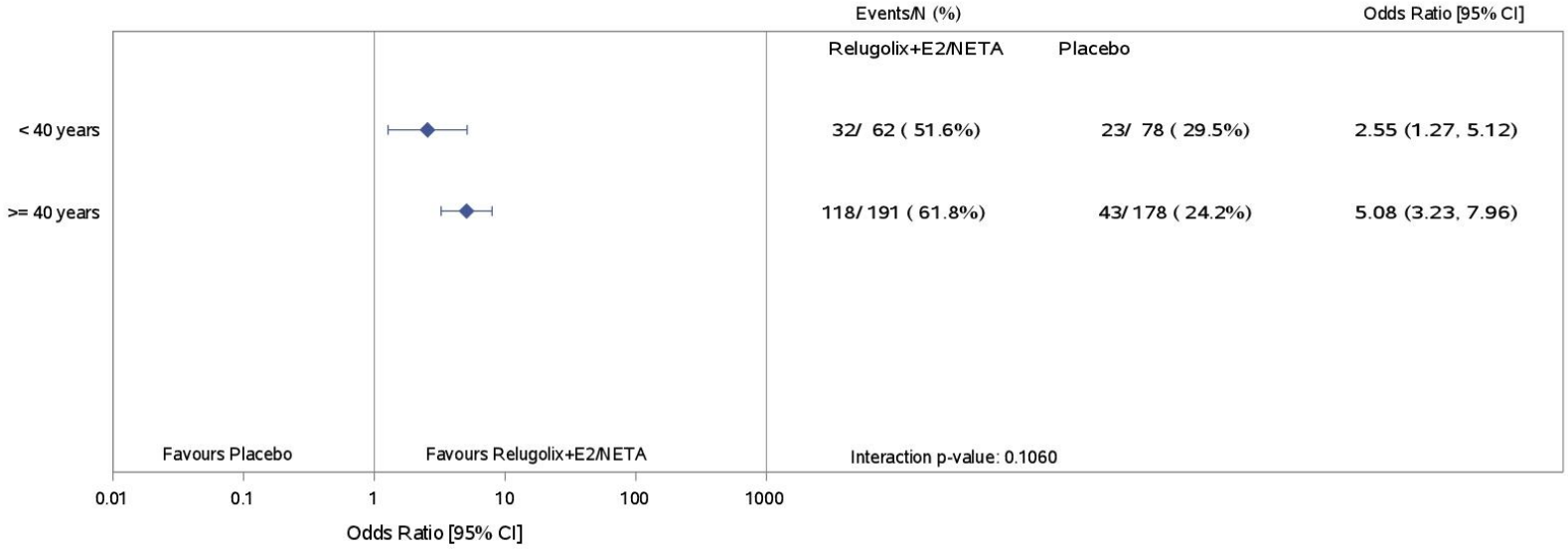
Figure QOL.UFSRAS25.MITT.S1.BIN.FP: Proportion of Responders with at Least 25 Points Increase in UFS-QoL Revised Activity Scale Score at Week 24, by Subgroup (mITT Population)
Study: Pooled
Subgroup: Age (years)



Results are based on a logistic regression model adjusted for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates using a one-stage fixed-effects IPD meta-analysis approach. A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
The interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the Odds Ratio and 95% CI. Missing subgroup levels are not included in estimation of the interaction p-value. The reference group is Placebo.
N: Number of patients in treatment group; NETA: Norethindrone acetate; mITT: Modified intent-to-treat; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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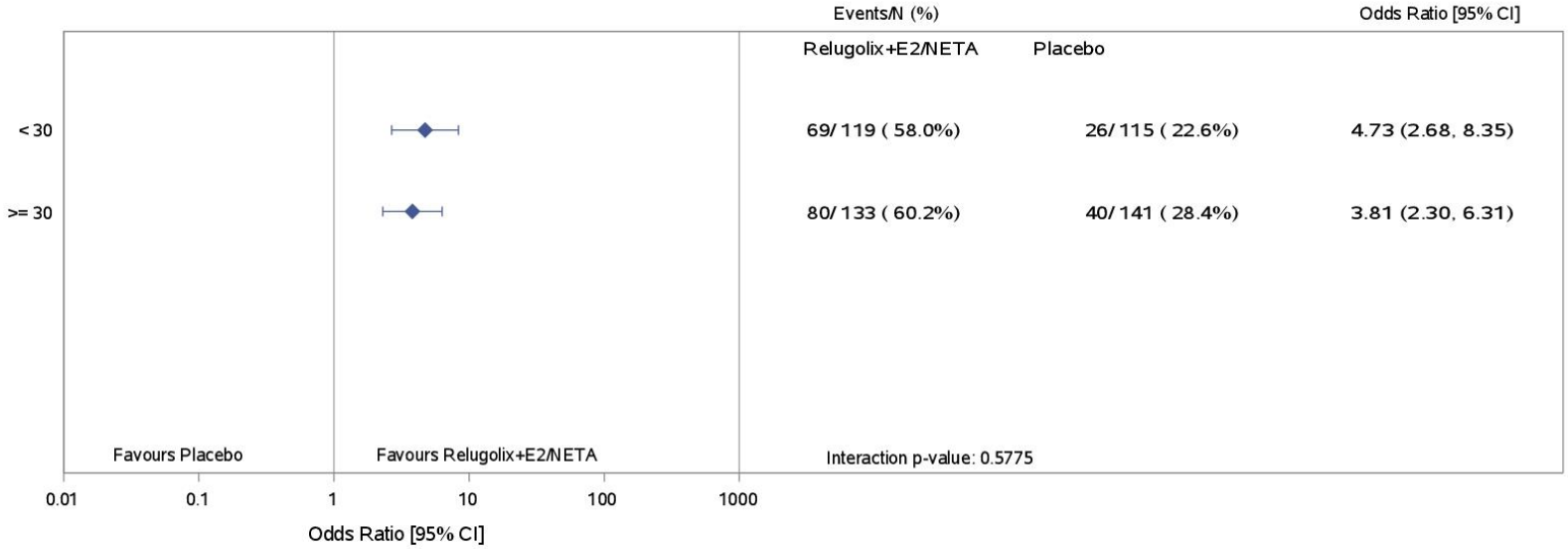
Figure QOL.UFSRAS25.MITT.S2.BIN.FP: Proportion of Responders with at Least 25 Points Increase in UFS-QoL Revised Activity Scale Score at Week 24, by Subgroup (mITT Population)
Study: Pooled
Subgroup: BMI (kg/m2) at Baseline



Results are based on a logistic regression model adjusted for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates using a one-stage fixed-effects IPD meta-analysis approach. A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
The interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the Odds Ratio and 95% CI. Missing subgroup levels are not included in estimation of the interaction p-value. The reference group is Placebo.
N: Number of patients in treatment group; NETA: Norethindrone acetate; mITT: Modified intent-to-treat; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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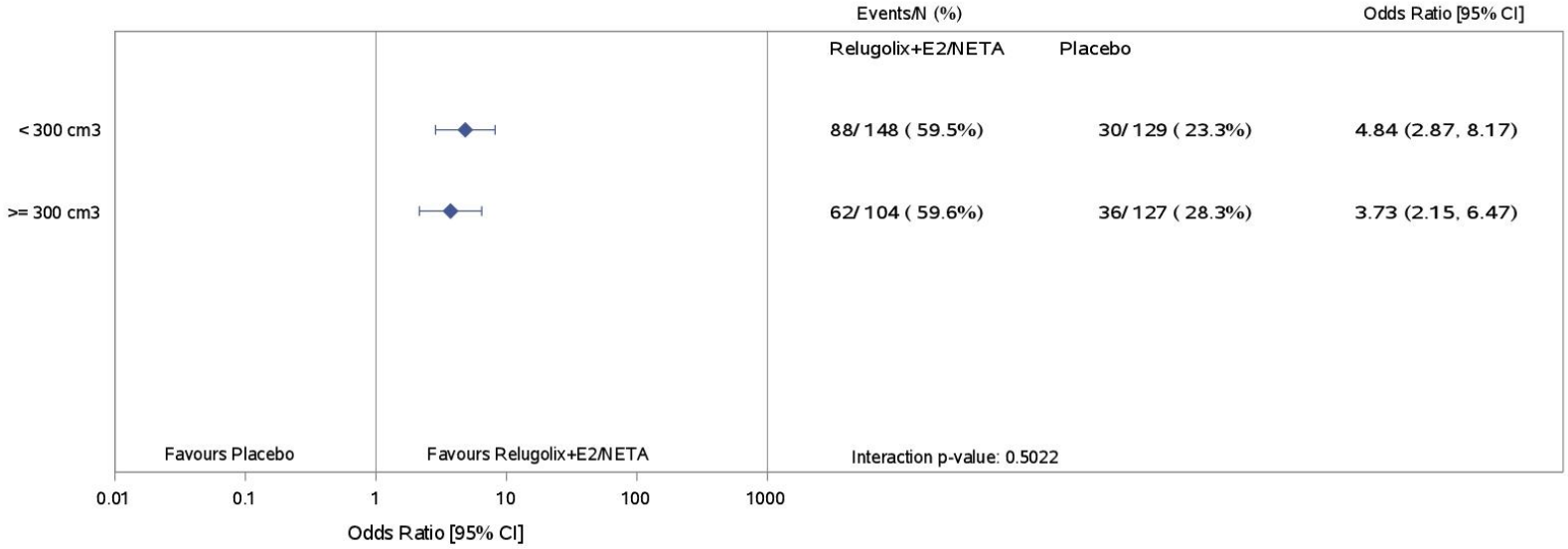
Figure QOL.UFSRAS25.MITT.S3.BIN.FP: Proportion of Responders with at Least 25 Points Increase in UFS-QoL Revised Activity Scale Score at Week 24, by Subgroup (mITT Population)
Study: Pooled
Subgroup: Uterine Volume at Baseline (cm3)



Results are based on a logistic regression model adjusted for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates using a one-stage fixed-effects IPD meta-analysis approach. A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
The interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the Odds Ratio and 95% CI. Missing subgroup levels are not included in estimation of the interaction p-value. The reference group is Placebo.
N: Number of patients in treatment group; NETA: Norethindrone acetate; mITT: Modified intent-to-treat; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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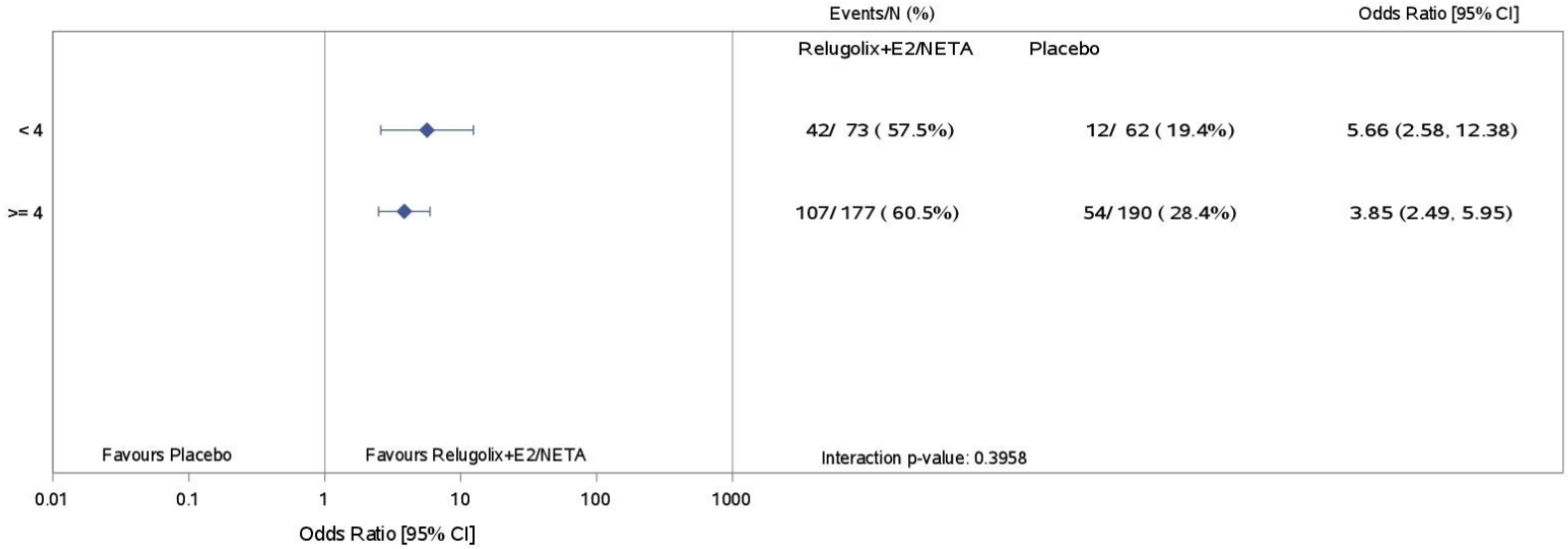
Figure QOL.UFSRAS25.MITT.S4.BIN.FP: Proportion of Responders with at Least 25 Points Increase in UFS-QoL Revised Activity Scale Score at Week 24, by Subgroup (mITT Population)
Study: Pooled
Subgroup: Maximum NRS Pain Score at Baseline



Results are based on a logistic regression model adjusted for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates using a one-stage fixed-effects IPD meta-analysis approach. A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
The interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the Odds Ratio and 95% CI. Missing subgroup levels are not included in estimation of the interaction p-value. The reference group is Placebo.
N: Number of patients in treatment group; NETA: Norethindrone acetate; mITT: Modified intent-to-treat; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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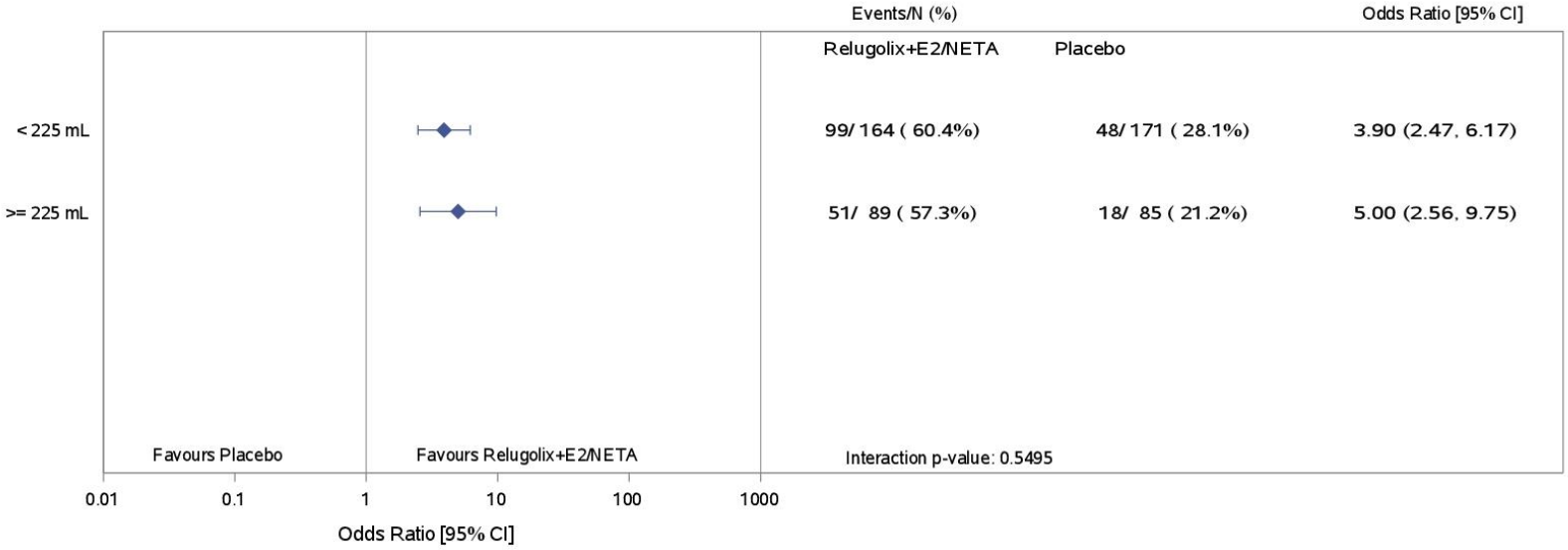
Figure QOL.UFSRAS25.MITT.S5.BIN.FP: Proportion of Responders with at Least 25 Points Increase in UFS-QoL Revised Activity Scale Score at Week 24, by Subgroup (mITT Population)
Study: Pooled
Subgroup: MBL Volume at Baseline (mL)



Results are based on a logistic regression model adjusted for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates using a one-stage fixed-effects IPD meta-analysis approach. A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
The interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the Odds Ratio and 95% CI. Missing subgroup levels are not included in estimation of the interaction p-value. The reference group is Placebo.
N: Number of patients in treatment group; NETA: Norethindrone acetate; mITT: Modified intent-to-treat; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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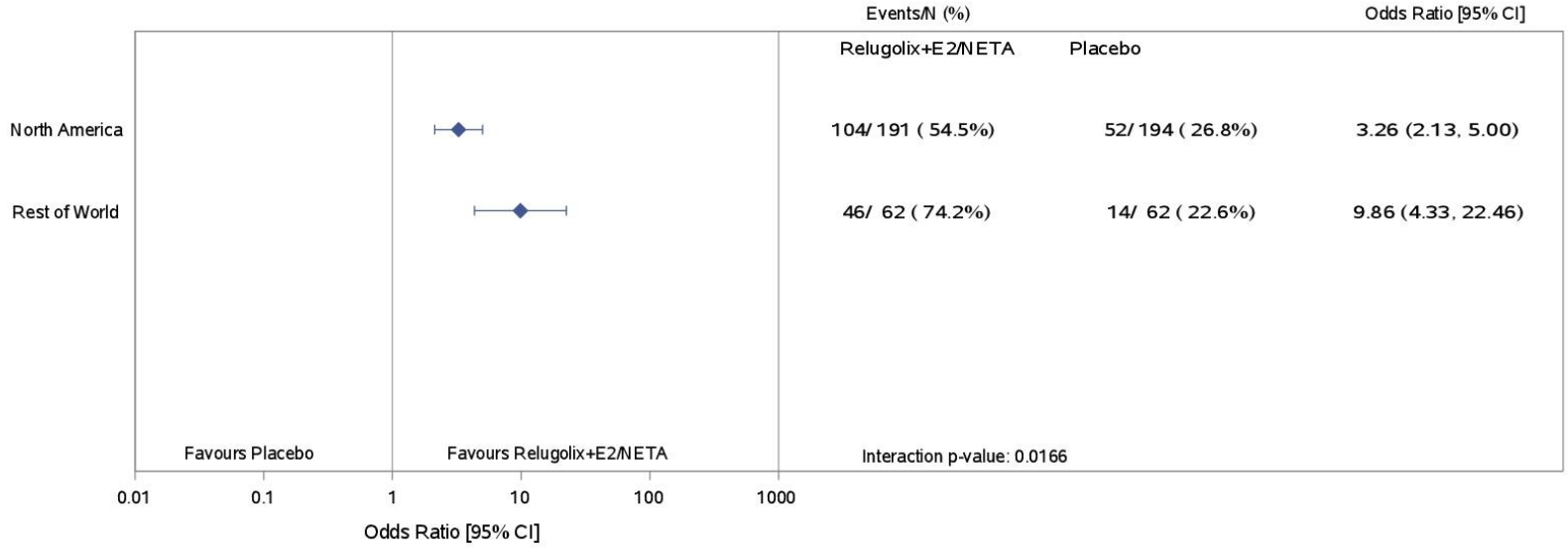
Figure QOL.UFSRAS25.MITT.S6.BIN.FP: Proportion of Responders with at Least 25 Points Increase in UFS-QoL Revised Activity Scale Score at Week 24, by Subgroup (mITT Population)
Study: Pooled
Subgroup: Geographic Region I



Results are based on a logistic regression model adjusted for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates using a one-stage fixed-effects IPD meta-analysis approach. A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
The interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the Odds Ratio and 95% CI. Missing subgroup levels are not included in estimation of the interaction p-value. The reference group is Placebo.
N: Number of patients in treatment group; NETA: Norethindrone acetate; mITT: Modified intent-to-treat; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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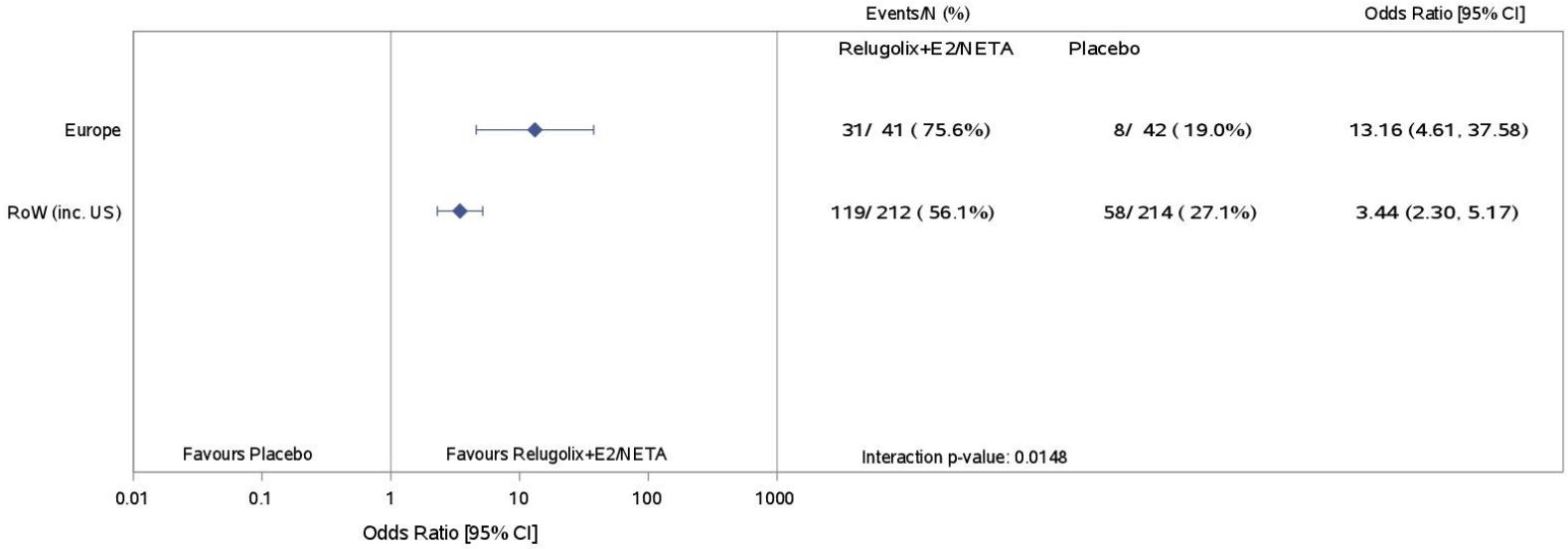
Figure QOL.UFSRAS25.MITT.S7.BIN.FP: Proportion of Responders with at Least 25 Points Increase in UFS-QoL Revised Activity Scale Score at Week 24, by Subgroup (mITT Population)
Study: Pooled
Subgroup: Geographic Region II



Results are based on a logistic regression model adjusted for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates using a one-stage fixed-effects IPD meta-analysis approach. A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
The interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the Odds Ratio and 95% CI. Missing subgroup levels are not included in estimation of the interaction p-value. The reference group is Placebo.
N: Number of patients in treatment group; NETA: Norethindrone acetate; mITT: Modified intent-to-treat; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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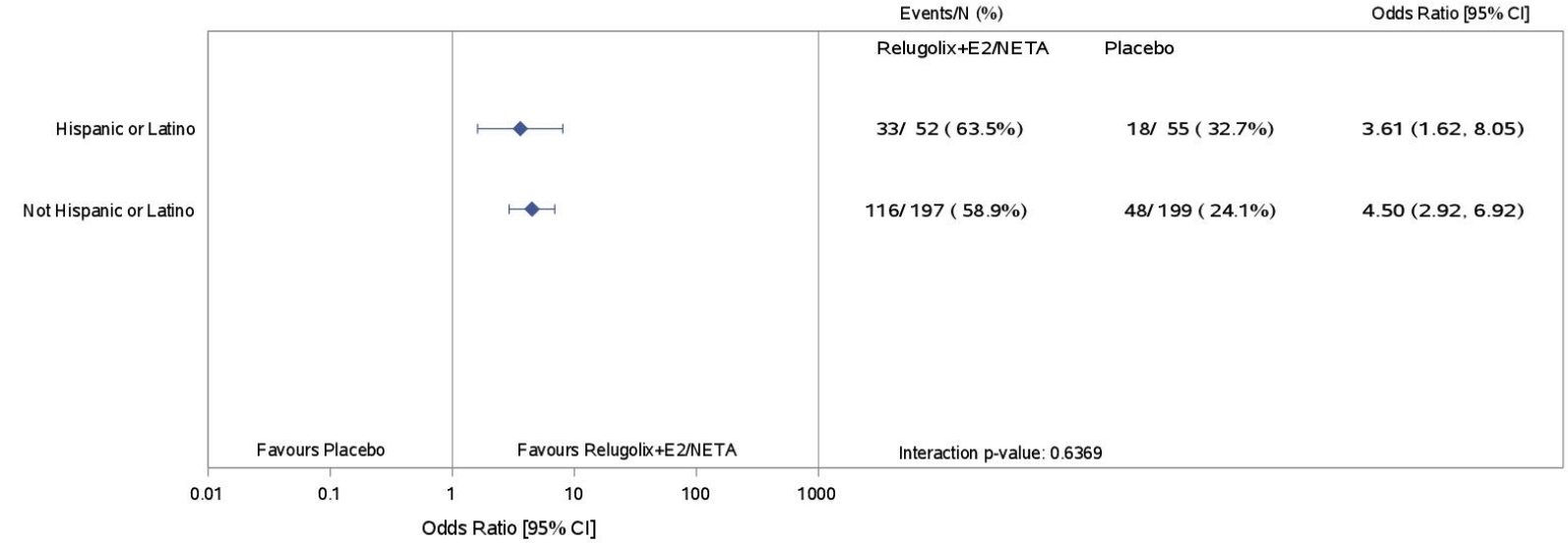
Figure QOL.UFSRAS25.MITT.S8.BIN.FP: Proportion of Responders with at Least 25 Points Increase in UFS-QoL Revised Activity Scale Score at Week 24, by Subgroup (mITT Population)
Study: Pooled
Subgroup: Ethnicity



Results are based on a logistic regression model adjusted for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates using a one-stage fixed-effects IPD meta-analysis approach. A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
The interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the Odds Ratio and 95% CI. Missing subgroup levels are not included in estimation of the interaction p-value. The reference group is Placebo.
N: Number of patients in treatment group; NETA: Norethindrone acetate; mITT: Modified intent-to-treat; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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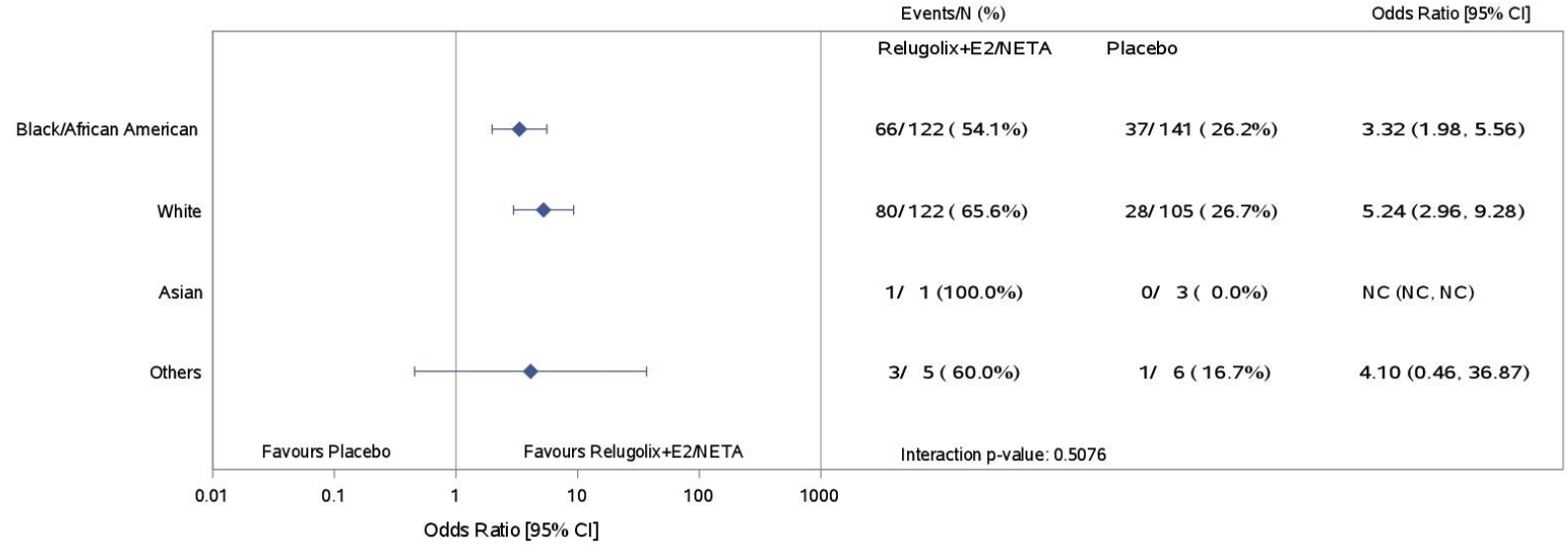
Figure QOL.UFSRAS25.MITT.S9.BIN.FP: Proportion of Responders with at Least 25 Points Increase in UFS-QoL Revised Activity Scale Score at Week 24, by Subgroup (mITT Population)
Study: Pooled
Subgroup: Race



Results are based on a logistic regression model adjusted for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates using a one-stage fixed-effects IPD meta-analysis approach. A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
The interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the Odds Ratio and 95% CI. Missing subgroup levels are not included in estimation of the interaction p-value. The reference group is Placebo.
N: Number of patients in treatment group; NETA: Norethindrone acetate; mITT: Modified intent-to-treat; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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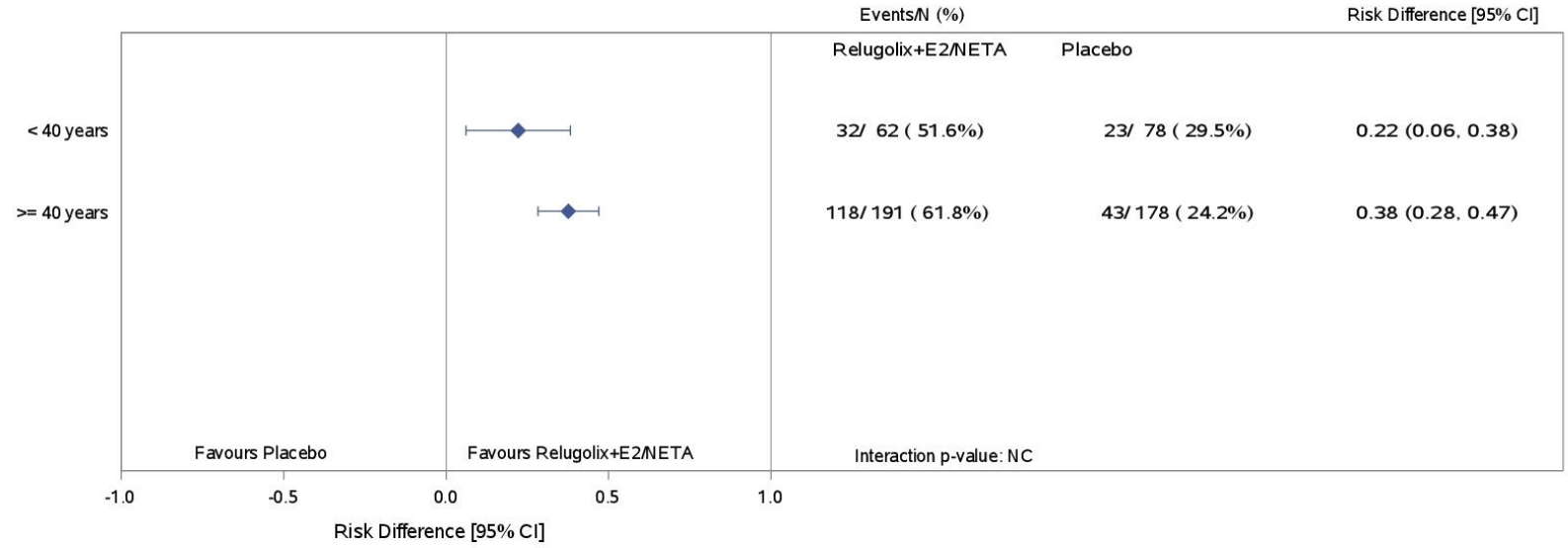
Figure QOL.UFSRAS25.MITT.S1.BIN.FP.RD: Proportion of Responders with at Least 25 Points Increase in UFS-QoL Revised Activity Scale Score at Week 24, by Subgroup (mITT Population) - Risk Difference
Study: Pooled
Subgroup: Age (years)



Results are based on a Mantel-Haenszel approach stratified by study using a one-stage fixed-effects IPD meta-analysis.
The reference group is Placebo.
N: Number of patients in treatment group; NETA: Norethindrone acetate; mITT: Modified intent-to-treat; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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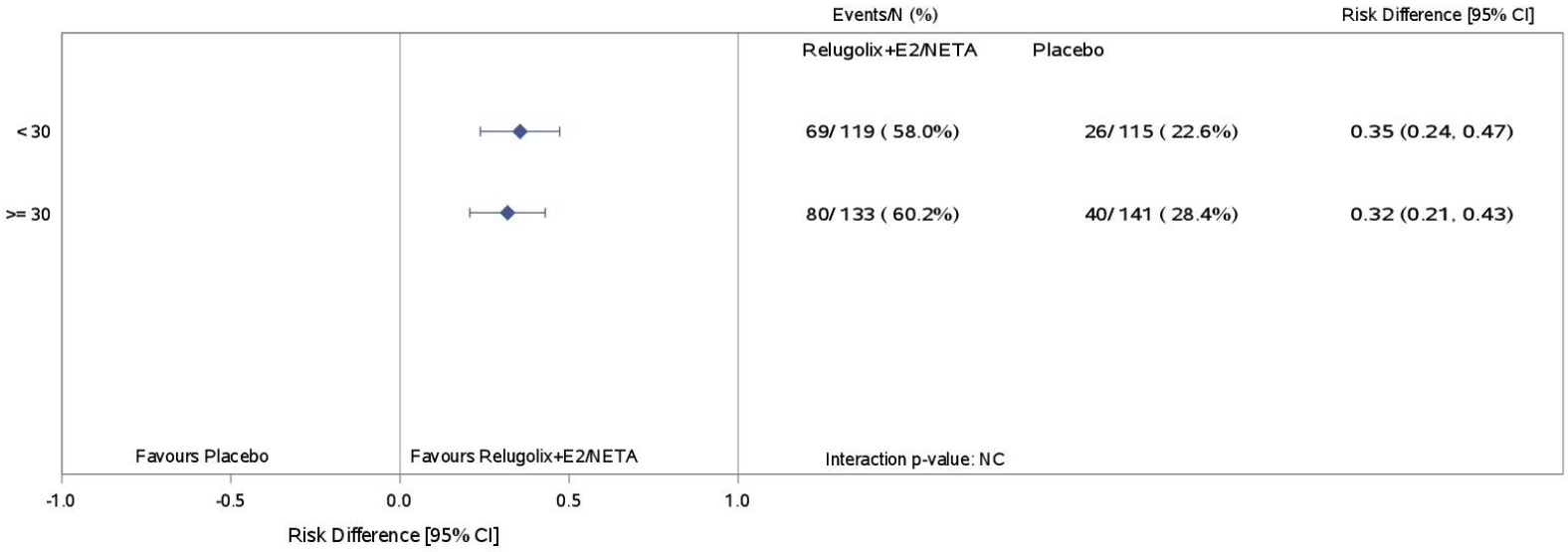
Figure QOL.UFSRAS25.MITT.S2.BIN.FP.RD: Proportion of Responders with at Least 25 Points Increase in UFS-QoL Revised Activity Scale Score at Week 24, by Subgroup (mITT Population) - Risk Difference
Study: Pooled
Subgroup: BMI (kg/m2) at Baseline



Results are based on a Mantel-Haenszel approach stratified by study using a one-stage fixed-effects IPD meta-analysis.
The reference group is Placebo.
N: Number of patients in treatment group; NETA: Norethindrone acetate; mITT: Modified intent-to-treat; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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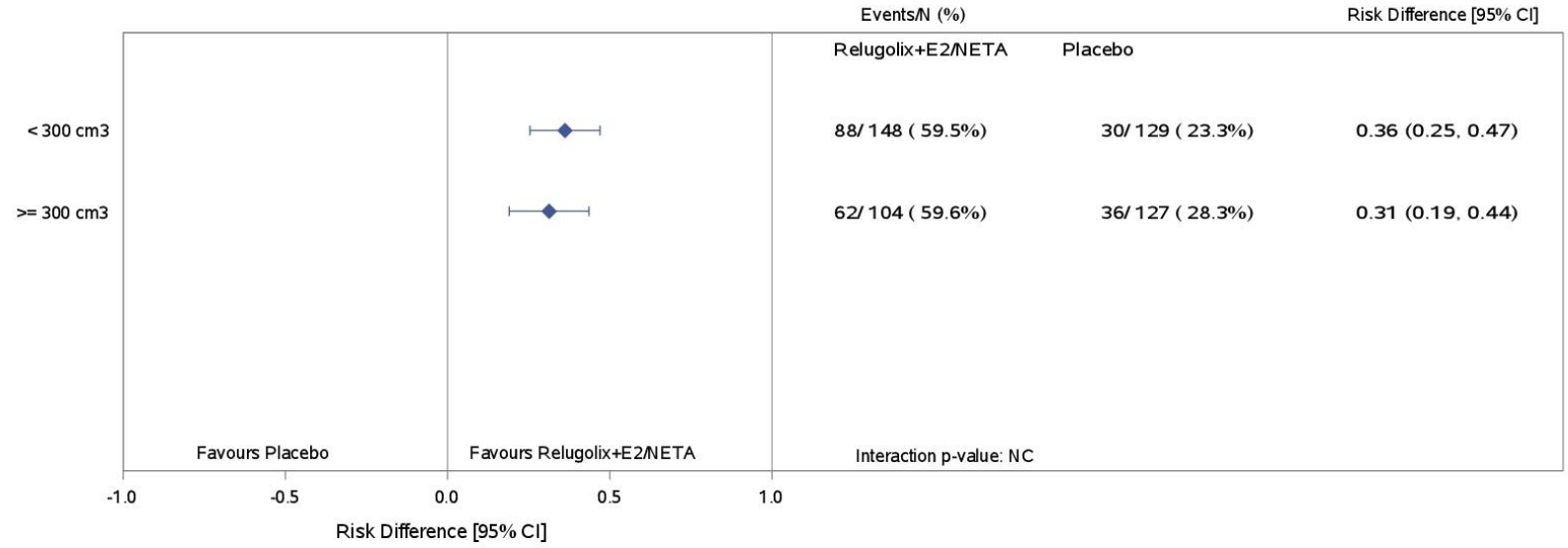
Figure QOL.UFSRAS25.MITT.S3.BIN.FP.RD: Proportion of Responders with at Least 25 Points Increase in UFS-QoL Revised Activity Scale Score at Week 24, by Subgroup (mITT Population) - Risk Difference
Study: Pooled
Subgroup: Uterine Volume at Baseline (cm3)



Results are based on a Mantel-Haenszel approach stratified by study using a one-stage fixed-effects IPD meta-analysis.
The reference group is Placebo.
N: Number of patients in treatment group; NETA: Norethindrone acetate; mITT: Modified intent-to-treat; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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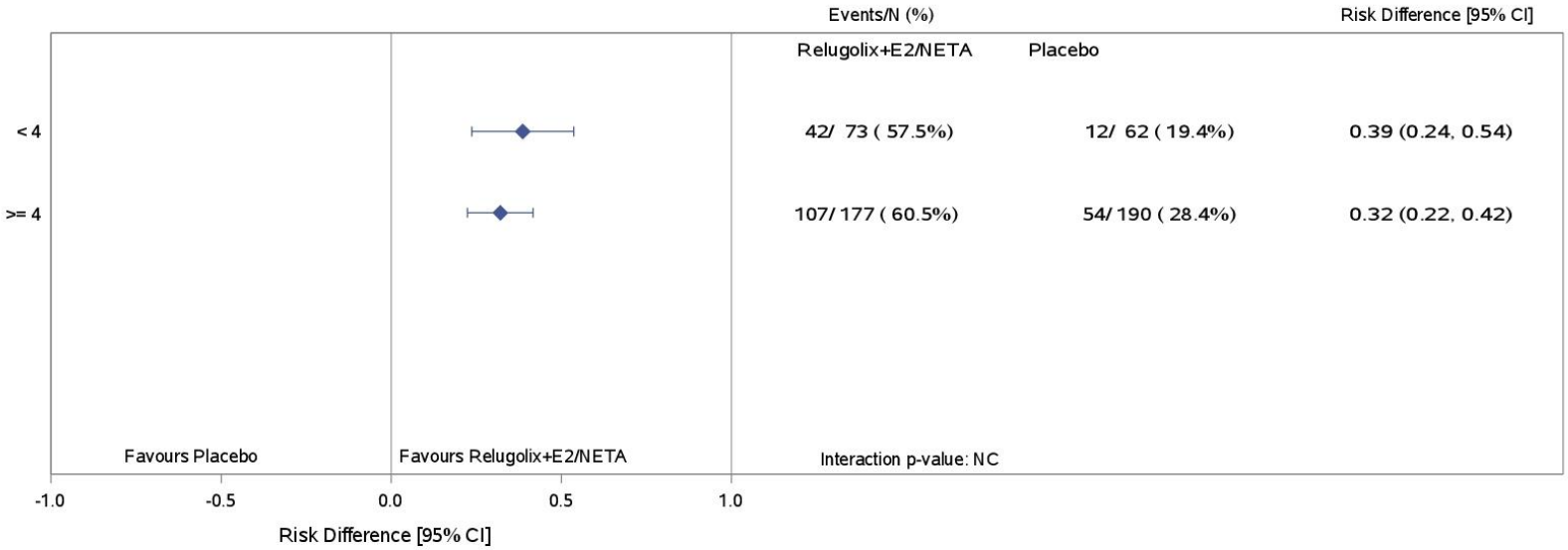
Figure QOL.UFSRAS25.MITT.S4.BIN.FP.RD: Proportion of Responders with at Least 25 Points Increase in UFS-QoL Revised Activity Scale Score at Week 24, by Subgroup (mITT Population) - Risk Difference
Study: Pooled
Subgroup: Maximum NRS Pain Score at Baseline



Results are based on a Mantel-Haenszel approach stratified by study using a one-stage fixed-effects IPD meta-analysis.
The reference group is Placebo.
N: Number of patients in treatment group; NETA: Norethindrone acetate; mITT: Modified intent-to-treat; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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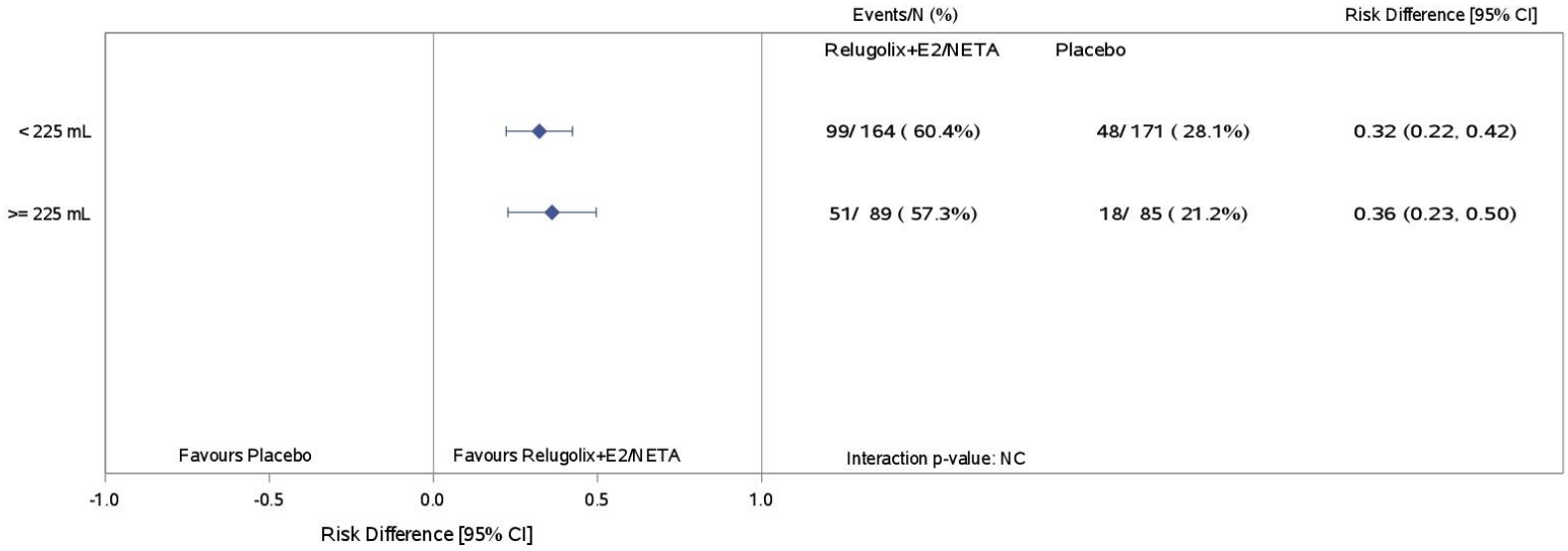
Figure QOL.UFSRAS25.MITT.S5.BIN.FP.RD: Proportion of Responders with at Least 25 Points Increase in UFS-QoL Revised Activity Scale Score at Week 24, by Subgroup (mITT Population) - Risk Difference
Study: Pooled
Subgroup: MBL Volume at Baseline (mL)



Results are based on a Mantel-Haenszel approach stratified by study using a one-stage fixed-effects IPD meta-analysis.
The reference group is Placebo.
N: Number of patients in treatment group; NETA: Norethindrone acetate; mITT: Modified intent-to-treat; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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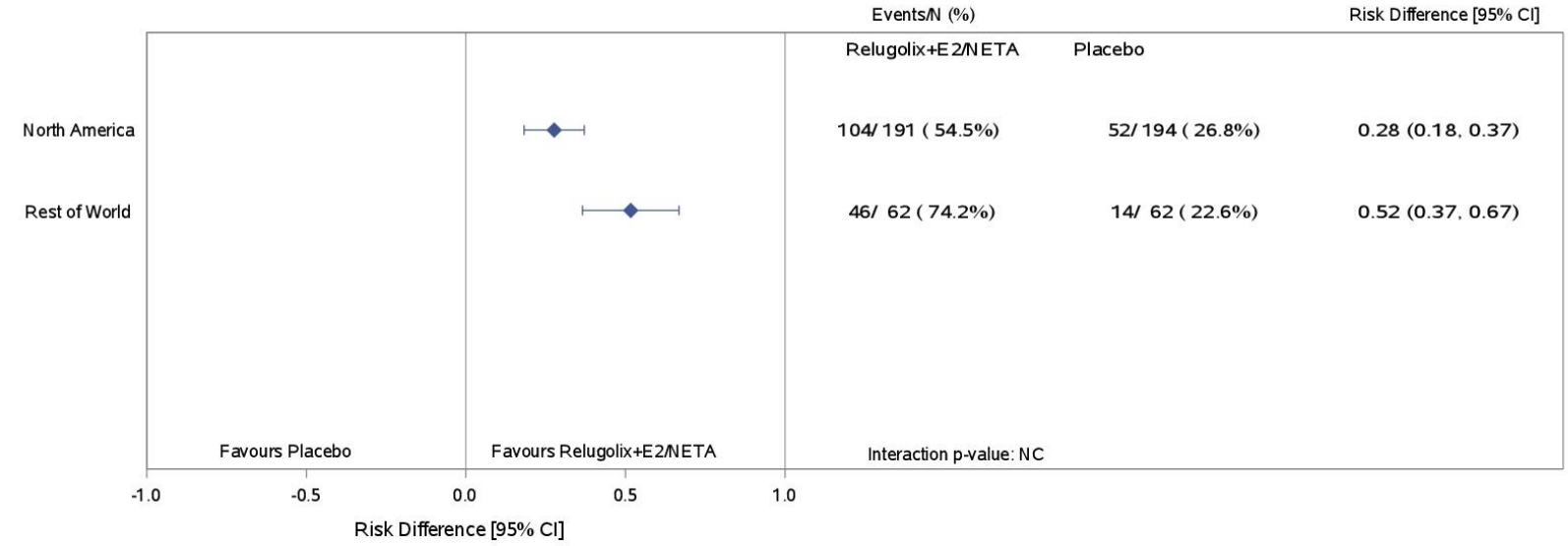
Figure QOL.UFSRAS25.MITT.S6.BIN.FP.RD: Proportion of Responders with at Least 25 Points Increase in UFS-QoL Revised Activity Scale Score at Week 24, by Subgroup (mITT Population) - Risk Difference
Study: Pooled
Subgroup: Geographic Region I



Results are based on a Mantel-Haenszel approach stratified by study using a one-stage fixed-effects IPD meta-analysis.
The reference group is Placebo.
N: Number of patients in treatment group; NETA: Norethindrone acetate; mITT: Modified intent-to-treat; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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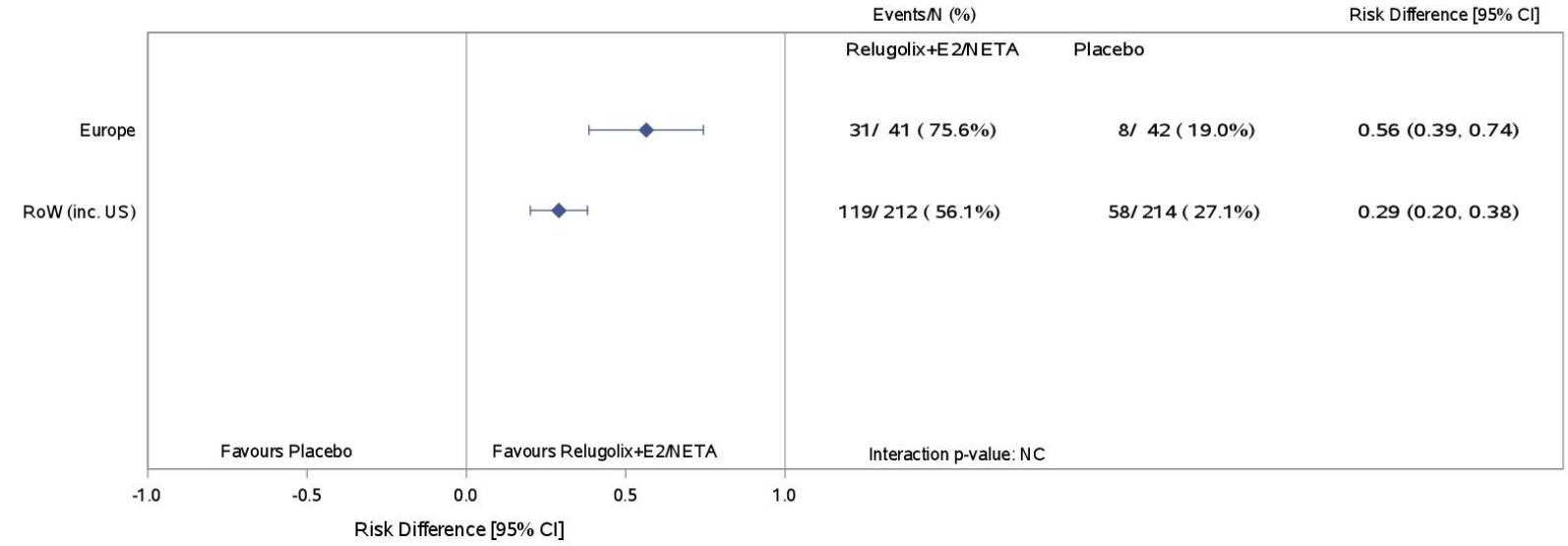
Figure QOL.UFSRAS25.MITT.S7.BIN.FP.RD: Proportion of Responders with at Least 25 Points Increase in UFS-QoL Revised Activity Scale Score at Week 24, by Subgroup (mITT Population) - Risk Difference
Study: Pooled
Subgroup: Geographic Region II



Results are based on a Mantel-Haenszel approach stratified by study using a one-stage fixed-effects IPD meta-analysis.
The reference group is Placebo.
N: Number of patients in treatment group; NETA: Norethindrone acetate; mITT: Modified intent-to-treat; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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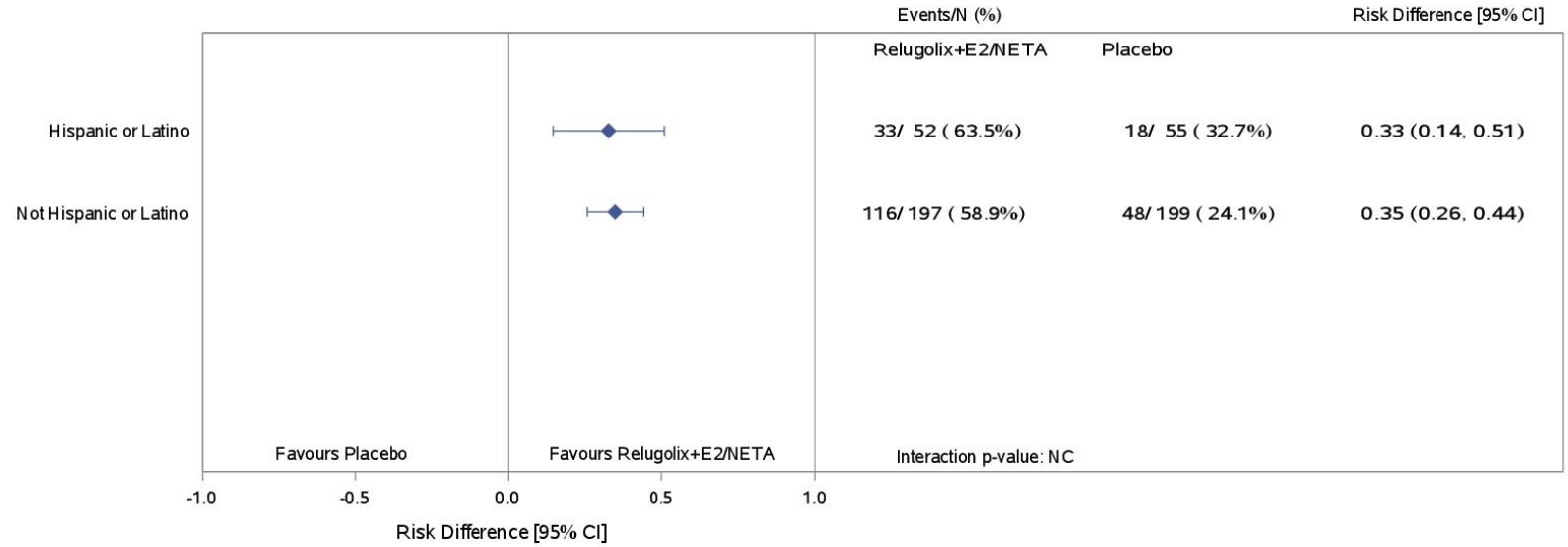
Analysis Plan: 13JAN2021 Confidential

Figure QOL.UFSRAS25.MITT.S8.BIN.FP.RD: Proportion of Responders with at Least 25 Points Increase in UFS-QoL Revised Activity Scale Score at Week 24, by Subgroup (mITT Population) - Risk Difference
Study: Pooled
Subgroup: Ethnicity



Results are based on a Mantel-Haenszel approach stratified by study using a one-stage fixed-effects IPD meta-analysis.
The reference group is Placebo.
N: Number of patients in treatment group; NETA: Norethindrone acetate; mITT: Modified intent-to-treat; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

SOURCE: X:\Numerus\Studies\MYV\MYV102\Analysis\Prod\Progs\TFLs\Fig_QOL_QS_S_BIN_FP.SAS Date/time of run: 30JUN21 10:27
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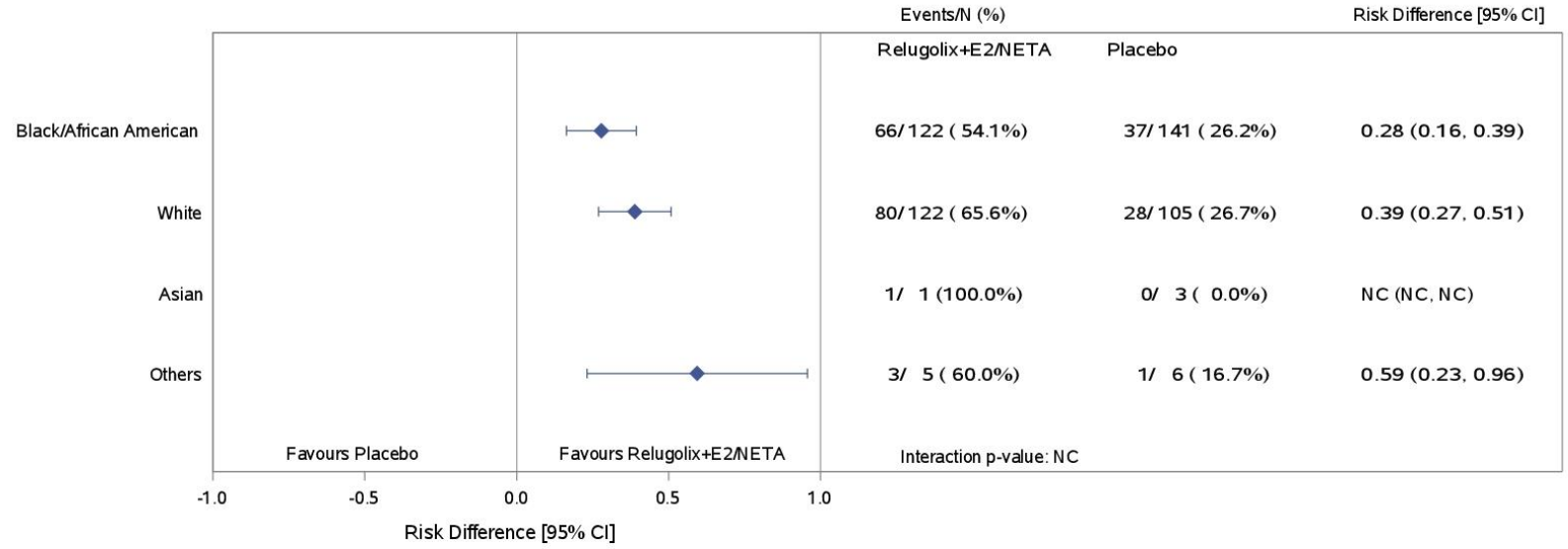
Figure QOL.UFSRAS25.MITT.S9.BIN.FP.RD: Proportion of Responders with at Least 25 Points Increase in UFS-QoL Revised Activity Scale Score at Week 24, by Subgroup (mITT Population) - Risk Difference
Study: Pooled
Subgroup: Race



Results are based on a Mantel-Haenszel approach stratified by study using a one-stage fixed-effects IPD meta-analysis.
The reference group is Placebo.
N: Number of patients in treatment group; NETA: Norethindrone acetate; mITT: Modified intent-to-treat; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

SOURCE: X:\Numerus\Studies\MYV\MYV102\Analysis\Prod\Progs\TFLs\Fig_QOL_QS_S_BIN_FP.SAS Date/time of run: 30JUN21 10:27
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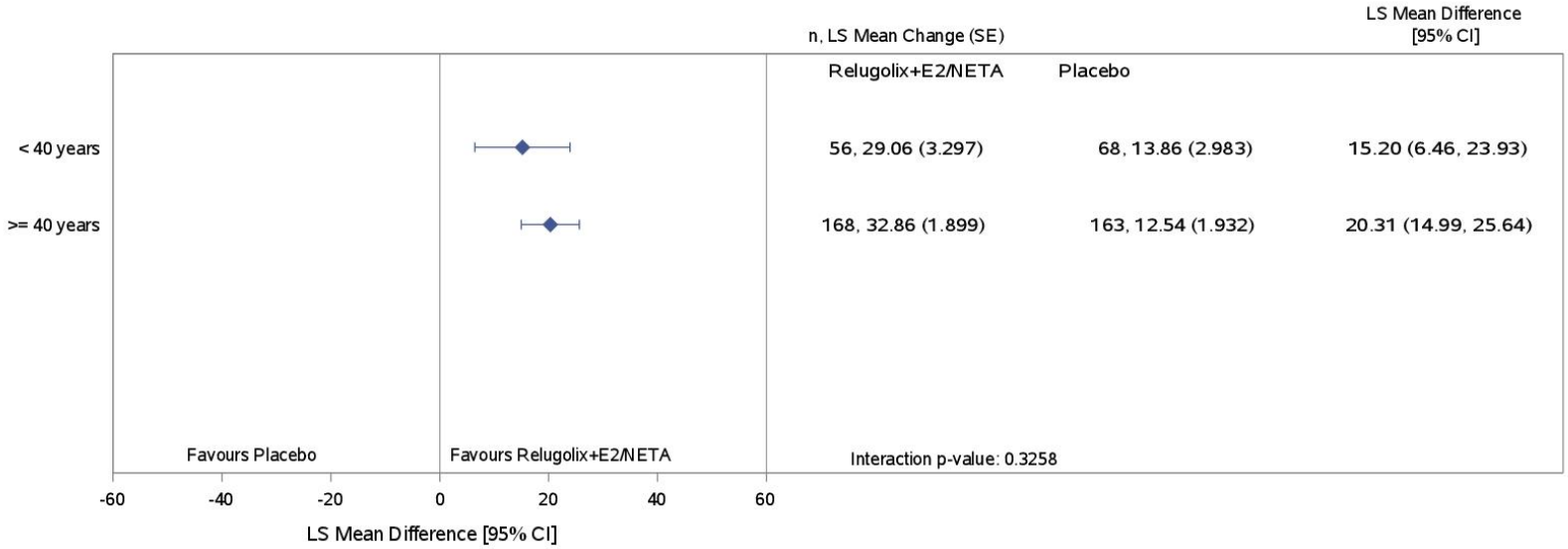
2.2.12 Summary of Average Change from Baseline in UFS-QoL Energy / Mood Scale Score Over 24 Weeks, by Subgroup (mITT Population)

Figure QOL.UFSEMS.MITT.S1.CON.FP: Summary of Average Change from Baseline in UFS-QoL Energy / Mood Scale Score Over 24 Weeks, by Subgroup (mITT Population)
Study: Pooled
Subgroup: Age (years)



Results are based on a mixed-effects model with study, treatment, visit, subgroup, treatment-by-visit interaction, and a subgroup-by-treatment interaction as fixed effects using a one-stage IPD meta-analysis approach. The multiple visits for each patient are the repeated measures as a random effect within each patient with an unstructured covariance.
The interaction p-value is based on the subgroup-by-treatment interaction term in the mixed-effects model used to compute the LS means, mean differences and 95% CIs. Missing subgroup levels are not included in estimation of the interaction p-value. The reference group is Placebo.
n: Number of patients with data; NETA: Norethindrone acetate; mITT: Modified intent-to-treat; LS: Least squares; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

SOURCE: X:\Numerus\Studies\MYV\MYV102\Analysis\Prod\Progs\TFLs\FIG_QOL_QS_S_CON_FP.SAS Date/time of run: 30JUN21 10:30
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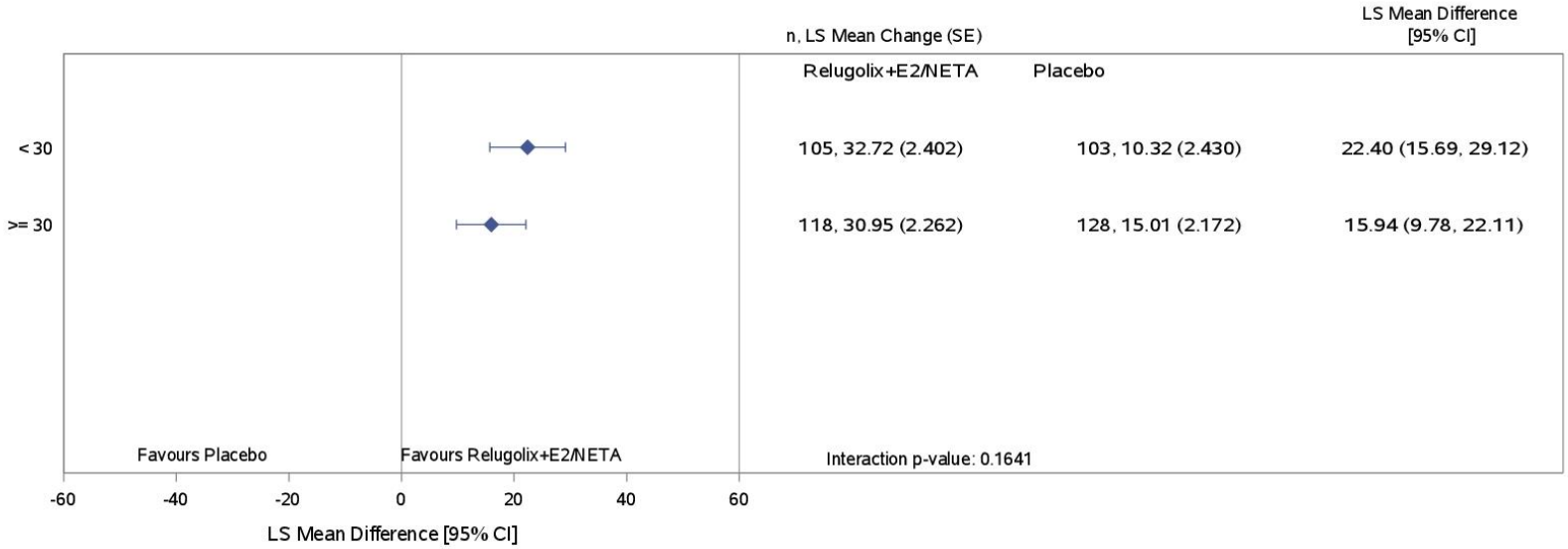
Figure QOL.UFSEMS.MITT.S2.CON.FP: Summary of Average Change from Baseline in UFS-QoL Energy / Mood Scale Score Over 24 Weeks, by Subgroup (mITT Population)
Study: Pooled
Subgroup: BMI (kg/m2) at Baseline



Results are based on a mixed-effects model with study, treatment, visit, subgroup, treatment-by-visit interaction, and a subgroup-by-treatment interaction as fixed effects using a one-stage IPD meta-analysis approach. The multiple visits for each patient are the repeated measures as a random effect within each patient with an unstructured covariance.
The interaction p-value is based on the subgroup-by-treatment interaction term in the mixed-effects model used to compute the LS means, mean differences and 95% CIs. Missing subgroup levels are not included in estimation of the interaction p-value. The reference group is Placebo.
n: Number of patients with data; NETA: Norethindrone acetate; mITT: Modified intent-to-treat; LS: Least squares; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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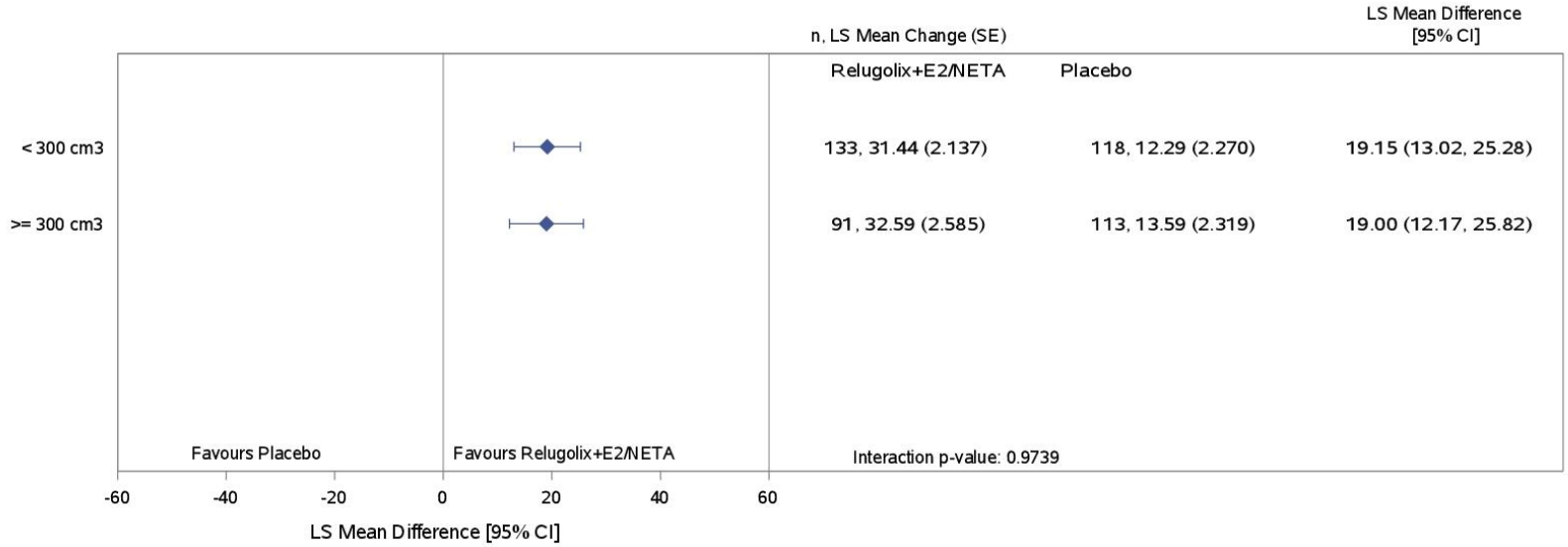
Figure QOL.UFSEMS.MITT.S3.CON.FP: Summary of Average Change from Baseline in UFS-QoL Energy / Mood Scale Score Over 24 Weeks, by Subgroup (mITT Population)
Study: Pooled
Subgroup: Uterine Volume at Baseline (cm3)



Results are based on a mixed-effects model with study, treatment, visit, subgroup, treatment-by-visit interaction, and a subgroup-by-treatment interaction as fixed effects using a one-stage IPD meta-analysis approach. The multiple visits for each patient are the repeated measures as a random effect within each patient with an unstructured covariance.
The interaction p-value is based on the subgroup-by-treatment interaction term in the mixed-effects model used to compute the LS means, mean differences and 95% CIs. Missing subgroup levels are not included in estimation of the interaction p-value. The reference group is Placebo.
n: Number of patients with data; NETA: Norethindrone acetate; mITT: Modified intent-to-treat; LS: Least squares; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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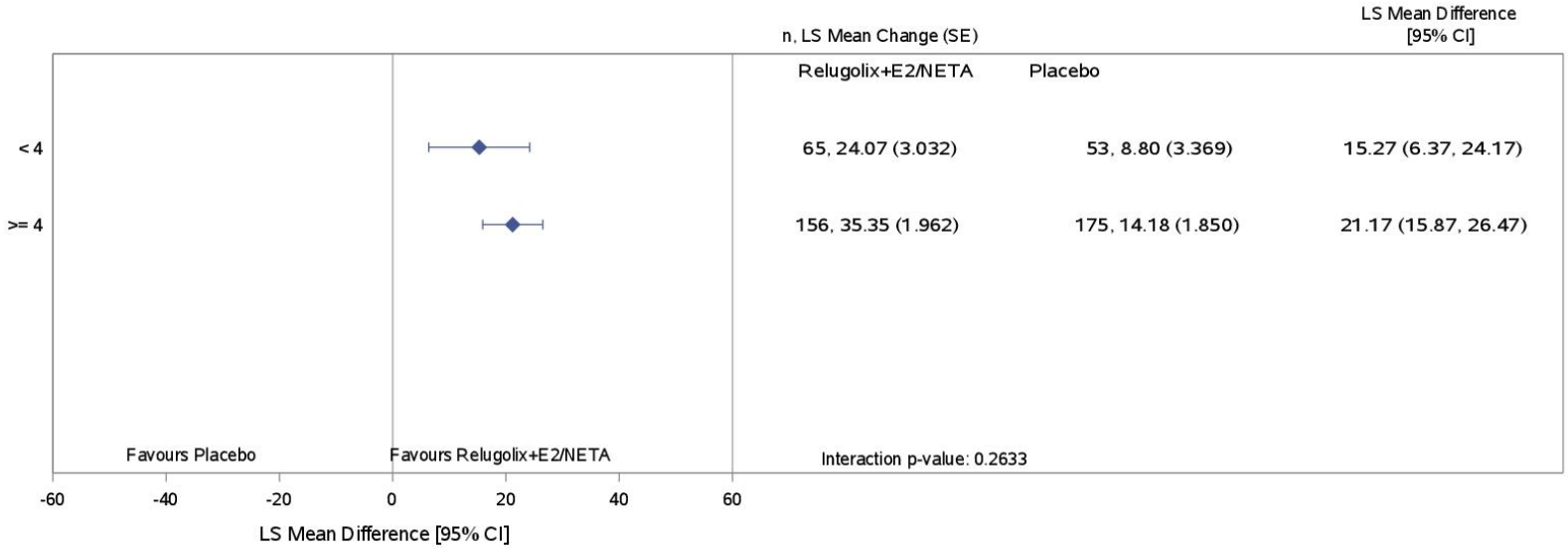
Figure QOL.UFSEMS.MITT.S4.CON.FP: Summary of Average Change from Baseline in UFS-QoL Energy / Mood Scale Score Over 24 Weeks, by Subgroup (mITT Population)
Study: Pooled
Subgroup: Maximum NRS Pain Score at Baseline



Results are based on a mixed-effects model with study, treatment, visit, subgroup, treatment-by-visit interaction, and a subgroup-by-treatment interaction as fixed effects using a one-stage IPD meta-analysis approach. The multiple visits for each patient are the repeated measures as a random effect within each patient with an unstructured covariance.
The interaction p-value is based on the subgroup-by-treatment interaction term in the mixed-effects model used to compute the LS means, mean differences and 95% CIs. Missing subgroup levels are not included in estimation of the interaction p-value. The reference group is Placebo.
n: Number of patients with data; NETA: Norethindrone acetate; mITT: Modified intent-to-treat; LS: Least squares; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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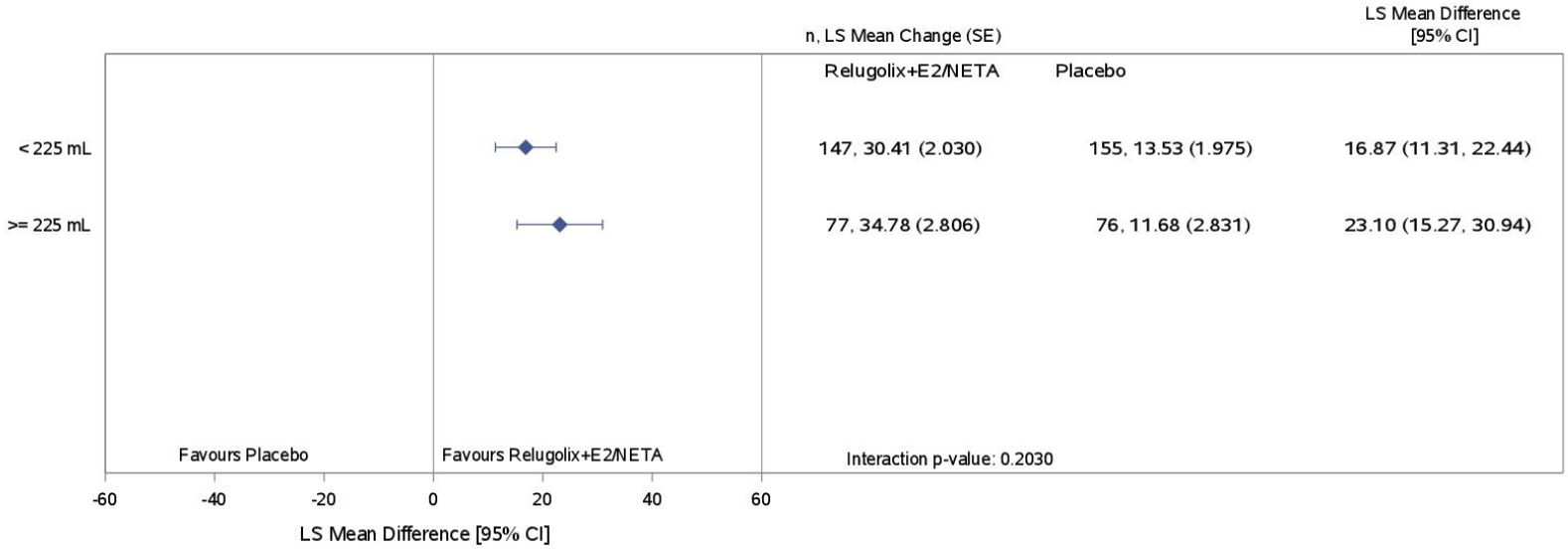
Figure QOL.UFSEMS.MITT.S5.CON.FP: Summary of Average Change from Baseline in UFS-QoL Energy / Mood Scale Score Over 24 Weeks, by Subgroup (mITT Population)
Study: Pooled
Subgroup: MBL Volume at Baseline (mL)



Results are based on a mixed-effects model with study, treatment, visit, subgroup, treatment-by-visit interaction, and a subgroup-by-treatment interaction as fixed effects using a one-stage IPD meta-analysis approach. The multiple visits for each patient are the repeated measures as a random effect within each patient with an unstructured covariance.
The interaction p-value is based on the subgroup-by-treatment interaction term in the mixed-effects model used to compute the LS means, mean differences and 95% CIs. Missing subgroup levels are not included in estimation of the interaction p-value. The reference group is Placebo.
n: Number of patients with data; NETA: Norethindrone acetate; mITT: Modified intent-to-treat; LS: Least squares; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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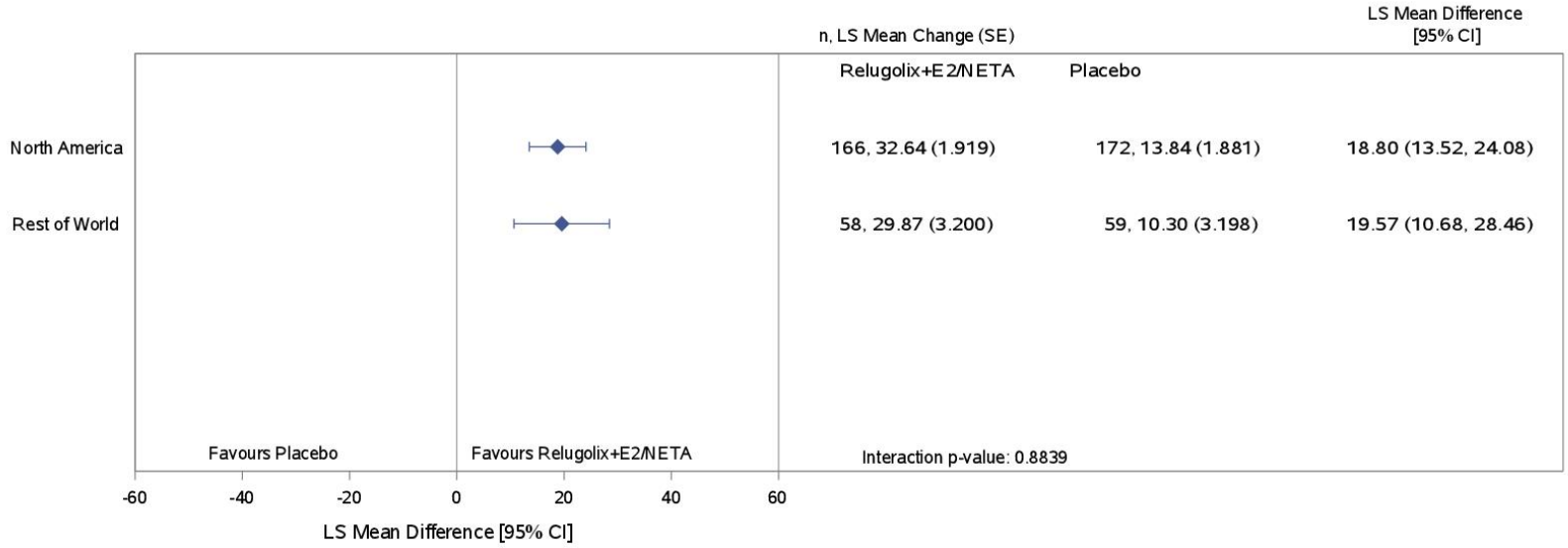
Figure QOL.UFSEMS.MITT.S6.CON.FP: Summary of Average Change from Baseline in UFS-QoL Energy / Mood Scale Score Over 24 Weeks, by Subgroup (mITT Population)
Study: Pooled
Subgroup: Geographic Region I



Results are based on a mixed-effects model with study, treatment, visit, subgroup, treatment-by-visit interaction, and a subgroup-by-treatment interaction as fixed effects using a one-stage IPD meta-analysis approach. The multiple visits for each patient are the repeated measures as a random effect within each patient with an unstructured covariance.
The interaction p-value is based on the subgroup-by-treatment interaction term in the mixed-effects model used to compute the LS means, mean differences and 95% CIs. Missing subgroup levels are not included in estimation of the interaction p-value. The reference group is Placebo.
n: Number of patients with data; NETA: Norethindrone acetate; mITT: Modified intent-to-treat; LS: Least squares; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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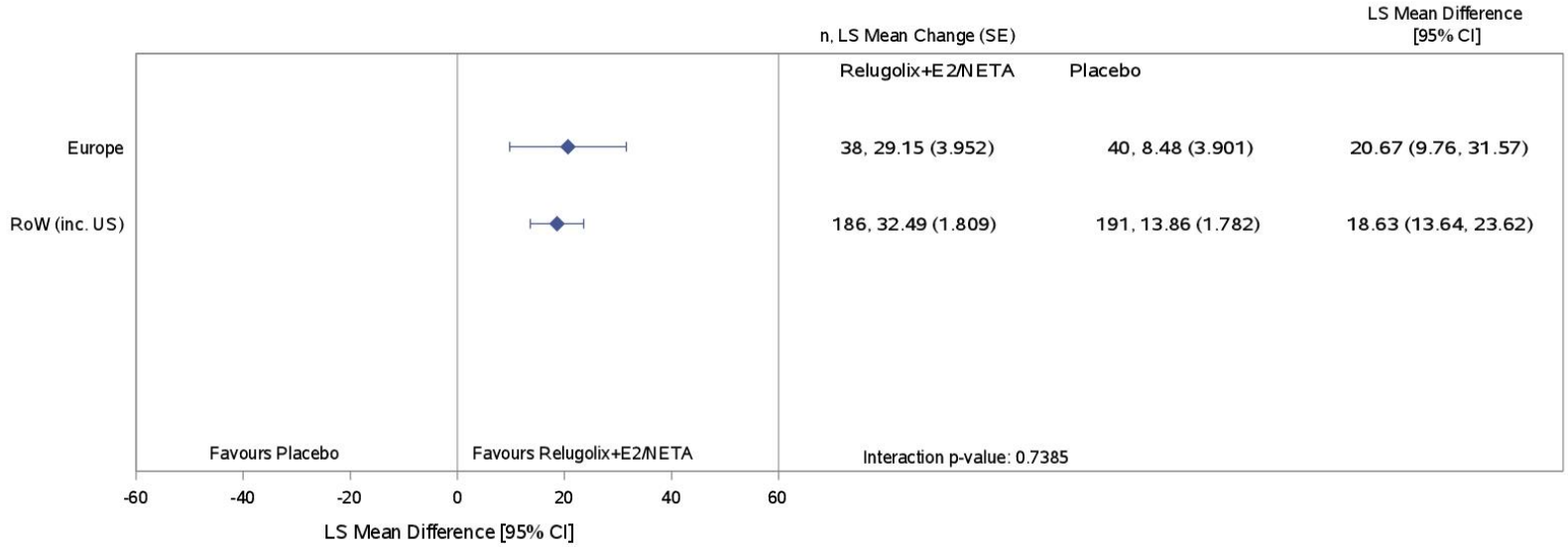
Figure QOL.UFSEMS.MITT.S7.CON.FP: Summary of Average Change from Baseline in UFS-QoL Energy / Mood Scale Score Over 24 Weeks, by Subgroup (mITT Population)
Study: Pooled
Subgroup: Geographic Region II



Results are based on a mixed-effects model with study, treatment, visit, subgroup, treatment-by-visit interaction, and a subgroup-by-treatment interaction as fixed effects using a one-stage IPD meta-analysis approach. The multiple visits for each patient are the repeated measures as a random effect within each patient with an unstructured covariance.
The interaction p-value is based on the subgroup-by-treatment interaction term in the mixed-effects model used to compute the LS means, mean differences and 95% CIs. Missing subgroup levels are not included in estimation of the interaction p-value. The reference group is Placebo.
n: Number of patients with data; NETA: Norethindrone acetate; mITT: Modified intent-to-treat; LS: Least squares; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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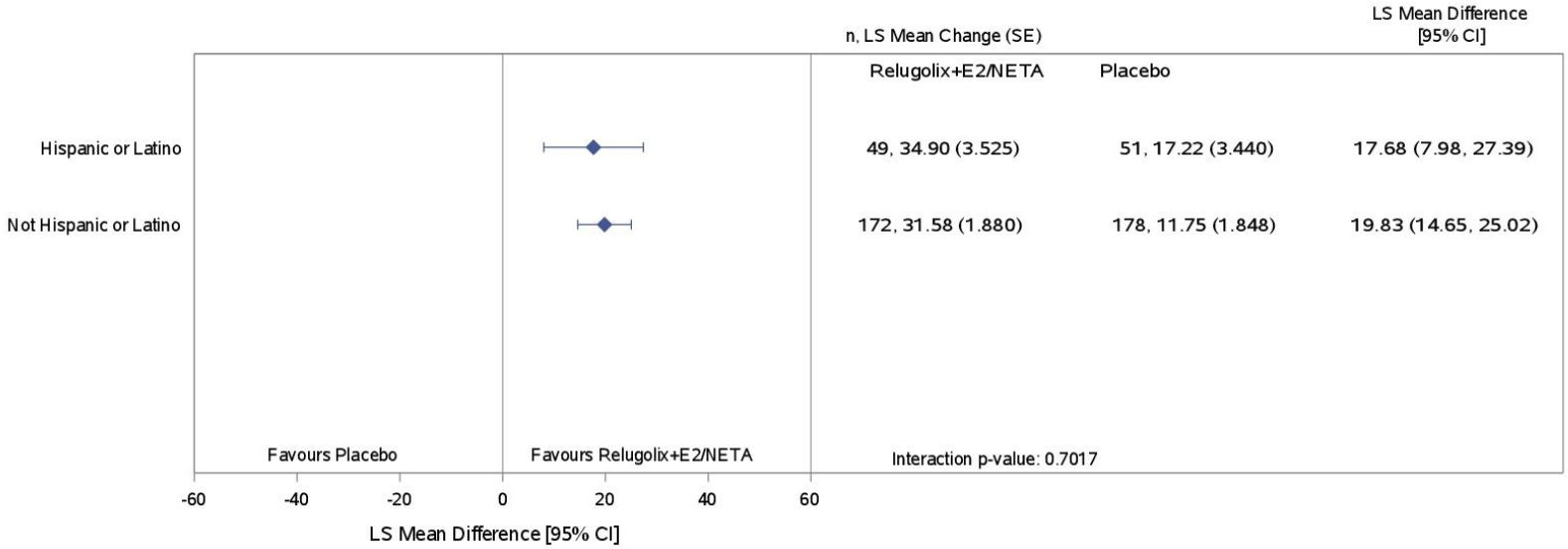
Figure QOL.UFSEMS.MITT.S8.CON.FP: Summary of Average Change from Baseline in UFS-QoL Energy / Mood Scale Score Over 24 Weeks, by Subgroup (mITT Population)
Study: Pooled
Subgroup: Ethnicity



Results are based on a mixed-effects model with study, treatment, visit, subgroup, treatment-by-visit interaction, and a subgroup-by-treatment interaction as fixed effects using a one-stage IPD meta-analysis approach. The multiple visits for each patient are the repeated measures as a random effect within each patient with an unstructured covariance.
The interaction p-value is based on the subgroup-by-treatment interaction term in the mixed-effects model used to compute the LS means, mean differences and 95% CIs. Missing subgroup levels are not included in estimation of the interaction p-value. The reference group is Placebo.
n: Number of patients with data; NETA: Norethindrone acetate; mITT: Modified intent-to-treat; LS: Least squares; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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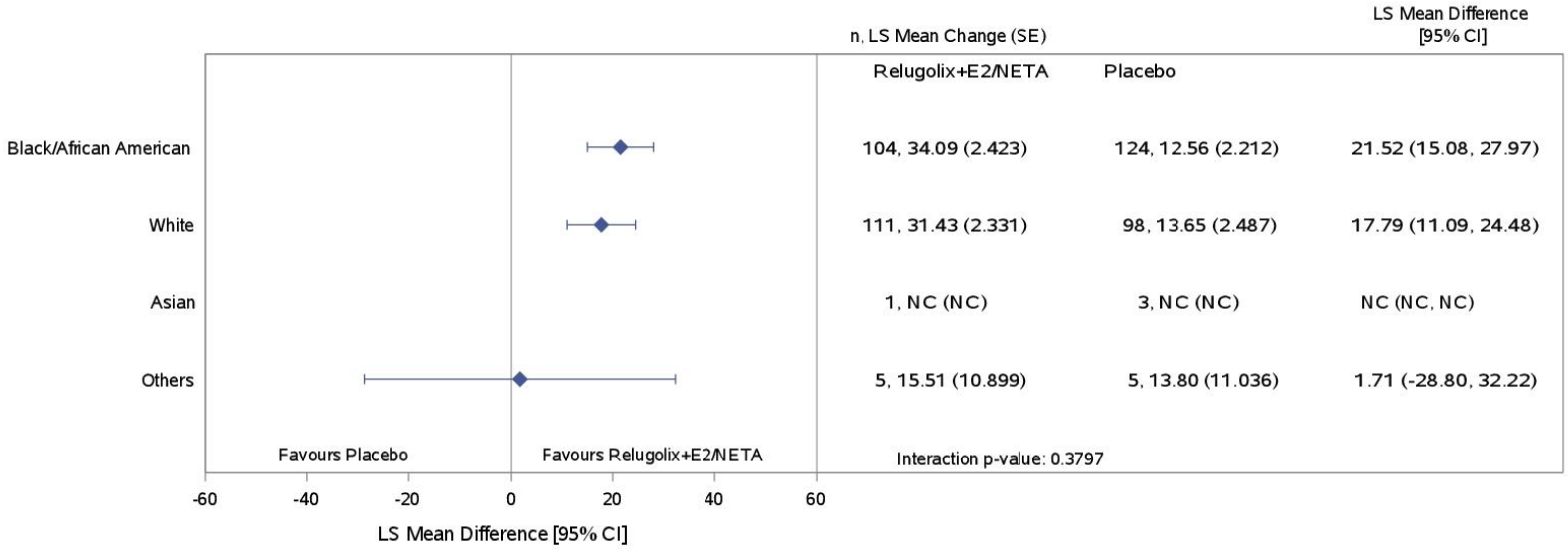
Figure QOL.UFSEMS.MITT.S9.CON.FP: Summary of Average Change from Baseline in UFS-QoL Energy / Mood Scale Score Over 24 Weeks, by Subgroup (mITT Population)
Study: Pooled
Subgroup: Race



Results are based on a mixed-effects model with study, treatment, visit, subgroup, treatment-by-visit interaction, and a subgroup-by-treatment interaction as fixed effects using a one-stage IPD meta-analysis approach. The multiple visits for each patient are the repeated measures as a random effect within each patient with an unstructured covariance.
The interaction p-value is based on the subgroup-by-treatment interaction term in the mixed-effects model used to compute the LS means, mean differences and 95% CIs. Missing subgroup levels are not included in estimation of the interaction p-value. The reference group is Placebo.
n: Number of patients with data; NETA: Norethindrone acetate; mITT: Modified intent-to-treat; LS: Least squares; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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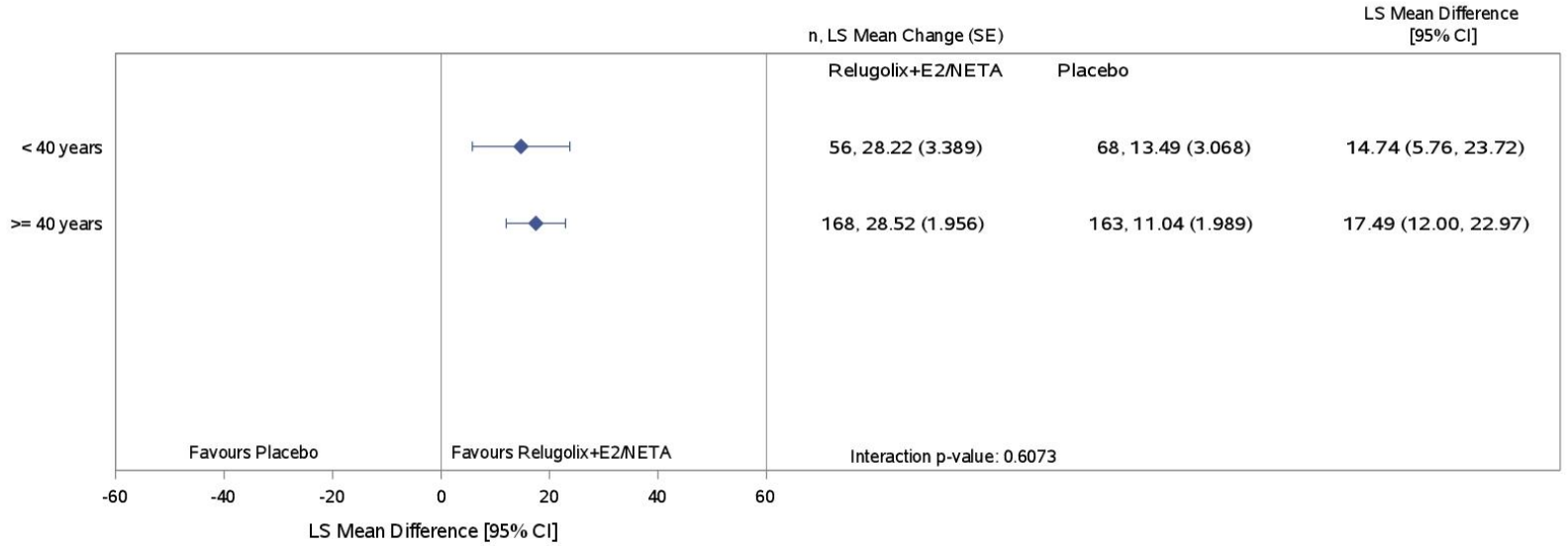
2.2.13 Summary of Average Change from Baseline in UFS-QoL Control Scale Score Over 24 Weeks, by Subgroup (mITT Population)

Figure QOL.UFSCONTR.MITT.S1.CON.FP: Summary of Average Change from Baseline in UFS-QoL Control Scale Score Over 24 Weeks, by Subgroup (mITT Population)
Study: Pooled
Subgroup: Age (years)



Results are based on a mixed-effects model with study, treatment, visit, subgroup, treatment-by-visit interaction, and a subgroup-by-treatment interaction as fixed effects using a one-stage IPD meta-analysis approach. The multiple visits for each patient are the repeated measures as a random effect within each patient with an unstructured covariance.
The interaction p-value is based on the subgroup-by-treatment interaction term in the mixed-effects model used to compute the LS means, mean differences and 95% CIs. Missing subgroup levels are not included in estimation of the interaction p-value. The reference group is Placebo.
n: Number of patients with data; NETA: Norethindrone acetate; mITT: Modified intent-to-treat; LS: Least squares; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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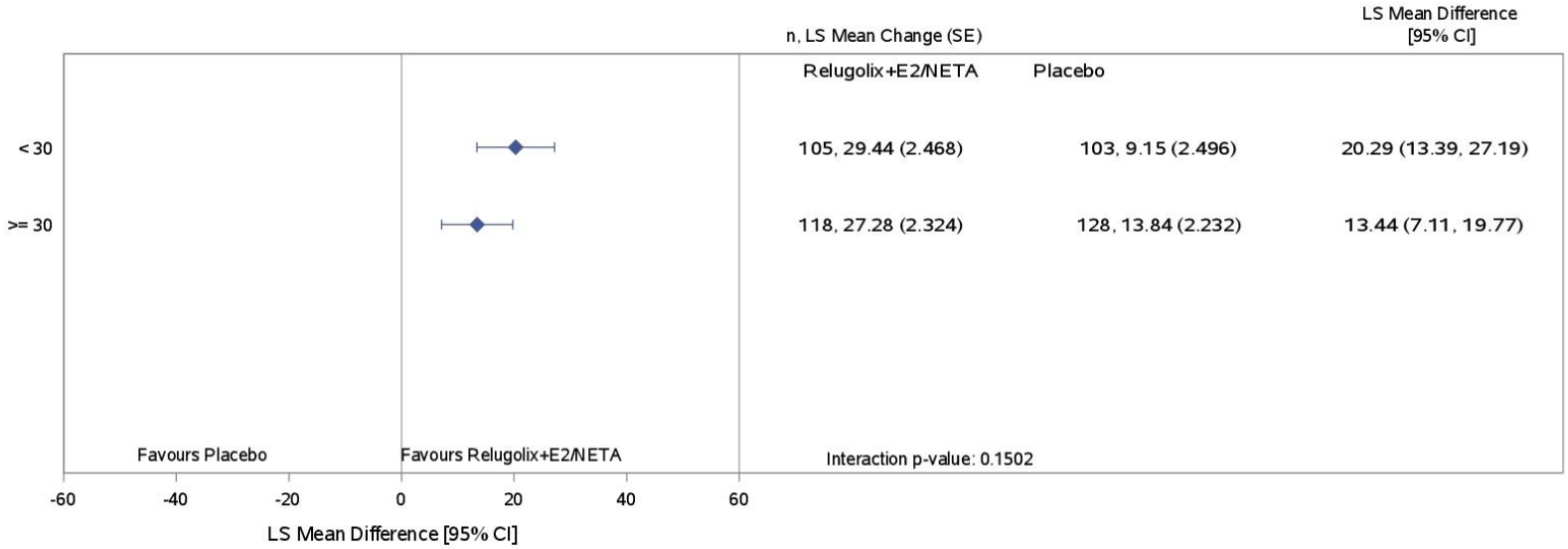
Figure QOL.UFSCONTR.MITT.S2.CON.FP: Summary of Average Change from Baseline in UFS-QoL Control Scale Score Over 24 Weeks, by Subgroup (mITT Population)
Study: Pooled
Subgroup: BMI (kg/m2) at Baseline



Results are based on a mixed-effects model with study, treatment, visit, subgroup, treatment-by-visit interaction, and a subgroup-by-treatment interaction as fixed effects using a one-stage IPD meta-analysis approach. The multiple visits for each patient are the repeated measures as a random effect within each patient with an unstructured covariance.
The interaction p-value is based on the subgroup-by-treatment interaction term in the mixed-effects model used to compute the LS means, mean differences and 95% CIs. Missing subgroup levels are not included in estimation of the interaction p-value. The reference group is Placebo.
n: Number of patients with data; NETA: Norethindrone acetate; mITT: Modified intent-to-treat; LS: Least squares; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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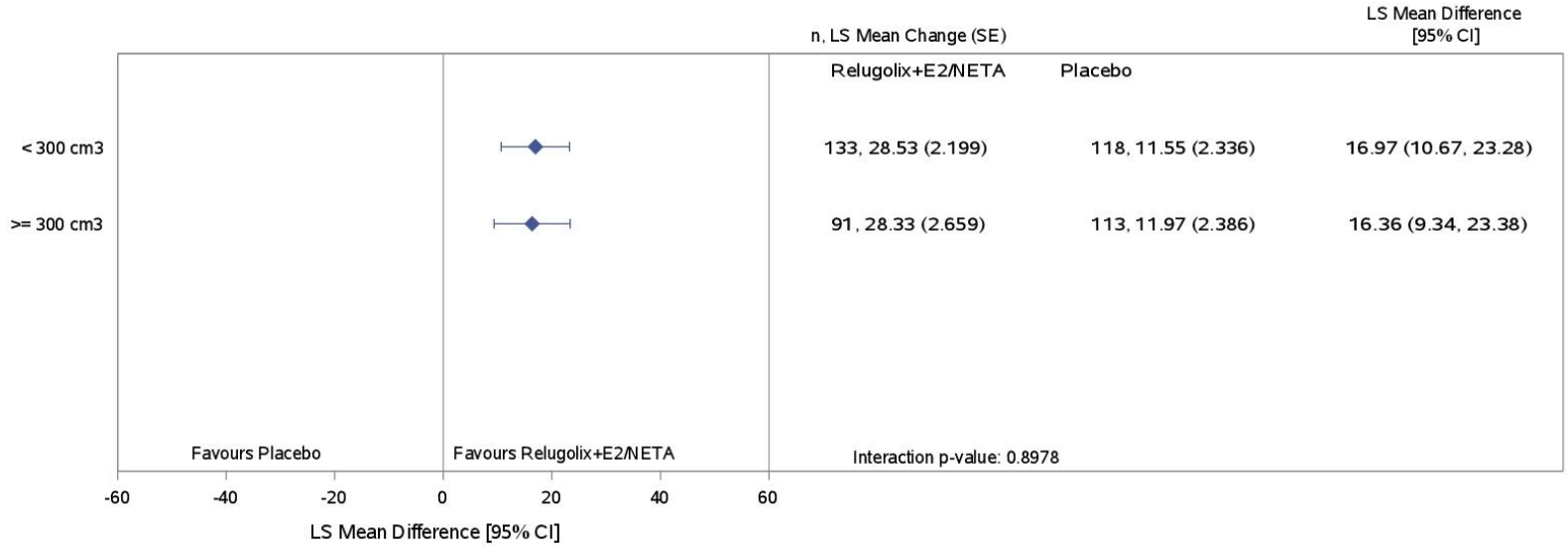
Figure QOL.UFSCONTR.MITT.S3.CON.FP: Summary of Average Change from Baseline in UFS-QoL Control Scale Score Over 24 Weeks, by Subgroup (mITT Population)
Study: Pooled
Subgroup: Uterine Volume at Baseline (cm3)



Results are based on a mixed-effects model with study, treatment, visit, subgroup, treatment-by-visit interaction, and a subgroup-by-treatment interaction as fixed effects using a one-stage IPD meta-analysis approach. The multiple visits for each patient are the repeated measures as a random effect within each patient with an unstructured covariance.
The interaction p-value is based on the subgroup-by-treatment interaction term in the mixed-effects model used to compute the LS means, mean differences and 95% CIs. Missing subgroup levels are not included in estimation of the interaction p-value. The reference group is Placebo.
n: Number of patients with data; NETA: Norethindrone acetate; mITT: Modified intent-to-treat; LS: Least squares; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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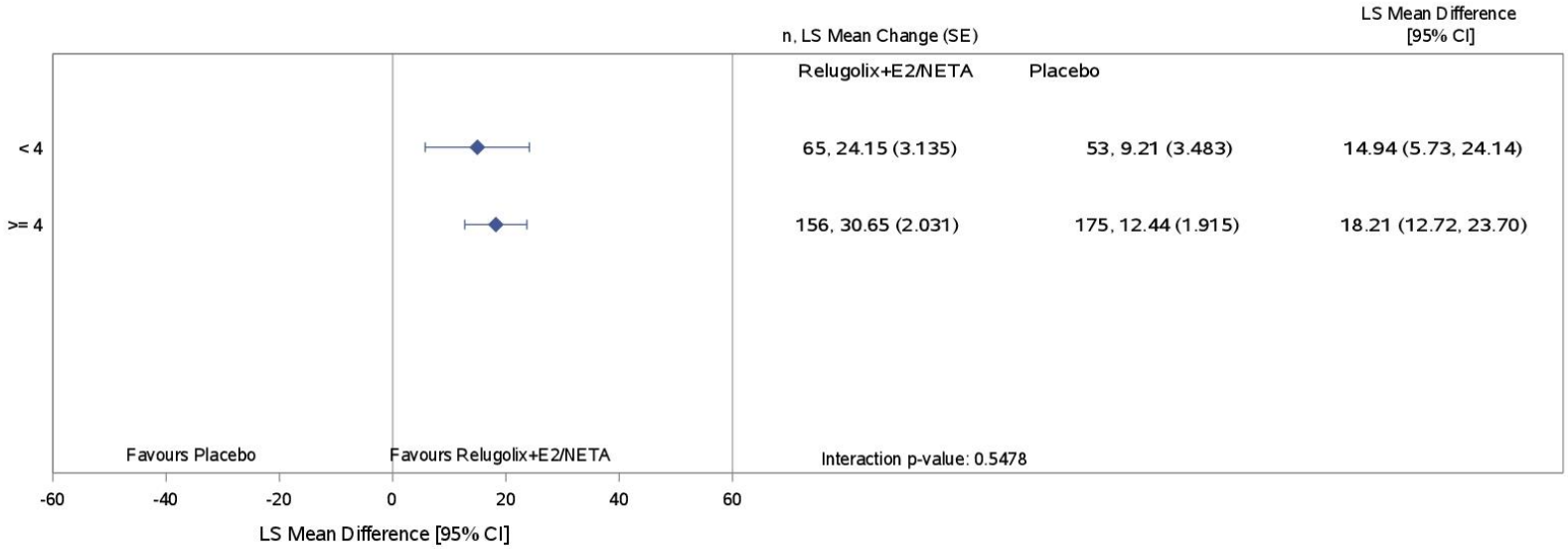
Figure QOL.UFSCONTR.MITT.S4.CON.FP: Summary of Average Change from Baseline in UFS-QoL Control Scale Score Over 24 Weeks, by Subgroup (mITT Population)
Study: Pooled
Subgroup: Maximum NRS Pain Score at Baseline



Results are based on a mixed-effects model with study, treatment, visit, subgroup, treatment-by-visit interaction, and a subgroup-by-treatment interaction as fixed effects using a one-stage IPD meta-analysis approach. The multiple visits for each patient are the repeated measures as a random effect within each patient with an unstructured covariance.
The interaction p-value is based on the subgroup-by-treatment interaction term in the mixed-effects model used to compute the LS means, mean differences and 95% CIs. Missing subgroup levels are not included in estimation of the interaction p-value. The reference group is Placebo.
n: Number of patients with data; NETA: Norethindrone acetate; mITT: Modified intent-to-treat; LS: Least squares; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

SOURCE: X:\Numerus\Studies\MYV\MYV102\Analysis\Prod\Progs\TFLs\FIG_QOL_QS_S_CON_FP.SAS Date/time of run: 30JUN21 10:30
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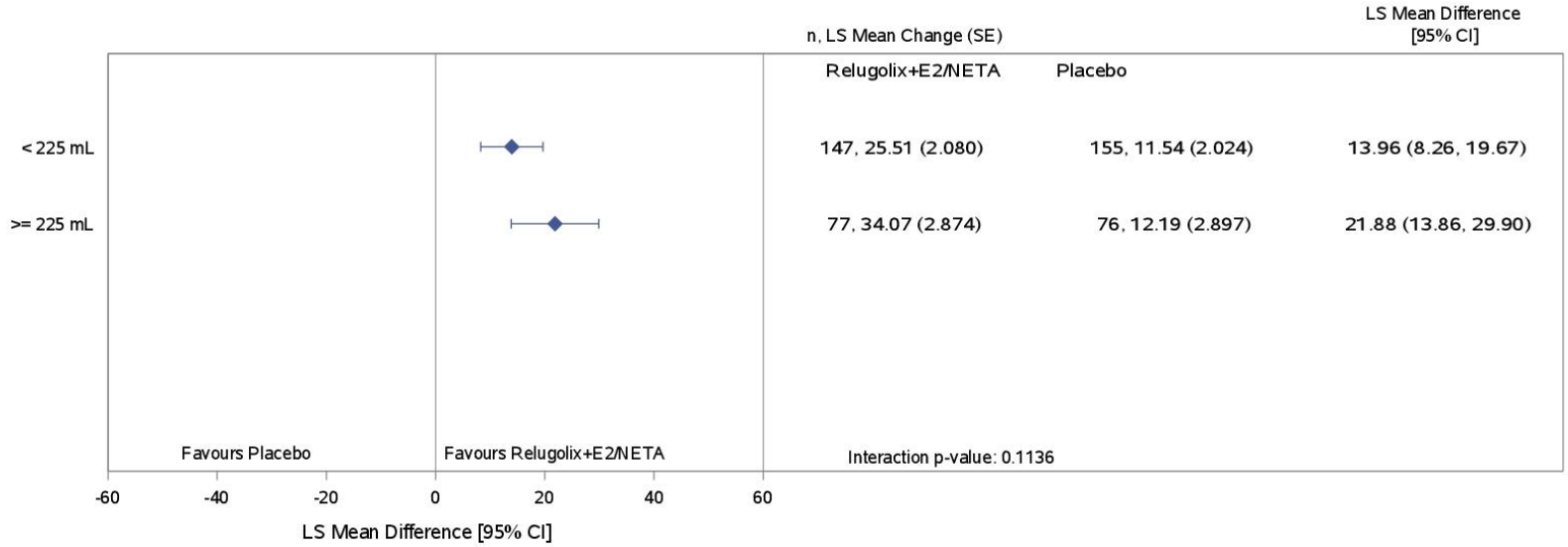
Figure QOL.UFSCONTR.MITT.S5.CON.FP: Summary of Average Change from Baseline in UFS-QoL Control Scale Score Over 24 Weeks, by Subgroup (mITT Population)
Study: Pooled
Subgroup: MBL Volume at Baseline (mL)



Results are based on a mixed-effects model with study, treatment, visit, subgroup, treatment-by-visit interaction, and a subgroup-by-treatment interaction as fixed effects using a one-stage IPD meta-analysis approach. The multiple visits for each patient are the repeated measures as a random effect within each patient with an unstructured covariance.
The interaction p-value is based on the subgroup-by-treatment interaction term in the mixed-effects model used to compute the LS means, mean differences and 95% CIs. Missing subgroup levels are not included in estimation of the interaction p-value. The reference group is Placebo.
n: Number of patients with data; NETA: Norethindrone acetate; mITT: Modified intent-to-treat; LS: Least squares; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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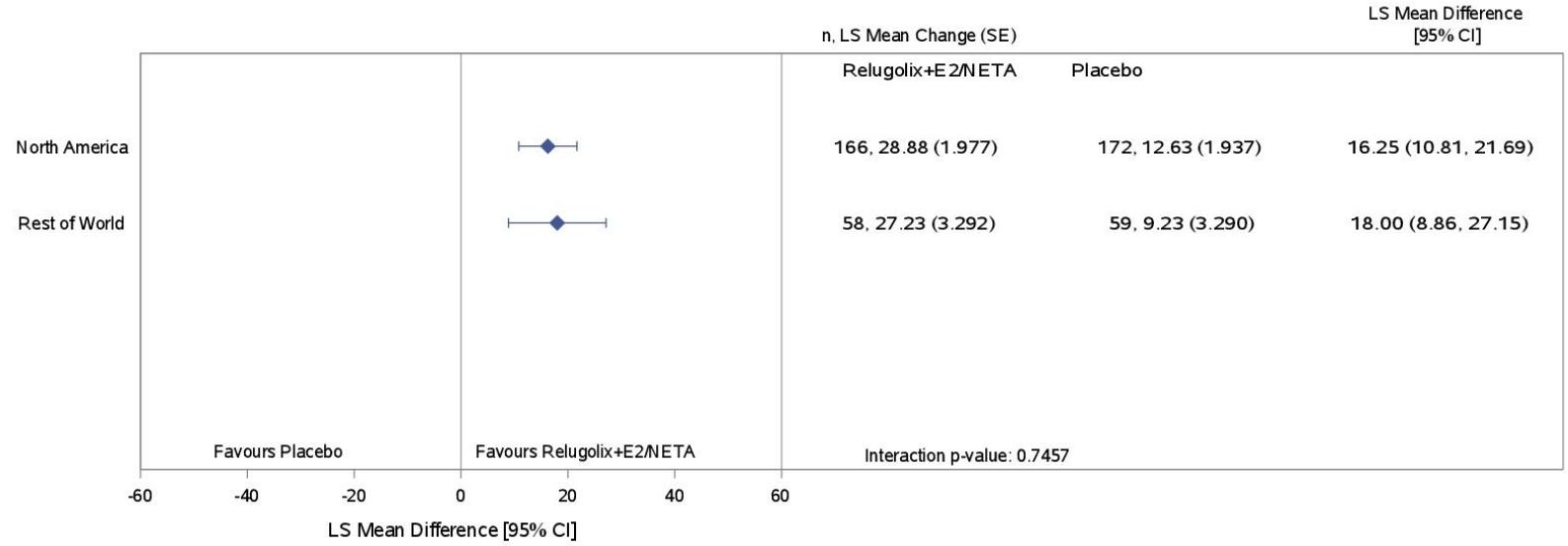
Figure QOL.UFSCONTR.MITT.S6.CON.FP: Summary of Average Change from Baseline in UFS-QoL Control Scale Score Over 24 Weeks, by Subgroup (mITT Population)
Study: Pooled
Subgroup: Geographic Region I



Results are based on a mixed-effects model with study, treatment, visit, subgroup, treatment-by-visit interaction, and a subgroup-by-treatment interaction as fixed effects using a one-stage IPD meta-analysis approach. The multiple visits for each patient are the repeated measures as a random effect within each patient with an unstructured covariance.
The interaction p-value is based on the subgroup-by-treatment interaction term in the mixed-effects model used to compute the LS means, mean differences and 95% CIs. Missing subgroup levels are not included in estimation of the interaction p-value. The reference group is Placebo.
n: Number of patients with data; NETA: Norethindrone acetate; mITT: Modified intent-to-treat; LS: Least squares; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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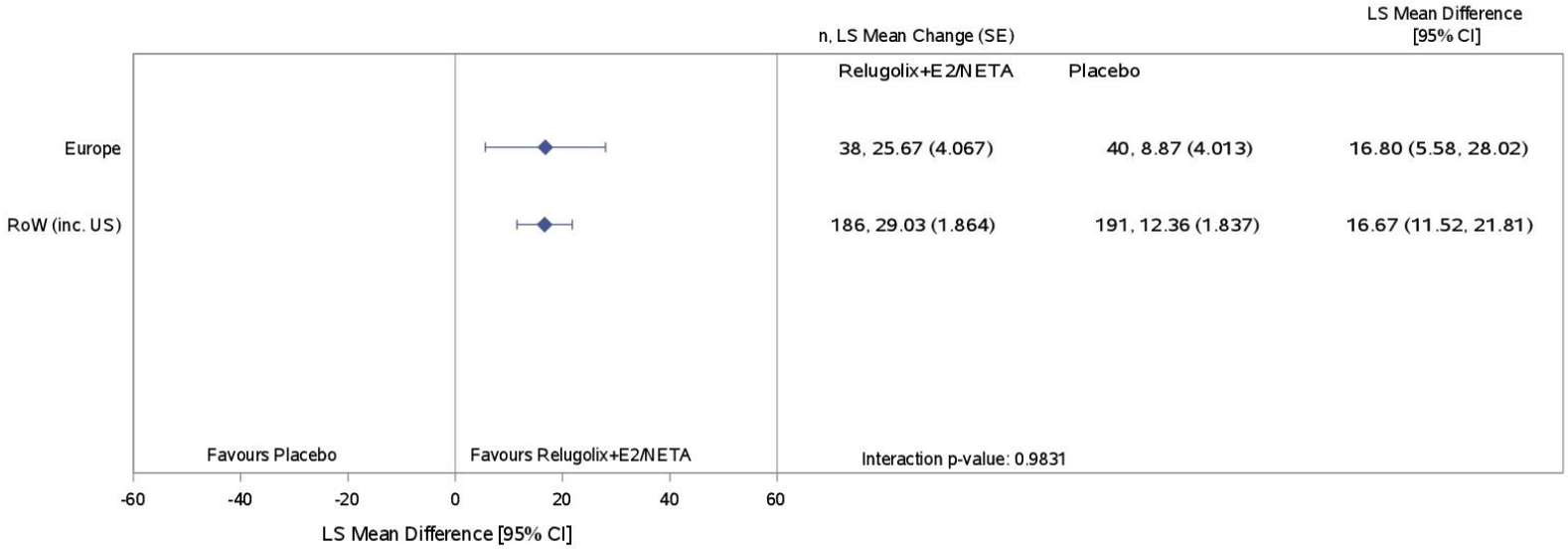
Figure QOL.UFSCONTR.MITT.S7.CON.FP: Summary of Average Change from Baseline in UFS-QoL Control Scale Score Over 24 Weeks, by Subgroup (mITT Population)
Study: Pooled
Subgroup: Geographic Region II



Results are based on a mixed-effects model with study, treatment, visit, subgroup, treatment-by-visit interaction, and a subgroup-by-treatment interaction as fixed effects using a one-stage IPD meta-analysis approach. The multiple visits for each patient are the repeated measures as a random effect within each patient with an unstructured covariance.
The interaction p-value is based on the subgroup-by-treatment interaction term in the mixed-effects model used to compute the LS means, mean differences and 95% CIs. Missing subgroup levels are not included in estimation of the interaction p-value. The reference group is Placebo.
n: Number of patients with data; NETA: Norethindrone acetate; mITT: Modified intent-to-treat; LS: Least squares; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

SOURCE: X:\Numerus\Studies\MYV\MYV102\Analysis\Prod\Progs\TFLs\FIG_QOL_QS_S_CON_FP.SAS Date/time of run: 30JUN21 10:30
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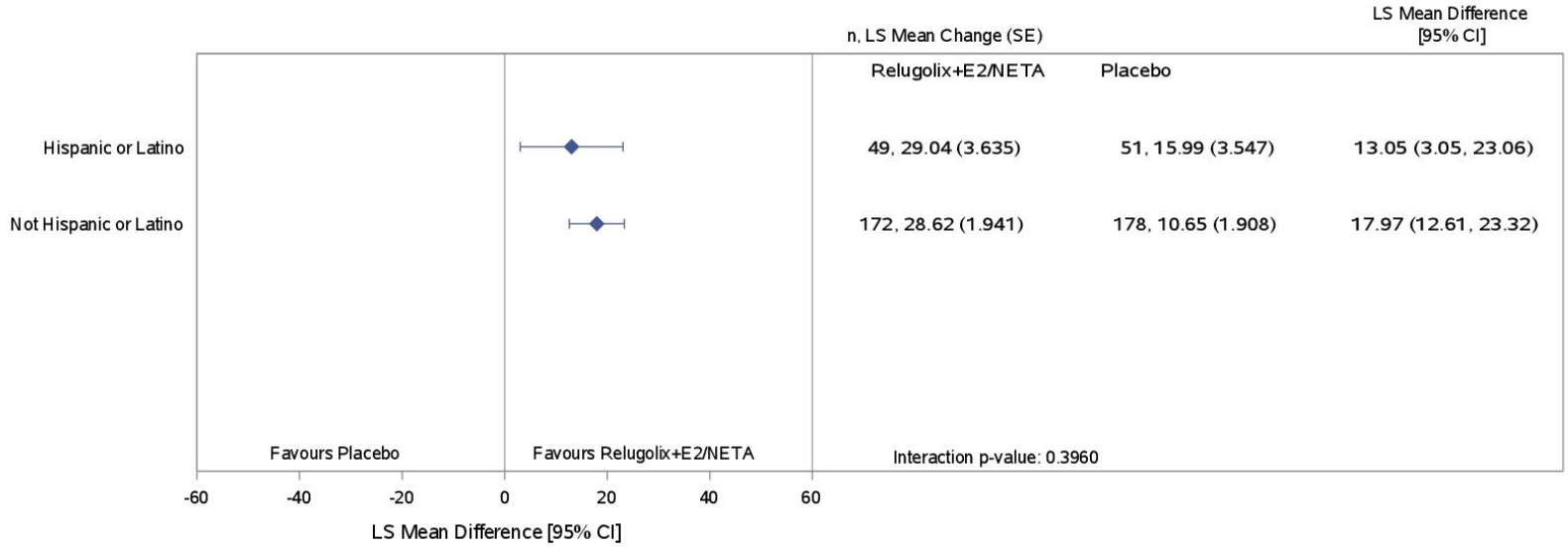
Figure QOL.UFSCONTR.MITT.S8.CON.FP: Summary of Average Change from Baseline in UFS-QoL Control Scale Score Over 24 Weeks, by Subgroup (mITT Population)
Study: Pooled
Subgroup: Ethnicity



Results are based on a mixed-effects model with study, treatment, visit, subgroup, treatment-by-visit interaction, and a subgroup-by-treatment interaction as fixed effects using a one-stage IPD meta-analysis approach. The multiple visits for each patient are the repeated measures as a random effect within each patient with an unstructured covariance.
The interaction p-value is based on the subgroup-by-treatment interaction term in the mixed-effects model used to compute the LS means, mean differences and 95% CIs. Missing subgroup levels are not included in estimation of the interaction p-value. The reference group is Placebo.
n: Number of patients with data; NETA: Norethindrone acetate; mITT: Modified intent-to-treat; LS: Least squares; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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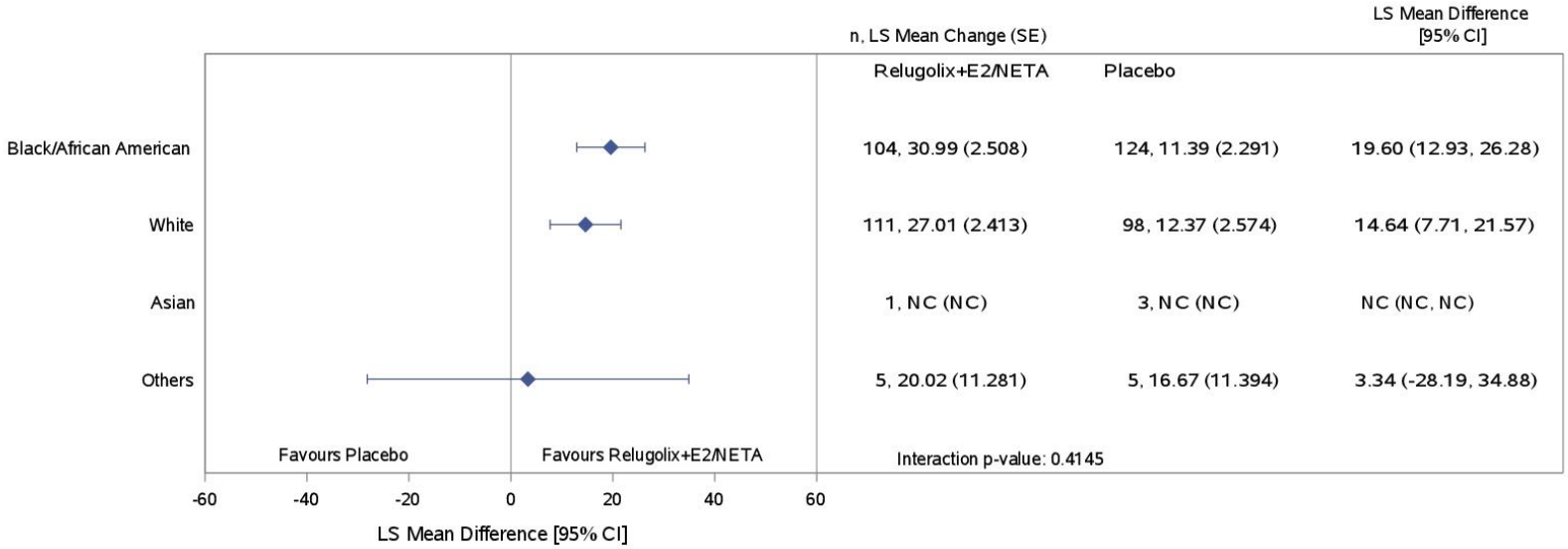
Figure QOL.UFSCONTR.MITT.S9.CON.FP: Summary of Average Change from Baseline in UFS-QoL Control Scale Score Over 24 Weeks, by Subgroup (mITT Population)
Study: Pooled
Subgroup: Race



Results are based on a mixed-effects model with study, treatment, visit, subgroup, treatment-by-visit interaction, and a subgroup-by-treatment interaction as fixed effects using a one-stage IPD meta-analysis approach. The multiple visits for each patient are the repeated measures as a random effect within each patient with an unstructured covariance.
The interaction p-value is based on the subgroup-by-treatment interaction term in the mixed-effects model used to compute the LS means, mean differences and 95% CIs. Missing subgroup levels are not included in estimation of the interaction p-value. The reference group is Placebo.
n: Number of patients with data; NETA: Norethindrone acetate; mITT: Modified intent-to-treat; LS: Least squares; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

SOURCE: X:\Numerus\Studies\MYV\MYV102\Analysis\Prod\Progs\TFLs\FIG_QOL_QS_S_CON_FP.SAS Date/time of run: 30JUN21 10:30
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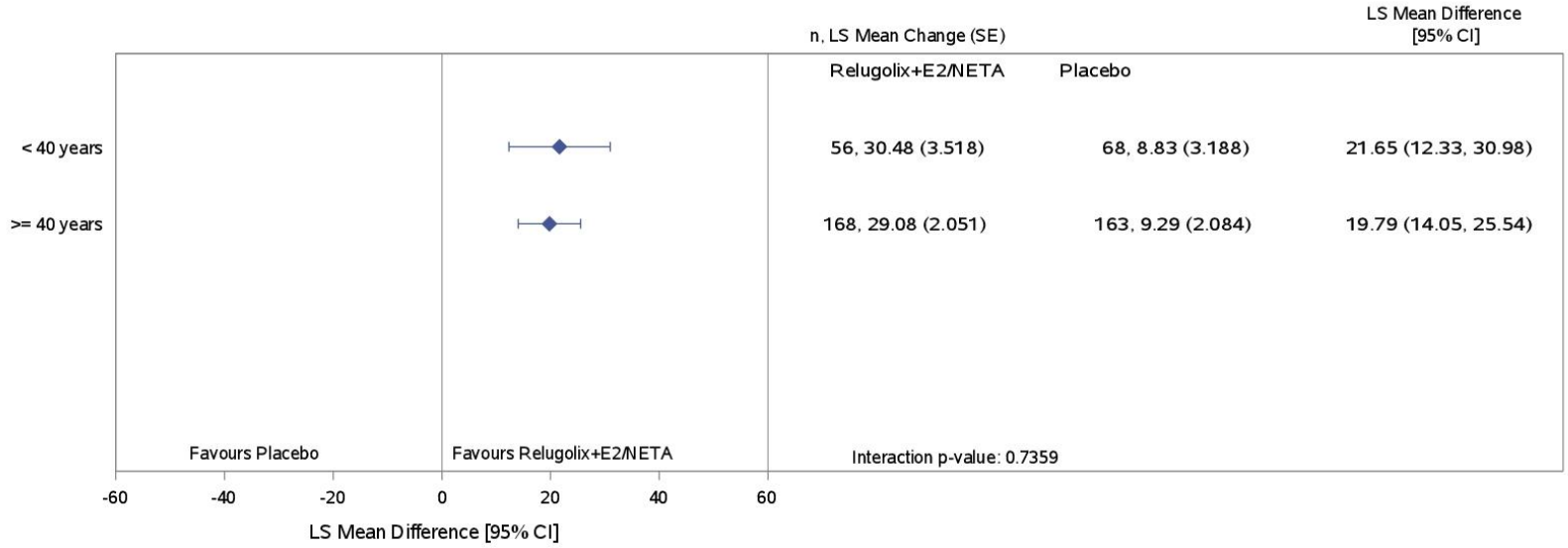
2.2.14 Summary of Average Change from Baseline in UFS-QoL Self-consciousness Scale Score Over 24 Weeks, by Subgroup (mITT Population)

Figure QOL.UFSCONS.MITT.S1.CON.FP: Summary of Average Change from Baseline in UFS-QoL Self-consciousness Scale Score Over 24 Weeks, by Subgroup (mITT Population)
Study: Pooled
Subgroup: Age (years)



Results are based on a mixed-effects model with study, treatment, visit, subgroup, treatment-by-visit interaction, and a subgroup-by-treatment interaction as fixed effects using a one-stage IPD meta-analysis approach. The multiple visits for each patient are the repeated measures as a random effect within each patient with an unstructured covariance.
The interaction p-value is based on the subgroup-by-treatment interaction term in the mixed-effects model used to compute the LS means, mean differences and 95% CIs. Missing subgroup levels are not included in estimation of the interaction p-value. The reference group is Placebo.
n: Number of patients with data; NETA: Norethindrone acetate; mITT: Modified intent-to-treat; LS: Least squares; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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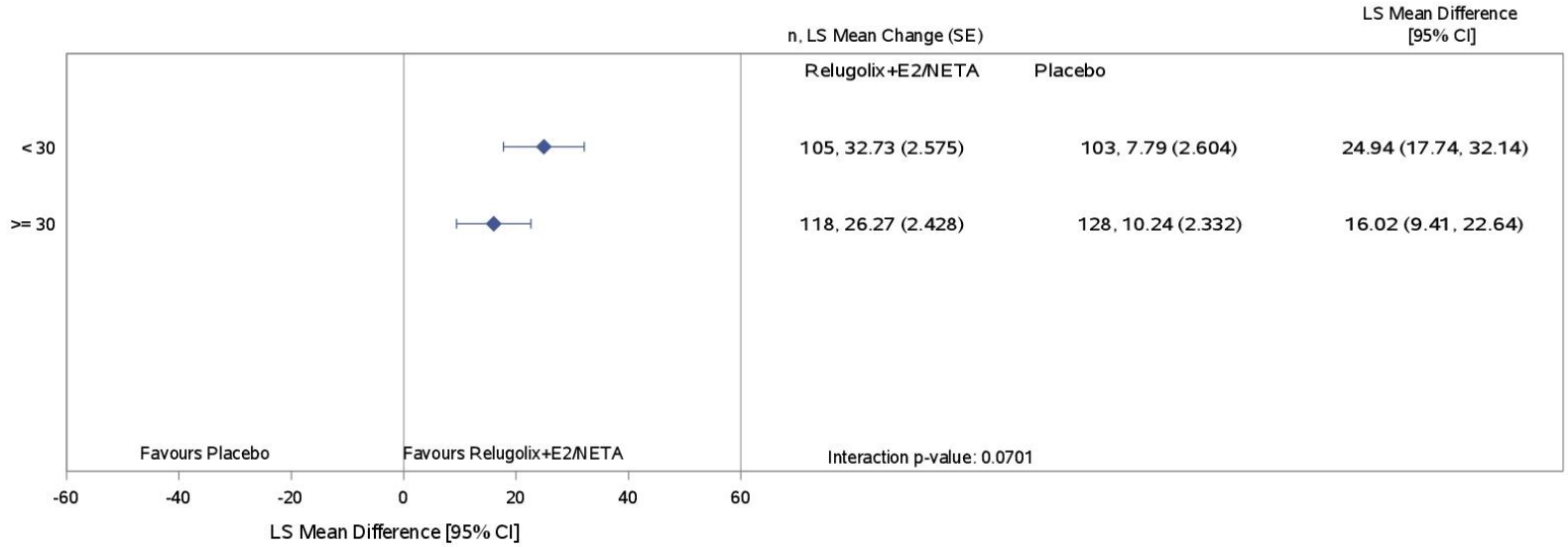
Figure QOL.UFSCONS.MITT.S2.CON.FP: Summary of Average Change from Baseline in UFS-QoL Self-consciousness Scale Score Over 24 Weeks, by Subgroup (mITT Population)
Study: Pooled
Subgroup: BMI (kg/m2) at Baseline



Results are based on a mixed-effects model with study, treatment, visit, subgroup, treatment-by-visit interaction, and a subgroup-by-treatment interaction as fixed effects using a one-stage IPD meta-analysis approach. The multiple visits for each patient are the repeated measures as a random effect within each patient with an unstructured covariance.
The interaction p-value is based on the subgroup-by-treatment interaction term in the mixed-effects model used to compute the LS means, mean differences and 95% CIs. Missing subgroup levels are not included in estimation of the interaction p-value. The reference group is Placebo.
n: Number of patients with data; NETA: Norethindrone acetate; mITT: Modified intent-to-treat; LS: Least squares; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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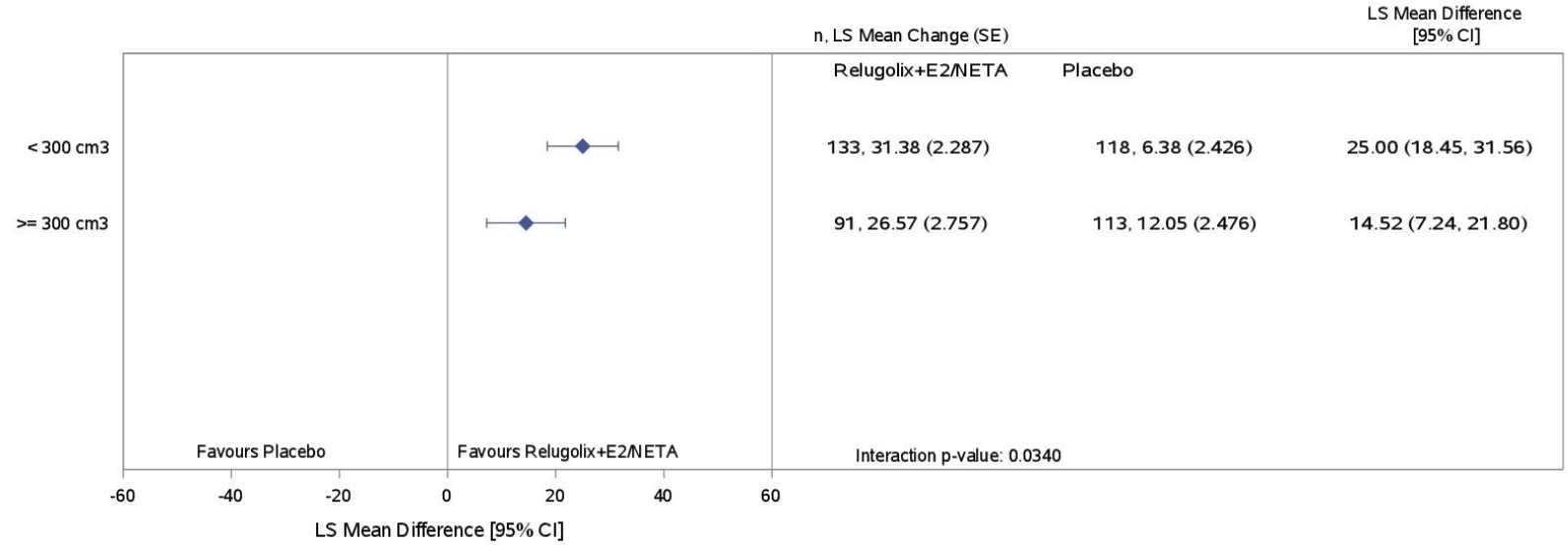
Figure QOL.UFSCONS.MITT.S3.CON.FP: Summary of Average Change from Baseline in UFS-QoL Self-consciousness Scale Score Over 24 Weeks, by Subgroup (mITT Population)
Study: Pooled
Subgroup: Uterine Volume at Baseline (cm3)



Results are based on a mixed-effects model with study, treatment, visit, subgroup, treatment-by-visit interaction, and a subgroup-by-treatment interaction as fixed effects using a one-stage IPD meta-analysis approach. The multiple visits for each patient are the repeated measures as a random effect within each patient with an unstructured covariance.
The interaction p-value is based on the subgroup-by-treatment interaction term in the mixed-effects model used to compute the LS means, mean differences and 95% CIs. Missing subgroup levels are not included in estimation of the interaction p-value. The reference group is Placebo.
n: Number of patients with data; NETA: Norethindrone acetate; mITT: Modified intent-to-treat; LS: Least squares; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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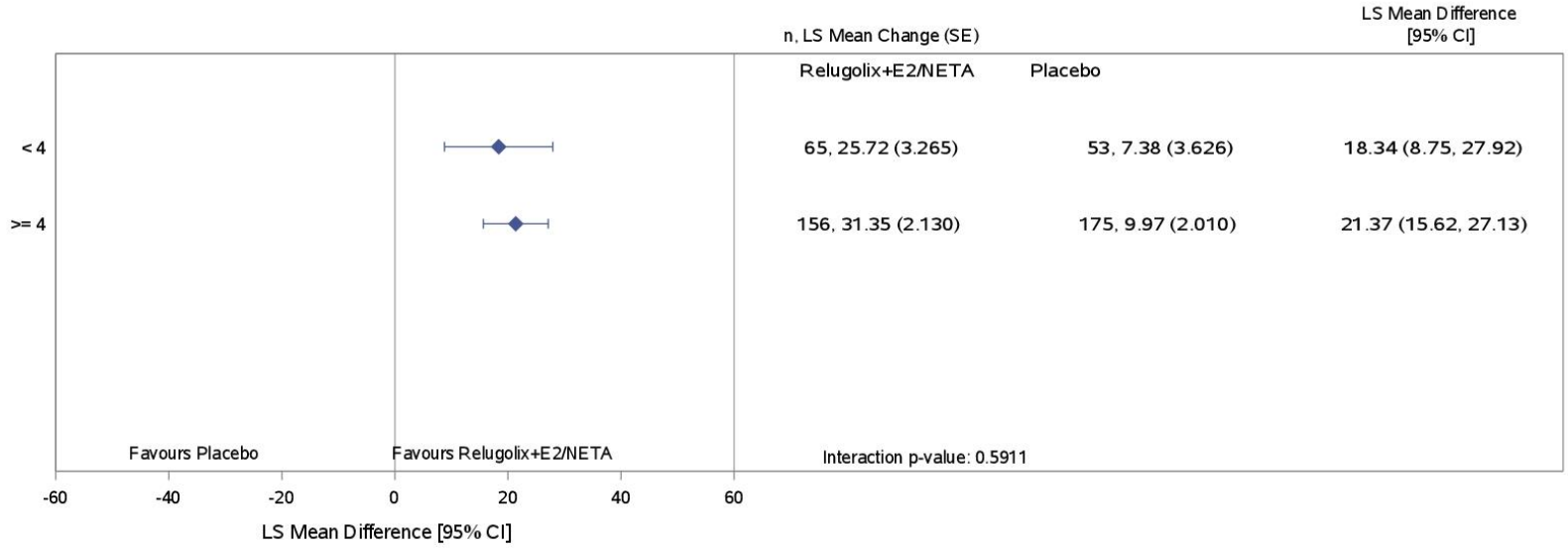
Figure QOL.UFSCONS.MITT.S4.CON.FP: Summary of Average Change from Baseline in UFS-QoL Self-consciousness Scale Score Over 24 Weeks, by Subgroup (mITT Population)
Study: Pooled
Subgroup: Maximum NRS Pain Score at Baseline



Results are based on a mixed-effects model with study, treatment, visit, subgroup, treatment-by-visit interaction, and a subgroup-by-treatment interaction as fixed effects using a one-stage IPD meta-analysis approach. The multiple visits for each patient are the repeated measures as a random effect within each patient with an unstructured covariance.
The interaction p-value is based on the subgroup-by-treatment interaction term in the mixed-effects model used to compute the LS means, mean differences and 95% CIs. Missing subgroup levels are not included in estimation of the interaction p-value. The reference group is Placebo.
n: Number of patients with data; NETA: Norethindrone acetate; mITT: Modified intent-to-treat; LS: Least squares; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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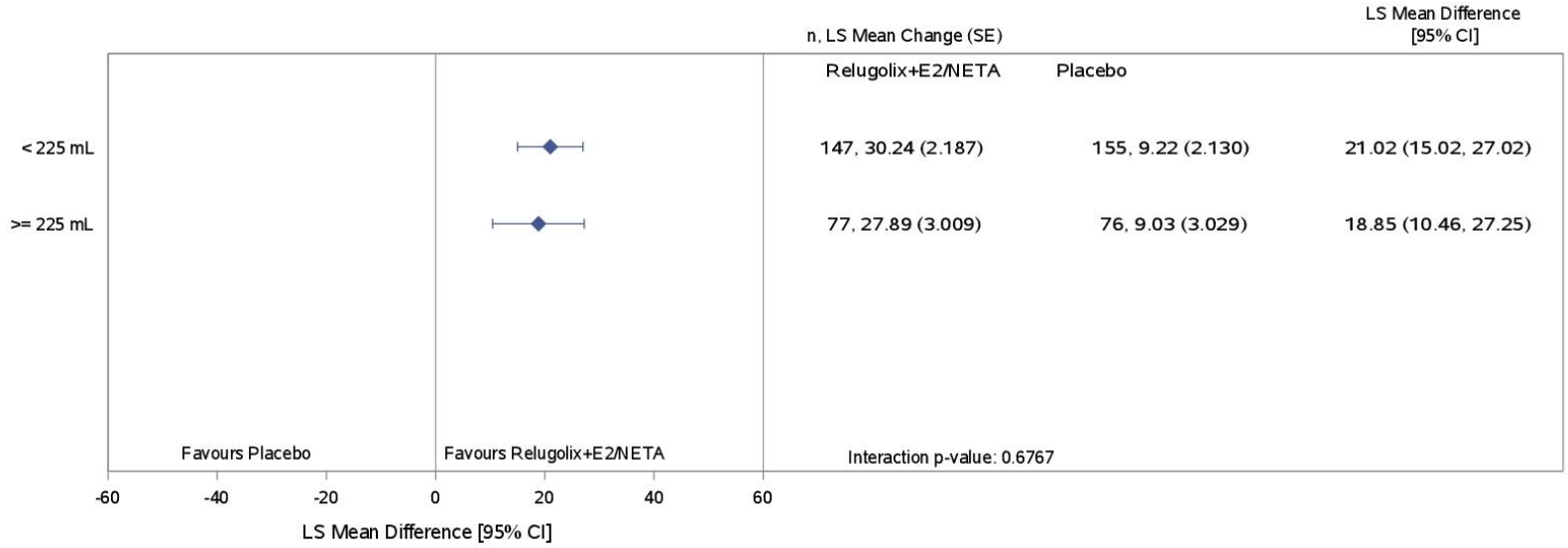
Figure QOL.UFSCONS.MITT.S5.CON.FP: Summary of Average Change from Baseline in UFS-QoL Self-consciousness Scale Score Over 24 Weeks, by Subgroup (mITT Population)
Study: Pooled
Subgroup: MBL Volume at Baseline (mL)



Results are based on a mixed-effects model with study, treatment, visit, subgroup, treatment-by-visit interaction, and a subgroup-by-treatment interaction as fixed effects using a one-stage IPD meta-analysis approach. The multiple visits for each patient are the repeated measures as a random effect within each patient with an unstructured covariance.
The interaction p-value is based on the subgroup-by-treatment interaction term in the mixed-effects model used to compute the LS means, mean differences and 95% CIs. Missing subgroup levels are not included in estimation of the interaction p-value. The reference group is Placebo.
n: Number of patients with data; NETA: Norethindrone acetate; mITT: Modified intent-to-treat; LS: Least squares; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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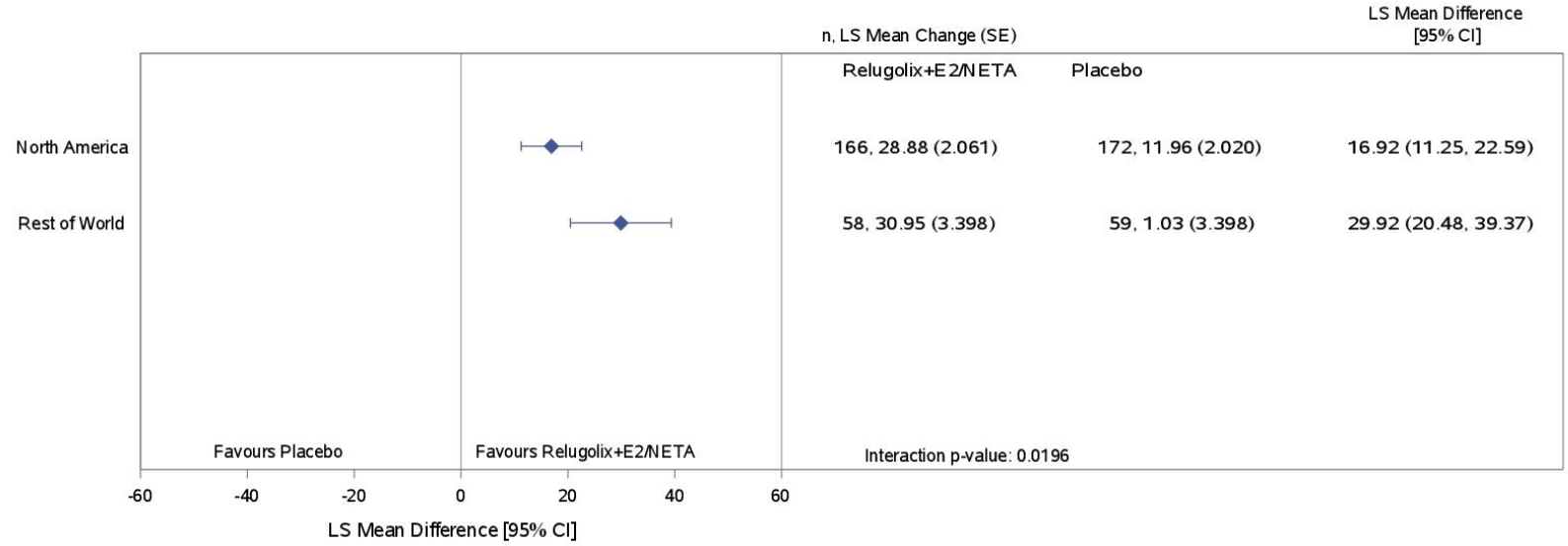
Figure QOL.UFSCONS.MITT.S6.CON.FP: Summary of Average Change from Baseline in UFS-QoL Self-consciousness Scale Score Over 24 Weeks, by Subgroup (mITT Population)
Study: Pooled
Subgroup: Geographic Region I



Results are based on a mixed-effects model with study, treatment, visit, subgroup, treatment-by-visit interaction, and a subgroup-by-treatment interaction as fixed effects using a one-stage IPD meta-analysis approach. The multiple visits for each patient are the repeated measures as a random effect within each patient with an unstructured covariance.
The interaction p-value is based on the subgroup-by-treatment interaction term in the mixed-effects model used to compute the LS means, mean differences and 95% CIs. Missing subgroup levels are not included in estimation of the interaction p-value. The reference group is Placebo.
n: Number of patients with data; NETA: Norethindrone acetate; mITT: Modified intent-to-treat; LS: Least squares; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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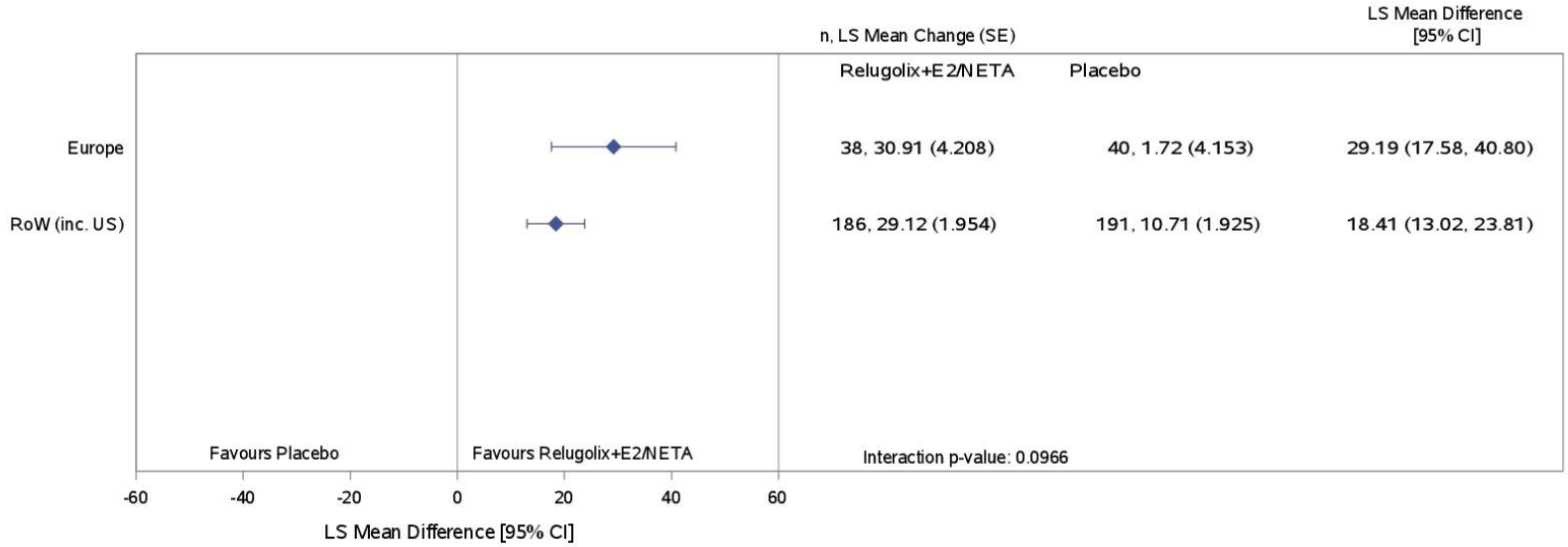
Figure QOL.UFSCONS.MITT.S7.CON.FP: Summary of Average Change from Baseline in UFS-QoL Self-consciousness Scale Score Over 24 Weeks, by Subgroup (mITT Population)
Study: Pooled
Subgroup: Geographic Region II



Results are based on a mixed-effects model with study, treatment, visit, subgroup, treatment-by-visit interaction, and a subgroup-by-treatment interaction as fixed effects using a one-stage IPD meta-analysis approach. The multiple visits for each patient are the repeated measures as a random effect within each patient with an unstructured covariance.
The interaction p-value is based on the subgroup-by-treatment interaction term in the mixed-effects model used to compute the LS means, mean differences and 95% CIs. Missing subgroup levels are not included in estimation of the interaction p-value. The reference group is Placebo.
n: Number of patients with data; NETA: Norethindrone acetate; mITT: Modified intent-to-treat; LS: Least squares; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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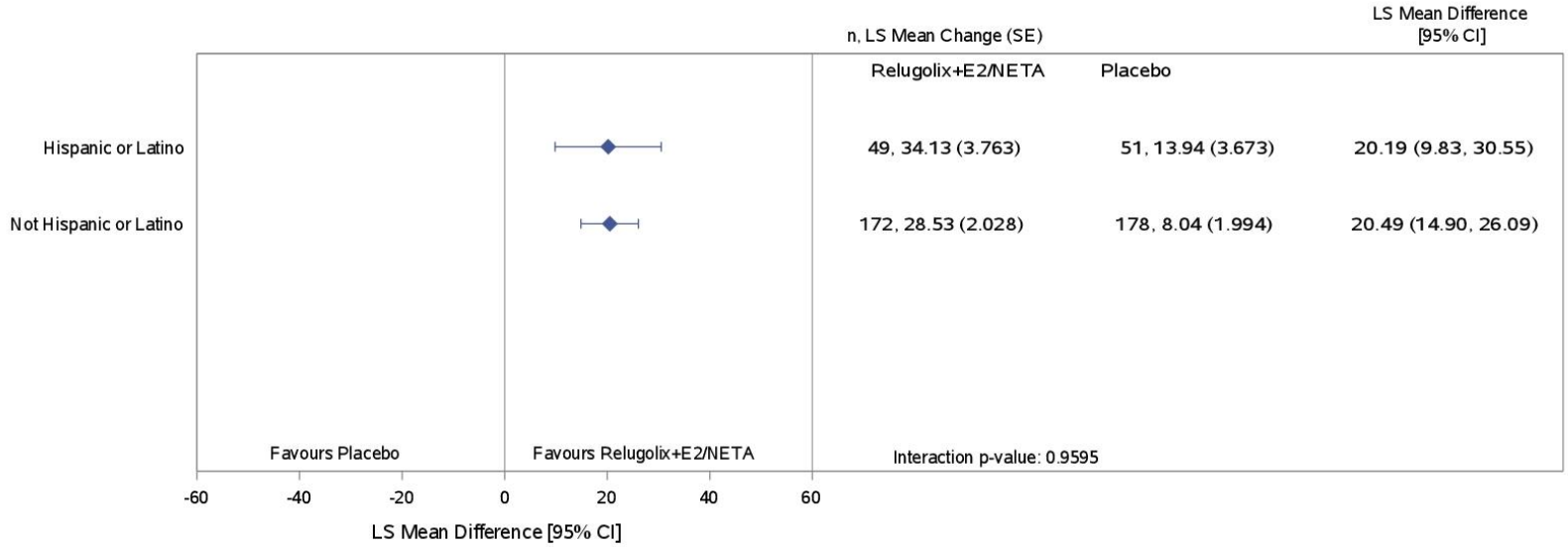
Figure QOL.UFSCONS.MITT.S8.CON.FP: Summary of Average Change from Baseline in UFS-QoL Self-consciousness Scale Score Over 24 Weeks, by Subgroup (mITT Population)
Study: Pooled
Subgroup: Ethnicity



Results are based on a mixed-effects model with study, treatment, visit, subgroup, treatment-by-visit interaction, and a subgroup-by-treatment interaction as fixed effects using a one-stage IPD meta-analysis approach. The multiple visits for each patient are the repeated measures as a random effect within each patient with an unstructured covariance.
The interaction p-value is based on the subgroup-by-treatment interaction term in the mixed-effects model used to compute the LS means, mean differences and 95% CIs. Missing subgroup levels are not included in estimation of the interaction p-value. The reference group is Placebo.
n: Number of patients with data; NETA: Norethindrone acetate; mITT: Modified intent-to-treat; LS: Least squares; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

SOURCE: X:\Numerus\Studies\MYV\MYV102\Analysis\Prod\Progs\TFLs\FIG_QOL_QS_S_CON_FP.SAS Date/time of run: 30JUN21 10:30
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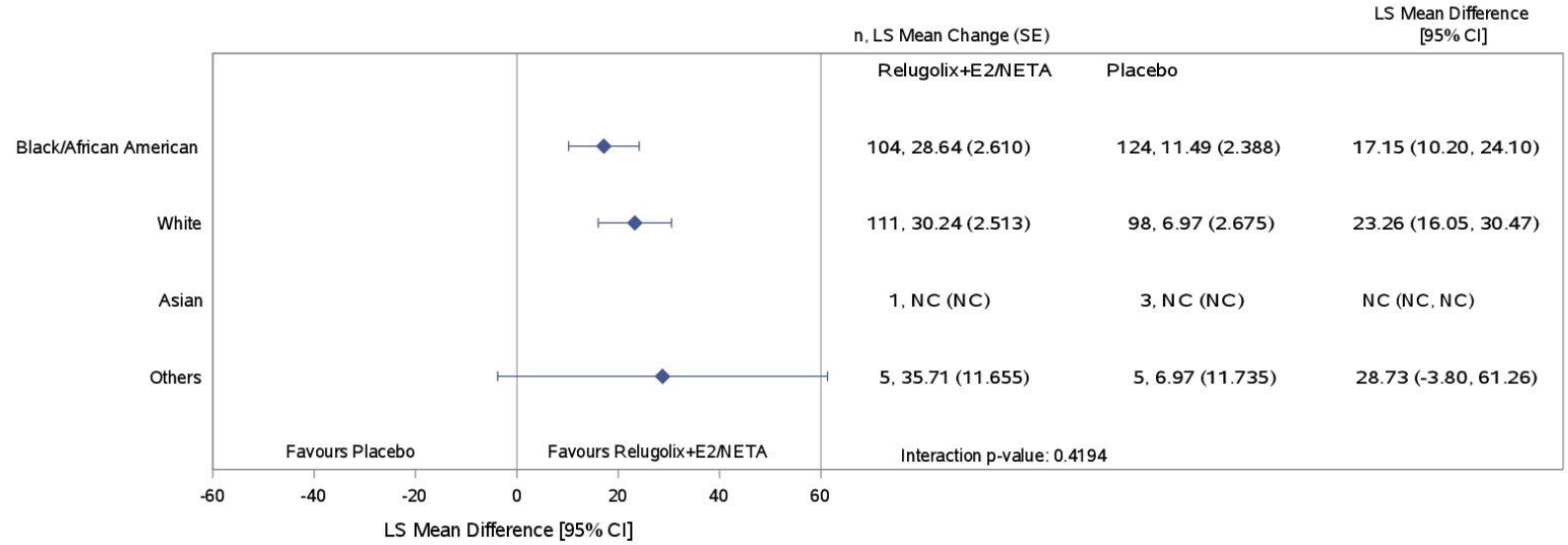
Figure QOL.UFSCONS.MITT.S9.CON.FP: Summary of Average Change from Baseline in UFS-QoL Self-consciousness Scale Score Over 24 Weeks, by Subgroup (mITT Population)
Study: Pooled
Subgroup: Race



Results are based on a mixed-effects model with study, treatment, visit, subgroup, treatment-by-visit interaction, and a subgroup-by-treatment interaction as fixed effects using a one-stage IPD meta-analysis approach. The multiple visits for each patient are the repeated measures as a random effect within each patient with an unstructured covariance.
The interaction p-value is based on the subgroup-by-treatment interaction term in the mixed-effects model used to compute the LS means, mean differences and 95% CIs. Missing subgroup levels are not included in estimation of the interaction p-value. The reference group is Placebo.
n: Number of patients with data; NETA: Norethindrone acetate; mITT: Modified intent-to-treat; LS: Least squares; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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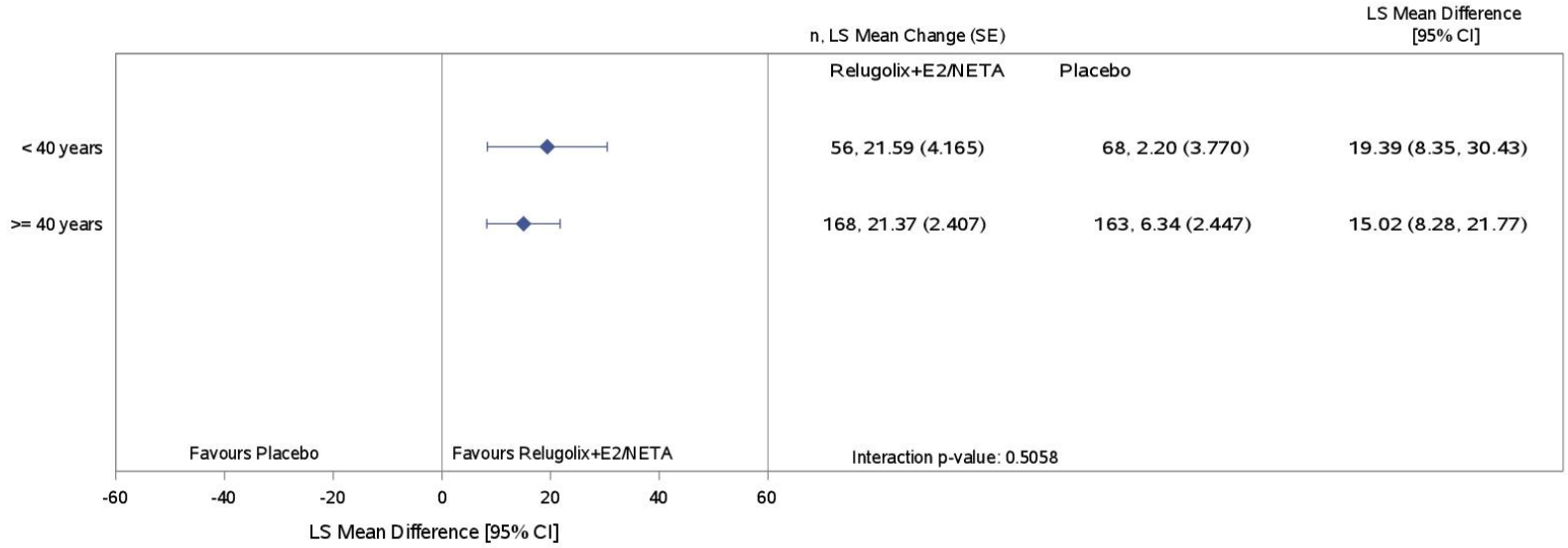
2.2.15 Summary of Average Change from Baseline in UFS-QoL Sexual Function Scale Score Over 24 Weeks, by Subgroup (mITT Population)

Figure QOL.UFSSFUNC.MITT.S1.CON.FP: Summary of Average Change from Baseline in UFS-QoL Sexual Function Scale Score Over 24 Weeks, by Subgroup (mITT Population)
Study: Pooled
Subgroup: Age (years)



Results are based on a mixed-effects model with study, treatment, visit, subgroup, treatment-by-visit interaction, and a subgroup-by-treatment interaction as fixed effects using a one-stage IPD meta-analysis approach. The multiple visits for each patient are the repeated measures as a random effect within each patient with an unstructured covariance.
The interaction p-value is based on the subgroup-by-treatment interaction term in the mixed-effects model used to compute the LS means, mean differences and 95% CIs. Missing subgroup levels are not included in estimation of the interaction p-value. The reference group is Placebo.
n: Number of patients with data; NETA: Norethindrone acetate; mITT: Modified intent-to-treat; LS: Least squares; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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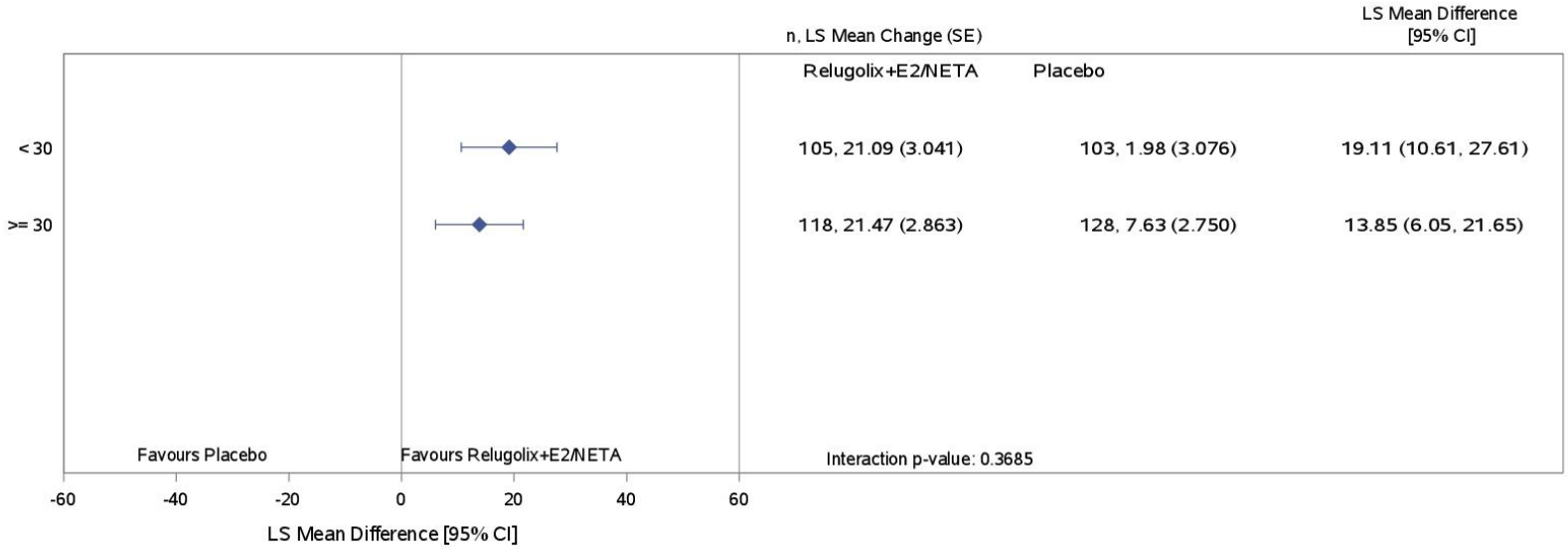
Figure QOL.UFSSFUNC.MITT.S2.CON.FP: Summary of Average Change from Baseline in UFS-QoL Sexual Function Scale Score Over 24 Weeks, by Subgroup (mITT Population)
Study: Pooled
Subgroup: BMI (kg/m2) at Baseline



Results are based on a mixed-effects model with study, treatment, visit, subgroup, treatment-by-visit interaction, and a subgroup-by-treatment interaction as fixed effects using a one-stage IPD meta-analysis approach. The multiple visits for each patient are the repeated measures as a random effect within each patient with an unstructured covariance.
The interaction p-value is based on the subgroup-by-treatment interaction term in the mixed-effects model used to compute the LS means, mean differences and 95% CIs. Missing subgroup levels are not included in estimation of the interaction p-value. The reference group is Placebo.
n: Number of patients with data; NETA: Norethindrone acetate; mITT: Modified intent-to-treat; LS: Least squares; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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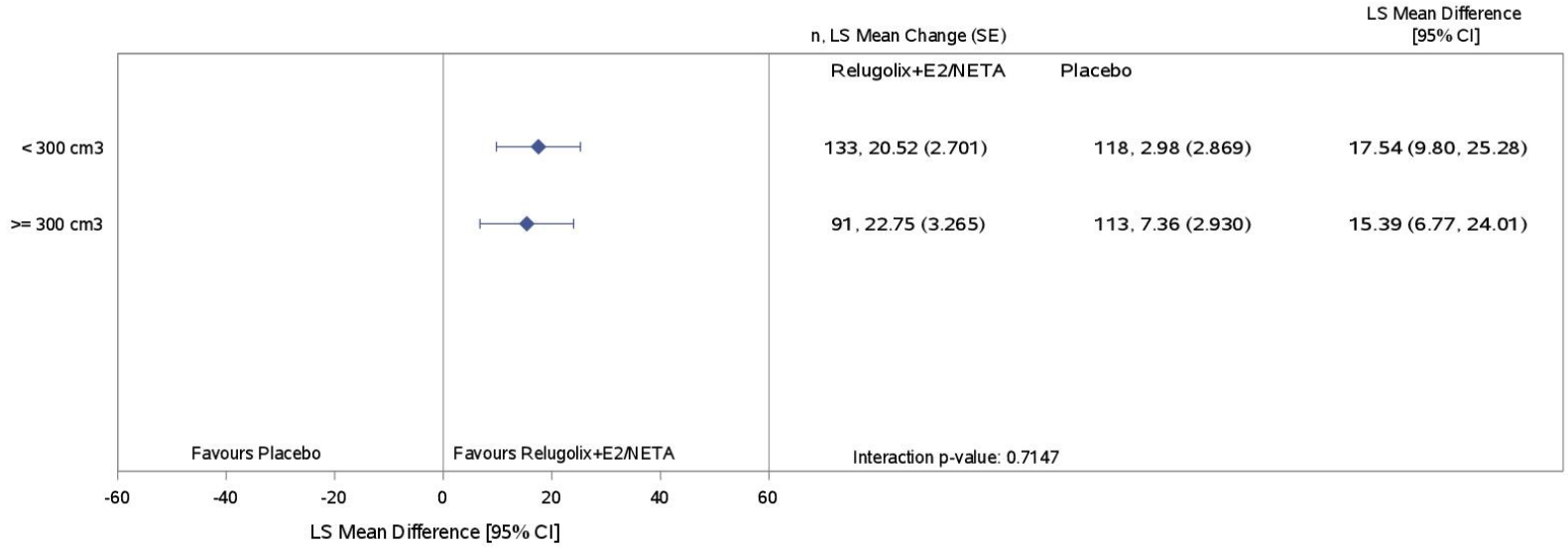
Figure QOL.UFSSFUNC.MITT.S3.CON.FP: Summary of Average Change from Baseline in UFS-QoL Sexual Function Scale Score Over 24 Weeks, by Subgroup (mITT Population)
Study: Pooled
Subgroup: Uterine Volume at Baseline (cm3)



Results are based on a mixed-effects model with study, treatment, visit, subgroup, treatment-by-visit interaction, and a subgroup-by-treatment interaction as fixed effects using a one-stage IPD meta-analysis approach. The multiple visits for each patient are the repeated measures as a random effect within each patient with an unstructured covariance.
The interaction p-value is based on the subgroup-by-treatment interaction term in the mixed-effects model used to compute the LS means, mean differences and 95% CIs. Missing subgroup levels are not included in estimation of the interaction p-value. The reference group is Placebo.
n: Number of patients with data; NETA: Norethindrone acetate; mITT: Modified intent-to-treat; LS: Least squares; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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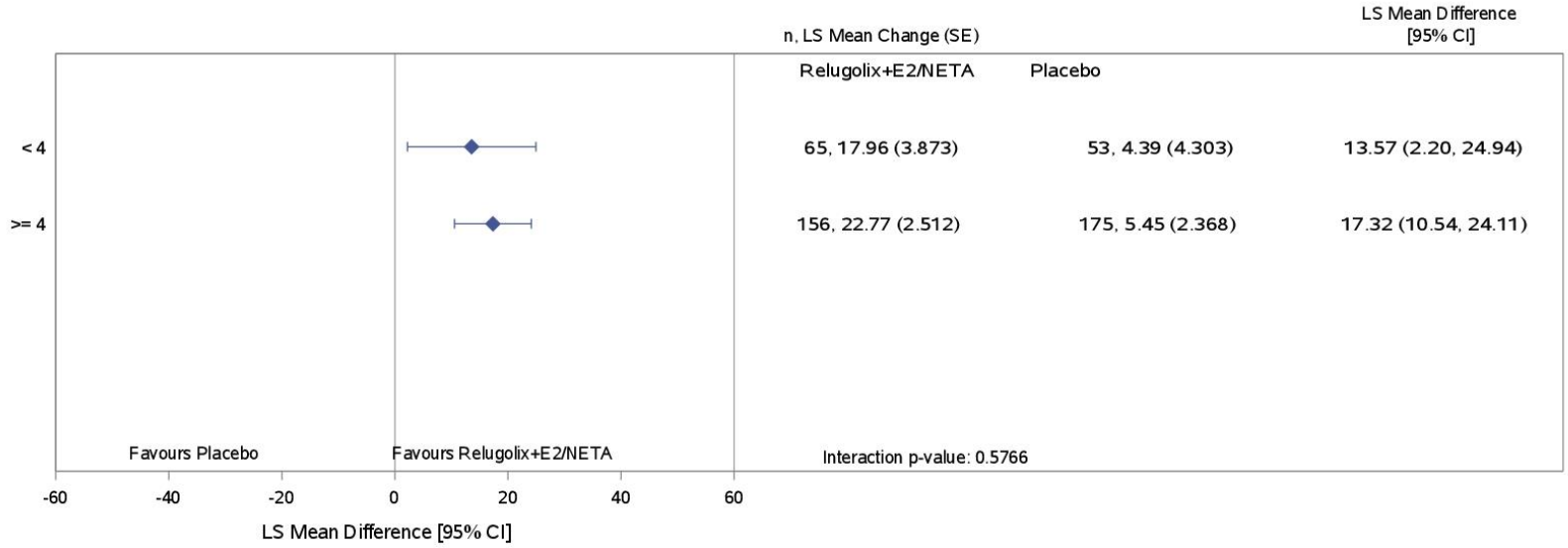
Figure QOL.UFSSFUNC.MITT.S4.CON.FP: Summary of Average Change from Baseline in UFS-QoL Sexual Function Scale Score Over 24 Weeks, by Subgroup (mITT Population)
Study: Pooled
Subgroup: Maximum NRS Pain Score at Baseline



Results are based on a mixed-effects model with study, treatment, visit, subgroup, treatment-by-visit interaction, and a subgroup-by-treatment interaction as fixed effects using a one-stage IPD meta-analysis approach. The multiple visits for each patient are the repeated measures as a random effect within each patient with an unstructured covariance.
The interaction p-value is based on the subgroup-by-treatment interaction term in the mixed-effects model used to compute the LS means, mean differences and 95% CIs. Missing subgroup levels are not included in estimation of the interaction p-value. The reference group is Placebo.
n: Number of patients with data; NETA: Norethindrone acetate; mITT: Modified intent-to-treat; LS: Least squares; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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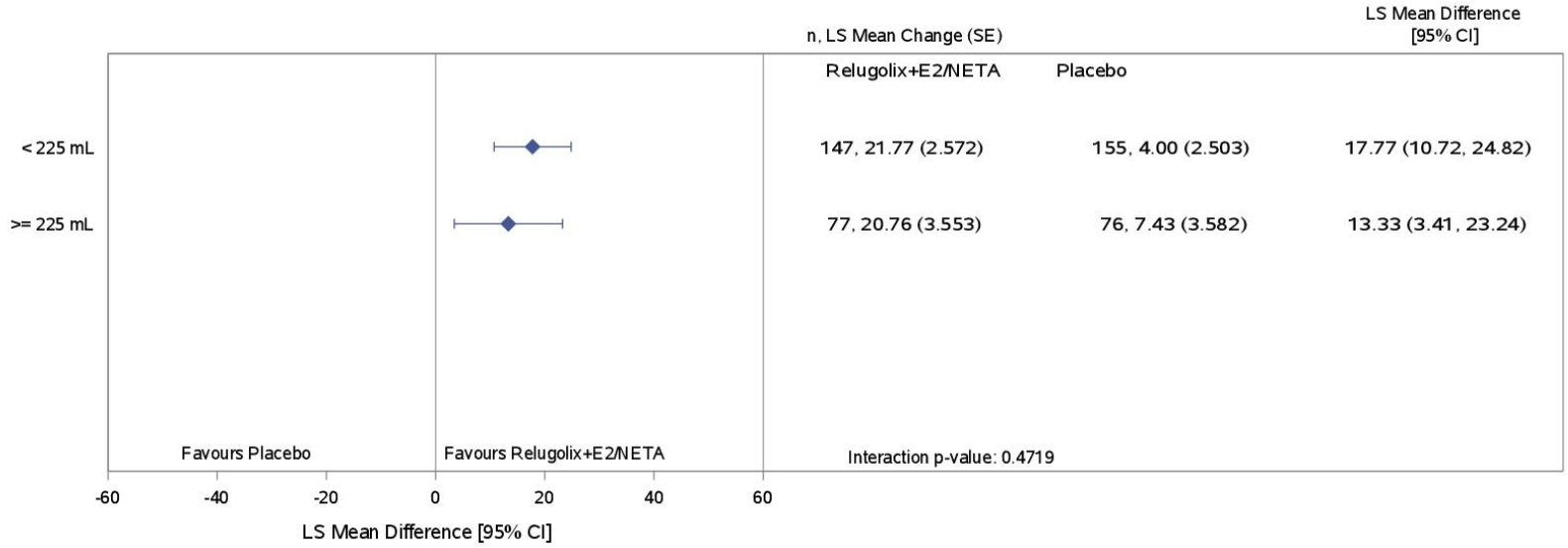
Figure QOL.UFSSFUNC.MITT.S5.CON.FP: Summary of Average Change from Baseline in UFS-QoL Sexual Function Scale Score Over 24 Weeks, by Subgroup (mITT Population)
Study: Pooled
Subgroup: MBL Volume at Baseline (mL)



Results are based on a mixed-effects model with study, treatment, visit, subgroup, treatment-by-visit interaction, and a subgroup-by-treatment interaction as fixed effects using a one-stage IPD meta-analysis approach. The multiple visits for each patient are the repeated measures as a random effect within each patient with an unstructured covariance.
The interaction p-value is based on the subgroup-by-treatment interaction term in the mixed-effects model used to compute the LS means, mean differences and 95% CIs. Missing subgroup levels are not included in estimation of the interaction p-value. The reference group is Placebo.
n: Number of patients with data; NETA: Norethindrone acetate; mITT: Modified intent-to-treat; LS: Least squares; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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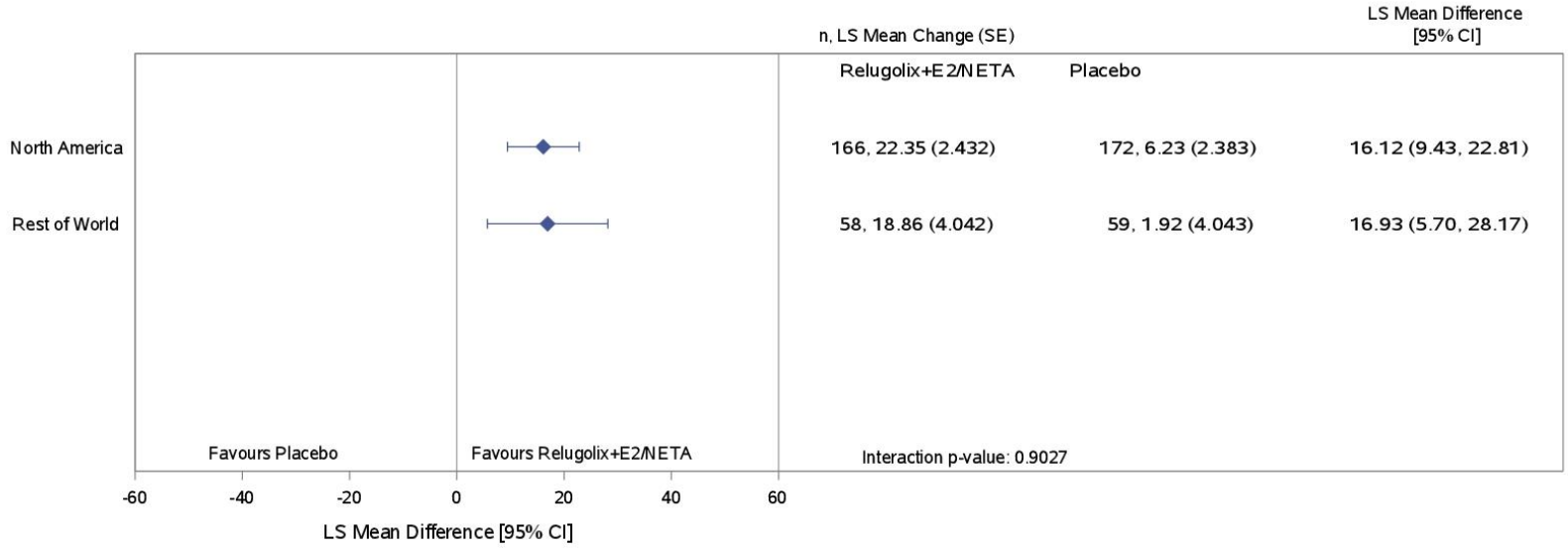
Figure QOL.UFSSFUNC.MITT.S6.CON.FP: Summary of Average Change from Baseline in UFS-QoL Sexual Function Scale Score Over 24 Weeks, by Subgroup (mITT Population)
Study: Pooled
Subgroup: Geographic Region I



Results are based on a mixed-effects model with study, treatment, visit, subgroup, treatment-by-visit interaction, and a subgroup-by-treatment interaction as fixed effects using a one-stage IPD meta-analysis approach. The multiple visits for each patient are the repeated measures as a random effect within each patient with an unstructured covariance.
The interaction p-value is based on the subgroup-by-treatment interaction term in the mixed-effects model used to compute the LS means, mean differences and 95% CIs. Missing subgroup levels are not included in estimation of the interaction p-value. The reference group is Placebo.
n: Number of patients with data; NETA: Norethindrone acetate; mITT: Modified intent-to-treat; LS: Least squares; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

SOURCE: X:\Numerus\Studies\MYV\MYV102\Analysis\Prod\Progs\TFLs\FIG_QOL_QS_S_CON_FP.SAS Date/time of run: 30JUN21 10:30
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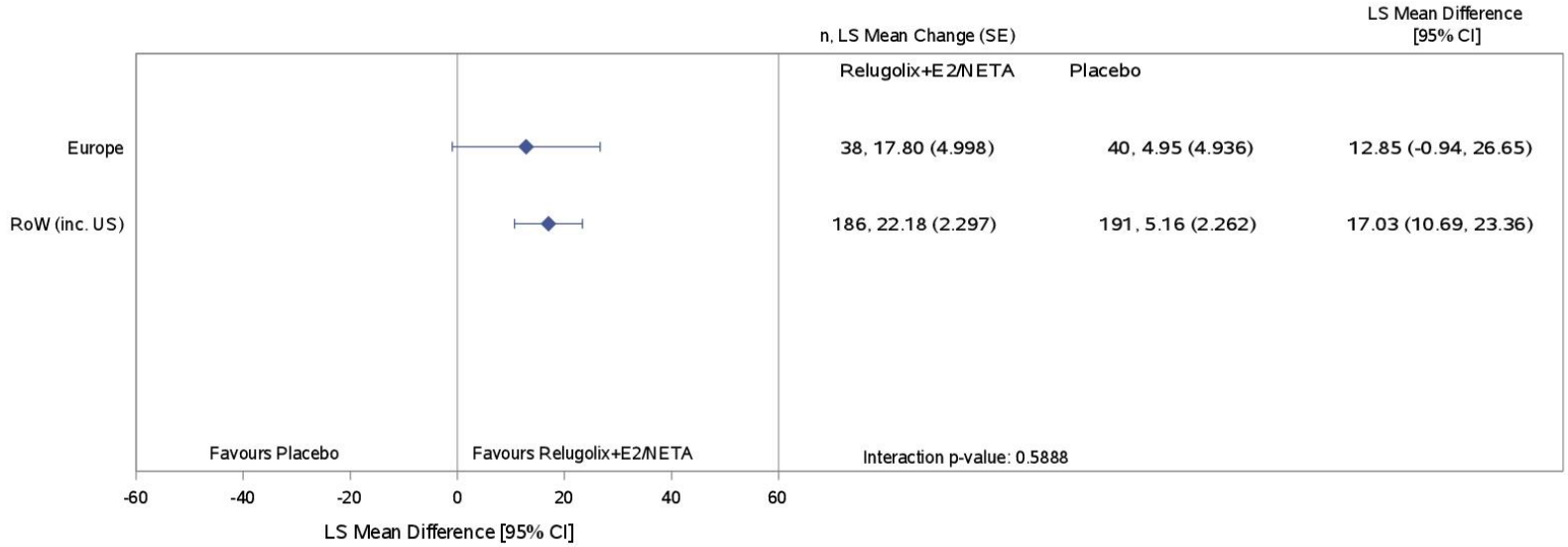
Figure QOL.UFSSFUNC.MITT.S7.CON.FP: Summary of Average Change from Baseline in UFS-QoL Sexual Function Scale Score Over 24 Weeks, by Subgroup (mITT Population)
Study: Pooled
Subgroup: Geographic Region II



Results are based on a mixed-effects model with study, treatment, visit, subgroup, treatment-by-visit interaction, and a subgroup-by-treatment interaction as fixed effects using a one-stage IPD meta-analysis approach. The multiple visits for each patient are the repeated measures as a random effect within each patient with an unstructured covariance.
The interaction p-value is based on the subgroup-by-treatment interaction term in the mixed-effects model used to compute the LS means, mean differences and 95% CIs. Missing subgroup levels are not included in estimation of the interaction p-value. The reference group is Placebo.
n: Number of patients with data; NETA: Norethindrone acetate; mITT: Modified intent-to-treat; LS: Least squares; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

SOURCE: X:\Numerus\Studies\MYV\MYV102\Analysis\Prod\Progs\TFLs\FIG_QOL_QS_S_CON_FP.SAS Date/time of run: 30JUN21 10:30
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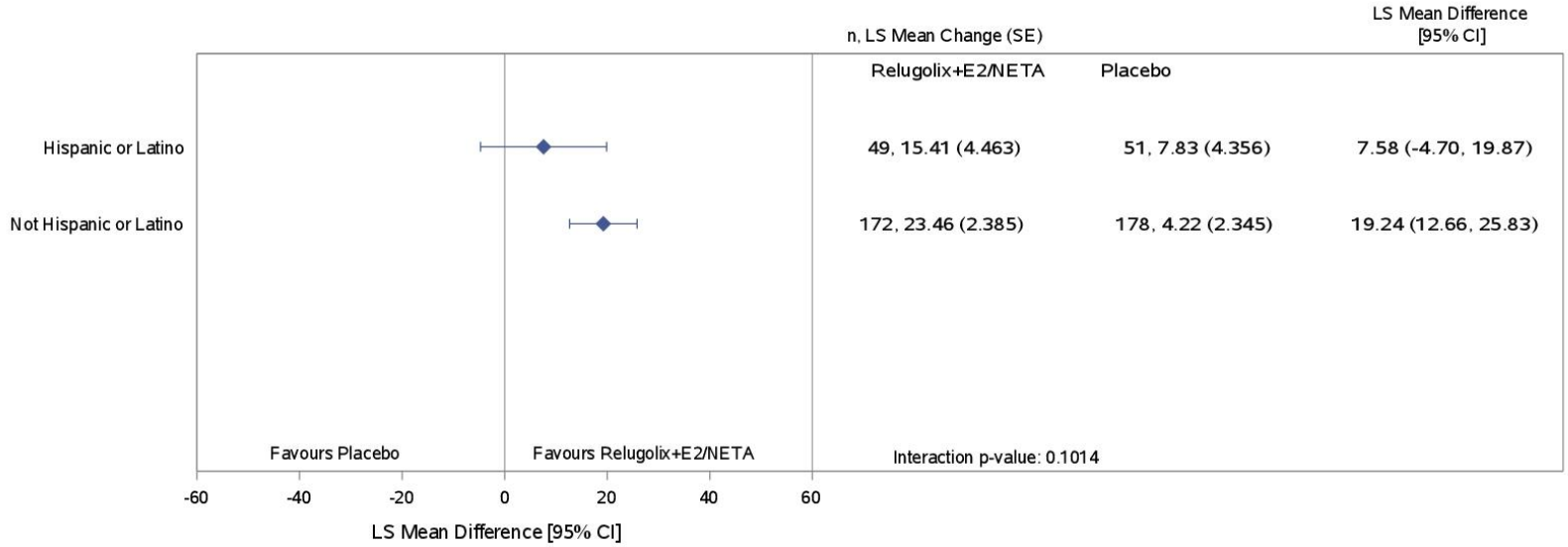
Figure QOL.UFSSFUNC.MITT.S8.CON.FP: Summary of Average Change from Baseline in UFS-QoL Sexual Function Scale Score Over 24 Weeks, by Subgroup (mITT Population)
Study: Pooled
Subgroup: Ethnicity



Results are based on a mixed-effects model with study, treatment, visit, subgroup, treatment-by-visit interaction, and a subgroup-by-treatment interaction as fixed effects using a one-stage IPD meta-analysis approach. The multiple visits for each patient are the repeated measures as a random effect within each patient with an unstructured covariance.
The interaction p-value is based on the subgroup-by-treatment interaction term in the mixed-effects model used to compute the LS means, mean differences and 95% CIs. Missing subgroup levels are not included in estimation of the interaction p-value. The reference group is Placebo.
n: Number of patients with data; NETA: Norethindrone acetate; mITT: Modified intent-to-treat; LS: Least squares; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

SOURCE: X:\Numerus\Studies\MYV\MYV102\Analysis\Prod\Progs\TFLs\FIG_QOL_QS_S_CON_FP.SAS Date/time of run: 30JUN21 10:30
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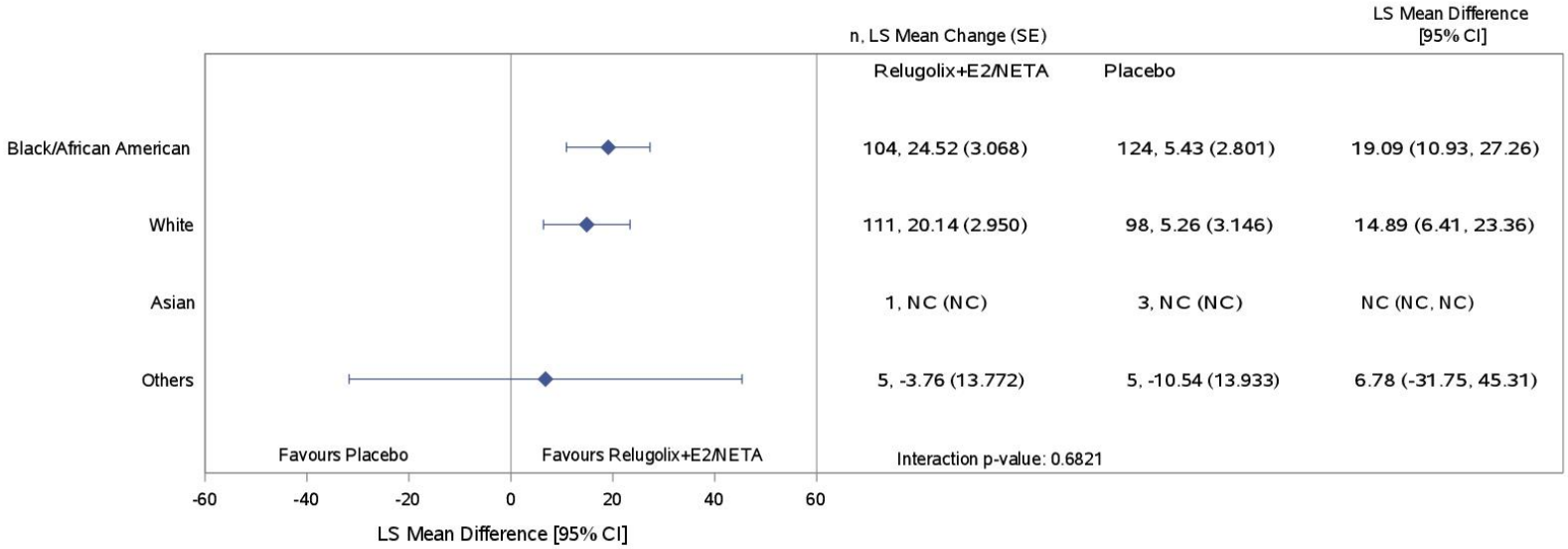
Figure QOL.UFSSFUNC.MITT.S9.CON.FP: Summary of Average Change from Baseline in UFS-QoL Sexual Function Scale Score Over 24 Weeks, by Subgroup (mITT Population)
Study: Pooled
Subgroup: Race



Results are based on a mixed-effects model with study, treatment, visit, subgroup, treatment-by-visit interaction, and a subgroup-by-treatment interaction as fixed effects using a one-stage IPD meta-analysis approach. The multiple visits for each patient are the repeated measures as a random effect within each patient with an unstructured covariance.
The interaction p-value is based on the subgroup-by-treatment interaction term in the mixed-effects model used to compute the LS means, mean differences and 95% CIs. Missing subgroup levels are not included in estimation of the interaction p-value. The reference group is Placebo.
n: Number of patients with data; NETA: Norethindrone acetate; mITT: Modified intent-to-treat; LS: Least squares; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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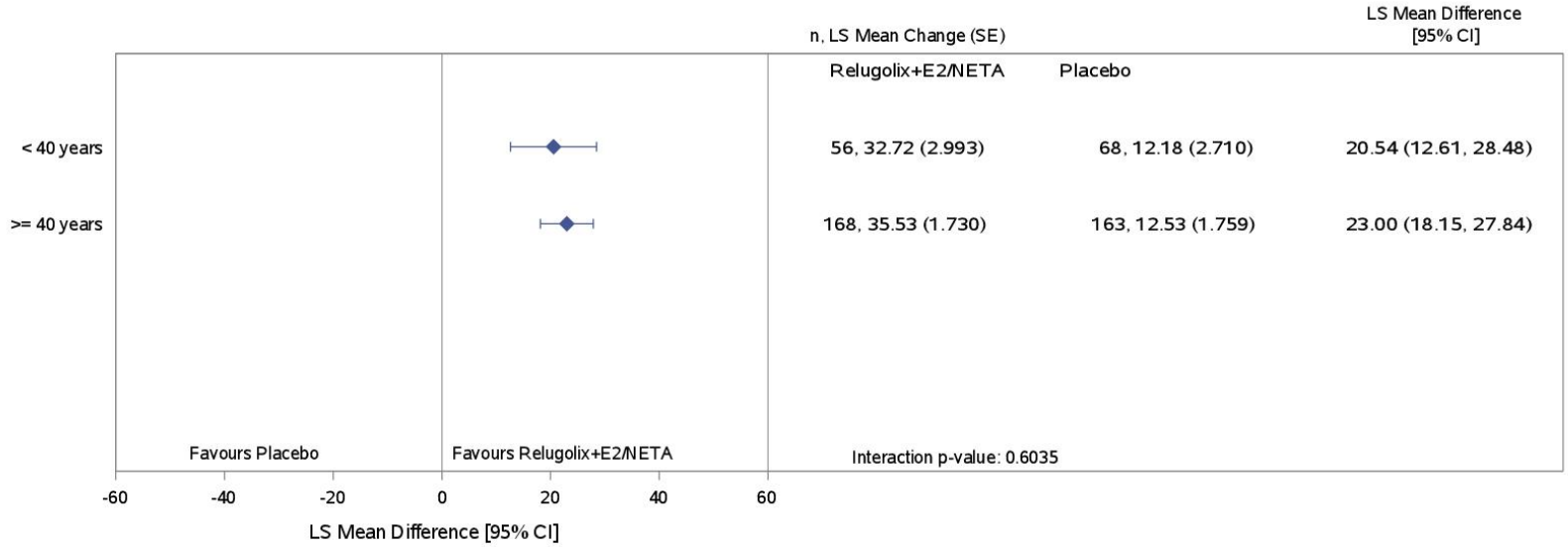
2.2.16 Summary of Average Change from Baseline in UFS-QoL Total Score Over 24 Weeks, by Subgroup (mITT Population)

Figure QOL.HRQLTOT.MITT.S1.CON.FP: Summary of Average Change from Baseline in UFS-QoL Total Score Over 24 Weeks, by Subgroup (mITT Population)
Study: Pooled
Subgroup: Age (years)



Results are based on a mixed-effects model with study, treatment, visit, subgroup, treatment-by-visit interaction, and a subgroup-by-treatment interaction as fixed effects using a one-stage IPD meta-analysis approach. The multiple visits for each patient are the repeated measures as a random effect within each patient with an unstructured covariance.
The interaction p-value is based on the subgroup-by-treatment interaction term in the mixed-effects model used to compute the LS means, mean differences and 95% CIs. Missing subgroup levels are not included in estimation of the interaction p-value. The reference group is Placebo.
n: Number of patients with data; NETA: Norethindrone acetate; mITT: Modified intent-to-treat; LS: Least squares; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

SOURCE: X:\Numerus\Studies\MYV\MYV102\Analysis\Prod\Progs\TFLs\FIG_QOL_QS_S_CON_FP.SAS Date/time of run: 30JUN21 10:30
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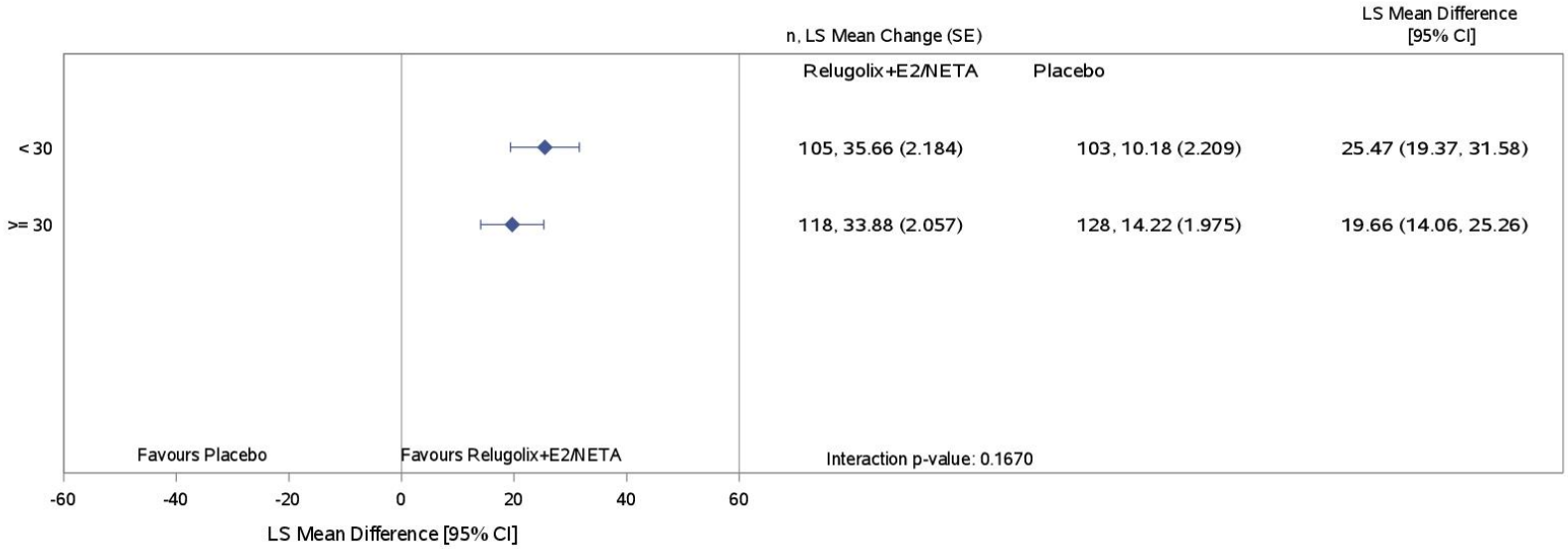
Figure QOL.HRQLTOT.MITT.S2.CON.FP: Summary of Average Change from Baseline in UFS-QoL Total Score Over 24 Weeks, by Subgroup (mITT Population)
Study: Pooled
Subgroup: BMI (kg/m2) at Baseline



Results are based on a mixed-effects model with study, treatment, visit, subgroup, treatment-by-visit interaction, and a subgroup-by-treatment interaction as fixed effects using a one-stage IPD meta-analysis approach. The multiple visits for each patient are the repeated measures as a random effect within each patient with an unstructured covariance.
The interaction p-value is based on the subgroup-by-treatment interaction term in the mixed-effects model used to compute the LS means, mean differences and 95% CIs. Missing subgroup levels are not included in estimation of the interaction p-value. The reference group is Placebo.
n: Number of patients with data; NETA: Norethindrone acetate; mITT: Modified intent-to-treat; LS: Least squares; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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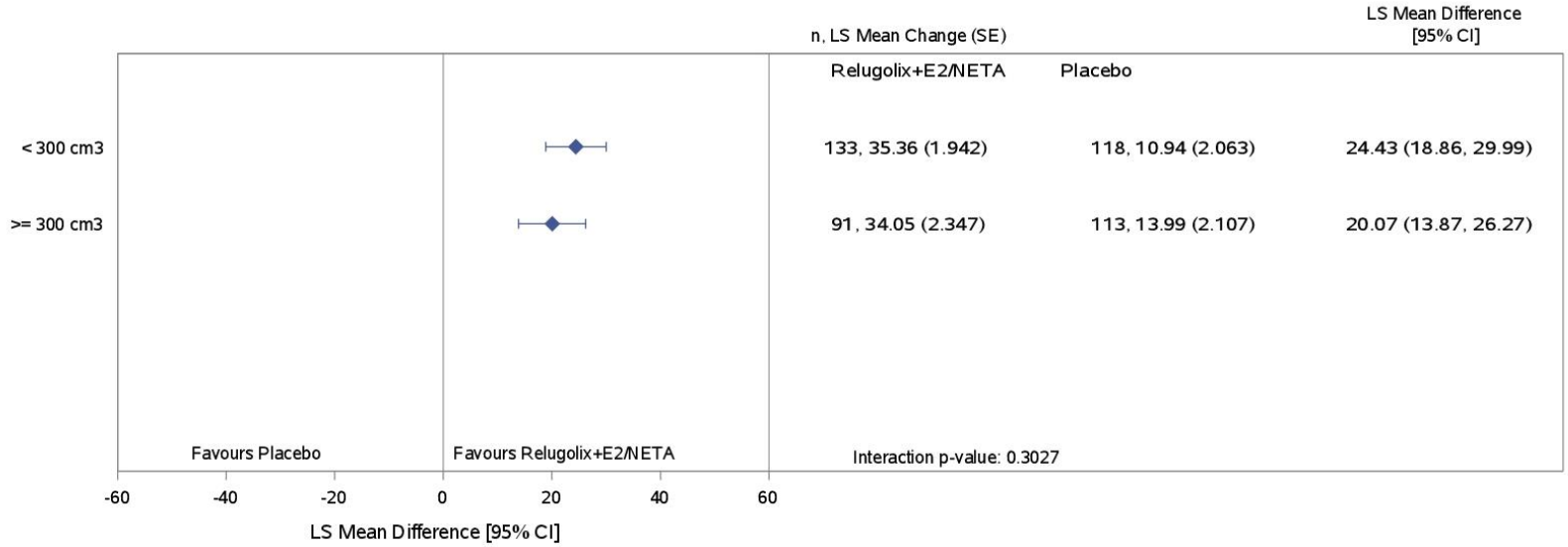
Figure QOL.HRQLTOT.MITT.S3.CON.FP: Summary of Average Change from Baseline in UFS-QoL Total Score Over 24 Weeks, by Subgroup (mITT Population)
Study: Pooled
Subgroup: Uterine Volume at Baseline (cm3)



Results are based on a mixed-effects model with study, treatment, visit, subgroup, treatment-by-visit interaction, and a subgroup-by-treatment interaction as fixed effects using a one-stage IPD meta-analysis approach. The multiple visits for each patient are the repeated measures as a random effect within each patient with an unstructured covariance.
The interaction p-value is based on the subgroup-by-treatment interaction term in the mixed-effects model used to compute the LS means, mean differences and 95% CIs. Missing subgroup levels are not included in estimation of the interaction p-value. The reference group is Placebo.
n: Number of patients with data; NETA: Norethindrone acetate; mITT: Modified intent-to-treat; LS: Least squares; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

SOURCE: X:\Numerus\Studies\MYV\MYV102\Analysis\Prod\Progs\TFLs\FIG_QOL_QS_S_CON_FP.SAS Date/time of run: 30JUN21 10:30
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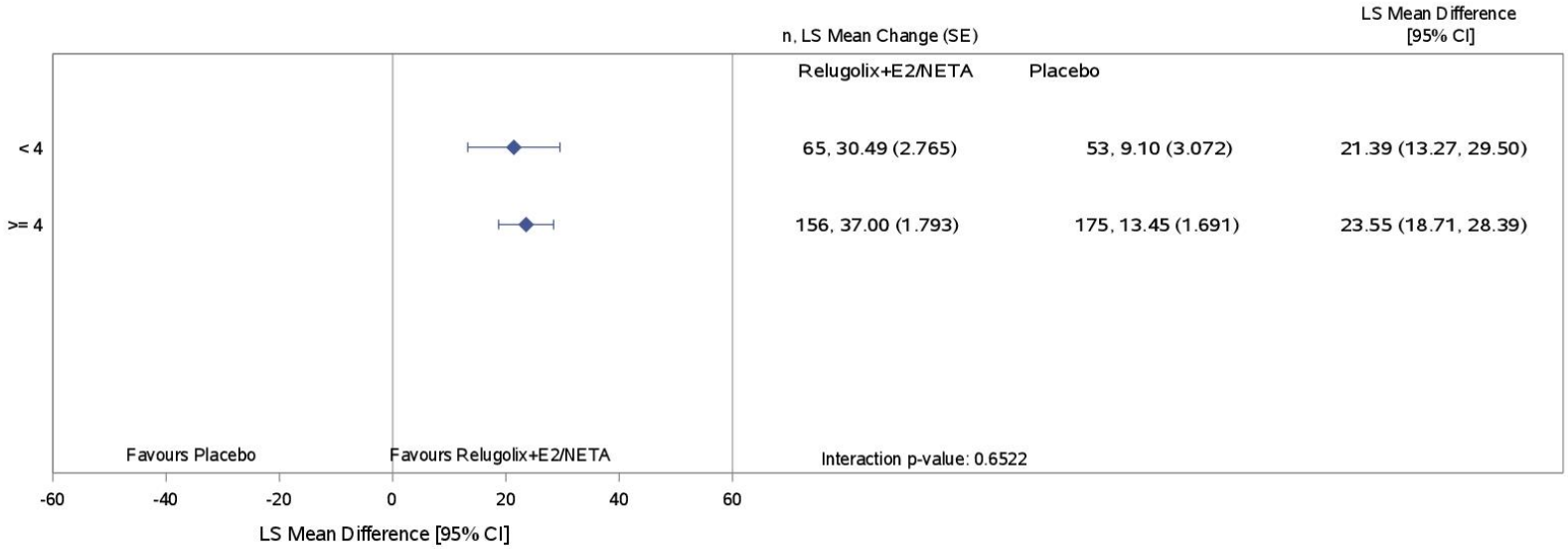
Figure QOL.HRQLTOT.MITT.S4.CON.FP: Summary of Average Change from Baseline in UFS-QoL Total Score Over 24 Weeks, by Subgroup (mITT Population)
Study: Pooled
Subgroup: Maximum NRS Pain Score at Baseline



Results are based on a mixed-effects model with study, treatment, visit, subgroup, treatment-by-visit interaction, and a subgroup-by-treatment interaction as fixed effects using a one-stage IPD meta-analysis approach. The multiple visits for each patient are the repeated measures as a random effect within each patient with an unstructured covariance.
The interaction p-value is based on the subgroup-by-treatment interaction term in the mixed-effects model used to compute the LS means, mean differences and 95% CIs. Missing subgroup levels are not included in estimation of the interaction p-value. The reference group is Placebo.
n: Number of patients with data; NETA: Norethindrone acetate; mITT: Modified intent-to-treat; LS: Least squares; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

SOURCE: X:\Numerus\Studies\MYV\MYV102\Analysis\Prod\Progs\TFLs\FIG_QOL_QS_S_CON_FP.SAS Date/time of run: 30JUN21 10:30
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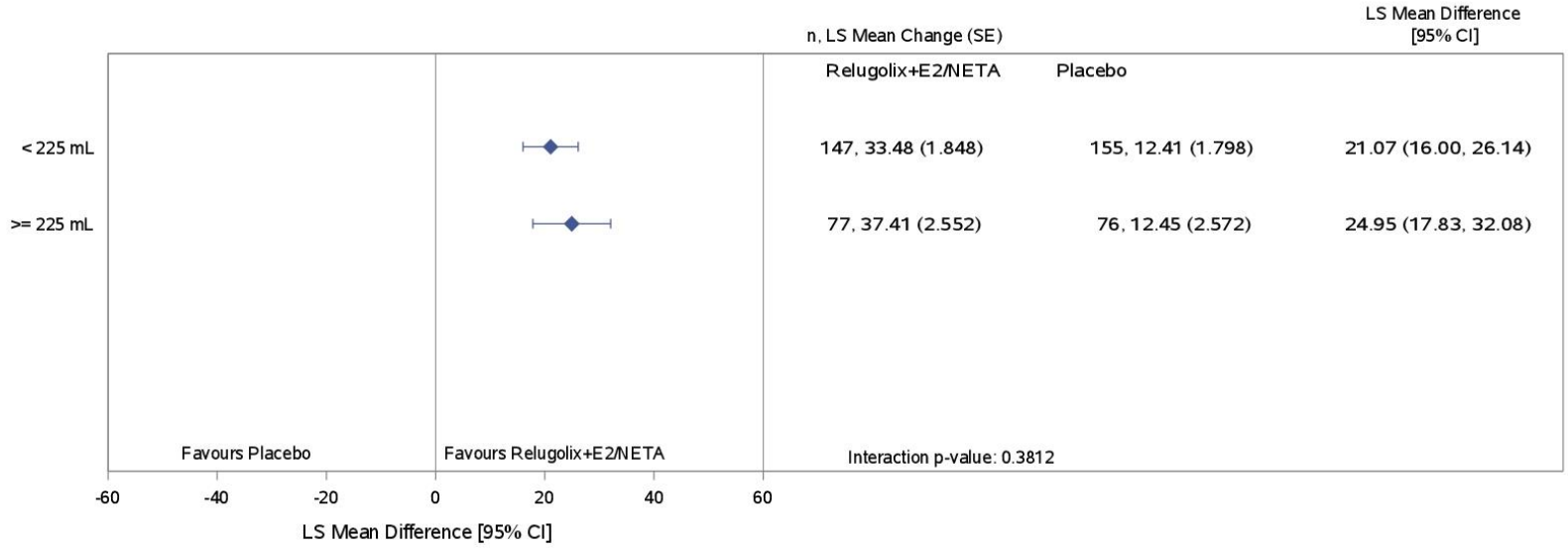
Figure QOL.HRQLTOT.MITT.S5.CON.FP: Summary of Average Change from Baseline in UFS-QoL Total Score Over 24 Weeks, by Subgroup (mITT Population)
Study: Pooled
Subgroup: MBL Volume at Baseline (mL)



Results are based on a mixed-effects model with study, treatment, visit, subgroup, treatment-by-visit interaction, and a subgroup-by-treatment interaction as fixed effects using a one-stage IPD meta-analysis approach. The multiple visits for each patient are the repeated measures as a random effect within each patient with an unstructured covariance.
The interaction p-value is based on the subgroup-by-treatment interaction term in the mixed-effects model used to compute the LS means, mean differences and 95% CIs. Missing subgroup levels are not included in estimation of the interaction p-value. The reference group is Placebo.
n: Number of patients with data; NETA: Norethindrone acetate; mITT: Modified intent-to-treat; LS: Least squares; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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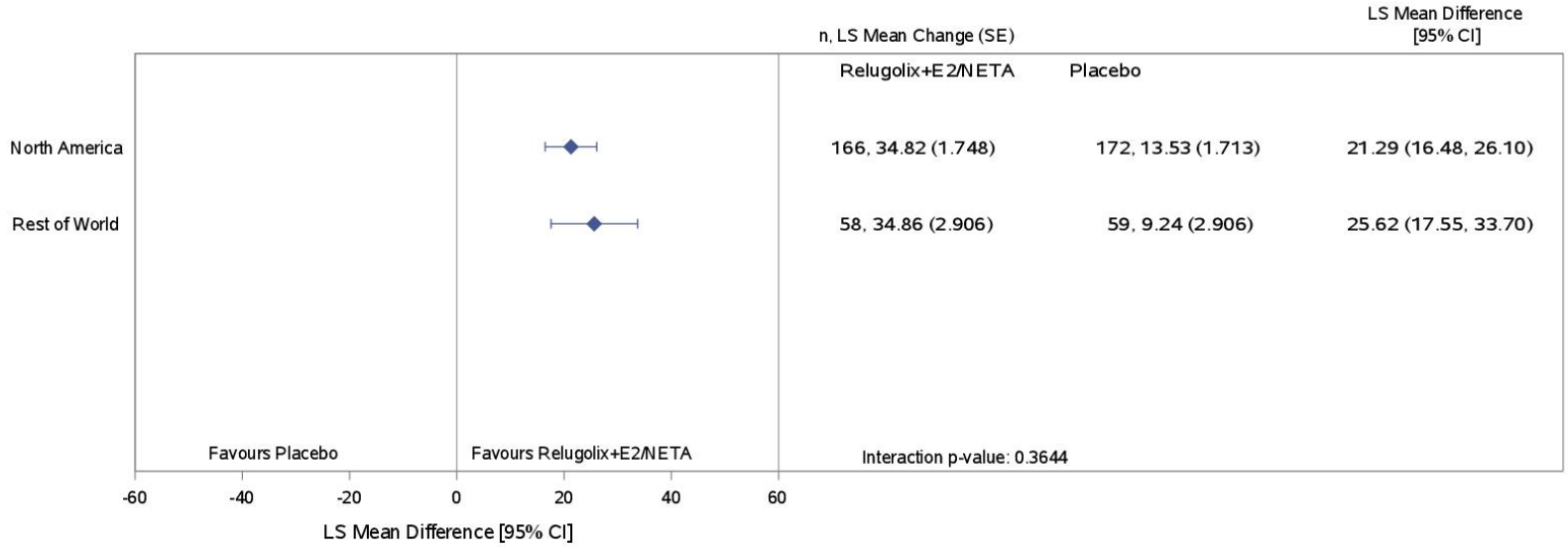
Figure QOL.HRQLTOT.MITT.S6.CON.FP: Summary of Average Change from Baseline in UFS-QoL Total Score Over 24 Weeks, by Subgroup (mITT Population)
Study: Pooled
Subgroup: Geographic Region I



Results are based on a mixed-effects model with study, treatment, visit, subgroup, treatment-by-visit interaction, and a subgroup-by-treatment interaction as fixed effects using a one-stage IPD meta-analysis approach. The multiple visits for each patient are the repeated measures as a random effect within each patient with an unstructured covariance.
The interaction p-value is based on the subgroup-by-treatment interaction term in the mixed-effects model used to compute the LS means, mean differences and 95% CIs. Missing subgroup levels are not included in estimation of the interaction p-value. The reference group is Placebo.
n: Number of patients with data; NETA: Norethindrone acetate; mITT: Modified intent-to-treat; LS: Least squares; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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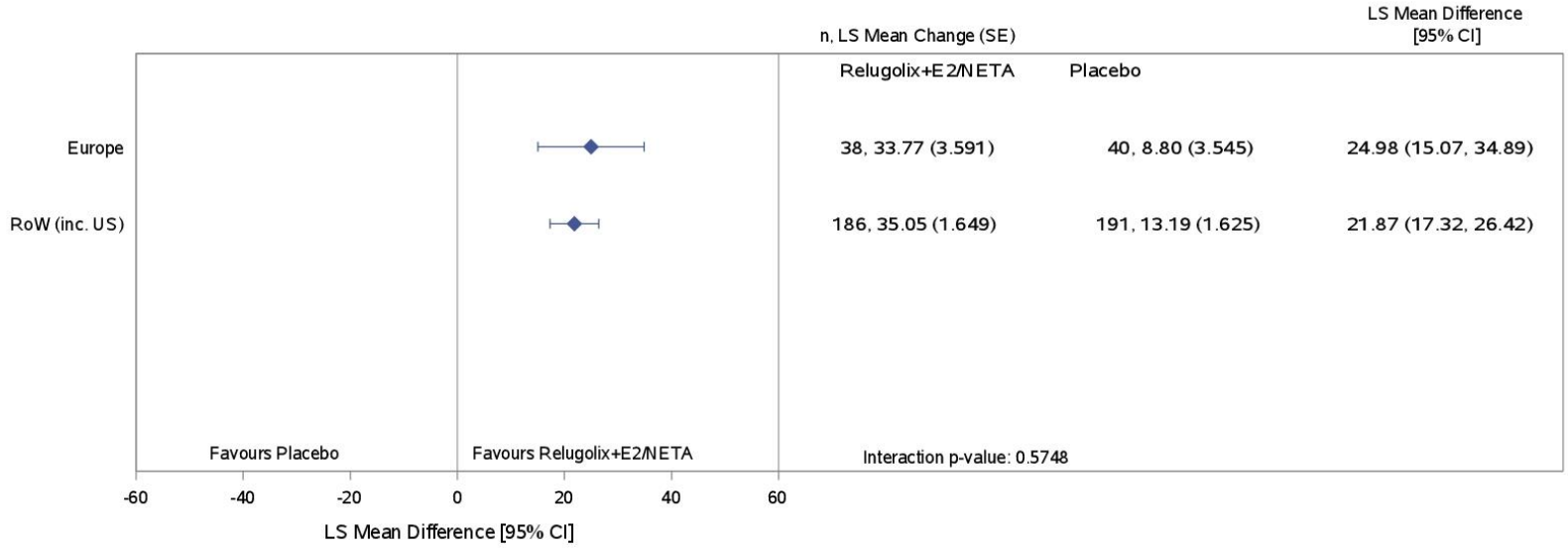
Figure QOL.HRQLTOT.MITT.S7.CON.FP: Summary of Average Change from Baseline in UFS-QoL Total Score Over 24 Weeks, by Subgroup (mITT Population)
Study: Pooled
Subgroup: Geographic Region II



Results are based on a mixed-effects model with study, treatment, visit, subgroup, treatment-by-visit interaction, and a subgroup-by-treatment interaction as fixed effects using a one-stage IPD meta-analysis approach. The multiple visits for each patient are the repeated measures as a random effect within each patient with an unstructured covariance.
The interaction p-value is based on the subgroup-by-treatment interaction term in the mixed-effects model used to compute the LS means, mean differences and 95% CIs. Missing subgroup levels are not included in estimation of the interaction p-value. The reference group is Placebo.
n: Number of patients with data; NETA: Norethindrone acetate; mITT: Modified intent-to-treat; LS: Least squares; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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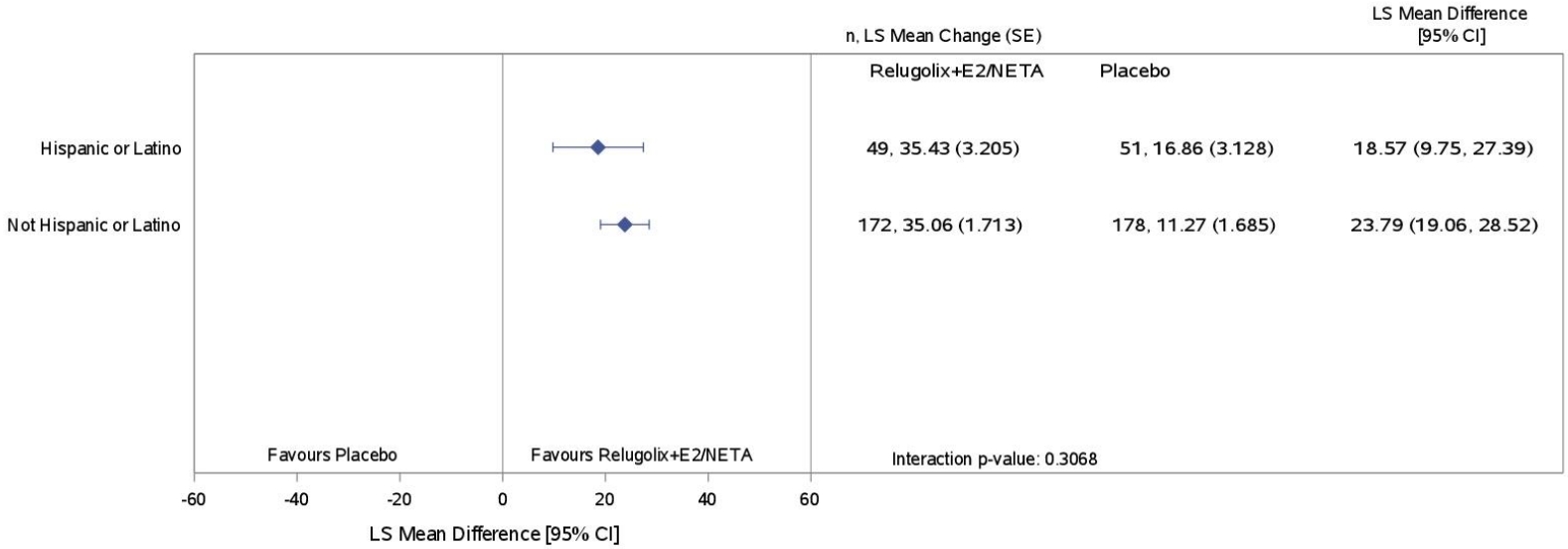
Figure QOL.HRQLTOT.MITT.S8.CON.FP: Summary of Average Change from Baseline in UFS-QoL Total Score Over 24 Weeks, by Subgroup (mITT Population)
Study: Pooled
Subgroup: Ethnicity



Results are based on a mixed-effects model with study, treatment, visit, subgroup, treatment-by-visit interaction, and a subgroup-by-treatment interaction as fixed effects using a one-stage IPD meta-analysis approach. The multiple visits for each patient are the repeated measures as a random effect within each patient with an unstructured covariance.
The interaction p-value is based on the subgroup-by-treatment interaction term in the mixed-effects model used to compute the LS means, mean differences and 95% CIs. Missing subgroup levels are not included in estimation of the interaction p-value. The reference group is Placebo.
n: Number of patients with data; NETA: Norethindrone acetate; mITT: Modified intent-to-treat; LS: Least squares; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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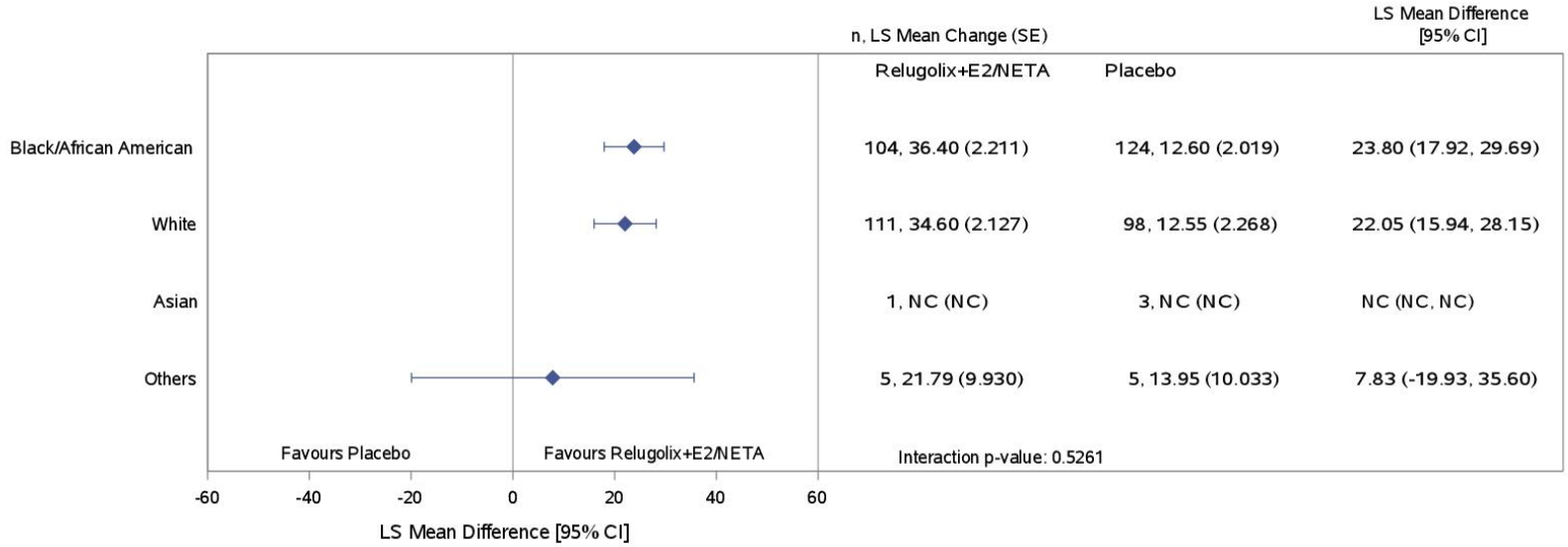
Figure QOL.HRQLTOT.MITT.S9.CON.FP: Summary of Average Change from Baseline in UFS-QoL Total Score Over 24 Weeks, by Subgroup (mITT Population)
Study: Pooled
Subgroup: Race



Results are based on a mixed-effects model with study, treatment, visit, subgroup, treatment-by-visit interaction, and a subgroup-by-treatment interaction as fixed effects using a one-stage IPD meta-analysis approach. The multiple visits for each patient are the repeated measures as a random effect within each patient with an unstructured covariance.
The interaction p-value is based on the subgroup-by-treatment interaction term in the mixed-effects model used to compute the LS means, mean differences and 95% CIs. Missing subgroup levels are not included in estimation of the interaction p-value. The reference group is Placebo.
n: Number of patients with data; NETA: Norethindrone acetate; mITT: Modified intent-to-treat; LS: Least squares; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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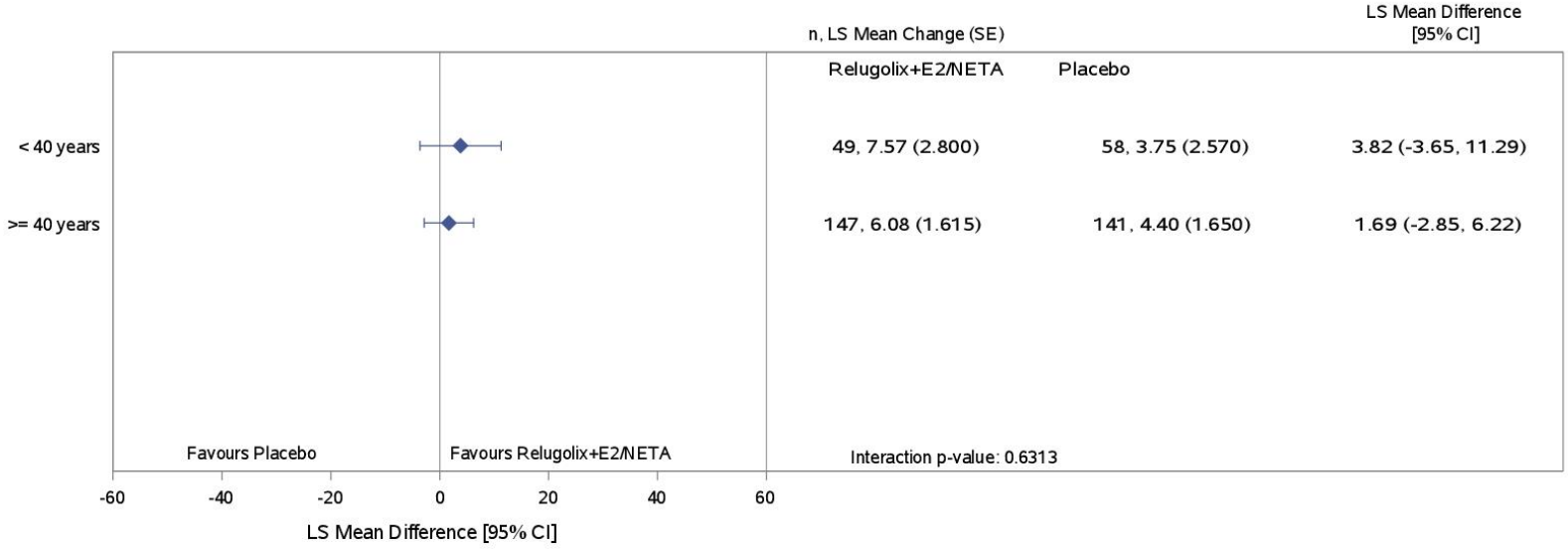
2.2.17 Summary of Mean Change from Baseline in European Quality of Life Five Dimension Five Level Scale (VAS Score) to Week 24, by Subgroup (mITT Population)

Figure QOL.EQVAS.MITT.S1.CON.FP: Summary of Mean Change from Baseline in European Quality of Life Five Dimension Five Level Scale (VAS Score) to Week 24, by Subgroup (mITT Population)
Study: Pooled
Subgroup: Age (years)



Results are based on an Analysis of Variance (ANOVA) model with study, treatment, subgroup, and a subgroup-by-treatment interaction as fixed effects using a one-stage IPD meta-analysis approach.
Interaction p-value is based on the subgroup-by-treatment interaction term in the ANOVA model used to compute the LS means, mean differences and 95% CIs. Missing subgroup levels are not included in estimation of the interaction p-value. The reference group is Placebo.
n: Number of patients with data; NETA: Norethindrone acetate; mITT: Modified intent-to-treat; LS: Least squares; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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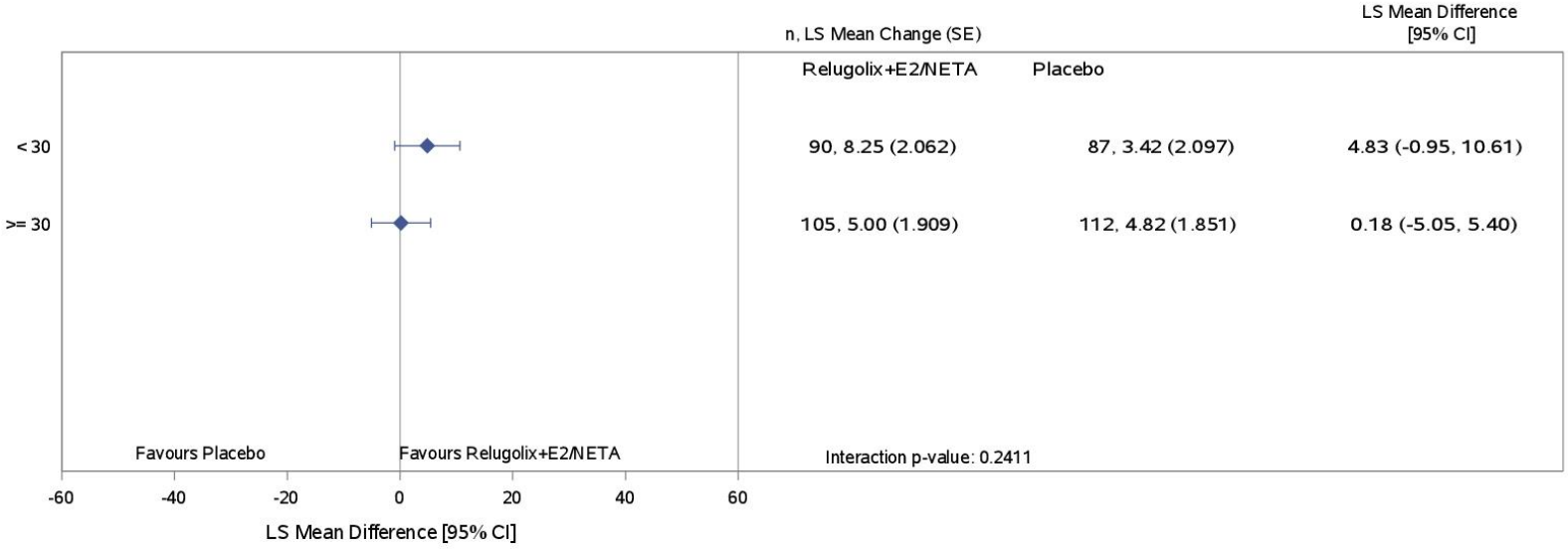
Figure QOL.EQVAS.MITT.S2.CON.FP: Summary of Mean Change from Baseline in European Quality of Life Five Dimension Five Level Scale (VAS Score) to Week 24, by Subgroup (mITT Population)
Study: Pooled
Subgroup: BMI (kg/m2) at Baseline



Results are based on an Analysis of Variance (ANOVA) model with study, treatment, subgroup, and a subgroup-by-treatment interaction as fixed effects using a one-stage IPD meta-analysis approach.
Interaction p-value is based on the subgroup-by-treatment interaction term in the ANOVA model used to compute the LS means, mean differences and 95% CIs. Missing subgroup levels are not included in estimation of the interaction p-value. The reference group is Placebo.
n: Number of patients with data; NETA: Norethindrone acetate; mITT: Modified intent-to-treat; LS: Least squares; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

SOURCE: X:\Numerus\Studies\MYV\MYV102\Analysis\Prod\Progs\TFLs\FIG_QOL_QS_S_CON_FP.SAS Date/time of run: 30JUN21 10:30
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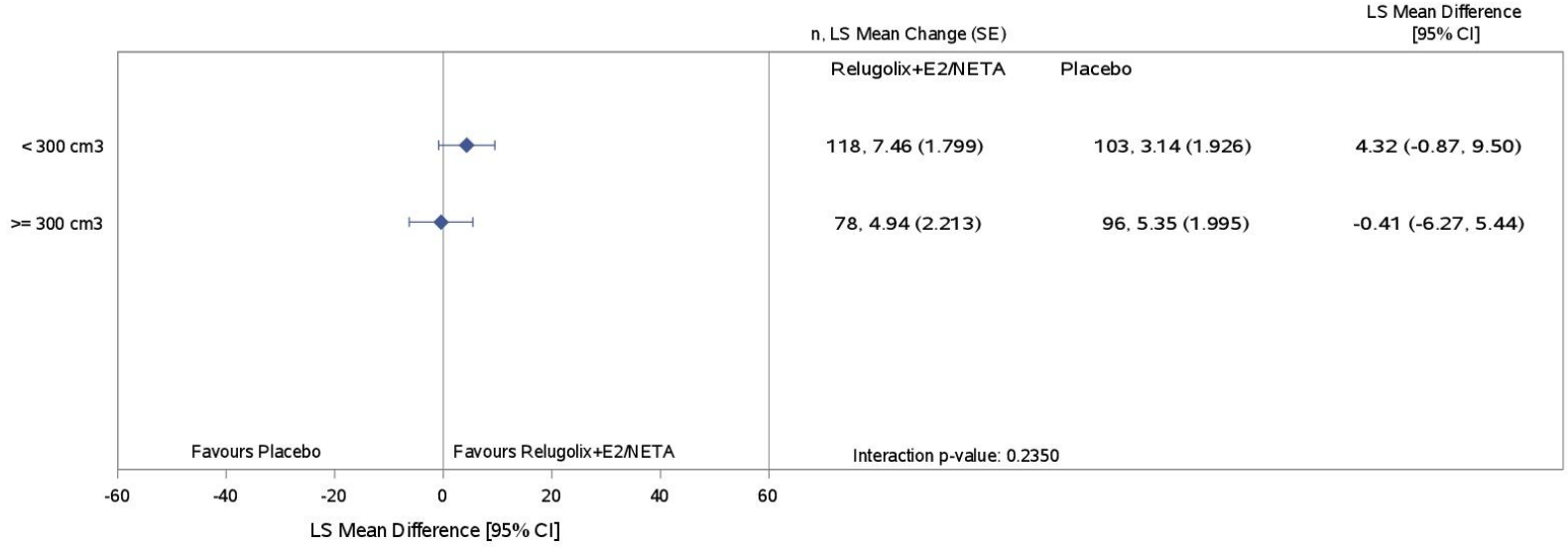
Figure QOL.EQVAS.MITT.S3.CON.FP: Summary of Mean Change from Baseline in European Quality of Life Five Dimension Five Level Scale (VAS Score) to Week 24, by Subgroup (mITT Population)
Study: Pooled
Subgroup: Uterine Volume at Baseline (cm3)



Results are based on an Analysis of Variance (ANOVA) model with study, treatment, subgroup, and a subgroup-by-treatment interaction as fixed effects using a one-stage IPD meta-analysis approach.
Interaction p-value is based on the subgroup-by-treatment interaction term in the ANOVA model used to compute the LS means, mean differences and 95% CIs. Missing subgroup levels are not included in estimation of the interaction p-value. The reference group is Placebo.
n: Number of patients with data; NETA: Norethindrone acetate; mITT: Modified intent-to-treat; LS: Least squares; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

SOURCE: X:\Numerus\Studies\MYV\MYV102\Analysis\Prod\Progs\TFLs\FIG_QOL_QS_S_CON_FP.SAS Date/time of run: 30JUN21 10:30
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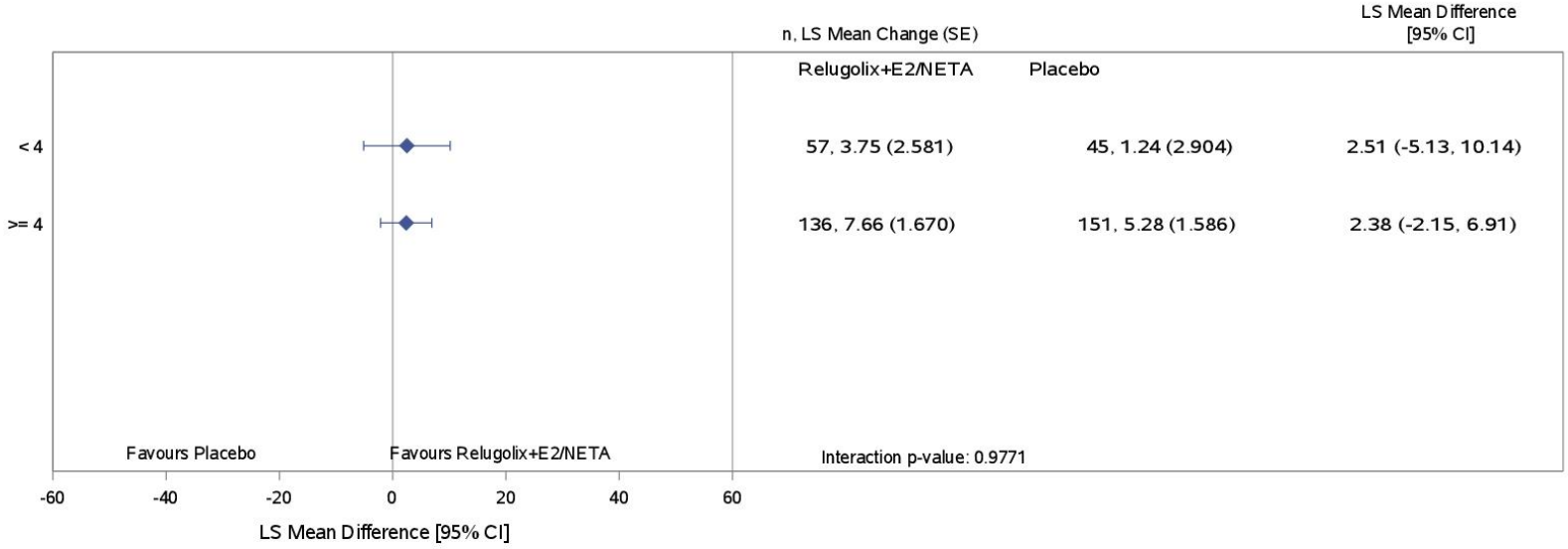
Figure QOL.EQVAS.MITT.S4.CON.FP: Summary of Mean Change from Baseline in European Quality of Life Five Dimension Five Level Scale (VAS Score) to Week 24, by Subgroup (mITT Population)
Study: Pooled
Subgroup: Maximum NRS Pain Score at Baseline



Results are based on an Analysis of Variance (ANOVA) model with study, treatment, subgroup, and a subgroup-by-treatment interaction as fixed effects using a one-stage IPD meta-analysis approach.
Interaction p-value is based on the subgroup-by-treatment interaction term in the ANOVA model used to compute the LS means, mean differences and 95% CIs. Missing subgroup levels are not included in estimation of the interaction p-value. The reference group is Placebo.
n: Number of patients with data; NETA: Norethindrone acetate; mITT: Modified intent-to-treat; LS: Least squares; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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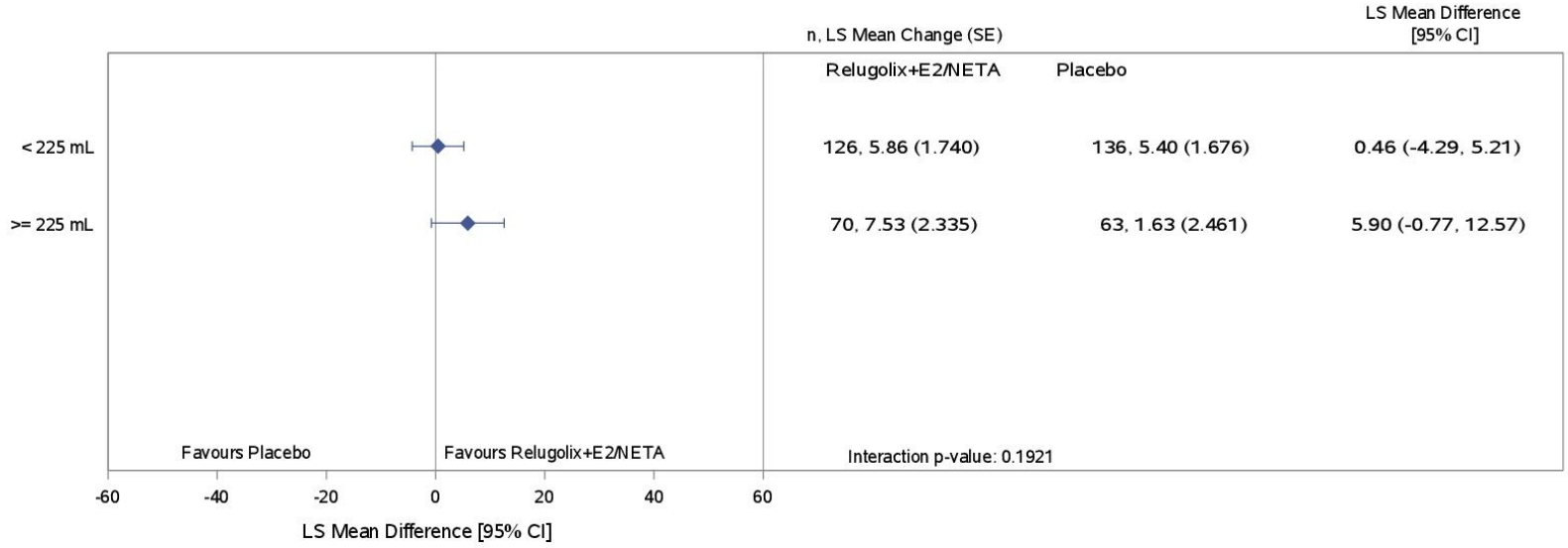
Figure QOL.EQVAS.MITT.S5.CON.FP: Summary of Mean Change from Baseline in European Quality of Life Five Dimension Five Level Scale (VAS Score) to Week 24, by Subgroup (mITT Population)
Study: Pooled
Subgroup: MBL Volume at Baseline (mL)



Results are based on an Analysis of Variance (ANOVA) model with study, treatment, subgroup, and a subgroup-by-treatment interaction as fixed effects using a one-stage IPD meta-analysis approach.
Interaction p-value is based on the subgroup-by-treatment interaction term in the ANOVA model used to compute the LS means, mean differences and 95% CIs. Missing subgroup levels are not included in estimation of the interaction p-value. The reference group is Placebo.
n: Number of patients with data; NETA: Norethindrone acetate; mITT: Modified intent-to-treat; LS: Least squares; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

SOURCE: X:\Numerus\Studies\MYV\MYV102\Analysis\Prod\Progs\TFLs\FIG_QOL_QS_S_CON_FP.SAS Date/time of run: 30JUN21 10:30
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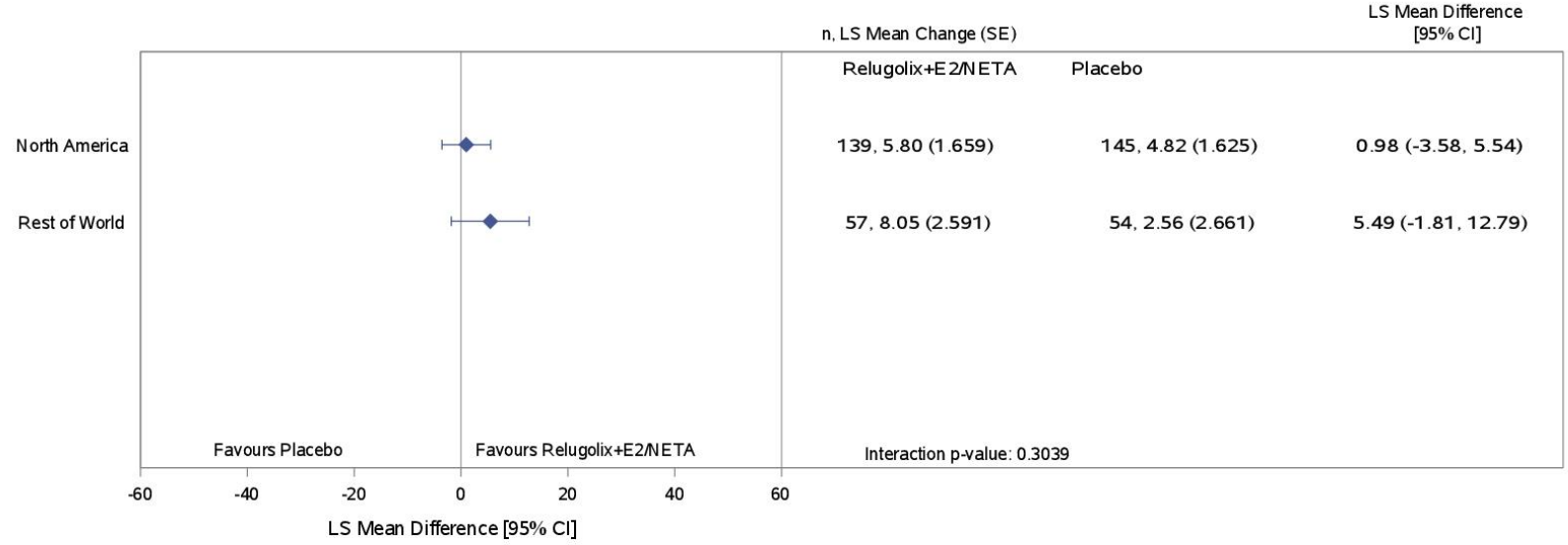
Figure QOL.EQVAS.MITT.S6.CON.FP: Summary of Mean Change from Baseline in European Quality of Life Five Dimension Five Level Scale (VAS Score) to Week 24, by Subgroup (mITT Population)
Study: Pooled
Subgroup: Geographic Region I



Results are based on an Analysis of Variance (ANOVA) model with study, treatment, subgroup, and a subgroup-by-treatment interaction as fixed effects using a one-stage IPD meta-analysis approach.
Interaction p-value is based on the subgroup-by-treatment interaction term in the ANOVA model used to compute the LS means, mean differences and 95% CIs. Missing subgroup levels are not included in estimation of the interaction p-value. The reference group is Placebo.
n: Number of patients with data; NETA: Norethindrone acetate; mITT: Modified intent-to-treat; LS: Least squares; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

SOURCE: X:\Numerus\Studies\MYV\MYV102\Analysis\Prod\Progs\TFLs\FIG_QOL_QS_S_CON_FP.SAS Date/time of run: 30JUN21 10:30
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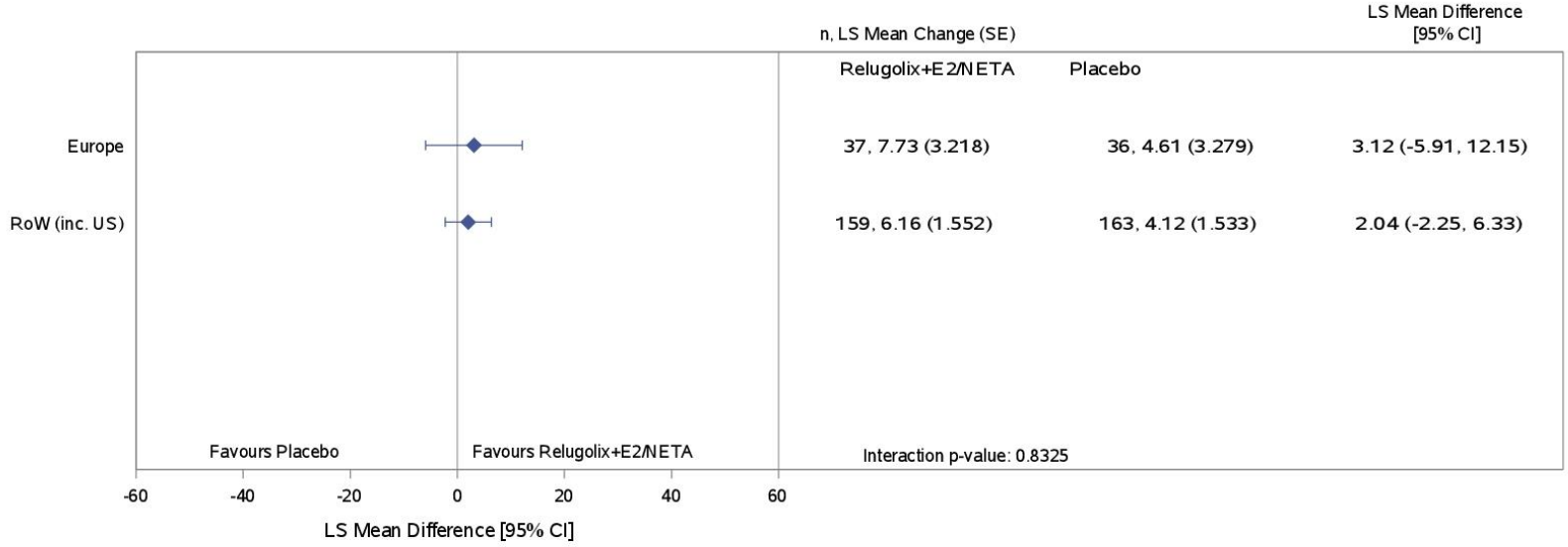
Figure QOL.EQVAS.MITT.S7.CON.FP: Summary of Mean Change from Baseline in European Quality of Life Five Dimension Five Level Scale (VAS Score) to Week 24, by Subgroup (mITT Population)
Study: Pooled
Subgroup: Geographic Region II



Results are based on an Analysis of Variance (ANOVA) model with study, treatment, subgroup, and a subgroup-by-treatment interaction as fixed effects using a one-stage IPD meta-analysis approach.
Interaction p-value is based on the subgroup-by-treatment interaction term in the ANOVA model used to compute the LS means, mean differences and 95% CIs. Missing subgroup levels are not included in estimation of the interaction p-value. The reference group is Placebo.
n: Number of patients with data; NETA: Norethindrone acetate; mITT: Modified intent-to-treat; LS: Least squares; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

SOURCE: X:\Numerus\Studies\MYV\MYV102\Analysis\Prod\Progs\TFLs\FIG_QOL_QS_S_CON_FP.SAS Date/time of run: 30JUN21 10:30
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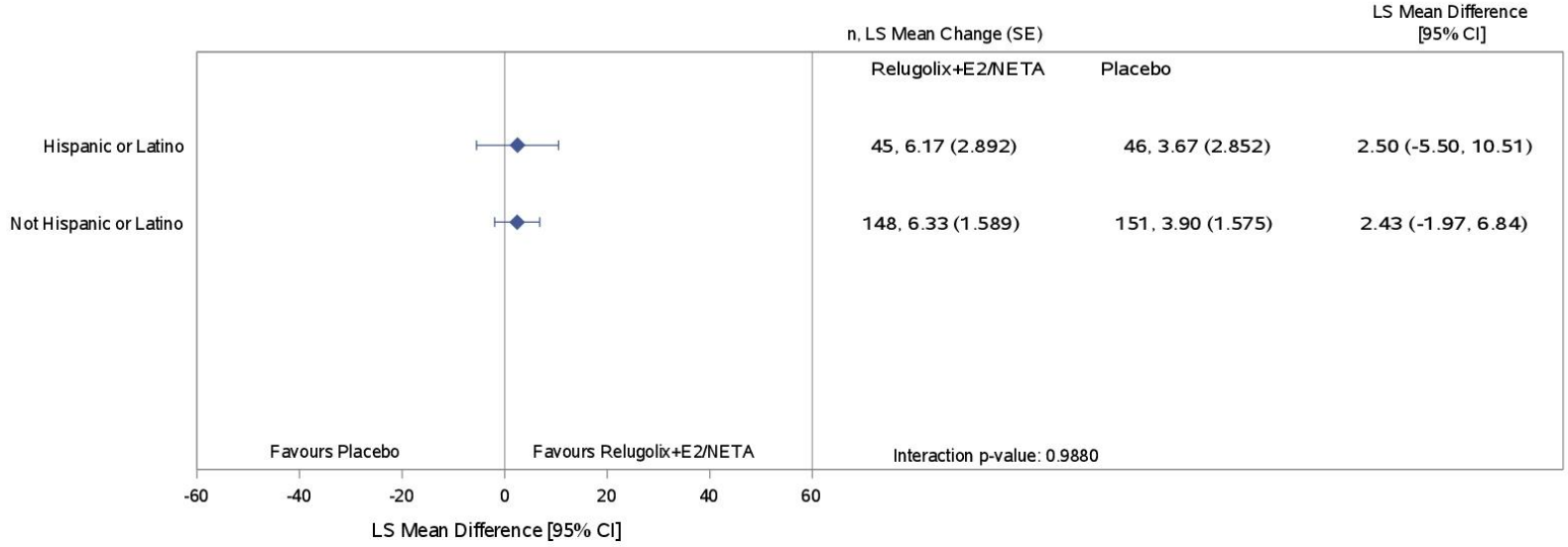
Figure QOL.EQVAS.MITT.S8.CON.FP: Summary of Mean Change from Baseline in European Quality of Life Five Dimension Five Level Scale (VAS Score) to Week 24, by Subgroup (mITT Population)
Study: Pooled
Subgroup: Ethnicity



Results are based on an Analysis of Variance (ANOVA) model with study, treatment, subgroup, and a subgroup-by-treatment interaction as fixed effects using a one-stage IPD meta-analysis approach.
Interaction p-value is based on the subgroup-by-treatment interaction term in the ANOVA model used to compute the LS means, mean differences and 95% CIs. Missing subgroup levels are not included in estimation of the interaction p-value. The reference group is Placebo.
n: Number of patients with data; NETA: Norethindrone acetate; mITT: Modified intent-to-treat; LS: Least squares; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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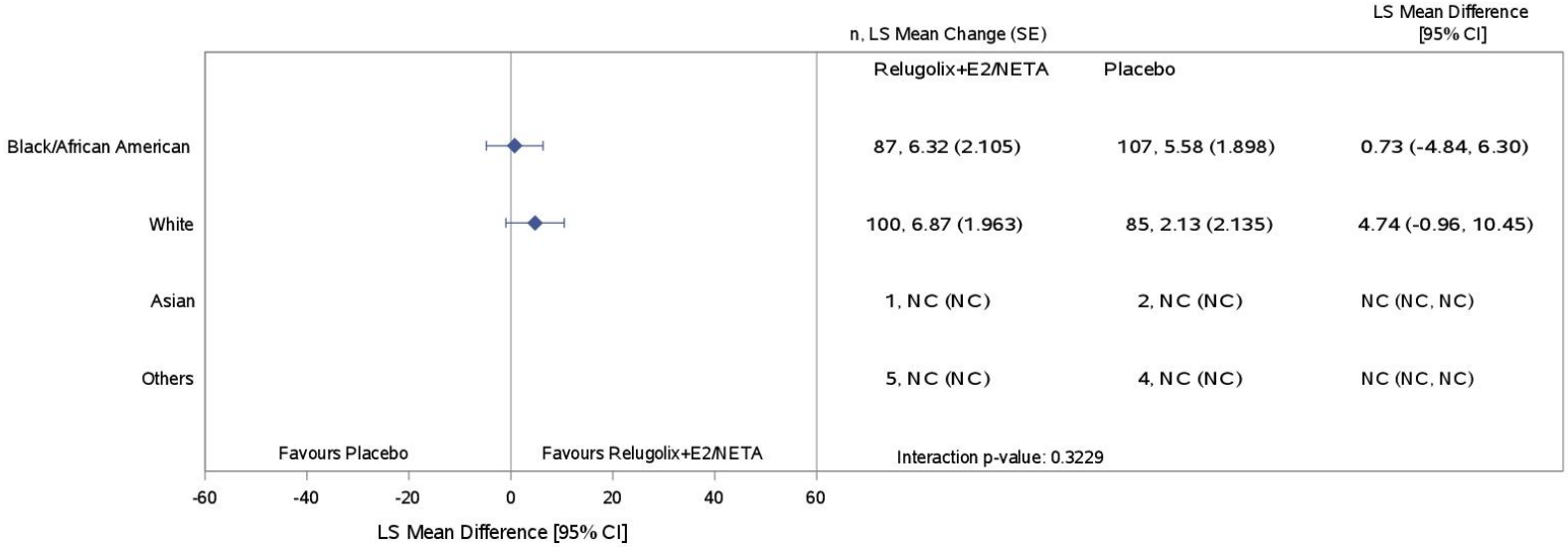
Figure QOL.EQVAS.MITT.S9.CON.FP: Summary of Mean Change from Baseline in European Quality of Life Five Dimension Five Level Scale (VAS Score) to Week 24, by Subgroup (mITT Population)
Study: Pooled
Subgroup: Race



Results are based on an Analysis of Variance (ANOVA) model with study, treatment, subgroup, and a subgroup-by-treatment interaction as fixed effects using a one-stage IPD meta-analysis approach.
Interaction p-value is based on the subgroup-by-treatment interaction term in the ANOVA model used to compute the LS means, mean differences and 95% CIs. Missing subgroup levels are not included in estimation of the interaction p-value. The reference group is Placebo.
n: Number of patients with data; NETA: Norethindrone acetate; mITT: Modified intent-to-treat; LS: Least squares; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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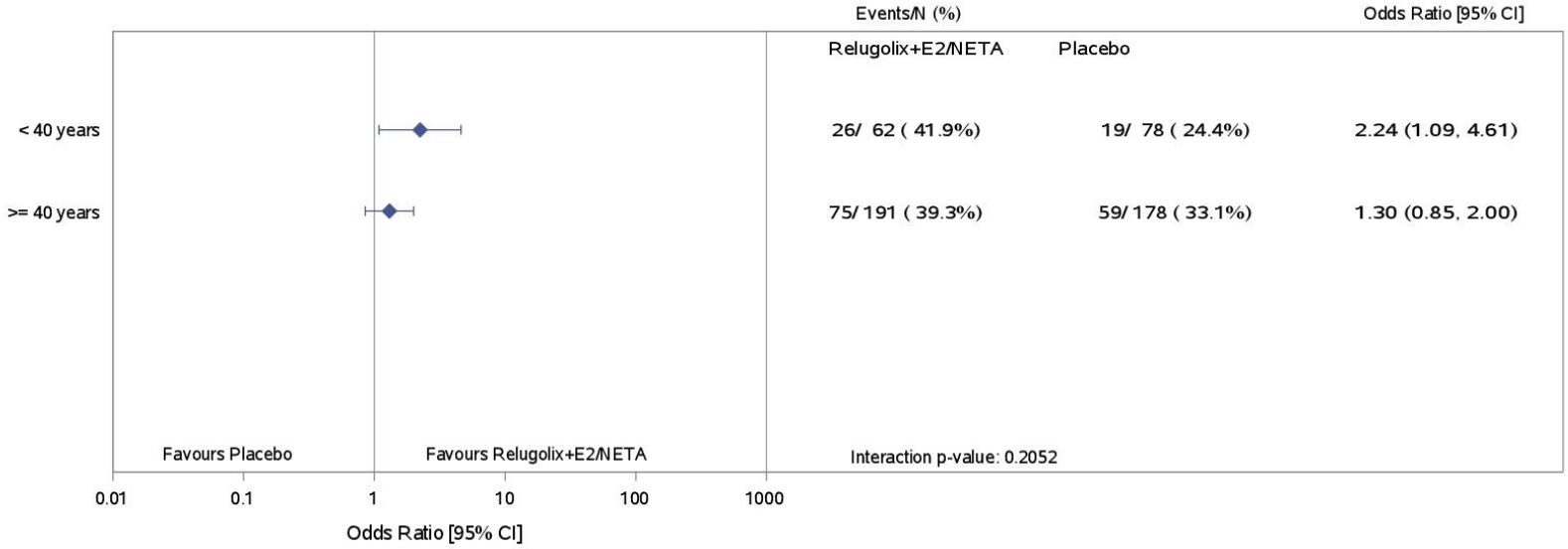
2.2.18 Proportion of Responders with at Least 7 Points Increase in EQ-5D-5L VAS scale at Week 24, by Subgroup (mITT Population)

Nachfolgend sind zunächst alle Forest Plots für das *Odds Ratio* dargestellt; gefolgt von den entsprechenden Forest Plots für *Risk Ratio* und *Risk Difference*.

