Dokumentvorlage, Version vom 18.11.2025

Dossier zur Nutzenbewertung gemäß § 35a SGB V

Mepolizumab (Nucala®)

GlaxoSmithKline GmbH & Co. KG

Anhang 4-G

Zusätzliche Erhaltungstherapie bei erwachsenen Patienten mit COPD, die durch eine erhöhte Anzahl an Eosinophilen im Blut gekennzeichnet ist und die trotz einer Kombinationstherapie aus einem ICS, einem LABA und einem LAMA unzureichend kontrolliert ist

Analysen für das Nutzendossier

Stand: 03.03.2026

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Ergebnisse zum direkten Vergleich von Mepolizumab + SoC gegenüber Placebo + SoC

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Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Table 111.1
Summary of Subjects in the mITT-300 Population

	PBO (N=578)	100 SC (N=568)	Total (N=1146)
208657	401 (69%)	403 (71%)	804 (70%)
MEA117113	87 (15%)	83 (15%)	170 (15%)
MEA117106	90 (16%)	82 (14%)	172 (15%)
208657 + MEA117113 + MEA117106	578 (100%)	568 (100%)	1146 (100%)

Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Table 111.2

Summary of Subject Disposition: Individual Studies and Meta-Analysis

	208657		MEA117113		MEA117106	
	PBO (N=401)	100 SC (N=403)	PBO (N=87)	100 SC (N=83)	PBO (N=90)	100 SC (N=82)
Subject Status						
Completed	331 (83%)	339 (84%)	69 (79%)	76 (92%)	81 (90%)	77 (94%)
Withdrawn Early	70 (17%)	64 (16%)	18 (21%)	7 (8%)	9 (10%)	5 (6%)
Primary reason [1]/ Subreason for study withdrawal [2]						
Adverse event	16 (4%)	15 (4%)	9 (10%)	2 (2%)	2 (2%)	1 (1%)
Death	11 (3%)	11 (3%)	4 (5%)	2 (2%)	1 (1%)	1 (1%)
Lack of efficacy	7 (2%)	2 (<1%)	1 (1%)	0	0	0
Exacerbation	2 (<1%)	0	0	0	0	0
Study terminated by sponsor	0	0	0	0	0	0
Lost to follow-up	5 (1%)	3 (<1%)	1 (1%)	0	0	0
Physician decision	7 (2%)	4 (<1%)	3 (3%)	1 (1%)	1 (1%)	1 (1%)
Withdrawal by subject	35 (9%)	40 (10%)	4 (5%)	4 (5%)	6 (7%)	3 (4%)

[1] Subjects may have only one primary reason for withdrawal.
[2] Subjects are not required to indicate subreasons, if given there may be more than one subreason.
Note: Study 208657 2/2 (PBO/Mepo 100 SC) subjects completed treatment as scheduled but later withdrew from the study. Study MEA117113 1/2 (PBO/Mepo 100 SC) subjects completed treatment as scheduled but later withdrew from the study.
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Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Table 111.2

Summary of Subject Disposition: Individual Studies and Meta-Analysis

	208657 + MEA117113 + MEA117106		
	PBO (N=578)	100 SC (N=568)	Total (N=1146)
Subject Status			
Completed	481 (83%)	492 (87%)	973 (85%)
Withdrawn Early	97 (17%)	76 (13%)	173 (15%)
Primary reason [1]/ Subreason for study withdrawal [2]			
Adverse event	27 (5%)	18 (3%)	45 (4%)
Death	16 (3%)	14 (2%)	30 (3%)
Lack of efficacy	8 (1%)	2 (<1%)	10 (<1%)
Exacerbation	2 (<1%)	0	2 (<1%)
Study terminated by sponsor	0	0	0
Lost to follow-up	6 (1%)	3 (<1%)	9 (<1%)
Physician decision	11 (2%)	6 (1%)	17 (1%)
Withdrawal by subject	45 (8%)	47 (8%)	92 (8%)

[1] Subjects may have only one primary reason for withdrawal.
[2] Subjects are not required to indicate subreasons, if given there may be more than one subreason.
Note: Study 208657 2/2 (PBO/Mepo 100 SC) subjects completed treatment as scheduled but later withdrew from the study. Study MEA117113 1/2 (PBO/Mepo 100 SC) subjects completed treatment as scheduled but later withdrew from the study.
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Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Table 111.3

Summary of Reasons for Withdrawal From Investigational Product: Individual Studies and Meta-Analysis

	208657		MEA117113		MEA117106	
	PBO (N=401)	100 SC (N=403)	PBO (N=87)	100 SC (N=83)	PBO (N=90)	100 SC (N=82)
Completion Status						
Completed study treatment as scheduled	314 (78%)	326 (81%)	66 (76%)	75 (90%)	72 (80%)	74 (90%)
Withdrew early from study treatment	87 (22%)	77 (19%)	21 (24%)	8 (10%)	18 (20%)	8 (10%)
Prematurely discontinued study treatment and study at the same time	38 (9%)	42 (10%)	7 (8%)	2 (2%)	4 (4%)	2 (2%)
Prematurely discontinued study treatment and continued in study	49 (12%)	35 (9%)	14 (16%)	6 (7%)	14 (16%)	6 (7%)
Completed study with off-treatment assessments	19 (5%)	15 (4%)	4 (5%)	3 (4%)	9 (10%)	3 (4%)
Did not complete study	30 (7%)	20 (5%)	10 (11%)	3 (4%)	5 (6%)	3 (4%)

[1] Subjects may have only one primary reason.
[2] Subjects are not required to indicate subreasons, if given there may be more than one subreason.
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Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Table 111.3

Summary of Reasons for Withdrawal From Investigational Product: Individual Studies and Meta-Analysis

	208657 + MEA117113 + MEA117106		
	PBO (N=578)	100 SC (N=568)	Total (N=1146)
Completion Status			
Completed study treatment as scheduled	452 (78%)	475 (84%)	927 (81%)
Withdrew early from study treatment	126 (22%)	93 (16%)	219 (19%)
Prematurely discontinued study treatment and study at the same time	49 (8%)	46 (8%)	95 (8%)
Prematurely discontinued study treatment and continued in study	77 (13%)	47 (8%)	124 (11%)
Completed study with off-treatment assessments	32 (6%)	21 (4%)	53 (5%)
Did not complete study	45 (8%)	26 (5%)	71 (6%)

[1] Subjects may have only one primary reason.
[2] Subjects are not required to indicate subreasons, if given there may be more than one subreason.
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Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Table 111.3

Summary of Reasons for Withdrawal From Investigational Product: Individual Studies and Meta-Analysis

	208657		MEA117113		MEA117106	
	PBO (N=401)	100 SC (N=403)	PBO (N=87)	100 SC (N=83)	PBO (N=90)	100 SC (N=82)
Primary reason for discontinuation of study treatment [1]/ Subreason for discontinuation of study treatment [2]						
Adverse event	21 (5%)	21 (5%)	12 (14%)	1 (1%)	8 (9%)	2 (2%)
Death	9 (2%)	9 (2%)	2 (2%)	1 (1%)	1 (1%)	1 (1%)
Lack of efficacy	13 (3%)	2 (<1%)	1 (1%)	0	1 (1%)	1 (1%)
Exacerbation	5 (1%)	1 (<1%)	0	0	0	0
Protocol deviation	1 (<1%)	0	1 (1%)	0	0	1 (1%)
Subject reached protocol-defined stopping criteria	3 (<1%)	2 (<1%)	0	0	0	0
ECG abnormality	0	1 (<1%)	0	0	0	0
Liver function test abnormality	2 (<1%)	0	0	0	0	0
Study terminated by sponsor	0	0	0	0	0	0
Lost to follow-up	1 (<1%)	2 (<1%)	0	1 (1%)	0	0
Physician decision	5 (1%)	5 (1%)	1 (1%)	1 (1%)	2 (2%)	1 (1%)
Withdrawal by subject	41 (10%)	44 (11%)	5 (6%)	5 (6%)	7 (8%)	3 (4%)
Investigator site closed	1 (<1%)	0	1 (1%)	0	0	0

[1] Subjects may have only one primary reason.
[2] Subjects are not required to indicate subreasons, if given there may be more than one subreason.
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Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Table 111.3

Summary of Reasons for Withdrawal From Investigational Product: Individual Studies and Meta-Analysis

	208657 + MEA117113 + MEA117106		
	PBO (N=578)	100 SC (N=568)	Total (N=1146)
Primary reason for discontinuation of study treatment [1]/ Subreason for discontinuation of study treatment [2]			
Adverse event	41 (7%)	24 (4%)	65 (6%)
Death	12 (2%)	11 (2%)	23 (2%)
Lack of efficacy	15 (3%)	3 (<1%)	18 (2%)
Exacerbation	5 (<1%)	1 (<1%)	6 (<1%)
Protocol deviation	2 (<1%)	1 (<1%)	3 (<1%)
Subject reached protocol-defined stopping criteria	3 (<1%)	2 (<1%)	5 (<1%)
ECG abnormality	0	1 (<1%)	1 (<1%)
Liver function test abnormality	2 (<1%)	0	2 (<1%)
Study terminated by sponsor	0	0	0
Lost to follow-up	1 (<1%)	3 (<1%)	4 (<1%)
Physician decision	8 (1%)	7 (1%)	15 (1%)
Withdrawal by subject	53 (9%)	52 (9%)	105 (9%)
Investigator site closed	2 (<1%)	0	2 (<1%)

[1] Subjects may have only one primary reason.
[2] Subjects are not required to indicate subreasons, if given there may be more than one subreason.
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Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Table 111.4

Summary of Demographic Characteristics: Individual Studies and Meta-Analysis

	208657		MEA117113		MEA117106	
	PBO (N=401)	100 SC (N=403)	PBO (N=87)	100 SC (N=83)	PBO (N=90)	100 SC (N=82)
Age (years)						
n	401	403	87	83	90	82
Mean	66.0	66.4	65.8	65.2	64.4	65.5
SD	7.91	8.10	8.58	9.28	9.24	8.38
Median	66.0	67.0	65.0	67.0	65.0	66.0
Min.	42	39	44	43	40	43
Max.	91	88	84	82	82	83
Age Group (years)						
<40	0	1 (<1%)	0	0	0	0
40 - <65	173 (43%)	142 (35%)	41 (47%)	34 (41%)	42 (47%)	38 (46%)
>=65	228 (57%)	260 (65%)	46 (53%)	49 (59%)	48 (53%)	44 (54%)
18-64	173 (43%)	143 (35%)	41 (47%)	34 (41%)	42 (47%)	38 (46%)
65-84	224 (56%)	257 (64%)	46 (53%)	49 (59%)	48 (53%)	44 (54%)
>=85	4 (<1%)	3 (<1%)	0	0	0	0
Sex						
n	401	403	87	83	90	82
Female	126 (31%)	127 (32%)	28 (32%)	33 (40%)	33 (37%)	29 (35%)
Male	275 (69%)	276 (68%)	59 (68%)	50 (60%)	57 (63%)	53 (65%)
Ethnicity						
n	401	403	87	83	90	82
HISPANIC OR LATINO	95 (24%)	94 (23%)	14 (16%)	12 (14%)	14 (16%)	14 (17%)
NOT HISPANIC OR LATINO	306 (76%)	309 (77%)	73 (84%)	71 (86%)	76 (84%)	68 (83%)

Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Table 111.4

Summary of Demographic Characteristics: Individual Studies and Meta-Analysis

	208657 + MEA117113 + MEA117106		
	PBO (N=578)	100 SC (N=568)	Total (N=1146)
Age (years)			
n	578	568	1146
Mean	65.7	66.1	65.9
SD	8.24	8.32	8.28
Median	66.0	67.0	67.0
Min.	40	39	39
Max.	91	88	91
Age Group (years)			
<40	0	1 (<1%)	1 (<1%)
40 - <65	256 (44%)	214 (38%)	470 (41%)
>=65	322 (56%)	353 (62%)	675 (59%)
18-64	256 (44%)	215 (38%)	471 (41%)
65-84	318 (55%)	350 (62%)	668 (58%)
>=85	4 (<1%)	3 (<1%)	7 (<1%)
Sex			
n	578	568	1146
Female	187 (32%)	189 (33%)	376 (33%)
Male	391 (68%)	379 (67%)	770 (67%)
Ethnicity			
n	578	568	1146
HISPANIC OR LATINO	123 (21%)	120 (21%)	243 (21%)
NOT HISPANIC OR LATINO	455 (79%)	448 (79%)	903 (79%)

Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Table 111.4

Summary of Demographic Characteristics: Individual Studies and Meta-Analysis

	208657		MEA117113		MEA117106	
	PBO (N=401)	100 SC (N=403)	PBO (N=87)	100 SC (N=83)	PBO (N=90)	100 SC (N=82)
Height (cm)						
n	401	403	87	83	90	82
Mean	167.4	167.2	167.6	167.1	166.6	165.1
SD	9.34	8.98	9.43	7.75	10.31	9.18
Median	167.0	167.0	167.0	168.0	167.0	165.5
Min.	143	140	143	150	141	138
Max.	196	193	193	183	189	192
Weight (kg)						
n	401	403	87	83	90	82
Mean	76.36	76.91	71.03	73.83	77.29	73.46
SD	17.964	17.970	14.317	16.162	20.496	16.939
Median	74.40	74.00	69.00	73.00	75.00	70.50
Min.	43.3	38.0	42.7	35.7	36.7	45.0
Max.	145.0	146.0	114.1	114.0	134.0	118.7
Body Mass Index (kg/m^2)						
n	401	403	87	83	90	82
Mean	27.13	27.38	25.19	26.40	27.58	26.83
SD	5.540	5.342	3.975	5.456	5.490	5.191
Median	26.23	26.85	25.72	25.56	27.00	26.80
Min.	16.1	15.2	16.9	15.9	17.1	17.6
Max.	50.6	43.0	35.2	41.0	42.1	42.8

Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Table 111.4

Summary of Demographic Characteristics: Individual Studies and Meta-Analysis

	208657 + MEA117113 + MEA117106		
	PBO (N=578)	100 SC (N=568)	Total (N=1146)
Height (cm)			
n	578	568	1146
Mean	167.3	166.9	167.1
SD	9.50	8.85	9.18
Median	167.0	167.0	167.0
Min.	141	138	138
Max.	196	193	196
Weight (kg)			
n	578	568	1146
Mean	75.70	75.96	75.83
SD	17.973	17.605	17.784
Median	73.00	74.00	74.00
Min.	36.7	35.7	35.7
Max.	145.0	146.0	146.0
Body Mass Index (kg/m^2)			
n	578	568	1146
Mean	26.91	27.16	27.03
SD	5.370	5.340	5.354
Median	26.18	26.66	26.39
Min.	16.1	15.2	15.2
Max.	50.6	43.0	50.6

Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Table 111.5

Summary of Race and Racial Combination Details: Individual Studies and Meta-Analysis

		208657		MEA117113		MEA117106	
Race	Race Detail	PBO (N=401)	100 SC (N=403)	PBO (N=87)	100 SC (N=83)	PBO (N=90)	100 SC (N=82)
n		401	403	87	83	90	82
AMERICAN INDIAN OR ALASKA NATIVE		2 (<1%)	3 (<1%)	0	0	5 (6%)	9 (11%)
ASIAN		56 (14%)	56 (14%)	18 (21%)	17 (20%)	1 (1%)	0
	CENTRAL/ SOUTH ASIAN HERITAGE	19 (5%)	18 (4%)	0	0	0	0
	EAST ASIAN HERITAGE	34 (8%)	33 (8%)	10 (11%)	11 (13%)	0	0
	JAPANESE HERITAGE	0	0	5 (6%)	4 (5%)	1 (1%)	0
	SOUTH EAST ASIAN HERITAGE	3 (<1%)	5 (1%)	3 (3%)	2 (2%)	0	0
BLACK OR AFRICAN AMERICAN		5 (1%)	5 (1%)	1 (1%)	1 (1%)	2 (2%)	2 (2%)
NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER		0	0	0	0	0	0

Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Table 111.5

Summary of Race and Racial Combination Details: Individual Studies and Meta-Analysis

		208657 + MEA117113 + MEA117106		
Race	Race Detail	PBO (N=578)	100 SC (N=568)	Total (N=1146)
n		578	568	1146
AMERICAN INDIAN OR ALASKA NATIVE		7 (1%)	12 (2%)	19 (2%)
ASIAN		75 (13%)	73 (13%)	148 (13%)
	CENTRAL/ SOUTH ASIAN HERITAGE	19 (3%)	18 (3%)	37 (3%)
	EAST ASIAN HERITAGE	44 (8%)	44 (8%)	88 (8%)
	JAPANESE HERITAGE	6 (1%)	4 (<1%)	10 (<1%)
	SOUTH EAST ASIAN HERITAGE	6 (1%)	7 (1%)	13 (1%)
BLACK OR AFRICAN AMERICAN		8 (1%)	8 (1%)	16 (1%)
NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER		0	0	0

Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Table 111.5

Summary of Race and Racial Combination Details: Individual Studies and Meta-Analysis

		208657		MEA117113		MEA117106	
Race	Race Detail	PBO (N=401)	100 SC (N=403)	PBO (N=87)	100 SC (N=83)	PBO (N=90)	100 SC (N=82)
WHITE		335 (84%)	338 (84%)	68 (78%)	65 (78%)	74 (82%)	68 (83%)
	ARABIC/ NORTH AFRICAN HERITAGE	4 (<1%)	5 (1%)	0	0	1 (1%)	0
	WHITE/ CAUCASIAN/ EUROPEAN HERITAGE	331 (83%)	333 (83%)	68 (78%)	65 (78%)	73 (81%)	68 (83%)
MIXED RACE		3 (<1%)	1 (<1%)	0	0	8 (9%)	3 (4%)
	AMERICAN INDIAN OR ALASKAN NATIVE & WHITE - WHITE/ CAUCASIAN/ EUROPEAN HERITAGE	3 (<1%)	0	0	0	8 (9%)	3 (4%)
	ASIAN - CENTRAL/ SOUTH ASIAN HERITAGE & WHITE - WHITE/ CAUCASIAN/ EUROPEAN HERITAGE	0	1 (<1%)	0	0	0	0

Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Table 111.5

Summary of Race and Racial Combination Details: Individual Studies and Meta-Analysis

		208657 + MEA117113 + MEA117106		
Race	Race Detail	PBO (N=578)	100 SC (N=568)	Total (N=1146)
WHITE		477 (83%)	471 (83%)	948 (83%)
	ARABIC/ NORTH AFRICAN HERITAGE	5 (<1%)	5 (<1%)	10 (<1%)
	WHITE/ CAUCASIAN/ EUROPEAN HERITAGE	472 (82%)	466 (82%)	938 (82%)
MIXED RACE		11 (2%)	4 (<1%)	15 (1%)
	AMERICAN INDIAN OR ALASKAN NATIVE & WHITE - WHITE/ CAUCASIAN/ EUROPEAN HERITAGE	11 (2%)	3 (<1%)	14 (1%)
	ASIAN - CENTRAL/ SOUTH ASIAN HERITAGE & WHITE - WHITE/ CAUCASIAN/ EUROPEAN HERITAGE	0	1 (<1%)	1 (<1%)

Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Table 10.3

Summary of Number of Subjects by Subgroup: Individual Studies and Meta-Analysis

	208657		MEA117113			MEA117106	
	PBO (N=401)	100 SC (N=403)	PBO (N=87)	100 SC (N=83)	300 SC (N=84)	PBO (N=90)	100 SC (N=82)
Screening Blood Eosinophil Categories							
n	401	403	87	83	84	90	82
<0.5 GI/L	249 (62%)	239 (59%)	55 (63%)	53 (64%)	50 (60%)	55 (61%)	59 (72%)
>=0.5 GI/L	152 (38%)	164 (41%)	32 (37%)	30 (36%)	34 (40%)	35 (39%)	23 (28%)
Age (years)							
n	401	403	87	83	84	90	82
<40	0	1 (<1%)	0	0	0	0	0
40 - <65	173 (43%)	142 (35%)	41 (47%)	34 (41%)	38 (45%)	42 (47%)	38 (46%)
>=65	228 (57%)	260 (65%)	46 (53%)	49 (59%)	46 (55%)	48 (53%)	44 (54%)
Sex							
n	401	403	87	83	84	90	82
Female	126 (31%)	127 (32%)	28 (32%)	33 (40%)	26 (31%)	33 (37%)	29 (35%)
Male	275 (69%)	276 (68%)	59 (68%)	50 (60%)	58 (69%)	57 (63%)	53 (65%)

[1] 208657: Europe includes Belgium, Denmark, France, Germany, Greece, Hungary, Ireland, Italy, Netherlands, Poland, Spain, Sweden, United Kingdom; Rest of world includes China, Republic of Korea, Taiwan, Argentina, Brazil, Mexico, Canada, Australia, New Zealand, Israel, India; MEA117113: Europe includes Denmark, Germany, Netherlands, United Kingdom, Romania, Slovakia and Ukraine; Rest of World includes Republic of Korea, Japan, Taiwan, Argentina, Chile, Australia and Canada. MEA117106: Europe includes Belgium, France, Greece, Italy, Norway, Spain, Sweden, Czech Republic, Estonia and Poland; Rest of World includes Australia, Canada, Mexico, Peru and Russian Federation.
[2] Classification based on post-bronchodilator FEV1 at Screening, Global Initiative for Chronic Obstructive Lung Disease (GOLD) Guidelines for COPD.
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Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Table 10.3

Summary of Number of Subjects by Subgroup: Individual Studies and Meta-Analysis

	208657 + MEA117113 + MEA117106				
	PBO (N=578)	100 SC (N=568)	300 SC (N=84)	PBO + 100 SC (N=1146)	Total (N=1230)
Screening Blood Eosinophil Categories					
n	578	568	84	1146	1230
<0.5 GI/L	359 (62%)	351 (62%)	50 (60%)	710 (62%)	760 (62%)
>=0.5 GI/L	219 (38%)	217 (38%)	34 (40%)	436 (38%)	470 (38%)
Age (years)					
n	578	568	84	1146	1230
<40	0	1 (<1%)	0	1 (<1%)	1 (<1%)
40 - <65	256 (44%)	214 (38%)	38 (45%)	470 (41%)	508 (41%)
>=65	322 (56%)	353 (62%)	46 (55%)	675 (59%)	721 (59%)
Sex					
n	578	568	84	1146	1230
Female	187 (32%)	189 (33%)	26 (31%)	376 (33%)	402 (33%)
Male	391 (68%)	379 (67%)	58 (69%)	770 (67%)	828 (67%)

[1] 208657: Europe includes Belgium, Denmark, France, Germany, Greece, Hungary, Ireland, Italy, Netherlands, Poland, Spain, Sweden, United Kingdom; Rest of world includes China, Republic of Korea, Taiwan, Argentina, Brazil, Mexico, Canada, Australia, New Zealand, Israel, India; MEA117113: Europe includes Denmark, Germany, Netherlands, United Kingdom, Romania, Slovakia and Ukraine; Rest of World includes Republic of Korea, Japan, Taiwan, Argentina, Chile, Australia and Canada. MEA117106: Europe includes Belgium, France, Greece, Italy, Norway, Spain, Sweden, Czech Republic, Estonia and Poland; Rest of World includes Australia, Canada, Mexico, Peru and Russian Federation.
[2] Classification based on post-bronchodilator FEV1 at Screening, Global Initiative for Chronic Obstructive Lung Disease (GOLD) Guidelines for COPD.
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Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Table 10.3

Summary of Number of Subjects by Subgroup: Individual Studies and Meta-Analysis

	208657		MEA117113			MEA117106	
	PBO (N=401)	100 SC (N=403)	PBO (N=87)	100 SC (N=83)	300 SC (N=84)	PBO (N=90)	100 SC (N=82)
Race							
n	401	403	87	83	84	90	82
African American/ African Heritage	5 (1%)	5 (1%)	1 (1%)	1 (1%)	1 (1%)	2 (2%)	2 (2%)
White	335 (84%)	338 (84%)	68 (78%)	65 (78%)	69 (82%)	74 (82%)	68 (83%)
Asian	56 (14%)	56 (14%)	18 (21%)	17 (20%)	14 (17%)	1 (1%)	0
Other	5 (1%)	4 (<1%)	0	0	0	13 (14%)	12 (15%)
Geographic Region [1]							
n	401	403	87	83	84	90	82
Europe	188 (47%)	193 (48%)	40 (46%)	44 (53%)	42 (50%)	45 (50%)	41 (50%)
United States	42 (10%)	41 (10%)	8 (9%)	7 (8%)	13 (15%)	7 (8%)	6 (7%)
Rest of World	171 (43%)	169 (42%)	39 (45%)	32 (39%)	29 (35%)	38 (42%)	35 (43%)
Exacerbations in the Previous Year							
n	401	403	87	83	84	90	82
<=2 exacerbations	312 (78%)	294 (73%)	56 (64%)	51 (61%)	58 (69%)	56 (62%)	54 (66%)
3 exacerbations	64 (16%)	70 (17%)	17 (20%)	12 (14%)	14 (17%)	22 (24%)	15 (18%)
>=4 exacerbations	25 (6%)	39 (10%)	14 (16%)	20 (24%)	12 (14%)	12 (13%)	13 (16%)

[1] 208657: Europe includes Belgium, Denmark, France, Germany, Greece, Hungary, Ireland, Italy, Netherlands, Poland, Spain, Sweden, United Kingdom; Rest of world includes China, Republic of Korea, Taiwan, Argentina, Brazil, Mexico, Canada, Australia, New Zealand, Israel, India; MEA117113: Europe includes Denmark, Germany, Netherlands, United Kingdom, Romania, Slovakia and Ukraine; Rest of World includes Republic of Korea, Japan, Taiwan, Argentina, Chile, Australia and Canada. MEA117106: Europe includes Belgium, France, Greece, Italy, Norway, Spain, Sweden, Czech Republic, Estonia and Poland; Rest of World includes Australia, Canada, Mexico, Peru and Russian Federation.
[2] Classification based on post-bronchodilator FEV1 at Screening, Global Initiative for Chronic Obstructive Lung Disease (GOLD) Guidelines for COPD.
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Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Table 10.3

Summary of Number of Subjects by Subgroup: Individual Studies and Meta-Analysis

	208657 + MEA117113 + MEA117106				
	PBO (N=578)	100 SC (N=568)	300 SC (N=84)	PBO + 100 SC (N=1146)	Total (N=1230)
Race					
n	578	568	84	1146	1230
African American/ African Heritage	8 (1%)	8 (1%)	1 (1%)	16 (1%)	17 (1%)
White	477 (83%)	471 (83%)	69 (82%)	948 (83%)	1017 (83%)
Asian	75 (13%)	73 (13%)	14 (17%)	148 (13%)	162 (13%)
Other	18 (3%)	16 (3%)	0	34 (3%)	34 (3%)
Geographic Region [1]					
n	578	568	84	1146	1230
Europe	273 (47%)	278 (49%)	42 (50%)	551 (48%)	593 (48%)
United States	57 (10%)	54 (10%)	13 (15%)	111 (10%)	124 (10%)
Rest of World	248 (43%)	236 (42%)	29 (35%)	484 (42%)	513 (42%)
Exacerbations in the Previous Year					
n	578	568	84	1146	1230
<=2 exacerbations	424 (73%)	399 (70%)	58 (69%)	823 (72%)	881 (72%)
3 exacerbations	103 (18%)	97 (17%)	14 (17%)	200 (17%)	214 (17%)
>=4 exacerbations	51 (9%)	72 (13%)	12 (14%)	123 (11%)	135 (11%)

[1] 208657: Europe includes Belgium, Denmark, France, Germany, Greece, Hungary, Ireland, Italy, Netherlands, Poland, Spain, Sweden, United Kingdom; Rest of world includes China, Republic of Korea, Taiwan, Argentina, Brazil, Mexico, Canada, Australia, New Zealand, Israel, India; MEA117113: Europe includes Denmark, Germany, Netherlands, United Kingdom, Romania, Slovakia and Ukraine; Rest of World includes Republic of Korea, Japan, Taiwan, Argentina, Chile, Australia and Canada. MEA117106: Europe includes Belgium, France, Greece, Italy, Norway, Spain, Sweden, Czech Republic, Estonia and Poland; Rest of World includes Australia, Canada, Mexico, Peru and Russian Federation.
[2] Classification based on post-bronchodilator FEV1 at Screening, Global Initiative for Chronic Obstructive Lung Disease (GOLD) Guidelines for COPD.
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Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Table 10.3

Summary of Number of Subjects by Subgroup: Individual Studies and Meta-Analysis

	208657		MEA117113			MEA117106	
	PBO (N=401)	100 SC (N=403)	PBO (N=87)	100 SC (N=83)	300 SC (N=84)	PBO (N=90)	100 SC (N=82)
Smoking Status at Screening							
n	401	403	87	83	84	90	82
Current	111 (28%)	111 (28%)	23 (26%)	22 (27%)	25 (30%)	28 (31%)	27 (33%)
Former	290 (72%)	292 (72%)	63 (72%)	61 (73%)	59 (70%)	55 (61%)	54 (66%)
Never	0	0	1 (1%)	0	0	7 (8%)	1 (1%)
Severity of Airflow Limitation (GOLD Guidelines) [2]							
n	401	403	87	83	84	90	82
Mild: >=80% predicted	3 (<1%)	2 (<1%)	1 (1%)	2 (2%)	1 (1%)	2 (2%)	1 (1%)
Moderate: >=50%-<80% predicted	181 (45%)	168 (42%)	31 (36%)	40 (48%)	29 (35%)	33 (37%)	30 (37%)
Severe: >=30%-<50% predicted	160 (40%)	180 (45%)	40 (46%)	31 (37%)	39 (46%)	48 (53%)	45 (55%)
Very Severe: <30% predicted	57 (14%)	53 (13%)	15 (17%)	10 (12%)	15 (18%)	7 (8%)	6 (7%)

[1] 208657: Europe includes Belgium, Denmark, France, Germany, Greece, Hungary, Ireland, Italy, Netherlands, Poland, Spain, Sweden, United Kingdom; Rest of world includes China, Republic of Korea, Taiwan, Argentina, Brazil, Mexico, Canada, Australia, New Zealand, Israel, India; MEA117113: Europe includes Denmark, Germany, Netherlands, United Kingdom, Romania, Slovakia and Ukraine; Rest of World includes Republic of Korea, Japan, Taiwan, Argentina, Chile, Australia and Canada. MEA117106: Europe includes Belgium, France, Greece, Italy, Norway, Spain, Sweden, Czech Republic, Estonia and Poland; Rest of World includes Australia, Canada, Mexico, Peru and Russian Federation.
[2] Classification based on post-bronchodilator FEV1 at Screening, Global Initiative for Chronic Obstructive Lung Disease (GOLD) Guidelines for COPD.
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Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Table 10.3

Summary of Number of Subjects by Subgroup: Individual Studies and Meta-Analysis

	208657 + MEA117113 + MEA117106				
	PBO (N=578)	100 SC (N=568)	300 SC (N=84)	PBO + 100 SC (N=1146)	Total (N=1230)
Smoking Status at Screening					
n	578	568	84	1146	1230
Current	162 (28%)	160 (28%)	25 (30%)	322 (28%)	347 (28%)
Former	408 (71%)	407 (72%)	59 (70%)	815 (71%)	874 (71%)
Never	8 (1%)	1 (<1%)	0	9 (<1%)	9 (<1%)
Severity of Airflow Limitation (GOLD Guidelines) [2]					
n	578	568	84	1146	1230
Mild: >=80% predicted	6 (1%)	5 (<1%)	1 (1%)	11 (<1%)	12 (<1%)
Moderate: >=50%-<80% predicted	245 (42%)	238 (42%)	29 (35%)	483 (42%)	512 (42%)
Severe: >=30%-<50% predicted	248 (43%)	256 (45%)	39 (46%)	504 (44%)	543 (44%)
Very Severe: <30% predicted	79 (14%)	69 (12%)	15 (18%)	148 (13%)	163 (13%)

[1] 208657: Europe includes Belgium, Denmark, France, Germany, Greece, Hungary, Ireland, Italy, Netherlands, Poland, Spain, Sweden, United Kingdom; Rest of world includes China, Republic of Korea, Taiwan, Argentina, Brazil, Mexico, Canada, Australia, New Zealand, Israel, India; MEA117113: Europe includes Denmark, Germany, Netherlands, United Kingdom, Romania, Slovakia and Ukraine; Rest of World includes Republic of Korea, Japan, Taiwan, Argentina, Chile, Australia and Canada. MEA117106: Europe includes Belgium, France, Greece, Italy, Norway, Spain, Sweden, Czech Republic, Estonia and Poland; Rest of World includes Australia, Canada, Mexico, Peru and Russian Federation.
[2] Classification based on post-bronchodilator FEV1 at Screening, Global Initiative for Chronic Obstructive Lung Disease (GOLD) Guidelines for COPD.
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Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Table 10.3

Summary of Number of Subjects by Subgroup: Individual Studies and Meta-Analysis

	208657		MEA117113			MEA117106	
	PBO (N=401)	100 SC (N=403)	PBO (N=87)	100 SC (N=83)	300 SC (N=84)	PBO (N=90)	100 SC (N=82)
Symptoms of Chronic Bronchitis							
n	393	390	87	82	84	88	79
Yes	267 (68%)	277 (71%)	56 (64%)	48 (59%)	52 (62%)	59 (67%)	51 (65%)
No	126 (32%)	113 (29%)	31 (36%)	34 (41%)	32 (38%)	29 (33%)	28 (35%)

[1] 208657: Europe includes Belgium, Denmark, France, Germany, Greece, Hungary, Ireland, Italy, Netherlands, Poland, Spain, Sweden, United Kingdom; Rest of world includes China, Republic of Korea, Taiwan, Argentina, Brazil, Mexico, Canada, Australia, New Zealand, Israel, India; MEA117113: Europe includes Denmark, Germany, Netherlands, United Kingdom, Romania, Slovakia and Ukraine; Rest of World includes Republic of Korea, Japan, Taiwan, Argentina, Chile, Australia and Canada. MEA117106: Europe includes Belgium, France, Greece, Italy, Norway, Spain, Sweden, Czech Republic, Estonia and Poland; Rest of World includes Australia, Canada, Mexico, Peru and Russian Federation.
[2] Classification based on post-bronchodilator FEV1 at Screening, Global Initiative for Chronic Obstructive Lung Disease (GOLD) Guidelines for COPD.
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Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Table 10.3

Summary of Number of Subjects by Subgroup: Individual Studies and Meta-Analysis

	208657 + MEA117113 + MEA117106				
	PBO (N=578)	100 SC (N=568)	300 SC (N=84)	PBO + 100 SC (N=1146)	Total (N=1230)
Symptoms of Chronic Bronchitis					
n	568	551	84	1119	1203
Yes	382 (67%)	376 (68%)	52 (62%)	758 (68%)	810 (67%)
No	186 (33%)	175 (32%)	32 (38%)	361 (32%)	393 (33%)

[1] 208657: Europe includes Belgium, Denmark, France, Germany, Greece, Hungary, Ireland, Italy, Netherlands, Poland, Spain, Sweden, United Kingdom; Rest of world includes China, Republic of Korea, Taiwan, Argentina, Brazil, Mexico, Canada, Australia, New Zealand, Israel, India; MEA117113: Europe includes Denmark, Germany, Netherlands, United Kingdom, Romania, Slovakia and Ukraine; Rest of World includes Republic of Korea, Japan, Taiwan, Argentina, Chile, Australia and Canada. MEA117106: Europe includes Belgium, France, Greece, Italy, Norway, Spain, Sweden, Czech Republic, Estonia and Poland; Rest of World includes Australia, Canada, Mexico, Peru and Russian Federation.
[2] Classification based on post-bronchodilator FEV1 at Screening, Global Initiative for Chronic Obstructive Lung Disease (GOLD) Guidelines for COPD.
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Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Table 10.3

Summary of Number of Subjects by Subgroup: Individual Studies and Meta-Analysis

	208657		MEA117113			MEA117106	
	PBO (N=401)	100 SC (N=403)	PBO (N=87)	100 SC (N=83)	300 SC (N=84)	PBO (N=90)	100 SC (N=82)
Symptoms of Chronic Bronchitis + screening blood eosinophils							
n	393	390	87	82	84	88	79
Symptoms of Chronic Bronchitis + >=500 screening blood eosinophils	101 (26%)	117 (30%)	21 (24%)	17 (21%)	21 (25%)	23 (26%)	13 (16%)
Symptoms of Chronic Bronchitis + <500 screening blood eosinophils	166 (42%)	160 (41%)	35 (40%)	31 (38%)	31 (37%)	36 (41%)	38 (48%)
No Symptoms of Chronic Bronchitis + >=500 screening blood eosinophils	47 (12%)	44 (11%)	11 (13%)	13 (16%)	13 (15%)	10 (11%)	10 (13%)
No Symptoms of Chronic Bronchitis + <500 screening blood eosinophils	79 (20%)	69 (18%)	20 (23%)	21 (26%)	19 (23%)	19 (22%)	18 (23%)

[1] 208657: Europe includes Belgium, Denmark, France, Germany, Greece, Hungary, Ireland, Italy, Netherlands, Poland, Spain, Sweden, United Kingdom; Rest of world includes China, Republic of Korea, Taiwan, Argentina, Brazil, Mexico, Canada, Australia, New Zealand, Israel, India; MEA117113: Europe includes Denmark, Germany, Netherlands, United Kingdom, Romania, Slovakia and Ukraine; Rest of World includes Republic of Korea, Japan, Taiwan, Argentina, Chile, Australia and Canada. MEA117106: Europe includes Belgium, France, Greece, Italy, Norway, Spain, Sweden, Czech Republic, Estonia and Poland; Rest of World includes Australia, Canada, Mexico, Peru and Russian Federation.
[2] Classification based on post-bronchodilator FEV1 at Screening, Global Initiative for Chronic Obstructive Lung Disease (GOLD) Guidelines for COPD.
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Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Table 10.3

Summary of Number of Subjects by Subgroup: Individual Studies and Meta-Analysis

	208657 + MEA117113 + MEA117106				
	PBO (N=578)	100 SC (N=568)	300 SC (N=84)	PBO + 100 SC (N=1146)	Total (N=1230)
Symptoms of Chronic Bronchitis + screening blood eosinophils					
n	568	551	84	1119	1203
Symptoms of Chronic Bronchitis + >=500 screening blood eosinophils	145 (26%)	147 (27%)	21 (25%)	292 (26%)	313 (26%)
Symptoms of Chronic Bronchitis + <500 screening blood eosinophils	237 (42%)	229 (42%)	31 (37%)	466 (42%)	497 (41%)
No Symptoms of Chronic Bronchitis + >=500 screening blood eosinophils	68 (12%)	67 (12%)	13 (15%)	135 (12%)	148 (12%)
No Symptoms of Chronic Bronchitis + <500 screening blood eosinophils	118 (21%)	108 (20%)	19 (23%)	226 (20%)	245 (20%)

[1] 208657: Europe includes Belgium, Denmark, France, Germany, Greece, Hungary, Ireland, Italy, Netherlands, Poland, Spain, Sweden, United Kingdom; Rest of world includes China, Republic of Korea, Taiwan, Argentina, Brazil, Mexico, Canada, Australia, New Zealand, Israel, India; MEA117113: Europe includes Denmark, Germany, Netherlands, United Kingdom, Romania, Slovakia and Ukraine; Rest of World includes Republic of Korea, Japan, Taiwan, Argentina, Chile, Australia and Canada. MEA117106: Europe includes Belgium, France, Greece, Italy, Norway, Spain, Sweden, Czech Republic, Estonia and Poland; Rest of World includes Australia, Canada, Mexico, Peru and Russian Federation.
[2] Classification based on post-bronchodilator FEV1 at Screening, Global Initiative for Chronic Obstructive Lung Disease (GOLD) Guidelines for COPD.
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Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Table 10.10

Summary of History of Tobacco Use: Individual Studies and Meta-Analysis

	208657		MEA117113			MEA117106	
	PBO (N=401)	100 SC (N=403)	PBO (N=87)	100 SC (N=83)	300 SC (N=84)	PBO (N=90)	100 SC (N=82)
Smoking History							
n	401	403	87	83	84	90	82
Never smoked	0	0	1 (1%)	0	0	7 (8%)	1 (1%)
Current smoker	111 (28%)	111 (28%)	23 (26%)	22 (27%)	25 (30%)	28 (31%)	27 (33%)
Former smoker	290 (72%)	292 (72%)	63 (72%)	61 (73%)	59 (70%)	55 (61%)	54 (66%)
Years Smoked Tobacco [1]							
n	398	401	86	83	84	83	81
Mean	37.9	38.1	36.7	35.5	35.5	37.0	37.6
SD	11.74	10.96	11.57	11.26	11.14	12.19	11.67
Median	40.0	40.0	37.5	35.0	35.5	40.0	40.0
Min.	10	10	11	10	15	7	10
Max.	65	67	67	60	59	62	66
Average Cigarettes/Day [1]							
n	399	400	86	83	84	83	81
Mean	22.7	23.0	23.5	23.7	22.9	22.8	24.4
SD	11.26	12.41	12.30	12.01	12.18	11.36	11.53
Median	20.0	20.0	20.0	20.0	20.0	20.0	20.0
Min.	4	4	10	5	5	6	10
Max.	100	100	80	60	80	66	70

[1] Information summarised for current and former smokers only.
[2] Smoking Pack Years = (Number of cigarettes smoked per day/20) x number of years smoked.
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Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Table 10.10

Summary of History of Tobacco Use: Individual Studies and Meta-Analysis

	208657 + MEA117113 + MEA117106				
	PBO (N=578)	100 SC (N=568)	300 SC (N=84)	PBO + 100 SC (N=1146)	Total (N=1230)
Smoking History					
n	578	568	84	1146	1230
Never smoked	8 (1%)	1 (<1%)	0	9 (<1%)	9 (<1%)
Current smoker	162 (28%)	160 (28%)	25 (30%)	322 (28%)	347 (28%)
Former smoker	408 (71%)	407 (72%)	59 (70%)	815 (71%)	874 (71%)
Years Smoked Tobacco [1]					
n	567	565	84	1132	1216
Mean	37.6	37.6	35.5	37.6	37.5
SD	11.77	11.12	11.14	11.45	11.43
Median	40.0	40.0	35.5	40.0	40.0
Min.	7	10	15	7	7
Max.	67	67	59	67	67
Average Cigarettes/Day [1]					
n	568	564	84	1132	1216
Mean	22.9	23.3	22.9	23.1	23.1
SD	11.42	12.22	12.18	11.82	11.84
Median	20.0	20.0	20.0	20.0	20.0
Min.	4	4	5	4	4
Max.	100	100	80	100	100

[1] Information summarised for current and former smokers only.
[2] Smoking Pack Years = (Number of cigarettes smoked per day/20) x number of years smoked.
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Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Table 10.10

Summary of History of Tobacco Use: Individual Studies and Meta-Analysis

	208657		MEA117113			MEA117106	
	PBO (N=401)	100 SC (N=403)	PBO (N=87)	100 SC (N=83)	300 SC (N=84)	PBO (N=90)	100 SC (N=82)
Smoking Pack Years [1][2]							
n	396	400	86	83	84	83	81
Mean	42.7	43.2	43.4	42.8	41.8	43.0	46.8
SD	23.74	25.99	28.34	29.86	29.97	28.99	29.55
Median	40.0	40.0	40.0	36.0	34.0	35.0	42.0
Min.	10	10	10	10	10	5	10
Max.	152	192	176	150	200	168	165

[1] Information summarised for current and former smokers only.
[2] Smoking Pack Years = (Number of cigarettes smoked per day/20) x number of years smoked.
/mnt/code/is_4/prod/tfls/t_sp_subst.sas 07SEP2024 14:00

Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Table 10.10

Summary of History of Tobacco Use: Individual Studies and Meta-Analysis

	208657 + MEA117113 + MEA117106				
	PBO (N=578)	100 SC (N=568)	300 SC (N=84)	PBO + 100 SC (N=1146)	Total (N=1230)
Smoking Pack Years [1][2]					
n	565	564	84	1129	1213
Mean	42.8	43.7	41.8	43.3	43.2
SD	25.26	27.10	29.97	26.18	26.45
Median	40.0	40.0	34.0	40.0	40.0
Min.	5	10	10	5	5
Max.	176	192	200	192	200

[1] Information summarised for current and former smokers only.
[2] Smoking Pack Years = (Number of cigarettes smoked per day/20) x number of years smoked.
/mnt/code/is_4/prod/tfls/t_sp_subst.sas 07SEP2024 14:00

Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Table 111.6

Summary of COPD History and Baseline Disease Characteristics: Individual Studies and Meta-Analysis

	208657		MEA117113		MEA117106	
	PBO (N=401)	100 SC (N=403)	PBO (N=87)	100 SC (N=83)	PBO (N=90)	100 SC (N=82)
Duration of COPD						
n	401	403	87	83	90	82
1-5 years	107 (27%)	104 (26%)	30 (34%)	29 (35%)	28 (31%)	30 (37%)
>5-10 years	143 (36%)	143 (35%)	37 (43%)	33 (40%)	35 (39%)	28 (34%)
>10-15 years	90 (22%)	89 (22%)	12 (14%)	8 (10%)	16 (18%)	11 (13%)
>15-20 years	40 (10%)	39 (10%)	5 (6%)	7 (8%)	4 (4%)	6 (7%)
>20-25 years	13 (3%)	16 (4%)	3 (3%)	5 (6%)	5 (6%)	3 (4%)
>25 years	8 (2%)	12 (3%)	0	1 (1%)	2 (2%)	4 (5%)
Duration of COPD (years)						
n	401	403	87	83	90	82
Mean	9.7	10.2	8.2	8.8	9.3	9.4
SD	5.88	6.65	5.10	7.10	6.58	7.06
Median	9.0	9.0	7.0	7.0	8.0	8.0
Min.	1	1	1	1	1	1
Max.	33	40	24	45	32	33
Severity of Airflow Limitation [1]						
n	401	403	87	83	90	82
Mild: >=80% predicted	3 (<1%)	2 (<1%)	1 (1%)	2 (2%)	2 (2%)	1 (1%)
Moderate: >=50%-<80% predicted	181 (45%)	168 (42%)	31 (36%)	40 (48%)	33 (37%)	30 (37%)
Severe: >=30%-<50% predicted	160 (40%)	180 (45%)	40 (46%)	31 (37%)	48 (53%)	45 (55%)
Very Severe: <30% predicted	57 (14%)	53 (13%)	15 (17%)	10 (12%)	7 (8%)	6 (7%)

[1] Classification based on post-bronchodilator FEV1 at Screening, Global Initiative for Chronic Obstructive Lung Disease (GOLD) Guidelines for COPD.
[2] Subjects with Cardiovascular comorbidity are defined as subjects with any past or current medical condition under Cardiac Disorders.
[3] Subjects with Other comorbidity are defined as subjects with any past or current medical condition other than under Cardiac Disorders.
[4] MMRC = Modified Medical Research Council Score.
[5] GERD = Gastroesophageal Reflux Disease.

Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Table 111.6

Summary of COPD History and Baseline Disease Characteristics: Individual Studies and Meta-Analysis

	208657 + MEA117113 + MEA117106		
	PBO (N=578)	100 SC (N=568)	Total (N=1146)
Duration of COPD			
n	578	568	1146
1-5 years	165 (29%)	163 (29%)	328 (29%)
>5-10 years	215 (37%)	204 (36%)	419 (37%)
>10-15 years	118 (20%)	108 (19%)	226 (20%)
>15-20 years	49 (8%)	52 (9%)	101 (9%)
>20-25 years	21 (4%)	24 (4%)	45 (4%)
>25 years	10 (2%)	17 (3%)	27 (2%)
Duration of COPD (years)			
n	578	568	1146
Mean	9.4	9.9	9.6
SD	5.90	6.79	6.36
Median	8.0	9.0	8.0
Min.	1	1	1
Max.	33	45	45
Severity of Airflow Limitation [1]			
n	578	568	1146
Mild: >=80% predicted	6 (1%)	5 (<1%)	11 (<1%)
Moderate: >=50%-<80% predicted	245 (42%)	238 (42%)	483 (42%)
Severe: >=30%-<50% predicted	248 (43%)	256 (45%)	504 (44%)
Very Severe: <30% predicted	79 (14%)	69 (12%)	148 (13%)

[1] Classification based on post-bronchodilator FEV1 at Screening, Global Initiative for Chronic Obstructive Lung Disease (GOLD) Guidelines for COPD.
[2] Subjects with Cardiovascular comorbidity are defined as subjects with any past or current medical condition under Cardiac Disorders.
[3] Subjects with Other comorbidity are defined as subjects with any past or current medical condition other than under Cardiac Disorders.
[4] MMRC = Modified Medical Research Council Score.
[5] GERD = Gastroesophageal Reflux Disease.

Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Table 111.6

Summary of COPD History and Baseline Disease Characteristics: Individual Studies and Meta-Analysis

	208657		MEA117113		MEA117106	
	PBO (N=401)	100 SC (N=403)	PBO (N=87)	100 SC (N=83)	PBO (N=90)	100 SC (N=82)
Cardiovascular Comorbidity [2]						
n	401	403	87	83	90	82
Yes	97 (24%)	103 (26%)	24 (28%)	22 (27%)	20 (22%)	17 (21%)
No	304 (76%)	300 (74%)	63 (72%)	61 (73%)	70 (78%)	65 (79%)
Other Comorbidity [3]						
n	401	403	87	83	90	82
Yes	323 (81%)	316 (78%)	72 (83%)	66 (80%)	68 (76%)	61 (74%)
No	78 (19%)	87 (22%)	15 (17%)	17 (20%)	22 (24%)	21 (26%)
MMRC Score at Screening [4]						
n	401	403	87	83	90	82
<2	98 (24%)	89 (22%)	9 (10%)	11 (13%)	22 (24%)	12 (15%)
>=2	301 (75%)	310 (77%)	78 (90%)	72 (87%)	68 (76%)	70 (85%)
Missing	2 (<1%)	4 (<1%)	0	0	0	0
Ever diagnosed with GERD [5]						
n	401	403	87	83	90	82
Yes	92 (23%)	85 (21%)	13 (15%)	14 (17%)	18 (20%)	12 (15%)
No	303 (76%)	311 (77%)	74 (85%)	69 (83%)	72 (80%)	70 (85%)
Missing	6 (1%)	7 (2%)	0	0	0	0

[1] Classification based on post-bronchodilator FEV1 at Screening, Global Initiative for Chronic Obstructive Lung Disease (GOLD) Guidelines for COPD.
[2] Subjects with Cardiovascular comorbidity are defined as subjects with any past or current medical condition under Cardiac Disorders.
[3] Subjects with Other comorbidity are defined as subjects with any past or current medical condition other than under Cardiac Disorders.
[4] MMRC = Modified Medical Research Council Score.
[5] GERD = Gastroesophageal Reflux Disease.
/mnt/code/postcsr_01/prod/tfls/t_sp_copd_bhar.sas 21JUL2025 21:59

Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Table 111.6

Summary of COPD History and Baseline Disease Characteristics: Individual Studies and Meta-Analysis

	208657 + MEA117113 + MEA117106		
	PBO (N=578)	100 SC (N=568)	Total (N=1146)
Cardiovascular Comorbidity [2]			
n	578	568	1146
Yes	141 (24%)	142 (25%)	283 (25%)
No	437 (76%)	426 (75%)	863 (75%)
Other Comorbidity [3]			
n	578	568	1146
Yes	463 (80%)	443 (78%)	906 (79%)
No	115 (20%)	125 (22%)	240 (21%)
MMRC Score at Screening [4]			
n	578	568	1146
<2	129 (22%)	112 (20%)	241 (21%)
>=2	447 (77%)	452 (80%)	899 (78%)
Missing	2 (<1%)	4 (<1%)	6 (<1%)
Ever diagnosed with GERD [5]			
n	578	568	1146
Yes	123 (21%)	111 (20%)	234 (20%)
No	449 (78%)	450 (79%)	899 (78%)
Missing	6 (1%)	7 (1%)	13 (1%)

[1] Classification based on post-bronchodilator FEV1 at Screening, Global Initiative for Chronic Obstructive Lung Disease (GOLD) Guidelines for COPD.
[2] Subjects with Cardiovascular comorbidity are defined as subjects with any past or current medical condition under Cardiac Disorders.
[3] Subjects with Other comorbidity are defined as subjects with any past or current medical condition other than under Cardiac Disorders.
[4] MMRC = Modified Medical Research Council Score.
[5] GERD = Gastroesophageal Reflux Disease.
/mnt/code/postcsr_01/prod/tfls/t_sp_copd_bhar.sas 21JUL2025 21:59

Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Table 111.7

Summary of Previous Exacerbation History: Individual Studies and Meta-Analysis

	208657		MEA117113		MEA117106	
	PBO (N=401)	100 SC (N=403)	PBO (N=87)	100 SC (N=83)	PBO (N=90)	100 SC (N=82)
Number of moderate/severe exacerbations						
n	401	403	87	83	90	82
0	3 (<1%)	0	0	0	0	0
>=1	398 (>99%)	403 (100%)	87 (100%)	83 (100%)	90 (100%)	82 (100%)
1	43 (11%)	40 (10%)	11 (13%)	8 (10%)	8 (9%)	8 (10%)
2	266 (66%)	254 (63%)	45 (52%)	43 (52%)	48 (53%)	46 (56%)
3	64 (16%)	70 (17%)	17 (20%)	12 (14%)	22 (24%)	15 (18%)
4	13 (3%)	20 (5%)	7 (8%)	11 (13%)	6 (7%)	6 (7%)
>4	12 (3%)	19 (5%)	7 (8%)	9 (11%)	6 (7%)	7 (9%)
Mean	2.2	2.3	2.6	2.8	2.6	2.6
SD	0.90	0.98	1.34	1.67	1.39	1.38
Median	2.0	2.0	2.0	2.0	2.0	2.0
Min.	0	1	1	1	1	1
Max.	8	7	8	10	10	8
Number of moderate exacerbations						
n	401	403	87	83	90	82
0	53 (13%)	53 (13%)	14 (16%)	9 (11%)	12 (13%)	16 (20%)
>=1	348 (87%)	350 (87%)	73 (84%)	74 (89%)	78 (87%)	66 (80%)
1	20 (5%)	13 (3%)	9 (10%)	7 (8%)	9 (10%)	11 (13%)
2	252 (63%)	251 (62%)	38 (44%)	40 (48%)	43 (48%)	37 (45%)
3	53 (13%)	60 (15%)	17 (20%)	14 (17%)	17 (19%)	9 (11%)
>3	23 (6%)	26 (6%)	9 (10%)	13 (16%)	9 (10%)	9 (11%)

Note: Number of exacerbations reported in the 12 months prior to study.

/mnt/code/postcsr_01/prod/tfls/t_sp_prev_exhis.sas 21JUL2025 21:59

Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Table 111.7

Summary of Previous Exacerbation History: Individual Studies and Meta-Analysis

	208657 + MEA117113 + MEA117106		
	PBO (N=578)	100 SC (N=568)	Total (N=1146)
Number of moderate/severe exacerbations			
n	578	568	1146
0	3 (<1%)	0	3 (<1%)
>=1	575 (>99%)	568 (100%)	1143 (>99%)
1	62 (11%)	56 (10%)	118 (10%)
2	359 (62%)	343 (60%)	702 (61%)
3	103 (18%)	97 (17%)	200 (17%)
4	26 (4%)	37 (7%)	63 (5%)
>4	25 (4%)	35 (6%)	60 (5%)
Mean	2.3	2.4	2.4
SD	1.08	1.18	1.13
Median	2.0	2.0	2.0
Min.	0	1	0
Max.	10	10	10
Number of moderate exacerbations			
n	578	568	1146
0	79 (14%)	78 (14%)	157 (14%)
>=1	499 (86%)	490 (86%)	989 (86%)
1	38 (7%)	31 (5%)	69 (6%)
2	333 (58%)	328 (58%)	661 (58%)
3	87 (15%)	83 (15%)	170 (15%)
>3	41 (7%)	48 (8%)	89 (8%)

Note: Number of exacerbations reported in the 12 months prior to study.

/mnt/code/postcsr_01/prod/tfls/t_sp_prev_exhis.sas 21JUL2025 21:59

Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Table 111.7

Summary of Previous Exacerbation History: Individual Studies and Meta-Analysis

	208657				MEA117113				MEA117106			
	PBO (N=401)		100 SC (N=403)		PBO (N=87)		100 SC (N=83)		PBO (N=90)		100 SC (N=82)	
Number of severe exacerbations												
n	401		403		87		83		90		82	
0	324	(81%)	315	(78%)	54	(62%)	54	(65%)	61	(68%)	50	(61%)
>=1	77	(19%)	88	(22%)	33	(38%)	29	(35%)	29	(32%)	32	(39%)
1	63	(16%)	67	(17%)	25	(29%)	26	(31%)	24	(27%)	17	(21%)
2	11	(3%)	9	(2%)	6	(7%)	2	(2%)	2	(2%)	10	(12%)
3	1	(<1%)	8	(2%)	1	(1%)	0		2	(2%)	2	(2%)
>3	2	(<1%)	4	(<1%)	1	(1%)	1	(1%)	1	(1%)	3	(4%)
Number of exacerbations treated with systemic corticosteroids and/or antibiotics but did not require hospitalisation/ER visit												
n	401		403		87		83		90		82	
0	64	(16%)	71	(18%)	16	(18%)	10	(12%)	17	(19%)	21	(26%)
>=1	337	(84%)	332	(82%)	71	(82%)	73	(88%)	73	(81%)	61	(74%)
1	35	(9%)	22	(5%)	9	(10%)	7	(8%)	10	(11%)	11	(13%)
2	226	(56%)	223	(55%)	39	(45%)	44	(53%)	39	(43%)	34	(41%)
3	55	(14%)	58	(14%)	17	(20%)	11	(13%)	15	(17%)	8	(10%)
>3	21	(5%)	29	(7%)	6	(7%)	11	(13%)	9	(10%)	8	(10%)

Note: Number of exacerbations reported in the 12 months prior to study.

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Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Table 111.7

Summary of Previous Exacerbation History: Individual Studies and Meta-Analysis

	208657 + MEA117113 + MEA117106					
	PBO (N=578)		100 SC (N=568)		Total (N=1146)	
Number of severe exacerbations						
n	578		568		1146	
0	439	(76%)	419	(74%)	858	(75%)
>=1	139	(24%)	149	(26%)	288	(25%)
1	112	(19%)	110	(19%)	222	(19%)
2	19	(3%)	21	(4%)	40	(3%)
3	4	(<1%)	10	(2%)	14	(1%)
>3	4	(<1%)	8	(1%)	12	(1%)
Number of exacerbations treated with systemic corticosteroids and/or antibiotics but did not require hospitalisation/ER visit						
n	578		568		1146	
0	97	(17%)	102	(18%)	199	(17%)
>=1	481	(83%)	466	(82%)	947	(83%)
1	54	(9%)	40	(7%)	94	(8%)
2	304	(53%)	301	(53%)	605	(53%)
3	87	(15%)	77	(14%)	164	(14%)
>3	36	(6%)	48	(8%)	84	(7%)

Note: Number of exacerbations reported in the 12 months prior to study.

Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Table 111.7

Summary of Previous Exacerbation History: Individual Studies and Meta-Analysis

	208657				MEA117113				MEA117106			
	PBO (N=401)		100 SC (N=403)		PBO (N=87)		100 SC (N=83)		PBO (N=90)		100 SC (N=82)	
Number of exacerbations required ER visit but not hospitalisation												
n	401		403		87		83		90		82	
0	349	(87%)	359	(89%)	80	(92%)	74	(89%)	80	(89%)	71	(87%)
>=1	52	(13%)	44	(11%)	7	(8%)	9	(11%)	10	(11%)	11	(13%)
1	31	(8%)	20	(5%)	5	(6%)	5	(6%)	3	(3%)	8	(10%)
2	16	(4%)	18	(4%)	1	(1%)	3	(4%)	6	(7%)	3	(4%)
3	4	(<1%)	5	(1%)	0		1	(1%)	0		0	
>3	1	(<1%)	1	(<1%)	1	(1%)	0		1	(1%)	0	
Number of exacerbations required hospitalisation in general ward without ICU												
n	401		403		87		83		90		82	
0	328	(82%)	319	(79%)	56	(64%)	56	(67%)	62	(69%)	51	(62%)
>=1	73	(18%)	84	(21%)	31	(36%)	27	(33%)	28	(31%)	31	(38%)
1	61	(15%)	63	(16%)	23	(26%)	24	(29%)	23	(26%)	18	(22%)
2	9	(2%)	10	(2%)	6	(7%)	2	(2%)	2	(2%)	8	(10%)
3	1	(<1%)	7	(2%)	1	(1%)	0		2	(2%)	2	(2%)
>3	2	(<1%)	4	(<1%)	1	(1%)	1	(1%)	1	(1%)	3	(4%)

Note: Number of exacerbations reported in the 12 months prior to study.

/mnt/code/postcsr_01/prod/tfls/t_sp_prev_exhis.sas 21JUL2025 21:59

Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Table 111.7

Summary of Previous Exacerbation History: Individual Studies and Meta-Analysis

	208657 + MEA117113 + MEA117106					
	PBO (N=578)		100 SC (N=568)		Total (N=1146)	
Number of exacerbations required ER visit but not hospitalisation						
n	578		568		1146	
0	509	(88%)	504	(89%)	1013	(88%)
>=1	69	(12%)	64	(11%)	133	(12%)
1	39	(7%)	33	(6%)	72	(6%)
2	23	(4%)	24	(4%)	47	(4%)
3	4	(<1%)	6	(1%)	10	(<1%)
>3	3	(<1%)	1	(<1%)	4	(<1%)
Number of exacerbations required hospitalisation in general ward without ICU						
n	578		568		1146	
0	446	(77%)	426	(75%)	872	(76%)
>=1	132	(23%)	142	(25%)	274	(24%)
1	107	(19%)	105	(18%)	212	(18%)
2	17	(3%)	20	(4%)	37	(3%)
3	4	(<1%)	9	(2%)	13	(1%)
>3	4	(<1%)	8	(1%)	12	(1%)

Note: Number of exacerbations reported in the 12 months prior to study.

Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Table 111.7

Summary of Previous Exacerbation History: Individual Studies and Meta-Analysis

	208657				MEA117113				MEA117106			
	PBO (N=401)		100 SC (N=403)		PBO (N=87)		100 SC (N=83)		PBO (N=90)		100 SC (N=82)	
Number of exacerbations required hospitalisation in ICU												
n	401		403		87		83		90		82	
0	395	(99%)	398	(99%)	84	(97%)	81	(98%)	89	(99%)	78	(95%)
>=1	6	(1%)	5	(1%)	3	(3%)	2	(2%)	1	(1%)	4	(5%)
1	6	(1%)	5	(1%)	3	(3%)	2	(2%)	1	(1%)	4	(5%)
2	0		0		0		0		0		0	
3	0		0		0		0		0		0	
>3	0		0		0		0		0		0	

Note: Number of exacerbations reported in the 12 months prior to study.

Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Table 111.7

Summary of Previous Exacerbation History: Individual Studies and Meta-Analysis

	208657 + MEA117113 + MEA117106					
	PBO (N=578)		100 SC (N=568)		Total (N=1146)	
Number of exacerbations required hospitalisation in ICU						
n	578		568		1146	
0	568	(98%)	557	(98%)	1125	(98%)
>=1	10	(2%)	11	(2%)	21	(2%)
1	10	(2%)	11	(2%)	21	(2%)
2	0		0		0	
3	0		0		0	
>3	0		0		0	

Note: Number of exacerbations reported in the 12 months prior to study.

Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Table 111.7

Summary of Previous Exacerbation History: Individual Studies and Meta-Analysis

	208657				MEA117113				MEA117106			
	PBO (N=401)		100 SC (N=403)		PBO (N=87)		100 SC (N=83)		PBO (N=90)		100 SC (N=82)	
Historical causes of exacerbations												
n	386		389		87		83		90		82	
RESPIRATORY INFECTION	183	(47%)	200	(51%)	48	(55%)	44	(53%)	60	(67%)	50	(61%)
COMMON COLD	84	(22%)	99	(25%)	40	(46%)	34	(41%)	26	(29%)	26	(32%)
COLD AIR / COLD WEATHER	93	(24%)	106	(27%)	30	(34%)	29	(35%)	22	(24%)	18	(22%)
UPPER RESPIRATORY INFECTION OTHER THAN COMMON COLD	100	(26%)	109	(28%)	23	(26%)	17	(20%)	17	(19%)	17	(21%)
LOWER RESPIRATORY INFECTION	83	(22%)	105	(27%)	27	(31%)	20	(24%)	17	(19%)	19	(23%)
UNKNOWN ETIOLOGY	89	(23%)	98	(25%)	16	(18%)	11	(13%)	14	(16%)	11	(13%)
TOBACCO SMOKE	47	(12%)	50	(13%)	17	(20%)	11	(13%)	13	(14%)	13	(16%)
AIR POLLUTION	49	(13%)	51	(13%)	16	(18%)	7	(8%)	13	(14%)	13	(16%)
EXERCISE	43	(11%)	39	(10%)	9	(10%)	13	(16%)	6	(7%)	9	(11%)
STRESS / EMOTIONS	28	(7%)	36	(9%)	12	(14%)	7	(8%)	4	(4%)	8	(10%)
WITHHOLDING OR REDUCING COPD MEDICATION	18	(5%)	29	(7%)	7	(8%)	9	(11%)	9	(10%)	9	(11%)
ALLERGY	13	(3%)	11	(3%)	5	(6%)	3	(4%)	4	(4%)	7	(9%)
OTHER	0		0		6	(7%)	10	(12%)	7	(8%)	2	(2%)
OTHER NSAIDS	1	(<1%)	0		0		0		1	(1%)	1	(1%)
ASPIRIN	0		0		1	(1%)	0		1	(1%)	0	
BETA-BLOCKERS	0		1	(<1%)	0		0		0		0	

Note: Number of exacerbations reported in the 12 months prior to study.

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Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Table 111.7

Summary of Previous Exacerbation History: Individual Studies and Meta-Analysis

	208657 + MEA117113 + MEA117106					
	PBO (N=578)		100 SC (N=568)		Total (N=1146)	
Historical causes of exacerbations						
n	563		554		1117	
RESPIRATORY INFECTION	291	(52%)	294	(53%)	585	(52%)
COMMON COLD	150	(27%)	159	(29%)	309	(28%)
COLD AIR / COLD WEATHER	145	(26%)	153	(28%)	298	(27%)
UPPER RESPIRATORY INFECTION OTHER THAN COMMON COLD	140	(25%)	143	(26%)	283	(25%)
LOWER RESPIRATORY INFECTION	127	(23%)	144	(26%)	271	(24%)
UNKNOWN ETIOLOGY	119	(21%)	120	(22%)	239	(21%)
TOBACCO SMOKE	77	(14%)	74	(13%)	151	(14%)
AIR POLLUTION	78	(14%)	71	(13%)	149	(13%)
EXERCISE	58	(10%)	61	(11%)	119	(11%)
STRESS / EMOTIONS	44	(8%)	51	(9%)	95	(9%)
WITHHOLDING OR REDUCING COPD MEDICATION	34	(6%)	47	(8%)	81	(7%)
ALLERGY	22	(4%)	21	(4%)	43	(4%)
OTHER	13	(2%)	12	(2%)	25	(2%)
OTHER NSAIDS	2	(<1%)	1	(<1%)	3	(<1%)
ASPIRIN	2	(<1%)	0		2	(<1%)
BETA-BLOCKERS	0		1	(<1%)	1	(<1%)

Note: Number of exacerbations reported in the 12 months prior to study.

Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Table 111.8
Summary of COPD Medications Started Prior to Treatment by
Respiratory Medication Class in Study 208657

Respiratory Medication Class Ingredient	PBO (N=401)	100 SC (N=403)	Total (N=804)
Any medication	401 (100%)	403 (100%)	804 (100%)
Corticosteroid			
Any medication	401 (100%)	403 (100%)	804 (100%)
FLUTICASONE FUROATE+VILANTEROL TRIFENATATE+UMECLIDINIUM BROMIDE	115 (29%)	107 (27%)	222 (28%)
SALMETEROL XINAFOATE+FLUTICASONE PROPIONATE	61 (15%)	75 (19%)	136 (17%)
BUDESONIDE+FORMOTEROL FUMARATE	66 (16%)	64 (16%)	130 (16%)
GLYCOPYRRONIUM BROMIDE+BECLOMETASONE DIPROPIONATE+FORMOTEROL FUMARATE	47 (12%)	51 (13%)	98 (12%)
BUDESONIDE	38 (9%)	48 (12%)	86 (11%)
PREDNISOLONE	39 (10%)	32 (8%)	71 (9%)
METHYLPREDNISOLONE	26 (6%)	35 (9%)	61 (8%)
FLUTICASONE FUROATE+VILANTEROL TRIFENATATE	26 (6%)	30 (7%)	56 (7%)
BECLOMETASONE DIPROPIONATE+FORMOTEROL FUMARATE	22 (5%)	28 (7%)	50 (6%)
PREDNISONE	28 (7%)	21 (5%)	49 (6%)
GLYCOPYRRONIUM BROMIDE+BUDESONIDE+FORMOTEROL FUMARATE	17 (4%)	20 (5%)	37 (5%)
FLUTICASONE PROPIONATE	20 (5%)	11 (3%)	31 (4%)
BUDESONIDE+FORMOTEROL	15 (4%)	11 (3%)	26 (3%)
CICLESONIDE	12 (3%)	11 (3%)	23 (3%)
FORMOTEROL FUMARATE+FLUTICASONE PROPIONATE	8 (2%)	7 (2%)	15 (2%)
METHYLPREDNISOLONE SODIUM SUCCINATE	5 (1%)	10 (2%)	15 (2%)
PREDNISONE ACETATE	7 (2%)	5 (1%)	12 (1%)
FLUTICASONE FUROATE	5 (1%)	5 (1%)	10 (1%)
FLUTICASONE	6 (1%)	3 (<1%)	9 (1%)
GLYCOPYRRONIUM BROMIDE+BUDESONIDE+FORMOTEROL	5 (1%)	2 (<1%)	7 (<1%)
BECLOMETASONE DIPROPIONATE	5 (1%)	1 (<1%)	6 (<1%)
SALMETEROL+FLUTICASONE	3 (<1%)	3 (<1%)	6 (<1%)
BECLOMETASONE+FORMOTEROL	4 (<1%)	1 (<1%)	5 (<1%)

Note: Includes all COPD medications started before the first dose of investigational product.
Note: Multi-component medications are displayed under the respiratory medication class of each component.
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Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Table 111.8
Summary of COPD Medications Started Prior to Treatment by
Respiratory Medication Class in Study 208657

Respiratory Medication Class Ingredient	PBO (N=401)		100 SC (N=403)		Total (N=804)	
HYDROCORTISONE	3	(<1%)	2	(<1%)	5	(<1%)
MOMETASONE FUROATE+FORMOTEROL FUMARATE	1	(<1%)	4	(<1%)	5	(<1%)
BUDESONIDE+LEVOSALBUTAMOL	2	(<1%)	1	(<1%)	3	(<1%)
DEFLAZACORT	1	(<1%)	2	(<1%)	3	(<1%)
GLYCOPYRRONIUM+BUDESONIDE+FORMOTEROL FUMARATE	3	(<1%)	0		3	(<1%)
MEPREDNISONE	1	(<1%)	2	(<1%)	3	(<1%)
PREDNISOLONE SODIUM SUCCINATE	0		3	(<1%)	3	(<1%)
BECLOMETASONE	1	(<1%)	1	(<1%)	2	(<1%)
DEXAMETHASONE SODIUM PHOSPHATE	1	(<1%)	1	(<1%)	2	(<1%)
FLUTICASONE FUROATE+VILANTEROL	0		2	(<1%)	2	(<1%)
FLUTICASONE FUROATE+VILANTEROL+UMECLIDINIUM	1	(<1%)	1	(<1%)	2	(<1%)
GLYCOPYRRONIUM BROMIDE+FORMOTEROL FUMARATE+FLUTICASONE PROPIONATE	0		2	(<1%)	2	(<1%)
GLYCOPYRRONIUM BROMIDE+MOMETASONE FUROATE+INDACATEROL ACETATE	1	(<1%)	1	(<1%)	2	(<1%)
SALMETEROL+FLUTICASONE PROPIONATE	0		2	(<1%)	2	(<1%)
BETAMETHASONE SODIUM PHOSPHATE	1	(<1%)	0		1	(<1%)
DEXAMETHASONE	1	(<1%)	0		1	(<1%)
FLUTICASONE+VILANTEROL+UMECLIDINIUM	1	(<1%)	0		1	(<1%)
FORMOTEROL FUMARATE+TIOTROPIUM BROMIDE+CICLESONIDE	1	(<1%)	0		1	(<1%)
FORMOTEROL+TIOTROPIUM+CICLESONIDE	1	(<1%)	0		1	(<1%)
GLYCOPYRRONIUM BROMIDE+BUDESONIDE+FORMOTEROL FUMARATE DIHYDRATE	0		1	(<1%)	1	(<1%)
GLYCOPYRRONIUM+FORMOTEROL+FLUTICASONE	0		1	(<1%)	1	(<1%)
HYDROCORTISONE SODIUM SUCCINATE	0		1	(<1%)	1	(<1%)
KENALOG (NOS)	0		1	(<1%)	1	(<1%)
MOMETASONE FUROATE	1	(<1%)	0		1	(<1%)
TRIAMCINOLONE	1	(<1%)	0		1	(<1%)

Note: Includes all COPD medications started before the first dose of investigational product.
Note: Multi-component medications are displayed under the respiratory medication class of each component.

Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Table 111.8
Summary of COPD Medications Started Prior to Treatment by
Respiratory Medication Class in Study 208657

Respiratory Medication Class Ingredient	PBO (N=401)	100 SC (N=403)	Total (N=804)
Long-acting anticholinergic			
Any medication	398 (>99%)	397 (99%)	795 (99%)
FLUTICASONE FUROATE+VILANTEROL TRIFENATATE+UMECLIDINIUM BROMIDE	115 (29%)	107 (27%)	222 (28%)
TIOTROPIUM BROMIDE MONOHYDRATE	97 (24%)	104 (26%)	201 (25%)
GLYCOPYRRONIUM BROMIDE+BECLOMETASONE DIPROPIONATE+FORMOTEROL FUMARATE	47 (12%)	51 (13%)	98 (12%)
TIOTROPIUM BROMIDE	43 (11%)	45 (11%)	88 (11%)
UMECLIDINIUM BROMIDE	19 (5%)	28 (7%)	47 (6%)
TIOTROPIUM	26 (6%)	17 (4%)	43 (5%)
GLYCOPYRRONIUM BROMIDE+BUDESONIDE+FORMOTEROL FUMARATE	17 (4%)	20 (5%)	37 (5%)
GLYCOPYRRONIUM BROMIDE	17 (4%)	19 (5%)	36 (4%)
VILANTEROL TRIFENATATE+UMECLIDINIUM BROMIDE	19 (5%)	14 (3%)	33 (4%)
GLYCOPYRRONIUM BROMIDE+INDACATEROL MALEATE	10 (2%)	18 (4%)	28 (3%)
TIOTROPIUM BROMIDE MONOHYDRATE+OLODATEROL HYDROCHLORIDE	12 (3%)	14 (3%)	26 (3%)
ACLIDINIUM BROMIDE	8 (2%)	4 (<1%)	12 (1%)
FORMOTEROL FUMARATE+ACLIDINIUM BROMIDE	6 (1%)	3 (<1%)	9 (1%)
GLYCOPYRRONIUM BROMIDE+BUDESONIDE+FORMOTEROL	5 (1%)	2 (<1%)	7 (<1%)
GLYCOPYRRONIUM BROMIDE+FORMOTEROL FUMARATE	3 (<1%)	4 (<1%)	7 (<1%)
UMECLIDINIUM	2 (<1%)	2 (<1%)	4 (<1%)
GLYCOPYRRONIUM+BUDESONIDE+FORMOTEROL FUMARATE	3 (<1%)	0	3 (<1%)
FLUTICASONE FUROATE+VILANTEROL+UMECLIDINIUM	1 (<1%)	1 (<1%)	2 (<1%)
GLYCOPYRRONIUM BROMIDE+FORMOTEROL	0	2 (<1%)	2 (<1%)
GLYCOPYRRONIUM BROMIDE+FORMOTEROL FUMARATE+FLUTICASONE PROPIONATE	0	2 (<1%)	2 (<1%)
GLYCOPYRRONIUM BROMIDE+MOMETASONE FUROATE+INDACATEROL ACETATE	1 (<1%)	1 (<1%)	2 (<1%)
FLUTICASONE+VILANTEROL+UMECLIDINIUM	1 (<1%)	0	1 (<1%)

Note: Includes all COPD medications started before the first dose of investigational product.
Note: Multi-component medications are displayed under the respiratory medication class of each component.

Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Table 111.8
Summary of COPD Medications Started Prior to Treatment by
Respiratory Medication Class in Study 208657

Respiratory Medication Class Ingredient	PBO (N=401)	100 SC (N=403)	Total (N=804)
FORMOTEROL FUMARATE+TIOTROPIUM BROMIDE	0	1 (<1%)	1 (<1%)
FORMOTEROL FUMARATE+TIOTROPIUM BROMIDE+CICLESONIDE	1 (<1%)	0	1 (<1%)
FORMOTEROL+TIOTROPIUM+CICLESONIDE	1 (<1%)	0	1 (<1%)
GLYCOPYRRONIUM	1 (<1%)	0	1 (<1%)
GLYCOPYRRONIUM BROMIDE+BUDESONIDE+FORMOTEROL FUMARATE DIHYDRATE	0	1 (<1%)	1 (<1%)
GLYCOPYRRONIUM+FORMOTEROL+FLUTICASONE	0	1 (<1%)	1 (<1%)
GLYCOPYRRONIUM+INDACATEROL	1 (<1%)	0	1 (<1%)
TIOTROPIUM+OLODATEROL	1 (<1%)	0	1 (<1%)

Note: Includes all COPD medications started before the first dose of investigational product.
Note: Multi-component medications are displayed under the respiratory medication class of each component.

Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Table 111.8
Summary of COPD Medications Started Prior to Treatment by
Respiratory Medication Class in Study 208657

Respiratory Medication Class Ingredient	PBO (N=401)		100 SC (N=403)		Total (N=804)	
Short-acting beta-2 agonist						
Any medication	293	(73%)	304	(75%)	597	(74%)
SALBUTAMOL	200	(50%)	220	(55%)	420	(52%)
FENOTEROL HYDROBROMIDE+IPRATROPIUM BROMIDE	40	(10%)	35	(9%)	75	(9%)
SALBUTAMOL SULFATE	33	(8%)	37	(9%)	70	(9%)
SALBUTAMOL SULFATE+IPRATROPIUM BROMIDE	4	(<1%)	15	(4%)	19	(2%)
FENOTEROL HYDROBROMIDE	9	(2%)	2	(<1%)	11	(1%)
SALBUTAMOL+IPRATROPIUM	8	(2%)	2	(<1%)	10	(1%)
TERBUTALINE SULFATE	4	(<1%)	6	(1%)	10	(1%)
AMINOPHYLLINE+CHLORPHENAMINE MALEATE+METHOXYPHENAMINE HYDROCHLORIDE+NOSCAPINE	4	(<1%)	5	(1%)	9	(1%)
BROMHEXINE HYDROCHLORIDE+GUAIFENESIN+TERBUTALINE SULFATE	5	(1%)	4	(<1%)	9	(1%)
PROAIR (NOS)	4	(<1%)	4	(<1%)	8	(<1%)
FENOTEROL+IPRATROPIUM BROMIDE	5	(1%)	2	(<1%)	7	(<1%)
GUAIFENESIN+AMBROXOL+LEVOSALBUTAMOL	5	(1%)	2	(<1%)	7	(<1%)
TERBUTALINE	3	(<1%)	4	(<1%)	7	(<1%)
SALBUTAMOL+IPRATROPIUM BROMIDE	4	(<1%)	2	(<1%)	6	(<1%)
EPHEDRA SINICA+ARCTIUM LAPPA+SCHISANDRA NOS+OCIMUM BASILICUM+LUMBRICUS TERRESTRIS+PEUCEDANUM (NOS)+HERBALS NOS	2	(<1%)	3	(<1%)	5	(<1%)
IPRATROPIUM+LEVOSALBUTAMOL	1	(<1%)	3	(<1%)	4	(<1%)
BUDESONIDE+LEVOSALBUTAMOL	2	(<1%)	1	(<1%)	3	(<1%)
LEVOSALBUTAMOL HYDROCHLORIDE	1	(<1%)	2	(<1%)	3	(<1%)
FENOTEROL+IPRATROPIUM	2	(<1%)	0		2	(<1%)
CLORPRENALINE HYDROCHLORIDE+PEARL+DECLOXIZINE HYDROCHLORIDE+CICADA SLOUGH+ELAEAGNUS PUNGENS LEAF+HERBALS NOS+BORNEOL	1	(<1%)	0		1	(<1%)

Note: Includes all COPD medications started before the first dose of investigational product.
Note: Multi-component medications are displayed under the respiratory medication class of each component.

Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Table 111.8
Summary of COPD Medications Started Prior to Treatment by
Respiratory Medication Class in Study 208657

Respiratory Medication Class Ingredient	PBO (N=401)	100 SC (N=403)	Total (N=804)
DIHYDROCODEINE BITARTRATE+CHLORPHENAMINE MALEATE+AMMONIUM CHLORIDE+METHYLEPHEDRINE HYDROCHLORIDE	0	1 (<1%)	1 (<1%)
DIHYDROCODEINE PHOSPHATE+CHLORPHENAMINE MALEATE+METHYLEPHEDRINE HYDROCHLORIDE	0	1 (<1%)	1 (<1%)
EPHEDRA SINICA+ARCTIUM LAPPA+COW BEZOAR+PHERETIMA (NOS)+HERBALS NOS+GYPSUM FIBROSUM	0	1 (<1%)	1 (<1%)
GUAIFENESIN+DIHYDROCODEINE BITARTRATE+CHLORPHENAMINE MALEATE+METHYLEPHEDRINE HYDROCHLORIDE	1 (<1%)	0	1 (<1%)
GUAIFENESIN+TERBUTALINE+AMBROXOL	1 (<1%)	0	1 (<1%)
LEVOSALBUTAMOL	0	1 (<1%)	1 (<1%)
PROCATEROL HYDROCHLORIDE	1 (<1%)	0	1 (<1%)
SALBUTAMOL SULFATE+IPRATROPIUM	0	1 (<1%)	1 (<1%)
SALBUTAMOL+AMBROXOL	0	1 (<1%)	1 (<1%)

Note: Includes all COPD medications started before the first dose of investigational product.
Note: Multi-component medications are displayed under the respiratory medication class of each component.

Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Table 111.8
Summary of COPD Medications Started Prior to Treatment by
Respiratory Medication Class in Study 208657

Respiratory Medication Class Ingredient	PBO (N=401)		100 SC (N=403)		Total (N=804)	
Long-acting beta-2 agonist - Group 3 (Twice per day)						
Any medication	267	(67%)	279	(69%)	546	(68%)
SALMETEROL XINAFOATE+FLUTICASONE PROPIONATE	61	(15%)	75	(19%)	136	(17%)
BUDESONIDE+FORMOTEROL FUMARATE	66	(16%)	64	(16%)	130	(16%)
GLYCOPYRRONIUM BROMIDE+BECLOMETASONE DIPROPIONATE+FORMOTEROL FUMARATE	47	(12%)	51	(13%)	98	(12%)
BECLOMETASONE DIPROPIONATE+FORMOTEROL FUMARATE	22	(5%)	28	(7%)	50	(6%)
GLYCOPYRRONIUM BROMIDE+BUDESONIDE+FORMOTEROL FUMARATE	17	(4%)	20	(5%)	37	(5%)
BUDESONIDE+FORMOTEROL	15	(4%)	11	(3%)	26	(3%)
FORMOTEROL FUMARATE	11	(3%)	13	(3%)	24	(3%)
FORMOTEROL	10	(2%)	10	(2%)	20	(2%)
SALMETEROL	15	(4%)	3	(<1%)	18	(2%)
FORMOTEROL FUMARATE+FLUTICASONE PROPIONATE	8	(2%)	7	(2%)	15	(2%)
FORMOTEROL FUMARATE+ACLIDINIUM BROMIDE	6	(1%)	3	(<1%)	9	(1%)
GLYCOPYRRONIUM BROMIDE+BUDESONIDE+FORMOTEROL	5	(1%)	2	(<1%)	7	(<1%)
GLYCOPYRRONIUM BROMIDE+FORMOTEROL FUMARATE	3	(<1%)	4	(<1%)	7	(<1%)
SALMETEROL+FLUTICASONE	3	(<1%)	3	(<1%)	6	(<1%)
BECLOMETASONE+FORMOTEROL	4	(<1%)	1	(<1%)	5	(<1%)
MOMETASONE FUROATE+FORMOTEROL FUMARATE	1	(<1%)	4	(<1%)	5	(<1%)
GLYCOPYRRONIUM+BUDESONIDE+FORMOTEROL FUMARATE	3	(<1%)	0		3	(<1%)
GLYCOPYRRONIUM BROMIDE+FORMOTEROL	0		2	(<1%)	2	(<1%)
GLYCOPYRRONIUM BROMIDE+FORMOTEROL FUMARATE+FLUTICASONE PROPIONATE	0		2	(<1%)	2	(<1%)
SALMETEROL+FLUTICASONE PROPIONATE	0		2	(<1%)	2	(<1%)
FORMOTEROL FUMARATE+TIOTROPIUM BROMIDE	0		1	(<1%)	1	(<1%)
FORMOTEROL FUMARATE+TIOTROPIUM BROMIDE+CICLESONIDE	1	(<1%)	0		1	(<1%)
FORMOTEROL+TIOTROPIUM+CICLESONIDE	1	(<1%)	0		1	(<1%)

Note: Includes all COPD medications started before the first dose of investigational product.
Note: Multi-component medications are displayed under the respiratory medication class of each component.

Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Table 111.8
Summary of COPD Medications Started Prior to Treatment by
Respiratory Medication Class in Study 208657

Respiratory Medication Class Ingredient	PBO (N=401)		100 SC (N=403)		Total (N=804)	
GLYCOPYRRONIUM BROMIDE+BUDESONIDE+FORMOTEROL FUMARATE DIHYDRATE	0		1	(<1%)	1	(<1%)
GLYCOPYRRONIUM+FORMOTEROL+FLUTICASONE	0		1	(<1%)	1	(<1%)
Long-acting beta-2 agonist - Group 2 (Once per day)						
Any medication	175	(44%)	171	(42%)	346	(43%)
FLUTICASONE FUROATE+VILANTEROL TRIFENATATE+UMECLIDINIUM BROMIDE	115	(29%)	107	(27%)	222	(28%)
FLUTICASONE FUROATE+VILANTEROL TRIFENATATE	26	(6%)	30	(7%)	56	(7%)
VILANTEROL TRIFENATATE+UMECLIDINIUM BROMIDE	19	(5%)	14	(3%)	33	(4%)
GLYCOPYRRONIUM BROMIDE+INDACATEROL MALEATE	10	(2%)	18	(4%)	28	(3%)
TIOTROPIUM BROMIDE MONOHYDRATE+OLODATEROL HYDROCHLORIDE	12	(3%)	14	(3%)	26	(3%)
VILANTEROL	3	(<1%)	1	(<1%)	4	(<1%)
FLUTICASONE FUROATE+VILANTEROL	0		2	(<1%)	2	(<1%)
FLUTICASONE FUROATE+VILANTEROL+UMECLIDINIUM	1	(<1%)	1	(<1%)	2	(<1%)
INDACATEROL MALEATE	1	(<1%)	1	(<1%)	2	(<1%)
FLUTICASONE+VILANTEROL+UMECLIDINIUM	1	(<1%)	0		1	(<1%)
GLYCOPYRRONIUM+INDACATEROL	1	(<1%)	0		1	(<1%)
INDACATEROL	1	(<1%)	0		1	(<1%)
OLODATEROL	1	(<1%)	0		1	(<1%)
TIOTROPIUM+OLODATEROL	1	(<1%)	0		1	(<1%)

Note: Includes all COPD medications started before the first dose of investigational product.
Note: Multi-component medications are displayed under the respiratory medication class of each component.

Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Table 111.8
Summary of COPD Medications Started Prior to Treatment by
Respiratory Medication Class in Study 208657

Respiratory Medication Class Ingredient	PBO (N=401)		100 SC (N=403)		Total (N=804)	
Short-acting anticholinergic						
Any medication	84	(21%)	83	(21%)	167	(21%)
FENOTEROL HYDROBROMIDE+IPRATROPIUM BROMIDE	40	(10%)	35	(9%)	75	(9%)
IPRATROPIUM BROMIDE	23	(6%)	25	(6%)	48	(6%)
SALBUTAMOL SULFATE+IPRATROPIUM BROMIDE	4	(<1%)	15	(4%)	19	(2%)
SALBUTAMOL+IPRATROPIUM	8	(2%)	2	(<1%)	10	(1%)
FENOTEROL+IPRATROPIUM BROMIDE	5	(1%)	2	(<1%)	7	(<1%)
IPRATROPIUM	4	(<1%)	2	(<1%)	6	(<1%)
SALBUTAMOL+IPRATROPIUM BROMIDE	4	(<1%)	2	(<1%)	6	(<1%)
IPRATROPIUM+LEVOSALBUTAMOL	1	(<1%)	3	(<1%)	4	(<1%)
FENOTEROL+IPRATROPIUM	2	(<1%)	0		2	(<1%)
SALBUTAMOL SULFATE+IPRATROPIUM	0		1	(<1%)	1	(<1%)

Note: Includes all COPD medications started before the first dose of investigational product.
Note: Multi-component medications are displayed under the respiratory medication class of each component.

Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Table 111.8
Summary of COPD Medications Started Prior to Treatment by
Respiratory Medication Class in Study 208657

Respiratory Medication Class Ingredient	PBO (N=401)		100 SC (N=403)		Total (N=804)	
Antiinfectives (antibiotics, antiseptics)						
Any medication	70	(17%)	73	(18%)	143	(18%)
AZITHROMYCIN	23	(6%)	22	(5%)	45	(6%)
AMOXICILLIN+CLAVULANIC ACID	16	(4%)	10	(2%)	26	(3%)
CEFIXIME	8	(2%)	9	(2%)	17	(2%)
CLARITHROMYCIN	8	(2%)	8	(2%)	16	(2%)
LEVOFLOXACIN	8	(2%)	8	(2%)	16	(2%)
PIPERACILLIN SODIUM+TAZOBACTAM SODIUM	2	(<1%)	7	(2%)	9	(1%)
CEFUROXIME	4	(<1%)	4	(<1%)	8	(<1%)
CIPROFLOXACIN	4	(<1%)	4	(<1%)	8	(<1%)
MOXIFLOXACIN HYDROCHLORIDE	3	(<1%)	5	(1%)	8	(<1%)
MOXIFLOXACIN	4	(<1%)	3	(<1%)	7	(<1%)
DOXYCYCLINE	4	(<1%)	2	(<1%)	6	(<1%)
AMOXICILLIN	4	(<1%)	1	(<1%)	5	(<1%)
AMOXICILLIN+CLAVULANATE POTASSIUM	0		3	(<1%)	3	(<1%)
AMPICILLIN SODIUM	1	(<1%)	2	(<1%)	3	(<1%)
DUOMOX (NOS)	1	(<1%)	2	(<1%)	3	(<1%)
SPIRAMYCIN	0		3	(<1%)	3	(<1%)
AMOXICILLIN TRIHYDRATE+CLAVULANATE POTASSIUM	0		2	(<1%)	2	(<1%)
CEFDITOREN PIVOXIL	1	(<1%)	1	(<1%)	2	(<1%)
CEFTRIAXONE SODIUM	1	(<1%)	1	(<1%)	2	(<1%)
CIPROFLOXACIN HYDROCHLORIDE	1	(<1%)	1	(<1%)	2	(<1%)
LEVOMENTHOL+PAPAVER SOMNIFERUM+MORUS (NOS)+ERIOBOTRYA JAPONICA+CAMPANULA (NOS)+CYNANCHUM GLAUCESCENS+HERBALS NOS	1	(<1%)	1	(<1%)	2	(<1%)
LEVOMENTHOL+PLATYCODON GRANDIFLORUS+PAPAVER SOMNIFERUM+ERIOBOTRYA JAPONICA+MORUS ALBA+CYNANCHUM STAUNTONII+STEMONA SESSILIFOLIA	0		2	(<1%)	2	(<1%)
NEMONOXACIN MALATE	1	(<1%)	1	(<1%)	2	(<1%)
SODIUM CHLORIDE+LEVOFLOXACIN	1	(<1%)	1	(<1%)	2	(<1%)

Note: Includes all COPD medications started before the first dose of investigational product.
Note: Multi-component medications are displayed under the respiratory medication class of each component.

Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Table 111.8
Summary of COPD Medications Started Prior to Treatment by
Respiratory Medication Class in Study 208657

Respiratory Medication Class Ingredient	PBO (N=401)		100 SC (N=403)		Total (N=804)	
SODIUM CHLORIDE+MOXIFLOXACIN HYDROCHLORIDE	0		2	(<1%)	2	(<1%)
SULFAMETHOXAZOLE+TRIMETHOPRIM	2	(<1%)	0		2	(<1%)
AMIKACIN	1	(<1%)	0		1	(<1%)
AMPICILLIN SODIUM+SULBACTAM SODIUM	1	(<1%)	0		1	(<1%)
ANTIBIOTICS NOS	1	(<1%)	0		1	(<1%)
BACTERIA NOS	0		1	(<1%)	1	(<1%)
BIAPENEM	0		1	(<1%)	1	(<1%)
CEFDINIR	1	(<1%)	0		1	(<1%)
CEFEPIME	1	(<1%)	0		1	(<1%)
CEFMINOX SODIUM	0		1	(<1%)	1	(<1%)
CEFOPERAZONE SODIUM+SULBACTAM SODIUM	0		1	(<1%)	1	(<1%)
CEFOTAXIME SODIUM	1	(<1%)	0		1	(<1%)
CEFPODOXIME PROXETIL	1	(<1%)	0		1	(<1%)
CEFPROZIL	0		1	(<1%)	1	(<1%)
CEFTAZIDIME	1	(<1%)	0		1	(<1%)
CEFTRIAXONE	1	(<1%)	0		1	(<1%)
CEFUROXIME AXETIL	0		1	(<1%)	1	(<1%)
CEFUROXIME SODIUM	1	(<1%)	0		1	(<1%)
CLAVULANIC ACID+CEFPODOXIME PROXETIL	1	(<1%)	0		1	(<1%)
DOXYCYCLINE HYCLATE	0		1	(<1%)	1	(<1%)
ETIMICIN SULFATE	0		1	(<1%)	1	(<1%)
LATAMOXEF SODIUM	0		1	(<1%)	1	(<1%)
LEVOFLOXACIN HYDROCHLORIDE	1	(<1%)	0		1	(<1%)
PIPERACILLIN SODIUM	1	(<1%)	0		1	(<1%)
PIPERACILLIN SODIUM+TAZOBACTAM	0		1	(<1%)	1	(<1%)
PLATYCODON GRANDIFLORUS ROOT+GLYCYRRHIZA SPP. ROOT WITH RHIZOME+GLEHNIA LITTORALIS ROOT+EPHEDRA SPP HERB+KITAGAWIA PRAERUPTORA ROOT+FRITILLARIA THUNBERGII BULB+HERBALS NOS	0		1	(<1%)	1	(<1%)

Note: Includes all COPD medications started before the first dose of investigational product.
Note: Multi-component medications are displayed under the respiratory medication class of each component.

Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Table 111.8
Summary of COPD Medications Started Prior to Treatment by
Respiratory Medication Class in Study 208657

Respiratory Medication Class Ingredient	PBO (N=401)	100 SC (N=403)	Total (N=804)
PLATYCODON GRANDIFLORUS ROOT+PORIA COCOS SCLEROTIUM+ASTER TATARICUS ROOT WITH RHIZOME+CALCIUM SULFATE DIHYDRATE+FRITILLARIA THUNBERGII BULB+HERBALS NOS	1 (<1%)	0	1 (<1%)
PLATYCODON GRANDIFLORUS ROOT+PORIA COCOS SCLEROTIUM+GLYCYRRHIZA SPP. ROOT WITH RHIZOME+PINELLIA TERNATA TUBER+DOLOMIAEA COSTUS ROOT+ZIZIPHUS JUJUBA FRUIT+HERBALS NOS	0	1 (<1%)	1 (<1%)
SCUTELLARIA BAICALENSIS ROOT+ISATIS TINCTORIA ROOT+LONICERA JAPONICA FLOWER BUD+FORSYTHIA SUSPENSA FRUIT+HOUTTUYNIA CORDATA WHOLE PLANT	0	1 (<1%)	1 (<1%)
SITAFLOXACIN	1 (<1%)	0	1 (<1%)
SODIUM CHLORIDE+CIPROFLOXACIN LACTATE	0	1 (<1%)	1 (<1%)
SUPRAX (NOS)	1 (<1%)	0	1 (<1%)

Note: Includes all COPD medications started before the first dose of investigational product.
Note: Multi-component medications are displayed under the respiratory medication class of each component.

Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Table 111.8
Summary of COPD Medications Started Prior to Treatment by
Respiratory Medication Class in Study 208657

Respiratory Medication Class Ingredient	PBO (N=401)		100 SC (N=403)		Total (N=804)	
Mucolytics						
Any medication	46	(11%)	58	(14%)	104	(13%)
ACETYLCYSTEINE	22	(5%)	23	(6%)	45	(6%)
ERDOSTEINE	12	(3%)	10	(2%)	22	(3%)
AMBROXOL ACEFYLLINATE	11	(3%)	9	(2%)	20	(2%)
CARBOCISTEINE	8	(2%)	10	(2%)	18	(2%)
AMBROXOL HYDROCHLORIDE	3	(<1%)	6	(1%)	9	(1%)
BROMHEXINE HYDROCHLORIDE+GUAIFENESIN+TERBUTALINE SULFATE	5	(1%)	4	(<1%)	9	(1%)
BROMHEXINE HYDROCHLORIDE	0		7	(2%)	7	(<1%)
GUAIFENESIN+AMBROXOL+LEVOSALBUTAMOL	5	(1%)	2	(<1%)	7	(<1%)
MUCOSOLVAN (NOS)	1	(<1%)	4	(<1%)	5	(<1%)
ACETYLCYSTEINE SODIUM+AMBROXOL ACEFYLLINATE	0		1	(<1%)	1	(<1%)
ACETYLCYSTEINE+AMBROXOL ACEFYLLINATE	0		1	(<1%)	1	(<1%)
AMBROXOL	0		1	(<1%)	1	(<1%)
FUDOSTEINE	0		1	(<1%)	1	(<1%)
GUAIFENESIN+DIHYDROCODEINE BITARTRATE+CHLORPHENAMINE MALEATE+METHYLEPHEDRINE HYDROCHLORIDE	1	(<1%)	0		1	(<1%)
GUAIFENESIN+GLYCEROL+BENZOIC ACID+CAMPHOR+AMMONIA+GLYCYRRHIZA SPP. ROOT WITH RHIZOME+HERBALS NOS	1	(<1%)	0		1	(<1%)
GUAIFENESIN+TERBUTALINE+AMBROXOL	1	(<1%)	0		1	(<1%)
SALBUTAMOL+AMBROXOL	0		1	(<1%)	1	(<1%)

Note: Includes all COPD medications started before the first dose of investigational product.
Note: Multi-component medications are displayed under the respiratory medication class of each component.

Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Table 111.8
Summary of COPD Medications Started Prior to Treatment by
Respiratory Medication Class in Study 208657

Respiratory Medication Class Ingredient	PBO (N=401)		100 SC (N=403)		Total (N=804)	
Xanthine						
Any medication	36	(9%)	56	(14%)	92	(11%)
THEOPHYLLINE	27	(7%)	30	(7%)	57	(7%)
DOXOFYLLINE	4	(<1%)	14	(3%)	18	(2%)
AMINOPHYLLINE+CHLORPHENAMINE MALEATE+METHOXYPHENAMINE HYDROCHLORIDE+NOSCAPINE	4	(<1%)	5	(1%)	9	(1%)
THEOPHYLLINE+ETOFYLLINE	2	(<1%)	6	(1%)	8	(<1%)
AMINOPHYLLINE	0		4	(<1%)	4	(<1%)
DIPROPHYLLINE	1	(<1%)	1	(<1%)	2	(<1%)
EUPHYLLIN (NOS)	1	(<1%)	1	(<1%)	2	(<1%)
THEOPHYLLINE SODIUM GLYCINATE	0		1	(<1%)	1	(<1%)
THEOPHYLLINE+ETOFYLLINE+MONTELUKAST	1	(<1%)	0		1	(<1%)
THEOPHYLLINE+MONTELUKAST SODIUM	1	(<1%)	0		1	(<1%)

Note: Includes all COPD medications started before the first dose of investigational product.
Note: Multi-component medications are displayed under the respiratory medication class of each component.

Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Table 111.8
Summary of COPD Medications Started Prior to Treatment by
Respiratory Medication Class in Study 208657

Respiratory Medication Class Ingredient	PBO (N=401)		100 SC (N=403)		Total (N=804)	
Other						
Any medication	39	(10%)	51	(13%)	90	(11%)
CINEOLE+PINENE+DIPENTEN	3	(<1%)	8	(2%)	11	(1%)
MONTELUKAST SODIUM+LEVOCETIRIZINE HYDROCHLORIDE	4	(<1%)	6	(1%)	10	(1%)
AMINOPHYLLINE+CHLORPHENAMINE MALEATE+METHOXYPHENAMINE HYDROCHLORIDE+NOSCAPINE	4	(<1%)	5	(1%)	9	(1%)
BRONCHODUAL (NOS)	5	(1%)	3	(<1%)	8	(<1%)
EPHEDRA SINICA+ARCTIUM LAPPA+SCHISANDRA NOS+OCIMUM BASILICUM+LUMBRICUS TERRESTRIS+PEUCEDANUM (NOS)+HERBALS NOS	2	(<1%)	3	(<1%)	5	(<1%)
MONTELUKAST+LEVOCETIRIZINE	4	(<1%)	1	(<1%)	5	(<1%)
TRADITIONAL CHINESE MEDICINE NOS	1	(<1%)	4	(<1%)	5	(<1%)
HEDERA HELIX EXTRACT	3	(<1%)	1	(<1%)	4	(<1%)
PARACETAMOL	2	(<1%)	1	(<1%)	3	(<1%)
POTASSIUM CHLORIDE	1	(<1%)	2	(<1%)	3	(<1%)
SODIUM CHLORIDE	0		3	(<1%)	3	(<1%)
UNCODED	1	(<1%)	2	(<1%)	3	(<1%)
ASARONE	1	(<1%)	1	(<1%)	2	(<1%)
BENZONATATE	2	(<1%)	0		2	(<1%)
GLYCOPYRRONIUM BROMIDE+MOMETASONE FUROATE+INDACATEROL ACETATE	1	(<1%)	1	(<1%)	2	(<1%)
HEDERA HELIX EXTRACT+RHIZOMA COPTIDIS EXTRACT	0		2	(<1%)	2	(<1%)
LEVOMENTHOL+PAPAVER SOMNIFERUM+MORUS (NOS)+ERIOBOTRYA JAPONICA+CAMPANULA (NOS)+CYNANCHUM GLAUCESCENS+HERBALS NOS	1	(<1%)	1	(<1%)	2	(<1%)
LEVOMENTHOL+PLATYCODON GRANDIFLORUS+PAPAVER SOMNIFERUM+ERIOBOTRYA JAPONICA+MORUS ALBA+CYNANCHUM STAUNTONII+STEMONA SESSILIFOLIA	0		2	(<1%)	2	(<1%)
LORATADINE	0		2	(<1%)	2	(<1%)
MONTELUKAST SODIUM+BILASTINE	2	(<1%)	0		2	(<1%)

Note: Includes all COPD medications started before the first dose of investigational product.
Note: Multi-component medications are displayed under the respiratory medication class of each component.

Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Table 111.8
Summary of COPD Medications Started Prior to Treatment by
Respiratory Medication Class in Study 208657

Respiratory Medication Class Ingredient	PBO (N=401)		100 SC (N=403)		Total (N=804)	
OPERATIONS AND PROCEDURES	1	(<1%)	1	(<1%)	2	(<1%)
SENECIO CANNABIFOLIUS	1	(<1%)	1	(<1%)	2	(<1%)
SODIUM CHLORIDE+LEVOFLOXACIN	1	(<1%)	1	(<1%)	2	(<1%)
SODIUM CHLORIDE+MOXIFLOXACIN HYDROCHLORIDE	0		2	(<1%)	2	(<1%)
AMINOMETHYLBENZOIC ACID	1	(<1%)	0		1	(<1%)
ANYCOUGH (NOS)	0		1	(<1%)	1	(<1%)
ASCORIL (NOS)	0		1	(<1%)	1	(<1%)
BENPROPERINE	1	(<1%)	0		1	(<1%)
BICARBONATE	0		1	(<1%)	1	(<1%)
CANNABIS SATIVA	0		1	(<1%)	1	(<1%)
CARTHAMUS TINCTORIUS+ANGELICA+SALVIA (NOS)+PAEONIA (NOS)+LIGUSTICUM CHUANXIANG	0		1	(<1%)	1	(<1%)
CHLORPHENAMINE MALEATE	1	(<1%)	0		1	(<1%)
CHYMOTRYPSIN	0		1	(<1%)	1	(<1%)
CINEOLE+PINENE	1	(<1%)	0		1	(<1%)
CLORPRENALINE HYDROCHLORIDE+PEARL+DECLOXIZINE HYDROCHLORIDE+CICADA SLOUGH+ELAEAGNUS PUNGENS LEAF+HERBALS NOS+BORNEOL	1	(<1%)	0		1	(<1%)
CODENAL (NOS)	0		1	(<1%)	1	(<1%)
COLECALCIFEROL	0		1	(<1%)	1	(<1%)
CORDYCEPS SINENSIS	0		1	(<1%)	1	(<1%)
DAYQUIL (NOS)	0		1	(<1%)	1	(<1%)
DIHYDROCODEINE	0		1	(<1%)	1	(<1%)
DIHYDROCODEINE BITARTRATE+CHLORPHENAMINE MALEATE+AMMONIUM CHLORIDE+METHYLEPHEDRINE HYDROCHLORIDE	0		1	(<1%)	1	(<1%)
DIHYDROCODEINE PHOSPHATE+CHLORPHENAMINE MALEATE+METHYLEPHEDRINE HYDROCHLORIDE	0		1	(<1%)	1	(<1%)
DIHYDROCODEINE THIOCYANATE	0		1	(<1%)	1	(<1%)
DOMPERIDONE+RABEPRAZOLE	0		1	(<1%)	1	(<1%)

Note: Includes all COPD medications started before the first dose of investigational product.
Note: Multi-component medications are displayed under the respiratory medication class of each component.
/mnt/code/postcsr_01/prod/tfls/t_sp_c1_prior_rmc_657.sas 21JUL2025 21:58

Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Table 111.8
Summary of COPD Medications Started Prior to Treatment by
Respiratory Medication Class in Study 208657

Respiratory Medication Class Ingredient	PBO (N=401)	100 SC (N=403)	Total (N=804)
EPHEDRA SINICA+ARCTIUM LAPPA+COW BEZOAR+PHERETIMA (NOS)+HERBALS NOS+GYPSUM FIBROSUM	0	1 (<1%)	1 (<1%)
ESOMEPRAZOLE MAGNESIUM	0	1 (<1%)	1 (<1%)
FEXOFENADINE	0	1 (<1%)	1 (<1%)
FEXOFENADINE HYDROCHLORIDE	1 (<1%)	0	1 (<1%)
FLUIDASA (NOS)	0	1 (<1%)	1 (<1%)
GEKKO GECKO	0	1 (<1%)	1 (<1%)
GUAIFENESIN+DIHYDROCODEINE BITARTRATE+CHLORPHENAMINE MALEATE+METHYLEPHEDRINE HYDROCHLORIDE	1 (<1%)	0	1 (<1%)
GUAIFENESIN+GLYCEROL+BENZOIC ACID+CAMPHOR+AMMONIA+GLYCYRRHIZA SPP. ROOT WITH RHIZOME+HERBALS NOS	1 (<1%)	0	1 (<1%)
HYDROCHLOROTHIAZIDE+VALSARTAN	1 (<1%)	0	1 (<1%)
IBUPROFEN	0	1 (<1%)	1 (<1%)
INTERFERON ALFA-1B	1 (<1%)	0	1 (<1%)
INVESTIGATIONAL COPD MEDICATION	0	1 (<1%)	1 (<1%)
LACTULOSE	0	1 (<1%)	1 (<1%)
LEVOCETIRIZINE HYDROCHLORIDE	0	1 (<1%)	1 (<1%)
LEVODROPROPIZINE	1 (<1%)	0	1 (<1%)
MEPYRAMINE	1 (<1%)	0	1 (<1%)
MINERALS NOS+VITAMINS NOS	0	1 (<1%)	1 (<1%)
MORPHINE SULFATE	0	1 (<1%)	1 (<1%)
MOSAPRIDE CITRATE	0	1 (<1%)	1 (<1%)
MYRTOL	1 (<1%)	0	1 (<1%)
OMEPRAZOLE	0	1 (<1%)	1 (<1%)

Note: Includes all COPD medications started before the first dose of investigational product.
Note: Multi-component medications are displayed under the respiratory medication class of each component.
/mnt/code/postcsr_01/prod/tfls/t_sp_c1_prior_rmc_657.sas 21JUL2025 21:58

Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Table 111.8
Summary of COPD Medications Started Prior to Treatment by
Respiratory Medication Class in Study 208657

Respiratory Medication Class Ingredient	PBO (N=401)	100 SC (N=403)	Total (N=804)
PAEONIA LACTIFLORA ROOT+GLYCYRRHIZA SPP. ROOT WITH RHIZOME+PINELLIA TERNATA TUBER+EPHEDRA SPP. STEM+FRITILLARIA THUNBERGII BULB+PHERETIMA SPP.+HERBALS NOS	0	1 (<1%)	1 (<1%)
PANTOPRAZOLE	0	1 (<1%)	1 (<1%)
PARACETAMOL+DEXTROMETHORPHAN+CHLORPHENAMINE+PSEUDOEPHEDRINE	0	1 (<1%)	1 (<1%)
PARACETAMOL+DEXTROMETHORPHAN+PHENYLEPHRINE	0	1 (<1%)	1 (<1%)
PIDOTIMOD	0	1 (<1%)	1 (<1%)
PIPRINHYDRINATE	0	1 (<1%)	1 (<1%)
PLANTAGO MAJOR	0	1 (<1%)	1 (<1%)
PLATYCODON GRANDIFLORUS ROOT+GLYCYRRHIZA SPP. ROOT WITH RHIZOME+GLEHNIA LITTORALIS ROOT+EPHEDRA SPP HERB+KITAGAWIA PRAERUPTORA ROOT+FRITILLARIA THUNBERGII BULB+HERBALS NOS	0	1 (<1%)	1 (<1%)
PLATYCODON GRANDIFLORUS ROOT+PORIA COCOS SCLEROTIUM+ASTER TATARICUS ROOT WITH RHIZOME+CALCIUM SULFATE DIHYDRATE+FRITILLARIA THUNBERGII BULB+HERBALS NOS	1 (<1%)	0	1 (<1%)
PLATYCODON GRANDIFLORUS ROOT+PORIA COCOS SCLEROTIUM+GLYCYRRHIZA SPP. ROOT WITH RHIZOME+PINELLIA TERNATA TUBER+DOLOMIAEA COSTUS ROOT+ZIZIPHUS JUJUBA FRUIT+HERBALS NOS	0	1 (<1%)	1 (<1%)
PROMETHAZINE	1 (<1%)	0	1 (<1%)
RANITIDINE HYDROCHLORIDE	0	1 (<1%)	1 (<1%)
SCUTELLARIA BAICALENSIS ROOT+ISATIS TINCTORIA ROOT+LONICERA JAPONICA FLOWER BUD+FORSYTHIA SUSPENSA FRUIT+HOUTTUYNIA CORDATA WHOLE PLANT	0	1 (<1%)	1 (<1%)
SIMVASTATIN	0	1 (<1%)	1 (<1%)
SODIUM BICARBONATE	0	1 (<1%)	1 (<1%)

Note: Includes all COPD medications started before the first dose of investigational product.
Note: Multi-component medications are displayed under the respiratory medication class of each component.

Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Table 111.8
Summary of COPD Medications Started Prior to Treatment by
Respiratory Medication Class in Study 208657

Respiratory Medication Class Ingredient	PBO (N=401)	100 SC (N=403)	Total (N=804)
SODIUM CHLORIDE+CIPROFLOXACIN LACTATE	0	1 (<1%)	1 (<1%)
SUDAFED (NOS)	1 (<1%)	0	1 (<1%)
THIAMINE HYDROCHLORIDE+NICOTINAMIDE+RIBOFLAVIN	0	1 (<1%)	1 (<1%)

Note: Includes all COPD medications started before the first dose of investigational product.
Note: Multi-component medications are displayed under the respiratory medication class of each component.

Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Table 111.8
Summary of COPD Medications Started Prior to Treatment by
Respiratory Medication Class in Study 208657

Respiratory Medication Class Ingredient	PBO (N=401)		100 SC (N=403)		Total (N=804)	
Leukotriene Receptor Antagonist						
Any medication	21	(5%)	22	(5%)	43	(5%)
MONTELUKAST SODIUM	6	(1%)	8	(2%)	14	(2%)
MONTELUKAST	4	(<1%)	8	(2%)	12	(1%)
MONTELUKAST SODIUM+LEVOCETIRIZINE HYDROCHLORIDE	4	(<1%)	6	(1%)	10	(1%)
MONTELUKAST+LEVOCETIRIZINE	4	(<1%)	1	(<1%)	5	(<1%)
MONTELUKAST SODIUM+BILASTINE	2	(<1%)	0		2	(<1%)
THEOPHYLLINE+ETOFYLLINE+MONTELUKAST	1	(<1%)	0		1	(<1%)
THEOPHYLLINE+MONTELUKAST SODIUM	1	(<1%)	0		1	(<1%)
Oxygen						
Any medication	21	(5%)	20	(5%)	41	(5%)
OXYGEN	21	(5%)	20	(5%)	41	(5%)
PDE4 Inhibitors						
Any medication	16	(4%)	24	(6%)	40	(5%)
ROFLUMILAST	16	(4%)	24	(6%)	40	(5%)
Antivirals						
Any medication	0		3	(<1%)	3	(<1%)
INFLUENZA VACCINE INACT SAG 4V	0		1	(<1%)	1	(<1%)
OSELTAMIVIR	0		1	(<1%)	1	(<1%)
TOZINAMERAN	0		1	(<1%)	1	(<1%)
UMIFENOVIR HYDROCHLORIDE	0		1	(<1%)	1	(<1%)
Antimycotics						
Any medication	1	(<1%)	0		1	(<1%)
GUAIFENESIN+GLYCEROL+BENZOIC ACID+CAMPHOR+AMMONIA+GLYCYRRHIZA SPP. ROOT WITH RHIZOME+HERBALS NOS	1	(<1%)	0		1	(<1%)

Note: Includes all COPD medications started before the first dose of investigational product.
Note: Multi-component medications are displayed under the respiratory medication class of each component.

Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Table 111.9
Summary of COPD Medications Started Prior to Treatment by
Respiratory Medication Class in Study MEA117113

Respiratory Medication Class Ingredient	PBO (N=87)	100 SC (N=83)	Total (N=170)
Any medication	87 (100%)	83 (100%)	170 (100%)
Corticosteroid - Inhaled			
Any medication	87 (100%)	82 (99%)	169 (>99%)
FLUTICASONE PROPIONATE+SALMETEROL XINAFOATE	50 (57%)	50 (60%)	100 (59%)
BUDESONIDE+FORMOTEROL FUMARATE	29 (33%)	21 (25%)	50 (29%)
BUDESONIDE	7 (8%)	3 (4%)	10 (6%)
BECLOMETASONE DIPROPIONATE+FORMOTEROL FUMARATE	2 (2%)	3 (4%)	5 (3%)
FLUTICASONE	3 (3%)	1 (1%)	4 (2%)
FLUTICASONE PROPIONATE	1 (1%)	3 (4%)	4 (2%)
FLUTICASONE+SALMETEROL	1 (1%)	3 (4%)	4 (2%)
FLUTICASONE FUROATE+VILANTEROL TRIFENATATE	1 (1%)	2 (2%)	3 (2%)
FLUTICASONE PROPIONATE+FORMOTEROL FUMARATE	2 (2%)	1 (1%)	3 (2%)
BECLOMETASONE DIPROPIONATE	1 (1%)	1 (1%)	2 (1%)
CICLESONIDE	0	2 (2%)	2 (1%)
FLUTICASONE PROPIONATE+SALMETEROL	1 (1%)	1 (1%)	2 (1%)
BECLOMETASONE+FORMOTEROL	0	1 (1%)	1 (<1%)
BUDESONIDE+FORMOTEROL	0	1 (1%)	1 (<1%)
FLUTICASONE FUROATE	1 (1%)	0	1 (<1%)
FORMOTEROL+MOMETASONE	0	1 (1%)	1 (<1%)
MOMETASONE FUROATE	1 (1%)	0	1 (<1%)
Long-acting anticholinergic			
Any medication	86 (99%)	83 (100%)	169 (>99%)
TIOTROPIUM BROMIDE	71 (82%)	70 (84%)	141 (83%)
TIOTROPIUM	4 (5%)	9 (11%)	13 (8%)
ACLIDINIUM BROMIDE	5 (6%)	3 (4%)	8 (5%)
GLYCOPYRRONIUM BROMIDE	5 (6%)	3 (4%)	8 (5%)
GLYCOPYRRONIUM BROMIDE+INDACATEROL MALEATE	3 (3%)	2 (2%)	5 (3%)
UMECLIDINIUM	1 (1%)	0	1 (<1%)

Note: Includes all COPD medications started before the first dose of investigational product.
Note: Multi-component medications are displayed under the respiratory medication class of each component.

Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Table 111.9
Summary of COPD Medications Started Prior to Treatment by
Respiratory Medication Class in Study MEA117113

Respiratory Medication Class Ingredient	PBO (N=87)	100 SC (N=83)	Total (N=170)
UMECLIDINIUM BROMIDE+VILANTEROL TRIFENATATE	1 (1%)	0	1 (<1%)
Long-acting beta-2 agonist			
Any medication	87 (100%)	82 (99%)	169 (>99%)
FLUTICASONE PROPIONATE+SALMETEROL XINAFOATE	50 (57%)	50 (60%)	100 (59%)
BUDESONIDE+FORMOTEROL FUMARATE	29 (33%)	21 (25%)	50 (29%)
INDACATEROL MALEATE	3 (3%)	3 (4%)	6 (4%)
SALMETEROL	4 (5%)	2 (2%)	6 (4%)
BECLOMETASONE DIPROPIONATE+FORMOTEROL FUMARATE	2 (2%)	3 (4%)	5 (3%)
GLYCOPYRRONIUM BROMIDE+INDACATEROL MALEATE	3 (3%)	2 (2%)	5 (3%)
FLUTICASONE+SALMETEROL	1 (1%)	3 (4%)	4 (2%)
FORMOTEROL FUMARATE	1 (1%)	3 (4%)	4 (2%)
FLUTICASONE FUROATE+VILANTEROL TRIFENATATE	1 (1%)	2 (2%)	3 (2%)
FLUTICASONE PROPIONATE+FORMOTEROL FUMARATE	2 (2%)	1 (1%)	3 (2%)
FLUTICASONE PROPIONATE+SALMETEROL	1 (1%)	1 (1%)	2 (1%)
INDACATEROL	1 (1%)	1 (1%)	2 (1%)
BECLOMETASONE+FORMOTEROL	0	1 (1%)	1 (<1%)
BUDESONIDE+FORMOTEROL	0	1 (1%)	1 (<1%)
FORMOTEROL	0	1 (1%)	1 (<1%)
FORMOTEROL+MOMETASONE	0	1 (1%)	1 (<1%)
UMECLIDINIUM BROMIDE+VILANTEROL TRIFENATATE	1 (1%)	0	1 (<1%)
VILANTEROL	1 (1%)	0	1 (<1%)
Short-acting beta-2 agonist			
Any medication	59 (68%)	66 (80%)	125 (74%)
SALBUTAMOL	41 (47%)	42 (51%)	83 (49%)
SALBUTAMOL SULFATE	7 (8%)	12 (14%)	19 (11%)
FENOTEROL HYDROBROMIDE+IPRATROPIUM BROMIDE	3 (3%)	7 (8%)	10 (6%)
IPRATROPIUM BROMIDE+SALBUTAMOL SULFATE	1 (1%)	6 (7%)	7 (4%)
TERBUTALINE SULFATE	2 (2%)	2 (2%)	4 (2%)

Note: Includes all COPD medications started before the first dose of investigational product.
Note: Multi-component medications are displayed under the respiratory medication class of each component.

Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Table 111.9
Summary of COPD Medications Started Prior to Treatment by
Respiratory Medication Class in Study MEA117113

Respiratory Medication Class Ingredient	PBO (N=87)		100 SC (N=83)		Total (N=170)	
FENOTEROL HYDROBROMIDE	1	(1%)	2	(2%)	3	(2%)
FENOTEROL+IPRATROPIUM BROMIDE	3	(3%)	0		3	(2%)
IPRATROPIUM+SALBUTAMOL	1	(1%)	2	(2%)	3	(2%)
PROAIR (NOS)	1	(1%)	1	(1%)	2	(1%)
FENOTEROL	1	(1%)	0		1	(<1%)
TULOBUTEROL HYDROCHLORIDE	0		1	(1%)	1	(<1%)
Corticosteroid - Systemic, oral, parenteral and intra-articular						
Any medication	33	(38%)	36	(43%)	69	(41%)
PREDNISOLONE	16	(18%)	21	(25%)	37	(22%)
PREDNISONE	12	(14%)	11	(13%)	23	(14%)
METHYLPREDNISOLONE	4	(5%)	8	(10%)	12	(7%)
METHYLPREDNISOLONE SODIUM SUCCINATE	4	(5%)	5	(6%)	9	(5%)
HYDROCORTISONE	3	(3%)	2	(2%)	5	(3%)
HYDROCORTISONE SODIUM SUCCINATE	3	(3%)	1	(1%)	4	(2%)
HYDROCORTISONE HYDROGEN SUCCINATE	2	(2%)	0		2	(1%)
CLOTRIMAZOLE+FLUOCINOLONE ACETONIDE+NEOMYCIN SULFATE	0		1	(1%)	1	(<1%)
Antiinfectives (antibiotics, antifungals, antivirals, antiseptics)						
Any medication	26	(30%)	30	(36%)	56	(33%)
AMOXICILLIN+CLAVULANIC ACID	3	(3%)	10	(12%)	13	(8%)
CLARITHROMYCIN	6	(7%)	7	(8%)	13	(8%)
AMOXICILLIN	4	(5%)	6	(7%)	10	(6%)
LEVOFLOXACIN	7	(8%)	3	(4%)	10	(6%)
AZITHROMYCIN	4	(5%)	4	(5%)	8	(5%)
CEFDITOREN PIVOXIL	2	(2%)	5	(6%)	7	(4%)
CEFUROXIME	2	(2%)	3	(4%)	5	(3%)

Note: Includes all COPD medications started before the first dose of investigational product.
Note: Multi-component medications are displayed under the respiratory medication class of each component.

Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Table 111.9
Summary of COPD Medications Started Prior to Treatment by
Respiratory Medication Class in Study MEA117113

Respiratory Medication Class Ingredient	PBO (N=87)		100 SC (N=83)		Total (N=170)	
CIPROFLOXACIN	1	(1%)	3	(4%)	4	(2%)
DOXYCYCLINE	2	(2%)	2	(2%)	4	(2%)
MOXIFLOXACIN	3	(3%)	1	(1%)	4	(2%)
CEFTRIAXONE	1	(1%)	2	(2%)	3	(2%)
ROXITHROMYCIN	0		3	(4%)	3	(2%)
AMIKACIN	1	(1%)	1	(1%)	2	(1%)
NORFLOXACIN	1	(1%)	1	(1%)	2	(1%)
PIPERACILLIN SODIUM+SULBACTAM SODIUM	0		2	(2%)	2	(1%)
PIPERACILLIN SODIUM+TAZOBACTAM SODIUM	2	(2%)	0		2	(1%)
AMPICILLIN SODIUM+SULBACTAM SODIUM	1	(1%)	0		1	(<1%)
AMPICILLIN+SULBACTAM	1	(1%)	0		1	(<1%)
CEFALEXIN	0		1	(1%)	1	(<1%)
CEFCAPENE PIVOXIL HYDROCHLORIDE	0		1	(1%)	1	(<1%)
CEFPODOXIME PROXETIL	0		1	(1%)	1	(<1%)
CEFROXADINE	1	(1%)	0		1	(<1%)
CEFTIBUTEN	1	(1%)	0		1	(<1%)
CEFUROXIME AXETIL	1	(1%)	0		1	(<1%)
CILASTATIN SODIUM+IMIPENEM	0		1	(1%)	1	(<1%)
CLINDAMYCIN	0		1	(1%)	1	(<1%)
CLOTRIMAZOLE+FLUOCINOLONE ACETONIDE+NEOMYCIN SULFATE	0		1	(1%)	1	(<1%)
GARENOXACIN MESILATE	1	(1%)	0		1	(<1%)
GEMIFLOXACIN MESILATE	0		1	(1%)	1	(<1%)
HAEMOPHILUS INFLUENZAE+KLEBSIELLA OZAENAE+KLEBSIELLA PNEUMONIAE+MORAXELLA CATARRHALIS+NEISSERIA CATARRHALIS+STAPHYLOCOCCUS AUREUS+STREPTOCOCCI	1	(1%)	0		1	(<1%)
MOXIFLOXACIN HYDROCHLORIDE	0		1	(1%)	1	(<1%)
TOSUFLOXACIN TOSILATE	1	(1%)	0		1	(<1%)

Note: Includes all COPD medications started before the first dose of investigational product.
Note: Multi-component medications are displayed under the respiratory medication class of each component.

Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Table 111.9
Summary of COPD Medications Started Prior to Treatment by
Respiratory Medication Class in Study MEA117113

Respiratory Medication Class Ingredient	PBO (N=87)		100 SC (N=83)		Total (N=170)	
Xanthine						
Any medication	24	(28%)	21	(25%)	45	(26%)
THEOPHYLLINE	14	(16%)	17	(20%)	31	(18%)
AMINOPHYLLINE	7	(8%)	4	(5%)	11	(6%)
DOXOFYLLINE	7	(8%)	3	(4%)	10	(6%)
DIPHENHYDRAMINE HYDROCHLORIDE+DIPROPHYLLINE+EPHEDRINE HYDROCHLORIDE+NOSCAPINE HYDROCHLORIDE+PAPAVERINE HYDROCHLORIDE	1	(1%)	0		1	(<1%)
ETOFYLLINE+THEOPHYLLINE	1	(1%)	0		1	(<1%)
Short-acting anticholinergic						
Any medication	16	(18%)	21	(25%)	37	(22%)
IPRATROPIUM BROMIDE	8	(9%)	7	(8%)	15	(9%)
FENOTEROL HYDROBROMIDE+IPRATROPIUM BROMIDE	3	(3%)	7	(8%)	10	(6%)
IPRATROPIUM BROMIDE+SALBUTAMOL SULFATE	1	(1%)	6	(7%)	7	(4%)
FENOTEROL+IPRATROPIUM BROMIDE	3	(3%)	0		3	(2%)
IPRATROPIUM+SALBUTAMOL	1	(1%)	2	(2%)	3	(2%)
Mucolytics						
Any medication	18	(21%)	18	(22%)	36	(21%)
ERDOSTEINE	9	(10%)	7	(8%)	16	(9%)
ACETYLCYSTEINE	4	(5%)	5	(6%)	9	(5%)
CARBOCISTEINE	4	(5%)	3	(4%)	7	(4%)
AMBROXOL ACEFYLLINATE	3	(3%)	0		3	(2%)
AMBROXOL HYDROCHLORIDE	0		2	(2%)	2	(1%)
GUAIFENESIN	0		2	(2%)	2	(1%)
AMBROXOL	0		1	(1%)	1	(<1%)
GUAIFENESIN+NOSCAPINE+PARACETAMOL+PHENYLEPHRINE HYDROCHLORIDE	0		1	(1%)	1	(<1%)

Note: Includes all COPD medications started before the first dose of investigational product.
Note: Multi-component medications are displayed under the respiratory medication class of each component.

Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Table 111.9
Summary of COPD Medications Started Prior to Treatment by
Respiratory Medication Class in Study MEA117113

Respiratory Medication Class Ingredient	PBO (N=87)		100 SC (N=83)		Total (N=170)	
MUCOSOLVAN (NOS)	0		1	(1%)	1	(<1%)
Other COPD medication						
Any medication	15	(17%)	11	(13%)	26	(15%)
HEDERA HELIX EXTRACT	2	(2%)	2	(2%)	4	(2%)
CLOPERASTINE FENDIZOATE	1	(1%)	2	(2%)	3	(2%)
CODEINE PHOSPHATE	1	(1%)	2	(2%)	3	(2%)
COUGH COLD PREPARATIONS NOS	1	(1%)	1	(1%)	2	(1%)
EBASTINE+PSEUDOEPHEDRINE HYDROCHLORIDE	0		2	(2%)	2	(1%)
FEXOFENADINE HYDROCHLORIDE	1	(1%)	1	(1%)	2	(1%)
HEDERA HELIX EXTRACT+RHIZOMA COPTIDIS EXTRACT	2	(2%)	0		2	(1%)
OMEPRAZOLE	2	(2%)	0		2	(1%)
STREPTODORNASE+STREPTOKINASE	1	(1%)	1	(1%)	2	(1%)
ACONITE+CITRUS AURANTIUM+CODEINE PHOSPHATE+SAPONARIA OFFICINALIS EXTRACT+THYMUS VULGARIS	0		1	(1%)	1	(<1%)
AEROTROP (NOS)	0		1	(1%)	1	(<1%)
AMBIGUOUS MEDICATION NOS	1	(1%)	0		1	(<1%)
AZELASTINE HYDROCHLORIDE	1	(1%)	0		1	(<1%)
BEPOTASTINE BESILATE	1	(1%)	0		1	(<1%)
DESLORATADINE+PSEUDOEPHEDRINE SULFATE	0		1	(1%)	1	(<1%)
DIPHENHYDRAMINE HYDROCHLORIDE+DIPROPHYLLINE+EPHEDRINE HYDROCHLORIDE+NOSCAPINE HYDROCHLORIDE+PAPAVERINE HYDROCHLORIDE	1	(1%)	0		1	(<1%)
FUROSEMIDE	1	(1%)	0		1	(<1%)
GUAIFENESIN+NOSCAPINE+PARACETAMOL+PHENYLEPHRINE HYDROCHLORIDE	0		1	(1%)	1	(<1%)

Note: Includes all COPD medications started before the first dose of investigational product.
Note: Multi-component medications are displayed under the respiratory medication class of each component.

Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Table 111.9
Summary of COPD Medications Started Prior to Treatment by
Respiratory Medication Class in Study MEA117113

Respiratory Medication Class Ingredient	PBO (N=87)		100 SC (N=83)		Total (N=170)	
HAEMOPHILUS INFLUENZAE+KLEBSIELLA OZAENAE+KLEBSIELLA PNEUMONIAE+MORAXELLA CATARRHALIS+NEISSERIA CATARRHALIS+STAPHYLOCOCCUS AUREUS+STREPTOCOCCI	1	(1%)	0		1	(<1%)
HYDROXYZINE HYDROCHLORIDE	0		1	(1%)	1	(<1%)
IBUPROFEN	0		1	(1%)	1	(<1%)
IPRAVENT (NOS)	0		1	(1%)	1	(<1%)
LEVOCETIRIZINE HYDROCHLORIDE	1	(1%)	0		1	(<1%)
LEVODROPROPIZINE	1	(1%)	0		1	(<1%)
LEVOTUSS (NOS)	1	(1%)	0		1	(<1%)
LOSARTAN	1	(1%)	0		1	(<1%)
MYRTOL	1	(1%)	0		1	(<1%)
OMNICEF (NOS)	0		1	(1%)	1	(<1%)
OXYCODONE HYDROCHLORIDE	0		1	(1%)	1	(<1%)
PARACETAMOL	0		1	(1%)	1	(<1%)
PSEUDOEPHEDRINE HYDROCHLORIDE	0		1	(1%)	1	(<1%)
PSEUDOEPHEDRINE HYDROCHLORIDE+TRIPROLIDINE HYDROCHLORIDE	0		1	(1%)	1	(<1%)
SULGLICOTIDE	1	(1%)	0		1	(<1%)
SUPRAX (NOS)	0		1	(1%)	1	(<1%)
TYLENOL #2 (NOS)	1	(1%)	0		1	(<1%)
Oxygen						
Any medication	11	(13%)	8	(10%)	19	(11%)
OXYGEN	11	(13%)	8	(10%)	19	(11%)
Leukotriene Receptor Antagonist						
Any medication	5	(6%)	10	(12%)	15	(9%)
MONTELUKAST SODIUM	5	(6%)	7	(8%)	12	(7%)
MONTELUKAST	0		3	(4%)	3	(2%)

Note: Includes all COPD medications started before the first dose of investigational product.
Note: Multi-component medications are displayed under the respiratory medication class of each component.

Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Table 111.9
Summary of COPD Medications Started Prior to Treatment by
Respiratory Medication Class in Study MEA117113

Respiratory Medication Class Ingredient	PBO (N=87)	100 SC (N=83)	Total (N=170)
PDE4 Inhibitors			
Any medication	5 (6%)	9 (11%)	14 (8%)
ROFLUMILAST	5 (6%)	9 (11%)	14 (8%)

Note: Includes all COPD medications started before the first dose of investigational product.
Note: Multi-component medications are displayed under the respiratory medication class of each component.

Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Table 111.10
Summary of COPD Medications Started Prior to Treatment by
Respiratory Medication Class in Study MEA117106

Respiratory Medication Class Ingredient	PBO (N=90)	100 SC (N=82)	Total (N=172)
Any medication	90 (100%)	82 (100%)	172 (100%)
Corticosteroid - Inhaled			
Any medication	90 (100%)	82 (100%)	172 (100%)
FLUTICASONE PROPIONATE+SALMETEROL XINAFOATE	46 (51%)	46 (56%)	92 (53%)
BUDESONIDE+FORMOTEROL FUMARATE	15 (17%)	13 (16%)	28 (16%)
FLUTICASONE PROPIONATE	15 (17%)	11 (13%)	26 (15%)
BUDESONIDE	14 (16%)	5 (6%)	19 (11%)
CICLESONIDE	9 (10%)	5 (6%)	14 (8%)
BECLOMETASONE DIPROPIONATE+FORMOTEROL FUMARATE	6 (7%)	3 (4%)	9 (5%)
FLUTICASONE PROPIONATE+SALMETEROL	4 (4%)	3 (4%)	7 (4%)
FLUTICASONE+SALMETEROL	3 (3%)	3 (4%)	6 (3%)
BECLOMETASONE	2 (2%)	3 (4%)	5 (3%)
FLUTICASONE	2 (2%)	3 (4%)	5 (3%)
FLUTICASONE PROPIONATE+FORMOTEROL FUMARATE	3 (3%)	1 (1%)	4 (2%)
BUDESONIDE+FORMOTEROL	2 (2%)	1 (1%)	3 (2%)
FLUTICASONE FUROATE+VILANTEROL TRIFENATATE	1 (1%)	1 (1%)	2 (1%)
FORMOTEROL FUMARATE+MOMETASONE FUROATE	1 (1%)	1 (1%)	2 (1%)
BECLOMETASONE DIPROPIONATE	1 (1%)	0	1 (<1%)
BECLOMETASONE+FORMOTEROL	1 (1%)	0	1 (<1%)
FLUTICASONE+FORMOTEROL	1 (1%)	0	1 (<1%)
FLUTICASONE+VILANTEROL	1 (1%)	0	1 (<1%)
PREDNISOLONE	1 (1%)	0	1 (<1%)
Long-acting beta-2 agonist			
Any medication	90 (100%)	82 (100%)	172 (100%)
FLUTICASONE PROPIONATE+SALMETEROL XINAFOATE	46 (51%)	46 (56%)	92 (53%)
BUDESONIDE+FORMOTEROL FUMARATE	15 (17%)	13 (16%)	28 (16%)
INDACATEROL MALEATE	9 (10%)	11 (13%)	20 (12%)
BECLOMETASONE DIPROPIONATE+FORMOTEROL FUMARATE	6 (7%)	3 (4%)	9 (5%)

Note: Includes all COPD medications started before the first dose of investigational product.
Note: Multi-component medications are displayed under the respiratory medication class of each component.

Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Table 111.10
Summary of COPD Medications Started Prior to Treatment by
Respiratory Medication Class in Study MEA117106

Respiratory Medication Class Ingredient	PBO (N=90)		100 SC (N=82)		Total (N=172)	
FORMOTEROL	6	(7%)	2	(2%)	8	(5%)
FLUTICASONE PROPIONATE+SALMETEROL	4	(4%)	3	(4%)	7	(4%)
FLUTICASONE+SALMETEROL	3	(3%)	3	(4%)	6	(3%)
SALMETEROL	3	(3%)	3	(4%)	6	(3%)
FLUTICASONE PROPIONATE+FORMOTEROL FUMARATE	3	(3%)	1	(1%)	4	(2%)
FORMOTEROL FUMARATE	3	(3%)	1	(1%)	4	(2%)
BUDESONIDE+FORMOTEROL	2	(2%)	1	(1%)	3	(2%)
GLYCOPYRRONIUM BROMIDE+INDACATEROL MALEATE	1	(1%)	2	(2%)	3	(2%)
INDACATEROL	1	(1%)	2	(2%)	3	(2%)
SALMETEROL XINAFOATE	1	(1%)	2	(2%)	3	(2%)
FLUTICASONE FUROATE+VILANTEROL TRIFENATATE	1	(1%)	1	(1%)	2	(1%)
FORMOTEROL FUMARATE+MOMETASONE FUROATE	1	(1%)	1	(1%)	2	(1%)
ARFORMOTEROL TARTRATE	0		1	(1%)	1	(<1%)
BECLOMETASONE+FORMOTEROL	1	(1%)	0		1	(<1%)
FLUTICASONE+FORMOTEROL	1	(1%)	0		1	(<1%)
FLUTICASONE+VILANTEROL	1	(1%)	0		1	(<1%)
Long-acting anticholinergic						
Any medication	89	(99%)	82	(100%)	171	(>99%)
TIOTROPIUM BROMIDE	66	(73%)	70	(85%)	136	(79%)
GLYCOPYRRONIUM BROMIDE	10	(11%)	10	(12%)	20	(12%)
TIOTROPIUM	13	(14%)	6	(7%)	19	(11%)
ACLIDINIUM BROMIDE	7	(8%)	1	(1%)	8	(5%)
GLYCOPYRRONIUM BROMIDE+INDACATEROL MALEATE	1	(1%)	2	(2%)	3	(2%)
Short-acting beta-2 agonist						
Any medication	67	(74%)	63	(77%)	130	(76%)
SALBUTAMOL	48	(53%)	50	(61%)	98	(57%)
FENOTEROL HYDROBROMIDE+IPRATROPIUM BROMIDE	10	(11%)	10	(12%)	20	(12%)
IPRATROPIUM BROMIDE+SALBUTAMOL SULFATE	6	(7%)	5	(6%)	11	(6%)

Note: Includes all COPD medications started before the first dose of investigational product.
Note: Multi-component medications are displayed under the respiratory medication class of each component.

Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Table 111.10
Summary of COPD Medications Started Prior to Treatment by
Respiratory Medication Class in Study MEA117106

Respiratory Medication Class Ingredient	PBO (N=90)		100 SC (N=82)		Total (N=172)	
TERBUTALINE SULFATE	8	(9%)	0		8	(5%)
SALBUTAMOL SULFATE	3	(3%)	3	(4%)	6	(3%)
PROAIR (NOS)	1	(1%)	3	(4%)	4	(2%)
FENOTEROL+IPRATROPIUM BROMIDE	1	(1%)	1	(1%)	2	(1%)
IPRATROPIUM+SALBUTAMOL	1	(1%)	1	(1%)	2	(1%)
IPRATROPIUM BROMIDE+SALBUTAMOL	1	(1%)	0		1	(<1%)
LEVOSALBUTAMOL HYDROCHLORIDE	0		1	(1%)	1	(<1%)
Corticosteroid - Systemic, oral, parenteral and intra-articular						
Any medication	53	(59%)	40	(49%)	93	(54%)
PREDNISONE	22	(24%)	23	(28%)	45	(26%)
METHYLPREDNISOLONE	13	(14%)	10	(12%)	23	(13%)
PREDNISOLONE	15	(17%)	7	(9%)	22	(13%)
DEFLAZACORT	5	(6%)	3	(4%)	8	(5%)
METHYLPREDNISOLONE HEMISUCCINATE	2	(2%)	2	(2%)	4	(2%)
PREDNISONE ACETATE	2	(2%)	2	(2%)	4	(2%)
METHYLPREDNISOLONE SODIUM SUCCINATE	1	(1%)	2	(2%)	3	(2%)
BETAMETHASONE SODIUM PHOSPHATE	0		2	(2%)	2	(1%)
BETAMETHASONE	1	(1%)	0		1	(<1%)
BETAMETHASONE+DEXCHLORPHENIRAMINE MALEATE	1	(1%)	0		1	(<1%)
DEXAMETHASONE	1	(1%)	0		1	(<1%)
DEXAMETHASONE SODIUM PHOSPHATE	1	(1%)	0		1	(<1%)
HYDROCORTISONE	1	(1%)	0		1	(<1%)
Antiinfectives (antibiotics, antifungals, antivirals, antiseptics)						
Any medication	47	(52%)	41	(50%)	88	(51%)
LEVOFLOXACIN	15	(17%)	18	(22%)	33	(19%)
AMOXICILLIN+CLAVULANIC ACID	10	(11%)	9	(11%)	19	(11%)

Note: Includes all COPD medications started before the first dose of investigational product.
Note: Multi-component medications are displayed under the respiratory medication class of each component.

Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Table 111.10
Summary of COPD Medications Started Prior to Treatment by
Respiratory Medication Class in Study MEA117106

Respiratory Medication Class Ingredient	PBO (N=90)		100 SC (N=82)		Total (N=172)	
AZITHROMYCIN	13	(14%)	6	(7%)	19	(11%)
CIPROFLOXACIN	8	(9%)	7	(9%)	15	(9%)
DOXYCYCLINE	5	(6%)	6	(7%)	11	(6%)
CLARITHROMYCIN	5	(6%)	5	(6%)	10	(6%)
MOXIFLOXACIN	5	(6%)	3	(4%)	8	(5%)
AMOXICILLIN+CLAVULANATE POTASSIUM	3	(3%)	3	(4%)	6	(3%)
CIPROFLOXACIN HYDROCHLORIDE	4	(4%)	2	(2%)	6	(3%)
SULFAMETHOXAZOLE+TRIMETHOPRIM	3	(3%)	3	(4%)	6	(3%)
AMOXICILLIN	3	(3%)	2	(2%)	5	(3%)
CEFTRIAXONE SODIUM	3	(3%)	2	(2%)	5	(3%)
CEFUROXIME	2	(2%)	2	(2%)	4	(2%)
CEFUROXIME AXETIL	2	(2%)	2	(2%)	4	(2%)
CEFTRIAXONE	3	(3%)	0		3	(2%)
CLAMOXYL (NOS)	2	(2%)	0		2	(1%)
ERYTHROMYCIN	1	(1%)	1	(1%)	2	(1%)
FLUCONAZOLE	0		2	(2%)	2	(1%)
PIPERACILLIN+TAZOBACTAM	2	(2%)	0		2	(1%)
SPIRAMYCIN	0		2	(2%)	2	(1%)
AMPISID (NOS)	1	(1%)	0		1	(<1%)
ANTIBIOTICS NOS	0		1	(1%)	1	(<1%)
BENZYLPENICILLIN	0		1	(1%)	1	(<1%)
CEFACLOR	0		1	(1%)	1	(<1%)
CEFALEXIN	1	(1%)	0		1	(<1%)
CEFDITOREN	0		1	(1%)	1	(<1%)
CEFDITOREN PIVOXIL	0		1	(1%)	1	(<1%)
CEFPODOXIME PROXETIL	1	(1%)	0		1	(<1%)
CEFTAZIDIME	0		1	(1%)	1	(<1%)
CEFZIL (NOS)	1	(1%)	0		1	(<1%)
CILASTATIN+IMIPENEM	1	(1%)	0		1	(<1%)
GENTAMICIN	1	(1%)	0		1	(<1%)

Note: Includes all COPD medications started before the first dose of investigational product.
Note: Multi-component medications are displayed under the respiratory medication class of each component.

Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Table 111.10
Summary of COPD Medications Started Prior to Treatment by
Respiratory Medication Class in Study MEA117106

Respiratory Medication Class Ingredient	PBO (N=90)		100 SC (N=82)		Total (N=172)	
PIPERACILLIN SODIUM+TAZOBACTAM SODIUM	1	(1%)	0		1	(<1%)
PRISTINAMYCIN	1	(1%)	0		1	(<1%)
ROXITHROMYCIN	0		1	(1%)	1	(<1%)
TOBRAMYCIN	1	(1%)	0		1	(<1%)
Short-acting anticholinergic						
Any medication	37	(41%)	27	(33%)	64	(37%)
IPRATROPIUM BROMIDE	19	(21%)	12	(15%)	31	(18%)
FENOTEROL HYDROBROMIDE+IPRATROPIUM BROMIDE	10	(11%)	10	(12%)	20	(12%)
IPRATROPIUM BROMIDE+SALBUTAMOL SULFATE	6	(7%)	5	(6%)	11	(6%)
IPRATROPIUM	3	(3%)	0		3	(2%)
FENOTEROL+IPRATROPIUM BROMIDE	1	(1%)	1	(1%)	2	(1%)
IPRATROPIUM+SALBUTAMOL	1	(1%)	1	(1%)	2	(1%)
IPRATROPIUM BROMIDE+SALBUTAMOL	1	(1%)	0		1	(<1%)
Xanthine						
Any medication	25	(28%)	18	(22%)	43	(25%)
THEOPHYLLINE	20	(22%)	17	(21%)	37	(22%)
AMINOPHYLLINE	5	(6%)	1	(1%)	6	(3%)
PENTOXIFYLLINE	0		1	(1%)	1	(<1%)
Mucolytics						
Any medication	13	(14%)	11	(13%)	24	(14%)
ACETYLCYSTEINE	8	(9%)	7	(9%)	15	(9%)
AMBROXOL HYDROCHLORIDE	2	(2%)	2	(2%)	4	(2%)
CARBOCISTEINE	2	(2%)	2	(2%)	4	(2%)
ERDOSTEINE	2	(2%)	2	(2%)	4	(2%)
AMBROXOL	1	(1%)	2	(2%)	3	(2%)
BROMHEXINE HYDROCHLORIDE	0		1	(1%)	1	(<1%)
CARBOCISTEINE LYSINE	0		1	(1%)	1	(<1%)

Note: Includes all COPD medications started before the first dose of investigational product.
Note: Multi-component medications are displayed under the respiratory medication class of each component.

Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Table 111.10
Summary of COPD Medications Started Prior to Treatment by
Respiratory Medication Class in Study MEA117106

Respiratory Medication Class Ingredient	PBO (N=90)		100 SC (N=82)		Total (N=172)	
MUCODOX (NOS)	1	(1%)	0		1	(<1%)
MUCOSOLVAN (NOS)	0		1	(1%)	1	(<1%)
Other COPD medication						
Any medication	8	(9%)	10	(12%)	18	(10%)
DUOMOX (NOS)	2	(2%)	1	(1%)	3	(2%)
ALENDRONATE SODIUM+COLECALCIFEROL	1	(1%)	0		1	(<1%)
BETAMETHASONE+DEXCHLORPHENIRAMINE MALEATE	1	(1%)	0		1	(<1%)
BRIMONIDINE TARTRATE	0		1	(1%)	1	(<1%)
CETIRIZINE	0		1	(1%)	1	(<1%)
CETIRIZINE HYDROCHLORIDE	0		1	(1%)	1	(<1%)
CILASTATIN+IMIPENEM	1	(1%)	0		1	(<1%)
CLEMASTINE	0		1	(1%)	1	(<1%)
COMPRESSED AIR	1	(1%)	0		1	(<1%)
FLUMIL (NOS)	0		1	(1%)	1	(<1%)
FUROSEMIDE	0		1	(1%)	1	(<1%)
LANSOPRAZOLE	1	(1%)	0		1	(<1%)
LORAZEPAM	1	(1%)	0		1	(<1%)
LOSARTAN POTASSIUM	0		1	(1%)	1	(<1%)
NEBIVOLOL HYDROCHLORIDE	0		1	(1%)	1	(<1%)
OMALIZUMAB	1	(1%)	0		1	(<1%)
POTASSIUM CHLORIDE	0		1	(1%)	1	(<1%)
SODIUM CHLORIDE	0		1	(1%)	1	(<1%)
Oxygen						
Any medication	6	(7%)	9	(11%)	15	(9%)
OXYGEN	6	(7%)	9	(11%)	15	(9%)
PDE4 Inhibitors						
Any medication	5	(6%)	4	(5%)	9	(5%)

Note: Includes all COPD medications started before the first dose of investigational product.
Note: Multi-component medications are displayed under the respiratory medication class of each component.

Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Table 111.10

Summary of COPD Medications Started Prior to Treatment by Respiratory Medication Class in Study MEA117106

Respiratory Medication Class Ingredient	PBO (N=90)		100 SC (N=82)		Total (N=172)	
ROFLUMILAST	5	(6%)	4	(5%)	9	(5%)
Leukotriene Receptor Antagonist						
Any medication	4	(4%)	3	(4%)	7	(4%)
MONTELUKAST SODIUM	3	(3%)	2	(2%)	5	(3%)
MONTELUKAST	1	(1%)	1	(1%)	2	(1%)
Corticosteroid - Other						
Any medication	0		2	(2%)	2	(1%)
DEFLAZACORT	0		1	(1%)	1	(<1%)
DEXAMETHASONE SODIUM PHOSPHATE	0		1	(1%)	1	(<1%)

Note: Includes all COPD medications started before the first dose of investigational product.
Note: Multi-component medications are displayed under the respiratory medication class of each component.

Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Table 111.11
Summary of COPD Medications Started Prior to Treatment by Ingredient in Study 208657

Ingredient	PBO (N=401)	100 SC (N=403)	Total (N=804)
Any medication	401 (100%)	403 (100%)	804 (100%)
SALBUTAMOL	200 (50%)	220 (55%)	420 (52%)
FLUTICASONE FUROATE+VILANTEROL TRIFENATATE+UMECLIDINIUM BROMIDE	115 (29%)	107 (27%)	222 (28%)
TIOTROPIUM BROMIDE MONOHYDRATE	97 (24%)	104 (26%)	201 (25%)
SALMETEROL XINAFOATE+FLUTICASONE PROPIONATE	61 (15%)	75 (19%)	136 (17%)
BUDESONIDE+FORMOTEROL FUMARATE	66 (16%)	64 (16%)	130 (16%)
GLYCOPYRRONIUM BROMIDE+BECLOMETASONE DIPROPIONATE+FORMOTEROL FUMARATE	47 (12%)	51 (13%)	98 (12%)
TIOTROPIUM BROMIDE	43 (11%)	45 (11%)	88 (11%)
BUDESONIDE	38 (9%)	48 (12%)	86 (11%)
FENOTEROL HYDROBROMIDE+IPRATROPIUM BROMIDE	40 (10%)	35 (9%)	75 (9%)
PREDNISOLONE	39 (10%)	32 (8%)	71 (9%)
SALBUTAMOL SULFATE	33 (8%)	37 (9%)	70 (9%)
METHYLPREDNISOLONE	26 (6%)	35 (9%)	61 (8%)
THEOPHYLLINE	27 (7%)	30 (7%)	57 (7%)
FLUTICASONE FUROATE+VILANTEROL TRIFENATATE	26 (6%)	30 (7%)	56 (7%)
BECLOMETASONE DIPROPIONATE+FORMOTEROL FUMARATE	22 (5%)	28 (7%)	50 (6%)
PREDNISONE	28 (7%)	21 (5%)	49 (6%)
IPRATROPIUM BROMIDE	23 (6%)	25 (6%)	48 (6%)
UMECLIDINIUM BROMIDE	19 (5%)	28 (7%)	47 (6%)
ACETYLCYSTEINE	22 (5%)	23 (6%)	45 (6%)
AZITHROMYCIN	23 (6%)	22 (5%)	45 (6%)
TIOTROPIUM	26 (6%)	17 (4%)	43 (5%)
OXYGEN	21 (5%)	20 (5%)	41 (5%)
ROFLUMILAST	16 (4%)	24 (6%)	40 (5%)
GLYCOPYRRONIUM BROMIDE+BUDESONIDE+FORMOTEROL FUMARATE	17 (4%)	20 (5%)	37 (5%)
GLYCOPYRRONIUM BROMIDE	17 (4%)	19 (5%)	36 (4%)
VILANTEROL TRIFENATATE+UMECLIDINIUM BROMIDE	19 (5%)	14 (3%)	33 (4%)
FLUTICASONE PROPIONATE	20 (5%)	11 (3%)	31 (4%)

Note: Includes all COPD medications started before the first dose of investigational product.
/mnt/code/postcsr_01/prod/tfls/t_sp_c1_prior_ing_657.sas 21JUL2025 22:00

Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Table 111.11
Summary of COPD Medications Started Prior to Treatment by Ingredient in Study 208657

Ingredient	PBO (N=401)		100 SC (N=403)		Total (N=804)	
GLYCOPYRRONIUM BROMIDE+INDACATEROL MALEATE	10	(2%)	18	(4%)	28	(3%)
AMOXICILLIN+CLAVULANIC ACID	16	(4%)	10	(2%)	26	(3%)
BUDESONIDE+FORMOTEROL	15	(4%)	11	(3%)	26	(3%)
TIOTROPIUM BROMIDE MONOHYDRATE+OLODATEROL HYDROCHLORIDE	12	(3%)	14	(3%)	26	(3%)
FORMOTEROL FUMARATE	11	(3%)	13	(3%)	24	(3%)
CICLESONIDE	12	(3%)	11	(3%)	23	(3%)
ERDOSTEINE	12	(3%)	10	(2%)	22	(3%)
AMBROXOL ACEFYLLINATE	11	(3%)	9	(2%)	20	(2%)
FORMOTEROL	10	(2%)	10	(2%)	20	(2%)
SALBUTAMOL SULFATE+IPRATROPIUM BROMIDE	4	(<1%)	15	(4%)	19	(2%)
CARBOCISTEINE	8	(2%)	10	(2%)	18	(2%)
DOXOFYLLINE	4	(<1%)	14	(3%)	18	(2%)
SALMETEROL	15	(4%)	3	(<1%)	18	(2%)
CEFIXIME	8	(2%)	9	(2%)	17	(2%)
CLARITHROMYCIN	8	(2%)	8	(2%)	16	(2%)
LEVOFLOXACIN	8	(2%)	8	(2%)	16	(2%)
FORMOTEROL FUMARATE+FLUTICASONE PROPIONATE	8	(2%)	7	(2%)	15	(2%)
METHYLPREDNISOLONE SODIUM SUCCINATE	5	(1%)	10	(2%)	15	(2%)
MONTELUKAST SODIUM	6	(1%)	8	(2%)	14	(2%)
ACLIDINIUM BROMIDE	8	(2%)	4	(<1%)	12	(1%)
MONTELUKAST	4	(<1%)	8	(2%)	12	(1%)
PREDNISONE ACETATE	7	(2%)	5	(1%)	12	(1%)
CINEOLE+PINENE+DIPENTEN	3	(<1%)	8	(2%)	11	(1%)
FENOTEROL HYDROBROMIDE	9	(2%)	2	(<1%)	11	(1%)
FLUTICASONE FUROATE	5	(1%)	5	(1%)	10	(1%)
MONTELUKAST SODIUM+LEVOCETIRIZINE HYDROCHLORIDE	4	(<1%)	6	(1%)	10	(1%)
SALBUTAMOL+IPRATROPIUM	8	(2%)	2	(<1%)	10	(1%)
TERBUTALINE SULFATE	4	(<1%)	6	(1%)	10	(1%)
AMBROXOL HYDROCHLORIDE	3	(<1%)	6	(1%)	9	(1%)

Note: Includes all COPD medications started before the first dose of investigational product.
/mnt/code/postcsr_01/prod/tfls/t_sp_c1_prior_ing_657.sas 21JUL2025 22:00

Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Table 111.11
Summary of COPD Medications Started Prior to Treatment by Ingredient in Study 208657

Ingredient	PBO (N=401)		100 SC (N=403)		Total (N=804)	
AMINOPHYLLINE+CHLORPHENAMINE MALEATE+METHOXYPHENAMINE HYDROCHLORIDE+NOSCAPINE	4	(<1%)	5	(1%)	9	(1%)
BROMHEXINE HYDROCHLORIDE+GUAIFENESIN+TERBUTALINE SULFATE	5	(1%)	4	(<1%)	9	(1%)
FLUTICASONE	6	(1%)	3	(<1%)	9	(1%)
FORMOTEROL FUMARATE+ACLIDINIUM BROMIDE	6	(1%)	3	(<1%)	9	(1%)
PIPERACILLIN SODIUM+TAZOBACTAM SODIUM	2	(<1%)	7	(2%)	9	(1%)
BRONCHODUAL (NOS)	5	(1%)	3	(<1%)	8	(<1%)
CEFUROXIME	4	(<1%)	4	(<1%)	8	(<1%)
CIPROFLOXACIN	4	(<1%)	4	(<1%)	8	(<1%)
MOXIFLOXACIN HYDROCHLORIDE	3	(<1%)	5	(1%)	8	(<1%)
PROAIR (NOS)	4	(<1%)	4	(<1%)	8	(<1%)
THEOPHYLLINE+ETOFYLLINE	2	(<1%)	6	(1%)	8	(<1%)
BROMHEXINE HYDROCHLORIDE	0		7	(2%)	7	(<1%)
FENOTEROL+IPRATROPIUM BROMIDE	5	(1%)	2	(<1%)	7	(<1%)
GLYCOPYRRONIUM BROMIDE+BUDESONIDE+FORMOTEROL	5	(1%)	2	(<1%)	7	(<1%)
GLYCOPYRRONIUM BROMIDE+FORMOTEROL FUMARATE	3	(<1%)	4	(<1%)	7	(<1%)
GUAIFENESIN+AMBROXOL+LEVOSALBUTAMOL	5	(1%)	2	(<1%)	7	(<1%)
MOXIFLOXACIN	4	(<1%)	3	(<1%)	7	(<1%)
TERBUTALINE	3	(<1%)	4	(<1%)	7	(<1%)
BECLOMETASONE DIPROPIONATE	5	(1%)	1	(<1%)	6	(<1%)
DOXYCYCLINE	4	(<1%)	2	(<1%)	6	(<1%)
IPRATROPIUM	4	(<1%)	2	(<1%)	6	(<1%)
SALBUTAMOL+IPRATROPIUM BROMIDE	4	(<1%)	2	(<1%)	6	(<1%)
SALMETEROL+FLUTICASONE	3	(<1%)	3	(<1%)	6	(<1%)
AMOXICILLIN	4	(<1%)	1	(<1%)	5	(<1%)
BECLOMETASONE+FORMOTEROL	4	(<1%)	1	(<1%)	5	(<1%)
EPHEDRA SINICA+ARCTIUM LAPPA+SCHISANDRA NOS+OCIMUM BASILICUM+LUMBRICUS TERRESTRIS+PEUCEDANUM (NOS)+HERBALS NOS	2	(<1%)	3	(<1%)	5	(<1%)
HYDROCORTISONE	3	(<1%)	2	(<1%)	5	(<1%)

Note: Includes all COPD medications started before the first dose of investigational product.
/mnt/code/postcsr_01/prod/tfls/t_sp_c1_prior_ing_657.sas 21JUL2025 22:00

Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Table 111.11
Summary of COPD Medications Started Prior to Treatment by Ingredient in Study 208657

Ingredient	PBO (N=401)		100 SC (N=403)		Total (N=804)	
MOMETASONE FUROATE+FORMOTEROL FUMARATE	1	(<1%)	4	(<1%)	5	(<1%)
MONTELUKAST+LEVOCETIRIZINE	4	(<1%)	1	(<1%)	5	(<1%)
MUCOSOLVAN (NOS)	1	(<1%)	4	(<1%)	5	(<1%)
TRADITIONAL CHINESE MEDICINE NOS	1	(<1%)	4	(<1%)	5	(<1%)
AMINOPHYLLINE	0		4	(<1%)	4	(<1%)
HEDERA HELIX EXTRACT	3	(<1%)	1	(<1%)	4	(<1%)
IPRATROPIUM+LEVOSALBUTAMOL	1	(<1%)	3	(<1%)	4	(<1%)
UMECLIDINIUM	2	(<1%)	2	(<1%)	4	(<1%)
VILANTEROL	3	(<1%)	1	(<1%)	4	(<1%)
AMOXICILLIN+CLAVULANATE POTASSIUM	0		3	(<1%)	3	(<1%)
AMPICILLIN SODIUM	1	(<1%)	2	(<1%)	3	(<1%)
BUDESONIDE+LEVOSALBUTAMOL	2	(<1%)	1	(<1%)	3	(<1%)
DEFLAZACORT	1	(<1%)	2	(<1%)	3	(<1%)
DUOMOX (NOS)	1	(<1%)	2	(<1%)	3	(<1%)
GLYCOPYRRONIUM+BUDESONIDE+FORMOTEROL FUMARATE	3	(<1%)	0		3	(<1%)
LEVOSALBUTAMOL HYDROCHLORIDE	1	(<1%)	2	(<1%)	3	(<1%)
MEPREDNISONE	1	(<1%)	2	(<1%)	3	(<1%)
PARACETAMOL	2	(<1%)	1	(<1%)	3	(<1%)
POTASSIUM CHLORIDE	1	(<1%)	2	(<1%)	3	(<1%)
PREDNISOLONE SODIUM SUCCINATE	0		3	(<1%)	3	(<1%)
SODIUM CHLORIDE	0		3	(<1%)	3	(<1%)
SPIRAMYCIN	0		3	(<1%)	3	(<1%)
UNCODED	1	(<1%)	2	(<1%)	3	(<1%)
AMOXICILLIN TRIHYDRATE+CLAVULANATE POTASSIUM	0		2	(<1%)	2	(<1%)
ASARONE	1	(<1%)	1	(<1%)	2	(<1%)
BECLOMETASONE	1	(<1%)	1	(<1%)	2	(<1%)
BENZONATATE	2	(<1%)	0		2	(<1%)
CEFDITOREN PIVOXIL	1	(<1%)	1	(<1%)	2	(<1%)
CEFTRIAXONE SODIUM	1	(<1%)	1	(<1%)	2	(<1%)
CIPROFLOXACIN HYDROCHLORIDE	1	(<1%)	1	(<1%)	2	(<1%)
DEXAMETHASONE SODIUM PHOSPHATE	1	(<1%)	1	(<1%)	2	(<1%)

Note: Includes all COPD medications started before the first dose of investigational product.
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Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Table 111.11
Summary of COPD Medications Started Prior to Treatment by Ingredient in Study 208657

Ingredient	PBO (N=401)		100 SC (N=403)		Total (N=804)	
DIPROPHYLLINE	1	(<1%)	1	(<1%)	2	(<1%)
EUPHYLLIN (NOS)	1	(<1%)	1	(<1%)	2	(<1%)
FENOTEROL+IPRATROPIUM	2	(<1%)	0		2	(<1%)
FLUTICASONE FUROATE+VILANTEROL	0		2	(<1%)	2	(<1%)
FLUTICASONE FUROATE+VILANTEROL+UMECLIDINIUM	1	(<1%)	1	(<1%)	2	(<1%)
GLYCOPYRRONIUM BROMIDE+FORMOTEROL	0		2	(<1%)	2	(<1%)
GLYCOPYRRONIUM BROMIDE+FORMOTEROL FUMARATE+FLUTICASONE PROPIONATE	0		2	(<1%)	2	(<1%)
GLYCOPYRRONIUM BROMIDE+MOMETASONE FUROATE+INDACATEROL ACETATE	1	(<1%)	1	(<1%)	2	(<1%)
HEDERA HELIX EXTRACT+RHIZOMA COPTIDIS EXTRACT	0		2	(<1%)	2	(<1%)
INDACATEROL MALEATE	1	(<1%)	1	(<1%)	2	(<1%)
LEVOMENTHOL+PAPAVER SOMNIFERUM+MORUS (NOS)+ERIOBOTRYA JAPONICA+CAMPANULA (NOS)+CYNANCHUM GLAUCESCENS+HERBALS NOS	1	(<1%)	1	(<1%)	2	(<1%)
LEVOMENTHOL+PLATYCODON GRANDIFLORUS+PAPAVER SOMNIFERUM+ERIOBOTRYA JAPONICA+MORUS ALBA+CYNANCHUM STAUNTONII+STEMONA SESSILIFOLIA	0		2	(<1%)	2	(<1%)
LORATADINE	0		2	(<1%)	2	(<1%)
MONTELUKAST SODIUM+BILASTINE	2	(<1%)	0		2	(<1%)
NEMONOXACIN MALATE	1	(<1%)	1	(<1%)	2	(<1%)
OPERATIONS AND PROCEDURES	1	(<1%)	1	(<1%)	2	(<1%)
SALMETEROL+FLUTICASONE PROPIONATE	0		2	(<1%)	2	(<1%)
SENECIO CANNABIFOLIUS	1	(<1%)	1	(<1%)	2	(<1%)
SODIUM CHLORIDE+LEVOFLOXACIN	1	(<1%)	1	(<1%)	2	(<1%)
SODIUM CHLORIDE+MOXIFLOXACIN HYDROCHLORIDE	0		2	(<1%)	2	(<1%)
SULFAMETHOXAZOLE+TRIMETHOPRIM	2	(<1%)	0		2	(<1%)
ACETYLCYSTEINE SODIUM+AMBROXOL ACEFYLLINATE	0		1	(<1%)	1	(<1%)
ACETYLCYSTEINE+AMBROXOL ACEFYLLINATE	0		1	(<1%)	1	(<1%)
AMBROXOL	0		1	(<1%)	1	(<1%)
AMIKACIN	1	(<1%)	0		1	(<1%)

Note: Includes all COPD medications started before the first dose of investigational product.
/mnt/code/postcsr_01/prod/tfls/t_sp_c1_prior_ing_657.sas 21JUL2025 22:00

Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Table 111.11
Summary of COPD Medications Started Prior to Treatment by Ingredient in Study 208657

Ingredient	PBO (N=401)		100 SC (N=403)		Total (N=804)	
AMINOMETHYLBENZOIC ACID	1	(<1%)	0		1	(<1%)
AMPICILLIN SODIUM+SULBACTAM SODIUM	1	(<1%)	0		1	(<1%)
ANTIBIOTICS NOS	1	(<1%)	0		1	(<1%)
ANYCOUGH (NOS)	0		1	(<1%)	1	(<1%)
ASCORIL (NOS)	0		1	(<1%)	1	(<1%)
BACTERIA NOS	0		1	(<1%)	1	(<1%)
BENPROPERINE	1	(<1%)	0		1	(<1%)
BETAMETHASONE SODIUM PHOSPHATE	1	(<1%)	0		1	(<1%)
BIAPENEM	0		1	(<1%)	1	(<1%)
BICARBONATE	0		1	(<1%)	1	(<1%)
CANNABIS SATIVA	0		1	(<1%)	1	(<1%)
CARTHAMUS TINCTORIUS+ANGELICA+SALVIA (NOS)+PAEONIA (NOS)+LIGUSTICUM CHUANXIANG	0		1	(<1%)	1	(<1%)
CEFDINIR	1	(<1%)	0		1	(<1%)
CEFEPIME	1	(<1%)	0		1	(<1%)
CEFMINOX SODIUM	0		1	(<1%)	1	(<1%)
CEFOPERAZONE SODIUM+SULBACTAM SODIUM	0		1	(<1%)	1	(<1%)
CEFOTAXIME SODIUM	1	(<1%)	0		1	(<1%)
CEFPODOXIME PROXETIL	1	(<1%)	0		1	(<1%)
CEFPROZIL	0		1	(<1%)	1	(<1%)
CEFTAZIDIME	1	(<1%)	0		1	(<1%)
CEFTRIAXONE	1	(<1%)	0		1	(<1%)
CEFUROXIME AXETIL	0		1	(<1%)	1	(<1%)
CEFUROXIME SODIUM	1	(<1%)	0		1	(<1%)
CHLORPHENAMINE MALEATE	1	(<1%)	0		1	(<1%)
CHYMOTRYPSIN	0		1	(<1%)	1	(<1%)
CINEOLE+PINENE	1	(<1%)	0		1	(<1%)
CLAVULANIC ACID+CEFPODOXIME PROXETIL	1	(<1%)	0		1	(<1%)
CLORPRENALINE HYDROCHLORIDE+PEARL+DECLOXIZINE HYDROCHLORIDE+CICADA SLOUGH+ELAEAGNUS PUNGENS LEAF+HERBALS NOS+BORNEOL	1	(<1%)	0		1	(<1%)

Note: Includes all COPD medications started before the first dose of investigational product.
/mnt/code/postcsr_01/prod/tfls/t_sp_c1_prior_ing_657.sas 21JUL2025 22:00

Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Table 111.11
Summary of COPD Medications Started Prior to Treatment by Ingredient in Study 208657

Ingredient	PBO (N=401)		100 SC (N=403)		Total (N=804)	
CODENAL (NOS)	0		1	(<1%)	1	(<1%)
COLECALCIFEROL	0		1	(<1%)	1	(<1%)
CORDYCEPS SINENSIS	0		1	(<1%)	1	(<1%)
DAYQUIL (NOS)	0		1	(<1%)	1	(<1%)
DEXAMETHASONE	1	(<1%)	0		1	(<1%)
DIHYDROCODEINE	0		1	(<1%)	1	(<1%)
DIHYDROCODEINE BITARTRATE+CHLORPHENAMINE MALEATE+AMMONIUM CHLORIDE+METHYLEPHEDRINE HYDROCHLORIDE	0		1	(<1%)	1	(<1%)
DIHYDROCODEINE PHOSPHATE+CHLORPHENAMINE MALEATE+METHYLEPHEDRINE HYDROCHLORIDE	0		1	(<1%)	1	(<1%)
DIHYDROCODEINE THIOCYANATE	0		1	(<1%)	1	(<1%)
DOMPERIDONE+RABEPRAZOLE	0		1	(<1%)	1	(<1%)
DOXYCYCLINE HYCLATE	0		1	(<1%)	1	(<1%)
EPHEDRA SINICA+ARCTIUM LAPPA+COW BEZOAR+PHERETIMA (NOS)+HERBALS NOS+GYPSUM FIBROSUM	0		1	(<1%)	1	(<1%)
ESOMEPRAZOLE MAGNESIUM	0		1	(<1%)	1	(<1%)
ETIMICIN SULFATE	0		1	(<1%)	1	(<1%)
FEXOFENADINE	0		1	(<1%)	1	(<1%)
FEXOFENADINE HYDROCHLORIDE	1	(<1%)	0		1	(<1%)
FLUIDASA (NOS)	0		1	(<1%)	1	(<1%)
FLUTICASONE+VILANTEROL+UMECLIDINIUM	1	(<1%)	0		1	(<1%)
FORMOTEROL FUMARATE+TIOTROPIUM BROMIDE	0		1	(<1%)	1	(<1%)
FORMOTEROL FUMARATE+TIOTROPIUM BROMIDE+CICLESONIDE	1	(<1%)	0		1	(<1%)
FORMOTEROL+TIOTROPIUM+CICLESONIDE	1	(<1%)	0		1	(<1%)
FUDOSTEINE	0		1	(<1%)	1	(<1%)
GEKKO GECKO	0		1	(<1%)	1	(<1%)
GLYCOPYRRONIUM	1	(<1%)	0		1	(<1%)
GLYCOPYRRONIUM BROMIDE+BUDESONIDE+FORMOTEROL FUMARATE DIHYDRATE	0		1	(<1%)	1	(<1%)
GLYCOPYRRONIUM+FORMOTEROL+FLUTICASONE	0		1	(<1%)	1	(<1%)

Note: Includes all COPD medications started before the first dose of investigational product.
/mnt/code/postcsr_01/prod/tfls/t_sp_c1_prior_ing_657.sas 21JUL2025 22:00

Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Table 111.11
Summary of COPD Medications Started Prior to Treatment by Ingredient in Study 208657

Ingredient	PBO (N=401)	100 SC (N=403)	Total (N=804)
GLYCOPYRRONIUM+INDACATEROL	1 (<1%)	0	1 (<1%)
GUAIFENESIN+DIHYDROCODEINE BITARTRATE+CHLORPHENAMINE MALEATE+METHYLEPHEDRINE HYDROCHLORIDE	1 (<1%)	0	1 (<1%)
GUAIFENESIN+GLYCEROL+BENZOIC ACID+CAMPHOR+AMMONIA+GLYCYRRHIZA SPP. ROOT WITH RHIZOME+HERBALS NOS	1 (<1%)	0	1 (<1%)
GUAIFENESIN+TERBUTALINE+AMBROXOL	1 (<1%)	0	1 (<1%)
HYDROCHLOROTHIAZIDE+VALSARTAN	1 (<1%)	0	1 (<1%)
HYDROCORTISONE SODIUM SUCCINATE	0	1 (<1%)	1 (<1%)
IBUPROFEN	0	1 (<1%)	1 (<1%)
INDACATEROL	1 (<1%)	0	1 (<1%)
INFLUENZA VACCINE INACT SAG 4V	0	1 (<1%)	1 (<1%)
INTERFERON ALFA-1B	1 (<1%)	0	1 (<1%)
INVESTIGATIONAL COPD MEDICATION	0	1 (<1%)	1 (<1%)
KENALOG (NOS)	0	1 (<1%)	1 (<1%)
LACTULOSE	0	1 (<1%)	1 (<1%)
LATAMOXEF SODIUM	0	1 (<1%)	1 (<1%)
LEVOCETIRIZINE HYDROCHLORIDE	0	1 (<1%)	1 (<1%)
LEVODROPROPIZINE	1 (<1%)	0	1 (<1%)
LEVOFLOXACIN HYDROCHLORIDE	1 (<1%)	0	1 (<1%)
LEVOSALBUTAMOL	0	1 (<1%)	1 (<1%)
MEPYRAMINE	1 (<1%)	0	1 (<1%)
MINERALS NOS+VITAMINS NOS	0	1 (<1%)	1 (<1%)
MOMETASONE FUROATE	1 (<1%)	0	1 (<1%)
MORPHINE SULFATE	0	1 (<1%)	1 (<1%)
MOSAPRIDE CITRATE	0	1 (<1%)	1 (<1%)
MYRTOL	1 (<1%)	0	1 (<1%)
OLODATEROL	1 (<1%)	0	1 (<1%)
OMEPRAZOLE	0	1 (<1%)	1 (<1%)
OSELTAMIVIR	0	1 (<1%)	1 (<1%)

Note: Includes all COPD medications started before the first dose of investigational product.
/mnt/code/postcsr_01/prod/tfls/t_sp_c1_prior_ing_657.sas 21JUL2025 22:00

Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Table 111.11
Summary of COPD Medications Started Prior to Treatment by Ingredient in Study 208657

Ingredient	PBO (N=401)		100 SC (N=403)		Total (N=804)	
PAEONIA LACTIFLORA ROOT+GLYCYRRHIZA SPP. ROOT WITH RHIZOME+PINELLIA TERNATA TUBER+EPHEDRA SPP. STEM+FRITILLARIA THUNBERGII BULB+PHERETIMA SPP.+HERBALS NOS	0		1	(<1%)	1	(<1%)
PANTOPRAZOLE	0		1	(<1%)	1	(<1%)
PARACETAMOL+DEXTROMETHORPHAN+CHLORPHENAMINE+PSEUDO EPHEDRINE	0		1	(<1%)	1	(<1%)
PARACETAMOL+DEXTROMETHORPHAN+PHENYLEPHRINE	0		1	(<1%)	1	(<1%)
PIDOTIMOD	0		1	(<1%)	1	(<1%)
PIPERACILLIN SODIUM	1	(<1%)	0		1	(<1%)
PIPERACILLIN SODIUM+TAZOBACTAM	0		1	(<1%)	1	(<1%)
PIPRINHYDRINATE	0		1	(<1%)	1	(<1%)
PLANTAGO MAJOR	0		1	(<1%)	1	(<1%)
PLATYCODON GRANDIFLORUS ROOT+GLYCYRRHIZA SPP. ROOT WITH RHIZOME+GLEHNIA LITTORALIS ROOT+EPHEDRA SPP HERB+KITAGAWIA PRAERUPTORA ROOT+FRITILLARIA THUNBERGII BULB+HERBALS NOS	0		1	(<1%)	1	(<1%)
PLATYCODON GRANDIFLORUS ROOT+PORIA COCOS SCLEROTIUM+ASTER TATARICUS ROOT WITH RHIZOME+CALCIUM SULFATE DIHYDRATE+FRITILLARIA THUNBERGII BULB+HERBALS NOS	1	(<1%)	0		1	(<1%)
PLATYCODON GRANDIFLORUS ROOT+PORIA COCOS SCLEROTIUM+GLYCYRRHIZA SPP. ROOT WITH RHIZOME+PINELLIA TERNATA TUBER+DOLOMIAEA COSTUS ROOT+ZIZIPHUS JUJUBA FRUIT+HERBALS NOS	0		1	(<1%)	1	(<1%)
PROCATEROL HYDROCHLORIDE	1	(<1%)	0		1	(<1%)
PROMETHAZINE	1	(<1%)	0		1	(<1%)
RANITIDINE HYDROCHLORIDE	0		1	(<1%)	1	(<1%)
SALBUTAMOL SULFATE+IPRATROPIUM	0		1	(<1%)	1	(<1%)
SALBUTAMOL+AMBROXOL	0		1	(<1%)	1	(<1%)

Note: Includes all COPD medications started before the first dose of investigational product.
/mnt/code/postcsr_01/prod/tfls/t_sp_c1_prior_ing_657.sas 21JUL2025 22:00

Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Table 111.11
Summary of COPD Medications Started Prior to Treatment by Ingredient in Study 208657

Ingredient	PBO (N=401)		100 SC (N=403)		Total (N=804)	
SCUTELLARIA BAICALENSIS ROOT+ISATIS TINCTORIA ROOT+LONICERA JAPONICA FLOWER BUD+FORSYTHIA SUSPENSA FRUIT+HOUTTUYNIA CORDATA WHOLE PLANT	0		1	(<1%)	1	(<1%)
SIMVASTATIN	0		1	(<1%)	1	(<1%)
SITAFLOXACIN	1	(<1%)	0		1	(<1%)
SODIUM BICARBONATE	0		1	(<1%)	1	(<1%)
SODIUM CHLORIDE+CIPROFLOXACIN LACTATE	0		1	(<1%)	1	(<1%)
SUDAFED (NOS)	1	(<1%)	0		1	(<1%)
SUPRAX (NOS)	1	(<1%)	0		1	(<1%)
THEOPHYLLINE SODIUM GLYCINATE	0		1	(<1%)	1	(<1%)
THEOPHYLLINE+ETOFYLLINE+MONTELUKAST	1	(<1%)	0		1	(<1%)
THEOPHYLLINE+MONTELUKAST SODIUM	1	(<1%)	0		1	(<1%)
THIAMINE HYDROCHLORIDE+NICOTINAMIDE+RIBOFLAVIN	0		1	(<1%)	1	(<1%)
TIOTROPIUM+OLODATEROL	1	(<1%)	0		1	(<1%)
TOZINAMERAN	0		1	(<1%)	1	(<1%)
TRIAMCINOLONE	1	(<1%)	0		1	(<1%)
UMIFENOVIR HYDROCHLORIDE	0		1	(<1%)	1	(<1%)

Note: Includes all COPD medications started before the first dose of investigational product.
/mnt/code/postcsr_01/prod/tfls/t_sp_c1_prior_ing_657.sas 21JUL2025 22:00

Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Table 111.12
Summary of COPD Medications Started Prior to Treatment by Ingredient in Study MEA117113

Ingredient	PBO (N=87)	100 SC (N=83)	Total (N=170)
Any medication	87 (100%)	83 (100%)	170 (100%)
TIOTROPIUM BROMIDE	71 (82%)	70 (84%)	141 (83%)
FLUTICASONE PROPIONATE+SALMETEROL XINAFOATE	50 (57%)	50 (60%)	100 (59%)
SALBUTAMOL	41 (47%)	42 (51%)	83 (49%)
BUDESONIDE+FORMOTEROL FUMARATE	29 (33%)	21 (25%)	50 (29%)
PREDNISOLONE	16 (18%)	21 (25%)	37 (22%)
THEOPHYLLINE	14 (16%)	17 (20%)	31 (18%)
PREDNISONE	12 (14%)	11 (13%)	23 (14%)
OXYGEN	11 (13%)	8 (10%)	19 (11%)
SALBUTAMOL SULFATE	7 (8%)	12 (14%)	19 (11%)
ERDOSTEINE	9 (10%)	7 (8%)	16 (9%)
IPRATROPIUM BROMIDE	8 (9%)	7 (8%)	15 (9%)
ROFLUMILAST	5 (6%)	9 (11%)	14 (8%)
AMOXICILLIN+CLAVULANIC ACID	3 (3%)	10 (12%)	13 (8%)
CLARITHROMYCIN	6 (7%)	7 (8%)	13 (8%)
TIOTROPIUM	4 (5%)	9 (11%)	13 (8%)
METHYLPREDNISOLONE	4 (5%)	8 (10%)	12 (7%)
MONTELUKAST SODIUM	5 (6%)	7 (8%)	12 (7%)
AMINOPHYLLINE	7 (8%)	4 (5%)	11 (6%)
AMOXICILLIN	4 (5%)	6 (7%)	10 (6%)
BUDESONIDE	7 (8%)	3 (4%)	10 (6%)
DOXOFYLLINE	7 (8%)	3 (4%)	10 (6%)
FENOTEROL HYDROBROMIDE+IPRATROPIUM BROMIDE	3 (3%)	7 (8%)	10 (6%)
LEVOFLOXACIN	7 (8%)	3 (4%)	10 (6%)
ACETYLCYSTEINE	4 (5%)	5 (6%)	9 (5%)
METHYLPREDNISOLONE SODIUM SUCCINATE	4 (5%)	5 (6%)	9 (5%)
ACLIDINIUM BROMIDE	5 (6%)	3 (4%)	8 (5%)
AZITHROMYCIN	4 (5%)	4 (5%)	8 (5%)
GLYCOPYRRONIUM BROMIDE	5 (6%)	3 (4%)	8 (5%)
CARBOCISTEINE	4 (5%)	3 (4%)	7 (4%)
CEFDITOREN PIVOXIL	2 (2%)	5 (6%)	7 (4%)

Note: Includes all COPD medications started before the first dose of investigational product.
/mnt/code/postcsr_01/prod/tfls/t_sp_cm_prior_ing_113.sas 21JUL2025 22:00

Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Table 111.12
Summary of COPD Medications Started Prior to Treatment by Ingredient in Study MEA117113

Ingredient	PBO (N=87)		100 SC (N=83)		Total (N=170)	
IPRATROPIUM BROMIDE+SALBUTAMOL SULFATE	1	(1%)	6	(7%)	7	(4%)
INDACATEROL MALEATE	3	(3%)	3	(4%)	6	(4%)
SALMETEROL	4	(5%)	2	(2%)	6	(4%)
BECLOMETASONE DIPROPIONATE+FORMOTEROL FUMARATE	2	(2%)	3	(4%)	5	(3%)
CEFUROXIME	2	(2%)	3	(4%)	5	(3%)
GLYCOPYRRONIUM BROMIDE+INDACATEROL MALEATE	3	(3%)	2	(2%)	5	(3%)
HYDROCORTISONE	3	(3%)	2	(2%)	5	(3%)
CIPROFLOXACIN	1	(1%)	3	(4%)	4	(2%)
DOXYCYCLINE	2	(2%)	2	(2%)	4	(2%)
FLUTICASONE	3	(3%)	1	(1%)	4	(2%)
FLUTICASONE PROPIONATE	1	(1%)	3	(4%)	4	(2%)
FLUTICASONE+SALMETEROL	1	(1%)	3	(4%)	4	(2%)
FORMOTEROL FUMARATE	1	(1%)	3	(4%)	4	(2%)
HEDERA HELIX EXTRACT	2	(2%)	2	(2%)	4	(2%)
HYDROCORTISONE SODIUM SUCCINATE	3	(3%)	1	(1%)	4	(2%)
MOXIFLOXACIN	3	(3%)	1	(1%)	4	(2%)
TERBUTALINE SULFATE	2	(2%)	2	(2%)	4	(2%)
AMBROXOL ACEFYLLINATE	3	(3%)	0		3	(2%)
CEFTRIAXONE	1	(1%)	2	(2%)	3	(2%)
CLOPERASTINE FENDIZOATE	1	(1%)	2	(2%)	3	(2%)
CODEINE PHOSPHATE	1	(1%)	2	(2%)	3	(2%)
FENOTEROL HYDROBROMIDE	1	(1%)	2	(2%)	3	(2%)
FENOTEROL+IPRATROPIUM BROMIDE	3	(3%)	0		3	(2%)
FLUTICASONE FUROATE+VILANTEROL TRIFENATATE	1	(1%)	2	(2%)	3	(2%)
FLUTICASONE PROPIONATE+FORMOTEROL FUMARATE	2	(2%)	1	(1%)	3	(2%)
IPRATROPIUM+SALBUTAMOL	1	(1%)	2	(2%)	3	(2%)
MONTELUKAST	0		3	(4%)	3	(2%)
ROXITHROMYCIN	0		3	(4%)	3	(2%)
AMBROXOL HYDROCHLORIDE	0		2	(2%)	2	(1%)
AMIKACIN	1	(1%)	1	(1%)	2	(1%)
BECLOMETASONE DIPROPIONATE	1	(1%)	1	(1%)	2	(1%)

Note: Includes all COPD medications started before the first dose of investigational product.

Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Table 111.12
Summary of COPD Medications Started Prior to Treatment by Ingredient in Study MEA117113

Ingredient	PBO (N=87)		100 SC (N=83)		Total (N=170)	
CICLESONIDE	0		2	(2%)	2	(1%)
COUGH COLD PREPARATIONS NOS	1	(1%)	1	(1%)	2	(1%)
EBASTINE+PSEUDOEPHEDRINE HYDROCHLORIDE	0		2	(2%)	2	(1%)
FEXOFENADINE HYDROCHLORIDE	1	(1%)	1	(1%)	2	(1%)
FLUTICASONE PROPIONATE+SALMETEROL	1	(1%)	1	(1%)	2	(1%)
GUAIFENESIN	0		2	(2%)	2	(1%)
HEDERA HELIX EXTRACT+RHIZOMA COPTIDIS EXTRACT	2	(2%)	0		2	(1%)
HYDROCORTISONE HYDROGEN SUCCINATE	2	(2%)	0		2	(1%)
INDACATEROL	1	(1%)	1	(1%)	2	(1%)
NORFLOXACIN	1	(1%)	1	(1%)	2	(1%)
OMEPRAZOLE	2	(2%)	0		2	(1%)
PIPERACILLIN SODIUM+SULBACTAM SODIUM	0		2	(2%)	2	(1%)
PIPERACILLIN SODIUM+TAZOBACTAM SODIUM	2	(2%)	0		2	(1%)
PROAIR (NOS)	1	(1%)	1	(1%)	2	(1%)
STREPTODORNASE+STREPTOKINASE	1	(1%)	1	(1%)	2	(1%)
ACONITE+CITRUS AURANTIUM+CODEINE PHOSPHATE+SAPONARIA OFFICINALIS EXTRACT+THYMUS VULGARIS	0		1	(1%)	1	(<1%)
AEROTROP (NOS)	0		1	(1%)	1	(<1%)
AMBIGUOUS MEDICATION NOS	1	(1%)	0		1	(<1%)
AMBROXOL	0		1	(1%)	1	(<1%)
AMPICILLIN SODIUM+SULBACTAM SODIUM	1	(1%)	0		1	(<1%)
AMPICILLIN+SULBACTAM	1	(1%)	0		1	(<1%)
AZELASTINE HYDROCHLORIDE	1	(1%)	0		1	(<1%)
BECLOMETASONE+FORMOTEROL	0		1	(1%)	1	(<1%)
BEPOTASTINE BESILATE	1	(1%)	0		1	(<1%)
BUDESONIDE+FORMOTEROL	0		1	(1%)	1	(<1%)
CEFALEXIN	0		1	(1%)	1	(<1%)
CEFCAPENE PIVOXIL HYDROCHLORIDE	0		1	(1%)	1	(<1%)
CEFPODOXIME PROXETIL	0		1	(1%)	1	(<1%)
CEFROXADINE	1	(1%)	0		1	(<1%)

Note: Includes all COPD medications started before the first dose of investigational product.
/mnt/code/postcsr_01/prod/tfls/t_sp_cm_prior_ing_113.sas 21JUL2025 22:00

Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Table 111.12
Summary of COPD Medications Started Prior to Treatment by Ingredient in Study MEA117113

Ingredient	PBO (N=87)		100 SC (N=83)		Total (N=170)	
CEFTIBUTEN	1	(1%)	0		1	(<1%)
CEFUROXIME AXETIL	1	(1%)	0		1	(<1%)
CILASTATIN SODIUM+IMIPENEM	0		1	(1%)	1	(<1%)
CLINDAMYCIN	0		1	(1%)	1	(<1%)
CLOTRIMAZOLE+FLUOCINOLONE ACETONIDE+NEOMYCIN SULFATE	0		1	(1%)	1	(<1%)
DESLORATADINE+PSEUDOEPHEDRINE SULFATE	0		1	(1%)	1	(<1%)
DIPHENHYDRAMINE HYDROCHLORIDE+DIPROPHYLLINE+EPHEDRINE HYDROCHLORIDE+NOSCAPINE HYDROCHLORIDE+PAPAVERINE HYDROCHLORIDE	1	(1%)	0		1	(<1%)
ETOFYLLINE+THEOPHYLLINE	1	(1%)	0		1	(<1%)
FENOTEROL	1	(1%)	0		1	(<1%)
FLUTICASONE FUROATE	1	(1%)	0		1	(<1%)
FORMOTEROL	0		1	(1%)	1	(<1%)
FORMOTEROL+MOMETASONE	0		1	(1%)	1	(<1%)
FUROSEMIDE	1	(1%)	0		1	(<1%)
GARENOXACIN MESILATE	1	(1%)	0		1	(<1%)
GEMIFLOXACIN MESILATE	0		1	(1%)	1	(<1%)
GUAIFENESIN+NOSCAPINE+PARACETAMOL+PHENYLEPHRINE HYDROCHLORIDE	0		1	(1%)	1	(<1%)
HAEMOPHILUS INFLUENZAE+KLEBSIELLA OZAENAE+KLEBSIELLA PNEUMONIAE+MORAXELLA CATARRHALIS+NEISSERIA CATARRHALIS+STAPHYLOCOCCUS AUREUS+STREPTOCOCCI	1	(1%)	0		1	(<1%)
HYDROXYZINE HYDROCHLORIDE	0		1	(1%)	1	(<1%)
IBUPROFEN	0		1	(1%)	1	(<1%)
IPRAVENT (NOS)	0		1	(1%)	1	(<1%)
LEVOCETIRIZINE HYDROCHLORIDE	1	(1%)	0		1	(<1%)
LEVODROPROPIZINE	1	(1%)	0		1	(<1%)
LEVOTUSS (NOS)	1	(1%)	0		1	(<1%)

Note: Includes all COPD medications started before the first dose of investigational product.
/mnt/code/postcsr_01/prod/tfls/t_sp_cm_prior_ing_113.sas 21JUL2025 22:00

Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Table 111.12
Summary of COPD Medications Started Prior to Treatment by Ingredient in Study MEA117113

Ingredient	PBO (N=87)		100 SC (N=83)		Total (N=170)	
LOSARTAN	1	(1%)	0		1	(<1%)
MOMETASONE FUROATE	1	(1%)	0		1	(<1%)
MOXIFLOXACIN HYDROCHLORIDE	0		1	(1%)	1	(<1%)
MUCOSOLVAN (NOS)	0		1	(1%)	1	(<1%)
MYRTOL	1	(1%)	0		1	(<1%)
OMNICEF (NOS)	0		1	(1%)	1	(<1%)
OXYCODONE HYDROCHLORIDE	0		1	(1%)	1	(<1%)
PARACETAMOL	0		1	(1%)	1	(<1%)
PSEUDOEPHEDRINE HYDROCHLORIDE	0		1	(1%)	1	(<1%)
PSEUDOEPHEDRINE HYDROCHLORIDE+TRIPROLIDINE HYDROCHLORIDE	0		1	(1%)	1	(<1%)
SULGLICOTIDE	1	(1%)	0		1	(<1%)
SUPRAX (NOS)	0		1	(1%)	1	(<1%)
TOSUFLOXACIN TOSILATE	1	(1%)	0		1	(<1%)
TULOBUTEROL HYDROCHLORIDE	0		1	(1%)	1	(<1%)
TYLENOL #2 (NOS)	1	(1%)	0		1	(<1%)
UMECLIDINIUM	1	(1%)	0		1	(<1%)
UMECLIDINIUM BROMIDE+VILANTEROL TRIFENATATE	1	(1%)	0		1	(<1%)
VILANTEROL	1	(1%)	0		1	(<1%)

Note: Includes all COPD medications started before the first dose of investigational product.
/mnt/code/postcsr_01/prod/tfls/t_sp_cm_prior_ing_113.sas 21JUL2025 22:00

Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Table 111.13
Summary of COPD Medications Started Prior to Treatment by Ingredient in Study MEA117106

Ingredient	PBO (N=90)	100 SC (N=82)	Total (N=172)
Any medication	90 (100%)	82 (100%)	172 (100%)
TIOTROPIUM BROMIDE	66 (73%)	70 (85%)	136 (79%)
SALBUTAMOL	48 (53%)	50 (61%)	98 (57%)
FLUTICASONE PROPIONATE+SALMETEROL XINAFOATE	46 (51%)	46 (56%)	92 (53%)
PREDNISONE	22 (24%)	23 (28%)	45 (26%)
THEOPHYLLINE	20 (22%)	17 (21%)	37 (22%)
LEVOFLOXACIN	15 (17%)	18 (22%)	33 (19%)
IPRATROPIUM BROMIDE	19 (21%)	12 (15%)	31 (18%)
BUDESONIDE+FORMOTEROL FUMARATE	15 (17%)	13 (16%)	28 (16%)
FLUTICASONE PROPIONATE	15 (17%)	11 (13%)	26 (15%)
METHYLPREDNISOLONE	13 (14%)	10 (12%)	23 (13%)
PREDNISOLONE	15 (17%)	7 (9%)	22 (13%)
FENOTEROL HYDROBROMIDE+IPRATROPIUM BROMIDE	10 (11%)	10 (12%)	20 (12%)
GLYCOPYRRONIUM BROMIDE	10 (11%)	10 (12%)	20 (12%)
INDACATEROL MALEATE	9 (10%)	11 (13%)	20 (12%)
AMOXICILLIN+CLAVULANIC ACID	10 (11%)	9 (11%)	19 (11%)
AZITHROMYCIN	13 (14%)	6 (7%)	19 (11%)
BUDESONIDE	14 (16%)	5 (6%)	19 (11%)
TIOTROPIUM	13 (14%)	6 (7%)	19 (11%)
ACETYLCYSTEINE	8 (9%)	7 (9%)	15 (9%)
CIPROFLOXACIN	8 (9%)	7 (9%)	15 (9%)
OXYGEN	6 (7%)	9 (11%)	15 (9%)
CICLESONIDE	9 (10%)	5 (6%)	14 (8%)
DOXYCYCLINE	5 (6%)	6 (7%)	11 (6%)
IPRATROPIUM BROMIDE+SALBUTAMOL SULFATE	6 (7%)	5 (6%)	11 (6%)
CLARITHROMYCIN	5 (6%)	5 (6%)	10 (6%)
BECLOMETASONE DIPROPIONATE+FORMOTEROL FUMARATE	6 (7%)	3 (4%)	9 (5%)
ROFLUMILAST	5 (6%)	4 (5%)	9 (5%)
ACLIDINIUM BROMIDE	7 (8%)	1 (1%)	8 (5%)
DEFLAZACORT	5 (6%)	3 (4%)	8 (5%)
FORMOTEROL	6 (7%)	2 (2%)	8 (5%)

Note: Includes all COPD medications started before the first dose of investigational product.

Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Table 111.13
Summary of COPD Medications Started Prior to Treatment by Ingredient in Study MEA117106

Ingredient	PBO (N=90)		100 SC (N=82)		Total (N=172)	
MOXIFLOXACIN	5	(6%)	3	(4%)	8	(5%)
TERBUTALINE SULFATE	8	(9%)	0		8	(5%)
FLUTICASONE PROPIONATE+SALMETEROL	4	(4%)	3	(4%)	7	(4%)
AMINOPHYLLINE	5	(6%)	1	(1%)	6	(3%)
AMOXICILLIN+CLAVULANATE POTASSIUM	3	(3%)	3	(4%)	6	(3%)
CIPROFLOXACIN HYDROCHLORIDE	4	(4%)	2	(2%)	6	(3%)
FLUTICASONE+SALMETEROL	3	(3%)	3	(4%)	6	(3%)
SALBUTAMOL SULFATE	3	(3%)	3	(4%)	6	(3%)
SALMETEROL	3	(3%)	3	(4%)	6	(3%)
SULFAMETHOXAZOLE+TRIMETHOPRIM	3	(3%)	3	(4%)	6	(3%)
AMOXICILLIN	3	(3%)	2	(2%)	5	(3%)
BECLOMETASONE	2	(2%)	3	(4%)	5	(3%)
CEFTRIAXONE SODIUM	3	(3%)	2	(2%)	5	(3%)
FLUTICASONE	2	(2%)	3	(4%)	5	(3%)
MONTELUKAST SODIUM	3	(3%)	2	(2%)	5	(3%)
AMBROXOL HYDROCHLORIDE	2	(2%)	2	(2%)	4	(2%)
CARBOCISTEINE	2	(2%)	2	(2%)	4	(2%)
CEFUROXIME	2	(2%)	2	(2%)	4	(2%)
CEFUROXIME AXETIL	2	(2%)	2	(2%)	4	(2%)
ERDOSTEINE	2	(2%)	2	(2%)	4	(2%)
FLUTICASONE PROPIONATE+FORMOTEROL FUMARATE	3	(3%)	1	(1%)	4	(2%)
FORMOTEROL FUMARATE	3	(3%)	1	(1%)	4	(2%)
METHYLPREDNISOLONE HEMISUCCINATE	2	(2%)	2	(2%)	4	(2%)
PREDNISONE ACETATE	2	(2%)	2	(2%)	4	(2%)
PROAIR (NOS)	1	(1%)	3	(4%)	4	(2%)
AMBROXOL	1	(1%)	2	(2%)	3	(2%)
BUDESONIDE+FORMOTEROL	2	(2%)	1	(1%)	3	(2%)
CEFTRIAXONE	3	(3%)	0		3	(2%)
DUOMOX (NOS)	2	(2%)	1	(1%)	3	(2%)
GLYCOPYRRONIUM BROMIDE+INDACATEROL MALEATE	1	(1%)	2	(2%)	3	(2%)
INDACATEROL	1	(1%)	2	(2%)	3	(2%)

Note: Includes all COPD medications started before the first dose of investigational product.

Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Table 111.13
Summary of COPD Medications Started Prior to Treatment by Ingredient in Study MEA117106

Ingredient	PBO (N=90)		100 SC (N=82)		Total (N=172)	
IPRATROPIUM	3	(3%)	0		3	(2%)
METHYLPREDNISOLONE SODIUM SUCCINATE	1	(1%)	2	(2%)	3	(2%)
SALMETEROL XINAFOATE	1	(1%)	2	(2%)	3	(2%)
BETAMETHASONE SODIUM PHOSPHATE	0		2	(2%)	2	(1%)
CLAMOXYL (NOS)	2	(2%)	0		2	(1%)
DEXAMETHASONE SODIUM PHOSPHATE	1	(1%)	1	(1%)	2	(1%)
ERYTHROMYCIN	1	(1%)	1	(1%)	2	(1%)
FENOTEROL+IPRATROPIUM BROMIDE	1	(1%)	1	(1%)	2	(1%)
FLUCONAZOLE	0		2	(2%)	2	(1%)
FLUTICASONE FUROATE+VILANTEROL TRIFENATATE	1	(1%)	1	(1%)	2	(1%)
FORMOTEROL FUMARATE+MOMETASONE FUROATE	1	(1%)	1	(1%)	2	(1%)
IPRATROPIUM+SALBUTAMOL	1	(1%)	1	(1%)	2	(1%)
MONTELUKAST	1	(1%)	1	(1%)	2	(1%)
PIPERACILLIN+TAZOBACTAM	2	(2%)	0		2	(1%)
SPIRAMYCIN	0		2	(2%)	2	(1%)
ALENDRONATE SODIUM+COLECALCIFEROL	1	(1%)	0		1	(<1%)
AMPISID (NOS)	1	(1%)	0		1	(<1%)
ANTIBIOTICS NOS	0		1	(1%)	1	(<1%)
ARFORMOTEROL TARTRATE	0		1	(1%)	1	(<1%)
BECLOMETASONE DIPROPIONATE	1	(1%)	0		1	(<1%)
BECLOMETASONE+FORMOTEROL	1	(1%)	0		1	(<1%)
BENZYLPENICILLIN	0		1	(1%)	1	(<1%)
BETAMETHASONE	1	(1%)	0		1	(<1%)
BETAMETHASONE+DEXCHLORPHENIRAMINE MALEATE	1	(1%)	0		1	(<1%)
BRIMONIDINE TARTRATE	0		1	(1%)	1	(<1%)
BROMHEXINE HYDROCHLORIDE	0		1	(1%)	1	(<1%)
CARBOCISTEINE LYSINE	0		1	(1%)	1	(<1%)
CEFACLOR	0		1	(1%)	1	(<1%)
CEFALEXIN	1	(1%)	0		1	(<1%)
CEFDITOREN	0		1	(1%)	1	(<1%)
CEFDITOREN PIVOXIL	0		1	(1%)	1	(<1%)

Note: Includes all COPD medications started before the first dose of investigational product.

Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Table 111.13
Summary of COPD Medications Started Prior to Treatment by Ingredient in Study MEA117106

Ingredient	PBO (N=90)		100 SC (N=82)		Total (N=172)	
CEFPODOXIME PROXETIL	1	(1%)	0		1	(<1%)
CEFTAZIDIME	0		1	(1%)	1	(<1%)
CEFZIL (NOS)	1	(1%)	0		1	(<1%)
CETIRIZINE	0		1	(1%)	1	(<1%)
CETIRIZINE HYDROCHLORIDE	0		1	(1%)	1	(<1%)
CILASTATIN+IMIPENEM	1	(1%)	0		1	(<1%)
CLEMASTINE	0		1	(1%)	1	(<1%)
COMPRESSED AIR	1	(1%)	0		1	(<1%)
DEXAMETHASONE	1	(1%)	0		1	(<1%)
FLUMIL (NOS)	0		1	(1%)	1	(<1%)
FLUTICASONE+FORMOTEROL	1	(1%)	0		1	(<1%)
FLUTICASONE+VILANTEROL	1	(1%)	0		1	(<1%)
FUROSEMIDE	0		1	(1%)	1	(<1%)
GENTAMICIN	1	(1%)	0		1	(<1%)
HYDROCORTISONE	1	(1%)	0		1	(<1%)
IPRATROPIUM BROMIDE+SALBUTAMOL	1	(1%)	0		1	(<1%)
LANSOPRAZOLE	1	(1%)	0		1	(<1%)
LEVOSALBUTAMOL HYDROCHLORIDE	0		1	(1%)	1	(<1%)
LORAZEPAM	1	(1%)	0		1	(<1%)
LOSARTAN POTASSIUM	0		1	(1%)	1	(<1%)
MUCODOX (NOS)	1	(1%)	0		1	(<1%)
MUCOSOLVAN (NOS)	0		1	(1%)	1	(<1%)
NEBIVOLOL HYDROCHLORIDE	0		1	(1%)	1	(<1%)
OMALIZUMAB	1	(1%)	0		1	(<1%)
PENTOXIFYLLINE	0		1	(1%)	1	(<1%)
PIPERACILLIN SODIUM+TAZOBACTAM SODIUM	1	(1%)	0		1	(<1%)
POTASSIUM CHLORIDE	0		1	(1%)	1	(<1%)
PRISTINAMYCIN	1	(1%)	0		1	(<1%)
ROXITHROMYCIN	0		1	(1%)	1	(<1%)
SODIUM CHLORIDE	0		1	(1%)	1	(<1%)
TOBRAMYCIN	1	(1%)	0		1	(<1%)

Note: Includes all COPD medications started before the first dose of investigational product.

Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Table 111.14
Summary of COPD Medications Started During Treatment by
Respiratory Medication Class in Study 208657

Respiratory Medication Class Ingredient	PBO (N=401)	100 SC (N=403)	Total (N=804)
Any medication	109 (27%)	87 (22%)	196 (24%)
Corticosteroid			
Any medication	78 (19%)	39 (10%)	117 (15%)
PREDNISOLONE	20 (5%)	4 (<1%)	24 (3%)
PREDNISONE	13 (3%)	4 (<1%)	17 (2%)
BUDESONIDE	7 (2%)	6 (1%)	13 (2%)
METHYLPREDNISOLONE	8 (2%)	5 (1%)	13 (2%)
GLYCOPYRRONIUM BROMIDE+BUDESONIDE+FORMOTEROL FUMARATE	8 (2%)	4 (<1%)	12 (1%)
FLUTICASONE FUROATE+VILANTEROL TRIFENATATE+UMECLIDINIUM BROMIDE	7 (2%)	3 (<1%)	10 (1%)
GLYCOPYRRONIUM BROMIDE+BECLOMETASONE DIPROPIONATE+FORMOTEROL FUMARATE	7 (2%)	3 (<1%)	10 (1%)
BUDESONIDE+FORMOTEROL FUMARATE	6 (1%)	3 (<1%)	9 (1%)
METHYLPREDNISOLONE SODIUM SUCCINATE	4 (<1%)	3 (<1%)	7 (<1%)
BUDESONIDE+FORMOTEROL	3 (<1%)	2 (<1%)	5 (<1%)
BECLOMETASONE DIPROPIONATE+FORMOTEROL FUMARATE	2 (<1%)	2 (<1%)	4 (<1%)
CICLESONIDE	1 (<1%)	3 (<1%)	4 (<1%)
SALMETEROL XINAFOATE+FLUTICASONE PROPIONATE	3 (<1%)	1 (<1%)	4 (<1%)
DEXAMETHASONE SODIUM PHOSPHATE	1 (<1%)	2 (<1%)	3 (<1%)
FLUTICASONE FUROATE+VILANTEROL TRIFENATATE	1 (<1%)	2 (<1%)	3 (<1%)
BECLOMETASONE	2 (<1%)	0	2 (<1%)
DEXAMETHASONE	1 (<1%)	1 (<1%)	2 (<1%)
FLUTICASONE FUROATE	1 (<1%)	1 (<1%)	2 (<1%)
HYDROCORTISONE	1 (<1%)	1 (<1%)	2 (<1%)
BETAMETHASONE SODIUM PHOSPHATE+BETAMETHASONE DIPROPIONATE	1 (<1%)	0	1 (<1%)
DECADRON (NOS)	1 (<1%)	0	1 (<1%)
DIPROSPAN (NOS)	1 (<1%)	0	1 (<1%)

Note: Includes COPD medications started after first dose and before last dose + 28 days.
Note: Multi-component medications are displayed under the respiratory medication class of each component.

Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Table 111.14
Summary of COPD Medications Started During Treatment by
Respiratory Medication Class in Study 208657

Respiratory Medication Class Ingredient	PBO (N=401)	100 SC (N=403)	Total (N=804)
FLUTICASONE	0	1 (<1%)	1 (<1%)
FLUTICASONE PROPIONATE	1 (<1%)	0	1 (<1%)
GLYCOPYRRONIUM BROMIDE+BECLOMETASONE DIPROPIONATE+FORMOTEROL FUMARATE DIHYDRATE	1 (<1%)	0	1 (<1%)
GLYCOPYRRONIUM BROMIDE+BUDESONIDE+FORMOTEROL FUMARATE DIHYDRATE	1 (<1%)	0	1 (<1%)
GLYCOPYRRONIUM BROMIDE+MOMETASONE FUROATE+INDACATEROL ACETATE	1 (<1%)	0	1 (<1%)
GLYCOPYRRONIUM+BECLOMETASONE+FORMOTEROL	1 (<1%)	0	1 (<1%)
MOMETASONE FUROATE+FORMOTEROL FUMARATE	0	1 (<1%)	1 (<1%)
SALMETEROL+FLUTICASONE	1 (<1%)	0	1 (<1%)

Note: Includes COPD medications started after first dose and before last dose + 28 days.
Note: Multi-component medications are displayed under the respiratory medication class of each component.

Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Table 111.14
Summary of COPD Medications Started During Treatment by
Respiratory Medication Class in Study 208657

Respiratory Medication Class Ingredient	PBO (N=401)	100 SC (N=403)	Total (N=804)
Long-acting anticholinergic			
Any medication	34 (8%)	18 (4%)	52 (6%)
GLYCOPYRRONIUM BROMIDE+BUDESONIDE+FORMOTEROL FUMARATE	8 (2%)	4 (<1%)	12 (1%)
FLUTICASONE FUROATE+VILANTEROL TRIFENATATE+UMECLIDINIUM BROMIDE	7 (2%)	3 (<1%)	10 (1%)
GLYCOPYRRONIUM BROMIDE+BECLOMETASONE DIPROPIONATE+FORMOTEROL FUMARATE	7 (2%)	3 (<1%)	10 (1%)
TIOTROPIUM BROMIDE MONOHYDRATE	4 (<1%)	3 (<1%)	7 (<1%)
TIOTROPIUM BROMIDE MONOHYDRATE+OLODATEROL HYDROCHLORIDE	3 (<1%)	3 (<1%)	6 (<1%)
TIOTROPIUM BROMIDE	3 (<1%)	2 (<1%)	5 (<1%)
GLYCOPYRRONIUM BROMIDE	2 (<1%)	0	2 (<1%)
TIOTROPIUM	2 (<1%)	0	2 (<1%)
UMECLIDINIUM	0	2 (<1%)	2 (<1%)
GLYCOPYRRONIUM BROMIDE+BECLOMETASONE DIPROPIONATE+FORMOTEROL FUMARATE DIHYDRATE	1 (<1%)	0	1 (<1%)
GLYCOPYRRONIUM BROMIDE+BUDESONIDE+FORMOTEROL FUMARATE DIHYDRATE	1 (<1%)	0	1 (<1%)
GLYCOPYRRONIUM BROMIDE+FORMOTEROL FUMARATE	1 (<1%)	0	1 (<1%)
GLYCOPYRRONIUM BROMIDE+INDACATEROL MALEATE	1 (<1%)	0	1 (<1%)
GLYCOPYRRONIUM BROMIDE+MOMETASONE FUROATE+INDACATEROL ACETATE	1 (<1%)	0	1 (<1%)
GLYCOPYRRONIUM+BECLOMETASONE+FORMOTEROL	1 (<1%)	0	1 (<1%)
TIOTROPIUM+OLODATEROL	1 (<1%)	0	1 (<1%)
UMECLIDINIUM BROMIDE	1 (<1%)	0	1 (<1%)
VILANTEROL TRIFENATATE+UMECLIDINIUM BROMIDE	1 (<1%)	0	1 (<1%)
VILANTEROL+UMECLIDINIUM	1 (<1%)	0	1 (<1%)

Note: Includes COPD medications started after first dose and before last dose + 28 days.
Note: Multi-component medications are displayed under the respiratory medication class of each component.

Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Table 111.14
Summary of COPD Medications Started During Treatment by
Respiratory Medication Class in Study 208657

Respiratory Medication Class Ingredient	PBO (N=401)	100 SC (N=403)	Total (N=804)
Short-acting beta-2 agonist			
Any medication	24 (6%)	28 (7%)	52 (6%)
SALBUTAMOL	12 (3%)	12 (3%)	24 (3%)
SALBUTAMOL SULFATE	4 (<1%)	7 (2%)	11 (1%)
FENOTEROL HYDROBROMIDE+IPRATROPIUM BROMIDE	3 (<1%)	2 (<1%)	5 (<1%)
AMINOPHYLLINE+CHLORPHENAMINE MALEATE+METHOXYPHENAMINE HYDROCHLORIDE+NOSCAPINE	2 (<1%)	2 (<1%)	4 (<1%)
SALBUTAMOL SULFATE+IPRATROPIUM BROMIDE	1 (<1%)	3 (<1%)	4 (<1%)
EPHEDRA SINICA+ARCTIUM LAPPA+SCHISANDRA NOS+OCIMUM BASILICUM+LUMBRICUS TERRESTRIS+PEUCEDANUM (NOS)+HERBALS NOS	1 (<1%)	1 (<1%)	2 (<1%)
BROMHEXINE HYDROCHLORIDE+GUAIFENESIN+TERBUTALINE SULFATE	0	1 (<1%)	1 (<1%)
DIHYDROCODEINE BITARTRATE+CHLORPHENAMINE MALEATE+AMMONIUM CHLORIDE+METHYLEPHEDRINE HYDROCHLORIDE+PELARGONIUM SIDOIDES	0	1 (<1%)	1 (<1%)
GUAIFENESIN+DIHYDROCODEINE BITARTRATE+CHLORPHENAMINE MALEATE+METHYLEPHEDRINE HYDROCHLORIDE	1 (<1%)	0	1 (<1%)
GUAIFENESIN+TERBUTALINE+AMBROXOL	0	1 (<1%)	1 (<1%)
LEVOSALBUTAMOL HYDROCHLORIDE	0	1 (<1%)	1 (<1%)
PROCATEROL HYDROCHLORIDE	1 (<1%)	0	1 (<1%)
SALBUTAMOL+IPRATROPIUM	1 (<1%)	0	1 (<1%)
SALBUTAMOL+IPRATROPIUM BROMIDE	1 (<1%)	0	1 (<1%)
TERBUTALINE	1 (<1%)	0	1 (<1%)

Note: Includes COPD medications started after first dose and before last dose + 28 days.
Note: Multi-component medications are displayed under the respiratory medication class of each component.

Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Table 111.14
Summary of COPD Medications Started During Treatment by
Respiratory Medication Class in Study 208657

Respiratory Medication Class Ingredient	PBO (N=401)	100 SC (N=403)	Total (N=804)
Antiinfectives (antibiotics, antiseptics)			
Any medication	24 (6%)	26 (6%)	50 (6%)
AZITHROMYCIN	10 (2%)	6 (1%)	16 (2%)
LEVOFLOXACIN	5 (1%)	3 (<1%)	8 (<1%)
AMOXICILLIN+CLAVULANIC ACID	1 (<1%)	3 (<1%)	4 (<1%)
DOXYCYCLINE	1 (<1%)	3 (<1%)	4 (<1%)
AMOXICILLIN	2 (<1%)	1 (<1%)	3 (<1%)
BENZYLPENICILLIN SODIUM	1 (<1%)	1 (<1%)	2 (<1%)
CEFDINIR	0	2 (<1%)	2 (<1%)
CEFDITOREN PIVOXIL	1 (<1%)	1 (<1%)	2 (<1%)
CLARITHROMYCIN	1 (<1%)	1 (<1%)	2 (<1%)
AMOXICILLIN SODIUM+CLAVULANIC ACID	0	1 (<1%)	1 (<1%)
AMOXICILLIN+CLAVULANATE POTASSIUM	0	1 (<1%)	1 (<1%)
AMPICILLIN	1 (<1%)	0	1 (<1%)
AMPICILLIN+SULBACTAM	0	1 (<1%)	1 (<1%)
BENZYLPENICILLIN	0	1 (<1%)	1 (<1%)
CEFDITOREN	1 (<1%)	0	1 (<1%)
CEFIXIME	0	1 (<1%)	1 (<1%)
CEFOPERAZONE SODIUM+SULBACTAM SODIUM	0	1 (<1%)	1 (<1%)
CEFPROZIL	0	1 (<1%)	1 (<1%)
CEFTAZIDIME	0	1 (<1%)	1 (<1%)
CEFUROXIME	1 (<1%)	0	1 (<1%)
CIPROFLOXACIN	1 (<1%)	0	1 (<1%)
CLAVULANIC ACID	1 (<1%)	0	1 (<1%)
DOXYCYCLINE HYDROCHLORIDE	0	1 (<1%)	1 (<1%)
FORSYTHIA SUSPENSA FRUIT+TRICHOSANTHES NOS+COPTIS SPP RHIZOME+CALCIUM SULFATE DIHYDRATE+PAEONIA SPP ROOT+GARDENIA JASMINOIDES FRUIT+HERBALS NOS	1 (<1%)	0	1 (<1%)
GLYCYRRHIZA (NOS)	1 (<1%)	0	1 (<1%)

Note: Includes COPD medications started after first dose and before last dose + 28 days.
Note: Multi-component medications are displayed under the respiratory medication class of each component.

Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Table 111.14
Summary of COPD Medications Started During Treatment by
Respiratory Medication Class in Study 208657

Respiratory Medication Class Ingredient	PBO (N=401)	100 SC (N=403)	Total (N=804)
ISATIS TINCTORIA ROOT	0	1 (<1%)	1 (<1%)
LATAMOXEF SODIUM	0	1 (<1%)	1 (<1%)
LEVOFLOXACIN LACTATE	0	1 (<1%)	1 (<1%)
LEVOMENTHOL+SOPHORA TONKINENSIS ROOT WITH RHIZOME+ARDISIA CRISPA LEAF+ARDISIA CRISPA ROOT+CICADA SLOUGH	1 (<1%)	0	1 (<1%)
LONICERA JAPONICA+SARCANDRA GLABRA+MENTHOL	1 (<1%)	0	1 (<1%)
MOXIFLOXACIN HYDROCHLORIDE	0	1 (<1%)	1 (<1%)
OPTAMOX (NOS)	1 (<1%)	0	1 (<1%)
PIPERACILLIN SODIUM+TAZOBACTAM SODIUM	0	1 (<1%)	1 (<1%)
PIPERACILLIN+TAZOBACTAM	1 (<1%)	0	1 (<1%)
REHMANNIA GLUTINOSA+CODONOPSIS PILOSULA+SCHISANDRA CHINENSIS FRUIT+MORUS ALBA ROOT BARK+ASTER TATARICUS ROOT WITH RHIZOME+ASTRAGALUS MONGHOLICUS ROOT	0	1 (<1%)	1 (<1%)
ROXITHROMYCIN	1 (<1%)	0	1 (<1%)
SITAFLOXACIN	0	1 (<1%)	1 (<1%)
SODIUM BENZOATE+CAMPHOR+PAPAVER SOMNIFERUM+GLYCYRRHIZA SPP. ROOT WITH RHIZOME+ILLICIUM VERUM OIL	1 (<1%)	0	1 (<1%)
SODIUM CHLORIDE+LEVOFLOXACIN	1 (<1%)	0	1 (<1%)
SULFAMETHOXAZOLE+TRIMETHOPRIM	1 (<1%)	0	1 (<1%)

Note: Includes COPD medications started after first dose and before last dose + 28 days.
Note: Multi-component medications are displayed under the respiratory medication class of each component.

Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Table 111.14
Summary of COPD Medications Started During Treatment by
Respiratory Medication Class in Study 208657

Respiratory Medication Class Ingredient	PBO (N=401)	100 SC (N=403)	Total (N=804)
Other			
Any medication	27 (7%)	20 (5%)	47 (6%)
CINEOLE+PINENE+DIPENTEN	3 (<1%)	7 (2%)	10 (1%)
SODIUM CHLORIDE	4 (<1%)	1 (<1%)	5 (<1%)
TRADITIONAL CHINESE MEDICINE NOS	1 (<1%)	4 (<1%)	5 (<1%)
AMINOPHYLLINE+CHLORPHENAMINE MALEATE+METHOXYPHENAMINE HYDROCHLORIDE+NOSCAPINE	2 (<1%)	2 (<1%)	4 (<1%)
FUROSEMIDE	3 (<1%)	0	3 (<1%)
PARACETAMOL	2 (<1%)	1 (<1%)	3 (<1%)
ENOXAPARIN SODIUM	2 (<1%)	0	2 (<1%)
EPHEDRA SINICA+ARCTIUM LAPPA+SCHISANDRA NOS+OCIMUM BASILICUM+LUMBRICUS TERRESTRIS+PEUCEDANUM (NOS)+HERBALS NOS	1 (<1%)	1 (<1%)	2 (<1%)
MORPHINE	2 (<1%)	0	2 (<1%)
ACETAZOLAMIDE	0	1 (<1%)	1 (<1%)
ACETYLSALICYLIC ACID	0	1 (<1%)	1 (<1%)
ANYCOUGH (NOS)	0	1 (<1%)	1 (<1%)
ASCORIL (NOS)	0	1 (<1%)	1 (<1%)
ASTRAGALUS MEMBRANACEUS+ATRACTYLODES MACROCEPHALA+SAPOSHNIKOVIA DIVARICATA	0	1 (<1%)	1 (<1%)
BISOPROLOL	1 (<1%)	0	1 (<1%)
CARTHAMUS TINCTORIUS+ANGELICA+SALVIA (NOS)+PAEONIA (NOS)+LIGUSTICUM CHUANXIANG	1 (<1%)	0	1 (<1%)
CETIRIZINE HYDROCHLORIDE	1 (<1%)	0	1 (<1%)
CINEOLE	1 (<1%)	0	1 (<1%)
CINEOLE+PINENE	1 (<1%)	0	1 (<1%)
COUGH COLD PREPARATIONS NOS	0	1 (<1%)	1 (<1%)
DESLORATADINE CITRATE DISODIUM	0	1 (<1%)	1 (<1%)

Note: Includes COPD medications started after first dose and before last dose + 28 days.
Note: Multi-component medications are displayed under the respiratory medication class of each component.

Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Table 111.14
Summary of COPD Medications Started During Treatment by
Respiratory Medication Class in Study 208657

Respiratory Medication Class Ingredient	PBO (N=401)	100 SC (N=403)	Total (N=804)
DIHYDROCODEINE BITARTRATE+CHLORPHENAMINE MALEATE+AMMONIUM CHLORIDE+METHYLEPHEDRINE HYDROCHLORIDE+PELARGONIUM SIDOIDES	0	1 (<1%)	1 (<1%)
ENALAPRIL	0	1 (<1%)	1 (<1%)
FORSYTHIA SUSPENSA FRUIT+TRICHOSANTHES NOS+COPTIS SPP RHIZOME+CALCIUM SULFATE DIHYDRATE+PAEONIA SPP ROOT+GARDENIA JASMINOIDES FRUIT+HERBALS NOS	1 (<1%)	0	1 (<1%)
GELOMYRTOL (NOS)	1 (<1%)	0	1 (<1%)
GLYCOPYRRONIUM BROMIDE+MOMETASONE FUROATE+INDACATEROL ACETATE	1 (<1%)	0	1 (<1%)
GLYCYRRHIZA SPP. ROOT WITH RHIZOME+ASTER TATARICUS ROOT WITH RHIZOME+EPHEDRA SPP. STEM+HERBALS NOS	0	1 (<1%)	1 (<1%)
GLYCYRRHIZA SPP. ROOT WITH RHIZOME+ASTER TATARICUS ROOT WITH RHIZOME+GEKKO GECKO+CALCIUM SULFATE DIHYDRATE+TURTLE CARAPACE+HERBALS NOS	1 (<1%)	0	1 (<1%)
GUAIFENESIN+DIHYDROCODEINE BITARTRATE+CHLORPHENAMINE MALEATE+METHYLEPHEDRINE HYDROCHLORIDE	1 (<1%)	0	1 (<1%)
GUAIFENESIN+PSEUDOEPHEDRINE HYDROCHLORIDE+PHOLCODINE+TRIPROLIDINE HYDROCHLORIDE	1 (<1%)	0	1 (<1%)
HEDERA HELIX	0	1 (<1%)	1 (<1%)
HEDERA HELIX EXTRACT+RHIZOMA COPTIDIS EXTRACT	1 (<1%)	0	1 (<1%)
HEPARIN (NOS)	0	1 (<1%)	1 (<1%)
IBUPROFEN	1 (<1%)	0	1 (<1%)
IMIDAZOLE SALICYLATE	0	1 (<1%)	1 (<1%)
ISATIS TINCTORIA+PRUNUS ARMENIACA+POGOSTEMON CABLIN+HERBALS NOS+RHUBARB+CALCIUM SULFATE	1 (<1%)	0	1 (<1%)

Note: Includes COPD medications started after first dose and before last dose + 28 days.
Note: Multi-component medications are displayed under the respiratory medication class of each component.

Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Table 111.14
Summary of COPD Medications Started During Treatment by
Respiratory Medication Class in Study 208657

Respiratory Medication Class Ingredient	PBO (N=401)	100 SC (N=403)	Total (N=804)
IVABRADINE HYDROCHLORIDE	1 (<1%)	0	1 (<1%)
LEVODROPROPIZINE	1 (<1%)	0	1 (<1%)
LEVOMENTHOL+SOPHORA TONKINENSIS ROOT WITH RHIZOME+ARDISIA CRISPA LEAF+ARDISIA CRISPA ROOT+CICADA SLOUGH	1 (<1%)	0	1 (<1%)
LONICERA JAPONICA+SARCANDRA GLABRA+MENTHOL	1 (<1%)	0	1 (<1%)
LORATADINE	0	1 (<1%)	1 (<1%)
MAGNESIUM	1 (<1%)	0	1 (<1%)
MAGNESIUM SULFATE	1 (<1%)	0	1 (<1%)
METAMIZOLE SODIUM	0	1 (<1%)	1 (<1%)
METOCLOPRAMIDE	0	1 (<1%)	1 (<1%)
MUCOLIT (NOS)	1 (<1%)	0	1 (<1%)
NADROPARIN	1 (<1%)	0	1 (<1%)
NUTRITIONAL SUPPLEMENT NOS	0	1 (<1%)	1 (<1%)
OMEPRAZOLE	0	1 (<1%)	1 (<1%)
PORIA COCOS SCLEROTIUM+GLYCYRRHIZA SPP. ROOT WITH RHIZOME+PINELLIA TERNATA TUBER+CITRUS X AURANTIUM FRUIT PEEL	1 (<1%)	0	1 (<1%)
POTASSIUM CHLORIDE	1 (<1%)	0	1 (<1%)
PROMETHAZINE HYDROCHLORIDE+AMMONIUM CHLORIDE+SULFOGAIACOL	0	1 (<1%)	1 (<1%)
PROMETHAZINE+DEXTROMETHORPHAN	0	1 (<1%)	1 (<1%)
PSEUDOEPHEDRINE HYDROCHLORIDE+EBASTINE	0	1 (<1%)	1 (<1%)
QUERCETIN	0	1 (<1%)	1 (<1%)
RABEPRAZOLE SODIUM	0	1 (<1%)	1 (<1%)
RADIX PLATYCODI+ERIOBOTRYA JAPONICA+STEMONA (NOS)	0	1 (<1%)	1 (<1%)

Note: Includes COPD medications started after first dose and before last dose + 28 days.
Note: Multi-component medications are displayed under the respiratory medication class of each component.

Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Table 111.14
Summary of COPD Medications Started During Treatment by
Respiratory Medication Class in Study 208657

Respiratory Medication Class Ingredient	PBO (N=401)	100 SC (N=403)	Total (N=804)
REHMANNIA GLUTINOSA+CODONOPSIS PILOSULA+SCHISANDRA CHINENSIS FRUIT+MORUS ALBA ROOT BARK+ASTER TATARICUS ROOT WITH RHIZOME+ASTRAGALUS MONGHOLICUS ROOT	0	1 (<1%)	1 (<1%)
REHMANNIAE RADIX+POGOSTEMON CABLIN OIL+FORSYTHIA NOS+ANEMARRHENA ASPHODELOIDES+RHIZOMA PHRAGMITIS+CALCIUM SULFATE+RHIZOMA CURCUMAE	0	1 (<1%)	1 (<1%)
SODIUM BENZOATE+CAMPHOR+PAPAVER SOMNIFERUM+GLYCYRRHIZA SPP. ROOT WITH RHIZOME+ILLICIUM VERUM OIL	1 (<1%)	0	1 (<1%)
SODIUM CHLORIDE+LEVOFLOXACIN	1 (<1%)	0	1 (<1%)
SPIRONOLACTONE	0	1 (<1%)	1 (<1%)
UNCODED	1 (<1%)	0	1 (<1%)
VITAMINS NOS	0	1 (<1%)	1 (<1%)
VITEX AGNUS CASTUS+ISATIS TINCTORIA+LONICERA JAPONICA+CHRYSANTHEMUM (NOS)+EVODIA RUTAECARPA+ILEX NOS	1 (<1%)	0	1 (<1%)

Note: Includes COPD medications started after first dose and before last dose + 28 days.
Note: Multi-component medications are displayed under the respiratory medication class of each component.

Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Table 111.14
Summary of COPD Medications Started During Treatment by
Respiratory Medication Class in Study 208657

Respiratory Medication Class Ingredient	PBO (N=401)	100 SC (N=403)	Total (N=804)
Long-acting beta-2 agonist - Group 3 (Twice per day)			
Any medication	30 (7%)	16 (4%)	46 (6%)
GLYCOPYRRONIUM BROMIDE+BUDESONIDE+FORMOTEROL FUMARATE	8 (2%)	4 (<1%)	12 (1%)
GLYCOPYRRONIUM BROMIDE+BECLOMETASONE DIPROPIONATE+FORMOTEROL FUMARATE	7 (2%)	3 (<1%)	10 (1%)
BUDESONIDE+FORMOTEROL FUMARATE	6 (1%)	3 (<1%)	9 (1%)
BUDESONIDE+FORMOTEROL	3 (<1%)	2 (<1%)	5 (<1%)
BECLOMETASONE DIPROPIONATE+FORMOTEROL FUMARATE	2 (<1%)	2 (<1%)	4 (<1%)
SALMETEROL XINAFOATE+FLUTICASONE PROPIONATE	3 (<1%)	1 (<1%)	4 (<1%)
FORMOTEROL	3 (<1%)	0	3 (<1%)
ARFORMOTEROL	0	1 (<1%)	1 (<1%)
FORMOTEROL FUMARATE	0	1 (<1%)	1 (<1%)
GLYCOPYRRONIUM BROMIDE+BECLOMETASONE DIPROPIONATE+FORMOTEROL FUMARATE DIHYDRATE	1 (<1%)	0	1 (<1%)
GLYCOPYRRONIUM BROMIDE+BUDESONIDE+FORMOTEROL FUMARATE DIHYDRATE	1 (<1%)	0	1 (<1%)
GLYCOPYRRONIUM BROMIDE+FORMOTEROL FUMARATE	1 (<1%)	0	1 (<1%)
GLYCOPYRRONIUM+BECLOMETASONE+FORMOTEROL	1 (<1%)	0	1 (<1%)
MOMETASONE FUROATE+FORMOTEROL FUMARATE	0	1 (<1%)	1 (<1%)
SALMETEROL	1 (<1%)	0	1 (<1%)
SALMETEROL+FLUTICASONE	1 (<1%)	0	1 (<1%)

Note: Includes COPD medications started after first dose and before last dose + 28 days.
Note: Multi-component medications are displayed under the respiratory medication class of each component.

Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Table 111.14
Summary of COPD Medications Started During Treatment by
Respiratory Medication Class in Study 208657

Respiratory Medication Class Ingredient	PBO (N=401)	100 SC (N=403)	Total (N=804)
Mucolytics			
Any medication	16 (4%)	22 (5%)	38 (5%)
ACETYLCYSTEINE	9 (2%)	9 (2%)	18 (2%)
AMBROXOL HYDROCHLORIDE	4 (<1%)	7 (2%)	11 (1%)
BROMHEXINE HYDROCHLORIDE	4 (<1%)	1 (<1%)	5 (<1%)
CARBOCISTEINE	2 (<1%)	3 (<1%)	5 (<1%)
MUCOSOLVAN (NOS)	2 (<1%)	2 (<1%)	4 (<1%)
ERDOSTEINE	0	3 (<1%)	3 (<1%)
ACETYLCYSTEINE+AMBROXOL ACEFYLLINATE	0	2 (<1%)	2 (<1%)
AMBROXOL ACEFYLLINATE	0	1 (<1%)	1 (<1%)
AMBROXOL ACEFYLLINATE+DOXOFYLLINE	0	1 (<1%)	1 (<1%)
BROMHEXINE HYDROCHLORIDE+GUAIFENESIN+TERBUTALINE SULFATE	0	1 (<1%)	1 (<1%)
GUAIFENESIN	0	1 (<1%)	1 (<1%)
GUAIFENESIN+DIHYDROCODEINE BITARTRATE+CHLORPHENAMINE MALEATE+METHYLEPHEDRINE HYDROCHLORIDE	1 (<1%)	0	1 (<1%)
GUAIFENESIN+PSEUDOEPHEDRINE HYDROCHLORIDE+PHOLCODINE+TRIPROLIDINE HYDROCHLORIDE	1 (<1%)	0	1 (<1%)
GUAIFENESIN+TERBUTALINE+AMBROXOL	0	1 (<1%)	1 (<1%)

Note: Includes COPD medications started after first dose and before last dose + 28 days.
Note: Multi-component medications are displayed under the respiratory medication class of each component.

Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Table 111.14
Summary of COPD Medications Started During Treatment by Respiratory Medication Class in Study 208657

Respiratory Medication Class Ingredient	PBO (N=401)	100 SC (N=403)	Total (N=804)
Short-acting anticholinergic			
Any medication	13 (3%)	13 (3%)	26 (3%)
IPRATROPIUM BROMIDE	7 (2%)	6 (1%)	13 (2%)
IPRATROPIUM	3 (<1%)	4 (<1%)	7 (<1%)
FENOTEROL HYDROBROMIDE+IPRATROPIUM BROMIDE	3 (<1%)	2 (<1%)	5 (<1%)
SALBUTAMOL SULFATE+IPRATROPIUM BROMIDE	1 (<1%)	3 (<1%)	4 (<1%)
SALBUTAMOL+IPRATROPIUM	1 (<1%)	0	1 (<1%)
SALBUTAMOL+IPRATROPIUM BROMIDE	1 (<1%)	0	1 (<1%)
Long-acting beta-2 agonist - Group 2 (Once per day)			
Any medication	15 (4%)	8 (2%)	23 (3%)
FLUTICASONE FUROATE+VILANTEROL TRIFENATATE+UMECLIDINIUM BROMIDE	7 (2%)	3 (<1%)	10 (1%)
TIOTROPIUM BROMIDE MONOHYDRATE+OLODATEROL HYDROCHLORIDE	3 (<1%)	3 (<1%)	6 (<1%)
FLUTICASONE FUROATE+VILANTEROL TRIFENATATE	1 (<1%)	2 (<1%)	3 (<1%)
GLYCOPYRRONIUM BROMIDE+INDACATEROL MALEATE	1 (<1%)	0	1 (<1%)
INDACATEROL MALEATE	1 (<1%)	0	1 (<1%)
OLODATEROL	1 (<1%)	0	1 (<1%)
TIOTROPIUM+OLODATEROL	1 (<1%)	0	1 (<1%)
TULOBUTEROL	1 (<1%)	0	1 (<1%)
VILANTEROL	0	1 (<1%)	1 (<1%)
VILANTEROL TRIFENATATE	1 (<1%)	0	1 (<1%)
VILANTEROL TRIFENATATE+UMECLIDINIUM BROMIDE	1 (<1%)	0	1 (<1%)
VILANTEROL+UMECLIDINIUM	1 (<1%)	0	1 (<1%)

Note: Includes COPD medications started after first dose and before last dose + 28 days.
Note: Multi-component medications are displayed under the respiratory medication class of each component.

Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Table 111.14
Summary of COPD Medications Started During Treatment by
Respiratory Medication Class in Study 208657

Respiratory Medication Class Ingredient	PBO (N=401)	100 SC (N=403)	Total (N=804)
Xanthine			
Any medication	12 (3%)	11 (3%)	23 (3%)
THEOPHYLLINE	6 (1%)	5 (1%)	11 (1%)
AMINOPHYLLINE	1 (<1%)	4 (<1%)	5 (<1%)
AMINOPHYLLINE+CHLORPHENAMINE MALEATE+METHOXYPHENAMINE HYDROCHLORIDE+NOSCAPINE	2 (<1%)	2 (<1%)	4 (<1%)
DOXOFYLLINE	1 (<1%)	3 (<1%)	4 (<1%)
THEOPHYLLINE SODIUM GLYCINATE	1 (<1%)	1 (<1%)	2 (<1%)
AMBROXOL ACEFYLLINATE+DOXOFYLLINE	0	1 (<1%)	1 (<1%)
THEOBROMINE	1 (<1%)	0	1 (<1%)
Oxygen			
Any medication	10 (2%)	7 (2%)	17 (2%)
OXYGEN	10 (2%)	7 (2%)	17 (2%)
PDE4 Inhibitors			
Any medication	4 (<1%)	3 (<1%)	7 (<1%)
ROFLUMILAST	4 (<1%)	3 (<1%)	7 (<1%)
Leukotriene Receptor Antagonist			
Any medication	2 (<1%)	3 (<1%)	5 (<1%)
MONTELUKAST SODIUM	2 (<1%)	3 (<1%)	5 (<1%)
Anti-IgE, Anti-IL5			
Any medication	0	1 (<1%)	1 (<1%)
OMALIZUMAB	0	1 (<1%)	1 (<1%)
Antivirals			
Any medication	0	1 (<1%)	1 (<1%)
OSELTAMIVIR	0	1 (<1%)	1 (<1%)

Note: Includes COPD medications started after first dose and before last dose + 28 days.
Note: Multi-component medications are displayed under the respiratory medication class of each component.

Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Table 111.15
Summary of COPD Medications Started During Treatment by
Respiratory Medication Class in Study MEA117113

Respiratory Medication Class Ingredient	PBO (N=87)	100 SC (N=83)	Total (N=170)
Any medication	58 (67%)	48 (58%)	106 (62%)
Corticosteroid - Systemic, oral, parenteral and intra-articular			
Any medication	53 (61%)	40 (48%)	93 (55%)
PREDNISOLONE	19 (22%)	21 (25%)	40 (24%)
PREDNISONE	16 (18%)	12 (14%)	28 (16%)
METHYLPREDNISOLONE	6 (7%)	6 (7%)	12 (7%)
MEPREDNISONE	7 (8%)	4 (5%)	11 (6%)
METHYLPREDNISOLONE SODIUM SUCCINATE	5 (6%)	4 (5%)	9 (5%)
HYDROCORTISONE	6 (7%)	1 (1%)	7 (4%)
DEXAMETHASONE	4 (5%)	1 (1%)	5 (3%)
BETAMETHASONE	3 (3%)	1 (1%)	4 (2%)
HYDROCORTISONE HYDROGEN SUCCINATE	2 (2%)	0	2 (1%)
PREDNISOLONE SODIUM SUCCINATE	1 (1%)	1 (1%)	2 (1%)
BETAMETHASONE+DESLORATADINE	1 (1%)	0	1 (<1%)
Antiinfectives (antibiotics, antifungals, antivirals, antiseptics)			
Any medication	44 (51%)	39 (47%)	83 (49%)
LEVOFLOXACIN	17 (20%)	10 (12%)	27 (16%)
CLARITHROMYCIN	7 (8%)	6 (7%)	13 (8%)
AMOXICILLIN	6 (7%)	6 (7%)	12 (7%)
AMOXICILLIN+CLAVULANATE POTASSIUM	5 (6%)	7 (8%)	12 (7%)
AMOXICILLIN+CLAVULANIC ACID	6 (7%)	6 (7%)	12 (7%)
AZITHROMYCIN	4 (5%)	6 (7%)	10 (6%)
CIPROFLOXACIN	5 (6%)	1 (1%)	6 (4%)
CEFTRIAXONE	2 (2%)	3 (4%)	5 (3%)
CEFUROXIME	1 (1%)	4 (5%)	5 (3%)
DOXYCYCLINE	3 (3%)	2 (2%)	5 (3%)

Note: Includes COPD medications started after first dose and before last dose + 28 days.
Note: Multi-component medications are displayed under the respiratory medication class of each component.

Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Table 111.15
Summary of COPD Medications Started During Treatment by
Respiratory Medication Class in Study MEA117113

Respiratory Medication Class Ingredient	PBO (N=87)	100 SC (N=83)	Total (N=170)
MOXIFLOXACIN HYDROCHLORIDE	1 (1%)	3 (4%)	4 (2%)
BENZYLPENICILLIN	1 (1%)	2 (2%)	3 (2%)
CEFTIBUTEN	1 (1%)	2 (2%)	3 (2%)
CEFTRIAXONE SODIUM	1 (1%)	2 (2%)	3 (2%)
MOXIFLOXACIN	2 (2%)	1 (1%)	3 (2%)
NORFLOXACIN	3 (3%)	0	3 (2%)
ROXITHROMYCIN	0	3 (4%)	3 (2%)
BIAXIN (NOS)	2 (2%)	0	2 (1%)
CEFALEXIN	2 (2%)	0	2 (1%)
CEFDITOREN PIVOXIL	1 (1%)	1 (1%)	2 (1%)
PIPERACILLIN SODIUM+TAZOBACTAM SODIUM	2 (2%)	0	2 (1%)
ACETYLCYSTEINE+AMOXICILLIN	1 (1%)	0	1 (<1%)
AMPICILLIN	1 (1%)	0	1 (<1%)
CEFDINIR	0	1 (1%)	1 (<1%)
CEFEPIME HYDROCHLORIDE	0	1 (1%)	1 (<1%)
CEFPODOXIME	0	1 (1%)	1 (<1%)
CEFPODOXIME PROXETIL	1 (1%)	0	1 (<1%)
CEFTAZIDIME	1 (1%)	0	1 (<1%)
CEFUROXIME AXETIL	1 (1%)	0	1 (<1%)
CEFUROXIME SODIUM	1 (1%)	0	1 (<1%)
CLAVULANIC ACID	1 (1%)	0	1 (<1%)
GENTAMICIN	1 (1%)	0	1 (<1%)
INFLUENZA VACCINE	0	1 (1%)	1 (<1%)
OPTAMOX (NOS)	0	1 (1%)	1 (<1%)
PHENOXYMETHYLPENICILLIN POTASSIUM	1 (1%)	0	1 (<1%)
PIPERACILLIN	0	1 (1%)	1 (<1%)
PIPERACILLIN SODIUM	1 (1%)	0	1 (<1%)
PIPERACILLIN+TAZOBACTAM	0	1 (1%)	1 (<1%)
PNEUMOCOCCAL VACCINE	0	1 (1%)	1 (<1%)
PROBIOTICS (NOS)	1 (1%)	0	1 (<1%)

Note: Includes COPD medications started after first dose and before last dose + 28 days.
Note: Multi-component medications are displayed under the respiratory medication class of each component.

Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Table 111.15
Summary of COPD Medications Started During Treatment by
Respiratory Medication Class in Study MEA117113

Respiratory Medication Class Ingredient	PBO (N=87)	100 SC (N=83)	Total (N=170)
SULFAMETHOXAZOLE+TRIMETHOPRIM	0	1 (1%)	1 (<1%)
TAZOBACTAM	0	1 (1%)	1 (<1%)
VANCOMYCIN	1 (1%)	0	1 (<1%)
Other COPD medication			
Any medication	14 (16%)	11 (13%)	25 (15%)
PARACETAMOL	4 (5%)	2 (2%)	6 (4%)
IBUPROFEN	3 (3%)	0	3 (2%)
HEDERA HELIX EXTRACT+RHIZOMA COPTIDIS EXTRACT	1 (1%)	1 (1%)	2 (1%)
LEVODROPROPIZINE	0	2 (2%)	2 (1%)
NOVALGIN NOS	2 (2%)	0	2 (1%)
OMNICEF (NOS)	1 (1%)	1 (1%)	2 (1%)
SODIUM CHLORIDE	1 (1%)	1 (1%)	2 (1%)
ACECLOFENAC	0	1 (1%)	1 (<1%)
ACTIFED (NOS)	1 (1%)	0	1 (<1%)
ANANAS COMOSUS+DEHYDROCHOLIC ACID+DIMETICONE, ACTIVATED+PANCREATIN+TRIMEBUTINE MALEATE	1 (1%)	0	1 (<1%)
AZELASTINE HYDROCHLORIDE	1 (1%)	0	1 (<1%)
BETAMETHASONE+DESLORATADINE	1 (1%)	0	1 (<1%)
CAFFEINE+PARACETAMOL+PROMETHAZINE METHYLENEDISALICYLATE+SALICYLAMIDE	1 (1%)	0	1 (<1%)
CAPTOPRIL	1 (1%)	0	1 (<1%)
CETIRIZINE	1 (1%)	0	1 (<1%)
CHLORPHENAMINE	0	1 (1%)	1 (<1%)
CLOPERASTINE FENDIZOATE	0	1 (1%)	1 (<1%)
CODEINE	1 (1%)	0	1 (<1%)
COMPRESSED AIR	0	1 (1%)	1 (<1%)
DALTEPARIN	0	1 (1%)	1 (<1%)
EBASTINE+PSEUDOEPHEDRINE HYDROCHLORIDE	1 (1%)	0	1 (<1%)
FAMOTIDINE	0	1 (1%)	1 (<1%)

Note: Includes COPD medications started after first dose and before last dose + 28 days.
Note: Multi-component medications are displayed under the respiratory medication class of each component.

Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Table 111.15
Summary of COPD Medications Started During Treatment by
Respiratory Medication Class in Study MEA117113

Respiratory Medication Class Ingredient	PBO (N=87)	100 SC (N=83)	Total (N=170)
FUROSEMIDE	1 (1%)	0	1 (<1%)
GAVISCON NOS	1 (1%)	0	1 (<1%)
GLUCOSE	0	1 (1%)	1 (<1%)
LAFUTIDINE	0	1 (1%)	1 (<1%)
LEVOSULPIRIDE	1 (1%)	0	1 (<1%)
MACROGOL+POTASSIUM CHLORIDE+SODIUM BICARBONATE+SODIUM CHLORIDE	1 (1%)	0	1 (<1%)
MYDOCALM (NOS)	1 (1%)	0	1 (<1%)
NOREPINEPHRINE	1 (1%)	0	1 (<1%)
PSEUDOEPHEDRINE	1 (1%)	0	1 (<1%)
PSEUDOEPHEDRINE HYDROCHLORIDE	1 (1%)	0	1 (<1%)
PSEUDOEPHEDRINE HYDROCHLORIDE+TRIPROLIDINE HYDROCHLORIDE	0	1 (1%)	1 (<1%)
RANITIDINE HYDROCHLORIDE	0	1 (1%)	1 (<1%)
SUDAFED (NOS)	0	1 (1%)	1 (<1%)
SUPRAX (NOS)	1 (1%)	0	1 (<1%)
TALNIFLUMATE	1 (1%)	0	1 (<1%)
THIAZINAMIUM METILSULFATE	0	1 (1%)	1 (<1%)
VALSARTAN	1 (1%)	0	1 (<1%)
Short-acting beta-2 agonist			
Any medication	16 (18%)	6 (7%)	22 (13%)
SALBUTAMOL	5 (6%)	2 (2%)	7 (4%)
IPRATROPIUM BROMIDE+SALBUTAMOL SULFATE	3 (3%)	2 (2%)	5 (3%)
SALBUTAMOL SULFATE	3 (3%)	2 (2%)	5 (3%)
FENOTEROL HYDROBROMIDE+IPRATROPIUM BROMIDE	4 (5%)	0	4 (2%)
PROCATEROL HYDROCHLORIDE	1 (1%)	1 (1%)	2 (1%)
FENOTEROL+IPRATROPIUM BROMIDE	1 (1%)	0	1 (<1%)
IPRATROPIUM+SALBUTAMOL	1 (1%)	0	1 (<1%)

Note: Includes COPD medications started after first dose and before last dose + 28 days.
Note: Multi-component medications are displayed under the respiratory medication class of each component.

Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Table 111.15
Summary of COPD Medications Started During Treatment by
Respiratory Medication Class in Study MEA117113

Respiratory Medication Class Ingredient	PBO (N=87)	100 SC (N=83)	Total (N=170)
Short-acting anticholinergic			
Any medication	13 (15%)	7 (8%)	20 (12%)
IPRATROPIUM BROMIDE	5 (6%)	4 (5%)	9 (5%)
IPRATROPIUM BROMIDE+SALBUTAMOL SULFATE	3 (3%)	2 (2%)	5 (3%)
FENOTEROL HYDROBROMIDE+IPRATROPIUM BROMIDE	4 (5%)	0	4 (2%)
IPRATROPIUM	0	2 (2%)	2 (1%)
FENOTEROL+IPRATROPIUM BROMIDE	1 (1%)	0	1 (<1%)
IPRATROPIUM+SALBUTAMOL	1 (1%)	0	1 (<1%)
Mucolytics			
Any medication	10 (11%)	9 (11%)	19 (11%)
ACETYLCYSTEINE	7 (8%)	4 (5%)	11 (6%)
ERDOSTEINE	2 (2%)	3 (4%)	5 (3%)
AMBROXOL HYDROCHLORIDE	2 (2%)	1 (1%)	3 (2%)
ACETYLCYSTEINE+AMOXICILLIN	1 (1%)	0	1 (<1%)
AMBROXOL	0	1 (1%)	1 (<1%)
BROMHEXINE HYDROCHLORIDE+GUAIFENESIN	0	1 (1%)	1 (<1%)
GUAIFENESIN	1 (1%)	0	1 (<1%)
Oxygen			
Any medication	9 (10%)	5 (6%)	14 (8%)
OXYGEN	9 (10%)	5 (6%)	14 (8%)
Xanthine			
Any medication	8 (9%)	3 (4%)	11 (6%)
AMINOPHYLLINE	4 (5%)	1 (1%)	5 (3%)
THEOPHYLLINE	3 (3%)	2 (2%)	5 (3%)
CAFFEINE+PARACETAMOL+PROMETHAZINE	1 (1%)	0	1 (<1%)
METHYLENEDISALICYLATE+SALICYLAMIDE			

Note: Includes COPD medications started after first dose and before last dose + 28 days.
Note: Multi-component medications are displayed under the respiratory medication class of each component.

Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Table 111.15
Summary of COPD Medications Started During Treatment by
Respiratory Medication Class in Study MEA117113

Respiratory Medication Class Ingredient	PBO (N=87)	100 SC (N=83)	Total (N=170)
Corticosteroid - Inhaled			
Any medication	3 (3%)	6 (7%)	9 (5%)
BUDESONIDE+FORMOTEROL FUMARATE	2 (2%)	4 (5%)	6 (4%)
FLUTICASONE PROPIONATE+SALMETEROL XINAFOATE	0	2 (2%)	2 (1%)
BECLOMETASONE DIPROPIONATE+FORMOTEROL FUMARATE	0	1 (1%)	1 (<1%)
DEXAMETHASONE	1 (1%)	0	1 (<1%)
Long-acting beta-2 agonist			
Any medication	3 (3%)	6 (7%)	9 (5%)
BUDESONIDE+FORMOTEROL FUMARATE	2 (2%)	4 (5%)	6 (4%)
FLUTICASONE PROPIONATE+SALMETEROL XINAFOATE	0	2 (2%)	2 (1%)
BECLOMETASONE DIPROPIONATE+FORMOTEROL FUMARATE	0	1 (1%)	1 (<1%)
SALMETEROL	1 (1%)	0	1 (<1%)
Long-acting anticholinergic			
Any medication	1 (1%)	3 (4%)	4 (2%)
TIOTROPIUM BROMIDE	1 (1%)	2 (2%)	3 (2%)
UMECLIDINIUM BROMIDE	0	1 (1%)	1 (<1%)
Nedocromil or Cromolyn Sodium			
Any medication	1 (1%)	1 (1%)	2 (1%)
CROMOGLICATE SODIUM	1 (1%)	1 (1%)	2 (1%)
Leukotriene Receptor Antagonist			
Any medication	0	1 (1%)	1 (<1%)
MONTELUKAST	0	1 (1%)	1 (<1%)
MONTELUKAST SODIUM	0	1 (1%)	1 (<1%)
PDE4 Inhibitors			
Any medication	0	1 (1%)	1 (<1%)

Note: Includes COPD medications started after first dose and before last dose + 28 days.
Note: Multi-component medications are displayed under the respiratory medication class of each component.

Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Table 111.15

Summary of COPD Medications Started During Treatment by Respiratory Medication Class in Study MEA117113

Respiratory Medication Class Ingredient	PBO (N=87)	100 SC (N=83)	Total (N=170)
ROFLUMILAST	0	1 (1%)	1 (<1%)

Note: Includes COPD medications started after first dose and before last dose + 28 days.
Note: Multi-component medications are displayed under the respiratory medication class of each component.

Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Table 111.16
Summary of COPD Medications Started During Treatment by
Respiratory Medication Class in Study MEA117106

Respiratory Medication Class Ingredient	PBO (N=90)	100 SC (N=82)	Total (N=172)
Any medication	71 (79%)	53 (65%)	124 (72%)
Antiinfectives (antibiotics, antifungals, antivirals, antiseptics)			
Any medication	63 (70%)	46 (56%)	109 (63%)
LEVOFLOXACIN	15 (17%)	13 (16%)	28 (16%)
AMOXICILLIN+CLAVULANIC ACID	19 (21%)	7 (9%)	26 (15%)
AZITHROMYCIN	7 (8%)	8 (10%)	15 (9%)
AMOXICILLIN+CLAVULANATE POTASSIUM	8 (9%)	6 (7%)	14 (8%)
DOXYCYCLINE	8 (9%)	6 (7%)	14 (8%)
MOXIFLOXACIN	6 (7%)	7 (9%)	13 (8%)
AMOXICILLIN	7 (8%)	5 (6%)	12 (7%)
CIPROFLOXACIN	1 (1%)	5 (6%)	6 (3%)
CLARITHROMYCIN	4 (4%)	2 (2%)	6 (3%)
CEFTRIAXONE	3 (3%)	2 (2%)	5 (3%)
CEFTRIAXONE SODIUM	4 (4%)	1 (1%)	5 (3%)
CEFUROXIME	0	5 (6%)	5 (3%)
PIPERACILLIN SODIUM+TAZOBACTAM SODIUM	0	5 (6%)	5 (3%)
SULFAMETHOXAZOLE+TRIMETHOPRIM	2 (2%)	3 (4%)	5 (3%)
CEFUROXIME AXETIL	3 (3%)	1 (1%)	4 (2%)
CIPROFLOXACIN HYDROCHLORIDE	2 (2%)	2 (2%)	4 (2%)
CEFALEXIN	2 (2%)	1 (1%)	3 (2%)
CEFDITOREN PIVOXIL	2 (2%)	1 (1%)	3 (2%)
CEFOTAXIME	1 (1%)	2 (2%)	3 (2%)
FUGENTIN (NOS)	2 (2%)	1 (1%)	3 (2%)
PRISTINAMYCIN	3 (3%)	0	3 (2%)
SPIRAMYCIN	3 (3%)	0	3 (2%)
AMPICILLIN	2 (2%)	0	2 (1%)
AMPISID (NOS)	2 (2%)	0	2 (1%)
BIAXIN (NOS)	1 (1%)	1 (1%)	2 (1%)

Note: Includes COPD medications started after first dose and before last dose + 28 days.
Note: Multi-component medications are displayed under the respiratory medication class of each component.

Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Table 111.16
Summary of COPD Medications Started During Treatment by
Respiratory Medication Class in Study MEA117106

Respiratory Medication Class Ingredient	PBO (N=90)	100 SC (N=82)	Total (N=172)
CEFTAZIDIME	0	2 (2%)	2 (1%)
DOXYCYCLINE HYDROCHLORIDE	1 (1%)	1 (1%)	2 (1%)
IMIPENEM	0	2 (2%)	2 (1%)
INFLUENZA VACCINE	1 (1%)	1 (1%)	2 (1%)
PROFLOX (NOS)	1 (1%)	1 (1%)	2 (1%)
ROXITHROMYCIN	1 (1%)	1 (1%)	2 (1%)
TOBRAMYCIN	0	2 (2%)	2 (1%)
ACYCLOVIR	1 (1%)	0	1 (<1%)
AMOXICILLIN+SULBACTAM PIVOXIL	0	1 (1%)	1 (<1%)
AMPICILLIN SODIUM+SULBACTAM SODIUM	1 (1%)	0	1 (<1%)
ANTIBIOTICS NOS	1 (1%)	0	1 (<1%)
BIFIDOBACTERIUM LACTIS+FRUCTOOLIGOSACCHARIDES+LACTOBACILLUS PLANTARUM+LACTOBACILLUS RHAMNOSUS	1 (1%)	0	1 (<1%)
CEFEPIME HYDROCHLORIDE	0	1 (1%)	1 (<1%)
CEFIXIME	1 (1%)	0	1 (<1%)
CEFOTAXIME SODIUM	0	1 (1%)	1 (<1%)
CEFZIL (NOS)	1 (1%)	0	1 (<1%)
CLINDAMYCIN	0	1 (1%)	1 (<1%)
COLISTIN	0	1 (1%)	1 (<1%)
DOXYCYCLINE MONOHYDRATE	1 (1%)	0	1 (<1%)
FLUCONAZOLE	0	1 (1%)	1 (<1%)
GENTAMICIN	0	1 (1%)	1 (<1%)
ITRACONAZOLE	1 (1%)	0	1 (<1%)
LACTOBACILLUS NOS	1 (1%)	0	1 (<1%)
LINCOMYCIN HYDROCHLORIDE	1 (1%)	0	1 (<1%)
METRONIDAZOLE+SPIRAMYCIN	1 (1%)	0	1 (<1%)
MOXIFLOXACIN HYDROCHLORIDE	1 (1%)	0	1 (<1%)
OSELTAMIVIR	1 (1%)	0	1 (<1%)
PIPERACILLIN+TAZOBACTAM	1 (1%)	0	1 (<1%)

Note: Includes COPD medications started after first dose and before last dose + 28 days.
Note: Multi-component medications are displayed under the respiratory medication class of each component.

Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Table 111.16
Summary of COPD Medications Started During Treatment by
Respiratory Medication Class in Study MEA117106

Respiratory Medication Class Ingredient	PBO (N=90)	100 SC (N=82)	Total (N=172)
PNEUMOCOCCAL VACCINE	1 (1%)	0	1 (<1%)
RIFAMPICIN	0	1 (1%)	1 (<1%)
VANCOMYCIN	0	1 (1%)	1 (<1%)
Corticosteroid - Systemic, oral, parenteral and intra-articular			
Any medication	65 (72%)	40 (49%)	105 (61%)
PREDNISONE	27 (30%)	18 (22%)	45 (26%)
METHYLPREDNISOLONE	20 (22%)	9 (11%)	29 (17%)
PREDNISOLONE	17 (19%)	11 (13%)	28 (16%)
METHYLPREDNISOLONE SODIUM SUCCINATE	8 (9%)	5 (6%)	13 (8%)
DEXAMETHASONE	4 (4%)	2 (2%)	6 (3%)
DEFLAZACORT	3 (3%)	1 (1%)	4 (2%)
BETAMETHASONE SODIUM PHOSPHATE	1 (1%)	2 (2%)	3 (2%)
HYDROCORTISONE SODIUM PHOSPHATE	2 (2%)	0	2 (1%)
BETAMETHASONE	1 (1%)	0	1 (<1%)
HYDROCORTISONE	0	1 (1%)	1 (<1%)
METHYLPREDNISOLONE HEMISUCCINATE	1 (1%)	0	1 (<1%)
PREDNISONE ACETATE	0	1 (1%)	1 (<1%)
TRIAMCINOLONE	0	1 (1%)	1 (<1%)
TRIAMCINOLONE DIACETATE	0	1 (1%)	1 (<1%)
Short-acting anticholinergic			
Any medication	25 (28%)	9 (11%)	34 (20%)
IPRATROPIUM BROMIDE	13 (14%)	4 (5%)	17 (10%)
IPRATROPIUM BROMIDE+SALBUTAMOL SULFATE	6 (7%)	3 (4%)	9 (5%)
FENOTEROL HYDROBROMIDE+IPRATROPIUM BROMIDE	5 (6%)	2 (2%)	7 (4%)
IPRATROPIUM	5 (6%)	0	5 (3%)
IPRATROPIUM+SALBUTAMOL	2 (2%)	0	2 (1%)
IPRATROPIUM BROMIDE+SALBUTAMOL	1 (1%)	0	1 (<1%)

Note: Includes COPD medications started after first dose and before last dose + 28 days.
Note: Multi-component medications are displayed under the respiratory medication class of each component.

Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Table 111.16
Summary of COPD Medications Started During Treatment by
Respiratory Medication Class in Study MEA117106

Respiratory Medication Class Ingredient	PBO (N=90)	100 SC (N=82)	Total (N=172)
Short-acting beta-2 agonist			
Any medication	22 (24%)	11 (13%)	33 (19%)
SALBUTAMOL	11 (12%)	1 (1%)	12 (7%)
IPRATROPIUM BROMIDE+SALBUTAMOL SULFATE	6 (7%)	3 (4%)	9 (5%)
FENOTEROL HYDROBROMIDE+IPRATROPIUM BROMIDE	5 (6%)	2 (2%)	7 (4%)
TERBUTALINE SULFATE	2 (2%)	3 (4%)	5 (3%)
IPRATROPIUM+SALBUTAMOL	2 (2%)	0	2 (1%)
SALBUTAMOL SULFATE	1 (1%)	1 (1%)	2 (1%)
FENOTEROL	0	1 (1%)	1 (<1%)
IPRATROPIUM BROMIDE+SALBUTAMOL	1 (1%)	0	1 (<1%)
LEVOSALBUTAMOL	1 (1%)	0	1 (<1%)
TERBUTALINE	1 (1%)	0	1 (<1%)
Mucolytics			
Any medication	20 (22%)	11 (13%)	31 (18%)
ACETYLCYSTEINE	11 (12%)	7 (9%)	18 (10%)
ERDOSTEINE	4 (4%)	3 (4%)	7 (4%)
AMBROXOL	2 (2%)	2 (2%)	4 (2%)
CARBOCISTEINE	1 (1%)	2 (2%)	3 (2%)
AMBROXOL HYDROCHLORIDE	2 (2%)	0	2 (1%)
GUAIFENESIN	1 (1%)	1 (1%)	2 (1%)
MUCOSOLVAN (NOS)	1 (1%)	1 (1%)	2 (1%)
BROMHEXINE HYDROCHLORIDE	1 (1%)	0	1 (<1%)
Other COPD medication			
Any medication	20 (22%)	10 (12%)	30 (17%)
PARACETAMOL	2 (2%)	3 (4%)	5 (3%)
OMEPRAZOLE	3 (3%)	1 (1%)	4 (2%)
SODIUM CHLORIDE	3 (3%)	1 (1%)	4 (2%)

Note: Includes COPD medications started after first dose and before last dose + 28 days.
Note: Multi-component medications are displayed under the respiratory medication class of each component.

Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Table 111.16
Summary of COPD Medications Started During Treatment by
Respiratory Medication Class in Study MEA117106

Respiratory Medication Class Ingredient	PBO (N=90)	100 SC (N=82)	Total (N=172)
DUOMOX (NOS)	3 (3%)	0	3 (2%)
HEPARIN (NOS)	2 (2%)	1 (1%)	3 (2%)
POTASSIUM CHLORIDE	3 (3%)	0	3 (2%)
IBUPROFEN	1 (1%)	1 (1%)	2 (1%)
ACETYLSALICYLIC ACID	1 (1%)	0	1 (<1%)
ACETYLSALICYLIC ACID+ASCORBIC ACID+RUTOSIDE	1 (1%)	0	1 (<1%)
AMBIGUOUS MEDICATION NOS	0	1 (1%)	1 (<1%)
BEMIPARIN	0	1 (1%)	1 (<1%)
BENADRYL (NOS)	0	1 (1%)	1 (<1%)
BICARBONATE	0	1 (1%)	1 (<1%)
BIFIDOBACTERIUM LACTIS+FRUCTOOLIGOSACCHARIDES+LACTOBACILLUS PLANTARUM+LACTOBACILLUS RHAMNOSUS	1 (1%)	0	1 (<1%)
BILASTINE	1 (1%)	0	1 (<1%)
BRONCHODILATOR (NOS)	1 (1%)	0	1 (<1%)
CHLORPHENAMINE+HYDROCODONE	1 (1%)	0	1 (<1%)
CODEINE PHOSPHATE+SULFOGAIACOL	1 (1%)	0	1 (<1%)
COMPRESSED AIR	1 (1%)	0	1 (<1%)
CORICIDIN (NOS)	0	1 (1%)	1 (<1%)
DECONGESTANT NOS	0	1 (1%)	1 (<1%)
DEXTRAN	1 (1%)	0	1 (<1%)
DEXTROMETHORPHAN	1 (1%)	0	1 (<1%)
DICLOFENAC	1 (1%)	0	1 (<1%)
ENOXAPARIN	0	1 (1%)	1 (<1%)
FENSPIRIDE	0	1 (1%)	1 (<1%)
FUROSEMIDE	0	1 (1%)	1 (<1%)
HOMATROPINE METHYLBROMIDE+HYDROCODONE BITARTRATE	1 (1%)	0	1 (<1%)
KETOPROFEN	0	1 (1%)	1 (<1%)
LORATADINE	0	1 (1%)	1 (<1%)
MELOXICAM	0	1 (1%)	1 (<1%)

Note: Includes COPD medications started after first dose and before last dose + 28 days.
Note: Multi-component medications are displayed under the respiratory medication class of each component.

Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Table 111.16
Summary of COPD Medications Started During Treatment by
Respiratory Medication Class in Study MEA117106

Respiratory Medication Class Ingredient	PBO (N=90)	100 SC (N=82)	Total (N=172)
NASAL PREPARATIONS	0	1 (1%)	1 (<1%)
NON-DRUG THERAPY	1 (1%)	0	1 (<1%)
OPERATIONS AND PROCEDURES	1 (1%)	0	1 (<1%)
PANTOPRAZOLE	0	1 (1%)	1 (<1%)
PARACETAMOL+PHENYLEPHRINE HYDROCHLORIDE	1 (1%)	0	1 (<1%)
ROBITUSSIN (NOS)	0	1 (1%)	1 (<1%)
TRAMADOL	0	1 (1%)	1 (<1%)
Corticosteroid - Inhaled			
Any medication	16 (18%)	7 (9%)	23 (13%)
BUDESONIDE	6 (7%)	1 (1%)	7 (4%)
BUDESONIDE+FORMOTEROL FUMARATE	1 (1%)	3 (4%)	4 (2%)
FLUTICASONE PROPIONATE+SALMETEROL XINAFOATE	2 (2%)	2 (2%)	4 (2%)
BECLOMETASONE	2 (2%)	1 (1%)	3 (2%)
FLUTICASONE PROPIONATE	2 (2%)	1 (1%)	3 (2%)
BECLOMETASONE DIPROPIONATE	2 (2%)	0	2 (1%)
BECLOMETASONE DIPROPIONATE+FORMOTEROL FUMARATE	1 (1%)	1 (1%)	2 (1%)
FLUNISOLIDE	2 (2%)	0	2 (1%)
FLUTICASONE FUROATE+VILANTEROL TRIFENATATE	0	1 (1%)	1 (<1%)
Oxygen			
Any medication	8 (9%)	5 (6%)	13 (8%)
OXYGEN	8 (9%)	5 (6%)	13 (8%)
Long-acting beta-2 agonist			
Any medication	5 (6%)	6 (7%)	11 (6%)
BUDESONIDE+FORMOTEROL FUMARATE	1 (1%)	3 (4%)	4 (2%)
FLUTICASONE PROPIONATE+SALMETEROL XINAFOATE	2 (2%)	2 (2%)	4 (2%)
BECLOMETASONE DIPROPIONATE+FORMOTEROL FUMARATE	1 (1%)	1 (1%)	2 (1%)
ACLIDINIUM+FORMOTEROL	1 (1%)	0	1 (<1%)

Note: Includes COPD medications started after first dose and before last dose + 28 days.
Note: Multi-component medications are displayed under the respiratory medication class of each component.

Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Table 111.16
Summary of COPD Medications Started During Treatment by
Respiratory Medication Class in Study MEA117106

Respiratory Medication Class Ingredient	PBO (N=90)	100 SC (N=82)	Total (N=172)
FLUTICASONE FUROATE+VILANTEROL TRIFENATATE	0	1 (1%)	1 (<1%)
FORMOTEROL	1 (1%)	0	1 (<1%)
INDACATEROL MALEATE	1 (1%)	0	1 (<1%)
Xanthine			
Any medication	9 (10%)	2 (2%)	11 (6%)
THEOPHYLLINE	6 (7%)	1 (1%)	7 (4%)
AMINOPHYLLINE	3 (3%)	1 (1%)	4 (2%)
Long-acting anticholinergic			
Any medication	5 (6%)	4 (5%)	9 (5%)
TIOTROPIUM BROMIDE	5 (6%)	2 (2%)	7 (4%)
ACLIDINIUM BROMIDE	0	2 (2%)	2 (1%)
ACLIDINIUM+FORMOTEROL	1 (1%)	0	1 (<1%)
Leukotriene Receptor Antagonist			
Any medication	2 (2%)	3 (4%)	5 (3%)
MONTELUKAST	1 (1%)	3 (4%)	4 (2%)
MONTELUKAST SODIUM	1 (1%)	0	1 (<1%)
Corticosteroid - Other			
Any medication	2 (2%)	1 (1%)	3 (2%)
BECLOMETASONE DIPROPIONATE	1 (1%)	0	1 (<1%)
FLUTICASONE FUROATE	1 (1%)	0	1 (<1%)
METHYLPREDNISOLONE SODIUM SUCCINATE	0	1 (1%)	1 (<1%)

Note: Includes COPD medications started after first dose and before last dose + 28 days.
Note: Multi-component medications are displayed under the respiratory medication class of each component.

Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Table 111.17
Summary of COPD Medications Started During Treatment by Ingredient in Study 208657

Ingredient	PBO (N=401)	100 SC (N=403)	Total (N=804)
Any medication	109 (27%)	87 (22%)	196 (24%)
PREDNISOLONE	20 (5%)	4 (<1%)	24 (3%)
SALBUTAMOL	12 (3%)	12 (3%)	24 (3%)
ACETYLCYSTEINE	9 (2%)	9 (2%)	18 (2%)
OXYGEN	10 (2%)	7 (2%)	17 (2%)
PREDNISONE	13 (3%)	4 (<1%)	17 (2%)
AZITHROMYCIN	10 (2%)	6 (1%)	16 (2%)
BUDESONIDE	7 (2%)	6 (1%)	13 (2%)
IPRATROPIUM BROMIDE	7 (2%)	6 (1%)	13 (2%)
METHYLPREDNISOLONE	8 (2%)	5 (1%)	13 (2%)
GLYCOPYRRONIUM BROMIDE+BUDESONIDE+FORMOTEROL FUMARATE	8 (2%)	4 (<1%)	12 (1%)
AMBROXOL HYDROCHLORIDE	4 (<1%)	7 (2%)	11 (1%)
SALBUTAMOL SULFATE	4 (<1%)	7 (2%)	11 (1%)
THEOPHYLLINE	6 (1%)	5 (1%)	11 (1%)
CINEOLE+PINENE+DIPENTEN	3 (<1%)	7 (2%)	10 (1%)
FLUTICASONE FUROATE+VILANTEROL TRIFENATATE+UMECLIDINIUM BROMIDE	7 (2%)	3 (<1%)	10 (1%)
GLYCOPYRRONIUM BROMIDE+BECLOMETASONE DIPROPIONATE+FORMOTEROL FUMARATE	7 (2%)	3 (<1%)	10 (1%)
BUDESONIDE+FORMOTEROL FUMARATE	6 (1%)	3 (<1%)	9 (1%)
LEVOFLOXACIN	5 (1%)	3 (<1%)	8 (<1%)
IPRATROPIUM	3 (<1%)	4 (<1%)	7 (<1%)
METHYLPREDNISOLONE SODIUM SUCCINATE	4 (<1%)	3 (<1%)	7 (<1%)
ROFLUMILAST	4 (<1%)	3 (<1%)	7 (<1%)
TIOTROPIUM BROMIDE MONOHYDRATE	4 (<1%)	3 (<1%)	7 (<1%)
TIOTROPIUM BROMIDE MONOHYDRATE+OLODATEROL HYDROCHLORIDE	3 (<1%)	3 (<1%)	6 (<1%)
AMINOPHYLLINE	1 (<1%)	4 (<1%)	5 (<1%)
BROMHEXINE HYDROCHLORIDE	4 (<1%)	1 (<1%)	5 (<1%)
BUDESONIDE+FORMOTEROL	3 (<1%)	2 (<1%)	5 (<1%)

Note: Includes all COPD medications started after first dose and before last dose + 28 days.
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Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Table 111.17
Summary of COPD Medications Started During Treatment by Ingredient in Study 208657

Ingredient	PBO (N=401)	100 SC (N=403)	Total (N=804)
CARBOCISTEINE	2 (<1%)	3 (<1%)	5 (<1%)
FENOTEROL HYDROBROMIDE+IPRATROPIUM BROMIDE	3 (<1%)	2 (<1%)	5 (<1%)
MONTELUKAST SODIUM	2 (<1%)	3 (<1%)	5 (<1%)
SODIUM CHLORIDE	4 (<1%)	1 (<1%)	5 (<1%)
TIOTROPIUM BROMIDE	3 (<1%)	2 (<1%)	5 (<1%)
TRADITIONAL CHINESE MEDICINE NOS	1 (<1%)	4 (<1%)	5 (<1%)
AMINOPHYLLINE+CHLORPHENAMINE MALEATE+METHOXYPHENAMINE HYDROCHLORIDE+NOSCAPINE	2 (<1%)	2 (<1%)	4 (<1%)
AMOXICILLIN+CLAVULANIC ACID	1 (<1%)	3 (<1%)	4 (<1%)
BECLOMETASONE DIPROPIONATE+FORMOTEROL FUMARATE	2 (<1%)	2 (<1%)	4 (<1%)
CICLESONIDE	1 (<1%)	3 (<1%)	4 (<1%)
DOXOFYLLINE	1 (<1%)	3 (<1%)	4 (<1%)
DOXYCYCLINE	1 (<1%)	3 (<1%)	4 (<1%)
MUCOSOLVAN (NOS)	2 (<1%)	2 (<1%)	4 (<1%)
SALBUTAMOL SULFATE+IPRATROPIUM BROMIDE	1 (<1%)	3 (<1%)	4 (<1%)
SALMETEROL XINAFOATE+FLUTICASONE PROPIONATE	3 (<1%)	1 (<1%)	4 (<1%)
AMOXICILLIN	2 (<1%)	1 (<1%)	3 (<1%)
DEXAMETHASONE SODIUM PHOSPHATE	1 (<1%)	2 (<1%)	3 (<1%)
ERDOSTEINE	0	3 (<1%)	3 (<1%)
FLUTICASONE FUROATE+VILANTEROL TRIFENATATE	1 (<1%)	2 (<1%)	3 (<1%)
FORMOTEROL	3 (<1%)	0	3 (<1%)
FUROSEMIDE	3 (<1%)	0	3 (<1%)
PARACETAMOL	2 (<1%)	1 (<1%)	3 (<1%)
ACETYLCYSTEINE+AMBROXOL ACEFYLLINATE	0	2 (<1%)	2 (<1%)
BECLOMETASONE	2 (<1%)	0	2 (<1%)
BENZYLPENICILLIN SODIUM	1 (<1%)	1 (<1%)	2 (<1%)
CEFDINIR	0	2 (<1%)	2 (<1%)
CEFDITOREN PIVOXIL	1 (<1%)	1 (<1%)	2 (<1%)
CLARITHROMYCIN	1 (<1%)	1 (<1%)	2 (<1%)
DEXAMETHASONE	1 (<1%)	1 (<1%)	2 (<1%)
ENOXAPARIN SODIUM	2 (<1%)	0	2 (<1%)

Note: Includes all COPD medications started after first dose and before last dose + 28 days.
/mnt/code/postcsr_01/prod/tfls/t_sp_c1_ontrt_ing_657.sas 21JUL2025 22:01

Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Table 111.17
Summary of COPD Medications Started During Treatment by Ingredient in Study 208657

Ingredient	PBO (N=401)	100 SC (N=403)	Total (N=804)
EPHEDRA SINICA+ARCTIUM LAPPA+SCHISANDRA NOS+OCIMUM BASILICUM+LUMBRICUS TERRESTRIS+PEUCEDANUM (NOS)+HERBALS NOS	1 (<1%)	1 (<1%)	2 (<1%)
FLUTICASONE FUROATE	1 (<1%)	1 (<1%)	2 (<1%)
GLYCOPYRRONIUM BROMIDE	2 (<1%)	0	2 (<1%)
HYDROCORTISONE	1 (<1%)	1 (<1%)	2 (<1%)
MORPHINE	2 (<1%)	0	2 (<1%)
THEOPHYLLINE SODIUM GLYCINATE	1 (<1%)	1 (<1%)	2 (<1%)
TIOTROPIUM	2 (<1%)	0	2 (<1%)
UMECLIDINIUM	0	2 (<1%)	2 (<1%)
ACETAZOLAMIDE	0	1 (<1%)	1 (<1%)
ACETYLSALICYLIC ACID	0	1 (<1%)	1 (<1%)
AMBROXOL ACEFYLLINATE	0	1 (<1%)	1 (<1%)
AMBROXOL ACEFYLLINATE+DOXOFYLLINE	0	1 (<1%)	1 (<1%)
AMOXICILLIN SODIUM+CLAVULANIC ACID	0	1 (<1%)	1 (<1%)
AMOXICILLIN+CLAVULANATE POTASSIUM	0	1 (<1%)	1 (<1%)
AMPICILLIN	1 (<1%)	0	1 (<1%)
AMPICILLIN+SULBACTAM	0	1 (<1%)	1 (<1%)
ANYCOUGH (NOS)	0	1 (<1%)	1 (<1%)
ARFORMOTEROL	0	1 (<1%)	1 (<1%)
ASCORIL (NOS)	0	1 (<1%)	1 (<1%)
ASTRAGALUS MEMBRANACEUS+ATRACTYLODES MACROCEPHALA+SAPOSHNIKOVIA DIVARICATA	0	1 (<1%)	1 (<1%)
BENZYLPENICILLIN	0	1 (<1%)	1 (<1%)
BETAMETHASONE SODIUM PHOSPHATE+BETAMETHASONE DIPROPIONATE	1 (<1%)	0	1 (<1%)
BISOPROLOL	1 (<1%)	0	1 (<1%)
BROMHEXINE HYDROCHLORIDE+GUAIFENESIN+TERBUTALINE SULFATE	0	1 (<1%)	1 (<1%)
CARTHAMUS TINCTORIUS+ANGELICA+SALVIA (NOS)+PAEONIA (NOS)+LIGUSTICUM CHUANXIANG	1 (<1%)	0	1 (<1%)

Note: Includes all COPD medications started after first dose and before last dose + 28 days.
/mnt/code/postcsr_01/prod/tfls/t_sp_c1_ontrt_ing_657.sas 21JUL2025 22:01

Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Table 111.17
Summary of COPD Medications Started During Treatment by Ingredient in Study 208657

Ingredient	PBO (N=401)	100 SC (N=403)	Total (N=804)
CEFDITOREN	1 (<1%)	0	1 (<1%)
CEFIXIME	0	1 (<1%)	1 (<1%)
CEFOPERAZONE SODIUM+SULBACTAM SODIUM	0	1 (<1%)	1 (<1%)
CEFPROZIL	0	1 (<1%)	1 (<1%)
CEFTAZIDIME	0	1 (<1%)	1 (<1%)
CEFUROXIME	1 (<1%)	0	1 (<1%)
CETIRIZINE HYDROCHLORIDE	1 (<1%)	0	1 (<1%)
CINEOLE	1 (<1%)	0	1 (<1%)
CINEOLE+PINENE	1 (<1%)	0	1 (<1%)
CIPROFLOXACIN	1 (<1%)	0	1 (<1%)
CLAVULANIC ACID	1 (<1%)	0	1 (<1%)
COUGH COLD PREPARATIONS NOS	0	1 (<1%)	1 (<1%)
DECADRON (NOS)	1 (<1%)	0	1 (<1%)
DESLORATADINE CITRATE DISODIUM	0	1 (<1%)	1 (<1%)
DIHYDROCODEINE BITARTRATE+CHLORPHENAMINE MALEATE+AMMONIUM CHLORIDE+METHYLEPHEDRINE HYDROCHLORIDE+PELARGONIUM SIDOIDES	0	1 (<1%)	1 (<1%)
DIPROSPAN (NOS)	1 (<1%)	0	1 (<1%)
DOXYCYCLINE HYDROCHLORIDE	0	1 (<1%)	1 (<1%)
ENALAPRIL	0	1 (<1%)	1 (<1%)
FLUTICASONE	0	1 (<1%)	1 (<1%)
FLUTICASONE PROPIONATE	1 (<1%)	0	1 (<1%)
FORMOTEROL FUMARATE	0	1 (<1%)	1 (<1%)
FORSYTHIA SUSPENSA FRUIT+TRICHOSANTHES NOS+COPTIS SPP RHIZOME+CALCIUM SULFATE DIHYDRATE+PAEONIA SPP ROOT+GARDENIA JASMINOIDES FRUIT+HERBALS NOS	1 (<1%)	0	1 (<1%)
GELOMYRTOL (NOS)	1 (<1%)	0	1 (<1%)
GLYCOPYRRONIUM BROMIDE+BECLOMETASONE DIPROPIONATE+FORMOTEROL FUMARATE DIHYDRATE	1 (<1%)	0	1 (<1%)
GLYCOPYRRONIUM BROMIDE+BUDESONIDE+FORMOTEROL FUMARATE DIHYDRATE	1 (<1%)	0	1 (<1%)

Note: Includes all COPD medications started after first dose and before last dose + 28 days.
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Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Table 111.17
Summary of COPD Medications Started During Treatment by Ingredient in Study 208657

Ingredient	PBO (N=401)	100 SC (N=403)	Total (N=804)
GLYCOPYRRONIUM BROMIDE+FORMOTEROL FUMARATE	1 (<1%)	0	1 (<1%)
GLYCOPYRRONIUM BROMIDE+INDACATEROL MALEATE	1 (<1%)	0	1 (<1%)
GLYCOPYRRONIUM BROMIDE+MOMETASONE FUROATE+INDACATEROL ACETATE	1 (<1%)	0	1 (<1%)
GLYCOPYRRONIUM+BECLOMETASONE+FORMOTEROL	1 (<1%)	0	1 (<1%)
GLYCYRRHIZA (NOS)	1 (<1%)	0	1 (<1%)
GLYCYRRHIZA SPP. ROOT WITH RHIZOME+ASTER TATARICUS ROOT WITH RHIZOME+EPHEDRA SPP. STEM+HERBALS NOS	0	1 (<1%)	1 (<1%)
GLYCYRRHIZA SPP. ROOT WITH RHIZOME+ASTER TATARICUS ROOT WITH RHIZOME+GEKKO GECKO+CALCIUM SULFATE DIHYDRATE+TURTLE CARAPACE+HERBALS NOS	1 (<1%)	0	1 (<1%)
GUAIFENESIN	0	1 (<1%)	1 (<1%)
GUAIFENESIN+DIHYDROCODEINE BITARTRATE+CHLORPHENAMINE MALEATE+METHYLEPHEDRINE HYDROCHLORIDE	1 (<1%)	0	1 (<1%)
GUAIFENESIN+PSEUDOEPHEDRINE HYDROCHLORIDE+PHOLCODINE+TRIPROLIDINE HYDROCHLORIDE	1 (<1%)	0	1 (<1%)
GUAIFENESIN+TERBUTALINE+AMBROXOL	0	1 (<1%)	1 (<1%)
HEDERA HELIX	0	1 (<1%)	1 (<1%)
HEDERA HELIX EXTRACT+RHIZOMA COPTIDIS EXTRACT	1 (<1%)	0	1 (<1%)
HEPARIN (NOS)	0	1 (<1%)	1 (<1%)
IBUPROFEN	1 (<1%)	0	1 (<1%)
IMIDAZOLE SALICYLATE	0	1 (<1%)	1 (<1%)
INDACATEROL MALEATE	1 (<1%)	0	1 (<1%)
ISATIS TINCTORIA ROOT	0	1 (<1%)	1 (<1%)
ISATIS TINCTORIA+PRUNUS ARMENIACA+POGOSTEMON CABLIN+HERBALS NOS+RHUBARB+CALCIUM SULFATE	1 (<1%)	0	1 (<1%)
IVABRADINE HYDROCHLORIDE	1 (<1%)	0	1 (<1%)
LATAMOXEF SODIUM	0	1 (<1%)	1 (<1%)
LEVODROPROPIZINE	1 (<1%)	0	1 (<1%)

Note: Includes all COPD medications started after first dose and before last dose + 28 days.
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Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Table 111.17
Summary of COPD Medications Started During Treatment by Ingredient in Study 208657

Ingredient	PBO (N=401)	100 SC (N=403)	Total (N=804)
LEVOFLOXACIN LACTATE	0	1 (<1%)	1 (<1%)
LEVOMENTHOL+SOPHORA TONKINENSIS ROOT WITH RHIZOME+ARDISIA CRISPA LEAF+ARDISIA CRISPA ROOT+CICADA SLOUGH	1 (<1%)	0	1 (<1%)
LEVOSALBUTAMOL HYDROCHLORIDE	0	1 (<1%)	1 (<1%)
LONICERA JAPONICA+SARCANDRA GLABRA+MENTHOL	1 (<1%)	0	1 (<1%)
LORATADINE	0	1 (<1%)	1 (<1%)
MAGNESIUM	1 (<1%)	0	1 (<1%)
MAGNESIUM SULFATE	1 (<1%)	0	1 (<1%)
METAMIZOLE SODIUM	0	1 (<1%)	1 (<1%)
METOCLOPRAMIDE	0	1 (<1%)	1 (<1%)
MOMETASONE FUROATE+FORMOTEROL FUMARATE	0	1 (<1%)	1 (<1%)
MOXIFLOXACIN HYDROCHLORIDE	0	1 (<1%)	1 (<1%)
MUCOLIT (NOS)	1 (<1%)	0	1 (<1%)
NADROPARIN	1 (<1%)	0	1 (<1%)
NUTRITIONAL SUPPLEMENT NOS	0	1 (<1%)	1 (<1%)
OLODATEROL	1 (<1%)	0	1 (<1%)
OMALIZUMAB	0	1 (<1%)	1 (<1%)
OMEPRAZOLE	0	1 (<1%)	1 (<1%)
OPTAMOX (NOS)	1 (<1%)	0	1 (<1%)
OSELTAMIVIR	0	1 (<1%)	1 (<1%)
PIPERACILLIN SODIUM+TAZOBACTAM SODIUM	0	1 (<1%)	1 (<1%)
PIPERACILLIN+TAZOBACTAM	1 (<1%)	0	1 (<1%)
PORIA COCOS SCLEROTIUM+GLYCYRRHIZA SPP. ROOT WITH RHIZOME+PINELLIA TERNATA TUBER+CITRUS X AURANTIUM FRUIT PEEL	1 (<1%)	0	1 (<1%)
POTASSIUM CHLORIDE	1 (<1%)	0	1 (<1%)
PROCATEROL HYDROCHLORIDE	1 (<1%)	0	1 (<1%)
PROMETHAZINE HYDROCHLORIDE+AMMONIUM CHLORIDE+SULFOGAIACOL	0	1 (<1%)	1 (<1%)
PROMETHAZINE+DEXTROMETHORPHAN	0	1 (<1%)	1 (<1%)

Note: Includes all COPD medications started after first dose and before last dose + 28 days.
/mnt/code/postcsr_01/prod/tfls/t_sp_c1_ontrt_ing_657.sas 21JUL2025 22:01

Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Table 111.17
Summary of COPD Medications Started During Treatment by Ingredient in Study 208657

Ingredient	PBO (N=401)	100 SC (N=403)	Total (N=804)
PSEUDOEPHEDRINE HYDROCHLORIDE+EBASTINE	0	1 (<1%)	1 (<1%)
QUERCETIN	0	1 (<1%)	1 (<1%)
RABEPRAZOLE SODIUM	0	1 (<1%)	1 (<1%)
RADIX PLATYCODI+ERIOBOTRYA JAPONICA+STEMONA (NOS)	0	1 (<1%)	1 (<1%)
REHMANNIA GLUTINOSA+CODONOPSIS PILOSULA+SCHISANDRA CHINENSIS FRUIT+MORUS ALBA ROOT BARK+ASTER TATARICUS ROOT WITH RHIZOME+ASTRAGALUS MONGHOLICUS ROOT	0	1 (<1%)	1 (<1%)
REHMANNIAE RADIX+POGOSTEMON CABLIN OIL+FORSYTHIA NOS+ANEMARRHENA ASPHODELOIDES+RHIZOMA PHRAGMITIS+CALCIUM SULFATE+RHIZOMA CURCUMAE	0	1 (<1%)	1 (<1%)
ROXITHROMYCIN	1 (<1%)	0	1 (<1%)
SALBUTAMOL+IPRATROPIUM	1 (<1%)	0	1 (<1%)
SALBUTAMOL+IPRATROPIUM BROMIDE	1 (<1%)	0	1 (<1%)
SALMETEROL	1 (<1%)	0	1 (<1%)
SALMETEROL+FLUTICASONE	1 (<1%)	0	1 (<1%)
SITAFLOXACIN	0	1 (<1%)	1 (<1%)
SODIUM BENZOATE+CAMPHOR+PAPAVER SOMNIFERUM+GLYCYRRHIZA SPP. ROOT WITH RHIZOME+ILLICIUM VERUM OIL	1 (<1%)	0	1 (<1%)
SODIUM CHLORIDE+LEVOFLOXACIN	1 (<1%)	0	1 (<1%)
SPIRONOLACTONE	0	1 (<1%)	1 (<1%)
SULFAMETHOXAZOLE+TRIMETHOPRIM	1 (<1%)	0	1 (<1%)
TERBUTALINE	1 (<1%)	0	1 (<1%)
THEOBROMINE	1 (<1%)	0	1 (<1%)
TIOTROPIUM+OLODATEROL	1 (<1%)	0	1 (<1%)
TULOBUTEROL	1 (<1%)	0	1 (<1%)
UMECLIDINIUM BROMIDE	1 (<1%)	0	1 (<1%)
UNCODED	1 (<1%)	0	1 (<1%)
VILANTEROL	0	1 (<1%)	1 (<1%)
VILANTEROL TRIFENATATE	1 (<1%)	0	1 (<1%)

Note: Includes all COPD medications started after first dose and before last dose + 28 days.
/mnt/code/postcsr_01/prod/tfls/t_sp_c1_ontrt_ing_657.sas 21JUL2025 22:01

Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Table 111.17

Summary of COPD Medications Started During Treatment by Ingredient in Study 208657

Ingredient	PBO (N=401)	100 SC (N=403)	Total (N=804)
VILANTEROL TRIFENATATE+UMECLIDINIUM BROMIDE	1 (<1%)	0	1 (<1%)
VILANTEROL+UMECLIDINIUM	1 (<1%)	0	1 (<1%)
VITAMINS NOS	0	1 (<1%)	1 (<1%)
VITEX AGNUS CASTUS+ISATIS TINCTORIA+LONICERA JAPONICA+CHRYSANTHEMUM (NOS)+EVODIA RUTAECARPA+ILEX NOS	1 (<1%)	0	1 (<1%)

Note: Includes all COPD medications started after first dose and before last dose + 28 days.

Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Table 111.18
Summary of COPD Medications Started During Treatment by Ingredient in Study MEA117113

Ingredient	PBO (N=87)	100 SC (N=83)	Total (N=170)
Any medication	58 (67%)	48 (58%)	106 (62%)
PREDNISOLONE	19 (22%)	21 (25%)	40 (24%)
PREDNISONE	16 (18%)	12 (14%)	28 (16%)
LEVOFLOXACIN	17 (20%)	10 (12%)	27 (16%)
OXYGEN	9 (10%)	5 (6%)	14 (8%)
CLARITHROMYCIN	7 (8%)	6 (7%)	13 (8%)
AMOXICILLIN	6 (7%)	6 (7%)	12 (7%)
AMOXICILLIN+CLAVULANATE POTASSIUM	5 (6%)	7 (8%)	12 (7%)
AMOXICILLIN+CLAVULANIC ACID	6 (7%)	6 (7%)	12 (7%)
METHYLPREDNISOLONE	6 (7%)	6 (7%)	12 (7%)
ACETYLCYSTEINE	7 (8%)	4 (5%)	11 (6%)
MEPREDNISONE	7 (8%)	4 (5%)	11 (6%)
AZITHROMYCIN	4 (5%)	6 (7%)	10 (6%)
IPRATROPIUM BROMIDE	5 (6%)	4 (5%)	9 (5%)
METHYLPREDNISOLONE SODIUM SUCCINATE	5 (6%)	4 (5%)	9 (5%)
HYDROCORTISONE	6 (7%)	1 (1%)	7 (4%)
SALBUTAMOL	5 (6%)	2 (2%)	7 (4%)
BUDESONIDE+FORMOTEROL FUMARATE	2 (2%)	4 (5%)	6 (4%)
CIPROFLOXACIN	5 (6%)	1 (1%)	6 (4%)
DEXAMETHASONE	5 (6%)	1 (1%)	6 (4%)
PARACETAMOL	4 (5%)	2 (2%)	6 (4%)
AMINOPHYLLINE	4 (5%)	1 (1%)	5 (3%)
CEFTRIAXONE	2 (2%)	3 (4%)	5 (3%)
CEFUROXIME	1 (1%)	4 (5%)	5 (3%)
DOXYCYCLINE	3 (3%)	2 (2%)	5 (3%)
ERDOSTEINE	2 (2%)	3 (4%)	5 (3%)
IPRATROPIUM BROMIDE+SALBUTAMOL SULFATE	3 (3%)	2 (2%)	5 (3%)
SALBUTAMOL SULFATE	3 (3%)	2 (2%)	5 (3%)
THEOPHYLLINE	3 (3%)	2 (2%)	5 (3%)
BETAMETHASONE	3 (3%)	1 (1%)	4 (2%)
FENOTEROL HYDROBROMIDE+IPRATROPIUM BROMIDE	4 (5%)	0	4 (2%)

Note: Includes all COPD medications started after first dose and before last dose + 28 days.
/mnt/code/postcsr_01/prod/tfls/t_sp_cm_ontrt_ing_113.sas 21JUL2025 22:01

Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Table 111.18
Summary of COPD Medications Started During Treatment by Ingredient in Study MEA117113

Ingredient	PBO (N=87)	100 SC (N=83)	Total (N=170)
MOXIFLOXACIN HYDROCHLORIDE	1 (1%)	3 (4%)	4 (2%)
AMBROXOL HYDROCHLORIDE	2 (2%)	1 (1%)	3 (2%)
BENZYLPENICILLIN	1 (1%)	2 (2%)	3 (2%)
CEFTIBUTEN	1 (1%)	2 (2%)	3 (2%)
CEFTRIAXONE SODIUM	1 (1%)	2 (2%)	3 (2%)
IBUPROFEN	3 (3%)	0	3 (2%)
MOXIFLOXACIN	2 (2%)	1 (1%)	3 (2%)
NORFLOXACIN	3 (3%)	0	3 (2%)
ROXITHROMYCIN	0	3 (4%)	3 (2%)
TIOTROPIUM BROMIDE	1 (1%)	2 (2%)	3 (2%)
BIAXIN (NOS)	2 (2%)	0	2 (1%)
CEFALEXIN	2 (2%)	0	2 (1%)
CEFDITOREN PIVOXIL	1 (1%)	1 (1%)	2 (1%)
CROMOGLICATE SODIUM	1 (1%)	1 (1%)	2 (1%)
FLUTICASONE PROPIONATE+SALMETEROL XINAFOATE	0	2 (2%)	2 (1%)
HEDERA HELIX EXTRACT+RHIZOMA COPTIDIS EXTRACT	1 (1%)	1 (1%)	2 (1%)
HYDROCORTISONE HYDROGEN SUCCINATE	2 (2%)	0	2 (1%)
IPRATROPIUM	0	2 (2%)	2 (1%)
LEVODROPROPIZINE	0	2 (2%)	2 (1%)
NOVALGIN NOS	2 (2%)	0	2 (1%)
OMNICEF (NOS)	1 (1%)	1 (1%)	2 (1%)
PIPERACILLIN SODIUM+TAZOBACTAM SODIUM	2 (2%)	0	2 (1%)
PREDNISOLONE SODIUM SUCCINATE	1 (1%)	1 (1%)	2 (1%)
PROCATEROL HYDROCHLORIDE	1 (1%)	1 (1%)	2 (1%)
SODIUM CHLORIDE	1 (1%)	1 (1%)	2 (1%)
ACECLOFENAC	0	1 (1%)	1 (<1%)
ACETYLCYSTEINE+AMOXICILLIN	1 (1%)	0	1 (<1%)
ACTIFED (NOS)	1 (1%)	0	1 (<1%)
AMBROXOL	0	1 (1%)	1 (<1%)
AMPICILLIN	1 (1%)	0	1 (<1%)

Note: Includes all COPD medications started after first dose and before last dose + 28 days.
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Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Table 111.18
Summary of COPD Medications Started During Treatment by Ingredient in Study MEA117113

Ingredient	PBO (N=87)	100 SC (N=83)	Total (N=170)
ANANAS COMOSUS+DEHYDROCHOLIC ACID+DIMETICONE, ACTIVATED+PANCREATIN+TRIMEBUTINE MALEATE	1 (1%)	0	1 (<1%)
AZELASTINE HYDROCHLORIDE	1 (1%)	0	1 (<1%)
BECLOMETASONE DIPROPIONATE+FORMOTEROL FUMARATE	0	1 (1%)	1 (<1%)
BETAMETHASONE+DESLORATADINE	1 (1%)	0	1 (<1%)
BROMHEXINE HYDROCHLORIDE+GUAIFENESIN	0	1 (1%)	1 (<1%)
CAFFEINE+PARACETAMOL+PROMETHAZINE METHYLENEDISALICYLATE+SALICYLAMIDE	1 (1%)	0	1 (<1%)
CAPTOPRIL	1 (1%)	0	1 (<1%)
CEFDINIR	0	1 (1%)	1 (<1%)
CEFEPIME HYDROCHLORIDE	0	1 (1%)	1 (<1%)
CEFPODOXIME	0	1 (1%)	1 (<1%)
CEFPODOXIME PROXETIL	1 (1%)	0	1 (<1%)
CEFTAZIDIME	1 (1%)	0	1 (<1%)
CEFUROXIME AXETIL	1 (1%)	0	1 (<1%)
CEFUROXIME SODIUM	1 (1%)	0	1 (<1%)
CETIRIZINE	1 (1%)	0	1 (<1%)
CHLORPHENAMINE	0	1 (1%)	1 (<1%)
CLAVULANIC ACID	1 (1%)	0	1 (<1%)
CLOPERASTINE FENDIZOATE	0	1 (1%)	1 (<1%)
CODEINE	1 (1%)	0	1 (<1%)
COMPRESSED AIR	0	1 (1%)	1 (<1%)
DALTEPARIN	0	1 (1%)	1 (<1%)
EBASTINE+PSEUDOEPHEDRINE HYDROCHLORIDE	1 (1%)	0	1 (<1%)
FAMOTIDINE	0	1 (1%)	1 (<1%)
FENOTEROL+IPRATROPIUM BROMIDE	1 (1%)	0	1 (<1%)
FUROSEMIDE	1 (1%)	0	1 (<1%)
GAVISCON NOS	1 (1%)	0	1 (<1%)
GENTAMICIN	1 (1%)	0	1 (<1%)
GLUCOSE	0	1 (1%)	1 (<1%)
GUAIFENESIN	1 (1%)	0	1 (<1%)

Note: Includes all COPD medications started after first dose and before last dose + 28 days.
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Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Table 111.18
Summary of COPD Medications Started During Treatment by Ingredient in Study MEA117113

Ingredient	PBO (N=87)	100 SC (N=83)	Total (N=170)
INFLUENZA VACCINE	0	1 (1%)	1 (<1%)
IPRATROPIUM+SALBUTAMOL	1 (1%)	0	1 (<1%)
LAFUTIDINE	0	1 (1%)	1 (<1%)
LEVOSULPIRIDE	1 (1%)	0	1 (<1%)
MACROGOL+POTASSIUM CHLORIDE+SODIUM BICARBONATE+SODIUM CHLORIDE	1 (1%)	0	1 (<1%)
MONTELUKAST	0	1 (1%)	1 (<1%)
MONTELUKAST SODIUM	0	1 (1%)	1 (<1%)
MYDOCALM (NOS)	1 (1%)	0	1 (<1%)
NOREPINEPHRINE	1 (1%)	0	1 (<1%)
OPTAMOX (NOS)	0	1 (1%)	1 (<1%)
PHENOXYMETHYLPENICILLIN POTASSIUM	1 (1%)	0	1 (<1%)
PIPERACILLIN	0	1 (1%)	1 (<1%)
PIPERACILLIN SODIUM	1 (1%)	0	1 (<1%)
PIPERACILLIN+TAZOBACTAM	0	1 (1%)	1 (<1%)
PNEUMOCOCCAL VACCINE	0	1 (1%)	1 (<1%)
PROBIOTICS (NOS)	1 (1%)	0	1 (<1%)
PSEUDOEPHEDRINE	1 (1%)	0	1 (<1%)
PSEUDOEPHEDRINE HYDROCHLORIDE	1 (1%)	0	1 (<1%)
PSEUDOEPHEDRINE HYDROCHLORIDE+TRIPROLIDINE HYDROCHLORIDE	0	1 (1%)	1 (<1%)
RANITIDINE HYDROCHLORIDE	0	1 (1%)	1 (<1%)
ROFLUMILAST	0	1 (1%)	1 (<1%)
SALMETEROL	1 (1%)	0	1 (<1%)
SUDAFED (NOS)	0	1 (1%)	1 (<1%)
SULFAMETHOXAZOLE+TRIMETHOPRIM	0	1 (1%)	1 (<1%)
SUPRAX (NOS)	1 (1%)	0	1 (<1%)
TALNIFLUMATE	1 (1%)	0	1 (<1%)
TAZOBACTAM	0	1 (1%)	1 (<1%)
THIAZINAMIUM METILSULFATE	0	1 (1%)	1 (<1%)
UMECLIDINIUM BROMIDE	0	1 (1%)	1 (<1%)

Note: Includes all COPD medications started after first dose and before last dose + 28 days.
/mnt/code/postcsr_01/prod/tfls/t_sp_cm_ontrt_ing_113.sas 21JUL2025 22:01

Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Table 111.18
Summary of COPD Medications Started During Treatment by Ingredient in Study MEA117113

Ingredient	PBO (N=87)	100 SC (N=83)	Total (N=170)
VALSARTAN	1 (1%)	0	1 (<1%)
VANCOMYCIN	1 (1%)	0	1 (<1%)

Note: Includes all COPD medications started after first dose and before last dose + 28 days.
/mnt/code/postcsr_01/prod/tfls/t_sp_cm_ontrt_ing_113.sas 21JUL2025 22:01

Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Table 111.19
Summary of COPD Medications Started During Treatment by Ingredient in Study MEA117106

Ingredient	PBO (N=90)	100 SC (N=82)	Total (N=172)
Any medication	71 (79%)	53 (65%)	124 (72%)
PREDNISONE	27 (30%)	18 (22%)	45 (26%)
METHYLPREDNISOLONE	20 (22%)	9 (11%)	29 (17%)
LEVOFLOXACIN	15 (17%)	13 (16%)	28 (16%)
PREDNISOLONE	17 (19%)	11 (13%)	28 (16%)
AMOXICILLIN+CLAVULANIC ACID	19 (21%)	7 (9%)	26 (15%)
ACETYLCYSTEINE	11 (12%)	7 (9%)	18 (10%)
IPRATROPIUM BROMIDE	13 (14%)	4 (5%)	17 (10%)
AZITHROMYCIN	7 (8%)	8 (10%)	15 (9%)
AMOXICILLIN+CLAVULANATE POTASSIUM	8 (9%)	6 (7%)	14 (8%)
DOXYCYCLINE	8 (9%)	6 (7%)	14 (8%)
METHYLPREDNISOLONE SODIUM SUCCINATE	8 (9%)	5 (6%)	13 (8%)
MOXIFLOXACIN	6 (7%)	7 (9%)	13 (8%)
OXYGEN	8 (9%)	5 (6%)	13 (8%)
AMOXICILLIN	7 (8%)	5 (6%)	12 (7%)
SALBUTAMOL	11 (12%)	1 (1%)	12 (7%)
IPRATROPIUM BROMIDE+SALBUTAMOL SULFATE	6 (7%)	3 (4%)	9 (5%)
BUDESONIDE	6 (7%)	1 (1%)	7 (4%)
ERDOSTEINE	4 (4%)	3 (4%)	7 (4%)
FENOTEROL HYDROBROMIDE+IPRATROPIUM BROMIDE	5 (6%)	2 (2%)	7 (4%)
THEOPHYLLINE	6 (7%)	1 (1%)	7 (4%)
TIOTROPIUM BROMIDE	5 (6%)	2 (2%)	7 (4%)
CIPROFLOXACIN	1 (1%)	5 (6%)	6 (3%)
CLARITHROMYCIN	4 (4%)	2 (2%)	6 (3%)
DEXAMETHASONE	4 (4%)	2 (2%)	6 (3%)
CEFTRIAXONE	3 (3%)	2 (2%)	5 (3%)
CEFTRIAXONE SODIUM	4 (4%)	1 (1%)	5 (3%)
CEFUROXIME	0	5 (6%)	5 (3%)
IPRATROPIUM	5 (6%)	0	5 (3%)
PARACETAMOL	2 (2%)	3 (4%)	5 (3%)
PIPERACILLIN SODIUM+TAZOBACTAM SODIUM	0	5 (6%)	5 (3%)

Note: Includes all COPD medications started after first dose and before last dose + 28 days.
/mnt/code/postcsr_01/prod/tfls/t_sp_cm_ontrt_ing_106.sas 21JUL2025 22:01

Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Table 111.19
Summary of COPD Medications Started During Treatment by Ingredient in Study MEA117106

Ingredient	PBO (N=90)		100 SC (N=82)		Total (N=172)	
SULFAMETHOXAZOLE+TRIMETHOPRIM	2	(2%)	3	(4%)	5	(3%)
TERBUTALINE SULFATE	2	(2%)	3	(4%)	5	(3%)
AMBROXOL	2	(2%)	2	(2%)	4	(2%)
AMINOPHYLLINE	3	(3%)	1	(1%)	4	(2%)
BUDESONIDE+FORMOTEROL FUMARATE	1	(1%)	3	(4%)	4	(2%)
CEFUROXIME AXETIL	3	(3%)	1	(1%)	4	(2%)
CIPROFLOXACIN HYDROCHLORIDE	2	(2%)	2	(2%)	4	(2%)
DEFLAZACORT	3	(3%)	1	(1%)	4	(2%)
FLUTICASONE PROPIONATE+SALMETEROL XINAFOATE	2	(2%)	2	(2%)	4	(2%)
MONTELUKAST	1	(1%)	3	(4%)	4	(2%)
OMEPRAZOLE	3	(3%)	1	(1%)	4	(2%)
SODIUM CHLORIDE	3	(3%)	1	(1%)	4	(2%)
BECLOMETASONE	2	(2%)	1	(1%)	3	(2%)
BECLOMETASONE DIPROPIONATE	3	(3%)	0		3	(2%)
BETAMETHASONE SODIUM PHOSPHATE	1	(1%)	2	(2%)	3	(2%)
CARBOCISTEINE	1	(1%)	2	(2%)	3	(2%)
CEFALEXIN	2	(2%)	1	(1%)	3	(2%)
CEFDITOREN PIVOXIL	2	(2%)	1	(1%)	3	(2%)
CEFOTAXIME	1	(1%)	2	(2%)	3	(2%)
DUOMOX (NOS)	3	(3%)	0		3	(2%)
FLUTICASONE PROPIONATE	2	(2%)	1	(1%)	3	(2%)
FUGENTIN (NOS)	2	(2%)	1	(1%)	3	(2%)
HEPARIN (NOS)	2	(2%)	1	(1%)	3	(2%)
POTASSIUM CHLORIDE	3	(3%)	0		3	(2%)
PRISTINAMYCIN	3	(3%)	0		3	(2%)
SPIRAMYCIN	3	(3%)	0		3	(2%)
ACLIDINIUM BROMIDE	0		2	(2%)	2	(1%)
AMBROXOL HYDROCHLORIDE	2	(2%)	0		2	(1%)
AMPICILLIN	2	(2%)	0		2	(1%)
AMPISID (NOS)	2	(2%)	0		2	(1%)
BECLOMETASONE DIPROPIONATE+FORMOTEROL FUMARATE	1	(1%)	1	(1%)	2	(1%)

Note: Includes all COPD medications started after first dose and before last dose + 28 days.
/mnt/code/postcsr_01/prod/tfls/t_sp_cm_ontrt_ing_106.sas 21JUL2025 22:01

Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Table 111.19
Summary of COPD Medications Started During Treatment by Ingredient in Study MEA117106

Ingredient	PBO (N=90)	100 SC (N=82)	Total (N=172)
BIAXIN (NOS)	1 (1%)	1 (1%)	2 (1%)
CEFTAZIDIME	0	2 (2%)	2 (1%)
DOXYCYCLINE HYDROCHLORIDE	1 (1%)	1 (1%)	2 (1%)
FLUNISOLIDE	2 (2%)	0	2 (1%)
GUAIFENESIN	1 (1%)	1 (1%)	2 (1%)
HYDROCORTISONE SODIUM PHOSPHATE	2 (2%)	0	2 (1%)
IBUPROFEN	1 (1%)	1 (1%)	2 (1%)
IMIPENEM	0	2 (2%)	2 (1%)
INFLUENZA VACCINE	1 (1%)	1 (1%)	2 (1%)
IPRATROPIUM+SALBUTAMOL	2 (2%)	0	2 (1%)
MUCOSOLVAN (NOS)	1 (1%)	1 (1%)	2 (1%)
PROFLOX (NOS)	1 (1%)	1 (1%)	2 (1%)
ROXITHROMYCIN	1 (1%)	1 (1%)	2 (1%)
SALBUTAMOL SULFATE	1 (1%)	1 (1%)	2 (1%)
TOBRAMYCIN	0	2 (2%)	2 (1%)
ACETYLSALICYLIC ACID	1 (1%)	0	1 (<1%)
ACETYLSALICYLIC ACID+ASCORBIC ACID+RUTOSIDE	1 (1%)	0	1 (<1%)
ACLIDINIUM+FORMOTEROL	1 (1%)	0	1 (<1%)
ACYCLOVIR	1 (1%)	0	1 (<1%)
AMBIGUOUS MEDICATION NOS	0	1 (1%)	1 (<1%)
AMOXICILLIN+SULBACTAM PIVOXIL	0	1 (1%)	1 (<1%)
AMPICILLIN SODIUM+SULBACTAM SODIUM	1 (1%)	0	1 (<1%)
ANTIBIOTICS NOS	1 (1%)	0	1 (<1%)
BEMIPARIN	0	1 (1%)	1 (<1%)
BENADRYL (NOS)	0	1 (1%)	1 (<1%)
BETAMETHASONE	1 (1%)	0	1 (<1%)
BICARBONATE	0	1 (1%)	1 (<1%)
BIFIDOBACTERIUM LACTIS+FRUCTOOLIGOSACCHARIDES+LACTOBACILLUS PLANTARUM+LACTOBACILLUS RHAMNOSUS	1 (1%)	0	1 (<1%)
BILASTINE	1 (1%)	0	1 (<1%)

Note: Includes all COPD medications started after first dose and before last dose + 28 days.
/mnt/code/postcsr_01/prod/tfls/t_sp_cm_ontrt_ing_106.sas 21JUL2025 22:01

Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Table 111.19
Summary of COPD Medications Started During Treatment by Ingredient in Study MEA117106

Ingredient	PBO (N=90)	100 SC (N=82)	Total (N=172)
BROMHEXINE HYDROCHLORIDE	1 (1%)	0	1 (<1%)
BRONCHODILATOR (NOS)	1 (1%)	0	1 (<1%)
CEFEPIME HYDROCHLORIDE	0	1 (1%)	1 (<1%)
CEFIXIME	1 (1%)	0	1 (<1%)
CEFOTAXIME SODIUM	0	1 (1%)	1 (<1%)
CEFZIL (NOS)	1 (1%)	0	1 (<1%)
CHLORPHENAMINE+HYDROCODONE	1 (1%)	0	1 (<1%)
CLINDAMYCIN	0	1 (1%)	1 (<1%)
CODEINE PHOSPHATE+SULFOGAIACOL	1 (1%)	0	1 (<1%)
COLISTIN	0	1 (1%)	1 (<1%)
COMPRESSED AIR	1 (1%)	0	1 (<1%)
CORICIDIN (NOS)	0	1 (1%)	1 (<1%)
DECONGESTANT NOS	0	1 (1%)	1 (<1%)
DEXTRAN	1 (1%)	0	1 (<1%)
DEXTROMETHORPHAN	1 (1%)	0	1 (<1%)
DICLOFENAC	1 (1%)	0	1 (<1%)
DOXYCYCLINE MONOHYDRATE	1 (1%)	0	1 (<1%)
ENOXAPARIN	0	1 (1%)	1 (<1%)
FENOTEROL	0	1 (1%)	1 (<1%)
FENSPIRIDE	0	1 (1%)	1 (<1%)
FLUCONAZOLE	0	1 (1%)	1 (<1%)
FLUTICASONE FUROATE	1 (1%)	0	1 (<1%)
FLUTICASONE FUROATE+VILANTEROL TRIFENATATE	0	1 (1%)	1 (<1%)
FORMOTEROL	1 (1%)	0	1 (<1%)
FUROSEMIDE	0	1 (1%)	1 (<1%)
GENTAMICIN	0	1 (1%)	1 (<1%)
HOMATROPINE METHYLBROMIDE+HYDROCODONE BITARTRATE	1 (1%)	0	1 (<1%)
HYDROCORTISONE	0	1 (1%)	1 (<1%)
INDACATEROL MALEATE	1 (1%)	0	1 (<1%)
IPRATROPIUM BROMIDE+SALBUTAMOL	1 (1%)	0	1 (<1%)
ITRACONAZOLE	1 (1%)	0	1 (<1%)

Note: Includes all COPD medications started after first dose and before last dose + 28 days.
/mnt/code/postcsr_01/prod/tfls/t_sp_cm_ontrt_ing_106.sas 21JUL2025 22:01

Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Table 111.19
Summary of COPD Medications Started During Treatment by Ingredient in Study MEA117106

Ingredient	PBO (N=90)	100 SC (N=82)	Total (N=172)
KETOPROFEN	0	1 (1%)	1 (<1%)
LACTOBACILLUS NOS	1 (1%)	0	1 (<1%)
LEVOSALBUTAMOL	1 (1%)	0	1 (<1%)
LINCOMYCIN HYDROCHLORIDE	1 (1%)	0	1 (<1%)
LORATADINE	0	1 (1%)	1 (<1%)
MELOXICAM	0	1 (1%)	1 (<1%)
METHYLPREDNISOLONE HEMISUCCINATE	1 (1%)	0	1 (<1%)
METRONIDAZOLE+SPIRAMYCIN	1 (1%)	0	1 (<1%)
MONTELUKAST SODIUM	1 (1%)	0	1 (<1%)
MOXIFLOXACIN HYDROCHLORIDE	1 (1%)	0	1 (<1%)
NASAL PREPARATIONS	0	1 (1%)	1 (<1%)
NON-DRUG THERAPY	1 (1%)	0	1 (<1%)
OPERATIONS AND PROCEDURES	1 (1%)	0	1 (<1%)
OSELTAMIVIR	1 (1%)	0	1 (<1%)
PANTOPRAZOLE	0	1 (1%)	1 (<1%)
PARACETAMOL+PHENYLEPHRINE HYDROCHLORIDE	1 (1%)	0	1 (<1%)
PIPERACILLIN+TAZOBACTAM	1 (1%)	0	1 (<1%)
PNEUMOCOCCAL VACCINE	1 (1%)	0	1 (<1%)
PREDNISONE ACETATE	0	1 (1%)	1 (<1%)
RIFAMPICIN	0	1 (1%)	1 (<1%)
ROBITUSSIN (NOS)	0	1 (1%)	1 (<1%)
TERBUTALINE	1 (1%)	0	1 (<1%)
TRAMADOL	0	1 (1%)	1 (<1%)
TRIAMCINOLONE	0	1 (1%)	1 (<1%)
TRIAMCINOLONE DIACETATE	0	1 (1%)	1 (<1%)
VANCOMYCIN	0	1 (1%)	1 (<1%)

Note: Includes all COPD medications started after first dose and before last dose + 28 days.
/mnt/code/postcsr_01/prod/tfls/t_sp_cm_ontrt_ing_106.sas 21JUL2025 22:01

Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Table 111.20

Summary of Non-COPD Medications Started During Treatment in Study 208657

ATC Level 1 Ingredient and Ingredient Combinations	PBO (N=401)	100 SC (N=403)	Total (N=804)
Any medication	341 (85%)	332 (82%)	673 (84%)
ANTIINFECTIVES FOR SYSTEMIC USE			
Any medication	289 (72%)	281 (70%)	570 (71%)
TOZINAMERAN	70 (17%)	71 (18%)	141 (18%)
AZITHROMYCIN	63 (16%)	46 (11%)	109 (14%)
LEVOFLOXACIN	49 (12%)	50 (12%)	99 (12%)
AMOXICILLIN+CLAVULANIC ACID	43 (11%)	35 (9%)	78 (10%)
AMOXICILLIN	30 (7%)	42 (10%)	72 (9%)
INFLUENZA VACCINE	30 (7%)	29 (7%)	59 (7%)
ELASOMERAN	25 (6%)	24 (6%)	49 (6%)
COVID-19 VACCINE	20 (5%)	28 (7%)	48 (6%)
DOXYCYCLINE	23 (6%)	21 (5%)	44 (5%)
AMOXICILLIN+CLAVULANATE POTASSIUM	25 (6%)	17 (4%)	42 (5%)
CLARITHROMYCIN	25 (6%)	16 (4%)	41 (5%)
COVID-19 VACCINE NRVV AD (CHADOX1 NCOV-19)	12 (3%)	17 (4%)	29 (4%)
CIPROFLOXACIN	13 (3%)	15 (4%)	28 (3%)
INFLUENZA VACCINE INACT SPLIT 4V	15 (4%)	13 (3%)	28 (3%)
AMOXICILLIN TRIHYDRATE+CLAVULANATE POTASSIUM	10 (2%)	14 (3%)	24 (3%)
MOXIFLOXACIN	12 (3%)	11 (3%)	23 (3%)
CEFTRIAXONE	14 (3%)	8 (2%)	22 (3%)
CEFUROXIME	10 (2%)	10 (2%)	20 (2%)
CEFIXIME	9 (2%)	8 (2%)	17 (2%)
CEFDINIR	9 (2%)	6 (1%)	15 (2%)
MOXIFLOXACIN HYDROCHLORIDE	7 (2%)	8 (2%)	15 (2%)
PIPERACILLIN SODIUM+TAZOBACTAM SODIUM	6 (1%)	9 (2%)	15 (2%)
INFLUENZA VACCINE INACT	7 (2%)	7 (2%)	14 (2%)
INFLUENZA VACCINE INACT SAG 4V	5 (1%)	9 (2%)	14 (2%)
NYSTATIN	9 (2%)	4 (<1%)	13 (2%)
OSELTAMIVIR PHOSPHATE	8 (2%)	5 (1%)	13 (2%)
PIPERACILLIN+TAZOBACTAM	7 (2%)	6 (1%)	13 (2%)

Note: A medication may be included in more than one ATC Level category and appear more than once.
Includes medications started after first dose and before last dose + 28 days.
/mnt/code/postcsr_01/prod/tfls/t_sp_c1_ncopd_on_657.sas 21JUL2025 22:02

Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Table 111.20

Summary of Non-COPD Medications Started During Treatment in Study 208657

ATC Level 1 Ingredient and Ingredient Combinations	PBO (N=401)	100 SC (N=403)	Total (N=804)
COVID-19 VACCINE INACTIVE (VERO)	7 (2%)	5 (1%)	12 (1%)
FLUCONAZOLE	6 (1%)	6 (1%)	12 (1%)
SODIUM CHLORIDE+LEVOFLOXACIN	9 (2%)	3 (<1%)	12 (1%)
CEFALEXIN	3 (<1%)	8 (2%)	11 (1%)
CEFTRIAXONE SODIUM	5 (1%)	6 (1%)	11 (1%)
CLAVULANIC ACID	5 (1%)	6 (1%)	11 (1%)
CEFOPERAZONE SODIUM+SULBACTAM SODIUM	7 (2%)	3 (<1%)	10 (1%)
CEFUROXIME AXETIL	6 (1%)	4 (<1%)	10 (1%)
MEROPENEM	4 (<1%)	6 (1%)	10 (1%)
PNEUMOCOCCAL VACCINE POLYSACCHARIDE 23 VALENT	7 (2%)	3 (<1%)	10 (1%)
CEFDITOREN PIVOXIL	4 (<1%)	5 (1%)	9 (1%)
METRONIDAZOLE	7 (2%)	2 (<1%)	9 (1%)
PNEUMOCOCCAL VACCINE	2 (<1%)	7 (2%)	9 (1%)
AD26 COV2 S VACCINE	4 (<1%)	4 (<1%)	8 (<1%)
AMPICILLIN+SULBACTAM	6 (1%)	2 (<1%)	8 (<1%)
AMPICILLIN SODIUM+SULBACTAM SODIUM	4 (<1%)	3 (<1%)	7 (<1%)
ACICLOVIR	2 (<1%)	4 (<1%)	6 (<1%)
AMPHOTERICIN B	4 (<1%)	2 (<1%)	6 (<1%)
AMPICILLIN	4 (<1%)	2 (<1%)	6 (<1%)
CEFACLOR	5 (1%)	1 (<1%)	6 (<1%)
SODIUM CHLORIDE+MOXIFLOXACIN HYDROCHLORIDE	2 (<1%)	4 (<1%)	6 (<1%)
CEFOTAXIME SODIUM	4 (<1%)	1 (<1%)	5 (<1%)
CEFTAZIDIME	0	5 (1%)	5 (<1%)
CIPROFLOXACIN HYDROCHLORIDE	3 (<1%)	2 (<1%)	5 (<1%)
INFLUENZA VACCINE INACT SAG 3V	2 (<1%)	3 (<1%)	5 (<1%)
OFLOXACIN	3 (<1%)	2 (<1%)	5 (<1%)
OPTAMOX (NOS)	2 (<1%)	3 (<1%)	5 (<1%)
RAXTOZINAMERAN	1 (<1%)	4 (<1%)	5 (<1%)
RITONAVIR+NIRMATRELVIR	2 (<1%)	3 (<1%)	5 (<1%)
SITAFLOXACIN	3 (<1%)	2 (<1%)	5 (<1%)
SULFAMETHOXAZOLE+TRIMETHOPRIM	2 (<1%)	3 (<1%)	5 (<1%)

Note: A medication may be included in more than one ATC Level category and appear more than once.
Includes medications started after first dose and before last dose + 28 days.
/mnt/code/postcsr_01/prod/tfls/t_sp_c1_ncopd_on_657.sas 21JUL2025 22:02

Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Table 111.20

Summary of Non-COPD Medications Started During Treatment in Study 208657

ATC Level 1 Ingredient and Ingredient Combinations	PBO (N=401)	100 SC (N=403)	Total (N=804)
TAZOBACTAM	2 (<1%)	3 (<1%)	5 (<1%)
AMOXICILLIN TRIHYDRATE	3 (<1%)	1 (<1%)	4 (<1%)
DOXYCYCLINE HYCLATE	4 (<1%)	0	4 (<1%)
FUSIDIC ACID	3 (<1%)	1 (<1%)	4 (<1%)
LATAMOXEF SODIUM	2 (<1%)	2 (<1%)	4 (<1%)
PIPERACILLIN	2 (<1%)	2 (<1%)	4 (<1%)
REMDESIVIR	1 (<1%)	3 (<1%)	4 (<1%)
ROXITHROMYCIN	2 (<1%)	2 (<1%)	4 (<1%)
VANCOMYCIN	2 (<1%)	2 (<1%)	4 (<1%)
BENZYLPENICILLIN	2 (<1%)	1 (<1%)	3 (<1%)
CEFOPERAZONE SODIUM+TAZOBACTAM SODIUM	1 (<1%)	2 (<1%)	3 (<1%)
CLINDAMYCIN	1 (<1%)	2 (<1%)	3 (<1%)
DOXYCYCLINE HYDROCHLORIDE	2 (<1%)	1 (<1%)	3 (<1%)
GENTAMICIN	1 (<1%)	2 (<1%)	3 (<1%)
LEVOFLOXACIN HYDROCHLORIDE	1 (<1%)	2 (<1%)	3 (<1%)
NEMONOXACIN MALATE	2 (<1%)	1 (<1%)	3 (<1%)
NITROFURANTOIN	1 (<1%)	2 (<1%)	3 (<1%)
OSELTAMIVIR	1 (<1%)	2 (<1%)	3 (<1%)
PHENOXYMETHYLPENICILLIN POTASSIUM	3 (<1%)	0	3 (<1%)
PIPERACILLIN SODIUM+TAZOBACTAM	2 (<1%)	1 (<1%)	3 (<1%)
TOZINAMERAN+RILTOZINAMERAN	0	3 (<1%)	3 (<1%)
VARICELLA ZOSTER VACCINE RGE (CHO)	1 (<1%)	2 (<1%)	3 (<1%)
AD5 COV2 S VACCINE	1 (<1%)	1 (<1%)	2 (<1%)
AMIKACIN	2 (<1%)	0	2 (<1%)
BENZYLPENICILLIN SODIUM	0	2 (<1%)	2 (<1%)
CALLICARPA NUDIFLORA LEAF	0	2 (<1%)	2 (<1%)
CEFAZOLIN	0	2 (<1%)	2 (<1%)
CEFAZOLIN SODIUM	1 (<1%)	1 (<1%)	2 (<1%)
CEFDITOREN	1 (<1%)	1 (<1%)	2 (<1%)
CEFIXIME TRIHYDRATE	1 (<1%)	1 (<1%)	2 (<1%)
CEFMINOX SODIUM	1 (<1%)	1 (<1%)	2 (<1%)

Note: A medication may be included in more than one ATC Level category and appear more than once.
Includes medications started after first dose and before last dose + 28 days.
/mnt/code/postcsr_01/prod/tfls/t_sp_c1_ncopd_on_657.sas 21JUL2025 22:02

Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Table 111.20

Summary of Non-COPD Medications Started During Treatment in Study 208657

ATC Level 1 Ingredient and Ingredient Combinations	PBO (N=401)	100 SC (N=403)	Total (N=804)
CEFPODOXIME	0	2 (<1%)	2 (<1%)
CEFPODOXIME PROXETIL	1 (<1%)	1 (<1%)	2 (<1%)
CEFPROZIL	1 (<1%)	1 (<1%)	2 (<1%)
CEFRADINE	2 (<1%)	0	2 (<1%)
CEFTIZOXIME SODIUM	1 (<1%)	1 (<1%)	2 (<1%)
CEFUROXIME SODIUM	2 (<1%)	0	2 (<1%)
CHLORAMPHENICOL	1 (<1%)	1 (<1%)	2 (<1%)
CLAVULANIC ACID+CEFPODOXIME	0	2 (<1%)	2 (<1%)
CLINDAMYCIN PALMITATE HYDROCHLORIDE	1 (<1%)	1 (<1%)	2 (<1%)
ERTAPENEM	1 (<1%)	1 (<1%)	2 (<1%)
ETHAMBUTOL DIHYDROCHLORIDE	1 (<1%)	1 (<1%)	2 (<1%)
FAMTOZINAMERAN+TOZINAMERAN	1 (<1%)	1 (<1%)	2 (<1%)
FORSYTHIA SUSPENSA FRUIT+GLYCYRRHIZA SPP. ROOT WITH RHIZOME+EPHEDRA SPP HERB+CALCIUM SULFATE DIHYDRATE+MENTHOL+ISATIS TINCTORIA SUBSP. TINCTORIA ROOT+HERBALS NOS	1 (<1%)	1 (<1%)	2 (<1%)
FOSFOMYCIN TROMETAMOL	1 (<1%)	1 (<1%)	2 (<1%)
GATIFLOXACIN	0	2 (<1%)	2 (<1%)
ISONIAZID	1 (<1%)	1 (<1%)	2 (<1%)
MICONAZOLE	0	2 (<1%)	2 (<1%)
MOLNUPIRAVIR	2 (<1%)	0	2 (<1%)
MUPIROCIN	2 (<1%)	0	2 (<1%)
PNEUMOCOCCAL 13 VALENT CONJUGATE VACCINE	1 (<1%)	1 (<1%)	2 (<1%)
PRISTINAMYCIN	1 (<1%)	1 (<1%)	2 (<1%)
RIBAVIRIN	1 (<1%)	1 (<1%)	2 (<1%)
SELEXID (NOS)	1 (<1%)	1 (<1%)	2 (<1%)
SULBACTAM	1 (<1%)	1 (<1%)	2 (<1%)
SULTAMICILLIN	1 (<1%)	1 (<1%)	2 (<1%)
TETANUS VACCINE	1 (<1%)	1 (<1%)	2 (<1%)
TOBRAMYCIN	2 (<1%)	0	2 (<1%)
AMOXICILLIN SODIUM+CLAVULANATE POTASSIUM	1 (<1%)	0	1 (<1%)

Note: A medication may be included in more than one ATC Level category and appear more than once.
Includes medications started after first dose and before last dose + 28 days.
/mnt/code/postcsr_01/prod/tfls/t_sp_c1_ncopd_on_657.sas 21JUL2025 22:02

Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Table 111.20

Summary of Non-COPD Medications Started During Treatment in Study 208657

ATC Level 1 Ingredient and Ingredient Combinations	PBO (N=401)	100 SC (N=403)	Total (N=804)
AMOXICILLIN TRIHYDRATE+AMBROXOL HYDROCHLORIDE	0	1 (<1%)	1 (<1%)
AMPICILLIN SODIUM	0	1 (<1%)	1 (<1%)
AMPICILLIN SODIUM+SULBACTAM	1 (<1%)	0	1 (<1%)
ANTIBIOTICS NOS	1 (<1%)	0	1 (<1%)
ANTOFLOXACIN HYDROCHLORIDE	0	1 (<1%)	1 (<1%)
AZITHROMYCIN DIHYDRATE	0	1 (<1%)	1 (<1%)
AZVUDINE	0	1 (<1%)	1 (<1%)
BAMLANIVIMAB	1 (<1%)	0	1 (<1%)
BENZATHINE BENZYLPENICILLIN	0	1 (<1%)	1 (<1%)
BIAXIN (NOS)	0	1 (<1%)	1 (<1%)
BRIVUDINE	1 (<1%)	0	1 (<1%)
CEFADROXIL	0	1 (<1%)	1 (<1%)
CEFALEXIN LYSINE	1 (<1%)	0	1 (<1%)
CEFAMANDOLE NAFATE	0	1 (<1%)	1 (<1%)
CEFEPIME	1 (<1%)	0	1 (<1%)
CEFOPERAZONE+SULBACTAM	1 (<1%)	0	1 (<1%)
CEFOPERAZONE+SULBACTAM SODIUM	0	1 (<1%)	1 (<1%)
CEFOTAXIME SODIUM+SULBACTAM SODIUM	1 (<1%)	0	1 (<1%)
CEFTAZIDIME PENTAHYDRATE	0	1 (<1%)	1 (<1%)
CEFTRIAXONE SODIUM+TAZOBACTAM SODIUM	1 (<1%)	0	1 (<1%)
CEFUROXIME+CLAVULANIC ACID	0	1 (<1%)	1 (<1%)
CEPHALOSPORIN NOS	0	1 (<1%)	1 (<1%)
CLARITHROMYCIN CITRATE	1 (<1%)	0	1 (<1%)
CLAVULANIC ACID+CEFPODOXIME PROXETIL	1 (<1%)	0	1 (<1%)
CLINDAMYCIN HYDROCHLORIDE	0	1 (<1%)	1 (<1%)
COVID-19 VACCINE INACTIVE (VERO) CZ02	1 (<1%)	0	1 (<1%)
COVID-19 VACCINE NRVV AD26 (JNJ 78436735)	0	1 (<1%)	1 (<1%)
DICLOXACILLIN SODIUM	1 (<1%)	0	1 (<1%)
DIPHTHERIA VACCINE	1 (<1%)	0	1 (<1%)
DUOMOX (NOS)	0	1 (<1%)	1 (<1%)
ELASOMERAN+DAVESOMERAN	0	1 (<1%)	1 (<1%)

Note: A medication may be included in more than one ATC Level category and appear more than once.
Includes medications started after first dose and before last dose + 28 days.
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Table 111.20
Summary of Non-COPD Medications Started During Treatment in Study 208657

ATC Level 1 Ingredient and Ingredient Combinations	PBO (N=401)	100 SC (N=403)	Total (N=804)
FAROPENEM	0	1 (<1%)	1 (<1%)
FORSYTHIA SUSPENSA FRUIT+LONICERA SPP. FLOWER BUD+CHRYSANTHEMUM INDICUM FLOWER HEAD+ARTEMISIA ANNUA HERB+KITAGAWIA PRAERUPTORA ROOT+ISATIS TINCTORIA SUBSP. TINCTORIA LEAF+HERBALS NOS	1 (<1%)	0	1 (<1%)
FOSFOMYCIN	0	1 (<1%)	1 (<1%)
FOSFOMYCIN SODIUM	1 (<1%)	0	1 (<1%)
GEMIFLOXACIN MESILATE	1 (<1%)	0	1 (<1%)
IMIPENEM+CILASTATIN SODIUM	1 (<1%)	0	1 (<1%)
ISATIS TINCTORIA ROOT+FORSYTHIA SUSPENSA FRUIT+ANEMARRHENA ASPHODELOIDES RHIZOME+CURCUMA SPP. ROOT TUBER+CALCIUM SULFATE DIHYDRATE+ACORUS CALAMUS VAR. ANGUSTATUS RHIZOME+HERBALS NOS	0	1 (<1%)	1 (<1%)
ITRACONAZOLE	1 (<1%)	0	1 (<1%)
KETOCONAZOLE	1 (<1%)	0	1 (<1%)
LEVOFLOXACIN HEMIHYDRATE	0	1 (<1%)	1 (<1%)
METRONIDAZOLE+COW BEZOAR	0	1 (<1%)	1 (<1%)
MICONAZOLE NITRATE	1 (<1%)	0	1 (<1%)
NORFLOXACIN	0	1 (<1%)	1 (<1%)
ORNIDAZOLE	0	1 (<1%)	1 (<1%)
PAZUFLOXACIN MESILATE	1 (<1%)	0	1 (<1%)
PERAMIVIR	0	1 (<1%)	1 (<1%)
PERTUSSIS VACCINE	1 (<1%)	0	1 (<1%)
PHENOXYMETHYLPENICILLIN	0	1 (<1%)	1 (<1%)
PIPERACILLIN SODIUM+SULBACTAM SODIUM	1 (<1%)	0	1 (<1%)
PIPERACILLIN+SULBACTAM	1 (<1%)	0	1 (<1%)
PIVMECILLINAM	0	1 (<1%)	1 (<1%)
PIVMECILLINAM HYDROCHLORIDE	0	1 (<1%)	1 (<1%)
PNEUMOCOCCAL VACCINE CONJ 7V (CRM197)	0	1 (<1%)	1 (<1%)
QUADRIVALENT INFLUENZA VACCINES	1 (<1%)	0	1 (<1%)
RIFAPENTINE	1 (<1%)	0	1 (<1%)

Note: A medication may be included in more than one ATC Level category and appear more than once.
Includes medications started after first dose and before last dose + 28 days.
/mnt/code/postcsr_01/prod/tfls/t_sp_c1_ncopd_on_657.sas 21JUL2025 22:02

Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Table 111.20

Summary of Non-COPD Medications Started During Treatment in Study 208657

ATC Level 1 Ingredient and Ingredient Combinations	PBO (N=401)	100 SC (N=403)	Total (N=804)
RITONAVIR+SIMNOTRELVIR	0	1 (<1%)	1 (<1%)
RSV VACCINE PROT. SUBUNIT PREF3	1 (<1%)	0	1 (<1%)
SCUTELLARIA BAICALENSIS ROOT+LONICERA JAPONICA FLOWER+FORSYTHIA SUSPENSA FRUIT+BEAR BILE+ANIMAL HORN NOS	1 (<1%)	0	1 (<1%)
SODIUM CHLORIDE+AZITHROMYCIN	1 (<1%)	0	1 (<1%)
SODIUM CHLORIDE+CEFTRIAXONE SODIUM	0	1 (<1%)	1 (<1%)
SODIUM CHLORIDE+ORNIDAZOLE	1 (<1%)	0	1 (<1%)
SPIRAMYCIN	1 (<1%)	0	1 (<1%)
SULFADIAZINE SILVER	1 (<1%)	0	1 (<1%)
SULFAMETHOXAZOLE	1 (<1%)	0	1 (<1%)
SUPRAX (NOS)	1 (<1%)	0	1 (<1%)
TETANUS VACCINE TOXOID+DIPHTHERIA VACCINE TOXOID	0	1 (<1%)	1 (<1%)
TETANUS VACCINE TOXOID+DIPHTHERIA VACCINE TOXOID+PERTUSSIS VACCINE ACELLULAR	0	1 (<1%)	1 (<1%)
TETANUS VACCINE TOXOID+POLIO VACCINE INACT 3V (VERO)+DIPHTHERIA VACCINE TOXOID+PERTUSSIS VACCINE ACELLULAR 5-COMPONENT	0	1 (<1%)	1 (<1%)
TETRACYCLINE	1 (<1%)	0	1 (<1%)
TICK-BORNE ENCEPHALITIS VACCINE	0	1 (<1%)	1 (<1%)
UMIFENOVIR HYDROCHLORIDE	1 (<1%)	0	1 (<1%)
VALACICLOVIR	0	1 (<1%)	1 (<1%)
VANCOMYCIN HYDROCHLORIDE	0	1 (<1%)	1 (<1%)
ZABOFLOXACIN ASPARTATE	0	1 (<1%)	1 (<1%)
ZOSTER VACCINE (NOS)	1 (<1%)	0	1 (<1%)
ALIMENTARY TRACT AND METABOLISM			
Any medication	246 (61%)	239 (59%)	485 (60%)
PREDNISONE	82 (20%)	71 (18%)	153 (19%)
PREDNISOLONE	62 (15%)	66 (16%)	128 (16%)
ACETYLCYSTEINE	40 (10%)	45 (11%)	85 (11%)

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Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Table 111.20

Summary of Non-COPD Medications Started During Treatment in Study 208657

ATC Level 1 Ingredient and Ingredient Combinations	PBO (N=401)	100 SC (N=403)	Total (N=804)
BUDESONIDE	18 (4%)	18 (4%)	36 (4%)
ACETYLSALICYLIC ACID	22 (5%)	12 (3%)	34 (4%)
DEXAMETHASONE	17 (4%)	17 (4%)	34 (4%)
POTASSIUM CHLORIDE	19 (5%)	13 (3%)	32 (4%)
BETAMETHASONE	20 (5%)	11 (3%)	31 (4%)
PANTOPRAZOLE	13 (3%)	18 (4%)	31 (4%)
SODIUM CHLORIDE	14 (3%)	17 (4%)	31 (4%)
OMEPRAZOLE	17 (4%)	12 (3%)	29 (4%)
DICLOFENAC	10 (2%)	11 (3%)	21 (3%)
COLECALCIFEROL	7 (2%)	10 (2%)	17 (2%)
HYDROCORTISONE	11 (3%)	6 (1%)	17 (2%)
LACTULOSE	8 (2%)	9 (2%)	17 (2%)
DEXAMETHASONE SODIUM PHOSPHATE	11 (3%)	4 (<1%)	15 (2%)
FAMOTIDINE	8 (2%)	7 (2%)	15 (2%)
DICLOFENAC SODIUM	2 (<1%)	11 (3%)	13 (2%)
NYSTATIN	9 (2%)	4 (<1%)	13 (2%)
RABEPRAZOLE SODIUM	5 (1%)	6 (1%)	11 (1%)
ASCORBIC ACID	6 (1%)	4 (<1%)	10 (1%)
METFORMIN	2 (<1%)	8 (2%)	10 (1%)
METFORMIN HYDROCHLORIDE	5 (1%)	5 (1%)	10 (1%)
PREDNISONE ACETATE	6 (1%)	4 (<1%)	10 (1%)
MAGNESIUM SULFATE	7 (2%)	2 (<1%)	9 (1%)
METRONIDAZOLE	7 (2%)	2 (<1%)	9 (1%)
ONDANSETRON	4 (<1%)	5 (1%)	9 (1%)
CALCIUM CARBONATE+COLECALCIFEROL	4 (<1%)	3 (<1%)	7 (<1%)
HYDROCORTISONE SODIUM SUCCINATE	2 (<1%)	5 (1%)	7 (<1%)
LANSOPRAZOLE	3 (<1%)	4 (<1%)	7 (<1%)
LOPERAMIDE HYDROCHLORIDE	2 (<1%)	5 (1%)	7 (<1%)
MAGNESIUM	3 (<1%)	4 (<1%)	7 (<1%)
PREDNISOLONE SODIUM SUCCINATE	4 (<1%)	3 (<1%)	7 (<1%)
AMPHOTERICIN B	4 (<1%)	2 (<1%)	6 (<1%)

Note: A medication may be included in more than one ATC Level category and appear more than once.
Includes medications started after first dose and before last dose + 28 days.
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Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Table 111.20

Summary of Non-COPD Medications Started During Treatment in Study 208657

ATC Level 1 Ingredient and Ingredient Combinations	PBO (N=401)	100 SC (N=403)	Total (N=804)
BECLOMETASONE DIPROPIONATE	3 (<1%)	3 (<1%)	6 (<1%)
EPINEPHRINE	3 (<1%)	3 (<1%)	6 (<1%)
ESOMEPRAZOLE MAGNESIUM	3 (<1%)	3 (<1%)	6 (<1%)
INSULIN GLARGINE	3 (<1%)	3 (<1%)	6 (<1%)
INSULIN HUMAN	3 (<1%)	3 (<1%)	6 (<1%)
MAGNESIUM HYDROXIDE	2 (<1%)	4 (<1%)	6 (<1%)
METOCLOPRAMIDE	3 (<1%)	3 (<1%)	6 (<1%)
MINERALS NOS+VITAMINS NOS	3 (<1%)	3 (<1%)	6 (<1%)
SEMAGLUTIDE	0	6 (1%)	6 (<1%)
VITAMIN D NOS	4 (<1%)	2 (<1%)	6 (<1%)
CODEINE	2 (<1%)	3 (<1%)	5 (<1%)
EMPAGLIFLOZIN	4 (<1%)	1 (<1%)	5 (<1%)
HYDROXYZINE	3 (<1%)	2 (<1%)	5 (<1%)
INSULIN NOS	5 (1%)	0	5 (<1%)
MACROGOL	2 (<1%)	3 (<1%)	5 (<1%)
PANTOPRAZOLE SODIUM	3 (<1%)	2 (<1%)	5 (<1%)
THIAMINE HYDROCHLORIDE	3 (<1%)	2 (<1%)	5 (<1%)
TRIAMCINOLONE ACETONIDE	4 (<1%)	1 (<1%)	5 (<1%)
CHOLINE SALICYLATE	1 (<1%)	3 (<1%)	4 (<1%)
DOXYCYCLINE HYCLATE	4 (<1%)	0	4 (<1%)
GLYCEROL	1 (<1%)	3 (<1%)	4 (<1%)
LINAGLIPTIN	3 (<1%)	1 (<1%)	4 (<1%)
LOPERAMIDE	2 (<1%)	2 (<1%)	4 (<1%)
METOCLOPRAMIDE HYDROCHLORIDE	0	4 (<1%)	4 (<1%)
MOVICOL (NOS)	1 (<1%)	3 (<1%)	4 (<1%)
SACCHAROMYCES BOULARDII	1 (<1%)	3 (<1%)	4 (<1%)
SIMETICONE	2 (<1%)	2 (<1%)	4 (<1%)
VANCOMYCIN	2 (<1%)	2 (<1%)	4 (<1%)
CHLORHEXIDINE GLUCONATE	1 (<1%)	2 (<1%)	3 (<1%)
CORDYCEPS SINENSIS	1 (<1%)	2 (<1%)	3 (<1%)
DAPAGLIFLOZIN	1 (<1%)	2 (<1%)	3 (<1%)

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Includes medications started after first dose and before last dose + 28 days.
/mnt/code/postcsr_01/prod/tfls/t_sp_c1_ncopd_on_657.sas 21JUL2025 22:02

Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Table 111.20

Summary of Non-COPD Medications Started During Treatment in Study 208657

ATC Level 1 Ingredient and Ingredient Combinations	PBO (N=401)	100 SC (N=403)	Total (N=804)
DAPAGLIFLOZIN PROPANEDIOL	1 (<1%)	2 (<1%)	3 (<1%)
DULAGLUTIDE	2 (<1%)	1 (<1%)	3 (<1%)
ESOMEPRAZOLE	1 (<1%)	2 (<1%)	3 (<1%)
GLIMEPIRIDE	1 (<1%)	2 (<1%)	3 (<1%)
GLYCYRRHIZA (NOS)	3 (<1%)	0	3 (<1%)
KETOPROFEN	0	3 (<1%)	3 (<1%)
LACTOBACILLUS NOS	2 (<1%)	1 (<1%)	3 (<1%)
MACROGOL+ELECTROLYTES NOS	2 (<1%)	1 (<1%)	3 (<1%)
MAGNESIUM OXIDE	1 (<1%)	2 (<1%)	3 (<1%)
MOSAPRIDE CITRATE	2 (<1%)	1 (<1%)	3 (<1%)
RIFAXIMIN	1 (<1%)	2 (<1%)	3 (<1%)
SENNA	2 (<1%)	1 (<1%)	3 (<1%)
SODIUM BICARBONATE	1 (<1%)	2 (<1%)	3 (<1%)
SODIUM GUALENATE+LEVOGLUTAMIDE	2 (<1%)	1 (<1%)	3 (<1%)
TRIMEBUTINE	1 (<1%)	2 (<1%)	3 (<1%)
ACETYLSALICYLATE LYSINE	2 (<1%)	0	2 (<1%)
ACTIVATED CHARCOAL	1 (<1%)	1 (<1%)	2 (<1%)
ATRACTYLODES MACROCEPHALA RHIZOME+SAPOSHNIKOVIA DIVARICATA ROOT+ASTRAGALUS MONGHOLICUS ROOT	1 (<1%)	1 (<1%)	2 (<1%)
BENZYDAMINE HYDROCHLORIDE	1 (<1%)	1 (<1%)	2 (<1%)
BISACODYL	1 (<1%)	1 (<1%)	2 (<1%)
BUTYLSCOPOLAMINE BROMIDE	0	2 (<1%)	2 (<1%)
CALCIFEDIOL	1 (<1%)	1 (<1%)	2 (<1%)
CALCIUM	1 (<1%)	1 (<1%)	2 (<1%)
CALCIUM GLUCONATE	1 (<1%)	1 (<1%)	2 (<1%)
CANAGLIFLOZIN	0	2 (<1%)	2 (<1%)
CIMETIDINE	0	2 (<1%)	2 (<1%)
CLOBETASOL PROPIONATE	1 (<1%)	1 (<1%)	2 (<1%)
DOMPERIDONE+PANTOPRAZOLE	1 (<1%)	1 (<1%)	2 (<1%)
DOMPERIDONE+RABEPRAZOLE	1 (<1%)	1 (<1%)	2 (<1%)
DOMPERIDONE+RABEPRAZOLE SODIUM	0	2 (<1%)	2 (<1%)

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Includes medications started after first dose and before last dose + 28 days.
/mnt/code/postcsr_01/prod/tfls/t_sp_c1_ncopd_on_657.sas 21JUL2025 22:02

Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Table 111.20

Summary of Non-COPD Medications Started During Treatment in Study 208657

ATC Level 1 Ingredient and Ingredient Combinations	PBO (N=401)	100 SC (N=403)	Total (N=804)
ESOMEPRAZOLE SODIUM	2 (<1%)	0	2 (<1%)
GAVISCON NOS	1 (<1%)	1 (<1%)	2 (<1%)
GLICLAZIDE	1 (<1%)	1 (<1%)	2 (<1%)
GLUCOSE+ELECTROLYTES NOS	2 (<1%)	0	2 (<1%)
INSULIN GLULISINE	1 (<1%)	1 (<1%)	2 (<1%)
INSULIN LISPRO	0	2 (<1%)	2 (<1%)
ITOPRIDE HYDROCHLORIDE	1 (<1%)	1 (<1%)	2 (<1%)
LACTOBACILLUS ACIDOPHILUS+BIFIDOBACTERIUM LONGUM+ENTEROCOCCUS FAECALIS	1 (<1%)	1 (<1%)	2 (<1%)
LACTOBACILLUS BULGARICUS+BIFIDOBACTERIUM LONGUM+STREPTOCOCCUS THERMOPHILUS	0	2 (<1%)	2 (<1%)
MAGNESIUM ASPARTATE	2 (<1%)	0	2 (<1%)
METFORMIN HYDROCHLORIDE+DAPAGLIFLOZIN PROPANEDIOL	1 (<1%)	1 (<1%)	2 (<1%)
MICONAZOLE	0	2 (<1%)	2 (<1%)
NICOTINAMIDE	2 (<1%)	0	2 (<1%)
PHLOROGLUCINOL	0	2 (<1%)	2 (<1%)
POLYENPHOSPHATIDYL CHOLINE	0	2 (<1%)	2 (<1%)
POTASSIUM	0	2 (<1%)	2 (<1%)
POTASSIUM ASPARTATE+MAGNESIUM ASPARTATE	2 (<1%)	0	2 (<1%)
POTASSIUM CHLORIDE+SODIUM BICARBONATE+SODIUM CHLORIDE+SODIUM SULFATE ANHYDROUS+MACROGOL 4000	1 (<1%)	1 (<1%)	2 (<1%)
POTASSIUM CITRATE	1 (<1%)	1 (<1%)	2 (<1%)
PYRIDOXINE HYDROCHLORIDE+MAGNESIUM CITRATE	2 (<1%)	0	2 (<1%)
RABEPRAZOLE	2 (<1%)	0	2 (<1%)
RANITIDINE HYDROCHLORIDE	1 (<1%)	1 (<1%)	2 (<1%)
RIBOFLAVIN	2 (<1%)	0	2 (<1%)
SILYBUM MARIANUM	1 (<1%)	1 (<1%)	2 (<1%)
SITAGLIPTIN	1 (<1%)	1 (<1%)	2 (<1%)
STEROIDS NOS	2 (<1%)	0	2 (<1%)
TEPRENONE	1 (<1%)	1 (<1%)	2 (<1%)

Note: A medication may be included in more than one ATC Level category and appear more than once.
Includes medications started after first dose and before last dose + 28 days.
/mnt/code/postcsr_01/prod/tfls/t_sp_c1_ncopd_on_657.sas 21JUL2025 22:02

Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Table 111.20

Summary of Non-COPD Medications Started During Treatment in Study 208657

ATC Level 1 Ingredient and Ingredient Combinations	PBO (N=401)	100 SC (N=403)	Total (N=804)
TIROPRAMIDE HYDROCHLORIDE	1 (<1%)	1 (<1%)	2 (<1%)
TRIAMCINOLONE	2 (<1%)	0	2 (<1%)
TRIMEBUTINE MALEATE	1 (<1%)	1 (<1%)	2 (<1%)
VILDAGLIPTIN	2 (<1%)	0	2 (<1%)
VITAMIN B SUBSTANCES NOS	0	2 (<1%)	2 (<1%)
VITAMINS NOS	1 (<1%)	1 (<1%)	2 (<1%)
ACARBOSE	0	1 (<1%)	1 (<1%)
ACETYLSALICYLIC ACID+SODIUM BICARBONATE+CITRIC ACID	1 (<1%)	0	1 (<1%)
AFTERBIOTIC (NOS)	0	1 (<1%)	1 (<1%)
ALMAGEL (NOS)	0	1 (<1%)	1 (<1%)
ALUMINIUM HYDROXIDE+MAGNESIUM CARBONATE	1 (<1%)	0	1 (<1%)
AMINO ACIDS NOS+POLAPREZINC+MAGNESIUM	1 (<1%)	0	1 (<1%)
BETA-HYDROXYBUTYRATE+HERBALS NOS+N-ACETYL GLUCOSAMINE			
ANGELICA SINENSIS ROOT+ATRACTYLODES MACROCEPHALA RHIZOME+SCROPHULARIA NINGPOENSIS ROOT+CORYDALIS YANHUSUO TUBER+PANAX NOTOGINSENG ROOT+CHICKEN'S GIZZARD-MEMBRANE+HERBALS NOS	0	1 (<1%)	1 (<1%)
ANISODAMINE HYDROBROMIDE	1 (<1%)	0	1 (<1%)
ANTIBIOTICS NOS	1 (<1%)	0	1 (<1%)
ARECA CATECHU+CYPERUS ROTUNDUS+CHICKEN'S GIZZARD-MEMBRANE+HERBALS NOS	0	1 (<1%)	1 (<1%)
ARTEMISIA ARGYI	1 (<1%)	0	1 (<1%)
ASCORBIC ACID+RETINOL ACETATE+TOCOPHEROL+DEXPANTHENOL+COLECALCIFEROL	0	1 (<1%)	1 (<1%)
ASCORBIC ACID+THIAMINE HYDROCHLORIDE+CYANOCOBALAMIN+PYRIDOXINE HYDROCHLORIDE+NICOTINAMIDE+RIBOFLAVIN+CALCIUM PANTOTHENATE	0	1 (<1%)	1 (<1%)
ASCORBIC ACID+TOCOPHEROL+ZINC+COPPER	0	1 (<1%)	1 (<1%)

Note: A medication may be included in more than one ATC Level category and appear more than once.
Includes medications started after first dose and before last dose + 28 days.

Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Table 111.20

Summary of Non-COPD Medications Started During Treatment in Study 208657

ATC Level 1 Ingredient and Ingredient Combinations	PBO (N=401)	100 SC (N=403)	Total (N=804)
ATROPINE	0	1 (<1%)	1 (<1%)
BACILLUS LICHENIFORMIS	0	1 (<1%)	1 (<1%)
BACILLUS SUBTILIS+ENTEROCOCCUS FAECIUM	0	1 (<1%)	1 (<1%)
BACILLUS SUBTILIS+STREPTOCOCCUS FAECALIS	0	1 (<1%)	1 (<1%)
BETAMETHASONE PHOSPHATE	0	1 (<1%)	1 (<1%)
BETAMETHASONE VALERATE	0	1 (<1%)	1 (<1%)
BICARBONATE	1 (<1%)	0	1 (<1%)
BICYCLOL	1 (<1%)	0	1 (<1%)
BIOTIN	0	1 (<1%)	1 (<1%)
BROMELAINS	0	1 (<1%)	1 (<1%)
CALCIUM CARBONATE	1 (<1%)	0	1 (<1%)
CALCIUM CHLORIDE	0	1 (<1%)	1 (<1%)
CALCIUM	0	1 (<1%)	1 (<1%)
CARBONATE+COLECALCIFEROL+MECOBALAMIN+PYRIDOXAL PHOSPHATE+LEVOMEFOLIC ACID			
CALTRATE (NOS)	0	1 (<1%)	1 (<1%)
CHLORHEXIDINE	0	1 (<1%)	1 (<1%)
CITRUS AURANTIUM+MAGNOLIA OFFICINALIS BARK+AUCKLANDIA COSTUS ROOT+RHUBARB	0	1 (<1%)	1 (<1%)
CLOTRIMAZOLE	0	1 (<1%)	1 (<1%)
COLESTYRAMINE	1 (<1%)	0	1 (<1%)
COLLAGEN	0	1 (<1%)	1 (<1%)
COLLOIDAL BISMUTH PECTIN	0	1 (<1%)	1 (<1%)
COPPER	1 (<1%)	0	1 (<1%)
CROMOGLICATE SODIUM	0	1 (<1%)	1 (<1%)
CURCUMA LONGA	0	1 (<1%)	1 (<1%)
CYANOCOBALAMIN+PYRIDOXINE HYDROCHLORIDE+BENFOTIAMINE	0	1 (<1%)	1 (<1%)
DEXAMETHASONE ACETATE	1 (<1%)	0	1 (<1%)
DEXAMETHASONE PALMITATE	0	1 (<1%)	1 (<1%)
DEXLANSOPRAZOLE	0	1 (<1%)	1 (<1%)

Note: A medication may be included in more than one ATC Level category and appear more than once.
Includes medications started after first dose and before last dose + 28 days.

Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Table 111.20

Summary of Non-COPD Medications Started During Treatment in Study 208657

ATC Level 1 Ingredient and Ingredient Combinations	PBO (N=401)	100 SC (N=403)	Total (N=804)
DEXPANTHENOL	0	1 (<1%)	1 (<1%)
DIMENHYDRINATE	0	1 (<1%)	1 (<1%)
DIPHENHYDRAMINE	1 (<1%)	0	1 (<1%)
DOCUSATE	1 (<1%)	0	1 (<1%)
DOMPERIDONE	0	1 (<1%)	1 (<1%)
DOMPERIDONE MALEATE+ESOMEPRAZOLE MAGNESIUM	0	1 (<1%)	1 (<1%)
DOMPERIDONE+ESOMEPRAZOLE	0	1 (<1%)	1 (<1%)
DROTAVERINE	0	1 (<1%)	1 (<1%)
DROTAVERINE HYDROCHLORIDE	1 (<1%)	0	1 (<1%)
DULCOLAX (NOS)	0	1 (<1%)	1 (<1%)
EMEND (NOS)	1 (<1%)	0	1 (<1%)
ENTEROCOCCUS FAECIUM+LACTOBACILLUS RHAMNOSUS	0	1 (<1%)	1 (<1%)
ERTUGLIFLOZIN	1 (<1%)	0	1 (<1%)
ESCHERICHIA COLI	0	1 (<1%)	1 (<1%)
FEXUPRAZAN HYDROCHLORIDE	1 (<1%)	0	1 (<1%)
FLEET ENEMA (NOS)	0	1 (<1%)	1 (<1%)
FOLIC ACID+CYANOCOBALAMIN+PYRIDOXINE HYDROCHLORIDE+CHROMIUM PICOLINATE+GYMNEMA SYLVESTRE EXTRACT+VITAMIN E SUBSTANCES+MORUS ALBA EXTRACT	0	1 (<1%)	1 (<1%)
FORLAX (NOS)	0	1 (<1%)	1 (<1%)
FORSYTHIA SUSPENSA FRUIT+TRICHOSANTHES NOS+COPTIS SPP RHIZOME+CALCIUM SULFATE DIHYDRATE+PAEONIA SPP ROOT+GARDENIA JASMINOIDES FRUIT+HERBALS NOS	1 (<1%)	0	1 (<1%)
GLIPIZIDE	1 (<1%)	0	1 (<1%)
GLYCYRRHIZIC ACID, AMMONIUM SALT+GLYCINE+DL-METHIONINE	1 (<1%)	0	1 (<1%)
GRANISETRON	1 (<1%)	0	1 (<1%)
HYDROCORTISONE ACETATE	0	1 (<1%)	1 (<1%)
HYDROCORTISONE SODIUM PHOSPHATE	1 (<1%)	0	1 (<1%)

Note: A medication may be included in more than one ATC Level category and appear more than once.
Includes medications started after first dose and before last dose + 28 days.
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Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Table 111.20

Summary of Non-COPD Medications Started During Treatment in Study 208657

ATC Level 1 Ingredient and Ingredient Combinations	PBO (N=401)	100 SC (N=403)	Total (N=804)
HYOSCINE+METAMIZOLE SODIUM	1 (<1%)	0	1 (<1%)
ILAPRAZOLE	0	1 (<1%)	1 (<1%)
ILAPRAZOLE SODIUM	0	1 (<1%)	1 (<1%)
INSULIN ASPART+INSULIN ASPART PROTAMINE	0	1 (<1%)	1 (<1%)
INSULIN ASPART+INSULIN DEGLUDEC	1 (<1%)	0	1 (<1%)
INSULIN HUMAN SEMISYNTHETIC	1 (<1%)	0	1 (<1%)
INULIN+LACTOBACILLUS RHAMNOSUS+LACTOBACILLUS CASEI	0	1 (<1%)	1 (<1%)
IPP (NOS)	1 (<1%)	0	1 (<1%)
ISOPHANE INSULIN	0	1 (<1%)	1 (<1%)
LACTOBACILLUS ACIDOPHILUS+BIFIDOBACTERIUM ANIMALIS	1 (<1%)	0	1 (<1%)
LACTOBACILLUS ACIDOPHILUS+LACTOBACILLUS LACTIS	0	1 (<1%)	1 (<1%)
LACTOBACILLUS RHAMNOSUS	0	1 (<1%)	1 (<1%)
LACTOBACILLUS ACIDOPHILUS+FRUCTOOLIGOSACCHARIDES+BIFIDOBACTERIUM LONGUM+STREPTOCOCCUS THERMOPHILUS	0	1 (<1%)	1 (<1%)
LAFUTIDINE	1 (<1%)	0	1 (<1%)
LEVOMENTHOL+CINEOLE+MENTHA PULEGIUM OIL+PINENE+CAMPHENE+BORNEOL	1 (<1%)	0	1 (<1%)
LIQUID PARAFFIN+MAGNESIUM HYDROXIDE	1 (<1%)	0	1 (<1%)
LIQUID PARAFFIN+MAGNESIUM HYDROXIDE+PICOSULFURIC ACID SODIUM	0	1 (<1%)	1 (<1%)
LONICERA JAPONICA+GLYCYRRHIZA (NOS)+OPHIOPOGON JAPONICUS+ASPARAGUS COCHINCHINENSIS+SCROPHULARIA NINGPOENSIS	0	1 (<1%)	1 (<1%)
MACROGOL 3350	1 (<1%)	0	1 (<1%)
MACROGOL 4000	1 (<1%)	0	1 (<1%)
MAGALDRATE+SIMETICONE	1 (<1%)	0	1 (<1%)
MAGNE-B6 (NOS)	0	1 (<1%)	1 (<1%)
MAGNESIUM CARBONATE	0	1 (<1%)	1 (<1%)

Note: A medication may be included in more than one ATC Level category and appear more than once.
Includes medications started after first dose and before last dose + 28 days.
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Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Table 111.20

Summary of Non-COPD Medications Started During Treatment in Study 208657

ATC Level 1 Ingredient and Ingredient Combinations	PBO (N=401)	100 SC (N=403)	Total (N=804)
MAGNESIUM ISOGLYCYRRHIZINATE	1 (<1%)	0	1 (<1%)
MAGNESIUM PIDOLATE	0	1 (<1%)	1 (<1%)
MEBEVERINE HYDROCHLORIDE	1 (<1%)	0	1 (<1%)
MECLOZINE	1 (<1%)	0	1 (<1%)
METFORMIN HYDROCHLORIDE+EMPAGLIFLOZIN	1 (<1%)	0	1 (<1%)
METFORMIN HYDROCHLORIDE+SAXAGLIPTIN	1 (<1%)	0	1 (<1%)
METFORMIN HYDROCHLORIDE+SITAGLIPTIN	1 (<1%)	0	1 (<1%)
METFORMIN HYDROCHLORIDE+VILDAGLIPTIN	1 (<1%)	0	1 (<1%)
METHYLTHIONINIUM CHLORIDE	1 (<1%)	0	1 (<1%)
MICONAZOLE NITRATE	1 (<1%)	0	1 (<1%)
MINERALS NOS	0	1 (<1%)	1 (<1%)
MINERALS NOS+PIPER NIGRUM EXTRACT+ECHINACEA PURPUREA EXTRACT+CURCUMA LONGA EXTRACT+TINOSPORA CORDIFOLIA EXTRACT+VITAMINS NOS	0	1 (<1%)	1 (<1%)
MOSAPRIDE	0	1 (<1%)	1 (<1%)
NEO-ANGIN (NOS)	1 (<1%)	0	1 (<1%)
NEOMYCIN SULFATE+KAOLIN+PECTIN	1 (<1%)	0	1 (<1%)
NICOTINIC ACID	1 (<1%)	0	1 (<1%)
OMEPRAZOLE SODIUM	0	1 (<1%)	1 (<1%)
OTILONIUM BROMIDE	0	1 (<1%)	1 (<1%)
OXYBUTYNIN	1 (<1%)	0	1 (<1%)
PANAX GINSENG ROOT WITH RHIZOME+OPHIOPOGON JAPONICUS ROOT TUBER+SCHISANDRA CHINENSIS FRUIT	1 (<1%)	0	1 (<1%)
PANCREATIN	1 (<1%)	0	1 (<1%)
PANCREATIN+ASPERGILLUS ORYZAE ENZYME	0	1 (<1%)	1 (<1%)
PANCREATIN+DIMETICONE+AZINTAMIDE+CELLULASE	1 (<1%)	0	1 (<1%)
PANCREATIN+DUODENUM EXTRACT	1 (<1%)	0	1 (<1%)
PANTOTHENIC ACID	1 (<1%)	0	1 (<1%)
PAPAVERINE HYDROCHLORIDE	0	1 (<1%)	1 (<1%)
PHOSPHATE-SANDOZ (NOS)	1 (<1%)	0	1 (<1%)
PICOSULFURIC ACID SODIUM	0	1 (<1%)	1 (<1%)

Note: A medication may be included in more than one ATC Level category and appear more than once.
Includes medications started after first dose and before last dose + 28 days.
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Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Table 111.20

Summary of Non-COPD Medications Started During Treatment in Study 208657

ATC Level 1 Ingredient and Ingredient Combinations	PBO (N=401)	100 SC (N=403)	Total (N=804)
PLANTAGO OVATA	0	1 (<1%)	1 (<1%)
POLAPREZINC	0	1 (<1%)	1 (<1%)
POLYCARBOPHIL CALCIUM	0	1 (<1%)	1 (<1%)
PORIA COCOS SCLEROTIUM+PAEONIA LACTIFLORA ROOT+BUPLEURUM SPP ROOT+GLYCYRRHIZA SPP. ROOT WITH RHIZOME+ANGELICA SINENSIS ROOT+ATRACTYLODES MACROCEPHALA RHIZOME+MENTHA CANADENSIS HERB	0	1 (<1%)	1 (<1%)
POTASSIUM CHLORIDE+POTASSIUM BICARBONATE	1 (<1%)	0	1 (<1%)
POTASSIUM CHLORIDE+SODIUM BICARBONATE+SODIUM CHLORIDE+MACROGOL	1 (<1%)	0	1 (<1%)
POTASSIUM CHLORIDE+SODIUM BICARBONATE+SODIUM CHLORIDE+MACROGOL 4000	0	1 (<1%)	1 (<1%)
POTASSIUM GLUCONATE	1 (<1%)	0	1 (<1%)
POTASSIUM MAGNESIUM ASPARTATE	1 (<1%)	0	1 (<1%)
POTASSIUM PHOSPHATE DIBASIC	1 (<1%)	0	1 (<1%)
PPI (NOS)	1 (<1%)	0	1 (<1%)
PROMETHAZINE HYDROCHLORIDE	1 (<1%)	0	1 (<1%)
PROTON PUMP INHIBITOR NOS	1 (<1%)	0	1 (<1%)
PYRIDOXINE HYDROCHLORIDE	1 (<1%)	0	1 (<1%)
RACECADOTRIL	1 (<1%)	0	1 (<1%)
RANITIDINE	1 (<1%)	0	1 (<1%)
REHYDRATION FLUID (NOS)	1 (<1%)	0	1 (<1%)
SAB SIMPLEX (NOS)	0	1 (<1%)	1 (<1%)
SACCHAROMYCES BOULARDII+MANNAN OLIGOSACCHARIDE	0	1 (<1%)	1 (<1%)
SAXAGLIPTIN	0	1 (<1%)	1 (<1%)
SELENIUM+MAGNESIUM+VITAMIN E SUBSTANCES+VITAMIN B NOS	1 (<1%)	0	1 (<1%)
SEPTORAL PROFILACTIC (NOS)	0	1 (<1%)	1 (<1%)
SILYBUM MARIANUM FRUIT+SCHISANDRA CHINENSIS FRUIT	0	1 (<1%)	1 (<1%)
SMECTITE	0	1 (<1%)	1 (<1%)

Note: A medication may be included in more than one ATC Level category and appear more than once.
Includes medications started after first dose and before last dose + 28 days.
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Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Table 111.20

Summary of Non-COPD Medications Started During Treatment in Study 208657

ATC Level 1 Ingredient and Ingredient Combinations	PBO (N=401)	100 SC (N=403)	Total (N=804)
SODIUM BICARBONATE+CALCIUM CARBONATE+SODIUM ALGINATE	1 (<1%)	0	1 (<1%)
SODIUM BICARBONATE+ESOMEPRAZOLE MAGNESIUM	0	1 (<1%)	1 (<1%)
SODIUM BICARBONATE+MAGNESIUM CARBONATE+BISMUTH ALUMINATE+GLYCYRRHIZA EXTRACT NOS+RHAMNUS FRANGULA+FOENICULUM VULGARE	1 (<1%)	0	1 (<1%)
SODIUM PHOSPHATE MONOBASIC	1 (<1%)	0	1 (<1%)
SOYA OIL+PERSEA AMERICANA OIL	0	1 (<1%)	1 (<1%)
TETRACYCLINE	1 (<1%)	0	1 (<1%)
THIAMINE HYDROCHLORIDE+CYANOCOBALAMIN+PYRIDOXINE HYDROCHLORIDE	0	1 (<1%)	1 (<1%)
THIAMINE HYDROCHLORIDE+PYRIDOXINE HYDROCHLORIDE+HYDROXOCOBALAMIN	1 (<1%)	0	1 (<1%)
THIAMINE MONONITRATE+CYANOCOBALAMIN+PYRIDOXINE HYDROCHLORIDE	0	1 (<1%)	1 (<1%)
THIAMINE+CYANOCOBALAMIN+PYRIDOXINE	0	1 (<1%)	1 (<1%)
THIAMINE+CYANOCOBALAMIN+PYRIDOXINE HYDROCHLORIDE	1 (<1%)	0	1 (<1%)
THYMUS VULGARIS	0	1 (<1%)	1 (<1%)
TOCOPHEROL	0	1 (<1%)	1 (<1%)
TOCOPHERYL ACETATE	0	1 (<1%)	1 (<1%)
TRYPSIN+PAPAIN+PEPSIN+URSODEOXYCHOLIC ACID+AMYLASE+ASPERGILLUS NIGER+ENZYME, NOS	0	1 (<1%)	1 (<1%)
URSODEOXYCHOLIC ACID	1 (<1%)	0	1 (<1%)
VANCOMYCIN HYDROCHLORIDE	0	1 (<1%)	1 (<1%)
VITAMIN B NOS	0	1 (<1%)	1 (<1%)
ZINC	1 (<1%)	0	1 (<1%)
ZINC SULFATE	0	1 (<1%)	1 (<1%)
ZINGIBER OFFICINALE RHIZOME+GLYCYRRHIZA SPP. ROOT WITH RHIZOME+ATRACTYLODES MACROCEPHALA RHIZOME+CODONOPSIS SPP ROOT	0	1 (<1%)	1 (<1%)

Note: A medication may be included in more than one ATC Level category and appear more than once.
Includes medications started after first dose and before last dose + 28 days.
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Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Table 111.20

Summary of Non-COPD Medications Started During Treatment in Study 208657

ATC Level 1 Ingredient and Ingredient Combinations	PBO (N=401)	100 SC (N=403)	Total (N=804)
SENSORY ORGANS			
Any medication	240 (60%)	225 (56%)	465 (58%)
PREDNISOLONE	62 (15%)	66 (16%)	128 (16%)
AZITHROMYCIN	63 (16%)	46 (11%)	109 (14%)
LEVOFLOXACIN	49 (12%)	50 (12%)	99 (12%)
ACETYLCYSTEINE	40 (10%)	45 (11%)	85 (11%)
METHYLPREDNISOLONE	37 (9%)	23 (6%)	60 (7%)
METHYLPREDNISOLONE SODIUM SUCCINATE	22 (5%)	22 (5%)	44 (5%)
DEXAMETHASONE	17 (4%)	17 (4%)	34 (4%)
POTASSIUM CHLORIDE	19 (5%)	13 (3%)	32 (4%)
SODIUM CHLORIDE	14 (3%)	17 (4%)	31 (4%)
CIPROFLOXACIN	13 (3%)	15 (4%)	28 (3%)
MOXIFLOXACIN	12 (3%)	11 (3%)	23 (3%)
DICLOFENAC	10 (2%)	11 (3%)	21 (3%)
HYDROCORTISONE	11 (3%)	6 (1%)	17 (2%)
DEXAMETHASONE SODIUM PHOSPHATE	11 (3%)	4 (<1%)	15 (2%)
MOXIFLOXACIN HYDROCHLORIDE	7 (2%)	8 (2%)	15 (2%)
DICLOFENAC SODIUM	2 (<1%)	11 (3%)	13 (2%)
ASCORBIC ACID	6 (1%)	4 (<1%)	10 (1%)
CYANOCOBALAMIN	3 (<1%)	6 (1%)	9 (1%)
CETIRIZINE HYDROCHLORIDE	5 (1%)	2 (<1%)	7 (<1%)
HYDROCORTISONE SODIUM SUCCINATE	2 (<1%)	5 (1%)	7 (<1%)
KETOROLAC	3 (<1%)	4 (<1%)	7 (<1%)
LIDOCAINE	4 (<1%)	3 (<1%)	7 (<1%)
PREDNISOLONE SODIUM SUCCINATE	4 (<1%)	3 (<1%)	7 (<1%)
ACICLOVIR	2 (<1%)	4 (<1%)	6 (<1%)
AMPICILLIN	4 (<1%)	2 (<1%)	6 (<1%)
EPINEPHRINE	3 (<1%)	3 (<1%)	6 (<1%)
HEPARIN (NOS)	3 (<1%)	3 (<1%)	6 (<1%)
PREDNISOLONE ACETATE	2 (<1%)	4 (<1%)	6 (<1%)
CIPROFLOXACIN HYDROCHLORIDE	3 (<1%)	2 (<1%)	5 (<1%)

Note: A medication may be included in more than one ATC Level category and appear more than once.
Includes medications started after first dose and before last dose + 28 days.
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Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Table 111.20

Summary of Non-COPD Medications Started During Treatment in Study 208657

ATC Level 1 Ingredient and Ingredient Combinations	PBO (N=401)	100 SC (N=403)	Total (N=804)
DECADRON (NOS)	3 (<1%)	2 (<1%)	5 (<1%)
MACROGOL	2 (<1%)	3 (<1%)	5 (<1%)
OFLOXACIN	3 (<1%)	2 (<1%)	5 (<1%)
TRIAMCINOLONE ACETONIDE	4 (<1%)	1 (<1%)	5 (<1%)
AZELASTINE HYDROCHLORIDE	3 (<1%)	1 (<1%)	4 (<1%)
BROMFENAC	2 (<1%)	2 (<1%)	4 (<1%)
CHOLINE SALICYLATE	1 (<1%)	3 (<1%)	4 (<1%)
CIPRODEX (NOS)	1 (<1%)	3 (<1%)	4 (<1%)
DEXAMETHASONE+TOBRAMYCIN	1 (<1%)	3 (<1%)	4 (<1%)
DICLOFENAC DIETHYLAMINE	2 (<1%)	2 (<1%)	4 (<1%)
FLURBIPROFEN	2 (<1%)	2 (<1%)	4 (<1%)
FUSIDIC ACID	3 (<1%)	1 (<1%)	4 (<1%)
GLYCEROL	1 (<1%)	3 (<1%)	4 (<1%)
KETOROLAC TROMETAMOL	1 (<1%)	3 (<1%)	4 (<1%)
LIDOCAINE HYDROCHLORIDE	2 (<1%)	2 (<1%)	4 (<1%)
VANCOMYCIN	2 (<1%)	2 (<1%)	4 (<1%)
XYLOMETAZOLINE HYDROCHLORIDE	1 (<1%)	3 (<1%)	4 (<1%)
BENZYLPENICILLIN	2 (<1%)	1 (<1%)	3 (<1%)
BETAMETHASONE SODIUM PHOSPHATE	1 (<1%)	2 (<1%)	3 (<1%)
CHLORHEXIDINE GLUCONATE	1 (<1%)	2 (<1%)	3 (<1%)
GENTAMICIN	1 (<1%)	2 (<1%)	3 (<1%)
HEPARIN SODIUM	2 (<1%)	1 (<1%)	3 (<1%)
HYALURONATE SODIUM	0	3 (<1%)	3 (<1%)
KETOTIFEN FUMARATE	1 (<1%)	2 (<1%)	3 (<1%)
LEVOFLOXACIN HYDROCHLORIDE	1 (<1%)	2 (<1%)	3 (<1%)
AMIKACIN	2 (<1%)	0	2 (<1%)
BENZYLPENICILLIN SODIUM	0	2 (<1%)	2 (<1%)
BORIC ACID+SODIUM BORATE	1 (<1%)	1 (<1%)	2 (<1%)
BUTYLSCOPOLAMINE BROMIDE	0	2 (<1%)	2 (<1%)
CHLORAMPHENICOL	1 (<1%)	1 (<1%)	2 (<1%)
CHYMOTRYPSIN	1 (<1%)	1 (<1%)	2 (<1%)

Note: A medication may be included in more than one ATC Level category and appear more than once.
Includes medications started after first dose and before last dose + 28 days.
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Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Table 111.20

Summary of Non-COPD Medications Started During Treatment in Study 208657

ATC Level 1 Ingredient and Ingredient Combinations	PBO (N=401)	100 SC (N=403)	Total (N=804)
CORTICOSTEROID NOS	2 (<1%)	0	2 (<1%)
DEXAMETHASONE+NEOMYCIN SULFATE+POLYMYXIN B SULFATE	1 (<1%)	1 (<1%)	2 (<1%)
DICLOFENAC HYDROXYETHYLPYRROLIDINE	2 (<1%)	0	2 (<1%)
EPHEDRINE	0	2 (<1%)	2 (<1%)
GATIFLOXACIN	0	2 (<1%)	2 (<1%)
INDOMETACIN	2 (<1%)	0	2 (<1%)
MICONAZOLE	0	2 (<1%)	2 (<1%)
PHENYLEPHRINE	0	2 (<1%)	2 (<1%)
POTASSIUM	0	2 (<1%)	2 (<1%)
PREDNISOLONE HEMISUCCINATE	2 (<1%)	0	2 (<1%)
RIBOFLAVIN	2 (<1%)	0	2 (<1%)
STEROIDS NOS	2 (<1%)	0	2 (<1%)
TIMOLOL MALEATE+LATANOPROST	2 (<1%)	0	2 (<1%)
TOBRAMYCIN	2 (<1%)	0	2 (<1%)
TRIAMCINOLONE	2 (<1%)	0	2 (<1%)
ACETAZOLAMIDE	0	1 (<1%)	1 (<1%)
ACETIC ACID	0	1 (<1%)	1 (<1%)
AFLIBERCEPT	1 (<1%)	0	1 (<1%)
ALBUMIN NORMAL HUMAN SERUM	0	1 (<1%)	1 (<1%)
AMPICILLIN SODIUM	0	1 (<1%)	1 (<1%)
ANTIBIOTICS NOS	1 (<1%)	0	1 (<1%)
ASCORBIC ACID+TOCOPHEROL+ZINC+COPPER	0	1 (<1%)	1 (<1%)
ATROPINE	0	1 (<1%)	1 (<1%)
AZELASTINE	1 (<1%)	0	1 (<1%)
AZITHROMYCIN DIHYDRATE	0	1 (<1%)	1 (<1%)
BETAXOLOL	1 (<1%)	0	1 (<1%)
BEVACIZUMAB	1 (<1%)	0	1 (<1%)
BRIMONIDINE	1 (<1%)	0	1 (<1%)
BRINZOLAMIDE	0	1 (<1%)	1 (<1%)
BROMFENAC SODIUM	0	1 (<1%)	1 (<1%)

Note: A medication may be included in more than one ATC Level category and appear more than once.
Includes medications started after first dose and before last dose + 28 days.
/mnt/code/postcsr_01/prod/tfls/t_sp_c1_ncopd_on_657.sas 21JUL2025 22:02

Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Table 111.20

Summary of Non-COPD Medications Started During Treatment in Study 208657

ATC Level 1 Ingredient and Ingredient Combinations	PBO (N=401)	100 SC (N=403)	Total (N=804)
CETIRIZINE	1 (<1%)	0	1 (<1%)
CHLORAMPHENICOL+DEXAMETHASONE SODIUM PHOSPHATE	0	1 (<1%)	1 (<1%)
CHLORHEXIDINE	0	1 (<1%)	1 (<1%)
CLONIDINE	1 (<1%)	0	1 (<1%)
COCAINE	0	1 (<1%)	1 (<1%)
CROMOGLICATE SODIUM	0	1 (<1%)	1 (<1%)
DESONIDE	0	1 (<1%)	1 (<1%)
DEXAMETHASONE ACETATE	1 (<1%)	0	1 (<1%)
DEXAMETHASONE PALMITATE	0	1 (<1%)	1 (<1%)
DEXAMETHASONE+CIPROFLOXACIN	0	1 (<1%)	1 (<1%)
DEXAMETHASONE+CIPROFLOXACIN HYDROCHLORIDE	1 (<1%)	0	1 (<1%)
DEXAMETHASONE+CIPROFLOXACIN HYDROCHLORIDE MONOHYDRATE	0	1 (<1%)	1 (<1%)
DEXAMETHASONE+HYPROMELLOSE+MOXIFLOXACIN	1 (<1%)	0	1 (<1%)
DEXAMETHASONE+MOXIFLOXACIN HYDROCHLORIDE	1 (<1%)	0	1 (<1%)
DEXAMETHASONE+OXYTETRACYCLINE	0	1 (<1%)	1 (<1%)
DEXPANTHENOL	0	1 (<1%)	1 (<1%)
DICLOFENAC DEANOL	1 (<1%)	0	1 (<1%)
EPINEPHRINE HYDROCHLORIDE	1 (<1%)	0	1 (<1%)
FLUDROCORTISONE	1 (<1%)	0	1 (<1%)
FLUOROMETHOLONE	0	1 (<1%)	1 (<1%)
FLURBIPROFEN AXETIL	0	1 (<1%)	1 (<1%)
FLURBIPROFEN SODIUM	0	1 (<1%)	1 (<1%)
HYALURONIC ACID+ECTOINE	1 (<1%)	0	1 (<1%)
HYDROCORTISONE ACETATE	0	1 (<1%)	1 (<1%)
HYDROCORTISONE SODIUM PHOSPHATE	1 (<1%)	0	1 (<1%)
HYDROCORTISONE+NEOMYCIN+POLYMYXIN B	0	1 (<1%)	1 (<1%)
HYPROMELLOSE	0	1 (<1%)	1 (<1%)
HYPROMELLOSE+PHOSPHOLIPIDS SOYBEAN+OZONISED SUNFLOWER OIL	1 (<1%)	0	1 (<1%)
INOSINE	1 (<1%)	0	1 (<1%)

Note: A medication may be included in more than one ATC Level category and appear more than once.
Includes medications started after first dose and before last dose + 28 days.
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Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Table 111.20

Summary of Non-COPD Medications Started During Treatment in Study 208657

ATC Level 1 Ingredient and Ingredient Combinations	PBO (N=401)	100 SC (N=403)	Total (N=804)
ISOSORBIDE	1 (<1%)	0	1 (<1%)
KETOTIFEN	1 (<1%)	0	1 (<1%)
LEVOFLOXACIN HEMIHYDRATE	0	1 (<1%)	1 (<1%)
LOTEPREDNOL ETABONATE	0	1 (<1%)	1 (<1%)
MACROGOL 4000	1 (<1%)	0	1 (<1%)
MICONAZOLE NITRATE	1 (<1%)	0	1 (<1%)
NEOSTIGMINE	0	1 (<1%)	1 (<1%)
NEPAFENAC	1 (<1%)	0	1 (<1%)
NITROFURAZONE	0	1 (<1%)	1 (<1%)
NORFLOXACIN	0	1 (<1%)	1 (<1%)
OMEGA-3 MARINE TRIGLYCERIDES+MINERALS NOS+RESVERATROL+ZEAXANTHIN+XANTOFYL+VITAMINS NOS	1 (<1%)	0	1 (<1%)
OTALGAN (NOS)	1 (<1%)	0	1 (<1%)
OTOMIZE (NOS)	1 (<1%)	0	1 (<1%)
PHENYLEPHRINE HYDROCHLORIDE	0	1 (<1%)	1 (<1%)
PIROXICAM	0	1 (<1%)	1 (<1%)
POTASSIUM CHLORIDE+SODIUM CHLORIDE+SODIUM ACETATE+CALCIUM CHLORIDE+SODIUM CITRATE+MAGNESIUM CHLORIDE	1 (<1%)	0	1 (<1%)
RECOMBINANT BOVINE BASIC FIBROBLAST GROWTH FACTOR	0	1 (<1%)	1 (<1%)
SILVER NITRATE	1 (<1%)	0	1 (<1%)
TERRAMYCIN NOS	1 (<1%)	0	1 (<1%)
TETRACAINE HYDROCHLORIDE	1 (<1%)	0	1 (<1%)
TETRACYCLINE	1 (<1%)	0	1 (<1%)
TIMOLOL MALEATE+DORZOLAMIDE HYDROCHLORIDE	1 (<1%)	0	1 (<1%)
TRIAMCINOLONE ACETONIDE+NYSTATIN+NEOMYCIN SULFATE+GRAMICIDIN	1 (<1%)	0	1 (<1%)
TROPICAMIDE	0	1 (<1%)	1 (<1%)
VANCOMYCIN HYDROCHLORIDE	0	1 (<1%)	1 (<1%)
XYLOMETAZOLINE	0	1 (<1%)	1 (<1%)

Note: A medication may be included in more than one ATC Level category and appear more than once.
Includes medications started after first dose and before last dose + 28 days.
/mnt/code/postcsr_01/prod/tfls/t_sp_c1_ncopd_on_657.sas 21JUL2025 22:02

Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Table 111.20

Summary of Non-COPD Medications Started During Treatment in Study 208657

ATC Level 1 Ingredient and Ingredient Combinations	PBO (N=401)	100 SC (N=403)	Total (N=804)
ZINC SULFATE	0	1 (<1%)	1 (<1%)
SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS			
Any medication	227 (57%)	205 (51%)	432 (54%)
PREDNISONE	82 (20%)	71 (18%)	153 (19%)
PREDNISOLONE	62 (15%)	66 (16%)	128 (16%)
METHYLPREDNISOLONE	37 (9%)	23 (6%)	60 (7%)
METHYLPREDNISOLONE SODIUM SUCCINATE	22 (5%)	22 (5%)	44 (5%)
MEPREDNISONE	24 (6%)	19 (5%)	43 (5%)
BUDESONIDE	18 (4%)	18 (4%)	36 (4%)
DEXAMETHASONE	17 (4%)	17 (4%)	34 (4%)
BETAMETHASONE	20 (5%)	11 (3%)	31 (4%)
HYDROCORTISONE	11 (3%)	6 (1%)	17 (2%)
DEXAMETHASONE SODIUM PHOSPHATE	11 (3%)	4 (<1%)	15 (2%)
PREDNISONE ACETATE	6 (1%)	4 (<1%)	10 (1%)
DEFLAZACORT	6 (1%)	2 (<1%)	8 (<1%)
HYDROCORTISONE SODIUM SUCCINATE	2 (<1%)	5 (1%)	7 (<1%)
PREDNISOLONE SODIUM SUCCINATE	4 (<1%)	3 (<1%)	7 (<1%)
PREDNISOLONE ACETATE	2 (<1%)	4 (<1%)	6 (<1%)
DECADRON (NOS)	3 (<1%)	2 (<1%)	5 (<1%)
TRIAMCINOLONE ACETONIDE	4 (<1%)	1 (<1%)	5 (<1%)
LEVOTHYROXINE	3 (<1%)	1 (<1%)	4 (<1%)
LEVOTHYROXINE SODIUM	2 (<1%)	2 (<1%)	4 (<1%)
BETAMETHASONE SODIUM PHOSPHATE	1 (<1%)	2 (<1%)	3 (<1%)
BETAMETHASONE+DESLORATADINE	3 (<1%)	0	3 (<1%)
MELATONIN	3 (<1%)	0	3 (<1%)
PROPRANOLOL	2 (<1%)	1 (<1%)	3 (<1%)
CALCIFEDIOL	1 (<1%)	1 (<1%)	2 (<1%)
CORTICOSTEROID NOS	2 (<1%)	0	2 (<1%)
PREDNISOLONE HEMISUCCINATE	2 (<1%)	0	2 (<1%)

Note: A medication may be included in more than one ATC Level category and appear more than once.
Includes medications started after first dose and before last dose + 28 days.
/mnt/code/postcsr_01/prod/tfls/t_sp_c1_ncopd_on_657.sas 21JUL2025 22:02

Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Table 111.20

Summary of Non-COPD Medications Started During Treatment in Study 208657

ATC Level 1 Ingredient and Ingredient Combinations	PBO (N=401)	100 SC (N=403)	Total (N=804)
STEROIDS NOS	2 (<1%)	0	2 (<1%)
THIAMAZOLE	2 (<1%)	0	2 (<1%)
TRIAMCINOLONE	2 (<1%)	0	2 (<1%)
BETAMETHASONE PHOSPHATE	0	1 (<1%)	1 (<1%)
BETAMETHASONE SODIUM PHOSPHATE+BETAMETHASONE DIPROPIONATE	1 (<1%)	0	1 (<1%)
BETAMETHASONE VALERATE	0	1 (<1%)	1 (<1%)
BETAMETHASONE+LORATADINE	0	1 (<1%)	1 (<1%)
CALCITONIN	0	1 (<1%)	1 (<1%)
CALCITONIN, SALMON	0	1 (<1%)	1 (<1%)
DEXAMETHASONE ACETATE	1 (<1%)	0	1 (<1%)
DEXAMETHASONE PALMITATE	0	1 (<1%)	1 (<1%)
DEXAMETHASONE SODIUM PHOSPHATE+DEXAMETHASONE ACETATE	1 (<1%)	0	1 (<1%)
FLUDROCORTISONE	1 (<1%)	0	1 (<1%)
GLUCAGON	0	1 (<1%)	1 (<1%)
HYDROCORTISONE ACETATE	0	1 (<1%)	1 (<1%)
HYDROCORTISONE SODIUM PHOSPHATE	1 (<1%)	0	1 (<1%)
METHYLPREDNISOLONE ACEPONATE	0	1 (<1%)	1 (<1%)
METHYLPREDNISOLONE ACETATE	1 (<1%)	0	1 (<1%)
RISEDRONIC ACID	0	1 (<1%)	1 (<1%)
SODIUM PERCHLORATE	0	1 (<1%)	1 (<1%)
RESPIRATORY SYSTEM			
Any medication	214 (53%)	205 (51%)	419 (52%)
PREDNISOLONE	62 (15%)	66 (16%)	128 (16%)
ACETYLCYSTEINE	40 (10%)	45 (11%)	85 (11%)
IBUPROFEN	25 (6%)	42 (10%)	67 (8%)
SALBUTAMOL	31 (8%)	27 (7%)	58 (7%)
IPRATROPIUM BROMIDE	22 (5%)	21 (5%)	43 (5%)
BUDESONIDE	18 (4%)	18 (4%)	36 (4%)

Note: A medication may be included in more than one ATC Level category and appear more than once.
Includes medications started after first dose and before last dose + 28 days.
/mnt/code/postcsr_01/prod/tfls/t_sp_c1_ncopd_on_657.sas 21JUL2025 22:02

Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Table 111.20

Summary of Non-COPD Medications Started During Treatment in Study 208657

ATC Level 1 Ingredient and Ingredient Combinations	PBO (N=401)	100 SC (N=403)	Total (N=804)
DEXAMETHASONE	17 (4%)	17 (4%)	34 (4%)
BETAMETHASONE	20 (5%)	11 (3%)	31 (4%)
OXYGEN	13 (3%)	18 (4%)	31 (4%)
SODIUM CHLORIDE	14 (3%)	17 (4%)	31 (4%)
AMBROXOL HYDROCHLORIDE	15 (4%)	13 (3%)	28 (3%)
LORATADINE	10 (2%)	12 (3%)	22 (3%)
DICLOFENAC	10 (2%)	11 (3%)	21 (3%)
DESLORATADINE	6 (1%)	13 (3%)	19 (2%)
AMINOPHYLLINE	10 (2%)	6 (1%)	16 (2%)
DEXAMETHASONE SODIUM PHOSPHATE	11 (3%)	4 (<1%)	15 (2%)
BROMHEXINE HYDROCHLORIDE	7 (2%)	7 (2%)	14 (2%)
DICLOFENAC SODIUM	2 (<1%)	11 (3%)	13 (2%)
MOMETASONE FUROATE	5 (1%)	8 (2%)	13 (2%)
SALBUTAMOL SULFATE+IPRATROPIUM BROMIDE	5 (1%)	8 (2%)	13 (2%)
CINEOLE+PINENE+DIPENTEN	6 (1%)	6 (1%)	12 (1%)
MONTELUKAST SODIUM	7 (2%)	5 (1%)	12 (1%)
DOXOFYLLINE	4 (<1%)	7 (2%)	11 (1%)
IPRATROPIUM	6 (1%)	5 (1%)	11 (1%)
THEOPHYLLINE	8 (2%)	3 (<1%)	11 (1%)
CARBOCISTEINE	6 (1%)	4 (<1%)	10 (1%)
PREDNISONE ACETATE	6 (1%)	4 (<1%)	10 (1%)
FENOTEROL HYDROBROMIDE+IPRATROPIUM BROMIDE	4 (<1%)	5 (1%)	9 (1%)
SALBUTAMOL SULFATE	4 (<1%)	5 (1%)	9 (1%)
AMINOPHYLLINE+CHLORPHENAMINE MALEATE+METHOXYPHENAMINE HYDROCHLORIDE+NOSCAPINE	5 (1%)	3 (<1%)	8 (<1%)
TERBUTALINE SULFATE	5 (1%)	3 (<1%)	8 (<1%)
CETIRIZINE HYDROCHLORIDE	5 (1%)	2 (<1%)	7 (<1%)
ERDOSTEINE	3 (<1%)	4 (<1%)	7 (<1%)
LIDOCAINE	4 (<1%)	3 (<1%)	7 (<1%)
PREDNISOLONE SODIUM SUCCINATE	4 (<1%)	3 (<1%)	7 (<1%)
BECLOMETASONE DIPROPIONATE	3 (<1%)	3 (<1%)	6 (<1%)

Note: A medication may be included in more than one ATC Level category and appear more than once.
Includes medications started after first dose and before last dose + 28 days.
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Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Table 111.20

Summary of Non-COPD Medications Started During Treatment in Study 208657

ATC Level 1 Ingredient and Ingredient Combinations	PBO (N=401)	100 SC (N=403)	Total (N=804)
EPINEPHRINE	3 (<1%)	3 (<1%)	6 (<1%)
FLUTICASONE PROPIONATE	4 (<1%)	2 (<1%)	6 (<1%)
GUAIFENESIN	3 (<1%)	3 (<1%)	6 (<1%)
CODEINE	2 (<1%)	3 (<1%)	5 (<1%)
FEXOFENADINE HYDROCHLORIDE	3 (<1%)	2 (<1%)	5 (<1%)
HYDROXYZINE	3 (<1%)	2 (<1%)	5 (<1%)
PARACETAMOL+AMANTADINE HYDROCHLORIDE+CAFFEINE+CHLORPHENAMINE MALEATE+COW BEZOAR	1 (<1%)	4 (<1%)	5 (<1%)
PARACETAMOL+DEXTROMETHORPHAN HYDROBROMIDE+CHLORPHENAMINE MALEATE+PSEUDOEPHEDRINE HYDROCHLORIDE	3 (<1%)	2 (<1%)	5 (<1%)
TRIAMCINOLONE ACETONIDE	4 (<1%)	1 (<1%)	5 (<1%)
AMBROXOL	2 (<1%)	2 (<1%)	4 (<1%)
AZELASTINE HYDROCHLORIDE	3 (<1%)	1 (<1%)	4 (<1%)
BENZONATATE	4 (<1%)	0	4 (<1%)
BRONCHIPRET (NOS)	2 (<1%)	2 (<1%)	4 (<1%)
FEXOFENADINE	3 (<1%)	1 (<1%)	4 (<1%)
FLURBIPROFEN	2 (<1%)	2 (<1%)	4 (<1%)
GLYCEROL	1 (<1%)	3 (<1%)	4 (<1%)
LEVOSALBUTAMOL HYDROCHLORIDE	2 (<1%)	2 (<1%)	4 (<1%)
LIDOCAINE HYDROCHLORIDE	2 (<1%)	2 (<1%)	4 (<1%)
PSEUDOEPHEDRINE	3 (<1%)	1 (<1%)	4 (<1%)
SALBUTAMOL+IPRATROPIUM BROMIDE	3 (<1%)	1 (<1%)	4 (<1%)
SUDAFED (NOS)	1 (<1%)	3 (<1%)	4 (<1%)
XYLOMETAZOLINE HYDROCHLORIDE	1 (<1%)	3 (<1%)	4 (<1%)
AERIUS (NOS)	1 (<1%)	2 (<1%)	3 (<1%)
AZELASTINE HYDROCHLORIDE+FLUTICASONE PROPIONATE	1 (<1%)	2 (<1%)	3 (<1%)
BENYLIN (NOS)	1 (<1%)	2 (<1%)	3 (<1%)
BETAMETHASONE SODIUM PHOSPHATE	1 (<1%)	2 (<1%)	3 (<1%)
CHLORHEXIDINE GLUCONATE	1 (<1%)	2 (<1%)	3 (<1%)

Note: A medication may be included in more than one ATC Level category and appear more than once.
Includes medications started after first dose and before last dose + 28 days.
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Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Table 111.20

Summary of Non-COPD Medications Started During Treatment in Study 208657

ATC Level 1 Ingredient and Ingredient Combinations	PBO (N=401)	100 SC (N=403)	Total (N=804)
DIPROPHYLLINE	3 (<1%)	0	3 (<1%)
FLUTICASONE	2 (<1%)	1 (<1%)	3 (<1%)
FLUTICASONE FUROATE	2 (<1%)	1 (<1%)	3 (<1%)
FLUTICASONE FUROATE+VILANTEROL TRIFENATATE+UMECLIDINIUM BROMIDE	2 (<1%)	1 (<1%)	3 (<1%)
GUAIFENESIN+AMBROXOL+LEVOSALBUTAMOL	1 (<1%)	2 (<1%)	3 (<1%)
KETOPROFEN	0	3 (<1%)	3 (<1%)
KETOTIFEN FUMARATE	1 (<1%)	2 (<1%)	3 (<1%)
MOMETASONE	1 (<1%)	2 (<1%)	3 (<1%)
MUCOSOLVAN (NOS)	1 (<1%)	2 (<1%)	3 (<1%)
PARACETAMOL+CAFFEINE+PHENYLEPHRINE HYDROCHLORIDE	0	3 (<1%)	3 (<1%)
PARACETAMOL+DEXTROMETHORPHAN HYDROBROMIDE+PSEUDOEPHEDRINE HYDROCHLORIDE	2 (<1%)	1 (<1%)	3 (<1%)
PARACETAMOL+GUAIFENESIN+PHENYLEPHRINE HYDROCHLORIDE	1 (<1%)	2 (<1%)	3 (<1%)
SALBUTAMOL+IPRATROPIUM	2 (<1%)	1 (<1%)	3 (<1%)
TERBUTALINE	1 (<1%)	2 (<1%)	3 (<1%)
ACETYLCYSTEINE+AMBROXOL ACEFYLLINATE	0	2 (<1%)	2 (<1%)
AEROVENT (NOS)	1 (<1%)	1 (<1%)	2 (<1%)
AMBROXOL ACEFYLLINATE+DOXOFYLLINE	0	2 (<1%)	2 (<1%)
ASCORBIC ACID+PARACETAMOL+CHLORPHENAMINE MALEATE+LONICERA SPP+NEPETA CATARIA+LOPHATHERUM NOS+HERBALS NOS	1 (<1%)	1 (<1%)	2 (<1%)
ATROPINE METHONITRATE+DEXAMETHASONE SODIUM METASULFOBENZOATE+PAPAVERINE HYDROCHLORIDE+METHOCARBAMOL+PROXYPHYLLINE+KHELLIN CARBONIC ACID ETHANOLAMINE+PENTETRAZOLE	2 (<1%)	0	2 (<1%)
AZELASTINE+FLUTICASONE	1 (<1%)	1 (<1%)	2 (<1%)
BENZYDAMINE HYDROCHLORIDE	1 (<1%)	1 (<1%)	2 (<1%)
BROMHEXINE	2 (<1%)	0	2 (<1%)
BUDESONIDE+FORMOTEROL	1 (<1%)	1 (<1%)	2 (<1%)

Note: A medication may be included in more than one ATC Level category and appear more than once.
Includes medications started after first dose and before last dose + 28 days.
/mnt/code/postcsr_01/prod/tfls/t_sp_c1_ncopd_on_657.sas 21JUL2025 22:02

Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Table 111.20

Summary of Non-COPD Medications Started During Treatment in Study 208657

ATC Level 1 Ingredient and Ingredient Combinations	PBO (N=401)	100 SC (N=403)	Total (N=804)
CHLORPHENAMINE MALEATE	2 (<1%)	0	2 (<1%)
CINEOLE	1 (<1%)	1 (<1%)	2 (<1%)
CODEINE PHOSPHATE	1 (<1%)	1 (<1%)	2 (<1%)
CORTICOSTEROID NOS	2 (<1%)	0	2 (<1%)
DESLORATADINE CITRATE DISODIUM	1 (<1%)	1 (<1%)	2 (<1%)
DEXTROMETHORPHAN HYDROBROMIDE	1 (<1%)	1 (<1%)	2 (<1%)
EBASTINE	1 (<1%)	1 (<1%)	2 (<1%)
EPHEDRINE	0	2 (<1%)	2 (<1%)
FENOTEROL+IPRATROPIUM BROMIDE	2 (<1%)	0	2 (<1%)
FLONASE (NOS)	1 (<1%)	1 (<1%)	2 (<1%)
GELOMYRTOL (NOS)	1 (<1%)	1 (<1%)	2 (<1%)
GENTIAN (NOS)+PRIMULA VERIS+SAMBUCUS NIGRA+VERBENA OFFICINALIS+RUMEX ACETOSA	0	2 (<1%)	2 (<1%)
GLYCOPYRRONIUM BROMIDE+BUDESONIDE+FORMOTEROL FUMARATE	2 (<1%)	0	2 (<1%)
GLYCYRRHIZA SPP. ROOT WITH RHIZOME+ASTER TATARICUS ROOT WITH RHIZOME+EPHEDRA SPP. STEM+HERBALS NOS	1 (<1%)	1 (<1%)	2 (<1%)
GLYCYRRHIZA SPP. ROOT WITH RHIZOME+NEPETA TENUIFOLIA HERB+ASTER TATARICUS+MENTHA CANADENSIS HERB+KITAGAWIA PRAERUPTORA ROOT+CITRUS X AURANTIUM FRUIT PEEL+HERBALS NOS	0	2 (<1%)	2 (<1%)
GUAIFENESIN+TERBUTALINE+AMBROXOL ACEFYLLINATE	0	2 (<1%)	2 (<1%)
IPRATROPIUM BROMIDE+LEVOSALBUTAMOL SULPHATE	1 (<1%)	1 (<1%)	2 (<1%)
LEMSIP (NOS)	1 (<1%)	1 (<1%)	2 (<1%)
LEVOCETIRIZINE	2 (<1%)	0	2 (<1%)
LEVOCETIRIZINE HYDROCHLORIDE	1 (<1%)	1 (<1%)	2 (<1%)
MUPIROCIN	2 (<1%)	0	2 (<1%)
MYRTOL	0	2 (<1%)	2 (<1%)

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Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Table 111.20
Summary of Non-COPD Medications Started During Treatment in Study 208657

ATC Level 1 Ingredient and Ingredient Combinations	PBO (N=401)	100 SC (N=403)	Total (N=804)
PAEONIA LACTIFLORA ROOT+GLYCYRRHIZA SPP. ROOT WITH RHIZOME+PINELLIA TERNATA TUBER+EPHEDRA SPP. STEM+FRITILLARIA THUNBERGII BULB+PHERETIMA SPP.+HERBALS NOS	1 (<1%)	1 (<1%)	2 (<1%)
PARACETAMOL+AMBROXOL HYDROCHLORIDE+OXATOMIDE	1 (<1%)	1 (<1%)	2 (<1%)
PARACETAMOL+HYDROCODONE	1 (<1%)	1 (<1%)	2 (<1%)
PHENYLEPHRINE	0	2 (<1%)	2 (<1%)
POTASSIUM CHLORIDE+SODIUM CHLORIDE+CALCIUM CHLORIDE	1 (<1%)	1 (<1%)	2 (<1%)
PREDNISOLONE HEMISUCCINATE	2 (<1%)	0	2 (<1%)
PSEUDOEPHEDRINE HYDROCHLORIDE+IBUPROFEN	1 (<1%)	1 (<1%)	2 (<1%)
REFRIANEX (NOS)	0	2 (<1%)	2 (<1%)
THEOPHYLLINE SODIUM GLYCINATE	1 (<1%)	1 (<1%)	2 (<1%)
TIOTROPIUM BROMIDE MONOHYDRATE+OLODATEROL HYDROCHLORIDE	0	2 (<1%)	2 (<1%)
TRIAMCINOLONE	2 (<1%)	0	2 (<1%)
ALSTONIA SCHOLARIS LEAF	0	1 (<1%)	1 (<1%)
ANTAZOLINE HYDROCHLORIDE	1 (<1%)	0	1 (<1%)
ANTIBIOTICS NOS	1 (<1%)	0	1 (<1%)
ANYCOUGH (NOS)	0	1 (<1%)	1 (<1%)
ASCORBIC ACID+PARACETAMOL+PHENIRAMINE MALEATE+PHENYLEPHRINE HYDROCHLORIDE	0	1 (<1%)	1 (<1%)
ASCORBIC ACID+PARACETAMOL+PHENYLEPHRINE HYDROCHLORIDE	0	1 (<1%)	1 (<1%)
ASCORBIC ACID+PARACETAMOL+CAFFEINE+CHLORPHENAMINE MALEATE	1 (<1%)	0	1 (<1%)
AZELASTINE	1 (<1%)	0	1 (<1%)
BACTERIA LYSATE NOS	0	1 (<1%)	1 (<1%)
BAMBUTEROL HYDROCHLORIDE	1 (<1%)	0	1 (<1%)
BENADRYL (NOS)	0	1 (<1%)	1 (<1%)
BENZOCAINE	0	1 (<1%)	1 (<1%)

Note: A medication may be included in more than one ATC Level category and appear more than once.
Includes medications started after first dose and before last dose + 28 days.

Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Table 111.20

Summary of Non-COPD Medications Started During Treatment in Study 208657

ATC Level 1 Ingredient and Ingredient Combinations	PBO (N=401)	100 SC (N=403)	Total (N=804)
BETAMETHASONE PHOSPHATE	0	1 (<1%)	1 (<1%)
BETAMETHASONE VALERATE	0	1 (<1%)	1 (<1%)
BILASTINE	1 (<1%)	0	1 (<1%)
BISOLVON (NOS)	1 (<1%)	0	1 (<1%)
BROMHEXINE HYDROCHLORIDE+GUAIFENESIN+TERBUTALINE SULFATE	1 (<1%)	0	1 (<1%)
BROMHEXINE+GUAIFENESIN+TERBUTALINE	0	1 (<1%)	1 (<1%)
BROMHEXINE HYDROCHLORIDE+PARACETAMOL+CHLORPHENAMINE MALEATE+PSEUDOEPHEDRINE SULFATE	0	1 (<1%)	1 (<1%)
BROMHEXINE HYDROCHLORIDE+PARACETAMOL+DEXTROMETHORPHAN HYDROBROMIDE+CHLORPHENAMINE MALEATE+PHENYLEPHRINE HYDROCHLORIDE	1 (<1%)	0	1 (<1%)
BROMHEXINE HYDROCHLORIDE+PARACETAMOL+PSEUDOEPHEDRINE SULFATE+LORATADINE	0	1 (<1%)	1 (<1%)
BRONCHODILATOR (NOS)	1 (<1%)	0	1 (<1%)
BRONCOREX (NOS)	1 (<1%)	0	1 (<1%)
BUDESONIDE+FORMOTEROL FUMARATE	0	1 (<1%)	1 (<1%)
BUTAMIRATE CITRATE	0	1 (<1%)	1 (<1%)
CAFFEINE+DIHYDROCODEINE BITARTRATE+CHLORPHENAMINE MALEATE+METHYLEPHEDRINE HYDROCHLORIDE	1 (<1%)	0	1 (<1%)
CAFFEINE+GLYCYRRHIZA (NOS)+POLYGALA NOS+PRUNUS DULCIS+CAMPANULA (NOS)+HERBALS NOS+BORNEOL	1 (<1%)	0	1 (<1%)
CALCIUM CARBONATE+ZINGIBER OFFICINALE SUBTERRANEOUS ROOT STOCK+PAEONIA LACTIFLORA ROOT+CINNAMOMUM CASSIA TWIG+ZIZIPHUS JUJUBA FRUIT+FOSSILIA OSSIS MASTODI+HERBALS NOS	1 (<1%)	0	1 (<1%)
CALCIUM SULFATE DIHYDRATE+HERBALS NOS	1 (<1%)	0	1 (<1%)

Note: A medication may be included in more than one ATC Level category and appear more than once.
Includes medications started after first dose and before last dose + 28 days.
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Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Table 111.20

Summary of Non-COPD Medications Started During Treatment in Study 208657

ATC Level 1 Ingredient and Ingredient Combinations	PBO (N=401)	100 SC (N=403)	Total (N=804)
CARBOCISTEINE LYSINE	0	1 (<1%)	1 (<1%)
CETIRIZINE	1 (<1%)	0	1 (<1%)
CETYLPYRIDINIUM CHLORIDE	0	1 (<1%)	1 (<1%)
CHLORHEXIDINE	0	1 (<1%)	1 (<1%)
CHLORPHENAMINE MALEATE+CROMOGLICATE SODIUM+NAPHAZOLINE HYDROCHLORIDE	1 (<1%)	0	1 (<1%)
CHLORPHENAMINE MALEATE+IBUPROFEN+PHENYLEPHRINE HYDROCHLORIDE	1 (<1%)	0	1 (<1%)
CLEMASTINE	1 (<1%)	0	1 (<1%)
CLOPERASTINE FENDIZOATE	0	1 (<1%)	1 (<1%)
COCAINE	0	1 (<1%)	1 (<1%)
COLD CAPSULES (NOS)	1 (<1%)	0	1 (<1%)
COMPOUND PHOLCODINE (NOS)	1 (<1%)	0	1 (<1%)
COUGH COLD PREPARATIONS NOS	1 (<1%)	0	1 (<1%)
CROMOGLICATE SODIUM	0	1 (<1%)	1 (<1%)
DEXAMETHASONE ACETATE	1 (<1%)	0	1 (<1%)
DEXAMETHASONE PALMITATE	0	1 (<1%)	1 (<1%)
DEXPANTHENOL	0	1 (<1%)	1 (<1%)
DEXTROMETHORPHAN HYDROBROMIDE+CHLORPHENAMINE MALEATE	1 (<1%)	0	1 (<1%)
DEXTROMETHORPHAN HYDROBROMIDE+LYSOZYME HYDROCHLORIDE+POTASSIUM CRESOLSULFONATE	1 (<1%)	0	1 (<1%)
DEXTROMETHORPHAN+CARBOCISTEINE	1 (<1%)	0	1 (<1%)
DICHLOROBENZYL ALCOHOL+LEVOMENTHOL+AMYLMETACRESOL	0	1 (<1%)	1 (<1%)
DIHYDROCODEINE	0	1 (<1%)	1 (<1%)
DIMENHYDRINATE	0	1 (<1%)	1 (<1%)
DIMENHYDRINATE+CINNARIZINE	1 (<1%)	0	1 (<1%)
DIMETINDENE MALEATE	1 (<1%)	0	1 (<1%)
DIPHENHYDRAMINE	1 (<1%)	0	1 (<1%)
DIPHENHYDRAMINE HYDROCHLORIDE+PARACETAMOL	0	1 (<1%)	1 (<1%)

Note: A medication may be included in more than one ATC Level category and appear more than once.
Includes medications started after first dose and before last dose + 28 days.
/mnt/code/postcsr_01/prod/tfls/t_sp_c1_ncopd_on_657.sas 21JUL2025 22:02

Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Table 111.20

Summary of Non-COPD Medications Started During Treatment in Study 208657

ATC Level 1 Ingredient and Ingredient Combinations	PBO (N=401)	100 SC (N=403)	Total (N=804)
DIPHENHYDRAMINE HYDROCHLORIDE+PARACETAMOL+EPHEDRINE HYDROCHLORIDE+CAFFEINE	1 (<1%)	0	1 (<1%)
EPHEDRA SINICA+PAPAVER SOMNIFERUM+VITEX NEGUNDO+CODONOPSIS SPP+ANDROGRAPHIS (NOS)+STEMONA JAPONICA+HERBALS NOS	0	1 (<1%)	1 (<1%)
EPHEDRINE HYDROCHLORIDE+LONICERA JAPONICA FLOWER+BAICALIN+MAGNOLIA SPP. FLOWER BUD+BORNEOL	1 (<1%)	0	1 (<1%)
EPINEPHRINE HYDROCHLORIDE	1 (<1%)	0	1 (<1%)
EQUATE ALLERGY RELIEF (NOS)	1 (<1%)	0	1 (<1%)
EUCALIPTINE (NOS)	0	1 (<1%)	1 (<1%)
FENOTEROL	0	1 (<1%)	1 (<1%)
FENOTEROL HYDROBROMIDE	1 (<1%)	0	1 (<1%)
FEXOFENADINE+MONTELUKAST	0	1 (<1%)	1 (<1%)
FLURBIPROFEN AXETIL	0	1 (<1%)	1 (<1%)
FLURBIPROFEN SODIUM	0	1 (<1%)	1 (<1%)
FORSYTHIA SUSPENSA FRUIT+TRICHOSANTHES NOS+COPTIS SPP RHIZOME+CALCIUM SULFATE DIHYDRATE+PAEONIA SPP ROOT+GARDENIA JASMINOIDES FRUIT+HERBALS NOS	1 (<1%)	0	1 (<1%)
GLYCOPYRRONIUM BROMIDE+BECLOMETASONE DIPROPIONATE+FORMOTEROL FUMARATE	0	1 (<1%)	1 (<1%)
GLYCOPYRRONIUM BROMIDE+INDACATEROL MALEATE	0	1 (<1%)	1 (<1%)
GLYCYRRHIZA EXTRACT NOS	0	1 (<1%)	1 (<1%)
GLYCYRRHIZA SPP. ROOT WITH RHIZOME+COW BEZOAR+TERMINALIA CHEBULA FRUIT+MENTHOL+INDIGO+BORNEOL	1 (<1%)	0	1 (<1%)
GLYCYRRHIZA SPP. ROOT WITH RHIZOME+MENTHA CANADENSIS HERB+PAPAVER SOMNIFERUM PERICARP+ZIZIPHUS JUJUBA FRUIT+RHEUM SPP. ROOT WITH RHIZOME+HERBALS NOS	1 (<1%)	0	1 (<1%)

Note: A medication may be included in more than one ATC Level category and appear more than once.
Includes medications started after first dose and before last dose + 28 days.
/mnt/code/postcsr_01/prod/tfls/t_sp_c1_ncopd_on_657.sas 21JUL2025 22:02

Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Table 111.20

Summary of Non-COPD Medications Started During Treatment in Study 208657

ATC Level 1 Ingredient and Ingredient Combinations	PBO (N=401)	100 SC (N=403)	Total (N=804)
GLYCYRRHIZA SPP. ROOT WITH RHIZOME+PERILLA FRUTESCENS+PINELLIA TERNATA TUBER+EPHEDRA SPP HERB+KITAGAWIA PRAERUPTORA ROOT+CITRUS X AURANTIUM+HERBALS NOS	1 (<1%)	0	1 (<1%)
GRIPPOSTAD C (NOS)	1 (<1%)	0	1 (<1%)
GUAIFENESIN+DEXTROMETHORPHAN	1 (<1%)	0	1 (<1%)
GUAIFENESIN+DIHYDROCODEINE BITARTRATE+CHLORPHENAMINE MALEATE+METHYLEPHEDRINE HYDROCHLORIDE	0	1 (<1%)	1 (<1%)
GUAIFENESIN+GLYCEROL+BENZOIC ACID+CAMPHOR+AMMONIA+ILLICIUM VERUM OIL+HERBALS NOS	1 (<1%)	0	1 (<1%)
GUAIFENESIN+LEVOMENTHOL	1 (<1%)	0	1 (<1%)
GUAIFENESIN+TERBUTALINE+AMBROXOL	0	1 (<1%)	1 (<1%)
HEDERA HELIX	0	1 (<1%)	1 (<1%)
HEDERA HELIX EXTRACT	1 (<1%)	0	1 (<1%)
HELICIDINE	0	1 (<1%)	1 (<1%)
HONEY+PLANTAGO LANCEOLATA+HELICHRYSUM (NOS)+GRINDELIA (NOS)	1 (<1%)	0	1 (<1%)
HYDROCODONE	1 (<1%)	0	1 (<1%)
IPRATROPIUM+LEVOSALBUTAMOL	0	1 (<1%)	1 (<1%)
KETOTIFEN	1 (<1%)	0	1 (<1%)
LEVOCETIRIZINE DIHYDROCHLORIDE	0	1 (<1%)	1 (<1%)
LEVODROPROPIZINE	0	1 (<1%)	1 (<1%)
LEVOMENTHOL+PAPAVER SOMNIFERUM+MORUS (NOS)+ERIOBOTRYA JAPONICA+CAMPANULA (NOS)+CYNANCHUM GLAUCESCENS+HERBALS NOS	1 (<1%)	0	1 (<1%)
LIDOCAINE HYDROCHLORIDE+DEQUALINIUM CHLORIDE+CETYLPYRIDINIUM CHLORIDE	0	1 (<1%)	1 (<1%)

Note: A medication may be included in more than one ATC Level category and appear more than once.
Includes medications started after first dose and before last dose + 28 days.
/mnt/code/postcsr_01/prod/tfls/t_sp_c1_ncopd_on_657.sas 21JUL2025 22:02

Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Table 111.20

Summary of Non-COPD Medications Started During Treatment in Study 208657

ATC Level 1 Ingredient and Ingredient Combinations	PBO (N=401)	100 SC (N=403)	Total (N=804)
LONICERA JAPONICA FLOWER BUD+PRUNUS SPP SEED+SCROPHULARIA NINGPOENSIS ROOT+CURCUMA SPP RHIZOME+CHICKEN'S GIZZARD-MEMBRANE+CICADA SLOUGH+HERBALS NOS	0	1 (<1%)	1 (<1%)
MECLOZINE	1 (<1%)	0	1 (<1%)
MEPYRAMINE	0	1 (<1%)	1 (<1%)
METHYL SALICYLATE+THYMOL+LEVOMENTHOL+CINEOLE	0	1 (<1%)	1 (<1%)
METHYLTHIONINIUM CHLORIDE	1 (<1%)	0	1 (<1%)
MONTELUKAST	0	1 (<1%)	1 (<1%)
MONTELUKAST SODIUM+LEVOCETIRIZINE HYDROCHLORIDE	0	1 (<1%)	1 (<1%)
MONTELUKAST+DESLORATADINE	1 (<1%)	0	1 (<1%)
MONTELUKAST+LEVOCETIRIZINE	0	1 (<1%)	1 (<1%)
OXYMETAZOLINE+FLUTICASONE	1 (<1%)	0	1 (<1%)
PARACETAMOL+CAFFEINE+CHLORPHENAMINE	0	1 (<1%)	1 (<1%)
PARACETAMOL+CAFFEINE+CHLORPHENAMINE MALEATE+PSEUDOEPHEDRINE HYDROCHLORIDE	1 (<1%)	0	1 (<1%)
PARACETAMOL+CHLORPHENAMINE MALEATE+PHENYLEPHRINE HYDROCHLORIDE	0	1 (<1%)	1 (<1%)
PARACETAMOL+CHLORPHENAMINE MALEATE+PSEUDOEPHEDRINE SULFATE	1 (<1%)	0	1 (<1%)
PARACETAMOL+DEXTROMETHORPHAN HYDROBROMIDE+PHENYLEPHRINE HYDROCHLORIDE	1 (<1%)	0	1 (<1%)
PARACETAMOL+GUAIFENESIN+CAFFEINE+CHLORPHENAMINE MALEATE+METHYLEPHEDRINE HYDROCHLORIDE	0	1 (<1%)	1 (<1%)
PARACETAMOL+GUAIFENESIN+CAFFEINE+CHLORPHENAMINE MALEATE+PHENYLEPHRINE HYDROCHLORIDE+PENTOXYVERINE CITRATE	0	1 (<1%)	1 (<1%)
PARACETAMOL+GUAIFENESIN+DEXTROMETHORPHAN HYDROBROMIDE+PSEUDOEPHEDRINE HYDROCHLORIDE	0	1 (<1%)	1 (<1%)
PARACETAMOL+PHENYLEPHRINE HYDROCHLORIDE	1 (<1%)	0	1 (<1%)
PHENYLEPHRINE HYDROCHLORIDE	0	1 (<1%)	1 (<1%)

Note: A medication may be included in more than one ATC Level category and appear more than once.
Includes medications started after first dose and before last dose + 28 days.
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Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Table 111.20

Summary of Non-COPD Medications Started During Treatment in Study 208657

ATC Level 1 Ingredient and Ingredient Combinations	PBO (N=401)	100 SC (N=403)	Total (N=804)
PINUS SYLVESTRIS OIL+EUCALYPTUS OIL (NOS)	0	1 (<1%)	1 (<1%)
PORIA COCOS+GLYCYRRHIZA SPP. ROOT WITH RHIZOME+ANEMARRHENA ASPHODELOIDES+MORUS ALBA ROOT BARK+GEKKO GECKO+HERBALS NOS	1 (<1%)	0	1 (<1%)
PRANLUKAST	1 (<1%)	0	1 (<1%)
PRIMULA VERIS+SAMBUCUS NIGRA+VERBENA OFFICINALIS+RUMEX CRISPUS+GENTIANA LUTEA	0	1 (<1%)	1 (<1%)
PROMETHAZINE HYDROCHLORIDE	1 (<1%)	0	1 (<1%)
PROMETHAZINE HYDROCHLORIDE+AMMONIUM CHLORIDE+SULFOGAIACOL	0	1 (<1%)	1 (<1%)
PROMETHAZINE HYDROCHLORIDE+DEXTROMETHORPHAN HYDROBROMIDE	0	1 (<1%)	1 (<1%)
PROMETHAZINE HYDROCHLORIDE+POLYSORBATE 20+MEGLUMINE BENZOATE	0	1 (<1%)	1 (<1%)
PROMETHAZINE+DEXTROMETHORPHAN	0	1 (<1%)	1 (<1%)
PSEUDOEPHEDRINE HYDROCHLORIDE	1 (<1%)	0	1 (<1%)
REPROTEROL	0	1 (<1%)	1 (<1%)
SCUTELLARIA BAICALENSIS ROOT+ISATIS TINCTORIA ROOT+PHELLODENDRON CHINENSE BARK+GARDENIA JASMINOIDES FRUIT+SCAPHIUM AFFINE SEED	1 (<1%)	0	1 (<1%)
SCUTELLARIA BAICALENSIS ROOT+PRUNUS SPP SEED+SCHISANDRA CHINENSIS FRUIT+MORUS ALBA ROOT BARK+EPHEDRA SPP HERB+CALCIUM SULFATE DIHYDRATE+HERBALS NOS	1 (<1%)	0	1 (<1%)
SEPTOLETE (NOS)	0	1 (<1%)	1 (<1%)
SODIUM BENZOATE+CAMPHOR+PAPAVER SOMNIFERUM+GLYCYRRHIZA SPP. ROOT WITH RHIZOME+ILLICIUM VERUM OIL	1 (<1%)	0	1 (<1%)
SODIUM CHLORIDE+AMBROXOL HYDROCHLORIDE	0	1 (<1%)	1 (<1%)

Note: A medication may be included in more than one ATC Level category and appear more than once.
Includes medications started after first dose and before last dose + 28 days.
/mnt/code/postcsr_01/prod/tfls/t_sp_c1_ncopd_on_657.sas 21JUL2025 22:02

Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Table 111.20

Summary of Non-COPD Medications Started During Treatment in Study 208657

ATC Level 1 Ingredient and Ingredient Combinations	PBO (N=401)	100 SC (N=403)	Total (N=804)
SOPHORA TONKINENSIS ROOT WITH RHIZOME+ARDISIA CRISPA LEAF+ARDISIA CRISPA ROOT+MENTHOL+CICADA SLOUGH	1 (<1%)	0	1 (<1%)
THYMUS VULGARIS	0	1 (<1%)	1 (<1%)
TUSSIONEX (NOS)	0	1 (<1%)	1 (<1%)
URGINEA MARITIMA+CAPSICUM ANNUUM	1 (<1%)	0	1 (<1%)
VERONICA LINARIIFOLIA SUBSP. DILATATA	0	1 (<1%)	1 (<1%)
VILANTEROL TRIFENATATE+UMECLIDINIUM BROMIDE	0	1 (<1%)	1 (<1%)
XYLOMETAZOLINE	0	1 (<1%)	1 (<1%)
ZINGIBER OFFICINALE RHIZOME+PLATYCODON GRANDIFLORUS ROOT+HOUTTUYNIA CORDATA+PINELLIA TERNATA TUBER+MENTHA CANADENSIS OIL+PHYLLOSTACHYS SPP. STALK JUICE+RHAPHIOLEPIS BIBAS LEAF	1 (<1%)	0	1 (<1%)
DERMATOLOGICALS			
Any medication	210 (52%)	179 (44%)	389 (48%)
PREDNISOLONE	62 (15%)	66 (16%)	128 (16%)
METHYLPREDNISOLONE	37 (9%)	23 (6%)	60 (7%)
METHYLPREDNISOLONE SODIUM SUCCINATE	22 (5%)	22 (5%)	44 (5%)
CLARITHROMYCIN	25 (6%)	16 (4%)	41 (5%)
BUDESONIDE	18 (4%)	18 (4%)	36 (4%)
DEXAMETHASONE	17 (4%)	17 (4%)	34 (4%)
BETAMETHASONE	20 (5%)	11 (3%)	31 (4%)
CIPROFLOXACIN	13 (3%)	15 (4%)	28 (3%)
DICLOFENAC	10 (2%)	11 (3%)	21 (3%)
HYDROCORTISONE	11 (3%)	6 (1%)	17 (2%)
DEXAMETHASONE SODIUM PHOSPHATE	11 (3%)	4 (<1%)	15 (2%)
DICLOFENAC SODIUM	2 (<1%)	11 (3%)	13 (2%)
GLYCERYL TRINITRATE	8 (2%)	5 (1%)	13 (2%)
MOMETASONE FUROATE	5 (1%)	8 (2%)	13 (2%)

Note: A medication may be included in more than one ATC Level category and appear more than once.
Includes medications started after first dose and before last dose + 28 days.
/mnt/code/postcsr_01/prod/tfls/t_sp_c1_ncopd_on_657.sas 21JUL2025 22:02

Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Table 111.20

Summary of Non-COPD Medications Started During Treatment in Study 208657

ATC Level 1 Ingredient and Ingredient Combinations	PBO (N=401)	100 SC (N=403)	Total (N=804)
NYSTATIN	9 (2%)	4 (<1%)	13 (2%)
FLUCONAZOLE	6 (1%)	6 (1%)	12 (1%)
ASCORBIC ACID	6 (1%)	4 (<1%)	10 (1%)
MAGNESIUM SULFATE	7 (2%)	2 (<1%)	9 (1%)
METRONIDAZOLE	7 (2%)	2 (<1%)	9 (1%)
CETIRIZINE HYDROCHLORIDE	5 (1%)	2 (<1%)	7 (<1%)
HYDROCORTISONE SODIUM SUCCINATE	2 (<1%)	5 (1%)	7 (<1%)
LIDOCAINE	4 (<1%)	3 (<1%)	7 (<1%)
PREDNISOLONE SODIUM SUCCINATE	4 (<1%)	3 (<1%)	7 (<1%)
ACICLOVIR	2 (<1%)	4 (<1%)	6 (<1%)
BECLOMETASONE DIPROPIONATE	3 (<1%)	3 (<1%)	6 (<1%)
FLUTICASONE PROPIONATE	4 (<1%)	2 (<1%)	6 (<1%)
PREDNISOLONE ACETATE	2 (<1%)	4 (<1%)	6 (<1%)
BETAMETHASONE SODIUM PHOSPHATE+BETAMETHASONE ACETATE	4 (<1%)	1 (<1%)	5 (<1%)
CIPROFLOXACIN HYDROCHLORIDE	3 (<1%)	2 (<1%)	5 (<1%)
FEXOFENADINE HYDROCHLORIDE	3 (<1%)	2 (<1%)	5 (<1%)
TRIAMCINOLONE ACETONIDE	4 (<1%)	1 (<1%)	5 (<1%)
FEXOFENADINE	3 (<1%)	1 (<1%)	4 (<1%)
FUSIDIC ACID	3 (<1%)	1 (<1%)	4 (<1%)
LIDOCAINE HYDROCHLORIDE	2 (<1%)	2 (<1%)	4 (<1%)
BETAMETHASONE SODIUM PHOSPHATE	1 (<1%)	2 (<1%)	3 (<1%)
CHLORHEXIDINE GLUCONATE	1 (<1%)	2 (<1%)	3 (<1%)
CLINDAMYCIN	1 (<1%)	2 (<1%)	3 (<1%)
FINASTERIDE	2 (<1%)	1 (<1%)	3 (<1%)
FLUTICASONE	2 (<1%)	1 (<1%)	3 (<1%)
GENTAMICIN	1 (<1%)	2 (<1%)	3 (<1%)
GLYCYRRHIZA (NOS)	3 (<1%)	0	3 (<1%)
HYALURONATE SODIUM	0	3 (<1%)	3 (<1%)
MOMETASONE	1 (<1%)	2 (<1%)	3 (<1%)
RIFAXIMIN	1 (<1%)	2 (<1%)	3 (<1%)

Note: A medication may be included in more than one ATC Level category and appear more than once.
Includes medications started after first dose and before last dose + 28 days.
/mnt/code/postcsr_01/prod/tfls/t_sp_c1_ncopd_on_657.sas 21JUL2025 22:02

Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Table 111.20

Summary of Non-COPD Medications Started During Treatment in Study 208657

ATC Level 1 Ingredient and Ingredient Combinations	PBO (N=401)	100 SC (N=403)	Total (N=804)
AMIKACIN	2 (<1%)	0	2 (<1%)
CALCIUM GLUCONATE	1 (<1%)	1 (<1%)	2 (<1%)
CHLORAMPHENICOL	1 (<1%)	1 (<1%)	2 (<1%)
CHLORPHENAMINE MALEATE	2 (<1%)	0	2 (<1%)
CLINDAMYCIN PALMITATE HYDROCHLORIDE	1 (<1%)	1 (<1%)	2 (<1%)
CLINDASOL NOS	1 (<1%)	1 (<1%)	2 (<1%)
CLOBETASOL PROPIONATE	1 (<1%)	1 (<1%)	2 (<1%)
CORTICOSTEROID NOS	2 (<1%)	0	2 (<1%)
FLONASE (NOS)	1 (<1%)	1 (<1%)	2 (<1%)
IVERMECTIN	2 (<1%)	0	2 (<1%)
MICONAZOLE	0	2 (<1%)	2 (<1%)
MUPIROCIN	2 (<1%)	0	2 (<1%)
POTASSIUM CHLORIDE+SODIUM CHLORIDE+CALCIUM CHLORIDE	1 (<1%)	1 (<1%)	2 (<1%)
PREDNISOLONE HEMISUCCINATE	2 (<1%)	0	2 (<1%)
STEROIDS NOS	2 (<1%)	0	2 (<1%)
TRIAMCINOLONE	2 (<1%)	0	2 (<1%)
AMMONIUM LACTATE	1 (<1%)	0	1 (<1%)
AMOROLFINE HYDROCHLORIDE	0	1 (<1%)	1 (<1%)
ANTIBIOTICS NOS	1 (<1%)	0	1 (<1%)
BENADRYL (NOS)	0	1 (<1%)	1 (<1%)
BENZOCAINE	0	1 (<1%)	1 (<1%)
BETAMETHASONE DIPROPIONATE+CALCIPOTRIOL	1 (<1%)	0	1 (<1%)
BETAMETHASONE DIPROPIONATE+SALICYLIC ACID	0	1 (<1%)	1 (<1%)
BETAMETHASONE PHOSPHATE	0	1 (<1%)	1 (<1%)
BETAMETHASONE SODIUM PHOSPHATE+BETAMETHASONE DIPROPIONATE	1 (<1%)	0	1 (<1%)
BETAMETHASONE VALERATE	0	1 (<1%)	1 (<1%)
BETAMETHASONE VALERATE+FUSIDIC ACID	0	1 (<1%)	1 (<1%)
BETAMETHASONE+CALCIPOTRIOL	0	1 (<1%)	1 (<1%)
BROMELAINS	0	1 (<1%)	1 (<1%)

Note: A medication may be included in more than one ATC Level category and appear more than once.
Includes medications started after first dose and before last dose + 28 days.
/mnt/code/postcsr_01/prod/tfls/t_sp_c1_ncopd_on_657.sas 21JUL2025 22:02

Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Table 111.20

Summary of Non-COPD Medications Started During Treatment in Study 208657

ATC Level 1 Ingredient and Ingredient Combinations	PBO (N=401)	100 SC (N=403)	Total (N=804)
CETIRIZINE	1 (<1%)	0	1 (<1%)
CETRARIA ISLANDICA	0	1 (<1%)	1 (<1%)
CETYLPYRIDINIUM CHLORIDE	0	1 (<1%)	1 (<1%)
CHLORHEXIDINE	0	1 (<1%)	1 (<1%)
CICLOPIROX OLAMINE	0	1 (<1%)	1 (<1%)
CLEMASTINE	1 (<1%)	0	1 (<1%)
CLINDAMYCIN HYDROCHLORIDE	0	1 (<1%)	1 (<1%)
CLOTRIMAZOLE	0	1 (<1%)	1 (<1%)
COCAINE	0	1 (<1%)	1 (<1%)
COLLAGEN	0	1 (<1%)	1 (<1%)
CROMOGLICATE SODIUM	0	1 (<1%)	1 (<1%)
CROTAMITON	0	1 (<1%)	1 (<1%)
DERMATOLOGICALS NOS	0	1 (<1%)	1 (<1%)
DESONIDE	0	1 (<1%)	1 (<1%)
DESOXIMETASONE	1 (<1%)	0	1 (<1%)
DEXAMETHASONE ACETATE	1 (<1%)	0	1 (<1%)
DEXAMETHASONE PALMITATE	0	1 (<1%)	1 (<1%)
DEXPANTHENOL	0	1 (<1%)	1 (<1%)
DICLOFENAC DEANOL	1 (<1%)	0	1 (<1%)
DIMETINDENE MALEATE	1 (<1%)	0	1 (<1%)
DIPHENHYDRAMINE	1 (<1%)	0	1 (<1%)
EMOLLIENTS AND PROTECTIVES	0	1 (<1%)	1 (<1%)
FAT EMULSIONS	0	1 (<1%)	1 (<1%)
FLUOROMETHOLONE	0	1 (<1%)	1 (<1%)
HYDROCORTISONE ACETATE	0	1 (<1%)	1 (<1%)
HYDROCORTISONE SODIUM PHOSPHATE	1 (<1%)	0	1 (<1%)
HYDROCORTISONE+NEOMYCIN+POLYMYXIN B	0	1 (<1%)	1 (<1%)
INOSINE	1 (<1%)	0	1 (<1%)
KENALOG (NOS)	1 (<1%)	0	1 (<1%)
KETOCONAZOLE	1 (<1%)	0	1 (<1%)
LAUROMACROGOL 400	1 (<1%)	0	1 (<1%)

Note: A medication may be included in more than one ATC Level category and appear more than once.
Includes medications started after first dose and before last dose + 28 days.
/mnt/code/postcsr_01/prod/tfls/t_sp_c1_ncopd_on_657.sas 21JUL2025 22:02

Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Table 111.20

Summary of Non-COPD Medications Started During Treatment in Study 208657

ATC Level 1 Ingredient and Ingredient Combinations	PBO (N=401)	100 SC (N=403)	Total (N=804)
LEVOCETIRIZINE DIHYDROCHLORIDE	0	1 (<1%)	1 (<1%)
LIDOCAINE HYDROCHLORIDE+NEOMYCIN SULFATE+POLYMYXIN B+BACITRACIN	0	1 (<1%)	1 (<1%)
LIQUID PARAFFIN+GLYCEROL+WHITE SOFT PARAFFIN	0	1 (<1%)	1 (<1%)
LIQUID	1 (<1%)	0	1 (<1%)
PARAFFIN+TOCOPHEROL+ARGININE+GLYCEROL+OENOTHERA BIENNIS OIL+AQUAPHILUS DOLOMIAE EXTRACT+CAPRYLIC/CAPRIC TRIGLYCERIDE			
MEPYRAMINE	0	1 (<1%)	1 (<1%)
METHYLPREDNISOLONE ACEPONATE	0	1 (<1%)	1 (<1%)
METHYLPREDNISOLONE ACETATE	1 (<1%)	0	1 (<1%)
METHYLTHIONINIUM CHLORIDE	1 (<1%)	0	1 (<1%)
MICONAZOLE NITRATE	1 (<1%)	0	1 (<1%)
NEOMYCIN SULFATE+CLOBETASOL PROPIONATE+KETOCONAZOLE	0	1 (<1%)	1 (<1%)
NITROFURAZONE	0	1 (<1%)	1 (<1%)
PANTOTHENIC ACID	1 (<1%)	0	1 (<1%)
PLATSUL-A (NOS)	0	1 (<1%)	1 (<1%)
PROMETHAZINE HYDROCHLORIDE	1 (<1%)	0	1 (<1%)
RECOMBINANT BOVINE BASIC FIBROBLAST GROWTH FACTOR	0	1 (<1%)	1 (<1%)
SALICYLIC ACID+FLUMETASONE	0	1 (<1%)	1 (<1%)
SILVER NITRATE	1 (<1%)	0	1 (<1%)
STREPTOKINASE+STREPTODORNASE	1 (<1%)	0	1 (<1%)
SULFADIAZINE SILVER	1 (<1%)	0	1 (<1%)
TALC	1 (<1%)	0	1 (<1%)
TERBINAFINE HYDROCHLORIDE	0	1 (<1%)	1 (<1%)
TERRAMYCIN NOS	1 (<1%)	0	1 (<1%)
TETRACAINE HYDROCHLORIDE	1 (<1%)	0	1 (<1%)
TETRACYCLINE	1 (<1%)	0	1 (<1%)
TOCOPHEROL	0	1 (<1%)	1 (<1%)

Note: A medication may be included in more than one ATC Level category and appear more than once.
Includes medications started after first dose and before last dose + 28 days.
/mnt/code/postcsr_01/prod/tfls/t_sp_c1_ncopd_on_657.sas 21JUL2025 22:02

Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Table 111.20

Summary of Non-COPD Medications Started During Treatment in Study 208657

ATC Level 1 Ingredient and Ingredient Combinations	PBO (N=401)	100 SC (N=403)	Total (N=804)
TRIAMCINOLONE ACETONIDE+NYSTATIN+NEOMYCIN SULFATE+GRAMICIDIN	1 (<1%)	0	1 (<1%)
TRIDERM (NOS)	0	1 (<1%)	1 (<1%)
TRYPSIN	1 (<1%)	0	1 (<1%)
UFENAMATE	0	1 (<1%)	1 (<1%)
UREA	0	1 (<1%)	1 (<1%)
ZINC	1 (<1%)	0	1 (<1%)
CARDIOVASCULAR SYSTEM			
Any medication	197 (49%)	183 (45%)	380 (47%)
PREDNISOLONE	62 (15%)	66 (16%)	128 (16%)
IBUPROFEN	25 (6%)	42 (10%)	67 (8%)
FUROSEMIDE	27 (7%)	18 (4%)	45 (6%)
IPRATROPIUM BROMIDE	22 (5%)	21 (5%)	43 (5%)
DEXAMETHASONE	17 (4%)	17 (4%)	34 (4%)
BETAMETHASONE	20 (5%)	11 (3%)	31 (4%)
ATORVASTATIN	13 (3%)	12 (3%)	25 (3%)
AMLODIPINE	10 (2%)	7 (2%)	17 (2%)
HYDROCORTISONE	11 (3%)	6 (1%)	17 (2%)
DEXAMETHASONE SODIUM PHOSPHATE	11 (3%)	4 (<1%)	15 (2%)
HYDROCHLOROTHIAZIDE	10 (2%)	5 (1%)	15 (2%)
TORASEMIDE	5 (1%)	9 (2%)	14 (2%)
GLYCERYL TRINITRATE	8 (2%)	5 (1%)	13 (2%)
ATORVASTATIN CALCIUM	6 (1%)	6 (1%)	12 (1%)
BISOPROLOL FUMARATE	7 (2%)	5 (1%)	12 (1%)
RAMIPRIL	7 (2%)	5 (1%)	12 (1%)
ROSUVASTATIN	6 (1%)	6 (1%)	12 (1%)
SPIRONOLACTONE	4 (<1%)	8 (2%)	12 (1%)
IPRATROPIUM	6 (1%)	5 (1%)	11 (1%)
BISOPROLOL	4 (<1%)	5 (1%)	9 (1%)
AMLODIPINE BESILATE	7 (2%)	1 (<1%)	8 (<1%)

Note: A medication may be included in more than one ATC Level category and appear more than once.
Includes medications started after first dose and before last dose + 28 days.
/mnt/code/postcsr_01/prod/tfls/t_sp_c1_ncopd_on_657.sas 21JUL2025 22:02

Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Table 111.20

Summary of Non-COPD Medications Started During Treatment in Study 208657

ATC Level 1 Ingredient and Ingredient Combinations	PBO (N=401)	100 SC (N=403)	Total (N=804)
METOPROLOL	6 (1%)	2 (<1%)	8 (<1%)
VALSARTAN	6 (1%)	2 (<1%)	8 (<1%)
CANDESARTAN	2 (<1%)	5 (1%)	7 (<1%)
HYDROCORTISONE SODIUM SUCCINATE	2 (<1%)	5 (1%)	7 (<1%)
LIDOCAINE	4 (<1%)	3 (<1%)	7 (<1%)
LOSARTAN	5 (1%)	2 (<1%)	7 (<1%)
PREDNISOLONE SODIUM SUCCINATE	4 (<1%)	3 (<1%)	7 (<1%)
AMIODARONE HYDROCHLORIDE	4 (<1%)	2 (<1%)	6 (<1%)
EPINEPHRINE	3 (<1%)	3 (<1%)	6 (<1%)
HEPARIN (NOS)	3 (<1%)	3 (<1%)	6 (<1%)
PREDNISOLONE ACETATE	2 (<1%)	4 (<1%)	6 (<1%)
EZETIMIBE	0	5 (1%)	5 (<1%)
HYDROCHLOROTHIAZIDE+AMILORIDE	3 (<1%)	2 (<1%)	5 (<1%)
LEVAMLODIPINE BESILATE	3 (<1%)	2 (<1%)	5 (<1%)
NEBIVOLOL	4 (<1%)	1 (<1%)	5 (<1%)
CAPTOPRIL	4 (<1%)	0	4 (<1%)
DIGOXIN	1 (<1%)	3 (<1%)	4 (<1%)
ENALAPRIL	0	4 (<1%)	4 (<1%)
IRBESARTAN	2 (<1%)	2 (<1%)	4 (<1%)
LERCANIDIPINE	3 (<1%)	1 (<1%)	4 (<1%)
LIDOCAINE HYDROCHLORIDE	2 (<1%)	2 (<1%)	4 (<1%)
METOPROLOL TARTRATE	3 (<1%)	1 (<1%)	4 (<1%)
NEBIVOLOL HYDROCHLORIDE	2 (<1%)	2 (<1%)	4 (<1%)
VERAPAMIL HYDROCHLORIDE	2 (<1%)	2 (<1%)	4 (<1%)
AMIODARONE	3 (<1%)	0	3 (<1%)
BETAHISTINE HYDROCHLORIDE	2 (<1%)	1 (<1%)	3 (<1%)
BETAHISTINE MESILATE	2 (<1%)	1 (<1%)	3 (<1%)
BETAMETHASONE SODIUM PHOSPHATE	1 (<1%)	2 (<1%)	3 (<1%)
DILTIAZEM HYDROCHLORIDE	1 (<1%)	2 (<1%)	3 (<1%)
HEPARIN SODIUM	2 (<1%)	1 (<1%)	3 (<1%)
ISOSORBIDE MONONITRATE	2 (<1%)	1 (<1%)	3 (<1%)

Note: A medication may be included in more than one ATC Level category and appear more than once.
Includes medications started after first dose and before last dose + 28 days.
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Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Table 111.20

Summary of Non-COPD Medications Started During Treatment in Study 208657

ATC Level 1 Ingredient and Ingredient Combinations	PBO (N=401)	100 SC (N=403)	Total (N=804)
IVABRADINE HYDROCHLORIDE	3 (<1%)	0	3 (<1%)
NIFEDIPINE	1 (<1%)	2 (<1%)	3 (<1%)
NOREPINEPHRINE	1 (<1%)	2 (<1%)	3 (<1%)
PROPRANOLOL	2 (<1%)	1 (<1%)	3 (<1%)
SIMVASTATIN	1 (<1%)	2 (<1%)	3 (<1%)
ASCORBIC ACID+HESPERIDIN METHYL CHALCONE+RUSCUS ACULEATUS	2 (<1%)	0	2 (<1%)
BUMETANIDE	1 (<1%)	1 (<1%)	2 (<1%)
CANDESARTAN CILEXETIL	1 (<1%)	1 (<1%)	2 (<1%)
DAFLON NOS	0	2 (<1%)	2 (<1%)
DESLANOSIDE	1 (<1%)	1 (<1%)	2 (<1%)
DIOSMIN (NON-PROPRIETARY)	0	2 (<1%)	2 (<1%)
EPHEDRINE	0	2 (<1%)	2 (<1%)
EPLERENONE	1 (<1%)	1 (<1%)	2 (<1%)
EZETIMIBE+ROSUVASTATIN CALCIUM	0	2 (<1%)	2 (<1%)
GINKGO BILOBA EXTRACT	2 (<1%)	0	2 (<1%)
INDAPAMIDE	2 (<1%)	0	2 (<1%)
INDOMETACIN	2 (<1%)	0	2 (<1%)
MOXONIDINE	1 (<1%)	1 (<1%)	2 (<1%)
NARDOSTACHYS JATAMANSI+CODONOPSIS SPP ROOT+PANAX NOTOGINSENG ROOT WITH RHIZOME+AMBER (FOSSILIZED TREE RESIN)+POLYGONATUM SPP. RHIZOME	1 (<1%)	1 (<1%)	2 (<1%)
NICORANDIL	2 (<1%)	0	2 (<1%)
NITRENDIPINE	1 (<1%)	1 (<1%)	2 (<1%)
NOREPINEPHRINE BITARTRATE	1 (<1%)	1 (<1%)	2 (<1%)
OLMESARTAN MEDOXOMIL	2 (<1%)	0	2 (<1%)
PACLITAXEL	1 (<1%)	1 (<1%)	2 (<1%)
PERINDOPRIL	1 (<1%)	1 (<1%)	2 (<1%)
PHENYLEPHRINE	0	2 (<1%)	2 (<1%)
POTASSIUM ASPARTATE+MAGNESIUM ASPARTATE	2 (<1%)	0	2 (<1%)
PRAVASTATIN SODIUM	2 (<1%)	0	2 (<1%)

Note: A medication may be included in more than one ATC Level category and appear more than once.
Includes medications started after first dose and before last dose + 28 days.
/mnt/code/postcsr_01/prod/tfls/t_sp_c1_ncopd_on_657.sas 21JUL2025 22:02

Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Table 111.20

Summary of Non-COPD Medications Started During Treatment in Study 208657

ATC Level 1 Ingredient and Ingredient Combinations	PBO (N=401)	100 SC (N=403)	Total (N=804)
PREDNISOLONE HEMISUCCINATE	2 (<1%)	0	2 (<1%)
RAMIPRIL+AMLODIPINE BESILATE	1 (<1%)	1 (<1%)	2 (<1%)
RANOLAZINE	1 (<1%)	1 (<1%)	2 (<1%)
ROSUVASTATIN CALCIUM	0	2 (<1%)	2 (<1%)
SILODOSIN	1 (<1%)	1 (<1%)	2 (<1%)
URAPIDIL	2 (<1%)	0	2 (<1%)
VIVACOR (NOS)	1 (<1%)	1 (<1%)	2 (<1%)
ACETAZOLAMIDE	0	1 (<1%)	1 (<1%)
ACETYLSALICYLIC ACID+RAMIPRIL+ATORVASTATIN CALCIUM	1 (<1%)	0	1 (<1%)
ALPROSTADIL	1 (<1%)	0	1 (<1%)
AMLODIPINE BESILATE+OLMESARTAN MEDOXOMIL	1 (<1%)	0	1 (<1%)
AMLODIPINE+OLMESARTAN	1 (<1%)	0	1 (<1%)
ATORVASTATIN CALCIUM+EZETIMIBE	1 (<1%)	0	1 (<1%)
ATROPINE	0	1 (<1%)	1 (<1%)
BENAZEPRIL HYDROCHLORIDE+AMLODIPINE BESILATE	1 (<1%)	0	1 (<1%)
BENDROFLUMETHIAZIDE+POTASSIUM CHLORIDE	0	1 (<1%)	1 (<1%)
BENZOCAINE	0	1 (<1%)	1 (<1%)
BETAHISTINE	1 (<1%)	0	1 (<1%)
BETAMETHASONE PHOSPHATE	0	1 (<1%)	1 (<1%)
BETAMETHASONE VALERATE	0	1 (<1%)	1 (<1%)
BETAXOLOL	1 (<1%)	0	1 (<1%)
BEZAFIBRATE	0	1 (<1%)	1 (<1%)
CALCIUM CARBONATE+ANGELICA SINENSIS ROOT+SALVIA MILTIORRHIZA ROOT WITH RHIZOME+EPIMEDIUM SPP LEAF+CODONOPSIS SPP ROOT+ASTRAGALUS MONGHOLICUS ROOT+HERBALS NOS	0	1 (<1%)	1 (<1%)
CARVEDILOL	0	1 (<1%)	1 (<1%)
CHLORTALIDONE	1 (<1%)	0	1 (<1%)
CLONIDINE	1 (<1%)	0	1 (<1%)
COLESTYRAMINE	1 (<1%)	0	1 (<1%)

Note: A medication may be included in more than one ATC Level category and appear more than once.
Includes medications started after first dose and before last dose + 28 days.
/mnt/code/postcsr_01/prod/tfls/t_sp_c1_ncopd_on_657.sas 21JUL2025 22:02

Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Table 111.20

Summary of Non-COPD Medications Started During Treatment in Study 208657

ATC Level 1 Ingredient and Ingredient Combinations	PBO (N=401)	100 SC (N=403)	Total (N=804)
DEXAMETHASONE ACETATE	1 (<1%)	0	1 (<1%)
DEXAMETHASONE PALMITATE	0	1 (<1%)	1 (<1%)
DILTIAZEM	0	1 (<1%)	1 (<1%)
DIOSMIN (NON-PROPRIETARY)+HESPERIDIN	0	1 (<1%)	1 (<1%)
DOPAMINE	0	1 (<1%)	1 (<1%)
DOXAZOSIN MESILATE	0	1 (<1%)	1 (<1%)
EPINEPHRINE HYDROCHLORIDE	1 (<1%)	0	1 (<1%)
ESCHERICHIA COLI	0	1 (<1%)	1 (<1%)
ETHANOL	1 (<1%)	0	1 (<1%)
EZECOR (NOS)	1 (<1%)	0	1 (<1%)
FELODIPINE	0	1 (<1%)	1 (<1%)
FLUOROMETHOLONE	0	1 (<1%)	1 (<1%)
GINKGO BILOBA LEAF EXTRACT	0	1 (<1%)	1 (<1%)
GINKGOLIDE A+GINKGOLIDE B+BILOBALIDE+GINKGOLIDE C	1 (<1%)	0	1 (<1%)
HEPARIN-FRACTION, SODIUM SALT	0	1 (<1%)	1 (<1%)
HESPERIDIN	1 (<1%)	0	1 (<1%)
HYDRALAZINE	1 (<1%)	0	1 (<1%)
HYDRALAZINE HYDROCHLORIDE	1 (<1%)	0	1 (<1%)
HYDROCHLOROTHIAZIDE+CANDESARTAN CILEXETIL	0	1 (<1%)	1 (<1%)
HYDROCHLOROTHIAZIDE+ENALAPRIL	1 (<1%)	0	1 (<1%)
HYDROCHLOROTHIAZIDE+IRBESARTAN	1 (<1%)	0	1 (<1%)
HYDROCHLOROTHIAZIDE+LOSARTAN	1 (<1%)	0	1 (<1%)
HYDROCHLOROTHIAZIDE+LOSARTAN POTASSIUM	0	1 (<1%)	1 (<1%)
HYDROCHLOROTHIAZIDE+OLMESARTAN MEDOXOMIL	1 (<1%)	0	1 (<1%)
HYDROCHLOROTHIAZIDE+RAMIPRIL	0	1 (<1%)	1 (<1%)
HYDROCORTISONE ACETATE	0	1 (<1%)	1 (<1%)
HYDROCORTISONE SODIUM PHOSPHATE	1 (<1%)	0	1 (<1%)
INDAPAMIDE+PERINDOPRIL	1 (<1%)	0	1 (<1%)
INDAPAMIDE+PERINDOPRIL ERBUMINE	1 (<1%)	0	1 (<1%)
INOSINE	1 (<1%)	0	1 (<1%)

Note: A medication may be included in more than one ATC Level category and appear more than once.
Includes medications started after first dose and before last dose + 28 days.
/mnt/code/postcsr_01/prod/tfls/t_sp_c1_ncopd_on_657.sas 21JUL2025 22:02

Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Table 111.20

Summary of Non-COPD Medications Started During Treatment in Study 208657

ATC Level 1 Ingredient and Ingredient Combinations	PBO (N=401)	100 SC (N=403)	Total (N=804)
ISOSORBIDE	1 (<1%)	0	1 (<1%)
IVABRADINE	0	1 (<1%)	1 (<1%)
IVABRADINE HYDROBROMIDE	0	1 (<1%)	1 (<1%)
LABETALOL	1 (<1%)	0	1 (<1%)
LAPPACONITINE HYDROBROMIDE	0	1 (<1%)	1 (<1%)
LISINOPRIL	1 (<1%)	0	1 (<1%)
LORISTA (NOS)	1 (<1%)	0	1 (<1%)
LOSARTAN POTASSIUM	1 (<1%)	0	1 (<1%)
LYSIMACHIA CHRISTINIAE WHOLE PLANT+CHRYSANTHEMUM INDICUM FLOWER HEAD+UNCARIA SPP. HOOK+CLEMATIS SPP. STEM	1 (<1%)	0	1 (<1%)
MANIDIPINE	1 (<1%)	0	1 (<1%)
METOPROLOL SUCCINATE	0	1 (<1%)	1 (<1%)
MONASCUS PURPUREUS	1 (<1%)	0	1 (<1%)
MONASCUS PURPUREUS+ATRACTYLODES MACROCEPHALA+ALISMA PLANTAGO-AQUATICA+CRATAEGUS PINNATIFIDA	1 (<1%)	0	1 (<1%)
NESIRITIDE	1 (<1%)	0	1 (<1%)
NICOTINIC ACID	1 (<1%)	0	1 (<1%)
NIMODIPINE	0	1 (<1%)	1 (<1%)
OMEGA-3 MARINE TRIGLYCERIDES	1 (<1%)	0	1 (<1%)
PANAX GINSENG EXTRACT+CINNAMOMUM CASSIA+COW BEZOAR+BUFONIS VENENUM+MOSCHUS NOS+LIQUIDAMBAR ORIENTALIS+BORNEOL	0	1 (<1%)	1 (<1%)
PANAX GINSENG ROOT WITH RHIZOME+OPHIOPOGON JAPONICUS ROOT TUBER+SCHISANDRA CHINENSIS FRUIT	1 (<1%)	0	1 (<1%)
PAPAVERINE HYDROCHLORIDE	0	1 (<1%)	1 (<1%)
PENTOXIFYLLINE	0	1 (<1%)	1 (<1%)
PERINDOPRIL ARGININE	1 (<1%)	0	1 (<1%)
PERINDOPRIL ARGININE+AMLODIPINE	1 (<1%)	0	1 (<1%)
PERINDOPRIL ERBUMINE	1 (<1%)	0	1 (<1%)

Note: A medication may be included in more than one ATC Level category and appear more than once.
Includes medications started after first dose and before last dose + 28 days.
/mnt/code/postcsr_01/prod/tfls/t_sp_c1_ncopd_on_657.sas 21JUL2025 22:02

Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Table 111.20

Summary of Non-COPD Medications Started During Treatment in Study 208657

ATC Level 1 Ingredient and Ingredient Combinations	PBO (N=401)	100 SC (N=403)	Total (N=804)
PERINDOPRIL ERBUMINE+AMLODIPINE BESILATE	0	1 (<1%)	1 (<1%)
PHENYLEPHRINE HYDROCHLORIDE	0	1 (<1%)	1 (<1%)
PRAMOCAINE HYDROCHLORIDE	0	1 (<1%)	1 (<1%)
PRAVASTATIN	0	1 (<1%)	1 (<1%)
PRAZOSIN	0	1 (<1%)	1 (<1%)
PROPAFENONE HYDROCHLORIDE	1 (<1%)	0	1 (<1%)
RECTOZORIN (NOS)	1 (<1%)	0	1 (<1%)
SPIRONOLACTONE+FUROSEMIDE	1 (<1%)	0	1 (<1%)
SPIRONOLACTONE+TORASEMIDE	0	1 (<1%)	1 (<1%)
SULODEXIDE	1 (<1%)	0	1 (<1%)
TERAZOSIN	1 (<1%)	0	1 (<1%)
TETRACAINE HYDROCHLORIDE	1 (<1%)	0	1 (<1%)
TITANOREINE (NOS)	1 (<1%)	0	1 (<1%)
TOLVAPTAN	1 (<1%)	0	1 (<1%)
VALSARTAN+SACUBITRIL	1 (<1%)	0	1 (<1%)
VINPOCETINE	1 (<1%)	0	1 (<1%)
XIPAMIDE	0	1 (<1%)	1 (<1%)
ZINC SULFATE	0	1 (<1%)	1 (<1%)
NERVOUS SYSTEM			
Any medication	160 (40%)	173 (43%)	333 (41%)
PARACETAMOL	66 (16%)	71 (18%)	137 (17%)
IBUPROFEN	25 (6%)	42 (10%)	67 (8%)
ACETYLSALICYLIC ACID	22 (5%)	12 (3%)	34 (4%)
METAMIZOLE SODIUM	12 (3%)	14 (3%)	26 (3%)
MORPHINE	9 (2%)	8 (2%)	17 (2%)
PREGABALIN	5 (1%)	9 (2%)	14 (2%)
TRAMADOL	6 (1%)	5 (1%)	11 (1%)
CYANOCOBALAMIN	3 (<1%)	6 (1%)	9 (1%)
ALPRAZOLAM	3 (<1%)	5 (1%)	8 (<1%)
METOPROLOL	6 (1%)	2 (<1%)	8 (<1%)

Note: A medication may be included in more than one ATC Level category and appear more than once.
Includes medications started after first dose and before last dose + 28 days.
/mnt/code/postcsr_01/prod/tfls/t_sp_c1_ncopd_on_657.sas 21JUL2025 22:02

Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Table 111.20

Summary of Non-COPD Medications Started During Treatment in Study 208657

ATC Level 1 Ingredient and Ingredient Combinations	PBO (N=401)	100 SC (N=403)	Total (N=804)
MORPHINE SULFATE	4 (<1%)	4 (<1%)	8 (<1%)
CLONAZEPAM	4 (<1%)	3 (<1%)	7 (<1%)
LIDOCAINE	4 (<1%)	3 (<1%)	7 (<1%)
PROPOFOL	3 (<1%)	4 (<1%)	7 (<1%)
ACETYLSALICYLIC ACID+PARACETAMOL+CAFFEINE	3 (<1%)	3 (<1%)	6 (<1%)
FENTANYL	3 (<1%)	3 (<1%)	6 (<1%)
SERTRALINE	2 (<1%)	4 (<1%)	6 (<1%)
TRAMADOL HYDROCHLORIDE	0	6 (1%)	6 (<1%)
CODEINE	2 (<1%)	3 (<1%)	5 (<1%)
GABAPENTIN	3 (<1%)	2 (<1%)	5 (<1%)
HYDROXYZINE	3 (<1%)	2 (<1%)	5 (<1%)
MIDAZOLAM	4 (<1%)	1 (<1%)	5 (<1%)
OXYCODONE	1 (<1%)	4 (<1%)	5 (<1%)
PARACETAMOL+AMANTADINE HYDROCHLORIDE+CAFFEINE+CHLORPHENAMINE MALEATE+COW BEZOAR	1 (<1%)	4 (<1%)	5 (<1%)
PARACETAMOL+DEXTROMETHORPHAN HYDROBROMIDE+CHLORPHENAMINE MALEATE+PSEUDOEPHEDRINE HYDROCHLORIDE	3 (<1%)	2 (<1%)	5 (<1%)
BUPROPION	2 (<1%)	2 (<1%)	4 (<1%)
CHOLINE SALICYLATE	1 (<1%)	3 (<1%)	4 (<1%)
CODEINE PHOSPHATE+PARACETAMOL+CAFFEINE	2 (<1%)	2 (<1%)	4 (<1%)
IBUFLAM (NOS)	0	4 (<1%)	4 (<1%)
KETOROLAC TROMETAMOL	1 (<1%)	3 (<1%)	4 (<1%)
LIDOCAINE HYDROCHLORIDE	2 (<1%)	2 (<1%)	4 (<1%)
METOPROLOL TARTRATE	3 (<1%)	1 (<1%)	4 (<1%)
NICOTINE	2 (<1%)	2 (<1%)	4 (<1%)
PARACETAMOL+TRAMADOL HYDROCHLORIDE	2 (<1%)	2 (<1%)	4 (<1%)
AMITRIPTYLINE	0	3 (<1%)	3 (<1%)
BETAHISTINE HYDROCHLORIDE	2 (<1%)	1 (<1%)	3 (<1%)
BETAHISTINE MESILATE	2 (<1%)	1 (<1%)	3 (<1%)

Note: A medication may be included in more than one ATC Level category and appear more than once.
Includes medications started after first dose and before last dose + 28 days.
/mnt/code/postcsr_01/prod/tfls/t_sp_c1_ncopd_on_657.sas 21JUL2025 22:02

Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Table 111.20

Summary of Non-COPD Medications Started During Treatment in Study 208657

ATC Level 1 Ingredient and Ingredient Combinations	PBO (N=401)	100 SC (N=403)	Total (N=804)
DIAZEPAM	1 (<1%)	2 (<1%)	3 (<1%)
LORAZEPAM	1 (<1%)	2 (<1%)	3 (<1%)
MELATONIN	3 (<1%)	0	3 (<1%)
NOVALGIN NOS	2 (<1%)	1 (<1%)	3 (<1%)
OXAZEPAM	3 (<1%)	0	3 (<1%)
OXYCODONE HYDROCHLORIDE	0	3 (<1%)	3 (<1%)
PARACETAMOL+CAFFEINE+CHLORPHENAMINE MALEATE+COW BEZOAR	1 (<1%)	2 (<1%)	3 (<1%)
PARACETAMOL+CAFFEINE+PHENYLEPHRINE HYDROCHLORIDE	0	3 (<1%)	3 (<1%)
PARACETAMOL+DEXTROMETHORPHAN HYDROBROMIDE+PSEUDOEPHEDRINE HYDROCHLORIDE	2 (<1%)	1 (<1%)	3 (<1%)
PROPRANOLOL	2 (<1%)	1 (<1%)	3 (<1%)
TRAZODONE	2 (<1%)	1 (<1%)	3 (<1%)
ZOLPIDEM TARTRATE	2 (<1%)	1 (<1%)	3 (<1%)
ACETYLSALICYLATE LYSINE	2 (<1%)	0	2 (<1%)
ALGOPYRIN (NOS)	1 (<1%)	1 (<1%)	2 (<1%)
CODEINE PHOSPHATE	1 (<1%)	1 (<1%)	2 (<1%)
CODEINE PHOSPHATE+PARACETAMOL	1 (<1%)	1 (<1%)	2 (<1%)
CYCLOBENZAPRINE	1 (<1%)	1 (<1%)	2 (<1%)
CYCLOBENZAPRINE HYDROCHLORIDE	2 (<1%)	0	2 (<1%)
DICLOFENAC POTASSIUM	1 (<1%)	1 (<1%)	2 (<1%)
ESTAZOLAM	0	2 (<1%)	2 (<1%)
GINKGO BILOBA EXTRACT	2 (<1%)	0	2 (<1%)
HALOPERIDOL	1 (<1%)	1 (<1%)	2 (<1%)
HYDROMORPHONE HYDROCHLORIDE	1 (<1%)	1 (<1%)	2 (<1%)
MEAVERIN (NOS)	2 (<1%)	0	2 (<1%)
MIDAZOLAM MALEATE	2 (<1%)	0	2 (<1%)
OXYCODONE HYDROCHLORIDE+NALOXONE HYDROCHLORIDE	1 (<1%)	1 (<1%)	2 (<1%)
PARACETAMOL+AMANTADINE HYDROCHLORIDE	1 (<1%)	1 (<1%)	2 (<1%)
PARACETAMOL+HYDROCODONE	1 (<1%)	1 (<1%)	2 (<1%)
PARACETAMOL+HYDROCODONE BITARTRATE	0	2 (<1%)	2 (<1%)

Note: A medication may be included in more than one ATC Level category and appear more than once.
Includes medications started after first dose and before last dose + 28 days.
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Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Table 111.20

Summary of Non-COPD Medications Started During Treatment in Study 208657

ATC Level 1 Ingredient and Ingredient Combinations	PBO (N=401)	100 SC (N=403)	Total (N=804)
PARACETAMOL+OXYCODONE HYDROCHLORIDE	2 (<1%)	0	2 (<1%)
PAROXETINE HYDROCHLORIDE	0	2 (<1%)	2 (<1%)
PRIDINOL	1 (<1%)	1 (<1%)	2 (<1%)
QUETIAPINE	1 (<1%)	1 (<1%)	2 (<1%)
REMIFENTANIL	0	2 (<1%)	2 (<1%)
TAPENTADOL	1 (<1%)	1 (<1%)	2 (<1%)
TOLPERISONE HYDROCHLORIDE	1 (<1%)	1 (<1%)	2 (<1%)
TRAMADOL HYDROCHLORIDE+DEXKETOPROFEN TROMETAMOL	1 (<1%)	1 (<1%)	2 (<1%)
ZOPICLONE	1 (<1%)	1 (<1%)	2 (<1%)
ACETYLCYSTEINE+TAURINE	0	1 (<1%)	1 (<1%)
ACETYLSALICYLIC ACID+ASCORBIC ACID	1 (<1%)	0	1 (<1%)
ACETYLSALICYLIC ACID+SODIUM BICARBONATE+CITRIC ACID	1 (<1%)	0	1 (<1%)
ACTRON (NOS)	0	1 (<1%)	1 (<1%)
AMITRIPTYLINE HYDROCHLORIDE	0	1 (<1%)	1 (<1%)
ANAESTHETICS, GENERAL	1 (<1%)	0	1 (<1%)
ANALGESIC, NOS	1 (<1%)	0	1 (<1%)
ASCORBIC ACID+CODEINE PHOSPHATE+PARACETAMOL	1 (<1%)	0	1 (<1%)
ASCORBIC ACID+PARACETAMOL+PHENYLEPHRINE HYDROCHLORIDE	0	1 (<1%)	1 (<1%)
ATARAX (NOS)	1 (<1%)	0	1 (<1%)
BENZOCAINE	0	1 (<1%)	1 (<1%)
BETAHISTINE	1 (<1%)	0	1 (<1%)
BROMAZEPAM	0	1 (<1%)	1 (<1%)
BROMFENAC SODIUM	0	1 (<1%)	1 (<1%)
BUPIVACAINE	1 (<1%)	0	1 (<1%)
BUPIVACAINE HYDROCHLORIDE	0	1 (<1%)	1 (<1%)
BUPROPION HYDROCHLORIDE	0	1 (<1%)	1 (<1%)
BUTORPHANOL TARTRATE	1 (<1%)	0	1 (<1%)
CANNABIDIOL	0	1 (<1%)	1 (<1%)

Note: A medication may be included in more than one ATC Level category and appear more than once.
Includes medications started after first dose and before last dose + 28 days.

Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Table 111.20

Summary of Non-COPD Medications Started During Treatment in Study 208657

ATC Level 1 Ingredient and Ingredient Combinations	PBO (N=401)	100 SC (N=403)	Total (N=804)
CARTHAMUS TINCTORIUS FLOWER+ACHYRANTHES BIDENTATA ROOT+GLYCYRRHIZA SPP. ROOT WITH RHIZOME+ANGELICA SINENSIS ROOT+ASTRAGALUS MONGHOLICUS ROOT+CITRUS X AURANTIUM UNRIPE FRUIT+HERBALS NOS	1 (<1%)	0	1 (<1%)
CLOMIPRAMINE HYDROCHLORIDE	1 (<1%)	0	1 (<1%)
CLONIDINE	1 (<1%)	0	1 (<1%)
COCAINE	0	1 (<1%)	1 (<1%)
CODEINE+PARACETAMOL	1 (<1%)	0	1 (<1%)
CYCLIZINE+DIPIPANONE	0	1 (<1%)	1 (<1%)
CYTISINICLINE	1 (<1%)	0	1 (<1%)
DEXMEDETOMIDINE HYDROCHLORIDE	1 (<1%)	0	1 (<1%)
DIHYDROCODEINE	0	1 (<1%)	1 (<1%)
DIOSCOREA NIPPONICA	1 (<1%)	0	1 (<1%)
DIPHENHYDRAMINE	1 (<1%)	0	1 (<1%)
DIPHENHYDRAMINE HYDROCHLORIDE+PARACETAMOL	0	1 (<1%)	1 (<1%)
DROPERIDOL	0	1 (<1%)	1 (<1%)
EPINEPHRINE+LIDOCAINE HYDROCHLORIDE	0	1 (<1%)	1 (<1%)
ESCITALOPRAM	0	1 (<1%)	1 (<1%)
ESKETAMINE	0	1 (<1%)	1 (<1%)
FLUNARIZINE DIHYDROCHLORIDE	1 (<1%)	0	1 (<1%)
FLUOXETINE	0	1 (<1%)	1 (<1%)
FORSYTHIA SUSPENSA FRUIT+PRUNUS SPP SEED+MORUS ALBA+MENTHA CANADENSIS HERB+ARCTIUM LAPPA FRUIT+ARTEMISIA ANNUA HERB+HERBALS NOS	1 (<1%)	0	1 (<1%)
GINKGO BILOBA LEAF EXTRACT	0	1 (<1%)	1 (<1%)
HYDROCODONE	1 (<1%)	0	1 (<1%)
HYDROMORPHONE	1 (<1%)	0	1 (<1%)
IBUPROFEN LYSINATE	1 (<1%)	0	1 (<1%)
IMIDAZOLE SALICYLATE	0	1 (<1%)	1 (<1%)

Note: A medication may be included in more than one ATC Level category and appear more than once.
Includes medications started after first dose and before last dose + 28 days.
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Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Table 111.20

Summary of Non-COPD Medications Started During Treatment in Study 208657

ATC Level 1 Ingredient and Ingredient Combinations	PBO (N=401)	100 SC (N=403)	Total (N=804)
INOSITOL+PANAX GINSENG ROOT+GINKGO BILOBA LEAF+PAULLINIA CUPANA+MINERALS NOS+VITAMINS NOS	1 (<1%)	0	1 (<1%)
LAMALINE (NOS)	1 (<1%)	0	1 (<1%)
LEVOBUPIVACAINE	1 (<1%)	0	1 (<1%)
LEVODOPA+BENSERAZIDE HYDROCHLORIDE	1 (<1%)	0	1 (<1%)
LEVODOPA+CARBIDOPA	0	1 (<1%)	1 (<1%)
MECLOZINE	1 (<1%)	0	1 (<1%)
MEPIVACAINE HYDROCHLORIDE	1 (<1%)	0	1 (<1%)
METOPROLOL SUCCINATE	0	1 (<1%)	1 (<1%)
MIANSERIN	1 (<1%)	0	1 (<1%)
MIRTAZAPINE	1 (<1%)	0	1 (<1%)
NALMEFENE HYDROCHLORIDE	1 (<1%)	0	1 (<1%)
NEFOPAM HYDROCHLORIDE	0	1 (<1%)	1 (<1%)
NEOSTIGMINE	0	1 (<1%)	1 (<1%)
NOLOTIL (NOS)	1 (<1%)	0	1 (<1%)
OLANZAPINE	1 (<1%)	0	1 (<1%)
OPIPRAMOL HYDROCHLORIDE	1 (<1%)	0	1 (<1%)
PANADOL (NOS)	1 (<1%)	0	1 (<1%)
PARACETAMOL+CAFFEINE	1 (<1%)	0	1 (<1%)
PARACETAMOL+CAFFEINE+CHLORPHENAMINE	0	1 (<1%)	1 (<1%)
PARACETAMOL+CAFFEINE+PHENYLEPHRINE HYDROCHLORIDE+LEVOCETIRIZINE DIHYDROCHLORIDE	0	1 (<1%)	1 (<1%)
PARACETAMOL+CAFFEINE+PROPYPHENAZONE	1 (<1%)	0	1 (<1%)
PARACETAMOL+CHLORPHENAMINE MALEATE+PHENYLEPHRINE HYDROCHLORIDE	0	1 (<1%)	1 (<1%)
PARACETAMOL+DIHYDROCODEINE BITARTRATE	1 (<1%)	0	1 (<1%)
PARACETAMOL+FLUPIRTINE	0	1 (<1%)	1 (<1%)
PARACETAMOL+FURSULTIAMINE	0	1 (<1%)	1 (<1%)
PARACETAMOL+OXYCODONE	0	1 (<1%)	1 (<1%)
PARACETAMOL+PHENYLEPHRINE HYDROCHLORIDE	1 (<1%)	0	1 (<1%)
PETHIDINE	1 (<1%)	0	1 (<1%)

Note: A medication may be included in more than one ATC Level category and appear more than once.
Includes medications started after first dose and before last dose + 28 days.
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Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Table 111.20

Summary of Non-COPD Medications Started During Treatment in Study 208657

ATC Level 1 Ingredient and Ingredient Combinations	PBO (N=401)	100 SC (N=403)	Total (N=804)
PIPAMPERONE HYDROCHLORIDE	1 (<1%)	0	1 (<1%)
PIRACETAM	0	1 (<1%)	1 (<1%)
PRAMIPEXOLE DIHYDROCHLORIDE	1 (<1%)	0	1 (<1%)
PRILOCAINE HYDROCHLORIDE	1 (<1%)	0	1 (<1%)
PROMETHAZINE HYDROCHLORIDE	1 (<1%)	0	1 (<1%)
PROPACETAMOL HYDROCHLORIDE	0	1 (<1%)	1 (<1%)
PROPOFOL+FAT EMULSIONS	1 (<1%)	0	1 (<1%)
ROPIVACAINE HYDROCHLORIDE	1 (<1%)	0	1 (<1%)
SUFENTANIL CITRATE	1 (<1%)	0	1 (<1%)
SUFENTANIL+ROPIVACAINE	0	1 (<1%)	1 (<1%)
TETRACAINE HYDROCHLORIDE	1 (<1%)	0	1 (<1%)
THIAMINE HYDROCHLORIDE+PYRIDOXINE HYDROCHLORIDE+PASSIFLORA EXTRACT+VALERIAN EXTRACT (NOS)	1 (<1%)	0	1 (<1%)
TILIDINE	1 (<1%)	0	1 (<1%)
TOPIRAMATE	1 (<1%)	0	1 (<1%)
TRIMIPRAMINE MALEATE	1 (<1%)	0	1 (<1%)
VINPOCETINE	1 (<1%)	0	1 (<1%)
GENITO URINARY SYSTEM AND SEX HORMONES			
Any medication	100 (25%)	111 (28%)	211 (26%)
IBUPROFEN	25 (6%)	42 (10%)	67 (8%)
SALBUTAMOL	31 (8%)	27 (7%)	58 (7%)
CIPROFLOXACIN	13 (3%)	15 (4%)	28 (3%)
NYSTATIN	9 (2%)	4 (<1%)	13 (2%)
METRONIDAZOLE	7 (2%)	2 (<1%)	9 (1%)
SALBUTAMOL SULFATE	4 (<1%)	5 (1%)	9 (1%)
TAMSULOSIN	4 (<1%)	3 (<1%)	7 (<1%)
AMPHOTERICIN B	4 (<1%)	2 (<1%)	6 (<1%)
MAGNESIUM HYDROXIDE	2 (<1%)	4 (<1%)	6 (<1%)
NAPROXEN	3 (<1%)	3 (<1%)	6 (<1%)

Note: A medication may be included in more than one ATC Level category and appear more than once.
Includes medications started after first dose and before last dose + 28 days.
/mnt/code/postcsr_01/prod/tfls/t_sp_c1_ncopd_on_657.sas 21JUL2025 22:02

Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Table 111.20

Summary of Non-COPD Medications Started During Treatment in Study 208657

ATC Level 1 Ingredient and Ingredient Combinations	PBO (N=401)	100 SC (N=403)	Total (N=804)
TAMSULOSIN HYDROCHLORIDE	4 (<1%)	2 (<1%)	6 (<1%)
CIPROFLOXACIN HYDROCHLORIDE	3 (<1%)	2 (<1%)	5 (<1%)
CLINDAMYCIN	1 (<1%)	2 (<1%)	3 (<1%)
FINASTERIDE	2 (<1%)	1 (<1%)	3 (<1%)
NITROFURANTOIN	1 (<1%)	2 (<1%)	3 (<1%)
SODIUM BICARBONATE	1 (<1%)	2 (<1%)	3 (<1%)
ALFUZOSIN	1 (<1%)	1 (<1%)	2 (<1%)
BENZYDAMINE HYDROCHLORIDE	1 (<1%)	1 (<1%)	2 (<1%)
CHLORAMPHENICOL	1 (<1%)	1 (<1%)	2 (<1%)
CLINDAMYCIN PALMITATE HYDROCHLORIDE	1 (<1%)	1 (<1%)	2 (<1%)
DUTASTERIDE	2 (<1%)	0	2 (<1%)
MICONAZOLE	0	2 (<1%)	2 (<1%)
POTASSIUM	0	2 (<1%)	2 (<1%)
SILODOSIN	1 (<1%)	1 (<1%)	2 (<1%)
SOLIFENACIN SUCCINATE	1 (<1%)	1 (<1%)	2 (<1%)
ACETIC ACID	0	1 (<1%)	1 (<1%)
ACETYLCYSTEINE+TAURINE	0	1 (<1%)	1 (<1%)
ALFUZOSIN HYDROCHLORIDE	1 (<1%)	0	1 (<1%)
ALPROSTADIL	1 (<1%)	0	1 (<1%)
ANTIBIOTICS NOS	1 (<1%)	0	1 (<1%)
BICARBONATE	1 (<1%)	0	1 (<1%)
CALCIUM CHLORIDE	0	1 (<1%)	1 (<1%)
CICLOPIROX OLAMINE	0	1 (<1%)	1 (<1%)
CLINDAMYCIN HYDROCHLORIDE	0	1 (<1%)	1 (<1%)
CLONIDINE	1 (<1%)	0	1 (<1%)
CLOTRIMAZOLE	0	1 (<1%)	1 (<1%)
COLLAGEN	0	1 (<1%)	1 (<1%)
COPPER	1 (<1%)	0	1 (<1%)
DOXAZOSIN MESILATE	0	1 (<1%)	1 (<1%)
ESTRADIOL+DYDROGESTERONE	1 (<1%)	0	1 (<1%)
FENOTEROL	0	1 (<1%)	1 (<1%)

Note: A medication may be included in more than one ATC Level category and appear more than once.
Includes medications started after first dose and before last dose + 28 days.
/mnt/code/postcsr_01/prod/tfls/t_sp_c1_ncopd_on_657.sas 21JUL2025 22:02

Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Table 111.20

Summary of Non-COPD Medications Started During Treatment in Study 208657

ATC Level 1 Ingredient and Ingredient Combinations	PBO (N=401)	100 SC (N=403)	Total (N=804)
FENOTEROL HYDROBROMIDE	1 (<1%)	0	1 (<1%)
IBUPROFEN LYSINATE	1 (<1%)	0	1 (<1%)
INOSINE	1 (<1%)	0	1 (<1%)
KETOCONAZOLE	1 (<1%)	0	1 (<1%)
METHYLSULFONYLMETHANE	0	1 (<1%)	1 (<1%)
METHYLTHIONINIUM CHLORIDE	1 (<1%)	0	1 (<1%)
METRONIDAZOLE+NYSTATIN	0	1 (<1%)	1 (<1%)
MICONAZOLE NITRATE	1 (<1%)	0	1 (<1%)
MIRABEGRON	0	1 (<1%)	1 (<1%)
ORNIDAZOLE	0	1 (<1%)	1 (<1%)
OXYBUTYNIN	1 (<1%)	0	1 (<1%)
PAPAVERINE HYDROCHLORIDE	0	1 (<1%)	1 (<1%)
PHENAZOPYRIDINE	0	1 (<1%)	1 (<1%)
PHENAZOPYRIDINE HYDROCHLORIDE	0	1 (<1%)	1 (<1%)
PORIA COCOS SCLEROTIUM+PAEONIA LACTIFLORA ROOT+SALVIA MILTIORRHIZA ROOT WITH RHIZOME+MORUS ALBA ROOT BARK+ASTRAGALUS MONGHOLICUS ROOT+HERBALS NOS	0	1 (<1%)	1 (<1%)
PRAZOSIN	0	1 (<1%)	1 (<1%)
SERENOA REPENS EXTRACT	0	1 (<1%)	1 (<1%)
SILDENAFIL CITRATE	0	1 (<1%)	1 (<1%)
STREPTOKINASE+STREPTODORNASE	1 (<1%)	0	1 (<1%)
TAMSULOSIN HYDROCHLORIDE+DUTASTERIDE	0	1 (<1%)	1 (<1%)
TERAZOSIN	1 (<1%)	0	1 (<1%)
URTICA DIOICA	0	1 (<1%)	1 (<1%)
MUSCULO-SKELETAL SYSTEM			
Any medication	92 (23%)	110 (27%)	202 (25%)
IBUPROFEN	25 (6%)	42 (10%)	67 (8%)
ACETYLSALICYLIC ACID	22 (5%)	12 (3%)	34 (4%)
DICLOFENAC	10 (2%)	11 (3%)	21 (3%)

Note: A medication may be included in more than one ATC Level category and appear more than once.
Includes medications started after first dose and before last dose + 28 days.
/mnt/code/postcsr_01/prod/tfls/t_sp_c1_ncopd_on_657.sas 21JUL2025 22:02

Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Table 111.20

Summary of Non-COPD Medications Started During Treatment in Study 208657

ATC Level 1 Ingredient and Ingredient Combinations	PBO (N=401)	100 SC (N=403)	Total (N=804)
DICLOFENAC SODIUM	2 (<1%)	11 (3%)	13 (2%)
ETORICOXIB	4 (<1%)	9 (2%)	13 (2%)
CELECOXIB	5 (1%)	4 (<1%)	9 (1%)
KETOROLAC	3 (<1%)	4 (<1%)	7 (<1%)
NAPROXEN	3 (<1%)	3 (<1%)	6 (<1%)
FOLIC ACID	1 (<1%)	4 (<1%)	5 (<1%)
ALLOPURINOL	1 (<1%)	3 (<1%)	4 (<1%)
BROMFENAC	2 (<1%)	2 (<1%)	4 (<1%)
DICLOFENAC DIETHYLAMINE	2 (<1%)	2 (<1%)	4 (<1%)
FLURBIPROFEN	2 (<1%)	2 (<1%)	4 (<1%)
IBUFLAM (NOS)	0	4 (<1%)	4 (<1%)
KETOROLAC TROMETAMOL	1 (<1%)	3 (<1%)	4 (<1%)
MELOXICAM	3 (<1%)	1 (<1%)	4 (<1%)
DEXKETOPROFEN TROMETAMOL	3 (<1%)	0	3 (<1%)
DIAZEPAM	1 (<1%)	2 (<1%)	3 (<1%)
FEBUXOSTAT	2 (<1%)	1 (<1%)	3 (<1%)
HYALURONATE SODIUM	0	3 (<1%)	3 (<1%)
KETOPROFEN	0	3 (<1%)	3 (<1%)
ALENDRONATE SODIUM	1 (<1%)	1 (<1%)	2 (<1%)
ALENDRONIC ACID	2 (<1%)	0	2 (<1%)
BENZYDAMINE HYDROCHLORIDE	1 (<1%)	1 (<1%)	2 (<1%)
COLCHICINE	2 (<1%)	0	2 (<1%)
CYCLOBENZAPRINE	1 (<1%)	1 (<1%)	2 (<1%)
CYCLOBENZAPRINE HYDROCHLORIDE	2 (<1%)	0	2 (<1%)
DEXIBUPROFEN	1 (<1%)	1 (<1%)	2 (<1%)
DICLOFENAC HYDROXYETHYLPYRROLIDINE	2 (<1%)	0	2 (<1%)
DICLOFENAC POTASSIUM	1 (<1%)	1 (<1%)	2 (<1%)
INDOMETACIN	2 (<1%)	0	2 (<1%)
LOXOPROFEN SODIUM	1 (<1%)	1 (<1%)	2 (<1%)
METHOCARBAMOL	1 (<1%)	1 (<1%)	2 (<1%)
PRIDINOL	1 (<1%)	1 (<1%)	2 (<1%)

Note: A medication may be included in more than one ATC Level category and appear more than once.
Includes medications started after first dose and before last dose + 28 days.
/mnt/code/postcsr_01/prod/tfls/t_sp_c1_ncopd_on_657.sas 21JUL2025 22:02

Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Table 111.20

Summary of Non-COPD Medications Started During Treatment in Study 208657

ATC Level 1 Ingredient and Ingredient Combinations	PBO (N=401)	100 SC (N=403)	Total (N=804)
ROCURONIUM	0	2 (<1%)	2 (<1%)
TIZANIDINE	1 (<1%)	1 (<1%)	2 (<1%)
TOLPERISONE HYDROCHLORIDE	1 (<1%)	1 (<1%)	2 (<1%)
ACECLOFENAC	0	1 (<1%)	1 (<1%)
AFLOQUALONE	1 (<1%)	0	1 (<1%)
BACLOFEN	0	1 (<1%)	1 (<1%)
BETAMETHASONE+CYANOCOBALAMIN+DICLOFENAC SODIUM	0	1 (<1%)	1 (<1%)
BIOFENAC (NOS)	1 (<1%)	0	1 (<1%)
BROMELAINS	0	1 (<1%)	1 (<1%)
BROMFENAC SODIUM	0	1 (<1%)	1 (<1%)
BRUFEN (NOS)	0	1 (<1%)	1 (<1%)
CALCIUM CARBONATE+COLECALCIFEROL+RISEDRONATE SODIUM	1 (<1%)	0	1 (<1%)
CARTHAMUS TINCTORIUS+ACONITUM SPP. ROOT TUBER+ACONITUM KUSNEZOFFII ROOT TUBER+PANAX NOTOGINSENG ROOT+DRYNARIA ROOSII RHIZOME+HERBALS NOS+BORNEOL	1 (<1%)	0	1 (<1%)
CHLORZOXAZONE	1 (<1%)	0	1 (<1%)
CHOLIC ACID+HYODEOXYCHOLIC ACID+CONCHA MARGARITIFERA+BAICALIN+BUFFALO HORN+HERBALS NOS	1 (<1%)	0	1 (<1%)
CHONDROITIN SULFATE SODIUM+GLUCOSAMINE SULFATE	1 (<1%)	0	1 (<1%)
CHONDROITIN SULFATE SODIUM+GLUCOSAMINE HYDROCHLORIDE	1 (<1%)	0	1 (<1%)
COLCHIMAX (NOS)	1 (<1%)	0	1 (<1%)
COLLAGEN	0	1 (<1%)	1 (<1%)
CURCUMA LONGA	0	1 (<1%)	1 (<1%)
DENOSUMAB	0	1 (<1%)	1 (<1%)
DEXKETOPROFEN	1 (<1%)	0	1 (<1%)
DICLOFENAC DEANOL	1 (<1%)	0	1 (<1%)
DICLOFENAC+PRIDINOL	0	1 (<1%)	1 (<1%)
DIOSCOREA NIPPONICA	1 (<1%)	0	1 (<1%)

Note: A medication may be included in more than one ATC Level category and appear more than once.
Includes medications started after first dose and before last dose + 28 days.
/mnt/code/postcsr_01/prod/tfls/t_sp_c1_ncopd_on_657.sas 21JUL2025 22:02

Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

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Summary of Non-COPD Medications Started During Treatment in Study 208657

ATC Level 1 Ingredient and Ingredient Combinations	PBO (N=401)	100 SC (N=403)	Total (N=804)
EPERISONE HYDROCHLORIDE	1 (<1%)	0	1 (<1%)
ETODOLAC	0	1 (<1%)	1 (<1%)
FLURBIPROFEN AXETIL	0	1 (<1%)	1 (<1%)
FLURBIPROFEN SODIUM	0	1 (<1%)	1 (<1%)
GLUCOSAMINE SULFATE+MELOXICAM	1 (<1%)	0	1 (<1%)
IBUPROFEN LYSINATE	1 (<1%)	0	1 (<1%)
IMRECOXIB	0	1 (<1%)	1 (<1%)
LIDOCAINE+DICLOFENAC SODIUM	0	1 (<1%)	1 (<1%)
LORNOXICAM	0	1 (<1%)	1 (<1%)
LOXOPROFEN	1 (<1%)	0	1 (<1%)
METHOTREXATE	0	1 (<1%)	1 (<1%)
METHYLSULFONYLMETHANE	0	1 (<1%)	1 (<1%)
NAPROXEN+ESOMEPRAZOLE MAGNESIUM	1 (<1%)	0	1 (<1%)
NIMESULIDE	1 (<1%)	0	1 (<1%)
NSAID'S	0	1 (<1%)	1 (<1%)
PARACETAMOL+CHLORZOXAZONE	1 (<1%)	0	1 (<1%)
PARACETAMOL+DICLOFENAC	1 (<1%)	0	1 (<1%)
PARACETAMOL+DICLOFENAC SODIUM	1 (<1%)	0	1 (<1%)
PARACETAMOL+IBUPROFEN	0	1 (<1%)	1 (<1%)
PARACETAMOL+SERRAPEPTASE+ACECLOFENAC	0	1 (<1%)	1 (<1%)
PIROXICAM	0	1 (<1%)	1 (<1%)
PRIDINOL MESILATE+MELOXICAM	1 (<1%)	0	1 (<1%)
RISEDRONIC ACID	0	1 (<1%)	1 (<1%)
SCUTELLARIA BAICALENSIS ROOT+COW BEZOAR+PEARL+PANAX NOTOGINSENG ROOT+MENTHA CANADENSIS HERB OIL+SWINE BILE+BORNEOL	0	1 (<1%)	1 (<1%)
SCUTELLARIA BAICALENSIS ROOT+LONICERA JAPONICA FLOWER+FORSYTHIA SUSPENSA FRUIT+BEAR BILE+ANIMAL HORN NOS	1 (<1%)	0	1 (<1%)
SOYA OIL+PERSEA AMERICANA OIL	0	1 (<1%)	1 (<1%)
STREPTOKINASE+STREPTODORNASE	1 (<1%)	0	1 (<1%)

Note: A medication may be included in more than one ATC Level category and appear more than once.
Includes medications started after first dose and before last dose + 28 days.
/mnt/code/postcsr_01/prod/tfls/t_sp_c1_ncopd_on_657.sas 21JUL2025 22:02

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Table 111.20

Summary of Non-COPD Medications Started During Treatment in Study 208657

ATC Level 1 Ingredient and Ingredient Combinations	PBO (N=401)	100 SC (N=403)	Total (N=804)
THIOCOLCHICOSIDE	0	1 (<1%)	1 (<1%)
TIZANIDINE HYDROCHLORIDE	1 (<1%)	0	1 (<1%)
TOLFENAMIC ACID	0	1 (<1%)	1 (<1%)
TRIAMCINOLONE HEXACETONIDE+HYALURONATE SODIUM	0	1 (<1%)	1 (<1%)
UFENAMATE	0	1 (<1%)	1 (<1%)
ZINC OXIDE+METHYL SALICYLATE+BEESWAX+COMMIPHORA MYRRHA+MENTHOL+BOSWELLIA SPP.+HERBALS NOS	1 (<1%)	0	1 (<1%)
ZOLEDRONIC ACID	1 (<1%)	0	1 (<1%)
VARIOUS			
Any medication	91 (23%)	100 (25%)	191 (24%)
ACETYLCYSTEINE	40 (10%)	45 (11%)	85 (11%)
POTASSIUM CHLORIDE	19 (5%)	13 (3%)	32 (4%)
OXYGEN	13 (3%)	18 (4%)	31 (4%)
TRADITIONAL CHINESE MEDICINE NOS	15 (4%)	12 (3%)	27 (3%)
CINEOLE+PINENE+DIPENTEN	6 (1%)	6 (1%)	12 (1%)
ASCORBIC ACID	6 (1%)	4 (<1%)	10 (1%)
CYANOCOBALAMIN	3 (<1%)	6 (1%)	9 (1%)
MAGNESIUM SULFATE	7 (2%)	2 (<1%)	9 (1%)
FOLIC ACID	1 (<1%)	4 (<1%)	5 (<1%)
GLUCOSE	4 (<1%)	1 (<1%)	5 (<1%)
GINSENG+SALVIA MILTIORRHIZA+BORNEOL	2 (<1%)	2 (<1%)	4 (<1%)
EPHEDRA SINICA+ARCTIUM LAPPA+SCHISANDRA NOS+OCIMUM BASILICUM+LUMBRICUS TERRESTRIS+PEUCEDANUM (NOS)+HERBALS NOS	2 (<1%)	1 (<1%)	3 (<1%)
GLYCYRRHIZA (NOS)	3 (<1%)	0	3 (<1%)
MEDICATION UNKNOWN	2 (<1%)	1 (<1%)	3 (<1%)
RADIX SCUTELLARIAE+RADIX ISATIDIS+GARDENIA JASMINOIDES+STERCULIAE LYCHNOPHERAE	2 (<1%)	1 (<1%)	3 (<1%)

Note: A medication may be included in more than one ATC Level category and appear more than once.
Includes medications started after first dose and before last dose + 28 days.
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Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Table 111.20

Summary of Non-COPD Medications Started During Treatment in Study 208657

ATC Level 1 Ingredient and Ingredient Combinations	PBO (N=401)	100 SC (N=403)	Total (N=804)
SCUTELLARIA BAICALENSIS+ZINGIBER OFFICINALE+ZIZIPHUS JUJUBA+BUPLEURUM FALCATUM+CODONOPSIS PILOSULA+GLYCYRRHIZA URALENSIS+PINELLIA TERNATA	1 (<1%)	2 (<1%)	3 (<1%)
SODIUM POLYSTYRENE SULFONATE	1 (<1%)	2 (<1%)	3 (<1%)
VITEX AGNUS CASTUS+ISATIS TINCTORIA+LONICERA JAPONICA+CHRYSANTHEMUM (NOS)+EVODIA RUTAECARPA+ILEX NOS	3 (<1%)	0	3 (<1%)
ATRACTYLODES MACROCEPHALA RHIZOME+SAPOSHNIKOVIA DIVARICATA ROOT+ASTRAGALUS MONGHOLICUS ROOT	1 (<1%)	1 (<1%)	2 (<1%)
CALLICARPA NUDIFLORA LEAF	0	2 (<1%)	2 (<1%)
FORSYTHIA SUSPENSA FRUIT+GLYCYRRHIZA SPP. ROOT WITH RHIZOME+EPHEDRA SPP HERB+CALCIUM SULFATE DIHYDRATE+MENTHOL+ISATIS TINCTORIA SUBSP. TINCTORIA ROOT+HERBALS NOS	1 (<1%)	1 (<1%)	2 (<1%)
GINKGO BILOBA EXTRACT	2 (<1%)	0	2 (<1%)
GLYCYRRHIZA SPP. ROOT WITH RHIZOME+ASTER TATARICUS ROOT WITH RHIZOME+EPHEDRA SPP. STEM+HERBALS NOS	1 (<1%)	1 (<1%)	2 (<1%)
GLYCYRRHIZA SPP. ROOT WITH RHIZOME+NEPETA TENUIFOLIA HERB+ASTER TATARICUS+MENTHA CANADENSIS HERB+KITAGAWIA PRAERUPTORA ROOT+CITRUS X AURANTIUM FRUIT PEEL+HERBALS NOS	0	2 (<1%)	2 (<1%)
HERBALS NOS	2 (<1%)	0	2 (<1%)
ISATIS TINCTORIA+PRUNUS ARMENIACA+POGOSTEMON CABLIN+HERBALS NOS+RHUBARB+CALCIUM SULFATE	2 (<1%)	0	2 (<1%)
NARDOSTACHYS JATAMANSI+CODONOPSIS SPP ROOT+PANAX NOTOGINSENG ROOT WITH RHIZOME+AMBER (FOSSILIZED TREE RESIN)+POLYGONATUM SPP. RHIZOME	1 (<1%)	1 (<1%)	2 (<1%)
NUTRITIONAL SUPPLEMENT NOS	0	2 (<1%)	2 (<1%)

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ATC Level 1 Ingredient and Ingredient Combinations	PBO (N=401)	100 SC (N=403)	Total (N=804)
PAEONIA LACTIFLORA ROOT+GLYCYRRHIZA SPP. ROOT WITH RHIZOME+PINELLIA TERNATA TUBER+EPHEDRA SPP. STEM+FRITILLARIA THUNBERGII BULB+PHERETIMA SPP.+HERBALS NOS	1 (<1%)	1 (<1%)	2 (<1%)
SILYBUM MARIANUM	1 (<1%)	1 (<1%)	2 (<1%)
ZINGIBER OFFICINALE+POLYGONUM MULTIFLORUM+GLYCYRRHIZA (NOS)+EPIMEDIUM (NOS)+VITAMIN B NOS	2 (<1%)	0	2 (<1%)
ACHYRANTHES BIDENTATA ROOT+ANGELICA SINENSIS ROOT+SALVIA MILTIORRHIZA ROOT+SENNA OBTUSIFOLIA+ILEX PUBESCENS+PANAX NOTOGINSENG ROOT+HERBALS NOS	1 (<1%)	0	1 (<1%)
ALSTONIA SCHOLARIS LEAF	0	1 (<1%)	1 (<1%)
AMINO ACIDS NOS+POLAPREZINC+MAGNESIUM BETA-HYDROXYBUTYRATE+HERBALS NOS+N-ACETYL GLUCOSAMINE	1 (<1%)	0	1 (<1%)
ANGELICA SINENSIS ROOT+ATRACTYLODES MACROCEPHALA RHIZOME+SCROPHULARIA NINGPOENSIS ROOT+CORYDALIS YANHUSUO TUBER+PANAX NOTOGINSENG ROOT+CHICKEN'S GIZZARD-MEMBRANE+HERBALS NOS	0	1 (<1%)	1 (<1%)
ANGELICA+FORSYTHIA NOS+MENTHA (NOS)+LIGUSTICUM (NOS)+MAGNOLIA NOS+XANTHIUM (NOS)+HERBALS NOS	1 (<1%)	0	1 (<1%)
ANGELICA+GLYCYRRHIZA (NOS)+ASTRAGALUS NOS+LONICERA SPP+CODONOPSIS SPP+SCROPHULARIA (NOS)+HERBALS NOS	0	1 (<1%)	1 (<1%)
ARECA CATECHU+CYPERUS ROTUNDUS+CHICKEN'S GIZZARD-MEMBRANE+HERBALS NOS	0	1 (<1%)	1 (<1%)
ARTEMISIA ARGYI	1 (<1%)	0	1 (<1%)
ASARONE	1 (<1%)	0	1 (<1%)
AZVUDINE	0	1 (<1%)	1 (<1%)

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BACILLUS CALMETTE GUERIN PURIFIED PROTEIN DERIVATIVE	1 (<1%)	0	1 (<1%)
BAMBUSA TULDOIDES	0	1 (<1%)	1 (<1%)
BICYCLOL	1 (<1%)	0	1 (<1%)
CALCIUM CARBONATE	1 (<1%)	0	1 (<1%)
CALCIUM CARBONATE+ANGELICA SINENSIS ROOT+SALVIA MILTIORRHIZA ROOT WITH RHIZOME+EPIMEDIUM SPP LEAF+CODONOPSIS SPP ROOT+ASTRAGALUS MONGHOLICUS ROOT+HERBALS NOS	0	1 (<1%)	1 (<1%)
CALCIUM CARBONATE+ZINGIBER OFFICINALE SUBTERRANEOUS ROOT STOCK+PAEONIA LACTIFLORA ROOT+CINNAMOMUM CASSIA TWIG+ZIZIPHUS JUJUBA FRUIT+FOSSILIA OSSIS MASTODI+HERBALS NOS	1 (<1%)	0	1 (<1%)
CALCIUM POLYSTYRENE SULFONATE	0	1 (<1%)	1 (<1%)
CALCIUM SULFATE DIHYDRATE+HERBALS NOS	1 (<1%)	0	1 (<1%)
CANNABIDIOL	0	1 (<1%)	1 (<1%)
CARRAGEENAN	0	1 (<1%)	1 (<1%)
CARTHAMUS TINCTORIUS FLOWER+ACHYRANTHES BIDENTATA ROOT+GLYCYRRHIZA SPP. ROOT WITH RHIZOME+ANGELICA SINENSIS ROOT+ASTRAGALUS MONGHOLICUS ROOT+CITRUS X AURANTIUM UNRIPE FRUIT+HERBALS NOS	1 (<1%)	0	1 (<1%)
CARTHAMUS TINCTORIUS+ACONITUM SPP. ROOT TUBER+ACONITUM KUSNEZOFFII ROOT TUBER+PANAX NOTOGINSENG ROOT+DRYNARIA ROOSII RHIZOME+HERBALS NOS+BORNEOL	1 (<1%)	0	1 (<1%)
CARTHAMUS TINCTORIUS+ANGELICA+SALVIA (NOS)+PAEONIA (NOS)+LIGUSTICUM CHUANXIANG	1 (<1%)	0	1 (<1%)
CARTHAMUS TINCTORIUS+REHMANNIAE RADIX+ARCTIUM LAPPA+ISATIS TINCTORIA+LONICERA JAPONICA+SCROPHULARIA (NOS)+HERBALS NOS	1 (<1%)	0	1 (<1%)

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CARTHAMUS TINCTORIUS+REHMANNIAE RADIX+GLYCYRRHIZA (NOS)+PLATYCODON NOS+PRUNUS PERSICA+PAEONIAE ALBA+HERBALS NOS	0	1 (<1%)	1 (<1%)
CETRARIA ISLANDICA	0	1 (<1%)	1 (<1%)
CHOLIC ACID+HYODEOXYCHOLIC ACID+CONCHA MARGARITIFERA+BAICALIN+BUFFALO HORN+HERBALS NOS	1 (<1%)	0	1 (<1%)
CINNAMOMUM VERUM+CORNUS OFFICINALIS+ALISMATIS RHIZOMA+PAEONIA SUFFRUTICOSA+DIOSCOREA NOS+HERBALS NOS	1 (<1%)	0	1 (<1%)
CITRUS AURANTIUM+MAGNOLIA OFFICINALIS BARK+AUCKLANDIA COSTUS ROOT+RHUBARB	0	1 (<1%)	1 (<1%)
COLECALCIFEROL+MAGNESIUM GLYCINATE+BORON GLYCINATE+VACCINIUM SPP.+ZINC AMINO ACID CHELATE	1 (<1%)	0	1 (<1%)
COLLAGEN	0	1 (<1%)	1 (<1%)
CORDYCEPS SINENSIS+PSORALEN+ASTRAGALUS NOS+PAEONIA (NOS)+HERBALS NOS	1 (<1%)	0	1 (<1%)
CORNUS OFFICINALIS+PORIA COCOS+REHMANNIA GLUTINOSA+PAEONIA SUFFRUTICOSA+DIOSCOREA OPPOSITIFOLIA+ALISMA ORIENTALIS	1 (<1%)	0	1 (<1%)
CORYDALIS (NOS)	0	1 (<1%)	1 (<1%)
CURCUMA LONGA	0	1 (<1%)	1 (<1%)
DIOSCOREA NIPPONICA	1 (<1%)	0	1 (<1%)
DRACAENA COCHINCHINENSIS RESIN	1 (<1%)	0	1 (<1%)
EPHEDRINE HYDROCHLORIDE+LONICERA JAPONICA FLOWER+BAICALIN+MAGNOLIA SPP. FLOWER BUD+BORNEOL	1 (<1%)	0	1 (<1%)
ETHANOL	1 (<1%)	0	1 (<1%)
FLUDEOXYGLUCOSE (18F)	1 (<1%)	0	1 (<1%)
FOLIC ACID+CYANOCOBALAMIN+PYRIDOXINE HYDROCHLORIDE+CHROMIUM PICOLINATE+GYMNEMA SYLVESTRE EXTRACT+VITAMIN E SUBSTANCES+MORUS ALBA EXTRACT	0	1 (<1%)	1 (<1%)

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FORSYTHIA NOS	0	1 (<1%)	1 (<1%)
FORSYTHIA SUSPENSA FRUIT+LONICERA SPP. FLOWER BUD+CHRYSANTHEMUM INDICUM FLOWER HEAD+ARTEMISIA ANNUA HERB+KITAGAWIA PRAERUPTORA ROOT+ISATIS TINCTORIA SUBSP. TINCTORIA LEAF+HERBALS NOS	1 (<1%)	0	1 (<1%)
FORSYTHIA SUSPENSA FRUIT+PRUNUS SPP SEED+MORUS ALBA+MENTHA CANADENSIS HERB+ARCTIUM LAPPA FRUIT+ARTEMISIA ANNUA HERB+HERBALS NOS	1 (<1%)	0	1 (<1%)
FORSYTHIA SUSPENSA FRUIT+TRICHOSANTHES NOS+COPTIS SPP RHIZOME+CALCIUM SULFATE DIHYDRATE+PAEONIA SPP ROOT+GARDENIA JASMINOIDES FRUIT+HERBALS NOS	1 (<1%)	0	1 (<1%)
GADOTERIDOL	0	1 (<1%)	1 (<1%)
GANODERMA LUCIDUM	0	1 (<1%)	1 (<1%)
GINKGO BILOBA LEAF EXTRACT	0	1 (<1%)	1 (<1%)
GINSENG+CINNAMOMUM CASSIA+COW BEZOAR+BUFONIS VENENUM+LIQUIDAMBAR ORIENTALIS+MUSK+BORNEOL	0	1 (<1%)	1 (<1%)
GINSENG+CINNAMOMUM CASSIA+COW BEZOAR+BUFONIS VENENUM+MOSCHUS NOS+STYRAX LIQUID+BORNEOL	1 (<1%)	0	1 (<1%)
GINSENG+SALVIA MILTIORRHIZA	0	1 (<1%)	1 (<1%)
GLUCOSE+WATER	0	1 (<1%)	1 (<1%)
GLYCYRRHIZA GLABRA+BUPLEURUM FALCATUM+PAEONIA (NOS)+PHELLODENDRON (NOS)+ACHYRANTHES NOS+SPARGANIUM (NOS)+HERBALS NOS	0	1 (<1%)	1 (<1%)
GLYCYRRHIZA GLABRA+ZIZIPHUS SPINOSA	0	1 (<1%)	1 (<1%)
GLYCYRRHIZA SPP. ROOT WITH RHIZOME+COW BEZOAR+TERMINALIA CHEBULA FRUIT+MENTHOL+INDIGO+BORNEOL	1 (<1%)	0	1 (<1%)

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GLYCYRRHIZA SPP. ROOT WITH RHIZOME+MENTHA CANADENSIS HERB+PAPAVER SOMNIFERUM PERICARP+ZIZIPHUS JUJUBA FRUIT+RHEUM SPP. ROOT WITH RHIZOME+HERBALS NOS	1 (<1%)	0	1 (<1%)
GLYCYRRHIZA SPP. ROOT WITH RHIZOME+PERILLA FRUTESCENS+PINELLIA TERNATA TUBER+EPHEDRA SPP HERB+KITAGAWIA PRAERUPTORA ROOT+CITRUS X AURANTIUM+HERBALS NOS	1 (<1%)	0	1 (<1%)
GLYCYRRHIZIC ACID, AMMONIUM SALT+GLYCINE+DL-METHIONINE	1 (<1%)	0	1 (<1%)
HEDERA HELIX	0	1 (<1%)	1 (<1%)
HEDERA HELIX EXTRACT	1 (<1%)	0	1 (<1%)
HONEY+PLANTAGO LANCEOLATA+HELICHRYSUM (NOS)+GRINDELIA (NOS)	1 (<1%)	0	1 (<1%)
HORDEUM DISTYCHUM+ASTRAGALUS NOS+CODONOPSIS SPP+CITRUS RETICULATA	1 (<1%)	0	1 (<1%)
HYPROMELLOSE	0	1 (<1%)	1 (<1%)
INDOMETACIN+COW BEZOAR+PEARL+PORCINE BILE+CORNU BUBALI+HERBALS NOS	0	1 (<1%)	1 (<1%)
INOSITOL+PANAX GINSENG ROOT+GINKGO BILOBA LEAF+PAULLINIA CUPANA+MINERALS NOS+VITAMINS NOS	1 (<1%)	0	1 (<1%)
IODINE (131 I)	0	1 (<1%)	1 (<1%)
IODIXANOL	1 (<1%)	0	1 (<1%)
IOHEXOL	1 (<1%)	0	1 (<1%)
IOPAMIDOL	0	1 (<1%)	1 (<1%)
IRON SUCROSE	1 (<1%)	0	1 (<1%)
ISATIS TINCTORIA ROOT+FORSYTHIA SUSPENSA FRUIT+ANEMARRHENA ASPHODELOIDES RHIZOME+CURCUMA SPP. ROOT TUBER+CALCIUM SULFATE DIHYDRATE+ACORUS CALAMUS VAR. ANGUSTATUS RHIZOME+HERBALS NOS	0	1 (<1%)	1 (<1%)

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ISATIS TINCTORIA+LONICERA JAPONICA+FORSYTHIA NOS+PRUNUS ARMENIACA+HERBALS NOS+RHUBARB+CALCIUM SULFATE	0	1 (<1%)	1 (<1%)
LEVOMENTHOL+MENTHA PIPERITA OIL+CITRULLUS LANATUS+BORNEOL	0	1 (<1%)	1 (<1%)
LONICERA JAPONICA FLOWER BUD+PRUNUS SPP SEED+SCROPHULARIA NINGPOENSIS ROOT+CURCUMA SPP RHIZOME+CHICKEN'S GIZZARD-MEMBRANE+CICADA SLOUGH+HERBALS NOS	0	1 (<1%)	1 (<1%)
LONICERA JAPONICA+GLYCYRRHIZA (NOS)+OPHIOPOGON JAPONICUS+ASPARAGUS COCHINCHINENSIS+SCROPHULARIA NINGPOENSIS	0	1 (<1%)	1 (<1%)
LONICERA SPP	0	1 (<1%)	1 (<1%)
LYSIMACHIA CHRISTINIAE WHOLE PLANT+CHRYSANTHEMUM INDICUM FLOWER HEAD+UNCARIA SPP. HOOK+CLEMATIS SPP. STEM	1 (<1%)	0	1 (<1%)
MAGNESIUM ISOGLYCYRRHIZINATE	1 (<1%)	0	1 (<1%)
MEDICAL DEVICES NOS	1 (<1%)	0	1 (<1%)
METHYLSULFONYLMETHANE	0	1 (<1%)	1 (<1%)
METHYLTHIONINIUM CHLORIDE	1 (<1%)	0	1 (<1%)
METRONIDAZOLE+COW BEZOAR	0	1 (<1%)	1 (<1%)
MONASCUS PURPUREUS	1 (<1%)	0	1 (<1%)
MONASCUS PURPUREUS+ATRACTYLODES MACROCEPHALA+ALISMA PLANTAGO-AQUATICA+CRATAEGUS PINNATIFIDA	1 (<1%)	0	1 (<1%)
PAEONIA LACTIFLORA+ASTRAGALUS NOS+PSORALEA CORYLIFOLIA	0	1 (<1%)	1 (<1%)
PAEONIAE ALBA+OPHIOPOGON (NOS)+CORYDALIS (NOS)+PANAX QUINQUEFOLIUM+DENDROBIUM NOS+LILIUM BROWNII+HERBALS NOS	0	1 (<1%)	1 (<1%)

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PANAX GINSENG EXTRACT+CINNAMOMUM CASSIA+COW BEZOAR+BUFONIS VENENUM+MOSCHUS NOS+LIQUIDAMBAR ORIENTALIS+BORNEOL	0	1 (<1%)	1 (<1%)
PANAX GINSENG ROOT WITH RHIZOME+OPHIOPOGON JAPONICUS ROOT TUBER+SCHISANDRA CHINENSIS FRUIT	1 (<1%)	0	1 (<1%)
PARIS POLYPHYLLA+EUPHORBIA HUMIFUSA+TOAD SKIN+CHILOPODA (NOS)	0	1 (<1%)	1 (<1%)
PERIPLANETA AMERICANA	0	1 (<1%)	1 (<1%)
PERIPLANETA AMERICANA EXTRACT	1 (<1%)	0	1 (<1%)
PLANTAGO OVATA	0	1 (<1%)	1 (<1%)
PORIA COCOS SCLEROTIUM+PAEONIA LACTIFLORA ROOT+BUPLEURUM SPP ROOT+GLYCYRRHIZA SPP. ROOT WITH RHIZOME+ANGELICA SINENSIS ROOT+ATRACTYLODES MACROCEPHALA RHIZOME+MENTHA CANADENSIS HERB	0	1 (<1%)	1 (<1%)
PORIA COCOS SCLEROTIUM+PAEONIA LACTIFLORA ROOT+SALVIA MILTIORRHIZA ROOT WITH RHIZOME+MORUS ALBA ROOT BARK+ASTRAGALUS MONGHOLICUS ROOT+HERBALS NOS	0	1 (<1%)	1 (<1%)
PORIA COCOS+GLYCYRRHIZA (NOS)+CHRYSANTHEMUM (NOS)+RHIZOMA PINELLIAE+HERBALS NOS+RHEUM OFFICINALE	0	1 (<1%)	1 (<1%)
PORIA COCOS+GLYCYRRHIZA SPP. ROOT WITH RHIZOME+ANEMARRHENA ASPHODELOIDES+MORUS ALBA ROOT BARK+GEKKO GECKO+HERBALS NOS	1 (<1%)	0	1 (<1%)
PORIA COCOS+REHMANNIA GLUTINOSA+PAEONIA SUFFRUTICOSA+DIOSCOREA OPPOSITIFOLIA+ANEMARRHENA ASPHODELOIDES+PHELLODENDRON CHINENSE+HERBALS NOS	1 (<1%)	0	1 (<1%)
POTASSIUM ASPARTATE	1 (<1%)	0	1 (<1%)
RADIOTHERAPY	1 (<1%)	0	1 (<1%)

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REHMANNIAE RADIX+POGOSTEMON CABLIN OIL+FORSYTHIA NOS+ANEMARRHENA ASPHODELOIDES+RHIZOMA PHRAGMITIS+CALCIUM SULFATE+RHIZOMA CURCUMAE	1 (<1%)	0	1 (<1%)
SALVIA MILTIORRHIZA+SCHISANDRA CHINENSIS+ZIZIPHUS SPINOSA	0	1 (<1%)	1 (<1%)
SCUTELLARIA BAICALENSIS ROOT+COW BEZOAR+PEARL+PANAX NOTOGINSENG ROOT+MENTHA CANADENSIS HERB OIL+SWINE BILE+BORNEOL	0	1 (<1%)	1 (<1%)
SCUTELLARIA BAICALENSIS ROOT+ISATIS TINCTORIA ROOT+PHELLODENDRON CHINENSE BARK+GARDENIA JASMINOIDES FRUIT+SCAPHIUM AFFINE SEED	1 (<1%)	0	1 (<1%)
SCUTELLARIA BAICALENSIS ROOT+LONICERA JAPONICA FLOWER+FORSYTHIA SUSPENSA FRUIT+BEAR BILE+ANIMAL HORN NOS	1 (<1%)	0	1 (<1%)
SCUTELLARIA BAICALENSIS ROOT+PRUNUS SPP SEED+SCHISANDRA CHINENSIS FRUIT+MORUS ALBA ROOT BARK+EPHEDRA SPP HERB+CALCIUM SULFATE DIHYDRATE+HERBALS NOS	1 (<1%)	0	1 (<1%)
SENECIO CANNABIFOLIUS	1 (<1%)	0	1 (<1%)
SILYBUM MARIANUM FRUIT+SCHISANDRA CHINENSIS FRUIT	0	1 (<1%)	1 (<1%)
SOPHORA TONKINENSIS ROOT WITH RHIZOME+ARDISIA CRISPA LEAF+ARDISIA CRISPA ROOT+MENTHOL+CICADA SLOUGH	1 (<1%)	0	1 (<1%)
SPLEEN EXTRACT, PROTEINFREE	0	1 (<1%)	1 (<1%)
TAMSULOSIN HYDROCHLORIDE+DUTASTERIDE	0	1 (<1%)	1 (<1%)
THESIUM CHINENSE	0	1 (<1%)	1 (<1%)
TUSSILAGO FARFARA+FRITILLARIA SPP+LILIUM NOS+PYRUS (NOS)+HERBALS NOS	0	1 (<1%)	1 (<1%)
URGINEA MARITIMA+CAPSICUM ANNUUM	1 (<1%)	0	1 (<1%)
VERONICA LINARIIFOLIA SUBSP. DILATATA	0	1 (<1%)	1 (<1%)

Note: A medication may be included in more than one ATC Level category and appear more than once.
Includes medications started after first dose and before last dose + 28 days.
/mnt/code/postcsr_01/prod/tfls/t_sp_c1_ncopd_on_657.sas 21JUL2025 22:02

Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Table 111.20

Summary of Non-COPD Medications Started During Treatment in Study 208657

ATC Level 1 Ingredient and Ingredient Combinations	PBO (N=401)	100 SC (N=403)	Total (N=804)
VIGNA UNGUICULATA	0	1 (<1%)	1 (<1%)
VITIS VINIFERA EXTRACT	1 (<1%)	0	1 (<1%)
ZEA MAYS+PLANTAGO MAJOR+GRONA STYRACIFOLIA HERB+PYRROSIA LINGUA LEAF	0	1 (<1%)	1 (<1%)
ZINGIBER OFFICINALE RHIZOME+GLYCYRRHIZA SPP. ROOT WITH RHIZOME+ATRACTYLODES MACROCEPHALA RHIZOME+CODONOPSIS SPP ROOT	0	1 (<1%)	1 (<1%)
ZINGIBER OFFICINALE RHIZOME+PLATYCODON GRANDIFLORUS ROOT+HOUTTUYNIA CORDATA+PINELLIA TERNATA TUBER+MENTHA CANADENSIS OIL+PHYLLOSTACHYS SPP. STALK JUICE+RHAPHIOLEPIS BIBAS LEAF	1 (<1%)	0	1 (<1%)
BLOOD AND BLOOD FORMING ORGANS			
Any medication	87 (22%)	81 (20%)	168 (21%)
ACETYLSALICYLIC ACID	22 (5%)	12 (3%)	34 (4%)
POTASSIUM CHLORIDE	19 (5%)	13 (3%)	32 (4%)
SODIUM CHLORIDE	14 (3%)	17 (4%)	31 (4%)
ENOXAPARIN SODIUM	12 (3%)	7 (2%)	19 (2%)
RIVAROXABAN	7 (2%)	5 (1%)	12 (1%)
CLOPIDOGREL	9 (2%)	2 (<1%)	11 (1%)
CLOPIDOGREL BISULFATE	5 (1%)	6 (1%)	11 (1%)
APIXABAN	5 (1%)	5 (1%)	10 (1%)
ENOXAPARIN	8 (2%)	2 (<1%)	10 (1%)
CYANOCOBALAMIN	3 (<1%)	6 (1%)	9 (1%)
MAGNESIUM SULFATE	7 (2%)	2 (<1%)	9 (1%)
EPINEPHRINE	3 (<1%)	3 (<1%)	6 (<1%)
HEPARIN (NOS)	3 (<1%)	3 (<1%)	6 (<1%)
DALTEPARIN SODIUM	3 (<1%)	2 (<1%)	5 (<1%)
FOLIC ACID	1 (<1%)	4 (<1%)	5 (<1%)
GLUCOSE	4 (<1%)	1 (<1%)	5 (<1%)

Note: A medication may be included in more than one ATC Level category and appear more than once.
Includes medications started after first dose and before last dose + 28 days.
/mnt/code/postcsr_01/prod/tfls/t_sp_c1_ncopd_on_657.sas 21JUL2025 22:02

Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Table 111.20

Summary of Non-COPD Medications Started During Treatment in Study 208657

ATC Level 1 Ingredient and Ingredient Combinations	PBO (N=401)	100 SC (N=403)	Total (N=804)
AMINO ACIDS NOS	1 (<1%)	3 (<1%)	4 (<1%)
CILOSTAZOL	2 (<1%)	2 (<1%)	4 (<1%)
GLYCEROL	1 (<1%)	3 (<1%)	4 (<1%)
MECOBALAMIN	1 (<1%)	3 (<1%)	4 (<1%)
POTASSIUM CHLORIDE+SODIUM CHLORIDE+CALCIUM CHLORIDE+SODIUM LACTATE	3 (<1%)	1 (<1%)	4 (<1%)
CHLORHEXIDINE GLUCONATE	1 (<1%)	2 (<1%)	3 (<1%)
HEPARIN SODIUM	2 (<1%)	1 (<1%)	3 (<1%)
NADROPARIN	2 (<1%)	1 (<1%)	3 (<1%)
NADROPARIN CALCIUM	1 (<1%)	2 (<1%)	3 (<1%)
RED BLOOD CELLS, CONCENTRATED	1 (<1%)	2 (<1%)	3 (<1%)
SODIUM BICARBONATE	1 (<1%)	2 (<1%)	3 (<1%)
SODIUM CHLORIDE+GLUCOSE	1 (<1%)	2 (<1%)	3 (<1%)
TICAGRELOR	3 (<1%)	0	3 (<1%)
TRANEXAMIC ACID	0	3 (<1%)	3 (<1%)
ACETYLSALICYLATE LYSINE	2 (<1%)	0	2 (<1%)
CALLICARPA NUDIFLORA LEAF	0	2 (<1%)	2 (<1%)
CHYMOTRYPSIN	1 (<1%)	1 (<1%)	2 (<1%)
FERROUS GLYCINE SULFATE	2 (<1%)	0	2 (<1%)
GLUCOSE+ELECTROLYTES NOS	2 (<1%)	0	2 (<1%)
POTASSIUM	0	2 (<1%)	2 (<1%)
POTASSIUM ASPARTATE+MAGNESIUM ASPARTATE	2 (<1%)	0	2 (<1%)
POTASSIUM CHLORIDE+SODIUM CHLORIDE+CALCIUM CHLORIDE	1 (<1%)	1 (<1%)	2 (<1%)
RINGER LACTATE (NOS)	1 (<1%)	1 (<1%)	2 (<1%)
SALVIA MILTIORRHIZA	1 (<1%)	1 (<1%)	2 (<1%)
WARFARIN SODIUM	0	2 (<1%)	2 (<1%)
ALBUMIN NORMAL HUMAN SERUM	0	1 (<1%)	1 (<1%)
ARGININE+TRYPTOPHAN, L-+BETAINE+GLYCINE+HISTIDINE+SERINE+CYSTEINE HYDROCHLORIDE	0	1 (<1%)	1 (<1%)

Note: A medication may be included in more than one ATC Level category and appear more than once.
Includes medications started after first dose and before last dose + 28 days.
/mnt/code/postcsr_01/prod/tfls/t_sp_c1_ncopd_on_657.sas 21JUL2025 22:02

Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Table 111.20

Summary of Non-COPD Medications Started During Treatment in Study 208657

ATC Level 1 Ingredient and Ingredient Combinations	PBO (N=401)	100 SC (N=403)	Total (N=804)
BEMIPARIN	0	1 (<1%)	1 (<1%)
BROMELAINS	0	1 (<1%)	1 (<1%)
CALCIUM CHLORIDE	0	1 (<1%)	1 (<1%)
CALCIUM CHLORIDE+GLYCINE+ALANINE	0	1 (<1%)	1 (<1%)
CERTOPARIN SODIUM	1 (<1%)	0	1 (<1%)
CETYLPYRIDINIUM CHLORIDE	0	1 (<1%)	1 (<1%)
CHLORHEXIDINE	0	1 (<1%)	1 (<1%)
COLLAGEN	0	1 (<1%)	1 (<1%)
DABIGATRAN ETEXILATE MESILATE	1 (<1%)	0	1 (<1%)
DRACAENA COCHINCHINENSIS RESIN	1 (<1%)	0	1 (<1%)
EDOXABAN TOSILATE	1 (<1%)	0	1 (<1%)
EPINEPHRINE HYDROCHLORIDE	1 (<1%)	0	1 (<1%)
ETAMSYLATE	0	1 (<1%)	1 (<1%)
FAT EMULSIONS	0	1 (<1%)	1 (<1%)
FERROUS FUMARATE	1 (<1%)	0	1 (<1%)
FERROUS SULPHATE	1 (<1%)	0	1 (<1%)
FERROUS SULPHATE+FOLIC ACID	0	1 (<1%)	1 (<1%)
FOLIC ACID+IRON POLYMALTOSE	0	1 (<1%)	1 (<1%)
FONDAPARINUX	1 (<1%)	0	1 (<1%)
FONDAPARINUX SODIUM	0	1 (<1%)	1 (<1%)
GLUCOSE+FAT EMULSIONS+AMINO ACIDS NOS	0	1 (<1%)	1 (<1%)
GLUCOSE+WATER	0	1 (<1%)	1 (<1%)
HEPARIN-FRACTION, SODIUM SALT	0	1 (<1%)	1 (<1%)
INTRAVENOUS FLUID (NOS)	1 (<1%)	0	1 (<1%)
IRON	0	1 (<1%)	1 (<1%)
IRON BISGLYCINATE	0	1 (<1%)	1 (<1%)
IRON POLYMALTOSE	0	1 (<1%)	1 (<1%)
IRON SUCROSE	1 (<1%)	0	1 (<1%)
LOW MOLECULAR WEIGHT HEPARIN	1 (<1%)	0	1 (<1%)
NITROFURAZONE	0	1 (<1%)	1 (<1%)
OXYPOLYGELATIN	1 (<1%)	0	1 (<1%)

Note: A medication may be included in more than one ATC Level category and appear more than once.
Includes medications started after first dose and before last dose + 28 days.
/mnt/code/postcsr_01/prod/tfls/t_sp_c1_ncopd_on_657.sas 21JUL2025 22:02

Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Table 111.20

Summary of Non-COPD Medications Started During Treatment in Study 208657

ATC Level 1 Ingredient and Ingredient Combinations	PBO (N=401)	100 SC (N=403)	Total (N=804)
PHENPROCOUMON	0	1 (<1%)	1 (<1%)
PHOSPHOLIPIDS (NOS)	1 (<1%)	0	1 (<1%)
PHYTOMENADIONE	1 (<1%)	0	1 (<1%)
POTASSIUM CHLORIDE+SODIUM CHLORIDE+GLUCONATE SODIUM+MAGNESIUM CHLORIDE+SODIUM ACETATE TRIHYDRATE	0	1 (<1%)	1 (<1%)
POTASSIUM CHLORIDE+SODIUM CHLORIDE+SODIUM ACETATE+GLUCONATE SODIUM+MAGNESIUM CHLORIDE	0	1 (<1%)	1 (<1%)
POTASSIUM CHLORIDE+SODIUM CHLORIDE+SODIUM ACETATE+CALCIUM CHLORIDE+SODIUM CITRATE+MAGNESIUM CHLORIDE	1 (<1%)	0	1 (<1%)
PRASUGREL	1 (<1%)	0	1 (<1%)
REHYDRATION FLUID (NOS)	1 (<1%)	0	1 (<1%)
SARPOGRELATE HYDROCHLORIDE	1 (<1%)	0	1 (<1%)
SODIUM CHLORIDE+SODIUM ACETATE+CALCIUM CHLORIDE+GLUCONATE SODIUM+MAGNESIUM CHLORIDE	0	1 (<1%)	1 (<1%)
SOYA OIL+MEDIUM CHAIN TRIGLYCERIDES+OMEGA-3 TRIGLYCERIDES	0	1 (<1%)	1 (<1%)
STREPTOKINASE+STREPTODORNASE	1 (<1%)	0	1 (<1%)
SULODEXIDE	1 (<1%)	0	1 (<1%)
TINZAPARIN	1 (<1%)	0	1 (<1%)
TIROFIBAN HYDROCHLORIDE	1 (<1%)	0	1 (<1%)
TRYPSIN	1 (<1%)	0	1 (<1%)
UREA	0	1 (<1%)	1 (<1%)
UROKINASE	0	1 (<1%)	1 (<1%)
WARFARIN	1 (<1%)	0	1 (<1%)
ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS			
Any medication	11 (3%)	7 (2%)	18 (2%)
CELECOXIB	5 (1%)	4 (<1%)	9 (1%)
PACLITAXEL	1 (<1%)	1 (<1%)	2 (<1%)

Note: A medication may be included in more than one ATC Level category and appear more than once.
Includes medications started after first dose and before last dose + 28 days.
/mnt/code/postcsr_01/prod/tfls/t_sp_c1_ncopd_on_657.sas 21JUL2025 22:02

Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Table 111.20

Summary of Non-COPD Medications Started During Treatment in Study 208657

ATC Level 1 Ingredient and Ingredient Combinations	PBO (N=401)	100 SC (N=403)	Total (N=804)
PEMBROLIZUMAB	2 (<1%)	0	2 (<1%)
AFLIBERCEPT	1 (<1%)	0	1 (<1%)
BEVACIZUMAB	1 (<1%)	0	1 (<1%)
BICALUTAMIDE	1 (<1%)	0	1 (<1%)
CARBOPLATIN	1 (<1%)	0	1 (<1%)
CYCLOPHOSPHAMIDE	0	1 (<1%)	1 (<1%)
EPIRUBICIN	0	1 (<1%)	1 (<1%)
INTERFERON ALFA-1B	0	1 (<1%)	1 (<1%)
LETROZOLE	1 (<1%)	0	1 (<1%)
LEUPRORELIN ACETATE	1 (<1%)	0	1 (<1%)
METHOTREXATE	0	1 (<1%)	1 (<1%)
PANAX GINSENG ROOT WITH RHIZOME+OPHIOPOGON JAPONICUS ROOT TUBER+SCHISANDRA CHINENSIS FRUIT	1 (<1%)	0	1 (<1%)
PEGFILGRASTIM	1 (<1%)	0	1 (<1%)
PIDOTIMOD	0	1 (<1%)	1 (<1%)
PIRARUBICIN HYDROCHLORIDE	0	1 (<1%)	1 (<1%)
TRASTUZUMAB	0	1 (<1%)	1 (<1%)
ANTIPARASITIC PRODUCTS, INSECTICIDES AND REPELLENTS			
Any medication	11 (3%)	5 (1%)	16 (2%)
METRONIDAZOLE	7 (2%)	2 (<1%)	9 (1%)
IVERMECTIN	2 (<1%)	0	2 (<1%)
CROTAMITON	0	1 (<1%)	1 (<1%)
MEBENDAZOLE	1 (<1%)	0	1 (<1%)
NITROFURAZONE	0	1 (<1%)	1 (<1%)
ORNIDAZOLE	0	1 (<1%)	1 (<1%)
PARIS POLYPHYLLA+EUPHORBIA HUMIFUSA+TOAD SKIN+CHILOPODA (NOS)	0	1 (<1%)	1 (<1%)
PIPERAZINE FERULATE	1 (<1%)	0	1 (<1%)

Note: A medication may be included in more than one ATC Level category and appear more than once.
Includes medications started after first dose and before last dose + 28 days.

Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Table 111.20

Summary of Non-COPD Medications Started During Treatment in Study 208657

ATC Level 1 Ingredient and Ingredient Combinations	PBO (N=401)	100 SC (N=403)	Total (N=804)
PHARMACOLOGICAL PROPERTIES CANNOT BE REFERENCED			
Any medication	4 (<1%)	5 (1%)	9 (1%)
UNCODED	4 (<1%)	5 (1%)	9 (1%)

Note: A medication may be included in more than one ATC Level category and appear more than once.
Includes medications started after first dose and before last dose + 28 days.
/mnt/code/postcsr_01/prod/tfls/t_sp_c1_ncopd_on_657.sas 21JUL2025 22:02

Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Table 111.21

Summary of Non-COPD Medications Started During Treatment in Study MEA117113

ATC Level 1 Ingredient and Ingredient Combinations	PBO (N=87)	100 SC (N=83)	Total (N=170)
Any medication	62 (71%)	68 (82%)	130 (76%)
ANTIINFECTIVES FOR SYSTEMIC USE			
Any medication	38 (44%)	41 (49%)	79 (46%)
LEVOFLOXACIN	8 (9%)	6 (7%)	14 (8%)
INFLUENZA VACCINE	6 (7%)	7 (8%)	13 (8%)
INFLUENZA VIRUS VACCINE INACTIVATED	5 (6%)	6 (7%)	11 (6%)
AMOXICILLIN	4 (5%)	6 (7%)	10 (6%)
AMOXICILLIN+CLAVULANATE POTASSIUM	6 (7%)	2 (2%)	8 (5%)
AMOXICILLIN+CLAVULANIC ACID	3 (3%)	4 (5%)	7 (4%)
CEFTRIAXONE	1 (1%)	3 (4%)	4 (2%)
CIPROFLOXACIN	2 (2%)	2 (2%)	4 (2%)
CLARITHROMYCIN	1 (1%)	3 (4%)	4 (2%)
NITROFURANTOIN	2 (2%)	2 (2%)	4 (2%)
CEFALEXIN	1 (1%)	2 (2%)	3 (2%)
CEFDITOREN PIVOXIL	2 (2%)	1 (1%)	3 (2%)
DOXYCYCLINE	2 (2%)	1 (1%)	3 (2%)
FLUCONAZOLE	3 (3%)	0	3 (2%)
ROXITHROMYCIN	1 (1%)	2 (2%)	3 (2%)
SULFAMETHOXAZOLE+TRIMETHOPRIM	1 (1%)	2 (2%)	3 (2%)
ACYCLOVIR	1 (1%)	1 (1%)	2 (1%)
CEFDINIR	0	2 (2%)	2 (1%)
CEFTIBUTEN	2 (2%)	0	2 (1%)
CLINDAMYCIN	1 (1%)	1 (1%)	2 (1%)
FOSFOMYCIN TROMETAMOL	1 (1%)	1 (1%)	2 (1%)
GENTAMICIN	2 (2%)	0	2 (1%)
NORFLOXACIN	2 (2%)	0	2 (1%)
OMNICEF (NOS)	1 (1%)	1 (1%)	2 (1%)
AMPICILLIN	0	1 (1%)	1 (<1%)
AZITHROMYCIN	0	1 (1%)	1 (<1%)
BENZYLPENICILLIN	0	1 (1%)	1 (<1%)

Note: A medication may be included in more than one ATC Level category and appear more than once.
Includes medications started after first dose and before last dose + 28 days.
/mnt/code/postcsr_01/prod/tfls/t_sp_cm_ncopd_on_113.sas 21JUL2025 22:02

Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Table 111.21

Summary of Non-COPD Medications Started During Treatment in Study MEA117113

ATC Level 1 Ingredient and Ingredient Combinations	PBO (N=87)	100 SC (N=83)	Total (N=170)
CEFACLOR	0	1 (1%)	1 (<1%)
CEFALEXIN SODIUM	0	1 (1%)	1 (<1%)
CEFCAPENE PIVOXIL HYDROCHLORIDE	0	1 (1%)	1 (<1%)
CEFEPIME HYDROCHLORIDE	1 (1%)	0	1 (<1%)
CEFIX (NOS)	1 (1%)	0	1 (<1%)
CEFOTETAN DISODIUM	1 (1%)	0	1 (<1%)
CEFRADINE	0	1 (1%)	1 (<1%)
CEFTRIAXONE SODIUM	1 (1%)	0	1 (<1%)
CEFUROXIME	0	1 (1%)	1 (<1%)
CEFUROXIME AXETIL	1 (1%)	0	1 (<1%)
CHLORAMPHENICOL	1 (1%)	0	1 (<1%)
CIPROFLOXACIN HYDROCHLORIDE	1 (1%)	0	1 (<1%)
DICLOXACILLIN SODIUM	0	1 (1%)	1 (<1%)
DIPHTHERIA TOXOID+PERTUSSIS TOXOID+POLIOMYELITIS VACCINE+TETANUS TOXOID	0	1 (1%)	1 (<1%)
DIPHTHERIA TOXOID+PERTUSSIS TOXOID ACELLULAR+TETANUS TOXOID	0	1 (1%)	1 (<1%)
DOXYCYCLINE HYDROCHLORIDE	0	1 (1%)	1 (<1%)
FAMCICLOVIR	1 (1%)	0	1 (<1%)
KETOCONAZOLE	1 (1%)	0	1 (<1%)
LINCOMYCIN HYDROCHLORIDE	0	1 (1%)	1 (<1%)
LINEZOLID	1 (1%)	0	1 (<1%)
MENINGOCOCCAL VACCINES (NOS)	0	1 (1%)	1 (<1%)
MICONAZOLE	1 (1%)	0	1 (<1%)
NEOMYCIN	0	1 (1%)	1 (<1%)
OFLOXACIN	1 (1%)	0	1 (<1%)
PIPEMIDIC ACID	0	1 (1%)	1 (<1%)
PIPERACILLIN+TAZOBACTAM	0	1 (1%)	1 (<1%)
PIVAMPICILLIN	0	1 (1%)	1 (<1%)
PNEUMOCOCCAL VACCINE	0	1 (1%)	1 (<1%)
SELEXID (NOS)	1 (1%)	0	1 (<1%)

Note: A medication may be included in more than one ATC Level category and appear more than once.
Includes medications started after first dose and before last dose + 28 days.

Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Table 111.21

Summary of Non-COPD Medications Started During Treatment in Study MEA117113

ATC Level 1 Ingredient and Ingredient Combinations	PBO (N=87)	100 SC (N=83)	Total (N=170)
TETANUS TOXOID	0	1 (1%)	1 (<1%)
TETRACYCLINE	0	1 (1%)	1 (<1%)
TRIVALENT INFLUENZA VACCINE	0	1 (1%)	1 (<1%)
NERVOUS SYSTEM			
Any medication	35 (40%)	39 (47%)	74 (44%)
PARACETAMOL	18 (21%)	21 (25%)	39 (23%)
IBUPROFEN	10 (11%)	9 (11%)	19 (11%)
METAMIZOLE SODIUM	0	4 (5%)	4 (2%)
NOVALGIN NOS	3 (3%)	1 (1%)	4 (2%)
PARACETAMOL+TRAMADOL HYDROCHLORIDE	2 (2%)	2 (2%)	4 (2%)
CITALOPRAM	1 (1%)	2 (2%)	3 (2%)
FENTANYL	2 (2%)	1 (1%)	3 (2%)
GABAPENTIN	0	3 (4%)	3 (2%)
LEVOSULPIRIDE	1 (1%)	2 (2%)	3 (2%)
PANADOL (NOS)	1 (1%)	2 (2%)	3 (2%)
ACETYLSALICYLIC ACID	1 (1%)	1 (1%)	2 (1%)
CODEINE	1 (1%)	1 (1%)	2 (1%)
CODEINE PHOSPHATE	0	2 (2%)	2 (1%)
CYCLOBENZAPRINE	2 (2%)	0	2 (1%)
CYCLOBENZAPRINE HYDROCHLORIDE	1 (1%)	1 (1%)	2 (1%)
HYDROMORPHONE HYDROCHLORIDE	2 (2%)	0	2 (1%)
KETOROLAC TROMETAMOL	1 (1%)	1 (1%)	2 (1%)
LIDOCAINE HYDROCHLORIDE	2 (2%)	0	2 (1%)
OXYCODONE HYDROCHLORIDE+PARACETAMOL	1 (1%)	1 (1%)	2 (1%)
PARACETAMOL+TRAMADOL	1 (1%)	1 (1%)	2 (1%)
PETHIDINE HYDROCHLORIDE	1 (1%)	1 (1%)	2 (1%)
PREGABALIN	1 (1%)	1 (1%)	2 (1%)
PROPACETAMOL HYDROCHLORIDE	1 (1%)	1 (1%)	2 (1%)
PROPOFOL	1 (1%)	1 (1%)	2 (1%)
TRAMADOL	1 (1%)	1 (1%)	2 (1%)

Note: A medication may be included in more than one ATC Level category and appear more than once.
Includes medications started after first dose and before last dose + 28 days.

Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Table 111.21

Summary of Non-COPD Medications Started During Treatment in Study MEA117113

ATC Level 1 Ingredient and Ingredient Combinations	PBO (N=87)	100 SC (N=83)	Total (N=170)
ZOLPIDEM TARTRATE	1 (1%)	1 (1%)	2 (1%)
ZOPICLONE	0	2 (2%)	2 (1%)
ALPRAZOLAM	0	1 (1%)	1 (<1%)
AMANTADINE HYDROCHLORIDE	0	1 (1%)	1 (<1%)
AMITRIPTYLINE	0	1 (1%)	1 (<1%)
ARTICAINE HYDROCHLORIDE+EPINEPHRINE HYDROCHLORIDE	1 (1%)	0	1 (<1%)
BETHANECHOL CHLORIDE	0	1 (1%)	1 (<1%)
BUPIVACAINE HYDROCHLORIDE	1 (1%)	0	1 (<1%)
BUPROPION HYDROCHLORIDE	1 (1%)	0	1 (<1%)
BUSPIRONE	1 (1%)	0	1 (<1%)
CAFFEINE+CHLORPHENAMINE MALEATE+CLOPERASTINE HYDROCHLORIDE+METHYLEPHEDRINE HYDROCHLORIDE+PARACETAMOL+SERRAPEPTASE	0	1 (1%)	1 (<1%)
CLONAZEPAM	0	1 (1%)	1 (<1%)
DIAZEPAM	1 (1%)	0	1 (<1%)
DICLOFENAC POTASSIUM	1 (1%)	0	1 (<1%)
DOXEPIN HYDROCHLORIDE	1 (1%)	0	1 (<1%)
ESTAZOLAM	0	1 (1%)	1 (<1%)
FENTANYL CITRATE	1 (1%)	0	1 (<1%)
FLUDIAZEPAM	1 (1%)	0	1 (<1%)
FLUOXETINE HYDROCHLORIDE	0	1 (1%)	1 (<1%)
GINKGO BILOBA	0	1 (1%)	1 (<1%)
HYDROCODONE	1 (1%)	0	1 (<1%)
HYDROCODONE BITARTRATE+PARACETAMOL	1 (1%)	0	1 (<1%)
HYDROCODONE+PARACETAMOL	0	1 (1%)	1 (<1%)
HYDROXYZINE	0	1 (1%)	1 (<1%)
HYDROXYZINE HYDROCHLORIDE	0	1 (1%)	1 (<1%)
LEVOBUPIVACAINE HYDROCHLORIDE	1 (1%)	0	1 (<1%)
LIDOCAINE	1 (1%)	0	1 (<1%)
MEPHENOXALONE	1 (1%)	0	1 (<1%)

Note: A medication may be included in more than one ATC Level category and appear more than once.
Includes medications started after first dose and before last dose + 28 days.

Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Table 111.21

Summary of Non-COPD Medications Started During Treatment in Study MEA117113

ATC Level 1 Ingredient and Ingredient Combinations	PBO (N=87)	100 SC (N=83)	Total (N=170)
MIDAZOLAM	1 (1%)	0	1 (<1%)
MORPHINE	0	1 (1%)	1 (<1%)
NALOXONE HYDROCHLORIDE+TILIDINE HYDROCHLORIDE	0	1 (1%)	1 (<1%)
NEFOPAM HYDROCHLORIDE	1 (1%)	0	1 (<1%)
NEOSTIGMINE METILSULFATE	0	1 (1%)	1 (<1%)
NICOTINE	0	1 (1%)	1 (<1%)
PARALEN (NOS)	1 (1%)	0	1 (<1%)
PAROXETINE HYDROCHLORIDE	0	1 (1%)	1 (<1%)
PETHIDINE	0	1 (1%)	1 (<1%)
PRILOCAINE HYDROCHLORIDE	0	1 (1%)	1 (<1%)
PROCHLORPERAZINE	0	1 (1%)	1 (<1%)
QUETIAPINE	1 (1%)	0	1 (<1%)
REMIFENTANIL HYDROCHLORIDE	1 (1%)	0	1 (<1%)
RIZE (NOS)	1 (1%)	0	1 (<1%)
SERENAL (NOS)	0	1 (1%)	1 (<1%)
SERTRALINE	1 (1%)	0	1 (<1%)
THIAMYLAL SODIUM	0	1 (1%)	1 (<1%)
TIANEPTINE	1 (1%)	0	1 (<1%)
TRAMADOL HYDROCHLORIDE	1 (1%)	0	1 (<1%)
TRIMIPRAMINE MALEATE	0	1 (1%)	1 (<1%)
SENSORY ORGANS			
Any medication	34 (39%)	36 (43%)	70 (41%)
LEVOFLOXACIN	8 (9%)	6 (7%)	14 (8%)
DICLOFENAC	3 (3%)	5 (6%)	8 (5%)
PREDNISOLONE	3 (3%)	4 (5%)	7 (4%)
ACETYLCYSTEINE	5 (6%)	1 (1%)	6 (4%)
METHYLPREDNISOLONE	1 (1%)	5 (6%)	6 (4%)
SODIUM CHLORIDE	2 (2%)	4 (5%)	6 (4%)
DEXAMETHASONE	3 (3%)	2 (2%)	5 (3%)
CIPROFLOXACIN	2 (2%)	2 (2%)	4 (2%)

Note: A medication may be included in more than one ATC Level category and appear more than once.
Includes medications started after first dose and before last dose + 28 days.
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Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Table 111.21

Summary of Non-COPD Medications Started During Treatment in Study MEA117113

ATC Level 1 Ingredient and Ingredient Combinations	PBO (N=87)	100 SC (N=83)	Total (N=170)
REBAMIPIDE	2 (2%)	2 (2%)	4 (2%)
DEXAMETHASONE+TOBRAMYCIN	2 (2%)	1 (1%)	3 (2%)
ACYCLOVIR	1 (1%)	1 (1%)	2 (1%)
CORTISONE	1 (1%)	1 (1%)	2 (1%)
FLUOROMETHOLONE	2 (2%)	0	2 (1%)
GENTAMICIN	2 (2%)	0	2 (1%)
HEPARIN (NOS)	1 (1%)	1 (1%)	2 (1%)
KETOROLAC TROMETAMOL	1 (1%)	1 (1%)	2 (1%)
LIDOCAINE HYDROCHLORIDE	2 (2%)	0	2 (1%)
METHYLPREDNISOLONE SODIUM SUCCINATE	2 (2%)	0	2 (1%)
NORFLOXACIN	2 (2%)	0	2 (1%)
OLOPATADINE HYDROCHLORIDE	2 (2%)	0	2 (1%)
TRIAMCINOLONE	0	2 (2%)	2 (1%)
AMPICILLIN	0	1 (1%)	1 (<1%)
ATROPINE	0	1 (1%)	1 (<1%)
AZELASTINE	0	1 (1%)	1 (<1%)
AZELASTINE HYDROCHLORIDE	0	1 (1%)	1 (<1%)
BENZYLPENICILLIN	0	1 (1%)	1 (<1%)
BETA BLOCKER NOS	0	1 (1%)	1 (<1%)
BIMATOPROST	1 (1%)	0	1 (<1%)
BRINZOLAMIDE	0	1 (1%)	1 (<1%)
CHLORAMPHENICOL	1 (1%)	0	1 (<1%)
CIPROFLOXACIN HYDROCHLORIDE	1 (1%)	0	1 (<1%)
DICLOFENAC SODIUM	0	1 (1%)	1 (<1%)
EPHEDRINE	0	1 (1%)	1 (<1%)
FAMCICLOVIR	1 (1%)	0	1 (<1%)
GLYCEROL	1 (1%)	0	1 (<1%)
HYALURONATE SODIUM	1 (1%)	0	1 (<1%)
HYDROCORTISONE	0	1 (1%)	1 (<1%)
HYDROCORTISONE SODIUM SUCCINATE	0	1 (1%)	1 (<1%)

Note: A medication may be included in more than one ATC Level category and appear more than once.
Includes medications started after first dose and before last dose + 28 days.
/mnt/code/postcsr_01/prod/tfls/t_sp_cm_ncopd_on_113.sas 21JUL2025 22:02

Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Table 111.21

Summary of Non-COPD Medications Started During Treatment in Study MEA117113

ATC Level 1 Ingredient and Ingredient Combinations	PBO (N=87)	100 SC (N=83)	Total (N=170)
HYDROCORTISONE+NEOMYCIN SULFATE+POLYMYXIN B SULFATE	1 (1%)	0	1 (<1%)
HYOSCINE BUTYLBROMIDE	1 (1%)	0	1 (<1%)
KETOROLAC	1 (1%)	0	1 (<1%)
LIDOCAINE	1 (1%)	0	1 (<1%)
MICONAZOLE	1 (1%)	0	1 (<1%)
NAPHAZOLINE NITRATE	0	1 (1%)	1 (<1%)
NEOSTIGMINE METILSULFATE	0	1 (1%)	1 (<1%)
NEPAFENAC	1 (1%)	0	1 (<1%)
OFLOXACIN	1 (1%)	0	1 (<1%)
OXYMETAZOLINE HYDROCHLORIDE	1 (1%)	0	1 (<1%)
PIROXICAM	0	1 (1%)	1 (<1%)
POTASSIUM IODIDE	1 (1%)	0	1 (<1%)
TETRACYCLINE	0	1 (1%)	1 (<1%)
TRIAMCINOLONE ACETONIDE	1 (1%)	0	1 (<1%)
RESPIRATORY SYSTEM			
Any medication	32 (37%)	36 (43%)	68 (40%)
PREDNISOLONE	3 (3%)	4 (5%)	7 (4%)
ACETYLCYSTEINE	5 (6%)	1 (1%)	6 (4%)
SODIUM CHLORIDE	2 (2%)	4 (5%)	6 (4%)
DEXAMETHASONE	3 (3%)	2 (2%)	5 (3%)
CETIRIZINE HYDROCHLORIDE	1 (1%)	3 (4%)	4 (2%)
HEDERA HELIX EXTRACT+RHIZOMA COPTIDIS EXTRACT	3 (3%)	1 (1%)	4 (2%)
PSEUDOEPHEDRINE HYDROCHLORIDE	1 (1%)	3 (4%)	4 (2%)
CARBINOXAMINE MALEATE+DEXTROMETHORPHAN HYDROBROMIDE+METHYLEPHEDRINE HYDROCHLORIDE+NOSCAPINE+SULFOGAIACOL	1 (1%)	2 (2%)	3 (2%)
FEXOFENADINE HYDROCHLORIDE	2 (2%)	1 (1%)	3 (2%)
LEVOCETIRIZINE	1 (1%)	2 (2%)	3 (2%)
LEVOCETIRIZINE HYDROCHLORIDE	1 (1%)	2 (2%)	3 (2%)

Note: A medication may be included in more than one ATC Level category and appear more than once.
Includes medications started after first dose and before last dose + 28 days.
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Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Table 111.21

Summary of Non-COPD Medications Started During Treatment in Study MEA117113

ATC Level 1 Ingredient and Ingredient Combinations	PBO (N=87)	100 SC (N=83)	Total (N=170)
MOMETASONE FUROATE	0	3 (4%)	3 (2%)
PSEUDOEPHEDRINE	2 (2%)	1 (1%)	3 (2%)
AMBROXOL HYDROCHLORIDE	1 (1%)	1 (1%)	2 (1%)
AMINOPHYLLINE	1 (1%)	1 (1%)	2 (1%)
BETAMETHASONE	1 (1%)	1 (1%)	2 (1%)
BROMHEXINE	2 (2%)	0	2 (1%)
CAFFEINE+PARACETAMOL+PROMETHAZINE METHYLENEDISALICYLATE+SALICYLAMIDE	1 (1%)	1 (1%)	2 (1%)
CARBOCISTEINE	0	2 (2%)	2 (1%)
CETIRIZINE	1 (1%)	1 (1%)	2 (1%)
CHLORPHENAMINE MALEATE	0	2 (2%)	2 (1%)
CODEINE	1 (1%)	1 (1%)	2 (1%)
CODEINE PHOSPHATE	0	2 (2%)	2 (1%)
COUGH COLD PREPARATIONS NOS	1 (1%)	1 (1%)	2 (1%)
FEXOFENADINE	0	2 (2%)	2 (1%)
FLONASE (NOS)	1 (1%)	1 (1%)	2 (1%)
FLUTICASONE FUROATE	1 (1%)	1 (1%)	2 (1%)
GUAIFENESIN	0	2 (2%)	2 (1%)
LEVODROPROPIZINE	0	2 (2%)	2 (1%)
LIDOCAINE HYDROCHLORIDE	2 (2%)	0	2 (1%)
LORATADINE	0	2 (2%)	2 (1%)
LORATADINE+PSEUDOEPHEDRINE	1 (1%)	1 (1%)	2 (1%)
MEQUITAZINE	1 (1%)	1 (1%)	2 (1%)
MYRTOL	0	2 (2%)	2 (1%)
OLOPATADINE HYDROCHLORIDE	2 (2%)	0	2 (1%)
TRIAMCINOLONE	0	2 (2%)	2 (1%)
ACTIFED (NOS)	1 (1%)	0	1 (<1%)
AFRIN (NOS)	1 (1%)	0	1 (<1%)
AMBROXOL	0	1 (1%)	1 (<1%)
AMBROXOL ACEFYLLINATE	1 (1%)	0	1 (<1%)
AMBROXOL HYDROCHLORIDE+OXATOMIDE+PARACETAMOL	0	1 (1%)	1 (<1%)

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Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Table 111.21

Summary of Non-COPD Medications Started During Treatment in Study MEA117113

ATC Level 1 Ingredient and Ingredient Combinations	PBO (N=87)	100 SC (N=83)	Total (N=170)
AMMONIUM CHLORIDE+CHLORPHENAMINE MALEATE+DIHYDROCODEINE BITARTRATE+METHYLEPHEDRINE HYDROCHLORIDE	0	1 (1%)	1 (<1%)
AZELASTINE	0	1 (1%)	1 (<1%)
AZELASTINE HYDROCHLORIDE	0	1 (1%)	1 (<1%)
BENZOCAINE+CETYLPYRIDINIUM CHLORIDE	1 (1%)	0	1 (<1%)
BENZONATATE	0	1 (1%)	1 (<1%)
BEPOTASTINE SALICYLATE	0	1 (1%)	1 (<1%)
BILASTINE	0	1 (1%)	1 (<1%)
BISOLVON (NOS)	1 (1%)	0	1 (<1%)
BROMHEXINE HYDROCHLORIDE	0	1 (1%)	1 (<1%)
BROWN MIXTURE (NOS)	0	1 (1%)	1 (<1%)
BUDESONIDE	1 (1%)	0	1 (<1%)
CAFFEINE+CHLORPHENAMINE MALEATE+CLOPERASTINE HYDROCHLORIDE+METHYLEPHEDRINE HYDROCHLORIDE+PARACETAMOL+SERRAPEPTASE	0	1 (1%)	1 (<1%)
CAFFEINE+CHLORPHENAMINE MALEATE+GUAIFENESIN+PARACETAMOL+PENTOXYVERINE CITRATE+PHENYLEPHRINE HYDROCHLORIDE	1 (1%)	0	1 (<1%)
CAFFEINE+CHLORPHENAMINE MALEATE+PARACETAMOL+PSEUDOEPHEDRINE HYDROCHLORIDE	0	1 (1%)	1 (<1%)
CALCIUM CHLORIDE+MAGNESIUM CHLORIDE+POTASSIUM CHLORIDE+SODIUM BICARBONATE+SODIUM CHLORIDE	0	1 (1%)	1 (<1%)
CHLORPHENAMINE	1 (1%)	0	1 (<1%)
CHLORQUINALDOL	0	1 (1%)	1 (<1%)
CICLESONIDE	0	1 (1%)	1 (<1%)
CLEMASTINE FUMARATE	0	1 (1%)	1 (<1%)
CODRAL COLD & FLU (NOS)	0	1 (1%)	1 (<1%)
CYCLIZINE	1 (1%)	0	1 (<1%)
DESLORATADINE	1 (1%)	0	1 (<1%)

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Includes medications started after first dose and before last dose + 28 days.
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Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Table 111.21

Summary of Non-COPD Medications Started During Treatment in Study MEA117113

ATC Level 1 Ingredient and Ingredient Combinations	PBO (N=87)	100 SC (N=83)	Total (N=170)
DEXCHLORPHENIRAMINE	0	1 (1%)	1 (<1%)
DEXCHLORPHENIRAMINE MALEATE	0	1 (1%)	1 (<1%)
DIFENIDOL	0	1 (1%)	1 (<1%)
DIMENHYDRINATE	1 (1%)	0	1 (<1%)
EPHEDRINE	0	1 (1%)	1 (<1%)
ERDOSTEINE	0	1 (1%)	1 (<1%)
FENSPIRIDE	0	1 (1%)	1 (<1%)
GLYCEROL	1 (1%)	0	1 (<1%)
GLYCOPYRRONIUM BROMIDE	1 (1%)	0	1 (<1%)
HYDROCODONE	1 (1%)	0	1 (<1%)
HYDROCODONE+PARACETAMOL	0	1 (1%)	1 (<1%)
HYDROXYZINE	0	1 (1%)	1 (<1%)
HYDROXYZINE HYDROCHLORIDE	0	1 (1%)	1 (<1%)
IBUDILAST	0	1 (1%)	1 (<1%)
IPRATROPIUM	0	1 (1%)	1 (<1%)
IPRATROPIUM+SALBUTAMOL	0	1 (1%)	1 (<1%)
LEVOTUSS (NOS)	0	1 (1%)	1 (<1%)
LIDOCAINE	1 (1%)	0	1 (<1%)
LORATADINE+PSEUDOEPHEDRINE SULFATE	0	1 (1%)	1 (<1%)
MOMETASONE	1 (1%)	0	1 (<1%)
MONTELUKAST SODIUM	1 (1%)	0	1 (<1%)
NAPHAZOLINE NITRATE	0	1 (1%)	1 (<1%)
NEOMYCIN	0	1 (1%)	1 (<1%)
NOSCAPINE	0	1 (1%)	1 (<1%)
OXYGEN	0	1 (1%)	1 (<1%)
OXYMETAZOLINE HYDROCHLORIDE	1 (1%)	0	1 (<1%)
PANCOLD A (NOS)	1 (1%)	0	1 (<1%)
PARACETAMOL+PSEUDOEPHEDRINE HYDROCHLORIDE	1 (1%)	0	1 (<1%)
POTASSIUM IODIDE	1 (1%)	0	1 (<1%)
POVIDONE-IODINE	0	1 (1%)	1 (<1%)

Note: A medication may be included in more than one ATC Level category and appear more than once.
Includes medications started after first dose and before last dose + 28 days.
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Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Table 111.21

Summary of Non-COPD Medications Started During Treatment in Study MEA117113

ATC Level 1 Ingredient and Ingredient Combinations	PBO (N=87)	100 SC (N=83)	Total (N=170)
PSEUDOEPHEDRINE HYDROCHLORIDE+TRIPROLIDINE HYDROCHLORIDE	0	1 (1%)	1 (<1%)
PSEUDOEPHEDRINE+TRIPROLIDINE	1 (1%)	0	1 (<1%)
RUPATADINE	0	1 (1%)	1 (<1%)
RUPATADINE FUMARATE	0	1 (1%)	1 (<1%)
SALBUTAMOL	1 (1%)	0	1 (<1%)
THEOPHYLLINE	0	1 (1%)	1 (<1%)
TRIAMCINOLONE ACETONIDE	1 (1%)	0	1 (<1%)
ALIMENTARY TRACT AND METABOLISM			
Any medication	30 (34%)	33 (40%)	63 (37%)
OMEPRAZOLE	7 (8%)	2 (2%)	9 (5%)
PREDNISOLONE	3 (3%)	4 (5%)	7 (4%)
PREDNISONE	4 (5%)	3 (4%)	7 (4%)
SODIUM CHLORIDE	2 (2%)	4 (5%)	6 (4%)
DEXAMETHASONE	3 (3%)	2 (2%)	5 (3%)
MAGNESIUM OXIDE	3 (3%)	2 (2%)	5 (3%)
RANITIDINE	3 (3%)	1 (1%)	4 (2%)
REBAMIPIDE	2 (2%)	2 (2%)	4 (2%)
BISACODYL	2 (2%)	1 (1%)	3 (2%)
CLOTRIMAZOLE	1 (1%)	2 (2%)	3 (2%)
LAFUTIDINE	2 (2%)	1 (1%)	3 (2%)
LEVOSULPIRIDE	1 (1%)	2 (2%)	3 (2%)
MACROGOL+POTASSIUM CHLORIDE+SODIUM BICARBONATE+SODIUM CHLORIDE	1 (1%)	2 (2%)	3 (2%)
METOCLOPRAMIDE	2 (2%)	1 (1%)	3 (2%)
PANTOPRAZOLE	2 (2%)	1 (1%)	3 (2%)
ACETYLSALICYLIC ACID	1 (1%)	1 (1%)	2 (1%)
BENZYDAMINE HYDROCHLORIDE	2 (2%)	0	2 (1%)
BETAMETHASONE	1 (1%)	1 (1%)	2 (1%)
COLECALCIFEROL	1 (1%)	1 (1%)	2 (1%)

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Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Table 111.21

Summary of Non-COPD Medications Started During Treatment in Study MEA117113

ATC Level 1 Ingredient and Ingredient Combinations	PBO (N=87)	100 SC (N=83)	Total (N=170)
DEXLANSOPRAZOLE	1 (1%)	1 (1%)	2 (1%)
ELECTROLYTES NOS+MACROGOL	0	2 (2%)	2 (1%)
LANSOPRAZOLE	0	2 (2%)	2 (1%)
LOPERAMIDE HYDROCHLORIDE	1 (1%)	1 (1%)	2 (1%)
MOSAPRIDE CITRATE	0	2 (2%)	2 (1%)
RANITIDINE HYDROCHLORIDE+SUCRALFATE+TRIPOTASSIUM DICITRATOBISMUTHATE	0	2 (2%)	2 (1%)
SENNA	1 (1%)	1 (1%)	2 (1%)
SENNOSIDES	1 (1%)	1 (1%)	2 (1%)
SODIUM PHOSPHATE DIBASIC+SODIUM PHOSPHATE MONOBASIC	2 (2%)	0	2 (1%)
TRIAMCINOLONE	0	2 (2%)	2 (1%)
VITAMINS NOS	2 (2%)	0	2 (1%)
ALFACALCIDOL	0	1 (1%)	1 (<1%)
ALMAGATE	0	1 (1%)	1 (<1%)
ALUMINIUM HYDROXIDE	0	1 (1%)	1 (<1%)
ATROPINE	0	1 (1%)	1 (<1%)
BACILLUS SUBTILIS+STREPTOCOCCUS FAECALIS	0	1 (1%)	1 (<1%)
BENEXATE HYDROCHLORIDE	1 (1%)	0	1 (<1%)
BENFOTIAMINE+CYANOCOBALAMIN+PYRIDOXINE HYDROCHLORIDE	0	1 (1%)	1 (<1%)
BENZOCAINE+CETYLPYRIDINIUM CHLORIDE	1 (1%)	0	1 (<1%)
BETAMETHASONE BUTYRATE PROPIONATE	1 (1%)	0	1 (<1%)
BIODIASTASE 2000+LIPASE+URSODEOXYCHOLIC ACID	0	1 (1%)	1 (<1%)
BUDESONIDE	1 (1%)	0	1 (<1%)
CALCIUM	1 (1%)	0	1 (<1%)
CALCIUM CARBONATE+COLECALCIFEROL	1 (1%)	0	1 (<1%)
CIMETROPIUM BROMIDE	1 (1%)	0	1 (<1%)
CITRIC ACID+POTASSIUM BICARBONATE+POTASSIUM CITRATE	0	1 (1%)	1 (<1%)

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Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Table 111.21

Summary of Non-COPD Medications Started During Treatment in Study MEA117113

ATC Level 1 Ingredient and Ingredient Combinations	PBO (N=87)	100 SC (N=83)	Total (N=170)
CYANOCOBALAMIN+CYPROHEPTADINE	0	1 (1%)	1 (<1%)
OROTATE+LEVOCARNITINE HYDROCHLORIDE+LYSINE HYDROCHLORIDE			
DIFENIDOL	0	1 (1%)	1 (<1%)
DIMENHYDRINATE	1 (1%)	0	1 (<1%)
DIMETICONE, ACTIVATED	1 (1%)	0	1 (<1%)
DOCUSATE SODIUM	0	1 (1%)	1 (<1%)
DOCUSATE SODIUM+SENNA	0	1 (1%)	1 (<1%)
ERGOCALCIFEROL	1 (1%)	0	1 (<1%)
ESCHERICHIA COLI	0	1 (1%)	1 (<1%)
ESOMEPRAZOLE MAGNESIUM	1 (1%)	0	1 (<1%)
FAMOTIDINE	0	1 (1%)	1 (<1%)
FLAVINE ADENINE DINUCLEOTIDE+LIVER EXTRACT	1 (1%)	0	1 (<1%)
FURSULTIAMINE HYDROCHLORIDE	1 (1%)	0	1 (<1%)
GLUCOSE+POTASSIUM NOS+SODIUM CHLORIDE	1 (1%)	0	1 (<1%)
GLYCEROL	1 (1%)	0	1 (<1%)
GLYCOPYRRONIUM BROMIDE	1 (1%)	0	1 (<1%)
GRANISETRON	1 (1%)	0	1 (<1%)
HYDROCORTISONE SODIUM SUCCINATE	0	1 (1%)	1 (<1%)
HYOSCINE BUTYLBROMIDE	1 (1%)	0	1 (<1%)
INSULIN DEGLUDEC	1 (1%)	0	1 (<1%)
INSULIN NOS	0	1 (1%)	1 (<1%)
LOPERAMIDE	1 (1%)	0	1 (<1%)
MACROGOL+POTASSIUM CHLORIDE+SODIUM BICARBONATE+SODIUM CHLORIDE+SODIUM SULFATE	1 (1%)	0	1 (<1%)
MAGNESIUM	1 (1%)	0	1 (<1%)
MAGNESIUM PHOSPHATE	0	1 (1%)	1 (<1%)
MAGNESIUM SULFATE	0	1 (1%)	1 (<1%)
METFORMIN HYDROCHLORIDE	1 (1%)	0	1 (<1%)
METOCLOPRAMIDE HYDROCHLORIDE	0	1 (1%)	1 (<1%)
MICONAZOLE	1 (1%)	0	1 (<1%)

Note: A medication may be included in more than one ATC Level category and appear more than once.
Includes medications started after first dose and before last dose + 28 days.
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Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Table 111.21

Summary of Non-COPD Medications Started During Treatment in Study MEA117113

ATC Level 1 Ingredient and Ingredient Combinations	PBO (N=87)	100 SC (N=83)	Total (N=170)
MINERALS NOS+VITAMINS NOS	1 (1%)	0	1 (<1%)
MOSAPRIDE	1 (1%)	0	1 (<1%)
NEO-ANGIN (NOS)	1 (1%)	0	1 (<1%)
NEOMYCIN	0	1 (1%)	1 (<1%)
NIFUROXAZIDE	1 (1%)	0	1 (<1%)
NIZATIDINE	0	1 (1%)	1 (<1%)
NORZYME (NOS)	1 (1%)	0	1 (<1%)
NYSTATIN	0	1 (1%)	1 (<1%)
ONDANSETRON	1 (1%)	0	1 (<1%)
OXYBUTYNIN HYDROCHLORIDE	0	1 (1%)	1 (<1%)
PANTOPRAZOLE SODIUM	0	1 (1%)	1 (<1%)
PARGEVERINE	1 (1%)	0	1 (<1%)
POLYCARBOPHIL CALCIUM	0	1 (1%)	1 (<1%)
POTASSIUM CHLORIDE	0	1 (1%)	1 (<1%)
POTASSIUM CHLORIDE+SODIUM ASCORBATE+SODIUM CHLORIDE+SODIUM SULFATE	1 (1%)	0	1 (<1%)
PROCHLORPERAZINE	0	1 (1%)	1 (<1%)
PROTONIX (NOS)	0	1 (1%)	1 (<1%)
SMECTITE	0	1 (1%)	1 (<1%)
SODIUM PICOSULFATE	1 (1%)	0	1 (<1%)
TETRACYCLINE	0	1 (1%)	1 (<1%)
THIAMINE	0	1 (1%)	1 (<1%)
TIROPRAMIDE HYDROCHLORIDE	0	1 (1%)	1 (<1%)
TRIAMCINOLONE ACETONIDE	1 (1%)	0	1 (<1%)
URSODEOXYCHOLIC ACID	1 (1%)	0	1 (<1%)
VIADIL (NOS)	1 (1%)	0	1 (<1%)
VITAMIN D NOS	1 (1%)	0	1 (<1%)
ZINC	1 (1%)	0	1 (<1%)
DERMATOLOGICALS			
Any medication	23 (26%)	22 (27%)	45 (26%)

Note: A medication may be included in more than one ATC Level category and appear more than once.
Includes medications started after first dose and before last dose + 28 days.
/mnt/code/postcsr_01/prod/tfls/t_sp_cm_ncopd_on_113.sas 21JUL2025 22:02

Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Table 111.21

Summary of Non-COPD Medications Started During Treatment in Study MEA117113

ATC Level 1 Ingredient and Ingredient Combinations	PBO (N=87)		100 SC (N=83)		Total (N=170)	
PREDNISOLONE	3	(3%)	4	(5%)	7	(4%)
METHYLPREDNISOLONE	1	(1%)	5	(6%)	6	(4%)
DEXAMETHASONE	3	(3%)	2	(2%)	5	(3%)
CLOTRIMAZOLE	1	(1%)	2	(2%)	3	(2%)
FLUCONAZOLE	3	(3%)	0		3	(2%)
MOMETASONE FUROATE	0		3	(4%)	3	(2%)
ACYCLOVIR	1	(1%)	1	(1%)	2	(1%)
BETAMETHASONE	1	(1%)	1	(1%)	2	(1%)
CLINDAMYCIN	1	(1%)	1	(1%)	2	(1%)
CORTISONE	1	(1%)	1	(1%)	2	(1%)
FLONASE (NOS)	1	(1%)	1	(1%)	2	(1%)
FLUOROMETHOLONE	2	(2%)	0		2	(1%)
GENTAMICIN	2	(2%)	0		2	(1%)
LIDOCAINE HYDROCHLORIDE	2	(2%)	0		2	(1%)
METHYLPREDNISOLONE SODIUM SUCCINATE	2	(2%)	0		2	(1%)
TRIAMCINOLONE	0		2	(2%)	2	(1%)
BETAMETHASONE BUTYRATE PROPIONATE	1	(1%)	0		1	(<1%)
BUDESONIDE	1	(1%)	0		1	(<1%)
CHLORAMPHENICOL	1	(1%)	0		1	(<1%)
CHLORQUINALDOL	0		1	(1%)	1	(<1%)
CLEMASTINE FUMARATE	0		1	(1%)	1	(<1%)
CLOBETASOL	0		1	(1%)	1	(<1%)
DICLOFENAC SODIUM	0		1	(1%)	1	(<1%)
DIFLUPREDNATE	1	(1%)	0		1	(<1%)
DOXEPIN HYDROCHLORIDE	1	(1%)	0		1	(<1%)
FLUPREDNIDENE ACETATE+NYSTATIN	1	(1%)	0		1	(<1%)
FURACIN (NOS)	0		1	(1%)	1	(<1%)
GLYCEROL	1	(1%)	0		1	(<1%)
GLYCERYL TRINITRATE	0		1	(1%)	1	(<1%)
HYALURONATE SODIUM	1	(1%)	0		1	(<1%)
HYDROCORTISONE	0		1	(1%)	1	(<1%)

Note: A medication may be included in more than one ATC Level category and appear more than once.
Includes medications started after first dose and before last dose + 28 days.
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Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Table 111.21

Summary of Non-COPD Medications Started During Treatment in Study MEA117113

ATC Level 1 Ingredient and Ingredient Combinations	PBO (N=87)	100 SC (N=83)	Total (N=170)
HYDROCORTISONE SODIUM SUCCINATE	0	1 (1%)	1 (<1%)
KETOCONAZOLE	1 (1%)	0	1 (<1%)
LIDOCAINE	1 (1%)	0	1 (<1%)
MAGNESIUM SULFATE	0	1 (1%)	1 (<1%)
METHYLPREDNISOLONE ACETATE	1 (1%)	0	1 (<1%)
MICONAZOLE	1 (1%)	0	1 (<1%)
MOMETASONE	1 (1%)	0	1 (<1%)
NEOMYCIN	0	1 (1%)	1 (<1%)
NYSTATIN	0	1 (1%)	1 (<1%)
POVIDONE-IODINE	0	1 (1%)	1 (<1%)
TETRACYCLINE	0	1 (1%)	1 (<1%)
TRIAMCINOLONE ACETONIDE	1 (1%)	0	1 (<1%)
ZINC	1 (1%)	0	1 (<1%)
ZINC OXIDE	1 (1%)	0	1 (<1%)
MUSCULO-SKELETAL SYSTEM			
Any medication	21 (24%)	24 (29%)	45 (26%)
IBUPROFEN	10 (11%)	9 (11%)	19 (11%)
DICLOFENAC	3 (3%)	5 (6%)	8 (5%)
LOXOPROFEN SODIUM	1 (1%)	3 (4%)	4 (2%)
MELOXICAM	0	4 (5%)	4 (2%)
NAPROXEN	3 (3%)	0	3 (2%)
ACETYLSALICYLIC ACID	1 (1%)	1 (1%)	2 (1%)
ALLOPURINOL	1 (1%)	1 (1%)	2 (1%)
BENZYDAMINE HYDROCHLORIDE	2 (2%)	0	2 (1%)
CELECOXIB	1 (1%)	1 (1%)	2 (1%)
CYCLOBENZAPRINE	2 (2%)	0	2 (1%)
CYCLOBENZAPRINE HYDROCHLORIDE	1 (1%)	1 (1%)	2 (1%)
DEXIBUPROFEN	0	2 (2%)	2 (1%)
ETODOLAC	0	2 (2%)	2 (1%)
KETOPROFEN	1 (1%)	1 (1%)	2 (1%)

Note: A medication may be included in more than one ATC Level category and appear more than once.
Includes medications started after first dose and before last dose + 28 days.
/mnt/code/postcsr_01/prod/tfls/t_sp_cm_ncopd_on_113.sas 21JUL2025 22:02

Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Table 111.21

Summary of Non-COPD Medications Started During Treatment in Study MEA117113

ATC Level 1 Ingredient and Ingredient Combinations	PBO (N=87)	100 SC (N=83)	Total (N=170)
KETOROLAC TROMETAMOL	1 (1%)	1 (1%)	2 (1%)
NIMESULIDE	0	2 (2%)	2 (1%)
ROCURONIUM BROMIDE	1 (1%)	1 (1%)	2 (1%)
STREPTODORNASE+STREPTOKINASE	1 (1%)	1 (1%)	2 (1%)
ZALTOPROFEN	0	2 (2%)	2 (1%)
ACECLOFENAC	1 (1%)	0	1 (<1%)
ALENDRONATE SODIUM+COLECALCIFEROL	1 (1%)	0	1 (<1%)
ATRACURIUM BESILATE	0	1 (1%)	1 (<1%)
BACLOFEN	1 (1%)	0	1 (<1%)
CARISOPRODOL+PARACETAMOL	0	1 (1%)	1 (<1%)
CHONDROITIN SULFATE	1 (1%)	0	1 (<1%)
CIMETROPIUM BROMIDE	1 (1%)	0	1 (<1%)
CLEMATIS NOS+PRUNELLA VULGARIS+TRICHOSANTHES NOS	1 (1%)	0	1 (<1%)
COLCHICINE	1 (1%)	0	1 (<1%)
DIACEREIN	0	1 (1%)	1 (<1%)
DICLOFENAC POTASSIUM	1 (1%)	0	1 (<1%)
DICLOFENAC SODIUM	0	1 (1%)	1 (<1%)
EPERISONE	1 (1%)	0	1 (<1%)
ETORICOXIB	0	1 (1%)	1 (<1%)
HYALURONATE SODIUM	1 (1%)	0	1 (<1%)
IBANDRONIC ACID	1 (1%)	0	1 (<1%)
KETO INJECTION (NOS)	0	1 (1%)	1 (<1%)
KETOROLAC	1 (1%)	0	1 (<1%)
MEPHENOXALONE	1 (1%)	0	1 (<1%)
MYDOCALM (NOS)	1 (1%)	0	1 (<1%)
NAPROXEN SODIUM	0	1 (1%)	1 (<1%)
ORPHENADRINE CITRATE+PARACETAMOL	0	1 (1%)	1 (<1%)
PIROXICAM	0	1 (1%)	1 (<1%)
SUPROFEN	1 (1%)	0	1 (<1%)
TIZANIDINE	1 (1%)	0	1 (<1%)
TOLFENAMIC ACID	0	1 (1%)	1 (<1%)

Note: A medication may be included in more than one ATC Level category and appear more than once.
Includes medications started after first dose and before last dose + 28 days.

Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Table 111.21

Summary of Non-COPD Medications Started During Treatment in Study MEA117113

ATC Level 1 Ingredient and Ingredient Combinations	PBO (N=87)	100 SC (N=83)	Total (N=170)
CARDIOVASCULAR SYSTEM			
Any medication	19 (22%)	18 (22%)	37 (22%)
PREDNISOLONE	3 (3%)	4 (5%)	7 (4%)
DEXAMETHASONE	3 (3%)	2 (2%)	5 (3%)
FUROSEMIDE	4 (5%)	1 (1%)	5 (3%)
AMLODIPINE	2 (2%)	1 (1%)	3 (2%)
LOSARTAN	2 (2%)	1 (1%)	3 (2%)
ATORVASTATIN CALCIUM	1 (1%)	1 (1%)	2 (1%)
BETAMETHASONE	1 (1%)	1 (1%)	2 (1%)
DILTIAZEM HYDROCHLORIDE	1 (1%)	1 (1%)	2 (1%)
FLUOROMETHOLONE	2 (2%)	0	2 (1%)
HEPARIN (NOS)	1 (1%)	1 (1%)	2 (1%)
HYDROCHLOROTHIAZIDE	2 (2%)	0	2 (1%)
LERCANIDIPINE HYDROCHLORIDE	0	2 (2%)	2 (1%)
LIDOCAINE HYDROCHLORIDE	2 (2%)	0	2 (1%)
AMIODARONE HYDROCHLORIDE	1 (1%)	0	1 (<1%)
ATORVASTATIN	0	1 (1%)	1 (<1%)
BETA BLOCKER NOS	0	1 (1%)	1 (<1%)
BETAMETHASONE BUTYRATE PROPIONATE	1 (1%)	0	1 (<1%)
BISOPROLOL FUMARATE	0	1 (1%)	1 (<1%)
CAPTOPRIL	1 (1%)	0	1 (<1%)
CARVEDILOL	1 (1%)	0	1 (<1%)
DIGOXIN	1 (1%)	0	1 (<1%)
ENALAPRIL	1 (1%)	0	1 (<1%)
ESCHERICHIA COLI	0	1 (1%)	1 (<1%)
ESMOLOL HYDROCHLORIDE	1 (1%)	0	1 (<1%)
GINKGO BILOBA	0	1 (1%)	1 (<1%)
GLYCERYL TRINITRATE	0	1 (1%)	1 (<1%)
HEPARINOID	1 (1%)	0	1 (<1%)
HYDRALAZINE	1 (1%)	0	1 (<1%)

Note: A medication may be included in more than one ATC Level category and appear more than once.
Includes medications started after first dose and before last dose + 28 days.
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Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Table 111.21

Summary of Non-COPD Medications Started During Treatment in Study MEA117113

ATC Level 1 Ingredient and Ingredient Combinations	PBO (N=87)	100 SC (N=83)	Total (N=170)
HYDROCORTISONE	0	1 (1%)	1 (<1%)
HYDROCORTISONE SODIUM SUCCINATE	0	1 (1%)	1 (<1%)
IRBESARTAN	0	1 (1%)	1 (<1%)
LACIDIPINE	0	1 (1%)	1 (<1%)
LIDOCAINE	1 (1%)	0	1 (<1%)
LIMAPROST	1 (1%)	0	1 (<1%)
LIMAPROST ALFADEX	1 (1%)	0	1 (<1%)
METOPROLOL	1 (1%)	0	1 (<1%)
NAFTOPIDIL	1 (1%)	0	1 (<1%)
NICAMETATE CITRATE	0	1 (1%)	1 (<1%)
NICARDIPINE HYDROCHLORIDE	0	1 (1%)	1 (<1%)
NICORANDIL	0	1 (1%)	1 (<1%)
NIFEDIPINE	1 (1%)	0	1 (<1%)
OLMESARTAN	0	1 (1%)	1 (<1%)
PROPAFENONE HYDROCHLORIDE	1 (1%)	0	1 (<1%)
RAMIPRIL	1 (1%)	0	1 (<1%)
SILODOSIN	0	1 (1%)	1 (<1%)
SPIRONOLACTONE	1 (1%)	0	1 (<1%)
TRICHLORMETHIAZIDE	0	1 (1%)	1 (<1%)
VASOTEC (NOS)	0	1 (1%)	1 (<1%)
SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS			
Any medication	17 (20%)	18 (22%)	35 (21%)
PREDNISOLONE	3 (3%)	4 (5%)	7 (4%)
PREDNISONE	4 (5%)	3 (4%)	7 (4%)
METHYLPREDNISOLONE	1 (1%)	5 (6%)	6 (4%)
DEXAMETHASONE	3 (3%)	2 (2%)	5 (3%)
BETAMETHASONE	1 (1%)	1 (1%)	2 (1%)
CORTISONE	1 (1%)	1 (1%)	2 (1%)
METHYLPREDNISOLONE SODIUM SUCCINATE	2 (2%)	0	2 (1%)

Note: A medication may be included in more than one ATC Level category and appear more than once.
Includes medications started after first dose and before last dose + 28 days.
/mnt/code/postcsr_01/prod/tfls/t_sp_cm_ncopd_on_113.sas 21JUL2025 22:02

Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Table 111.21

Summary of Non-COPD Medications Started During Treatment in Study MEA117113

ATC Level 1 Ingredient and Ingredient Combinations	PBO (N=87)	100 SC (N=83)	Total (N=170)
TRIAMCINOLONE	0	2 (2%)	2 (1%)
BUDESONIDE	1 (1%)	0	1 (<1%)
DESMOPRESSIN	0	1 (1%)	1 (<1%)
HYDROCORTISONE	0	1 (1%)	1 (<1%)
HYDROCORTISONE SODIUM SUCCINATE	0	1 (1%)	1 (<1%)
LEVOTHYROXINE SODIUM+LIOTHYRONINE HYDROCHLORIDE	1 (1%)	0	1 (<1%)
MEPREDNISONE	1 (1%)	0	1 (<1%)
METHYLPREDNISOLONE ACETATE	1 (1%)	0	1 (<1%)
POTASSIUM IODIDE	1 (1%)	0	1 (<1%)
TRIAMCINOLONE ACETONIDE	1 (1%)	0	1 (<1%)
GENITO URINARY SYSTEM AND SEX HORMONES			
Any medication	17 (20%)	16 (19%)	33 (19%)
IBUPROFEN	10 (11%)	9 (11%)	19 (11%)
NITROFURANTOIN	2 (2%)	2 (2%)	4 (2%)
CLOTRIMAZOLE	1 (1%)	2 (2%)	3 (2%)
MEGESTROL ACETATE	1 (1%)	2 (2%)	3 (2%)
NAPROXEN	3 (3%)	0	3 (2%)
TAMSULOSIN HYDROCHLORIDE	1 (1%)	2 (2%)	3 (2%)
BENZYDAMINE HYDROCHLORIDE	2 (2%)	0	2 (1%)
CLINDAMYCIN	1 (1%)	1 (1%)	2 (1%)
ALFUZOSIN HYDROCHLORIDE	1 (1%)	0	1 (<1%)
CHLORAMPHENICOL	1 (1%)	0	1 (<1%)
CHLORQUINALDOL	0	1 (1%)	1 (<1%)
DUTASTERIDE+TAMSULOSIN HYDROCHLORIDE	0	1 (1%)	1 (<1%)
ESTRADIOL	0	1 (1%)	1 (<1%)
FESOTERODINE	1 (1%)	0	1 (<1%)
KETOCONAZOLE	1 (1%)	0	1 (<1%)
MICONAZOLE	1 (1%)	0	1 (<1%)
MIRODENAFIL HYDROCHLORIDE	1 (1%)	0	1 (<1%)
NAFTOPIDIL	1 (1%)	0	1 (<1%)

Note: A medication may be included in more than one ATC Level category and appear more than once.
Includes medications started after first dose and before last dose + 28 days.
/mnt/code/postcsr_01/prod/tfls/t_sp_cm_ncopd_on_113.sas 21JUL2025 22:02

Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Table 111.21

Summary of Non-COPD Medications Started During Treatment in Study MEA117113

ATC Level 1 Ingredient and Ingredient Combinations	PBO (N=87)	100 SC (N=83)	Total (N=170)
NAPROXEN SODIUM	0	1 (1%)	1 (<1%)
NORETHISTERONE ACETATE	0	1 (1%)	1 (<1%)
NYSTATIN	0	1 (1%)	1 (<1%)
OXYBUTYNIN HYDROCHLORIDE	0	1 (1%)	1 (<1%)
PHENAZOPYRIDINE	0	1 (1%)	1 (<1%)
POVIDONE-IODINE	0	1 (1%)	1 (<1%)
SILODOSIN	0	1 (1%)	1 (<1%)
SOLIFENACIN SUCCINATE	0	1 (1%)	1 (<1%)
TAMSULOSIN	0	1 (1%)	1 (<1%)
BLOOD AND BLOOD FORMING ORGANS			
Any medication	11 (13%)	16 (19%)	27 (16%)
SODIUM CHLORIDE	2 (2%)	4 (5%)	6 (4%)
DALTEPARIN	1 (1%)	2 (2%)	3 (2%)
ENOXAPARIN	1 (1%)	2 (2%)	3 (2%)
ACETYLSALICYLIC ACID	1 (1%)	1 (1%)	2 (1%)
CALCIUM CHLORIDE+POTASSIUM CHLORIDE+SODIUM CHLORIDE+SODIUM LACTATE	1 (1%)	1 (1%)	2 (1%)
FERROUS GLUCONATE	1 (1%)	1 (1%)	2 (1%)
GLUCOSE	2 (2%)	0	2 (1%)
HEPARIN (NOS)	1 (1%)	1 (1%)	2 (1%)
STREPTODORNASE+STREPTOKINASE	1 (1%)	1 (1%)	2 (1%)
AMINO ACIDS NOS	1 (1%)	0	1 (<1%)
AMINO ACIDS NOS+ISOLEUCINE+LEUCINE+LYSINE ACETATE+METHIONINE+PHENYLALANINE+VALINE	1 (1%)	0	1 (<1%)
CALCIUM CHLORIDE+GLUCONATE SODIUM+MAGNESIUM CHLORIDE+SODIUM ACETATE+SODIUM CHLORIDE	1 (1%)	0	1 (<1%)
CALCIUM FOLINATE	1 (1%)	0	1 (<1%)
CYANOCOBALAMIN	1 (1%)	0	1 (<1%)
ENOXAPARIN SODIUM	0	1 (1%)	1 (<1%)
FERROUS FUMARATE	0	1 (1%)	1 (<1%)

Note: A medication may be included in more than one ATC Level category and appear more than once.
Includes medications started after first dose and before last dose + 28 days.

Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Table 111.21

Summary of Non-COPD Medications Started During Treatment in Study MEA117113

ATC Level 1 Ingredient and Ingredient Combinations	PBO (N=87)	100 SC (N=83)	Total (N=170)
GLUCOSE+POTASSIUM NOS+SODIUM CHLORIDE	1 (1%)	0	1 (<1%)
GLUCOSE+SODIUM CHLORIDE	1 (1%)	0	1 (<1%)
HEPARINOID	1 (1%)	0	1 (<1%)
HETASTARCH	1 (1%)	0	1 (<1%)
HYALURONIDASE	1 (1%)	0	1 (<1%)
LIMAPROST ALFADEX	1 (1%)	0	1 (<1%)
MAGNESIUM PHOSPHATE	0	1 (1%)	1 (<1%)
MAGNESIUM SULFATE	0	1 (1%)	1 (<1%)
MECOBALAMIN	1 (1%)	0	1 (<1%)
MEDIUM CHAIN TRIGLYCERIDES+OLEA EUROPAEA OIL+OMEGA-3 MARINE TRIGLYCERIDES+SOYA OIL	0	1 (1%)	1 (<1%)
NADROPARIN	0	1 (1%)	1 (<1%)
NEOMYCIN	0	1 (1%)	1 (<1%)
POTASSIUM CHLORIDE	0	1 (1%)	1 (<1%)
STREPTOKINASE	0	1 (1%)	1 (<1%)
VITAMIN B12 SUBSTANCES	0	1 (1%)	1 (<1%)
VARIOUS			
Any medication	11 (13%)	9 (11%)	20 (12%)
ACETYLCYSTEINE	5 (6%)	1 (1%)	6 (4%)
GLUCOSE	2 (2%)	0	2 (1%)
HERBALS NOS	1 (1%)	1 (1%)	2 (1%)
ACONITUM+ATROPINE SULFATE+MERCURIC CYANIDE	0	1 (1%)	1 (<1%)
ALISMATIS RHIZOMA+CORNUS OFFICINALIS+GLYCYRRHIZA (NOS)+HERBALS NOS+PACHYMA HOELEN+RHIZOMA COPTIDIS+SCHISANDRA NOS	0	1 (1%)	1 (<1%)
AMBIGUOUS MEDICATION NOS	1 (1%)	0	1 (<1%)
ARTEMISIA EXTRACT (NOS)	0	1 (1%)	1 (<1%)
BIMATOPROST	1 (1%)	0	1 (<1%)
CALCIUM FOLINATE	1 (1%)	0	1 (<1%)
CARTILAGE	1 (1%)	0	1 (<1%)

Note: A medication may be included in more than one ATC Level category and appear more than once.
Includes medications started after first dose and before last dose + 28 days.
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Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Table 111.21

Summary of Non-COPD Medications Started During Treatment in Study MEA117113

ATC Level 1 Ingredient and Ingredient Combinations	PBO (N=87)	100 SC (N=83)	Total (N=170)
CORYDALIS (NOS)	0	1 (1%)	1 (<1%)
DUTASTERIDE+TAMSULOSIN HYDROCHLORIDE	0	1 (1%)	1 (<1%)
GINKGO BILOBA	0	1 (1%)	1 (<1%)
MAGNESIUM SULFATE	0	1 (1%)	1 (<1%)
METHIONINE+PHENYLALANINE+RHODIOLA ROSEA EXTRACT+TYROSINE	1 (1%)	0	1 (<1%)
NALOXONE HYDROCHLORIDE	1 (1%)	0	1 (<1%)
OLEA EUROPAEA OIL+SOYA OIL	1 (1%)	0	1 (<1%)
OXYGEN	0	1 (1%)	1 (<1%)
POTASSIUM IODIDE	1 (1%)	0	1 (<1%)
SUGAMMADEX SODIUM	1 (1%)	0	1 (<1%)
VITIS VINIFERA EXTRACT	0	1 (1%)	1 (<1%)
ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS			
Any medication	2 (2%)	3 (4%)	5 (3%)
MEGESTROL ACETATE	1 (1%)	2 (2%)	3 (2%)
ESTRADIOL	0	1 (1%)	1 (<1%)
FLUOROURACIL	1 (1%)	0	1 (<1%)
ANTIPARASITIC PRODUCTS, INSECTICIDES AND REPELLENTS			
Any medication	0	1 (1%)	1 (<1%)
CHLORQUINALDOL	0	1 (1%)	1 (<1%)

Note: A medication may be included in more than one ATC Level category and appear more than once.
Includes medications started after first dose and before last dose + 28 days.
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Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Table 111.22

Summary of Non-COPD Medications Started During Treatment in Study MEA117106

ATC Level 1 Ingredient and Ingredient Combinations	PBO (N=90)	100 SC (N=82)	Total (N=172)
Any medication	63 (70%)	60 (73%)	123 (72%)
ANTIINFECTIVES FOR SYSTEMIC USE			
Any medication	40 (44%)	34 (41%)	74 (43%)
INFLUENZA VACCINE	12 (13%)	9 (11%)	21 (12%)
AMOXICILLIN+CLAVULANIC ACID	6 (7%)	3 (4%)	9 (5%)
AMOXICILLIN	5 (6%)	3 (4%)	8 (5%)
PNEUMOCOCCAL VACCINE	3 (3%)	4 (5%)	7 (4%)
CIPROFLOXACIN	3 (3%)	3 (4%)	6 (3%)
AZITHROMYCIN	2 (2%)	3 (4%)	5 (3%)
LEVOFLOXACIN	3 (3%)	2 (2%)	5 (3%)
CEFTRIAXONE SODIUM	4 (4%)	0	4 (2%)
CLARITHROMYCIN	3 (3%)	1 (1%)	4 (2%)
ACYCLOVIR	1 (1%)	2 (2%)	3 (2%)
CEFALEXIN	1 (1%)	2 (2%)	3 (2%)
CLINDAMYCIN	1 (1%)	2 (2%)	3 (2%)
DOXYCYCLINE	3 (3%)	0	3 (2%)
FLUCONAZOLE	2 (2%)	1 (1%)	3 (2%)
INFLUENZA VIRUS VACCINE INACTIVATED	0	3 (4%)	3 (2%)
MOXIFLOXACIN	2 (2%)	1 (1%)	3 (2%)
OSELTAMIVIR PHOSPHATE	2 (2%)	1 (1%)	3 (2%)
TETANUS TOXOID	1 (1%)	2 (2%)	3 (2%)
AMOXICILLIN+CLAVULANATE POTASSIUM	1 (1%)	1 (1%)	2 (1%)
CEFADROXIL	0	2 (2%)	2 (1%)
CEFUROXIME AXETIL	2 (2%)	0	2 (1%)
CIPROFLOXACIN HYDROCHLORIDE	1 (1%)	1 (1%)	2 (1%)
IMIDAZOLYLETHANAMIDE PENTANDIOIC ACID	2 (2%)	0	2 (1%)
SULFAMETHOXAZOLE+TRIMETHOPRIM	0	2 (2%)	2 (1%)
AMIKACIN	1 (1%)	0	1 (<1%)
AMPICILLIN	0	1 (1%)	1 (<1%)
CEFIXIME	1 (1%)	0	1 (<1%)

Note: A medication may be included in more than one ATC Level category and appear more than once.
Includes medications started after first dose and before last dose + 28 days.

Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Table 111.22

Summary of Non-COPD Medications Started During Treatment in Study MEA117106

ATC Level 1 Ingredient and Ingredient Combinations	PBO (N=90)	100 SC (N=82)	Total (N=172)
CEFTAZIDIME	1 (1%)	0	1 (<1%)
CEFTRIAXONE	1 (1%)	0	1 (<1%)
CEFUROXIME	0	1 (1%)	1 (<1%)
CEFUROXIME SODIUM	1 (1%)	0	1 (<1%)
CILASTATIN+IMIPENEM	1 (1%)	0	1 (<1%)
COLISTIN	1 (1%)	0	1 (<1%)
DIPHTHERIA TOXOID+PERTUSSIS TOXOID+TETANUS TOXOID	1 (1%)	0	1 (<1%)
ERYTHROMYCIN	0	1 (1%)	1 (<1%)
FUGENTIN (NOS)	0	1 (1%)	1 (<1%)
FUSIDATE SODIUM	1 (1%)	0	1 (<1%)
FUSIDIC ACID	1 (1%)	0	1 (<1%)
HEPATITIS A VACCINE+HEPATITIS B VACCINE	0	1 (1%)	1 (<1%)
IMMUNOGLOBULIN HUMAN ANTI-TETANUS	0	1 (1%)	1 (<1%)
INOSINE PRANOBEX	1 (1%)	0	1 (<1%)
MEROPENEM	1 (1%)	0	1 (<1%)
METRONIDAZOLE	0	1 (1%)	1 (<1%)
MICONAZOLE	0	1 (1%)	1 (<1%)
MOXIFLOXACIN HYDROCHLORIDE	1 (1%)	0	1 (<1%)
MUPIROCIN	1 (1%)	0	1 (<1%)
PIPERACILLIN SODIUM+TAZOBACTAM SODIUM	0	1 (1%)	1 (<1%)
PIPERACILLIN+TAZOBACTAM	1 (1%)	0	1 (<1%)
PRISTINAMYCIN	1 (1%)	0	1 (<1%)
ROXITHROMYCIN	0	1 (1%)	1 (<1%)
SULFACETAMIDE SODIUM	0	1 (1%)	1 (<1%)
TILORONE HYDROCHLORIDE	0	1 (1%)	1 (<1%)
TOBRAMYCIN	1 (1%)	0	1 (<1%)
VANCOMYCIN	1 (1%)	0	1 (<1%)
VARICELLA ZOSTER VIRUS VACCINE, LIVE, OKA STRAIN	0	1 (1%)	1 (<1%)
NERVOUS SYSTEM			

Note: A medication may be included in more than one ATC Level category and appear more than once.
Includes medications started after first dose and before last dose + 28 days.

Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Table 111.22

Summary of Non-COPD Medications Started During Treatment in Study MEA117106

ATC Level 1 Ingredient and Ingredient Combinations	PBO (N=90)	100 SC (N=82)	Total (N=172)
Any medication	42 (47%)	31 (38%)	73 (42%)
PARACETAMOL	24 (27%)	9 (11%)	33 (19%)
ACETYLSALICYLIC ACID	8 (9%)	2 (2%)	10 (6%)
IBUPROFEN	6 (7%)	3 (4%)	9 (5%)
PANADOL (NOS)	2 (2%)	3 (4%)	5 (3%)
ALPRAZOLAM	2 (2%)	2 (2%)	4 (2%)
CODEINE PHOSPHATE+PARACETAMOL	2 (2%)	2 (2%)	4 (2%)
OXYCODONE HYDROCHLORIDE	3 (3%)	1 (1%)	4 (2%)
GABAPENTIN	1 (1%)	2 (2%)	3 (2%)
LORAZEPAM	1 (1%)	2 (2%)	3 (2%)
TRAMADOL	2 (2%)	1 (1%)	3 (2%)
TRAMADOL HYDROCHLORIDE	2 (2%)	1 (1%)	3 (2%)
ATARAX (NOS)	1 (1%)	1 (1%)	2 (1%)
DIAZEPAM	1 (1%)	1 (1%)	2 (1%)
FENTANYL	1 (1%)	1 (1%)	2 (1%)
HYDROMORPHONE HYDROCHLORIDE	0	2 (2%)	2 (1%)
LIDOCAINE	1 (1%)	1 (1%)	2 (1%)
MORPHINE	2 (2%)	0	2 (1%)
PREGABALIN	1 (1%)	1 (1%)	2 (1%)
PROPOFOL	1 (1%)	1 (1%)	2 (1%)
TRAZODONE	2 (2%)	0	2 (1%)
ACETYLSALICYLATE LYSINE	0	1 (1%)	1 (<1%)
ACETYLSALICYLIC ACID+CAFFEINE	0	1 (1%)	1 (<1%)
ACETYLSALICYLIC ACID+CAFFEINE+PARACETAMOL	0	1 (1%)	1 (<1%)
BETAHISTINE	0	1 (1%)	1 (<1%)
BUPIVACAINE	0	1 (1%)	1 (<1%)
CAFFEINE+CODEINE PHOSPHATE+PARACETAMOL	1 (1%)	0	1 (<1%)
CAFFEINE+PARACETAMOL	0	1 (1%)	1 (<1%)
CINNARIZINE	0	1 (1%)	1 (<1%)
CITALOPRAM	0	1 (1%)	1 (<1%)
CLONAZEPAM	0	1 (1%)	1 (<1%)

Note: A medication may be included in more than one ATC Level category and appear more than once.
Includes medications started after first dose and before last dose + 28 days.
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Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Table 111.22

Summary of Non-COPD Medications Started During Treatment in Study MEA117106

ATC Level 1 Ingredient and Ingredient Combinations	PBO (N=90)	100 SC (N=82)	Total (N=172)
CLONIDINE	1 (1%)	0	1 (<1%)
CODEINE	1 (1%)	0	1 (<1%)
DIPOTASSIUM CLORAZEPATE	1 (1%)	0	1 (<1%)
ESCITALOPRAM OXALATE	0	1 (1%)	1 (<1%)
ETOMIDATE SULFATE	1 (1%)	0	1 (<1%)
HALOPERIDOL	1 (1%)	0	1 (<1%)
HYDROXYZINE	1 (1%)	0	1 (<1%)
HYDROXYZINE HYDROCHLORIDE	1 (1%)	0	1 (<1%)
HYOSCINE	0	1 (1%)	1 (<1%)
KETOROLAC TROMETAMOL	1 (1%)	0	1 (<1%)
LEVETIRACETAM	0	1 (1%)	1 (<1%)
MEFENAMIC ACID	1 (1%)	0	1 (<1%)
METAMIZOLE MAGNESIUM	1 (1%)	0	1 (<1%)
METOCLOPRAMIDE HYDROCHLORIDE+PARACETAMOL	1 (1%)	0	1 (<1%)
MIDAZOLAM	0	1 (1%)	1 (<1%)
MIRTAZAPINE	0	1 (1%)	1 (<1%)
NALOXONE HYDROCHLORIDE+OXYCODONE HYDROCHLORIDE	0	1 (1%)	1 (<1%)
NICOTINE	1 (1%)	0	1 (<1%)
NOVALGIN NOS	1 (1%)	0	1 (<1%)
OXYCODONE	0	1 (1%)	1 (<1%)
OXYCODONE HYDROCHLORIDE+PARACETAMOL	1 (1%)	0	1 (<1%)
OXYCODONE+PARACETAMOL	0	1 (1%)	1 (<1%)
PARACETAMOL+TRAMADOL	0	1 (1%)	1 (<1%)
PARACETAMOL+TRAMADOL HYDROCHLORIDE	1 (1%)	0	1 (<1%)
PERAZINE DIMALEATE	1 (1%)	0	1 (<1%)
PIRACETAM	0	1 (1%)	1 (<1%)
PIRITRAMIDE	0	1 (1%)	1 (<1%)
PYRALGIN (NOS)	1 (1%)	0	1 (<1%)
ROPIVACAINE	1 (1%)	0	1 (<1%)
TEMAZEPAM	1 (1%)	0	1 (<1%)
VARENICLINE TARTRATE	0	1 (1%)	1 (<1%)

Note: A medication may be included in more than one ATC Level category and appear more than once.
Includes medications started after first dose and before last dose + 28 days.

Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Table 111.22

Summary of Non-COPD Medications Started During Treatment in Study MEA117106

ATC Level 1 Ingredient and Ingredient Combinations	PBO (N=90)	100 SC (N=82)	Total (N=172)
VENLAFAXINE HYDROCHLORIDE	0	1 (1%)	1 (<1%)
ALIMENTARY TRACT AND METABOLISM			
Any medication	39 (43%)	30 (37%)	69 (40%)
ACETYLSALICYLIC ACID	8 (9%)	2 (2%)	10 (6%)
OMEPRAZOLE	5 (6%)	5 (6%)	10 (6%)
PANTOPRAZOLE	3 (3%)	2 (2%)	5 (3%)
PREDNISONE	2 (2%)	3 (4%)	5 (3%)
SODIUM CHLORIDE	4 (4%)	1 (1%)	5 (3%)
ESOMEPRAZOLE MAGNESIUM	3 (3%)	1 (1%)	4 (2%)
POTASSIUM CHLORIDE	2 (2%)	2 (2%)	4 (2%)
BETAMETHASONE	2 (2%)	1 (1%)	3 (2%)
CALCIUM CARBONATE	2 (2%)	1 (1%)	3 (2%)
DEXAMETHASONE	1 (1%)	2 (2%)	3 (2%)
INSULIN GLARGINE	1 (1%)	2 (2%)	3 (2%)
INSULIN HUMAN	2 (2%)	1 (1%)	3 (2%)
NYSTATIN	1 (1%)	2 (2%)	3 (2%)
PREDNISOLONE	3 (3%)	0	3 (2%)
VITAMIN D NOS	2 (2%)	1 (1%)	3 (2%)
DEXLANSOPRAZOLE	1 (1%)	1 (1%)	2 (1%)
DIMENHYDRINATE	1 (1%)	1 (1%)	2 (1%)
GAVISCON NOS	1 (1%)	1 (1%)	2 (1%)
INSULIN ASPART	0	2 (2%)	2 (1%)
INSULIN DETEMIR	1 (1%)	1 (1%)	2 (1%)
INSULIN HUMAN INJECTION (ISOPHANE)	1 (1%)	1 (1%)	2 (1%)
INSULIN LISPRO	1 (1%)	1 (1%)	2 (1%)
LANSOPRAZOLE	1 (1%)	1 (1%)	2 (1%)
MACROGOL+POTASSIUM CHLORIDE+SODIUM BICARBONATE+SODIUM CHLORIDE	2 (2%)	0	2 (1%)
METOCLOPRAMIDE	1 (1%)	1 (1%)	2 (1%)
PROTONIX (NOS)	2 (2%)	0	2 (1%)

Note: A medication may be included in more than one ATC Level category and appear more than once.
Includes medications started after first dose and before last dose + 28 days.
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Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Table 111.22

Summary of Non-COPD Medications Started During Treatment in Study MEA117106

ATC Level 1 Ingredient and Ingredient Combinations	PBO (N=90)	100 SC (N=82)	Total (N=172)
VITAMINS NOS	2 (2%)	0	2 (1%)
ACETYLSALICYLATE LYSINE	0	1 (1%)	1 (<1%)
BIOTIN	1 (1%)	0	1 (<1%)
BUDESONIDE	1 (1%)	0	1 (<1%)
CALCIUM	1 (1%)	0	1 (<1%)
CALCIUM CARBONATE+COLECALCIFEROL+COPPER SULFATE+MAGNESIUM OXIDE+MANGANESE SULFATE+ZINC OXIDE	1 (1%)	0	1 (<1%)
CALCIUM CARBONATE+COLECALCIFEROL+FERROUS FUMARATE+MAGNESIUM OXIDE+MANGANESE SULFATE	1 (1%)	0	1 (<1%)
CALCIUM GLUCONATE	1 (1%)	0	1 (<1%)
CALCIUM+COLECALCIFEROL	1 (1%)	0	1 (<1%)
CETALKONIUM CHLORIDE+CHOLINE SALICYLATE	1 (1%)	0	1 (<1%)
CHLORHEXIDINE GLUCONATE	1 (1%)	0	1 (<1%)
CHOLINE	1 (1%)	0	1 (<1%)
ALFOSCERATE+CYANOCOBALAMIN+NICOTINAMIDE+PYRIDOXINE HYDROCHLORIDE+RIBOFLAVIN+THIAMINE NITRATE+TOCOPHERYL ACETATE	0	1 (1%)	1 (<1%)
CINNARIZINE	1 (1%)	0	1 (<1%)
COLISTIN	0	1 (1%)	1 (<1%)
DOCUSATE SODIUM	0	1 (1%)	1 (<1%)
DOCUSATE SODIUM+SENNA	1 (1%)	0	1 (<1%)
DOCUSATE SODIUM+SENNOSIDES	0	1 (1%)	1 (<1%)
DOMPERIDONE	1 (1%)	0	1 (<1%)
ELECTROLYTES NOS+MACROGOL	1 (1%)	0	1 (<1%)
GALVUS (NOS)	0	1 (1%)	1 (<1%)
HYOSCINE	1 (1%)	0	1 (<1%)
HYOSCINE BUTYLBROMIDE	1 (1%)	0	1 (<1%)
INSULIN HUMAN SEMISYNTHETIC	0	1 (1%)	1 (<1%)
INSULIN HUMAN+INSULIN ISOPHANE, HUMAN BIOSYNTHETIC			

Note: A medication may be included in more than one ATC Level category and appear more than once.
Includes medications started after first dose and before last dose + 28 days.
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Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Table 111.22

Summary of Non-COPD Medications Started During Treatment in Study MEA117106

ATC Level 1 Ingredient and Ingredient Combinations	PBO (N=90)	100 SC (N=82)	Total (N=172)
INSULIN NOS	0	1 (1%)	1 (<1%)
LACTOBACILLUS ACIDOPHILUS+LACTOBACILLUS RHAMNOSUS	1 (1%)	0	1 (<1%)
LACTULOSE	1 (1%)	0	1 (<1%)
LIQUID PARAFFIN	1 (1%)	0	1 (<1%)
LOMOTIL NOS	0	1 (1%)	1 (<1%)
MACROGOL	0	1 (1%)	1 (<1%)
MACROGOL+POTASSIUM CHLORIDE+SODIUM BICARBONATE+SODIUM CHLORIDE+SODIUM SULFATE	1 (1%)	0	1 (<1%)
MAGNESIUM GLUCEPTATE	0	1 (1%)	1 (<1%)
MAGNESIUM SULFATE	1 (1%)	0	1 (<1%)
METFORMIN	1 (1%)	0	1 (<1%)
METRONIDAZOLE	0	1 (1%)	1 (<1%)
MICONAZOLE	0	1 (1%)	1 (<1%)
MINERALS NOS+VITAMINS NOS	1 (1%)	0	1 (<1%)
NIZATIDINE	0	1 (1%)	1 (<1%)
ONDANSETRON	0	1 (1%)	1 (<1%)
ORLISTAT	0	1 (1%)	1 (<1%)
PANTOPRAZOLE SODIUM	0	1 (1%)	1 (<1%)
POTASSIUM BITARTRATE+SODIUM BICARBONATE	1 (1%)	0	1 (<1%)
POTASSIUM PHOSPHATE DIBASIC	1 (1%)	0	1 (<1%)
RABEPRAZOLE	0	1 (1%)	1 (<1%)
RANITIDINE HYDROCHLORIDE	1 (1%)	0	1 (<1%)
SENNA	0	1 (1%)	1 (<1%)
SILYBUM MARIANUM EXTRACT	1 (1%)	0	1 (<1%)
SMECTITE	0	1 (1%)	1 (<1%)
SODIUM BICARBONATE	1 (1%)	0	1 (<1%)
SODIUM BICARBONATE+SODIUM CHLORIDE	0	1 (1%)	1 (<1%)
SORBITOL	1 (1%)	0	1 (<1%)
STEROIDS NOS	1 (1%)	0	1 (<1%)
TAURINE	0	1 (1%)	1 (<1%)

Note: A medication may be included in more than one ATC Level category and appear more than once.
Includes medications started after first dose and before last dose + 28 days.
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Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Table 111.22

Summary of Non-COPD Medications Started During Treatment in Study MEA117106

ATC Level 1 Ingredient and Ingredient Combinations	PBO (N=90)	100 SC (N=82)	Total (N=172)
TRIAMCINOLONE ACETONIDE	0	1 (1%)	1 (<1%)
TRIMEBUTINE	1 (1%)	0	1 (<1%)
VANCOMYCIN	1 (1%)	0	1 (<1%)
VERTIGO-VOMEX (NOS)	0	1 (1%)	1 (<1%)
VITAMIN B SUBSTANCES NOS	0	1 (1%)	1 (<1%)
SENSORY ORGANS			
Any medication	26 (29%)	28 (34%)	54 (31%)
DICLOFENAC	2 (2%)	7 (9%)	9 (5%)
CIPROFLOXACIN	3 (3%)	3 (4%)	6 (3%)
LEVOFLOXACIN	3 (3%)	2 (2%)	5 (3%)
SODIUM CHLORIDE	4 (4%)	1 (1%)	5 (3%)
ACYCLOVIR	1 (1%)	2 (2%)	3 (2%)
DEXAMETHASONE	1 (1%)	2 (2%)	3 (2%)
MOXIFLOXACIN	2 (2%)	1 (1%)	3 (2%)
PREDNISOLONE	3 (3%)	0	3 (2%)
CIPROFLOXACIN HYDROCHLORIDE	1 (1%)	1 (1%)	2 (1%)
CLIOQUINOL+FLUMETASONE PIVALATE	0	2 (2%)	2 (1%)
CORTISONE	1 (1%)	1 (1%)	2 (1%)
HEPARIN (NOS)	1 (1%)	1 (1%)	2 (1%)
LIDOCAINE	1 (1%)	1 (1%)	2 (1%)
METHYLPREDNISOLONE SODIUM SUCCINATE	0	2 (2%)	2 (1%)
ACETYLCYSTEINE	0	1 (1%)	1 (<1%)
AMIKACIN	1 (1%)	0	1 (<1%)
AMPICILLIN	0	1 (1%)	1 (<1%)
BACITRACIN	1 (1%)	0	1 (<1%)
BACITRACIN ZINC+POLYMYXIN B SULFATE	1 (1%)	0	1 (<1%)
CHLORHEXIDINE GLUCONATE	1 (1%)	0	1 (<1%)
CLOBETASONE BUTYRATE	0	1 (1%)	1 (<1%)
CLONIDINE	1 (1%)	0	1 (<1%)
CORTICOSTEROID NOS	0	1 (1%)	1 (<1%)

Note: A medication may be included in more than one ATC Level category and appear more than once.
Includes medications started after first dose and before last dose + 28 days.
/mnt/code/postcsr_01/prod/tfls/t_sp_cm_ncopd_on_106.sas 21JUL2025 22:03

Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Table 111.22

Summary of Non-COPD Medications Started During Treatment in Study MEA117106

ATC Level 1 Ingredient and Ingredient Combinations	PBO (N=90)	100 SC (N=82)	Total (N=172)
ERYTHROMYCIN	0	1 (1%)	1 (<1%)
FLUDROCORTISONE+GRAMICIDIN+NEOMYCIN	0	1 (1%)	1 (<1%)
FUSIDATE SODIUM	1 (1%)	0	1 (<1%)
FUSIDIC ACID	1 (1%)	0	1 (<1%)
HEPARIN SODIUM	0	1 (1%)	1 (<1%)
HYDROCORTISONE	0	1 (1%)	1 (<1%)
HYOSCINE	0	1 (1%)	1 (<1%)
HYOSCINE BUTYLBROMIDE	1 (1%)	0	1 (<1%)
KETOROLAC TROMETAMOL	1 (1%)	0	1 (<1%)
LEVOCABASTINE	1 (1%)	0	1 (<1%)
LIQUID PARAFFIN	1 (1%)	0	1 (<1%)
MACROGOL	0	1 (1%)	1 (<1%)
MICONAZOLE	0	1 (1%)	1 (<1%)
MOXIFLOXACIN HYDROCHLORIDE	1 (1%)	0	1 (<1%)
PIROXICAM	0	1 (1%)	1 (<1%)
SULFACETAMIDE SODIUM	0	1 (1%)	1 (<1%)
TOBRAMYCIN	1 (1%)	0	1 (<1%)
TRAVOPROST	0	1 (1%)	1 (<1%)
TRIAMCINOLONE ACETONIDE	0	1 (1%)	1 (<1%)
XYLOMETAZOLINE HYDROCHLORIDE	0	1 (1%)	1 (<1%)
RESPIRATORY SYSTEM			
Any medication	27 (30%)	24 (29%)	51 (30%)
LORATADINE	1 (1%)	4 (5%)	5 (3%)
SODIUM CHLORIDE	4 (4%)	1 (1%)	5 (3%)
IBUPROFEN+PSEUDOEPHEDRINE HYDROCHLORIDE	2 (2%)	2 (2%)	4 (2%)
BENADRYL (NOS)	2 (2%)	1 (1%)	3 (2%)
BETAMETHASONE	2 (2%)	1 (1%)	3 (2%)
CETIRIZINE HYDROCHLORIDE	1 (1%)	2 (2%)	3 (2%)
DEXAMETHASONE	1 (1%)	2 (2%)	3 (2%)
PREDNISOLONE	3 (3%)	0	3 (2%)

Note: A medication may be included in more than one ATC Level category and appear more than once.
Includes medications started after first dose and before last dose + 28 days.
/mnt/code/postcsr_01/prod/tfls/t_sp_cm_ncopd_on_106.sas 21JUL2025 22:03

Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Table 111.22

Summary of Non-COPD Medications Started During Treatment in Study MEA117106

ATC Level 1 Ingredient and Ingredient Combinations	PBO (N=90)	100 SC (N=82)	Total (N=172)
CETIRIZINE	1 (1%)	1 (1%)	2 (1%)
DEXTROMETHORPHAN HYDROBROMIDE+GUAIFENESIN	2 (2%)	0	2 (1%)
DEXTROMETHORPHAN HYDROBROMIDE+PARACETAMOL+PSEUDOEPHEDRINE HYDROCHLORIDE	1 (1%)	1 (1%)	2 (1%)
DIMENHYDRINATE	1 (1%)	1 (1%)	2 (1%)
ERDOSTEINE	0	2 (2%)	2 (1%)
FLUTICASONE FUROATE	2 (2%)	0	2 (1%)
LEVODROPROPIZINE	1 (1%)	1 (1%)	2 (1%)
LIDOCAINE	1 (1%)	1 (1%)	2 (1%)
MOMETASONE FUROATE	0	2 (2%)	2 (1%)
ROBITUSSIN (NOS)	1 (1%)	1 (1%)	2 (1%)
ACETYLCYSTEINE	0	1 (1%)	1 (<1%)
AERIUS (NOS)	1 (1%)	0	1 (<1%)
AMANTADINE+CAFFEINE+CHLORPHENAMINE+PARACETAMOL	0	1 (1%)	1 (<1%)
AMBROXOL	1 (1%)	0	1 (<1%)
AMBROXOL HYDROCHLORIDE	0	1 (1%)	1 (<1%)
AMMONIUM CARBONATE+CAMPHOR+LEVOMENTHOL+POTASSIUM BICARBONATE	1 (1%)	0	1 (<1%)
AZELASTINE HYDROCHLORIDE+FLUTICASONE PROPIONATE	0	1 (1%)	1 (<1%)
BACITRACIN	1 (1%)	0	1 (<1%)
BILASTINE	1 (1%)	0	1 (<1%)
BUDESONIDE	1 (1%)	0	1 (<1%)
CARBOCISTEINE	0	1 (1%)	1 (<1%)
CETIRIZINE HYDROCHLORIDE+PSEUDOEPHEDRINE HYDROCHLORIDE	0	1 (1%)	1 (<1%)
CETIRIZINE+PSEUDOEPHEDRINE	1 (1%)	0	1 (<1%)
CHLORHEXIDINE GLUCONATE	1 (1%)	0	1 (<1%)
CHLORPHENAMINE MALEATE	1 (1%)	0	1 (<1%)

Note: A medication may be included in more than one ATC Level category and appear more than once.
Includes medications started after first dose and before last dose + 28 days.
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Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Table 111.22

Summary of Non-COPD Medications Started During Treatment in Study MEA117106

ATC Level 1 Ingredient and Ingredient Combinations	PBO (N=90)	100 SC (N=82)	Total (N=172)
CHLORPHENAMINE MALEATE+DEXTROMETHORPHAN HYDROBROMIDE+PARACETAMOL+PSEUDOEPHEDRINE HYDROCHLORIDE	1 (1%)	0	1 (<1%)
CODEINE	1 (1%)	0	1 (<1%)
CODIPRONT (NOS)	1 (1%)	0	1 (<1%)
COLDREX (NOS)	1 (1%)	0	1 (<1%)
CORICIDIN (NOS)	0	1 (1%)	1 (<1%)
DAYQUIL (NOS)	1 (1%)	0	1 (<1%)
DEXCHLORPHENIRAMINE MALEATE	1 (1%)	0	1 (<1%)
EBASTINE	1 (1%)	0	1 (<1%)
FEXOFENADINE	0	1 (1%)	1 (<1%)
FEXOFENADINE HYDROCHLORIDE	1 (1%)	0	1 (<1%)
FLONASE (NOS)	1 (1%)	0	1 (<1%)
FLUNISOLIDE	1 (1%)	0	1 (<1%)
GUAIFENESIN	1 (1%)	0	1 (<1%)
GUAIFENESIN+PSEUDOEPHEDRINE HYDROCHLORIDE	1 (1%)	0	1 (<1%)
HEXORAL (NOS)	0	1 (1%)	1 (<1%)
HYDROXYZINE	1 (1%)	0	1 (<1%)
HYDROXYZINE HYDROCHLORIDE	1 (1%)	0	1 (<1%)
LEVOCABASTINE	1 (1%)	0	1 (<1%)
MECLOZINE HYDROCHLORIDE+PYRIDOXINE HYDROCHLORIDE	0	1 (1%)	1 (<1%)
MUPIROCIN	1 (1%)	0	1 (<1%)
PANADOL COLD AND FLU (NOS)	0	1 (1%)	1 (<1%)
PHOLCODINE	0	1 (1%)	1 (<1%)
POVIDONE-IODINE	0	1 (1%)	1 (<1%)
PSEUDOEPHEDRINE HYDROCHLORIDE	1 (1%)	0	1 (<1%)
SALBUTAMOL SULFATE	0	1 (1%)	1 (<1%)
SODIUM BICARBONATE+SODIUM CHLORIDE	0	1 (1%)	1 (<1%)
TERAFLU (NOS)	1 (1%)	0	1 (<1%)
THERAFLU (NOS)	1 (1%)	0	1 (<1%)
TRIAMCINOLONE ACETONIDE	0	1 (1%)	1 (<1%)

Note: A medication may be included in more than one ATC Level category and appear more than once.
Includes medications started after first dose and before last dose + 28 days.
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Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Table 111.22

Summary of Non-COPD Medications Started During Treatment in Study MEA117106

ATC Level 1 Ingredient and Ingredient Combinations	PBO (N=90)	100 SC (N=82)	Total (N=172)
TUSSIONEX (NOS)	1 (1%)	0	1 (<1%)
XYLOMETAZOLINE HYDROCHLORIDE	0	1 (1%)	1 (<1%)
MUSCULO-SKELETAL SYSTEM			
Any medication	24 (27%)	22 (27%)	46 (27%)
ACETYLSALICYLIC ACID	8 (9%)	2 (2%)	10 (6%)
DICLOFENAC	2 (2%)	7 (9%)	9 (5%)
IBUPROFEN	6 (7%)	3 (4%)	9 (5%)
NAPROXEN	1 (1%)	3 (4%)	4 (2%)
KETOPROFEN	1 (1%)	2 (2%)	3 (2%)
MELOXICAM	2 (2%)	1 (1%)	3 (2%)
ALLOPURINOL	2 (2%)	0	2 (1%)
DENOSUMAB	1 (1%)	1 (1%)	2 (1%)
ALENDRONIC ACID	0	1 (1%)	1 (<1%)
ARNICA MONTANA EXTRACT+CALENDULA OFFICINALIS+HYPERICUM PERFORATUM EXTRACT+MELALEUCA ALTERNIFOLIA OIL	0	1 (1%)	1 (<1%)
COLCHICINE	1 (1%)	0	1 (<1%)
DICLOFENAC SODIUM+PRIDINOL MESILATE	0	1 (1%)	1 (<1%)
FEBUXOSTAT	1 (1%)	0	1 (<1%)
IBANDRONIC ACID	1 (1%)	0	1 (<1%)
KETOROLAC TROMETAMOL	1 (1%)	0	1 (<1%)
LORNOXICAM	0	1 (1%)	1 (<1%)
MEFENAMIC ACID	1 (1%)	0	1 (<1%)
METAXALONE	0	1 (1%)	1 (<1%)
NIMESULIDE	1 (1%)	0	1 (<1%)
NISE (NOS)	0	1 (1%)	1 (<1%)
NOVO PROFEN (NOS)	0	1 (1%)	1 (<1%)
PIROXICAM	0	1 (1%)	1 (<1%)
QUININE SULPHATE	0	1 (1%)	1 (<1%)
ROCURONIUM BROMIDE	1 (1%)	0	1 (<1%)

Note: A medication may be included in more than one ATC Level category and appear more than once.
Includes medications started after first dose and before last dose + 28 days.

Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Table 111.22

Summary of Non-COPD Medications Started During Treatment in Study MEA117106

ATC Level 1 Ingredient and Ingredient Combinations	PBO (N=90)	100 SC (N=82)	Total (N=172)
SUXAMETHONIUM CHLORIDE	0	1 (1%)	1 (<1%)
ZOLEDRONIC ACID	0	1 (1%)	1 (<1%)
CARDIOVASCULAR SYSTEM			
Any medication	23 (26%)	22 (27%)	45 (26%)
FUROSEMIDE	7 (8%)	6 (7%)	13 (8%)
ATORVASTATIN CALCIUM	3 (3%)	0	3 (2%)
BETAMETHASONE	2 (2%)	1 (1%)	3 (2%)
BISOPROLOL FUMARATE	2 (2%)	1 (1%)	3 (2%)
DEXAMETHASONE	1 (1%)	2 (2%)	3 (2%)
PREDNISOLONE	3 (3%)	0	3 (2%)
RAMIPRIL	2 (2%)	1 (1%)	3 (2%)
SIMVASTATIN	1 (1%)	2 (2%)	3 (2%)
SPIRONOLACTONE	2 (2%)	1 (1%)	3 (2%)
ALDACTONE (NOS)	2 (2%)	0	2 (1%)
AMIODARONE HYDROCHLORIDE	0	2 (2%)	2 (1%)
AMLODIPINE BESILATE	2 (2%)	0	2 (1%)
ATORVASTATIN	0	2 (2%)	2 (1%)
CANDESARTAN CILEXETIL	0	2 (2%)	2 (1%)
DILTIAZEM	1 (1%)	1 (1%)	2 (1%)
HEPARIN (NOS)	1 (1%)	1 (1%)	2 (1%)
LIDOCAINE	1 (1%)	1 (1%)	2 (1%)
LISINOPRIL	1 (1%)	1 (1%)	2 (1%)
LOSARTAN POTASSIUM	2 (2%)	0	2 (1%)
METOPROLOL	1 (1%)	1 (1%)	2 (1%)
METOPROLOL TARTRATE	1 (1%)	1 (1%)	2 (1%)
PERINDOPRIL	1 (1%)	1 (1%)	2 (1%)
TORASEMIDE	1 (1%)	1 (1%)	2 (1%)
AMILORIDE+HYDROCHLOROTHIAZIDE	1 (1%)	0	1 (<1%)
AMIODARONE	0	1 (1%)	1 (<1%)
BETAHISTINE	0	1 (1%)	1 (<1%)

Note: A medication may be included in more than one ATC Level category and appear more than once.
Includes medications started after first dose and before last dose + 28 days.
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Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Table 111.22

Summary of Non-COPD Medications Started During Treatment in Study MEA117106

ATC Level 1 Ingredient and Ingredient Combinations	PBO (N=90)	100 SC (N=82)	Total (N=172)
BISOPROLOL	0	1 (1%)	1 (<1%)
CARVEDILOL	1 (1%)	0	1 (<1%)
CLONIDINE	1 (1%)	0	1 (<1%)
DAFLON NOS	0	1 (1%)	1 (<1%)
DILTIAZEM HYDROCHLORIDE	0	1 (1%)	1 (<1%)
ENALAPRIL	0	1 (1%)	1 (<1%)
EPLERENONE	1 (1%)	0	1 (<1%)
FLUOCINOLONE ACETONIDE	0	1 (1%)	1 (<1%)
GLYCERYL TRINITRATE	1 (1%)	0	1 (<1%)
HEPARIN SODIUM	0	1 (1%)	1 (<1%)
HYDROCHLOROTHIAZIDE	1 (1%)	0	1 (<1%)
HYDROCORTISONE	0	1 (1%)	1 (<1%)
ISOSORBIDE DINITRATE	0	1 (1%)	1 (<1%)
LABETALOL	0	1 (1%)	1 (<1%)
LOSARTAN	1 (1%)	0	1 (<1%)
METOPROLOL SUCCINATE	0	1 (1%)	1 (<1%)
MOLSIDOMINE	1 (1%)	0	1 (<1%)
NEBIVOLOL HYDROCHLORIDE	1 (1%)	0	1 (<1%)
OLMESARTAN	1 (1%)	0	1 (<1%)
PERINDOPRIL ERBUMINE	1 (1%)	0	1 (<1%)
QUININE SULPHATE	0	1 (1%)	1 (<1%)
ROSUVASTATIN CALCIUM	1 (1%)	0	1 (<1%)
TAURINE	0	1 (1%)	1 (<1%)
TELMISARTAN	1 (1%)	0	1 (<1%)
VALSARTAN	1 (1%)	0	1 (<1%)
DERMATOLOGICALS			
Any medication	19 (21%)	21 (26%)	40 (23%)
ACYCLOVIR	1 (1%)	2 (2%)	3 (2%)
BENADRYL (NOS)	2 (2%)	1 (1%)	3 (2%)
BETAMETHASONE	2 (2%)	1 (1%)	3 (2%)

Note: A medication may be included in more than one ATC Level category and appear more than once.
Includes medications started after first dose and before last dose + 28 days.
/mnt/code/postcsr_01/prod/tfls/t_sp_cm_ncopd_on_106.sas 21JUL2025 22:03

Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Table 111.22

Summary of Non-COPD Medications Started During Treatment in Study MEA117106

ATC Level 1 Ingredient and Ingredient Combinations	PBO (N=90)	100 SC (N=82)	Total (N=172)
CLINDAMYCIN	1 (1%)	2 (2%)	3 (2%)
DEXAMETHASONE	1 (1%)	2 (2%)	3 (2%)
FLUCONAZOLE	2 (2%)	1 (1%)	3 (2%)
NYSTATIN	1 (1%)	2 (2%)	3 (2%)
PREDNISOLONE	3 (3%)	0	3 (2%)
BETAMETHASONE DIPROPIONATE+SALICYLIC ACID	1 (1%)	1 (1%)	2 (1%)
CLIOQUINOL+FLUMETASONE PIVALATE	0	2 (2%)	2 (1%)
CORTISONE	1 (1%)	1 (1%)	2 (1%)
GRAMICIDIN+NEOMYCIN SULFATE+NYSTATIN+TRIAMCINOLONE ACETONIDE	1 (1%)	1 (1%)	2 (1%)
LIDOCAINE	1 (1%)	1 (1%)	2 (1%)
METHYLPREDNISOLONE SODIUM SUCCINATE	0	2 (2%)	2 (1%)
MOMETASONE FUROATE	0	2 (2%)	2 (1%)
ALGINIC ACID+GLUCOSE+GLUCOSE OXIDASE+GUAIACOL+HYPROLOSE+LACTOPEROXIDASE+MACROGOL	1 (1%)	0	1 (<1%)
AMIKACIN	1 (1%)	0	1 (<1%)
BACITRACIN	1 (1%)	0	1 (<1%)
BACITRACIN ZINC+POLYMYXIN B SULFATE	1 (1%)	0	1 (<1%)
BETADERM (NOS)	1 (1%)	0	1 (<1%)
BETAMETHASONE+CALCIPOTRIOL	0	1 (1%)	1 (<1%)
BUDESONIDE	1 (1%)	0	1 (<1%)
CALCIUM GLUCONATE	1 (1%)	0	1 (<1%)
CANESTEN (NOS)	0	1 (1%)	1 (<1%)
CETRIMIDE+CHLORHEXIDINE GLUCONATE	0	1 (1%)	1 (<1%)
CHLORHEXIDINE GLUCONATE	1 (1%)	0	1 (<1%)
CLOBETASONE BUTYRATE	0	1 (1%)	1 (<1%)
DERMATOLOGICALS NOS	0	1 (1%)	1 (<1%)
ERYTHROMYCIN	0	1 (1%)	1 (<1%)
FLONASE (NOS)	1 (1%)	0	1 (<1%)
FLUOCINOLONE ACETONIDE	0	1 (1%)	1 (<1%)

Note: A medication may be included in more than one ATC Level category and appear more than once.
Includes medications started after first dose and before last dose + 28 days.

Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Table 111.22

Summary of Non-COPD Medications Started During Treatment in Study MEA117106

ATC Level 1 Ingredient and Ingredient Combinations	PBO (N=90)	100 SC (N=82)	Total (N=172)
FUSIDATE SODIUM	1 (1%)	0	1 (<1%)
FUSIDIC ACID	1 (1%)	0	1 (<1%)
GLYCERYL TRINITRATE	1 (1%)	0	1 (<1%)
HYDROCORTISONE	0	1 (1%)	1 (<1%)
IODINE	0	1 (1%)	1 (<1%)
ISOSORBIDE DINITRATE	0	1 (1%)	1 (<1%)
LIQUID PARAFFIN	1 (1%)	0	1 (<1%)
LIQUID PARAFFIN+WOOL FAT	0	1 (1%)	1 (<1%)
MAGNESIUM SULFATE	1 (1%)	0	1 (<1%)
METHYLPREDNISOLONE ACETATE	1 (1%)	0	1 (<1%)
METRONIDAZOLE	0	1 (1%)	1 (<1%)
MICONAZOLE	0	1 (1%)	1 (<1%)
MUPIROCIN	1 (1%)	0	1 (<1%)
POVIDONE-IODINE	0	1 (1%)	1 (<1%)
TERBINAFINE HYDROCHLORIDE	1 (1%)	0	1 (<1%)
TRIAMCINOLONE ACETONIDE	0	1 (1%)	1 (<1%)
BLOOD AND BLOOD FORMING ORGANS			
Any medication	18 (20%)	11 (13%)	29 (17%)
ACETYLSALICYLIC ACID	8 (9%)	2 (2%)	10 (6%)
SODIUM CHLORIDE	4 (4%)	1 (1%)	5 (3%)
ENOXAPARIN	2 (2%)	2 (2%)	4 (2%)
POTASSIUM CHLORIDE	2 (2%)	2 (2%)	4 (2%)
DALTEPARIN SODIUM	1 (1%)	2 (2%)	3 (2%)
ENOXAPARIN SODIUM	1 (1%)	2 (2%)	3 (2%)
BEMIPARIN SODIUM	2 (2%)	0	2 (1%)
FOLIC ACID	1 (1%)	1 (1%)	2 (1%)
HEPARIN (NOS)	1 (1%)	1 (1%)	2 (1%)
NADROPARIN CALCIUM	2 (2%)	0	2 (1%)
RIVAROXABAN	2 (2%)	0	2 (1%)
ACETYLSALICYLATE LYSINE	0	1 (1%)	1 (<1%)

Note: A medication may be included in more than one ATC Level category and appear more than once.
Includes medications started after first dose and before last dose + 28 days.
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Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Table 111.22

Summary of Non-COPD Medications Started During Treatment in Study MEA117106

ATC Level 1 Ingredient and Ingredient Combinations	PBO (N=90)	100 SC (N=82)	Total (N=172)
APIXABAN	0	1 (1%)	1 (<1%)
BEMIPARIN	1 (1%)	0	1 (<1%)
CALCIUM CHLORIDE+POTASSIUM CHLORIDE+SODIUM CHLORIDE+SODIUM LACTATE	1 (1%)	0	1 (<1%)
CHLORHEXIDINE GLUCONATE	1 (1%)	0	1 (<1%)
CLOPIDOGREL BISULFATE	1 (1%)	0	1 (<1%)
CYANOCOBALAMIN	1 (1%)	0	1 (<1%)
ETAMSYLATE	1 (1%)	0	1 (<1%)
FERROUS GLUCONATE	1 (1%)	0	1 (<1%)
FERROUS SULPHATE	1 (1%)	0	1 (<1%)
GLUCOSE	1 (1%)	0	1 (<1%)
HEPARIN SODIUM	0	1 (1%)	1 (<1%)
IRON	0	1 (1%)	1 (<1%)
MAGNESIUM SULFATE	1 (1%)	0	1 (<1%)
RED BLOOD CELLS	1 (1%)	0	1 (<1%)
SODIUM BICARBONATE	1 (1%)	0	1 (<1%)
SORBITOL	1 (1%)	0	1 (<1%)
TARDYFERON (NOS)	1 (1%)	0	1 (<1%)
WARFARIN SODIUM	0	1 (1%)	1 (<1%)
GENITO URINARY SYSTEM AND SEX HORMONES			
Any medication	11 (12%)	13 (16%)	24 (14%)
IBUPROFEN	6 (7%)	3 (4%)	9 (5%)
NAPROXEN	1 (1%)	3 (4%)	4 (2%)
CLINDAMYCIN	1 (1%)	2 (2%)	3 (2%)
NYSTATIN	1 (1%)	2 (2%)	3 (2%)
BACITRACIN	1 (1%)	0	1 (<1%)
DUTASTERIDE	0	1 (1%)	1 (<1%)
FESOTERODINE	1 (1%)	0	1 (<1%)
MEGESTROL	1 (1%)	0	1 (<1%)
METRONIDAZOLE	0	1 (1%)	1 (<1%)

Note: A medication may be included in more than one ATC Level category and appear more than once.
Includes medications started after first dose and before last dose + 28 days.

Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Table 111.22

Summary of Non-COPD Medications Started During Treatment in Study MEA117106

ATC Level 1 Ingredient and Ingredient Combinations	PBO (N=90)	100 SC (N=82)	Total (N=172)
MICONAZOLE	0	1 (1%)	1 (<1%)
POVIDONE-IODINE	0	1 (1%)	1 (<1%)
TAMSULOSIN HYDROCHLORIDE	1 (1%)	0	1 (<1%)
SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS			
Any medication	11 (12%)	11 (13%)	22 (13%)
PREDNISONE	2 (2%)	3 (4%)	5 (3%)
BETAMETHASONE	2 (2%)	1 (1%)	3 (2%)
DEXAMETHASONE	1 (1%)	2 (2%)	3 (2%)
PREDNISOLONE	3 (3%)	0	3 (2%)
CORTISONE	1 (1%)	1 (1%)	2 (1%)
METHYLPREDNISOLONE SODIUM SUCCINATE	0	2 (2%)	2 (1%)
BUDESONIDE	1 (1%)	0	1 (<1%)
CORTICOSTEROID NOS	0	1 (1%)	1 (<1%)
CORTIVAZOL	1 (1%)	0	1 (<1%)
DEFLAZACORT	1 (1%)	0	1 (<1%)
HYDROCORTISONE	0	1 (1%)	1 (<1%)
IODINE	0	1 (1%)	1 (<1%)
LEVOTHYROXINE SODIUM	0	1 (1%)	1 (<1%)
METHYLPREDNISOLONE ACETATE	1 (1%)	0	1 (<1%)
TRIAMCINOLONE ACETONIDE	0	1 (1%)	1 (<1%)
VARIOUS			
Any medication	6 (7%)	5 (6%)	11 (6%)
AMBIGUOUS MEDICATION NOS	2 (2%)	0	2 (1%)
COMPRESSED AIR	1 (1%)	1 (1%)	2 (1%)
MEDICATION UNKNOWN	1 (1%)	1 (1%)	2 (1%)
ACETYLCYSTEINE	0	1 (1%)	1 (<1%)
CALCIUM POLYSTYRENE SULFONATE	1 (1%)	0	1 (<1%)
DROMAIUS NOVAEHOLLANDIAE OIL	0	1 (1%)	1 (<1%)

Note: A medication may be included in more than one ATC Level category and appear more than once.
Includes medications started after first dose and before last dose + 28 days.
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Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Table 111.22

Summary of Non-COPD Medications Started During Treatment in Study MEA117106

ATC Level 1 Ingredient and Ingredient Combinations	PBO (N=90)	100 SC (N=82)	Total (N=172)
GLUCOSE	1 (1%)	0	1 (<1%)
IOPAMIDOL	0	1 (1%)	1 (<1%)
MAGNESIUM SULFATE	1 (1%)	0	1 (<1%)
ORIGANUM VULGARE OIL	1 (1%)	0	1 (<1%)
SESAMUM INDICUM OIL	0	1 (1%)	1 (<1%)
SORBITOL	1 (1%)	0	1 (<1%)
ANTIPARASITIC PRODUCTS, INSECTICIDES AND REPELLENTS			
Any medication	0	2 (2%)	2 (1%)
METRONIDAZOLE	0	1 (1%)	1 (<1%)
QUININE SULPHATE	0	1 (1%)	1 (<1%)
ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS			
Any medication	1 (1%)	0	1 (<1%)
BICALUTAMIDE	1 (1%)	0	1 (<1%)
LEUPRORELIN ACETATE	1 (1%)	0	1 (<1%)
MEGESTROL	1 (1%)	0	1 (<1%)

Note: A medication may be included in more than one ATC Level category and appear more than once.
Includes medications started after first dose and before last dose + 28 days.
/mnt/code/postcsr_01/prod/tfls/t_sp_cm_ncopd_on_106.sas 21JUL2025 22:03

Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Table 111.23

Summary of Compliance of eCOA Assessments: CAT

		208657		
Timepoint		PBO (N=401)	100 SC (N=403)	Total (N=804)
Overall	Overall compliance - CAT	96%	96%	96%
Baseline	No. subjects remaining in study	401	403	804
	No. subjects with CAT present	395 (99%)	397 (99%)	792 (99%)
Week 4	No. subjects remaining in study	NA	NA	NA
	No. subjects with CAT present	NA	NA	NA
Week 8	No. subjects remaining in study	NA	NA	NA
	No. subjects with CAT present	NA	NA	NA
Week 12	No. subjects remaining in study	395	398	793
	No. subjects with CAT present	372 (94%)	376 (94%)	748 (94%)
Week 16	No. subjects remaining in study	NA	NA	NA
	No. subjects with CAT present	NA	NA	NA
Week 20	No. subjects remaining in study	NA	NA	NA
	No. subjects with CAT present	NA	NA	NA
Week 24	No. subjects remaining in study	384	389	773
	No. subjects with CAT present	369 (96%)	369 (95%)	738 (95%)
Week 28	No. subjects remaining in study	NA	NA	NA
	No. subjects with CAT present	NA	NA	NA
Week 32	No. subjects remaining in study	NA	NA	NA
	No. subjects with CAT present	NA	NA	NA

NA: No data collection is scheduled at these visits according to the protocol's schedule of activities.
Overall Compliance is calculated as: (Total number of completed eCOAs across all subjects / Total expected number of completed eCOAs across all subjects) x 100.
/mnt/code/postcsr_01/prod/tfls/t_sp_ecoa_cat.sas 21JUL2025 22:03

Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Table 111.23
Summary of Compliance of eCOA Assessments: CAT

		MEA117113		
Timepoint		PBO (N=87)	100 SC (N=83)	Total (N=170)
Overall	Overall compliance - CAT	95%	95%	95%
Baseline	No. subjects remaining in study	87	83	170
	No. subjects with CAT present	85 (98%)	81 (98%)	166 (98%)
Week 4	No. subjects remaining in study	87	83	170
	No. subjects with CAT present	87 (100%)	78 (94%)	165 (97%)
Week 8	No. subjects remaining in study	87	83	170
	No. subjects with CAT present	82 (94%)	80 (96%)	162 (95%)
Week 12	No. subjects remaining in study	85	83	168
	No. subjects with CAT present	81 (95%)	76 (92%)	157 (93%)
Week 16	No. subjects remaining in study	83	83	166
	No. subjects with CAT present	80 (96%)	81 (98%)	161 (97%)
Week 20	No. subjects remaining in study	83	82	165
	No. subjects with CAT present	78 (94%)	78 (95%)	156 (95%)
Week 24	No. subjects remaining in study	81	82	163
	No. subjects with CAT present	77 (95%)	75 (91%)	152 (93%)
Week 28	No. subjects remaining in study	81	80	161
	No. subjects with CAT present	77 (95%)	75 (94%)	152 (94%)
Week 32	No. subjects remaining in study	79	80	159
	No. subjects with CAT present	70 (89%)	76 (95%)	146 (92%)

NA: No data collection is scheduled at these visits according to the protocol's schedule of activities.
Overall Compliance is calculated as: (Total number of completed eCOAs across all subjects / Total expected number of completed eCOAs across all subjects) x 100.
/mnt/code/postcsr_01/prod/tfls/t_sp_ecoa_cat.sas 21JUL2025 22:03

Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Table 111.23
Summary of Compliance of eCOA Assessments: CAT

		MEA117106		
Timepoint		PBO (N=90)	100 SC (N=82)	Total (N=172)
Overall	Overall compliance - CAT	91%	96%	93%
Baseline	No. subjects remaining in study	90	82	172
	No. subjects with CAT present	85 (94%)	80 (98%)	165 (96%)
Week 4	No. subjects remaining in study	90	82	172
	No. subjects with CAT present	86 (96%)	80 (98%)	166 (97%)
Week 8	No. subjects remaining in study	88	81	169
	No. subjects with CAT present	83 (94%)	78 (96%)	161 (95%)
Week 12	No. subjects remaining in study	88	81	169
	No. subjects with CAT present	83 (94%)	79 (98%)	162 (96%)
Week 16	No. subjects remaining in study	88	81	169
	No. subjects with CAT present	81 (92%)	79 (98%)	160 (95%)
Week 20	No. subjects remaining in study	86	81	167
	No. subjects with CAT present	81 (94%)	79 (98%)	160 (96%)
Week 24	No. subjects remaining in study	86	81	167
	No. subjects with CAT present	76 (88%)	77 (95%)	153 (92%)
Week 28	No. subjects remaining in study	86	81	167
	No. subjects with CAT present	75 (87%)	76 (94%)	151 (90%)
Week 32	No. subjects remaining in study	85	81	166
	No. subjects with CAT present	76 (89%)	79 (98%)	155 (93%)

NA: No data collection is scheduled at these visits according to the protocol's schedule of activities.
Overall Compliance is calculated as: (Total number of completed eCOAs across all subjects / Total expected number of completed eCOAs across all subjects) x 100.
/mnt/code/postcsr_01/prod/tfls/t_sp_ecoa_cat.sas 21JUL2025 22:03

Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Table 111.23
Summary of Compliance of eCOA Assessments: CAT

Timepoint		208657 PBO (N=401)	208657 100 SC (N=403)	Total (N=804)
Week 36	No. subjects remaining in study	378	382	760
	No. subjects with CAT present	363 (96%)	367 (96%)	730 (96%)
Week 40	No. subjects remaining in study	NA	NA	NA
	No. subjects with CAT present	NA	NA	NA
Week 44	No. subjects remaining in study	NA	NA	NA
	No. subjects with CAT present	NA	NA	NA
Week 48	No. subjects remaining in study	NA	NA	NA
	No. subjects with CAT present	NA	NA	NA
Week 52	No. subjects remaining in study	364	364	728
	No. subjects with CAT present	342 (94%)	344 (95%)	686 (94%)

NA: No data collection is scheduled at these visits according to the protocol's schedule of activities.
Overall Compliance is calculated as: (Total number of completed eCOAs across all subjects / Total expected number of completed eCOAs across all subjects) x 100.
/mnt/code/postcsr_01/prod/tfls/t_sp_ecoa_cat.sas 21JUL2025 22:03

Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Table 111.23
Summary of Compliance of eCOA Assessments: CAT

Timepoint		MEA117113 PBO (N=87)		MEA117113 100 SC (N=83)		MEA117113 Total (N=170)	
Week 36	No. subjects remaining in study	76		79		155	
	No. subjects with CAT present	72	(95%)	72	(91%)	144	(93%)
Week 40	No. subjects remaining in study	74		79		153	
	No. subjects with CAT present	69	(93%)	75	(95%)	144	(94%)
Week 44	No. subjects remaining in study	73		79		152	
	No. subjects with CAT present	70	(96%)	76	(96%)	146	(96%)
Week 48	No. subjects remaining in study	73		79		152	
	No. subjects with CAT present	68	(93%)	76	(96%)	144	(95%)
Week 52	No. subjects remaining in study	70		78		148	
	No. subjects with CAT present	67	(96%)	74	(95%)	141	(95%)

NA: No data collection is scheduled at these visits according to the protocol's schedule of activities.
Overall Compliance is calculated as: (Total number of completed eCOAs across all subjects / Total expected number of completed eCOAs across all subjects) x 100.

Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Table 111.23

Summary of Compliance of eCOA Assessments: CAT

Timepoint		MEA117106 PBO (N=90)		MEA117106 100 SC (N=82)		MEA117106 Total (N=172)	
Week 36	No. subjects remaining in study	84		80		164	
	No. subjects with CAT present	74	(88%)	73	(91%)	147	(90%)
Week 40	No. subjects remaining in study	84		79		163	
	No. subjects with CAT present	74	(88%)	75	(95%)	149	(91%)
Week 44	No. subjects remaining in study	84		79		163	
	No. subjects with CAT present	75	(89%)	75	(95%)	150	(92%)
Week 48	No. subjects remaining in study	84		79		163	
	No. subjects with CAT present	74	(88%)	77	(97%)	151	(93%)
Week 52	No. subjects remaining in study	81		78		159	
	No. subjects with CAT present	74	(91%)	73	(94%)	147	(92%)

NA: No data collection is scheduled at these visits according to the protocol's schedule of activities.
Overall Compliance is calculated as: (Total number of completed eCOAs across all subjects / Total expected number of completed eCOAs across all subjects) x 100.
/mnt/code/postcsr_01/prod/tfls/t_sp_ecoa_cat.sas 21JUL2025 22:03

Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Table 111.24

Summary of Compliance of eCOA Assessments: SGRQ

		208657		
Timepoint		PBO (N=401)	100 SC (N=403)	Total (N=804)
Overall	Overall compliance - SGRQ	95%	95%	95%
Baseline	No. subjects remaining in study	401	403	804
	No. subjects with SGRQ present	394 (98%)	397 (99%)	791 (98%)
Week 12	No. subjects remaining in study	395	398	793
	No. subjects with SGRQ present	370 (94%)	374 (94%)	744 (94%)
Week 24	No. subjects remaining in study	384	389	773
	No. subjects with SGRQ present	369 (96%)	367 (94%)	736 (95%)
Week 36	No. subjects remaining in study	378	382	760
	No. subjects with SGRQ present	360 (95%)	367 (96%)	727 (96%)
Week 52	No. subjects remaining in study	364	364	728
	No. subjects with SGRQ present	341 (94%)	343 (94%)	684 (94%)

Overall Compliance is calculated as: (Total number of completed eCOAs across all subjects / Total expected number of completed eCOAs across all subjects) x 100.

Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Table 111.24

Summary of Compliance of eCOA Assessments: SGRQ

		MEA117113		
Timepoint		PBO (N=87)	100 SC (N=83)	Total (N=170)
Overall	Overall compliance - SGRQ	98%	96%	97%
Baseline	No. subjects remaining in study	87	83	170
	No. subjects with SGRQ present	86 (99%)	83 (100%)	169 (>99%)
Week 12	No. subjects remaining in study	85	83	168
	No. subjects with SGRQ present	83 (98%)	80 (96%)	163 (97%)
Week 24	No. subjects remaining in study	81	82	163
	No. subjects with SGRQ present	79 (98%)	75 (91%)	154 (94%)
Week 36	No. subjects remaining in study	76	79	155
	No. subjects with SGRQ present	73 (96%)	75 (95%)	148 (95%)
Week 52	No. subjects remaining in study	72	79	151
	No. subjects with SGRQ present	70 (97%)	75 (95%)	145 (96%)

Overall Compliance is calculated as: (Total number of completed eCOAs across all subjects / Total expected number of completed eCOAs across all subjects) x 100.

/mnt/code/postcsr_01/prod/tfls/t_sp_ecoa_sgrq.sas 21JUL2025 22:04

Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Table 111.24

Summary of Compliance of eCOA Assessments: SGRQ

		MEA117106		
Timepoint		PBO (N=90)	100 SC (N=82)	Total (N=172)
Overall	Overall compliance - SGRQ	93%	97%	95%
Baseline	No. subjects remaining in study	90	82	172
	No. subjects with SGRQ present	88 (98%)	80 (98%)	168 (98%)
Week 12	No. subjects remaining in study	88	82	170
	No. subjects with SGRQ present	83 (94%)	81 (99%)	164 (96%)
Week 24	No. subjects remaining in study	87	81	168
	No. subjects with SGRQ present	80 (92%)	78 (96%)	158 (94%)
Week 36	No. subjects remaining in study	84	80	164
	No. subjects with SGRQ present	75 (89%)	76 (95%)	151 (92%)
Week 52	No. subjects remaining in study	81	79	160
	No. subjects with SGRQ present	75 (93%)	78 (99%)	153 (96%)

Overall Compliance is calculated as: (Total number of completed eCOAs across all subjects / Total expected number of completed eCOAs across all subjects) x 100.

/mnt/code/postcsr_01/prod/tfls/t_sp_ecoa_sgrq.sas 21JUL2025 22:04

Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Table 111.25

Summary of Compliance of eCOA Assessments: E-RS: COPD (Study 208657)

Timepoint		PBO (N=401)	100 SC (N=403)	Total (N=804)
Overall	Overall compliance - E-RS: COPD	96%	96%	96%
Baseline	No. subjects remaining in study	401	403	804
	No. subjects with E-RS: COPD present	399 (>99%)	403 (100%)	802 (>99%)
Weeks 1-4	No. subjects remaining in study	401	403	804
	No. subjects with E-RS: COPD present	390 (97%)	400 (>99%)	790 (98%)
Weeks 5-8	No. subjects remaining in study	399	401	800
	No. subjects with E-RS: COPD present	386 (97%)	392 (98%)	778 (97%)
Weeks 9-12	No. subjects remaining in study	394	399	793
	No. subjects with E-RS: COPD present	386 (98%)	390 (98%)	776 (98%)
Weeks 13-16	No. subjects remaining in study	391	396	787
	No. subjects with E-RS: COPD present	375 (96%)	381 (96%)	756 (96%)
Weeks 17-20	No. subjects remaining in study	387	392	779
	No. subjects with E-RS: COPD present	370 (96%)	374 (95%)	744 (96%)
Weeks 21-24	No. subjects remaining in study	385	389	774
	No. subjects with E-RS: COPD present	363 (94%)	367 (94%)	730 (94%)
Weeks 25-28	No. subjects remaining in study	380	387	767
	No. subjects with E-RS: COPD present	358 (94%)	363 (94%)	721 (94%)
Weeks 29-32	No. subjects remaining in study	376	384	760
	No. subjects with E-RS: COPD present	362 (96%)	366 (95%)	728 (96%)

Subjects must complete assessments on at least 16 days within a visit cycle to be considered compliant for that visit.

Overall Compliance is calculated as: (Total number of completed eCOAs across all subjects / Total expected number of completed eCOAs across all subjects) x 100.

/mnt/code/postcsr_01/prod/tfls/t_sp_ecoa_copd.sas 21JUL2025 22:03

Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Table 111.25

Summary of Compliance of eCOA Assessments: E-RS: COPD (Study 208657)

Timepoint		PBO (N=401)		100 SC (N=403)		Total (N=804)	
Weeks 33-36	No. subjects remaining in study	375		382		757	
	No. subjects with E-RS: COPD present	356	(95%)	360	(94%)	716	(95%)
Weeks 37-40	No. subjects remaining in study	375		376		751	
	No. subjects with E-RS: COPD present	361	(96%)	353	(94%)	714	(95%)
Weeks 41-44	No. subjects remaining in study	373		373		746	
	No. subjects with E-RS: COPD present	355	(95%)	347	(93%)	702	(94%)
Weeks 45-48	No. subjects remaining in study	366		369		735	
	No. subjects with E-RS: COPD present	347	(95%)	348	(94%)	695	(95%)
Weeks 49-52	No. subjects remaining in study	363		366		729	
	No. subjects with E-RS: COPD present	331	(91%)	338	(92%)	669	(92%)

Subjects must complete assessments on at least 16 days within a visit cycle to be considered compliant for that visit.
Overall Compliance is calculated as: (Total number of completed eCOAs across all subjects / Total expected number of completed eCOAs across all subjects) x 100.

Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Table 111.26

Summary of Compliance of eCOA Assessments: EQ-5D VAS

		208657		
Timepoint		PBO (N=401)	100 SC (N=403)	Total (N=804)
Overall	Overall compliance - EQ-5D	96%	95%	96%
Baseline	No. subjects remaining in study	401	403	804
	No. subjects with EQ-5D present	394 (98%)	396 (98%)	790 (98%)
Week 24	No. subjects remaining in study	388	392	780
	No. subjects with EQ-5D present	374 (96%)	367 (94%)	741 (95%)
Week 52	No. subjects remaining in study	367	370	737
	No. subjects with EQ-5D present	344 (94%)	347 (94%)	691 (94%)

Overall Compliance is calculated as: (Total number of completed eCOAs across all subjects / Total expected number of completed eCOAs across all subjects) x 100.

Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Table 111.26
Summary of Compliance of eCOA Assessments: EQ-5D VAS

		MEA117113		
Timepoint		PBO (N=87)	100 SC (N=83)	Total (N=170)
Overall	Overall compliance - EQ-5D	98%	95%	96%
Baseline	No. subjects remaining in study	87	83	170
	No. subjects with EQ-5D present	86 (99%)	80 (96%)	166 (98%)
Week 24	No. subjects remaining in study	83	82	165
	No. subjects with EQ-5D present	80 (96%)	77 (94%)	157 (95%)
Week 52	No. subjects remaining in study	72	79	151
	No. subjects with EQ-5D present	70 (97%)	75 (95%)	145 (96%)

Overall Compliance is calculated as: (Total number of completed eCOAs across all subjects / Total expected number of completed eCOAs across all subjects) x 100.

Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Table 111.26

Summary of Compliance of eCOA Assessments: EQ-5D VAS

Timepoint		MEA117106 PBO (N=90)	MEA117106 100 SC (N=82)	MEA117106 Total (N=172)
Overall	Overall compliance - EQ-5D	93%	95%	94%
Baseline	No. subjects remaining in study	90	82	172
	No. subjects with EQ-5D present	85 (94%)	78 (95%)	163 (95%)
Week 24	No. subjects remaining in study	87	82	169
	No. subjects with EQ-5D present	81 (93%)	78 (95%)	159 (94%)
Week 52	No. subjects remaining in study	82	79	161
	No. subjects with EQ-5D present	75 (91%)	74 (94%)	149 (93%)

Overall Compliance is calculated as: (Total number of completed eCOAs across all subjects / Total expected number of completed eCOAs across all subjects) x 100.

Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Table 111.27

Summary of Compliance of eCOA Assessments: PGI-C (Study 208657)

Timepoint		PBO (N=401)	100 SC (N=403)	Total (N=804)
Overall	Overall compliance - PGI-C	92%	91%	92%
Week 8	No. subjects remaining in study	393	393	786
	No. subjects with PGI-C present	358 (91%)	355 (90%)	713 (91%)
Week 20	No. subjects remaining in study	390	393	783
	No. subjects with PGI-C present	361 (93%)	360 (92%)	721 (92%)
Week 32	No. subjects remaining in study	383	387	770
	No. subjects with PGI-C present	351 (92%)	356 (92%)	707 (92%)
Week 44	No. subjects remaining in study	374	380	754
	No. subjects with PGI-C present	342 (91%)	345 (91%)	687 (91%)
Week 52	No. subjects remaining in study	362	364	726
	No. subjects with PGI-C present	336 (93%)	337 (93%)	673 (93%)

Overall Compliance is calculated as: (Total number of completed eCOAs across all subjects / Total expected number of completed eCOAs across all subjects) x 100.

Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Table 111.28

Summary of Compliance of eCOA Assessments: PGI-S (Study 208657)

Timepoint		PBO (N=401)	100 SC (N=403)	Total (N=804)
Overall	Overall compliance - PGI-S	96%	97%	96%
Baseline	No. subjects remaining in study	401	401	802
	No. subjects with PGI-S present	395 (99%)	396 (99%)	791 (99%)
Week 52	No. subjects remaining in study	375	371	746
	No. subjects with PGI-S present	353 (94%)	349 (94%)	702 (94%)

Overall Compliance is calculated as: (Total number of completed eCOAs across all subjects / Total expected number of completed eCOAs across all subjects) x 100.

Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Table 111.29

Summary of Compliance of eCOA Assessments: Subject Global Rating of Activity Limitation (GRAL)

		MEA117113		
Timepoint		PBO (N=87)	100 SC (N=83)	Total (N=170)
Overall	Overall compliance - GRAL	94%	94%	94%
Baseline	No. subjects remaining in study	87	83	170
	No. subjects with GRAL present	86 (99%)	80 (96%)	166 (98%)
Week 4	No. subjects remaining in study	87	83	170
	No. subjects with GRAL present	87 (100%)	78 (94%)	165 (97%)
Week 8	No. subjects remaining in study	87	83	170
	No. subjects with GRAL present	82 (94%)	79 (95%)	161 (95%)
Week 12	No. subjects remaining in study	86	83	169
	No. subjects with GRAL present	81 (94%)	76 (92%)	157 (93%)
Week 16	No. subjects remaining in study	84	83	167
	No. subjects with GRAL present	80 (95%)	80 (96%)	160 (96%)
Week 20	No. subjects remaining in study	83	83	166
	No. subjects with GRAL present	78 (94%)	78 (94%)	156 (94%)
Week 24	No. subjects remaining in study	83	82	165
	No. subjects with GRAL present	77 (93%)	72 (88%)	149 (90%)
Week 28	No. subjects remaining in study	81	81	162
	No. subjects with GRAL present	77 (95%)	74 (91%)	151 (93%)
Week 32	No. subjects remaining in study	81	80	161
	No. subjects with GRAL present	69 (85%)	74 (93%)	143 (89%)

Overall Compliance is calculated as: (Total number of completed eCOAs across all subjects / Total expected number of completed eCOAs across all subjects) x 100.

Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Table 111.29

Summary of Compliance of eCOA Assessments: Subject Global Rating of Activity Limitation (GRAL)

		MEA117106		
Timepoint		PBO (N=90)	100 SC (N=82)	Total (N=172)
Overall	Overall compliance - GRAL	90%	95%	93%
Baseline	No. subjects remaining in study	90	82	172
	No. subjects with GRAL present	85 (94%)	76 (93%)	161 (94%)
Week 4	No. subjects remaining in study	90	82	172
	No. subjects with GRAL present	84 (93%)	80 (98%)	164 (95%)
Week 8	No. subjects remaining in study	89	81	170
	No. subjects with GRAL present	82 (92%)	78 (96%)	160 (94%)
Week 12	No. subjects remaining in study	88	81	169
	No. subjects with GRAL present	83 (94%)	79 (98%)	162 (96%)
Week 16	No. subjects remaining in study	88	81	169
	No. subjects with GRAL present	80 (91%)	79 (98%)	159 (94%)
Week 20	No. subjects remaining in study	87	81	168
	No. subjects with GRAL present	80 (92%)	79 (98%)	159 (95%)
Week 24	No. subjects remaining in study	86	81	167
	No. subjects with GRAL present	76 (88%)	77 (95%)	153 (92%)
Week 28	No. subjects remaining in study	86	81	167
	No. subjects with GRAL present	75 (87%)	76 (94%)	151 (90%)
Week 32	No. subjects remaining in study	86	81	167
	No. subjects with GRAL present	76 (88%)	79 (98%)	155 (93%)

Overall Compliance is calculated as: (Total number of completed eCOAs across all subjects / Total expected number of completed eCOAs across all subjects) x 100.

Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Table 111.29

Summary of Compliance of eCOA Assessments: Subject Global Rating of Activity Limitation (GRAL)

		MEA117113		
Timepoint		PBO (N=87)	100 SC (N=83)	Total (N=170)
Week 36	No. subjects remaining in study	78	80	158
	No. subjects with GRAL present	71 (91%)	72 (90%)	143 (91%)
Week 40	No. subjects remaining in study	74	79	153
	No. subjects with GRAL present	69 (93%)	74 (94%)	143 (93%)
Week 44	No. subjects remaining in study	74	79	153
	No. subjects with GRAL present	69 (93%)	76 (96%)	145 (95%)
Week 48	No. subjects remaining in study	73	79	152
	No. subjects with GRAL present	68 (93%)	76 (96%)	144 (95%)
Week 52	No. subjects remaining in study	70	78	148
	No. subjects with GRAL present	67 (96%)	74 (95%)	141 (95%)

Overall Compliance is calculated as: (Total number of completed eCOAs across all subjects / Total expected number of completed eCOAs across all subjects) x 100.

Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Table 111.29

Summary of Compliance of eCOA Assessments: Subject Global Rating of Activity Limitation (GRAL)

		MEA117106		
Timepoint		PBO (N=90)	100 SC (N=82)	Total (N=172)
Week 36	No. subjects remaining in study	85	81	166
	No. subjects with GRAL present	74 (87%)	73 (90%)	147 (89%)
Week 40	No. subjects remaining in study	84	80	164
	No. subjects with GRAL present	74 (88%)	75 (94%)	149 (91%)
Week 44	No. subjects remaining in study	84	79	163
	No. subjects with GRAL present	74 (88%)	74 (94%)	148 (91%)
Week 48	No. subjects remaining in study	84	79	163
	No. subjects with GRAL present	74 (88%)	77 (97%)	151 (93%)
Week 52	No. subjects remaining in study	81	78	159
	No. subjects with GRAL present	73 (90%)	73 (94%)	146 (92%)

Overall Compliance is calculated as: (Total number of completed eCOAs across all subjects / Total expected number of completed eCOAs across all subjects) x 100.

Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Table 111.30

Summary of Compliance of eCOA Assessments: Subject Global Rating of Activity Change (GRAC)

		MEA117113		
Timepoint		PBO (N=87)	100 SC (N=83)	Total (N=170)
Overall	Overall compliance - GRAC	93%	93%	93%
Week 4	No. subjects remaining in study	87	83	170
	No. subjects with GRAC present	86 (99%)	76 (92%)	162 (95%)
Week 8	No. subjects remaining in study	87	83	170
	No. subjects with GRAC present	82 (94%)	79 (95%)	161 (95%)
Week 12	No. subjects remaining in study	86	83	169
	No. subjects with GRAC present	81 (94%)	75 (90%)	156 (92%)
Week 16	No. subjects remaining in study	84	83	167
	No. subjects with GRAC present	80 (95%)	80 (96%)	160 (96%)
Week 20	No. subjects remaining in study	83	83	166
	No. subjects with GRAC present	76 (92%)	77 (93%)	153 (92%)
Week 24	No. subjects remaining in study	83	82	165
	No. subjects with GRAC present	76 (92%)	71 (87%)	147 (89%)
Week 28	No. subjects remaining in study	81	81	162
	No. subjects with GRAC present	76 (94%)	74 (91%)	150 (93%)
Week 32	No. subjects remaining in study	81	80	161
	No. subjects with GRAC present	69 (85%)	74 (93%)	143 (89%)
Week 36	No. subjects remaining in study	78	80	158
	No. subjects with GRAC present	71 (91%)	72 (90%)	143 (91%)

Overall Compliance is calculated as: (Total number of completed eCOAs across all subjects / Total expected number of completed eCOAs across all subjects) x 100.

Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Table 111.30

Summary of Compliance of eCOA Assessments: Subject Global Rating of Activity Change (GRAC)

		MEA117106		
Timepoint		PBO (N=90)	100 SC (N=82)	Total (N=172)
Overall	Overall compliance - GRAC	89%	95%	92%
Week 4	No. subjects remaining in study	88	82	170
	No. subjects with GRAC present	84 (95%)	79 (96%)	163 (96%)
Week 8	No. subjects remaining in study	88	81	169
	No. subjects with GRAC present	79 (90%)	76 (94%)	155 (92%)
Week 12	No. subjects remaining in study	88	81	169
	No. subjects with GRAC present	81 (92%)	79 (98%)	160 (95%)
Week 16	No. subjects remaining in study	88	81	169
	No. subjects with GRAC present	80 (91%)	78 (96%)	158 (93%)
Week 20	No. subjects remaining in study	87	81	168
	No. subjects with GRAC present	80 (92%)	79 (98%)	159 (95%)
Week 24	No. subjects remaining in study	86	81	167
	No. subjects with GRAC present	76 (88%)	77 (95%)	153 (92%)
Week 28	No. subjects remaining in study	86	81	167
	No. subjects with GRAC present	75 (87%)	76 (94%)	151 (90%)
Week 32	No. subjects remaining in study	86	81	167
	No. subjects with GRAC present	75 (87%)	79 (98%)	154 (92%)
Week 36	No. subjects remaining in study	85	81	166
	No. subjects with GRAC present	73 (86%)	72 (89%)	145 (87%)

Overall Compliance is calculated as: (Total number of completed eCOAs across all subjects / Total expected number of completed eCOAs across all subjects) x 100.

Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Table 111.30

Summary of Compliance of eCOA Assessments: Subject Global Rating of Activity Change (GRAC)

Timepoint		MEA117113 PBO (N=87)	MEA117113 100 SC (N=83)	MEA117113 Total (N=170)
Week 40	No. subjects remaining in study	74	79	153
	No. subjects with GRAC present	69 (93%)	73 (92%)	142 (93%)
Week 44	No. subjects remaining in study	74	79	153
	No. subjects with GRAC present	69 (93%)	76 (96%)	145 (95%)
Week 48	No. subjects remaining in study	73	79	152
	No. subjects with GRAC present	68 (93%)	75 (95%)	143 (94%)
Week 52	No. subjects remaining in study	70	78	148
	No. subjects with GRAC present	67 (96%)	74 (95%)	141 (95%)

Overall Compliance is calculated as: (Total number of completed eCOAs across all subjects / Total expected number of completed eCOAs across all subjects) x 100.

Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Table 111.30

Summary of Compliance of eCOA Assessments: Subject Global Rating of Activity Change (GRAC)

		MEA117106		
Timepoint		PBO (N=90)	100 SC (N=82)	Total (N=172)
Week 40	No. subjects remaining in study	84	80	164
	No. subjects with GRAC present	73 (87%)	74 (93%)	147 (90%)
Week 44	No. subjects remaining in study	84	79	163
	No. subjects with GRAC present	74 (88%)	74 (94%)	148 (91%)
Week 48	No. subjects remaining in study	84	79	163
	No. subjects with GRAC present	74 (88%)	77 (97%)	151 (93%)
Week 52	No. subjects remaining in study	81	78	159
	No. subjects with GRAC present	72 (89%)	72 (92%)	144 (91%)

Overall Compliance is calculated as: (Total number of completed eCOAs across all subjects / Total expected number of completed eCOAs across all subjects) x 100.

Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Table 111.31
Summary of Study Duration

	208657		MEA117113		MEA117106	
	PBO (N=401)	100 SC (N=403)	PBO (N=87)	100 SC (N=83)	PBO (N=90)	100 SC (N=82)
Duration of Study (months)						
n	401	403	87	83	90	82
Mean	14.9	15.5	12.4	13.4	13.1	13.5
SD	5.86	5.97	3.08	1.80	2.72	1.74
Median	12.2	12.3	13.8	13.8	13.8	13.8
Min.	1	1	2	4	1	1
Max.	27	25	15	15	18	16

Note: Duration of Study (months) = (End of study date - Randomisation date + 1)x12/365.25.
/mnt/code/postcsr_01/prod/tfls/t_sp_stdur.sas 21JUL2025 22:03

Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Table 211.1

Overview of Moderate/Severe Exacerbations: Studies MEA117113 and MEA117106

Study Phase: On- and Off-Treatment

	MEA117113		MEA117106	
	PBO (N=87)	100 SC (N=83)	PBO (N=90)	100 SC (N=82)
Moderate/Severe Exacerbations				
Number of subjects	55 (63%)	45 (54%)	73 (81%)	48 (59%)
Number of exacerbations	127	115	172	114
Moderate Exacerbations				
Number of subjects	52 (60%)	43 (52%)	67 (74%)	43 (52%)
Number of exacerbations	109	101	149	95
Severe Exacerbations				
Number of subjects	14 (16%)	10 (12%)	17 (19%)	12 (15%)
Number of exacerbations	18	14	23	19
Exacerbations requiring ED/Hospitalization				
Number of subjects	18 (21%)	13 (16%)	21 (23%)	15 (18%)
Number of exacerbations	25	17	27	23

Note: MEA117113 and MEA117106 studies of 52 weeks duration.

/mnt/code/postcsr_01/prod/tfls/t_e_exac_overview_mea.sas 25JUL2025 11:00

Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Table 211.1

Overview of Moderate/Severe Exacerbations: Studies MEA117113 and MEA117106

Study Phase: On-Treatment

	MEA117113		MEA117106	
	PBO (N=87)	100 SC (N=83)	PBO (N=90)	100 SC (N=82)
Moderate/Severe Exacerbations				
Number of subjects	55 (63%)	45 (54%)	72 (80%)	48 (59%)
Number of exacerbations	125	111	159	113
Moderate Exacerbations				
Number of subjects	52 (60%)	43 (52%)	66 (73%)	43 (52%)
Number of exacerbations	107	97	137	94
Severe Exacerbations				
Number of subjects	14 (16%)	10 (12%)	17 (19%)	12 (15%)
Number of exacerbations	18	14	22	19
Exacerbations requiring ED/Hospitalization				
Number of subjects	18 (21%)	13 (16%)	21 (23%)	15 (18%)
Number of exacerbations	25	17	26	23

Note: MEA117113 and MEA117106 studies of 52 weeks duration.

/mnt/code/postcsr_01/prod/tfls/t_e_exac_overview_mea.sas 25JUL2025 11:00

Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Table 211.1

Overview of Moderate/Severe Exacerbations: Studies MEA117113 and MEA117106

Study Phase: Off-Treatment

	MEA117113		MEA117106	
	PBO (N=87)	100 SC (N=83)	PBO (N=90)	100 SC (N=82)
Moderate/Severe Exacerbations				
Number of subjects	1 (1%)	1 (1%)	5 (6%)	1 (1%)
Number of exacerbations	2	4	13	1
Moderate Exacerbations				
Number of subjects	1 (1%)	1 (1%)	4 (4%)	1 (1%)
Number of exacerbations	2	4	12	1
Severe Exacerbations				
Number of subjects	0	0	1 (1%)	0
Number of exacerbations	0	0	1	0
Exacerbations requiring ED/Hospitalization				
Number of subjects	0	0	1 (1%)	0
Number of exacerbations	0	0	1	0

Note: MEA117113 and MEA117106 studies of 52 weeks duration.

/mnt/code/postcsr_01/prod/tfls/t_e_exac_overview_mea.sas 25JUL2025 11:00

Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Table 211.1

Overview of Moderate/Severe Exacerbations: Studies MEA117113 and MEA117106

Study Phase: Post-Treatment

	MEA117113		MEA117106	
	PBO (N=87)	100 SC (N=83)	PBO (N=90)	100 SC (N=82)
Moderate/Severe Exacerbations				
Number of subjects	11 (13%)	12 (14%)	13 (14%)	17 (21%)
Number of exacerbations	12	12	14	17
Moderate Exacerbations				
Number of subjects	8 (9%)	12 (14%)	10 (11%)	13 (16%)
Number of exacerbations	9	12	11	13
Severe Exacerbations				
Number of subjects	3 (3%)	0	3 (3%)	4 (5%)
Number of exacerbations	3	0	3	4
Exacerbations requiring ED/Hospitalization				
Number of subjects	4 (5%)	1 (1%)	3 (3%)	5 (6%)
Number of exacerbations	5	1	3	5

Note: MEA117113 and MEA117106 studies of 52 weeks duration.

/mnt/code/postcsr_01/prod/tfls/t_e_exac_overview_mea.sas 25JUL2025 11:00

Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Table 211.2
Overview of Moderate/Severe Exacerbations: Study 208657

Study Phase: On- and Off-Treatment

	PBO (N=401)	100 SC (N=403)
Moderate/Severe Exacerbations		
Number of subjects	226 (56%)	202 (50%)
Number of exacerbations	554	482
Moderate Exacerbations		
Number of subjects	200 (50%)	184 (46%)
Number of exacerbations	469	409
Severe Exacerbations		
Number of subjects	59 (15%)	46 (11%)
Number of exacerbations	85	73
Exacerbations requiring ED/Hospitalization		
Number of subjects	71 (18%)	56 (14%)
Number of exacerbations	107	89

Note: 208657 study of 52-104 weeks duration.

Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Table 211.2
Overview of Moderate/Severe Exacerbations: Study 208657

Study Phase: On-Treatment

	PBO (N=401)	100 SC (N=403)
Moderate/Severe Exacerbations		
Number of subjects	223 (56%)	202 (50%)
Number of exacerbations	536	465
Moderate Exacerbations		
Number of subjects	196 (49%)	184 (46%)
Number of exacerbations	458	401
Severe Exacerbations		
Number of subjects	57 (14%)	45 (11%)
Number of exacerbations	78	64
Exacerbations requiring ED/Hospitalization		
Number of subjects	69 (17%)	55 (14%)
Number of exacerbations	100	79

Note: 208657 study of 52-104 weeks duration.
/mnt/code/postcsr_01/prod/tfls/t_e_exac_overview_mati.sas 25JUL2025 11:01

Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Table 211.2
Overview of Moderate/Severe Exacerbations: Study 208657

Study Phase: Off-Treatment

	PBO (N=401)	100 SC (N=403)
Moderate/Severe Exacerbations		
Number of subjects	10 (2%)	8 (2%)
Number of exacerbations	18	17
Moderate Exacerbations		
Number of subjects	8 (2%)	5 (1%)
Number of exacerbations	11	8
Severe Exacerbations		
Number of subjects	5 (1%)	5 (1%)
Number of exacerbations	7	9
Exacerbations requiring ED/Hospitalization		
Number of subjects	5 (1%)	5 (1%)
Number of exacerbations	7	10

Note: 208657 study of 52-104 weeks duration.
/mnt/code/postcsr_01/prod/tfls/t_e_exac_overview_mati.sas 25JUL2025 11:01

Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Table 211.3

Summary of Frequency of Moderate/Severe Exacerbations: Studies MEA117113 and MEA117106

Study Phase: On- and Off-Treatment

	MEA117113		MEA117106	
	PBO (N=87)	100 SC (N=83)	PBO (N=90)	100 SC (N=82)
n	87	83	90	82
0	32 (37%)	38 (46%)	17 (19%)	34 (41%)
1	19 (22%)	14 (17%)	32 (36%)	17 (21%)
2	19 (22%)	13 (16%)	14 (16%)	16 (20%)
3	8 (9%)	11 (13%)	13 (14%)	8 (10%)
4	3 (3%)	2 (2%)	7 (8%)	2 (2%)
5	3 (3%)	3 (4%)	2 (2%)	1 (1%)
6	2 (2%)	0	2 (2%)	2 (2%)
7	1 (1%)	0	1 (1%)	0
8	0	0	2 (2%)	2 (2%)
9	0	1 (1%)	0	0
10	0	1 (1%)	0	0
>=11	0	0	0	0
Total number of subjects with >=1 exacerbation	55 (63%)	45 (54%)	73 (81%)	48 (59%)
Total number of exacerbations	127	115	172	114

Note: MEA117113 and MEA117106 studies of 52 weeks duration.

Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Table 211.3

Summary of Frequency of Moderate/Severe Exacerbations: Studies MEA117113 and MEA117106

Study Phase: On-Treatment

	MEA117113		MEA117106	
	PBO (N=87)	100 SC (N=83)	PBO (N=90)	100 SC (N=82)
n	87	83	90	82
0	32 (37%)	38 (46%)	18 (20%)	34 (41%)
1	20 (23%)	15 (18%)	34 (38%)	17 (21%)
2	19 (22%)	13 (16%)	16 (18%)	17 (21%)
3	7 (8%)	11 (13%)	10 (11%)	7 (9%)
4	3 (3%)	2 (2%)	6 (7%)	2 (2%)
5	3 (3%)	2 (2%)	2 (2%)	1 (1%)
6	2 (2%)	0	1 (1%)	2 (2%)
7	1 (1%)	0	1 (1%)	0
8	0	0	2 (2%)	2 (2%)
9	0	1 (1%)	0	0
10	0	1 (1%)	0	0
>=11	0	0	0	0
Total number of subjects with >=1 exacerbation	55 (63%)	45 (54%)	72 (80%)	48 (59%)
Total number of exacerbations	125	111	159	113

Note: MEA117113 and MEA117106 studies of 52 weeks duration.

Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Table 211.3

Summary of Frequency of Moderate/Severe Exacerbations: Studies MEA117113 and MEA117106

Study Phase: Off-Treatment

	MEA117113		MEA117106	
	PBO (N=87)	100 SC (N=83)	PBO (N=90)	100 SC (N=82)
n	87	83	90	82
0	86 (99%)	82 (99%)	85 (94%)	81 (99%)
1	0	0	2 (2%)	1 (1%)
2	1 (1%)	0	0	0
3	0	0	2 (2%)	0
4	0	1 (1%)	0	0
5	0	0	1 (1%)	0
6	0	0	0	0
7	0	0	0	0
8	0	0	0	0
9	0	0	0	0
10	0	0	0	0
>=11	0	0	0	0
Total number of subjects with >=1 exacerbation	1 (1%)	1 (1%)	5 (6%)	1 (1%)
Total number of exacerbations	2	4	13	1

Note: MEA117113 and MEA117106 studies of 52 weeks duration.

/mnt/code/postcsr_01/prod/tfls/t_e_mdsvex_sum.sas 25JUL2025 11:01

Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Table 211.3

Summary of Frequency of Moderate/Severe Exacerbations: Studies MEA117113 and MEA117106

Study Phase: Post-Treatment

	MEA117113		MEA117106	
	PBO (N=87)	100 SC (N=83)	PBO (N=90)	100 SC (N=82)
n	87	83	90	82
0	76 (87%)	71 (86%)	77 (86%)	65 (79%)
1	10 (11%)	12 (14%)	12 (13%)	17 (21%)
2	1 (1%)	0	1 (1%)	0
3	0	0	0	0
4	0	0	0	0
5	0	0	0	0
6	0	0	0	0
7	0	0	0	0
8	0	0	0	0
9	0	0	0	0
10	0	0	0	0
>=11	0	0	0	0
Total number of subjects with >=1 exacerbation	11 (13%)	12 (14%)	13 (14%)	17 (21%)
Total number of exacerbations	12	12	14	17

Note: MEA117113 and MEA117106 studies of 52 weeks duration.

Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Table 211.4

Summary of Frequency of Annualized Moderate/Severe Exacerbations: Study 208657

Study Phase: On- and Off-Treatment

	PBO (N=401)	100 SC (N=403)
Number of annualized exacerbations		
n	401	403
0-<1	243 (61%)	263 (65%)
1-<2	77 (19%)	70 (17%)
2-<3	36 (9%)	30 (7%)
3-<4	16 (4%)	21 (5%)
4-<5	11 (3%)	8 (2%)
5-<6	6 (1%)	5 (1%)
6-<7	2 (<1%)	3 (<1%)
7-<8	2 (<1%)	1 (<1%)
8-<9	2 (<1%)	2 (<1%)
9-<10	2 (<1%)	0
>=10	4 (<1%)	0
Total number of subjects with >=1 exacerbation	226 (56%)	202 (50%)
Total number of exacerbations	554	482

Note: 208657 study of 52-104 weeks duration.

/mnt/code/postcsr_01/prod/tfls/t_e_armdsv_sum.sas 25JUL2025 11:01

Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Table 211.4

Summary of Frequency of Annualized Moderate/Severe Exacerbations: Study 208657

Study Phase: On-Treatment

	PBO (N=401)	100 SC (N=403)
Number of annualized exacerbations		
n	401	403
0-<1	246 (61%)	262 (65%)
1-<2	76 (19%)	71 (18%)
2-<3	34 (8%)	27 (7%)
3-<4	12 (3%)	20 (5%)
4-<5	9 (2%)	13 (3%)
5-<6	7 (2%)	5 (1%)
6-<7	4 (<1%)	3 (<1%)
7-<8	4 (<1%)	1 (<1%)
8-<9	0	0
9-<10	2 (<1%)	0
>=10	7 (2%)	1 (<1%)
Total number of subjects with >=1 exacerbation	223 (56%)	202 (50%)
Total number of exacerbations	536	465

Note: 208657 study of 52-104 weeks duration.

/mnt/code/postcsr_01/prod/tfls/t_e_armdsv_sum.sas 25JUL2025 11:01

Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Table 211.4

Summary of Frequency of Annualized Moderate/Severe Exacerbations: Study 208657

Study Phase: Off-Treatment

	PBO (N=401)	100 SC (N=403)
Number of annualized exacerbations		
n	401	403
0-<1	393 (98%)	395 (98%)
1-<2	1 (<1%)	0
2-<3	3 (<1%)	2 (<1%)
3-<4	0	0
4-<5	3 (<1%)	0
5-<6	0	4 (<1%)
6-<7	0	0
7-<8	0	0
8-<9	0	0
9-<10	0	0
>=10	1 (<1%)	2 (<1%)
Total number of subjects with >=1 exacerbation	10 (2%)	8 (2%)
Total number of exacerbations	18	17

Note: 208657 study of 52-104 weeks duration.

/mnt/code/postcsr_01/prod/tfls/t_e_armdsv_sum.sas 25JUL2025 11:01

Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Table 211.5

Analysis of Rate of Moderate/Severe Exacerbations: Individual studies and Meta-Analysis
(Negative Binomial Model)

	PBO (N=578)	100 SC (N=568)
208657		
n	401	403
Exacerbation rate/year	1.01	0.80
Rate Ratio vs Placebo [1]		0.79
95% CI		(0.66, 0.94)
p-value		0.011
MEA117113		
n	87	83
Exacerbation rate/year	1.43	1.22
Rate Ratio vs Placebo [1]		0.85
95% CI		(0.59, 1.22)
p-value		0.387
MEA117106		
n	90	82
Exacerbation rate/year	1.94	1.32
Rate Ratio vs Placebo [1]		0.68
95% CI		(0.50, 0.92)
p-value		0.013

[1] Analysis performed using a negative binomial regression model with covariates of treatment group, smoking status, baseline % predicted FEV1, number of exacerbations in previous year (as an ordinal variable), and geographic region (as defined for the study/ISE) with log(time in on- and off-treatment period) as an offset variable. Estimates based on weighting applied to each level of class variable determined from observed proportions.
[2] Analysis model as in footnote [1] with an additional covariate of study.
[3] Analysis model as in footnote [2] with an additional covariate of study*treatment interaction.
/mnt/code/postcsr_01/prod/tfls/t_e_msevex_nb.sas 25JUL2025 11:02

Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Table 211.5

Analysis of Rate of Moderate/Severe Exacerbations: Individual studies and Meta-Analysis
(Negative Binomial Model)

	PBO (N=578)	100 SC (N=568)
208657 + MEA117113 + MEA117106		
n	578	568
Exacerbation rate/year	1.25	0.98
Rate Ratio vs Placebo [2]		0.79
95% CI		(0.68, 0.91)
p-value		0.002
p-value for study*treatment interaction [3]		0.683

[1] Analysis performed using a negative binomial regression model with covariates of treatment group, smoking status, baseline % predicted FEV1, number of exacerbations in previous year (as an ordinal variable), and geographic region (as defined for the study/ISE) with log(time in on- and off-treatment period) as an offset variable. Estimates based on weighting applied to each level of class variable determined from observed proportions.
[2] Analysis model as in footnote [1] with an additional covariate of study.
[3] Analysis model as in footnote [2] with an additional covariate of study*treatment interaction.
/mnt/code/postcsr_01/prod/tfls/t_e_msevex_nb.sas 25JUL2025 11:02

Population: Modified Intent-to-Treat Population with Eosinophils 300 cells/uL or More

Table 211.6

Analysis of Time to First Moderate/Severe Exacerbation: Individual Studies and Meta-Analysis

	PBO (N=578)	100 SC (N=568)
208657		
n	401	403
By week 8		
Subjects with event	60 (15%)	45 (11%)
Probability of an exacerbation [1]	15.1%	11.3%
95% CI	(11.9%, 19.0%)	(8.5%, 14.8%)
By week 16		
Subjects with event	101 (25%)	86 (21%)
Probability of an exacerbation [1]	25.6%	21.6%
95% CI	(21.6%, 30.2%)	(17.9%, 26.0%)
By week 24		
Subjects with event	139 (35%)	112 (28%)
Probability of an exacerbation [1]	35.4%	28.3%
95% CI	(30.9%, 40.3%)	(24.2%, 33.1%)
By week 32		
Subjects with event	163 (41%)	132 (33%)
Probability of an exacerbation [1]	41.6%	33.6%
95% CI	(36.9%, 46.7%)	(29.1%, 38.5%)
By week 40		
Subjects with event	184 (46%)	155 (38%)
Probability of an exacerbation [1]	47.1%	39.8%
95% CI	(42.3%, 52.2%)	(35.1%, 44.8%)

[1] Kaplan-Meier estimate.
[2] Estimated from a Cox Proportional Hazards Model with covariates of treatment group, smoking status, baseline % predicted FEV1, number of exacerbations in previous year (as an ordinal variable), and geographic region (as defined for the study/ISE).
[3] Analysis model as in footnote [2] with an additional covariate of study.
[4] Analysis model as in footnote [3] with an additional covariate of study*treatment interaction.
/mnt/code/postcsr_01/prod/tfls/t_e_tte_msevex.sas 25JUL2025 11:02

Population: Modified Intent-to-Treat Population with Eosinophils 300 cells/uL or More

Table 211.6

Analysis of Time to First Moderate/Severe Exacerbation: Individual Studies and Meta-Analysis

	PBO (N=578)	100 SC (N=568)
By week 48		
Subjects with event	200 (50%)	174 (43%)
Probability of an exacerbation [1]	51.4%	44.9%
95% CI	(46.6%, 56.5%)	(40.1%, 50.1%)
By week 52		
Subjects with event	207 (52%)	178 (44%)
Probability of an exacerbation [1]	53.4%	46.1%
95% CI	(48.5%, 58.5%)	(41.2%, 51.2%)
By week 56		
Subjects with event	208 (52%)	179 (44%)
Probability of an exacerbation [1]	54.0%	46.7%
95% CI	(49.0%, 59.2%)	(41.7%, 51.9%)
By week 64		
Subjects with event	215 (54%)	186 (46%)
Probability of an exacerbation [1]	58.9%	51.4%
95% CI	(53.3%, 64.6%)	(45.8%, 57.2%)
By week 72		
Subjects with event	217 (54%)	192 (48%)
Probability of an exacerbation [1]	60.5%	55.9%
95% CI	(54.7%, 66.4%)	(49.8%, 62.2%)

[1] Kaplan-Meier estimate.
[2] Estimated from a Cox Proportional Hazards Model with covariates of treatment group, smoking status, baseline % predicted FEV1, number of exacerbations in previous year (as an ordinal variable), and geographic region (as defined for the study/ISE).
[3] Analysis model as in footnote [2] with an additional covariate of study.
[4] Analysis model as in footnote [3] with an additional covariate of study*treatment interaction.
/mnt/code/postcsr_01/prod/tfls/t_e_tte_msevex.sas 25JUL2025 11:02

Population: Modified Intent-to-Treat Population with Eosinophils 300 cells/uL or More

Table 211.6

Analysis of Time to First Moderate/Severe Exacerbation: Individual Studies and Meta-Analysis

	PBO (N=578)	100 SC (N=568)
By week 80		
Subjects with event	219 (55%)	196 (49%)
Probability of an exacerbation [1]	62.3%	59.0%
95% CI	(56.2%, 68.4%)	(52.6%, 65.5%)
By week 88		
Subjects with event	221 (55%)	198 (49%)
Probability of an exacerbation [1]	64.2%	60.6%
95% CI	(57.9%, 70.5%)	(54.1%, 67.2%)
By week 96		
Subjects with event	224 (56%)	200 (50%)
Probability of an exacerbation [1]	67.2%	62.3%
95% CI	(60.5%, 73.8%)	(55.6%, 69.0%)
By week 104		
Subjects with event	225 (56%)	202 (50%)
Probability of an exacerbation [1]	68.3%	64.5%
95% CI	(61.4%, 74.9%)	(57.5%, 71.4%)
Hazard ratio (Mepo/Placebo) [2]		0.77
95% CI		(0.64, 0.93)
p-value		0.009

[1] Kaplan-Meier estimate.
[2] Estimated from a Cox Proportional Hazards Model with covariates of treatment group, smoking status, baseline % predicted FEV1, number of exacerbations in previous year (as an ordinal variable), and geographic region (as defined for the study/ISE).
[3] Analysis model as in footnote [2] with an additional covariate of study.
[4] Analysis model as in footnote [3] with an additional covariate of study*treatment interaction.
/mnt/code/postcsr_01/prod/tfls/t_e_tte_msevex.sas 25JUL2025 11:02

Population: Modified Intent-to-Treat Population with Eosinophils 300 cells/uL or More

Table 211.6

Analysis of Time to First Moderate/Severe Exacerbation: Individual Studies and Meta-Analysis

	PBO (N=578)	100 SC (N=568)
MEA117113		
n	87	83
By week 8		
Subjects with event	19 (22%)	20 (24%)
Probability of an exacerbation [1]	21.9%	24.1%
95% CI	(14.5%, 32.1%)	(16.3%, 34.8%)
By week 16		
Subjects with event	35 (40%)	28 (34%)
Probability of an exacerbation [1]	41.0%	33.7%
95% CI	(31.4%, 52.2%)	(24.7%, 45.0%)
By week 24		
Subjects with event	43 (49%)	34 (41%)
Probability of an exacerbation [1]	50.8%	41.1%
95% CI	(40.7%, 61.9%)	(31.4%, 52.4%)
By week 32		
Subjects with event	50 (57%)	35 (42%)
Probability of an exacerbation [1]	59.5%	42.3%
95% CI	(49.2%, 70.1%)	(32.5%, 53.7%)
By week 40		
Subjects with event	53 (61%)	42 (51%)
Probability of an exacerbation [1]	63.3%	51.1%
95% CI	(53.0%, 73.6%)	(40.8%, 62.3%)

[1] Kaplan-Meier estimate.
[2] Estimated from a Cox Proportional Hazards Model with covariates of treatment group, smoking status, baseline % predicted FEV1, number of exacerbations in previous year (as an ordinal variable), and geographic region (as defined for the study/ISE).
[3] Analysis model as in footnote [2] with an additional covariate of study.
[4] Analysis model as in footnote [3] with an additional covariate of study*treatment interaction.
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Population: Modified Intent-to-Treat Population with Eosinophils 300 cells/uL or More

Table 211.6

Analysis of Time to First Moderate/Severe Exacerbation: Individual Studies and Meta-Analysis

	PBO (N=578)	100 SC (N=568)
By week 48		
Subjects with event	55 (63%)	44 (53%)
Probability of an exacerbation [1]	65.8%	53.6%
95% CI	(55.6%, 75.9%)	(43.3%, 64.7%)
By week 52		
Subjects with event	55 (63%)	45 (54%)
Probability of an exacerbation [1]	65.8%	54.9%
95% CI	(55.6%, 75.9%)	(44.5%, 65.9%)
Hazard ratio (Mepo/Placebo) [2]		0.83
95% CI		(0.55, 1.24)
p-value		0.363

[1] Kaplan-Meier estimate.
[2] Estimated from a Cox Proportional Hazards Model with covariates of treatment group, smoking status, baseline % predicted FEV1, number of exacerbations in previous year (as an ordinal variable), and geographic region (as defined for the study/ISE).
[3] Analysis model as in footnote [2] with an additional covariate of study.
[4] Analysis model as in footnote [3] with an additional covariate of study*treatment interaction.
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Population: Modified Intent-to-Treat Population with Eosinophils 300 cells/uL or More

Table 211.6

Analysis of Time to First Moderate/Severe Exacerbation: Individual Studies and Meta-Analysis

	PBO (N=578)	100 SC (N=568)
MEA117106		
n	90	82
By week 8		
Subjects with event	32 (36%)	13 (16%)
Probability of an exacerbation [1]	35.7%	16.0%
95% CI	(26.7%, 46.5%)	(9.6%, 26.0%)
By week 16		
Subjects with event	45 (50%)	25 (30%)
Probability of an exacerbation [1]	50.4%	30.8%
95% CI	(40.5%, 61.1%)	(22.0%, 42.1%)
By week 24		
Subjects with event	51 (57%)	34 (41%)
Probability of an exacerbation [1]	57.3%	41.9%
95% CI	(47.3%, 67.7%)	(32.1%, 53.4%)
By week 32		
Subjects with event	58 (64%)	42 (51%)
Probability of an exacerbation [1]	65.3%	51.8%
95% CI	(55.4%, 75.1%)	(41.5%, 63.0%)
By week 40		
Subjects with event	63 (70%)	45 (55%)
Probability of an exacerbation [1]	71.1%	55.6%
95% CI	(61.5%, 80.2%)	(45.2%, 66.6%)

[1] Kaplan-Meier estimate.
[2] Estimated from a Cox Proportional Hazards Model with covariates of treatment group, smoking status, baseline % predicted FEV1, number of exacerbations in previous year (as an ordinal variable), and geographic region (as defined for the study/ISE).
[3] Analysis model as in footnote [2] with an additional covariate of study.
[4] Analysis model as in footnote [3] with an additional covariate of study*treatment interaction.
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Population: Modified Intent-to-Treat Population with Eosinophils 300 cells/uL or More

Table 211.6

Analysis of Time to First Moderate/Severe Exacerbation: Individual Studies and Meta-Analysis

	PBO (N=578)	100 SC (N=568)
By week 48		
Subjects with event	69 (77%)	45 (55%)
Probability of an exacerbation [1]	78.1%	55.6%
95% CI	(68.9%, 86.0%)	(45.2%, 66.6%)
By week 52		
Subjects with event	73 (81%)	47 (57%)
Probability of an exacerbation [1]	82.7%	58.6%
95% CI	(74.1%, 89.7%)	(48.0%, 69.5%)
Hazard ratio (Mepo/Placebo) [2]		0.50
95% CI		(0.34, 0.72)
p-value		<0.001

[1] Kaplan-Meier estimate.
[2] Estimated from a Cox Proportional Hazards Model with covariates of treatment group, smoking status, baseline % predicted FEV1, number of exacerbations in previous year (as an ordinal variable), and geographic region (as defined for the study/ISE).
[3] Analysis model as in footnote [2] with an additional covariate of study.
[4] Analysis model as in footnote [3] with an additional covariate of study*treatment interaction.
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Population: Modified Intent-to-Treat Population with Eosinophils 300 cells/uL or More

Table 211.6

Analysis of Time to First Moderate/Severe Exacerbation: Individual Studies and Meta-Analysis

	PBO (N=578)	100 SC (N=568)
208657 + MEA117113 + MEA117106		
n	578	568
By week 8		
Subjects with event	111 (19%)	78 (14%)
Probability of an exacerbation [1]	19.4%	13.8%
95% CI	(16.4%, 22.8%)	(11.2%, 17.0%)
By week 16		
Subjects with event	181 (31%)	139 (24%)
Probability of an exacerbation [1]	31.8%	24.7%
95% CI	(28.1%, 35.8%)	(21.4%, 28.5%)
By week 24		
Subjects with event	233 (40%)	180 (32%)
Probability of an exacerbation [1]	41.1%	32.2%
95% CI	(37.2%, 45.3%)	(28.5%, 36.2%)
By week 32		
Subjects with event	271 (47%)	209 (37%)
Probability of an exacerbation [1]	48.0%	37.5%
95% CI	(44.0%, 52.2%)	(33.7%, 41.7%)
By week 40		
Subjects with event	300 (52%)	242 (43%)
Probability of an exacerbation [1]	53.3%	43.8%
95% CI	(49.2%, 57.5%)	(39.7%, 48.0%)

[1] Kaplan-Meier estimate.
[2] Estimated from a Cox Proportional Hazards Model with covariates of treatment group, smoking status, baseline % predicted FEV1, number of exacerbations in previous year (as an ordinal variable), and geographic region (as defined for the study/ISE).
[3] Analysis model as in footnote [2] with an additional covariate of study.
[4] Analysis model as in footnote [3] with an additional covariate of study*treatment interaction.
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Population: Modified Intent-to-Treat Population with Eosinophils 300 cells/uL or More

Table 211.6

Analysis of Time to First Moderate/Severe Exacerbation: Individual Studies and Meta-Analysis

	PBO (N=578)	100 SC (N=568)
By week 48		
Subjects with event	324 (56%)	263 (46%)
Probability of an exacerbation [1]	57.8%	47.8%
95% CI	(53.7%, 61.9%)	(43.7%, 52.0%)
By week 52		
Subjects with event	335 (58%)	270 (48%)
Probability of an exacerbation [1]	59.9%	49.2%
95% CI	(55.8%, 64.0%)	(45.0%, 53.5%)
By week 56		
Subjects with event	336 (58%)	272 (48%)
Probability of an exacerbation [1]	60.4%	50.0%
95% CI	(56.3%, 64.6%)	(45.8%, 54.4%)
By week 64		
Subjects with event	343 (59%)	279 (49%)
Probability of an exacerbation [1]	64.6%	54.5%
95% CI	(59.9%, 69.3%)	(49.5%, 59.5%)
By week 72		
Subjects with event	345 (60%)	285 (50%)
Probability of an exacerbation [1]	66.0%	58.7%
95% CI	(61.0%, 70.9%)	(53.2%, 64.3%)

[1] Kaplan-Meier estimate.
[2] Estimated from a Cox Proportional Hazards Model with covariates of treatment group, smoking status, baseline % predicted FEV1, number of exacerbations in previous year (as an ordinal variable), and geographic region (as defined for the study/ISE).
[3] Analysis model as in footnote [2] with an additional covariate of study.
[4] Analysis model as in footnote [3] with an additional covariate of study*treatment interaction.
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Population: Modified Intent-to-Treat Population with Eosinophils 300 cells/uL or More

Table 211.6

Analysis of Time to First Moderate/Severe Exacerbation: Individual Studies and Meta-Analysis

	PBO (N=578)	100 SC (N=568)
By week 80		
Subjects with event	347 (60%)	289 (51%)
Probability of an exacerbation [1]	67.5%	61.6%
95% CI	(62.3%, 72.6%)	(55.7%, 67.5%)
By week 88		
Subjects with event	349 (60%)	291 (51%)
Probability of an exacerbation [1]	69.2%	63.1%
95% CI	(63.8%, 74.5%)	(57.1%, 69.0%)
By week 96		
Subjects with event	352 (61%)	293 (52%)
Probability of an exacerbation [1]	71.8%	64.7%
95% CI	(66.0%, 77.3%)	(58.5%, 70.8%)
By week 104		
Subjects with event	353 (61%)	295 (52%)
Probability of an exacerbation [1]	72.7%	66.8%
95% CI	(66.8%, 78.3%)	(60.3%, 73.1%)
Hazard ratio (Mepo/Placebo) [3]		0.72
95% CI		(0.62, 0.85)
p-value		<0.001
p-value for study*treatment interaction [4]		0.136

[1] Kaplan-Meier estimate.
[2] Estimated from a Cox Proportional Hazards Model with covariates of treatment group, smoking status, baseline % predicted FEV1, number of exacerbations in previous year (as an ordinal variable), and geographic region (as defined for the study/ISE).
[3] Analysis model as in footnote [2] with an additional covariate of study.
[4] Analysis model as in footnote [3] with an additional covariate of study*treatment interaction.
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Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Table 211.7

Summary of Frequency of Exacerbations Requiring ED/Hospitalization: Studies MEA117113 and MEA117106

Study Phase: On- and Off-Treatment

	MEA117113		MEA117106	
	PBO (N=87)	100 SC (N=83)	PBO (N=90)	100 SC (N=82)
n	87	83	90	82
0	69 (79%)	70 (84%)	69 (77%)	67 (82%)
1	14 (16%)	10 (12%)	16 (18%)	9 (11%)
2	1 (1%)	2 (2%)	4 (4%)	4 (5%)
3	3 (3%)	1 (1%)	1 (1%)	2 (2%)
4	0	0	0	0
5	0	0	0	0
6	0	0	0	0
7	0	0	0	0
8	0	0	0	0
9	0	0	0	0
10	0	0	0	0
>=11	0	0	0	0
Total number of subjects with >=1 exacerbation	18 (21%)	13 (16%)	21 (23%)	15 (18%)
Total number of exacerbations	25	17	27	23

Note: MEA117113 and MEA117106 studies of 52 weeks duration.

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Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Table 211.7

Summary of Frequency of Exacerbations Requiring ED/Hospitalization: Studies MEA117113 and MEA117106

Study Phase: On-Treatment

	MEA117113		MEA117106	
	PBO (N=87)	100 SC (N=83)	PBO (N=90)	100 SC (N=82)
n	87	83	90	82
0	69 (79%)	70 (84%)	69 (77%)	67 (82%)
1	14 (16%)	10 (12%)	17 (19%)	9 (11%)
2	1 (1%)	2 (2%)	3 (3%)	4 (5%)
3	3 (3%)	1 (1%)	1 (1%)	2 (2%)
4	0	0	0	0
5	0	0	0	0
6	0	0	0	0
7	0	0	0	0
8	0	0	0	0
9	0	0	0	0
10	0	0	0	0
>=11	0	0	0	0
Total number of subjects with >=1 exacerbation	18 (21%)	13 (16%)	21 (23%)	15 (18%)
Total number of exacerbations	25	17	26	23

Note: MEA117113 and MEA117106 studies of 52 weeks duration.

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Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Table 211.7

Summary of Frequency of Exacerbations Requiring ED/Hospitalization: Studies MEA117113 and MEA117106

Study Phase: Off-Treatment

	MEA117113		MEA117106	
	PBO (N=87)	100 SC (N=83)	PBO (N=90)	100 SC (N=82)
n	87	83	90	82
0	87 (100%)	83 (100%)	89 (99%)	82 (100%)
1	0	0	1 (1%)	0
2	0	0	0	0
3	0	0	0	0
4	0	0	0	0
5	0	0	0	0
6	0	0	0	0
7	0	0	0	0
8	0	0	0	0
9	0	0	0	0
10	0	0	0	0
>=11	0	0	0	0
Total number of subjects with >=1 exacerbation	0	0	1 (1%)	0
Total number of exacerbations	0	0	1	0

Note: MEA117113 and MEA117106 studies of 52 weeks duration.

Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Table 211.7

Summary of Frequency of Exacerbations Requiring ED/Hospitalization: Studies MEA117113 and MEA117106

Study Phase: Post-Treatment

	MEA117113		MEA117106	
	PBO (N=87)	100 SC (N=83)	PBO (N=90)	100 SC (N=82)
n	87	83	90	82
0	83 (95%)	82 (99%)	87 (97%)	77 (94%)
1	3 (3%)	1 (1%)	3 (3%)	5 (6%)
2	1 (1%)	0	0	0
3	0	0	0	0
4	0	0	0	0
5	0	0	0	0
6	0	0	0	0
7	0	0	0	0
8	0	0	0	0
9	0	0	0	0
10	0	0	0	0
>=11	0	0	0	0
Total number of subjects with >=1 exacerbation	4 (5%)	1 (1%)	3 (3%)	5 (6%)
Total number of exacerbations	5	1	3	5

Note: MEA117113 and MEA117106 studies of 52 weeks duration.

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Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Table 211.8

Summary of Frequency of Annualized Exacerbations Requiring ED/Hospitalization: Study 208657

Study Phase: On- and Off-Treatment

	PBO (N=401)	100 SC (N=403)
Number of annualized exacerbations		
n	401	403
0-<1	361 (90%)	367 (91%)
1-<2	26 (6%)	24 (6%)
2-<3	7 (2%)	5 (1%)
3-<4	2 (<1%)	2 (<1%)
4-<5	1 (<1%)	3 (<1%)
5-<6	2 (<1%)	0
6-<7	0	0
7-<8	1 (<1%)	0
8-<9	0	2 (<1%)
9-<10	1 (<1%)	0
>=10	0	0
Total number of subjects with >=1 exacerbation	71 (18%)	56 (14%)
Total number of exacerbations	107	89

Note: 208657 study of 52-104 weeks duration.

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Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Table 211.8

Summary of Frequency of Annualized Exacerbations Requiring ED/Hospitalization: Study 208657

Study Phase: On-Treatment

	PBO (N=401)	100 SC (N=403)
Number of annualized exacerbations		
n	401	403
0-<1	361 (90%)	368 (91%)
1-<2	26 (6%)	25 (6%)
2-<3	7 (2%)	2 (<1%)
3-<4	1 (<1%)	3 (<1%)
4-<5	0	3 (<1%)
5-<6	2 (<1%)	1 (<1%)
6-<7	1 (<1%)	0
7-<8	1 (<1%)	0
8-<9	0	0
9-<10	1 (<1%)	0
>=10	1 (<1%)	1 (<1%)
Total number of subjects with >=1 exacerbation	69 (17%)	55 (14%)
Total number of exacerbations	100	79

Note: 208657 study of 52-104 weeks duration.

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Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Table 211.8

Summary of Frequency of Annualized Exacerbations Requiring ED/Hospitalization: Study 208657

Study Phase: Off-Treatment

	PBO (N=401)	100 SC (N=403)
Number of annualized exacerbations		
n	401	403
0-<1	396 (99%)	398 (99%)
1-<2	3 (<1%)	0
2-<3	0	1 (<1%)
3-<4	1 (<1%)	0
4-<5	1 (<1%)	0
5-<6	0	2 (<1%)
6-<7	0	0
7-<8	0	0
8-<9	0	0
9-<10	0	0
>=10	0	2 (<1%)
Total number of subjects with >=1 exacerbation	5 (1%)	5 (1%)
Total number of exacerbations	7	10

Note: 208657 study of 52-104 weeks duration.

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Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Table 211.9

Analysis of Rate of Exacerbations Requiring ED/Hospitalization: Individual studies and Meta-Analysis (Negative Binomial Model)

	PBO (N=578)	100 SC (N=568)
208657		
n	401	403
Exacerbation rate/year	0.20	0.13
Rate Ratio vs Placebo [1]		0.65
95% CI		(0.43, 0.96)
p-value		0.032
MEA117113		
n	87	83
Exacerbation rate/year	0.25	0.16
Rate Ratio vs Placebo [1]		0.62
95% CI		(0.26, 1.49)
p-value		0.285
MEA117106		
n	90	82
Exacerbation rate/year	0.24	0.21
Rate Ratio vs Placebo [1]		0.88
95% CI		(0.47, 1.67)
p-value		0.701

[1] Analysis performed using a negative binomial regression model with covariates of treatment group, smoking status, baseline % predicted FEV1, number of exacerbations in previous year (as an ordinal variable), and geographic region (as defined for the study/ISE) with log(time in on- and off-treatment period) as an offset variable. Estimates based on weighting applied to each level of class variable determined from observed proportions.
[2] Analysis model as in footnote [1] with an additional covariate of study.
[3] Analysis model as in footnote [2] with an additional covariate of study*treatment interaction.
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Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Table 211.9

Analysis of Rate of Exacerbations Requiring ED/Hospitalization: Individual studies and Meta-Analysis (Negative Binomial Model)

	PBO (N=578)	100 SC (N=568)
208657 + MEA117113 + MEA117106		
n	578	568
Exacerbation rate/year	0.23	0.16
Rate Ratio vs Placebo [2]		0.71
95% CI		(0.51, 0.98)
p-value		0.038
p-value for study*treatment interaction [3]		0.828

[1] Analysis performed using a negative binomial regression model with covariates of treatment group, smoking status, baseline % predicted FEV1, number of exacerbations in previous year (as an ordinal variable), and geographic region (as defined for the study/ISE) with log(time in on- and off-treatment period) as an offset variable. Estimates based on weighting applied to each level of class variable determined from observed proportions.
[2] Analysis model as in footnote [1] with an additional covariate of study.
[3] Analysis model as in footnote [2] with an additional covariate of study*treatment interaction.
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Population: Modified Intent-to-Treat Population with Eosinophils 300 cells/uL or More

Table 211.10

Analysis of Time to First Exacerbation Requiring ED/Hospitalization: Individual Studies and Meta-Analysis

	PBO (N=578)	100 SC (N=568)
208657		
n	401	403
By week 8		
Subjects with event	13 (3%)	12 (3%)
Probability of an exacerbation [1]	3.3%	3.0%
95% CI	(1.9%, 5.6%)	(1.7%, 5.2%)
By week 16		
Subjects with event	25 (6%)	19 (5%)
Probability of an exacerbation [1]	6.4%	4.8%
95% CI	(4.3%, 9.3%)	(3.1%, 7.4%)
By week 24		
Subjects with event	37 (9%)	26 (6%)
Probability of an exacerbation [1]	9.5%	6.6%
95% CI	(7.0%, 12.9%)	(4.5%, 9.5%)
By week 32		
Subjects with event	47 (12%)	32 (8%)
Probability of an exacerbation [1]	12.1%	8.2%
95% CI	(9.3%, 15.8%)	(5.8%, 11.3%)
By week 40		
Subjects with event	54 (13%)	40 (10%)
Probability of an exacerbation [1]	14.0%	10.3%
95% CI	(10.9%, 17.9%)	(7.6%, 13.8%)

[1] Kaplan-Meier estimate.
[2] Estimated from a Cox Proportional Hazards Model with covariates of treatment group, smoking status, baseline % predicted FEV1, number of exacerbations in previous year (as an ordinal variable), and geographic region (as defined for the study/ISE).
[3] Analysis model as in footnote [2] with an additional covariate of study.
[4] Analysis model as in footnote [3] with an additional covariate of study*treatment interaction.
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Population: Modified Intent-to-Treat Population with Eosinophils 300 cells/uL or More

Table 211.10

Analysis of Time to First Exacerbation Requiring ED/Hospitalization: Individual Studies and Meta-Analysis

	PBO (N=578)	100 SC (N=568)
By week 48		
Subjects with event	60 (15%)	47 (12%)
Probability of an exacerbation [1]	15.6%	12.2%
95% CI	(12.3%, 19.7%)	(9.3%, 15.9%)
By week 52		
Subjects with event	62 (15%)	49 (12%)
Probability of an exacerbation [1]	16.2%	12.7%
95% CI	(12.8%, 20.3%)	(9.8%, 16.5%)
By week 56		
Subjects with event	63 (16%)	50 (12%)
Probability of an exacerbation [1]	16.8%	13.3%
95% CI	(13.3%, 21.0%)	(10.2%, 17.2%)
By week 64		
Subjects with event	66 (16%)	52 (13%)
Probability of an exacerbation [1]	18.8%	14.5%
95% CI	(14.8%, 23.6%)	(11.1%, 18.8%)
By week 72		
Subjects with event	67 (17%)	53 (13%)
Probability of an exacerbation [1]	19.6%	15.3%
95% CI	(15.4%, 24.7%)	(11.6%, 19.8%)

[1] Kaplan-Meier estimate.
[2] Estimated from a Cox Proportional Hazards Model with covariates of treatment group, smoking status, baseline % predicted FEV1, number of exacerbations in previous year (as an ordinal variable), and geographic region (as defined for the study/ISE).
[3] Analysis model as in footnote [2] with an additional covariate of study.
[4] Analysis model as in footnote [3] with an additional covariate of study*treatment interaction.
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Population: Modified Intent-to-Treat Population with Eosinophils 300 cells/uL or More

Table 211.10

Analysis of Time to First Exacerbation Requiring ED/Hospitalization: Individual Studies and Meta-Analysis

	PBO (N=578)	100 SC (N=568)
By week 80		
Subjects with event	68 (17%)	55 (14%)
Probability of an exacerbation [1]	20.4%	16.8%
95% CI	(16.0%, 25.7%)	(12.8%, 21.9%)
By week 88		
Subjects with event	70 (17%)	55 (14%)
Probability of an exacerbation [1]	22.2%	16.8%
95% CI	(17.4%, 28.1%)	(12.8%, 21.9%)
By week 96		
Subjects with event	70 (17%)	56 (14%)
Probability of an exacerbation [1]	22.2%	17.6%
95% CI	(17.4%, 28.1%)	(13.4%, 23.0%)
By week 104		
Subjects with event	71 (18%)	56 (14%)
Probability of an exacerbation [1]	23.4%	17.6%
95% CI	(18.2%, 29.7%)	(13.4%, 23.0%)
Hazard ratio (Mepo/Placebo) [2]		0.73
95% CI		(0.51, 1.04)
p-value		0.079

[1] Kaplan-Meier estimate.
[2] Estimated from a Cox Proportional Hazards Model with covariates of treatment group, smoking status, baseline % predicted FEV1, number of exacerbations in previous year (as an ordinal variable), and geographic region (as defined for the study/ISE).
[3] Analysis model as in footnote [2] with an additional covariate of study.
[4] Analysis model as in footnote [3] with an additional covariate of study*treatment interaction.
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Population: Modified Intent-to-Treat Population with Eosinophils 300 cells/uL or More

Table 211.10

Analysis of Time to First Exacerbation Requiring ED/Hospitalization: Individual Studies and Meta-Analysis

	PBO (N=578)	100 SC (N=568)
MEA117113		
n	87	83
By week 8		
Subjects with event	3 (3%)	3 (4%)
Probability of an exacerbation [1]	3.4%	3.6%
95% CI	(1.1%, 10.3%)	(1.2%, 10.8%)
By week 16		
Subjects with event	6 (7%)	5 (6%)
Probability of an exacerbation [1]	7.0%	6.0%
95% CI	(3.2%, 14.9%)	(2.6%, 13.9%)
By week 24		
Subjects with event	9 (10%)	8 (10%)
Probability of an exacerbation [1]	10.6%	9.7%
95% CI	(5.7%, 19.4%)	(4.9%, 18.4%)
By week 32		
Subjects with event	14 (16%)	8 (10%)
Probability of an exacerbation [1]	16.7%	9.7%
95% CI	(10.3%, 26.6%)	(4.9%, 18.4%)
By week 40		
Subjects with event	18 (21%)	8 (10%)
Probability of an exacerbation [1]	21.8%	9.7%
95% CI	(14.3%, 32.4%)	(4.9%, 18.4%)

[1] Kaplan-Meier estimate.
[2] Estimated from a Cox Proportional Hazards Model with covariates of treatment group, smoking status, baseline % predicted FEV1, number of exacerbations in previous year (as an ordinal variable), and geographic region (as defined for the study/ISE).
[3] Analysis model as in footnote [2] with an additional covariate of study.
[4] Analysis model as in footnote [3] with an additional covariate of study*treatment interaction.
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Population: Modified Intent-to-Treat Population with Eosinophils 300 cells/uL or More

Table 211.10

Analysis of Time to First Exacerbation Requiring ED/Hospitalization: Individual Studies and Meta-Analysis

	PBO (N=578)	100 SC (N=568)
By week 48		
Subjects with event	18 (21%)	11 (13%)
Probability of an exacerbation [1]	21.8%	13.4%
95% CI	(14.3%, 32.4%)	(7.7%, 22.9%)
By week 52		
Subjects with event	18 (21%)	13 (16%)
Probability of an exacerbation [1]	21.8%	16.0%
95% CI	(14.3%, 32.4%)	(9.6%, 25.9%)
Hazard ratio (Mepo/Placebo) [2]		0.81
95% CI		(0.39, 1.67)
p-value		0.562

[1] Kaplan-Meier estimate.
[2] Estimated from a Cox Proportional Hazards Model with covariates of treatment group, smoking status, baseline % predicted FEV1, number of exacerbations in previous year (as an ordinal variable), and geographic region (as defined for the study/ISE).
[3] Analysis model as in footnote [2] with an additional covariate of study.
[4] Analysis model as in footnote [3] with an additional covariate of study*treatment interaction.
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Population: Modified Intent-to-Treat Population with Eosinophils 300 cells/uL or More

Table 211.10

Analysis of Time to First Exacerbation Requiring ED/Hospitalization: Individual Studies and Meta-Analysis

	PBO (N=578)	100 SC (N=568)
MEA117106		
n	90	82
By week 8		
Subjects with event	7 (8%)	3 (4%)
Probability of an exacerbation [1]	7.8%	3.7%
95% CI	(3.8%, 15.7%)	(1.2%, 11.0%)
By week 16		
Subjects with event	8 (9%)	5 (6%)
Probability of an exacerbation [1]	8.9%	6.2%
95% CI	(4.6%, 17.1%)	(2.6%, 14.2%)
By week 24		
Subjects with event	12 (13%)	8 (10%)
Probability of an exacerbation [1]	13.5%	9.9%
95% CI	(7.9%, 22.6%)	(5.1%, 18.8%)
By week 32		
Subjects with event	16 (18%)	12 (15%)
Probability of an exacerbation [1]	18.2%	14.8%
95% CI	(11.5%, 27.9%)	(8.7%, 24.6%)
By week 40		
Subjects with event	18 (20%)	13 (16%)
Probability of an exacerbation [1]	20.5%	16.1%
95% CI	(13.5%, 30.6%)	(9.7%, 26.0%)

[1] Kaplan-Meier estimate.
[2] Estimated from a Cox Proportional Hazards Model with covariates of treatment group, smoking status, baseline % predicted FEV1, number of exacerbations in previous year (as an ordinal variable), and geographic region (as defined for the study/ISE).
[3] Analysis model as in footnote [2] with an additional covariate of study.
[4] Analysis model as in footnote [3] with an additional covariate of study*treatment interaction.
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Population: Modified Intent-to-Treat Population with Eosinophils 300 cells/uL or More

Table 211.10

Analysis of Time to First Exacerbation Requiring ED/Hospitalization: Individual Studies and Meta-Analysis

	PBO (N=578)	100 SC (N=568)
By week 48		
Subjects with event	20 (22%)	14 (17%)
Probability of an exacerbation [1]	22.9%	17.3%
95% CI	(15.4%, 33.2%)	(10.6%, 27.5%)
By week 52		
Subjects with event	21 (23%)	15 (18%)
Probability of an exacerbation [1]	24.2%	18.6%
95% CI	(16.5%, 34.6%)	(11.6%, 28.9%)
Hazard ratio (Mepo/Placebo) [2]		0.68
95% CI		(0.35, 1.34)
p-value		0.267

[1] Kaplan-Meier estimate.
[2] Estimated from a Cox Proportional Hazards Model with covariates of treatment group, smoking status, baseline % predicted FEV1, number of exacerbations in previous year (as an ordinal variable), and geographic region (as defined for the study/ISE).
[3] Analysis model as in footnote [2] with an additional covariate of study.
[4] Analysis model as in footnote [3] with an additional covariate of study*treatment interaction.
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Population: Modified Intent-to-Treat Population with Eosinophils 300 cells/uL or More

Table 211.10

Analysis of Time to First Exacerbation Requiring ED/Hospitalization: Individual Studies and Meta-Analysis

	PBO (N=578)	100 SC (N=568)
208657 + MEA117113 + MEA117106		
n	578	568
By week 8		
Subjects with event	23 (4%)	18 (3%)
Probability of an exacerbation [1]	4.0%	3.2%
95% CI	(2.7%, 6.0%)	(2.0%, 5.0%)
By week 16		
Subjects with event	39 (7%)	29 (5%)
Probability of an exacerbation [1]	6.9%	5.2%
95% CI	(5.1%, 9.3%)	(3.6%, 7.3%)
By week 24		
Subjects with event	58 (10%)	42 (7%)
Probability of an exacerbation [1]	10.3%	7.5%
95% CI	(8.0%, 13.1%)	(5.6%, 10.0%)
By week 32		
Subjects with event	77 (13%)	52 (9%)
Probability of an exacerbation [1]	13.8%	9.4%
95% CI	(11.2%, 16.9%)	(7.2%, 12.1%)
By week 40		
Subjects with event	90 (16%)	61 (11%)
Probability of an exacerbation [1]	16.2%	11.0%
95% CI	(13.3%, 19.5%)	(8.7%, 14.0%)

[1] Kaplan-Meier estimate.
[2] Estimated from a Cox Proportional Hazards Model with covariates of treatment group, smoking status, baseline % predicted FEV1, number of exacerbations in previous year (as an ordinal variable), and geographic region (as defined for the study/ISE).
[3] Analysis model as in footnote [2] with an additional covariate of study.
[4] Analysis model as in footnote [3] with an additional covariate of study*treatment interaction.
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Population: Modified Intent-to-Treat Population with Eosinophils 300 cells/uL or More

Table 211.10

Analysis of Time to First Exacerbation Requiring ED/Hospitalization: Individual Studies and Meta-Analysis

	PBO (N=578)	100 SC (N=568)
By week 48		
Subjects with event	98 (17%)	72 (13%)
Probability of an exacerbation [1]	17.7%	13.1%
95% CI	(14.7%, 21.1%)	(10.6%, 16.2%)
By week 52		
Subjects with event	101 (17%)	77 (14%)
Probability of an exacerbation [1]	18.2%	14.1%
95% CI	(15.3%, 21.7%)	(11.4%, 17.3%)
By week 56		
Subjects with event	102 (18%)	78 (14%)
Probability of an exacerbation [1]	18.8%	14.6%
95% CI	(15.7%, 22.5%)	(11.8%, 18.0%)
By week 64		
Subjects with event	105 (18%)	80 (14%)
Probability of an exacerbation [1]	20.8%	15.8%
95% CI	(17.1%, 25.1%)	(12.7%, 19.7%)
By week 72		
Subjects with event	106 (18%)	81 (14%)
Probability of an exacerbation [1]	21.6%	16.6%
95% CI	(17.7%, 26.1%)	(13.2%, 20.7%)

[1] Kaplan-Meier estimate.
[2] Estimated from a Cox Proportional Hazards Model with covariates of treatment group, smoking status, baseline % predicted FEV1, number of exacerbations in previous year (as an ordinal variable), and geographic region (as defined for the study/ISE).
[3] Analysis model as in footnote [2] with an additional covariate of study.
[4] Analysis model as in footnote [3] with an additional covariate of study*treatment interaction.
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Population: Modified Intent-to-Treat Population with Eosinophils 300 cells/uL or More

Table 211.10

Analysis of Time to First Exacerbation Requiring ED/Hospitalization: Individual Studies and Meta-Analysis

	PBO (N=578)	100 SC (N=568)
By week 80		
Subjects with event	107 (19%)	83 (15%)
Probability of an exacerbation [1]	22.4%	18.1%
95% CI	(18.3%, 27.2%)	(14.3%, 22.8%)
By week 88		
Subjects with event	109 (19%)	83 (15%)
Probability of an exacerbation [1]	24.1%	18.1%
95% CI	(19.6%, 29.6%)	(14.3%, 22.8%)
By week 96		
Subjects with event	109 (19%)	84 (15%)
Probability of an exacerbation [1]	24.1%	18.9%
95% CI	(19.6%, 29.6%)	(14.9%, 23.9%)
By week 104		
Subjects with event	110 (19%)	84 (15%)
Probability of an exacerbation [1]	25.3%	18.9%
95% CI	(20.3%, 31.1%)	(14.9%, 23.9%)
Hazard ratio (Mepo/Placebo) [3]		0.74
95% CI		(0.56, 0.98)
p-value		0.037
p-value for study*treatment interaction [4]		>0.999

[1] Kaplan-Meier estimate.
[2] Estimated from a Cox Proportional Hazards Model with covariates of treatment group, smoking status, baseline % predicted FEV1, number of exacerbations in previous year (as an ordinal variable), and geographic region (as defined for the study/ISE).
[3] Analysis model as in footnote [2] with an additional covariate of study.
[4] Analysis model as in footnote [3] with an additional covariate of study*treatment interaction.
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Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Table 211.11

Summary of Frequency of Severe Exacerbations: Studies MEA117113 and MEA117106

Study Phase: On- and Off-Treatment

	MEA117113		MEA117106	
	PBO (N=87)	100 SC (N=83)	PBO (N=90)	100 SC (N=82)
n	87	83	90	82
0	73 (84%)	73 (88%)	73 (81%)	70 (85%)
1	11 (13%)	7 (8%)	12 (13%)	7 (9%)
2	2 (2%)	2 (2%)	4 (4%)	3 (4%)
3	1 (1%)	1 (1%)	1 (1%)	2 (2%)
4	0	0	0	0
5	0	0	0	0
6	0	0	0	0
7	0	0	0	0
8	0	0	0	0
9	0	0	0	0
10	0	0	0	0
>=11	0	0	0	0
Total number of subjects with >=1 exacerbation	14 (16%)	10 (12%)	17 (19%)	12 (15%)
Total number of exacerbations	18	14	23	19

Note: MEA117113 and MEA117106 studies of 52 weeks duration.

Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Table 211.11

Summary of Frequency of Severe Exacerbations: Studies MEA117113 and MEA117106

Study Phase: On-Treatment

	MEA117113		MEA117106	
	PBO (N=87)	100 SC (N=83)	PBO (N=90)	100 SC (N=82)
n	87	83	90	82
0	73 (84%)	73 (88%)	73 (81%)	70 (85%)
1	11 (13%)	7 (8%)	13 (14%)	7 (9%)
2	2 (2%)	2 (2%)	3 (3%)	3 (4%)
3	1 (1%)	1 (1%)	1 (1%)	2 (2%)
4	0	0	0	0
5	0	0	0	0
6	0	0	0	0
7	0	0	0	0
8	0	0	0	0
9	0	0	0	0
10	0	0	0	0
>=11	0	0	0	0
Total number of subjects with >=1 exacerbation	14 (16%)	10 (12%)	17 (19%)	12 (15%)
Total number of exacerbations	18	14	22	19

Note: MEA117113 and MEA117106 studies of 52 weeks duration.

Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Table 211.11

Summary of Frequency of Severe Exacerbations: Studies MEA117113 and MEA117106

Study Phase: Off-Treatment

	MEA117113		MEA117106	
	PBO (N=87)	100 SC (N=83)	PBO (N=90)	100 SC (N=82)
n	87	83	90	82
0	87 (100%)	83 (100%)	89 (99%)	82 (100%)
1	0	0	1 (1%)	0
2	0	0	0	0
3	0	0	0	0
4	0	0	0	0
5	0	0	0	0
6	0	0	0	0
7	0	0	0	0
8	0	0	0	0
9	0	0	0	0
10	0	0	0	0
>=11	0	0	0	0
Total number of subjects with >=1 exacerbation	0	0	1 (1%)	0
Total number of exacerbations	0	0	1	0

Note: MEA117113 and MEA117106 studies of 52 weeks duration.

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Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Table 211.11

Summary of Frequency of Severe Exacerbations: Studies MEA117113 and MEA117106

Study Phase: Post-Treatment

	MEA117113		MEA117106	
	PBO (N=87)	100 SC (N=83)	PBO (N=90)	100 SC (N=82)
n	87	83	90	82
0	84 (97%)	83 (100%)	87 (97%)	78 (95%)
1	3 (3%)	0	3 (3%)	4 (5%)
2	0	0	0	0
3	0	0	0	0
4	0	0	0	0
5	0	0	0	0
6	0	0	0	0
7	0	0	0	0
8	0	0	0	0
9	0	0	0	0
10	0	0	0	0
>=11	0	0	0	0
Total number of subjects with >=1 exacerbation	3 (3%)	0	3 (3%)	4 (5%)
Total number of exacerbations	3	0	3	4

Note: MEA117113 and MEA117106 studies of 52 weeks duration.

Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Table 211.12

Summary of Frequency of Annualized Severe Exacerbations: Study 208657

Study Phase: On- and Off-Treatment

	PBO (N=401)	100 SC (N=403)
Number of annualized exacerbations		
n	401	403
0-<1	368 (92%)	378 (94%)
1-<2	21 (5%)	16 (4%)
2-<3	5 (1%)	2 (<1%)
3-<4	2 (<1%)	3 (<1%)
4-<5	2 (<1%)	3 (<1%)
5-<6	2 (<1%)	0
6-<7	0	0
7-<8	0	0
8-<9	0	1 (<1%)
9-<10	1 (<1%)	0
>=10	0	0
Total number of subjects with >=1 exacerbation	59 (15%)	46 (11%)
Total number of exacerbations	85	73

Note: 208657 study of 52-104 weeks duration.

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Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Table 211.12

Summary of Frequency of Annualized Severe Exacerbations: Study 208657

Study Phase: On-Treatment

	PBO (N=401)	100 SC (N=403)
Number of annualized exacerbations		
n	401	403
0-<1	367 (92%)	379 (94%)
1-<2	23 (6%)	17 (4%)
2-<3	4 (<1%)	1 (<1%)
3-<4	1 (<1%)	2 (<1%)
4-<5	1 (<1%)	3 (<1%)
5-<6	2 (<1%)	1 (<1%)
6-<7	1 (<1%)	0
7-<8	0	0
8-<9	0	0
9-<10	1 (<1%)	0
>=10	1 (<1%)	0
Total number of subjects with >=1 exacerbation	57 (14%)	45 (11%)
Total number of exacerbations	78	64

Note: 208657 study of 52-104 weeks duration.

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Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Table 211.12

Summary of Frequency of Annualized Severe Exacerbations: Study 208657

Study Phase: Off-Treatment

	PBO (N=401)	100 SC (N=403)
Number of annualized exacerbations		
n	401	403
0-<1	396 (99%)	398 (99%)
1-<2	3 (<1%)	0
2-<3	0	0
3-<4	1 (<1%)	2 (<1%)
4-<5	1 (<1%)	0
5-<6	0	1 (<1%)
6-<7	0	0
7-<8	0	0
8-<9	0	0
9-<10	0	0
>=10	0	2 (<1%)
Total number of subjects with >=1 exacerbation	5 (1%)	5 (1%)
Total number of exacerbations	7	9

Note: 208657 study of 52-104 weeks duration.

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Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Table 211.13

Analysis of Rate of Severe Exacerbations: Individual studies and Meta-Analysis
(Negative Binomial Model)

	PBO (N=578)	100 SC (N=568)
208657		
n	401	403
Exacerbation rate/year	0.15	0.10
Rate Ratio vs Placebo [1]		0.66
95% CI		(0.43, 1.01)
p-value		0.055
MEA117113		
n	87	83
Exacerbation rate/year	0.13	0.10
Rate Ratio vs Placebo [1]		0.75
95% CI		(0.28, 1.99)
p-value		0.568
MEA117106		
n	90	82
Exacerbation rate/year	0.19	0.16
Rate Ratio vs Placebo [1]		0.85
95% CI		(0.41, 1.77)
p-value		0.668

[1] Analysis performed using a negative binomial regression model with covariates of treatment group, smoking status, baseline % predicted FEV1, number of exacerbations in previous year (as an ordinal variable), and geographic region (as defined for the study/ISE) with log(time in on- and off-treatment period) as an offset variable. Estimates based on weighting applied to each level of class variable determined from observed proportions.
[2] Analysis model as in footnote [1] with an additional covariate of study.
[3] Analysis model as in footnote [2] with an additional covariate of study*treatment interaction.
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Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Table 211.13

Analysis of Rate of Severe Exacerbations: Individual studies and Meta-Analysis
(Negative Binomial Model)

	PBO (N=578)	100 SC (N=568)
208657 + MEA117113 + MEA117106		
n	578	568
Exacerbation rate/year	0.17	0.13
Rate Ratio vs Placebo [2]		0.75
95% CI		(0.52, 1.07)
p-value		0.113
p-value for study*treatment interaction [3]		0.931

[1] Analysis performed using a negative binomial regression model with covariates of treatment group, smoking status, baseline % predicted FEV1, number of exacerbations in previous year (as an ordinal variable), and geographic region (as defined for the study/ISE) with log(time in on- and off-treatment period) as an offset variable. Estimates based on weighting applied to each level of class variable determined from observed proportions.
[2] Analysis model as in footnote [1] with an additional covariate of study.
[3] Analysis model as in footnote [2] with an additional covariate of study*treatment interaction.
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Population: Modified Intent-to-Treat Population with Eosinophils 300 cells/uL or More

Table 211.14

Analysis of Time to First Severe Exacerbation: Individual Studies and Meta-Analysis

	PBO (N=578)	100 SC (N=568)
208657		
n	401	403
By week 8		
Subjects with event	11 (3%)	11 (3%)
Probability of an exacerbation [1]	2.8%	2.8%
95% CI	(1.5%, 5.0%)	(1.5%, 4.9%)
By week 16		
Subjects with event	20 (5%)	15 (4%)
Probability of an exacerbation [1]	5.1%	3.8%
95% CI	(3.3%, 7.8%)	(2.3%, 6.2%)
By week 24		
Subjects with event	29 (7%)	21 (5%)
Probability of an exacerbation [1]	7.4%	5.3%
95% CI	(5.2%, 10.5%)	(3.5%, 8.0%)
By week 32		
Subjects with event	39 (10%)	25 (6%)
Probability of an exacerbation [1]	10.1%	6.4%
95% CI	(7.5%, 13.5%)	(4.3%, 9.3%)
By week 40		
Subjects with event	45 (11%)	33 (8%)
Probability of an exacerbation [1]	11.7%	8.5%
95% CI	(8.8%, 15.3%)	(6.1%, 11.8%)

[1] Kaplan-Meier estimate.
[2] Estimated from a Cox Proportional Hazards Model with covariates of treatment group, smoking status, baseline % predicted FEV1, number of exacerbations in previous year (as an ordinal variable), and geographic region (as defined for the study/ISE).
[3] Analysis model as in footnote [2] with an additional covariate of study.
[4] Analysis model as in footnote [3] with an additional covariate of study*treatment interaction.
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Population: Modified Intent-to-Treat Population with Eosinophils 300 cells/uL or More

Table 211.14

Analysis of Time to First Severe Exacerbation: Individual Studies and Meta-Analysis

	PBO (N=578)	100 SC (N=568)
By week 48		
Subjects with event	49 (12%)	36 (9%)
Probability of an exacerbation [1]	12.7%	9.3%
95% CI	(9.8%, 16.5%)	(6.8%, 12.7%)
By week 52		
Subjects with event	50 (12%)	38 (9%)
Probability of an exacerbation [1]	13.0%	9.9%
95% CI	(10.0%, 16.8%)	(7.3%, 13.3%)
By week 56		
Subjects with event	50 (12%)	39 (10%)
Probability of an exacerbation [1]	13.0%	10.4%
95% CI	(10.0%, 16.8%)	(7.7%, 14.1%)
By week 64		
Subjects with event	54 (13%)	42 (10%)
Probability of an exacerbation [1]	15.7%	12.3%
95% CI	(12.0%, 20.4%)	(9.0%, 16.5%)
By week 72		
Subjects with event	55 (14%)	43 (11%)
Probability of an exacerbation [1]	16.5%	13.0%
95% CI	(12.6%, 21.5%)	(9.6%, 17.6%)

[1] Kaplan-Meier estimate.
[2] Estimated from a Cox Proportional Hazards Model with covariates of treatment group, smoking status, baseline % predicted FEV1, number of exacerbations in previous year (as an ordinal variable), and geographic region (as defined for the study/ISE).
[3] Analysis model as in footnote [2] with an additional covariate of study.
[4] Analysis model as in footnote [3] with an additional covariate of study*treatment interaction.
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Population: Modified Intent-to-Treat Population with Eosinophils 300 cells/uL or More

Table 211.14

Analysis of Time to First Severe Exacerbation: Individual Studies and Meta-Analysis

	PBO (N=578)	100 SC (N=568)
By week 80		
Subjects with event	56 (14%)	45 (11%)
Probability of an exacerbation [1]	17.3%	14.6%
95% CI	(13.2%, 22.5%)	(10.7%, 19.7%)
By week 88		
Subjects with event	58 (14%)	45 (11%)
Probability of an exacerbation [1]	19.1%	14.6%
95% CI	(14.5%, 25.0%)	(10.7%, 19.7%)
By week 96		
Subjects with event	58 (14%)	46 (11%)
Probability of an exacerbation [1]	19.1%	15.4%
95% CI	(14.5%, 25.0%)	(11.3%, 20.8%)
By week 104		
Subjects with event	59 (15%)	46 (11%)
Probability of an exacerbation [1]	20.3%	15.4%
95% CI	(15.3%, 26.6%)	(11.3%, 20.8%)
Hazard ratio (Mepo/Placebo) [2]		0.74
95% CI		(0.50, 1.08)
p-value		0.120

[1] Kaplan-Meier estimate.
[2] Estimated from a Cox Proportional Hazards Model with covariates of treatment group, smoking status, baseline % predicted FEV1, number of exacerbations in previous year (as an ordinal variable), and geographic region (as defined for the study/ISE).
[3] Analysis model as in footnote [2] with an additional covariate of study.
[4] Analysis model as in footnote [3] with an additional covariate of study*treatment interaction.
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Population: Modified Intent-to-Treat Population with Eosinophils 300 cells/uL or More

Table 211.14

Analysis of Time to First Severe Exacerbation: Individual Studies and Meta-Analysis

	PBO (N=578)	100 SC (N=568)
MEA117113		
n	87	83
By week 8		
Subjects with event	2 (2%)	2 (2%)
Probability of an exacerbation [1]	2.3%	2.4%
95% CI	(0.6%, 8.9%)	(0.6%, 9.3%)
By week 16		
Subjects with event	5 (6%)	3 (4%)
Probability of an exacerbation [1]	5.9%	3.6%
95% CI	(2.5%, 13.5%)	(1.2%, 10.8%)
By week 24		
Subjects with event	8 (9%)	6 (7%)
Probability of an exacerbation [1]	9.5%	7.2%
95% CI	(4.9%, 18.1%)	(3.3%, 15.4%)
By week 32		
Subjects with event	11 (13%)	6 (7%)
Probability of an exacerbation [1]	13.1%	7.2%
95% CI	(7.5%, 22.5%)	(3.3%, 15.4%)
By week 40		
Subjects with event	14 (16%)	6 (7%)
Probability of an exacerbation [1]	16.9%	7.2%
95% CI	(10.4%, 26.9%)	(3.3%, 15.4%)

[1] Kaplan-Meier estimate.
[2] Estimated from a Cox Proportional Hazards Model with covariates of treatment group, smoking status, baseline % predicted FEV1, number of exacerbations in previous year (as an ordinal variable), and geographic region (as defined for the study/ISE).
[3] Analysis model as in footnote [2] with an additional covariate of study.
[4] Analysis model as in footnote [3] with an additional covariate of study*treatment interaction.
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Population: Modified Intent-to-Treat Population with Eosinophils 300 cells/uL or More

Table 211.14

Analysis of Time to First Severe Exacerbation: Individual Studies and Meta-Analysis

	PBO (N=578)	100 SC (N=568)
By week 48		
Subjects with event	14 (16%)	8 (10%)
Probability of an exacerbation [1]	16.9%	9.8%
95% CI	(10.4%, 26.9%)	(5.0%, 18.6%)
By week 52		
Subjects with event	14 (16%)	10 (12%)
Probability of an exacerbation [1]	16.9%	12.4%
95% CI	(10.4%, 26.9%)	(6.8%, 21.8%)
Hazard ratio (Mepo/Placebo) [2]		0.78
95% CI		(0.34, 1.79)
p-value		0.556

[1] Kaplan-Meier estimate.
[2] Estimated from a Cox Proportional Hazards Model with covariates of treatment group, smoking status, baseline % predicted FEV1, number of exacerbations in previous year (as an ordinal variable), and geographic region (as defined for the study/ISE).
[3] Analysis model as in footnote [2] with an additional covariate of study.
[4] Analysis model as in footnote [3] with an additional covariate of study*treatment interaction.
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Population: Modified Intent-to-Treat Population with Eosinophils 300 cells/uL or More

Table 211.14

Analysis of Time to First Severe Exacerbation: Individual Studies and Meta-Analysis

	PBO (N=578)	100 SC (N=568)
MEA117106		
n	90	82
By week 8		
Subjects with event	5 (6%)	3 (4%)
Probability of an exacerbation [1]	5.6%	3.7%
95% CI	(2.4%, 12.9%)	(1.2%, 11.0%)
By week 16		
Subjects with event	6 (7%)	4 (5%)
Probability of an exacerbation [1]	6.7%	4.9%
95% CI	(3.1%, 14.4%)	(1.9%, 12.6%)
By week 24		
Subjects with event	9 (10%)	7 (9%)
Probability of an exacerbation [1]	10.2%	8.6%
95% CI	(5.5%, 18.7%)	(4.2%, 17.2%)
By week 32		
Subjects with event	13 (14%)	10 (12%)
Probability of an exacerbation [1]	14.9%	12.3%
95% CI	(8.9%, 24.3%)	(6.8%, 21.7%)
By week 40		
Subjects with event	14 (16%)	11 (13%)
Probability of an exacerbation [1]	16.1%	13.6%
95% CI	(9.9%, 25.7%)	(7.8%, 23.2%)

[1] Kaplan-Meier estimate.
[2] Estimated from a Cox Proportional Hazards Model with covariates of treatment group, smoking status, baseline % predicted FEV1, number of exacerbations in previous year (as an ordinal variable), and geographic region (as defined for the study/ISE).
[3] Analysis model as in footnote [2] with an additional covariate of study.
[4] Analysis model as in footnote [3] with an additional covariate of study*treatment interaction.
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Population: Modified Intent-to-Treat Population with Eosinophils 300 cells/uL or More

Table 211.14

Analysis of Time to First Severe Exacerbation: Individual Studies and Meta-Analysis

	PBO (N=578)	100 SC (N=568)
By week 48		
Subjects with event	16 (18%)	12 (15%)
Probability of an exacerbation [1]	18.5%	14.8%
95% CI	(11.8%, 28.4%)	(8.7%, 24.6%)
By week 52		
Subjects with event	17 (19%)	12 (15%)
Probability of an exacerbation [1]	19.8%	14.8%
95% CI	(12.8%, 29.9%)	(8.7%, 24.6%)
Hazard ratio (Mepo/Placebo) [2]		0.71
95% CI		(0.33, 1.50)
p-value		0.368

[1] Kaplan-Meier estimate.
[2] Estimated from a Cox Proportional Hazards Model with covariates of treatment group, smoking status, baseline % predicted FEV1, number of exacerbations in previous year (as an ordinal variable), and geographic region (as defined for the study/ISE).
[3] Analysis model as in footnote [2] with an additional covariate of study.
[4] Analysis model as in footnote [3] with an additional covariate of study*treatment interaction.
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Population: Modified Intent-to-Treat Population with Eosinophils 300 cells/uL or More

Table 211.14

Analysis of Time to First Severe Exacerbation: Individual Studies and Meta-Analysis

	PBO (N=578)	100 SC (N=568)
208657 + MEA117113 + MEA117106		
n	578	568
By week 8		
Subjects with event	18 (3%)	16 (3%)
Probability of an exacerbation [1]	3.1%	2.8%
95% CI	(2.0%, 4.9%)	(1.7%, 4.6%)
By week 16		
Subjects with event	31 (5%)	22 (4%)
Probability of an exacerbation [1]	5.5%	3.9%
95% CI	(3.9%, 7.7%)	(2.6%, 5.9%)
By week 24		
Subjects with event	46 (8%)	34 (6%)
Probability of an exacerbation [1]	8.2%	6.1%
95% CI	(6.2%, 10.8%)	(4.4%, 8.4%)
By week 32		
Subjects with event	63 (11%)	41 (7%)
Probability of an exacerbation [1]	11.3%	7.4%
95% CI	(8.9%, 14.2%)	(5.5%, 9.9%)
By week 40		
Subjects with event	73 (13%)	50 (9%)
Probability of an exacerbation [1]	13.1%	9.1%
95% CI	(10.6%, 16.2%)	(7.0%, 11.8%)

[1] Kaplan-Meier estimate.
[2] Estimated from a Cox Proportional Hazards Model with covariates of treatment group, smoking status, baseline % predicted FEV1, number of exacerbations in previous year (as an ordinal variable), and geographic region (as defined for the study/ISE).
[3] Analysis model as in footnote [2] with an additional covariate of study.
[4] Analysis model as in footnote [3] with an additional covariate of study*treatment interaction.
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Population: Modified Intent-to-Treat Population with Eosinophils 300 cells/uL or More

Table 211.14

Analysis of Time to First Severe Exacerbation: Individual Studies and Meta-Analysis

	PBO (N=578)	100 SC (N=568)
By week 48		
Subjects with event	79 (14%)	56 (10%)
Probability of an exacerbation [1]	14.3%	10.2%
95% CI	(11.6%, 17.5%)	(8.0%, 13.1%)
By week 52		
Subjects with event	81 (14%)	60 (11%)
Probability of an exacerbation [1]	14.6%	11.0%
95% CI	(12.0%, 17.9%)	(8.6%, 13.9%)
By week 56		
Subjects with event	81 (14%)	61 (11%)
Probability of an exacerbation [1]	14.6%	11.5%
95% CI	(12.0%, 17.9%)	(9.0%, 14.7%)
By week 64		
Subjects with event	85 (15%)	64 (11%)
Probability of an exacerbation [1]	17.3%	13.3%
95% CI	(13.8%, 21.5%)	(10.3%, 17.2%)
By week 72		
Subjects with event	86 (15%)	65 (11%)
Probability of an exacerbation [1]	18.0%	14.1%
95% CI	(14.4%, 22.6%)	(10.8%, 18.2%)

[1] Kaplan-Meier estimate.
[2] Estimated from a Cox Proportional Hazards Model with covariates of treatment group, smoking status, baseline % predicted FEV1, number of exacerbations in previous year (as an ordinal variable), and geographic region (as defined for the study/ISE).
[3] Analysis model as in footnote [2] with an additional covariate of study.
[4] Analysis model as in footnote [3] with an additional covariate of study*treatment interaction.
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Population: Modified Intent-to-Treat Population with Eosinophils 300 cells/uL or More

Table 211.14

Analysis of Time to First Severe Exacerbation: Individual Studies and Meta-Analysis

	PBO (N=578)	100 SC (N=568)
By week 80		
Subjects with event	87 (15%)	67 (12%)
Probability of an exacerbation [1]	18.9%	15.6%
95% CI	(14.9%, 23.6%)	(11.9%, 20.4%)
By week 88		
Subjects with event	89 (15%)	67 (12%)
Probability of an exacerbation [1]	20.6%	15.6%
95% CI	(16.2%, 26.1%)	(11.9%, 20.4%)
By week 96		
Subjects with event	89 (15%)	68 (12%)
Probability of an exacerbation [1]	20.6%	16.4%
95% CI	(16.2%, 26.1%)	(12.5%, 21.5%)
By week 104		
Subjects with event	90 (16%)	68 (12%)
Probability of an exacerbation [1]	21.8%	16.4%
95% CI	(17.0%, 27.7%)	(12.5%, 21.5%)
Hazard ratio (Mepo/Placebo) [3]		0.73
95% CI		(0.53, 1.01)
p-value		0.055
p-value for study*treatment interaction [4]		0.998

[1] Kaplan-Meier estimate.
[2] Estimated from a Cox Proportional Hazards Model with covariates of treatment group, smoking status, baseline % predicted FEV1, number of exacerbations in previous year (as an ordinal variable), and geographic region (as defined for the study/ISE).
[3] Analysis model as in footnote [2] with an additional covariate of study.
[4] Analysis model as in footnote [3] with an additional covariate of study*treatment interaction.
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Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Table 211.15

Summary of COPD Assessment Test (CAT) Score: Individual Studies and Meta-Analysis

	208657		MEA117113		MEA117106	
	PBO (N=401)	100 SC (N=403)	PBO (N=87)	100 SC (N=83)	PBO (N=90)	100 SC (N=82)
Baseline Total Score						
n	394	391	86	80	85	78
Mean	19.1	19.2	19.3	19.4	19.4	18.8
SD	6.75	6.97	7.39	7.42	8.10	7.90
Median	19.0	19.0	20.0	19.5	21.0	19.0
Min.	0	1	3	3	4	5
Max.	38	39	34	32	36	35
Week 12 Total Score						
n	372	376	81	76	83	79
Mean	17.0	16.8	18.8	16.1	19.1	16.2
SD	7.20	7.45	8.20	7.06	7.67	7.47
Median	17.0	17.0	18.0	16.0	20.0	16.0
Min.	2	0	0	2	2	1
Max.	36	40	37	31	39	35
Week 12 Change from Baseline						
n	366	367	80	73	79	75
Mean	-2.1	-2.4	-0.1	-3.1	-0.2	-2.5
SD	6.31	6.41	5.18	6.98	6.16	5.58
Median	-2.0	-2.0	0.0	-3.0	-1.0	-2.0
Min.	-26	-22	-18	-20	-17	-16
Max.	17	15	14	20	22	10

Note: Includes visits up to Week 52 for study 208657.

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Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Table 211.15

Summary of COPD Assessment Test (CAT) Score: Individual Studies and Meta-Analysis

	208657 + MEA117113 + MEA117106		
	PBO (N=578)	100 SC (N=568)	Total (N=1146)
Baseline Total Score			
n	565	549	1114
Mean	19.2	19.1	19.2
SD	7.05	7.17	7.11
Median	19.0	19.0	19.0
Min.	0	1	0
Max.	38	39	39
Week 12 Total Score			
n	536	531	1067
Mean	17.6	16.6	17.1
SD	7.47	7.39	7.44
Median	18.0	17.0	17.0
Min.	0	0	0
Max.	39	40	40
Week 12 Change from Baseline			
n	525	515	1040
Mean	-1.5	-2.5	-2.0
SD	6.18	6.37	6.29
Median	-1.0	-2.0	-2.0
Min.	-26	-22	-26
Max.	22	20	22

Note: Includes visits up to Week 52 for study 208657.

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Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Table 211.15

Summary of COPD Assessment Test (CAT) Score: Individual Studies and Meta-Analysis

	208657		MEA117113		MEA117106	
	PBO (N=401)	100 SC (N=403)	PBO (N=87)	100 SC (N=83)	PBO (N=90)	100 SC (N=82)
Week 24 Total Score						
n	369	369	77	75	76	77
Mean	17.0	17.2	17.7	15.9	19.5	16.3
SD	6.99	7.66	7.66	6.32	7.90	7.69
Median	17.0	17.0	18.0	17.0	21.0	15.0
Min.	0	1	0	1	2	0
Max.	39	40	36	31	34	32
Week 24 Change from Baseline						
n	363	358	76	72	72	73
Mean	-2.0	-2.2	-1.0	-3.2	-0.2	-2.4
SD	6.28	6.26	5.81	6.30	6.01	7.84
Median	-2.0	-2.0	-0.5	-3.5	0.0	-2.0
Min.	-23	-30	-26	-18	-17	-25
Max.	17	16	10	17	15	18

Note: Includes visits up to Week 52 for study 208657.

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Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Table 211.15

Summary of COPD Assessment Test (CAT) Score: Individual Studies and Meta-Analysis

	208657 + MEA117113 + MEA117106		
	PBO (N=578)	100 SC (N=568)	Total (N=1146)
Week 24 Total Score			
n	522	521	1043
Mean	17.5	16.9	17.2
SD	7.27	7.49	7.38
Median	18.0	17.0	17.0
Min.	0	0	0
Max.	39	40	40
Week 24 Change from Baseline			
n	511	503	1014
Mean	-1.6	-2.4	-2.0
SD	6.20	6.51	6.36
Median	-1.0	-2.0	-2.0
Min.	-26	-30	-30
Max.	17	18	18

Note: Includes visits up to Week 52 for study 208657.

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Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Table 211.15

Summary of COPD Assessment Test (CAT) Score: Individual Studies and Meta-Analysis

	208657		MEA117113		MEA117106	
	PBO (N=401)	100 SC (N=403)	PBO (N=87)	100 SC (N=83)	PBO (N=90)	100 SC (N=82)
Week 36 Total Score						
n	363	367	72	72	74	73
Mean	16.9	16.8	18.0	17.7	16.9	16.6
SD	7.08	7.37	7.38	6.94	7.56	7.19
Median	17.0	16.0	18.0	18.0	17.0	17.0
Min.	1	1	1	3	1	4
Max.	40	36	34	33	33	30
Week 36 Change from Baseline						
n	356	357	71	69	69	70
Mean	-2.1	-2.4	-0.6	-1.4	-2.7	-1.9
SD	6.80	6.83	6.27	7.55	7.09	7.12
Median	-2.0	-2.0	0.0	-2.0	-3.0	-1.0
Min.	-24	-28	-26	-22	-23	-27
Max.	18	19	13	15	14	14

Note: Includes visits up to Week 52 for study 208657.

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Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Table 211.15

Summary of COPD Assessment Test (CAT) Score: Individual Studies and Meta-Analysis

	208657 + MEA117113 + MEA117106		
	PBO (N=578)	100 SC (N=568)	Total (N=1146)
Week 36 Total Score			
n	509	512	1021
Mean	17.1	16.9	17.0
SD	7.19	7.28	7.23
Median	17.0	17.0	17.0
Min.	1	1	1
Max.	40	36	40
Week 36 Change from Baseline			
n	496	496	992
Mean	-2.0	-2.2	-2.1
SD	6.78	6.97	6.87
Median	-2.0	-2.0	-2.0
Min.	-26	-28	-28
Max.	18	19	19

Note: Includes visits up to Week 52 for study 208657.

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Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Table 211.15

Summary of COPD Assessment Test (CAT) Score: Individual Studies and Meta-Analysis

	208657		MEA117113		MEA117106	
	PBO (N=401)	100 SC (N=403)	PBO (N=87)	100 SC (N=83)	PBO (N=90)	100 SC (N=82)
Week 52 Total Score						
n	342	344	67	74	74	73
Mean	16.3	16.9	18.1	16.6	18.4	16.9
SD	7.26	7.48	7.98	7.44	7.39	7.37
Median	16.0	16.0	19.0	17.0	17.5	17.0
Min.	0	0	3	1	2	1
Max.	35	37	39	30	36	33
Week 52 Change from Baseline						
n	337	334	66	71	70	69
Mean	-2.6	-2.4	-0.9	-2.4	-0.9	-1.8
SD	6.86	7.42	5.85	6.44	7.80	6.82
Median	-2.0	-1.0	-1.0	-1.0	-1.0	-1.0
Min.	-21	-26	-25	-21	-24	-26
Max.	16	18	16	12	16	12

Note: Includes visits up to Week 52 for study 208657.

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Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Table 211.15

Summary of COPD Assessment Test (CAT) Score: Individual Studies and Meta-Analysis

	208657 + MEA117113 + MEA117106		
	PBO (N=578)	100 SC (N=568)	Total (N=1146)
Week 52 Total Score			
n	483	491	974
Mean	16.9	16.8	16.9
SD	7.42	7.44	7.43
Median	17.0	16.0	17.0
Min.	0	0	0
Max.	39	37	39
Week 52 Change from Baseline			
n	473	474	947
Mean	-2.1	-2.3	-2.2
SD	6.90	7.19	7.04
Median	-2.0	-1.0	-2.0
Min.	-25	-26	-26
Max.	16	18	18

Note: Includes visits up to Week 52 for study 208657.

Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Table 211.16

Summary and Analysis of COPD Assessment Test (CAT) Responders at Week 52:
Subjects With At Least 6-point Improvement in Total Score From Baseline:
Individual Studies and Meta-Analysis

	PBO (N=578)	100 SC (N=568)
208657		
n	394	391
Responder [1]	110 (28%)	106 (27%)
Non-responder	284 (72%)	285 (73%)
No change/worsening	227 (58%)	228 (58%)
Withdrawal from study prior to visit	37 (9%)	37 (9%)
Missing visit [2]	20 (5%)	20 (5%)
Inverse Odds Ratio to Placebo [3]		1.07
95% CI		(0.76, 1.50)
Inverse Relative Risk [4]		1.04
95% CI		(0.80, 1.36)
p-value		0.762
Absolute Risk Reduction [4]		0.01
95% CI		(-0.17, 0.20)

[1] Defined as a participant with a >=6-point improvement (decrease) from baseline in CAT score.
[2] Participants with an intercurrent event of either treatment interruption or treatment discontinuation related to the COVID-19 pandemic have data set to missing following the event. Missing data was not imputed.
[3] Analysis performed using a logistic regression model with covariates of baseline score, geographic region (as defined for the study/ISE), smoking status (current vs. never/ex-smoker) and treatment group.
[4] Analysis used poisson regression model with covariates as in [3] (risk difference uses identity link).
[5] Analysis model as in footnote [3] and [4] with an additional covariate of study. [6] Analysis model as in footnote [4] with an additional covariate of study*treatment interaction. Note: Inverse Odds Ratio <1, Inverse Relative Risk < 1, risk difference < 0 correspond to a benefit of Mepolizumab over Placebo.
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Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Table 211.16

Summary and Analysis of COPD Assessment Test (CAT) Responders at Week 52:
Subjects With At Least 6-point Improvement in Total Score From Baseline:
Individual Studies and Meta-Analysis

	PBO (N=578)		100 SC (N=568)	
MEA117113				
n	86		80	
Responder [1]	9	(10%)	21	(26%)
Non-responder	77	(90%)	59	(74%)
No change/worsening	57	(66%)	50	(63%)
Withdrawal from study prior to visit	17	(20%)	5	(6%)
Missing visit [2]	3	(3%)	4	(5%)
Inverse Odds Ratio to Placebo [3]			0.30	
95% CI			(0.13, 0.74)	
Inverse Relative Risk [4]			0.40	
95% CI			(0.18, 0.88)	
p-value			0.024	
Absolute Risk Reduction [4]			-0.17	
95% CI			(-0.58, 0.25)	

[1] Defined as a participant with a >=6-point improvement (decrease) from baseline in CAT score.
[2] Participants with an intercurrent event of either treatment interruption or treatment discontinuation related to the COVID-19 pandemic have data set to missing following the event. Missing data was not imputed.
[3] Analysis performed using a logistic regression model with covariates of baseline score, geographic region (as defined for the study/ISE), smoking status (current vs. never/ex-smoker) and treatment group.
[4] Analysis used poisson regression model with covariates as in [3] (risk difference uses identity link).
[5] Analysis model as in footnote [3] and [4] with an additional covariate of study. [6] Analysis model as in footnote [4] with an additional covariate of study*treatment interaction. Note: Inverse Odds Ratio <1, Inverse Relative Risk < 1, risk difference < 0 correspond to a benefit of Mepolizumab over Placebo.
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Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Table 211.16

Summary and Analysis of COPD Assessment Test (CAT) Responders at Week 52:
Subjects With At Least 6-point Improvement in Total Score From Baseline:
Individual Studies and Meta-Analysis

	PBO (N=578)	100 SC (N=568)
MEA117106		
n	85	78
Responder [1]	17 (20%)	19 (24%)
Non-responder	68 (80%)	59 (76%)
No change/worsening	53 (62%)	50 (64%)
Withdrawal from study prior to visit	8 (9%)	4 (5%)
Missing visit [2]	7 (8%)	5 (6%)
Inverse Odds Ratio to Placebo [3]		0.67
95% CI		(0.29, 1.56)
Inverse Relative Risk [4]		0.80
95% CI		(0.41, 1.54)
p-value		0.499
Absolute Risk Reduction [4]		-0.06
95% CI		(-0.47, 0.35)

[1] Defined as a participant with a >=6-point improvement (decrease) from baseline in CAT score.
[2] Participants with an intercurrent event of either treatment interruption or treatment discontinuation related to the COVID-19 pandemic have data set to missing following the event. Missing data was not imputed.
[3] Analysis performed using a logistic regression model with covariates of baseline score, geographic region (as defined for the study/ISE), smoking status (current vs. never/ex-smoker) and treatment group.
[4] Analysis used poisson regression model with covariates as in [3] (risk difference uses identity link).
[5] Analysis model as in footnote [3] and [4] with an additional covariate of study. [6] Analysis model as in footnote [4] with an additional covariate of study*treatment interaction. Note: Inverse Odds Ratio <1, Inverse Relative Risk < 1, risk difference < 0 correspond to a benefit of Mepolizumab over Placebo.
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Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Table 211.16

Summary and Analysis of COPD Assessment Test (CAT) Responders at Week 52:
Subjects With At Least 6-point Improvement in Total Score From Baseline:
Individual Studies and Meta-Analysis

	PBO (N=578)		100 SC (N=568)	
208657 + MEA117113 + MEA117106				
n	565		549	
Responder [1]	136	(24%)	146	(27%)
Non-responder	429	(76%)	403	(73%)
No change/worsening	337	(60%)	328	(60%)
Withdrawal from study prior to visit	62	(11%)	46	(8%)
Missing visit [2]	30	(5%)	29	(5%)
Inverse Odds Ratio to Placebo [3,5]			0.87	
95% CI			(0.65, 1.16)	
Inverse Relative Risk [4,5]			0.92	
95% CI			(0.72, 1.16)	
p-value			0.458	
Absolute Risk Reduction [4,5]			-0.02	
95% CI			(-0.18, 0.13)	
p-value for study*treatment interaction [6]			0.054	

[1] Defined as a participant with a >=6-point improvement (decrease) from baseline in CAT score.
[2] Participants with an intercurrent event of either treatment interruption or treatment discontinuation related to the COVID-19 pandemic have data set to missing following the event. Missing data was not imputed.
[3] Analysis performed using a logistic regression model with covariates of baseline score, geographic region (as defined for the study/ISE), smoking status (current vs. never/ex-smoker) and treatment group.
[4] Analysis used poisson regression model with covariates as in [3] (risk difference uses identity link).
[5] Analysis model as in footnote [3] and [4] with an additional covariate of study. [6] Analysis model as in footnote [4] with an additional covariate of study*treatment interaction. Note: Inverse Odds Ratio <1, Inverse Relative Risk < 1, risk difference < 0 correspond to a benefit of Mepolizumab over Placebo.
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Population: Modified Intent-to-treat Population with Eosinophils 300 cells/uL or More

Table 211.17

Analysis of Change from Baseline in COPD Assessment Test (CAT) Score - Mixed Model Repeated Measures: Individual Studies and Meta-Analysis

Visit: Week 12

	PBO (N=578)	100 SC (N=568)
208657		
n [1]	383	380
n [2]	366	367
LS Mean (SE)	17.0 (0.30)	16.7 (0.30)
LS Mean Change (SE)	-2.1 (0.30)	-2.4 (0.30)
Column vs Placebo [3]		
Difference		-0.3
95% CI		(-1.14, 0.53)
p-value		0.471
Corrected Hedges' g [6]		-0.05
95% CI		(-0.20, 0.09)

[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the given time point.
[3] Analysis performed using mixed model repeated measures with covariates of baseline score, geographic region (as defined for the study/ISE), smoking status (current vs. never/ex-smoker), treatment and visit, plus interaction terms for visit by baseline and visit by treatment group.
[4] Analysis model as in footnote [3] with an additional covariate of study.
[5] Analysis model as in footnote [4] with an additional covariate of study*treatment interaction.
[6] Based on covariate adjusted means. Note: Estimates are based on weighting applied to each level of class variable determined from observed proportions. Note: Includes visits up to Week 52 for study 208657.
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Population: Modified Intent-to-treat Population with Eosinophils 300 cells/uL or More

Table 211.17

Analysis of Change from Baseline in COPD Assessment Test (CAT) Score - Mixed Model Repeated Measures: Individual Studies and Meta-Analysis

Visit: Week 12

	PBO (N=578)	100 SC (N=568)
MEA117113		
n [1]	81	78
n [2]	80	73
LS Mean (SE)	18.7 (0.64)	15.9 (0.66)
LS Mean Change (SE)	-0.1 (0.64)	-2.9 (0.66)
Column vs Placebo [3]		
Difference		-2.8
95% CI		(-4.56, -0.95)
p-value		0.003
Corrected Hedges' g [6]		-0.48
95% CI		(-0.80, -0.16)

[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the given time point.
[3] Analysis performed using mixed model repeated measures with covariates of baseline score, geographic region (as defined for the study/ISE), smoking status (current vs. never/ex-smoker), treatment and visit, plus interaction terms for visit by baseline and visit by treatment group.
[4] Analysis model as in footnote [3] with an additional covariate of study.
[5] Analysis model as in footnote [4] with an additional covariate of study*treatment interaction.
[6] Based on covariate adjusted means. Note: Estimates are based on weighting applied to each level of class variable determined from observed proportions. Note: Includes visits up to Week 52 for study 208657.
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Population: Modified Intent-to-treat Population with Eosinophils 300 cells/uL or More

Table 211.17

Analysis of Change from Baseline in COPD Assessment Test (CAT) Score - Mixed Model Repeated Measures: Individual Studies and Meta-Analysis

Visit: Week 12

	PBO (N=578)	100 SC (N=568)
MEA117106		
n [1]	82	77
n [2]	79	75
LS Mean (SE)	19.0 (0.59)	16.4 (0.61)
LS Mean Change (SE)	-0.1 (0.59)	-2.7 (0.61)
Column vs Placebo [3]		
Difference		-2.6
95% CI		(-4.28, -0.93)
p-value		0.003
Corrected Hedges' g [6]		-0.49
95% CI		(-0.82, -0.17)

[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the given time point.
[3] Analysis performed using mixed model repeated measures with covariates of baseline score, geographic region (as defined for the study/ISE), smoking status (current vs. never/ex-smoker), treatment and visit, plus interaction terms for visit by baseline and visit by treatment group.
[4] Analysis model as in footnote [3] with an additional covariate of study.
[5] Analysis model as in footnote [4] with an additional covariate of study*treatment interaction.
[6] Based on covariate adjusted means. Note: Estimates are based on weighting applied to each level of class variable determined from observed proportions. Note: Includes visits up to Week 52 for study 208657.
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Population: Modified Intent-to-treat Population with Eosinophils 300 cells/uL or More

Table 211.17

Analysis of Change from Baseline in COPD Assessment Test (CAT) Score - Mixed Model Repeated Measures: Individual Studies and Meta-Analysis

Visit: Week 12

	PBO (N=578)	100 SC (N=568)
208657 + MEA117113 + MEA117106		
n [1]	546	535
n [2]	525	515
LS Mean (SE)	17.6 (0.25)	16.6 (0.25)
LS Mean Change (SE)	-1.4 (0.25)	-2.5 (0.25)
Column vs Placebo [4]		
Difference		-1.0
95% CI		(-1.72, -0.33)
p-value		0.004
Corrected Hedges' g [6]		-0.18
95% CI		(-0.30, -0.06)

[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the given time point.
[3] Analysis performed using mixed model repeated measures with covariates of baseline score, geographic region (as defined for the study/ISE), smoking status (current vs. never/ex-smoker), treatment and visit, plus interaction terms for visit by baseline and visit by treatment group.
[4] Analysis model as in footnote [3] with an additional covariate of study.
[5] Analysis model as in footnote [4] with an additional covariate of study*treatment interaction.
[6] Based on covariate adjusted means. Note: Estimates are based on weighting applied to each level of class variable determined from observed proportions. Note: Includes visits up to Week 52 for study 208657.
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Population: Modified Intent-to-treat Population with Eosinophils 300 cells/uL or More

Table 211.17

Analysis of Change from Baseline in COPD Assessment Test (CAT) Score - Mixed Model Repeated Measures: Individual Studies and Meta-Analysis

Visit: Week 24

	PBO (N=578)	100 SC (N=568)
208657		
n [1]	383	380
n [2]	363	358
LS Mean (SE)	17.1 (0.30)	17.0 (0.30)
LS Mean Change (SE)	-2.0 (0.30)	-2.1 (0.30)
Column vs Placebo [3]		
Difference		-0.1
95% CI		(-0.92, 0.73)
p-value		0.823
Corrected Hedges' g [6]		-0.02
95% CI		(-0.16, 0.13)

[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the given time point.
[3] Analysis performed using mixed model repeated measures with covariates of baseline score, geographic region (as defined for the study/ISE), smoking status (current vs. never/ex-smoker), treatment and visit, plus interaction terms for visit by baseline and visit by treatment group.
[4] Analysis model as in footnote [3] with an additional covariate of study.
[5] Analysis model as in footnote [4] with an additional covariate of study*treatment interaction.
[6] Based on covariate adjusted means. Note: Estimates are based on weighting applied to each level of class variable determined from observed proportions. Note: Includes visits up to Week 52 for study 208657.
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Population: Modified Intent-to-treat Population with Eosinophils 300 cells/uL or More

Table 211.17

Analysis of Change from Baseline in COPD Assessment Test (CAT) Score - Mixed Model Repeated Measures: Individual Studies and Meta-Analysis

Visit: Week 24

	PBO (N=578)	100 SC (N=568)
MEA117113		
n [1]	81	78
n [2]	76	72
LS Mean (SE)	18.0 (0.63)	15.6 (0.64)
LS Mean Change (SE)	-0.8 (0.63)	-3.2 (0.64)
Column vs Placebo [3]		
Difference		-2.4
95% CI		(-4.16, -0.64)
p-value		0.008
Corrected Hedges' g [6]		-0.44
95% CI		(-0.77, -0.11)

[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the given time point.
[3] Analysis performed using mixed model repeated measures with covariates of baseline score, geographic region (as defined for the study/ISE), smoking status (current vs. never/ex-smoker), treatment and visit, plus interaction terms for visit by baseline and visit by treatment group.
[4] Analysis model as in footnote [3] with an additional covariate of study.
[5] Analysis model as in footnote [4] with an additional covariate of study*treatment interaction.
[6] Based on covariate adjusted means. Note: Estimates are based on weighting applied to each level of class variable determined from observed proportions. Note: Includes visits up to Week 52 for study 208657.
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Population: Modified Intent-to-treat Population with Eosinophils 300 cells/uL or More

Table 211.17

Analysis of Change from Baseline in COPD Assessment Test (CAT) Score - Mixed Model Repeated Measures: Individual Studies and Meta-Analysis

Visit: Week 24

	PBO (N=578)	100 SC (N=568)
MEA117106		
n [1]	82	77
n [2]	72	73
LS Mean (SE)	19.1 (0.70)	16.5 (0.71)
LS Mean Change (SE)	0.0 (0.70)	-2.6 (0.71)
Column vs Placebo [3]		
Difference		-2.6
95% CI		(-4.59, -0.65)
p-value		0.010
Corrected Hedges' g [6]		-0.43
95% CI		(-0.76, -0.11)

[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the given time point.
[3] Analysis performed using mixed model repeated measures with covariates of baseline score, geographic region (as defined for the study/ISE), smoking status (current vs. never/ex-smoker), treatment and visit, plus interaction terms for visit by baseline and visit by treatment group.
[4] Analysis model as in footnote [3] with an additional covariate of study.
[5] Analysis model as in footnote [4] with an additional covariate of study*treatment interaction.
[6] Based on covariate adjusted means. Note: Estimates are based on weighting applied to each level of class variable determined from observed proportions. Note: Includes visits up to Week 52 for study 208657.
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Population: Modified Intent-to-treat Population with Eosinophils 300 cells/uL or More

Table 211.17

Analysis of Change from Baseline in COPD Assessment Test (CAT) Score - Mixed Model Repeated Measures: Individual Studies and Meta-Analysis

Visit: Week 24

	PBO (N=578)	100 SC (N=568)
208657 + MEA117113 + MEA117106		
n [1]	546	535
n [2]	511	503
LS Mean (SE)	17.6 (0.25)	16.8 (0.26)
LS Mean Change (SE)	-1.5 (0.25)	-2.3 (0.26)
Column vs Placebo [4]		
Difference		-0.8
95% CI		(-1.51, -0.10)
p-value		0.025
Corrected Hedges' g [6]		-0.14
95% CI		(-0.26, -0.02)

[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the given time point.
[3] Analysis performed using mixed model repeated measures with covariates of baseline score, geographic region (as defined for the study/ISE), smoking status (current vs. never/ex-smoker), treatment and visit, plus interaction terms for visit by baseline and visit by treatment group.
[4] Analysis model as in footnote [3] with an additional covariate of study.
[5] Analysis model as in footnote [4] with an additional covariate of study*treatment interaction.
[6] Based on covariate adjusted means. Note: Estimates are based on weighting applied to each level of class variable determined from observed proportions. Note: Includes visits up to Week 52 for study 208657.
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Population: Modified Intent-to-treat Population with Eosinophils 300 cells/uL or More

Table 211.17

Analysis of Change from Baseline in COPD Assessment Test (CAT) Score - Mixed Model Repeated Measures: Individual Studies and Meta-Analysis

Visit: Week 36

	PBO (N=578)	100 SC (N=568)
208657		
n [1]	383	380
n [2]	356	357
LS Mean (SE)	17.1 (0.32)	16.8 (0.32)
LS Mean Change (SE)	-2.0 (0.32)	-2.3 (0.32)
Column vs Placebo [3]		
Difference		-0.3
95% CI		(-1.19, 0.57)
p-value		0.489
Corrected Hedges' g [6]		-0.05
95% CI		(-0.20, 0.09)

[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the given time point.
[3] Analysis performed using mixed model repeated measures with covariates of baseline score, geographic region (as defined for the study/ISE), smoking status (current vs. never/ex-smoker), treatment and visit, plus interaction terms for visit by baseline and visit by treatment group.
[4] Analysis model as in footnote [3] with an additional covariate of study.
[5] Analysis model as in footnote [4] with an additional covariate of study*treatment interaction.
[6] Based on covariate adjusted means. Note: Estimates are based on weighting applied to each level of class variable determined from observed proportions. Note: Includes visits up to Week 52 for study 208657.
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Population: Modified Intent-to-treat Population with Eosinophils 300 cells/uL or More

Table 211.17

Analysis of Change from Baseline in COPD Assessment Test (CAT) Score - Mixed Model Repeated Measures: Individual Studies and Meta-Analysis

Visit: Week 36

	PBO (N=578)	100 SC (N=568)
MEA117113		
n [1]	81	78
n [2]	71	69
LS Mean (SE)	18.4 (0.70)	17.7 (0.70)
LS Mean Change (SE)	-0.5 (0.70)	-1.1 (0.70)
Column vs Placebo [3]		
Difference		-0.7
95% CI		(-2.61, 1.29)
p-value		0.505
Corrected Hedges' g [6]		-0.11
95% CI		(-0.44, 0.22)

[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the given time point.
[3] Analysis performed using mixed model repeated measures with covariates of baseline score, geographic region (as defined for the study/ISE), smoking status (current vs. never/ex-smoker), treatment and visit, plus interaction terms for visit by baseline and visit by treatment group.
[4] Analysis model as in footnote [3] with an additional covariate of study.
[5] Analysis model as in footnote [4] with an additional covariate of study*treatment interaction.
[6] Based on covariate adjusted means. Note: Estimates are based on weighting applied to each level of class variable determined from observed proportions. Note: Includes visits up to Week 52 for study 208657.
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Population: Modified Intent-to-treat Population with Eosinophils 300 cells/uL or More

Table 211.17

Analysis of Change from Baseline in COPD Assessment Test (CAT) Score - Mixed Model Repeated Measures: Individual Studies and Meta-Analysis

Visit: Week 36

	PBO (N=578)	100 SC (N=568)
MEA117106		
n [1]	82	77
n [2]	69	70
LS Mean (SE)	16.7 (0.68)	17.1 (0.68)
LS Mean Change (SE)	-2.3 (0.68)	-2.0 (0.68)
Column vs Placebo [3]		
Difference		0.3
95% CI		(-1.56, 2.23)
p-value		0.724
Corrected Hedges' g [6]		0.06
95% CI		(-0.27, 0.39)

[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the given time point.
[3] Analysis performed using mixed model repeated measures with covariates of baseline score, geographic region (as defined for the study/ISE), smoking status (current vs. never/ex-smoker), treatment and visit, plus interaction terms for visit by baseline and visit by treatment group.
[4] Analysis model as in footnote [3] with an additional covariate of study.
[5] Analysis model as in footnote [4] with an additional covariate of study*treatment interaction.
[6] Based on covariate adjusted means. Note: Estimates are based on weighting applied to each level of class variable determined from observed proportions. Note: Includes visits up to Week 52 for study 208657.
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Population: Modified Intent-to-treat Population with Eosinophils 300 cells/uL or More

Table 211.17

Analysis of Change from Baseline in COPD Assessment Test (CAT) Score - Mixed Model Repeated Measures: Individual Studies and Meta-Analysis

Visit: Week 36

	PBO (N=578)	100 SC (N=568)
208657 + MEA117113 + MEA117106		
n [1]	546	535
n [2]	496	496
LS Mean (SE)	17.3 (0.27)	17.0 (0.27)
LS Mean Change (SE)	-1.7 (0.27)	-2.0 (0.27)
Column vs Placebo [4]		
Difference		-0.3
95% CI		(-1.05, 0.44)
p-value		0.428
Corrected Hedges' g [6]		-0.05
95% CI		(-0.17, 0.07)

[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the given time point.
[3] Analysis performed using mixed model repeated measures with covariates of baseline score, geographic region (as defined for the study/ISE), smoking status (current vs. never/ex-smoker), treatment and visit, plus interaction terms for visit by baseline and visit by treatment group.
[4] Analysis model as in footnote [3] with an additional covariate of study.
[5] Analysis model as in footnote [4] with an additional covariate of study*treatment interaction.
[6] Based on covariate adjusted means. Note: Estimates are based on weighting applied to each level of class variable determined from observed proportions. Note: Includes visits up to Week 52 for study 208657.
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Population: Modified Intent-to-treat Population with Eosinophils 300 cells/uL or More

Table 211.17

Analysis of Change from Baseline in COPD Assessment Test (CAT) Score - Mixed Model Repeated Measures: Individual Studies and Meta-Analysis

Visit: Week 52

	PBO (N=578)	100 SC (N=568)
208657		
n [1]	383	380
n [2]	337	334
LS Mean (SE)	16.6 (0.34)	17.0 (0.34)
LS Mean Change (SE)	-2.5 (0.34)	-2.1 (0.34)
Column vs Placebo [3]		
Difference		0.3
95% CI		(-0.60, 1.28)
p-value		0.478
Corrected Hedges' g [6]		0.05
95% CI		(-0.10, 0.21)

[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the given time point.
[3] Analysis performed using mixed model repeated measures with covariates of baseline score, geographic region (as defined for the study/ISE), smoking status (current vs. never/ex-smoker), treatment and visit, plus interaction terms for visit by baseline and visit by treatment group.
[4] Analysis model as in footnote [3] with an additional covariate of study.
[5] Analysis model as in footnote [4] with an additional covariate of study*treatment interaction.
[6] Based on covariate adjusted means. Note: Estimates are based on weighting applied to each level of class variable determined from observed proportions. Note: Includes visits up to Week 52 for study 208657.
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Population: Modified Intent-to-treat Population with Eosinophils 300 cells/uL or More

Table 211.17

Analysis of Change from Baseline in COPD Assessment Test (CAT) Score - Mixed Model Repeated Measures: Individual Studies and Meta-Analysis

Visit: Week 52

	PBO (N=578)	100 SC (N=568)
MEA117113		
n [1]	81	78
n [2]	66	71
LS Mean (SE)	18.2 (0.72)	16.8 (0.72)
LS Mean Change (SE)	-0.6 (0.72)	-2.0 (0.72)
Column vs Placebo [3]		
Difference		-1.4
95% CI		(-3.38, 0.63)
p-value		0.178
Corrected Hedges' g [6]		-0.23
95% CI		(-0.57, 0.11)

[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the given time point.
[3] Analysis performed using mixed model repeated measures with covariates of baseline score, geographic region (as defined for the study/ISE), smoking status (current vs. never/ex-smoker), treatment and visit, plus interaction terms for visit by baseline and visit by treatment group.
[4] Analysis model as in footnote [3] with an additional covariate of study.
[5] Analysis model as in footnote [4] with an additional covariate of study*treatment interaction.
[6] Based on covariate adjusted means. Note: Estimates are based on weighting applied to each level of class variable determined from observed proportions. Note: Includes visits up to Week 52 for study 208657.
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Population: Modified Intent-to-treat Population with Eosinophils 300 cells/uL or More

Table 211.17

Analysis of Change from Baseline in COPD Assessment Test (CAT) Score - Mixed Model Repeated Measures: Individual Studies and Meta-Analysis

Visit: Week 52

	PBO (N=578)	100 SC (N=568)
MEA117106		
n [1]	82	77
n [2]	70	69
LS Mean (SE)	18.7 (0.69)	17.0 (0.69)
LS Mean Change (SE)	-0.4 (0.69)	-2.0 (0.69)
Column vs Placebo [3]		
Difference		-1.6
95% CI		(-3.56, 0.30)
p-value		0.098
Corrected Hedges' g [6]		-0.28
95% CI		(-0.62, 0.05)

[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the given time point.
[3] Analysis performed using mixed model repeated measures with covariates of baseline score, geographic region (as defined for the study/ISE), smoking status (current vs. never/ex-smoker), treatment and visit, plus interaction terms for visit by baseline and visit by treatment group.
[4] Analysis model as in footnote [3] with an additional covariate of study.
[5] Analysis model as in footnote [4] with an additional covariate of study*treatment interaction.
[6] Based on covariate adjusted means. Note: Estimates are based on weighting applied to each level of class variable determined from observed proportions. Note: Includes visits up to Week 52 for study 208657.
/mnt/code/postcsr_01/prod/tfls/t_e_mmrm_cat_chg.sas 30OCT2025 13:31

Population: Modified Intent-to-treat Population with Eosinophils 300 cells/uL or More

Table 211.17

Analysis of Change from Baseline in COPD Assessment Test (CAT) Score - Mixed Model Repeated Measures: Individual Studies and Meta-Analysis

Visit: Week 52

	PBO (N=578)	100 SC (N=568)
208657 + MEA117113 + MEA117106		
n [1]	546	535
n [2]	473	474
LS Mean (SE)	17.2 (0.28)	17.0 (0.28)
LS Mean Change (SE)	-1.8 (0.28)	-2.0 (0.28)
Column vs Placebo [4]		
Difference		-0.2
95% CI		(-0.99, 0.58)
p-value		0.610
Corrected Hedges' g [6]		-0.03
95% CI		(-0.16, 0.09)
p-value for study*treatment interaction [5]		0.028

[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the given time point.
[3] Analysis performed using mixed model repeated measures with covariates of baseline score, geographic region (as defined for the study/ISE), smoking status (current vs. never/ex-smoker), treatment and visit, plus interaction terms for visit by baseline and visit by treatment group.
[4] Analysis model as in footnote [3] with an additional covariate of study.
[5] Analysis model as in footnote [4] with an additional covariate of study*treatment interaction.
[6] Based on covariate adjusted means. Note: Estimates are based on weighting applied to each level of class variable determined from observed proportions. Note: Includes visits up to Week 52 for study 208657.
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Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Table 211.18
Summary of St George's Respiratory Questionnaire-COPD (SGRQ-C) Total Score:
Individual Studies and Meta-Analysis

	208657		MEA117113		MEA117106	
	PBO (N=401)	100 SC (N=403)	PBO (N=87)	100 SC (N=83)	PBO (N=90)	100 SC (N=82)
Baseline Total Score						
n	393	390	87	82	88	79
Mean	53.9	55.4	53.6	53.4	55.1	54.3
SD	17.86	17.70	17.10	16.69	16.27	17.54
Median	54.9	56.1	52.3	54.4	56.3	57.0
Min.	7	9	13	16	16	22
Max.	91	93	88	89	87	86
Week 12 Total Score						
n	370	374	83	80	83	81
Mean	49.9	48.6	51.1	47.9	51.8	48.0
SD	19.33	19.12	19.20	17.68	17.24	18.52
Median	50.1	48.4	52.8	47.8	54.6	47.8
Min.	5	3	7	9	17	12
Max.	91	93	86	85	87	84
Week 12 Change from Baseline						
n	363	364	83	79	81	78
Mean	-3.7	-6.6	-1.5	-5.5	-2.8	-6.2
SD	13.92	14.22	11.00	14.52	12.46	12.69
Median	-3.6	-5.4	0.0	-2.8	-2.2	-4.5
Min.	-47	-58	-39	-43	-32	-43
Max.	40	36	29	24	25	22

Note: Includes visits up to Week 52 for study 208657.
Note: SGRQ scores calculated from conversions applied to SGRQ-C scores (SGRQ-C manual March 2016).
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Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Table 211.18
Summary of St George's Respiratory Questionnaire-COPD (SGRQ-C) Total Score:
Individual Studies and Meta-Analysis

	208657 + MEA117113 + MEA117106		
	PBO (N=578)	100 SC (N=568)	Total (N=1146)
Baseline Total Score			
n	568	551	1119
Mean	54.0	54.9	54.5
SD	17.49	17.52	17.50
Median	54.9	55.7	55.1
Min.	7	9	7
Max.	91	93	93
Week 12 Total Score			
n	536	535	1071
Mean	50.4	48.4	49.4
SD	18.98	18.79	18.91
Median	51.4	48.1	49.6
Min.	5	3	3
Max.	91	93	93
Week 12 Change from Baseline			
n	527	521	1048
Mean	-3.2	-6.4	-4.8
SD	13.28	14.03	13.74
Median	-2.7	-5.0	-3.5
Min.	-47	-58	-58
Max.	40	36	40

Note: Includes visits up to Week 52 for study 208657.
Note: SGRQ scores calculated from conversions applied to SGRQ-C scores (SGRQ-C manual March 2016).
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Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Table 211.18
Summary of St George's Respiratory Questionnaire-COPD (SGRQ-C) Total Score:
Individual Studies and Meta-Analysis

	208657		MEA117113		MEA117106	
	PBO (N=401)	100 SC (N=403)	PBO (N=87)	100 SC (N=83)	PBO (N=90)	100 SC (N=82)
Week 24 Total Score						
n	369	367	79	75	80	78
Mean	48.5	48.0	50.2	46.1	52.3	47.5
SD	18.87	19.38	18.08	16.85	17.95	19.96
Median	48.3	46.5	50.7	45.0	52.0	47.1
Min.	5	7	5	6	15	6
Max.	90	91	86	82	89	86
Week 24 Change from Baseline						
n	362	356	79	74	78	75
Mean	-5.0	-7.4	-2.2	-8.1	-2.9	-6.7
SD	14.65	14.87	10.52	16.50	14.11	15.62
Median	-3.5	-4.7	-2.1	-6.7	-2.2	-5.8
Min.	-67	-65	-47	-59	-41	-53
Max.	44	24	17	34	35	32

Note: Includes visits up to Week 52 for study 208657.
Note: SGRQ scores calculated from conversions applied to SGRQ-C scores (SGRQ-C manual March 2016).
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Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Table 211.18

Summary of St George's Respiratory Questionnaire-COPD (SGRQ-C) Total Score: Individual Studies and Meta-Analysis

	208657 + MEA117113 + MEA117106		
	PBO (N=578)	100 SC (N=568)	Total (N=1146)
Week 24 Total Score			
n	528	520	1048
Mean	49.4	47.6	48.5
SD	18.63	19.10	18.88
Median	49.8	46.5	48.1
Min.	5	6	5
Max.	90	91	91
Week 24 Change from Baseline			
n	519	505	1024
Mean	-4.2	-7.4	-5.8
SD	14.05	15.20	14.71
Median	-2.9	-5.0	-3.8
Min.	-67	-65	-67
Max.	44	34	44

Note: Includes visits up to Week 52 for study 208657.
Note: SGRQ scores calculated from conversions applied to SGRQ-C scores (SGRQ-C manual March 2016).
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Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Table 211.18
Summary of St George's Respiratory Questionnaire-COPD (SGRQ-C) Total Score:
Individual Studies and Meta-Analysis

	208657		MEA117113		MEA117106	
	PBO (N=401)	100 SC (N=403)	PBO (N=87)	100 SC (N=83)	PBO (N=90)	100 SC (N=82)
Week 36 Total Score						
n	360	367	73	75	75	76
Mean	47.2	47.0	47.3	47.2	50.9	48.5
SD	19.28	20.14	18.08	17.53	18.00	19.76
Median	45.5	45.8	48.5	47.4	52.4	48.6
Min.	3	5	6	7	11	9
Max.	91	93	82	86	89	85
Week 36 Change from Baseline						
n	352	356	73	74	73	73
Mean	-6.1	-8.2	-3.7	-5.8	-3.6	-5.4
SD	16.15	16.64	11.74	15.83	16.53	15.24
Median	-5.7	-6.7	-1.5	-3.9	-1.8	-3.4
Min.	-61	-74	-49	-50	-51	-40
Max.	58	43	18	30	43	31

Note: Includes visits up to Week 52 for study 208657.
Note: SGRQ scores calculated from conversions applied to SGRQ-C scores (SGRQ-C manual March 2016).
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Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Table 211.18

Summary of St George's Respiratory Questionnaire-COPD (SGRQ-C) Total Score: Individual Studies and Meta-Analysis

	208657 + MEA117113 + MEA117106		
	PBO (N=578)	100 SC (N=568)	Total (N=1146)
Week 36 Total Score			
n	508	518	1026
Mean	47.8	47.2	47.5
SD	18.94	19.70	19.32
Median	47.0	46.4	46.7
Min.	3	5	3
Max.	91	93	93
Week 36 Change from Baseline			
n	498	503	1001
Mean	-5.4	-7.4	-6.4
SD	15.65	16.34	16.03
Median	-4.4	-6.5	-5.0
Min.	-61	-74	-74
Max.	58	43	58

Note: Includes visits up to Week 52 for study 208657.
Note: SGRQ scores calculated from conversions applied to SGRQ-C scores (SGRQ-C manual March 2016).
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Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Table 211.18
Summary of St George's Respiratory Questionnaire-COPD (SGRQ-C) Total Score:
Individual Studies and Meta-Analysis

	208657		MEA117113		MEA117106	
	PBO (N=401)	100 SC (N=403)	PBO (N=87)	100 SC (N=83)	PBO (N=90)	100 SC (N=82)
Week 52 Total Score						
n	341	343	70	75	75	78
Mean	47.4	46.1	47.5	45.7	50.2	48.8
SD	19.17	19.77	19.34	18.88	18.96	18.88
Median	48.1	45.6	49.4	43.7	52.3	46.7
Min.	3	5	9	9	13	14
Max.	91	93	83	82	88	87
Week 52 Change from Baseline						
n	335	333	70	74	73	75
Mean	-5.9	-9.2	-3.7	-7.5	-4.7	-4.8
SD	16.93	17.92	13.30	16.72	20.60	14.62
Median	-5.0	-6.2	-3.3	-4.4	-5.3	-5.1
Min.	-64	-67	-49	-49	-69	-40
Max.	45	39	24	20	48	31

Note: Includes visits up to Week 52 for study 208657.
Note: SGRQ scores calculated from conversions applied to SGRQ-C scores (SGRQ-C manual March 2016).
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Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Table 211.18

Summary of St George's Respiratory Questionnaire-COPD (SGRQ-C) Total Score: Individual Studies and Meta-Analysis

	208657 + MEA117113 + MEA117106		
	PBO (N=578)	100 SC (N=568)	Total (N=1146)
Week 52 Total Score			
n	486	496	982
Mean	47.9	46.4	47.1
SD	19.14	19.49	19.32
Median	48.8	45.4	46.8
Min.	3	5	3
Max.	91	93	93
Week 52 Change from Baseline			
n	478	482	960
Mean	-5.4	-8.2	-6.8
SD	17.06	17.30	17.23
Median	-4.7	-5.5	-5.1
Min.	-69	-67	-69
Max.	48	39	48

Note: Includes visits up to Week 52 for study 208657.
Note: SGRQ scores calculated from conversions applied to SGRQ-C scores (SGRQ-C manual March 2016).
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Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Table 211.19

Summary and Analysis of St George's Respiratory Questionnaire-COPD (SGRQ-C) Responders at Week 52:
Subjects With At Least 15-point Improvement in Total Score From Baseline:
Individual Studies and Meta-Analysis

	PBO (N=578)		100 SC (N=568)	
208657				
n	393		390	
Responder [1]	77	(20%)	92	(24%)
Non-responder	316	(80%)	298	(76%)
No change/worsening	258	(66%)	241	(62%)
Withdrawal from study prior to visit	37	(9%)	37	(9%)
Missing visit [2]	21	(5%)	20	(5%)
Inverse Odds Ratio to Placebo [3]			0.80	
95% CI			(0.56, 1.15)	
Inverse Relative Risk [4]			0.86	
95% CI			(0.63, 1.16)	
p-value			0.315	
Absolute Risk Reduction [4]			-0.03	
95% CI			(-0.22, 0.16)	

[1] Defined as a participant with a >=15-point improvement (increase) from baseline in SGRQ score.
[2] Participants with an intercurrent event of either treatment interruption or treatment discontinuation related to the COVID-19 pandemic have data set to missing following the event. Missing data was not imputed.
[3] Analysis performed using a logistic regression model with covariates of baseline score, geographic region (as defined for the study/ISE), smoking status (current vs. never/ex-smoker) and treatment group.
[4] Analysis used poisson regression model with covariates as in [3] (risk difference uses identity link).
[5] Analysis model as in footnote [3] and [4] with an additional covariate of study. [6] Analysis model as in footnote [4] with an additional covariate of study*treatment interaction. Note: Inverse Odds Ratio <1, Inverse Relative Risk < 1, risk difference < 0 correspond to a benefit of Mepolizumab over Placebo.
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Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Table 211.19

Summary and Analysis of St George's Respiratory Questionnaire-COPD (SGRQ-C) Responders at Week 52:
Subjects With At Least 15-point Improvement in Total Score From Baseline:
Individual Studies and Meta-Analysis

	PBO (N=578)		100 SC (N=568)	
MEA117113				
n	87		82	
Responder [1]	12	(14%)	21	(26%)
Non-responder	75	(86%)	61	(74%)
No change/worsening	58	(67%)	53	(65%)
Withdrawal from study prior to visit	15	(17%)	4	(5%)
Missing visit [2]	2	(2%)	4	(5%)
Inverse Odds Ratio to Placebo [3]			0.41	
95% CI			(0.18, 0.93)	
Inverse Relative Risk [4]			0.51	
95% CI			(0.25, 1.03)	
p-value			0.062	
Absolute Risk Reduction [4]			-0.13	
95% CI			(-0.54, 0.27)	

[1] Defined as a participant with a >=15-point improvement (increase) from baseline in SGRQ score.
[2] Participants with an intercurrent event of either treatment interruption or treatment discontinuation related to the COVID-19 pandemic have data set to missing following the event. Missing data was not imputed.
[3] Analysis performed using a logistic regression model with covariates of baseline score, geographic region (as defined for the study/ISE), smoking status (current vs. never/ex-smoker) and treatment group.
[4] Analysis used poisson regression model with covariates as in [3] (risk difference uses identity link).
[5] Analysis model as in footnote [3] and [4] with an additional covariate of study. [6] Analysis model as in footnote [4] with an additional covariate of study*treatment interaction. Note: Inverse Odds Ratio <1, Inverse Relative Risk < 1, risk difference < 0 correspond to a benefit of Mepolizumab over Placebo.
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Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Table 211.19

Summary and Analysis of St George's Respiratory Questionnaire-COPD (SGRQ-C) Responders at Week 52:
Subjects With At Least 15-point Improvement in Total Score From Baseline:
Individual Studies and Meta-Analysis

	PBO (N=578)	100 SC (N=568)
MEA117106		
n	88	79
Responder [1]	18 (20%)	17 (22%)
Non-responder	70 (80%)	62 (78%)
No change/worsening	55 (63%)	58 (73%)
Withdrawal from study prior to visit	9 (10%)	3 (4%)
Missing visit [2]	6 (7%)	1 (1%)
Inverse Odds Ratio to Placebo [3]		0.87
95% CI		(0.38, 1.99)
Inverse Relative Risk [4]		0.91
95% CI		(0.47, 1.77)
p-value		0.784
Absolute Risk Reduction [4]		-0.02
95% CI		(-0.42, 0.39)

[1] Defined as a participant with a >=15-point improvement (increase) from baseline in SGRQ score.
[2] Participants with an intercurrent event of either treatment interruption or treatment discontinuation related to the COVID-19 pandemic have data set to missing following the event. Missing data was not imputed.
[3] Analysis performed using a logistic regression model with covariates of baseline score, geographic region (as defined for the study/ISE), smoking status (current vs. never/ex-smoker) and treatment group.
[4] Analysis used poisson regression model with covariates as in [3] (risk difference uses identity link).
[5] Analysis model as in footnote [3] and [4] with an additional covariate of study. [6] Analysis model as in footnote [4] with an additional covariate of study*treatment interaction. Note: Inverse Odds Ratio <1, Inverse Relative Risk < 1, risk difference < 0 correspond to a benefit of Mepolizumab over Placebo.
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Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Table 211.19

Summary and Analysis of St George's Respiratory Questionnaire-COPD (SGRQ-C) Responders at Week 52:
Subjects With At Least 15-point Improvement in Total Score From Baseline:
Individual Studies and Meta-Analysis

	PBO (N=578)	100 SC (N=568)
208657 + MEA117113 + MEA117106		
n	568	551
Responder [1]	107 (19%)	130 (24%)
Non-responder	461 (81%)	421 (76%)
No change/worsening	371 (65%)	352 (64%)
Withdrawal from study prior to visit	61 (11%)	44 (8%)
Missing visit [2]	29 (5%)	25 (5%)
Inverse Odds Ratio to Placebo [3,5]		0.75
95% CI		(0.56, 1.01)
Inverse Relative Risk [4,5]		0.81
95% CI		(0.63, 1.05)
p-value		0.117
Absolute Risk Reduction [4,5]		-0.04
95% CI		(-0.20, 0.11)
p-value for study*treatment interaction [6]		0.398

[1] Defined as a participant with a >=15-point improvement (increase) from baseline in SGRQ score.
[2] Participants with an intercurrent event of either treatment interruption or treatment discontinuation related to the COVID-19 pandemic have data set to missing following the event. Missing data was not imputed.
[3] Analysis performed using a logistic regression model with covariates of baseline score, geographic region (as defined for the study/ISE), smoking status (current vs. never/ex-smoker) and treatment group.
[4] Analysis used poisson regression model with covariates as in [3] (risk difference uses identity link).
[5] Analysis model as in footnote [3] and [4] with an additional covariate of study. [6] Analysis model as in footnote [4] with an additional covariate of study*treatment interaction. Note: Inverse Odds Ratio <1, Inverse Relative Risk < 1, risk difference < 0 correspond to a benefit of Mepolizumab over Placebo.
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Population: Modified Intent-to-treat Population with Eosinophils 300 cells/uL or More

Table 211.20

Analysis of Change from Baseline in St George's Respiratory Questionnaire-COPD (SGRQ-C) Total Score - Mixed Model Repeated Measures: Individual Studies and Meta-Analysis

Visit: Week 12

	PBO (N=578)	100 SC (N=568)
208657		
n [1]	382	378
n [2]	363	364
LS Mean (SE)	50.4 (0.70)	47.7 (0.70)
LS Mean Change (SE)	-3.8 (0.70)	-6.6 (0.70)
Column vs Placebo [3]		
Difference		-2.7
95% CI		(-4.66, -0.77)
p-value		0.007
Corrected Hedges' g [6]		-0.20
95% CI		(-0.35, -0.06)

[1] Number of subjects with analysable data for one or more time points. [2] Number of subjects with analysable data at the given time point. [3] Analysis performed using mixed model repeated measures with covariates of baseline score, geographic region (as defined for the study/ISE), smoking status (current vs.never/ex-smoker), treatment and visit, plus interaction terms for visit by baseline and visit by treatment group. [4] Analysis model as in footnote [3] with an additional covariate of study. [5] Analysis model as in footnote [4] with an additional covariate of study*treatment interaction. [6] Based on covariate adjusted means. Note: Estimates are based on weighting applied to each level of class variable determined from observed proportions. Note: Includes visits up to Week 52 for study 208657. Note: SGRQ scores calculated from conversions applied to SGRQ-C scores (SGRQ-C manual March 2016).

Population: Modified Intent-to-treat Population with Eosinophils 300 cells/uL or More

Table 211.20

Analysis of Change from Baseline in St George's Respiratory Questionnaire-COPD (SGRQ-C) Total Score - Mixed Model Repeated Measures: Individual Studies and Meta-Analysis

Visit: Week 12

	PBO (N=578)	100 SC (N=568)
MEA117113		
n [1]	84	82
n [2]	83	79
LS Mean (SE)	50.7 (1.31)	46.7 (1.34)
LS Mean Change (SE)	-1.4 (1.31)	-5.4 (1.34)
Column vs Placebo [3]		
Difference		-4.0
95% CI		(-7.68, -0.29)
p-value		0.035
Corrected Hedges' g [6]		-0.33
95% CI		(-0.64, -0.02)

[1] Number of subjects with analysable data for one or more time points. [2] Number of subjects with analysable data at the given time point. [3] Analysis performed using mixed model repeated measures with covariates of baseline score, geographic region (as defined for the study/ISE), smoking status (current vs.never/ex-smoker), treatment and visit, plus interaction terms for visit by baseline and visit by treatment group. [4] Analysis model as in footnote [3] with an additional covariate of study. [5] Analysis model as in footnote [4] with an additional covariate of study*treatment interaction. [6] Based on covariate adjusted means. Note: Estimates are based on weighting applied to each level of class variable determined from observed proportions. Note: Includes visits up to Week 52 for study 208657. Note: SGRQ scores calculated from conversions applied to SGRQ-C scores (SGRQ-C manual March 2016).

Population: Modified Intent-to-treat Population with Eosinophils 300 cells/uL or More

Table 211.20

Analysis of Change from Baseline in St George's Respiratory Questionnaire-COPD (SGRQ-C) Total Score - Mixed Model Repeated Measures: Individual Studies and Meta-Analysis

Visit: Week 12

	PBO (N=578)	100 SC (N=568)
MEA117106		
n [1]	85	79
n [2]	81	78
LS Mean (SE)	52.0 (1.29)	48.2 (1.33)
LS Mean Change (SE)	-2.5 (1.29)	-6.2 (1.33)
Column vs Placebo [3]		
Difference		-3.7
95% CI		(-7.40, -0.08)
p-value		0.046
Corrected Hedges' g [6]		-0.32
95% CI		(-0.63, -0.01)

[1] Number of subjects with analysable data for one or more time points. [2] Number of subjects with analysable data at the given time point. [3] Analysis performed using mixed model repeated measures with covariates of baseline score, geographic region (as defined for the study/ISE), smoking status (current vs.never/ex-smoker), treatment and visit, plus interaction terms for visit by baseline and visit by treatment group. [4] Analysis model as in footnote [3] with an additional covariate of study. [5] Analysis model as in footnote [4] with an additional covariate of study*treatment interaction. [6] Based on covariate adjusted means. Note: Estimates are based on weighting applied to each level of class variable determined from observed proportions. Note: Includes visits up to Week 52 for study 208657. Note: SGRQ scores calculated from conversions applied to SGRQ-C scores (SGRQ-C manual March 2016).

Population: Modified Intent-to-treat Population with Eosinophils 300 cells/uL or More

Table 211.20

Analysis of Change from Baseline in St George's Respiratory Questionnaire-COPD (SGRQ-C) Total Score - Mixed Model Repeated Measures: Individual Studies and Meta-Analysis

Visit: Week 12

	PBO (N=578)	100 SC (N=568)
208657 + MEA117113 + MEA117106		
n [1]	551	539
n [2]	527	521
LS Mean (SE)	50.7 (0.56)	47.6 (0.57)
LS Mean Change (SE)	-3.1 (0.56)	-6.2 (0.57)
Column vs Placebo [4]		
Difference		-3.1
95% CI		(-4.65, -1.54)
p-value		0.001
Corrected Hedges' g [6]		-0.24
95% CI		(-0.36, -0.12)

[1] Number of subjects with analysable data for one or more time points. [2] Number of subjects with analysable data at the given time point. [3] Analysis performed using mixed model repeated measures with covariates of baseline score, geographic region (as defined for the study/ISE), smoking status (current vs.never/ex-smoker), treatment and visit, plus interaction terms for visit by baseline and visit by treatment group. [4] Analysis model as in footnote [3] with an additional covariate of study. [5] Analysis model as in footnote [4] with an additional covariate of study*treatment interaction. [6] Based on covariate adjusted means. Note: Estimates are based on weighting applied to each level of class variable determined from observed proportions. Note: Includes visits up to Week 52 for study 208657. Note: SGRQ scores calculated from conversions applied to SGRQ-C scores (SGRQ-C manual March 2016).

Population: Modified Intent-to-treat Population with Eosinophils 300 cells/uL or More

Table 211.20

Analysis of Change from Baseline in St George's Respiratory Questionnaire-COPD (SGRQ-C) Total Score - Mixed Model Repeated Measures: Individual Studies and Meta-Analysis

Visit: Week 24

	PBO (N=578)	100 SC (N=568)
208657		
n [1]	382	378
n [2]	362	356
LS Mean (SE)	49.3 (0.72)	47.1 (0.73)
LS Mean Change (SE)	-5.0 (0.72)	-7.1 (0.73)
Column vs Placebo [3]		
Difference		-2.1
95% CI		(-4.15, -0.13)
p-value		0.037
Corrected Hedges' g [6]		-0.16
95% CI		(-0.30, -0.01)

[1] Number of subjects with analysable data for one or more time points. [2] Number of subjects with analysable data at the given time point. [3] Analysis performed using mixed model repeated measures with covariates of baseline score, geographic region (as defined for the study/ISE), smoking status (current vs.never/ex-smoker), treatment and visit, plus interaction terms for visit by baseline and visit by treatment group. [4] Analysis model as in footnote [3] with an additional covariate of study. [5] Analysis model as in footnote [4] with an additional covariate of study*treatment interaction. [6] Based on covariate adjusted means. Note: Estimates are based on weighting applied to each level of class variable determined from observed proportions. Note: Includes visits up to Week 52 for study 208657. Note: SGRQ scores calculated from conversions applied to SGRQ-C scores (SGRQ-C manual March 2016).

Population: Modified Intent-to-treat Population with Eosinophils 300 cells/uL or More

Table 211.20

Analysis of Change from Baseline in St George's Respiratory Questionnaire-COPD (SGRQ-C) Total Score - Mixed Model Repeated Measures: Individual Studies and Meta-Analysis

Visit: Week 24

	PBO (N=578)	100 SC (N=568)
MEA117113		
n [1]	84	82
n [2]	79	74
LS Mean (SE)	50.1 (1.46)	44.5 (1.49)
LS Mean Change (SE)	-1.9 (1.46)	-7.5 (1.49)
Column vs Placebo [3]		
Difference		-5.6
95% CI		(-9.72, -1.50)
p-value		0.008
Corrected Hedges' g [6]		-0.43
95% CI		(-0.75, -0.11)

[1] Number of subjects with analysable data for one or more time points. [2] Number of subjects with analysable data at the given time point. [3] Analysis performed using mixed model repeated measures with covariates of baseline score, geographic region (as defined for the study/ISE), smoking status (current vs.never/ex-smoker), treatment and visit, plus interaction terms for visit by baseline and visit by treatment group. [4] Analysis model as in footnote [3] with an additional covariate of study. [5] Analysis model as in footnote [4] with an additional covariate of study*treatment interaction. [6] Based on covariate adjusted means. Note: Estimates are based on weighting applied to each level of class variable determined from observed proportions. Note: Includes visits up to Week 52 for study 208657. Note: SGRQ scores calculated from conversions applied to SGRQ-C scores (SGRQ-C manual March 2016).