Figure QOL.EQVAS7.MITT.S1.BIN.FP: Proportion of Responders with at Least 7 Points Increase in EQ-5D-5L VAS scale at Week 24, by Subgroup (mITT Population)
Study: Pooled
Subgroup: Age (years)



Results are based on a logistic regression model adjusted for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates using a one-stage fixed-effects IPD meta-analysis approach. A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
The interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the Odds Ratio and 95% CI. Missing subgroup levels are not included in estimation of the interaction p-value. The reference group is Placebo.
N: Number of patients in treatment group; NETA: Norethindrone acetate; mITT: Modified intent-to-treat; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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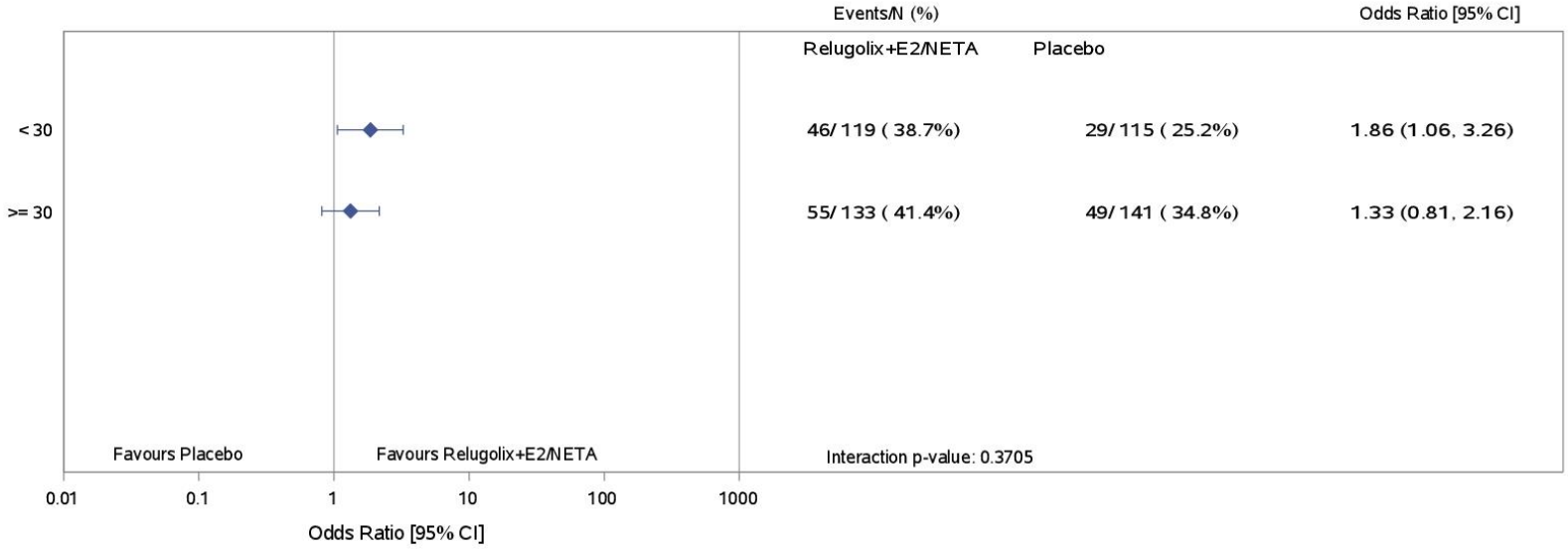
Figure QOL.EQVAS7.MITT.S2.BIN.FP: Proportion of Responders with at Least 7 Points Increase in EQ-5D-5L VAS scale at Week 24, by Subgroup (mITT Population)
Study: Pooled
Subgroup: BMI (kg/m2) at Baseline



Results are based on a logistic regression model adjusted for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates using a one-stage fixed-effects IPD meta-analysis approach. A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
The interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the Odds Ratio and 95% CI. Missing subgroup levels are not included in estimation of the interaction p-value. The reference group is Placebo.
N: Number of patients in treatment group; NETA: Norethindrone acetate; mITT: Modified intent-to-treat; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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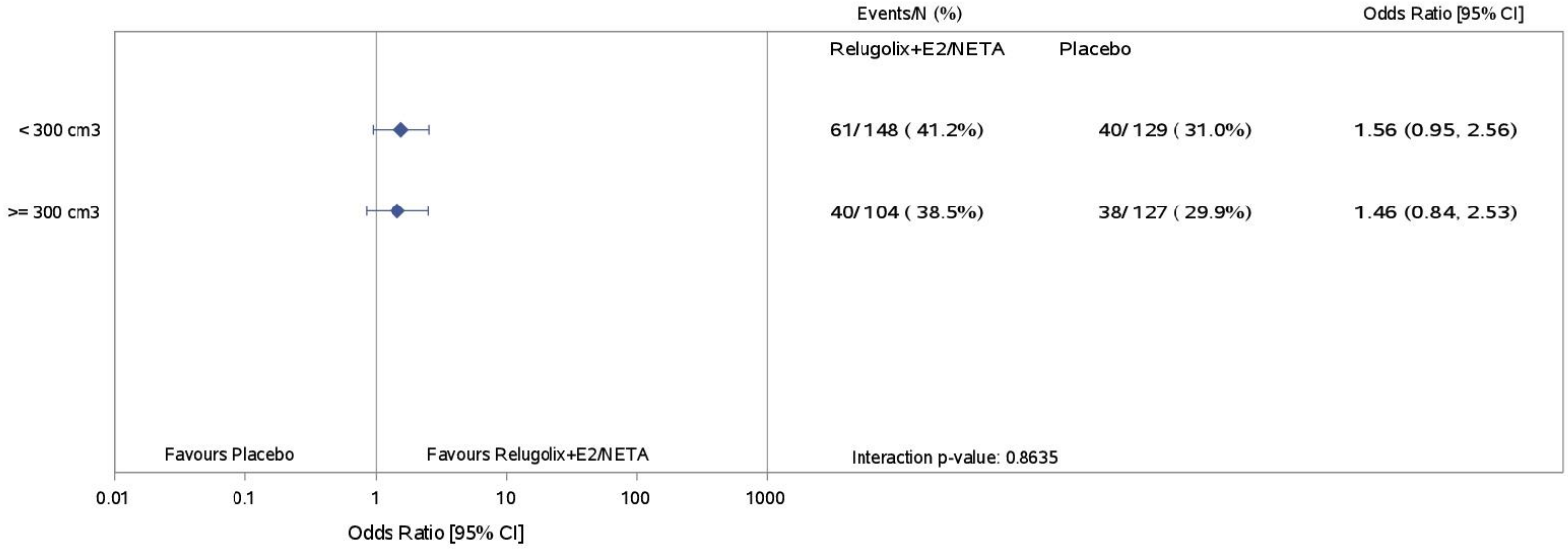
Figure QOL.EQVAS7.MITT.S3.BIN.FP: Proportion of Responders with at Least 7 Points Increase in EQ-5D-5L VAS scale at Week 24, by Subgroup (mITT Population)
Study: Pooled
Subgroup: Uterine Volume at Baseline (cm3)



Results are based on a logistic regression model adjusted for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates using a one-stage fixed-effects IPD meta-analysis approach. A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
The interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the Odds Ratio and 95% CI. Missing subgroup levels are not included in estimation of the interaction p-value. The reference group is Placebo.
N: Number of patients in treatment group; NETA: Norethindrone acetate; mITT: Modified intent-to-treat; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

SOURCE: X:\Numerus\Studies\MYV\MYV102\Analysis\Prod\Progs\TFLs\Fig_QOL_QS_S_BIN_FP.SAS Date/time of run: 30JUN21 10:27
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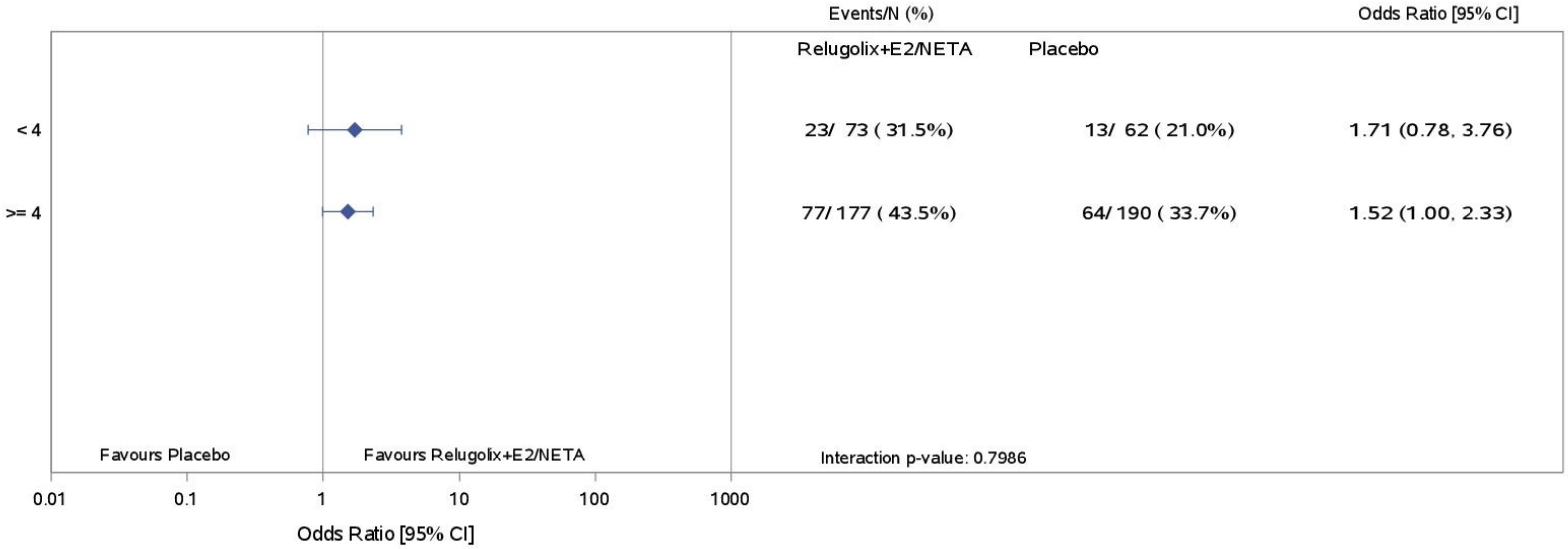
Figure QOL.EQVAS7.MITT.S4.BIN.FP: Proportion of Responders with at Least 7 Points Increase in EQ-5D-5L VAS scale at Week 24, by Subgroup (mITT Population)
Study: Pooled
Subgroup: Maximum NRS Pain Score at Baseline



Results are based on a logistic regression model adjusted for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates using a one-stage fixed-effects IPD meta-analysis approach. A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
The interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the Odds Ratio and 95% CI. Missing subgroup levels are not included in estimation of the interaction p-value. The reference group is Placebo.
N: Number of patients in treatment group; NETA: Norethindrone acetate; mITT: Modified intent-to-treat; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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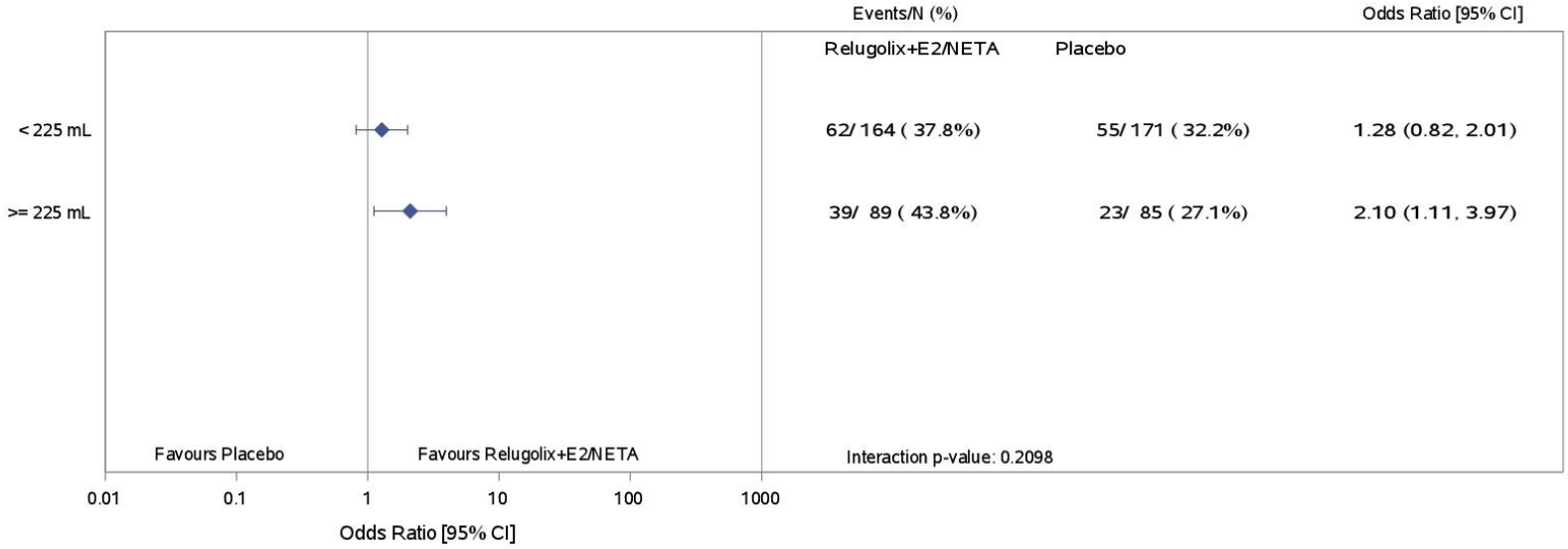
Figure QOL.EQVAS7.MITT.S5.BIN.FP: Proportion of Responders with at Least 7 Points Increase in EQ-5D-5L VAS scale at Week 24, by Subgroup (mITT Population)
Study: Pooled
Subgroup: MBL Volume at Baseline (mL)



Results are based on a logistic regression model adjusted for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates using a one-stage fixed-effects IPD meta-analysis approach. A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
The interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the Odds Ratio and 95% CI. Missing subgroup levels are not included in estimation of the interaction p-value. The reference group is Placebo.
N: Number of patients in treatment group; NETA: Norethindrone acetate; mITT: Modified intent-to-treat; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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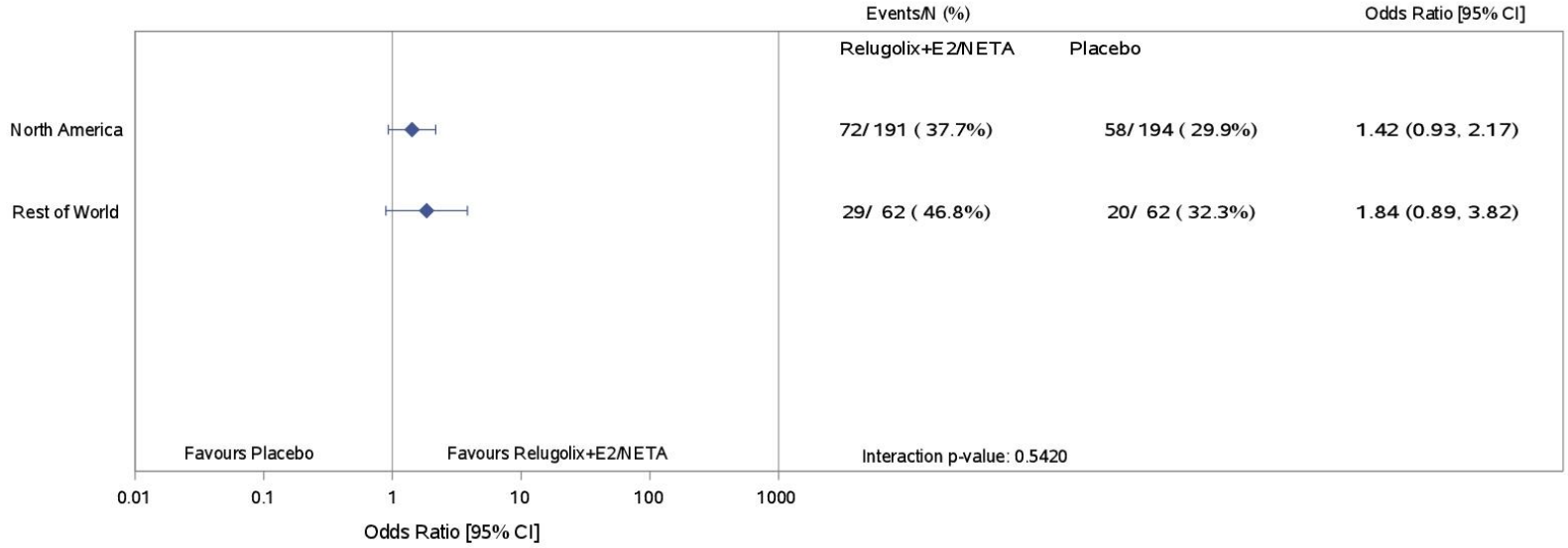
Figure QOL.EQVAS7.MITT.S6.BIN.FP: Proportion of Responders with at Least 7 Points Increase in EQ-5D-5L VAS scale at Week 24, by Subgroup (mITT Population)
Study: Pooled
Subgroup: Geographic Region I



Results are based on a logistic regression model adjusted for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates using a one-stage fixed-effects IPD meta-analysis approach. A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
The interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the Odds Ratio and 95% CI. Missing subgroup levels are not included in estimation of the interaction p-value. The reference group is Placebo.
N: Number of patients in treatment group; NETA: Norethindrone acetate; mITT: Modified intent-to-treat; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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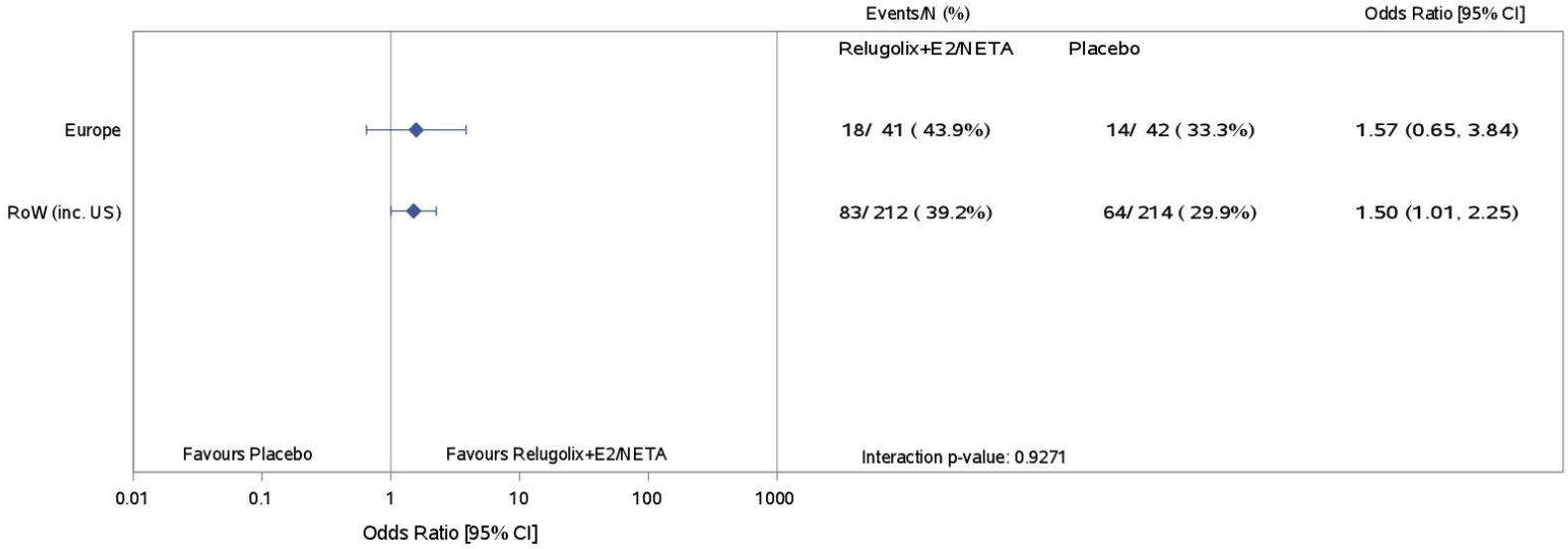
Figure QOL.EQVAS7.MITT.S7.BIN.FP: Proportion of Responders with at Least 7 Points Increase in EQ-5D-5L VAS scale at Week 24, by Subgroup (mITT Population)
Study: Pooled
Subgroup: Geographic Region II



Results are based on a logistic regression model adjusted for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates using a one-stage fixed-effects IPD meta-analysis approach. A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
The interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the Odds Ratio and 95% CI. Missing subgroup levels are not included in estimation of the interaction p-value. The reference group is Placebo.
N: Number of patients in treatment group; NETA: Norethindrone acetate; mITT: Modified intent-to-treat; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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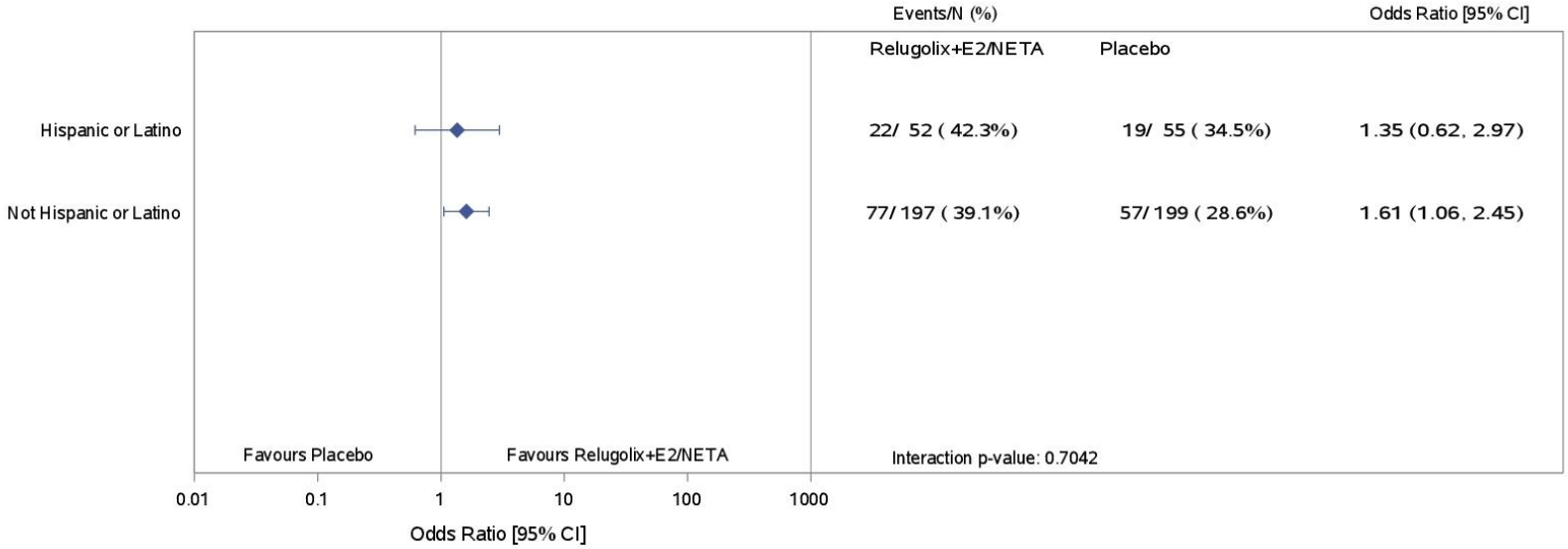
Figure QOL.EQVAS7.MITT.S8.BIN.FP: Proportion of Responders with at Least 7 Points Increase in EQ-5D-5L VAS scale at Week 24, by Subgroup (mITT Population)
Study: Pooled
Subgroup: Ethnicity



Results are based on a logistic regression model adjusted for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates using a one-stage fixed-effects IPD meta-analysis approach. A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
The interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the Odds Ratio and 95% CI. Missing subgroup levels are not included in estimation of the interaction p-value. The reference group is Placebo.
N: Number of patients in treatment group; NETA: Norethindrone acetate; mITT: Modified intent-to-treat; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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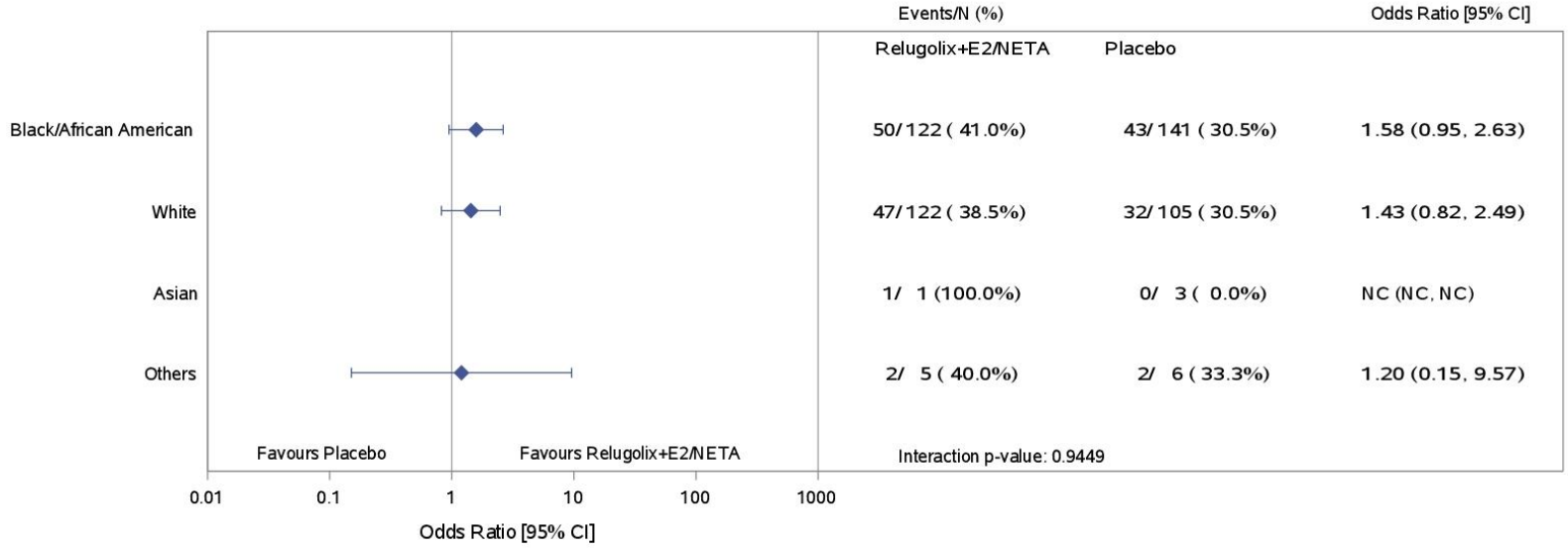
Figure QOL.EQVAS7.MITT.S9.BIN.FP: Proportion of Responders with at Least 7 Points Increase in EQ-5D-5L VAS scale at Week 24, by Subgroup (mITT Population)
Study: Pooled
Subgroup: Race



Results are based on a logistic regression model adjusted for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates using a one-stage fixed-effects IPD meta-analysis approach. A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
The interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the Odds Ratio and 95% CI. Missing subgroup levels are not included in estimation of the interaction p-value. The reference group is Placebo.
N: Number of patients in treatment group; NETA: Norethindrone acetate; mITT: Modified intent-to-treat; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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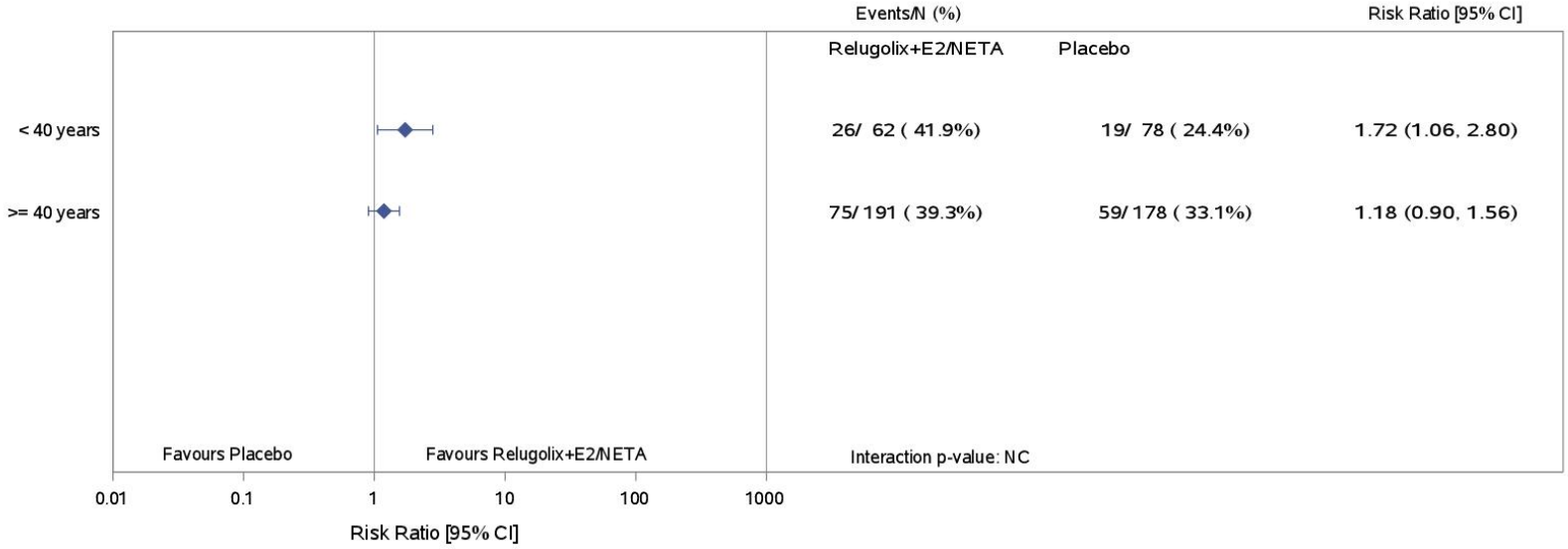
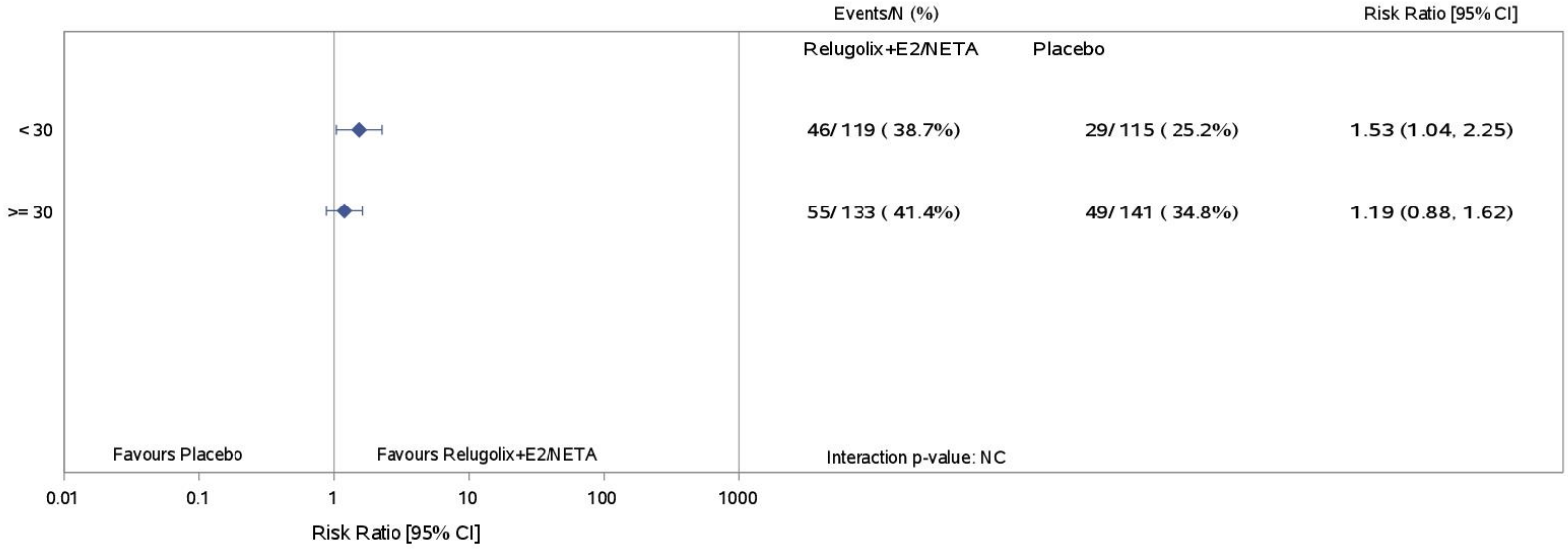
Figure QOL.EQVAS7.MITT.S1.BIN.FP.RR: Proportion of Responders with at Least 7 Points Increase in EQ-5D-5L VAS scale at Week 24, by Subgroup (mITT Population) - Risk Ratio
Study: Pooled
Subgroup: Age (years)



Results are based on a Cochran-Mantel-Haenszel approach stratified by study using a one-stage fixed-effects IPD meta-analysis. A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
The reference group is Placebo.
N: Number of patients in treatment group; NETA: Norethindrone acetate; mITT: Modified intent-to-treat; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

SOURCE: X:\Numerus\Studies\MYV\MYV102\Analysis\Prod\Progs\TFLs\Fig_QOL_QS_S_BIN_FP.SAS Date/time of run: 30JUN21 10:27
Analysis Plan: 13JAN2021 Confidential

Figure QOL.EQVAS7.MITT.S2.BIN.FP.RR: Proportion of Responders with at Least 7 Points Increase in EQ-5D-5L VAS scale at Week 24, by Subgroup (mITT Population) - Risk Ratio
Study: Pooled
Subgroup: BMI (kg/m2) at Baseline



Results are based on a Cochran-Mantel-Haenszel approach stratified by study using a one-stage fixed-effects IPD meta-analysis. A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
The reference group is Placebo.
N: Number of patients in treatment group; NETA: Norethindrone acetate; mITT: Modified intent-to-treat; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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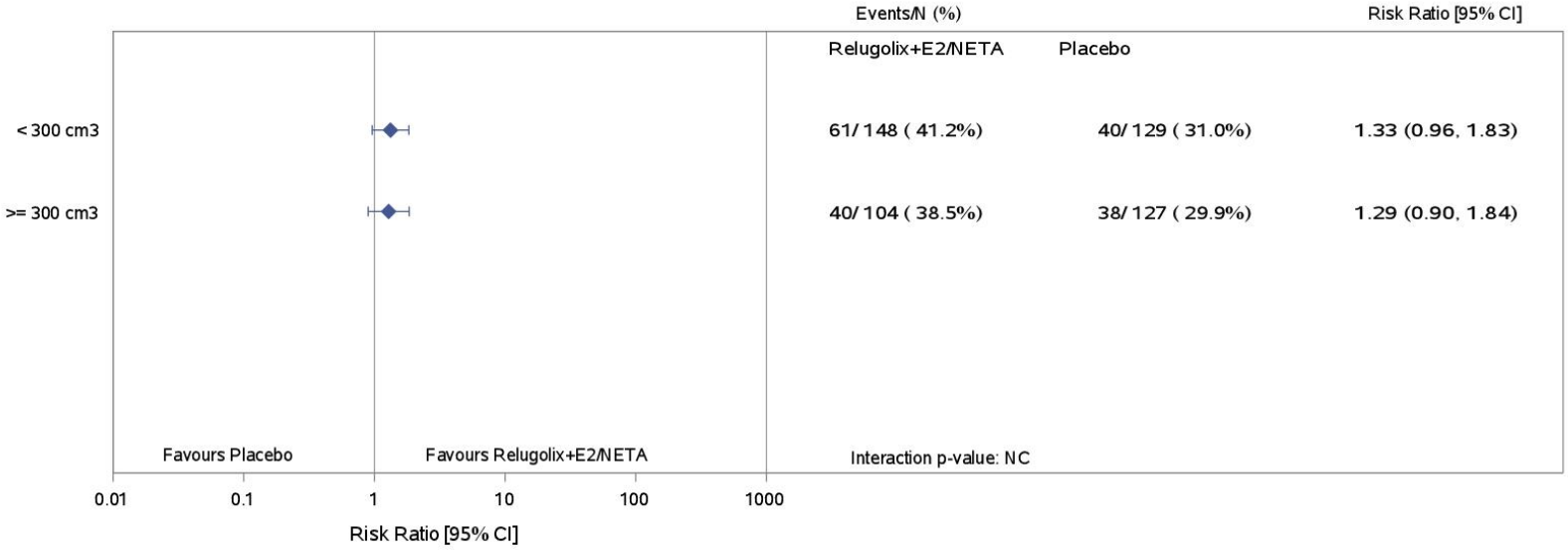
Figure QOL.EQVAS7.MITT.S3.BIN.FP.RR: Proportion of Responders with at Least 7 Points Increase in EQ-5D-5L VAS scale at Week 24, by Subgroup (mITT Population) - Risk Ratio
Study: Pooled
Subgroup: Uterine Volume at Baseline (cm3)



Results are based on a Cochran-Mantel-Haenszel approach stratified by study using a one-stage fixed-effects IPD meta-analysis. A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
The reference group is Placebo.
N: Number of patients in treatment group; NETA: Norethindrone acetate; mITT: Modified intent-to-treat; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

SOURCE: X:\Numerus\Studies\MYV\MYV102\Analysis\Prod\Progs\TFLs\Fig_QOL_QS_S_BIN_FP.SAS Date/time of run: 30JUN21 10:27
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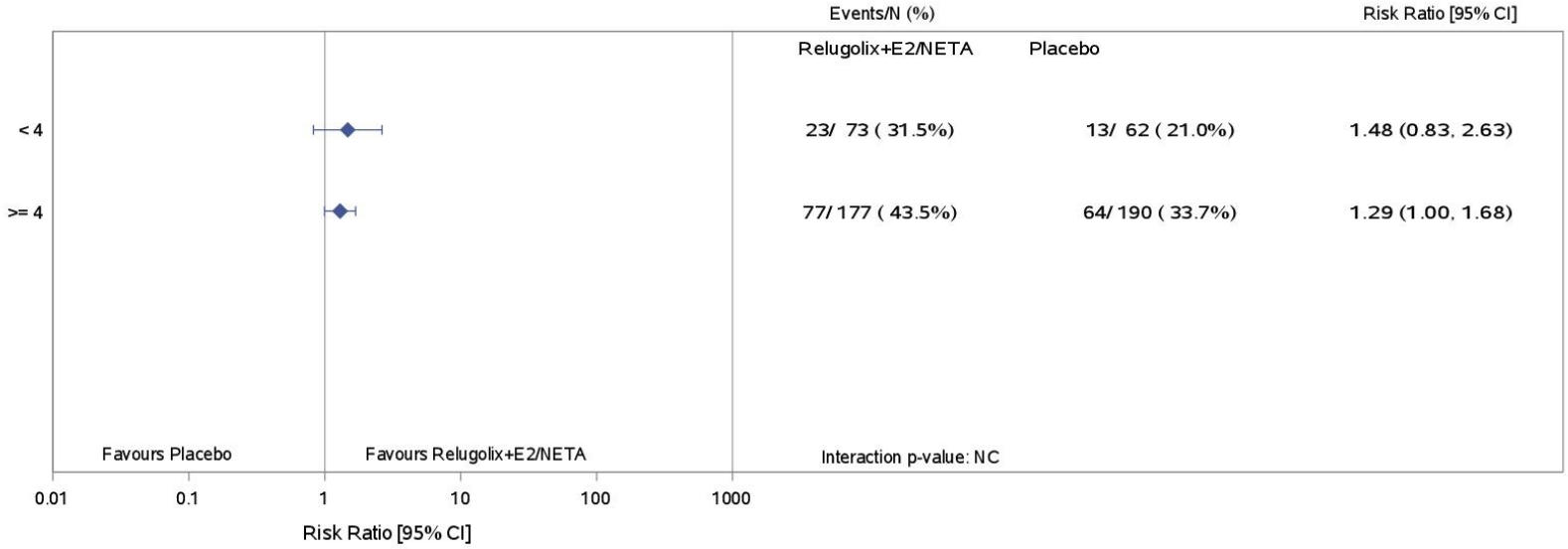
Figure QOL.EQVAS7.MITT.S4.BIN.FP.RR: Proportion of Responders with at Least 7 Points Increase in EQ-5D-5L VAS scale at Week 24, by Subgroup (mITT Population) - Risk Ratio
Study: Pooled
Subgroup: Maximum NRS Pain Score at Baseline



Results are based on a Cochran-Mantel-Haenszel approach stratified by study using a one-stage fixed-effects IPD meta-analysis. A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
The reference group is Placebo.
N: Number of patients in treatment group; NETA: Norethindrone acetate; mITT: Modified intent-to-treat; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

SOURCE: X:\Numerus\Studies\MYV\MYV102\Analysis\Prod\Progs\TFLs\Fig_QOL_QS_S_BIN_FP.SAS Date/time of run: 30JUN21 10:27
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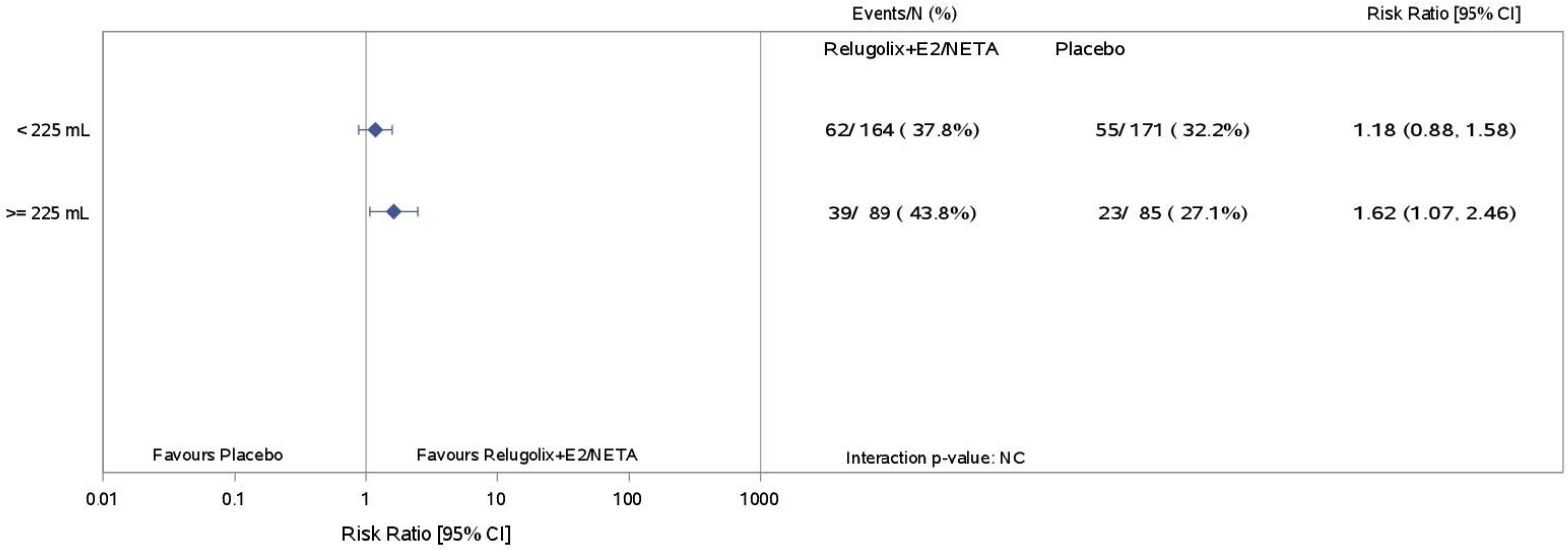
Figure QOL.EQVAS7.MITT.S5.BIN.FP.RR: Proportion of Responders with at Least 7 Points Increase in EQ-5D-5L VAS scale at Week 24, by Subgroup (mITT Population) - Risk Ratio
Study: Pooled
Subgroup: MBL Volume at Baseline (mL)



Results are based on a Cochran-Mantel-Haenszel approach stratified by study using a one-stage fixed-effects IPD meta-analysis. A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
The reference group is Placebo.
N: Number of patients in treatment group; NETA: Norethindrone acetate; mITT: Modified intent-to-treat; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

SOURCE: X:\Numerus\Studies\MYV\MYV102\Analysis\Prod\Progs\TFLs\Fig_QOL_QS_S_BIN_FP.SAS Date/time of run: 30JUN21 10:27
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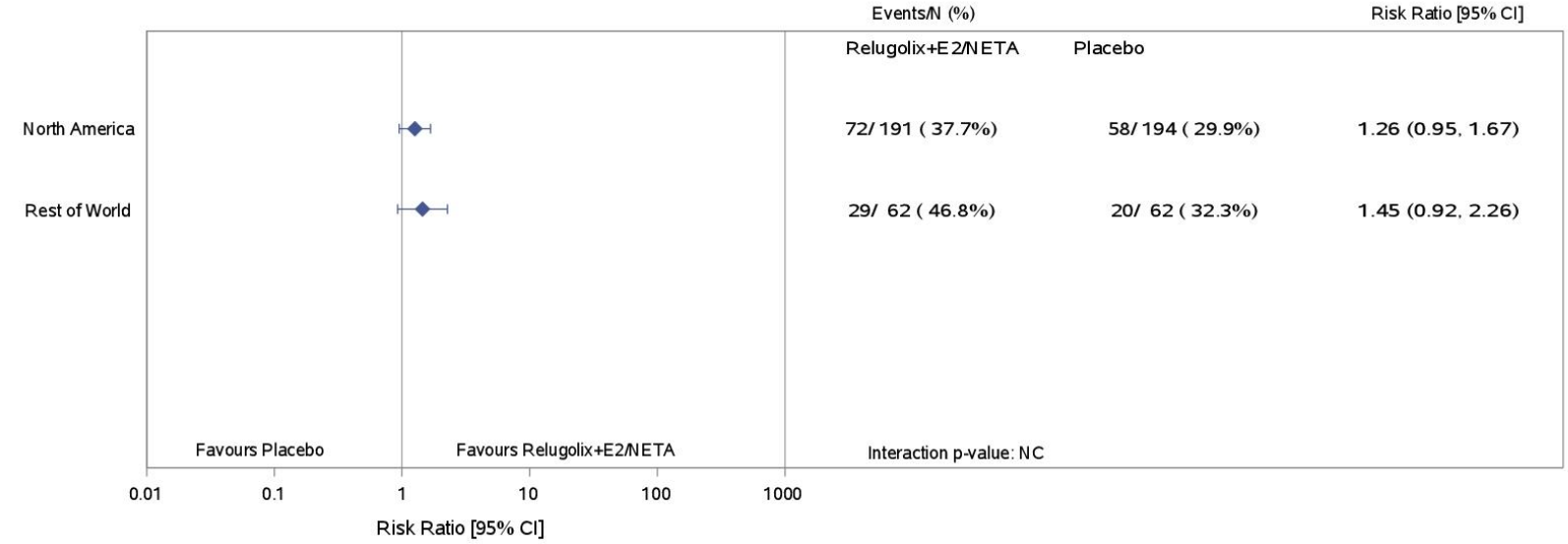
Figure QOL.EQVAS7.MITT.S6.BIN.FP.RR: Proportion of Responders with at Least 7 Points Increase in EQ-5D-5L VAS scale at Week 24, by Subgroup (mITT Population) - Risk Ratio
Study: Pooled
Subgroup: Geographic Region I



Results are based on a Cochran-Mantel-Haenszel approach stratified by study using a one-stage fixed-effects IPD meta-analysis. A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
The reference group is Placebo.
N: Number of patients in treatment group; NETA: Norethindrone acetate; mITT: Modified intent-to-treat; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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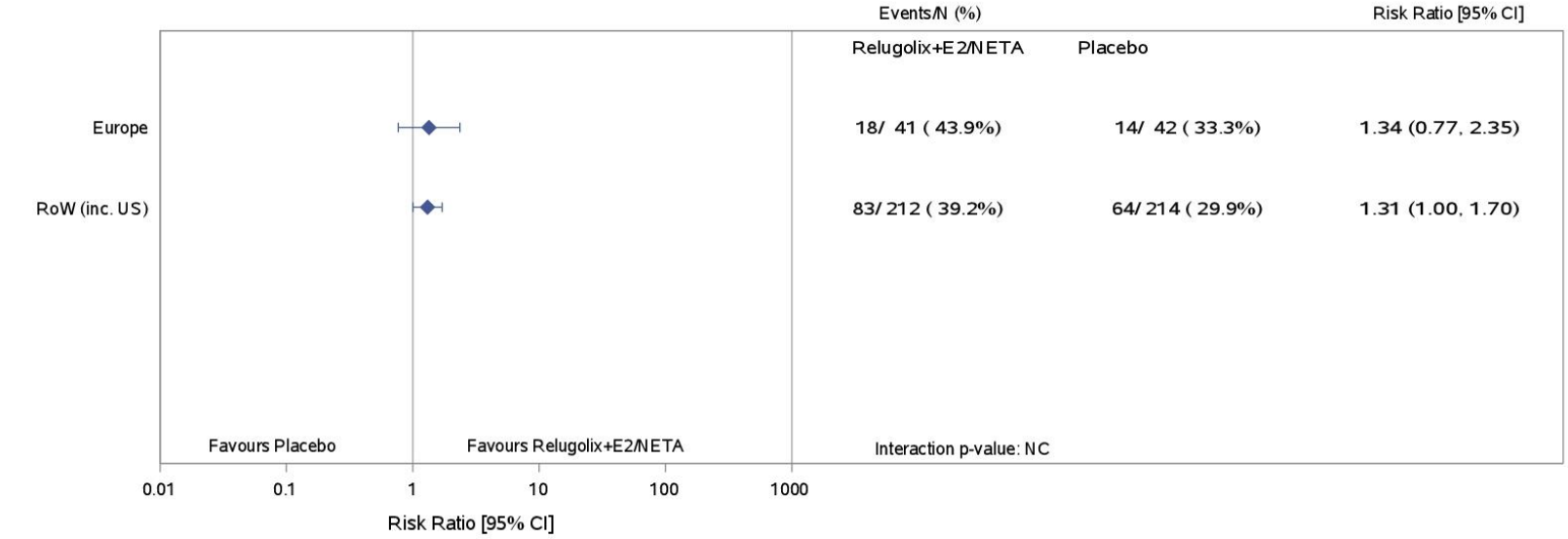
Figure QOL.EQVAS7.MITT.S7.BIN.FP.RR: Proportion of Responders with at Least 7 Points Increase in EQ-5D-5L VAS scale at Week 24, by Subgroup (mITT Population) - Risk Ratio
Study: Pooled
Subgroup: Geographic Region II



Results are based on a Cochran-Mantel-Haenszel approach stratified by study using a one-stage fixed-effects IPD meta-analysis. A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
The reference group is Placebo.
N: Number of patients in treatment group; NETA: Norethindrone acetate; mITT: Modified intent-to-treat; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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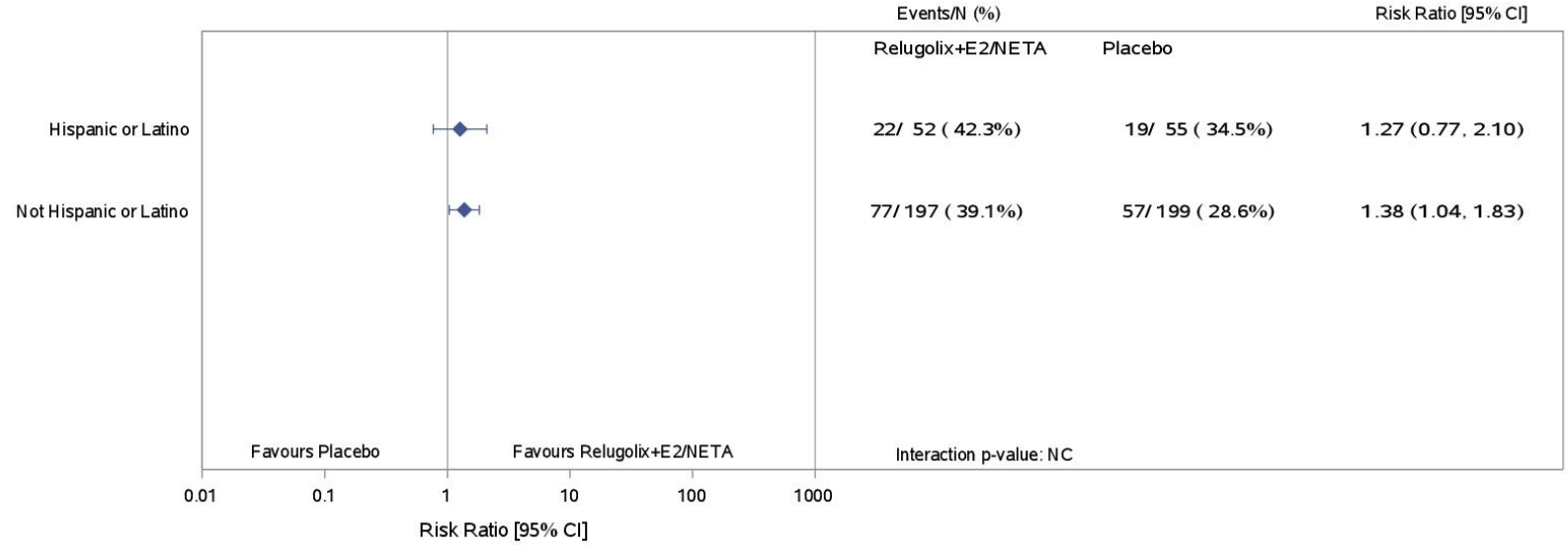
Figure QOL.EQVAS7.MITT.S8.BIN.FP.RR: Proportion of Responders with at Least 7 Points Increase in EQ-5D-5L VAS scale at Week 24, by Subgroup (mITT Population) - Risk Ratio
Study: Pooled
Subgroup: Ethnicity



Results are based on a Cochran-Mantel-Haenszel approach stratified by study using a one-stage fixed-effects IPD meta-analysis. A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
The reference group is Placebo.
N: Number of patients in treatment group; NETA: Norethindrone acetate; mITT: Modified intent-to-treat; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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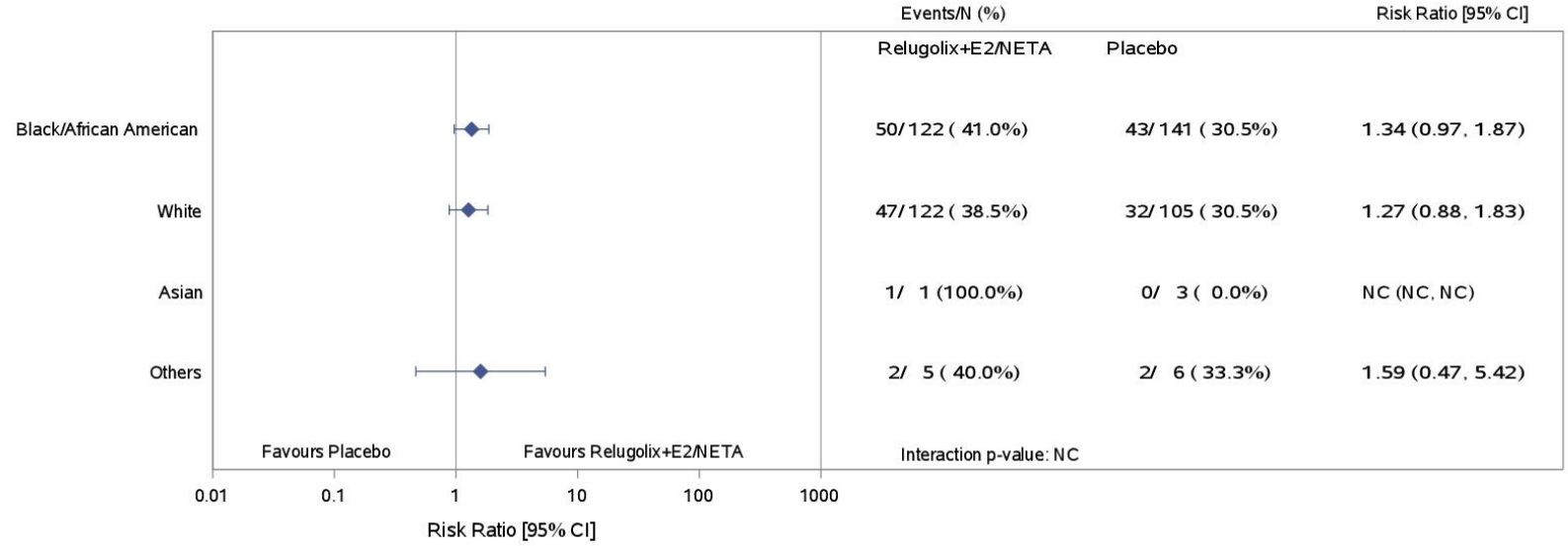
Figure QOL.EQVAS7.MITT.S9.BIN.FP.RR: Proportion of Responders with at Least 7 Points Increase in EQ-5D-5L VAS scale at Week 24, by Subgroup (mITT Population) - Risk Ratio
Study: Pooled
Subgroup: Race



Results are based on a Cochran-Mantel-Haenszel approach stratified by study using a one-stage fixed-effects IPD meta-analysis. A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
The reference group is Placebo.
N: Number of patients in treatment group; NETA: Norethindrone acetate; mITT: Modified intent-to-treat; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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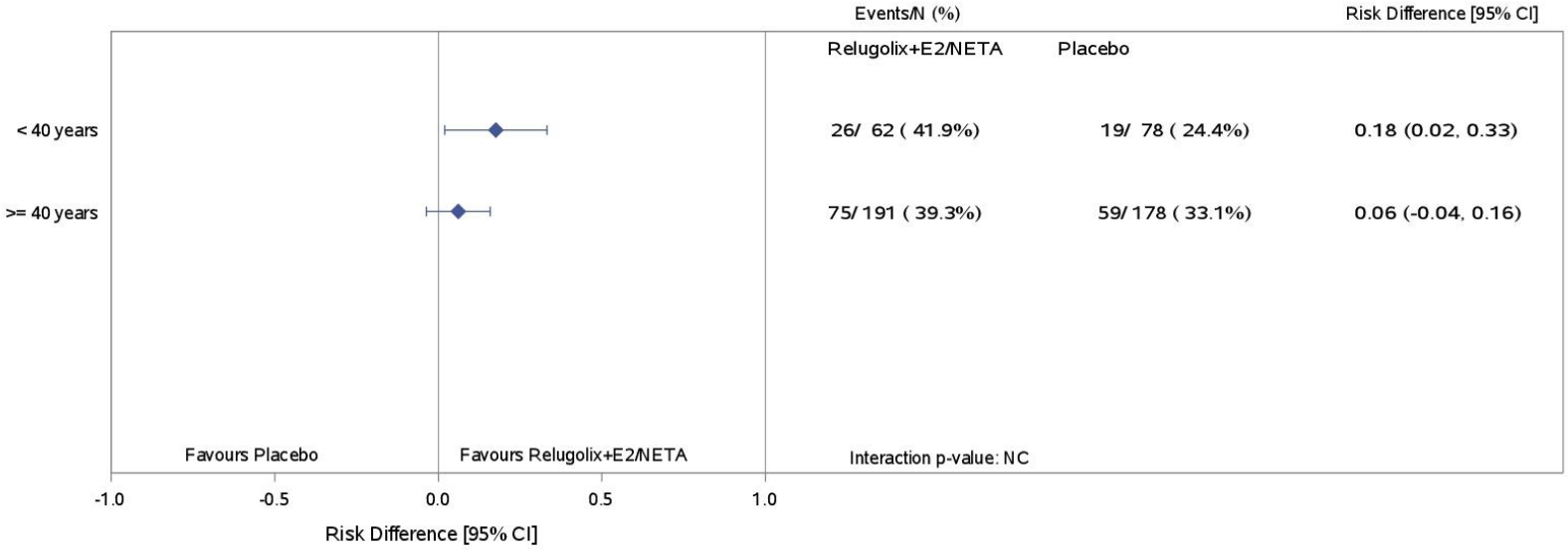
Figure QOL.EQVAS7.MITT.S1.BIN.FP.RD: Proportion of Responders with at Least 7 Points Increase in EQ-5D-5L VAS scale at Week 24, by Subgroup (mITT Population) - Risk Difference
Study: Pooled
Subgroup: Age (years)



Results are based on a Mantel-Haenszel approach stratified by study using a one-stage fixed-effects IPD meta-analysis.
The reference group is Placebo.
N: Number of patients in treatment group; NETA: Norethindrone acetate; mITT: Modified intent-to-treat; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

SOURCE: X:\Numerus\Studies\MYV\MYV102\Analysis\Prod\Progs\TFLs\Fig_QOL_QS_S_BIN_FP.SAS Date/time of run: 30JUN21 10:27
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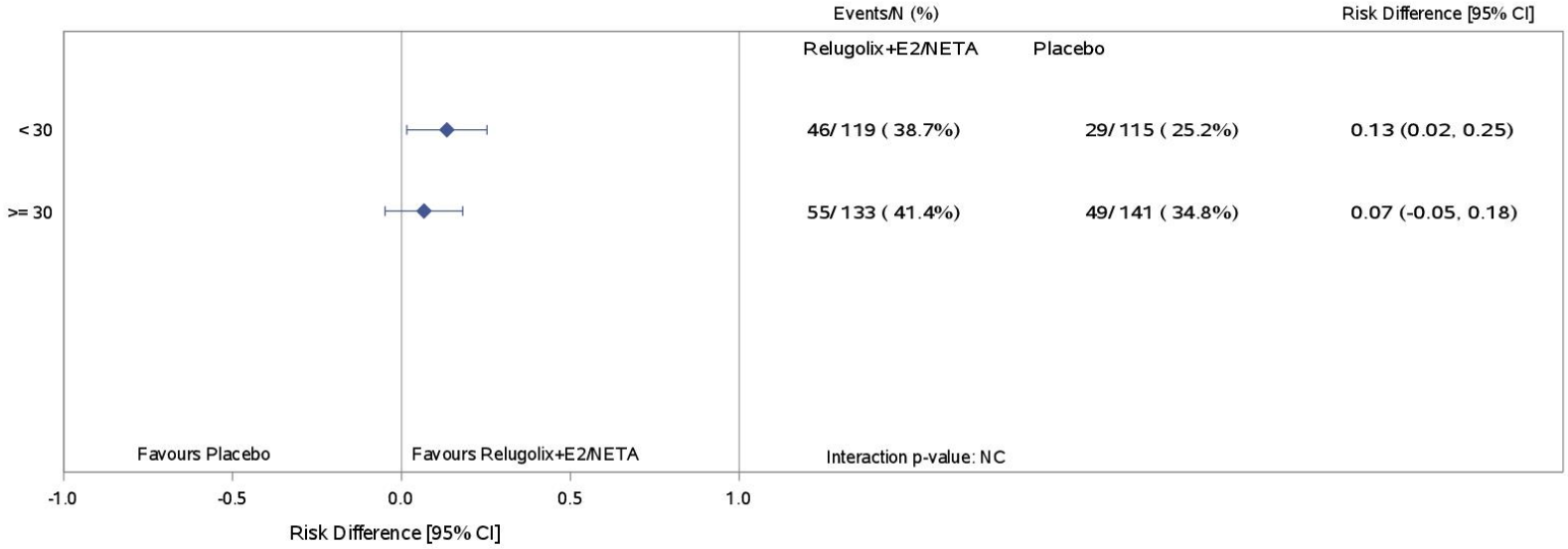
Figure QOL.EQVAS7.MITT.S2.BIN.FP.RD: Proportion of Responders with at Least 7 Points Increase in EQ-5D-5L VAS scale at Week 24, by Subgroup (mITT Population) - Risk Difference
Study: Pooled
Subgroup: BMI (kg/m2) at Baseline



Results are based on a Mantel-Haenszel approach stratified by study using a one-stage fixed-effects IPD meta-analysis.
The reference group is Placebo.
N: Number of patients in treatment group; NETA: Norethindrone acetate; mITT: Modified intent-to-treat; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

SOURCE: X:\Numerus\Studies\MYV\MYV102\Analysis\Prod\Progs\TFLs\Fig_QOL_QS_S_BIN_FP.SAS Date/time of run: 30JUN21 10:27
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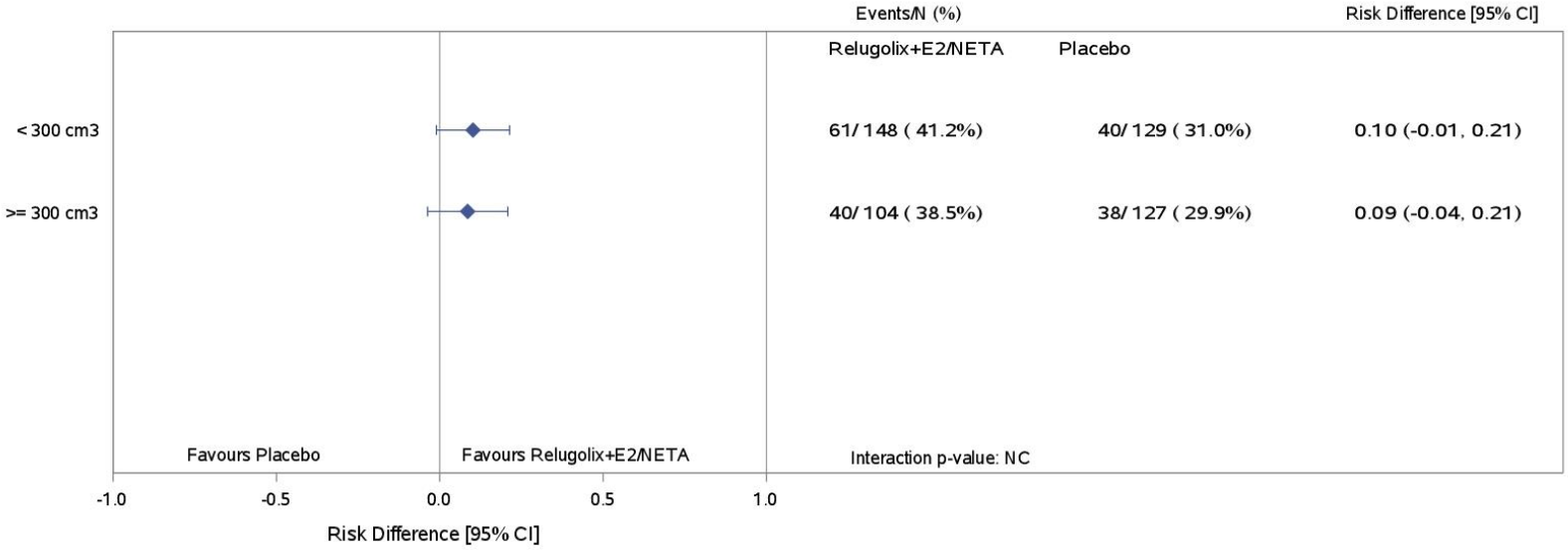
Figure QOL.EQVAS7.MITT.S3.BIN.FP.RD: Proportion of Responders with at Least 7 Points Increase in EQ-5D-5L VAS scale at Week 24, by Subgroup (mITT Population) - Risk Difference
Study: Pooled
Subgroup: Uterine Volume at Baseline (cm3)



Results are based on a Mantel-Haenszel approach stratified by study using a one-stage fixed-effects IPD meta-analysis.
The reference group is Placebo.
N: Number of patients in treatment group; NETA: Norethindrone acetate; mITT: Modified intent-to-treat; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

SOURCE: X:\Numerus\Studies\MYV\MYV102\Analysis\Prod\Progs\TFLs\Fig_QOL_QS_S_BIN_FP.SAS Date/time of run: 30JUN21 10:27
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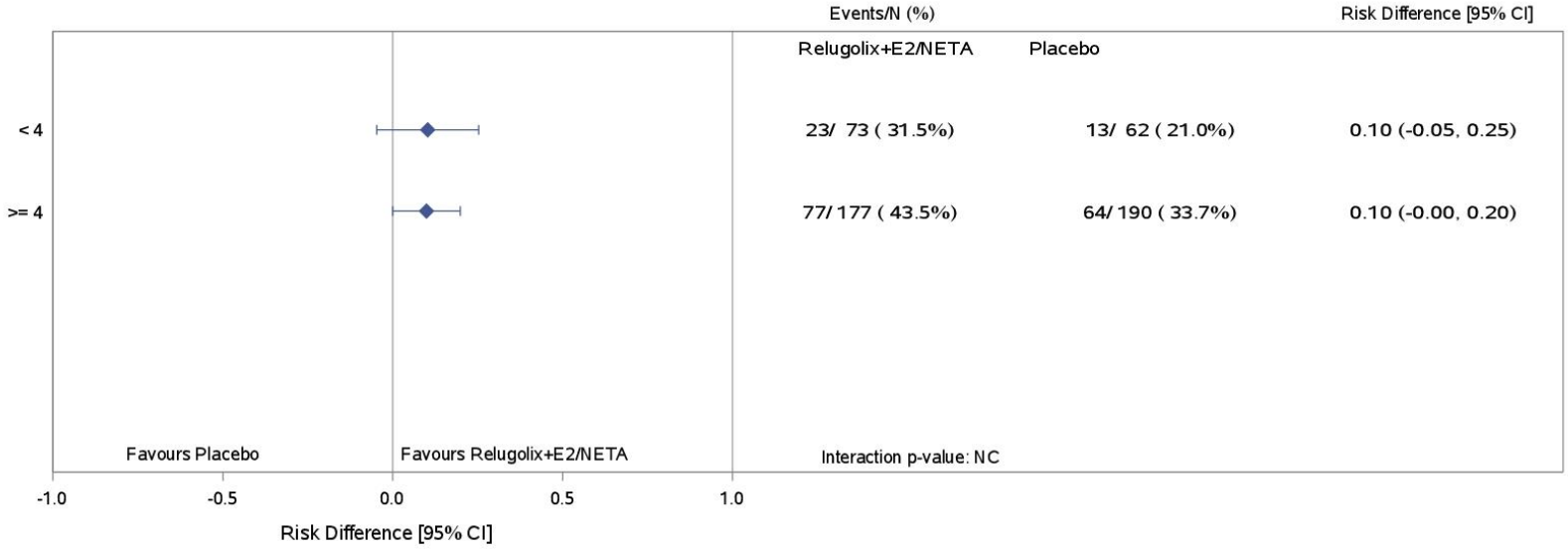
Figure QOL.EQVAS7.MITT.S4.BIN.FP.RD: Proportion of Responders with at Least 7 Points Increase in EQ-5D-5L VAS scale at Week 24, by Subgroup (mITT Population) - Risk Difference
Study: Pooled
Subgroup: Maximum NRS Pain Score at Baseline



Results are based on a Mantel-Haenszel approach stratified by study using a one-stage fixed-effects IPD meta-analysis.
The reference group is Placebo.
N: Number of patients in treatment group; NETA: Norethindrone acetate; mITT: Modified intent-to-treat; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

SOURCE: X:\Numerus\Studies\MYV\MYV102\Analysis\Prod\Progs\TFLs\Fig_QOL_QS_S_BIN_FP.SAS Date/time of run: 30JUN21 10:27
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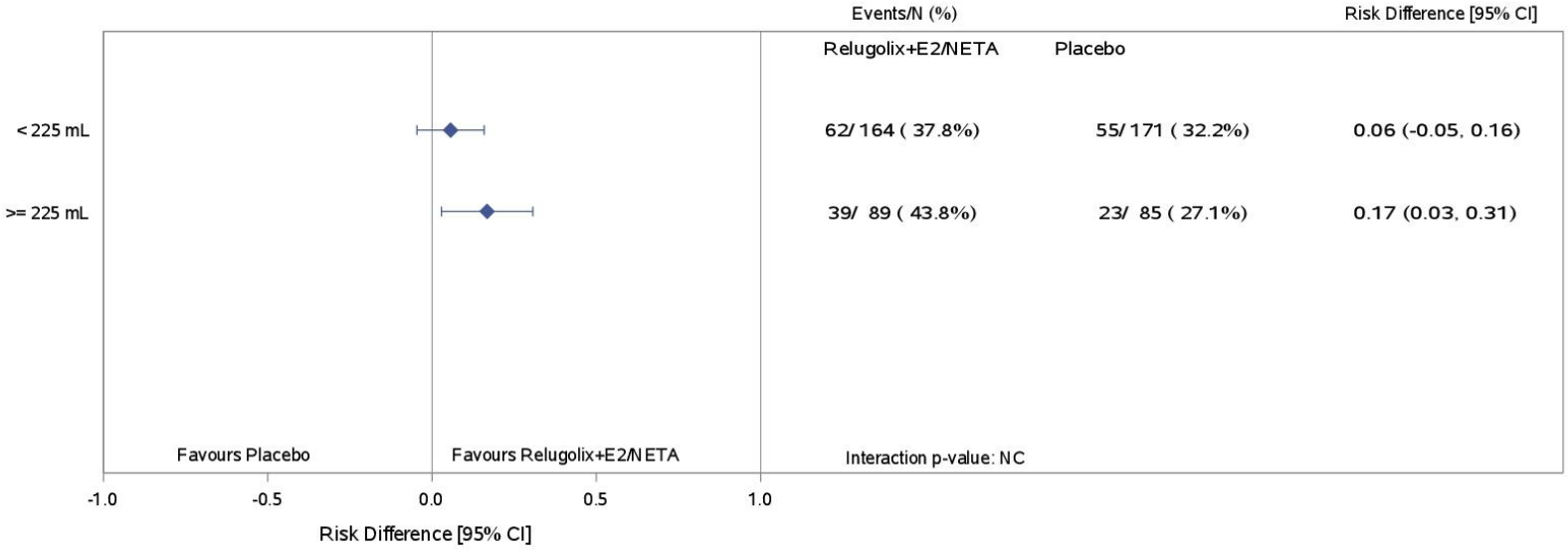
Figure QOL.EQVAS7.MITT.S5.BIN.FP.RD: Proportion of Responders with at Least 7 Points Increase in EQ-5D-5L VAS scale at Week 24, by Subgroup (mITT Population) - Risk Difference
Study: Pooled
Subgroup: MBL Volume at Baseline (mL)



Results are based on a Mantel-Haenszel approach stratified by study using a one-stage fixed-effects IPD meta-analysis.
The reference group is Placebo.
N: Number of patients in treatment group; NETA: Norethindrone acetate; mITT: Modified intent-to-treat; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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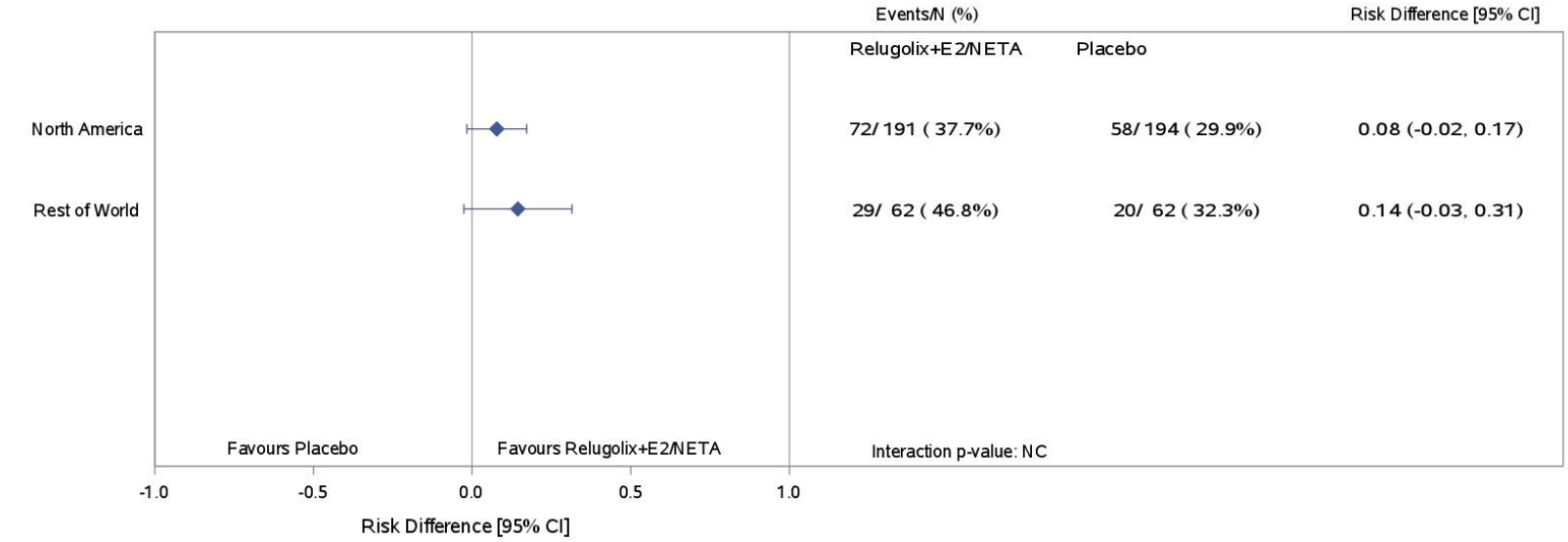
Figure QOL.EQVAS7.MITT.S6.BIN.FP.RD: Proportion of Responders with at Least 7 Points Increase in EQ-5D-5L VAS scale at Week 24, by Subgroup (mITT Population) - Risk Difference
Study: Pooled
Subgroup: Geographic Region I



Results are based on a Mantel-Haenszel approach stratified by study using a one-stage fixed-effects IPD meta-analysis.
The reference group is Placebo.
N: Number of patients in treatment group; NETA: Norethindrone acetate; mITT: Modified intent-to-treat; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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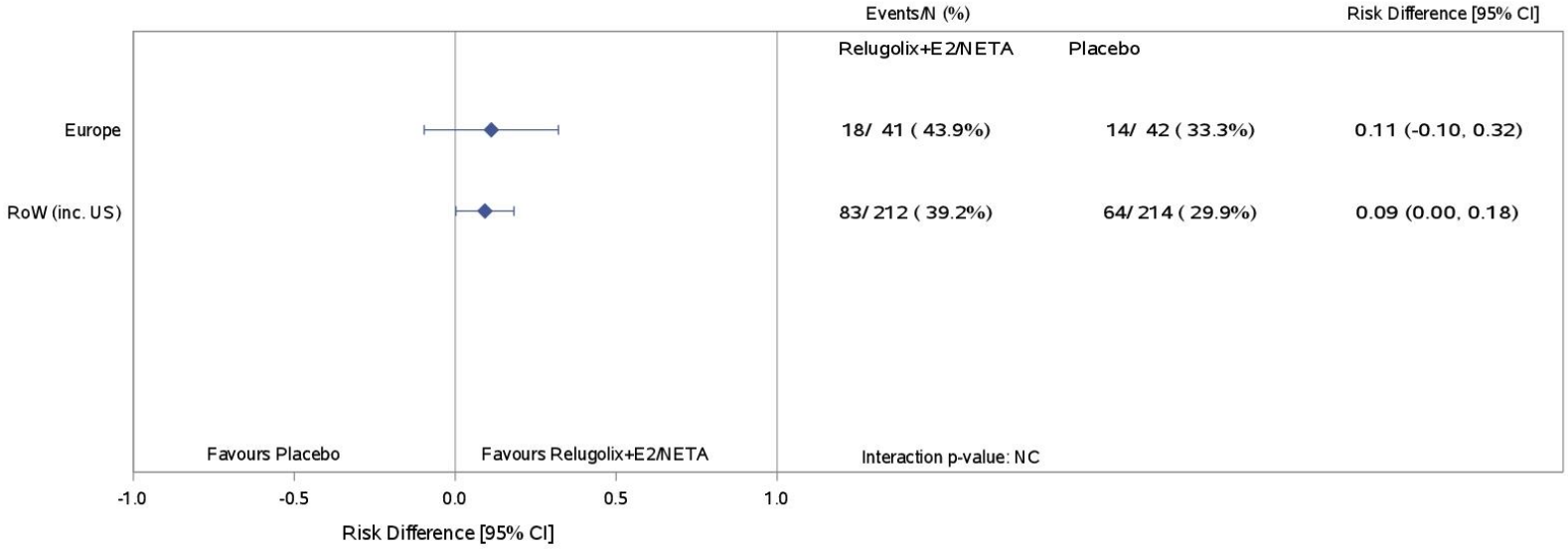
Figure QOL.EQVAS7.MITT.S7.BIN.FP.RD: Proportion of Responders with at Least 7 Points Increase in EQ-5D-5L VAS scale at Week 24, by Subgroup (mITT Population) - Risk Difference
Study: Pooled
Subgroup: Geographic Region II



Results are based on a Mantel-Haenszel approach stratified by study using a one-stage fixed-effects IPD meta-analysis.
The reference group is Placebo.
N: Number of patients in treatment group; NETA: Norethindrone acetate; mITT: Modified intent-to-treat; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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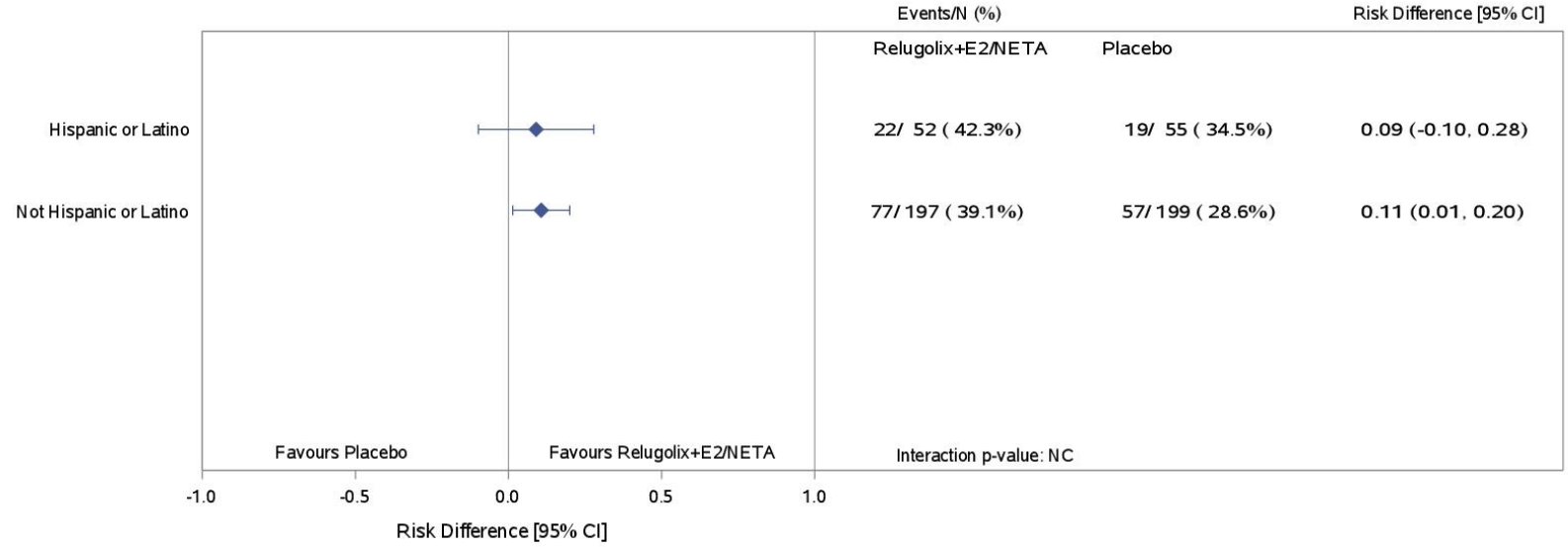
Figure QOL.EQVAS7.MITT.S8.BIN.FP.RD: Proportion of Responders with at Least 7 Points Increase in EQ-5D-5L VAS scale at Week 24, by Subgroup (mITT Population) - Risk Difference
Study: Pooled
Subgroup: Ethnicity



Results are based on a Mantel-Haenszel approach stratified by study using a one-stage fixed-effects IPD meta-analysis.
The reference group is Placebo.
N: Number of patients in treatment group; NETA: Norethindrone acetate; mITT: Modified intent-to-treat; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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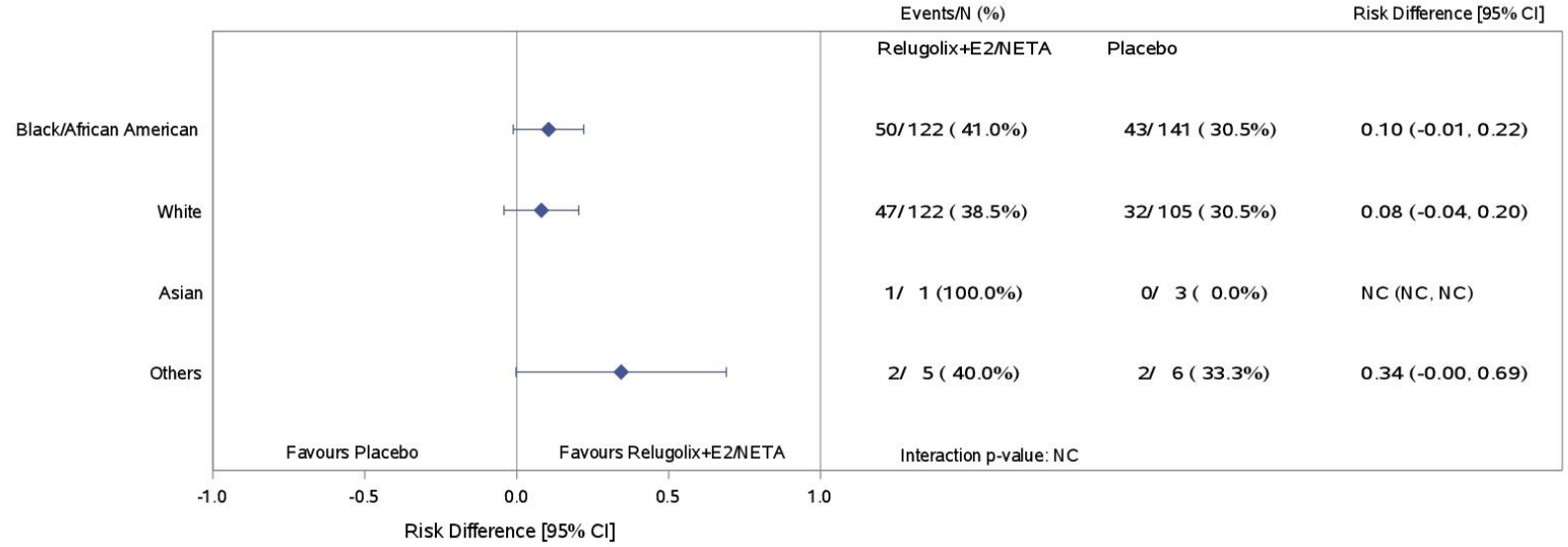
Figure QOL.EQVAS7.MITT.S9.BIN.FP.RD: Proportion of Responders with at Least 7 Points Increase in EQ-5D-5L VAS scale at Week 24, by Subgroup (mITT Population) - Risk Difference
Study: Pooled
Subgroup: Race



Results are based on a Mantel-Haenszel approach stratified by study using a one-stage fixed-effects IPD meta-analysis.
The reference group is Placebo.
N: Number of patients in treatment group; NETA: Norethindrone acetate; mITT: Modified intent-to-treat; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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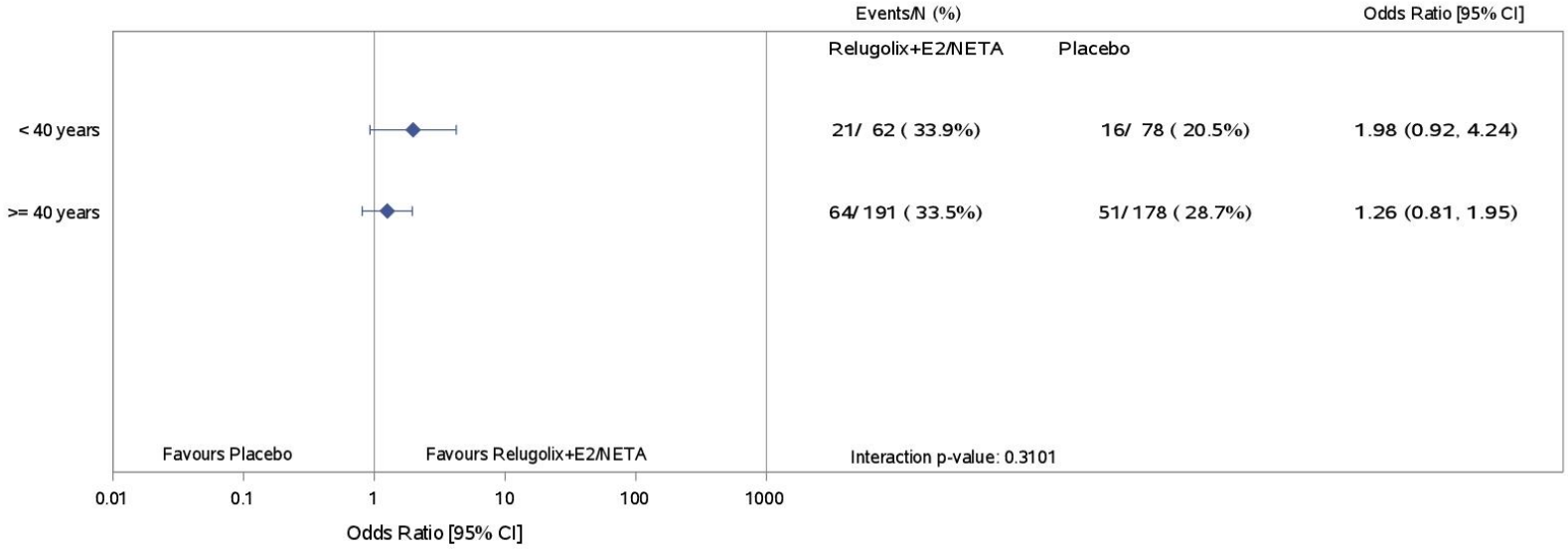
2.2.19 Proportion of Responders with at Least 10 Points Increase in EQ-5D-5L VAS scale at Week 24, by Subgroup (mITT Population)

Nachfolgend sind zunächst alle Forest Plots für das *Odds Ratio* dargestellt; gefolgt von den entsprechenden Forest Plots für *Risk Ratio* und *Risk Difference*.

Figure QOL.EQVAS10.MITT.S1.BIN.FP: Proportion of Responders with at Least 10 Points Increase in EQ-5D-5L VAS scale at Week 24, by Subgroup (mITT Population)
Study: Pooled
Subgroup: Age (years)



Results are based on a logistic regression model adjusted for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates using a one-stage fixed-effects IPD meta-analysis approach. A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
The interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the Odds Ratio and 95% CI. Missing subgroup levels are not included in estimation of the interaction p-value. The reference group is Placebo.
N: Number of patients in treatment group; NETA: Norethindrone acetate; mITT: Modified intent-to-treat; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

SOURCE: X:\Numerus\Studies\MYV\MYV102\Analysis\Prod\Progs\TFLs\Fig_QOL_QS_S_BIN_FP.SAS Date/time of run: 30JUN21 10:27
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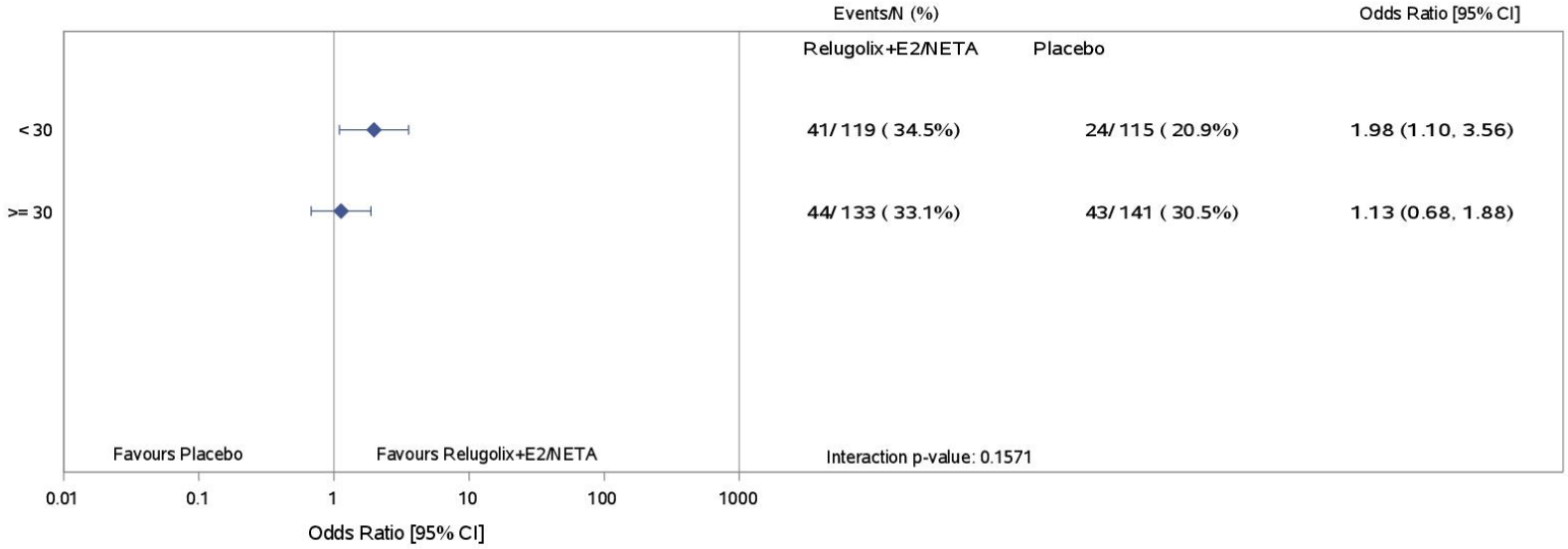
Figure QOL.EQVAS10.MITT.S2.BIN.FP: Proportion of Responders with at Least 10 Points Increase in EQ-5D-5L VAS scale at Week 24, by Subgroup (mITT Population)
Study: Pooled
Subgroup: BMI (kg/m2) at Baseline



Results are based on a logistic regression model adjusted for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates using a one-stage fixed-effects IPD meta-analysis approach. A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
The interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the Odds Ratio and 95% CI. Missing subgroup levels are not included in estimation of the interaction p-value. The reference group is Placebo.
N: Number of patients in treatment group; NETA: Norethindrone acetate; mITT: Modified intent-to-treat; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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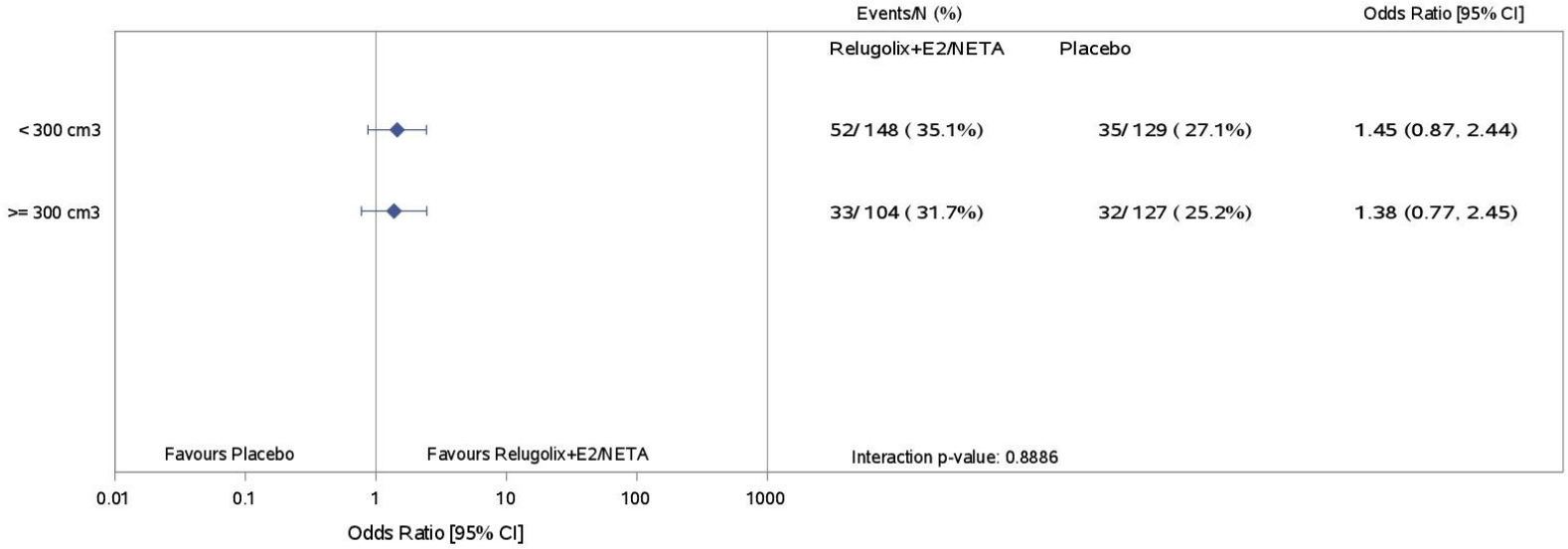
Figure QOL.EQVAS10.MITT.S3.BIN.FP: Proportion of Responders with at Least 10 Points Increase in EQ-5D-5L VAS scale at Week 24, by Subgroup (mITT Population)
Study: Pooled
Subgroup: Uterine Volume at Baseline (cm3)



Results are based on a logistic regression model adjusted for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates using a one-stage fixed-effects IPD meta-analysis approach. A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
The interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the Odds Ratio and 95% CI. Missing subgroup levels are not included in estimation of the interaction p-value. The reference group is Placebo.
N: Number of patients in treatment group; NETA: Norethindrone acetate; mITT: Modified intent-to-treat; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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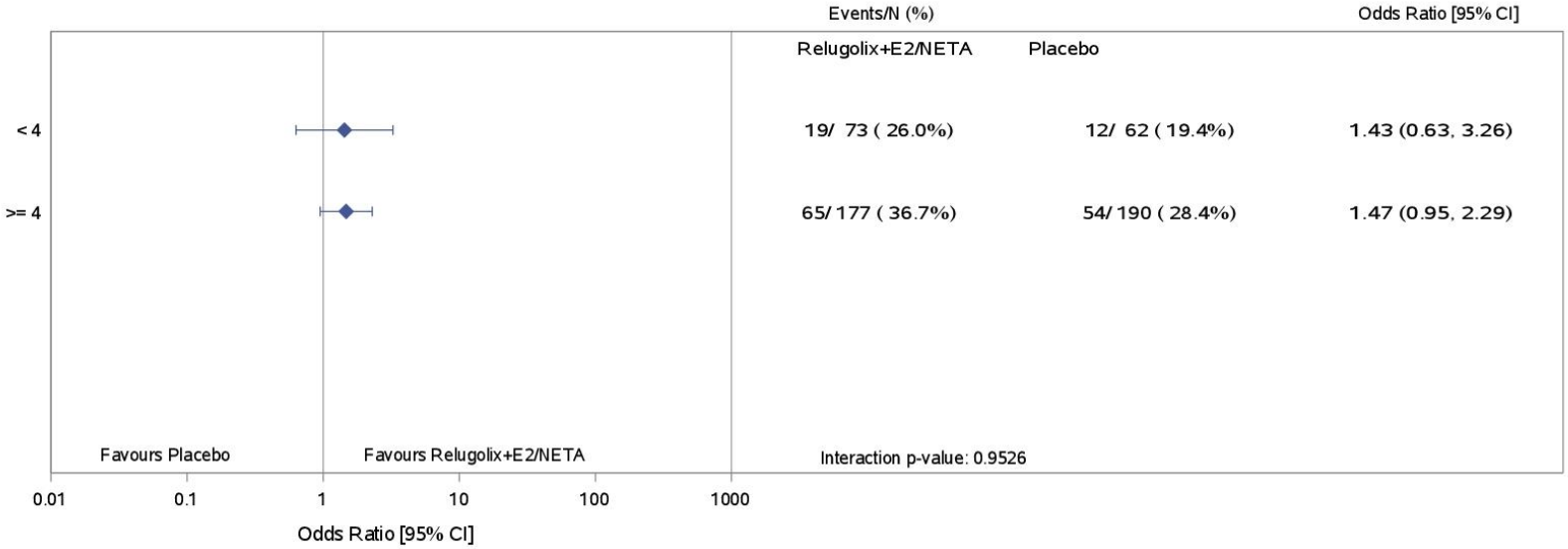
Figure QOL.EQVAS10.MITT.S4.BIN.FP: Proportion of Responders with at Least 10 Points Increase in EQ-5D-5L VAS scale at Week 24, by Subgroup (mITT Population)
Study: Pooled
Subgroup: Maximum NRS Pain Score at Baseline



Results are based on a logistic regression model adjusted for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates using a one-stage fixed-effects IPD meta-analysis approach. A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
The interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the Odds Ratio and 95% CI. Missing subgroup levels are not included in estimation of the interaction p-value. The reference group is Placebo.
N: Number of patients in treatment group; NETA: Norethindrone acetate; mITT: Modified intent-to-treat; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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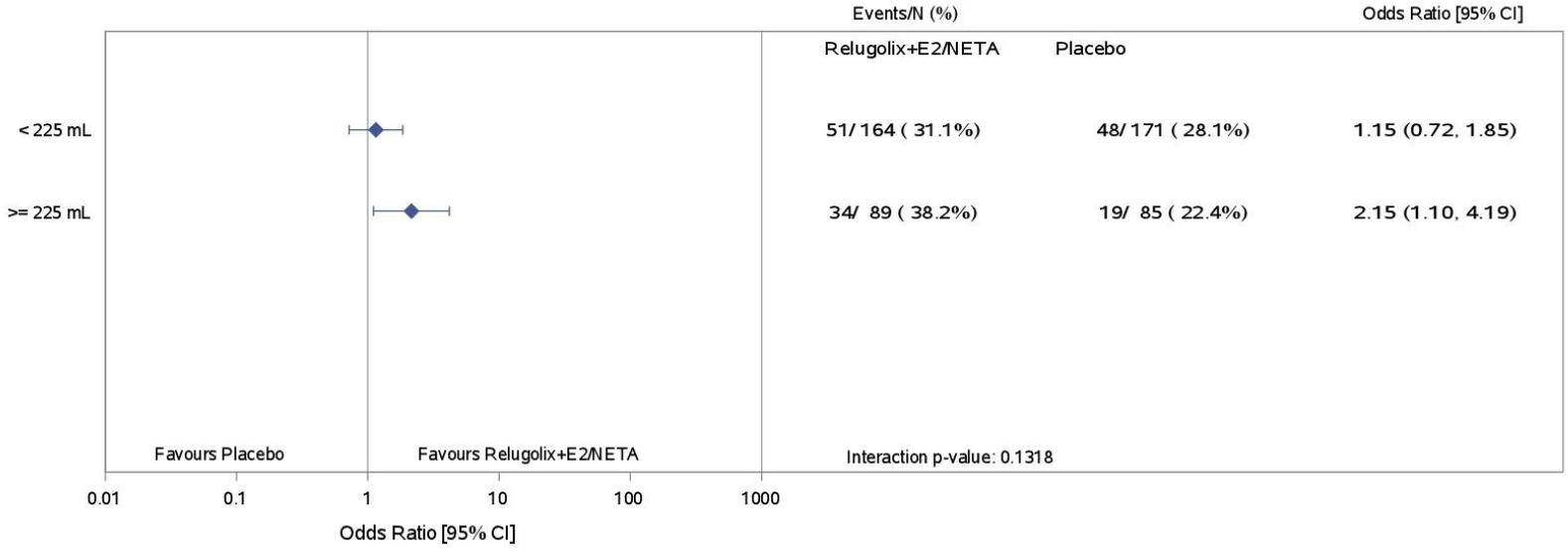
Figure QOL.EQVAS10.MITT.S5.BIN.FP: Proportion of Responders with at Least 10 Points Increase in EQ-5D-5L VAS scale at Week 24, by Subgroup (mITT Population)
Study: Pooled
Subgroup: MBL Volume at Baseline (mL)



Results are based on a logistic regression model adjusted for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates using a one-stage fixed-effects IPD meta-analysis approach. A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
The interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the Odds Ratio and 95% CI. Missing subgroup levels are not included in estimation of the interaction p-value. The reference group is Placebo.
N: Number of patients in treatment group; NETA: Norethindrone acetate; mITT: Modified intent-to-treat; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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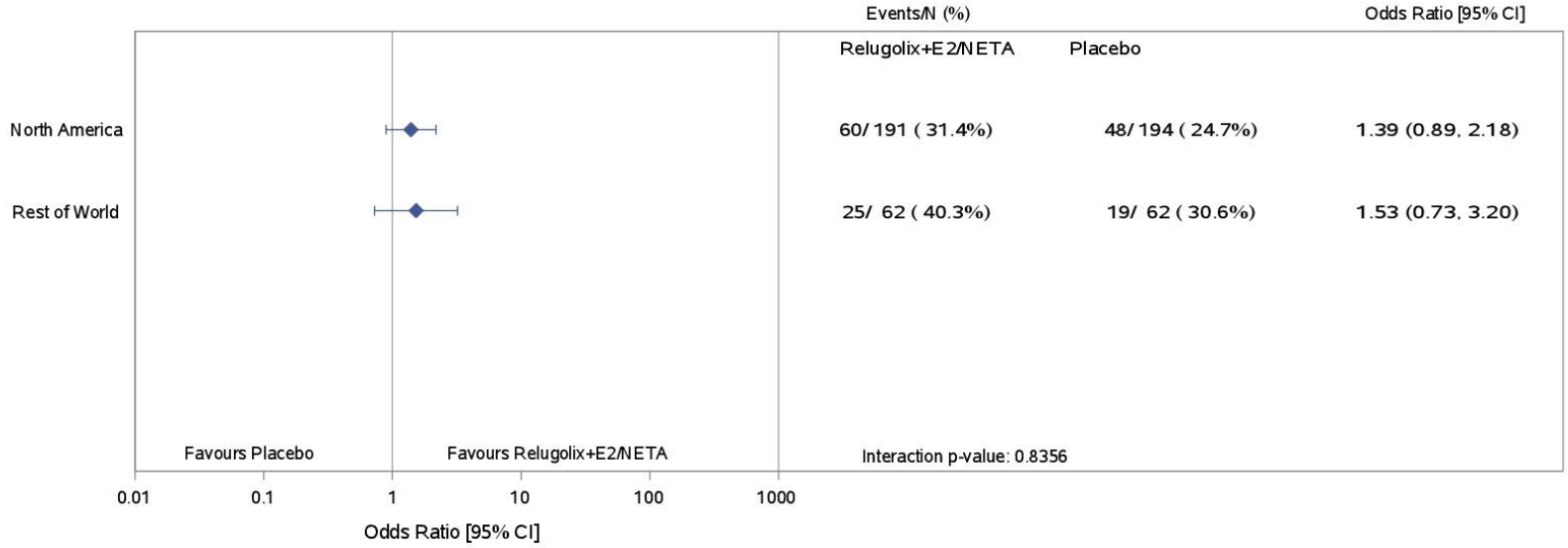
Figure QOL.EQVAS10.MITT.S6.BIN.FP: Proportion of Responders with at Least 10 Points Increase in EQ-5D-5L VAS scale at Week 24, by Subgroup (mITT Population)
Study: Pooled
Subgroup: Geographic Region I



Results are based on a logistic regression model adjusted for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates using a one-stage fixed-effects IPD meta-analysis approach. A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
The interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the Odds Ratio and 95% CI. Missing subgroup levels are not included in estimation of the interaction p-value. The reference group is Placebo.
N: Number of patients in treatment group; NETA: Norethindrone acetate; mITT: Modified intent-to-treat; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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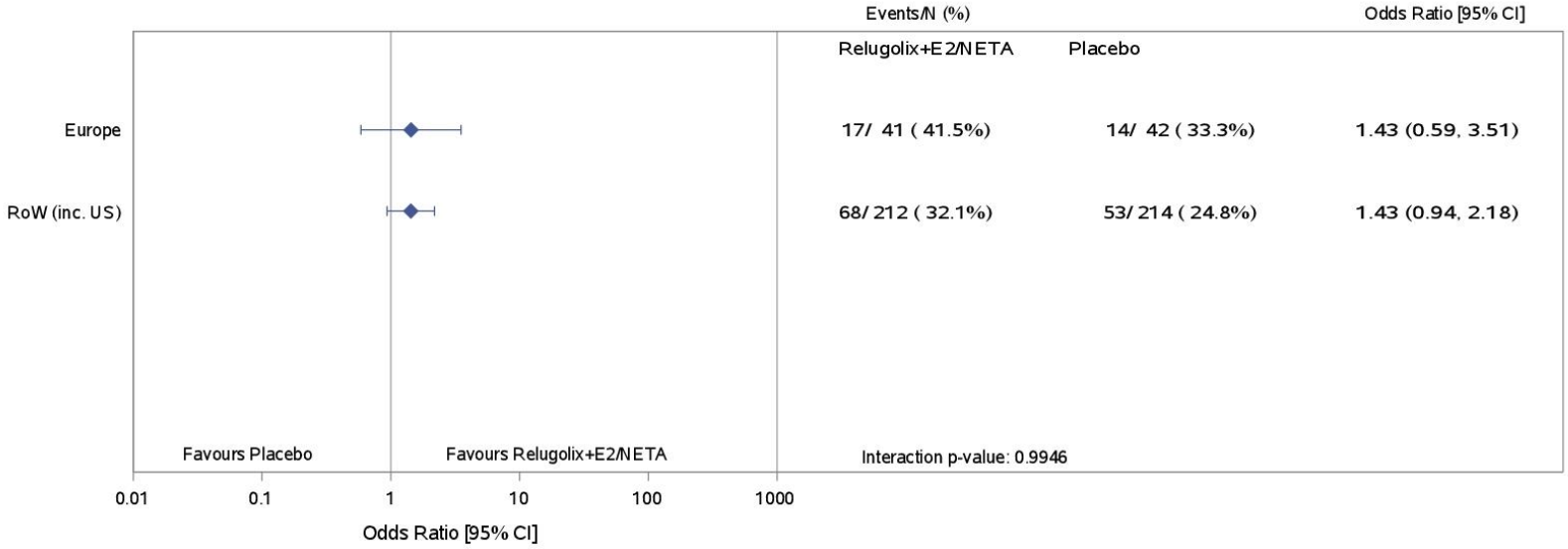
Figure QOL.EQVAS10.MITT.S7.BIN.FP: Proportion of Responders with at Least 10 Points Increase in EQ-5D-5L VAS scale at Week 24, by Subgroup (mITT Population)
Study: Pooled
Subgroup: Geographic Region II



Results are based on a logistic regression model adjusted for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates using a one-stage fixed-effects IPD meta-analysis approach. A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
The interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the Odds Ratio and 95% CI. Missing subgroup levels are not included in estimation of the interaction p-value. The reference group is Placebo.
N: Number of patients in treatment group; NETA: Norethindrone acetate; mITT: Modified intent-to-treat; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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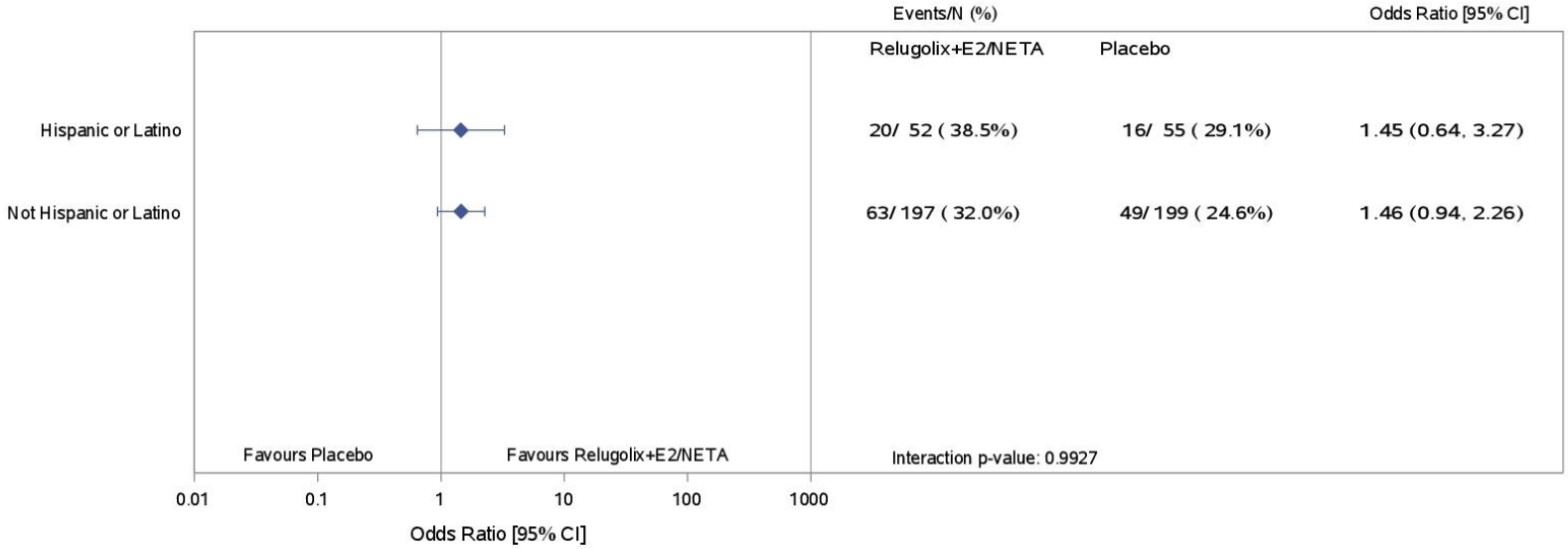
Figure QOL.EQVAS10.MITT.S8.BIN.FP: Proportion of Responders with at Least 10 Points Increase in EQ-5D-5L VAS scale at Week 24, by Subgroup (mITT Population)
Study: Pooled
Subgroup: Ethnicity



Results are based on a logistic regression model adjusted for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates using a one-stage fixed-effects IPD meta-analysis approach. A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
The interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the Odds Ratio and 95% CI. Missing subgroup levels are not included in estimation of the interaction p-value. The reference group is Placebo.
N: Number of patients in treatment group; NETA: Norethindrone acetate; mITT: Modified intent-to-treat; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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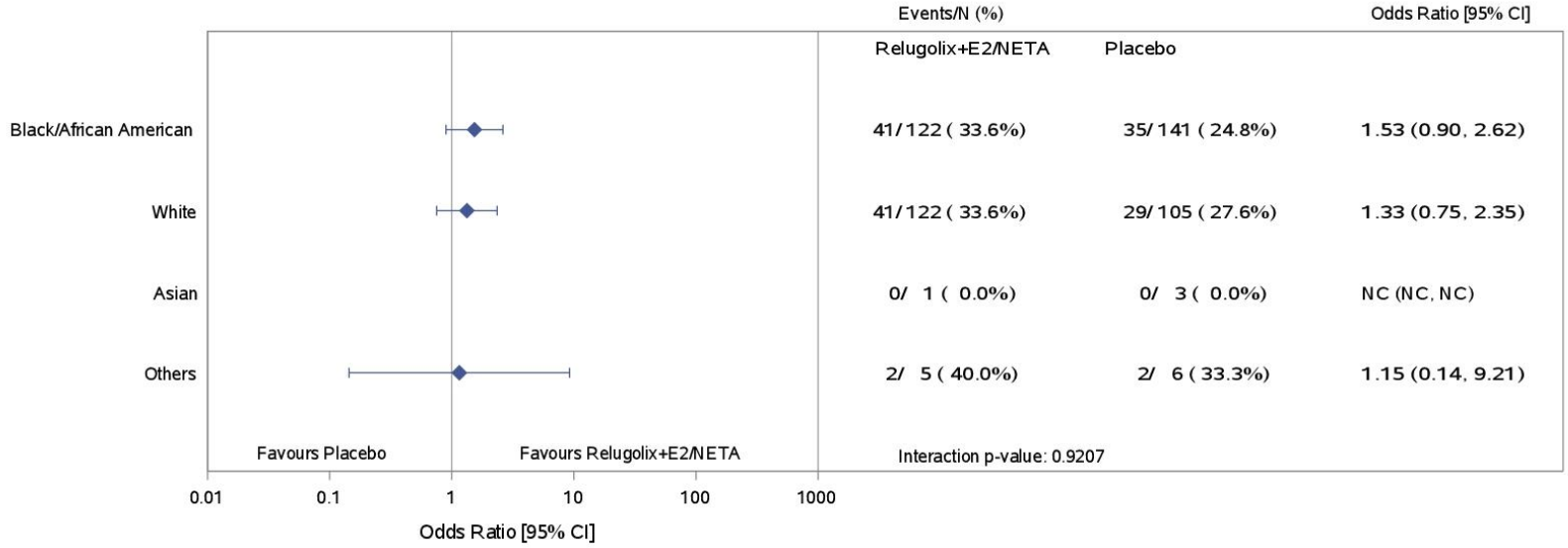
Figure QOL.EQVAS10.MITT.S9.BIN.FP: Proportion of Responders with at Least 10 Points Increase in EQ-5D-5L VAS scale at Week 24, by Subgroup (mITT Population)
Study: Pooled
Subgroup: Race



Results are based on a logistic regression model adjusted for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates using a one-stage fixed-effects IPD meta-analysis approach. A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
The interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the Odds Ratio and 95% CI. Missing subgroup levels are not included in estimation of the interaction p-value. The reference group is Placebo.
N: Number of patients in treatment group; NETA: Norethindrone acetate; mITT: Modified intent-to-treat; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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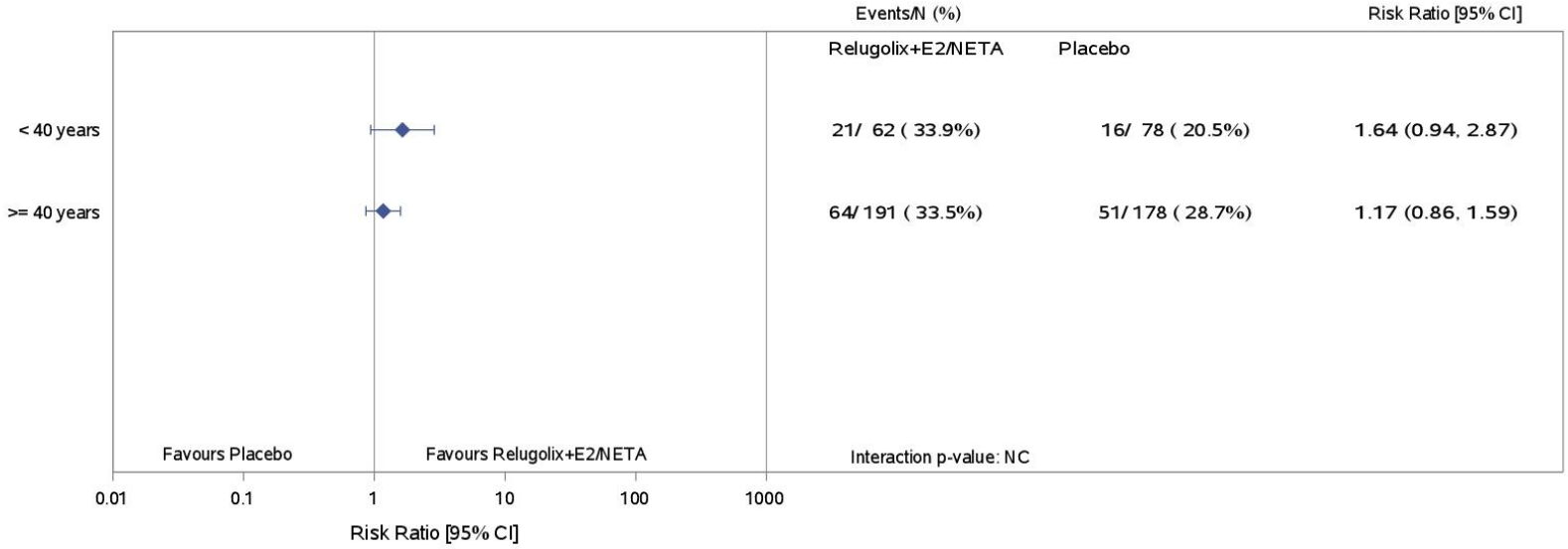
Figure QOL.EQVAS10.MITT.S1.BIN.FP.RR: Proportion of Responders with at Least 10 Points Increase in EQ-5D-5L VAS scale at Week 24, by Subgroup (mITT Population) - Risk Ratio
Study: Pooled
Subgroup: Age (years)



Results are based on a Cochran-Mantel-Haenszel approach stratified by study using a one-stage fixed-effects IPD meta-analysis. A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
The reference group is Placebo.
N: Number of patients in treatment group; NETA: Norethindrone acetate; mITT: Modified intent-to-treat; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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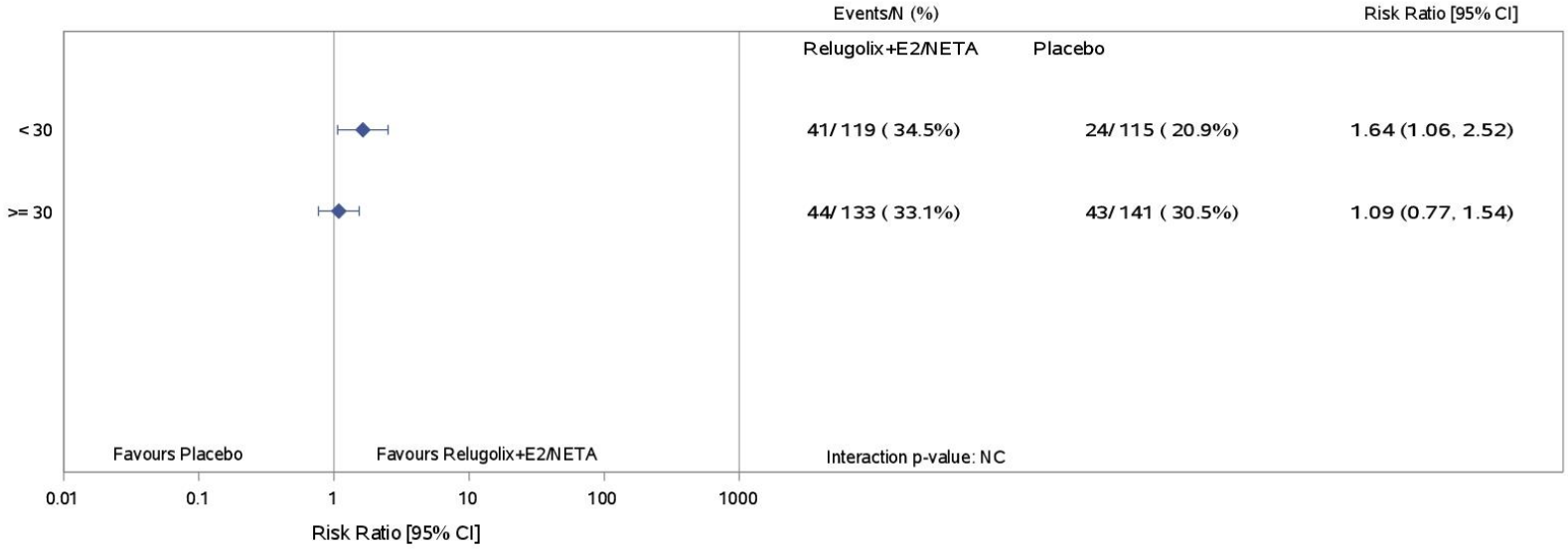
Figure QOL.EQVAS10.MITT.S2.BIN.FP.RR: Proportion of Responders with at Least 10 Points Increase in EQ-5D-5L VAS scale at Week 24, by Subgroup (mITT Population) - Risk Ratio
Study: Pooled
Subgroup: BMI (kg/m2) at Baseline



Results are based on a Cochran-Mantel-Haenszel approach stratified by study using a one-stage fixed-effects IPD meta-analysis. A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
The reference group is Placebo.
N: Number of patients in treatment group; NETA: Norethindrone acetate; mITT: Modified intent-to-treat; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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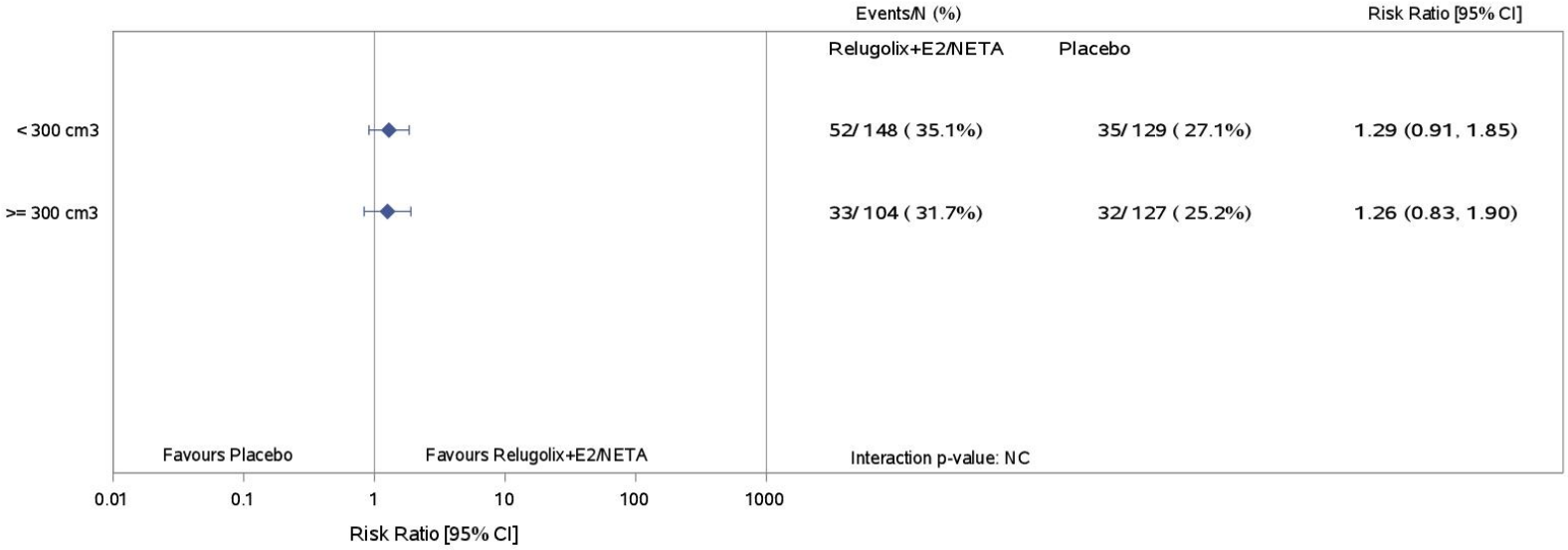
Figure QOL.EQVAS10.MITT.S3.BIN.FP.RR: Proportion of Responders with at Least 10 Points Increase in EQ-5D-5L VAS scale at Week 24, by Subgroup (mITT Population) - Risk Ratio
Study: Pooled
Subgroup: Uterine Volume at Baseline (cm3)



Results are based on a Cochran-Mantel-Haenszel approach stratified by study using a one-stage fixed-effects IPD meta-analysis. A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
The reference group is Placebo.
N: Number of patients in treatment group; NETA: Norethindrone acetate; mITT: Modified intent-to-treat; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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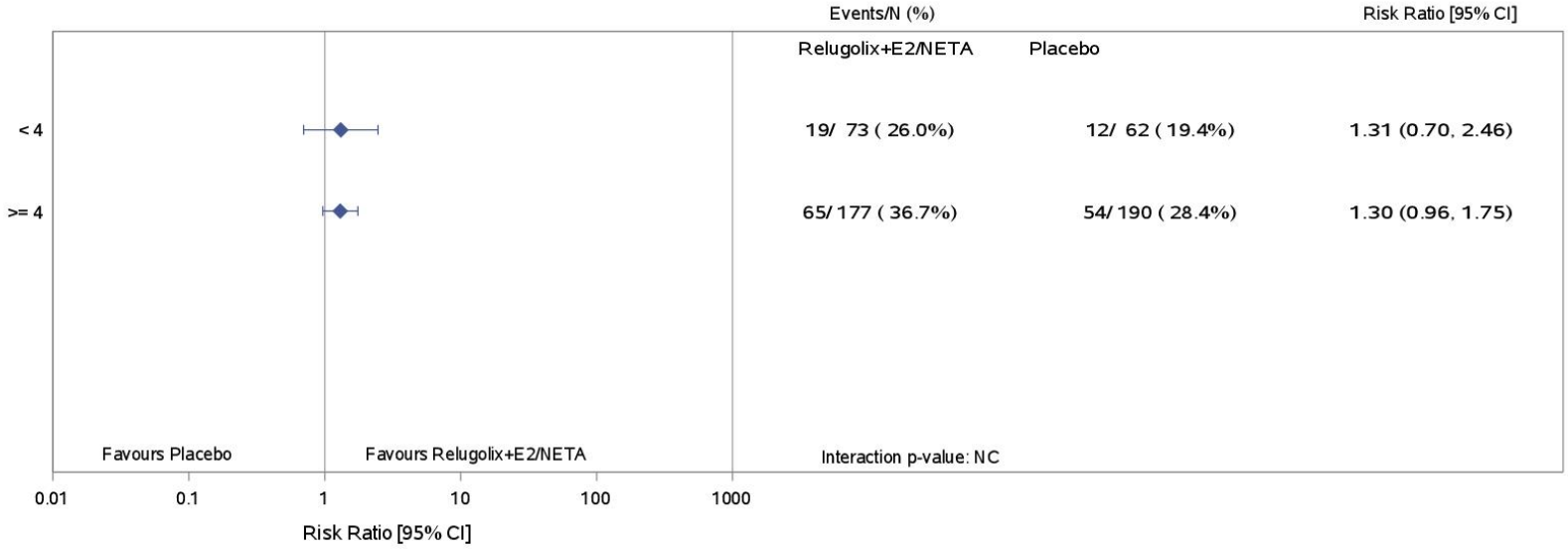
Figure QOL.EQVAS10.MITT.S4.BIN.FP.RR: Proportion of Responders with at Least 10 Points Increase in EQ-5D-5L VAS scale at Week 24, by Subgroup (mITT Population) - Risk Ratio
Study: Pooled
Subgroup: Maximum NRS Pain Score at Baseline



Results are based on a Cochran-Mantel-Haenszel approach stratified by study using a one-stage fixed-effects IPD meta-analysis. A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
The reference group is Placebo.
N: Number of patients in treatment group; NETA: Norethindrone acetate; mITT: Modified intent-to-treat; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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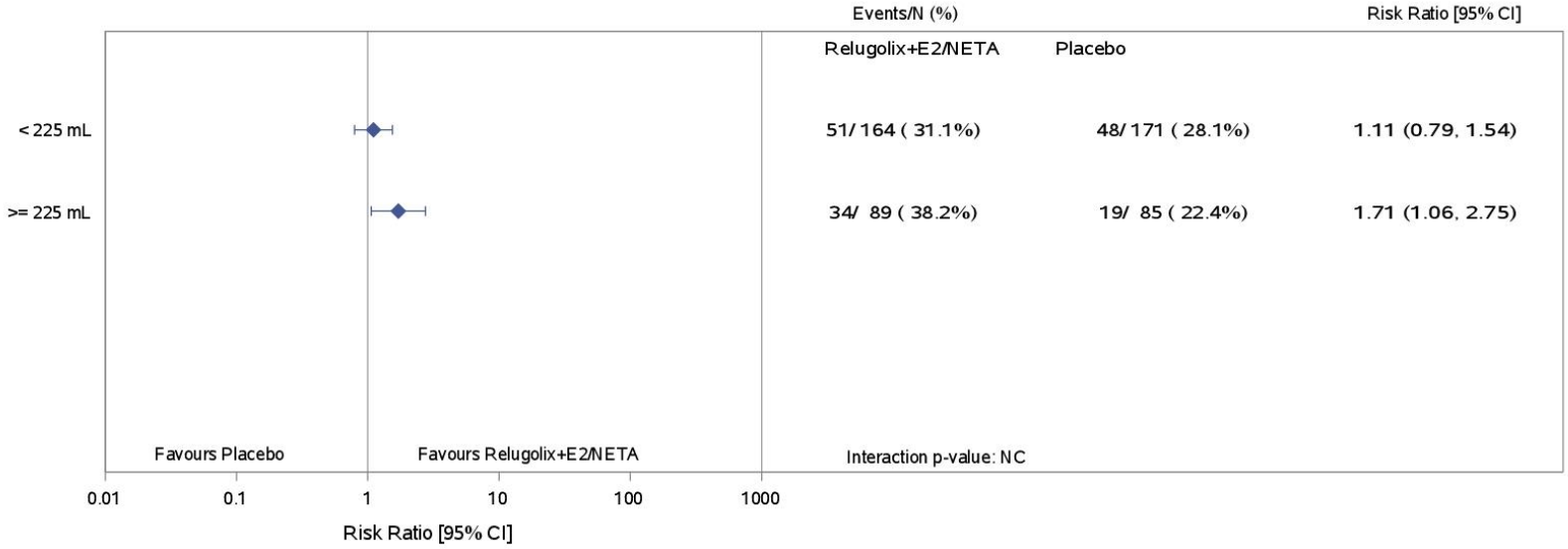
Figure QOL.EQVAS10.MITT.S5.BIN.FP.RR: Proportion of Responders with at Least 10 Points Increase in EQ-5D-5L VAS scale at Week 24, by Subgroup (mITT Population) - Risk Ratio
Study: Pooled
Subgroup: MBL Volume at Baseline (mL)



Results are based on a Cochran-Mantel-Haenszel approach stratified by study using a one-stage fixed-effects IPD meta-analysis. A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
The reference group is Placebo.
N: Number of patients in treatment group; NETA: Norethindrone acetate; mITT: Modified intent-to-treat; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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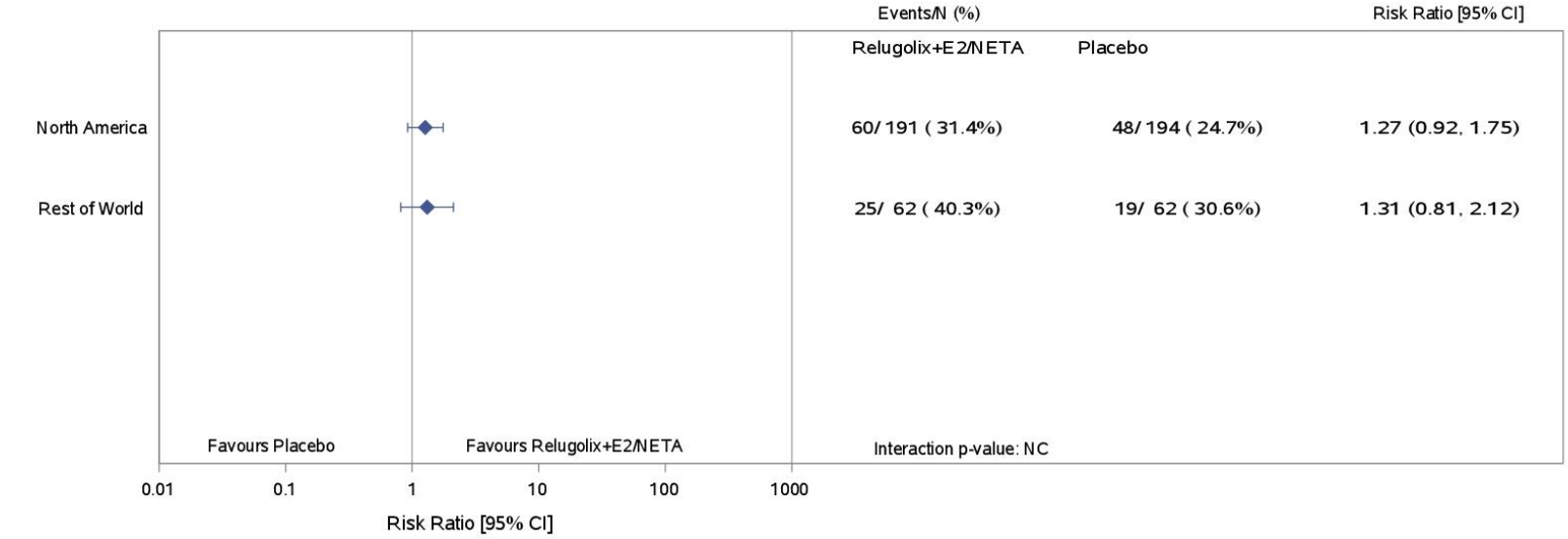
Figure QOL.EQVAS10.MITT.S6.BIN.FP.RR: Proportion of Responders with at Least 10 Points Increase in EQ-5D-5L VAS scale at Week 24, by Subgroup (mITT Population) - Risk Ratio
Study: Pooled
Subgroup: Geographic Region I



Results are based on a Cochran-Mantel-Haenszel approach stratified by study using a one-stage fixed-effects IPD meta-analysis. A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
The reference group is Placebo.
N: Number of patients in treatment group; NETA: Norethindrone acetate; mITT: Modified intent-to-treat; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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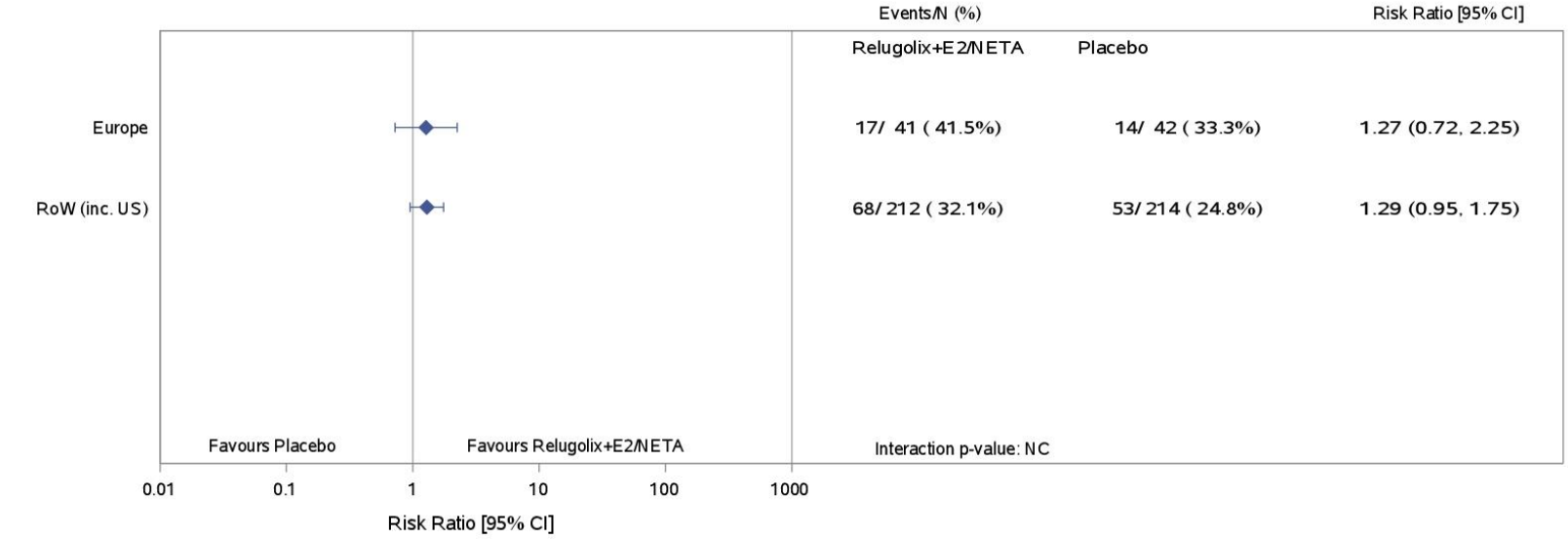
Figure QOL.EQVAS10.MITT.S7.BIN.FP.RR: Proportion of Responders with at Least 10 Points Increase in EQ-5D-5L VAS scale at Week 24, by Subgroup (mITT Population) - Risk Ratio
Study: Pooled
Subgroup: Geographic Region II



Results are based on a Cochran-Mantel-Haenszel approach stratified by study using a one-stage fixed-effects IPD meta-analysis. A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
The reference group is Placebo.
N: Number of patients in treatment group; NETA: Norethindrone acetate; mITT: Modified intent-to-treat; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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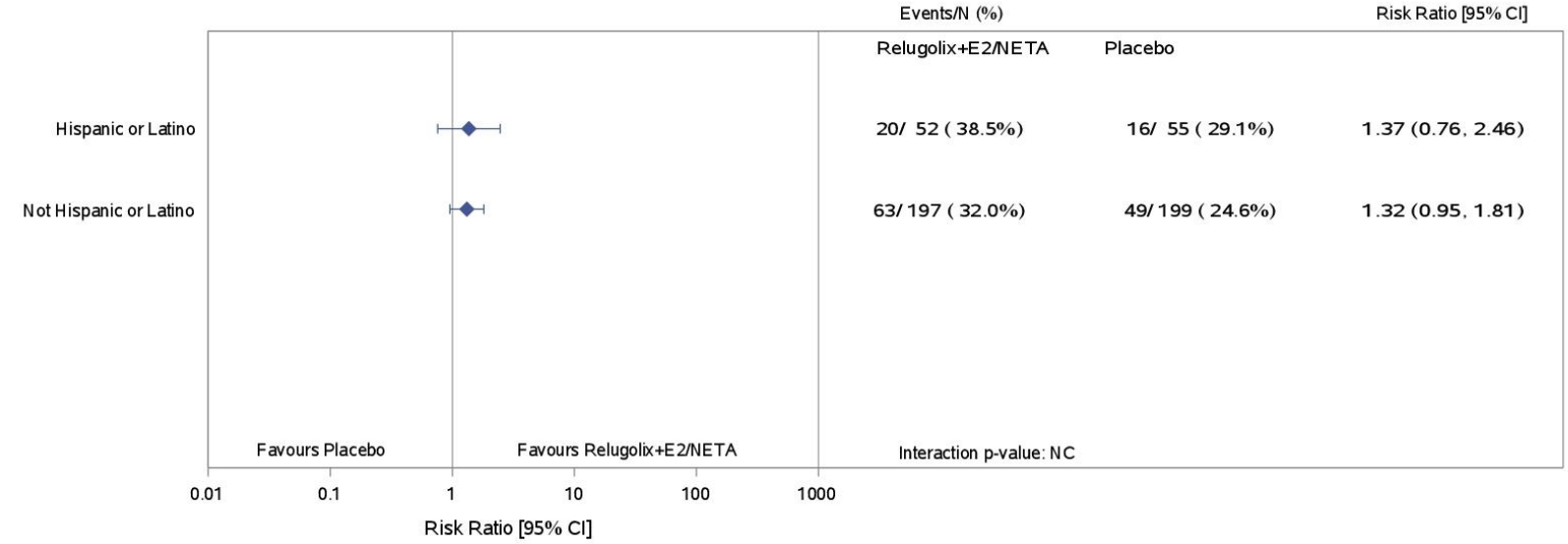
Figure QOL.EQVAS10.MITT.S8.BIN.FP.RR: Proportion of Responders with at Least 10 Points Increase in EQ-5D-5L VAS scale at Week 24, by Subgroup (mITT Population) - Risk Ratio
Study: Pooled
Subgroup: Ethnicity



Results are based on a Cochran-Mantel-Haenszel approach stratified by study using a one-stage fixed-effects IPD meta-analysis. A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
The reference group is Placebo.
N: Number of patients in treatment group; NETA: Norethindrone acetate; mITT: Modified intent-to-treat; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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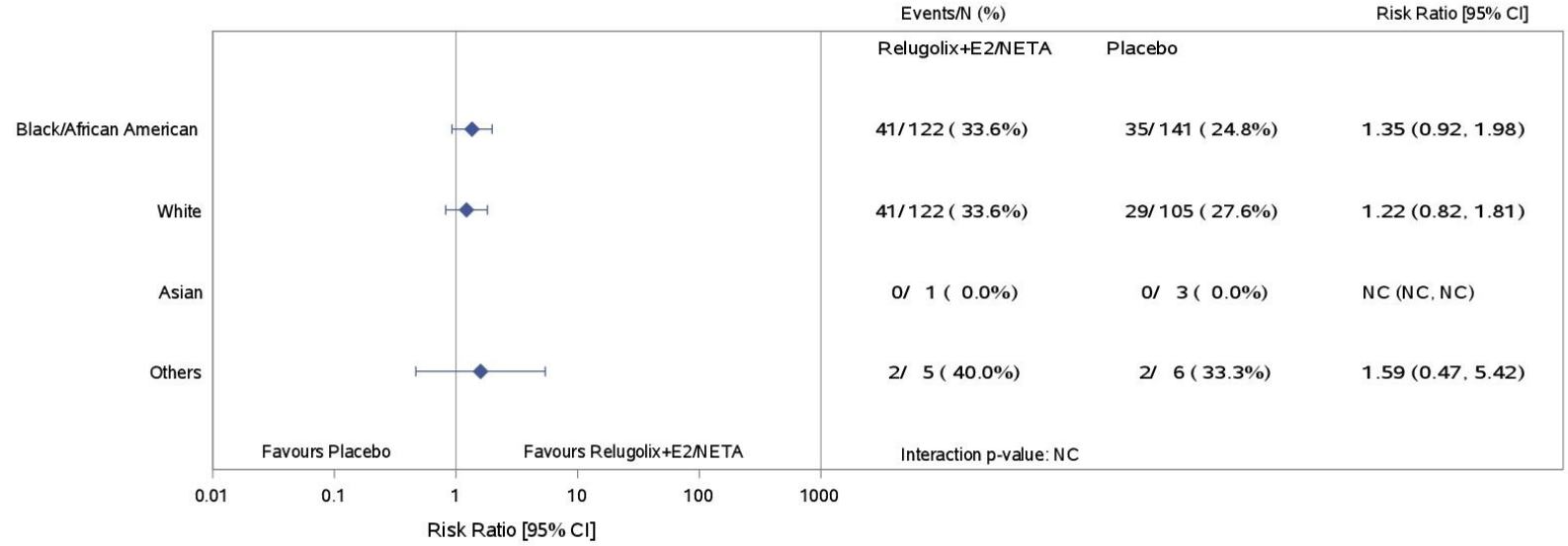
Figure QOL.EQVAS10.MITT.S9.BIN.FP.RR: Proportion of Responders with at Least 10 Points Increase in EQ-5D-5L VAS scale at Week 24, by Subgroup (mITT Population) - Risk Ratio
Study: Pooled
Subgroup: Race



Results are based on a Cochran-Mantel-Haenszel approach stratified by study using a one-stage fixed-effects IPD meta-analysis. A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
The reference group is Placebo.
N: Number of patients in treatment group; NETA: Norethindrone acetate; mITT: Modified intent-to-treat; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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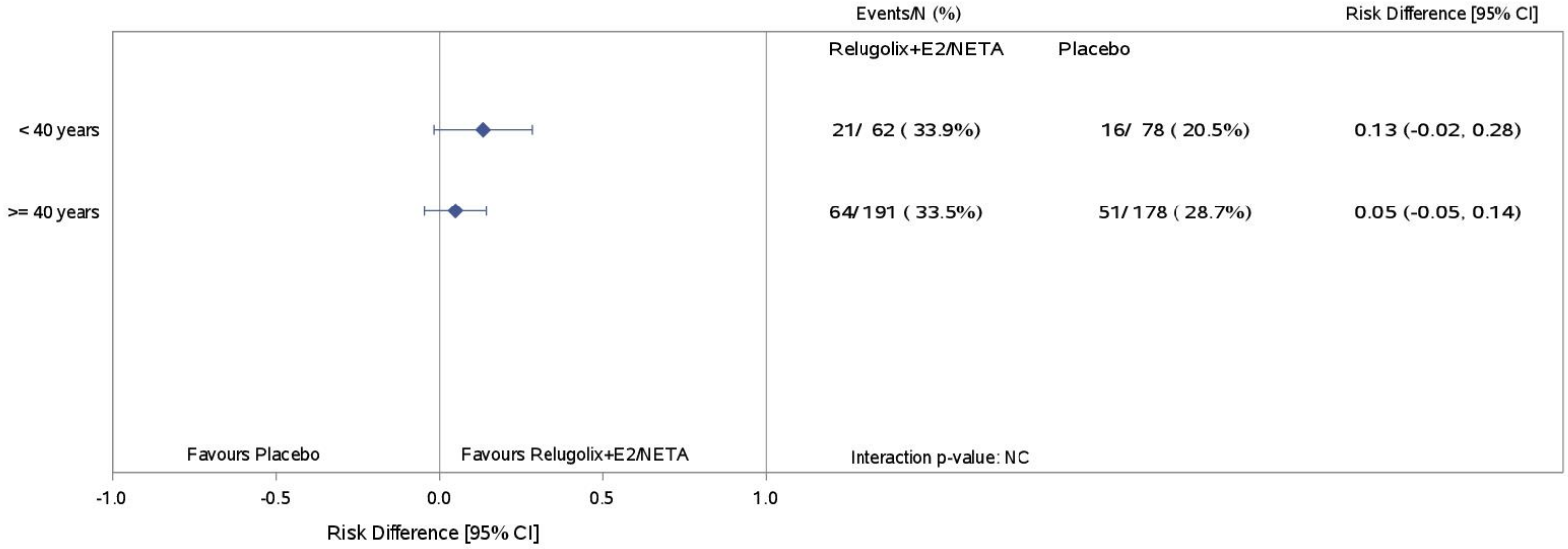
Figure QOL.EQVAS10.MITT.S1.BIN.FP.RD: Proportion of Responders with at Least 10 Points Increase in EQ-5D-5L VAS scale at Week 24, by Subgroup (mITT Population) - Risk Difference
Study: Pooled
Subgroup: Age (years)



Results are based on a Mantel-Haenszel approach stratified by study using a one-stage fixed-effects IPD meta-analysis.
The reference group is Placebo.
N: Number of patients in treatment group; NETA: Norethindrone acetate; mITT: Modified intent-to-treat; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

SOURCE: X:\Numerus\Studies\MYV\MYV102\Analysis\Prod\Progs\TFLs\Fig_QOL_QS_S_BIN_FP.SAS Date/time of run: 30JUN21 10:27
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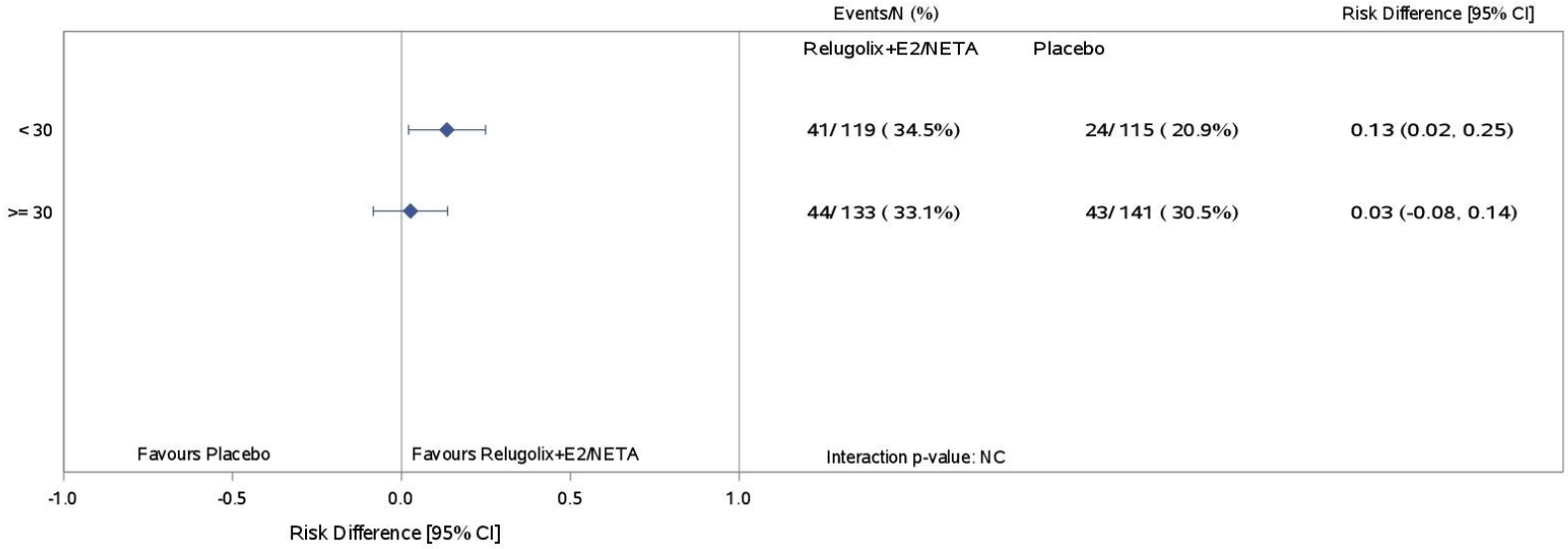
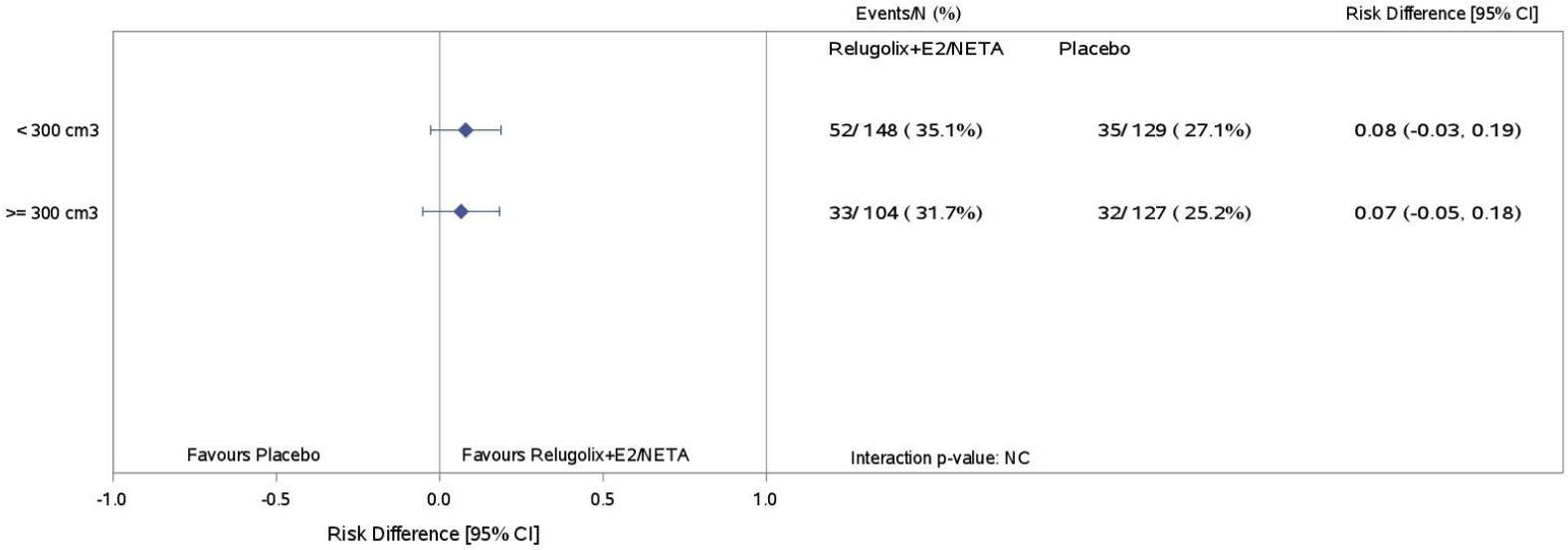
Figure QOL.EQVAS10.MITT.S2.BIN.FP.RD: Proportion of Responders with at Least 10 Points Increase in EQ-5D-5L VAS scale at Week 24, by Subgroup (mITT Population) - Risk Difference
Study: Pooled
Subgroup: BMI (kg/m2) at Baseline



Results are based on a Mantel-Haenszel approach stratified by study using a one-stage fixed-effects IPD meta-analysis.
The reference group is Placebo.
N: Number of patients in treatment group; NETA: Norethindrone acetate; mITT: Modified intent-to-treat; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

SOURCE: X:\Numerus\Studies\MYV\MYV102\Analysis\Prod\Progs\TFLs\Fig_QOL_QS_S_BIN_FP.SAS Date/time of run: 30JUN21 10:27
Analysis Plan: 13JAN2021 Confidential

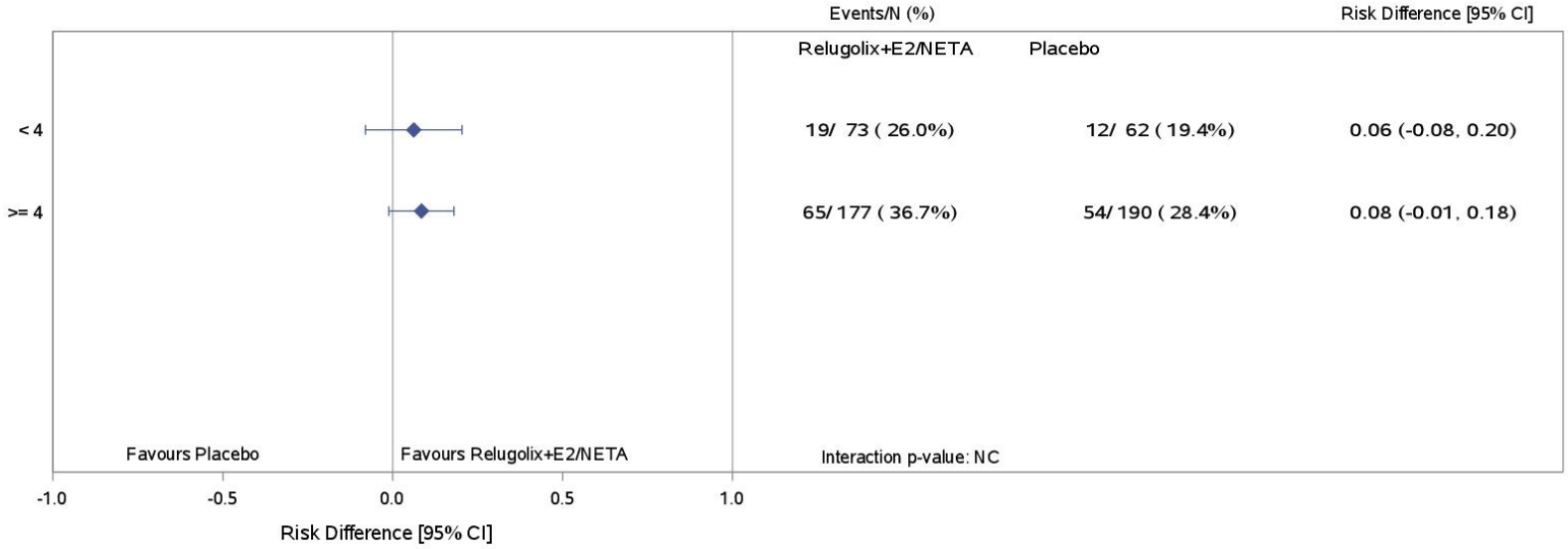
Figure QOL.EQVAS10.MITT.S3.BIN.FP.RD: Proportion of Responders with at Least 10 Points Increase in EQ-5D-5L VAS scale at Week 24, by Subgroup (mITT Population) - Risk Difference
Study: Pooled
Subgroup: Uterine Volume at Baseline (cm3)



Results are based on a Mantel-Haenszel approach stratified by study using a one-stage fixed-effects IPD meta-analysis.
The reference group is Placebo.
N: Number of patients in treatment group; NETA: Norethindrone acetate; mITT: Modified intent-to-treat; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

SOURCE: X:\Numerus\Studies\MYV\MYV102\Analysis\Prod\Progs\TFLs\Fig_QOL_QS_S_BIN_FP.SAS Date/time of run: 30JUN21 10:27
Analysis Plan: 13JAN2021 Confidential

Figure QOL.EQVAS10.MITT.S4.BIN.FP.RD: Proportion of Responders with at Least 10 Points Increase in EQ-5D-5L VAS scale at Week 24, by Subgroup (mITT Population) - Risk Difference
Study: Pooled
Subgroup: Maximum NRS Pain Score at Baseline



Results are based on a Mantel-Haenszel approach stratified by study using a one-stage fixed-effects IPD meta-analysis.
The reference group is Placebo.
N: Number of patients in treatment group; NETA: Norethindrone acetate; mITT: Modified intent-to-treat; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

SOURCE: X:\Numerus\Studies\MYV\MYV102\Analysis\Prod\Progs\TFLs\Fig_QOL_QS_S_BIN_FP.SAS Date/time of run: 30JUN21 10:27
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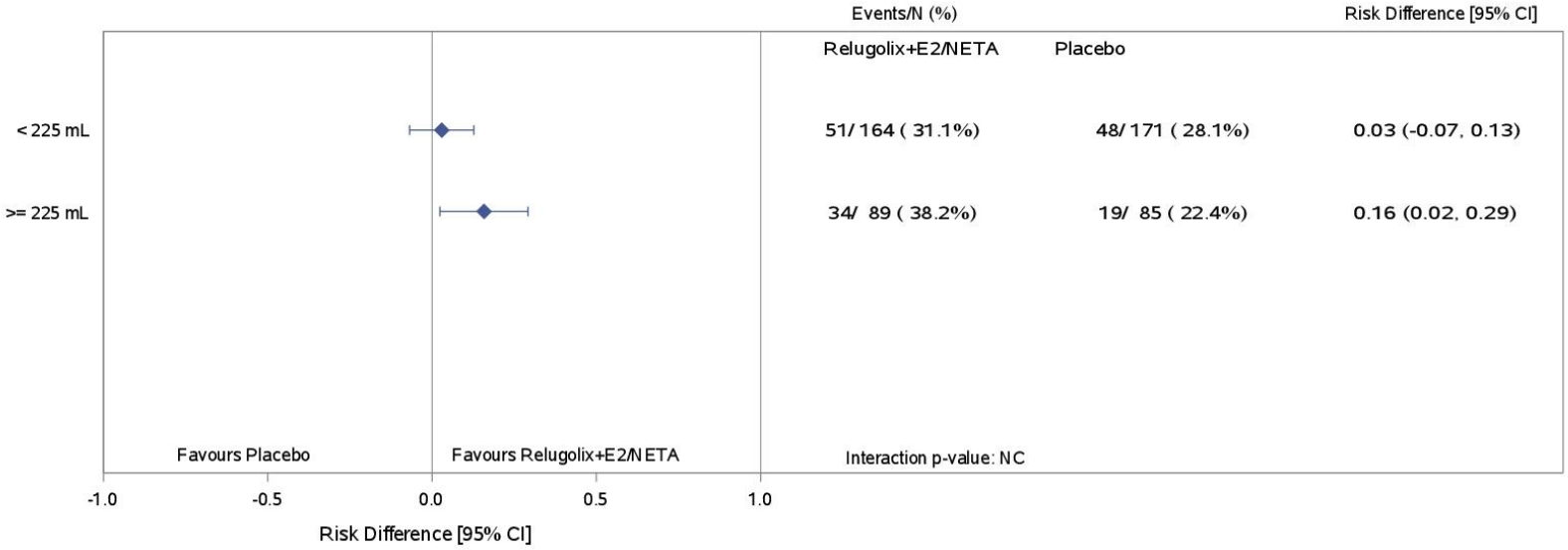
Figure QOL.EQVAS10.MITT.S5.BIN.FP.RD: Proportion of Responders with at Least 10 Points Increase in EQ-5D-5L VAS scale at Week 24, by Subgroup (mITT Population) - Risk Difference
Study: Pooled
Subgroup: MBL Volume at Baseline (mL)



Results are based on a Mantel-Haenszel approach stratified by study using a one-stage fixed-effects IPD meta-analysis.
The reference group is Placebo.
N: Number of patients in treatment group; NETA: Norethindrone acetate; mITT: Modified intent-to-treat; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

SOURCE: X:\Numerus\Studies\MYV\MYV102\Analysis\Prod\Progs\TFLs\Fig_QOL_QS_S_BIN_FP.SAS Date/time of run: 30JUN21 10:27
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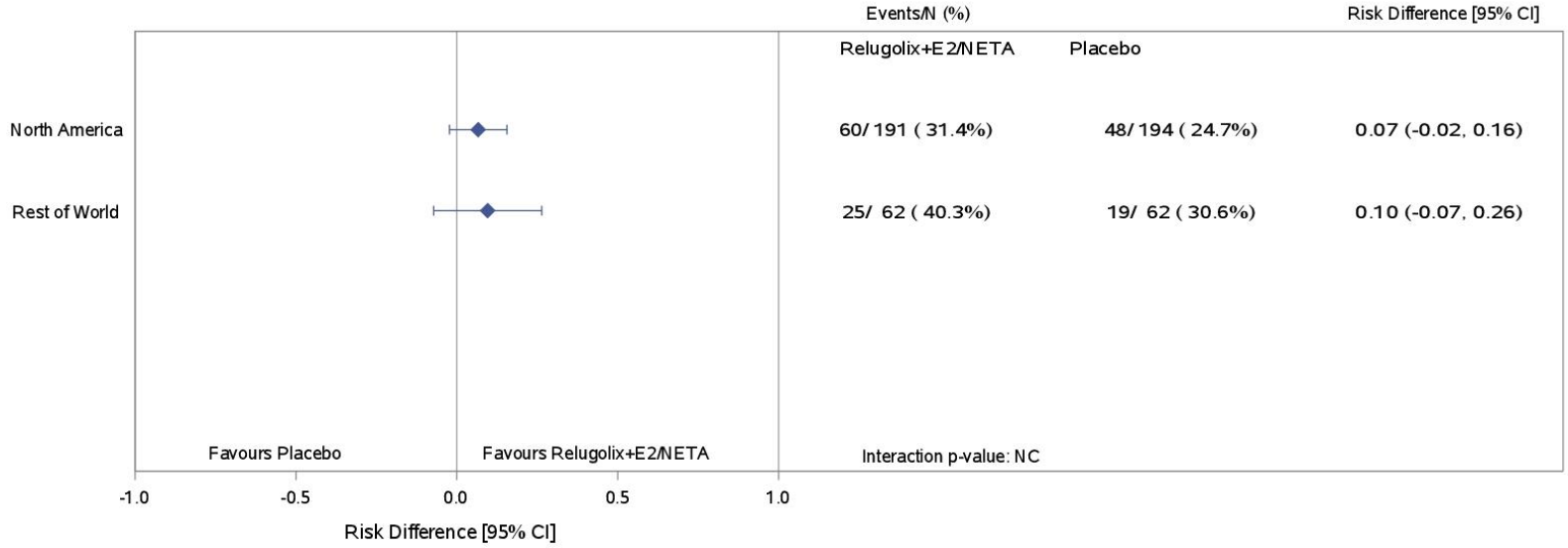
Figure QOL.EQVAS10.MITT.S6.BIN.FP.RD: Proportion of Responders with at Least 10 Points Increase in EQ-5D-5L VAS scale at Week 24, by Subgroup (mITT Population) - Risk Difference
Study: Pooled
Subgroup: Geographic Region I



Results are based on a Mantel-Haenszel approach stratified by study using a one-stage fixed-effects IPD meta-analysis.
The reference group is Placebo.
N: Number of patients in treatment group; NETA: Norethindrone acetate; mITT: Modified intent-to-treat; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

SOURCE: X:\Numerus\Studies\MYV\MYV102\Analysis\Prod\Progs\TFLs\Fig_QOL_QS_S_BIN_FP.SAS Date/time of run: 30JUN21 10:27
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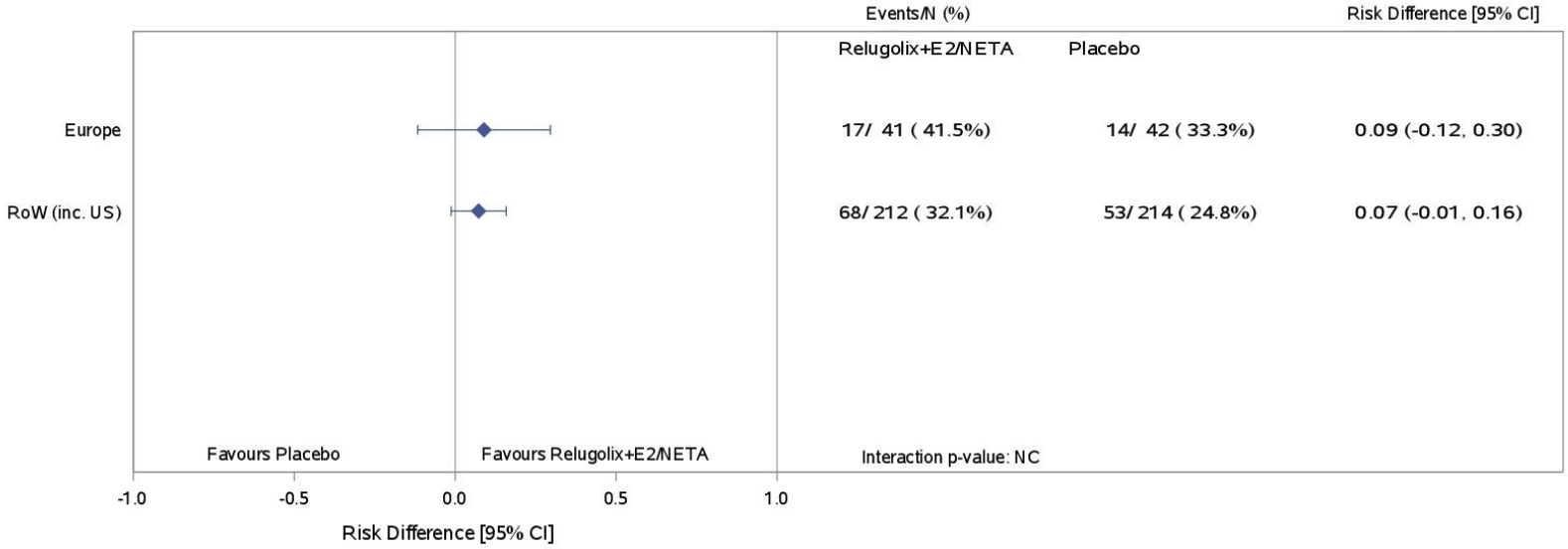
Figure QOL.EQVAS10.MITT.S7.BIN.FP.RD: Proportion of Responders with at Least 10 Points Increase in EQ-5D-5L VAS scale at Week 24, by Subgroup (mITT Population) - Risk Difference
Study: Pooled
Subgroup: Geographic Region II



Results are based on a Mantel-Haenszel approach stratified by study using a one-stage fixed-effects IPD meta-analysis.
The reference group is Placebo.
N: Number of patients in treatment group; NETA: Norethindrone acetate; mITT: Modified intent-to-treat; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

SOURCE: X:\Numerus\Studies\MYV\MYV102\Analysis\Prod\Progs\TFLs\Fig_QOL_QS_S_BIN_FP.SAS Date/time of run: 30JUN21 10:27
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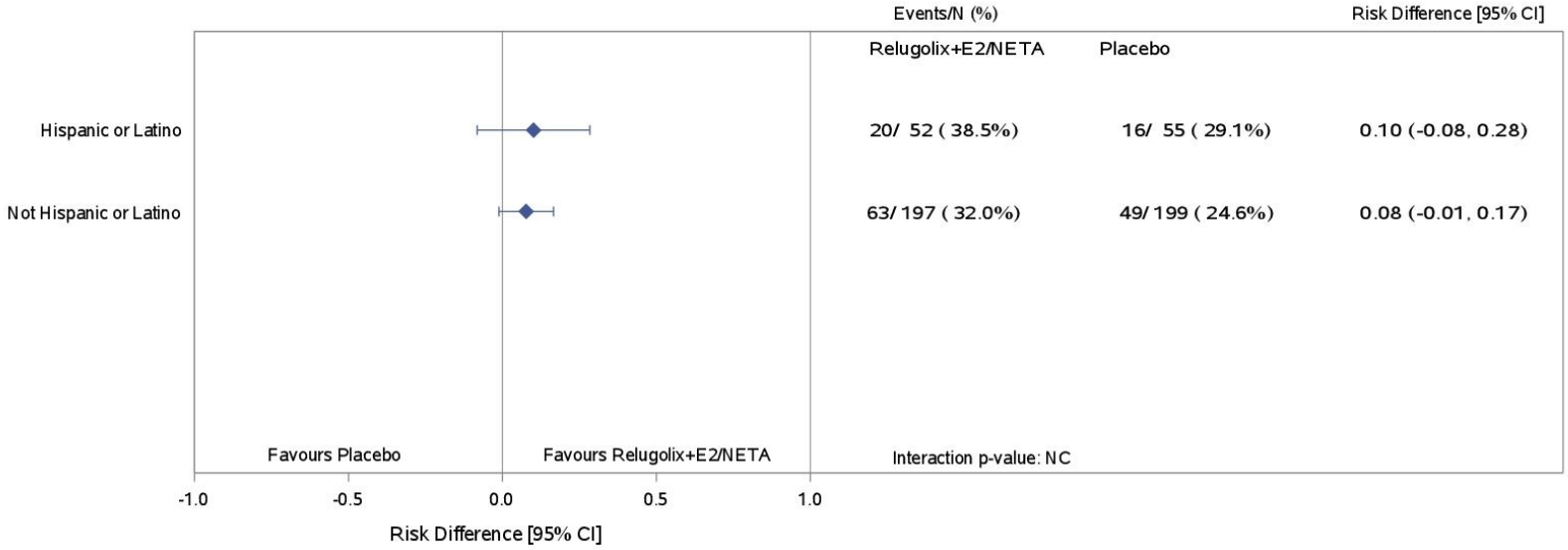
Myovant Sciences, Inc.: LIBERTY AMNOG

Figure QOL.EQVAS10.MITT.S8.BIN.FP.RD: Proportion of Responders with at Least 10 Points Increase in EQ-5D-5L VAS scale at Week 24, by Subgroup (mITT Population) - Risk Difference
Study: Pooled
Subgroup: Ethnicity



Results are based on a Mantel-Haenszel approach stratified by study using a one-stage fixed-effects IPD meta-analysis.
The reference group is Placebo.
N: Number of patients in treatment group; NETA: Norethindrone acetate; mITT: Modified intent-to-treat; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

SOURCE: X:\Numerus\Studies\MYV\MYV102\Analysis\Prod\Progs\TFLs\Fig_QOL_QS_S_BIN_FP.SAS Date/time of run: 30JUN21 10:27
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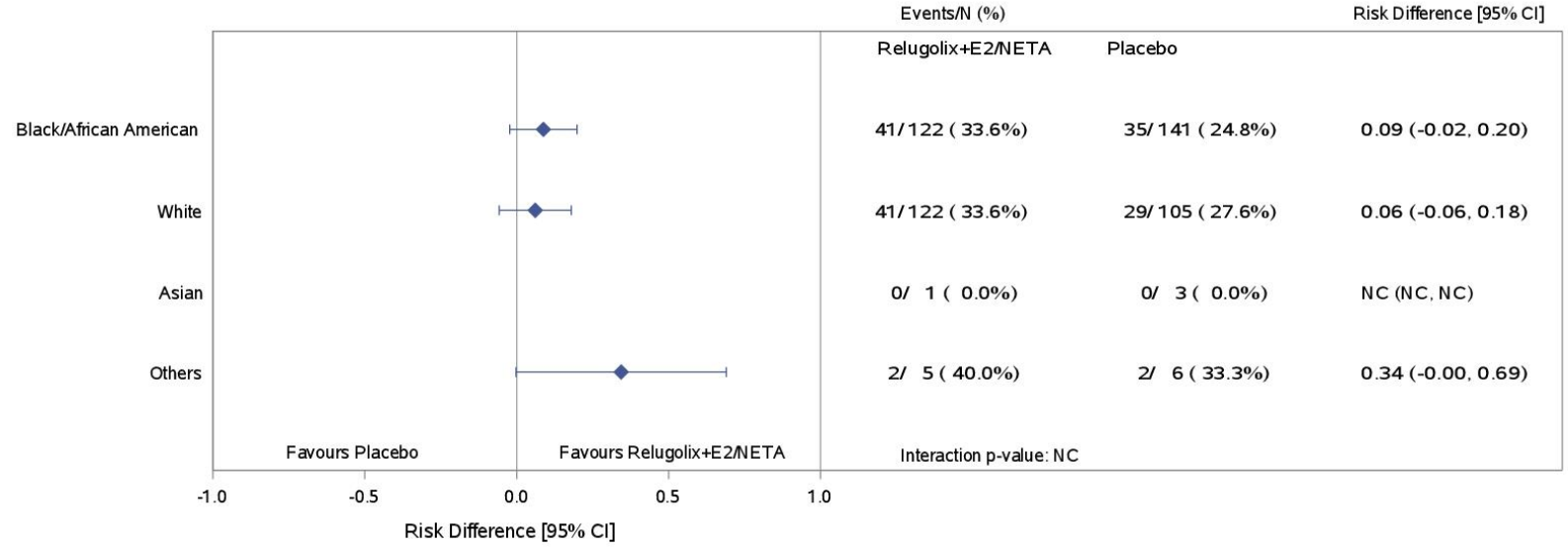
Figure QOL.EQVAS10.MITT.S9.BIN.FP.RD: Proportion of Responders with at Least 10 Points Increase in EQ-5D-5L VAS scale at Week 24, by Subgroup (mITT Population) - Risk Difference
Study: Pooled
Subgroup: Race



Results are based on a Mantel-Haenszel approach stratified by study using a one-stage fixed-effects IPD meta-analysis.
The reference group is Placebo.
N: Number of patients in treatment group; NETA: Norethindrone acetate; mITT: Modified intent-to-treat; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

SOURCE: X:\Numerus\Studies\MYV\MYV102\Analysis\Prod\Progs\TFLs\Fig_QOL_QS_S_BIN_FP.SAS Date/time of run: 30JUN21 10:27
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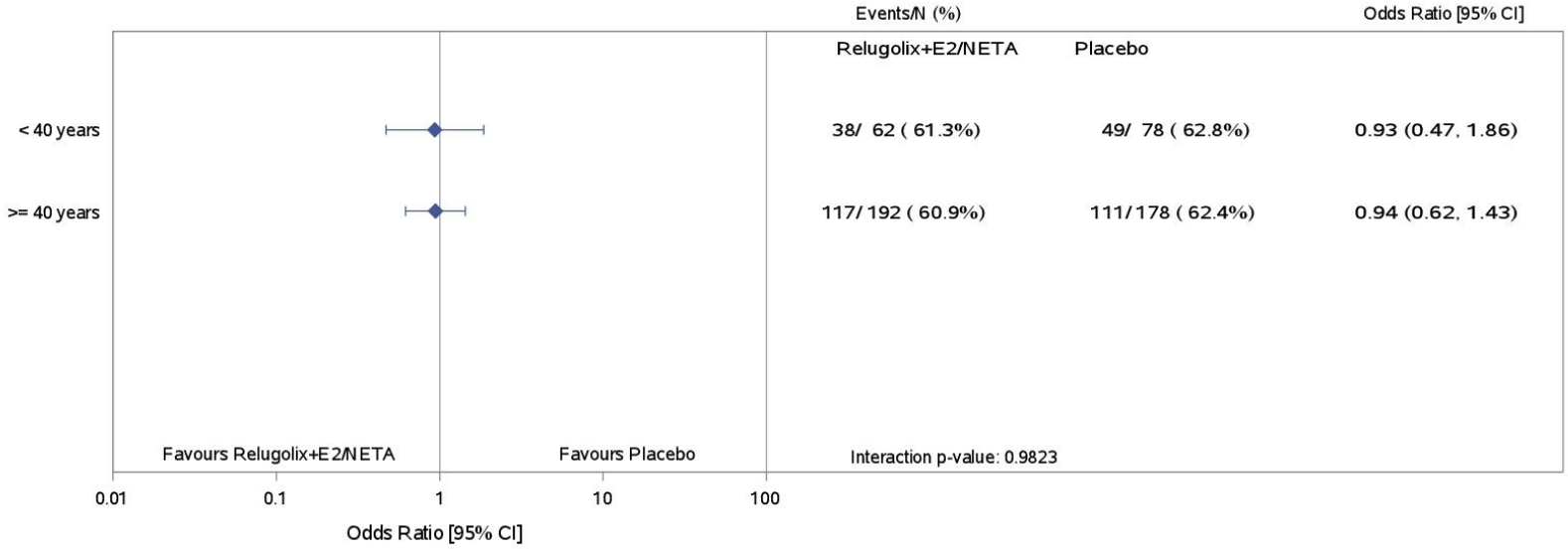
2.3 Sicherheit

2.3.1 Proportion of Patients With at Least One Treatment Emergent Adverse Event, by Subgroup (Safety Population)

Nachfolgend sind zunächst alle Forest Plots für das *Odds Ratio* dargestellt; gefolgt von den entsprechenden Forest Plots für *Risk Ratio* und *Risk Difference*.

Figure SAF.TEAE.ANY.S1.BIN.FP: Proportion of Patients With at Least One Treatment Emergent Adverse Event, by Subgroup (Safety Population)
Study: Pooled
Subgroup: Age (years)



Results are based on a logistic regression model adjusted for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates using a one-stage fixed-effects IPD meta-analysis approach. A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
The interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the Odds Ratio and 95% CI. Missing subgroup levels are not included in estimation of the interaction p-value. The reference group is Placebo. Patients with multiple events are counted only once. MedDRA (version 22.0).
N: Number of patients in treatment group; NETA: Norethindrone acetate; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

SOURCE: X:\Numerus\Studies\MYV\MYV102\Analysis\Prod\Progs\TFLs\Fig_SAF_AE_S_BIN_FP.SAS Date/time of run: 01JUL21 10:03
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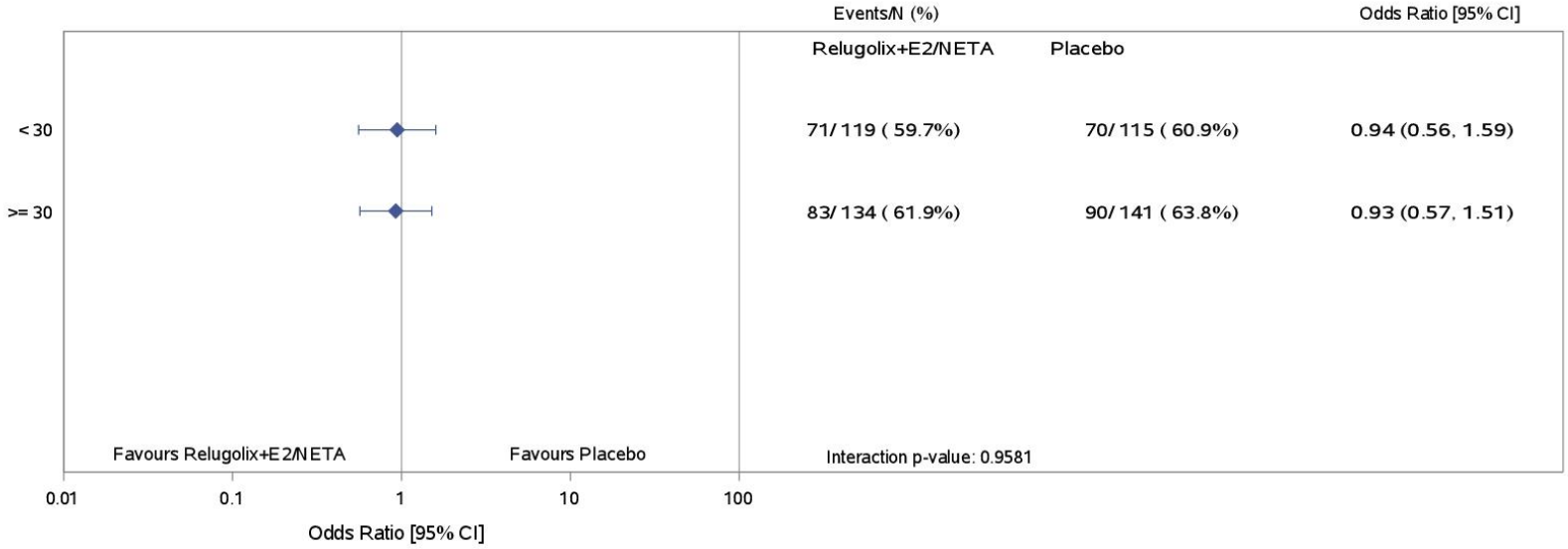
Figure SAF.TEAE.ANY.S2.BIN.FP: Proportion of Patients With at Least One Treatment Emergent Adverse Event, by Subgroup (Safety Population)
Study: Pooled
Subgroup: BMI (kg/m2) at Baseline



Results are based on a logistic regression model adjusted for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates using a one-stage fixed-effects IPD meta-analysis approach. A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
The interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the Odds Ratio and 95% CI. Missing subgroup levels are not included in estimation of the interaction p-value. The reference group is Placebo. Patients with multiple events are counted only once. MedDRA (version 22.0).
N: Number of patients in treatment group; NETA: Norethindrone acetate; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

SOURCE: X:\Numerus\Studies\MYV\MYV102\Analysis\Prod\Progs\TFLs\Fig_SAF_AE_S_BIN_FP.SAS Date/time of run: 01JUL21 10:03
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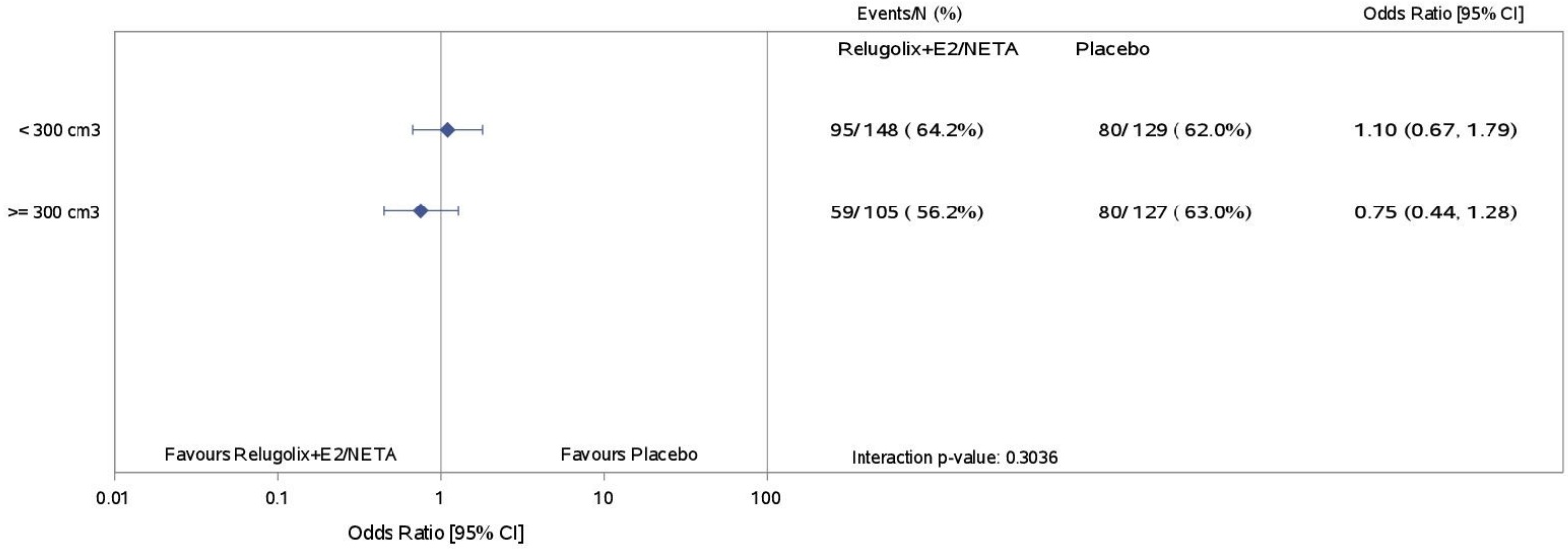
Figure SAF.TEAE.ANY.S3.BIN.FP: Proportion of Patients With at Least One Treatment Emergent Adverse Event, by Subgroup (Safety Population)
Study: Pooled
Subgroup: Uterine Volume at Baseline (cm3)



Results are based on a logistic regression model adjusted for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates using a one-stage fixed-effects IPD meta-analysis approach. A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
The interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the Odds Ratio and 95% CI. Missing subgroup levels are not included in estimation of the interaction p-value. The reference group is Placebo. Patients with multiple events are counted only once. MedDRA (version 22.0).
N: Number of patients in treatment group; NETA: Norethindrone acetate; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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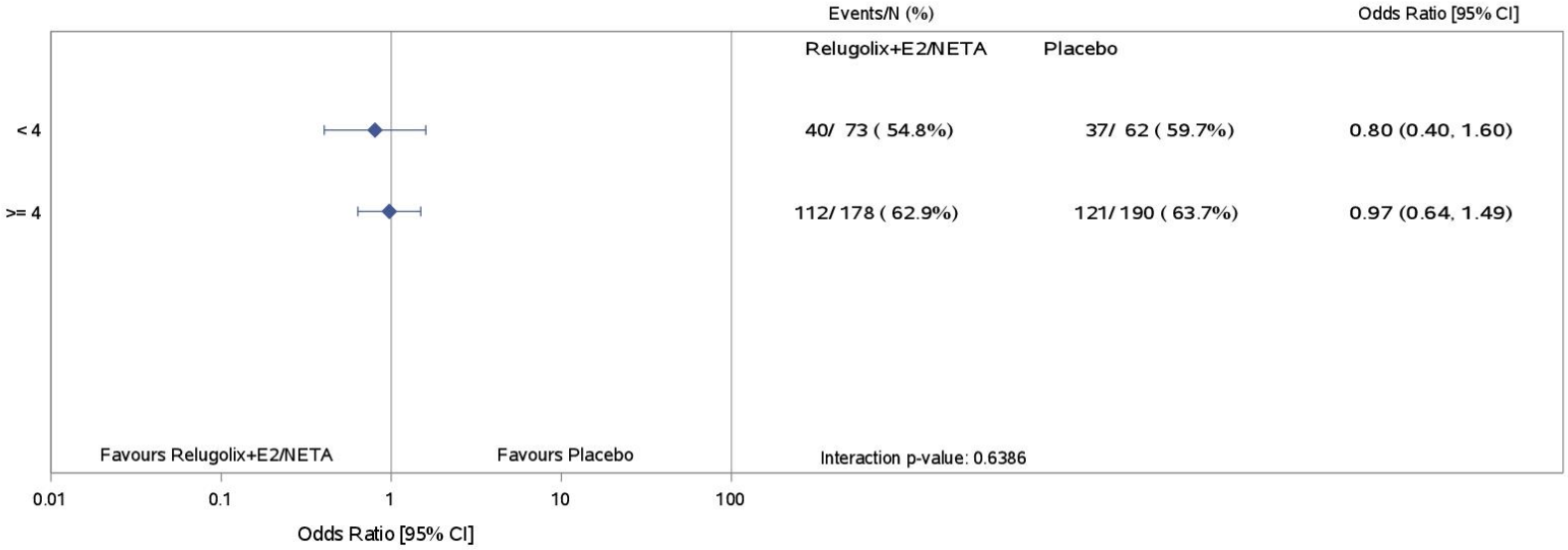
Figure SAF.TEAE.ANY.S4.BIN.FP: Proportion of Patients With at Least One Treatment Emergent Adverse Event, by Subgroup (Safety Population)
Study: Pooled
Subgroup: Maximum NRS Pain Score at Baseline



Results are based on a logistic regression model adjusted for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates using a one-stage fixed-effects IPD meta-analysis approach. A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
The interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the Odds Ratio and 95% CI. Missing subgroup levels are not included in estimation of the interaction p-value. The reference group is Placebo. Patients with multiple events are counted only once. MedDRA (version 22.0).
N: Number of patients in treatment group; NETA: Norethindrone acetate; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

SOURCE: X:\Numerus\Studies\MYV\MYV102\Analysis\Prod\Progs\TFLs\Fig_SAF_AE_S_BIN_FP.SAS Date/time of run: 01JUL21 10:03
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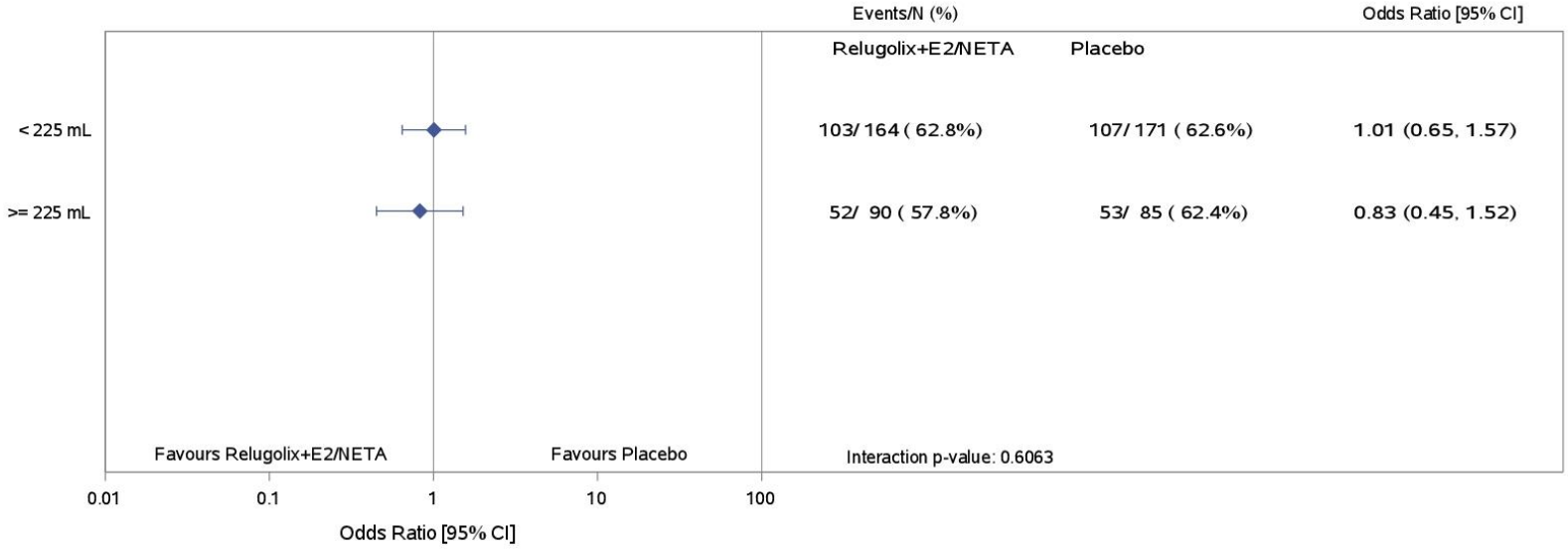
Figure SAF.TEAE.ANY.S5.BIN.FP: Proportion of Patients With at Least One Treatment Emergent Adverse Event, by Subgroup (Safety Population)
Study: Pooled
Subgroup: MBL Volume at Baseline (mL)



Results are based on a logistic regression model adjusted for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates using a one-stage fixed-effects IPD meta-analysis approach. A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
The interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the Odds Ratio and 95% CI. Missing subgroup levels are not included in estimation of the interaction p-value. The reference group is Placebo. Patients with multiple events are counted only once. MedDRA (version 22.0).
N: Number of patients in treatment group; NETA: Norethindrone acetate; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

SOURCE: X:\Numerus\Studies\MYV\MYV102\Analysis\Prod\Progs\TFLs\Fig_SAF_AE_S_BIN_FP.SAS Date/time of run: 01JUL21 10:03
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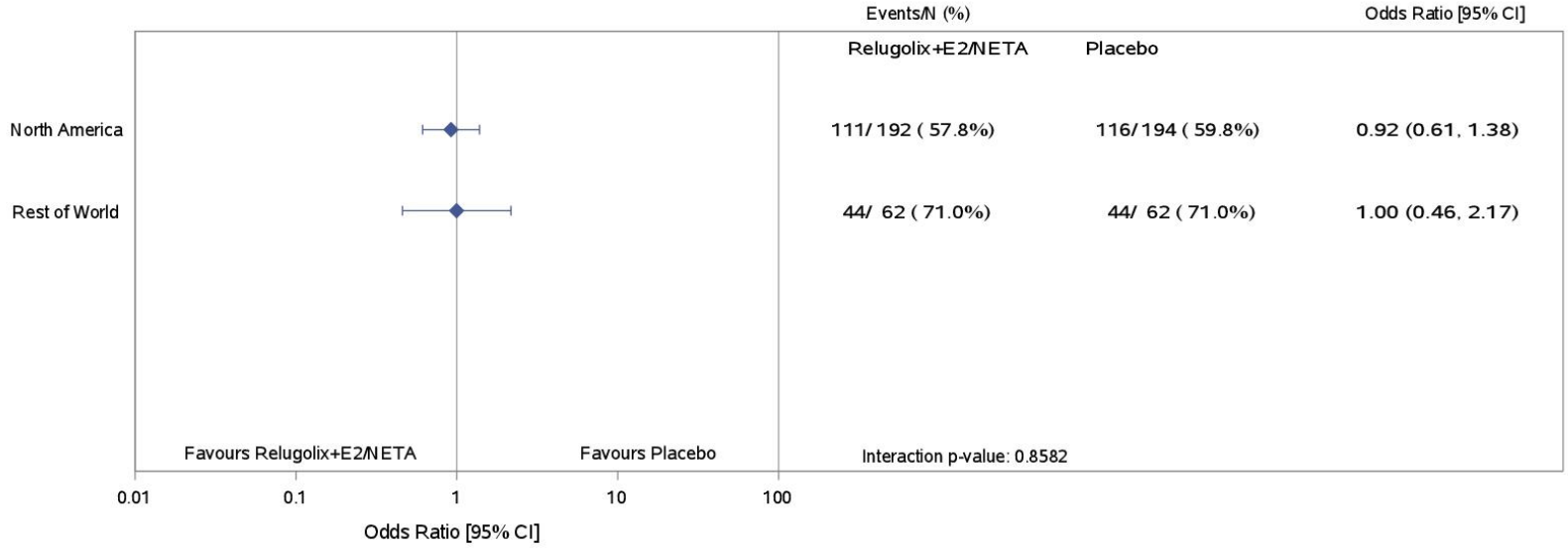
Figure SAF.TEAE.ANY.S6.BIN.FP: Proportion of Patients With at Least One Treatment Emergent Adverse Event, by Subgroup (Safety Population)
Study: Pooled
Subgroup: Geographic Region I



Results are based on a logistic regression model adjusted for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates using a one-stage fixed-effects IPD meta-analysis approach. A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
The interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the Odds Ratio and 95% CI. Missing subgroup levels are not included in estimation of the interaction p-value. The reference group is Placebo. Patients with multiple events are counted only once. MedDRA (version 22.0).
N: Number of patients in treatment group; NETA: Norethindrone acetate; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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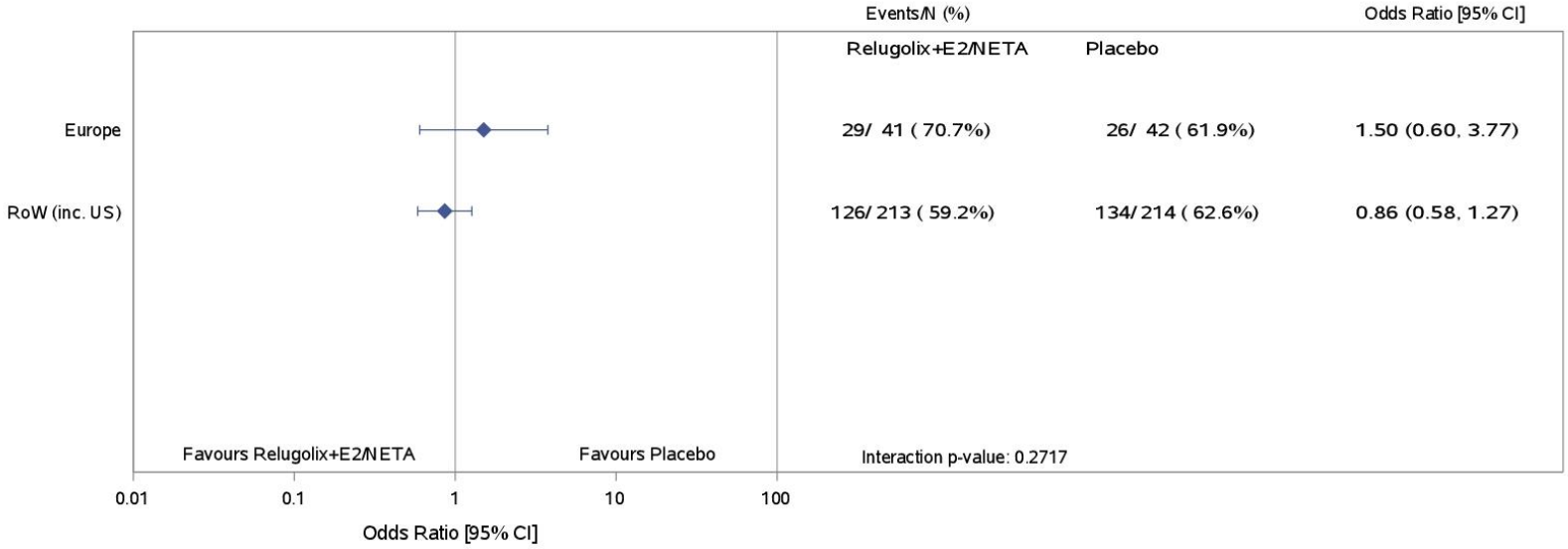
Figure SAF.TEAE.ANY.S7.BIN.FP: Proportion of Patients With at Least One Treatment Emergent Adverse Event, by Subgroup (Safety Population)
Study: Pooled
Subgroup: Geographic Region II



Results are based on a logistic regression model adjusted for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates using a one-stage fixed-effects IPD meta-analysis approach. A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
The interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the Odds Ratio and 95% CI. Missing subgroup levels are not included in estimation of the interaction p-value. The reference group is Placebo. Patients with multiple events are counted only once. MedDRA (version 22.0).
N: Number of patients in treatment group; NETA: Norethindrone acetate; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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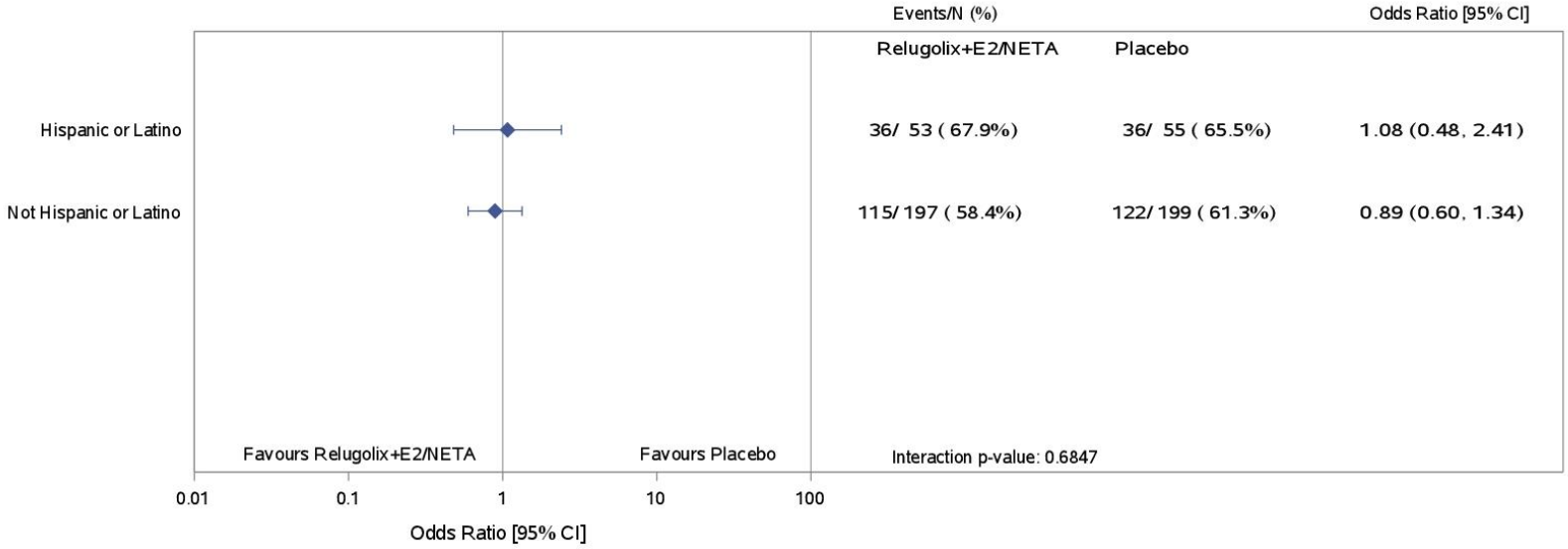
Figure SAF.TEAE.ANY.S8.BIN.FP: Proportion of Patients With at Least One Treatment Emergent Adverse Event, by Subgroup (Safety Population)
Study: Pooled
Subgroup: Ethnicity



Results are based on a logistic regression model adjusted for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates using a one-stage fixed-effects IPD meta-analysis approach. A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
The interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the Odds Ratio and 95% CI. Missing subgroup levels are not included in estimation of the interaction p-value. The reference group is Placebo. Patients with multiple events are counted only once. MedDRA (version 22.0).
N: Number of patients in treatment group; NETA: Norethindrone acetate; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

SOURCE: X:\Numerus\Studies\MYV\MYV102\Analysis\Prod\Progs\TFLs\Fig_SAF_AE_S_BIN_FP.SAS Date/time of run: 01JUL21 10:03
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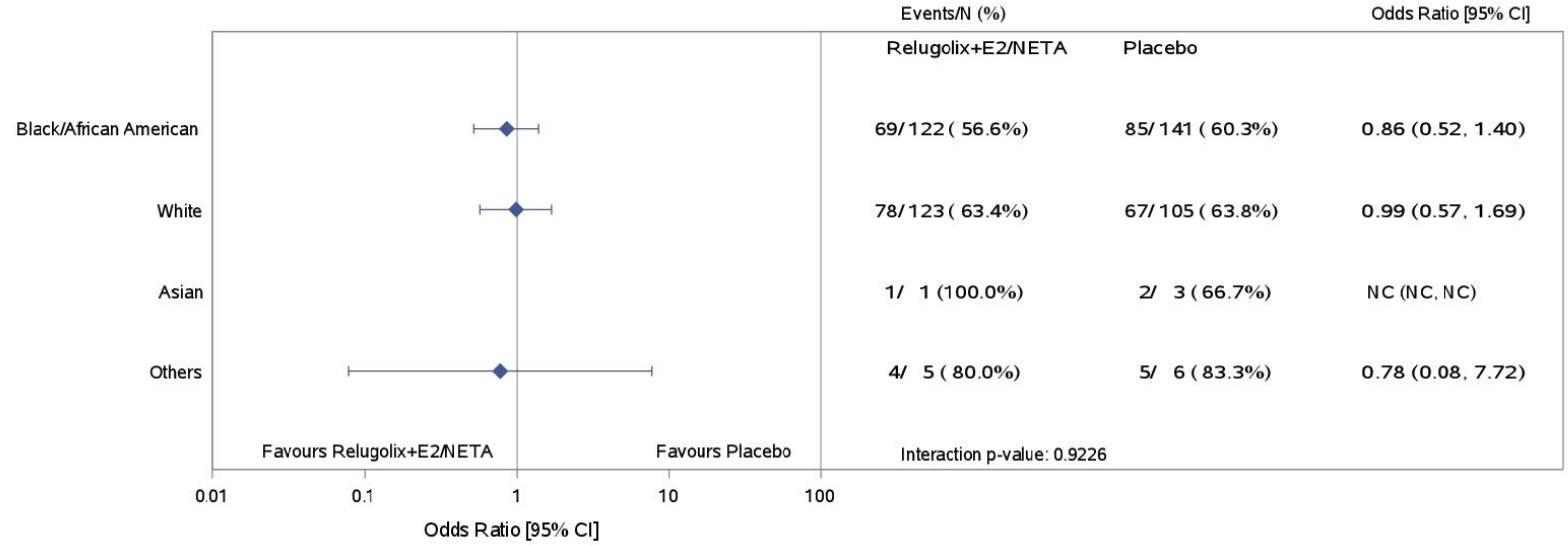
Figure SAF.TEAE.ANY.S9.BIN.FP: Proportion of Patients With at Least One Treatment Emergent Adverse Event, by Subgroup (Safety Population)
Study: Pooled
Subgroup: Race



Results are based on a logistic regression model adjusted for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates using a one-stage fixed-effects IPD meta-analysis approach. A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
The interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the Odds Ratio and 95% CI. Missing subgroup levels are not included in estimation of the interaction p-value. The reference group is Placebo. Patients with multiple events are counted only once. MedDRA (version 22.0).
N: Number of patients in treatment group; NETA: Norethindrone acetate; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

SOURCE: X:\Numerus\Studies\MYV\MYV102\Analysis\Prod\Progs\TFLs\Fig_SAF_AE_S_BIN_FP.SAS Date/time of run: 01JUL21 10:03
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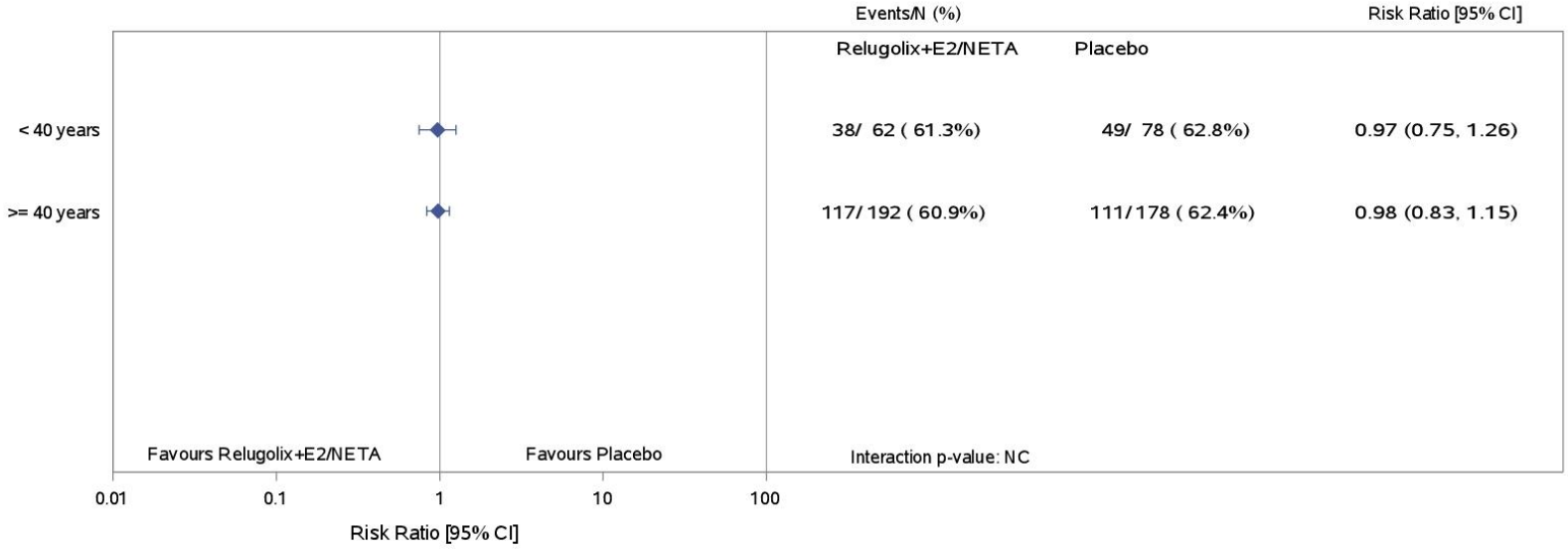
Figure SAF.TEAE.ANY.S1.BIN.FP.RR: Proportion of Patients With at Least One Treatment Emergent Adverse Event, by Subgroup (Safety Population) - Risk Ratio
Study: Pooled
Subgroup: Age (years)



Results are based on a Cochran-Mantel-Haenszel approach stratified by study using a one-stage fixed-effects IPD meta-analysis. A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
The reference group is Placebo. Patients with multiple events are counted only once. MedDRA (version 22.0).
N: Number of patients in treatment group; NETA: Norethindrone acetate; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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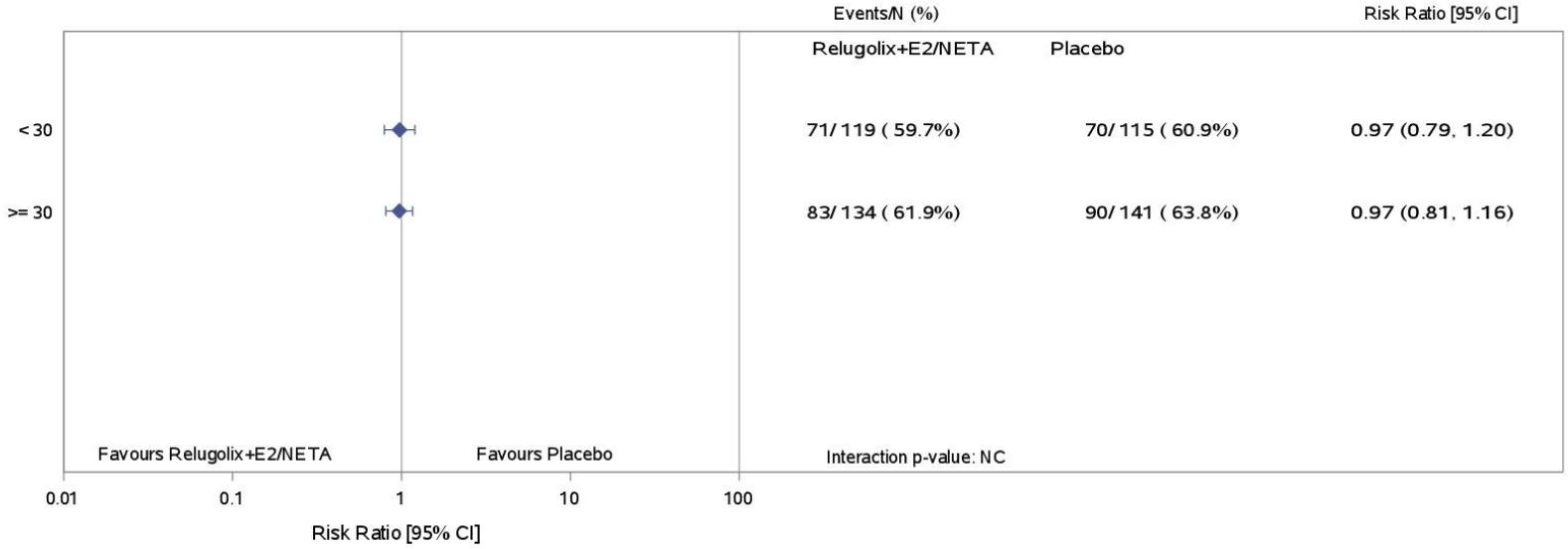
Figure SAF.TEAE.ANY.S2.BIN.FP.RR: Proportion of Patients With at Least One Treatment Emergent Adverse Event, by Subgroup (Safety Population) - Risk Ratio
Study: Pooled
Subgroup: BMI (kg/m2) at Baseline



Results are based on a Cochran-Mantel-Haenszel approach stratified by study using a one-stage fixed-effects IPD meta-analysis. A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
The reference group is Placebo. Patients with multiple events are counted only once. MedDRA (version 22.0).
N: Number of patients in treatment group; NETA: Norethindrone acetate; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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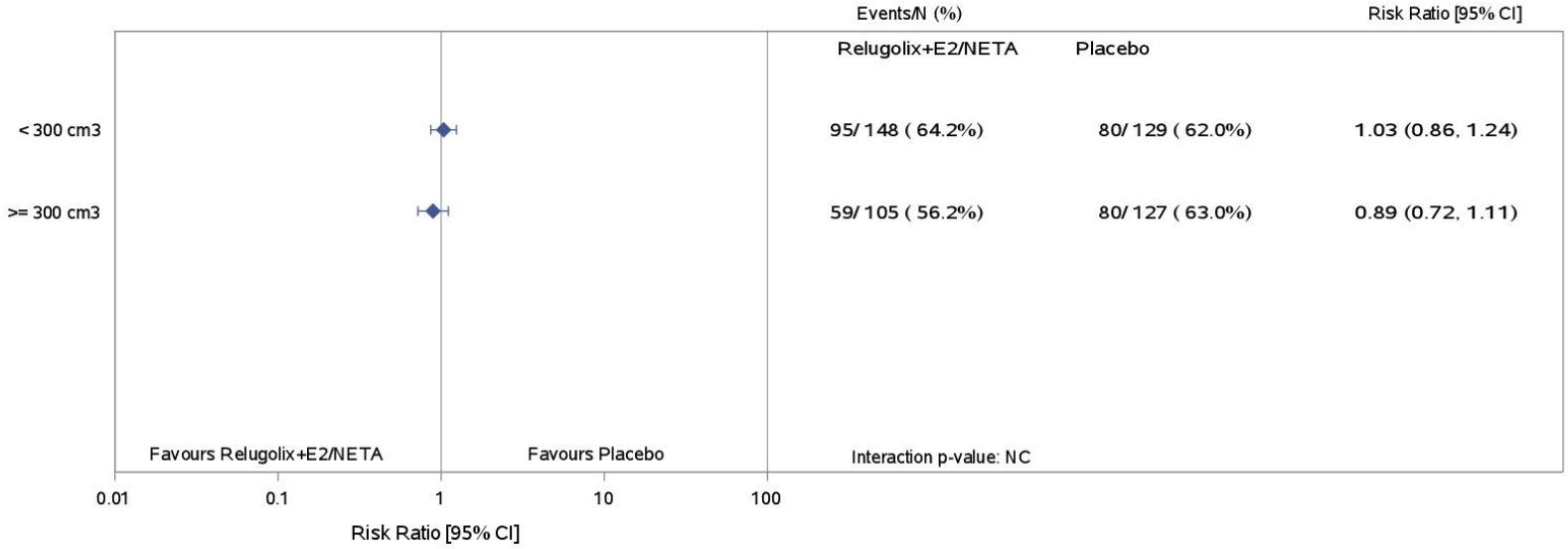
Figure SAF.TEAE.ANY.S3.BIN.FP.RR: Proportion of Patients With at Least One Treatment Emergent Adverse Event, by Subgroup (Safety Population) - Risk Ratio
Study: Pooled
Subgroup: Uterine Volume at Baseline (cm3)



Results are based on a Cochran-Mantel-Haenszel approach stratified by study using a one-stage fixed-effects IPD meta-analysis. A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
The reference group is Placebo. Patients with multiple events are counted only once. MedDRA (version 22.0).
N: Number of patients in treatment group; NETA: Norethindrone acetate; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

SOURCE: X:\Numerus\Studies\MYV\MYV102\Analysis\Prod\Progs\TFLs\Fig_SAF_AE_S_BIN_FP.SAS Date/time of run: 01JUL21 10:03
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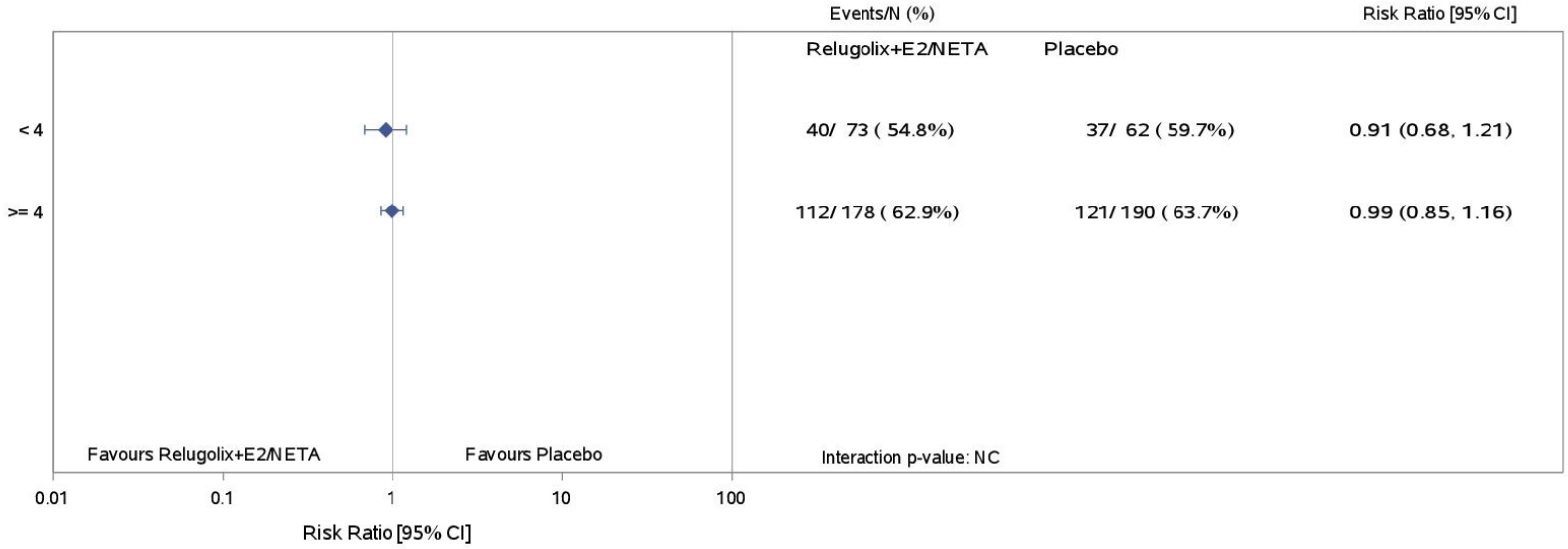
Figure SAF.TEAE.ANY.S4.BIN.FP.RR: Proportion of Patients With at Least One Treatment Emergent Adverse Event, by Subgroup (Safety Population) - Risk Ratio
Study: Pooled
Subgroup: Maximum NRS Pain Score at Baseline



Results are based on a Cochran-Mantel-Haenszel approach stratified by study using a one-stage fixed-effects IPD meta-analysis. A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
The reference group is Placebo. Patients with multiple events are counted only once. MedDRA (version 22.0).
N: Number of patients in treatment group; NETA: Norethindrone acetate; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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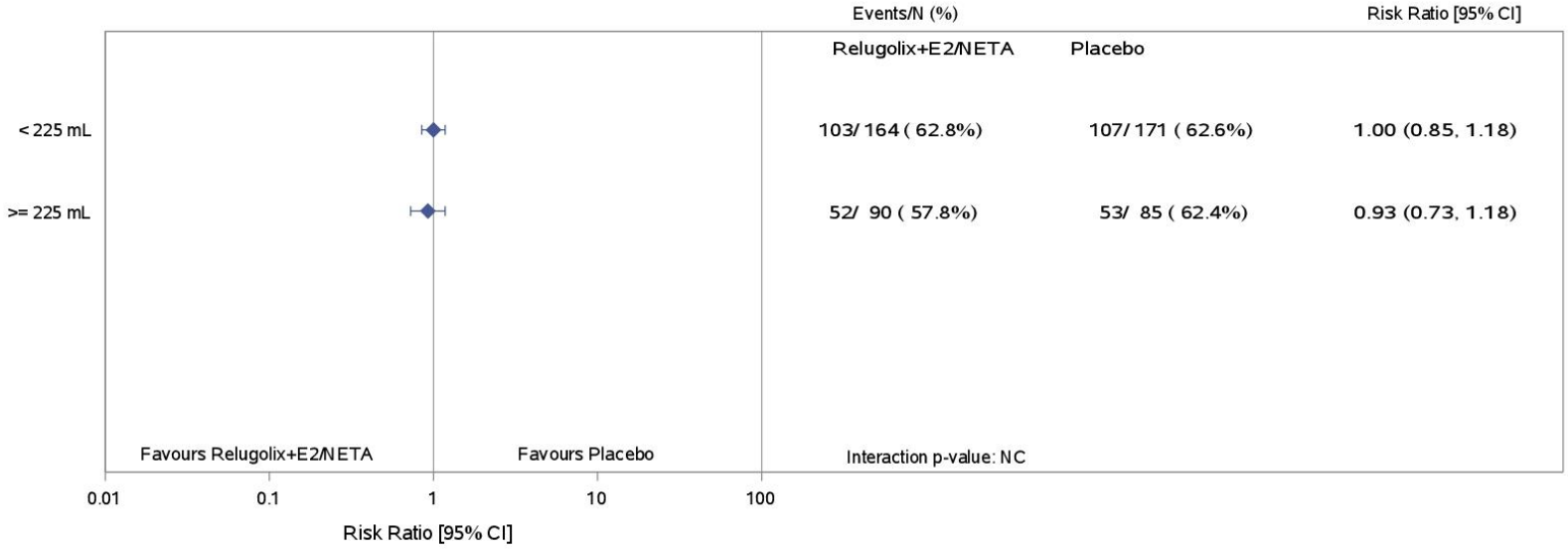
Figure SAF.TEAE.ANY.S5.BIN.FP.RR: Proportion of Patients With at Least One Treatment Emergent Adverse Event, by Subgroup (Safety Population) - Risk Ratio
Study: Pooled
Subgroup: MBL Volume at Baseline (mL)



Results are based on a Cochran-Mantel-Haenszel approach stratified by study using a one-stage fixed-effects IPD meta-analysis. A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
The reference group is Placebo. Patients with multiple events are counted only once. MedDRA (version 22.0).
N: Number of patients in treatment group; NETA: Norethindrone acetate; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

SOURCE: X:\Numerus\Studies\MYV\MYV102\Analysis\Prod\Progs\TFLs\Fig_SAF_AE_S_BIN_FP.SAS Date/time of run: 01JUL21 10:03
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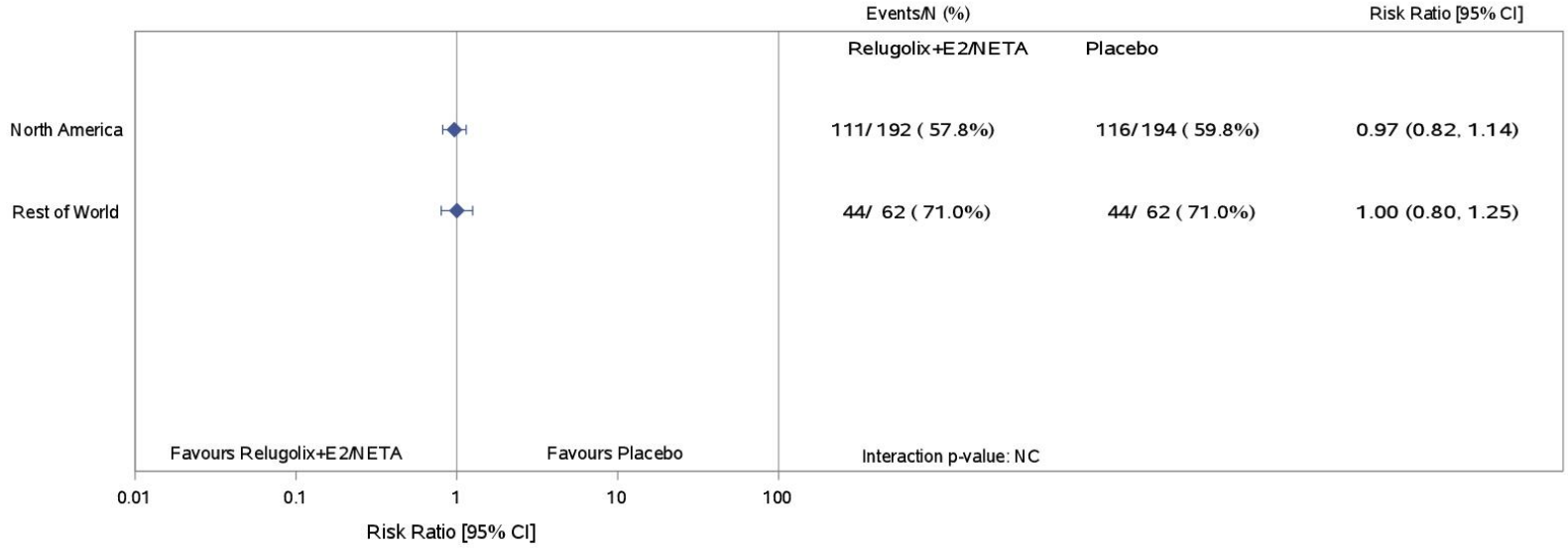
Figure SAF.TEAE.ANY.S6.BIN.FP.RR: Proportion of Patients With at Least One Treatment Emergent Adverse Event, by Subgroup (Safety Population) - Risk Ratio
Study: Pooled
Subgroup: Geographic Region I



Results are based on a Cochran-Mantel-Haenszel approach stratified by study using a one-stage fixed-effects IPD meta-analysis. A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
The reference group is Placebo. Patients with multiple events are counted only once. MedDRA (version 22.0).
N: Number of patients in treatment group; NETA: Norethindrone acetate; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

SOURCE: X:\Numerus\Studies\MYV\MYV102\Analysis\Prod\Progs\TFLs\Fig_SAF_AE_S_BIN_FP.SAS Date/time of run: 01JUL21 10:03
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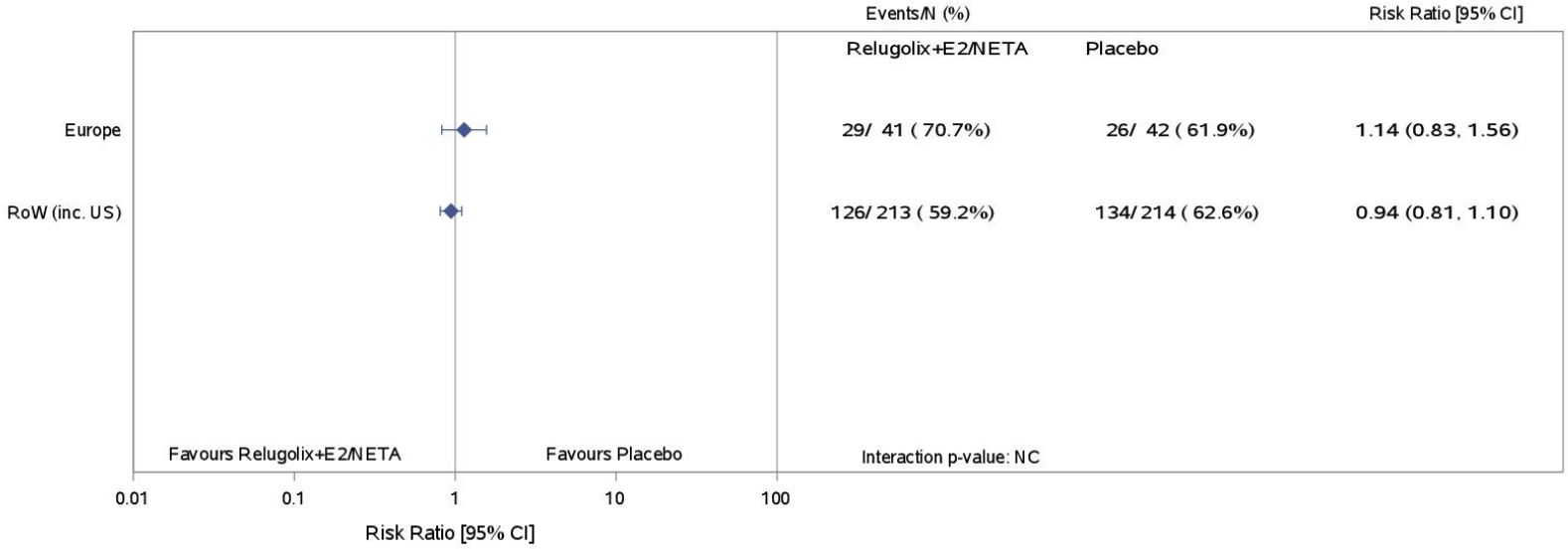
Figure SAF.TEAE.ANY.S7.BIN.FP.RR: Proportion of Patients With at Least One Treatment Emergent Adverse Event, by Subgroup (Safety Population) - Risk Ratio
Study: Pooled
Subgroup: Geographic Region II



Results are based on a Cochran-Mantel-Haenszel approach stratified by study using a one-stage fixed-effects IPD meta-analysis. A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
The reference group is Placebo. Patients with multiple events are counted only once. MedDRA (version 22.0).
N: Number of patients in treatment group; NETA: Norethindrone acetate; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

SOURCE: X:\Numerus\Studies\MYV\MYV102\Analysis\Prod\Progs\TFLs\Fig_SAF_AE_S_BIN_FP.SAS Date/time of run: 01JUL21 10:03
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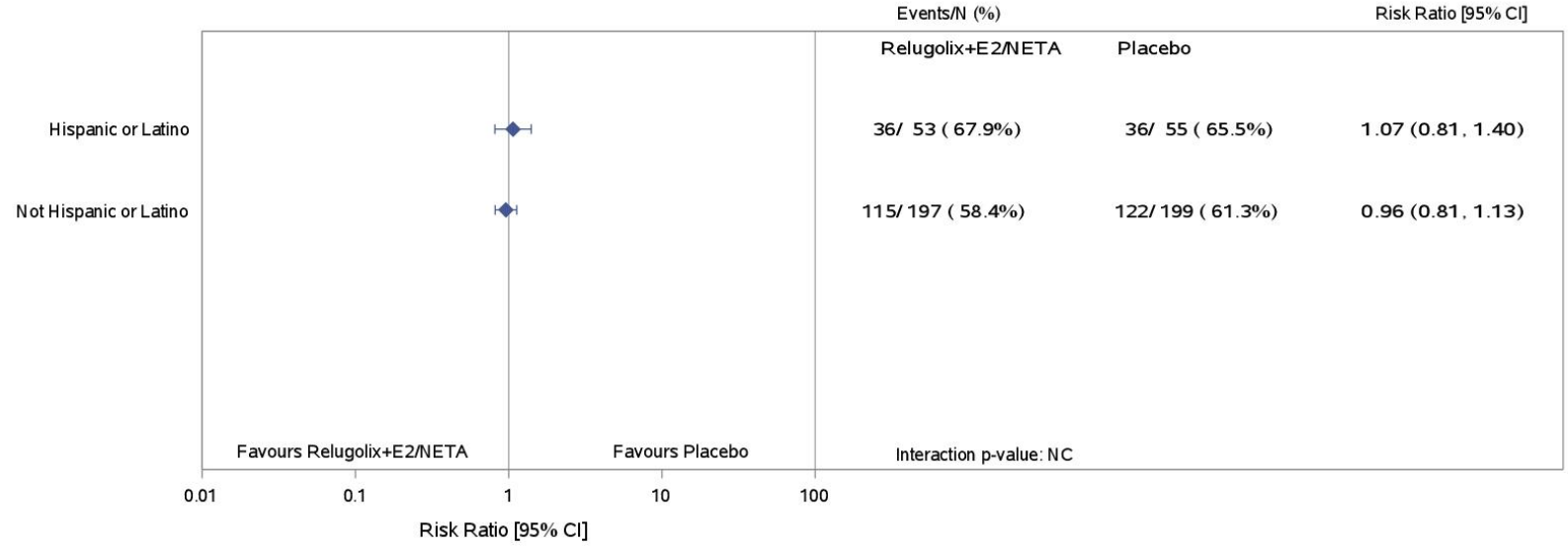
Figure SAF.TEAE.ANY.S8.BIN.FP.RR: Proportion of Patients With at Least One Treatment Emergent Adverse Event, by Subgroup (Safety Population) - Risk Ratio
Study: Pooled
Subgroup: Ethnicity



Results are based on a Cochran-Mantel-Haenszel approach stratified by study using a one-stage fixed-effects IPD meta-analysis. A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
The reference group is Placebo. Patients with multiple events are counted only once. MedDRA (version 22.0).
N: Number of patients in treatment group; NETA: Norethindrone acetate; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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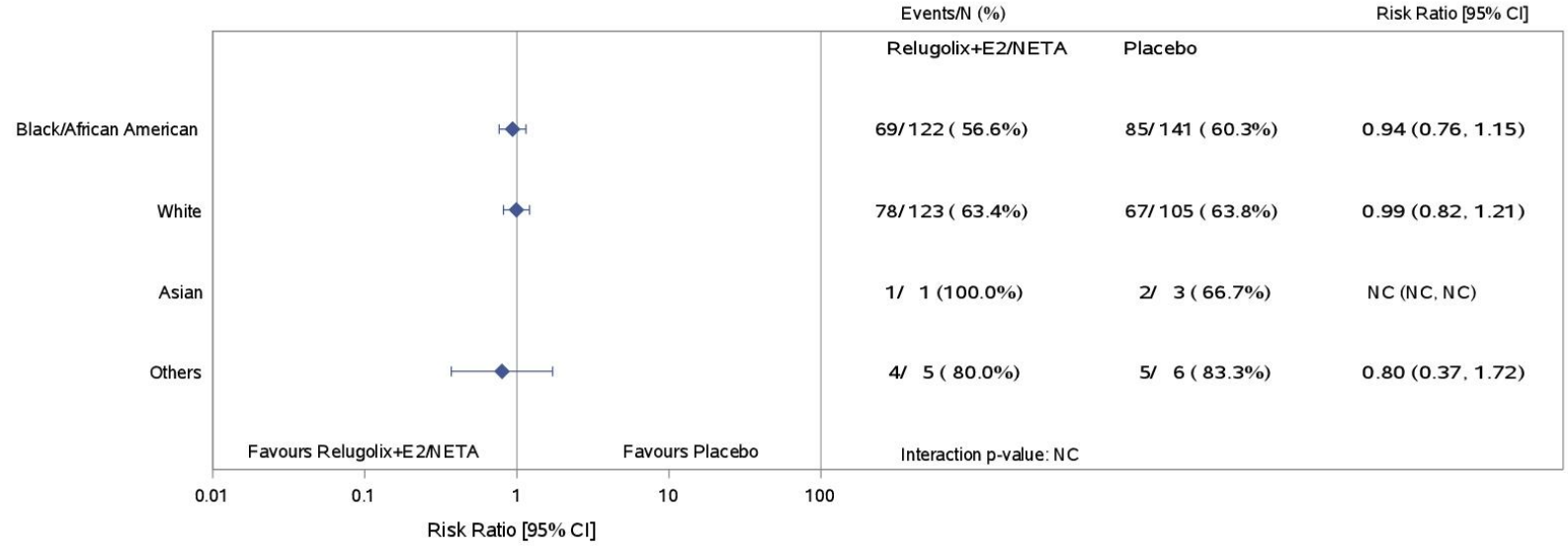
Figure SAF.TEAE.ANY.S9.BIN.FP.RR: Proportion of Patients With at Least One Treatment Emergent Adverse Event, by Subgroup (Safety Population) - Risk Ratio
Study: Pooled
Subgroup: Race



Results are based on a Cochran-Mantel-Haenszel approach stratified by study using a one-stage fixed-effects IPD meta-analysis. A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
The reference group is Placebo. Patients with multiple events are counted only once. MedDRA (version 22.0).
N: Number of patients in treatment group; NETA: Norethindrone acetate; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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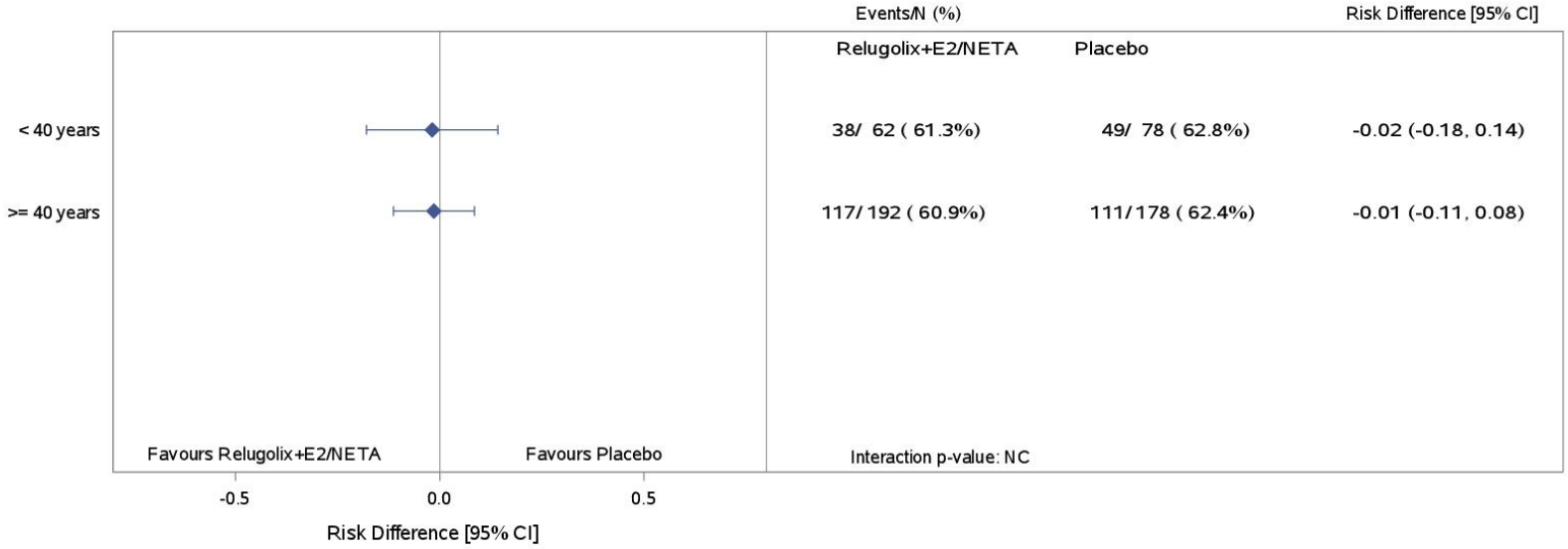
Figure SAF.TEAE.ANY.S1.BIN.FP.RD: Proportion of Patients With at Least One Treatment Emergent Adverse Event, by Subgroup (Safety Population) - Risk Difference
Study: Pooled
Subgroup: Age (years)



Results are based on a Mantel-Haenszel approach stratified by study using a one-stage fixed-effects IPD meta-analysis.
The reference group is Placebo. Patients with multiple events are counted only once. MedDRA (version 22.0).
N: Number of patients in treatment group; NETA: Norethindrone acetate; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

SOURCE: X:\Numerus\Studies\MYV\MYV102\Analysis\Prod\Progs\TFLs\Fig_SAF_AE_S_BIN_FP.SAS Date/time of run: 01JUL21 10:03
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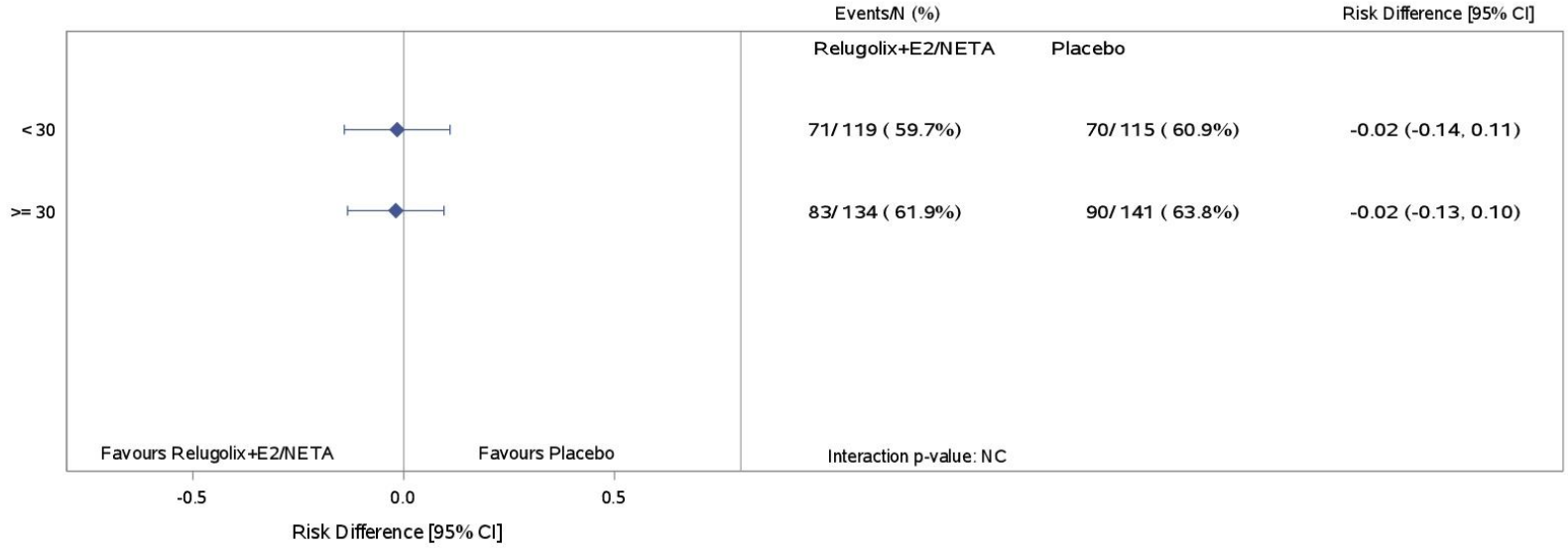
Figure SAF.TEAE.ANY.S2.BIN.FP.RD: Proportion of Patients With at Least One Treatment Emergent Adverse Event, by Subgroup (Safety Population) - Risk Difference
Study: Pooled
Subgroup: BMI (kg/m2) at Baseline



Results are based on a Mantel-Haenszel approach stratified by study using a one-stage fixed-effects IPD meta-analysis.
The reference group is Placebo. Patients with multiple events are counted only once. MedDRA (version 22.0).
N: Number of patients in treatment group; NETA: Norethindrone acetate; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

SOURCE: X:\Numerus\Studies\MYV\MYV102\Analysis\Prod\Progs\TFLs\Fig_SAF_AE_S_BIN_FP.SAS Date/time of run: 01JUL21 10:03
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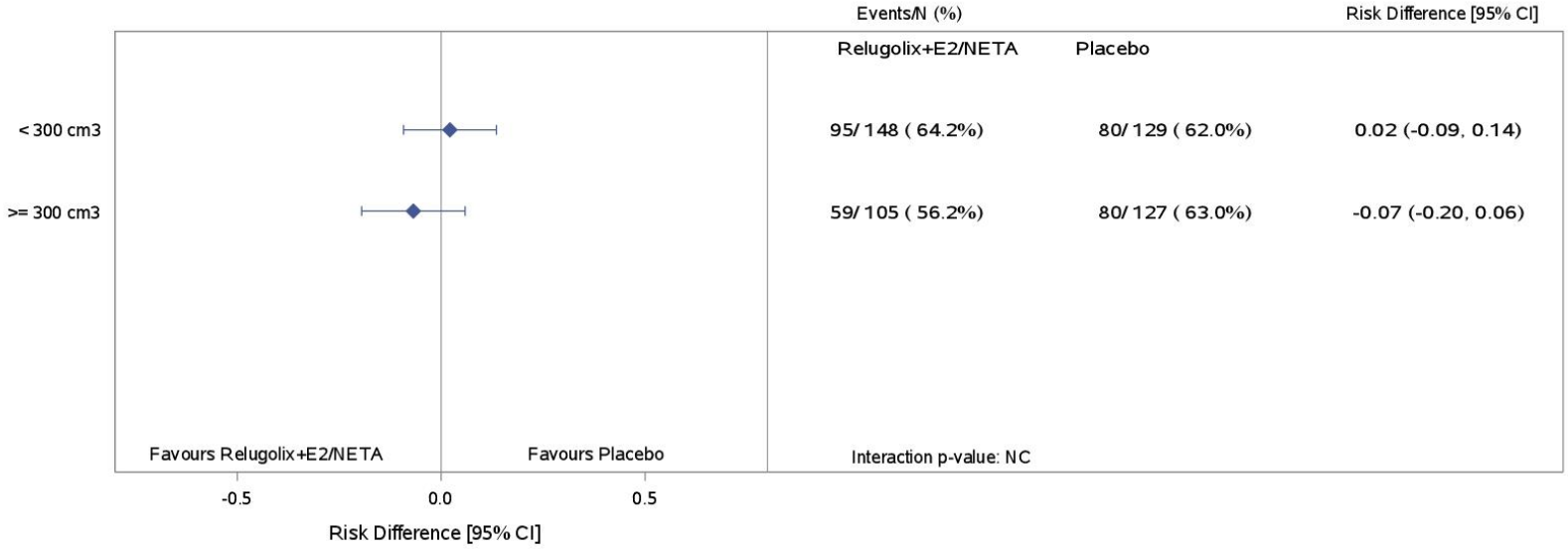
Figure SAF.TEAE.ANY.S3.BIN.FP.RD: Proportion of Patients With at Least One Treatment Emergent Adverse Event, by Subgroup (Safety Population) - Risk Difference
Study: Pooled
Subgroup: Uterine Volume at Baseline (cm3)



Results are based on a Mantel-Haenszel approach stratified by study using a one-stage fixed-effects IPD meta-analysis.
The reference group is Placebo. Patients with multiple events are counted only once. MedDRA (version 22.0).
N: Number of patients in treatment group; NETA: Norethindrone acetate; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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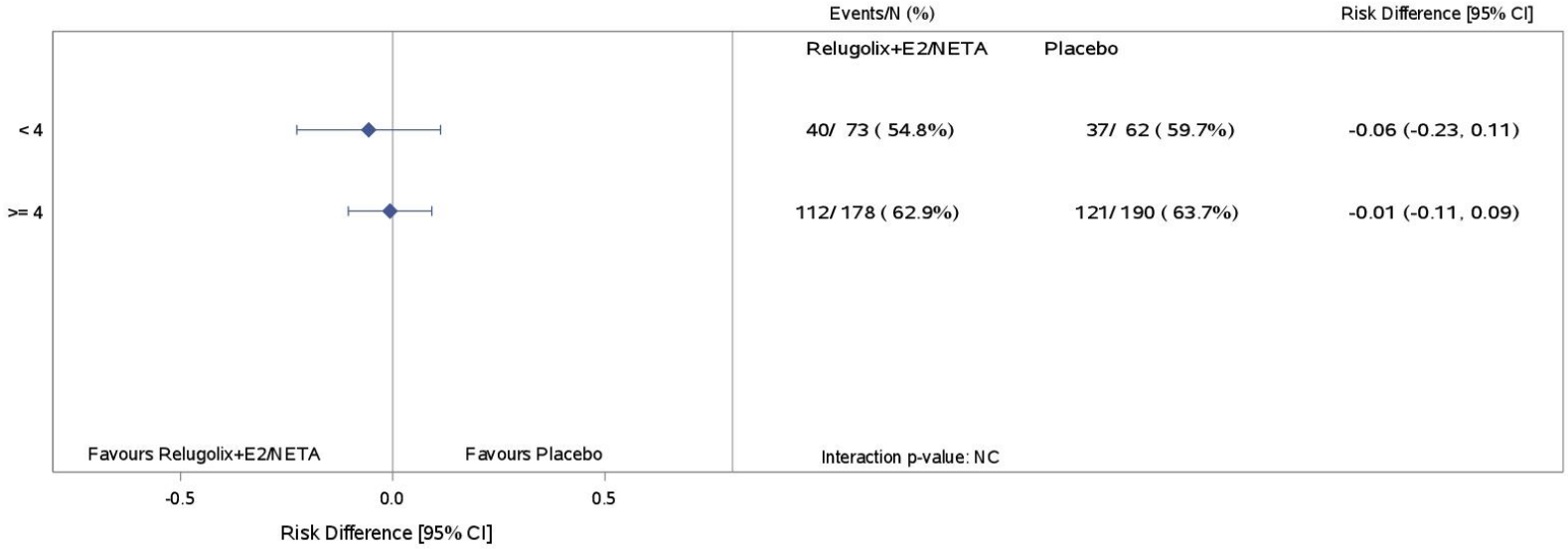
Figure SAF.TEAE.ANY.S4.BIN.FP.RD: Proportion of Patients With at Least One Treatment Emergent Adverse Event, by Subgroup (Safety Population) - Risk Difference
Study: Pooled
Subgroup: Maximum NRS Pain Score at Baseline



Results are based on a Mantel-Haenszel approach stratified by study using a one-stage fixed-effects IPD meta-analysis.
The reference group is Placebo. Patients with multiple events are counted only once. MedDRA (version 22.0).
N: Number of patients in treatment group; NETA: Norethindrone acetate; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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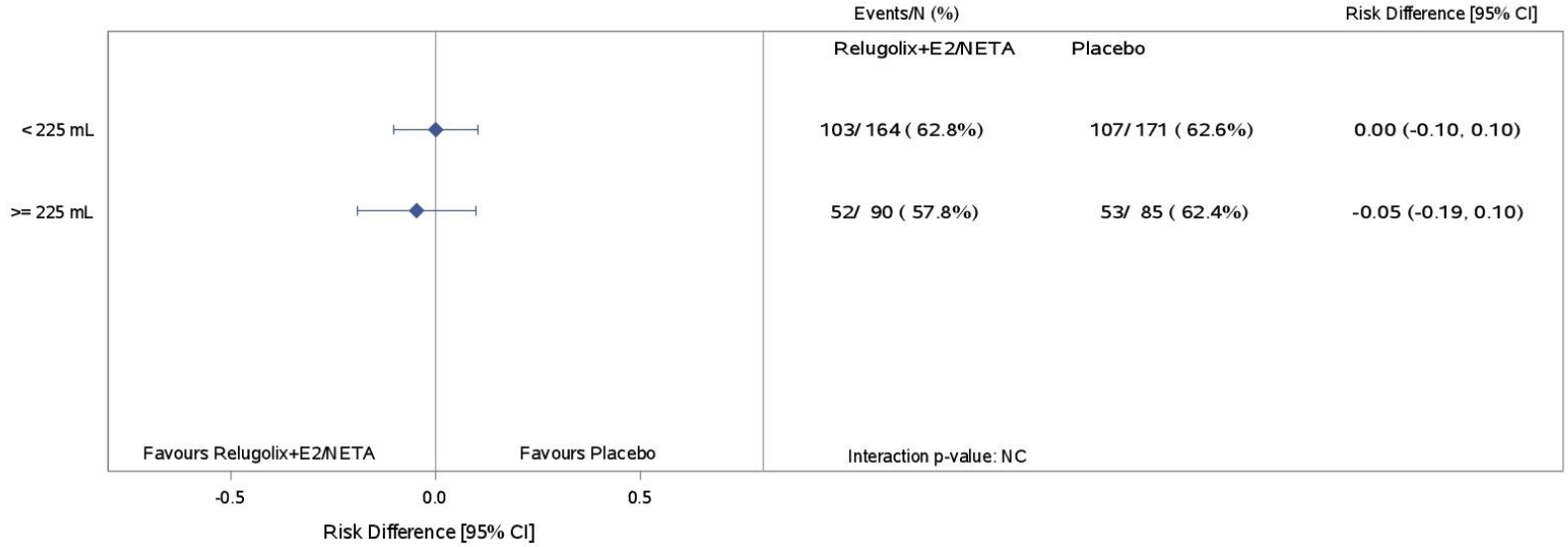
Figure SAF.TEAE.ANY.S5.BIN.FP.RD: Proportion of Patients With at Least One Treatment Emergent Adverse Event, by Subgroup (Safety Population) - Risk Difference
Study: Pooled
Subgroup: MBL Volume at Baseline (mL)



Results are based on a Mantel-Haenszel approach stratified by study using a one-stage fixed-effects IPD meta-analysis.
The reference group is Placebo. Patients with multiple events are counted only once. MedDRA (version 22.0).
N: Number of patients in treatment group; NETA: Norethindrone acetate; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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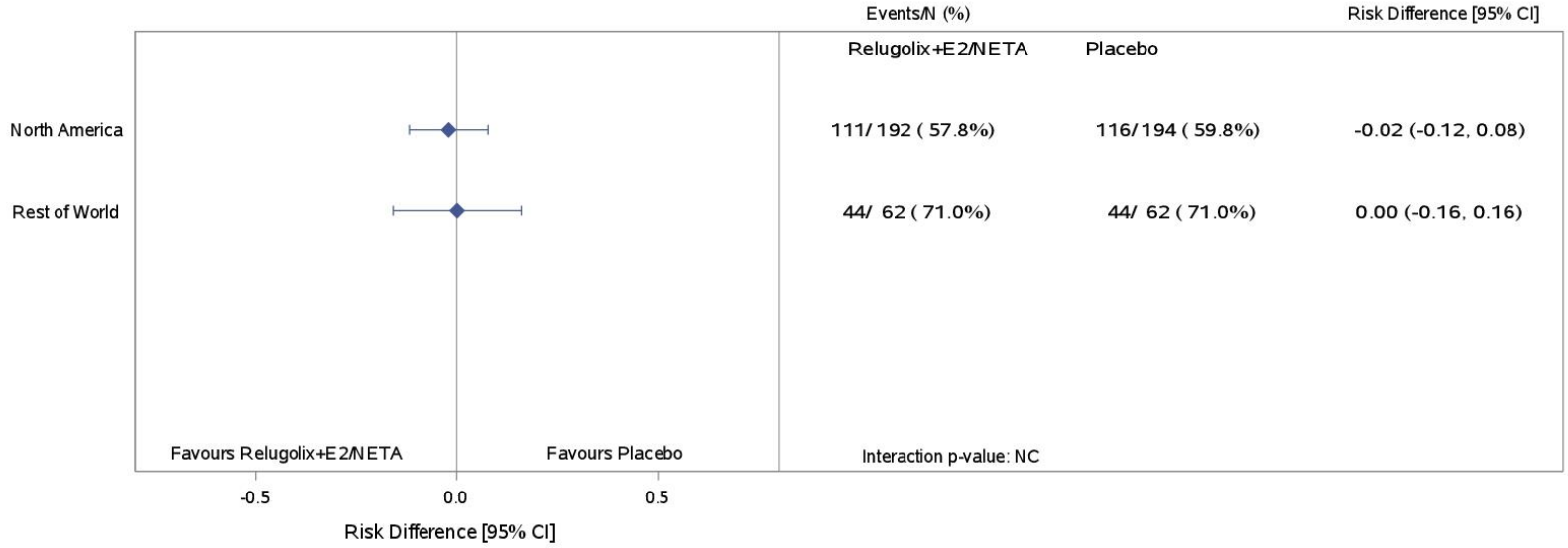
Figure SAF.TEAE.ANY.S6.BIN.FP.RD: Proportion of Patients With at Least One Treatment Emergent Adverse Event, by Subgroup (Safety Population) - Risk Difference
Study: Pooled
Subgroup: Geographic Region I



Results are based on a Mantel-Haenszel approach stratified by study using a one-stage fixed-effects IPD meta-analysis.
The reference group is Placebo. Patients with multiple events are counted only once. MedDRA (version 22.0).
N: Number of patients in treatment group; NETA: Norethindrone acetate; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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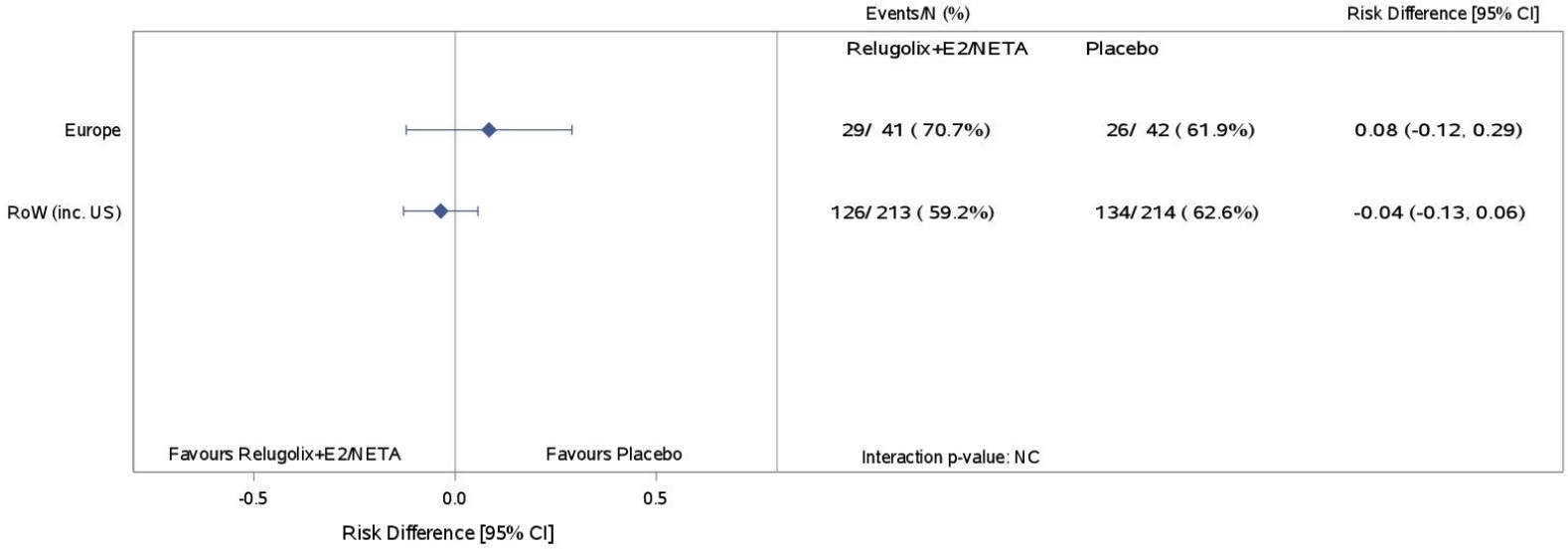
Figure SAF.TEAE.ANY.S7.BIN.FP.RD: Proportion of Patients With at Least One Treatment Emergent Adverse Event, by Subgroup (Safety Population) - Risk Difference
Study: Pooled
Subgroup: Geographic Region II



Results are based on a Mantel-Haenszel approach stratified by study using a one-stage fixed-effects IPD meta-analysis.
The reference group is Placebo. Patients with multiple events are counted only once. MedDRA (version 22.0).
N: Number of patients in treatment group; NETA: Norethindrone acetate; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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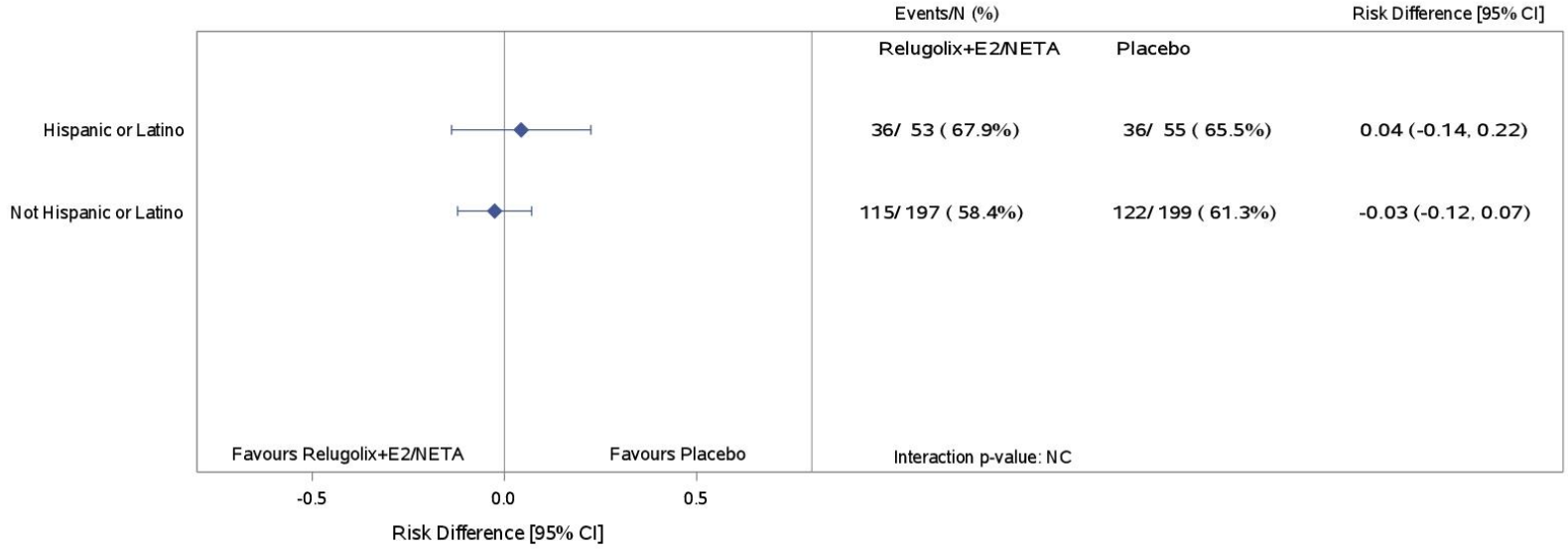
Figure SAF.TEAE.ANY.S8.BIN.FP.RD: Proportion of Patients With at Least One Treatment Emergent Adverse Event, by Subgroup (Safety Population) - Risk Difference
Study: Pooled
Subgroup: Ethnicity



Results are based on a Mantel-Haenszel approach stratified by study using a one-stage fixed-effects IPD meta-analysis.
The reference group is Placebo. Patients with multiple events are counted only once. MedDRA (version 22.0).
N: Number of patients in treatment group; NETA: Norethindrone acetate; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

SOURCE: X:\Numerus\Studies\MYV\MYV102\Analysis\Prod\Progs\TFLs\Fig_SAF_AE_S_BIN_FP.SAS Date/time of run: 01JUL21 10:03
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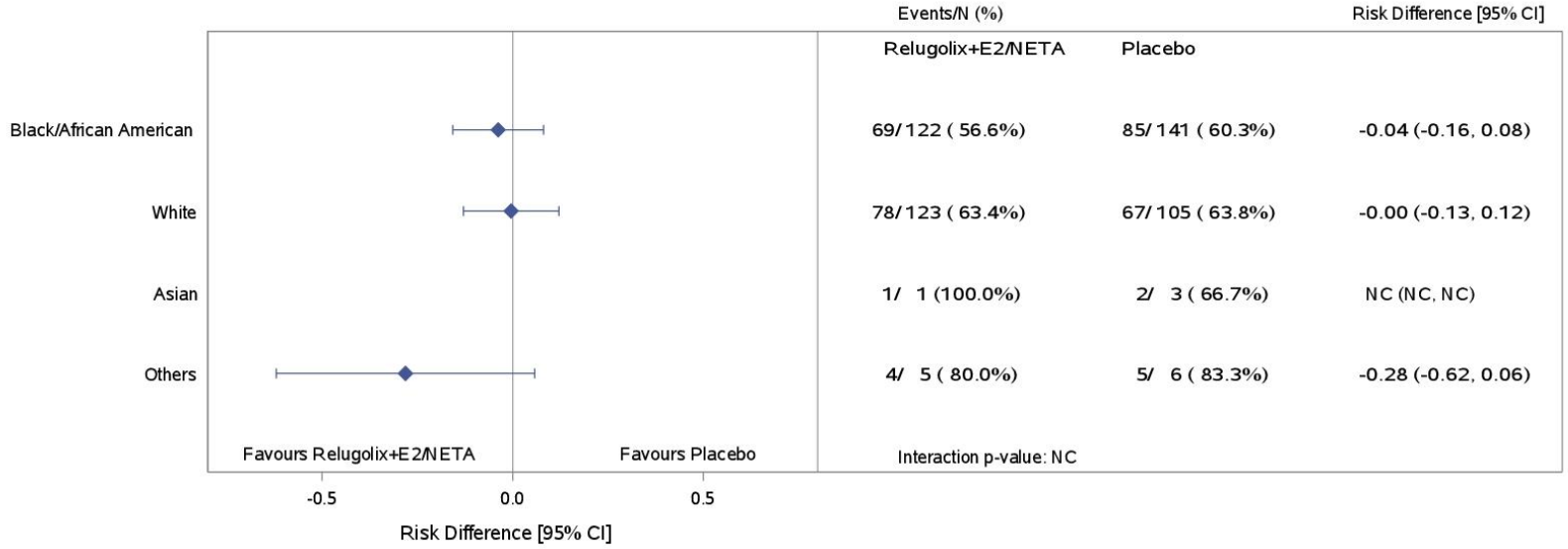
Figure SAF.TEAE.ANY.S9.BIN.FP.RD: Proportion of Patients With at Least One Treatment Emergent Adverse Event, by Subgroup (Safety Population) - Risk Difference
Study: Pooled
Subgroup: Race



Results are based on a Mantel-Haenszel approach stratified by study using a one-stage fixed-effects IPD meta-analysis.
The reference group is Placebo. Patients with multiple events are counted only once. MedDRA (version 22.0).
N: Number of patients in treatment group; NETA: Norethindrone acetate; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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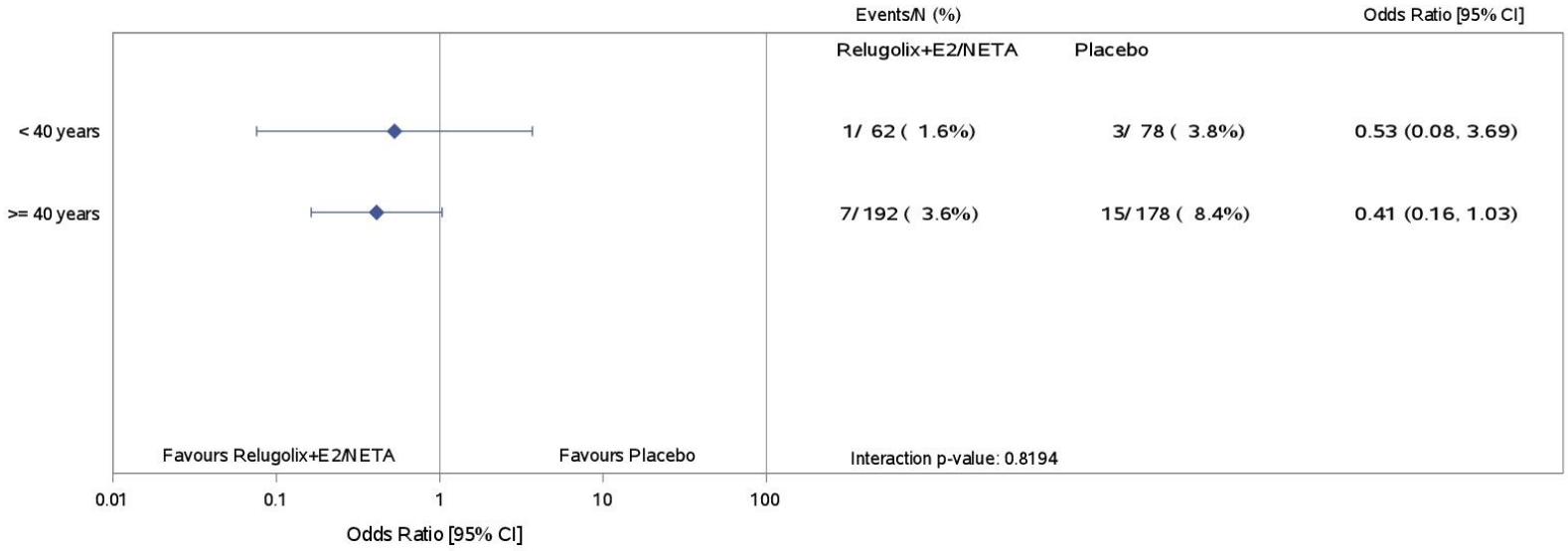
2.3.2 Frequent Treatment Emergent Adverse Events by System Organ Class and Preferred Term, by Subgroup (Safety Population)

Figure SAF.TEAE.SPT.S1.BIN.FP: Frequent Treatment Emergent Adverse Events by System Organ Class and Preferred Term, by Subgroup (Safety Population)
Study: Pooled
System Organ Class: Blood and lymphatic system disorders, Preferred Term: Any
Subgroup: Age (years)



Results are based on a logistic regression model adjusted for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates using a one-stage fixed-effects IPD meta-analysis approach. A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
The interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the Odds Ratio and 95% CI. Missing subgroup levels are not included in estimation of the interaction p-value. The reference group is Placebo. Patients with multiple events are counted only once. MedDRA (version 22.0).
Patients with multiple events for a given PT or SOC are counted only once for each PT and SOC. Only SOCs or PTs for which there are at least 10% of patients with an event in at least one treatment group OR at least 10 patients with an event overall and at least 1% of patients with an event in at least one treatment group in the overall safety population are considered. Further, only SOCs and PTs for which there is a significant treatment effect (p-value <0.05) in the overall safety population are presented. Events are sorted alphabetically by SOC and PT and then by subgroup within each. MedDRA (version 22.0).
N: Number of patients in treatment group; NETA: Norethindrone acetate; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

SOURCE: X:\Numerus\Studies\MYV\MYV102\Analysis\Prod\Progs\TFLs\Fig_SAF_AE_SPT_S_BIN_FP.SAS Date/time of run: 01JUL21 10:00
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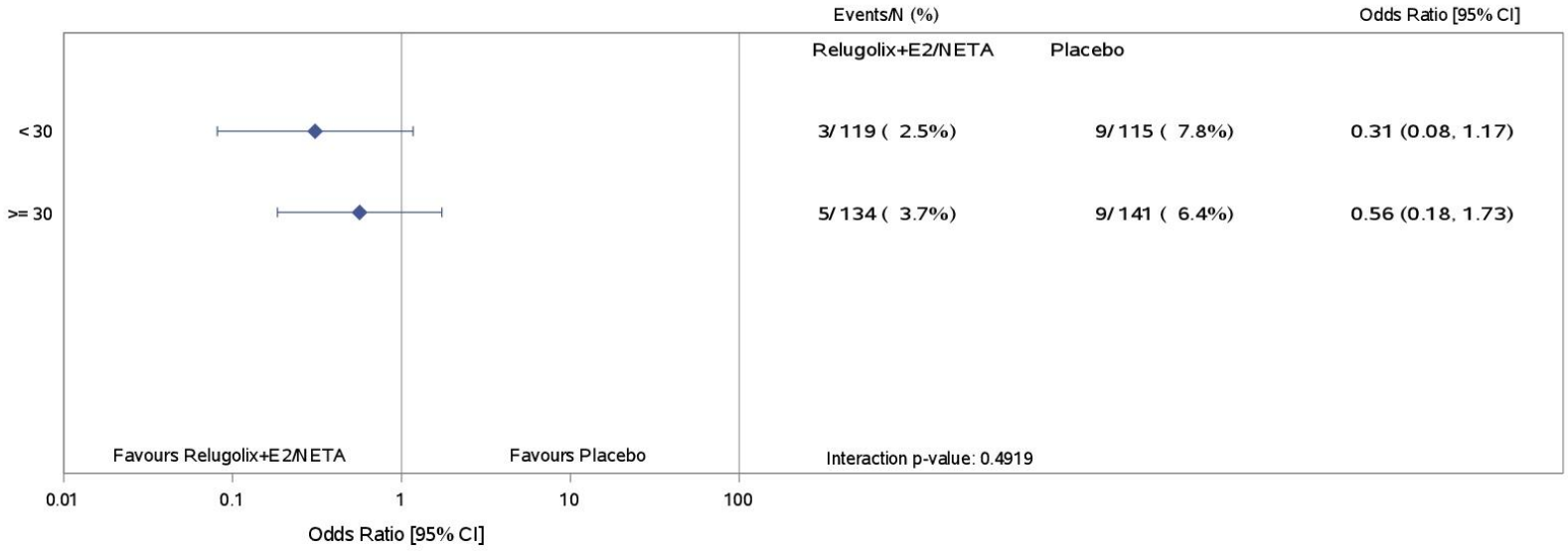
Figure SAF.TEAE.SPT.S2.BIN.FP: Frequent Treatment Emergent Adverse Events by System Organ Class and Preferred Term, by Subgroup (Safety Population)
Study: Pooled
System Organ Class: Blood and lymphatic system disorders, Preferred Term: Any
Subgroup: BMI (kg/m2) at Baseline



Results are based on a logistic regression model adjusted for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates using a one-stage fixed-effects IPD meta-analysis approach. A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
The interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the Odds Ratio and 95% CI. Missing subgroup levels are not included in estimation of the interaction p-value. The reference group is Placebo. Patients with multiple events are counted only once. MedDRA (version 22.0).
Patients with multiple events for a given PT or SOC are counted only once for each PT and SOC. Only SOCs or PTs for which there are at least 10% of patients with an event in at least one treatment group OR at least 10 patients with an event overall and at least 1% of patients with an event in at least one treatment group in the overall safety population are considered. Further, only SOCs and PTs for which there is a significant treatment effect (p-value <0.05) in the overall safety population are presented. Events are sorted alphabetically by SOC and PT and then by subgroup within each. MedDRA (version 22.0).
N: Number of patients in treatment group; NETA: Norethindrone acetate; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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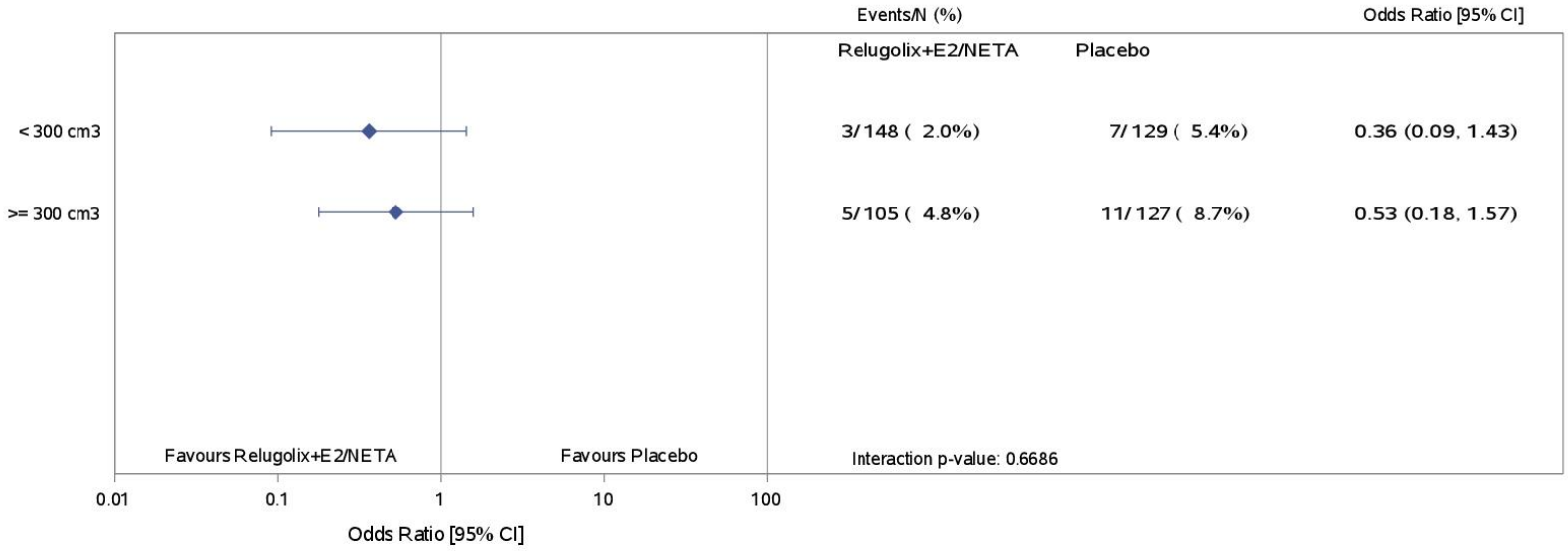
Figure SAF.TEAE.SPT.S3.BIN.FP: Frequent Treatment Emergent Adverse Events by System Organ Class and Preferred Term, by Subgroup (Safety Population)
Study: Pooled
System Organ Class: Blood and lymphatic system disorders, Preferred Term: Any
Subgroup: Uterine Volume at Baseline (cm3)



Results are based on a logistic regression model adjusted for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates using a one-stage fixed-effects IPD meta-analysis approach. A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
The interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the Odds Ratio and 95% CI. Missing subgroup levels are not included in estimation of the interaction p-value. The reference group is Placebo. Patients with multiple events are counted only once. MedDRA (version 22.0).
Patients with multiple events for a given PT or SOC are counted only once for each PT and SOC. Only SOCs or PTs for which there are at least 10% of patients with an event in at least one treatment group OR at least 10 patients with an event overall and at least 1% of patients with an event in at least one treatment group in the overall safety population are considered. Further, only SOCs and PTs for which there is a significant treatment effect (p-value <0.05) in the overall safety population are presented. Events are sorted alphabetically by SOC and PT and then by subgroup within each. MedDRA (version 22.0).
N: Number of patients in treatment group; NETA: Norethindrone acetate; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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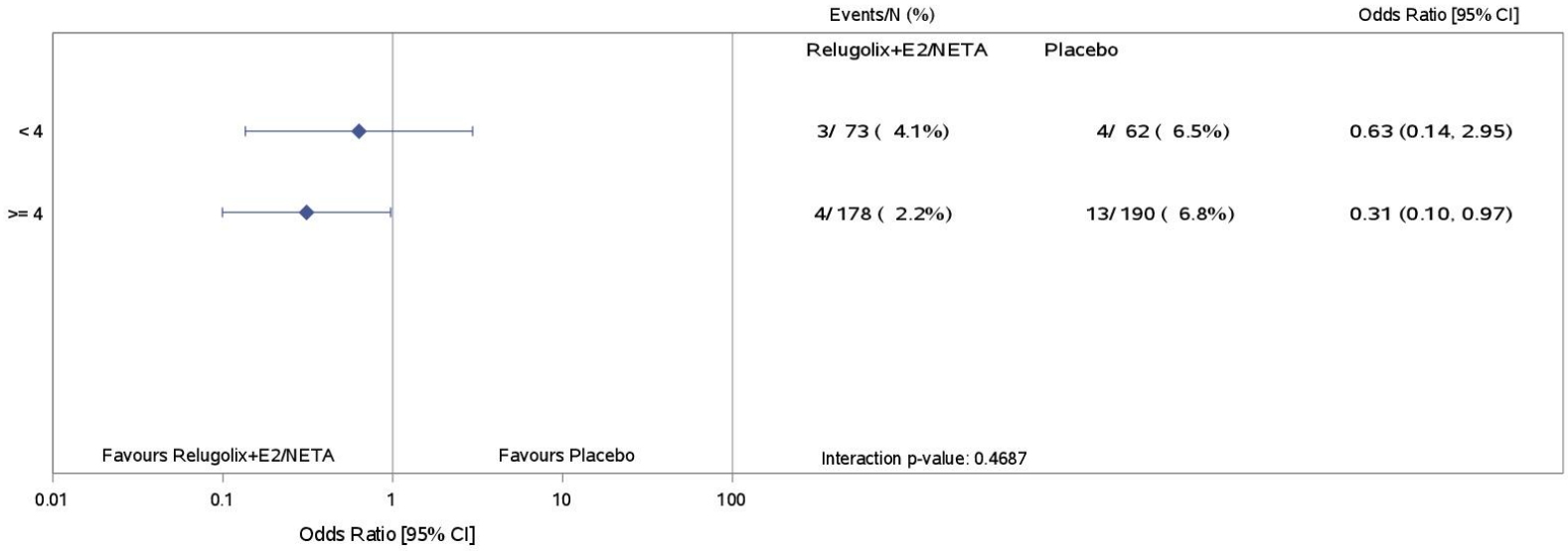
Figure SAF.TEAE.SPT.S4.BIN.FP: Frequent Treatment Emergent Adverse Events by System Organ Class and Preferred Term, by Subgroup (Safety Population)
Study: Pooled
System Organ Class: Blood and lymphatic system disorders, Preferred Term: Any
Subgroup: Maximum NRS Pain Score at Baseline



Results are based on a logistic regression model adjusted for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates using a one-stage fixed-effects IPD meta-analysis approach. A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
The interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the Odds Ratio and 95% CI. Missing subgroup levels are not included in estimation of the interaction p-value. The reference group is Placebo. Patients with multiple events are counted only once. MedDRA (version 22.0).
Patients with multiple events for a given PT or SOC are counted only once for each PT and SOC. Only SOCs or PTs for which there are at least 10% of patients with an event in at least one treatment group OR at least 10 patients with an event overall and at least 1% of patients with an event in at least one treatment group in the overall safety population are considered. Further, only SOCs and PTs for which there is a significant treatment effect (p-value <0.05) in the overall safety population are presented. Events are sorted alphabetically by SOC and PT and then by subgroup within each. MedDRA (version 22.0).
N: Number of patients in treatment group; NETA: Norethindrone acetate; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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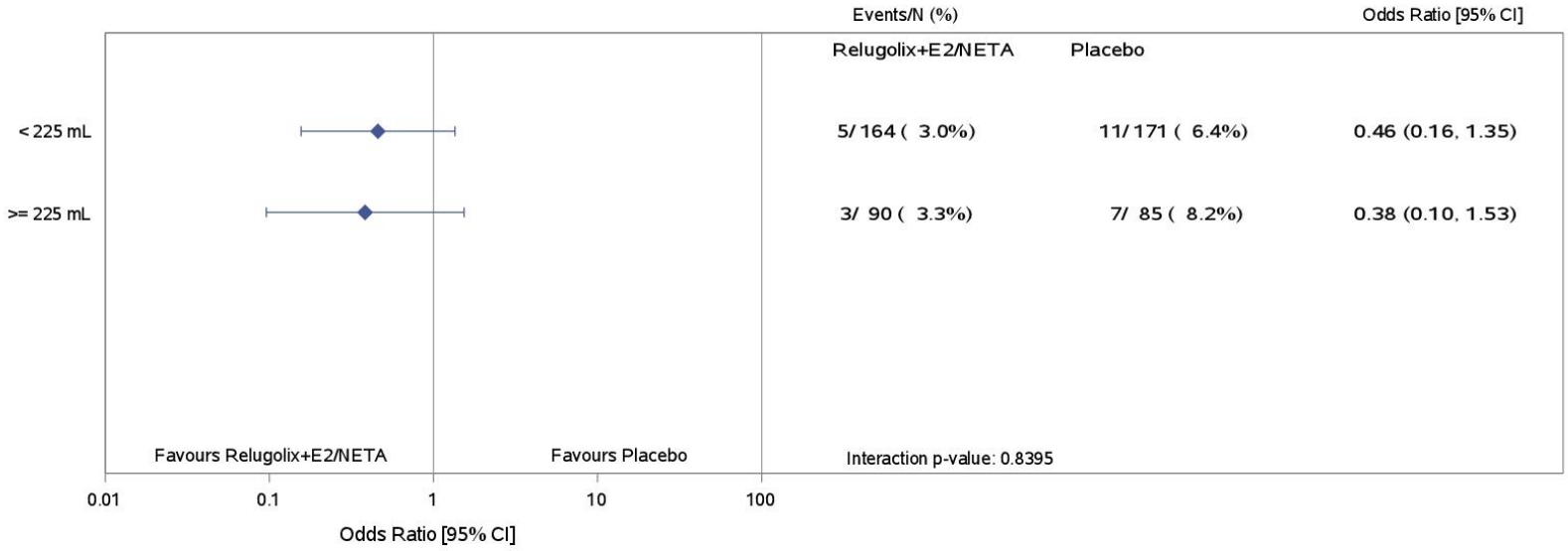
Figure SAF.TEAE.SPT.S5.BIN.FP: Frequent Treatment Emergent Adverse Events by System Organ Class and Preferred Term, by Subgroup (Safety Population)
Study: Pooled
System Organ Class: Blood and lymphatic system disorders, Preferred Term: Any
Subgroup: MBL Volume at Baseline (mL)



Results are based on a logistic regression model adjusted for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates using a one-stage fixed-effects IPD meta-analysis approach. A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
The interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the Odds Ratio and 95% CI. Missing subgroup levels are not included in estimation of the interaction p-value. The reference group is Placebo. Patients with multiple events are counted only once. MedDRA (version 22.0).
Patients with multiple events for a given PT or SOC are counted only once for each PT and SOC. Only SOCs or PTs for which there are at least 10% of patients with an event in at least one treatment group OR at least 10 patients with an event overall and at least 1% of patients with an event in at least one treatment group in the overall safety population are considered. Further, only SOCs and PTs for which there is a significant treatment effect (p-value <0.05) in the overall safety population are presented. Events are sorted alphabetically by SOC and PT and then by subgroup within each. MedDRA (version 22.0).
N: Number of patients in treatment group; NETA: Norethindrone acetate; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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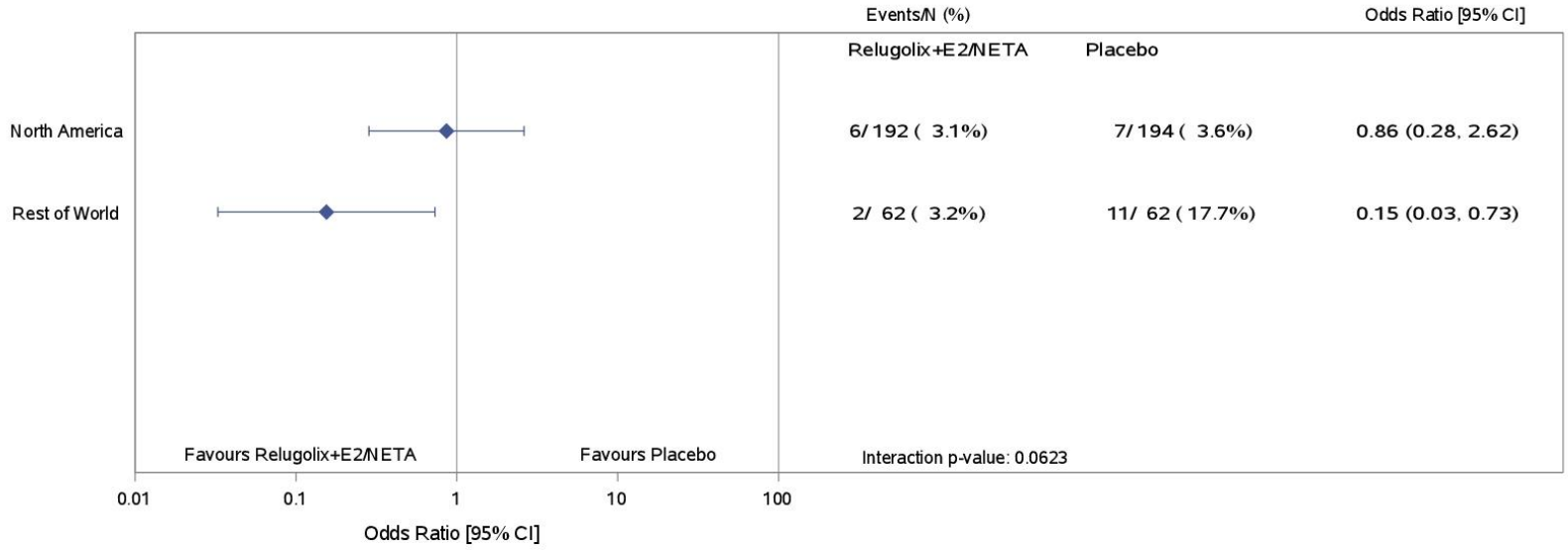
Figure SAF.TEAE.SPT.S6.BIN.FP: Frequent Treatment Emergent Adverse Events by System Organ Class and Preferred Term, by Subgroup (Safety Population)
Study: Pooled
System Organ Class: Blood and lymphatic system disorders, Preferred Term: Any
Subgroup: Geographic Region I



Results are based on a logistic regression model adjusted for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates using a one-stage fixed-effects IPD meta-analysis approach. A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
The interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the Odds Ratio and 95% CI. Missing subgroup levels are not included in estimation of the interaction p-value. The reference group is Placebo. Patients with multiple events are counted only once. MedDRA (version 22.0).
Patients with multiple events for a given PT or SOC are counted only once for each PT and SOC. Only SOCs or PTs for which there are at least 10% of patients with an event in at least one treatment group OR at least 10 patients with an event overall and at least 1% of patients with an event in at least one treatment group in the overall safety population are considered. Further, only SOCs and PTs for which there is a significant treatment effect (p-value <0.05) in the overall safety population are presented. Events are sorted alphabetically by SOC and PT and then by subgroup within each. MedDRA (version 22.0).
N: Number of patients in treatment group; NETA: Norethindrone acetate; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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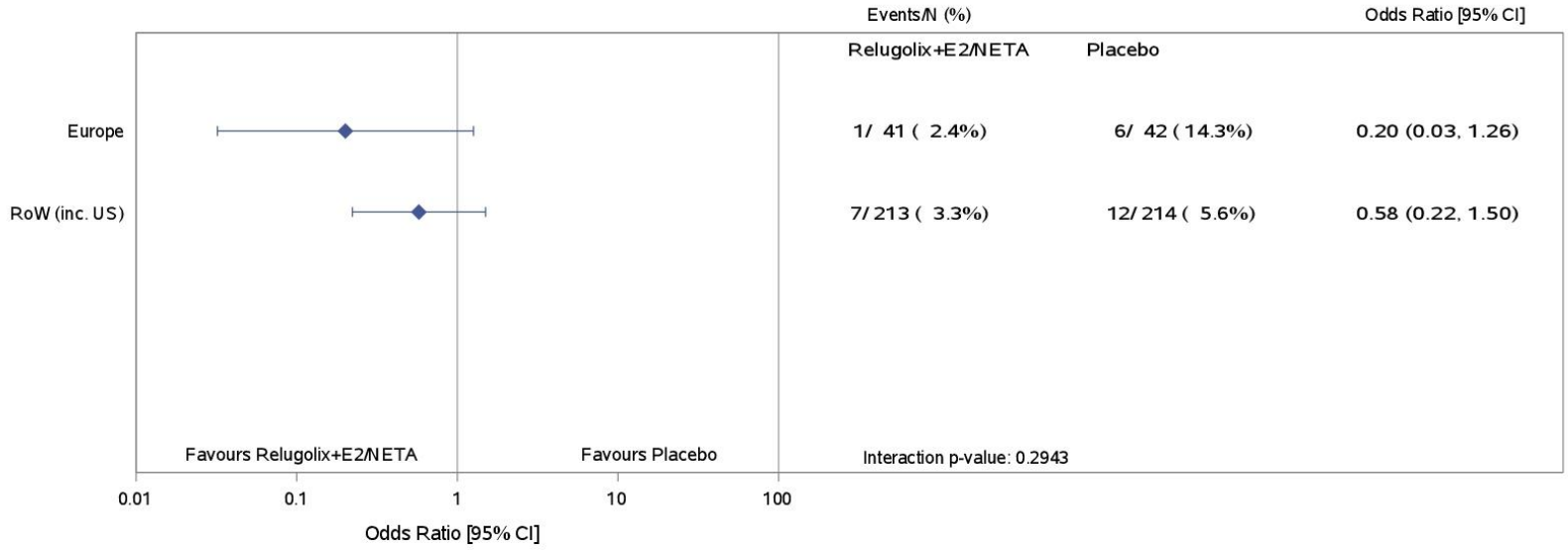
Figure SAF.TEAE.SPT.S7.BIN.FP: Frequent Treatment Emergent Adverse Events by System Organ Class and Preferred Term, by Subgroup (Safety Population)
Study: Pooled
System Organ Class: Blood and lymphatic system disorders, Preferred Term: Any
Subgroup: Geographic Region II



Results are based on a logistic regression model adjusted for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates using a one-stage fixed-effects IPD meta-analysis approach. A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
The interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the Odds Ratio and 95% CI. Missing subgroup levels are not included in estimation of the interaction p-value. The reference group is Placebo. Patients with multiple events are counted only once. MedDRA (version 22.0).
Patients with multiple events for a given PT or SOC are counted only once for each PT and SOC. Only SOCs or PTs for which there are at least 10% of patients with an event in at least one treatment group OR at least 10 patients with an event overall and at least 1% of patients with an event in at least one treatment group in the overall safety population are considered. Further, only SOCs and PTs for which there is a significant treatment effect (p-value <0.05) in the overall safety population are presented. Events are sorted alphabetically by SOC and PT and then by subgroup within each. MedDRA (version 22.0).
N: Number of patients in treatment group; NETA: Norethindrone acetate; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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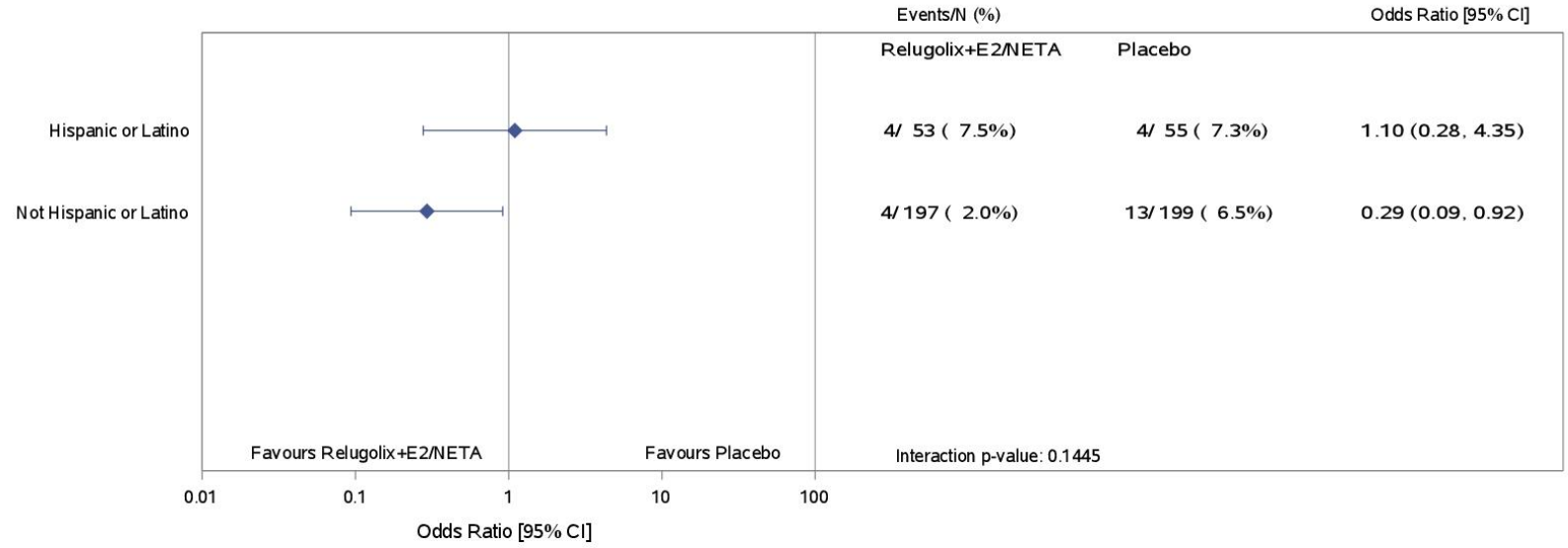
Figure SAF.TEAE.SPT.S8.BIN.FP: Frequent Treatment Emergent Adverse Events by System Organ Class and Preferred Term, by Subgroup (Safety Population)
Study: Pooled
System Organ Class: Blood and lymphatic system disorders, Preferred Term: Any
Subgroup: Ethnicity



Results are based on a logistic regression model adjusted for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates using a one-stage fixed-effects IPD meta-analysis approach. A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
The interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the Odds Ratio and 95% CI. Missing subgroup levels are not included in estimation of the interaction p-value. The reference group is Placebo. Patients with multiple events are counted only once. MedDRA (version 22.0).
Patients with multiple events for a given PT or SOC are counted only once for each PT and SOC. Only SOCs or PTs for which there are at least 10% of patients with an event in at least one treatment group OR at least 10 patients with an event overall and at least 1% of patients with an event in at least one treatment group in the overall safety population are considered. Further, only SOCs and PTs for which there is a significant treatment effect (p-value <0.05) in the overall safety population are presented. Events are sorted alphabetically by SOC and PT and then by subgroup within each. MedDRA (version 22.0).
N: Number of patients in treatment group; NETA: Norethindrone acetate; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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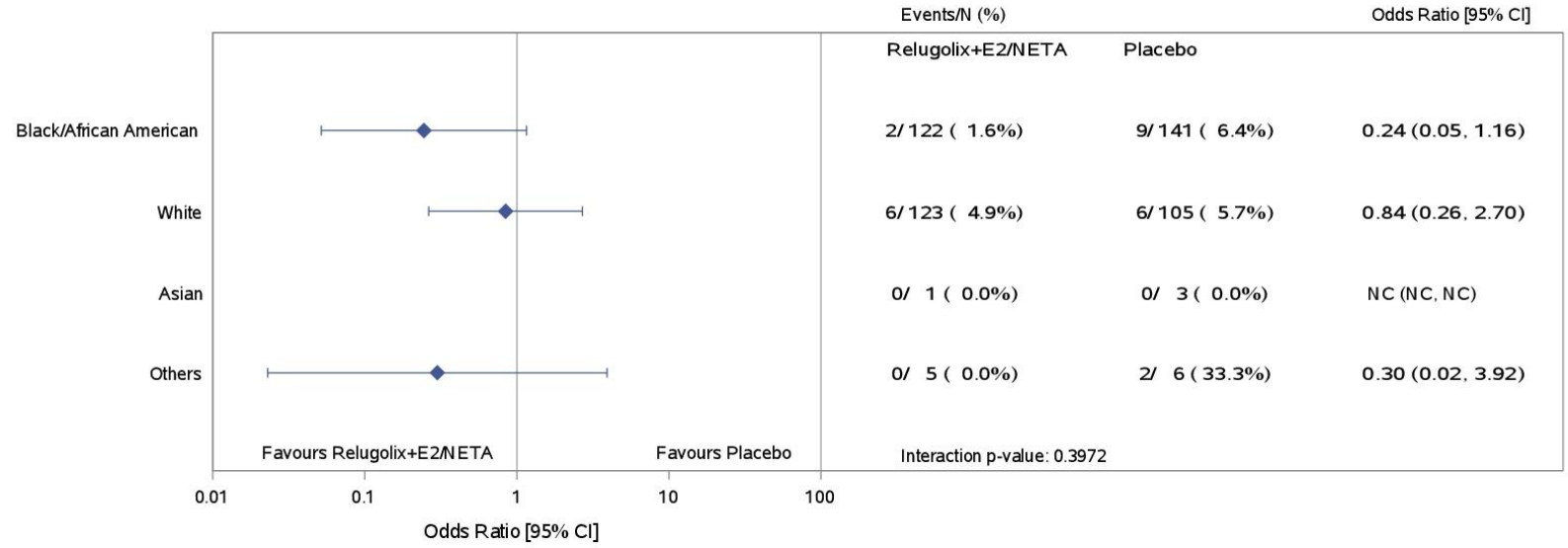
Figure SAF.TEAE.SPT.S9.BIN.FP: Frequent Treatment Emergent Adverse Events by System Organ Class and Preferred Term, by Subgroup (Safety Population)
Study: Pooled
System Organ Class: Blood and lymphatic system disorders, Preferred Term: Any
Subgroup: Race



Results are based on a logistic regression model adjusted for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates using a one-stage fixed-effects IPD meta-analysis approach. A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
The interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the Odds Ratio and 95% CI. Missing subgroup levels are not included in estimation of the interaction p-value. The reference group is Placebo. Patients with multiple events are counted only once. MedDRA (version 22.0).
Patients with multiple events for a given PT or SOC are counted only once for each PT and SOC. Only SOCs or PTs for which there are at least 10% of patients with an event in at least one treatment group OR at least 10 patients with an event overall and at least 1% of patients with an event in at least one treatment group in the overall safety population are considered. Further, only SOCs and PTs for which there is a significant treatment effect (p-value <0.05) in the overall safety population are presented. Events are sorted alphabetically by SOC and PT and then by subgroup within each. MedDRA (version 22.0).
N: Number of patients in treatment group; NETA: Norethindrone acetate; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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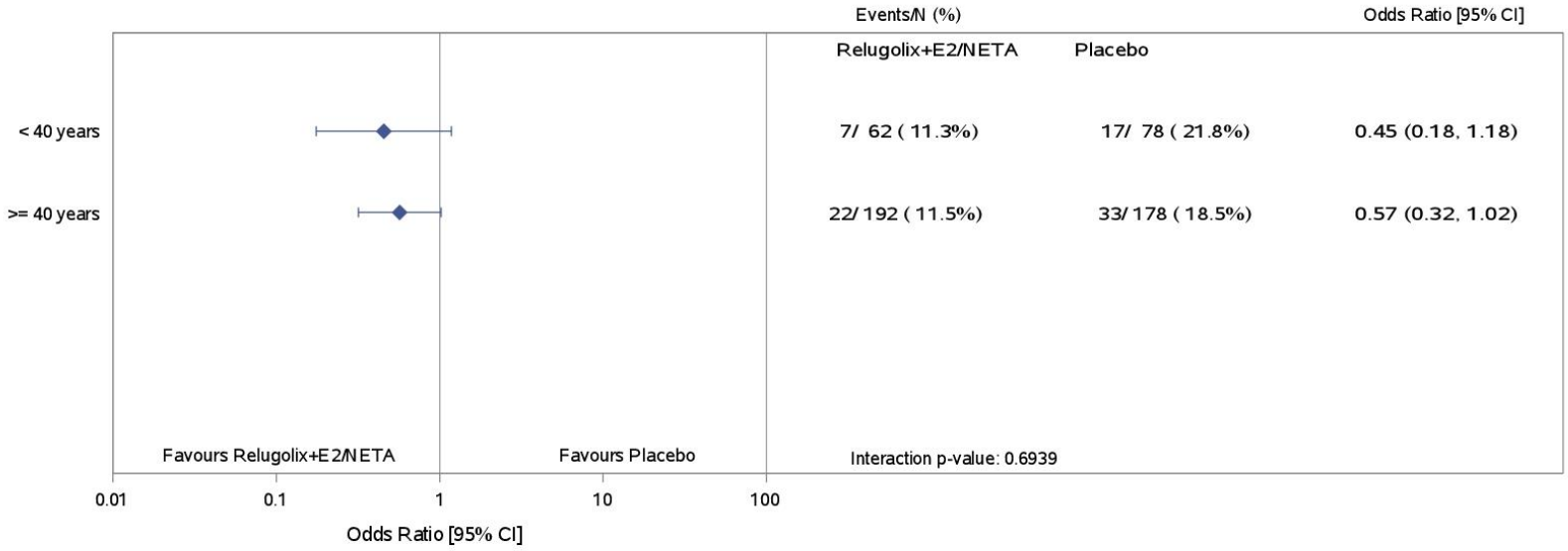
Figure SAF.TEAE.SPT.S1.BIN.FP: Frequent Treatment Emergent Adverse Events by System Organ Class and Preferred Term, by Subgroup (Safety Population)
Study: Pooled
System Organ Class: Nervous system disorders, Preferred Term: Any
Subgroup: Age (years)



Results are based on a logistic regression model adjusted for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates using a one-stage fixed-effects IPD meta-analysis approach. A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
The interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the Odds Ratio and 95% CI. Missing subgroup levels are not included in estimation of the interaction p-value. The reference group is Placebo. Patients with multiple events are counted only once. MedDRA (version 22.0).
Patients with multiple events for a given PT or SOC are counted only once for each PT and SOC. Only SOCs or PTs for which there are at least 10% of patients with an event in at least one treatment group OR at least 10 patients with an event overall and at least 1% of patients with an event in at least one treatment group in the overall safety population are considered. Further, only SOCs and PTs for which there is a significant treatment effect (p-value <0.05) in the overall safety population are presented. Events are sorted alphabetically by SOC and PT and then by subgroup within each. MedDRA (version 22.0).
N: Number of patients in treatment group; NETA: Norethindrone acetate; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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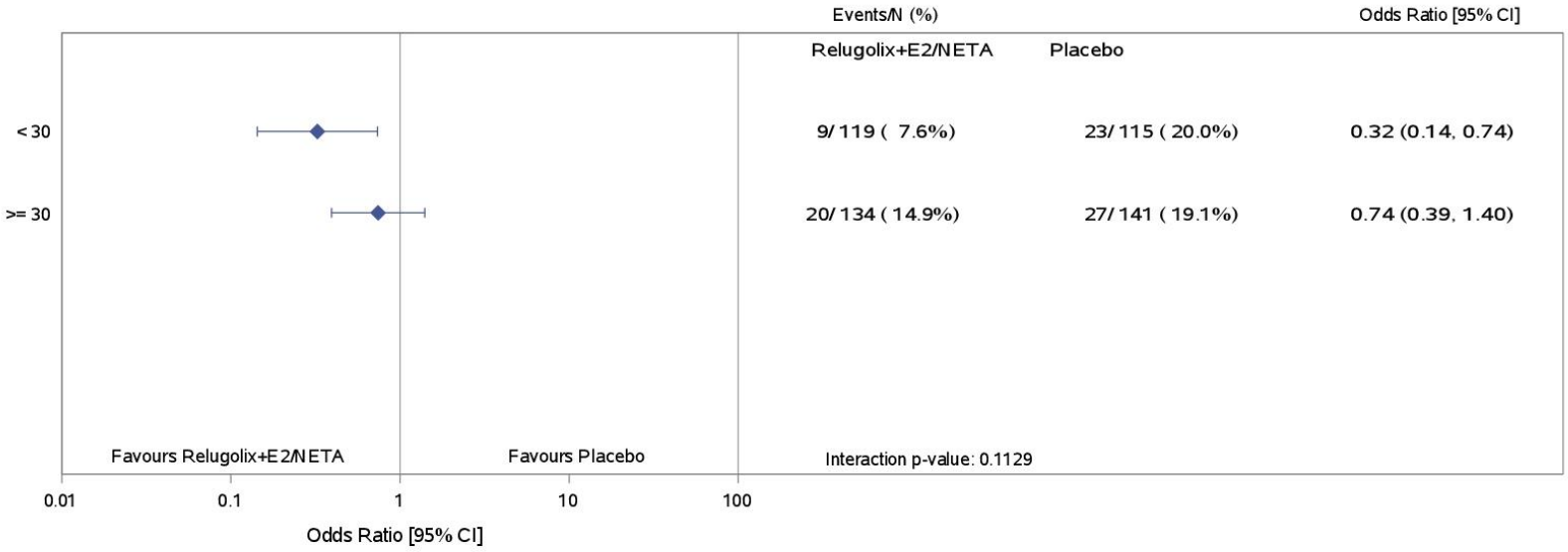
Figure SAF.TEAE.SPT.S2.BIN.FP: Frequent Treatment Emergent Adverse Events by System Organ Class and Preferred Term, by Subgroup (Safety Population)
Study: Pooled
System Organ Class: Nervous system disorders, Preferred Term: Any
Subgroup: BMI (kg/m2) at Baseline



Results are based on a logistic regression model adjusted for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates using a one-stage fixed-effects IPD meta-analysis approach. A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
The interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the Odds Ratio and 95% CI. Missing subgroup levels are not included in estimation of the interaction p-value. The reference group is Placebo. Patients with multiple events are counted only once. MedDRA (version 22.0).
Patients with multiple events for a given PT or SOC are counted only once for each PT and SOC. Only SOCs or PTs for which there are at least 10% of patients with an event in at least one treatment group OR at least 10 patients with an event overall and at least 1% of patients with an event in at least one treatment group in the overall safety population are considered. Further, only SOCs and PTs for which there is a significant treatment effect (p-value <0.05) in the overall safety population are presented. Events are sorted alphabetically by SOC and PT and then by subgroup within each. MedDRA (version 22.0).
N: Number of patients in treatment group; NETA: Norethindrone acetate; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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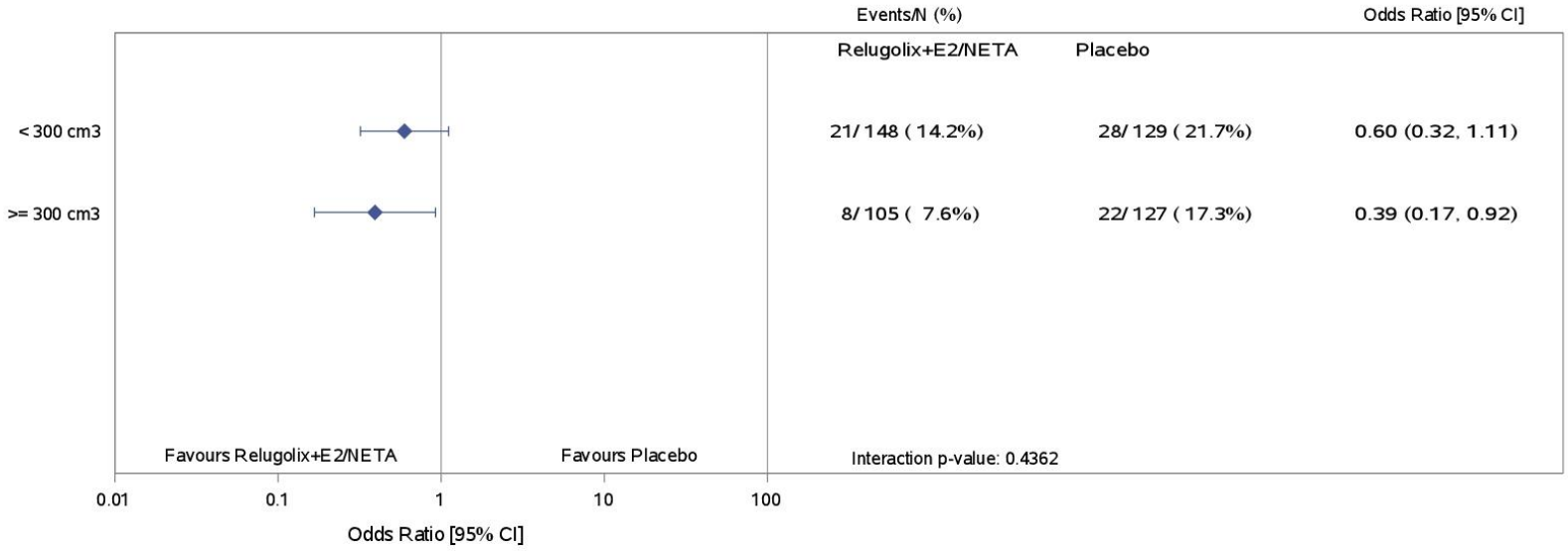
Figure SAF.TEAE.SPT.S3.BIN.FP: Frequent Treatment Emergent Adverse Events by System Organ Class and Preferred Term, by Subgroup (Safety Population)
Study: Pooled
System Organ Class: Nervous system disorders, Preferred Term: Any
Subgroup: Uterine Volume at Baseline (cm3)



Results are based on a logistic regression model adjusted for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates using a one-stage fixed-effects IPD meta-analysis approach. A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
The interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the Odds Ratio and 95% CI. Missing subgroup levels are not included in estimation of the interaction p-value. The reference group is Placebo. Patients with multiple events are counted only once. MedDRA (version 22.0).
Patients with multiple events for a given PT or SOC are counted only once for each PT and SOC. Only SOCs or PTs for which there are at least 10% of patients with an event in at least one treatment group OR at least 10 patients with an event overall and at least 1% of patients with an event in at least one treatment group in the overall safety population are considered. Further, only SOCs and PTs for which there is a significant treatment effect (p-value <0.05) in the overall safety population are presented. Events are sorted alphabetically by SOC and PT and then by subgroup within each. MedDRA (version 22.0).
N: Number of patients in treatment group; NETA: Norethindrone acetate; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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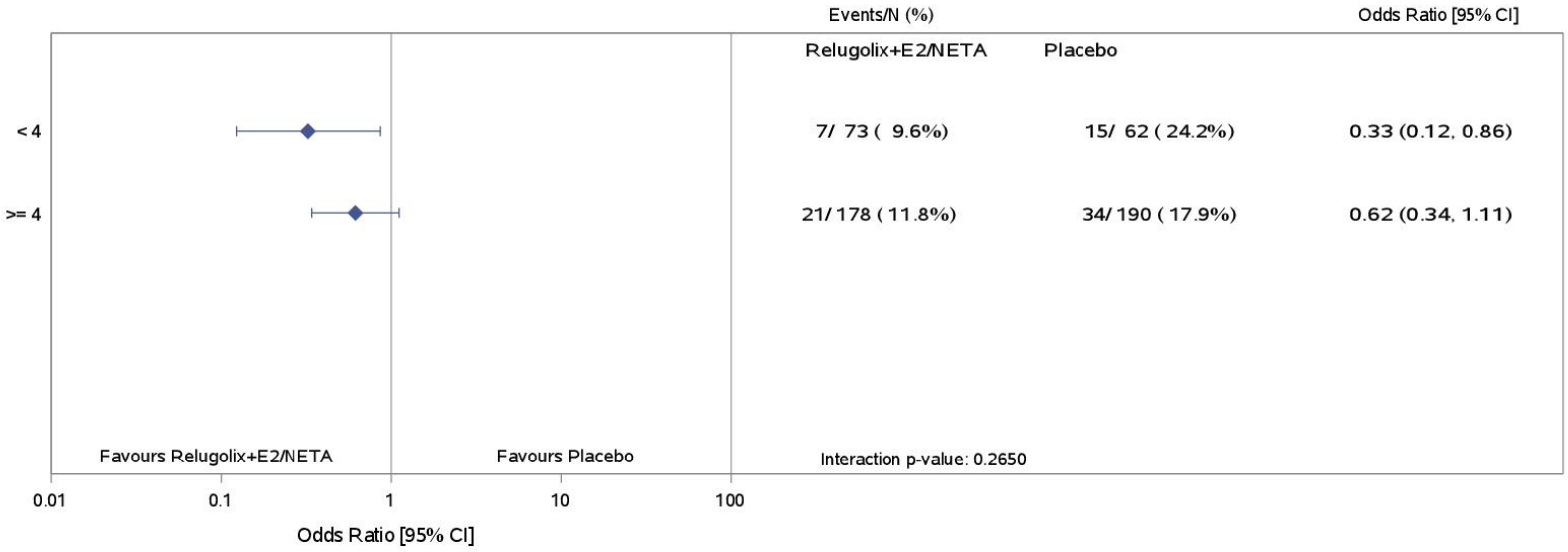
Figure SAF.TEAE.SPT.S4.BIN.FP: Frequent Treatment Emergent Adverse Events by System Organ Class and Preferred Term, by Subgroup (Safety Population)
Study: Pooled
System Organ Class: Nervous system disorders, Preferred Term: Any
Subgroup: Maximum NRS Pain Score at Baseline



Results are based on a logistic regression model adjusted for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates using a one-stage fixed-effects IPD meta-analysis approach. A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
The interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the Odds Ratio and 95% CI. Missing subgroup levels are not included in estimation of the interaction p-value. The reference group is Placebo. Patients with multiple events are counted only once. MedDRA (version 22.0).
Patients with multiple events for a given PT or SOC are counted only once for each PT and SOC. Only SOCs or PTs for which there are at least 10% of patients with an event in at least one treatment group OR at least 10 patients with an event overall and at least 1% of patients with an event in at least one treatment group in the overall safety population are considered. Further, only SOCs and PTs for which there is a significant treatment effect (p-value <0.05) in the overall safety population are presented. Events are sorted alphabetically by SOC and PT and then by subgroup within each. MedDRA (version 22.0).
N: Number of patients in treatment group; NETA: Norethindrone acetate; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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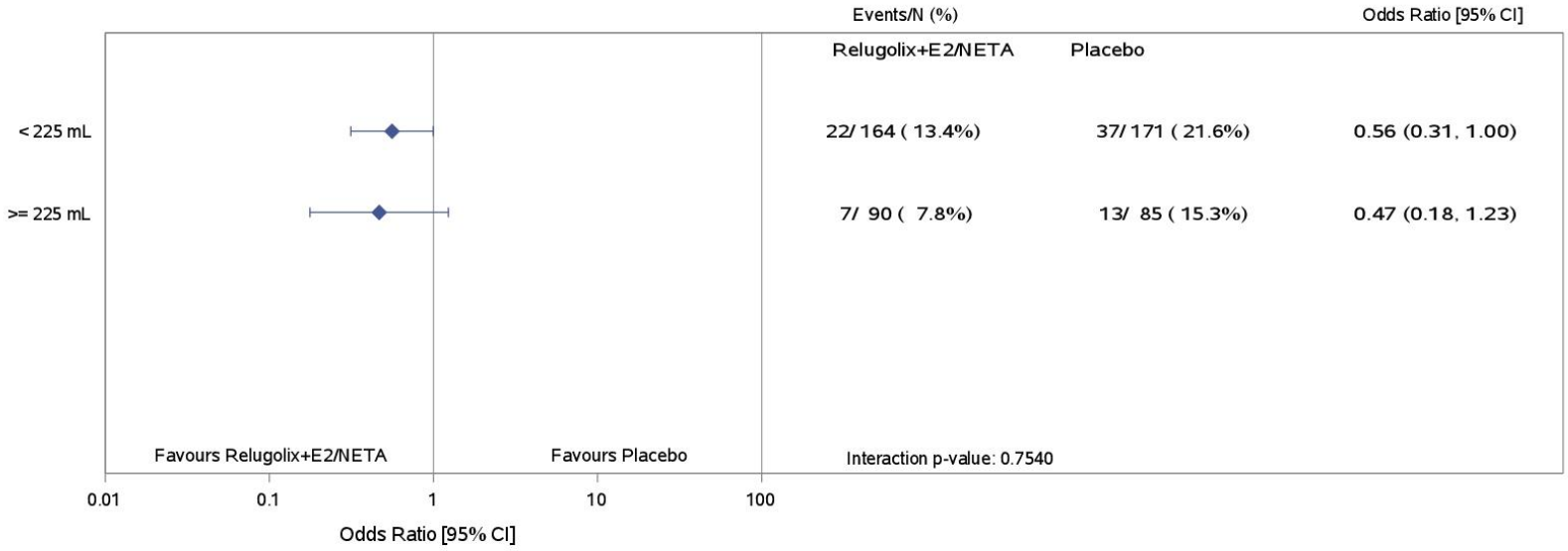
Figure SAF.TEAE.SPT.S5.BIN.FP: Frequent Treatment Emergent Adverse Events by System Organ Class and Preferred Term, by Subgroup (Safety Population)
Study: Pooled
System Organ Class: Nervous system disorders, Preferred Term: Any
Subgroup: MBL Volume at Baseline (mL)



Results are based on a logistic regression model adjusted for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates using a one-stage fixed-effects IPD meta-analysis approach. A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
The interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the Odds Ratio and 95% CI. Missing subgroup levels are not included in estimation of the interaction p-value. The reference group is Placebo. Patients with multiple events are counted only once. MedDRA (version 22.0).
Patients with multiple events for a given PT or SOC are counted only once for each PT and SOC. Only SOCs or PTs for which there are at least 10% of patients with an event in at least one treatment group OR at least 10 patients with an event overall and at least 1% of patients with an event in at least one treatment group in the overall safety population are considered. Further, only SOCs and PTs for which there is a significant treatment effect (p-value <0.05) in the overall safety population are presented. Events are sorted alphabetically by SOC and PT and then by subgroup within each. MedDRA (version 22.0).
N: Number of patients in treatment group; NETA: Norethindrone acetate; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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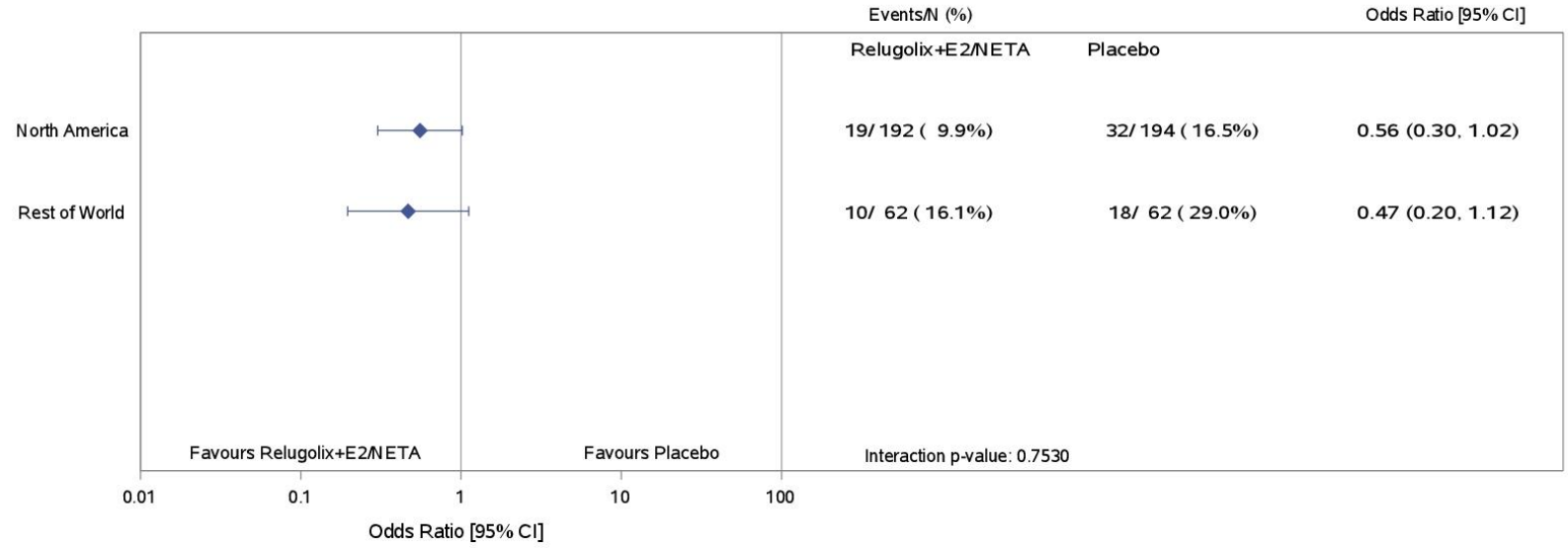
Figure SAF.TEAE.SPT.S6.BIN.FP: Frequent Treatment Emergent Adverse Events by System Organ Class and Preferred Term, by Subgroup (Safety Population)
Study: Pooled
System Organ Class: Nervous system disorders, Preferred Term: Any
Subgroup: Geographic Region I



Results are based on a logistic regression model adjusted for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates using a one-stage fixed-effects IPD meta-analysis approach. A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
The interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the Odds Ratio and 95% CI. Missing subgroup levels are not included in estimation of the interaction p-value. The reference group is Placebo. Patients with multiple events are counted only once. MedDRA (version 22.0).
Patients with multiple events for a given PT or SOC are counted only once for each PT and SOC. Only SOCs or PTs for which there are at least 10% of patients with an event in at least one treatment group OR at least 10 patients with an event overall and at least 1% of patients with an event in at least one treatment group in the overall safety population are considered. Further, only SOCs and PTs for which there is a significant treatment effect (p-value <0.05) in the overall safety population are presented. Events are sorted alphabetically by SOC and PT and then by subgroup within each. MedDRA (version 22.0).
N: Number of patients in treatment group; NETA: Norethindrone acetate; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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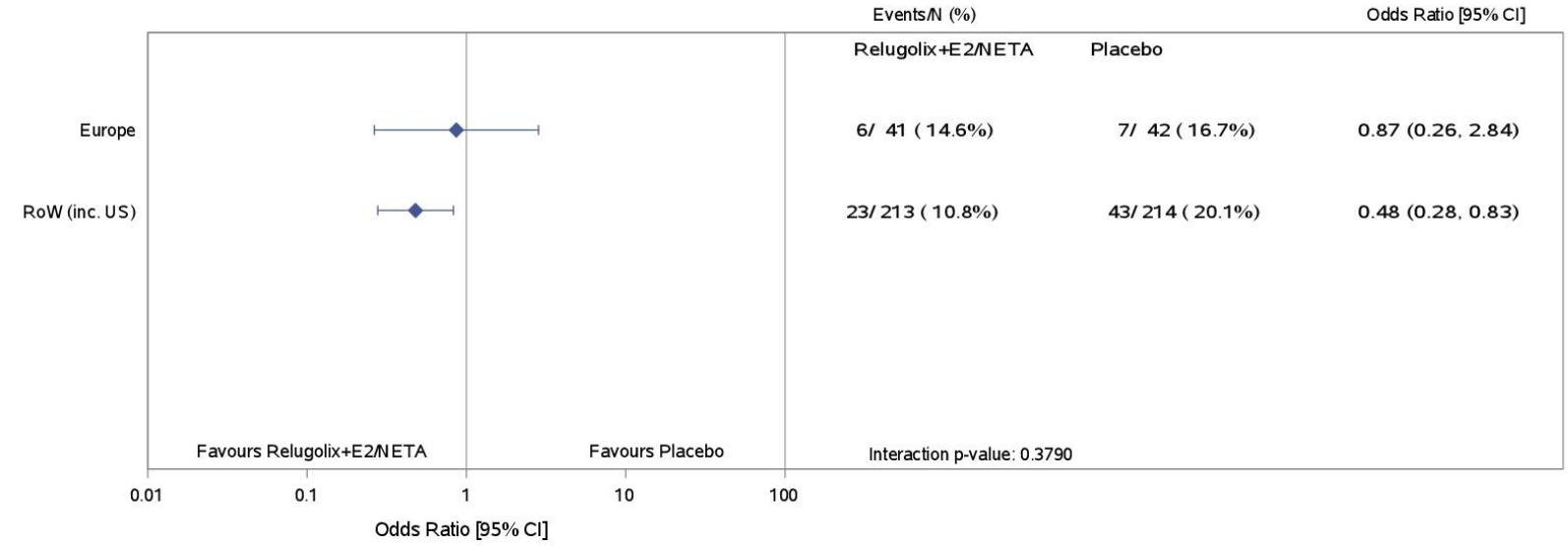
Figure SAF.TEAE.SPT.S7.BIN.FP: Frequent Treatment Emergent Adverse Events by System Organ Class and Preferred Term, by Subgroup (Safety Population)
Study: Pooled
System Organ Class: Nervous system disorders, Preferred Term: Any
Subgroup: Geographic Region II



Results are based on a logistic regression model adjusted for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates using a one-stage fixed-effects IPD meta-analysis approach. A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
The interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the Odds Ratio and 95% CI. Missing subgroup levels are not included in estimation of the interaction p-value. The reference group is Placebo. Patients with multiple events are counted only once. MedDRA (version 22.0).
Patients with multiple events for a given PT or SOC are counted only once for each PT and SOC. Only SOCs or PTs for which there are at least 10% of patients with an event in at least one treatment group OR at least 10 patients with an event overall and at least 1% of patients with an event in at least one treatment group in the overall safety population are considered. Further, only SOCs and PTs for which there is a significant treatment effect (p-value <0.05) in the overall safety population are presented. Events are sorted alphabetically by SOC and PT and then by subgroup within each. MedDRA (version 22.0).
N: Number of patients in treatment group; NETA: Norethindrone acetate; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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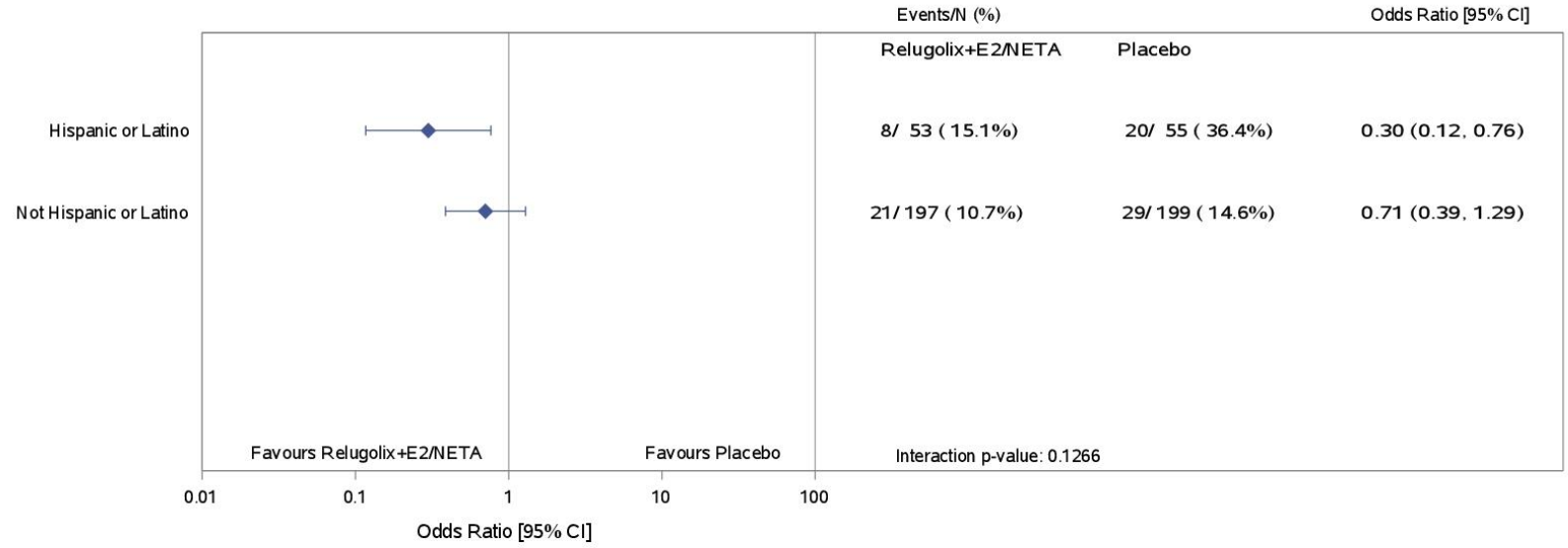
Figure SAF.TEAE.SPT.S8.BIN.FP: Frequent Treatment Emergent Adverse Events by System Organ Class and Preferred Term, by Subgroup (Safety Population)
Study: Pooled
System Organ Class: Nervous system disorders, Preferred Term: Any
Subgroup: Ethnicity



Results are based on a logistic regression model adjusted for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates using a one-stage fixed-effects IPD meta-analysis approach. A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
The interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the Odds Ratio and 95% CI. Missing subgroup levels are not included in estimation of the interaction p-value. The reference group is Placebo. Patients with multiple events are counted only once. MedDRA (version 22.0).
Patients with multiple events for a given PT or SOC are counted only once for each PT and SOC. Only SOCs or PTs for which there are at least 10% of patients with an event in at least one treatment group OR at least 10 patients with an event overall and at least 1% of patients with an event in at least one treatment group in the overall safety population are considered. Further, only SOCs and PTs for which there is a significant treatment effect (p-value <0.05) in the overall safety population are presented. Events are sorted alphabetically by SOC and PT and then by subgroup within each. MedDRA (version 22.0).
N: Number of patients in treatment group; NETA: Norethindrone acetate; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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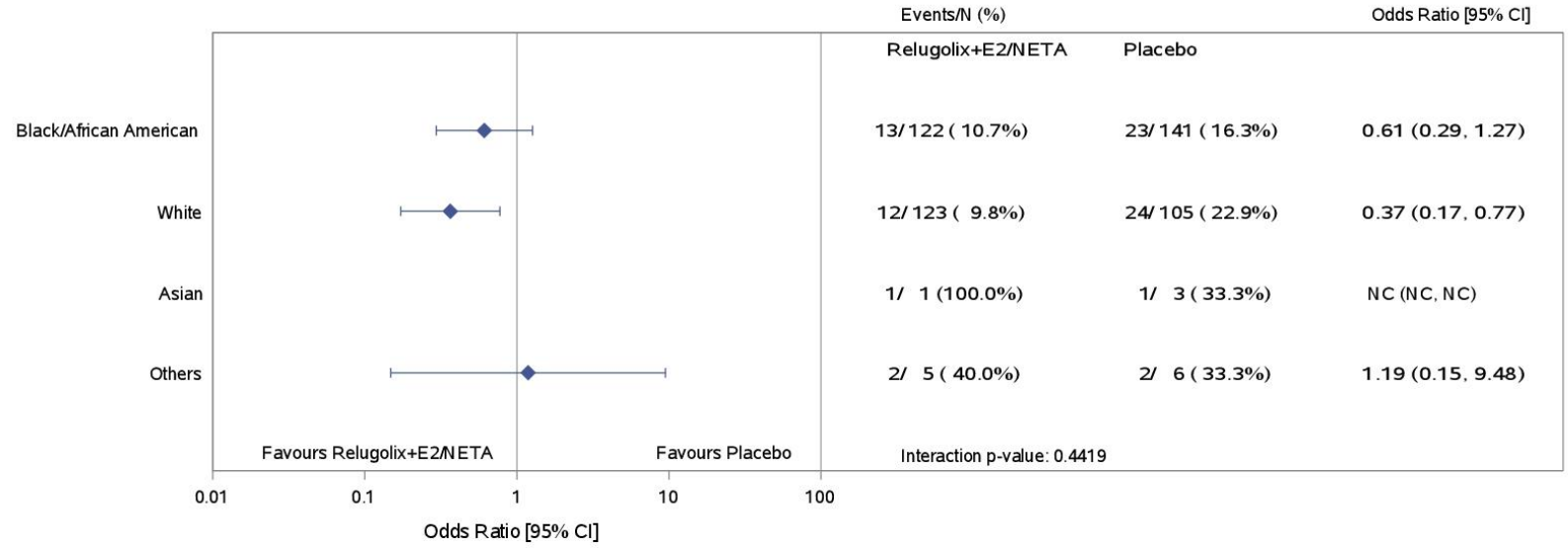
Figure SAF.TEAE.SPT.S9.BIN.FP: Frequent Treatment Emergent Adverse Events by System Organ Class and Preferred Term, by Subgroup (Safety Population)
Study: Pooled
System Organ Class: Nervous system disorders, Preferred Term: Any
Subgroup: Race



Results are based on a logistic regression model adjusted for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates using a one-stage fixed-effects IPD meta-analysis approach. A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
The interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the Odds Ratio and 95% CI. Missing subgroup levels are not included in estimation of the interaction p-value. The reference group is Placebo. Patients with multiple events are counted only once. MedDRA (version 22.0).
Patients with multiple events for a given PT or SOC are counted only once for each PT and SOC. Only SOCs or PTs for which there are at least 10% of patients with an event in at least one treatment group OR at least 10 patients with an event overall and at least 1% of patients with an event in at least one treatment group in the overall safety population are considered. Further, only SOCs and PTs for which there is a significant treatment effect (p-value <0.05) in the overall safety population are presented. Events are sorted alphabetically by SOC and PT and then by subgroup within each. MedDRA (version 22.0).
N: Number of patients in treatment group; NETA: Norethindrone acetate; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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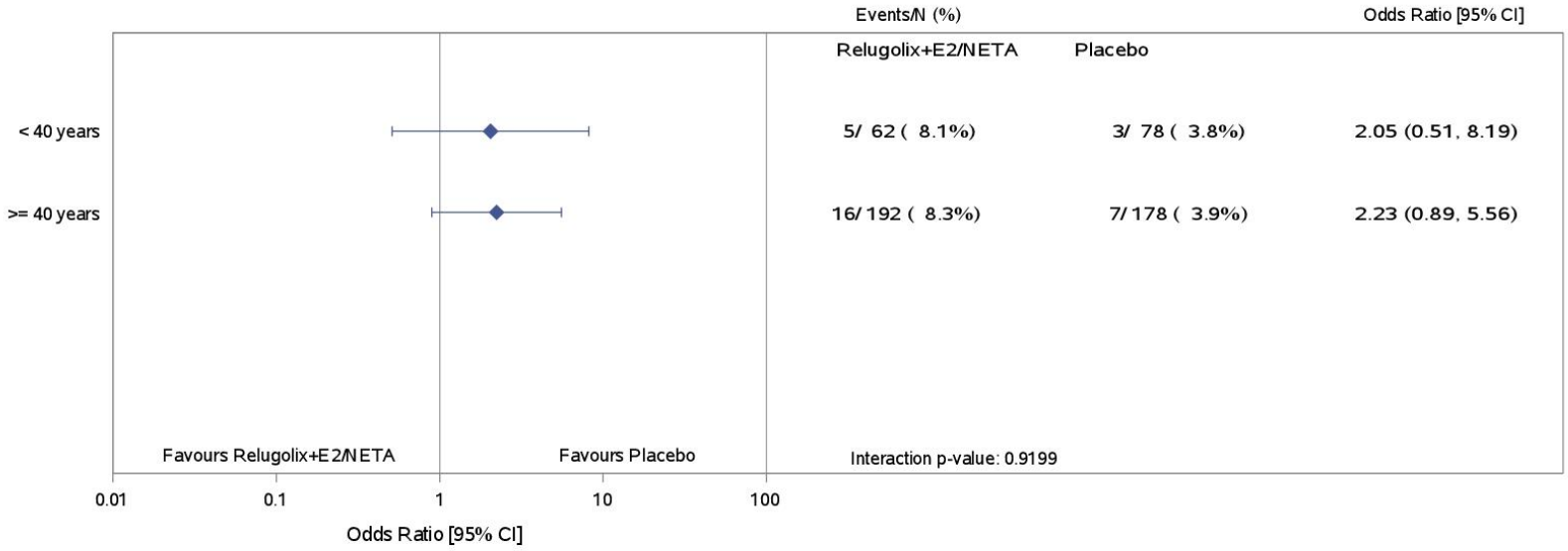
Figure SAF.TEAE.SPT.S1.BIN.FP: Frequent Treatment Emergent Adverse Events by System Organ Class and Preferred Term, by Subgroup (Safety Population)
Study: Pooled
System Organ Class: Psychiatric disorders, Preferred Term: Any
Subgroup: Age (years)



Results are based on a logistic regression model adjusted for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates using a one-stage fixed-effects IPD meta-analysis approach. A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
The interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the Odds Ratio and 95% CI. Missing subgroup levels are not included in estimation of the interaction p-value. The reference group is Placebo. Patients with multiple events are counted only once. MedDRA (version 22.0).
Patients with multiple events for a given PT or SOC are counted only once for each PT and SOC. Only SOCs or PTs for which there are at least 10% of patients with an event in at least one treatment group OR at least 10 patients with an event overall and at least 1% of patients with an event in at least one treatment group in the overall safety population are considered. Further, only SOCs and PTs for which there is a significant treatment effect (p-value <0.05) in the overall safety population are presented. Events are sorted alphabetically by SOC and PT and then by subgroup within each. MedDRA (version 22.0).
N: Number of patients in treatment group; NETA: Norethindrone acetate; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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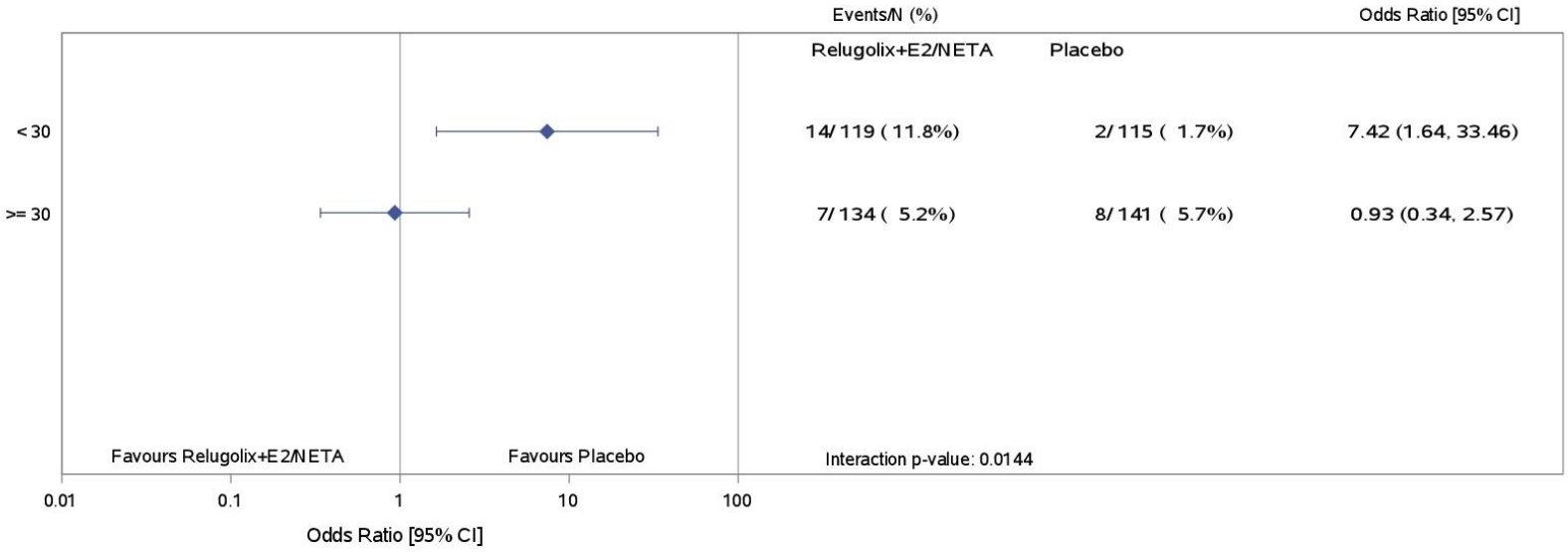
Figure SAF.TEAE.SPT.S2.BIN.FP: Frequent Treatment Emergent Adverse Events by System Organ Class and Preferred Term, by Subgroup (Safety Population)
Study: Pooled
System Organ Class: Psychiatric disorders, Preferred Term: Any
Subgroup: BMI (kg/m2) at Baseline



Results are based on a logistic regression model adjusted for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates using a one-stage fixed-effects IPD meta-analysis approach. A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
The interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the Odds Ratio and 95% CI. Missing subgroup levels are not included in estimation of the interaction p-value. The reference group is Placebo. Patients with multiple events are counted only once. MedDRA (version 22.0).
Patients with multiple events for a given PT or SOC are counted only once for each PT and SOC. Only SOCs or PTs for which there are at least 10% of patients with an event in at least one treatment group OR at least 10 patients with an event overall and at least 1% of patients with an event in at least one treatment group in the overall safety population are considered. Further, only SOCs and PTs for which there is a significant treatment effect (p-value <0.05) in the overall safety population are presented. Events are sorted alphabetically by SOC and PT and then by subgroup within each. MedDRA (version 22.0).
N: Number of patients in treatment group; NETA: Norethindrone acetate; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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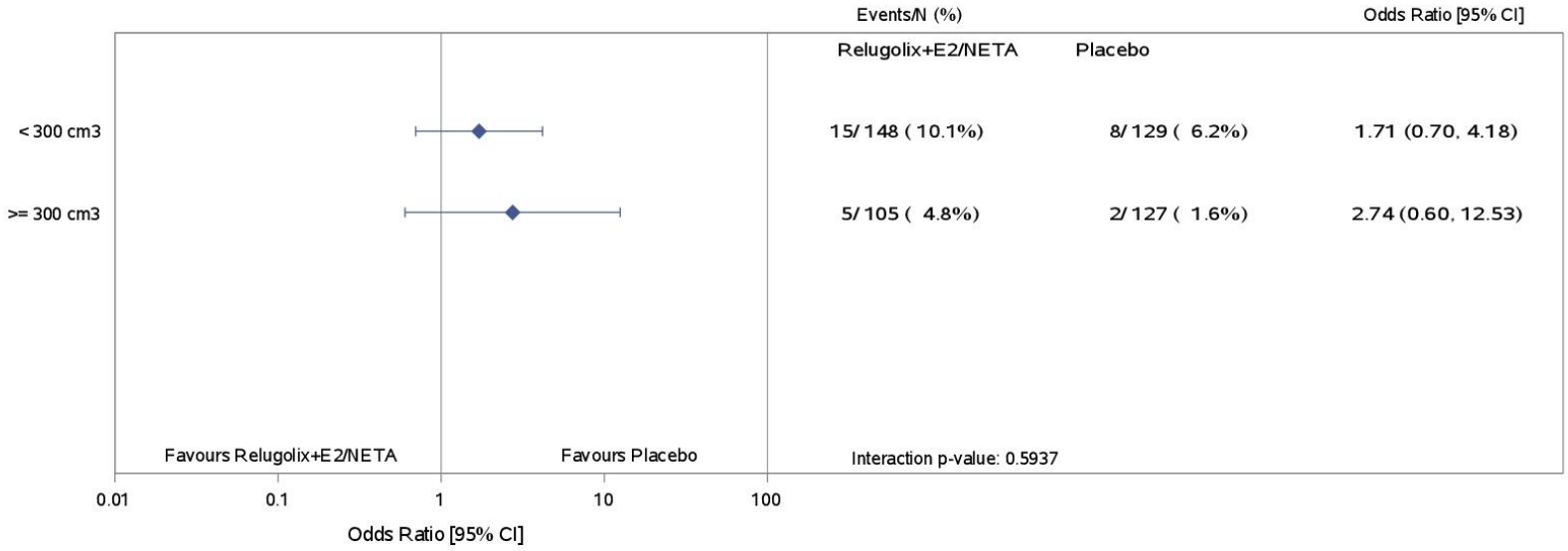
Figure SAF.TEAE.SPT.S3.BIN.FP: Frequent Treatment Emergent Adverse Events by System Organ Class and Preferred Term, by Subgroup (Safety Population)
Study: Pooled
System Organ Class: Psychiatric disorders, Preferred Term: Any
Subgroup: Uterine Volume at Baseline (cm3)



Results are based on a logistic regression model adjusted for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates using a one-stage fixed-effects IPD meta-analysis approach. A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
The interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the Odds Ratio and 95% CI. Missing subgroup levels are not included in estimation of the interaction p-value. The reference group is Placebo. Patients with multiple events are counted only once. MedDRA (version 22.0).
Patients with multiple events for a given PT or SOC are counted only once for each PT and SOC. Only SOCs or PTs for which there are at least 10% of patients with an event in at least one treatment group OR at least 10 patients with an event overall and at least 1% of patients with an event in at least one treatment group in the overall safety population are considered. Further, only SOCs and PTs for which there is a significant treatment effect (p-value <0.05) in the overall safety population are presented. Events are sorted alphabetically by SOC and PT and then by subgroup within each. MedDRA (version 22.0).
N: Number of patients in treatment group; NETA: Norethindrone acetate; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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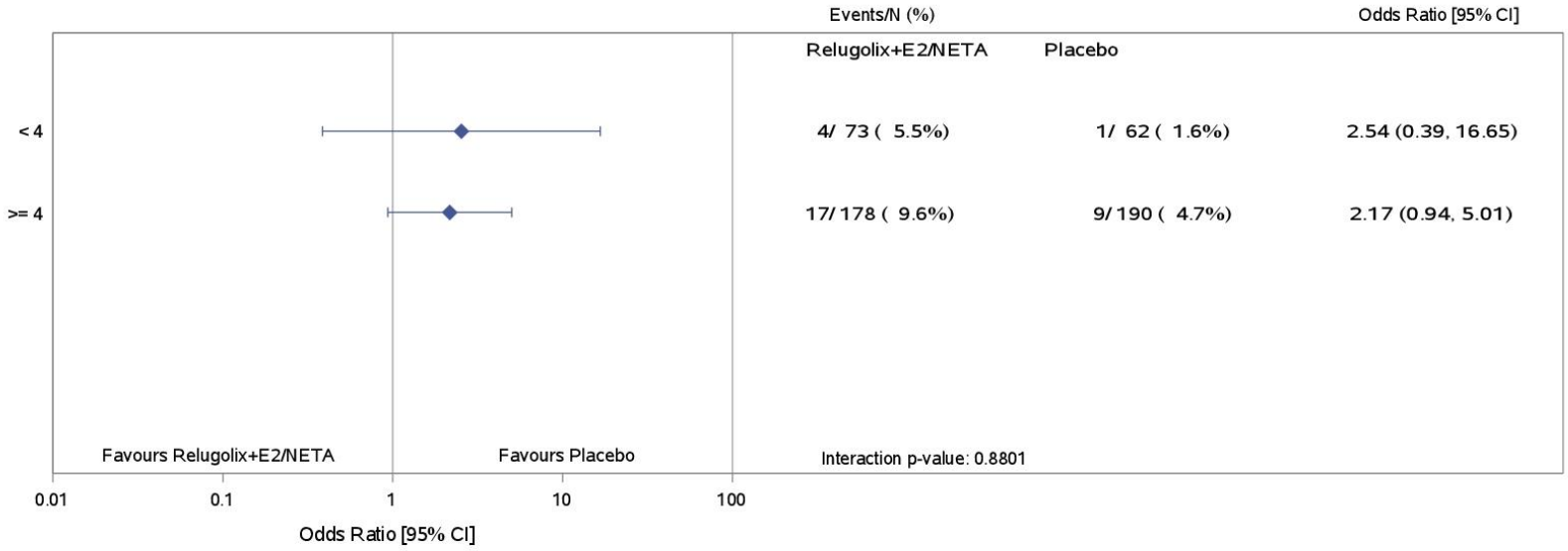
Figure SAF.TEAE.SPT.S4.BIN.FP: Frequent Treatment Emergent Adverse Events by System Organ Class and Preferred Term, by Subgroup (Safety Population)
Study: Pooled
System Organ Class: Psychiatric disorders, Preferred Term: Any
Subgroup: Maximum NRS Pain Score at Baseline



Results are based on a logistic regression model adjusted for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates using a one-stage fixed-effects IPD meta-analysis approach. A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
The interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the Odds Ratio and 95% CI. Missing subgroup levels are not included in estimation of the interaction p-value. The reference group is Placebo. Patients with multiple events are counted only once. MedDRA (version 22.0).
Patients with multiple events for a given PT or SOC are counted only once for each PT and SOC. Only SOCs or PTs for which there are at least 10% of patients with an event in at least one treatment group OR at least 10 patients with an event overall and at least 1% of patients with an event in at least one treatment group in the overall safety population are considered. Further, only SOCs and PTs for which there is a significant treatment effect (p-value <0.05) in the overall safety population are presented. Events are sorted alphabetically by SOC and PT and then by subgroup within each. MedDRA (version 22.0).
N: Number of patients in treatment group; NETA: Norethindrone acetate; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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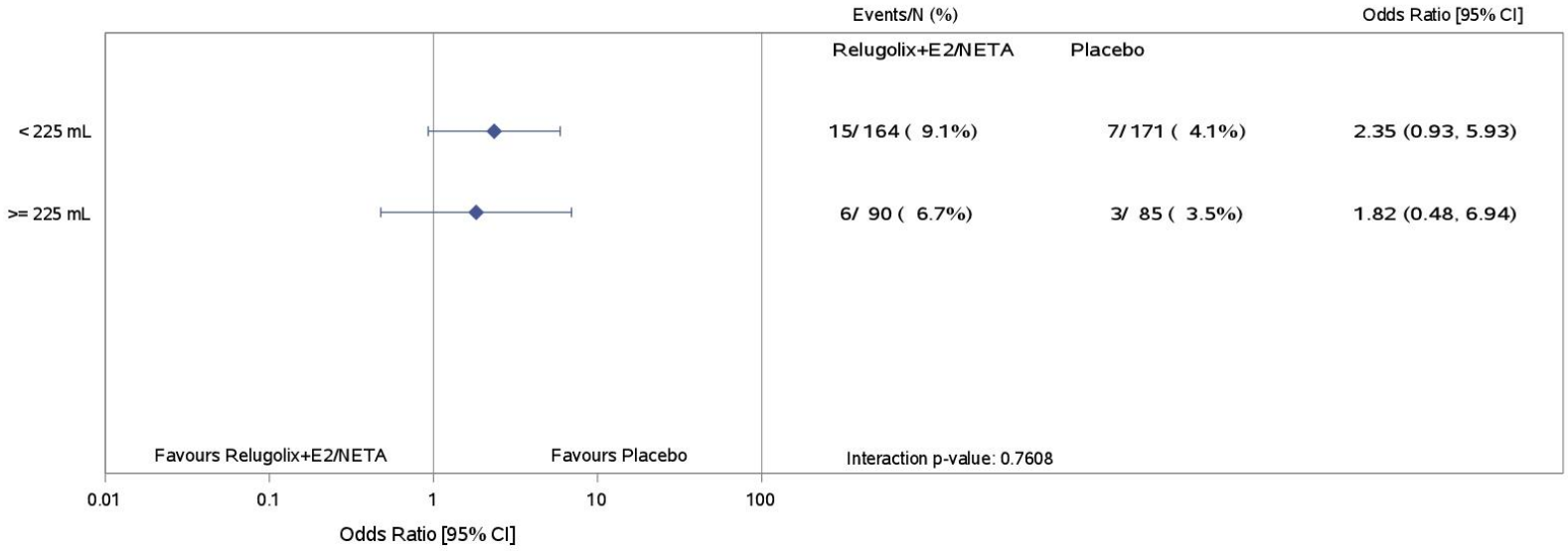
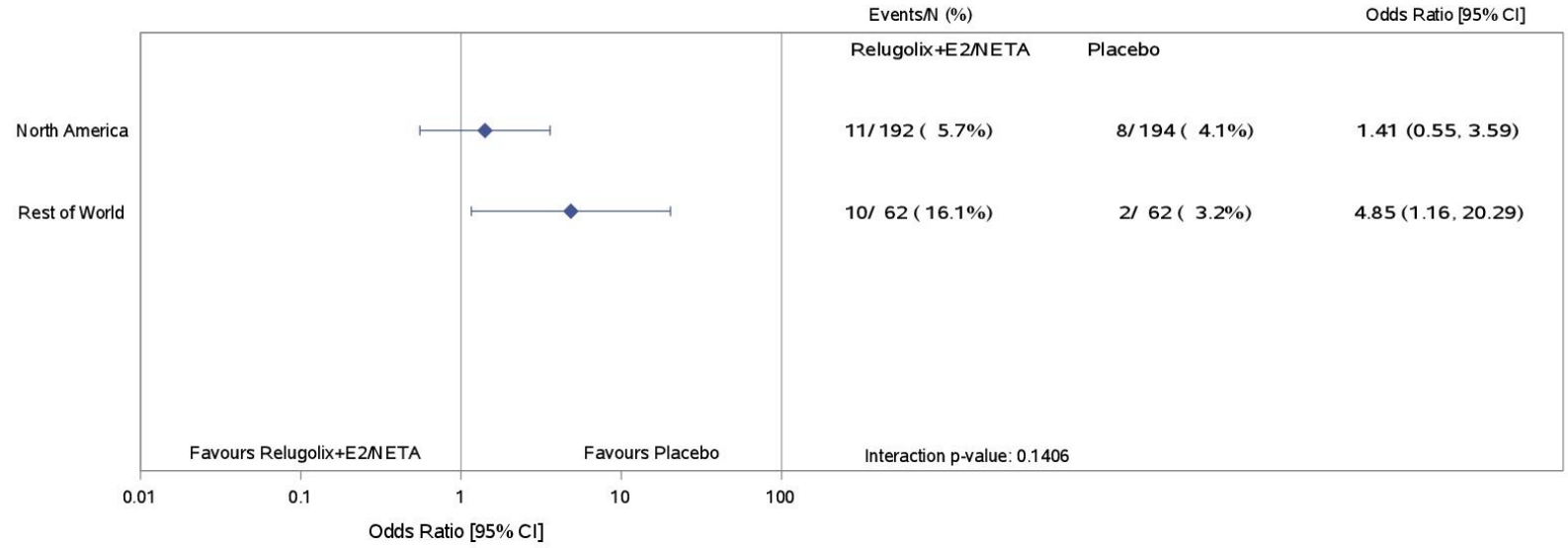
Figure SAF.TEAE.SPT.S5.BIN.FP: Frequent Treatment Emergent Adverse Events by System Organ Class and Preferred Term, by Subgroup (Safety Population)
Study: Pooled
System Organ Class: Psychiatric disorders, Preferred Term: Any
Subgroup: MBL Volume at Baseline (mL)



Results are based on a logistic regression model adjusted for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates using a one-stage fixed-effects IPD meta-analysis approach. A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
The interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the Odds Ratio and 95% CI. Missing subgroup levels are not included in estimation of the interaction p-value. The reference group is Placebo. Patients with multiple events are counted only once. MedDRA (version 22.0).
Patients with multiple events for a given PT or SOC are counted only once for each PT and SOC. Only SOCs or PTs for which there are at least 10% of patients with an event in at least one treatment group OR at least 10 patients with an event overall and at least 1% of patients with an event in at least one treatment group in the overall safety population are considered. Further, only SOCs and PTs for which there is a significant treatment effect (p-value <0.05) in the overall safety population are presented. Events are sorted alphabetically by SOC and PT and then by subgroup within each. MedDRA (version 22.0).
N: Number of patients in treatment group; NETA: Norethindrone acetate; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

Figure SAF.TEAE.SPT.S6.BIN.FP: Frequent Treatment Emergent Adverse Events by System Organ Class and Preferred Term, by Subgroup (Safety Population)
Study: Pooled
System Organ Class: Psychiatric disorders, Preferred Term: Any
Subgroup: Geographic Region I



Results are based on a logistic regression model adjusted for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates using a one-stage fixed-effects IPD meta-analysis approach. A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
The interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the Odds Ratio and 95% CI. Missing subgroup levels are not included in estimation of the interaction p-value. The reference group is Placebo. Patients with multiple events are counted only once. MedDRA (version 22.0).
Patients with multiple events for a given PT or SOC are counted only once for each PT and SOC. Only SOCs or PTs for which there are at least 10% of patients with an event in at least one treatment group OR at least 10 patients with an event overall and at least 1% of patients with an event in at least one treatment group in the overall safety population are considered. Further, only SOCs and PTs for which there is a significant treatment effect (p-value <0.05) in the overall safety population are presented. Events are sorted alphabetically by SOC and PT and then by subgroup within each. MedDRA (version 22.0).
N: Number of patients in treatment group; NETA: Norethindrone acetate; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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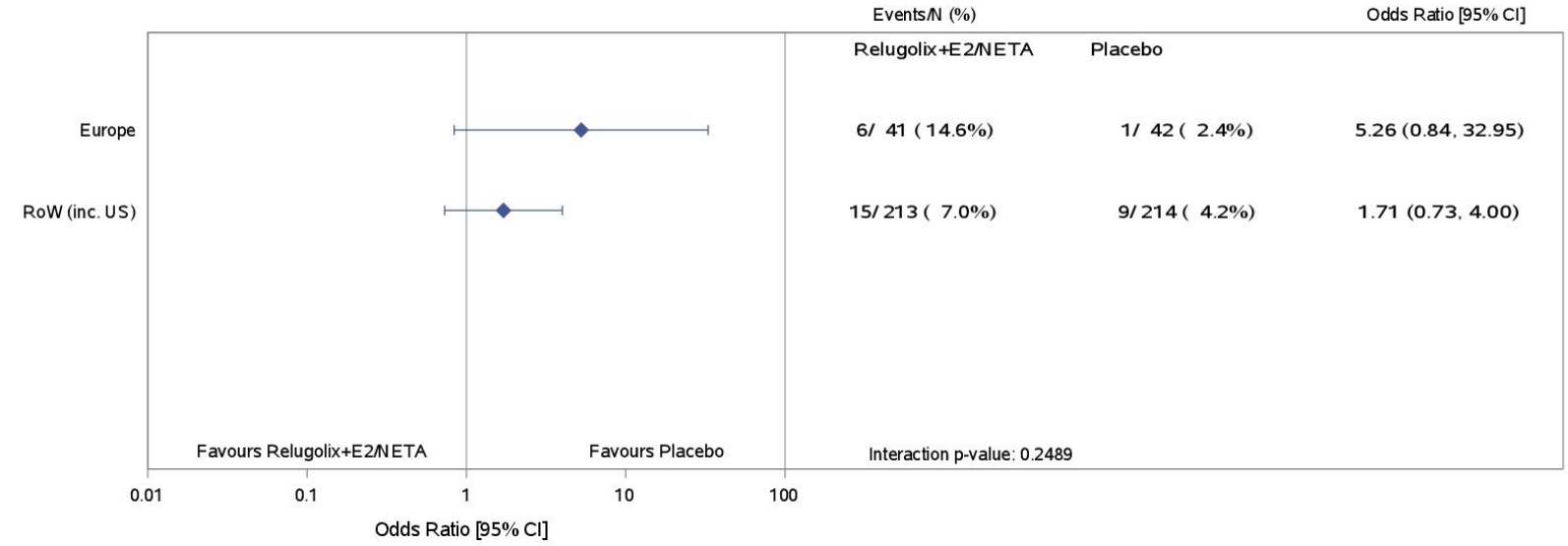
Figure SAF.TEAE.SPT.S7.BIN.FP: Frequent Treatment Emergent Adverse Events by System Organ Class and Preferred Term, by Subgroup (Safety Population)
Study: Pooled
System Organ Class: Psychiatric disorders, Preferred Term: Any
Subgroup: Geographic Region II



Results are based on a logistic regression model adjusted for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates using a one-stage fixed-effects IPD meta-analysis approach. A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
The interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the Odds Ratio and 95% CI. Missing subgroup levels are not included in estimation of the interaction p-value. The reference group is Placebo. Patients with multiple events are counted only once. MedDRA (version 22.0).
Patients with multiple events for a given PT or SOC are counted only once for each PT and SOC. Only SOCs or PTs for which there are at least 10% of patients with an event in at least one treatment group OR at least 10 patients with an event overall and at least 1% of patients with an event in at least one treatment group in the overall safety population are considered. Further, only SOCs and PTs for which there is a significant treatment effect (p-value <0.05) in the overall safety population are presented. Events are sorted alphabetically by SOC and PT and then by subgroup within each. MedDRA (version 22.0).
N: Number of patients in treatment group; NETA: Norethindrone acetate; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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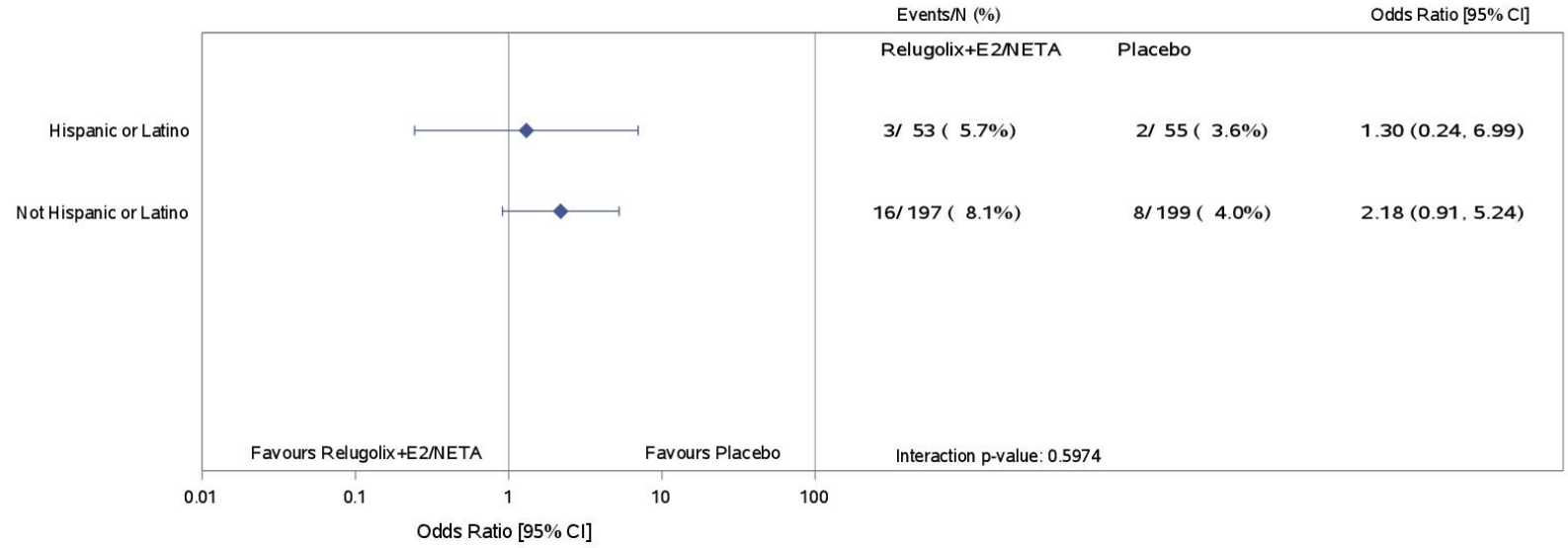
Figure SAF.TEAE.SPT.S8.BIN.FP: Frequent Treatment Emergent Adverse Events by System Organ Class and Preferred Term, by Subgroup (Safety Population)
Study: Pooled
System Organ Class: Psychiatric disorders, Preferred Term: Any
Subgroup: Ethnicity



Results are based on a logistic regression model adjusted for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates using a one-stage fixed-effects IPD meta-analysis approach. A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
The interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the Odds Ratio and 95% CI. Missing subgroup levels are not included in estimation of the interaction p-value. The reference group is Placebo. Patients with multiple events are counted only once. MedDRA (version 22.0).
Patients with multiple events for a given PT or SOC are counted only once for each PT and SOC. Only SOCs or PTs for which there are at least 10% of patients with an event in at least one treatment group OR at least 10 patients with an event overall and at least 1% of patients with an event in at least one treatment group in the overall safety population are considered. Further, only SOCs and PTs for which there is a significant treatment effect (p-value <0.05) in the overall safety population are presented. Events are sorted alphabetically by SOC and PT and then by subgroup within each. MedDRA (version 22.0).
N: Number of patients in treatment group; NETA: Norethindrone acetate; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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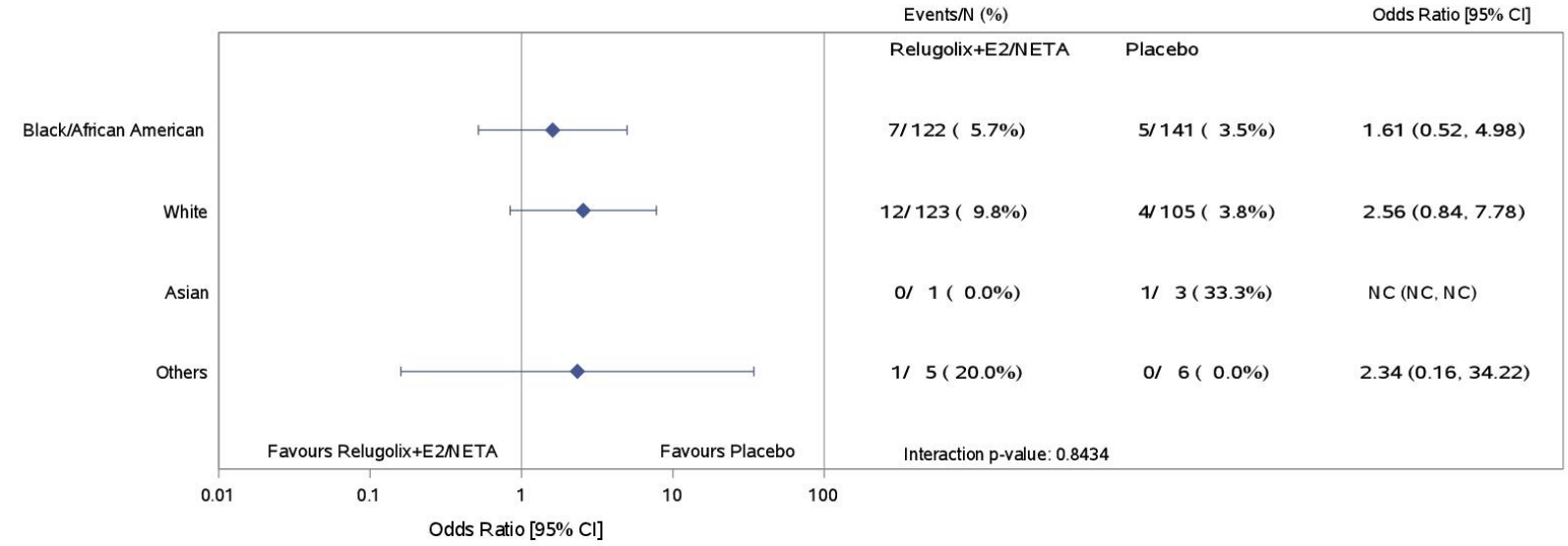
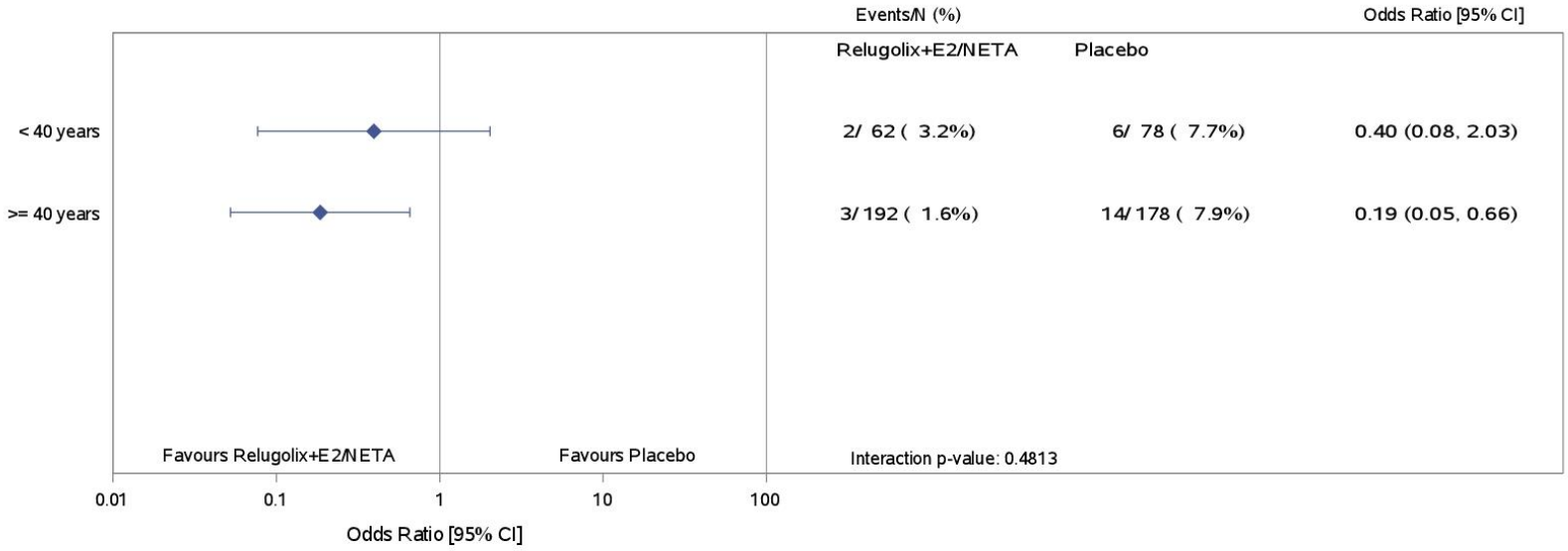
Figure SAF.TEAE.SPT.S9.BIN.FP: Frequent Treatment Emergent Adverse Events by System Organ Class and Preferred Term, by Subgroup (Safety Population)
Study: Pooled
System Organ Class: Psychiatric disorders, Preferred Term: Any
Subgroup: Race



Results are based on a logistic regression model adjusted for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates using a one-stage fixed-effects IPD meta-analysis approach. A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
The interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the Odds Ratio and 95% CI. Missing subgroup levels are not included in estimation of the interaction p-value. The reference group is Placebo. Patients with multiple events are counted only once. MedDRA (version 22.0).
Patients with multiple events for a given PT or SOC are counted only once for each PT and SOC. Only SOCs or PTs for which there are at least 10% of patients with an event in at least one treatment group OR at least 10 patients with an event overall and at least 1% of patients with an event in at least one treatment group in the overall safety population are considered. Further, only SOCs and PTs for which there is a significant treatment effect (p-value <0.05) in the overall safety population are presented. Events are sorted alphabetically by SOC and PT and then by subgroup within each. MedDRA (version 22.0).
N: Number of patients in treatment group; NETA: Norethindrone acetate; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

Figure SAF.TEAE.SPT.S1.BIN.FP: Frequent Treatment Emergent Adverse Events by System Organ Class and Preferred Term, by Subgroup (Safety Population)
Study: Pooled
System Organ Class: Respiratory, thoracic and mediastinal disorders, Preferred Term: Any
Subgroup: Age (years)



Results are based on a logistic regression model adjusted for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates using a one-stage fixed-effects IPD meta-analysis approach. A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
The interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the Odds Ratio and 95% CI. Missing subgroup levels are not included in estimation of the interaction p-value. The reference group is Placebo. Patients with multiple events are counted only once. MedDRA (version 22.0).
Patients with multiple events for a given PT or SOC are counted only once for each PT and SOC. Only SOCs or PTs for which there are at least 10% of patients with an event in at least one treatment group OR at least 10 patients with an event overall and at least 1% of patients with an event in at least one treatment group in the overall safety population are considered. Further, only SOCs and PTs for which there is a significant treatment effect (p-value <0.05) in the overall safety population are presented. Events are sorted alphabetically by SOC and PT and then by subgroup within each. MedDRA (version 22.0).
N: Number of patients in treatment group; NETA: Norethindrone acetate; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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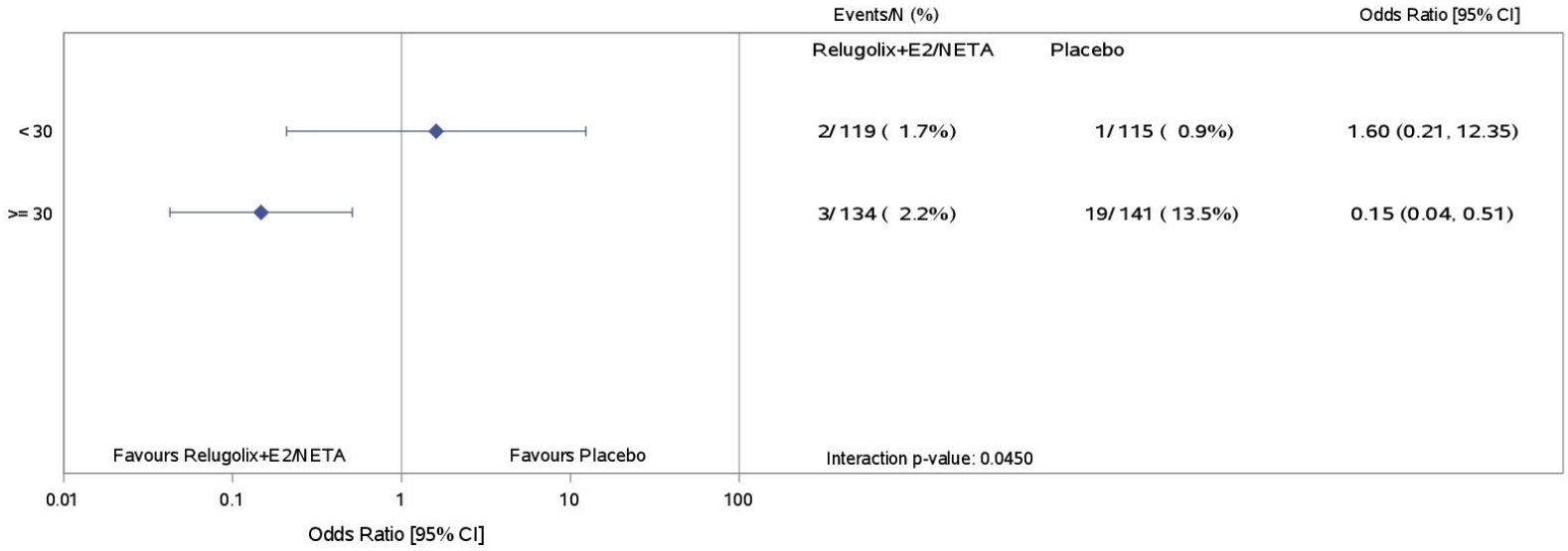
Figure SAF.TEAE.SPT.S2.BIN.FP: Frequent Treatment Emergent Adverse Events by System Organ Class and Preferred Term, by Subgroup (Safety Population)
Study: Pooled
System Organ Class: Respiratory, thoracic and mediastinal disorders, Preferred Term: Any
Subgroup: BMI (kg/m2) at Baseline



Results are based on a logistic regression model adjusted for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates using a one-stage fixed-effects IPD meta-analysis approach. A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
The interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the Odds Ratio and 95% CI. Missing subgroup levels are not included in estimation of the interaction p-value. The reference group is Placebo. Patients with multiple events are counted only once. MedDRA (version 22.0).
Patients with multiple events for a given PT or SOC are counted only once for each PT and SOC. Only SOCs or PTs for which there are at least 10% of patients with an event in at least one treatment group OR at least 10 patients with an event overall and at least 1% of patients with an event in at least one treatment group in the overall safety population are considered. Further, only SOCs and PTs for which there is a significant treatment effect (p-value <0.05) in the overall safety population are presented. Events are sorted alphabetically by SOC and PT and then by subgroup within each. MedDRA (version 22.0).
N: Number of patients in treatment group; NETA: Norethindrone acetate; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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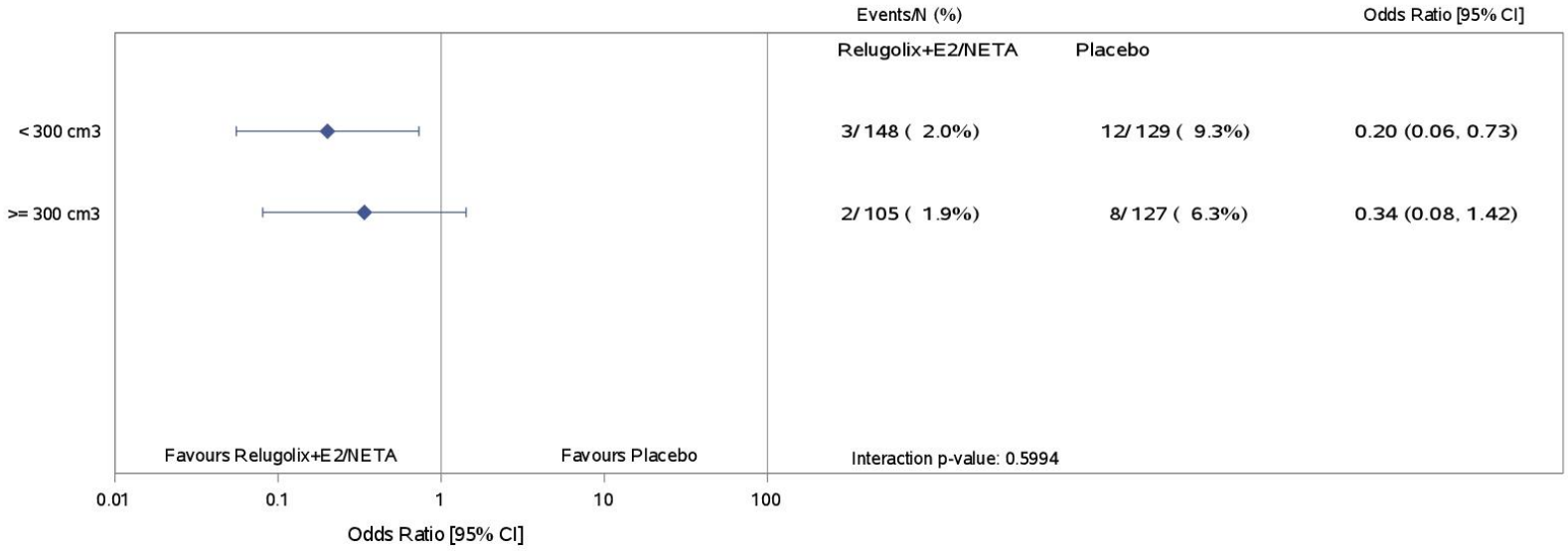
Figure SAF.TEAE.SPT.S3.BIN.FP: Frequent Treatment Emergent Adverse Events by System Organ Class and Preferred Term, by Subgroup (Safety Population)
Study: Pooled
System Organ Class: Respiratory, thoracic and mediastinal disorders, Preferred Term: Any
Subgroup: Uterine Volume at Baseline (cm3)



Results are based on a logistic regression model adjusted for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates using a one-stage fixed-effects IPD meta-analysis approach. A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
The interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the Odds Ratio and 95% CI. Missing subgroup levels are not included in estimation of the interaction p-value. The reference group is Placebo. Patients with multiple events are counted only once. MedDRA (version 22.0).
Patients with multiple events for a given PT or SOC are counted only once for each PT and SOC. Only SOCs or PTs for which there are at least 10% of patients with an event in at least one treatment group OR at least 10 patients with an event overall and at least 1% of patients with an event in at least one treatment group in the overall safety population are considered. Further, only SOCs and PTs for which there is a significant treatment effect (p-value <0.05) in the overall safety population are presented. Events are sorted alphabetically by SOC and PT and then by subgroup within each. MedDRA (version 22.0).
N: Number of patients in treatment group; NETA: Norethindrone acetate; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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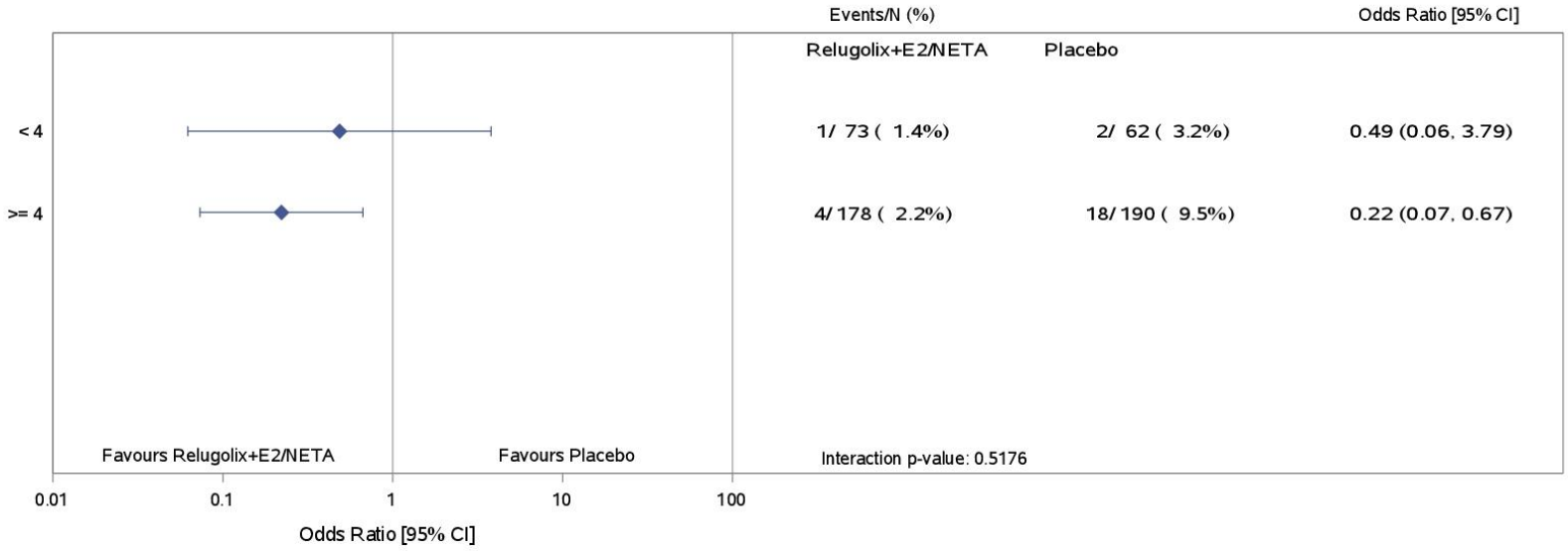
Figure SAF.TEAE.SPT.S4.BIN.FP: Frequent Treatment Emergent Adverse Events by System Organ Class and Preferred Term, by Subgroup (Safety Population)
Study: Pooled
System Organ Class: Respiratory, thoracic and mediastinal disorders, Preferred Term: Any
Subgroup: Maximum NRS Pain Score at Baseline



Results are based on a logistic regression model adjusted for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates using a one-stage fixed-effects IPD meta-analysis approach. A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
The interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the Odds Ratio and 95% CI. Missing subgroup levels are not included in estimation of the interaction p-value. The reference group is Placebo. Patients with multiple events are counted only once. MedDRA (version 22.0).
Patients with multiple events for a given PT or SOC are counted only once for each PT and SOC. Only SOCs or PTs for which there are at least 10% of patients with an event in at least one treatment group OR at least 10 patients with an event overall and at least 1% of patients with an event in at least one treatment group in the overall safety population are considered. Further, only SOCs and PTs for which there is a significant treatment effect (p-value <0.05) in the overall safety population are presented. Events are sorted alphabetically by SOC and PT and then by subgroup within each. MedDRA (version 22.0).
N: Number of patients in treatment group; NETA: Norethindrone acetate; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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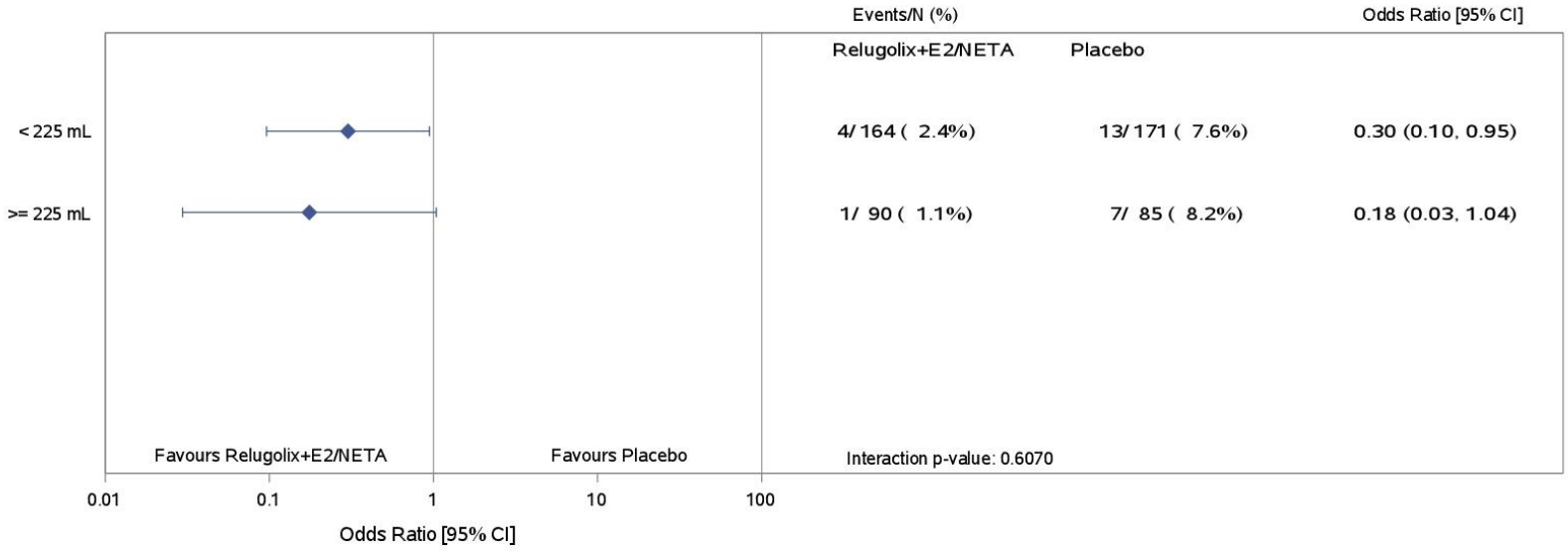
Figure SAF.TEAE.SPT.S5.BIN.FP: Frequent Treatment Emergent Adverse Events by System Organ Class and Preferred Term, by Subgroup (Safety Population)
Study: Pooled
System Organ Class: Respiratory, thoracic and mediastinal disorders, Preferred Term: Any
Subgroup: MBL Volume at Baseline (mL)



Results are based on a logistic regression model adjusted for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates using a one-stage fixed-effects IPD meta-analysis approach. A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
The interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the Odds Ratio and 95% CI. Missing subgroup levels are not included in estimation of the interaction p-value. The reference group is Placebo. Patients with multiple events are counted only once. MedDRA (version 22.0).
Patients with multiple events for a given PT or SOC are counted only once for each PT and SOC. Only SOCs or PTs for which there are at least 10% of patients with an event in at least one treatment group OR at least 10 patients with an event overall and at least 1% of patients with an event in at least one treatment group in the overall safety population are considered. Further, only SOCs and PTs for which there is a significant treatment effect (p-value <0.05) in the overall safety population are presented. Events are sorted alphabetically by SOC and PT and then by subgroup within each. MedDRA (version 22.0).
N: Number of patients in treatment group; NETA: Norethindrone acetate; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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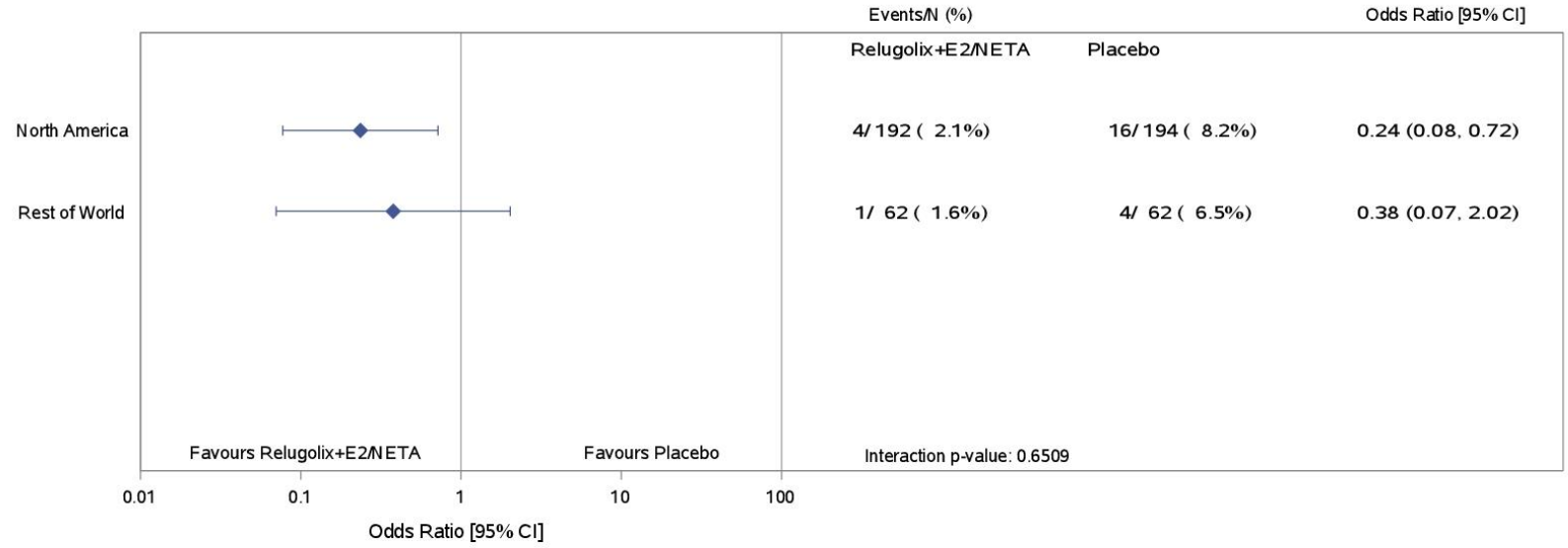
Figure SAF.TEAE.SPT.S6.BIN.FP: Frequent Treatment Emergent Adverse Events by System Organ Class and Preferred Term, by Subgroup (Safety Population)
Study: Pooled
System Organ Class: Respiratory, thoracic and mediastinal disorders, Preferred Term: Any
Subgroup: Geographic Region I



Results are based on a logistic regression model adjusted for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates using a one-stage fixed-effects IPD meta-analysis approach. A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
The interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the Odds Ratio and 95% CI. Missing subgroup levels are not included in estimation of the interaction p-value. The reference group is Placebo. Patients with multiple events are counted only once. MedDRA (version 22.0).
Patients with multiple events for a given PT or SOC are counted only once for each PT and SOC. Only SOCs or PTs for which there are at least 10% of patients with an event in at least one treatment group OR at least 10 patients with an event overall and at least 1% of patients with an event in at least one treatment group in the overall safety population are considered. Further, only SOCs and PTs for which there is a significant treatment effect (p-value <0.05) in the overall safety population are presented. Events are sorted alphabetically by SOC and PT and then by subgroup within each. MedDRA (version 22.0).
N: Number of patients in treatment group; NETA: Norethindrone acetate; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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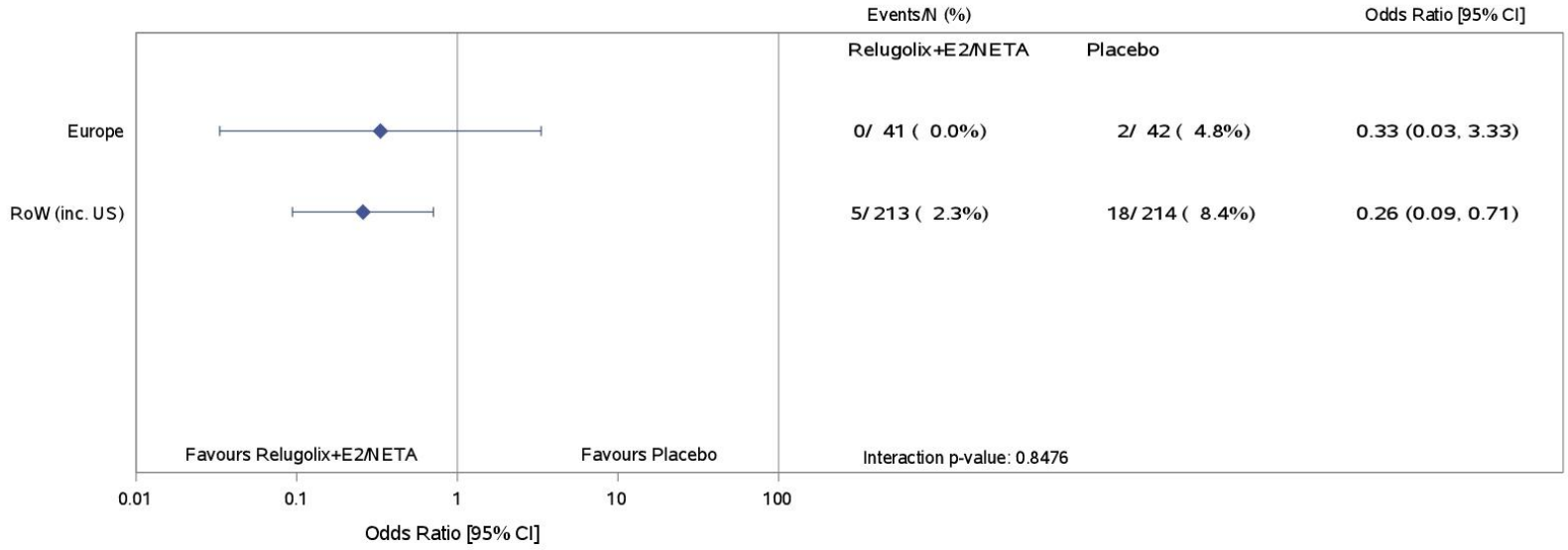
Figure SAF.TEAE.SPT.S7.BIN.FP: Frequent Treatment Emergent Adverse Events by System Organ Class and Preferred Term, by Subgroup (Safety Population)
Study: Pooled
System Organ Class: Respiratory, thoracic and mediastinal disorders, Preferred Term: Any
Subgroup: Geographic Region II



Results are based on a logistic regression model adjusted for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates using a one-stage fixed-effects IPD meta-analysis approach. A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
The interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the Odds Ratio and 95% CI. Missing subgroup levels are not included in estimation of the interaction p-value. The reference group is Placebo. Patients with multiple events are counted only once. MedDRA (version 22.0).
Patients with multiple events for a given PT or SOC are counted only once for each PT and SOC. Only SOCs or PTs for which there are at least 10% of patients with an event in at least one treatment group OR at least 10 patients with an event overall and at least 1% of patients with an event in at least one treatment group in the overall safety population are considered. Further, only SOCs and PTs for which there is a significant treatment effect (p-value <0.05) in the overall safety population are presented. Events are sorted alphabetically by SOC and PT and then by subgroup within each. MedDRA (version 22.0).
N: Number of patients in treatment group; NETA: Norethindrone acetate; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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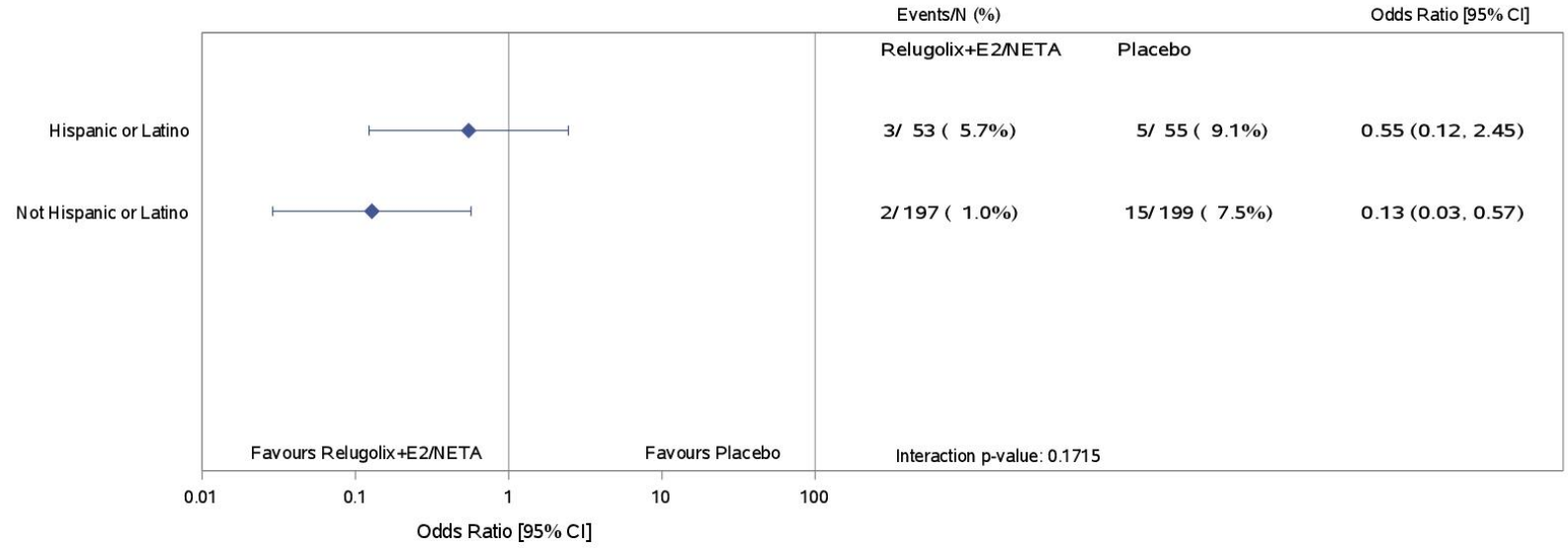
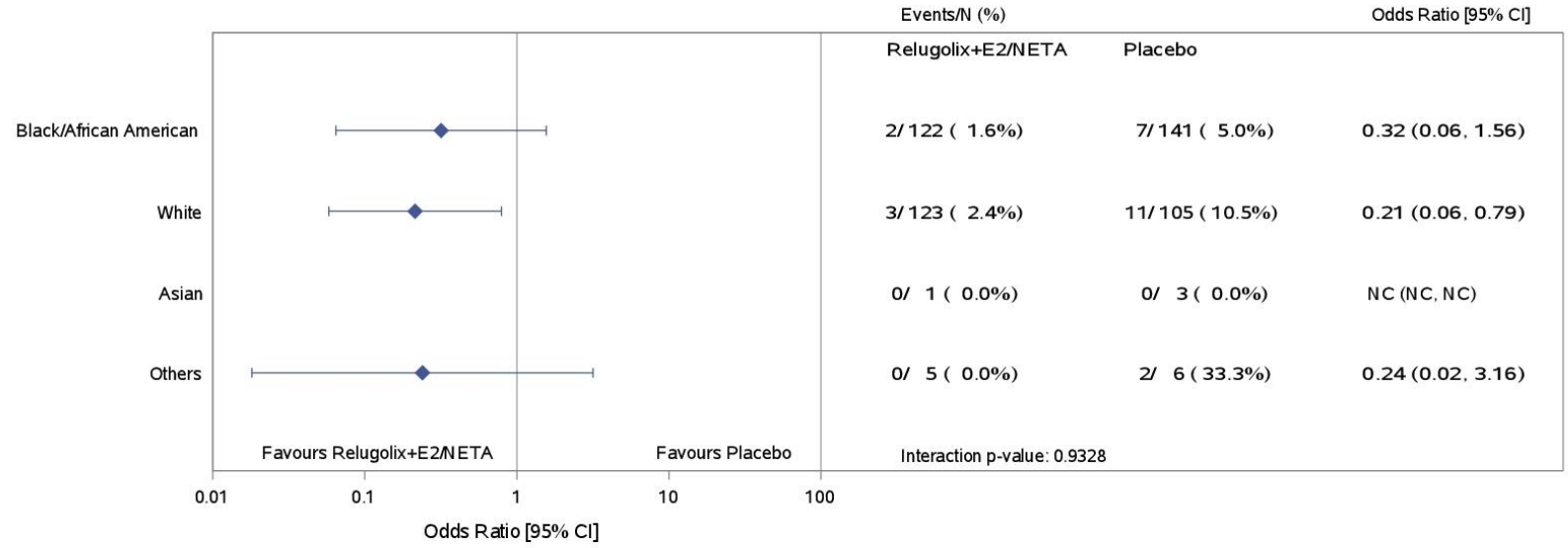
Figure SAF.TEAE.SPT.S8.BIN.FP: Frequent Treatment Emergent Adverse Events by System Organ Class and Preferred Term, by Subgroup (Safety Population)
Study: Pooled
System Organ Class: Respiratory, thoracic and mediastinal disorders, Preferred Term: Any
Subgroup: Ethnicity



Results are based on a logistic regression model adjusted for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates using a one-stage fixed-effects IPD meta-analysis approach. A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
The interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the Odds Ratio and 95% CI. Missing subgroup levels are not included in estimation of the interaction p-value. The reference group is Placebo. Patients with multiple events are counted only once. MedDRA (version 22.0).
Patients with multiple events for a given PT or SOC are counted only once for each PT and SOC. Only SOCs or PTs for which there are at least 10% of patients with an event in at least one treatment group OR at least 10 patients with an event overall and at least 1% of patients with an event in at least one treatment group in the overall safety population are considered. Further, only SOCs and PTs for which there is a significant treatment effect (p-value <0.05) in the overall safety population are presented. Events are sorted alphabetically by SOC and PT and then by subgroup within each. MedDRA (version 22.0).
N: Number of patients in treatment group; NETA: Norethindrone acetate; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

Figure SAF.TEAE.SPT.S9.BIN.FP: Frequent Treatment Emergent Adverse Events by System Organ Class and Preferred Term, by Subgroup (Safety Population)
Study: Pooled
System Organ Class: Respiratory, thoracic and mediastinal disorders, Preferred Term: Any
Subgroup: Race



Results are based on a logistic regression model adjusted for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates using a one-stage fixed-effects IPD meta-analysis approach. A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
The interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the Odds Ratio and 95% CI. Missing subgroup levels are not included in estimation of the interaction p-value. The reference group is Placebo. Patients with multiple events are counted only once. MedDRA (version 22.0).
Patients with multiple events for a given PT or SOC are counted only once for each PT and SOC. Only SOCs or PTs for which there are at least 10% of patients with an event in at least one treatment group OR at least 10 patients with an event overall and at least 1% of patients with an event in at least one treatment group in the overall safety population are considered. Further, only SOCs and PTs for which there is a significant treatment effect (p-value <0.05) in the overall safety population are presented. Events are sorted alphabetically by SOC and PT and then by subgroup within each. MedDRA (version 22.0).
N: Number of patients in treatment group; NETA: Norethindrone acetate; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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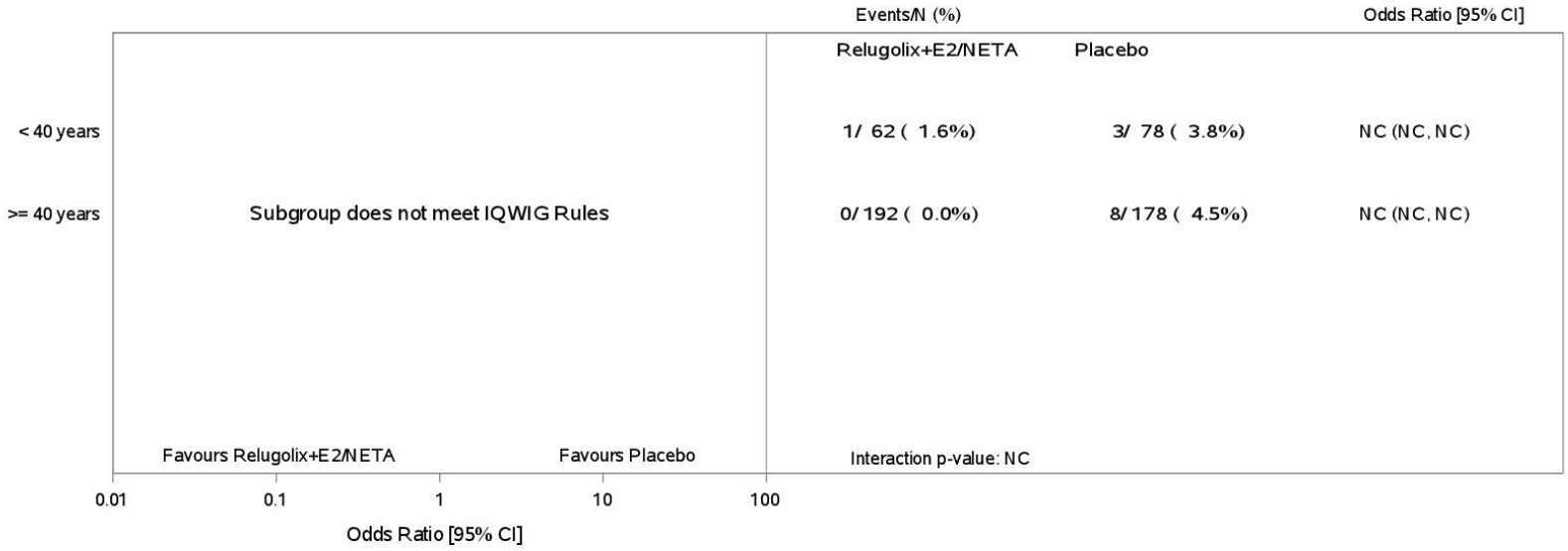
Figure SAF.TEAE.SPT.S1.BIN.FP: Frequent Treatment Emergent Adverse Events by System Organ Class and Preferred Term, by Subgroup (Safety Population)
Study: Pooled
System Organ Class: Respiratory, thoracic and mediastinal disorders, Preferred Term: Cough
Subgroup: Age (years)



Results are based on a logistic regression model adjusted for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates using a one-stage fixed-effects IPD meta-analysis approach. A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
The interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the Odds Ratio and 95% CI. Missing subgroup levels are not included in estimation of the interaction p-value. The reference group is Placebo. Patients with multiple events are counted only once. MedDRA (version 22.0).
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N: Number of patients in treatment group; NETA: Norethindrone acetate; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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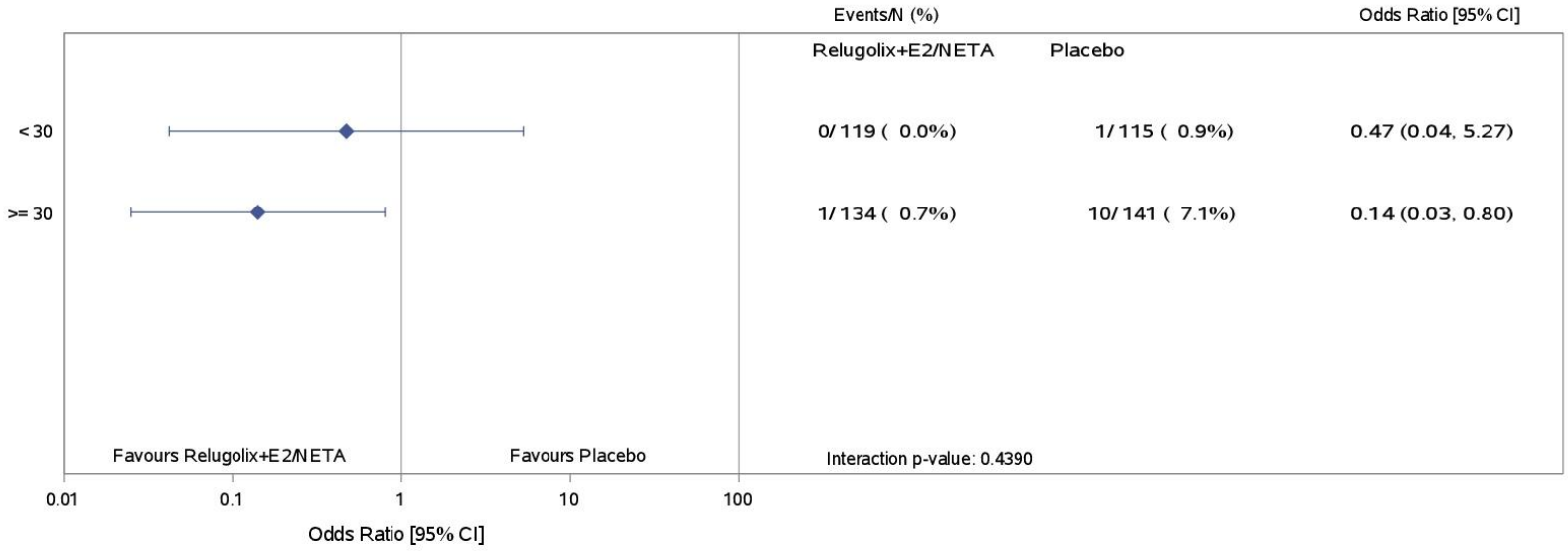
Figure SAF.TEAE.SPT.S2.BIN.FP: Frequent Treatment Emergent Adverse Events by System Organ Class and Preferred Term, by Subgroup (Safety Population)
Study: Pooled
System Organ Class: Respiratory, thoracic and mediastinal disorders, Preferred Term: Cough
Subgroup: BMI (kg/m2) at Baseline



Results are based on a logistic regression model adjusted for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates using a one-stage fixed-effects IPD meta-analysis approach. A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
The interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the Odds Ratio and 95% CI. Missing subgroup levels are not included in estimation of the interaction p-value. The reference group is Placebo. Patients with multiple events are counted only once. MedDRA (version 22.0).
Patients with multiple events for a given PT or SOC are counted only once for each PT and SOC. Only SOCs or PTs for which there are at least 10% of patients with an event in at least one treatment group OR at least 10 patients with an event overall and at least 1% of patients with an event in at least one treatment group in the overall safety population are considered. Further, only SOCs and PTs for which there is a significant treatment effect (p-value <0.05) in the overall safety population are presented. Events are sorted alphabetically by SOC and PT and then by subgroup within each. MedDRA (version 22.0).
N: Number of patients in treatment group; NETA: Norethindrone acetate; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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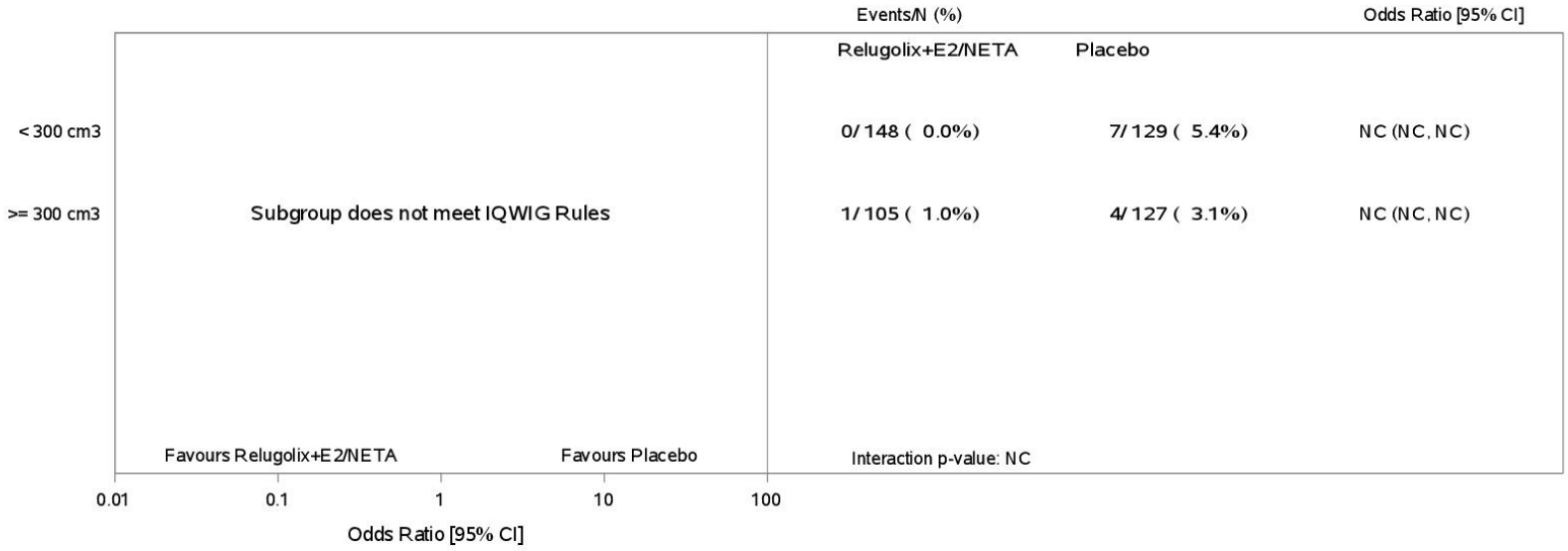
Figure SAF.TEAE.SPT.S3.BIN.FP: Frequent Treatment Emergent Adverse Events by System Organ Class and Preferred Term, by Subgroup (Safety Population)
Study: Pooled
System Organ Class: Respiratory, thoracic and mediastinal disorders, Preferred Term: Cough
Subgroup: Uterine Volume at Baseline (cm3)



Results are based on a logistic regression model adjusted for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates using a one-stage fixed-effects IPD meta-analysis approach. A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
The interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the Odds Ratio and 95% CI. Missing subgroup levels are not included in estimation of the interaction p-value. The reference group is Placebo. Patients with multiple events are counted only once. MedDRA (version 22.0).
Patients with multiple events for a given PT or SOC are counted only once for each PT and SOC. Only SOCs or PTs for which there are at least 10% of patients with an event in at least one treatment group OR at least 10 patients with an event overall and at least 1% of patients with an event in at least one treatment group in the overall safety population are considered. Further, only SOCs and PTs for which there is a significant treatment effect (p-value <0.05) in the overall safety population are presented. Events are sorted alphabetically by SOC and PT and then by subgroup within each. MedDRA (version 22.0).
N: Number of patients in treatment group; NETA: Norethindrone acetate; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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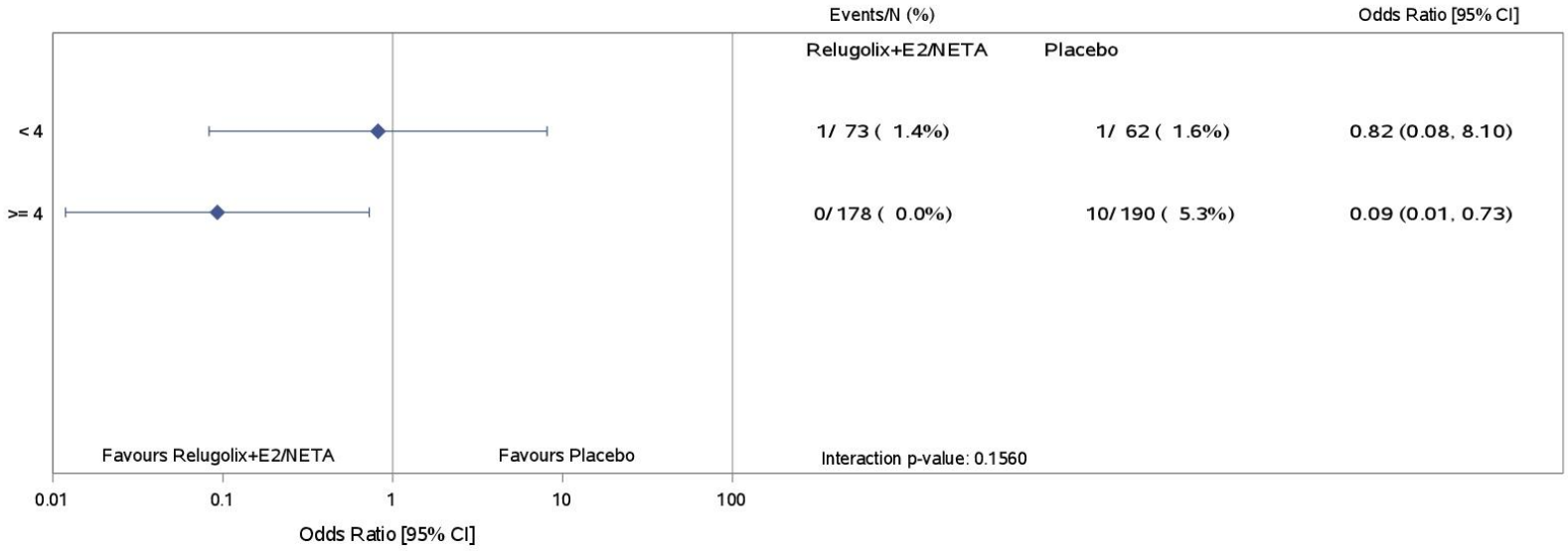
Figure SAF.TEAE.SPT.S4.BIN.FP: Frequent Treatment Emergent Adverse Events by System Organ Class and Preferred Term, by Subgroup (Safety Population)
Study: Pooled
System Organ Class: Respiratory, thoracic and mediastinal disorders, Preferred Term: Cough
Subgroup: Maximum NRS Pain Score at Baseline



Results are based on a logistic regression model adjusted for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates using a one-stage fixed-effects IPD meta-analysis approach. A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
The interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the Odds Ratio and 95% CI. Missing subgroup levels are not included in estimation of the interaction p-value. The reference group is Placebo. Patients with multiple events are counted only once. MedDRA (version 22.0).
Patients with multiple events for a given PT or SOC are counted only once for each PT and SOC. Only SOCs or PTs for which there are at least 10% of patients with an event in at least one treatment group OR at least 10 patients with an event overall and at least 1% of patients with an event in at least one treatment group in the overall safety population are considered. Further, only SOCs and PTs for which there is a significant treatment effect (p-value <0.05) in the overall safety population are presented. Events are sorted alphabetically by SOC and PT and then by subgroup within each. MedDRA (version 22.0).
N: Number of patients in treatment group; NETA: Norethindrone acetate; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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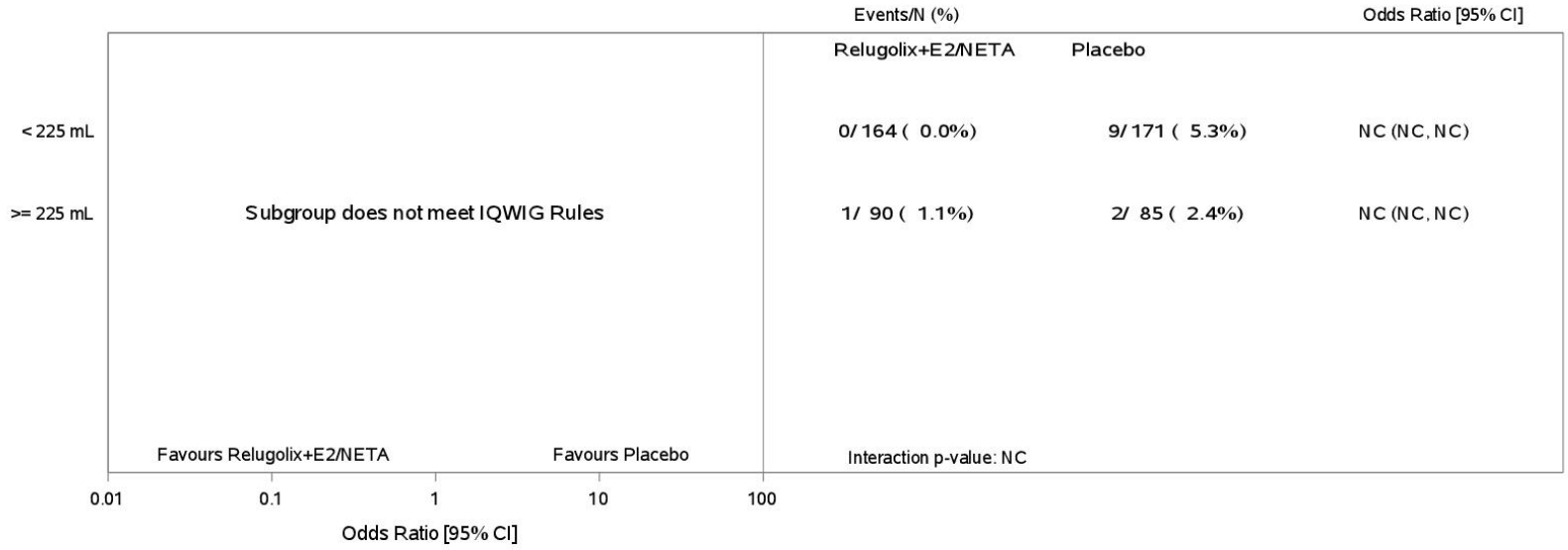
Figure SAF.TEAE.SPT.S5.BIN.FP: Frequent Treatment Emergent Adverse Events by System Organ Class and Preferred Term, by Subgroup (Safety Population)
Study: Pooled
System Organ Class: Respiratory, thoracic and mediastinal disorders, Preferred Term: Cough
Subgroup: MBL Volume at Baseline (mL)



Results are based on a logistic regression model adjusted for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates using a one-stage fixed-effects IPD meta-analysis approach. A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
The interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the Odds Ratio and 95% CI. Missing subgroup levels are not included in estimation of the interaction p-value. The reference group is Placebo. Patients with multiple events are counted only once. MedDRA (version 22.0).
Patients with multiple events for a given PT or SOC are counted only once for each PT and SOC. Only SOCs or PTs for which there are at least 10% of patients with an event in at least one treatment group OR at least 10 patients with an event overall and at least 1% of patients with an event in at least one treatment group in the overall safety population are considered. Further, only SOCs and PTs for which there is a significant treatment effect (p-value <0.05) in the overall safety population are presented. Events are sorted alphabetically by SOC and PT and then by subgroup within each. MedDRA (version 22.0).
N: Number of patients in treatment group; NETA: Norethindrone acetate; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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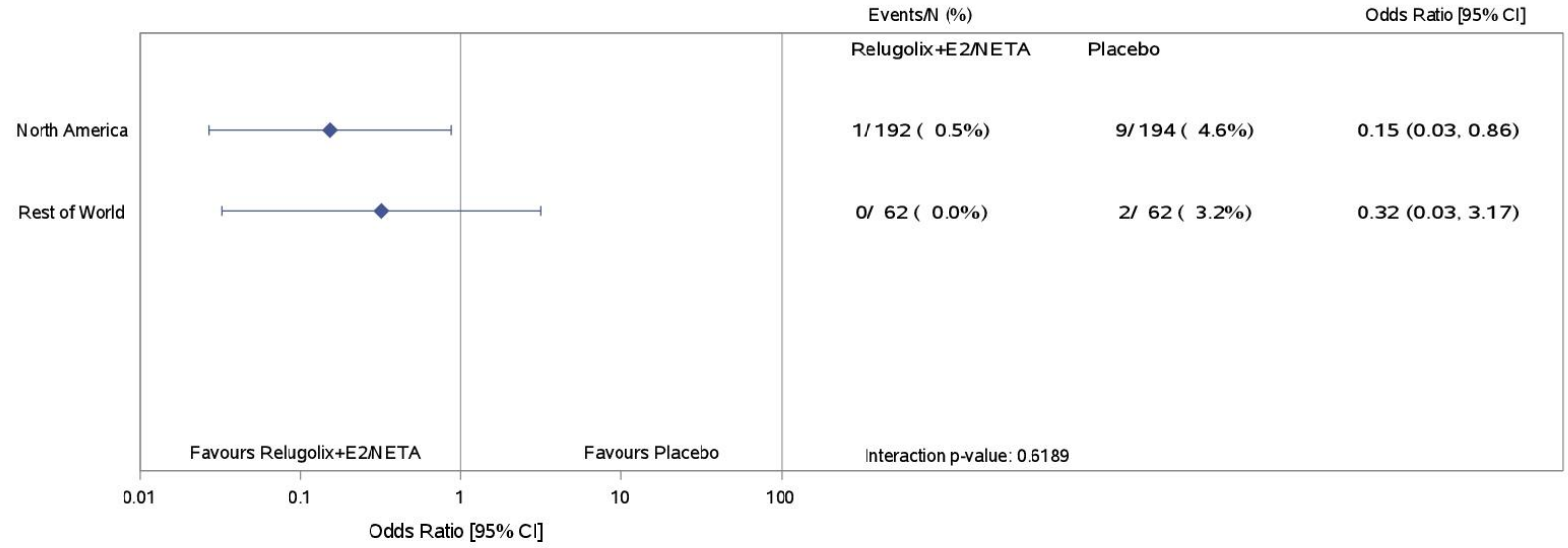
Figure SAF.TEAE.SPT.S6.BIN.FP: Frequent Treatment Emergent Adverse Events by System Organ Class and Preferred Term, by Subgroup (Safety Population)
Study: Pooled
System Organ Class: Respiratory, thoracic and mediastinal disorders, Preferred Term: Cough
Subgroup: Geographic Region I



Results are based on a logistic regression model adjusted for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates using a one-stage fixed-effects IPD meta-analysis approach. A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
The interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the Odds Ratio and 95% CI. Missing subgroup levels are not included in estimation of the interaction p-value. The reference group is Placebo. Patients with multiple events are counted only once. MedDRA (version 22.0).
Patients with multiple events for a given PT or SOC are counted only once for each PT and SOC. Only SOCs or PTs for which there are at least 10% of patients with an event in at least one treatment group OR at least 10 patients with an event overall and at least 1% of patients with an event in at least one treatment group in the overall safety population are considered. Further, only SOCs and PTs for which there is a significant treatment effect (p-value <0.05) in the overall safety population are presented. Events are sorted alphabetically by SOC and PT and then by subgroup within each. MedDRA (version 22.0).
N: Number of patients in treatment group; NETA: Norethindrone acetate; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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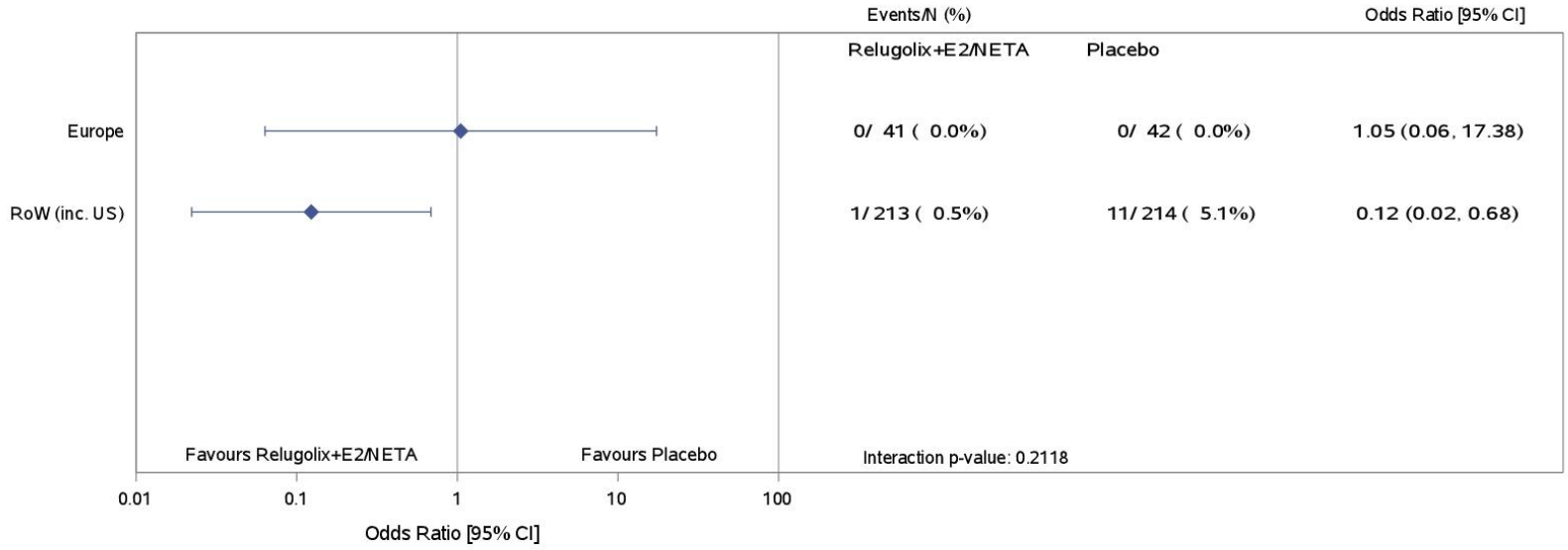
Figure SAF.TEAE.SPT.S7.BIN.FP: Frequent Treatment Emergent Adverse Events by System Organ Class and Preferred Term, by Subgroup (Safety Population)
Study: Pooled
System Organ Class: Respiratory, thoracic and mediastinal disorders, Preferred Term: Cough
Subgroup: Geographic Region II



Results are based on a logistic regression model adjusted for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates using a one-stage fixed-effects IPD meta-analysis approach. A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
The interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the Odds Ratio and 95% CI. Missing subgroup levels are not included in estimation of the interaction p-value. The reference group is Placebo. Patients with multiple events are counted only once. MedDRA (version 22.0).
Patients with multiple events for a given PT or SOC are counted only once for each PT and SOC. Only SOCs or PTs for which there are at least 10% of patients with an event in at least one treatment group OR at least 10 patients with an event overall and at least 1% of patients with an event in at least one treatment group in the overall safety population are considered. Further, only SOCs and PTs for which there is a significant treatment effect (p-value <0.05) in the overall safety population are presented. Events are sorted alphabetically by SOC and PT and then by subgroup within each. MedDRA (version 22.0).
N: Number of patients in treatment group; NETA: Norethindrone acetate; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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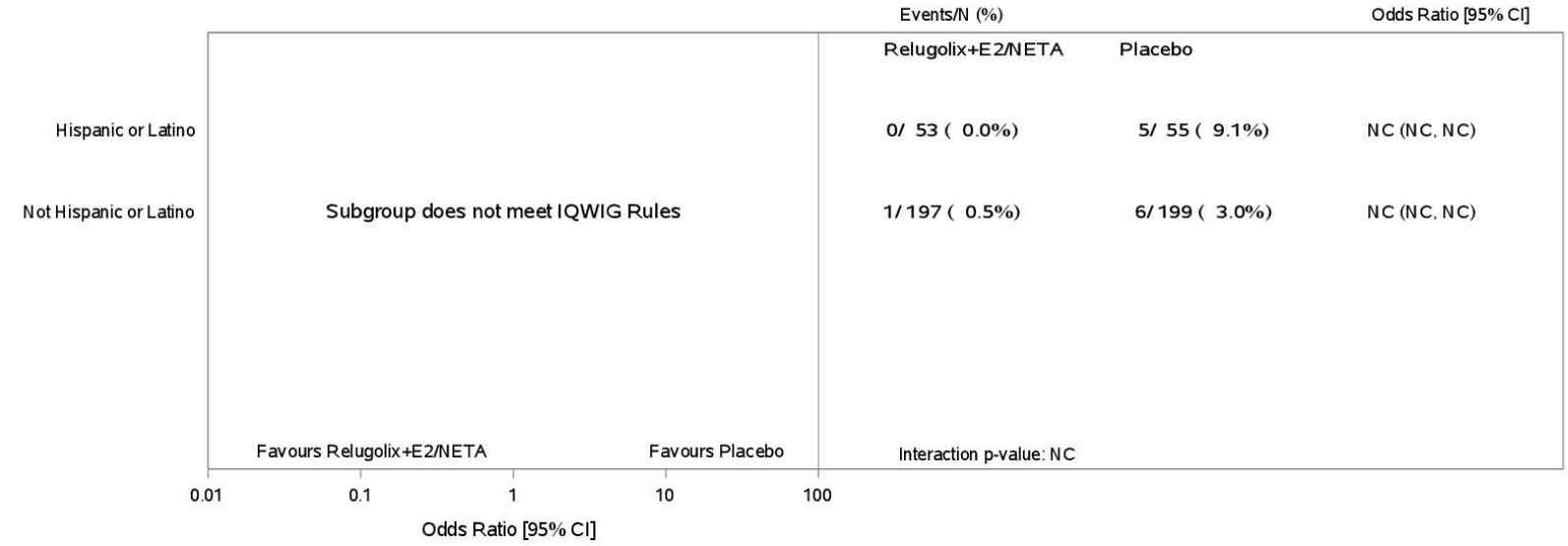
Figure SAF.TEAE.SPT.S8.BIN.FP: Frequent Treatment Emergent Adverse Events by System Organ Class and Preferred Term, by Subgroup (Safety Population)
Study: Pooled
System Organ Class: Respiratory, thoracic and mediastinal disorders, Preferred Term: Cough
Subgroup: Ethnicity



Results are based on a logistic regression model adjusted for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates using a one-stage fixed-effects IPD meta-analysis approach. A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
The interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the Odds Ratio and 95% CI. Missing subgroup levels are not included in estimation of the interaction p-value. The reference group is Placebo. Patients with multiple events are counted only once. MedDRA (version 22.0).
Patients with multiple events for a given PT or SOC are counted only once for each PT and SOC. Only SOCs or PTs for which there are at least 10% of patients with an event in at least one treatment group OR at least 10 patients with an event overall and at least 1% of patients with an event in at least one treatment group in the overall safety population are considered. Further, only SOCs and PTs for which there is a significant treatment effect (p-value <0.05) in the overall safety population are presented. Events are sorted alphabetically by SOC and PT and then by subgroup within each. MedDRA (version 22.0).
N: Number of patients in treatment group; NETA: Norethindrone acetate; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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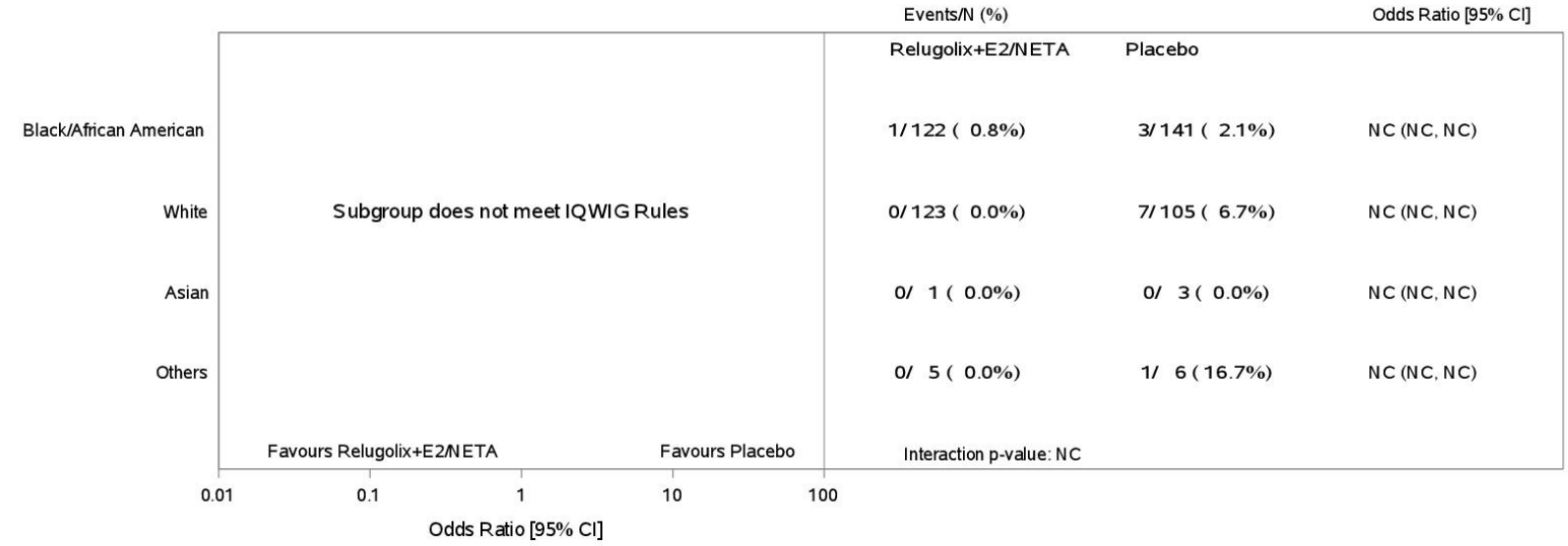
Figure SAF.TEAE.SPT.S9.BIN.FP: Frequent Treatment Emergent Adverse Events by System Organ Class and Preferred Term, by Subgroup (Safety Population)
Study: Pooled
System Organ Class: Respiratory, thoracic and mediastinal disorders, Preferred Term: Cough
Subgroup: Race



Results are based on a logistic regression model adjusted for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates using a one-stage fixed-effects IPD meta-analysis approach. A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
The interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the Odds Ratio and 95% CI. Missing subgroup levels are not included in estimation of the interaction p-value. The reference group is Placebo. Patients with multiple events are counted only once. MedDRA (version 22.0).
Patients with multiple events for a given PT or SOC are counted only once for each PT and SOC. Only SOCs or PTs for which there are at least 10% of patients with an event in at least one treatment group OR at least 10 patients with an event overall and at least 1% of patients with an event in at least one treatment group in the overall safety population are considered. Further, only SOCs and PTs for which there is a significant treatment effect (p-value <0.05) in the overall safety population are presented. Events are sorted alphabetically by SOC and PT and then by subgroup within each. MedDRA (version 22.0).
N: Number of patients in treatment group; NETA: Norethindrone acetate; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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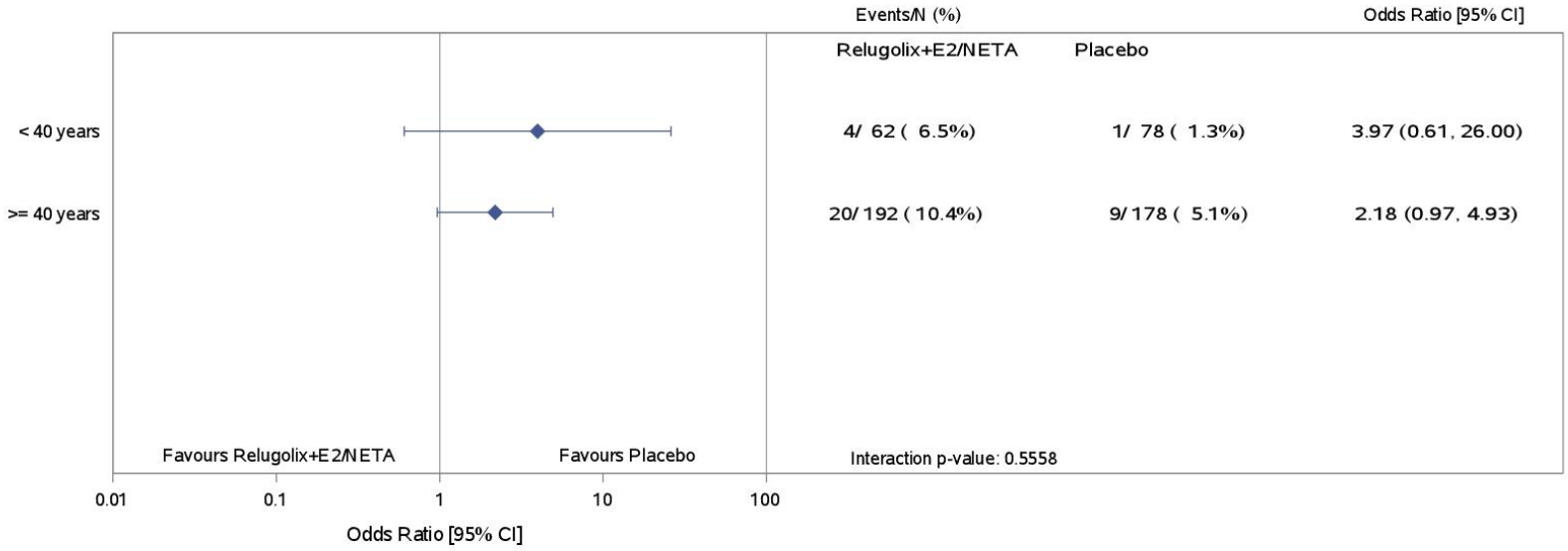
Figure SAF.TEAE.SPT.S1.BIN.FP: Frequent Treatment Emergent Adverse Events by System Organ Class and Preferred Term, by Subgroup (Safety Population)
Study: Pooled
System Organ Class: Skin and subcutaneous tissue disorders, Preferred Term: Any
Subgroup: Age (years)



Results are based on a logistic regression model adjusted for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates using a one-stage fixed-effects IPD meta-analysis approach. A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
The interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the Odds Ratio and 95% CI. Missing subgroup levels are not included in estimation of the interaction p-value. The reference group is Placebo. Patients with multiple events are counted only once. MedDRA (version 22.0).
Patients with multiple events for a given PT or SOC are counted only once for each PT and SOC. Only SOCs or PTs for which there are at least 10% of patients with an event in at least one treatment group OR at least 10 patients with an event overall and at least 1% of patients with an event in at least one treatment group in the overall safety population are considered. Further, only SOCs and PTs for which there is a significant treatment effect (p-value <0.05) in the overall safety population are presented. Events are sorted alphabetically by SOC and PT and then by subgroup within each. MedDRA (version 22.0).
N: Number of patients in treatment group; NETA: Norethindrone acetate; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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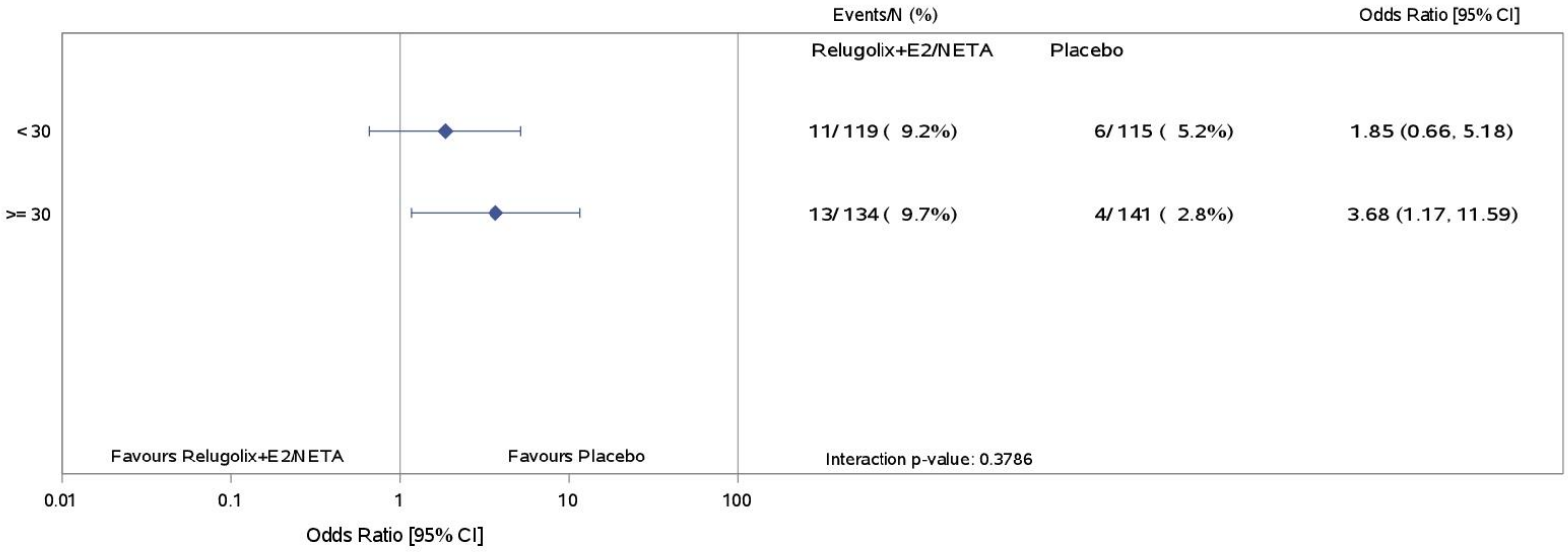
Figure SAF.TEAE.SPT.S2.BIN.FP: Frequent Treatment Emergent Adverse Events by System Organ Class and Preferred Term, by Subgroup (Safety Population)
Study: Pooled
System Organ Class: Skin and subcutaneous tissue disorders, Preferred Term: Any
Subgroup: BMI (kg/m2) at Baseline



Results are based on a logistic regression model adjusted for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates using a one-stage fixed-effects IPD meta-analysis approach. A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
The interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the Odds Ratio and 95% CI. Missing subgroup levels are not included in estimation of the interaction p-value. The reference group is Placebo. Patients with multiple events are counted only once. MedDRA (version 22.0).
Patients with multiple events for a given PT or SOC are counted only once for each PT and SOC. Only SOCs or PTs for which there are at least 10% of patients with an event in at least one treatment group OR at least 10 patients with an event overall and at least 1% of patients with an event in at least one treatment group in the overall safety population are considered. Further, only SOCs and PTs for which there is a significant treatment effect (p-value <0.05) in the overall safety population are presented. Events are sorted alphabetically by SOC and PT and then by subgroup within each. MedDRA (version 22.0).
N: Number of patients in treatment group; NETA: Norethindrone acetate; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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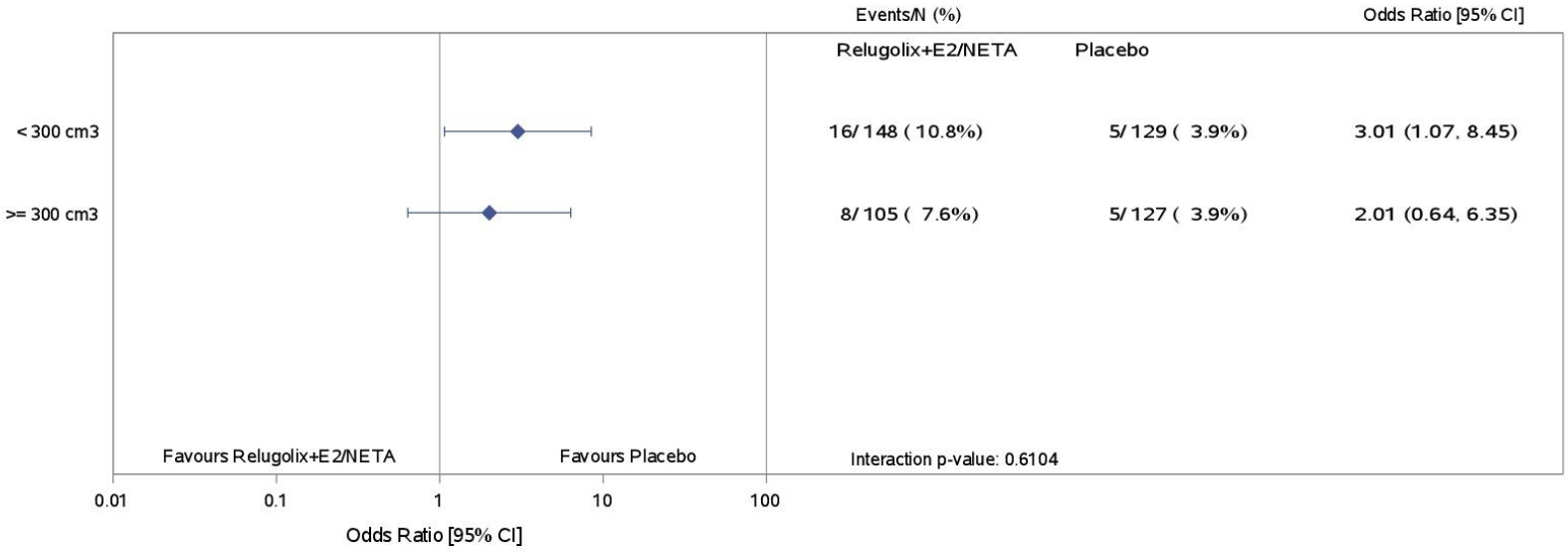
Figure SAF.TEAE.SPT.S3.BIN.FP: Frequent Treatment Emergent Adverse Events by System Organ Class and Preferred Term, by Subgroup (Safety Population)
Study: Pooled
System Organ Class: Skin and subcutaneous tissue disorders, Preferred Term: Any
Subgroup: Uterine Volume at Baseline (cm3)



Results are based on a logistic regression model adjusted for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates using a one-stage fixed-effects IPD meta-analysis approach. A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
The interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the Odds Ratio and 95% CI. Missing subgroup levels are not included in estimation of the interaction p-value. The reference group is Placebo. Patients with multiple events are counted only once. MedDRA (version 22.0).
Patients with multiple events for a given PT or SOC are counted only once for each PT and SOC. Only SOCs or PTs for which there are at least 10% of patients with an event in at least one treatment group OR at least 10 patients with an event overall and at least 1% of patients with an event in at least one treatment group in the overall safety population are considered. Further, only SOCs and PTs for which there is a significant treatment effect (p-value <0.05) in the overall safety population are presented. Events are sorted alphabetically by SOC and PT and then by subgroup within each. MedDRA (version 22.0).
N: Number of patients in treatment group; NETA: Norethindrone acetate; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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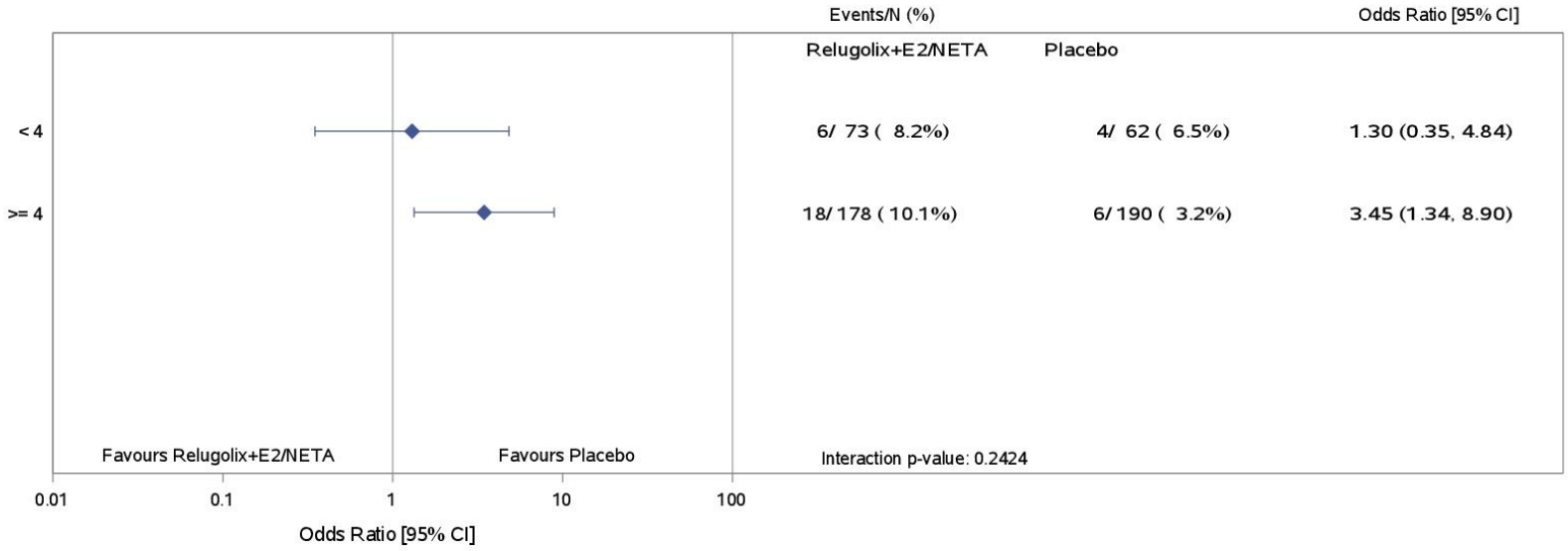
Figure SAF.TEAE.SPT.S4.BIN.FP: Frequent Treatment Emergent Adverse Events by System Organ Class and Preferred Term, by Subgroup (Safety Population)
Study: Pooled
System Organ Class: Skin and subcutaneous tissue disorders, Preferred Term: Any
Subgroup: Maximum NRS Pain Score at Baseline



Results are based on a logistic regression model adjusted for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates using a one-stage fixed-effects IPD meta-analysis approach. A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
The interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the Odds Ratio and 95% CI. Missing subgroup levels are not included in estimation of the interaction p-value. The reference group is Placebo. Patients with multiple events are counted only once. MedDRA (version 22.0).
Patients with multiple events for a given PT or SOC are counted only once for each PT and SOC. Only SOCs or PTs for which there are at least 10% of patients with an event in at least one treatment group OR at least 10 patients with an event overall and at least 1% of patients with an event in at least one treatment group in the overall safety population are considered. Further, only SOCs and PTs for which there is a significant treatment effect (p-value <0.05) in the overall safety population are presented. Events are sorted alphabetically by SOC and PT and then by subgroup within each. MedDRA (version 22.0).
N: Number of patients in treatment group; NETA: Norethindrone acetate; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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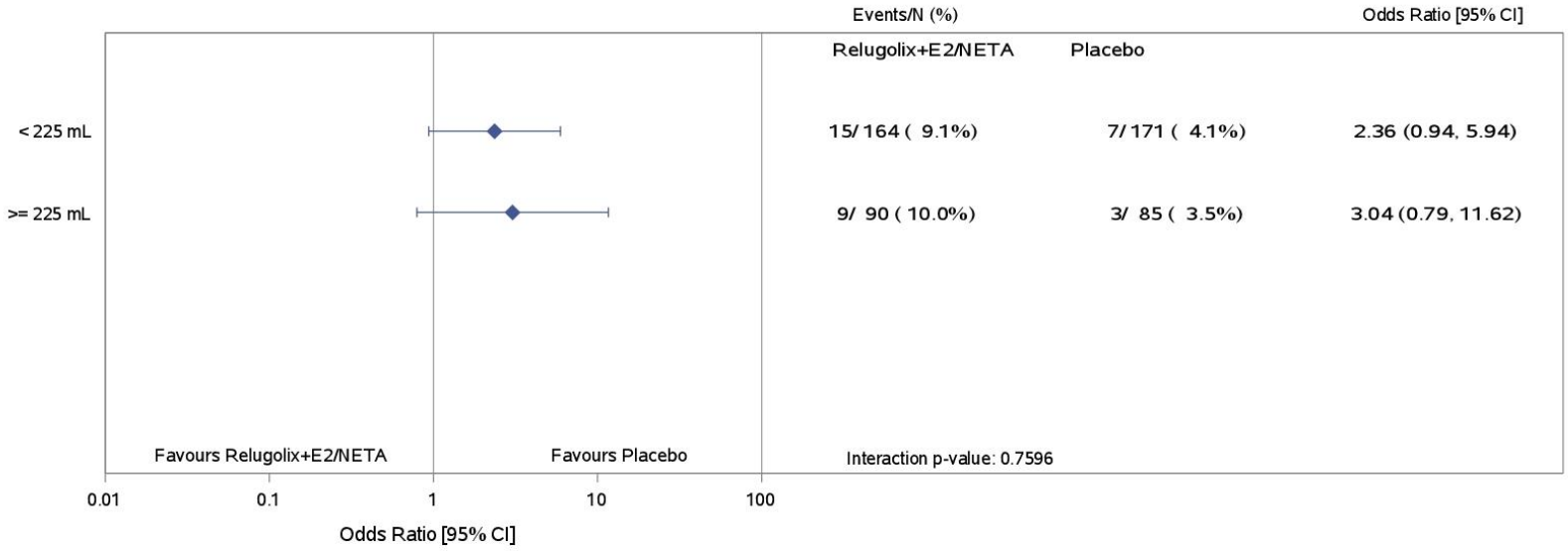
Figure SAF.TEAE.SPT.S5.BIN.FP: Frequent Treatment Emergent Adverse Events by System Organ Class and Preferred Term, by Subgroup (Safety Population)
Study: Pooled
System Organ Class: Skin and subcutaneous tissue disorders, Preferred Term: Any
Subgroup: MBL Volume at Baseline (mL)



Results are based on a logistic regression model adjusted for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates using a one-stage fixed-effects IPD meta-analysis approach. A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
The interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the Odds Ratio and 95% CI. Missing subgroup levels are not included in estimation of the interaction p-value. The reference group is Placebo. Patients with multiple events are counted only once. MedDRA (version 22.0).
Patients with multiple events for a given PT or SOC are counted only once for each PT and SOC. Only SOCs or PTs for which there are at least 10% of patients with an event in at least one treatment group OR at least 10 patients with an event overall and at least 1% of patients with an event in at least one treatment group in the overall safety population are considered. Further, only SOCs and PTs for which there is a significant treatment effect (p-value <0.05) in the overall safety population are presented. Events are sorted alphabetically by SOC and PT and then by subgroup within each. MedDRA (version 22.0).
N: Number of patients in treatment group; NETA: Norethindrone acetate; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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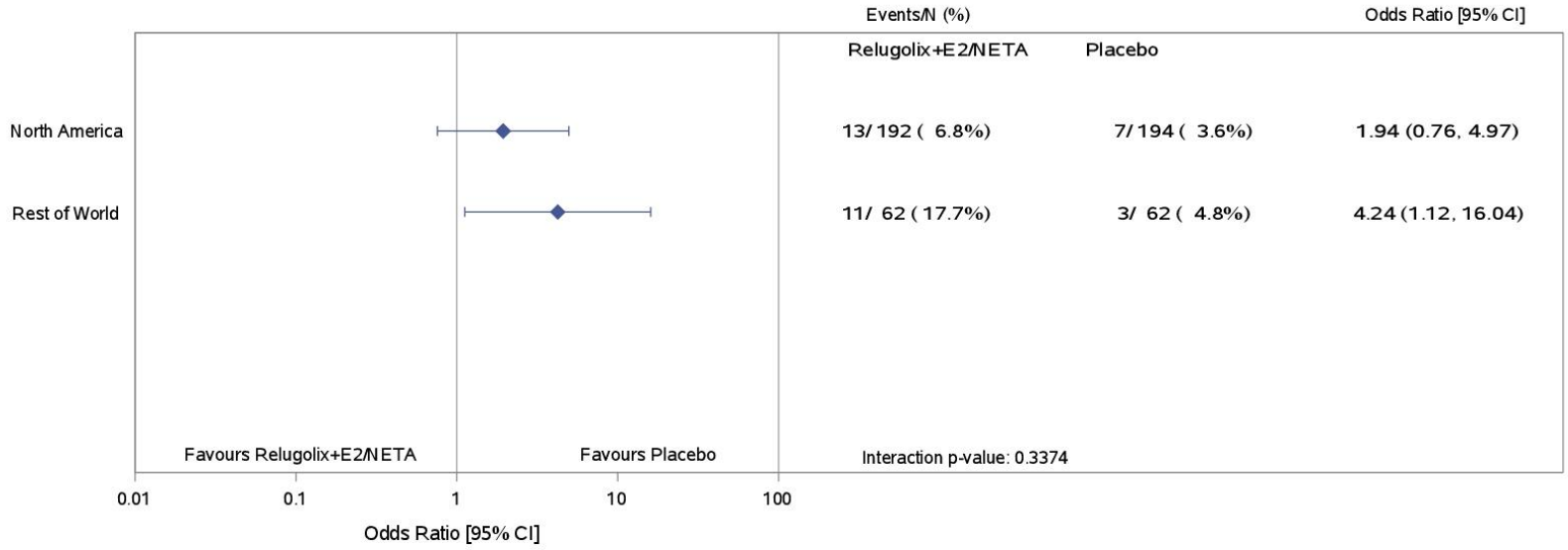
Figure SAF.TEAE.SPT.S6.BIN.FP: Frequent Treatment Emergent Adverse Events by System Organ Class and Preferred Term, by Subgroup (Safety Population)
Study: Pooled
System Organ Class: Skin and subcutaneous tissue disorders, Preferred Term: Any
Subgroup: Geographic Region I



Results are based on a logistic regression model adjusted for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates using a one-stage fixed-effects IPD meta-analysis approach. A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
The interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the Odds Ratio and 95% CI. Missing subgroup levels are not included in estimation of the interaction p-value. The reference group is Placebo. Patients with multiple events are counted only once. MedDRA (version 22.0).
Patients with multiple events for a given PT or SOC are counted only once for each PT and SOC. Only SOCs or PTs for which there are at least 10% of patients with an event in at least one treatment group OR at least 10 patients with an event overall and at least 1% of patients with an event in at least one treatment group in the overall safety population are considered. Further, only SOCs and PTs for which there is a significant treatment effect (p-value <0.05) in the overall safety population are presented. Events are sorted alphabetically by SOC and PT and then by subgroup within each. MedDRA (version 22.0).
N: Number of patients in treatment group; NETA: Norethindrone acetate; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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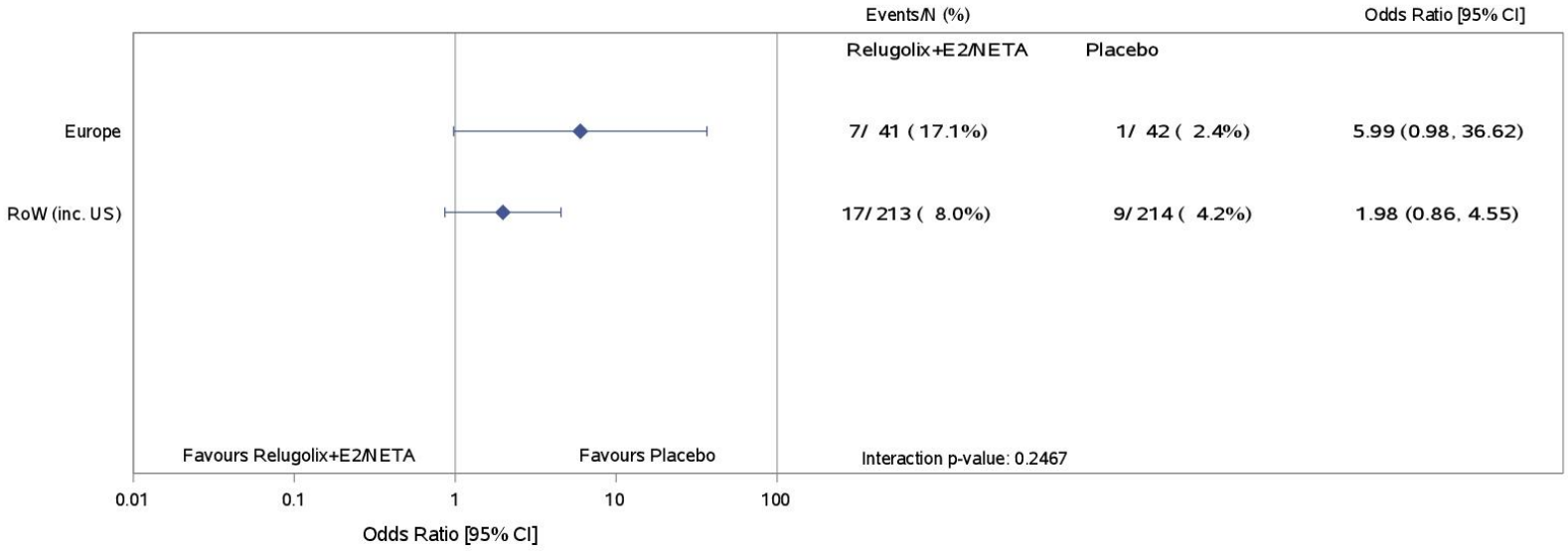
Figure SAF.TEAE.SPT.S7.BIN.FP: Frequent Treatment Emergent Adverse Events by System Organ Class and Preferred Term, by Subgroup (Safety Population)
Study: Pooled
System Organ Class: Skin and subcutaneous tissue disorders, Preferred Term: Any
Subgroup: Geographic Region II



Results are based on a logistic regression model adjusted for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates using a one-stage fixed-effects IPD meta-analysis approach. A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
The interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the Odds Ratio and 95% CI. Missing subgroup levels are not included in estimation of the interaction p-value. The reference group is Placebo. Patients with multiple events are counted only once. MedDRA (version 22.0).
Patients with multiple events for a given PT or SOC are counted only once for each PT and SOC. Only SOCs or PTs for which there are at least 10% of patients with an event in at least one treatment group OR at least 10 patients with an event overall and at least 1% of patients with an event in at least one treatment group in the overall safety population are considered. Further, only SOCs and PTs for which there is a significant treatment effect (p-value <0.05) in the overall safety population are presented. Events are sorted alphabetically by SOC and PT and then by subgroup within each. MedDRA (version 22.0).
N: Number of patients in treatment group; NETA: Norethindrone acetate; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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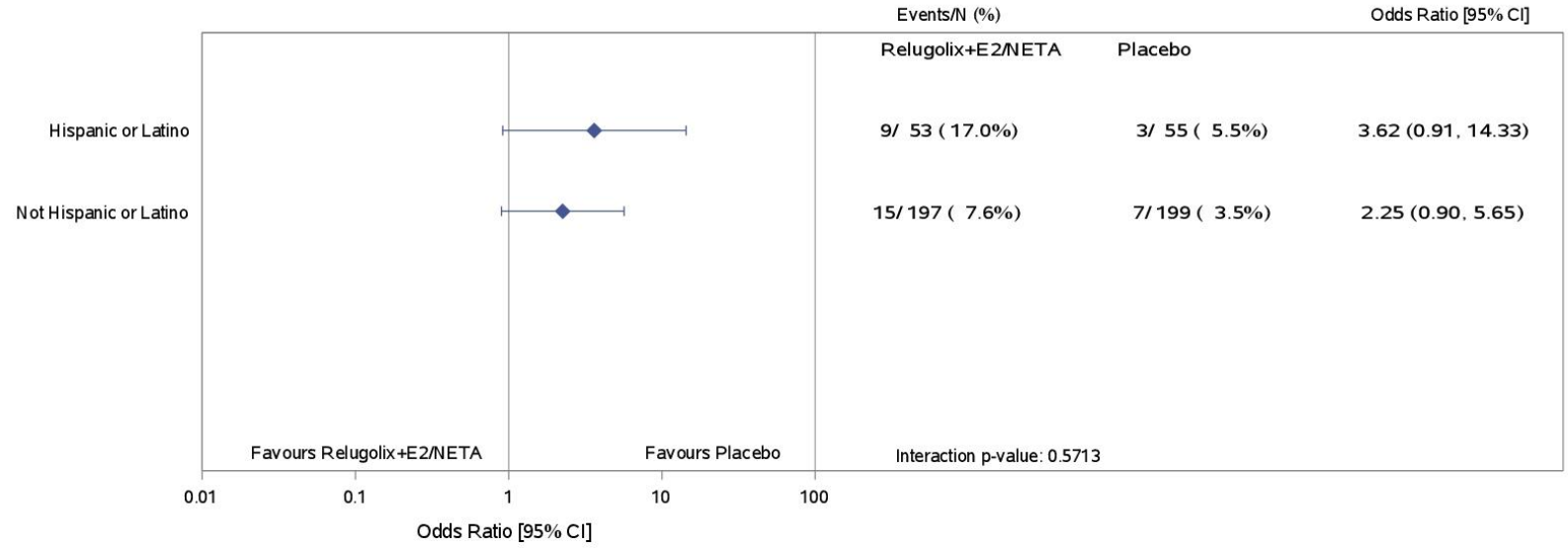
Figure SAF.TEAE.SPT.S8.BIN.FP: Frequent Treatment Emergent Adverse Events by System Organ Class and Preferred Term, by Subgroup (Safety Population)
Study: Pooled
System Organ Class: Skin and subcutaneous tissue disorders, Preferred Term: Any
Subgroup: Ethnicity



Results are based on a logistic regression model adjusted for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates using a one-stage fixed-effects IPD meta-analysis approach. A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
The interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the Odds Ratio and 95% CI. Missing subgroup levels are not included in estimation of the interaction p-value. The reference group is Placebo. Patients with multiple events are counted only once. MedDRA (version 22.0).
Patients with multiple events for a given PT or SOC are counted only once for each PT and SOC. Only SOCs or PTs for which there are at least 10% of patients with an event in at least one treatment group OR at least 10 patients with an event overall and at least 1% of patients with an event in at least one treatment group in the overall safety population are considered. Further, only SOCs and PTs for which there is a significant treatment effect (p-value <0.05) in the overall safety population are presented. Events are sorted alphabetically by SOC and PT and then by subgroup within each. MedDRA (version 22.0).
N: Number of patients in treatment group; NETA: Norethindrone acetate; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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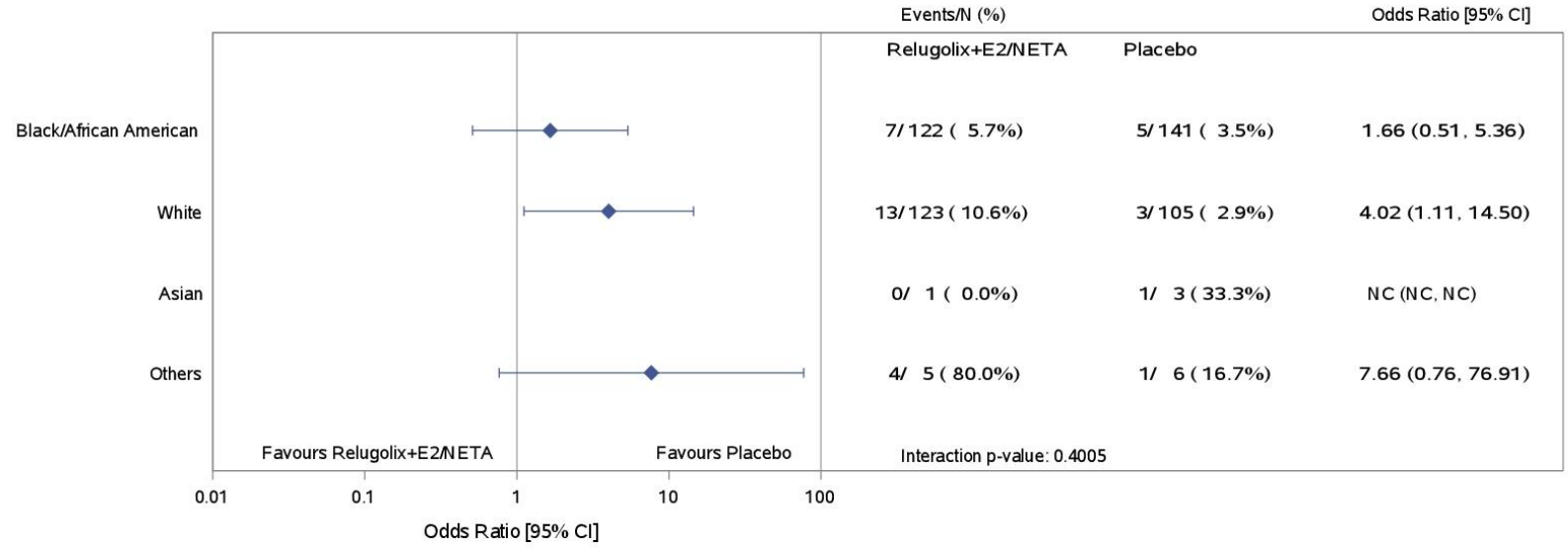
Figure SAF.TEAE.SPT.S9.BIN.FP: Frequent Treatment Emergent Adverse Events by System Organ Class and Preferred Term, by Subgroup (Safety Population)
Study: Pooled
System Organ Class: Skin and subcutaneous tissue disorders, Preferred Term: Any
Subgroup: Race



Results are based on a logistic regression model adjusted for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates using a one-stage fixed-effects IPD meta-analysis approach. A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
The interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the Odds Ratio and 95% CI. Missing subgroup levels are not included in estimation of the interaction p-value. The reference group is Placebo. Patients with multiple events are counted only once. MedDRA (version 22.0).
Patients with multiple events for a given PT or SOC are counted only once for each PT and SOC. Only SOCs or PTs for which there are at least 10% of patients with an event in at least one treatment group OR at least 10 patients with an event overall and at least 1% of patients with an event in at least one treatment group in the overall safety population are considered. Further, only SOCs and PTs for which there is a significant treatment effect (p-value <0.05) in the overall safety population are presented. Events are sorted alphabetically by SOC and PT and then by subgroup within each. MedDRA (version 22.0).
N: Number of patients in treatment group; NETA: Norethindrone acetate; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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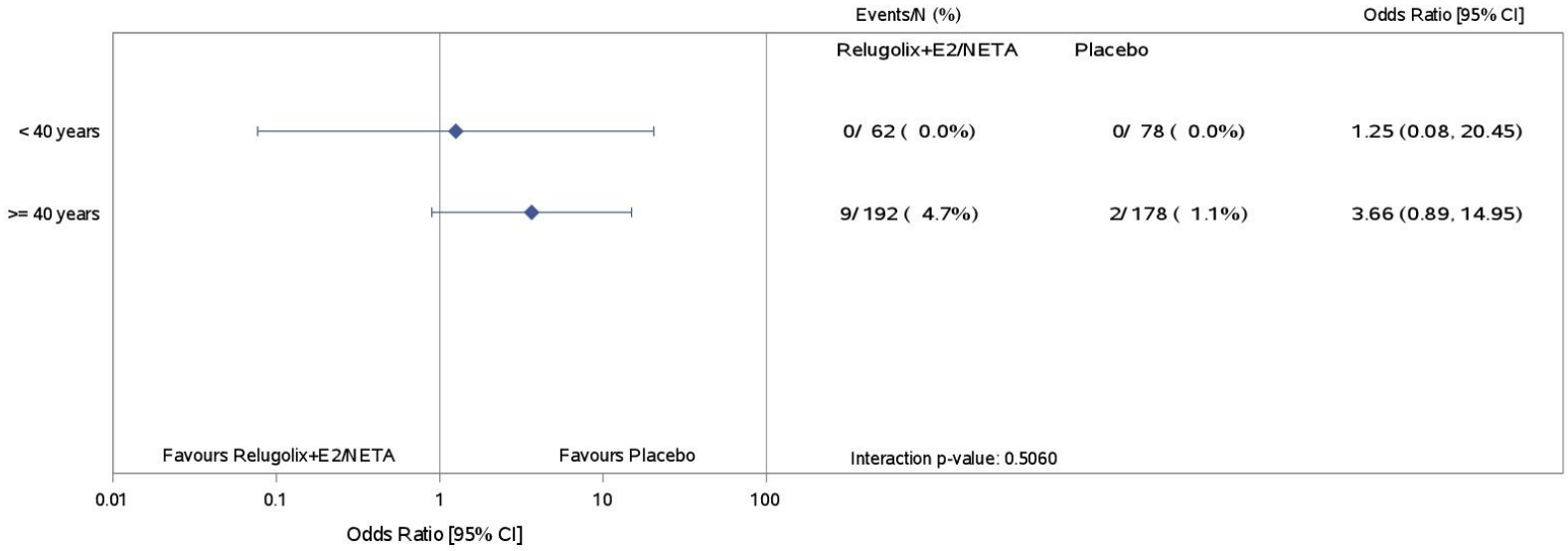
Figure SAF.TEAE.SPT.S1.BIN.FP: Frequent Treatment Emergent Adverse Events by System Organ Class and Preferred Term, by Subgroup (Safety Population)
Study: Pooled
System Organ Class: Skin and subcutaneous tissue disorders, Preferred Term: Alopecia
Subgroup: Age (years)



Results are based on a logistic regression model adjusted for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates using a one-stage fixed-effects IPD meta-analysis approach. A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
The interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the Odds Ratio and 95% CI. Missing subgroup levels are not included in estimation of the interaction p-value. The reference group is Placebo. Patients with multiple events are counted only once. MedDRA (version 22.0).
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N: Number of patients in treatment group; NETA: Norethindrone acetate; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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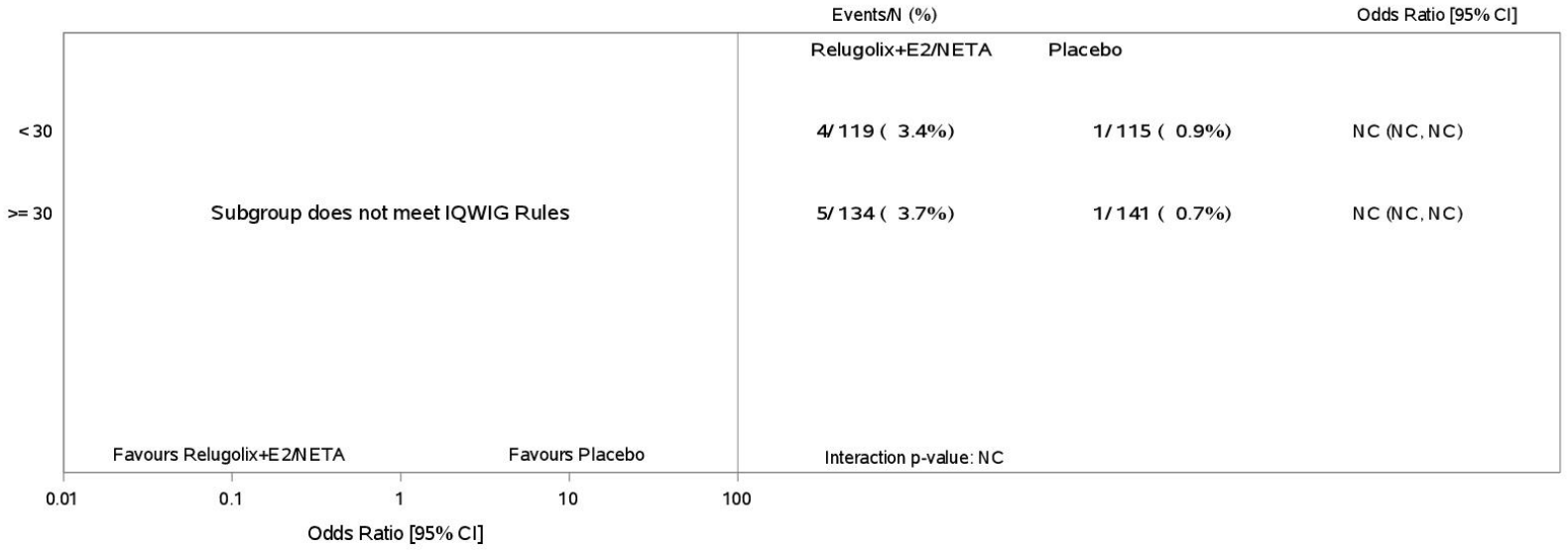
Figure SAF.TEAE.SPT.S2.BIN.FP: Frequent Treatment Emergent Adverse Events by System Organ Class and Preferred Term, by Subgroup (Safety Population)
Study: Pooled
System Organ Class: Skin and subcutaneous tissue disorders, Preferred Term: Alopecia
Subgroup: BMI (kg/m2) at Baseline



Results are based on a logistic regression model adjusted for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates using a one-stage fixed-effects IPD meta-analysis approach. A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
The interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the Odds Ratio and 95% CI. Missing subgroup levels are not included in estimation of the interaction p-value. The reference group is Placebo. Patients with multiple events are counted only once. MedDRA (version 22.0).
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N: Number of patients in treatment group; NETA: Norethindrone acetate; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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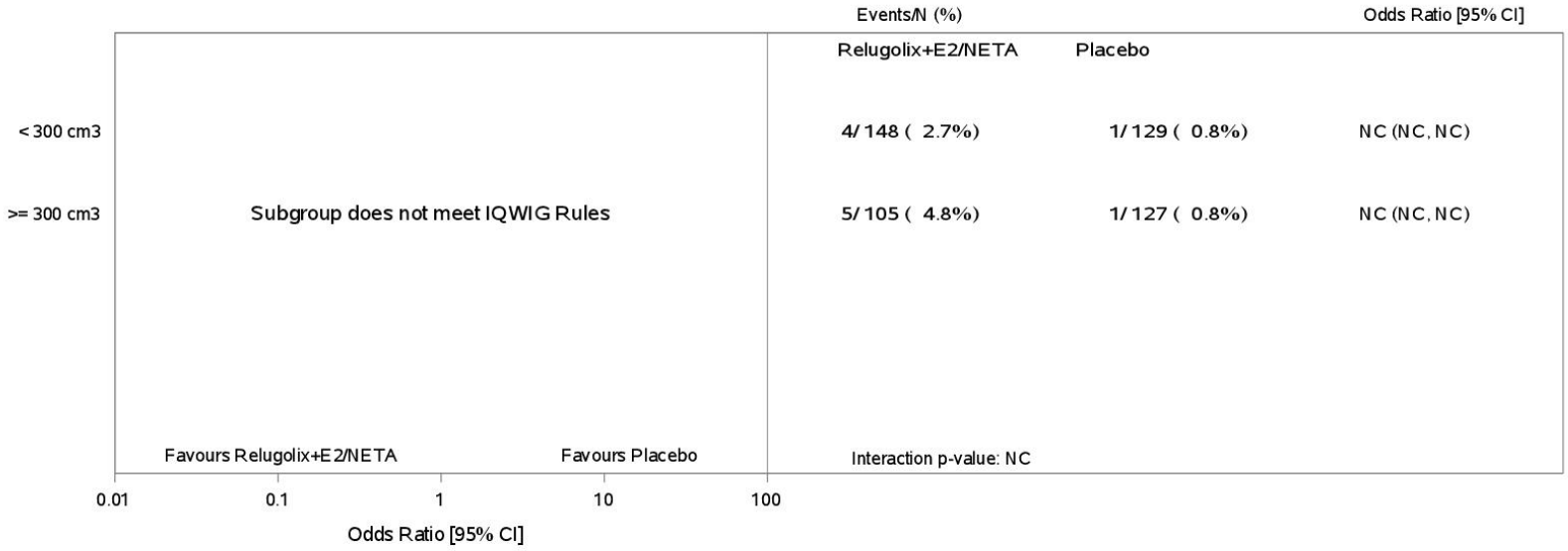
Figure SAF.TEAE.SPT.S3.BIN.FP: Frequent Treatment Emergent Adverse Events by System Organ Class and Preferred Term, by Subgroup (Safety Population)
Study: Pooled
System Organ Class: Skin and subcutaneous tissue disorders, Preferred Term: Alopecia
Subgroup: Uterine Volume at Baseline (cm3)



Results are based on a logistic regression model adjusted for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates using a one-stage fixed-effects IPD meta-analysis approach. A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
The interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the Odds Ratio and 95% CI. Missing subgroup levels are not included in estimation of the interaction p-value. The reference group is Placebo. Patients with multiple events are counted only once. MedDRA (version 22.0).
Patients with multiple events for a given PT or SOC are counted only once for each PT and SOC. Only SOCs or PTs for which there are at least 10% of patients with an event in at least one treatment group OR at least 10 patients with an event overall and at least 1% of patients with an event in at least one treatment group in the overall safety population are considered. Further, only SOCs and PTs for which there is a significant treatment effect (p-value <0.05) in the overall safety population are presented. Events are sorted alphabetically by SOC and PT and then by subgroup within each. MedDRA (version 22.0).
N: Number of patients in treatment group; NETA: Norethindrone acetate; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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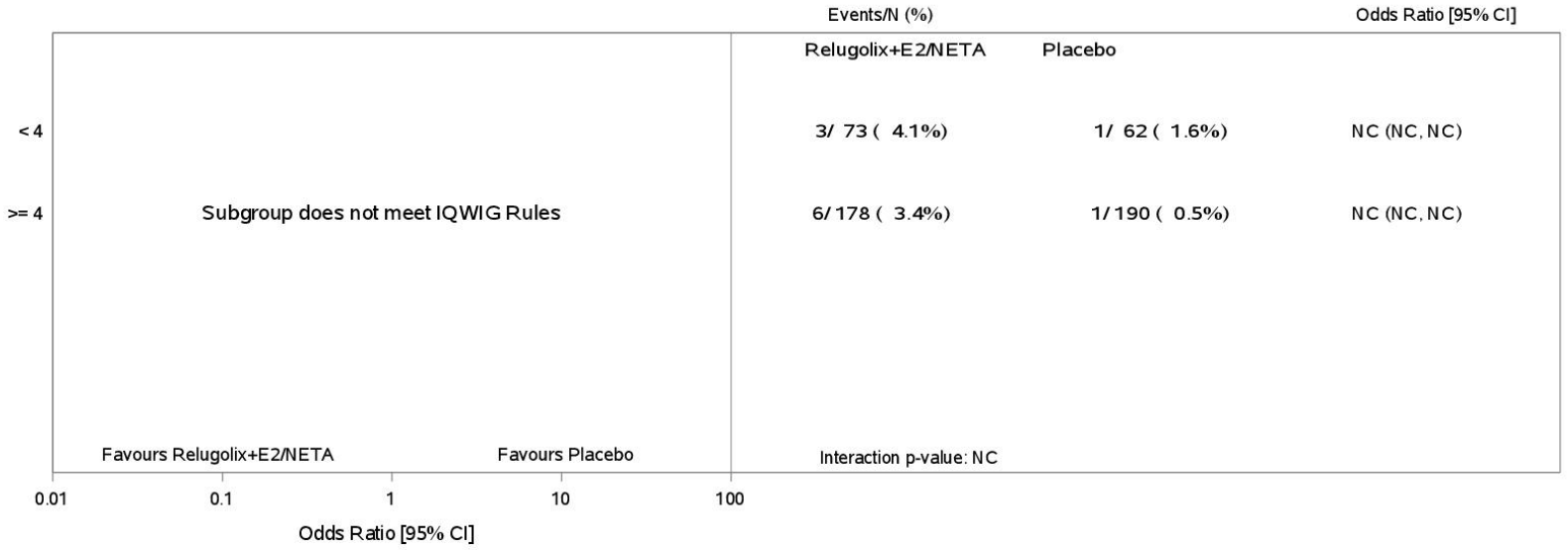
Figure SAF.TEAE.SPT.S4.BIN.FP: Frequent Treatment Emergent Adverse Events by System Organ Class and Preferred Term, by Subgroup (Safety Population)
Study: Pooled
System Organ Class: Skin and subcutaneous tissue disorders, Preferred Term: Alopecia
Subgroup: Maximum NRS Pain Score at Baseline



Results are based on a logistic regression model adjusted for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates using a one-stage fixed-effects IPD meta-analysis approach. A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
The interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the Odds Ratio and 95% CI. Missing subgroup levels are not included in estimation of the interaction p-value. The reference group is Placebo. Patients with multiple events are counted only once. MedDRA (version 22.0).
Patients with multiple events for a given PT or SOC are counted only once for each PT and SOC. Only SOCs or PTs for which there are at least 10% of patients with an event in at least one treatment group OR at least 10 patients with an event overall and at least 1% of patients with an event in at least one treatment group in the overall safety population are considered. Further, only SOCs and PTs for which there is a significant treatment effect (p-value <0.05) in the overall safety population are presented. Events are sorted alphabetically by SOC and PT and then by subgroup within each. MedDRA (version 22.0).
N: Number of patients in treatment group; NETA: Norethindrone acetate; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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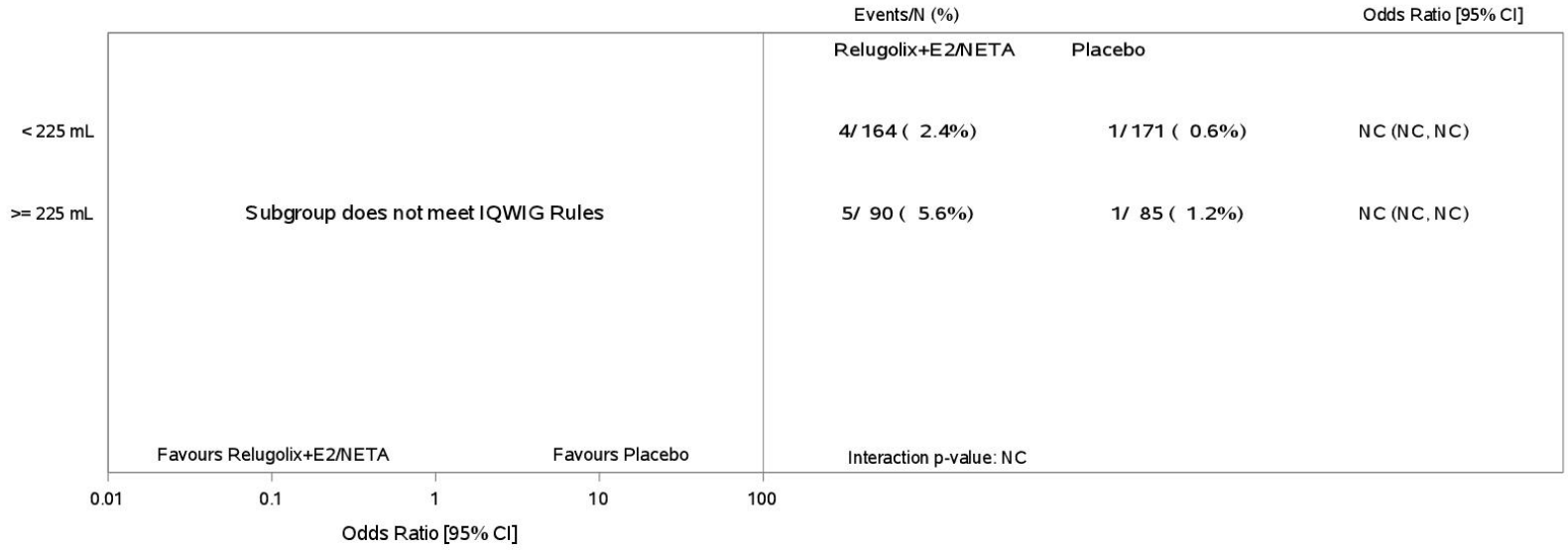
Figure SAF.TEAE.SPT.S5.BIN.FP: Frequent Treatment Emergent Adverse Events by System Organ Class and Preferred Term, by Subgroup (Safety Population)
Study: Pooled
System Organ Class: Skin and subcutaneous tissue disorders, Preferred Term: Alopecia
Subgroup: MBL Volume at Baseline (mL)



Results are based on a logistic regression model adjusted for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates using a one-stage fixed-effects IPD meta-analysis approach. A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
The interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the Odds Ratio and 95% CI. Missing subgroup levels are not included in estimation of the interaction p-value. The reference group is Placebo. Patients with multiple events are counted only once. MedDRA (version 22.0).
Patients with multiple events for a given PT or SOC are counted only once for each PT and SOC. Only SOCs or PTs for which there are at least 10% of patients with an event in at least one treatment group OR at least 10 patients with an event overall and at least 1% of patients with an event in at least one treatment group in the overall safety population are considered. Further, only SOCs and PTs for which there is a significant treatment effect (p-value <0.05) in the overall safety population are presented. Events are sorted alphabetically by SOC and PT and then by subgroup within each. MedDRA (version 22.0).
N: Number of patients in treatment group; NETA: Norethindrone acetate; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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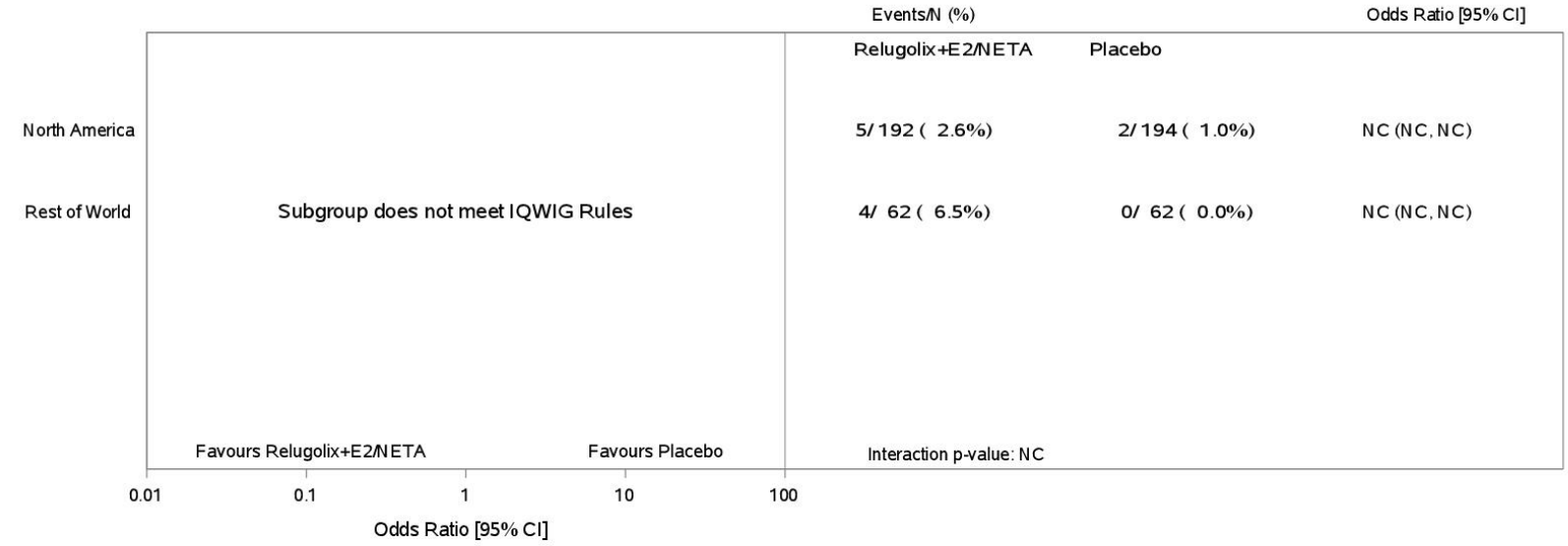
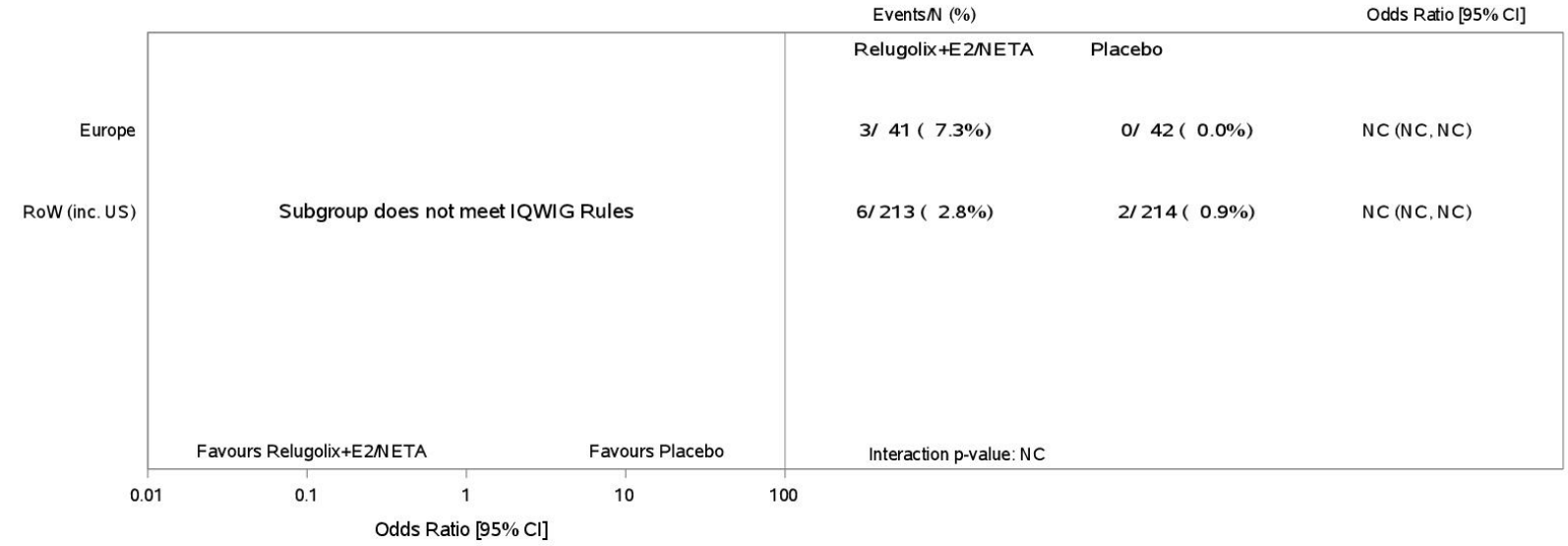
Figure SAF.TEAE.SPT.S6.BIN.FP: Frequent Treatment Emergent Adverse Events by System Organ Class and Preferred Term, by Subgroup (Safety Population)
Study: Pooled
System Organ Class: Skin and subcutaneous tissue disorders, Preferred Term: Alopecia
Subgroup: Geographic Region I



Results are based on a logistic regression model adjusted for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates using a one-stage fixed-effects IPD meta-analysis approach. A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
The interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the Odds Ratio and 95% CI. Missing subgroup levels are not included in estimation of the interaction p-value. The reference group is Placebo. Patients with multiple events are counted only once. MedDRA (version 22.0).
Patients with multiple events for a given PT or SOC are counted only once for each PT and SOC. Only SOCs or PTs for which there are at least 10% of patients with an event in at least one treatment group OR at least 10 patients with an event overall and at least 1% of patients with an event in at least one treatment group in the overall safety population are considered. Further, only SOCs and PTs for which there is a significant treatment effect (p-value <0.05) in the overall safety population are presented. Events are sorted alphabetically by SOC and PT and then by subgroup within each. MedDRA (version 22.0).
N: Number of patients in treatment group; NETA: Norethindrone acetate; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

Figure SAF.TEAE.SPT.S7.BIN.FP: Frequent Treatment Emergent Adverse Events by System Organ Class and Preferred Term, by Subgroup (Safety Population)
Study: Pooled
System Organ Class: Skin and subcutaneous tissue disorders, Preferred Term: Alopecia
Subgroup: Geographic Region II



Results are based on a logistic regression model adjusted for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates using a one-stage fixed-effects IPD meta-analysis approach. A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
The interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the Odds Ratio and 95% CI. Missing subgroup levels are not included in estimation of the interaction p-value. The reference group is Placebo. Patients with multiple events are counted only once. MedDRA (version 22.0).
Patients with multiple events for a given PT or SOC are counted only once for each PT and SOC. Only SOCs or PTs for which there are at least 10% of patients with an event in at least one treatment group OR at least 10 patients with an event overall and at least 1% of patients with an event in at least one treatment group in the overall safety population are considered. Further, only SOCs and PTs for which there is a significant treatment effect (p-value <0.05) in the overall safety population are presented. Events are sorted alphabetically by SOC and PT and then by subgroup within each. MedDRA (version 22.0).
N: Number of patients in treatment group; NETA: Norethindrone acetate; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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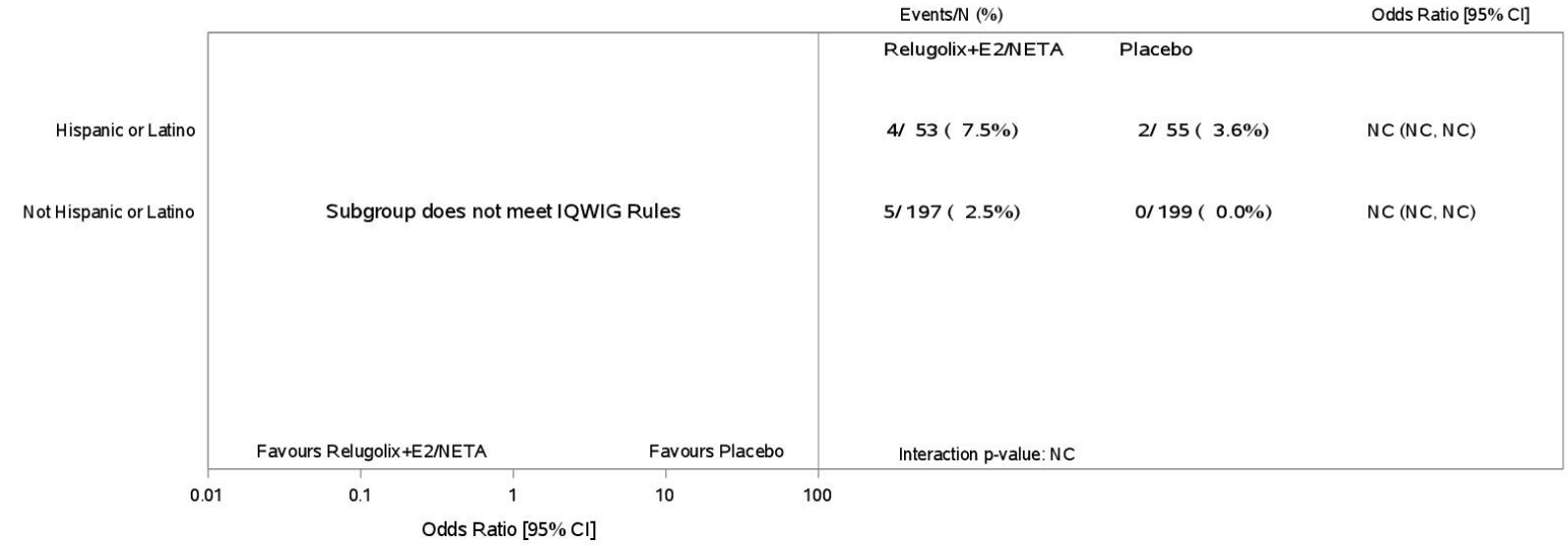
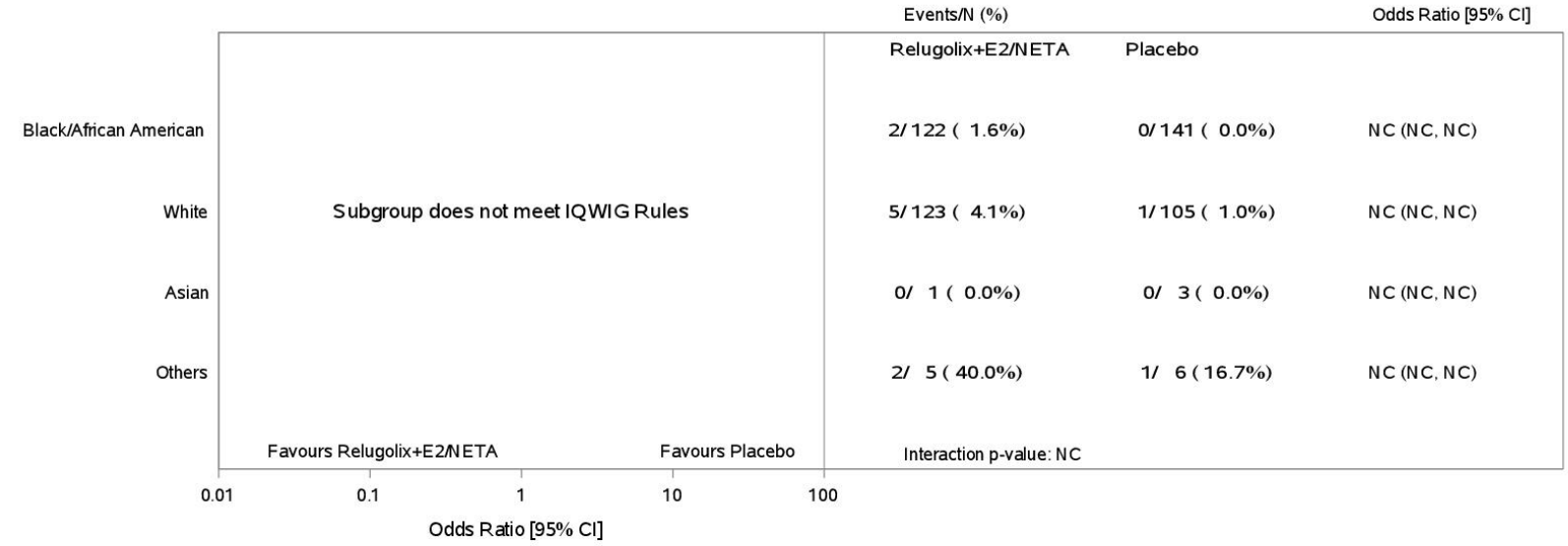
Figure SAF.TEAE.SPT.S8.BIN.FP: Frequent Treatment Emergent Adverse Events by System Organ Class and Preferred Term, by Subgroup (Safety Population)
Study: Pooled
System Organ Class: Skin and subcutaneous tissue disorders, Preferred Term: Alopecia
Subgroup: Ethnicity