Population: Modified Intent-to-treat Population with Eosinophils 300 cells/uL or More

Table 211.20

Analysis of Change from Baseline in St George's Respiratory Questionnaire-COPD (SGRQ-C) Total Score - Mixed Model Repeated Measures: Individual Studies and Meta-Analysis

Visit: Week 24

	PBO (N=578)	100 SC (N=568)
MEA117106		
n [1]	85	79
n [2]	78	75
LS Mean (SE)	51.9 (1.56)	47.8 (1.60)
LS Mean Change (SE)	-2.6 (1.56)	-6.7 (1.60)
Column vs Placebo [3]		
Difference		-4.1
95% CI		(-8.53, 0.31)
p-value		0.069
Corrected Hedges' g [6]		-0.30
95% CI		(-0.61, 0.02)

[1] Number of subjects with analysable data for one or more time points. [2] Number of subjects with analysable data at the given time point. [3] Analysis performed using mixed model repeated measures with covariates of baseline score, geographic region (as defined for the study/ISE), smoking status (current vs.never/ex-smoker), treatment and visit, plus interaction terms for visit by baseline and visit by treatment group. [4] Analysis model as in footnote [3] with an additional covariate of study. [5] Analysis model as in footnote [4] with an additional covariate of study*treatment interaction. [6] Based on covariate adjusted means. Note: Estimates are based on weighting applied to each level of class variable determined from observed proportions. Note: Includes visits up to Week 52 for study 208657. Note: SGRQ scores calculated from conversions applied to SGRQ-C scores (SGRQ-C manual March 2016).

Population: Modified Intent-to-treat Population with Eosinophils 300 cells/uL or More

Table 211.20

Analysis of Change from Baseline in St George's Respiratory Questionnaire-COPD (SGRQ-C) Total Score - Mixed Model Repeated Measures: Individual Studies and Meta-Analysis

Visit: Week 24

	PBO (N=578)	100 SC (N=568)
208657 + MEA117113 + MEA117106		
n [1]	551	539
n [2]	519	505
LS Mean (SE)	49.8 (0.60)	46.8 (0.61)
LS Mean Change (SE)	-4.0 (0.60)	-7.0 (0.61)
Column vs Placebo [4]		
Difference		-3.0
95% CI		(-4.65, -1.31)
p-value		0.001
Corrected Hedges' g [6]		-0.22
95% CI		(-0.34, -0.09)

[1] Number of subjects with analysable data for one or more time points. [2] Number of subjects with analysable data at the given time point. [3] Analysis performed using mixed model repeated measures with covariates of baseline score, geographic region (as defined for the study/ISE), smoking status (current vs.never/ex-smoker), treatment and visit, plus interaction terms for visit by baseline and visit by treatment group. [4] Analysis model as in footnote [3] with an additional covariate of study. [5] Analysis model as in footnote [4] with an additional covariate of study*treatment interaction. [6] Based on covariate adjusted means. Note: Estimates are based on weighting applied to each level of class variable determined from observed proportions. Note: Includes visits up to Week 52 for study 208657. Note: SGRQ scores calculated from conversions applied to SGRQ-C scores (SGRQ-C manual March 2016).

Population: Modified Intent-to-treat Population with Eosinophils 300 cells/uL or More

Table 211.20

Analysis of Change from Baseline in St George's Respiratory Questionnaire-COPD (SGRQ-C) Total Score - Mixed Model Repeated Measures: Individual Studies and Meta-Analysis

Visit: Week 36

	PBO (N=578)	100 SC (N=568)
208657		
n [1]	382	378
n [2]	352	356
LS Mean (SE)	48.2 (0.80)	46.5 (0.80)
LS Mean Change (SE)	-6.0 (0.80)	-7.7 (0.80)
Column vs Placebo [3]		
Difference		-1.7
95% CI		(-3.90, 0.54)
p-value		0.138
Corrected Hedges' g [6]		-0.11
95% CI		(-0.26, 0.04)

[1] Number of subjects with analysable data for one or more time points. [2] Number of subjects with analysable data at the given time point. [3] Analysis performed using mixed model repeated measures with covariates of baseline score, geographic region (as defined for the study/ISE), smoking status (current vs.never/ex-smoker), treatment and visit, plus interaction terms for visit by baseline and visit by treatment group. [4] Analysis model as in footnote [3] with an additional covariate of study. [5] Analysis model as in footnote [4] with an additional covariate of study*treatment interaction. [6] Based on covariate adjusted means. Note: Estimates are based on weighting applied to each level of class variable determined from observed proportions. Note: Includes visits up to Week 52 for study 208657. Note: SGRQ scores calculated from conversions applied to SGRQ-C scores (SGRQ-C manual March 2016).

Population: Modified Intent-to-treat Population with Eosinophils 300 cells/uL or More

Table 211.20

Analysis of Change from Baseline in St George's Respiratory Questionnaire-COPD (SGRQ-C) Total Score - Mixed Model Repeated Measures: Individual Studies and Meta-Analysis

Visit: Week 36

	PBO (N=578)	100 SC (N=568)
MEA117113		
n [1]	84	82
n [2]	73	74
LS Mean (SE)	48.5 (1.54)	47.0 (1.54)
LS Mean Change (SE)	-3.5 (1.54)	-5.1 (1.54)
Column vs Placebo [3]		
Difference		-1.6
95% CI		(-5.84, 2.74)
p-value		0.477
Corrected Hedges' g [6]		-0.12
95% CI		(-0.44, 0.21)

[1] Number of subjects with analysable data for one or more time points. [2] Number of subjects with analysable data at the given time point. [3] Analysis performed using mixed model repeated measures with covariates of baseline score, geographic region (as defined for the study/ISE), smoking status (current vs.never/ex-smoker), treatment and visit, plus interaction terms for visit by baseline and visit by treatment group. [4] Analysis model as in footnote [3] with an additional covariate of study. [5] Analysis model as in footnote [4] with an additional covariate of study*treatment interaction. [6] Based on covariate adjusted means. Note: Estimates are based on weighting applied to each level of class variable determined from observed proportions. Note: Includes visits up to Week 52 for study 208657. Note: SGRQ scores calculated from conversions applied to SGRQ-C scores (SGRQ-C manual March 2016).

Population: Modified Intent-to-treat Population with Eosinophils 300 cells/uL or More

Table 211.20

Analysis of Change from Baseline in St George's Respiratory Questionnaire-COPD (SGRQ-C) Total Score - Mixed Model Repeated Measures: Individual Studies and Meta-Analysis

Visit: Week 36

	PBO (N=578)	100 SC (N=568)
MEA117106		
n [1]	85	79
n [2]	73	73
LS Mean (SE)	51.5 (1.66)	49.1 (1.68)
LS Mean Change (SE)	-2.9 (1.66)	-5.4 (1.68)
Column vs Placebo [3]		
Difference		-2.5
95% CI		(-7.12, 2.21)
p-value		0.301
Corrected Hedges' g [6]		-0.17
95% CI		(-0.50, 0.15)

[1] Number of subjects with analysable data for one or more time points. [2] Number of subjects with analysable data at the given time point. [3] Analysis performed using mixed model repeated measures with covariates of baseline score, geographic region (as defined for the study/ISE), smoking status (current vs.never/ex-smoker), treatment and visit, plus interaction terms for visit by baseline and visit by treatment group. [4] Analysis model as in footnote [3] with an additional covariate of study. [5] Analysis model as in footnote [4] with an additional covariate of study*treatment interaction. [6] Based on covariate adjusted means. Note: Estimates are based on weighting applied to each level of class variable determined from observed proportions. Note: Includes visits up to Week 52 for study 208657. Note: SGRQ scores calculated from conversions applied to SGRQ-C scores (SGRQ-C manual March 2016).

Population: Modified Intent-to-treat Population with Eosinophils 300 cells/uL or More

Table 211.20

Analysis of Change from Baseline in St George's Respiratory Questionnaire-COPD (SGRQ-C) Total Score - Mixed Model Repeated Measures: Individual Studies and Meta-Analysis

Visit: Week 36

	PBO (N=578)	100 SC (N=568)
208657 + MEA117113 + MEA117106		
n [1]	551	539
n [2]	498	503
LS Mean (SE)	48.8 (0.66)	47.0 (0.66)
LS Mean Change (SE)	-5.0 (0.66)	-6.9 (0.66)
Column vs Placebo [4]		
Difference		-1.8
95% CI		(-3.63, 0.01)
p-value		0.051
Corrected Hedges' g [6]		-0.12
95% CI		(-0.25, 0.00)

[1] Number of subjects with analysable data for one or more time points. [2] Number of subjects with analysable data at the given time point. [3] Analysis performed using mixed model repeated measures with covariates of baseline score, geographic region (as defined for the study/ISE), smoking status (current vs.never/ex-smoker), treatment and visit, plus interaction terms for visit by baseline and visit by treatment group. [4] Analysis model as in footnote [3] with an additional covariate of study.
[5] Analysis model as in footnote [4] with an additional covariate of study*treatment interaction.
[6] Based on covariate adjusted means. Note: Estimates are based on weighting applied to each level of class variable determined from observed proportions. Note: Includes visits up to Week 52 for study 208657.
Note: SGRQ scores calculated from conversions applied to SGRQ-C scores (SGRQ-C manual March 2016).
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Population: Modified Intent-to-treat Population with Eosinophils 300 cells/uL or More

Table 211.20

Analysis of Change from Baseline in St George's Respiratory Questionnaire-COPD (SGRQ-C) Total Score - Mixed Model Repeated Measures: Individual Studies and Meta-Analysis

Visit: Week 52

	PBO (N=578)	100 SC (N=568)
208657		
n [1]	382	378
n [2]	335	333
LS Mean (SE)	48.5 (0.85)	46.2 (0.85)
LS Mean Change (SE)	-5.8 (0.85)	-8.1 (0.85)
Column vs Placebo [3]		
Difference		-2.4
95% CI		(-4.71, 0.00)
p-value		0.051
Corrected Hedges' g [6]		-0.15
95% CI		(-0.30, 0.00)

[1] Number of subjects with analysable data for one or more time points. [2] Number of subjects with analysable data at the given time point. [3] Analysis performed using mixed model repeated measures with covariates of baseline score, geographic region (as defined for the study/ISE), smoking status (current vs.never/ex-smoker), treatment and visit, plus interaction terms for visit by baseline and visit by treatment group. [4] Analysis model as in footnote [3] with an additional covariate of study. [5] Analysis model as in footnote [4] with an additional covariate of study*treatment interaction. [6] Based on covariate adjusted means. Note: Estimates are based on weighting applied to each level of class variable determined from observed proportions. Note: Includes visits up to Week 52 for study 208657. Note: SGRQ scores calculated from conversions applied to SGRQ-C scores (SGRQ-C manual March 2016).

Population: Modified Intent-to-treat Population with Eosinophils 300 cells/uL or More

Table 211.20

Analysis of Change from Baseline in St George's Respiratory Questionnaire-COPD (SGRQ-C) Total Score - Mixed Model Repeated Measures: Individual Studies and Meta-Analysis

Visit: Week 52

	PBO (N=578)	100 SC (N=568)
MEA117113		
n [1]	84	82
n [2]	70	74
LS Mean (SE)	48.8 (1.69)	45.6 (1.67)
LS Mean Change (SE)	-3.3 (1.69)	-6.4 (1.67)
Column vs Placebo [3]		
Difference		-3.2
95% CI		(-7.85, 1.50)
p-value		0.183
Corrected Hedges' g [6]		-0.22
95% CI		(-0.55, 0.11)

[1] Number of subjects with analysable data for one or more time points. [2] Number of subjects with analysable data at the given time point. [3] Analysis performed using mixed model repeated measures with covariates of baseline score, geographic region (as defined for the study/ISE), smoking status (current vs.never/ex-smoker), treatment and visit, plus interaction terms for visit by baseline and visit by treatment group. [4] Analysis model as in footnote [3] with an additional covariate of study. [5] Analysis model as in footnote [4] with an additional covariate of study*treatment interaction. [6] Based on covariate adjusted means. Note: Estimates are based on weighting applied to each level of class variable determined from observed proportions. Note: Includes visits up to Week 52 for study 208657. Note: SGRQ scores calculated from conversions applied to SGRQ-C scores (SGRQ-C manual March 2016).

Population: Modified Intent-to-treat Population with Eosinophils 300 cells/uL or More

Table 211.20

Analysis of Change from Baseline in St George's Respiratory Questionnaire-COPD (SGRQ-C) Total Score - Mixed Model Repeated Measures: Individual Studies and Meta-Analysis

Visit: Week 52

	PBO (N=578)	100 SC (N=568)
MEA117106		
n [1]	85	79
n [2]	73	75
LS Mean (SE)	50.7 (1.80)	49.8 (1.82)
LS Mean Change (SE)	-3.8 (1.80)	-4.6 (1.82)
Column vs Placebo [3]		
Difference		-0.9
95% CI		(-5.93, 4.20)
p-value		0.737
Corrected Hedges' g [6]		-0.06
95% CI		(-0.38, 0.27)

[1] Number of subjects with analysable data for one or more time points. [2] Number of subjects with analysable data at the given time point. [3] Analysis performed using mixed model repeated measures with covariates of baseline score, geographic region (as defined for the study/ISE), smoking status (current vs.never/ex-smoker), treatment and visit, plus interaction terms for visit by baseline and visit by treatment group. [4] Analysis model as in footnote [3] with an additional covariate of study. [5] Analysis model as in footnote [4] with an additional covariate of study*treatment interaction. [6] Based on covariate adjusted means. Note: Estimates are based on weighting applied to each level of class variable determined from observed proportions. Note: Includes visits up to Week 52 for study 208657. Note: SGRQ scores calculated from conversions applied to SGRQ-C scores (SGRQ-C manual March 2016).

Population: Modified Intent-to-treat Population with Eosinophils 300 cells/uL or More

Table 211.20

Analysis of Change from Baseline in St George's Respiratory Questionnaire-COPD (SGRQ-C) Total Score - Mixed Model Repeated Measures: Individual Studies and Meta-Analysis

Visit: Week 52

	PBO (N=578)	100 SC (N=568)
208657 + MEA117113 + MEA117106		
n [1]	551	539
n [2]	478	482
LS Mean (SE)	48.9 (0.70)	46.7 (0.70)
LS Mean Change (SE)	-4.9 (0.70)	-7.2 (0.70)
Column vs Placebo [4]		
Difference		-2.2
95% CI		(-4.19, -0.30)
p-value		0.024
Corrected Hedges' g [6]		-0.15
95% CI		(-0.27, -0.02)
p-value for study*treatment interaction [5]		0.708

[1] Number of subjects with analysable data for one or more time points. [2] Number of subjects with analysable data at the given time point. [3] Analysis performed using mixed model repeated measures with covariates of baseline score, geographic region (as defined for the study/ISE), smoking status (current vs.never/ex-smoker), treatment and visit, plus interaction terms for visit by baseline and visit by treatment group. [4] Analysis model as in footnote [3] with an additional covariate of study. [5] Analysis model as in footnote [4] with an additional covariate of study*treatment interaction. [6] Based on covariate adjusted means. Note: Estimates are based on weighting applied to each level of class variable determined from observed proportions. Note: Includes visits up to Week 52 for study 208657. Note: SGRQ scores calculated from conversions applied to SGRQ-C scores (SGRQ-C manual March 2016).

Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Table 211.21
Summary of St George's Respiratory Questionnaire-COPD (SGRQ-C) Domain Scores:
Individual Studies and Meta-Analysis

Domain Score: Activity Domain

	208657		MEA117113		MEA117106	
	PBO (N=401)	100 SC (N=403)	PBO (N=87)	100 SC (N=83)	PBO (N=90)	100 SC (N=82)
Baseline Domain Score						
n	393	390	87	82	88	79
Mean	69.1	70.7	69.1	67.7	69.3	69.3
SD	20.00	18.54	19.82	17.85	17.89	17.20
Median	72.9	73.0	73.2	65.8	72.5	66.0
Min.	7	7	13	14	20	14
Max.	94	94	94	94	94	94
Week 12 Domain Score						
n	370	374	83	80	83	81
Mean	64.8	65.5	66.0	63.8	66.6	62.4
SD	22.00	21.19	23.64	20.61	20.42	20.93
Median	66.0	65.8	72.5	65.5	65.8	59.7
Min.	7	7	7	7	7	14
Max.	94	94	94	94	94	94
Week 12 Change from Baseline						
n	363	364	83	79	81	78
Mean	-3.7	-5.3	-2.2	-3.6	-1.8	-6.5
SD	16.47	17.03	15.73	15.30	17.11	16.24
Median	-0.3	-0.7	0.0	0.0	0.0	0.0
Min.	-80	-80	-60	-52	-45	-61
Max.	52	49	35	35	48	21

Note: Includes visits up to Week 52 for study 208657.
Note: SGRQ scores calculated from conversions applied to SGRQ-C scores (SGRQ-C manual March 2016).
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Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Table 211.21
Summary of St George's Respiratory Questionnaire-COPD (SGRQ-C) Domain Scores:
Individual Studies and Meta-Analysis

Domain Score: Activity Domain

	208657 + MEA117113 + MEA117106		
	PBO (N=578)	100 SC (N=568)	Total (N=1146)
Baseline Domain Score			
n	568	551	1119
Mean	69.1	70.0	69.6
SD	19.63	18.25	18.96
Median	72.9	72.9	72.9
Min.	7	7	7
Max.	94	94	94
Week 12 Domain Score			
n	536	535	1071
Mean	65.3	64.7	65.0
SD	22.00	21.06	21.52
Median	66.0	65.8	65.8
Min.	7	7	7
Max.	94	94	94
Week 12 Change from Baseline			
n	527	521	1048
Mean	-3.2	-5.2	-4.2
SD	16.44	16.65	16.57
Median	0.0	-0.2	0.0
Min.	-80	-80	-80
Max.	52	49	52

Note: Includes visits up to Week 52 for study 208657.
Note: SGRQ scores calculated from conversions applied to SGRQ-C scores (SGRQ-C manual March 2016).
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Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Table 211.21
Summary of St George's Respiratory Questionnaire-COPD (SGRQ-C) Domain Scores:
Individual Studies and Meta-Analysis

Domain Score: Activity Domain

	208657		MEA117113		MEA117106	
	PBO (N=401)	100 SC (N=403)	PBO (N=87)	100 SC (N=83)	PBO (N=90)	100 SC (N=82)
Week 24 Domain Score						
n	369	367	79	75	80	78
Mean	64.5	65.0	66.2	63.2	66.4	63.6
SD	21.01	21.19	21.86	20.30	18.72	22.79
Median	65.8	65.8	67.7	65.8	66.0	65.8
Min.	7	7	7	7	20	7
Max.	94	94	94	94	94	94
Week 24 Change from Baseline						
n	362	356	79	74	78	75
Mean	-4.0	-5.7	-1.8	-5.9	-2.4	-5.4
SD	16.20	17.67	13.19	16.05	16.72	18.47
Median	0.0	-0.6	0.0	-6.0	0.0	-1.0
Min.	-67	-74	-53	-60	-53	-80
Max.	52	47	33	41	41	41

Note: Includes visits up to Week 52 for study 208657.
Note: SGRQ scores calculated from conversions applied to SGRQ-C scores (SGRQ-C manual March 2016).
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Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Table 211.21
Summary of St George's Respiratory Questionnaire-COPD (SGRQ-C) Domain Scores:
Individual Studies and Meta-Analysis

Domain Score: Activity Domain

	208657 + MEA117113 + MEA117106		
	PBO (N=578)	100 SC (N=568)	Total (N=1146)
Week 24 Domain Score			
n	528	520	1048
Mean	65.0	64.6	64.8
SD	20.79	21.28	21.03
Median	65.8	65.8	65.8
Min.	7	7	7
Max.	94	94	94
Week 24 Change from Baseline			
n	519	505	1024
Mean	-3.5	-5.7	-4.5
SD	15.85	17.53	16.73
Median	0.0	-0.9	-0.1
Min.	-67	-80	-80
Max.	52	47	52

Note: Includes visits up to Week 52 for study 208657.
Note: SGRQ scores calculated from conversions applied to SGRQ-C scores (SGRQ-C manual March 2016).
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Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Table 211.21
Summary of St George's Respiratory Questionnaire-COPD (SGRQ-C) Domain Scores:
Individual Studies and Meta-Analysis

Domain Score: Activity Domain

	208657		MEA117113		MEA117106	
	PBO (N=401)	100 SC (N=403)	PBO (N=87)	100 SC (N=83)	PBO (N=90)	100 SC (N=82)
Week 36 Domain Score						
n	360	367	73	75	75	76
Mean	62.6	64.1	63.2	62.8	65.6	64.4
SD	21.67	22.74	21.78	20.97	19.53	21.42
Median	65.5	65.8	66.0	60.3	66.0	65.8
Min.	7	7	7	7	13	7
Max.	94	94	94	94	94	94
Week 36 Change from Baseline						
n	352	356	73	74	73	73
Mean	-5.4	-6.5	-3.5	-4.2	-2.8	-4.5
SD	18.14	19.15	14.78	15.13	19.15	17.01
Median	-6.3	-6.3	-0.6	-5.8	0.0	0.0
Min.	-80	-80	-53	-52	-60	-54
Max.	55	59	27	35	54	33

Note: Includes visits up to Week 52 for study 208657.
Note: SGRQ scores calculated from conversions applied to SGRQ-C scores (SGRQ-C manual March 2016).
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Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Table 211.21
Summary of St George's Respiratory Questionnaire-COPD (SGRQ-C) Domain Scores:
Individual Studies and Meta-Analysis

Domain Score: Activity Domain

	208657 + MEA117113 + MEA117106		
	PBO (N=578)	100 SC (N=568)	Total (N=1146)
Week 36 Domain Score			
n	508	518	1026
Mean	63.1	63.9	63.5
SD	21.37	22.26	21.82
Median	65.8	65.8	65.8
Min.	7	7	7
Max.	94	94	94
Week 36 Change from Baseline			
n	498	503	1001
Mean	-4.7	-5.9	-5.3
SD	17.84	18.30	18.07
Median	-1.0	-5.4	-1.0
Min.	-80	-80	-80
Max.	55	59	59

Note: Includes visits up to Week 52 for study 208657.
Note: SGRQ scores calculated from conversions applied to SGRQ-C scores (SGRQ-C manual March 2016).
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Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Table 211.21
Summary of St George's Respiratory Questionnaire-COPD (SGRQ-C) Domain Scores:
Individual Studies and Meta-Analysis

Domain Score: Activity Domain

	208657		MEA117113		MEA117106	
	PBO (N=401)	100 SC (N=403)	PBO (N=87)	100 SC (N=83)	PBO (N=90)	100 SC (N=82)
Week 52 Domain Score						
n	341	343	70	75	75	78
Mean	63.2	63.0	62.2	62.0	66.2	65.9
SD	22.36	22.49	23.28	22.37	20.96	20.48
Median	65.8	65.8	66.3	65.2	66.0	65.8
Min.	7	7	7	13	13	13
Max.	94	94	94	94	94	94
Week 52 Change from Baseline						
n	335	333	70	74	73	75
Mean	-4.9	-7.5	-4.8	-5.1	-3.3	-2.5
SD	18.62	19.95	15.60	17.55	22.21	17.61
Median	-0.1	-0.3	-0.3	-0.2	-0.2	0.0
Min.	-80	-73	-48	-73	-68	-53
Max.	59	47	22	28	53	41

Note: Includes visits up to Week 52 for study 208657.
Note: SGRQ scores calculated from conversions applied to SGRQ-C scores (SGRQ-C manual March 2016).
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Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Table 211.21
Summary of St George's Respiratory Questionnaire-COPD (SGRQ-C) Domain Scores:
Individual Studies and Meta-Analysis

Domain Score: Activity Domain

	208657 + MEA117113 + MEA117106		
	PBO (N=578)	100 SC (N=568)	Total (N=1146)
Week 52 Domain Score			
n	486	496	982
Mean	63.5	63.3	63.4
SD	22.27	22.15	22.20
Median	65.8	65.8	65.8
Min.	7	7	7
Max.	94	94	94
Week 52 Change from Baseline			
n	478	482	960
Mean	-4.7	-6.4	-5.5
SD	18.78	19.31	19.06
Median	-0.1	-0.1	-0.1
Min.	-80	-73	-80
Max.	59	47	59

Note: Includes visits up to Week 52 for study 208657.
Note: SGRQ scores calculated from conversions applied to SGRQ-C scores (SGRQ-C manual March 2016).
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Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Table 211.21
Summary of St George's Respiratory Questionnaire-COPD (SGRQ-C) Domain Scores:
Individual Studies and Meta-Analysis

Domain Score: Impacts Domain

	208657		MEA117113		MEA117106	
	PBO (N=401)	100 SC (N=403)	PBO (N=87)	100 SC (N=83)	PBO (N=90)	100 SC (N=82)
Baseline Domain Score						
n	393	390	87	82	88	79
Mean	41.1	42.6	40.0	40.6	42.2	41.0
SD	21.20	21.72	20.19	19.69	19.16	20.39
Median	39.6	40.3	41.1	42.2	42.9	41.6
Min.	2	2	6	6	4	4
Max.	90	90	85	85	85	82
Week 12 Domain Score						
n	370	374	83	80	83	81
Mean	37.8	35.4	37.9	34.3	38.7	36.1
SD	22.18	22.14	21.17	19.65	19.27	21.00
Median	35.9	32.3	34.3	29.9	39.2	35.7
Min.	2	2	2	2	2	2
Max.	90	90	85	80	85	80
Week 12 Change from Baseline						
n	363	364	83	79	81	78
Mean	-3.3	-6.9	-0.9	-6.4	-3.1	-5.0
SD	17.05	16.89	12.37	17.66	14.94	15.38
Median	-4.1	-4.7	0.0	-3.2	-1.3	-4.6
Min.	-53	-68	-39	-55	-36	-61
Max.	52	48	30	31	38	29

Note: Includes visits up to Week 52 for study 208657.
Note: SGRQ scores calculated from conversions applied to SGRQ-C scores (SGRQ-C manual March 2016).
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Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Table 211.21
Summary of St George's Respiratory Questionnaire-COPD (SGRQ-C) Domain Scores:
Individual Studies and Meta-Analysis

Domain Score: Impacts Domain

	208657 + MEA117113 + MEA117106		
	PBO (N=578)	100 SC (N=568)	Total (N=1146)
Baseline Domain Score			
n	568	551	1119
Mean	41.1	42.1	41.6
SD	20.72	21.23	20.97
Median	40.5	41.2	40.7
Min.	2	2	2
Max.	90	90	90
Week 12 Domain Score			
n	536	535	1071
Mean	37.9	35.3	36.6
SD	21.57	21.58	21.60
Median	36.2	31.9	34.0
Min.	2	2	2
Max.	90	90	90
Week 12 Change from Baseline			
n	527	521	1048
Mean	-2.9	-6.5	-4.7
SD	16.08	16.78	16.52
Median	-2.3	-4.5	-4.2
Min.	-53	-68	-68
Max.	52	48	52

Note: Includes visits up to Week 52 for study 208657.
Note: SGRQ scores calculated from conversions applied to SGRQ-C scores (SGRQ-C manual March 2016).
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Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Table 211.21
Summary of St George's Respiratory Questionnaire-COPD (SGRQ-C) Domain Scores:
Individual Studies and Meta-Analysis

Domain Score: Impacts Domain

	208657		MEA117113		MEA117106	
	PBO (N=401)	100 SC (N=403)	PBO (N=87)	100 SC (N=83)	PBO (N=90)	100 SC (N=82)
Week 24 Domain Score						
n	369	367	79	75	80	78
Mean	35.9	34.9	37.5	32.4	39.9	34.3
SD	21.86	22.53	20.44	18.27	21.17	21.83
Median	33.5	31.4	35.0	30.8	40.7	30.2
Min.	2	2	2	2	4	2
Max.	90	90	82	71	85	85
Week 24 Change from Baseline						
n	362	356	79	74	78	75
Mean	-5.0	-7.9	-1.2	-8.7	-2.5	-6.6
SD	18.33	17.49	13.22	21.07	16.49	18.01
Median	-4.5	-5.7	0.0	-5.6	-2.4	-4.8
Min.	-79	-72	-48	-62	-43	-57
Max.	54	30	26	56	51	35

Note: Includes visits up to Week 52 for study 208657.
Note: SGRQ scores calculated from conversions applied to SGRQ-C scores (SGRQ-C manual March 2016).
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Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Table 211.21
Summary of St George's Respiratory Questionnaire-COPD (SGRQ-C) Domain Scores:
Individual Studies and Meta-Analysis

Domain Score: Impacts Domain

	208657 + MEA117113 + MEA117106		
	PBO (N=578)	100 SC (N=568)	Total (N=1146)
Week 24 Domain Score			
n	528	520	1048
Mean	36.7	34.4	35.6
SD	21.56	21.84	21.72
Median	34.9	31.0	32.3
Min.	2	2	2
Max.	90	90	90
Week 24 Change from Baseline			
n	519	505	1024
Mean	-4.0	-7.8	-5.9
SD	17.41	18.10	17.85
Median	-3.2	-5.6	-4.3
Min.	-79	-72	-79
Max.	54	56	56

Note: Includes visits up to Week 52 for study 208657.
Note: SGRQ scores calculated from conversions applied to SGRQ-C scores (SGRQ-C manual March 2016).
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Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Table 211.21
Summary of St George's Respiratory Questionnaire-COPD (SGRQ-C) Domain Scores:
Individual Studies and Meta-Analysis

Domain Score: Impacts Domain

	208657		MEA117113		MEA117106	
	PBO (N=401)	100 SC (N=403)	PBO (N=87)	100 SC (N=83)	PBO (N=90)	100 SC (N=82)
Week 36 Domain Score						
n	360	367	73	75	75	76
Mean	34.8	33.9	34.2	34.4	38.7	35.9
SD	21.77	22.67	19.43	19.52	20.83	21.77
Median	32.4	29.0	30.4	31.6	36.5	31.0
Min.	2	2	4	2	4	4
Max.	87	90	80	85	90	80
Week 36 Change from Baseline						
n	352	356	73	74	73	73
Mean	-6.0	-8.6	-2.6	-5.7	-3.3	-4.8
SD	19.80	19.29	13.39	20.17	18.36	17.94
Median	-5.3	-6.7	-0.6	-4.1	-1.1	-5.0
Min.	-65	-79	-48	-59	-57	-41
Max.	74	47	22	42	51	40

Note: Includes visits up to Week 52 for study 208657.
Note: SGRQ scores calculated from conversions applied to SGRQ-C scores (SGRQ-C manual March 2016).
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Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Table 211.21
Summary of St George's Respiratory Questionnaire-COPD (SGRQ-C) Domain Scores:
Individual Studies and Meta-Analysis

Domain Score: Impacts Domain

	208657 + MEA117113 + MEA117106		
	PBO (N=578)	100 SC (N=568)	Total (N=1146)
Week 36 Domain Score			
n	508	518	1026
Mean	35.3	34.2	34.8
SD	21.32	22.08	21.70
Median	32.6	30.1	31.4
Min.	2	2	2
Max.	90	90	90
Week 36 Change from Baseline			
n	498	503	1001
Mean	-5.1	-7.6	-6.4
SD	18.81	19.26	19.06
Median	-4.3	-6.1	-4.7
Min.	-65	-79	-79
Max.	74	47	74

Note: Includes visits up to Week 52 for study 208657.
Note: SGRQ scores calculated from conversions applied to SGRQ-C scores (SGRQ-C manual March 2016).
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Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Table 211.21
Summary of St George's Respiratory Questionnaire-COPD (SGRQ-C) Domain Scores:
Individual Studies and Meta-Analysis

Domain Score: Impacts Domain

	208657		MEA117113		MEA117106	
	PBO (N=401)	100 SC (N=403)	PBO (N=87)	100 SC (N=83)	PBO (N=90)	100 SC (N=82)
Week 52 Domain Score						
n	341	343	70	75	75	78
Mean	35.3	32.8	34.6	32.7	37.4	36.0
SD	21.19	22.20	20.92	20.19	21.76	21.32
Median	33.6	28.9	31.8	28.7	35.2	30.5
Min.	2	2	2	2	4	2
Max.	90	90	73	81	85	86
Week 52 Change from Baseline						
n	335	333	70	74	73	75
Mean	-5.5	-9.6	-2.5	-7.5	-4.7	-4.3
SD	20.84	20.64	15.63	20.19	23.74	17.41
Median	-4.7	-6.5	-2.4	-4.0	-6.5	-3.9
Min.	-77	-77	-53	-55	-71	-38
Max.	54	54	38	38	65	46

Note: Includes visits up to Week 52 for study 208657.
Note: SGRQ scores calculated from conversions applied to SGRQ-C scores (SGRQ-C manual March 2016).
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Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Table 211.21
Summary of St George's Respiratory Questionnaire-COPD (SGRQ-C) Domain Scores:
Individual Studies and Meta-Analysis

Domain Score: Impacts Domain

	208657 + MEA117113 + MEA117106		
	PBO (N=578)	100 SC (N=568)	Total (N=1146)
Week 52 Domain Score			
n	486	496	982
Mean	35.5	33.3	34.4
SD	21.22	21.76	21.51
Median	33.2	29.3	31.4
Min.	2	2	2
Max.	90	90	90
Week 52 Change from Baseline			
n	478	482	960
Mean	-5.0	-8.5	-6.7
SD	20.63	20.15	20.46
Median	-4.4	-5.8	-4.7
Min.	-77	-77	-77
Max.	65	54	65

Note: Includes visits up to Week 52 for study 208657.
Note: SGRQ scores calculated from conversions applied to SGRQ-C scores (SGRQ-C manual March 2016).
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Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Table 211.21
Summary of St George's Respiratory Questionnaire-COPD (SGRQ-C) Domain Scores:
Individual Studies and Meta-Analysis

Domain Score: Symptoms Domain

	208657		MEA117113		MEA117106	
	PBO (N=401)	100 SC (N=403)	PBO (N=87)	100 SC (N=83)	PBO (N=90)	100 SC (N=82)
Baseline Domain Score						
n	393	390	87	82	88	79
Mean	66.6	67.7	68.2	68.0	69.8	68.7
SD	17.77	17.74	18.36	19.69	18.12	20.17
Median	68.4	69.0	71.1	71.4	70.2	71.0
Min.	12	1	15	18	15	10
Max.	100	100	100	100	100	95
Week 12 Domain Score						
n	370	374	83	80	83	81
Mean	60.9	59.2	65.6	62.1	66.5	59.5
SD	19.46	20.88	20.19	19.11	18.99	19.75
Median	61.0	59.3	71.8	62.0	67.4	60.0
Min.	6	1	10	16	31	10
Max.	100	100	100	100	100	95
Week 12 Change from Baseline						
n	363	364	83	79	81	78
Mean	-5.0	-8.3	-1.6	-5.8	-3.6	-9.1
SD	17.98	17.99	15.41	16.65	14.21	15.06
Median	-3.6	-7.0	0.0	-6.6	-3.1	-8.0
Min.	-70	-64	-47	-40	-38	-59
Max.	55	53	33	35	46	26

Note: Includes visits up to Week 52 for study 208657.
Note: SGRQ scores calculated from conversions applied to SGRQ-C scores (SGRQ-C manual March 2016).
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Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Table 211.21
Summary of St George's Respiratory Questionnaire-COPD (SGRQ-C) Domain Scores:
Individual Studies and Meta-Analysis

Domain Score: Symptoms Domain

	208657 + MEA117113 + MEA117106		
	PBO (N=578)	100 SC (N=568)	Total (N=1146)
Baseline Domain Score			
n	568	551	1119
Mean	67.3	67.9	67.6
SD	17.93	18.37	18.14
Median	69.4	70.0	69.5
Min.	12	1	1
Max.	100	100	100
Week 12 Domain Score			
n	536	535	1071
Mean	62.5	59.7	61.1
SD	19.61	20.45	20.08
Median	62.7	60.7	61.3
Min.	6	1	1
Max.	100	100	100
Week 12 Change from Baseline			
n	527	521	1048
Mean	-4.3	-8.0	-6.1
SD	17.08	17.38	17.32
Median	-2.9	-7.0	-4.9
Min.	-70	-64	-70
Max.	55	53	55

Note: Includes visits up to Week 52 for study 208657.
Note: SGRQ scores calculated from conversions applied to SGRQ-C scores (SGRQ-C manual March 2016).
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Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Table 211.21
Summary of St George's Respiratory Questionnaire-COPD (SGRQ-C) Domain Scores:
Individual Studies and Meta-Analysis

Domain Score: Symptoms Domain

	208657		MEA117113		MEA117106	
	PBO (N=401)	100 SC (N=403)	PBO (N=87)	100 SC (N=83)	PBO (N=90)	100 SC (N=82)
Week 24 Domain Score						
n	369	367	79	75	80	78
Mean	59.4	58.3	61.3	58.2	65.7	59.7
SD	19.71	20.44	19.43	18.30	20.36	19.71
Median	59.2	57.8	66.1	58.2	65.5	59.6
Min.	1	6	10	8	6	1
Max.	100	100	100	97	100	97
Week 24 Change from Baseline						
n	362	356	79	74	78	75
Mean	-6.7	-9.2	-6.0	-10.2	-4.9	-8.9
SD	18.16	18.03	16.82	19.96	18.54	15.50
Median	-5.2	-7.3	-3.3	-12.1	-4.2	-6.4
Min.	-79	-77	-64	-64	-70	-52
Max.	50	35	38	30	31	31

Note: Includes visits up to Week 52 for study 208657.
Note: SGRQ scores calculated from conversions applied to SGRQ-C scores (SGRQ-C manual March 2016).
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Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Table 211.21
Summary of St George's Respiratory Questionnaire-COPD (SGRQ-C) Domain Scores:
Individual Studies and Meta-Analysis

Domain Score: Symptoms Domain

	208657 + MEA117113 + MEA117106		
	PBO (N=578)	100 SC (N=568)	Total (N=1146)
Week 24 Domain Score			
n	528	520	1048
Mean	60.7	58.5	59.6
SD	19.85	20.01	19.95
Median	60.5	58.0	59.2
Min.	1	1	1
Max.	100	100	100
Week 24 Change from Baseline			
n	519	505	1024
Mean	-6.3	-9.3	-7.8
SD	18.00	17.95	18.03
Median	-4.8	-7.5	-6.1
Min.	-79	-77	-79
Max.	50	35	50

Note: Includes visits up to Week 52 for study 208657.
Note: SGRQ scores calculated from conversions applied to SGRQ-C scores (SGRQ-C manual March 2016).
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Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Table 211.21
Summary of St George's Respiratory Questionnaire-COPD (SGRQ-C) Domain Scores:
Individual Studies and Meta-Analysis

Domain Score: Symptoms Domain

	208657		MEA117113		MEA117106	
	PBO (N=401)	100 SC (N=403)	PBO (N=87)	100 SC (N=83)	PBO (N=90)	100 SC (N=82)
Week 36 Domain Score						
n	360	367	73	75	75	76
Mean	58.5	57.3	60.0	59.0	62.3	59.1
SD	19.89	21.25	20.16	18.58	18.43	21.96
Median	59.5	56.8	64.3	60.1	60.9	58.1
Min.	1	1	1	10	15	1
Max.	97	100	100	97	97	97
Week 36 Change from Baseline						
n	352	356	73	74	73	73
Mean	-7.7	-10.0	-7.4	-8.8	-5.8	-9.2
SD	18.89	18.59	18.25	21.03	17.40	18.37
Median	-6.3	-8.8	-4.4	-6.9	-4.9	-9.1
Min.	-79	-66	-64	-66	-45	-83
Max.	56	48	40	34	34	30

Note: Includes visits up to Week 52 for study 208657.
Note: SGRQ scores calculated from conversions applied to SGRQ-C scores (SGRQ-C manual March 2016).
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Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Table 211.21
Summary of St George's Respiratory Questionnaire-COPD (SGRQ-C) Domain Scores:
Individual Studies and Meta-Analysis

Domain Score: Symptoms Domain

	208657 + MEA117113 + MEA117106		
	PBO (N=578)	100 SC (N=568)	Total (N=1146)
Week 36 Domain Score			
n	508	518	1026
Mean	59.3	57.8	58.5
SD	19.73	20.97	20.37
Median	59.7	58.1	59.4
Min.	1	1	1
Max.	100	100	100
Week 36 Change from Baseline			
n	498	503	1001
Mean	-7.4	-9.7	-8.5
SD	18.56	18.90	18.76
Median	-5.5	-8.8	-7.1
Min.	-79	-83	-83
Max.	56	48	56

Note: Includes visits up to Week 52 for study 208657.
Note: SGRQ scores calculated from conversions applied to SGRQ-C scores (SGRQ-C manual March 2016).
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Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Table 211.21
Summary of St George's Respiratory Questionnaire-COPD (SGRQ-C) Domain Scores:
Individual Studies and Meta-Analysis

Domain Score: Symptoms Domain

	208657		MEA117113		MEA117106	
	PBO (N=401)	100 SC (N=403)	PBO (N=87)	100 SC (N=83)	PBO (N=90)	100 SC (N=82)
Week 52 Domain Score						
n	341	343	70	75	75	78
Mean	56.9	56.9	61.8	56.9	61.4	57.8
SD	20.46	20.23	20.80	21.44	19.34	21.03
Median	56.9	54.6	66.5	55.1	61.2	58.4
Min.	1	1	7	8	15	10
Max.	97	100	100	97	100	97
Week 52 Change from Baseline						
n	335	333	70	74	73	75
Mean	-9.1	-10.6	-5.3	-11.9	-7.2	-10.4
SD	18.76	19.48	20.43	22.17	20.08	17.38
Median	-9.0	-7.9	-1.4	-11.5	-9.5	-9.1
Min.	-77	-73	-81	-69	-65	-78
Max.	52	38	40	28	53	42

Note: Includes visits up to Week 52 for study 208657.
Note: SGRQ scores calculated from conversions applied to SGRQ-C scores (SGRQ-C manual March 2016).
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Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Table 211.21
Summary of St George's Respiratory Questionnaire-COPD (SGRQ-C) Domain Scores:
Individual Studies and Meta-Analysis

Domain Score: Symptoms Domain

	208657 + MEA117113 + MEA117106		
	PBO (N=578)	100 SC (N=568)	Total (N=1146)
Week 52 Domain Score			
n	486	496	982
Mean	58.3	57.1	57.7
SD	20.41	20.50	20.46
Median	59.1	55.0	56.6
Min.	1	1	1
Max.	100	100	100
Week 52 Change from Baseline			
n	478	482	960
Mean	-8.2	-10.7	-9.5
SD	19.23	19.58	19.43
Median	-7.8	-8.6	-8.2
Min.	-81	-78	-81
Max.	53	42	53

Note: Includes visits up to Week 52 for study 208657.
Note: SGRQ scores calculated from conversions applied to SGRQ-C scores (SGRQ-C manual March 2016).
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Population: Modified Intent-to-treat Population with Eosinophils 300 cells/uL or More

Table 211.22

Analysis of Change from Baseline in St George's Respiratory Questionnaire-COPD (SGRQ-C) Domain Scores - Mixed Model Repeated Measures: Individual Studies and Meta-Analysis

Domain Score: Activity Domain
Visit: Week 12

	PBO (N=578)	100 SC (N=568)
208657		
n [1]	382	378
n [2]	363	364
LS Mean (SE)	65.6 (0.83)	64.4 (0.84)
LS Mean Change (SE)	-3.9 (0.83)	-5.1 (0.84)
Column vs Placebo [3]		
Difference		-1.2
95% CI		(-3.53, 1.11)
p-value		0.305
Corrected Hedges' g [6]		-0.08
95% CI		(-0.22, 0.07)

[1] Number of subjects with analysable data for one or more time points. [2] Number of subjects with analysable data at the given time point. [3] Analysis performed using mixed model repeated measures with covariates of baseline score, geographic region (as defined for the study/ISE), smoking status (current vs.never/ex-smoker), treatment and visit, plus interaction terms for visit by baseline and visit by treatment group. [4] Analysis model as in footnote [3] with an additional covariate of study.
[5] Analysis model as in footnote [4] with an additional covariate of study*treatment interaction.
[6] Based on covariate adjusted means. Note: Estimates are based on weighting applied to each level of class variable determined from observed proportions. Note: Includes visits up to Week 52 for study 208657.
Note: SGRQ scores calculated from conversions applied to SGRQ-C scores (SGRQ-C manual March 2016).
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Population: Modified Intent-to-treat Population with Eosinophils 300 cells/uL or More

Table 211.22

Analysis of Change from Baseline in St George's Respiratory Questionnaire-COPD (SGRQ-C) Domain Scores - Mixed Model Repeated Measures: Individual Studies and Meta-Analysis

Domain Score: Activity Domain
Visit: Week 12

	PBO (N=578)	100 SC (N=568)
MEA117113		
n [1]	84	82
n [2]	83	79
LS Mean (SE)	65.2 (1.53)	63.6 (1.56)
LS Mean Change (SE)	-2.0 (1.53)	-3.6 (1.56)
Column vs Placebo [3]		
Difference		-1.6
95% CI		(-5.87, 2.72)
p-value		0.470
Corrected Hedges' g [6]		-0.11
95% CI		(-0.42, 0.20)

[1] Number of subjects with analysable data for one or more time points. [2] Number of subjects with analysable data at the given time point. [3] Analysis performed using mixed model repeated measures with covariates of baseline score, geographic region (as defined for the study/ISE), smoking status (current vs.never/ex-smoker), treatment and visit, plus interaction terms for visit by baseline and visit by treatment group. [4] Analysis model as in footnote [3] with an additional covariate of study. [5] Analysis model as in footnote [4] with an additional covariate of study*treatment interaction. [6] Based on covariate adjusted means. Note: Estimates are based on weighting applied to each level of class variable determined from observed proportions. Note: Includes visits up to Week 52 for study 208657. Note: SGRQ scores calculated from conversions applied to SGRQ-C scores (SGRQ-C manual March 2016).
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Population: Modified Intent-to-treat Population with Eosinophils 300 cells/uL or More

Table 211.22

Analysis of Change from Baseline in St George's Respiratory Questionnaire-COPD (SGRQ-C) Domain Scores - Mixed Model Repeated Measures: Individual Studies and Meta-Analysis

Domain Score: Activity Domain
Visit: Week 12

	PBO (N=578)	100 SC (N=568)
MEA117106		
n [1]	85	79
n [2]	81	78
LS Mean (SE)	67.2 (1.71)	62.5 (1.76)
LS Mean Change (SE)	-1.9 (1.71)	-6.6 (1.76)
Column vs Placebo [3]		
Difference		-4.7
95% CI		(-9.53, 0.15)
p-value		0.058
Corrected Hedges' g [6]		-0.30
95% CI		(-0.61, 0.01)

[1] Number of subjects with analysable data for one or more time points. [2] Number of subjects with analysable data at the given time point. [3] Analysis performed using mixed model repeated measures with covariates of baseline score, geographic region (as defined for the study/ISE), smoking status (current vs.never/ex-smoker), treatment and visit, plus interaction terms for visit by baseline and visit by treatment group. [4] Analysis model as in footnote [3] with an additional covariate of study. [5] Analysis model as in footnote [4] with an additional covariate of study*treatment interaction. [6] Based on covariate adjusted means. Note: Estimates are based on weighting applied to each level of class variable determined from observed proportions. Note: Includes visits up to Week 52 for study 208657. Note: SGRQ scores calculated from conversions applied to SGRQ-C scores (SGRQ-C manual March 2016).
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Population: Modified Intent-to-treat Population with Eosinophils 300 cells/uL or More

Table 211.22

Analysis of Change from Baseline in St George's Respiratory Questionnaire-COPD (SGRQ-C) Domain Scores - Mixed Model Repeated Measures: Individual Studies and Meta-Analysis

Domain Score: Activity Domain
Visit: Week 12

	PBO (N=578)	100 SC (N=568)
208657 + MEA117113 + MEA117106		
n [1]	551	539
n [2]	527	521
LS Mean (SE)	65.8 (0.68)	64.0 (0.68)
LS Mean Change (SE)	-3.1 (0.68)	-5.0 (0.68)
Column vs Placebo [4]		
Difference		-1.9
95% CI		(-3.74, 0.00)
p-value		0.051
Corrected Hedges' g [6]		-0.12
95% CI		(-0.24, 0.00)

[1] Number of subjects with analysable data for one or more time points. [2] Number of subjects with analysable data at the given time point. [3] Analysis performed using mixed model repeated measures with covariates of baseline score, geographic region (as defined for the study/ISE), smoking status (current vs.never/ex-smoker), treatment and visit, plus interaction terms for visit by baseline and visit by treatment group. [4] Analysis model as in footnote [3] with an additional covariate of study.
[5] Analysis model as in footnote [4] with an additional covariate of study*treatment interaction.
[6] Based on covariate adjusted means. Note: Estimates are based on weighting applied to each level of class variable determined from observed proportions. Note: Includes visits up to Week 52 for study 208657.
Note: SGRQ scores calculated from conversions applied to SGRQ-C scores (SGRQ-C manual March 2016).
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Population: Modified Intent-to-treat Population with Eosinophils 300 cells/uL or More

Table 211.22

Analysis of Change from Baseline in St George's Respiratory Questionnaire-COPD (SGRQ-C) Domain Scores - Mixed Model Repeated Measures: Individual Studies and Meta-Analysis

Domain Score: Activity Domain
Visit: Week 24

	PBO (N=578)	100 SC (N=568)
208657		
n [1]	382	378
n [2]	362	356
LS Mean (SE)	65.2 (0.83)	64.1 (0.84)
LS Mean Change (SE)	-4.2 (0.83)	-5.3 (0.84)
Column vs Placebo [3]		
Difference		-1.1
95% CI		(-3.42, 1.20)
p-value		0.346
Corrected Hedges' g [6]		-0.07
95% CI		(-0.22, 0.08)

[1] Number of subjects with analysable data for one or more time points. [2] Number of subjects with analysable data at the given time point. [3] Analysis performed using mixed model repeated measures with covariates of baseline score, geographic region (as defined for the study/ISE), smoking status (current vs.never/ex-smoker), treatment and visit, plus interaction terms for visit by baseline and visit by treatment group. [4] Analysis model as in footnote [3] with an additional covariate of study. [5] Analysis model as in footnote [4] with an additional covariate of study*treatment interaction. [6] Based on covariate adjusted means. Note: Estimates are based on weighting applied to each level of class variable determined from observed proportions. Note: Includes visits up to Week 52 for study 208657. Note: SGRQ scores calculated from conversions applied to SGRQ-C scores (SGRQ-C manual March 2016).
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Population: Modified Intent-to-treat Population with Eosinophils 300 cells/uL or More

Table 211.22

Analysis of Change from Baseline in St George's Respiratory Questionnaire-COPD (SGRQ-C) Domain Scores - Mixed Model Repeated Measures: Individual Studies and Meta-Analysis

Domain Score: Activity Domain
Visit: Week 24

	PBO (N=578)	100 SC (N=568)
MEA117113		
n [1]	84	82
n [2]	79	74
LS Mean (SE)	65.9 (1.63)	61.7 (1.67)
LS Mean Change (SE)	-1.3 (1.63)	-5.6 (1.67)
Column vs Placebo [3]		
Difference		-4.2
95% CI		(-8.82, 0.34)
p-value		0.070
Corrected Hedges' g [6]		-0.29
95% CI		(-0.61, 0.03)

[1] Number of subjects with analysable data for one or more time points. [2] Number of subjects with analysable data at the given time point. [3] Analysis performed using mixed model repeated measures with covariates of baseline score, geographic region (as defined for the study/ISE), smoking status (current vs.never/ex-smoker), treatment and visit, plus interaction terms for visit by baseline and visit by treatment group. [4] Analysis model as in footnote [3] with an additional covariate of study. [5] Analysis model as in footnote [4] with an additional covariate of study*treatment interaction. [6] Based on covariate adjusted means. Note: Estimates are based on weighting applied to each level of class variable determined from observed proportions. Note: Includes visits up to Week 52 for study 208657. Note: SGRQ scores calculated from conversions applied to SGRQ-C scores (SGRQ-C manual March 2016).
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Population: Modified Intent-to-treat Population with Eosinophils 300 cells/uL or More

Table 211.22

Analysis of Change from Baseline in St George's Respiratory Questionnaire-COPD (SGRQ-C) Domain Scores - Mixed Model Repeated Measures: Individual Studies and Meta-Analysis

Domain Score: Activity Domain
Visit: Week 24

	PBO (N=578)	100 SC (N=568)
MEA117106		
n [1]	85	79
n [2]	78	75
LS Mean (SE)	67.1 (1.83)	63.7 (1.88)
LS Mean Change (SE)	-2.0 (1.83)	-5.3 (1.88)
Column vs Placebo [3]		
Difference		-3.4
95% CI		(-8.54, 1.82)
p-value		0.203
Corrected Hedges' g [6]		-0.21
95% CI		(-0.52, 0.11)

[1] Number of subjects with analysable data for one or more time points. [2] Number of subjects with analysable data at the given time point. [3] Analysis performed using mixed model repeated measures with covariates of baseline score, geographic region (as defined for the study/ISE), smoking status (current vs.never/ex-smoker), treatment and visit, plus interaction terms for visit by baseline and visit by treatment group. [4] Analysis model as in footnote [3] with an additional covariate of study. [5] Analysis model as in footnote [4] with an additional covariate of study*treatment interaction. [6] Based on covariate adjusted means. Note: Estimates are based on weighting applied to each level of class variable determined from observed proportions. Note: Includes visits up to Week 52 for study 208657. Note: SGRQ scores calculated from conversions applied to SGRQ-C scores (SGRQ-C manual March 2016).
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Population: Modified Intent-to-treat Population with Eosinophils 300 cells/uL or More

Table 211.22

Analysis of Change from Baseline in St George's Respiratory Questionnaire-COPD (SGRQ-C) Domain Scores - Mixed Model Repeated Measures: Individual Studies and Meta-Analysis

Domain Score: Activity Domain
Visit: Week 24

	PBO (N=578)	100 SC (N=568)
208657 + MEA117113 + MEA117106		
n [1]	551	539
n [2]	519	505
LS Mean (SE)	65.7 (0.69)	63.7 (0.70)
LS Mean Change (SE)	-3.3 (0.69)	-5.2 (0.70)
Column vs Placebo [4]		
Difference		-2.0
95% CI		(-3.88, -0.05)
p-value		0.045
Corrected Hedges' g [6]		-0.13
95% CI		(-0.25, 0.00)

[1] Number of subjects with analysable data for one or more time points. [2] Number of subjects with analysable data at the given time point. [3] Analysis performed using mixed model repeated measures with covariates of baseline score, geographic region (as defined for the study/ISE), smoking status (current vs.never/ex-smoker), treatment and visit, plus interaction terms for visit by baseline and visit by treatment group. [4] Analysis model as in footnote [3] with an additional covariate of study.
[5] Analysis model as in footnote [4] with an additional covariate of study*treatment interaction.
[6] Based on covariate adjusted means. Note: Estimates are based on weighting applied to each level of class variable determined from observed proportions. Note: Includes visits up to Week 52 for study 208657.
Note: SGRQ scores calculated from conversions applied to SGRQ-C scores (SGRQ-C manual March 2016).
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Population: Modified Intent-to-treat Population with Eosinophils 300 cells/uL or More

Table 211.22

Analysis of Change from Baseline in St George's Respiratory Questionnaire-COPD (SGRQ-C) Domain Scores - Mixed Model Repeated Measures: Individual Studies and Meta-Analysis

Domain Score: Activity Domain
Visit: Week 36

	PBO (N=578)	100 SC (N=568)
208657		
n [1]	382	378
n [2]	352	356
LS Mean (SE)	63.8 (0.92)	63.6 (0.92)
LS Mean Change (SE)	-5.6 (0.92)	-5.9 (0.92)
Column vs Placebo [3]		
Difference		-0.2
95% CI		(-2.78, 2.33)
p-value		0.863
Corrected Hedges' g [6]		-0.01
95% CI		(-0.16, 0.13)

[1] Number of subjects with analysable data for one or more time points. [2] Number of subjects with analysable data at the given time point. [3] Analysis performed using mixed model repeated measures with covariates of baseline score, geographic region (as defined for the study/ISE), smoking status (current vs.never/ex-smoker), treatment and visit, plus interaction terms for visit by baseline and visit by treatment group. [4] Analysis model as in footnote [3] with an additional covariate of study. [5] Analysis model as in footnote [4] with an additional covariate of study*treatment interaction. [6] Based on covariate adjusted means. Note: Estimates are based on weighting applied to each level of class variable determined from observed proportions. Note: Includes visits up to Week 52 for study 208657. Note: SGRQ scores calculated from conversions applied to SGRQ-C scores (SGRQ-C manual March 2016).
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Population: Modified Intent-to-treat Population with Eosinophils 300 cells/uL or More

Table 211.22

Analysis of Change from Baseline in St George's Respiratory Questionnaire-COPD (SGRQ-C) Domain Scores - Mixed Model Repeated Measures: Individual Studies and Meta-Analysis

Domain Score: Activity Domain
Visit: Week 36

	PBO (N=578)	100 SC (N=568)
MEA117113		
n [1]	84	82
n [2]	73	74
LS Mean (SE)	64.2 (1.71)	63.6 (1.71)
LS Mean Change (SE)	-3.0 (1.71)	-3.7 (1.71)
Column vs Placebo [3]		
Difference		-0.7
95% CI		(-5.44, 4.10)
p-value		0.782
Corrected Hedges' g [6]		-0.05
95% CI		(-0.37, 0.28)

[1] Number of subjects with analysable data for one or more time points. [2] Number of subjects with analysable data at the given time point. [3] Analysis performed using mixed model repeated measures with covariates of baseline score, geographic region (as defined for the study/ISE), smoking status (current vs.never/ex-smoker), treatment and visit, plus interaction terms for visit by baseline and visit by treatment group. [4] Analysis model as in footnote [3] with an additional covariate of study. [5] Analysis model as in footnote [4] with an additional covariate of study*treatment interaction. [6] Based on covariate adjusted means. Note: Estimates are based on weighting applied to each level of class variable determined from observed proportions. Note: Includes visits up to Week 52 for study 208657. Note: SGRQ scores calculated from conversions applied to SGRQ-C scores (SGRQ-C manual March 2016).
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Population: Modified Intent-to-treat Population with Eosinophils 300 cells/uL or More

Table 211.22

Analysis of Change from Baseline in St George's Respiratory Questionnaire-COPD (SGRQ-C) Domain Scores - Mixed Model Repeated Measures: Individual Studies and Meta-Analysis

Domain Score: Activity Domain
Visit: Week 36

	PBO (N=578)	100 SC (N=568)
MEA117106		
n [1]	85	79
n [2]	73	73
LS Mean (SE)	66.5 (1.89)	64.6 (1.92)
LS Mean Change (SE)	-2.6 (1.89)	-4.4 (1.92)
Column vs Placebo [3]		
Difference		-1.8
95% CI		(-7.17, 3.49)
p-value		0.497
Corrected Hedges' g [6]		-0.11
95% CI		(-0.44, 0.21)

[1] Number of subjects with analysable data for one or more time points. [2] Number of subjects with analysable data at the given time point. [3] Analysis performed using mixed model repeated measures with covariates of baseline score, geographic region (as defined for the study/ISE), smoking status (current vs.never/ex-smoker), treatment and visit, plus interaction terms for visit by baseline and visit by treatment group. [4] Analysis model as in footnote [3] with an additional covariate of study. [5] Analysis model as in footnote [4] with an additional covariate of study*treatment interaction. [6] Based on covariate adjusted means. Note: Estimates are based on weighting applied to each level of class variable determined from observed proportions. Note: Includes visits up to Week 52 for study 208657. Note: SGRQ scores calculated from conversions applied to SGRQ-C scores (SGRQ-C manual March 2016).
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Population: Modified Intent-to-treat Population with Eosinophils 300 cells/uL or More

Table 211.22

Analysis of Change from Baseline in St George's Respiratory Questionnaire-COPD (SGRQ-C) Domain Scores - Mixed Model Repeated Measures: Individual Studies and Meta-Analysis

Domain Score: Activity Domain
Visit: Week 36

	PBO (N=578)	100 SC (N=568)
208657 + MEA117113 + MEA117106		
n [1]	551	539
n [2]	498	503
LS Mean (SE)	64.3 (0.75)	63.7 (0.75)
LS Mean Change (SE)	-4.6 (0.75)	-5.2 (0.75)
Column vs Placebo [4]		
Difference		-0.6
95% CI		(-2.66, 1.49)
p-value		0.580
Corrected Hedges' g [6]		-0.03
95% CI		(-0.16, 0.09)

[1] Number of subjects with analysable data for one or more time points. [2] Number of subjects with analysable data at the given time point. [3] Analysis performed using mixed model repeated measures with covariates of baseline score, geographic region (as defined for the study/ISE), smoking status (current vs.never/ex-smoker), treatment and visit, plus interaction terms for visit by baseline and visit by treatment group. [4] Analysis model as in footnote [3] with an additional covariate of study.
[5] Analysis model as in footnote [4] with an additional covariate of study*treatment interaction.
[6] Based on covariate adjusted means. Note: Estimates are based on weighting applied to each level of class variable determined from observed proportions. Note: Includes visits up to Week 52 for study 208657.
Note: SGRQ scores calculated from conversions applied to SGRQ-C scores (SGRQ-C manual March 2016).
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Population: Modified Intent-to-treat Population with Eosinophils 300 cells/uL or More

Table 211.22

Analysis of Change from Baseline in St George's Respiratory Questionnaire-COPD (SGRQ-C) Domain Scores - Mixed Model Repeated Measures: Individual Studies and Meta-Analysis

Domain Score: Activity Domain
Visit: Week 52

	PBO (N=578)	100 SC (N=568)
208657		
n [1]	382	378
n [2]	335	333
LS Mean (SE)	64.5 (0.97)	62.9 (0.97)
LS Mean Change (SE)	-5.0 (0.97)	-6.5 (0.97)
Column vs Placebo [3]		
Difference		-1.6
95% CI		(-4.26, 1.12)
p-value		0.253
Corrected Hedges' g [6]		-0.09
95% CI		(-0.24, 0.06)

[1] Number of subjects with analysable data for one or more time points. [2] Number of subjects with analysable data at the given time point. [3] Analysis performed using mixed model repeated measures with covariates of baseline score, geographic region (as defined for the study/ISE), smoking status (current vs.never/ex-smoker), treatment and visit, plus interaction terms for visit by baseline and visit by treatment group. [4] Analysis model as in footnote [3] with an additional covariate of study. [5] Analysis model as in footnote [4] with an additional covariate of study*treatment interaction. [6] Based on covariate adjusted means. Note: Estimates are based on weighting applied to each level of class variable determined from observed proportions. Note: Includes visits up to Week 52 for study 208657. Note: SGRQ scores calculated from conversions applied to SGRQ-C scores (SGRQ-C manual March 2016).
/mnt/code/postcsr_01/prod/tfls/t_e_mmrm_sgrq_chg_dom.sas 30OCT2025 13:29

Population: Modified Intent-to-treat Population with Eosinophils 300 cells/uL or More

Table 211.22

Analysis of Change from Baseline in St George's Respiratory Questionnaire-COPD (SGRQ-C) Domain Scores - Mixed Model Repeated Measures: Individual Studies and Meta-Analysis

Domain Score: Activity Domain
Visit: Week 52

	PBO (N=578)	100 SC (N=568)
MEA117113		
n [1]	84	82
n [2]	70	74
LS Mean (SE)	63.2 (1.86)	62.8 (1.83)
LS Mean Change (SE)	-4.0 (1.86)	-4.5 (1.83)
Column vs Placebo [3]		
Difference		-0.5
95% CI		(-5.61, 4.66)
p-value		0.857
Corrected Hedges' g [6]		-0.03
95% CI		(-0.36, 0.30)

[1] Number of subjects with analysable data for one or more time points. [2] Number of subjects with analysable data at the given time point. [3] Analysis performed using mixed model repeated measures with covariates of baseline score, geographic region (as defined for the study/ISE), smoking status (current vs.never/ex-smoker), treatment and visit, plus interaction terms for visit by baseline and visit by treatment group. [4] Analysis model as in footnote [3] with an additional covariate of study. [5] Analysis model as in footnote [4] with an additional covariate of study*treatment interaction. [6] Based on covariate adjusted means. Note: Estimates are based on weighting applied to each level of class variable determined from observed proportions. Note: Includes visits up to Week 52 for study 208657. Note: SGRQ scores calculated from conversions applied to SGRQ-C scores (SGRQ-C manual March 2016).
/mnt/code/postcsr_01/prod/tfls/t_e_mmrm_sgrq_chg_dom.sas 30OCT2025 13:29

Population: Modified Intent-to-treat Population with Eosinophils 300 cells/uL or More

Table 211.22

Analysis of Change from Baseline in St George's Respiratory Questionnaire-COPD (SGRQ-C) Domain Scores - Mixed Model Repeated Measures: Individual Studies and Meta-Analysis

Domain Score: Activity Domain
Visit: Week 52

	PBO (N=578)	100 SC (N=568)
MEA117106		
n [1]	85	79
n [2]	73	75
LS Mean (SE)	66.6 (2.04)	66.9 (2.05)
LS Mean Change (SE)	-2.5 (2.04)	-2.2 (2.05)
Column vs Placebo [3]		
Difference		0.3
95% CI		(-5.43, 5.99)
p-value		0.924
Corrected Hedges' g [6]		0.02
95% CI		(-0.31, 0.34)

[1] Number of subjects with analysable data for one or more time points. [2] Number of subjects with analysable data at the given time point. [3] Analysis performed using mixed model repeated measures with covariates of baseline score, geographic region (as defined for the study/ISE), smoking status (current vs.never/ex-smoker), treatment and visit, plus interaction terms for visit by baseline and visit by treatment group. [4] Analysis model as in footnote [3] with an additional covariate of study. [5] Analysis model as in footnote [4] with an additional covariate of study*treatment interaction. [6] Based on covariate adjusted means. Note: Estimates are based on weighting applied to each level of class variable determined from observed proportions. Note: Includes visits up to Week 52 for study 208657. Note: SGRQ scores calculated from conversions applied to SGRQ-C scores (SGRQ-C manual March 2016).
/mnt/code/postcsr_01/prod/tfls/t_e_mmrm_sgrq_chg_dom.sas 30OCT2025 13:29

Population: Modified Intent-to-treat Population with Eosinophils 300 cells/uL or More

Table 211.22

Analysis of Change from Baseline in St George's Respiratory Questionnaire-COPD (SGRQ-C) Domain Scores - Mixed Model Repeated Measures: Individual Studies and Meta-Analysis

Domain Score: Activity Domain
Visit: Week 52

	PBO (N=578)	100 SC (N=568)
208657 + MEA117113 + MEA117106		
n [1]	551	539
n [2]	478	482
LS Mean (SE)	64.7 (0.79)	63.5 (0.79)
LS Mean Change (SE)	-4.3 (0.79)	-5.4 (0.79)
Column vs Placebo [4]		
Difference		-1.2
95% CI		(-3.36, 1.04)
p-value		0.302
Corrected Hedges' g [6]		-0.07
95% CI		(-0.19, 0.06)
p-value for study*treatment interaction [5]		0.706

[1] Number of subjects with analysable data for one or more time points. [2] Number of subjects with analysable data at the given time point. [3] Analysis performed using mixed model repeated measures with covariates of baseline score, geographic region (as defined for the study/ISE), smoking status (current vs.never/ex-smoker), treatment and visit, plus interaction terms for visit by baseline and visit by treatment group. [4] Analysis model as in footnote [3] with an additional covariate of study.
[5] Analysis model as in footnote [4] with an additional covariate of study*treatment interaction.
[6] Based on covariate adjusted means. Note: Estimates are based on weighting applied to each level of class variable determined from observed proportions. Note: Includes visits up to Week 52 for study 208657.
Note: SGRQ scores calculated from conversions applied to SGRQ-C scores (SGRQ-C manual March 2016).
/mnt/code/postcsr_01/prod/tfls/t_e_mmrm_sgrq_chg_dom.sas 30OCT2025 13:29

Population: Modified Intent-to-treat Population with Eosinophils 300 cells/uL or More

Table 211.22

Analysis of Change from Baseline in St George's Respiratory Questionnaire-COPD (SGRQ-C) Domain Scores - Mixed Model Repeated Measures: Individual Studies and Meta-Analysis

Domain Score: Impacts Domain
Visit: Week 12

	PBO (N=578)	100 SC (N=568)
208657		
n [1]	382	378
n [2]	363	364
LS Mean (SE)	38.1 (0.82)	34.7 (0.83)
LS Mean Change (SE)	-3.4 (0.82)	-6.8 (0.83)
Column vs Placebo [3]		
Difference		-3.4
95% CI		(-5.67, -1.09)
p-value		0.004
Corrected Hedges' g [6]		-0.21
95% CI		(-0.36, -0.07)

[1] Number of subjects with analysable data for one or more time points. [2] Number of subjects with analysable data at the given time point. [3] Analysis performed using mixed model repeated measures with covariates of baseline score, geographic region (as defined for the study/ISE), smoking status (current vs.never/ex-smoker), treatment and visit, plus interaction terms for visit by baseline and visit by treatment group. [4] Analysis model as in footnote [3] with an additional covariate of study. [5] Analysis model as in footnote [4] with an additional covariate of study*treatment interaction. [6] Based on covariate adjusted means. Note: Estimates are based on weighting applied to each level of class variable determined from observed proportions. Note: Includes visits up to Week 52 for study 208657. Note: SGRQ scores calculated from conversions applied to SGRQ-C scores (SGRQ-C manual March 2016). /mnt/code/postcsr_01/prod/tfls/t_e_mmrm_sgrq_chg_dom.sas 30OCT2025 13:29

Population: Modified Intent-to-treat Population with Eosinophils 300 cells/uL or More

Table 211.22

Analysis of Change from Baseline in St George's Respiratory Questionnaire-COPD (SGRQ-C) Domain Scores - Mixed Model Repeated Measures: Individual Studies and Meta-Analysis

Domain Score: Impacts Domain
Visit: Week 12

	PBO (N=578)	100 SC (N=568)
MEA117113		
n [1]	84	82
n [2]	83	79
LS Mean (SE)	37.4 (1.56)	32.5 (1.59)
LS Mean Change (SE)	-1.0 (1.56)	-5.9 (1.59)
Column vs Placebo [3]		
Difference		-4.9
95% CI		(-9.28, -0.52)
p-value		0.029
Corrected Hedges' g [6]		-0.34
95% CI		(-0.65, -0.03)

[1] Number of subjects with analysable data for one or more time points. [2] Number of subjects with analysable data at the given time point. [3] Analysis performed using mixed model repeated measures with covariates of baseline score, geographic region (as defined for the study/ISE), smoking status (current vs.never/ex-smoker), treatment and visit, plus interaction terms for visit by baseline and visit by treatment group. [4] Analysis model as in footnote [3] with an additional covariate of study. [5] Analysis model as in footnote [4] with an additional covariate of study*treatment interaction. [6] Based on covariate adjusted means. Note: Estimates are based on weighting applied to each level of class variable determined from observed proportions. Note: Includes visits up to Week 52 for study 208657. Note: SGRQ scores calculated from conversions applied to SGRQ-C scores (SGRQ-C manual March 2016).
/mnt/code/postcsr_01/prod/tfls/t_e_mmrm_sgrq_chg_dom.sas 30OCT2025 13:29

Population: Modified Intent-to-treat Population with Eosinophils 300 cells/uL or More

Table 211.22

Analysis of Change from Baseline in St George's Respiratory Questionnaire-COPD (SGRQ-C) Domain Scores - Mixed Model Repeated Measures: Individual Studies and Meta-Analysis

Domain Score: Impacts Domain
Visit: Week 12

	PBO (N=578)	100 SC (N=568)
MEA117106		
n [1]	85	79
n [2]	81	78
LS Mean (SE)	38.6 (1.54)	36.4 (1.58)
LS Mean Change (SE)	-2.8 (1.54)	-5.0 (1.58)
Column vs Placebo [3]		
Difference		-2.3
95% CI		(-6.62, 2.11)
p-value		0.310
Corrected Hedges' g [6]		-0.16
95% CI		(-0.47, 0.15)

[1] Number of subjects with analysable data for one or more time points. [2] Number of subjects with analysable data at the given time point. [3] Analysis performed using mixed model repeated measures with covariates of baseline score, geographic region (as defined for the study/ISE), smoking status (current vs.never/ex-smoker), treatment and visit, plus interaction terms for visit by baseline and visit by treatment group. [4] Analysis model as in footnote [3] with an additional covariate of study. [5] Analysis model as in footnote [4] with an additional covariate of study*treatment interaction. [6] Based on covariate adjusted means. Note: Estimates are based on weighting applied to each level of class variable determined from observed proportions. Note: Includes visits up to Week 52 for study 208657. Note: SGRQ scores calculated from conversions applied to SGRQ-C scores (SGRQ-C manual March 2016).
/mnt/code/postcsr_01/prod/tfls/t_e_mmrm_sgrq_chg_dom.sas 30OCT2025 13:29

Population: Modified Intent-to-treat Population with Eosinophils 300 cells/uL or More

Table 211.22

Analysis of Change from Baseline in St George's Respiratory Questionnaire-COPD (SGRQ-C) Domain Scores - Mixed Model Repeated Measures: Individual Studies and Meta-Analysis

Domain Score: Impacts Domain
Visit: Week 12

	PBO (N=578)	100 SC (N=568)
208657 + MEA117113 + MEA117106		
n [1]	551	539
n [2]	527	521
LS Mean (SE)	38.1 (0.66)	34.6 (0.67)
LS Mean Change (SE)	-2.8 (0.66)	-6.3 (0.67)
Column vs Placebo [4]		
Difference		-3.5
95% CI		(-5.34, -1.66)
p-value		0.001
Corrected Hedges' g [6]		-0.23
95% CI		(-0.35, -0.11)

[1] Number of subjects with analysable data for one or more time points. [2] Number of subjects with analysable data at the given time point. [3] Analysis performed using mixed model repeated measures with covariates of baseline score, geographic region (as defined for the study/ISE), smoking status (current vs.never/ex-smoker), treatment and visit, plus interaction terms for visit by baseline and visit by treatment group. [4] Analysis model as in footnote [3] with an additional covariate of study.
[5] Analysis model as in footnote [4] with an additional covariate of study*treatment interaction.
[6] Based on covariate adjusted means. Note: Estimates are based on weighting applied to each level of class variable determined from observed proportions. Note: Includes visits up to Week 52 for study 208657.
Note: SGRQ scores calculated from conversions applied to SGRQ-C scores (SGRQ-C manual March 2016).
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Population: Modified Intent-to-treat Population with Eosinophils 300 cells/uL or More

Table 211.22

Analysis of Change from Baseline in St George's Respiratory Questionnaire-COPD (SGRQ-C) Domain Scores - Mixed Model Repeated Measures: Individual Studies and Meta-Analysis

Domain Score: Impacts Domain
Visit: Week 24

	PBO (N=578)	100 SC (N=568)
208657		
n [1]	382	378
n [2]	362	356
LS Mean (SE)	36.6 (0.86)	34.0 (0.86)
LS Mean Change (SE)	-4.9 (0.86)	-7.5 (0.86)
Column vs Placebo [3]		
Difference		-2.6
95% CI		(-5.02, -0.23)
p-value		0.032
Corrected Hedges' g [6]		-0.16
95% CI		(-0.31, -0.01)

[1] Number of subjects with analysable data for one or more time points. [2] Number of subjects with analysable data at the given time point. [3] Analysis performed using mixed model repeated measures with covariates of baseline score, geographic region (as defined for the study/ISE), smoking status (current vs.never/ex-smoker), treatment and visit, plus interaction terms for visit by baseline and visit by treatment group. [4] Analysis model as in footnote [3] with an additional covariate of study. [5] Analysis model as in footnote [4] with an additional covariate of study*treatment interaction. [6] Based on covariate adjusted means. Note: Estimates are based on weighting applied to each level of class variable determined from observed proportions. Note: Includes visits up to Week 52 for study 208657. Note: SGRQ scores calculated from conversions applied to SGRQ-C scores (SGRQ-C manual March 2016).
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Population: Modified Intent-to-treat Population with Eosinophils 300 cells/uL or More

Table 211.22

Analysis of Change from Baseline in St George's Respiratory Questionnaire-COPD (SGRQ-C) Domain Scores - Mixed Model Repeated Measures: Individual Studies and Meta-Analysis

Domain Score: Impacts Domain
Visit: Week 24

	PBO (N=578)	100 SC (N=568)
MEA117113		
n [1]	84	82
n [2]	79	74
LS Mean (SE)	37.3 (1.73)	30.8 (1.77)
LS Mean Change (SE)	-1.1 (1.73)	-7.6 (1.77)
Column vs Placebo [3]		
Difference		-6.5
95% CI		(-11.34, -1.58)
p-value		0.010
Corrected Hedges' g [6]		-0.42
95% CI		(-0.74, -0.10)

[1] Number of subjects with analysable data for one or more time points. [2] Number of subjects with analysable data at the given time point. [3] Analysis performed using mixed model repeated measures with covariates of baseline score, geographic region (as defined for the study/ISE), smoking status (current vs.never/ex-smoker), treatment and visit, plus interaction terms for visit by baseline and visit by treatment group. [4] Analysis model as in footnote [3] with an additional covariate of study.
[5] Analysis model as in footnote [4] with an additional covariate of study*treatment interaction.
[6] Based on covariate adjusted means. Note: Estimates are based on weighting applied to each level of class variable determined from observed proportions. Note: Includes visits up to Week 52 for study 208657.
Note: SGRQ scores calculated from conversions applied to SGRQ-C scores (SGRQ-C manual March 2016).
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Population: Modified Intent-to-treat Population with Eosinophils 300 cells/uL or More

Table 211.22

Analysis of Change from Baseline in St George's Respiratory Questionnaire-COPD (SGRQ-C) Domain Scores - Mixed Model Repeated Measures: Individual Studies and Meta-Analysis

Domain Score: Impacts Domain
Visit: Week 24

	PBO (N=578)	100 SC (N=568)
MEA117106		
n [1]	85	79
n [2]	78	75
LS Mean (SE)	39.2 (1.80)	34.8 (1.84)
LS Mean Change (SE)	-2.3 (1.80)	-6.7 (1.84)
Column vs Placebo [3]		
Difference		-4.4
95% CI		(-9.47, 0.71)
p-value		0.091
Corrected Hedges' g [6]		-0.27
95% CI		(-0.59, 0.04)

[1] Number of subjects with analysable data for one or more time points. [2] Number of subjects with analysable data at the given time point. [3] Analysis performed using mixed model repeated measures with covariates of baseline score, geographic region (as defined for the study/ISE), smoking status (current vs.never/ex-smoker), treatment and visit, plus interaction terms for visit by baseline and visit by treatment group. [4] Analysis model as in footnote [3] with an additional covariate of study. [5] Analysis model as in footnote [4] with an additional covariate of study*treatment interaction. [6] Based on covariate adjusted means. Note: Estimates are based on weighting applied to each level of class variable determined from observed proportions. Note: Includes visits up to Week 52 for study 208657. Note: SGRQ scores calculated from conversions applied to SGRQ-C scores (SGRQ-C manual March 2016).
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Population: Modified Intent-to-treat Population with Eosinophils 300 cells/uL or More

Table 211.22

Analysis of Change from Baseline in St George's Respiratory Questionnaire-COPD (SGRQ-C) Domain Scores - Mixed Model Repeated Measures: Individual Studies and Meta-Analysis

Domain Score: Impacts Domain
Visit: Week 24

	PBO (N=578)	100 SC (N=568)
208657 + MEA117113 + MEA117106		
n [1]	551	539
n [2]	519	505
LS Mean (SE)	37.1 (0.71)	33.6 (0.72)
LS Mean Change (SE)	-3.8 (0.71)	-7.3 (0.72)
Column vs Placebo [4]		
Difference		-3.5
95% CI		(-5.50, -1.55)
p-value		0.001
Corrected Hedges' g [6]		-0.22
95% CI		(-0.34, -0.09)

[1] Number of subjects with analysable data for one or more time points. [2] Number of subjects with analysable data at the given time point. [3] Analysis performed using mixed model repeated measures with covariates of baseline score, geographic region (as defined for the study/ISE), smoking status (current vs.never/ex-smoker), treatment and visit, plus interaction terms for visit by baseline and visit by treatment group. [4] Analysis model as in footnote [3] with an additional covariate of study.
[5] Analysis model as in footnote [4] with an additional covariate of study*treatment interaction.
[6] Based on covariate adjusted means. Note: Estimates are based on weighting applied to each level of class variable determined from observed proportions. Note: Includes visits up to Week 52 for study 208657.
Note: SGRQ scores calculated from conversions applied to SGRQ-C scores (SGRQ-C manual March 2016).
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Population: Modified Intent-to-treat Population with Eosinophils 300 cells/uL or More

Table 211.22

Analysis of Change from Baseline in St George's Respiratory Questionnaire-COPD (SGRQ-C) Domain Scores - Mixed Model Repeated Measures: Individual Studies and Meta-Analysis

Domain Score: Impacts Domain
Visit: Week 36

	PBO (N=578)	100 SC (N=568)
208657		
n [1]	382	378
n [2]	352	356
LS Mean (SE)	35.7 (0.92)	33.3 (0.92)
LS Mean Change (SE)	-5.8 (0.92)	-8.2 (0.92)
Column vs Placebo [3]		
Difference		-2.4
95% CI		(-4.97, 0.15)
p-value		0.065
Corrected Hedges' g [6]		-0.14
95% CI		(-0.29, 0.01)

[1] Number of subjects with analysable data for one or more time points. [2] Number of subjects with analysable data at the given time point. [3] Analysis performed using mixed model repeated measures with covariates of baseline score, geographic region (as defined for the study/ISE), smoking status (current vs.never/ex-smoker), treatment and visit, plus interaction terms for visit by baseline and visit by treatment group. [4] Analysis model as in footnote [3] with an additional covariate of study. [5] Analysis model as in footnote [4] with an additional covariate of study*treatment interaction. [6] Based on covariate adjusted means. Note: Estimates are based on weighting applied to each level of class variable determined from observed proportions. Note: Includes visits up to Week 52 for study 208657. Note: SGRQ scores calculated from conversions applied to SGRQ-C scores (SGRQ-C manual March 2016).
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Population: Modified Intent-to-treat Population with Eosinophils 300 cells/uL or More

Table 211.22

Analysis of Change from Baseline in St George's Respiratory Questionnaire-COPD (SGRQ-C) Domain Scores - Mixed Model Repeated Measures: Individual Studies and Meta-Analysis

Domain Score: Impacts Domain
Visit: Week 36

	PBO (N=578)	100 SC (N=568)
MEA117113		
n [1]	84	82
n [2]	73	74
LS Mean (SE)	35.6 (1.80)	33.7 (1.79)
LS Mean Change (SE)	-2.8 (1.80)	-4.7 (1.79)
Column vs Placebo [3]		
Difference		-1.9
95% CI		(-6.88, 3.13)
p-value		0.462
Corrected Hedges' g [6]		-0.12
95% CI		(-0.44, 0.20)

[1] Number of subjects with analysable data for one or more time points. [2] Number of subjects with analysable data at the given time point. [3] Analysis performed using mixed model repeated measures with covariates of baseline score, geographic region (as defined for the study/ISE), smoking status (current vs.never/ex-smoker), treatment and visit, plus interaction terms for visit by baseline and visit by treatment group. [4] Analysis model as in footnote [3] with an additional covariate of study. [5] Analysis model as in footnote [4] with an additional covariate of study*treatment interaction. [6] Based on covariate adjusted means. Note: Estimates are based on weighting applied to each level of class variable determined from observed proportions. Note: Includes visits up to Week 52 for study 208657. Note: SGRQ scores calculated from conversions applied to SGRQ-C scores (SGRQ-C manual March 2016).
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Population: Modified Intent-to-treat Population with Eosinophils 300 cells/uL or More

Table 211.22

Analysis of Change from Baseline in St George's Respiratory Questionnaire-COPD (SGRQ-C) Domain Scores - Mixed Model Repeated Measures: Individual Studies and Meta-Analysis

Domain Score: Impacts Domain
Visit: Week 36

	PBO (N=578)	100 SC (N=568)
MEA117106		
n [1]	85	79
n [2]	73	73
LS Mean (SE)	39.0 (1.87)	36.9 (1.90)
LS Mean Change (SE)	-2.4 (1.87)	-4.5 (1.90)
Column vs Placebo [3]		
Difference		-2.1
95% CI		(-7.42, 3.14)
p-value		0.425
Corrected Hedges' g [6]		-0.13
95% CI		(-0.46, 0.19)

[1] Number of subjects with analysable data for one or more time points. [2] Number of subjects with analysable data at the given time point. [3] Analysis performed using mixed model repeated measures with covariates of baseline score, geographic region (as defined for the study/ISE), smoking status (current vs.never/ex-smoker), treatment and visit, plus interaction terms for visit by baseline and visit by treatment group. [4] Analysis model as in footnote [3] with an additional covariate of study.
[5] Analysis model as in footnote [4] with an additional covariate of study*treatment interaction.
[6] Based on covariate adjusted means. Note: Estimates are based on weighting applied to each level of class variable determined from observed proportions. Note: Includes visits up to Week 52 for study 208657.
Note: SGRQ scores calculated from conversions applied to SGRQ-C scores (SGRQ-C manual March 2016).
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Population: Modified Intent-to-treat Population with Eosinophils 300 cells/uL or More

Table 211.22

Analysis of Change from Baseline in St George's Respiratory Questionnaire-COPD (SGRQ-C) Domain Scores - Mixed Model Repeated Measures: Individual Studies and Meta-Analysis

Domain Score: Impacts Domain
Visit: Week 36

	PBO (N=578)	100 SC (N=568)
208657 + MEA117113 + MEA117106		
n [1]	551	539
n [2]	498	503
LS Mean (SE)	36.2 (0.76)	33.8 (0.76)
LS Mean Change (SE)	-4.6 (0.76)	-7.0 (0.76)
Column vs Placebo [4]		
Difference		-2.3
95% CI		(-4.44, -0.25)
p-value		0.029
Corrected Hedges' g [6]		-0.14
95% CI		(-0.26, -0.01)

[1] Number of subjects with analysable data for one or more time points. [2] Number of subjects with analysable data at the given time point. [3] Analysis performed using mixed model repeated measures with covariates of baseline score, geographic region (as defined for the study/ISE), smoking status (current vs.never/ex-smoker), treatment and visit, plus interaction terms for visit by baseline and visit by treatment group. [4] Analysis model as in footnote [3] with an additional covariate of study.
[5] Analysis model as in footnote [4] with an additional covariate of study*treatment interaction.
[6] Based on covariate adjusted means. Note: Estimates are based on weighting applied to each level of class variable determined from observed proportions. Note: Includes visits up to Week 52 for study 208657.
Note: SGRQ scores calculated from conversions applied to SGRQ-C scores (SGRQ-C manual March 2016).
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Population: Modified Intent-to-treat Population with Eosinophils 300 cells/uL or More

Table 211.22

Analysis of Change from Baseline in St George's Respiratory Questionnaire-COPD (SGRQ-C) Domain Scores - Mixed Model Repeated Measures: Individual Studies and Meta-Analysis

Domain Score: Impacts Domain
Visit: Week 52

	PBO (N=578)	100 SC (N=568)
208657		
n [1]	382	378
n [2]	335	333
LS Mean (SE)	36.2 (0.97)	32.9 (0.97)
LS Mean Change (SE)	-5.3 (0.97)	-8.6 (0.97)
Column vs Placebo [3]		
Difference		-3.3
95% CI		(-6.02, -0.63)
p-value		0.016
Corrected Hedges' g [6]		-0.19
95% CI		(-0.34, -0.04)

[1] Number of subjects with analysable data for one or more time points. [2] Number of subjects with analysable data at the given time point. [3] Analysis performed using mixed model repeated measures with covariates of baseline score, geographic region (as defined for the study/ISE), smoking status (current vs.never/ex-smoker), treatment and visit, plus interaction terms for visit by baseline and visit by treatment group. [4] Analysis model as in footnote [3] with an additional covariate of study. [5] Analysis model as in footnote [4] with an additional covariate of study*treatment interaction. [6] Based on covariate adjusted means. Note: Estimates are based on weighting applied to each level of class variable determined from observed proportions. Note: Includes visits up to Week 52 for study 208657. Note: SGRQ scores calculated from conversions applied to SGRQ-C scores (SGRQ-C manual March 2016).
/mnt/code/postcsr_01/prod/tfls/t_e_mmrm_sgrq_chg_dom.sas 30OCT2025 13:29

Population: Modified Intent-to-treat Population with Eosinophils 300 cells/uL or More

Table 211.22

Analysis of Change from Baseline in St George's Respiratory Questionnaire-COPD (SGRQ-C) Domain Scores - Mixed Model Repeated Measures: Individual Studies and Meta-Analysis

Domain Score: Impacts Domain
Visit: Week 52

	PBO (N=578)	100 SC (N=568)
MEA117113		
n [1]	84	82
n [2]	70	74
LS Mean (SE)	36.2 (1.95)	32.3 (1.92)
LS Mean Change (SE)	-2.2 (1.95)	-6.0 (1.92)
Column vs Placebo [3]		
Difference		-3.8
95% CI		(-9.21, 1.59)
p-value		0.166
Corrected Hedges' g [6]		-0.23
95% CI		(-0.56, 0.10)

[1] Number of subjects with analysable data for one or more time points. [2] Number of subjects with analysable data at the given time point. [3] Analysis performed using mixed model repeated measures with covariates of baseline score, geographic region (as defined for the study/ISE), smoking status (current vs.never/ex-smoker), treatment and visit, plus interaction terms for visit by baseline and visit by treatment group. [4] Analysis model as in footnote [3] with an additional covariate of study.
[5] Analysis model as in footnote [4] with an additional covariate of study*treatment interaction.
[6] Based on covariate adjusted means. Note: Estimates are based on weighting applied to each level of class variable determined from observed proportions. Note: Includes visits up to Week 52 for study 208657.
Note: SGRQ scores calculated from conversions applied to SGRQ-C scores (SGRQ-C manual March 2016).
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Population: Modified Intent-to-treat Population with Eosinophils 300 cells/uL or More

Table 211.22

Analysis of Change from Baseline in St George's Respiratory Questionnaire-COPD (SGRQ-C) Domain Scores - Mixed Model Repeated Measures: Individual Studies and Meta-Analysis

Domain Score: Impacts Domain
Visit: Week 52

	PBO (N=578)	100 SC (N=568)
MEA117106		
n [1]	85	79
n [2]	73	75
LS Mean (SE)	37.8 (2.09)	37.3 (2.11)
LS Mean Change (SE)	-3.7 (2.09)	-4.2 (2.11)
Column vs Placebo [3]		
Difference		-0.5
95% CI		(-6.35, 5.39)
p-value		0.873
Corrected Hedges' g [6]		-0.03
95% CI		(-0.35, 0.30)

[1] Number of subjects with analysable data for one or more time points. [2] Number of subjects with analysable data at the given time point. [3] Analysis performed using mixed model repeated measures with covariates of baseline score, geographic region (as defined for the study/ISE), smoking status (current vs.never/ex-smoker), treatment and visit, plus interaction terms for visit by baseline and visit by treatment group. [4] Analysis model as in footnote [3] with an additional covariate of study.
[5] Analysis model as in footnote [4] with an additional covariate of study*treatment interaction.
[6] Based on covariate adjusted means. Note: Estimates are based on weighting applied to each level of class variable determined from observed proportions. Note: Includes visits up to Week 52 for study 208657.
Note: SGRQ scores calculated from conversions applied to SGRQ-C scores (SGRQ-C manual March 2016).
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Population: Modified Intent-to-treat Population with Eosinophils 300 cells/uL or More

Table 211.22

Analysis of Change from Baseline in St George's Respiratory Questionnaire-COPD (SGRQ-C) Domain Scores - Mixed Model Repeated Measures: Individual Studies and Meta-Analysis

Domain Score: Impacts Domain
Visit: Week 52

	PBO (N=578)	100 SC (N=568)
208657 + MEA117113 + MEA117106		
n [1]	551	539
n [2]	478	482
LS Mean (SE)	36.4 (0.80)	33.4 (0.81)
LS Mean Change (SE)	-4.4 (0.80)	-7.4 (0.81)
Column vs Placebo [4]		
Difference		-3.0
95% CI		(-5.19, -0.73)
p-value		0.010
Corrected Hedges' g [6]		-0.17
95% CI		(-0.29, -0.04)
p-value for study*treatment interaction [5]		0.735

[1] Number of subjects with analysable data for one or more time points. [2] Number of subjects with analysable data at the given time point. [3] Analysis performed using mixed model repeated measures with covariates of baseline score, geographic region (as defined for the study/ISE), smoking status (current vs.never/ex-smoker), treatment and visit, plus interaction terms for visit by baseline and visit by treatment group. [4] Analysis model as in footnote [3] with an additional covariate of study.
[5] Analysis model as in footnote [4] with an additional covariate of study*treatment interaction.
[6] Based on covariate adjusted means. Note: Estimates are based on weighting applied to each level of class variable determined from observed proportions. Note: Includes visits up to Week 52 for study 208657.
Note: SGRQ scores calculated from conversions applied to SGRQ-C scores (SGRQ-C manual March 2016).
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Population: Modified Intent-to-treat Population with Eosinophils 300 cells/uL or More

Table 211.22

Analysis of Change from Baseline in St George's Respiratory Questionnaire-COPD (SGRQ-C) Domain Scores - Mixed Model Repeated Measures: Individual Studies and Meta-Analysis

Domain Score: Symptoms Domain
Visit: Week 12

	PBO (N=578)	100 SC (N=568)
208657		
n [1]	382	378
n [2]	363	364
LS Mean (SE)	61.5 (0.85)	58.6 (0.85)
LS Mean Change (SE)	-5.3 (0.85)	-8.2 (0.85)
Column vs Placebo [3]		
Difference		-2.9
95% CI		(-5.25, -0.50)
p-value		0.018
Corrected Hedges' g [6]		-0.18
95% CI		(-0.32, -0.03)

[1] Number of subjects with analysable data for one or more time points. [2] Number of subjects with analysable data at the given time point. [3] Analysis performed using mixed model repeated measures with covariates of baseline score, geographic region (as defined for the study/ISE), smoking status (current vs.never/ex-smoker), treatment and visit, plus interaction terms for visit by baseline and visit by treatment group. [4] Analysis model as in footnote [3] with an additional covariate of study. [5] Analysis model as in footnote [4] with an additional covariate of study*treatment interaction. [6] Based on covariate adjusted means. Note: Estimates are based on weighting applied to each level of class variable determined from observed proportions. Note: Includes visits up to Week 52 for study 208657. Note: SGRQ scores calculated from conversions applied to SGRQ-C scores (SGRQ-C manual March 2016).
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Population: Modified Intent-to-treat Population with Eosinophils 300 cells/uL or More

Table 211.22

Analysis of Change from Baseline in St George's Respiratory Questionnaire-COPD (SGRQ-C) Domain Scores - Mixed Model Repeated Measures: Individual Studies and Meta-Analysis

Domain Score: Symptoms Domain
Visit: Week 12

	PBO (N=578)	100 SC (N=568)
MEA117113		
n [1]	84	82
n [2]	83	79
LS Mean (SE)	66.3 (1.64)	61.1 (1.66)
LS Mean Change (SE)	-1.3 (1.64)	-6.5 (1.66)
Column vs Placebo [3]		
Difference		-5.2
95% CI		(-9.80, -0.60)
p-value		0.027
Corrected Hedges' g [6]		-0.35
95% CI		(-0.66, -0.04)

[1] Number of subjects with analysable data for one or more time points. [2] Number of subjects with analysable data at the given time point. [3] Analysis performed using mixed model repeated measures with covariates of baseline score, geographic region (as defined for the study/ISE), smoking status (current vs.never/ex-smoker), treatment and visit, plus interaction terms for visit by baseline and visit by treatment group. [4] Analysis model as in footnote [3] with an additional covariate of study. [5] Analysis model as in footnote [4] with an additional covariate of study*treatment interaction. [6] Based on covariate adjusted means. Note: Estimates are based on weighting applied to each level of class variable determined from observed proportions. Note: Includes visits up to Week 52 for study 208657. Note: SGRQ scores calculated from conversions applied to SGRQ-C scores (SGRQ-C manual March 2016).
/mnt/code/postcsr_01/prod/tfls/t_e_mmrm_sgrq_chg_dom.sas 30OCT2025 13:29

Population: Modified Intent-to-treat Population with Eosinophils 300 cells/uL or More

Table 211.22

Analysis of Change from Baseline in St George's Respiratory Questionnaire-COPD (SGRQ-C) Domain Scores - Mixed Model Repeated Measures: Individual Studies and Meta-Analysis

Domain Score: Symptoms Domain
Visit: Week 12

	PBO (N=578)	100 SC (N=568)
MEA117106		
n [1]	85	79
n [2]	81	78
LS Mean (SE)	66.0 (1.49)	59.8 (1.53)
LS Mean Change (SE)	-3.0 (1.49)	-9.2 (1.53)
Column vs Placebo [3]		
Difference		-6.2
95% CI		(-10.39, -1.96)
p-value		0.005
Corrected Hedges' g [6]		-0.46
95% CI		(-0.77, -0.14)

[1] Number of subjects with analysable data for one or more time points. [2] Number of subjects with analysable data at the given time point. [3] Analysis performed using mixed model repeated measures with covariates of baseline score, geographic region (as defined for the study/ISE), smoking status (current vs.never/ex-smoker), treatment and visit, plus interaction terms for visit by baseline and visit by treatment group. [4] Analysis model as in footnote [3] with an additional covariate of study.
[5] Analysis model as in footnote [4] with an additional covariate of study*treatment interaction.
[6] Based on covariate adjusted means. Note: Estimates are based on weighting applied to each level of class variable determined from observed proportions. Note: Includes visits up to Week 52 for study 208657.
Note: SGRQ scores calculated from conversions applied to SGRQ-C scores (SGRQ-C manual March 2016).
/mnt/code/postcsr_01/prod/tfls/t_e_mmrm_sgrq_chg_dom.sas 30OCT2025 13:29

Population: Modified Intent-to-treat Population with Eosinophils 300 cells/uL or More

Table 211.22

Analysis of Change from Baseline in St George's Respiratory Questionnaire-COPD (SGRQ-C) Domain Scores - Mixed Model Repeated Measures: Individual Studies and Meta-Analysis

Domain Score: Symptoms Domain
Visit: Week 12

	PBO (N=578)	100 SC (N=568)
208657 + MEA117113 + MEA117106		
n [1]	551	539
n [2]	527	521
LS Mean (SE)	63.1 (0.69)	59.3 (0.69)
LS Mean Change (SE)	-4.2 (0.69)	-7.9 (0.69)
Column vs Placebo [4]		
Difference		-3.8
95% CI		(-5.67, -1.87)
p-value		0.001
Corrected Hedges' g [6]		-0.24
95% CI		(-0.36, -0.12)

[1] Number of subjects with analysable data for one or more time points. [2] Number of subjects with analysable data at the given time point. [3] Analysis performed using mixed model repeated measures with covariates of baseline score, geographic region (as defined for the study/ISE), smoking status (current vs.never/ex-smoker), treatment and visit, plus interaction terms for visit by baseline and visit by treatment group. [4] Analysis model as in footnote [3] with an additional covariate of study.
[5] Analysis model as in footnote [4] with an additional covariate of study*treatment interaction.
[6] Based on covariate adjusted means. Note: Estimates are based on weighting applied to each level of class variable determined from observed proportions. Note: Includes visits up to Week 52 for study 208657.
Note: SGRQ scores calculated from conversions applied to SGRQ-C scores (SGRQ-C manual March 2016).
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Population: Modified Intent-to-treat Population with Eosinophils 300 cells/uL or More

Table 211.22

Analysis of Change from Baseline in St George's Respiratory Questionnaire-COPD (SGRQ-C) Domain Scores - Mixed Model Repeated Measures: Individual Studies and Meta-Analysis

Domain Score: Symptoms Domain
Visit: Week 24

	PBO (N=578)	100 SC (N=568)
208657		
n [1]	382	378
n [2]	362	356
LS Mean (SE)	59.8 (0.84)	57.8 (0.85)
LS Mean Change (SE)	-7.0 (0.84)	-9.0 (0.85)
Column vs Placebo [3]		
Difference		-2.0
95% CI		(-4.33, 0.37)
p-value		0.099
Corrected Hedges' g [6]		-0.12
95% CI		(-0.27, 0.02)

[1] Number of subjects with analysable data for one or more time points. [2] Number of subjects with analysable data at the given time point. [3] Analysis performed using mixed model repeated measures with covariates of baseline score, geographic region (as defined for the study/ISE), smoking status (current vs.never/ex-smoker), treatment and visit, plus interaction terms for visit by baseline and visit by treatment group. [4] Analysis model as in footnote [3] with an additional covariate of study.
[5] Analysis model as in footnote [4] with an additional covariate of study*treatment interaction.
[6] Based on covariate adjusted means. Note: Estimates are based on weighting applied to each level of class variable determined from observed proportions. Note: Includes visits up to Week 52 for study 208657.
Note: SGRQ scores calculated from conversions applied to SGRQ-C scores (SGRQ-C manual March 2016).
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Population: Modified Intent-to-treat Population with Eosinophils 300 cells/uL or More

Table 211.22

Analysis of Change from Baseline in St George's Respiratory Questionnaire-COPD (SGRQ-C) Domain Scores - Mixed Model Repeated Measures: Individual Studies and Meta-Analysis

Domain Score: Symptoms Domain
Visit: Week 24

	PBO (N=578)	100 SC (N=568)
MEA117113		
n [1]	84	82
n [2]	79	74
LS Mean (SE)	62.2 (1.80)	57.0 (1.84)
LS Mean Change (SE)	-5.4 (1.80)	-10.6 (1.84)
Column vs Placebo [3]		
Difference		-5.2
95% CI		(-10.28, -0.13)
p-value		0.045
Corrected Hedges' g [6]		-0.32
95% CI		(-0.64, -0.01)

[1] Number of subjects with analysable data for one or more time points. [2] Number of subjects with analysable data at the given time point. [3] Analysis performed using mixed model repeated measures with covariates of baseline score, geographic region (as defined for the study/ISE), smoking status (current vs.never/ex-smoker), treatment and visit, plus interaction terms for visit by baseline and visit by treatment group. [4] Analysis model as in footnote [3] with an additional covariate of study. [5] Analysis model as in footnote [4] with an additional covariate of study*treatment interaction. [6] Based on covariate adjusted means. Note: Estimates are based on weighting applied to each level of class variable determined from observed proportions. Note: Includes visits up to Week 52 for study 208657. Note: SGRQ scores calculated from conversions applied to SGRQ-C scores (SGRQ-C manual March 2016).
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Population: Modified Intent-to-treat Population with Eosinophils 300 cells/uL or More

Table 211.22

Analysis of Change from Baseline in St George's Respiratory Questionnaire-COPD (SGRQ-C) Domain Scores - Mixed Model Repeated Measures: Individual Studies and Meta-Analysis

Domain Score: Symptoms Domain
Visit: Week 24

	PBO (N=578)	100 SC (N=568)
MEA117106		
n [1]	85	79
n [2]	78	75
LS Mean (SE)	64.4 (1.75)	59.8 (1.79)
LS Mean Change (SE)	-4.6 (1.75)	-9.2 (1.79)
Column vs Placebo [3]		
Difference		-4.5
95% CI		(-9.48, 0.42)
p-value		0.073
Corrected Hedges' g [6]		-0.29
95% CI		(-0.61, 0.03)

[1] Number of subjects with analysable data for one or more time points. [2] Number of subjects with analysable data at the given time point. [3] Analysis performed using mixed model repeated measures with covariates of baseline score, geographic region (as defined for the study/ISE), smoking status (current vs.never/ex-smoker), treatment and visit, plus interaction terms for visit by baseline and visit by treatment group. [4] Analysis model as in footnote [3] with an additional covariate of study. [5] Analysis model as in footnote [4] with an additional covariate of study*treatment interaction. [6] Based on covariate adjusted means. Note: Estimates are based on weighting applied to each level of class variable determined from observed proportions. Note: Includes visits up to Week 52 for study 208657. Note: SGRQ scores calculated from conversions applied to SGRQ-C scores (SGRQ-C manual March 2016).
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Population: Modified Intent-to-treat Population with Eosinophils 300 cells/uL or More

Table 211.22

Analysis of Change from Baseline in St George's Respiratory Questionnaire-COPD (SGRQ-C) Domain Scores - Mixed Model Repeated Measures: Individual Studies and Meta-Analysis

Domain Score: Symptoms Domain
Visit: Week 24

	PBO (N=578)	100 SC (N=568)
208657 + MEA117113 + MEA117106		
n [1]	551	539
n [2]	519	505
LS Mean (SE)	61.0 (0.71)	58.2 (0.72)
LS Mean Change (SE)	-6.3 (0.71)	-9.1 (0.72)
Column vs Placebo [4]		
Difference		-2.8
95% CI		(-4.79, -0.83)
p-value		0.006
Corrected Hedges' g [6]		-0.17
95% CI		(-0.30, -0.05)

[1] Number of subjects with analysable data for one or more time points. [2] Number of subjects with analysable data at the given time point. [3] Analysis performed using mixed model repeated measures with covariates of baseline score, geographic region (as defined for the study/ISE), smoking status (current vs.never/ex-smoker), treatment and visit, plus interaction terms for visit by baseline and visit by treatment group. [4] Analysis model as in footnote [3] with an additional covariate of study.
[5] Analysis model as in footnote [4] with an additional covariate of study*treatment interaction.
[6] Based on covariate adjusted means. Note: Estimates are based on weighting applied to each level of class variable determined from observed proportions. Note: Includes visits up to Week 52 for study 208657.
Note: SGRQ scores calculated from conversions applied to SGRQ-C scores (SGRQ-C manual March 2016).
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Population: Modified Intent-to-treat Population with Eosinophils 300 cells/uL or More

Table 211.22

Analysis of Change from Baseline in St George's Respiratory Questionnaire-COPD (SGRQ-C) Domain Scores - Mixed Model Repeated Measures: Individual Studies and Meta-Analysis

Domain Score: Symptoms Domain
Visit: Week 36

	PBO (N=578)	100 SC (N=568)
208657		
n [1]	382	378
n [2]	352	356
LS Mean (SE)	59.0 (0.90)	57.2 (0.89)
LS Mean Change (SE)	-7.8 (0.90)	-9.6 (0.89)
Column vs Placebo [3]		
Difference		-1.8
95% CI		(-4.26, 0.72)
p-value		0.163
Corrected Hedges' g [6]		-0.10
95% CI		(-0.25, 0.04)

[1] Number of subjects with analysable data for one or more time points. [2] Number of subjects with analysable data at the given time point. [3] Analysis performed using mixed model repeated measures with covariates of baseline score, geographic region (as defined for the study/ISE), smoking status (current vs.never/ex-smoker), treatment and visit, plus interaction terms for visit by baseline and visit by treatment group. [4] Analysis model as in footnote [3] with an additional covariate of study.
[5] Analysis model as in footnote [4] with an additional covariate of study*treatment interaction.
[6] Based on covariate adjusted means. Note: Estimates are based on weighting applied to each level of class variable determined from observed proportions. Note: Includes visits up to Week 52 for study 208657.
Note: SGRQ scores calculated from conversions applied to SGRQ-C scores (SGRQ-C manual March 2016).
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Population: Modified Intent-to-treat Population with Eosinophils 300 cells/uL or More

Table 211.22

Analysis of Change from Baseline in St George's Respiratory Questionnaire-COPD (SGRQ-C) Domain Scores - Mixed Model Repeated Measures: Individual Studies and Meta-Analysis

Domain Score: Symptoms Domain
Visit: Week 36

	PBO (N=578)	100 SC (N=568)
MEA117113		
n [1]	84	82
n [2]	73	74
LS Mean (SE)	60.6 (1.92)	58.8 (1.91)
LS Mean Change (SE)	-7.0 (1.92)	-8.7 (1.91)
Column vs Placebo [3]		
Difference		-1.7
95% CI		(-7.07, 3.59)
p-value		0.521
Corrected Hedges' g [6]		-0.11
95% CI		(-0.43, 0.22)

[1] Number of subjects with analysable data for one or more time points. [2] Number of subjects with analysable data at the given time point. [3] Analysis performed using mixed model repeated measures with covariates of baseline score, geographic region (as defined for the study/ISE), smoking status (current vs.never/ex-smoker), treatment and visit, plus interaction terms for visit by baseline and visit by treatment group. [4] Analysis model as in footnote [3] with an additional covariate of study. [5] Analysis model as in footnote [4] with an additional covariate of study*treatment interaction. [6] Based on covariate adjusted means. Note: Estimates are based on weighting applied to each level of class variable determined from observed proportions. Note: Includes visits up to Week 52 for study 208657. Note: SGRQ scores calculated from conversions applied to SGRQ-C scores (SGRQ-C manual March 2016).
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Population: Modified Intent-to-treat Population with Eosinophils 300 cells/uL or More

Table 211.22

Analysis of Change from Baseline in St George's Respiratory Questionnaire-COPD (SGRQ-C) Domain Scores - Mixed Model Repeated Measures: Individual Studies and Meta-Analysis

Domain Score: Symptoms Domain
Visit: Week 36

	PBO (N=578)	100 SC (N=568)
MEA117106		
n [1]	85	79
n [2]	73	73
LS Mean (SE)	63.5 (1.83)	59.1 (1.86)
LS Mean Change (SE)	-5.5 (1.83)	-9.9 (1.86)
Column vs Placebo [3]		
Difference		-4.5
95% CI		(-9.60, 0.70)
p-value		0.090
Corrected Hedges' g [6]		-0.28
95% CI		(-0.61, 0.04)

[1] Number of subjects with analysable data for one or more time points. [2] Number of subjects with analysable data at the given time point. [3] Analysis performed using mixed model repeated measures with covariates of baseline score, geographic region (as defined for the study/ISE), smoking status (current vs.never/ex-smoker), treatment and visit, plus interaction terms for visit by baseline and visit by treatment group. [4] Analysis model as in footnote [3] with an additional covariate of study. [5] Analysis model as in footnote [4] with an additional covariate of study*treatment interaction. [6] Based on covariate adjusted means. Note: Estimates are based on weighting applied to each level of class variable determined from observed proportions. Note: Includes visits up to Week 52 for study 208657. Note: SGRQ scores calculated from conversions applied to SGRQ-C scores (SGRQ-C manual March 2016).
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Population: Modified Intent-to-treat Population with Eosinophils 300 cells/uL or More

Table 211.22

Analysis of Change from Baseline in St George's Respiratory Questionnaire-COPD (SGRQ-C) Domain Scores - Mixed Model Repeated Measures: Individual Studies and Meta-Analysis

Domain Score: Symptoms Domain
Visit: Week 36

	PBO (N=578)	100 SC (N=568)
208657 + MEA117113 + MEA117106		
n [1]	551	539
n [2]	498	503
LS Mean (SE)	60.0 (0.76)	57.9 (0.76)
LS Mean Change (SE)	-7.3 (0.76)	-9.4 (0.76)
Column vs Placebo [4]		
Difference		-2.1
95% CI		(-4.21, -0.03)
p-value		0.047
Corrected Hedges' g [6]		-0.13
95% CI		(-0.25, 0.00)

[1] Number of subjects with analysable data for one or more time points. [2] Number of subjects with analysable data at the given time point. [3] Analysis performed using mixed model repeated measures with covariates of baseline score, geographic region (as defined for the study/ISE), smoking status (current vs.never/ex-smoker), treatment and visit, plus interaction terms for visit by baseline and visit by treatment group. [4] Analysis model as in footnote [3] with an additional covariate of study.
[5] Analysis model as in footnote [4] with an additional covariate of study*treatment interaction.
[6] Based on covariate adjusted means. Note: Estimates are based on weighting applied to each level of class variable determined from observed proportions. Note: Includes visits up to Week 52 for study 208657.
Note: SGRQ scores calculated from conversions applied to SGRQ-C scores (SGRQ-C manual March 2016).
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Population: Modified Intent-to-treat Population with Eosinophils 300 cells/uL or More

Table 211.22

Analysis of Change from Baseline in St George's Respiratory Questionnaire-COPD (SGRQ-C) Domain Scores - Mixed Model Repeated Measures: Individual Studies and Meta-Analysis

Domain Score: Symptoms Domain
Visit: Week 52

	PBO (N=578)	100 SC (N=568)
208657		
n [1]	382	378
n [2]	335	333
LS Mean (SE)	57.7 (0.92)	57.1 (0.92)
LS Mean Change (SE)	-9.1 (0.92)	-9.7 (0.92)
Column vs Placebo [3]		
Difference		-0.6
95% CI		(-3.15, 1.94)
p-value		0.642
Corrected Hedges' g [6]		-0.04
95% CI		(-0.19, 0.12)

[1] Number of subjects with analysable data for one or more time points. [2] Number of subjects with analysable data at the given time point. [3] Analysis performed using mixed model repeated measures with covariates of baseline score, geographic region (as defined for the study/ISE), smoking status (current vs.never/ex-smoker), treatment and visit, plus interaction terms for visit by baseline and visit by treatment group. [4] Analysis model as in footnote [3] with an additional covariate of study. [5] Analysis model as in footnote [4] with an additional covariate of study*treatment interaction. [6] Based on covariate adjusted means. Note: Estimates are based on weighting applied to each level of class variable determined from observed proportions. Note: Includes visits up to Week 52 for study 208657. Note: SGRQ scores calculated from conversions applied to SGRQ-C scores (SGRQ-C manual March 2016).
/mnt/code/postcsr_01/prod/tfls/t_e_mmrm_sgrq_chg_dom.sas 30OCT2025 13:29

Population: Modified Intent-to-treat Population with Eosinophils 300 cells/uL or More

Table 211.22

Analysis of Change from Baseline in St George's Respiratory Questionnaire-COPD (SGRQ-C) Domain Scores - Mixed Model Repeated Measures: Individual Studies and Meta-Analysis

Domain Score: Symptoms Domain
Visit: Week 52

	PBO (N=578)	100 SC (N=568)
MEA117113		
n [1]	84	82
n [2]	70	74
LS Mean (SE)	62.1 (2.05)	56.6 (2.03)
LS Mean Change (SE)	-5.5 (2.05)	-11.0 (2.03)
Column vs Placebo [3]		
Difference		-5.5
95% CI		(-11.16, 0.20)
p-value		0.059
Corrected Hedges' g [6]		-0.32
95% CI		(-0.64, 0.01)

[1] Number of subjects with analysable data for one or more time points. [2] Number of subjects with analysable data at the given time point. [3] Analysis performed using mixed model repeated measures with covariates of baseline score, geographic region (as defined for the study/ISE), smoking status (current vs.never/ex-smoker), treatment and visit, plus interaction terms for visit by baseline and visit by treatment group. [4] Analysis model as in footnote [3] with an additional covariate of study. [5] Analysis model as in footnote [4] with an additional covariate of study*treatment interaction. [6] Based on covariate adjusted means. Note: Estimates are based on weighting applied to each level of class variable determined from observed proportions. Note: Includes visits up to Week 52 for study 208657. Note: SGRQ scores calculated from conversions applied to SGRQ-C scores (SGRQ-C manual March 2016).
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Population: Modified Intent-to-treat Population with Eosinophils 300 cells/uL or More

Table 211.22

Analysis of Change from Baseline in St George's Respiratory Questionnaire-COPD (SGRQ-C) Domain Scores - Mixed Model Repeated Measures: Individual Studies and Meta-Analysis

Domain Score: Symptoms Domain
Visit: Week 52

	PBO (N=578)	100 SC (N=568)
MEA117106		
n [1]	85	79
n [2]	73	75
LS Mean (SE)	62.0 (1.91)	58.1 (1.91)
LS Mean Change (SE)	-7.0 (1.91)	-10.9 (1.91)
Column vs Placebo [3]		
Difference		-3.9
95% CI		(-9.22, 1.47)
p-value		0.155
Corrected Hedges' g [6]		-0.23
95% CI		(-0.56, 0.09)

[1] Number of subjects with analysable data for one or more time points. [2] Number of subjects with analysable data at the given time point. [3] Analysis performed using mixed model repeated measures with covariates of baseline score, geographic region (as defined for the study/ISE), smoking status (current vs.never/ex-smoker), treatment and visit, plus interaction terms for visit by baseline and visit by treatment group. [4] Analysis model as in footnote [3] with an additional covariate of study.
[5] Analysis model as in footnote [4] with an additional covariate of study*treatment interaction.
[6] Based on covariate adjusted means. Note: Estimates are based on weighting applied to each level of class variable determined from observed proportions. Note: Includes visits up to Week 52 for study 208657.
Note: SGRQ scores calculated from conversions applied to SGRQ-C scores (SGRQ-C manual March 2016).
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Population: Modified Intent-to-treat Population with Eosinophils 300 cells/uL or More

Table 211.22

Analysis of Change from Baseline in St George's Respiratory Questionnaire-COPD (SGRQ-C) Domain Scores - Mixed Model Repeated Measures: Individual Studies and Meta-Analysis

Domain Score: Symptoms Domain
Visit: Week 52

	PBO (N=578)	100 SC (N=568)
208657 + MEA117113 + MEA117106		
n [1]	551	539
n [2]	478	482
LS Mean (SE)	59.1 (0.78)	57.3 (0.78)
LS Mean Change (SE)	-8.1 (0.78)	-9.9 (0.78)
Column vs Placebo [4]		
Difference		-1.8
95% CI		(-3.97, 0.36)
p-value		0.102
Corrected Hedges' g [6]		-0.11
95% CI		(-0.23, 0.02)
p-value for study*treatment interaction [5]		0.360

[1] Number of subjects with analysable data for one or more time points. [2] Number of subjects with analysable data at the given time point. [3] Analysis performed using mixed model repeated measures with covariates of baseline score, geographic region (as defined for the study/ISE), smoking status (current vs.never/ex-smoker), treatment and visit, plus interaction terms for visit by baseline and visit by treatment group. [4] Analysis model as in footnote [3] with an additional covariate of study.
[5] Analysis model as in footnote [4] with an additional covariate of study*treatment interaction.
[6] Based on covariate adjusted means. Note: Estimates are based on weighting applied to each level of class variable determined from observed proportions. Note: Includes visits up to Week 52 for study 208657.
Note: SGRQ scores calculated from conversions applied to SGRQ-C scores (SGRQ-C manual March 2016).
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Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Table 211.24
Summary of EQ-5D VAS Score:
Individual Studies and Meta-Analysis

	208657		MEA117113		MEA117106	
	PBO (N=401)	100 SC (N=403)	PBO (N=87)	100 SC (N=83)	PBO (N=90)	100 SC (N=82)
Baseline VAS Score						
n	368	366	86	80	85	78
Mean	60.9	60.1	60.1	65.1	60.9	61.3
SD	17.54	16.86	14.91	16.82	16.58	19.41
Median	61.0	61.0	60.0	65.0	57.0	61.0
Min.	4	9	22	25	28	18
Max.	100	100	100	100	100	100
Week 24 VAS Score						
n	374	367	80	77	81	78
Mean	63.5	63.6	63.5	68.5	64.1	68.9
SD	18.62	18.19	16.22	14.50	18.46	16.77
Median	66.5	65.0	64.5	70.0	66.0	70.0
Min.	0	0	10	33	24	23
Max.	100	100	97	94	100	100
Week 24 Change from Baseline						
n	343	334	79	74	76	74
Mean	2.2	3.0	1.9	3.6	4.0	7.8
SD	17.63	18.67	18.17	15.50	16.83	18.60
Median	2.0	2.0	1.0	0.0	3.0	8.0
Min.	-54	-79	-40	-30	-39	-50
Max.	55	78	57	57	50	60

Note: Includes visits up to Week 52 for study 208657.
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Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Table 211.24
Summary of EQ-5D VAS Score:
Individual Studies and Meta-Analysis

	208657 + MEA117113 + MEA117106		
	PBO (N=578)	100 SC (N=568)	Total (N=1146)
Baseline VAS Score			
n	539	524	1063
Mean	60.8	61.0	60.9
SD	16.97	17.32	17.14
Median	60.0	61.0	61.0
Min.	4	9	4
Max.	100	100	100
Week 24 VAS Score			
n	535	522	1057
Mean	63.6	65.1	64.3
SD	18.23	17.61	17.94
Median	66.0	68.0	67.0
Min.	0	0	0
Max.	100	100	100
Week 24 Change from Baseline			
n	498	482	980
Mean	2.4	3.8	3.1
SD	17.57	18.26	17.92
Median	2.0	3.0	2.0
Min.	-54	-79	-79
Max.	57	78	78

Note: Includes visits up to Week 52 for study 208657.
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Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Table 211.24
Summary of EQ-5D VAS Score:
Individual Studies and Meta-Analysis

	208657		MEA117113		MEA117106	
	PBO (N=401)	100 SC (N=403)	PBO (N=87)	100 SC (N=83)	PBO (N=90)	100 SC (N=82)
Week 52 VAS Score						
n	344	347	70	75	75	74
Mean	63.6	65.4	66.4	68.8	68.8	69.4
SD	19.05	18.30	15.33	16.11	17.62	15.43
Median	68.0	70.0	66.5	70.0	70.0	70.0
Min.	0	15	34	30	30	41
Max.	100	100	100	94	100	100
Week 52 Change from Baseline						
n	316	316	69	72	71	70
Mean	2.1	4.8	5.5	3.5	7.5	8.5
SD	19.35	18.99	16.03	17.17	18.23	16.51
Median	1.0	4.0	5.0	1.0	8.0	8.0
Min.	-100	-59	-43	-37	-50	-27
Max.	60	82	55	37	51	60

Note: Includes visits up to Week 52 for study 208657.
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Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Table 211.24
Summary of EQ-5D VAS Score:
Individual Studies and Meta-Analysis

	208657 + MEA117113 + MEA117106		
	PBO (N=578)	100 SC (N=568)	Total (N=1146)
Week 52 VAS Score			
n	489	496	985
Mean	64.8	66.5	65.6
SD	18.42	17.63	18.04
Median	68.0	70.0	69.0
Min.	0	15	0
Max.	100	100	100
Week 52 Change from Baseline			
n	456	458	914
Mean	3.5	5.2	4.3
SD	18.79	18.38	18.60
Median	3.0	4.5	4.0
Min.	-100	-59	-100
Max.	60	82	82

Note: Includes visits up to Week 52 for study 208657.
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Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Table 211.25

Summary and Analysis of EQ-5D VAS Responders at Week 52:
Subjects With At Least 15-point Improvement in Total Score From Baseline:
Individual Studies and Meta-Analysis

	PBO (N=578)		100 SC (N=568)	
208657				
n	368		367	
Responder [1]	74	(20%)	88	(24%)
Non-responder	294	(80%)	279	(76%)
No change/worsening	242	(66%)	228	(62%)
Withdrawal from study prior to visit	33	(9%)	31	(8%)
Missing visit [2]	19	(5%)	20	(5%)
Inverse Odds Ratio to Placebo [3]			0.80	
95% CI			(0.55, 1.16)	
Inverse Relative Risk [4]			0.85	
95% CI			(0.63, 1.16)	
p-value			0.316	
Absolute Risk Reduction [4]			-0.03	
95% CI			(-0.23, 0.16)	

[1] Defined as a participant with a >=15-point improvement (decrease) from baseline in EQ-5D VAS score.
[2] Participants with an intercurrent event of either treatment interruption or treatment discontinuation related to the COVID-19 pandemic have data set to missing following the event. Missing data was not imputed.
[3] Analysis performed using a logistic regression model with covariates of baseline score, geographic region (as defined for the study/ISE), smoking status (current vs. never/ex-smoker) and treatment group.
[4] Analysis used poisson regression model with covariates as in [3] (risk difference uses identity link).
[5] Analysis model as in footnote [3] and [4] with an additional covariate of study. [6] Analysis model as in footnote [4] with an additional covariate of study*treatment interaction. Note: Inverse Odds Ratio <1, Inverse Relative Risk < 1, risk difference < 0 correspond to a benefit of Mepolizumab over Placebo.
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Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Table 211.25

Summary and Analysis of EQ-5D VAS Responders at Week 52:
Subjects With At Least 15-point Improvement in Total Score From Baseline:
Individual Studies and Meta-Analysis

	PBO (N=578)		100 SC (N=568)	
MEA117113				
n	86		80	
Responder [1]	15	(17%)	18	(23%)
Non-responder	71	(83%)	62	(78%)
No change/worsening	54	(63%)	54	(68%)
Withdrawal from study prior to visit	15	(17%)	4	(5%)
Missing visit [2]	2	(2%)	4	(5%)
Inverse Odds Ratio to Placebo [3]			0.55	
95% CI			(0.24, 1.26)	
Inverse Relative Risk [4]			0.65	
95% CI			(0.33, 1.31)	
p-value			0.234	
Absolute Risk Reduction [4]			-0.10	
95% CI			(-0.52, 0.31)	

[1] Defined as a participant with a >=15-point improvement (decrease) from baseline in EQ-5D VAS score.
[2] Participants with an intercurrent event of either treatment interruption or treatment discontinuation related to the COVID-19 pandemic have data set to missing following the event. Missing data was not imputed.
[3] Analysis performed using a logistic regression model with covariates of baseline score, geographic region (as defined for the study/ISE), smoking status (current vs. never/ex-smoker) and treatment group.
[4] Analysis used poisson regression model with covariates as in [3] (risk difference uses identity link).
[5] Analysis model as in footnote [3] and [4] with an additional covariate of study. [6] Analysis model as in footnote [4] with an additional covariate of study*treatment interaction. Note: Inverse Odds Ratio <1, Inverse Relative Risk < 1, risk difference < 0 correspond to a benefit of Mepolizumab over Placebo.
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Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Table 211.25

Summary and Analysis of EQ-5D VAS Responders at Week 52:
Subjects With At Least 15-point Improvement in Total Score From Baseline:
Individual Studies and Meta-Analysis

	PBO (N=578)	100 SC (N=568)
MEA117106		
n	85	78
Responder [1]	22 (26%)	19 (24%)
Non-responder	63 (74%)	59 (76%)
No change/worsening	49 (58%)	51 (65%)
Withdrawal from study prior to visit	8 (9%)	3 (4%)
Missing visit [2]	6 (7%)	5 (6%)
Inverse Odds Ratio to Placebo [3]		1.22
95% CI		(0.54, 2.77)
Inverse Relative Risk [4]		1.20
95% CI		(0.64, 2.25)
p-value		0.567
Absolute Risk Reduction [4]		0.01
95% CI		(-0.40, 0.41)

[1] Defined as a participant with a >=15-point improvement (decrease) from baseline in EQ-5D VAS score.
[2] Participants with an intercurrent event of either treatment interruption or treatment discontinuation related to the COVID-19 pandemic have data set to missing following the event. Missing data was not imputed.
[3] Analysis performed using a logistic regression model with covariates of baseline score, geographic region (as defined for the study/ISE), smoking status (current vs. never/ex-smoker) and treatment group.
[4] Analysis used poisson regression model with covariates as in [3] (risk difference uses identity link).
[5] Analysis model as in footnote [3] and [4] with an additional covariate of study. [6] Analysis model as in footnote [4] with an additional covariate of study*treatment interaction. Note: Inverse Odds Ratio <1, Inverse Relative Risk < 1, risk difference < 0 correspond to a benefit of Mepolizumab over Placebo.
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Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Table 211.25

Summary and Analysis of EQ-5D VAS Responders at Week 52:
Subjects With At Least 15-point Improvement in Total Score From Baseline:
Individual Studies and Meta-Analysis

	PBO (N=578)	100 SC (N=568)
208657 + MEA117113 + MEA117106		
n	539	525
Responder [1]	111 (21%)	125 (24%)
Non-responder	428 (79%)	400 (76%)
No change/worsening	345 (64%)	333 (63%)
Withdrawal from study prior to visit	56 (10%)	38 (7%)
Missing visit [2]	27 (5%)	29 (6%)
Inverse Odds Ratio to Placebo [3,5]		0.81
95% CI		(0.59, 1.10)
Inverse Relative Risk [4,5]		0.87
95% CI		(0.68, 1.13)
p-value		0.296
Absolute Risk Reduction [4,5]		-0.04
95% CI		(-0.20, 0.12)
p-value for study*treatment interaction [6]		0.535

[1] Defined as a participant with a >=15-point improvement (decrease) from baseline in EQ-5D VAS score.
[2] Participants with an intercurrent event of either treatment interruption or treatment discontinuation related to the COVID-19 pandemic have data set to missing following the event. Missing data was not imputed.
[3] Analysis performed using a logistic regression model with covariates of baseline score, geographic region (as defined for the study/ISE), smoking status (current vs. never/ex-smoker) and treatment group.
[4] Analysis used poisson regression model with covariates as in [3] (risk difference uses identity link).
[5] Analysis model as in footnote [3] and [4] with an additional covariate of study. [6] Analysis model as in footnote [4] with an additional covariate of study*treatment interaction. Note: Inverse Odds Ratio <1, Inverse Relative Risk < 1, risk difference < 0 correspond to a benefit of Mepolizumab over Placebo.
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Population: Modified Intent-to-treat Population with Eosinophils 300 cells/uL or More

Table 211.26

Analysis of Change From Baseline in EQ-5D VAS Score - Mixed Model Repeated Measures: Individual Studies and Meta-Analysis

Visit: Week 24

	PBO (N=578)	100 SC (N=568)
208657		
n [1]	352	348
n [2]	343	334
LS Mean (SE)	63.3 (0.87)	63.7 (0.88)
LS Mean Change (SE)	2.5 (0.87)	2.8 (0.88)
Column vs Placebo [3]		
Difference		0.3
95% CI		(-2.10, 2.74)
p-value		0.795
Corrected Hedges' g [6]		0.02
95% CI		(-0.13, 0.17)

[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the given time point.
[3] Analysis performed using mixed model repeated measures with covariates of baseline score, geographic region (as defined for the study/ISE), smoking status (current vs. never/ex-smoker), treatment and visit, plus interaction terms for visit by baseline and visit by treatment group.
[4] Analysis model as in footnote [3] with an additional covariate of study.
[5] Analysis model as in footnote [4] with an additional covariate of study*treatment interaction.
[6] Based on covariate adjusted means. Note: Estimates are based on weighting applied to each level of class variable determined from observed proportions. Note: Includes visits up to Week 52 for study 208657.
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Population: Modified Intent-to-treat Population with Eosinophils 300 cells/uL or More

Table 211.26

Analysis of Change From Baseline in EQ-5D VAS Score - Mixed Model Repeated Measures: Individual Studies and Meta-Analysis

Visit: Week 24

	PBO (N=578)	100 SC (N=568)
MEA117113		
n [1]	82	78
n [2]	79	74
LS Mean (SE)	63.6 (1.69)	68.5 (1.74)
LS Mean Change (SE)	0.7 (1.69)	5.6 (1.74)
Column vs Placebo [3]		
Difference		4.9
95% CI		(0.14, 9.70)
p-value		0.044
Corrected Hedges' g [6]		0.33
95% CI		(0.01, 0.65)

[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the given time point.
[3] Analysis performed using mixed model repeated measures with covariates of baseline score, geographic region (as defined for the study/ISE), smoking status (current vs. never/ex-smoker), treatment and visit, plus interaction terms for visit by baseline and visit by treatment group.
[4] Analysis model as in footnote [3] with an additional covariate of study.
[5] Analysis model as in footnote [4] with an additional covariate of study*treatment interaction.
[6] Based on covariate adjusted means. Note: Estimates are based on weighting applied to each level of class variable determined from observed proportions. Note: Includes visits up to Week 52 for study 208657.
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Population: Modified Intent-to-treat Population with Eosinophils 300 cells/uL or More

Table 211.26

Analysis of Change From Baseline in EQ-5D VAS Score - Mixed Model Repeated Measures: Individual Studies and Meta-Analysis

Visit: Week 24

	PBO (N=578)	100 SC (N=568)
MEA117106		
n [1]	79	77
n [2]	76	74
LS Mean (SE)	64.0 (1.77)	68.9 (1.79)
LS Mean Change (SE)	3.5 (1.77)	8.3 (1.79)
Column vs Placebo [3]		
Difference		4.8
95% CI		(-0.13, 9.81)
p-value		0.057
Corrected Hedges' g [6]		0.31
95% CI		(-0.01, 0.63)

[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the given time point.
[3] Analysis performed using mixed model repeated measures with covariates of baseline score, geographic region (as defined for the study/ISE), smoking status (current vs. never/ex-smoker), treatment and visit, plus interaction terms for visit by baseline and visit by treatment group.
[4] Analysis model as in footnote [3] with an additional covariate of study.
[5] Analysis model as in footnote [4] with an additional covariate of study*treatment interaction.
[6] Based on covariate adjusted means. Note: Estimates are based on weighting applied to each level of class variable determined from observed proportions. Note: Includes visits up to Week 52 for study 208657.
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Population: Modified Intent-to-treat Population with Eosinophils 300 cells/uL or More

Table 211.26

Analysis of Change From Baseline in EQ-5D VAS Score - Mixed Model Repeated Measures: Individual Studies and Meta-Analysis

Visit: Week 24

	PBO (N=578)	100 SC (N=568)
208657 + MEA117113 + MEA117106		
n [1]	513	503
n [2]	498	482
LS Mean (SE)	63.6 (0.71)	65.2 (0.72)
LS Mean Change (SE)	2.4 (0.71)	3.9 (0.72)
Column vs Placebo [4]		
Difference		1.6
95% CI		(-0.39, 3.55)
p-value		0.116
Corrected Hedges' g [6]		0.10
95% CI		(-0.03, 0.23)

[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the given time point.
[3] Analysis performed using mixed model repeated measures with covariates of baseline score, geographic region (as defined for the study/ISE), smoking status (current vs. never/ex-smoker), treatment and visit, plus interaction terms for visit by baseline and visit by treatment group.
[4] Analysis model as in footnote [3] with an additional covariate of study.
[5] Analysis model as in footnote [4] with an additional covariate of study*treatment interaction.
[6] Based on covariate adjusted means. Note: Estimates are based on weighting applied to each level of class variable determined from observed proportions. Note: Includes visits up to Week 52 for study 208657.
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Population: Modified Intent-to-treat Population with Eosinophils 300 cells/uL or More

Table 211.26

Analysis of Change From Baseline in EQ-5D VAS Score - Mixed Model Repeated Measures: Individual Studies and Meta-Analysis

Visit: Week 52

	PBO (N=578)	100 SC (N=568)
208657		
n [1]	352	348
n [2]	316	316
LS Mean (SE)	63.1 (0.94)	65.3 (0.94)
LS Mean Change (SE)	2.2 (0.94)	4.4 (0.94)
Column vs Placebo [3]		
Difference		2.2
95% CI		(-0.40, 4.83)
p-value		0.097
Corrected Hedges' g [6]		0.13
95% CI		(-0.02, 0.29)

[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the given time point.
[3] Analysis performed using mixed model repeated measures with covariates of baseline score, geographic region (as defined for the study/ISE), smoking status (current vs. never/ex-smoker), treatment and visit, plus interaction terms for visit by baseline and visit by treatment group.
[4] Analysis model as in footnote [3] with an additional covariate of study.
[5] Analysis model as in footnote [4] with an additional covariate of study*treatment interaction.
[6] Based on covariate adjusted means. Note: Estimates are based on weighting applied to each level of class variable determined from observed proportions. Note: Includes visits up to Week 52 for study 208657.
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Population: Modified Intent-to-treat Population with Eosinophils 300 cells/uL or More

Table 211.26

Analysis of Change From Baseline in EQ-5D VAS Score - Mixed Model Repeated Measures: Individual Studies and Meta-Analysis

Visit: Week 52

	PBO (N=578)	100 SC (N=568)
MEA117113		
n [1]	82	78
n [2]	69	72
LS Mean (SE)	66.6 (1.76)	67.4 (1.73)
LS Mean Change (SE)	3.8 (1.76)	4.6 (1.73)
Column vs Placebo [3]		
Difference		0.8
95% CI		(-4.06, 5.72)
p-value		0.738
Corrected Hedges' g [6]		0.06
95% CI		(-0.27, 0.39)

[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the given time point.
[3] Analysis performed using mixed model repeated measures with covariates of baseline score, geographic region (as defined for the study/ISE), smoking status (current vs. never/ex-smoker), treatment and visit, plus interaction terms for visit by baseline and visit by treatment group.
[4] Analysis model as in footnote [3] with an additional covariate of study.
[5] Analysis model as in footnote [4] with an additional covariate of study*treatment interaction.
[6] Based on covariate adjusted means. Note: Estimates are based on weighting applied to each level of class variable determined from observed proportions. Note: Includes visits up to Week 52 for study 208657.
/mnt/code/postcsr_01/prod/tfls/t_e_mmrm_eq5d_chg.sas 30OCT2025 13:29

Population: Modified Intent-to-treat Population with Eosinophils 300 cells/uL or More

Table 211.26

Analysis of Change From Baseline in EQ-5D VAS Score - Mixed Model Repeated Measures: Individual Studies and Meta-Analysis

Visit: Week 52

	PBO (N=578)	100 SC (N=568)
MEA117106		
n [1]	79	77
n [2]	71	70
LS Mean (SE)	67.6 (1.68)	69.3 (1.69)
LS Mean Change (SE)	7.1 (1.68)	8.8 (1.69)
Column vs Placebo [3]		
Difference		1.7
95% CI		(-2.98, 6.43)
p-value		0.470
Corrected Hedges' g [6]		0.12
95% CI		(-0.21, 0.45)

[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the given time point.
[3] Analysis performed using mixed model repeated measures with covariates of baseline score, geographic region (as defined for the study/ISE), smoking status (current vs. never/ex-smoker), treatment and visit, plus interaction terms for visit by baseline and visit by treatment group.
[4] Analysis model as in footnote [3] with an additional covariate of study.
[5] Analysis model as in footnote [4] with an additional covariate of study*treatment interaction.
[6] Based on covariate adjusted means. Note: Estimates are based on weighting applied to each level of class variable determined from observed proportions. Note: Includes visits up to Week 52 for study 208657.
/mnt/code/postcsr_01/prod/tfls/t_e_mmrm_eq5d_chg.sas 30OCT2025 13:29

Population: Modified Intent-to-treat Population with Eosinophils 300 cells/uL or More

Table 211.26

Analysis of Change From Baseline in EQ-5D VAS Score - Mixed Model Repeated Measures: Individual Studies and Meta-Analysis

Visit: Week 52

	PBO (N=578)	100 SC (N=568)
208657 + MEA117113 + MEA117106		
n [1]	513	503
n [2]	456	458
LS Mean (SE)	64.4 (0.75)	66.3 (0.75)
LS Mean Change (SE)	3.2 (0.75)	5.1 (0.75)
Column vs Placebo [4]		
Difference		1.9
95% CI		(-0.17, 3.97)
p-value		0.073
Corrected Hedges' g [6]		0.12
95% CI		(-0.01, 0.25)
p-value for study*treatment interaction [5]		0.587

[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the given time point.
[3] Analysis performed using mixed model repeated measures with covariates of baseline score, geographic region (as defined for the study/ISE), smoking status (current vs. never/ex-smoker), treatment and visit, plus interaction terms for visit by baseline and visit by treatment group.
[4] Analysis model as in footnote [3] with an additional covariate of study.
[5] Analysis model as in footnote [4] with an additional covariate of study*treatment interaction.
[6] Based on covariate adjusted means. Note: Estimates are based on weighting applied to each level of class variable determined from observed proportions. Note: Includes visits up to Week 52 for study 208657.
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Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Table 211.27
Summary of Evaluating Respiratory Symptoms in COPD
(E-RS: COPD) Score (Study 208657)

Parameter: E-RS Total Score

	PBO (N=401)	100 SC (N=403)
Baseline Total Score		
n	399	403
Mean	12.94	13.16
SD	6.790	6.796
Median	13.00	13.14
Min.	0.0	0.0
Max.	32.0	34.0
Weeks 1-4 Total Score		
n	390	400
Mean	12.46	12.41
SD	6.446	6.660
Median	12.34	12.09
Min.	0.0	0.0
Max.	32.5	31.5
Weeks 1-4 Change from Baseline		
n	389	400
Mean	-0.44	-0.69
SD	3.206	3.433
Median	-0.07	-0.16
Min.	-14.0	-15.3
Max.	12.1	15.6

Note: Includes data reported up to Week 52.
Note: Higher scores indicate more severe symptoms.
/mnt/code/postcsr_01/prod/tfls/t_e_evrespsym.sas 25JUL2025 11:07

Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Table 211.27
Summary of Evaluating Respiratory Symptoms in COPD
(E-RS: COPD) Score (Study 208657)

Parameter: E-RS Total Score

	PBO (N=401)	100 SC (N=403)
Weeks 5-8 Total Score		
n	386	392
Mean	12.21	11.88
SD	6.607	6.859
Median	12.31	11.56
Min.	0.0	0.0
Max.	32.9	30.9
Weeks 5-8 Change from Baseline		
n	384	392
Mean	-0.74	-1.20
SD	4.480	4.449
Median	-0.32	-0.57
Min.	-17.8	-23.1
Max.	20.1	15.6

Note: Includes data reported up to Week 52.
Note: Higher scores indicate more severe symptoms.
/mnt/code/postcsr_01/prod/tfls/t_e_evrespsym.sas 25JUL2025 11:07

Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Table 211.27
Summary of Evaluating Respiratory Symptoms in COPD
(E-RS: COPD) Score (Study 208657)

Parameter: E-RS Total Score

	PBO (N=401)	100 SC (N=403)
Weeks 9-12 Total Score		
n	386	390
Mean	11.96	11.77
SD	6.563	7.213
Median	12.16	11.77
Min.	0.0	0.0
Max.	33.5	29.3
Weeks 9-12 Change from Baseline		
n	384	390
Mean	-0.94	-1.40
SD	4.810	4.990
Median	-0.42	-0.66
Min.	-17.7	-23.1
Max.	18.4	12.6

Note: Includes data reported up to Week 52.
Note: Higher scores indicate more severe symptoms.

Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Table 211.27
Summary of Evaluating Respiratory Symptoms in COPD
(E-RS: COPD) Score (Study 208657)

Parameter: E-RS Total Score

	PBO (N=401)	100 SC (N=403)
Weeks 13-16 Total Score		
n	372	381
Mean	11.83	11.76
SD	6.676	7.041
Median	11.54	11.64
Min.	0.0	0.0
Max.	32.5	30.1
Weeks 13-16 Change from Baseline		
n	370	381
Mean	-1.02	-1.27
SD	5.091	5.065
Median	-0.74	-0.61
Min.	-17.4	-23.1
Max.	17.7	13.2

Note: Includes data reported up to Week 52.
Note: Higher scores indicate more severe symptoms.
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Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Table 211.27
Summary of Evaluating Respiratory Symptoms in COPD
(E-RS: COPD) Score (Study 208657)

Parameter: E-RS Total Score

	PBO (N=401)	100 SC (N=403)
Weeks 17-20 Total Score		
n	369	374
Mean	11.87	11.64
SD	6.792	7.304
Median	11.43	11.24
Min.	0.0	0.0
Max.	31.6	34.6
Weeks 17-20 Change from Baseline		
n	367	374
Mean	-0.91	-1.47
SD	4.783	5.289
Median	-0.55	-0.62
Min.	-16.9	-23.0
Max.	14.7	14.2

Note: Includes data reported up to Week 52.
Note: Higher scores indicate more severe symptoms.

Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Table 211.27
Summary of Evaluating Respiratory Symptoms in COPD
(E-RS: COPD) Score (Study 208657)

Parameter: E-RS Total Score

	PBO (N=401)	100 SC (N=403)
Weeks 21-24 Total Score		
n	361	367
Mean	11.54	11.57
SD	6.668	7.367
Median	11.20	11.00
Min.	0.0	0.0
Max.	31.3	34.0
Weeks 21-24 Change from Baseline		
n	359	367
Mean	-1.37	-1.47
SD	4.894	5.488
Median	-0.98	-0.64
Min.	-17.4	-26.0
Max.	12.9	15.0

Note: Includes data reported up to Week 52.
Note: Higher scores indicate more severe symptoms.
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Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Table 211.27
Summary of Evaluating Respiratory Symptoms in COPD
(E-RS: COPD) Score (Study 208657)

Parameter: E-RS Total Score

	PBO (N=401)	100 SC (N=403)
Weeks 25-28 Total Score		
n	358	363
Mean	11.56	11.40
SD	6.712	7.401
Median	11.45	11.00
Min.	0.0	0.0
Max.	35.0	34.3
Weeks 25-28 Change from Baseline		
n	356	363
Mean	-1.12	-1.66
SD	5.158	5.567
Median	-0.74	-0.76
Min.	-16.1	-27.0
Max.	18.2	15.0

Note: Includes data reported up to Week 52.
Note: Higher scores indicate more severe symptoms.

Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Table 211.27
Summary of Evaluating Respiratory Symptoms in COPD
(E-RS: COPD) Score (Study 208657)

Parameter: E-RS Total Score

	PBO (N=401)	100 SC (N=403)
Weeks 29-32 Total Score		
n	361	366
Mean	11.32	11.47
SD	6.600	7.553
Median	11.00	11.00
Min.	0.0	0.0
Max.	33.0	34.6
Weeks 29-32 Change from Baseline		
n	359	366
Mean	-1.45	-1.69
SD	5.093	5.724
Median	-0.93	-0.86
Min.	-15.3	-25.5
Max.	16.3	17.6

Note: Includes data reported up to Week 52.
Note: Higher scores indicate more severe symptoms.
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Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Table 211.27
Summary of Evaluating Respiratory Symptoms in COPD
(E-RS: COPD) Score (Study 208657)

Parameter: E-RS Total Score

	PBO (N=401)	100 SC (N=403)
Weeks 33-36 Total Score		
n	356	360
Mean	11.26	11.41
SD	6.896	7.437
Median	10.92	11.02
Min.	0.0	0.0
Max.	33.0	34.4
Weeks 33-36 Change from Baseline		
n	354	360
Mean	-1.46	-1.72
SD	5.394	5.601
Median	-1.11	-0.70
Min.	-17.7	-24.4
Max.	16.9	11.3

Note: Includes data reported up to Week 52.
Note: Higher scores indicate more severe symptoms.
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Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Table 211.27
Summary of Evaluating Respiratory Symptoms in COPD
(E-RS: COPD) Score (Study 208657)

Parameter: E-RS Total Score

	PBO (N=401)	100 SC (N=403)
Weeks 37-40 Total Score		
n	361	353
Mean	11.43	11.50
SD	6.921	7.317
Median	11.30	11.00
Min.	0.0	0.0
Max.	31.8	34.5
Weeks 37-40 Change from Baseline		
n	359	353
Mean	-1.29	-1.57
SD	5.668	5.629
Median	-1.18	-0.71
Min.	-16.3	-23.0
Max.	16.4	13.3

Note: Includes data reported up to Week 52.
Note: Higher scores indicate more severe symptoms.
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Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Table 211.27
Summary of Evaluating Respiratory Symptoms in COPD
(E-RS: COPD) Score (Study 208657)

Parameter: E-RS Total Score

	PBO (N=401)	100 SC (N=403)
Weeks 41-44 Total Score		
n	354	347
Mean	11.43	11.25
SD	6.661	7.439
Median	11.62	11.04
Min.	0.0	0.0
Max.	31.4	36.1
Weeks 41-44 Change from Baseline		
n	352	347
Mean	-1.38	-1.77
SD	5.570	5.800
Median	-0.86	-0.80
Min.	-16.8	-24.6
Max.	18.4	14.9

Note: Includes data reported up to Week 52.
Note: Higher scores indicate more severe symptoms.

Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Table 211.27
Summary of Evaluating Respiratory Symptoms in COPD
(E-RS: COPD) Score (Study 208657)

Parameter: E-RS Total Score

	PBO (N=401)	100 SC (N=403)
Weeks 45-48 Total Score		
n	347	348
Mean	11.47	11.26
SD	6.667	7.405
Median	11.43	11.00
Min.	0.0	0.0
Max.	30.9	36.0
Weeks 45-48 Change from Baseline		
n	345	348
Mean	-1.26	-1.82
SD	5.594	5.736
Median	-0.82	-0.73
Min.	-15.9	-23.6
Max.	17.1	10.8

Note: Includes data reported up to Week 52.
Note: Higher scores indicate more severe symptoms.
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Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Table 211.27
Summary of Evaluating Respiratory Symptoms in COPD
(E-RS: COPD) Score (Study 208657)

Parameter: E-RS Total Score

	PBO (N=401)	100 SC (N=403)
Weeks 49-52 Total Score		
n	326	331
Mean	11.27	11.28
SD	6.657	7.387
Median	11.12	11.00
Min.	0.0	0.0
Max.	31.1	35.9
Weeks 49-52 Change from Baseline		
n	324	331
Mean	-1.22	-1.77
SD	5.480	5.819
Median	-0.57	-0.71
Min.	-15.9	-25.5
Max.	16.9	12.2

Note: Includes data reported up to Week 52.
Note: Higher scores indicate more severe symptoms.
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Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Table 211.27
Summary of Evaluating Respiratory Symptoms in COPD
(E-RS: COPD) Score (Study 208657)

Parameter: E-RS Breathlessness Score

	PBO (N=401)	100 SC (N=403)
Baseline Total Score		
n	399	403
Mean	6.86	6.96
SD	3.879	3.839
Median	6.71	7.00
Min.	0.0	0.0
Max.	16.0	17.0
Weeks 1-4 Total Score		
n	390	400
Mean	6.64	6.69
SD	3.797	3.835
Median	6.58	6.57
Min.	0.0	0.0
Max.	15.9	16.7
Weeks 1-4 Change from Baseline		
n	389	400
Mean	-0.19	-0.24
SD	1.698	1.864
Median	-0.01	0.00
Min.	-8.9	-8.0
Max.	7.0	7.5

Note: Includes data reported up to Week 52.
Note: Higher scores indicate more severe symptoms.
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Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Table 211.27
Summary of Evaluating Respiratory Symptoms in COPD
(E-RS: COPD) Score (Study 208657)

Parameter: E-RS Breathlessness Score

	PBO (N=401)	100 SC (N=403)
Weeks 5-8 Total Score		
n	386	392
Mean	6.54	6.43
SD	3.794	3.963
Median	6.45	6.29
Min.	0.0	0.0
Max.	15.9	16.0
Weeks 5-8 Change from Baseline		
n	384	392
Mean	-0.30	-0.48
SD	2.363	2.415
Median	-0.08	-0.03
Min.	-11.8	-12.7
Max.	8.5	7.9

Note: Includes data reported up to Week 52.
Note: Higher scores indicate more severe symptoms.
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Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Table 211.27
Summary of Evaluating Respiratory Symptoms in COPD
(E-RS: COPD) Score (Study 208657)

Parameter: E-RS Breathlessness Score

	PBO (N=401)	100 SC (N=403)
Weeks 9-12 Total Score		
n	386	390
Mean	6.41	6.36
SD	3.820	4.140
Median	6.30	6.11
Min.	0.0	0.0
Max.	16.2	16.0
Weeks 9-12 Change from Baseline		
n	384	390
Mean	-0.40	-0.58
SD	2.587	2.691
Median	-0.13	-0.05
Min.	-11.5	-12.7
Max.	8.5	8.3

Note: Includes data reported up to Week 52.
Note: Higher scores indicate more severe symptoms.
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Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Table 211.27
Summary of Evaluating Respiratory Symptoms in COPD
(E-RS: COPD) Score (Study 208657)

Parameter: E-RS Breathlessness Score

	PBO (N=401)	100 SC (N=403)
Weeks 13-16 Total Score		
n	372	381
Mean	6.31	6.42
SD	3.873	4.060
Median	5.98	6.07
Min.	0.0	0.0
Max.	15.0	16.0
Weeks 13-16 Change from Baseline		
n	370	381
Mean	-0.45	-0.46
SD	2.771	2.736
Median	-0.29	-0.07
Min.	-11.1	-12.7
Max.	10.4	7.4

Note: Includes data reported up to Week 52.
Note: Higher scores indicate more severe symptoms.
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Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Table 211.27
Summary of Evaluating Respiratory Symptoms in COPD
(E-RS: COPD) Score (Study 208657)

Parameter: E-RS Breathlessness Score

	PBO (N=401)	100 SC (N=403)
Weeks 17-20 Total Score		
n	369	374
Mean	6.33	6.33
SD	3.894	4.155
Median	6.11	5.98
Min.	0.0	0.0
Max.	15.4	16.5
Weeks 17-20 Change from Baseline		
n	367	374
Mean	-0.41	-0.59
SD	2.617	2.843
Median	-0.13	-0.07
Min.	-10.9	-12.6
Max.	8.1	6.2

Note: Includes data reported up to Week 52.
Note: Higher scores indicate more severe symptoms.
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Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Table 211.27
Summary of Evaluating Respiratory Symptoms in COPD
(E-RS: COPD) Score (Study 208657)

Parameter: E-RS Breathlessness Score

	PBO (N=401)	100 SC (N=403)
Weeks 21-24 Total Score		
n	361	367
Mean	6.22	6.29
SD	3.818	4.190
Median	6.00	5.84
Min.	0.0	0.0
Max.	15.3	16.8
Weeks 21-24 Change from Baseline		
n	359	367
Mean	-0.61	-0.58
SD	2.600	2.947
Median	-0.29	-0.10
Min.	-11.2	-12.7
Max.	7.2	7.5

Note: Includes data reported up to Week 52.
Note: Higher scores indicate more severe symptoms.
/mnt/code/postcsr_01/prod/tfls/t_e_evrespsym.sas 25JUL2025 11:07

Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Table 211.27
Summary of Evaluating Respiratory Symptoms in COPD
(E-RS: COPD) Score (Study 208657)

Parameter: E-RS Breathlessness Score

	PBO (N=401)	100 SC (N=403)
Weeks 25-28 Total Score		
n	358	363
Mean	6.25	6.19
SD	3.826	4.196
Median	6.11	5.92
Min.	0.0	0.0
Max.	16.0	17.0
Weeks 25-28 Change from Baseline		
n	356	363
Mean	-0.43	-0.71
SD	2.670	3.001
Median	-0.20	-0.14
Min.	-9.0	-12.8
Max.	8.8	7.6

Note: Includes data reported up to Week 52.
Note: Higher scores indicate more severe symptoms.
/mnt/code/postcsr_01/prod/tfls/t_e_evrespsym.sas 25JUL2025 11:07

Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Table 211.27
Summary of Evaluating Respiratory Symptoms in COPD
(E-RS: COPD) Score (Study 208657)

Parameter: E-RS Breathlessness Score

	PBO (N=401)	100 SC (N=403)
Weeks 29-32 Total Score		
n	361	366
Mean	6.12	6.21
SD	3.851	4.215
Median	6.00	5.73
Min.	0.0	0.0
Max.	15.9	17.0
Weeks 29-32 Change from Baseline		
n	359	366
Mean	-0.58	-0.74
SD	2.719	3.046
Median	-0.39	-0.20
Min.	-8.1	-12.7
Max.	9.3	9.2

Note: Includes data reported up to Week 52.
Note: Higher scores indicate more severe symptoms.
/mnt/code/postcsr_01/prod/tfls/t_e_evrespsym.sas 25JUL2025 11:07

Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Table 211.27
Summary of Evaluating Respiratory Symptoms in COPD
(E-RS: COPD) Score (Study 208657)

Parameter: E-RS Breathlessness Score

	PBO (N=401)	100 SC (N=403)
Weeks 33-36 Total Score		
n	356	360
Mean	6.09	6.18
SD	3.980	4.199
Median	5.81	5.75
Min.	0.0	0.0
Max.	15.9	17.0
Weeks 33-36 Change from Baseline		
n	354	360
Mean	-0.61	-0.77
SD	2.940	3.041
Median	-0.48	-0.14
Min.	-11.5	-12.7
Max.	11.5	6.4

Note: Includes data reported up to Week 52.
Note: Higher scores indicate more severe symptoms.

Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Table 211.27
Summary of Evaluating Respiratory Symptoms in COPD
(E-RS: COPD) Score (Study 208657)

Parameter: E-RS Breathlessness Score

	PBO (N=401)	100 SC (N=403)
Weeks 37-40 Total Score		
n	361	353
Mean	6.16	6.24
SD	3.944	4.197
Median	6.00	5.96
Min.	0.0	0.0
Max.	15.3	17.0
Weeks 37-40 Change from Baseline		
n	359	353
Mean	-0.53	-0.68
SD	3.018	3.065
Median	-0.29	-0.07
Min.	-11.9	-12.6
Max.	12.4	6.6

Note: Includes data reported up to Week 52.
Note: Higher scores indicate more severe symptoms.

Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Table 211.27
Summary of Evaluating Respiratory Symptoms in COPD
(E-RS: COPD) Score (Study 208657)

Parameter: E-RS Breathlessness Score

	PBO (N=401)	100 SC (N=403)
Weeks 41-44 Total Score		
n	354	347
Mean	6.14	6.13
SD	3.832	4.236
Median	6.14	5.94
Min.	0.0	0.0
Max.	15.8	17.0
Weeks 41-44 Change from Baseline		
n	352	347
Mean	-0.60	-0.75
SD	2.987	3.156
Median	-0.30	-0.04
Min.	-10.8	-13.1
Max.	12.4	6.6

Note: Includes data reported up to Week 52.
Note: Higher scores indicate more severe symptoms.
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Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Table 211.27
Summary of Evaluating Respiratory Symptoms in COPD
(E-RS: COPD) Score (Study 208657)

Parameter: E-RS Breathlessness Score

	PBO (N=401)	100 SC (N=403)
Weeks 45-48 Total Score		
n	347	348
Mean	6.21	6.12
SD	3.865	4.216
Median	6.07	5.96
Min.	0.0	0.0
Max.	15.6	17.0
Weeks 45-48 Change from Baseline		
n	345	348
Mean	-0.49	-0.78
SD	2.990	3.155
Median	-0.29	-0.17
Min.	-7.8	-12.9
Max.	11.9	7.0

Note: Includes data reported up to Week 52.
Note: Higher scores indicate more severe symptoms.

Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Table 211.27
Summary of Evaluating Respiratory Symptoms in COPD
(E-RS: COPD) Score (Study 208657)

Parameter: E-RS Breathlessness Score

	PBO (N=401)	100 SC (N=403)
Weeks 49-52 Total Score		
n	326	331
Mean	6.12	6.12
SD	3.871	4.227
Median	6.04	5.93
Min.	0.0	0.0
Max.	15.4	17.0
Weeks 49-52 Change from Baseline		
n	324	331
Mean	-0.46	-0.80
SD	3.008	3.223
Median	-0.33	-0.18
Min.	-9.4	-13.9
Max.	12.1	7.4

Note: Includes data reported up to Week 52.
Note: Higher scores indicate more severe symptoms.

Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Table 211.27
Summary of Evaluating Respiratory Symptoms in COPD
(E-RS: COPD) Score (Study 208657)

Parameter: E-RS Cough and Sputum Score

	PBO (N=401)	100 SC (N=403)
Baseline Total Score		
n	399	403
Mean	3.23	3.32
SD	1.826	1.718
Median	3.29	3.57
Min.	0.0	0.0
Max.	8.4	7.9
Weeks 1-4 Total Score		
n	390	400
Mean	3.06	3.07
SD	1.668	1.677
Median	3.09	3.15
Min.	0.0	0.0
Max.	7.4	7.5
Weeks 1-4 Change from Baseline		
n	389	400
Mean	-0.17	-0.25
SD	0.938	0.994
Median	-0.04	-0.11
Min.	-3.8	-4.8
Max.	2.9	4.3

Note: Includes data reported up to Week 52.
Note: Higher scores indicate more severe symptoms.
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Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Table 211.27
Summary of Evaluating Respiratory Symptoms in COPD
(E-RS: COPD) Score (Study 208657)

Parameter: E-RS Cough and Sputum Score

	PBO (N=401)	100 SC (N=403)
Weeks 5-8 Total Score		
n	386	392
Mean	2.93	2.88
SD	1.729	1.705
Median	3.00	3.04
Min.	0.0	0.0
Max.	7.7	7.2
Weeks 5-8 Change from Baseline		
n	384	392
Mean	-0.32	-0.44
SD	1.244	1.205
Median	-0.11	-0.25
Min.	-5.5	-5.5
Max.	5.6	3.2

Note: Includes data reported up to Week 52.
Note: Higher scores indicate more severe symptoms.
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Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Table 211.27
Summary of Evaluating Respiratory Symptoms in COPD
(E-RS: COPD) Score (Study 208657)

Parameter: E-RS Cough and Sputum Score

	PBO (N=401)	100 SC (N=403)
Weeks 9-12 Total Score		
n	386	390
Mean	2.88	2.86
SD	1.698	1.739
Median	3.00	3.00
Min.	0.0	0.0
Max.	7.5	7.1
Weeks 9-12 Change from Baseline		
n	384	390
Mean	-0.34	-0.49
SD	1.354	1.357
Median	-0.14	-0.32
Min.	-6.4	-5.3
Max.	5.2	3.9

Note: Includes data reported up to Week 52.
Note: Higher scores indicate more severe symptoms.
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Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Table 211.27
Summary of Evaluating Respiratory Symptoms in COPD
(E-RS: COPD) Score (Study 208657)

Parameter: E-RS Cough and Sputum Score

	PBO (N=401)	100 SC (N=403)
Weeks 13-16 Total Score		
n	372	381
Mean	2.84	2.80
SD	1.718	1.731
Median	3.00	3.00
Min.	0.0	0.0
Max.	7.4	7.0
Weeks 13-16 Change from Baseline		
n	370	381
Mean	-0.38	-0.51
SD	1.392	1.454
Median	-0.14	-0.29
Min.	-6.5	-5.3
Max.	4.2	4.5

Note: Includes data reported up to Week 52.
Note: Higher scores indicate more severe symptoms.

Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Table 211.27
Summary of Evaluating Respiratory Symptoms in COPD
(E-RS: COPD) Score (Study 208657)

Parameter: E-RS Cough and Sputum Score

	PBO (N=401)	100 SC (N=403)
Weeks 17-20 Total Score		
n	369	374
Mean	2.84	2.77
SD	1.736	1.797
Median	3.00	3.00
Min.	0.0	0.0
Max.	7.5	8.0
Weeks 17-20 Change from Baseline		
n	367	374
Mean	-0.36	-0.56
SD	1.340	1.461
Median	-0.17	-0.30
Min.	-5.1	-5.8
Max.	4.3	5.0

Note: Includes data reported up to Week 52.
Note: Higher scores indicate more severe symptoms.
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Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Table 211.27
Summary of Evaluating Respiratory Symptoms in COPD
(E-RS: COPD) Score (Study 208657)

Parameter: E-RS Cough and Sputum Score

	PBO (N=401)	100 SC (N=403)
Weeks 21-24 Total Score		
n	361	367
Mean	2.76	2.74
SD	1.727	1.788
Median	3.00	3.00
Min.	0.0	0.0
Max.	7.9	8.1
Weeks 21-24 Change from Baseline		
n	359	367
Mean	-0.47	-0.56
SD	1.419	1.472
Median	-0.24	-0.30
Min.	-6.2	-6.8
Max.	4.5	5.0

Note: Includes data reported up to Week 52.
Note: Higher scores indicate more severe symptoms.
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Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Table 211.27
Summary of Evaluating Respiratory Symptoms in COPD
(E-RS: COPD) Score (Study 208657)

Parameter: E-RS Cough and Sputum Score

	PBO (N=401)	100 SC (N=403)
Weeks 25-28 Total Score		
n	358	363
Mean	2.74	2.74
SD	1.769	1.844
Median	2.89	3.00
Min.	0.0	0.0
Max.	8.5	10.2
Weeks 25-28 Change from Baseline		
n	356	363
Mean	-0.44	-0.58
SD	1.450	1.515
Median	-0.18	-0.26
Min.	-5.5	-7.3
Max.	4.6	6.0

Note: Includes data reported up to Week 52.
Note: Higher scores indicate more severe symptoms.

Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Table 211.27
Summary of Evaluating Respiratory Symptoms in COPD
(E-RS: COPD) Score (Study 208657)

Parameter: E-RS Cough and Sputum Score

	PBO (N=401)	100 SC (N=403)
Weeks 29-32 Total Score		
n	361	366
Mean	2.72	2.73
SD	1.745	1.862
Median	2.95	3.00
Min.	0.0	0.0
Max.	8.1	10.6
Weeks 29-32 Change from Baseline		
n	359	366
Mean	-0.50	-0.59
SD	1.444	1.538
Median	-0.27	-0.32
Min.	-6.2	-6.4
Max.	4.1	5.6

Note: Includes data reported up to Week 52.
Note: Higher scores indicate more severe symptoms.
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Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Table 211.27
Summary of Evaluating Respiratory Symptoms in COPD
(E-RS: COPD) Score (Study 208657)

Parameter: E-RS Cough and Sputum Score

	PBO (N=401)	100 SC (N=403)
Weeks 33-36 Total Score		
n	356	360
Mean	2.68	2.73
SD	1.807	1.857
Median	2.93	3.00
Min.	0.0	0.0
Max.	8.0	11.0
Weeks 33-36 Change from Baseline		
n	354	360
Mean	-0.52	-0.58
SD	1.525	1.528
Median	-0.28	-0.32
Min.	-5.5	-6.1
Max.	4.4	6.0

Note: Includes data reported up to Week 52.
Note: Higher scores indicate more severe symptoms.

Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Table 211.27
Summary of Evaluating Respiratory Symptoms in COPD
(E-RS: COPD) Score (Study 208657)

Parameter: E-RS Cough and Sputum Score

	PBO (N=401)	100 SC (N=403)
Weeks 37-40 Total Score		
n	361	353
Mean	2.72	2.75
SD	1.800	1.826
Median	3.00	3.00
Min.	0.0	0.0
Max.	7.6	11.0
Weeks 37-40 Change from Baseline		
n	359	353
Mean	-0.47	-0.54
SD	1.547	1.540
Median	-0.31	-0.34
Min.	-5.9	-5.5
Max.	4.5	4.5

Note: Includes data reported up to Week 52.
Note: Higher scores indicate more severe symptoms.

Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Table 211.27
Summary of Evaluating Respiratory Symptoms in COPD
(E-RS: COPD) Score (Study 208657)

Parameter: E-RS Cough and Sputum Score

	PBO (N=401)	100 SC (N=403)
Weeks 41-44 Total Score		
n	354	347
Mean	2.74	2.68
SD	1.719	1.851
Median	2.96	2.96
Min.	0.0	0.0
Max.	7.9	11.0
Weeks 41-44 Change from Baseline		
n	352	347
Mean	-0.48	-0.61
SD	1.515	1.536
Median	-0.27	-0.43
Min.	-5.4	-5.7
Max.	4.7	4.5

Note: Includes data reported up to Week 52.
Note: Higher scores indicate more severe symptoms.
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Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Table 211.27
Summary of Evaluating Respiratory Symptoms in COPD
(E-RS: COPD) Score (Study 208657)

Parameter: E-RS Cough and Sputum Score

	PBO (N=401)	100 SC (N=403)
Weeks 45-48 Total Score		
n	347	348
Mean	2.73	2.68
SD	1.733	1.838
Median	3.00	2.96
Min.	0.0	0.0
Max.	7.3	9.1
Weeks 45-48 Change from Baseline		
n	345	348
Mean	-0.45	-0.62
SD	1.535	1.524
Median	-0.21	-0.41
Min.	-5.4	-6.0
Max.	4.2	3.0

Note: Includes data reported up to Week 52.
Note: Higher scores indicate more severe symptoms.
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Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Table 211.27
Summary of Evaluating Respiratory Symptoms in COPD
(E-RS: COPD) Score (Study 208657)

Parameter: E-RS Cough and Sputum Score

	PBO (N=401)	100 SC (N=403)
Weeks 49-52 Total Score		
n	326	331
Mean	2.69	2.69
SD	1.778	1.817
Median	2.94	2.93
Min.	0.0	0.0
Max.	7.2	10.1
Weeks 49-52 Change from Baseline		
n	324	331
Mean	-0.43	-0.58
SD	1.528	1.498
Median	-0.24	-0.29
Min.	-5.5	-5.5
Max.	4.7	4.1

Note: Includes data reported up to Week 52.
Note: Higher scores indicate more severe symptoms.

Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Table 211.27
Summary of Evaluating Respiratory Symptoms in COPD
(E-RS: COPD) Score (Study 208657)

Parameter: E-RS Chest Score

	PBO (N=401)	100 SC (N=403)
Baseline Total Score		
n	399	403
Mean	2.85	2.88
SD	2.004	2.126
Median	3.00	3.00
Min.	0.0	0.0
Max.	9.4	10.3
Weeks 1-4 Total Score		
n	390	400
Mean	2.76	2.66
SD	1.951	2.001
Median	2.84	2.77
Min.	0.0	0.0
Max.	11.5	8.1
Weeks 1-4 Change from Baseline		
n	389	400
Mean	-0.07	-0.20
SD	1.090	1.068
Median	0.00	-0.01
Min.	-5.2	-4.1
Max.	3.8	4.9

Note: Includes data reported up to Week 52.
Note: Higher scores indicate more severe symptoms.

Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Table 211.27
Summary of Evaluating Respiratory Symptoms in COPD
(E-RS: COPD) Score (Study 208657)

Parameter: E-RS Chest Score

	PBO (N=401)	100 SC (N=403)
Weeks 5-8 Total Score		
n	386	392
Mean	2.75	2.57
SD	2.044	2.049
Median	2.78	2.58
Min.	0.0	0.0
Max.	12.0	8.7
Weeks 5-8 Change from Baseline		
n	384	392
Mean	-0.13	-0.29
SD	1.465	1.405
Median	-0.02	-0.08
Min.	-5.5	-5.7
Max.	6.3	4.5

Note: Includes data reported up to Week 52.
Note: Higher scores indicate more severe symptoms.
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Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Table 211.27
Summary of Evaluating Respiratory Symptoms in COPD
(E-RS: COPD) Score (Study 208657)

Parameter: E-RS Chest Score

	PBO (N=401)	100 SC (N=403)
Weeks 9-12 Total Score		
n	386	390
Mean	2.67	2.54
SD	2.000	2.143
Median	2.93	2.59
Min.	0.0	0.0
Max.	12.0	8.6
Weeks 9-12 Change from Baseline		
n	384	390
Mean	-0.19	-0.34
SD	1.565	1.620
Median	0.00	-0.14
Min.	-5.2	-5.9
Max.	5.4	5.4

Note: Includes data reported up to Week 52.
Note: Higher scores indicate more severe symptoms.
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Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Table 211.27
Summary of Evaluating Respiratory Symptoms in COPD
(E-RS: COPD) Score (Study 208657)

Parameter: E-RS Chest Score

	PBO (N=401)	100 SC (N=403)
Weeks 13-16 Total Score		
n	372	381
Mean	2.67	2.55
SD	2.039	2.109
Median	2.78	2.57
Min.	0.0	0.0
Max.	12.0	8.3
Weeks 13-16 Change from Baseline		
n	370	381
Mean	-0.18	-0.30
SD	1.663	1.571
Median	0.00	-0.13
Min.	-5.2	-5.4
Max.	5.2	4.9

Note: Includes data reported up to Week 52.
Note: Higher scores indicate more severe symptoms.
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Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Table 211.27
Summary of Evaluating Respiratory Symptoms in COPD
(E-RS: COPD) Score (Study 208657)

Parameter: E-RS Chest Score

	PBO (N=401)	100 SC (N=403)
Weeks 17-20 Total Score		
n	369	374
Mean	2.70	2.55
SD	2.081	2.160
Median	2.89	2.59
Min.	0.0	0.0
Max.	12.0	10.6
Weeks 17-20 Change from Baseline		
n	367	374
Mean	-0.13	-0.32
SD	1.578	1.669
Median	0.00	-0.13
Min.	-5.5	-6.1
Max.	4.3	4.6

Note: Includes data reported up to Week 52.
Note: Higher scores indicate more severe symptoms.
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Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Table 211.27
Summary of Evaluating Respiratory Symptoms in COPD
(E-RS: COPD) Score (Study 208657)

Parameter: E-RS Chest Score

	PBO (N=401)	100 SC (N=403)
Weeks 21-24 Total Score		
n	361	367
Mean	2.56	2.54
SD	2.060	2.199
Median	2.75	2.67
Min.	0.0	0.0
Max.	12.0	10.0
Weeks 21-24 Change from Baseline		
n	359	367
Mean	-0.29	-0.32
SD	1.657	1.745
Median	-0.14	-0.08
Min.	-5.3	-6.7
Max.	4.3	4.8

Note: Includes data reported up to Week 52.
Note: Higher scores indicate more severe symptoms.
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Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Table 211.27
Summary of Evaluating Respiratory Symptoms in COPD
(E-RS: COPD) Score (Study 208657)

Parameter: E-RS Chest Score

	PBO (N=401)	100 SC (N=403)
Weeks 25-28 Total Score		
n	358	363
Mean	2.57	2.47
SD	2.079	2.197
Median	2.65	2.33
Min.	0.0	0.0
Max.	11.7	10.5
Weeks 25-28 Change from Baseline		
n	356	363
Mean	-0.25	-0.37
SD	1.728	1.757
Median	-0.11	-0.13
Min.	-5.3	-6.9
Max.	6.5	4.8

Note: Includes data reported up to Week 52.
Note: Higher scores indicate more severe symptoms.

Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Table 211.27
Summary of Evaluating Respiratory Symptoms in COPD
(E-RS: COPD) Score (Study 208657)

Parameter: E-RS Chest Score

	PBO (N=401)	100 SC (N=403)
Weeks 29-32 Total Score		
n	361	366
Mean	2.48	2.53
SD	2.045	2.286
Median	2.42	2.60
Min.	0.0	0.0
Max.	12.0	10.7
Weeks 29-32 Change from Baseline		
n	359	366
Mean	-0.37	-0.35
SD	1.743	1.847
Median	-0.14	-0.10
Min.	-6.1	-7.0
Max.	5.2	5.8

Note: Includes data reported up to Week 52.
Note: Higher scores indicate more severe symptoms.
/mnt/code/postcsr_01/prod/tfls/t_e_evrespsym.sas 25JUL2025 11:07

Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Table 211.27
Summary of Evaluating Respiratory Symptoms in COPD
(E-RS: COPD) Score (Study 208657)

Parameter: E-RS Chest Score

	PBO (N=401)	100 SC (N=403)
Weeks 33-36 Total Score		
n	356	360
Mean	2.49	2.50
SD	2.098	2.236
Median	2.28	2.33
Min.	0.0	0.0
Max.	12.0	10.3
Weeks 33-36 Change from Baseline		
n	354	360
Mean	-0.33	-0.37
SD	1.751	1.790
Median	-0.16	-0.09
Min.	-6.1	-6.5
Max.	5.9	5.6

Note: Includes data reported up to Week 52.
Note: Higher scores indicate more severe symptoms.

Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Table 211.27
Summary of Evaluating Respiratory Symptoms in COPD
(E-RS: COPD) Score (Study 208657)

Parameter: E-RS Chest Score

	PBO (N=401)	100 SC (N=403)
Weeks 37-40 Total Score		
n	361	353
Mean	2.55	2.51
SD	2.143	2.202
Median	2.44	2.43
Min.	0.0	0.0
Max.	12.0	10.3
Weeks 37-40 Change from Baseline		
n	359	353
Mean	-0.28	-0.34
SD	1.850	1.827
Median	-0.14	-0.07
Min.	-6.2	-5.5
Max.	5.6	5.0

Note: Includes data reported up to Week 52.
Note: Higher scores indicate more severe symptoms.

Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Table 211.27
Summary of Evaluating Respiratory Symptoms in COPD
(E-RS: COPD) Score (Study 208657)

Parameter: E-RS Chest Score

	PBO (N=401)	100 SC (N=403)
Weeks 41-44 Total Score		
n	354	347
Mean	2.55	2.44
SD	2.096	2.205
Median	2.63	2.14
Min.	0.0	0.0
Max.	12.0	10.5
Weeks 41-44 Change from Baseline		
n	352	347
Mean	-0.30	-0.41
SD	1.824	1.835
Median	-0.12	-0.14
Min.	-6.0	-6.3
Max.	7.3	4.8

Note: Includes data reported up to Week 52.
Note: Higher scores indicate more severe symptoms.
/mnt/code/postcsr_01/prod/tfls/t_e_evrespsym.sas 25JUL2025 11:07

Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Table 211.27
Summary of Evaluating Respiratory Symptoms in COPD
(E-RS: COPD) Score (Study 208657)

Parameter: E-RS Chest Score

	PBO (N=401)	100 SC (N=403)
Weeks 45-48 Total Score		
n	347	348
Mean	2.53	2.46
SD	2.072	2.208
Median	2.73	2.23
Min.	0.0	0.0
Max.	11.9	11.0
Weeks 45-48 Change from Baseline		
n	345	348
Mean	-0.32	-0.42
SD	1.822	1.763
Median	-0.14	-0.14
Min.	-6.5	-5.3
Max.	6.3	4.4

Note: Includes data reported up to Week 52.
Note: Higher scores indicate more severe symptoms.
/mnt/code/postcsr_01/prod/tfls/t_e_evrespsym.sas 25JUL2025 11:07

Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Table 211.27
Summary of Evaluating Respiratory Symptoms in COPD
(E-RS: COPD) Score (Study 208657)

Parameter: E-RS Chest Score

	PBO (N=401)	100 SC (N=403)
Weeks 49-52 Total Score		
n	326	331
Mean	2.45	2.47
SD	2.077	2.217
Median	2.36	2.35
Min.	0.0	0.0
Max.	12.0	10.9
Weeks 49-52 Change from Baseline		
n	324	331
Mean	-0.32	-0.38
SD	1.750	1.820
Median	-0.05	0.00
Min.	-6.3	-6.1
Max.	5.6	4.3

Note: Includes data reported up to Week 52.
Note: Higher scores indicate more severe symptoms.
/mnt/code/postcsr_01/prod/tfls/t_e_evrespsym.sas 25JUL2025 11:07

Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Table 211.28

Analysis of Evaluating Respiratory Symptoms in COPD (E-RS: COPD) Responders at Weeks 49-52: Participants with at Least 6-point Improvement in Score from Baseline (Study 208657)

	PBO (N=401)	100 SC (N=403)
n	399	403
Responder [1]	61 (15%)	67 (17%)
Non-responder	338 (85%)	336 (83%)
No change/worsening	263 (66%)	264 (66%)
Withdrawal from study prior to visit	38 (10%)	37 (9%)
Missing visit [2]	37 (9%)	35 (9%)
Inverse Odds Ratio to Placebo [3]		0.92
95% CI		(0.61, 1.38)
Inverse Relative Risk [4]		0.93
95% CI		(0.66, 1.32)
p-value		0.689
Absolute Risk Reduction [4]		-0.01
95% CI		(-0.20, 0.18)

[1] Defined as a participant with a >=6-point improvement (decrease) from baseline in ERS total score.
[2] Participants with an intercurrent event of either treatment interruption or treatment discontinuation related to the COVID-19 pandemic have data set to missing following the event. Missing data was not imputed.
[3] Analysis performed using a logistic regression model with covariates of baseline score, geographic region (as defined for the study/ISE), smoking status (current vs. never/ex-smoker) and treatment group.
[4] Analysis used poisson regression model with covariates as in [3] (risk difference uses identity link).
Note: Inverse Odds Ratio <1, Inverse Relative Risk < 1, risk difference < 0 correspond to a benefit of Mepolizumab over Placebo.
/mnt/code/postcsr_01/prod/tfls/t_e_ers_resp.sas 25JUL2025 11:07

Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Table 211.29

Analysis of Evaluating Respiratory Symptoms in COPD (E-RS: COPD) Breathlessness Subscale Score Responders at Weeks 49-52: Participants with at Least 2.55-point Improvement in Score from Baseline (Study 208657)

	PBO (N=401)	100 SC (N=403)
n	399	403
Responder [1]	78 (20%)	76 (19%)
Non-responder	321 (80%)	327 (81%)
No change/worsening	246 (62%)	255 (63%)
Withdrawal from study prior to visit	38 (10%)	37 (9%)
Missing visit [2]	37 (9%)	35 (9%)
Inverse Odds Ratio to Placebo [3]		1.07
95% CI		(0.74, 1.54)
Inverse Relative Risk [4]		1.04
95% CI		(0.76, 1.42)
p-value		0.821
Absolute Risk Reduction [4]		0.01
95% CI		(-0.18, 0.19)

[1] "Breathlessness": Responder defined as having >=2.55-point improvement (decrease) from baseline.
[2] Participants with an intercurrent event of either treatment interruption or treatment discontinuation related to the COVID-19 pandemic have data set to missing following the event. Missing data was not imputed.
[3] Analysis performed using a logistic regression model with covariates of baseline score, geographic region (as defined for the study/ISE), smoking status (current vs. never/ex-smoker) and treatment group.
[4] Analysis used poisson regression model with covariates as in [3] (risk difference uses identity link).
Note: Inverse Odds Ratio <1, Inverse Relative Risk < 1, risk difference < 0 correspond to a benefit of Mepolizumab over Placebo.
/mnt/code/postcsr_01/prod/tfls/t_e_ers_brthrsp.sas 25JUL2025 11:07

Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Table 211.30

Analysis of Evaluating Respiratory Symptoms in COPD (E-RS: COPD) Chest Subscale Score Responders at Weeks 49-52: Participants with at Least 1.8-point Improvement in Score from Baseline (Study 208657)

	PBO (N=401)	100 SC (N=403)
n	399	403
Responder [1]	63 (16%)	69 (17%)
Non-responder	336 (84%)	334 (83%)
No change/worsening	261 (65%)	262 (65%)
Withdrawal from study prior to visit	38 (10%)	37 (9%)
Missing visit [2]	37 (9%)	35 (9%)
Inverse Odds Ratio to Placebo [3]		0.94
95% CI		(0.62, 1.41)
Inverse Relative Risk [4]		0.96
95% CI		(0.68, 1.35)
p-value		0.812
Absolute Risk Reduction [4]		-0.01
95% CI		(-0.20, 0.17)

[1] "Chest": Responder defined as having >=1.8-point improvement (decrease) from baseline.
[2] Participants with an intercurrent event of either treatment interruption or treatment discontinuation related to the COVID-19 pandemic have data set to missing following the event. Missing data was not imputed.
[3] Analysis performed using a logistic regression model with covariates of baseline score, geographic region (as defined for the study/ISE), smoking status (current vs. never/ex-smoker) and treatment group.
[4] Analysis used poisson regression model with covariates as in [3] (risk difference uses identity link).
Note: Inverse Odds Ratio <1, Inverse Relative Risk < 1, risk difference < 0 correspond to a benefit of Mepolizumab over Placebo.
/mnt/code/postcsr_01/prod/tfls/t_e_ers_chstrsp.sas 25JUL2025 11:08

Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Table 211.31

Analysis of Evaluating Respiratory Symptoms in COPD (E-RS: COPD) Cough and Sputum Subscale Score Responders at Weeks 49-52: Participants with at Least 1.65-point Improvement in Score from Baseline (Study 208657)

	PBO (N=401)	100 SC (N=403)
n	399	403
Responder [1]	68 (17%)	69 (17%)
Non-responder	331 (83%)	334 (83%)
No change/worsening	256 (64%)	262 (65%)
Withdrawal from study prior to visit	38 (10%)	37 (9%)
Missing visit [2]	37 (9%)	35 (9%)
Inverse Odds Ratio to Placebo [3]		1.04
95% CI		(0.70, 1.54)
Inverse Relative Risk [4]		1.02
95% CI		(0.73, 1.43)
p-value		0.891
Absolute Risk Reduction [4]		0.01
95% CI		(-0.18, 0.19)

[1] "Cough and Sputum": Responder defined as having >=1.65-point improvement (decrease) from baseline.
[2] Participants with an intercurrent event of either treatment interruption or treatment discontinuation related to the COVID-19 pandemic have data set to missing following the event. Missing data was not imputed.
[3] Analysis performed using a logistic regression model with covariates of baseline score, geographic region (as defined for the study/ISE), smoking status (current vs. never/ex-smoker) and treatment group.
[4] Analysis used poisson regression model with covariates as in [3] (risk difference uses identity link).
Note: Inverse Odds Ratio <1, Inverse Relative Risk < 1, risk difference < 0 correspond to a benefit of Mepolizumab over Placebo.
/mnt/code/postcsr_01/prod/tfls/t_e_ers_cghsrsp.sas 25JUL2025 11:08

Population: Modified Intent-to-treat Population with Eosinophils 300 cells/uL or More

Table 211.32

Analysis of Change from Baseline in Evaluating Respiratory Symptoms in COPD (E-RS: COPD) Score - Mixed Model Repeated Measures (Study 208657)

Visit: Weeks 1-4

	PBO (N=401)	100 SC (N=403)
n [1]	398	402
n [2]	389	400
LS Mean (SE)	12.5 (0.16)	12.3 (0.16)
LS Mean Change (SE)	-0.5 (0.16)	-0.7 (0.16)
Column vs Placebo [3]		
Difference		-0.2
95% CI		(-0.64, 0.23)
p-value		0.355
Corrected Hedges' g [4]		-0.07
95% CI		(-0.21, 0.07)

[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the given time point.
[3] Analysis performed using mixed model repeated measures with covariates of baseline score, geographic region, smoking status (current vs. never/ex-smoker), treatment and visit, plus interaction terms for visit by baseline and visit by treatment group.
[4] Based on covariate adjusted means.
Note: Estimates are based on weighting applied to each level of class variable determined from observed proportions.
/mnt/code/postcsr_01/prod/tfls/t_e_mmrm_ers_chg.sas 30OCT2025 13:30

Population: Modified Intent-to-treat Population with Eosinophils 300 cells/uL or More

Table 211.32

Analysis of Change from Baseline in Evaluating Respiratory Symptoms in COPD (E-RS: COPD) Score - Mixed Model Repeated Measures (Study 208657)

Visit: Weeks 5-8

	PBO (N=401)	100 SC (N=403)
n [1]	398	402
n [2]	384	392
LS Mean (SE)	12.2 (0.21)	11.8 (0.21)
LS Mean Change (SE)	-0.7 (0.21)	-1.1 (0.21)
Column vs Placebo [3]		
Difference		-0.4
95% CI		(-1.03, 0.15)
p-value		0.144
Corrected Hedges' g [4]		-0.11
95% CI		(-0.25, 0.04)

[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the given time point.
[3] Analysis performed using mixed model repeated measures with covariates of baseline score, geographic region, smoking status (current vs. never/ex-smoker), treatment and visit, plus interaction terms for visit by baseline and visit by treatment group.
[4] Based on covariate adjusted means.
Note: Estimates are based on weighting applied to each level of class variable determined from observed proportions.
/mnt/code/postcsr_01/prod/tfls/t_e_mmrm_ers_chg.sas 30OCT2025 13:30

Population: Modified Intent-to-treat Population with Eosinophils 300 cells/uL or More

Table 211.32

Analysis of Change from Baseline in Evaluating Respiratory Symptoms in COPD (E-RS: COPD) Score - Mixed Model Repeated Measures (Study 208657)

Visit: Weeks 9-12

	PBO (N=401)	100 SC (N=403)
n [1]	398	402
n [2]	384	390
LS Mean (SE)	12.1 (0.23)	11.7 (0.23)
LS Mean Change (SE)	-0.9 (0.23)	-1.3 (0.23)
Column vs Placebo [3]		
Difference		-0.4
95% CI		(-1.07, 0.23)
p-value		0.202
Corrected Hedges' g [4]		-0.09
95% CI		(-0.23, 0.05)

[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the given time point.
[3] Analysis performed using mixed model repeated measures with covariates of baseline score, geographic region, smoking status (current vs. never/ex-smoker), treatment and visit, plus interaction terms for visit by baseline and visit by treatment group.
[4] Based on covariate adjusted means.
Note: Estimates are based on weighting applied to each level of class variable determined from observed proportions.
/mnt/code/postcsr_01/prod/tfls/t_e_mmrm_ers_chg.sas 30OCT2025 13:30

Population: Modified Intent-to-treat Population with Eosinophils 300 cells/uL or More

Table 211.32

Analysis of Change from Baseline in Evaluating Respiratory Symptoms in COPD (E-RS: COPD) Score - Mixed Model Repeated Measures (Study 208657)

Visit: Weeks 13-16

	PBO (N=401)	100 SC (N=403)
n [1]	398	402
n [2]	370	381
LS Mean (SE)	12.0 (0.24)	11.7 (0.24)
LS Mean Change (SE)	-0.9 (0.24)	-1.2 (0.24)
Column vs Placebo [3]		
Difference		-0.3
95% CI		(-1.00, 0.35)
p-value		0.346
Corrected Hedges' g [4]		-0.07
95% CI		(-0.21, 0.07)

[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the given time point.
[3] Analysis performed using mixed model repeated measures with covariates of baseline score, geographic region, smoking status (current vs. never/ex-smoker), treatment and visit, plus interaction terms for visit by baseline and visit by treatment group.
[4] Based on covariate adjusted means.
Note: Estimates are based on weighting applied to each level of class variable determined from observed proportions.
/mnt/code/postcsr_01/prod/tfls/t_e_mmrm_ers_chg.sas 30OCT2025 13:30

Population: Modified Intent-to-treat Population with Eosinophils 300 cells/uL or More

Table 211.32

Analysis of Change from Baseline in Evaluating Respiratory Symptoms in COPD (E-RS: COPD) Score - Mixed Model Repeated Measures (Study 208657)

Visit: Weeks 17-20

	PBO (N=401)	100 SC (N=403)
n [1]	398	402
n [2]	367	374
LS Mean (SE)	12.1 (0.25)	11.5 (0.24)
LS Mean Change (SE)	-0.9 (0.25)	-1.4 (0.24)
Column vs Placebo [3]		
Difference		-0.5
95% CI		(-1.22, 0.14)
p-value		0.121
Corrected Hedges' g [4]		-0.11
95% CI		(-0.26, 0.03)

[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the given time point.
[3] Analysis performed using mixed model repeated measures with covariates of baseline score, geographic region, smoking status (current vs. never/ex-smoker), treatment and visit, plus interaction terms for visit by baseline and visit by treatment group.
[4] Based on covariate adjusted means.
Note: Estimates are based on weighting applied to each level of class variable determined from observed proportions.
/mnt/code/postcsr_01/prod/tfls/t_e_mmrm_ers_chg.sas 30OCT2025 13:30

Population: Modified Intent-to-treat Population with Eosinophils 300 cells/uL or More

Table 211.32

Analysis of Change from Baseline in Evaluating Respiratory Symptoms in COPD (E-RS: COPD) Score - Mixed Model Repeated Measures (Study 208657)

Visit: Weeks 21-24

	PBO (N=401)	100 SC (N=403)
n [1]	398	402
n [2]	359	367
LS Mean (SE)	11.7 (0.25)	11.5 (0.25)
LS Mean Change (SE)	-1.2 (0.25)	-1.4 (0.25)
Column vs Placebo [3]		
Difference		-0.2
95% CI		(-0.90, 0.48)
p-value		0.550
Corrected Hedges' g [4]		-0.04
95% CI		(-0.19, 0.10)

[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the given time point.
[3] Analysis performed using mixed model repeated measures with covariates of baseline score, geographic region, smoking status (current vs. never/ex-smoker), treatment and visit, plus interaction terms for visit by baseline and visit by treatment group.
[4] Based on covariate adjusted means.
Note: Estimates are based on weighting applied to each level of class variable determined from observed proportions.
/mnt/code/postcsr_01/prod/tfls/t_e_mmrm_ers_chg.sas 30OCT2025 13:30

Population: Modified Intent-to-treat Population with Eosinophils 300 cells/uL or More

Table 211.32

Analysis of Change from Baseline in Evaluating Respiratory Symptoms in COPD (E-RS: COPD) Score - Mixed Model Repeated Measures (Study 208657)

Visit: Weeks 25-28

	PBO (N=401)	100 SC (N=403)
n [1]	398	402
n [2]	356	363
LS Mean (SE)	11.8 (0.26)	11.3 (0.26)
LS Mean Change (SE)	-1.1 (0.26)	-1.6 (0.26)
Column vs Placebo [3]		
Difference		-0.5
95% CI		(-1.25, 0.19)
p-value		0.149
Corrected Hedges' g [4]		-0.11
95% CI		(-0.25, 0.04)

[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the given time point.
[3] Analysis performed using mixed model repeated measures with covariates of baseline score, geographic region, smoking status (current vs. never/ex-smoker), treatment and visit, plus interaction terms for visit by baseline and visit by treatment group.
[4] Based on covariate adjusted means.
Note: Estimates are based on weighting applied to each level of class variable determined from observed proportions.
/mnt/code/postcsr_01/prod/tfls/t_e_mmrm_ers_chg.sas 30OCT2025 13:30

Population: Modified Intent-to-treat Population with Eosinophils 300 cells/uL or More

Table 211.32

Analysis of Change from Baseline in Evaluating Respiratory Symptoms in COPD (E-RS: COPD) Score - Mixed Model Repeated Measures (Study 208657)

Visit: Weeks 29-32

	PBO (N=401)	100 SC (N=403)
n [1]	398	402
n [2]	359	366
LS Mean (SE)	11.6 (0.26)	11.4 (0.26)
LS Mean Change (SE)	-1.3 (0.26)	-1.6 (0.26)
Column vs Placebo [3]		
Difference		-0.2
95% CI		(-0.94, 0.52)
p-value		0.574
Corrected Hedges' g [4]		-0.04
95% CI		(-0.19, 0.10)

[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the given time point.
[3] Analysis performed using mixed model repeated measures with covariates of baseline score, geographic region, smoking status (current vs. never/ex-smoker), treatment and visit, plus interaction terms for visit by baseline and visit by treatment group.
[4] Based on covariate adjusted means.
Note: Estimates are based on weighting applied to each level of class variable determined from observed proportions.
/mnt/code/postcsr_01/prod/tfls/t_e_mmrm_ers_chg.sas 30OCT2025 13:30

Population: Modified Intent-to-treat Population with Eosinophils 300 cells/uL or More

Table 211.32

Analysis of Change from Baseline in Evaluating Respiratory Symptoms in COPD (E-RS: COPD) Score - Mixed Model Repeated Measures (Study 208657)

Visit: Weeks 33-36

	PBO (N=401)	100 SC (N=403)
n [1]	398	402
n [2]	354	360
LS Mean (SE)	11.5 (0.27)	11.4 (0.27)
LS Mean Change (SE)	-1.4 (0.27)	-1.5 (0.27)
Column vs Placebo [3]		
Difference		-0.1
95% CI		(-0.90, 0.60)
p-value		0.699
Corrected Hedges' g [4]		-0.03
95% CI		(-0.18, 0.12)

[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the given time point.
[3] Analysis performed using mixed model repeated measures with covariates of baseline score, geographic region, smoking status (current vs. never/ex-smoker), treatment and visit, plus interaction terms for visit by baseline and visit by treatment group.
[4] Based on covariate adjusted means.
Note: Estimates are based on weighting applied to each level of class variable determined from observed proportions.
/mnt/code/postcsr_01/prod/tfls/t_e_mmrm_ers_chg.sas 30OCT2025 13:30

Population: Modified Intent-to-treat Population with Eosinophils 300 cells/uL or More

Table 211.32

Analysis of Change from Baseline in Evaluating Respiratory Symptoms in COPD (E-RS: COPD) Score - Mixed Model Repeated Measures (Study 208657)

Visit: Weeks 37-40

	PBO (N=401)	100 SC (N=403)
n [1]	398	402
n [2]	359	353
LS Mean (SE)	11.8 (0.28)	11.6 (0.28)
LS Mean Change (SE)	-1.2 (0.28)	-1.3 (0.28)
Column vs Placebo [3]		
Difference		-0.2
95% CI		(-0.93, 0.60)
p-value		0.678
Corrected Hedges' g [4]		-0.03
95% CI		(-0.18, 0.12)

[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the given time point.
[3] Analysis performed using mixed model repeated measures with covariates of baseline score, geographic region, smoking status (current vs. never/ex-smoker), treatment and visit, plus interaction terms for visit by baseline and visit by treatment group.
[4] Based on covariate adjusted means.
Note: Estimates are based on weighting applied to each level of class variable determined from observed proportions.
/mnt/code/postcsr_01/prod/tfls/t_e_mmrm_ers_chg.sas 30OCT2025 13:30

Population: Modified Intent-to-treat Population with Eosinophils 300 cells/uL or More

Table 211.32

Analysis of Change from Baseline in Evaluating Respiratory Symptoms in COPD (E-RS: COPD) Score - Mixed Model Repeated Measures (Study 208657)

Visit: Weeks 41-44

	PBO (N=401)	100 SC (N=403)
n [1]	398	402
n [2]	352	347
LS Mean (SE)	11.7 (0.28)	11.5 (0.28)
LS Mean Change (SE)	-1.2 (0.28)	-1.5 (0.28)
Column vs Placebo [3]		
Difference		-0.2
95% CI		(-0.99, 0.55)
p-value		0.579
Corrected Hedges' g [4]		-0.04
95% CI		(-0.19, 0.11)

[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the given time point.
[3] Analysis performed using mixed model repeated measures with covariates of baseline score, geographic region, smoking status (current vs. never/ex-smoker), treatment and visit, plus interaction terms for visit by baseline and visit by treatment group.
[4] Based on covariate adjusted means.
Note: Estimates are based on weighting applied to each level of class variable determined from observed proportions.
/mnt/code/postcsr_01/prod/tfls/t_e_mmrm_ers_chg.sas 30OCT2025 13:30

Population: Modified Intent-to-treat Population with Eosinophils 300 cells/uL or More

Table 211.32

Analysis of Change from Baseline in Evaluating Respiratory Symptoms in COPD (E-RS: COPD) Score - Mixed Model Repeated Measures (Study 208657)

Visit: Weeks 45-48

	PBO (N=401)	100 SC (N=403)
n [1]	398	402
n [2]	345	348
LS Mean (SE)	11.7 (0.28)	11.5 (0.28)
LS Mean Change (SE)	-1.2 (0.28)	-1.4 (0.28)
Column vs Placebo [3]		
Difference		-0.2
95% CI		(-1.00, 0.55)
p-value		0.573
Corrected Hedges' g [4]		-0.04
95% CI		(-0.19, 0.11)

[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the given time point.
[3] Analysis performed using mixed model repeated measures with covariates of baseline score, geographic region, smoking status (current vs. never/ex-smoker), treatment and visit, plus interaction terms for visit by baseline and visit by treatment group.
[4] Based on covariate adjusted means.
Note: Estimates are based on weighting applied to each level of class variable determined from observed proportions.
/mnt/code/postcsr_01/prod/tfls/t_e_mmrm_ers_chg.sas 30OCT2025 13:30

Population: Modified Intent-to-treat Population with Eosinophils 300 cells/uL or More

Table 211.32

Analysis of Change from Baseline in Evaluating Respiratory Symptoms in COPD (E-RS: COPD) Score - Mixed Model Repeated Measures (Study 208657)

Visit: Weeks 49-52

	PBO (N=401)	100 SC (N=403)
n [1]	398	402
n [2]	324	331
LS Mean (SE)	11.7 (0.28)	11.5 (0.28)
LS Mean Change (SE)	-1.2 (0.28)	-1.5 (0.28)
Column vs Placebo [3]		
Difference		-0.2
95% CI		(-1.01, 0.54)
p-value		0.555
Corrected Hedges' g [4]		-0.05
95% CI		(-0.20, 0.11)

[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the given time point.
[3] Analysis performed using mixed model repeated measures with covariates of baseline score, geographic region, smoking status (current vs. never/ex-smoker), treatment and visit, plus interaction terms for visit by baseline and visit by treatment group.
[4] Based on covariate adjusted means.
Note: Estimates are based on weighting applied to each level of class variable determined from observed proportions.
/mnt/code/postcsr_01/prod/tfls/t_e_mmrm_ers_chg.sas 30OCT2025 13:30

Population: Modified Intent-to-treat Population with Eosinophils 300 cells/uL or More

Table 211.33

Analysis of Change from Baseline in Evaluating Respiratory Symptoms in COPD (E-RS: COPD)
Breathlessness Subscale Score - Mixed Model Repeated Measures (Study 208657)

Visit: Weeks 1-4

	PBO (N=401)	100 SC (N=403)
n [1]	398	402
n [2]	389	400
LS Mean (SE)	6.6 (0.09)	6.6 (0.09)
LS Mean Change (SE)	-0.2 (0.09)	-0.2 (0.09)
Column vs Placebo [3]		
Difference		0.0
95% CI		(-0.26, 0.22)
p-value		0.856
Corrected Hedges' g [4]		-0.01
95% CI		(-0.15, 0.13)

[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the given time point.
[3] Analysis performed using mixed model repeated measures with covariates of baseline score, geographic region, smoking status (current vs. never/ex-smoker), treatment and visit, plus interaction terms for visit by baseline and visit by treatment group.
[4] Based on covariate adjusted means.
Note: Estimates are based on weighting applied to each level of class variable determined from observed proportions.
/mnt/code/postcsr_01/prod/tfls/t_e_mmrm_ers_brth.sas 30OCT2025 13:31

Population: Modified Intent-to-treat Population with Eosinophils 300 cells/uL or More

Table 211.33

Analysis of Change from Baseline in Evaluating Respiratory Symptoms in COPD (E-RS: COPD)
Breathlessness Subscale Score - Mixed Model Repeated Measures (Study 208657)

Visit: Weeks 5-8

	PBO (N=401)	100 SC (N=403)
n [1]	398	402
n [2]	384	392
LS Mean (SE)	6.6 (0.12)	6.4 (0.12)
LS Mean Change (SE)	-0.3 (0.12)	-0.4 (0.12)
Column vs Placebo [3]		
Difference		-0.2
95% CI		(-0.48, 0.16)
p-value		0.321
Corrected Hedges' g [4]		-0.07
95% CI		(-0.21, 0.07)

[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the given time point.
[3] Analysis performed using mixed model repeated measures with covariates of baseline score, geographic region, smoking status (current vs. never/ex-smoker), treatment and visit, plus interaction terms for visit by baseline and visit by treatment group.
[4] Based on covariate adjusted means.
Note: Estimates are based on weighting applied to each level of class variable determined from observed proportions.
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Population: Modified Intent-to-treat Population with Eosinophils 300 cells/uL or More

Table 211.33

Analysis of Change from Baseline in Evaluating Respiratory Symptoms in COPD (E-RS: COPD)
Breathlessness Subscale Score - Mixed Model Repeated Measures (Study 208657)

Visit: Weeks 9-12

	PBO (N=401)	100 SC (N=403)
n [1]	398	402
n [2]	384	390
LS Mean (SE)	6.5 (0.13)	6.3 (0.13)
LS Mean Change (SE)	-0.4 (0.13)	-0.5 (0.13)
Column vs Placebo [3]		
Difference		-0.2
95% CI		(-0.52, 0.19)
p-value		0.362
Corrected Hedges' g [4]		-0.07
95% CI		(-0.21, 0.08)

[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the given time point.
[3] Analysis performed using mixed model repeated measures with covariates of baseline score, geographic region, smoking status (current vs. never/ex-smoker), treatment and visit, plus interaction terms for visit by baseline and visit by treatment group.
[4] Based on covariate adjusted means.
Note: Estimates are based on weighting applied to each level of class variable determined from observed proportions.
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Population: Modified Intent-to-treat Population with Eosinophils 300 cells/uL or More

Table 211.33

Analysis of Change from Baseline in Evaluating Respiratory Symptoms in COPD (E-RS: COPD)
Breathlessness Subscale Score - Mixed Model Repeated Measures (Study 208657)

Visit: Weeks 13-16

	PBO (N=401)	100 SC (N=403)
n [1]	398	402
n [2]	370	381
LS Mean (SE)	6.4 (0.13)	6.4 (0.13)
LS Mean Change (SE)	-0.4 (0.13)	-0.5 (0.13)
Column vs Placebo [3]		
Difference		0.0
95% CI		(-0.42, 0.33)
p-value		0.815
Corrected Hedges' g [4]		-0.02
95% CI		(-0.16, 0.13)

[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the given time point.
[3] Analysis performed using mixed model repeated measures with covariates of baseline score, geographic region, smoking status (current vs. never/ex-smoker), treatment and visit, plus interaction terms for visit by baseline and visit by treatment group.
[4] Based on covariate adjusted means.
Note: Estimates are based on weighting applied to each level of class variable determined from observed proportions.
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Population: Modified Intent-to-treat Population with Eosinophils 300 cells/uL or More

Table 211.33

Analysis of Change from Baseline in Evaluating Respiratory Symptoms in COPD (E-RS: COPD) Breathlessness Subscale Score - Mixed Model Repeated Measures (Study 208657)

Visit: Weeks 17-20

	PBO (N=401)	100 SC (N=403)
n [1]	398	402
n [2]	367	374
LS Mean (SE)	6.5 (0.13)	6.3 (0.13)
LS Mean Change (SE)	-0.4 (0.13)	-0.6 (0.13)
Column vs Placebo [3]		
Difference		-0.2
95% CI		(-0.56, 0.18)
p-value		0.326
Corrected Hedges' g [4]		-0.07
95% CI		(-0.22, 0.07)

[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the given time point.
[3] Analysis performed using mixed model repeated measures with covariates of baseline score, geographic region, smoking status (current vs. never/ex-smoker), treatment and visit, plus interaction terms for visit by baseline and visit by treatment group.
[4] Based on covariate adjusted means.
Note: Estimates are based on weighting applied to each level of class variable determined from observed proportions.
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Population: Modified Intent-to-treat Population with Eosinophils 300 cells/uL or More

Table 211.33

Analysis of Change from Baseline in Evaluating Respiratory Symptoms in COPD (E-RS: COPD)
Breathlessness Subscale Score - Mixed Model Repeated Measures (Study 208657)

Visit: Weeks 21-24

	PBO (N=401)	100 SC (N=403)
n [1]	398	402
n [2]	359	367
LS Mean (SE)	6.3 (0.14)	6.3 (0.13)
LS Mean Change (SE)	-0.5 (0.14)	-0.6 (0.13)
Column vs Placebo [3]		
Difference		0.0
95% CI		(-0.42, 0.33)
p-value		0.801
Corrected Hedges' g [4]		-0.02
95% CI		(-0.16, 0.13)

[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the given time point.
[3] Analysis performed using mixed model repeated measures with covariates of baseline score, geographic region, smoking status (current vs. never/ex-smoker), treatment and visit, plus interaction terms for visit by baseline and visit by treatment group.
[4] Based on covariate adjusted means.
Note: Estimates are based on weighting applied to each level of class variable determined from observed proportions.
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Population: Modified Intent-to-treat Population with Eosinophils 300 cells/uL or More

Table 211.33

Analysis of Change from Baseline in Evaluating Respiratory Symptoms in COPD (E-RS: COPD)
Breathlessness Subscale Score - Mixed Model Repeated Measures (Study 208657)

Visit: Weeks 25-28

	PBO (N=401)	100 SC (N=403)
n [1]	398	402
n [2]	356	363
LS Mean (SE)	6.4 (0.14)	6.1 (0.14)
LS Mean Change (SE)	-0.4 (0.14)	-0.7 (0.14)
Column vs Placebo [3]		
Difference		-0.3
95% CI		(-0.66, 0.11)
p-value		0.168
Corrected Hedges' g [4]		-0.10
95% CI		(-0.25, 0.04)

[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the given time point.
[3] Analysis performed using mixed model repeated measures with covariates of baseline score, geographic region, smoking status (current vs. never/ex-smoker), treatment and visit, plus interaction terms for visit by baseline and visit by treatment group.
[4] Based on covariate adjusted means.
Note: Estimates are based on weighting applied to each level of class variable determined from observed proportions.
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Population: Modified Intent-to-treat Population with Eosinophils 300 cells/uL or More

Table 211.33

Analysis of Change from Baseline in Evaluating Respiratory Symptoms in COPD (E-RS: COPD)
Breathlessness Subscale Score - Mixed Model Repeated Measures (Study 208657)

Visit: Weeks 29-32

	PBO (N=401)	100 SC (N=403)
n [1]	398	402
n [2]	359	366
LS Mean (SE)	6.3 (0.14)	6.2 (0.14)
LS Mean Change (SE)	-0.6 (0.14)	-0.7 (0.14)
Column vs Placebo [3]		
Difference		-0.1
95% CI		(-0.52, 0.27)
p-value		0.535
Corrected Hedges' g [4]		-0.05
95% CI		(-0.19, 0.10)

[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the given time point.
[3] Analysis performed using mixed model repeated measures with covariates of baseline score, geographic region, smoking status (current vs. never/ex-smoker), treatment and visit, plus interaction terms for visit by baseline and visit by treatment group.
[4] Based on covariate adjusted means.
Note: Estimates are based on weighting applied to each level of class variable determined from observed proportions.
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Population: Modified Intent-to-treat Population with Eosinophils 300 cells/uL or More

Table 211.33

Analysis of Change from Baseline in Evaluating Respiratory Symptoms in COPD (E-RS: COPD)
Breathlessness Subscale Score - Mixed Model Repeated Measures (Study 208657)

Visit: Weeks 33-36

	PBO (N=401)	100 SC (N=403)
n [1]	398	402
n [2]	354	360
LS Mean (SE)	6.2 (0.15)	6.2 (0.15)
LS Mean Change (SE)	-0.6 (0.15)	-0.7 (0.15)
Column vs Placebo [3]		
Difference		-0.1
95% CI		(-0.50, 0.32)
p-value		0.675
Corrected Hedges' g [4]		-0.03
95% CI		(-0.18, 0.12)

[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the given time point.
[3] Analysis performed using mixed model repeated measures with covariates of baseline score, geographic region, smoking status (current vs. never/ex-smoker), treatment and visit, plus interaction terms for visit by baseline and visit by treatment group.
[4] Based on covariate adjusted means.
Note: Estimates are based on weighting applied to each level of class variable determined from observed proportions.
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Population: Modified Intent-to-treat Population with Eosinophils 300 cells/uL or More

Table 211.33

Analysis of Change from Baseline in Evaluating Respiratory Symptoms in COPD (E-RS: COPD) Breathlessness Subscale Score - Mixed Model Repeated Measures (Study 208657)

Visit: Weeks 37-40

	PBO (N=401)	100 SC (N=403)
n [1]	398	402
n [2]	359	353
LS Mean (SE)	6.4 (0.15)	6.3 (0.15)
LS Mean Change (SE)	-0.5 (0.15)	-0.6 (0.15)
Column vs Placebo [3]		
Difference		-0.1
95% CI		(-0.53, 0.31)
p-value		0.604
Corrected Hedges' g [4]		-0.04
95% CI		(-0.19, 0.11)

[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the given time point.
[3] Analysis performed using mixed model repeated measures with covariates of baseline score, geographic region, smoking status (current vs. never/ex-smoker), treatment and visit, plus interaction terms for visit by baseline and visit by treatment group.
[4] Based on covariate adjusted means.
Note: Estimates are based on weighting applied to each level of class variable determined from observed proportions.
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Population: Modified Intent-to-treat Population with Eosinophils 300 cells/uL or More

Table 211.33

Analysis of Change from Baseline in Evaluating Respiratory Symptoms in COPD (E-RS: COPD) Breathlessness Subscale Score - Mixed Model Repeated Measures (Study 208657)

Visit: Weeks 41-44

	PBO (N=401)	100 SC (N=403)
n [1]	398	402
n [2]	352	347
LS Mean (SE)	6.3 (0.15)	6.2 (0.15)
LS Mean Change (SE)	-0.5 (0.15)	-0.6 (0.15)
Column vs Placebo [3]		
Difference		-0.1
95% CI		(-0.52, 0.32)
p-value		0.645
Corrected Hedges' g [4]		-0.03
95% CI		(-0.18, 0.11)

[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the given time point.
[3] Analysis performed using mixed model repeated measures with covariates of baseline score, geographic region, smoking status (current vs. never/ex-smoker), treatment and visit, plus interaction terms for visit by baseline and visit by treatment group.
[4] Based on covariate adjusted means.
Note: Estimates are based on weighting applied to each level of class variable determined from observed proportions.
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Population: Modified Intent-to-treat Population with Eosinophils 300 cells/uL or More

Table 211.33

Analysis of Change from Baseline in Evaluating Respiratory Symptoms in COPD (E-RS: COPD) Breathlessness Subscale Score - Mixed Model Repeated Measures (Study 208657)

Visit: Weeks 45-48

	PBO (N=401)	100 SC (N=403)
n [1]	398	402
n [2]	345	348
LS Mean (SE)	6.4 (0.15)	6.2 (0.15)
LS Mean Change (SE)	-0.5 (0.15)	-0.6 (0.15)
Column vs Placebo [3]		
Difference		-0.1
95% CI		(-0.56, 0.29)
p-value		0.534
Corrected Hedges' g [4]		-0.05
95% CI		(-0.20, 0.10)

[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the given time point.
[3] Analysis performed using mixed model repeated measures with covariates of baseline score, geographic region, smoking status (current vs. never/ex-smoker), treatment and visit, plus interaction terms for visit by baseline and visit by treatment group.
[4] Based on covariate adjusted means.
Note: Estimates are based on weighting applied to each level of class variable determined from observed proportions.
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Population: Modified Intent-to-treat Population with Eosinophils 300 cells/uL or More

Table 211.33

Analysis of Change from Baseline in Evaluating Respiratory Symptoms in COPD (E-RS: COPD) Breathlessness Subscale Score - Mixed Model Repeated Measures (Study 208657)

Visit: Weeks 49-52

	PBO (N=401)	100 SC (N=403)
n [1]	398	402
n [2]	324	331
LS Mean (SE)	6.4 (0.16)	6.2 (0.15)
LS Mean Change (SE)	-0.5 (0.16)	-0.6 (0.15)
Column vs Placebo [3]		
Difference		-0.2
95% CI		(-0.60, 0.26)
p-value		0.434
Corrected Hedges' g [4]		-0.06
95% CI		(-0.21, 0.09)

[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the given time point.
[3] Analysis performed using mixed model repeated measures with covariates of baseline score, geographic region, smoking status (current vs. never/ex-smoker), treatment and visit, plus interaction terms for visit by baseline and visit by treatment group.
[4] Based on covariate adjusted means.
Note: Estimates are based on weighting applied to each level of class variable determined from observed proportions.
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Population: Modified Intent-to-treat Population with Eosinophils 300 cells/uL or More

Table 211.34

Analysis of Change from Baseline in Evaluating Respiratory Symptoms in COPD (E-RS: COPD) Chest Subscale Score - Mixed Model Repeated Measures (Study 208657)

Visit: Weeks 1-4

	PBO (N=401)	100 SC (N=403)
n [1]	398	402
n [2]	389	400
LS Mean (SE)	2.8 (0.05)	2.6 (0.05)
LS Mean Change (SE)	-0.1 (0.05)	-0.2 (0.05)
Column vs Placebo [3]		
Difference		-0.1
95% CI		(-0.26, 0.02)
p-value		0.087
Corrected Hedges' g [4]		-0.12
95% CI		(-0.26, 0.02)

[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the given time point.
[3] Analysis performed using mixed model repeated measures with covariates of baseline score, geographic region, smoking status (current vs. never/ex-smoker), treatment and visit, plus interaction terms for visit by baseline and visit by treatment group.
[4] Based on covariate adjusted means.
Note: Estimates are based on weighting applied to each level of class variable determined from observed proportions.
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Population: Modified Intent-to-treat Population with Eosinophils 300 cells/uL or More

Table 211.34

Analysis of Change from Baseline in Evaluating Respiratory Symptoms in COPD (E-RS: COPD) Chest Subscale Score - Mixed Model Repeated Measures (Study 208657)

Visit: Weeks 5-8

	PBO (N=401)	100 SC (N=403)
n [1]	398	402
n [2]	384	392
LS Mean (SE)	2.7 (0.07)	2.6 (0.07)
LS Mean Change (SE)	-0.1 (0.07)	-0.3 (0.07)
Column vs Placebo [3]		
Difference		-0.2
95% CI		(-0.36, 0.01)
p-value		0.064
Corrected Hedges' g [4]		-0.13
95% CI		(-0.27, 0.01)

[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the given time point.
[3] Analysis performed using mixed model repeated measures with covariates of baseline score, geographic region, smoking status (current vs. never/ex-smoker), treatment and visit, plus interaction terms for visit by baseline and visit by treatment group.
[4] Based on covariate adjusted means.
Note: Estimates are based on weighting applied to each level of class variable determined from observed proportions.
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Population: Modified Intent-to-treat Population with Eosinophils 300 cells/uL or More

Table 211.34

Analysis of Change from Baseline in Evaluating Respiratory Symptoms in COPD (E-RS: COPD) Chest Subscale Score - Mixed Model Repeated Measures (Study 208657)

Visit: Weeks 9-12

	PBO (N=401)	100 SC (N=403)
n [1]	398	402
n [2]	384	390
LS Mean (SE)	2.7 (0.07)	2.5 (0.07)
LS Mean Change (SE)	-0.2 (0.07)	-0.3 (0.07)
Column vs Placebo [3]		
Difference		-0.2
95% CI		(-0.36, 0.05)
p-value		0.149
Corrected Hedges' g [4]		-0.10
95% CI		(-0.24, 0.04)

[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the given time point.
[3] Analysis performed using mixed model repeated measures with covariates of baseline score, geographic region, smoking status (current vs. never/ex-smoker), treatment and visit, plus interaction terms for visit by baseline and visit by treatment group.
[4] Based on covariate adjusted means.
Note: Estimates are based on weighting applied to each level of class variable determined from observed proportions.
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Population: Modified Intent-to-treat Population with Eosinophils 300 cells/uL or More

Table 211.34

Analysis of Change from Baseline in Evaluating Respiratory Symptoms in COPD (E-RS: COPD) Chest Subscale Score - Mixed Model Repeated Measures (Study 208657)

Visit: Weeks 13-16

	PBO (N=401)	100 SC (N=403)
n [1]	398	402
n [2]	370	381
LS Mean (SE)	2.7 (0.08)	2.6 (0.08)
LS Mean Change (SE)	-0.1 (0.08)	-0.3 (0.08)
Column vs Placebo [3]		
Difference		-0.2
95% CI		(-0.37, 0.06)
p-value		0.154
Corrected Hedges' g [4]		-0.10
95% CI		(-0.25, 0.04)

[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the given time point.
[3] Analysis performed using mixed model repeated measures with covariates of baseline score, geographic region, smoking status (current vs. never/ex-smoker), treatment and visit, plus interaction terms for visit by baseline and visit by treatment group.
[4] Based on covariate adjusted means.
Note: Estimates are based on weighting applied to each level of class variable determined from observed proportions.
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Population: Modified Intent-to-treat Population with Eosinophils 300 cells/uL or More

Table 211.34

Analysis of Change from Baseline in Evaluating Respiratory Symptoms in COPD (E-RS: COPD) Chest Subscale Score - Mixed Model Repeated Measures (Study 208657)

Visit: Weeks 17-20

	PBO (N=401)	100 SC (N=403)
n [1]	398	402
n [2]	367	374
LS Mean (SE)	2.7 (0.08)	2.5 (0.08)
LS Mean Change (SE)	-0.1 (0.08)	-0.3 (0.08)
Column vs Placebo [3]		
Difference		-0.2
95% CI		(-0.42, 0.02)
p-value		0.069
Corrected Hedges' g [4]		-0.13
95% CI		(-0.28, 0.01)

[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the given time point.
[3] Analysis performed using mixed model repeated measures with covariates of baseline score, geographic region, smoking status (current vs. never/ex-smoker), treatment and visit, plus interaction terms for visit by baseline and visit by treatment group.
[4] Based on covariate adjusted means.
Note: Estimates are based on weighting applied to each level of class variable determined from observed proportions.
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Population: Modified Intent-to-treat Population with Eosinophils 300 cells/uL or More

Table 211.34

Analysis of Change from Baseline in Evaluating Respiratory Symptoms in COPD (E-RS: COPD) Chest Subscale Score - Mixed Model Repeated Measures (Study 208657)

Visit: Weeks 21-24

	PBO (N=401)	100 SC (N=403)
n [1]	398	402
n [2]	359	367
LS Mean (SE)	2.6 (0.08)	2.5 (0.08)
LS Mean Change (SE)	-0.2 (0.08)	-0.3 (0.08)
Column vs Placebo [3]		
Difference		-0.1
95% CI		(-0.30, 0.15)
p-value		0.509
Corrected Hedges' g [4]		-0.05
95% CI		(-0.19, 0.10)

[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the given time point.
[3] Analysis performed using mixed model repeated measures with covariates of baseline score, geographic region, smoking status (current vs. never/ex-smoker), treatment and visit, plus interaction terms for visit by baseline and visit by treatment group.
[4] Based on covariate adjusted means.
Note: Estimates are based on weighting applied to each level of class variable determined from observed proportions.
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Population: Modified Intent-to-treat Population with Eosinophils 300 cells/uL or More

Table 211.34

Analysis of Change from Baseline in Evaluating Respiratory Symptoms in COPD (E-RS: COPD) Chest Subscale Score - Mixed Model Repeated Measures (Study 208657)

Visit: Weeks 25-28

	PBO (N=401)	100 SC (N=403)
n [1]	398	402
n [2]	356	363
LS Mean (SE)	2.6 (0.08)	2.5 (0.08)
LS Mean Change (SE)	-0.2 (0.08)	-0.4 (0.08)
Column vs Placebo [3]		
Difference		-0.1
95% CI		(-0.37, 0.09)
p-value		0.227
Corrected Hedges' g [4]		-0.09
95% CI		(-0.24, 0.06)

[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the given time point.
[3] Analysis performed using mixed model repeated measures with covariates of baseline score, geographic region, smoking status (current vs. never/ex-smoker), treatment and visit, plus interaction terms for visit by baseline and visit by treatment group.
[4] Based on covariate adjusted means.
Note: Estimates are based on weighting applied to each level of class variable determined from observed proportions.
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Population: Modified Intent-to-treat Population with Eosinophils 300 cells/uL or More

Table 211.34

Analysis of Change from Baseline in Evaluating Respiratory Symptoms in COPD (E-RS: COPD) Chest Subscale Score - Mixed Model Repeated Measures (Study 208657)

Visit: Weeks 29-32

	PBO (N=401)	100 SC (N=403)
n [1]	398	402
n [2]	359	366
LS Mean (SE)	2.5 (0.09)	2.5 (0.09)
LS Mean Change (SE)	-0.3 (0.09)	-0.3 (0.09)
Column vs Placebo [3]		
Difference		0.0
95% CI		(-0.25, 0.22)
p-value		0.904
Corrected Hedges' g [4]		-0.01
95% CI		(-0.15, 0.14)

[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the given time point.
[3] Analysis performed using mixed model repeated measures with covariates of baseline score, geographic region, smoking status (current vs. never/ex-smoker), treatment and visit, plus interaction terms for visit by baseline and visit by treatment group.
[4] Based on covariate adjusted means.
Note: Estimates are based on weighting applied to each level of class variable determined from observed proportions.
/mnt/code/postcsr_01/prod/tfls/t_e_mmrm_ers_chst.sas 30OCT2025 13:32

Population: Modified Intent-to-treat Population with Eosinophils 300 cells/uL or More

Table 211.34

Analysis of Change from Baseline in Evaluating Respiratory Symptoms in COPD (E-RS: COPD) Chest Subscale Score - Mixed Model Repeated Measures (Study 208657)

Visit: Weeks 33-36

	PBO (N=401)	100 SC (N=403)
n [1]	398	402
n [2]	354	360
LS Mean (SE)	2.6 (0.09)	2.5 (0.09)
LS Mean Change (SE)	-0.3 (0.09)	-0.3 (0.09)
Column vs Placebo [3]		
Difference		0.0
95% CI		(-0.28, 0.19)
p-value		0.697
Corrected Hedges' g [4]		-0.03
95% CI		(-0.18, 0.12)

[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the given time point.
[3] Analysis performed using mixed model repeated measures with covariates of baseline score, geographic region, smoking status (current vs. never/ex-smoker), treatment and visit, plus interaction terms for visit by baseline and visit by treatment group.
[4] Based on covariate adjusted means.
Note: Estimates are based on weighting applied to each level of class variable determined from observed proportions.
/mnt/code/postcsr_01/prod/tfls/t_e_mmrm_ers_chst.sas 30OCT2025 13:32

Population: Modified Intent-to-treat Population with Eosinophils 300 cells/uL or More

Table 211.34

Analysis of Change from Baseline in Evaluating Respiratory Symptoms in COPD (E-RS: COPD) Chest Subscale Score - Mixed Model Repeated Measures (Study 208657)

Visit: Weeks 37-40

	PBO (N=401)	100 SC (N=403)
n [1]	398	402
n [2]	359	353
LS Mean (SE)	2.6 (0.09)	2.6 (0.09)
LS Mean Change (SE)	-0.2 (0.09)	-0.3 (0.09)
Column vs Placebo [3]		
Difference		0.0
95% CI		(-0.29, 0.20)
p-value		0.698
Corrected Hedges' g [4]		-0.03
95% CI		(-0.18, 0.12)

[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the given time point.
[3] Analysis performed using mixed model repeated measures with covariates of baseline score, geographic region, smoking status (current vs. never/ex-smoker), treatment and visit, plus interaction terms for visit by baseline and visit by treatment group.
[4] Based on covariate adjusted means.
Note: Estimates are based on weighting applied to each level of class variable determined from observed proportions.
/mnt/code/postcsr_01/prod/tfls/t_e_mmrm_ers_chst.sas 30OCT2025 13:32

Population: Modified Intent-to-treat Population with Eosinophils 300 cells/uL or More

Table 211.34

Analysis of Change from Baseline in Evaluating Respiratory Symptoms in COPD (E-RS: COPD) Chest Subscale Score - Mixed Model Repeated Measures (Study 208657)

Visit: Weeks 41-44

	PBO (N=401)	100 SC (N=403)
n [1]	398	402
n [2]	352	347
LS Mean (SE)	2.6 (0.09)	2.5 (0.09)
LS Mean Change (SE)	-0.2 (0.09)	-0.3 (0.09)
Column vs Placebo [3]		
Difference		-0.1
95% CI		(-0.31, 0.18)
p-value		0.587
Corrected Hedges' g [4]		-0.04
95% CI		(-0.19, 0.11)

[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the given time point.
[3] Analysis performed using mixed model repeated measures with covariates of baseline score, geographic region, smoking status (current vs. never/ex-smoker), treatment and visit, plus interaction terms for visit by baseline and visit by treatment group.
[4] Based on covariate adjusted means.
Note: Estimates are based on weighting applied to each level of class variable determined from observed proportions.
/mnt/code/postcsr_01/prod/tfls/t_e_mmrm_ers_chst.sas 30OCT2025 13:32

Population: Modified Intent-to-treat Population with Eosinophils 300 cells/uL or More

Table 211.34

Analysis of Change from Baseline in Evaluating Respiratory Symptoms in COPD (E-RS: COPD) Chest Subscale Score - Mixed Model Repeated Measures (Study 208657)

Visit: Weeks 45-48

	PBO (N=401)	100 SC (N=403)
n [1]	398	402
n [2]	345	348
LS Mean (SE)	2.6 (0.09)	2.5 (0.09)
LS Mean Change (SE)	-0.3 (0.09)	-0.3 (0.09)
Column vs Placebo [3]		
Difference		-0.1
95% CI		(-0.29, 0.19)
p-value		0.679
Corrected Hedges' g [4]		-0.03
95% CI		(-0.18, 0.12)

[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the given time point.
[3] Analysis performed using mixed model repeated measures with covariates of baseline score, geographic region, smoking status (current vs. never/ex-smoker), treatment and visit, plus interaction terms for visit by baseline and visit by treatment group.
[4] Based on covariate adjusted means.
Note: Estimates are based on weighting applied to each level of class variable determined from observed proportions.
/mnt/code/postcsr_01/prod/tfls/t_e_mmrm_ers_chst.sas 30OCT2025 13:32

Population: Modified Intent-to-treat Population with Eosinophils 300 cells/uL or More

Table 211.34

Analysis of Change from Baseline in Evaluating Respiratory Symptoms in COPD (E-RS: COPD) Chest Subscale Score - Mixed Model Repeated Measures (Study 208657)

Visit: Weeks 49-52

	PBO (N=401)	100 SC (N=403)
n [1]	398	402
n [2]	324	331
LS Mean (SE)	2.6 (0.09)	2.5 (0.09)
LS Mean Change (SE)	-0.3 (0.09)	-0.3 (0.09)
Column vs Placebo [3]		
Difference		0.0
95% CI		(-0.26, 0.23)
p-value		0.901
Corrected Hedges' g [4]		-0.01
95% CI		(-0.16, 0.14)

[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the given time point.
[3] Analysis performed using mixed model repeated measures with covariates of baseline score, geographic region, smoking status (current vs. never/ex-smoker), treatment and visit, plus interaction terms for visit by baseline and visit by treatment group.
[4] Based on covariate adjusted means.
Note: Estimates are based on weighting applied to each level of class variable determined from observed proportions.
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Population: Modified Intent-to-treat Population with Eosinophils 300 cells/uL or More

Table 211.35

Analysis of Change from Baseline in Evaluating Respiratory Symptoms in COPD (E-RS: COPD)
Cough and Sputum Subscale Score - Mixed Model Repeated Measures (Study 208657)

Visit: Weeks 1-4

	PBO (N=401)	100 SC (N=403)
n [1]	398	402
n [2]	389	400
LS Mean (SE)	3.1 (0.04)	3.0 (0.04)
LS Mean Change (SE)	-0.2 (0.04)	-0.2 (0.04)
Column vs Placebo [3]		
Difference		-0.1
95% CI		(-0.18, 0.07)
p-value		0.361
Corrected Hedges' g [4]		-0.07
95% CI		(-0.20, 0.07)

[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the given time point.
[3] Analysis performed using mixed model repeated measures with covariates of baseline score, geographic region, smoking status (current vs. never/ex-smoker), treatment and visit, plus interaction terms for visit by baseline and visit by treatment group.
[4] Based on covariate adjusted means.
Note: Estimates are based on weighting applied to each level of class variable determined from observed proportions.
/mnt/code/postcsr_01/prod/tfls/t_e_mmrm_ers_cghs.sas 30OCT2025 13:30

Population: Modified Intent-to-treat Population with Eosinophils 300 cells/uL or More

Table 211.35

Analysis of Change from Baseline in Evaluating Respiratory Symptoms in COPD (E-RS: COPD)
Cough and Sputum Subscale Score - Mixed Model Repeated Measures (Study 208657)

Visit: Weeks 5-8

	PBO (N=401)	100 SC (N=403)
n [1]	398	402
n [2]	384	392
LS Mean (SE)	2.9 (0.06)	2.8 (0.06)
LS Mean Change (SE)	-0.3 (0.06)	-0.4 (0.06)
Column vs Placebo [3]		
Difference		-0.1
95% CI		(-0.25, 0.06)
p-value		0.233
Corrected Hedges' g [4]		-0.09
95% CI		(-0.23, 0.06)

[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the given time point.
[3] Analysis performed using mixed model repeated measures with covariates of baseline score, geographic region, smoking status (current vs. never/ex-smoker), treatment and visit, plus interaction terms for visit by baseline and visit by treatment group.
[4] Based on covariate adjusted means.
Note: Estimates are based on weighting applied to each level of class variable determined from observed proportions.
/mnt/code/postcsr_01/prod/tfls/t_e_mmrm_ers_cghs.sas 30OCT2025 13:30

Population: Modified Intent-to-treat Population with Eosinophils 300 cells/uL or More

Table 211.35

Analysis of Change from Baseline in Evaluating Respiratory Symptoms in COPD (E-RS: COPD)
Cough and Sputum Subscale Score - Mixed Model Repeated Measures (Study 208657)

Visit: Weeks 9-12

	PBO (N=401)	100 SC (N=403)
n [1]	398	402
n [2]	384	390
LS Mean (SE)	2.9 (0.06)	2.8 (0.06)
LS Mean Change (SE)	-0.3 (0.06)	-0.4 (0.06)
Column vs Placebo [3]		
Difference		-0.1
95% CI		(-0.27, 0.08)
p-value		0.273
Corrected Hedges' g [4]		-0.08
95% CI		(-0.22, 0.06)

[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the given time point.
[3] Analysis performed using mixed model repeated measures with covariates of baseline score, geographic region, smoking status (current vs. never/ex-smoker), treatment and visit, plus interaction terms for visit by baseline and visit by treatment group.
[4] Based on covariate adjusted means.
Note: Estimates are based on weighting applied to each level of class variable determined from observed proportions.
/mnt/code/postcsr_01/prod/tfls/t_e_mmrm_ers_cghs.sas 30OCT2025 13:30

Population: Modified Intent-to-treat Population with Eosinophils 300 cells/uL or More

Table 211.35

Analysis of Change from Baseline in Evaluating Respiratory Symptoms in COPD (E-RS: COPD)
Cough and Sputum Subscale Score - Mixed Model Repeated Measures (Study 208657)

Visit: Weeks 13-16

	PBO (N=401)	100 SC (N=403)
n [1]	398	402
n [2]	370	381
LS Mean (SE)	2.9 (0.07)	2.8 (0.06)
LS Mean Change (SE)	-0.4 (0.07)	-0.5 (0.06)
Column vs Placebo [3]		
Difference		-0.1
95% CI		(-0.29, 0.07)
p-value		0.213
Corrected Hedges' g [4]		-0.09
95% CI		(-0.23, 0.05)

[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the given time point.
[3] Analysis performed using mixed model repeated measures with covariates of baseline score, geographic region, smoking status (current vs. never/ex-smoker), treatment and visit, plus interaction terms for visit by baseline and visit by treatment group.
[4] Based on covariate adjusted means.
Note: Estimates are based on weighting applied to each level of class variable determined from observed proportions.
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Population: Modified Intent-to-treat Population with Eosinophils 300 cells/uL or More

Table 211.35

Analysis of Change from Baseline in Evaluating Respiratory Symptoms in COPD (E-RS: COPD)
Cough and Sputum Subscale Score - Mixed Model Repeated Measures (Study 208657)

Visit: Weeks 17-20

	PBO (N=401)	100 SC (N=403)
n [1]	398	402
n [2]	367	374
LS Mean (SE)	2.9 (0.07)	2.7 (0.07)
LS Mean Change (SE)	-0.4 (0.07)	-0.5 (0.07)
Column vs Placebo [3]		
Difference		-0.1
95% CI		(-0.32, 0.04)
p-value		0.134
Corrected Hedges' g [4]		-0.11
95% CI		(-0.25, 0.03)

[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the given time point.
[3] Analysis performed using mixed model repeated measures with covariates of baseline score, geographic region, smoking status (current vs. never/ex-smoker), treatment and visit, plus interaction terms for visit by baseline and visit by treatment group.
[4] Based on covariate adjusted means.
Note: Estimates are based on weighting applied to each level of class variable determined from observed proportions.
/mnt/code/postcsr_01/prod/tfls/t_e_mmrm_ers_cghs.sas 30OCT2025 13:30

Population: Modified Intent-to-treat Population with Eosinophils 300 cells/uL or More

Table 211.35

Analysis of Change from Baseline in Evaluating Respiratory Symptoms in COPD (E-RS: COPD)
Cough and Sputum Subscale Score - Mixed Model Repeated Measures (Study 208657)

Visit: Weeks 21-24

	PBO (N=401)	100 SC (N=403)
n [1]	398	402
n [2]	359	367
LS Mean (SE)	2.8 (0.07)	2.7 (0.07)
LS Mean Change (SE)	-0.5 (0.07)	-0.5 (0.07)
Column vs Placebo [3]		
Difference		-0.1
95% CI		(-0.26, 0.10)
p-value		0.396
Corrected Hedges' g [4]		-0.06
95% CI		(-0.21, 0.08)

[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the given time point.
[3] Analysis performed using mixed model repeated measures with covariates of baseline score, geographic region, smoking status (current vs. never/ex-smoker), treatment and visit, plus interaction terms for visit by baseline and visit by treatment group.
[4] Based on covariate adjusted means.
Note: Estimates are based on weighting applied to each level of class variable determined from observed proportions.
/mnt/code/postcsr_01/prod/tfls/t_e_mmrm_ers_cghs.sas 30OCT2025 13:30

Population: Modified Intent-to-treat Population with Eosinophils 300 cells/uL or More

Table 211.35

Analysis of Change from Baseline in Evaluating Respiratory Symptoms in COPD (E-RS: COPD)
Cough and Sputum Subscale Score - Mixed Model Repeated Measures (Study 208657)

Visit: Weeks 25-28

	PBO (N=401)	100 SC (N=403)
n [1]	398	402
n [2]	356	363
LS Mean (SE)	2.8 (0.07)	2.7 (0.07)
LS Mean Change (SE)	-0.4 (0.07)	-0.5 (0.07)
Column vs Placebo [3]		
Difference		-0.1
95% CI		(-0.30, 0.09)
p-value		0.280
Corrected Hedges' g [4]		-0.08
95% CI		(-0.23, 0.07)

[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the given time point.
[3] Analysis performed using mixed model repeated measures with covariates of baseline score, geographic region, smoking status (current vs. never/ex-smoker), treatment and visit, plus interaction terms for visit by baseline and visit by treatment group.
[4] Based on covariate adjusted means.
Note: Estimates are based on weighting applied to each level of class variable determined from observed proportions.
/mnt/code/postcsr_01/prod/tfls/t_e_mmrm_ers_cghs.sas 30OCT2025 13:30

Population: Modified Intent-to-treat Population with Eosinophils 300 cells/uL or More

Table 211.35

Analysis of Change from Baseline in Evaluating Respiratory Symptoms in COPD (E-RS: COPD)
Cough and Sputum Subscale Score - Mixed Model Repeated Measures (Study 208657)

Visit: Weeks 29-32

	PBO (N=401)	100 SC (N=403)
n [1]	398	402
n [2]	359	366
LS Mean (SE)	2.8 (0.07)	2.7 (0.07)
LS Mean Change (SE)	-0.5 (0.07)	-0.6 (0.07)
Column vs Placebo [3]		
Difference		-0.1
95% CI		(-0.25, 0.14)
p-value		0.564
Corrected Hedges' g [4]		-0.04
95% CI		(-0.19, 0.10)

[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the given time point.
[3] Analysis performed using mixed model repeated measures with covariates of baseline score, geographic region, smoking status (current vs. never/ex-smoker), treatment and visit, plus interaction terms for visit by baseline and visit by treatment group.
[4] Based on covariate adjusted means.
Note: Estimates are based on weighting applied to each level of class variable determined from observed proportions.
/mnt/code/postcsr_01/prod/tfls/t_e_mmrm_ers_cghs.sas 30OCT2025 13:30

Population: Modified Intent-to-treat Population with Eosinophils 300 cells/uL or More

Table 211.35

Analysis of Change from Baseline in Evaluating Respiratory Symptoms in COPD (E-RS: COPD)
Cough and Sputum Subscale Score - Mixed Model Repeated Measures (Study 208657)

Visit: Weeks 33-36

	PBO (N=401)	100 SC (N=403)
n [1]	398	402
n [2]	354	360
LS Mean (SE)	2.7 (0.07)	2.7 (0.07)
LS Mean Change (SE)	-0.5 (0.07)	-0.5 (0.07)
Column vs Placebo [3]		
Difference		0.0
95% CI		(-0.20, 0.20)
p-value		0.992
Corrected Hedges' g [4]		0.00
95% CI		(-0.15, 0.15)

[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the given time point.
[3] Analysis performed using mixed model repeated measures with covariates of baseline score, geographic region, smoking status (current vs. never/ex-smoker), treatment and visit, plus interaction terms for visit by baseline and visit by treatment group.
[4] Based on covariate adjusted means.
Note: Estimates are based on weighting applied to each level of class variable determined from observed proportions.
/mnt/code/postcsr_01/prod/tfls/t_e_mmrm_ers_cghs.sas 30OCT2025 13:30

Population: Modified Intent-to-treat Population with Eosinophils 300 cells/uL or More

Table 211.35

Analysis of Change from Baseline in Evaluating Respiratory Symptoms in COPD (E-RS: COPD)
Cough and Sputum Subscale Score - Mixed Model Repeated Measures (Study 208657)

Visit: Weeks 37-40

	PBO (N=401)	100 SC (N=403)
n [1]	398	402
n [2]	359	353
LS Mean (SE)	2.8 (0.07)	2.8 (0.07)
LS Mean Change (SE)	-0.5 (0.07)	-0.5 (0.07)
Column vs Placebo [3]		
Difference		0.0
95% CI		(-0.20, 0.21)
p-value		0.948
Corrected Hedges' g [4]		0.00
95% CI		(-0.14, 0.15)

[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the given time point.
[3] Analysis performed using mixed model repeated measures with covariates of baseline score, geographic region, smoking status (current vs. never/ex-smoker), treatment and visit, plus interaction terms for visit by baseline and visit by treatment group.
[4] Based on covariate adjusted means.
Note: Estimates are based on weighting applied to each level of class variable determined from observed proportions.
/mnt/code/postcsr_01/prod/tfls/t_e_mmrm_ers_cghs.sas 30OCT2025 13:30

Population: Modified Intent-to-treat Population with Eosinophils 300 cells/uL or More

Table 211.35

Analysis of Change from Baseline in Evaluating Respiratory Symptoms in COPD (E-RS: COPD)
Cough and Sputum Subscale Score - Mixed Model Repeated Measures (Study 208657)

Visit: Weeks 41-44

	PBO (N=401)	100 SC (N=403)
n [1]	398	402
n [2]	352	347
LS Mean (SE)	2.8 (0.07)	2.7 (0.07)
LS Mean Change (SE)	-0.5 (0.07)	-0.5 (0.07)
Column vs Placebo [3]		
Difference		0.0
95% CI		(-0.24, 0.16)
p-value		0.670
Corrected Hedges' g [4]		-0.03
95% CI		(-0.18, 0.12)

[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the given time point.
[3] Analysis performed using mixed model repeated measures with covariates of baseline score, geographic region, smoking status (current vs. never/ex-smoker), treatment and visit, plus interaction terms for visit by baseline and visit by treatment group.
[4] Based on covariate adjusted means.
Note: Estimates are based on weighting applied to each level of class variable determined from observed proportions.
/mnt/code/postcsr_01/prod/tfls/t_e_mmrm_ers_cghs.sas 30OCT2025 13:30

Population: Modified Intent-to-treat Population with Eosinophils 300 cells/uL or More

Table 211.35

Analysis of Change from Baseline in Evaluating Respiratory Symptoms in COPD (E-RS: COPD)
Cough and Sputum Subscale Score - Mixed Model Repeated Measures (Study 208657)

Visit: Weeks 45-48

	PBO (N=401)	100 SC (N=403)
n [1]	398	402
n [2]	345	348
LS Mean (SE)	2.8 (0.07)	2.7 (0.07)
LS Mean Change (SE)	-0.5 (0.07)	-0.5 (0.07)
Column vs Placebo [3]		
Difference		0.0
95% CI		(-0.23, 0.17)
p-value		0.752
Corrected Hedges' g [4]		-0.02
95% CI		(-0.17, 0.12)

[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the given time point.
[3] Analysis performed using mixed model repeated measures with covariates of baseline score, geographic region, smoking status (current vs. never/ex-smoker), treatment and visit, plus interaction terms for visit by baseline and visit by treatment group.
[4] Based on covariate adjusted means.
Note: Estimates are based on weighting applied to each level of class variable determined from observed proportions.
/mnt/code/postcsr_01/prod/tfls/t_e_mmrm_ers_cghs.sas 30OCT2025 13:30

Population: Modified Intent-to-treat Population with Eosinophils 300 cells/uL or More

Table 211.35

Analysis of Change from Baseline in Evaluating Respiratory Symptoms in COPD (E-RS: COPD)
Cough and Sputum Subscale Score - Mixed Model Repeated Measures (Study 208657)

Visit: Weeks 49-52

	PBO (N=401)	100 SC (N=403)
n [1]	398	402
n [2]	324	331
LS Mean (SE)	2.8 (0.07)	2.7 (0.07)
LS Mean Change (SE)	-0.5 (0.07)	-0.5 (0.07)
Column vs Placebo [3]		
Difference		0.0
95% CI		(-0.25, 0.16)
p-value		0.651
Corrected Hedges' g [4]		-0.04
95% CI		(-0.19, 0.12)

[1] Number of subjects with analysable data for one or more time points.
[2] Number of subjects with analysable data at the given time point.
[3] Analysis performed using mixed model repeated measures with covariates of baseline score, geographic region, smoking status (current vs. never/ex-smoker), treatment and visit, plus interaction terms for visit by baseline and visit by treatment group.
[4] Based on covariate adjusted means.
Note: Estimates are based on weighting applied to each level of class variable determined from observed proportions.
/mnt/code/postcsr_01/prod/tfls/t_e_mmrm_ers_cghs.sas 30OCT2025 13:30

Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Table 211.36

Proportion of Subjects Requiring Re-hospitalization for a COPD exacerbation within 30 Days of a Previous Hospitalization for a COPD Exacerbation: Individual Studies and Meta-Analysis

	PBO (N=578)	100 SC (N=568)
MEA117113		
n	87	83
Re-hospitalization for COPD exacerbation within 30 Days	0	1 (1%)
No re-hospitalization for a COPD exacerbation within 30 Days	87 (100%)	82 (99%)
Odds Ratio to Placebo [1]		Non-Est
95% CI		Non-Est
Relative Risk [2]		Non-Est
95% CI		Non-Est
p-value		Non-Est
Absolute Risk Reduction [2]		Non-Est
95% CI		Non-Est

[1] Analysis performed using a logistic regression model with covariates of geographic region (as defined for the study/ISE), smoking status (current vs. never/ex-smoker) and treatment group.
[2] Analysis used poisson regression model with covariates as in [1] (risk difference uses identity link).
[3] Analysis model as in footnote [1] and [2] with an additional covariate of study.
[4] Analysis model as in footnote [3] with an additional covariate of study*treatment interaction.
/mnt/code/postcsr_01/prod/tfls/t_e_exac_copd.sas 25JUL2025 11:09

Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Table 211.36

Proportion of Subjects Requiring Re-hospitalization for a COPD exacerbation within 30 Days of a Previous Hospitalization for a COPD Exacerbation: Individual Studies and Meta-Analysis

	PBO (N=578)	100 SC (N=568)
MEA117106		
n	90	82
Re-hospitalization for COPD exacerbation within 30 Days	3 (3%)	2 (2%)
No re-hospitalization for a COPD exacerbation within 30 Days	87 (97%)	80 (98%)
Odds Ratio to Placebo [1]		Non-Est
95% CI		Non-Est
Relative Risk [2]		0.70
95% CI		(0.12, 4.20)
p-value		0.697
Absolute Risk Reduction [2]		Non-Est
95% CI		Non-Est

[1] Analysis performed using a logistic regression model with covariates of geographic region (as defined for the study/ISE), smoking status (current vs. never/ex-smoker) and treatment group.
[2] Analysis used poisson regression model with covariates as in [1] (risk difference uses identity link).
[3] Analysis model as in footnote [1] and [2] with an additional covariate of study.
[4] Analysis model as in footnote [3] with an additional covariate of study*treatment interaction.
/mnt/code/postcsr_01/prod/tfls/t_e_exac_copd.sas 25JUL2025 11:09

Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Table 211.36

Proportion of Subjects Requiring Re-hospitalization for a COPD exacerbation within 30 Days of a Previous Hospitalization for a COPD Exacerbation: Individual Studies and Meta-Analysis

	PBO (N=578)	100 SC (N=568)
MEA117113 + MEA117106		
n	177	165
Re-hospitalization for COPD exacerbation within 30 Days	3 (2%)	3 (2%)
No re-hospitalization for a COPD exacerbation within 30 Days	174 (98%)	162 (98%)
Odds Ratio to Placebo [1,3]		Non-Est
95% CI		Non-Est
Relative Risk [2,3]		1.09
95% CI		(0.22, 5.40)
p-value		0.916
Absolute Risk Reduction [2,3]		Non-Est
95% CI		Non-Est
p-value for study*treatment interaction [4]		0.208

[1] Analysis performed using a logistic regression model with covariates of geographic region (as defined for the study/ISE), smoking status (current vs. never/ex-smoker) and treatment group.
[2] Analysis used poisson regression model with covariates as in [1] (risk difference uses identity link).
[3] Analysis model as in footnote [1] and [2] with an additional covariate of study.
[4] Analysis model as in footnote [3] with an additional covariate of study*treatment interaction.
/mnt/code/postcsr_01/prod/tfls/t_e_exac_copd.sas 25JUL2025 11:09

Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Table 211.37

Proportion of Subjects Requiring Re-hospitalization for any reason within 30 Days of a Previous Hospitalization for a COPD Exacerbation: Individual Studies and Meta-Analysis

	PBO (N=578)	100 SC (N=568)
MEA117113		
n	87	83
Re-hospitalization for any reason within 30 Days	1 (1%)	2 (2%)
No re-hospitalization for any reason within 30 Days	86 (99%)	81 (98%)
Odds Ratio to Placebo [1]		Non-Est
95% CI		Non-Est
Relative Risk [2]		Non-Est
95% CI		Non-Est
p-value		Non-Est
Absolute Risk Reduction [2]		Non-Est
95% CI		Non-Est

[1] Analysis performed using a logistic regression model with covariates of geographic region (as defined for the study/ISE), smoking status (current vs. never/ex-smoker) and treatment group.
[2] Analysis used poisson regression model with covariates as in [1] (risk difference uses identity link).
[3] Analysis model as in footnote [1] and [2] with an additional covariate of study.
[4] Analysis model as in footnote [3] with an additional covariate of study*treatment interaction.
Note: Odds Ratio <1, Relative Risk < 1, risk difference < 0 correspond to a benefit of Mepolizumab over Placebo.
/mnt/code/postcsr_01/prod/tfls/t_e_exac_any.sas 25JUL2025 11:10

Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Table 211.37

Proportion of Subjects Requiring Re-hospitalization for any reason within 30 Days of a Previous Hospitalization for a COPD Exacerbation: Individual Studies and Meta-Analysis

	PBO (N=578)	100 SC (N=568)
MEA117106		
n	90	82
Re-hospitalization for any reason within 30 Days	5 (6%)	3 (4%)
No re-hospitalization for any reason within 30 Days	85 (94%)	79 (96%)
Odds Ratio to Placebo [1]		Non-Est
95% CI		Non-Est
Relative Risk [2]		0.62
95% CI		(0.15, 2.60)
p-value		0.513
Absolute Risk Reduction [2]		Non-Est
95% CI		Non-Est

[1] Analysis performed using a logistic regression model with covariates of geographic region (as defined for the study/ISE), smoking status (current vs. never/ex-smoker) and treatment group.
[2] Analysis used poisson regression model with covariates as in [1] (risk difference uses identity link).
[3] Analysis model as in footnote [1] and [2] with an additional covariate of study.
[4] Analysis model as in footnote [3] with an additional covariate of study*treatment interaction.
Note: Odds Ratio <1, Relative Risk < 1, risk difference < 0 correspond to a benefit of Mepolizumab over Placebo.
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Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Table 211.37

Proportion of Subjects Requiring Re-hospitalization for any reason within 30 Days of a Previous Hospitalization for a COPD Exacerbation: Individual Studies and Meta-Analysis

	PBO (N=578)	100 SC (N=568)
MEA117113 + MEA117106		
n	177	165
Re-hospitalization for any reason within 30 Days	6 (3%)	5 (3%)
No re-hospitalization for any reason within 30 Days	171 (97%)	160 (97%)
Odds Ratio to Placebo [1,3]		Non-Est
95% CI		Non-Est
Relative Risk [2,3]		0.90
95% CI		(0.28, 2.96)
p-value		0.867
Absolute Risk Reduction [2,3]		Non-Est
95% CI		Non-Est
p-value for study*treatment interaction [4]		0.396

[1] Analysis performed using a logistic regression model with covariates of geographic region (as defined for the study/ISE), smoking status (current vs. never/ex-smoker) and treatment group.
[2] Analysis used poisson regression model with covariates as in [1] (risk difference uses identity link).
[3] Analysis model as in footnote [1] and [2] with an additional covariate of study.
[4] Analysis model as in footnote [3] with an additional covariate of study*treatment interaction.
Note: Odds Ratio <1, Relative Risk < 1, risk difference < 0 correspond to a benefit of Mepolizumab over Placebo.
/mnt/code/postcsr_01/prod/tfls/t_e_exac_any.sas 25JUL2025 11:10

Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Table 211.38

Analysis of PGI-S Responders at Week 52: Participants Achieving ≥1-step Improvement from baseline

(Study 208657)

	PBO (N=401)		100 SC (N=403)	
n	391		387	
Responder [1]	79	(20%)	101	(26%)
Non-responder	312	(80%)	286	(74%)
No change/worsening	266	(68%)	235	(61%)
Withdrawal from study prior to visit	26	(7%)	30	(8%)
Missing visit [2]	20	(5%)	21	(5%)
Inverse Odds Ratio to Placebo [3]			0.73	
95% CI			(0.51, 1.05)	
Inverse Relative Risk [4]			0.81	
95% CI			(0.60, 1.09)	
p-value			0.164	
Absolute Risk Reduction [4]			-0.04	
95% CI			(-0.23, 0.15)	

[1] Defined as a participant achieving >=1-step improvement from baseline.
[2] Participants with an intercurrent event of either treatment interruption or treatment discontinuation related to the COVID-19 pandemic have data set to missing following the event. Missing data was not imputed.
[3] Analysis performed using a logistic regression model with covariates of baseline score, geographic region (as defined for the study/ISE), smoking status (current vs. never/ex-smoker) and treatment group.
[4] Analysis used poisson regression model with covariates as in [3] (risk difference uses identity link).
Note: Inverse Odds Ratio <1, Inverse Relative Risk < 1, risk difference < 0 correspond to a benefit of Mepolizumab over Placebo.
/mnt/code/postcsr_01/prod/tfls/t_e_pgis_resp.sas 25JUL2025 11:09

Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Table 211.39

Analysis of PGI-C Responders at Week 52: Participants Achieving Categories of “much better”, “better” or “slightly better” (Study 208657)

	PBO (N=401)		100 SC (N=403)	
n	401		403	
Responder [1]	248	(62%)	246	(61%)
Non-responder	153	(38%)	157	(39%)
No change/worsening	88	(22%)	91	(23%)
Withdrawal from study prior to visit	39	(10%)	39	(10%)
Missing visit [2]	26	(6%)	27	(7%)
Inverse Odds Ratio to Placebo [3]			1.03	
95% CI			(0.76, 1.38)	
Inverse Relative Risk [4]			1.01	
95% CI			(0.85, 1.20)	
p-value			0.913	
Absolute Risk Reduction [4]			0.01	
95% CI			(-0.16, 0.17)	

[1] Defined as achieving categories of 'much better', 'better' or 'slightly better' (improvement).
[2] Participants with an intercurrent event of either treatment interruption or treatment discontinuation related to the COVID-19 pandemic have data set to missing following the event. Missing data was not imputed.
[3] Analysis performed using a logistic regression model with covariates of geographic region (as defined for the study/ISE), smoking status (current vs. never/ex-smoker) and treatment group.
[4] Analysis used poisson regression model with covariates as in [3] (risk difference uses identity link).
Note: Inverse Odds Ratio <1, Inverse Relative Risk < 1, risk difference < 0 correspond to a benefit of Mepolizumab over Placebo.
/mnt/code/postcsr_01/prod/tfls/t_e_pgic_resp.sas 25JUL2025 11:10

Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Table 211.40

Analysis of Subject Global Rating of Activity Limitation Responders at Week 52:
Participants Achieving Changes in the Status to Next Higher Categories from Baseline
(Studies MEA117113 and MEA117106)

	PBO (N=177)	100 SC (N=165)
MEA117113		
n	86	80
Responder [1]	18 (21%)	25 (31%)
Non-responder	68 (79%)	55 (69%)
No change/worsening	48 (56%)	46 (58%)
Withdrawal from study prior to visit	17 (20%)	5 (6%)
Missing visit [2]	3 (3%)	4 (5%)
Inverse Odds Ratio to Placebo [3]		0.42
95% CI		(0.19, 0.93)
Inverse Relative Risk [4]		0.61
95% CI		(0.33, 1.13)
p-value		0.119
Absolute Risk Reduction [4]		-0.16
95% CI		(-0.56, 0.25)

[1] Defined as subjects changing the status to next higher category from baseline.
[2] Participants with an intercurrent event of either treatment interruption or treatment discontinuation related to the COVID-19 pandemic have data set to missing following the event. Missing data was not imputed.
[3] Analysis performed using a logistic regression model with covariates of baseline score, geographic region (as defined for the study/ISE), smoking status (current vs. never/ex-smoker) and treatment group.
[4] Analysis used poisson regression model with covariates as in [3] (risk difference uses identity link).
[5] Analysis model as in footnote [3] and [4] with an additional covariate of study. [6] Analysis model as in footnote [4] with an additional covariate of study*treatment interaction. Note: Inverse Odds Ratio <1, Inverse Relative Risk < 1, risk difference < 0 correspond to a benefit of Mepolizumab over Placebo.
/mnt/code/postcsr_01/prod/tfls/t_e_rgial_resp.sas 25JUL2025 11:10

Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Table 211.40

Analysis of Subject Global Rating of Activity Limitation Responders at Week 52:
Participants Achieving Changes in the Status to Next Higher Categories from Baseline
(Studies MEA117113 and MEA117106)

	PBO (N=177)	100 SC (N=165)
MEA117106		
n	85	76
Responder [1]	15 (18%)	22 (29%)
Non-responder	70 (82%)	54 (71%)
No change/worsening	54 (64%)	45 (59%)
Withdrawal from study prior to visit	8 (9%)	4 (5%)
Missing visit [2]	8 (9%)	5 (7%)
Inverse Odds Ratio to Placebo [3]		0.45
95% CI		(0.18, 1.10)
Inverse Relative Risk [4]		0.66
95% CI		(0.34, 1.29)
p-value		0.224
Absolute Risk Reduction [4]		-0.11
95% CI		(-0.52, 0.30)

[1] Defined as subjects changing the status to next higher category from baseline.
[2] Participants with an intercurrent event of either treatment interruption or treatment discontinuation related to the COVID-19 pandemic have data set to missing following the event. Missing data was not imputed.
[3] Analysis performed using a logistic regression model with covariates of baseline score, geographic region (as defined for the study/ISE), smoking status (current vs. never/ex-smoker) and treatment group.
[4] Analysis used poisson regression model with covariates as in [3] (risk difference uses identity link).
[5] Analysis model as in footnote [3] and [4] with an additional covariate of study. [6] Analysis model as in footnote [4] with an additional covariate of study*treatment interaction. Note: Inverse Odds Ratio <1, Inverse Relative Risk < 1, risk difference < 0 correspond to a benefit of Mepolizumab over Placebo.
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Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Table 211.40

Analysis of Subject Global Rating of Activity Limitation Responders at Week 52:
Participants Achieving Changes in the Status to Next Higher Categories from Baseline
(Studies MEA117113 and MEA117106)

	PBO (N=177)		100 SC (N=165)	
MEA117113 + MEA117106				
n	171		156	
Responder [1]	33	(19%)	47	(30%)
Non-responder	138	(81%)	109	(70%)
No change/worsening	102	(60%)	91	(58%)
Withdrawal from study prior to visit	25	(15%)	9	(6%)
Missing visit [2]	11	(6%)	9	(6%)
Inverse Odds Ratio to Placebo [3,5]			0.45	
95% CI			(0.26, 0.80)	
Inverse Relative Risk [4,5]			0.64	
95% CI			(0.41, 0.99)	
p-value			0.047	
Absolute Risk Reduction [4,5]			-0.13	
95% CI			(-0.42, 0.15)	
p-value for study*treatment interaction [6]			0.948	

[1] Defined as subjects changing the status to next higher category from baseline.
[2] Participants with an intercurrent event of either treatment interruption or treatment discontinuation related to the COVID-19 pandemic have data set to missing following the event. Missing data was not imputed.
[3] Analysis performed using a logistic regression model with covariates of baseline score, geographic region (as defined for the study/ISE), smoking status (current vs. never/ex-smoker) and treatment group.
[4] Analysis used poisson regression model with covariates as in [3] (risk difference uses identity link).
[5] Analysis model as in footnote [3] and [4] with an additional covariate of study. [6] Analysis model as in footnote [4] with an additional covariate of study*treatment interaction. Note: Inverse Odds Ratio <1, Inverse Relative Risk < 1, risk difference < 0 correspond to a benefit of Mepolizumab over Placebo.
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Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Table 211.41

Analysis of Subject Global Rating of Activity Change Responders at Week 52:
Participants Achieving Categories of “much better”, “better” or “slightly better”
(Studies MEA117113 and MEA117106)

	PBO (N=177)	100 SC (N=165)
MEA117113		
n	87	83
Responder [1]	21 (24%)	28 (34%)
Non-responder	66 (76%)	55 (66%)
No change/worsening	46 (53%)	46 (55%)
Withdrawal from study prior to visit	17 (20%)	5 (6%)
Missing visit [2]	3 (3%)	4 (5%)
Inverse Odds Ratio to Placebo [3]		0.56
95% CI		(0.28, 1.12)
Inverse Relative Risk [4]		0.68
95% CI		(0.38, 1.20)
p-value		0.181
Absolute Risk Reduction [4]		-0.12
95% CI		(-0.51, 0.28)

[1] Defined as achieving categories of 'much better', 'better' or 'slightly better' (improvement).
[2] Participants with an intercurrent event of either treatment interruption or treatment discontinuation related to the COVID-19 pandemic have data set to missing following the event. Missing data was not imputed.
[3] Analysis performed using a logistic regression model with covariates of geographic region (as defined for the study/ISE), smoking status (current vs. never/ex-smoker) and treatment group.
[4] Analysis used poisson regression model with covariates as in [3] (risk difference uses identity link).
[5] Analysis model as in footnote [3] and [4] with an additional covariate of study. [6] Analysis model as in footnote [4] with an additional covariate of study*treatment interaction. Note: Inverse Odds Ratio <1, Inverse Relative Risk < 1, risk difference < 0 correspond to a benefit of Mepolizumab over Placebo.
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Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Table 211.41

Analysis of Subject Global Rating of Activity Change Responders at Week 52:
Participants Achieving Categories of “much better”, “better” or “slightly better”
(Studies MEA117113 and MEA117106)

	PBO (N=177)	100 SC (N=165)
MEA117106		
n	90	82
Responder [1]	23 (26%)	26 (32%)
Non-responder	67 (74%)	56 (68%)
No change/worsening	49 (54%)	46 (56%)
Withdrawal from study prior to visit	9 (10%)	4 (5%)
Missing visit [2]	9 (10%)	6 (7%)
Inverse Odds Ratio to Placebo [3]		0.72
95% CI		(0.36, 1.41)
Inverse Relative Risk [4]		0.80
95% CI		(0.45, 1.39)
p-value		0.425
Absolute Risk Reduction [4]		-0.06
95% CI		(-0.45, 0.33)

[1] Defined as achieving categories of 'much better', 'better' or 'slightly better' (improvement).
[2] Participants with an intercurrent event of either treatment interruption or treatment discontinuation related to the COVID-19 pandemic have data set to missing following the event. Missing data was not imputed.
[3] Analysis performed using a logistic regression model with covariates of geographic region (as defined for the study/ISE), smoking status (current vs. never/ex-smoker) and treatment group.
[4] Analysis used poisson regression model with covariates as in [3] (risk difference uses identity link).
[5] Analysis model as in footnote [3] and [4] with an additional covariate of study. [6] Analysis model as in footnote [4] with an additional covariate of study*treatment interaction. Note: Inverse Odds Ratio <1, Inverse Relative Risk < 1, risk difference < 0 correspond to a benefit of Mepolizumab over Placebo.
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Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Table 211.41

Analysis of Subject Global Rating of Activity Change Responders at Week 52:
Participants Achieving Categories of “much better”, “better” or “slightly better”
(Studies MEA117113 and MEA117106)

	PBO (N=177)		100 SC (N=165)	
MEA117113 + MEA117106				
n	177		165	
Responder [1]	44	(25%)	54	(33%)
Non-responder	133	(75%)	111	(67%)
No change/worsening	95	(54%)	92	(56%)
Withdrawal from study prior to visit	26	(15%)	9	(5%)
Missing visit [2]	12	(7%)	10	(6%)
Inverse Odds Ratio to Placebo [3,5]			0.67	
95% CI			(0.42, 1.08)	
Inverse Relative Risk [4,5]			0.76	
95% CI			(0.51, 1.13)	
p-value			0.171	
Absolute Risk Reduction [4,5]			-0.08	
95% CI			(-0.36, 0.20)	
p-value for study*treatment interaction [6]			0.783	

[1] Defined as achieving categories of 'much better', 'better' or 'slightly better' (improvement).
[2] Participants with an intercurrent event of either treatment interruption or treatment discontinuation related to the COVID-19 pandemic have data set to missing following the event. Missing data was not imputed.
[3] Analysis performed using a logistic regression model with covariates of geographic region (as defined for the study/ISE), smoking status (current vs. never/ex-smoker) and treatment group.
[4] Analysis used poisson regression model with covariates as in [3] (risk difference uses identity link).
[5] Analysis model as in footnote [3] and [4] with an additional covariate of study. [6] Analysis model as in footnote [4] with an additional covariate of study*treatment interaction. Note: Inverse Odds Ratio <1, Inverse Relative Risk < 1, risk difference < 0 correspond to a benefit of Mepolizumab over Placebo.
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Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Table 211.23

Summary of Subject Rated Response to Therapy at Week 52: Individual Studies and Meta-Analysis

	PBO (N=578)		100 SC (N=568)	
208657				
n	336		337	
Significantly Improved	46	(14%)	35	(10%)
Moderately Improved	66	(20%)	92	(27%)
Mildly Improved	114	(34%)	84	(25%)
No Change	92	(27%)	98	(29%)
Mildly Worse	11	(3%)	18	(5%)
Moderately Worse	7	(2%)	9	(3%)
Significantly Worse	0		1	(<1%)
MEA117113				
n	68		74	
Significantly Improved	3	(4%)	8	(11%)
Moderately Improved	7	(10%)	15	(20%)
Mildly Improved	17	(25%)	24	(32%)
No Change	34	(50%)	20	(27%)
Mildly Worse	4	(6%)	5	(7%)
Moderately Worse	3	(4%)	2	(3%)
Significantly Worse	0		0	
MEA117106				
n	73		74	
Significantly Improved	5	(7%)	7	(9%)
Moderately Improved	12	(16%)	16	(22%)
Mildly Improved	22	(30%)	24	(32%)
No Change	27	(37%)	22	(30%)
Mildly Worse	5	(7%)	5	(7%)
Moderately Worse	2	(3%)	0	
Significantly Worse	0		0	

Note: Assessments in Japan based on the last 3 months instead of since the last visit (MEA117113 only).

Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Table 211.23

Summary of Subject Rated Response to Therapy at Week 52: Individual Studies and Meta-Analysis

	PBO (N=578)	100 SC (N=568)
208657 + MEA117113 + MEA117106		
n	477	485
Significantly Improved	54 (11%)	50 (10%)
Moderately Improved	85 (18%)	123 (25%)
Mildly Improved	153 (32%)	132 (27%)
No Change	153 (32%)	140 (29%)
Mildly Worse	20 (4%)	28 (6%)
Moderately Worse	12 (3%)	11 (2%)
Significantly Worse	0	1 (<1%)

Note: Assessments in Japan based on the last 3 months instead of since the last visit (MEA117113 only).

Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Table 211.42

Analysis of Subject Rated Response to Therapy Responders at Week 52: Participants Achieving 'Significantly Improved', 'Moderately Improved', 'Mildly Improved' Status: Individual Studies and Meta-Analysis

	PBO (N=578)		100 SC (N=568)	
208657				
n	401		403	
Responder [1]	226	(56%)	211	(52%)
Non-responder	175	(44%)	192	(48%)
No change/worsening	110	(27%)	126	(31%)
Withdrawal from study prior to visit	39	(10%)	39	(10%)
Missing visit [2]	26	(6%)	27	(7%)
Inverse Odds Ratio to Placebo [3]			1.18	
95% CI			(0.88, 1.59)	
Inverse Relative Risk [4]			1.07	
95% CI			(0.89, 1.29)	
p-value			0.461	
Absolute Risk Reduction [4]			0.03	
95% CI			(-0.13, 0.20)	

[1] Defined as a participant achieving 'Significantly Improved', 'Moderately Improved', 'Mildly Improved'.
[2] Participants with an intercurrent event of either treatment interruption or treatment discontinuation related to the COVID-19 pandemic have data set to missing following the event. Missing data was not imputed.
[3] Analysis performed using a logistic regression model with covariates of geographic region (as defined for the study/ISE), smoking status (current vs. never/ex-smoker) and treatment group.
[4] Analysis used poisson regression model with covariates as in [3] (risk difference uses identity link).
[5] Analysis model as in footnote [3] and [4] with an additional covariate of study. [6] Analysis model as in footnote [4] with an additional covariate of study*treatment interaction. Note: Inverse Odds Ratio <1, Inverse Relative Risk < 1, risk difference < 0 correspond to a benefit of Mepolizumab over Placebo.
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Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Table 211.42

Analysis of Subject Rated Response to Therapy Responders at Week 52: Participants Achieving 'Significantly Improved', 'Moderately Improved', 'Mildly Improved' Status: Individual Studies and Meta-Analysis

	PBO (N=578)		100 SC (N=568)	
MEA117113				
n	87		83	
Responder [1]	27	(31%)	47	(57%)
Non-responder	60	(69%)	36	(43%)
No change/worsening	41	(47%)	27	(33%)
Withdrawal from study prior to visit	17	(20%)	5	(6%)
Missing visit [2]	2	(2%)	4	(5%)
Inverse Odds Ratio to Placebo [3]			0.28	
95% CI			(0.14, 0.55)	
Inverse Relative Risk [4]			0.52	
95% CI			(0.32, 0.84)	
p-value			0.007	
Absolute Risk Reduction [4]			-0.29	
95% CI			(-0.67, 0.09)	

[1] Defined as a participant achieving 'Significantly Improved', 'Moderately Improved', 'Mildly Improved'.
[2] Participants with an intercurrent event of either treatment interruption or treatment discontinuation related to the COVID-19 pandemic have data set to missing following the event. Missing data was not imputed.
[3] Analysis performed using a logistic regression model with covariates of geographic region (as defined for the study/ISE), smoking status (current vs. never/ex-smoker) and treatment group.
[4] Analysis used poisson regression model with covariates as in [3] (risk difference uses identity link).
[5] Analysis model as in footnote [3] and [4] with an additional covariate of study. [6] Analysis model as in footnote [4] with an additional covariate of study*treatment interaction. Note: Inverse Odds Ratio <1, Inverse Relative Risk < 1, risk difference < 0 correspond to a benefit of Mepolizumab over Placebo.
/mnt/code/postcsr_01/prod/tfls/t_e_srr_resp.sas 25JUL2025 11:11

Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Table 211.42

Analysis of Subject Rated Response to Therapy Responders at Week 52: Participants Achieving 'Significantly Improved', 'Moderately Improved', 'Mildly Improved' Status: Individual Studies and Meta-Analysis

	PBO (N=578)		100 SC (N=568)	
MEA117106				
n	90		82	
Responder [1]	39	(43%)	47	(57%)
Non-responder	51	(57%)	35	(43%)
No change/worsening	34	(38%)	27	(33%)
Withdrawal from study prior to visit	9	(10%)	3	(4%)
Missing visit [2]	8	(9%)	5	(6%)
Inverse Odds Ratio to Placebo [3]			0.53	
95% CI			(0.28, 0.99)	
Inverse Relative Risk [4]			0.75	
95% CI			(0.49, 1.14)	
p-value			0.175	
Absolute Risk Reduction [4]			-0.13	
95% CI			(-0.50, 0.23)	

[1] Defined as a participant achieving 'Significantly Improved', 'Moderately Improved', 'Mildly Improved'.
[2] Participants with an intercurrent event of either treatment interruption or treatment discontinuation related to the COVID-19 pandemic have data set to missing following the event. Missing data was not imputed.
[3] Analysis performed using a logistic regression model with covariates of geographic region (as defined for the study/ISE), smoking status (current vs. never/ex-smoker) and treatment group.
[4] Analysis used poisson regression model with covariates as in [3] (risk difference uses identity link).
[5] Analysis model as in footnote [3] and [4] with an additional covariate of study. [6] Analysis model as in footnote [4] with an additional covariate of study*treatment interaction. Note: Inverse Odds Ratio <1, Inverse Relative Risk < 1, risk difference < 0 correspond to a benefit of Mepolizumab over Placebo.
/mnt/code/postcsr_01/prod/tfls/t_e_srr_resp.sas 25JUL2025 11:11

Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Table 211.42

Analysis of Subject Rated Response to Therapy Responders at Week 52: Participants Achieving 'Significantly Improved', 'Moderately Improved', 'Mildly Improved' Status: Individual Studies and Meta-Analysis

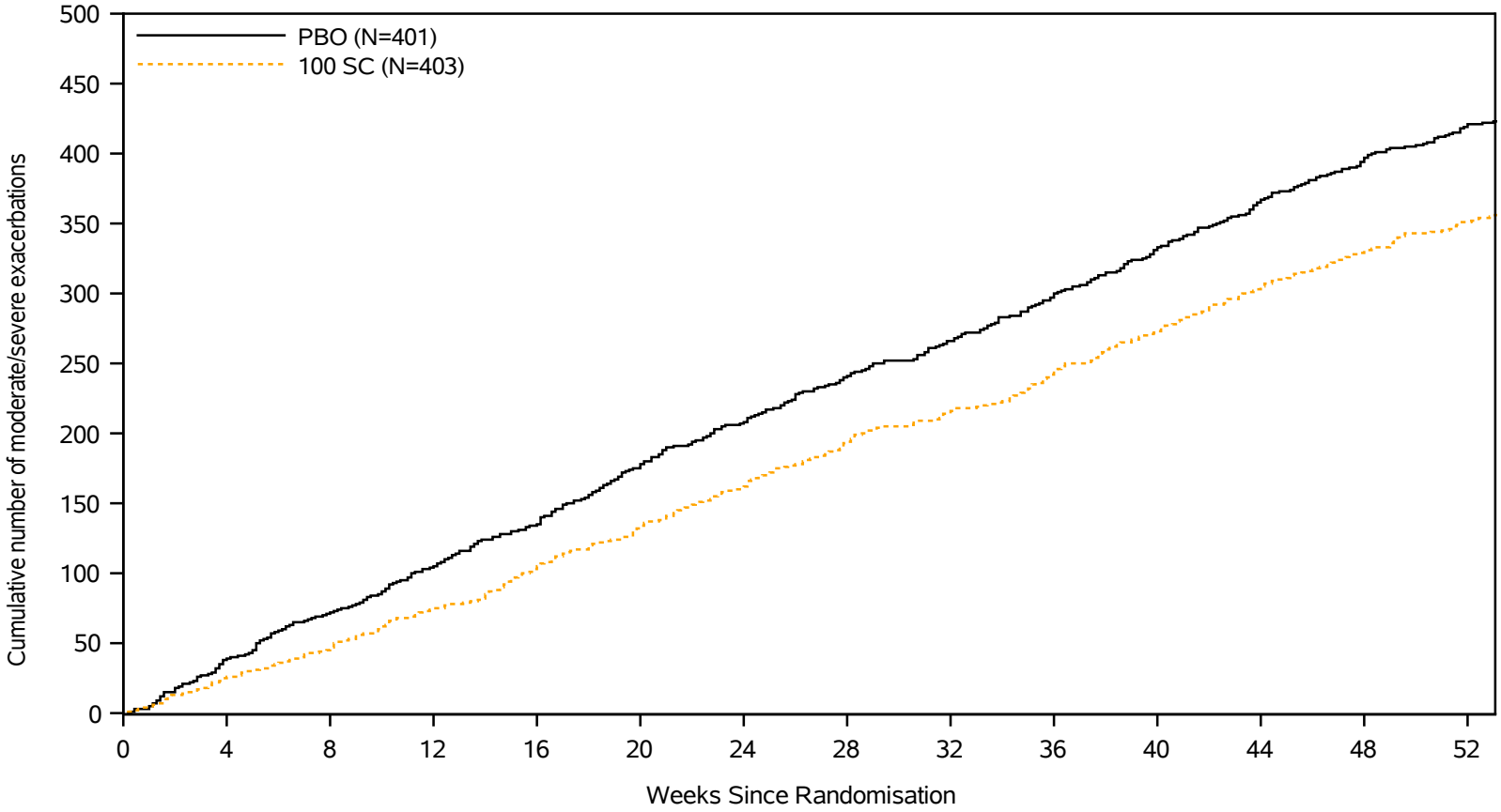
	PBO (N=578)		100 SC (N=568)	
208657 + MEA117113 + MEA117106				
n	578		568	
Responder [1]	292	(51%)	305	(54%)
Non-responder	286	(49%)	263	(46%)
No change/worsening	185	(32%)	180	(32%)
Withdrawal from study prior to visit	65	(11%)	47	(8%)
Missing visit [2]	36	(6%)	36	(6%)
Inverse Odds Ratio to Placebo [3,5]			0.88	
95% CI			(0.69, 1.11)	
Inverse Relative Risk [4,5]			0.94	
95% CI			(0.80, 1.10)	
p-value			0.444	
Absolute Risk Reduction [4,5]			-0.03	
95% CI			(-0.17, 0.11)	
p-value for study*treatment interaction [6]			0.015	

[1] Defined as a participant achieving 'Significantly Improved', 'Moderately Improved', 'Mildly Improved'.
[2] Participants with an intercurrent event of either treatment interruption or treatment discontinuation related to the COVID-19 pandemic have data set to missing following the event. Missing data was not imputed.
[3] Analysis performed using a logistic regression model with covariates of geographic region (as defined for the study/ISE), smoking status (current vs. never/ex-smoker) and treatment group.
[4] Analysis used poisson regression model with covariates as in [3] (risk difference uses identity link).
[5] Analysis model as in footnote [3] and [4] with an additional covariate of study. [6] Analysis model as in footnote [4] with an additional covariate of study*treatment interaction. Note: Inverse Odds Ratio <1, Inverse Relative Risk < 1, risk difference < 0 correspond to a benefit of Mepolizumab over Placebo.
/mnt/code/postcsr_01/prod/tfls/t_e_srr_resp.sas 25JUL2025 11:11

Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Figure 211.1
Cumulative Number of Moderate/Severe Exacerbations: Individual Studies

Study: 208657

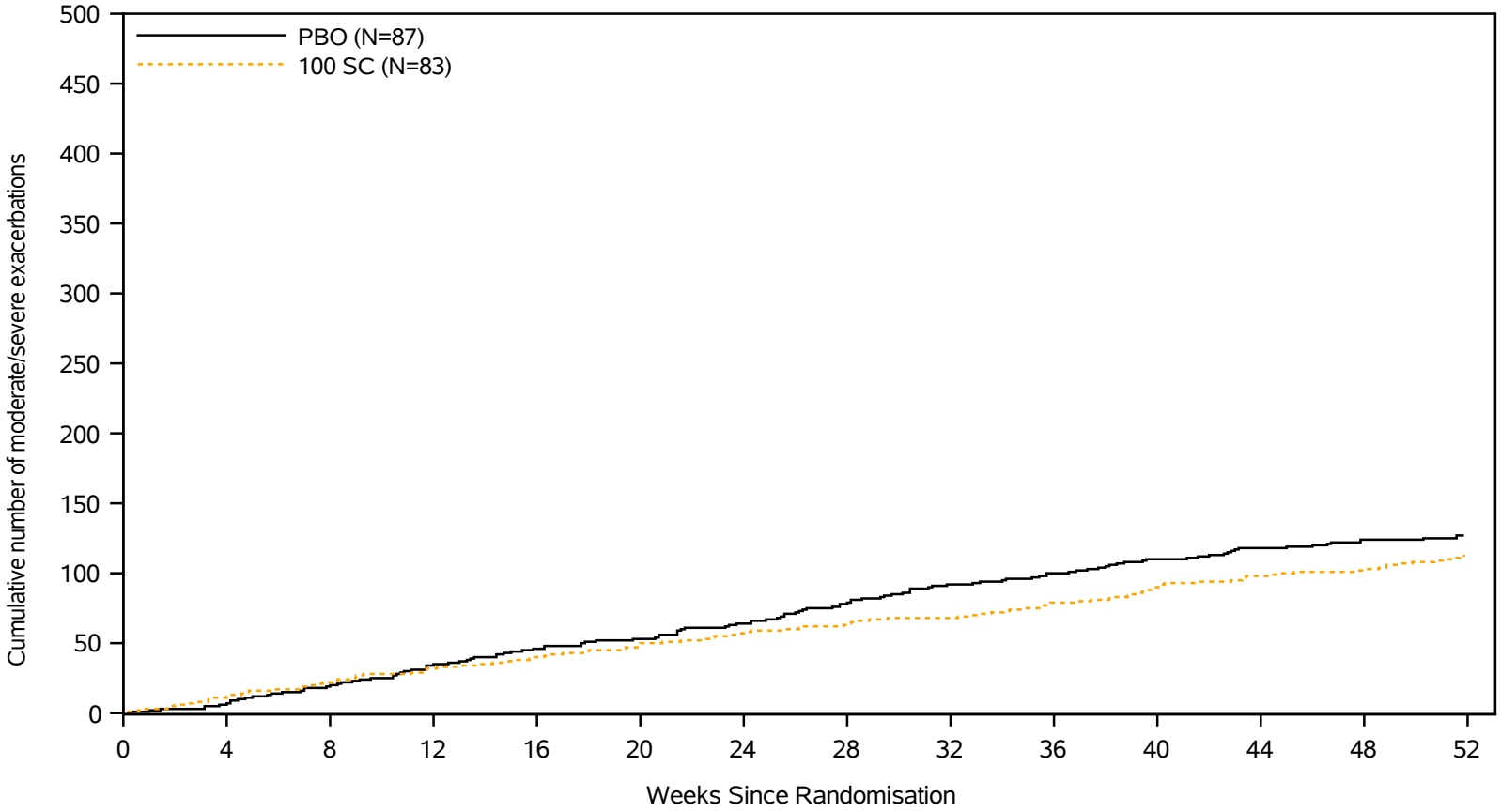


Note: Contains both on-treatment and off-treatment exacerbation data.
/mnt/code/postcsr_01/prod/tfls/f_e_cm_exac.sas 25JUL2025 13:30

Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Figure 211.1
Cumulative Number of Moderate/Severe Exacerbations: Individual Studies

Study: MEA117113

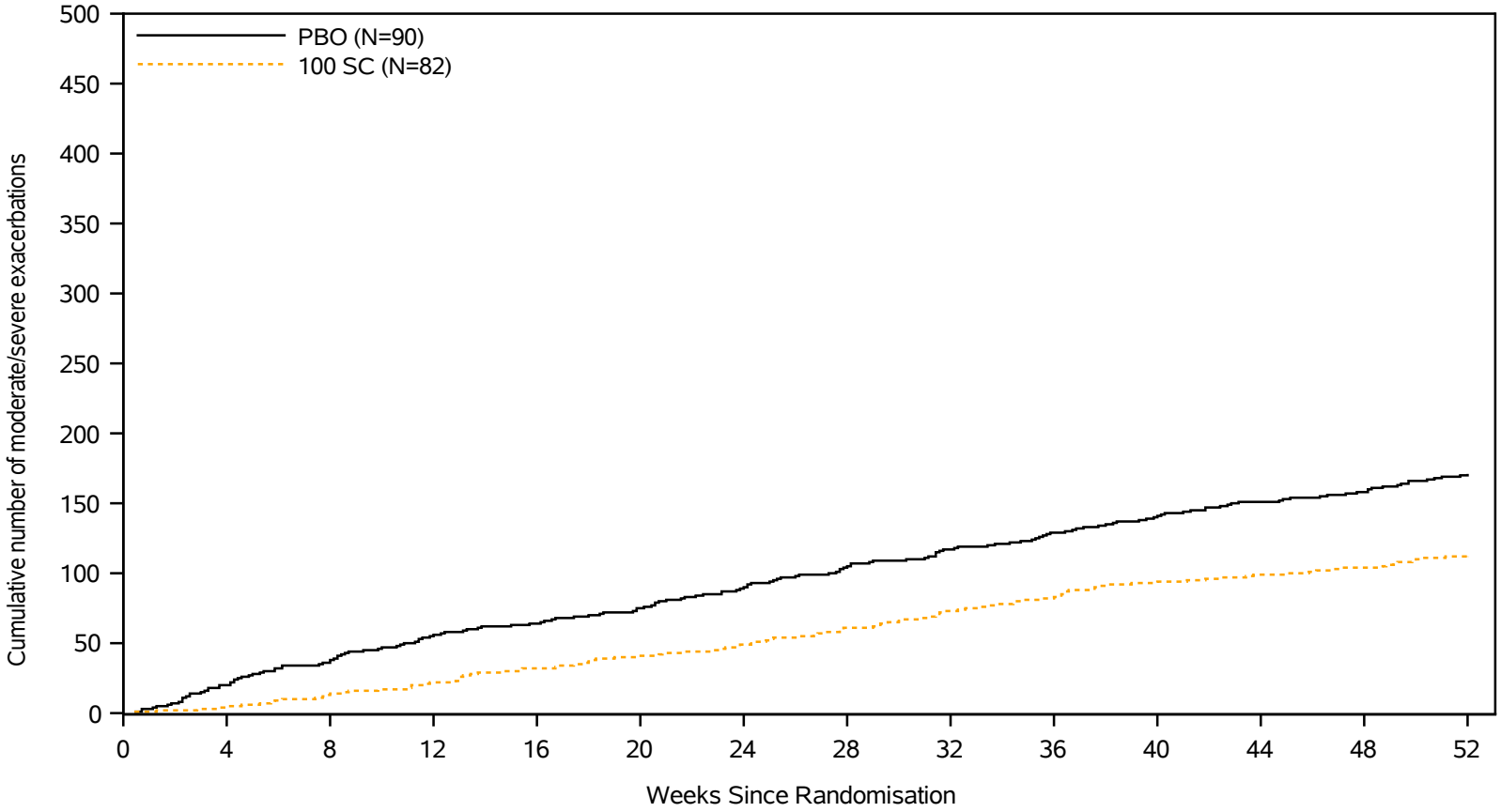


Note: Contains both on-treatment and off-treatment exacerbation data.
/mnt/code/postcsr_01/prod/tfls/f_e_cm_exac.sas 25JUL2025 13:30

Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Figure 211.1
Cumulative Number of Moderate/Severe Exacerbations: Individual Studies

Study: MEA117106

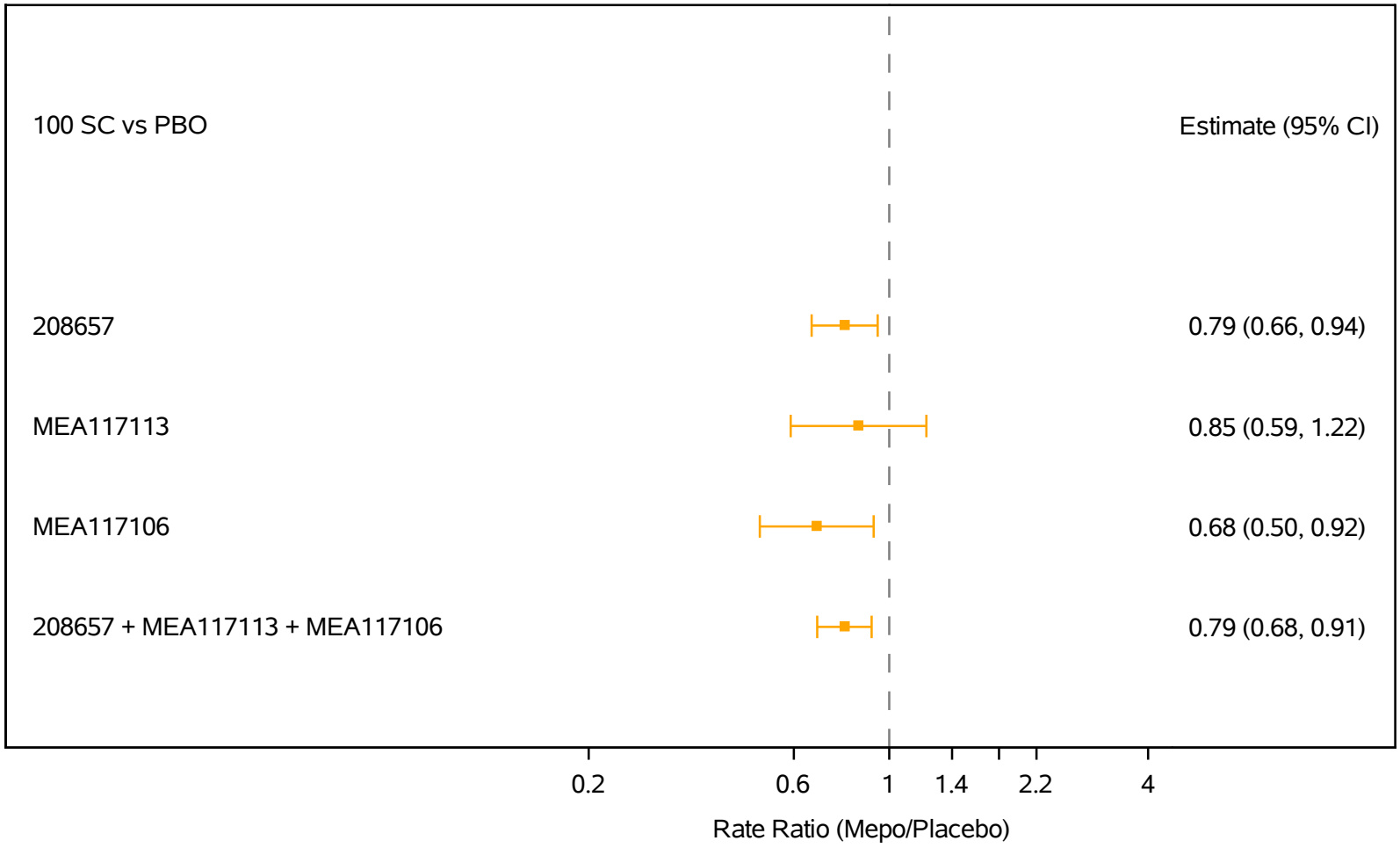


Note: Contains both on-treatment and off-treatment exacerbation data.
/mnt/code/postcsr_01/prod/tfls/f_e_cm_exac.sas 25JUL2025 13:30

Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Figure 211.2

Forest Plot of Rate Ratio for Moderate/Severe Exacerbations: Individual Studies and Meta-Analysis

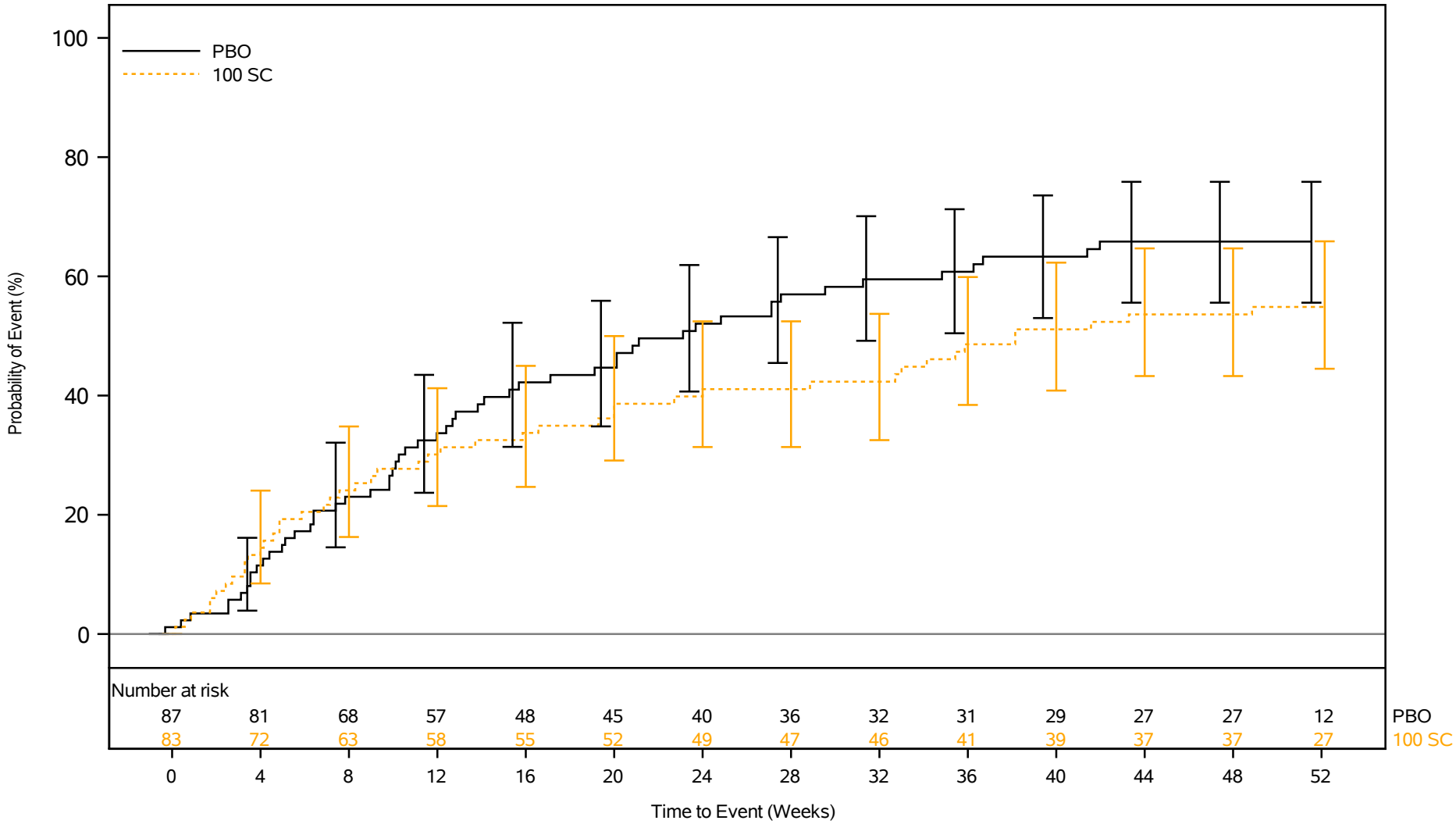


Horizontal bars indicate 95% confidence intervals for the Mepo/Placebo rate ratio.

Population: Modified Intent-to-Treat Population with Eosinophils 300 cells/uL or More

Figure 211.3
Kaplan-Meier Cumulative Incidence Curve for Time to First Moderate/Severe Exacerbation:
Individual Studies and Meta-Analysis

Study: MEA117113

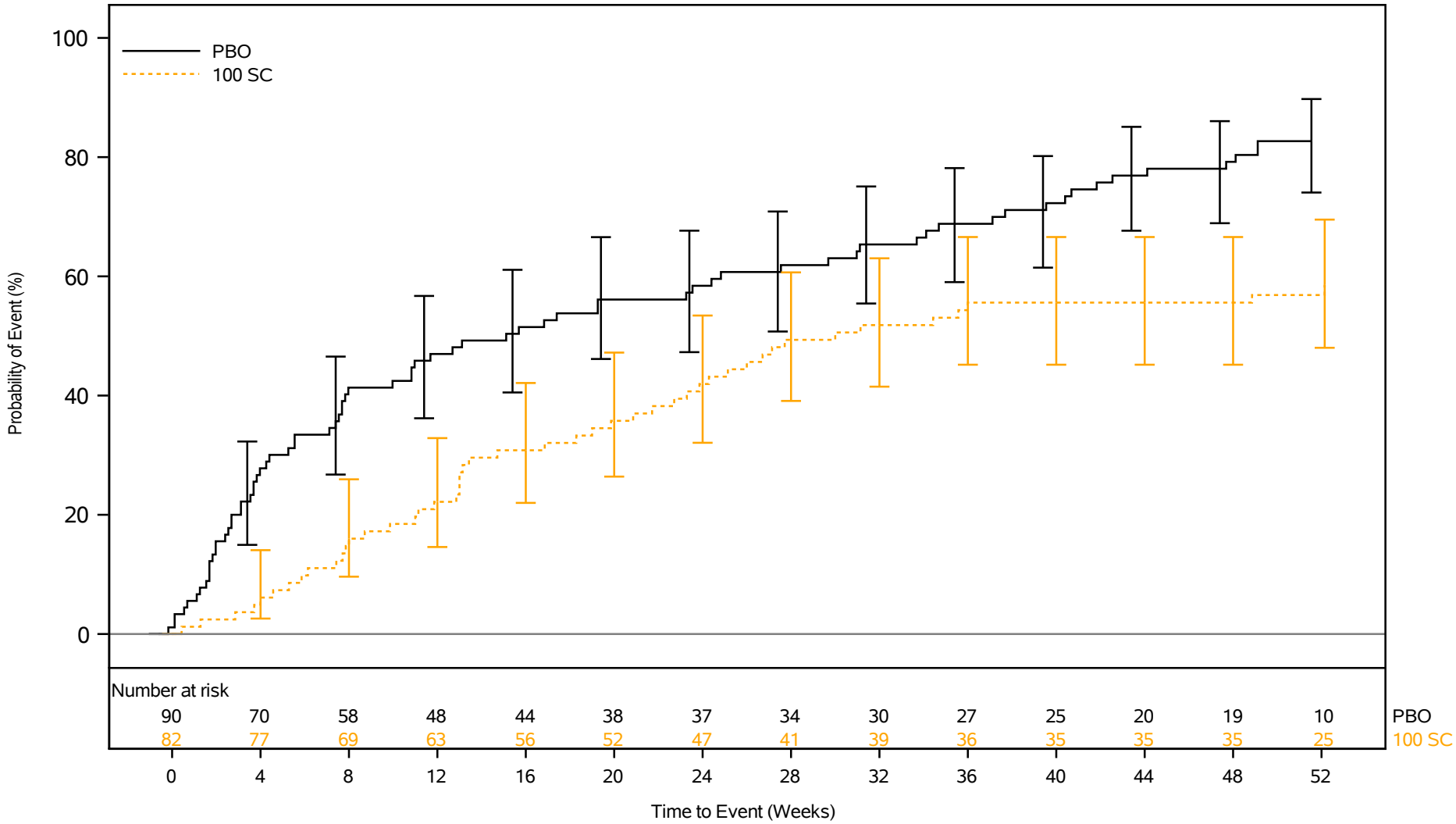


Note: Vertical bars represent 95% confidence intervals.
/mnt/code/postcsr_01/prod/tfls/f_e_km_msevex.sas 25JUL2025 13:32

Population: Modified Intent-to-Treat Population with Eosinophils 300 cells/uL or More

Figure 211.3
Kaplan-Meier Cumulative Incidence Curve for Time to First Moderate/Severe Exacerbation:
Individual Studies and Meta-Analysis

Study: MEA117106

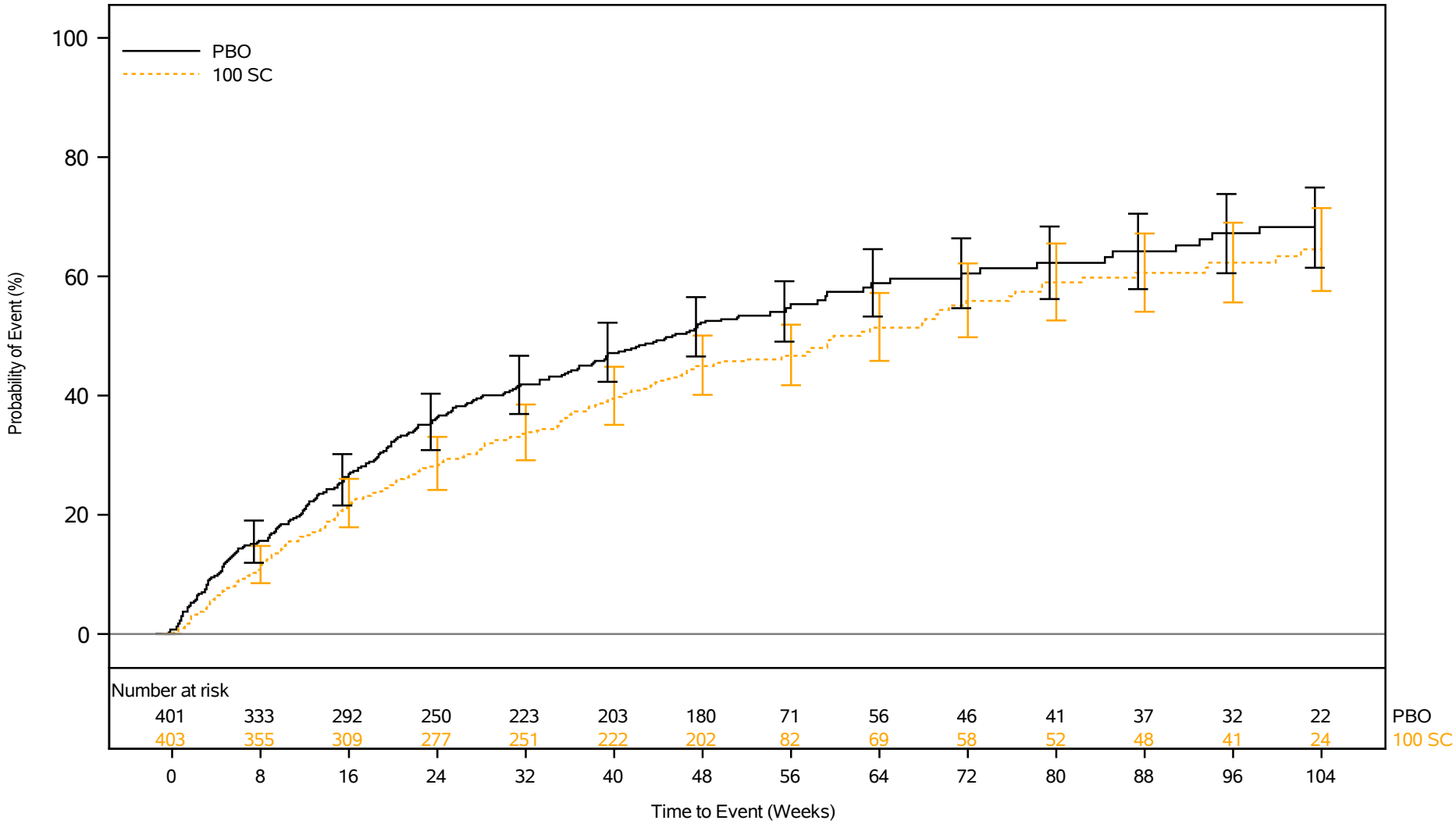


Note: Vertical bars represent 95% confidence intervals.
/mnt/code/postcsr_01/prod/tfls/f_e_km_msevex.sas 25JUL2025 13:32

Population: Modified Intent-to-Treat Population with Eosinophils 300 cells/uL or More

Figure 20.15
Kaplan-Meier Cumulative Incidence Curve for Time to First Moderate/Severe Exacerbation:
Individual Studies and Meta-Analysis

Study: 208657

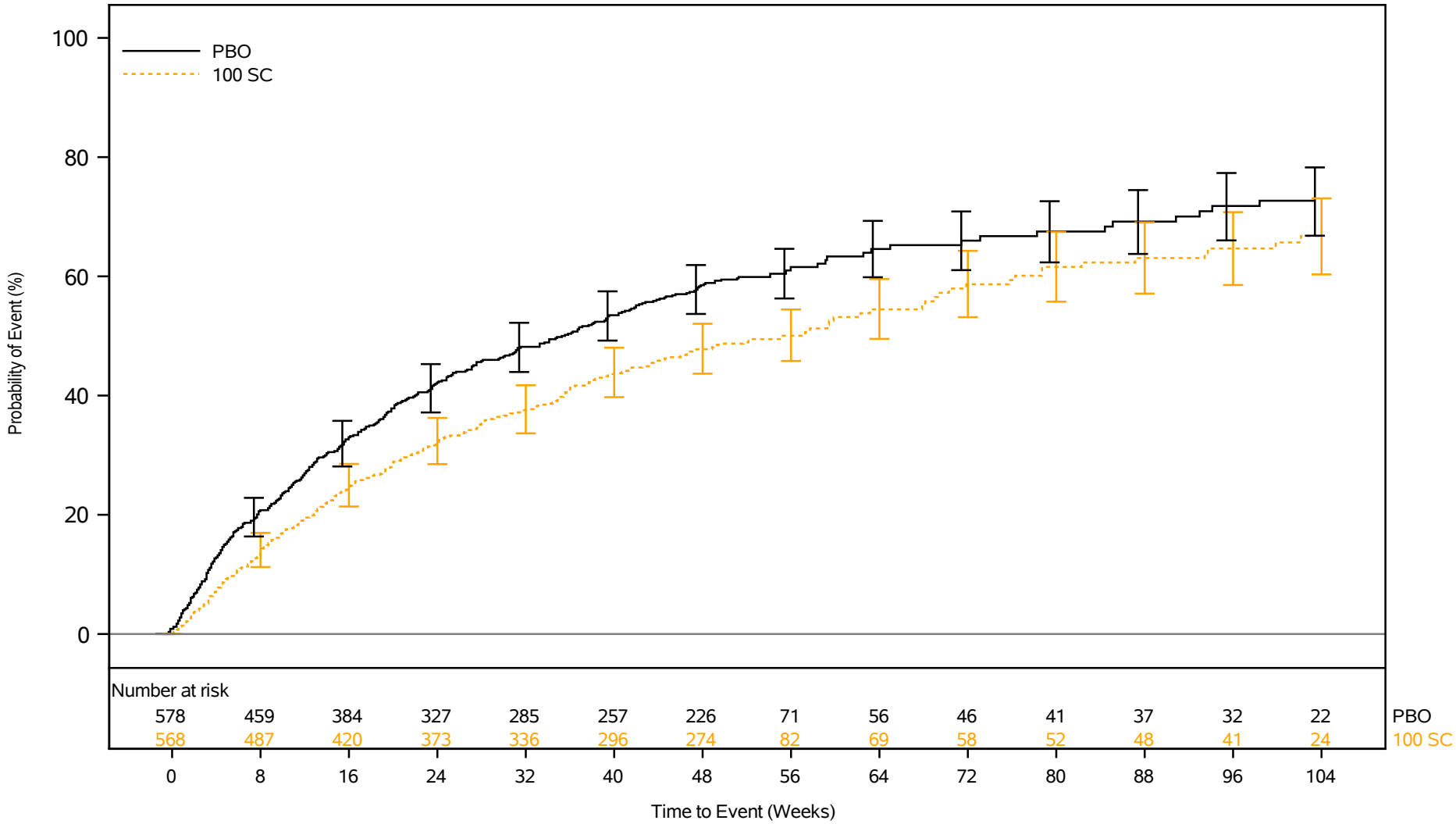


Note: Vertical bars represent 95% confidence intervals.
/mnt/code/is_4/prod/tfls/f_e_km_msevex.sas 03OCT2024 18:14

Population: Modified Intent-to-Treat Population with Eosinophils 300 cells/uL or More

Figure 20.15
Kaplan-Meier Cumulative Incidence Curve for Time to First Moderate/Severe Exacerbation:
Individual Studies and Meta-Analysis

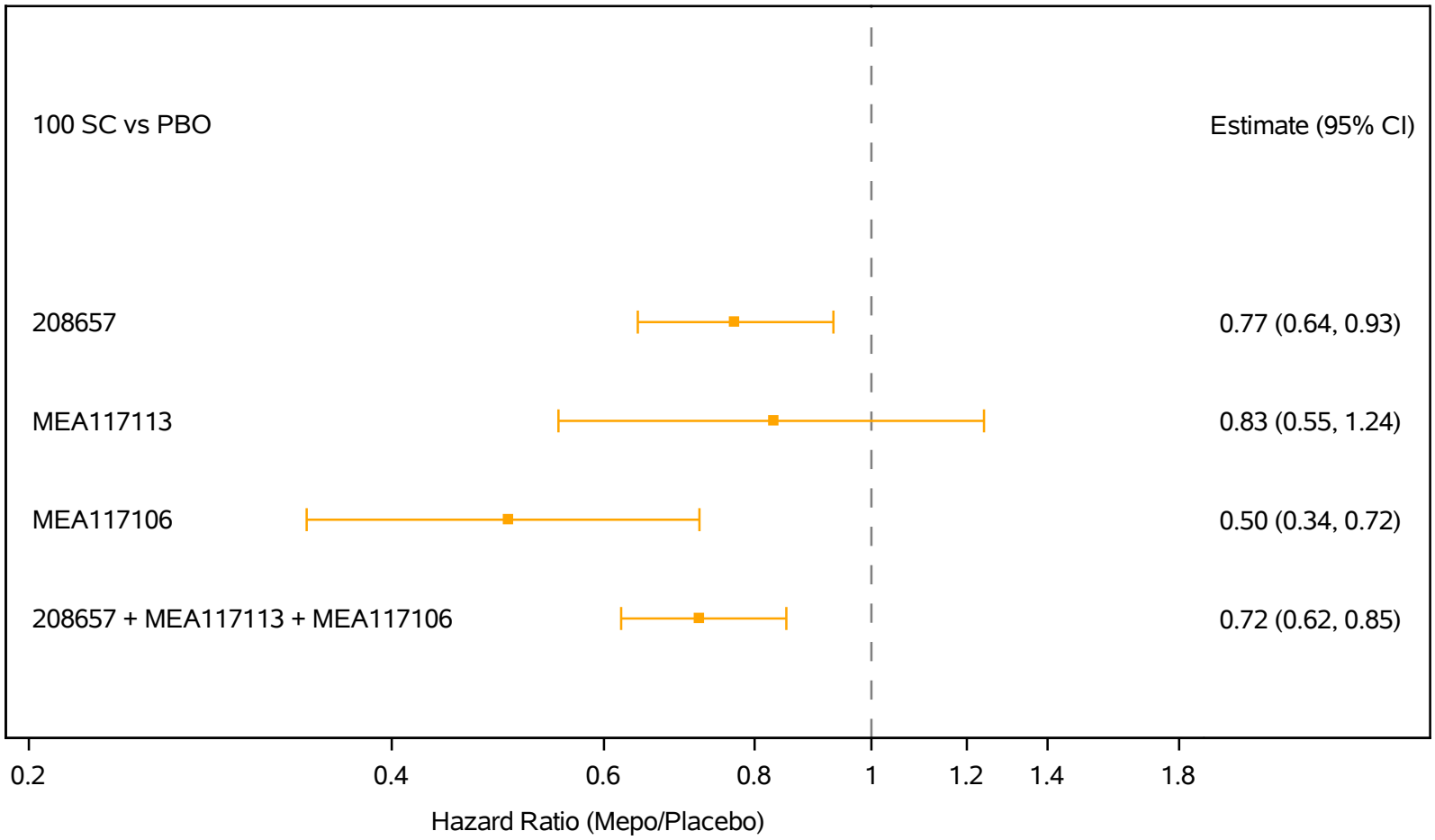
Study: 208657 + MEA117113 + MEA117106



Note: Vertical bars represent 95% confidence intervals.
/mnt/code/is_4/prod/tfls/f_e_km_msevex.sas 03OCT2024 18:14

Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Figure 211.4
Forest Plot of Hazard Ratio for Moderate/Severe Exacerbations:
Individual Studies and Meta-Analysis

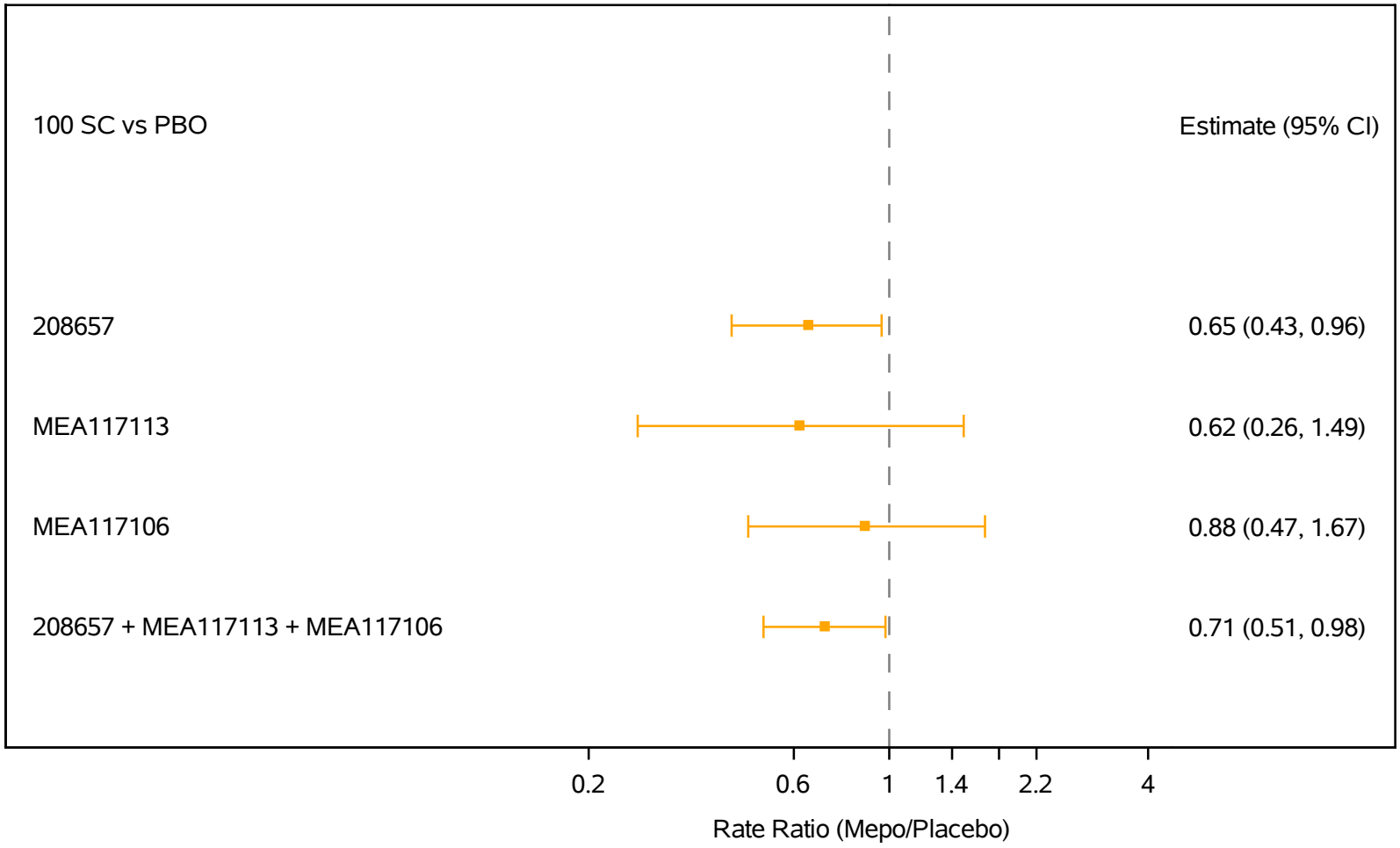


Horizontal bars indicate 95% confidence intervals for the Mepo/Placebo hazard ratio.
/mnt/code/postcsr_01/prod/tfls/f_e_tte_msevex.sas 25JUL2025 13:31

Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Figure 211.5

Forest Plot Rate Ratio for Exacerbations Requiring ED/Hospitalization: Individual Studies and Meta-Analysis



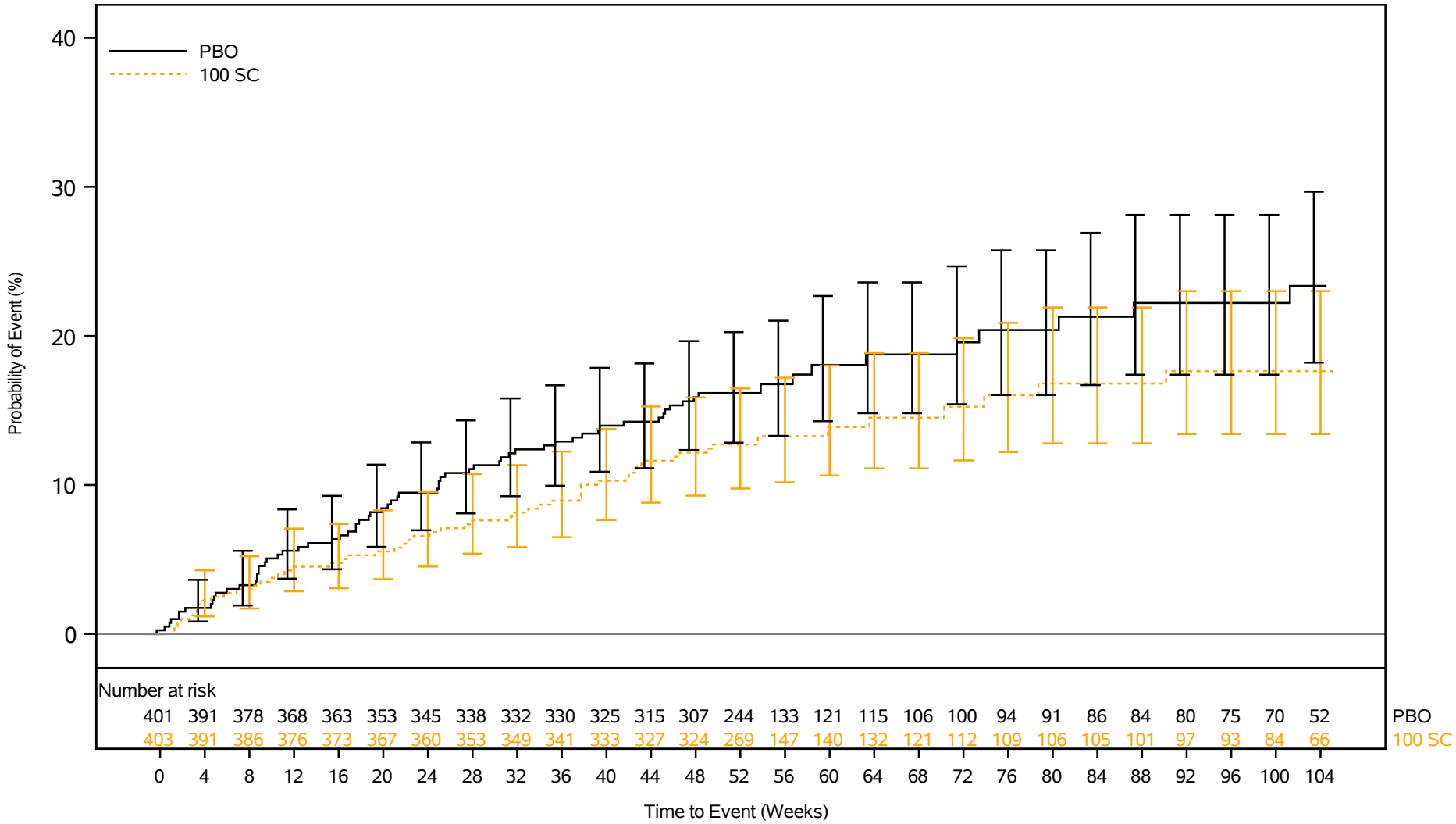
Horizontal bars indicate 95% confidence intervals for the Mepo/Placebo rate ratio.