Results are based on a logistic regression model adjusted for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates using a one-stage fixed-effects IPD meta-analysis approach. A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
The interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the Odds Ratio and 95% CI. Missing subgroup levels are not included in estimation of the interaction p-value. The reference group is Placebo. Patients with multiple events are counted only once. MedDRA (version 22.0).
Patients with multiple events for a given PT or SOC are counted only once for each PT and SOC. Only SOCs or PTs for which there are at least 10% of patients with an event in at least one treatment group OR at least 10 patients with an event overall and at least 1% of patients with an event in at least one treatment group in the overall safety population are considered. Further, only SOCs and PTs for which there is a significant treatment effect (p-value <0.05) in the overall safety population are presented. Events are sorted alphabetically by SOC and PT and then by subgroup within each. MedDRA (version 22.0).
N: Number of patients in treatment group; NETA: Norethindrone acetate; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

Figure SAF.TEAE.SPT.S9.BIN.FP: Frequent Treatment Emergent Adverse Events by System Organ Class and Preferred Term, by Subgroup (Safety Population)
Study: Pooled
System Organ Class: Skin and subcutaneous tissue disorders, Preferred Term: Alopecia
Subgroup: Race



Results are based on a logistic regression model adjusted for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates using a one-stage fixed-effects IPD meta-analysis approach. A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
The interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the Odds Ratio and 95% CI. Missing subgroup levels are not included in estimation of the interaction p-value. The reference group is Placebo. Patients with multiple events are counted only once. MedDRA (version 22.0).
Patients with multiple events for a given PT or SOC are counted only once for each PT and SOC. Only SOCs or PTs for which there are at least 10% of patients with an event in at least one treatment group OR at least 10 patients with an event overall and at least 1% of patients with an event in at least one treatment group in the overall safety population are considered. Further, only SOCs and PTs for which there is a significant treatment effect (p-value <0.05) in the overall safety population are presented. Events are sorted alphabetically by SOC and PT and then by subgroup within each. MedDRA (version 22.0).
N: Number of patients in treatment group; NETA: Norethindrone acetate; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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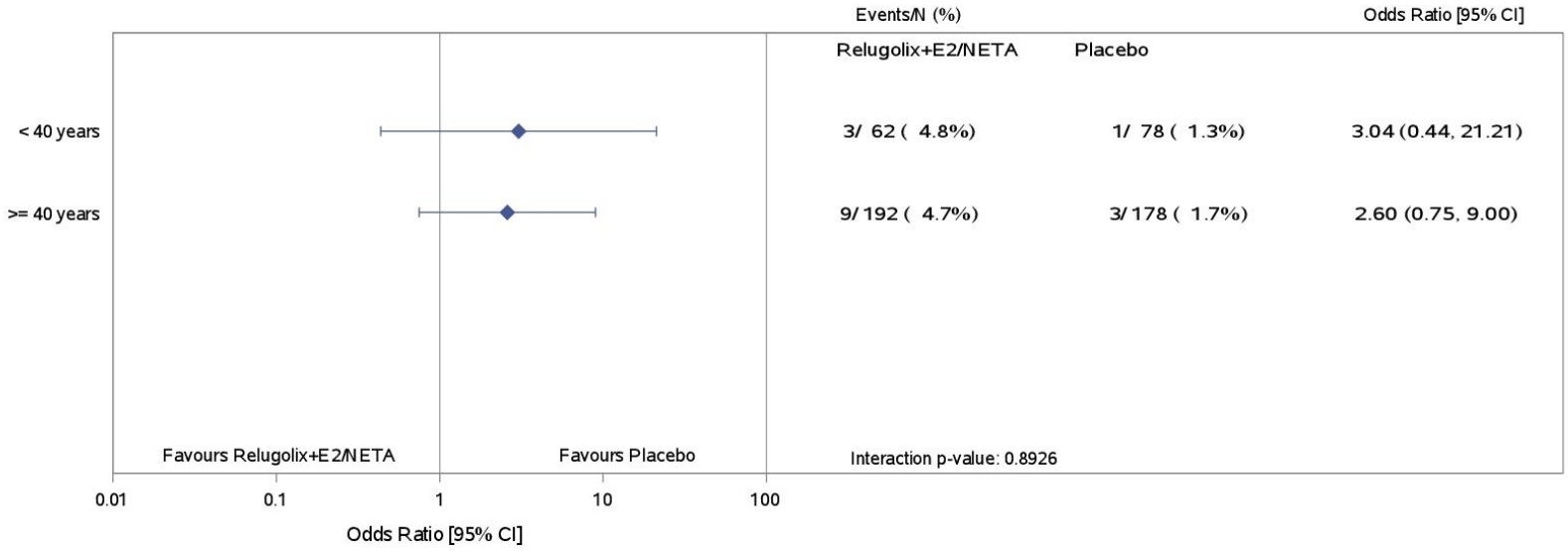
Figure SAF.TEAE.SPT.S1.BIN.FP: Frequent Treatment Emergent Adverse Events by System Organ Class and Preferred Term, by Subgroup (Safety Population)
Study: Pooled
System Organ Class: Vascular disorders, Preferred Term: Hypertension
Subgroup: Age (years)



Results are based on a logistic regression model adjusted for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates using a one-stage fixed-effects IPD meta-analysis approach. A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
The interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the Odds Ratio and 95% CI. Missing subgroup levels are not included in estimation of the interaction p-value. The reference group is Placebo. Patients with multiple events are counted only once. MedDRA (version 22.0).
Patients with multiple events for a given PT or SOC are counted only once for each PT and SOC. Only SOCs or PTs for which there are at least 10% of patients with an event in at least one treatment group OR at least 10 patients with an event overall and at least 1% of patients with an event in at least one treatment group in the overall safety population are considered. Further, only SOCs and PTs for which there is a significant treatment effect (p-value <0.05) in the overall safety population are presented. Events are sorted alphabetically by SOC and PT and then by subgroup within each. MedDRA (version 22.0).
N: Number of patients in treatment group; NETA: Norethindrone acetate; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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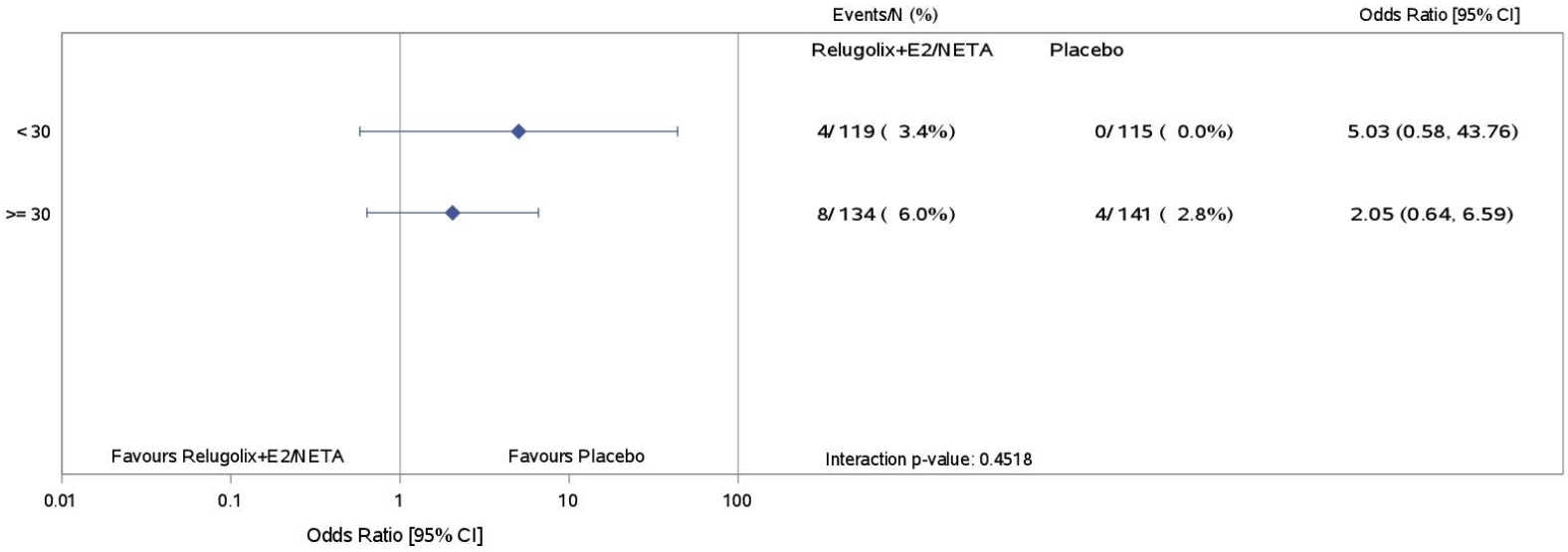
Figure SAF.TEAE.SPT.S2.BIN.FP: Frequent Treatment Emergent Adverse Events by System Organ Class and Preferred Term, by Subgroup (Safety Population)
Study: Pooled
System Organ Class: Vascular disorders, Preferred Term: Hypertension
Subgroup: BMI (kg/m2) at Baseline



Results are based on a logistic regression model adjusted for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates using a one-stage fixed-effects IPD meta-analysis approach. A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
The interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the Odds Ratio and 95% CI. Missing subgroup levels are not included in estimation of the interaction p-value. The reference group is Placebo. Patients with multiple events are counted only once. MedDRA (version 22.0).
Patients with multiple events for a given PT or SOC are counted only once for each PT and SOC. Only SOCs or PTs for which there are at least 10% of patients with an event in at least one treatment group OR at least 10 patients with an event overall and at least 1% of patients with an event in at least one treatment group in the overall safety population are considered. Further, only SOCs and PTs for which there is a significant treatment effect (p-value <0.05) in the overall safety population are presented. Events are sorted alphabetically by SOC and PT and then by subgroup within each. MedDRA (version 22.0).
N: Number of patients in treatment group; NETA: Norethindrone acetate; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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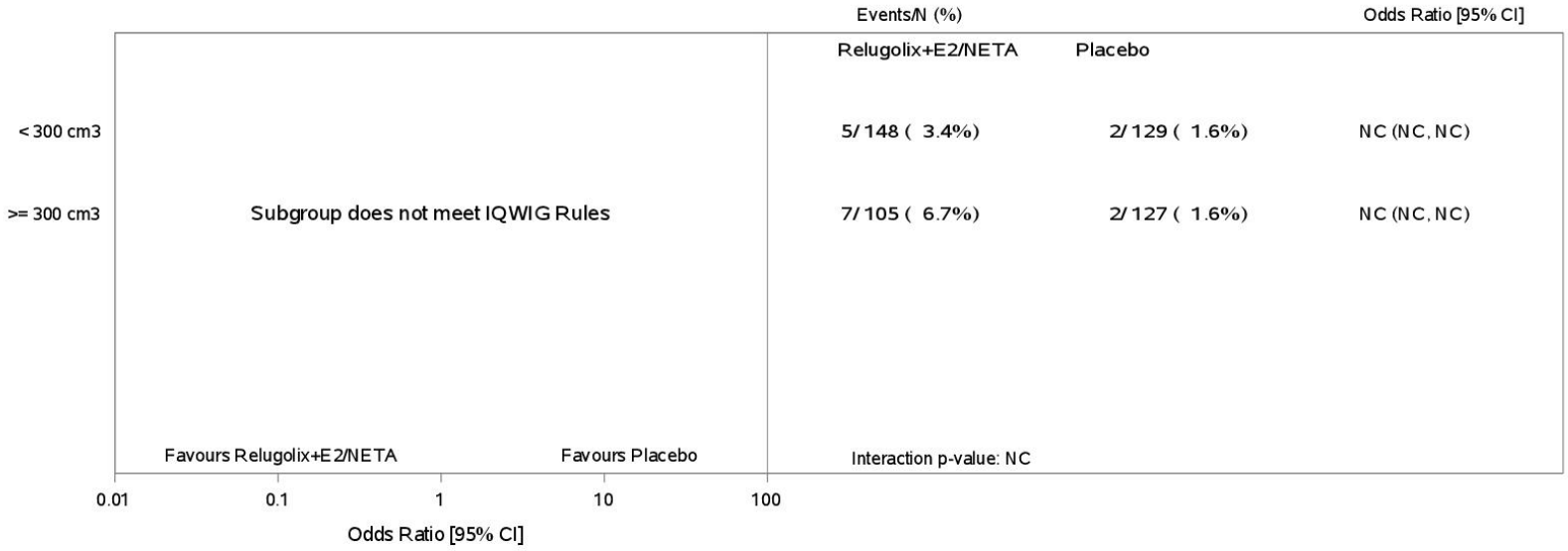
Figure SAF.TEAE.SPT.S3.BIN.FP: Frequent Treatment Emergent Adverse Events by System Organ Class and Preferred Term, by Subgroup (Safety Population)
Study: Pooled
System Organ Class: Vascular disorders, Preferred Term: Hypertension
Subgroup: Uterine Volume at Baseline (cm3)



Results are based on a logistic regression model adjusted for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates using a one-stage fixed-effects IPD meta-analysis approach. A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
The interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the Odds Ratio and 95% CI. Missing subgroup levels are not included in estimation of the interaction p-value. The reference group is Placebo. Patients with multiple events are counted only once. MedDRA (version 22.0).
Patients with multiple events for a given PT or SOC are counted only once for each PT and SOC. Only SOCs or PTs for which there are at least 10% of patients with an event in at least one treatment group OR at least 10 patients with an event overall and at least 1% of patients with an event in at least one treatment group in the overall safety population are considered. Further, only SOCs and PTs for which there is a significant treatment effect (p-value <0.05) in the overall safety population are presented. Events are sorted alphabetically by SOC and PT and then by subgroup within each. MedDRA (version 22.0).
N: Number of patients in treatment group; NETA: Norethindrone acetate; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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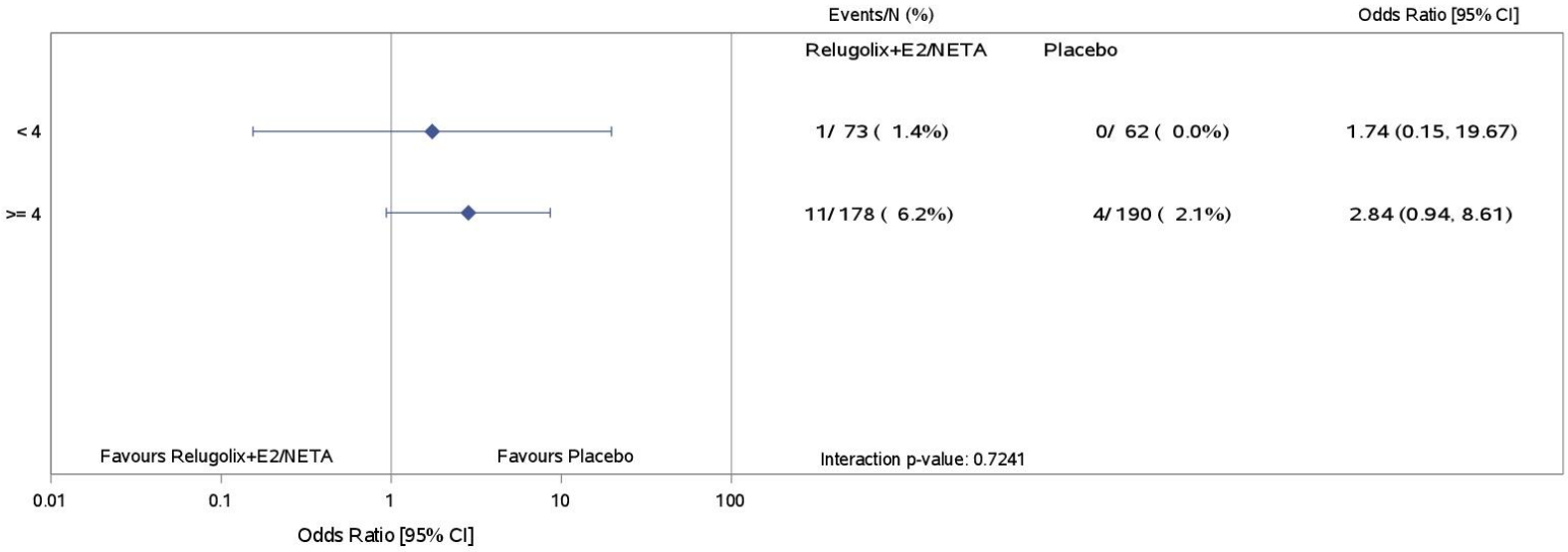
Figure SAF.TEAE.SPT.S4.BIN.FP: Frequent Treatment Emergent Adverse Events by System Organ Class and Preferred Term, by Subgroup (Safety Population)
Study: Pooled
System Organ Class: Vascular disorders, Preferred Term: Hypertension
Subgroup: Maximum NRS Pain Score at Baseline



Results are based on a logistic regression model adjusted for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates using a one-stage fixed-effects IPD meta-analysis approach. A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
The interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the Odds Ratio and 95% CI. Missing subgroup levels are not included in estimation of the interaction p-value. The reference group is Placebo. Patients with multiple events are counted only once. MedDRA (version 22.0).
Patients with multiple events for a given PT or SOC are counted only once for each PT and SOC. Only SOCs or PTs for which there are at least 10% of patients with an event in at least one treatment group OR at least 10 patients with an event overall and at least 1% of patients with an event in at least one treatment group in the overall safety population are considered. Further, only SOCs and PTs for which there is a significant treatment effect (p-value <0.05) in the overall safety population are presented. Events are sorted alphabetically by SOC and PT and then by subgroup within each. MedDRA (version 22.0).
N: Number of patients in treatment group; NETA: Norethindrone acetate; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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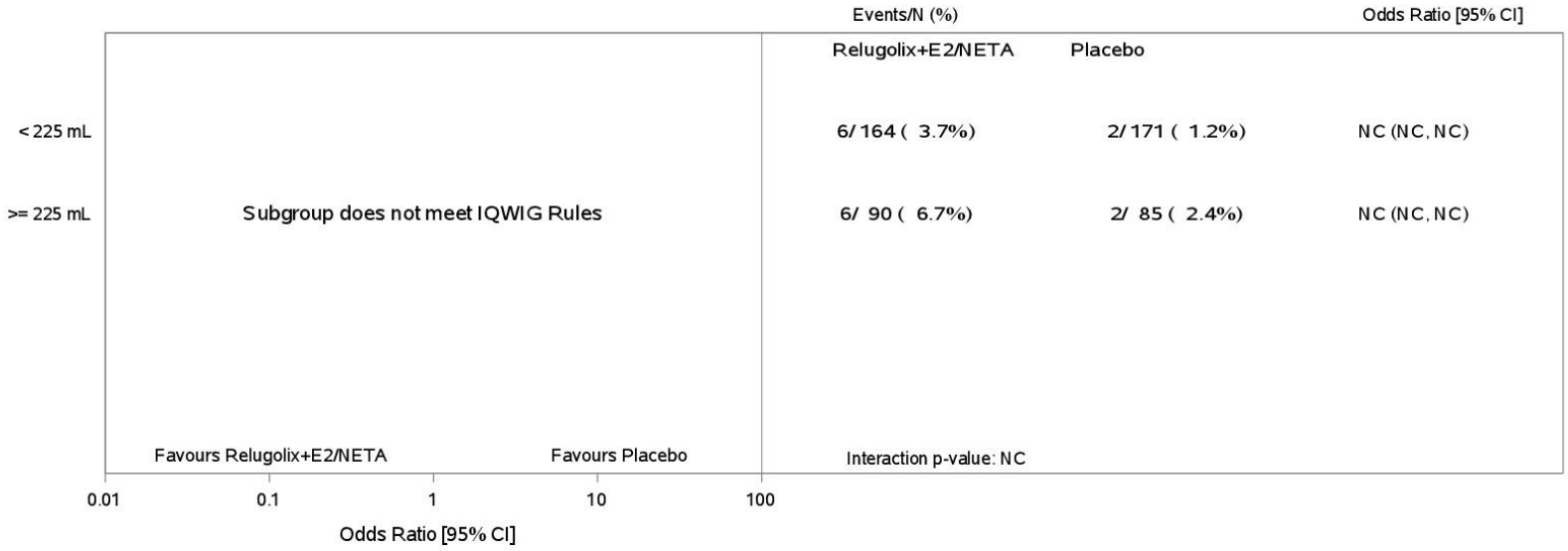
Figure SAF.TEAE.SPT.S5.BIN.FP: Frequent Treatment Emergent Adverse Events by System Organ Class and Preferred Term, by Subgroup (Safety Population)
Study: Pooled
System Organ Class: Vascular disorders, Preferred Term: Hypertension
Subgroup: MBL Volume at Baseline (mL)



Results are based on a logistic regression model adjusted for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates using a one-stage fixed-effects IPD meta-analysis approach. A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
The interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the Odds Ratio and 95% CI. Missing subgroup levels are not included in estimation of the interaction p-value. The reference group is Placebo. Patients with multiple events are counted only once. MedDRA (version 22.0).
Patients with multiple events for a given PT or SOC are counted only once for each PT and SOC. Only SOCs or PTs for which there are at least 10% of patients with an event in at least one treatment group OR at least 10 patients with an event overall and at least 1% of patients with an event in at least one treatment group in the overall safety population are considered. Further, only SOCs and PTs for which there is a significant treatment effect (p-value <0.05) in the overall safety population are presented. Events are sorted alphabetically by SOC and PT and then by subgroup within each. MedDRA (version 22.0).
N: Number of patients in treatment group; NETA: Norethindrone acetate; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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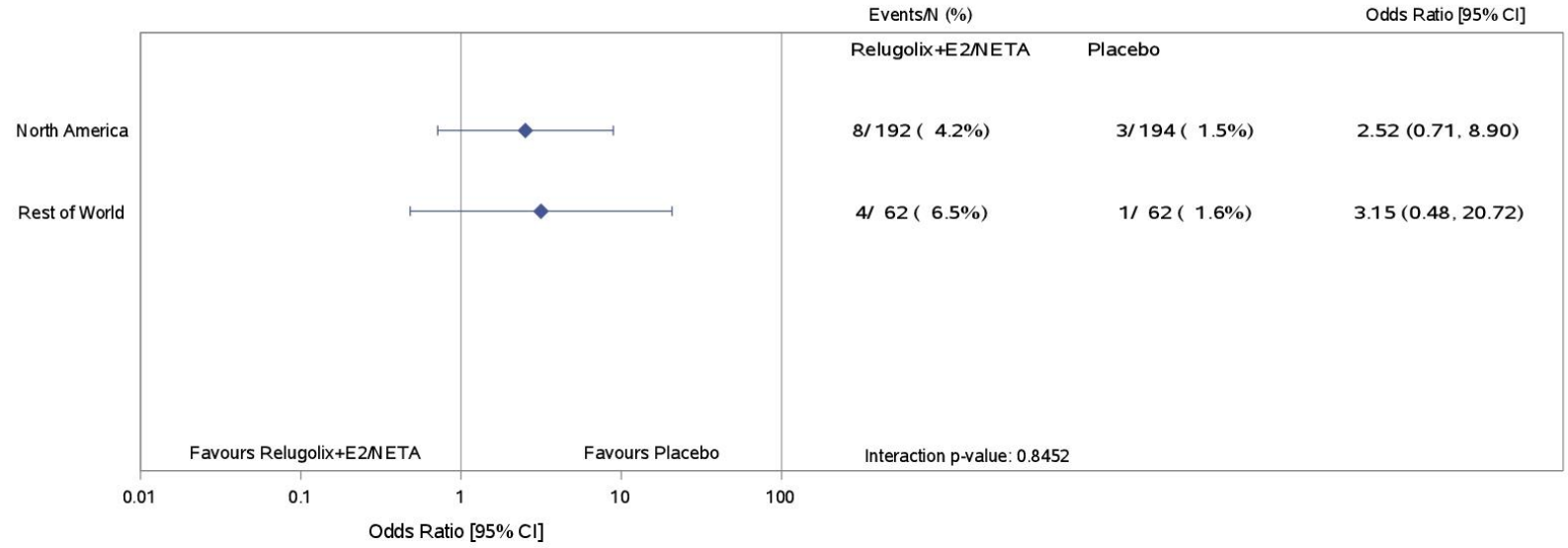
Figure SAF.TEAE.SPT.S6.BIN.FP: Frequent Treatment Emergent Adverse Events by System Organ Class and Preferred Term, by Subgroup (Safety Population)
Study: Pooled
System Organ Class: Vascular disorders, Preferred Term: Hypertension
Subgroup: Geographic Region I



Results are based on a logistic regression model adjusted for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates using a one-stage fixed-effects IPD meta-analysis approach. A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
The interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the Odds Ratio and 95% CI. Missing subgroup levels are not included in estimation of the interaction p-value. The reference group is Placebo. Patients with multiple events are counted only once. MedDRA (version 22.0).
Patients with multiple events for a given PT or SOC are counted only once for each PT and SOC. Only SOCs or PTs for which there are at least 10% of patients with an event in at least one treatment group OR at least 10 patients with an event overall and at least 1% of patients with an event in at least one treatment group in the overall safety population are considered. Further, only SOCs and PTs for which there is a significant treatment effect (p-value <0.05) in the overall safety population are presented. Events are sorted alphabetically by SOC and PT and then by subgroup within each. MedDRA (version 22.0).
N: Number of patients in treatment group; NETA: Norethindrone acetate; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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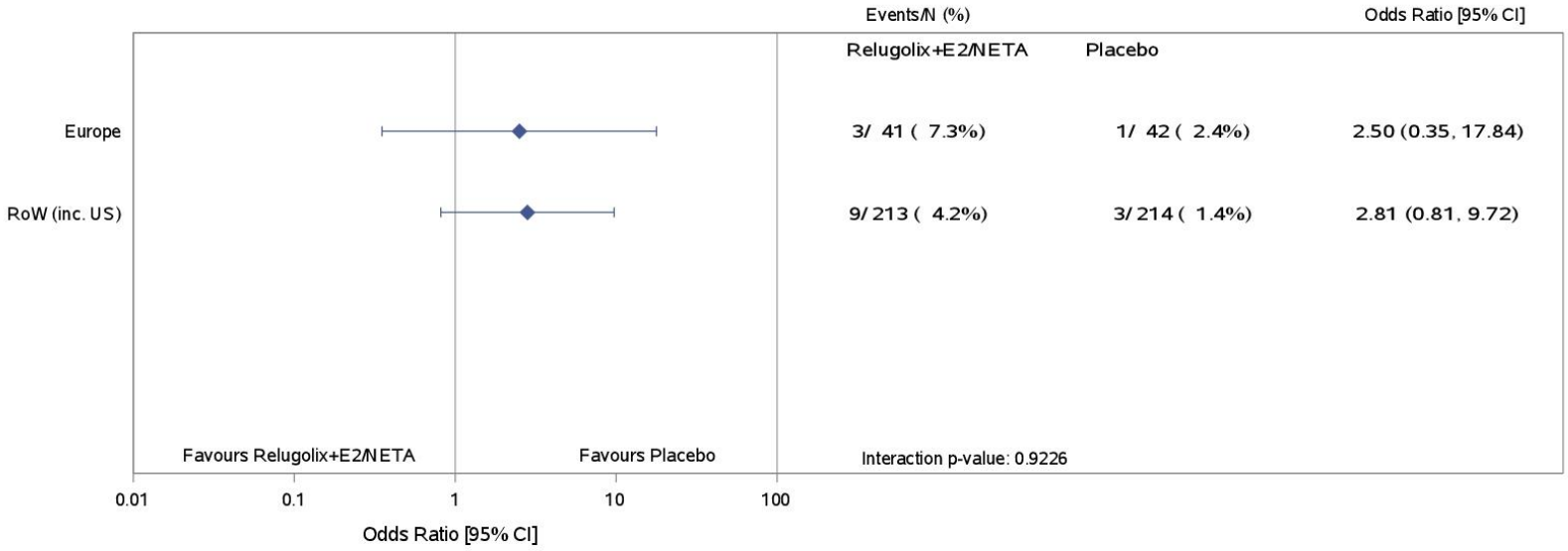
Figure SAF.TEAE.SPT.S7.BIN.FP: Frequent Treatment Emergent Adverse Events by System Organ Class and Preferred Term, by Subgroup (Safety Population)
Study: Pooled
System Organ Class: Vascular disorders, Preferred Term: Hypertension
Subgroup: Geographic Region II



Results are based on a logistic regression model adjusted for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates using a one-stage fixed-effects IPD meta-analysis approach. A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
The interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the Odds Ratio and 95% CI. Missing subgroup levels are not included in estimation of the interaction p-value. The reference group is Placebo. Patients with multiple events are counted only once. MedDRA (version 22.0).
Patients with multiple events for a given PT or SOC are counted only once for each PT and SOC. Only SOCs or PTs for which there are at least 10% of patients with an event in at least one treatment group OR at least 10 patients with an event overall and at least 1% of patients with an event in at least one treatment group in the overall safety population are considered. Further, only SOCs and PTs for which there is a significant treatment effect (p-value <0.05) in the overall safety population are presented. Events are sorted alphabetically by SOC and PT and then by subgroup within each. MedDRA (version 22.0).
N: Number of patients in treatment group; NETA: Norethindrone acetate; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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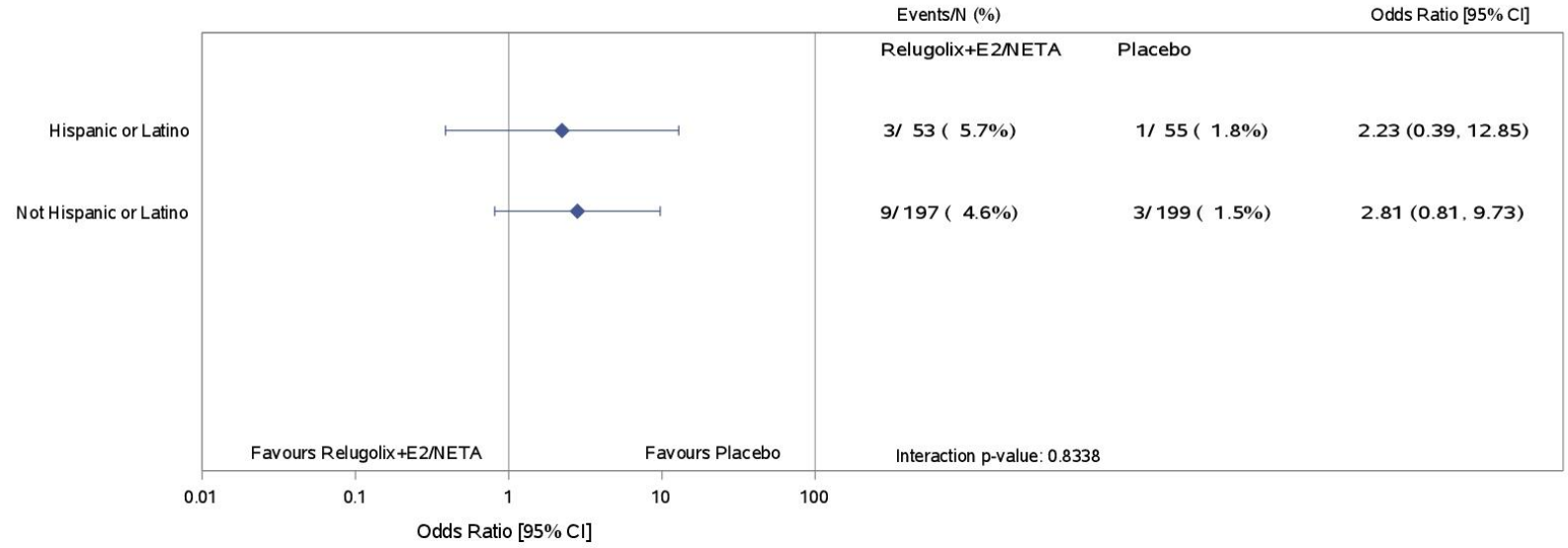
Figure SAF.TEAE.SPT.S8.BIN.FP: Frequent Treatment Emergent Adverse Events by System Organ Class and Preferred Term, by Subgroup (Safety Population)
Study: Pooled
System Organ Class: Vascular disorders, Preferred Term: Hypertension
Subgroup: Ethnicity



Results are based on a logistic regression model adjusted for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates using a one-stage fixed-effects IPD meta-analysis approach. A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
The interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the Odds Ratio and 95% CI. Missing subgroup levels are not included in estimation of the interaction p-value. The reference group is Placebo. Patients with multiple events are counted only once. MedDRA (version 22.0).
Patients with multiple events for a given PT or SOC are counted only once for each PT and SOC. Only SOCs or PTs for which there are at least 10% of patients with an event in at least one treatment group OR at least 10 patients with an event overall and at least 1% of patients with an event in at least one treatment group in the overall safety population are considered. Further, only SOCs and PTs for which there is a significant treatment effect (p-value <0.05) in the overall safety population are presented. Events are sorted alphabetically by SOC and PT and then by subgroup within each. MedDRA (version 22.0).
N: Number of patients in treatment group; NETA: Norethindrone acetate; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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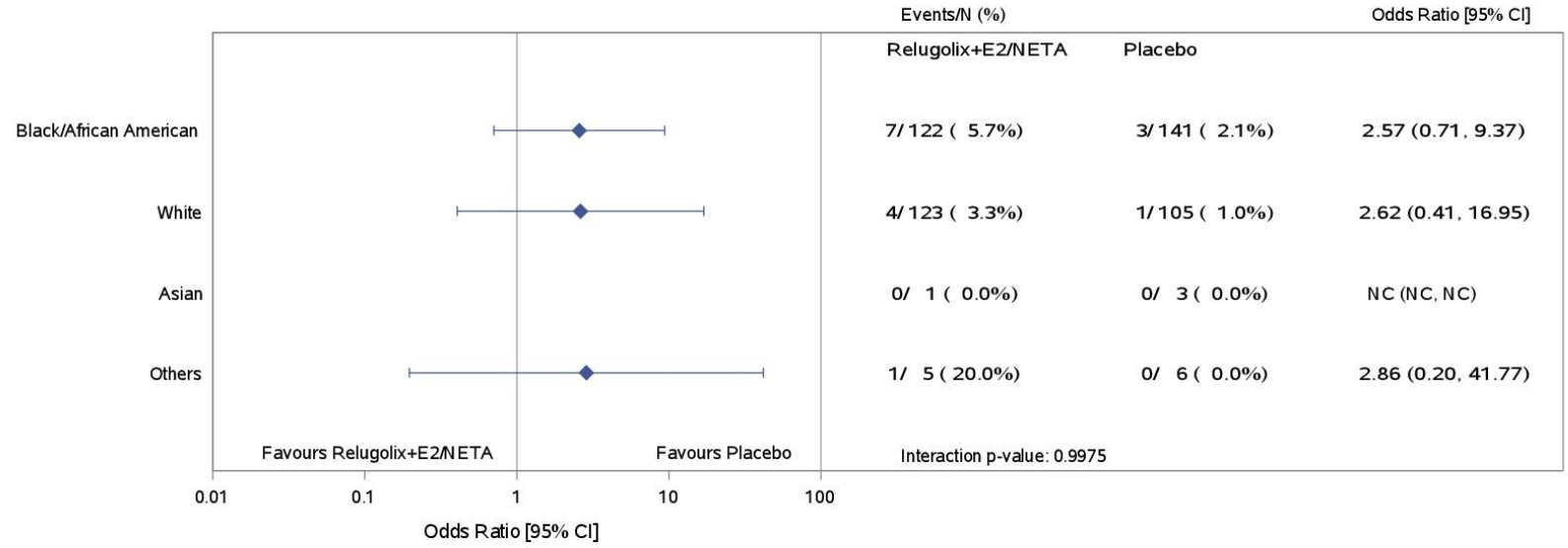
Figure SAF.TEAE.SPT.S9.BIN.FP: Frequent Treatment Emergent Adverse Events by System Organ Class and Preferred Term, by Subgroup (Safety Population)
Study: Pooled
System Organ Class: Vascular disorders, Preferred Term: Hypertension
Subgroup: Race



Results are based on a logistic regression model adjusted for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates using a one-stage fixed-effects IPD meta-analysis approach. A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
The interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the Odds Ratio and 95% CI. Missing subgroup levels are not included in estimation of the interaction p-value. The reference group is Placebo. Patients with multiple events are counted only once. MedDRA (version 22.0).
Patients with multiple events for a given PT or SOC are counted only once for each PT and SOC. Only SOCs or PTs for which there are at least 10% of patients with an event in at least one treatment group OR at least 10 patients with an event overall and at least 1% of patients with an event in at least one treatment group in the overall safety population are considered. Further, only SOCs and PTs for which there is a significant treatment effect (p-value <0.05) in the overall safety population are presented. Events are sorted alphabetically by SOC and PT and then by subgroup within each. MedDRA (version 22.0).
N: Number of patients in treatment group; NETA: Norethindrone acetate; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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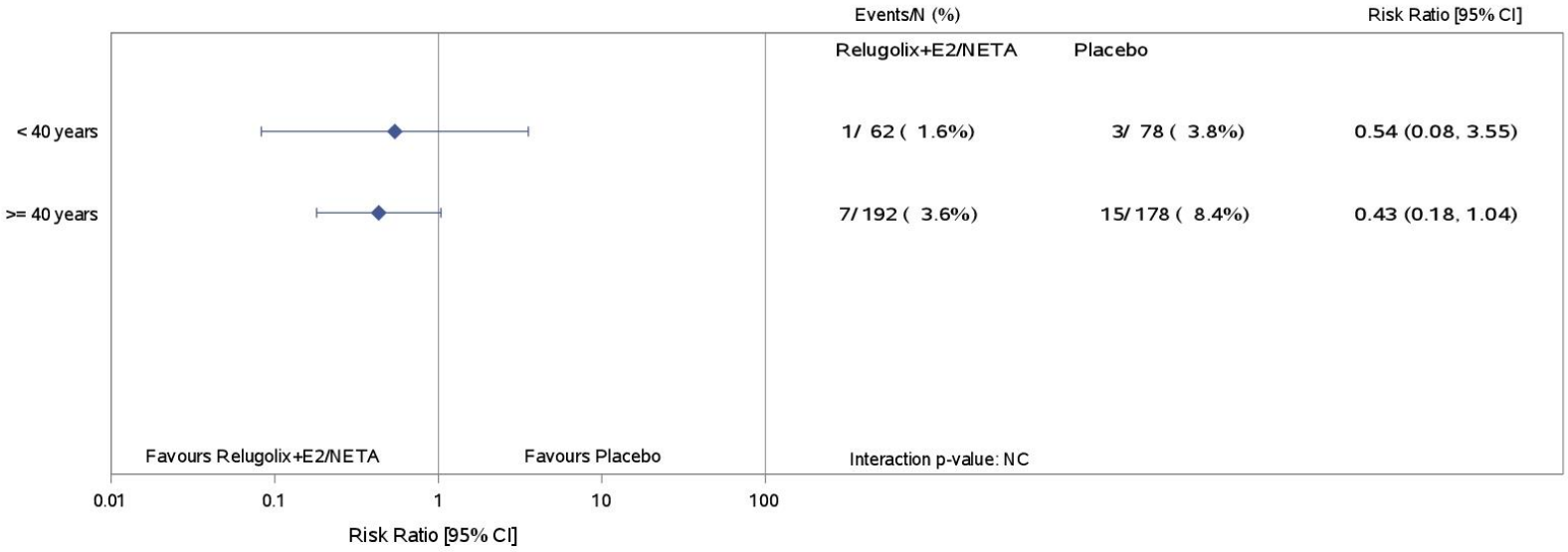
Figure SAF.TEAE.SPT.S1.BIN.FP.RR: Frequent Treatment Emergent Adverse Events by System Organ Class and Preferred Term, by Subgroup (Safety Population) - Risk Ratio
Study: Pooled
System Organ Class: Blood and lymphatic system disorders, Preferred Term: Any
Subgroup: Age (years)



Results are based on a Cochran-Mantel-Haenszel approach stratified by study using a one-stage fixed-effects IPD meta-analysis. A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
The reference group is Placebo. Patients with multiple events are counted only once. MedDRA (version 22.0).
Patients with multiple events for a given PT or SOC are counted only once for each PT and SOC. Only SOCs or PTs for which there are at least 10% of patients with an event in at least one treatment group OR at least 10 patients with an event overall and at least 1% of patients with an event in at least one treatment group in the overall safety population are considered. Further, only SOCs and PTs for which there is a significant treatment effect (p-value <0.05) in the overall safety population are presented. Events are sorted alphabetically by SOC and PT and then by subgroup within each. MedDRA (version 22.0).
N: Number of patients in treatment group; NETA: Norethindrone acetate; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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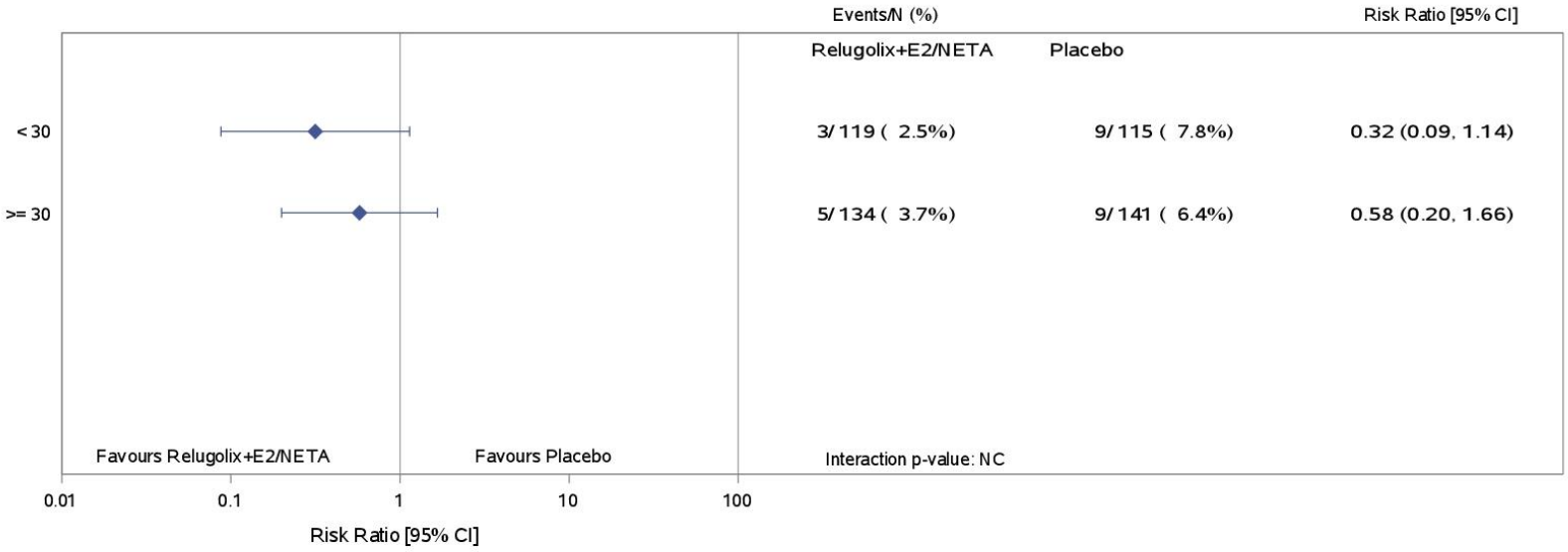
Figure SAF.TEAE.SPT.S2.BIN.FP.RR: Frequent Treatment Emergent Adverse Events by System Organ Class and Preferred Term, by Subgroup (Safety Population) - Risk Ratio
Study: Pooled
System Organ Class: Blood and lymphatic system disorders, Preferred Term: Any
Subgroup: BMI (kg/m2) at Baseline



Results are based on a Cochran-Mantel-Haenszel approach stratified by study using a one-stage fixed-effects IPD meta-analysis. A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
The reference group is Placebo. Patients with multiple events are counted only once. MedDRA (version 22.0).
Patients with multiple events for a given PT or SOC are counted only once for each PT and SOC. Only SOCs or PTs for which there are at least 10% of patients with an event in at least one treatment group OR at least 10 patients with an event overall and at least 1% of patients with an event in at least one treatment group in the overall safety population are considered. Further, only SOCs and PTs for which there is a significant treatment effect (p-value <0.05) in the overall safety population are presented. Events are sorted alphabetically by SOC and PT and then by subgroup within each. MedDRA (version 22.0).
N: Number of patients in treatment group; NETA: Norethindrone acetate; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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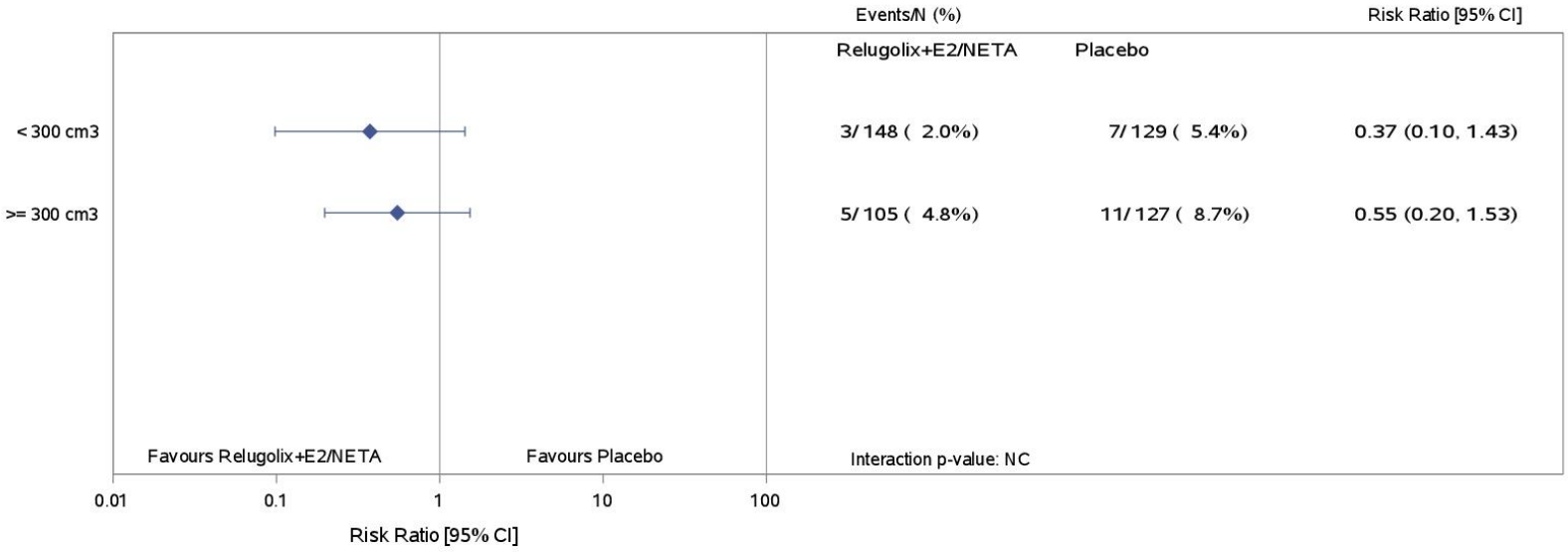
Figure SAF.TEAE.SPT.S3.BIN.FP.RR: Frequent Treatment Emergent Adverse Events by System Organ Class and Preferred Term, by Subgroup (Safety Population) - Risk Ratio
Study: Pooled
System Organ Class: Blood and lymphatic system disorders, Preferred Term: Any
Subgroup: Uterine Volume at Baseline (cm3)



Results are based on a Cochran-Mantel-Haenszel approach stratified by study using a one-stage fixed-effects IPD meta-analysis. A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
The reference group is Placebo. Patients with multiple events are counted only once. MedDRA (version 22.0).
Patients with multiple events for a given PT or SOC are counted only once for each PT and SOC. Only SOCs or PTs for which there are at least 10% of patients with an event in at least one treatment group OR at least 10 patients with an event overall and at least 1% of patients with an event in at least one treatment group in the overall safety population are considered. Further, only SOCs and PTs for which there is a significant treatment effect (p-value <0.05) in the overall safety population are presented. Events are sorted alphabetically by SOC and PT and then by subgroup within each. MedDRA (version 22.0).
N: Number of patients in treatment group; NETA: Norethindrone acetate; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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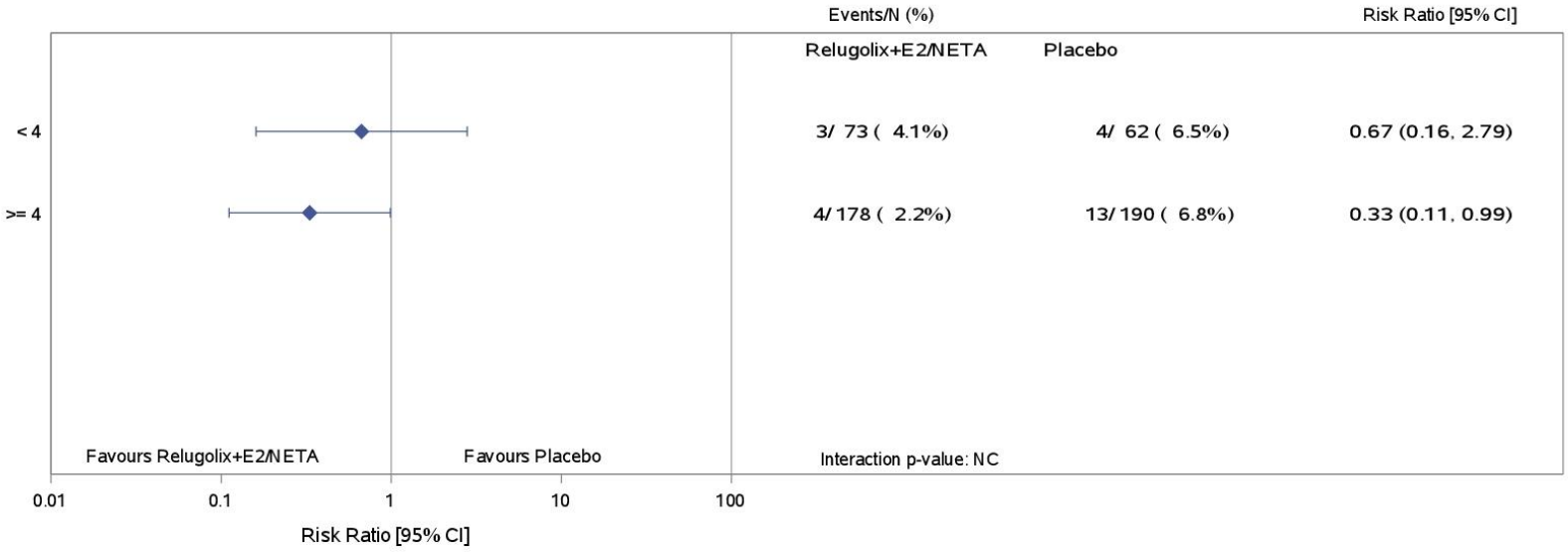
Figure SAF.TEAE.SPT.S4.BIN.FP.RR: Frequent Treatment Emergent Adverse Events by System Organ Class and Preferred Term, by Subgroup (Safety Population) - Risk Ratio
Study: Pooled
System Organ Class: Blood and lymphatic system disorders, Preferred Term: Any
Subgroup: Maximum NRS Pain Score at Baseline



Results are based on a Cochran-Mantel-Haenszel approach stratified by study using a one-stage fixed-effects IPD meta-analysis. A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
The reference group is Placebo. Patients with multiple events are counted only once. MedDRA (version 22.0).
Patients with multiple events for a given PT or SOC are counted only once for each PT and SOC. Only SOCs or PTs for which there are at least 10% of patients with an event in at least one treatment group OR at least 10 patients with an event overall and at least 1% of patients with an event in at least one treatment group in the overall safety population are considered. Further, only SOCs and PTs for which there is a significant treatment effect (p-value <0.05) in the overall safety population are presented. Events are sorted alphabetically by SOC and PT and then by subgroup within each. MedDRA (version 22.0).
N: Number of patients in treatment group; NETA: Norethindrone acetate; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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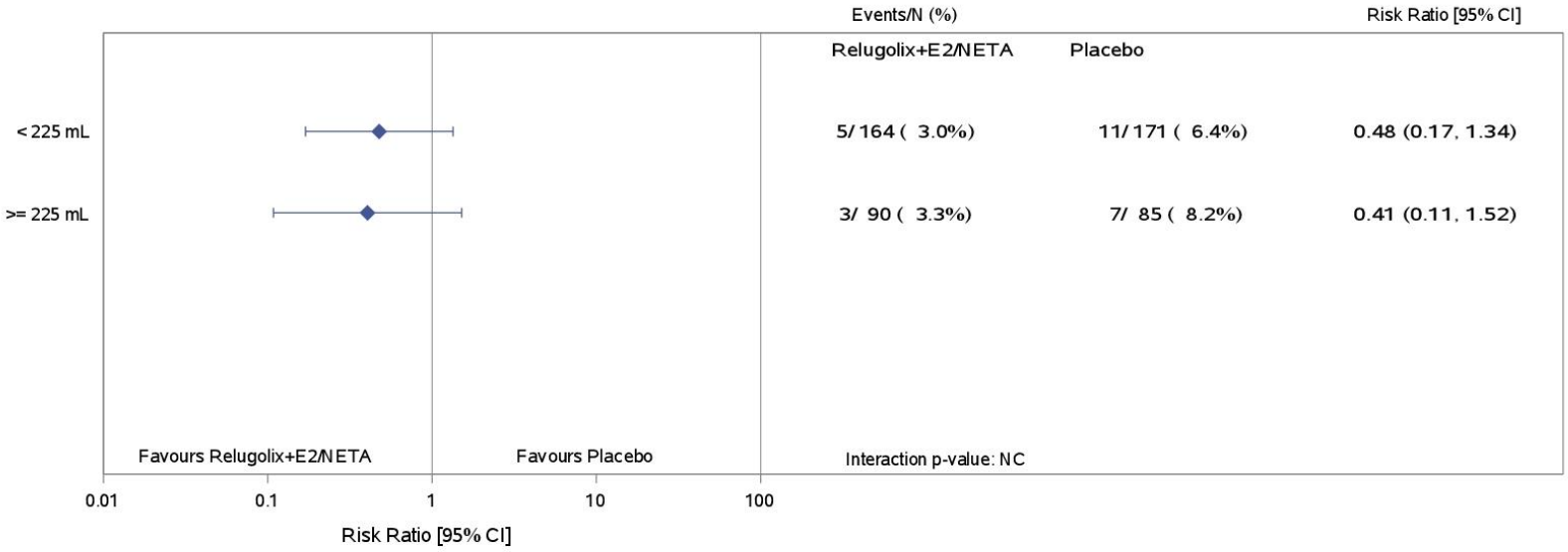
Figure SAF.TEAE.SPT.S5.BIN.FP.RR: Frequent Treatment Emergent Adverse Events by System Organ Class and Preferred Term, by Subgroup (Safety Population) - Risk Ratio
Study: Pooled
System Organ Class: Blood and lymphatic system disorders, Preferred Term: Any
Subgroup: MBL Volume at Baseline (mL)



Results are based on a Cochran-Mantel-Haenszel approach stratified by study using a one-stage fixed-effects IPD meta-analysis. A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
The reference group is Placebo. Patients with multiple events are counted only once. MedDRA (version 22.0).
Patients with multiple events for a given PT or SOC are counted only once for each PT and SOC. Only SOCs or PTs for which there are at least 10% of patients with an event in at least one treatment group OR at least 10 patients with an event overall and at least 1% of patients with an event in at least one treatment group in the overall safety population are considered. Further, only SOCs and PTs for which there is a significant treatment effect (p-value <0.05) in the overall safety population are presented. Events are sorted alphabetically by SOC and PT and then by subgroup within each. MedDRA (version 22.0).
N: Number of patients in treatment group; NETA: Norethindrone acetate; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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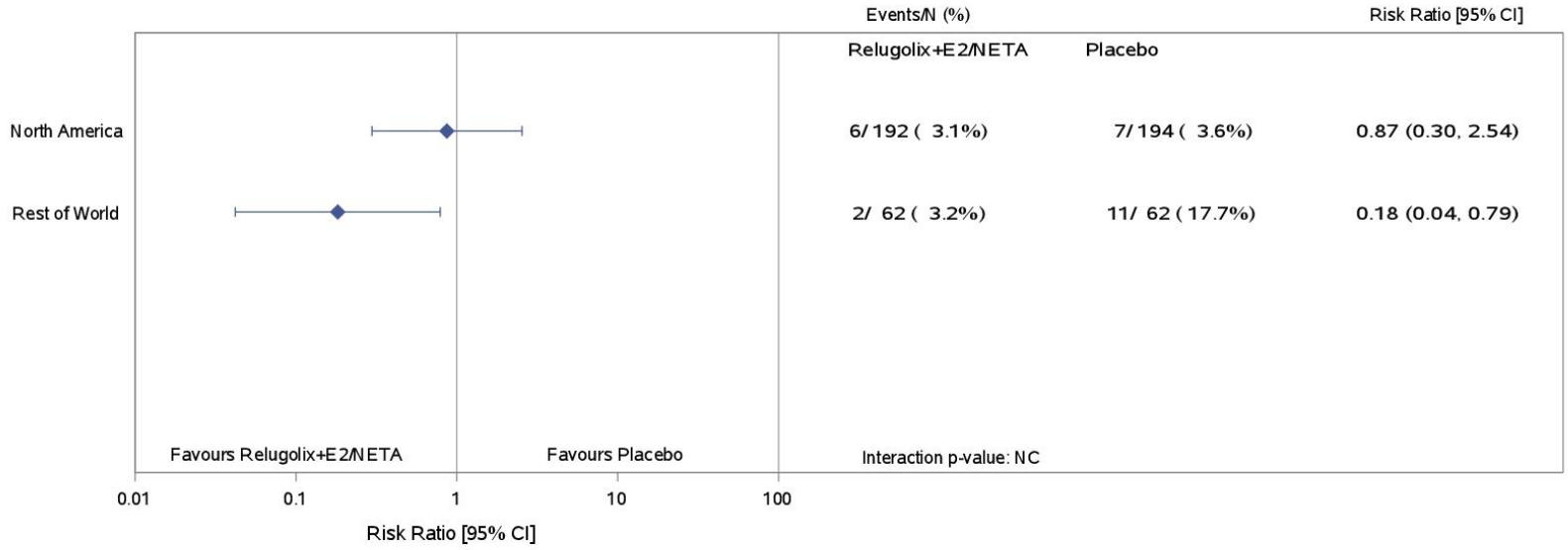
Figure SAF.TEAE.SPT.S6.BIN.FP.RR: Frequent Treatment Emergent Adverse Events by System Organ Class and Preferred Term, by Subgroup (Safety Population) - Risk Ratio
Study: Pooled
System Organ Class: Blood and lymphatic system disorders, Preferred Term: Any
Subgroup: Geographic Region I



Results are based on a Cochran-Mantel-Haenszel approach stratified by study using a one-stage fixed-effects IPD meta-analysis. A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
The reference group is Placebo. Patients with multiple events are counted only once. MedDRA (version 22.0).
Patients with multiple events for a given PT or SOC are counted only once for each PT and SOC. Only SOCs or PTs for which there are at least 10% of patients with an event in at least one treatment group OR at least 10 patients with an event overall and at least 1% of patients with an event in at least one treatment group in the overall safety population are considered. Further, only SOCs and PTs for which there is a significant treatment effect (p-value <0.05) in the overall safety population are presented. Events are sorted alphabetically by SOC and PT and then by subgroup within each. MedDRA (version 22.0).
N: Number of patients in treatment group; NETA: Norethindrone acetate; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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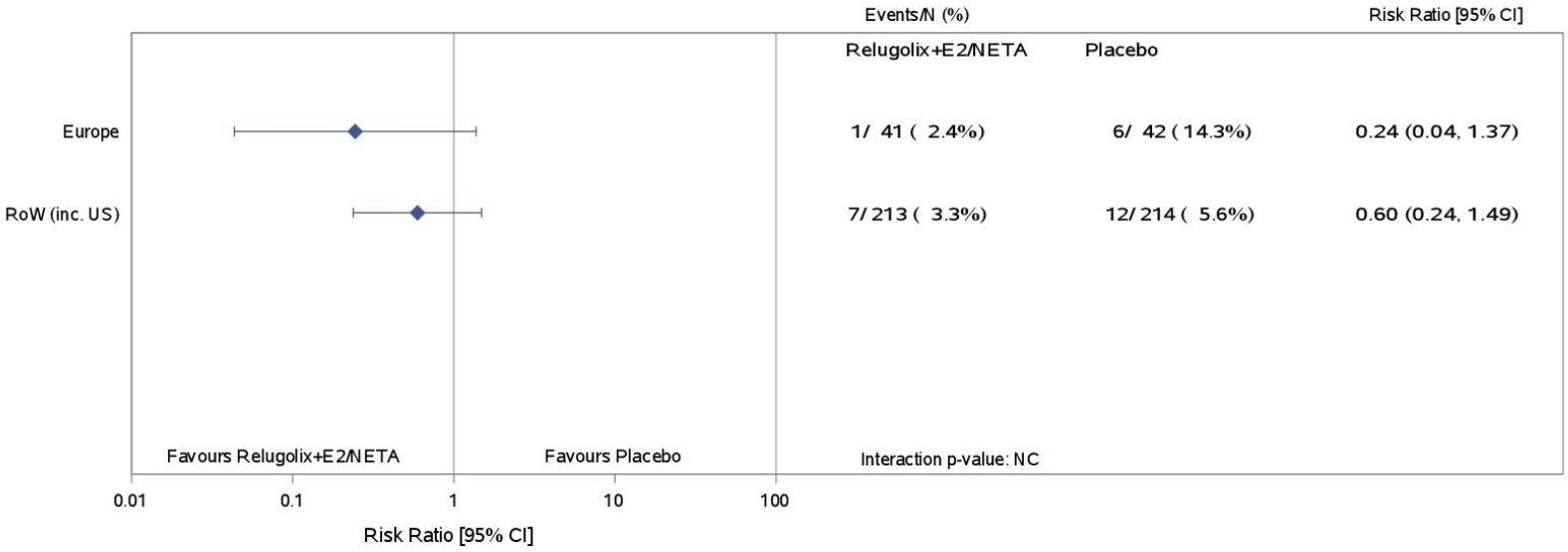
Figure SAF.TEAE.SPT.S7.BIN.FP.RR: Frequent Treatment Emergent Adverse Events by System Organ Class and Preferred Term, by Subgroup (Safety Population) - Risk Ratio
Study: Pooled
System Organ Class: Blood and lymphatic system disorders, Preferred Term: Any
Subgroup: Geographic Region II



Results are based on a Cochran-Mantel-Haenszel approach stratified by study using a one-stage fixed-effects IPD meta-analysis. A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
The reference group is Placebo. Patients with multiple events are counted only once. MedDRA (version 22.0).
Patients with multiple events for a given PT or SOC are counted only once for each PT and SOC. Only SOCs or PTs for which there are at least 10% of patients with an event in at least one treatment group OR at least 10 patients with an event overall and at least 1% of patients with an event in at least one treatment group in the overall safety population are considered. Further, only SOCs and PTs for which there is a significant treatment effect (p-value <0.05) in the overall safety population are presented. Events are sorted alphabetically by SOC and PT and then by subgroup within each. MedDRA (version 22.0).
N: Number of patients in treatment group; NETA: Norethindrone acetate; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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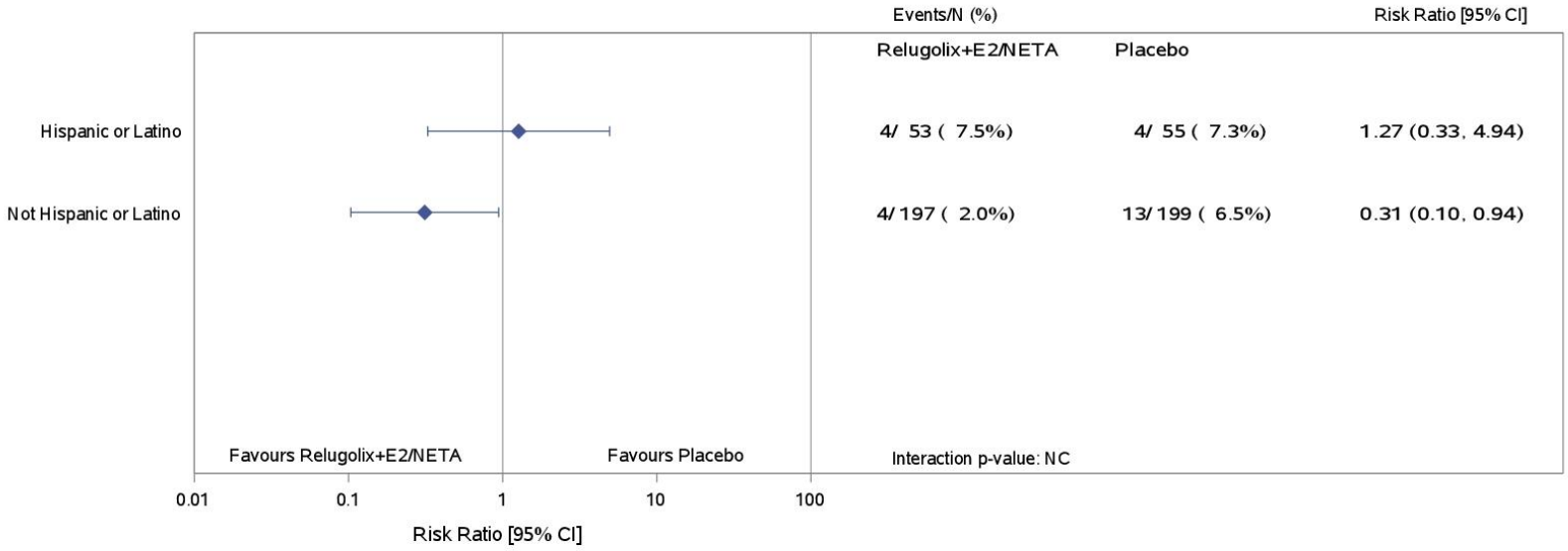
Figure SAF.TEAE.SPT.S8.BIN.FP.RR: Frequent Treatment Emergent Adverse Events by System Organ Class and Preferred Term, by Subgroup (Safety Population) - Risk Ratio
Study: Pooled
System Organ Class: Blood and lymphatic system disorders, Preferred Term: Any
Subgroup: Ethnicity



Results are based on a Cochran-Mantel-Haenszel approach stratified by study using a one-stage fixed-effects IPD meta-analysis. A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
The reference group is Placebo. Patients with multiple events are counted only once. MedDRA (version 22.0).
Patients with multiple events for a given PT or SOC are counted only once for each PT and SOC. Only SOCs or PTs for which there are at least 10% of patients with an event in at least one treatment group OR at least 10 patients with an event overall and at least 1% of patients with an event in at least one treatment group in the overall safety population are considered. Further, only SOCs and PTs for which there is a significant treatment effect (p-value <0.05) in the overall safety population are presented. Events are sorted alphabetically by SOC and PT and then by subgroup within each. MedDRA (version 22.0).
N: Number of patients in treatment group; NETA: Norethindrone acetate; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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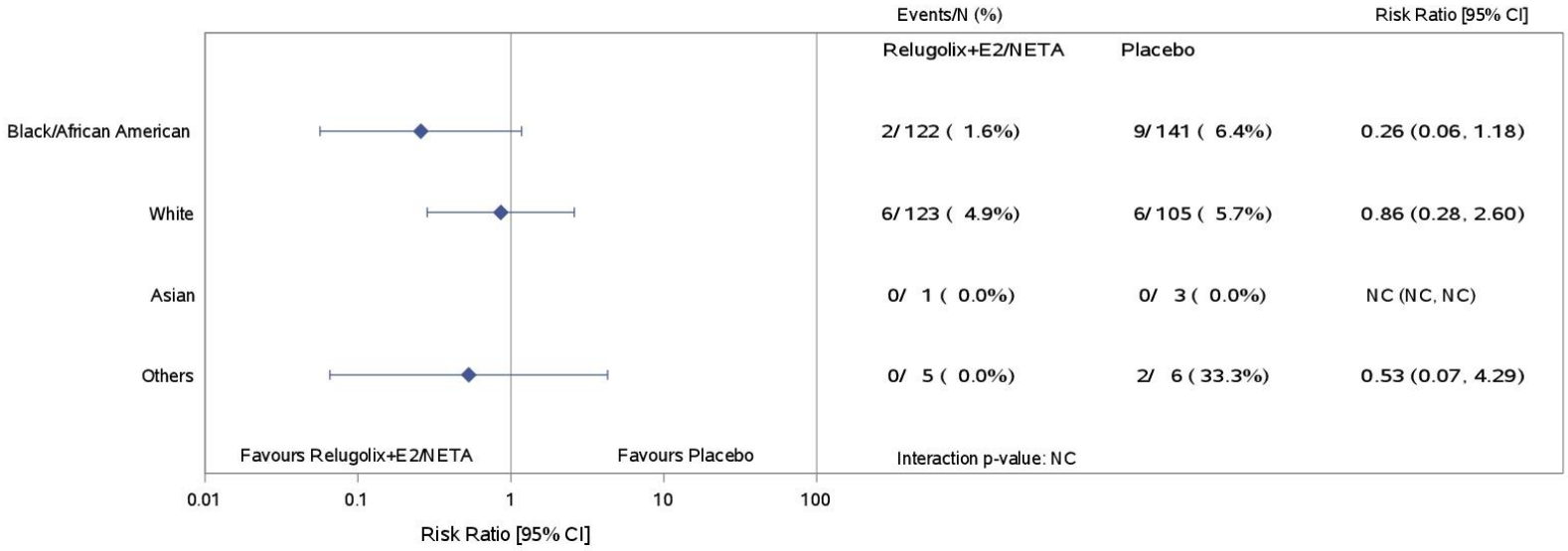
Figure SAF.TEAE.SPT.S9.BIN.FP.RR: Frequent Treatment Emergent Adverse Events by System Organ Class and Preferred Term, by Subgroup (Safety Population) - Risk Ratio
Study: Pooled
System Organ Class: Blood and lymphatic system disorders, Preferred Term: Any
Subgroup: Race



Results are based on a Cochran-Mantel-Haenszel approach stratified by study using a one-stage fixed-effects IPD meta-analysis. A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
The reference group is Placebo. Patients with multiple events are counted only once. MedDRA (version 22.0).
Patients with multiple events for a given PT or SOC are counted only once for each PT and SOC. Only SOCs or PTs for which there are at least 10% of patients with an event in at least one treatment group OR at least 10 patients with an event overall and at least 1% of patients with an event in at least one treatment group in the overall safety population are considered. Further, only SOCs and PTs for which there is a significant treatment effect (p-value <0.05) in the overall safety population are presented. Events are sorted alphabetically by SOC and PT and then by subgroup within each. MedDRA (version 22.0).
N: Number of patients in treatment group; NETA: Norethindrone acetate; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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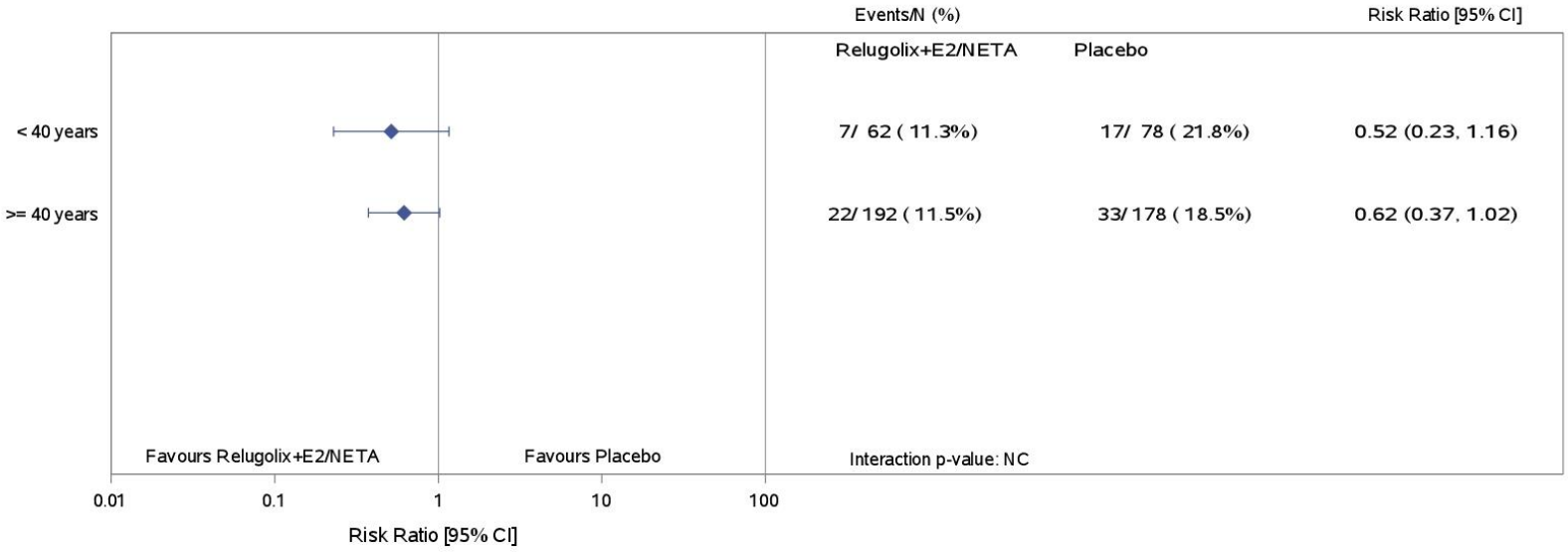
Figure SAF.TEAE.SPT.S1.BIN.FP.RR: Frequent Treatment Emergent Adverse Events by System Organ Class and Preferred Term, by Subgroup (Safety Population) - Risk Ratio
Study: Pooled
System Organ Class: Nervous system disorders, Preferred Term: Any
Subgroup: Age (years)



Results are based on a Cochran-Mantel-Haenszel approach stratified by study using a one-stage fixed-effects IPD meta-analysis. A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
The reference group is Placebo. Patients with multiple events are counted only once. MedDRA (version 22.0).
Patients with multiple events for a given PT or SOC are counted only once for each PT and SOC. Only SOCs or PTs for which there are at least 10% of patients with an event in at least one treatment group OR at least 10 patients with an event overall and at least 1% of patients with an event in at least one treatment group in the overall safety population are considered. Further, only SOCs and PTs for which there is a significant treatment effect (p-value <0.05) in the overall safety population are presented. Events are sorted alphabetically by SOC and PT and then by subgroup within each. MedDRA (version 22.0).
N: Number of patients in treatment group; NETA: Norethindrone acetate; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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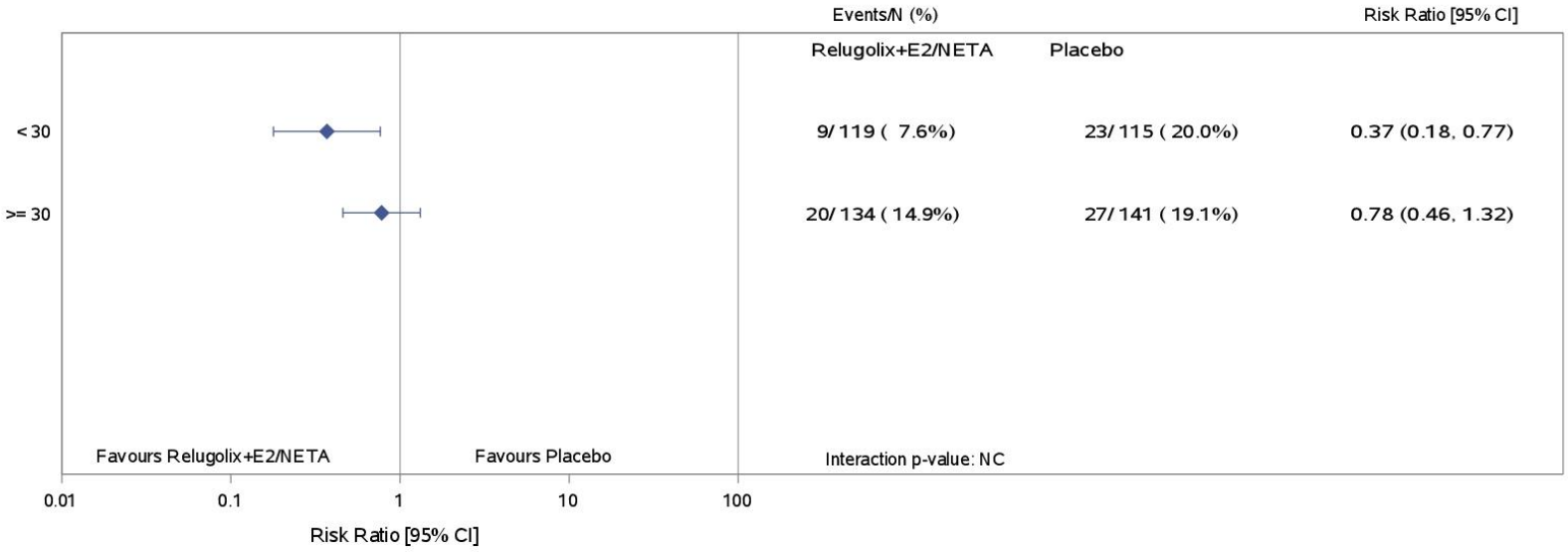
Figure SAF.TEAE.SPT.S2.BIN.FP.RR: Frequent Treatment Emergent Adverse Events by System Organ Class and Preferred Term, by Subgroup (Safety Population) - Risk Ratio
Study: Pooled
System Organ Class: Nervous system disorders, Preferred Term: Any
Subgroup: BMI (kg/m2) at Baseline



Results are based on a Cochran-Mantel-Haenszel approach stratified by study using a one-stage fixed-effects IPD meta-analysis. A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
The reference group is Placebo. Patients with multiple events are counted only once. MedDRA (version 22.0).
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N: Number of patients in treatment group; NETA: Norethindrone acetate; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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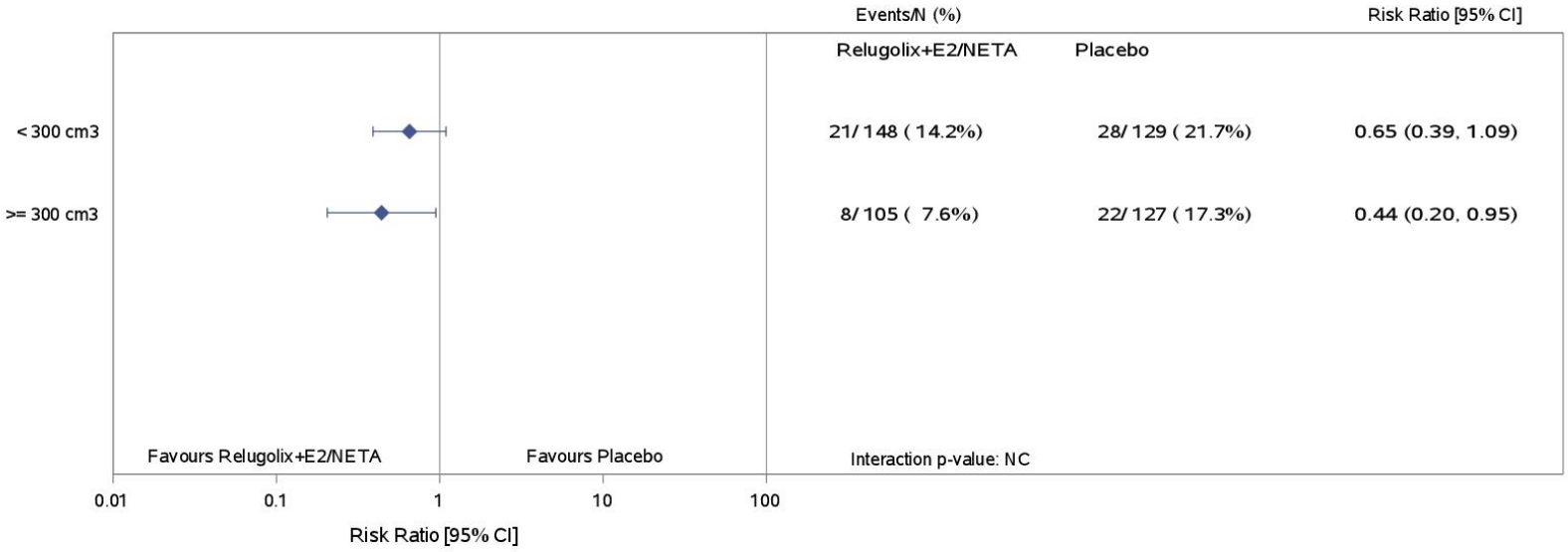
Figure SAF.TEAE.SPT.S3.BIN.FP.RR: Frequent Treatment Emergent Adverse Events by System Organ Class and Preferred Term, by Subgroup (Safety Population) - Risk Ratio
Study: Pooled
System Organ Class: Nervous system disorders, Preferred Term: Any
Subgroup: Uterine Volume at Baseline (cm3)



Results are based on a Cochran-Mantel-Haenszel approach stratified by study using a one-stage fixed-effects IPD meta-analysis. A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
The reference group is Placebo. Patients with multiple events are counted only once. MedDRA (version 22.0).
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N: Number of patients in treatment group; NETA: Norethindrone acetate; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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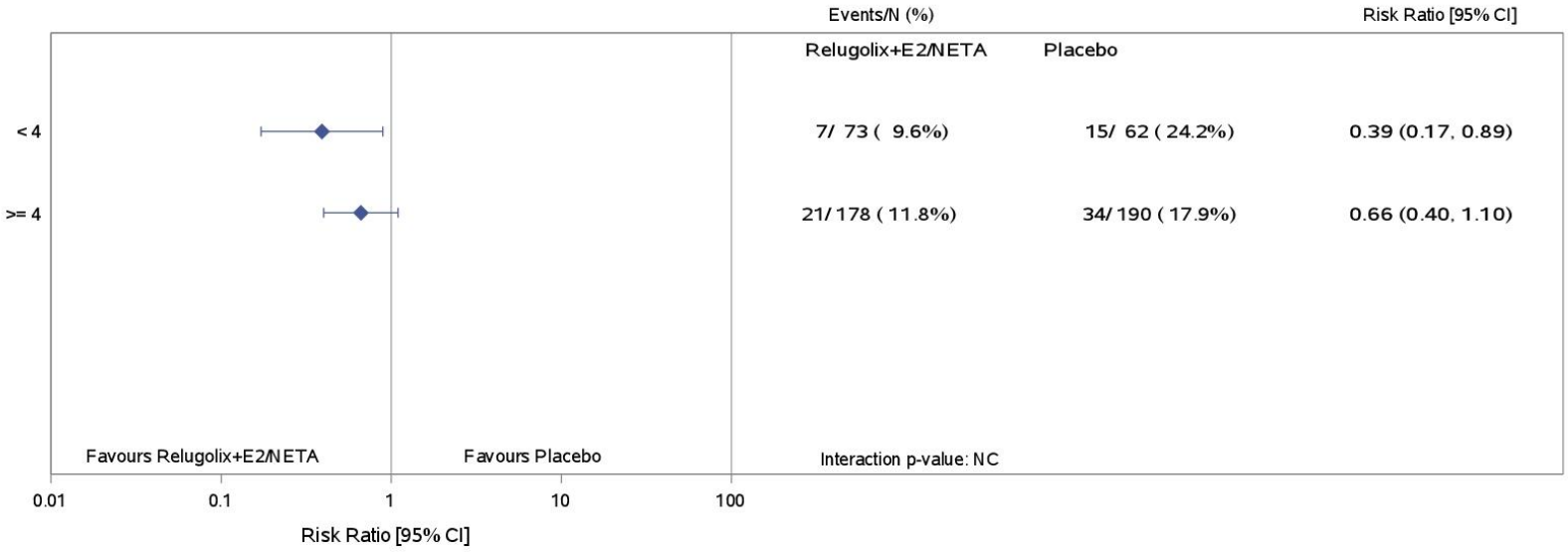
Figure SAF.TEAE.SPT.S4.BIN.FP.RR: Frequent Treatment Emergent Adverse Events by System Organ Class and Preferred Term, by Subgroup (Safety Population) - Risk Ratio
Study: Pooled
System Organ Class: Nervous system disorders, Preferred Term: Any
Subgroup: Maximum NRS Pain Score at Baseline



Results are based on a Cochran-Mantel-Haenszel approach stratified by study using a one-stage fixed-effects IPD meta-analysis. A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
The reference group is Placebo. Patients with multiple events are counted only once. MedDRA (version 22.0).
Patients with multiple events for a given PT or SOC are counted only once for each PT and SOC. Only SOCs or PTs for which there are at least 10% of patients with an event in at least one treatment group OR at least 10 patients with an event overall and at least 1% of patients with an event in at least one treatment group in the overall safety population are considered. Further, only SOCs and PTs for which there is a significant treatment effect (p-value <0.05) in the overall safety population are presented. Events are sorted alphabetically by SOC and PT and then by subgroup within each. MedDRA (version 22.0).
N: Number of patients in treatment group; NETA: Norethindrone acetate; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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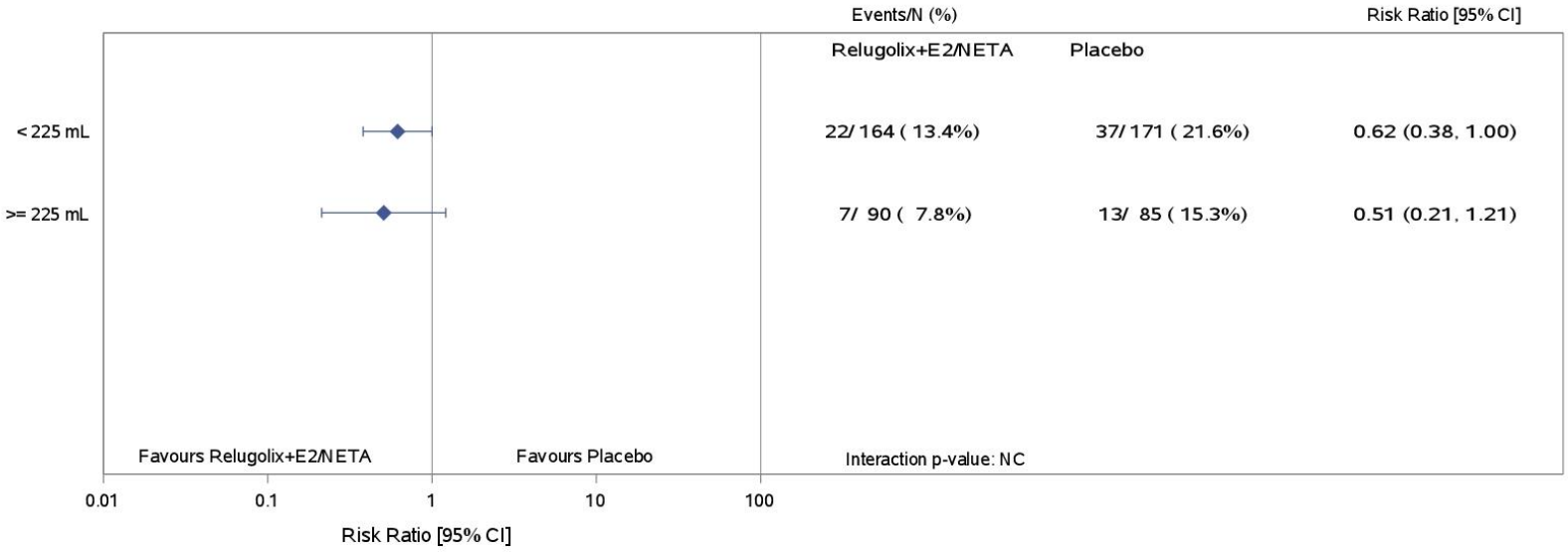
Figure SAF.TEAE.SPT.S5.BIN.FP.RR: Frequent Treatment Emergent Adverse Events by System Organ Class and Preferred Term, by Subgroup (Safety Population) - Risk Ratio
Study: Pooled
System Organ Class: Nervous system disorders, Preferred Term: Any
Subgroup: MBL Volume at Baseline (mL)



Results are based on a Cochran-Mantel-Haenszel approach stratified by study using a one-stage fixed-effects IPD meta-analysis. A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
The reference group is Placebo. Patients with multiple events are counted only once. MedDRA (version 22.0).
Patients with multiple events for a given PT or SOC are counted only once for each PT and SOC. Only SOCs or PTs for which there are at least 10% of patients with an event in at least one treatment group OR at least 10 patients with an event overall and at least 1% of patients with an event in at least one treatment group in the overall safety population are considered. Further, only SOCs and PTs for which there is a significant treatment effect (p-value <0.05) in the overall safety population are presented. Events are sorted alphabetically by SOC and PT and then by subgroup within each. MedDRA (version 22.0).
N: Number of patients in treatment group; NETA: Norethindrone acetate; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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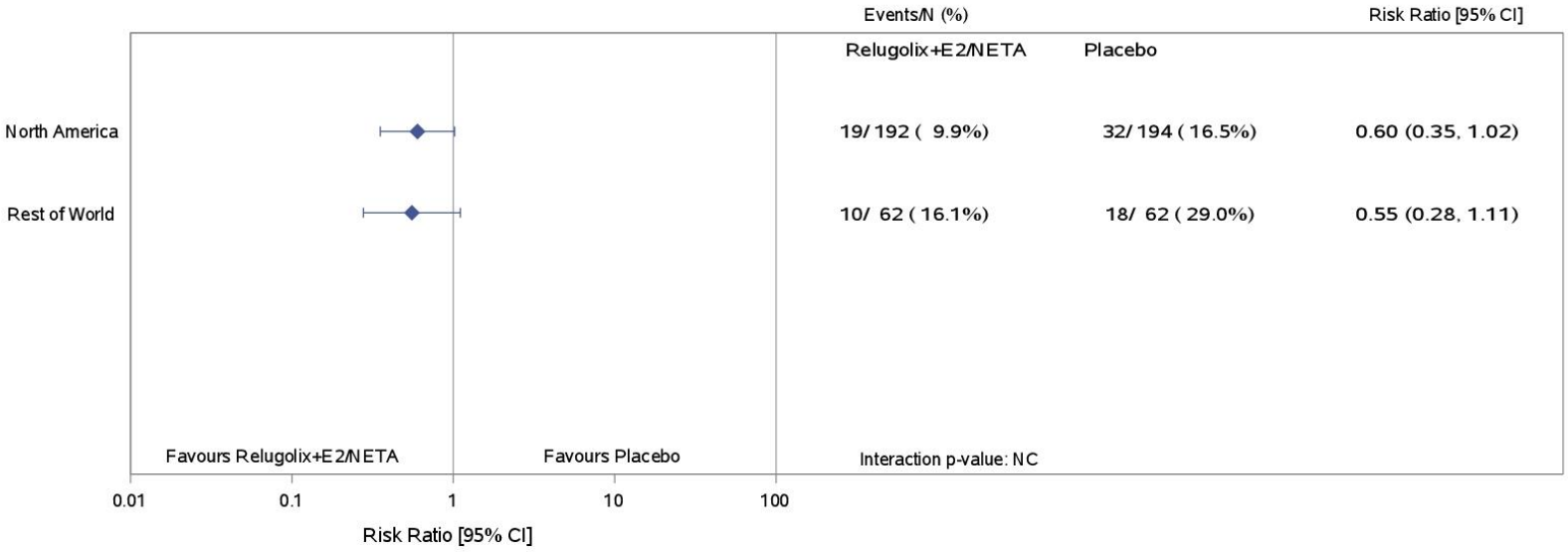
Figure SAF.TEAE.SPT.S6.BIN.FP.RR: Frequent Treatment Emergent Adverse Events by System Organ Class and Preferred Term, by Subgroup (Safety Population) - Risk Ratio
Study: Pooled
System Organ Class: Nervous system disorders, Preferred Term: Any
Subgroup: Geographic Region I



Results are based on a Cochran-Mantel-Haenszel approach stratified by study using a one-stage fixed-effects IPD meta-analysis. A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
The reference group is Placebo. Patients with multiple events are counted only once. MedDRA (version 22.0).
Patients with multiple events for a given PT or SOC are counted only once for each PT and SOC. Only SOCs or PTs for which there are at least 10% of patients with an event in at least one treatment group OR at least 10 patients with an event overall and at least 1% of patients with an event in at least one treatment group in the overall safety population are considered. Further, only SOCs and PTs for which there is a significant treatment effect (p-value <0.05) in the overall safety population are presented. Events are sorted alphabetically by SOC and PT and then by subgroup within each. MedDRA (version 22.0).
N: Number of patients in treatment group; NETA: Norethindrone acetate; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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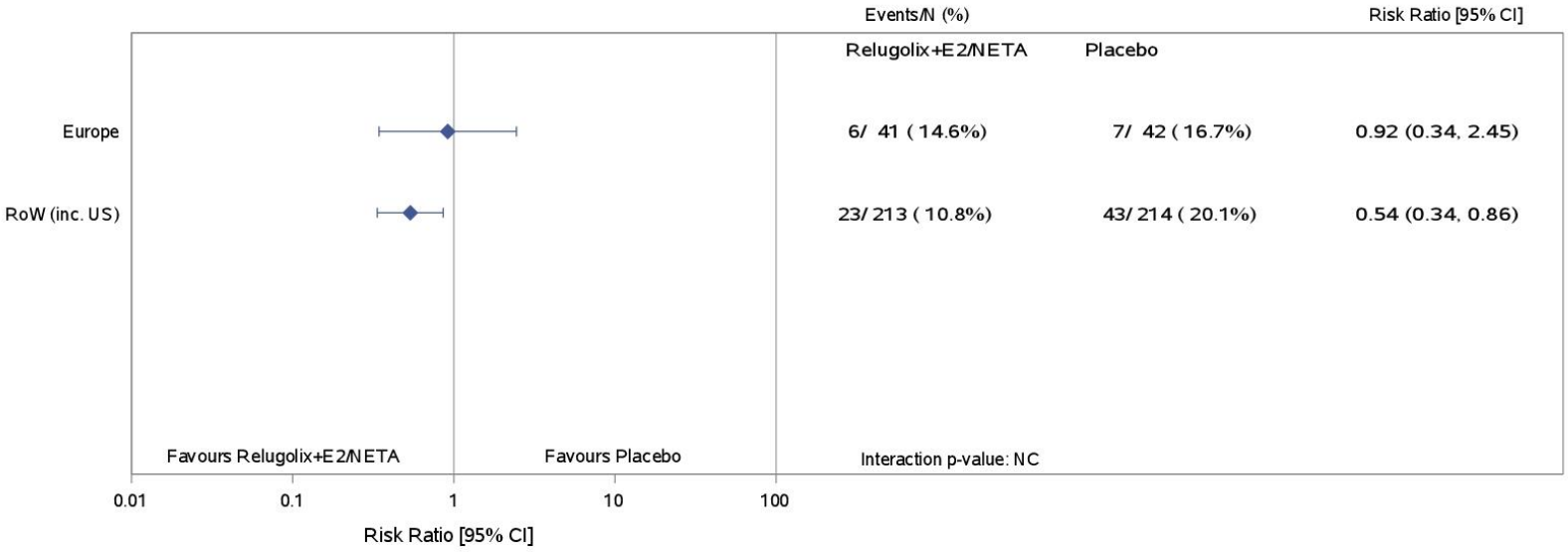
Figure SAF.TEAE.SPT.S7.BIN.FP.RR: Frequent Treatment Emergent Adverse Events by System Organ Class and Preferred Term, by Subgroup (Safety Population) - Risk Ratio
Study: Pooled
System Organ Class: Nervous system disorders, Preferred Term: Any
Subgroup: Geographic Region II



Results are based on a Cochran-Mantel-Haenszel approach stratified by study using a one-stage fixed-effects IPD meta-analysis. A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
The reference group is Placebo. Patients with multiple events are counted only once. MedDRA (version 22.0).
Patients with multiple events for a given PT or SOC are counted only once for each PT and SOC. Only SOCs or PTs for which there are at least 10% of patients with an event in at least one treatment group OR at least 10 patients with an event overall and at least 1% of patients with an event in at least one treatment group in the overall safety population are considered. Further, only SOCs and PTs for which there is a significant treatment effect (p-value <0.05) in the overall safety population are presented. Events are sorted alphabetically by SOC and PT and then by subgroup within each. MedDRA (version 22.0).
N: Number of patients in treatment group; NETA: Norethindrone acetate; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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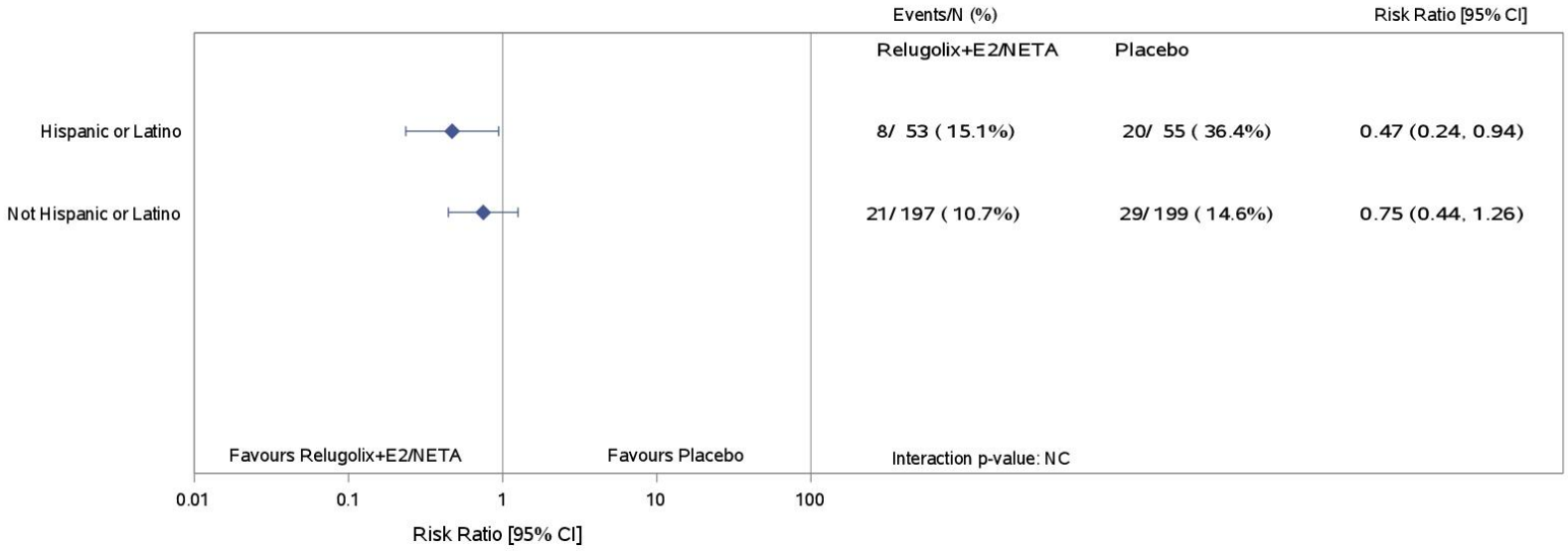
Figure SAF.TEAE.SPT.S8.BIN.FP.RR: Frequent Treatment Emergent Adverse Events by System Organ Class and Preferred Term, by Subgroup (Safety Population) - Risk Ratio
Study: Pooled
System Organ Class: Nervous system disorders, Preferred Term: Any
Subgroup: Ethnicity



Results are based on a Cochran-Mantel-Haenszel approach stratified by study using a one-stage fixed-effects IPD meta-analysis. A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
The reference group is Placebo. Patients with multiple events are counted only once. MedDRA (version 22.0).
Patients with multiple events for a given PT or SOC are counted only once for each PT and SOC. Only SOCs or PTs for which there are at least 10% of patients with an event in at least one treatment group OR at least 10 patients with an event overall and at least 1% of patients with an event in at least one treatment group in the overall safety population are considered. Further, only SOCs and PTs for which there is a significant treatment effect (p-value <0.05) in the overall safety population are presented. Events are sorted alphabetically by SOC and PT and then by subgroup within each. MedDRA (version 22.0).
N: Number of patients in treatment group; NETA: Norethindrone acetate; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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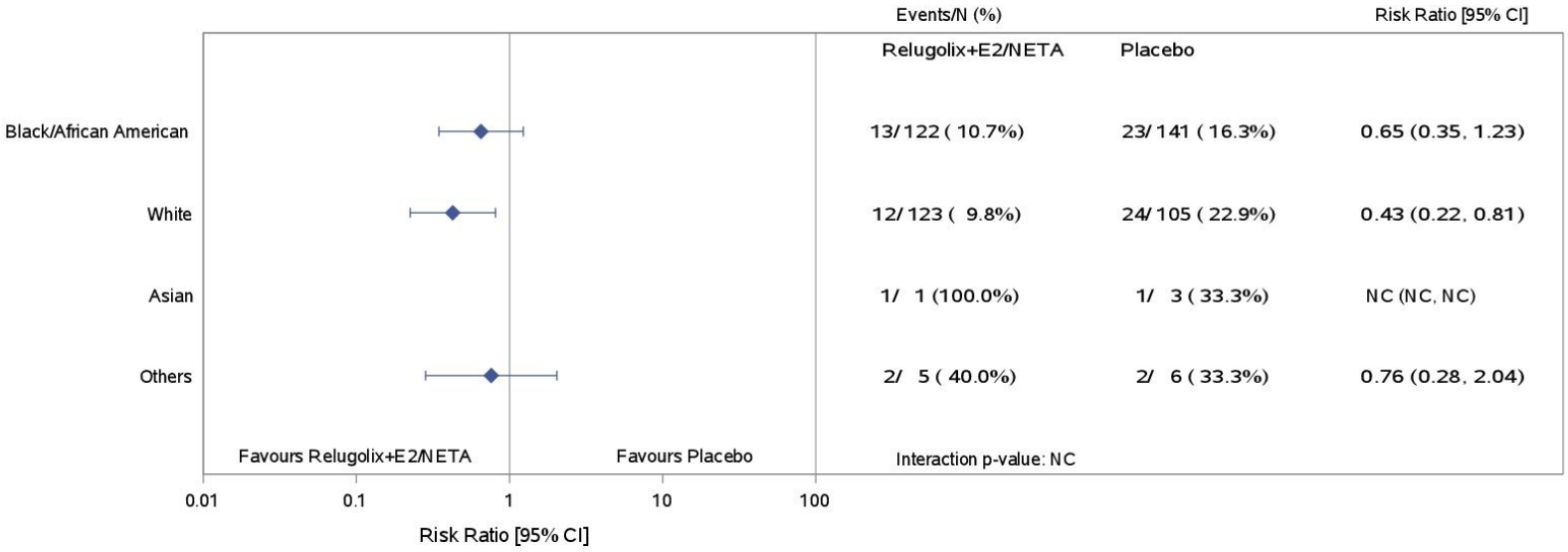
Figure SAF.TEAE.SPT.S9.BIN.FP.RR: Frequent Treatment Emergent Adverse Events by System Organ Class and Preferred Term, by Subgroup (Safety Population) - Risk Ratio
Study: Pooled
System Organ Class: Nervous system disorders, Preferred Term: Any
Subgroup: Race



Results are based on a Cochran-Mantel-Haenszel approach stratified by study using a one-stage fixed-effects IPD meta-analysis. A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
The reference group is Placebo. Patients with multiple events are counted only once. MedDRA (version 22.0).
Patients with multiple events for a given PT or SOC are counted only once for each PT and SOC. Only SOCs or PTs for which there are at least 10% of patients with an event in at least one treatment group OR at least 10 patients with an event overall and at least 1% of patients with an event in at least one treatment group in the overall safety population are considered. Further, only SOCs and PTs for which there is a significant treatment effect (p-value <0.05) in the overall safety population are presented. Events are sorted alphabetically by SOC and PT and then by subgroup within each. MedDRA (version 22.0).
N: Number of patients in treatment group; NETA: Norethindrone acetate; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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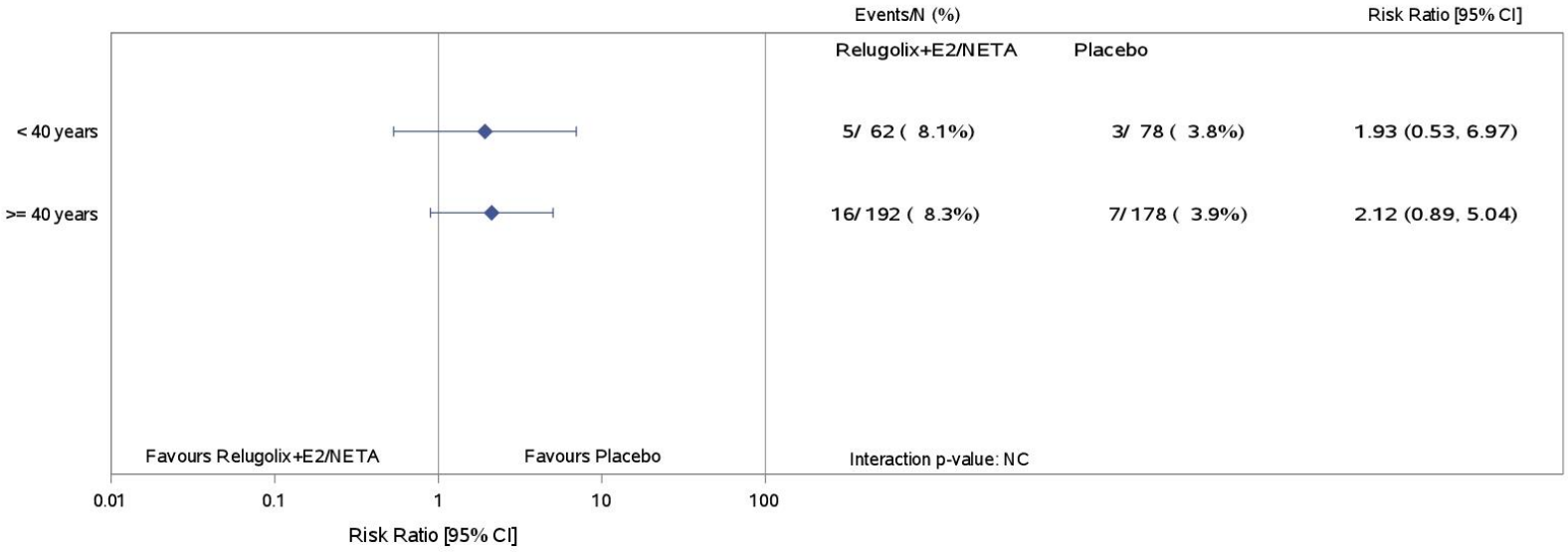
Figure SAF.TEAE.SPT.S1.BIN.FP.RR: Frequent Treatment Emergent Adverse Events by System Organ Class and Preferred Term, by Subgroup (Safety Population) - Risk Ratio
Study: Pooled
System Organ Class: Psychiatric disorders, Preferred Term: Any
Subgroup: Age (years)



Results are based on a Cochran-Mantel-Haenszel approach stratified by study using a one-stage fixed-effects IPD meta-analysis. A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
The reference group is Placebo. Patients with multiple events are counted only once. MedDRA (version 22.0).
Patients with multiple events for a given PT or SOC are counted only once for each PT and SOC. Only SOCs or PTs for which there are at least 10% of patients with an event in at least one treatment group OR at least 10 patients with an event overall and at least 1% of patients with an event in at least one treatment group in the overall safety population are considered. Further, only SOCs and PTs for which there is a significant treatment effect (p-value <0.05) in the overall safety population are presented. Events are sorted alphabetically by SOC and PT and then by subgroup within each. MedDRA (version 22.0).
N: Number of patients in treatment group; NETA: Norethindrone acetate; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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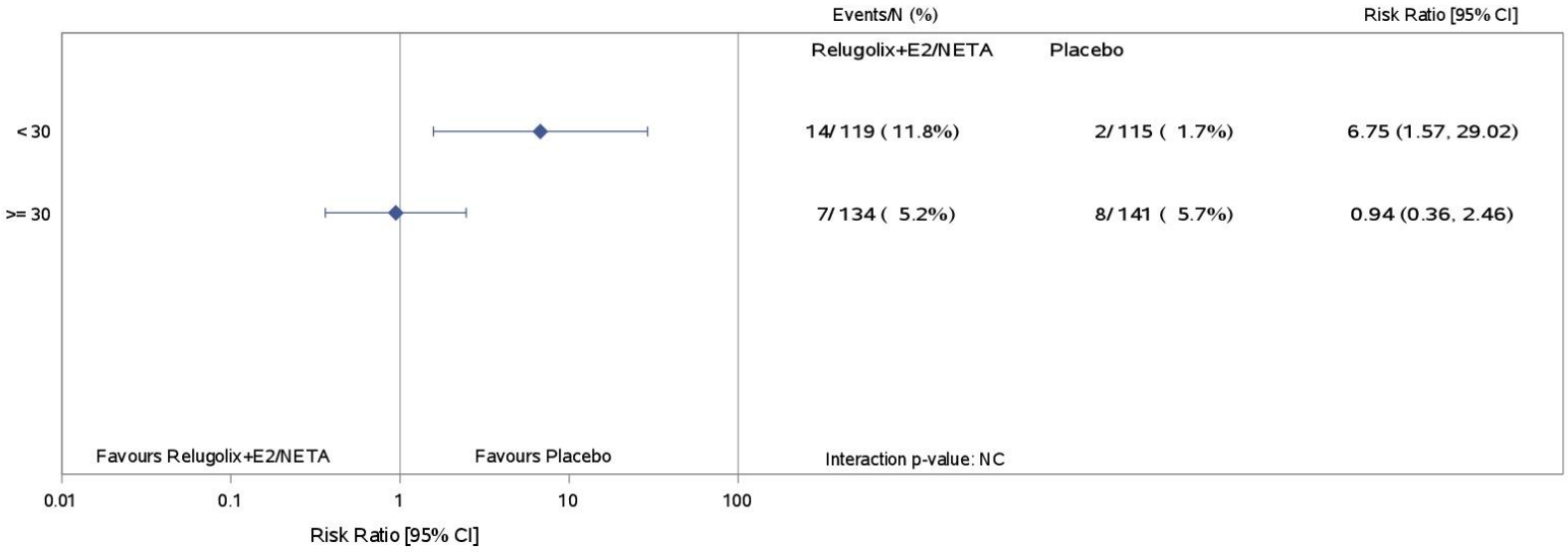
Figure SAF.TEAE.SPT.S2.BIN.FP.RR: Frequent Treatment Emergent Adverse Events by System Organ Class and Preferred Term, by Subgroup (Safety Population) - Risk Ratio
Study: Pooled
System Organ Class: Psychiatric disorders, Preferred Term: Any
Subgroup: BMI (kg/m2) at Baseline



Results are based on a Cochran-Mantel-Haenszel approach stratified by study using a one-stage fixed-effects IPD meta-analysis. A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
The reference group is Placebo. Patients with multiple events are counted only once. MedDRA (version 22.0).
Patients with multiple events for a given PT or SOC are counted only once for each PT and SOC. Only SOCs or PTs for which there are at least 10% of patients with an event in at least one treatment group OR at least 10 patients with an event overall and at least 1% of patients with an event in at least one treatment group in the overall safety population are considered. Further, only SOCs and PTs for which there is a significant treatment effect (p-value <0.05) in the overall safety population are presented. Events are sorted alphabetically by SOC and PT and then by subgroup within each. MedDRA (version 22.0).
N: Number of patients in treatment group; NETA: Norethindrone acetate; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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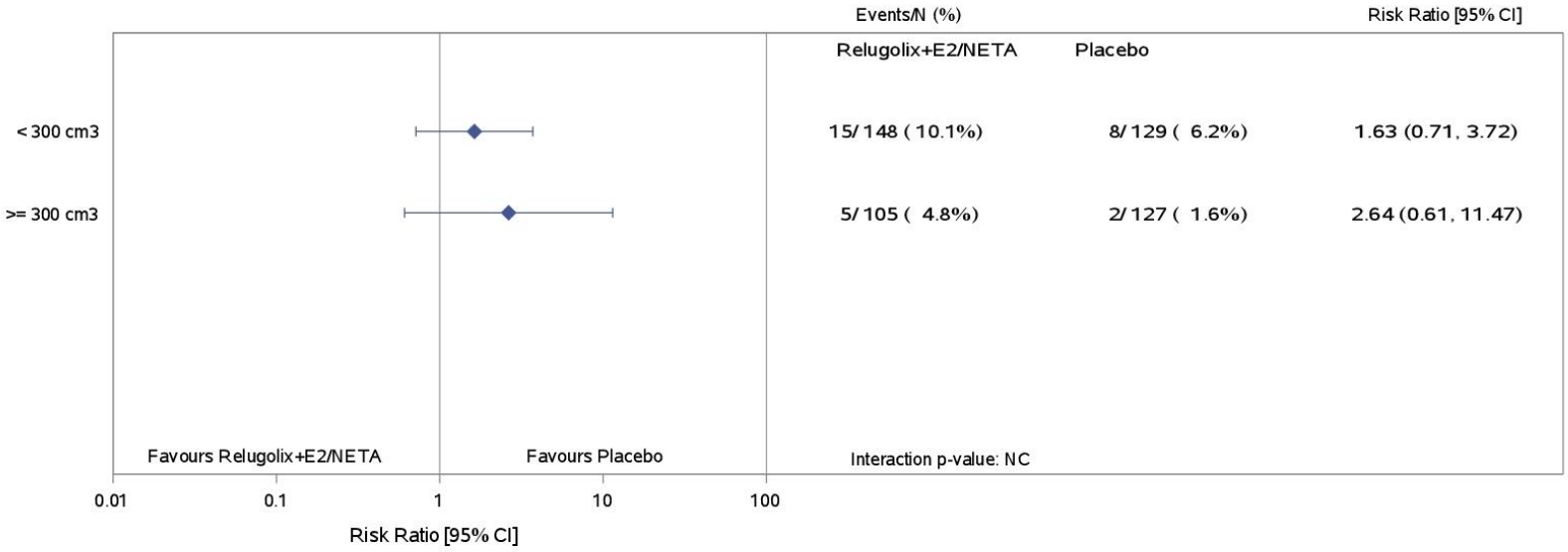
Figure SAF.TEAE.SPT.S3.BIN.FP.RR: Frequent Treatment Emergent Adverse Events by System Organ Class and Preferred Term, by Subgroup (Safety Population) - Risk Ratio
Study: Pooled
System Organ Class: Psychiatric disorders, Preferred Term: Any
Subgroup: Uterine Volume at Baseline (cm3)



Results are based on a Cochran-Mantel-Haenszel approach stratified by study using a one-stage fixed-effects IPD meta-analysis. A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
The reference group is Placebo. Patients with multiple events are counted only once. MedDRA (version 22.0).
Patients with multiple events for a given PT or SOC are counted only once for each PT and SOC. Only SOCs or PTs for which there are at least 10% of patients with an event in at least one treatment group OR at least 10 patients with an event overall and at least 1% of patients with an event in at least one treatment group in the overall safety population are considered. Further, only SOCs and PTs for which there is a significant treatment effect (p-value <0.05) in the overall safety population are presented. Events are sorted alphabetically by SOC and PT and then by subgroup within each. MedDRA (version 22.0).
N: Number of patients in treatment group; NETA: Norethindrone acetate; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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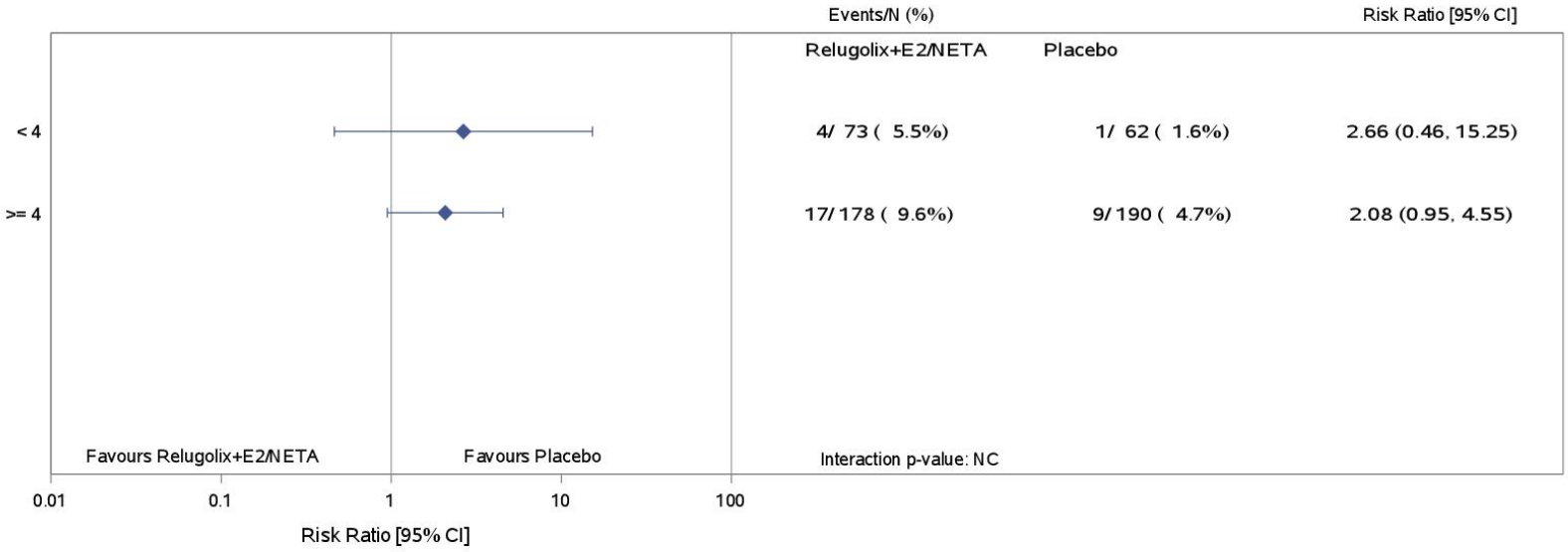
Figure SAF.TEAE.SPT.S4.BIN.FP.RR: Frequent Treatment Emergent Adverse Events by System Organ Class and Preferred Term, by Subgroup (Safety Population) - Risk Ratio
Study: Pooled
System Organ Class: Psychiatric disorders, Preferred Term: Any
Subgroup: Maximum NRS Pain Score at Baseline



Results are based on a Cochran-Mantel-Haenszel approach stratified by study using a one-stage fixed-effects IPD meta-analysis. A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
The reference group is Placebo. Patients with multiple events are counted only once. MedDRA (version 22.0).
Patients with multiple events for a given PT or SOC are counted only once for each PT and SOC. Only SOCs or PTs for which there are at least 10% of patients with an event in at least one treatment group OR at least 10 patients with an event overall and at least 1% of patients with an event in at least one treatment group in the overall safety population are considered. Further, only SOCs and PTs for which there is a significant treatment effect (p-value <0.05) in the overall safety population are presented. Events are sorted alphabetically by SOC and PT and then by subgroup within each. MedDRA (version 22.0).
N: Number of patients in treatment group; NETA: Norethindrone acetate; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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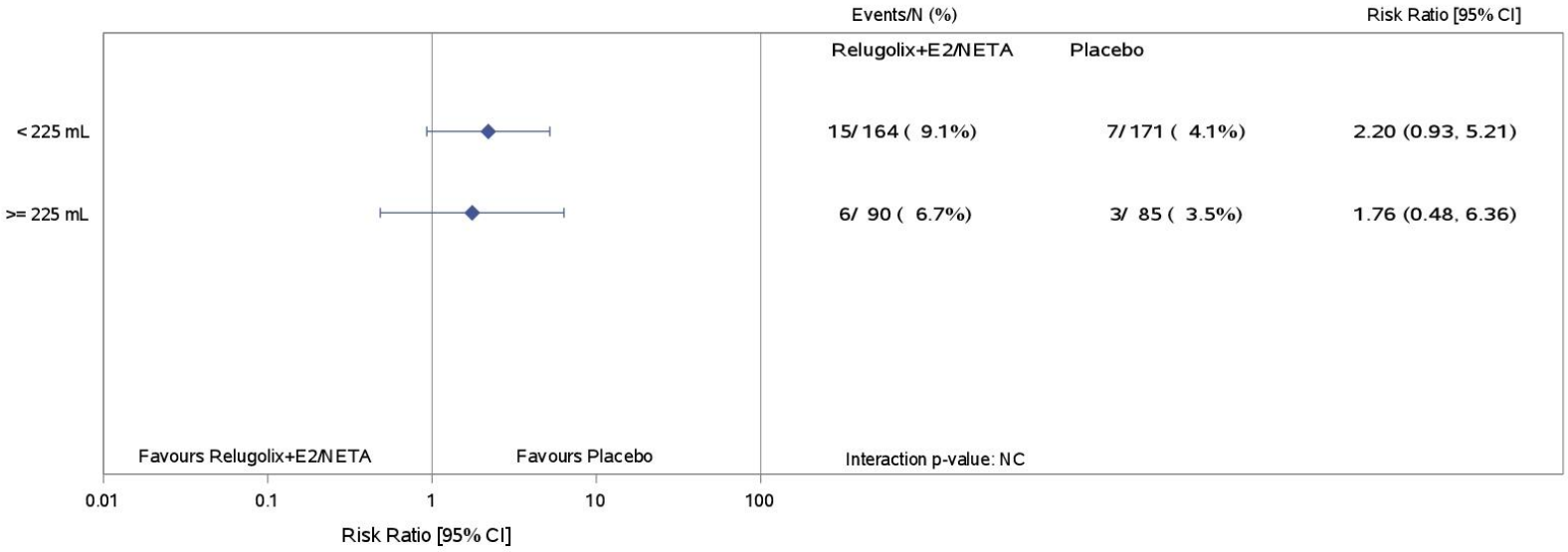
Figure SAF.TEAE.SPT.S5.BIN.FP.RR: Frequent Treatment Emergent Adverse Events by System Organ Class and Preferred Term, by Subgroup (Safety Population) - Risk Ratio
Study: Pooled
System Organ Class: Psychiatric disorders, Preferred Term: Any
Subgroup: MBL Volume at Baseline (mL)



Results are based on a Cochran-Mantel-Haenszel approach stratified by study using a one-stage fixed-effects IPD meta-analysis. A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
The reference group is Placebo. Patients with multiple events are counted only once. MedDRA (version 22.0).
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N: Number of patients in treatment group; NETA: Norethindrone acetate; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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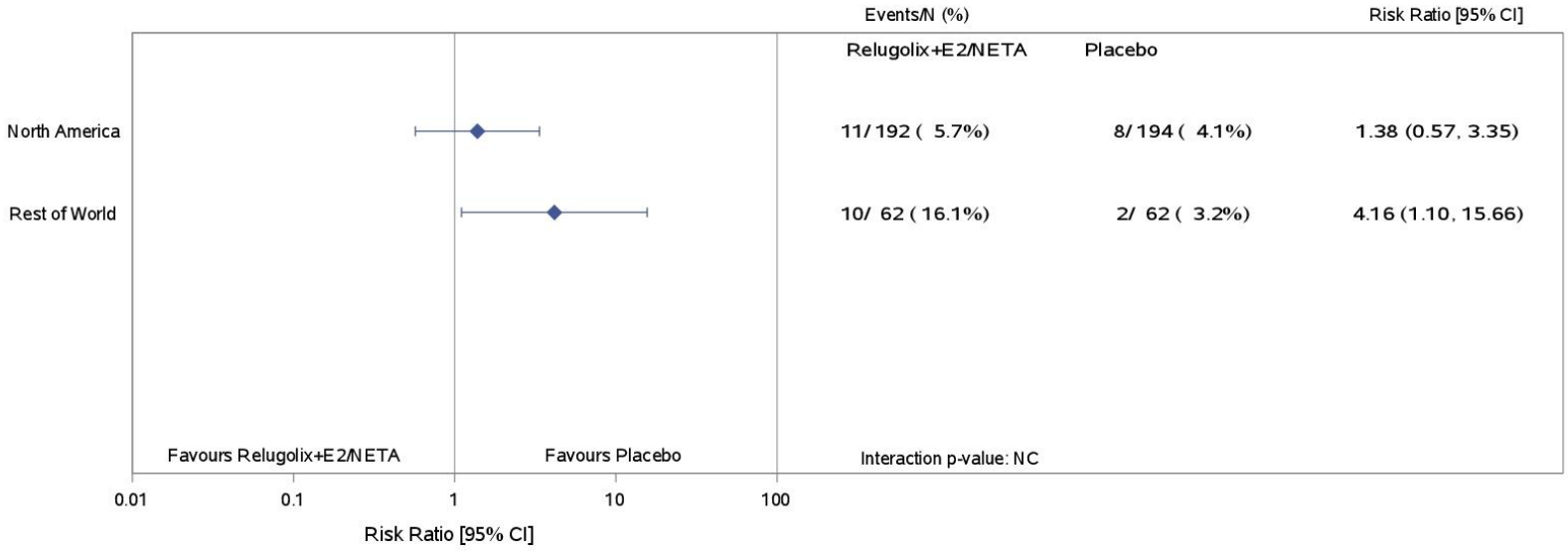
Figure SAF.TEAE.SPT.S6.BIN.FP.RR: Frequent Treatment Emergent Adverse Events by System Organ Class and Preferred Term, by Subgroup (Safety Population) - Risk Ratio
Study: Pooled
System Organ Class: Psychiatric disorders, Preferred Term: Any
Subgroup: Geographic Region I



Results are based on a Cochran-Mantel-Haenszel approach stratified by study using a one-stage fixed-effects IPD meta-analysis. A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
The reference group is Placebo. Patients with multiple events are counted only once. MedDRA (version 22.0).
Patients with multiple events for a given PT or SOC are counted only once for each PT and SOC. Only SOCs or PTs for which there are at least 10% of patients with an event in at least one treatment group OR at least 10 patients with an event overall and at least 1% of patients with an event in at least one treatment group in the overall safety population are considered. Further, only SOCs and PTs for which there is a significant treatment effect (p-value <0.05) in the overall safety population are presented. Events are sorted alphabetically by SOC and PT and then by subgroup within each. MedDRA (version 22.0).
N: Number of patients in treatment group; NETA: Norethindrone acetate; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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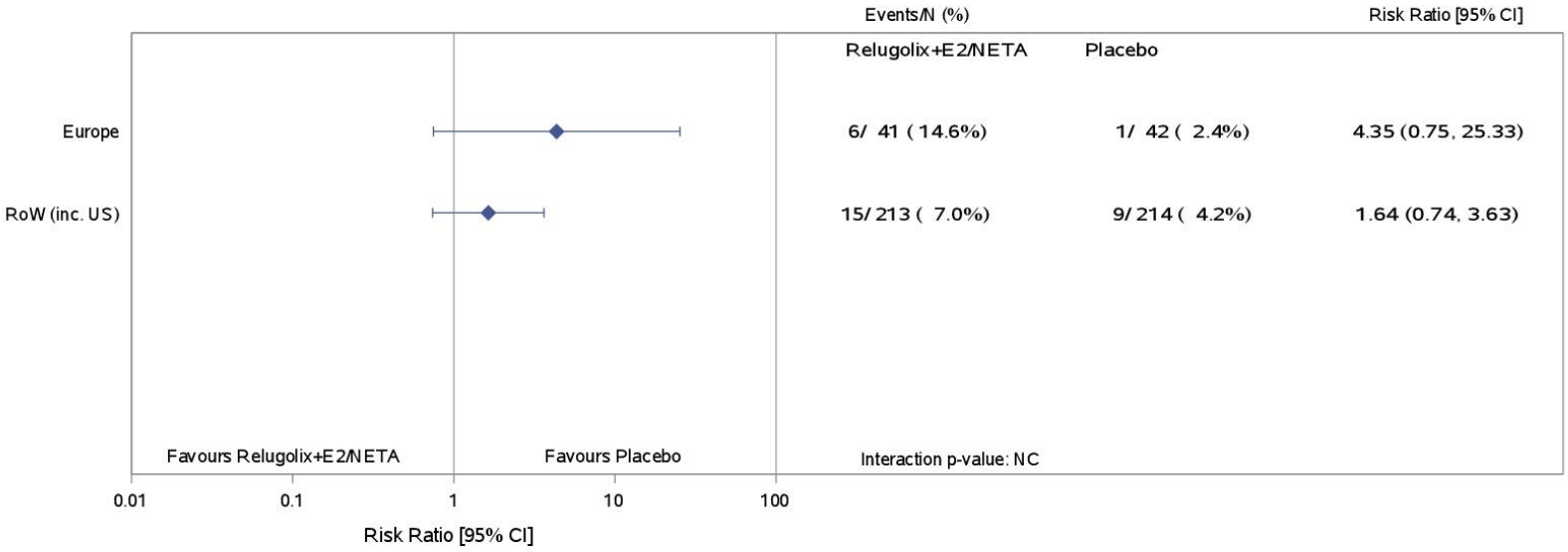
Figure SAF.TEAE.SPT.S7.BIN.FP.RR: Frequent Treatment Emergent Adverse Events by System Organ Class and Preferred Term, by Subgroup (Safety Population) - Risk Ratio
Study: Pooled
System Organ Class: Psychiatric disorders, Preferred Term: Any
Subgroup: Geographic Region II



Results are based on a Cochran-Mantel-Haenszel approach stratified by study using a one-stage fixed-effects IPD meta-analysis. A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
The reference group is Placebo. Patients with multiple events are counted only once. MedDRA (version 22.0).
Patients with multiple events for a given PT or SOC are counted only once for each PT and SOC. Only SOCs or PTs for which there are at least 10% of patients with an event in at least one treatment group OR at least 10 patients with an event overall and at least 1% of patients with an event in at least one treatment group in the overall safety population are considered. Further, only SOCs and PTs for which there is a significant treatment effect (p-value <0.05) in the overall safety population are presented. Events are sorted alphabetically by SOC and PT and then by subgroup within each. MedDRA (version 22.0).
N: Number of patients in treatment group; NETA: Norethindrone acetate; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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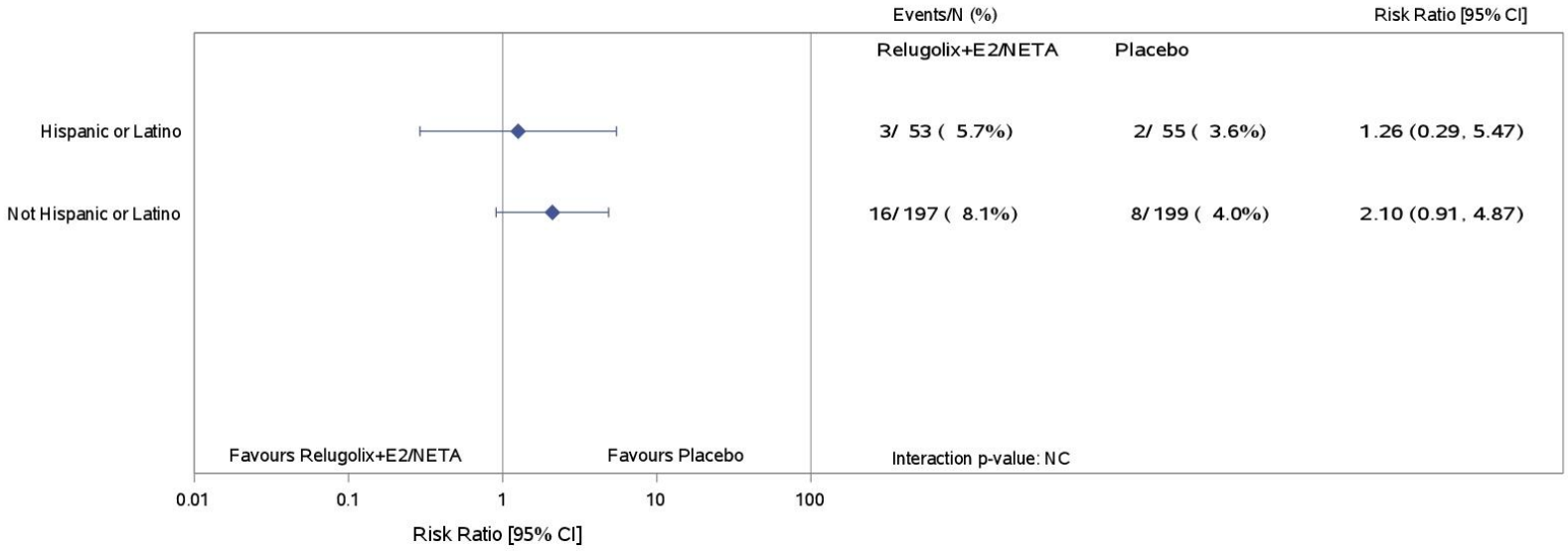
Figure SAF.TEAE.SPT.S8.BIN.FP.RR: Frequent Treatment Emergent Adverse Events by System Organ Class and Preferred Term, by Subgroup (Safety Population) - Risk Ratio
Study: Pooled
System Organ Class: Psychiatric disorders, Preferred Term: Any
Subgroup: Ethnicity



Results are based on a Cochran-Mantel-Haenszel approach stratified by study using a one-stage fixed-effects IPD meta-analysis. A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
The reference group is Placebo. Patients with multiple events are counted only once. MedDRA (version 22.0).
Patients with multiple events for a given PT or SOC are counted only once for each PT and SOC. Only SOCs or PTs for which there are at least 10% of patients with an event in at least one treatment group OR at least 10 patients with an event overall and at least 1% of patients with an event in at least one treatment group in the overall safety population are considered. Further, only SOCs and PTs for which there is a significant treatment effect (p-value <0.05) in the overall safety population are presented. Events are sorted alphabetically by SOC and PT and then by subgroup within each. MedDRA (version 22.0).
N: Number of patients in treatment group; NETA: Norethindrone acetate; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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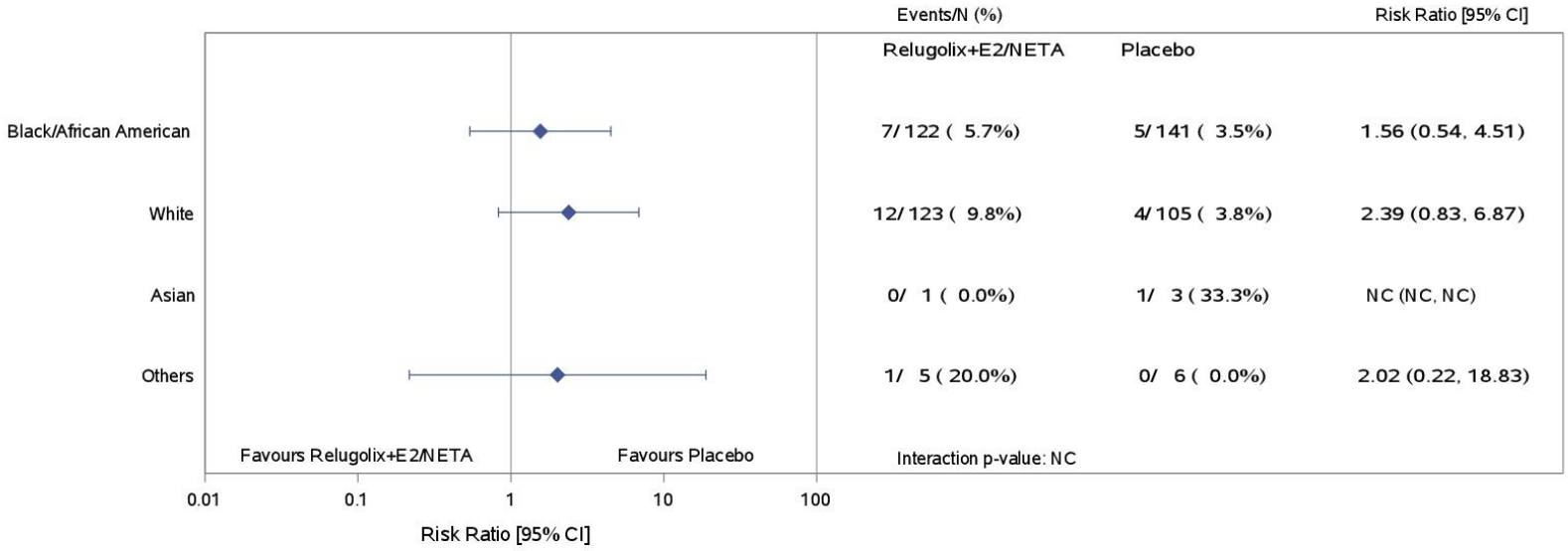
Figure SAF.TEAE.SPT.S9.BIN.FP.RR: Frequent Treatment Emergent Adverse Events by System Organ Class and Preferred Term, by Subgroup (Safety Population) - Risk Ratio
Study: Pooled
System Organ Class: Psychiatric disorders, Preferred Term: Any
Subgroup: Race



Results are based on a Cochran-Mantel-Haenszel approach stratified by study using a one-stage fixed-effects IPD meta-analysis. A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
The reference group is Placebo. Patients with multiple events are counted only once. MedDRA (version 22.0).
Patients with multiple events for a given PT or SOC are counted only once for each PT and SOC. Only SOCs or PTs for which there are at least 10% of patients with an event in at least one treatment group OR at least 10 patients with an event overall and at least 1% of patients with an event in at least one treatment group in the overall safety population are considered. Further, only SOCs and PTs for which there is a significant treatment effect (p-value <0.05) in the overall safety population are presented. Events are sorted alphabetically by SOC and PT and then by subgroup within each. MedDRA (version 22.0).
N: Number of patients in treatment group; NETA: Norethindrone acetate; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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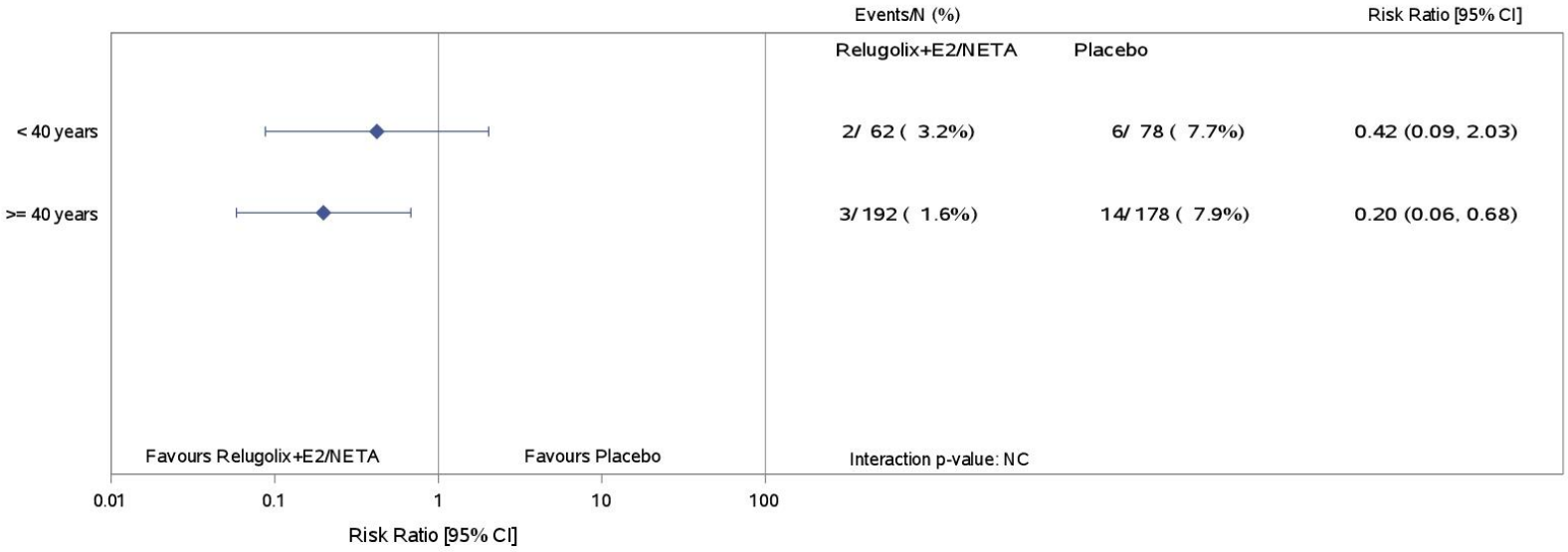
Figure SAF.TEAE.SPT.S1.BIN.FP.RR: Frequent Treatment Emergent Adverse Events by System Organ Class and Preferred Term, by Subgroup (Safety Population) - Risk Ratio
Study: Pooled
System Organ Class: Respiratory, thoracic and mediastinal disorders, Preferred Term: Any
Subgroup: Age (years)



Results are based on a Cochran-Mantel-Haenszel approach stratified by study using a one-stage fixed-effects IPD meta-analysis. A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
The reference group is Placebo. Patients with multiple events are counted only once. MedDRA (version 22.0).
Patients with multiple events for a given PT or SOC are counted only once for each PT and SOC. Only SOCs or PTs for which there are at least 10% of patients with an event in at least one treatment group OR at least 10 patients with an event overall and at least 1% of patients with an event in at least one treatment group in the overall safety population are considered. Further, only SOCs and PTs for which there is a significant treatment effect (p-value <0.05) in the overall safety population are presented. Events are sorted alphabetically by SOC and PT and then by subgroup within each. MedDRA (version 22.0).
N: Number of patients in treatment group; NETA: Norethindrone acetate; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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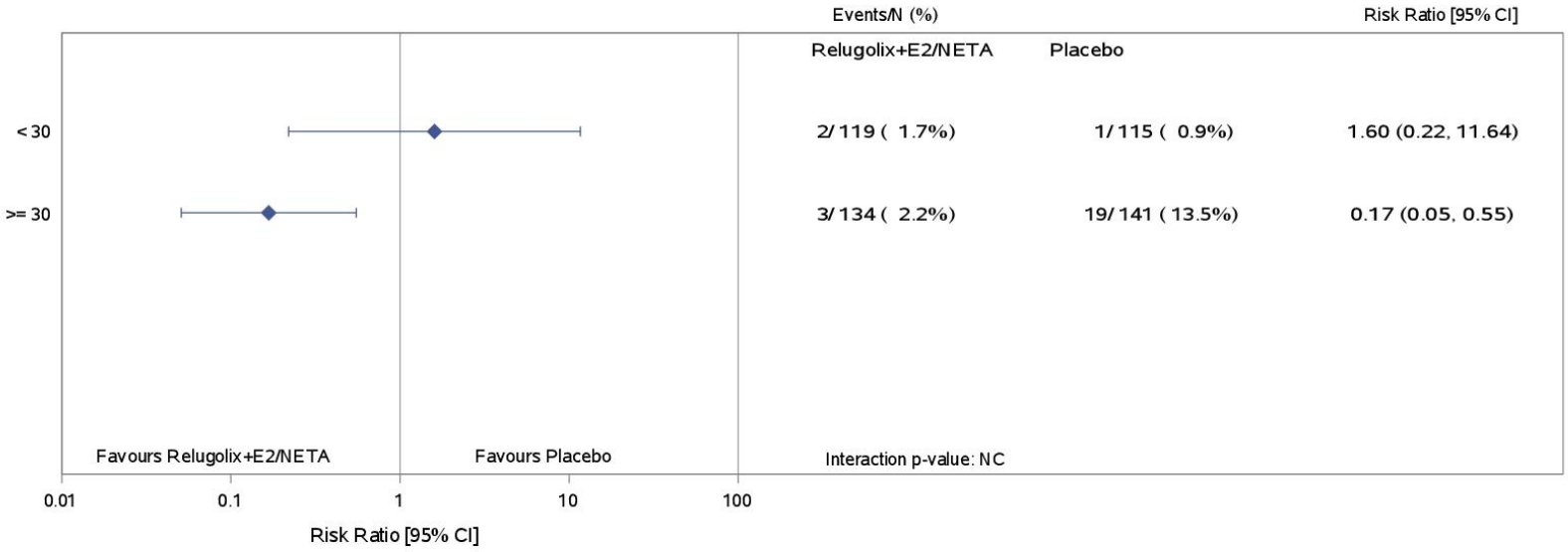
Figure SAF.TEAE.SPT.S2.BIN.FP.RR: Frequent Treatment Emergent Adverse Events by System Organ Class and Preferred Term, by Subgroup (Safety Population) - Risk Ratio
Study: Pooled
System Organ Class: Respiratory, thoracic and mediastinal disorders, Preferred Term: Any
Subgroup: BMI (kg/m2) at Baseline



Results are based on a Cochran-Mantel-Haenszel approach stratified by study using a one-stage fixed-effects IPD meta-analysis. A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
The reference group is Placebo. Patients with multiple events are counted only once. MedDRA (version 22.0).
Patients with multiple events for a given PT or SOC are counted only once for each PT and SOC. Only SOCs or PTs for which there are at least 10% of patients with an event in at least one treatment group OR at least 10 patients with an event overall and at least 1% of patients with an event in at least one treatment group in the overall safety population are considered. Further, only SOCs and PTs for which there is a significant treatment effect (p-value <0.05) in the overall safety population are presented. Events are sorted alphabetically by SOC and PT and then by subgroup within each. MedDRA (version 22.0).
N: Number of patients in treatment group; NETA: Norethindrone acetate; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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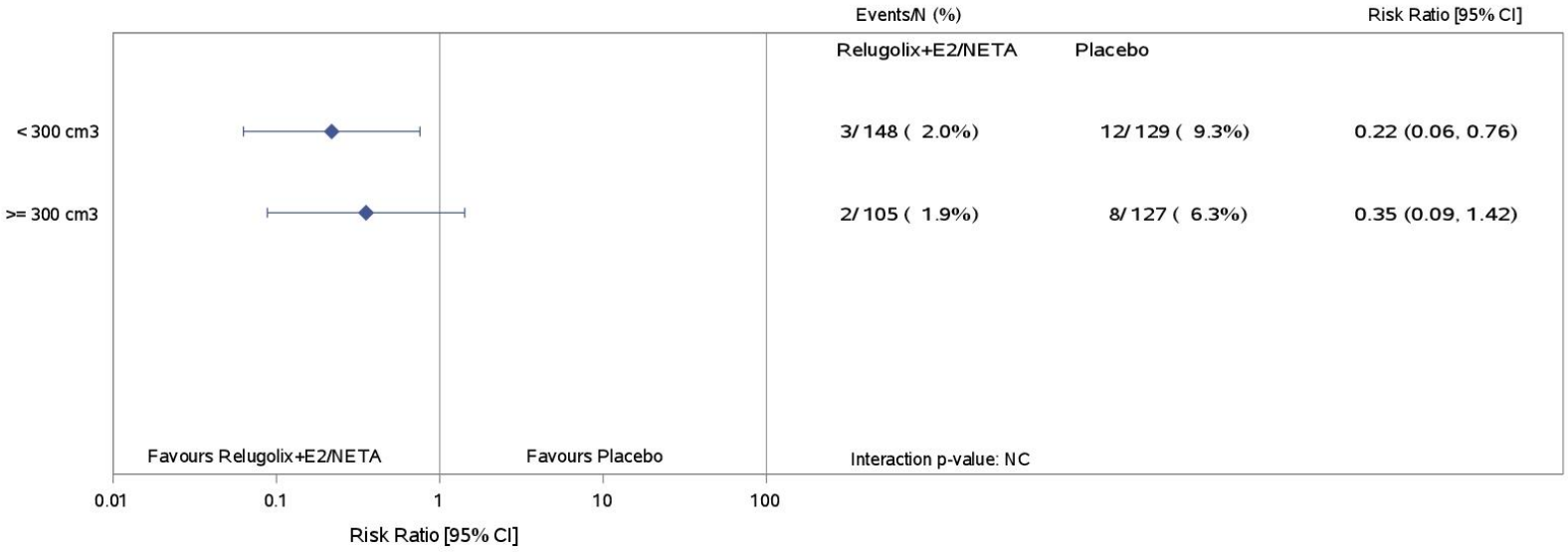
Figure SAF.TEAE.SPT.S3.BIN.FP.RR: Frequent Treatment Emergent Adverse Events by System Organ Class and Preferred Term, by Subgroup (Safety Population) - Risk Ratio
Study: Pooled
System Organ Class: Respiratory, thoracic and mediastinal disorders, Preferred Term: Any
Subgroup: Uterine Volume at Baseline (cm3)



Results are based on a Cochran-Mantel-Haenszel approach stratified by study using a one-stage fixed-effects IPD meta-analysis. A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
The reference group is Placebo. Patients with multiple events are counted only once. MedDRA (version 22.0).
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N: Number of patients in treatment group; NETA: Norethindrone acetate; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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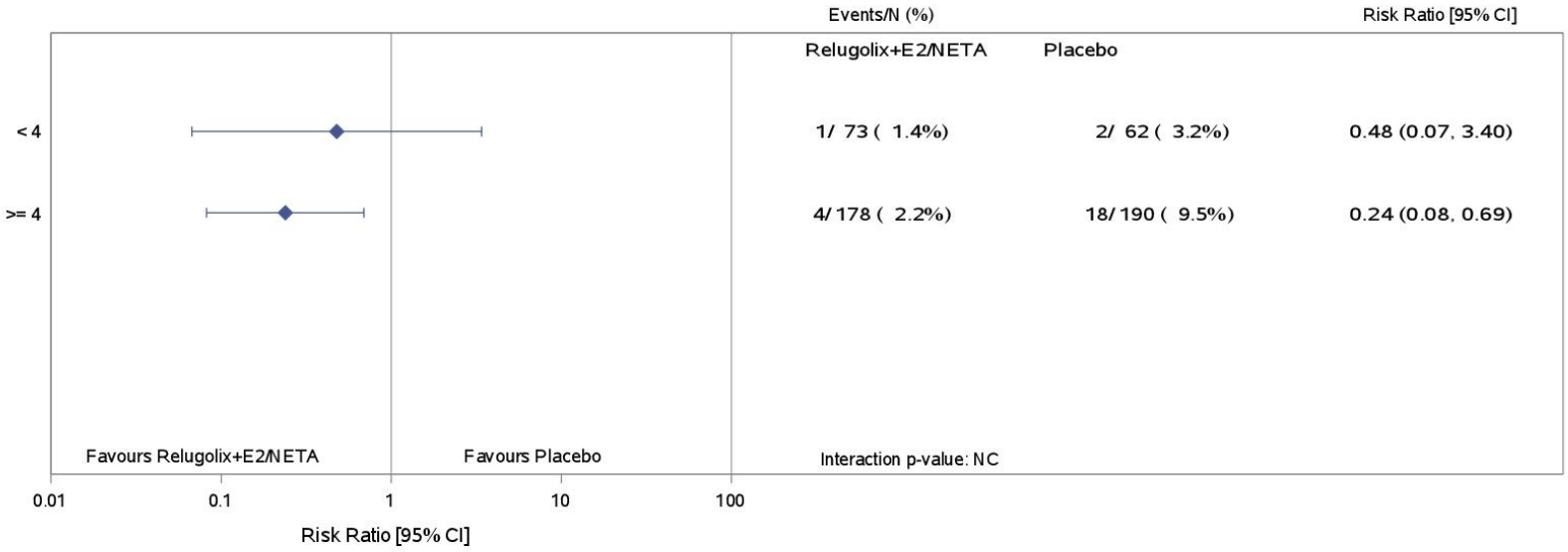
Figure SAF.TEAE.SPT.S4.BIN.FP.RR: Frequent Treatment Emergent Adverse Events by System Organ Class and Preferred Term, by Subgroup (Safety Population) - Risk Ratio
Study: Pooled
System Organ Class: Respiratory, thoracic and mediastinal disorders, Preferred Term: Any
Subgroup: Maximum NRS Pain Score at Baseline



Results are based on a Cochran-Mantel-Haenszel approach stratified by study using a one-stage fixed-effects IPD meta-analysis. A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
The reference group is Placebo. Patients with multiple events are counted only once. MedDRA (version 22.0).
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N: Number of patients in treatment group; NETA: Norethindrone acetate; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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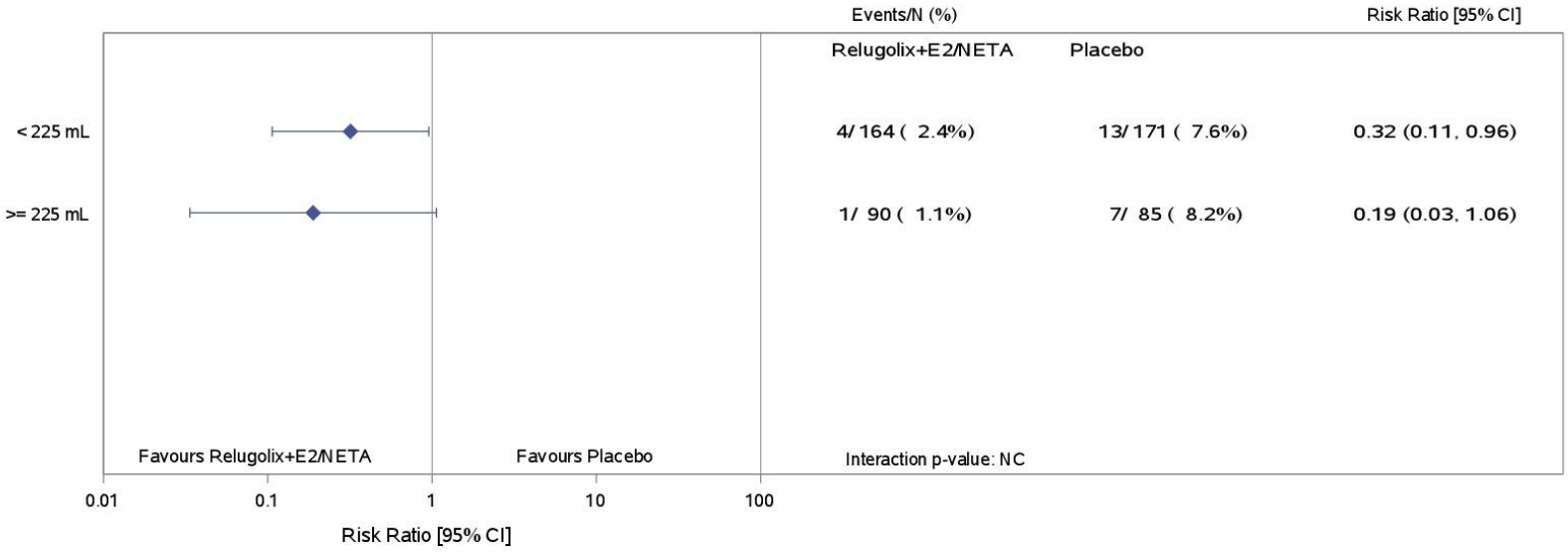
Figure SAF.TEAE.SPT.S5.BIN.FP.RR: Frequent Treatment Emergent Adverse Events by System Organ Class and Preferred Term, by Subgroup (Safety Population) - Risk Ratio
Study: Pooled
System Organ Class: Respiratory, thoracic and mediastinal disorders, Preferred Term: Any
Subgroup: MBL Volume at Baseline (mL)



Results are based on a Cochran-Mantel-Haenszel approach stratified by study using a one-stage fixed-effects IPD meta-analysis. A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
The reference group is Placebo. Patients with multiple events are counted only once. MedDRA (version 22.0).
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N: Number of patients in treatment group; NETA: Norethindrone acetate; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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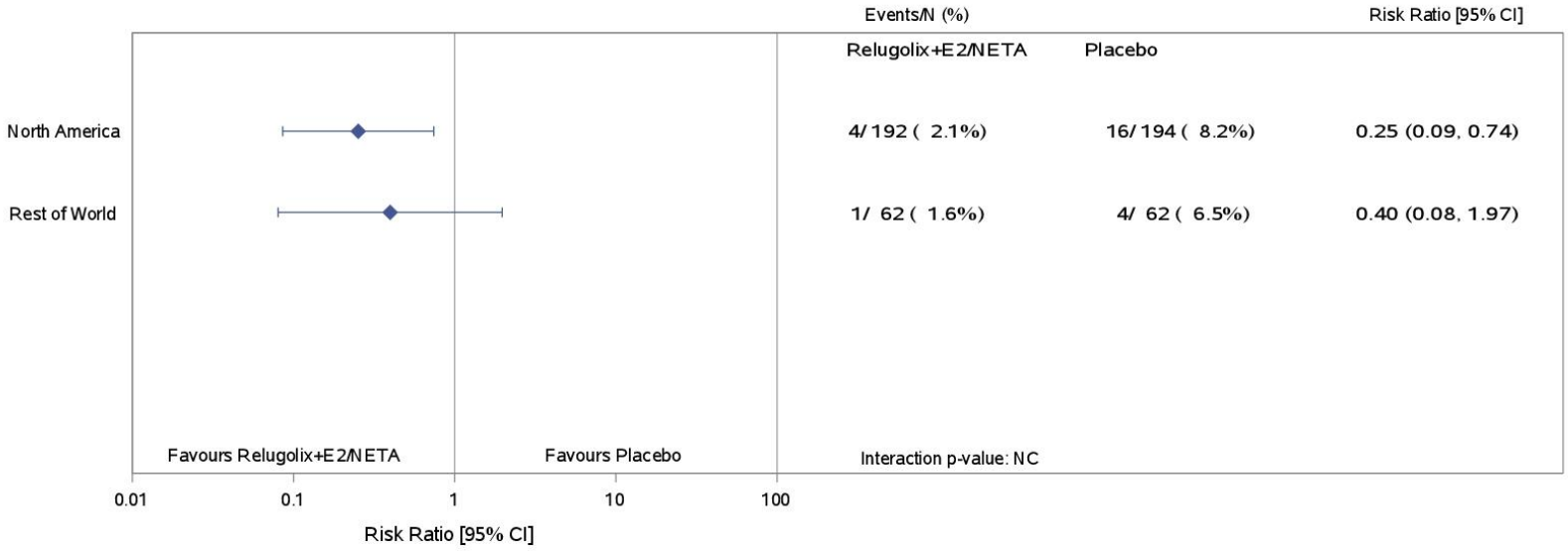
Figure SAF.TEAE.SPT.S6.BIN.FP.RR: Frequent Treatment Emergent Adverse Events by System Organ Class and Preferred Term, by Subgroup (Safety Population) - Risk Ratio
Study: Pooled
System Organ Class: Respiratory, thoracic and mediastinal disorders, Preferred Term: Any
Subgroup: Geographic Region I



Results are based on a Cochran-Mantel-Haenszel approach stratified by study using a one-stage fixed-effects IPD meta-analysis. A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
The reference group is Placebo. Patients with multiple events are counted only once. MedDRA (version 22.0).
Patients with multiple events for a given PT or SOC are counted only once for each PT and SOC. Only SOCs or PTs for which there are at least 10% of patients with an event in at least one treatment group OR at least 10 patients with an event overall and at least 1% of patients with an event in at least one treatment group in the overall safety population are considered. Further, only SOCs and PTs for which there is a significant treatment effect (p-value <0.05) in the overall safety population are presented. Events are sorted alphabetically by SOC and PT and then by subgroup within each. MedDRA (version 22.0).
N: Number of patients in treatment group; NETA: Norethindrone acetate; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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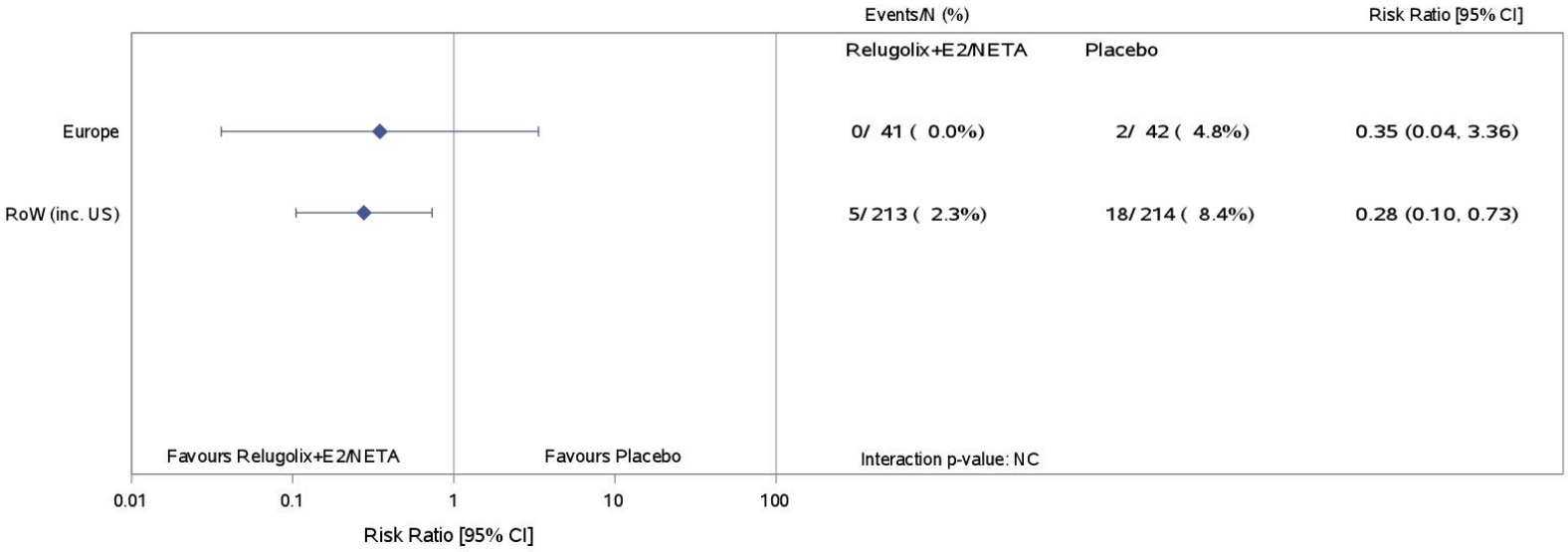
Figure SAF.TEAE.SPT.S7.BIN.FP.RR: Frequent Treatment Emergent Adverse Events by System Organ Class and Preferred Term, by Subgroup (Safety Population) - Risk Ratio
Study: Pooled
System Organ Class: Respiratory, thoracic and mediastinal disorders, Preferred Term: Any
Subgroup: Geographic Region II



Results are based on a Cochran-Mantel-Haenszel approach stratified by study using a one-stage fixed-effects IPD meta-analysis. A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
The reference group is Placebo. Patients with multiple events are counted only once. MedDRA (version 22.0).
Patients with multiple events for a given PT or SOC are counted only once for each PT and SOC. Only SOCs or PTs for which there are at least 10% of patients with an event in at least one treatment group OR at least 10 patients with an event overall and at least 1% of patients with an event in at least one treatment group in the overall safety population are considered. Further, only SOCs and PTs for which there is a significant treatment effect (p-value <0.05) in the overall safety population are presented. Events are sorted alphabetically by SOC and PT and then by subgroup within each. MedDRA (version 22.0).
N: Number of patients in treatment group; NETA: Norethindrone acetate; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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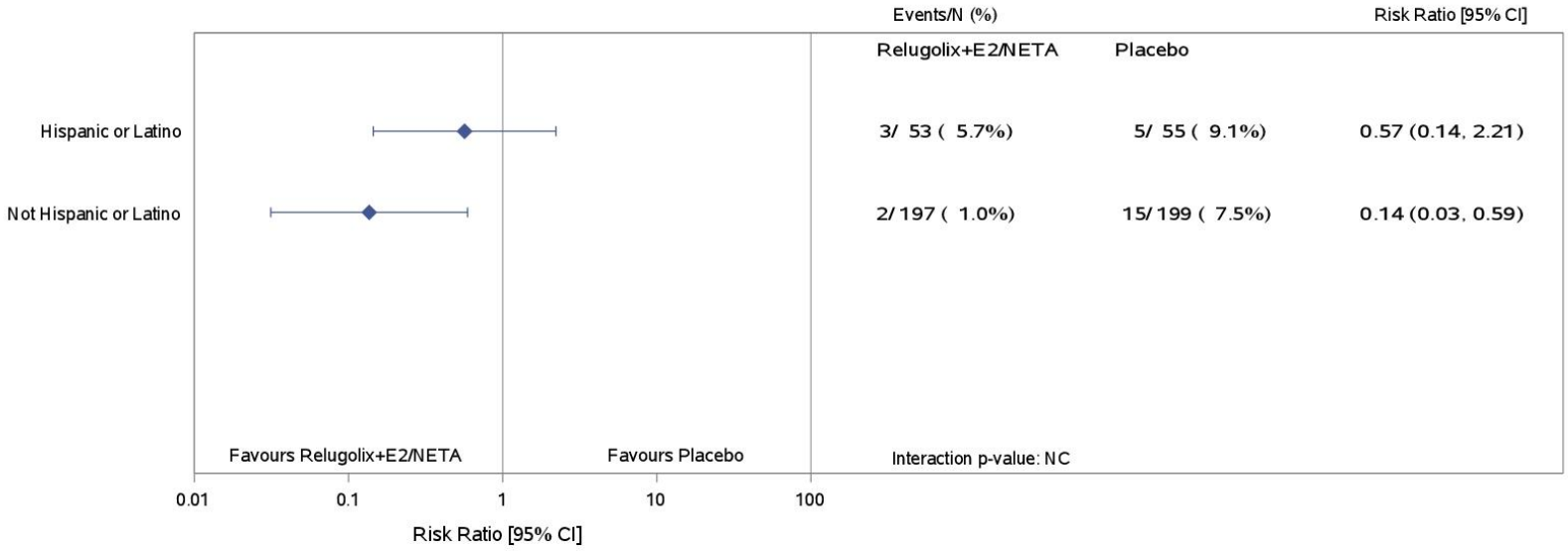
Figure SAF.TEAE.SPT.S8.BIN.FP.RR: Frequent Treatment Emergent Adverse Events by System Organ Class and Preferred Term, by Subgroup (Safety Population) - Risk Ratio
Study: Pooled
System Organ Class: Respiratory, thoracic and mediastinal disorders, Preferred Term: Any
Subgroup: Ethnicity



Results are based on a Cochran-Mantel-Haenszel approach stratified by study using a one-stage fixed-effects IPD meta-analysis. A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
The reference group is Placebo. Patients with multiple events are counted only once. MedDRA (version 22.0).
Patients with multiple events for a given PT or SOC are counted only once for each PT and SOC. Only SOCs or PTs for which there are at least 10% of patients with an event in at least one treatment group OR at least 10 patients with an event overall and at least 1% of patients with an event in at least one treatment group in the overall safety population are considered. Further, only SOCs and PTs for which there is a significant treatment effect (p-value <0.05) in the overall safety population are presented. Events are sorted alphabetically by SOC and PT and then by subgroup within each. MedDRA (version 22.0).
N: Number of patients in treatment group; NETA: Norethindrone acetate; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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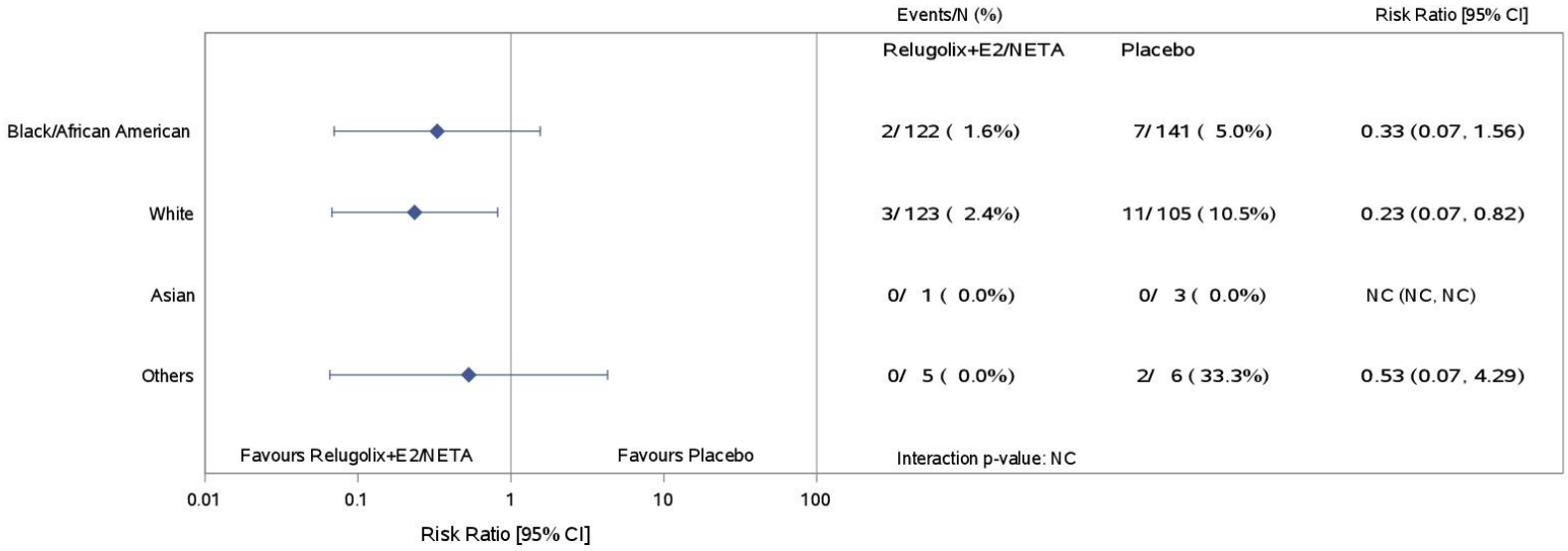
Figure SAF.TEAE.SPT.S9.BIN.FP.RR: Frequent Treatment Emergent Adverse Events by System Organ Class and Preferred Term, by Subgroup (Safety Population) - Risk Ratio
Study: Pooled
System Organ Class: Respiratory, thoracic and mediastinal disorders, Preferred Term: Any
Subgroup: Race



Results are based on a Cochran-Mantel-Haenszel approach stratified by study using a one-stage fixed-effects IPD meta-analysis. A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
The reference group is Placebo. Patients with multiple events are counted only once. MedDRA (version 22.0).
Patients with multiple events for a given PT or SOC are counted only once for each PT and SOC. Only SOCs or PTs for which there are at least 10% of patients with an event in at least one treatment group OR at least 10 patients with an event overall and at least 1% of patients with an event in at least one treatment group in the overall safety population are considered. Further, only SOCs and PTs for which there is a significant treatment effect (p-value <0.05) in the overall safety population are presented. Events are sorted alphabetically by SOC and PT and then by subgroup within each. MedDRA (version 22.0).
N: Number of patients in treatment group; NETA: Norethindrone acetate; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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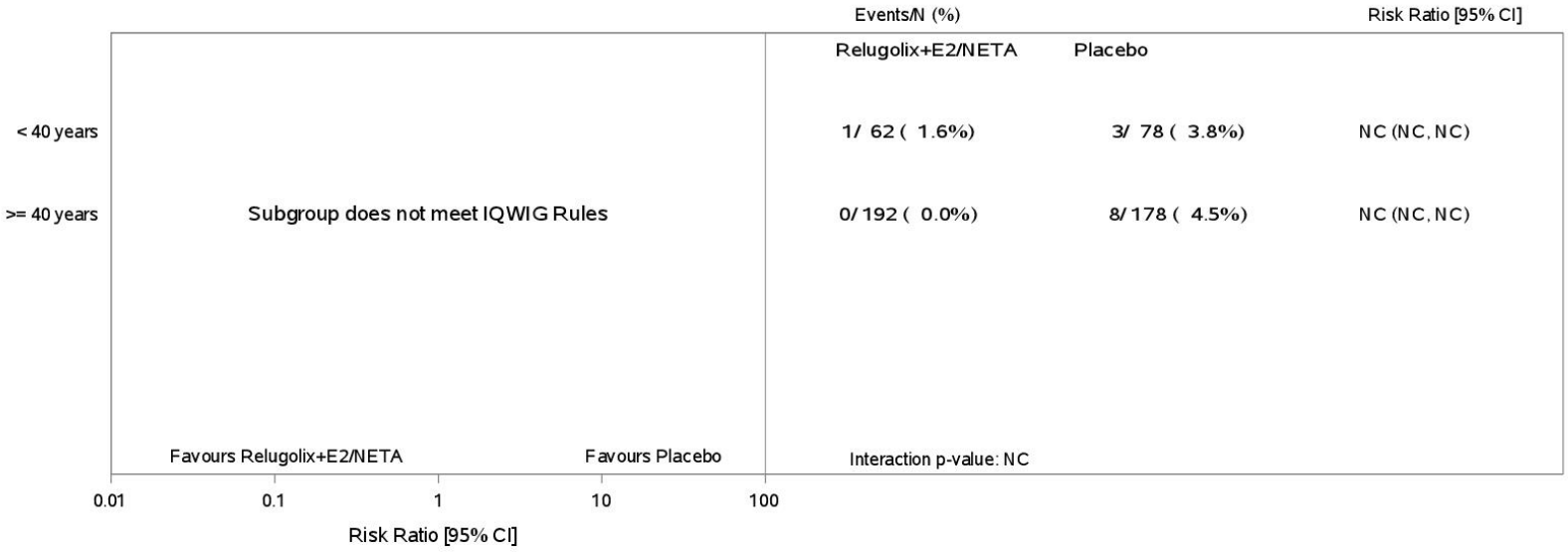
Figure SAF.TEAE.SPT.S1.BIN.FP.RR: Frequent Treatment Emergent Adverse Events by System Organ Class and Preferred Term, by Subgroup (Safety Population) - Risk Ratio
Study: Pooled
System Organ Class: Respiratory, thoracic and mediastinal disorders, Preferred Term: Cough
Subgroup: Age (years)



Results are based on a Cochran-Mantel-Haenszel approach stratified by study using a one-stage fixed-effects IPD meta-analysis. A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
The reference group is Placebo. Patients with multiple events are counted only once. MedDRA (version 22.0).
Patients with multiple events for a given PT or SOC are counted only once for each PT and SOC. Only SOCs or PTs for which there are at least 10% of patients with an event in at least one treatment group OR at least 10 patients with an event overall and at least 1% of patients with an event in at least one treatment group in the overall safety population are considered. Further, only SOCs and PTs for which there is a significant treatment effect (p-value <0.05) in the overall safety population are presented. Events are sorted alphabetically by SOC and PT and then by subgroup within each. MedDRA (version 22.0).
N: Number of patients in treatment group; NETA: Norethindrone acetate; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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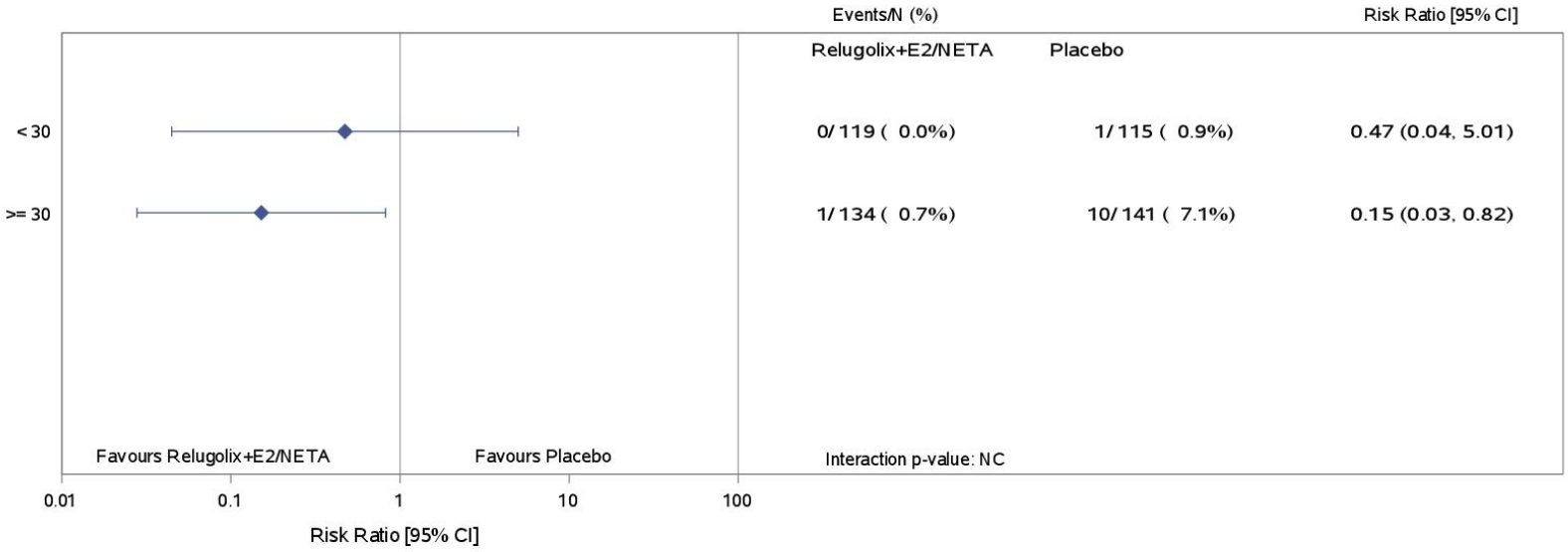
Figure SAF.TEAE.SPT.S2.BIN.FP.RR: Frequent Treatment Emergent Adverse Events by System Organ Class and Preferred Term, by Subgroup (Safety Population) - Risk Ratio
Study: Pooled
System Organ Class: Respiratory, thoracic and mediastinal disorders, Preferred Term: Cough
Subgroup: BMI (kg/m2) at Baseline



Results are based on a Cochran-Mantel-Haenszel approach stratified by study using a one-stage fixed-effects IPD meta-analysis. A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
The reference group is Placebo. Patients with multiple events are counted only once. MedDRA (version 22.0).
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N: Number of patients in treatment group; NETA: Norethindrone acetate; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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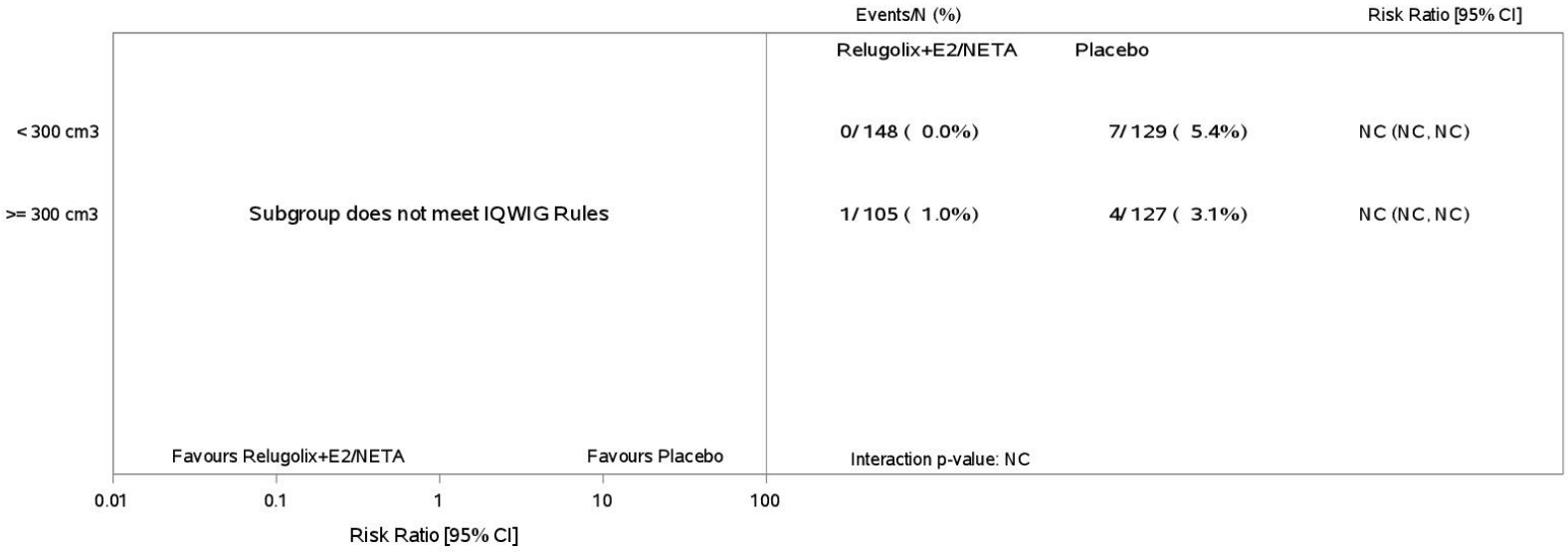
Figure SAF.TEAE.SPT.S3.BIN.FP.RR: Frequent Treatment Emergent Adverse Events by System Organ Class and Preferred Term, by Subgroup (Safety Population) - Risk Ratio
Study: Pooled
System Organ Class: Respiratory, thoracic and mediastinal disorders, Preferred Term: Cough
Subgroup: Uterine Volume at Baseline (cm3)



Results are based on a Cochran-Mantel-Haenszel approach stratified by study using a one-stage fixed-effects IPD meta-analysis. A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
The reference group is Placebo. Patients with multiple events are counted only once. MedDRA (version 22.0).
Patients with multiple events for a given PT or SOC are counted only once for each PT and SOC. Only SOCs or PTs for which there are at least 10% of patients with an event in at least one treatment group OR at least 10 patients with an event overall and at least 1% of patients with an event in at least one treatment group in the overall safety population are considered. Further, only SOCs and PTs for which there is a significant treatment effect (p-value <0.05) in the overall safety population are presented. Events are sorted alphabetically by SOC and PT and then by subgroup within each. MedDRA (version 22.0).
N: Number of patients in treatment group; NETA: Norethindrone acetate; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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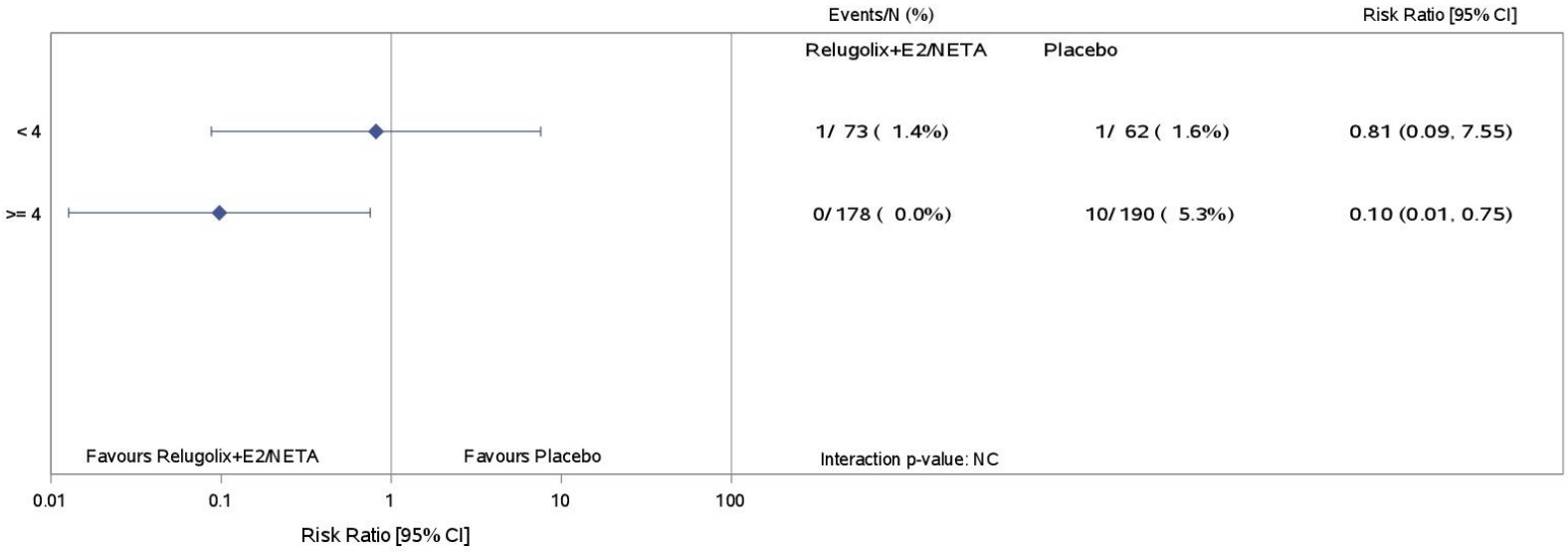
Figure SAF.TEAE.SPT.S4.BIN.FP.RR: Frequent Treatment Emergent Adverse Events by System Organ Class and Preferred Term, by Subgroup (Safety Population) - Risk Ratio
Study: Pooled
System Organ Class: Respiratory, thoracic and mediastinal disorders, Preferred Term: Cough
Subgroup: Maximum NRS Pain Score at Baseline



Results are based on a Cochran-Mantel-Haenszel approach stratified by study using a one-stage fixed-effects IPD meta-analysis. A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
The reference group is Placebo. Patients with multiple events are counted only once. MedDRA (version 22.0).
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N: Number of patients in treatment group; NETA: Norethindrone acetate; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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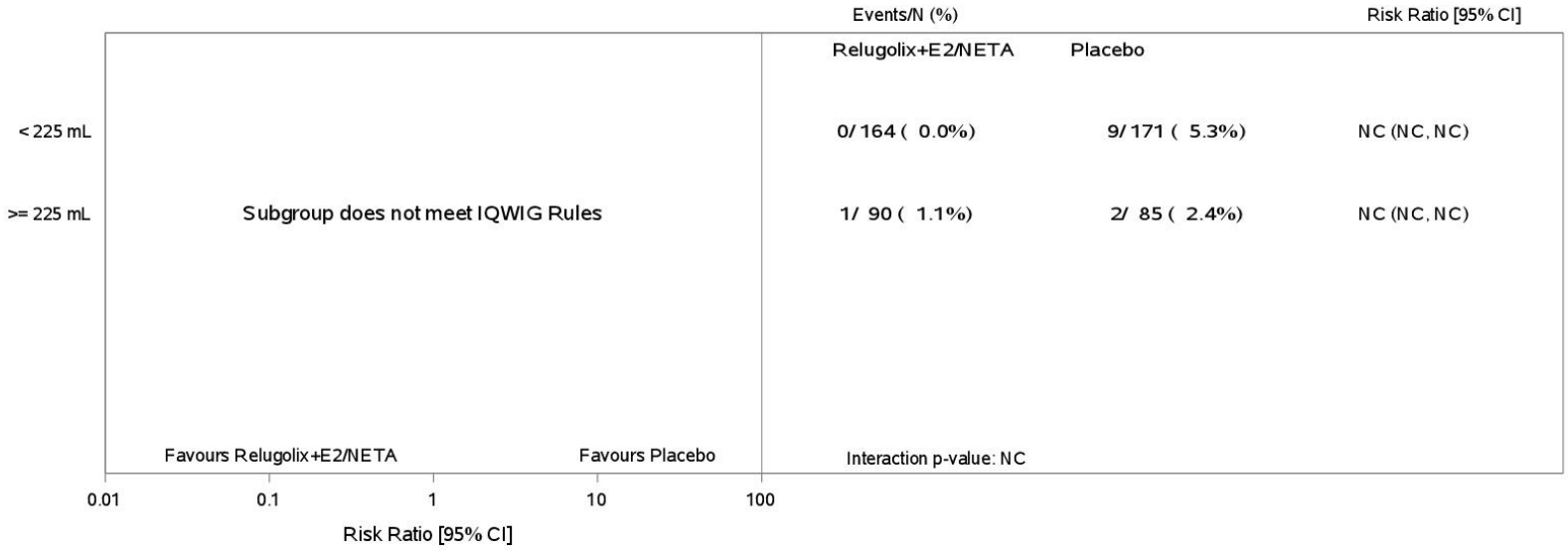
Figure SAF.TEAE.SPT.S5.BIN.FP.RR: Frequent Treatment Emergent Adverse Events by System Organ Class and Preferred Term, by Subgroup (Safety Population) - Risk Ratio
Study: Pooled
System Organ Class: Respiratory, thoracic and mediastinal disorders, Preferred Term: Cough
Subgroup: MBL Volume at Baseline (mL)



Results are based on a Cochran-Mantel-Haenszel approach stratified by study using a one-stage fixed-effects IPD meta-analysis. A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
The reference group is Placebo. Patients with multiple events are counted only once. MedDRA (version 22.0).
Patients with multiple events for a given PT or SOC are counted only once for each PT and SOC. Only SOCs or PTs for which there are at least 10% of patients with an event in at least one treatment group OR at least 10 patients with an event overall and at least 1% of patients with an event in at least one treatment group in the overall safety population are considered. Further, only SOCs and PTs for which there is a significant treatment effect (p-value <0.05) in the overall safety population are presented. Events are sorted alphabetically by SOC and PT and then by subgroup within each. MedDRA (version 22.0).
N: Number of patients in treatment group; NETA: Norethindrone acetate; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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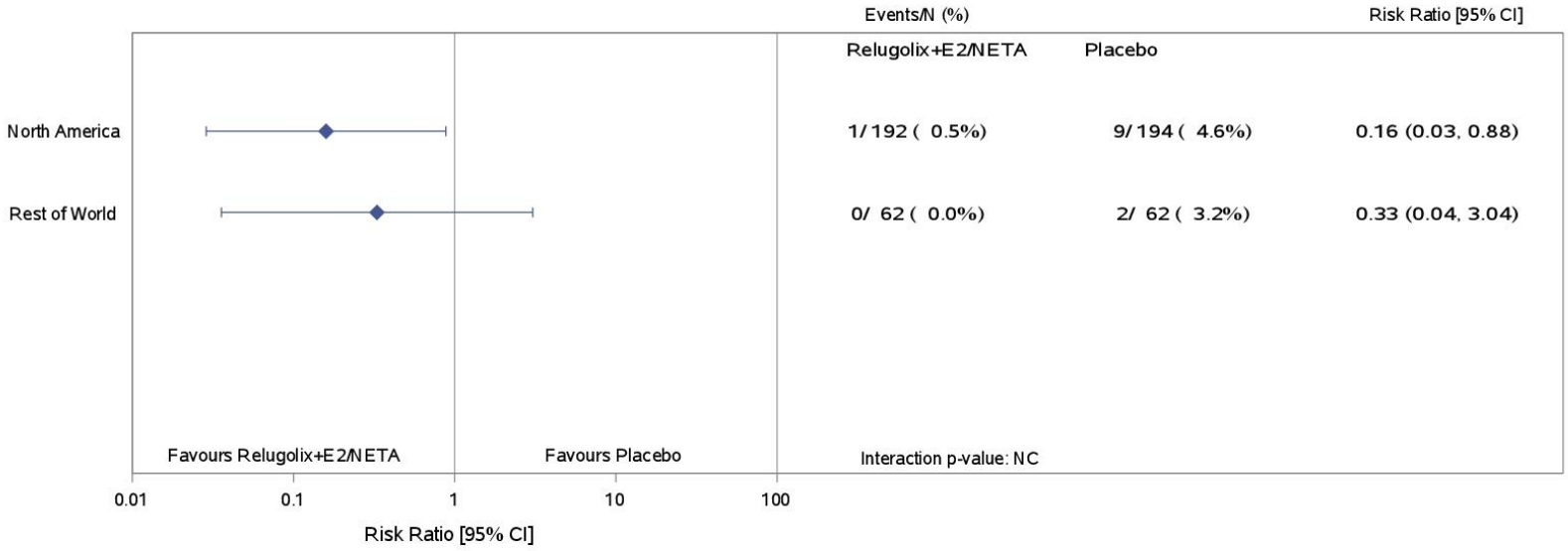
Figure SAF.TEAE.SPT.S6.BIN.FP.RR: Frequent Treatment Emergent Adverse Events by System Organ Class and Preferred Term, by Subgroup (Safety Population) - Risk Ratio
Study: Pooled
System Organ Class: Respiratory, thoracic and mediastinal disorders, Preferred Term: Cough
Subgroup: Geographic Region I



Results are based on a Cochran-Mantel-Haenszel approach stratified by study using a one-stage fixed-effects IPD meta-analysis. A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
The reference group is Placebo. Patients with multiple events are counted only once. MedDRA (version 22.0).
Patients with multiple events for a given PT or SOC are counted only once for each PT and SOC. Only SOCs or PTs for which there are at least 10% of patients with an event in at least one treatment group OR at least 10 patients with an event overall and at least 1% of patients with an event in at least one treatment group in the overall safety population are considered. Further, only SOCs and PTs for which there is a significant treatment effect (p-value <0.05) in the overall safety population are presented. Events are sorted alphabetically by SOC and PT and then by subgroup within each. MedDRA (version 22.0).
N: Number of patients in treatment group; NETA: Norethindrone acetate; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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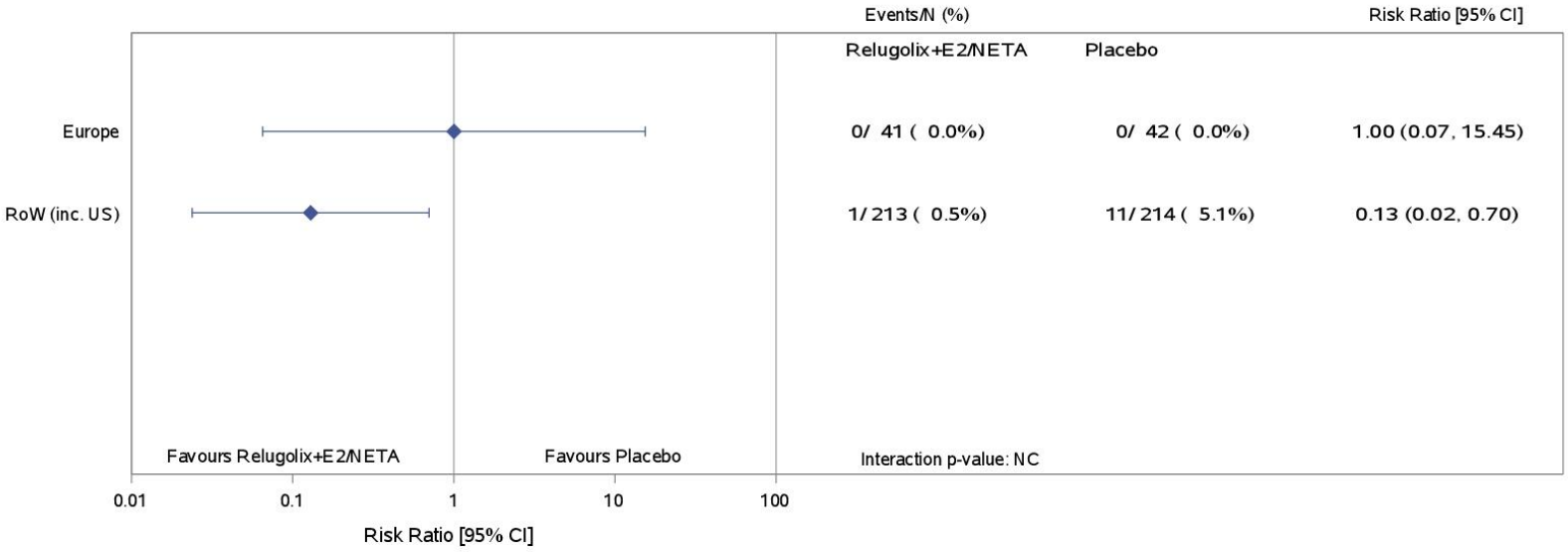
Figure SAF.TEAE.SPT.S7.BIN.FP.RR: Frequent Treatment Emergent Adverse Events by System Organ Class and Preferred Term, by Subgroup (Safety Population) - Risk Ratio
Study: Pooled
System Organ Class: Respiratory, thoracic and mediastinal disorders, Preferred Term: Cough
Subgroup: Geographic Region II



Results are based on a Cochran-Mantel-Haenszel approach stratified by study using a one-stage fixed-effects IPD meta-analysis. A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
The reference group is Placebo. Patients with multiple events are counted only once. MedDRA (version 22.0).
Patients with multiple events for a given PT or SOC are counted only once for each PT and SOC. Only SOCs or PTs for which there are at least 10% of patients with an event in at least one treatment group OR at least 10 patients with an event overall and at least 1% of patients with an event in at least one treatment group in the overall safety population are considered. Further, only SOCs and PTs for which there is a significant treatment effect (p-value <0.05) in the overall safety population are presented. Events are sorted alphabetically by SOC and PT and then by subgroup within each. MedDRA (version 22.0).
N: Number of patients in treatment group; NETA: Norethindrone acetate; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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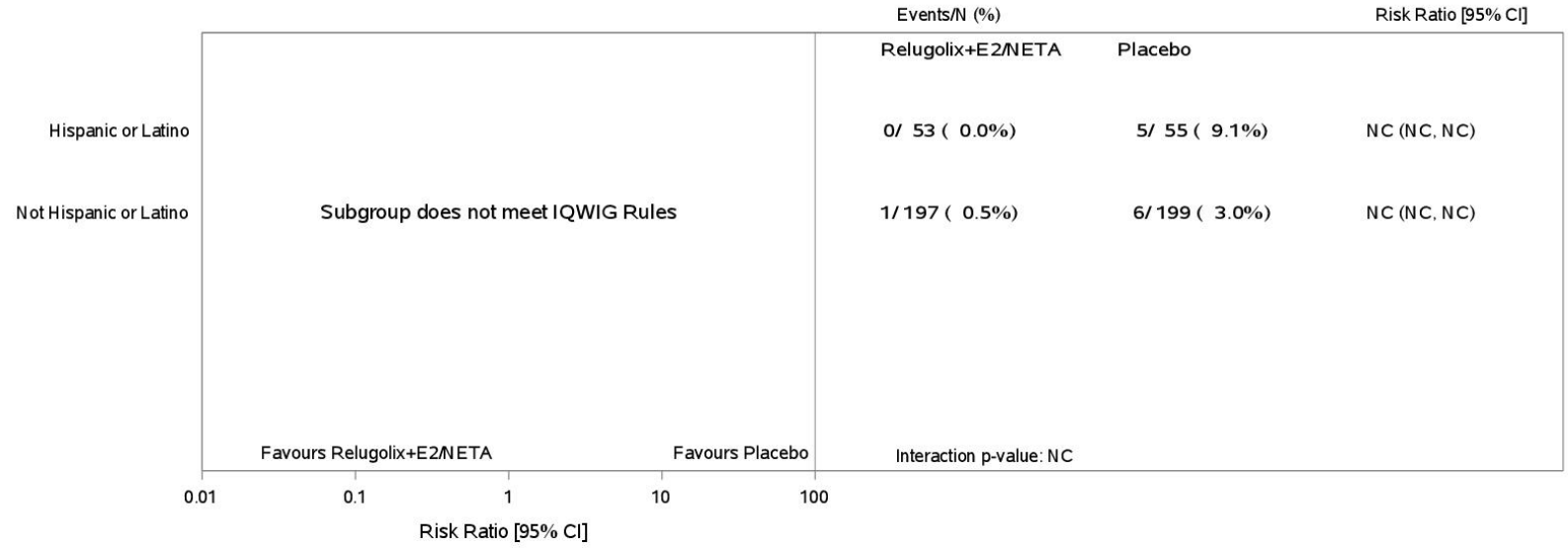
Figure SAF.TEAE.SPT.S8.BIN.FP.RR: Frequent Treatment Emergent Adverse Events by System Organ Class and Preferred Term, by Subgroup (Safety Population) - Risk Ratio
Study: Pooled
System Organ Class: Respiratory, thoracic and mediastinal disorders, Preferred Term: Cough
Subgroup: Ethnicity



Results are based on a Cochran-Mantel-Haenszel approach stratified by study using a one-stage fixed-effects IPD meta-analysis. A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
The reference group is Placebo. Patients with multiple events are counted only once. MedDRA (version 22.0).
Patients with multiple events for a given PT or SOC are counted only once for each PT and SOC. Only SOCs or PTs for which there are at least 10% of patients with an event in at least one treatment group OR at least 10 patients with an event overall and at least 1% of patients with an event in at least one treatment group in the overall safety population are considered. Further, only SOCs and PTs for which there is a significant treatment effect (p-value <0.05) in the overall safety population are presented. Events are sorted alphabetically by SOC and PT and then by subgroup within each. MedDRA (version 22.0).
N: Number of patients in treatment group; NETA: Norethindrone acetate; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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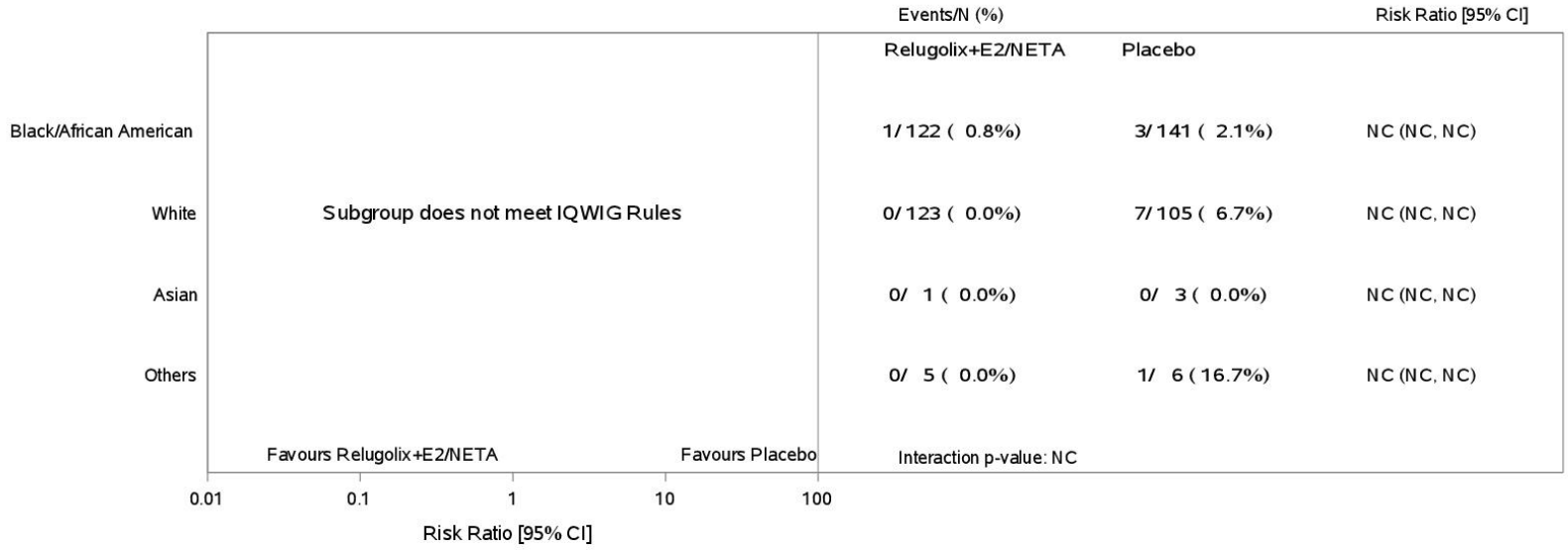
Figure SAF.TEAE.SPT.S9.BIN.FP.RR: Frequent Treatment Emergent Adverse Events by System Organ Class and Preferred Term, by Subgroup (Safety Population) - Risk Ratio
Study: Pooled
System Organ Class: Respiratory, thoracic and mediastinal disorders, Preferred Term: Cough
Subgroup: Race



Results are based on a Cochran-Mantel-Haenszel approach stratified by study using a one-stage fixed-effects IPD meta-analysis. A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
The reference group is Placebo. Patients with multiple events are counted only once. MedDRA (version 22.0).
Patients with multiple events for a given PT or SOC are counted only once for each PT and SOC. Only SOCs or PTs for which there are at least 10% of patients with an event in at least one treatment group OR at least 10 patients with an event overall and at least 1% of patients with an event in at least one treatment group in the overall safety population are considered. Further, only SOCs and PTs for which there is a significant treatment effect (p-value <0.05) in the overall safety population are presented. Events are sorted alphabetically by SOC and PT and then by subgroup within each. MedDRA (version 22.0).
N: Number of patients in treatment group; NETA: Norethindrone acetate; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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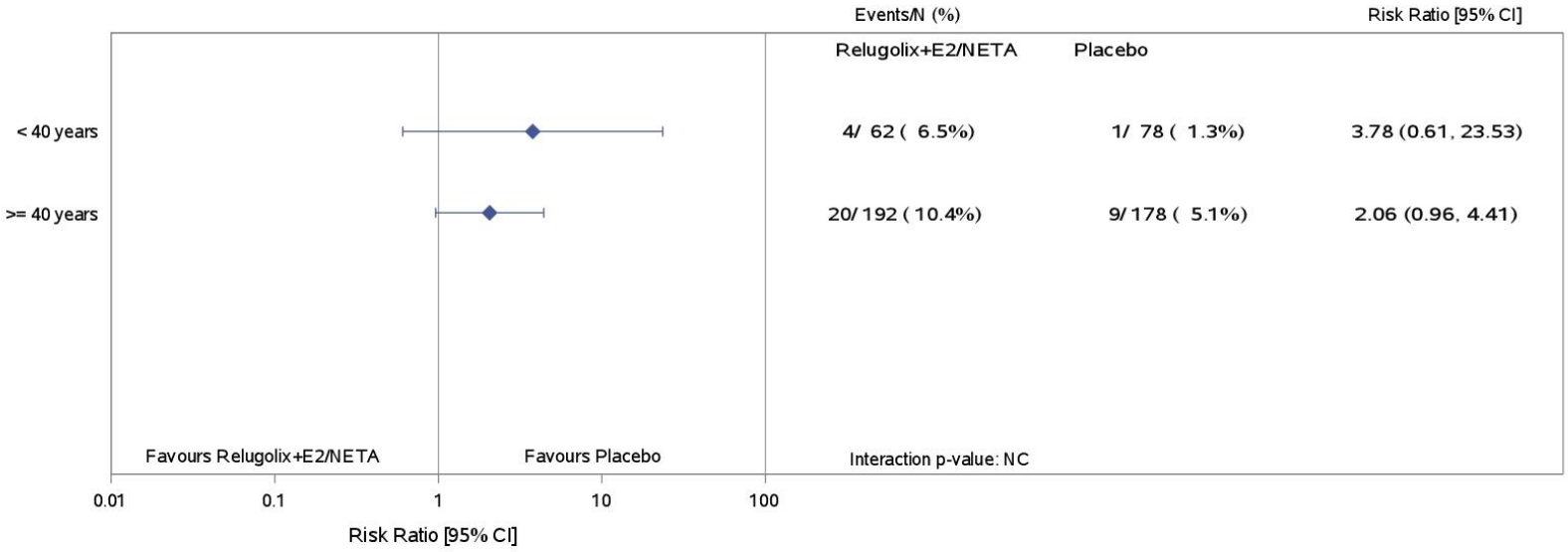
Figure SAF.TEAE.SPT.S1.BIN.FP.RR: Frequent Treatment Emergent Adverse Events by System Organ Class and Preferred Term, by Subgroup (Safety Population) - Risk Ratio
Study: Pooled
System Organ Class: Skin and subcutaneous tissue disorders, Preferred Term: Any
Subgroup: Age (years)



Results are based on a Cochran-Mantel-Haenszel approach stratified by study using a one-stage fixed-effects IPD meta-analysis. A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
The reference group is Placebo. Patients with multiple events are counted only once. MedDRA (version 22.0).
Patients with multiple events for a given PT or SOC are counted only once for each PT and SOC. Only SOCs or PTs for which there are at least 10% of patients with an event in at least one treatment group OR at least 10 patients with an event overall and at least 1% of patients with an event in at least one treatment group in the overall safety population are considered. Further, only SOCs and PTs for which there is a significant treatment effect (p-value <0.05) in the overall safety population are presented. Events are sorted alphabetically by SOC and PT and then by subgroup within each. MedDRA (version 22.0).
N: Number of patients in treatment group; NETA: Norethindrone acetate; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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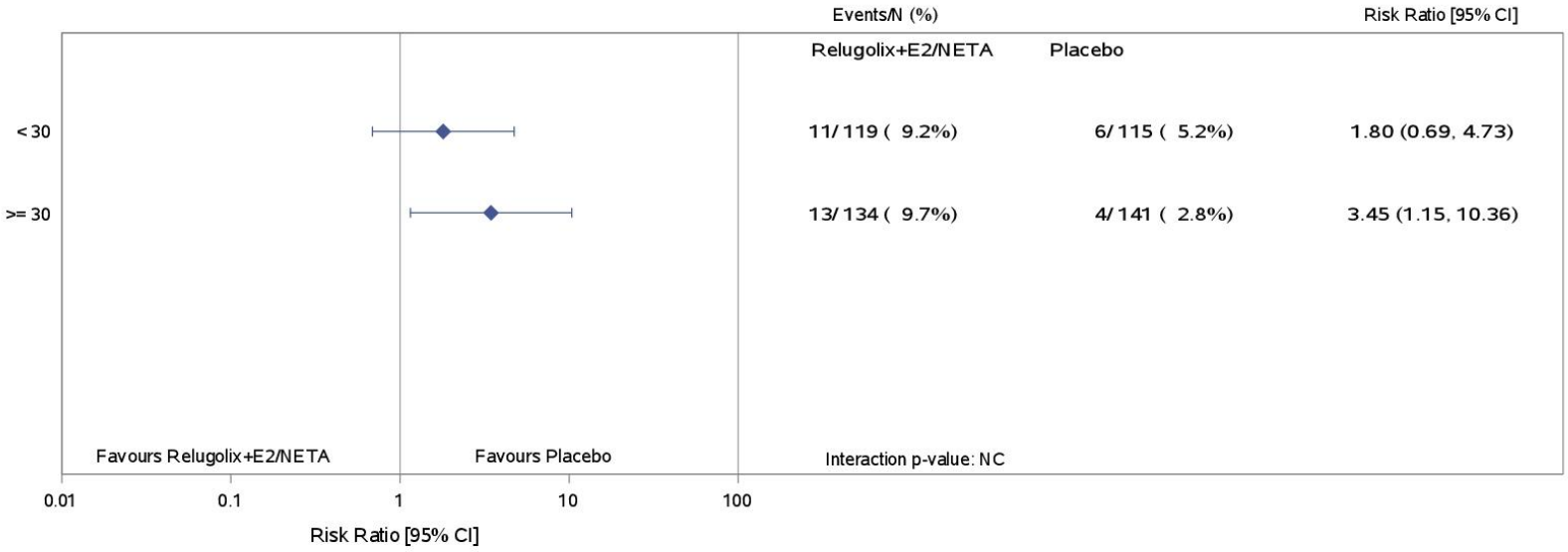
Figure SAF.TEAE.SPT.S2.BIN.FP.RR: Frequent Treatment Emergent Adverse Events by System Organ Class and Preferred Term, by Subgroup (Safety Population) - Risk Ratio
Study: Pooled
System Organ Class: Skin and subcutaneous tissue disorders, Preferred Term: Any
Subgroup: BMI (kg/m2) at Baseline



Results are based on a Cochran-Mantel-Haenszel approach stratified by study using a one-stage fixed-effects IPD meta-analysis. A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
The reference group is Placebo. Patients with multiple events are counted only once. MedDRA (version 22.0).
Patients with multiple events for a given PT or SOC are counted only once for each PT and SOC. Only SOCs or PTs for which there are at least 10% of patients with an event in at least one treatment group OR at least 10 patients with an event overall and at least 1% of patients with an event in at least one treatment group in the overall safety population are considered. Further, only SOCs and PTs for which there is a significant treatment effect (p-value <0.05) in the overall safety population are presented. Events are sorted alphabetically by SOC and PT and then by subgroup within each. MedDRA (version 22.0).
N: Number of patients in treatment group; NETA: Norethindrone acetate; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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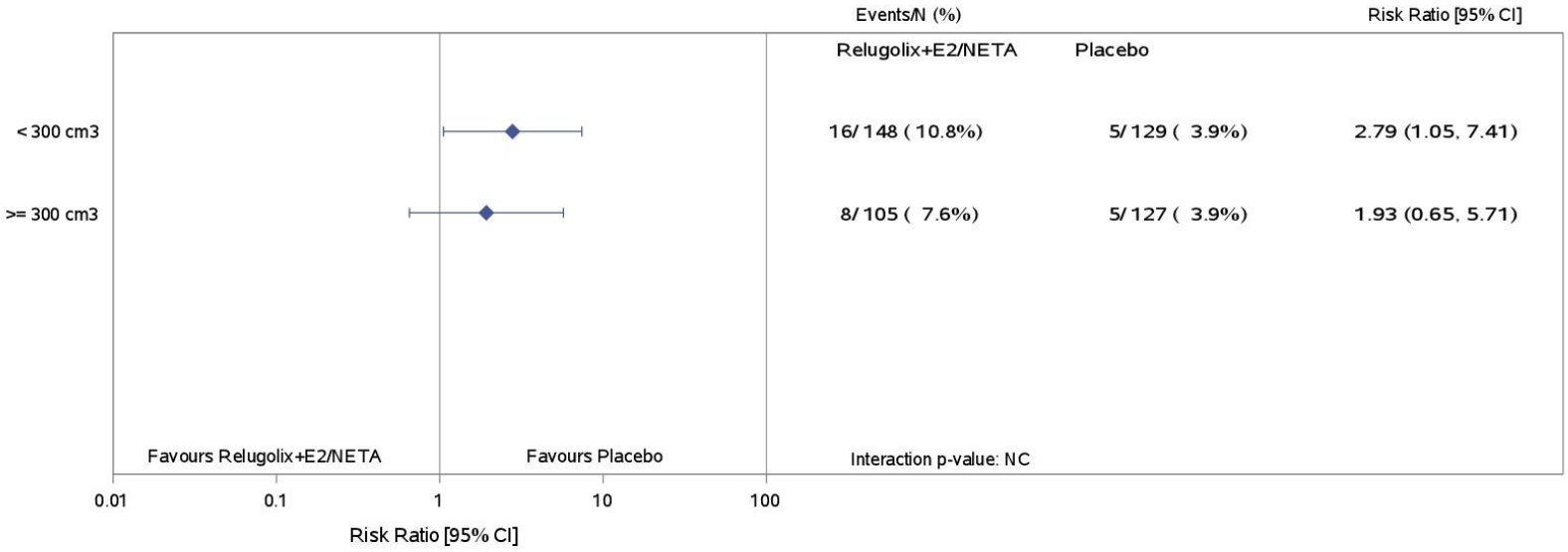
Figure SAF.TEAE.SPT.S3.BIN.FP.RR: Frequent Treatment Emergent Adverse Events by System Organ Class and Preferred Term, by Subgroup (Safety Population) - Risk Ratio
Study: Pooled
System Organ Class: Skin and subcutaneous tissue disorders, Preferred Term: Any
Subgroup: Uterine Volume at Baseline (cm3)



Results are based on a Cochran-Mantel-Haenszel approach stratified by study using a one-stage fixed-effects IPD meta-analysis. A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
The reference group is Placebo. Patients with multiple events are counted only once. MedDRA (version 22.0).
Patients with multiple events for a given PT or SOC are counted only once for each PT and SOC. Only SOCs or PTs for which there are at least 10% of patients with an event in at least one treatment group OR at least 10 patients with an event overall and at least 1% of patients with an event in at least one treatment group in the overall safety population are considered. Further, only SOCs and PTs for which there is a significant treatment effect (p-value <0.05) in the overall safety population are presented. Events are sorted alphabetically by SOC and PT and then by subgroup within each. MedDRA (version 22.0).
N: Number of patients in treatment group; NETA: Norethindrone acetate; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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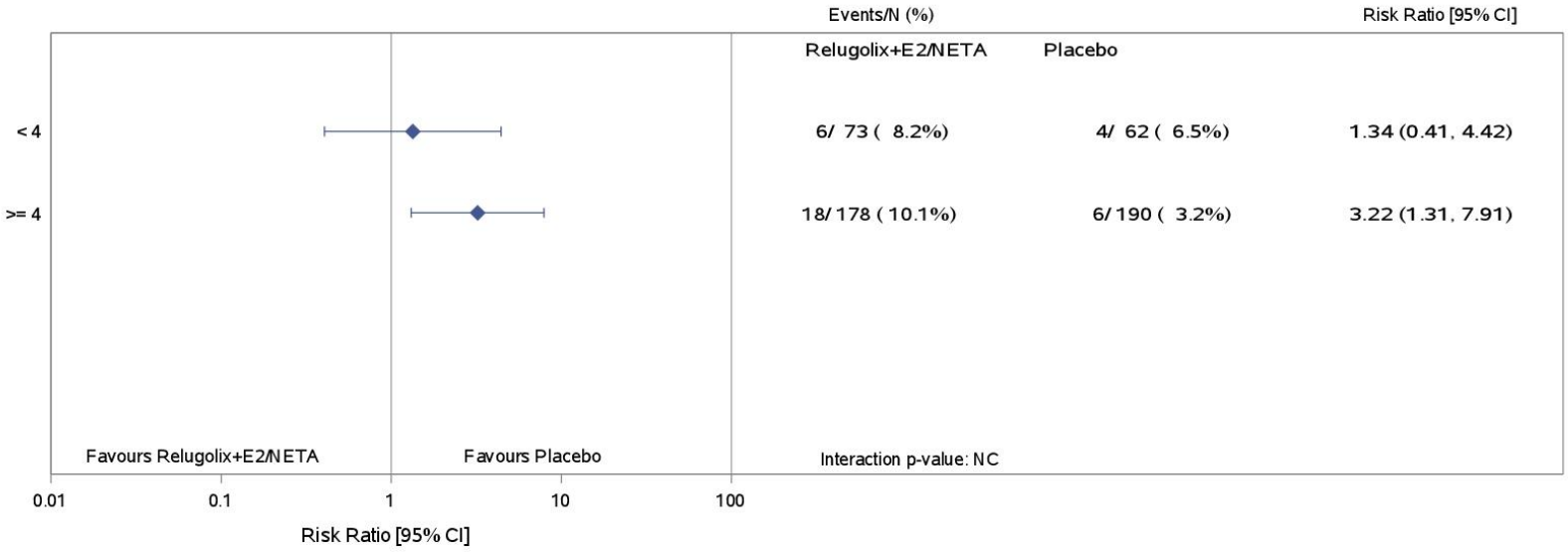
Figure SAF.TEAE.SPT.S4.BIN.FP.RR: Frequent Treatment Emergent Adverse Events by System Organ Class and Preferred Term, by Subgroup (Safety Population) - Risk Ratio
Study: Pooled
System Organ Class: Skin and subcutaneous tissue disorders, Preferred Term: Any
Subgroup: Maximum NRS Pain Score at Baseline



Results are based on a Cochran-Mantel-Haenszel approach stratified by study using a one-stage fixed-effects IPD meta-analysis. A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
The reference group is Placebo. Patients with multiple events are counted only once. MedDRA (version 22.0).
Patients with multiple events for a given PT or SOC are counted only once for each PT and SOC. Only SOCs or PTs for which there are at least 10% of patients with an event in at least one treatment group OR at least 10 patients with an event overall and at least 1% of patients with an event in at least one treatment group in the overall safety population are considered. Further, only SOCs and PTs for which there is a significant treatment effect (p-value <0.05) in the overall safety population are presented. Events are sorted alphabetically by SOC and PT and then by subgroup within each. MedDRA (version 22.0).
N: Number of patients in treatment group; NETA: Norethindrone acetate; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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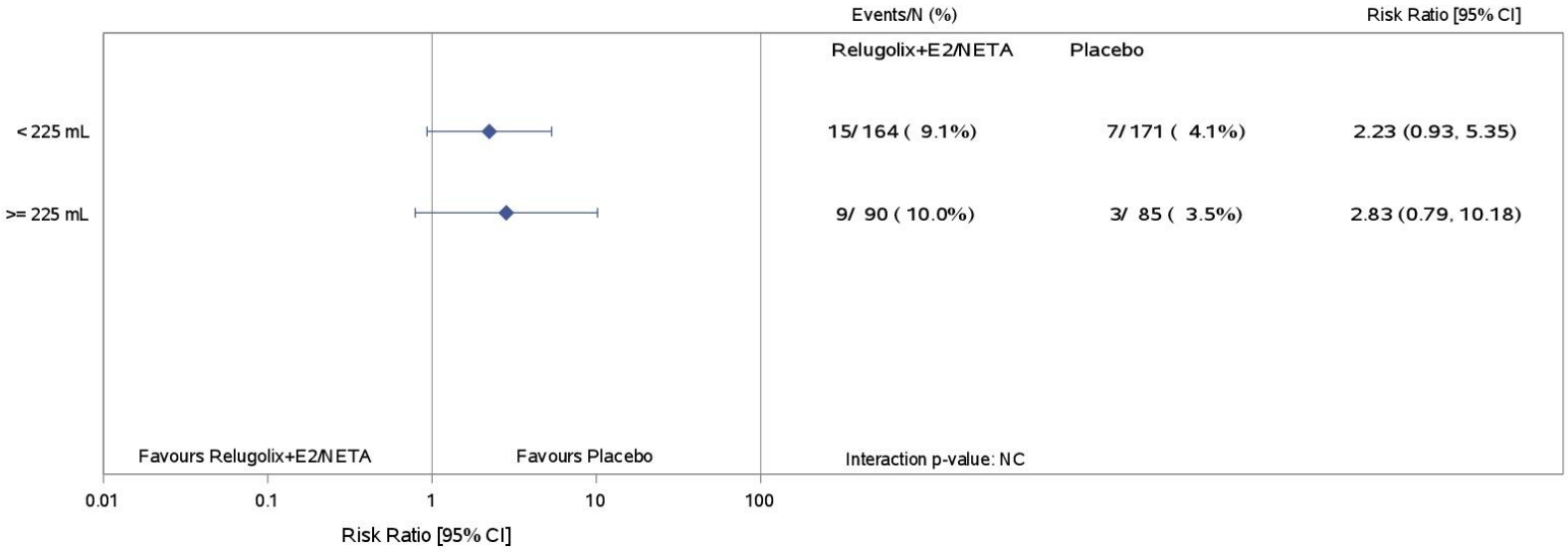
Figure SAF.TEAE.SPT.S5.BIN.FP.RR: Frequent Treatment Emergent Adverse Events by System Organ Class and Preferred Term, by Subgroup (Safety Population) - Risk Ratio
Study: Pooled
System Organ Class: Skin and subcutaneous tissue disorders, Preferred Term: Any
Subgroup: MBL Volume at Baseline (mL)



Results are based on a Cochran-Mantel-Haenszel approach stratified by study using a one-stage fixed-effects IPD meta-analysis. A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
The reference group is Placebo. Patients with multiple events are counted only once. MedDRA (version 22.0).
Patients with multiple events for a given PT or SOC are counted only once for each PT and SOC. Only SOCs or PTs for which there are at least 10% of patients with an event in at least one treatment group OR at least 10 patients with an event overall and at least 1% of patients with an event in at least one treatment group in the overall safety population are considered. Further, only SOCs and PTs for which there is a significant treatment effect (p-value <0.05) in the overall safety population are presented. Events are sorted alphabetically by SOC and PT and then by subgroup within each. MedDRA (version 22.0).
N: Number of patients in treatment group; NETA: Norethindrone acetate; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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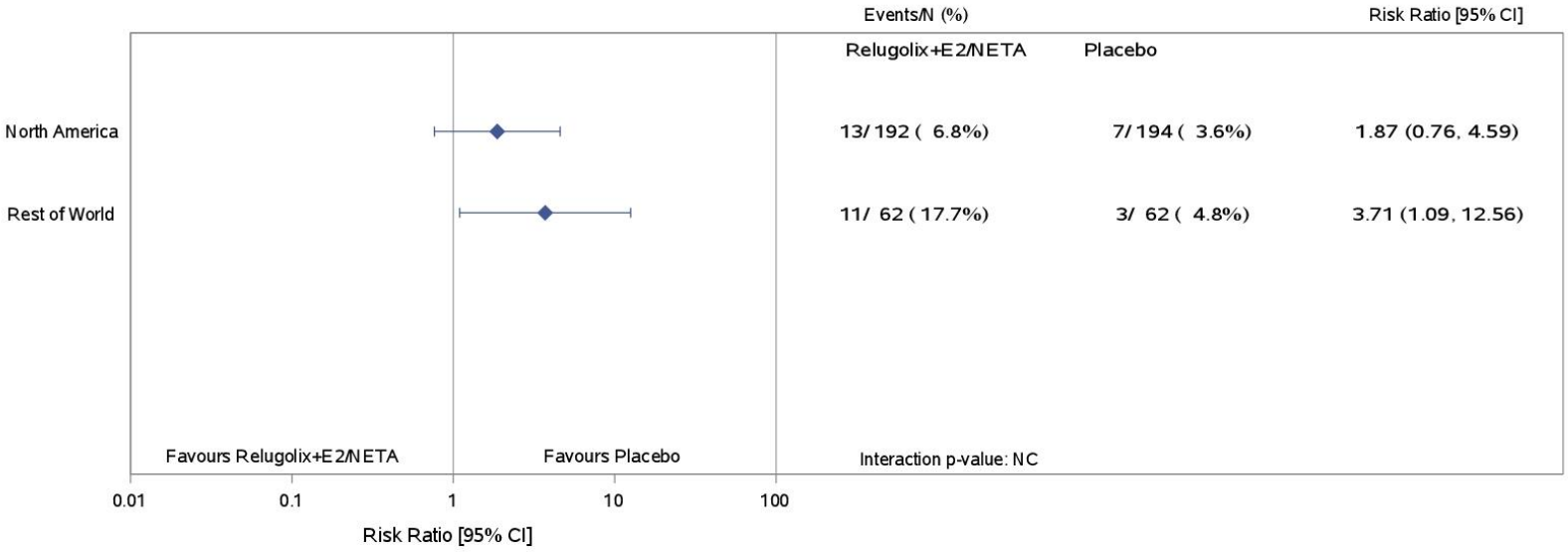
Figure SAF.TEAE.SPT.S6.BIN.FP.RR: Frequent Treatment Emergent Adverse Events by System Organ Class and Preferred Term, by Subgroup (Safety Population) - Risk Ratio
Study: Pooled
System Organ Class: Skin and subcutaneous tissue disorders, Preferred Term: Any
Subgroup: Geographic Region I



Results are based on a Cochran-Mantel-Haenszel approach stratified by study using a one-stage fixed-effects IPD meta-analysis. A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
The reference group is Placebo. Patients with multiple events are counted only once. MedDRA (version 22.0).
Patients with multiple events for a given PT or SOC are counted only once for each PT and SOC. Only SOCs or PTs for which there are at least 10% of patients with an event in at least one treatment group OR at least 10 patients with an event overall and at least 1% of patients with an event in at least one treatment group in the overall safety population are considered. Further, only SOCs and PTs for which there is a significant treatment effect (p-value <0.05) in the overall safety population are presented. Events are sorted alphabetically by SOC and PT and then by subgroup within each. MedDRA (version 22.0).
N: Number of patients in treatment group; NETA: Norethindrone acetate; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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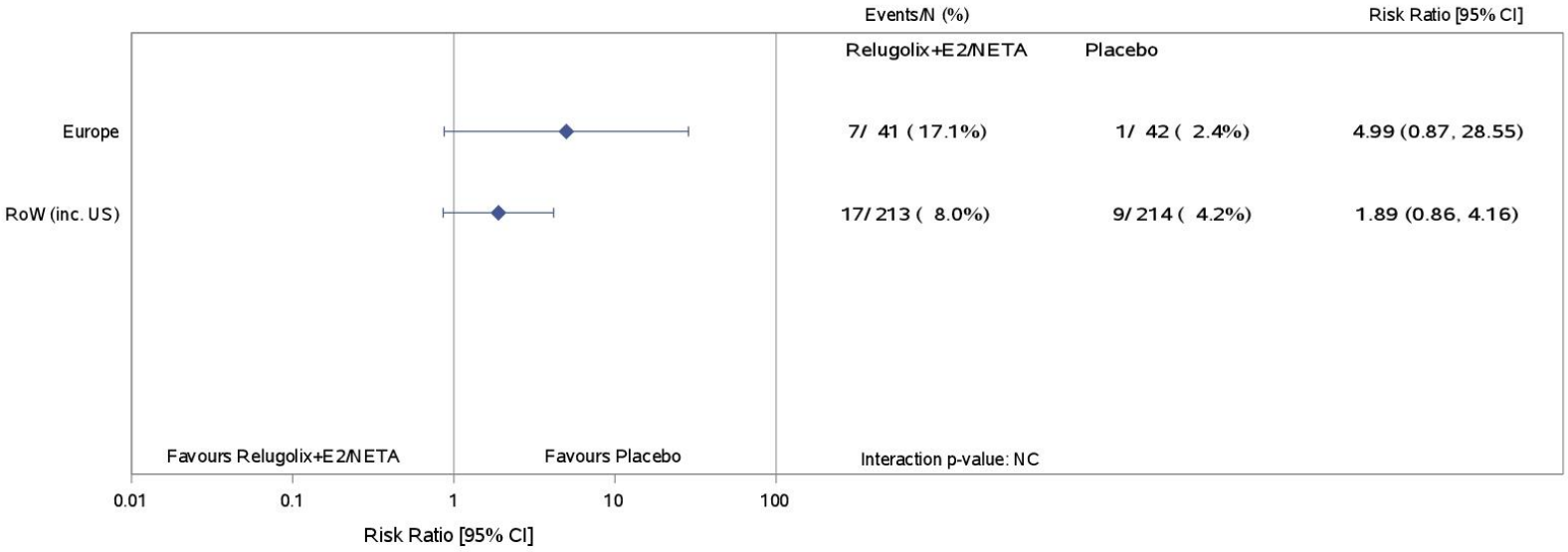
Figure SAF.TEAE.SPT.S7.BIN.FP.RR: Frequent Treatment Emergent Adverse Events by System Organ Class and Preferred Term, by Subgroup (Safety Population) - Risk Ratio
Study: Pooled
System Organ Class: Skin and subcutaneous tissue disorders, Preferred Term: Any
Subgroup: Geographic Region II



Results are based on a Cochran-Mantel-Haenszel approach stratified by study using a one-stage fixed-effects IPD meta-analysis. A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
The reference group is Placebo. Patients with multiple events are counted only once. MedDRA (version 22.0).
Patients with multiple events for a given PT or SOC are counted only once for each PT and SOC. Only SOCs or PTs for which there are at least 10% of patients with an event in at least one treatment group OR at least 10 patients with an event overall and at least 1% of patients with an event in at least one treatment group in the overall safety population are considered. Further, only SOCs and PTs for which there is a significant treatment effect (p-value <0.05) in the overall safety population are presented. Events are sorted alphabetically by SOC and PT and then by subgroup within each. MedDRA (version 22.0).
N: Number of patients in treatment group; NETA: Norethindrone acetate; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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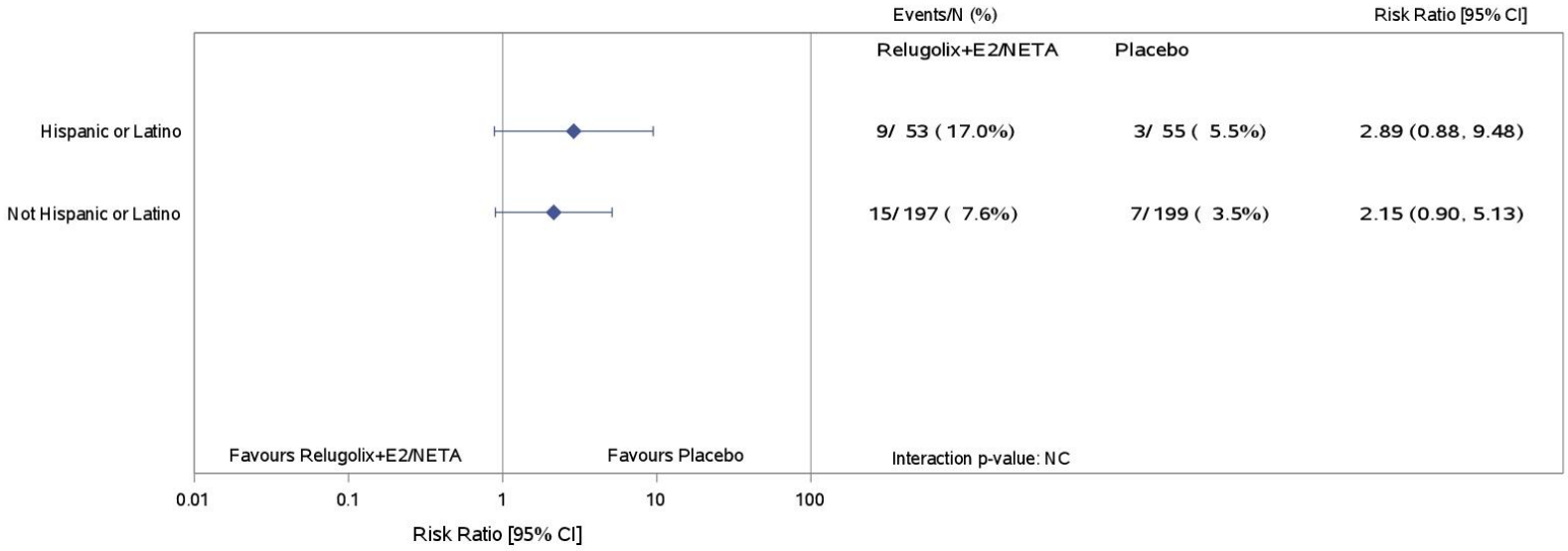
Figure SAF.TEAE.SPT.S8.BIN.FP.RR: Frequent Treatment Emergent Adverse Events by System Organ Class and Preferred Term, by Subgroup (Safety Population) - Risk Ratio
Study: Pooled
System Organ Class: Skin and subcutaneous tissue disorders, Preferred Term: Any
Subgroup: Ethnicity



Results are based on a Cochran-Mantel-Haenszel approach stratified by study using a one-stage fixed-effects IPD meta-analysis. A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
The reference group is Placebo. Patients with multiple events are counted only once. MedDRA (version 22.0).
Patients with multiple events for a given PT or SOC are counted only once for each PT and SOC. Only SOCs or PTs for which there are at least 10% of patients with an event in at least one treatment group OR at least 10 patients with an event overall and at least 1% of patients with an event in at least one treatment group in the overall safety population are considered. Further, only SOCs and PTs for which there is a significant treatment effect (p-value <0.05) in the overall safety population are presented. Events are sorted alphabetically by SOC and PT and then by subgroup within each. MedDRA (version 22.0).
N: Number of patients in treatment group; NETA: Norethindrone acetate; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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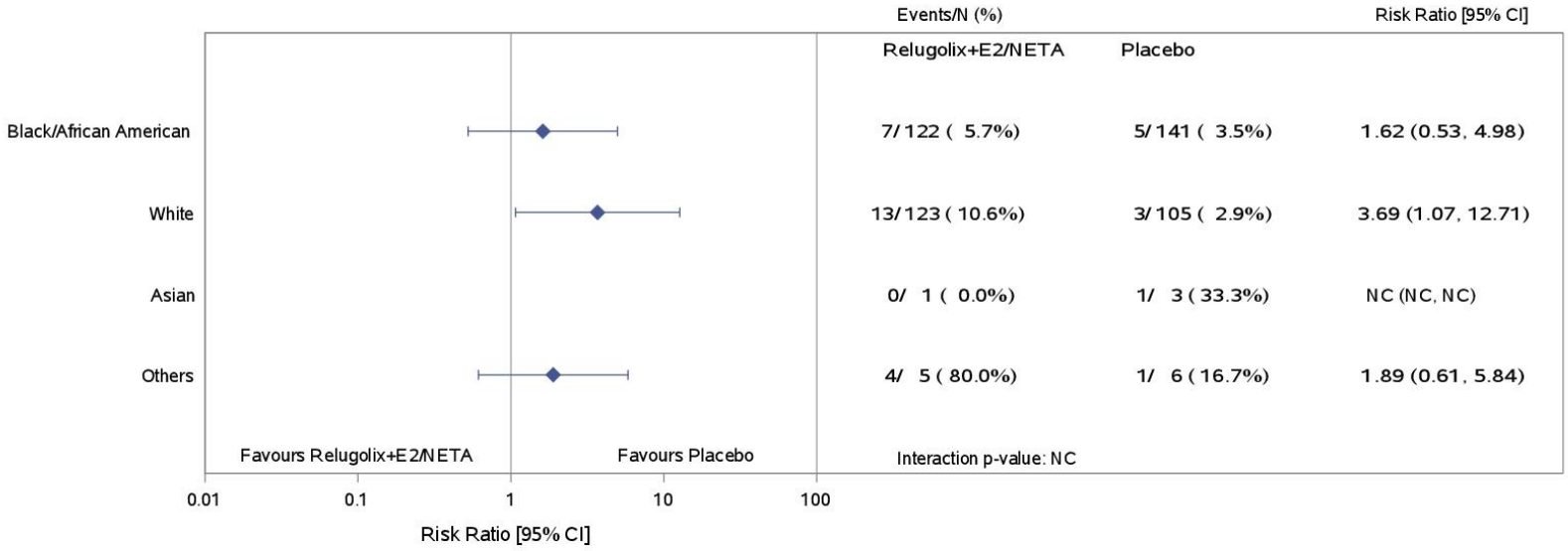
Figure SAF.TEAE.SPT.S9.BIN.FP.RR: Frequent Treatment Emergent Adverse Events by System Organ Class and Preferred Term, by Subgroup (Safety Population) - Risk Ratio
Study: Pooled
System Organ Class: Skin and subcutaneous tissue disorders, Preferred Term: Any
Subgroup: Race



Results are based on a Cochran-Mantel-Haenszel approach stratified by study using a one-stage fixed-effects IPD meta-analysis. A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
The reference group is Placebo. Patients with multiple events are counted only once. MedDRA (version 22.0).
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N: Number of patients in treatment group; NETA: Norethindrone acetate; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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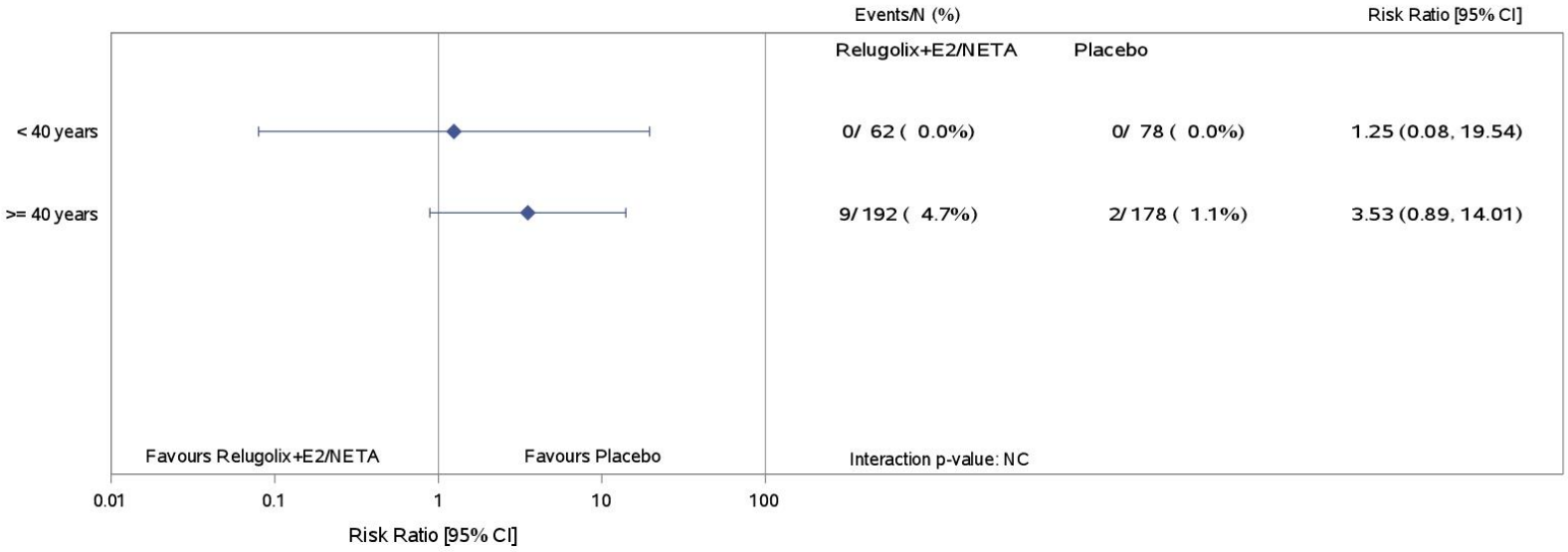
Figure SAF.TEAE.SPT.S1.BIN.FP.RR: Frequent Treatment Emergent Adverse Events by System Organ Class and Preferred Term, by Subgroup (Safety Population) - Risk Ratio
Study: Pooled
System Organ Class: Skin and subcutaneous tissue disorders, Preferred Term: Alopecia
Subgroup: Age (years)



Results are based on a Cochran-Mantel-Haenszel approach stratified by study using a one-stage fixed-effects IPD meta-analysis. A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
The reference group is Placebo. Patients with multiple events are counted only once. MedDRA (version 22.0).
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N: Number of patients in treatment group; NETA: Norethindrone acetate; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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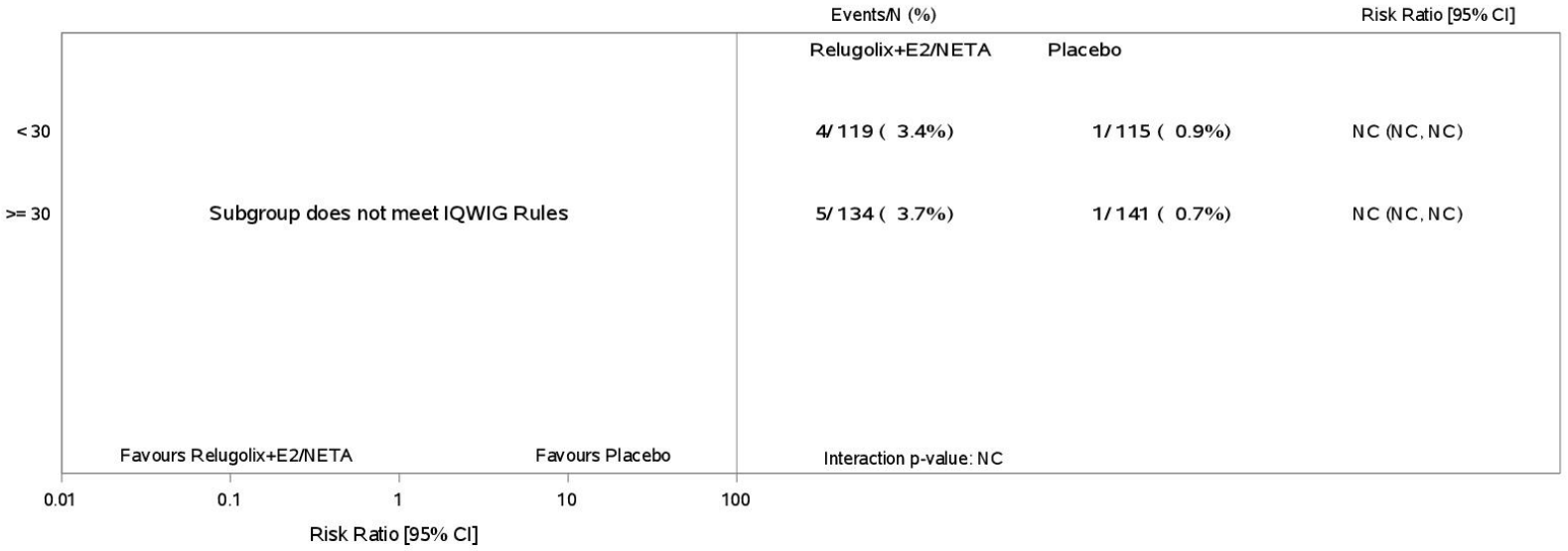
Figure SAF.TEAE.SPT.S2.BIN.FP.RR: Frequent Treatment Emergent Adverse Events by System Organ Class and Preferred Term, by Subgroup (Safety Population) - Risk Ratio
Study: Pooled
System Organ Class: Skin and subcutaneous tissue disorders, Preferred Term: Alopecia
Subgroup: BMI (kg/m2) at Baseline



Results are based on a Cochran-Mantel-Haenszel approach stratified by study using a one-stage fixed-effects IPD meta-analysis. A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
The reference group is Placebo. Patients with multiple events are counted only once. MedDRA (version 22.0).
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N: Number of patients in treatment group; NETA: Norethindrone acetate; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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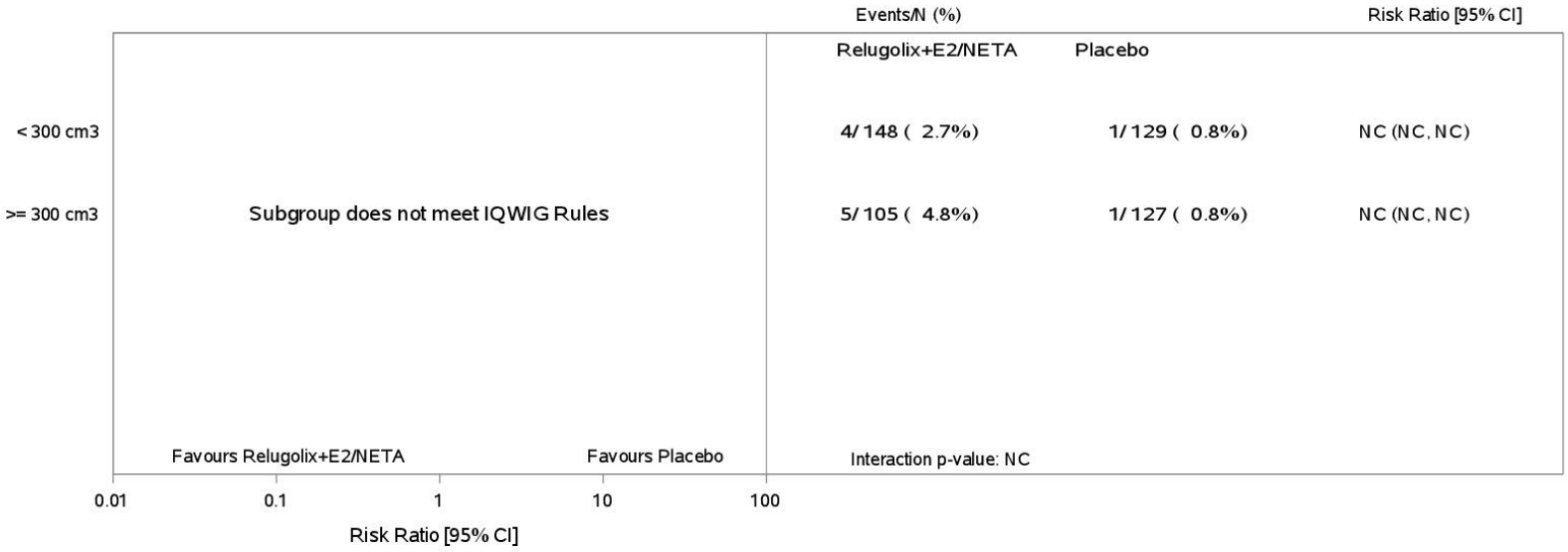
Figure SAF.TEAE.SPT.S3.BIN.FP.RR: Frequent Treatment Emergent Adverse Events by System Organ Class and Preferred Term, by Subgroup (Safety Population) - Risk Ratio
Study: Pooled
System Organ Class: Skin and subcutaneous tissue disorders, Preferred Term: Alopecia
Subgroup: Uterine Volume at Baseline (cm3)



Results are based on a Cochran-Mantel-Haenszel approach stratified by study using a one-stage fixed-effects IPD meta-analysis. A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
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N: Number of patients in treatment group; NETA: Norethindrone acetate; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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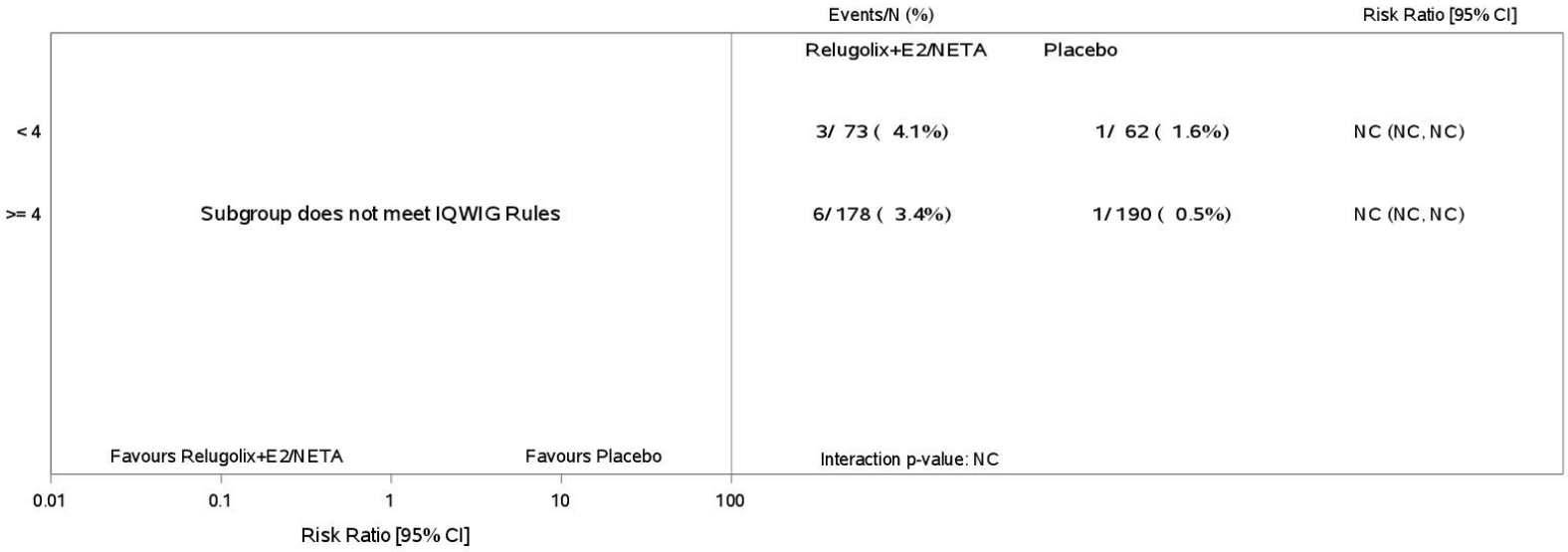
Figure SAF.TEAE.SPT.S4.BIN.FP.RR: Frequent Treatment Emergent Adverse Events by System Organ Class and Preferred Term, by Subgroup (Safety Population) - Risk Ratio
Study: Pooled
System Organ Class: Skin and subcutaneous tissue disorders, Preferred Term: Alopecia
Subgroup: Maximum NRS Pain Score at Baseline



Results are based on a Cochran-Mantel-Haenszel approach stratified by study using a one-stage fixed-effects IPD meta-analysis. A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
The reference group is Placebo. Patients with multiple events are counted only once. MedDRA (version 22.0).
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N: Number of patients in treatment group; NETA: Norethindrone acetate; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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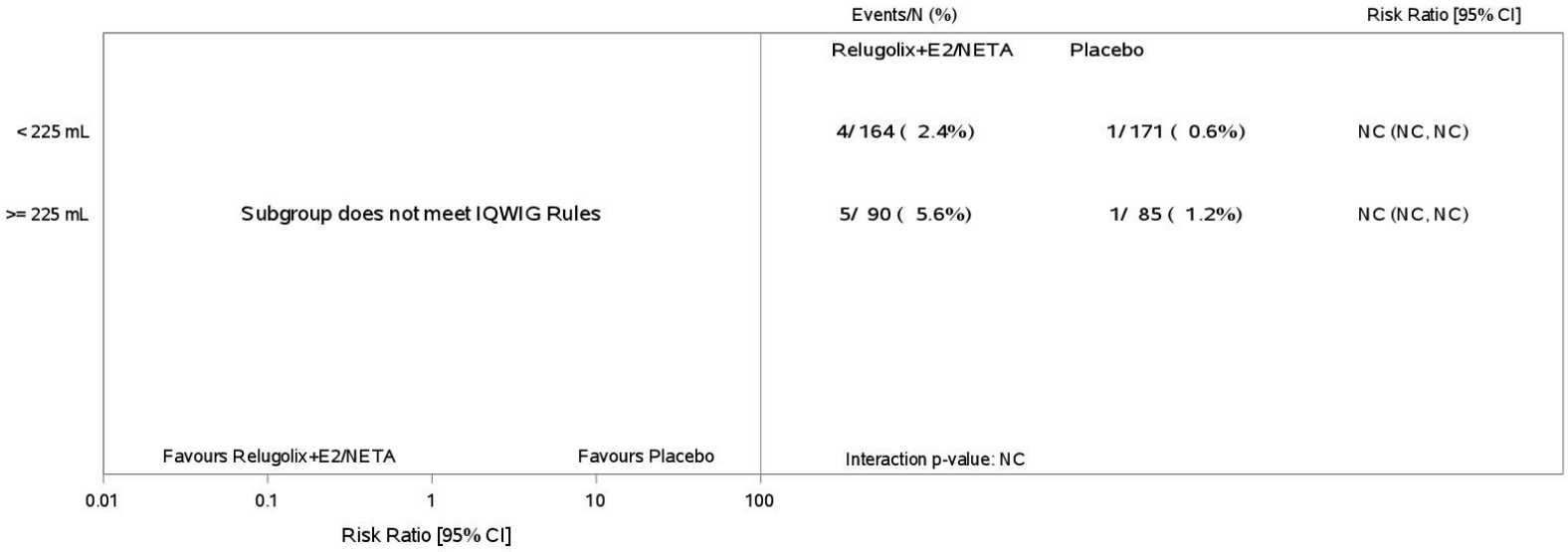
Figure SAF.TEAE.SPT.S5.BIN.FP.RR: Frequent Treatment Emergent Adverse Events by System Organ Class and Preferred Term, by Subgroup (Safety Population) - Risk Ratio
Study: Pooled
System Organ Class: Skin and subcutaneous tissue disorders, Preferred Term: Alopecia
Subgroup: MBL Volume at Baseline (mL)



Results are based on a Cochran-Mantel-Haenszel approach stratified by study using a one-stage fixed-effects IPD meta-analysis. A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
The reference group is Placebo. Patients with multiple events are counted only once. MedDRA (version 22.0).
Patients with multiple events for a given PT or SOC are counted only once for each PT and SOC. Only SOCs or PTs for which there are at least 10% of patients with an event in at least one treatment group OR at least 10 patients with an event overall and at least 1% of patients with an event in at least one treatment group in the overall safety population are considered. Further, only SOCs and PTs for which there is a significant treatment effect (p-value <0.05) in the overall safety population are presented. Events are sorted alphabetically by SOC and PT and then by subgroup within each. MedDRA (version 22.0).
N: Number of patients in treatment group; NETA: Norethindrone acetate; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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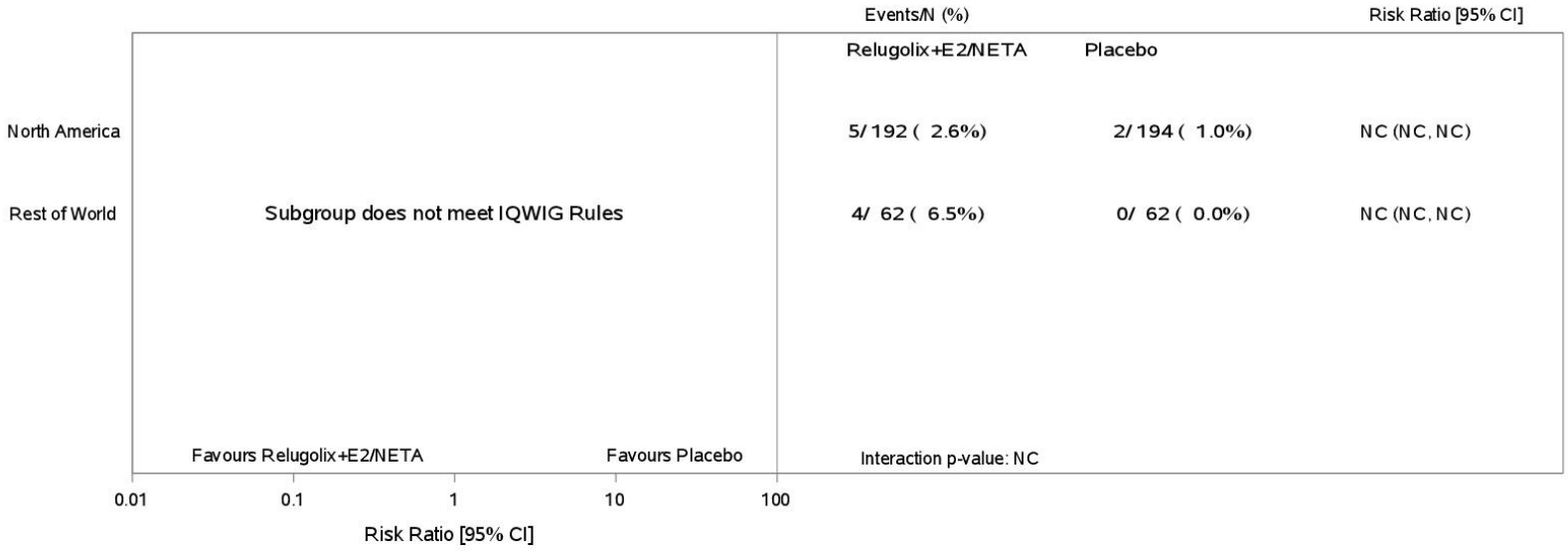
Figure SAF.TEAE.SPT.S6.BIN.FP.RR: Frequent Treatment Emergent Adverse Events by System Organ Class and Preferred Term, by Subgroup (Safety Population) - Risk Ratio
Study: Pooled
System Organ Class: Skin and subcutaneous tissue disorders, Preferred Term: Alopecia
Subgroup: Geographic Region I



Results are based on a Cochran-Mantel-Haenszel approach stratified by study using a one-stage fixed-effects IPD meta-analysis. A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
The reference group is Placebo. Patients with multiple events are counted only once. MedDRA (version 22.0).
Patients with multiple events for a given PT or SOC are counted only once for each PT and SOC. Only SOCs or PTs for which there are at least 10% of patients with an event in at least one treatment group OR at least 10 patients with an event overall and at least 1% of patients with an event in at least one treatment group in the overall safety population are considered. Further, only SOCs and PTs for which there is a significant treatment effect (p-value <0.05) in the overall safety population are presented. Events are sorted alphabetically by SOC and PT and then by subgroup within each. MedDRA (version 22.0).
N: Number of patients in treatment group; NETA: Norethindrone acetate; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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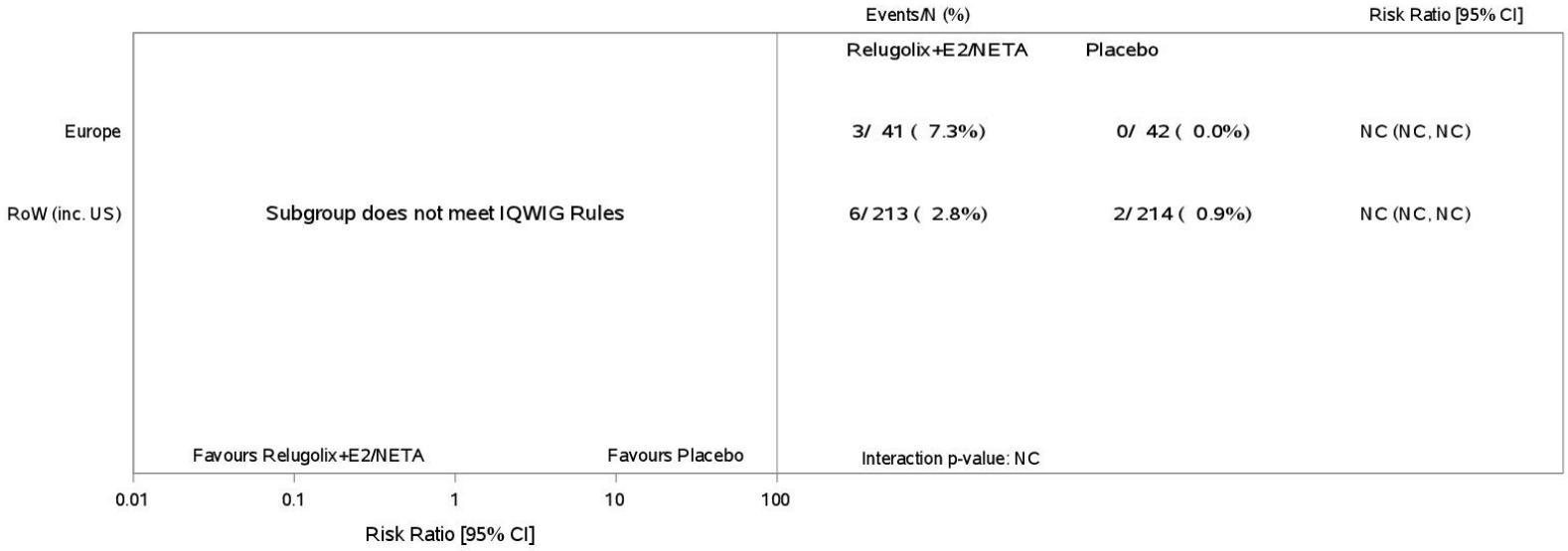
Figure SAF.TEAE.SPT.S7.BIN.FP.RR: Frequent Treatment Emergent Adverse Events by System Organ Class and Preferred Term, by Subgroup (Safety Population) - Risk Ratio
Study: Pooled
System Organ Class: Skin and subcutaneous tissue disorders, Preferred Term: Alopecia
Subgroup: Geographic Region II



Results are based on a Cochran-Mantel-Haenszel approach stratified by study using a one-stage fixed-effects IPD meta-analysis. A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
The reference group is Placebo. Patients with multiple events are counted only once. MedDRA (version 22.0).
Patients with multiple events for a given PT or SOC are counted only once for each PT and SOC. Only SOCs or PTs for which there are at least 10% of patients with an event in at least one treatment group OR at least 10 patients with an event overall and at least 1% of patients with an event in at least one treatment group in the overall safety population are considered. Further, only SOCs and PTs for which there is a significant treatment effect (p-value <0.05) in the overall safety population are presented. Events are sorted alphabetically by SOC and PT and then by subgroup within each. MedDRA (version 22.0).
N: Number of patients in treatment group; NETA: Norethindrone acetate; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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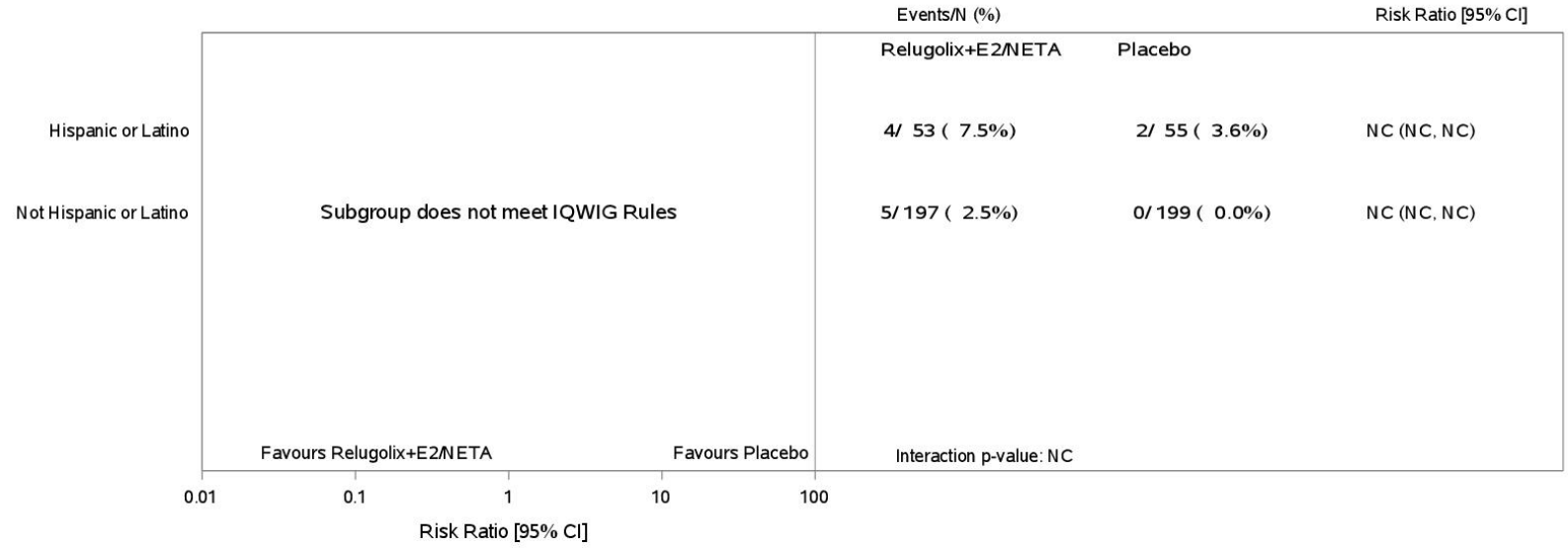
Figure SAF.TEAE.SPT.S8.BIN.FP.RR: Frequent Treatment Emergent Adverse Events by System Organ Class and Preferred Term, by Subgroup (Safety Population) - Risk Ratio
Study: Pooled
System Organ Class: Skin and subcutaneous tissue disorders, Preferred Term: Alopecia
Subgroup: Ethnicity



Results are based on a Cochran-Mantel-Haenszel approach stratified by study using a one-stage fixed-effects IPD meta-analysis. A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
The reference group is Placebo. Patients with multiple events are counted only once. MedDRA (version 22.0).
Patients with multiple events for a given PT or SOC are counted only once for each PT and SOC. Only SOCs or PTs for which there are at least 10% of patients with an event in at least one treatment group OR at least 10 patients with an event overall and at least 1% of patients with an event in at least one treatment group in the overall safety population are considered. Further, only SOCs and PTs for which there is a significant treatment effect (p-value <0.05) in the overall safety population are presented. Events are sorted alphabetically by SOC and PT and then by subgroup within each. MedDRA (version 22.0).
N: Number of patients in treatment group; NETA: Norethindrone acetate; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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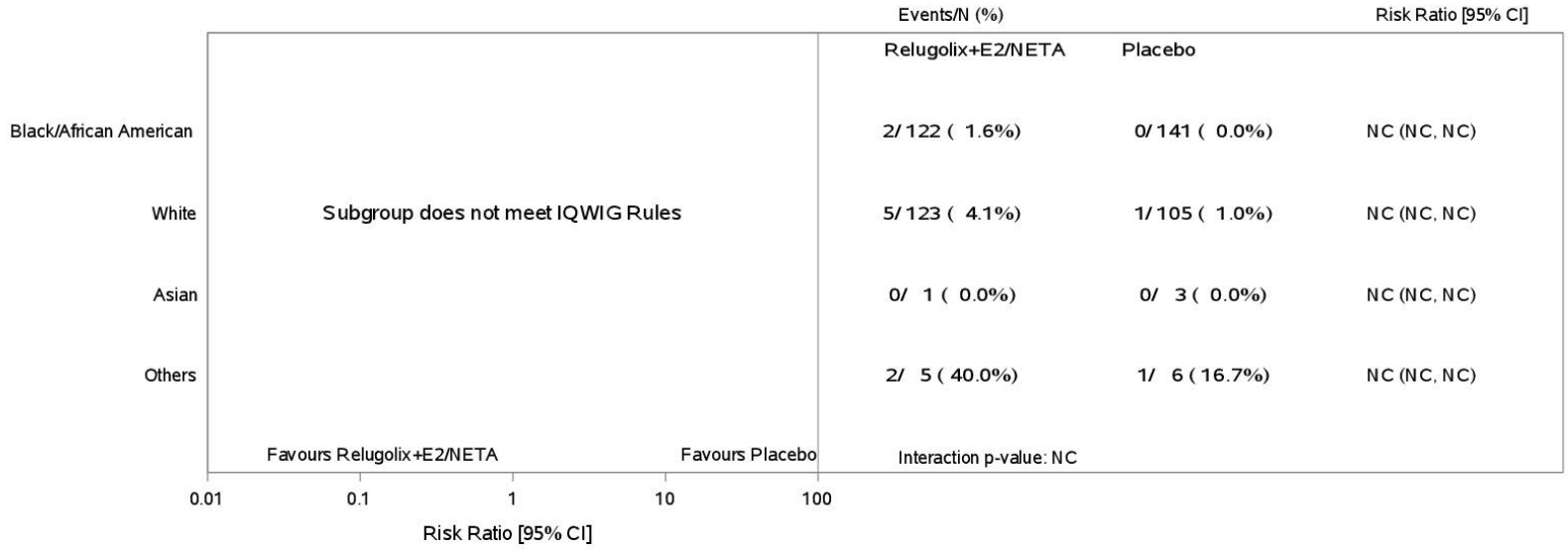
Figure SAF.TEAE.SPT.S9.BIN.FP.RR: Frequent Treatment Emergent Adverse Events by System Organ Class and Preferred Term, by Subgroup (Safety Population) - Risk Ratio
Study: Pooled
System Organ Class: Skin and subcutaneous tissue disorders, Preferred Term: Alopecia
Subgroup: Race



Results are based on a Cochran-Mantel-Haenszel approach stratified by study using a one-stage fixed-effects IPD meta-analysis. A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
The reference group is Placebo. Patients with multiple events are counted only once. MedDRA (version 22.0).
Patients with multiple events for a given PT or SOC are counted only once for each PT and SOC. Only SOCs or PTs for which there are at least 10% of patients with an event in at least one treatment group OR at least 10 patients with an event overall and at least 1% of patients with an event in at least one treatment group in the overall safety population are considered. Further, only SOCs and PTs for which there is a significant treatment effect (p-value <0.05) in the overall safety population are presented. Events are sorted alphabetically by SOC and PT and then by subgroup within each. MedDRA (version 22.0).
N: Number of patients in treatment group; NETA: Norethindrone acetate; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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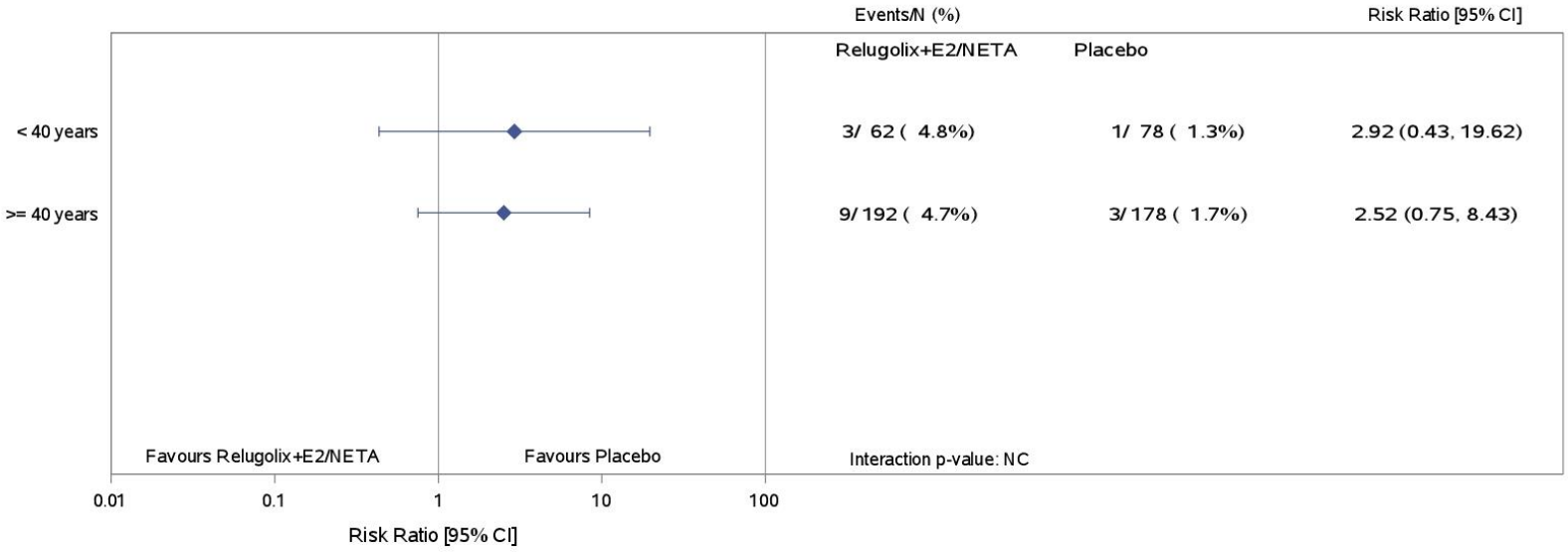
Figure SAF.TEAE.SPT.S1.BIN.FP.RR: Frequent Treatment Emergent Adverse Events by System Organ Class and Preferred Term, by Subgroup (Safety Population) - Risk Ratio
Study: Pooled
System Organ Class: Vascular disorders, Preferred Term: Hypertension
Subgroup: Age (years)



Results are based on a Cochran-Mantel-Haenszel approach stratified by study using a one-stage fixed-effects IPD meta-analysis. A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
The reference group is Placebo. Patients with multiple events are counted only once. MedDRA (version 22.0).
Patients with multiple events for a given PT or SOC are counted only once for each PT and SOC. Only SOCs or PTs for which there are at least 10% of patients with an event in at least one treatment group OR at least 10 patients with an event overall and at least 1% of patients with an event in at least one treatment group in the overall safety population are considered. Further, only SOCs and PTs for which there is a significant treatment effect (p-value <0.05) in the overall safety population are presented. Events are sorted alphabetically by SOC and PT and then by subgroup within each. MedDRA (version 22.0).
N: Number of patients in treatment group; NETA: Norethindrone acetate; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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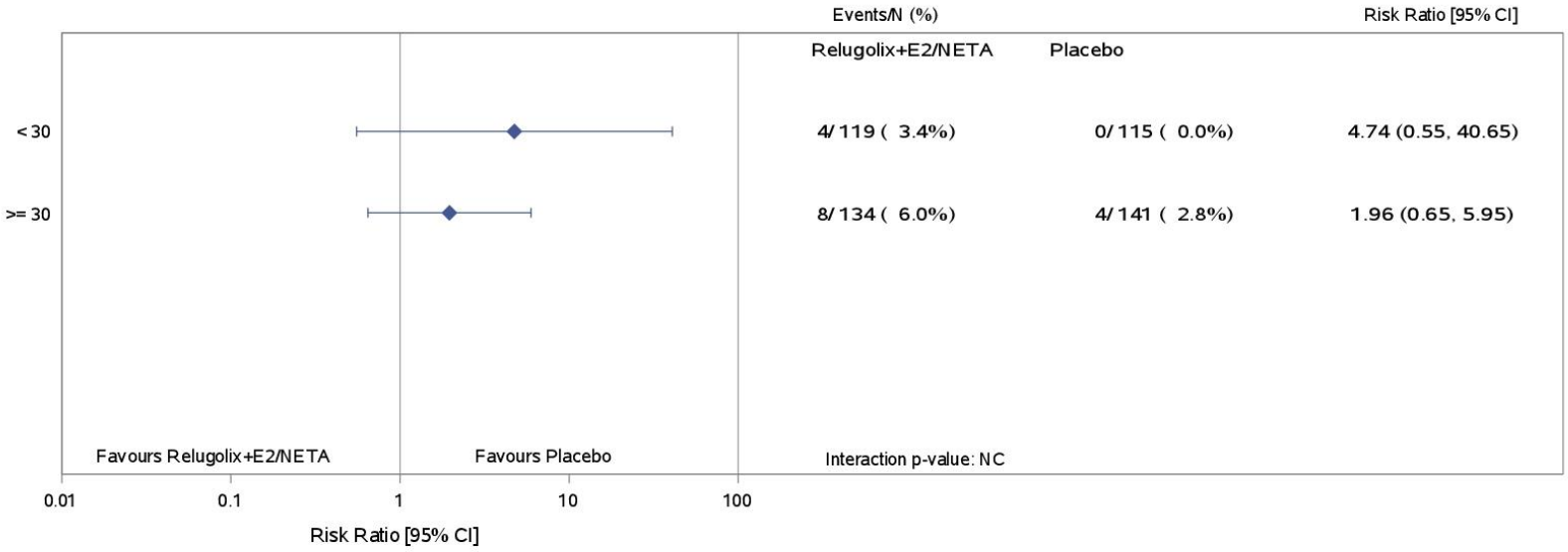
Figure SAF.TEAE.SPT.S2.BIN.FP.RR: Frequent Treatment Emergent Adverse Events by System Organ Class and Preferred Term, by Subgroup (Safety Population) - Risk Ratio
Study: Pooled
System Organ Class: Vascular disorders, Preferred Term: Hypertension
Subgroup: BMI (kg/m2) at Baseline



Results are based on a Cochran-Mantel-Haenszel approach stratified by study using a one-stage fixed-effects IPD meta-analysis. A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
The reference group is Placebo. Patients with multiple events are counted only once. MedDRA (version 22.0).
Patients with multiple events for a given PT or SOC are counted only once for each PT and SOC. Only SOCs or PTs for which there are at least 10% of patients with an event in at least one treatment group OR at least 10 patients with an event overall and at least 1% of patients with an event in at least one treatment group in the overall safety population are considered. Further, only SOCs and PTs for which there is a significant treatment effect (p-value <0.05) in the overall safety population are presented. Events are sorted alphabetically by SOC and PT and then by subgroup within each. MedDRA (version 22.0).
N: Number of patients in treatment group; NETA: Norethindrone acetate; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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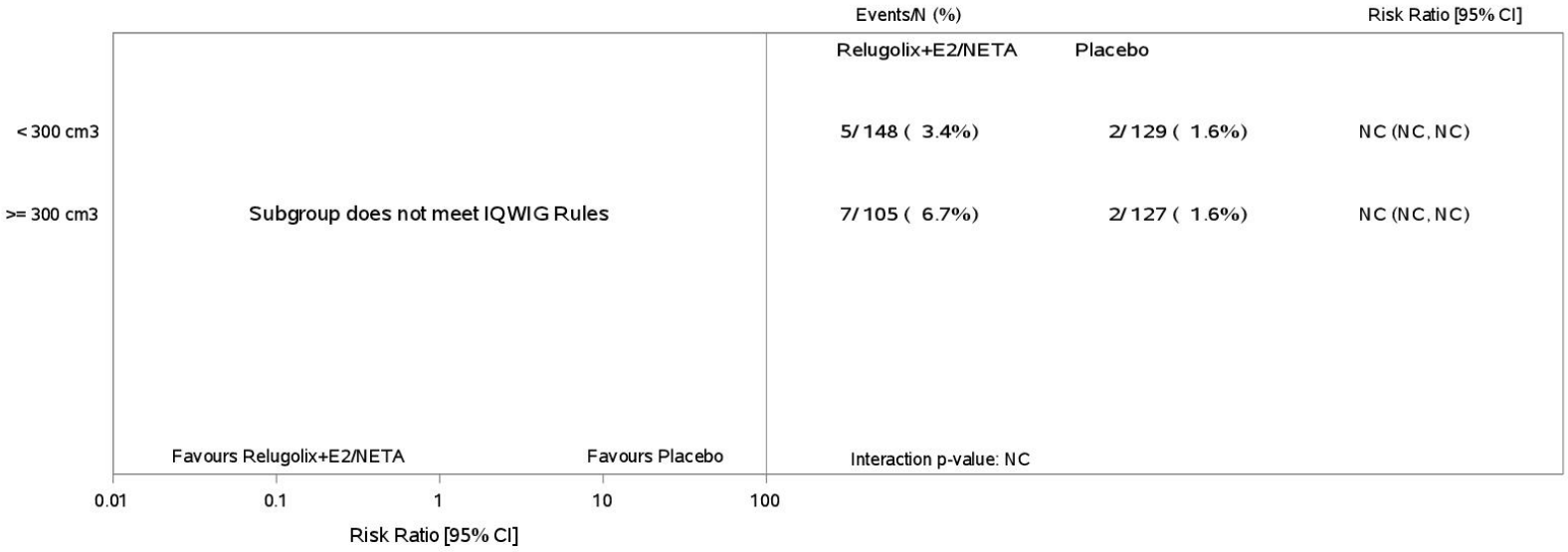
Figure SAF.TEAE.SPT.S3.BIN.FP.RR: Frequent Treatment Emergent Adverse Events by System Organ Class and Preferred Term, by Subgroup (Safety Population) - Risk Ratio
Study: Pooled
System Organ Class: Vascular disorders, Preferred Term: Hypertension
Subgroup: Uterine Volume at Baseline (cm3)



Results are based on a Cochran-Mantel-Haenszel approach stratified by study using a one-stage fixed-effects IPD meta-analysis. A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
The reference group is Placebo. Patients with multiple events are counted only once. MedDRA (version 22.0).
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N: Number of patients in treatment group; NETA: Norethindrone acetate; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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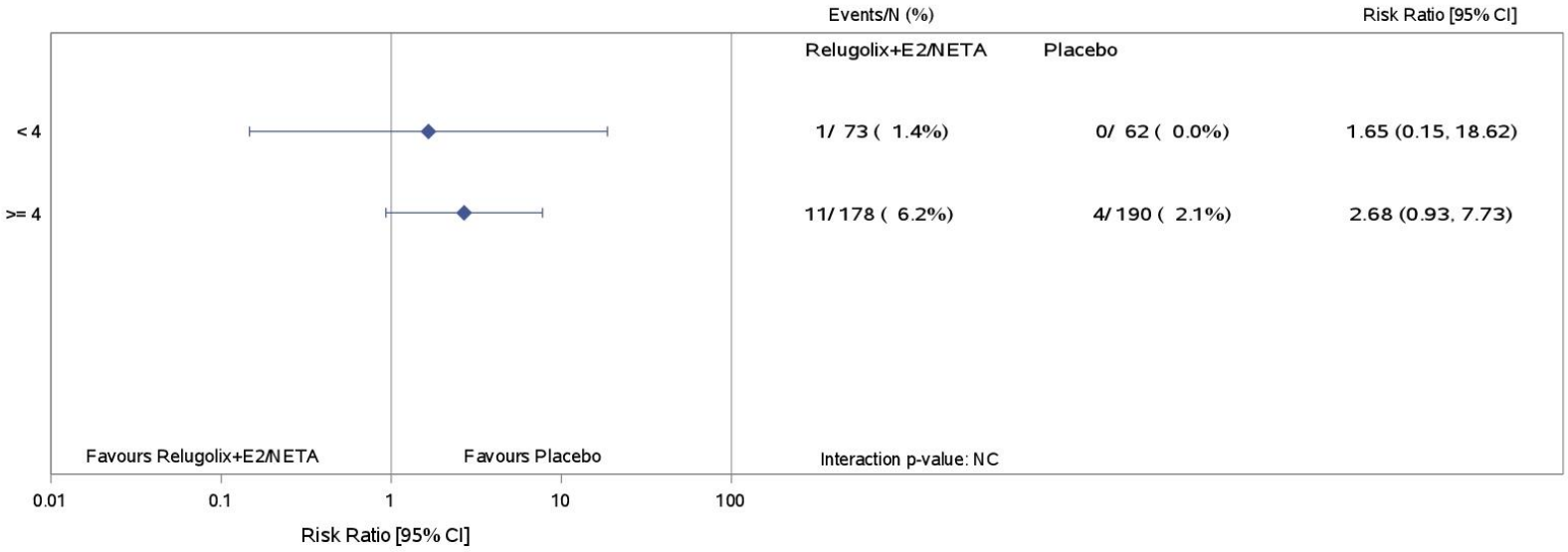
Figure SAF.TEAE.SPT.S4.BIN.FP.RR: Frequent Treatment Emergent Adverse Events by System Organ Class and Preferred Term, by Subgroup (Safety Population) - Risk Ratio
Study: Pooled
System Organ Class: Vascular disorders, Preferred Term: Hypertension
Subgroup: Maximum NRS Pain Score at Baseline



Results are based on a Cochran-Mantel-Haenszel approach stratified by study using a one-stage fixed-effects IPD meta-analysis. A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
The reference group is Placebo. Patients with multiple events are counted only once. MedDRA (version 22.0).
Patients with multiple events for a given PT or SOC are counted only once for each PT and SOC. Only SOCs or PTs for which there are at least 10% of patients with an event in at least one treatment group OR at least 10 patients with an event overall and at least 1% of patients with an event in at least one treatment group in the overall safety population are considered. Further, only SOCs and PTs for which there is a significant treatment effect (p-value <0.05) in the overall safety population are presented. Events are sorted alphabetically by SOC and PT and then by subgroup within each. MedDRA (version 22.0).
N: Number of patients in treatment group; NETA: Norethindrone acetate; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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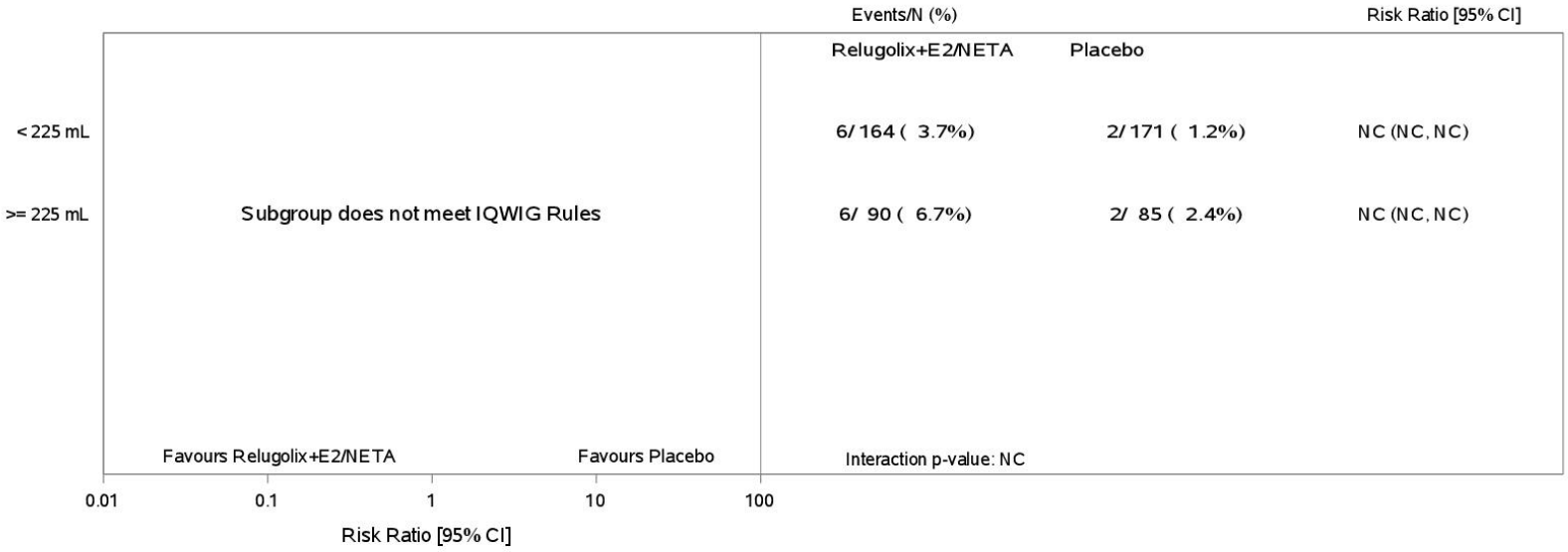
Figure SAF.TEAE.SPT.S5.BIN.FP.RR: Frequent Treatment Emergent Adverse Events by System Organ Class and Preferred Term, by Subgroup (Safety Population) - Risk Ratio
Study: Pooled
System Organ Class: Vascular disorders, Preferred Term: Hypertension
Subgroup: MBL Volume at Baseline (mL)



Results are based on a Cochran-Mantel-Haenszel approach stratified by study using a one-stage fixed-effects IPD meta-analysis. A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
The reference group is Placebo. Patients with multiple events are counted only once. MedDRA (version 22.0).
Patients with multiple events for a given PT or SOC are counted only once for each PT and SOC. Only SOCs or PTs for which there are at least 10% of patients with an event in at least one treatment group OR at least 10 patients with an event overall and at least 1% of patients with an event in at least one treatment group in the overall safety population are considered. Further, only SOCs and PTs for which there is a significant treatment effect (p-value <0.05) in the overall safety population are presented. Events are sorted alphabetically by SOC and PT and then by subgroup within each. MedDRA (version 22.0).
N: Number of patients in treatment group; NETA: Norethindrone acetate; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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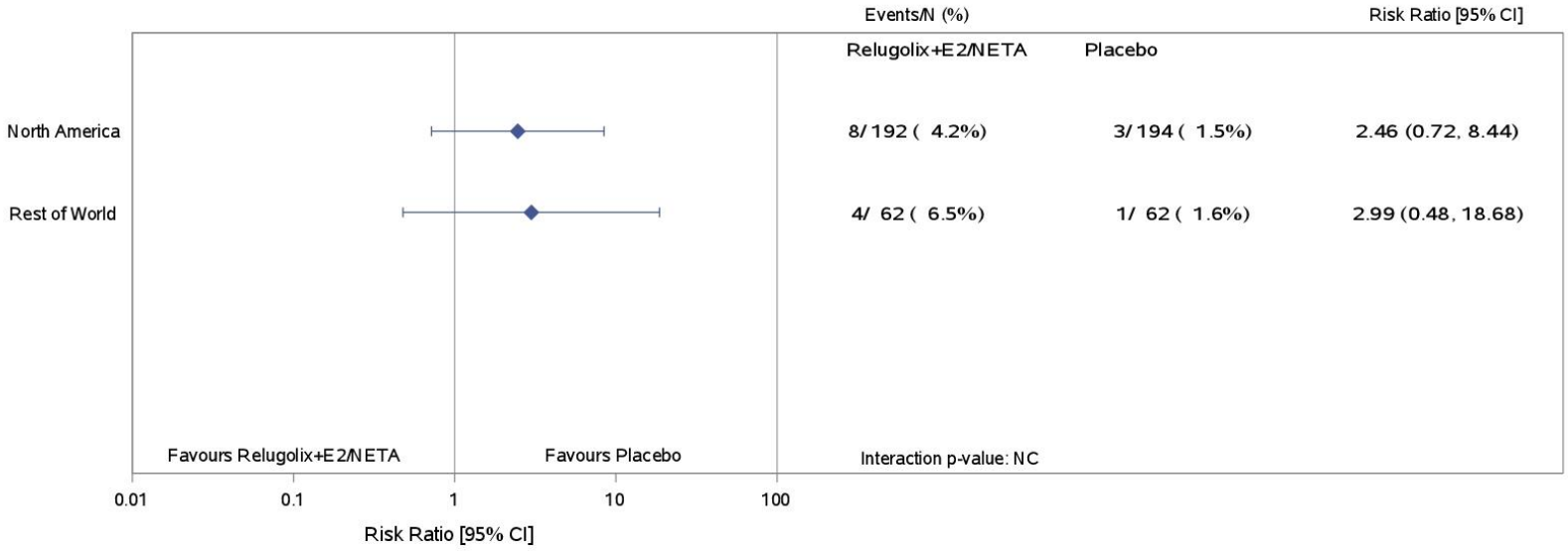
Figure SAF.TEAE.SPT.S6.BIN.FP.RR: Frequent Treatment Emergent Adverse Events by System Organ Class and Preferred Term, by Subgroup (Safety Population) - Risk Ratio
Study: Pooled
System Organ Class: Vascular disorders, Preferred Term: Hypertension
Subgroup: Geographic Region I



Results are based on a Cochran-Mantel-Haenszel approach stratified by study using a one-stage fixed-effects IPD meta-analysis. A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
The reference group is Placebo. Patients with multiple events are counted only once. MedDRA (version 22.0).
Patients with multiple events for a given PT or SOC are counted only once for each PT and SOC. Only SOCs or PTs for which there are at least 10% of patients with an event in at least one treatment group OR at least 10 patients with an event overall and at least 1% of patients with an event in at least one treatment group in the overall safety population are considered. Further, only SOCs and PTs for which there is a significant treatment effect (p-value <0.05) in the overall safety population are presented. Events are sorted alphabetically by SOC and PT and then by subgroup within each. MedDRA (version 22.0).
N: Number of patients in treatment group; NETA: Norethindrone acetate; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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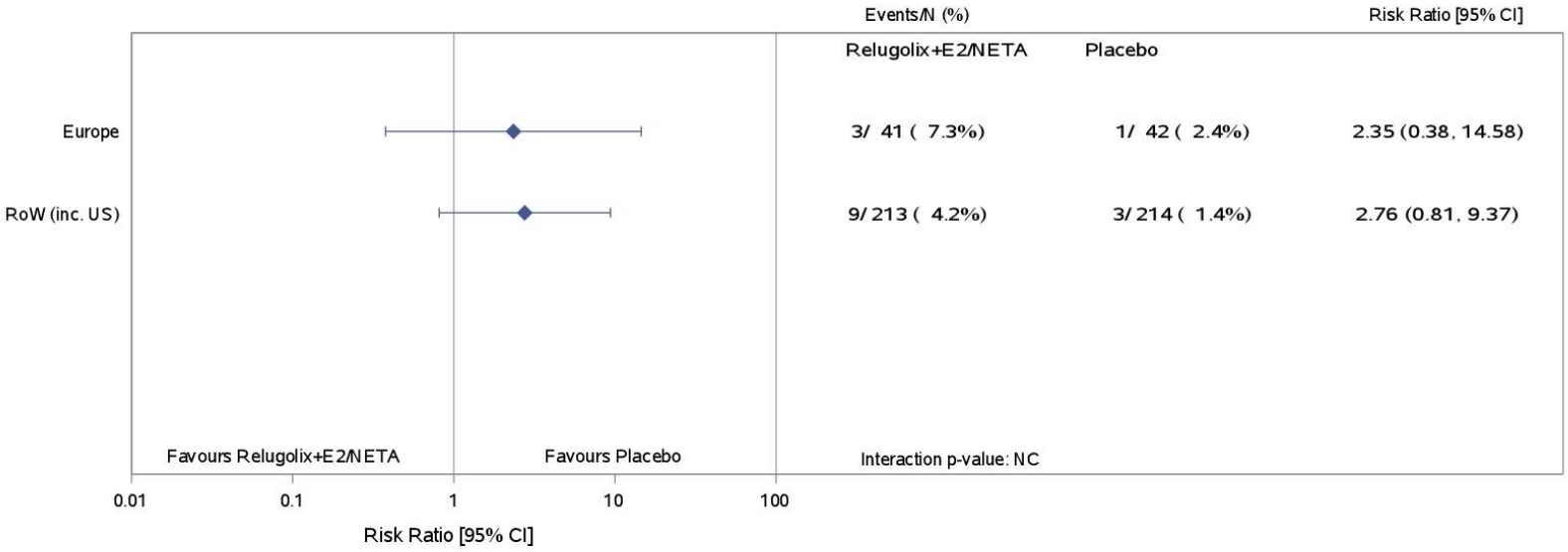
Figure SAF.TEAE.SPT.S7.BIN.FP.RR: Frequent Treatment Emergent Adverse Events by System Organ Class and Preferred Term, by Subgroup (Safety Population) - Risk Ratio
Study: Pooled
System Organ Class: Vascular disorders, Preferred Term: Hypertension
Subgroup: Geographic Region II



Results are based on a Cochran-Mantel-Haenszel approach stratified by study using a one-stage fixed-effects IPD meta-analysis. A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
The reference group is Placebo. Patients with multiple events are counted only once. MedDRA (version 22.0).
Patients with multiple events for a given PT or SOC are counted only once for each PT and SOC. Only SOCs or PTs for which there are at least 10% of patients with an event in at least one treatment group OR at least 10 patients with an event overall and at least 1% of patients with an event in at least one treatment group in the overall safety population are considered. Further, only SOCs and PTs for which there is a significant treatment effect (p-value <0.05) in the overall safety population are presented. Events are sorted alphabetically by SOC and PT and then by subgroup within each. MedDRA (version 22.0).
N: Number of patients in treatment group; NETA: Norethindrone acetate; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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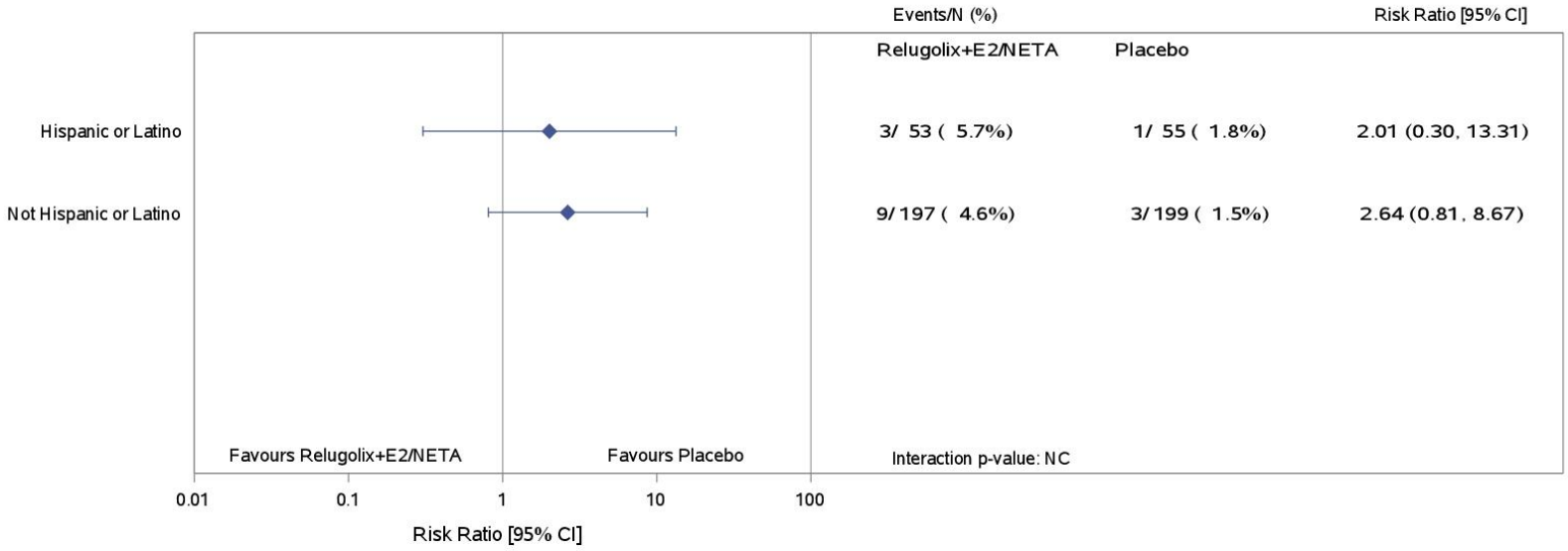
Figure SAF.TEAE.SPT.S8.BIN.FP.RR: Frequent Treatment Emergent Adverse Events by System Organ Class and Preferred Term, by Subgroup (Safety Population) - Risk Ratio
Study: Pooled
System Organ Class: Vascular disorders, Preferred Term: Hypertension
Subgroup: Ethnicity



Results are based on a Cochran-Mantel-Haenszel approach stratified by study using a one-stage fixed-effects IPD meta-analysis. A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
The reference group is Placebo. Patients with multiple events are counted only once. MedDRA (version 22.0).
Patients with multiple events for a given PT or SOC are counted only once for each PT and SOC. Only SOCs or PTs for which there are at least 10% of patients with an event in at least one treatment group OR at least 10 patients with an event overall and at least 1% of patients with an event in at least one treatment group in the overall safety population are considered. Further, only SOCs and PTs for which there is a significant treatment effect (p-value <0.05) in the overall safety population are presented. Events are sorted alphabetically by SOC and PT and then by subgroup within each. MedDRA (version 22.0).
N: Number of patients in treatment group; NETA: Norethindrone acetate; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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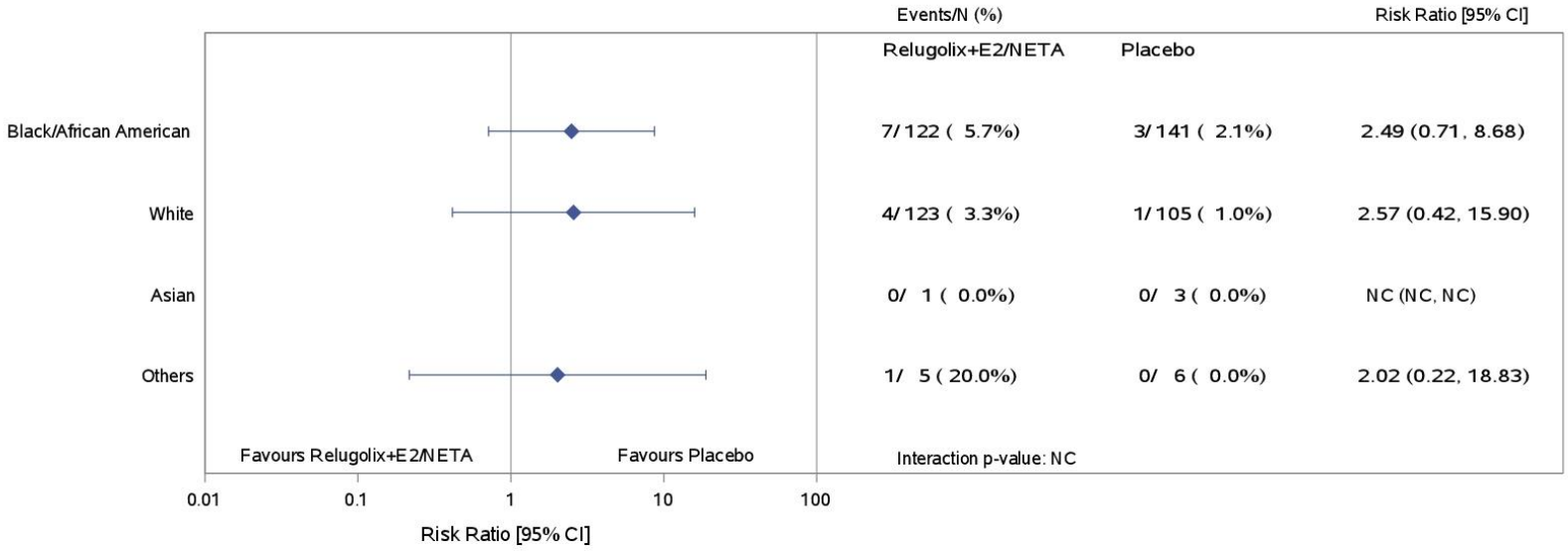
Figure SAF.TEAE.SPT.S9.BIN.FP.RR: Frequent Treatment Emergent Adverse Events by System Organ Class and Preferred Term, by Subgroup (Safety Population) - Risk Ratio
Study: Pooled
System Organ Class: Vascular disorders, Preferred Term: Hypertension
Subgroup: Race



Results are based on a Cochran-Mantel-Haenszel approach stratified by study using a one-stage fixed-effects IPD meta-analysis. A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
The reference group is Placebo. Patients with multiple events are counted only once. MedDRA (version 22.0).
Patients with multiple events for a given PT or SOC are counted only once for each PT and SOC. Only SOCs or PTs for which there are at least 10% of patients with an event in at least one treatment group OR at least 10 patients with an event overall and at least 1% of patients with an event in at least one treatment group in the overall safety population are considered. Further, only SOCs and PTs for which there is a significant treatment effect (p-value <0.05) in the overall safety population are presented. Events are sorted alphabetically by SOC and PT and then by subgroup within each. MedDRA (version 22.0).
N: Number of patients in treatment group; NETA: Norethindrone acetate; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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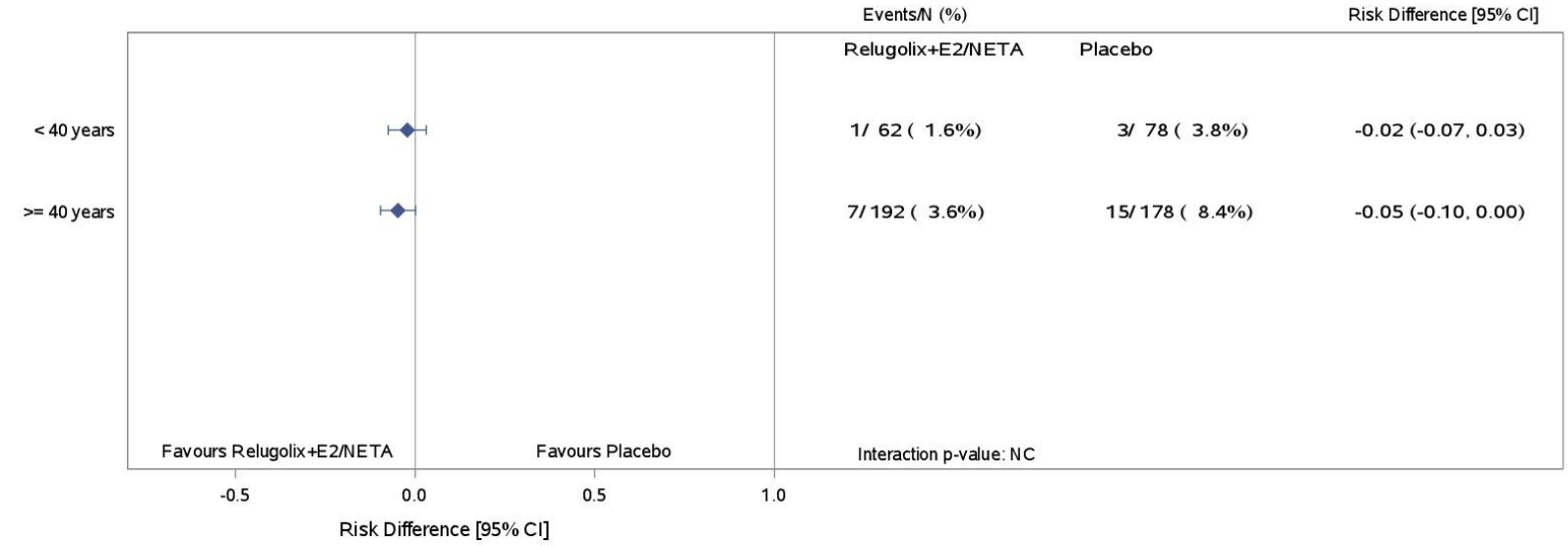
Figure SAF.TEAE.SPT.S1.BIN.FP.RD: Frequent Treatment Emergent Adverse Events by System Organ Class and Preferred Term, by Subgroup (Safety Population) - Risk Difference
Study: Pooled
System Organ Class: Blood and lymphatic system disorders, Preferred Term: Any
Subgroup: Age (years)



Results are based on a Mantel-Haenszel approach stratified by study using a one-stage fixed-effects IPD meta-analysis.
The reference group is Placebo. Patients with multiple events are counted only once. MedDRA (version 22.0).
Patients with multiple events for a given PT or SOC are counted only once for each PT and SOC. Only SOCs or PTs for which there are at least 10% of patients with an event in at least one treatment group OR at least 10 patients with an event overall and at least 1% of patients with an event in at least one treatment group in the overall safety population are considered. Further, only SOCs and PTs for which there is a significant treatment effect (p-value <0.05) in the overall safety population are presented. Events are sorted alphabetically by SOC and PT and then by subgroup within each. MedDRA (version 22.0).
N: Number of patients in treatment group; NETA: Norethindrone acetate; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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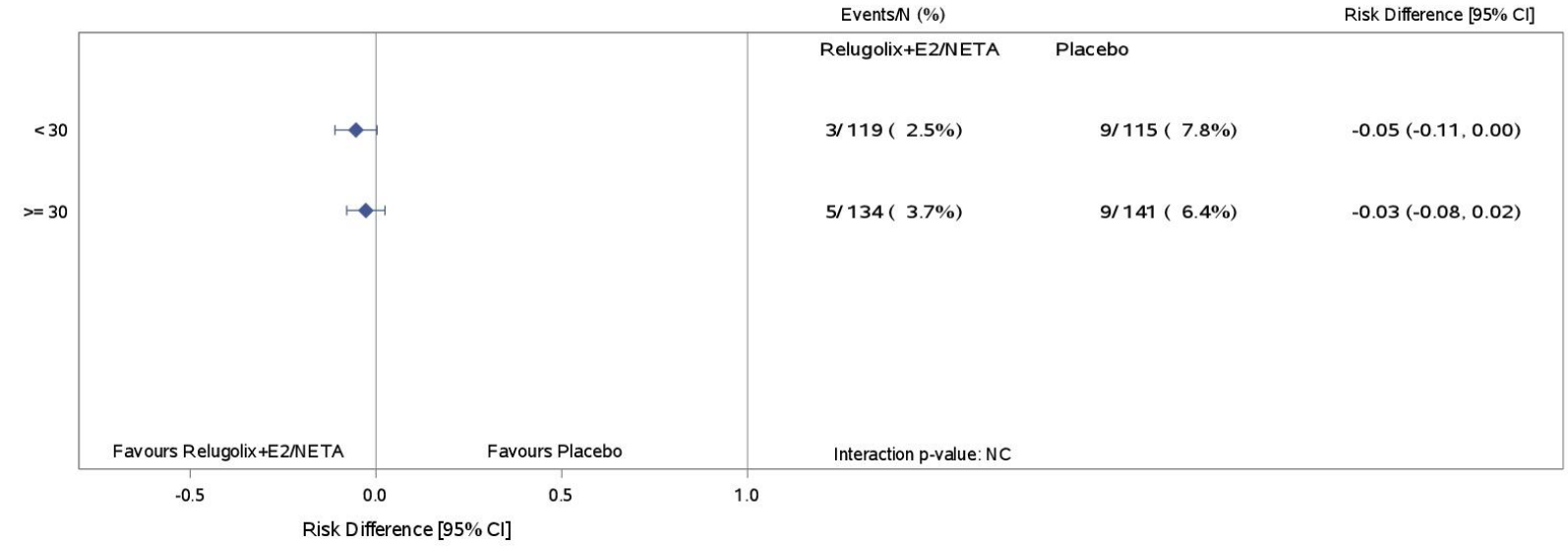
Figure SAF.TEAE.SPT.S2.BIN.FP.RD: Frequent Treatment Emergent Adverse Events by System Organ Class and Preferred Term, by Subgroup (Safety Population) - Risk Difference
Study: Pooled
System Organ Class: Blood and lymphatic system disorders, Preferred Term: Any
Subgroup: BMI (kg/m2) at Baseline



Results are based on a Mantel-Haenszel approach stratified by study using a one-stage fixed-effects IPD meta-analysis.
The reference group is Placebo. Patients with multiple events are counted only once. MedDRA (version 22.0).
Patients with multiple events for a given PT or SOC are counted only once for each PT and SOC. Only SOCs or PTs for which there are at least 10% of patients with an event in at least one treatment group OR at least 10 patients with an event overall and at least 1% of patients with an event in at least one treatment group in the overall safety population are considered. Further, only SOCs and PTs for which there is a significant treatment effect (p-value <0.05) in the overall safety population are presented. Events are sorted alphabetically by SOC and PT and then by subgroup within each. MedDRA (version 22.0).
N: Number of patients in treatment group; NETA: Norethindrone acetate; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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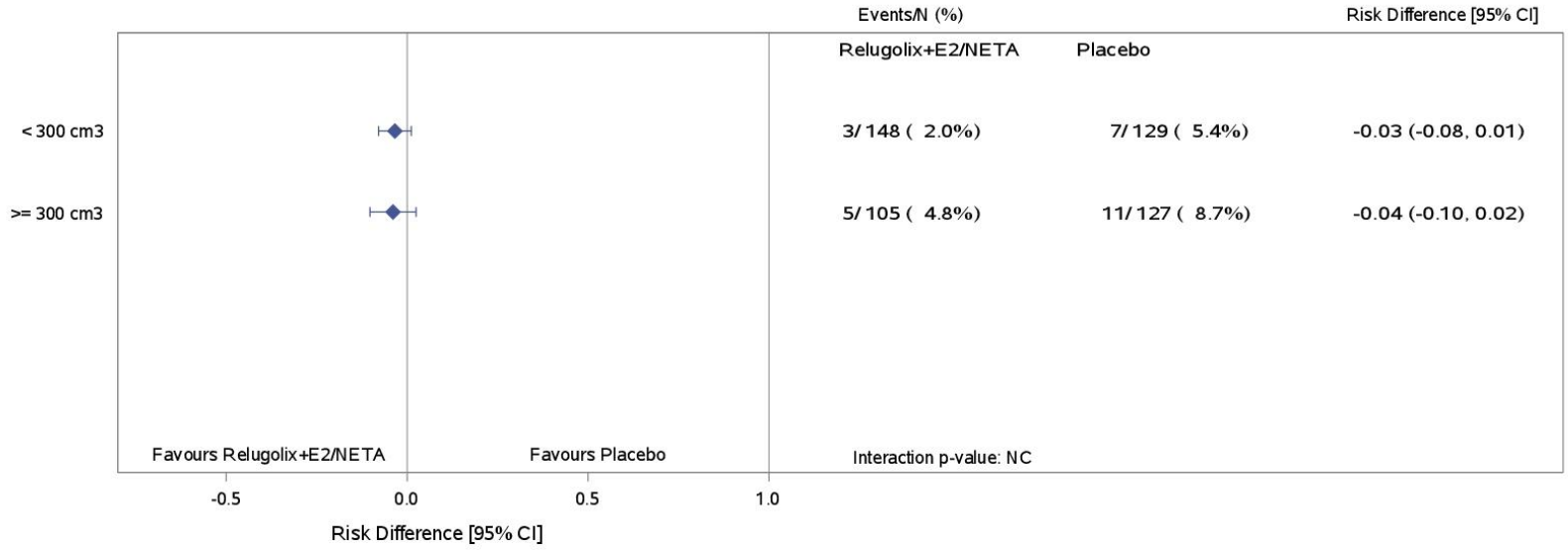
Figure SAF.TEAE.SPT.S3.BIN.FP.RD: Frequent Treatment Emergent Adverse Events by System Organ Class and Preferred Term, by Subgroup (Safety Population) - Risk Difference
Study: Pooled
System Organ Class: Blood and lymphatic system disorders, Preferred Term: Any
Subgroup: Uterine Volume at Baseline (cm3)



Results are based on a Mantel-Haenszel approach stratified by study using a one-stage fixed-effects IPD meta-analysis.
The reference group is Placebo. Patients with multiple events are counted only once. MedDRA (version 22.0).
Patients with multiple events for a given PT or SOC are counted only once for each PT and SOC. Only SOCs or PTs for which there are at least 10% of patients with an event in at least one treatment group OR at least 10 patients with an event overall and at least 1% of patients with an event in at least one treatment group in the overall safety population are considered. Further, only SOCs and PTs for which there is a significant treatment effect (p-value <0.05) in the overall safety population are presented. Events are sorted alphabetically by SOC and PT and then by subgroup within each. MedDRA (version 22.0).
N: Number of patients in treatment group; NETA: Norethindrone acetate; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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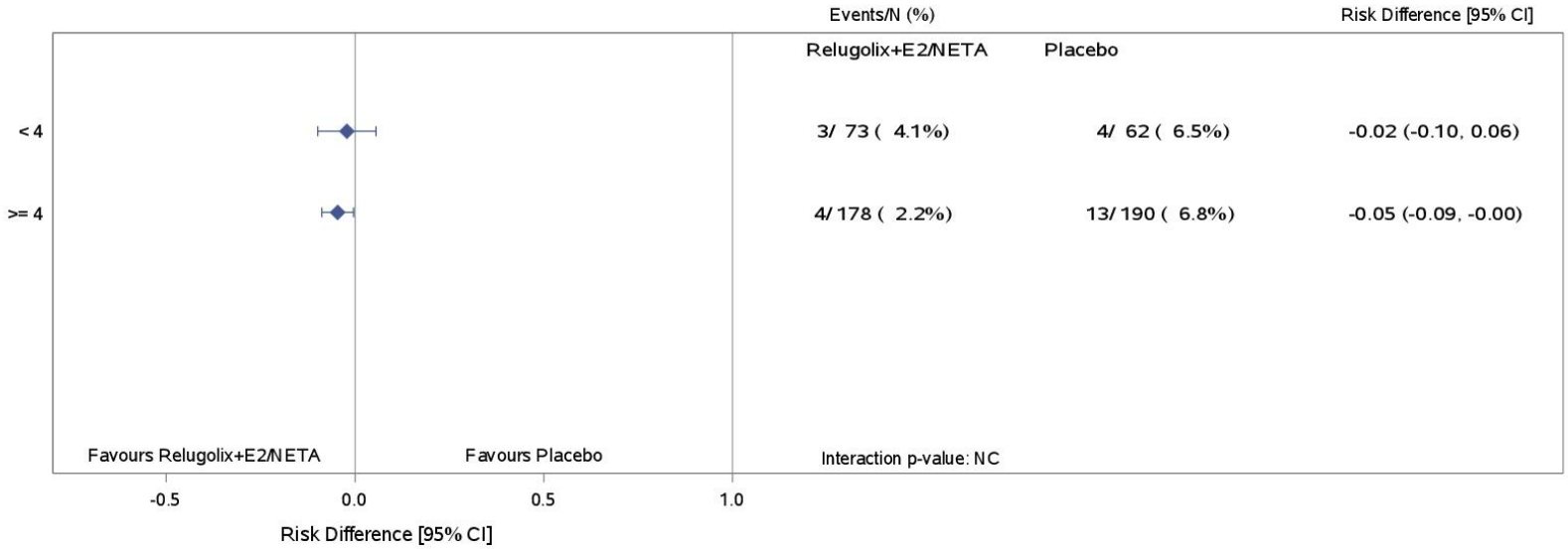
Figure SAF.TEAE.SPT.S4.BIN.FP.RD: Frequent Treatment Emergent Adverse Events by System Organ Class and Preferred Term, by Subgroup (Safety Population) - Risk Difference
Study: Pooled
System Organ Class: Blood and lymphatic system disorders, Preferred Term: Any
Subgroup: Maximum NRS Pain Score at Baseline



Results are based on a Mantel-Haenszel approach stratified by study using a one-stage fixed-effects IPD meta-analysis.
The reference group is Placebo. Patients with multiple events are counted only once. MedDRA (version 22.0).
Patients with multiple events for a given PT or SOC are counted only once for each PT and SOC. Only SOCs or PTs for which there are at least 10% of patients with an event in at least one treatment group OR at least 10 patients with an event overall and at least 1% of patients with an event in at least one treatment group in the overall safety population are considered. Further, only SOCs and PTs for which there is a significant treatment effect (p-value <0.05) in the overall safety population are presented. Events are sorted alphabetically by SOC and PT and then by subgroup within each. MedDRA (version 22.0).
N: Number of patients in treatment group; NETA: Norethindrone acetate; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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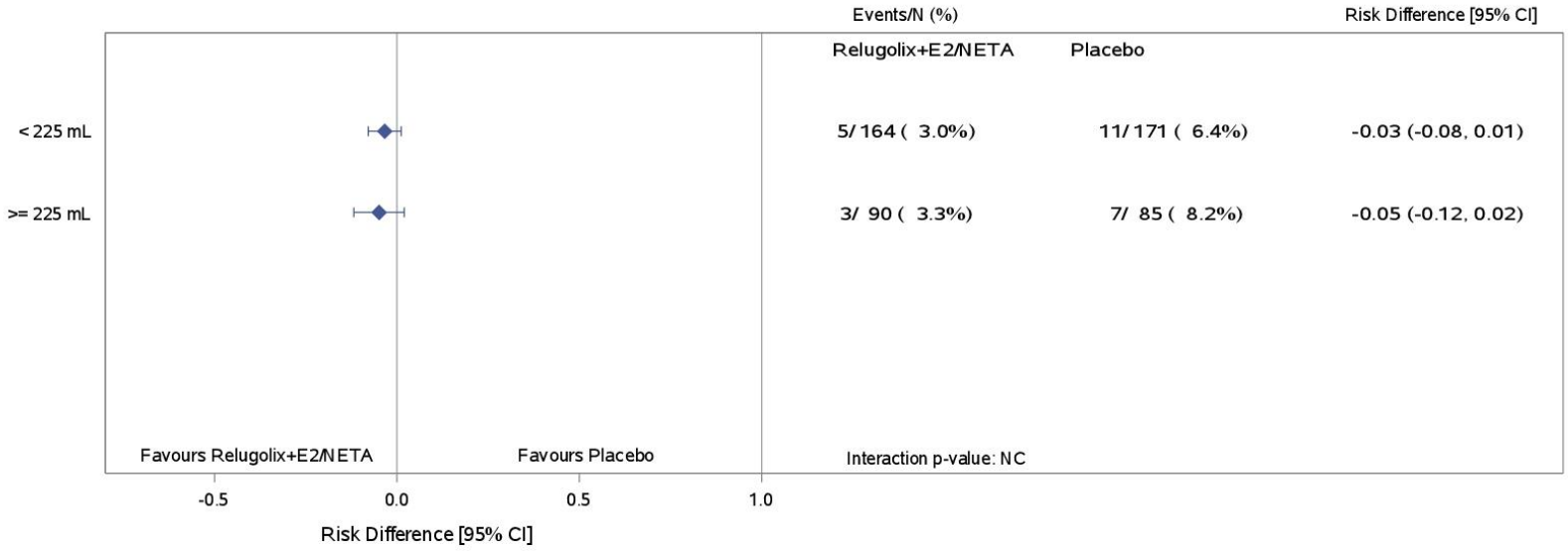
Figure SAF.TEAE.SPT.S5.BIN.FP.RD: Frequent Treatment Emergent Adverse Events by System Organ Class and Preferred Term, by Subgroup (Safety Population) - Risk Difference
Study: Pooled
System Organ Class: Blood and lymphatic system disorders, Preferred Term: Any
Subgroup: MBL Volume at Baseline (mL)



Results are based on a Mantel-Haenszel approach stratified by study using a one-stage fixed-effects IPD meta-analysis.
The reference group is Placebo. Patients with multiple events are counted only once. MedDRA (version 22.0).
Patients with multiple events for a given PT or SOC are counted only once for each PT and SOC. Only SOCs or PTs for which there are at least 10% of patients with an event in at least one treatment group OR at least 10 patients with an event overall and at least 1% of patients with an event in at least one treatment group in the overall safety population are considered. Further, only SOCs and PTs for which there is a significant treatment effect (p-value <0.05) in the overall safety population are presented. Events are sorted alphabetically by SOC and PT and then by subgroup within each. MedDRA (version 22.0).
N: Number of patients in treatment group; NETA: Norethindrone acetate; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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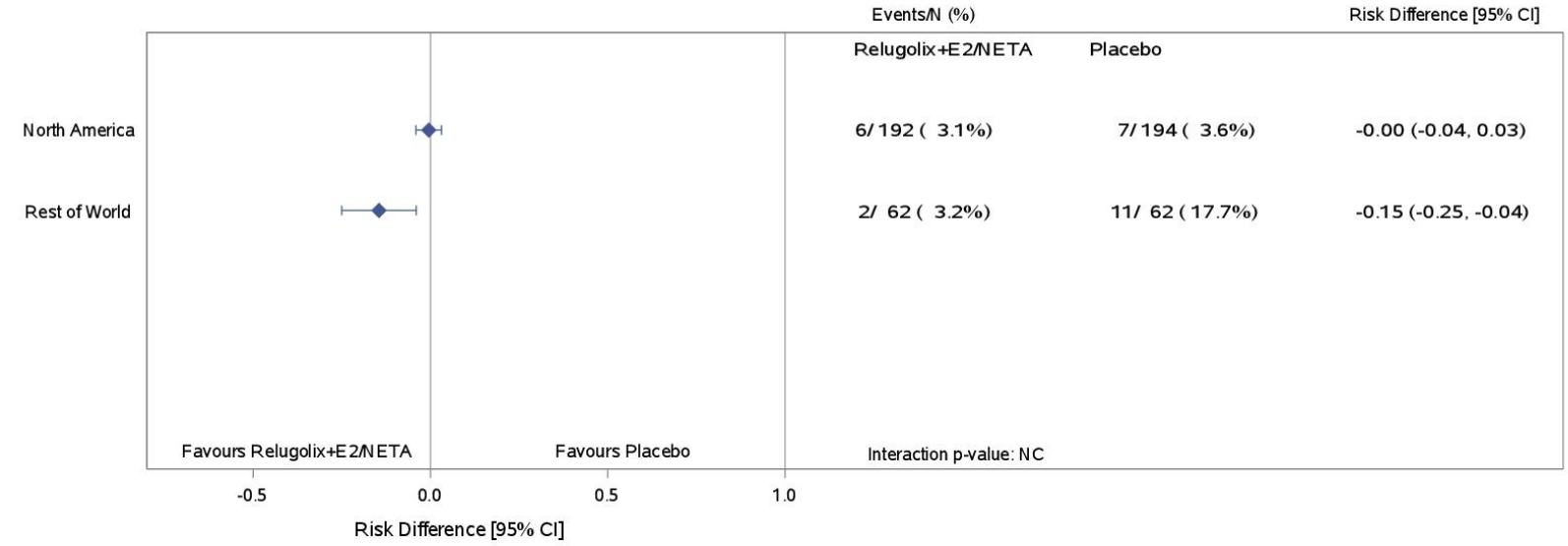
Figure SAF.TEAE.SPT.S6.BIN.FP.RD: Frequent Treatment Emergent Adverse Events by System Organ Class and Preferred Term, by Subgroup (Safety Population) - Risk Difference
Study: Pooled
System Organ Class: Blood and lymphatic system disorders, Preferred Term: Any
Subgroup: Geographic Region I



Results are based on a Mantel-Haenszel approach stratified by study using a one-stage fixed-effects IPD meta-analysis.
The reference group is Placebo. Patients with multiple events are counted only once. MedDRA (version 22.0).
Patients with multiple events for a given PT or SOC are counted only once for each PT and SOC. Only SOCs or PTs for which there are at least 10% of patients with an event in at least one treatment group OR at least 10 patients with an event overall and at least 1% of patients with an event in at least one treatment group in the overall safety population are considered. Further, only SOCs and PTs for which there is a significant treatment effect (p-value <0.05) in the overall safety population are presented. Events are sorted alphabetically by SOC and PT and then by subgroup within each. MedDRA (version 22.0).
N: Number of patients in treatment group; NETA: Norethindrone acetate; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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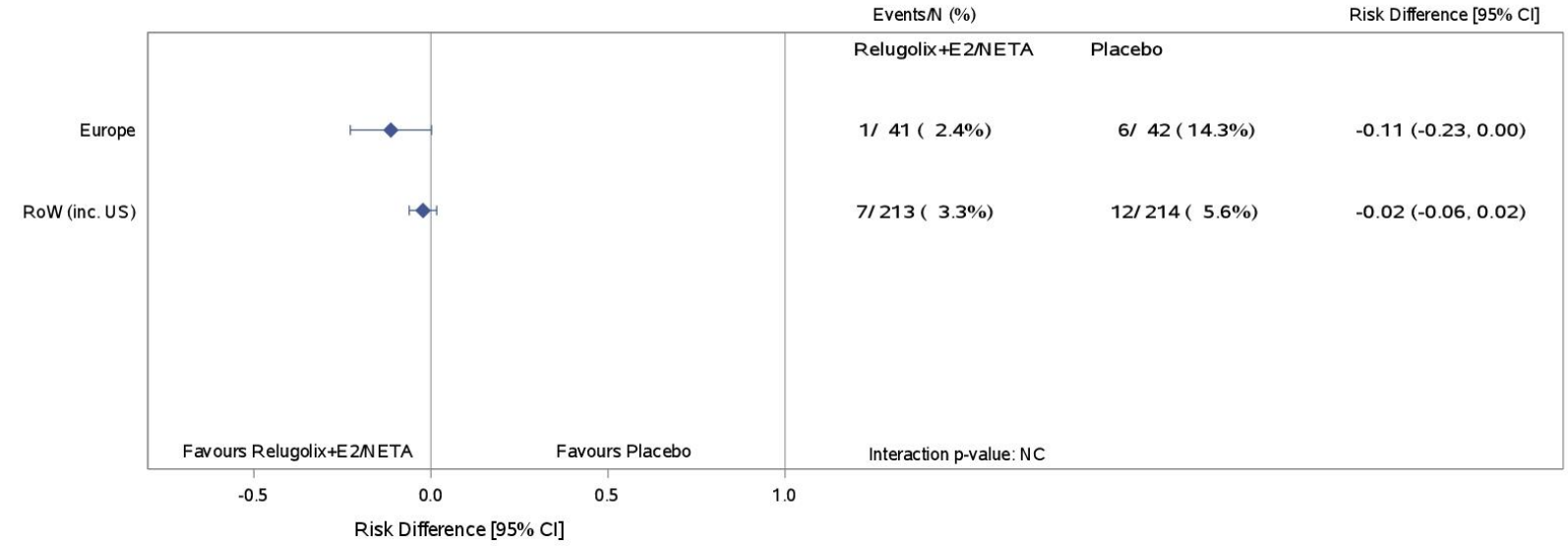
Figure SAF.TEAE.SPT.S7.BIN.FP.RD: Frequent Treatment Emergent Adverse Events by System Organ Class and Preferred Term, by Subgroup (Safety Population) - Risk Difference
Study: Pooled
System Organ Class: Blood and lymphatic system disorders, Preferred Term: Any
Subgroup: Geographic Region II



Results are based on a Mantel-Haenszel approach stratified by study using a one-stage fixed-effects IPD meta-analysis.
The reference group is Placebo. Patients with multiple events are counted only once. MedDRA (version 22.0).
Patients with multiple events for a given PT or SOC are counted only once for each PT and SOC. Only SOCs or PTs for which there are at least 10% of patients with an event in at least one treatment group OR at least 10 patients with an event overall and at least 1% of patients with an event in at least one treatment group in the overall safety population are considered. Further, only SOCs and PTs for which there is a significant treatment effect (p-value <0.05) in the overall safety population are presented. Events are sorted alphabetically by SOC and PT and then by subgroup within each. MedDRA (version 22.0).
N: Number of patients in treatment group; NETA: Norethindrone acetate; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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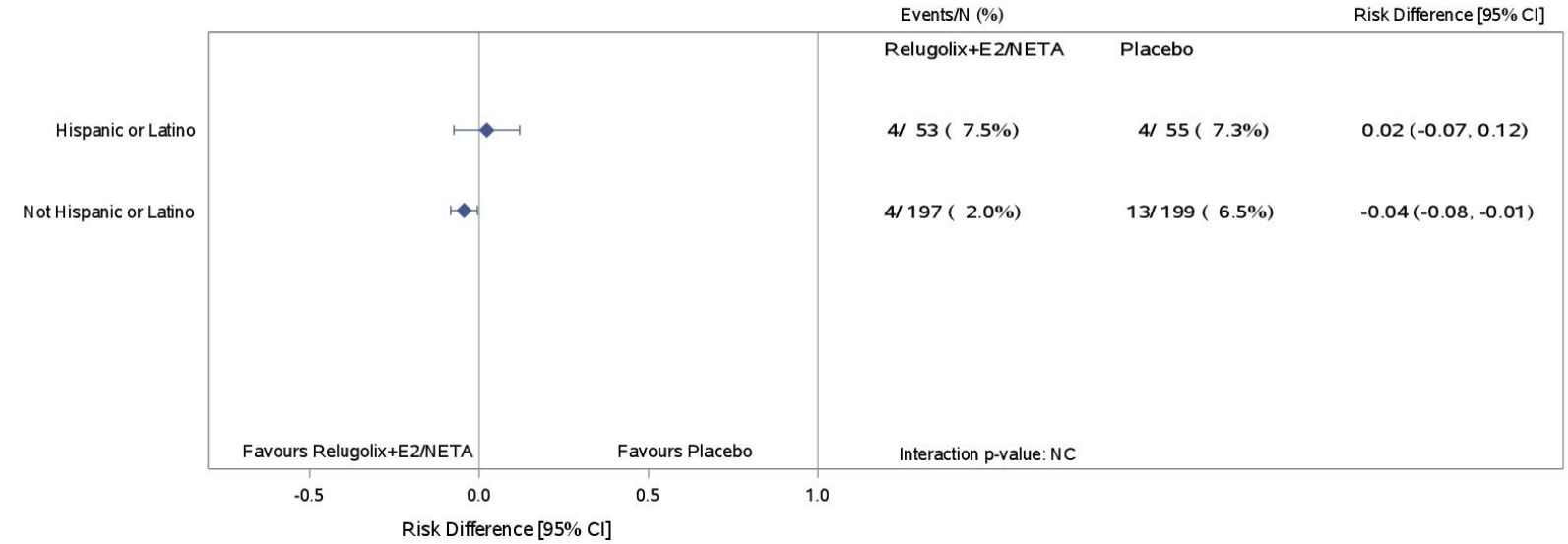
Figure SAF.TEAE.SPT.S8.BIN.FP.RD: Frequent Treatment Emergent Adverse Events by System Organ Class and Preferred Term, by Subgroup (Safety Population) - Risk Difference
Study: Pooled
System Organ Class: Blood and lymphatic system disorders, Preferred Term: Any
Subgroup: Ethnicity



Results are based on a Mantel-Haenszel approach stratified by study using a one-stage fixed-effects IPD meta-analysis.
The reference group is Placebo. Patients with multiple events are counted only once. MedDRA (version 22.0).
Patients with multiple events for a given PT or SOC are counted only once for each PT and SOC. Only SOCs or PTs for which there are at least 10% of patients with an event in at least one treatment group OR at least 10 patients with an event overall and at least 1% of patients with an event in at least one treatment group in the overall safety population are considered. Further, only SOCs and PTs for which there is a significant treatment effect (p-value <0.05) in the overall safety population are presented. Events are sorted alphabetically by SOC and PT and then by subgroup within each. MedDRA (version 22.0).
N: Number of patients in treatment group; NETA: Norethindrone acetate; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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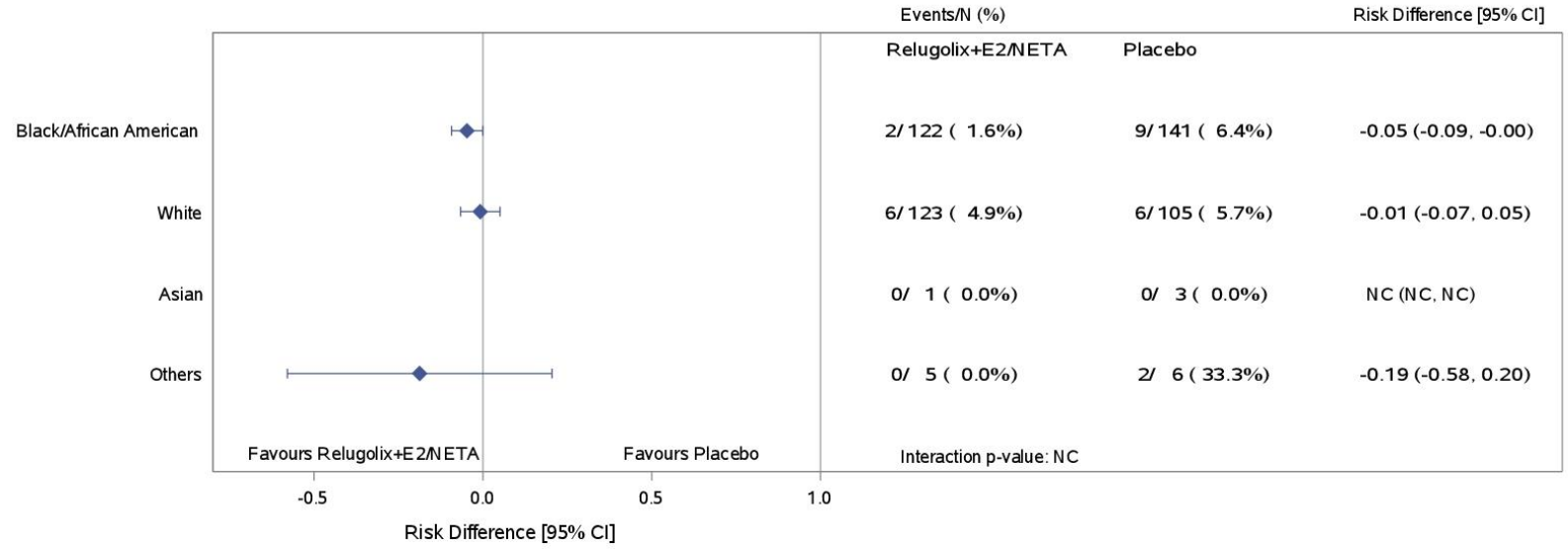
Figure SAF.TEAE.SPT.S9.BIN.FP.RD: Frequent Treatment Emergent Adverse Events by System Organ Class and Preferred Term, by Subgroup (Safety Population) - Risk Difference
Study: Pooled
System Organ Class: Blood and lymphatic system disorders, Preferred Term: Any
Subgroup: Race



Results are based on a Mantel-Haenszel approach stratified by study using a one-stage fixed-effects IPD meta-analysis.
The reference group is Placebo. Patients with multiple events are counted only once. MedDRA (version 22.0).
Patients with multiple events for a given PT or SOC are counted only once for each PT and SOC. Only SOCs or PTs for which there are at least 10% of patients with an event in at least one treatment group OR at least 10 patients with an event overall and at least 1% of patients with an event in at least one treatment group in the overall safety population are considered. Further, only SOCs and PTs for which there is a significant treatment effect (p-value <0.05) in the overall safety population are presented. Events are sorted alphabetically by SOC and PT and then by subgroup within each. MedDRA (version 22.0).
N: Number of patients in treatment group; NETA: Norethindrone acetate; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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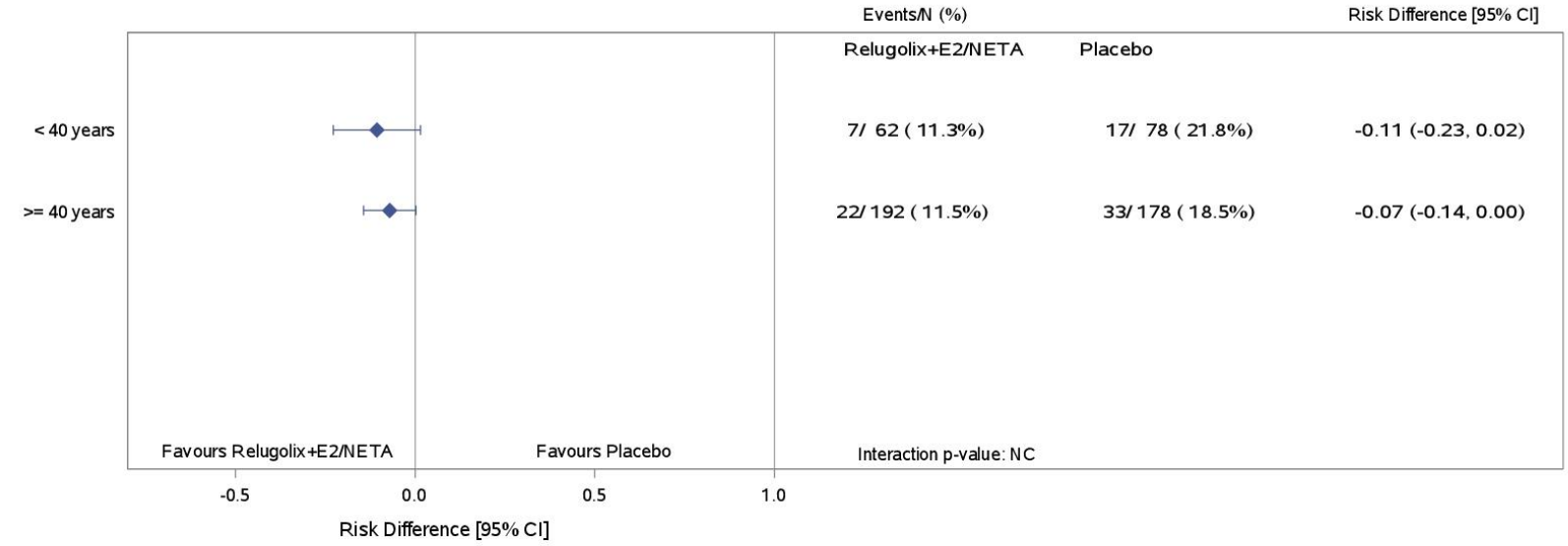
Figure SAF.TEAE.SPT.S1.BIN.FP.RD: Frequent Treatment Emergent Adverse Events by System Organ Class and Preferred Term, by Subgroup (Safety Population) - Risk Difference
Study: Pooled
System Organ Class: Nervous system disorders, Preferred Term: Any
Subgroup: Age (years)



Results are based on a Mantel-Haenszel approach stratified by study using a one-stage fixed-effects IPD meta-analysis.
The reference group is Placebo. Patients with multiple events are counted only once. MedDRA (version 22.0).
Patients with multiple events for a given PT or SOC are counted only once for each PT and SOC. Only SOCs or PTs for which there are at least 10% of patients with an event in at least one treatment group OR at least 10 patients with an event overall and at least 1% of patients with an event in at least one treatment group in the overall safety population are considered. Further, only SOCs and PTs for which there is a significant treatment effect (p-value <0.05) in the overall safety population are presented. Events are sorted alphabetically by SOC and PT and then by subgroup within each. MedDRA (version 22.0).
N: Number of patients in treatment group; NETA: Norethindrone acetate; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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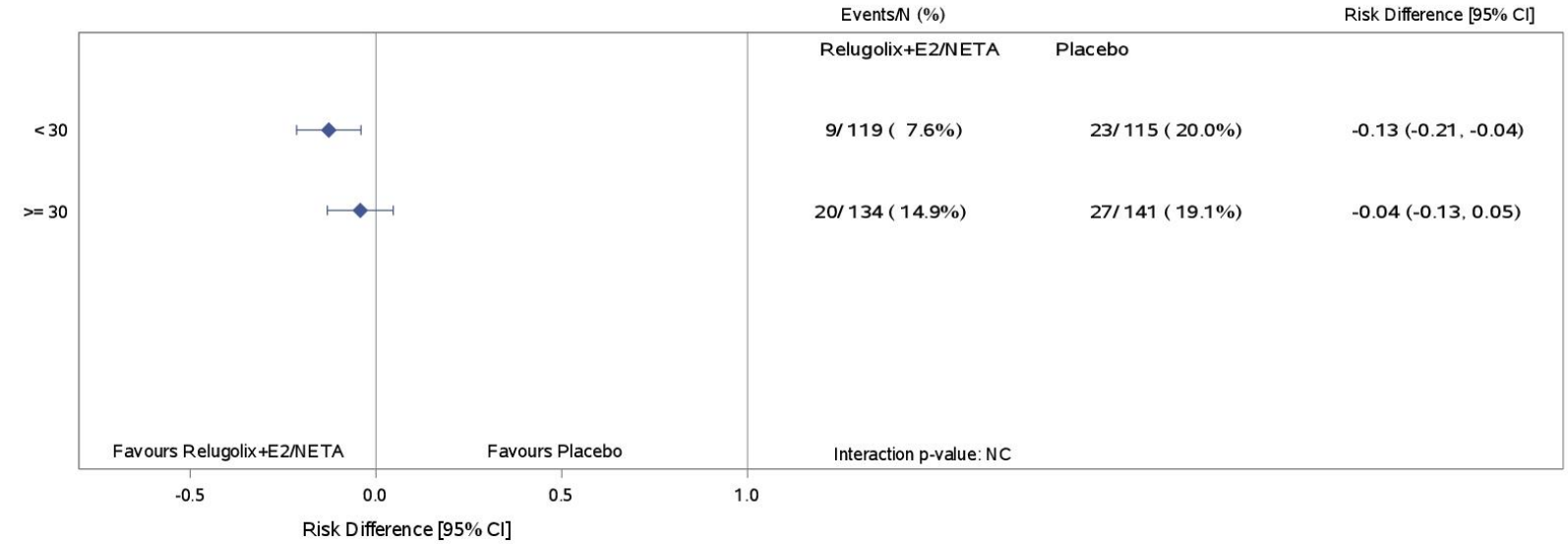
Figure SAF.TEAE.SPT.S2.BIN.FP.RD: Frequent Treatment Emergent Adverse Events by System Organ Class and Preferred Term, by Subgroup (Safety Population) - Risk Difference
Study: Pooled
System Organ Class: Nervous system disorders, Preferred Term: Any
Subgroup: BMI (kg/m2) at Baseline



Results are based on a Mantel-Haenszel approach stratified by study using a one-stage fixed-effects IPD meta-analysis.
The reference group is Placebo. Patients with multiple events are counted only once. MedDRA (version 22.0).
Patients with multiple events for a given PT or SOC are counted only once for each PT and SOC. Only SOCs or PTs for which there are at least 10% of patients with an event in at least one treatment group OR at least 10 patients with an event overall and at least 1% of patients with an event in at least one treatment group in the overall safety population are considered. Further, only SOCs and PTs for which there is a significant treatment effect (p-value <0.05) in the overall safety population are presented. Events are sorted alphabetically by SOC and PT and then by subgroup within each. MedDRA (version 22.0).
N: Number of patients in treatment group; NETA: Norethindrone acetate; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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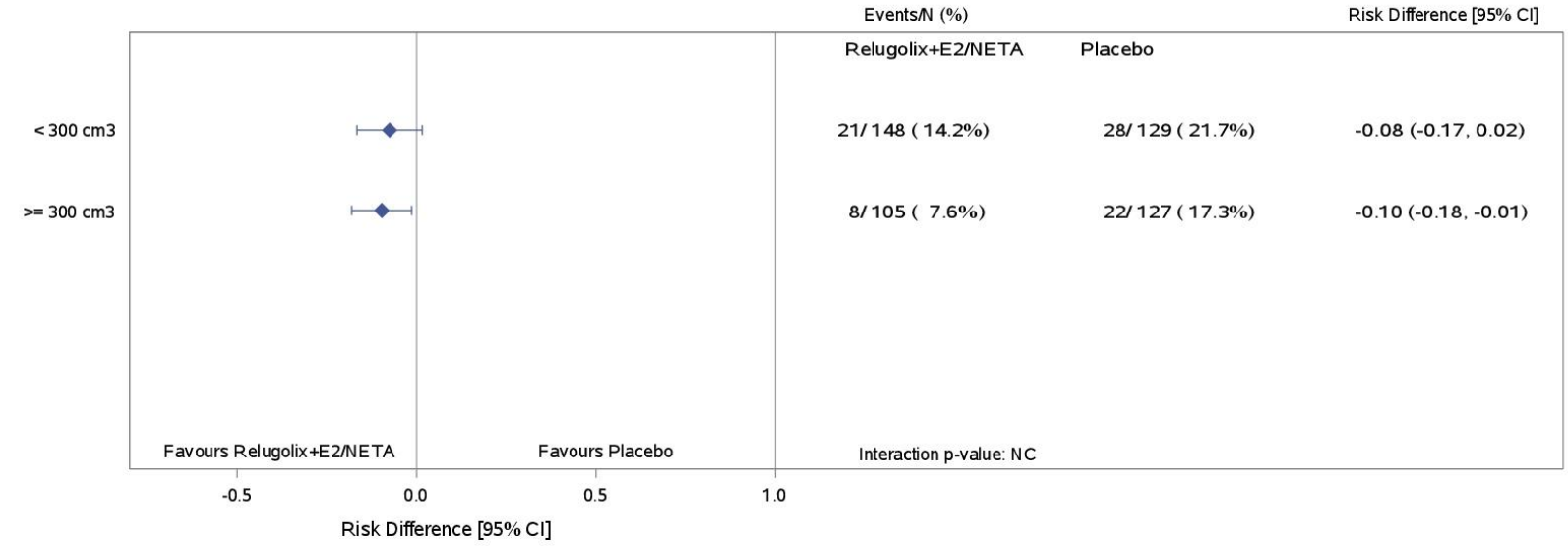
Figure SAF.TEAE.SPT.S3.BIN.FP.RD: Frequent Treatment Emergent Adverse Events by System Organ Class and Preferred Term, by Subgroup (Safety Population) - Risk Difference
Study: Pooled
System Organ Class: Nervous system disorders, Preferred Term: Any
Subgroup: Uterine Volume at Baseline (cm3)



Results are based on a Mantel-Haenszel approach stratified by study using a one-stage fixed-effects IPD meta-analysis.
The reference group is Placebo. Patients with multiple events are counted only once. MedDRA (version 22.0).
Patients with multiple events for a given PT or SOC are counted only once for each PT and SOC. Only SOCs or PTs for which there are at least 10% of patients with an event in at least one treatment group OR at least 10 patients with an event overall and at least 1% of patients with an event in at least one treatment group in the overall safety population are considered. Further, only SOCs and PTs for which there is a significant treatment effect (p-value <0.05) in the overall safety population are presented. Events are sorted alphabetically by SOC and PT and then by subgroup within each. MedDRA (version 22.0).
N: Number of patients in treatment group; NETA: Norethindrone acetate; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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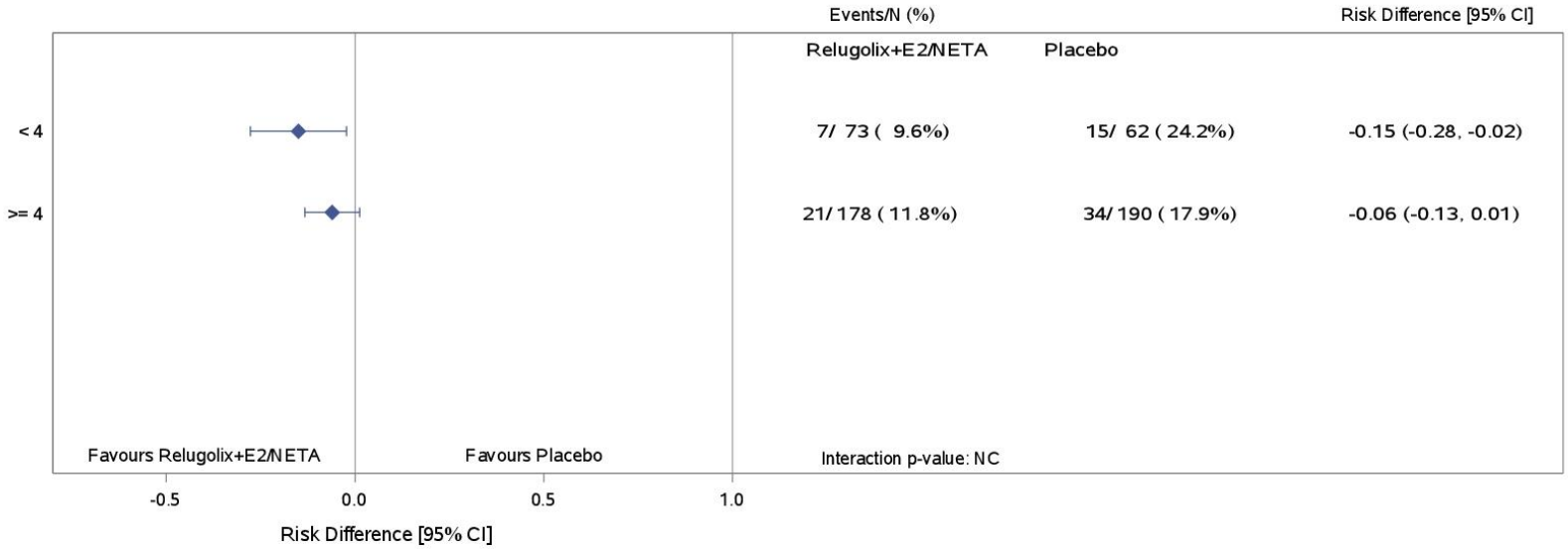
Figure SAF.TEAE.SPT.S4.BIN.FP.RD: Frequent Treatment Emergent Adverse Events by System Organ Class and Preferred Term, by Subgroup (Safety Population) - Risk Difference
Study: Pooled
System Organ Class: Nervous system disorders, Preferred Term: Any
Subgroup: Maximum NRS Pain Score at Baseline



Results are based on a Mantel-Haenszel approach stratified by study using a one-stage fixed-effects IPD meta-analysis.
The reference group is Placebo. Patients with multiple events are counted only once. MedDRA (version 22.0).
Patients with multiple events for a given PT or SOC are counted only once for each PT and SOC. Only SOCs or PTs for which there are at least 10% of patients with an event in at least one treatment group OR at least 10 patients with an event overall and at least 1% of patients with an event in at least one treatment group in the overall safety population are considered. Further, only SOCs and PTs for which there is a significant treatment effect (p-value <0.05) in the overall safety population are presented. Events are sorted alphabetically by SOC and PT and then by subgroup within each. MedDRA (version 22.0).
N: Number of patients in treatment group; NETA: Norethindrone acetate; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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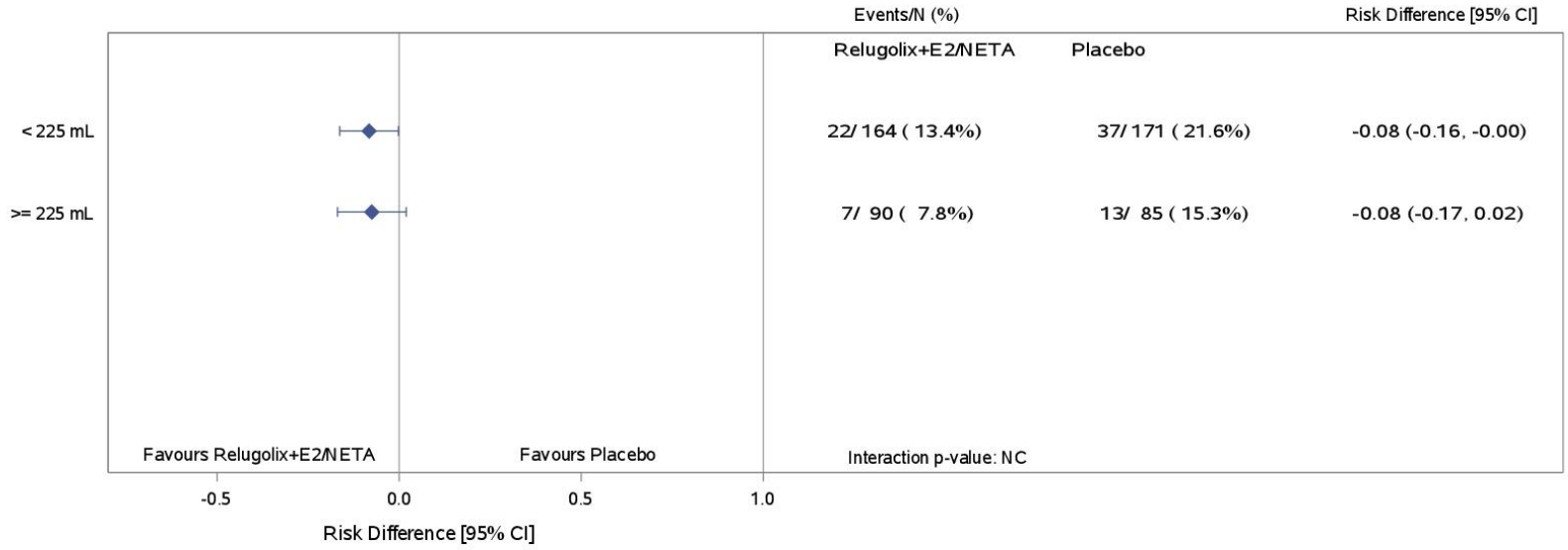
Figure SAF.TEAE.SPT.S5.BIN.FP.RD: Frequent Treatment Emergent Adverse Events by System Organ Class and Preferred Term, by Subgroup (Safety Population) - Risk Difference
Study: Pooled
System Organ Class: Nervous system disorders, Preferred Term: Any
Subgroup: MBL Volume at Baseline (mL)



Results are based on a Mantel-Haenszel approach stratified by study using a one-stage fixed-effects IPD meta-analysis.
The reference group is Placebo. Patients with multiple events are counted only once. MedDRA (version 22.0).
Patients with multiple events for a given PT or SOC are counted only once for each PT and SOC. Only SOCs or PTs for which there are at least 10% of patients with an event in at least one treatment group OR at least 10 patients with an event overall and at least 1% of patients with an event in at least one treatment group in the overall safety population are considered. Further, only SOCs and PTs for which there is a significant treatment effect (p-value <0.05) in the overall safety population are presented. Events are sorted alphabetically by SOC and PT and then by subgroup within each. MedDRA (version 22.0).
N: Number of patients in treatment group; NETA: Norethindrone acetate; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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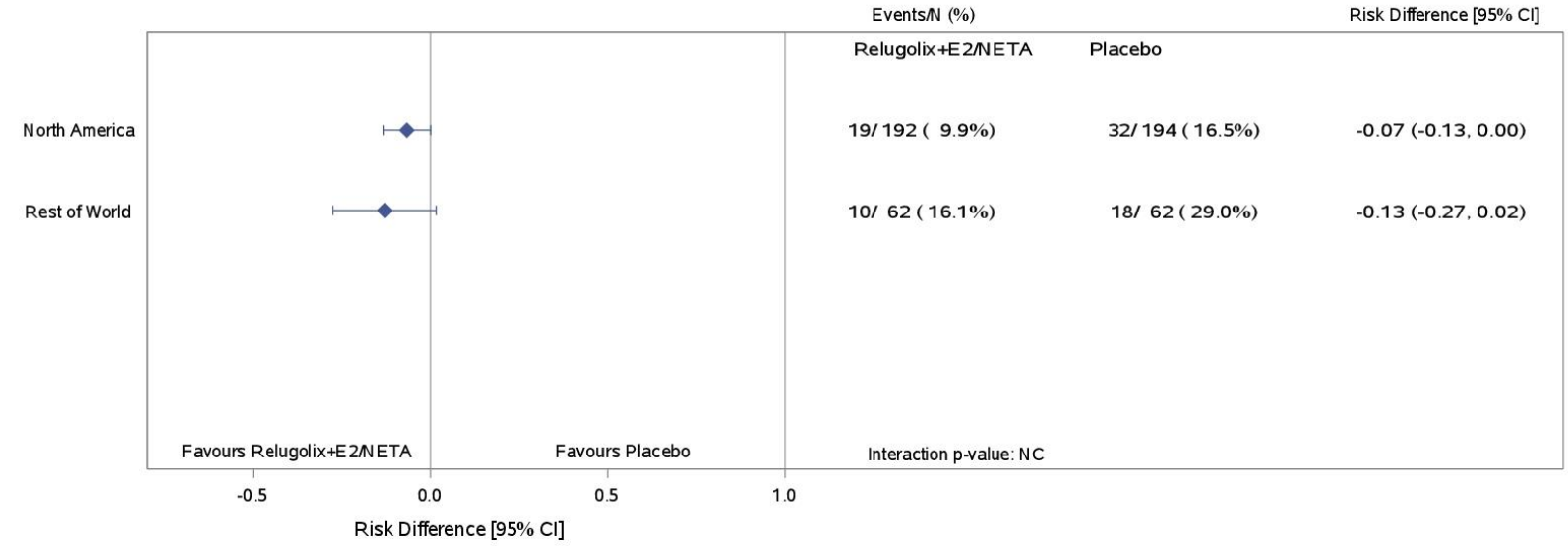
Figure SAF.TEAE.SPT.S6.BIN.FP.RD: Frequent Treatment Emergent Adverse Events by System Organ Class and Preferred Term, by Subgroup (Safety Population) - Risk Difference
Study: Pooled
System Organ Class: Nervous system disorders, Preferred Term: Any
Subgroup: Geographic Region I



Results are based on a Mantel-Haenszel approach stratified by study using a one-stage fixed-effects IPD meta-analysis.
The reference group is Placebo. Patients with multiple events are counted only once. MedDRA (version 22.0).
Patients with multiple events for a given PT or SOC are counted only once for each PT and SOC. Only SOCs or PTs for which there are at least 10% of patients with an event in at least one treatment group OR at least 10 patients with an event overall and at least 1% of patients with an event in at least one treatment group in the overall safety population are considered. Further, only SOCs and PTs for which there is a significant treatment effect (p-value <0.05) in the overall safety population are presented. Events are sorted alphabetically by SOC and PT and then by subgroup within each. MedDRA (version 22.0).
N: Number of patients in treatment group; NETA: Norethindrone acetate; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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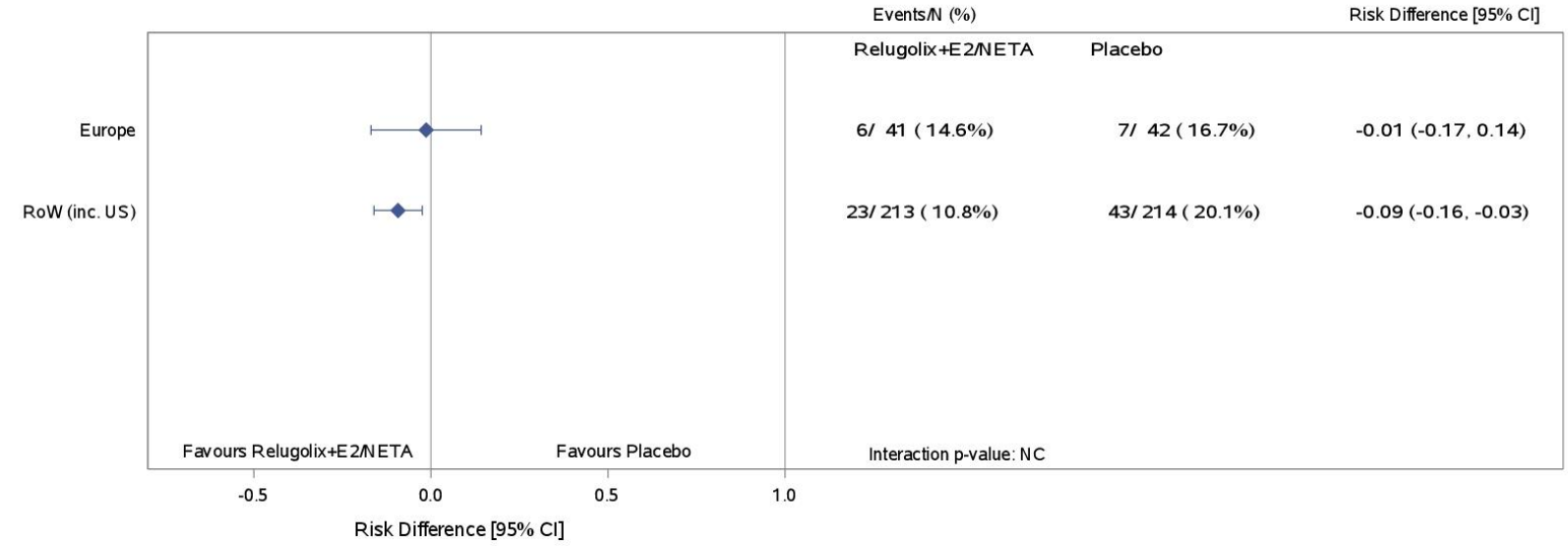
Figure SAF.TEAE.SPT.S7.BIN.FP.RD: Frequent Treatment Emergent Adverse Events by System Organ Class and Preferred Term, by Subgroup (Safety Population) - Risk Difference
Study: Pooled
System Organ Class: Nervous system disorders, Preferred Term: Any
Subgroup: Geographic Region II



Results are based on a Mantel-Haenszel approach stratified by study using a one-stage fixed-effects IPD meta-analysis.
The reference group is Placebo. Patients with multiple events are counted only once. MedDRA (version 22.0).
Patients with multiple events for a given PT or SOC are counted only once for each PT and SOC. Only SOCs or PTs for which there are at least 10% of patients with an event in at least one treatment group OR at least 10 patients with an event overall and at least 1% of patients with an event in at least one treatment group in the overall safety population are considered. Further, only SOCs and PTs for which there is a significant treatment effect (p-value <0.05) in the overall safety population are presented. Events are sorted alphabetically by SOC and PT and then by subgroup within each. MedDRA (version 22.0).
N: Number of patients in treatment group; NETA: Norethindrone acetate; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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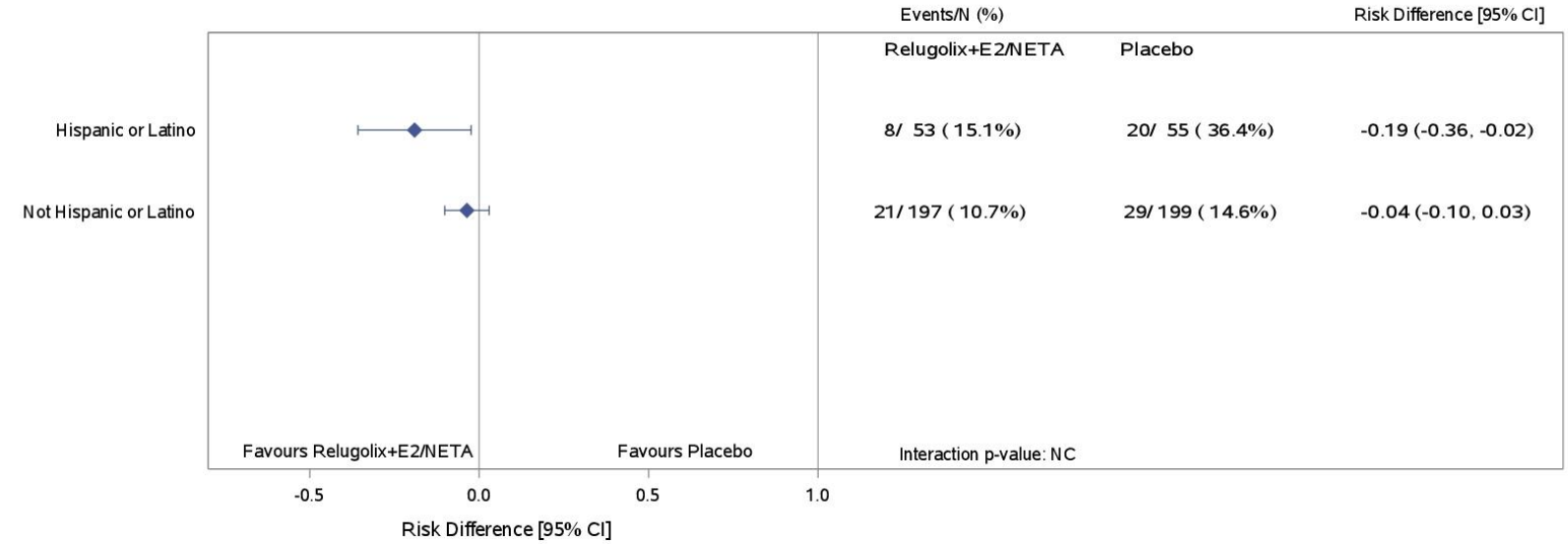
Figure SAF.TEAE.SPT.S8.BIN.FP.RD: Frequent Treatment Emergent Adverse Events by System Organ Class and Preferred Term, by Subgroup (Safety Population) - Risk Difference
Study: Pooled
System Organ Class: Nervous system disorders, Preferred Term: Any
Subgroup: Ethnicity



Results are based on a Mantel-Haenszel approach stratified by study using a one-stage fixed-effects IPD meta-analysis.
The reference group is Placebo. Patients with multiple events are counted only once. MedDRA (version 22.0).
Patients with multiple events for a given PT or SOC are counted only once for each PT and SOC. Only SOCs or PTs for which there are at least 10% of patients with an event in at least one treatment group OR at least 10 patients with an event overall and at least 1% of patients with an event in at least one treatment group in the overall safety population are considered. Further, only SOCs and PTs for which there is a significant treatment effect (p-value <0.05) in the overall safety population are presented. Events are sorted alphabetically by SOC and PT and then by subgroup within each. MedDRA (version 22.0).
N: Number of patients in treatment group; NETA: Norethindrone acetate; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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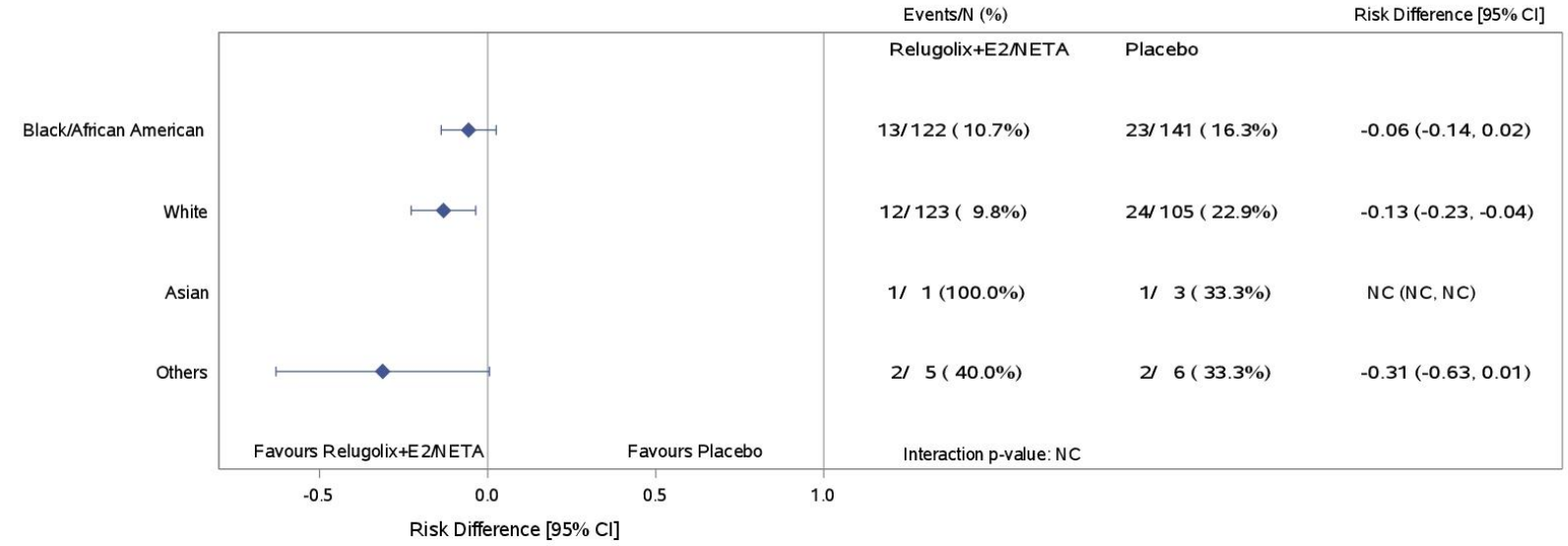
Figure SAF.TEAE.SPT.S9.BIN.FP.RD: Frequent Treatment Emergent Adverse Events by System Organ Class and Preferred Term, by Subgroup (Safety Population) - Risk Difference
Study: Pooled
System Organ Class: Nervous system disorders, Preferred Term: Any
Subgroup: Race



Results are based on a Mantel-Haenszel approach stratified by study using a one-stage fixed-effects IPD meta-analysis.
The reference group is Placebo. Patients with multiple events are counted only once. MedDRA (version 22.0).
Patients with multiple events for a given PT or SOC are counted only once for each PT and SOC. Only SOCs or PTs for which there are at least 10% of patients with an event in at least one treatment group OR at least 10 patients with an event overall and at least 1% of patients with an event in at least one treatment group in the overall safety population are considered. Further, only SOCs and PTs for which there is a significant treatment effect (p-value <0.05) in the overall safety population are presented. Events are sorted alphabetically by SOC and PT and then by subgroup within each. MedDRA (version 22.0).
N: Number of patients in treatment group; NETA: Norethindrone acetate; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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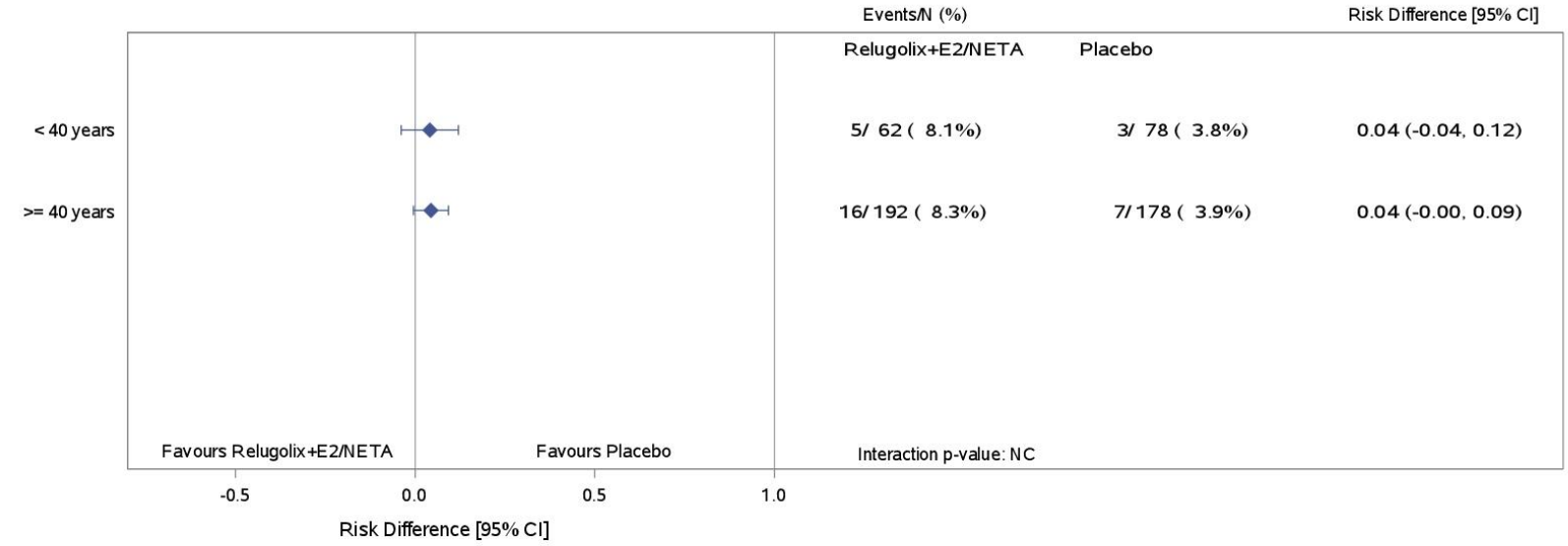
Figure SAF.TEAE.SPT.S1.BIN.FP.RD: Frequent Treatment Emergent Adverse Events by System Organ Class and Preferred Term, by Subgroup (Safety Population) - Risk Difference
Study: Pooled
System Organ Class: Psychiatric disorders, Preferred Term: Any
Subgroup: Age (years)



Results are based on a Mantel-Haenszel approach stratified by study using a one-stage fixed-effects IPD meta-analysis.
The reference group is Placebo. Patients with multiple events are counted only once. MedDRA (version 22.0).
Patients with multiple events for a given PT or SOC are counted only once for each PT and SOC. Only SOCs or PTs for which there are at least 10% of patients with an event in at least one treatment group OR at least 10 patients with an event overall and at least 1% of patients with an event in at least one treatment group in the overall safety population are considered. Further, only SOCs and PTs for which there is a significant treatment effect (p-value <0.05) in the overall safety population are presented. Events are sorted alphabetically by SOC and PT and then by subgroup within each. MedDRA (version 22.0).
N: Number of patients in treatment group; NETA: Norethindrone acetate; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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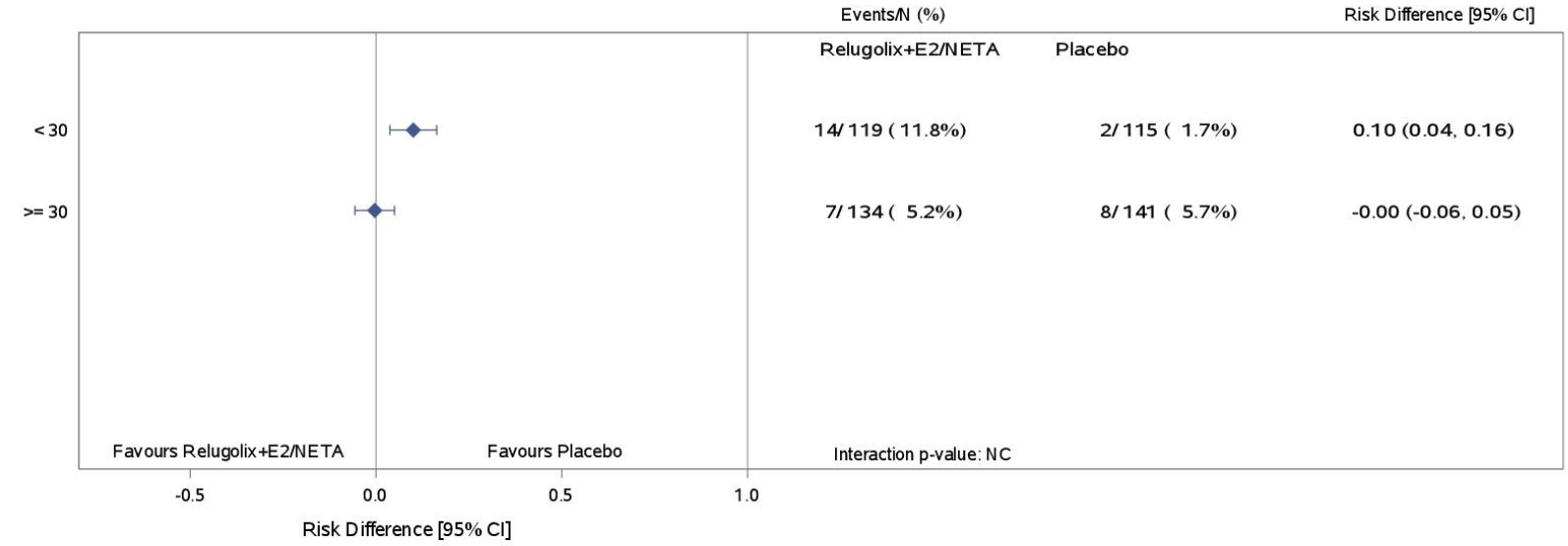
Figure SAF.TEAE.SPT.S2.BIN.FP.RD: Frequent Treatment Emergent Adverse Events by System Organ Class and Preferred Term, by Subgroup (Safety Population) - Risk Difference
Study: Pooled
System Organ Class: Psychiatric disorders, Preferred Term: Any
Subgroup: BMI (kg/m2) at Baseline



Results are based on a Mantel-Haenszel approach stratified by study using a one-stage fixed-effects IPD meta-analysis.
The reference group is Placebo. Patients with multiple events are counted only once. MedDRA (version 22.0).
Patients with multiple events for a given PT or SOC are counted only once for each PT and SOC. Only SOCs or PTs for which there are at least 10% of patients with an event in at least one treatment group OR at least 10 patients with an event overall and at least 1% of patients with an event in at least one treatment group in the overall safety population are considered. Further, only SOCs and PTs for which there is a significant treatment effect (p-value <0.05) in the overall safety population are presented. Events are sorted alphabetically by SOC and PT and then by subgroup within each. MedDRA (version 22.0).
N: Number of patients in treatment group; NETA: Norethindrone acetate; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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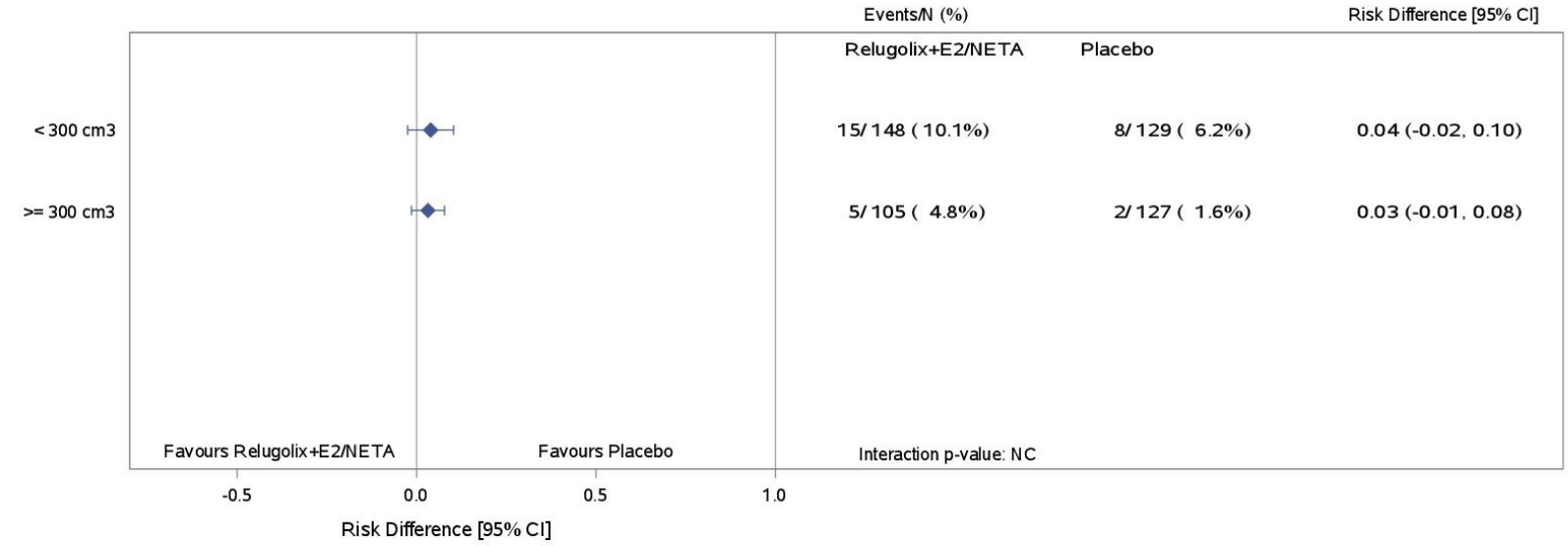
Figure SAF.TEAE.SPT.S3.BIN.FP.RD: Frequent Treatment Emergent Adverse Events by System Organ Class and Preferred Term, by Subgroup (Safety Population) - Risk Difference
Study: Pooled
System Organ Class: Psychiatric disorders, Preferred Term: Any
Subgroup: Uterine Volume at Baseline (cm3)



Results are based on a Mantel-Haenszel approach stratified by study using a one-stage fixed-effects IPD meta-analysis.
The reference group is Placebo. Patients with multiple events are counted only once. MedDRA (version 22.0).
Patients with multiple events for a given PT or SOC are counted only once for each PT and SOC. Only SOCs or PTs for which there are at least 10% of patients with an event in at least one treatment group OR at least 10 patients with an event overall and at least 1% of patients with an event in at least one treatment group in the overall safety population are considered. Further, only SOCs and PTs for which there is a significant treatment effect (p-value <0.05) in the overall safety population are presented. Events are sorted alphabetically by SOC and PT and then by subgroup within each. MedDRA (version 22.0).
N: Number of patients in treatment group; NETA: Norethindrone acetate; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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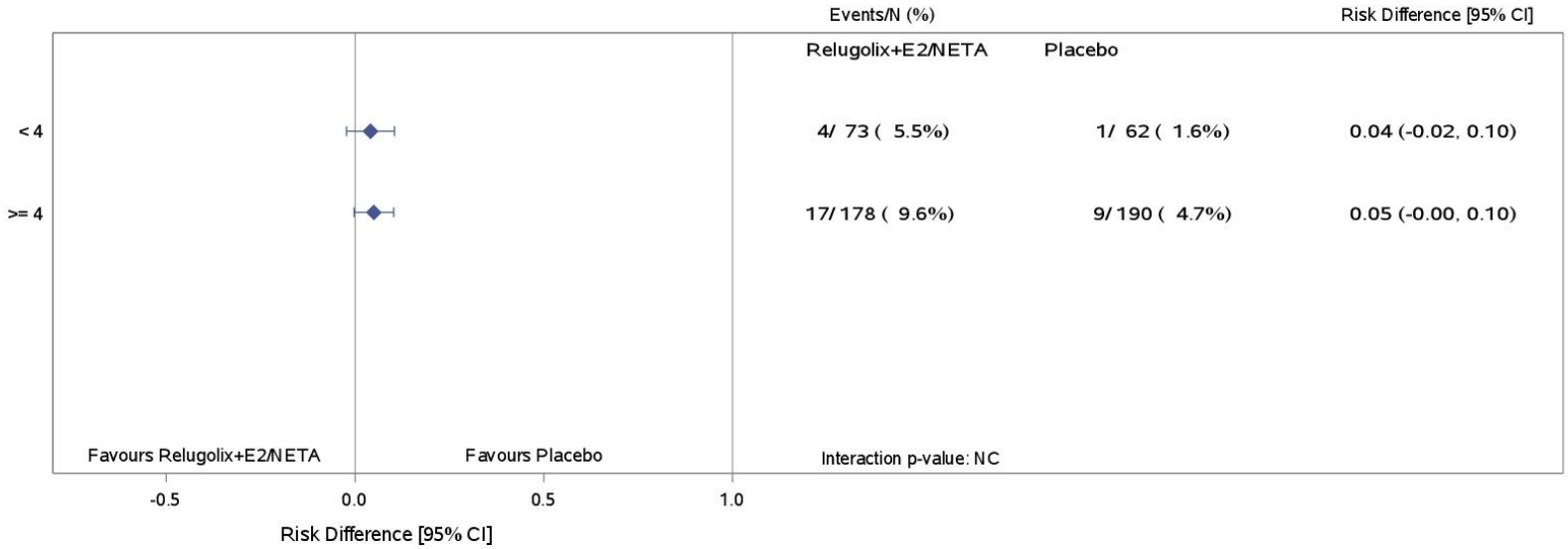
Figure SAF.TEAE.SPT.S4.BIN.FP.RD: Frequent Treatment Emergent Adverse Events by System Organ Class and Preferred Term, by Subgroup (Safety Population) - Risk Difference
Study: Pooled
System Organ Class: Psychiatric disorders, Preferred Term: Any
Subgroup: Maximum NRS Pain Score at Baseline



Results are based on a Mantel-Haenszel approach stratified by study using a one-stage fixed-effects IPD meta-analysis.
The reference group is Placebo. Patients with multiple events are counted only once. MedDRA (version 22.0).
Patients with multiple events for a given PT or SOC are counted only once for each PT and SOC. Only SOCs or PTs for which there are at least 10% of patients with an event in at least one treatment group OR at least 10 patients with an event overall and at least 1% of patients with an event in at least one treatment group in the overall safety population are considered. Further, only SOCs and PTs for which there is a significant treatment effect (p-value <0.05) in the overall safety population are presented. Events are sorted alphabetically by SOC and PT and then by subgroup within each. MedDRA (version 22.0).
N: Number of patients in treatment group; NETA: Norethindrone acetate; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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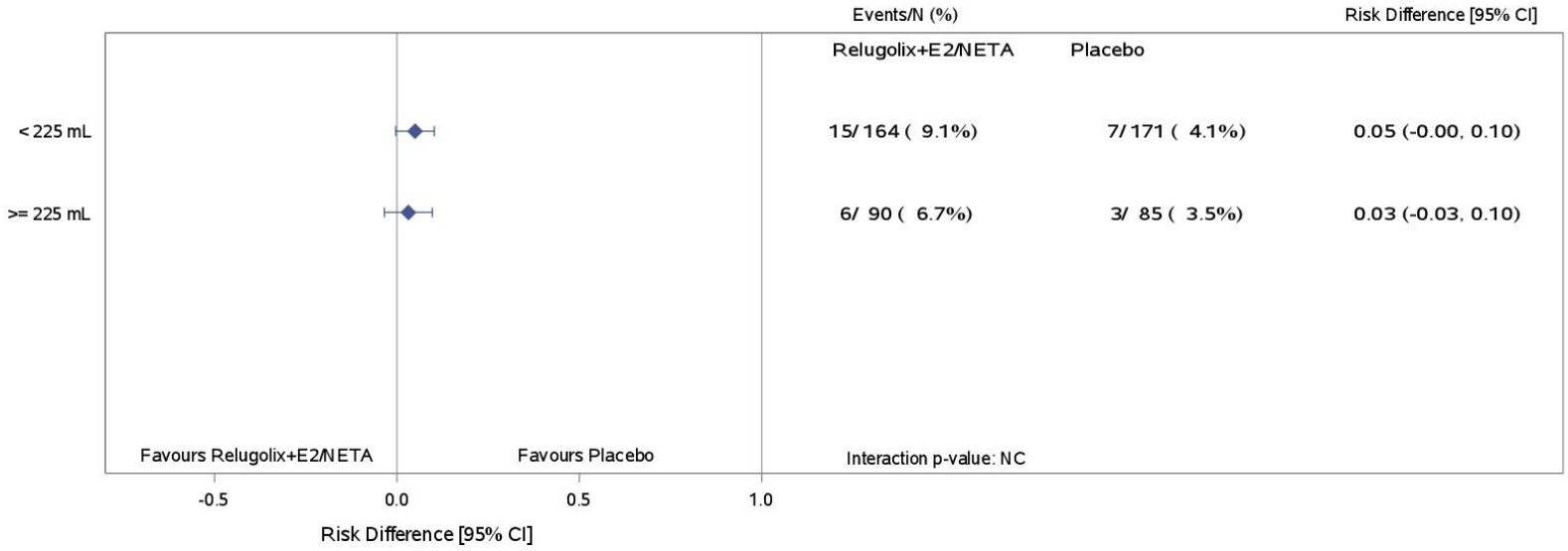
Figure SAF.TEAE.SPT.S5.BIN.FP.RD: Frequent Treatment Emergent Adverse Events by System Organ Class and Preferred Term, by Subgroup (Safety Population) - Risk Difference
Study: Pooled
System Organ Class: Psychiatric disorders, Preferred Term: Any
Subgroup: MBL Volume at Baseline (mL)



Results are based on a Mantel-Haenszel approach stratified by study using a one-stage fixed-effects IPD meta-analysis.
The reference group is Placebo. Patients with multiple events are counted only once. MedDRA (version 22.0).
Patients with multiple events for a given PT or SOC are counted only once for each PT and SOC. Only SOCs or PTs for which there are at least 10% of patients with an event in at least one treatment group OR at least 10 patients with an event overall and at least 1% of patients with an event in at least one treatment group in the overall safety population are considered. Further, only SOCs and PTs for which there is a significant treatment effect (p-value <0.05) in the overall safety population are presented. Events are sorted alphabetically by SOC and PT and then by subgroup within each. MedDRA (version 22.0).
N: Number of patients in treatment group; NETA: Norethindrone acetate; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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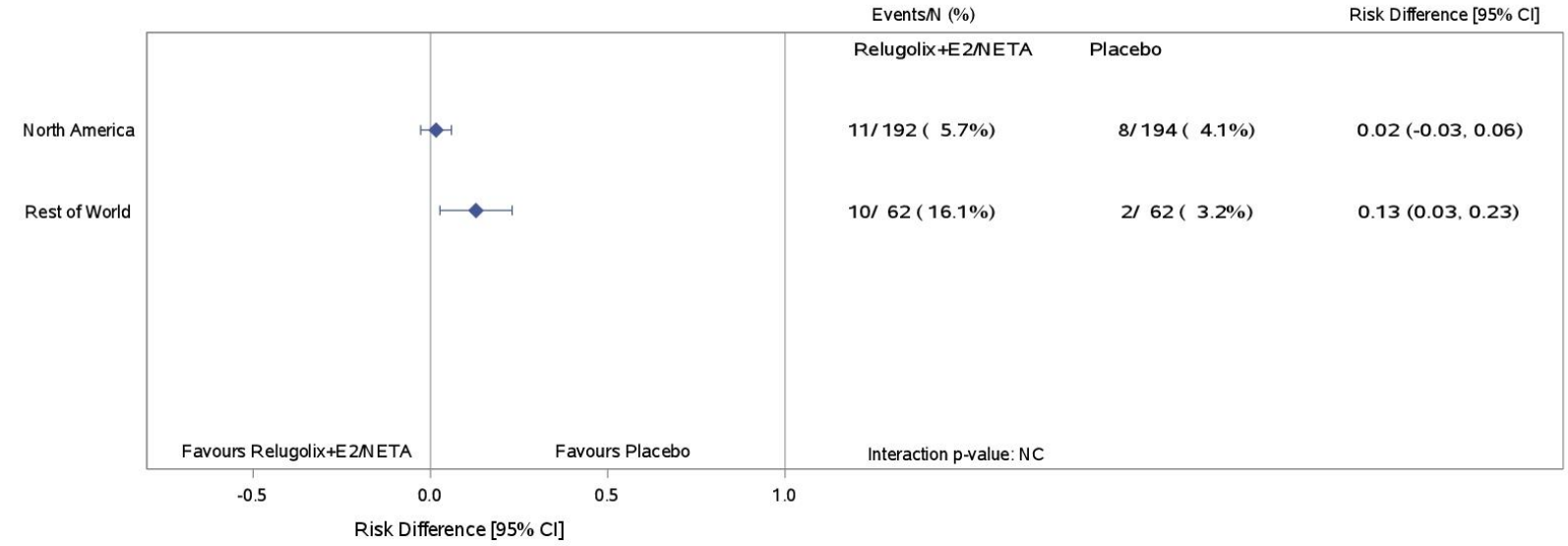
Figure SAF.TEAE.SPT.S6.BIN.FP.RD: Frequent Treatment Emergent Adverse Events by System Organ Class and Preferred Term, by Subgroup (Safety Population) - Risk Difference
Study: Pooled
System Organ Class: Psychiatric disorders, Preferred Term: Any
Subgroup: Geographic Region I



Results are based on a Mantel-Haenszel approach stratified by study using a one-stage fixed-effects IPD meta-analysis.
The reference group is Placebo. Patients with multiple events are counted only once. MedDRA (version 22.0).
Patients with multiple events for a given PT or SOC are counted only once for each PT and SOC. Only SOCs or PTs for which there are at least 10% of patients with an event in at least one treatment group OR at least 10 patients with an event overall and at least 1% of patients with an event in at least one treatment group in the overall safety population are considered. Further, only SOCs and PTs for which there is a significant treatment effect (p-value <0.05) in the overall safety population are presented. Events are sorted alphabetically by SOC and PT and then by subgroup within each. MedDRA (version 22.0).
N: Number of patients in treatment group; NETA: Norethindrone acetate; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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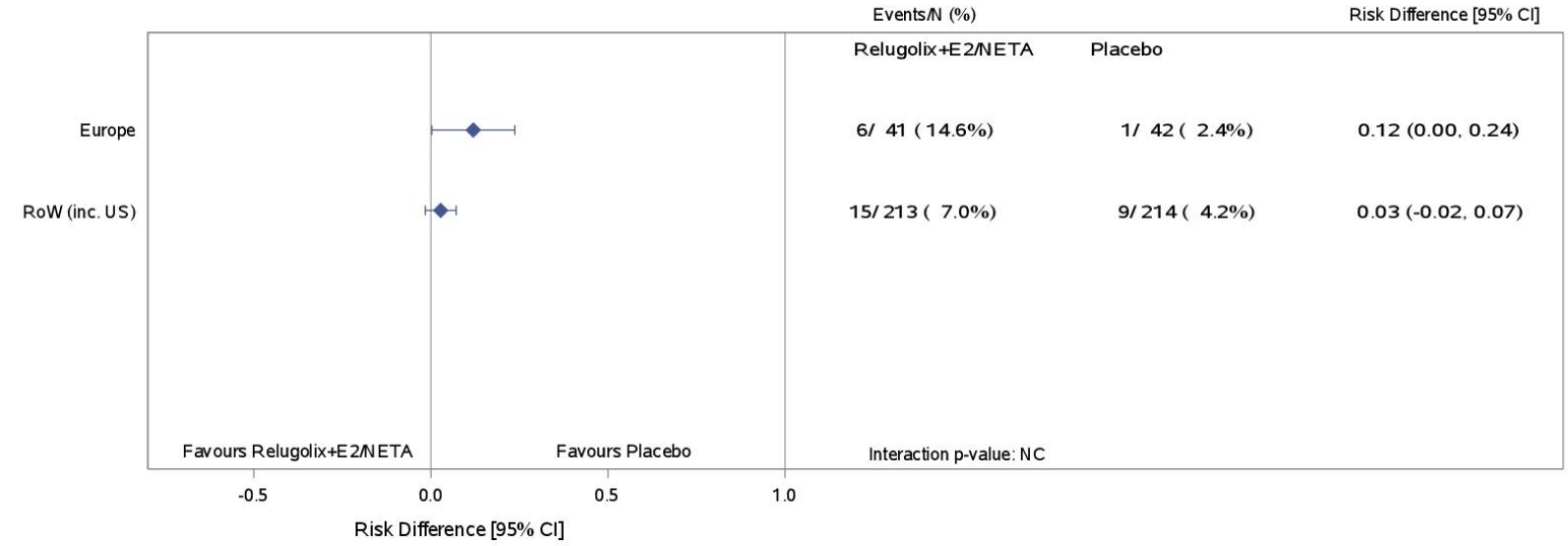
Figure SAF.TEAE.SPT.S7.BIN.FP.RD: Frequent Treatment Emergent Adverse Events by System Organ Class and Preferred Term, by Subgroup (Safety Population) - Risk Difference
Study: Pooled
System Organ Class: Psychiatric disorders, Preferred Term: Any
Subgroup: Geographic Region II



Results are based on a Mantel-Haenszel approach stratified by study using a one-stage fixed-effects IPD meta-analysis.
The reference group is Placebo. Patients with multiple events are counted only once. MedDRA (version 22.0).
Patients with multiple events for a given PT or SOC are counted only once for each PT and SOC. Only SOCs or PTs for which there are at least 10% of patients with an event in at least one treatment group OR at least 10 patients with an event overall and at least 1% of patients with an event in at least one treatment group in the overall safety population are considered. Further, only SOCs and PTs for which there is a significant treatment effect (p-value <0.05) in the overall safety population are presented. Events are sorted alphabetically by SOC and PT and then by subgroup within each. MedDRA (version 22.0).
N: Number of patients in treatment group; NETA: Norethindrone acetate; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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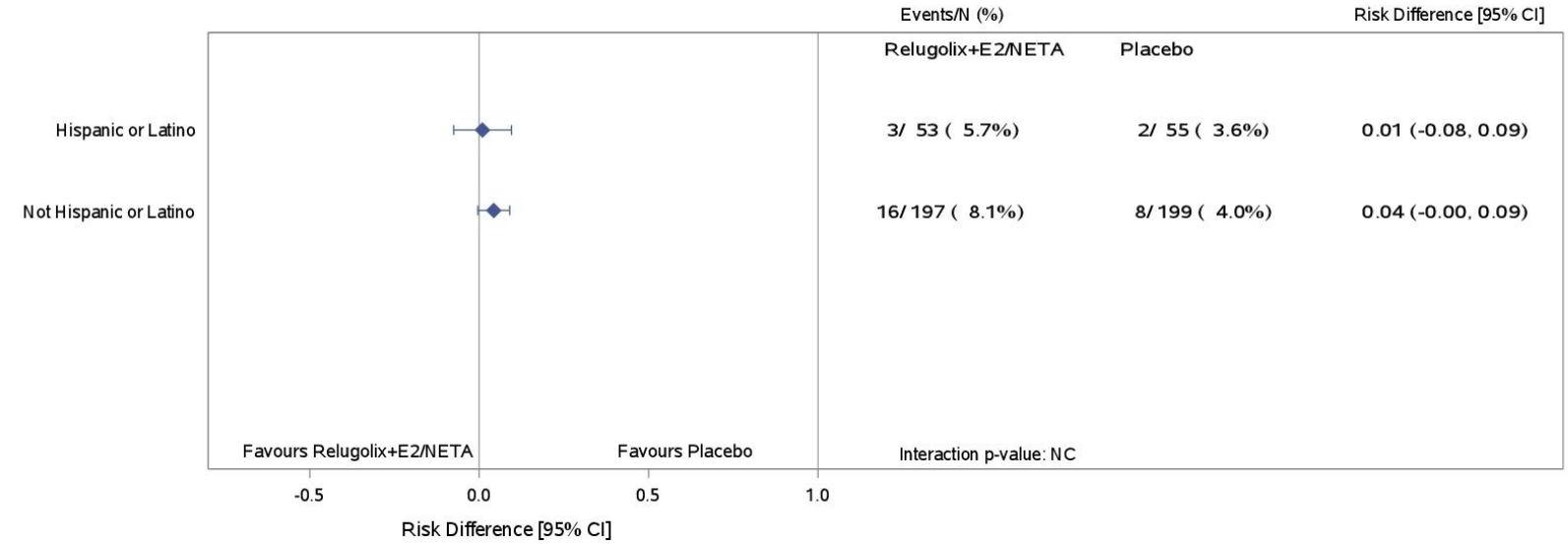
Figure SAF.TEAE.SPT.S8.BIN.FP.RD: Frequent Treatment Emergent Adverse Events by System Organ Class and Preferred Term, by Subgroup (Safety Population) - Risk Difference
Study: Pooled
System Organ Class: Psychiatric disorders, Preferred Term: Any
Subgroup: Ethnicity



Results are based on a Mantel-Haenszel approach stratified by study using a one-stage fixed-effects IPD meta-analysis.
The reference group is Placebo. Patients with multiple events are counted only once. MedDRA (version 22.0).
Patients with multiple events for a given PT or SOC are counted only once for each PT and SOC. Only SOCs or PTs for which there are at least 10% of patients with an event in at least one treatment group OR at least 10 patients with an event overall and at least 1% of patients with an event in at least one treatment group in the overall safety population are considered. Further, only SOCs and PTs for which there is a significant treatment effect (p-value <0.05) in the overall safety population are presented. Events are sorted alphabetically by SOC and PT and then by subgroup within each. MedDRA (version 22.0).
N: Number of patients in treatment group; NETA: Norethindrone acetate; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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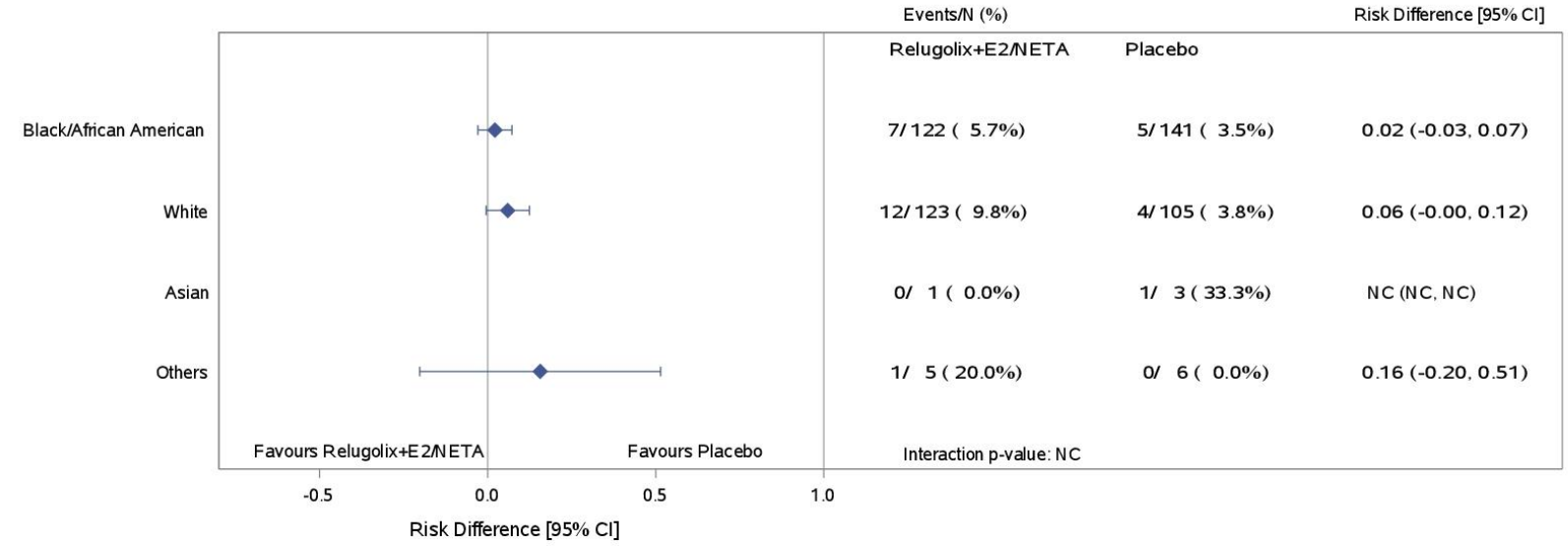
Figure SAF.TEAE.SPT.S9.BIN.FP.RD: Frequent Treatment Emergent Adverse Events by System Organ Class and Preferred Term, by Subgroup (Safety Population) - Risk Difference
Study: Pooled
System Organ Class: Psychiatric disorders, Preferred Term: Any
Subgroup: Race



Results are based on a Mantel-Haenszel approach stratified by study using a one-stage fixed-effects IPD meta-analysis.
The reference group is Placebo. Patients with multiple events are counted only once. MedDRA (version 22.0).
Patients with multiple events for a given PT or SOC are counted only once for each PT and SOC. Only SOCs or PTs for which there are at least 10% of patients with an event in at least one treatment group OR at least 10 patients with an event overall and at least 1% of patients with an event in at least one treatment group in the overall safety population are considered. Further, only SOCs and PTs for which there is a significant treatment effect (p-value <0.05) in the overall safety population are presented. Events are sorted alphabetically by SOC and PT and then by subgroup within each. MedDRA (version 22.0).
N: Number of patients in treatment group; NETA: Norethindrone acetate; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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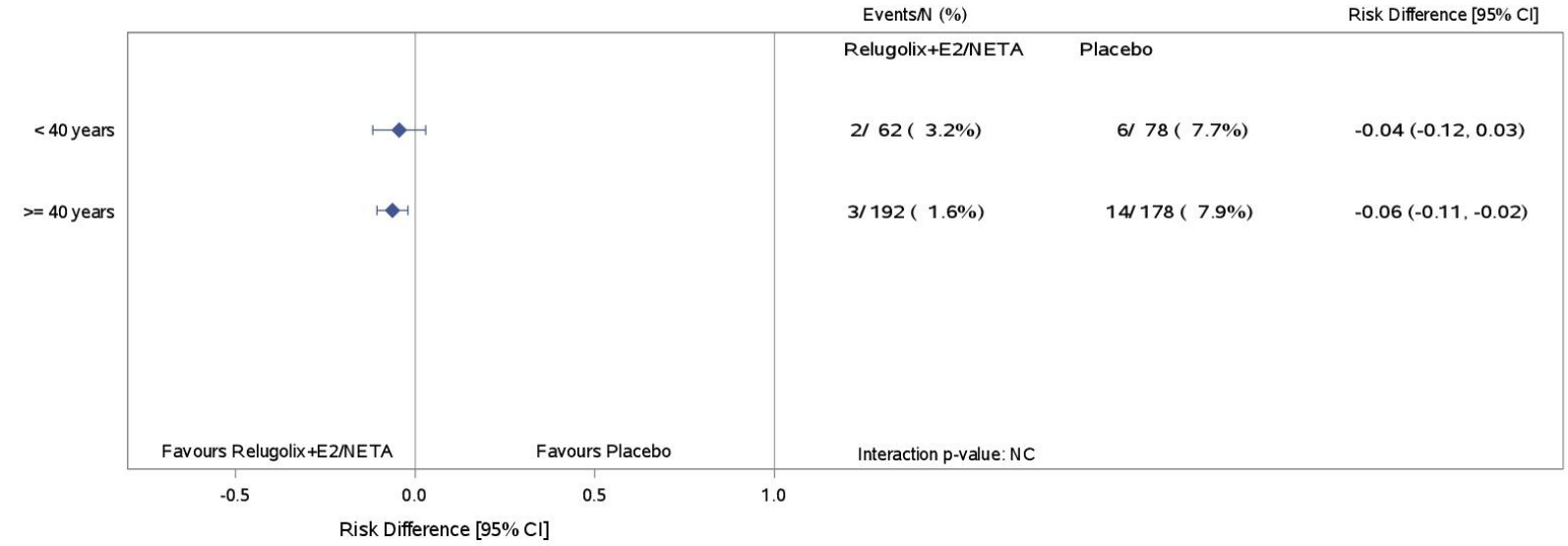
Figure SAF.TEAE.SPT.S1.BIN.FP.RD: Frequent Treatment Emergent Adverse Events by System Organ Class and Preferred Term, by Subgroup (Safety Population) - Risk Difference
Study: Pooled
System Organ Class: Respiratory, thoracic and mediastinal disorders, Preferred Term: Any
Subgroup: Age (years)



Results are based on a Mantel-Haenszel approach stratified by study using a one-stage fixed-effects IPD meta-analysis.
The reference group is Placebo. Patients with multiple events are counted only once. MedDRA (version 22.0).
Patients with multiple events for a given PT or SOC are counted only once for each PT and SOC. Only SOCs or PTs for which there are at least 10% of patients with an event in at least one treatment group OR at least 10 patients with an event overall and at least 1% of patients with an event in at least one treatment group in the overall safety population are considered. Further, only SOCs and PTs for which there is a significant treatment effect (p-value <0.05) in the overall safety population are presented. Events are sorted alphabetically by SOC and PT and then by subgroup within each. MedDRA (version 22.0).
N: Number of patients in treatment group; NETA: Norethindrone acetate; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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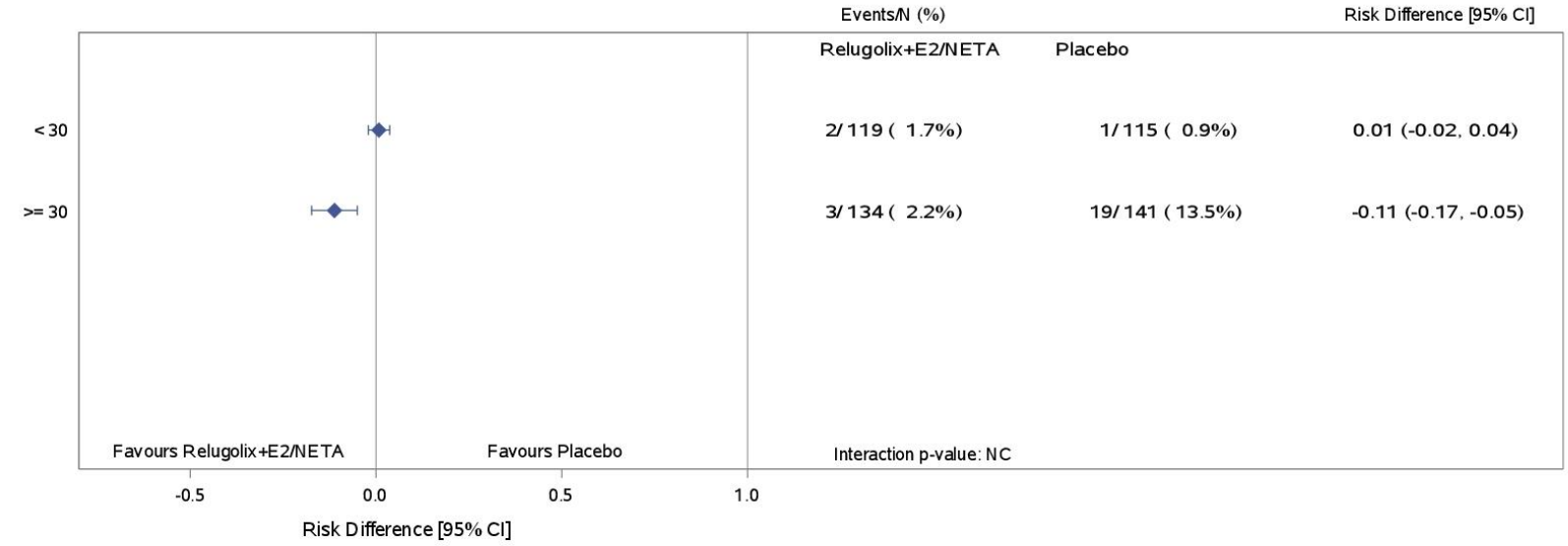
Figure SAF.TEAE.SPT.S2.BIN.FP.RD: Frequent Treatment Emergent Adverse Events by System Organ Class and Preferred Term, by Subgroup (Safety Population) - Risk Difference
Study: Pooled
System Organ Class: Respiratory, thoracic and mediastinal disorders, Preferred Term: Any
Subgroup: BMI (kg/m2) at Baseline



Results are based on a Mantel-Haenszel approach stratified by study using a one-stage fixed-effects IPD meta-analysis.
The reference group is Placebo. Patients with multiple events are counted only once. MedDRA (version 22.0).
Patients with multiple events for a given PT or SOC are counted only once for each PT and SOC. Only SOCs or PTs for which there are at least 10% of patients with an event in at least one treatment group OR at least 10 patients with an event overall and at least 1% of patients with an event in at least one treatment group in the overall safety population are considered. Further, only SOCs and PTs for which there is a significant treatment effect (p-value <0.05) in the overall safety population are presented. Events are sorted alphabetically by SOC and PT and then by subgroup within each. MedDRA (version 22.0).
N: Number of patients in treatment group; NETA: Norethindrone acetate; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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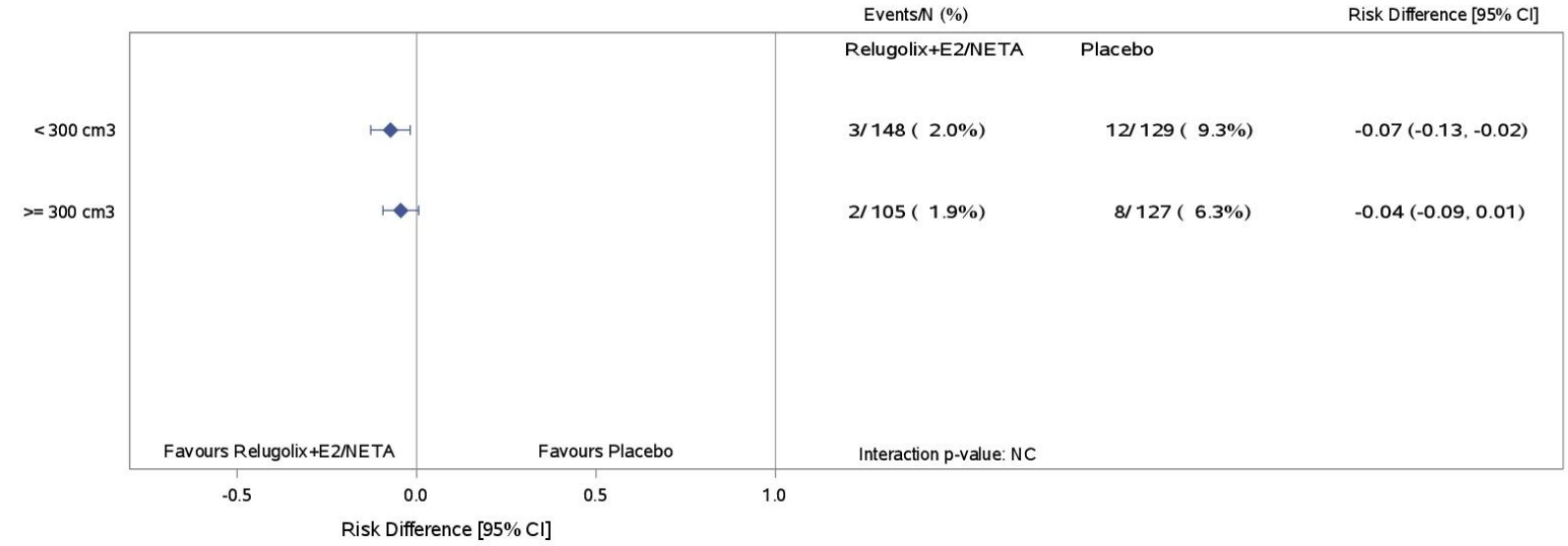
Figure SAF.TEAE.SPT.S3.BIN.FP.RD: Frequent Treatment Emergent Adverse Events by System Organ Class and Preferred Term, by Subgroup (Safety Population) - Risk Difference
Study: Pooled
System Organ Class: Respiratory, thoracic and mediastinal disorders, Preferred Term: Any
Subgroup: Uterine Volume at Baseline (cm3)



Results are based on a Mantel-Haenszel approach stratified by study using a one-stage fixed-effects IPD meta-analysis.
The reference group is Placebo. Patients with multiple events are counted only once. MedDRA (version 22.0).
Patients with multiple events for a given PT or SOC are counted only once for each PT and SOC. Only SOCs or PTs for which there are at least 10% of patients with an event in at least one treatment group OR at least 10 patients with an event overall and at least 1% of patients with an event in at least one treatment group in the overall safety population are considered. Further, only SOCs and PTs for which there is a significant treatment effect (p-value <0.05) in the overall safety population are presented. Events are sorted alphabetically by SOC and PT and then by subgroup within each. MedDRA (version 22.0).
N: Number of patients in treatment group; NETA: Norethindrone acetate; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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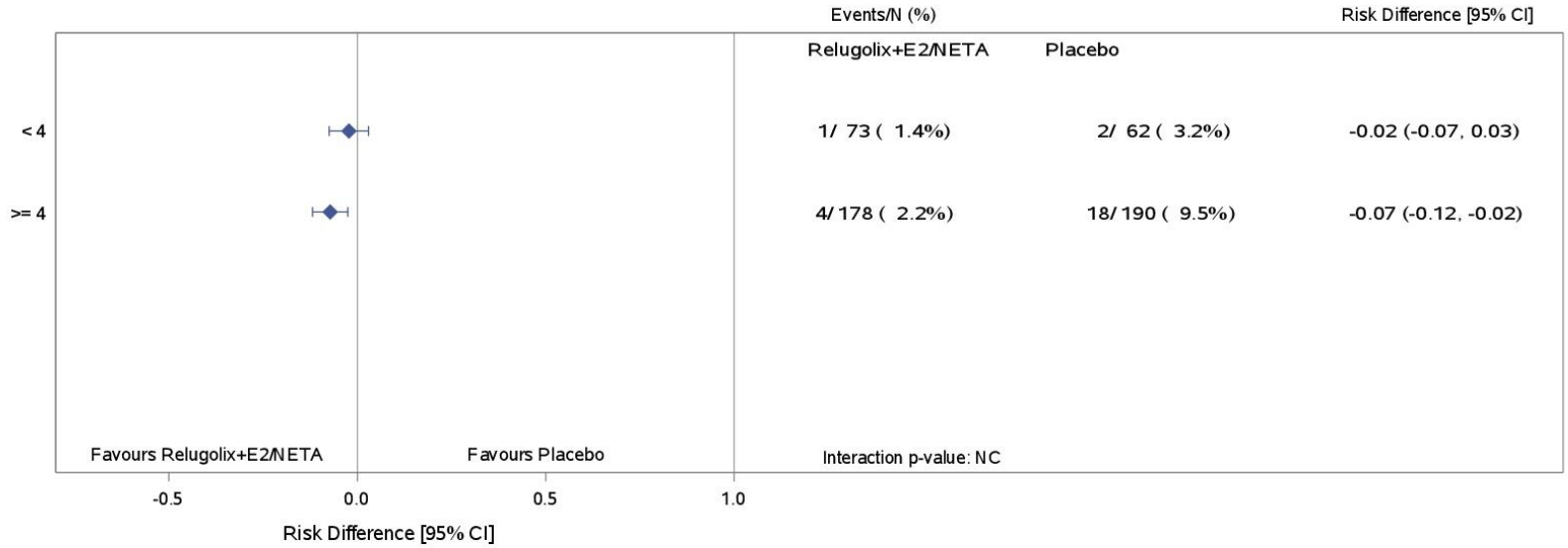
Figure SAF.TEAE.SPT.S4.BIN.FP.RD: Frequent Treatment Emergent Adverse Events by System Organ Class and Preferred Term, by Subgroup (Safety Population) - Risk Difference
Study: Pooled
System Organ Class: Respiratory, thoracic and mediastinal disorders, Preferred Term: Any
Subgroup: Maximum NRS Pain Score at Baseline



Results are based on a Mantel-Haenszel approach stratified by study using a one-stage fixed-effects IPD meta-analysis.
The reference group is Placebo. Patients with multiple events are counted only once. MedDRA (version 22.0).
Patients with multiple events for a given PT or SOC are counted only once for each PT and SOC. Only SOCs or PTs for which there are at least 10% of patients with an event in at least one treatment group OR at least 10 patients with an event overall and at least 1% of patients with an event in at least one treatment group in the overall safety population are considered. Further, only SOCs and PTs for which there is a significant treatment effect (p-value <0.05) in the overall safety population are presented. Events are sorted alphabetically by SOC and PT and then by subgroup within each. MedDRA (version 22.0).
N: Number of patients in treatment group; NETA: Norethindrone acetate; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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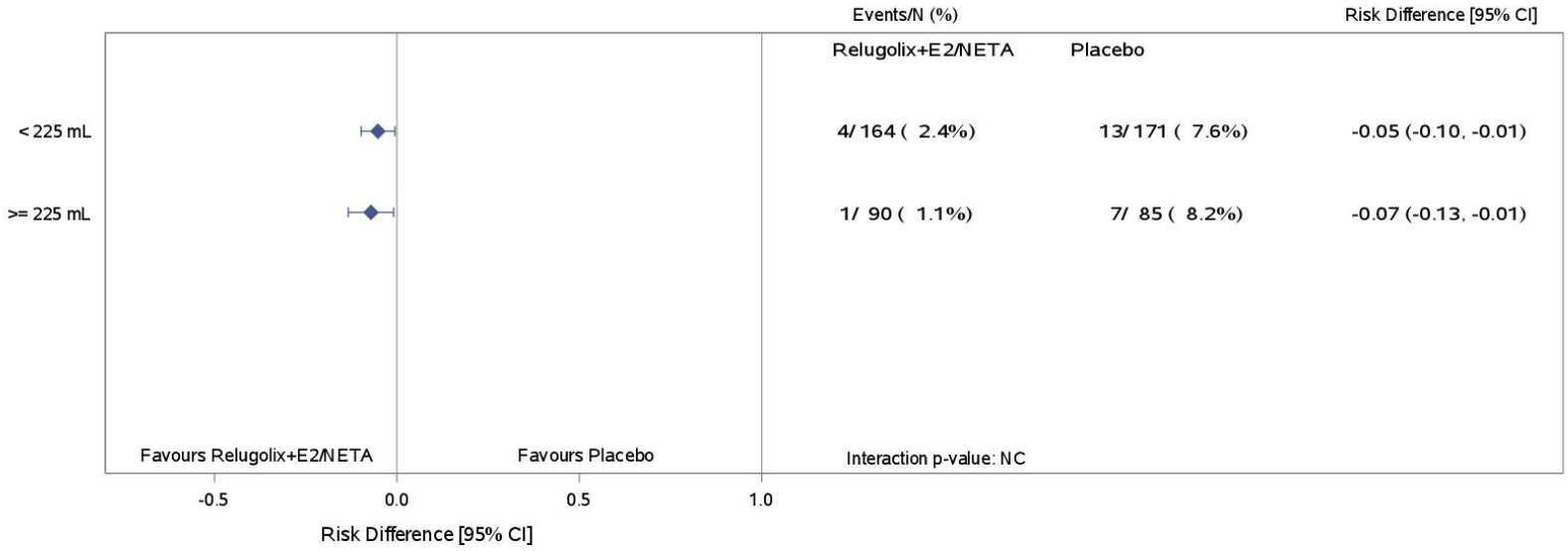
Figure SAF.TEAE.SPT.S5.BIN.FP.RD: Frequent Treatment Emergent Adverse Events by System Organ Class and Preferred Term, by Subgroup (Safety Population) - Risk Difference
Study: Pooled
System Organ Class: Respiratory, thoracic and mediastinal disorders, Preferred Term: Any
Subgroup: MBL Volume at Baseline (mL)



Results are based on a Mantel-Haenszel approach stratified by study using a one-stage fixed-effects IPD meta-analysis.
The reference group is Placebo. Patients with multiple events are counted only once. MedDRA (version 22.0).
Patients with multiple events for a given PT or SOC are counted only once for each PT and SOC. Only SOCs or PTs for which there are at least 10% of patients with an event in at least one treatment group OR at least 10 patients with an event overall and at least 1% of patients with an event in at least one treatment group in the overall safety population are considered. Further, only SOCs and PTs for which there is a significant treatment effect (p-value <0.05) in the overall safety population are presented. Events are sorted alphabetically by SOC and PT and then by subgroup within each. MedDRA (version 22.0).
N: Number of patients in treatment group; NETA: Norethindrone acetate; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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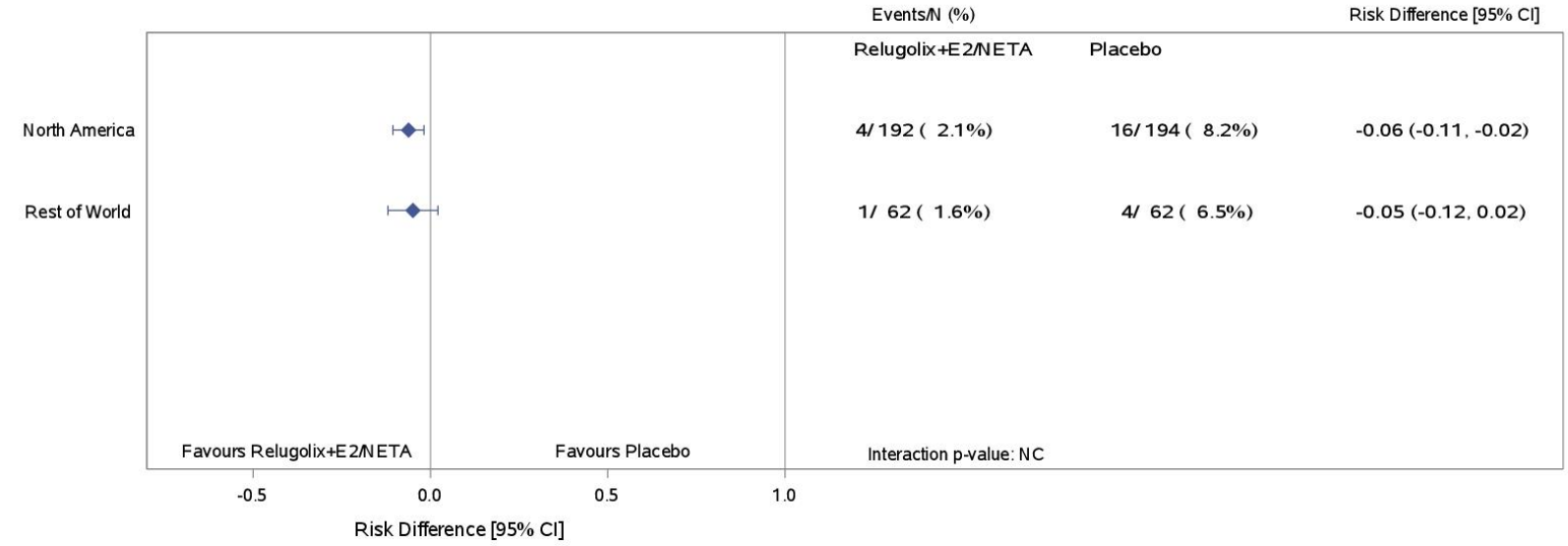
Figure SAF.TEAE.SPT.S6.BIN.FP.RD: Frequent Treatment Emergent Adverse Events by System Organ Class and Preferred Term, by Subgroup (Safety Population) - Risk Difference
Study: Pooled
System Organ Class: Respiratory, thoracic and mediastinal disorders, Preferred Term: Any
Subgroup: Geographic Region I



Results are based on a Mantel-Haenszel approach stratified by study using a one-stage fixed-effects IPD meta-analysis.
The reference group is Placebo. Patients with multiple events are counted only once. MedDRA (version 22.0).
Patients with multiple events for a given PT or SOC are counted only once for each PT and SOC. Only SOCs or PTs for which there are at least 10% of patients with an event in at least one treatment group OR at least 10 patients with an event overall and at least 1% of patients with an event in at least one treatment group in the overall safety population are considered. Further, only SOCs and PTs for which there is a significant treatment effect (p-value <0.05) in the overall safety population are presented. Events are sorted alphabetically by SOC and PT and then by subgroup within each. MedDRA (version 22.0).
N: Number of patients in treatment group; NETA: Norethindrone acetate; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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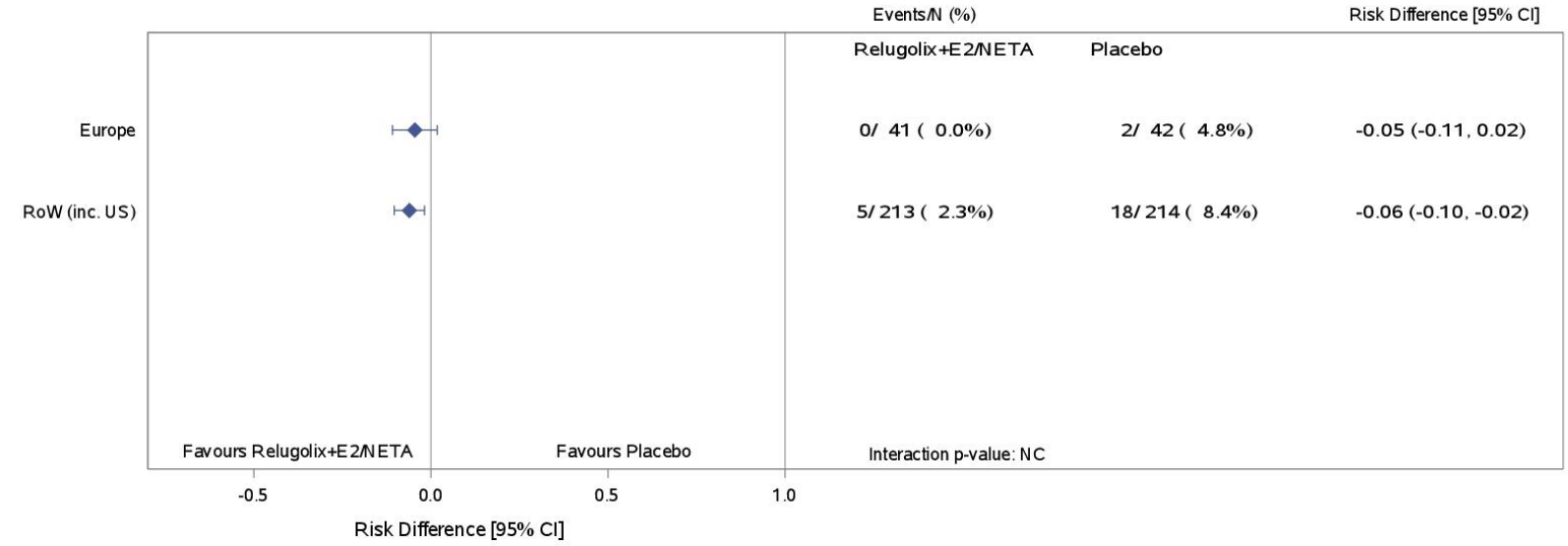
Figure SAF.TEAE.SPT.S7.BIN.FP.RD: Frequent Treatment Emergent Adverse Events by System Organ Class and Preferred Term, by Subgroup (Safety Population) - Risk Difference
Study: Pooled
System Organ Class: Respiratory, thoracic and mediastinal disorders, Preferred Term: Any
Subgroup: Geographic Region II



Results are based on a Mantel-Haenszel approach stratified by study using a one-stage fixed-effects IPD meta-analysis.
The reference group is Placebo. Patients with multiple events are counted only once. MedDRA (version 22.0).
Patients with multiple events for a given PT or SOC are counted only once for each PT and SOC. Only SOCs or PTs for which there are at least 10% of patients with an event in at least one treatment group OR at least 10 patients with an event overall and at least 1% of patients with an event in at least one treatment group in the overall safety population are considered. Further, only SOCs and PTs for which there is a significant treatment effect (p-value <0.05) in the overall safety population are presented. Events are sorted alphabetically by SOC and PT and then by subgroup within each. MedDRA (version 22.0).
N: Number of patients in treatment group; NETA: Norethindrone acetate; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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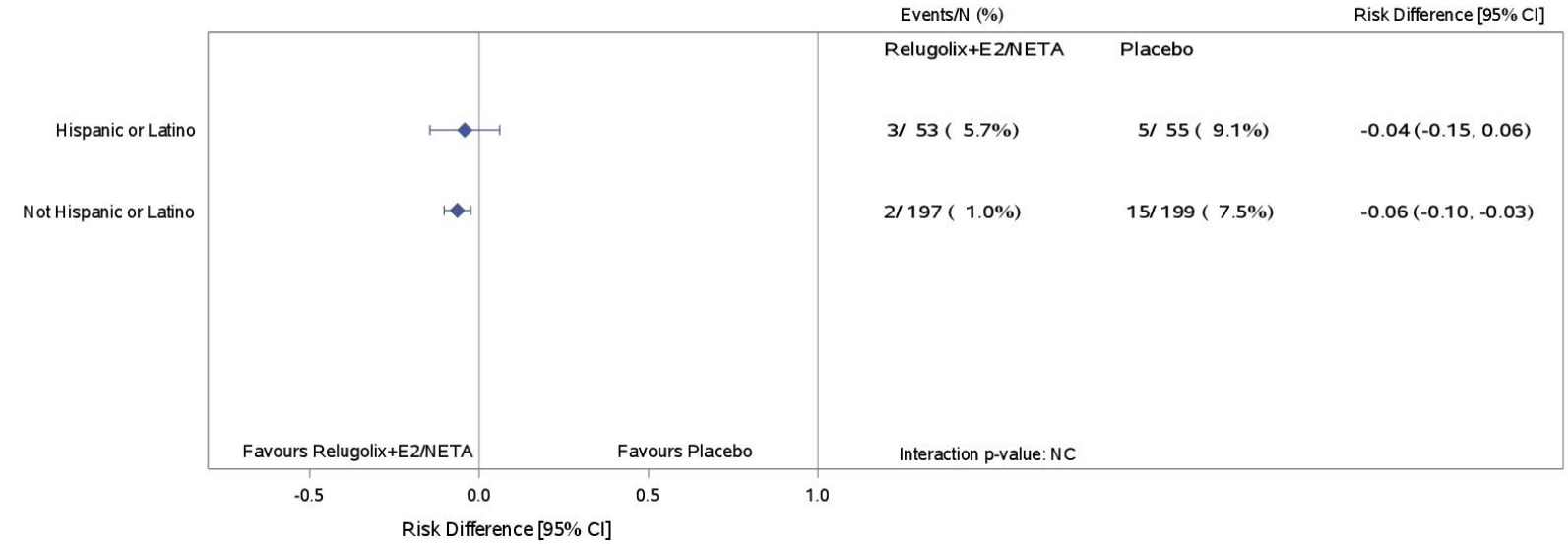
Figure SAF.TEAE.SPT.S8.BIN.FP.RD: Frequent Treatment Emergent Adverse Events by System Organ Class and Preferred Term, by Subgroup (Safety Population) - Risk Difference
Study: Pooled
System Organ Class: Respiratory, thoracic and mediastinal disorders, Preferred Term: Any
Subgroup: Ethnicity



Results are based on a Mantel-Haenszel approach stratified by study using a one-stage fixed-effects IPD meta-analysis.
The reference group is Placebo. Patients with multiple events are counted only once. MedDRA (version 22.0).
Patients with multiple events for a given PT or SOC are counted only once for each PT and SOC. Only SOCs or PTs for which there are at least 10% of patients with an event in at least one treatment group OR at least 10 patients with an event overall and at least 1% of patients with an event in at least one treatment group in the overall safety population are considered. Further, only SOCs and PTs for which there is a significant treatment effect (p-value <0.05) in the overall safety population are presented. Events are sorted alphabetically by SOC and PT and then by subgroup within each. MedDRA (version 22.0).
N: Number of patients in treatment group; NETA: Norethindrone acetate; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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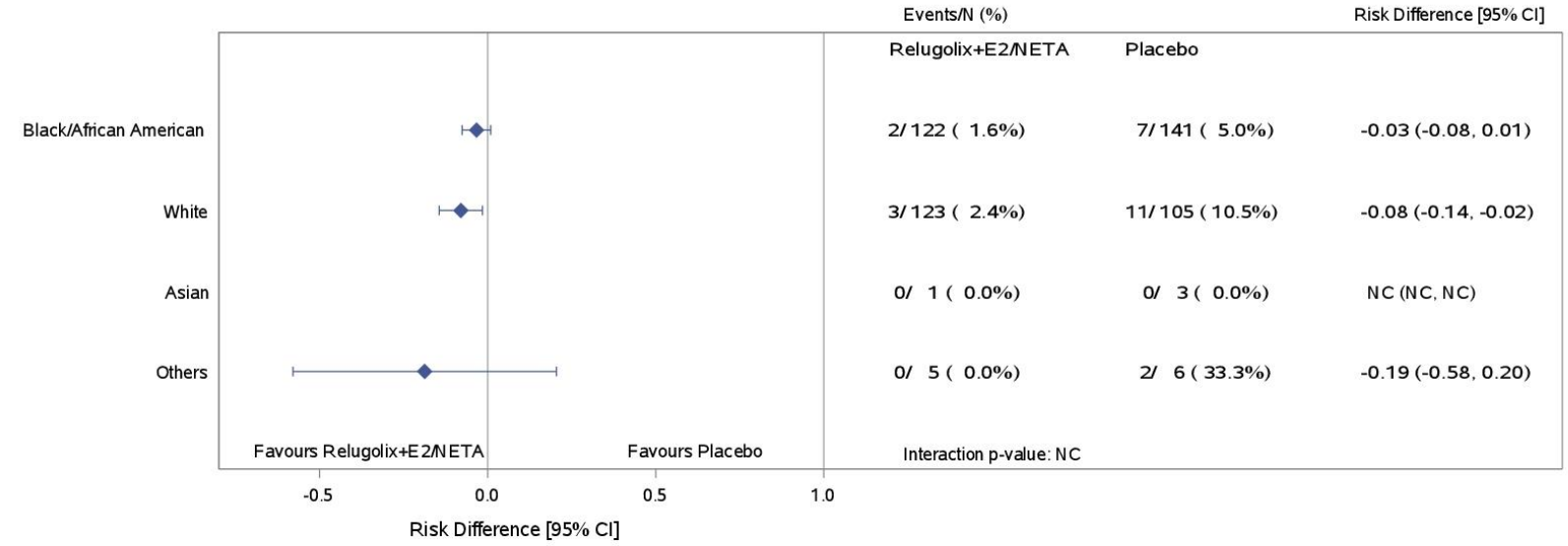
Figure SAF.TEAE.SPT.S9.BIN.FP.RD: Frequent Treatment Emergent Adverse Events by System Organ Class and Preferred Term, by Subgroup (Safety Population) - Risk Difference
Study: Pooled
System Organ Class: Respiratory, thoracic and mediastinal disorders, Preferred Term: Any
Subgroup: Race



Results are based on a Mantel-Haenszel approach stratified by study using a one-stage fixed-effects IPD meta-analysis.
The reference group is Placebo. Patients with multiple events are counted only once. MedDRA (version 22.0).
Patients with multiple events for a given PT or SOC are counted only once for each PT and SOC. Only SOCs or PTs for which there are at least 10% of patients with an event in at least one treatment group OR at least 10 patients with an event overall and at least 1% of patients with an event in at least one treatment group in the overall safety population are considered. Further, only SOCs and PTs for which there is a significant treatment effect (p-value <0.05) in the overall safety population are presented. Events are sorted alphabetically by SOC and PT and then by subgroup within each. MedDRA (version 22.0).
N: Number of patients in treatment group; NETA: Norethindrone acetate; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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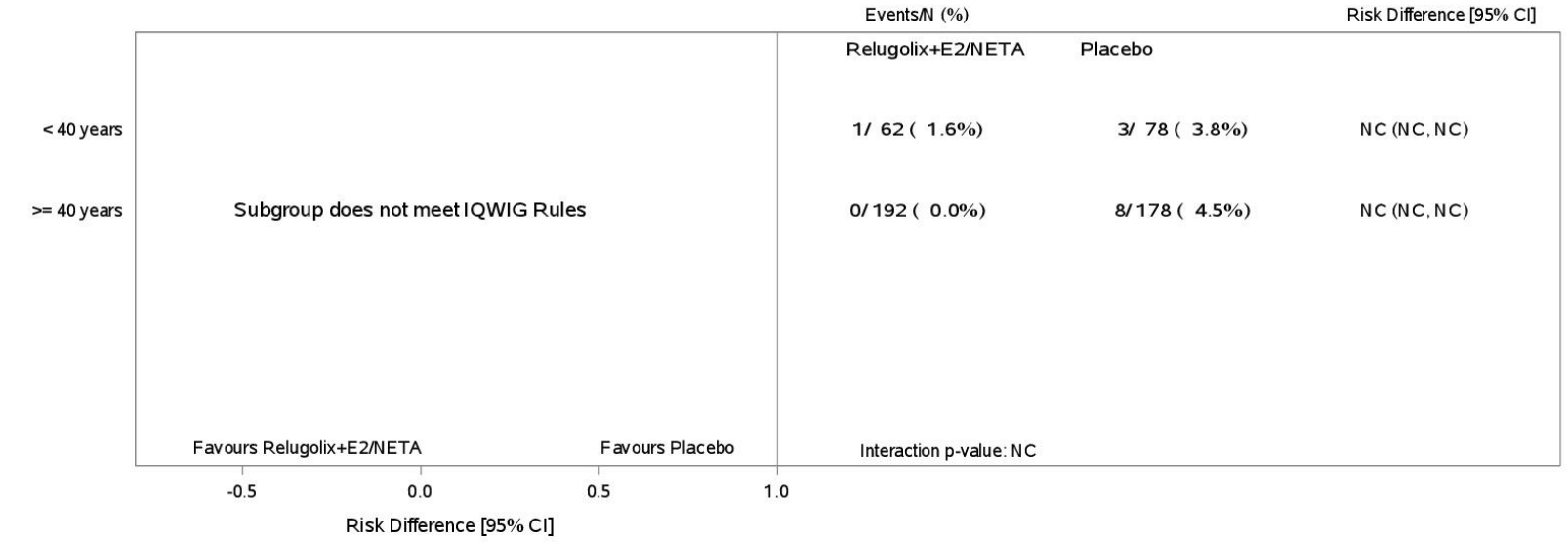
Figure SAF.TEAE.SPT.S1.BIN.FP.RD: Frequent Treatment Emergent Adverse Events by System Organ Class and Preferred Term, by Subgroup (Safety Population) - Risk Difference
Study: Pooled
System Organ Class: Respiratory, thoracic and mediastinal disorders, Preferred Term: Cough
Subgroup: Age (years)



Results are based on a Mantel-Haenszel approach stratified by study using a one-stage fixed-effects IPD meta-analysis.
The reference group is Placebo. Patients with multiple events are counted only once. MedDRA (version 22.0).
Patients with multiple events for a given PT or SOC are counted only once for each PT and SOC. Only SOCs or PTs for which there are at least 10% of patients with an event in at least one treatment group OR at least 10 patients with an event overall and at least 1% of patients with an event in at least one treatment group in the overall safety population are considered. Further, only SOCs and PTs for which there is a significant treatment effect (p-value <0.05) in the overall safety population are presented. Events are sorted alphabetically by SOC and PT and then by subgroup within each. MedDRA (version 22.0).
N: Number of patients in treatment group; NETA: Norethindrone acetate; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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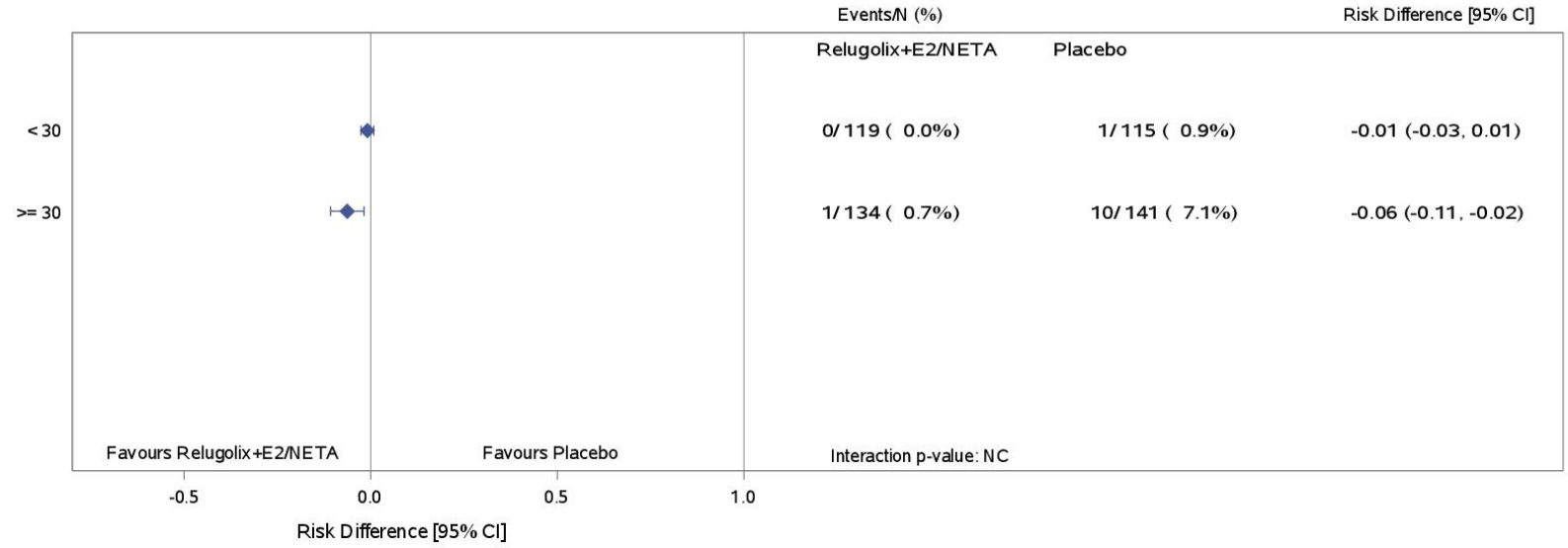
Figure SAF.TEAE.SPT.S2.BIN.FP.RD: Frequent Treatment Emergent Adverse Events by System Organ Class and Preferred Term, by Subgroup (Safety Population) - Risk Difference
Study: Pooled
System Organ Class: Respiratory, thoracic and mediastinal disorders, Preferred Term: Cough
Subgroup: BMI (kg/m2) at Baseline



Results are based on a Mantel-Haenszel approach stratified by study using a one-stage fixed-effects IPD meta-analysis.
The reference group is Placebo. Patients with multiple events are counted only once. MedDRA (version 22.0).
Patients with multiple events for a given PT or SOC are counted only once for each PT and SOC. Only SOCs or PTs for which there are at least 10% of patients with an event in at least one treatment group OR at least 10 patients with an event overall and at least 1% of patients with an event in at least one treatment group in the overall safety population are considered. Further, only SOCs and PTs for which there is a significant treatment effect (p-value <0.05) in the overall safety population are presented. Events are sorted alphabetically by SOC and PT and then by subgroup within each. MedDRA (version 22.0).
N: Number of patients in treatment group; NETA: Norethindrone acetate; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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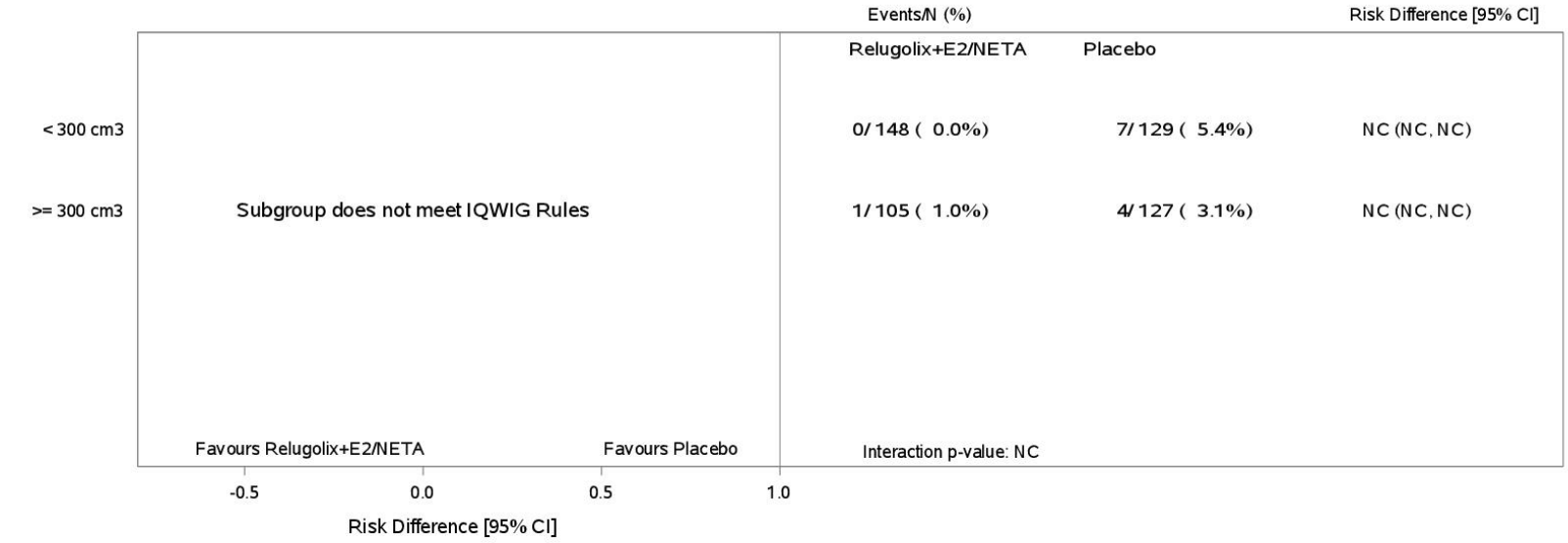
Figure SAF.TEAE.SPT.S3.BIN.FP.RD: Frequent Treatment Emergent Adverse Events by System Organ Class and Preferred Term, by Subgroup (Safety Population) - Risk Difference
Study: Pooled
System Organ Class: Respiratory, thoracic and mediastinal disorders, Preferred Term: Cough
Subgroup: Uterine Volume at Baseline (cm3)



Results are based on a Mantel-Haenszel approach stratified by study using a one-stage fixed-effects IPD meta-analysis.
The reference group is Placebo. Patients with multiple events are counted only once. MedDRA (version 22.0).
Patients with multiple events for a given PT or SOC are counted only once for each PT and SOC. Only SOCs or PTs for which there are at least 10% of patients with an event in at least one treatment group OR at least 10 patients with an event overall and at least 1% of patients with an event in at least one treatment group in the overall safety population are considered. Further, only SOCs and PTs for which there is a significant treatment effect (p-value <0.05) in the overall safety population are presented. Events are sorted alphabetically by SOC and PT and then by subgroup within each. MedDRA (version 22.0).
N: Number of patients in treatment group; NETA: Norethindrone acetate; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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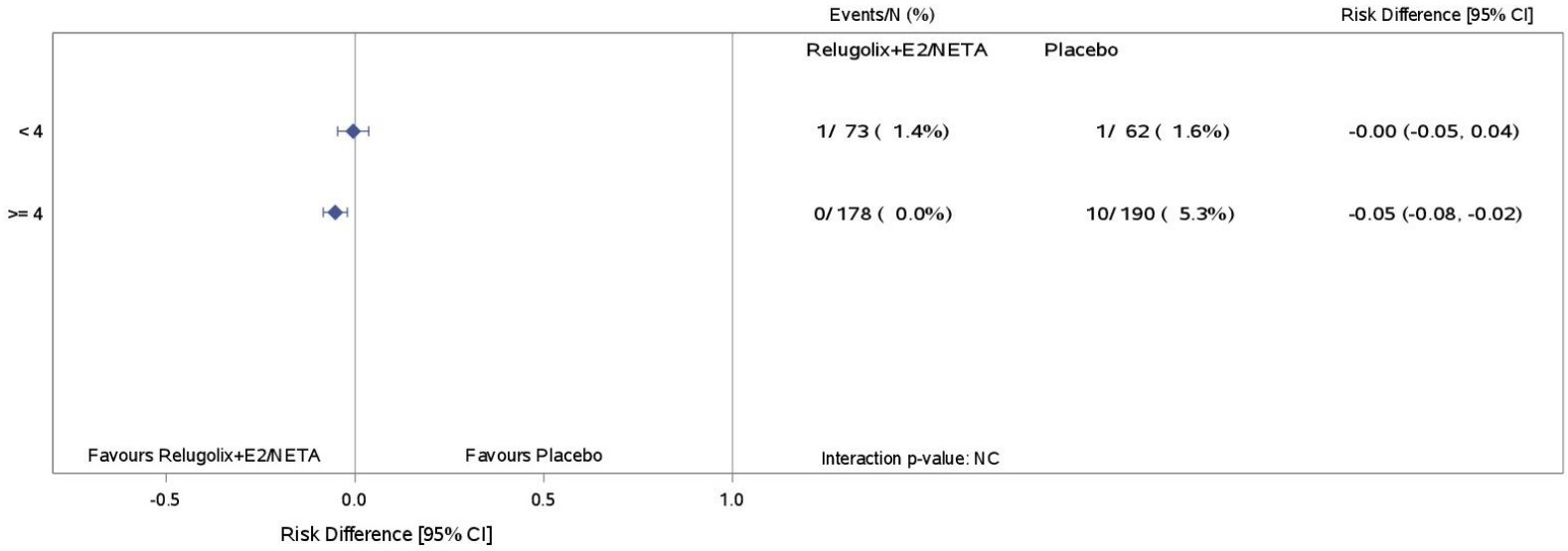
Figure SAF.TEAE.SPT.S4.BIN.FP.RD: Frequent Treatment Emergent Adverse Events by System Organ Class and Preferred Term, by Subgroup (Safety Population) - Risk Difference
Study: Pooled
System Organ Class: Respiratory, thoracic and mediastinal disorders, Preferred Term: Cough
Subgroup: Maximum NRS Pain Score at Baseline



Results are based on a Mantel-Haenszel approach stratified by study using a one-stage fixed-effects IPD meta-analysis.
The reference group is Placebo. Patients with multiple events are counted only once. MedDRA (version 22.0).
Patients with multiple events for a given PT or SOC are counted only once for each PT and SOC. Only SOCs or PTs for which there are at least 10% of patients with an event in at least one treatment group OR at least 10 patients with an event overall and at least 1% of patients with an event in at least one treatment group in the overall safety population are considered. Further, only SOCs and PTs for which there is a significant treatment effect (p-value <0.05) in the overall safety population are presented. Events are sorted alphabetically by SOC and PT and then by subgroup within each. MedDRA (version 22.0).
N: Number of patients in treatment group; NETA: Norethindrone acetate; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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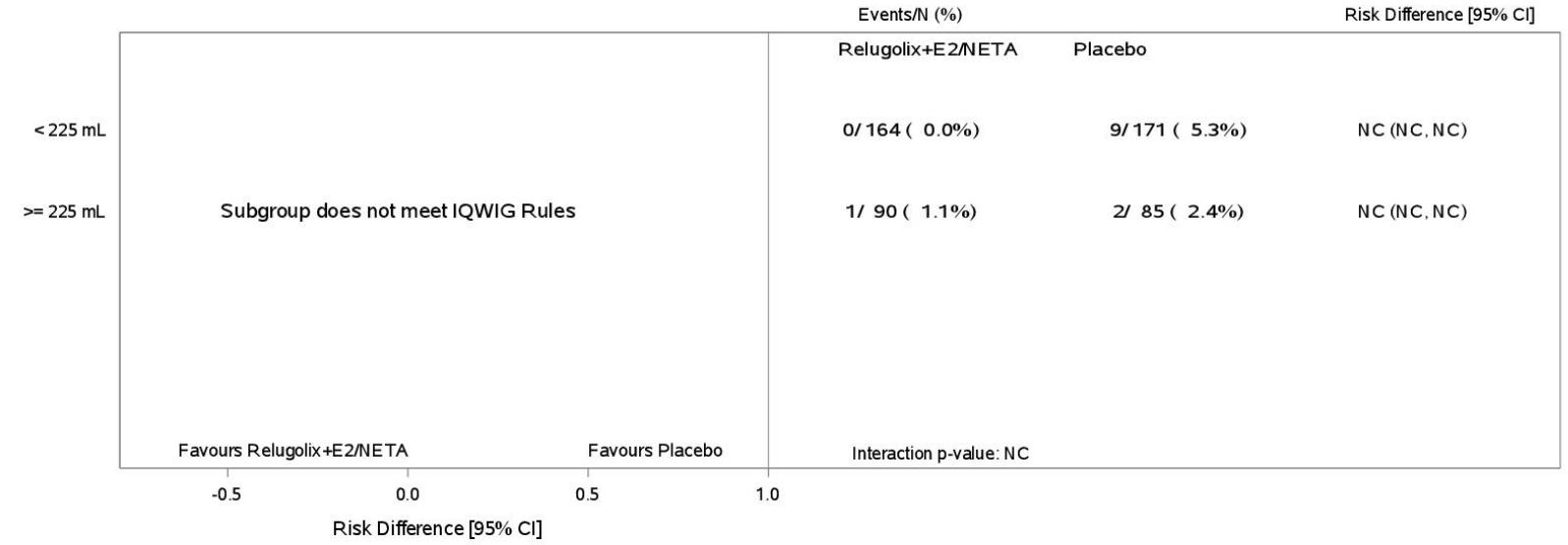
Figure SAF.TEAE.SPT.S5.BIN.FP.RD: Frequent Treatment Emergent Adverse Events by System Organ Class and Preferred Term, by Subgroup (Safety Population) - Risk Difference
Study: Pooled
System Organ Class: Respiratory, thoracic and mediastinal disorders, Preferred Term: Cough
Subgroup: MBL Volume at Baseline (mL)



Results are based on a Mantel-Haenszel approach stratified by study using a one-stage fixed-effects IPD meta-analysis.
The reference group is Placebo. Patients with multiple events are counted only once. MedDRA (version 22.0).
Patients with multiple events for a given PT or SOC are counted only once for each PT and SOC. Only SOCs or PTs for which there are at least 10% of patients with an event in at least one treatment group OR at least 10 patients with an event overall and at least 1% of patients with an event in at least one treatment group in the overall safety population are considered. Further, only SOCs and PTs for which there is a significant treatment effect (p-value <0.05) in the overall safety population are presented. Events are sorted alphabetically by SOC and PT and then by subgroup within each. MedDRA (version 22.0).
N: Number of patients in treatment group; NETA: Norethindrone acetate; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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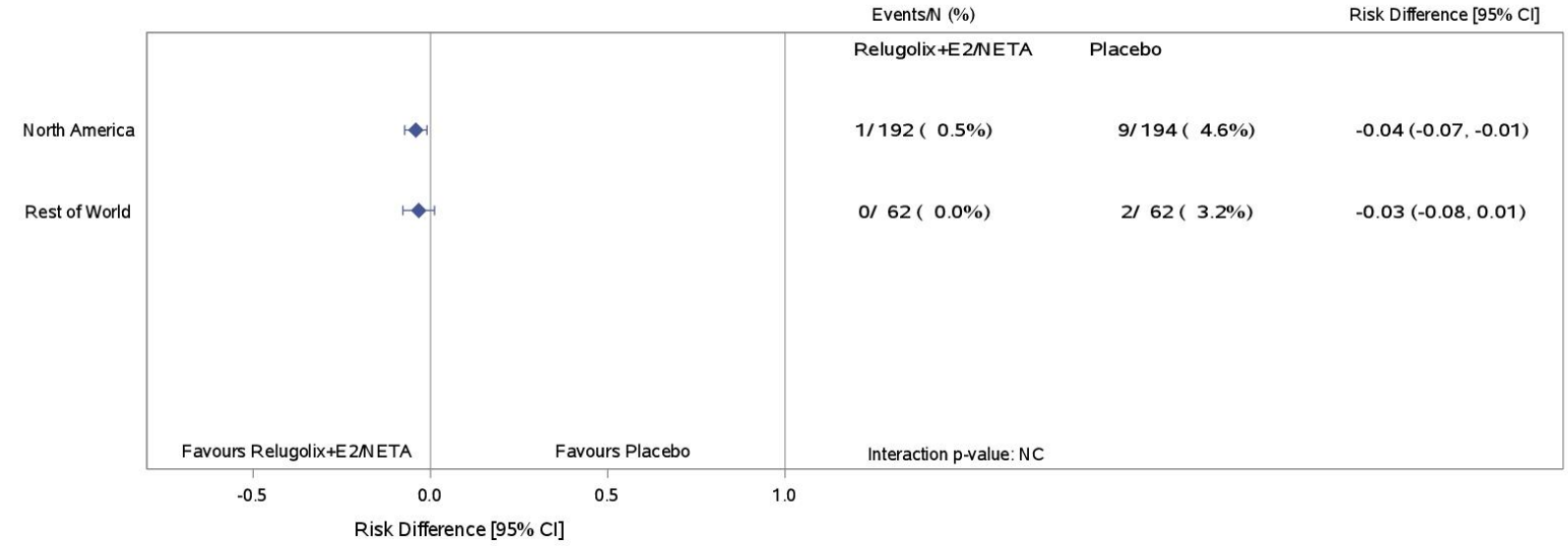
Figure SAF.TEAE.SPT.S6.BIN.FP.RD: Frequent Treatment Emergent Adverse Events by System Organ Class and Preferred Term, by Subgroup (Safety Population) - Risk Difference
Study: Pooled
System Organ Class: Respiratory, thoracic and mediastinal disorders, Preferred Term: Cough
Subgroup: Geographic Region I



Results are based on a Mantel-Haenszel approach stratified by study using a one-stage fixed-effects IPD meta-analysis.
The reference group is Placebo. Patients with multiple events are counted only once. MedDRA (version 22.0).
Patients with multiple events for a given PT or SOC are counted only once for each PT and SOC. Only SOCs or PTs for which there are at least 10% of patients with an event in at least one treatment group OR at least 10 patients with an event overall and at least 1% of patients with an event in at least one treatment group in the overall safety population are considered. Further, only SOCs and PTs for which there is a significant treatment effect (p-value <0.05) in the overall safety population are presented. Events are sorted alphabetically by SOC and PT and then by subgroup within each. MedDRA (version 22.0).
N: Number of patients in treatment group; NETA: Norethindrone acetate; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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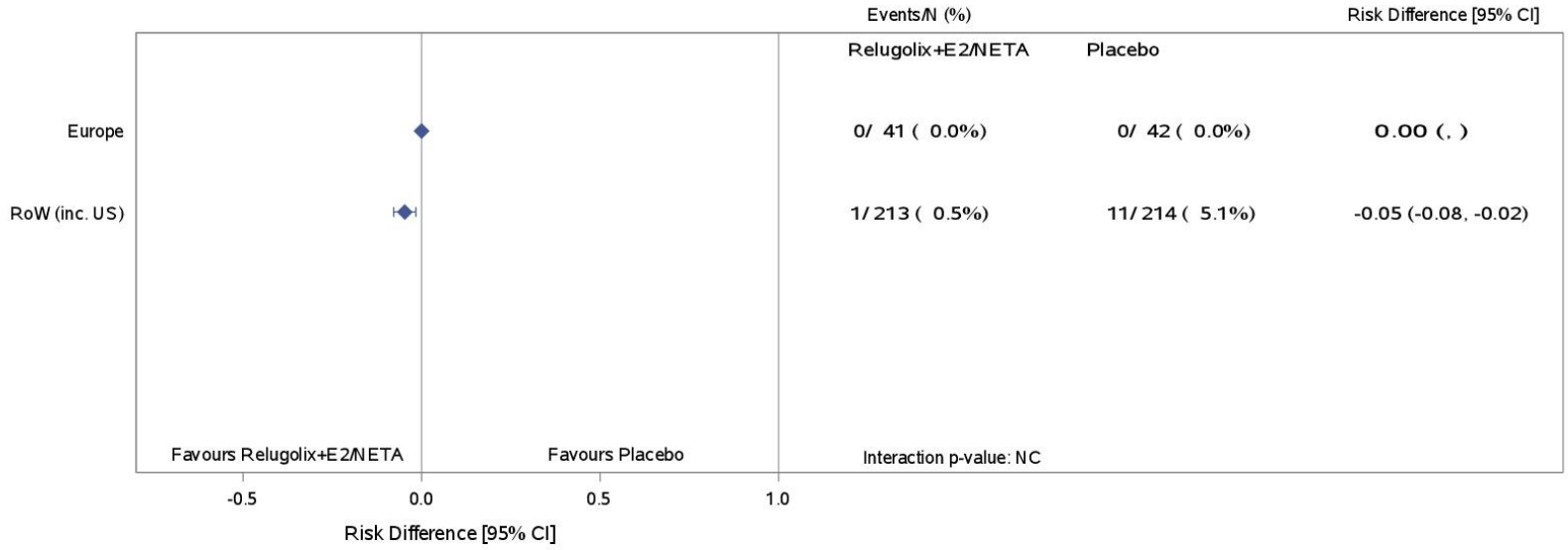
Figure SAF.TEAE.SPT.S7.BIN.FP.RD: Frequent Treatment Emergent Adverse Events by System Organ Class and Preferred Term, by Subgroup (Safety Population) - Risk Difference
Study: Pooled
System Organ Class: Respiratory, thoracic and mediastinal disorders, Preferred Term: Cough
Subgroup: Geographic Region II



Results are based on a Mantel-Haenszel approach stratified by study using a one-stage fixed-effects IPD meta-analysis.
The reference group is Placebo. Patients with multiple events are counted only once. MedDRA (version 22.0).
Patients with multiple events for a given PT or SOC are counted only once for each PT and SOC. Only SOCs or PTs for which there are at least 10% of patients with an event in at least one treatment group OR at least 10 patients with an event overall and at least 1% of patients with an event in at least one treatment group in the overall safety population are considered. Further, only SOCs and PTs for which there is a significant treatment effect (p-value <0.05) in the overall safety population are presented. Events are sorted alphabetically by SOC and PT and then by subgroup within each. MedDRA (version 22.0).
N: Number of patients in treatment group; NETA: Norethindrone acetate; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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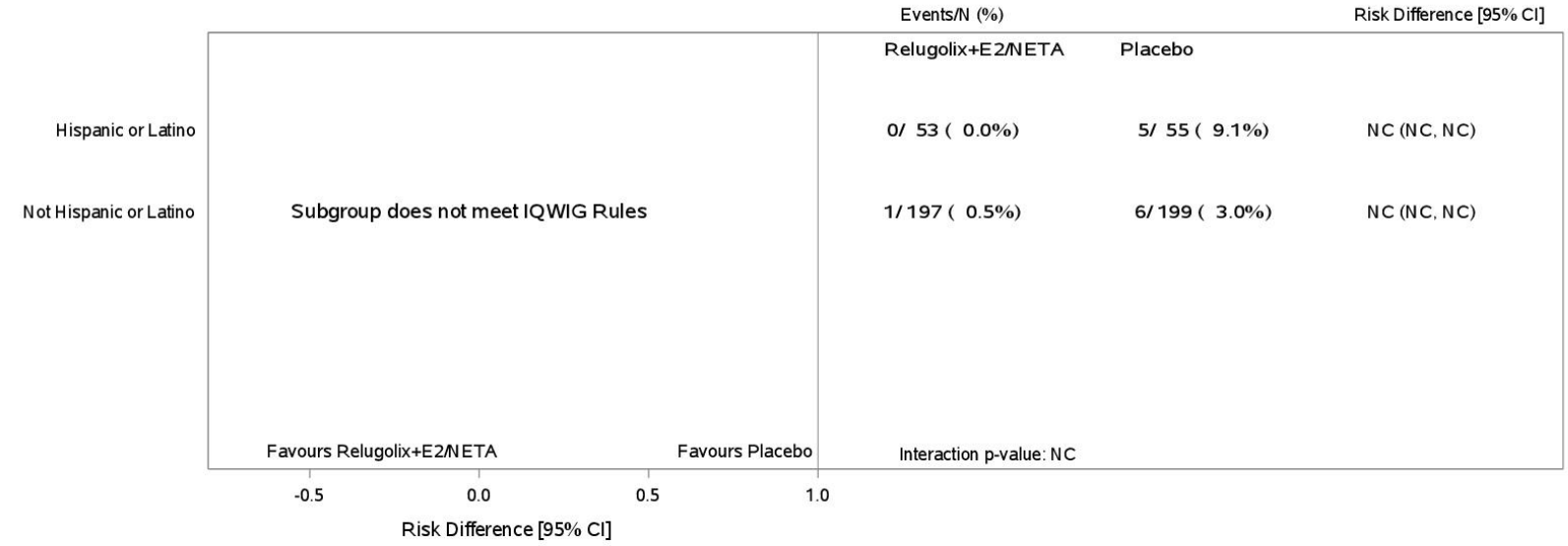
Figure SAF.TEAE.SPT.S8.BIN.FP.RD: Frequent Treatment Emergent Adverse Events by System Organ Class and Preferred Term, by Subgroup (Safety Population) - Risk Difference
Study: Pooled
System Organ Class: Respiratory, thoracic and mediastinal disorders, Preferred Term: Cough
Subgroup: Ethnicity



Results are based on a Mantel-Haenszel approach stratified by study using a one-stage fixed-effects IPD meta-analysis.
The reference group is Placebo. Patients with multiple events are counted only once. MedDRA (version 22.0).
Patients with multiple events for a given PT or SOC are counted only once for each PT and SOC. Only SOCs or PTs for which there are at least 10% of patients with an event in at least one treatment group OR at least 10 patients with an event overall and at least 1% of patients with an event in at least one treatment group in the overall safety population are considered. Further, only SOCs and PTs for which there is a significant treatment effect (p-value <0.05) in the overall safety population are presented. Events are sorted alphabetically by SOC and PT and then by subgroup within each. MedDRA (version 22.0).
N: Number of patients in treatment group; NETA: Norethindrone acetate; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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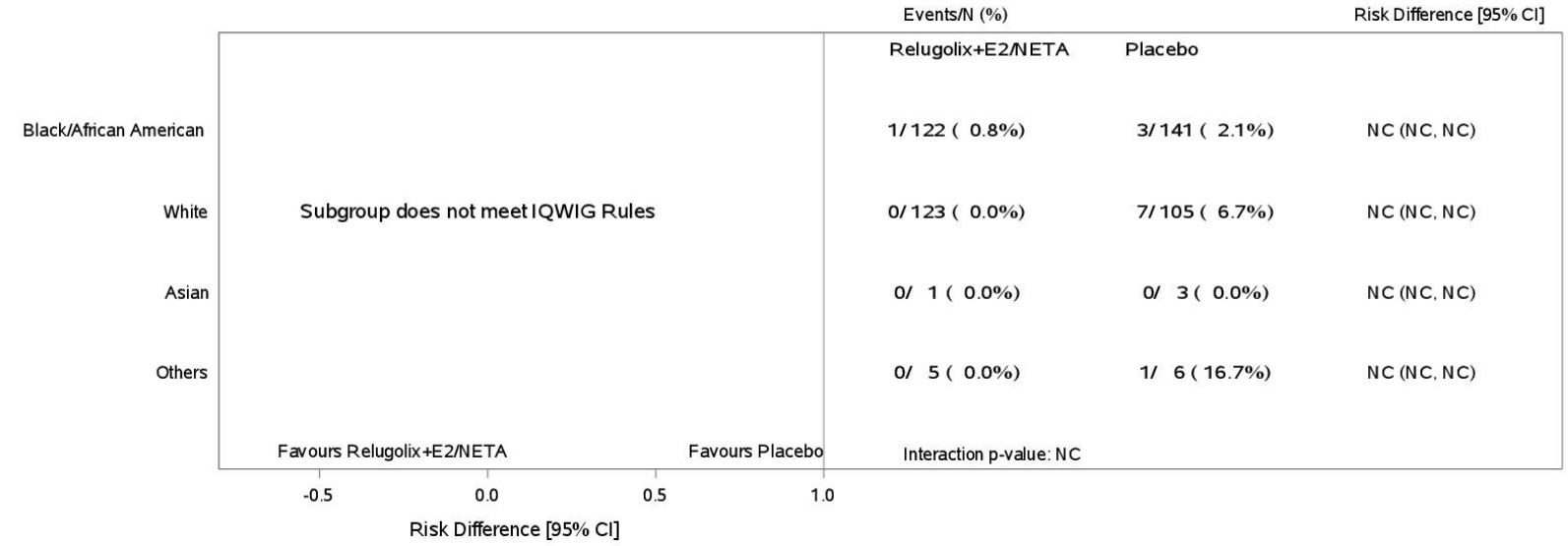
Figure SAF.TEAE.SPT.S9.BIN.FP.RD: Frequent Treatment Emergent Adverse Events by System Organ Class and Preferred Term, by Subgroup (Safety Population) - Risk Difference
Study: Pooled
System Organ Class: Respiratory, thoracic and mediastinal disorders, Preferred Term: Cough
Subgroup: Race



Results are based on a Mantel-Haenszel approach stratified by study using a one-stage fixed-effects IPD meta-analysis.
The reference group is Placebo. Patients with multiple events are counted only once. MedDRA (version 22.0).
Patients with multiple events for a given PT or SOC are counted only once for each PT and SOC. Only SOCs or PTs for which there are at least 10% of patients with an event in at least one treatment group OR at least 10 patients with an event overall and at least 1% of patients with an event in at least one treatment group in the overall safety population are considered. Further, only SOCs and PTs for which there is a significant treatment effect (p-value <0.05) in the overall safety population are presented. Events are sorted alphabetically by SOC and PT and then by subgroup within each. MedDRA (version 22.0).
N: Number of patients in treatment group; NETA: Norethindrone acetate; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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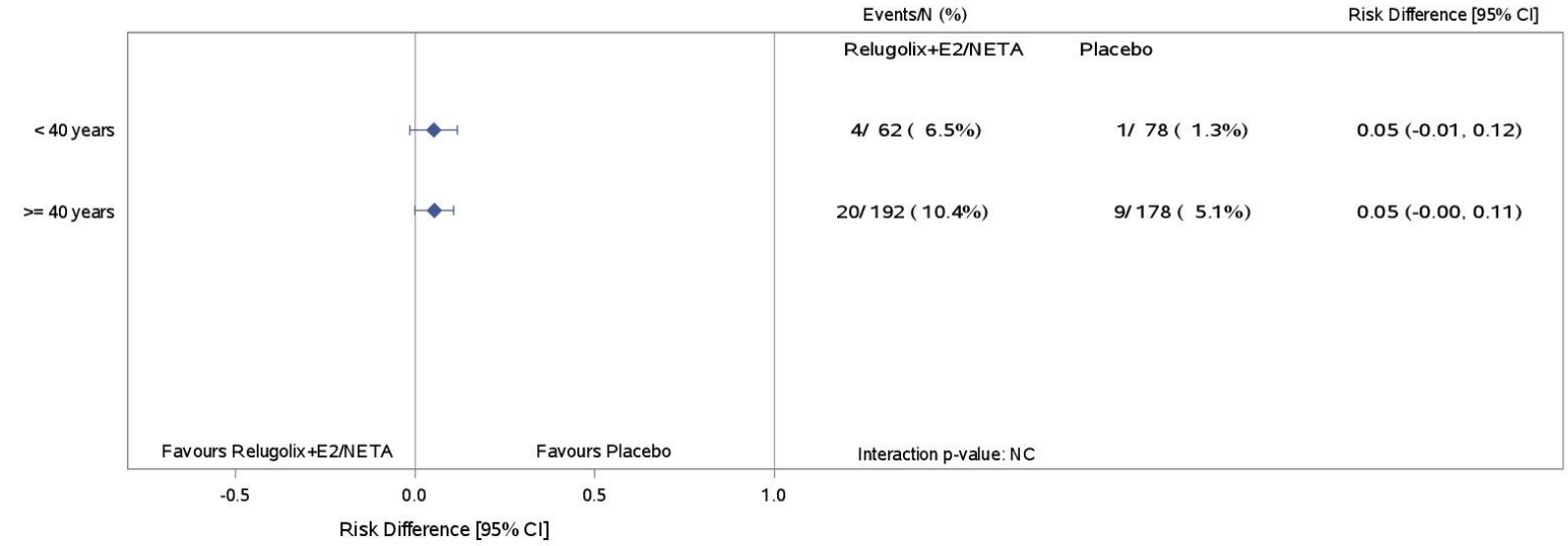
Figure SAF.TEAE.SPT.S1.BIN.FP.RD: Frequent Treatment Emergent Adverse Events by System Organ Class and Preferred Term, by Subgroup (Safety Population) - Risk Difference
Study: Pooled
System Organ Class: Skin and subcutaneous tissue disorders, Preferred Term: Any
Subgroup: Age (years)



Results are based on a Mantel-Haenszel approach stratified by study using a one-stage fixed-effects IPD meta-analysis.
The reference group is Placebo. Patients with multiple events are counted only once. MedDRA (version 22.0).
Patients with multiple events for a given PT or SOC are counted only once for each PT and SOC. Only SOCs or PTs for which there are at least 10% of patients with an event in at least one treatment group OR at least 10 patients with an event overall and at least 1% of patients with an event in at least one treatment group in the overall safety population are considered. Further, only SOCs and PTs for which there is a significant treatment effect (p-value <0.05) in the overall safety population are presented. Events are sorted alphabetically by SOC and PT and then by subgroup within each. MedDRA (version 22.0).
N: Number of patients in treatment group; NETA: Norethindrone acetate; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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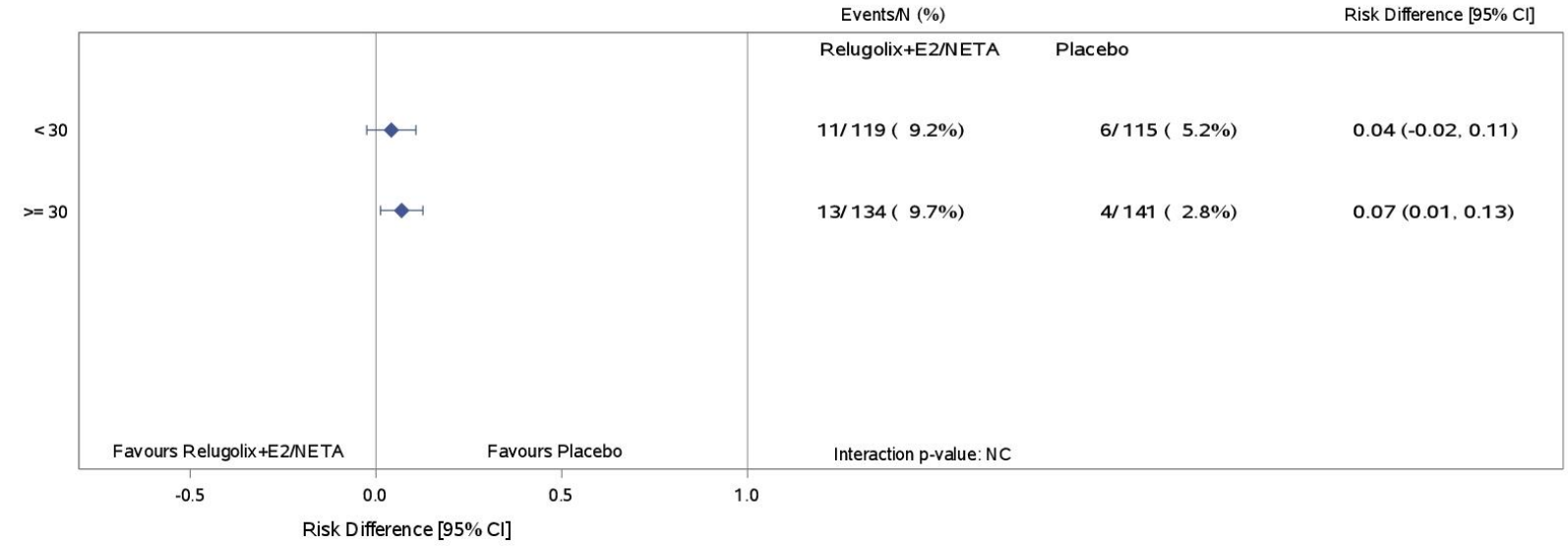
Figure SAF.TEAE.SPT.S2.BIN.FP.RD: Frequent Treatment Emergent Adverse Events by System Organ Class and Preferred Term, by Subgroup (Safety Population) - Risk Difference
Study: Pooled
System Organ Class: Skin and subcutaneous tissue disorders, Preferred Term: Any
Subgroup: BMI (kg/m2) at Baseline



Results are based on a Mantel-Haenszel approach stratified by study using a one-stage fixed-effects IPD meta-analysis.
The reference group is Placebo. Patients with multiple events are counted only once. MedDRA (version 22.0).
Patients with multiple events for a given PT or SOC are counted only once for each PT and SOC. Only SOCs or PTs for which there are at least 10% of patients with an event in at least one treatment group OR at least 10 patients with an event overall and at least 1% of patients with an event in at least one treatment group in the overall safety population are considered. Further, only SOCs and PTs for which there is a significant treatment effect (p-value <0.05) in the overall safety population are presented. Events are sorted alphabetically by SOC and PT and then by subgroup within each. MedDRA (version 22.0).
N: Number of patients in treatment group; NETA: Norethindrone acetate; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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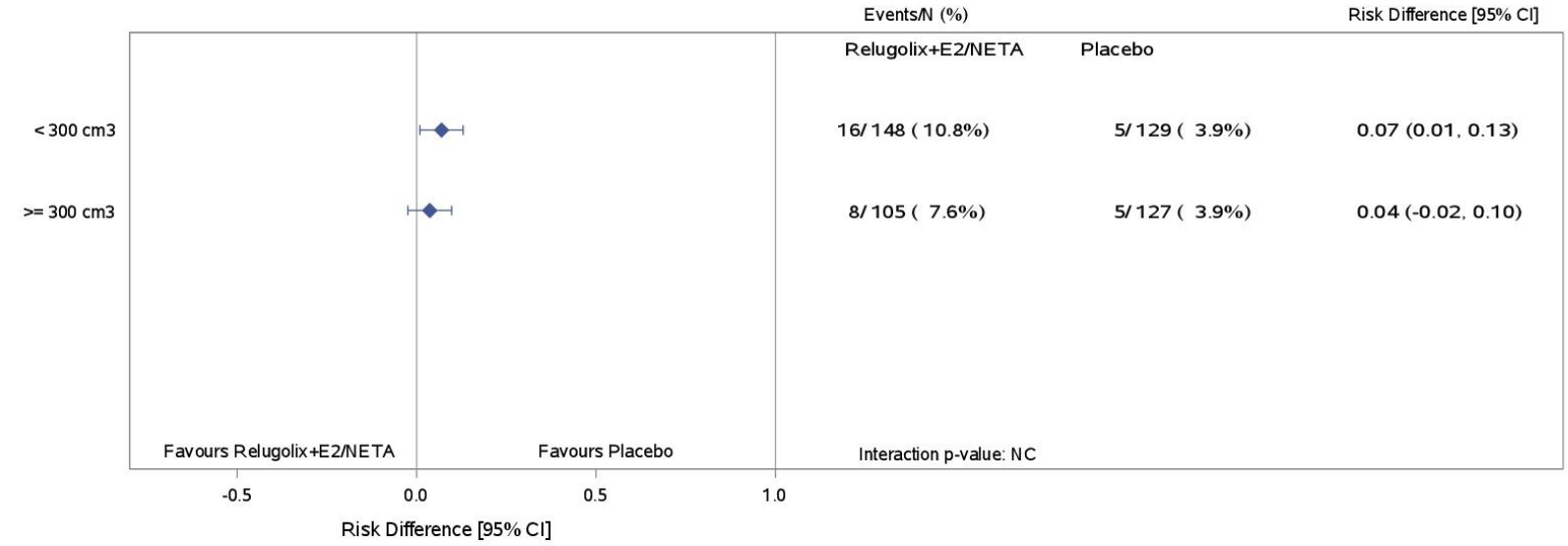
Figure SAF.TEAE.SPT.S3.BIN.FP.RD: Frequent Treatment Emergent Adverse Events by System Organ Class and Preferred Term, by Subgroup (Safety Population) - Risk Difference
Study: Pooled
System Organ Class: Skin and subcutaneous tissue disorders, Preferred Term: Any
Subgroup: Uterine Volume at Baseline (cm3)



Results are based on a Mantel-Haenszel approach stratified by study using a one-stage fixed-effects IPD meta-analysis.
The reference group is Placebo. Patients with multiple events are counted only once. MedDRA (version 22.0).
Patients with multiple events for a given PT or SOC are counted only once for each PT and SOC. Only SOCs or PTs for which there are at least 10% of patients with an event in at least one treatment group OR at least 10 patients with an event overall and at least 1% of patients with an event in at least one treatment group in the overall safety population are considered. Further, only SOCs and PTs for which there is a significant treatment effect (p-value <0.05) in the overall safety population are presented. Events are sorted alphabetically by SOC and PT and then by subgroup within each. MedDRA (version 22.0).
N: Number of patients in treatment group; NETA: Norethindrone acetate; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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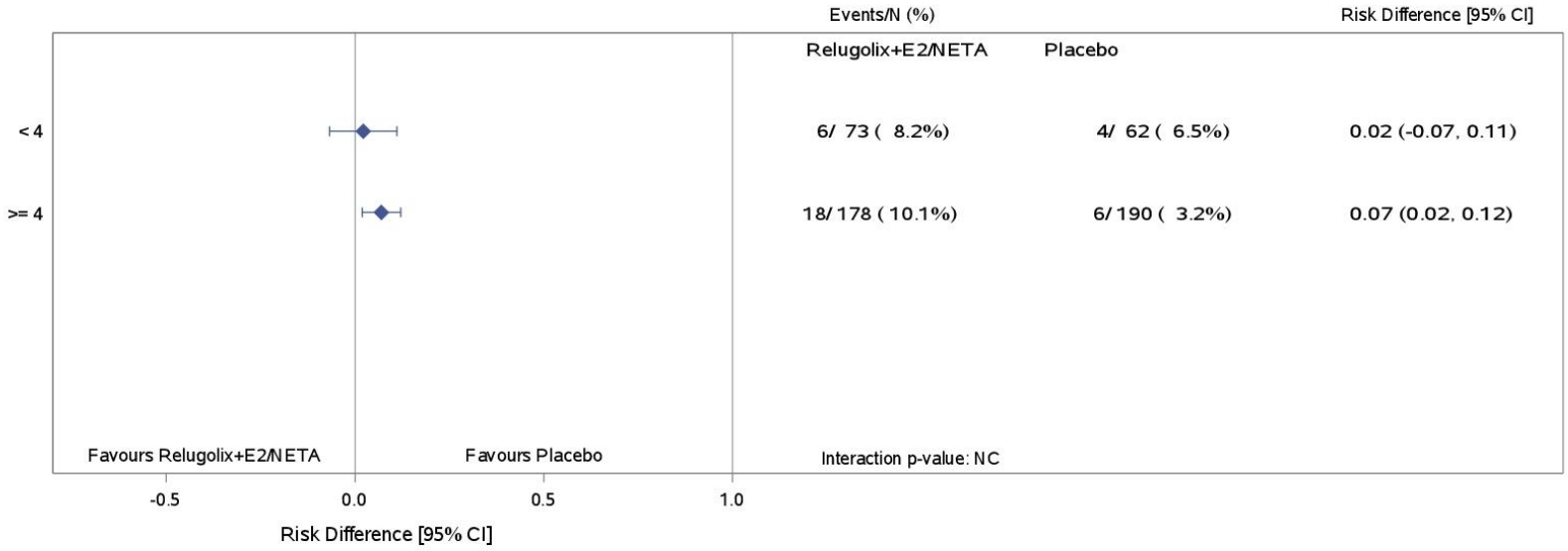
Figure SAF.TEAE.SPT.S4.BIN.FP.RD: Frequent Treatment Emergent Adverse Events by System Organ Class and Preferred Term, by Subgroup (Safety Population) - Risk Difference
Study: Pooled
System Organ Class: Skin and subcutaneous tissue disorders, Preferred Term: Any
Subgroup: Maximum NRS Pain Score at Baseline



Results are based on a Mantel-Haenszel approach stratified by study using a one-stage fixed-effects IPD meta-analysis.
The reference group is Placebo. Patients with multiple events are counted only once. MedDRA (version 22.0).
Patients with multiple events for a given PT or SOC are counted only once for each PT and SOC. Only SOCs or PTs for which there are at least 10% of patients with an event in at least one treatment group OR at least 10 patients with an event overall and at least 1% of patients with an event in at least one treatment group in the overall safety population are considered. Further, only SOCs and PTs for which there is a significant treatment effect (p-value <0.05) in the overall safety population are presented. Events are sorted alphabetically by SOC and PT and then by subgroup within each. MedDRA (version 22.0).
N: Number of patients in treatment group; NETA: Norethindrone acetate; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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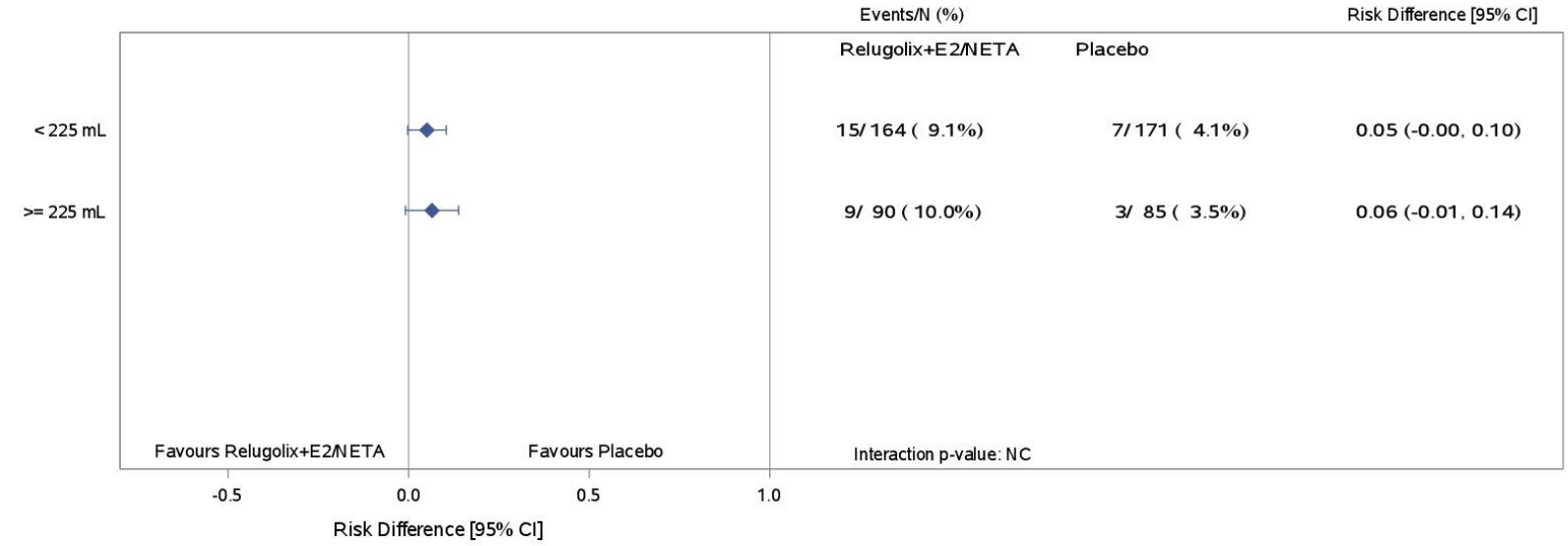
Figure SAF.TEAE.SPT.S5.BIN.FP.RD: Frequent Treatment Emergent Adverse Events by System Organ Class and Preferred Term, by Subgroup (Safety Population) - Risk Difference
Study: Pooled
System Organ Class: Skin and subcutaneous tissue disorders, Preferred Term: Any
Subgroup: MBL Volume at Baseline (mL)



Results are based on a Mantel-Haenszel approach stratified by study using a one-stage fixed-effects IPD meta-analysis.
The reference group is Placebo. Patients with multiple events are counted only once. MedDRA (version 22.0).
Patients with multiple events for a given PT or SOC are counted only once for each PT and SOC. Only SOCs or PTs for which there are at least 10% of patients with an event in at least one treatment group OR at least 10 patients with an event overall and at least 1% of patients with an event in at least one treatment group in the overall safety population are considered. Further, only SOCs and PTs for which there is a significant treatment effect (p-value <0.05) in the overall safety population are presented. Events are sorted alphabetically by SOC and PT and then by subgroup within each. MedDRA (version 22.0).
N: Number of patients in treatment group; NETA: Norethindrone acetate; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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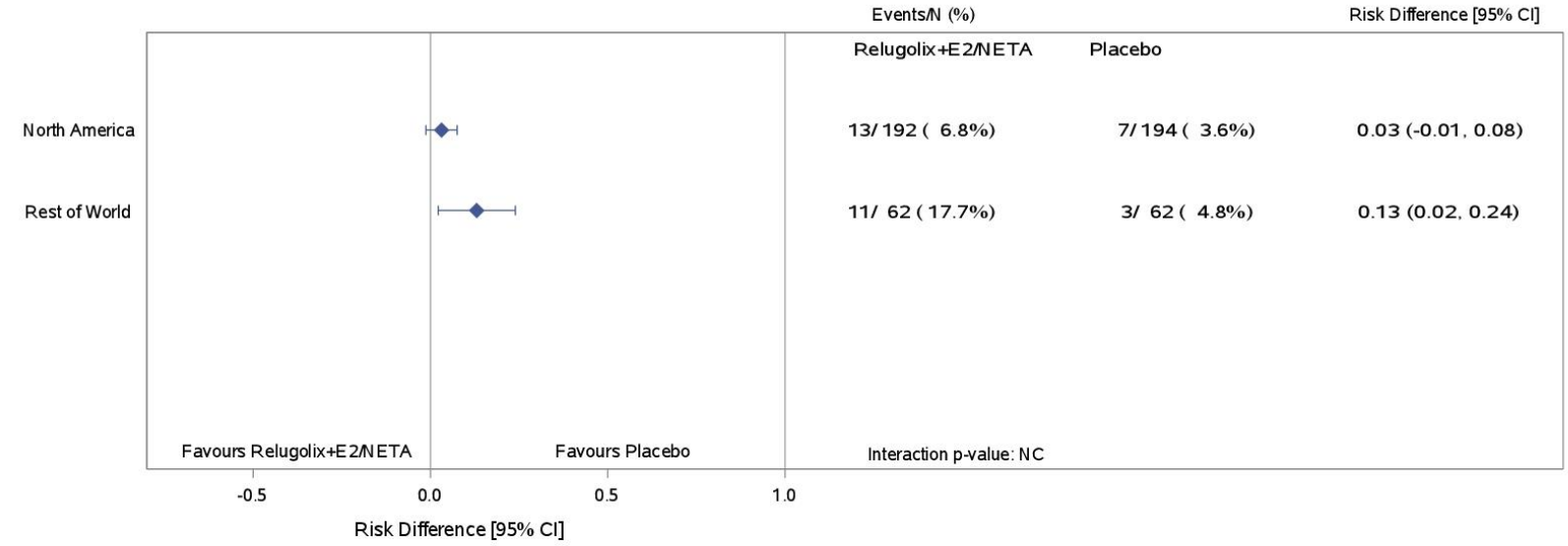
Figure SAF.TEAE.SPT.S6.BIN.FP.RD: Frequent Treatment Emergent Adverse Events by System Organ Class and Preferred Term, by Subgroup (Safety Population) - Risk Difference
Study: Pooled
System Organ Class: Skin and subcutaneous tissue disorders, Preferred Term: Any
Subgroup: Geographic Region I



Results are based on a Mantel-Haenszel approach stratified by study using a one-stage fixed-effects IPD meta-analysis.
The reference group is Placebo. Patients with multiple events are counted only once. MedDRA (version 22.0).
Patients with multiple events for a given PT or SOC are counted only once for each PT and SOC. Only SOCs or PTs for which there are at least 10% of patients with an event in at least one treatment group OR at least 10 patients with an event overall and at least 1% of patients with an event in at least one treatment group in the overall safety population are considered. Further, only SOCs and PTs for which there is a significant treatment effect (p-value <0.05) in the overall safety population are presented. Events are sorted alphabetically by SOC and PT and then by subgroup within each. MedDRA (version 22.0).
N: Number of patients in treatment group; NETA: Norethindrone acetate; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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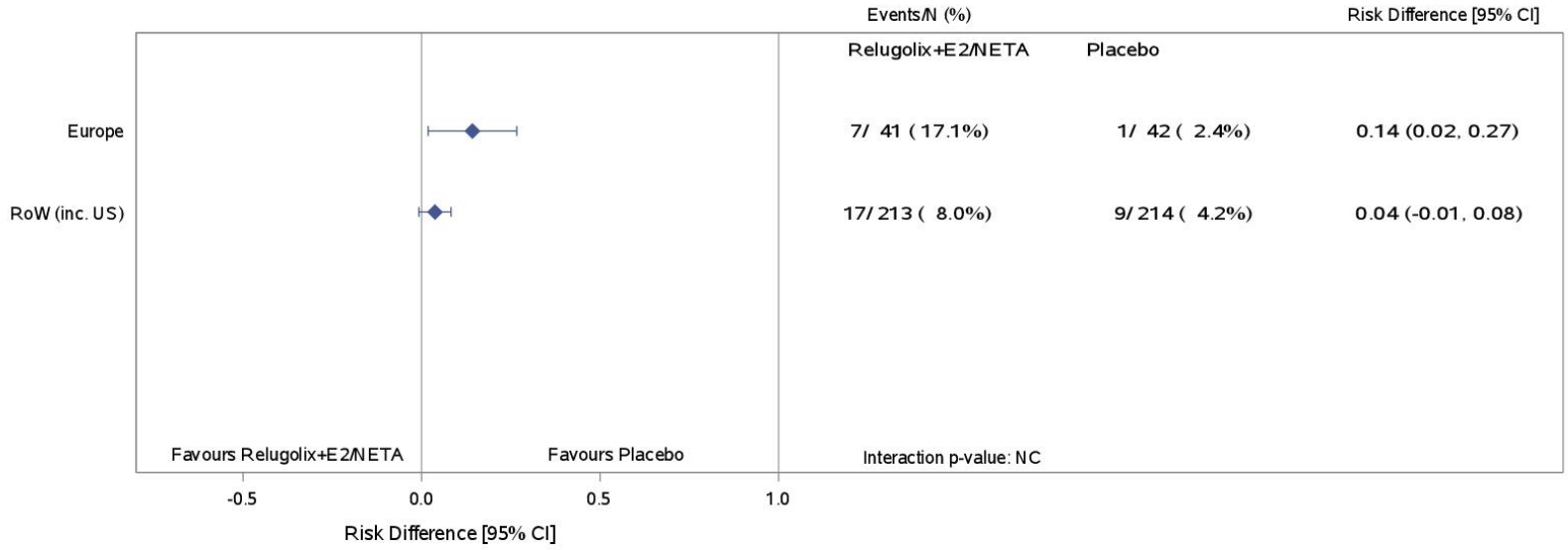
Figure SAF.TEAE.SPT.S7.BIN.FP.RD: Frequent Treatment Emergent Adverse Events by System Organ Class and Preferred Term, by Subgroup (Safety Population) - Risk Difference
Study: Pooled
System Organ Class: Skin and subcutaneous tissue disorders, Preferred Term: Any
Subgroup: Geographic Region II



Results are based on a Mantel-Haenszel approach stratified by study using a one-stage fixed-effects IPD meta-analysis.
The reference group is Placebo. Patients with multiple events are counted only once. MedDRA (version 22.0).
Patients with multiple events for a given PT or SOC are counted only once for each PT and SOC. Only SOCs or PTs for which there are at least 10% of patients with an event in at least one treatment group OR at least 10 patients with an event overall and at least 1% of patients with an event in at least one treatment group in the overall safety population are considered. Further, only SOCs and PTs for which there is a significant treatment effect (p-value <0.05) in the overall safety population are presented. Events are sorted alphabetically by SOC and PT and then by subgroup within each. MedDRA (version 22.0).
N: Number of patients in treatment group; NETA: Norethindrone acetate; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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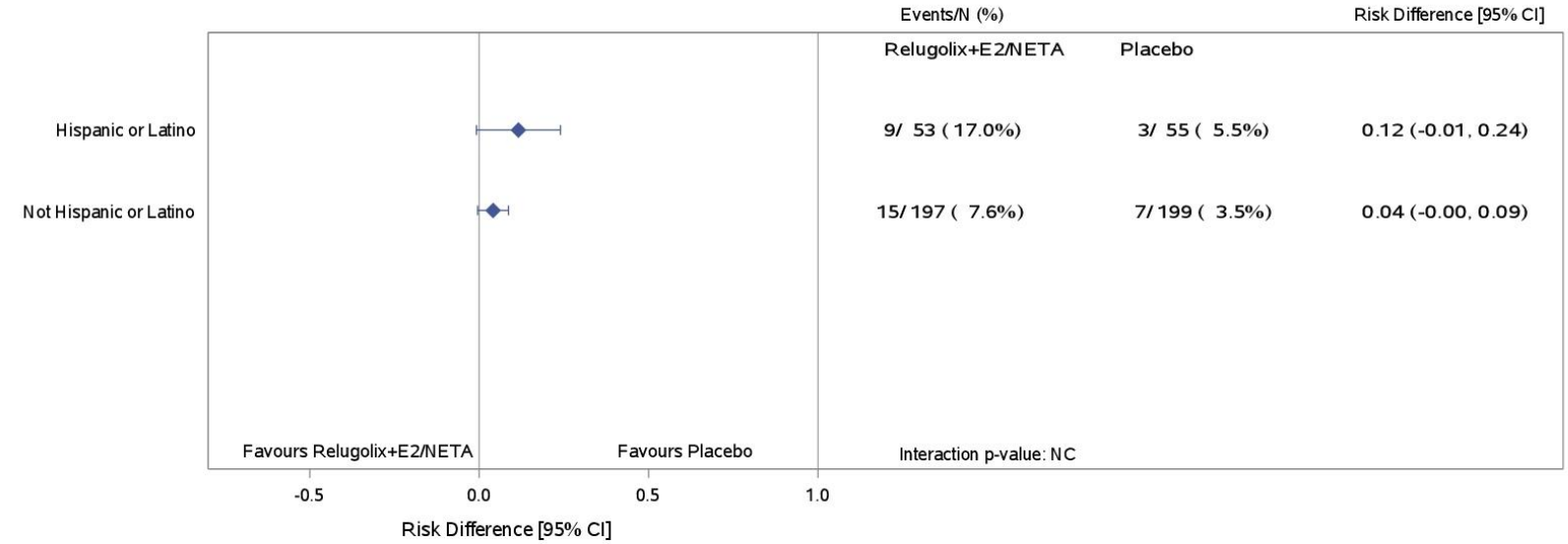
Figure SAF.TEAE.SPT.S8.BIN.FP.RD: Frequent Treatment Emergent Adverse Events by System Organ Class and Preferred Term, by Subgroup (Safety Population) - Risk Difference
Study: Pooled
System Organ Class: Skin and subcutaneous tissue disorders, Preferred Term: Any
Subgroup: Ethnicity



Results are based on a Mantel-Haenszel approach stratified by study using a one-stage fixed-effects IPD meta-analysis.
The reference group is Placebo. Patients with multiple events are counted only once. MedDRA (version 22.0).
Patients with multiple events for a given PT or SOC are counted only once for each PT and SOC. Only SOCs or PTs for which there are at least 10% of patients with an event in at least one treatment group OR at least 10 patients with an event overall and at least 1% of patients with an event in at least one treatment group in the overall safety population are considered. Further, only SOCs and PTs for which there is a significant treatment effect (p-value <0.05) in the overall safety population are presented. Events are sorted alphabetically by SOC and PT and then by subgroup within each. MedDRA (version 22.0).
N: Number of patients in treatment group; NETA: Norethindrone acetate; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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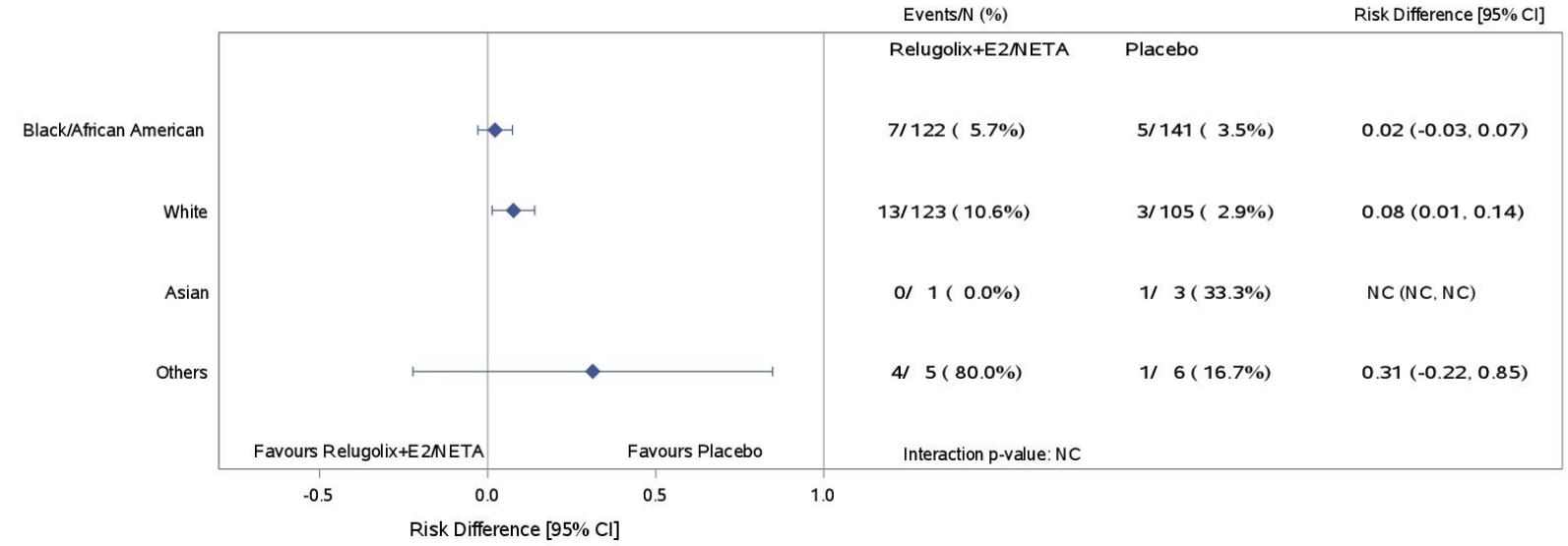
Figure SAF.TEAE.SPT.S9.BIN.FP.RD: Frequent Treatment Emergent Adverse Events by System Organ Class and Preferred Term, by Subgroup (Safety Population) - Risk Difference
Study: Pooled
System Organ Class: Skin and subcutaneous tissue disorders, Preferred Term: Any
Subgroup: Race



Results are based on a Mantel-Haenszel approach stratified by study using a one-stage fixed-effects IPD meta-analysis.
The reference group is Placebo. Patients with multiple events are counted only once. MedDRA (version 22.0).
Patients with multiple events for a given PT or SOC are counted only once for each PT and SOC. Only SOCs or PTs for which there are at least 10% of patients with an event in at least one treatment group OR at least 10 patients with an event overall and at least 1% of patients with an event in at least one treatment group in the overall safety population are considered. Further, only SOCs and PTs for which there is a significant treatment effect (p-value <0.05) in the overall safety population are presented. Events are sorted alphabetically by SOC and PT and then by subgroup within each. MedDRA (version 22.0).
N: Number of patients in treatment group; NETA: Norethindrone acetate; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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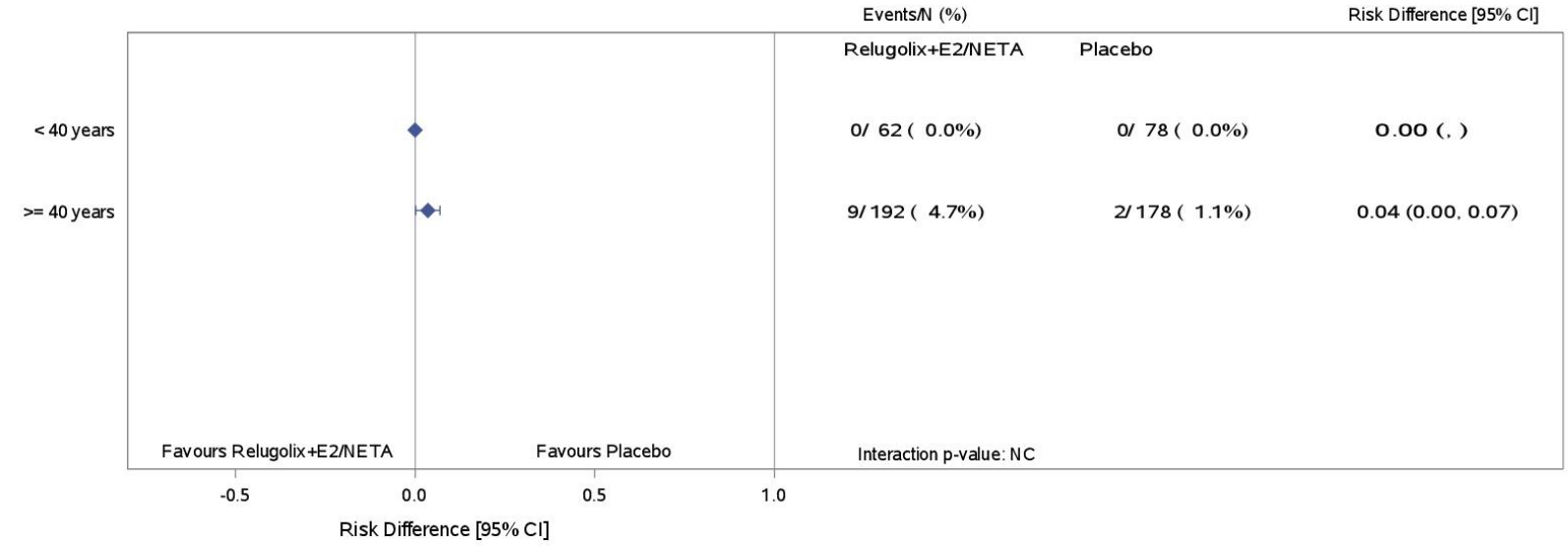
Figure SAF.TEAE.SPT.S1.BIN.FP.RD: Frequent Treatment Emergent Adverse Events by System Organ Class and Preferred Term, by Subgroup (Safety Population) - Risk Difference
Study: Pooled
System Organ Class: Skin and subcutaneous tissue disorders, Preferred Term: Alopecia
Subgroup: Age (years)



Results are based on a Mantel-Haenszel approach stratified by study using a one-stage fixed-effects IPD meta-analysis.
The reference group is Placebo. Patients with multiple events are counted only once. MedDRA (version 22.0).
Patients with multiple events for a given PT or SOC are counted only once for each PT and SOC. Only SOCs or PTs for which there are at least 10% of patients with an event in at least one treatment group OR at least 10 patients with an event overall and at least 1% of patients with an event in at least one treatment group in the overall safety population are considered. Further, only SOCs and PTs for which there is a significant treatment effect (p-value <0.05) in the overall safety population are presented. Events are sorted alphabetically by SOC and PT and then by subgroup within each. MedDRA (version 22.0).
N: Number of patients in treatment group; NETA: Norethindrone acetate; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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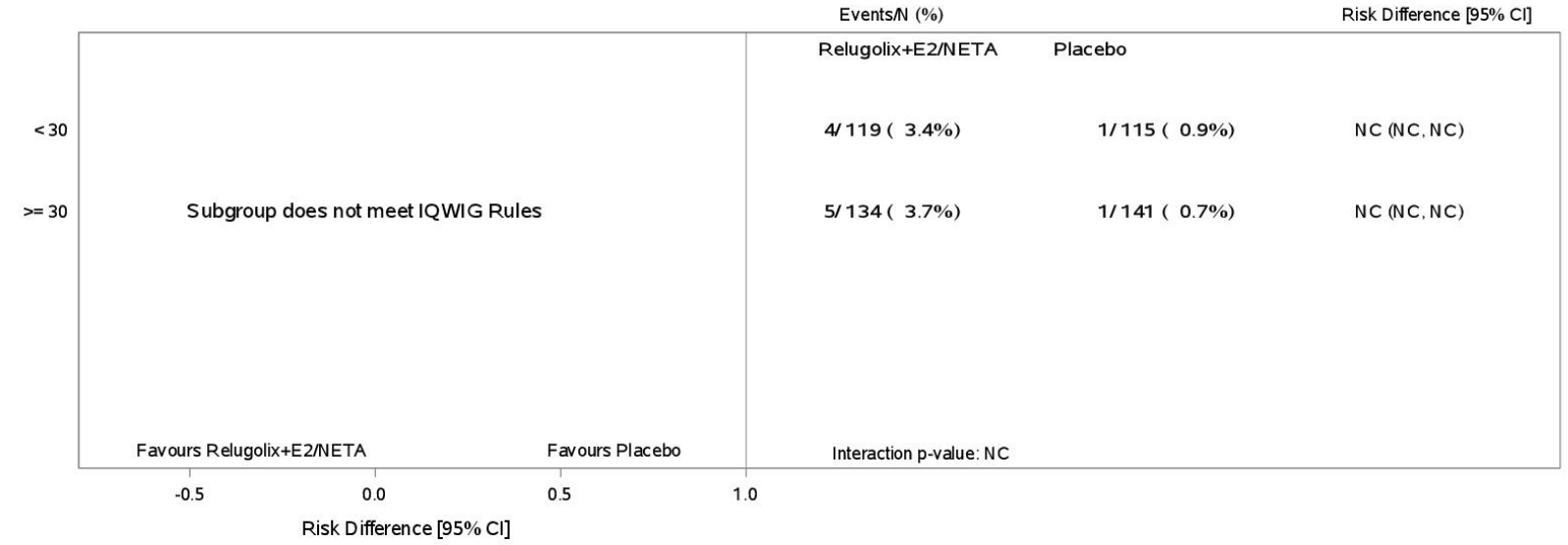
Figure SAF.TEAE.SPT.S2.BIN.FP.RD: Frequent Treatment Emergent Adverse Events by System Organ Class and Preferred Term, by Subgroup (Safety Population) - Risk Difference
Study: Pooled
System Organ Class: Skin and subcutaneous tissue disorders, Preferred Term: Alopecia
Subgroup: BMI (kg/m2) at Baseline



Results are based on a Mantel-Haenszel approach stratified by study using a one-stage fixed-effects IPD meta-analysis.
The reference group is Placebo. Patients with multiple events are counted only once. MedDRA (version 22.0).
Patients with multiple events for a given PT or SOC are counted only once for each PT and SOC. Only SOCs or PTs for which there are at least 10% of patients with an event in at least one treatment group OR at least 10 patients with an event overall and at least 1% of patients with an event in at least one treatment group in the overall safety population are considered. Further, only SOCs and PTs for which there is a significant treatment effect (p-value <0.05) in the overall safety population are presented. Events are sorted alphabetically by SOC and PT and then by subgroup within each. MedDRA (version 22.0).
N: Number of patients in treatment group; NETA: Norethindrone acetate; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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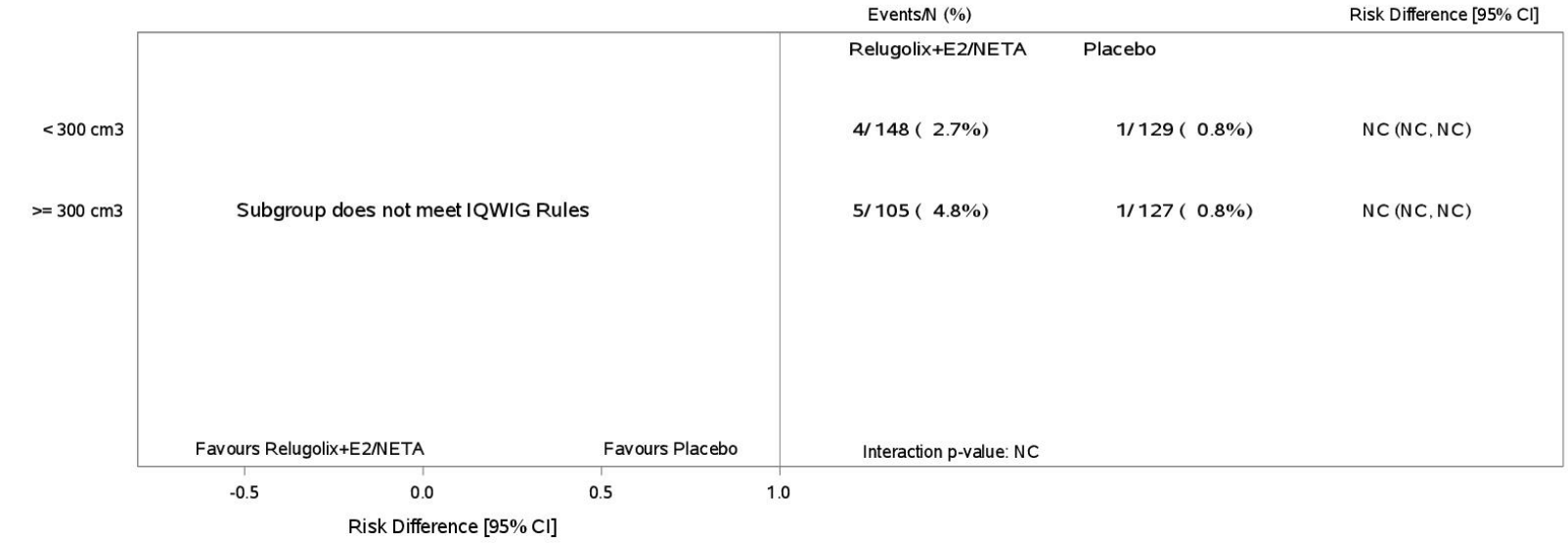
Figure SAF.TEAE.SPT.S3.BIN.FP.RD: Frequent Treatment Emergent Adverse Events by System Organ Class and Preferred Term, by Subgroup (Safety Population) - Risk Difference
Study: Pooled
System Organ Class: Skin and subcutaneous tissue disorders, Preferred Term: Alopecia
Subgroup: Uterine Volume at Baseline (cm3)



Results are based on a Mantel-Haenszel approach stratified by study using a one-stage fixed-effects IPD meta-analysis.
The reference group is Placebo. Patients with multiple events are counted only once. MedDRA (version 22.0).
Patients with multiple events for a given PT or SOC are counted only once for each PT and SOC. Only SOCs or PTs for which there are at least 10% of patients with an event in at least one treatment group OR at least 10 patients with an event overall and at least 1% of patients with an event in at least one treatment group in the overall safety population are considered. Further, only SOCs and PTs for which there is a significant treatment effect (p-value <0.05) in the overall safety population are presented. Events are sorted alphabetically by SOC and PT and then by subgroup within each. MedDRA (version 22.0).
N: Number of patients in treatment group; NETA: Norethindrone acetate; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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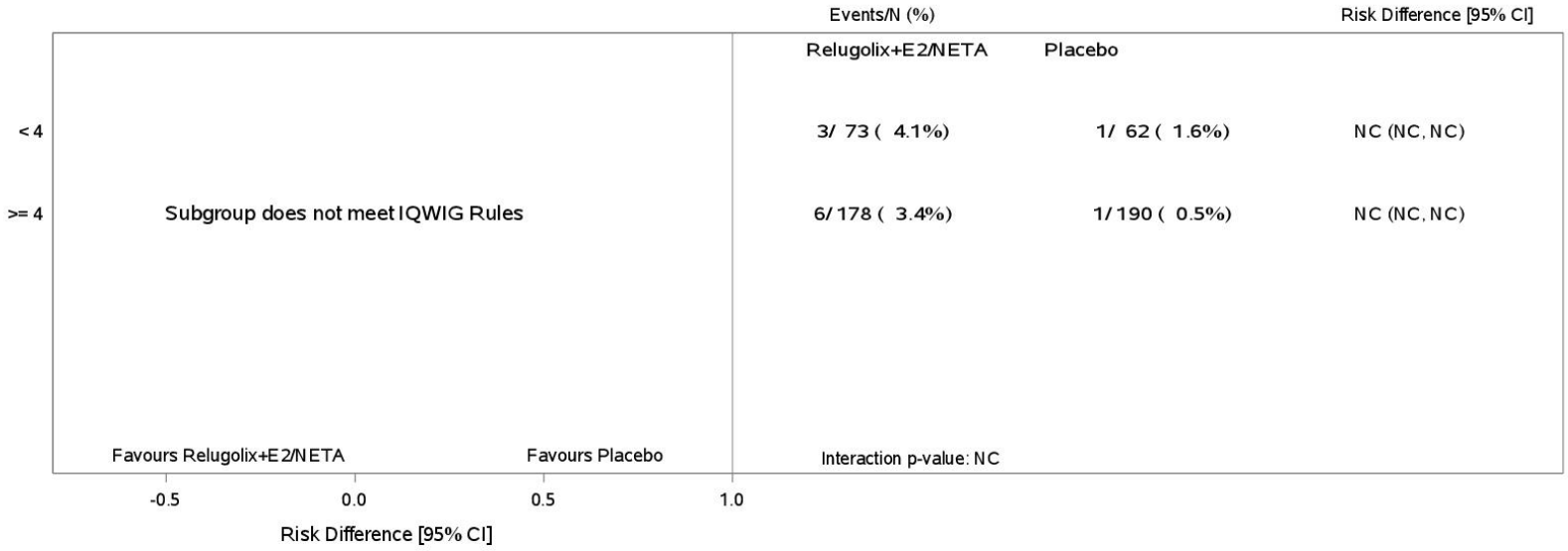
Figure SAF.TEAE.SPT.S4.BIN.FP.RD: Frequent Treatment Emergent Adverse Events by System Organ Class and Preferred Term, by Subgroup (Safety Population) - Risk Difference
Study: Pooled
System Organ Class: Skin and subcutaneous tissue disorders, Preferred Term: Alopecia
Subgroup: Maximum NRS Pain Score at Baseline



Results are based on a Mantel-Haenszel approach stratified by study using a one-stage fixed-effects IPD meta-analysis.
The reference group is Placebo. Patients with multiple events are counted only once. MedDRA (version 22.0).
Patients with multiple events for a given PT or SOC are counted only once for each PT and SOC. Only SOCs or PTs for which there are at least 10% of patients with an event in at least one treatment group OR at least 10 patients with an event overall and at least 1% of patients with an event in at least one treatment group in the overall safety population are considered. Further, only SOCs and PTs for which there is a significant treatment effect (p-value <0.05) in the overall safety population are presented. Events are sorted alphabetically by SOC and PT and then by subgroup within each. MedDRA (version 22.0).
N: Number of patients in treatment group; NETA: Norethindrone acetate; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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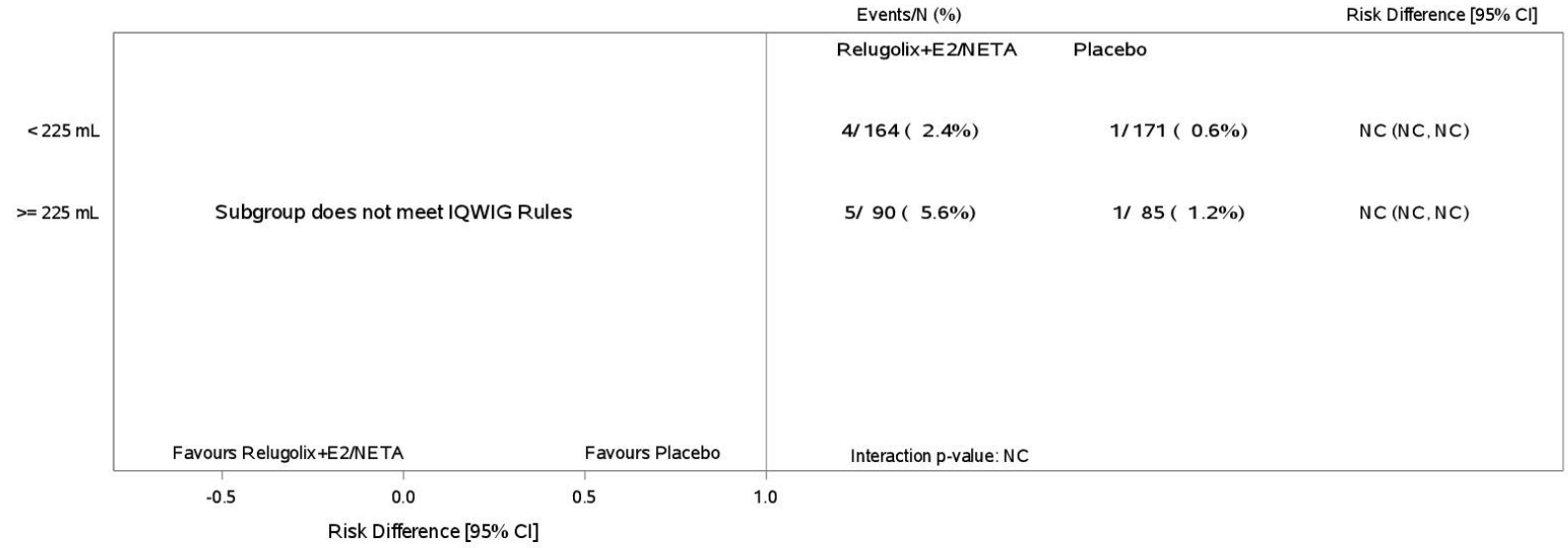
Figure SAF.TEAE.SPT.S5.BIN.FP.RD: Frequent Treatment Emergent Adverse Events by System Organ Class and Preferred Term, by Subgroup (Safety Population) - Risk Difference
Study: Pooled
System Organ Class: Skin and subcutaneous tissue disorders, Preferred Term: Alopecia
Subgroup: MBL Volume at Baseline (mL)



Results are based on a Mantel-Haenszel approach stratified by study using a one-stage fixed-effects IPD meta-analysis.
The reference group is Placebo. Patients with multiple events are counted only once. MedDRA (version 22.0).
Patients with multiple events for a given PT or SOC are counted only once for each PT and SOC. Only SOCs or PTs for which there are at least 10% of patients with an event in at least one treatment group OR at least 10 patients with an event overall and at least 1% of patients with an event in at least one treatment group in the overall safety population are considered. Further, only SOCs and PTs for which there is a significant treatment effect (p-value <0.05) in the overall safety population are presented. Events are sorted alphabetically by SOC and PT and then by subgroup within each. MedDRA (version 22.0).
N: Number of patients in treatment group; NETA: Norethindrone acetate; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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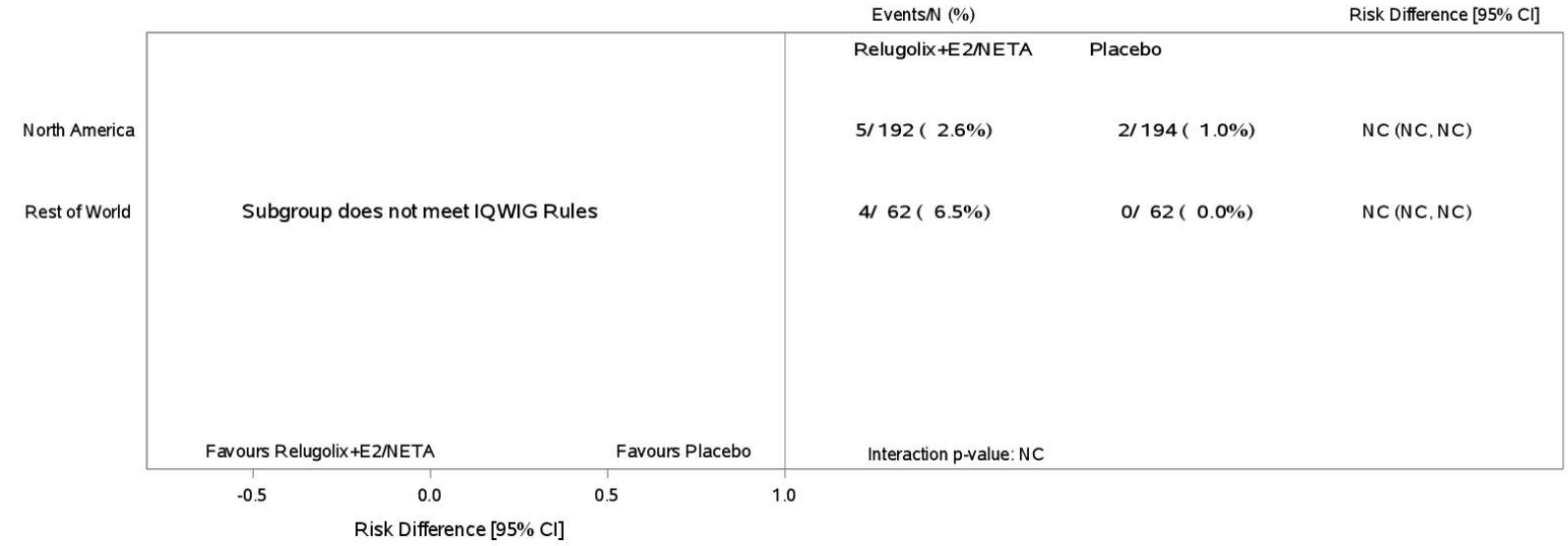
Figure SAF.TEAE.SPT.S6.BIN.FP.RD: Frequent Treatment Emergent Adverse Events by System Organ Class and Preferred Term, by Subgroup (Safety Population) - Risk Difference
Study: Pooled
System Organ Class: Skin and subcutaneous tissue disorders, Preferred Term: Alopecia
Subgroup: Geographic Region I



Results are based on a Mantel-Haenszel approach stratified by study using a one-stage fixed-effects IPD meta-analysis.
The reference group is Placebo. Patients with multiple events are counted only once. MedDRA (version 22.0).
Patients with multiple events for a given PT or SOC are counted only once for each PT and SOC. Only SOCs or PTs for which there are at least 10% of patients with an event in at least one treatment group OR at least 10 patients with an event overall and at least 1% of patients with an event in at least one treatment group in the overall safety population are considered. Further, only SOCs and PTs for which there is a significant treatment effect (p-value <0.05) in the overall safety population are presented. Events are sorted alphabetically by SOC and PT and then by subgroup within each. MedDRA (version 22.0).
N: Number of patients in treatment group; NETA: Norethindrone acetate; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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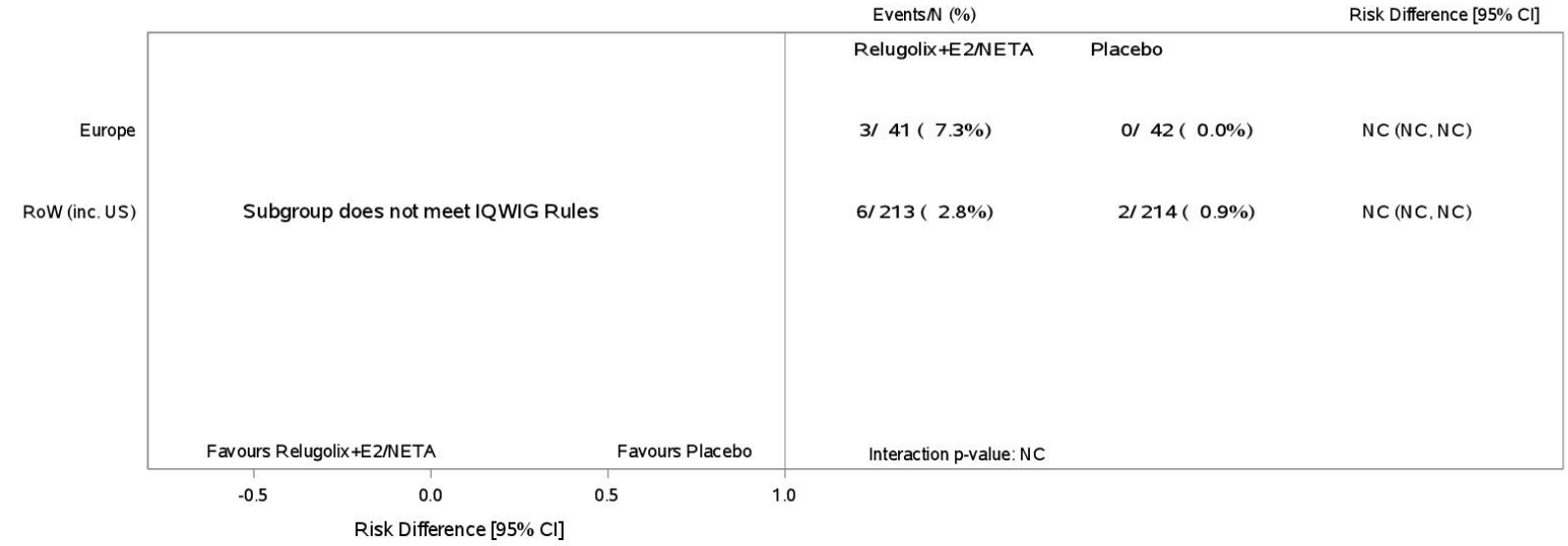
Figure SAF.TEAE.SPT.S7.BIN.FP.RD: Frequent Treatment Emergent Adverse Events by System Organ Class and Preferred Term, by Subgroup (Safety Population) - Risk Difference
Study: Pooled
System Organ Class: Skin and subcutaneous tissue disorders, Preferred Term: Alopecia
Subgroup: Geographic Region II



Results are based on a Mantel-Haenszel approach stratified by study using a one-stage fixed-effects IPD meta-analysis.
The reference group is Placebo. Patients with multiple events are counted only once. MedDRA (version 22.0).
Patients with multiple events for a given PT or SOC are counted only once for each PT and SOC. Only SOCs or PTs for which there are at least 10% of patients with an event in at least one treatment group OR at least 10 patients with an event overall and at least 1% of patients with an event in at least one treatment group in the overall safety population are considered. Further, only SOCs and PTs for which there is a significant treatment effect (p-value <0.05) in the overall safety population are presented. Events are sorted alphabetically by SOC and PT and then by subgroup within each. MedDRA (version 22.0).
N: Number of patients in treatment group; NETA: Norethindrone acetate; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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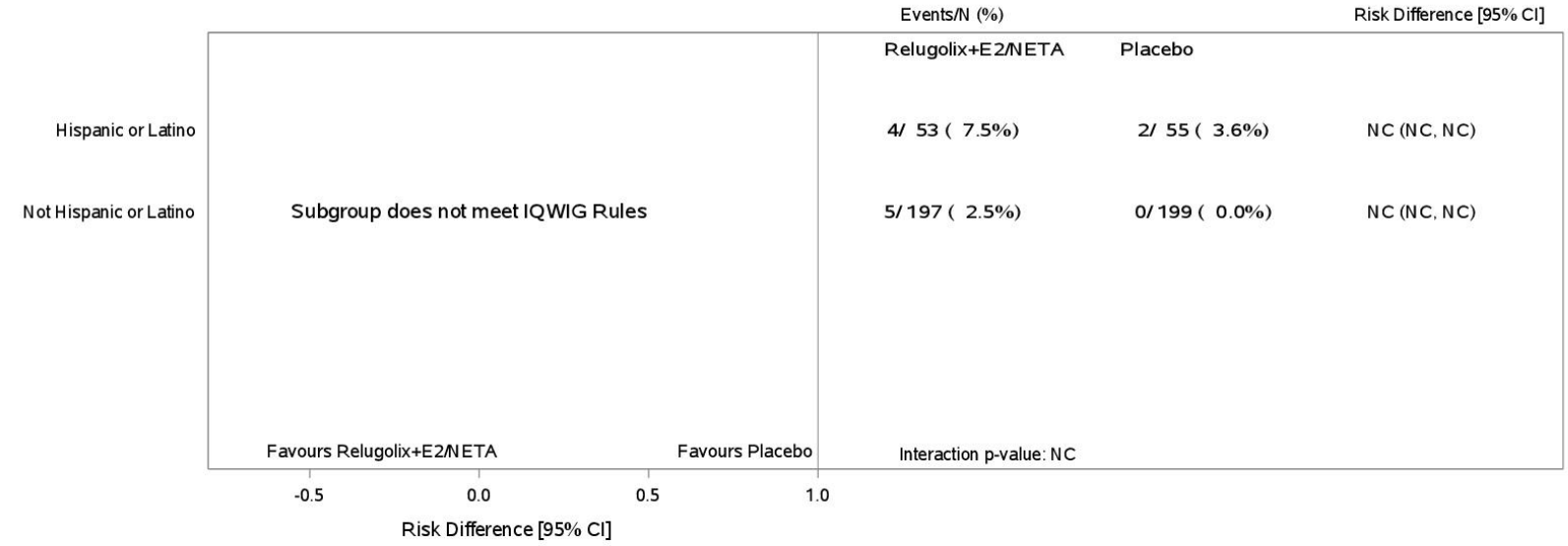
Figure SAF.TEAE.SPT.S8.BIN.FP.RD: Frequent Treatment Emergent Adverse Events by System Organ Class and Preferred Term, by Subgroup (Safety Population) - Risk Difference
Study: Pooled
System Organ Class: Skin and subcutaneous tissue disorders, Preferred Term: Alopecia
Subgroup: Ethnicity



Results are based on a Mantel-Haenszel approach stratified by study using a one-stage fixed-effects IPD meta-analysis.
The reference group is Placebo. Patients with multiple events are counted only once. MedDRA (version 22.0).
Patients with multiple events for a given PT or SOC are counted only once for each PT and SOC. Only SOCs or PTs for which there are at least 10% of patients with an event in at least one treatment group OR at least 10 patients with an event overall and at least 1% of patients with an event in at least one treatment group in the overall safety population are considered. Further, only SOCs and PTs for which there is a significant treatment effect (p-value <0.05) in the overall safety population are presented. Events are sorted alphabetically by SOC and PT and then by subgroup within each. MedDRA (version 22.0).
N: Number of patients in treatment group; NETA: Norethindrone acetate; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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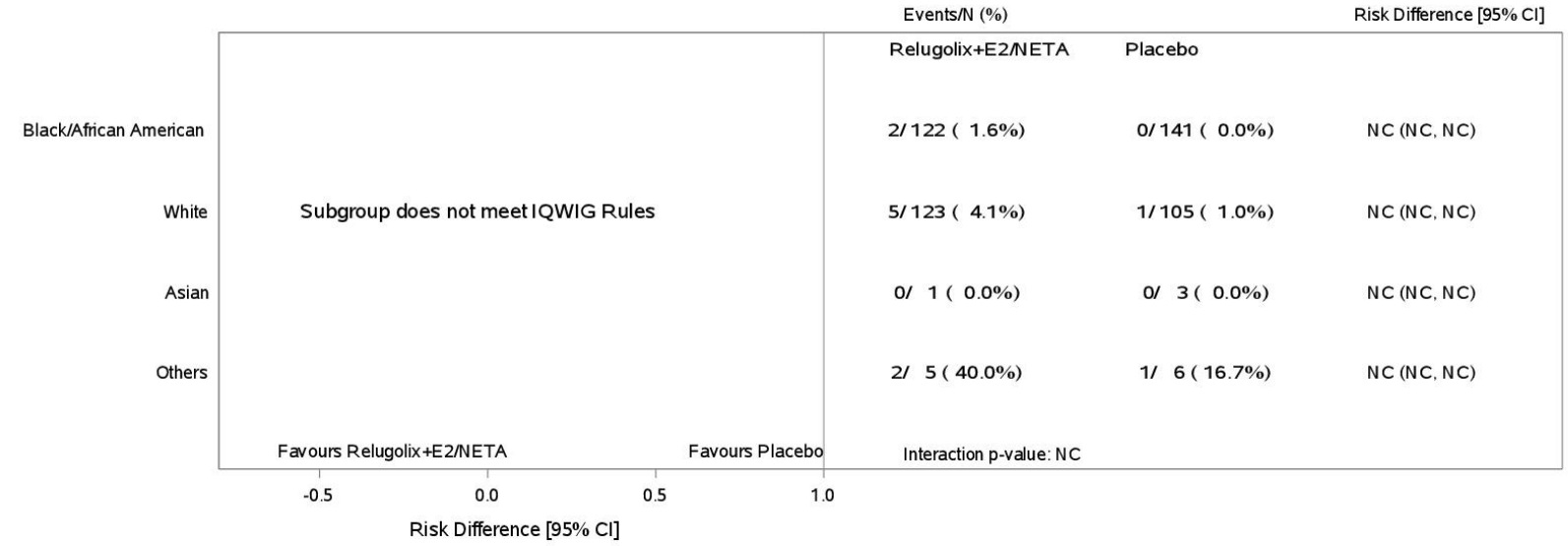
Figure SAF.TEAE.SPT.S9.BIN.FP.RD: Frequent Treatment Emergent Adverse Events by System Organ Class and Preferred Term, by Subgroup (Safety Population) - Risk Difference
Study: Pooled
System Organ Class: Skin and subcutaneous tissue disorders, Preferred Term: Alopecia
Subgroup: Race



Results are based on a Mantel-Haenszel approach stratified by study using a one-stage fixed-effects IPD meta-analysis.
The reference group is Placebo. Patients with multiple events are counted only once. MedDRA (version 22.0).
Patients with multiple events for a given PT or SOC are counted only once for each PT and SOC. Only SOCs or PTs for which there are at least 10% of patients with an event in at least one treatment group OR at least 10 patients with an event overall and at least 1% of patients with an event in at least one treatment group in the overall safety population are considered. Further, only SOCs and PTs for which there is a significant treatment effect (p-value <0.05) in the overall safety population are presented. Events are sorted alphabetically by SOC and PT and then by subgroup within each. MedDRA (version 22.0).
N: Number of patients in treatment group; NETA: Norethindrone acetate; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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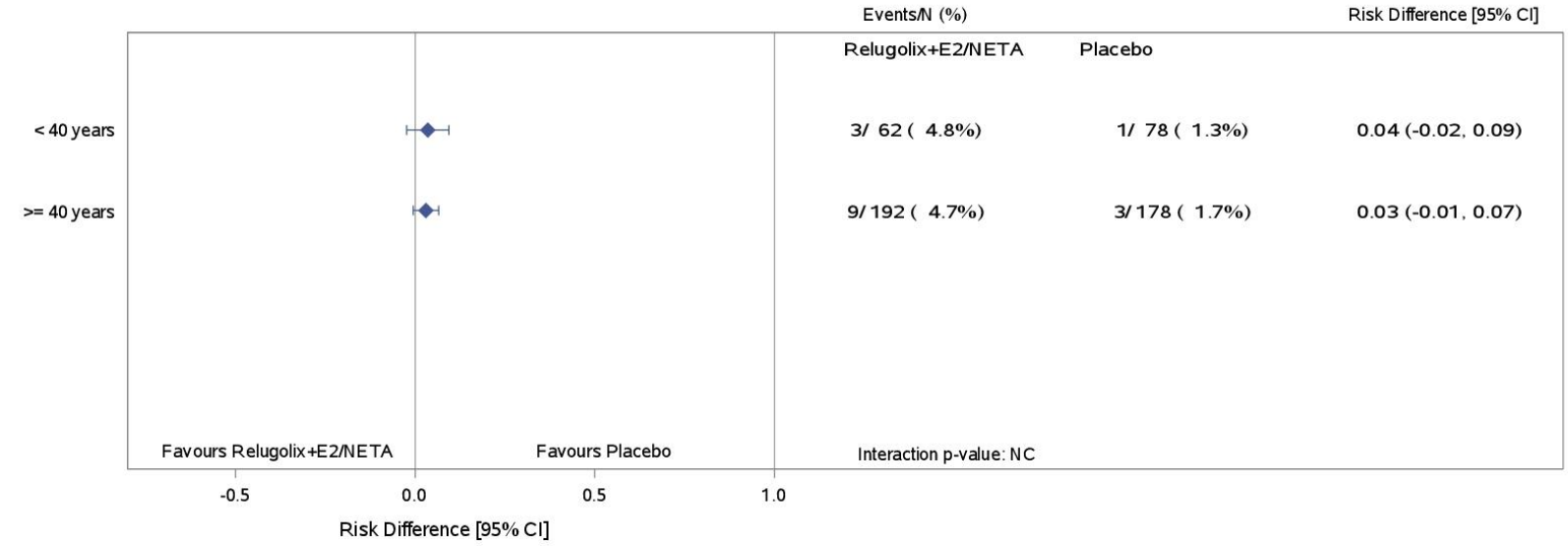
Figure SAF.TEAE.SPT.S1.BIN.FP.RD: Frequent Treatment Emergent Adverse Events by System Organ Class and Preferred Term, by Subgroup (Safety Population) - Risk Difference
Study: Pooled
System Organ Class: Vascular disorders, Preferred Term: Hypertension
Subgroup: Age (years)



Results are based on a Mantel-Haenszel approach stratified by study using a one-stage fixed-effects IPD meta-analysis.
The reference group is Placebo. Patients with multiple events are counted only once. MedDRA (version 22.0).
Patients with multiple events for a given PT or SOC are counted only once for each PT and SOC. Only SOCs or PTs for which there are at least 10% of patients with an event in at least one treatment group OR at least 10 patients with an event overall and at least 1% of patients with an event in at least one treatment group in the overall safety population are considered. Further, only SOCs and PTs for which there is a significant treatment effect (p-value <0.05) in the overall safety population are presented. Events are sorted alphabetically by SOC and PT and then by subgroup within each. MedDRA (version 22.0).
N: Number of patients in treatment group; NETA: Norethindrone acetate; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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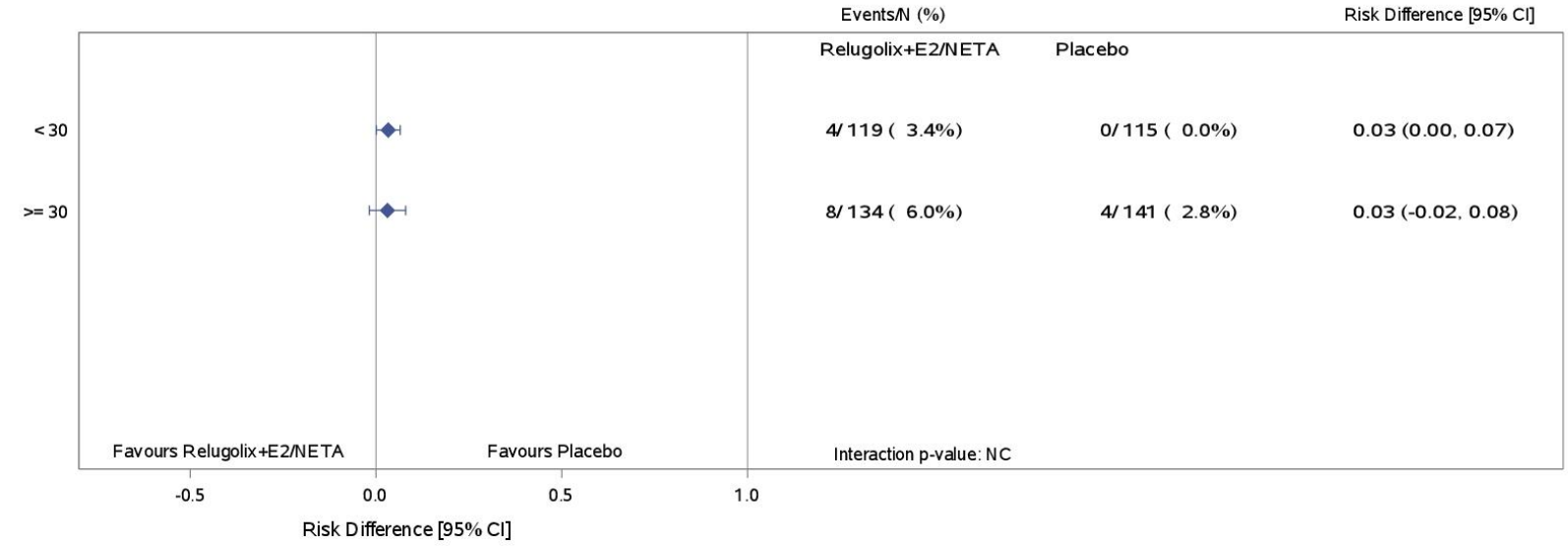
Figure SAF.TEAE.SPT.S2.BIN.FP.RD: Frequent Treatment Emergent Adverse Events by System Organ Class and Preferred Term, by Subgroup (Safety Population) - Risk Difference
Study: Pooled
System Organ Class: Vascular disorders, Preferred Term: Hypertension
Subgroup: BMI (kg/m2) at Baseline



Results are based on a Mantel-Haenszel approach stratified by study using a one-stage fixed-effects IPD meta-analysis.
The reference group is Placebo. Patients with multiple events are counted only once. MedDRA (version 22.0).
Patients with multiple events for a given PT or SOC are counted only once for each PT and SOC. Only SOCs or PTs for which there are at least 10% of patients with an event in at least one treatment group OR at least 10 patients with an event overall and at least 1% of patients with an event in at least one treatment group in the overall safety population are considered. Further, only SOCs and PTs for which there is a significant treatment effect (p-value <0.05) in the overall safety population are presented. Events are sorted alphabetically by SOC and PT and then by subgroup within each. MedDRA (version 22.0).
N: Number of patients in treatment group; NETA: Norethindrone acetate; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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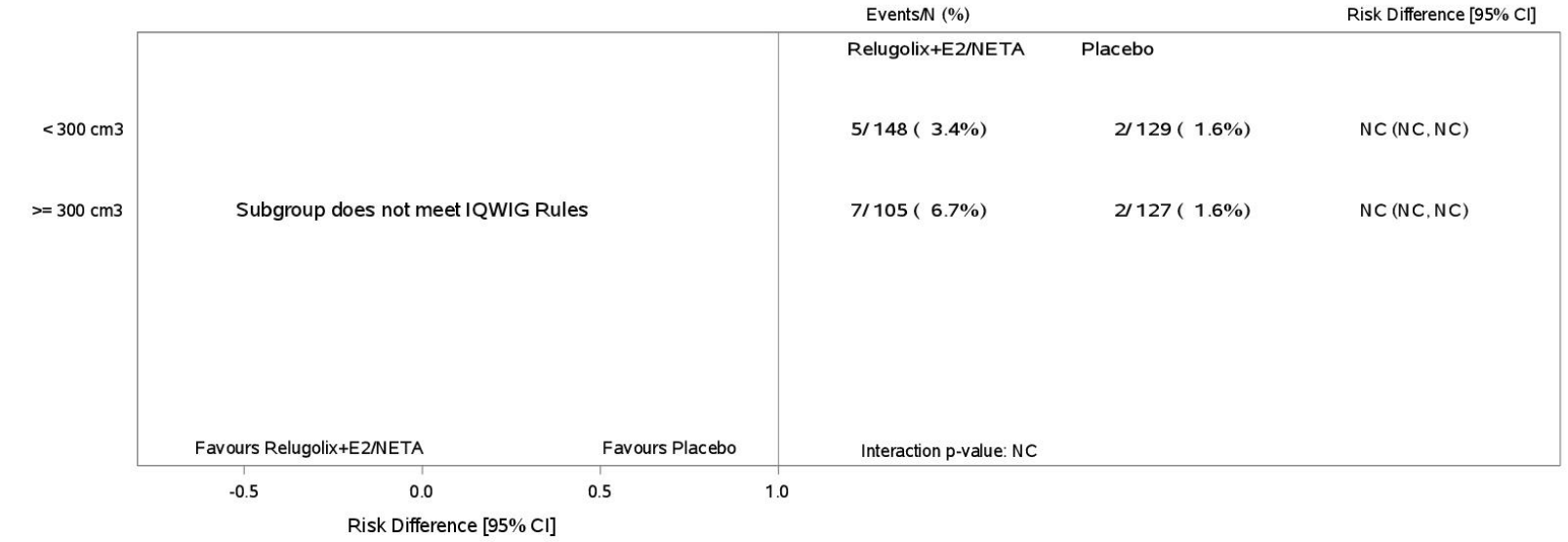
Figure SAF.TEAE.SPT.S3.BIN.FP.RD: Frequent Treatment Emergent Adverse Events by System Organ Class and Preferred Term, by Subgroup (Safety Population) - Risk Difference
Study: Pooled
System Organ Class: Vascular disorders, Preferred Term: Hypertension
Subgroup: Uterine Volume at Baseline (cm3)



Results are based on a Mantel-Haenszel approach stratified by study using a one-stage fixed-effects IPD meta-analysis.
The reference group is Placebo. Patients with multiple events are counted only once. MedDRA (version 22.0).
Patients with multiple events for a given PT or SOC are counted only once for each PT and SOC. Only SOCs or PTs for which there are at least 10% of patients with an event in at least one treatment group OR at least 10 patients with an event overall and at least 1% of patients with an event in at least one treatment group in the overall safety population are considered. Further, only SOCs and PTs for which there is a significant treatment effect (p-value <0.05) in the overall safety population are presented. Events are sorted alphabetically by SOC and PT and then by subgroup within each. MedDRA (version 22.0).
N: Number of patients in treatment group; NETA: Norethindrone acetate; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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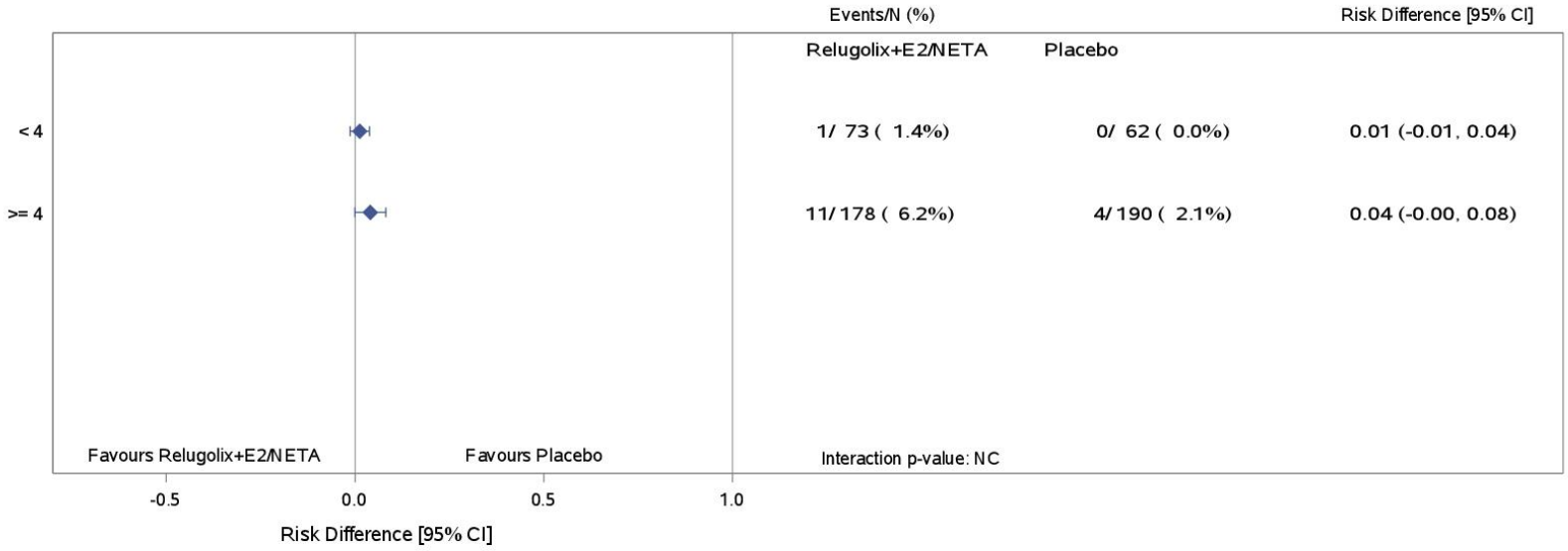
Figure SAF.TEAE.SPT.S4.BIN.FP.RD: Frequent Treatment Emergent Adverse Events by System Organ Class and Preferred Term, by Subgroup (Safety Population) - Risk Difference
Study: Pooled
System Organ Class: Vascular disorders, Preferred Term: Hypertension
Subgroup: Maximum NRS Pain Score at Baseline



Results are based on a Mantel-Haenszel approach stratified by study using a one-stage fixed-effects IPD meta-analysis.
The reference group is Placebo. Patients with multiple events are counted only once. MedDRA (version 22.0).
Patients with multiple events for a given PT or SOC are counted only once for each PT and SOC. Only SOCs or PTs for which there are at least 10% of patients with an event in at least one treatment group OR at least 10 patients with an event overall and at least 1% of patients with an event in at least one treatment group in the overall safety population are considered. Further, only SOCs and PTs for which there is a significant treatment effect (p-value <0.05) in the overall safety population are presented. Events are sorted alphabetically by SOC and PT and then by subgroup within each. MedDRA (version 22.0).
N: Number of patients in treatment group; NETA: Norethindrone acetate; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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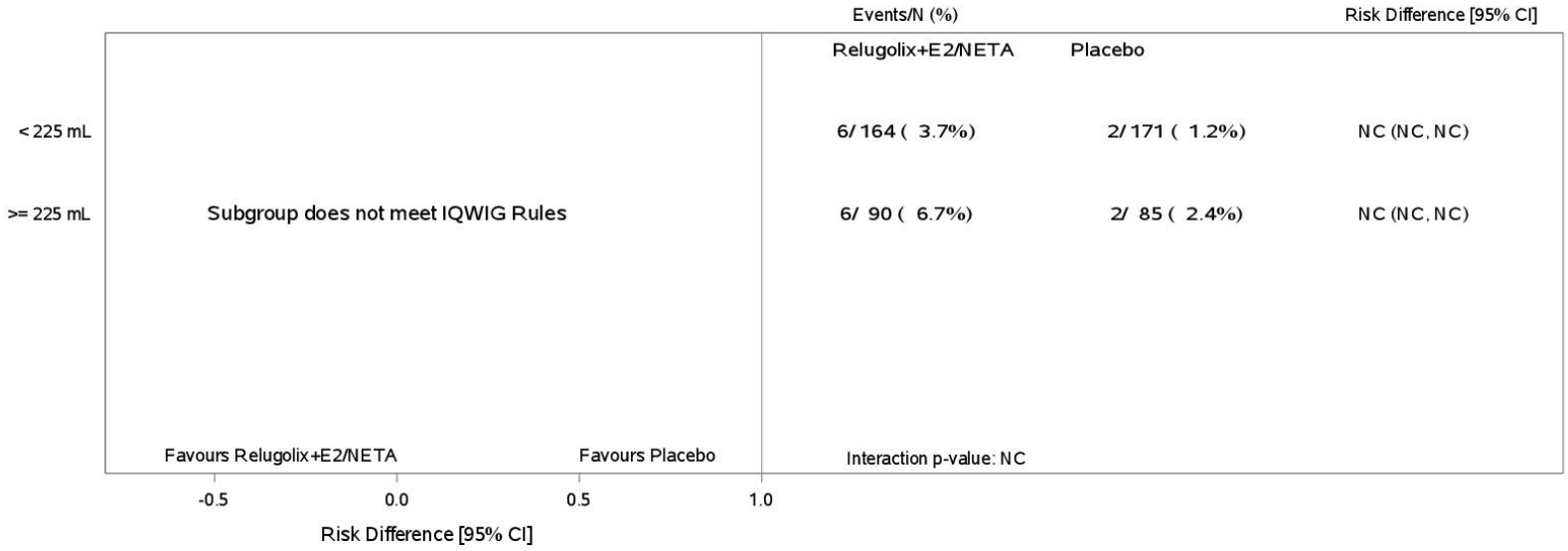
Figure SAF.TEAE.SPT.S5.BIN.FP.RD: Frequent Treatment Emergent Adverse Events by System Organ Class and Preferred Term, by Subgroup (Safety Population) - Risk Difference
Study: Pooled
System Organ Class: Vascular disorders, Preferred Term: Hypertension
Subgroup: MBL Volume at Baseline (mL)



Results are based on a Mantel-Haenszel approach stratified by study using a one-stage fixed-effects IPD meta-analysis.
The reference group is Placebo. Patients with multiple events are counted only once. MedDRA (version 22.0).
Patients with multiple events for a given PT or SOC are counted only once for each PT and SOC. Only SOCs or PTs for which there are at least 10% of patients with an event in at least one treatment group OR at least 10 patients with an event overall and at least 1% of patients with an event in at least one treatment group in the overall safety population are considered. Further, only SOCs and PTs for which there is a significant treatment effect (p-value <0.05) in the overall safety population are presented. Events are sorted alphabetically by SOC and PT and then by subgroup within each. MedDRA (version 22.0).
N: Number of patients in treatment group; NETA: Norethindrone acetate; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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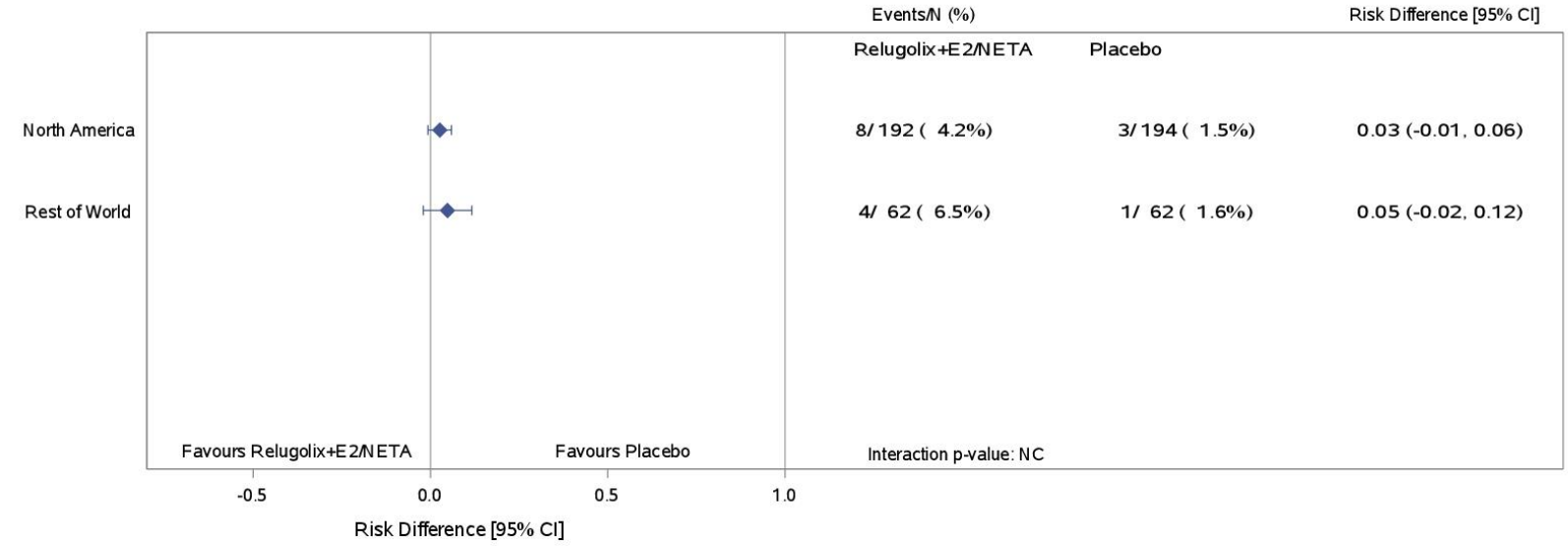
Figure SAF.TEAE.SPT.S6.BIN.FP.RD: Frequent Treatment Emergent Adverse Events by System Organ Class and Preferred Term, by Subgroup (Safety Population) - Risk Difference
Study: Pooled
System Organ Class: Vascular disorders, Preferred Term: Hypertension
Subgroup: Geographic Region I



Results are based on a Mantel-Haenszel approach stratified by study using a one-stage fixed-effects IPD meta-analysis.
The reference group is Placebo. Patients with multiple events are counted only once. MedDRA (version 22.0).
Patients with multiple events for a given PT or SOC are counted only once for each PT and SOC. Only SOCs or PTs for which there are at least 10% of patients with an event in at least one treatment group OR at least 10 patients with an event overall and at least 1% of patients with an event in at least one treatment group in the overall safety population are considered. Further, only SOCs and PTs for which there is a significant treatment effect (p-value <0.05) in the overall safety population are presented. Events are sorted alphabetically by SOC and PT and then by subgroup within each. MedDRA (version 22.0).
N: Number of patients in treatment group; NETA: Norethindrone acetate; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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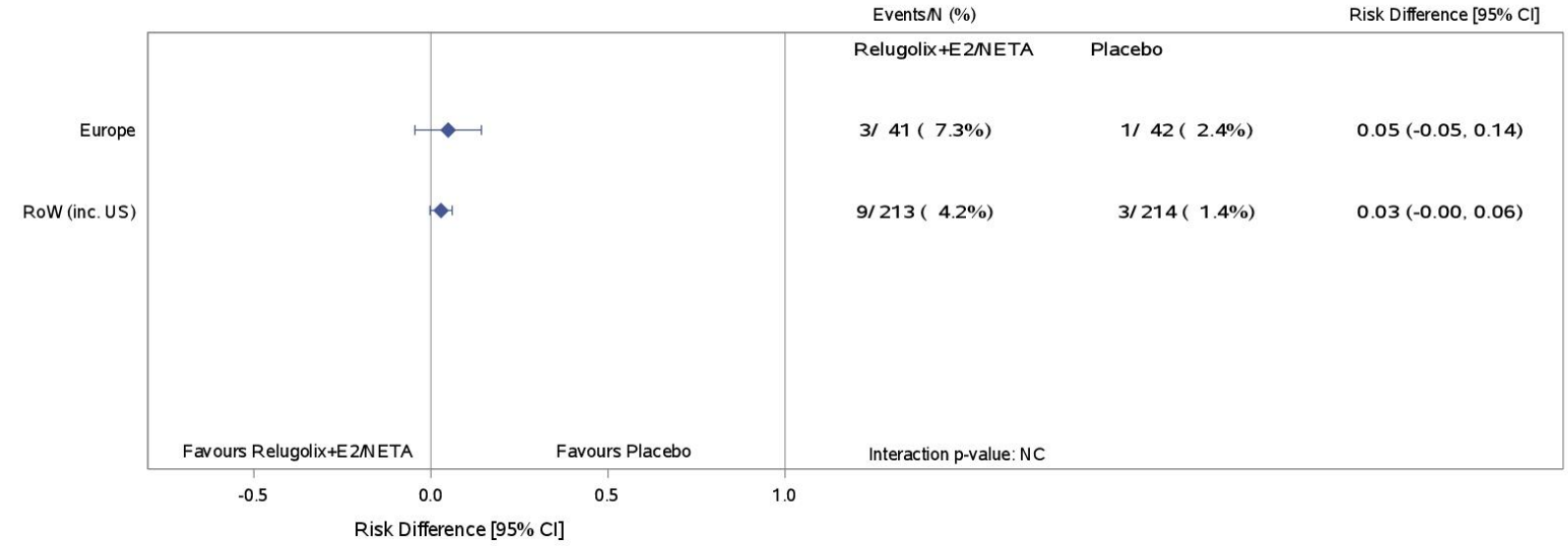
Figure SAF.TEAE.SPT.S7.BIN.FP.RD: Frequent Treatment Emergent Adverse Events by System Organ Class and Preferred Term, by Subgroup (Safety Population) - Risk Difference
Study: Pooled
System Organ Class: Vascular disorders, Preferred Term: Hypertension
Subgroup: Geographic Region II



Results are based on a Mantel-Haenszel approach stratified by study using a one-stage fixed-effects IPD meta-analysis.
The reference group is Placebo. Patients with multiple events are counted only once. MedDRA (version 22.0).
Patients with multiple events for a given PT or SOC are counted only once for each PT and SOC. Only SOCs or PTs for which there are at least 10% of patients with an event in at least one treatment group OR at least 10 patients with an event overall and at least 1% of patients with an event in at least one treatment group in the overall safety population are considered. Further, only SOCs and PTs for which there is a significant treatment effect (p-value <0.05) in the overall safety population are presented. Events are sorted alphabetically by SOC and PT and then by subgroup within each. MedDRA (version 22.0).
N: Number of patients in treatment group; NETA: Norethindrone acetate; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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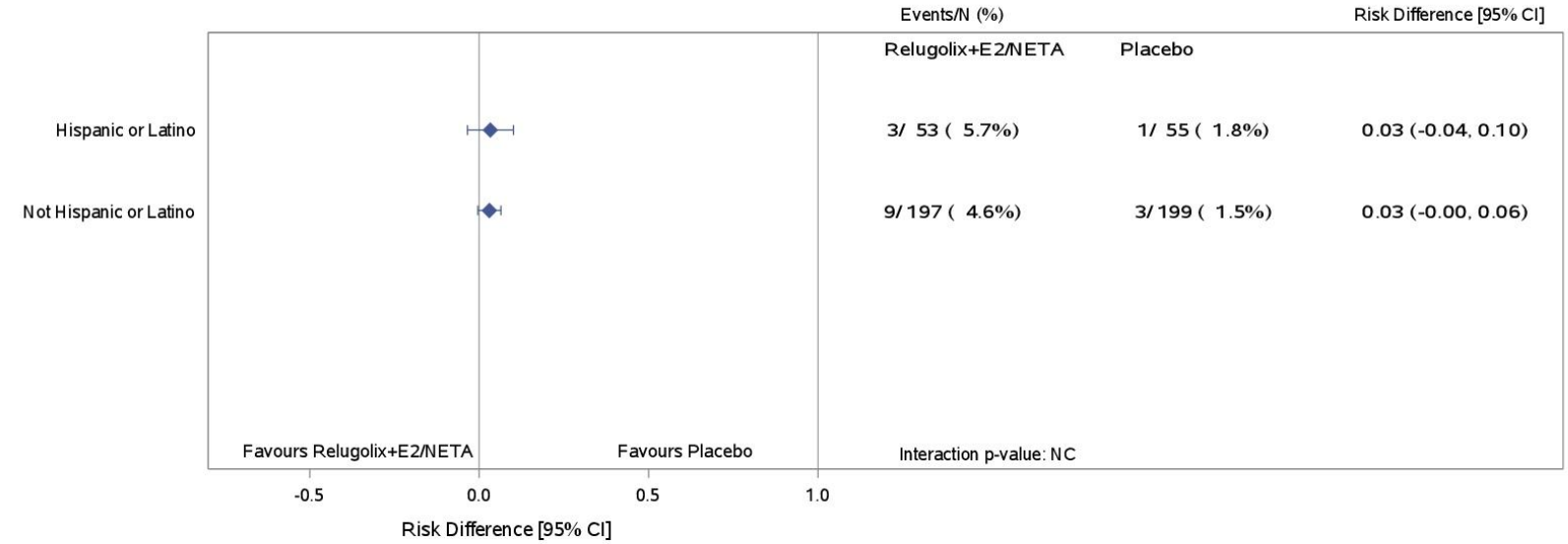
Figure SAF.TEAE.SPT.S8.BIN.FP.RD: Frequent Treatment Emergent Adverse Events by System Organ Class and Preferred Term, by Subgroup (Safety Population) - Risk Difference
Study: Pooled
System Organ Class: Vascular disorders, Preferred Term: Hypertension
Subgroup: Ethnicity



Results are based on a Mantel-Haenszel approach stratified by study using a one-stage fixed-effects IPD meta-analysis.
The reference group is Placebo. Patients with multiple events are counted only once. MedDRA (version 22.0).
Patients with multiple events for a given PT or SOC are counted only once for each PT and SOC. Only SOCs or PTs for which there are at least 10% of patients with an event in at least one treatment group OR at least 10 patients with an event overall and at least 1% of patients with an event in at least one treatment group in the overall safety population are considered. Further, only SOCs and PTs for which there is a significant treatment effect (p-value <0.05) in the overall safety population are presented. Events are sorted alphabetically by SOC and PT and then by subgroup within each. MedDRA (version 22.0).
N: Number of patients in treatment group; NETA: Norethindrone acetate; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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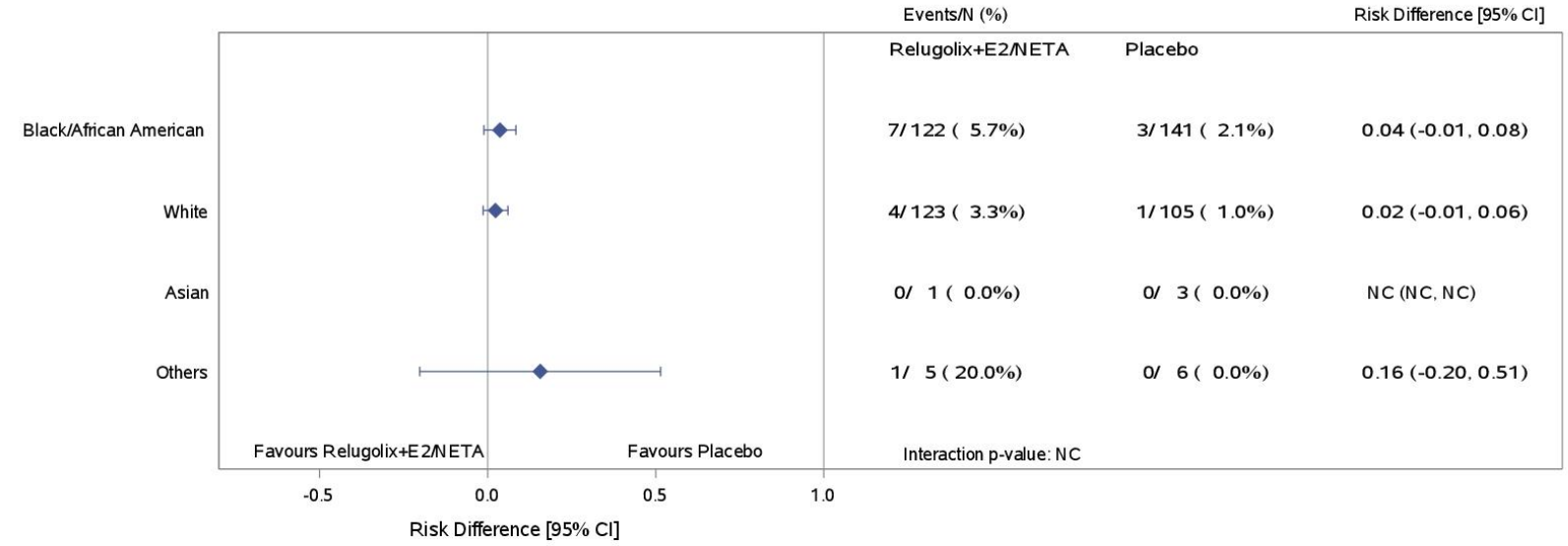
Figure SAF.TEAE.SPT.S9.BIN.FP.RD: Frequent Treatment Emergent Adverse Events by System Organ Class and Preferred Term, by Subgroup (Safety Population) - Risk Difference
Study: Pooled
System Organ Class: Vascular disorders, Preferred Term: Hypertension
Subgroup: Race



Results are based on a Mantel-Haenszel approach stratified by study using a one-stage fixed-effects IPD meta-analysis.
The reference group is Placebo. Patients with multiple events are counted only once. MedDRA (version 22.0).
Patients with multiple events for a given PT or SOC are counted only once for each PT and SOC. Only SOCs or PTs for which there are at least 10% of patients with an event in at least one treatment group OR at least 10 patients with an event overall and at least 1% of patients with an event in at least one treatment group in the overall safety population are considered. Further, only SOCs and PTs for which there is a significant treatment effect (p-value <0.05) in the overall safety population are presented. Events are sorted alphabetically by SOC and PT and then by subgroup within each. MedDRA (version 22.0).
N: Number of patients in treatment group; NETA: Norethindrone acetate; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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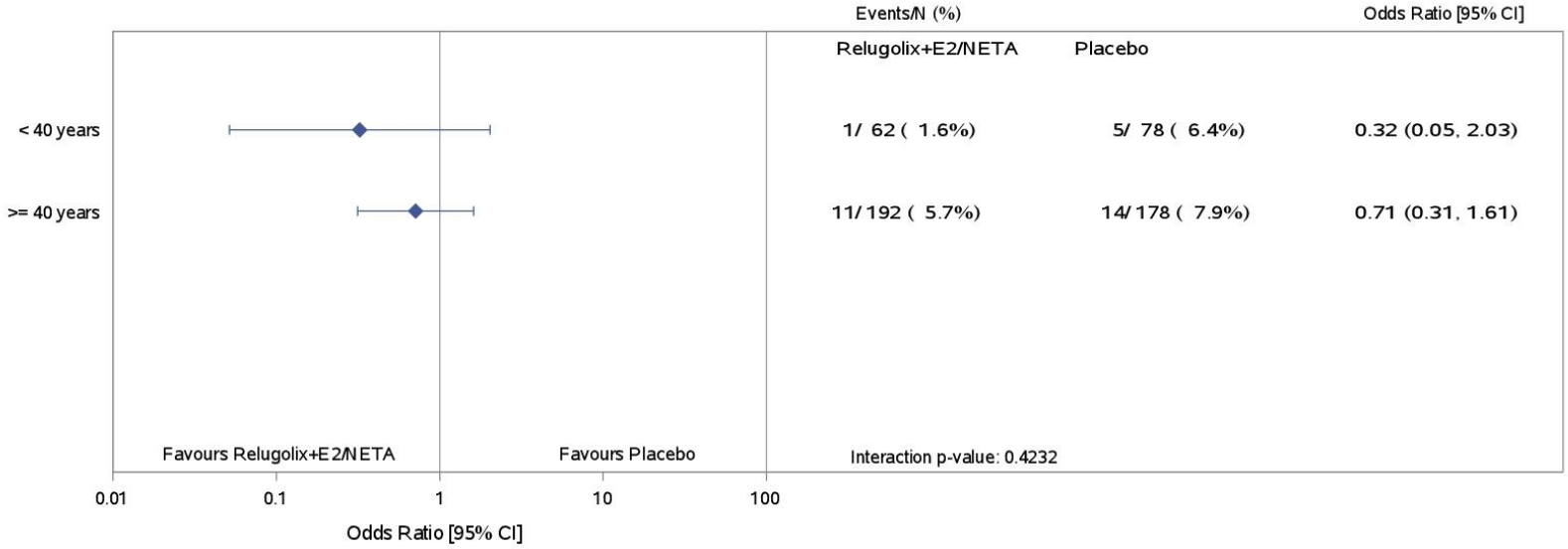
2.3.3 Proportion of Patients With at Least One Grade 3 or Above Treatment Emergent Adverse Event, by Subgroup (Safety Population)

Nachfolgend sind zunächst alle Forest Plots für das *Odds Ratio* dargestellt; gefolgt von den entsprechenden Forest Plots für *Risk Ratio* und *Risk Difference*.

Figure SAF.G34TEAE.ANY.S1.BIN.FP: Proportion of Patients With at Least One Grade 3 or Above Treatment Emergent Adverse Event, by Subgroup (Safety Population)
Study: Pooled
Subgroup: Age (years)



Results are based on a logistic regression model adjusted for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates using a one-stage fixed-effects IPD meta-analysis approach. A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
The interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the Odds Ratio and 95% CI. Missing subgroup levels are not included in estimation of the interaction p-value. The reference group is Placebo. Patients with multiple events are counted only once. MedDRA (version 22.0).
N: Number of patients in treatment group; NETA: Norethindrone acetate; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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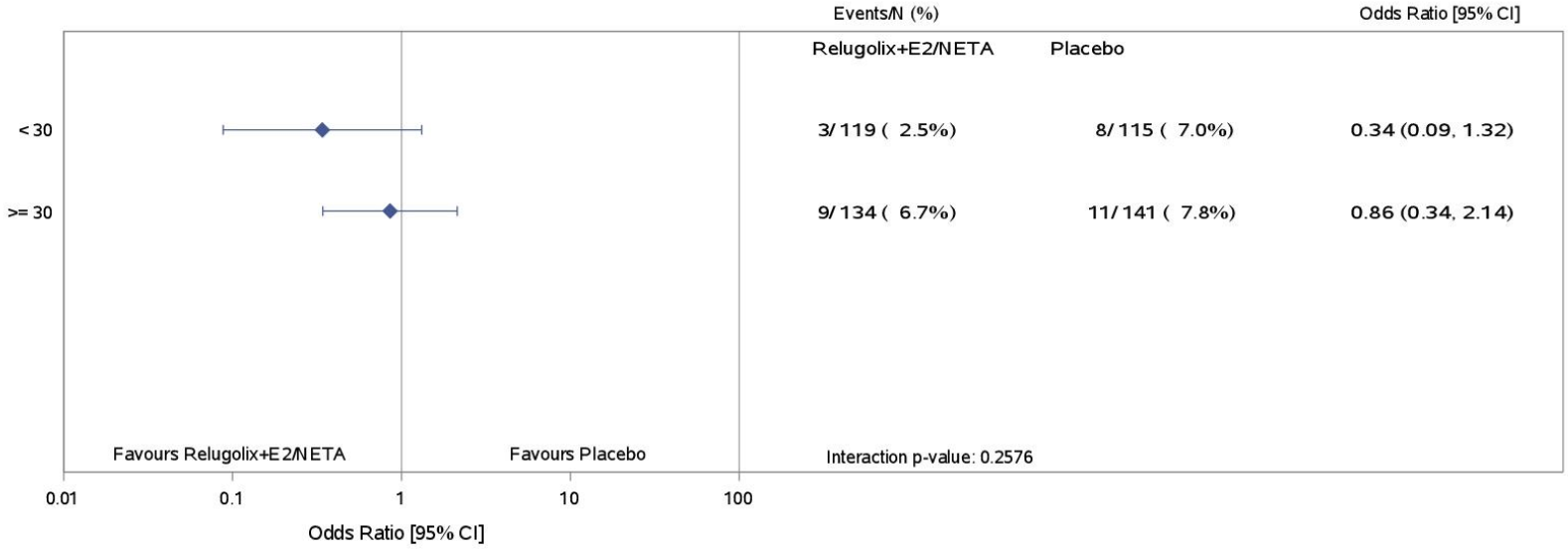
Figure SAF.G34TEAE.ANY.S2.BIN.FP: Proportion of Patients With at Least One Grade 3 or Above Treatment Emergent Adverse Event, by Subgroup (Safety Population)
Study: Pooled
Subgroup: BMI (kg/m2) at Baseline



Results are based on a logistic regression model adjusted for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates using a one-stage fixed-effects IPD meta-analysis approach. A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
The interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the Odds Ratio and 95% CI. Missing subgroup levels are not included in estimation of the interaction p-value. The reference group is Placebo. Patients with multiple events are counted only once. MedDRA (version 22.0).
N: Number of patients in treatment group; NETA: Norethindrone acetate; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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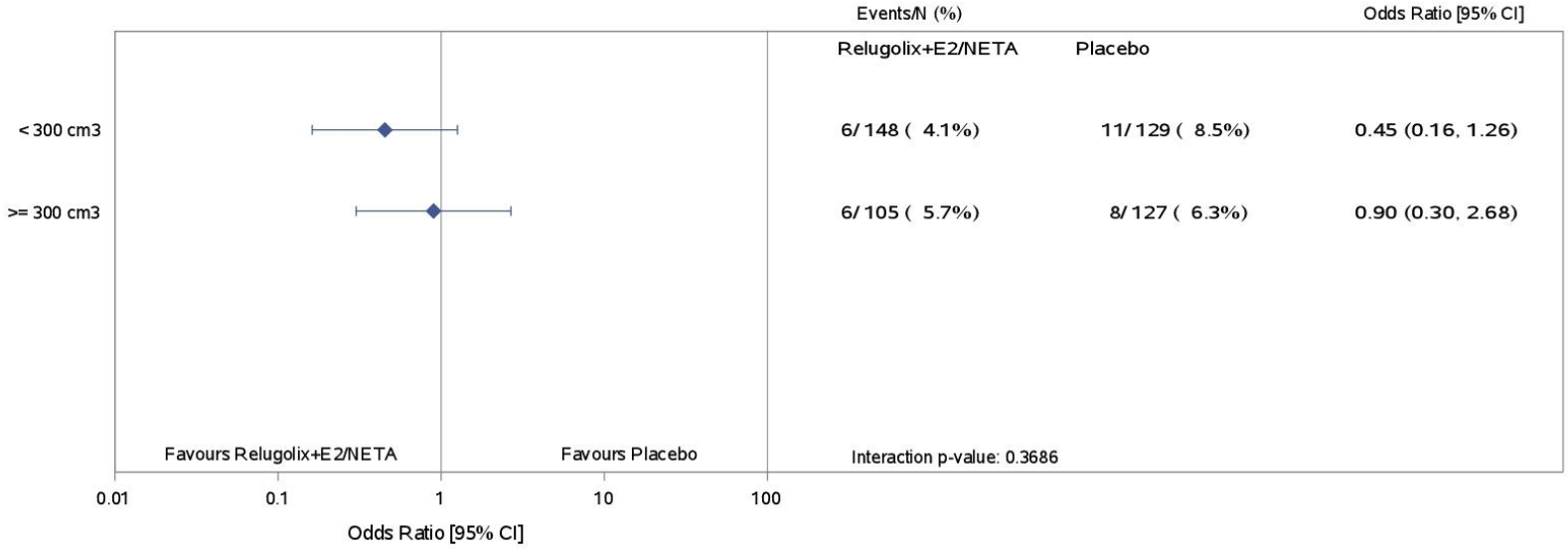
Figure SAF.G34TEAE.ANY.S3.BIN.FP: Proportion of Patients With at Least One Grade 3 or Above Treatment Emergent Adverse Event, by Subgroup (Safety Population)
Study: Pooled
Subgroup: Uterine Volume at Baseline (cm3)



Results are based on a logistic regression model adjusted for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates using a one-stage fixed-effects IPD meta-analysis approach. A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
The interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the Odds Ratio and 95% CI. Missing subgroup levels are not included in estimation of the interaction p-value. The reference group is Placebo. Patients with multiple events are counted only once. MedDRA (version 22.0).
N: Number of patients in treatment group; NETA: Norethindrone acetate; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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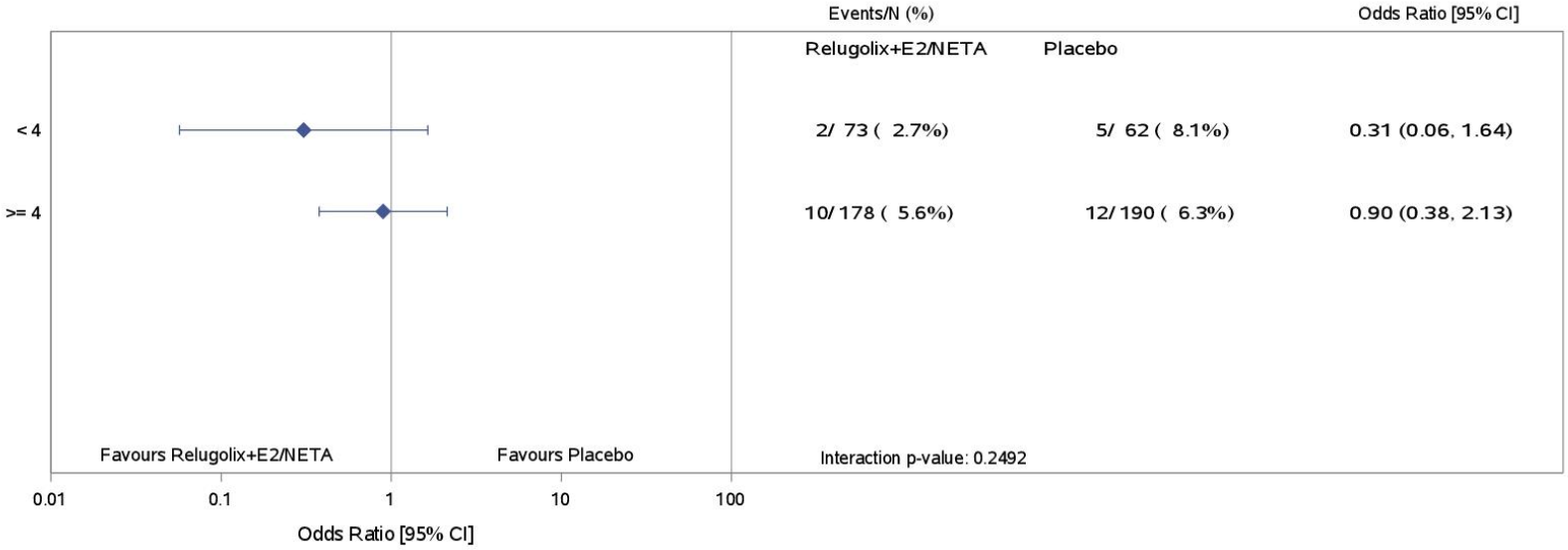
Figure SAF.G34TEAE.ANY.S4.BIN.FP: Proportion of Patients With at Least One Grade 3 or Above Treatment Emergent Adverse Event, by Subgroup (Safety Population)
Study: Pooled
Subgroup: Maximum NRS Pain Score at Baseline



Results are based on a logistic regression model adjusted for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates using a one-stage fixed-effects IPD meta-analysis approach. A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
The interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the Odds Ratio and 95% CI. Missing subgroup levels are not included in estimation of the interaction p-value. The reference group is Placebo. Patients with multiple events are counted only once. MedDRA (version 22.0).
N: Number of patients in treatment group; NETA: Norethindrone acetate; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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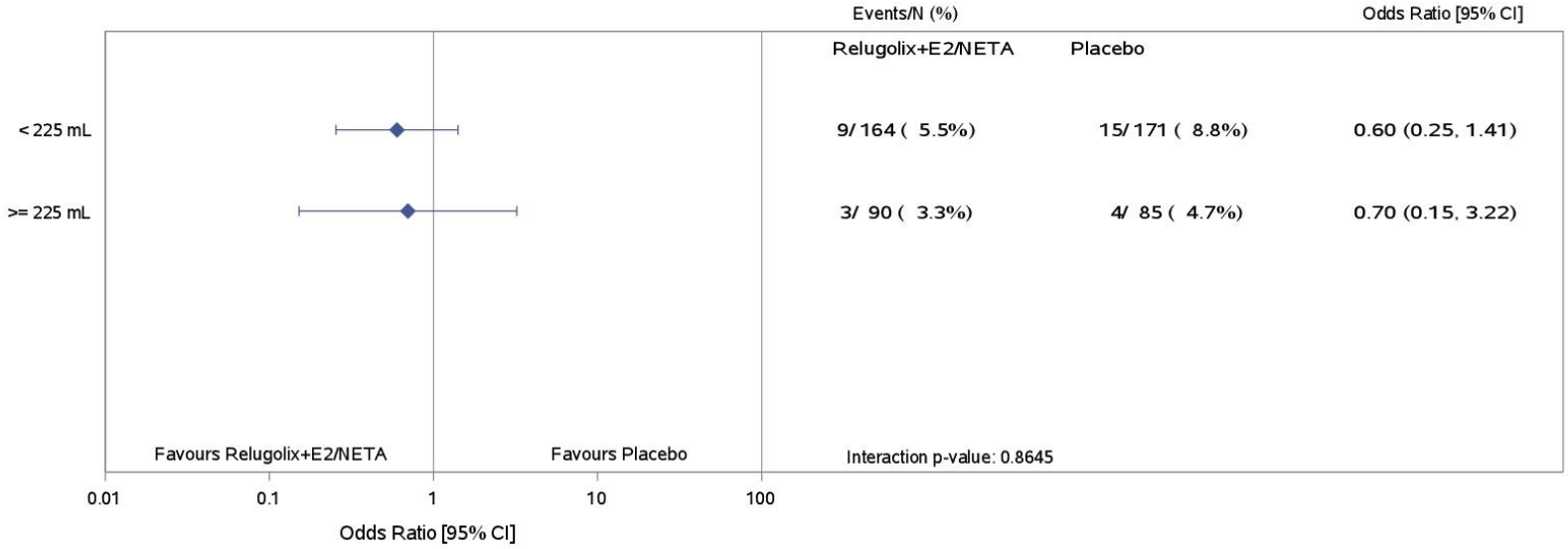
Figure SAF.G34TEAE.ANY.S5.BIN.FP: Proportion of Patients With at Least One Grade 3 or Above Treatment Emergent Adverse Event, by Subgroup (Safety Population)
Study: Pooled
Subgroup: MBL Volume at Baseline (mL)



Results are based on a logistic regression model adjusted for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates using a one-stage fixed-effects IPD meta-analysis approach. A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
The interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the Odds Ratio and 95% CI. Missing subgroup levels are not included in estimation of the interaction p-value. The reference group is Placebo. Patients with multiple events are counted only once. MedDRA (version 22.0).
N: Number of patients in treatment group; NETA: Norethindrone acetate; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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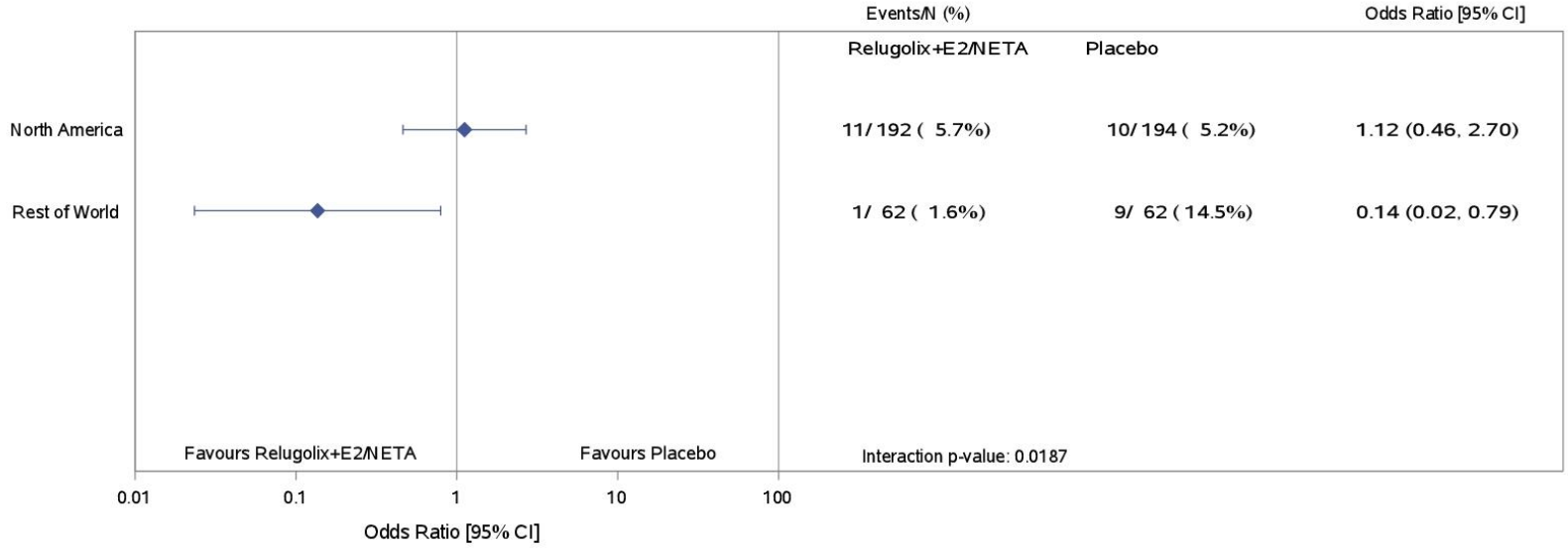
Figure SAF.G34TEAE.ANY.S6.BIN.FP: Proportion of Patients With at Least One Grade 3 or Above Treatment Emergent Adverse Event, by Subgroup (Safety Population)
Study: Pooled
Subgroup: Geographic Region I



Results are based on a logistic regression model adjusted for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates using a one-stage fixed-effects IPD meta-analysis approach. A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
The interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the Odds Ratio and 95% CI. Missing subgroup levels are not included in estimation of the interaction p-value. The reference group is Placebo. Patients with multiple events are counted only once. MedDRA (version 22.0).
N: Number of patients in treatment group; NETA: Norethindrone acetate; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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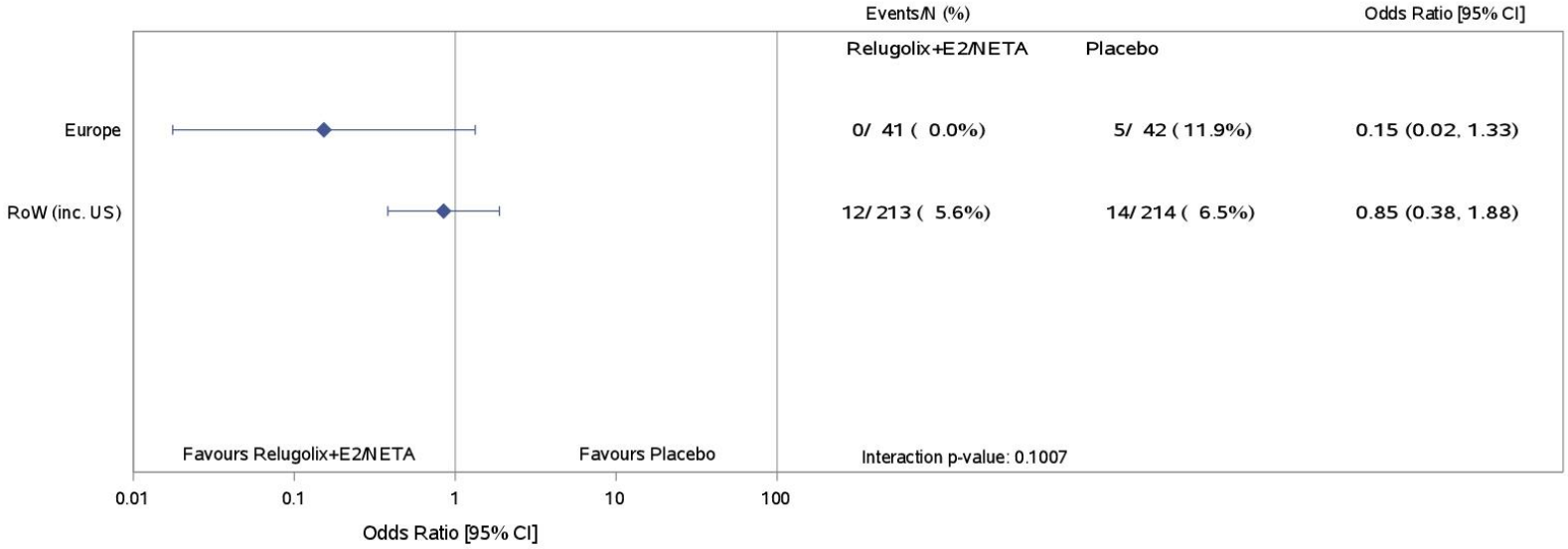
Figure SAF.G34TEAE.ANY.S7.BIN.FP: Proportion of Patients With at Least One Grade 3 or Above Treatment Emergent Adverse Event, by Subgroup (Safety Population)
Study: Pooled
Subgroup: Geographic Region II



Results are based on a logistic regression model adjusted for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates using a one-stage fixed-effects IPD meta-analysis approach. A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
The interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the Odds Ratio and 95% CI. Missing subgroup levels are not included in estimation of the interaction p-value. The reference group is Placebo. Patients with multiple events are counted only once. MedDRA (version 22.0).
N: Number of patients in treatment group; NETA: Norethindrone acetate; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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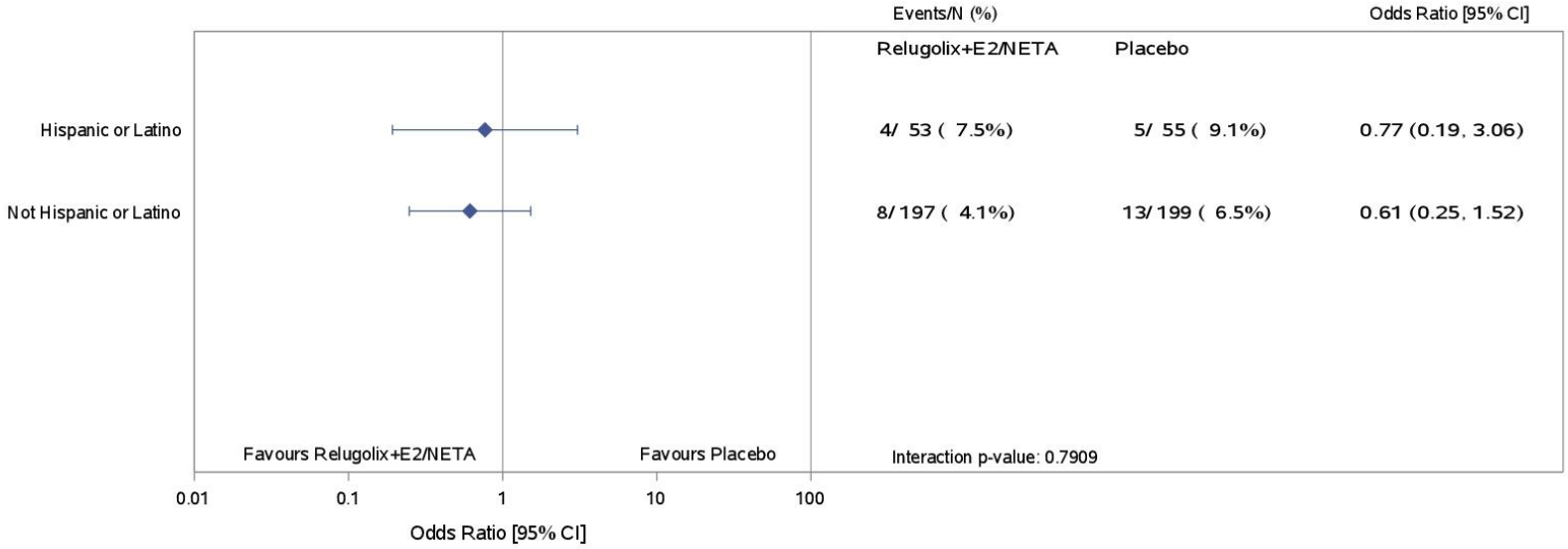
Figure SAF.G34TEAE.ANY.S8.BIN.FP: Proportion of Patients With at Least One Grade 3 or Above Treatment Emergent Adverse Event, by Subgroup (Safety Population)
Study: Pooled
Subgroup: Ethnicity



Results are based on a logistic regression model adjusted for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates using a one-stage fixed-effects IPD meta-analysis approach. A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
The interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the Odds Ratio and 95% CI. Missing subgroup levels are not included in estimation of the interaction p-value. The reference group is Placebo. Patients with multiple events are counted only once. MedDRA (version 22.0).
N: Number of patients in treatment group; NETA: Norethindrone acetate; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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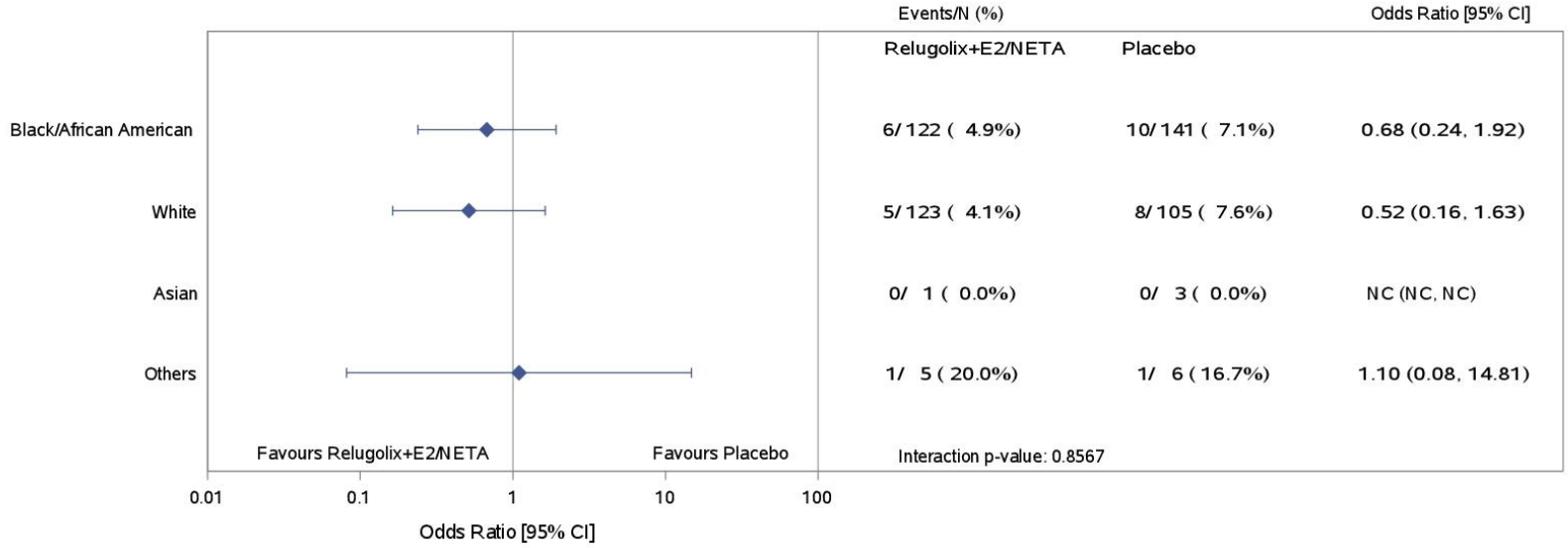
Figure SAF.G34TEAE.ANY.S9.BIN.FP: Proportion of Patients With at Least One Grade 3 or Above Treatment Emergent Adverse Event, by Subgroup (Safety Population)
Study: Pooled
Subgroup: Race



Results are based on a logistic regression model adjusted for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates using a one-stage fixed-effects IPD meta-analysis approach. A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
The interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the Odds Ratio and 95% CI. Missing subgroup levels are not included in estimation of the interaction p-value. The reference group is Placebo. Patients with multiple events are counted only once. MedDRA (version 22.0).
N: Number of patients in treatment group; NETA: Norethindrone acetate; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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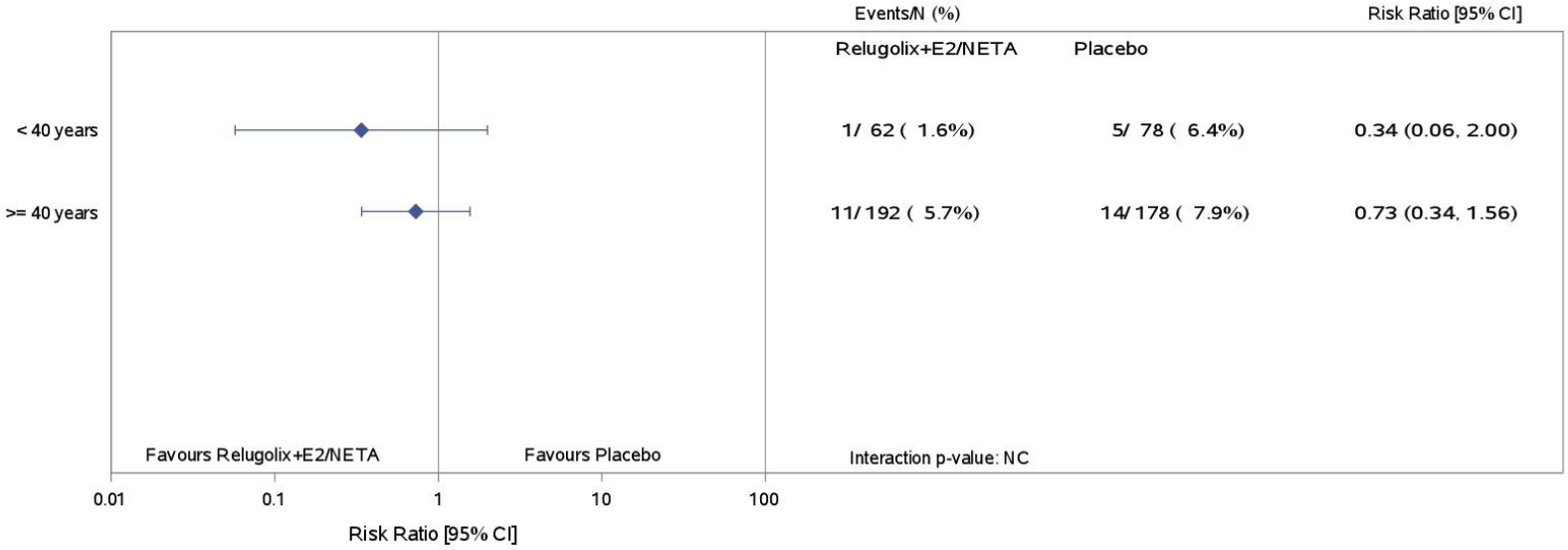
Figure SAF.G34TEAE.ANY.S1.BIN.FP.RR: Proportion of Patients With at Least One Grade 3 or Above Treatment Emergent Adverse Event, by Subgroup (Safety Population) - Risk Ratio
Study: Pooled
Subgroup: Age (years)



Results are based on a Cochran-Mantel-Haenszel approach stratified by study using a one-stage fixed-effects IPD meta-analysis. A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
The reference group is Placebo. Patients with multiple events are counted only once. MedDRA (version 22.0).
N: Number of patients in treatment group; NETA: Norethindrone acetate; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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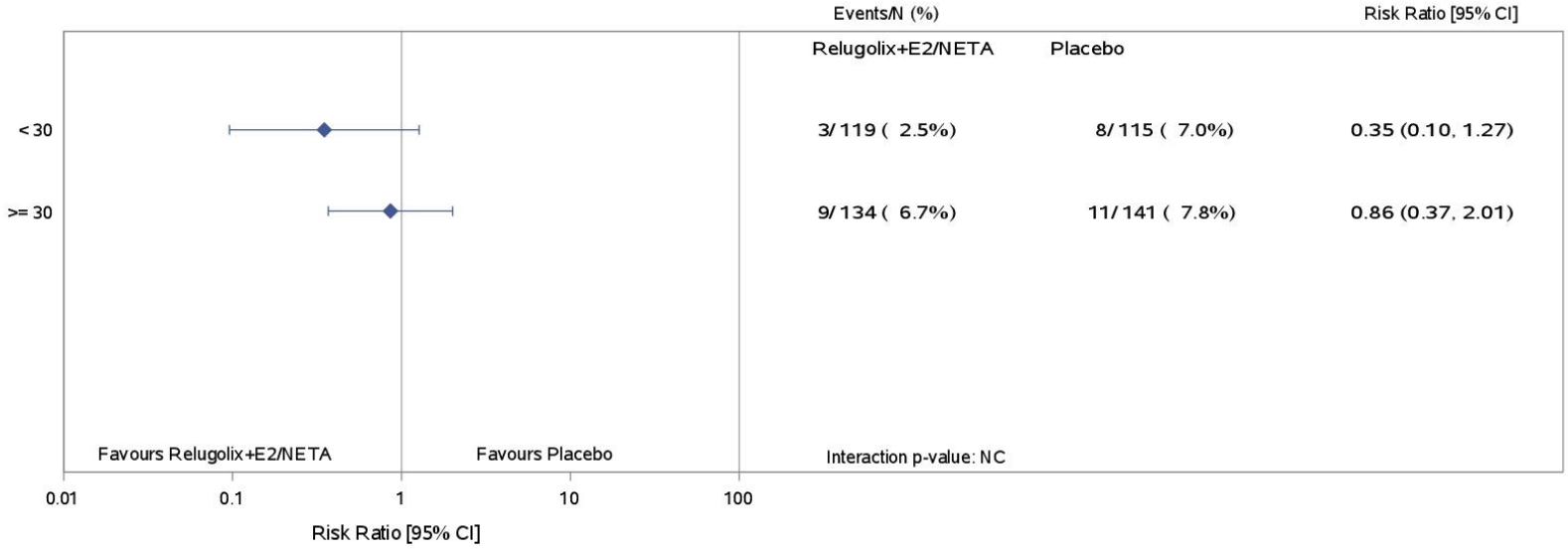
Figure SAF.G34TEAE.ANY.S2.BIN.FP.RR: Proportion of Patients With at Least One Grade 3 or Above Treatment Emergent Adverse Event, by Subgroup (Safety Population) - Risk Ratio
Study: Pooled
Subgroup: BMI (kg/m2) at Baseline



Results are based on a Cochran-Mantel-Haenszel approach stratified by study using a one-stage fixed-effects IPD meta-analysis. A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
The reference group is Placebo. Patients with multiple events are counted only once. MedDRA (version 22.0).
N: Number of patients in treatment group; NETA: Norethindrone acetate; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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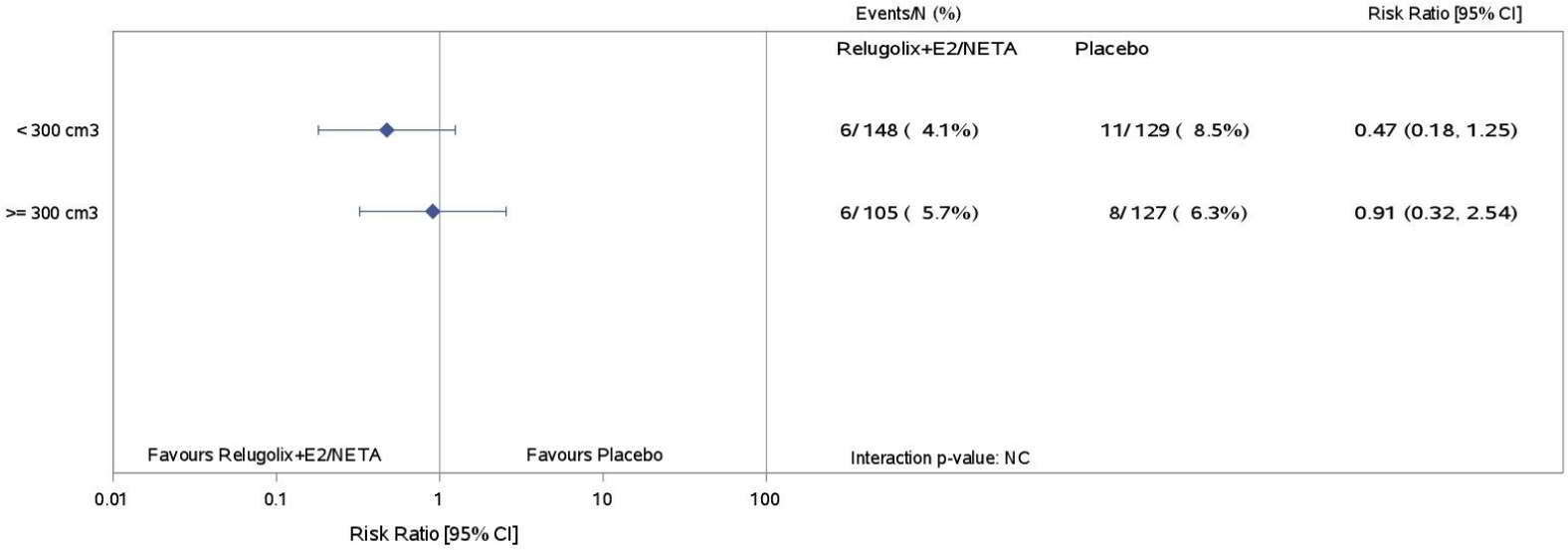
Figure SAF.G34TEAE.ANY.S3.BIN.FP.RR: Proportion of Patients With at Least One Grade 3 or Above Treatment Emergent Adverse Event, by Subgroup (Safety Population) - Risk Ratio
Study: Pooled
Subgroup: Uterine Volume at Baseline (cm3)



Results are based on a Cochran-Mantel-Haenszel approach stratified by study using a one-stage fixed-effects IPD meta-analysis. A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
The reference group is Placebo. Patients with multiple events are counted only once. MedDRA (version 22.0).
N: Number of patients in treatment group; NETA: Norethindrone acetate; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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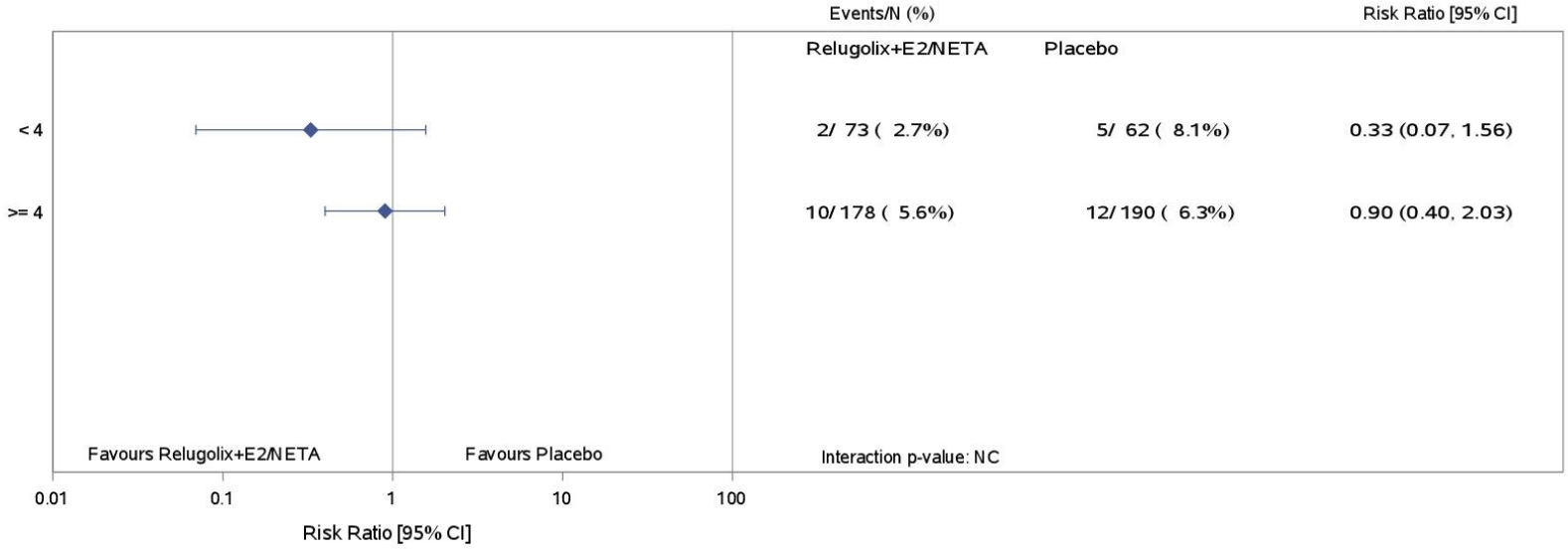
Figure SAF.G34TEAE.ANY.S4.BIN.FP.RR: Proportion of Patients With at Least One Grade 3 or Above Treatment Emergent Adverse Event, by Subgroup (Safety Population) - Risk Ratio
Study: Pooled
Subgroup: Maximum NRS Pain Score at Baseline



Results are based on a Cochran-Mantel-Haenszel approach stratified by study using a one-stage fixed-effects IPD meta-analysis. A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
The reference group is Placebo. Patients with multiple events are counted only once. MedDRA (version 22.0).
N: Number of patients in treatment group; NETA: Norethindrone acetate; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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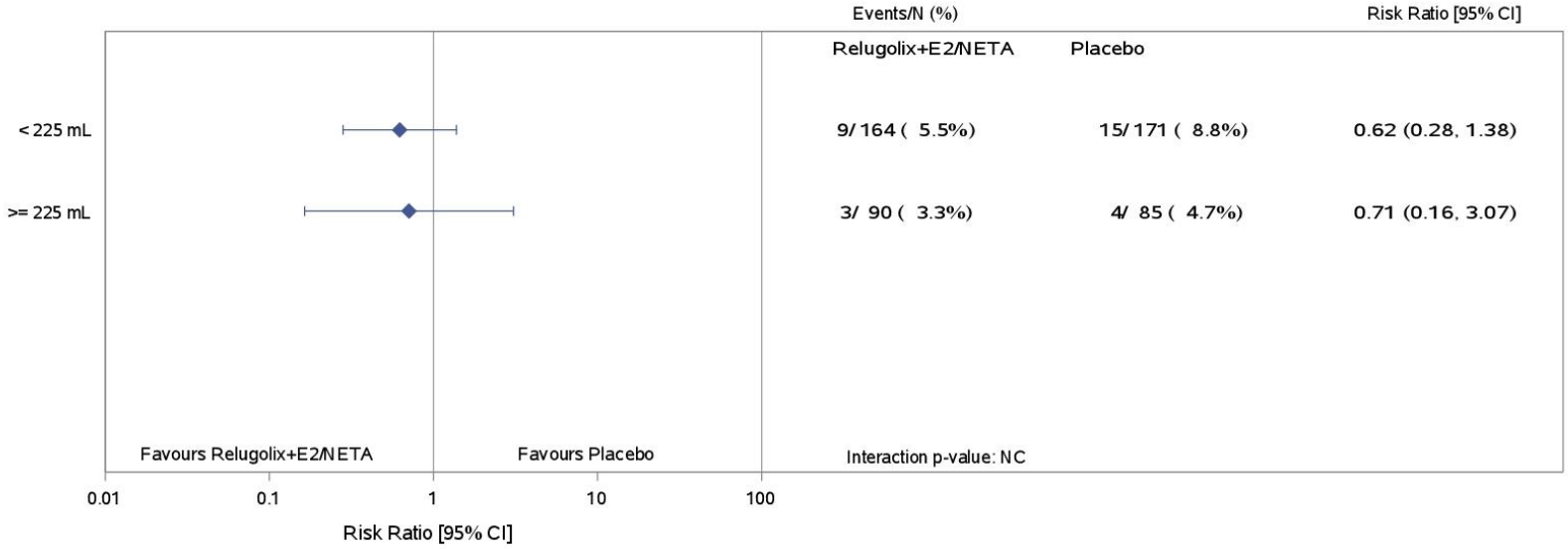
Figure SAF.G34TEAE.ANY.S5.BIN.FP.RR: Proportion of Patients With at Least One Grade 3 or Above Treatment Emergent Adverse Event, by Subgroup (Safety Population) - Risk Ratio
Study: Pooled
Subgroup: MBL Volume at Baseline (mL)



Results are based on a Cochran-Mantel-Haenszel approach stratified by study using a one-stage fixed-effects IPD meta-analysis. A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
The reference group is Placebo. Patients with multiple events are counted only once. MedDRA (version 22.0).
N: Number of patients in treatment group; NETA: Norethindrone acetate; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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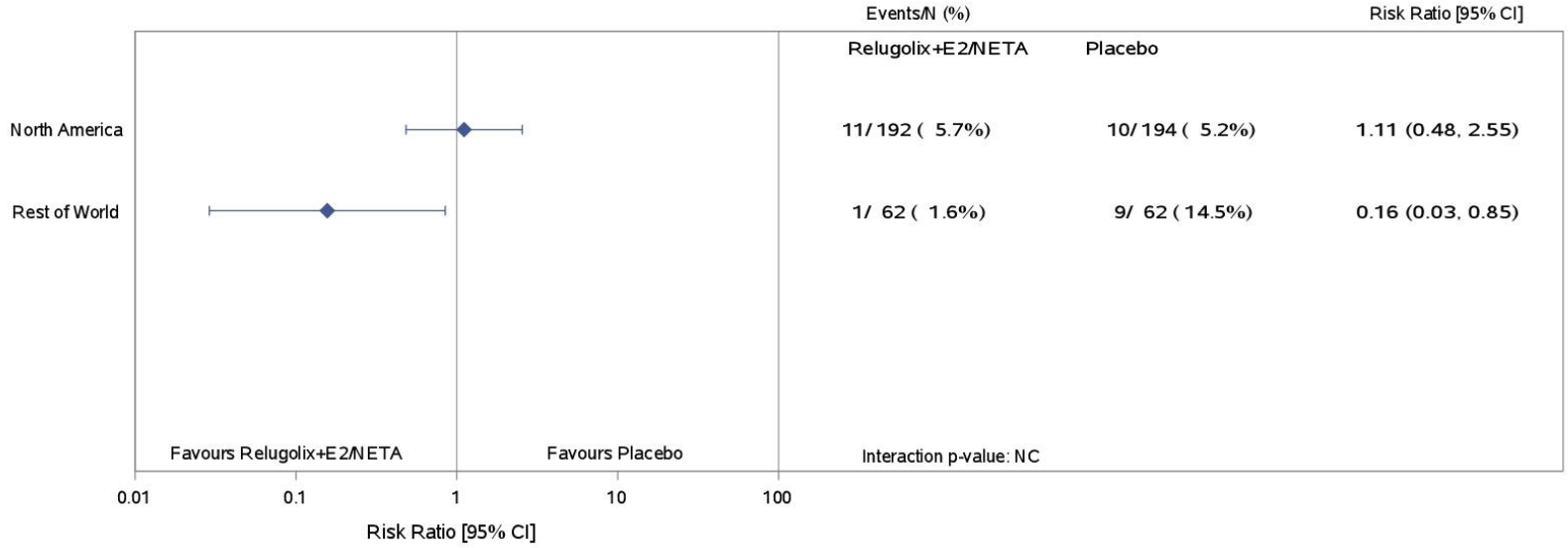
Figure SAF.G34TEAE.ANY.S6.BIN.FP.RR: Proportion of Patients With at Least One Grade 3 or Above Treatment Emergent Adverse Event, by Subgroup (Safety Population) - Risk Ratio
Study: Pooled
Subgroup: Geographic Region I



Results are based on a Cochran-Mantel-Haenszel approach stratified by study using a one-stage fixed-effects IPD meta-analysis. A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
The reference group is Placebo. Patients with multiple events are counted only once. MedDRA (version 22.0).
N: Number of patients in treatment group; NETA: Norethindrone acetate; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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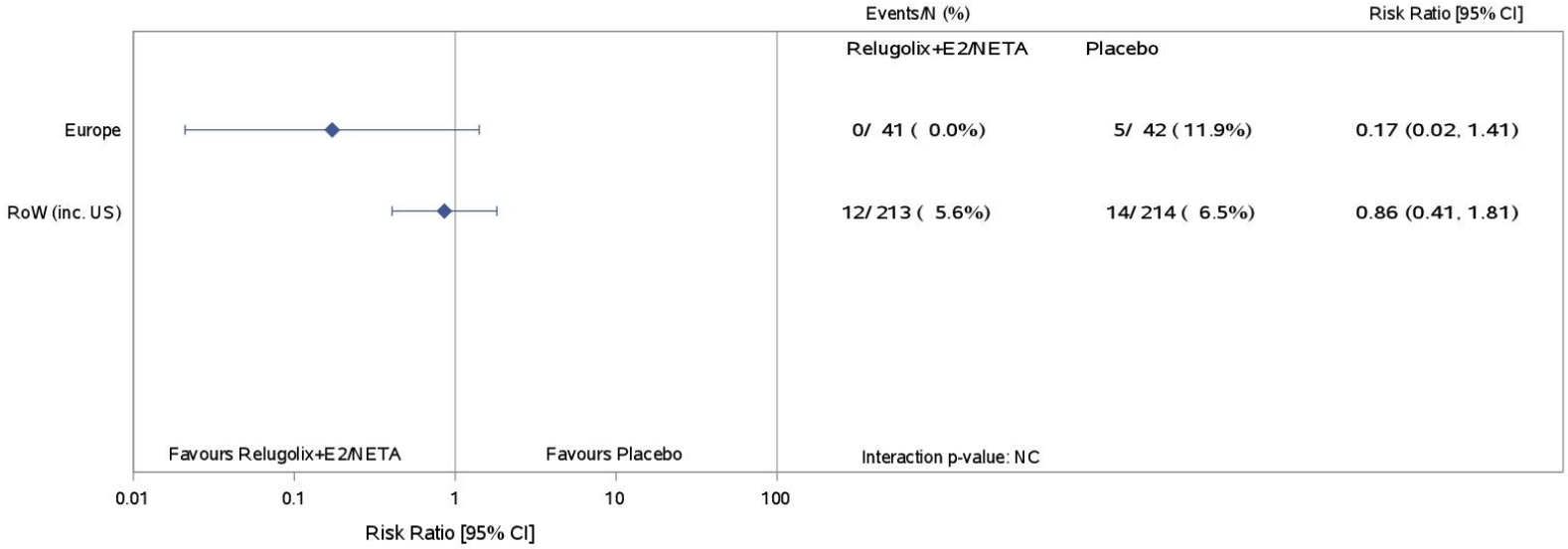
Figure SAF.G34TEAE.ANY.S7.BIN.FP.RR: Proportion of Patients With at Least One Grade 3 or Above Treatment Emergent Adverse Event, by Subgroup (Safety Population) - Risk Ratio
Study: Pooled
Subgroup: Geographic Region II



Results are based on a Cochran-Mantel-Haenszel approach stratified by study using a one-stage fixed-effects IPD meta-analysis. A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
The reference group is Placebo. Patients with multiple events are counted only once. MedDRA (version 22.0).
N: Number of patients in treatment group; NETA: Norethindrone acetate; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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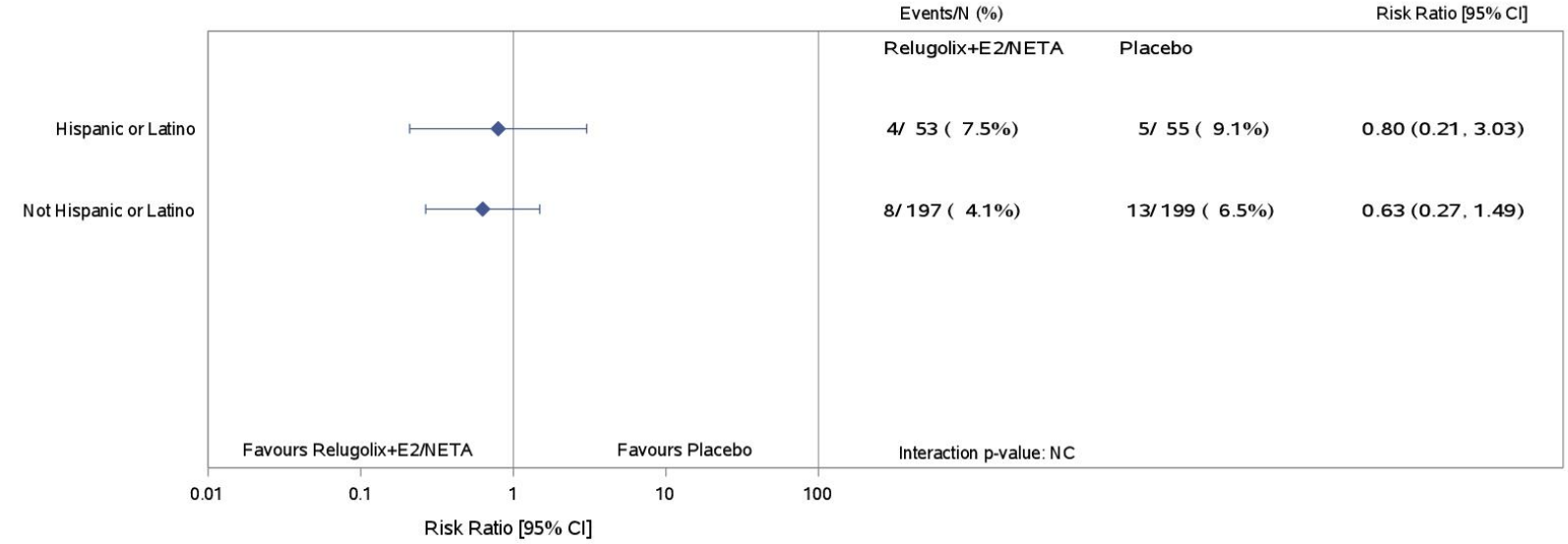
Figure SAF.G34TEAE.ANY.S8.BIN.FP.RR: Proportion of Patients With at Least One Grade 3 or Above Treatment Emergent Adverse Event, by Subgroup (Safety Population) - Risk Ratio
Study: Pooled
Subgroup: Ethnicity



Results are based on a Cochran-Mantel-Haenszel approach stratified by study using a one-stage fixed-effects IPD meta-analysis. A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
The reference group is Placebo. Patients with multiple events are counted only once. MedDRA (version 22.0).
N: Number of patients in treatment group; NETA: Norethindrone acetate; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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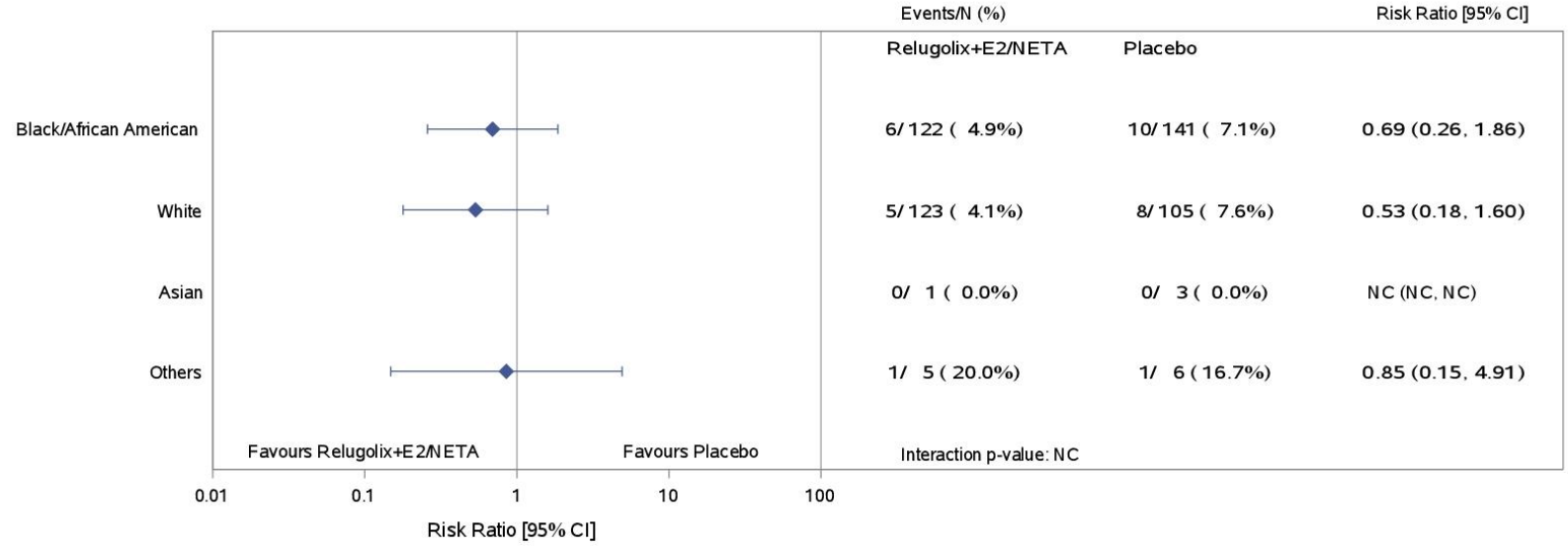
Figure SAF.G34TEAE.ANY.S9.BIN.FP.RR: Proportion of Patients With at Least One Grade 3 or Above Treatment Emergent Adverse Event, by Subgroup (Safety Population) - Risk Ratio
Study: Pooled
Subgroup: Race



Results are based on a Cochran-Mantel-Haenszel approach stratified by study using a one-stage fixed-effects IPD meta-analysis. A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
The reference group is Placebo. Patients with multiple events are counted only once. MedDRA (version 22.0).
N: Number of patients in treatment group; NETA: Norethindrone acetate; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

SOURCE: X:\Numerus\Studies\MYV\MYV102\Analysis\Prod\Progs\TFLs\Fig_SAF_AE_S_BIN_FP.SAS Date/time of run: 01JUL21 10:03
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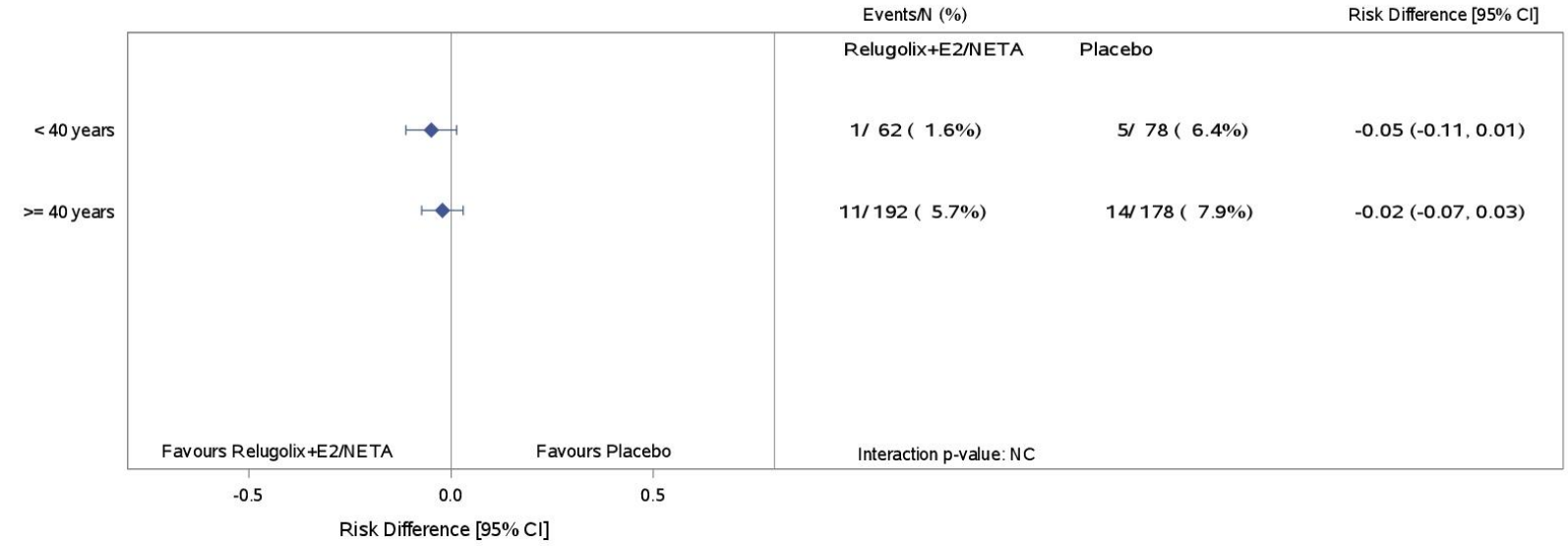
Figure SAF.G34TEAE.ANY.S1.BIN.FP.RD: Proportion of Patients With at Least One Grade 3 or Above Treatment Emergent Adverse Event, by Subgroup (Safety Population) - Risk Difference
Study: Pooled
Subgroup: Age (years)



Results are based on a Mantel-Haenszel approach stratified by study using a one-stage fixed-effects IPD meta-analysis.
The reference group is Placebo. Patients with multiple events are counted only once. MedDRA (version 22.0).
N: Number of patients in treatment group; NETA: Norethindrone acetate; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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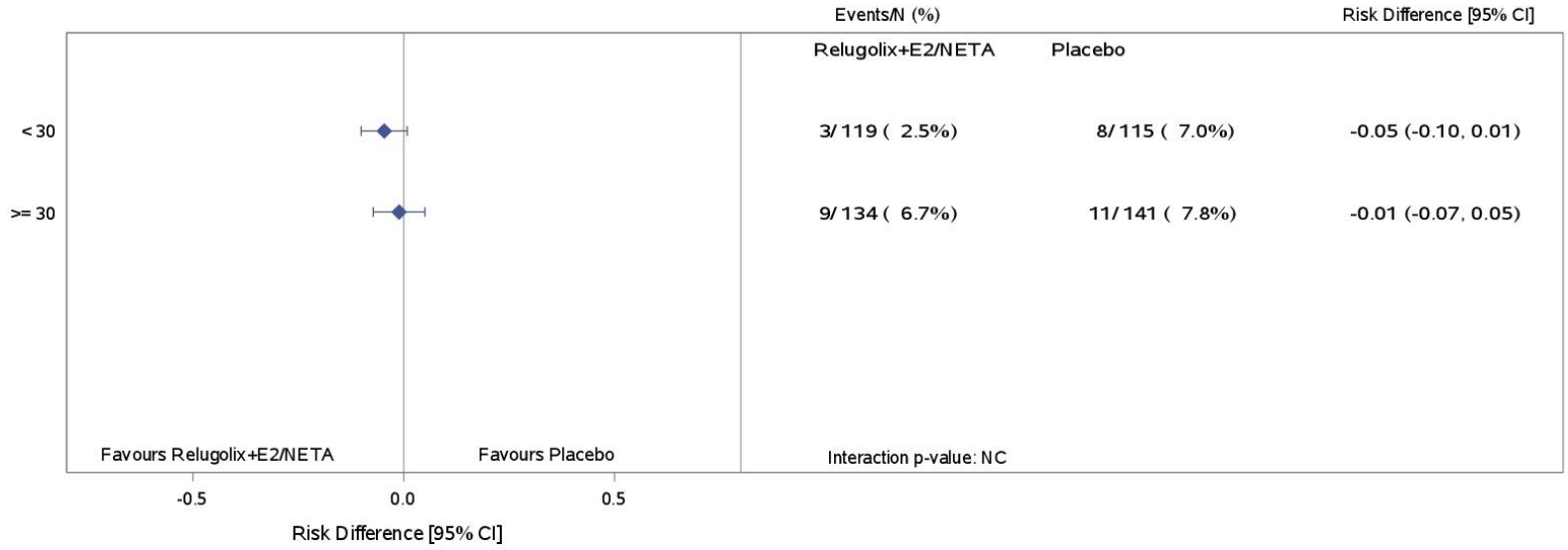
Figure SAF.G34TEAE.ANY.S2.BIN.FP.RD: Proportion of Patients With at Least One Grade 3 or Above Treatment Emergent Adverse Event, by Subgroup (Safety Population) - Risk Difference
Study: Pooled
Subgroup: BMI (kg/m2) at Baseline



Results are based on a Mantel-Haenszel approach stratified by study using a one-stage fixed-effects IPD meta-analysis.
The reference group is Placebo. Patients with multiple events are counted only once. MedDRA (version 22.0).
N: Number of patients in treatment group; NETA: Norethindrone acetate; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

SOURCE: X:\Numerus\Studies\MYV\MYV102\Analysis\Prod\Progs\TFLs\Fig_SAF_AE_S_BIN_FP.SAS Date/time of run: 01JUL21 10:03
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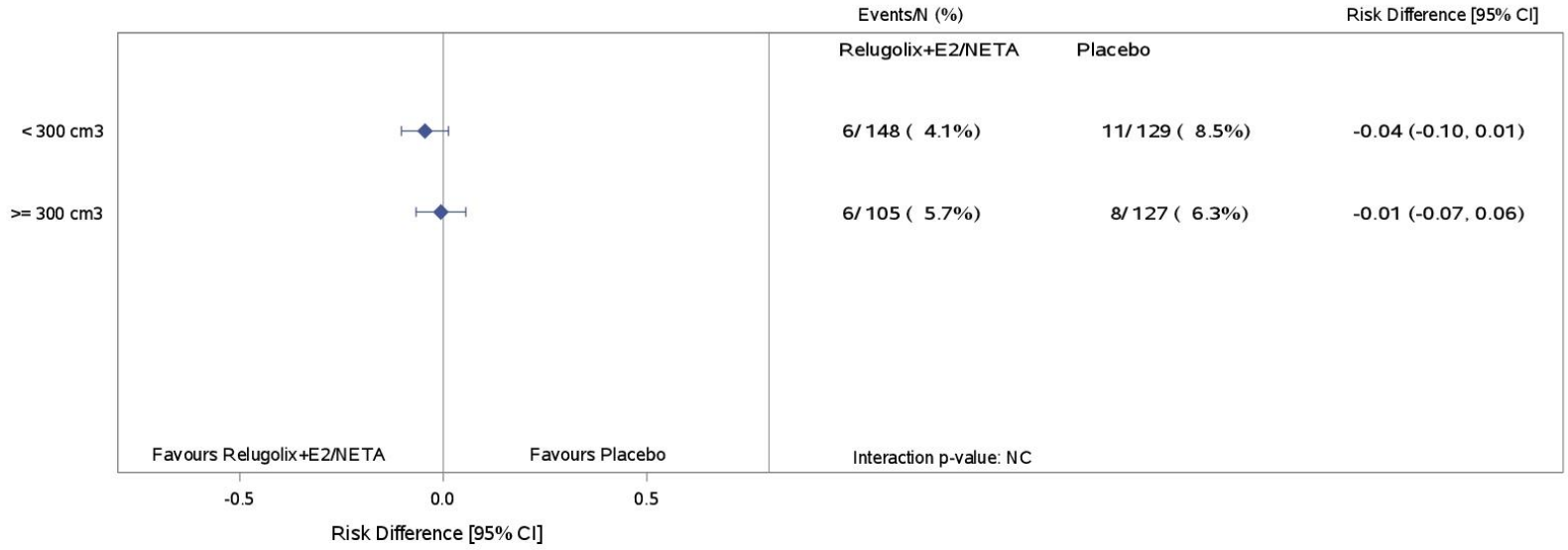
Figure SAF.G34TEAE.ANY.S3.BIN.FP.RD: Proportion of Patients With at Least One Grade 3 or Above Treatment Emergent Adverse Event, by Subgroup (Safety Population) - Risk Difference
Study: Pooled
Subgroup: Uterine Volume at Baseline (cm3)



Results are based on a Mantel-Haenszel approach stratified by study using a one-stage fixed-effects IPD meta-analysis.
The reference group is Placebo. Patients with multiple events are counted only once. MedDRA (version 22.0).
N: Number of patients in treatment group; NETA: Norethindrone acetate; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

SOURCE: X:\Numerus\Studies\MYV\MYV102\Analysis\Prod\Progs\TFLs\Fig_SAF_AE_S_BIN_FP.SAS Date/time of run: 01JUL21 10:03
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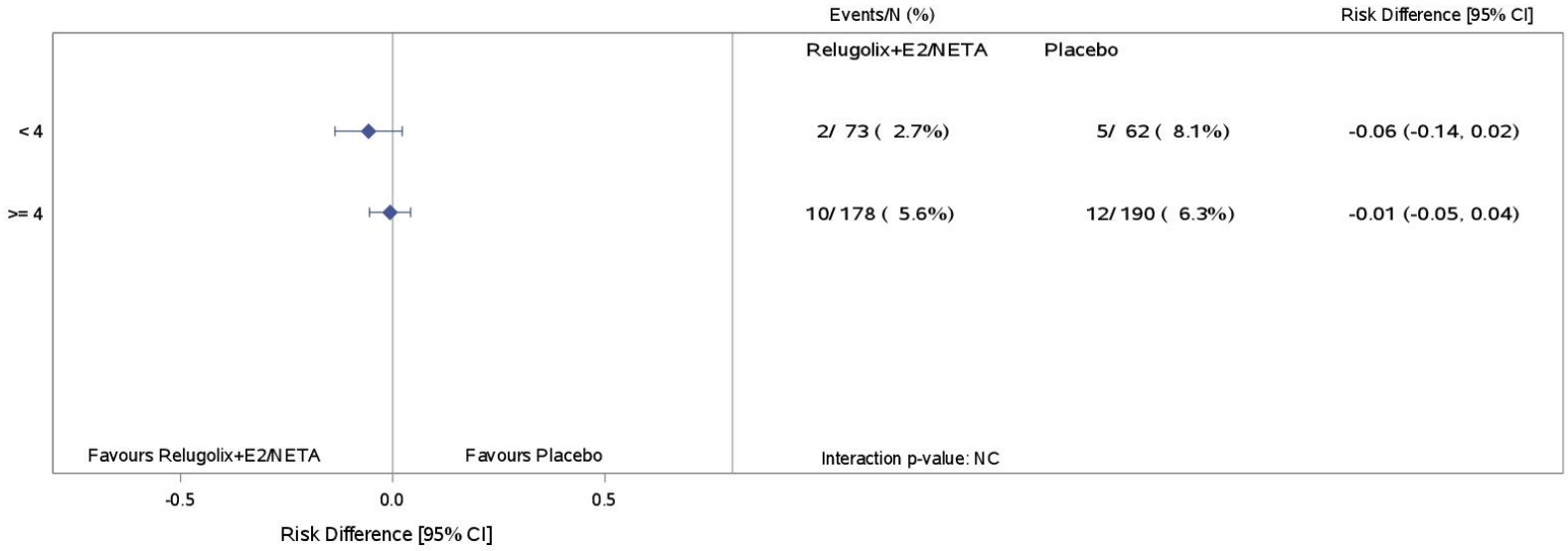
Figure SAF.G34TEAE.ANY.S4.BIN.FP.RD: Proportion of Patients With at Least One Grade 3 or Above Treatment Emergent Adverse Event, by Subgroup (Safety Population) - Risk Difference
Study: Pooled
Subgroup: Maximum NRS Pain Score at Baseline



Results are based on a Mantel-Haenszel approach stratified by study using a one-stage fixed-effects IPD meta-analysis.
The reference group is Placebo. Patients with multiple events are counted only once. MedDRA (version 22.0).
N: Number of patients in treatment group; NETA: Norethindrone acetate; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

SOURCE: X:\Numerus\Studies\MYV\MYV102\Analysis\Prod\Progs\TFLs\Fig_SAF_AE_S_BIN_FP.SAS Date/time of run: 01JUL21 10:03
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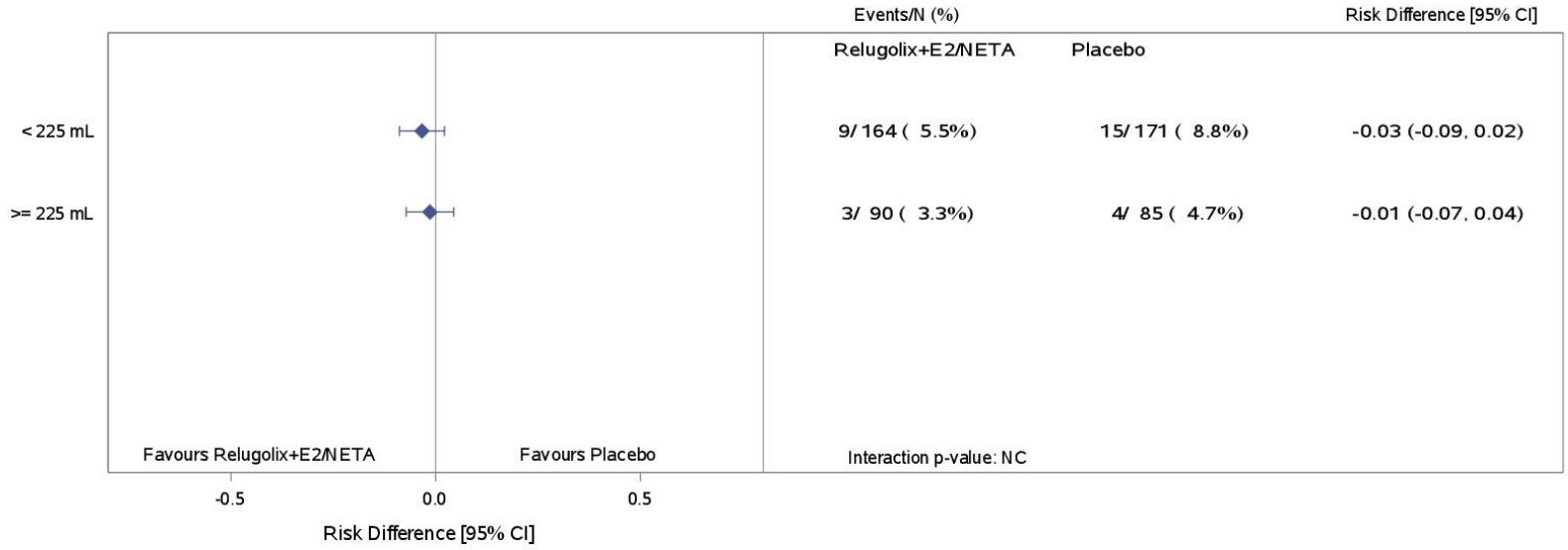
Figure SAF.G34TEAE.ANY.S5.BIN.FP.RD: Proportion of Patients With at Least One Grade 3 or Above Treatment Emergent Adverse Event, by Subgroup (Safety Population) - Risk Difference
Study: Pooled
Subgroup: MBL Volume at Baseline (mL)



Results are based on a Mantel-Haenszel approach stratified by study using a one-stage fixed-effects IPD meta-analysis.
The reference group is Placebo. Patients with multiple events are counted only once. MedDRA (version 22.0).
N: Number of patients in treatment group; NETA: Norethindrone acetate; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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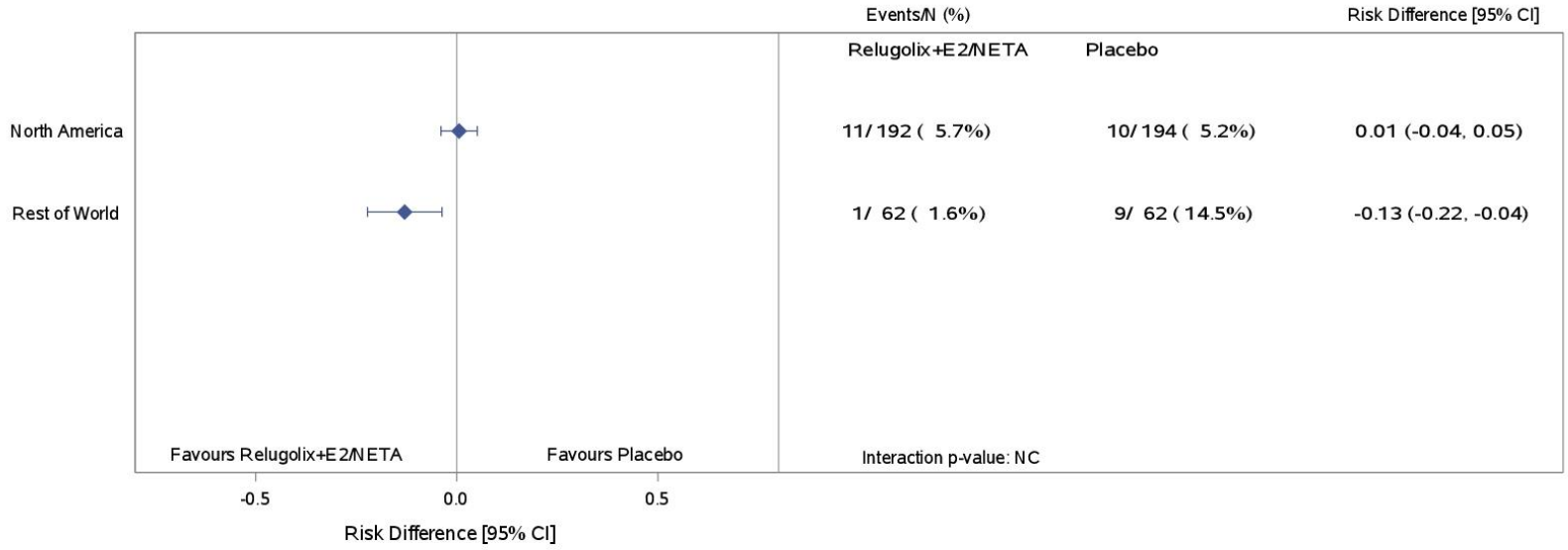
Figure SAF.G34TEAE.ANY.S6.BIN.FP.RD: Proportion of Patients With at Least One Grade 3 or Above Treatment Emergent Adverse Event, by Subgroup (Safety Population) - Risk Difference
Study: Pooled
Subgroup: Geographic Region I



Results are based on a Mantel-Haenszel approach stratified by study using a one-stage fixed-effects IPD meta-analysis.
The reference group is Placebo. Patients with multiple events are counted only once. MedDRA (version 22.0).
N: Number of patients in treatment group; NETA: Norethindrone acetate; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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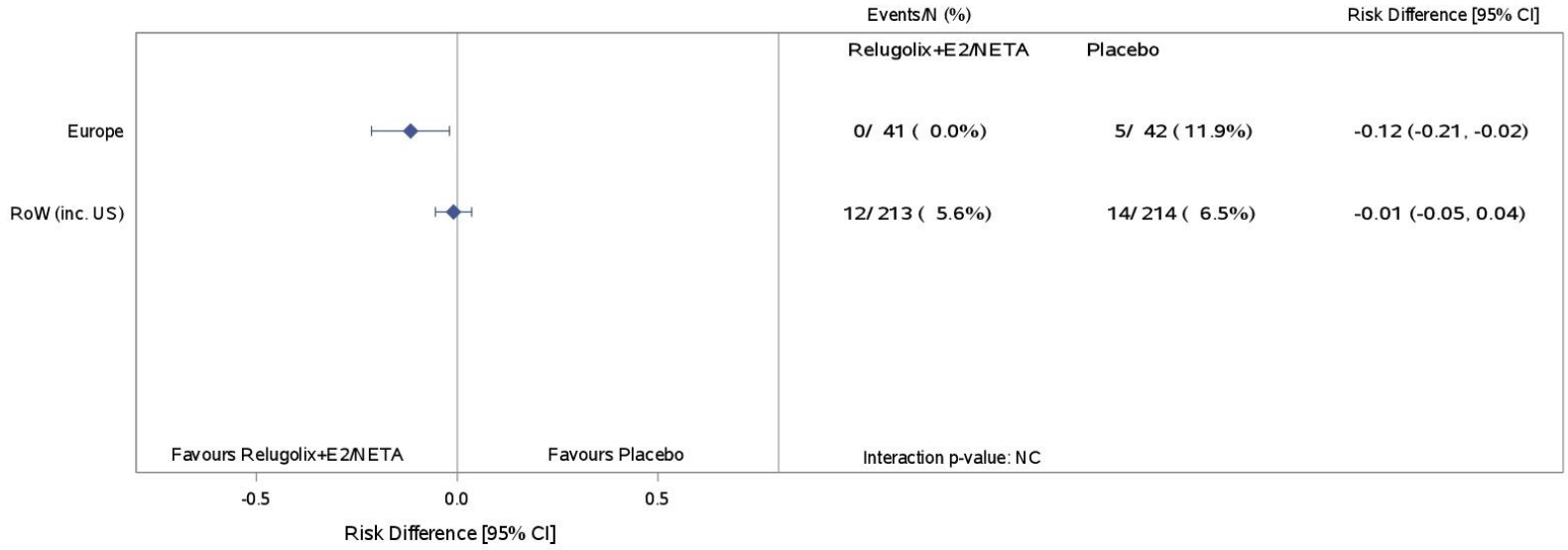
Figure SAF.G34TEAE.ANY.S7.BIN.FP.RD: Proportion of Patients With at Least One Grade 3 or Above Treatment Emergent Adverse Event, by Subgroup (Safety Population) - Risk Difference
Study: Pooled
Subgroup: Geographic Region II



Results are based on a Mantel-Haenszel approach stratified by study using a one-stage fixed-effects IPD meta-analysis.
The reference group is Placebo. Patients with multiple events are counted only once. MedDRA (version 22.0).
N: Number of patients in treatment group; NETA: Norethindrone acetate; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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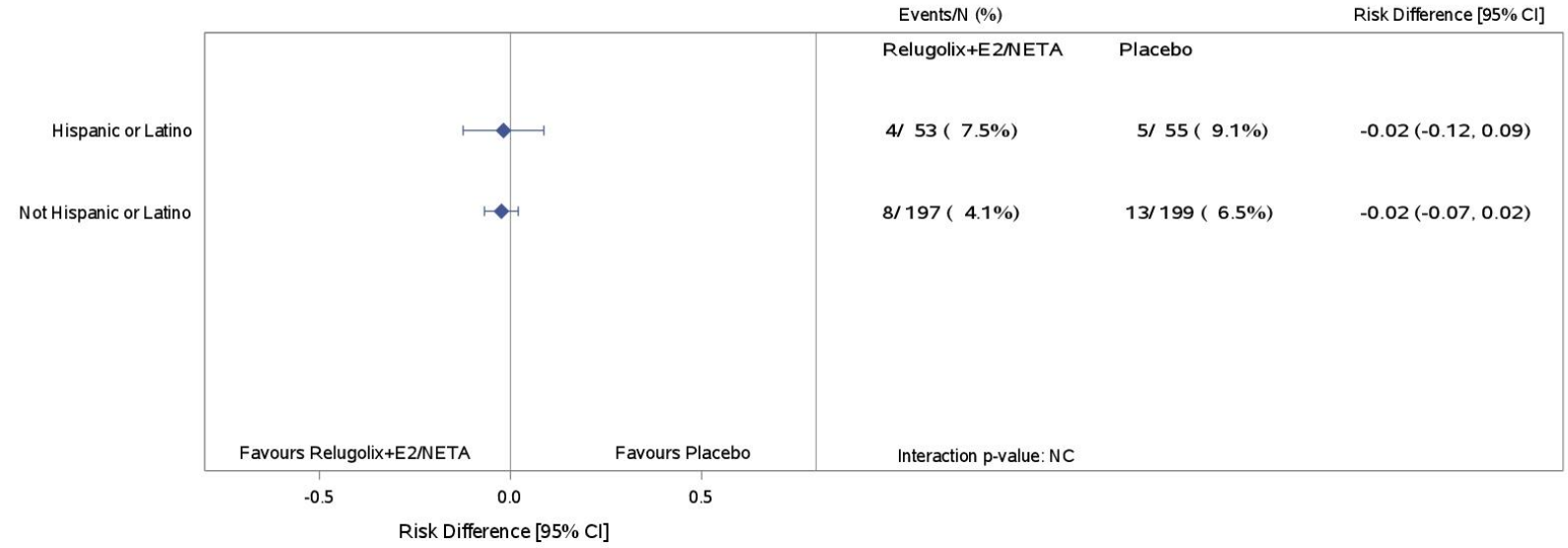
Figure SAF.G34TEAE.ANY.S8.BIN.FP.RD: Proportion of Patients With at Least One Grade 3 or Above Treatment Emergent Adverse Event, by Subgroup (Safety Population) - Risk Difference
Study: Pooled
Subgroup: Ethnicity



Results are based on a Mantel-Haenszel approach stratified by study using a one-stage fixed-effects IPD meta-analysis.
The reference group is Placebo. Patients with multiple events are counted only once. MedDRA (version 22.0).
N: Number of patients in treatment group; NETA: Norethindrone acetate; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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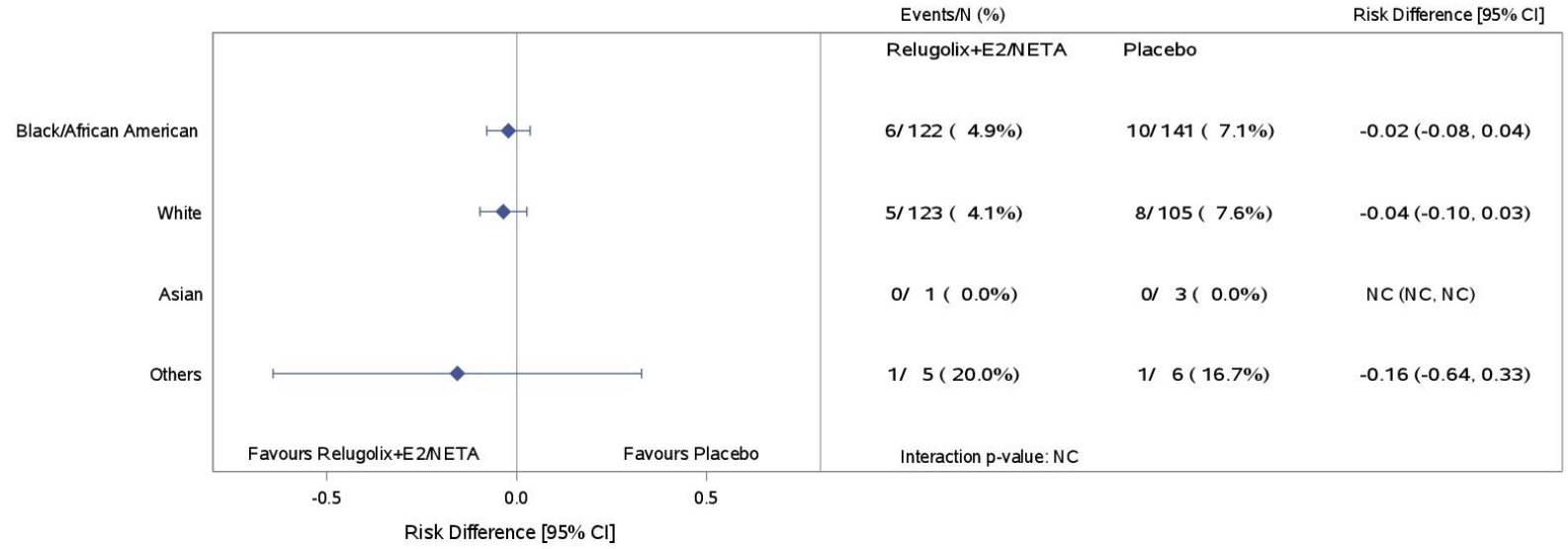
Figure SAF.G34TEAE.ANY.S9.BIN.FP.RD: Proportion of Patients With at Least One Grade 3 or Above Treatment Emergent Adverse Event, by Subgroup (Safety Population) - Risk Difference
Study: Pooled
Subgroup: Race



Results are based on a Mantel-Haenszel approach stratified by study using a one-stage fixed-effects IPD meta-analysis.
The reference group is Placebo. Patients with multiple events are counted only once. MedDRA (version 22.0).
N: Number of patients in treatment group; NETA: Norethindrone acetate; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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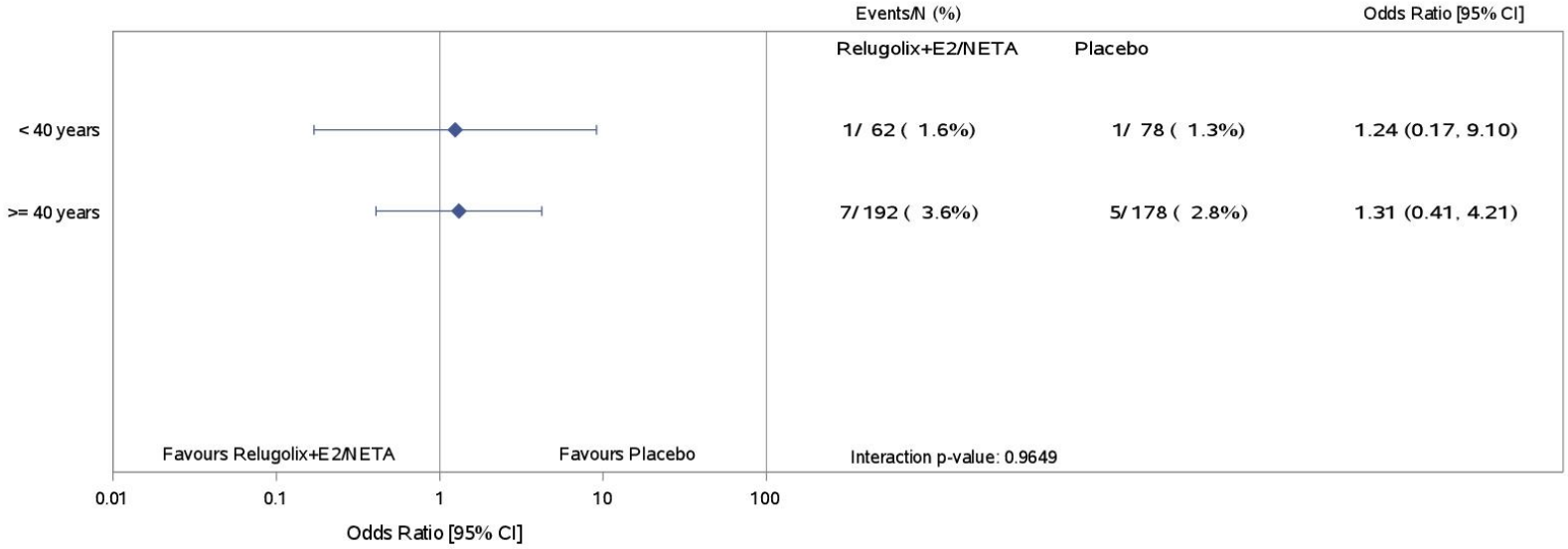
2.3.4 Proportion of Patients With at Least One Serious Treatment Emergent Adverse Event, by Subgroup (Safety Population)

Nachfolgend sind zunächst alle Forest Plots für das *Odds Ratio* dargestellt; gefolgt von den entsprechenden Forest Plots für *Risk Ratio* und *Risk Difference*.

Figure SAF.STEAE.ANY.S1.BIN.FP: Proportion of Patients With at Least One Serious Treatment Emergent Adverse Event, by Subgroup (Safety Population)
Study: Pooled
Subgroup: Age (years)



Results are based on a logistic regression model adjusted for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates using a one-stage fixed-effects IPD meta-analysis approach. A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
The interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the Odds Ratio and 95% CI. Missing subgroup levels are not included in estimation of the interaction p-value. The reference group is Placebo. Patients with multiple events are counted only once. MedDRA (version 22.0).
N: Number of patients in treatment group; NETA: Norethindrone acetate; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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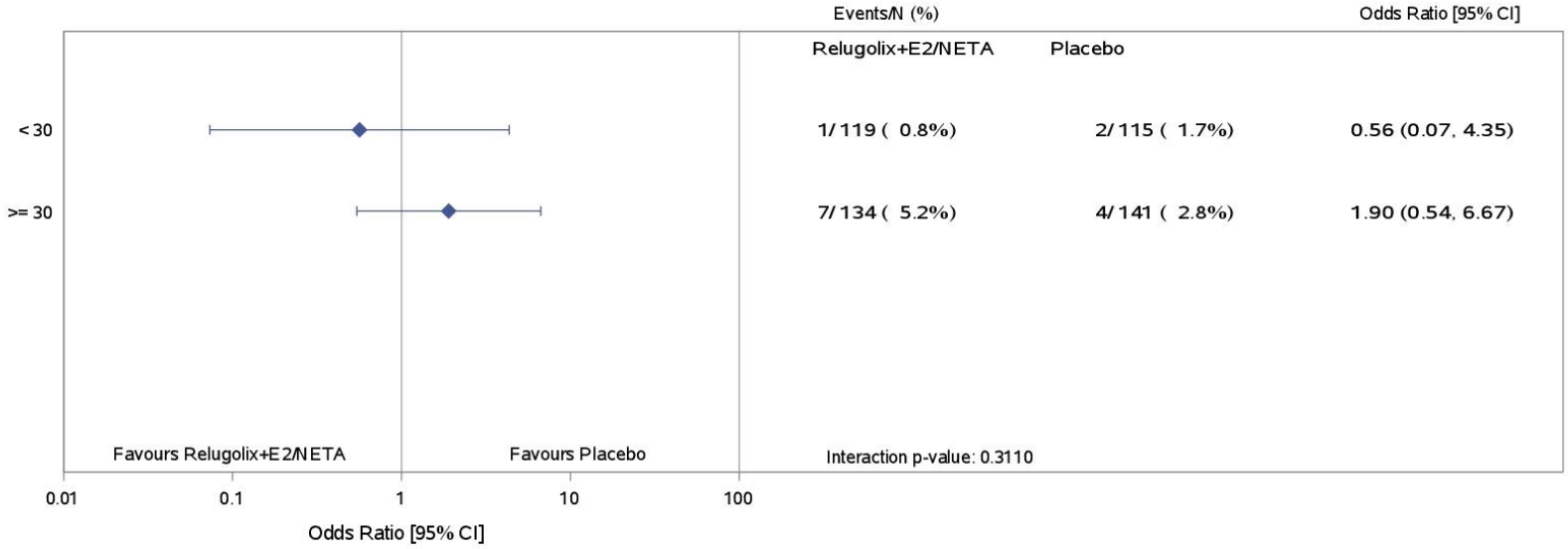
Figure SAF.STEAE.ANY.S2.BIN.FP: Proportion of Patients With at Least One Serious Treatment Emergent Adverse Event, by Subgroup (Safety Population)
Study: Pooled
Subgroup: BMI (kg/m2) at Baseline



Results are based on a logistic regression model adjusted for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates using a one-stage fixed-effects IPD meta-analysis approach. A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
The interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the Odds Ratio and 95% CI. Missing subgroup levels are not included in estimation of the interaction p-value. The reference group is Placebo. Patients with multiple events are counted only once. MedDRA (version 22.0).
N: Number of patients in treatment group; NETA: Norethindrone acetate; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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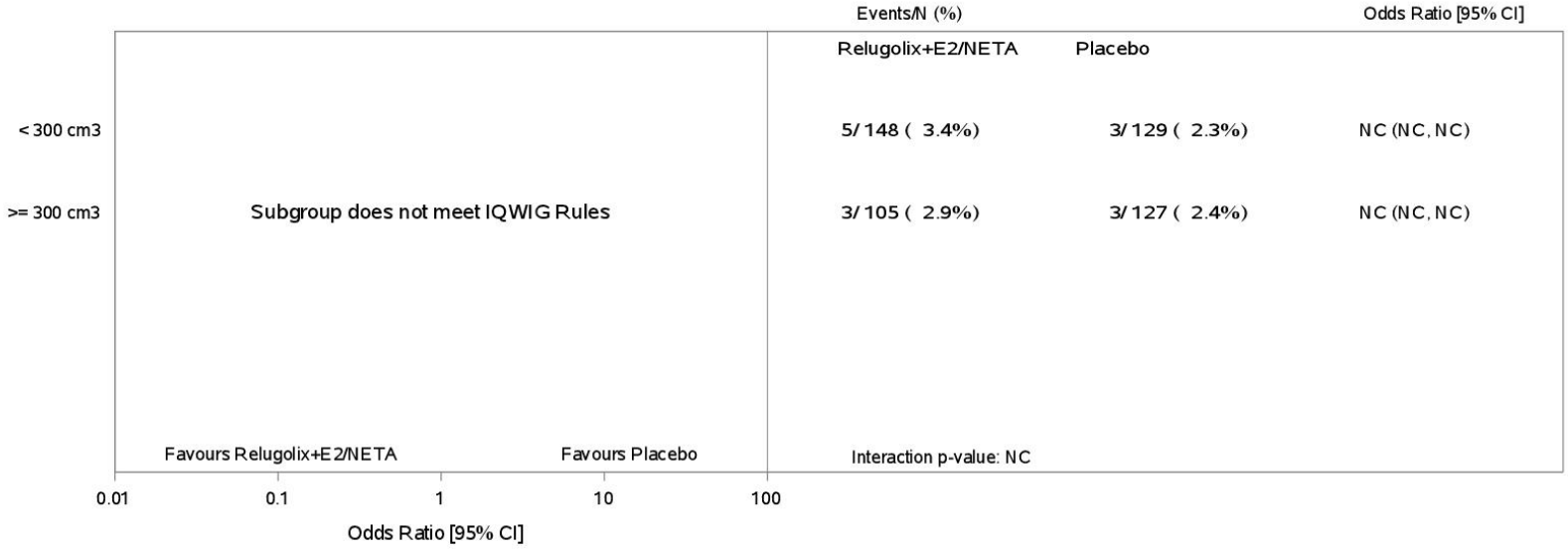
Figure SAF.STEAE.ANY.S3.BIN.FP: Proportion of Patients With at Least One Serious Treatment Emergent Adverse Event, by Subgroup (Safety Population)
Study: Pooled
Subgroup: Uterine Volume at Baseline (cm3)



Results are based on a logistic regression model adjusted for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates using a one-stage fixed-effects IPD meta-analysis approach. A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
The interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the Odds Ratio and 95% CI. Missing subgroup levels are not included in estimation of the interaction p-value. The reference group is Placebo. Patients with multiple events are counted only once. MedDRA (version 22.0).
N: Number of patients in treatment group; NETA: Norethindrone acetate; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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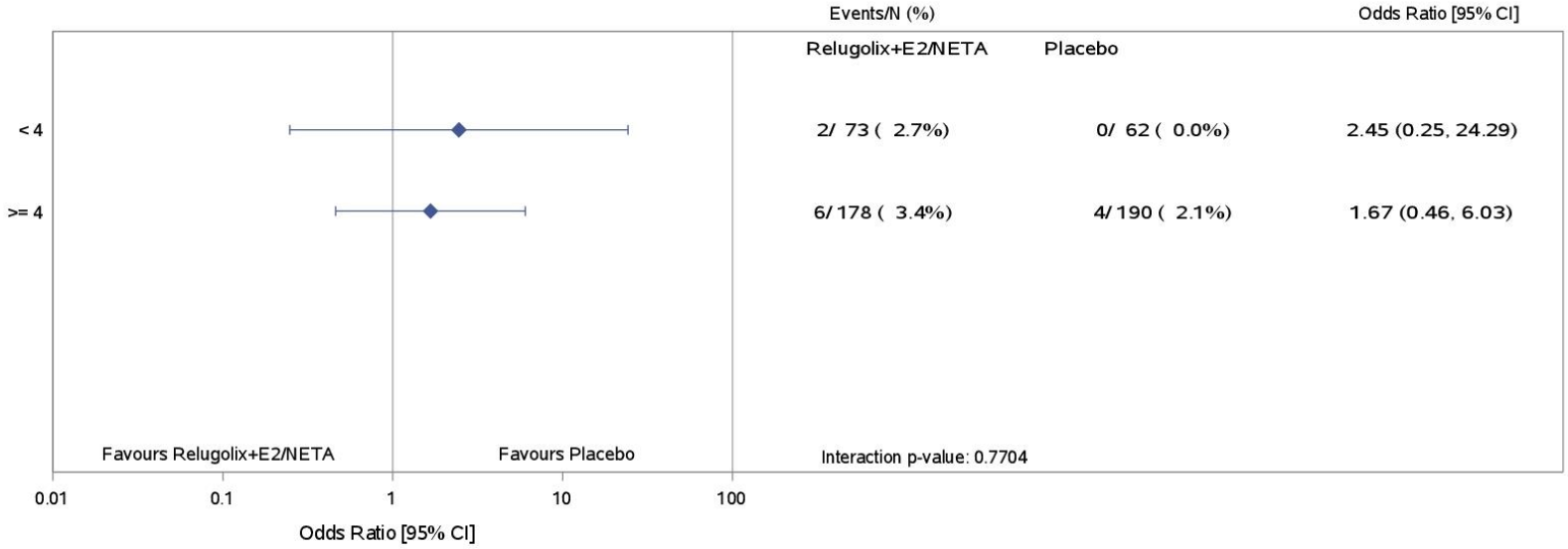
Figure SAF.STEAE.ANY.S4.BIN.FP: Proportion of Patients With at Least One Serious Treatment Emergent Adverse Event, by Subgroup (Safety Population)
Study: Pooled
Subgroup: Maximum NRS Pain Score at Baseline



Results are based on a logistic regression model adjusted for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates using a one-stage fixed-effects IPD meta-analysis approach. A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
The interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the Odds Ratio and 95% CI. Missing subgroup levels are not included in estimation of the interaction p-value. The reference group is Placebo. Patients with multiple events are counted only once. MedDRA (version 22.0).
N: Number of patients in treatment group; NETA: Norethindrone acetate; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

SOURCE: X:\Numerus\Studies\MYV\MYV102\Analysis\Prod\Progs\TFLs\Fig_SAF_AE_S_BIN_FP.SAS Date/time of run: 01JUL21 10:03
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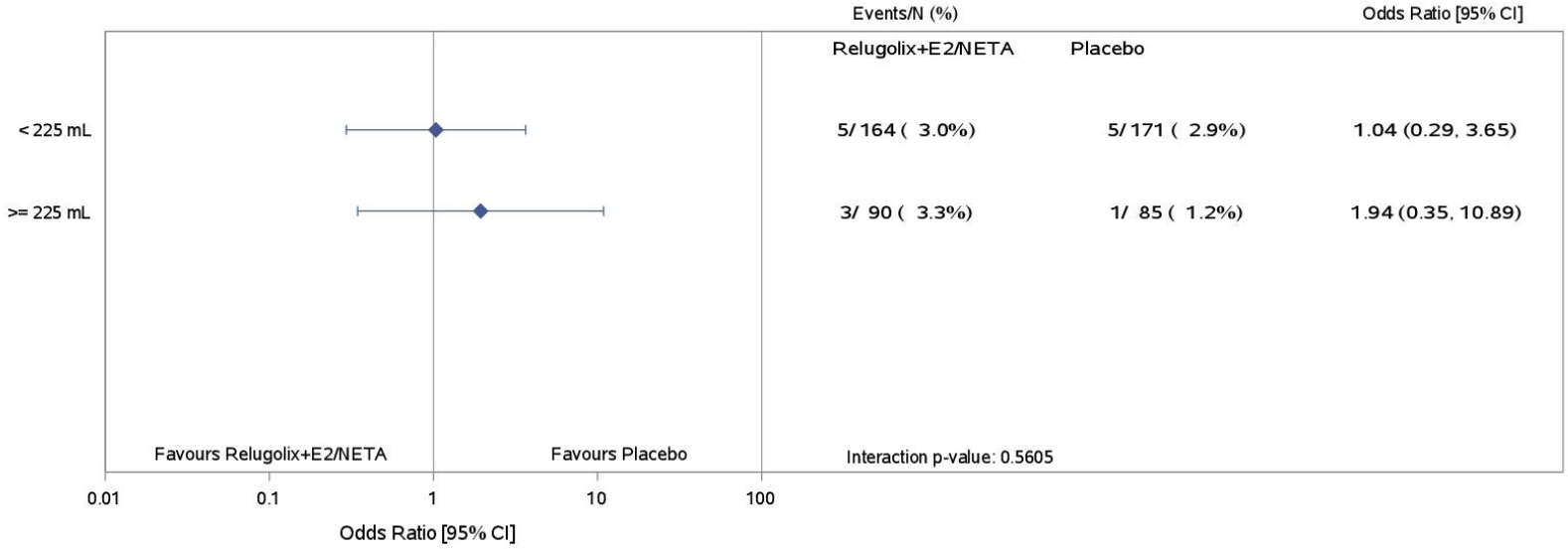
Figure SAF.STEAE.ANY.S5.BIN.FP: Proportion of Patients With at Least One Serious Treatment Emergent Adverse Event, by Subgroup (Safety Population)
Study: Pooled
Subgroup: MBL Volume at Baseline (mL)



Results are based on a logistic regression model adjusted for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates using a one-stage fixed-effects IPD meta-analysis approach. A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
The interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the Odds Ratio and 95% CI. Missing subgroup levels are not included in estimation of the interaction p-value. The reference group is Placebo. Patients with multiple events are counted only once. MedDRA (version 22.0).
N: Number of patients in treatment group; NETA: Norethindrone acetate; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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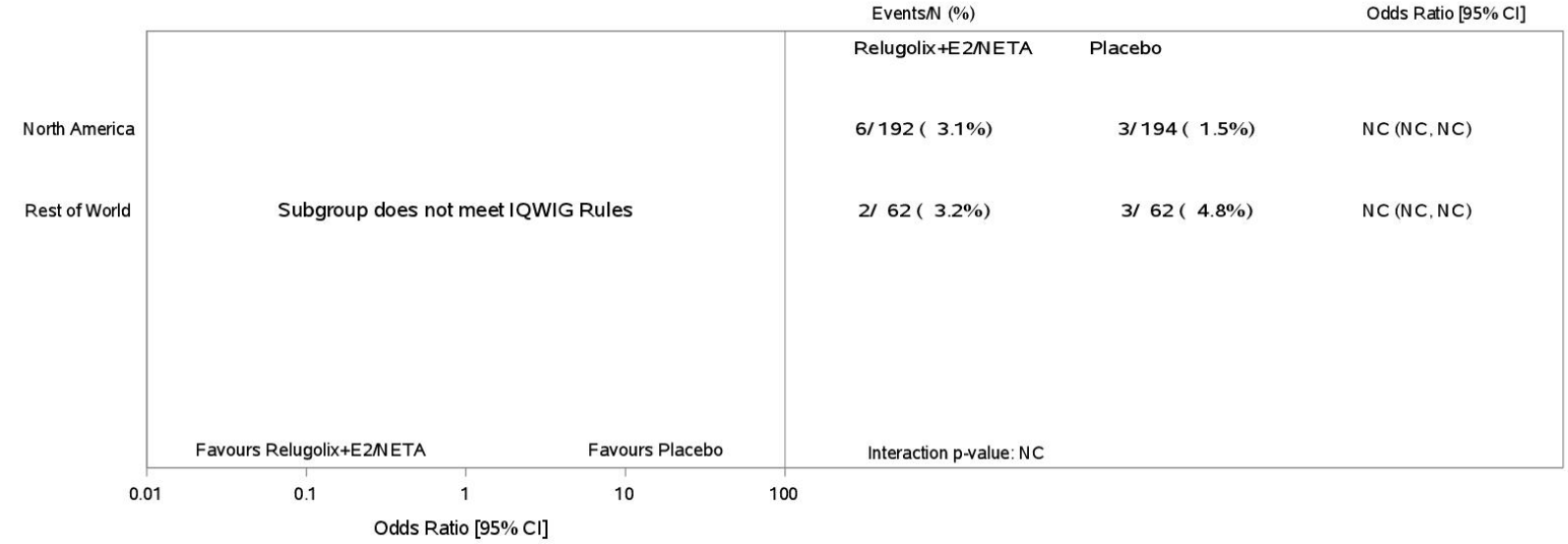
Figure SAF.STEAE.ANY.S6.BIN.FP: Proportion of Patients With at Least One Serious Treatment Emergent Adverse Event, by Subgroup (Safety Population)
Study: Pooled
Subgroup: Geographic Region I



Results are based on a logistic regression model adjusted for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates using a one-stage fixed-effects IPD meta-analysis approach. A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
The interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the Odds Ratio and 95% CI. Missing subgroup levels are not included in estimation of the interaction p-value. The reference group is Placebo. Patients with multiple events are counted only once. MedDRA (version 22.0).
N: Number of patients in treatment group; NETA: Norethindrone acetate; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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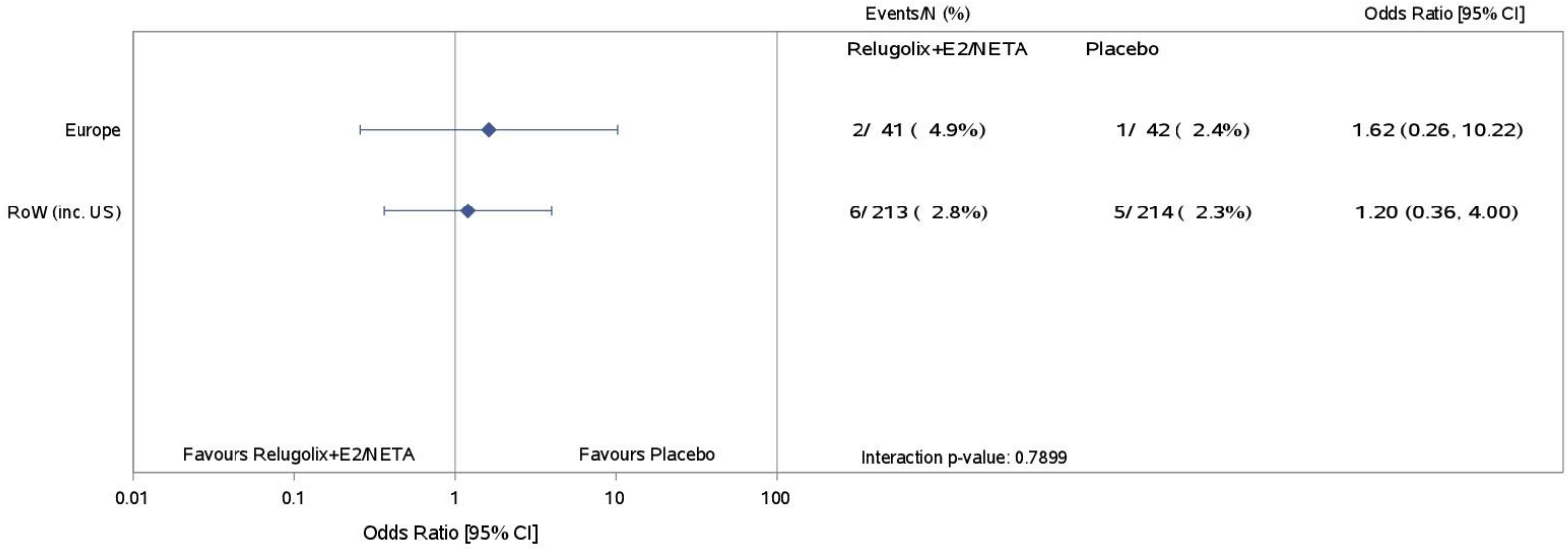
Figure SAF.STEAE.ANY.S7.BIN.FP: Proportion of Patients With at Least One Serious Treatment Emergent Adverse Event, by Subgroup (Safety Population)
Study: Pooled
Subgroup: Geographic Region II



Results are based on a logistic regression model adjusted for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates using a one-stage fixed-effects IPD meta-analysis approach. A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
The interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the Odds Ratio and 95% CI. Missing subgroup levels are not included in estimation of the interaction p-value. The reference group is Placebo. Patients with multiple events are counted only once. MedDRA (version 22.0).
N: Number of patients in treatment group; NETA: Norethindrone acetate; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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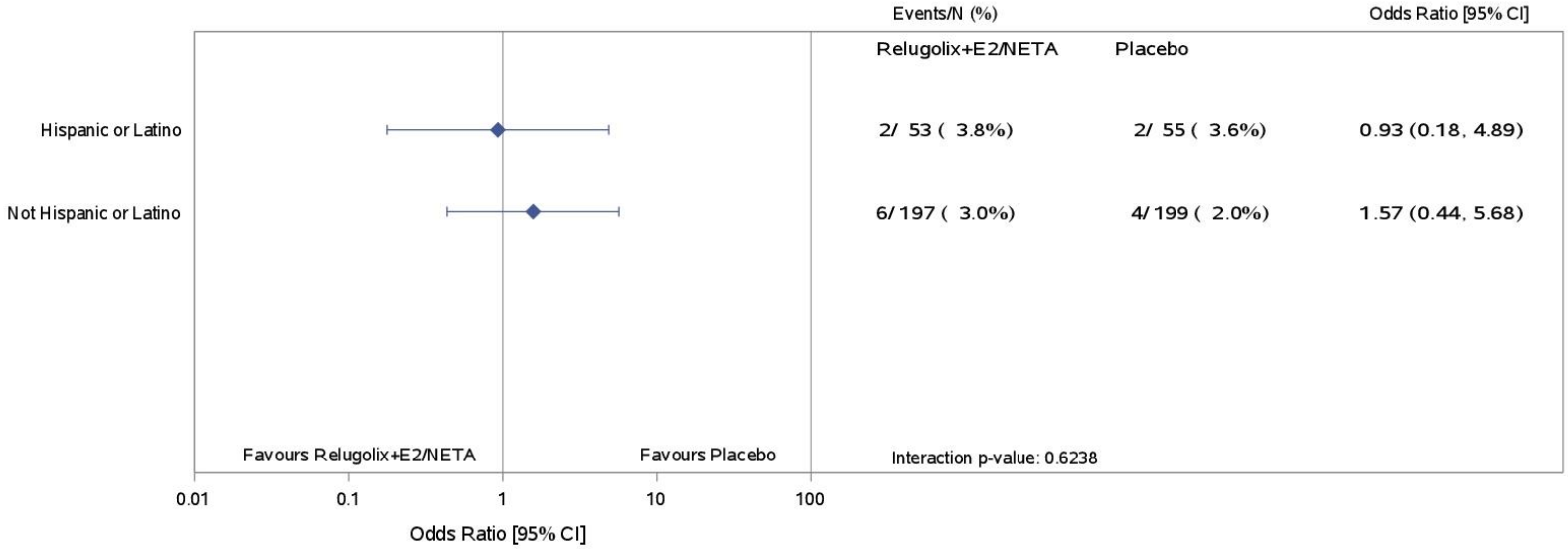
Figure SAF.STEAE.ANY.S8.BIN.FP: Proportion of Patients With at Least One Serious Treatment Emergent Adverse Event, by Subgroup (Safety Population)
Study: Pooled
Subgroup: Ethnicity



Results are based on a logistic regression model adjusted for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates using a one-stage fixed-effects IPD meta-analysis approach. A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
The interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the Odds Ratio and 95% CI. Missing subgroup levels are not included in estimation of the interaction p-value. The reference group is Placebo. Patients with multiple events are counted only once. MedDRA (version 22.0).
N: Number of patients in treatment group; NETA: Norethindrone acetate; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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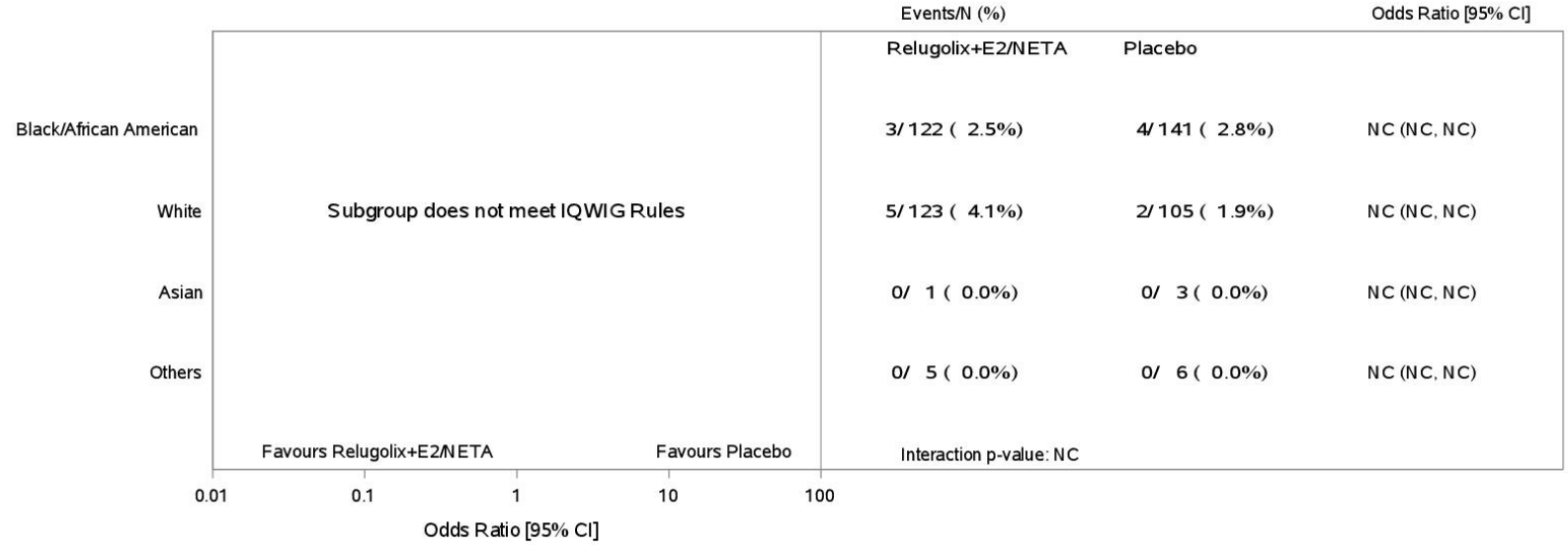
Figure SAF.STEAE.ANY.S9.BIN.FP: Proportion of Patients With at Least One Serious Treatment Emergent Adverse Event, by Subgroup (Safety Population)
Study: Pooled
Subgroup: Race



Results are based on a logistic regression model adjusted for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates using a one-stage fixed-effects IPD meta-analysis approach. A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
The interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the Odds Ratio and 95% CI. Missing subgroup levels are not included in estimation of the interaction p-value. The reference group is Placebo. Patients with multiple events are counted only once. MedDRA (version 22.0).
N: Number of patients in treatment group; NETA: Norethindrone acetate; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

SOURCE: X:\Numerus\Studies\MYV\MYV102\Analysis\Prod\Progs\TFLs\Fig_SAF_AE_S_BIN_FP.SAS Date/time of run: 01JUL21 10:03
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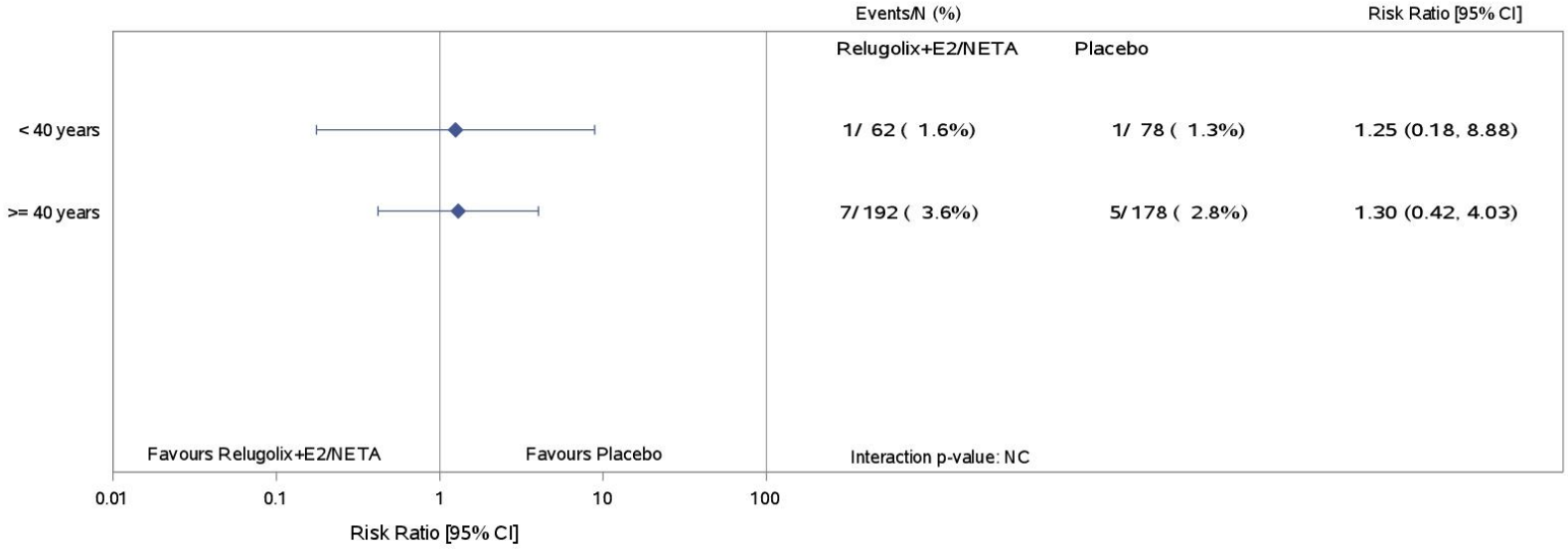
Figure SAF.STEAE.ANY.S1.BIN.FP.RR: Proportion of Patients With at Least One Serious Treatment Emergent Adverse Event, by Subgroup (Safety Population) - Risk Ratio
Study: Pooled
Subgroup: Age (years)



Results are based on a Cochran-Mantel-Haenszel approach stratified by study using a one-stage fixed-effects IPD meta-analysis. A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
The reference group is Placebo. Patients with multiple events are counted only once. MedDRA (version 22.0).
N: Number of patients in treatment group; NETA: Norethindrone acetate; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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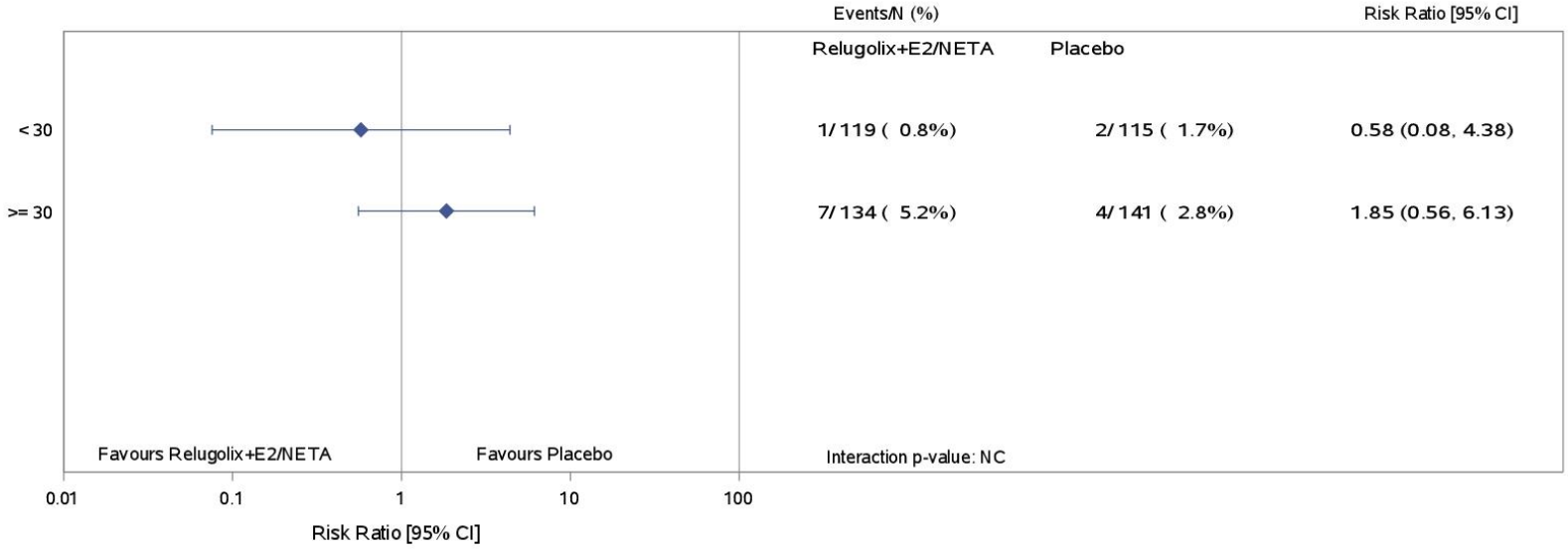
Figure SAF.STEAE.ANY.S2.BIN.FP.RR: Proportion of Patients With at Least One Serious Treatment Emergent Adverse Event, by Subgroup (Safety Population) - Risk Ratio
Study: Pooled
Subgroup: BMI (kg/m2) at Baseline



Results are based on a Cochran-Mantel-Haenszel approach stratified by study using a one-stage fixed-effects IPD meta-analysis. A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
The reference group is Placebo. Patients with multiple events are counted only once. MedDRA (version 22.0).
N: Number of patients in treatment group; NETA: Norethindrone acetate; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

SOURCE: X:\Numerus\Studies\MYV\MYV102\Analysis\Prod\Progs\TFLs\Fig_SAF_AE_S_BIN_FP.SAS Date/time of run: 01JUL21 10:03
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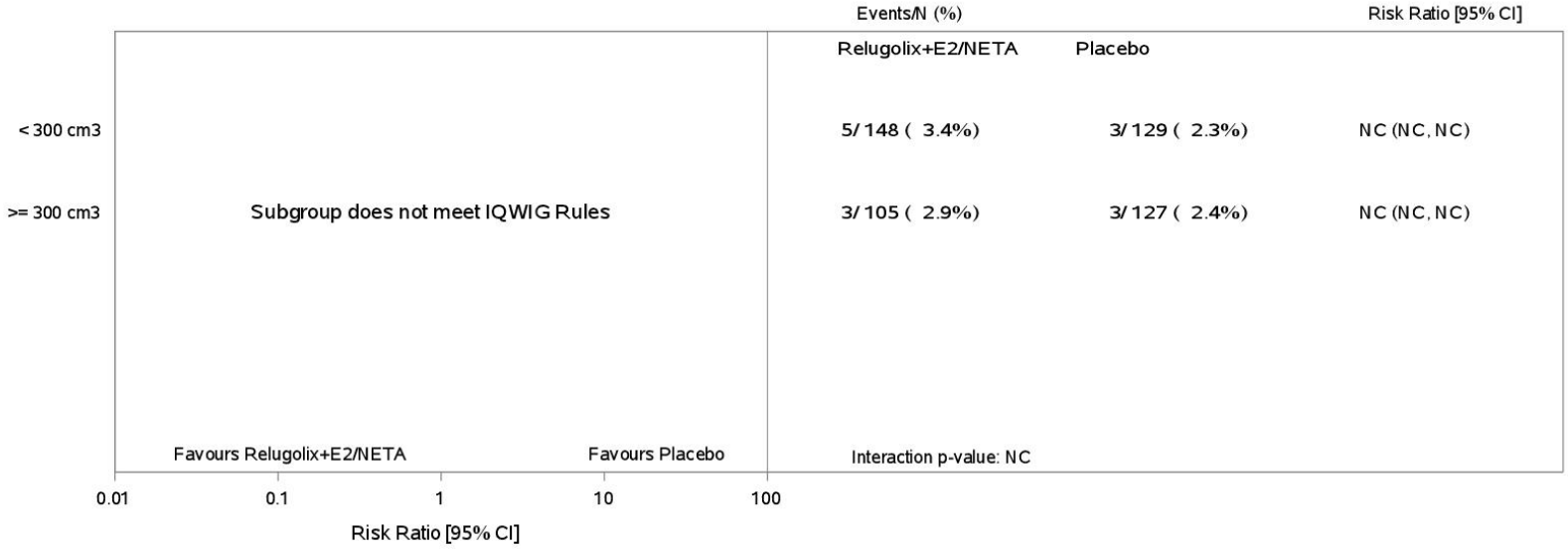
Figure SAF.STEAE.ANY.S3.BIN.FP.RR: Proportion of Patients With at Least One Serious Treatment Emergent Adverse Event, by Subgroup (Safety Population) - Risk Ratio
Study: Pooled
Subgroup: Uterine Volume at Baseline (cm3)



Results are based on a Cochran-Mantel-Haenszel approach stratified by study using a one-stage fixed-effects IPD meta-analysis. A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
The reference group is Placebo. Patients with multiple events are counted only once. MedDRA (version 22.0).
N: Number of patients in treatment group; NETA: Norethindrone acetate; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

SOURCE: X:\Numerus\Studies\MYV\MYV102\Analysis\Prod\Progs\TFLs\Fig_SAF_AE_S_BIN_FP.SAS Date/time of run: 01JUL21 10:03
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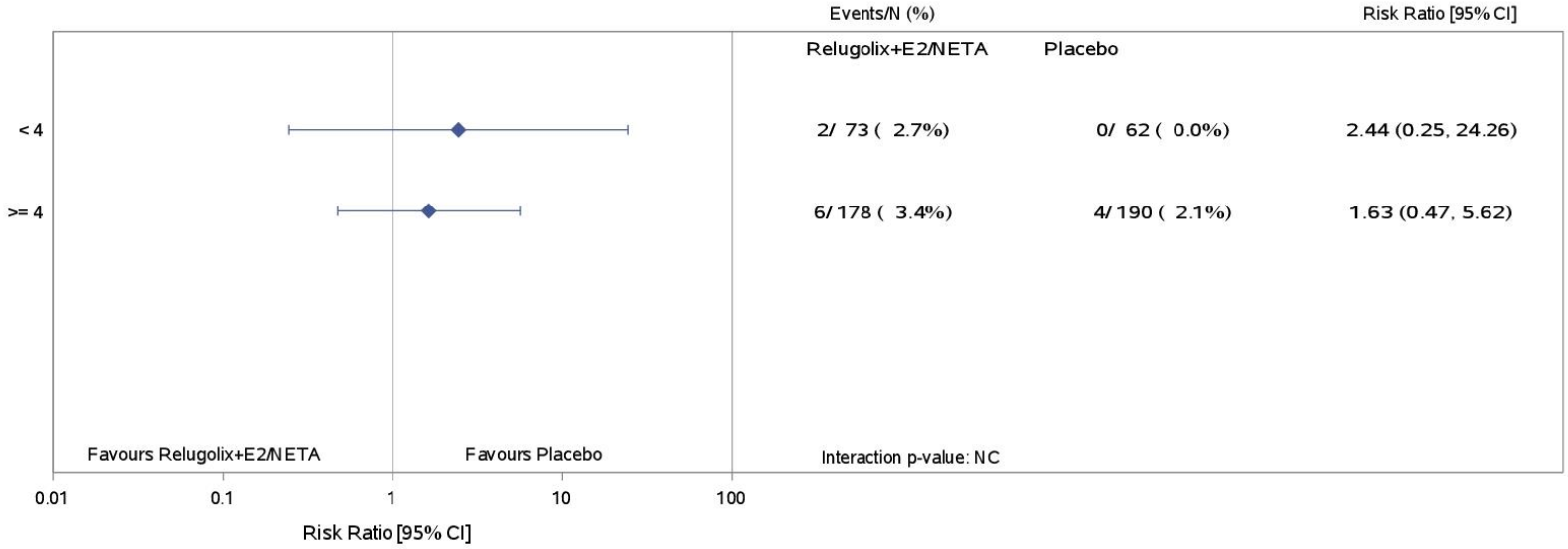
Figure SAF.STEAE.ANY.S4.BIN.FP.RR: Proportion of Patients With at Least One Serious Treatment Emergent Adverse Event, by Subgroup (Safety Population) - Risk Ratio
Study: Pooled
Subgroup: Maximum NRS Pain Score at Baseline



Results are based on a Cochran-Mantel-Haenszel approach stratified by study using a one-stage fixed-effects IPD meta-analysis. A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
The reference group is Placebo. Patients with multiple events are counted only once. MedDRA (version 22.0).
N: Number of patients in treatment group; NETA: Norethindrone acetate; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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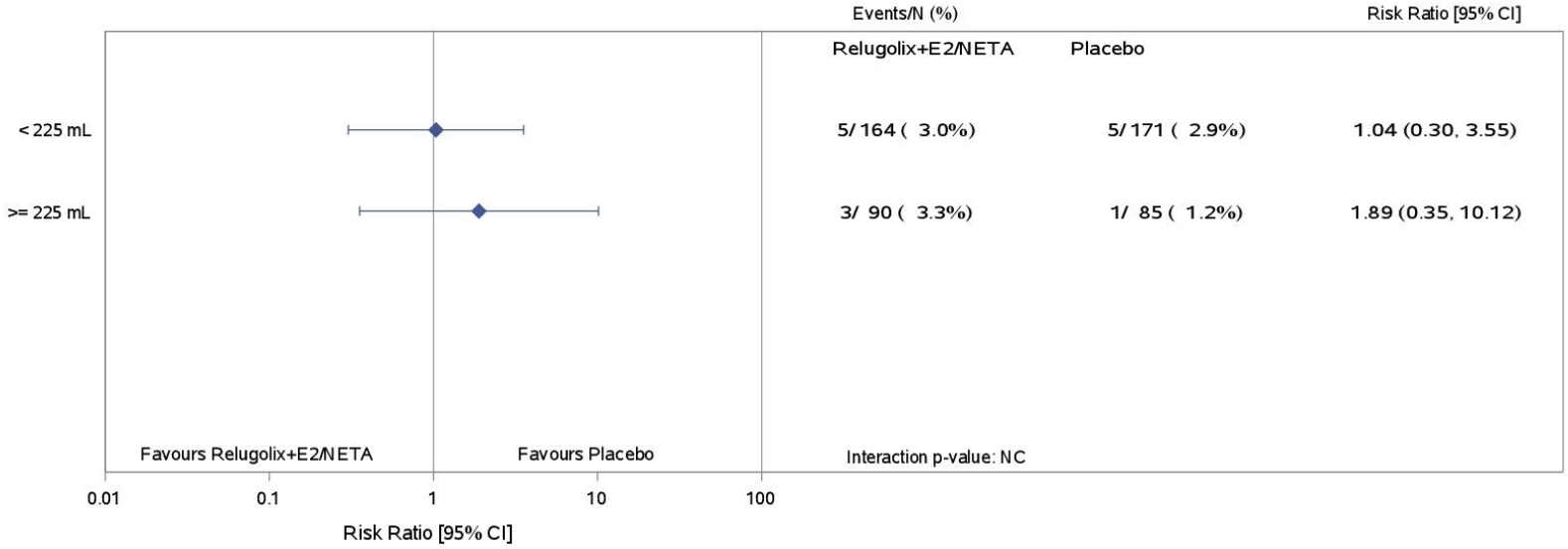
Figure SAF.STEAE.ANY.S5.BIN.FP.RR: Proportion of Patients With at Least One Serious Treatment Emergent Adverse Event, by Subgroup (Safety Population) - Risk Ratio
Study: Pooled
Subgroup: MBL Volume at Baseline (mL)



Results are based on a Cochran-Mantel-Haenszel approach stratified by study using a one-stage fixed-effects IPD meta-analysis. A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
The reference group is Placebo. Patients with multiple events are counted only once. MedDRA (version 22.0).
N: Number of patients in treatment group; NETA: Norethindrone acetate; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

SOURCE: X:\Numerus\Studies\MYV\MYV102\Analysis\Prod\Progs\TFLs\Fig_SAF_AE_S_BIN_FP.SAS Date/time of run: 01JUL21 10:03
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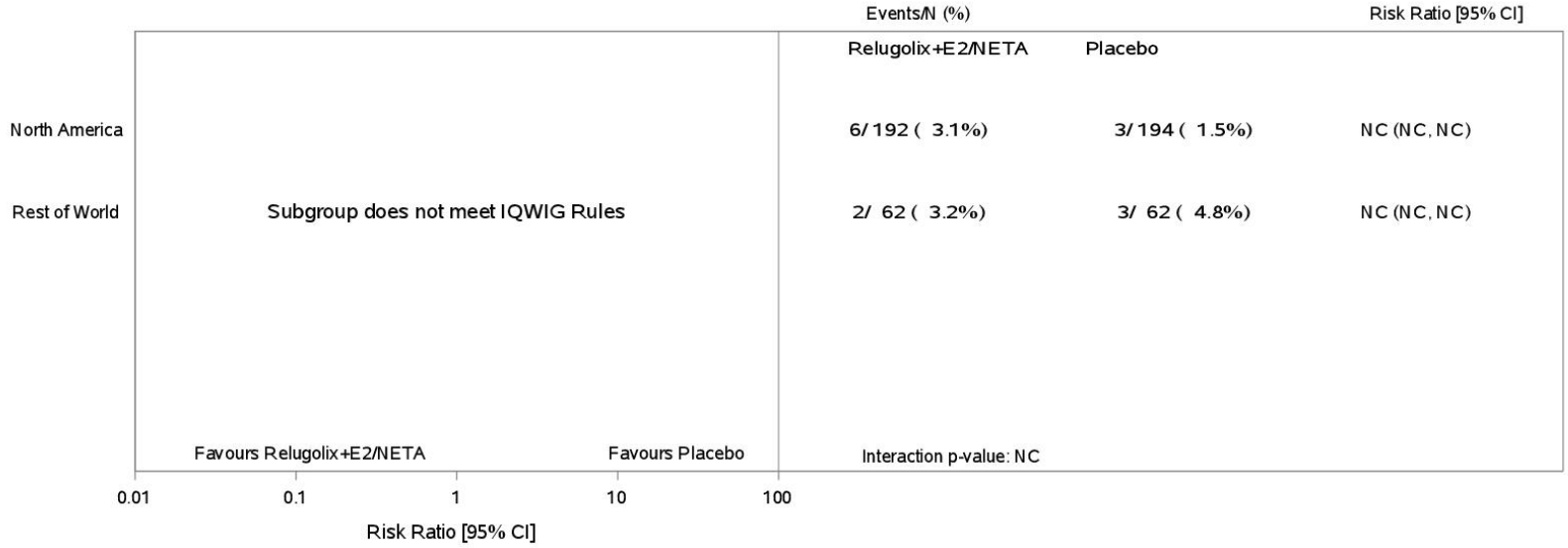
Figure SAF.STEAE.ANY.S6.BIN.FP.RR: Proportion of Patients With at Least One Serious Treatment Emergent Adverse Event, by Subgroup (Safety Population) - Risk Ratio
Study: Pooled
Subgroup: Geographic Region I



Results are based on a Cochran-Mantel-Haenszel approach stratified by study using a one-stage fixed-effects IPD meta-analysis. A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
The reference group is Placebo. Patients with multiple events are counted only once. MedDRA (version 22.0).
N: Number of patients in treatment group; NETA: Norethindrone acetate; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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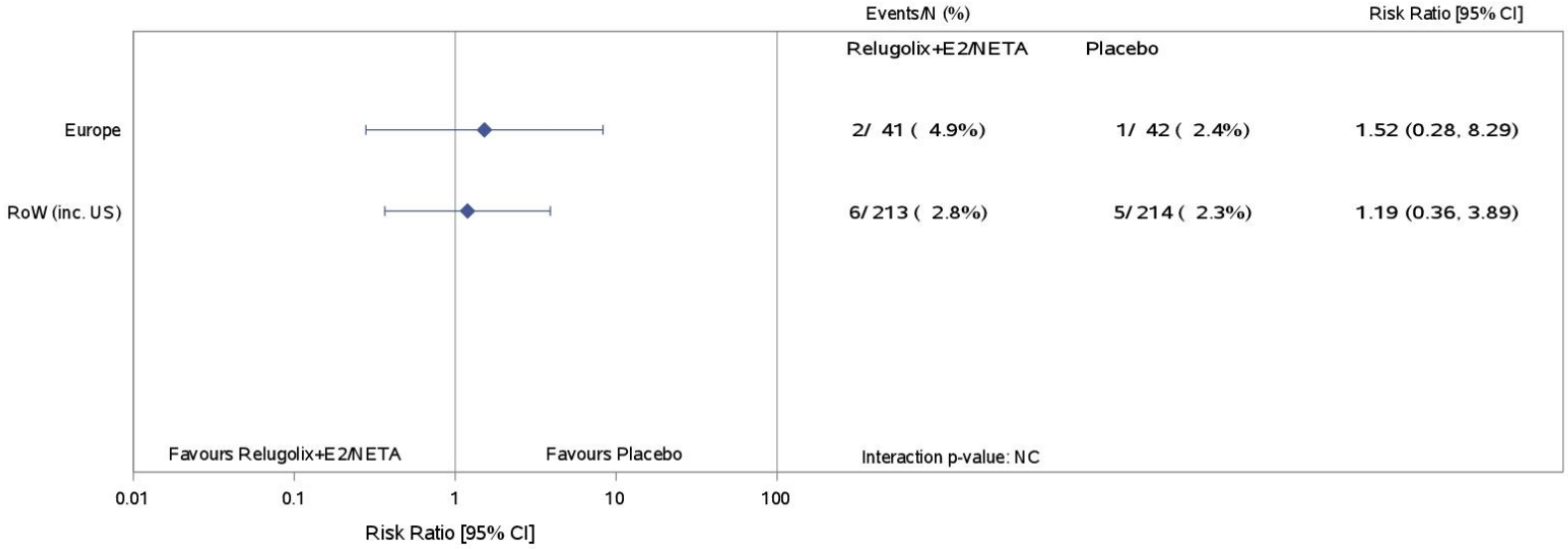
Figure SAF.STEAE.ANY.S7.BIN.FP.RR: Proportion of Patients With at Least One Serious Treatment Emergent Adverse Event, by Subgroup (Safety Population) - Risk Ratio
Study: Pooled
Subgroup: Geographic Region II



Results are based on a Cochran-Mantel-Haenszel approach stratified by study using a one-stage fixed-effects IPD meta-analysis. A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
The reference group is Placebo. Patients with multiple events are counted only once. MedDRA (version 22.0).
N: Number of patients in treatment group; NETA: Norethindrone acetate; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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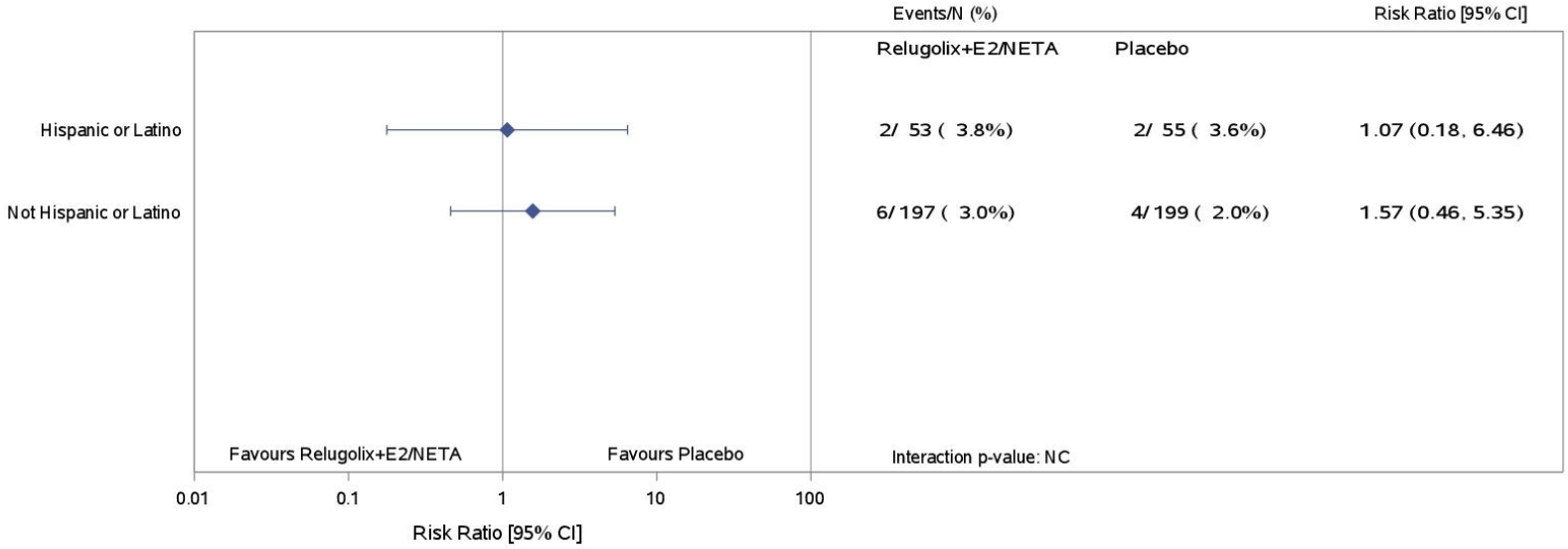
Figure SAF.STEAE.ANY.S8.BIN.FP.RR: Proportion of Patients With at Least One Serious Treatment Emergent Adverse Event, by Subgroup (Safety Population) - Risk Ratio
Study: Pooled
Subgroup: Ethnicity



Results are based on a Cochran-Mantel-Haenszel approach stratified by study using a one-stage fixed-effects IPD meta-analysis. A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
The reference group is Placebo. Patients with multiple events are counted only once. MedDRA (version 22.0).
N: Number of patients in treatment group; NETA: Norethindrone acetate; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

SOURCE: X:\Numerus\Studies\MYV\MYV102\Analysis\Prod\Progs\TFLs\Fig_SAF_AE_S_BIN_FP.SAS Date/time of run: 01JUL21 10:03
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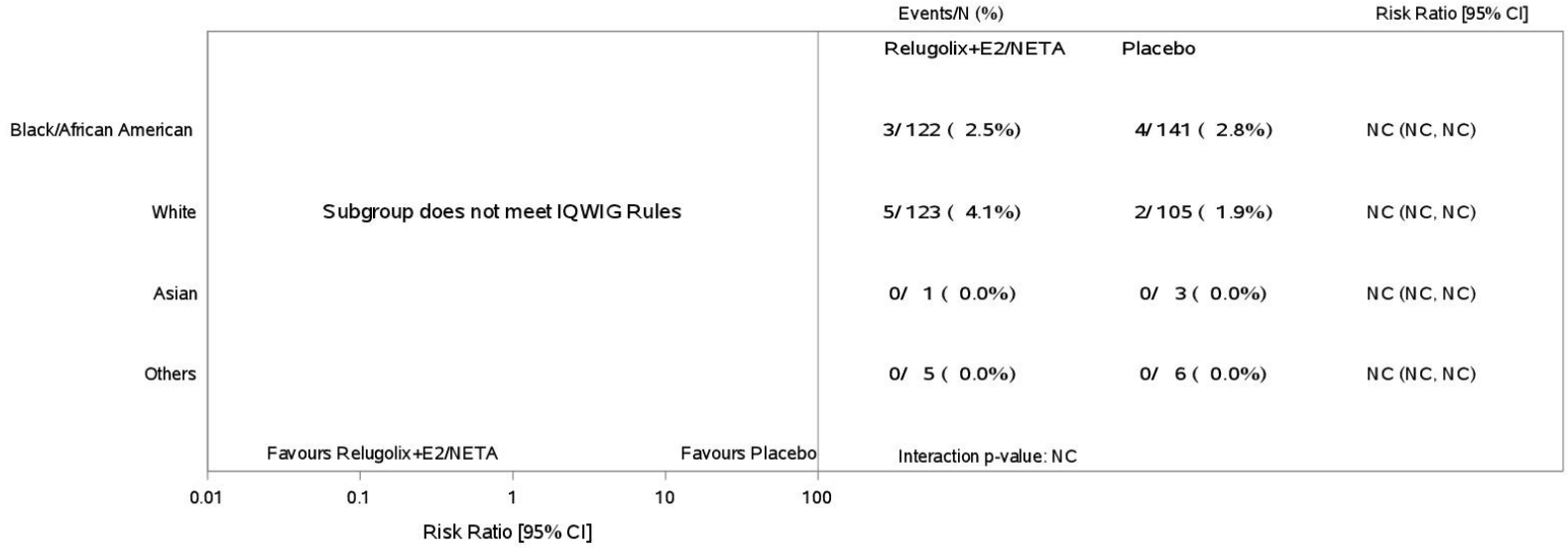
Figure SAF.STEAE.ANY.S9.BIN.FP.RR: Proportion of Patients With at Least One Serious Treatment Emergent Adverse Event, by Subgroup (Safety Population) - Risk Ratio
Study: Pooled
Subgroup: Race



Results are based on a Cochran-Mantel-Haenszel approach stratified by study using a one-stage fixed-effects IPD meta-analysis. A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
The reference group is Placebo. Patients with multiple events are counted only once. MedDRA (version 22.0).
N: Number of patients in treatment group; NETA: Norethindrone acetate; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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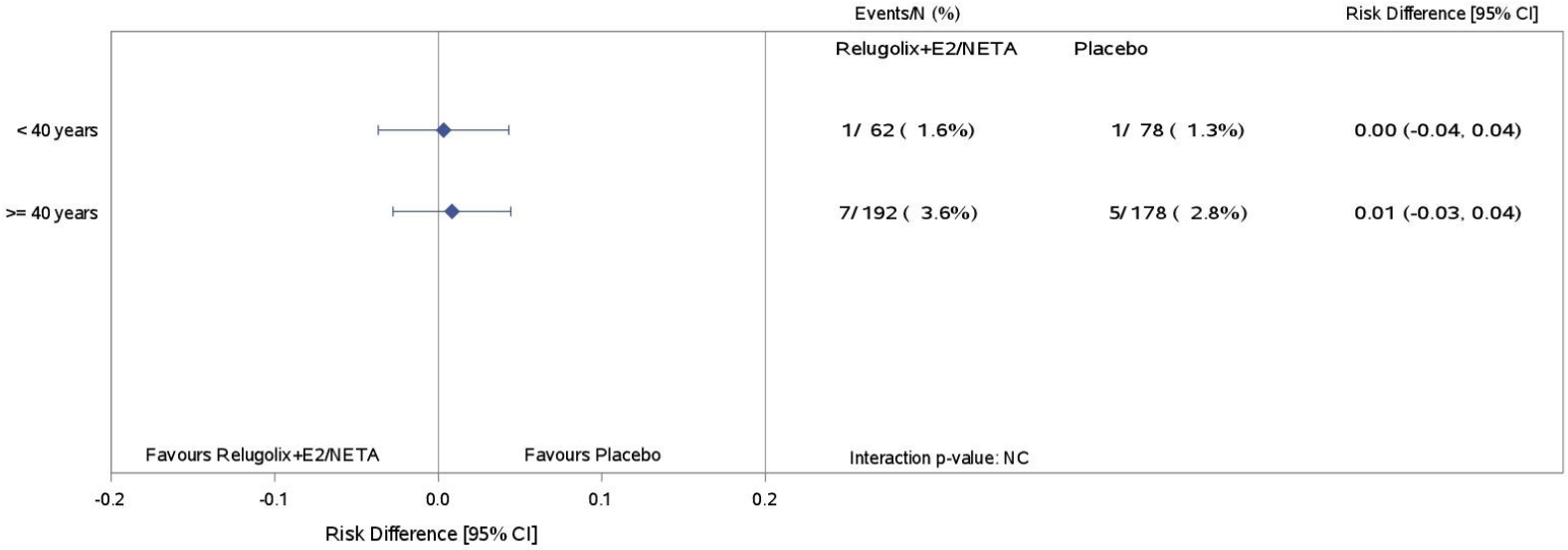
Figure SAF.STEAE.ANY.S1.BIN.FP.RD: Proportion of Patients With at Least One Serious Treatment Emergent Adverse Event, by Subgroup (Safety Population) - Risk Difference
Study: Pooled
Subgroup: Age (years)



Results are based on a Mantel-Haenszel approach stratified by study using a one-stage fixed-effects IPD meta-analysis.
The reference group is Placebo. Patients with multiple events are counted only once. MedDRA (version 22.0).
N: Number of patients in treatment group; NETA: Norethindrone acetate; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

SOURCE: X:\Numerus\Studies\MYV\MYV102\Analysis\Prod\Progs\TFLs\Fig_SAF_AE_S_BIN_FP.SAS Date/time of run: 01JUL21 10:03
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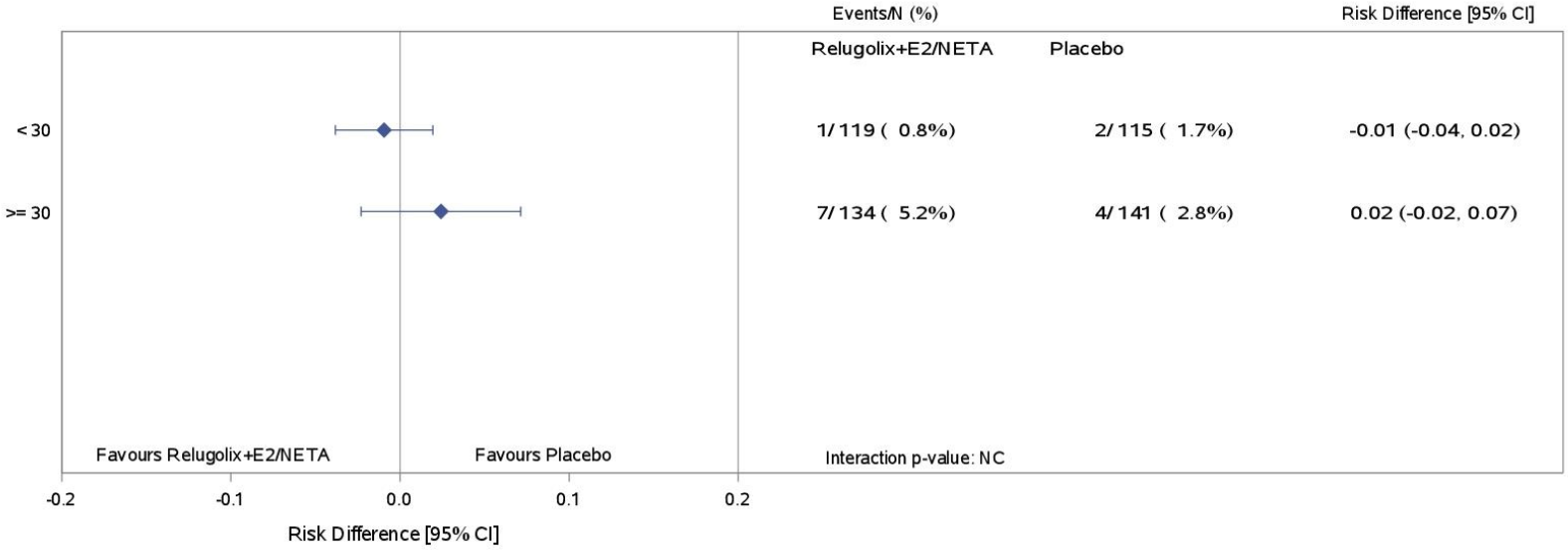
Figure SAF.STEAE.ANY.S2.BIN.FP.RD: Proportion of Patients With at Least One Serious Treatment Emergent Adverse Event, by Subgroup (Safety Population) - Risk Difference
Study: Pooled
Subgroup: BMI (kg/m2) at Baseline



Results are based on a Mantel-Haenszel approach stratified by study using a one-stage fixed-effects IPD meta-analysis.
The reference group is Placebo. Patients with multiple events are counted only once. MedDRA (version 22.0).
N: Number of patients in treatment group; NETA: Norethindrone acetate; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

SOURCE: X:\Numerus\Studies\MYV\MYV102\Analysis\Prod\Progs\TFLs\Fig_SAF_AE_S_BIN_FP.SAS Date/time of run: 01JUL21 10:03
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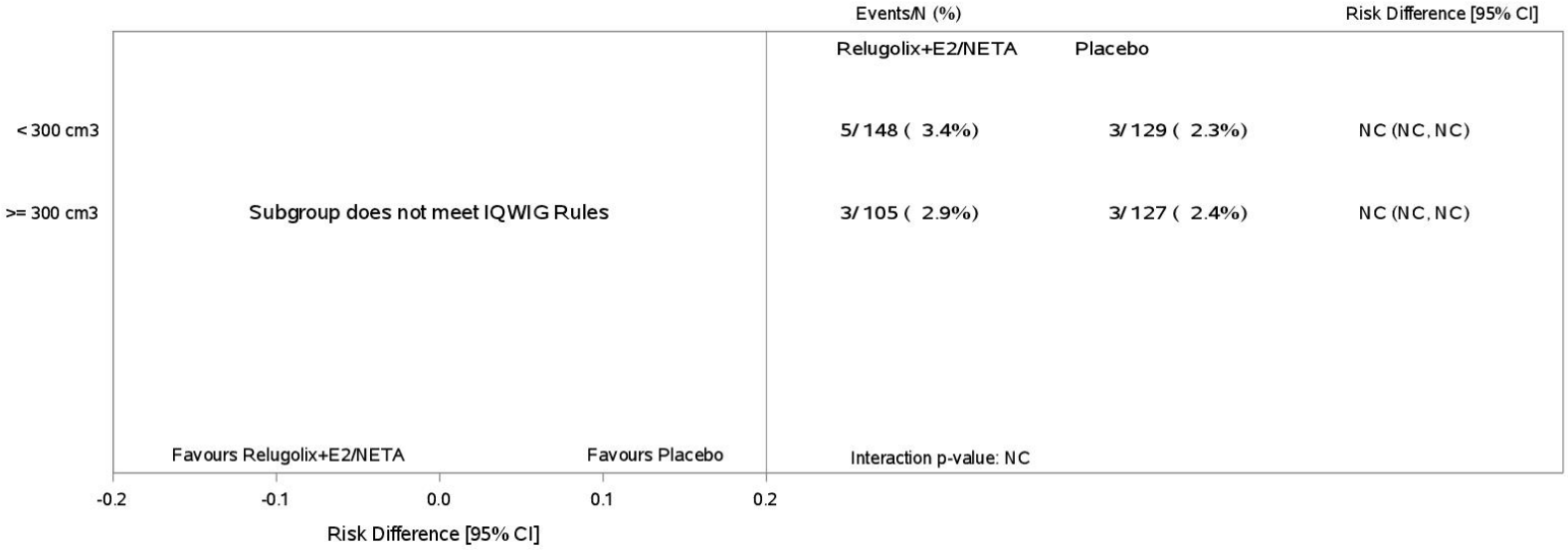
Figure SAF.STEAE.ANY.S3.BIN.FP.RD: Proportion of Patients With at Least One Serious Treatment Emergent Adverse Event, by Subgroup (Safety Population) - Risk Difference
Study: Pooled
Subgroup: Uterine Volume at Baseline (cm3)



Results are based on a Mantel-Haenszel approach stratified by study using a one-stage fixed-effects IPD meta-analysis.
The reference group is Placebo. Patients with multiple events are counted only once. MedDRA (version 22.0).
N: Number of patients in treatment group; NETA: Norethindrone acetate; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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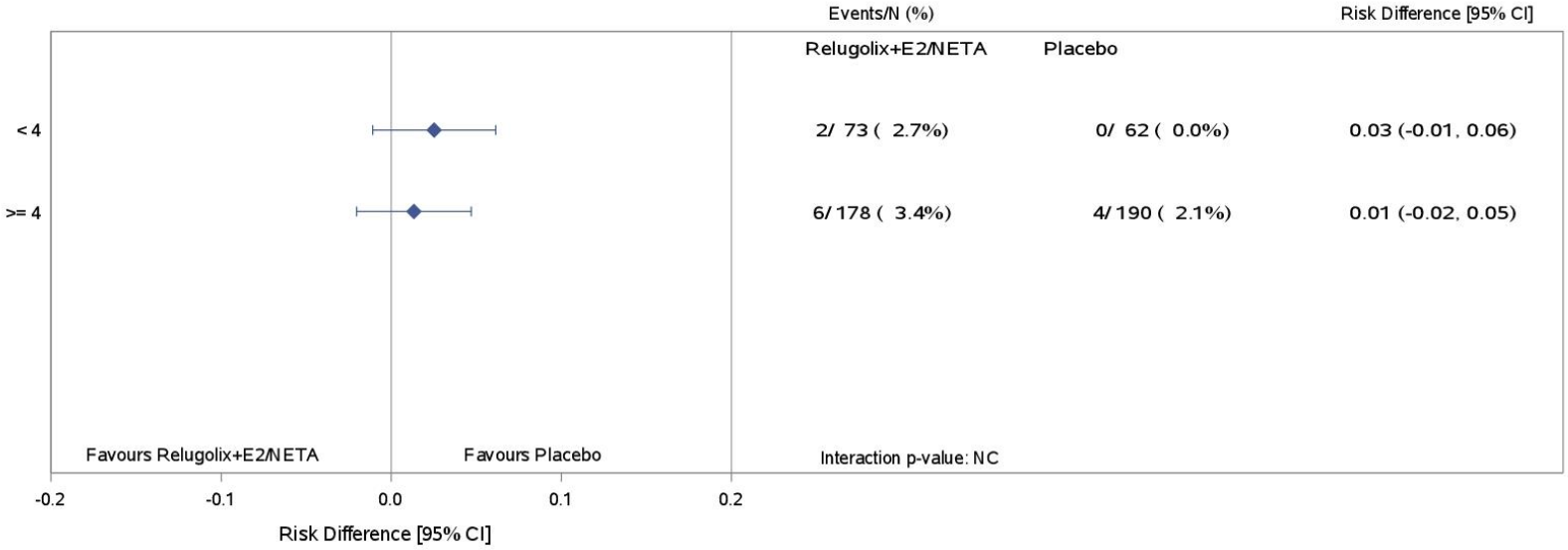
Figure SAF.STEAE.ANY.S4.BIN.FP.RD: Proportion of Patients With at Least One Serious Treatment Emergent Adverse Event, by Subgroup (Safety Population) - Risk Difference
Study: Pooled
Subgroup: Maximum NRS Pain Score at Baseline



Results are based on a Mantel-Haenszel approach stratified by study using a one-stage fixed-effects IPD meta-analysis.
The reference group is Placebo. Patients with multiple events are counted only once. MedDRA (version 22.0).
N: Number of patients in treatment group; NETA: Norethindrone acetate; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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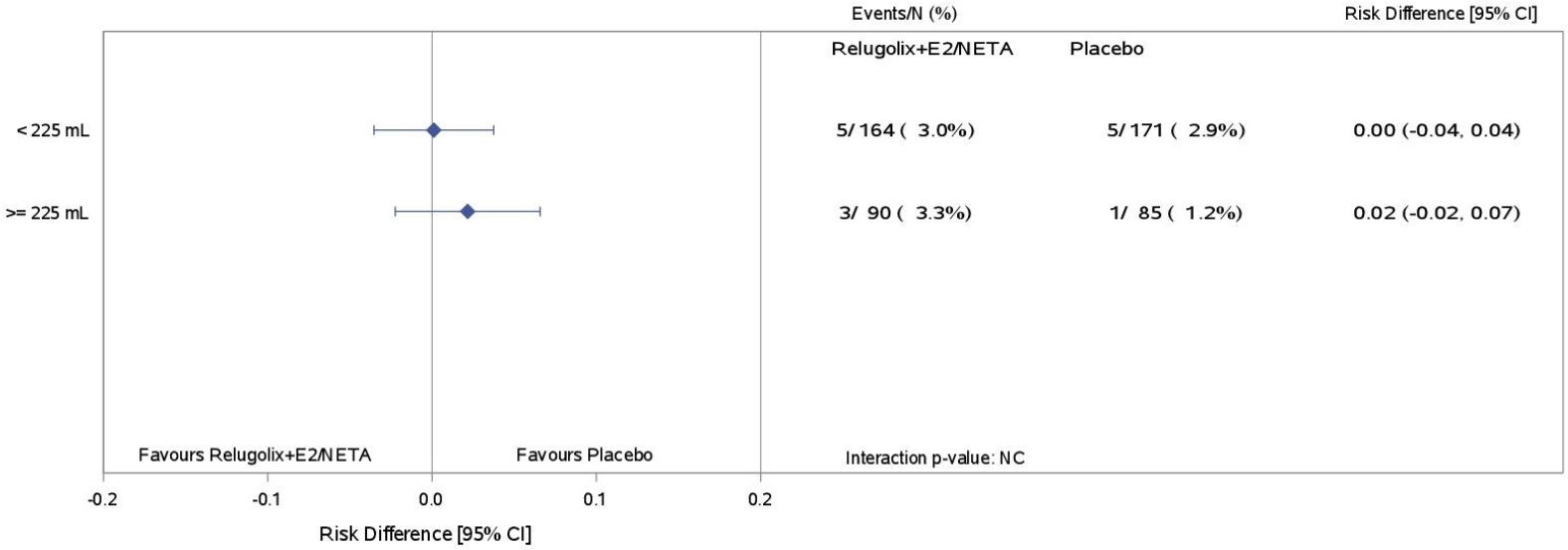
Figure SAF.STEAE.ANY.S5.BIN.FP.RD: Proportion of Patients With at Least One Serious Treatment Emergent Adverse Event, by Subgroup (Safety Population) - Risk Difference
Study: Pooled
Subgroup: MBL Volume at Baseline (mL)



Results are based on a Mantel-Haenszel approach stratified by study using a one-stage fixed-effects IPD meta-analysis.
The reference group is Placebo. Patients with multiple events are counted only once. MedDRA (version 22.0).
N: Number of patients in treatment group; NETA: Norethindrone acetate; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

SOURCE: X:\Numerus\Studies\MYV\MYV102\Analysis\Prod\Progs\TFLs\Fig_SAF_AE_S_BIN_FP.SAS Date/time of run: 01JUL21 10:03
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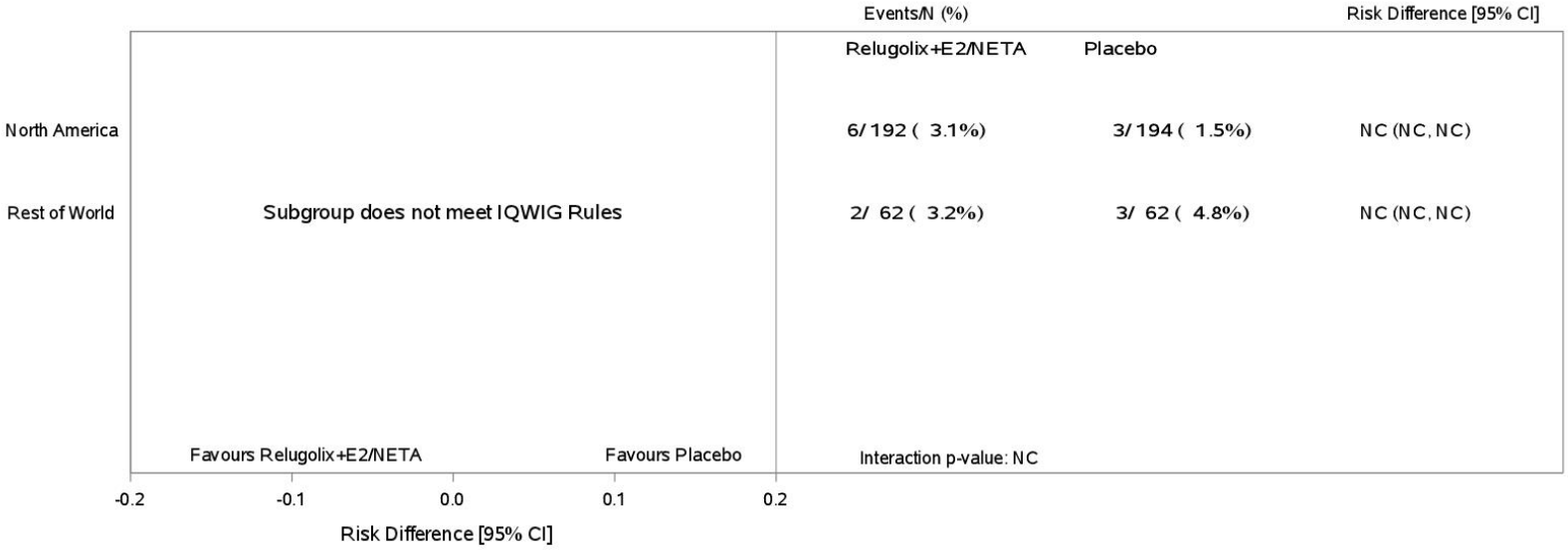
Figure SAF.STEAE.ANY.S6.BIN.FP.RD: Proportion of Patients With at Least One Serious Treatment Emergent Adverse Event, by Subgroup (Safety Population) - Risk Difference
Study: Pooled
Subgroup: Geographic Region I



Results are based on a Mantel-Haenszel approach stratified by study using a one-stage fixed-effects IPD meta-analysis.
The reference group is Placebo. Patients with multiple events are counted only once. MedDRA (version 22.0).
N: Number of patients in treatment group; NETA: Norethindrone acetate; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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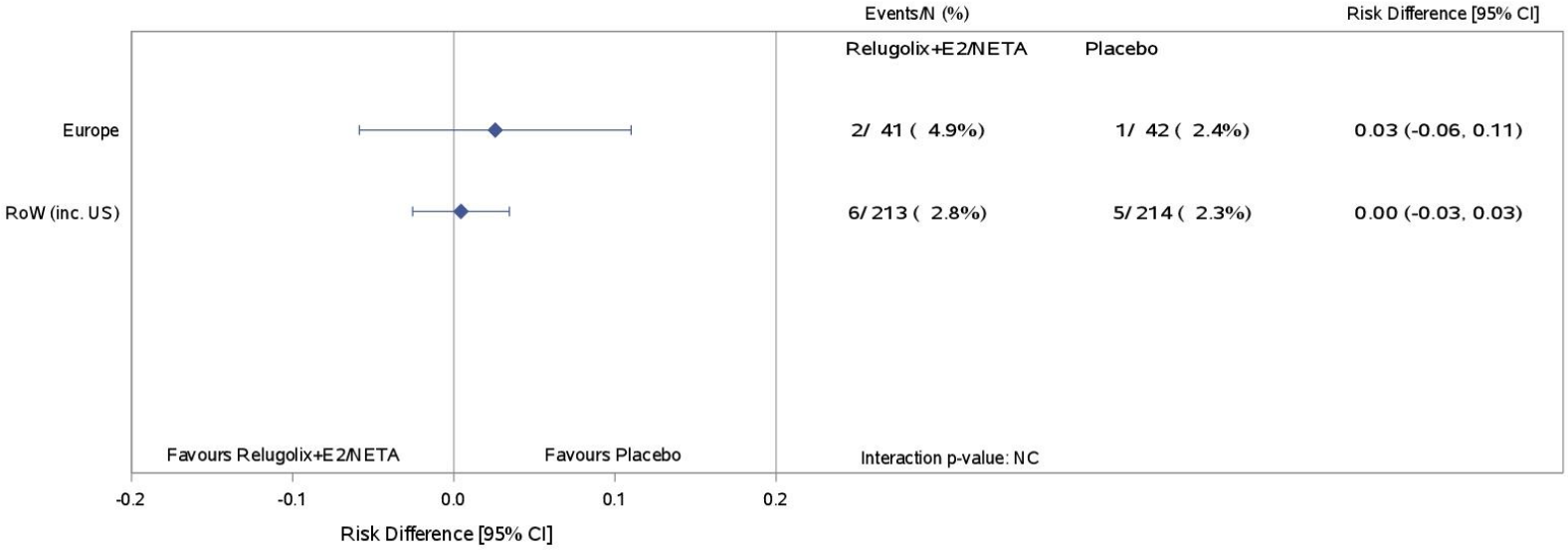
Figure SAF.STEAE.ANY.S7.BIN.FP.RD: Proportion of Patients With at Least One Serious Treatment Emergent Adverse Event, by Subgroup (Safety Population) - Risk Difference
Study: Pooled
Subgroup: Geographic Region II



Results are based on a Mantel-Haenszel approach stratified by study using a one-stage fixed-effects IPD meta-analysis.
The reference group is Placebo. Patients with multiple events are counted only once. MedDRA (version 22.0).
N: Number of patients in treatment group; NETA: Norethindrone acetate; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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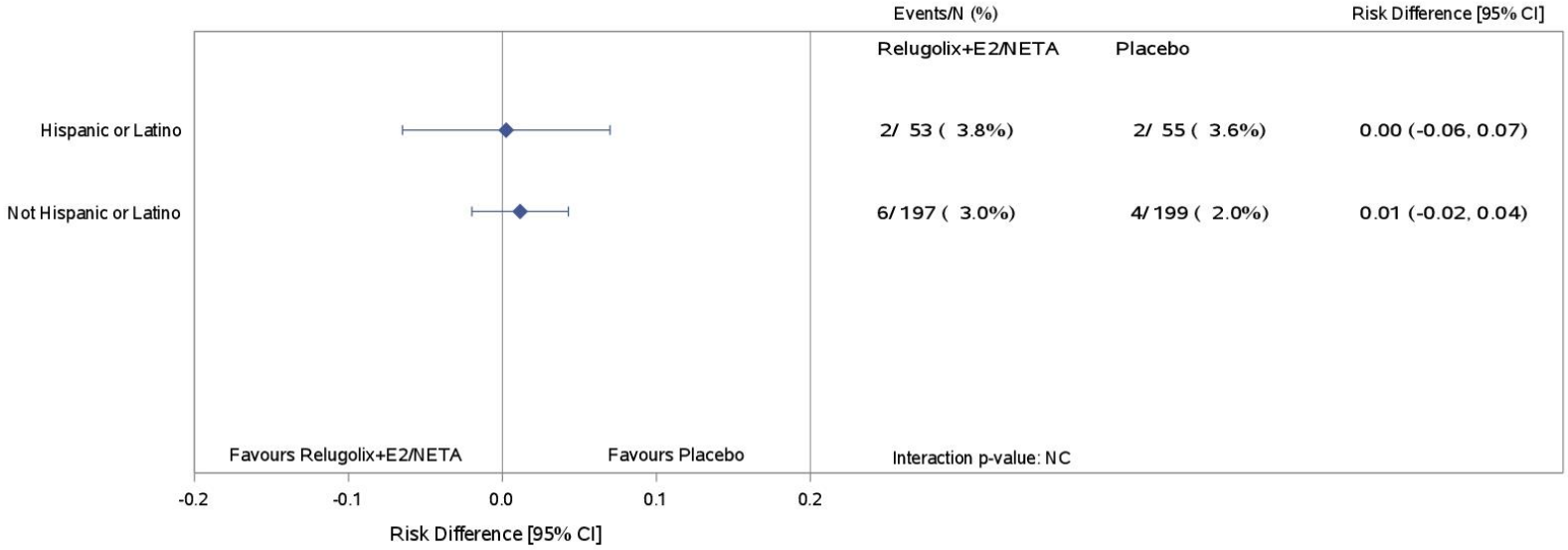
Figure SAF.STEAE.ANY.S8.BIN.FP.RD: Proportion of Patients With at Least One Serious Treatment Emergent Adverse Event, by Subgroup (Safety Population) - Risk Difference
Study: Pooled
Subgroup: Ethnicity



Results are based on a Mantel-Haenszel approach stratified by study using a one-stage fixed-effects IPD meta-analysis.
The reference group is Placebo. Patients with multiple events are counted only once. MedDRA (version 22.0).
N: Number of patients in treatment group; NETA: Norethindrone acetate; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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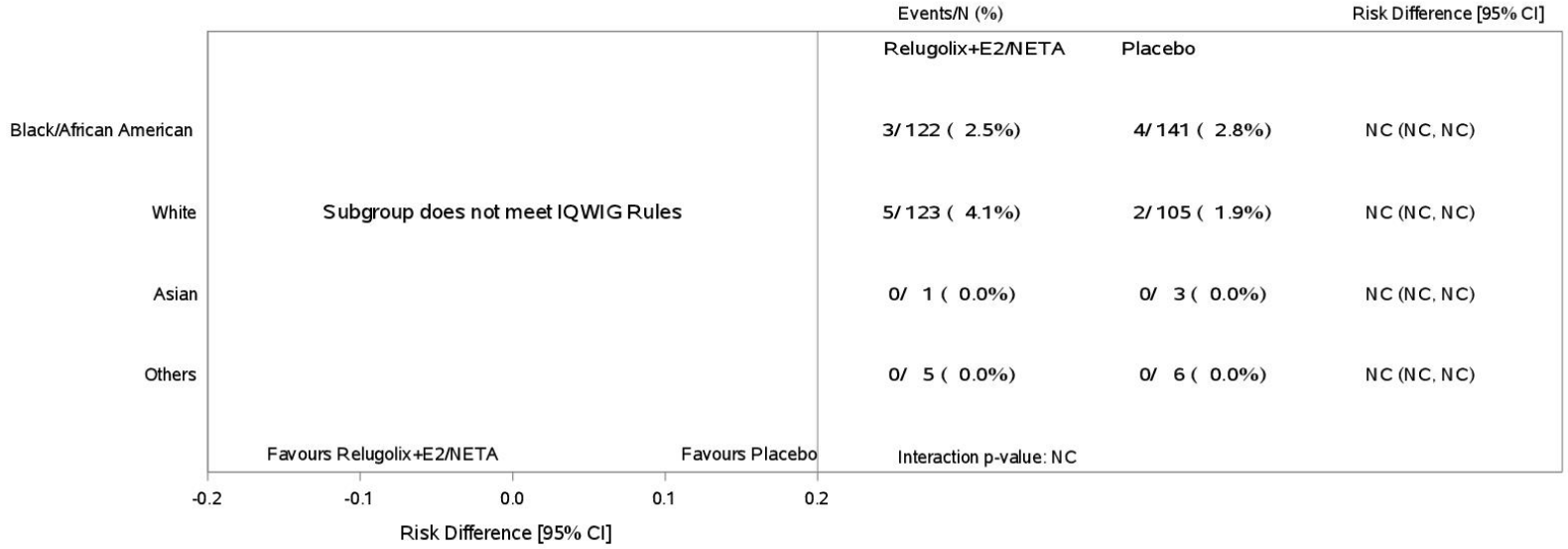
Figure SAF.STEAE.ANY.S9.BIN.FP.RD: Proportion of Patients With at Least One Serious Treatment Emergent Adverse Event, by Subgroup (Safety Population) - Risk Difference
Study: Pooled
Subgroup: Race



Results are based on a Mantel-Haenszel approach stratified by study using a one-stage fixed-effects IPD meta-analysis.
The reference group is Placebo. Patients with multiple events are counted only once. MedDRA (version 22.0).
N: Number of patients in treatment group; NETA: Norethindrone acetate; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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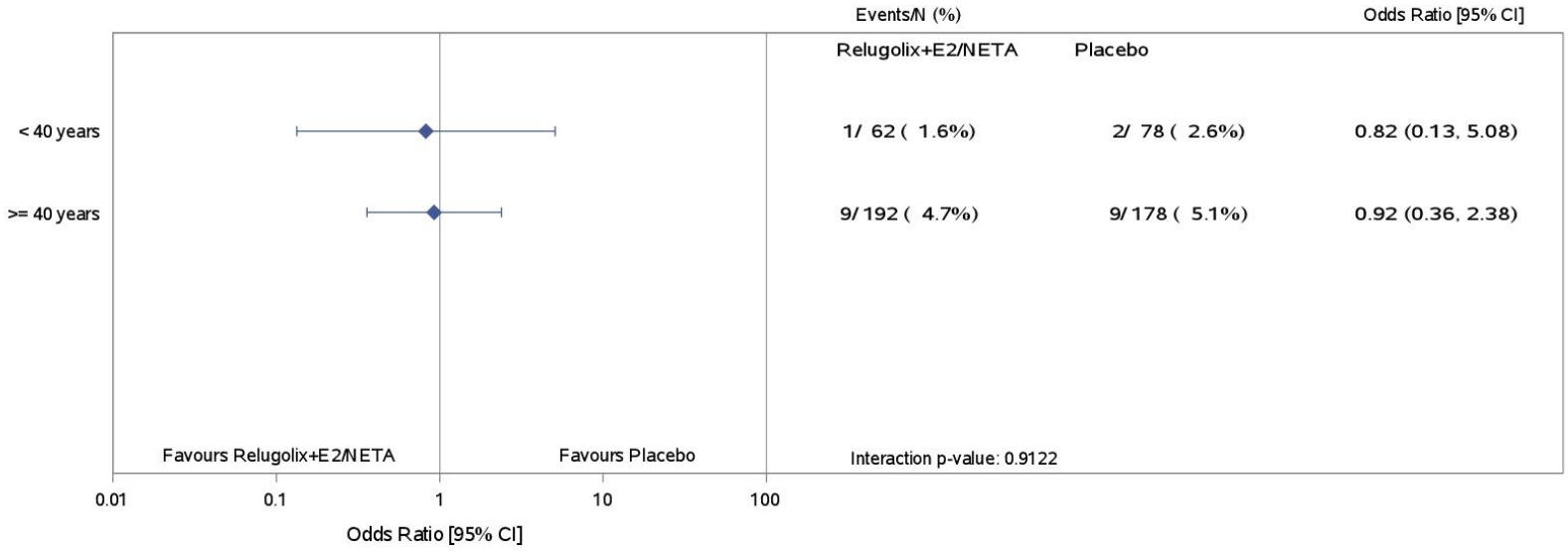
2.3.5 Proportion of Patients With at Least One Treatment Emergent Adverse Event with Action Taken of Study Treatment Discontinuation, by Subgroup (Safety Population)

Nachfolgend sind zunächst alle Forest Plots für das *Odds Ratio* dargestellt; gefolgt von den entsprechenden Forest Plots für *Risk Ratio* und *Risk Difference*.

Figure SAF.TEAED.ANY.S1.BIN.FP: Proportion of Patients With at Least One Treatment Emergent Adverse Event with Action Taken of Study Treatment Discontinuation, by Subgroup (Safety Population)
Study: Pooled
Subgroup: Age (years)



Results are based on a logistic regression model adjusted for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates using a one-stage fixed-effects IPD meta-analysis approach. A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
The interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the Odds Ratio and 95% CI. Missing subgroup levels are not included in estimation of the interaction p-value. The reference group is Placebo. Patients with multiple events are counted only once. MedDRA (version 22.0).
N: Number of patients in treatment group; NETA: Norethindrone acetate; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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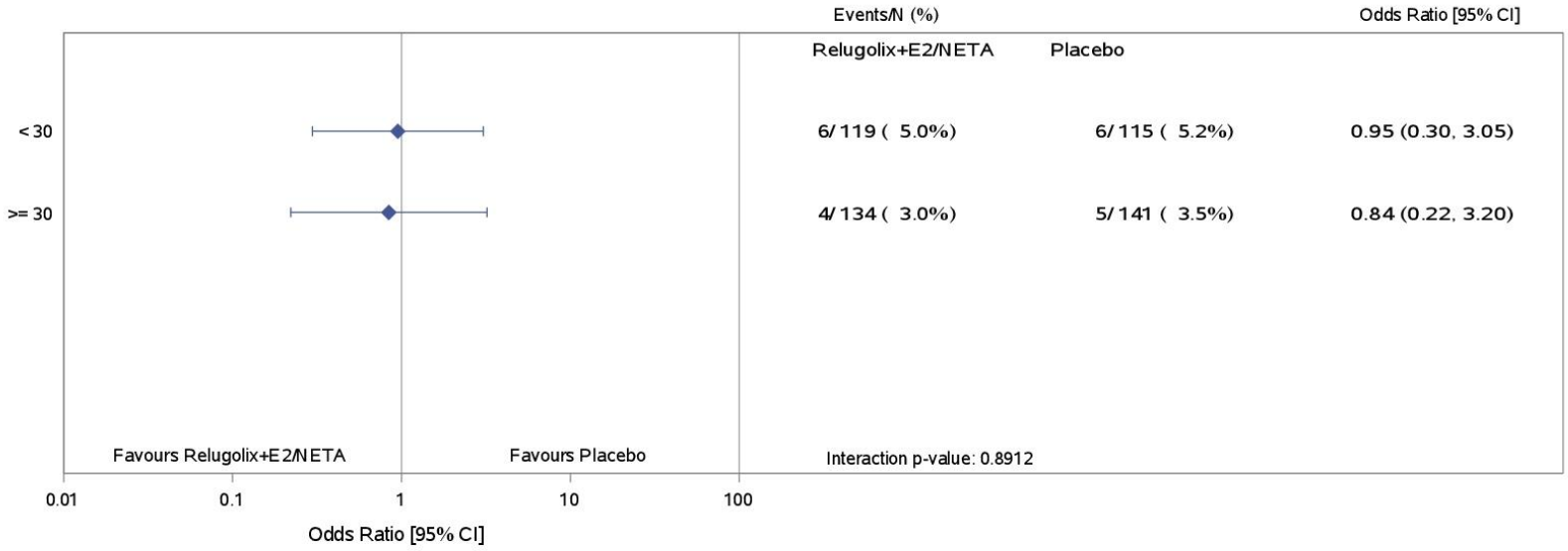
Figure SAF.TEAED.ANY.S2.BIN.FP: Proportion of Patients With at Least One Treatment Emergent Adverse Event with Action Taken of Study Treatment Discontinuation, by Subgroup (Safety Population)
Study: Pooled
Subgroup: BMI (kg/m2) at Baseline



Results are based on a logistic regression model adjusted for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates using a one-stage fixed-effects IPD meta-analysis approach. A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
The interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the Odds Ratio and 95% CI. Missing subgroup levels are not included in estimation of the interaction p-value. The reference group is Placebo. Patients with multiple events are counted only once. MedDRA (version 22.0).
N: Number of patients in treatment group; NETA: Norethindrone acetate; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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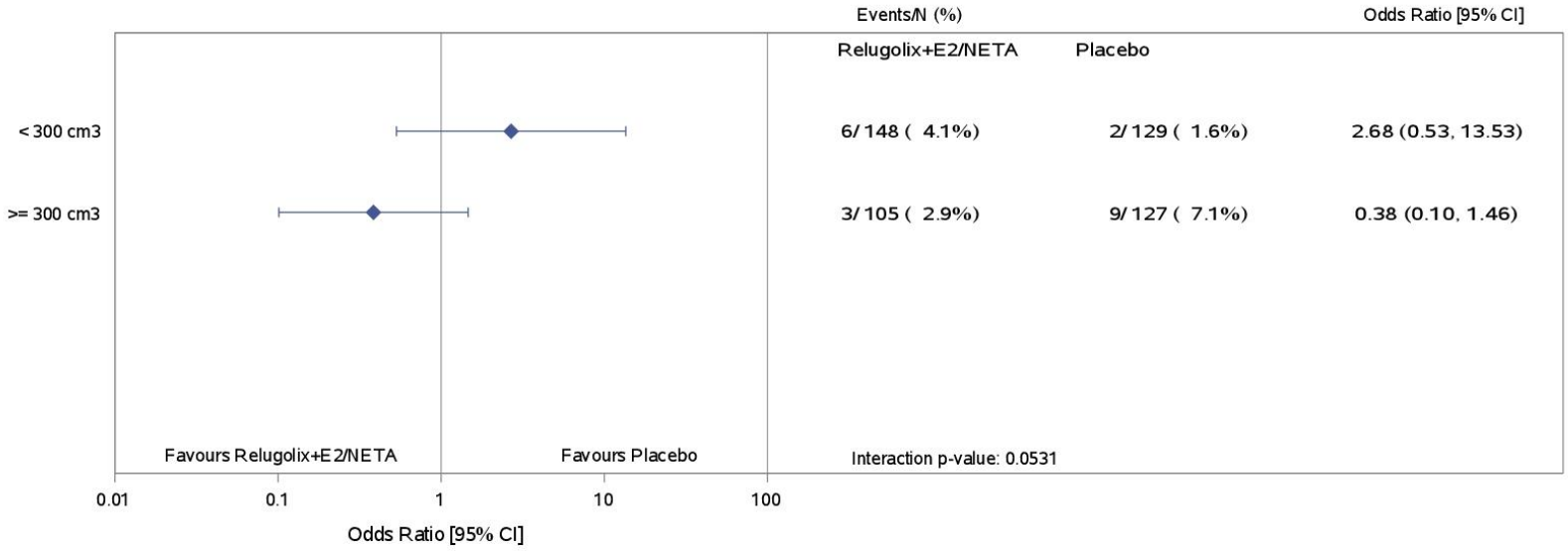
Figure SAF.TEAED.ANY.S3.BIN.FP: Proportion of Patients With at Least One Treatment Emergent Adverse Event with Action Taken of Study Treatment Discontinuation, by Subgroup (Safety Population)
Study: Pooled
Subgroup: Uterine Volume at Baseline (cm3)



Results are based on a logistic regression model adjusted for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates using a one-stage fixed-effects IPD meta-analysis approach. A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
The interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the Odds Ratio and 95% CI. Missing subgroup levels are not included in estimation of the interaction p-value. The reference group is Placebo. Patients with multiple events are counted only once. MedDRA (version 22.0).
N: Number of patients in treatment group; NETA: Norethindrone acetate; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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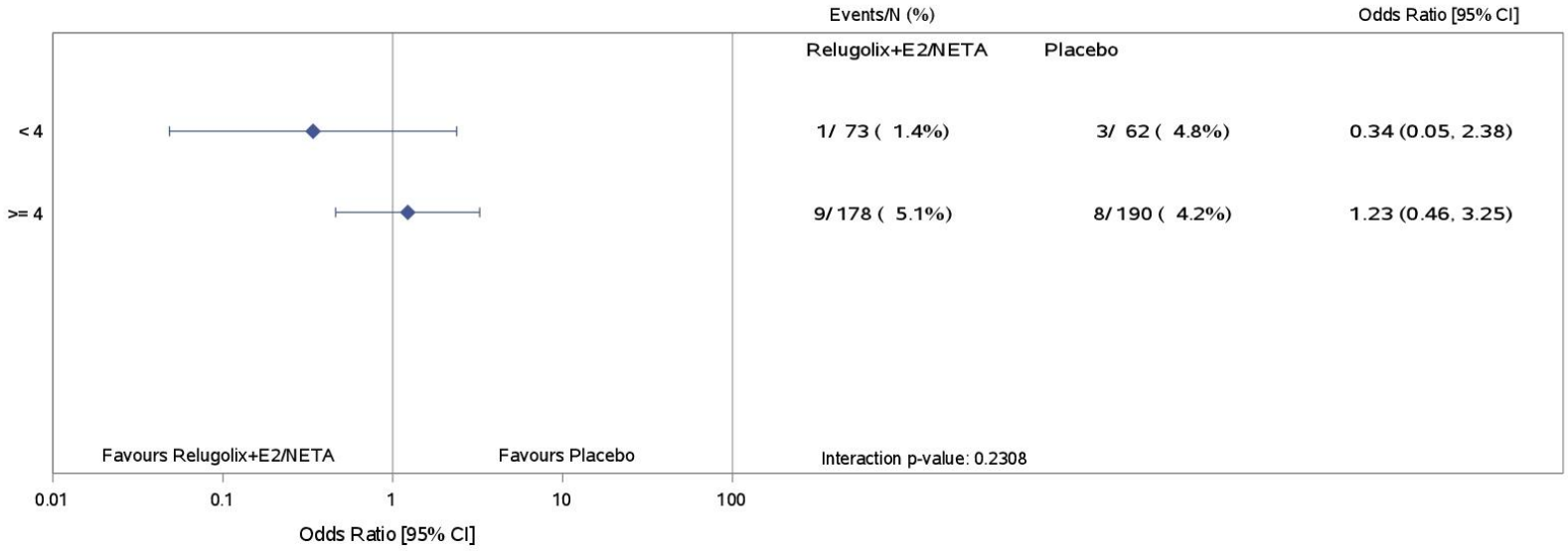
Figure SAF.TEAED.ANY.S4.BIN.FP: Proportion of Patients With at Least One Treatment Emergent Adverse Event with Action Taken of Study Treatment Discontinuation, by Subgroup (Safety Population)
Study: Pooled
Subgroup: Maximum NRS Pain Score at Baseline



Results are based on a logistic regression model adjusted for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates using a one-stage fixed-effects IPD meta-analysis approach. A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
The interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the Odds Ratio and 95% CI. Missing subgroup levels are not included in estimation of the interaction p-value. The reference group is Placebo. Patients with multiple events are counted only once. MedDRA (version 22.0).
N: Number of patients in treatment group; NETA: Norethindrone acetate; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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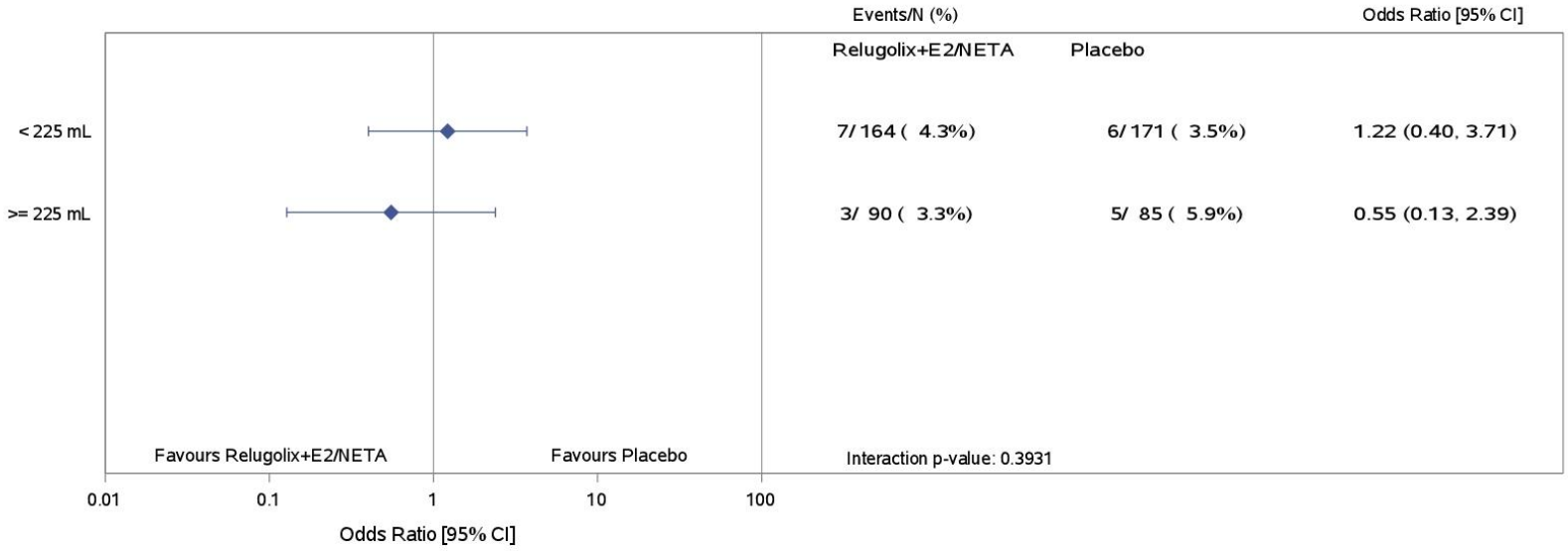
Figure SAF.TEAED.ANY.S5.BIN.FP: Proportion of Patients With at Least One Treatment Emergent Adverse Event with Action Taken of Study Treatment Discontinuation, by Subgroup (Safety Population)
Study: Pooled
Subgroup: MBL Volume at Baseline (mL)



Results are based on a logistic regression model adjusted for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates using a one-stage fixed-effects IPD meta-analysis approach. A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
The interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the Odds Ratio and 95% CI. Missing subgroup levels are not included in estimation of the interaction p-value. The reference group is Placebo. Patients with multiple events are counted only once. MedDRA (version 22.0).
N: Number of patients in treatment group; NETA: Norethindrone acetate; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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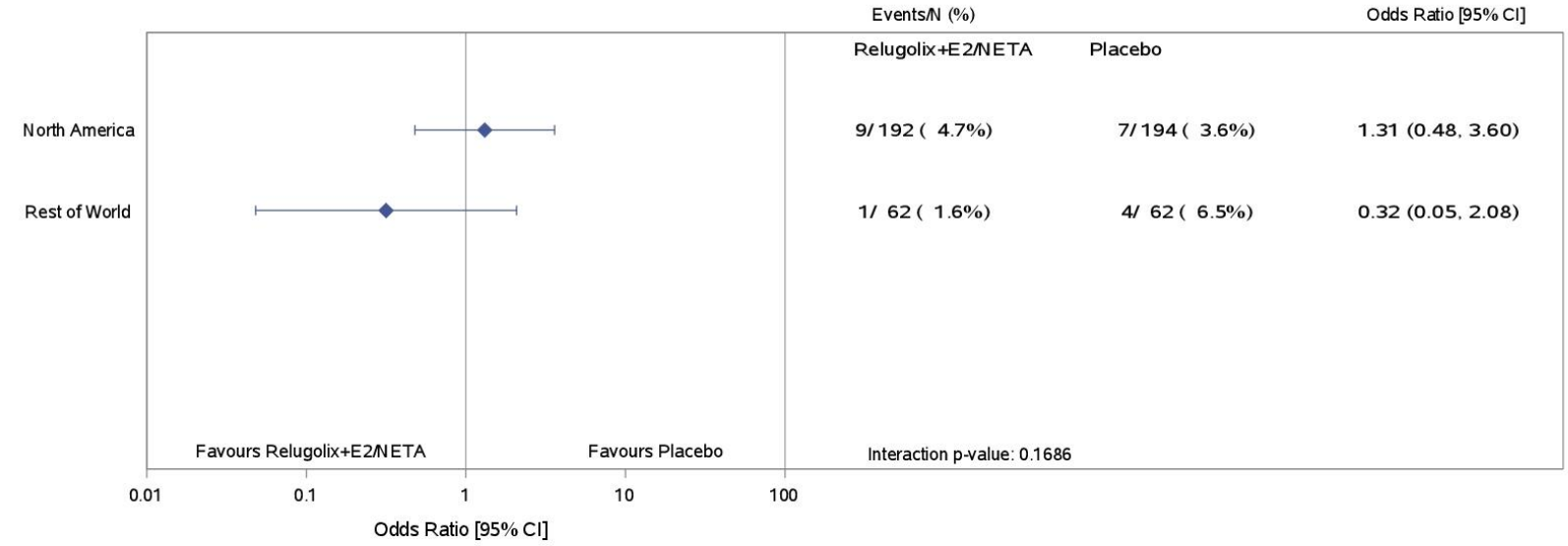
Figure SAF.TEAED.ANY.S6.BIN.FP: Proportion of Patients With at Least One Treatment Emergent Adverse Event with Action Taken of Study Treatment Discontinuation, by Subgroup (Safety Population)
Study: Pooled
Subgroup: Geographic Region I



Results are based on a logistic regression model adjusted for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates using a one-stage fixed-effects IPD meta-analysis approach. A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
The interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the Odds Ratio and 95% CI. Missing subgroup levels are not included in estimation of the interaction p-value. The reference group is Placebo. Patients with multiple events are counted only once. MedDRA (version 22.0).
N: Number of patients in treatment group; NETA: Norethindrone acetate; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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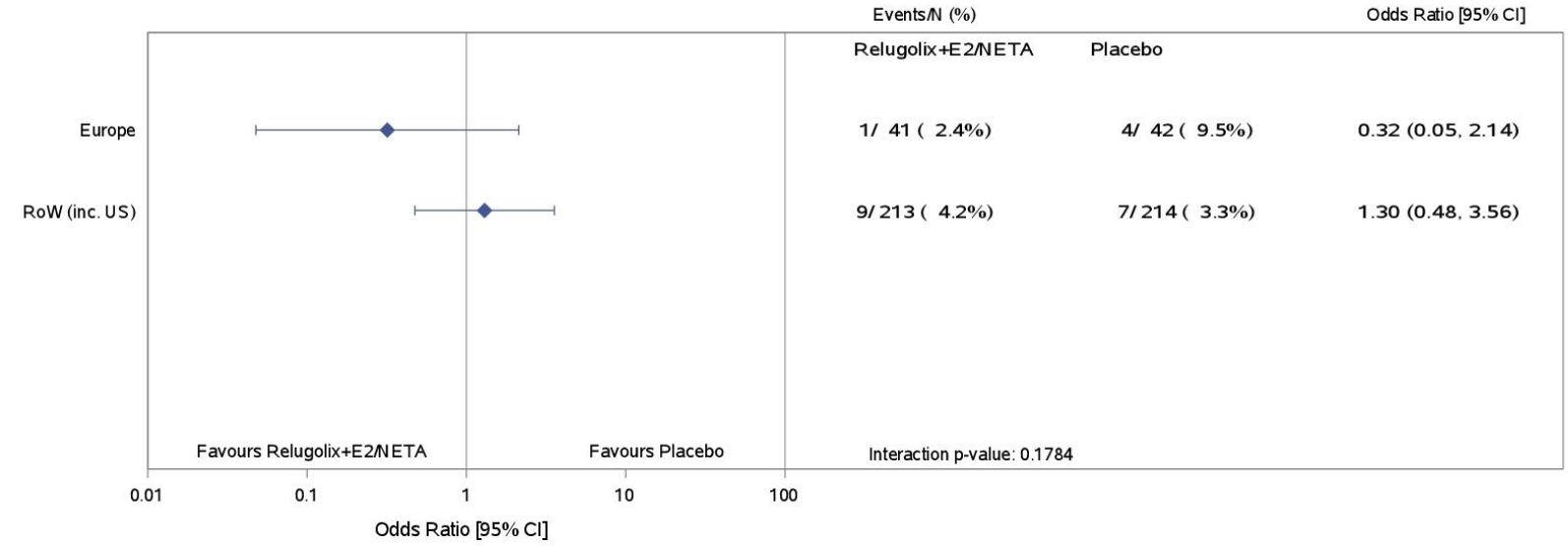
Figure SAF.TEAED.ANY.S7.BIN.FP: Proportion of Patients With at Least One Treatment Emergent Adverse Event with Action Taken of Study Treatment Discontinuation, by Subgroup (Safety Population)
Study: Pooled
Subgroup: Geographic Region II



Results are based on a logistic regression model adjusted for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates using a one-stage fixed-effects IPD meta-analysis approach. A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
The interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the Odds Ratio and 95% CI. Missing subgroup levels are not included in estimation of the interaction p-value. The reference group is Placebo. Patients with multiple events are counted only once. MedDRA (version 22.0).
N: Number of patients in treatment group; NETA: Norethindrone acetate; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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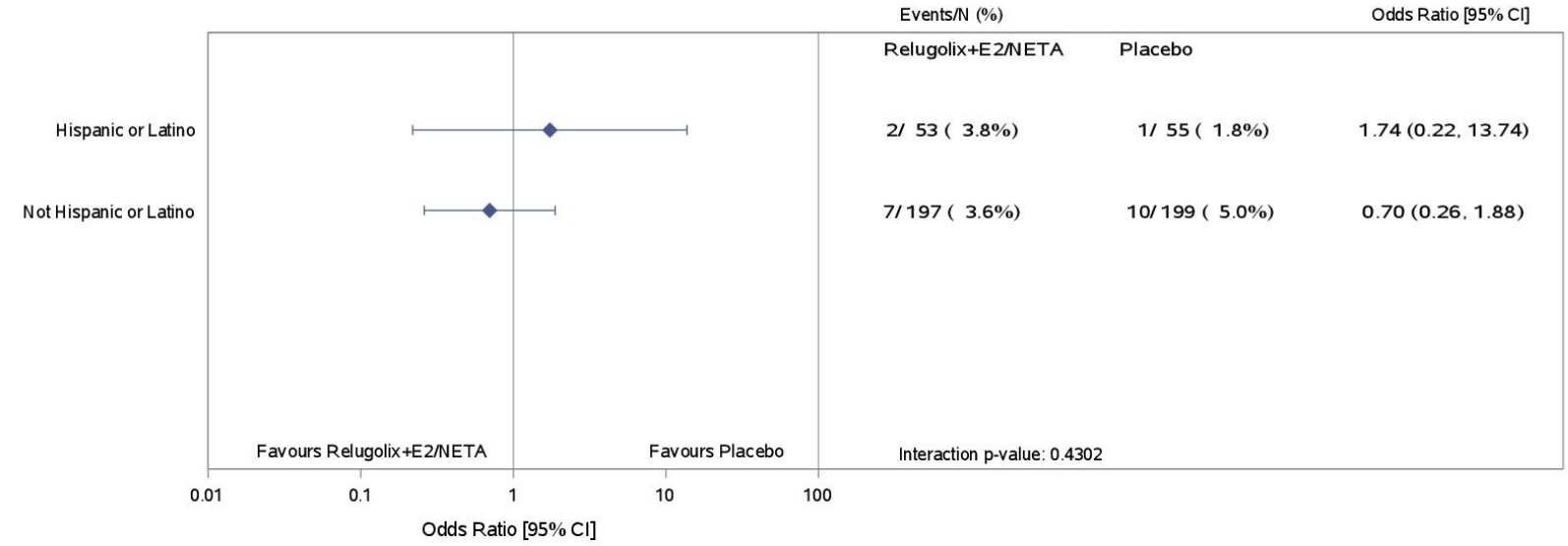
Figure SAF.TEAED.ANY.S8.BIN.FP: Proportion of Patients With at Least One Treatment Emergent Adverse Event with Action Taken of Study Treatment Discontinuation, by Subgroup (Safety Population)
Study: Pooled
Subgroup: Ethnicity



Results are based on a logistic regression model adjusted for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates using a one-stage fixed-effects IPD meta-analysis approach. A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
The interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the Odds Ratio and 95% CI. Missing subgroup levels are not included in estimation of the interaction p-value. The reference group is Placebo. Patients with multiple events are counted only once. MedDRA (version 22.0).
N: Number of patients in treatment group; NETA: Norethindrone acetate; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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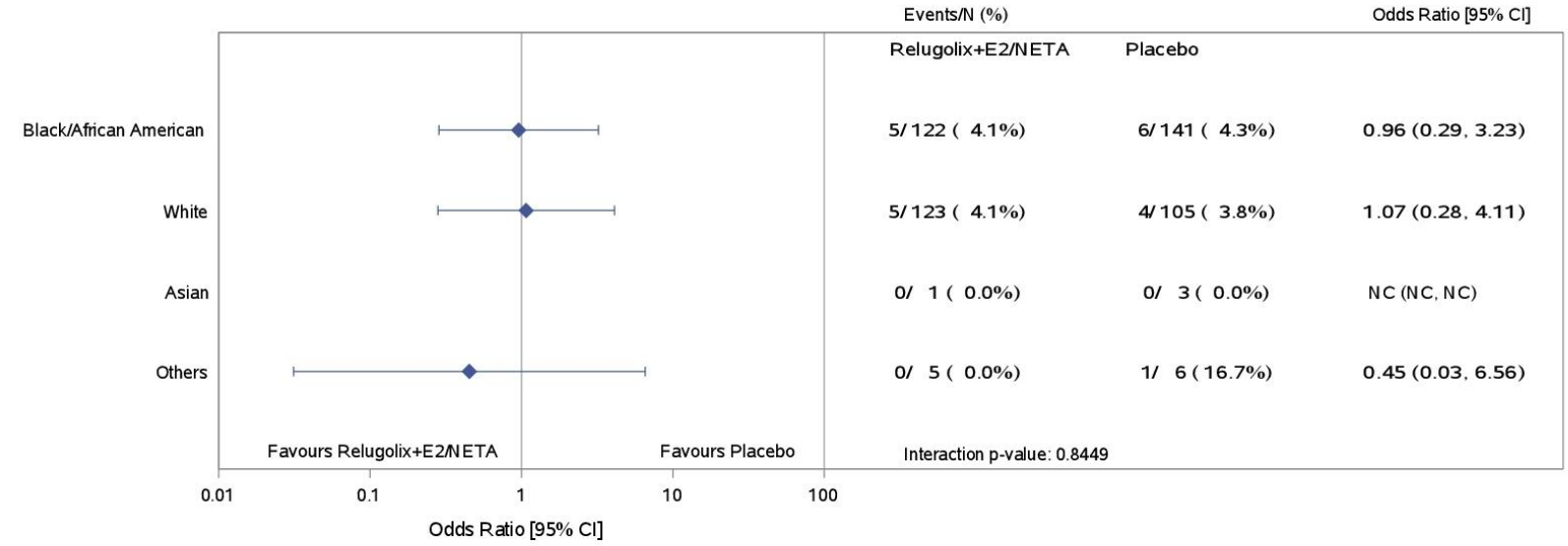
Figure SAF.TEAED.ANY.S9.BIN.FP: Proportion of Patients With at Least One Treatment Emergent Adverse Event with Action Taken of Study Treatment Discontinuation, by Subgroup (Safety Population)
Study: Pooled
Subgroup: Race



Results are based on a logistic regression model adjusted for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates using a one-stage fixed-effects IPD meta-analysis approach. A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
The interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the Odds Ratio and 95% CI. Missing subgroup levels are not included in estimation of the interaction p-value. The reference group is Placebo. Patients with multiple events are counted only once. MedDRA (version 22.0).
N: Number of patients in treatment group; NETA: Norethindrone acetate; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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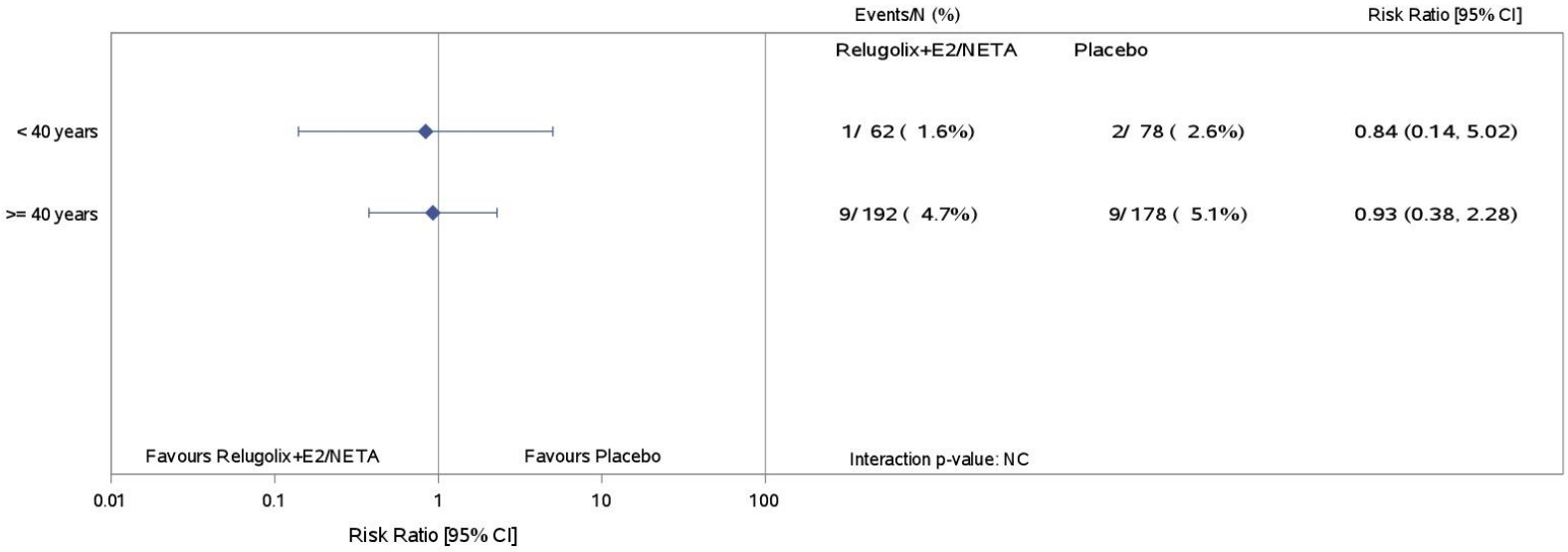
Figure SAF.TEAED.ANY.S1.BIN.FP.RR: Proportion of Patients With at Least One Treatment Emergent Adverse Event with Action Taken of Study Treatment Discontinuation, by Subgroup (Safety Population) - Risk Ratio
Study: Pooled
Subgroup: Age (years)



Results are based on a Cochran-Mantel-Haenszel approach stratified by study using a one-stage fixed-effects IPD meta-analysis. A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
The reference group is Placebo. Patients with multiple events are counted only once. MedDRA (version 22.0).
N: Number of patients in treatment group; NETA: Norethindrone acetate; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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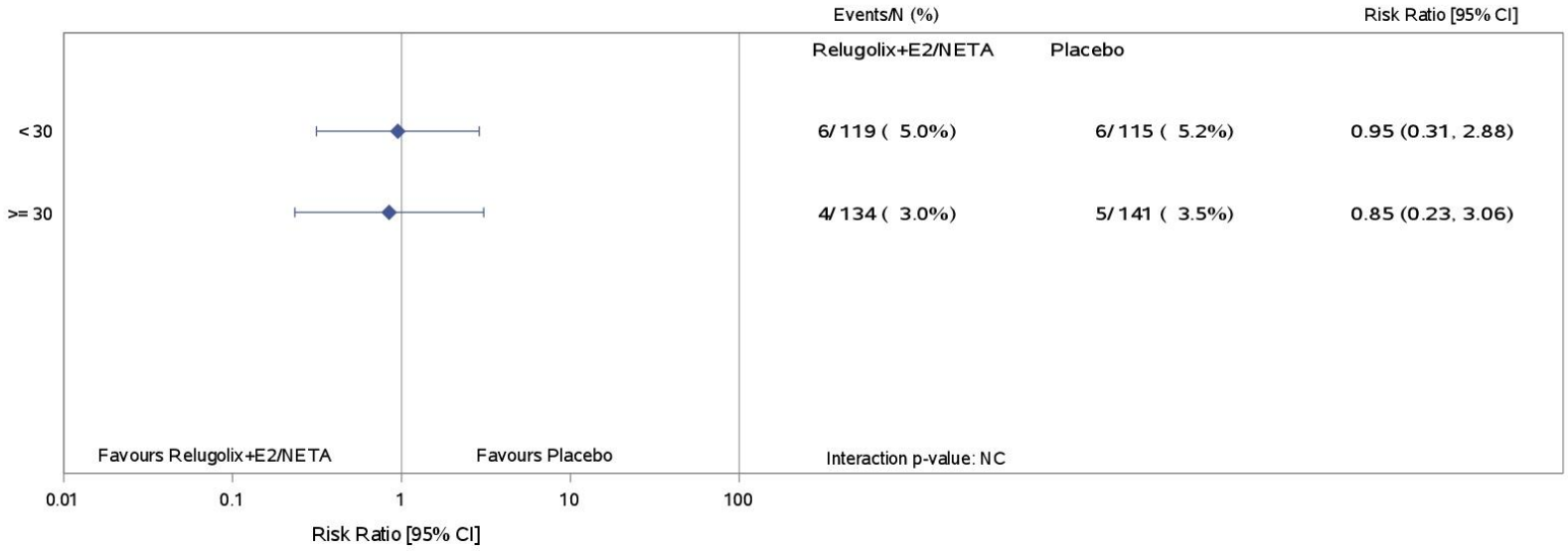
Figure SAF.TEAED.ANY.S2.BIN.FP.RR: Proportion of Patients With at Least One Treatment Emergent Adverse Event with Action Taken of Study Treatment Discontinuation, by Subgroup (Safety Population) - Risk Ratio
Study: Pooled
Subgroup: BMI (kg/m2) at Baseline



Results are based on a Cochran-Mantel-Haenszel approach stratified by study using a one-stage fixed-effects IPD meta-analysis. A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
The reference group is Placebo. Patients with multiple events are counted only once. MedDRA (version 22.0).
N: Number of patients in treatment group; NETA: Norethindrone acetate; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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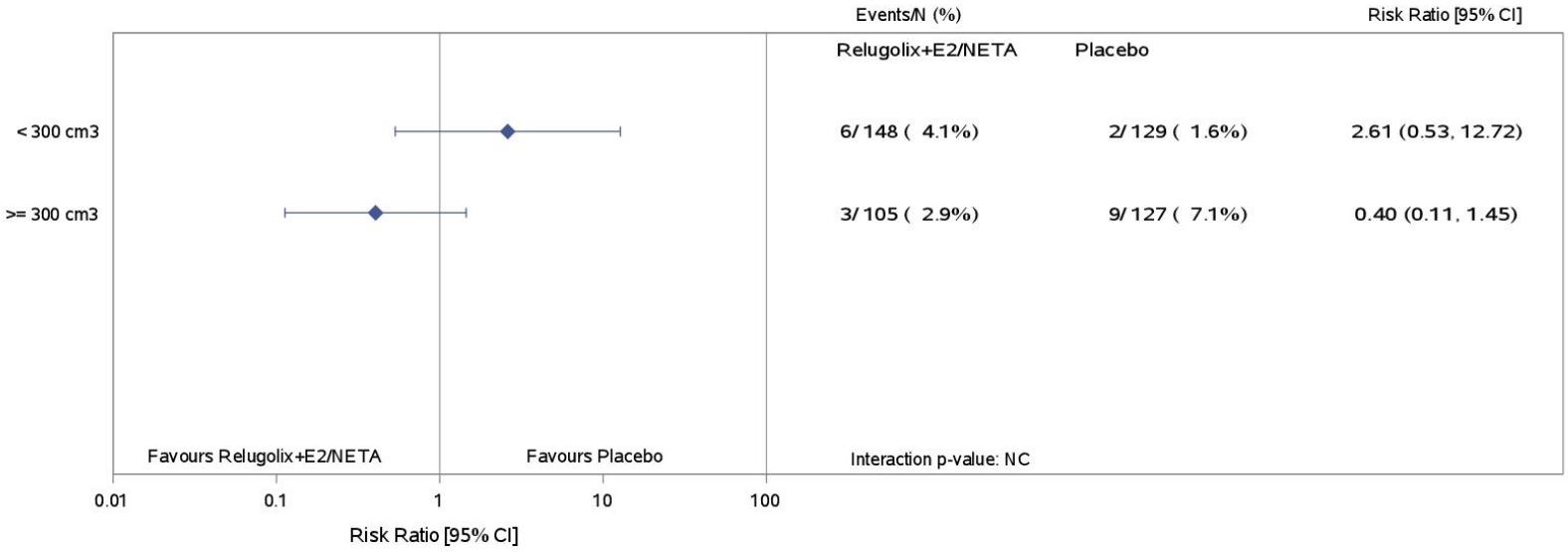
Figure SAF.TEAED.ANY.S3.BIN.FP.RR: Proportion of Patients With at Least One Treatment Emergent Adverse Event with Action Taken of Study Treatment Discontinuation, by Subgroup (Safety Population) - Risk Ratio
Study: Pooled
Subgroup: Uterine Volume at Baseline (cm3)



Results are based on a Cochran-Mantel-Haenszel approach stratified by study using a one-stage fixed-effects IPD meta-analysis. A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
The reference group is Placebo. Patients with multiple events are counted only once. MedDRA (version 22.0).
N: Number of patients in treatment group; NETA: Norethindrone acetate; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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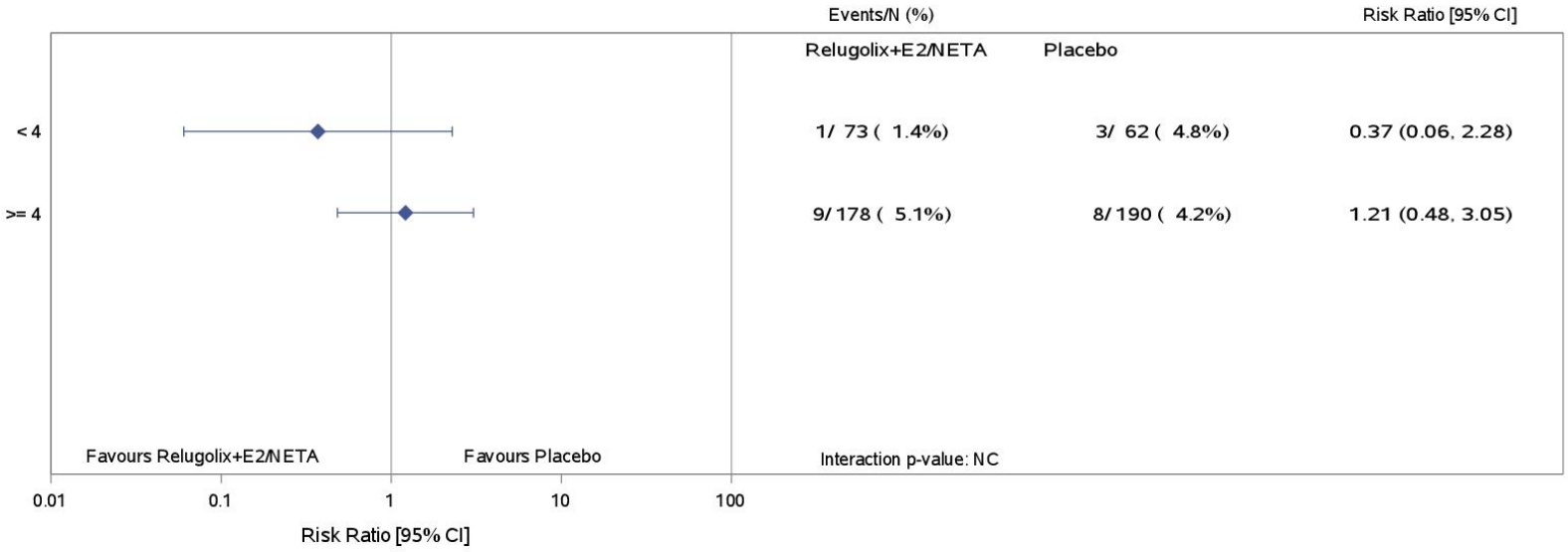
Figure SAF.TEAED.ANY.S4.BIN.FP.RR: Proportion of Patients With at Least One Treatment Emergent Adverse Event with Action Taken of Study Treatment Discontinuation, by Subgroup (Safety Population) - Risk Ratio
Study: Pooled
Subgroup: Maximum NRS Pain Score at Baseline



Results are based on a Cochran-Mantel-Haenszel approach stratified by study using a one-stage fixed-effects IPD meta-analysis. A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
The reference group is Placebo. Patients with multiple events are counted only once. MedDRA (version 22.0).
N: Number of patients in treatment group; NETA: Norethindrone acetate; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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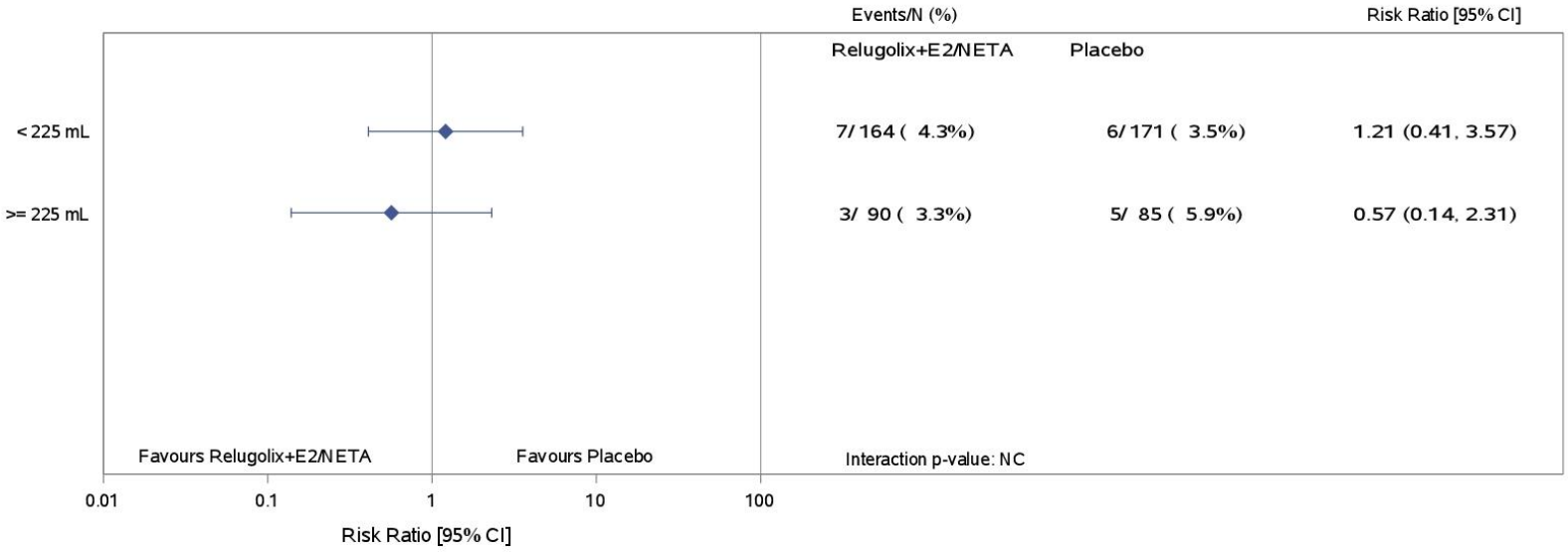
Figure SAF.TEAED.ANY.S5.BIN.FP.RR: Proportion of Patients With at Least One Treatment Emergent Adverse Event with Action Taken of Study Treatment Discontinuation, by Subgroup (Safety Population) - Risk Ratio
Study: Pooled
Subgroup: MBL Volume at Baseline (mL)



Results are based on a Cochran-Mantel-Haenszel approach stratified by study using a one-stage fixed-effects IPD meta-analysis. A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
The reference group is Placebo. Patients with multiple events are counted only once. MedDRA (version 22.0).
N: Number of patients in treatment group; NETA: Norethindrone acetate; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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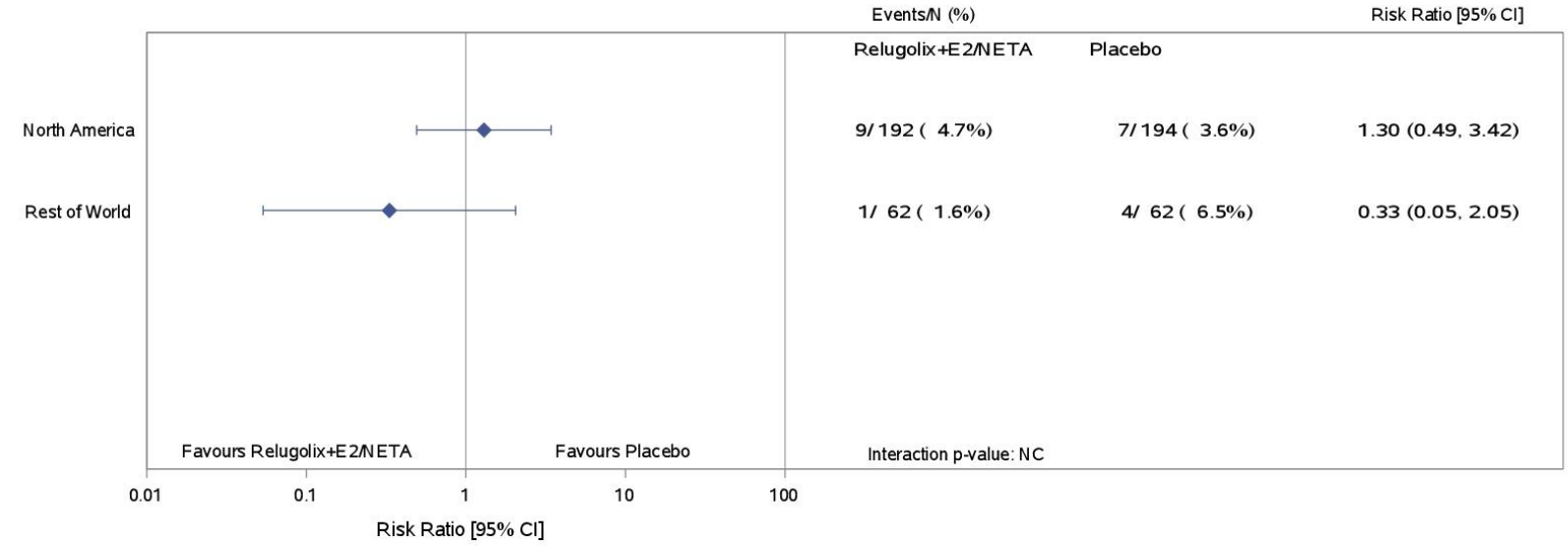
Figure SAF.TEAED.ANY.S6.BIN.FP.RR: Proportion of Patients With at Least One Treatment Emergent Adverse Event with Action Taken of Study Treatment Discontinuation, by Subgroup (Safety Population) - Risk Ratio
Study: Pooled
Subgroup: Geographic Region I



Results are based on a Cochran-Mantel-Haenszel approach stratified by study using a one-stage fixed-effects IPD meta-analysis. A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
The reference group is Placebo. Patients with multiple events are counted only once. MedDRA (version 22.0).
N: Number of patients in treatment group; NETA: Norethindrone acetate; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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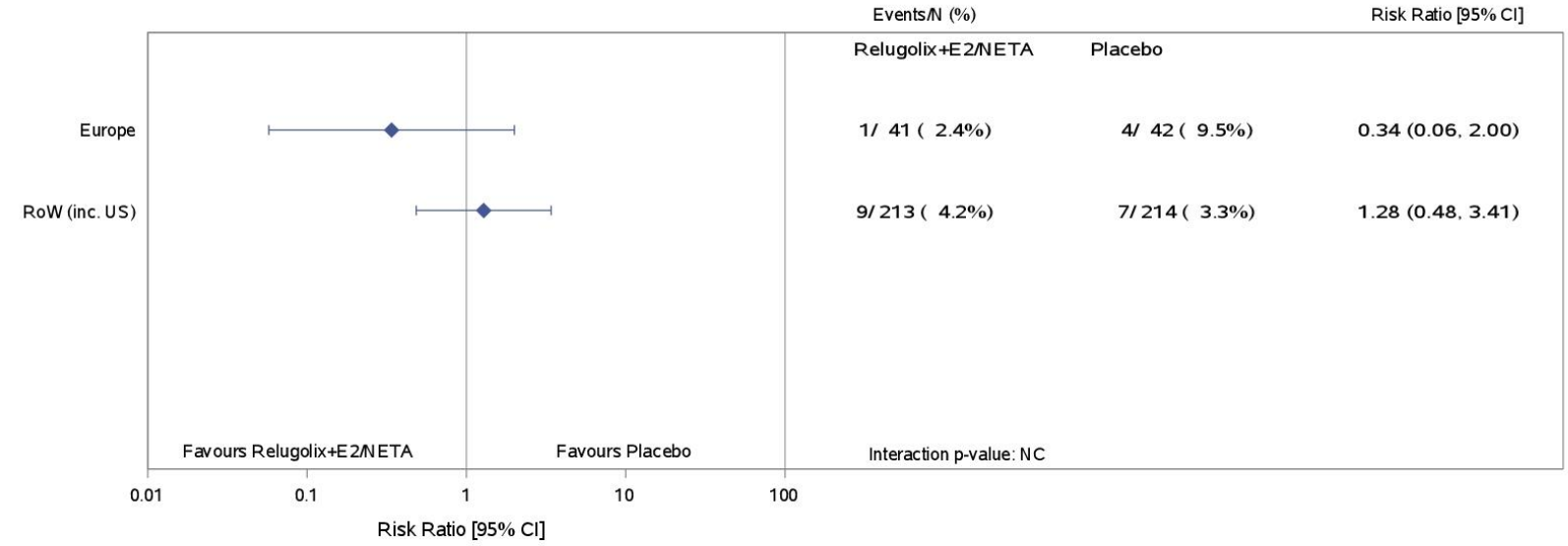
Figure SAF.TEAED.ANY.S7.BIN.FP.RR: Proportion of Patients With at Least One Treatment Emergent Adverse Event with Action Taken of Study Treatment Discontinuation, by Subgroup (Safety Population) - Risk Ratio
Study: Pooled
Subgroup: Geographic Region II



Results are based on a Cochran-Mantel-Haenszel approach stratified by study using a one-stage fixed-effects IPD meta-analysis. A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
The reference group is Placebo. Patients with multiple events are counted only once. MedDRA (version 22.0).
N: Number of patients in treatment group; NETA: Norethindrone acetate; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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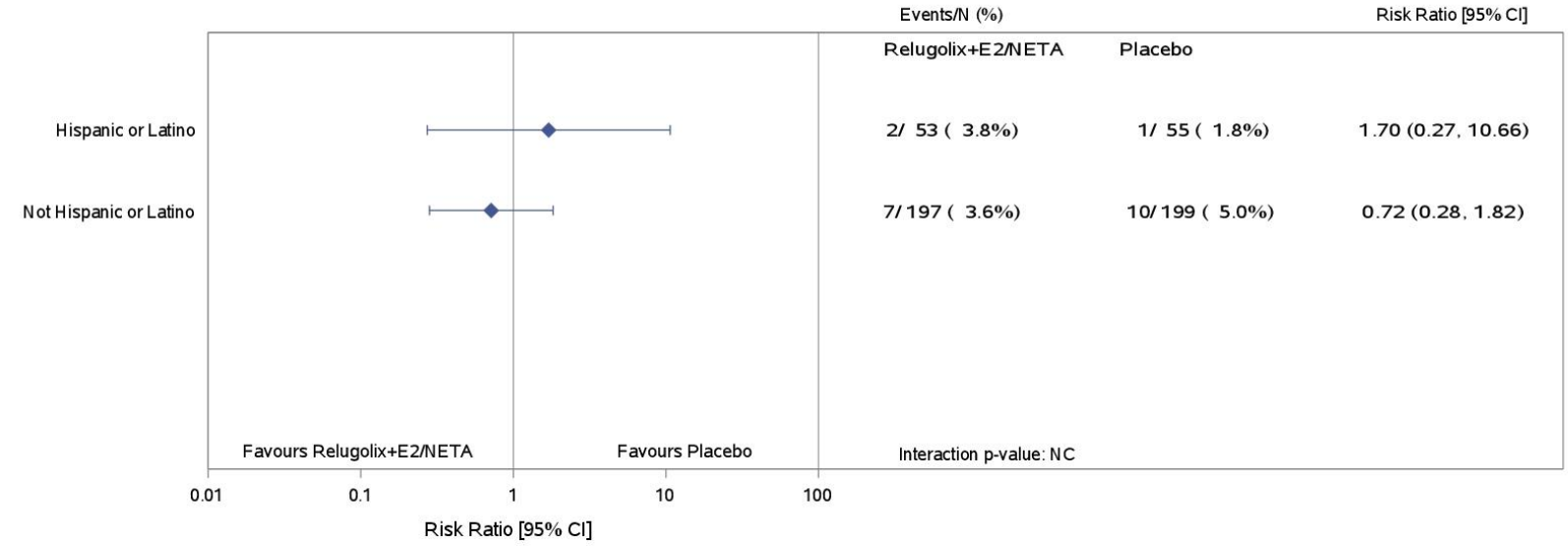
Figure SAF.TEAED.ANY.S8.BIN.FP.RR: Proportion of Patients With at Least One Treatment Emergent Adverse Event with Action Taken of Study Treatment Discontinuation, by Subgroup (Safety Population) - Risk Ratio
Study: Pooled
Subgroup: Ethnicity



Results are based on a Cochran-Mantel-Haenszel approach stratified by study using a one-stage fixed-effects IPD meta-analysis. A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
The reference group is Placebo. Patients with multiple events are counted only once. MedDRA (version 22.0).
N: Number of patients in treatment group; NETA: Norethindrone acetate; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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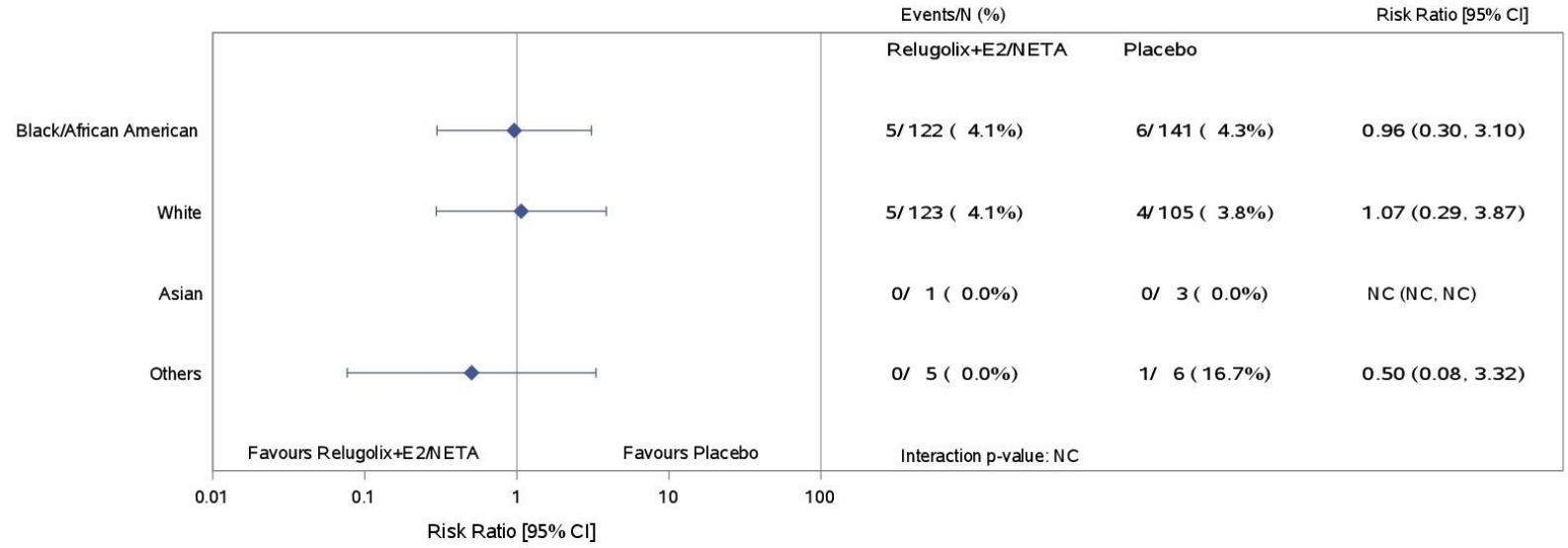
Figure SAF.TEAED.ANY.S9.BIN.FP.RR: Proportion of Patients With at Least One Treatment Emergent Adverse Event with Action Taken of Study Treatment Discontinuation, by Subgroup (Safety Population) - Risk Ratio
Study: Pooled
Subgroup: Race



Results are based on a Cochran-Mantel-Haenszel approach stratified by study using a one-stage fixed-effects IPD meta-analysis. A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
The reference group is Placebo. Patients with multiple events are counted only once. MedDRA (version 22.0).
N: Number of patients in treatment group; NETA: Norethindrone acetate; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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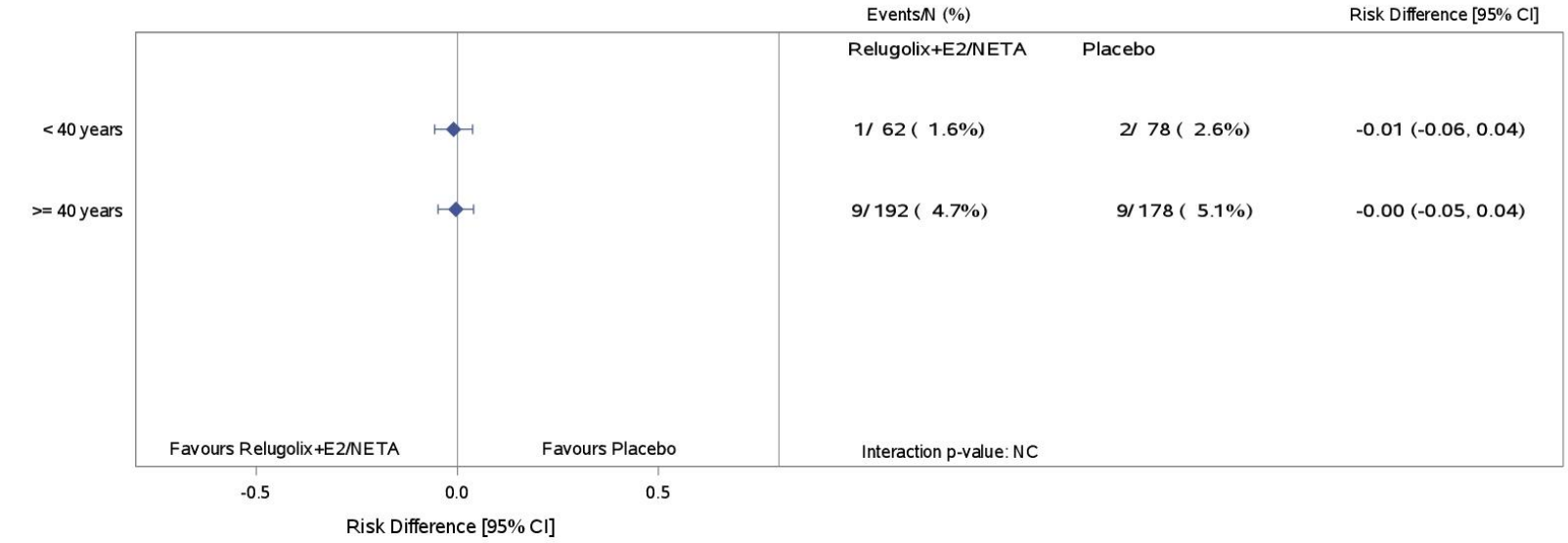
Figure SAF.TEAED.ANY.S1.BIN.FP.RD: Proportion of Patients With at Least One Treatment Emergent Adverse Event with Action Taken of Study Treatment Discontinuation, by Subgroup (Safety Population) - Risk Difference
Study: Pooled
Subgroup: Age (years)



Results are based on a Mantel-Haenszel approach stratified by study using a one-stage fixed-effects IPD meta-analysis.
The reference group is Placebo. Patients with multiple events are counted only once. MedDRA (version 22.0).
N: Number of patients in treatment group; NETA: Norethindrone acetate; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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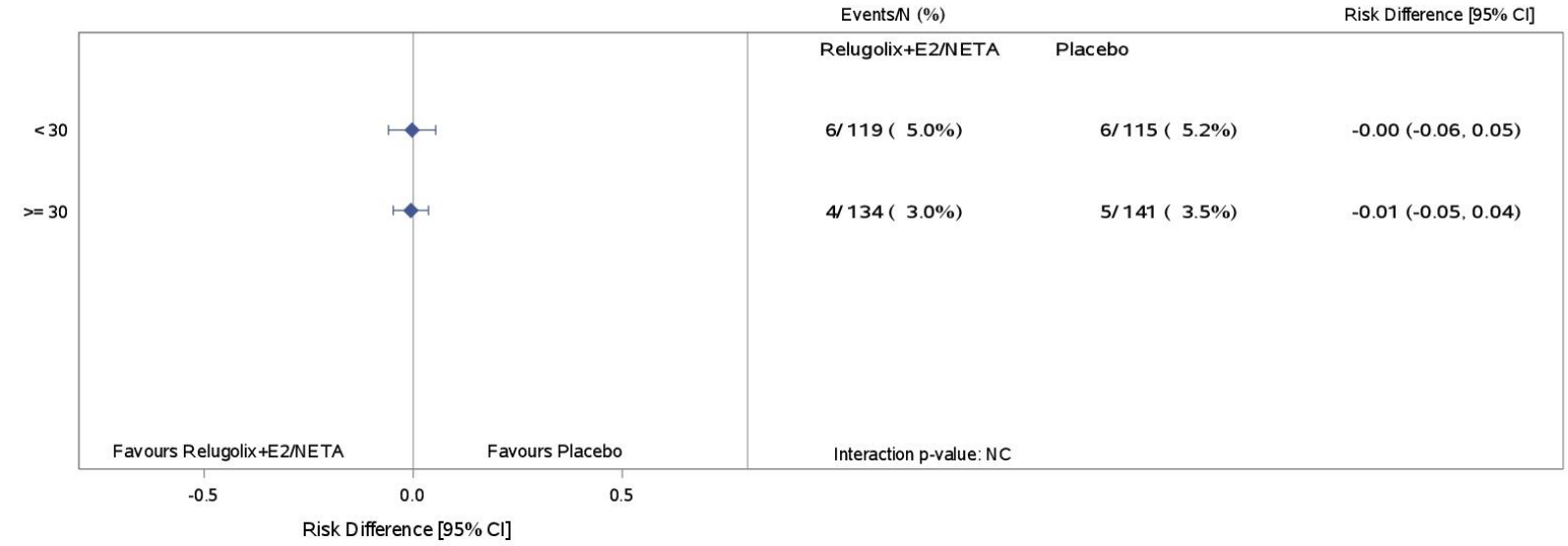
Figure SAF.TEAED.ANY.S2.BIN.FP.RD: Proportion of Patients With at Least One Treatment Emergent Adverse Event with Action Taken of Study Treatment Discontinuation, by Subgroup (Safety Population) - Risk Difference
Study: Pooled
Subgroup: BMI (kg/m2) at Baseline



Results are based on a Mantel-Haenszel approach stratified by study using a one-stage fixed-effects IPD meta-analysis.
The reference group is Placebo. Patients with multiple events are counted only once. MedDRA (version 22.0).
N: Number of patients in treatment group; NETA: Norethindrone acetate; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

SOURCE: X:\Numerus\Studies\MYV\MYV102\Analysis\Prod\Progs\TFLs\Fig_SAF_AE_S_BIN_FP.SAS Date/time of run: 01JUL21 10:03
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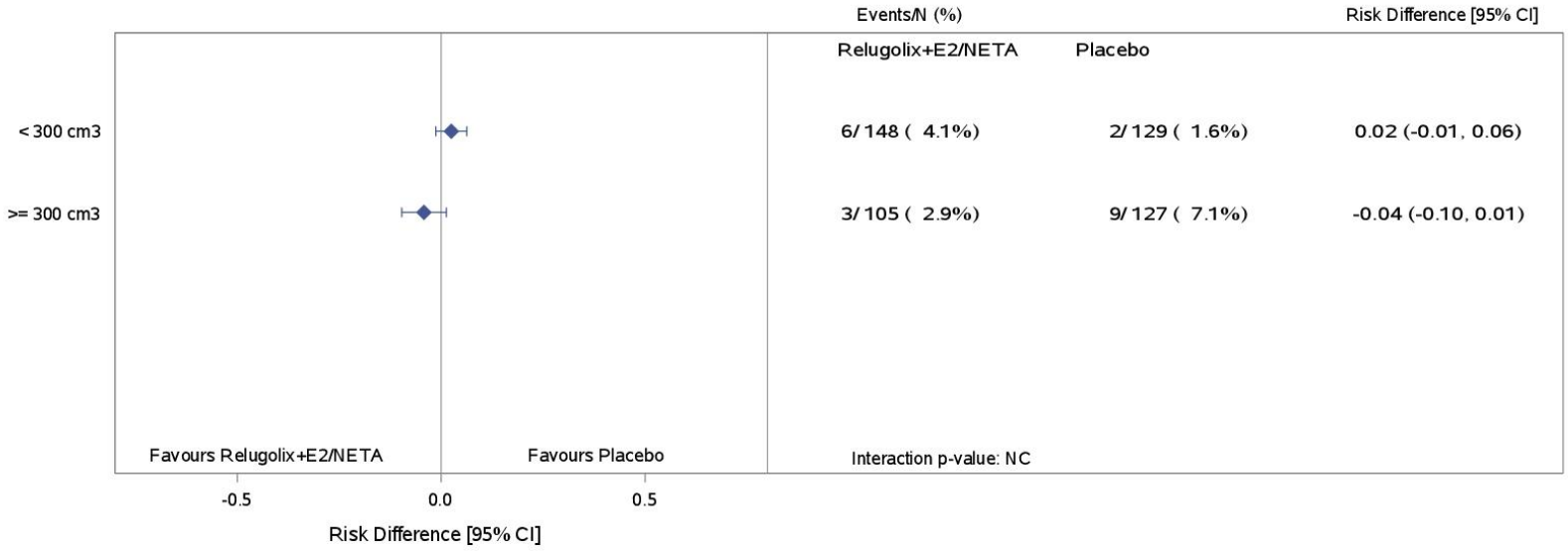
Figure SAF.TEAED.ANY.S3.BIN.FP.RD: Proportion of Patients With at Least One Treatment Emergent Adverse Event with Action Taken of Study Treatment Discontinuation, by Subgroup (Safety Population) - Risk Difference
Study: Pooled
Subgroup: Uterine Volume at Baseline (cm3)



Results are based on a Mantel-Haenszel approach stratified by study using a one-stage fixed-effects IPD meta-analysis.
The reference group is Placebo. Patients with multiple events are counted only once. MedDRA (version 22.0).
N: Number of patients in treatment group; NETA: Norethindrone acetate; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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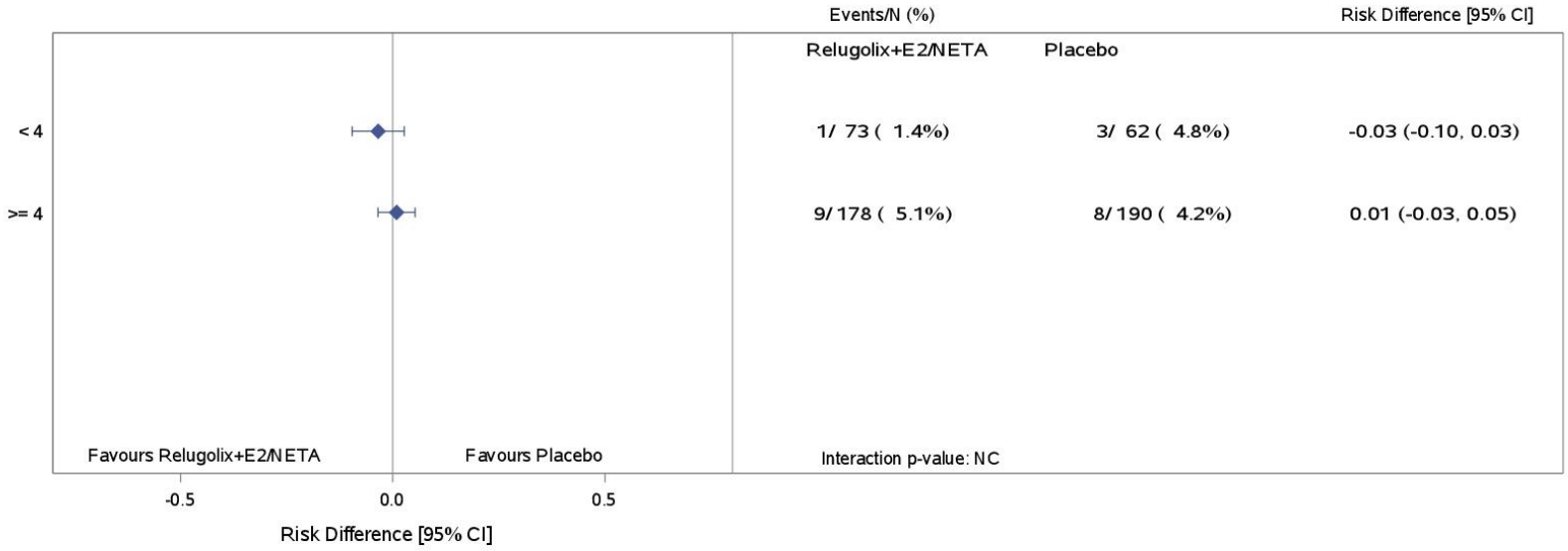
Figure SAF.TEAED.ANY.S4.BIN.FP.RD: Proportion of Patients With at Least One Treatment Emergent Adverse Event with Action Taken of Study Treatment Discontinuation, by Subgroup (Safety Population) - Risk Difference
Study: Pooled
Subgroup: Maximum NRS Pain Score at Baseline



Results are based on a Mantel-Haenszel approach stratified by study using a one-stage fixed-effects IPD meta-analysis.
The reference group is Placebo. Patients with multiple events are counted only once. MedDRA (version 22.0).
N: Number of patients in treatment group; NETA: Norethindrone acetate; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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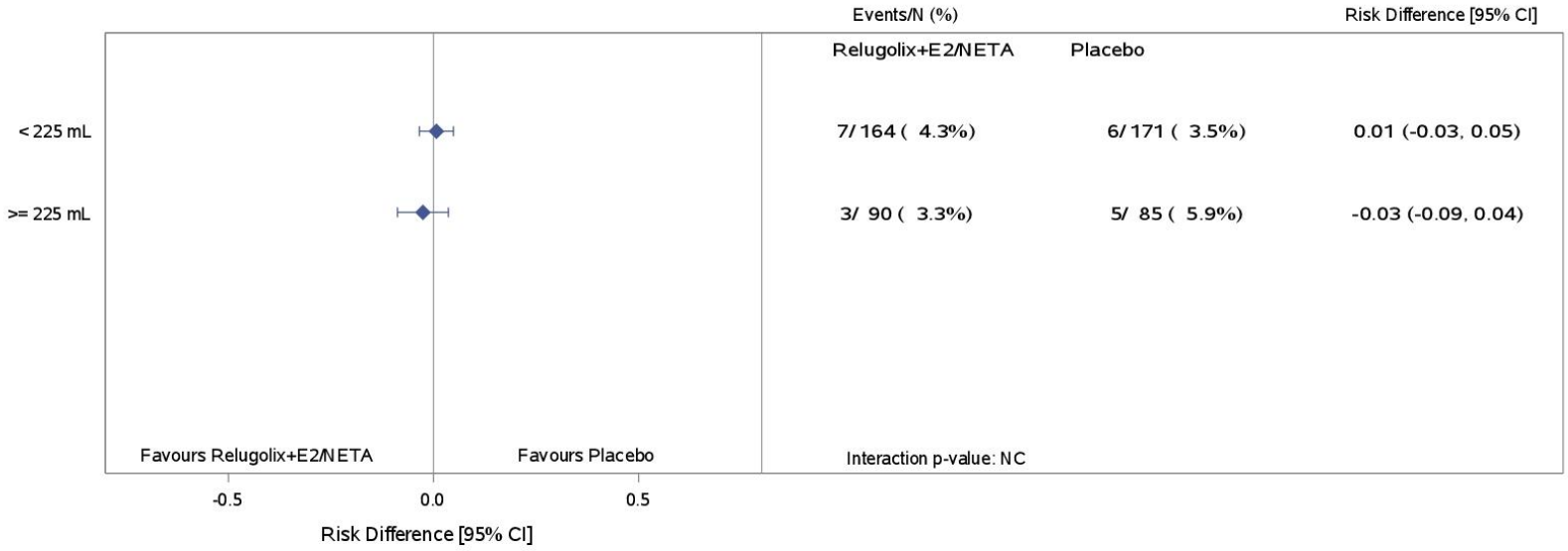
Figure SAF.TEAED.ANY.S5.BIN.FP.RD: Proportion of Patients With at Least One Treatment Emergent Adverse Event with Action Taken of Study Treatment Discontinuation, by Subgroup (Safety Population) - Risk Difference
Study: Pooled
Subgroup: MBL Volume at Baseline (mL)



Results are based on a Mantel-Haenszel approach stratified by study using a one-stage fixed-effects IPD meta-analysis.
The reference group is Placebo. Patients with multiple events are counted only once. MedDRA (version 22.0).
N: Number of patients in treatment group; NETA: Norethindrone acetate; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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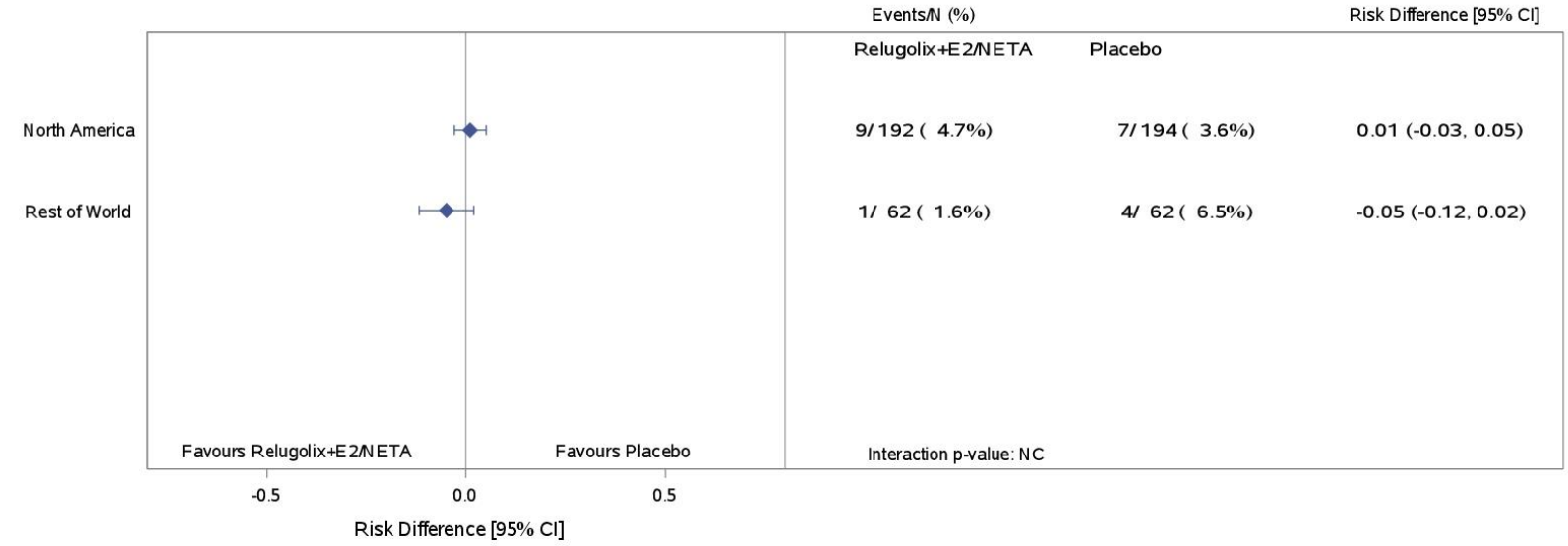
Figure SAF.TEAED.ANY.S6.BIN.FP.RD: Proportion of Patients With at Least One Treatment Emergent Adverse Event with Action Taken of Study Treatment Discontinuation, by Subgroup (Safety Population) - Risk Difference
Study: Pooled
Subgroup: Geographic Region I



Results are based on a Mantel-Haenszel approach stratified by study using a one-stage fixed-effects IPD meta-analysis.
The reference group is Placebo. Patients with multiple events are counted only once. MedDRA (version 22.0).
N: Number of patients in treatment group; NETA: Norethindrone acetate; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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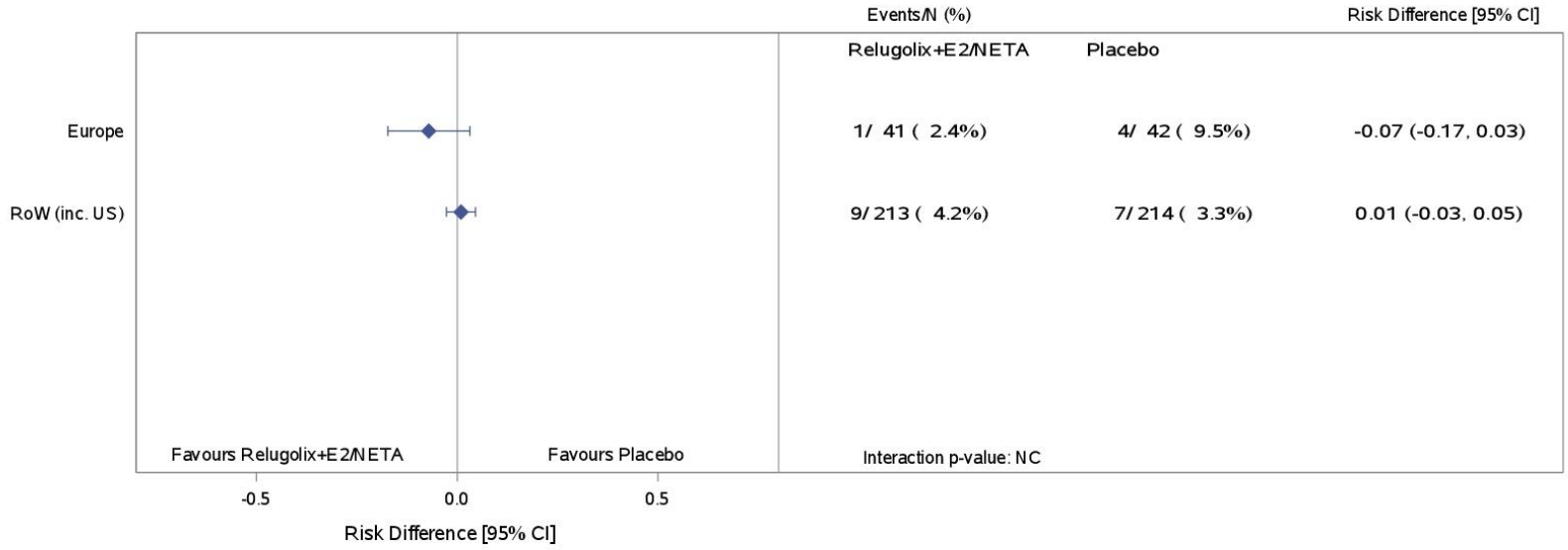
Figure SAF.TEAED.ANY.S7.BIN.FP.RD: Proportion of Patients With at Least One Treatment Emergent Adverse Event with Action Taken of Study Treatment Discontinuation, by Subgroup (Safety Population) - Risk Difference
Study: Pooled
Subgroup: Geographic Region II



Results are based on a Mantel-Haenszel approach stratified by study using a one-stage fixed-effects IPD meta-analysis.
The reference group is Placebo. Patients with multiple events are counted only once. MedDRA (version 22.0).
N: Number of patients in treatment group; NETA: Norethindrone acetate; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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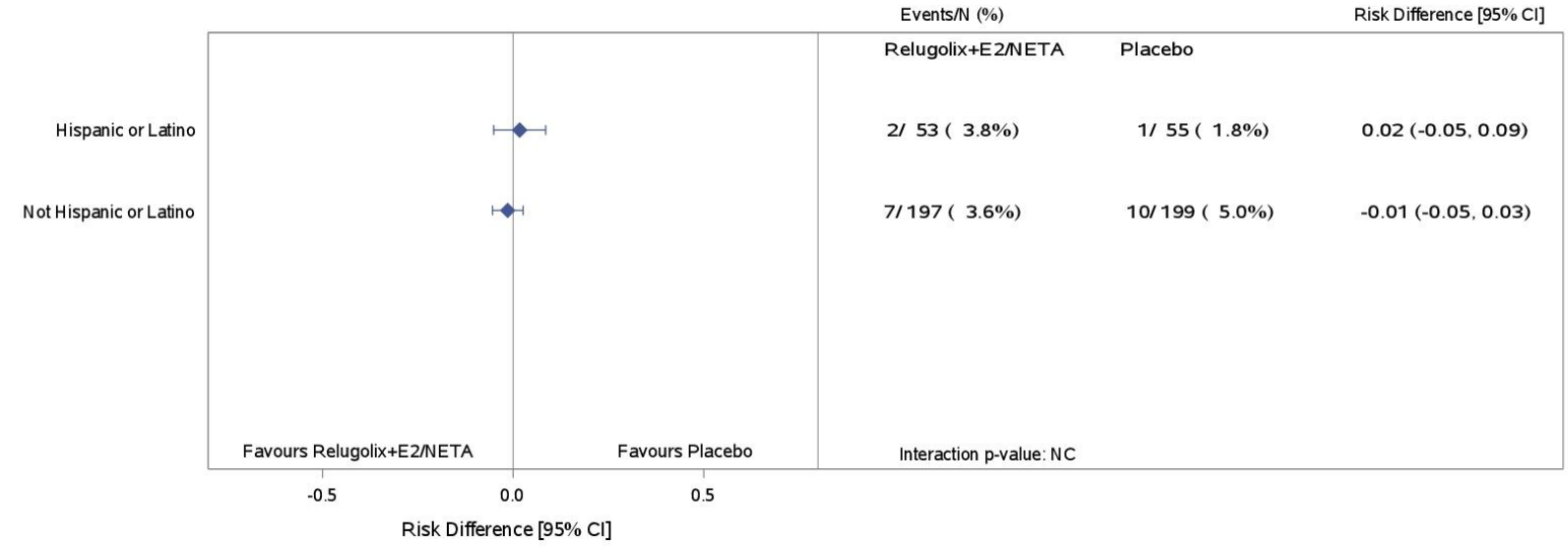
Figure SAF.TEAED.ANY.S8.BIN.FP.RD: Proportion of Patients With at Least One Treatment Emergent Adverse Event with Action Taken of Study Treatment Discontinuation, by Subgroup (Safety Population) - Risk Difference
Study: Pooled
Subgroup: Ethnicity



Results are based on a Mantel-Haenszel approach stratified by study using a one-stage fixed-effects IPD meta-analysis.
The reference group is Placebo. Patients with multiple events are counted only once. MedDRA (version 22.0).
N: Number of patients in treatment group; NETA: Norethindrone acetate; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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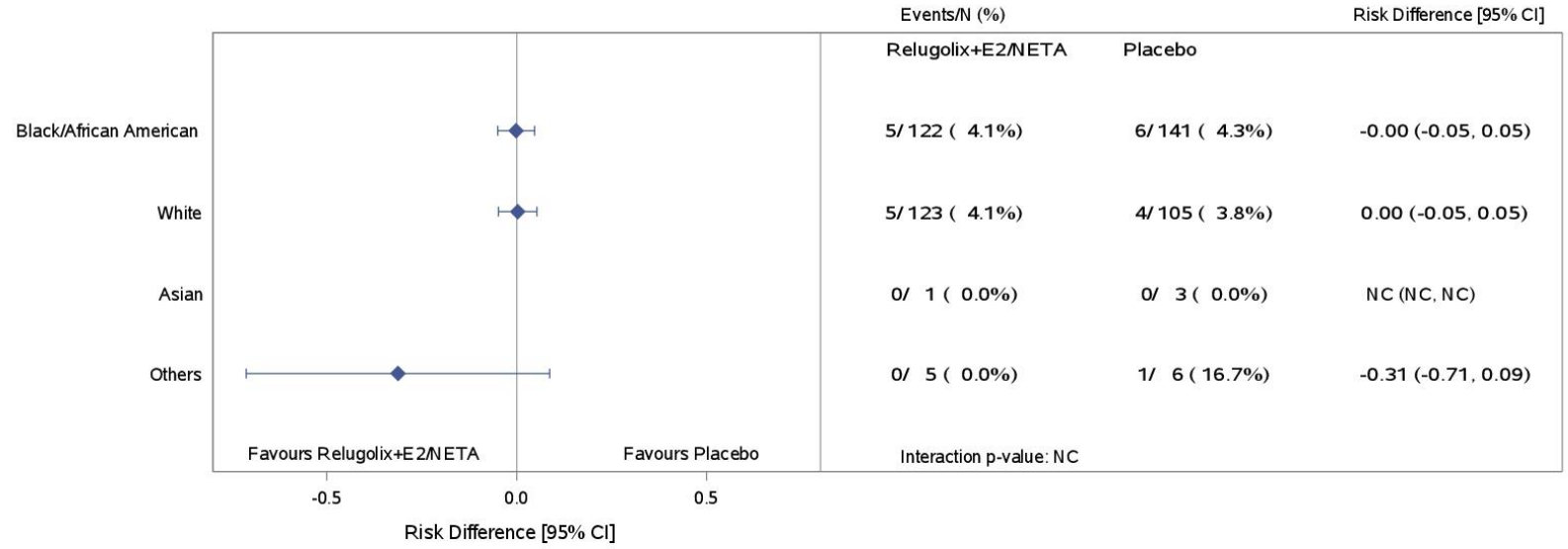
Figure SAF.TEAED.ANY.S9.BIN.FP.RD: Proportion of Patients With at Least One Treatment Emergent Adverse Event with Action Taken of Study Treatment Discontinuation, by Subgroup (Safety Population) - Risk Difference
Study: Pooled
Subgroup: Race



Results are based on a Mantel-Haenszel approach stratified by study using a one-stage fixed-effects IPD meta-analysis.
The reference group is Placebo. Patients with multiple events are counted only once. MedDRA (version 22.0).
N: Number of patients in treatment group; NETA: Norethindrone acetate; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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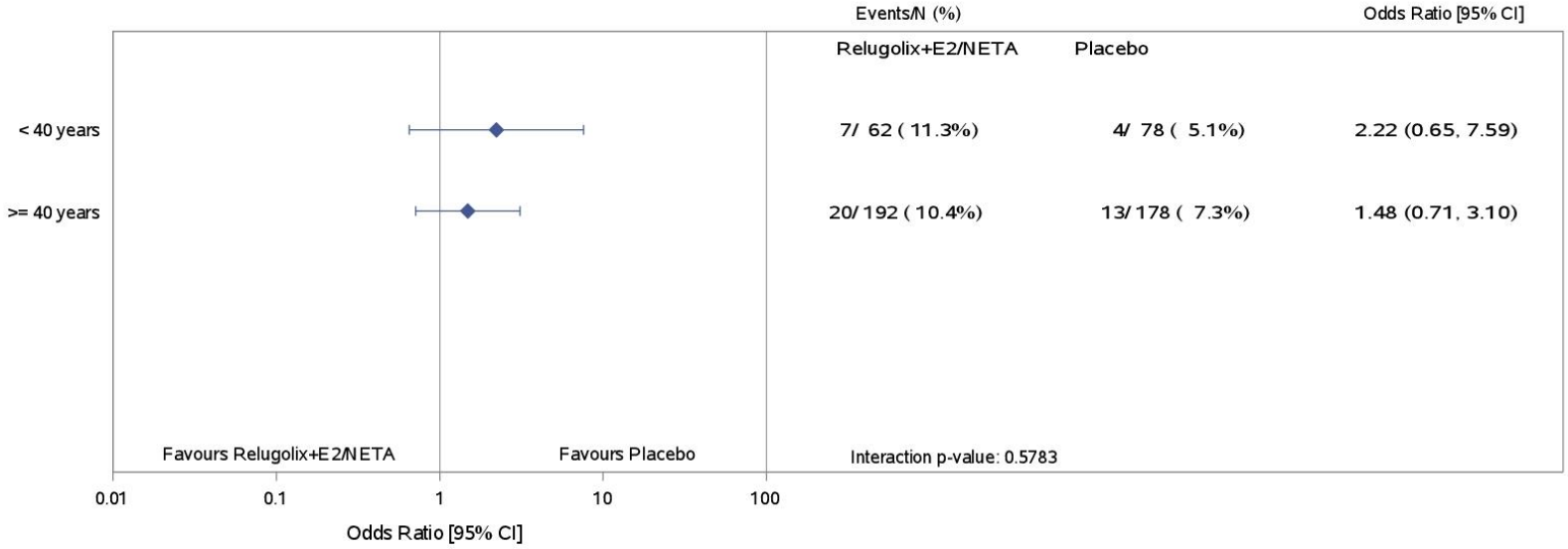
2.3.6 Proportion of Patients With at Least One Vasomotor Symptom Event, by Subgroup (Safety Population)

Nachfolgend sind zunächst alle Forest Plots für das *Odds Ratio* dargestellt; gefolgt von den entsprechenden Forest Plots für *Risk Ratio* und *Risk Difference*.

Figure SAF.VASOANY.ANY.S1.BIN.FP: Proportion of Patients With at Least One Vasomotor Symptom Event, by Subgroup (Safety Population)
Study: Pooled
Subgroup: Age (years)



Results are based on a logistic regression model adjusted for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates using a one-stage fixed-effects IPD meta-analysis approach. A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
The interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the Odds Ratio and 95% CI. Missing subgroup levels are not included in estimation of the interaction p-value. The reference group is Placebo. Patients with multiple events are counted only once. MedDRA (version 22.0).
N: Number of patients in treatment group; NETA: Norethindrone acetate; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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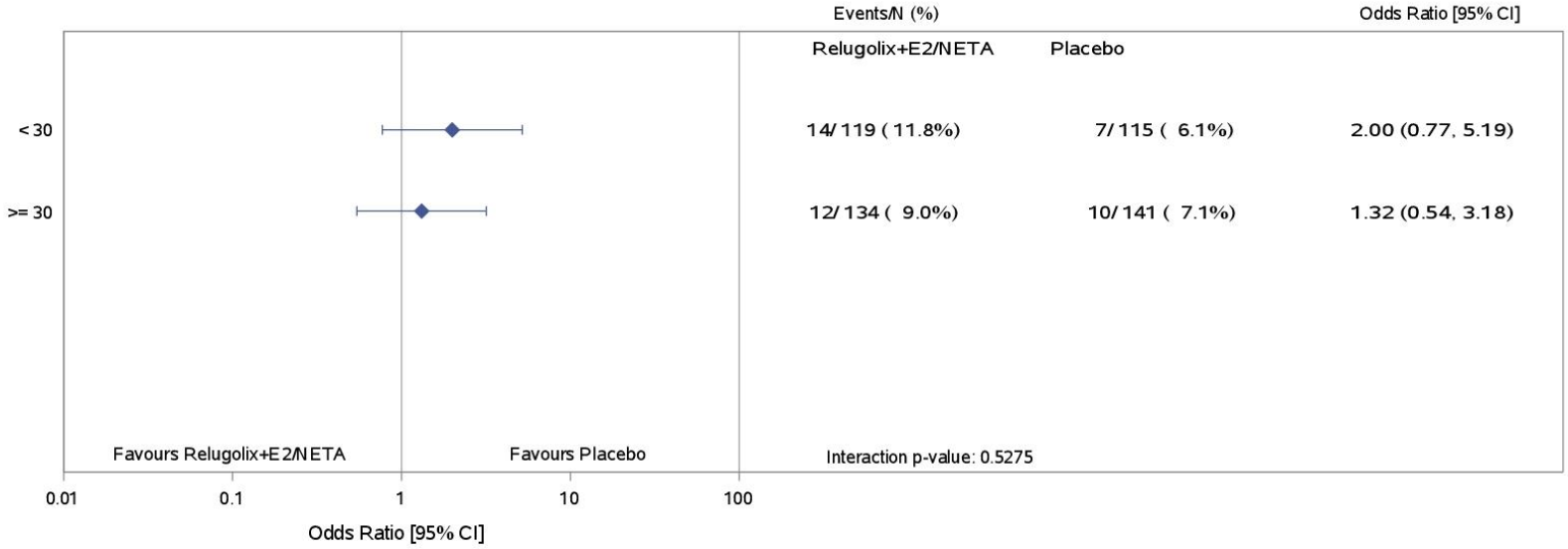
Figure SAF.VASOANY.ANY.S2.BIN.FP: Proportion of Patients With at Least One Vasomotor Symptom Event, by Subgroup (Safety Population)
Study: Pooled
Subgroup: BMI (kg/m2) at Baseline



Results are based on a logistic regression model adjusted for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates using a one-stage fixed-effects IPD meta-analysis approach. A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
The interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the Odds Ratio and 95% CI. Missing subgroup levels are not included in estimation of the interaction p-value. The reference group is Placebo. Patients with multiple events are counted only once. MedDRA (version 22.0).
N: Number of patients in treatment group; NETA: Norethindrone acetate; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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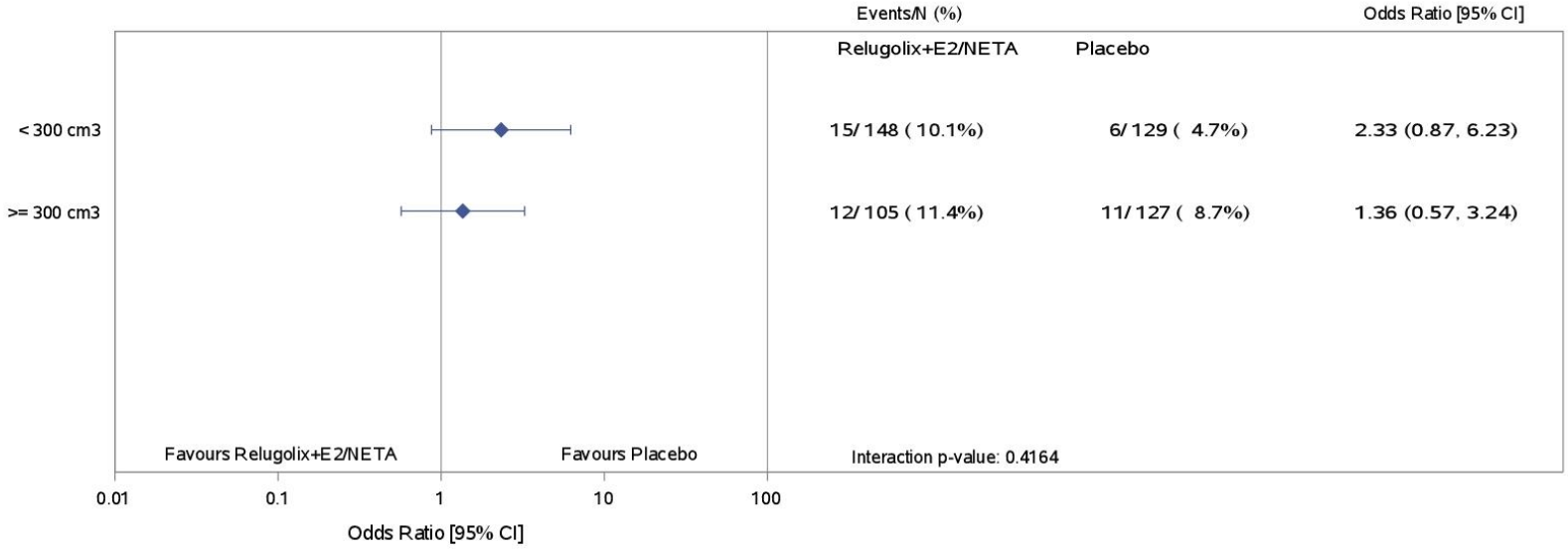
Figure SAF.VASOANY.ANY.S3.BIN.FP: Proportion of Patients With at Least One Vasomotor Symptom Event, by Subgroup (Safety Population)
Study: Pooled
Subgroup: Uterine Volume at Baseline (cm3)



Results are based on a logistic regression model adjusted for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates using a one-stage fixed-effects IPD meta-analysis approach. A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
The interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the Odds Ratio and 95% CI. Missing subgroup levels are not included in estimation of the interaction p-value. The reference group is Placebo. Patients with multiple events are counted only once. MedDRA (version 22.0).
N: Number of patients in treatment group; NETA: Norethindrone acetate; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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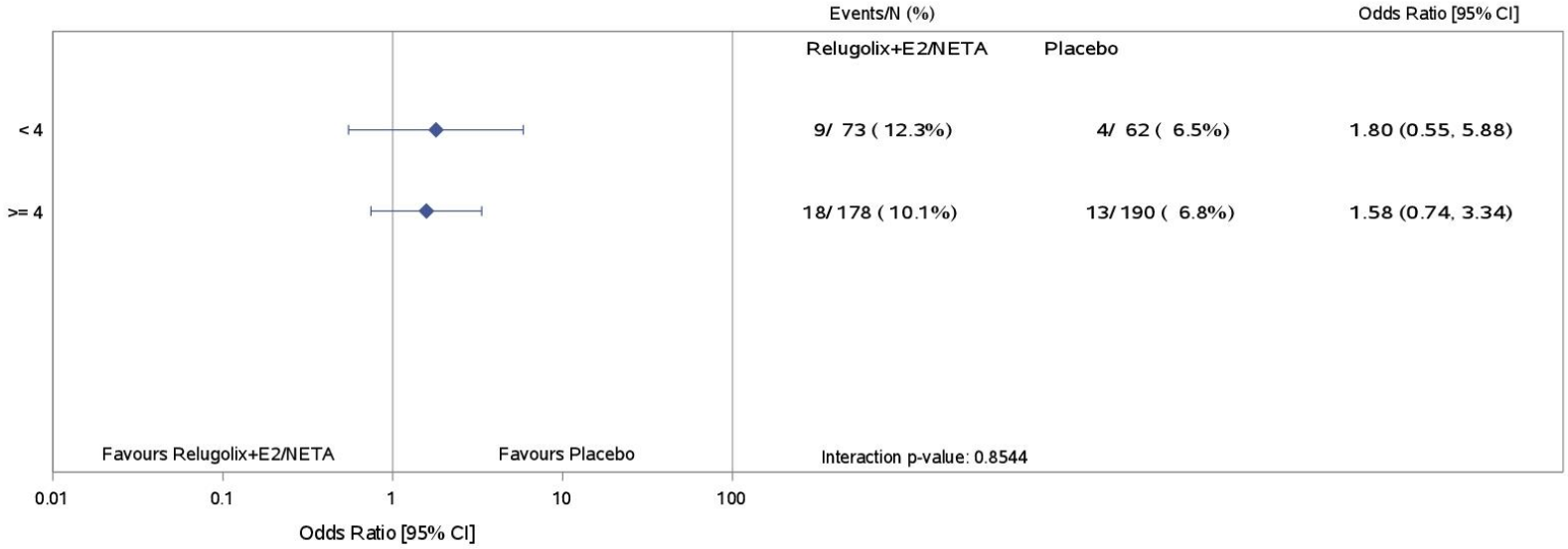
Figure SAF.VASOANY.ANY.S4.BIN.FP: Proportion of Patients With at Least One Vasomotor Symptom Event, by Subgroup (Safety Population)
Study: Pooled
Subgroup: Maximum NRS Pain Score at Baseline



Results are based on a logistic regression model adjusted for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates using a one-stage fixed-effects IPD meta-analysis approach. A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
The interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the Odds Ratio and 95% CI. Missing subgroup levels are not included in estimation of the interaction p-value. The reference group is Placebo. Patients with multiple events are counted only once. MedDRA (version 22.0).
N: Number of patients in treatment group; NETA: Norethindrone acetate; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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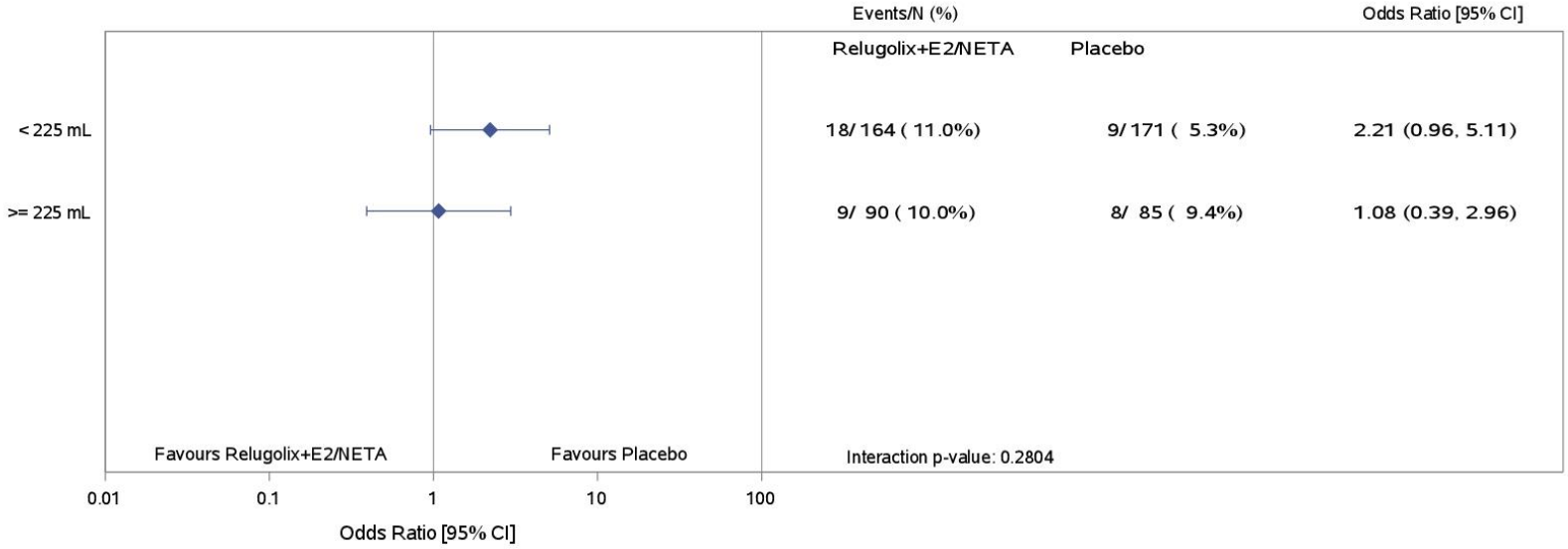
Figure SAF.VASOANY.ANY.S5.BIN.FP: Proportion of Patients With at Least One Vasomotor Symptom Event, by Subgroup (Safety Population)
Study: Pooled
Subgroup: MBL Volume at Baseline (mL)



Results are based on a logistic regression model adjusted for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates using a one-stage fixed-effects IPD meta-analysis approach. A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
The interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the Odds Ratio and 95% CI. Missing subgroup levels are not included in estimation of the interaction p-value. The reference group is Placebo. Patients with multiple events are counted only once. MedDRA (version 22.0).
N: Number of patients in treatment group; NETA: Norethindrone acetate; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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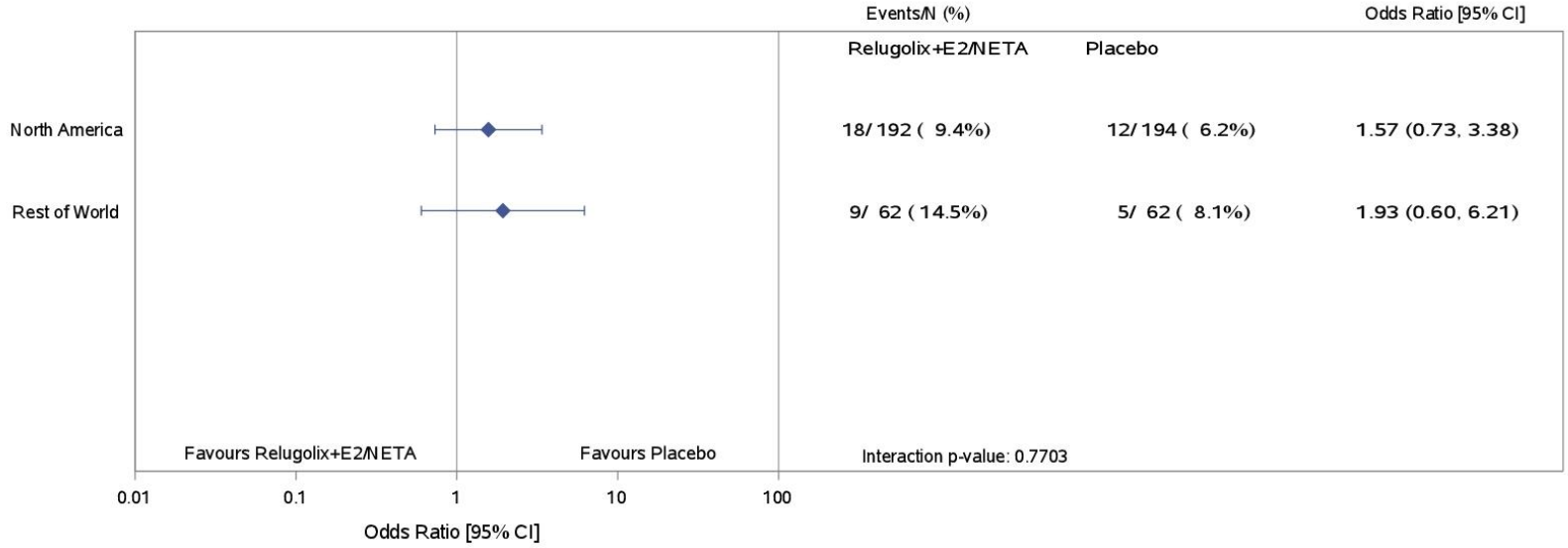
Figure SAF.VASOANY.ANY.S6.BIN.FP: Proportion of Patients With at Least One Vasomotor Symptom Event, by Subgroup (Safety Population)
Study: Pooled
Subgroup: Geographic Region I



Results are based on a logistic regression model adjusted for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates using a one-stage fixed-effects IPD meta-analysis approach. A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
The interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the Odds Ratio and 95% CI. Missing subgroup levels are not included in estimation of the interaction p-value. The reference group is Placebo. Patients with multiple events are counted only once. MedDRA (version 22.0).
N: Number of patients in treatment group; NETA: Norethindrone acetate; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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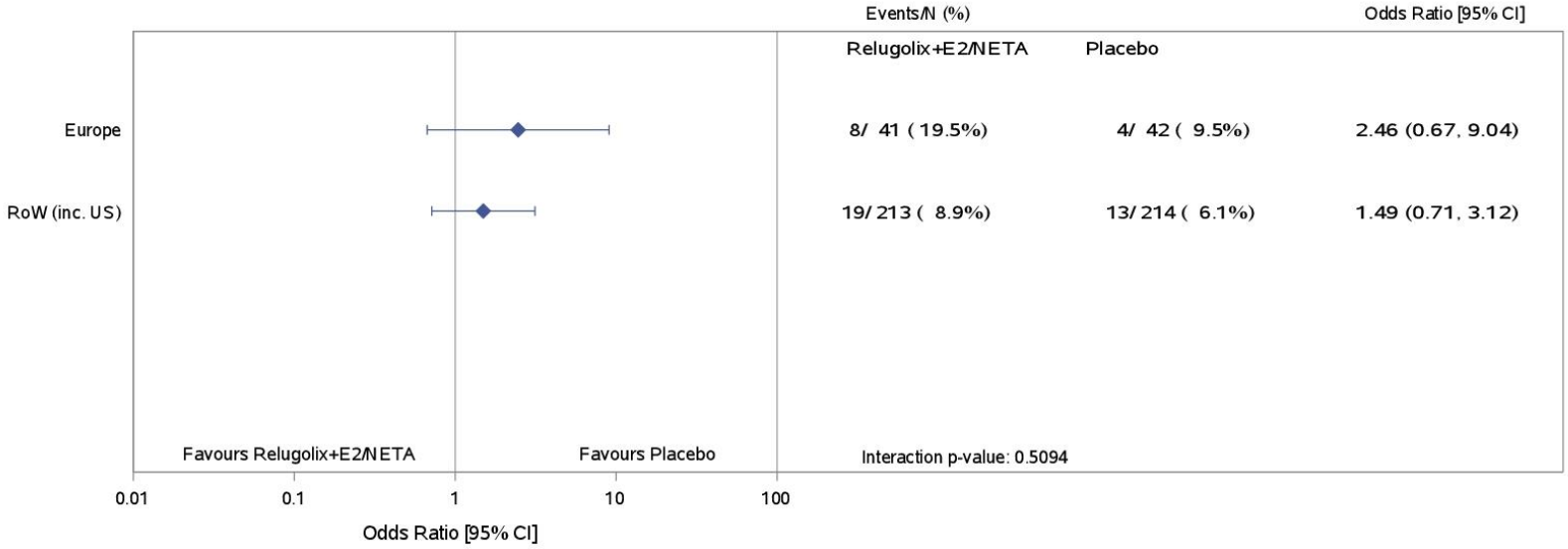
Figure SAF.VASOANY.ANY.S7.BIN.FP: Proportion of Patients With at Least One Vasomotor Symptom Event, by Subgroup (Safety Population)
Study: Pooled
Subgroup: Geographic Region II



Results are based on a logistic regression model adjusted for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates using a one-stage fixed-effects IPD meta-analysis approach. A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
The interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the Odds Ratio and 95% CI. Missing subgroup levels are not included in estimation of the interaction p-value. The reference group is Placebo. Patients with multiple events are counted only once. MedDRA (version 22.0).
N: Number of patients in treatment group; NETA: Norethindrone acetate; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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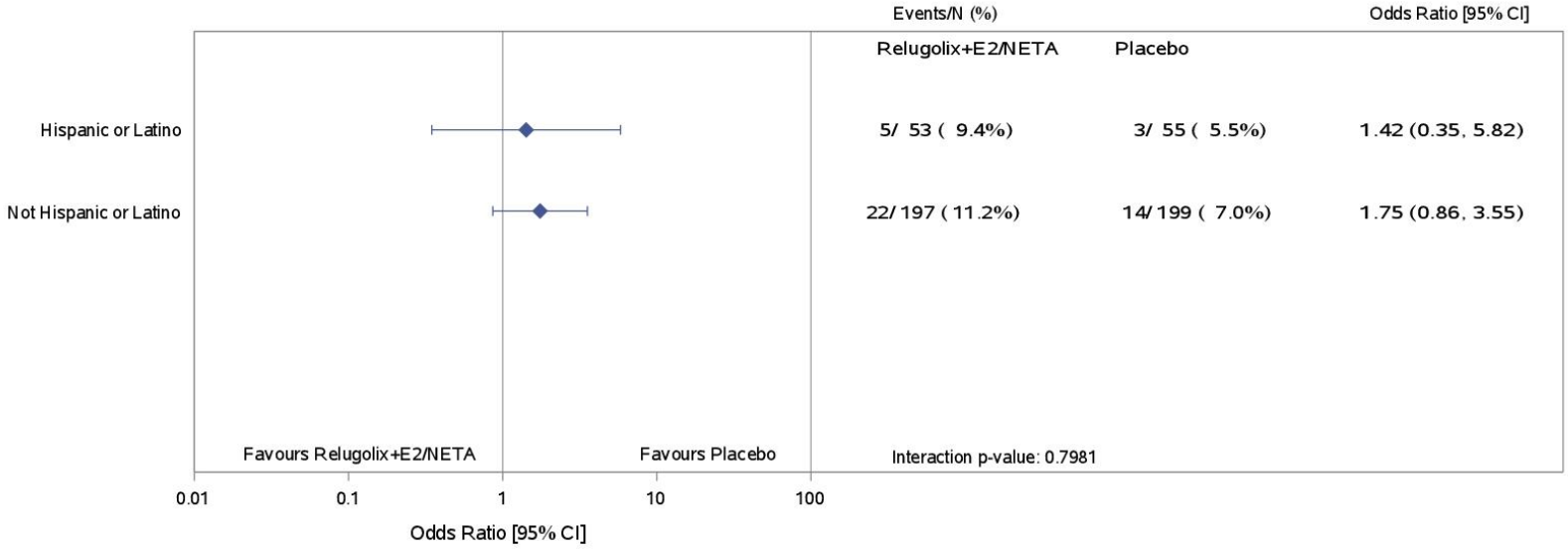
Figure SAF.VASOANY.ANY.S8.BIN.FP: Proportion of Patients With at Least One Vasomotor Symptom Event, by Subgroup (Safety Population)
Study: Pooled
Subgroup: Ethnicity



Results are based on a logistic regression model adjusted for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates using a one-stage fixed-effects IPD meta-analysis approach. A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
The interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the Odds Ratio and 95% CI. Missing subgroup levels are not included in estimation of the interaction p-value. The reference group is Placebo. Patients with multiple events are counted only once. MedDRA (version 22.0).
N: Number of patients in treatment group; NETA: Norethindrone acetate; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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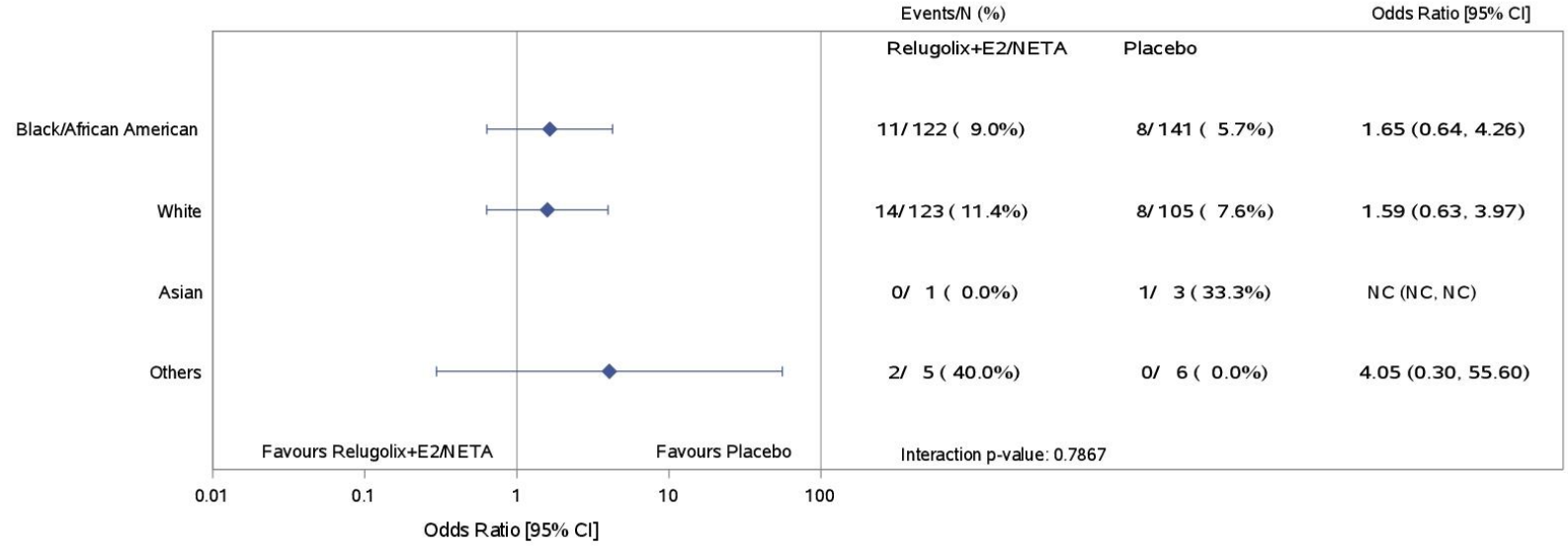
Figure SAF.VASOANY.ANY.S9.BIN.FP: Proportion of Patients With at Least One Vasomotor Symptom Event, by Subgroup (Safety Population)
Study: Pooled
Subgroup: Race



Results are based on a logistic regression model adjusted for study, treatment group, subgroup and a subgroup-by-treatment interaction as covariates using a one-stage fixed-effects IPD meta-analysis approach. A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
The interaction p-value is based on the subgroup-by-treatment interaction term in the logistic regression model used to estimate the Odds Ratio and 95% CI. Missing subgroup levels are not included in estimation of the interaction p-value. The reference group is Placebo. Patients with multiple events are counted only once. MedDRA (version 22.0).
N: Number of patients in treatment group; NETA: Norethindrone acetate; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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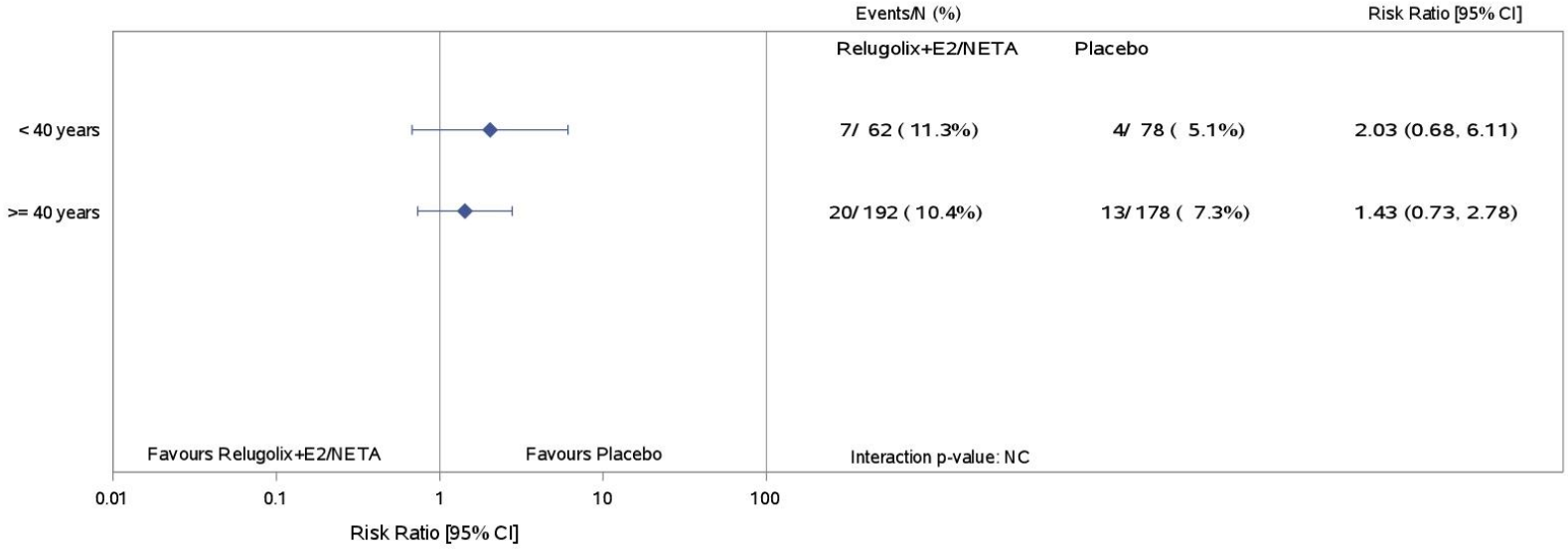
Figure SAF.VASOANY.ANY.S1.BIN.FP.RR: Proportion of Patients With at Least One Vasomotor Symptom Event, by Subgroup (Safety Population) - Risk Ratio
Study: Pooled
Subgroup: Age (years)



Results are based on a Cochran-Mantel-Haenszel approach stratified by study using a one-stage fixed-effects IPD meta-analysis. A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
The reference group is Placebo. Patients with multiple events are counted only once. MedDRA (version 22.0).
N: Number of patients in treatment group; NETA: Norethindrone acetate; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

SOURCE: X:\Numerus\Studies\MYV\MYV102\Analysis\Prod\Progs\TFLs\Fig_SAF_AE_S_BIN_FP.SAS Date/time of run: 01JUL21 10:03
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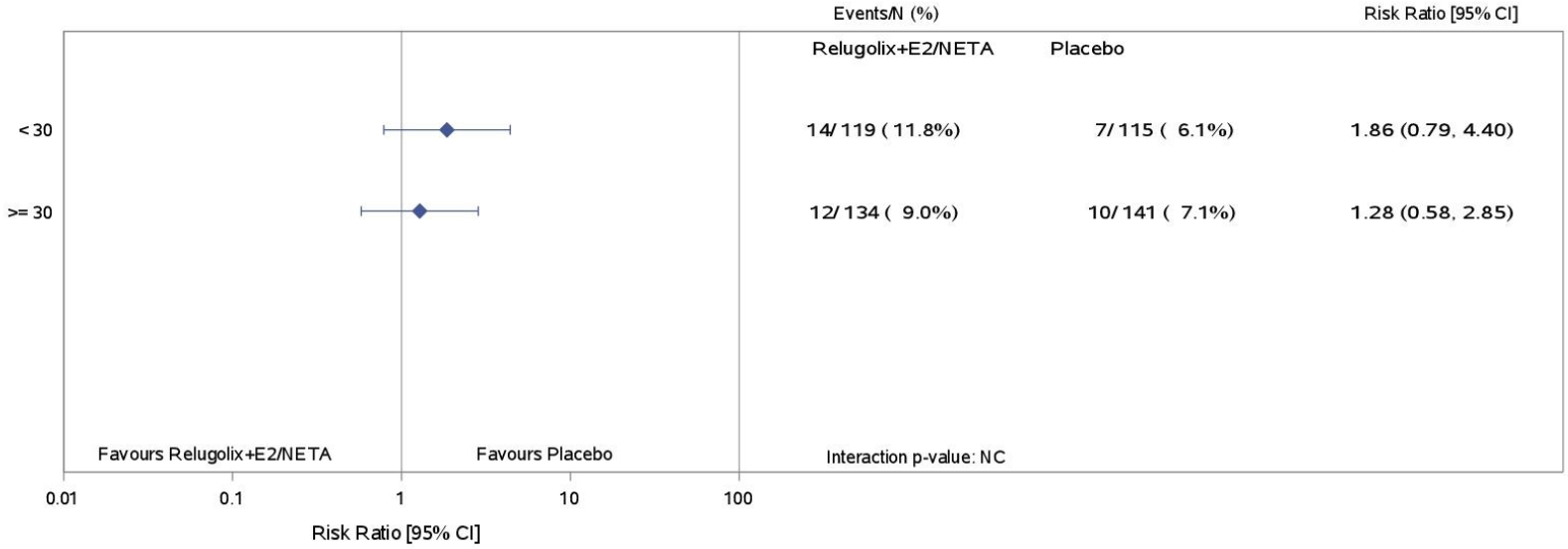
Figure SAF.VASOANY.ANY.S2.BIN.FP.RR: Proportion of Patients With at Least One Vasomotor Symptom Event, by Subgroup (Safety Population) - Risk Ratio
Study: Pooled
Subgroup: BMI (kg/m2) at Baseline



Results are based on a Cochran-Mantel-Haenszel approach stratified by study using a one-stage fixed-effects IPD meta-analysis. A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
The reference group is Placebo. Patients with multiple events are counted only once. MedDRA (version 22.0).
N: Number of patients in treatment group; NETA: Norethindrone acetate; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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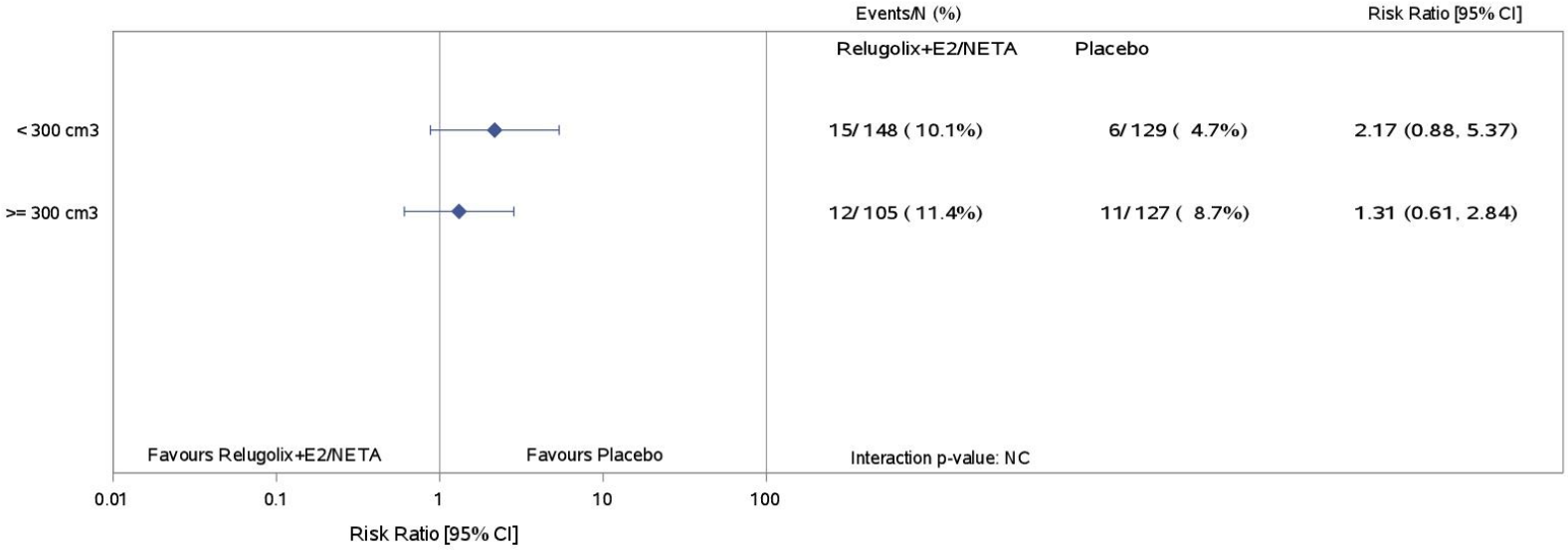
Figure SAF.VASOANY.ANY.S3.BIN.FP.RR: Proportion of Patients With at Least One Vasomotor Symptom Event, by Subgroup (Safety Population) - Risk Ratio
Study: Pooled
Subgroup: Uterine Volume at Baseline (cm3)



Results are based on a Cochran-Mantel-Haenszel approach stratified by study using a one-stage fixed-effects IPD meta-analysis. A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
The reference group is Placebo. Patients with multiple events are counted only once. MedDRA (version 22.0).
N: Number of patients in treatment group; NETA: Norethindrone acetate; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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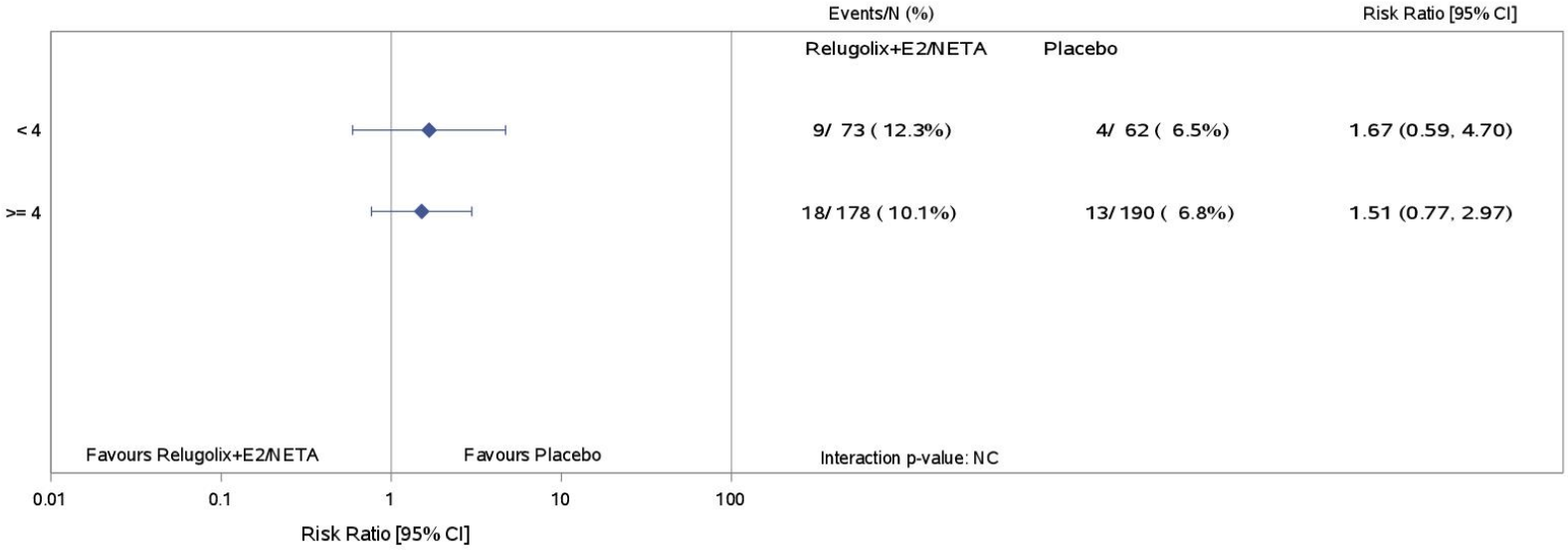
Figure SAF.VASOANY.ANY.S4.BIN.FP.RR: Proportion of Patients With at Least One Vasomotor Symptom Event, by Subgroup (Safety Population) - Risk Ratio
Study: Pooled
Subgroup: Maximum NRS Pain Score at Baseline



Results are based on a Cochran-Mantel-Haenszel approach stratified by study using a one-stage fixed-effects IPD meta-analysis. A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
The reference group is Placebo. Patients with multiple events are counted only once. MedDRA (version 22.0).
N: Number of patients in treatment group; NETA: Norethindrone acetate; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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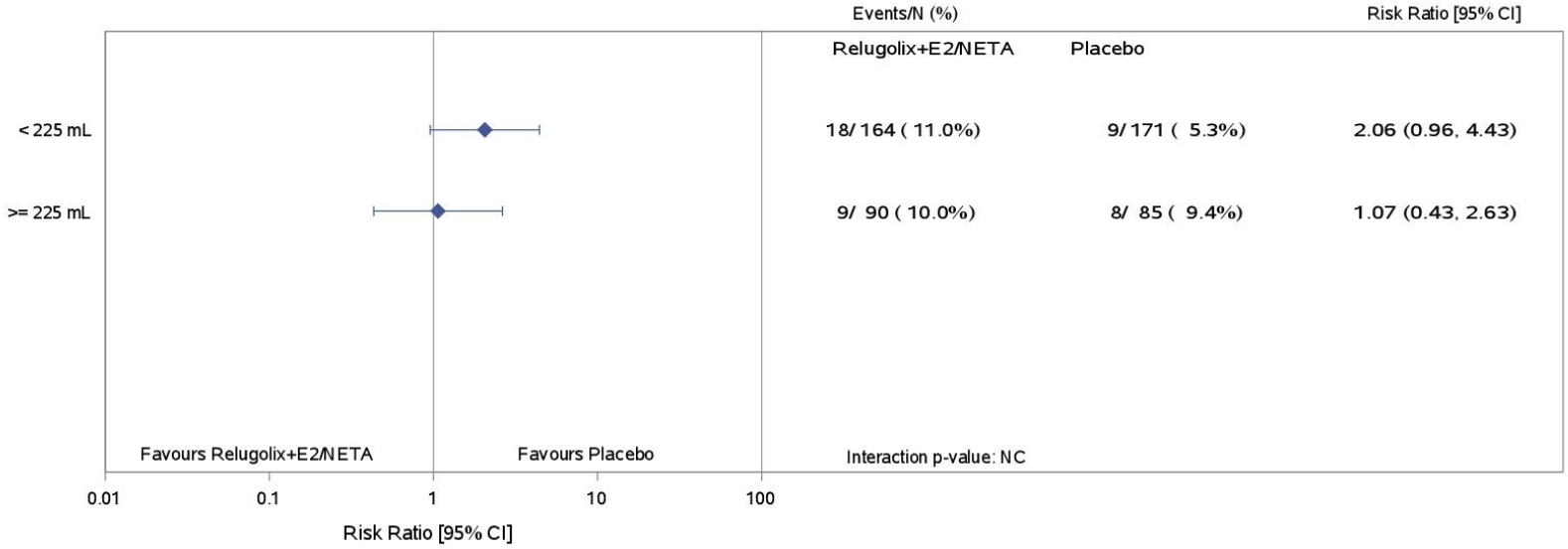
Figure SAF.VASOANY.ANY.S5.BIN.FP.RR: Proportion of Patients With at Least One Vasomotor Symptom Event, by Subgroup (Safety Population) - Risk Ratio
Study: Pooled
Subgroup: MBL Volume at Baseline (mL)



Results are based on a Cochran-Mantel-Haenszel approach stratified by study using a one-stage fixed-effects IPD meta-analysis. A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
The reference group is Placebo. Patients with multiple events are counted only once. MedDRA (version 22.0).
N: Number of patients in treatment group; NETA: Norethindrone acetate; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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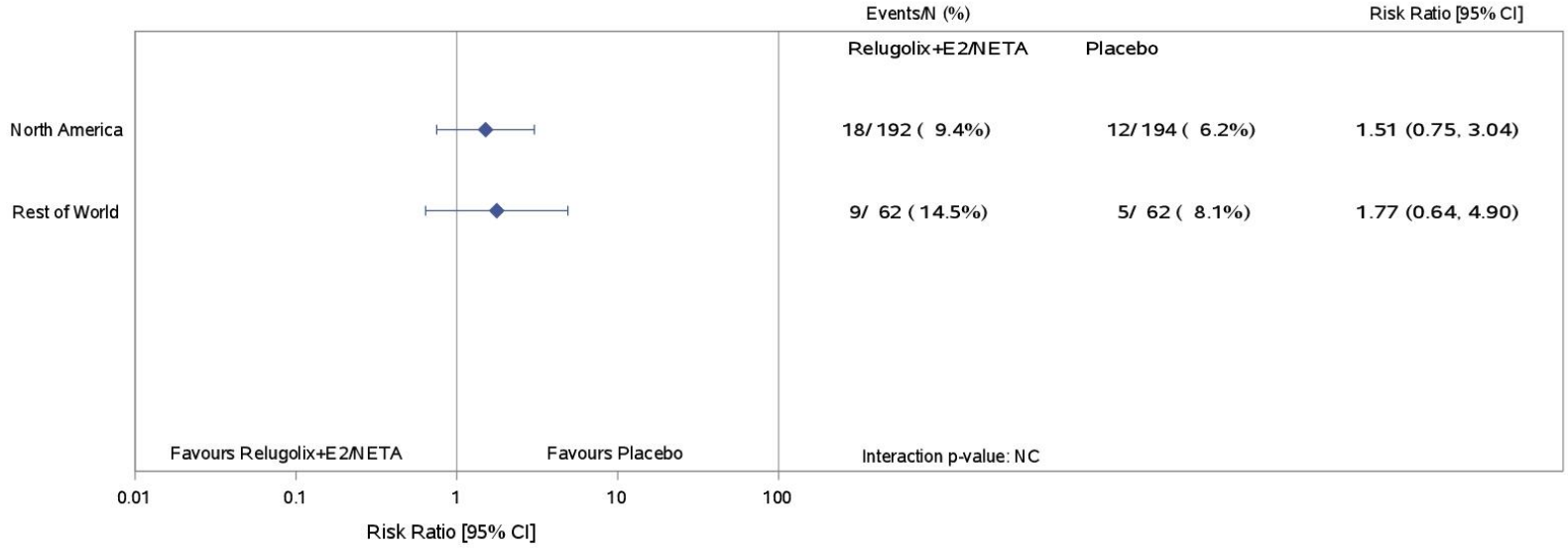
Figure SAF.VASOANY.ANY.S6.BIN.FP.RR: Proportion of Patients With at Least One Vasomotor Symptom Event, by Subgroup (Safety Population) - Risk Ratio
Study: Pooled
Subgroup: Geographic Region I



Results are based on a Cochran-Mantel-Haenszel approach stratified by study using a one-stage fixed-effects IPD meta-analysis. A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
The reference group is Placebo. Patients with multiple events are counted only once. MedDRA (version 22.0).
N: Number of patients in treatment group; NETA: Norethindrone acetate; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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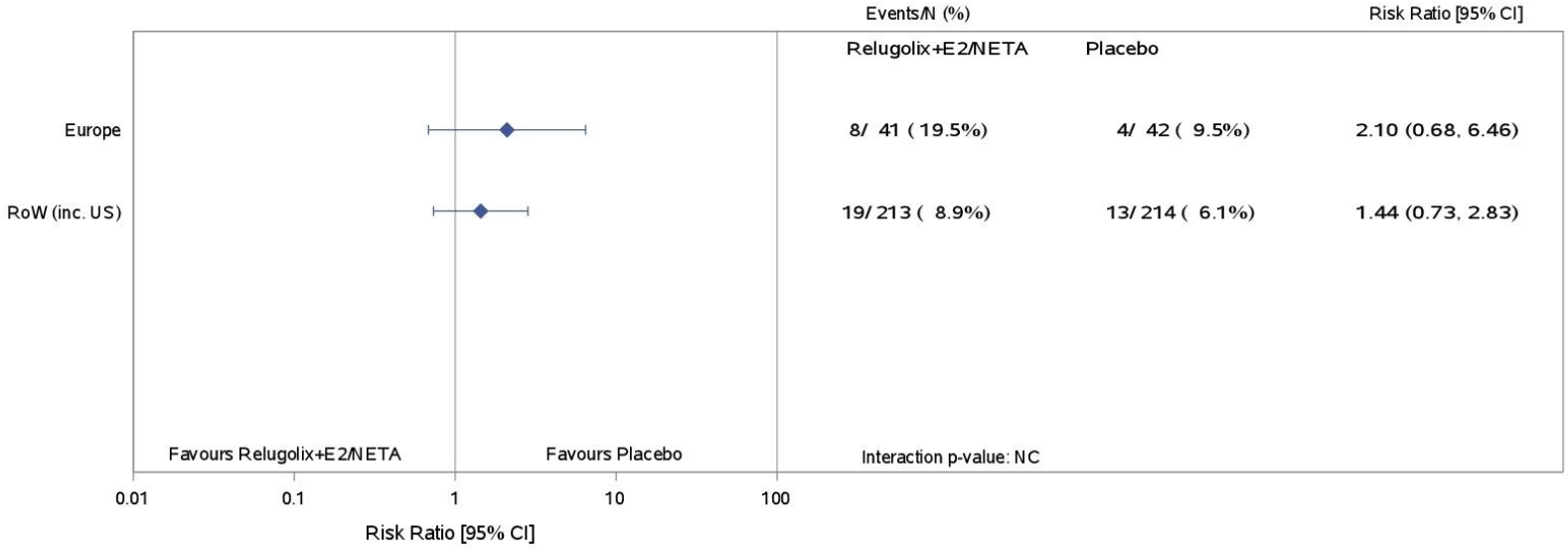
Figure SAF.VASOANY.ANY.S7.BIN.FP.RR: Proportion of Patients With at Least One Vasomotor Symptom Event, by Subgroup (Safety Population) - Risk Ratio
Study: Pooled
Subgroup: Geographic Region II



Results are based on a Cochran-Mantel-Haenszel approach stratified by study using a one-stage fixed-effects IPD meta-analysis. A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
The reference group is Placebo. Patients with multiple events are counted only once. MedDRA (version 22.0).
N: Number of patients in treatment group; NETA: Norethindrone acetate; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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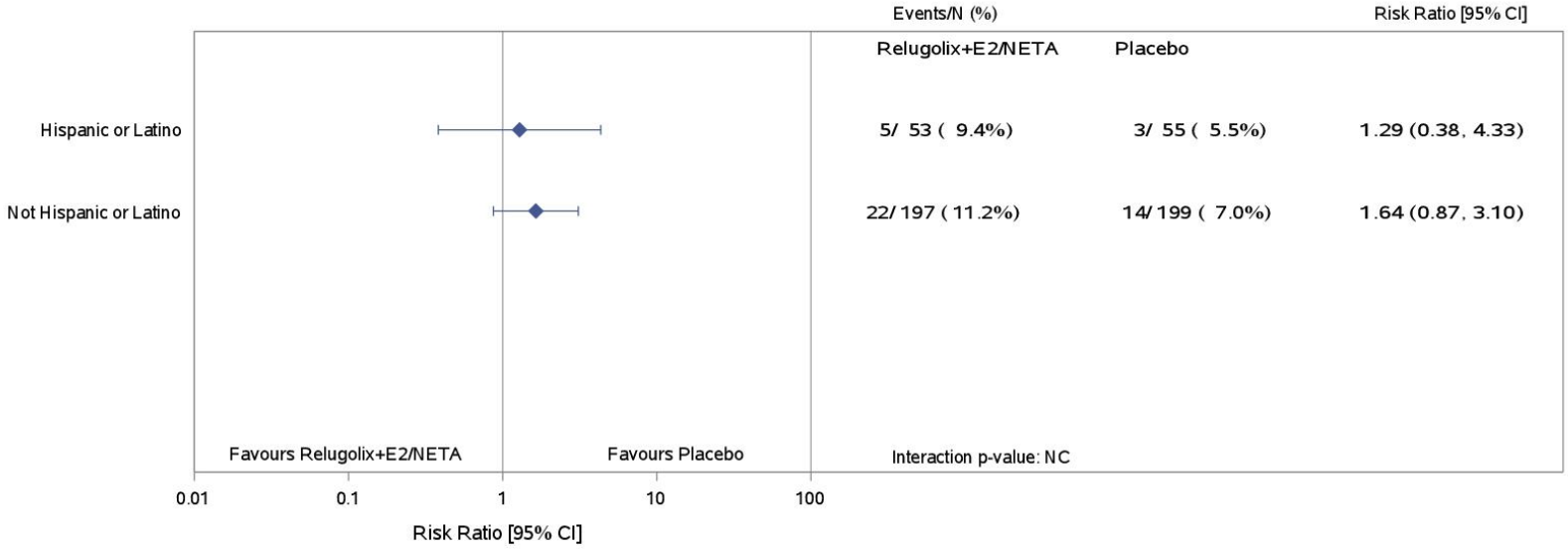
Figure SAF.VASOANY.ANY.S8.BIN.FP.RR: Proportion of Patients With at Least One Vasomotor Symptom Event, by Subgroup (Safety Population) - Risk Ratio
Study: Pooled
Subgroup: Ethnicity



Results are based on a Cochran-Mantel-Haenszel approach stratified by study using a one-stage fixed-effects IPD meta-analysis. A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
The reference group is Placebo. Patients with multiple events are counted only once. MedDRA (version 22.0).
N: Number of patients in treatment group; NETA: Norethindrone acetate; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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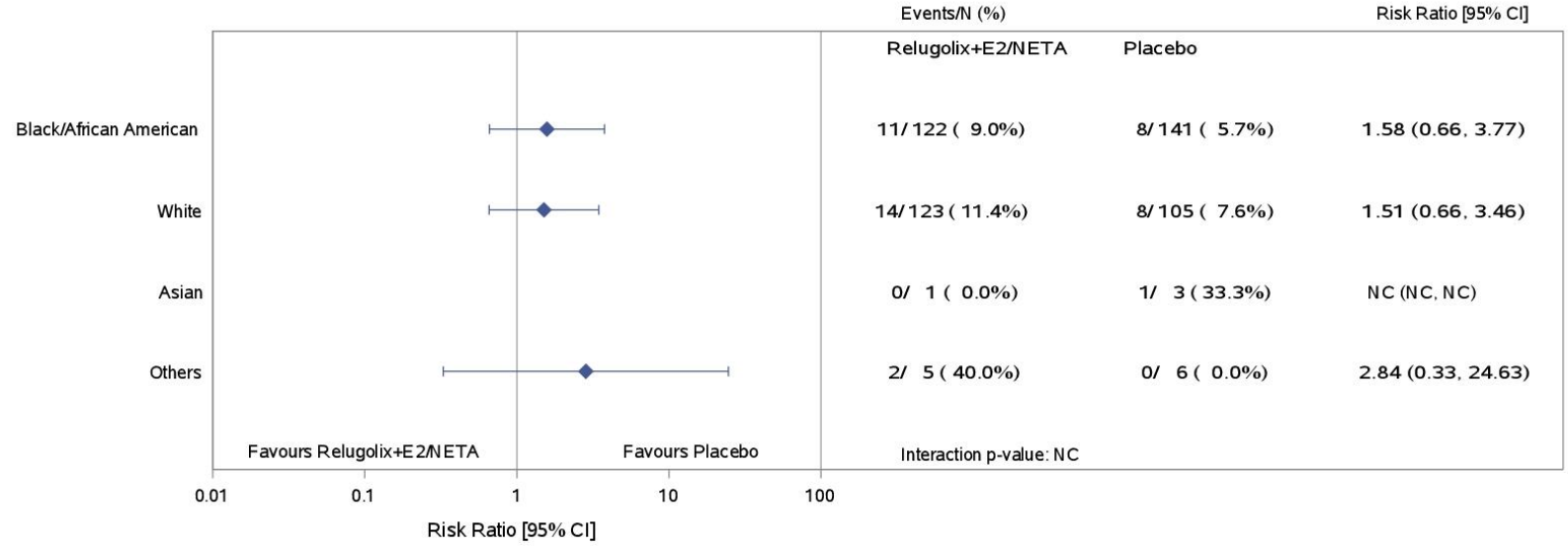
Figure SAF.VASOANY.ANY.S9.BIN.FP.RR: Proportion of Patients With at Least One Vasomotor Symptom Event, by Subgroup (Safety Population) - Risk Ratio
Study: Pooled
Subgroup: Race



Results are based on a Cochran-Mantel-Haenszel approach stratified by study using a one-stage fixed-effects IPD meta-analysis. A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
The reference group is Placebo. Patients with multiple events are counted only once. MedDRA (version 22.0).
N: Number of patients in treatment group; NETA: Norethindrone acetate; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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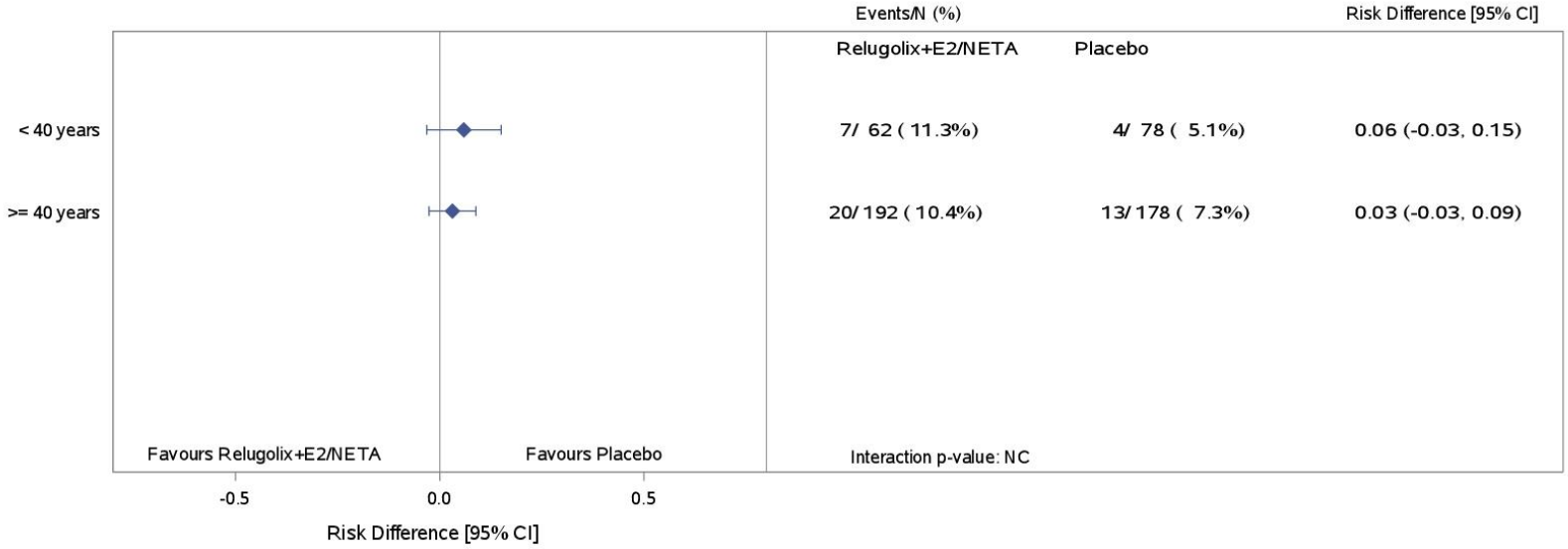
Figure SAF.VASOANY.ANY.S1.BIN.FP.RD: Proportion of Patients With at Least One Vasomotor Symptom Event, by Subgroup (Safety Population) - Risk Difference
Study: Pooled
Subgroup: Age (years)



Results are based on a Mantel-Haenszel approach stratified by study using a one-stage fixed-effects IPD meta-analysis.
The reference group is Placebo. Patients with multiple events are counted only once. MedDRA (version 22.0).
N: Number of patients in treatment group; NETA: Norethindrone acetate; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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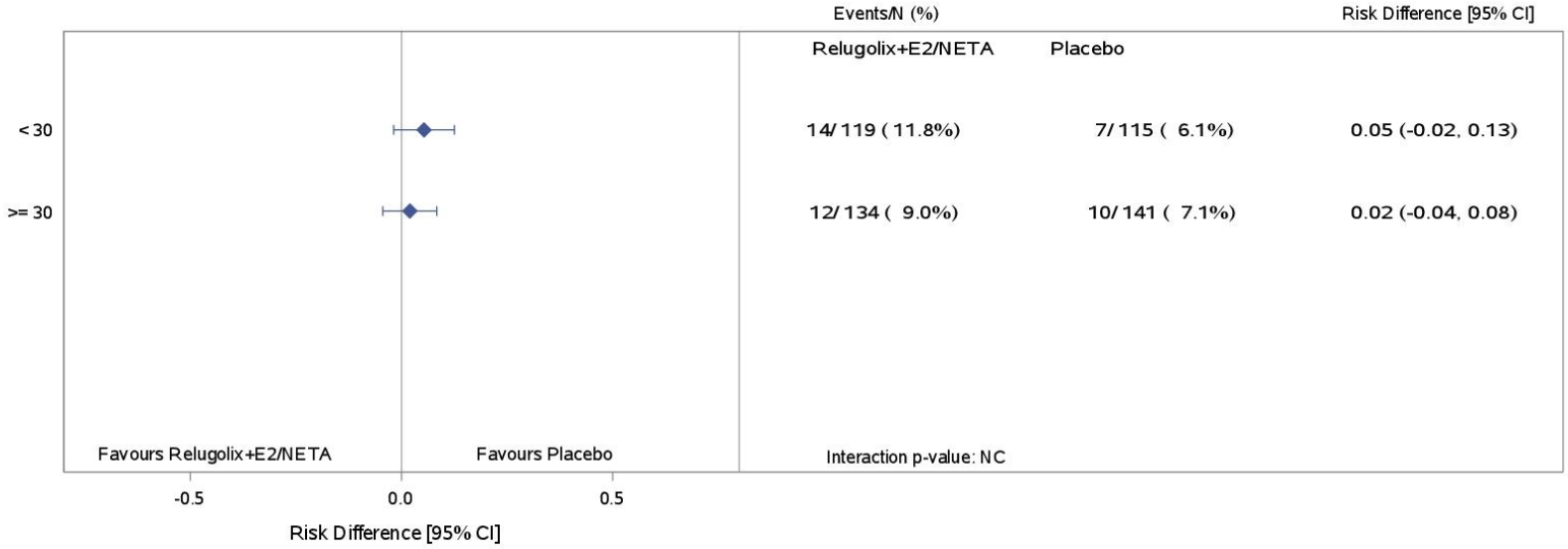
Figure SAF.VASOANY.ANY.S2.BIN.FP.RD: Proportion of Patients With at Least One Vasomotor Symptom Event, by Subgroup (Safety Population) - Risk Difference
Study: Pooled
Subgroup: BMI (kg/m2) at Baseline



Results are based on a Mantel-Haenszel approach stratified by study using a one-stage fixed-effects IPD meta-analysis.
The reference group is Placebo. Patients with multiple events are counted only once. MedDRA (version 22.0).
N: Number of patients in treatment group; NETA: Norethindrone acetate; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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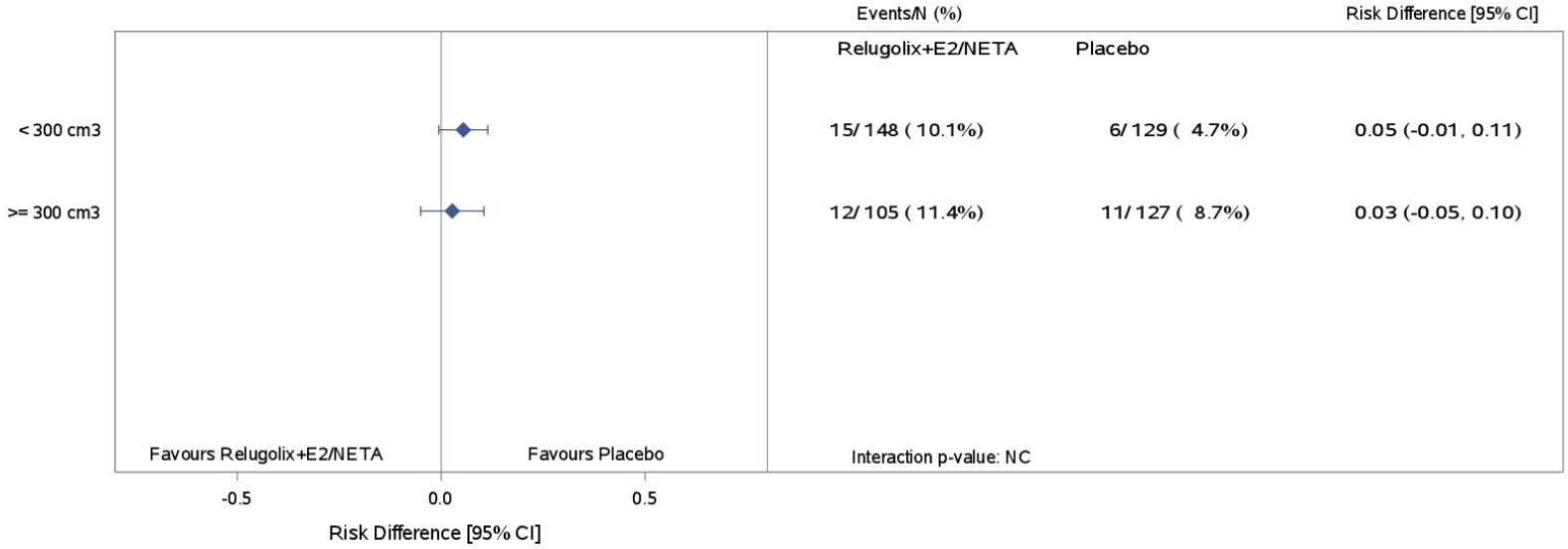
Figure SAF.VASOANY.ANY.S3.BIN.FP.RD: Proportion of Patients With at Least One Vasomotor Symptom Event, by Subgroup (Safety Population) - Risk Difference
Study: Pooled
Subgroup: Uterine Volume at Baseline (cm3)



Results are based on a Mantel-Haenszel approach stratified by study using a one-stage fixed-effects IPD meta-analysis.
The reference group is Placebo. Patients with multiple events are counted only once. MedDRA (version 22.0).
N: Number of patients in treatment group; NETA: Norethindrone acetate; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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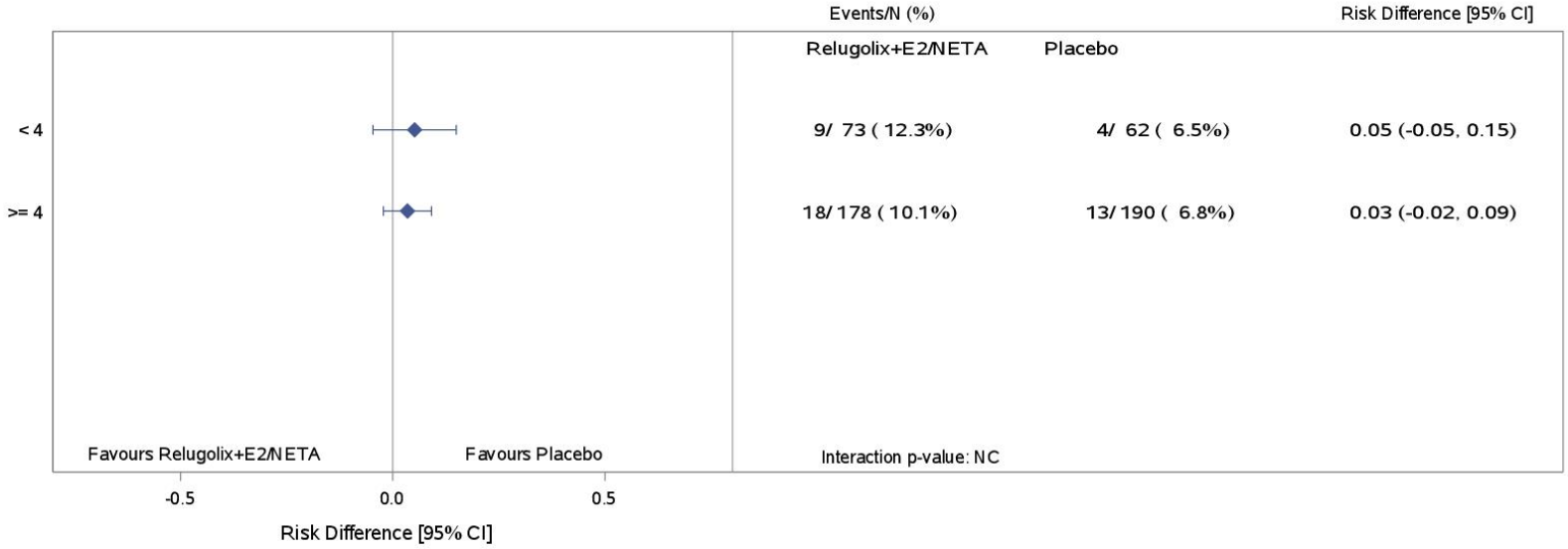
Figure SAF.VASOANY.ANY.S4.BIN.FP.RD: Proportion of Patients With at Least One Vasomotor Symptom Event, by Subgroup (Safety Population) - Risk Difference
Study: Pooled
Subgroup: Maximum NRS Pain Score at Baseline



Results are based on a Mantel-Haenszel approach stratified by study using a one-stage fixed-effects IPD meta-analysis.
The reference group is Placebo. Patients with multiple events are counted only once. MedDRA (version 22.0).
N: Number of patients in treatment group; NETA: Norethindrone acetate; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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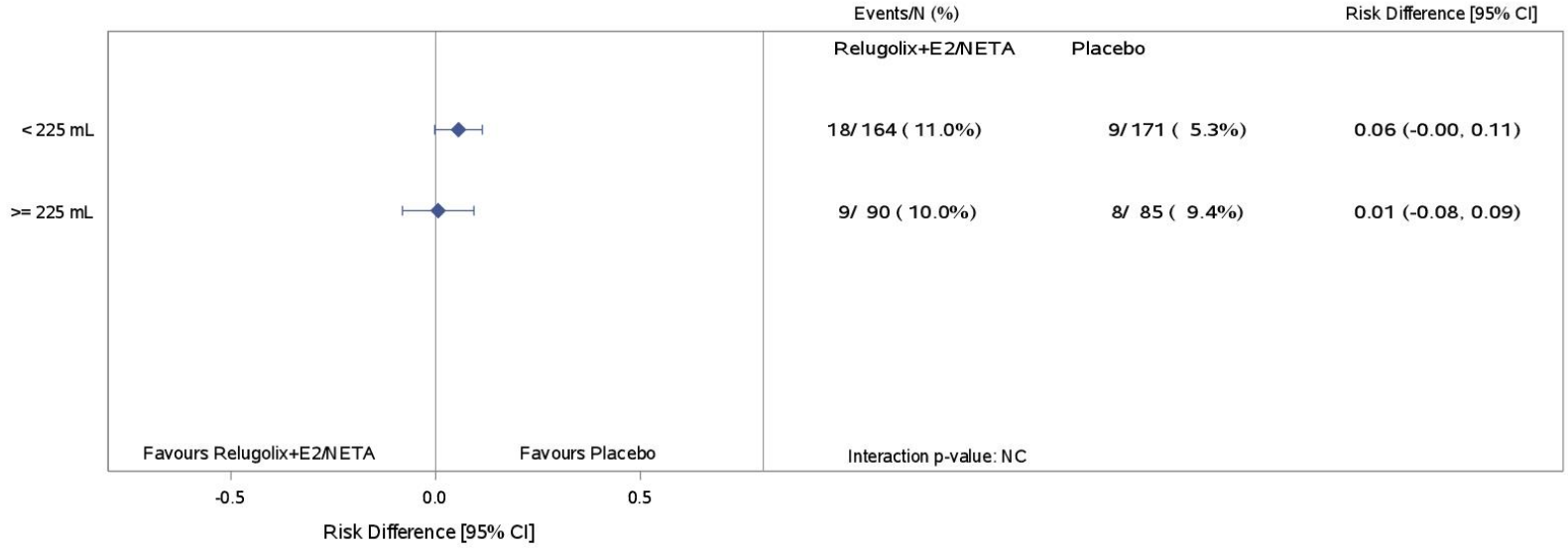
Figure SAF.VASOANY.ANY.S5.BIN.FP.RD: Proportion of Patients With at Least One Vasomotor Symptom Event, by Subgroup (Safety Population) - Risk Difference
Study: Pooled
Subgroup: MBL Volume at Baseline (mL)



Results are based on a Mantel-Haenszel approach stratified by study using a one-stage fixed-effects IPD meta-analysis.
The reference group is Placebo. Patients with multiple events are counted only once. MedDRA (version 22.0).
N: Number of patients in treatment group; NETA: Norethindrone acetate; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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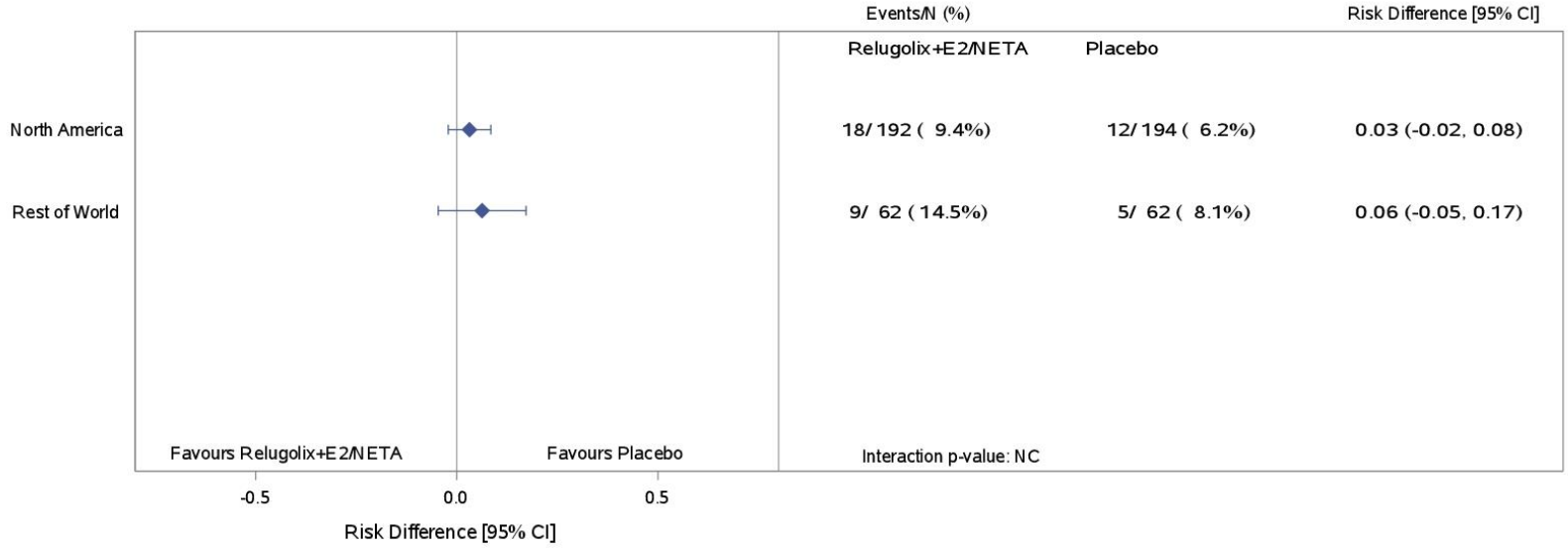
Figure SAF.VASOANY.ANY.S6.BIN.FP.RD: Proportion of Patients With at Least One Vasomotor Symptom Event, by Subgroup (Safety Population) - Risk Difference
Study: Pooled
Subgroup: Geographic Region I



Results are based on a Mantel-Haenszel approach stratified by study using a one-stage fixed-effects IPD meta-analysis.
The reference group is Placebo. Patients with multiple events are counted only once. MedDRA (version 22.0).
N: Number of patients in treatment group; NETA: Norethindrone acetate; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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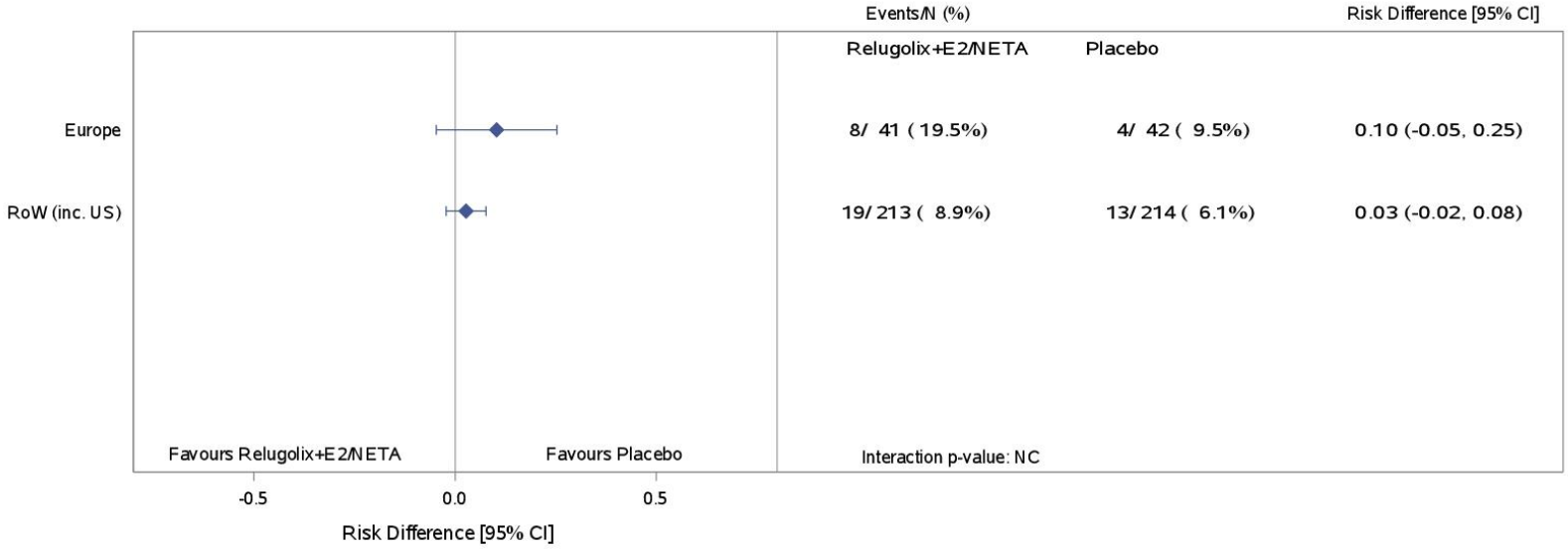
Figure SAF.VASOANY.ANY.S7.BIN.FP.RD: Proportion of Patients With at Least One Vasomotor Symptom Event, by Subgroup (Safety Population) - Risk Difference
Study: Pooled
Subgroup: Geographic Region II



Results are based on a Mantel-Haenszel approach stratified by study using a one-stage fixed-effects IPD meta-analysis.
The reference group is Placebo. Patients with multiple events are counted only once. MedDRA (version 22.0).
N: Number of patients in treatment group; NETA: Norethindrone acetate; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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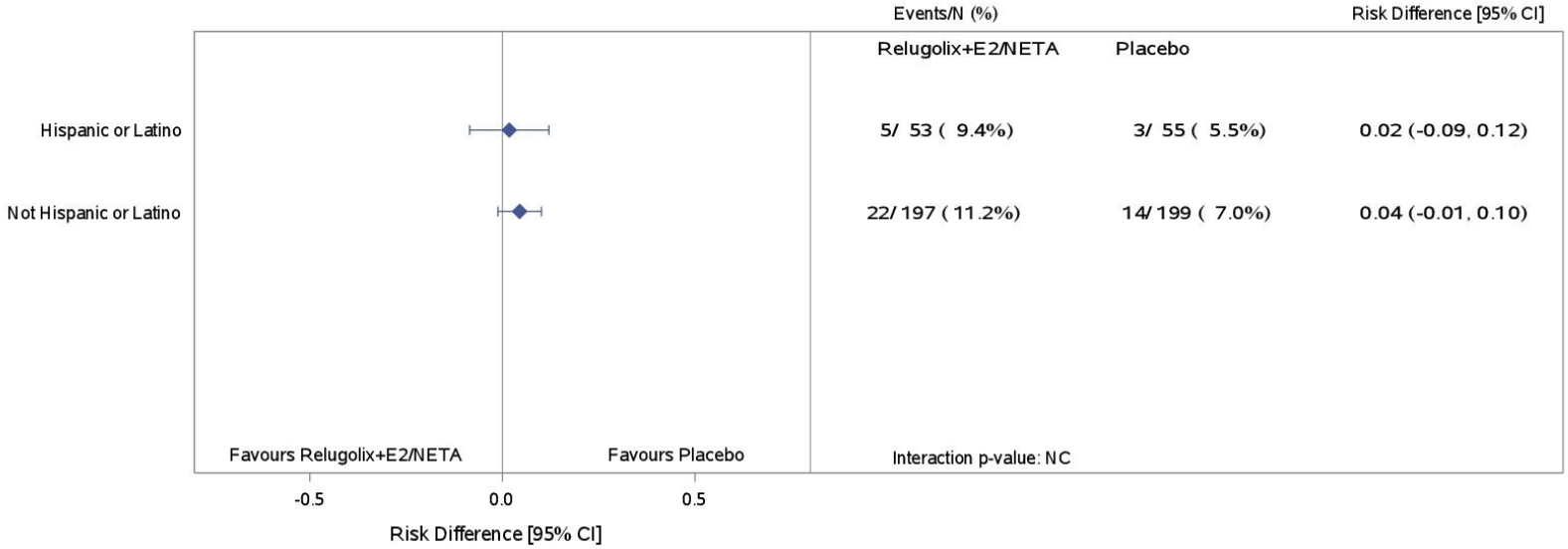
Figure SAF.VASOANY.ANY.S8.BIN.FP.RD: Proportion of Patients With at Least One Vasomotor Symptom Event, by Subgroup (Safety Population) - Risk Difference
Study: Pooled
Subgroup: Ethnicity



Results are based on a Mantel-Haenszel approach stratified by study using a one-stage fixed-effects IPD meta-analysis.
The reference group is Placebo. Patients with multiple events are counted only once. MedDRA (version 22.0).
N: Number of patients in treatment group; NETA: Norethindrone acetate; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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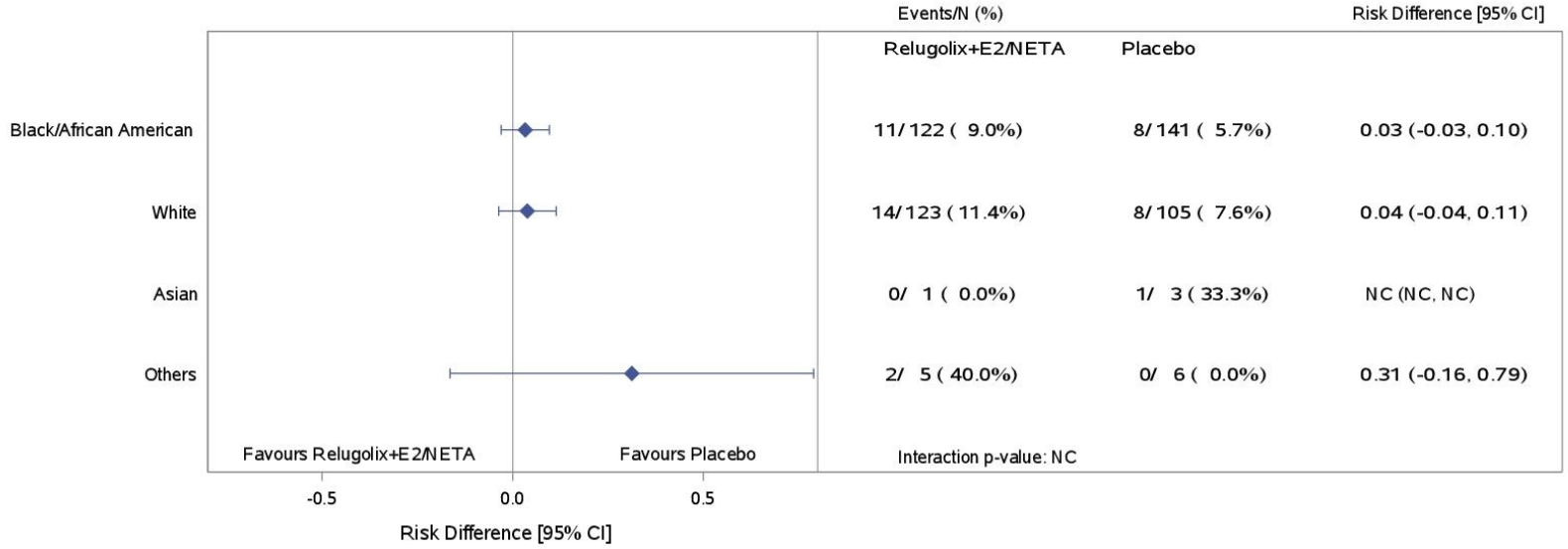
Figure SAF.VASOANY.ANY.S9.BIN.FP.RD: Proportion of Patients With at Least One Vasomotor Symptom Event, by Subgroup (Safety Population) - Risk Difference
Study: Pooled
Subgroup: Race



Results are based on a Mantel-Haenszel approach stratified by study using a one-stage fixed-effects IPD meta-analysis.
The reference group is Placebo. Patients with multiple events are counted only once. MedDRA (version 22.0).
N: Number of patients in treatment group; NETA: Norethindrone acetate; MBL: Menstrual Blood Loss; IPD: Individual Patient Data; NC: Not Calculated.

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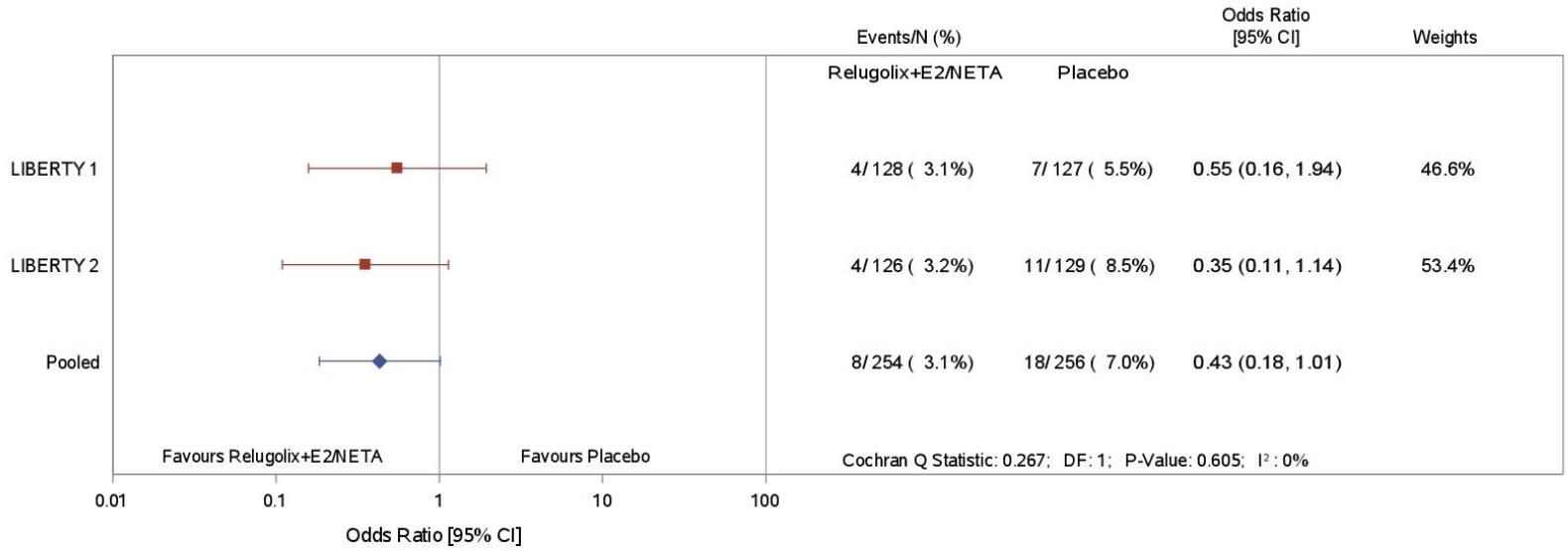
3 Meta-analytische Zusammenfassung der UE unabhängig vom Schweregrad auf Ebene der SOC und PT – Forest Plots

3.1 Odds Ratio

Figure SAF.TEAE.SPT.BIN.FP: Frequent Treatment Emergent Adverse Events by System Organ Class and Preferred Term (Safety Population)
System Organ Class: Blood and lymphatic system disorders, Preferred Term: Any



Results are based on logistic regression models. The analysis of LIBERTY 1 and LIBERTY 2 was adjusted for treatment group. The pooled analysis was also adjusted for study as a fixed effect. The reference group is Placebo. Patients with multiple events for a given PT or SOC are counted only once for each PT and SOC. Only SOCs or PTs for which there are at least 10% of patients with an event in at least one treatment group OR at least 10 patients with an event overall and at least 1% of patients with an event in at least one treatment group for the pooled analysis are presented. Events are sorted by SOC alphabetically and then by decreasing frequency of PT in the Relugolix+E2/NETA group for the pooled analysis. MedDRA (version 22.0).
A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
Relative weights are based on an inverse variance approach.
N: Number of patients in treatment group; NETA: Norethindrone acetate; DF: Degrees of freedom; IPD: Individual Patient Data.

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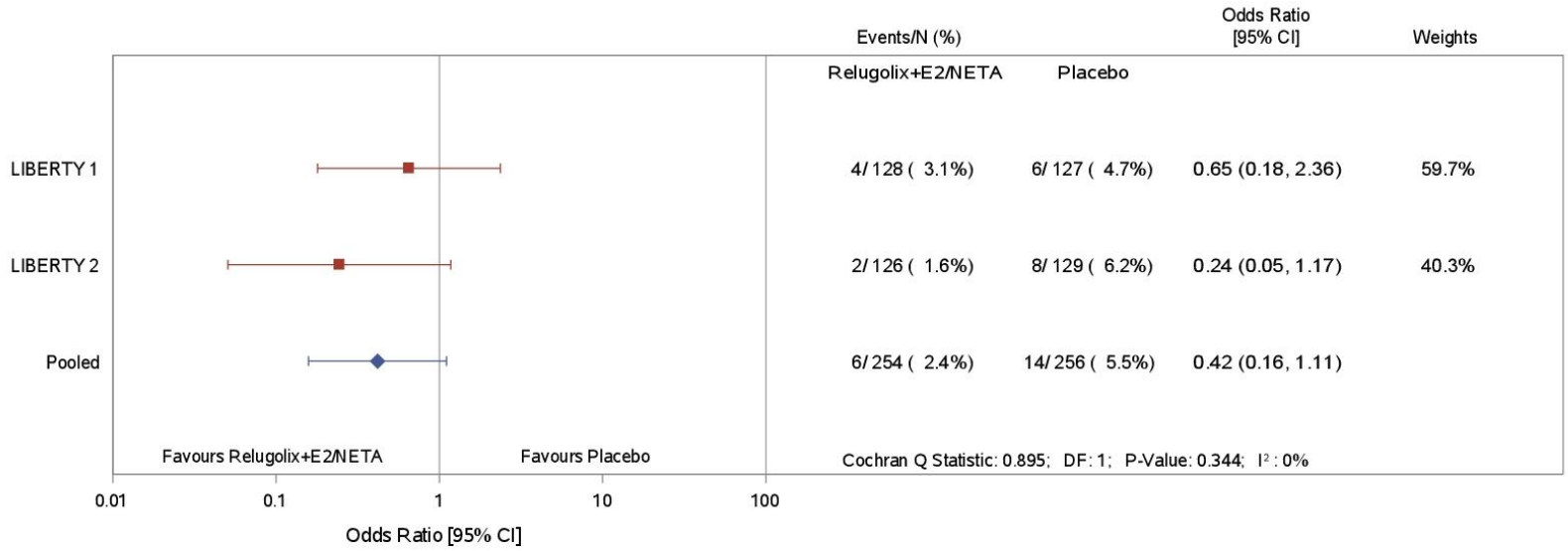
Figure SAF.TEAE.SPT.BIN.FP: Frequent Treatment Emergent Adverse Events by System Organ Class and Preferred Term (Safety Population)
System Organ Class: Blood and lymphatic system disorders, Preferred Term: Anaemia



Results are based on logistic regression models. The analysis of LIBERTY 1 and LIBERTY 2 was adjusted for treatment group. The pooled analysis was also adjusted for study as a fixed effect. The reference group is Placebo. Patients with multiple events for a given PT or SOC are counted only once for each PT and SOC. Only SOCs or PTs for which there are at least 10% of patients with an event in at least one treatment group OR at least 10 patients with an event overall and at least 1% of patients with an event in at least one treatment group for the pooled analysis are presented. Events are sorted by SOC alphabetically and then by decreasing frequency of PT in the Relugolix+E2/NETA group for the pooled analysis. MedDRA (version 22.0).
A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
Relative weights are based on an inverse variance approach.
N: Number of patients in treatment group; NETA: Norethindrone acetate; DF: Degrees of freedom; IPD: Individual Patient Data.

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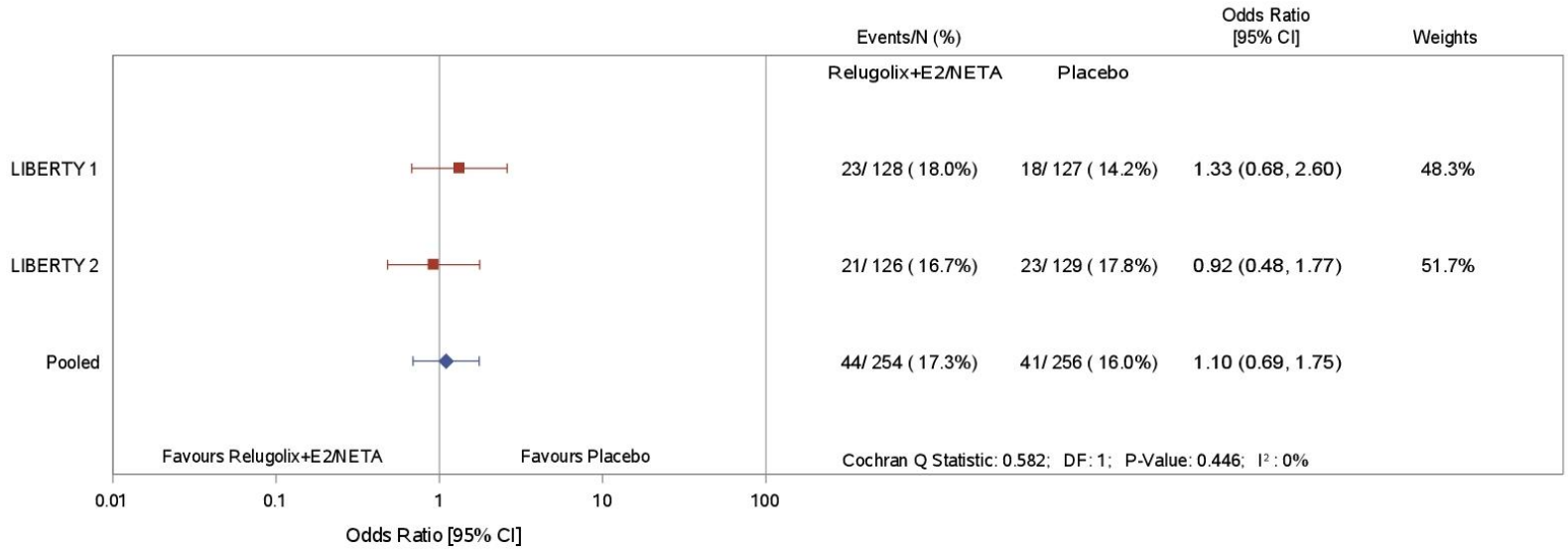
Figure SAF.TEAE.SPT.BIN.FP: Frequent Treatment Emergent Adverse Events by System Organ Class and Preferred Term (Safety Population)
System Organ Class: Gastrointestinal disorders, Preferred Term: Any



Results are based on logistic regression models. The analysis of LIBERTY 1 and LIBERTY 2 was adjusted for treatment group. The pooled analysis was also adjusted for study as a fixed effect. The reference group is Placebo. Patients with multiple events for a given PT or SOC are counted only once for each PT and SOC. Only SOCs or PTs for which there are at least 10% of patients with an event in at least one treatment group OR at least 10 patients with an event overall and at least 1% of patients with an event in at least one treatment group for the pooled analysis are presented. Events are sorted by SOC alphabetically and then by decreasing frequency of PT in the Relugolix+E2/NETA group for the pooled analysis. MedDRA (version 22.0).
A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
Relative weights are based on an inverse variance approach.
N: Number of patients in treatment group; NETA: Norethindrone acetate; DF: Degrees of freedom; IPD: Individual Patient Data.

SOURCE: X:\Numerus\Studies\MYV\MYV102\Analysis\Prod\Progs\TFLs\Fig_SAF_AE_SPT_BIN_FP.SAS Date/time of run: 28JUN21 16:01
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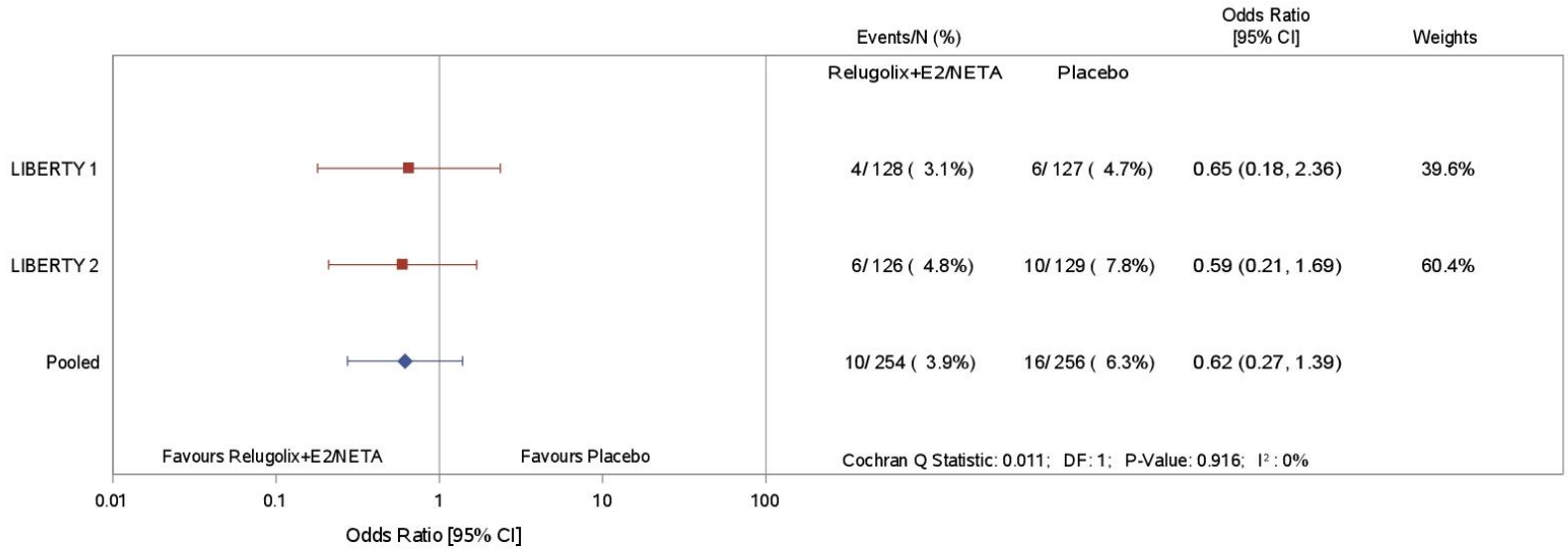
Figure SAF.TEAE.SPT.BIN.FP: Frequent Treatment Emergent Adverse Events by System Organ Class and Preferred Term (Safety Population)
System Organ Class: Gastrointestinal disorders, Preferred Term: Nausea



Results are based on logistic regression models. The analysis of LIBERTY 1 and LIBERTY 2 was adjusted for treatment group. The pooled analysis was also adjusted for study as a fixed effect. The reference group is Placebo. Patients with multiple events for a given PT or SOC are counted only once for each PT and SOC. Only SOCs or PTs for which there are at least 10% of patients with an event in at least one treatment group OR at least 10 patients with an event overall and at least 1% of patients with an event in at least one treatment group for the pooled analysis are presented. Events are sorted by SOC alphabetically and then by decreasing frequency of PT in the Relugolix+E2/NETA group for the pooled analysis. MedDRA (version 22.0).
A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
Relative weights are based on an inverse variance approach.
N: Number of patients in treatment group; NETA: Norethindrone acetate; DF: Degrees of freedom; IPD: Individual Patient Data.

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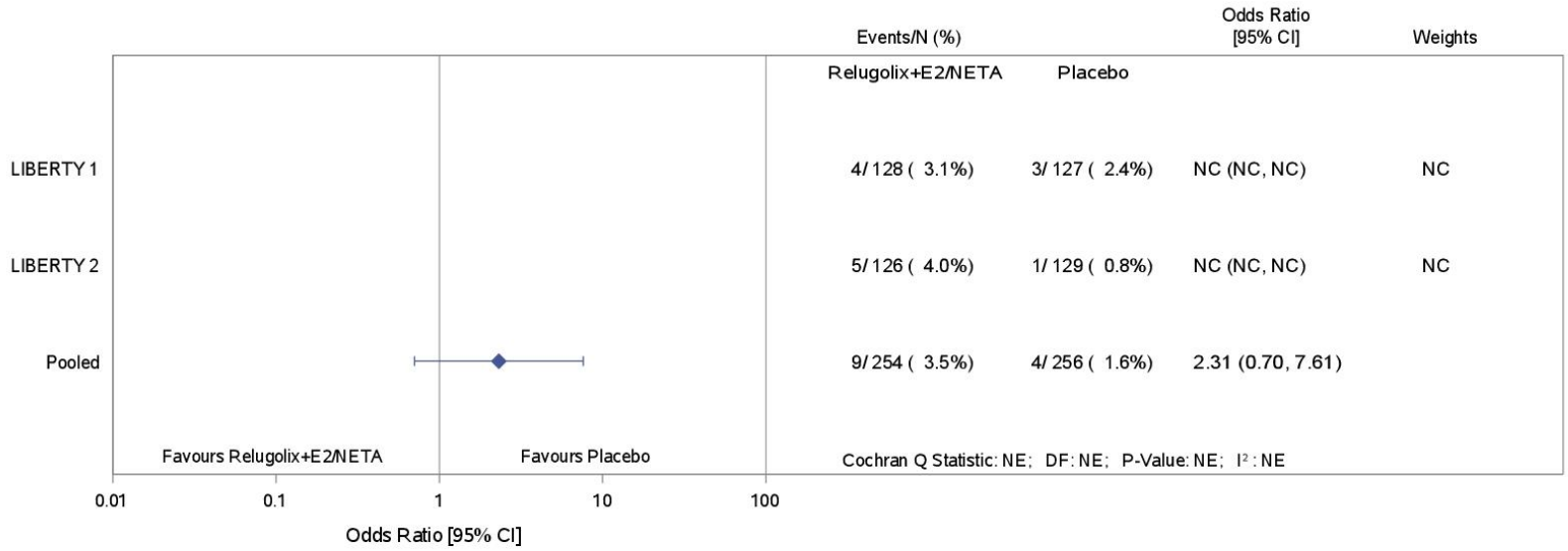
Figure SAF.TEAE.SPT.BIN.FP: Frequent Treatment Emergent Adverse Events by System Organ Class and Preferred Term (Safety Population)
System Organ Class: Gastrointestinal disorders, Preferred Term: Abdominal pain



Results are based on logistic regression models. The analysis of LIBERTY 1 and LIBERTY 2 was adjusted for treatment group. The pooled analysis was also adjusted for study as a fixed effect. The reference group is Placebo. Patients with multiple events for a given PT or SOC are counted only once for each PT and SOC. Only SOCs or PTs for which there are at least 10% of patients with an event in at least one treatment group OR at least 10 patients with an event overall and at least 1% of patients with an event in at least one treatment group for the pooled analysis are presented. Events are sorted by SOC alphabetically and then by decreasing frequency of PT in the Relugolix+E2/NETA group for the pooled analysis. MedDRA (version 22.0).
A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
Relative weights are based on an inverse variance approach.
N: Number of patients in treatment group; NETA: Norethindrone acetate; DF: Degrees of freedom; IPD: Individual Patient Data. NC: Not calculated. NE: Non-estimable.

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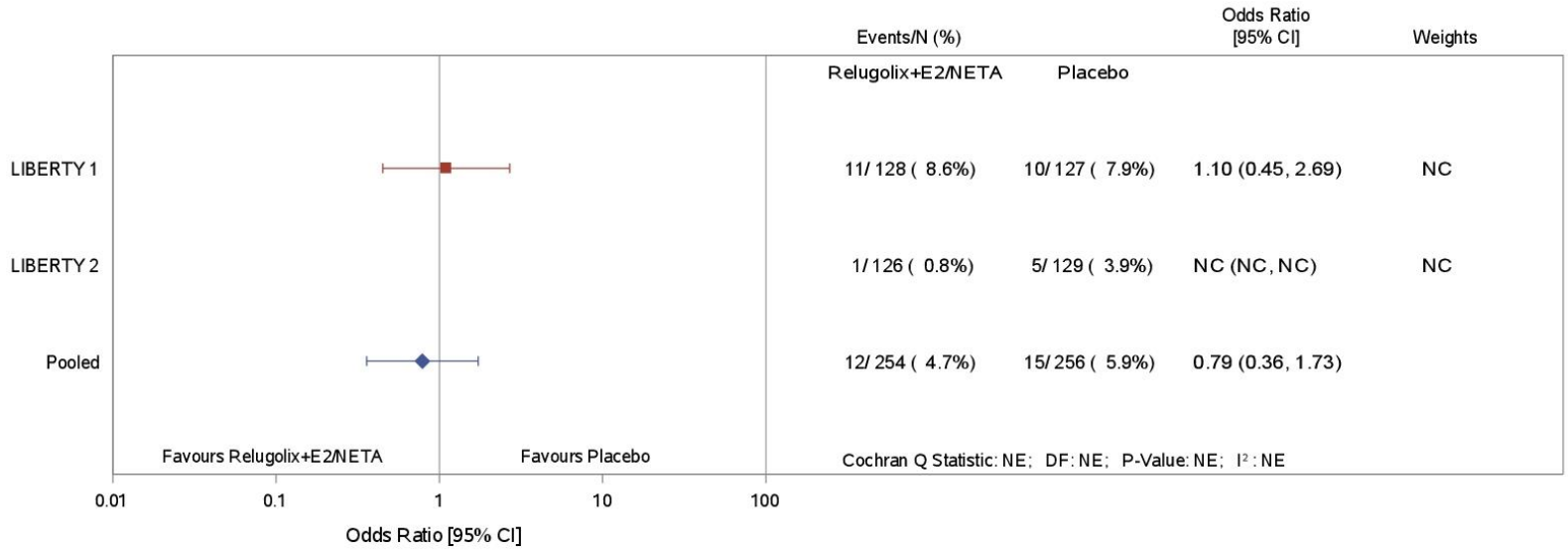
Figure SAF.TEAE.SPT.BIN.FP: Frequent Treatment Emergent Adverse Events by System Organ Class and Preferred Term (Safety Population)
System Organ Class: General disorders and administration site conditions, Preferred Term: Any



Results are based on logistic regression models. The analysis of LIBERTY 1 and LIBERTY 2 was adjusted for treatment group. The pooled analysis was also adjusted for study as a fixed effect. The reference group is Placebo. Patients with multiple events for a given PT or SOC are counted only once for each PT and SOC. Only SOCs or PTs for which there are at least 10% of patients with an event in at least one treatment group OR at least 10 patients with an event overall and at least 1% of patients with an event in at least one treatment group for the pooled analysis are presented. Events are sorted by SOC alphabetically and then by decreasing frequency of PT in the Relugolix+E2/NETA group for the pooled analysis. MedDRA (version 22.0).
A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
Relative weights are based on an inverse variance approach.
N: Number of patients in treatment group; NETA: Norethindrone acetate; DF: Degrees of freedom; IPD: Individual Patient Data. NC: Not calculated. NE: Non-estimable.

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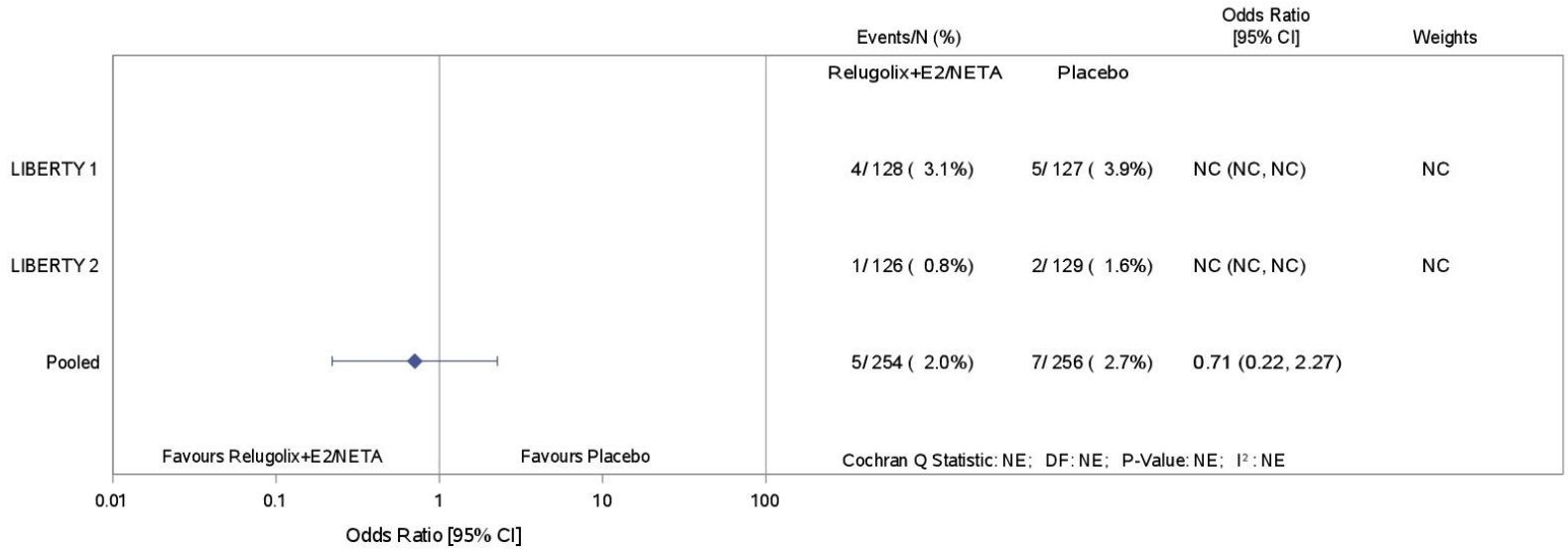
Figure SAF.TEAE.SPT.BIN.FP: Frequent Treatment Emergent Adverse Events by System Organ Class and Preferred Term (Safety Population)
System Organ Class: General disorders and administration site conditions, Preferred Term: Fatigue



Results are based on logistic regression models. The analysis of LIBERTY 1 and LIBERTY 2 was adjusted for treatment group. The pooled analysis was also adjusted for study as a fixed effect. The reference group is Placebo. Patients with multiple events for a given PT or SOC are counted only once for each PT and SOC. Only SOCs or PTs for which there are at least 10% of patients with an event in at least one treatment group OR at least 10 patients with an event overall and at least 1% of patients with an event in at least one treatment group for the pooled analysis are presented. Events are sorted by SOC alphabetically and then by decreasing frequency of PT in the Relugolix+E2/NETA group for the pooled analysis. MedDRA (version 22.0).
A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
Relative weights are based on an inverse variance approach.
N: Number of patients in treatment group; NETA: Norethindrone acetate; DF: Degrees of freedom; IPD: Individual Patient Data. NC: Not calculated. NE: Non-estimable.

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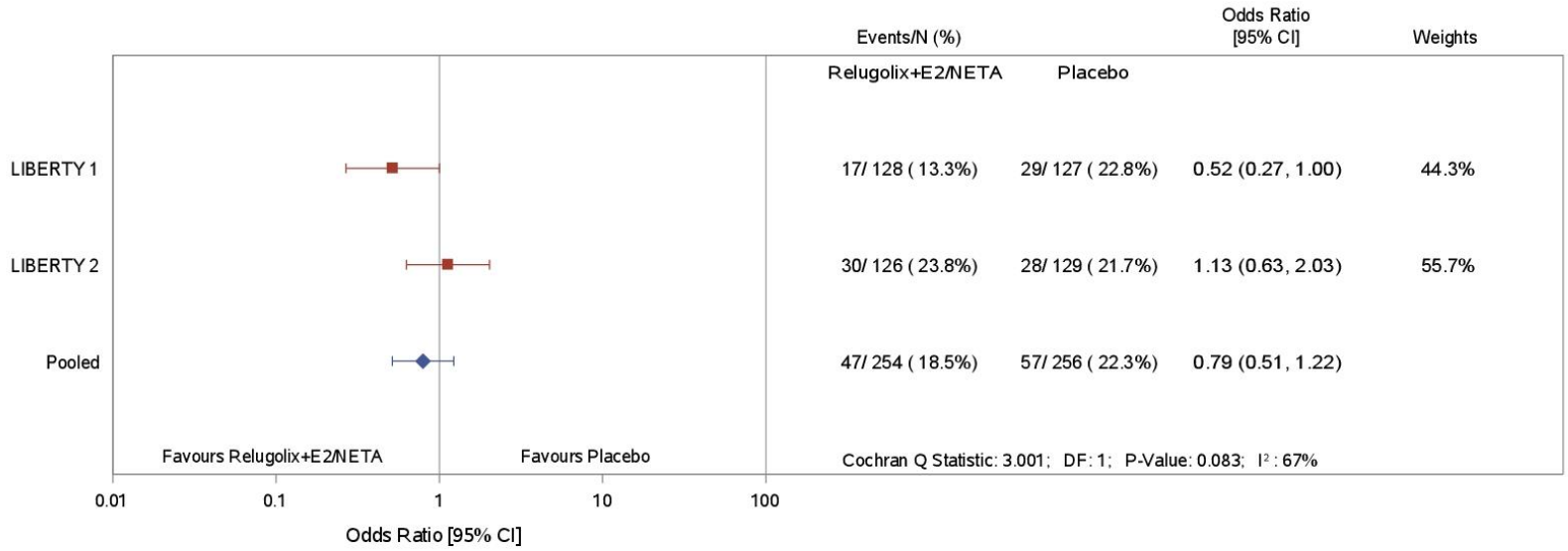
Figure SAF.TEAE.SPT.BIN.FP: Frequent Treatment Emergent Adverse Events by System Organ Class and Preferred Term (Safety Population)
System Organ Class: Infections and infestations, Preferred Term: Any



Results are based on logistic regression models. The analysis of LIBERTY 1 and LIBERTY 2 was adjusted for treatment group. The pooled analysis was also adjusted for study as a fixed effect. The reference group is Placebo. Patients with multiple events for a given PT or SOC are counted only once for each PT and SOC. Only SOCs or PTs for which there are at least 10% of patients with an event in at least one treatment group OR at least 10 patients with an event overall and at least 1% of patients with an event in at least one treatment group for the pooled analysis are presented. Events are sorted by SOC alphabetically and then by decreasing frequency of PT in the Relugolix+E2/NETA group for the pooled analysis. MedDRA (version 22.0).
A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
Relative weights are based on an inverse variance approach.
N: Number of patients in treatment group; NETA: Norethindrone acetate; DF: Degrees of freedom; IPD: Individual Patient Data.

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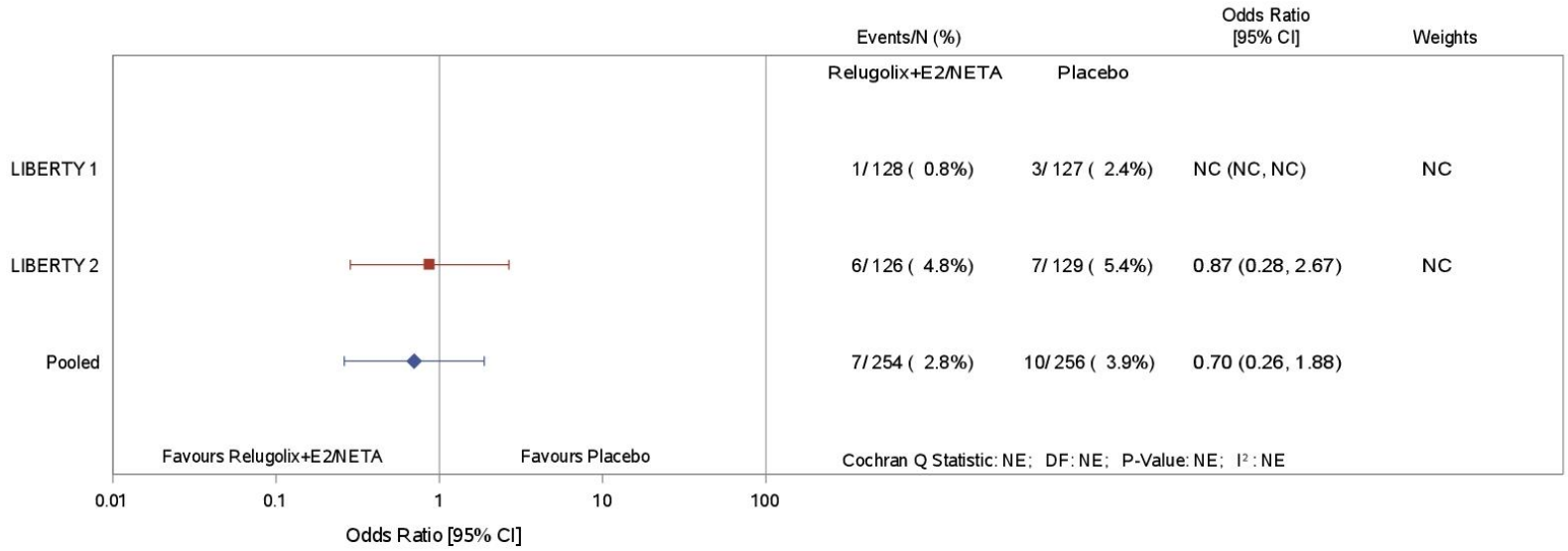
Figure SAF.TEAE.SPT.BIN.FP: Frequent Treatment Emergent Adverse Events by System Organ Class and Preferred Term (Safety Population)
System Organ Class: Infections and infestations, Preferred Term: Upper respiratory tract infection



Results are based on logistic regression models. The analysis of LIBERTY 1 and LIBERTY 2 was adjusted for treatment group. The pooled analysis was also adjusted for study as a fixed effect. The reference group is Placebo. Patients with multiple events for a given PT or SOC are counted only once for each PT and SOC. Only SOCs or PTs for which there are at least 10% of patients with an event in at least one treatment group OR at least 10 patients with an event overall and at least 1% of patients with an event in at least one treatment group for the pooled analysis are presented. Events are sorted by SOC alphabetically and then by decreasing frequency of PT in the Relugolix+E2/NETA group for the pooled analysis. MedDRA (version 22.0).
A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
Relative weights are based on an inverse variance approach.
N: Number of patients in treatment group; NETA: Norethindrone acetate; DF: Degrees of freedom; IPD: Individual Patient Data. NC: Not calculated. NE: Non-estimable.

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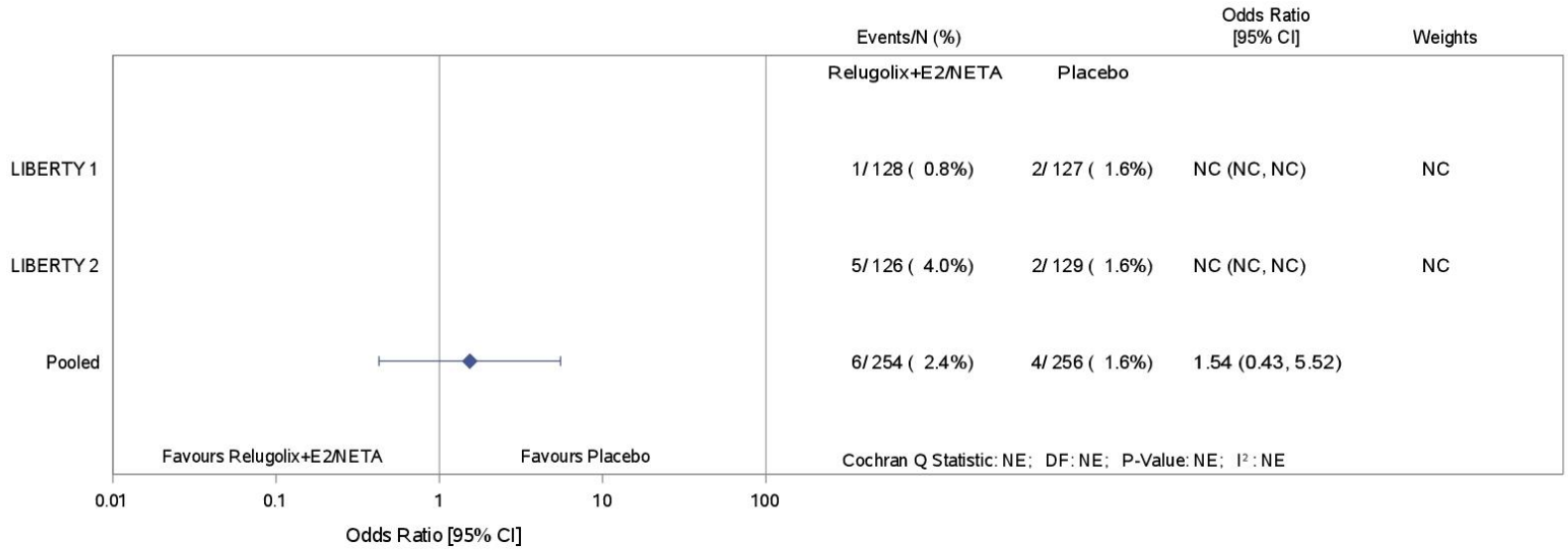
Figure SAF.TEAE.SPT.BIN.FP: Frequent Treatment Emergent Adverse Events by System Organ Class and Preferred Term (Safety Population)
System Organ Class: Infections and infestations, Preferred Term: Bronchitis



Results are based on logistic regression models. The analysis of LIBERTY 1 and LIBERTY 2 was adjusted for treatment group. The pooled analysis was also adjusted for study as a fixed effect. The reference group is Placebo. Patients with multiple events for a given PT or SOC are counted only once for each PT and SOC. Only SOCs or PTs for which there are at least 10% of patients with an event in at least one treatment group OR at least 10 patients with an event overall and at least 1% of patients with an event in at least one treatment group for the pooled analysis are presented. Events are sorted by SOC alphabetically and then by decreasing frequency of PT in the Relugolix+E2/NETA group for the pooled analysis. MedDRA (version 22.0).
A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
Relative weights are based on an inverse variance approach.
N: Number of patients in treatment group; NETA: Norethindrone acetate; DF: Degrees of freedom; IPD: Individual Patient Data. NC: Not calculated. NE: Non-estimable.

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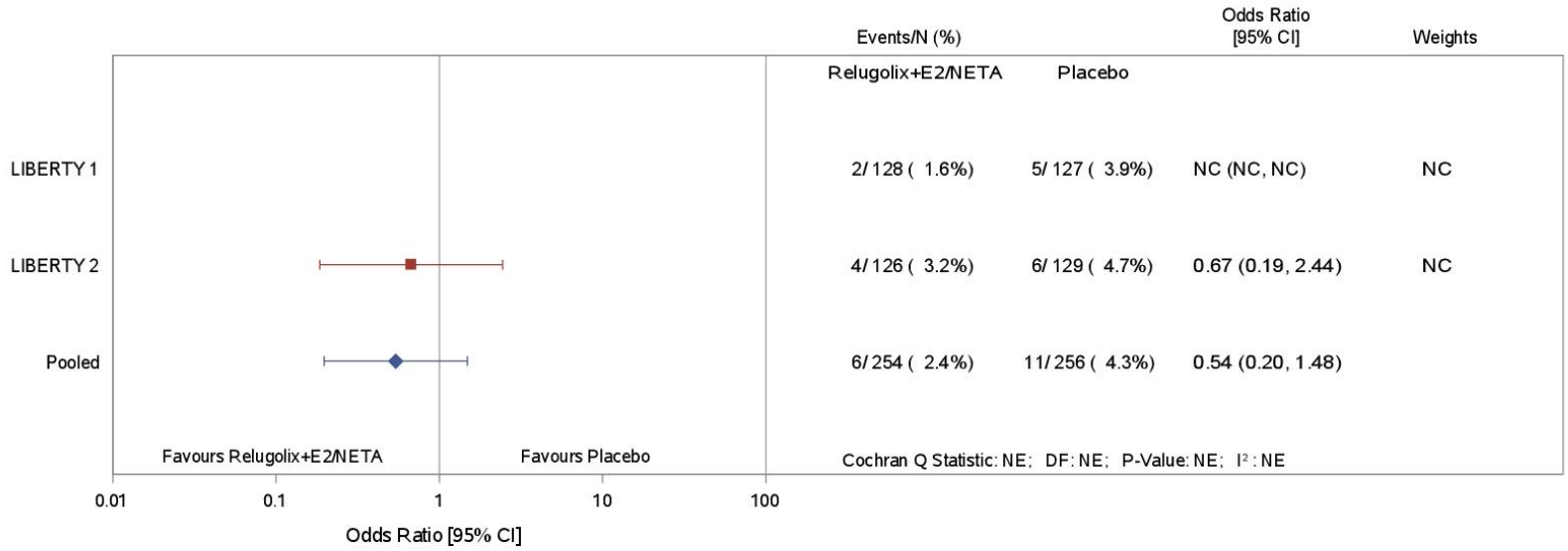
Figure SAF.TEAE.SPT.BIN.FP: Frequent Treatment Emergent Adverse Events by System Organ Class and Preferred Term (Safety Population)
System Organ Class: Infections and infestations, Preferred Term: Nasopharyngitis



Results are based on logistic regression models. The analysis of LIBERTY 1 and LIBERTY 2 was adjusted for treatment group. The pooled analysis was also adjusted for study as a fixed effect. The reference group is Placebo. Patients with multiple events for a given PT or SOC are counted only once for each PT and SOC. Only SOCs or PTs for which there are at least 10% of patients with an event in at least one treatment group OR at least 10 patients with an event overall and at least 1% of patients with an event in at least one treatment group for the pooled analysis are presented. Events are sorted by SOC alphabetically and then by decreasing frequency of PT in the Relugolix+E2/NETA group for the pooled analysis. MedDRA (version 22.0).
A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
Relative weights are based on an inverse variance approach.
N: Number of patients in treatment group; NETA: Norethindrone acetate; DF: Degrees of freedom; IPD: Individual Patient Data. NC: Not calculated. NE: Non-estimable.

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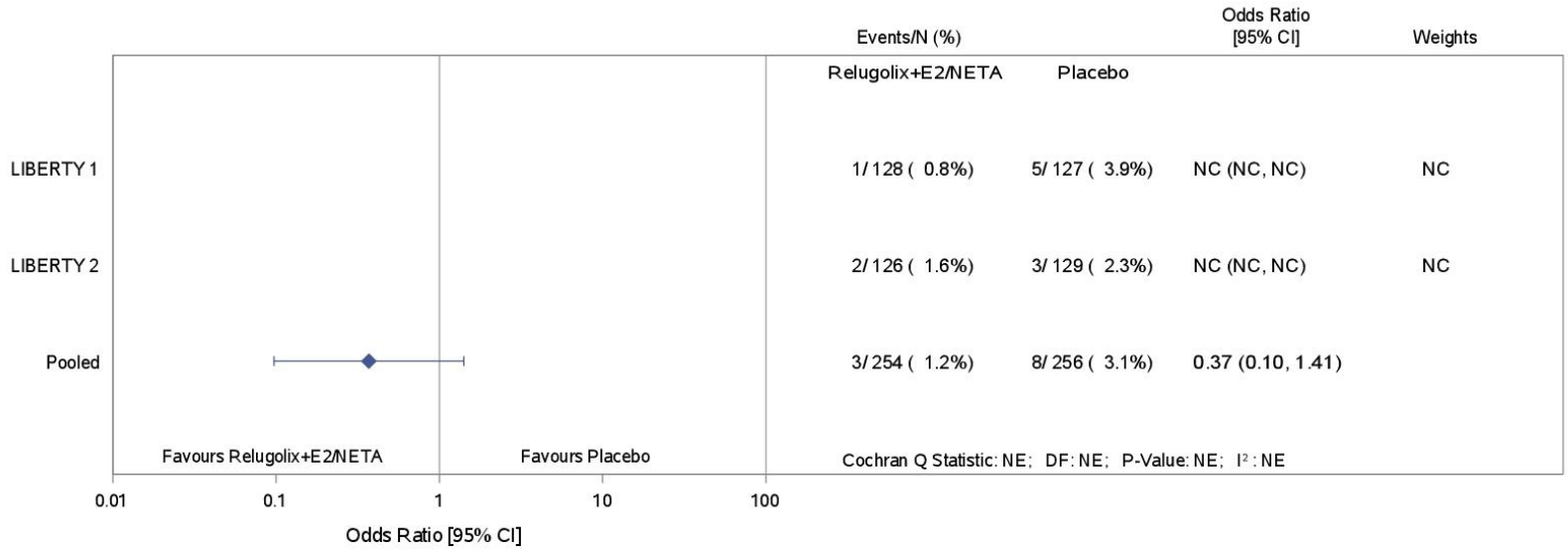
Figure SAF.TEAE.SPT.BIN.FP: Frequent Treatment Emergent Adverse Events by System Organ Class and Preferred Term (Safety Population)
System Organ Class: Infections and infestations, Preferred Term: Urinary tract infection



Results are based on logistic regression models. The analysis of LIBERTY 1 and LIBERTY 2 was adjusted for treatment group. The pooled analysis was also adjusted for study as a fixed effect. The reference group is Placebo. Patients with multiple events for a given PT or SOC are counted only once for each PT and SOC. Only SOCs or PTs for which there are at least 10% of patients with an event in at least one treatment group OR at least 10 patients with an event overall and at least 1% of patients with an event in at least one treatment group for the pooled analysis are presented. Events are sorted by SOC alphabetically and then by decreasing frequency of PT in the Relugolix+E2/NETA group for the pooled analysis. MedDRA (version 22.0).
A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
Relative weights are based on an inverse variance approach.
N: Number of patients in treatment group; NETA: Norethindrone acetate; DF: Degrees of freedom; IPD: Individual Patient Data. NC: Not calculated. NE: Non-estimable.

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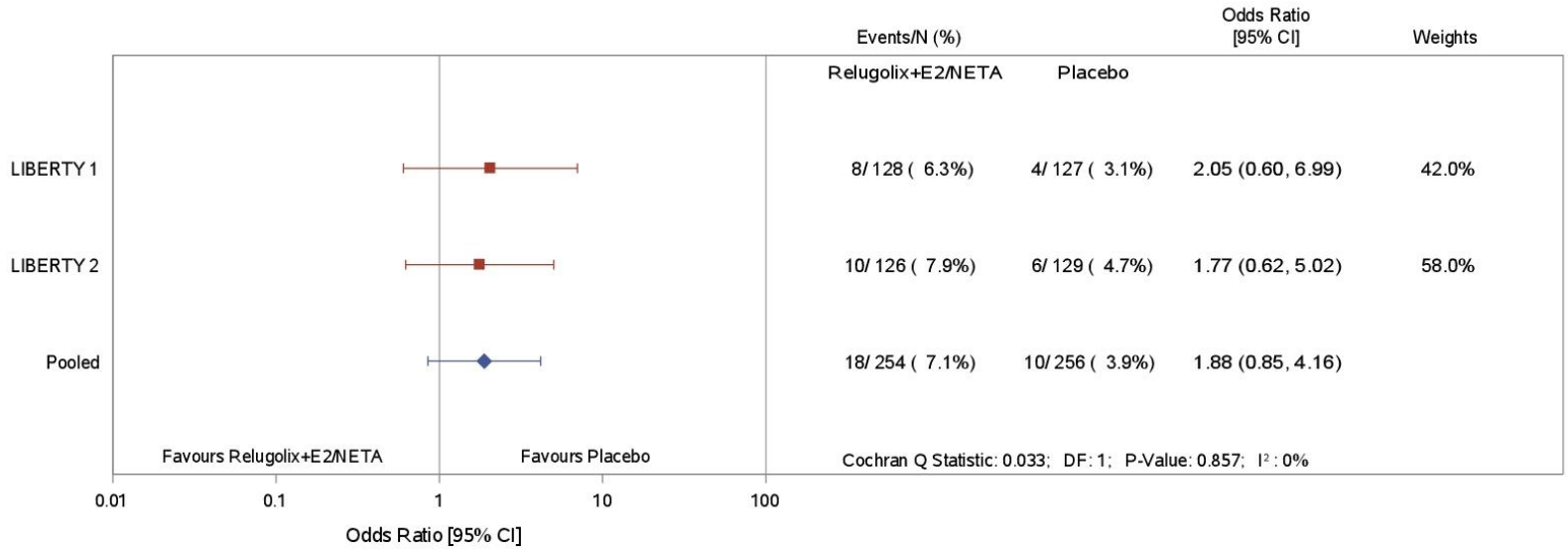
Figure SAF.TEAE.SPT.BIN.FP: Frequent Treatment Emergent Adverse Events by System Organ Class and Preferred Term (Safety Population)
System Organ Class: Injury, poisoning and procedural complications, Preferred Term: Any



Results are based on logistic regression models. The analysis of LIBERTY 1 and LIBERTY 2 was adjusted for treatment group. The pooled analysis was also adjusted for study as a fixed effect. The reference group is Placebo. Patients with multiple events for a given PT or SOC are counted only once for each PT and SOC. Only SOCs or PTs for which there are at least 10% of patients with an event in at least one treatment group OR at least 10 patients with an event overall and at least 1% of patients with an event in at least one treatment group for the pooled analysis are presented. Events are sorted by SOC alphabetically and then by decreasing frequency of PT in the Relugolix+E2/NETA group for the pooled analysis. MedDRA (version 22.0).
A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
Relative weights are based on an inverse variance approach.
N: Number of patients in treatment group; NETA: Norethindrone acetate; DF: Degrees of freedom; IPD: Individual Patient Data.

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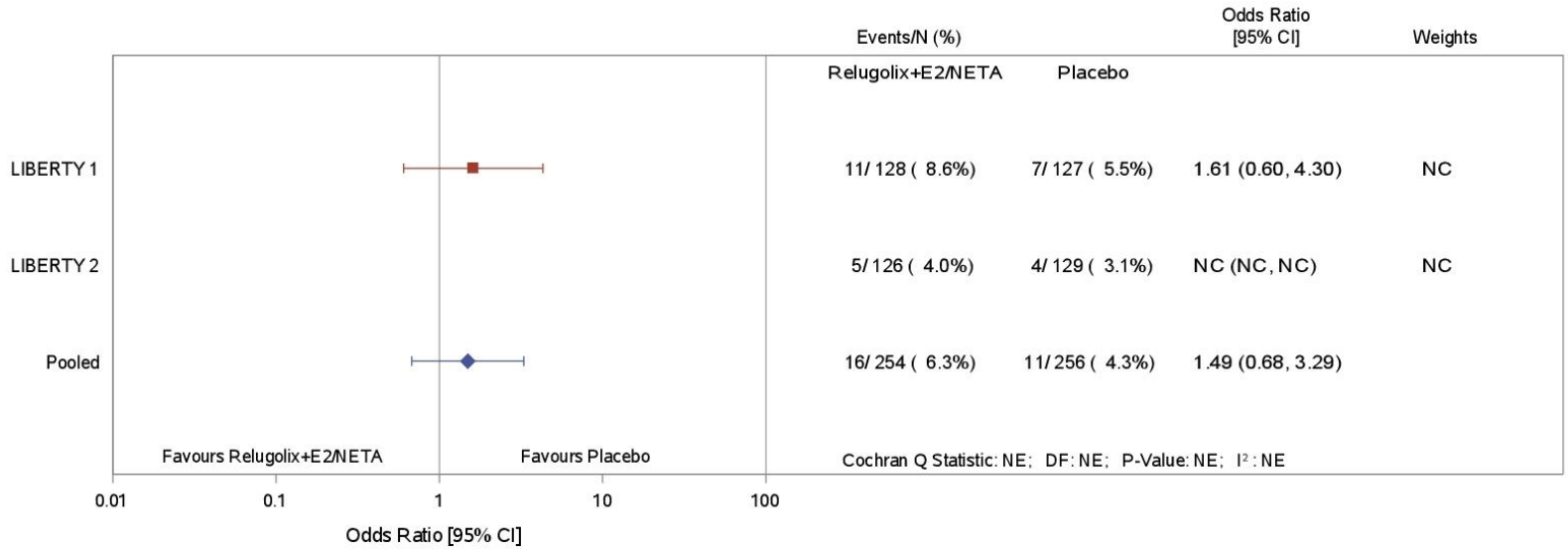
Figure SAF.TEAE.SPT.BIN.FP: Frequent Treatment Emergent Adverse Events by System Organ Class and Preferred Term (Safety Population)
System Organ Class: Investigations, Preferred Term: Any



Results are based on logistic regression models. The analysis of LIBERTY 1 and LIBERTY 2 was adjusted for treatment group. The pooled analysis was also adjusted for study as a fixed effect. The reference group is Placebo. Patients with multiple events for a given PT or SOC are counted only once for each PT and SOC. Only SOCs or PTs for which there are at least 10% of patients with an event in at least one treatment group OR at least 10 patients with an event overall and at least 1% of patients with an event in at least one treatment group for the pooled analysis are presented. Events are sorted by SOC alphabetically and then by decreasing frequency of PT in the Relugolix+E2/NETA group for the pooled analysis. MedDRA (version 22.0).
A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
Relative weights are based on an inverse variance approach.
N: Number of patients in treatment group; NETA: Norethindrone acetate; DF: Degrees of freedom; IPD: Individual Patient Data. NC: Not calculated. NE: Non-estimable.

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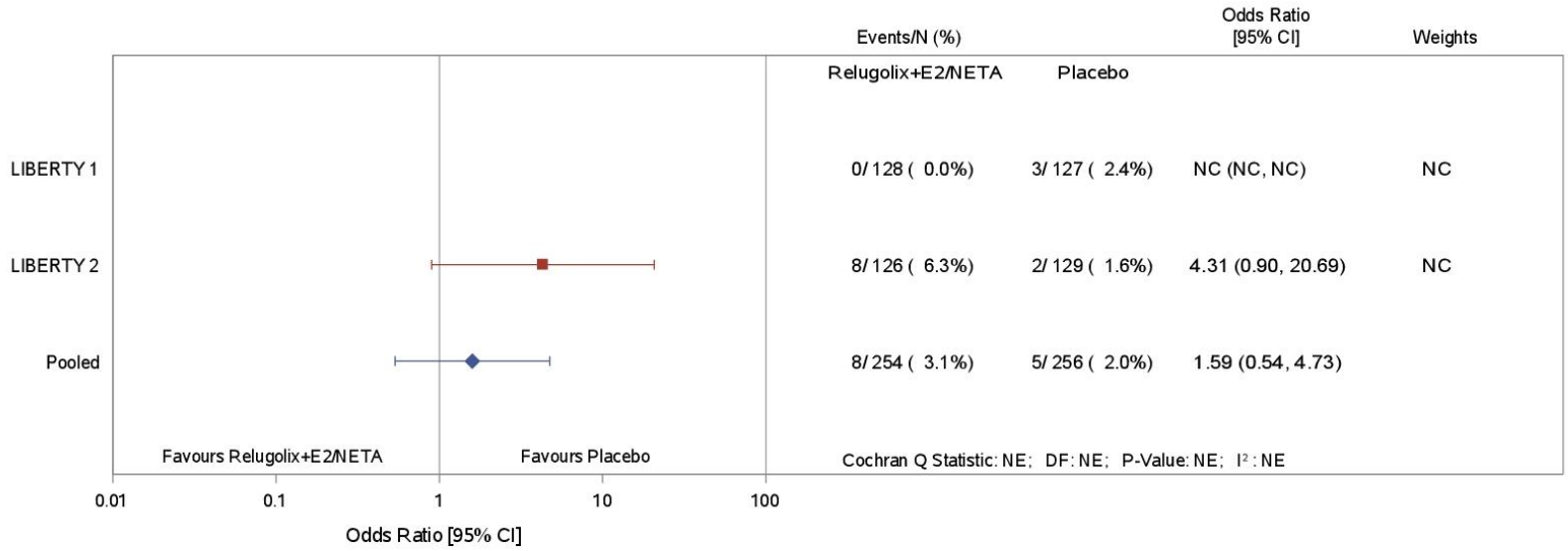
Figure SAF.TEAE.SPT.BIN.FP: Frequent Treatment Emergent Adverse Events by System Organ Class and Preferred Term (Safety Population)
System Organ Class: Metabolism and nutrition disorders, Preferred Term: Any



Results are based on logistic regression models. The analysis of LIBERTY 1 and LIBERTY 2 was adjusted for treatment group. The pooled analysis was also adjusted for study as a fixed effect. The reference group is Placebo. Patients with multiple events for a given PT or SOC are counted only once for each PT and SOC. Only SOCs or PTs for which there are at least 10% of patients with an event in at least one treatment group OR at least 10 patients with an event overall and at least 1% of patients with an event in at least one treatment group for the pooled analysis are presented. Events are sorted by SOC alphabetically and then by decreasing frequency of PT in the Relugolix+E2/NETA group for the pooled analysis. MedDRA (version 22.0).
A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
Relative weights are based on an inverse variance approach.
N: Number of patients in treatment group; NETA: Norethindrone acetate; DF: Degrees of freedom; IPD: Individual Patient Data. NC: Not calculated. NE: Non-estimable.

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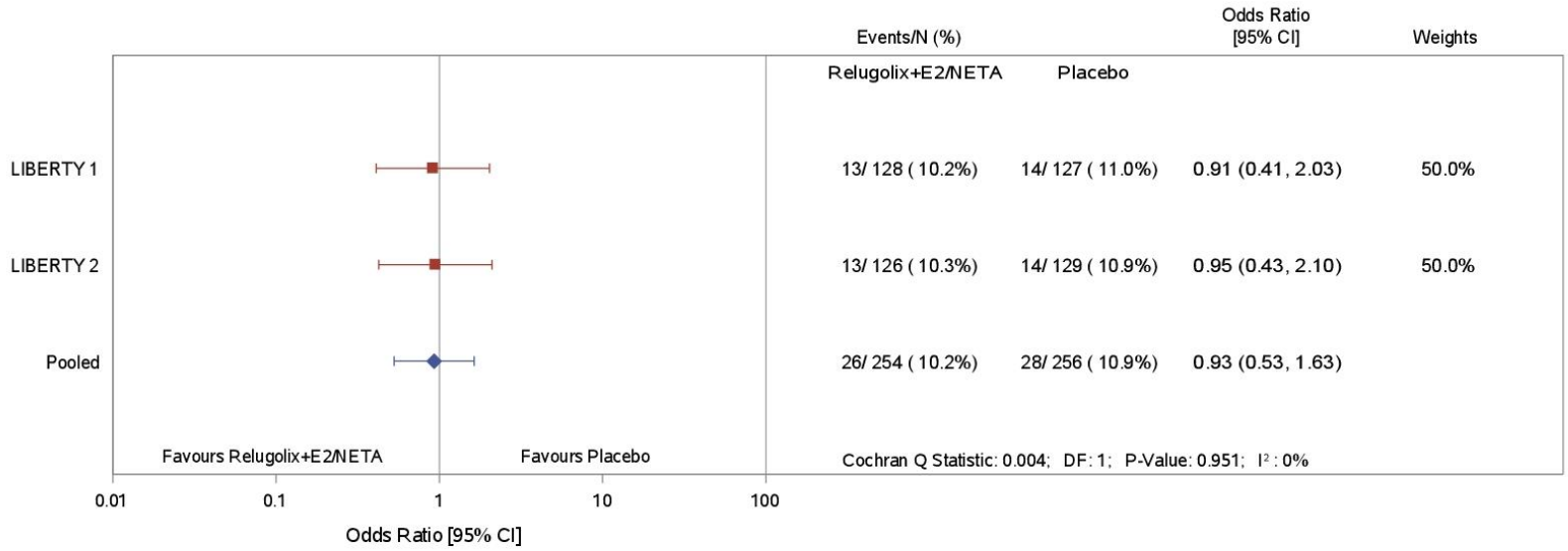
Figure SAF.TEAE.SPT.BIN.FP: Frequent Treatment Emergent Adverse Events by System Organ Class and Preferred Term (Safety Population)
System Organ Class: Musculoskeletal and connective tissue disorders, Preferred Term: Any



Results are based on logistic regression models. The analysis of LIBERTY 1 and LIBERTY 2 was adjusted for treatment group. The pooled analysis was also adjusted for study as a fixed effect. The reference group is Placebo. Patients with multiple events for a given PT or SOC are counted only once for each PT and SOC. Only SOCs or PTs for which there are at least 10% of patients with an event in at least one treatment group OR at least 10 patients with an event overall and at least 1% of patients with an event in at least one treatment group for the pooled analysis are presented. Events are sorted by SOC alphabetically and then by decreasing frequency of PT in the Relugolix+E2/NETA group for the pooled analysis. MedDRA (version 22.0).
A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
Relative weights are based on an inverse variance approach.
N: Number of patients in treatment group; NETA: Norethindrone acetate; DF: Degrees of freedom; IPD: Individual Patient Data.

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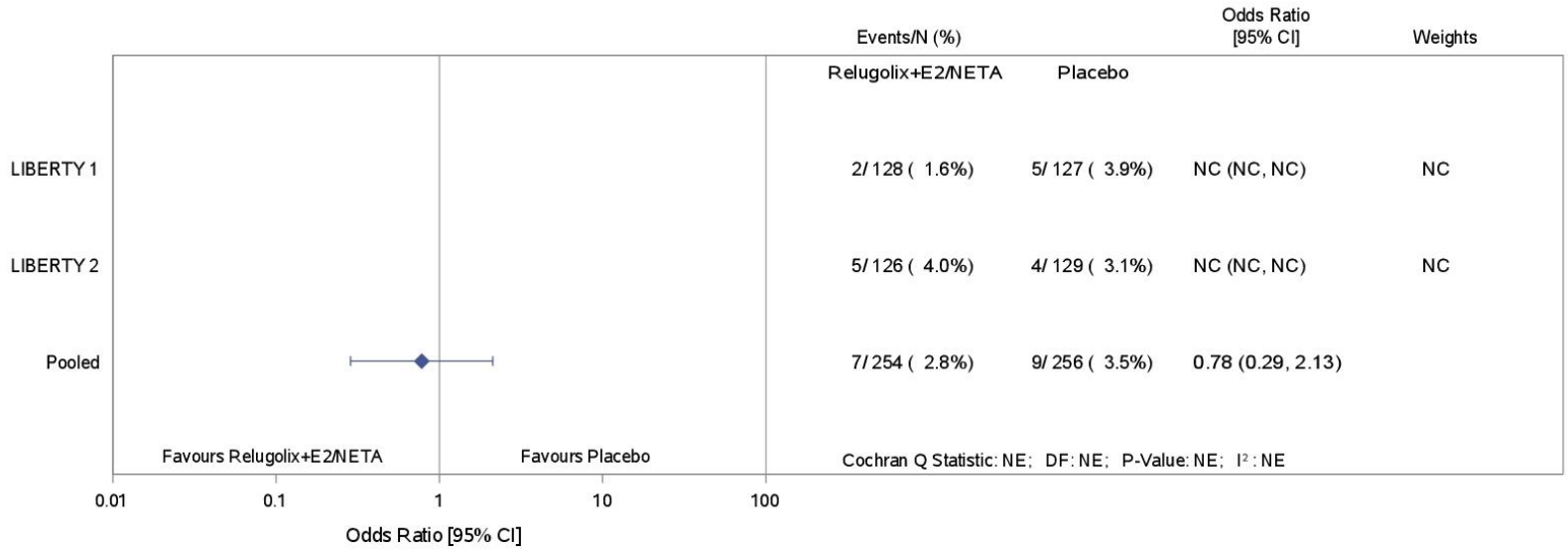
Figure SAF.TEAE.SPT.BIN.FP: Frequent Treatment Emergent Adverse Events by System Organ Class and Preferred Term (Safety Population)
System Organ Class: Musculoskeletal and connective tissue disorders, Preferred Term: Back pain



Results are based on logistic regression models. The analysis of LIBERTY 1 and LIBERTY 2 was adjusted for treatment group. The pooled analysis was also adjusted for study as a fixed effect. The reference group is Placebo. Patients with multiple events for a given PT or SOC are counted only once for each PT and SOC. Only SOCs or PTs for which there are at least 10% of patients with an event in at least one treatment group OR at least 10 patients with an event overall and at least 1% of patients with an event in at least one treatment group for the pooled analysis are presented. Events are sorted by SOC alphabetically and then by decreasing frequency of PT in the Relugolix+E2/NETA group for the pooled analysis. MedDRA (version 22.0).
A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
Relative weights are based on an inverse variance approach.
N: Number of patients in treatment group; NETA: Norethindrone acetate; DF: Degrees of freedom; IPD: Individual Patient Data. NC: Not calculated. NE: Non-estimable.

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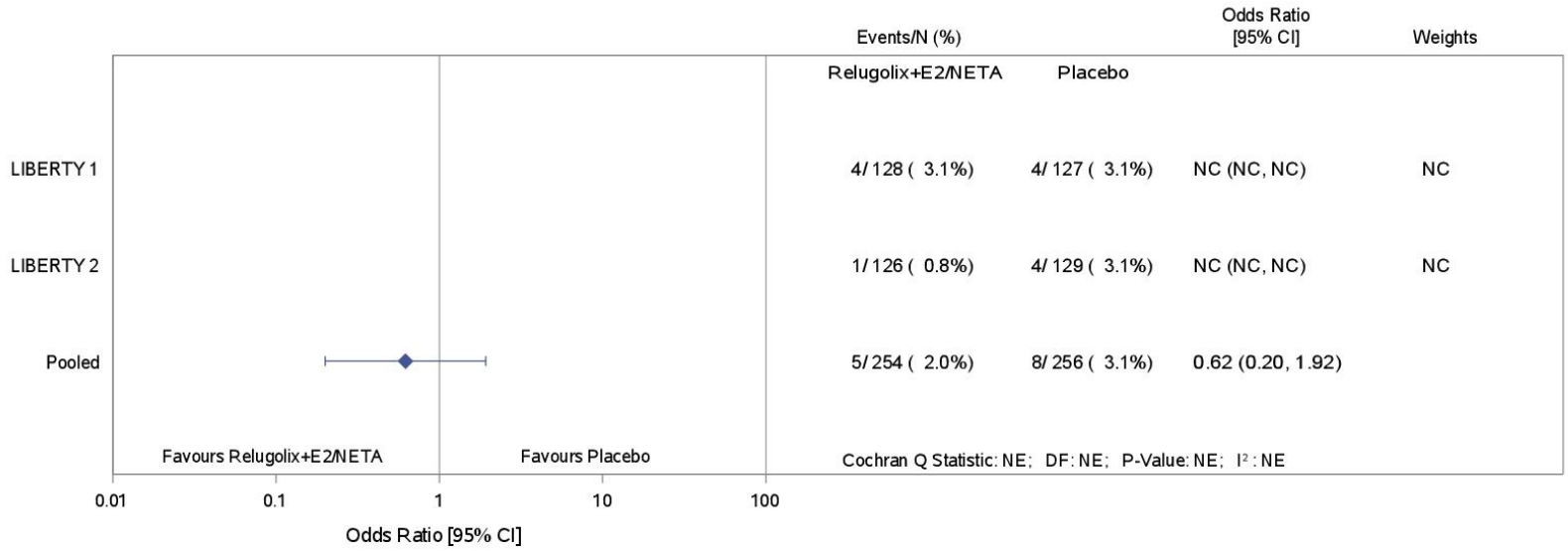
Figure SAF.TEAE.SPT.BIN.FP: Frequent Treatment Emergent Adverse Events by System Organ Class and Preferred Term (Safety Population)
System Organ Class: Musculoskeletal and connective tissue disorders, Preferred Term: Arthralgia



Results are based on logistic regression models. The analysis of LIBERTY 1 and LIBERTY 2 was adjusted for treatment group. The pooled analysis was also adjusted for study as a fixed effect. The reference group is Placebo. Patients with multiple events for a given PT or SOC are counted only once for each PT and SOC. Only SOCs or PTs for which there are at least 10% of patients with an event in at least one treatment group OR at least 10 patients with an event overall and at least 1% of patients with an event in at least one treatment group for the pooled analysis are presented. Events are sorted by SOC alphabetically and then by decreasing frequency of PT in the Relugolix+E2/NETA group for the pooled analysis. MedDRA (version 22.0).
A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
Relative weights are based on an inverse variance approach.
N: Number of patients in treatment group; NETA: Norethindrone acetate; DF: Degrees of freedom; IPD: Individual Patient Data. NC: Not calculated. NE: Non-estimable.

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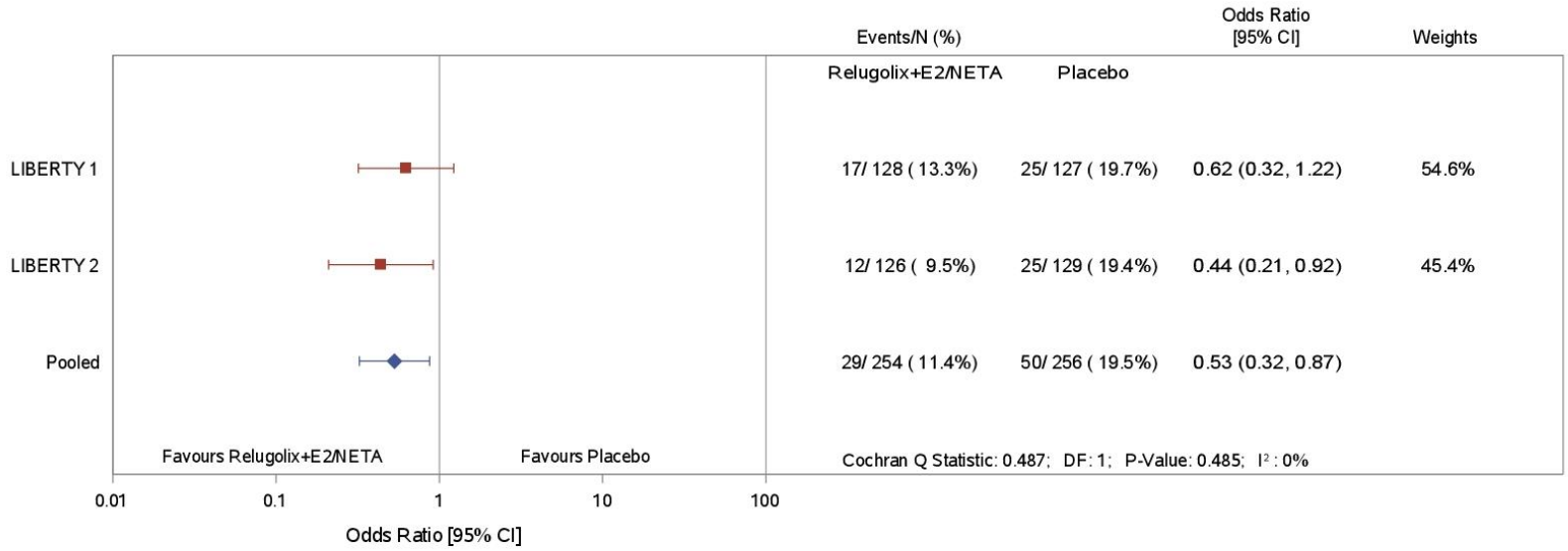
Figure SAF.TEAE.SPT.BIN.FP: Frequent Treatment Emergent Adverse Events by System Organ Class and Preferred Term (Safety Population)
System Organ Class: Nervous system disorders, Preferred Term: Any



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A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
Relative weights are based on an inverse variance approach.
N: Number of patients in treatment group; NETA: Norethindrone acetate; DF: Degrees of freedom; IPD: Individual Patient Data.

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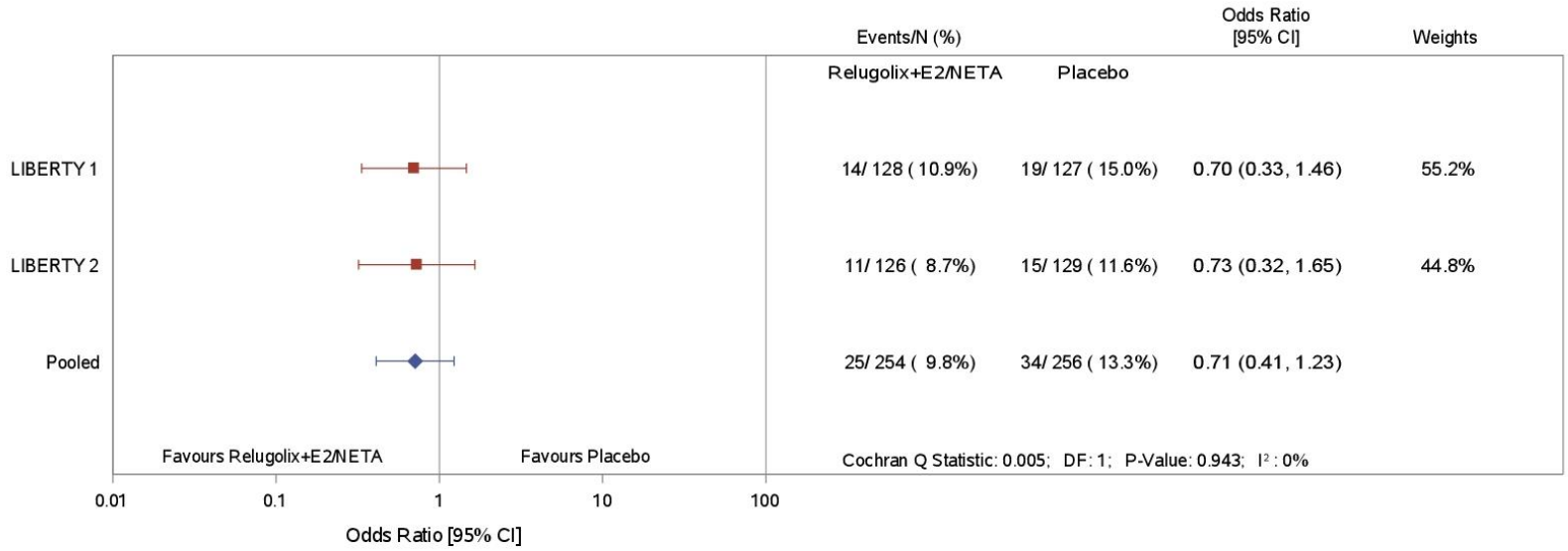
Figure SAF.TEAE.SPT.BIN.FP: Frequent Treatment Emergent Adverse Events by System Organ Class and Preferred Term (Safety Population)
System Organ Class: Nervous system disorders, Preferred Term: Headache



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A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
Relative weights are based on an inverse variance approach.
N: Number of patients in treatment group; NETA: Norethindrone acetate; DF: Degrees of freedom; IPD: Individual Patient Data.

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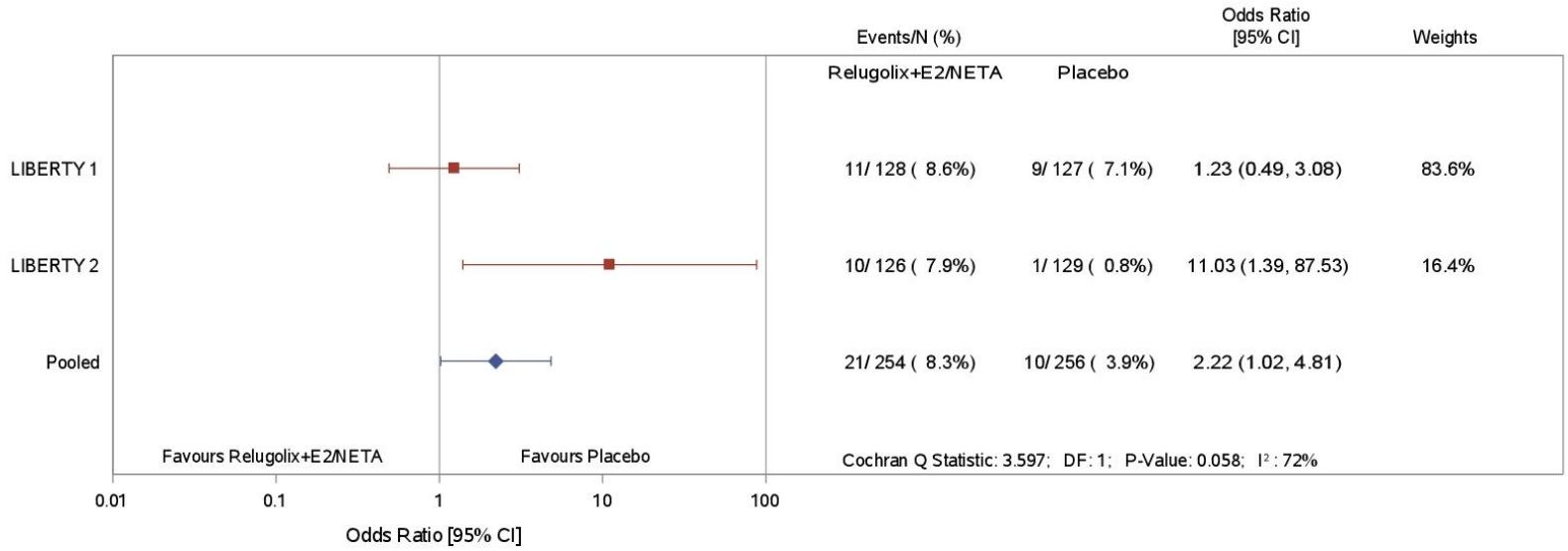
Figure SAF.TEAE.SPT.BIN.FP: Frequent Treatment Emergent Adverse Events by System Organ Class and Preferred Term (Safety Population)
System Organ Class: Psychiatric disorders, Preferred Term: Any



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A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
Relative weights are based on an inverse variance approach.
N: Number of patients in treatment group; NETA: Norethindrone acetate; DF: Degrees of freedom; IPD: Individual Patient Data.

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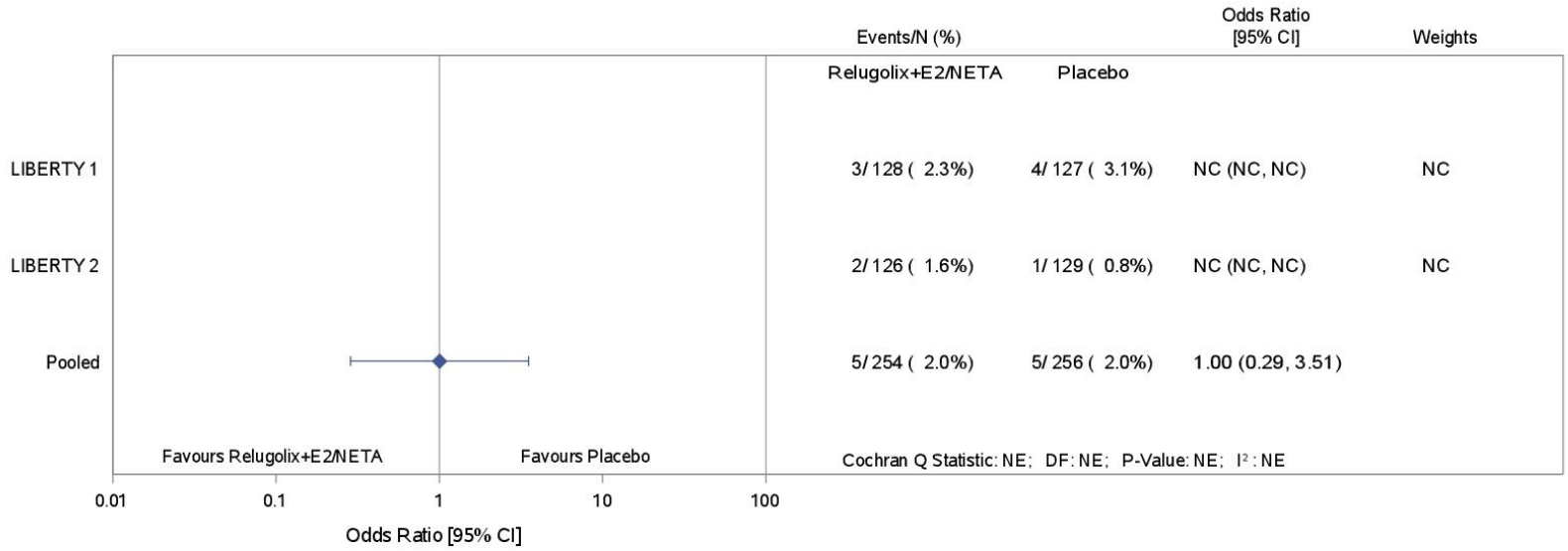
Figure SAF.TEAE.SPT.BIN.FP: Frequent Treatment Emergent Adverse Events by System Organ Class and Preferred Term (Safety Population)
System Organ Class: Psychiatric disorders, Preferred Term: Insomnia



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Relative weights are based on an inverse variance approach.
N: Number of patients in treatment group; NETA: Norethindrone acetate; DF: Degrees of freedom; IPD: Individual Patient Data. NC: Not calculated. NE: Non-estimable.

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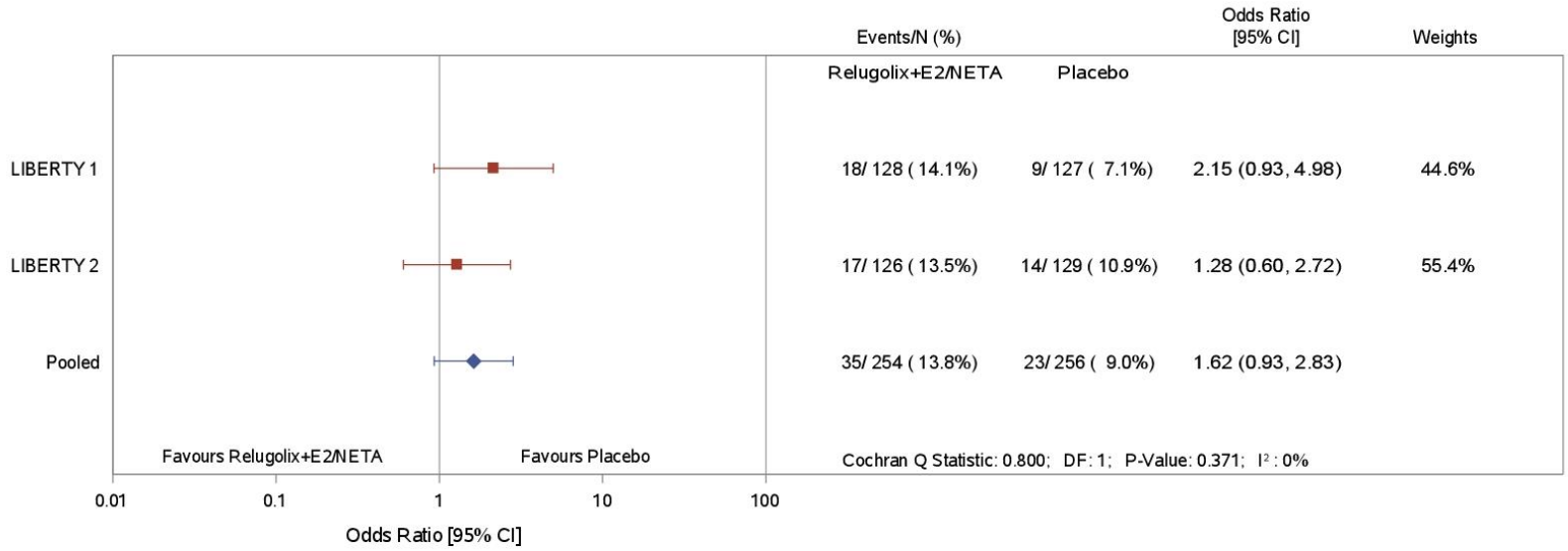
Figure SAF.TEAE.SPT.BIN.FP: Frequent Treatment Emergent Adverse Events by System Organ Class and Preferred Term (Safety Population)
System Organ Class: Reproductive system and breast disorders, Preferred Term: Any



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A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
Relative weights are based on an inverse variance approach.
N: Number of patients in treatment group; NETA: Norethindrone acetate; DF: Degrees of freedom; IPD: Individual Patient Data.

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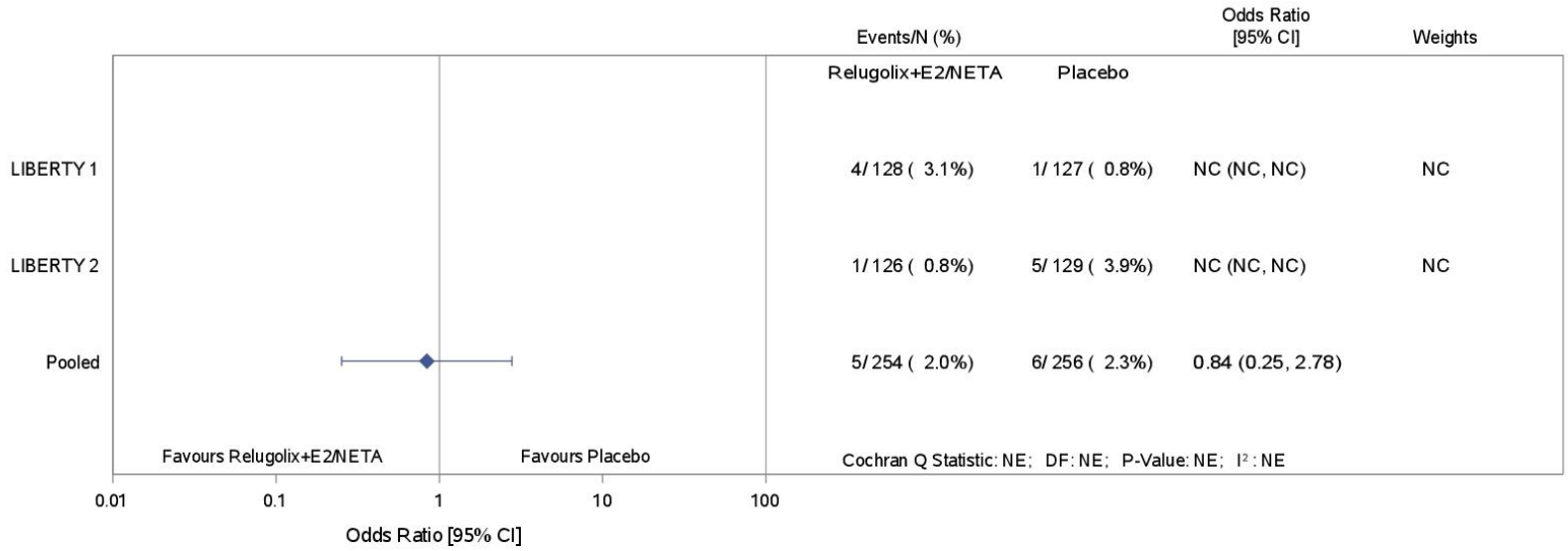
Figure SAF.TEAE.SPT.BIN.FP: Frequent Treatment Emergent Adverse Events by System Organ Class and Preferred Term (Safety Population)
System Organ Class: Reproductive system and breast disorders, Preferred Term: Pelvic pain



Results are based on logistic regression models. The analysis of LIBERTY 1 and LIBERTY 2 was adjusted for treatment group. The pooled analysis was also adjusted for study as a fixed effect. The reference group is Placebo. Patients with multiple events for a given PT or SOC are counted only once for each PT and SOC. Only SOCs or PTs for which there are at least 10% of patients with an event in at least one treatment group OR at least 10 patients with an event overall and at least 1% of patients with an event in at least one treatment group for the pooled analysis are presented. Events are sorted by SOC alphabetically and then by decreasing frequency of PT in the Relugolix+E2/NETA group for the pooled analysis. MedDRA (version 22.0).
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Relative weights are based on an inverse variance approach.
N: Number of patients in treatment group; NETA: Norethindrone acetate; DF: Degrees of freedom; IPD: Individual Patient Data. NC: Not calculated. NE: Non-estimable.

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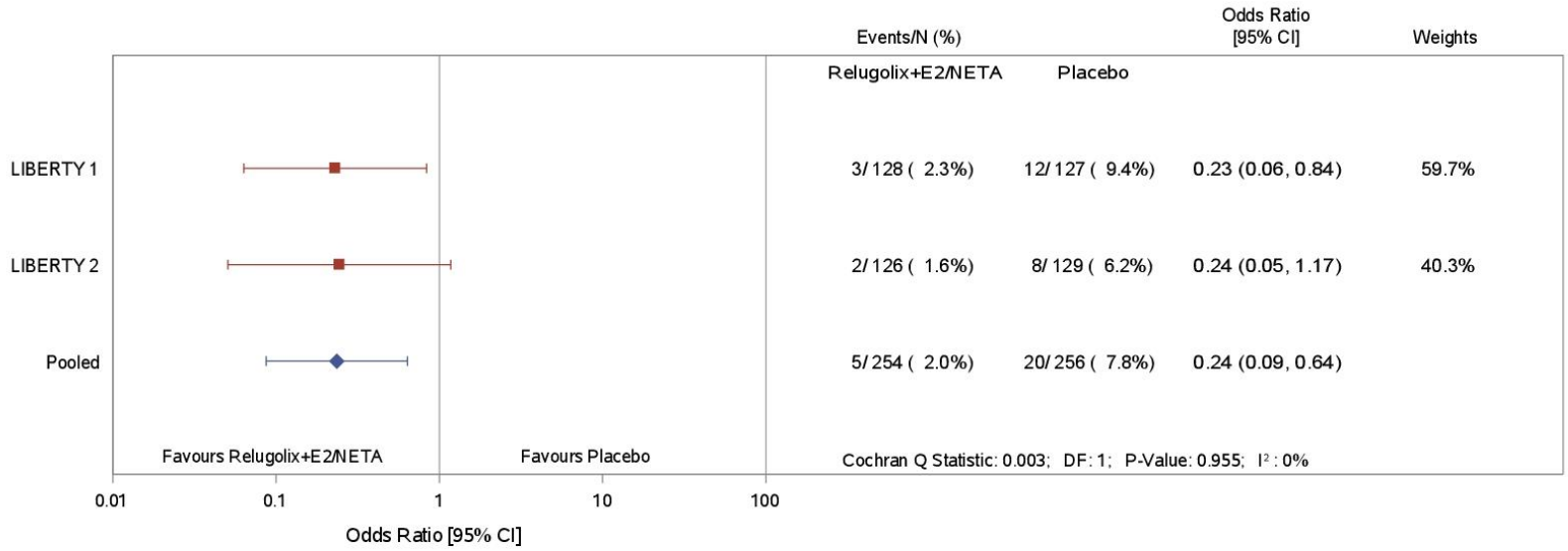
Figure SAF.TEAE.SPT.BIN.FP: Frequent Treatment Emergent Adverse Events by System Organ Class and Preferred Term (Safety Population)
System Organ Class: Respiratory, thoracic and mediastinal disorders, Preferred Term: Any



Results are based on logistic regression models. The analysis of LIBERTY 1 and LIBERTY 2 was adjusted for treatment group. The pooled analysis was also adjusted for study as a fixed effect. The reference group is Placebo. Patients with multiple events for a given PT or SOC are counted only once for each PT and SOC. Only SOCs or PTs for which there are at least 10% of patients with an event in at least one treatment group OR at least 10 patients with an event overall and at least 1% of patients with an event in at least one treatment group for the pooled analysis are presented. Events are sorted by SOC alphabetically and then by decreasing frequency of PT in the Relugolix+E2/NETA group for the pooled analysis. MedDRA (version 22.0).
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Relative weights are based on an inverse variance approach.
N: Number of patients in treatment group; NETA: Norethindrone acetate; DF: Degrees of freedom; IPD: Individual Patient Data.

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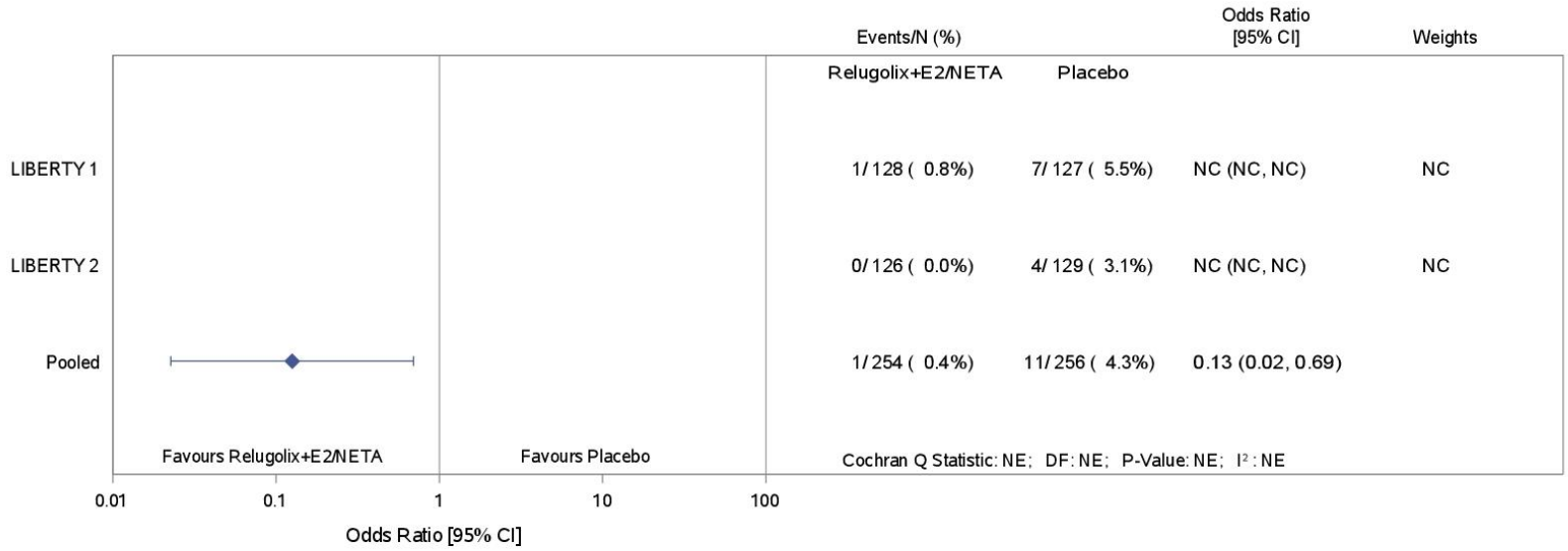
Figure SAF.TEAE.SPT.BIN.FP: Frequent Treatment Emergent Adverse Events by System Organ Class and Preferred Term (Safety Population)
System Organ Class: Respiratory, thoracic and mediastinal disorders, Preferred Term: Cough



Results are based on logistic regression models. The analysis of LIBERTY 1 and LIBERTY 2 was adjusted for treatment group. The pooled analysis was also adjusted for study as a fixed effect. The reference group is Placebo. Patients with multiple events for a given PT or SOC are counted only once for each PT and SOC. Only SOCs or PTs for which there are at least 10% of patients with an event in at least one treatment group OR at least 10 patients with an event overall and at least 1% of patients with an event in at least one treatment group for the pooled analysis are presented. Events are sorted by SOC alphabetically and then by decreasing frequency of PT in the Relugolix+E2/NETA group for the pooled analysis. MedDRA (version 22.0).
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Relative weights are based on an inverse variance approach.
N: Number of patients in treatment group; NETA: Norethindrone acetate; DF: Degrees of freedom; IPD: Individual Patient Data. NC: Not calculated. NE: Non-estimable.

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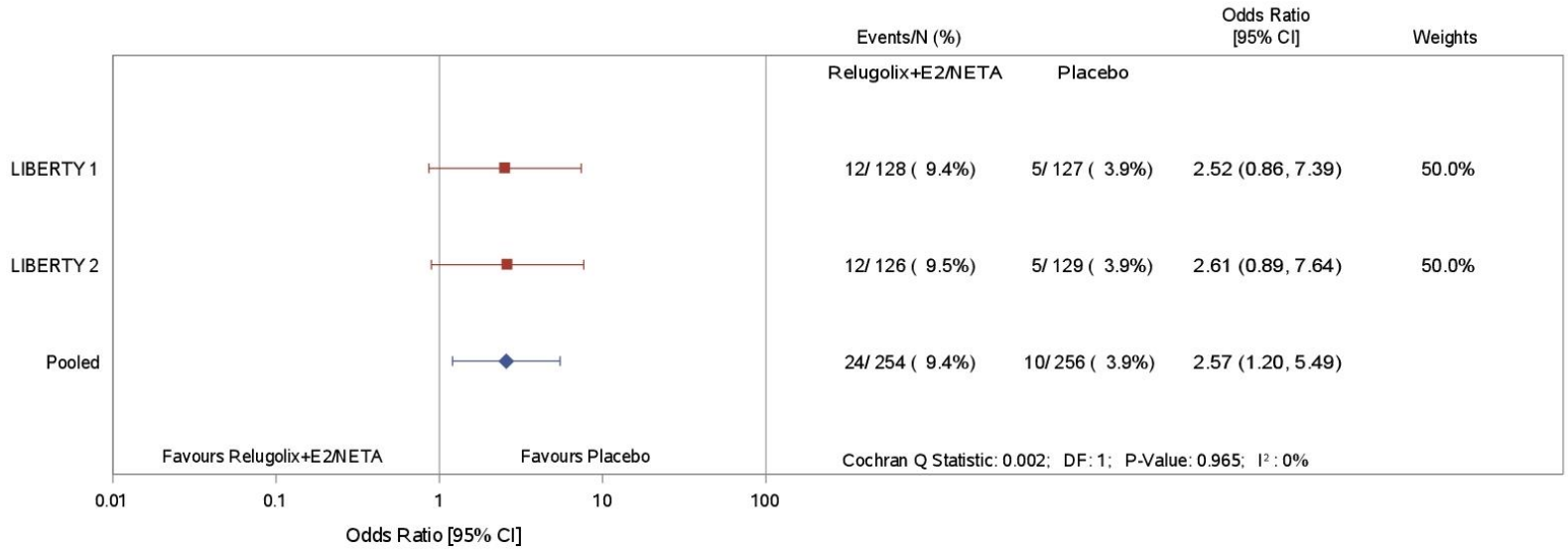
Figure SAF.TEAE.SPT.BIN.FP: Frequent Treatment Emergent Adverse Events by System Organ Class and Preferred Term (Safety Population)
System Organ Class: Skin and subcutaneous tissue disorders, Preferred Term: Any



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A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
Relative weights are based on an inverse variance approach.
N: Number of patients in treatment group; NETA: Norethindrone acetate; DF: Degrees of freedom; IPD: Individual Patient Data.

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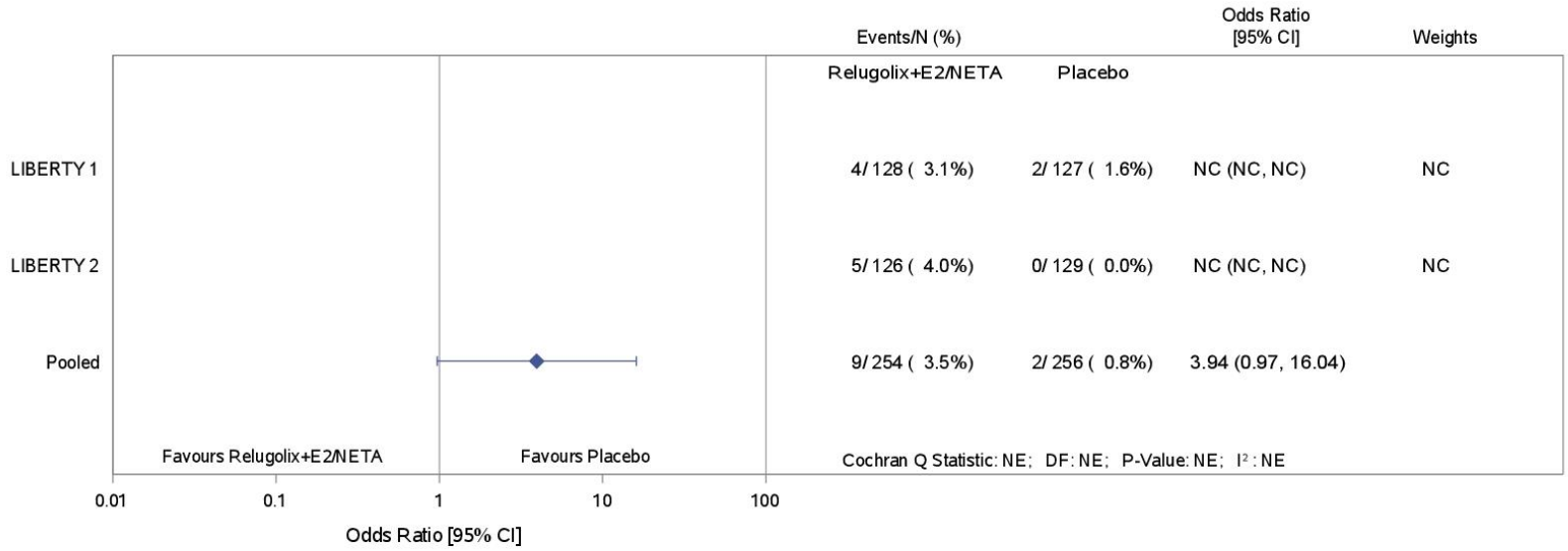
Figure SAF.TEAE.SPT.BIN.FP: Frequent Treatment Emergent Adverse Events by System Organ Class and Preferred Term (Safety Population)
System Organ Class: Skin and subcutaneous tissue disorders, Preferred Term: Alopecia



Results are based on logistic regression models. The analysis of LIBERTY 1 and LIBERTY 2 was adjusted for treatment group. The pooled analysis was also adjusted for study as a fixed effect. The reference group is Placebo. Patients with multiple events for a given PT or SOC are counted only once for each PT and SOC. Only SOCs or PTs for which there are at least 10% of patients with an event in at least one treatment group OR at least 10 patients with an event overall and at least 1% of patients with an event in at least one treatment group for the pooled analysis are presented. Events are sorted by SOC alphabetically and then by decreasing frequency of PT in the Relugolix+E2/NETA group for the pooled analysis. MedDRA (version 22.0).
A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
Relative weights are based on an inverse variance approach.
N: Number of patients in treatment group; NETA: Norethindrone acetate; DF: Degrees of freedom; IPD: Individual Patient Data. NC: Not calculated. NE: Non-estimable.

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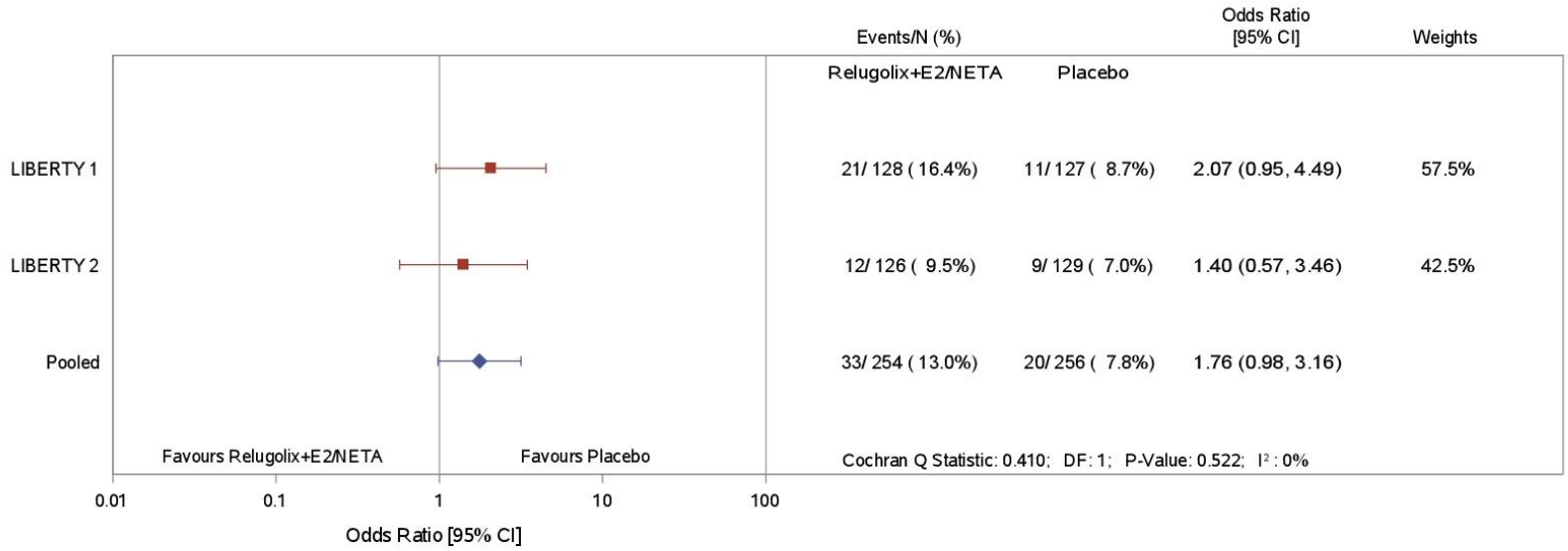
Figure SAF.TEAE.SPT.BIN.FP: Frequent Treatment Emergent Adverse Events by System Organ Class and Preferred Term (Safety Population)
System Organ Class: Vascular disorders, Preferred Term: Any



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Relative weights are based on an inverse variance approach.
N: Number of patients in treatment group; NETA: Norethindrone acetate; DF: Degrees of freedom; IPD: Individual Patient Data.

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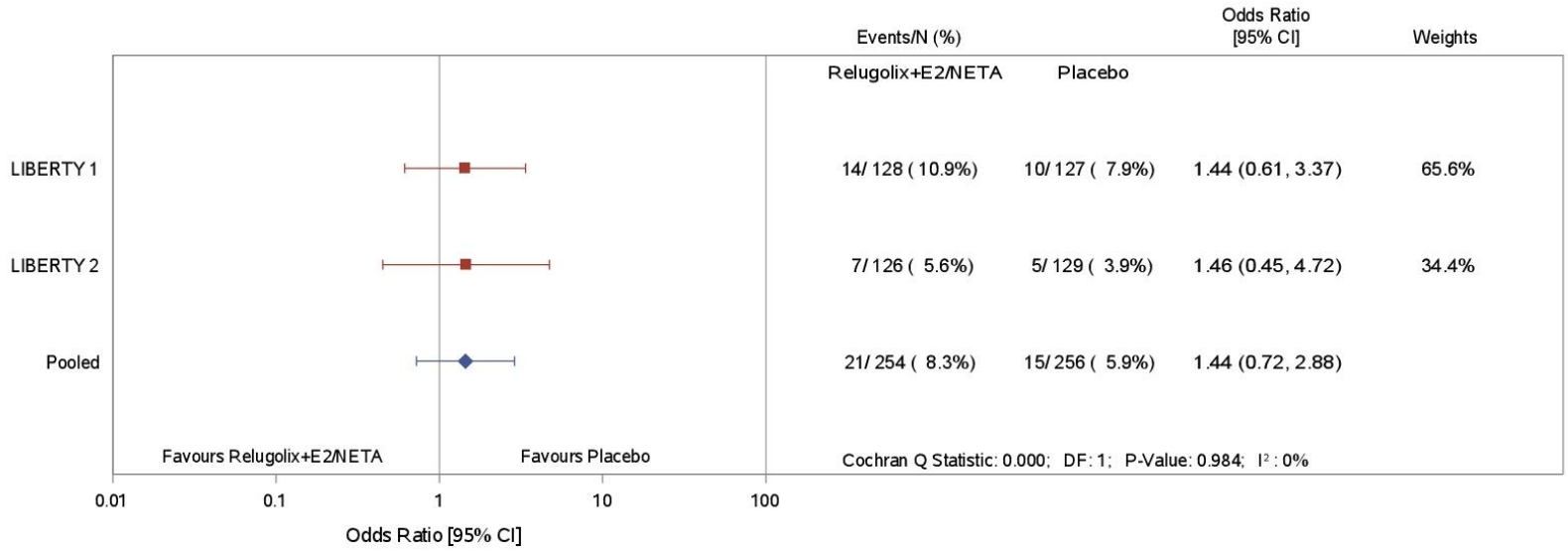
Figure SAF.TEAE.SPT.BIN.FP: Frequent Treatment Emergent Adverse Events by System Organ Class and Preferred Term (Safety Population)
System Organ Class: Vascular disorders, Preferred Term: Hot flush



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N: Number of patients in treatment group; NETA: Norethindrone acetate; DF: Degrees of freedom; IPD: Individual Patient Data.

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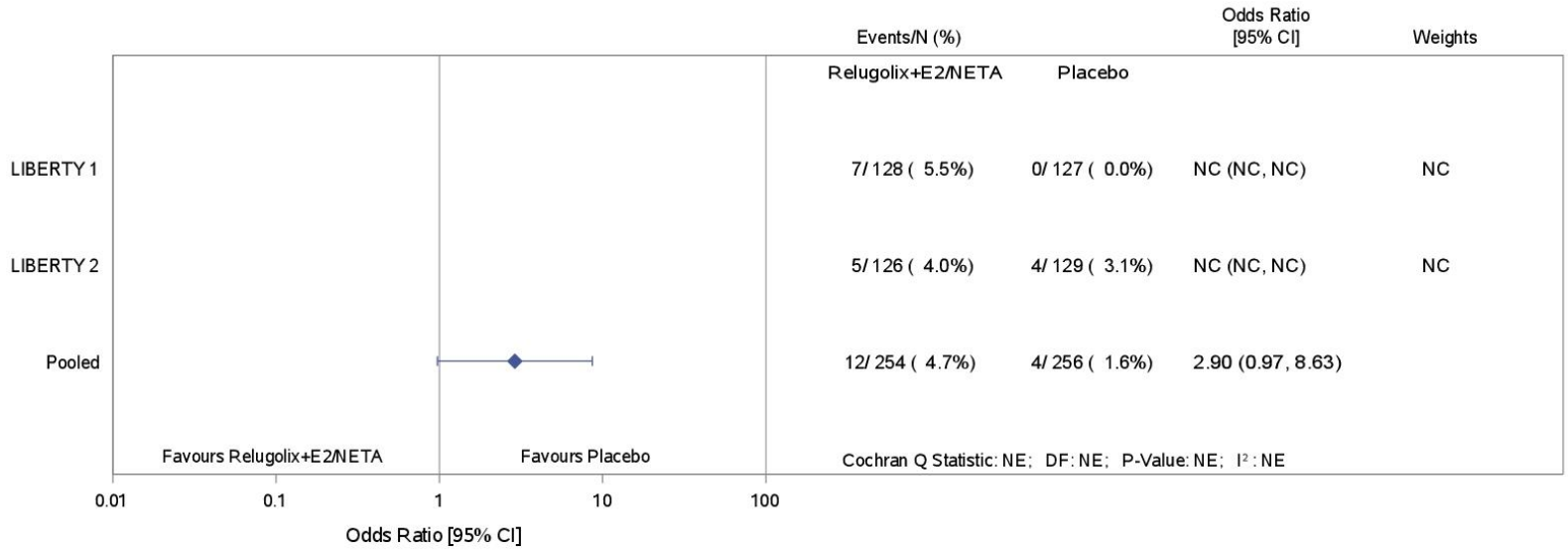
Figure SAF.TEAE.SPT.BIN.FP: Frequent Treatment Emergent Adverse Events by System Organ Class and Preferred Term (Safety Population)
System Organ Class: Vascular disorders, Preferred Term: Hypertension



Results are based on logistic regression models. The analysis of LIBERTY 1 and LIBERTY 2 was adjusted for treatment group. The pooled analysis was also adjusted for study as a fixed effect. The reference group is Placebo. Patients with multiple events for a given PT or SOC are counted only once for each PT and SOC. Only SOCs or PTs for which there are at least 10% of patients with an event in at least one treatment group OR at least 10 patients with an event overall and at least 1% of patients with an event in at least one treatment group for the pooled analysis are presented. Events are sorted by SOC alphabetically and then by decreasing frequency of PT in the Relugolix+E2/NETA group for the pooled analysis. MedDRA (version 22.0).
A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
Relative weights are based on an inverse variance approach.
N: Number of patients in treatment group; NETA: Norethindrone acetate; DF: Degrees of freedom; IPD: Individual Patient Data. NC: Not calculated. NE: Non-estimable.

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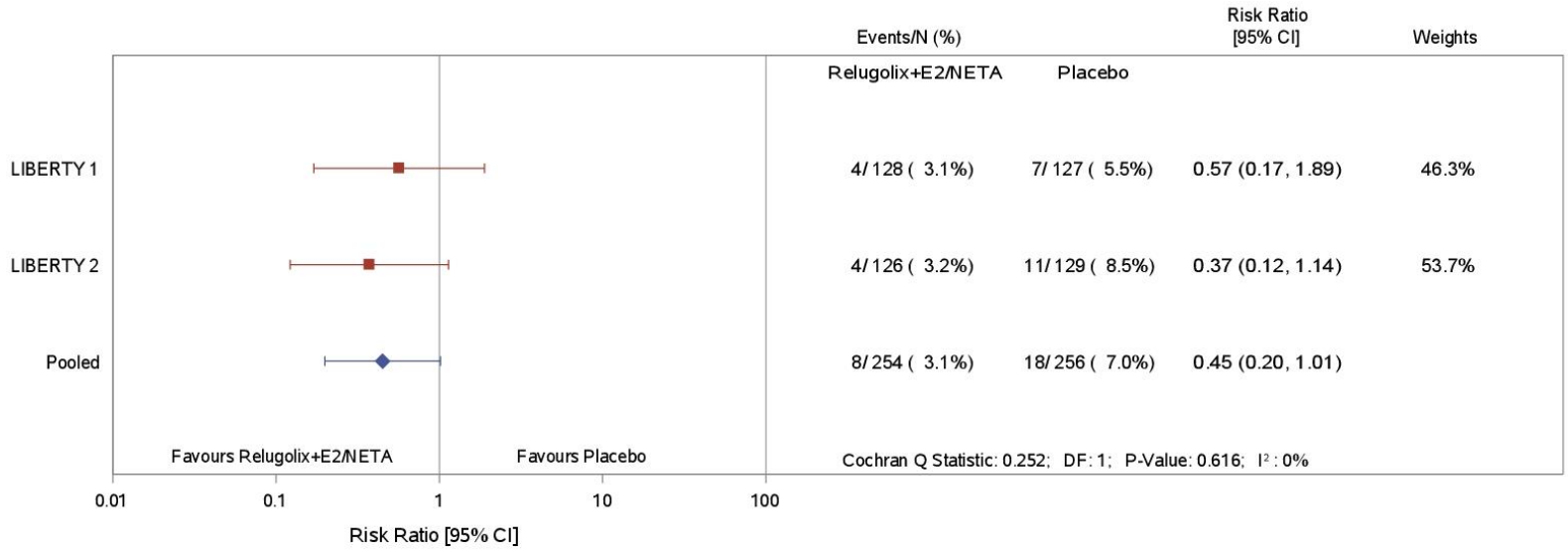
3.2 Risk Ratio

Figure SAF.TEAE.SPT.BIN.FP.RR: Frequent Treatment Emergent Adverse Events by System Organ Class and Preferred Term (Safety Population) - Risk Ratio
System Organ Class: Blood and lymphatic system disorders, Preferred Term: Any



Results are based on a Cochran-Mantel-Haenszel approach for the pooled analysis, stratified by study. The analysis of LIBERTY 1 and LIBERTY 2 was based on an unstratified approach.
The reference group is Placebo. Patients with multiple events for a given PT or SOC are counted only once for each PT and SOC. Only SOCs or PTs for which there are at least 10% of patients with an event in at least one treatment group OR at least 10 patients with an event overall and at least 1% of patients with an event in at least one treatment group for the pooled analysis are presented. Events are sorted by SOC alphabetically and then by decreasing frequency of PT in the Relugolix+E2/NETA group for the pooled analysis. MedDRA (version 22.0).
A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
Relative weights are based on an inverse variance approach.
N: Number of patients in treatment group; NETA: Norethindrone acetate; DF: Degrees of freedom; IPD: Individual Patient Data.

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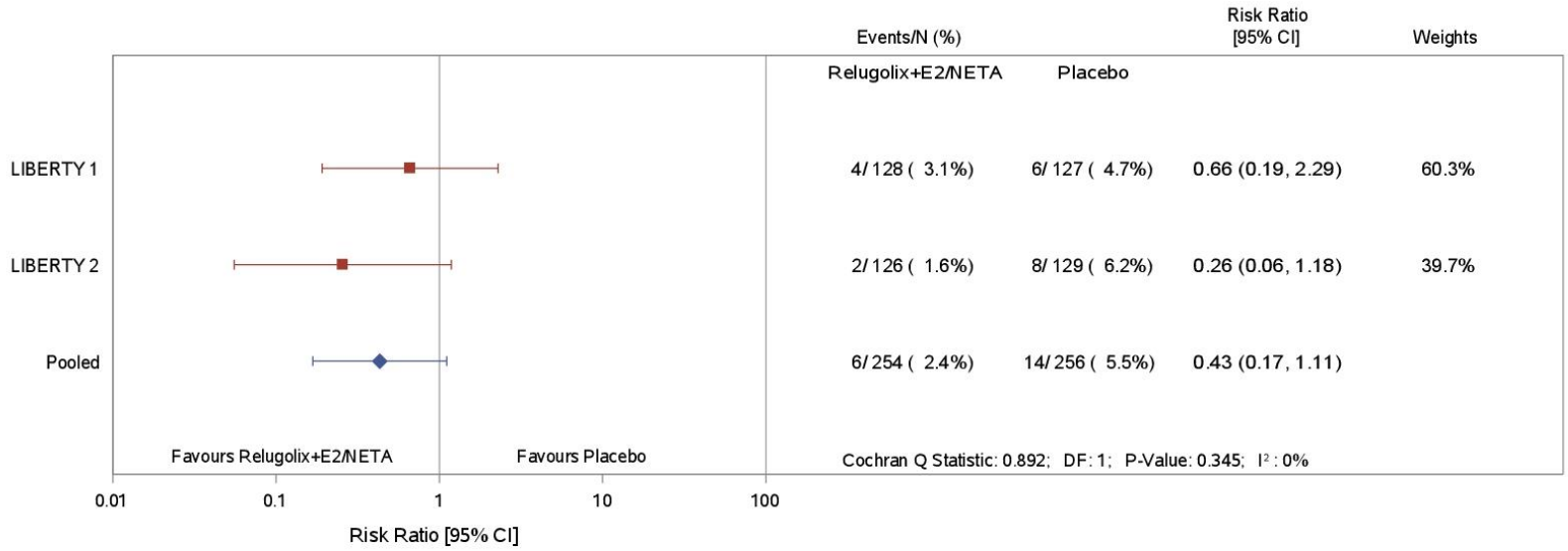
Figure SAF.TEAE.SPT.BIN.FP.RR: Frequent Treatment Emergent Adverse Events by System Organ Class and Preferred Term (Safety Population) - Risk Ratio
System Organ Class: Blood and lymphatic system disorders, Preferred Term: Anaemia



Results are based on a Cochran-Mantel-Haenszel approach for the pooled analysis, stratified by study. The analysis of LIBERTY 1 and LIBERTY 2 was based on an unstratified approach.
The reference group is Placebo. Patients with multiple events for a given PT or SOC are counted only once for each PT and SOC. Only SOCs or PTs for which there are at least 10% of patients with an event in at least one treatment group OR at least 10 patients with an event overall and at least 1% of patients with an event in at least one treatment group for the pooled analysis are presented. Events are sorted by SOC alphabetically and then by decreasing frequency of PT in the Relugolix+E2/NETA group for the pooled analysis. MedDRA (version 22.0).
A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
Relative weights are based on an inverse variance approach.
N: Number of patients in treatment group; NETA: Norethindrone acetate; DF: Degrees of freedom; IPD: Individual Patient Data.

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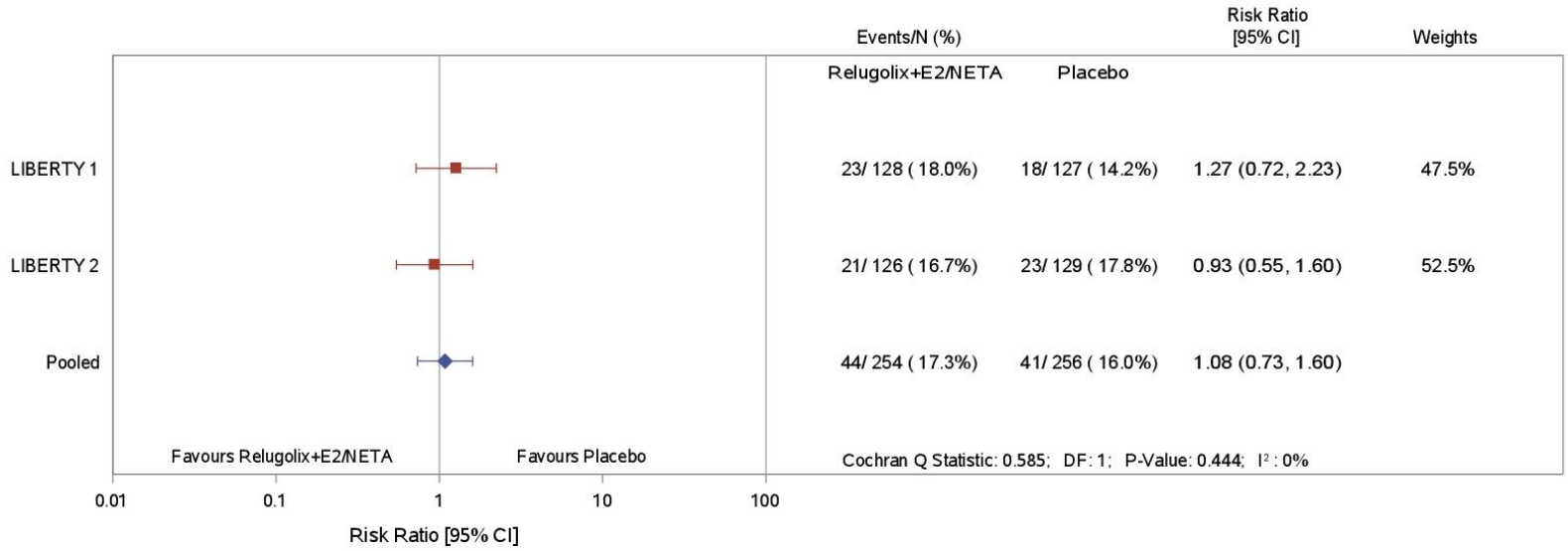
Figure SAF.TEAE.SPT.BIN.FP.RR: Frequent Treatment Emergent Adverse Events by System Organ Class and Preferred Term (Safety Population) - Risk Ratio
System Organ Class: Gastrointestinal disorders, Preferred Term: Any



Results are based on a Cochran-Mantel-Haenszel approach for the pooled analysis, stratified by study. The analysis of LIBERTY 1 and LIBERTY 2 was based on an unstratified approach.
The reference group is Placebo. Patients with multiple events for a given PT or SOC are counted only once for each PT and SOC. Only SOCs or PTs for which there are at least 10% of patients with an event in at least one treatment group OR at least 10 patients with an event overall and at least 1% of patients with an event in at least one treatment group for the pooled analysis are presented. Events are sorted by SOC alphabetically and then by decreasing frequency of PT in the Relugolix+E2/NETA group for the pooled analysis. MedDRA (version 22.0).
A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
Relative weights are based on an inverse variance approach.
N: Number of patients in treatment group; NETA: Norethindrone acetate; DF: Degrees of freedom; IPD: Individual Patient Data.

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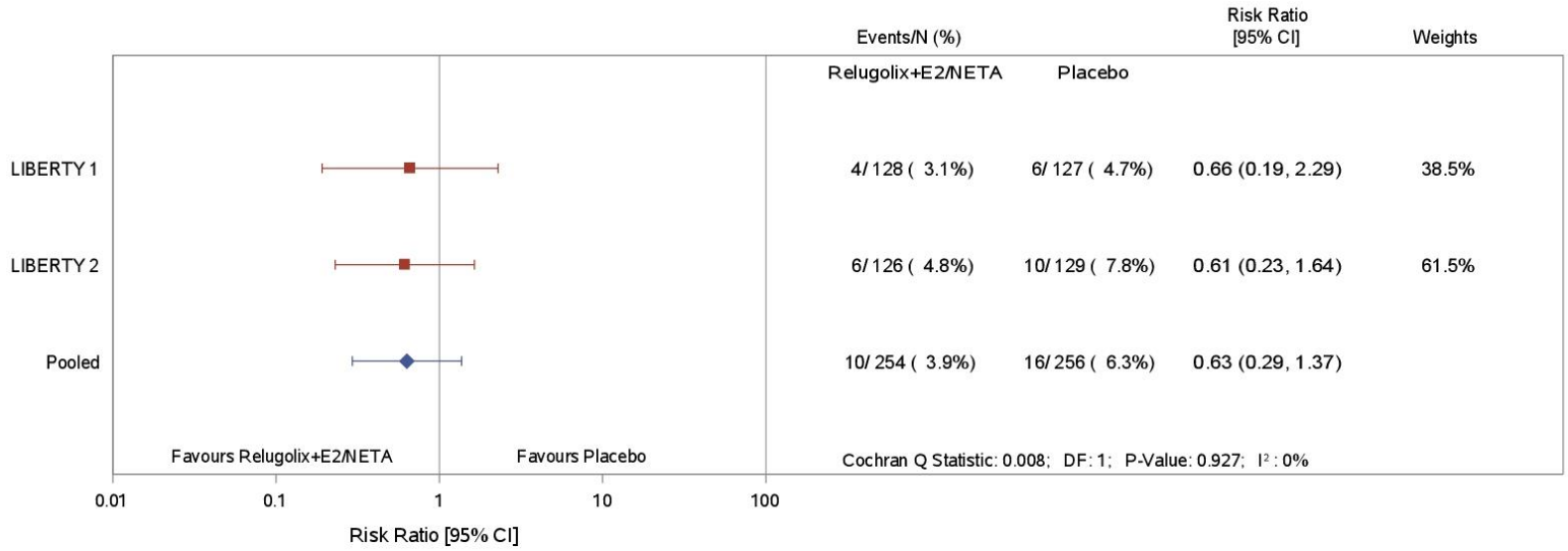
Figure SAF.TEAE.SPT.BIN.FP.RR: Frequent Treatment Emergent Adverse Events by System Organ Class and Preferred Term (Safety Population) - Risk Ratio
System Organ Class: Gastrointestinal disorders, Preferred Term: Nausea



Results are based on a Cochran-Mantel-Haenszel approach for the pooled analysis, stratified by study. The analysis of LIBERTY 1 and LIBERTY 2 was based on an unstratified approach.
The reference group is Placebo. Patients with multiple events for a given PT or SOC are counted only once for each PT and SOC. Only SOCs or PTs for which there are at least 10% of patients with an event in at least one treatment group OR at least 10 patients with an event overall and at least 1% of patients with an event in at least one treatment group for the pooled analysis are presented. Events are sorted by SOC alphabetically and then by decreasing frequency of PT in the Relugolix+E2/NETA group for the pooled analysis. MedDRA (version 22.0).
A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
Relative weights are based on an inverse variance approach.
N: Number of patients in treatment group; NETA: Norethindrone acetate; DF: Degrees of freedom; IPD: Individual Patient Data.

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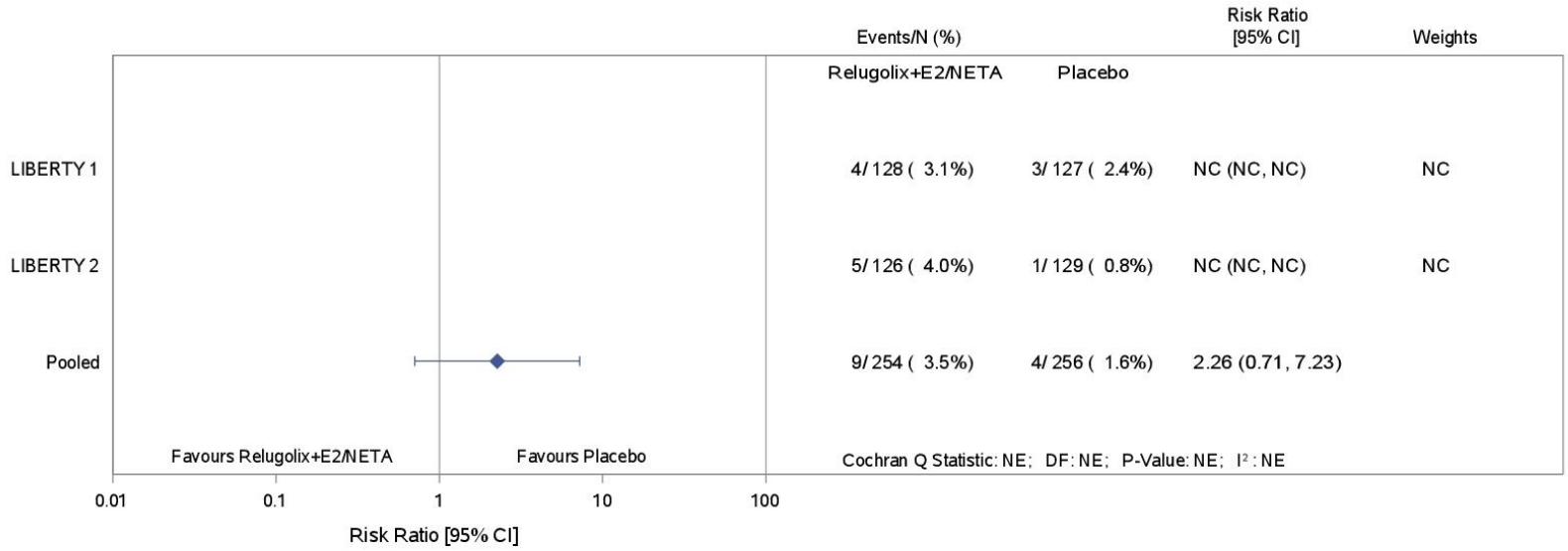
Figure SAF.TEAE.SPT.BIN.FP.RR: Frequent Treatment Emergent Adverse Events by System Organ Class and Preferred Term (Safety Population) - Risk Ratio
System Organ Class: Gastrointestinal disorders, Preferred Term: Abdominal pain



Results are based on a Cochran-Mantel-Haenszel approach for the pooled analysis, stratified by study. The analysis of LIBERTY 1 and LIBERTY 2 was based on an unstratified approach.
The reference group is Placebo. Patients with multiple events for a given PT or SOC are counted only once for each PT and SOC. Only SOCs or PTs for which there are at least 10% of patients with an event in at least one treatment group OR at least 10 patients with an event overall and at least 1% of patients with an event in at least one treatment group for the pooled analysis are presented. Events are sorted by SOC alphabetically and then by decreasing frequency of PT in the Relugolix+E2/NETA group for the pooled analysis. MedDRA (version 22.0).
A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
Relative weights are based on an inverse variance approach.
N: Number of patients in treatment group; NETA: Norethindrone acetate; DF: Degrees of freedom; IPD: Individual Patient Data. NC: Not calculated. NE: Non-estimable.

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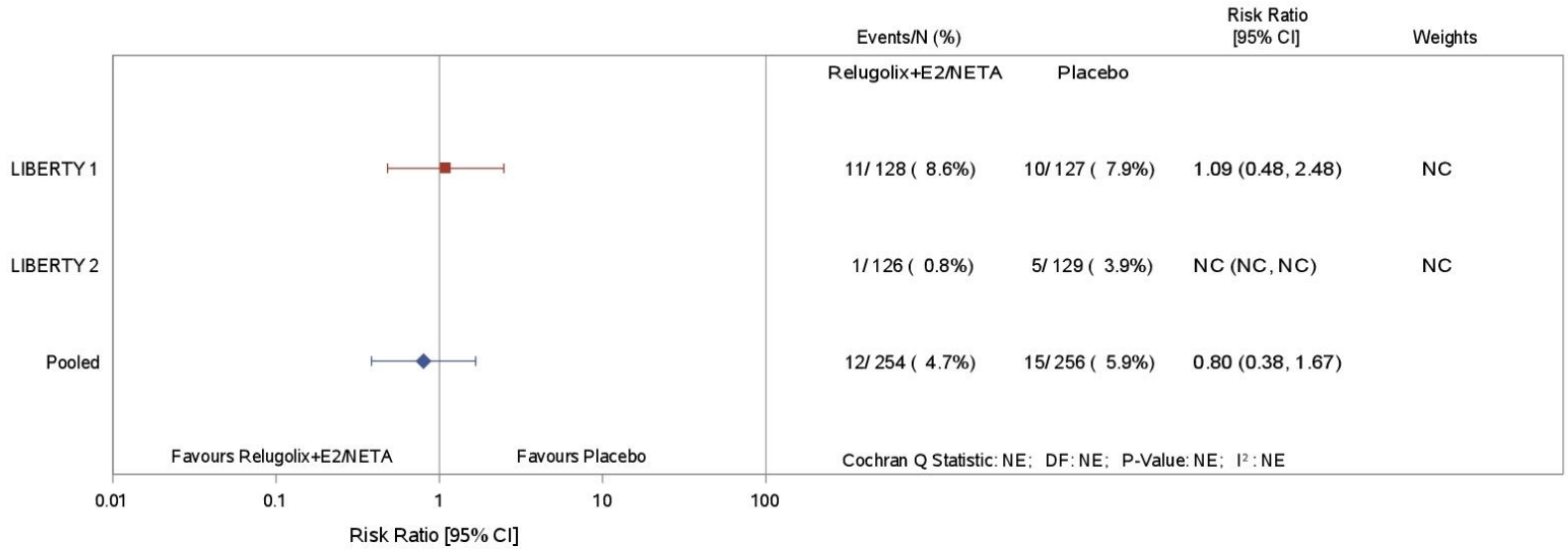
Figure SAF.TEAE.SPT.BIN.FP.RR: Frequent Treatment Emergent Adverse Events by System Organ Class and Preferred Term (Safety Population) - Risk Ratio
System Organ Class: General disorders and administration site conditions, Preferred Term: Any



Results are based on a Cochran-Mantel-Haenszel approach for the pooled analysis, stratified by study. The analysis of LIBERTY 1 and LIBERTY 2 was based on an unstratified approach.
The reference group is Placebo. Patients with multiple events for a given PT or SOC are counted only once for each PT and SOC. Only SOCs or PTs for which there are at least 10% of patients with an event in at least one treatment group OR at least 10 patients with an event overall and at least 1% of patients with an event in at least one treatment group for the pooled analysis are presented. Events are sorted by SOC alphabetically and then by decreasing frequency of PT in the Relugolix+E2/NETA group for the pooled analysis. MedDRA (version 22.0).
A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
Relative weights are based on an inverse variance approach.
N: Number of patients in treatment group; NETA: Norethindrone acetate; DF: Degrees of freedom; IPD: Individual Patient Data. NC: Not calculated. NE: Non-estimable.

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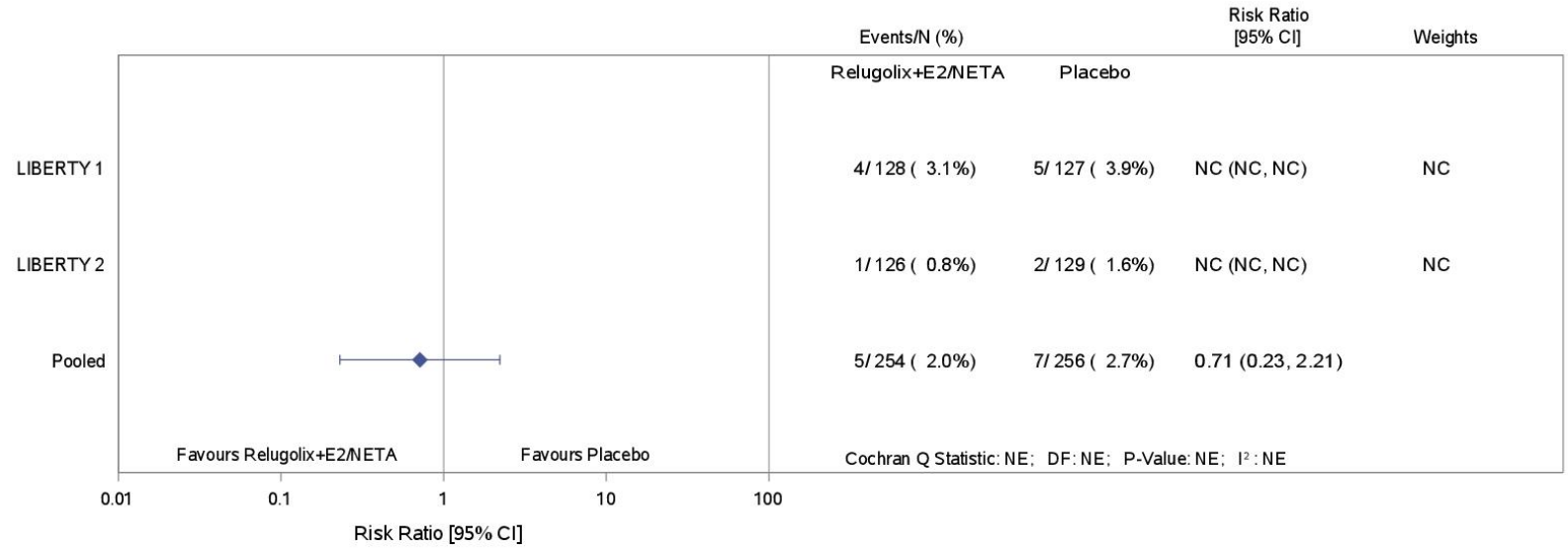
Figure SAF.TEAE.SPT.BIN.FP.RR: Frequent Treatment Emergent Adverse Events by System Organ Class and Preferred Term (Safety Population) - Risk Ratio
System Organ Class: General disorders and administration site conditions, Preferred Term: Fatigue



Results are based on a Cochran-Mantel-Haenszel approach for the pooled analysis, stratified by study. The analysis of LIBERTY 1 and LIBERTY 2 was based on an unstratified approach.
The reference group is Placebo. Patients with multiple events for a given PT or SOC are counted only once for each PT and SOC. Only SOCs or PTs for which there are at least 10% of patients with an event in at least one treatment group OR at least 10 patients with an event overall and at least 1% of patients with an event in at least one treatment group for the pooled analysis are presented. Events are sorted by SOC alphabetically and then by decreasing frequency of PT in the Relugolix+E2/NETA group for the pooled analysis. MedDRA (version 22.0).
A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
Relative weights are based on an inverse variance approach.
N: Number of patients in treatment group; NETA: Norethindrone acetate; DF: Degrees of freedom; IPD: Individual Patient Data. NC: Not calculated. NE: Non-estimable.

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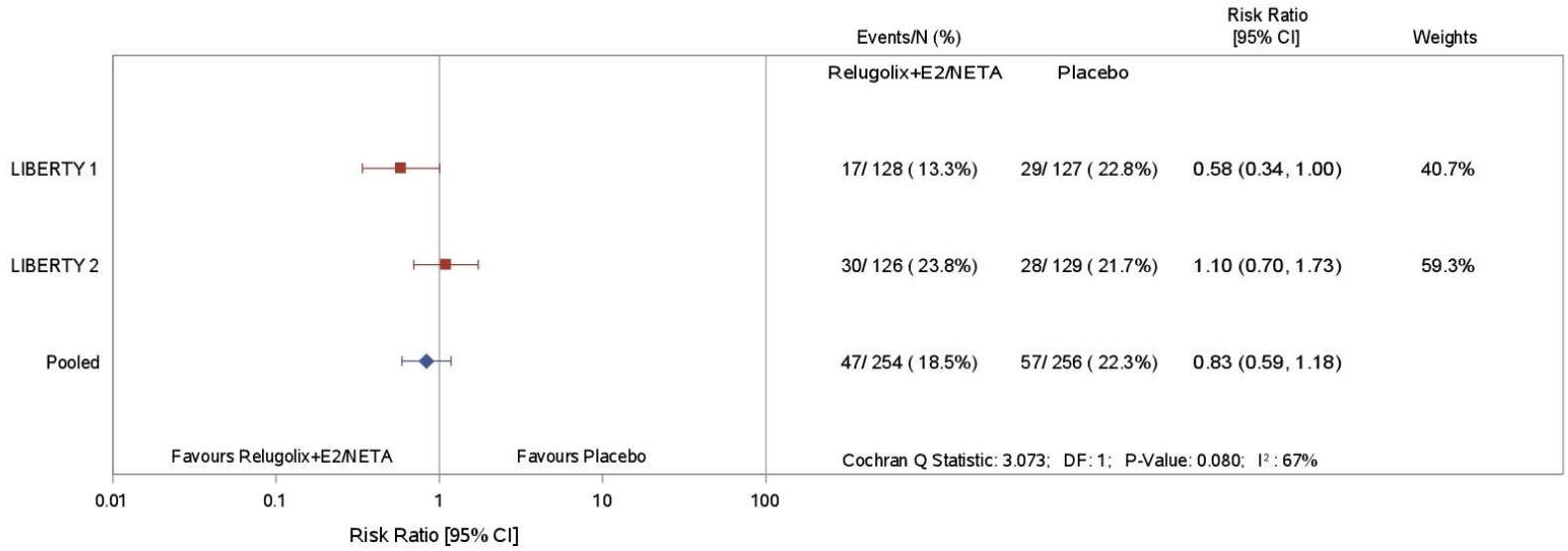
Figure SAF.TEAE.SPT.BIN.FP.RR: Frequent Treatment Emergent Adverse Events by System Organ Class and Preferred Term (Safety Population) - Risk Ratio
System Organ Class: Infections and infestations, Preferred Term: Any



Results are based on a Cochran-Mantel-Haenszel approach for the pooled analysis, stratified by study. The analysis of LIBERTY 1 and LIBERTY 2 was based on an unstratified approach.
The reference group is Placebo. Patients with multiple events for a given PT or SOC are counted only once for each PT and SOC. Only SOCs or PTs for which there are at least 10% of patients with an event in at least one treatment group OR at least 10 patients with an event overall and at least 1% of patients with an event in at least one treatment group for the pooled analysis are presented. Events are sorted by SOC alphabetically and then by decreasing frequency of PT in the Relugolix+E2/NETA group for the pooled analysis. MedDRA (version 22.0).
A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
Relative weights are based on an inverse variance approach.
N: Number of patients in treatment group; NETA: Norethindrone acetate; DF: Degrees of freedom; IPD: Individual Patient Data.

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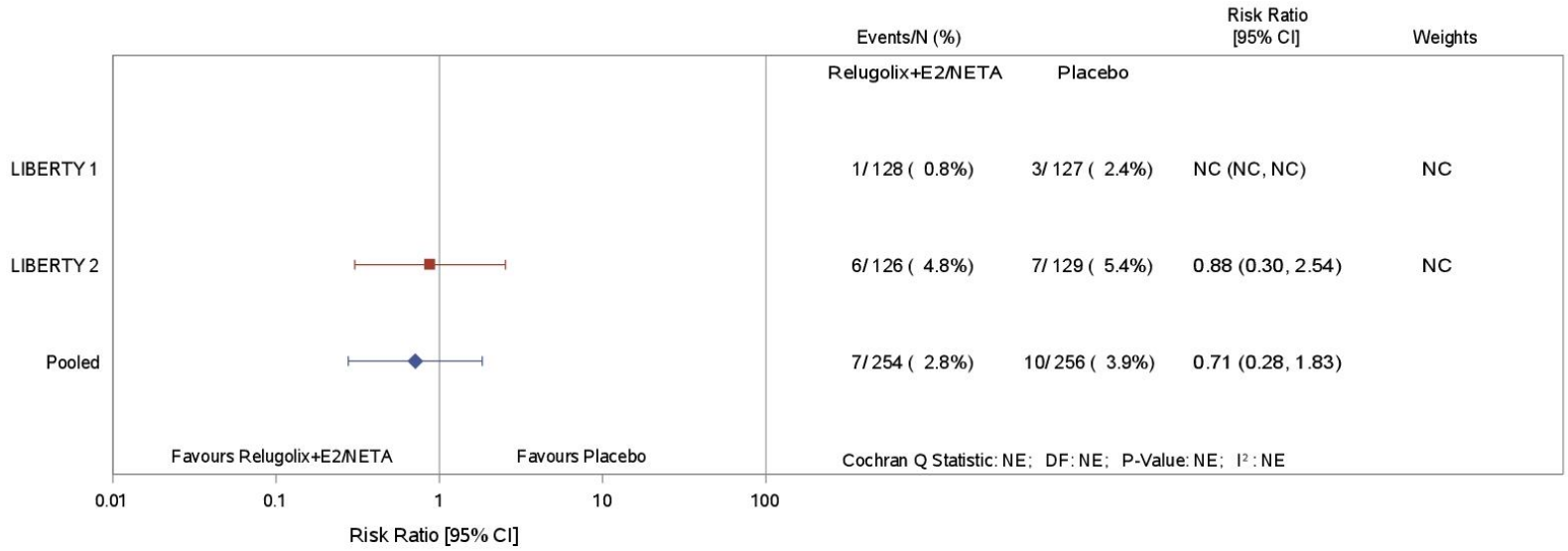
Figure SAF.TEAE.SPT.BIN.FP.RR: Frequent Treatment Emergent Adverse Events by System Organ Class and Preferred Term (Safety Population) - Risk Ratio
System Organ Class: Infections and infestations, Preferred Term: Upper respiratory tract infection



Results are based on a Cochran-Mantel-Haenszel approach for the pooled analysis, stratified by study. The analysis of LIBERTY 1 and LIBERTY 2 was based on an unstratified approach.
The reference group is Placebo. Patients with multiple events for a given PT or SOC are counted only once for each PT and SOC. Only SOCs or PTs for which there are at least 10% of patients with an event in at least one treatment group OR at least 10 patients with an event overall and at least 1% of patients with an event in at least one treatment group for the pooled analysis are presented. Events are sorted by SOC alphabetically and then by decreasing frequency of PT in the Relugolix+E2/NETA group for the pooled analysis. MedDRA (version 22.0).
A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
Relative weights are based on an inverse variance approach.
N: Number of patients in treatment group; NETA: Norethindrone acetate; DF: Degrees of freedom; IPD: Individual Patient Data. NC: Not calculated. NE: Non-estimable.

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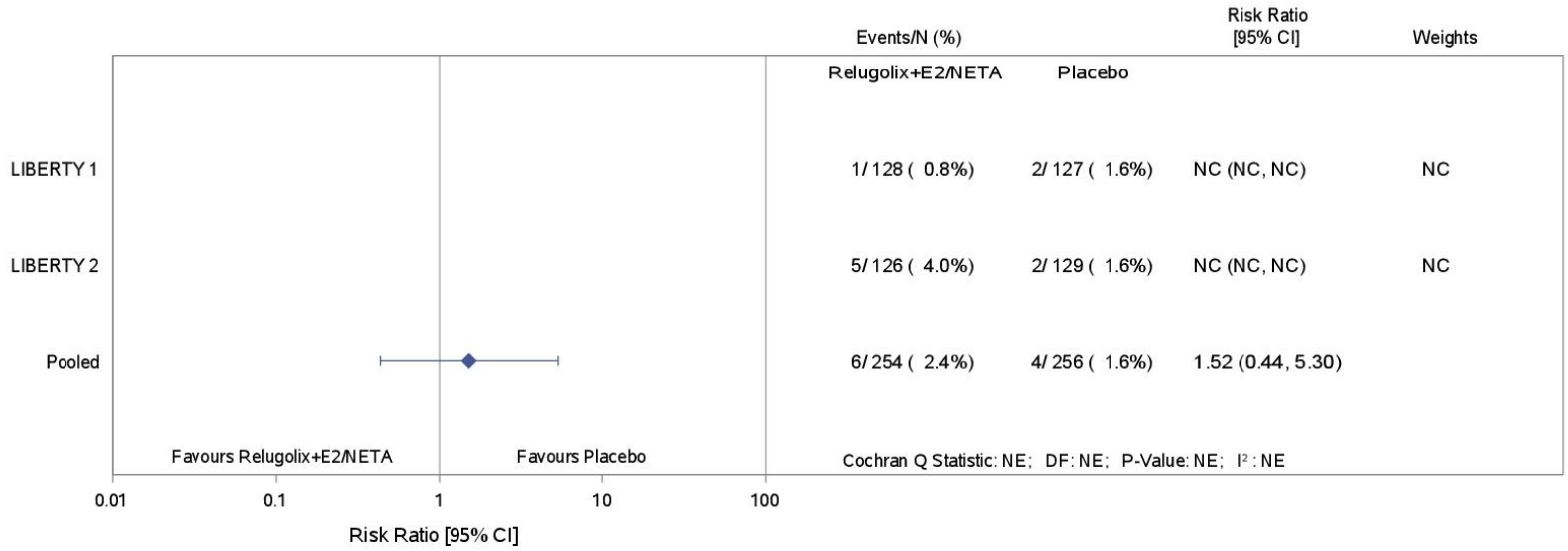
Figure SAF.TEAE.SPT.BIN.FP.RR: Frequent Treatment Emergent Adverse Events by System Organ Class and Preferred Term (Safety Population) - Risk Ratio
System Organ Class: Infections and infestations, Preferred Term: Bronchitis



Results are based on a Cochran-Mantel-Haenszel approach for the pooled analysis, stratified by study. The analysis of LIBERTY 1 and LIBERTY 2 was based on an unstratified approach.
The reference group is Placebo. Patients with multiple events for a given PT or SOC are counted only once for each PT and SOC. Only SOCs or PTs for which there are at least 10% of patients with an event in at least one treatment group OR at least 10 patients with an event overall and at least 1% of patients with an event in at least one treatment group for the pooled analysis are presented. Events are sorted by SOC alphabetically and then by decreasing frequency of PT in the Relugolix+E2/NETA group for the pooled analysis. MedDRA (version 22.0).
A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
Relative weights are based on an inverse variance approach.
N: Number of patients in treatment group; NETA: Norethindrone acetate; DF: Degrees of freedom; IPD: Individual Patient Data. NC: Not calculated. NE: Non-estimable.

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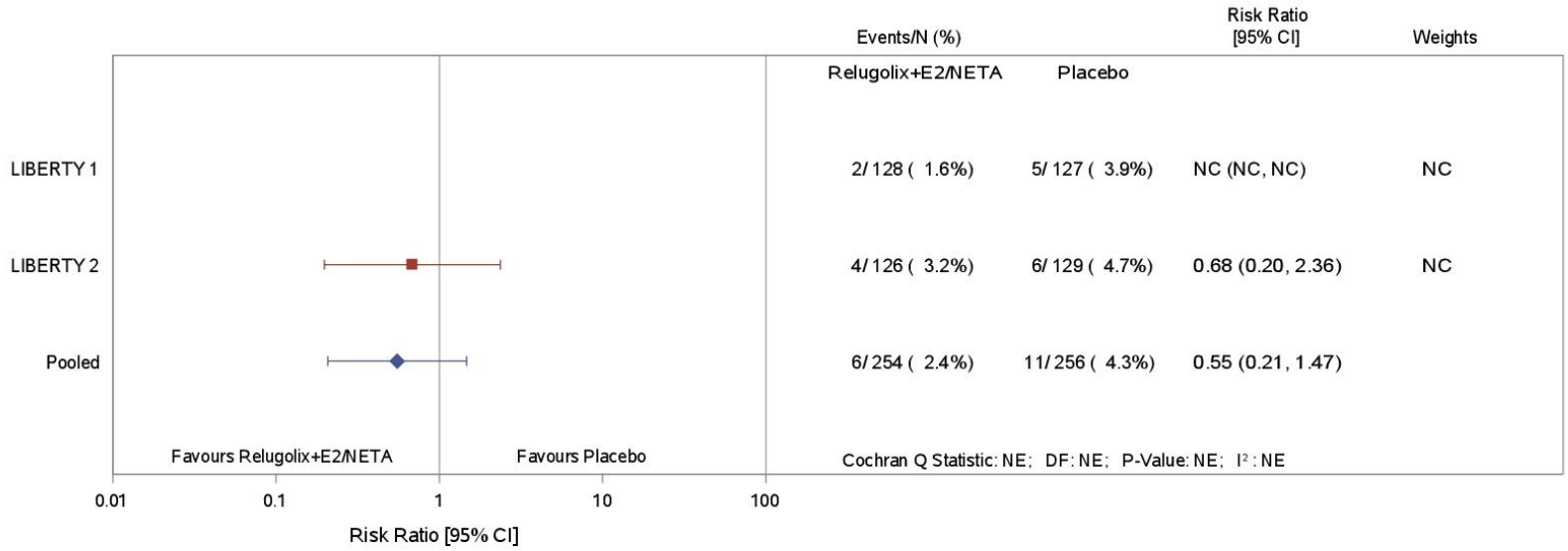
Figure SAF.TEAE.SPT.BIN.FP.RR: Frequent Treatment Emergent Adverse Events by System Organ Class and Preferred Term (Safety Population) - Risk Ratio
System Organ Class: Infections and infestations, Preferred Term: Nasopharyngitis



Results are based on a Cochran-Mantel-Haenszel approach for the pooled analysis, stratified by study. The analysis of LIBERTY 1 and LIBERTY 2 was based on an unstratified approach.
The reference group is Placebo. Patients with multiple events for a given PT or SOC are counted only once for each PT and SOC. Only SOCs or PTs for which there are at least 10% of patients with an event in at least one treatment group OR at least 10 patients with an event overall and at least 1% of patients with an event in at least one treatment group for the pooled analysis are presented. Events are sorted by SOC alphabetically and then by decreasing frequency of PT in the Relugolix+E2/NETA group for the pooled analysis. MedDRA (version 22.0).
A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
Relative weights are based on an inverse variance approach.
N: Number of patients in treatment group; NETA: Norethindrone acetate; DF: Degrees of freedom; IPD: Individual Patient Data. NC: Not calculated. NE: Non-estimable.

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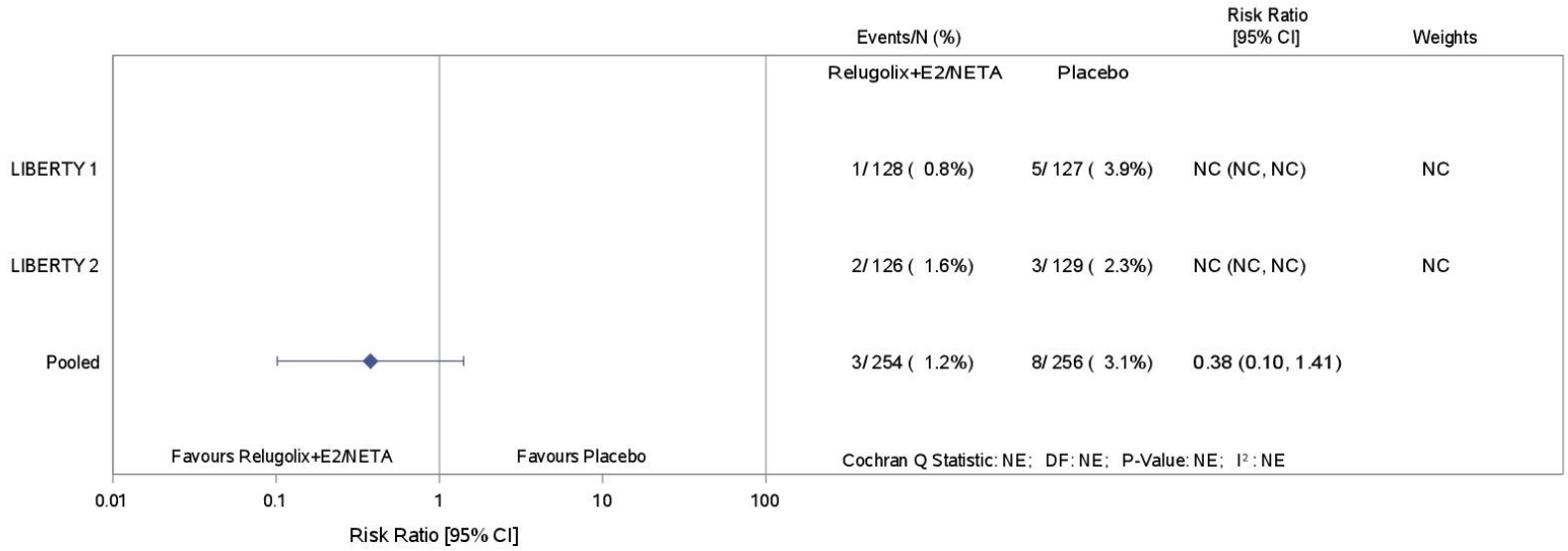
Figure SAF.TEAE.SPT.BIN.FP.RR: Frequent Treatment Emergent Adverse Events by System Organ Class and Preferred Term (Safety Population) - Risk Ratio
System Organ Class: Infections and infestations, Preferred Term: Urinary tract infection



Results are based on a Cochran-Mantel-Haenszel approach for the pooled analysis, stratified by study. The analysis of LIBERTY 1 and LIBERTY 2 was based on an unstratified approach.
The reference group is Placebo. Patients with multiple events for a given PT or SOC are counted only once for each PT and SOC. Only SOCs or PTs for which there are at least 10% of patients with an event in at least one treatment group OR at least 10 patients with an event overall and at least 1% of patients with an event in at least one treatment group for the pooled analysis are presented. Events are sorted by SOC alphabetically and then by decreasing frequency of PT in the Relugolix+E2/NETA group for the pooled analysis. MedDRA (version 22.0).
A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
Relative weights are based on an inverse variance approach.
N: Number of patients in treatment group; NETA: Norethindrone acetate; DF: Degrees of freedom; IPD: Individual Patient Data. NC: Not calculated. NE: Non-estimable.

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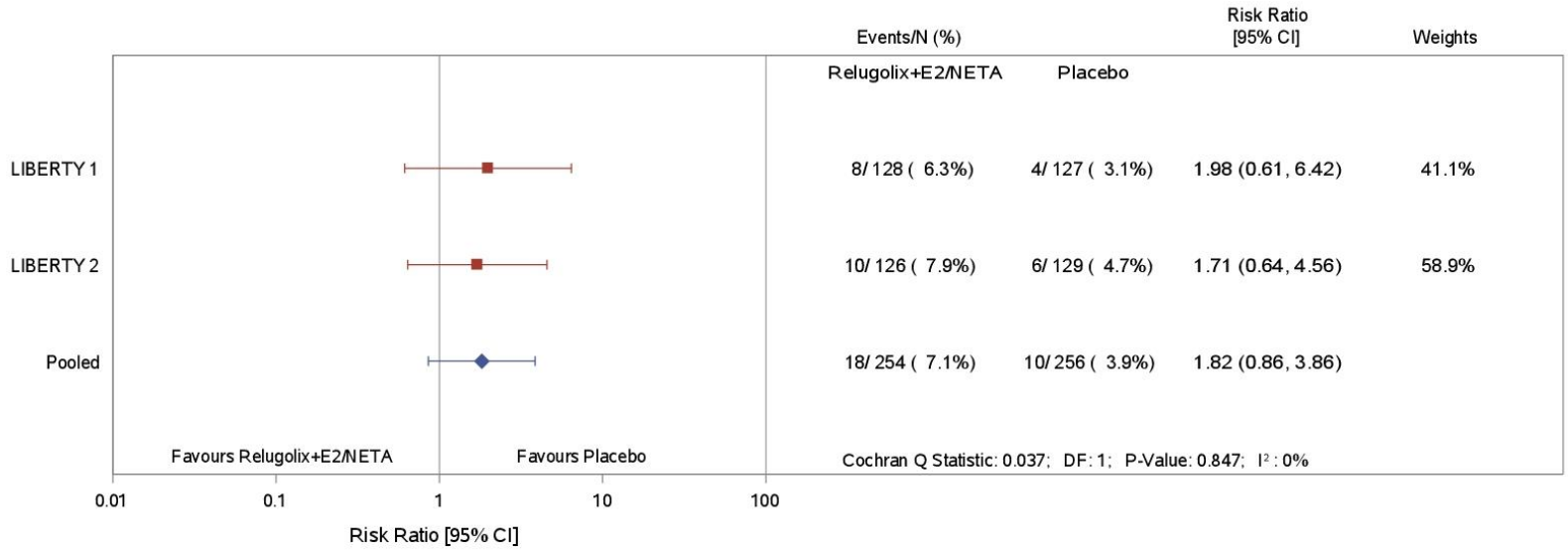
Figure SAF.TEAE.SPT.BIN.FP.RR: Frequent Treatment Emergent Adverse Events by System Organ Class and Preferred Term (Safety Population) - Risk Ratio
System Organ Class: Injury, poisoning and procedural complications, Preferred Term: Any



Results are based on a Cochran-Mantel-Haenszel approach for the pooled analysis, stratified by study. The analysis of LIBERTY 1 and LIBERTY 2 was based on an unstratified approach.
The reference group is Placebo. Patients with multiple events for a given PT or SOC are counted only once for each PT and SOC. Only SOCs or PTs for which there are at least 10% of patients with an event in at least one treatment group OR at least 10 patients with an event overall and at least 1% of patients with an event in at least one treatment group for the pooled analysis are presented. Events are sorted by SOC alphabetically and then by decreasing frequency of PT in the Relugolix+E2/NETA group for the pooled analysis. MedDRA (version 22.0).
A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
Relative weights are based on an inverse variance approach.
N: Number of patients in treatment group; NETA: Norethindrone acetate; DF: Degrees of freedom; IPD: Individual Patient Data.

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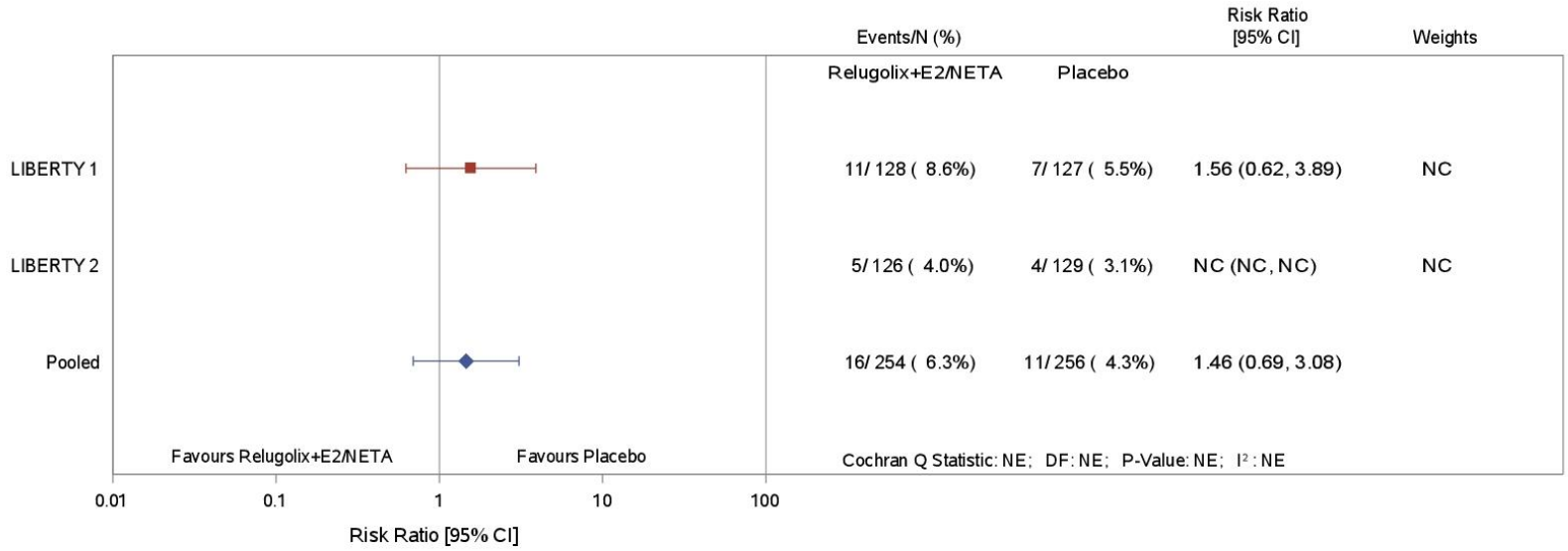
Figure SAF.TEAE.SPT.BIN.FP.RR: Frequent Treatment Emergent Adverse Events by System Organ Class and Preferred Term (Safety Population) - Risk Ratio
System Organ Class: Investigations, Preferred Term: Any



Results are based on a Cochran-Mantel-Haenszel approach for the pooled analysis, stratified by study. The analysis of LIBERTY 1 and LIBERTY 2 was based on an unstratified approach.
The reference group is Placebo. Patients with multiple events for a given PT or SOC are counted only once for each PT and SOC. Only SOCs or PTs for which there are at least 10% of patients with an event in at least one treatment group OR at least 10 patients with an event overall and at least 1% of patients with an event in at least one treatment group for the pooled analysis are presented. Events are sorted by SOC alphabetically and then by decreasing frequency of PT in the Relugolix+E2/NETA group for the pooled analysis. MedDRA (version 22.0).
A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
Relative weights are based on an inverse variance approach.
N: Number of patients in treatment group; NETA: Norethindrone acetate; DF: Degrees of freedom; IPD: Individual Patient Data. NC: Not calculated. NE: Non-estimable.

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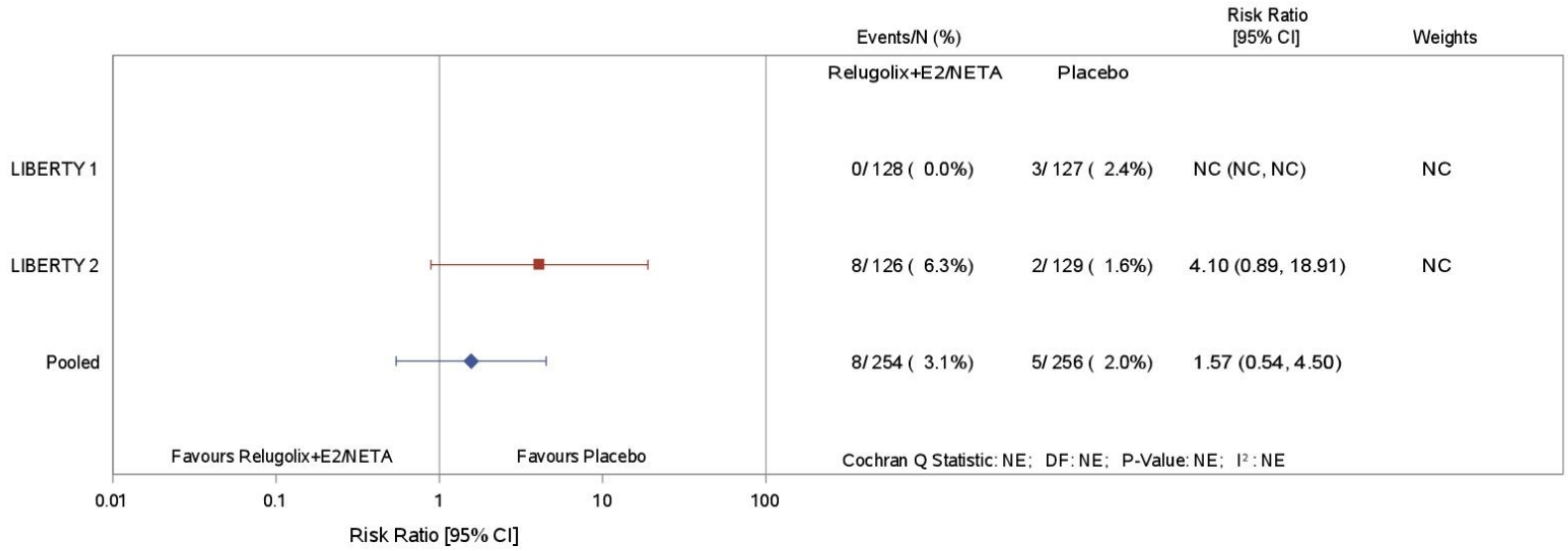
Figure SAF.TEAE.SPT.BIN.FP.RR: Frequent Treatment Emergent Adverse Events by System Organ Class and Preferred Term (Safety Population) - Risk Ratio
System Organ Class: Metabolism and nutrition disorders, Preferred Term: Any



Results are based on a Cochran-Mantel-Haenszel approach for the pooled analysis, stratified by study. The analysis of LIBERTY 1 and LIBERTY 2 was based on an unstratified approach.
The reference group is Placebo. Patients with multiple events for a given PT or SOC are counted only once for each PT and SOC. Only SOCs or PTs for which there are at least 10% of patients with an event in at least one treatment group OR at least 10 patients with an event overall and at least 1% of patients with an event in at least one treatment group for the pooled analysis are presented. Events are sorted by SOC alphabetically and then by decreasing frequency of PT in the Relugolix+E2/NETA group for the pooled analysis. MedDRA (version 22.0).
A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
Relative weights are based on an inverse variance approach.
N: Number of patients in treatment group; NETA: Norethindrone acetate; DF: Degrees of freedom; IPD: Individual Patient Data. NC: Not calculated. NE: Non-estimable.

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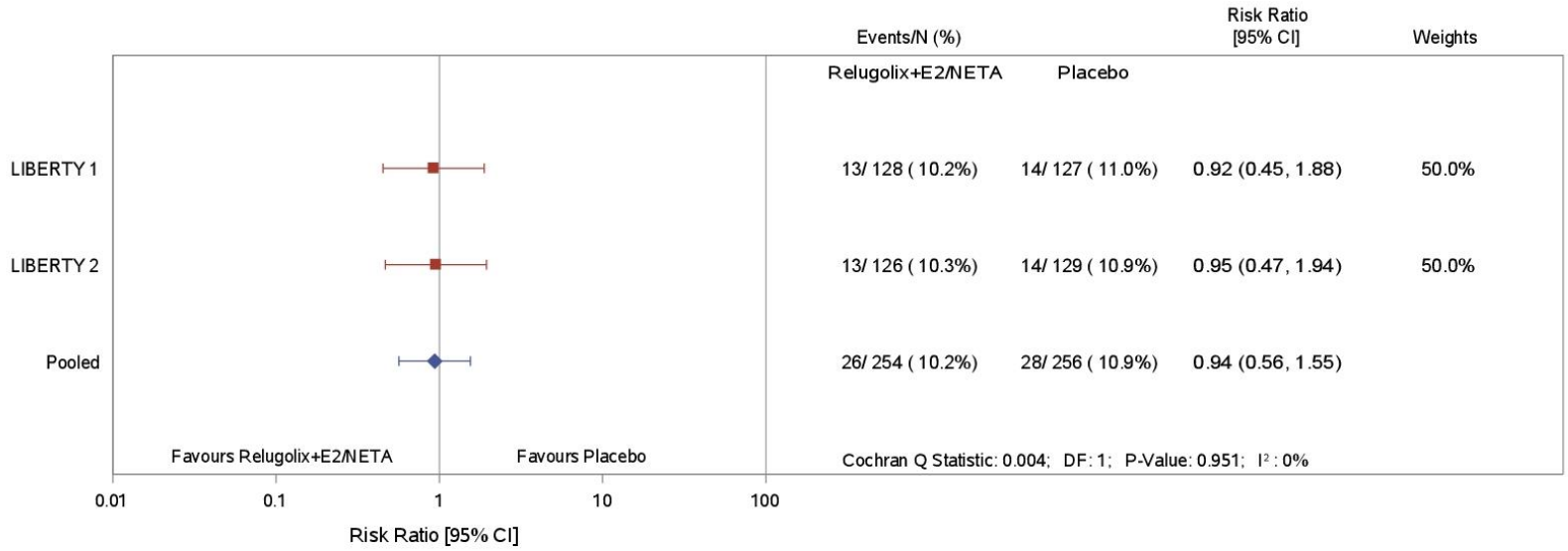
Figure SAF.TEAE.SPT.BIN.FP.RR: Frequent Treatment Emergent Adverse Events by System Organ Class and Preferred Term (Safety Population) - Risk Ratio
System Organ Class: Musculoskeletal and connective tissue disorders, Preferred Term: Any



Results are based on a Cochran-Mantel-Haenszel approach for the pooled analysis, stratified by study. The analysis of LIBERTY 1 and LIBERTY 2 was based on an unstratified approach.
The reference group is Placebo. Patients with multiple events for a given PT or SOC are counted only once for each PT and SOC. Only SOCs or PTs for which there are at least 10% of patients with an event in at least one treatment group OR at least 10 patients with an event overall and at least 1% of patients with an event in at least one treatment group for the pooled analysis are presented. Events are sorted by SOC alphabetically and then by decreasing frequency of PT in the Relugolix+E2/NETA group for the pooled analysis. MedDRA (version 22.0).
A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
Relative weights are based on an inverse variance approach.
N: Number of patients in treatment group; NETA: Norethindrone acetate; DF: Degrees of freedom; IPD: Individual Patient Data.

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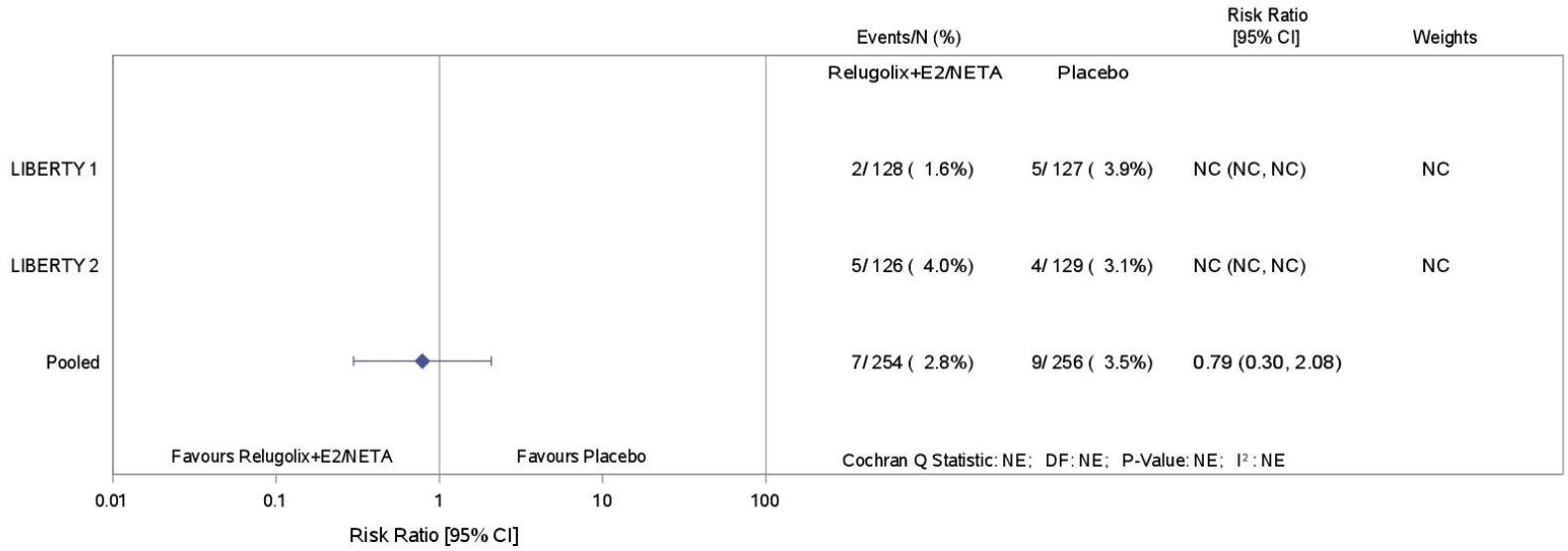
Figure SAF.TEAE.SPT.BIN.FP.RR: Frequent Treatment Emergent Adverse Events by System Organ Class and Preferred Term (Safety Population) - Risk Ratio
System Organ Class: Musculoskeletal and connective tissue disorders, Preferred Term: Back pain



Results are based on a Cochran-Mantel-Haenszel approach for the pooled analysis, stratified by study. The analysis of LIBERTY 1 and LIBERTY 2 was based on an unstratified approach.
The reference group is Placebo. Patients with multiple events for a given PT or SOC are counted only once for each PT and SOC. Only SOCs or PTs for which there are at least 10% of patients with an event in at least one treatment group OR at least 10 patients with an event overall and at least 1% of patients with an event in at least one treatment group for the pooled analysis are presented. Events are sorted by SOC alphabetically and then by decreasing frequency of PT in the Relugolix+E2/NETA group for the pooled analysis. MedDRA (version 22.0).
A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
Relative weights are based on an inverse variance approach.
N: Number of patients in treatment group; NETA: Norethindrone acetate; DF: Degrees of freedom; IPD: Individual Patient Data. NC: Not calculated. NE: Non-estimable.

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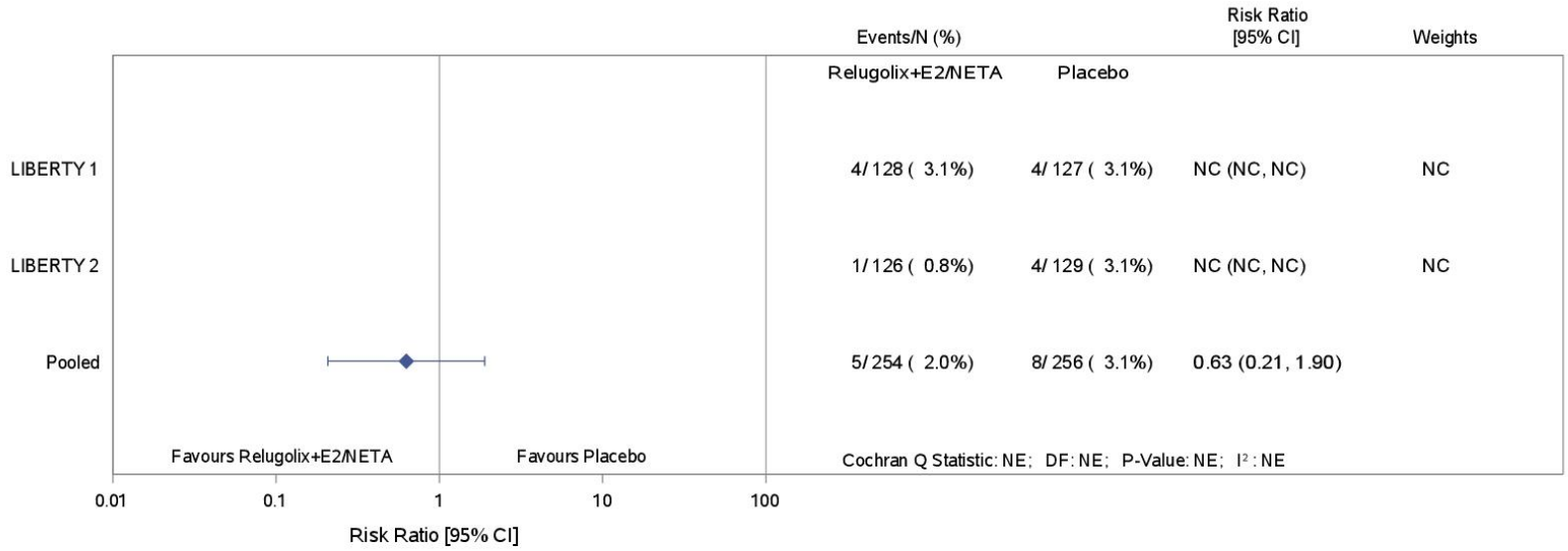
Figure SAF.TEAE.SPT.BIN.FP.RR: Frequent Treatment Emergent Adverse Events by System Organ Class and Preferred Term (Safety Population) - Risk Ratio
System Organ Class: Musculoskeletal and connective tissue disorders, Preferred Term: Arthralgia



Results are based on a Cochran-Mantel-Haenszel approach for the pooled analysis, stratified by study. The analysis of LIBERTY 1 and LIBERTY 2 was based on an unstratified approach.
The reference group is Placebo. Patients with multiple events for a given PT or SOC are counted only once for each PT and SOC. Only SOCs or PTs for which there are at least 10% of patients with an event in at least one treatment group OR at least 10 patients with an event overall and at least 1% of patients with an event in at least one treatment group for the pooled analysis are presented. Events are sorted by SOC alphabetically and then by decreasing frequency of PT in the Relugolix+E2/NETA group for the pooled analysis. MedDRA (version 22.0).
A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
Relative weights are based on an inverse variance approach.
N: Number of patients in treatment group; NETA: Norethindrone acetate; DF: Degrees of freedom; IPD: Individual Patient Data. NC: Not calculated. NE: Non-estimable.

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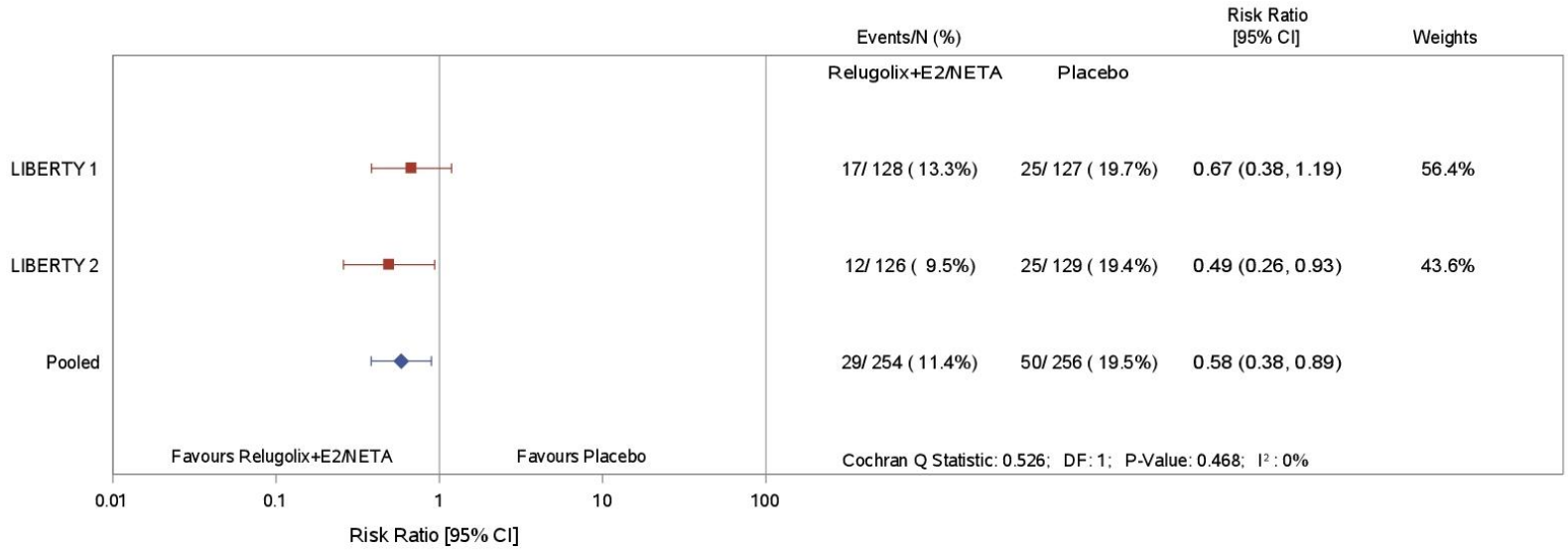
Figure SAF.TEAE.SPT.BIN.FP.RR: Frequent Treatment Emergent Adverse Events by System Organ Class and Preferred Term (Safety Population) - Risk Ratio
System Organ Class: Nervous system disorders, Preferred Term: Any



Results are based on a Cochran-Mantel-Haenszel approach for the pooled analysis, stratified by study. The analysis of LIBERTY 1 and LIBERTY 2 was based on an unstratified approach.
The reference group is Placebo. Patients with multiple events for a given PT or SOC are counted only once for each PT and SOC. Only SOCs or PTs for which there are at least 10% of patients with an event in at least one treatment group OR at least 10 patients with an event overall and at least 1% of patients with an event in at least one treatment group for the pooled analysis are presented. Events are sorted by SOC alphabetically and then by decreasing frequency of PT in the Relugolix+E2/NETA group for the pooled analysis. MedDRA (version 22.0).
A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
Relative weights are based on an inverse variance approach.
N: Number of patients in treatment group; NETA: Norethindrone acetate; DF: Degrees of freedom; IPD: Individual Patient Data.

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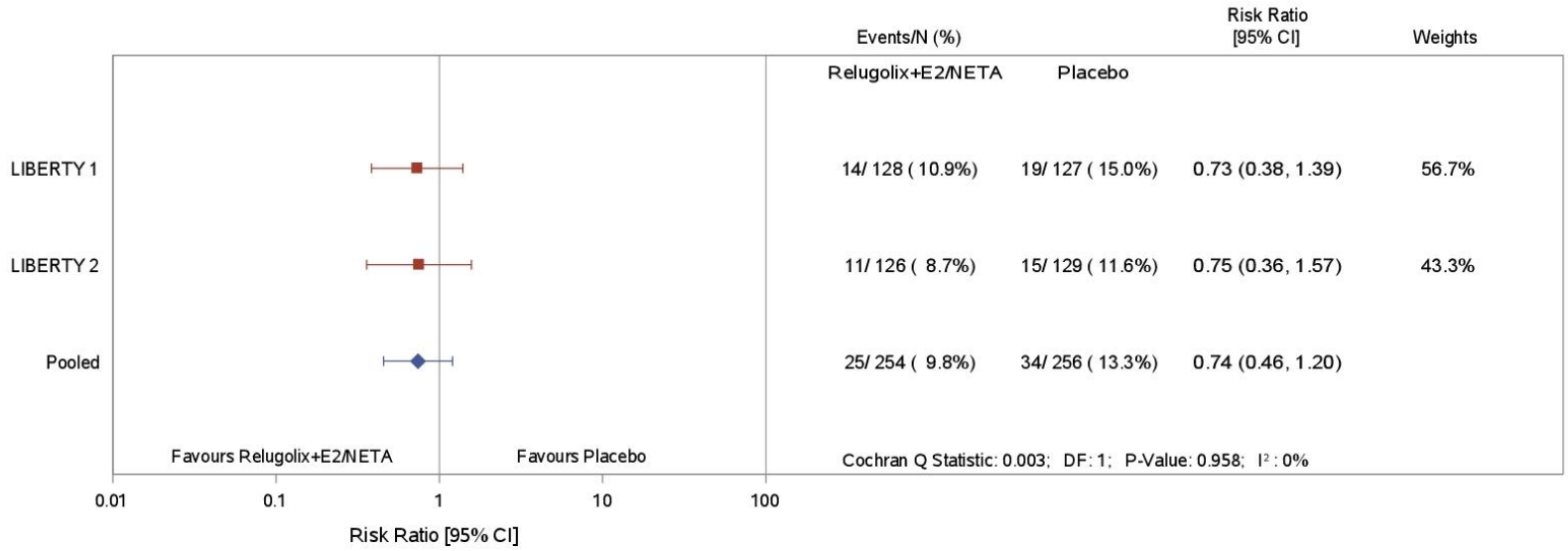
Figure SAF.TEAE.SPT.BIN.FP.RR: Frequent Treatment Emergent Adverse Events by System Organ Class and Preferred Term (Safety Population) - Risk Ratio
System Organ Class: Nervous system disorders, Preferred Term: Headache



Results are based on a Cochran-Mantel-Haenszel approach for the pooled analysis, stratified by study. The analysis of LIBERTY 1 and LIBERTY 2 was based on an unstratified approach.
The reference group is Placebo. Patients with multiple events for a given PT or SOC are counted only once for each PT and SOC. Only SOCs or PTs for which there are at least 10% of patients with an event in at least one treatment group OR at least 10 patients with an event overall and at least 1% of patients with an event in at least one treatment group for the pooled analysis are presented. Events are sorted by SOC alphabetically and then by decreasing frequency of PT in the Relugolix+E2/NETA group for the pooled analysis. MedDRA (version 22.0).
A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
Relative weights are based on an inverse variance approach.
N: Number of patients in treatment group; NETA: Norethindrone acetate; DF: Degrees of freedom; IPD: Individual Patient Data.

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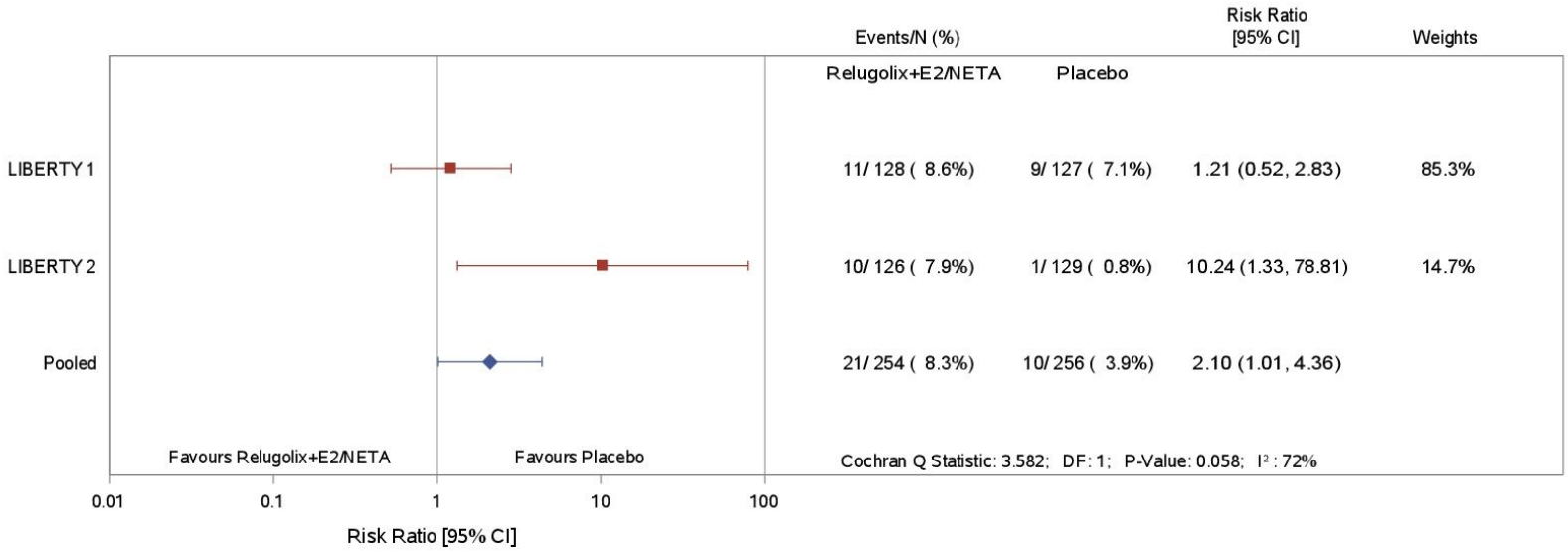
Figure SAF.TEAE.SPT.BIN.FP.RR: Frequent Treatment Emergent Adverse Events by System Organ Class and Preferred Term (Safety Population) - Risk Ratio
System Organ Class: Psychiatric disorders, Preferred Term: Any



Results are based on a Cochran-Mantel-Haenszel approach for the pooled analysis, stratified by study. The analysis of LIBERTY 1 and LIBERTY 2 was based on an unstratified approach.
The reference group is Placebo. Patients with multiple events for a given PT or SOC are counted only once for each PT and SOC. Only SOCs or PTs for which there are at least 10% of patients with an event in at least one treatment group OR at least 10 patients with an event overall and at least 1% of patients with an event in at least one treatment group for the pooled analysis are presented. Events are sorted by SOC alphabetically and then by decreasing frequency of PT in the Relugolix+E2/NETA group for the pooled analysis. MedDRA (version 22.0).
A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
Relative weights are based on an inverse variance approach.
N: Number of patients in treatment group; NETA: Norethindrone acetate; DF: Degrees of freedom; IPD: Individual Patient Data.

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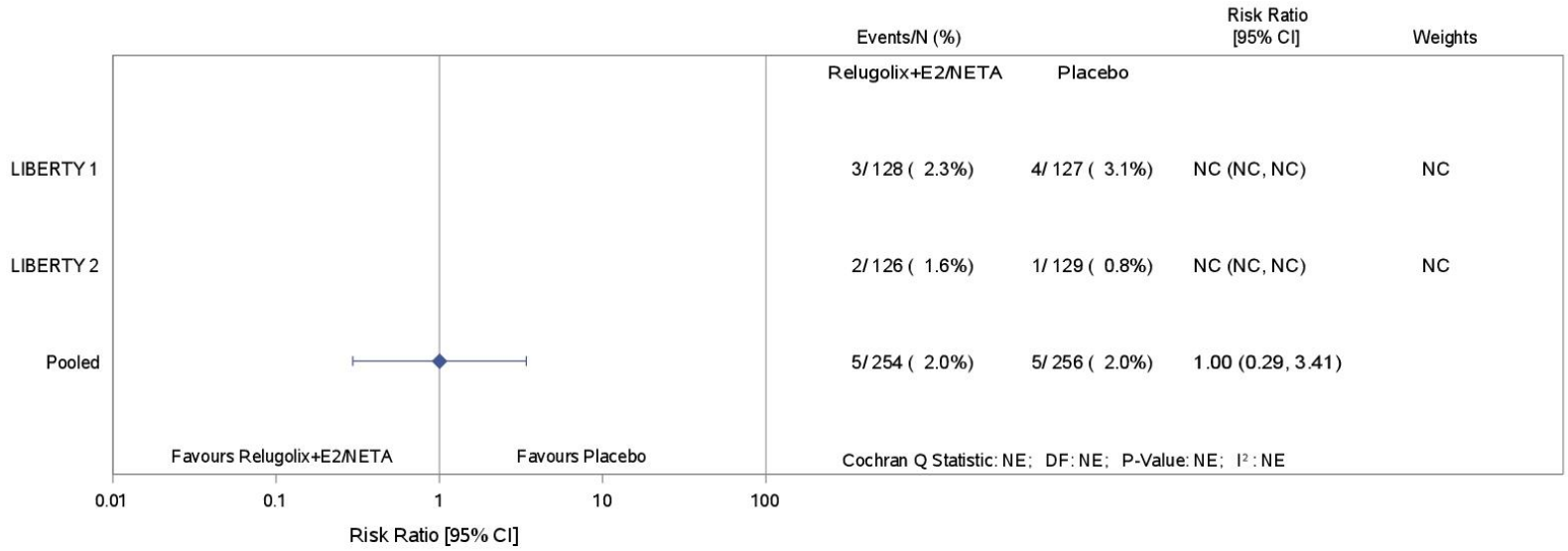
Figure SAF.TEAE.SPT.BIN.FP.RR: Frequent Treatment Emergent Adverse Events by System Organ Class and Preferred Term (Safety Population) - Risk Ratio
System Organ Class: Psychiatric disorders, Preferred Term: Insomnia



Results are based on a Cochran-Mantel-Haenszel approach for the pooled analysis, stratified by study. The analysis of LIBERTY 1 and LIBERTY 2 was based on an unstratified approach.
The reference group is Placebo. Patients with multiple events for a given PT or SOC are counted only once for each PT and SOC. Only SOCs or PTs for which there are at least 10% of patients with an event in at least one treatment group OR at least 10 patients with an event overall and at least 1% of patients with an event in at least one treatment group for the pooled analysis are presented. Events are sorted by SOC alphabetically and then by decreasing frequency of PT in the Relugolix+E2/NETA group for the pooled analysis. MedDRA (version 22.0).
A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
Relative weights are based on an inverse variance approach.
N: Number of patients in treatment group; NETA: Norethindrone acetate; DF: Degrees of freedom; IPD: Individual Patient Data. NC: Not calculated. NE: Non-estimable.

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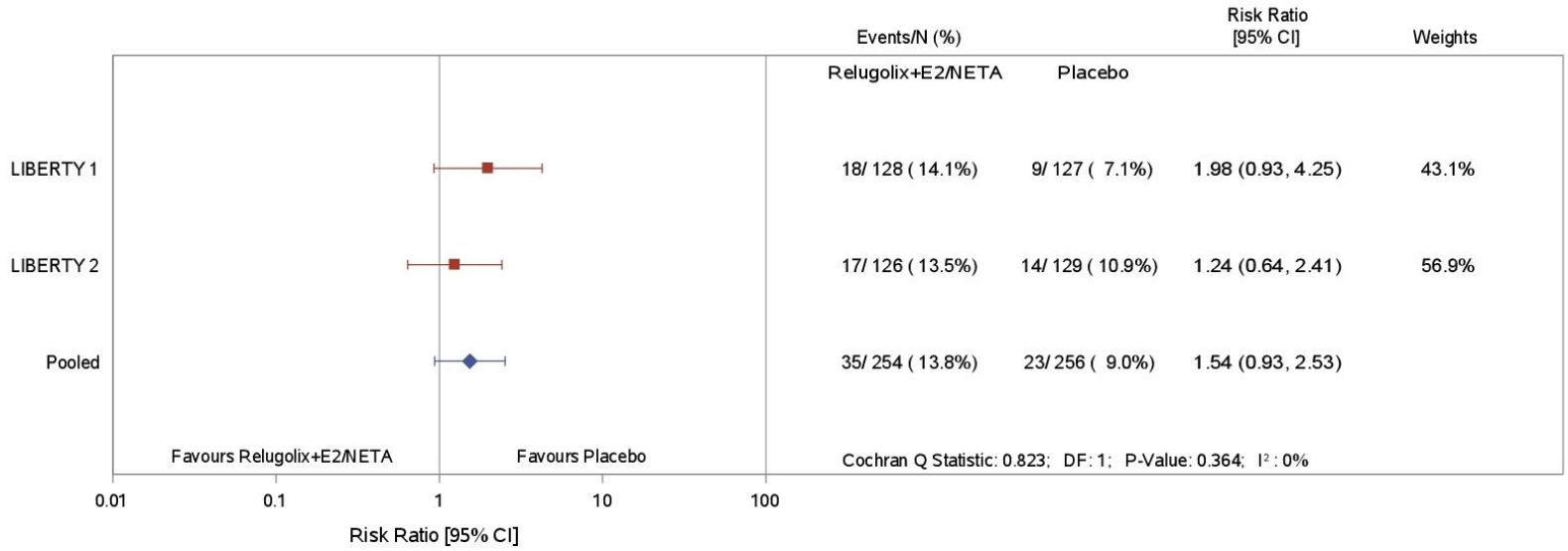
Figure SAF.TEAE.SPT.BIN.FP.RR: Frequent Treatment Emergent Adverse Events by System Organ Class and Preferred Term (Safety Population) - Risk Ratio
System Organ Class: Reproductive system and breast disorders, Preferred Term: Any



Results are based on a Cochran-Mantel-Haenszel approach for the pooled analysis, stratified by study. The analysis of LIBERTY 1 and LIBERTY 2 was based on an unstratified approach.
The reference group is Placebo. Patients with multiple events for a given PT or SOC are counted only once for each PT and SOC. Only SOCs or PTs for which there are at least 10% of patients with an event in at least one treatment group OR at least 10 patients with an event overall and at least 1% of patients with an event in at least one treatment group for the pooled analysis are presented. Events are sorted by SOC alphabetically and then by decreasing frequency of PT in the Relugolix+E2/NETA group for the pooled analysis. MedDRA (version 22.0).
A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
Relative weights are based on an inverse variance approach.
N: Number of patients in treatment group; NETA: Norethindrone acetate; DF: Degrees of freedom; IPD: Individual Patient Data.

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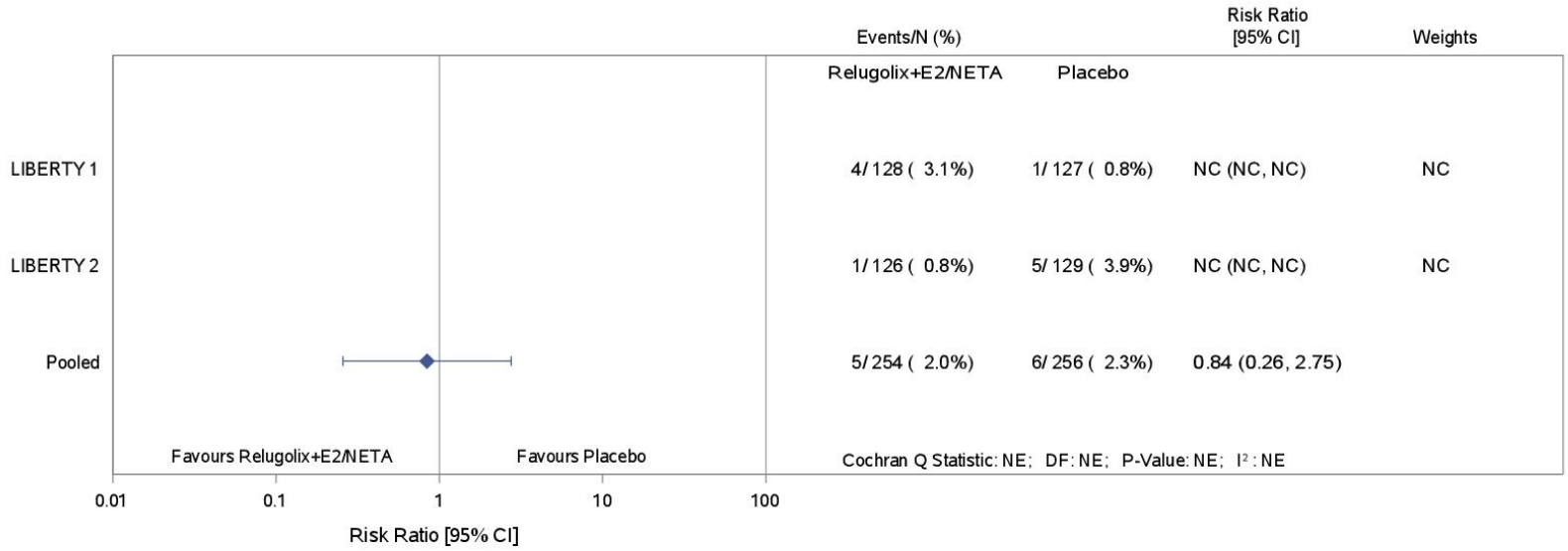
Figure SAF.TEAE.SPT.BIN.FP.RR: Frequent Treatment Emergent Adverse Events by System Organ Class and Preferred Term (Safety Population) - Risk Ratio
System Organ Class: Reproductive system and breast disorders, Preferred Term: Pelvic pain



Results are based on a Cochran-Mantel-Haenszel approach for the pooled analysis, stratified by study. The analysis of LIBERTY 1 and LIBERTY 2 was based on an unstratified approach.
The reference group is Placebo. Patients with multiple events for a given PT or SOC are counted only once for each PT and SOC. Only SOCs or PTs for which there are at least 10% of patients with an event in at least one treatment group OR at least 10 patients with an event overall and at least 1% of patients with an event in at least one treatment group for the pooled analysis are presented. Events are sorted by SOC alphabetically and then by decreasing frequency of PT in the Relugolix+E2/NETA group for the pooled analysis. MedDRA (version 22.0).
A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
Relative weights are based on an inverse variance approach.
N: Number of patients in treatment group; NETA: Norethindrone acetate; DF: Degrees of freedom; IPD: Individual Patient Data. NC: Not calculated. NE: Non-estimable.

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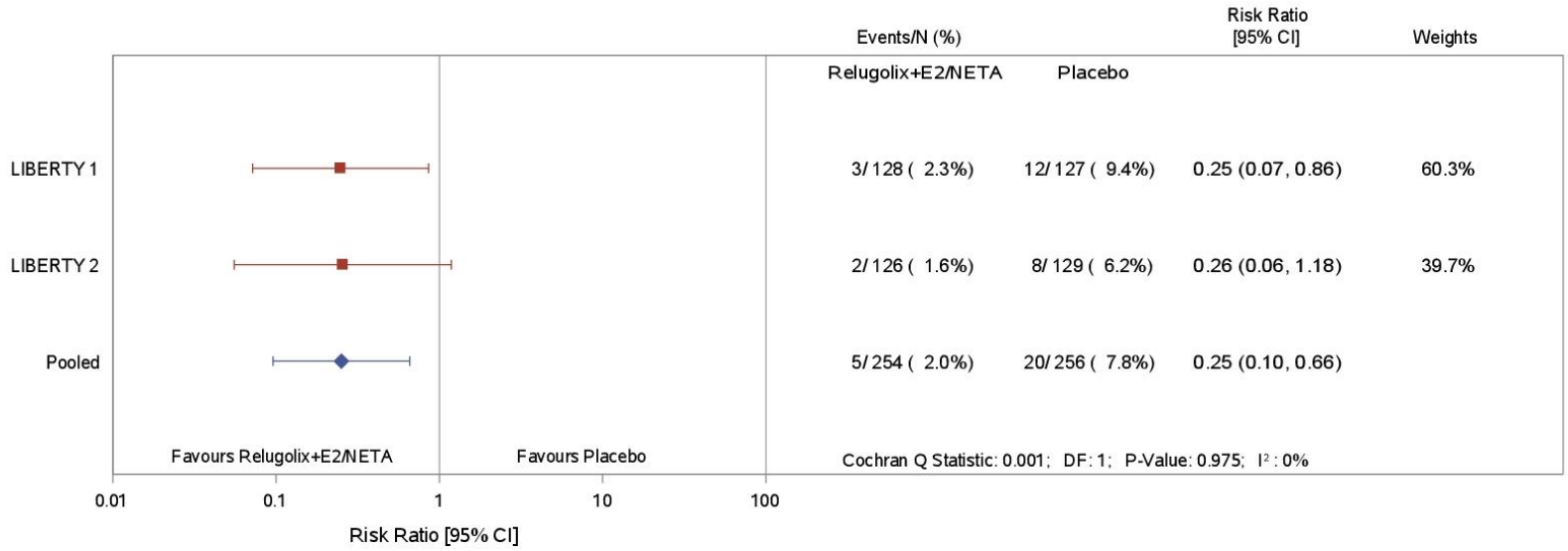
Figure SAF.TEAE.SPT.BIN.FP.RR: Frequent Treatment Emergent Adverse Events by System Organ Class and Preferred Term (Safety Population) - Risk Ratio
System Organ Class: Respiratory, thoracic and mediastinal disorders, Preferred Term: Any



Results are based on a Cochran-Mantel-Haenszel approach for the pooled analysis, stratified by study. The analysis of LIBERTY 1 and LIBERTY 2 was based on an unstratified approach.
The reference group is Placebo. Patients with multiple events for a given PT or SOC are counted only once for each PT and SOC. Only SOCs or PTs for which there are at least 10% of patients with an event in at least one treatment group OR at least 10 patients with an event overall and at least 1% of patients with an event in at least one treatment group for the pooled analysis are presented. Events are sorted by SOC alphabetically and then by decreasing frequency of PT in the Relugolix+E2/NETA group for the pooled analysis. MedDRA (version 22.0).
A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
Relative weights are based on an inverse variance approach.
N: Number of patients in treatment group; NETA: Norethindrone acetate; DF: Degrees of freedom; IPD: Individual Patient Data.

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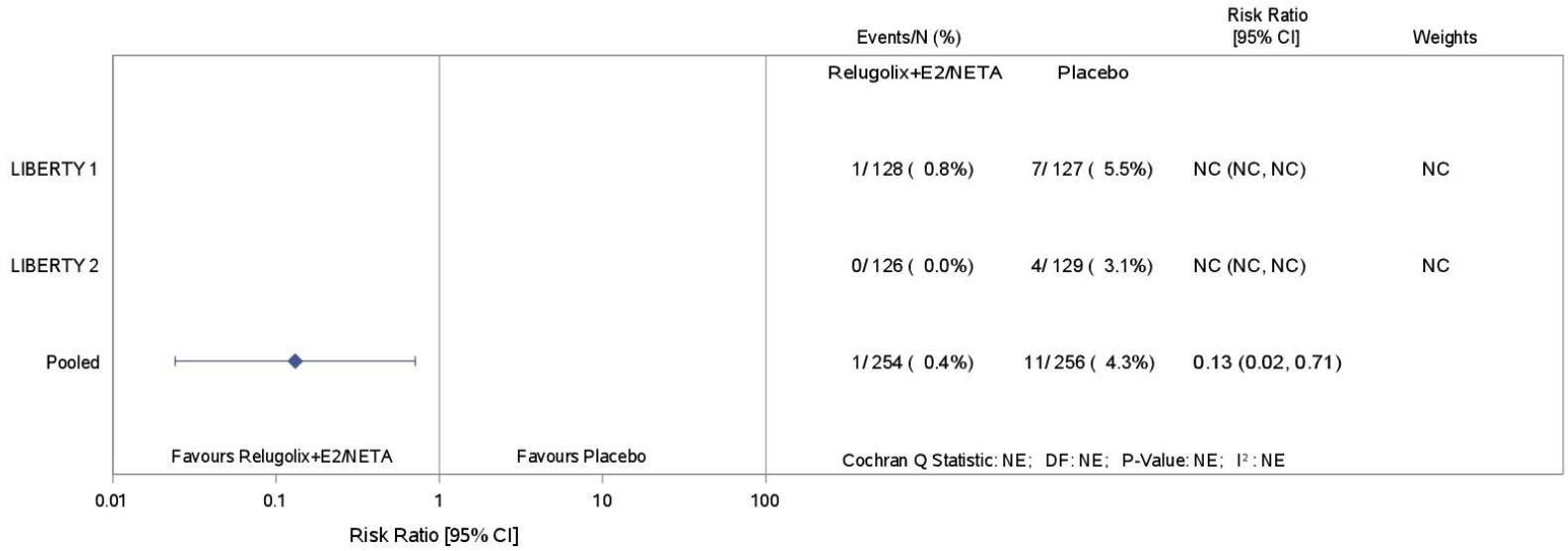
Figure SAF.TEAE.SPT.BIN.FP.RR: Frequent Treatment Emergent Adverse Events by System Organ Class and Preferred Term (Safety Population) - Risk Ratio
System Organ Class: Respiratory, thoracic and mediastinal disorders, Preferred Term: Cough



Results are based on a Cochran-Mantel-Haenszel approach for the pooled analysis, stratified by study. The analysis of LIBERTY 1 and LIBERTY 2 was based on an unstratified approach.
The reference group is Placebo. Patients with multiple events for a given PT or SOC are counted only once for each PT and SOC. Only SOCs or PTs for which there are at least 10% of patients with an event in at least one treatment group OR at least 10 patients with an event overall and at least 1% of patients with an event in at least one treatment group for the pooled analysis are presented. Events are sorted by SOC alphabetically and then by decreasing frequency of PT in the Relugolix+E2/NETA group for the pooled analysis. MedDRA (version 22.0).
A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
Relative weights are based on an inverse variance approach.
N: Number of patients in treatment group; NETA: Norethindrone acetate; DF: Degrees of freedom; IPD: Individual Patient Data. NC: Not calculated. NE: Non-estimable.

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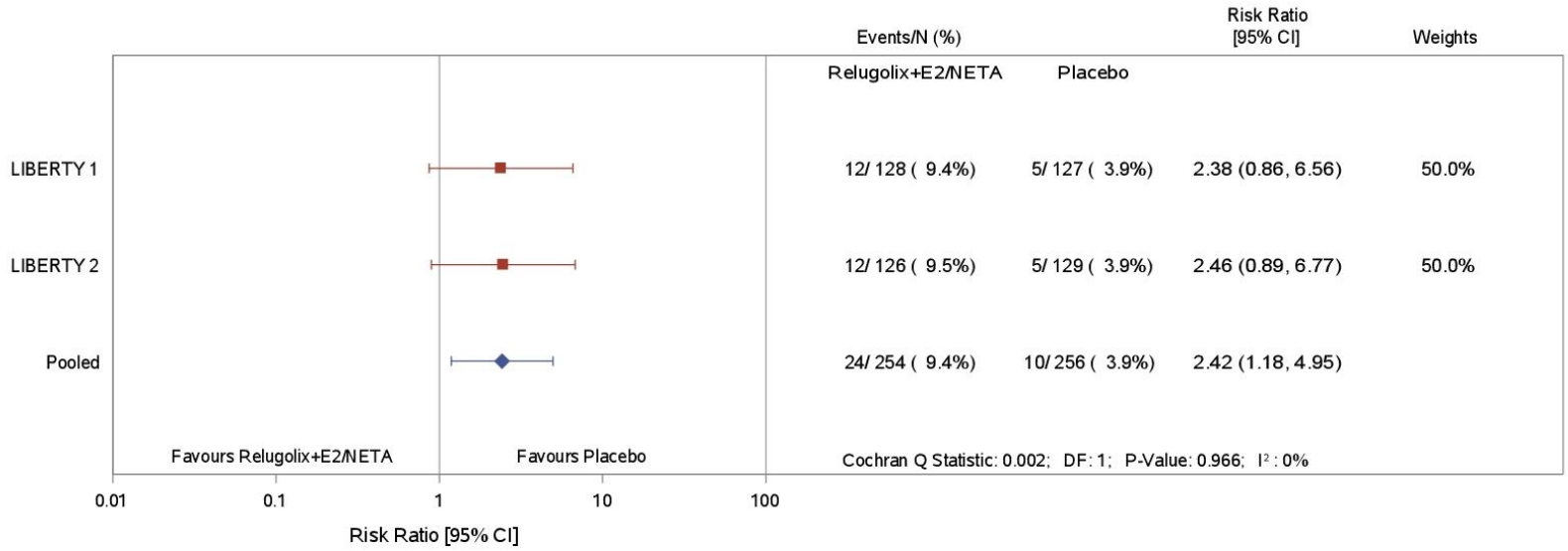
Figure SAF.TEAE.SPT.BIN.FP.RR: Frequent Treatment Emergent Adverse Events by System Organ Class and Preferred Term (Safety Population) - Risk Ratio
System Organ Class: Skin and subcutaneous tissue disorders, Preferred Term: Any



Results are based on a Cochran-Mantel-Haenszel approach for the pooled analysis, stratified by study. The analysis of LIBERTY 1 and LIBERTY 2 was based on an unstratified approach.
The reference group is Placebo. Patients with multiple events for a given PT or SOC are counted only once for each PT and SOC. Only SOCs or PTs for which there are at least 10% of patients with an event in at least one treatment group OR at least 10 patients with an event overall and at least 1% of patients with an event in at least one treatment group for the pooled analysis are presented. Events are sorted by SOC alphabetically and then by decreasing frequency of PT in the Relugolix+E2/NETA group for the pooled analysis. MedDRA (version 22.0).
A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
Relative weights are based on an inverse variance approach.
N: Number of patients in treatment group; NETA: Norethindrone acetate; DF: Degrees of freedom; IPD: Individual Patient Data.

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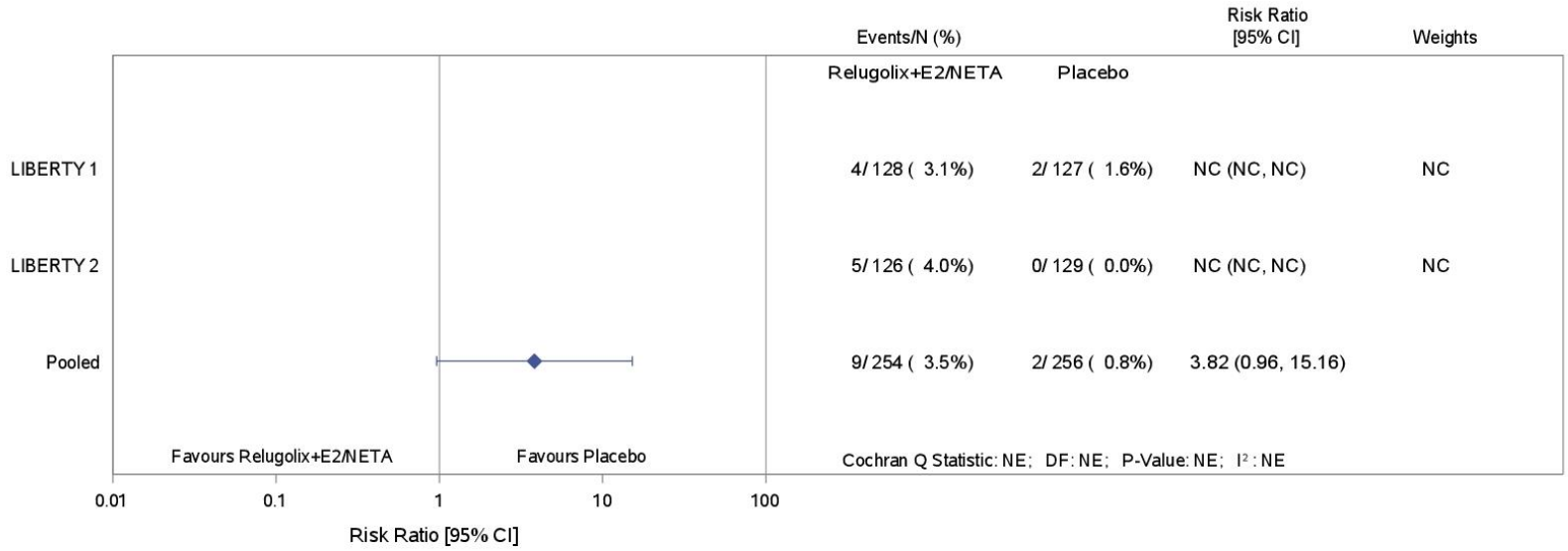
Figure SAF.TEAE.SPT.BIN.FP.RR: Frequent Treatment Emergent Adverse Events by System Organ Class and Preferred Term (Safety Population) - Risk Ratio
System Organ Class: Skin and subcutaneous tissue disorders, Preferred Term: Alopecia



Results are based on a Cochran-Mantel-Haenszel approach for the pooled analysis, stratified by study. The analysis of LIBERTY 1 and LIBERTY 2 was based on an unstratified approach.
The reference group is Placebo. Patients with multiple events for a given PT or SOC are counted only once for each PT and SOC. Only SOCs or PTs for which there are at least 10% of patients with an event in at least one treatment group OR at least 10 patients with an event overall and at least 1% of patients with an event in at least one treatment group for the pooled analysis are presented. Events are sorted by SOC alphabetically and then by decreasing frequency of PT in the Relugolix+E2/NETA group for the pooled analysis. MedDRA (version 22.0).
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Relative weights are based on an inverse variance approach.
N: Number of patients in treatment group; NETA: Norethindrone acetate; DF: Degrees of freedom; IPD: Individual Patient Data. NC: Not calculated. NE: Non-estimable.

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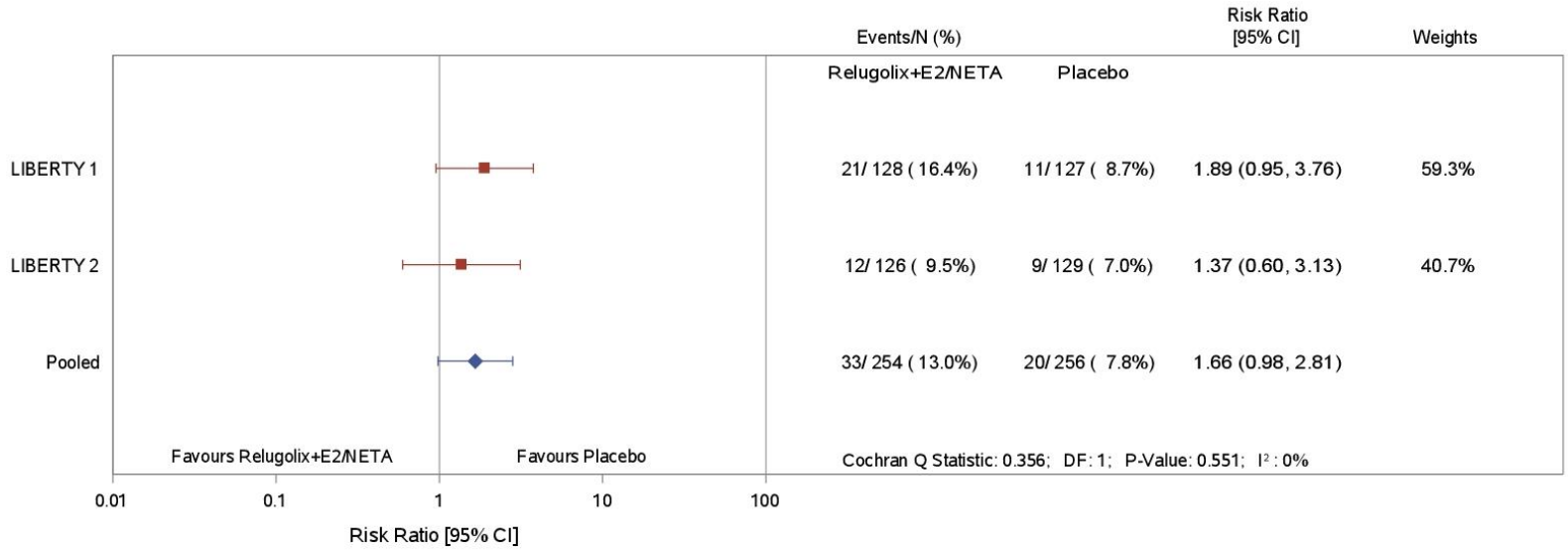
Figure SAF.TEAE.SPT.BIN.FP.RR: Frequent Treatment Emergent Adverse Events by System Organ Class and Preferred Term (Safety Population) - Risk Ratio
System Organ Class: Vascular disorders, Preferred Term: Any



Results are based on a Cochran-Mantel-Haenszel approach for the pooled analysis, stratified by study. The analysis of LIBERTY 1 and LIBERTY 2 was based on an unstratified approach.
The reference group is Placebo. Patients with multiple events for a given PT or SOC are counted only once for each PT and SOC. Only SOCs or PTs for which there are at least 10% of patients with an event in at least one treatment group OR at least 10 patients with an event overall and at least 1% of patients with an event in at least one treatment group for the pooled analysis are presented. Events are sorted by SOC alphabetically and then by decreasing frequency of PT in the Relugolix+E2/NETA group for the pooled analysis. MedDRA (version 22.0).
A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
Relative weights are based on an inverse variance approach.
N: Number of patients in treatment group; NETA: Norethindrone acetate; DF: Degrees of freedom; IPD: Individual Patient Data.

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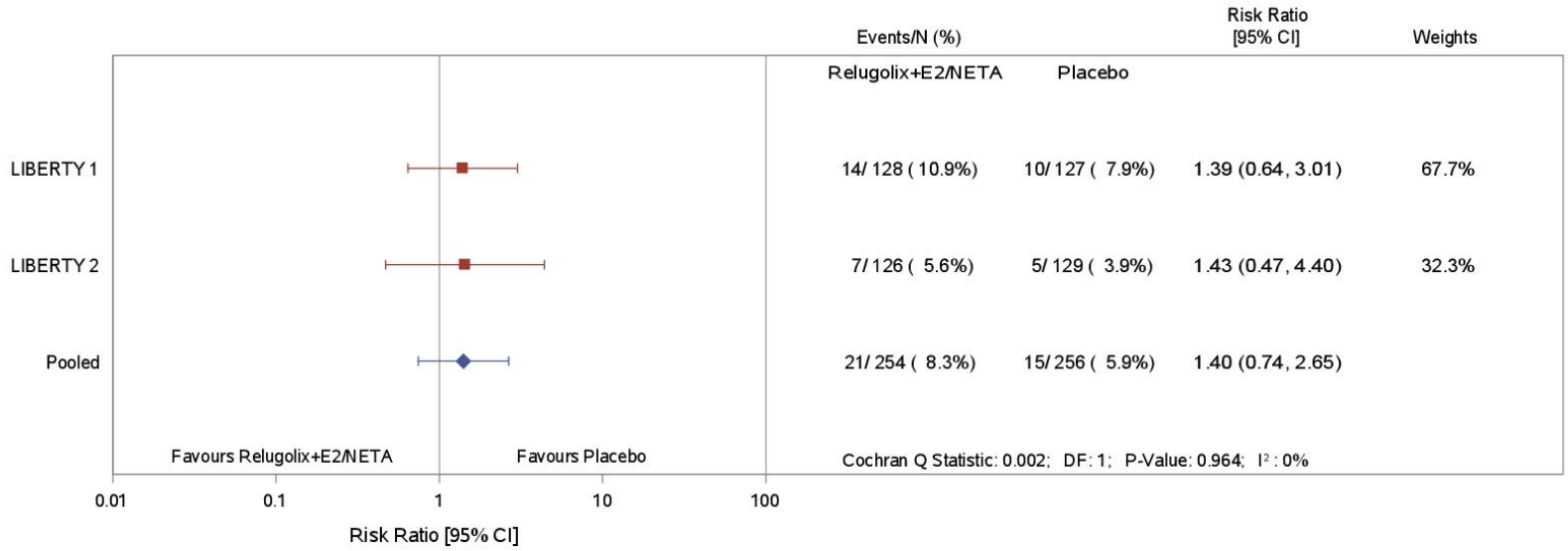
Figure SAF.TEAE.SPT.BIN.FP.RR: Frequent Treatment Emergent Adverse Events by System Organ Class and Preferred Term (Safety Population) - Risk Ratio
System Organ Class: Vascular disorders, Preferred Term: Hot flush



Results are based on a Cochran-Mantel-Haenszel approach for the pooled analysis, stratified by study. The analysis of LIBERTY 1 and LIBERTY 2 was based on an unstratified approach.
The reference group is Placebo. Patients with multiple events for a given PT or SOC are counted only once for each PT and SOC. Only SOCs or PTs for which there are at least 10% of patients with an event in at least one treatment group OR at least 10 patients with an event overall and at least 1% of patients with an event in at least one treatment group for the pooled analysis are presented. Events are sorted by SOC alphabetically and then by decreasing frequency of PT in the Relugolix+E2/NETA group for the pooled analysis. MedDRA (version 22.0).
A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
Relative weights are based on an inverse variance approach.
N: Number of patients in treatment group; NETA: Norethindrone acetate; DF: Degrees of freedom; IPD: Individual Patient Data.

SOURCE: X:\Numerus\Studies\MYV\MYV102\Analysis\Prod\Progs\TFLs\Fig_SAF_AE_SPT_BIN_FP.SAS Date/time of run: 28JUN21 16:01
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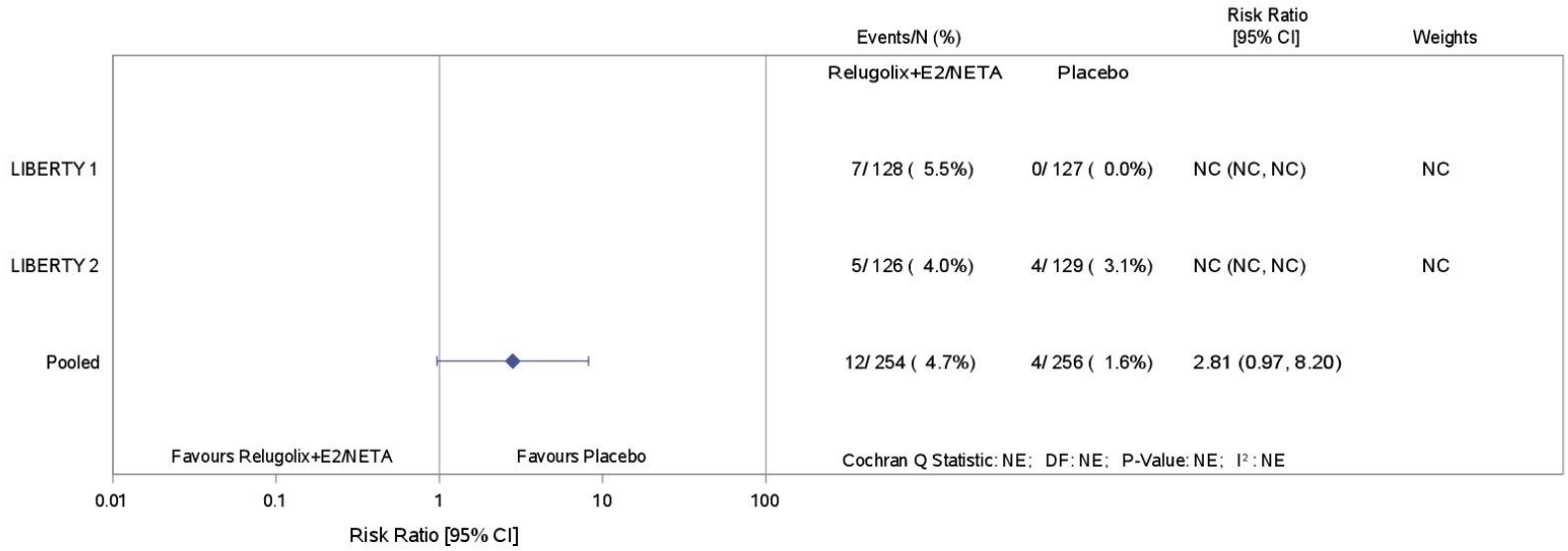
Figure SAF.TEAE.SPT.BIN.FP.RR: Frequent Treatment Emergent Adverse Events by System Organ Class and Preferred Term (Safety Population) - Risk Ratio
System Organ Class: Vascular disorders, Preferred Term: Hypertension



Results are based on a Cochran-Mantel-Haenszel approach for the pooled analysis, stratified by study. The analysis of LIBERTY 1 and LIBERTY 2 was based on an unstratified approach.
The reference group is Placebo. Patients with multiple events for a given PT or SOC are counted only once for each PT and SOC. Only SOCs or PTs for which there are at least 10% of patients with an event in at least one treatment group OR at least 10 patients with an event overall and at least 1% of patients with an event in at least one treatment group for the pooled analysis are presented. Events are sorted by SOC alphabetically and then by decreasing frequency of PT in the Relugolix+E2/NETA group for the pooled analysis. MedDRA (version 22.0).
A continuity correction is applied if zero events are observed in a given treatment group/stratum or if 100% of patients have an event in a given treatment group/stratum.
Relative weights are based on an inverse variance approach.
N: Number of patients in treatment group; NETA: Norethindrone acetate; DF: Degrees of freedom; IPD: Individual Patient Data. NC: Not calculated. NE: Non-estimable.

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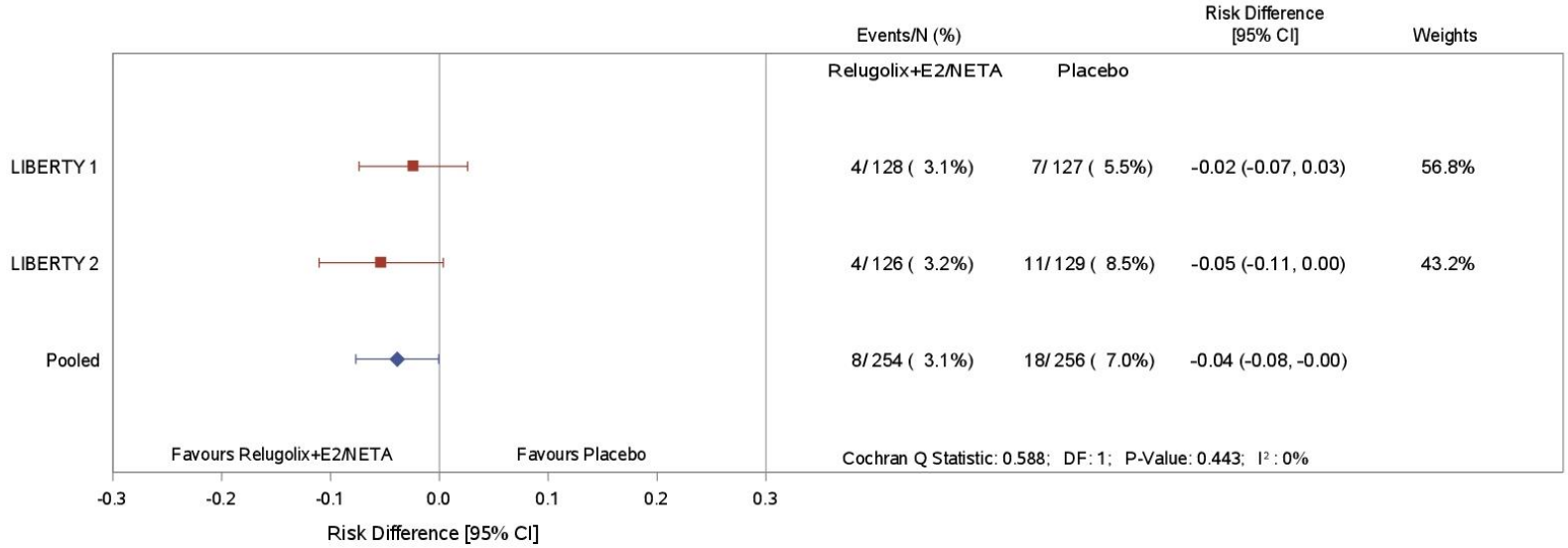
3.3 Risk Difference

Figure SAF.TEAE.SPT.BIN.FP.RD: Frequent Treatment Emergent Adverse Events by System Organ Class and Preferred Term (Safety Population) - Risk Difference
System Organ Class: Blood and lymphatic system disorders, Preferred Term: Any



Results are based on a Mantel-Haenszel approach for the pooled analysis, stratified by study. The analysis of LIBERTY 1 and LIBERTY 2 was based on an unstratified approach. The reference group is Placebo. Patients with multiple events for a given PT or SOC are counted only once for each PT and SOC. Only SOCs or PTs for which there are at least 10% of patients with an event in at least one treatment group OR at least 10 patients with an event overall and at least 1% of patients with an event in at least one treatment group for the pooled analysis are presented. Events are sorted by SOC alphabetically and then by decreasing frequency of PT in the Relugolix+E2/NETA group for the pooled analysis. MedDRA (version 22.0).
Relative weights are based on an inverse variance approach.
N: Number of patients in treatment group; NETA: Norethindrone acetate; DF: Degrees of freedom; IPD: Individual Patient Data.

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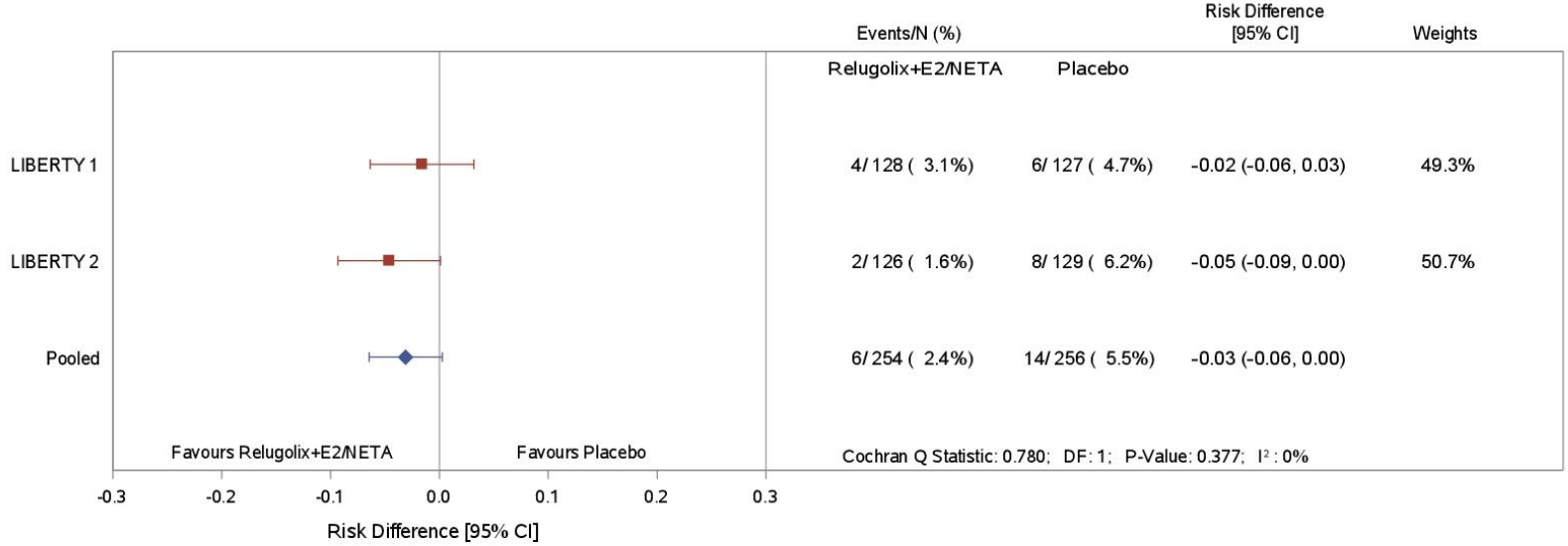
Figure SAF.TEAE.SPT.BIN.FP.RD: Frequent Treatment Emergent Adverse Events by System Organ Class and Preferred Term (Safety Population) - Risk Difference
System Organ Class: Blood and lymphatic system disorders, Preferred Term: Anaemia



Results are based on a Mantel-Haenszel approach for the pooled analysis, stratified by study. The analysis of LIBERTY 1 and LIBERTY 2 was based on an unstratified approach. The reference group is Placebo. Patients with multiple events for a given PT or SOC are counted only once for each PT and SOC. Only SOCs or PTs for which there are at least 10% of patients with an event in at least one treatment group OR at least 10 patients with an event overall and at least 1% of patients with an event in at least one treatment group for the pooled analysis are presented. Events are sorted by SOC alphabetically and then by decreasing frequency of PT in the Relugolix+E2/NETA group for the pooled analysis. MedDRA (version 22.0).
Relative weights are based on an inverse variance approach.
N: Number of patients in treatment group; NETA: Norethindrone acetate; DF: Degrees of freedom; IPD: Individual Patient Data.

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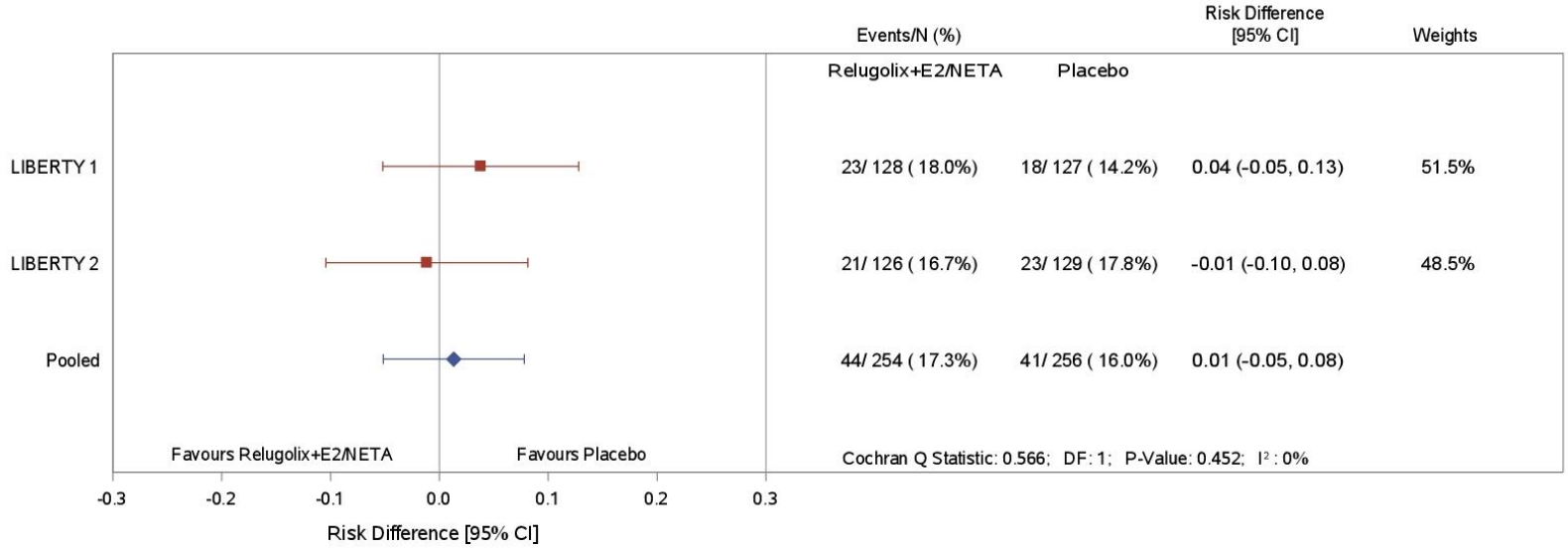
Figure SAF.TEAE.SPT.BIN.FP.RD: Frequent Treatment Emergent Adverse Events by System Organ Class and Preferred Term (Safety Population) - Risk Difference
System Organ Class: Gastrointestinal disorders, Preferred Term: Any



Results are based on a Mantel-Haenszel approach for the pooled analysis, stratified by study. The analysis of LIBERTY 1 and LIBERTY 2 was based on an unstratified approach. The reference group is Placebo. Patients with multiple events for a given PT or SOC are counted only once for each PT and SOC. Only SOCs or PTs for which there are at least 10% of patients with an event in at least one treatment group OR at least 10 patients with an event overall and at least 1% of patients with an event in at least one treatment group for the pooled analysis are presented. Events are sorted by SOC alphabetically and then by decreasing frequency of PT in the Relugolix+E2/NETA group for the pooled analysis. MedDRA (version 22.0).
Relative weights are based on an inverse variance approach.
N: Number of patients in treatment group; NETA: Norethindrone acetate; DF: Degrees of freedom; IPD: Individual Patient Data.

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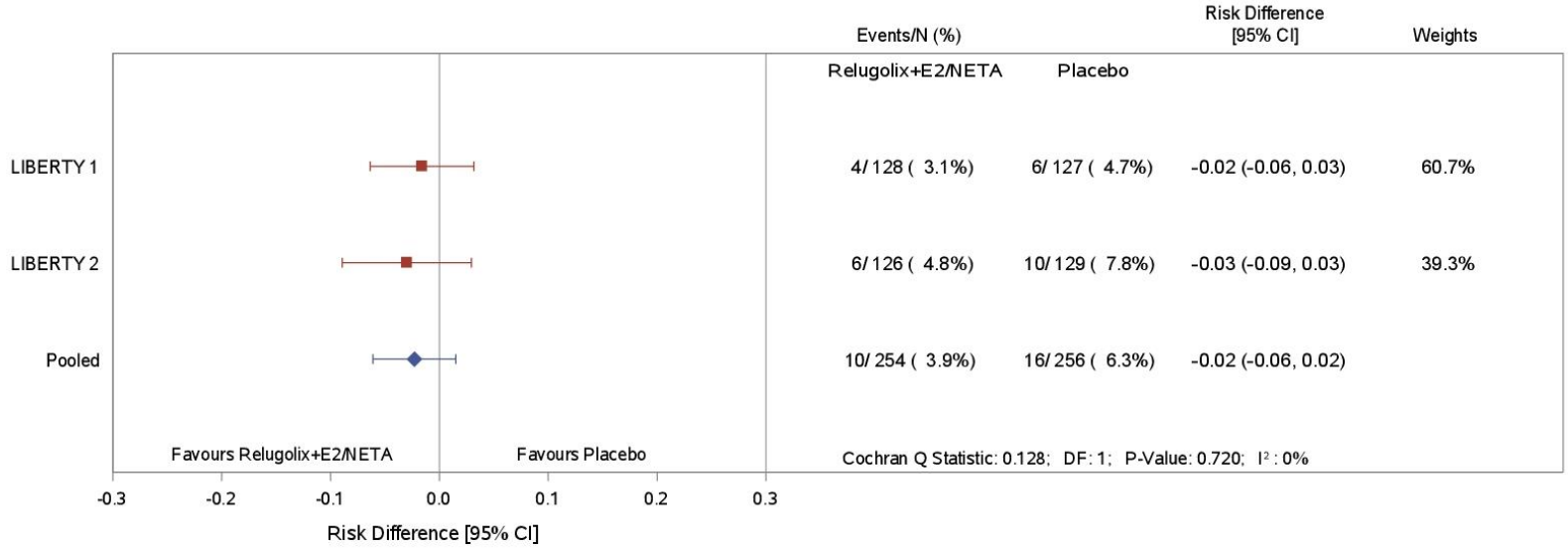
Figure SAF.TEAE.SPT.BIN.FP.RD: Frequent Treatment Emergent Adverse Events by System Organ Class and Preferred Term (Safety Population) - Risk Difference
System Organ Class: Gastrointestinal disorders, Preferred Term: Nausea



Results are based on a Mantel-Haenszel approach for the pooled analysis, stratified by study. The analysis of LIBERTY 1 and LIBERTY 2 was based on an unstratified approach. The reference group is Placebo. Patients with multiple events for a given PT or SOC are counted only once for each PT and SOC. Only SOCs or PTs for which there are at least 10% of patients with an event in at least one treatment group OR at least 10 patients with an event overall and at least 1% of patients with an event in at least one treatment group for the pooled analysis are presented. Events are sorted by SOC alphabetically and then by decreasing frequency of PT in the Relugolix+E2/NETA group for the pooled analysis. MedDRA (version 22.0).
Relative weights are based on an inverse variance approach.
N: Number of patients in treatment group; NETA: Norethindrone acetate; DF: Degrees of freedom; IPD: Individual Patient Data.

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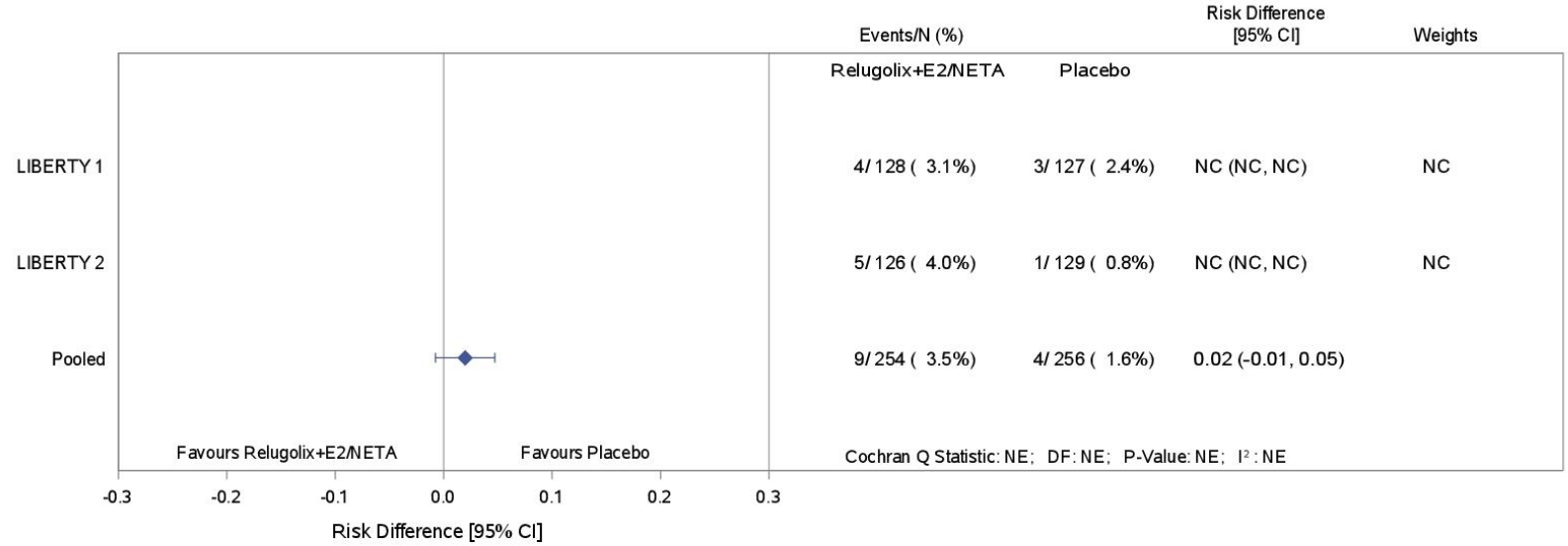
Figure SAF.TEAE.SPT.BIN.FP.RD: Frequent Treatment Emergent Adverse Events by System Organ Class and Preferred Term (Safety Population) - Risk Difference
System Organ Class: Gastrointestinal disorders, Preferred Term: Abdominal pain



Results are based on a Mantel-Haenszel approach for the pooled analysis, stratified by study. The analysis of LIBERTY 1 and LIBERTY 2 was based on an unstratified approach. The reference group is Placebo. Patients with multiple events for a given PT or SOC are counted only once for each PT and SOC. Only SOCs or PTs for which there are at least 10% of patients with an event in at least one treatment group OR at least 10 patients with an event overall and at least 1% of patients with an event in at least one treatment group for the pooled analysis are presented. Events are sorted by SOC alphabetically and then by decreasing frequency of PT in the Relugolix+E2/NETA group for the pooled analysis. MedDRA (version 22.0).
Relative weights are based on an inverse variance approach.
N: Number of patients in treatment group; NETA: Norethindrone acetate; DF: Degrees of freedom; IPD: Individual Patient Data. NC: Not calculated. NE: Non-estimable.

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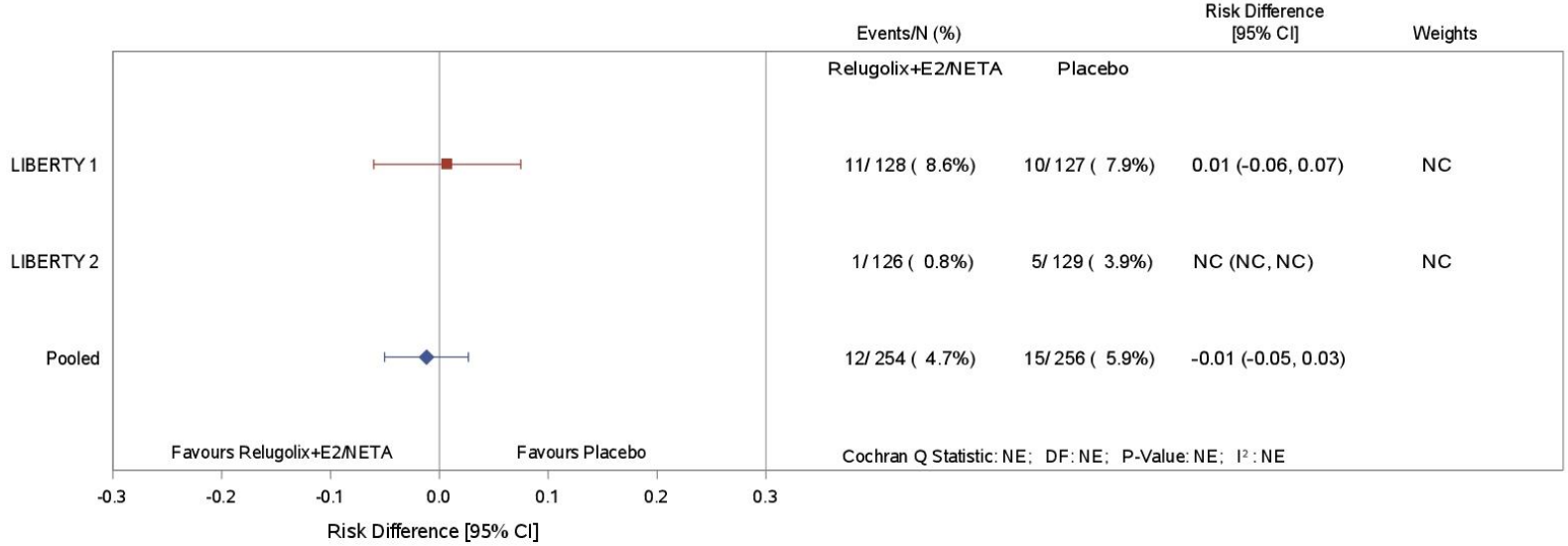
Figure SAF.TEAE.SPT.BIN.FP.RD: Frequent Treatment Emergent Adverse Events by System Organ Class and Preferred Term (Safety Population) - Risk Difference
System Organ Class: General disorders and administration site conditions, Preferred Term: Any



Results are based on a Mantel-Haenszel approach for the pooled analysis, stratified by study. The analysis of LIBERTY 1 and LIBERTY 2 was based on an unstratified approach. The reference group is Placebo. Patients with multiple events for a given PT or SOC are counted only once for each PT and SOC. Only SOCs or PTs for which there are at least 10% of patients with an event in at least one treatment group OR at least 10 patients with an event overall and at least 1% of patients with an event in at least one treatment group for the pooled analysis are presented. Events are sorted by SOC alphabetically and then by decreasing frequency of PT in the Relugolix+E2/NETA group for the pooled analysis. MedDRA (version 22.0).
Relative weights are based on an inverse variance approach.
N: Number of patients in treatment group; NETA: Norethindrone acetate; DF: Degrees of freedom; IPD: Individual Patient Data. NC: Not calculated. NE: Non-estimable.

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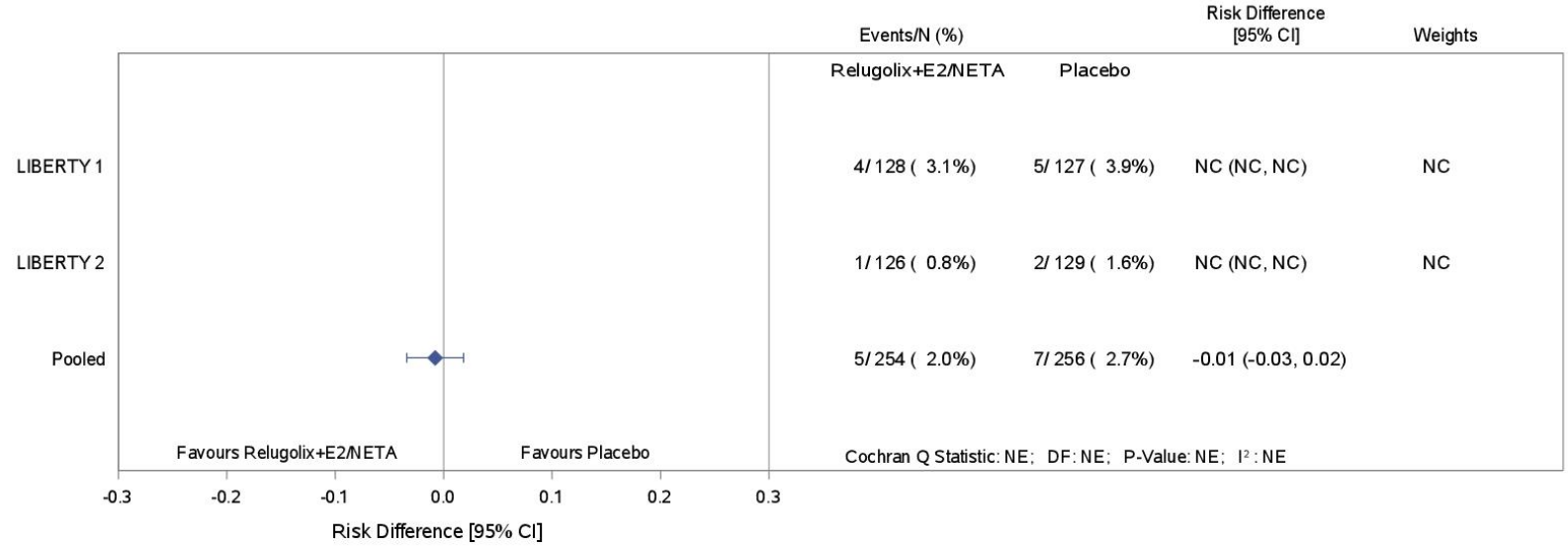
Figure SAF.TEAE.SPT.BIN.FP.RD: Frequent Treatment Emergent Adverse Events by System Organ Class and Preferred Term (Safety Population) - Risk Difference
System Organ Class: General disorders and administration site conditions, Preferred Term: Fatigue



Results are based on a Mantel-Haenszel approach for the pooled analysis, stratified by study. The analysis of LIBERTY 1 and LIBERTY 2 was based on an unstratified approach. The reference group is Placebo. Patients with multiple events for a given PT or SOC are counted only once for each PT and SOC. Only SOCs or PTs for which there are at least 10% of patients with an event in at least one treatment group OR at least 10 patients with an event overall and at least 1% of patients with an event in at least one treatment group for the pooled analysis are presented. Events are sorted by SOC alphabetically and then by decreasing frequency of PT in the Relugolix+E2/NETA group for the pooled analysis. MedDRA (version 22.0).
Relative weights are based on an inverse variance approach.
N: Number of patients in treatment group; NETA: Norethindrone acetate; DF: Degrees of freedom; IPD: Individual Patient Data. NC: Not calculated. NE: Non-estimable.

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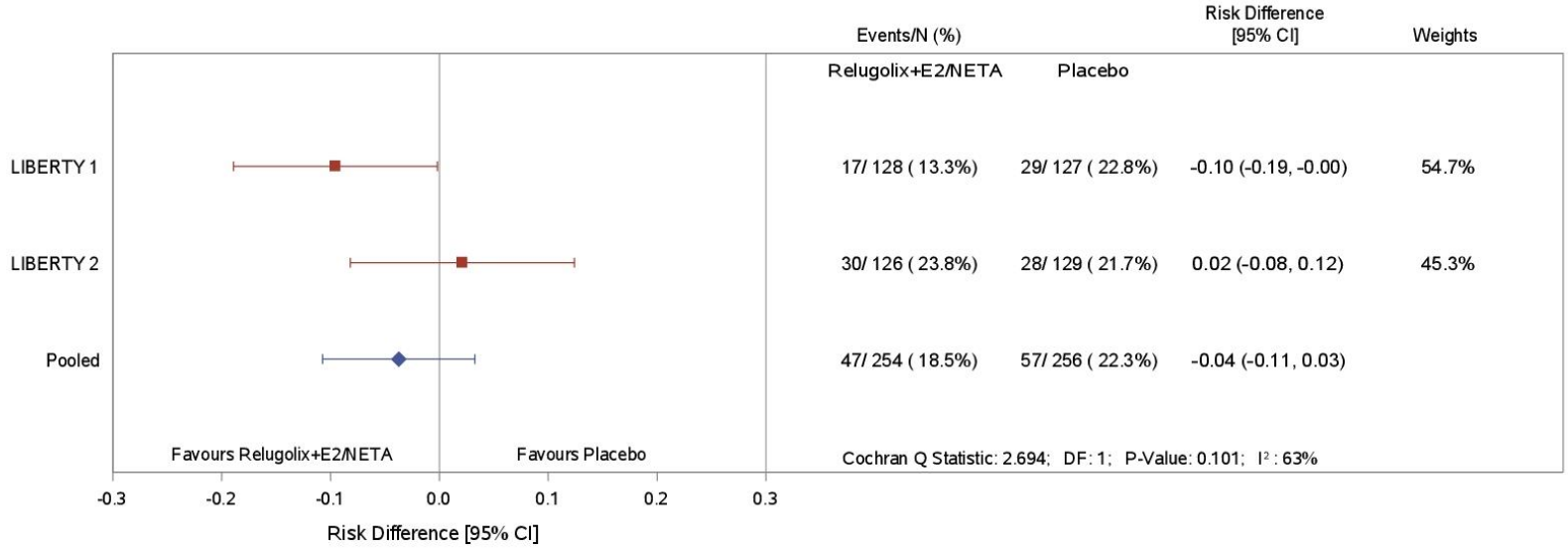
Figure SAF.TEAE.SPT.BIN.FP.RD: Frequent Treatment Emergent Adverse Events by System Organ Class and Preferred Term (Safety Population) - Risk Difference
System Organ Class: Infections and infestations, Preferred Term: Any



Results are based on a Mantel-Haenszel approach for the pooled analysis, stratified by study. The analysis of LIBERTY 1 and LIBERTY 2 was based on an unstratified approach. The reference group is Placebo. Patients with multiple events for a given PT or SOC are counted only once for each PT and SOC. Only SOCs or PTs for which there are at least 10% of patients with an event in at least one treatment group OR at least 10 patients with an event overall and at least 1% of patients with an event in at least one treatment group for the pooled analysis are presented. Events are sorted by SOC alphabetically and then by decreasing frequency of PT in the Relugolix+E2/NETA group for the pooled analysis. MedDRA (version 22.0).
Relative weights are based on an inverse variance approach.
N: Number of patients in treatment group; NETA: Norethindrone acetate; DF: Degrees of freedom; IPD: Individual Patient Data.

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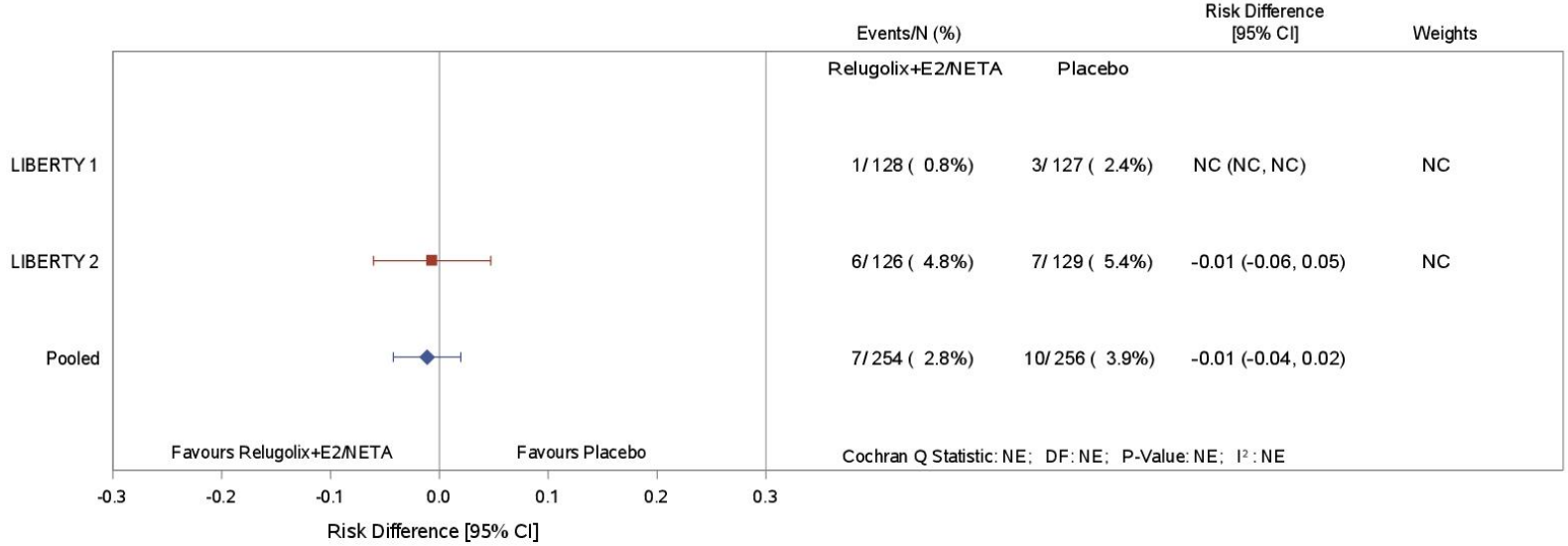
Figure SAF.TEAE.SPT.BIN.FP.RD: Frequent Treatment Emergent Adverse Events by System Organ Class and Preferred Term (Safety Population) - Risk Difference
System Organ Class: Infections and infestations, Preferred Term: Upper respiratory tract infection



Results are based on a Mantel-Haenszel approach for the pooled analysis, stratified by study. The analysis of LIBERTY 1 and LIBERTY 2 was based on an unstratified approach. The reference group is Placebo. Patients with multiple events for a given PT or SOC are counted only once for each PT and SOC. Only SOCs or PTs for which there are at least 10% of patients with an event in at least one treatment group OR at least 10 patients with an event overall and at least 1% of patients with an event in at least one treatment group for the pooled analysis are presented. Events are sorted by SOC alphabetically and then by decreasing frequency of PT in the Relugolix+E2/NETA group for the pooled analysis. MedDRA (version 22.0).
Relative weights are based on an inverse variance approach.
N: Number of patients in treatment group; NETA: Norethindrone acetate; DF: Degrees of freedom; IPD: Individual Patient Data. NC: Not calculated. NE: Non-estimable.

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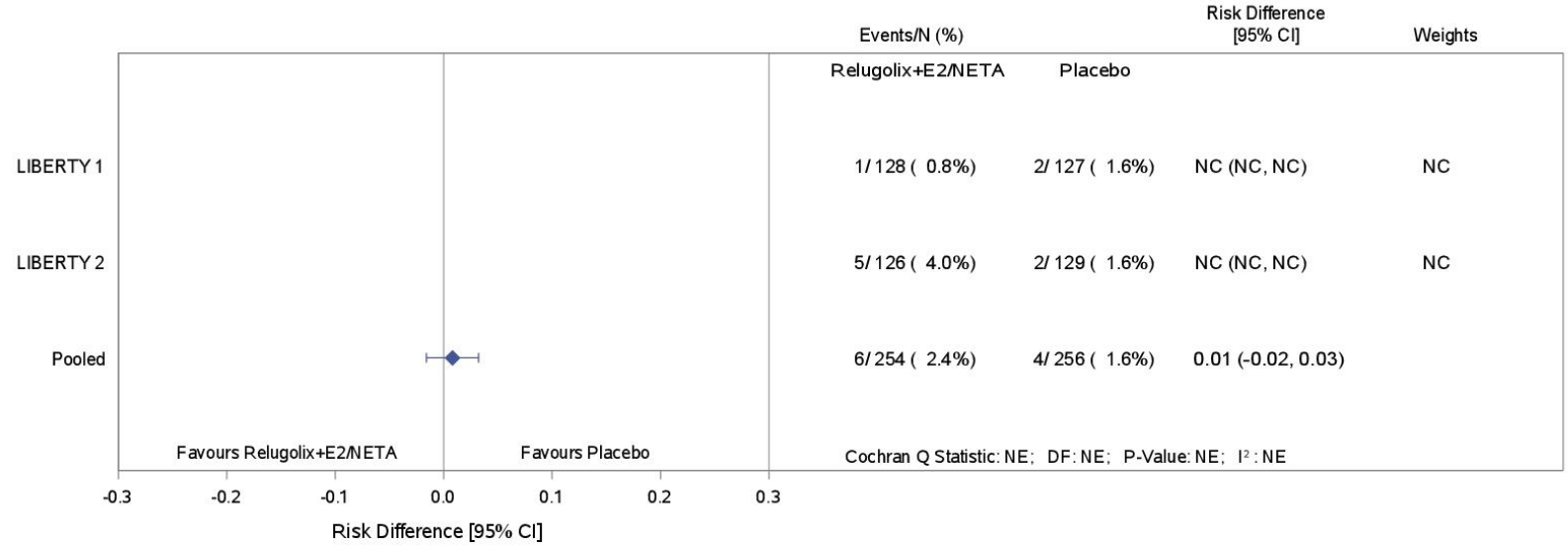
Figure SAF.TEAE.SPT.BIN.FP.RD: Frequent Treatment Emergent Adverse Events by System Organ Class and Preferred Term (Safety Population) - Risk Difference
System Organ Class: Infections and infestations, Preferred Term: Bronchitis



Results are based on a Mantel-Haenszel approach for the pooled analysis, stratified by study. The analysis of LIBERTY 1 and LIBERTY 2 was based on an unstratified approach. The reference group is Placebo. Patients with multiple events for a given PT or SOC are counted only once for each PT and SOC. Only SOCs or PTs for which there are at least 10% of patients with an event in at least one treatment group OR at least 10 patients with an event overall and at least 1% of patients with an event in at least one treatment group for the pooled analysis are presented. Events are sorted by SOC alphabetically and then by decreasing frequency of PT in the Relugolix+E2/NETA group for the pooled analysis. MedDRA (version 22.0).
Relative weights are based on an inverse variance approach.
N: Number of patients in treatment group; NETA: Norethindrone acetate; DF: Degrees of freedom; IPD: Individual Patient Data. NC: Not calculated. NE: Non-estimable.

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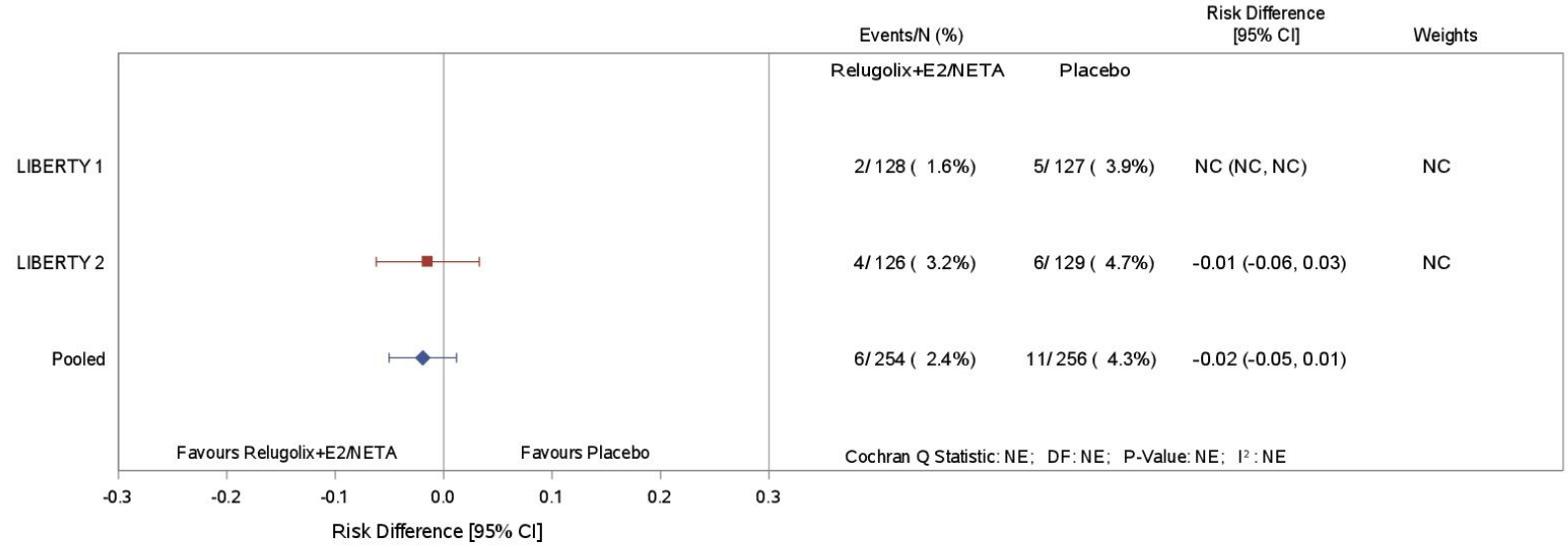
Figure SAF.TEAE.SPT.BIN.FP.RD: Frequent Treatment Emergent Adverse Events by System Organ Class and Preferred Term (Safety Population) - Risk Difference
System Organ Class: Infections and infestations, Preferred Term: Nasopharyngitis



Results are based on a Mantel-Haenszel approach for the pooled analysis, stratified by study. The analysis of LIBERTY 1 and LIBERTY 2 was based on an unstratified approach. The reference group is Placebo. Patients with multiple events for a given PT or SOC are counted only once for each PT and SOC. Only SOCs or PTs for which there are at least 10% of patients with an event in at least one treatment group OR at least 10 patients with an event overall and at least 1% of patients with an event in at least one treatment group for the pooled analysis are presented. Events are sorted by SOC alphabetically and then by decreasing frequency of PT in the Relugolix+E2/NETA group for the pooled analysis. MedDRA (version 22.0).
Relative weights are based on an inverse variance approach.
N: Number of patients in treatment group; NETA: Norethindrone acetate; DF: Degrees of freedom; IPD: Individual Patient Data. NC: Not calculated. NE: Non-estimable.

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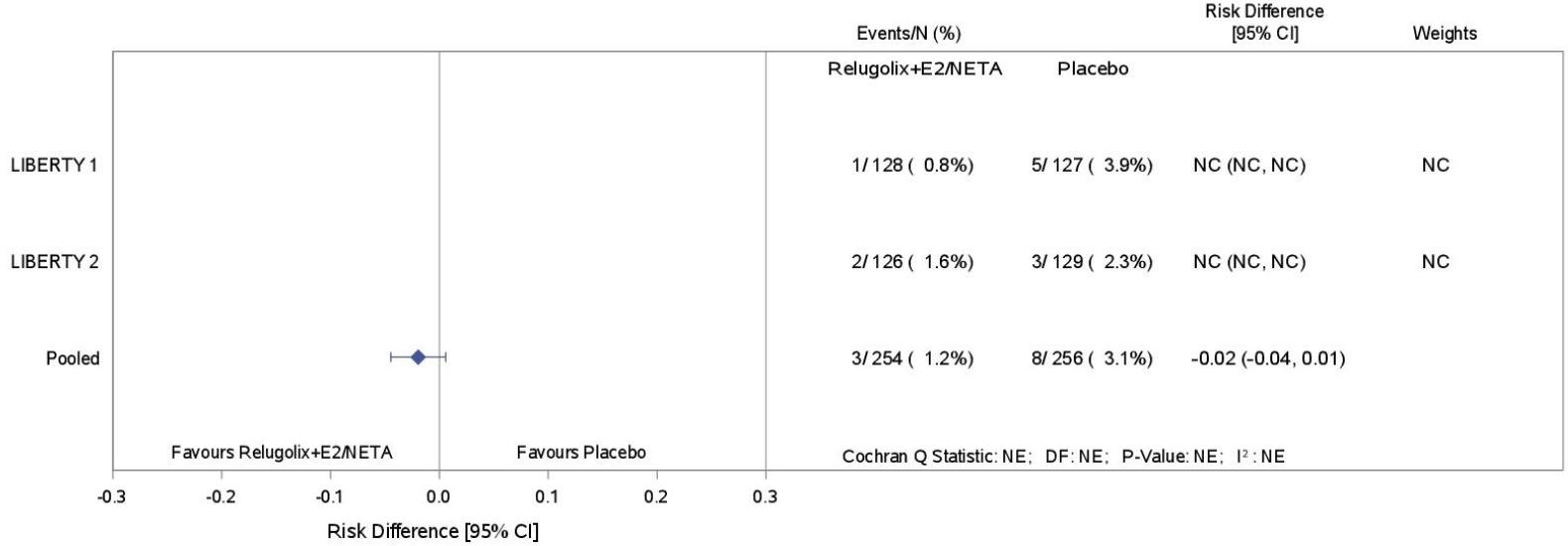
Figure SAF.TEAE.SPT.BIN.FP.RD: Frequent Treatment Emergent Adverse Events by System Organ Class and Preferred Term (Safety Population) - Risk Difference
System Organ Class: Infections and infestations, Preferred Term: Urinary tract infection



Results are based on a Mantel-Haenszel approach for the pooled analysis, stratified by study. The analysis of LIBERTY 1 and LIBERTY 2 was based on an unstratified approach. The reference group is Placebo. Patients with multiple events for a given PT or SOC are counted only once for each PT and SOC. Only SOCs or PTs for which there are at least 10% of patients with an event in at least one treatment group OR at least 10 patients with an event overall and at least 1% of patients with an event in at least one treatment group for the pooled analysis are presented. Events are sorted by SOC alphabetically and then by decreasing frequency of PT in the Relugolix+E2/NETA group for the pooled analysis. MedDRA (version 22.0).
Relative weights are based on an inverse variance approach.
N: Number of patients in treatment group; NETA: Norethindrone acetate; DF: Degrees of freedom; IPD: Individual Patient Data. NC: Not calculated. NE: Non-estimable.

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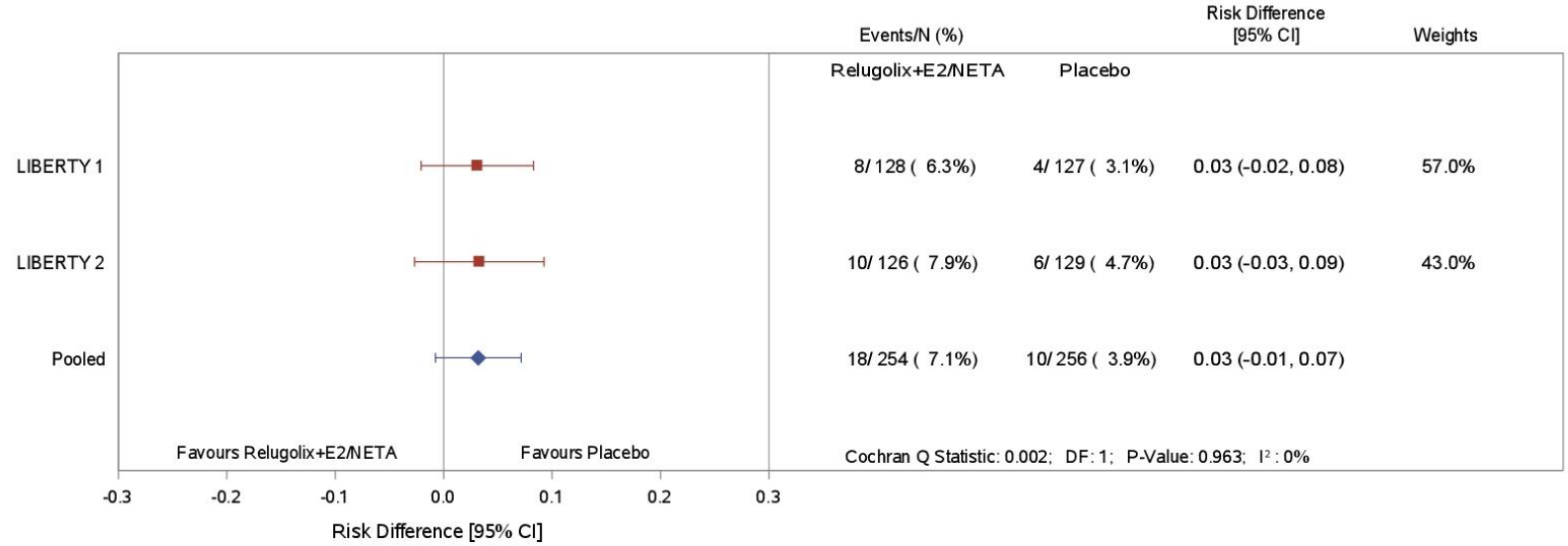
Figure SAF.TEAE.SPT.BIN.FP.RD: Frequent Treatment Emergent Adverse Events by System Organ Class and Preferred Term (Safety Population) - Risk Difference
System Organ Class: Injury, poisoning and procedural complications, Preferred Term: Any



Results are based on a Mantel-Haenszel approach for the pooled analysis, stratified by study. The analysis of LIBERTY 1 and LIBERTY 2 was based on an unstratified approach. The reference group is Placebo. Patients with multiple events for a given PT or SOC are counted only once for each PT and SOC. Only SOCs or PTs for which there are at least 10% of patients with an event in at least one treatment group OR at least 10 patients with an event overall and at least 1% of patients with an event in at least one treatment group for the pooled analysis are presented. Events are sorted by SOC alphabetically and then by decreasing frequency of PT in the Relugolix+E2/NETA group for the pooled analysis. MedDRA (version 22.0).
Relative weights are based on an inverse variance approach.
N: Number of patients in treatment group; NETA: Norethindrone acetate; DF: Degrees of freedom; IPD: Individual Patient Data.

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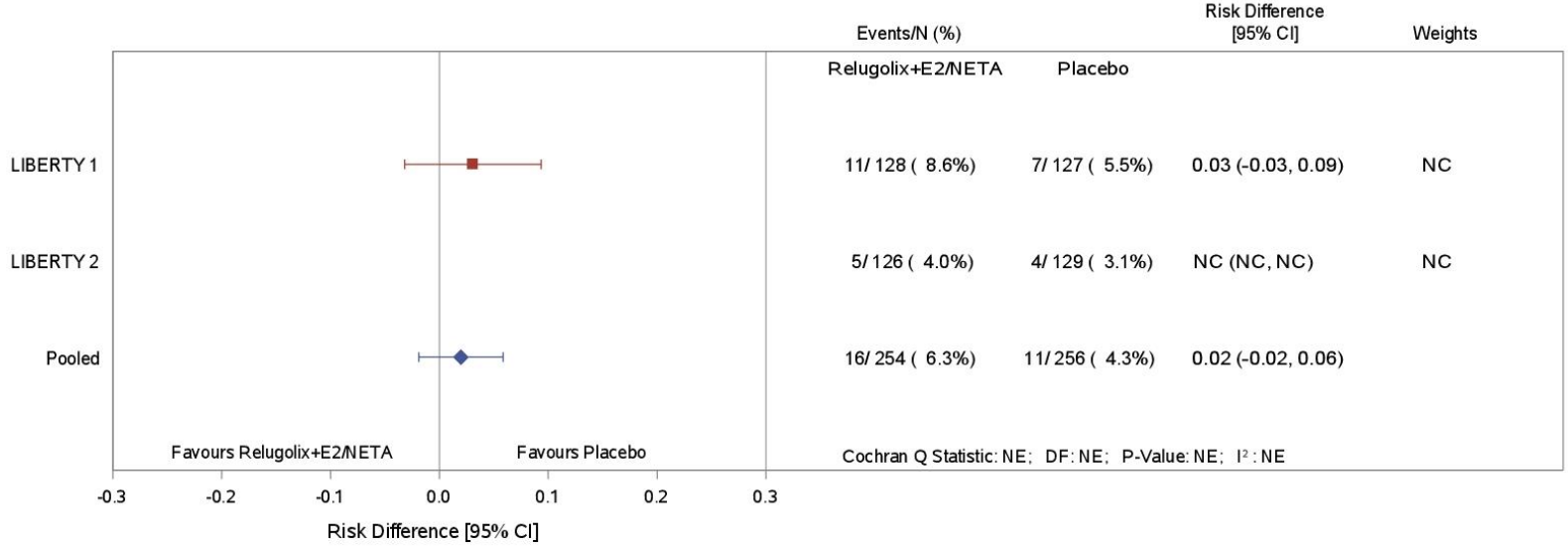
Figure SAF.TEAE.SPT.BIN.FP.RD: Frequent Treatment Emergent Adverse Events by System Organ Class and Preferred Term (Safety Population) - Risk Difference
System Organ Class: Investigations, Preferred Term: Any



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Relative weights are based on an inverse variance approach.
N: Number of patients in treatment group; NETA: Norethindrone acetate; DF: Degrees of freedom; IPD: Individual Patient Data. NC: Not calculated. NE: Non-estimable.

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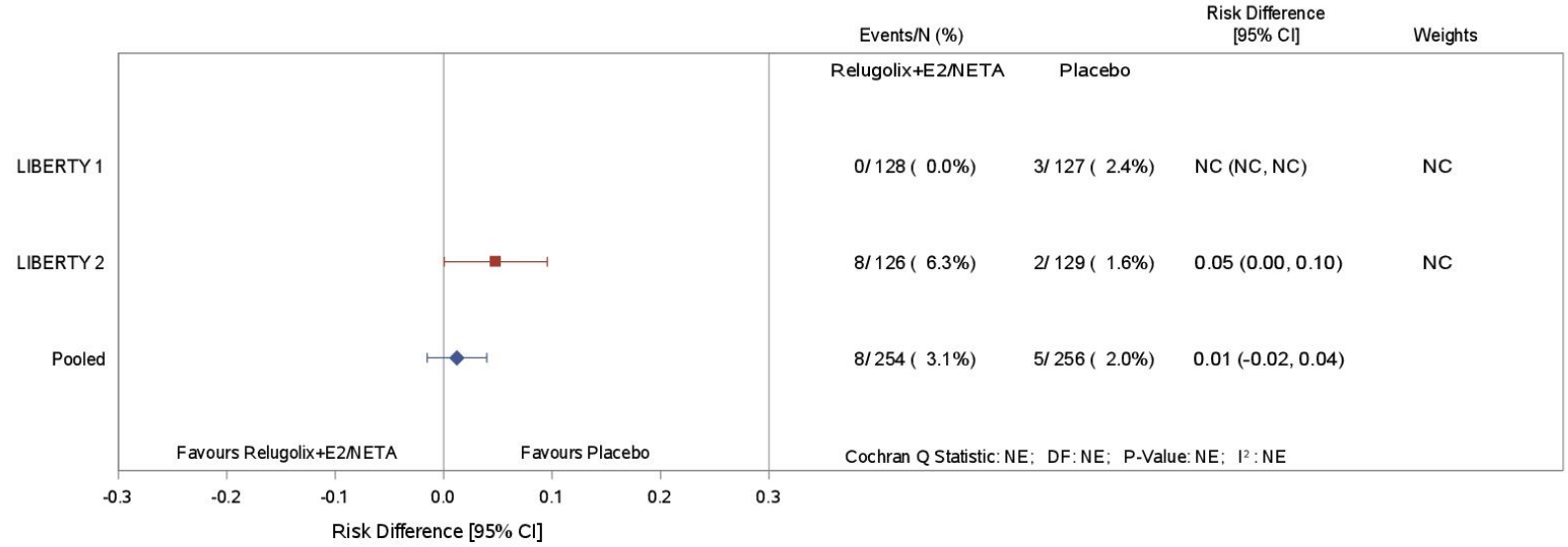
Figure SAF.TEAE.SPT.BIN.FP.RD: Frequent Treatment Emergent Adverse Events by System Organ Class and Preferred Term (Safety Population) - Risk Difference
System Organ Class: Metabolism and nutrition disorders, Preferred Term: Any



Results are based on a Mantel-Haenszel approach for the pooled analysis, stratified by study. The analysis of LIBERTY 1 and LIBERTY 2 was based on an unstratified approach. The reference group is Placebo. Patients with multiple events for a given PT or SOC are counted only once for each PT and SOC. Only SOCs or PTs for which there are at least 10% of patients with an event in at least one treatment group OR at least 10 patients with an event overall and at least 1% of patients with an event in at least one treatment group for the pooled analysis are presented. Events are sorted by SOC alphabetically and then by decreasing frequency of PT in the Relugolix+E2/NETA group for the pooled analysis. MedDRA (version 22.0).
Relative weights are based on an inverse variance approach.
N: Number of patients in treatment group; NETA: Norethindrone acetate; DF: Degrees of freedom; IPD: Individual Patient Data. NC: Not calculated. NE: Non-estimable.

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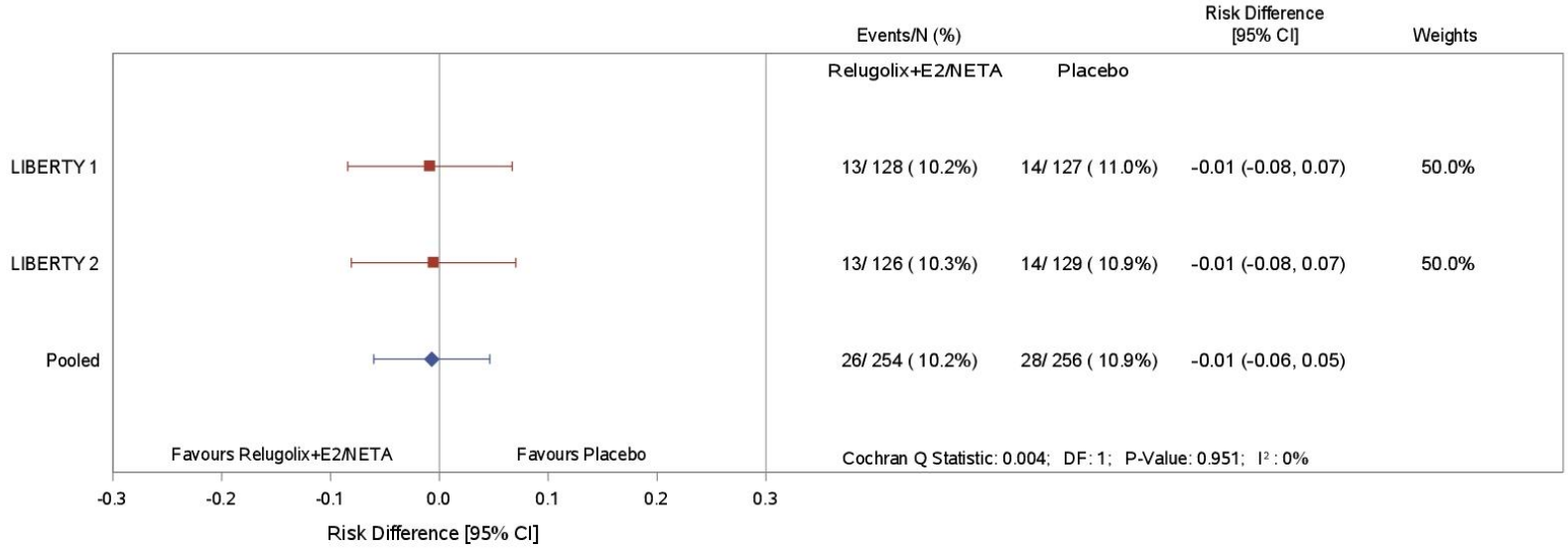
Figure SAF.TEAE.SPT.BIN.FP.RD: Frequent Treatment Emergent Adverse Events by System Organ Class and Preferred Term (Safety Population) - Risk Difference
System Organ Class: Musculoskeletal and connective tissue disorders, Preferred Term: Any



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Relative weights are based on an inverse variance approach.
N: Number of patients in treatment group; NETA: Norethindrone acetate; DF: Degrees of freedom; IPD: Individual Patient Data.

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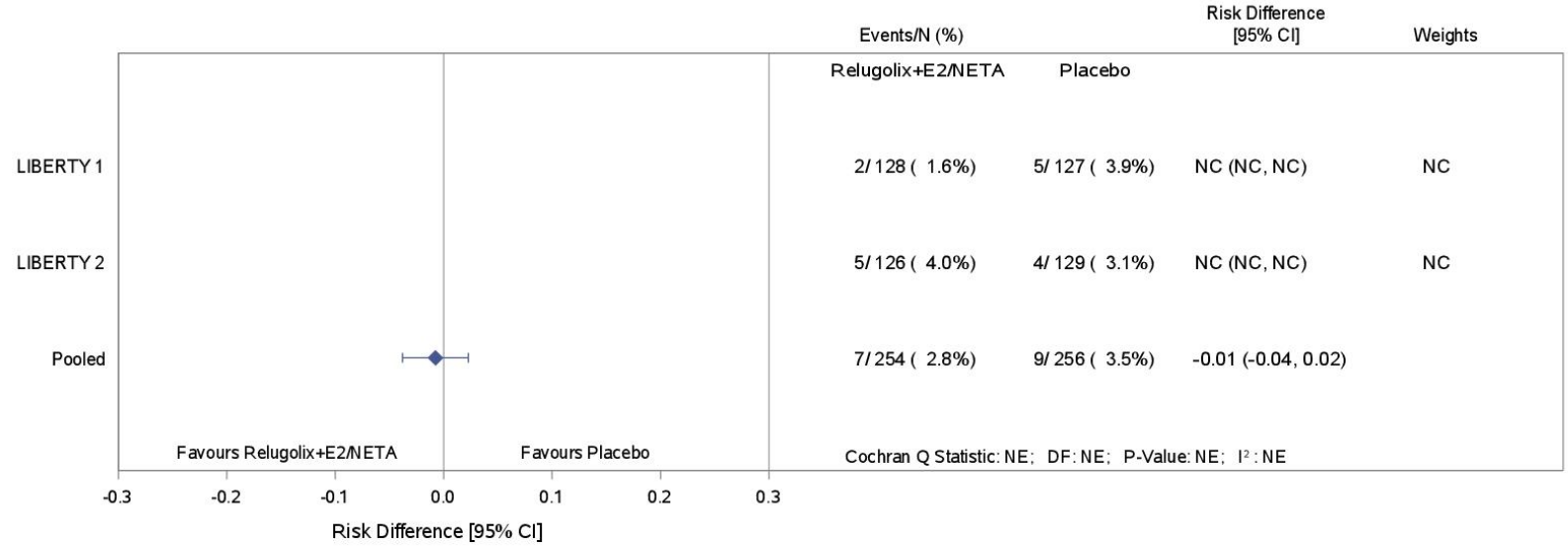
Figure SAF.TEAE.SPT.BIN.FP.RD: Frequent Treatment Emergent Adverse Events by System Organ Class and Preferred Term (Safety Population) - Risk Difference
System Organ Class: Musculoskeletal and connective tissue disorders, Preferred Term: Back pain



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Relative weights are based on an inverse variance approach.
N: Number of patients in treatment group; NETA: Norethindrone acetate; DF: Degrees of freedom; IPD: Individual Patient Data. NC: Not calculated. NE: Non-estimable.

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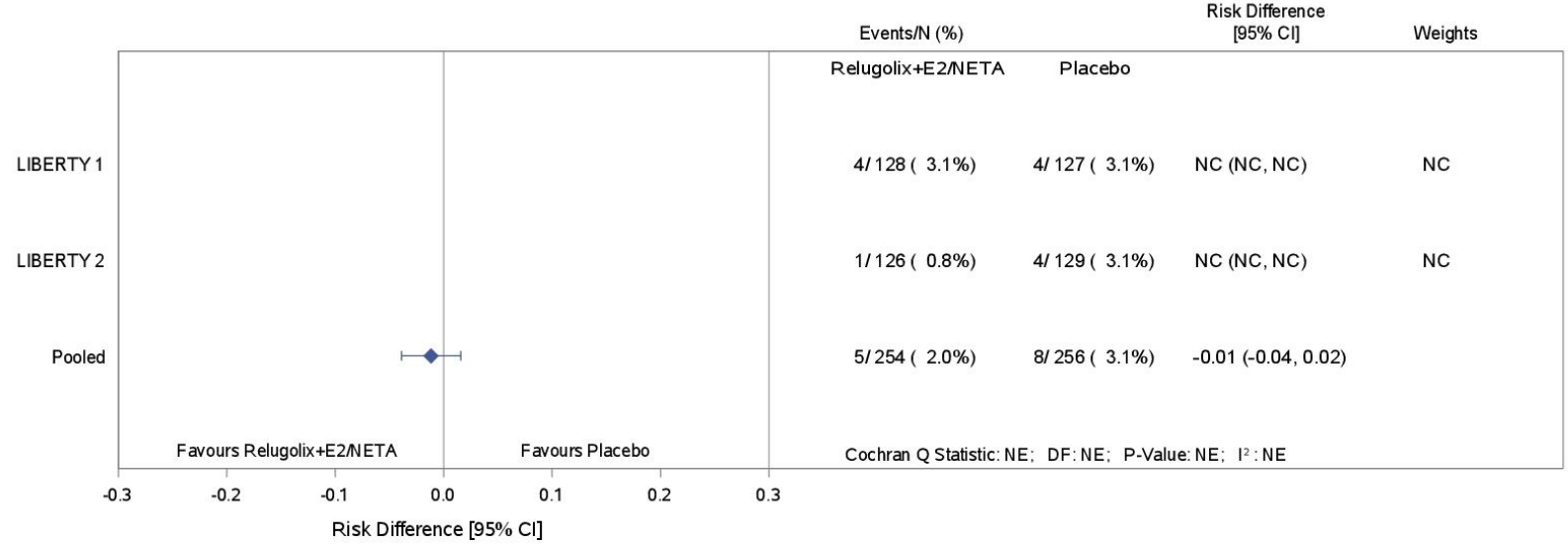
Figure SAF.TEAE.SPT.BIN.FP.RD: Frequent Treatment Emergent Adverse Events by System Organ Class and Preferred Term (Safety Population) - Risk Difference
System Organ Class: Musculoskeletal and connective tissue disorders, Preferred Term: Arthralgia



Results are based on a Mantel-Haenszel approach for the pooled analysis, stratified by study. The analysis of LIBERTY 1 and LIBERTY 2 was based on an unstratified approach. The reference group is Placebo. Patients with multiple events for a given PT or SOC are counted only once for each PT and SOC. Only SOCs or PTs for which there are at least 10% of patients with an event in at least one treatment group OR at least 10 patients with an event overall and at least 1% of patients with an event in at least one treatment group for the pooled analysis are presented. Events are sorted by SOC alphabetically and then by decreasing frequency of PT in the Relugolix+E2/NETA group for the pooled analysis. MedDRA (version 22.0).
Relative weights are based on an inverse variance approach.
N: Number of patients in treatment group; NETA: Norethindrone acetate; DF: Degrees of freedom; IPD: Individual Patient Data. NC: Not calculated. NE: Non-estimable.

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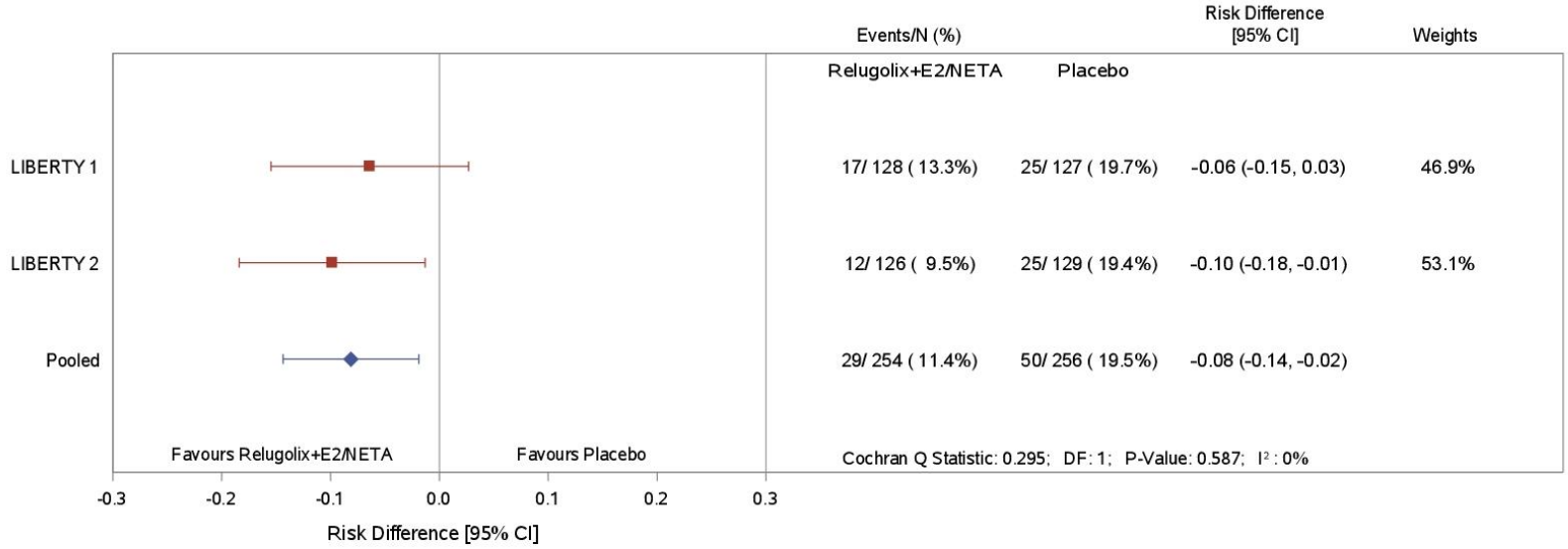
Figure SAF.TEAE.SPT.BIN.FP.RD: Frequent Treatment Emergent Adverse Events by System Organ Class and Preferred Term (Safety Population) - Risk Difference
System Organ Class: Nervous system disorders, Preferred Term: Any



Results are based on a Mantel-Haenszel approach for the pooled analysis, stratified by study. The analysis of LIBERTY 1 and LIBERTY 2 was based on an unstratified approach. The reference group is Placebo. Patients with multiple events for a given PT or SOC are counted only once for each PT and SOC. Only SOCs or PTs for which there are at least 10% of patients with an event in at least one treatment group OR at least 10 patients with an event overall and at least 1% of patients with an event in at least one treatment group for the pooled analysis are presented. Events are sorted by SOC alphabetically and then by decreasing frequency of PT in the Relugolix+E2/NETA group for the pooled analysis. MedDRA (version 22.0).
Relative weights are based on an inverse variance approach.
N: Number of patients in treatment group; NETA: Norethindrone acetate; DF: Degrees of freedom; IPD: Individual Patient Data.

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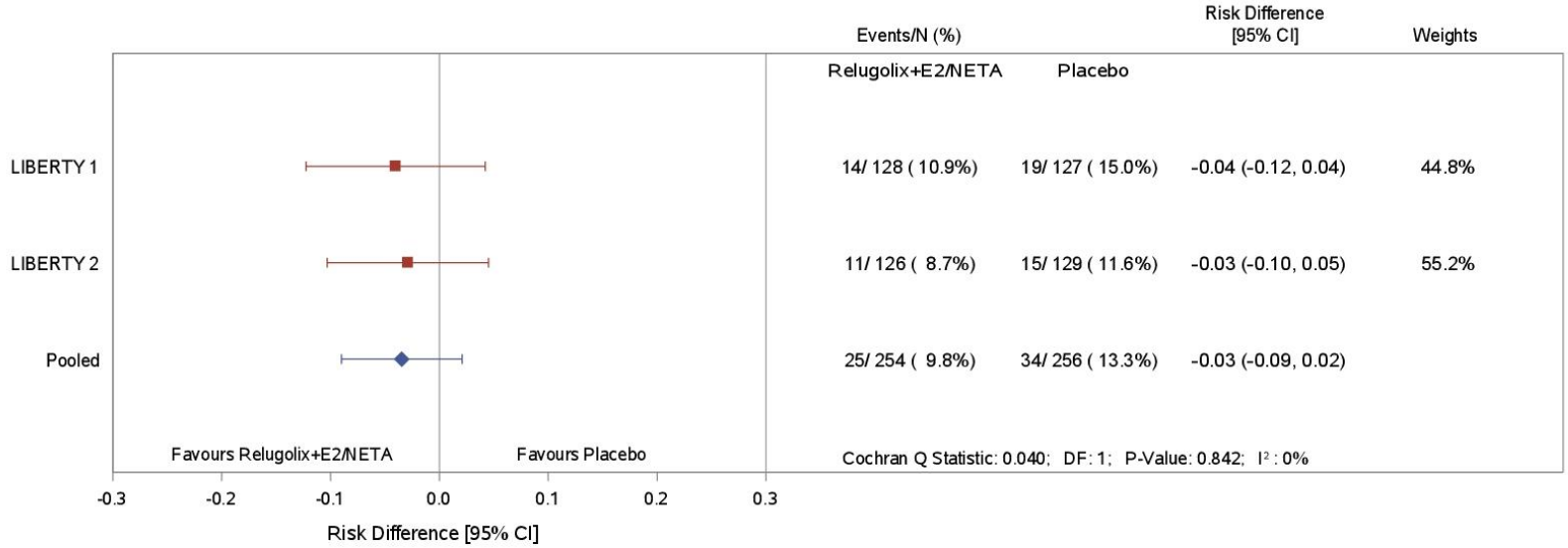
Figure SAF.TEAE.SPT.BIN.FP.RD: Frequent Treatment Emergent Adverse Events by System Organ Class and Preferred Term (Safety Population) - Risk Difference
System Organ Class: Nervous system disorders, Preferred Term: Headache



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Relative weights are based on an inverse variance approach.
N: Number of patients in treatment group; NETA: Norethindrone acetate; DF: Degrees of freedom; IPD: Individual Patient Data.

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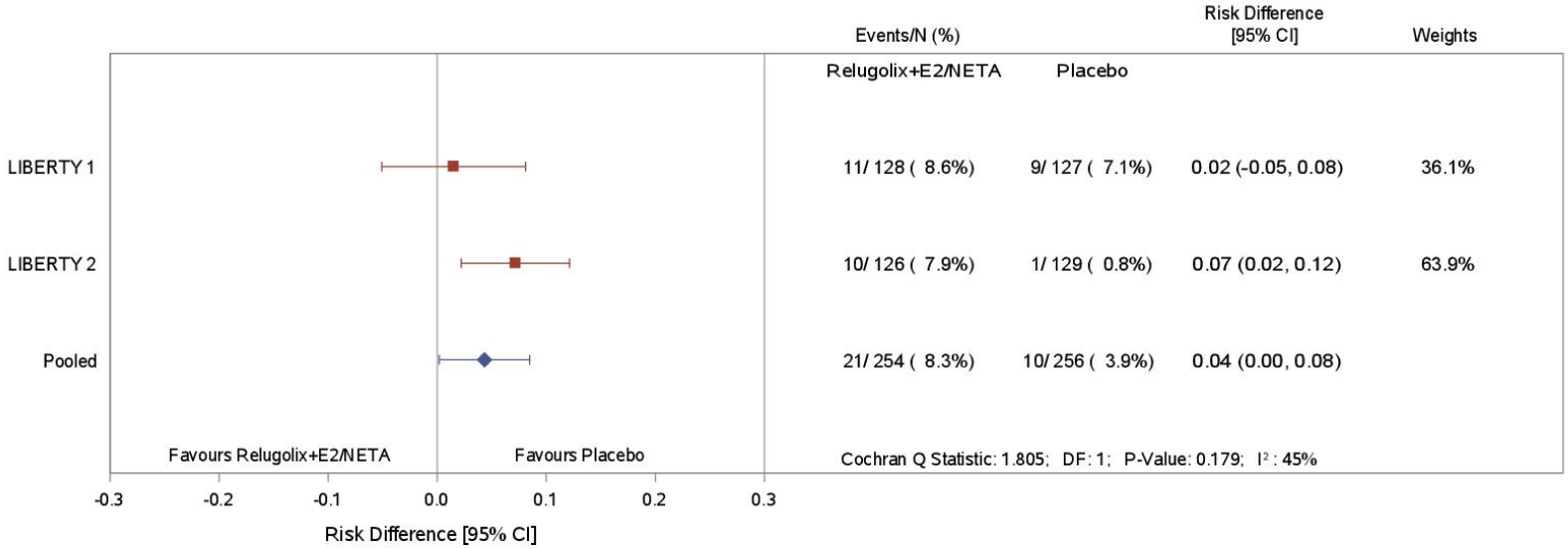
Figure SAF.TEAE.SPT.BIN.FP.RD: Frequent Treatment Emergent Adverse Events by System Organ Class and Preferred Term (Safety Population) - Risk Difference
System Organ Class: Psychiatric disorders, Preferred Term: Any



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Relative weights are based on an inverse variance approach.
N: Number of patients in treatment group; NETA: Norethindrone acetate; DF: Degrees of freedom; IPD: Individual Patient Data.

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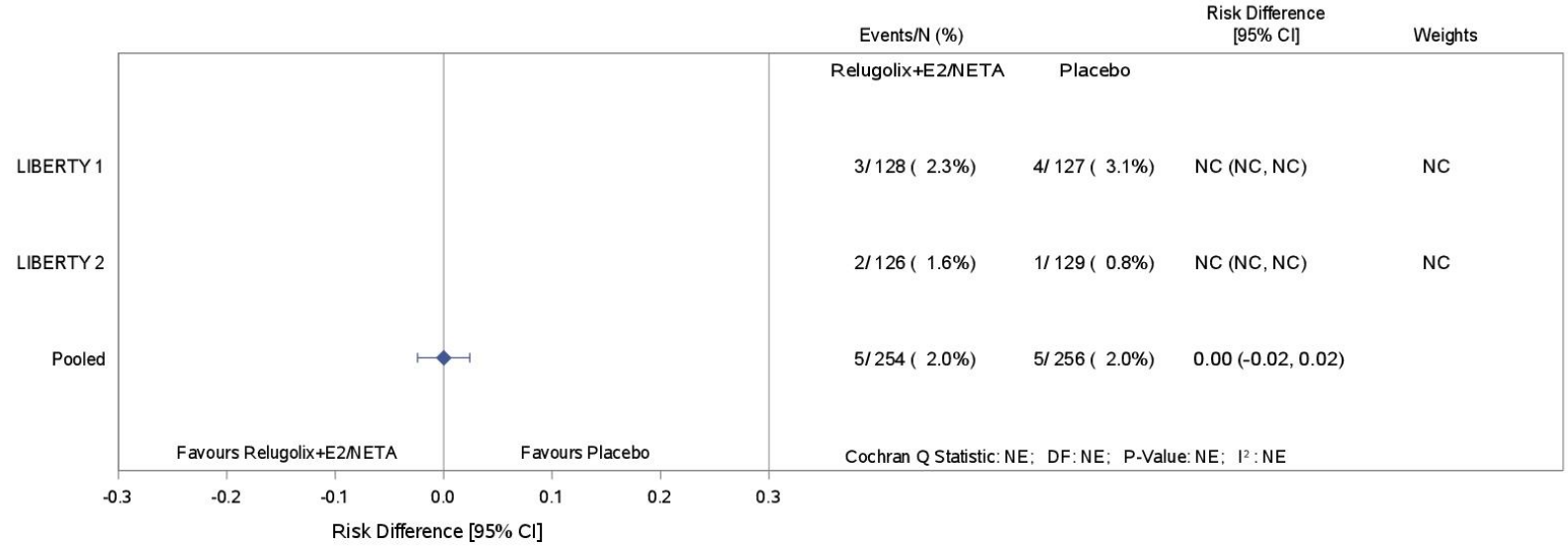
Figure SAF.TEAE.SPT.BIN.FP.RD: Frequent Treatment Emergent Adverse Events by System Organ Class and Preferred Term (Safety Population) - Risk Difference
System Organ Class: Psychiatric disorders, Preferred Term: Insomnia



Results are based on a Mantel-Haenszel approach for the pooled analysis, stratified by study. The analysis of LIBERTY 1 and LIBERTY 2 was based on an unstratified approach. The reference group is Placebo. Patients with multiple events for a given PT or SOC are counted only once for each PT and SOC. Only SOCs or PTs for which there are at least 10% of patients with an event in at least one treatment group OR at least 10 patients with an event overall and at least 1% of patients with an event in at least one treatment group for the pooled analysis are presented. Events are sorted by SOC alphabetically and then by decreasing frequency of PT in the Relugolix+E2/NETA group for the pooled analysis. MedDRA (version 22.0).
Relative weights are based on an inverse variance approach.
N: Number of patients in treatment group; NETA: Norethindrone acetate; DF: Degrees of freedom; IPD: Individual Patient Data. NC: Not calculated. NE: Non-estimable.

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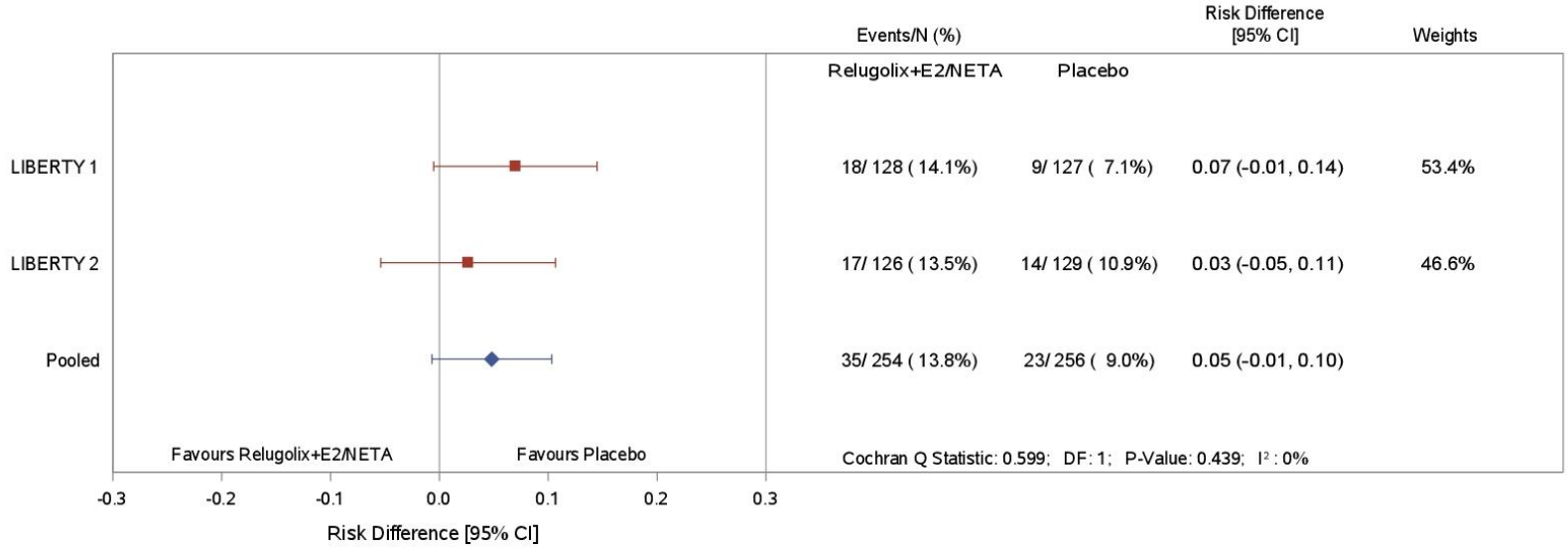
Figure SAF.TEAE.SPT.BIN.FP.RD: Frequent Treatment Emergent Adverse Events by System Organ Class and Preferred Term (Safety Population) - Risk Difference
System Organ Class: Reproductive system and breast disorders, Preferred Term: Any



Results are based on a Mantel-Haenszel approach for the pooled analysis, stratified by study. The analysis of LIBERTY 1 and LIBERTY 2 was based on an unstratified approach. The reference group is Placebo. Patients with multiple events for a given PT or SOC are counted only once for each PT and SOC. Only SOCs or PTs for which there are at least 10% of patients with an event in at least one treatment group OR at least 10 patients with an event overall and at least 1% of patients with an event in at least one treatment group for the pooled analysis are presented. Events are sorted by SOC alphabetically and then by decreasing frequency of PT in the Relugolix+E2/NETA group for the pooled analysis. MedDRA (version 22.0).
Relative weights are based on an inverse variance approach.
N: Number of patients in treatment group; NETA: Norethindrone acetate; DF: Degrees of freedom; IPD: Individual Patient Data.

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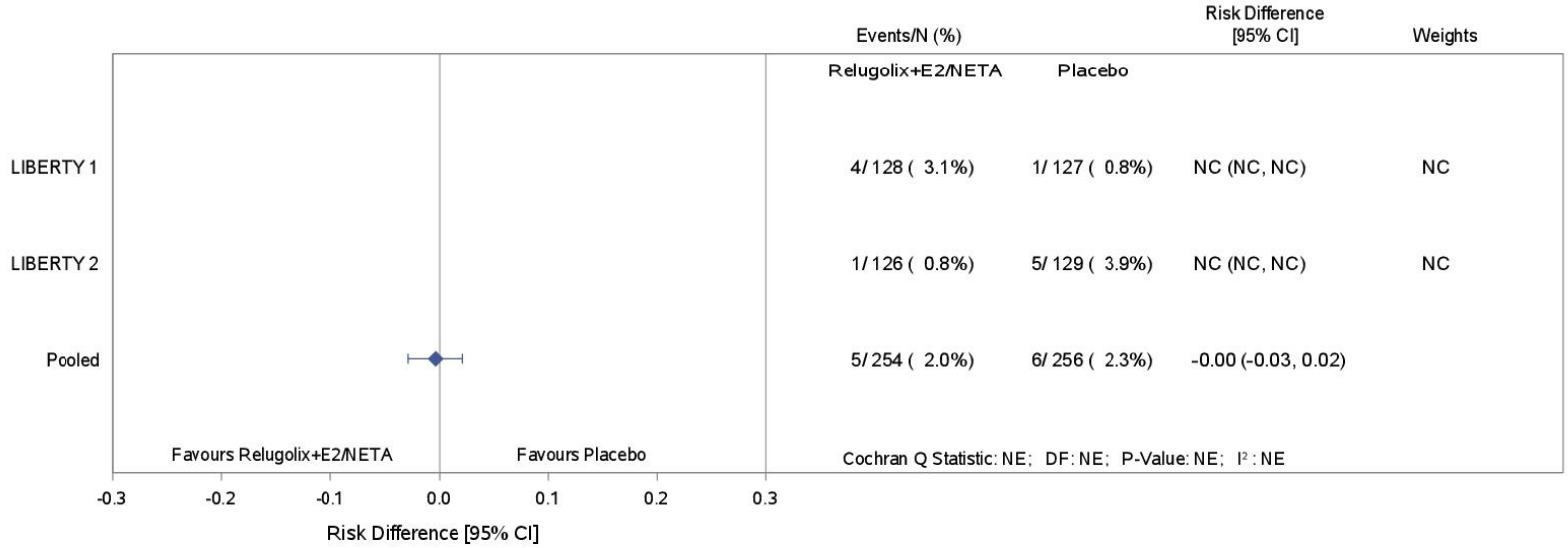
Figure SAF.TEAE.SPT.BIN.FP.RD: Frequent Treatment Emergent Adverse Events by System Organ Class and Preferred Term (Safety Population) - Risk Difference
System Organ Class: Reproductive system and breast disorders, Preferred Term: Pelvic pain



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Relative weights are based on an inverse variance approach.
N: Number of patients in treatment group; NETA: Norethindrone acetate; DF: Degrees of freedom; IPD: Individual Patient Data. NC: Not calculated. NE: Non-estimable.

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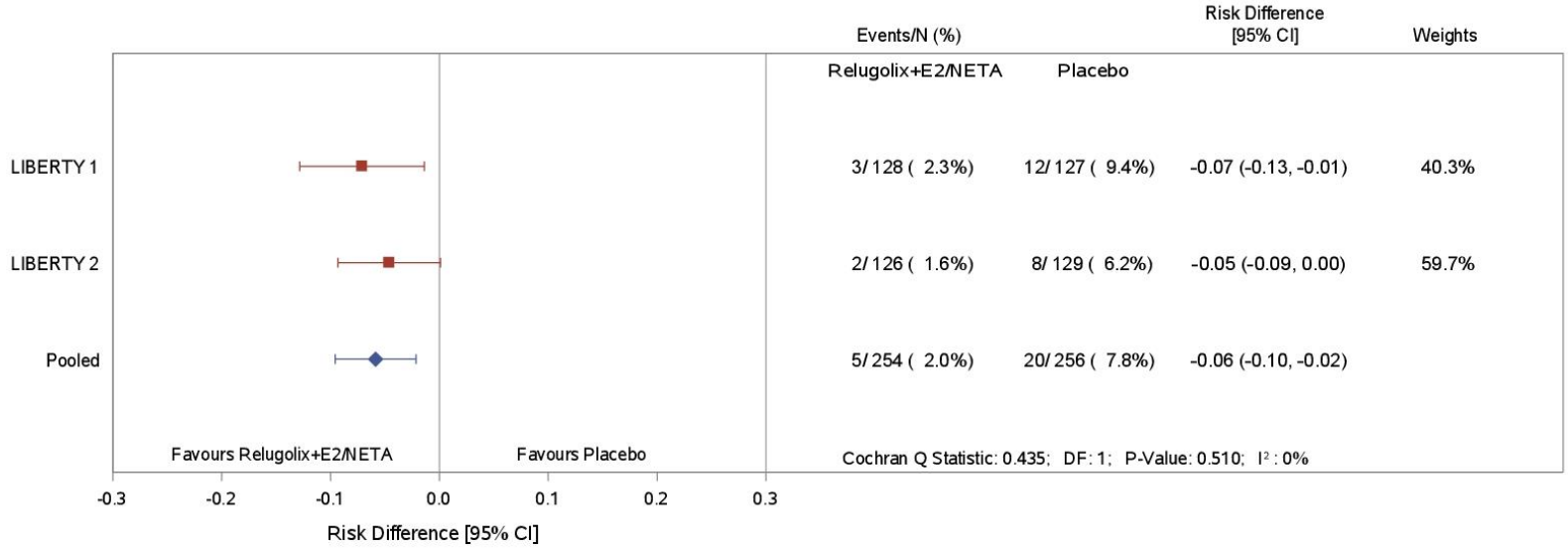
Figure SAF.TEAE.SPT.BIN.FP.RD: Frequent Treatment Emergent Adverse Events by System Organ Class and Preferred Term (Safety Population) - Risk Difference
System Organ Class: Respiratory, thoracic and mediastinal disorders, Preferred Term: Any



Results are based on a Mantel-Haenszel approach for the pooled analysis, stratified by study. The analysis of LIBERTY 1 and LIBERTY 2 was based on an unstratified approach. The reference group is Placebo. Patients with multiple events for a given PT or SOC are counted only once for each PT and SOC. Only SOCs or PTs for which there are at least 10% of patients with an event in at least one treatment group OR at least 10 patients with an event overall and at least 1% of patients with an event in at least one treatment group for the pooled analysis are presented. Events are sorted by SOC alphabetically and then by decreasing frequency of PT in the Relugolix+E2/NETA group for the pooled analysis. MedDRA (version 22.0).
Relative weights are based on an inverse variance approach.
N: Number of patients in treatment group; NETA: Norethindrone acetate; DF: Degrees of freedom; IPD: Individual Patient Data.

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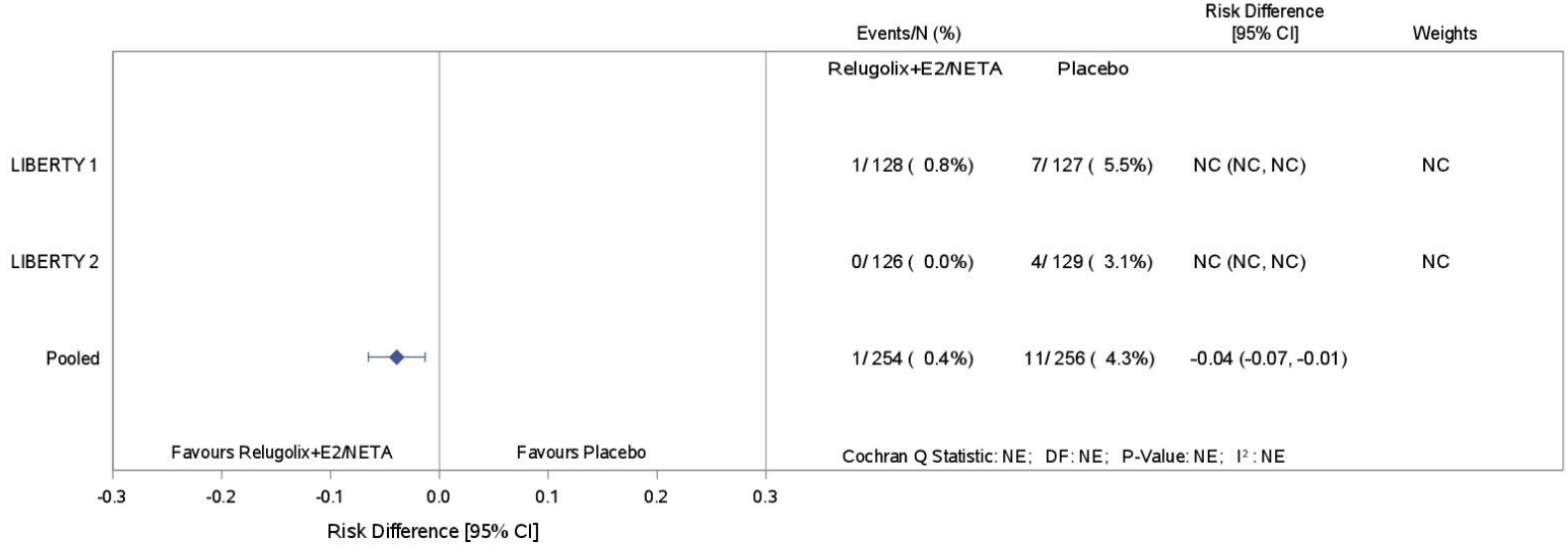
Figure SAF.TEAE.SPT.BIN.FP.RD: Frequent Treatment Emergent Adverse Events by System Organ Class and Preferred Term (Safety Population) - Risk Difference
System Organ Class: Respiratory, thoracic and mediastinal disorders, Preferred Term: Cough



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Relative weights are based on an inverse variance approach.
N: Number of patients in treatment group; NETA: Norethindrone acetate; DF: Degrees of freedom; IPD: Individual Patient Data. NC: Not calculated. NE: Non-estimable.

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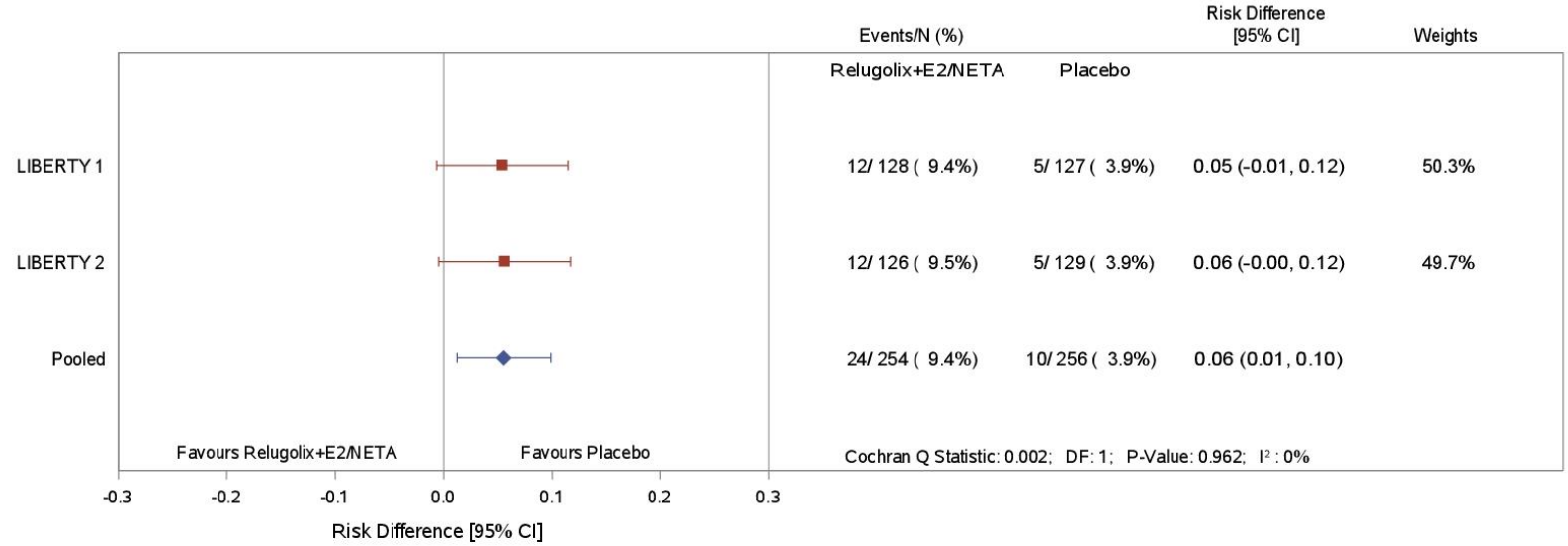
Figure SAF.TEAE.SPT.BIN.FP.RD: Frequent Treatment Emergent Adverse Events by System Organ Class and Preferred Term (Safety Population) - Risk Difference
System Organ Class: Skin and subcutaneous tissue disorders, Preferred Term: Any



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Relative weights are based on an inverse variance approach.
N: Number of patients in treatment group; NETA: Norethindrone acetate; DF: Degrees of freedom; IPD: Individual Patient Data.

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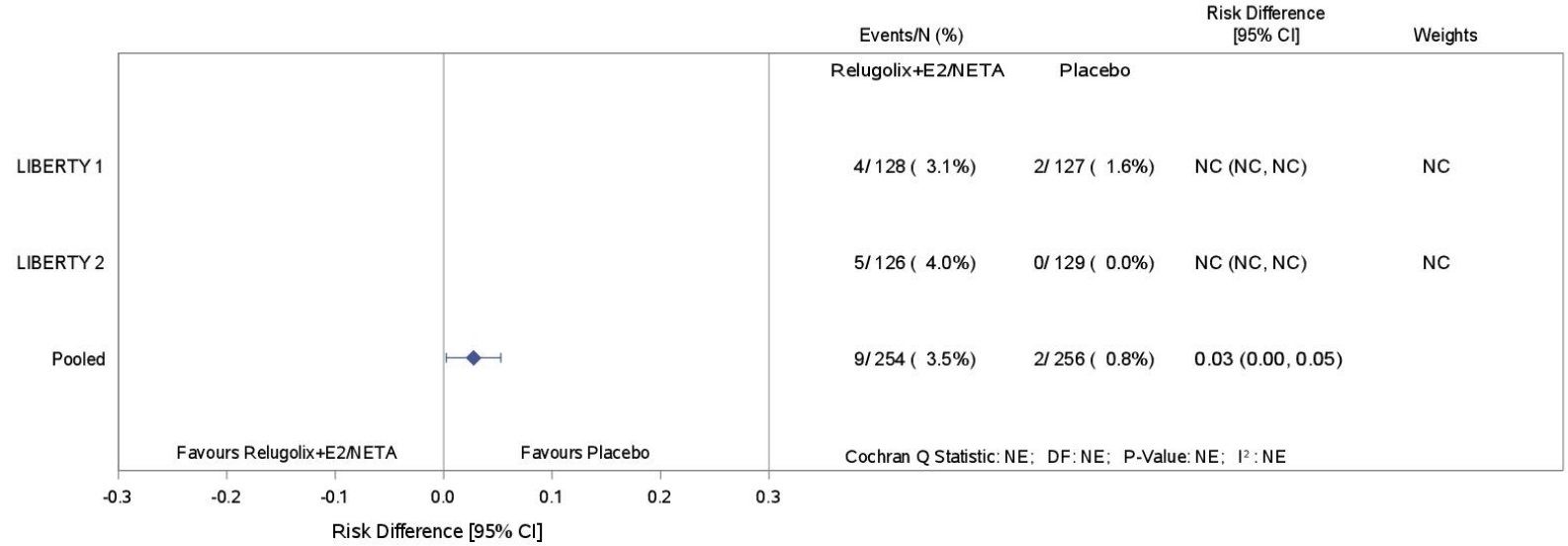
Figure SAF.TEAE.SPT.BIN.FP.RD: Frequent Treatment Emergent Adverse Events by System Organ Class and Preferred Term (Safety Population) - Risk Difference
System Organ Class: Skin and subcutaneous tissue disorders, Preferred Term: Alopecia



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Relative weights are based on an inverse variance approach.
N: Number of patients in treatment group; NETA: Norethindrone acetate; DF: Degrees of freedom; IPD: Individual Patient Data. NC: Not calculated. NE: Non-estimable.

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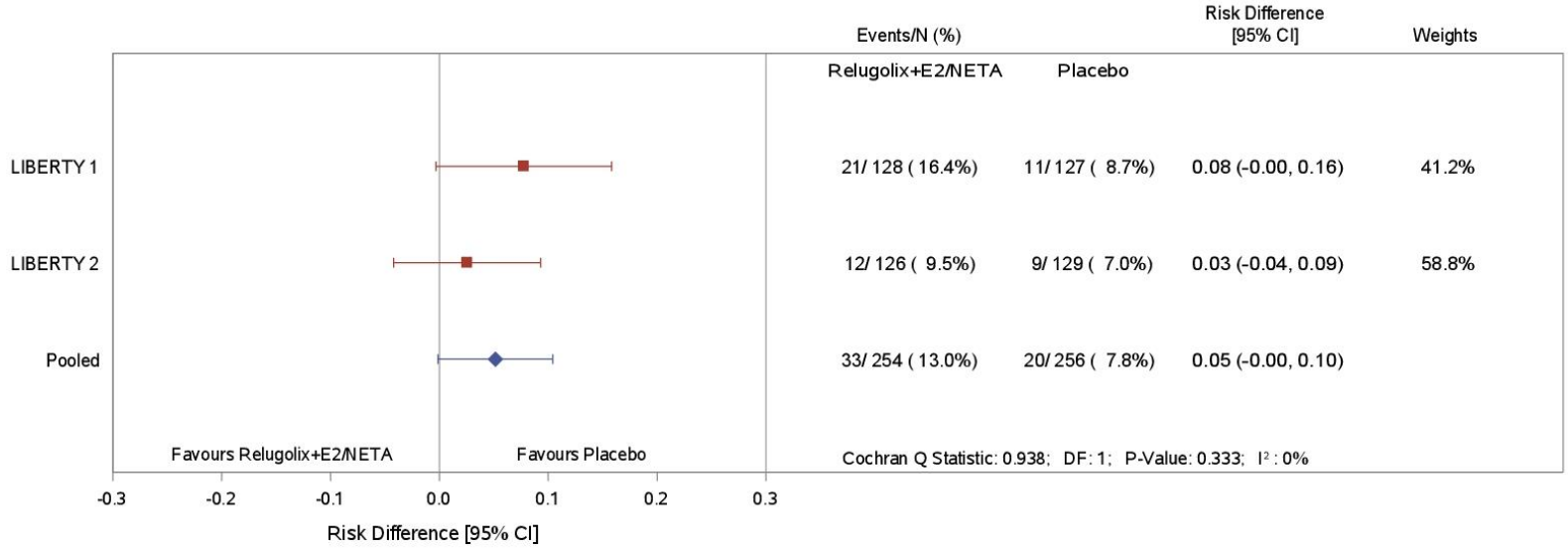
Figure SAF.TEAE.SPT.BIN.FP.RD: Frequent Treatment Emergent Adverse Events by System Organ Class and Preferred Term (Safety Population) - Risk Difference
System Organ Class: Vascular disorders, Preferred Term: Any



Results are based on a Mantel-Haenszel approach for the pooled analysis, stratified by study. The analysis of LIBERTY 1 and LIBERTY 2 was based on an unstratified approach. The reference group is Placebo. Patients with multiple events for a given PT or SOC are counted only once for each PT and SOC. Only SOCs or PTs for which there are at least 10% of patients with an event in at least one treatment group OR at least 10 patients with an event overall and at least 1% of patients with an event in at least one treatment group for the pooled analysis are presented. Events are sorted by SOC alphabetically and then by decreasing frequency of PT in the Relugolix+E2/NETA group for the pooled analysis. MedDRA (version 22.0).
Relative weights are based on an inverse variance approach.
N: Number of patients in treatment group; NETA: Norethindrone acetate; DF: Degrees of freedom; IPD: Individual Patient Data.

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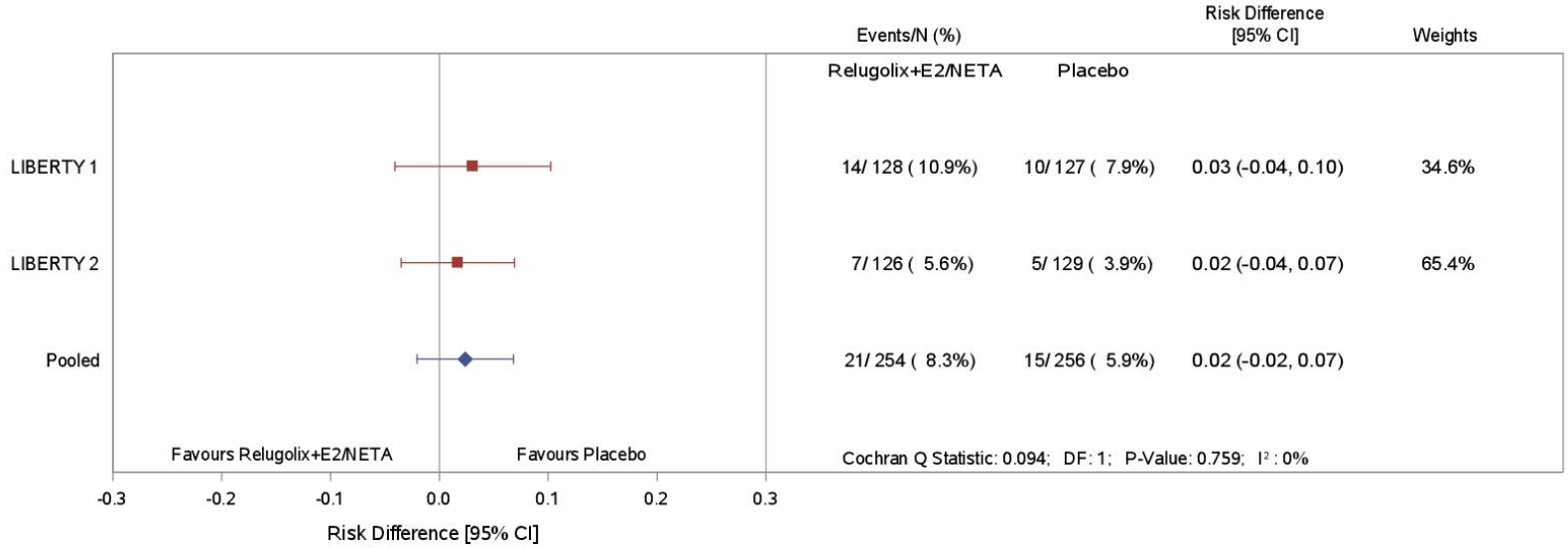
Figure SAF.TEAE.SPT.BIN.FP.RD: Frequent Treatment Emergent Adverse Events by System Organ Class and Preferred Term (Safety Population) - Risk Difference
System Organ Class: Vascular disorders, Preferred Term: Hot flush



Results are based on a Mantel-Haenszel approach for the pooled analysis, stratified by study. The analysis of LIBERTY 1 and LIBERTY 2 was based on an unstratified approach. The reference group is Placebo. Patients with multiple events for a given PT or SOC are counted only once for each PT and SOC. Only SOCs or PTs for which there are at least 10% of patients with an event in at least one treatment group OR at least 10 patients with an event overall and at least 1% of patients with an event in at least one treatment group for the pooled analysis are presented. Events are sorted by SOC alphabetically and then by decreasing frequency of PT in the Relugolix+E2/NETA group for the pooled analysis. MedDRA (version 22.0).
Relative weights are based on an inverse variance approach.
N: Number of patients in treatment group; NETA: Norethindrone acetate; DF: Degrees of freedom; IPD: Individual Patient Data.

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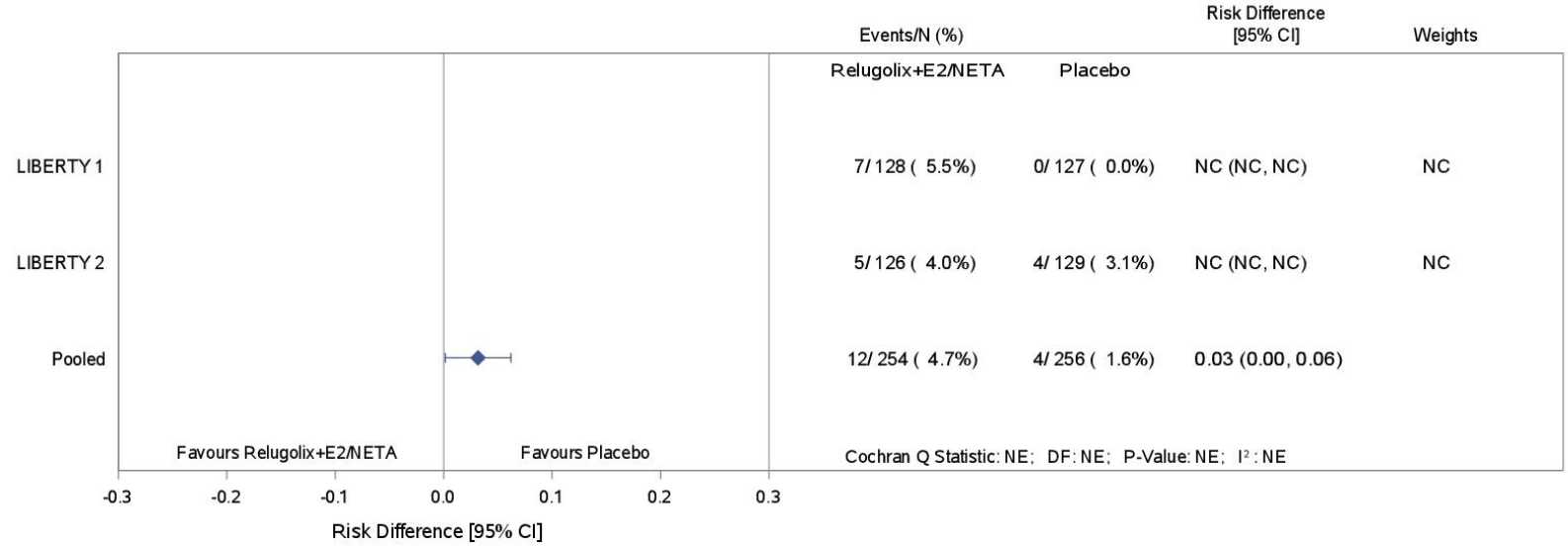
Figure SAF.TEAE.SPT.BIN.FP.RD: Frequent Treatment Emergent Adverse Events by System Organ Class and Preferred Term (Safety Population) - Risk Difference
System Organ Class: Vascular disorders, Preferred Term: Hypertension



Results are based on a Mantel-Haenszel approach for the pooled analysis, stratified by study. The analysis of LIBERTY 1 and LIBERTY 2 was based on an unstratified approach. The reference group is Placebo. Patients with multiple events for a given PT or SOC are counted only once for each PT and SOC. Only SOCs or PTs for which there are at least 10% of patients with an event in at least one treatment group OR at least 10 patients with an event overall and at least 1% of patients with an event in at least one treatment group for the pooled analysis are presented. Events are sorted by SOC alphabetically and then by decreasing frequency of PT in the Relugolix+E2/NETA group for the pooled analysis. MedDRA (version 22.0).
Relative weights are based on an inverse variance approach.
N: Number of patients in treatment group; NETA: Norethindrone acetate; DF: Degrees of freedom; IPD: Individual Patient Data. NC: Not calculated. NE: Non-estimable.

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