/mnt/code/postcsr_01/prod/tfls/f_e_hspexac_nb.sas 25JUL2025 13:31

Population: Modified Intent-to-Treat Population with Eosinophils 300 cells/uL or More

Figure 211.6
Kaplan-Meier Cumulative Incidence Curve for Time to First Exacerbations Requiring ED/Hospitalization:
Individual Studies and Meta-Analysis

Study: 208657

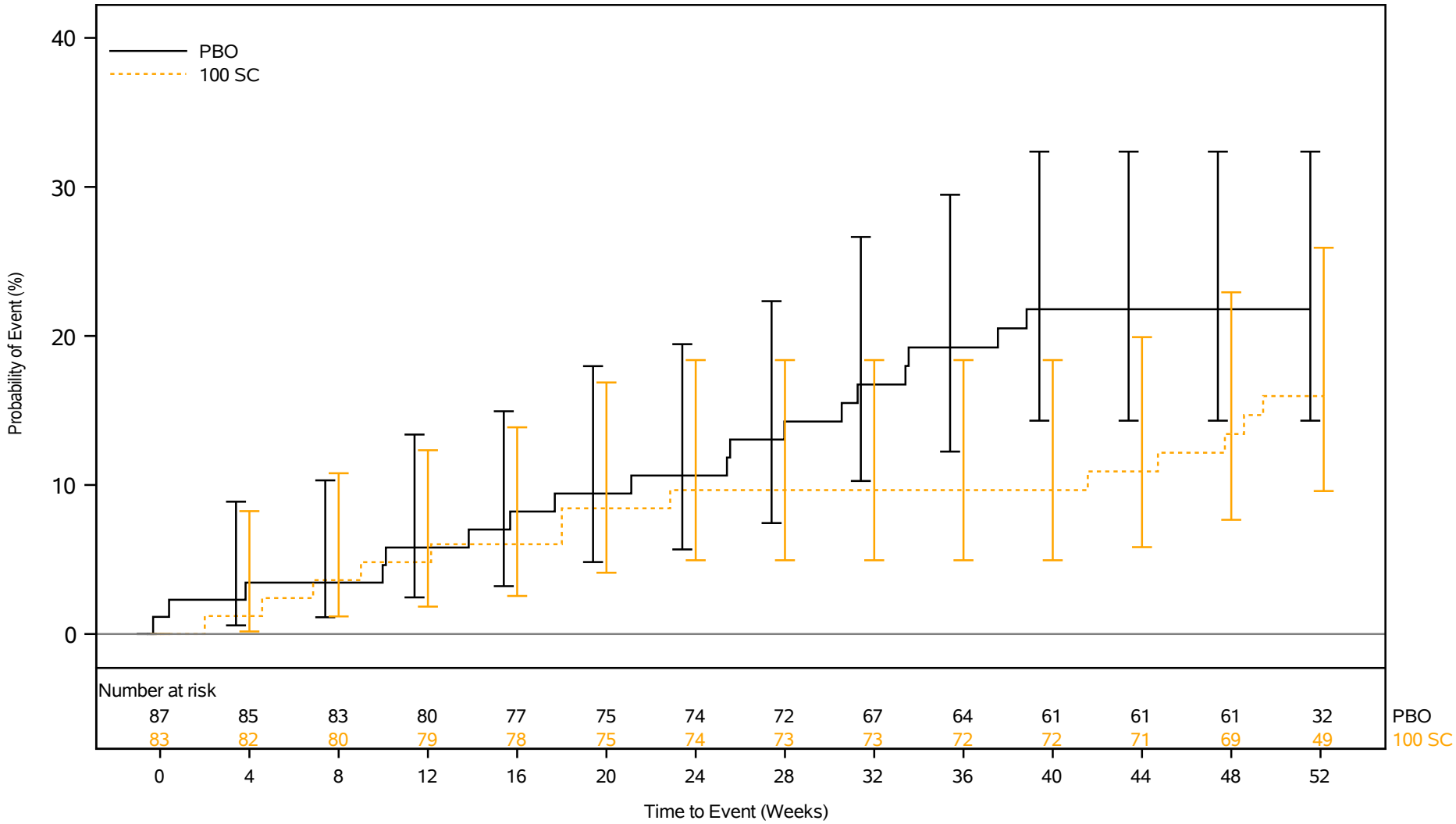


Note: Vertical bars represent 95% confidence intervals.
/mnt/code/postcsr_01/prod/tfls/f_e_km_hspexac.sas 24OCT2025 18:38

Population: Modified Intent-to-Treat Population with Eosinophils 300 cells/uL or More

Figure 211.6
Kaplan-Meier Cumulative Incidence Curve for Time to First Exacerbations Requiring ED/Hospitalization:
Individual Studies and Meta-Analysis

Study: MEA117113

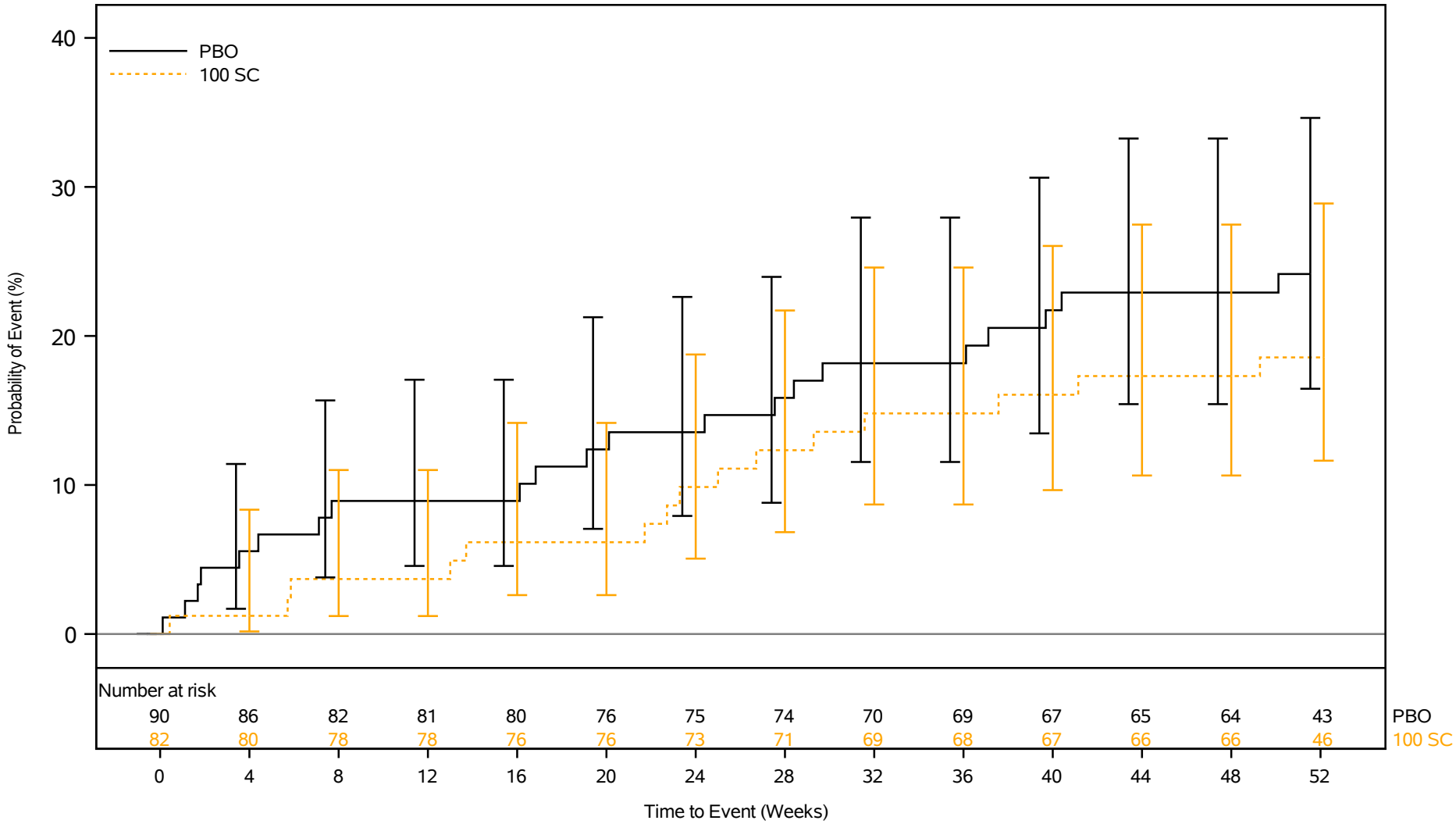


Note: Vertical bars represent 95% confidence intervals.
/mnt/code/postcsr_01/prod/tfls/f_e_km_hspexac.sas 24OCT2025 18:38

Population: Modified Intent-to-Treat Population with Eosinophils 300 cells/uL or More

Figure 211.6
Kaplan-Meier Cumulative Incidence Curve for Time to First Exacerbations Requiring ED/Hospitalization:
Individual Studies and Meta-Analysis

Study: MEA117106

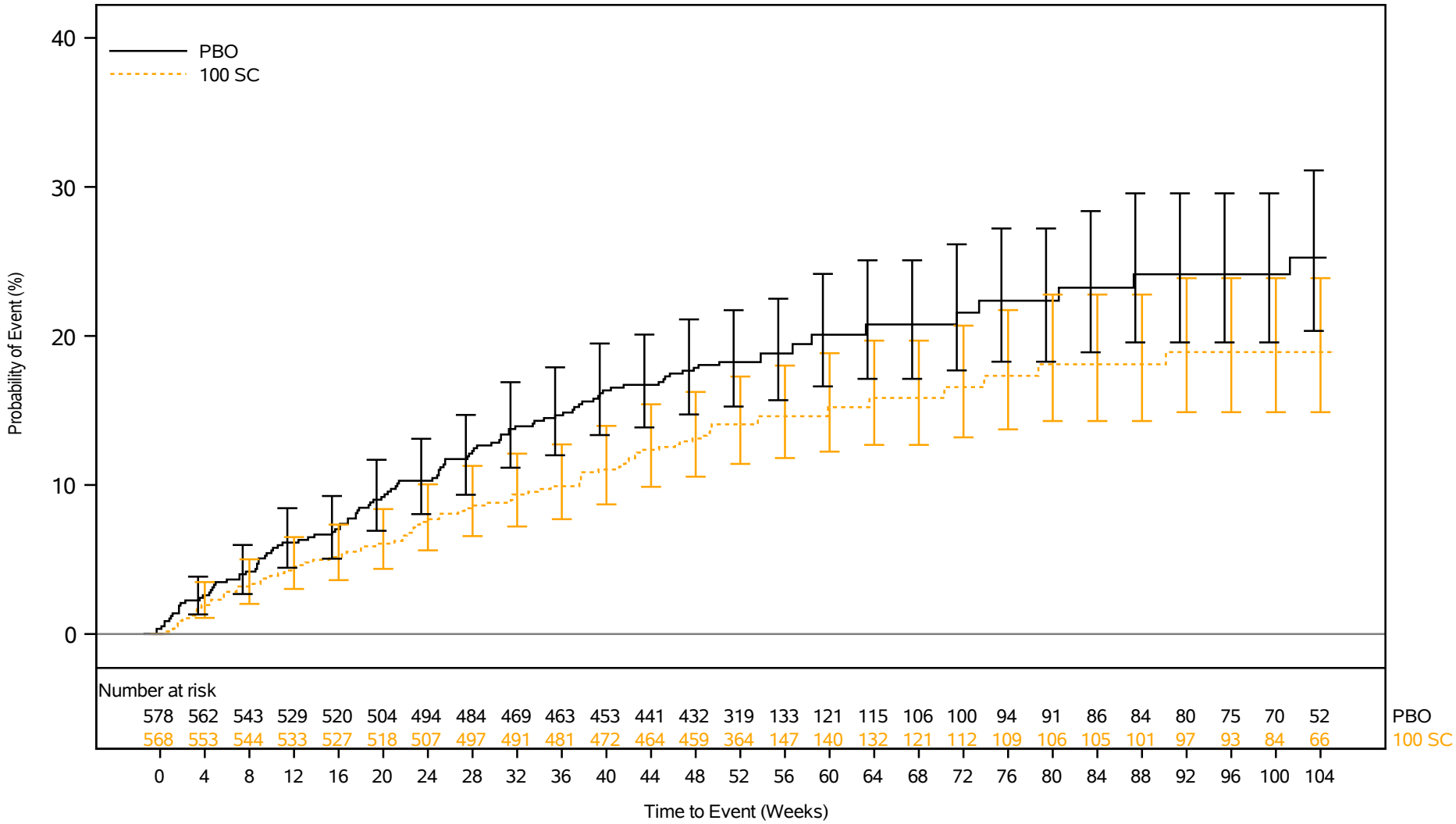


Note: Vertical bars represent 95% confidence intervals.
/mnt/code/postcsr_01/prod/tfls/f_e_km_hspexac.sas 24OCT2025 18:38

Population: Modified Intent-to-Treat Population with Eosinophils 300 cells/uL or More

Figure 211.6
Kaplan-Meier Cumulative Incidence Curve for Time to First Exacerbations Requiring ED/Hospitalization:
Individual Studies and Meta-Analysis

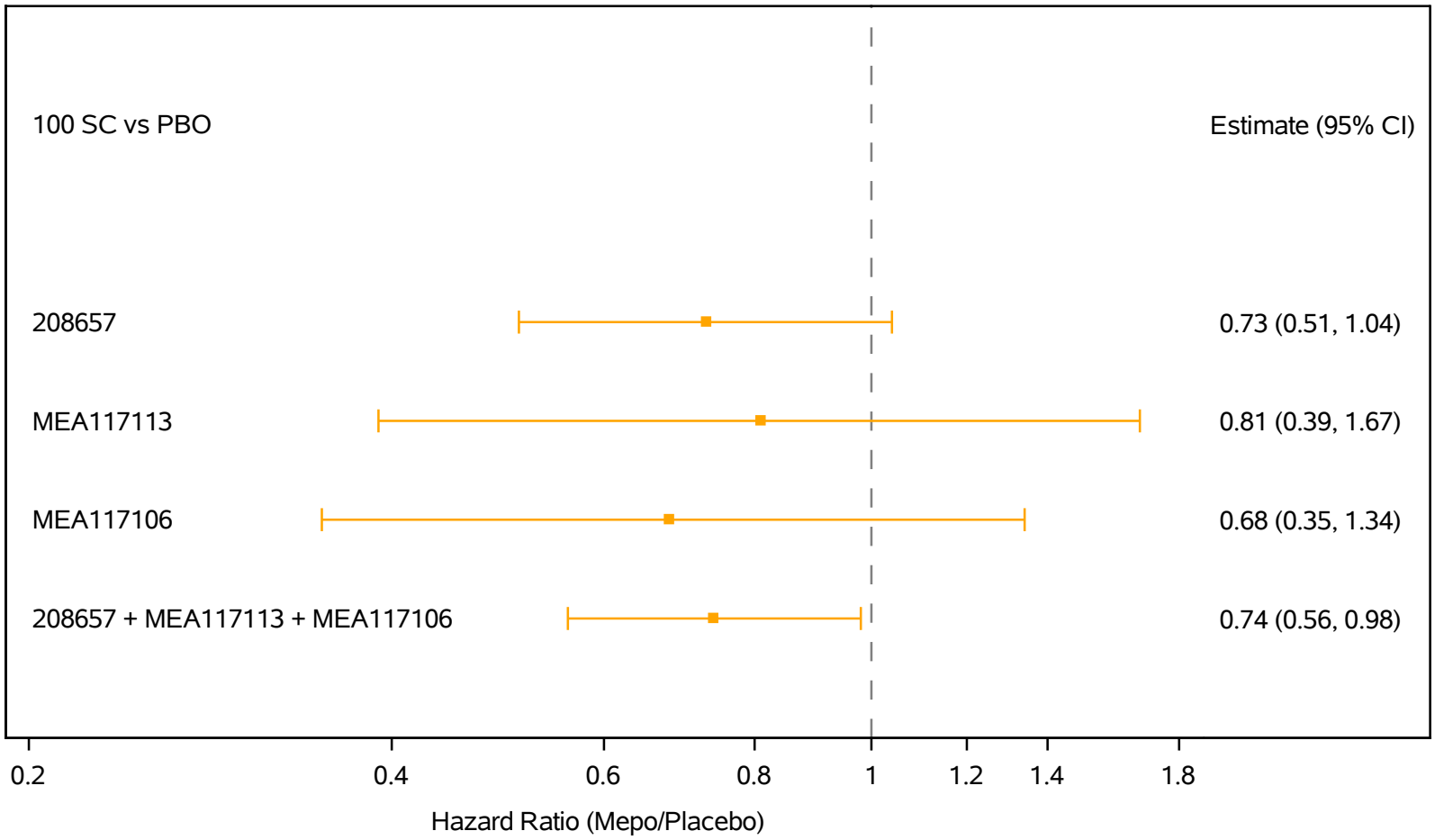
Study: 208657 + MEA117113 + MEA117106



Note: Vertical bars represent 95% confidence intervals.
/mnt/code/postcsr_01/prod/tfls/f_e_km_hspexac.sas 24OCT2025 18:38

Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

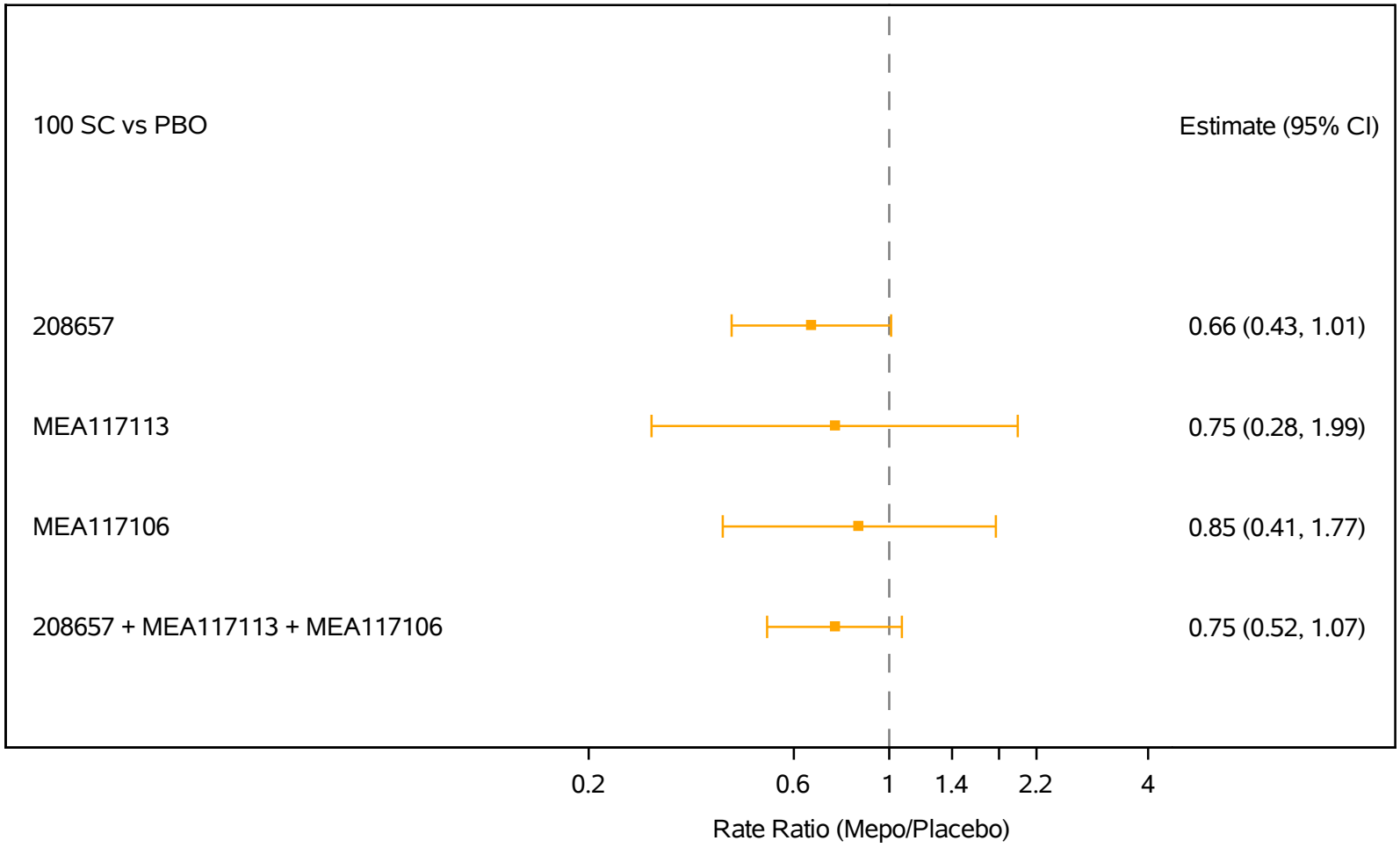
Figure 211.7
Forest Plot of Hazard Ratio for Exacerbations Requiring ED/Hospitalization:
Individual Studies and Meta-Analysis



Horizontal bars indicate 95% confidence intervals for the Mepo/Placebo hazard ratio.
/mnt/code/postcsr_01/prod/tfls/f_e_tte_hspexac.sas 25JUL2025 13:31

Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Figure 211.8
Forest Plot of Rate Ratio for Severe Exacerbation: Individual Studies and Meta-Analysis

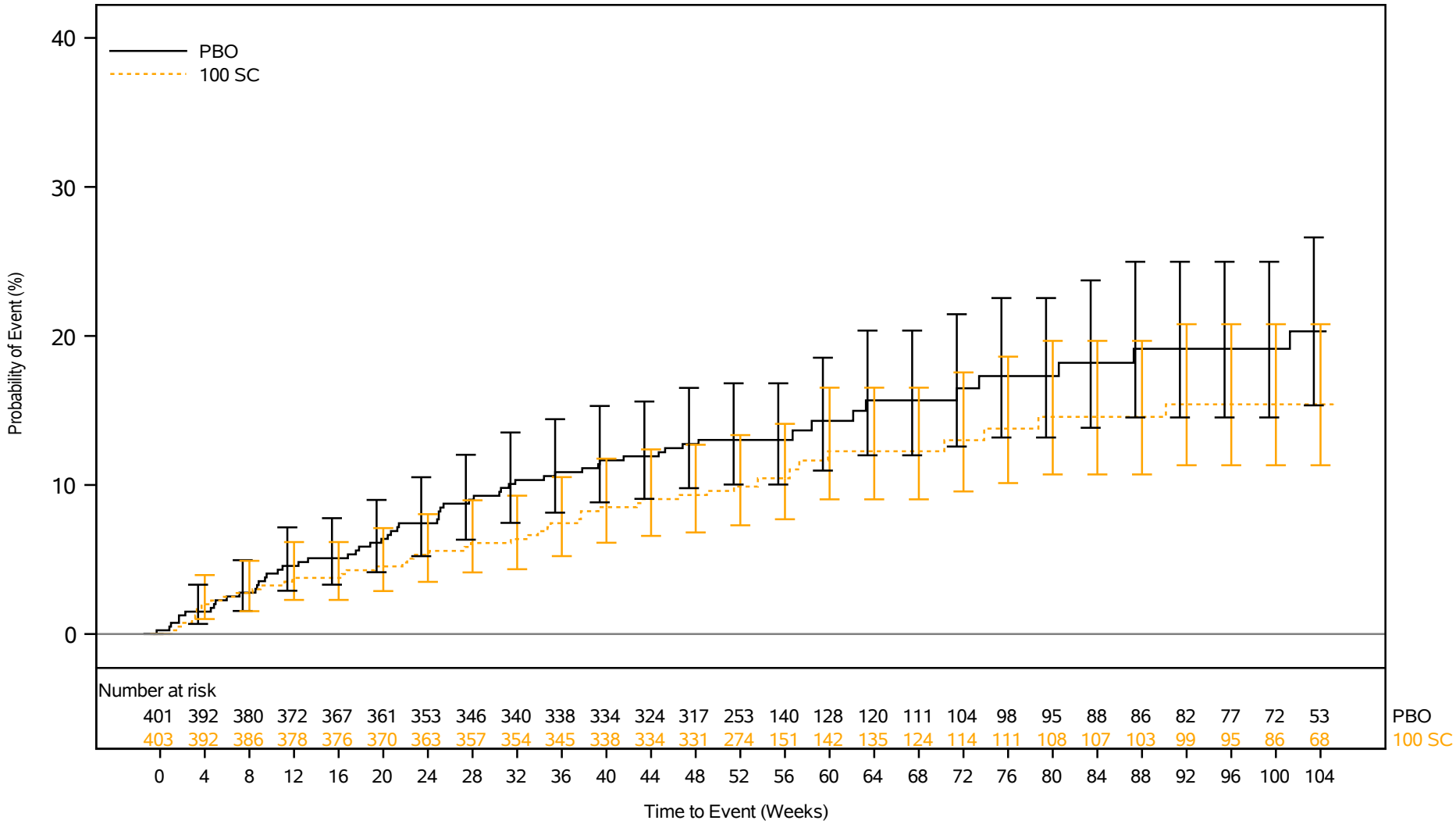


Horizontal bars indicate 95% confidence intervals for the Mepo/Placebo rate ratio.

Population: Modified Intent-to-Treat Population with Eosinophils 300 cells/uL or More

Figure 211.9
Kaplan-Meier Cumulative Incidence Curve for Time to First Severe Exacerbation:
Individual Studies and Meta-Analysis

Study: 208657

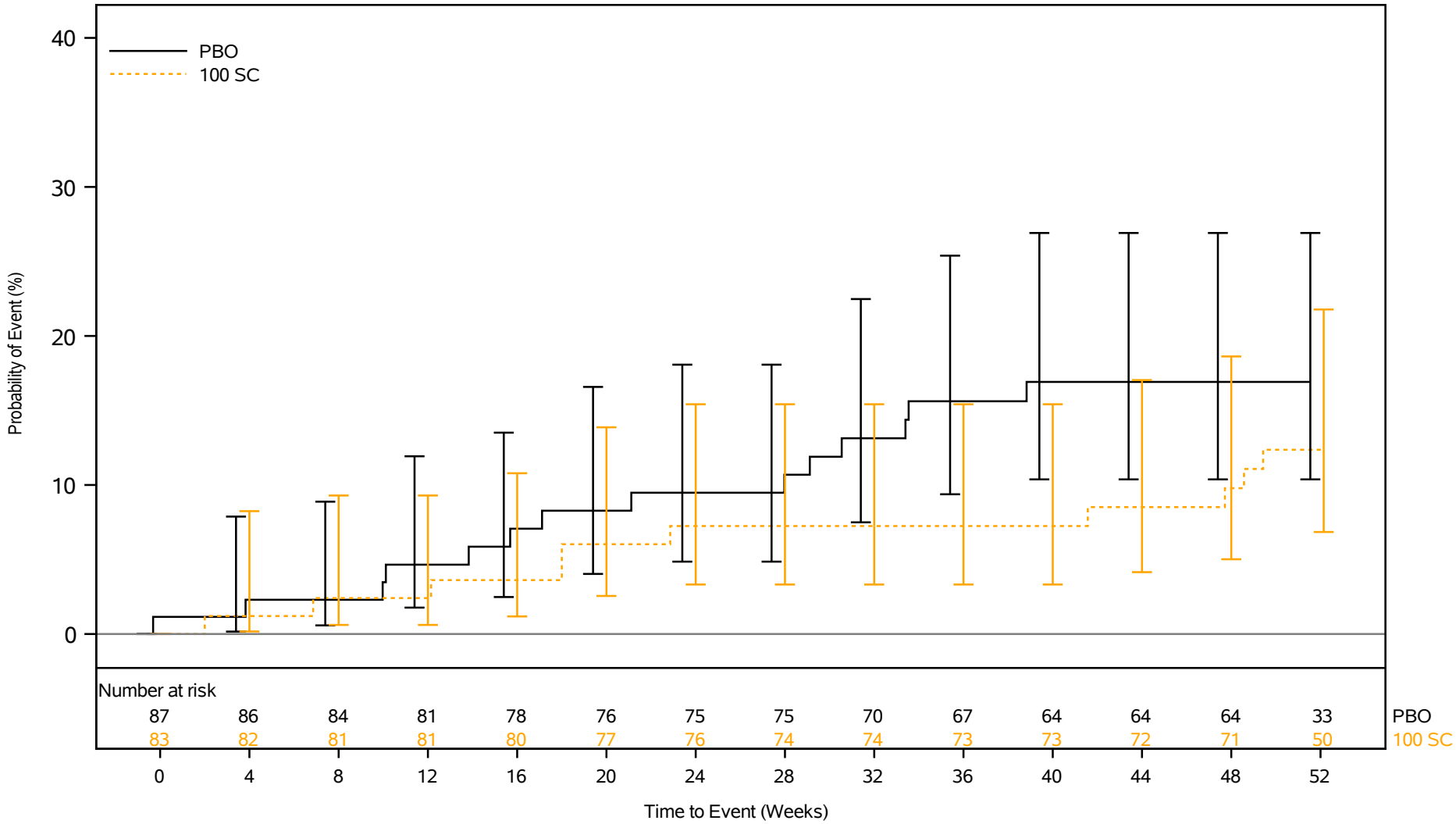


Note: Vertical bars represent 95% confidence intervals.
/mnt/code/postcsr_01/prod/tfls/f_e_km_sevex.sas 24OCT2025 18:38

Population: Modified Intent-to-Treat Population with Eosinophils 300 cells/uL or More

Figure 211.9
Kaplan-Meier Cumulative Incidence Curve for Time to First Severe Exacerbation:
Individual Studies and Meta-Analysis

Study: MEA117113

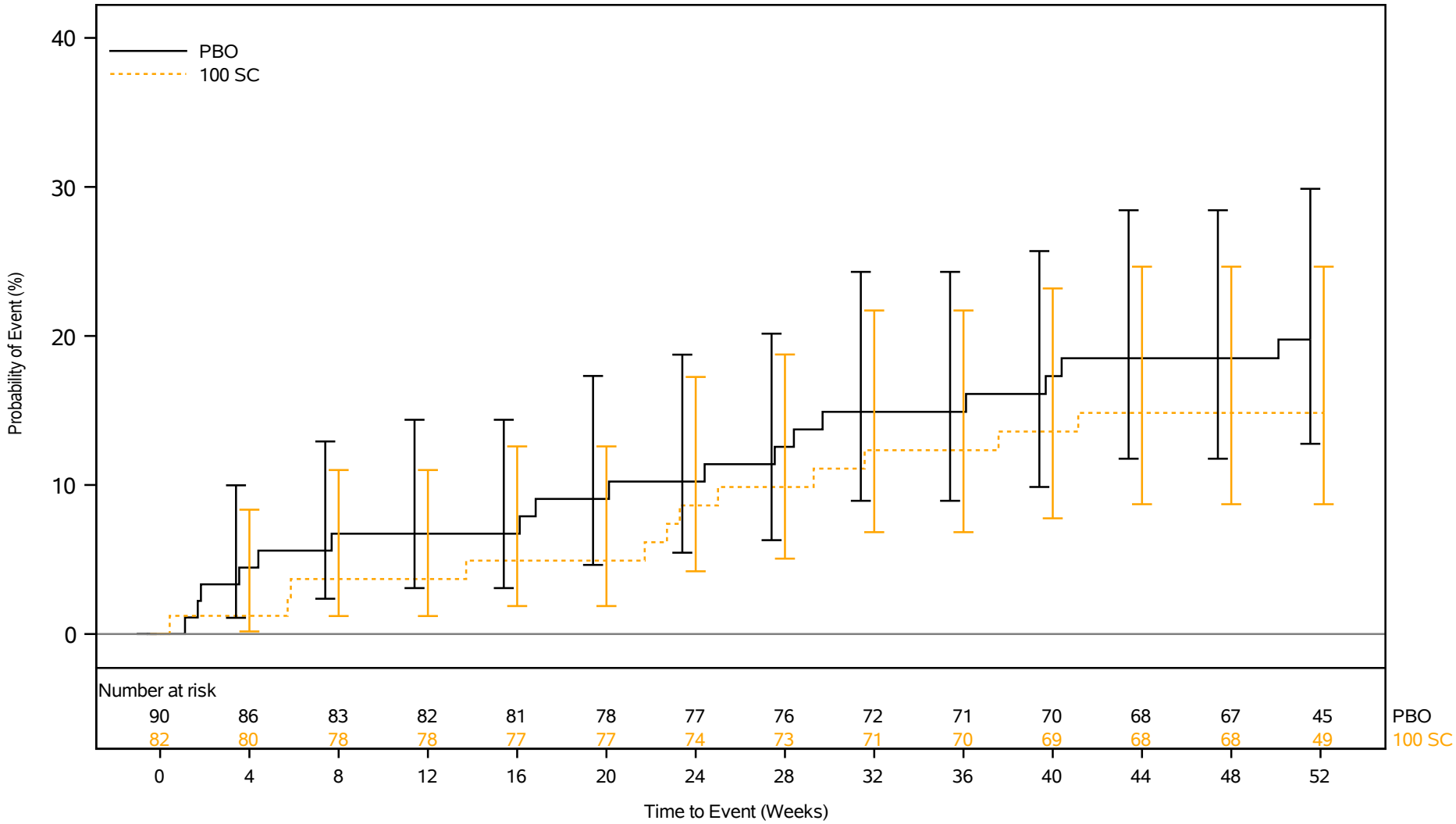


Note: Vertical bars represent 95% confidence intervals.
/mnt/code/postcsr_01/prod/tfls/f_e_km_sevex.sas 24OCT2025 18:38

Population: Modified Intent-to-Treat Population with Eosinophils 300 cells/uL or More

Figure 211.9
Kaplan-Meier Cumulative Incidence Curve for Time to First Severe Exacerbation:
Individual Studies and Meta-Analysis

Study: MEA117106

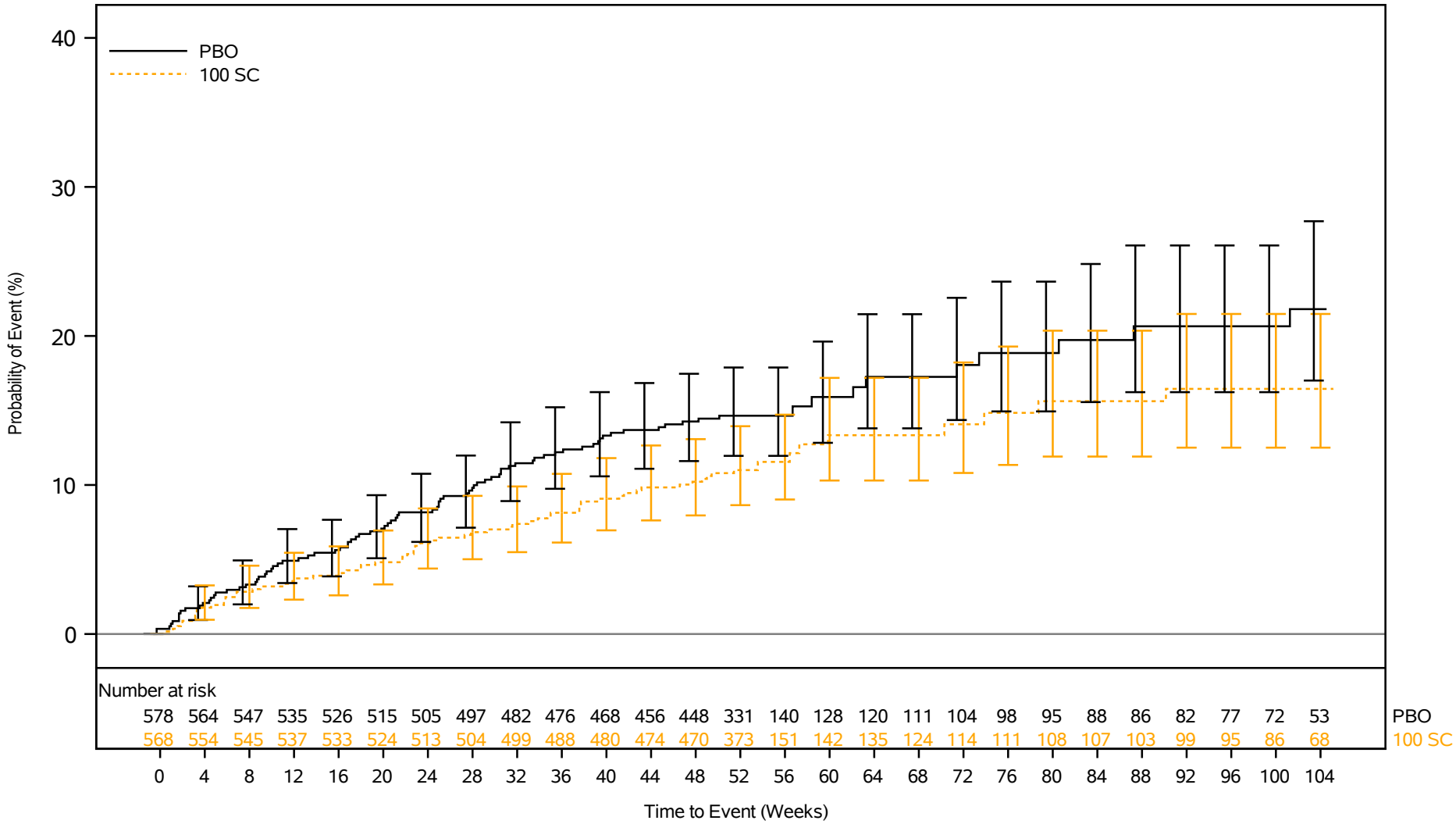


Note: Vertical bars represent 95% confidence intervals.
/mnt/code/postcsr_01/prod/tfls/f_e_km_sevex.sas 24OCT2025 18:38

Population: Modified Intent-to-Treat Population with Eosinophils 300 cells/uL or More

Figure 211.9
Kaplan-Meier Cumulative Incidence Curve for Time to First Severe Exacerbation:
Individual Studies and Meta-Analysis

Study: 208657 + MEA117113 + MEA117106

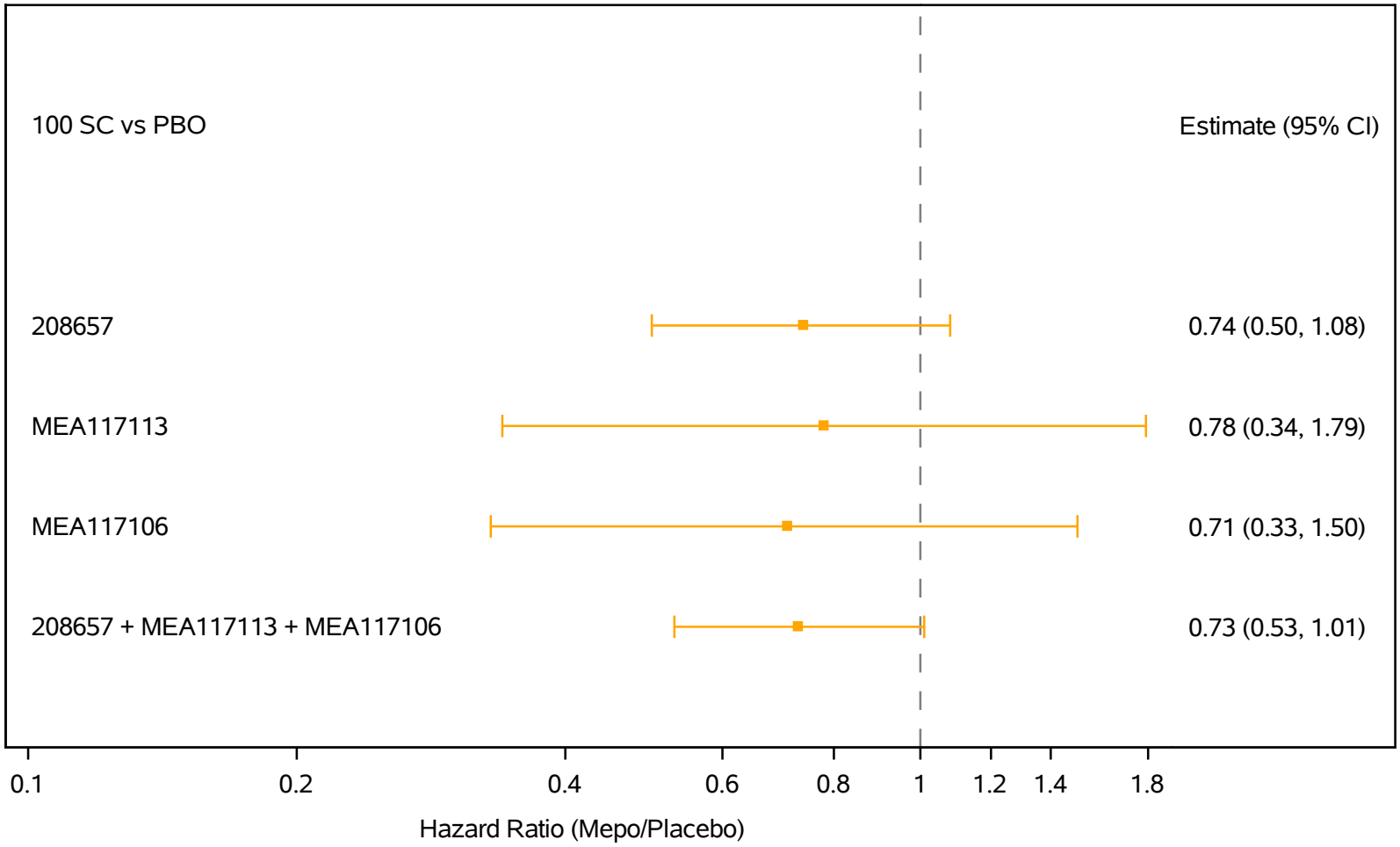


Note: Vertical bars represent 95% confidence intervals.
/mnt/code/postcsr_01/prod/tfls/f_e_km_sevex.sas 24OCT2025 18:38

Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Figure 211.10

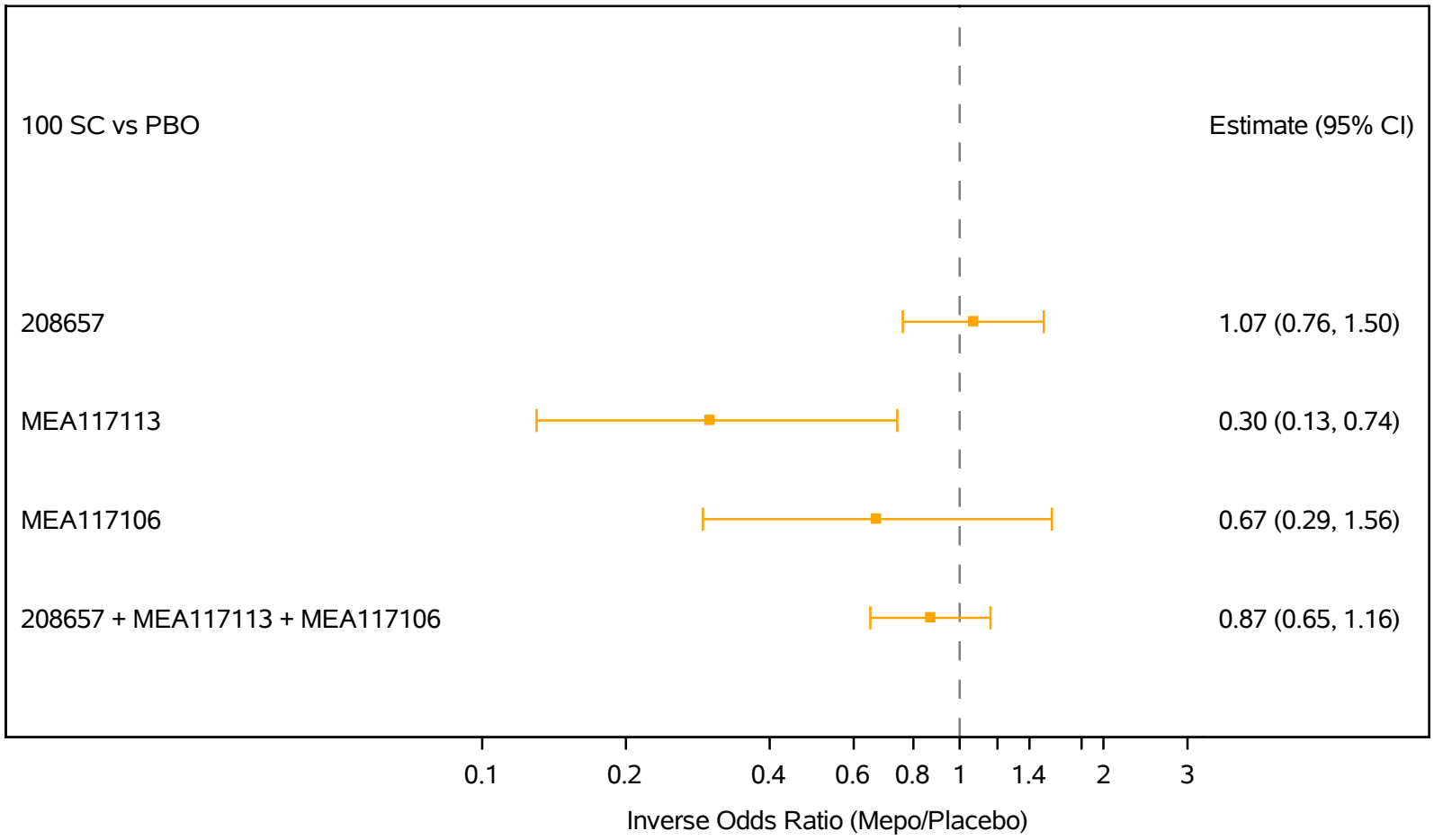
Forest Plot of Hazard Ratio for Severe Exacerbation: Individual Studies and Meta-Analysis



Horizontal bars indicate 95% confidence intervals for the Mepo/Placebo hazard ratio.

Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

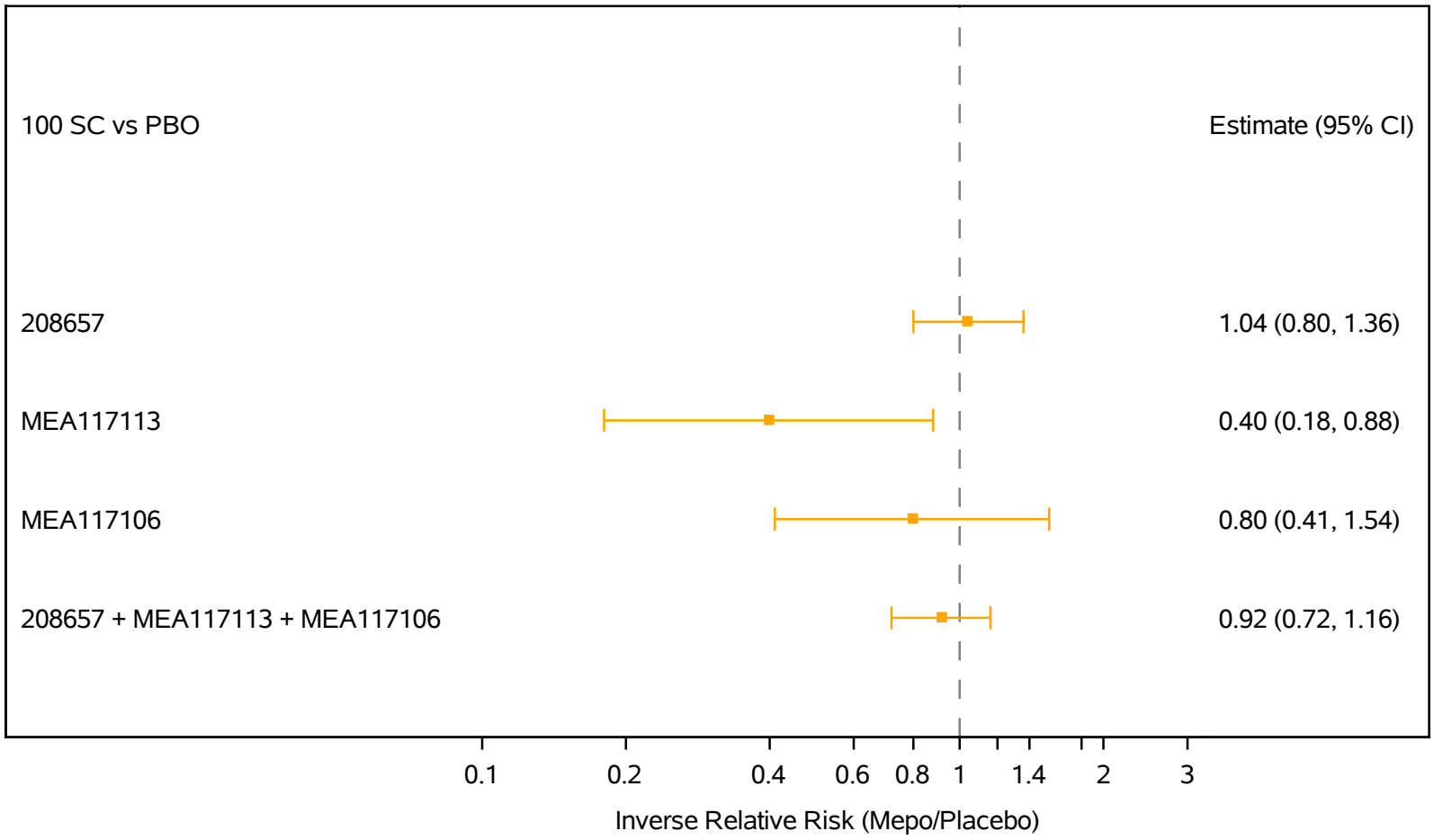
Figure 211.11
Forest Plot of Odds Ratio for COPD Assessment Test (CAT) Responders:
Individual Studies and Meta-Analysis



Horizontal bars indicate 95% confidence intervals for the Mepo/Placebo inverse odds ratio.
/mnt/code/postcsr_01/prod/tfls/f_e_cat_resp_or.sas 25JUL2025 13:32

Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Figure 211.12
Forest Plot of Relative Risk for COPD Assessment Test (CAT) Responders:
Individual Studies and Meta-Analysis

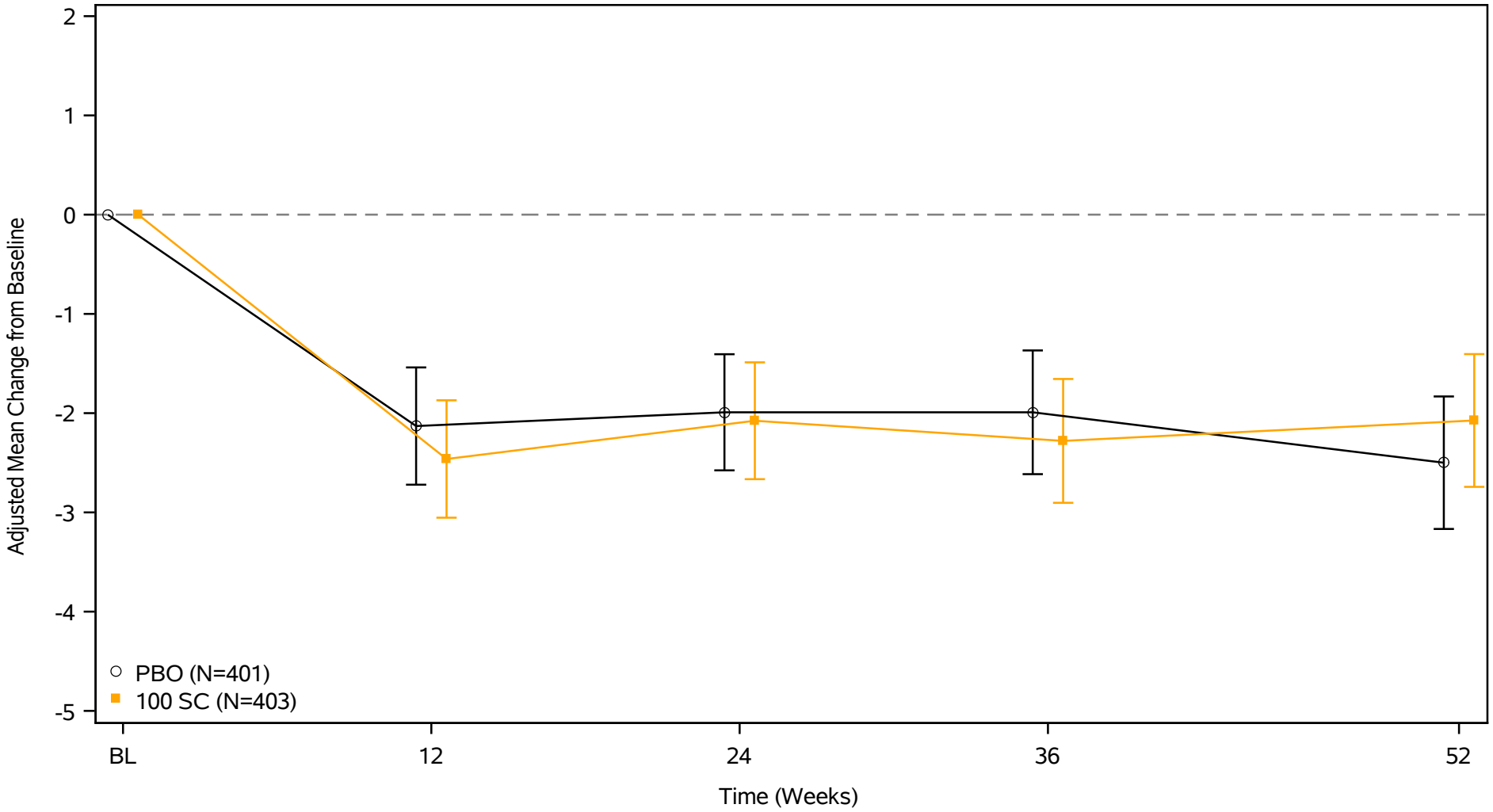


Horizontal bars indicate 95% confidence intervals for the Mepo/Placebo inverse relative risk.
/mnt/code/postcsr_01/prod/tfls/f_e_cat_resp_rr.sas 25JUL2025 13:32

Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Figure 20.23
Figure of COPD Assessment Test (CAT) Score: Change from Baseline:
Individual Studies and Meta-Analysis

Study: 208657

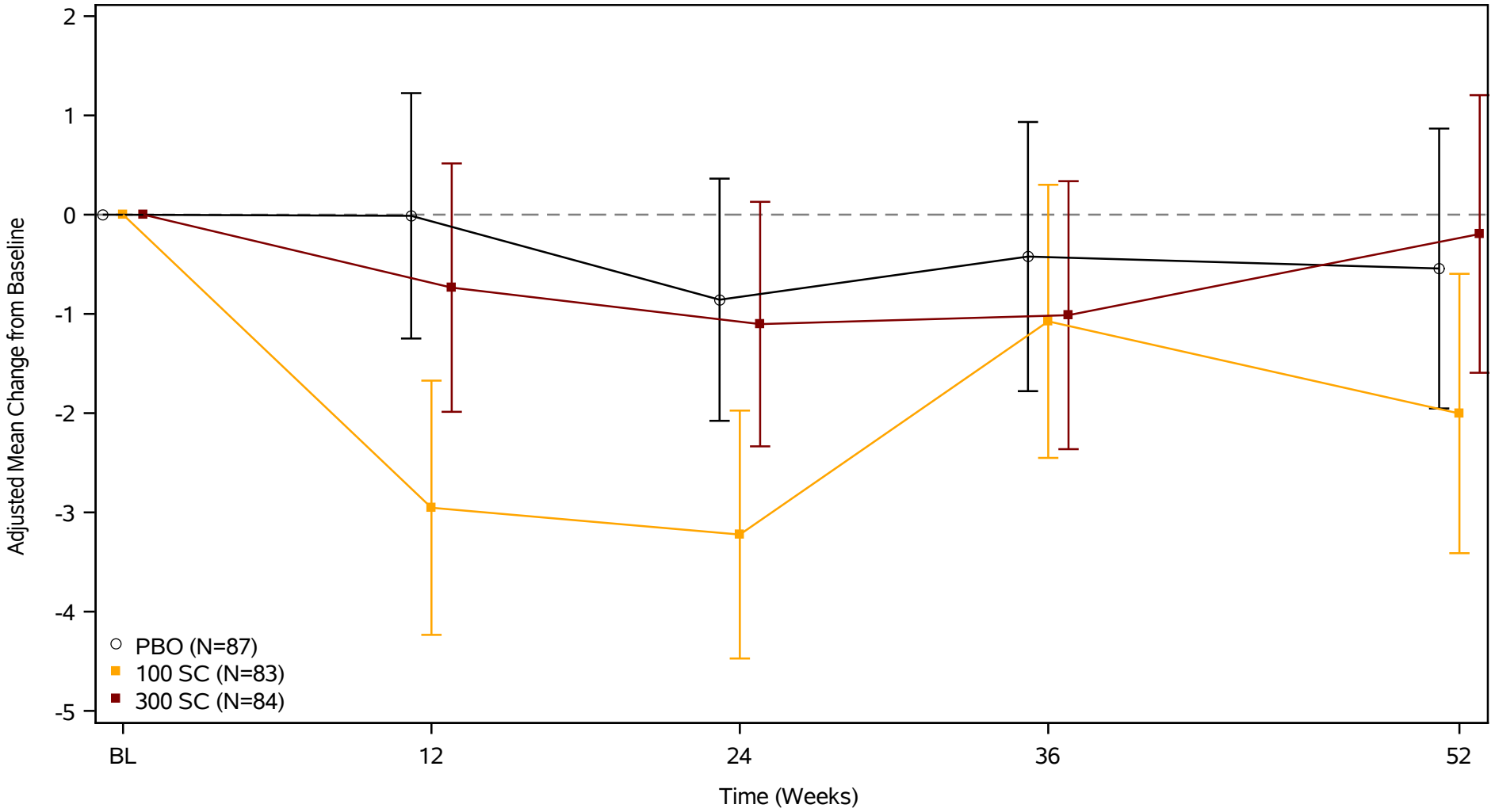


Note: Visits up to Week 52 displayed.
Note: Vertical bars represent 95% confidence intervals.
/mnt/code/is_4/prod/tfls/f_e_mmrm_cat_chg_fig.sas 10SEP2024 13:39

Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Figure 20.23
Figure of COPD Assessment Test (CAT) Score: Change from Baseline:
Individual Studies and Meta-Analysis

Study: MEA117113

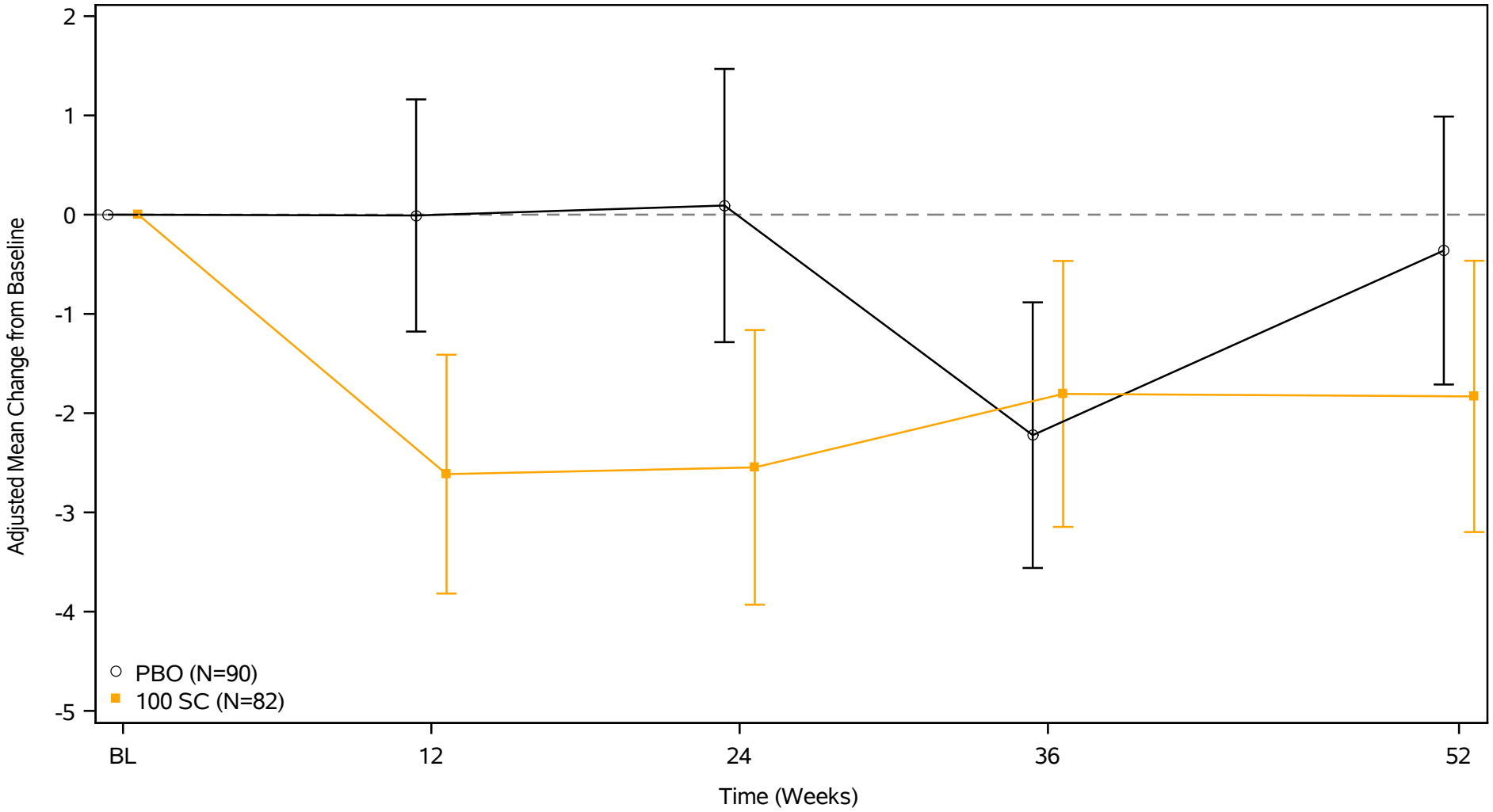


Note: Visits up to Week 52 displayed.
Note: Vertical bars represent 95% confidence intervals.
/mnt/code/is_4/prod/tfls/f_e_mmrm_cat_chg_fig.sas 10SEP2024 13:39

Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Figure 20.23
Figure of COPD Assessment Test (CAT) Score: Change from Baseline:
Individual Studies and Meta-Analysis

Study: MEA117106

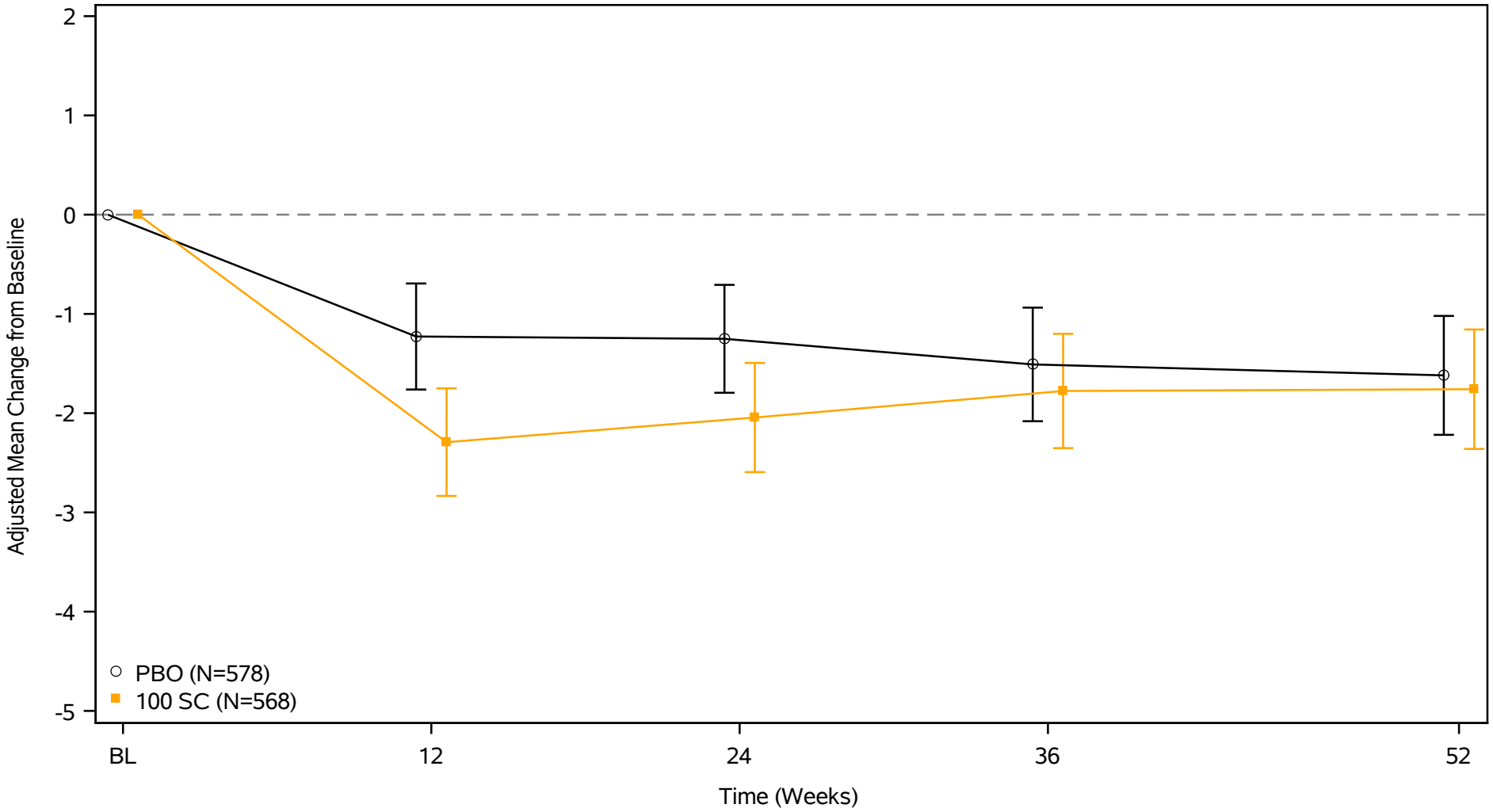


Note: Visits up to Week 52 displayed.
Note: Vertical bars represent 95% confidence intervals.
/mnt/code/is_4/prod/tfls/f_e_mmrm_cat_chg_fig.sas 10SEP2024 13:39

Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Figure 20.23
Figure of COPD Assessment Test (CAT) Score: Change from Baseline:
Individual Studies and Meta-Analysis

Study: 208657 + MEA117113 + MEA117106

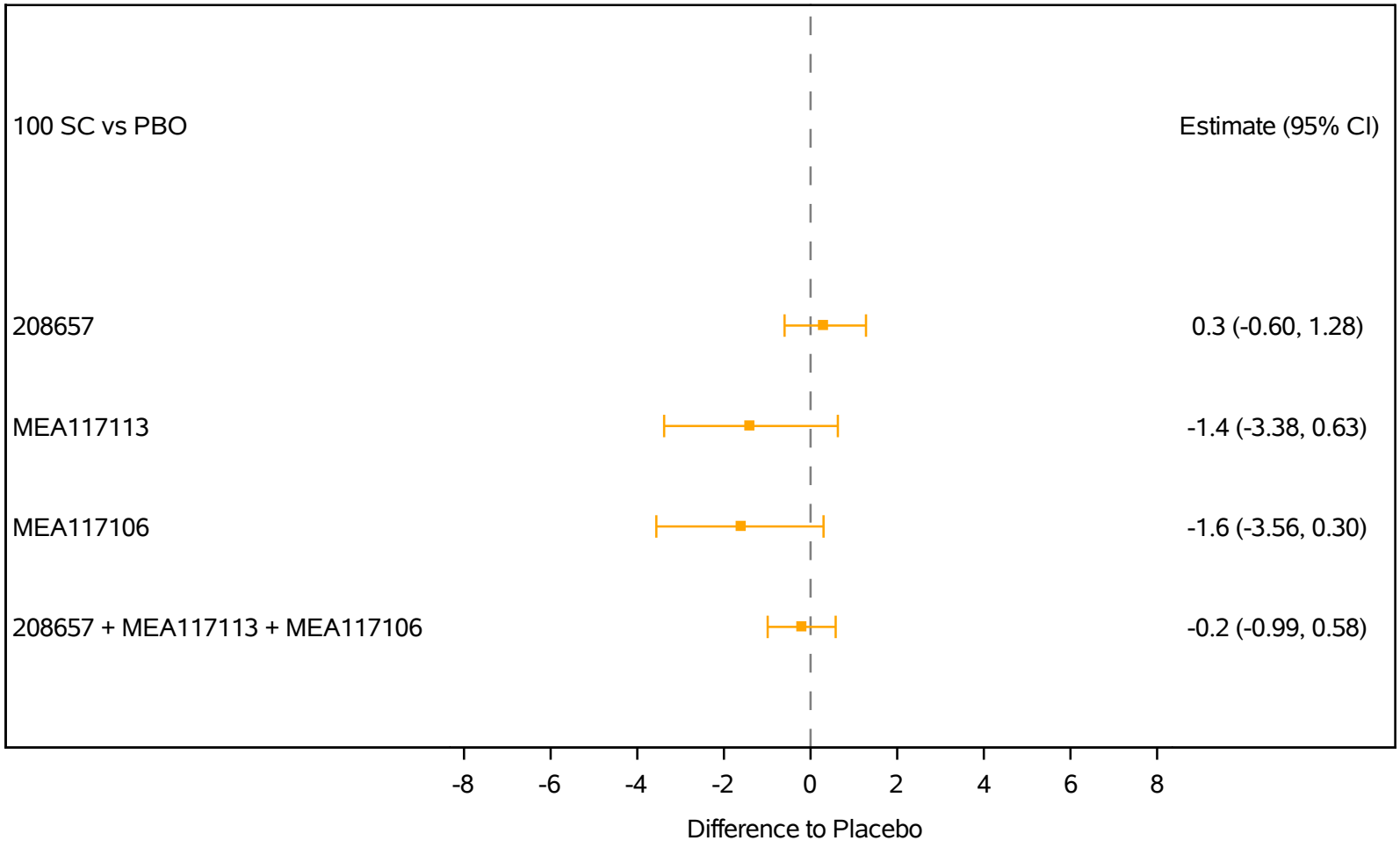


Note: Visits up to Week 52 displayed.
Note: Vertical bars represent 95% confidence intervals.
/mnt/code/is_4/prod/tfls/f_e_mmrm_cat_chg_fig.sas 10SEP2024 13:39

Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Figure 211.13

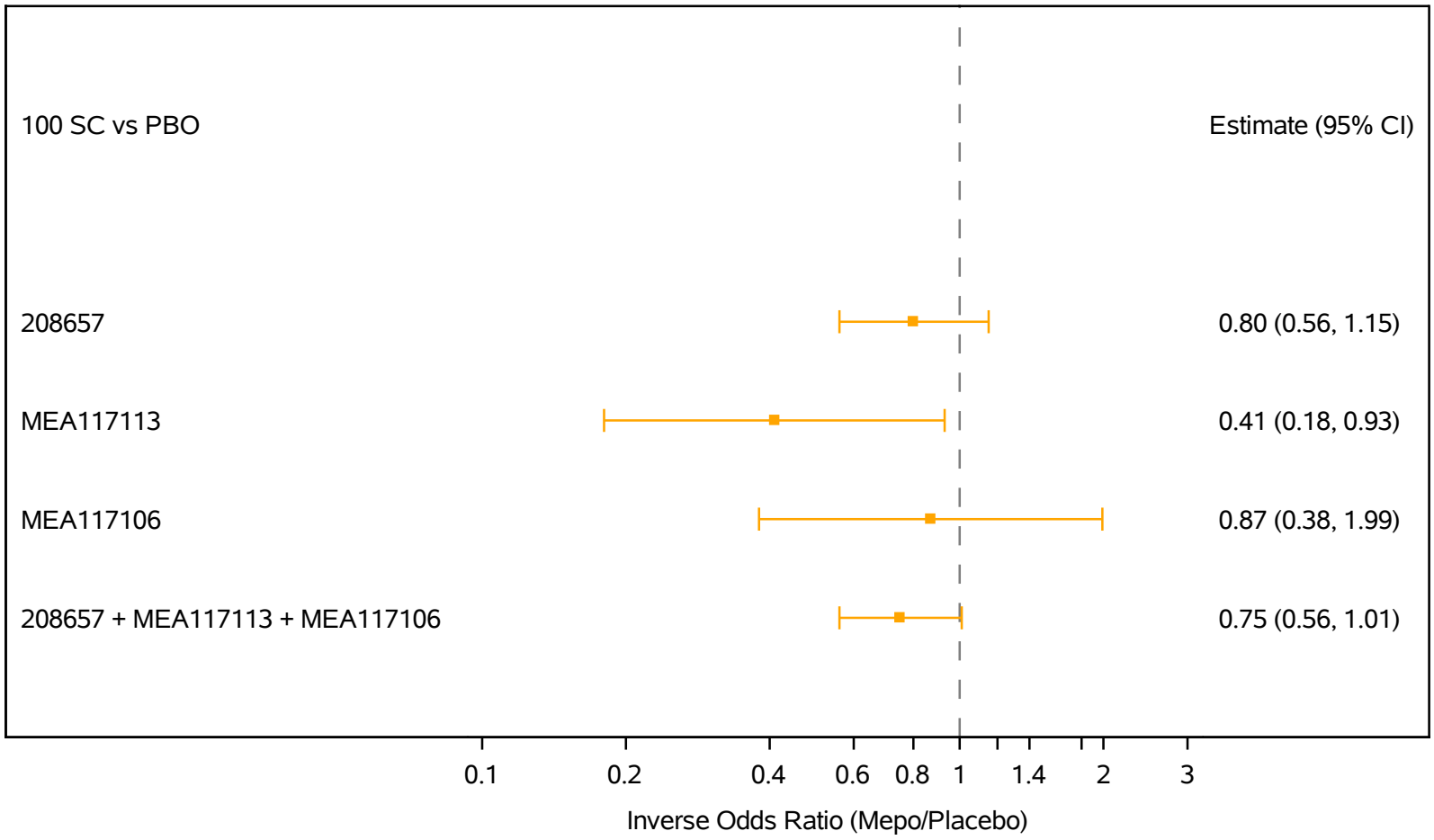
Forest Plot of COPD Assessment Test (CAT) Score: Change from Baseline: Individual Studies and Meta-Analysis



Note: Horizontal bars represent 95% confidence intervals for Mepo-Placebo difference.

Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Figure 211.14
Forest Plot of Odds Ratio for St George's Respiratory Questionnaire-COPD (SGRQ-C)
Responders: Individual Studies and Meta-Analysis

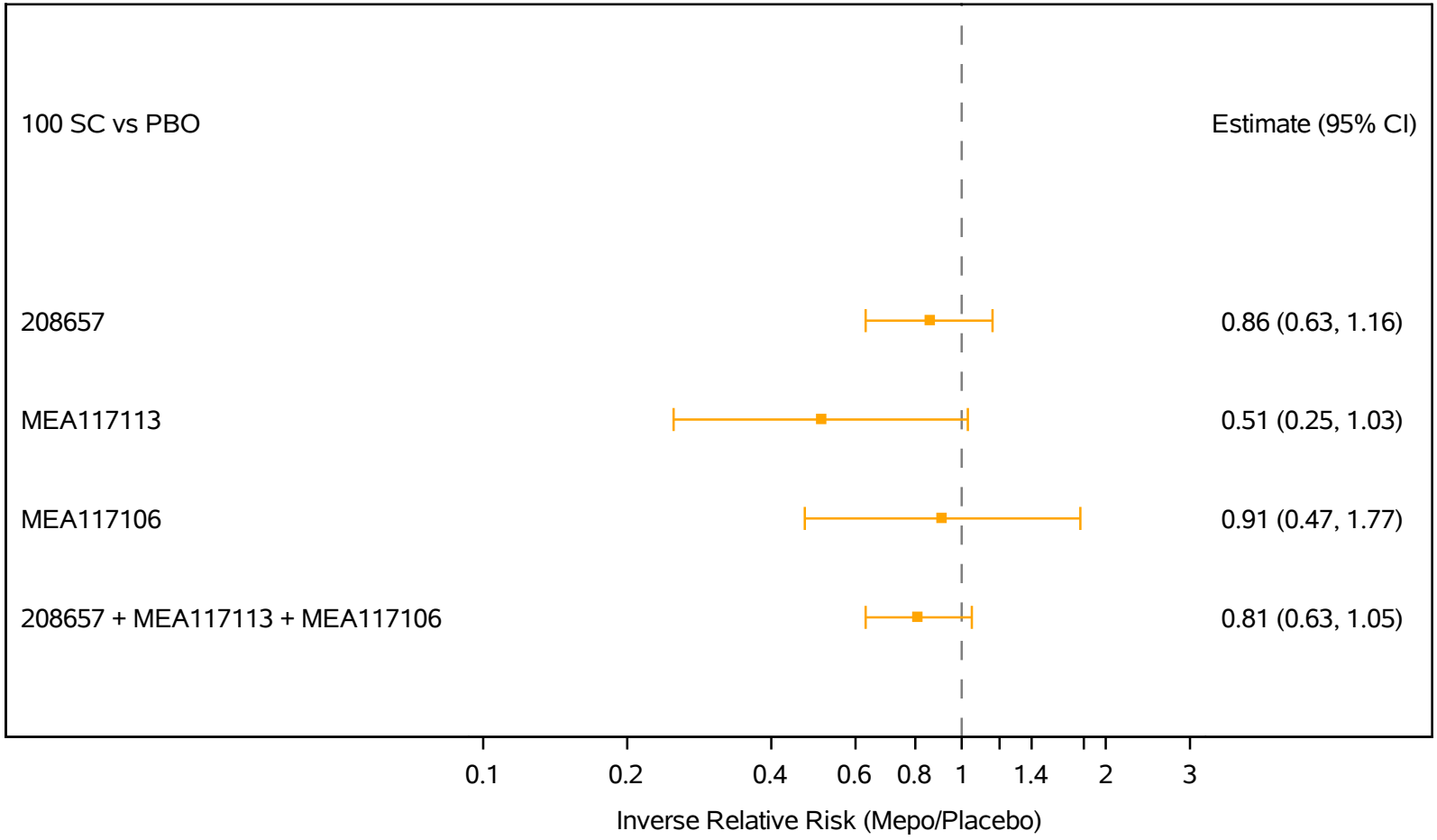


Horizontal bars indicate 95% confidence intervals for the Mepo/Placebo inverse odds ratio.
/mnt/code/postcsr_01/prod/tfls/f_e_sgrq_resp_or.sas 25JUL2025 13:32

Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Figure 211.15

Forest Plot of Relative Risk for St George's Respiratory Questionnaire-COPD (SGRQ-C)
Responders: Individual Studies and Meta-Analysis

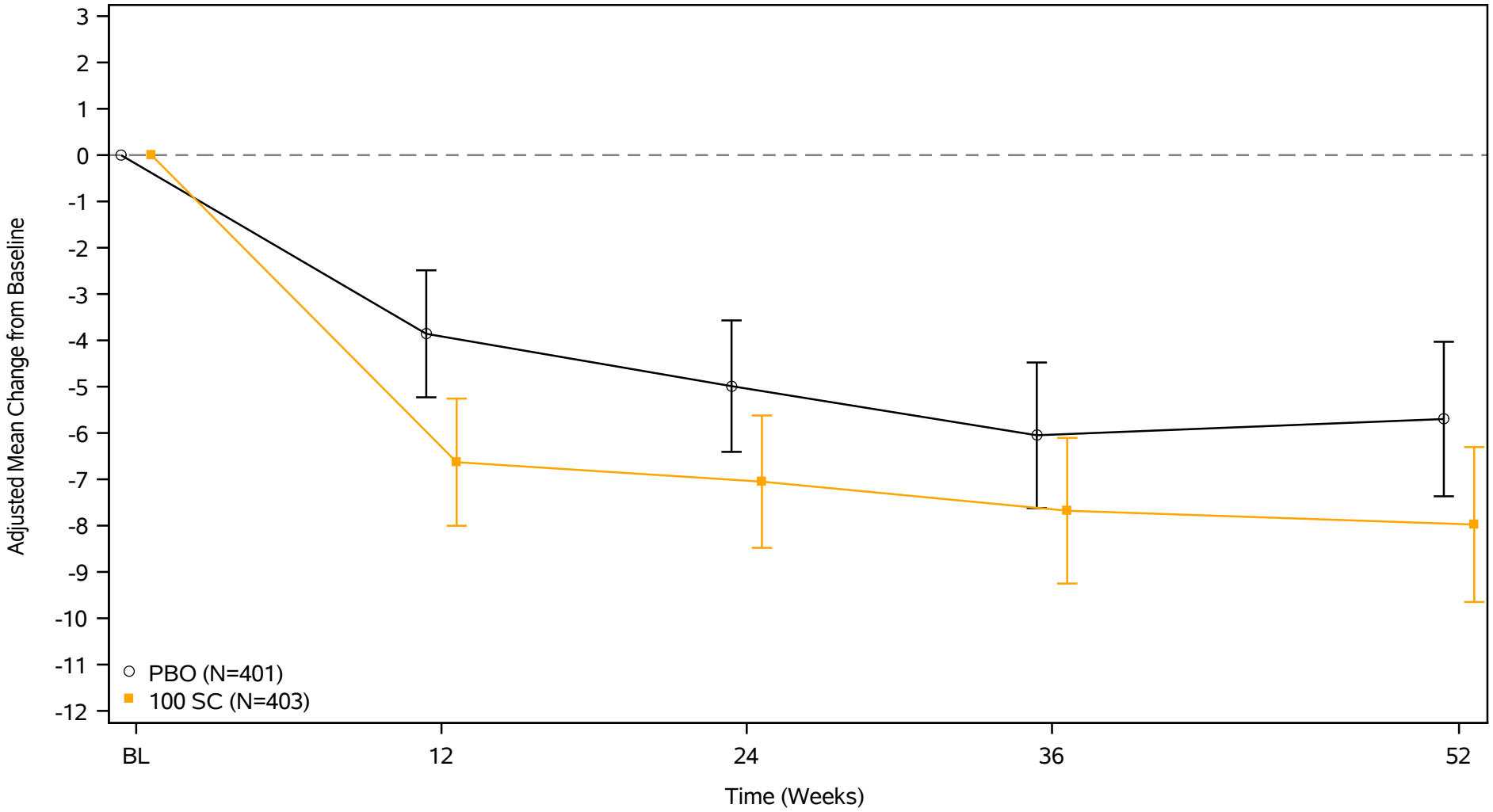


Horizontal bars indicate 95% confidence intervals for the Mepo/Placebo inverse relative risk.
/mnt/code/postcsr_01/prod/tfls/f_e_sgrq_resp_rr.sas 25JUL2025 13:33

Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Figure 20.30
Figure of St George's Respiratory Questionnaire (SGRQ-C) Total Score:
Change from Baseline: Individual Studies and Meta-Analysis

Study: 208657

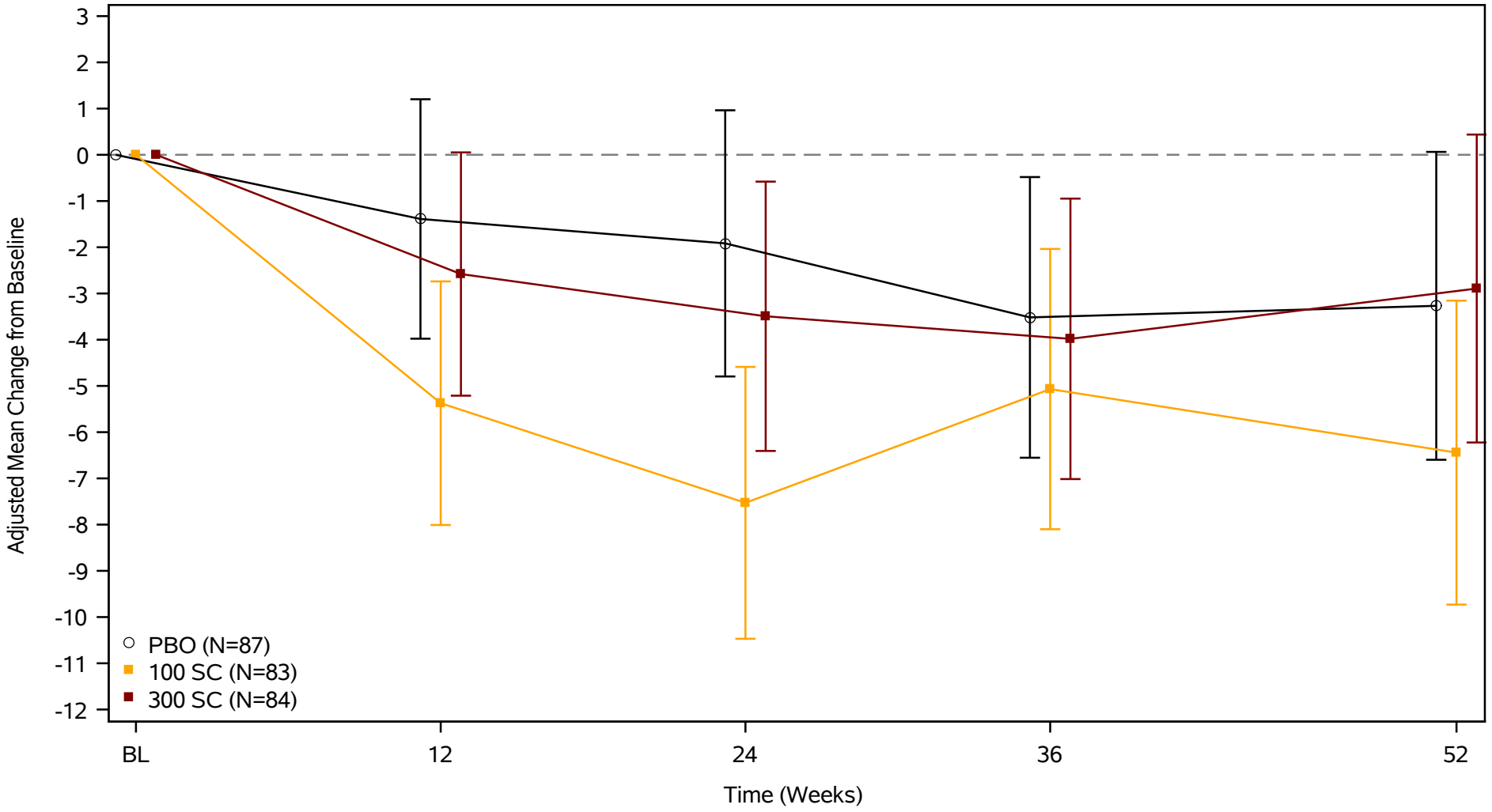


Note: Visits up to Week 52 displayed.
Note: Vertical bars represent 95% confidence intervals.
/mnt/code/is_4/prod/tfls/f_e_mmrm_sgrq_chg_fig.sas 10SEP2024 13:38

Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Figure 20.30
Figure of St George's Respiratory Questionnaire (SGRQ-C) Total Score:
Change from Baseline: Individual Studies and Meta-Analysis

Study: MEA117113

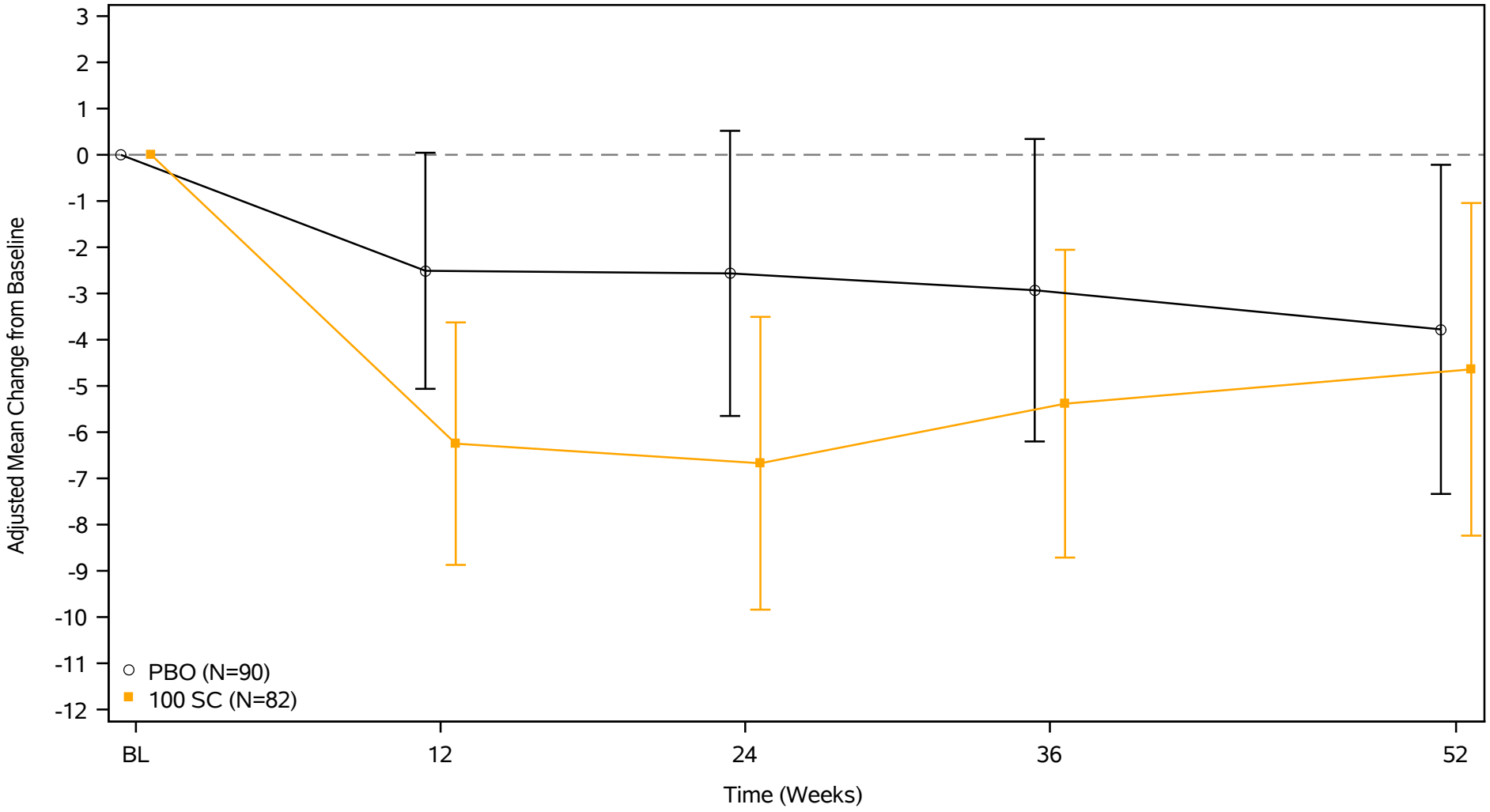


Note: Visits up to Week 52 displayed.
Note: Vertical bars represent 95% confidence intervals.
/mnt/code/is_4/prod/tfls/f_e_mmrm_sgrq_chg_fig.sas 10SEP2024 13:38

Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Figure 20.30
Figure of St George's Respiratory Questionnaire (SGRQ-C) Total Score:
Change from Baseline: Individual Studies and Meta-Analysis

Study: MEA117106

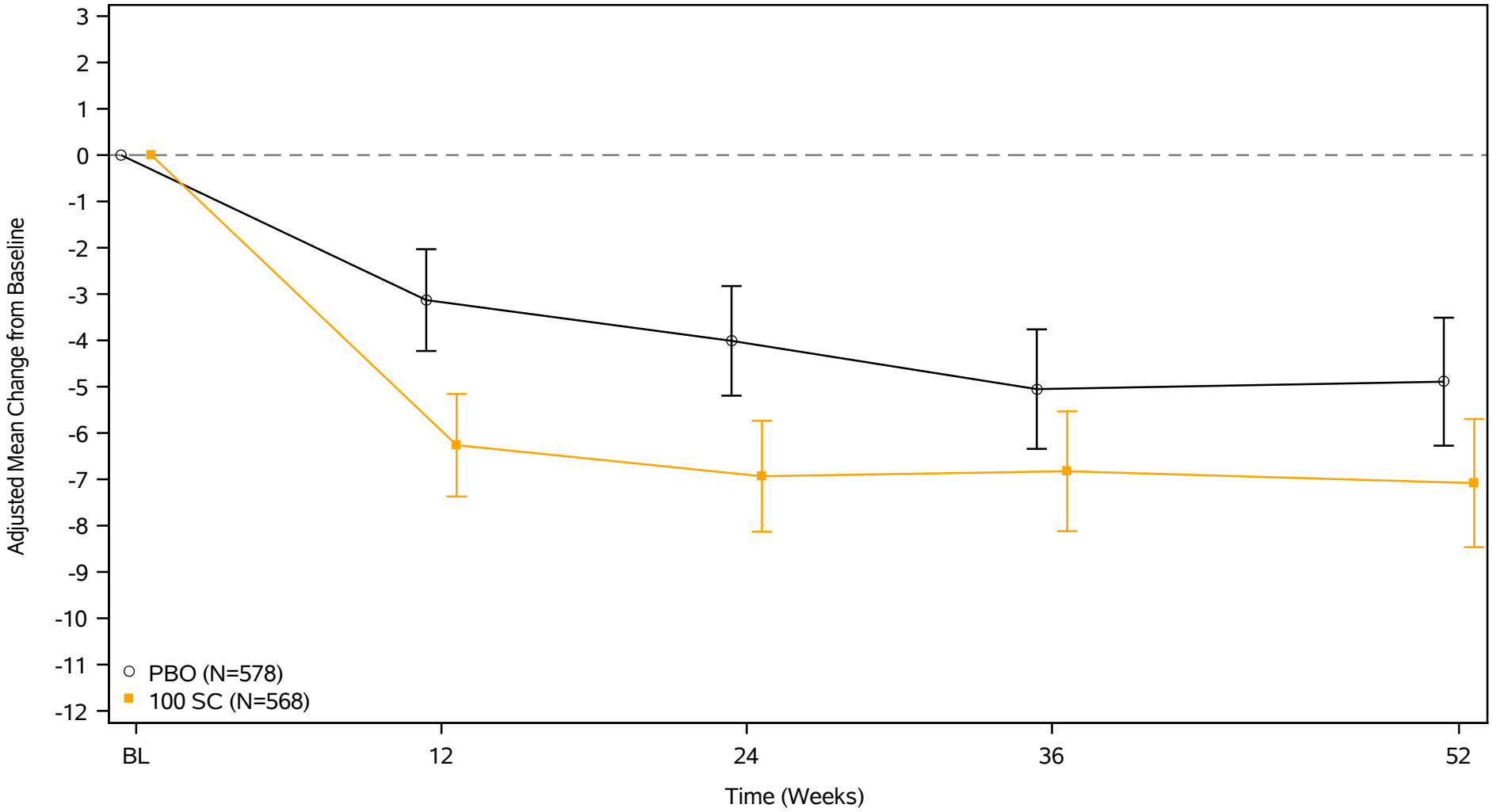


Note: Visits up to Week 52 displayed.
Note: Vertical bars represent 95% confidence intervals.
/mnt/code/is_4/prod/tfls/f_e_mmrm_sgrq_chg_fig.sas 10SEP2024 13:38

Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Figure 20.30
Figure of St George's Respiratory Questionnaire (SGRQ-C) Total Score:
Change from Baseline: Individual Studies and Meta-Analysis

Study: 208657 + MEA117113 + MEA117106

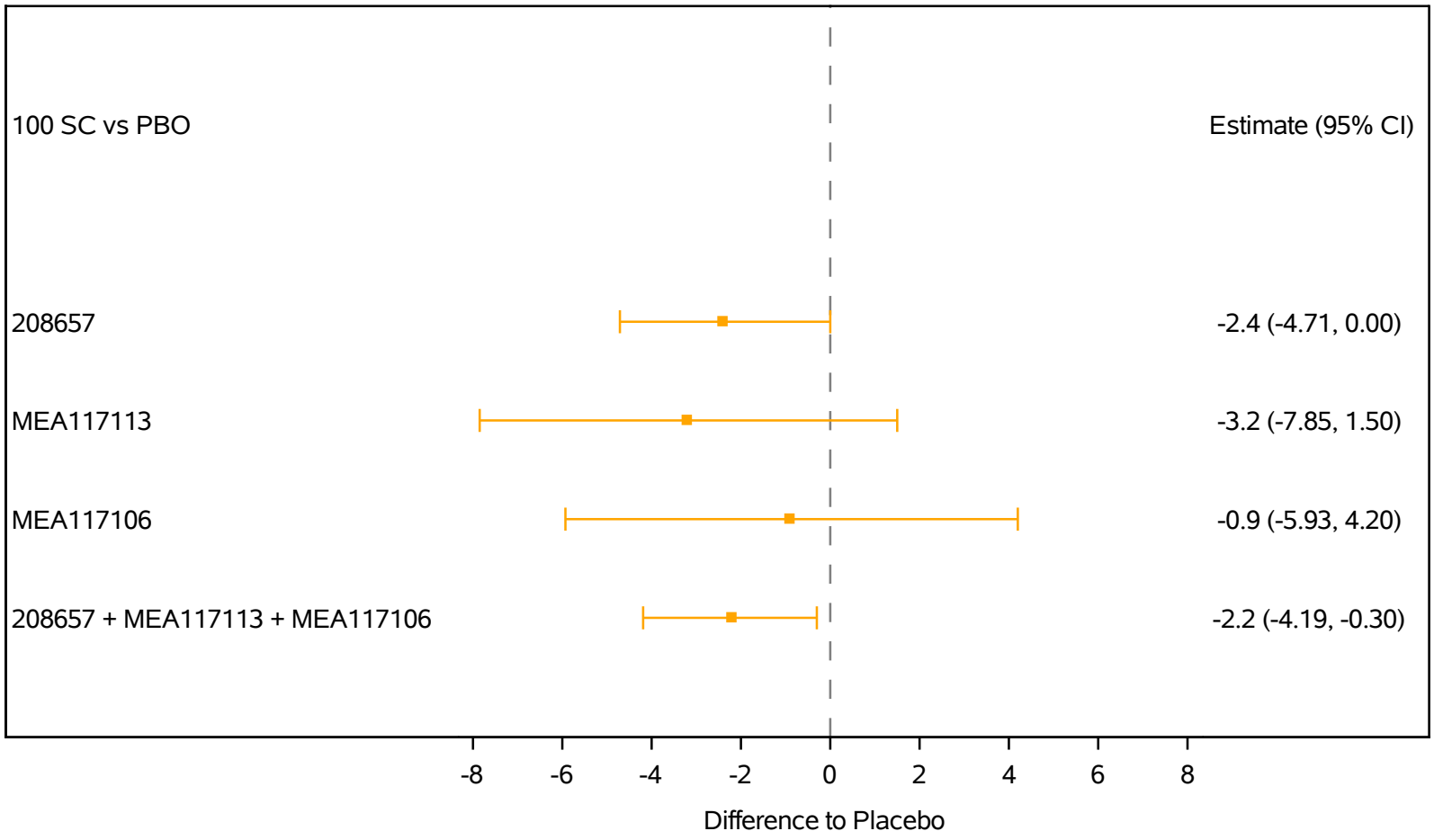


Note: Visits up to Week 52 displayed.
Note: Vertical bars represent 95% confidence intervals.
/mnt/code/is_4/prod/tfls/f_e_mmrm_sgrq_chg_fig.sas 10SEP2024 13:38

Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Figure 211.16

Forest Plot of St George's Respiratory Questionnaire-COPD (SGRQ-C) Total Score: Change from Baseline: Individual Studies and Meta-Analysis



Note: Horizontal bars represent 95% confidence intervals for Mepo-Placebo difference.

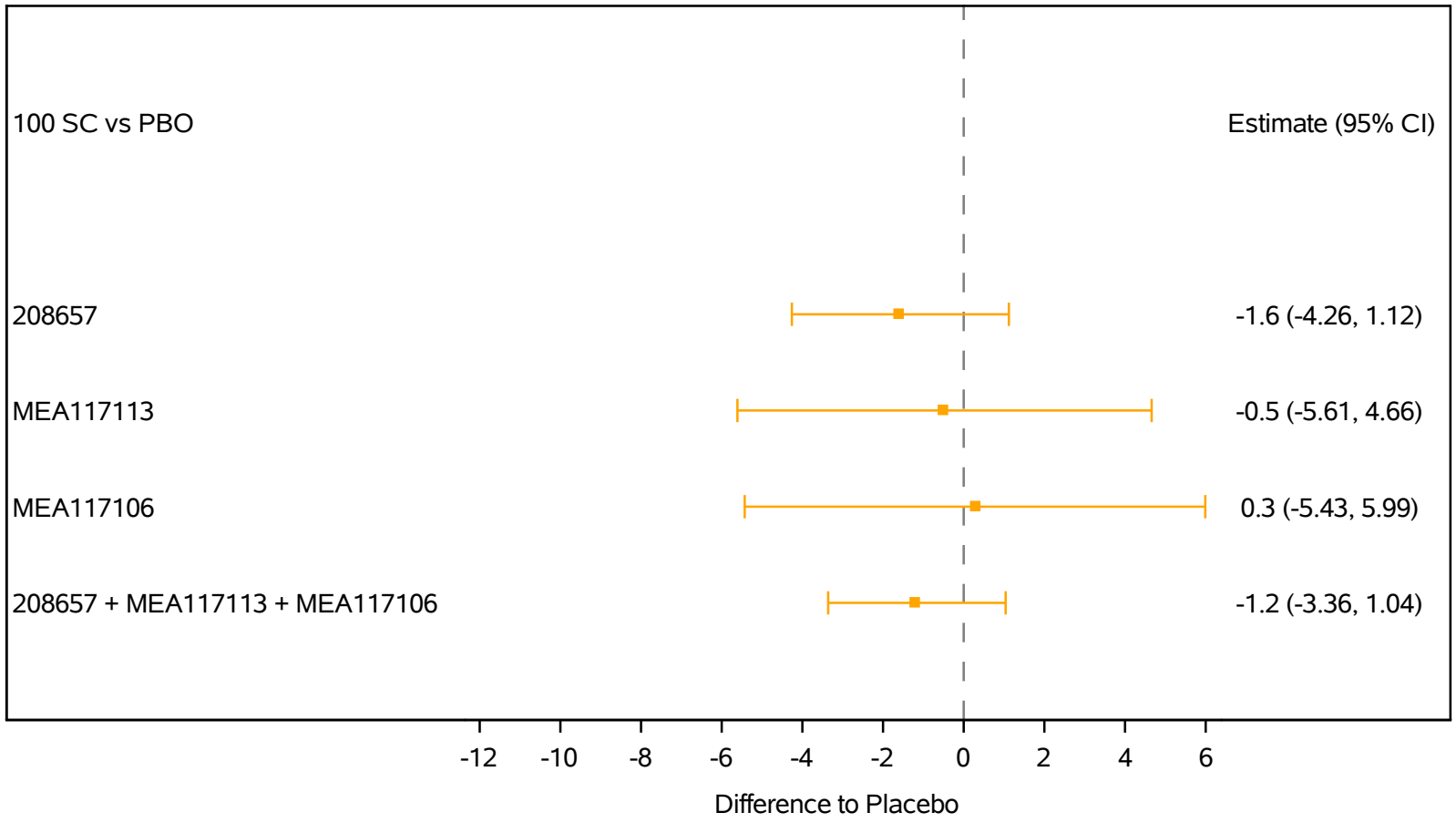
/mnt/code/postcsr_01/prod/tfls/f_e_sgrq_chg_wk52.sas 25JUL2025 13:33

Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Figure 211.17

Forest Plot of St George's Respiratory Questionnaire-COPD (SGRQ-C) Score by Domain: Change from Baseline: Individual Studies and Meta-Analysis

Domain Score: Activity Domain



Note: Horizontal bars represent 95% confidence intervals for Mepo-Placebo difference.

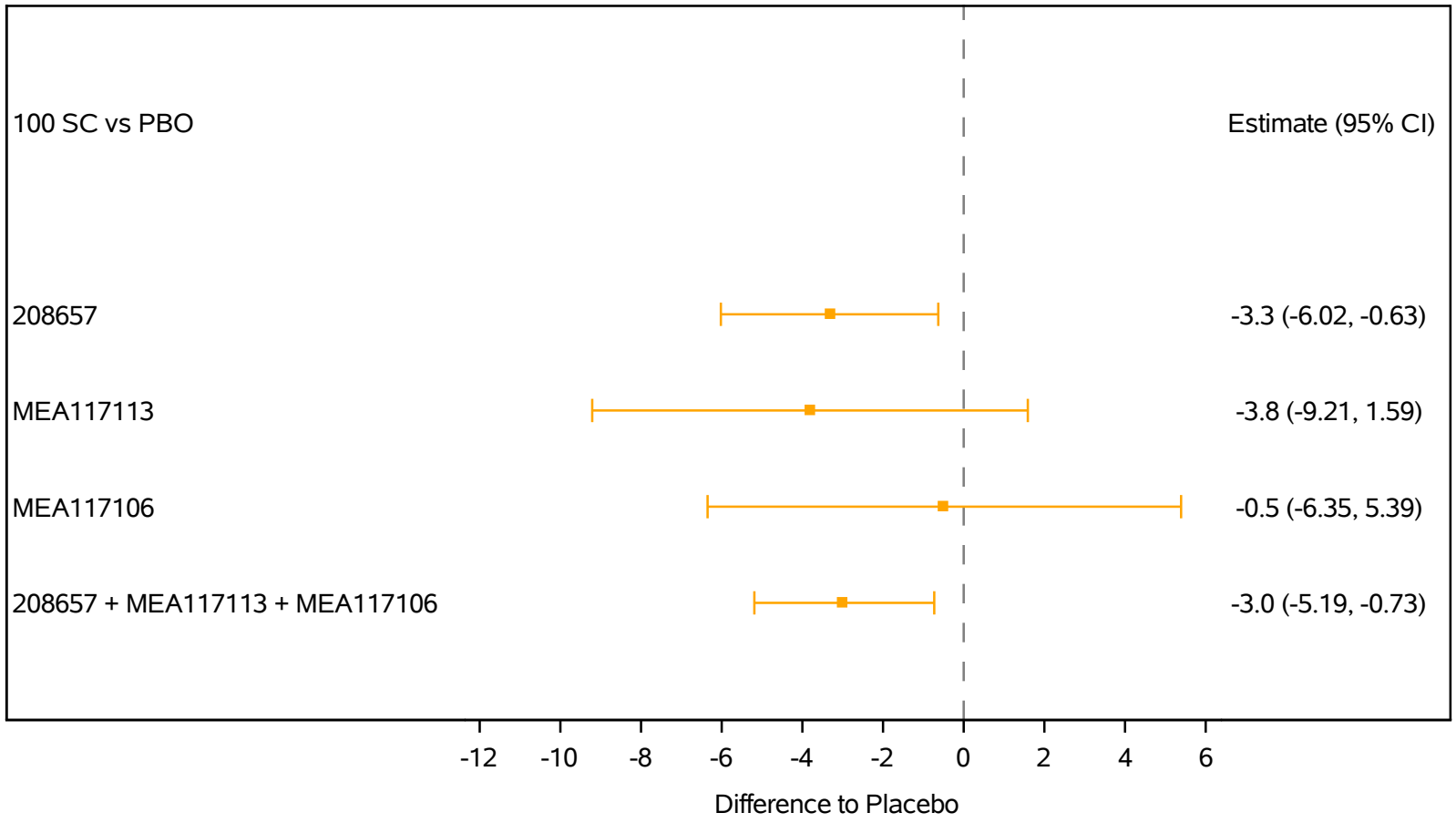
/mnt/code/postcsr_01/prod/tfls/f_e_sgrq_chg_dom.sas 25JUL2025 13:34

Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Figure 211.17

Forest Plot of St George's Respiratory Questionnaire-COPD (SGRQ-C) Score by Domain: Change from Baseline: Individual Studies and Meta-Analysis

Domain Score: Impacts Domain

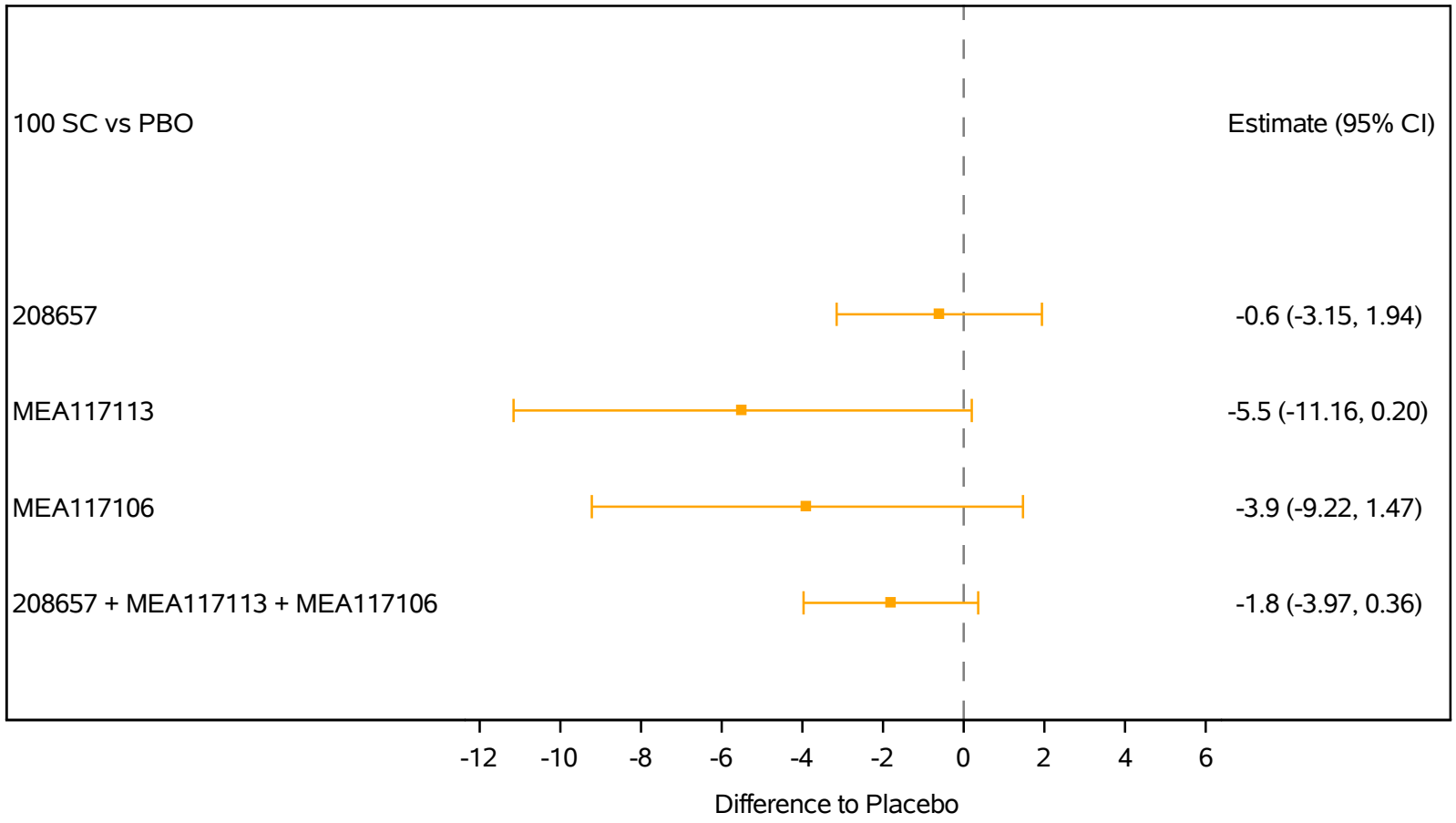


Note: Horizontal bars represent 95% confidence intervals for Mepo-Placebo difference.

/mnt/code/postcsr_01/prod/tfls/f_e_sgrq_chg_dom.sas 25JUL2025 13:34

Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

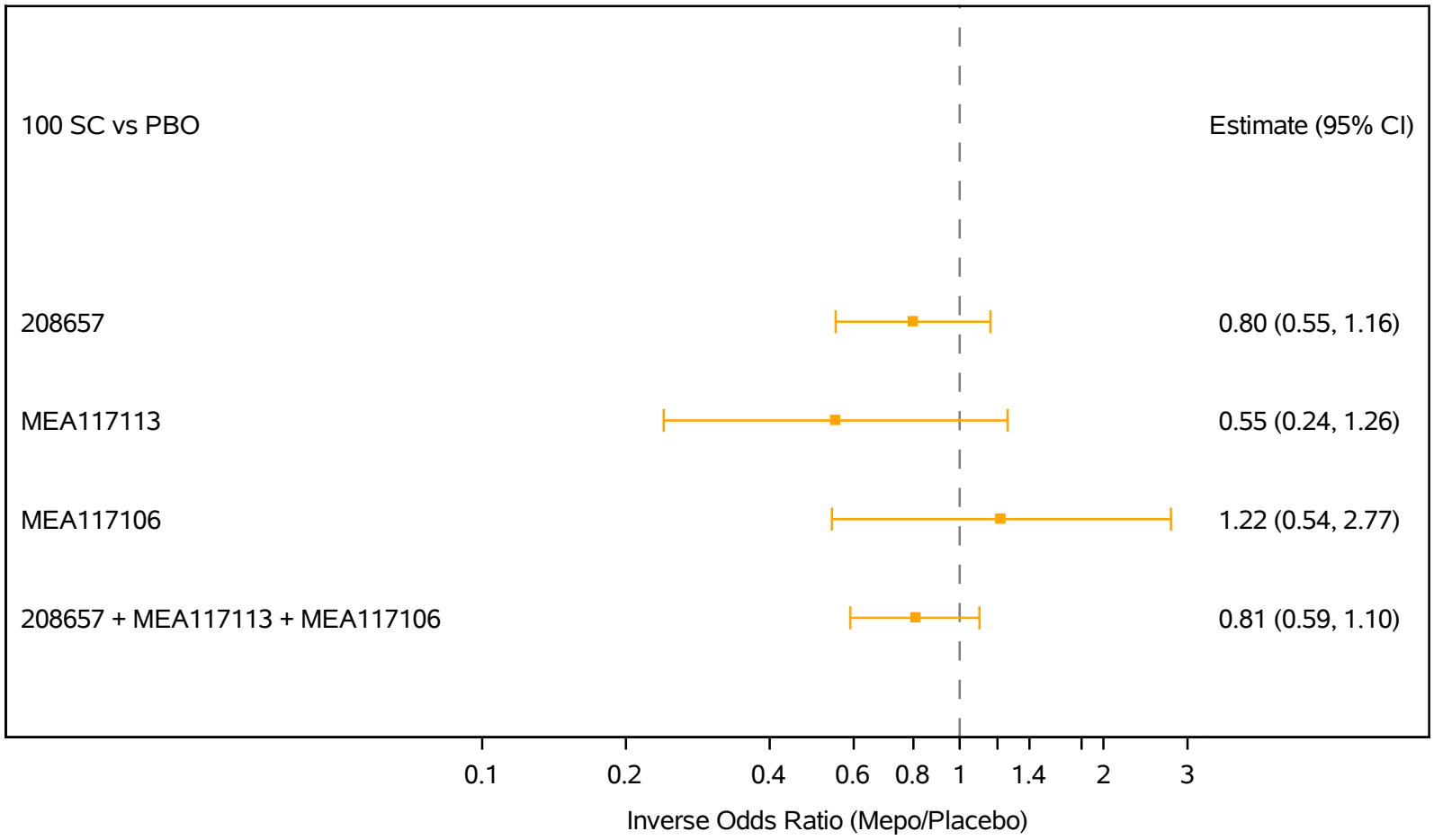
Figure 211.17
Forest Plot of St George's Respiratory Questionnaire-COPD (SGRQ-C) Score by Domain: Change from Baseline: Individual Studies and Meta-Analysis
Domain Score: Symptoms Domain



Note: Horizontal bars represent 95% confidence intervals for Mepo-Placebo difference.
/mnt/code/postcsr_01/prod/tfls/f_e_sgrq_chg_dom.sas 25JUL2025 13:34

Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

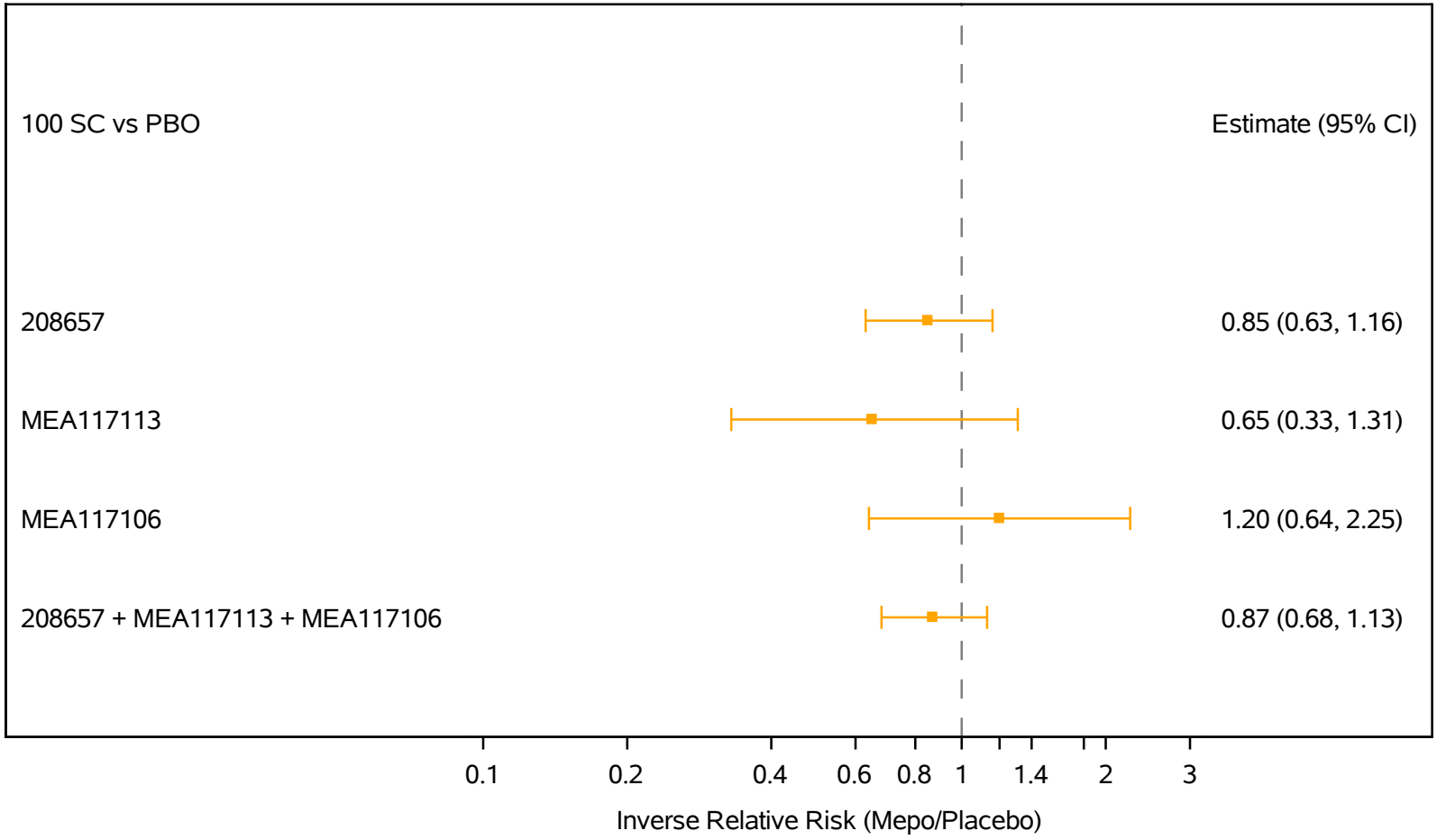
Figure 211.18
Forest Plot of Odds Ratio for EQ-5D VAS score Responders:
Individual Studies and Meta-Analysis



Horizontal bars indicate 95% confidence intervals for the Mepo/Placebo inverse odds ratio.
/mnt/code/postcsr_01/prod/tfls/f_e_eq5d_resp_or.sas 25JUL2025 13:34

Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Figure 211.19
Forest Plot of Relative Risk for EQ-5D VAS score Responders:
Individual Studies and Meta-Analysis

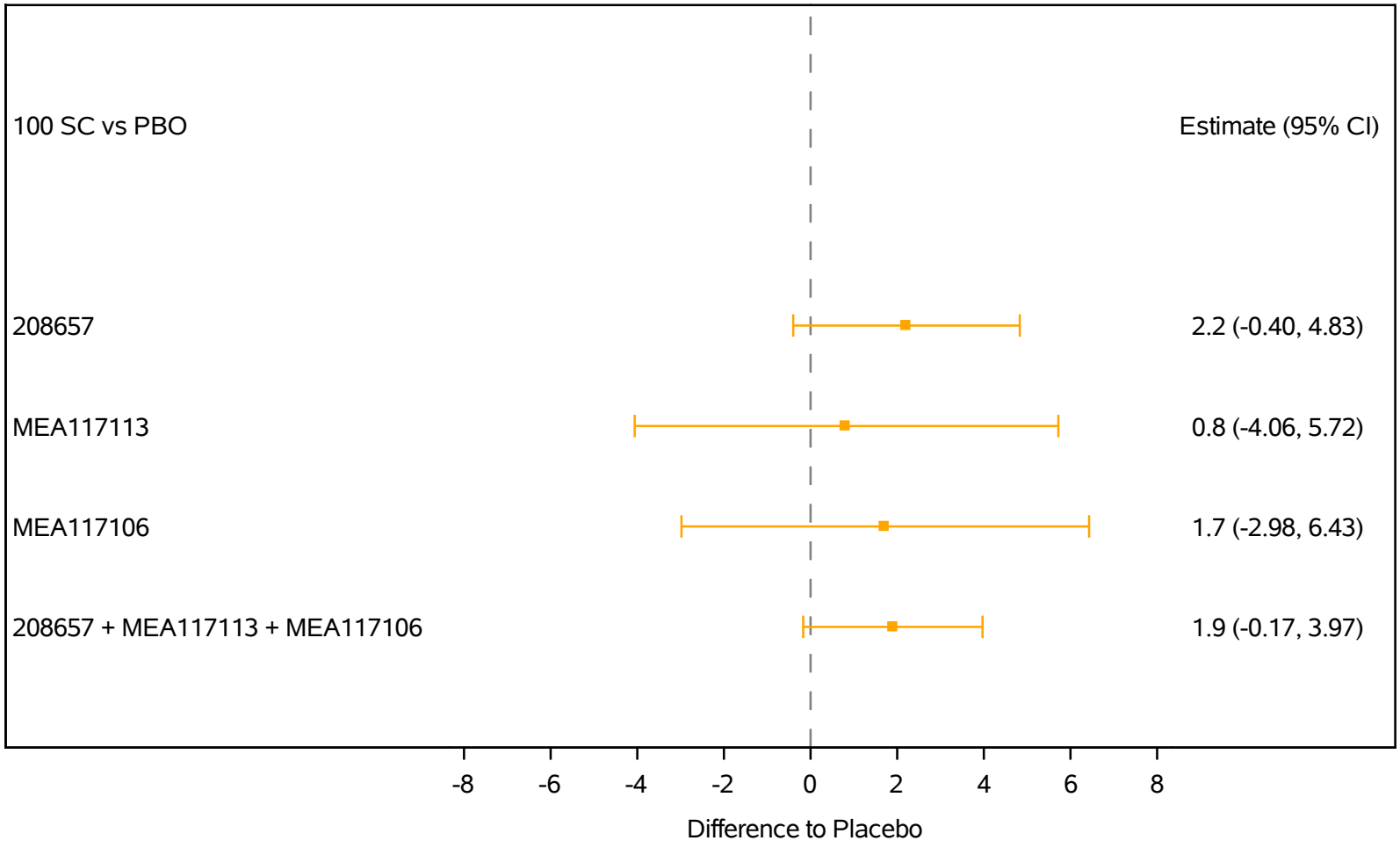


Horizontal bars indicate 95% confidence intervals for the Mepo/Placebo inverse relative risk.
/mnt/code/postcsr_01/prod/tfls/f_e_eq5d_resp_rr.sas 25JUL2025 13:34

Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

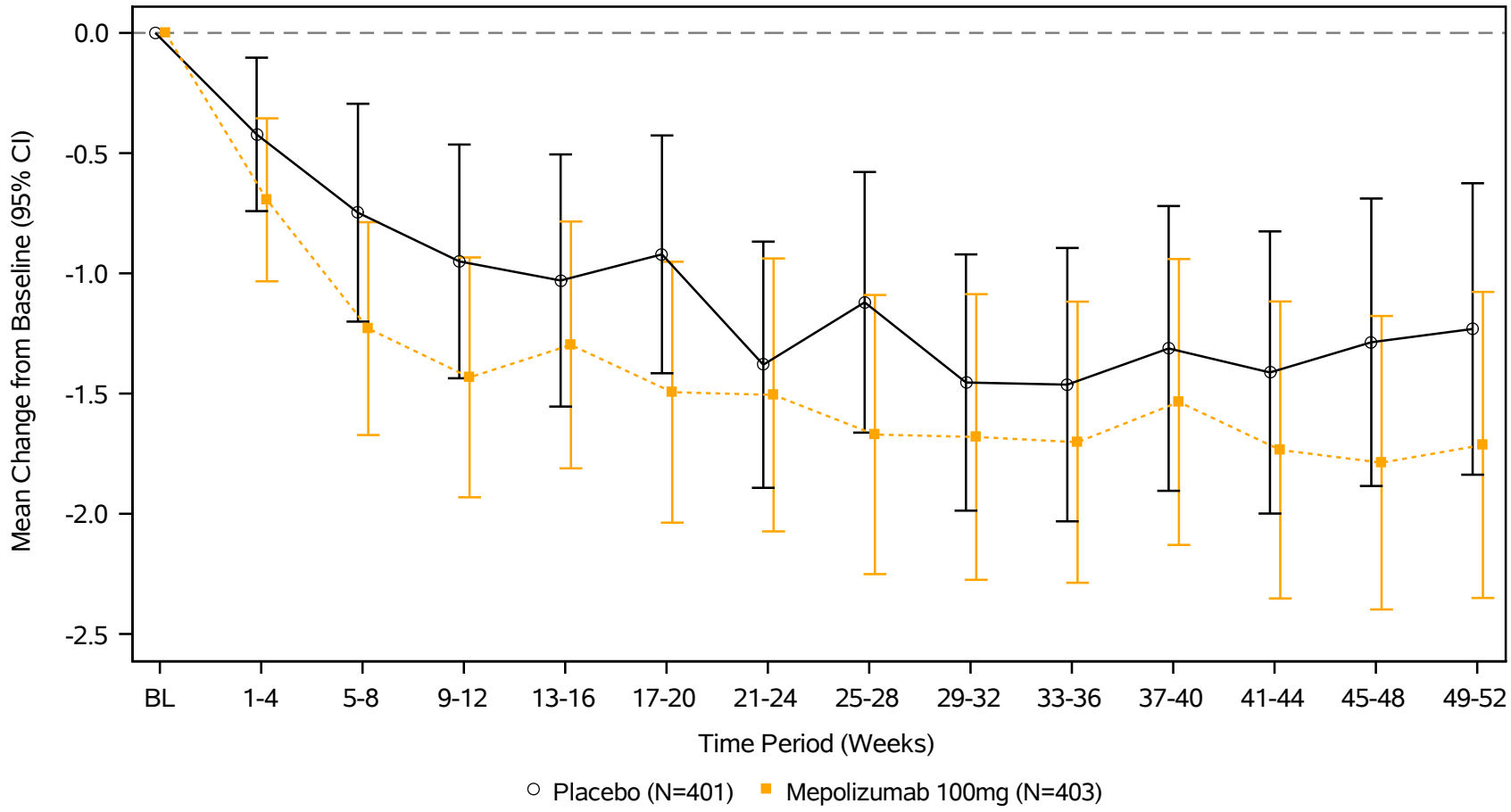
Figure 211.20

Forest Plot of EQ-5D VAS score: Change from Baseline: Individual Studies and Meta-Analysis



Note: Horizontal bars represent 95% confidence intervals for Mepo-Placebo difference.

Figure 2.44
Figure of Evaluating Respiratory Symptoms in COPD (E-RS: COPD) Score Change from Baseline



Note: Includes data reported up to Week 52.
Note: Intercurrent events (ICE) of treatment interruption/discontinuation related to the COVID-19 pandemic handled with a hypothetical strategy. All other ICE are handled with a treatment policy strategy.
/mnt/code/prod/tfls/f_e_cfb_ers.sas 06SEP2024 14:46

Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Figure 211.21

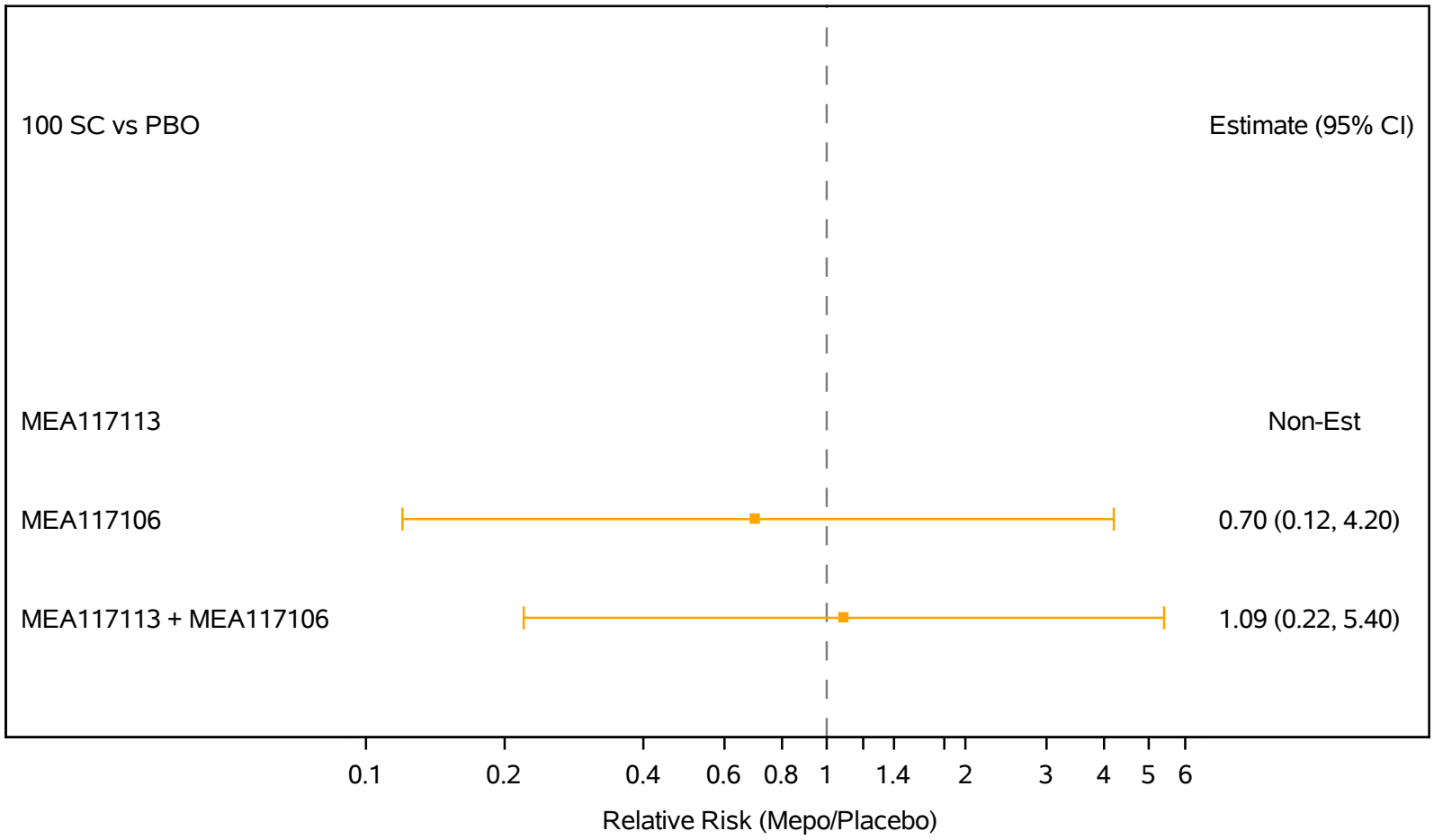
Forest Plot of Odds ratio for Proportion of Subjects Requiring Re-hospitalization for a COPD exacerbation within 30 Days of a Previous Hospitalization for a COPD Exacerbation: Individual Studies and Meta-Analysis

Odds ratio was non-estimable

Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Figure 211.22

Forest Plot of Relative Risk for Proportion of Subjects Requiring Re-hospitalization for a COPD exacerbation within 30 Days of a Previous Hospitalization for a COPD Exacerbation: Individual Studies and Meta-Analysis



Horizontal bars indicate 95% confidence intervals for the Mepo/Placebo relative risk.

/mnt/code/postcsr_01/prod/tfls/f_e_exac_copd_rr.sas 25JUL2025 13:35

Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Figure 211.23

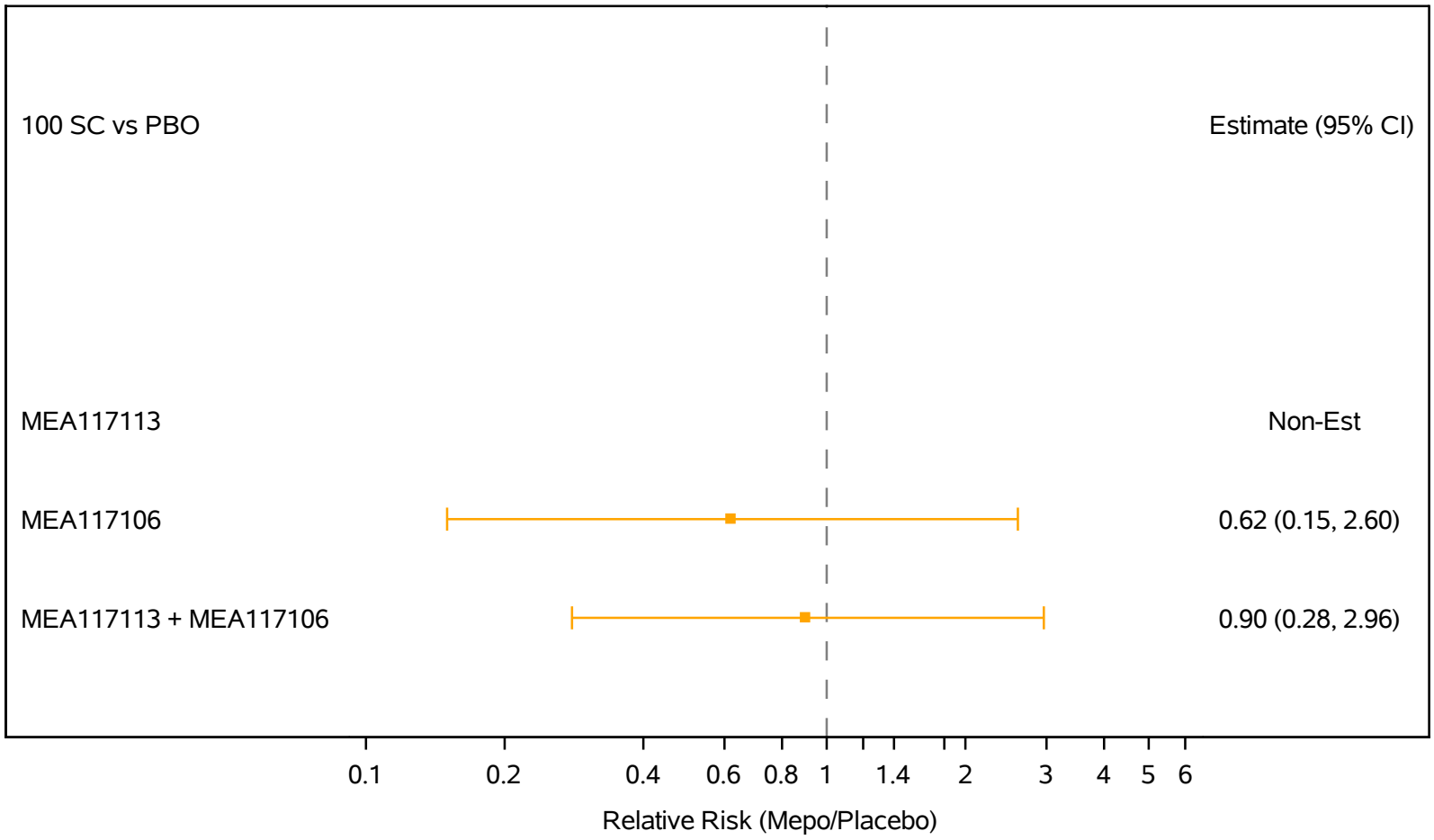
Forest Plot of Odds ratio for Proportion of Subjects Requiring Re-hospitalization for any reason within 30 Days of a Previous Hospitalization for a COPD Exacerbation: Individual Studies and Meta-Analysis

Odds ratio was non-estimable

Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Figure 211.24

Forest Plot of Relative Risk for Proportion of Subjects Requiring Re-hospitalization for any reason within 30 Days of a Previous Hospitalization for a COPD Exacerbation: Individual Studies and Meta-Analysis



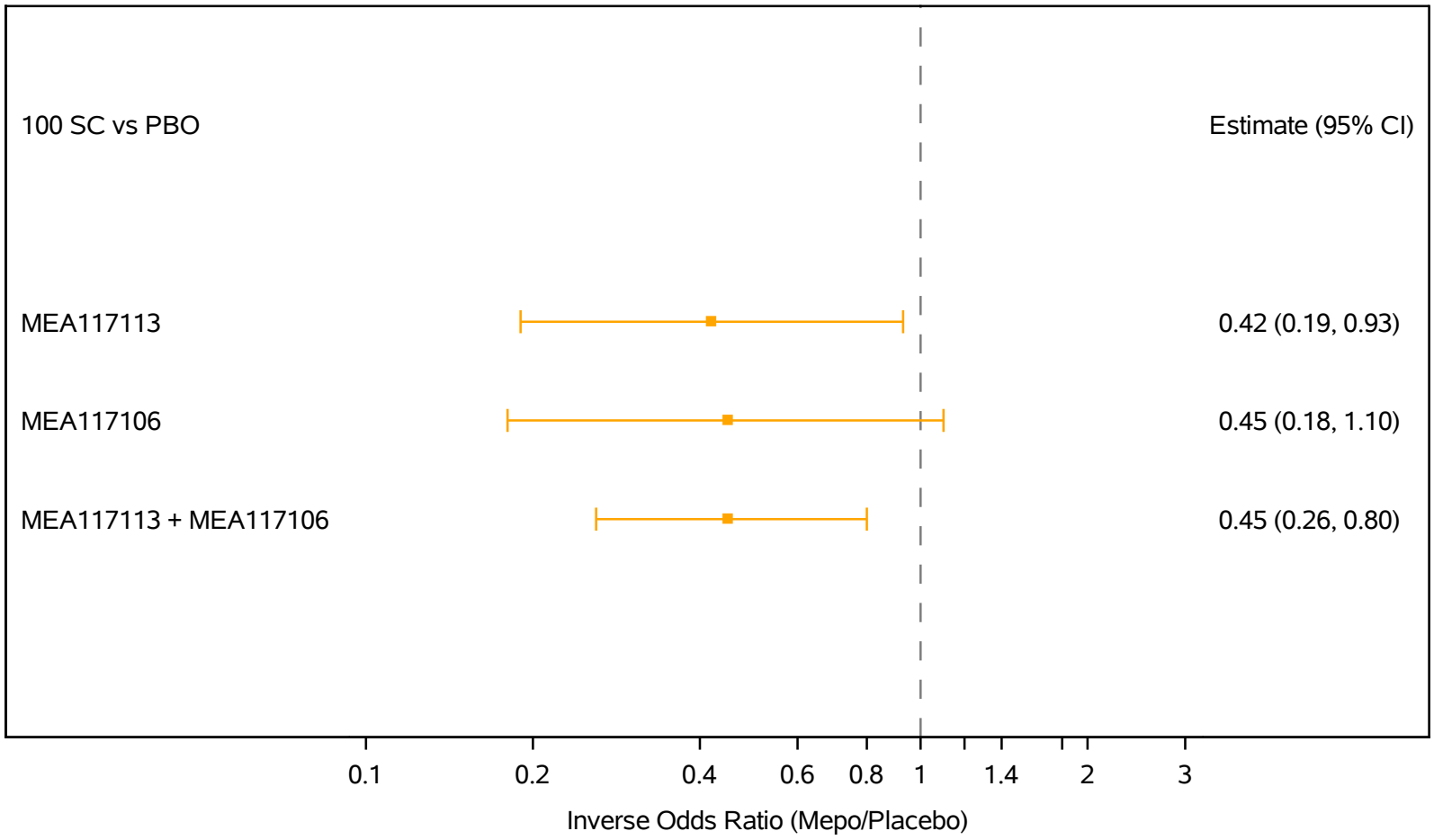
Horizontal bars indicate 95% confidence intervals for the Mepo/Placebo relative risk.

/mnt/code/postcsr_01/prod/tfls/f_e_exac_any_rr.sas 25JUL2025 13:35

Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Figure 211.25

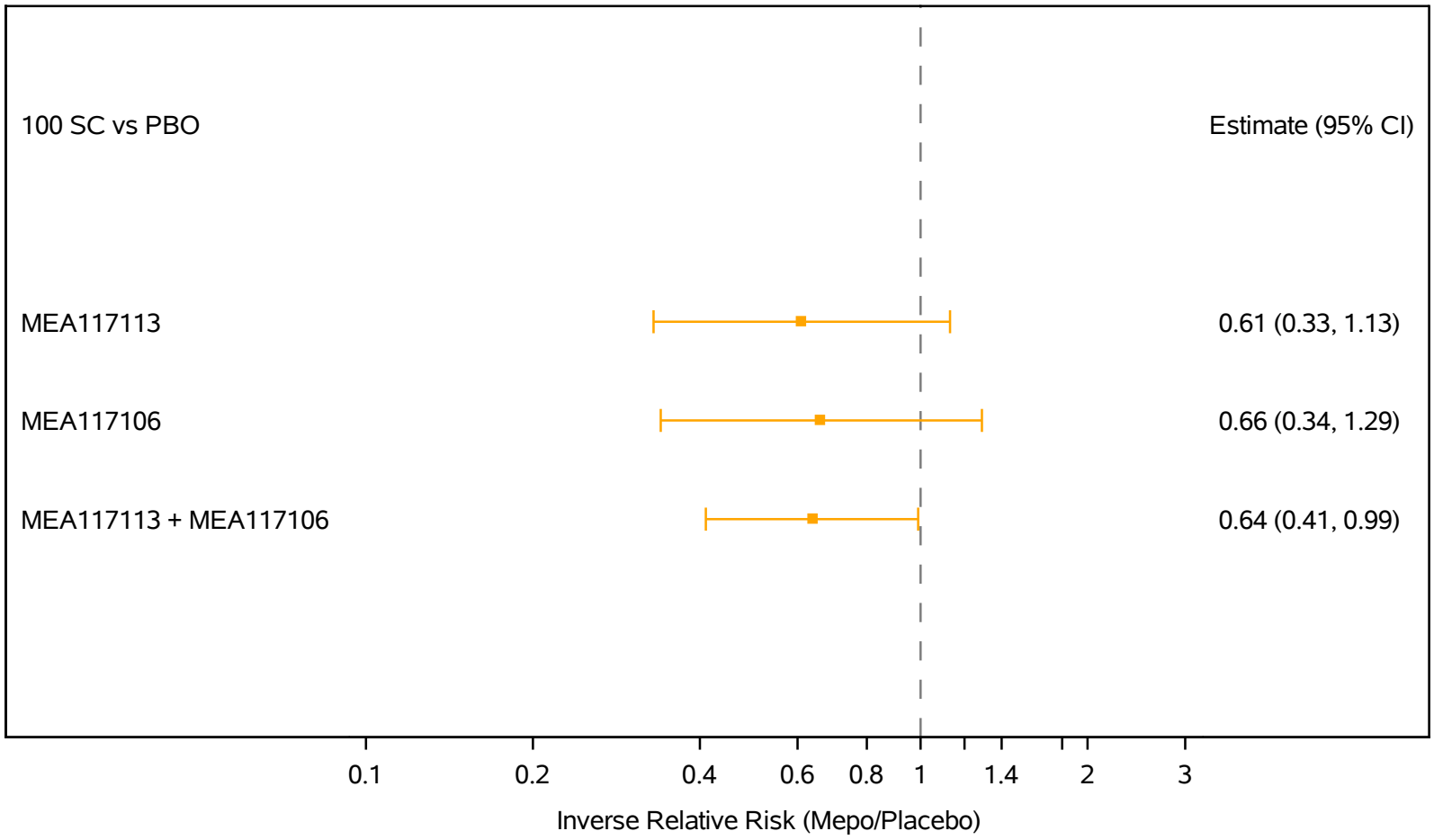
Forest Plot of Odds ratio for Proportion of Subject Global Rating of Activity Limitation Responders at Week 52
(Studies MEA117113 and MEA117106)



Horizontal bars indicate 95% confidence intervals for the Mepo/Placebo inverse odds ratio.
/mnt/code/postcsr_01/prod/tfls/f_e_rgial_resp_or.sas 25JUL2025 13:35

Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Figure 211.26
Forest Plot of Relative Risk for Proportion of Subject Global Rating of Activity Limitation Responders at Week 52
(Studies MEA117113 and MEA117106)

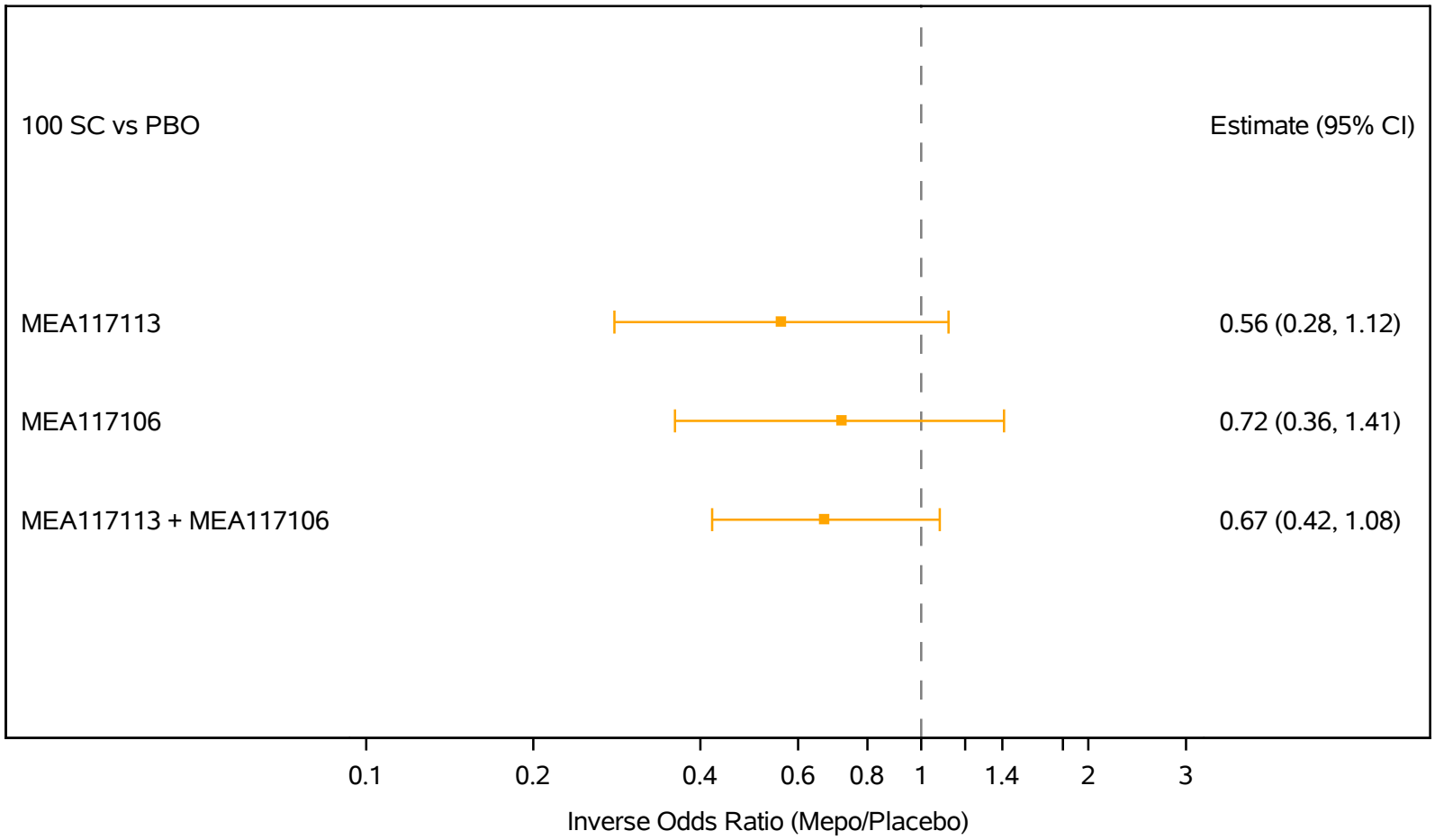


Horizontal bars indicate 95% confidence intervals for the Mepo/Placebo inverse relative risk.
/mnt/code/postcsr_01/prod/tfls/f_e_rgial_resp_rr.sas 25JUL2025 13:36

Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Figure 211.27

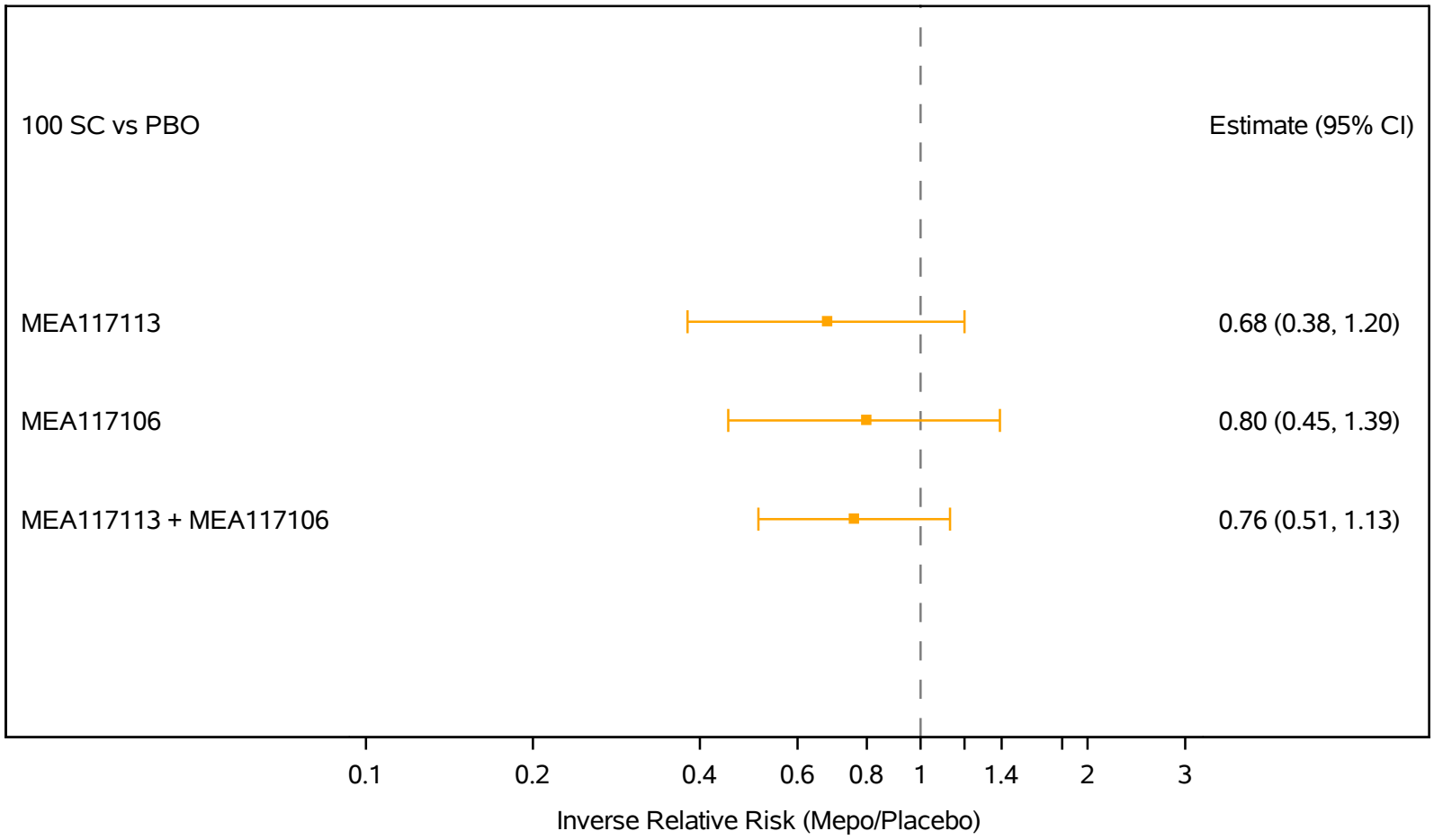
Forest Plot of Odds ratio for Proportion of Subject Global Rating of Activity Change Responders at Week 52
(Studies MEA117113 and MEA117106)



Horizontal bars indicate 95% confidence intervals for the Mepo/Placebo inverse odds ratio.
/mnt/code/postcsr_01/prod/tfls/f_e_rgical_resp_or.sas 25JUL2025 13:36

Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Figure 211.28
Forest Plot of Relative Risk for Proportion of Subject Global Rating of Activity Change Responders at Week 52
(Studies MEA117113 and MEA117106)

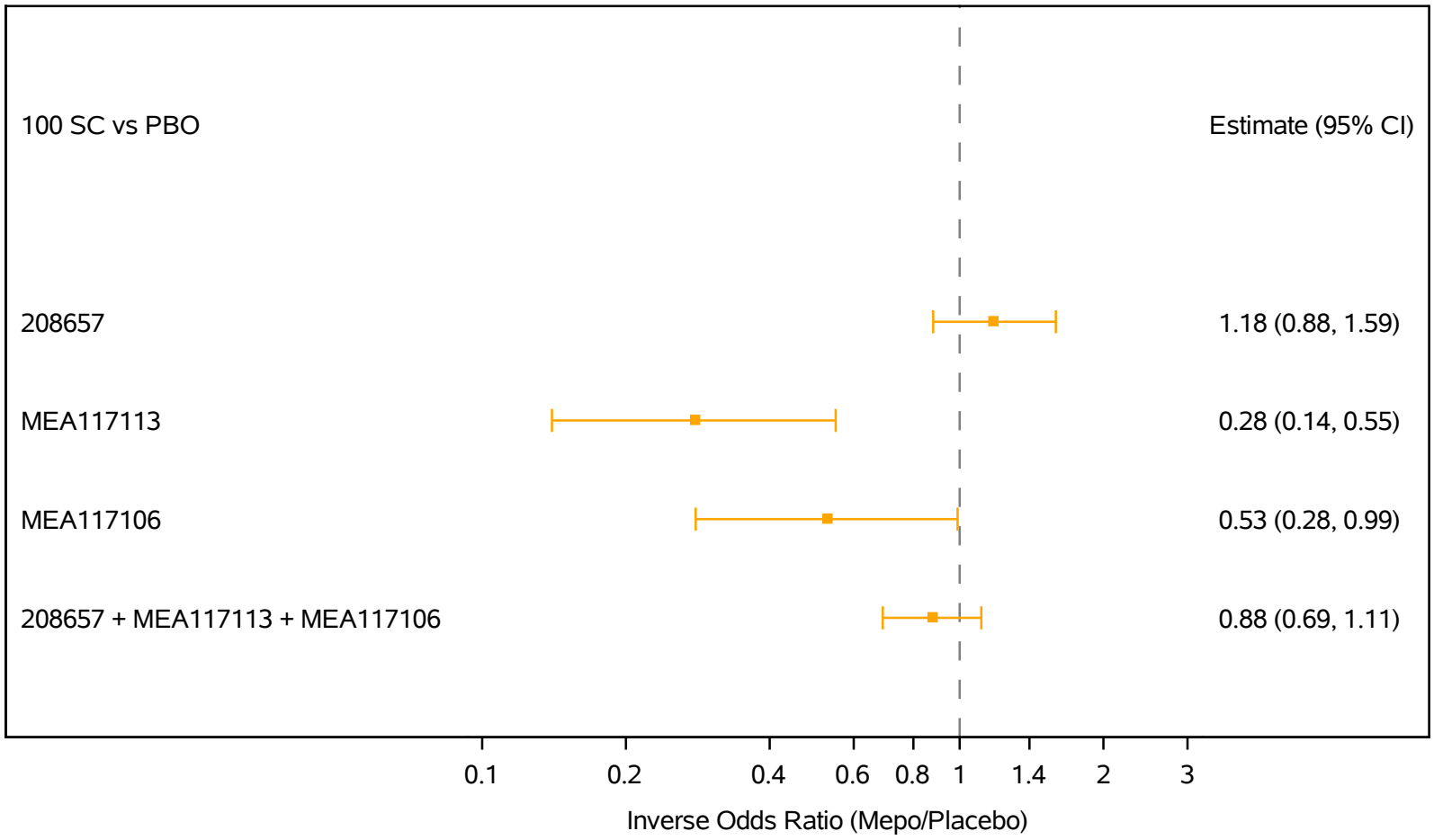


Horizontal bars indicate 95% confidence intervals for the Mepo/Placebo inverse relative risk.
/mnt/code/postcsr_01/prod/tfls/f_e_rgical_resp_rr.sas 25JUL2025 13:38

Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Figure 211.29

Forest Plot of Odds ratio for Proportion of Subject Rated Response to Therapy Responder at Week 52: Individual Studies and Meta-Analysis

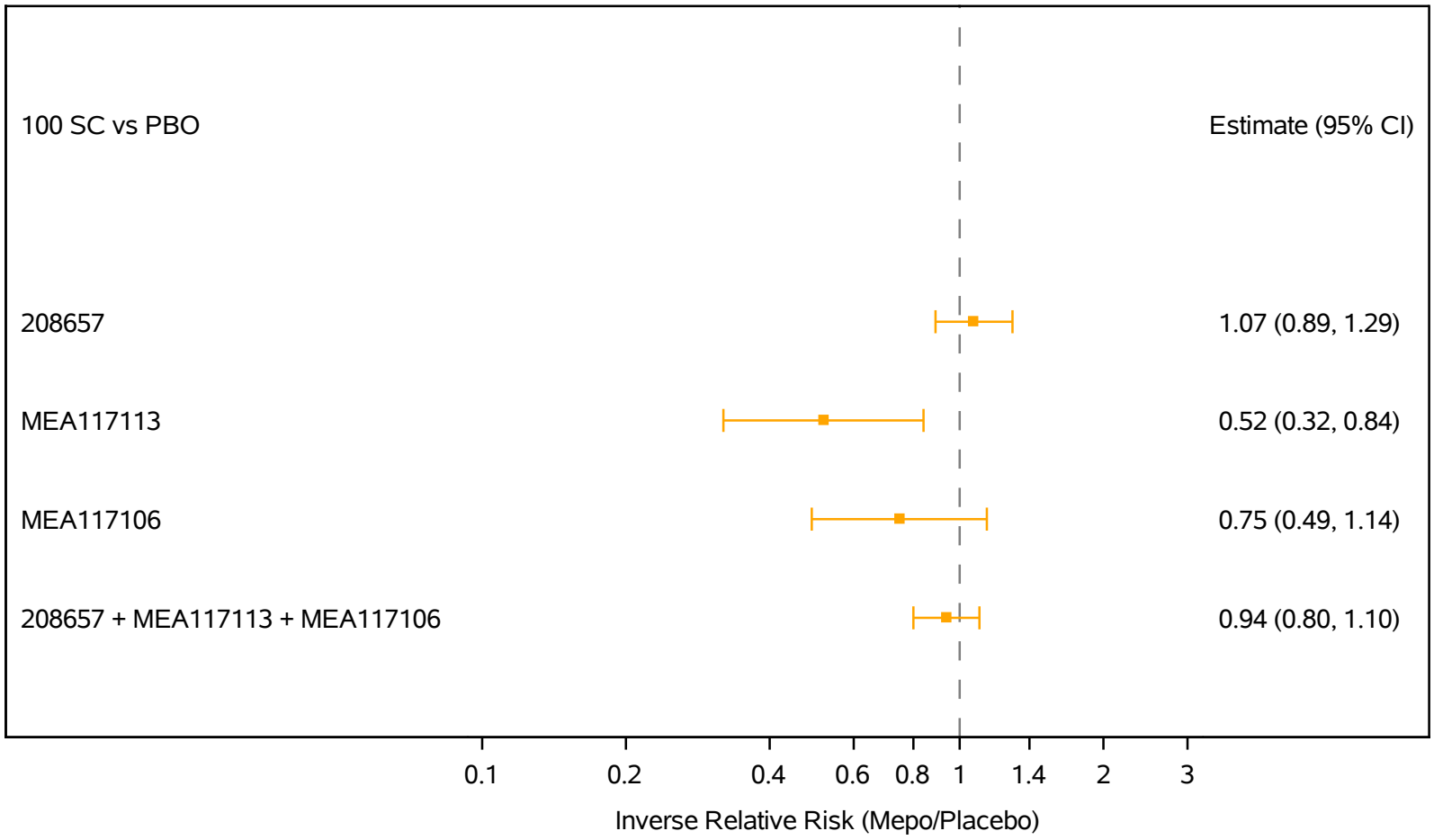


Horizontal bars indicate 95% confidence intervals for the Mepo/Placebo inverse odds ratio.

/mnt/code/postcsr_01/prod/tfls/f_e_srr_resp_or.sas 25JUL2025 13:38

Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Figure 211.30
Forest Plot of Relative Risk for Proportion of Subject Rated Response to Therapy Responder at Week 52:
Individual Studies and Meta-Analysis



Horizontal bars indicate 95% confidence intervals for the Mepo/Placebo inverse relative risk.
/mnt/code/postcsr_01/prod/tfls/f_e_srr_resp_rr.sas 25JUL2025 13:36

Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Table 311.1
Summary of Exposure to Study Medication by Dose

	208657		MEA117113		MEA117106	
	PBO (N=401)	100 SC (N=403)	PBO (N=87)	100 SC (N=83)	PBO (N=90)	100 SC (N=82)
Exposure (Months)						
n	401	403	87	83	90	82
Mean	14.5	15.1	10.5	11.3	10.7	11.5
SD	6.00	6.23	3.08	2.38	3.03	1.75
Median	12.1	12.2	12.0	12.0	12.0	12.0
Min.	1	1	1	1	1	1
Max.	25	25	13	13	13	12
Range of exposure [1]						
n	401	403	87	83	90	82
1 - <3	16 (4%)	12 (3%)	4 (5%)	2 (2%)	5 (6%)	1 (1%)
3 - <6	11 (3%)	14 (3%)	5 (6%)	3 (4%)	3 (3%)	1 (1%)
6 - <9	12 (3%)	13 (3%)	7 (8%)	2 (2%)	7 (8%)	4 (5%)
9 - <12	17 (4%)	11 (3%)	5 (6%)	1 (1%)	3 (3%)	2 (2%)
12 - <15	208 (52%)	197 (49%)	66 (76%)	75 (90%)	72 (80%)	74 (90%)
15 - <18	25 (6%)	29 (7%)	0	0	0	0
18 - <21	17 (4%)	12 (3%)	0	0	0	0
21 - <24	23 (6%)	25 (6%)	0	0	0	0
24 - <36	72 (18%)	90 (22%)	0	0	0	0
Total subject years exposure [2]	483.19	507.43	76.30	78.36	80.29	78.84

[1] Range of exposure based on subject exposure rounded to the nearest whole month.
[2] Sum across subjects of (treatment stop date - treatment start date + 29)/365.25
Note: Exposure (Therapeutic Coverage) = Treatment stop date - Treatment start date + 29.
/mnt/code/postcsr_01/prod/tfls/t_s_exp_copd.sas 17JUL2025 17:12

Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Table 311.1
Summary of Exposure to Study Medication by Dose

	208657 + MEA117113 + MEA117106		
	PBO (N=578)	100 SC (N=568)	Total (N=1146)
Exposure (Months)			
n	578	568	1146
Mean	13.3	14.0	13.7
SD	5.56	5.62	5.60
Median	12.0	12.1	12.0
Min.	1	1	1
Max.	25	25	25
Range of exposure [1]			
n	578	568	1146
1 - <3	25 (4%)	15 (3%)	40 (3%)
3 - <6	19 (3%)	18 (3%)	37 (3%)
6 - <9	26 (4%)	19 (3%)	45 (4%)
9 - <12	25 (4%)	14 (2%)	39 (3%)
12 - <15	346 (60%)	346 (61%)	692 (60%)
15 - <18	25 (4%)	29 (5%)	54 (5%)
18 - <21	17 (3%)	12 (2%)	29 (3%)
21 - <24	23 (4%)	25 (4%)	48 (4%)
24 - <36	72 (12%)	90 (16%)	162 (14%)
Total subject years exposure [2]	639.78	664.63	1304.41

[1] Range of exposure based on subject exposure rounded to the nearest whole month.
[2] Sum across subjects of (treatment stop date - treatment start date + 29)/365.25
Note: Exposure (Therapeutic Coverage) = Treatment stop date - Treatment start date + 29.
/mnt/code/postcsr_01/prod/tfls/t_s_exp_copd.sas 17JUL2025 17:12

Population: Modified Intent-to-Treat Population with Eosinophils 300 cells/uL or More

Table 311.2
Summary and Analysis of On-Treatment Adverse Events
Occurring in >=10% of patients or in >=10 and >=1% of patients by SOC and PT:
Individual Studies and Meta-Analysis

Study: 208657

System Organ Class/Preferred Term	PBO	100 SC	Odds Ratio (95% CI) [1]	Relative Risk (95% CI) [1]	Risk Difference (95% CI) [1]	p-value [2]
Number of subjects (N)	401	403				
ANY EVENT	307 (77%)	299 (74%)	0.88 (0.64,1.21)	0.97 (0.90,1.05)	-0.02 (-0.08,0.04)	0.462
Infections and infestations	172 (43%)	190 (47%)	1.19 (0.90,1.57)	1.10 (0.94,1.28)	0.04 (-0.03,0.11)	0.229
COVID-19	49 (12%)	50 (12%)	1.02 (0.67,1.55)	1.02 (0.70,1.47)	0.00 (-0.04,0.05)	>0.999
Nasopharyngitis	32 (8%)	41 (10%)	1.31 (0.80,2.12)	1.27 (0.82,1.98)	0.02 (-0.02,0.06)	0.326
Pneumonia	27 (7%)	30 (7%)	1.11 (0.65,1.91)	1.11 (0.67,1.83)	0.01 (-0.03,0.04)	0.784
Upper respiratory tract infection	20 (5%)	25 (6%)	1.26 (0.69,2.31)	1.24 (0.70,2.20)	0.01 (-0.02,0.04)	0.540
Influenza	19 (5%)	19 (5%)	0.99 (0.52,1.91)	1.00 (0.53,1.85)	0.00 (-0.03,0.03)	>0.999
Urinary tract infection	7 (2%)	18 (4%)	2.63 (1.09,6.37)	2.56 (1.08,6.06)	0.03 (0.00,0.05)	0.040
Bronchitis	11 (3%)	8 (2%)	0.72 (0.29,1.80)	0.72 (0.29,1.78)	-0.01 (-0.03,0.01)	0.497

[1] For individual studies, the estimates are from frequency tables. In meta-analysis, odds ratio is from logistic regression and relative risk is from the poisson regression model with treatment and study as the covariates.
[2] For individual studies, p-value is from the Fisher’s exact test and for meta-analysis p-value is based on the poisson regression model.
Note: Asymptotic 95% CI’s are reported.
Note: Includes all SOC and PT which meet the given criteria in any treatment arm. If SOC meets the criteria but none of its PT meets the criteria then only the SOC is displayed.
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Population: Modified Intent-to-Treat Population with Eosinophils 300 cells/uL or More

Table 311.2
Summary and Analysis of On-Treatment Adverse Events
Occurring in >=10% of patients or in >=10 and >=1% of patients by SOC and PT:
Individual Studies and Meta-Analysis

Study: 208657

System Organ Class/Preferred Term	PBO	100 SC	Odds Ratio (95% CI) [1]	Relative Risk (95% CI) [1]	Risk Difference (95% CI) [1]	p-value [2]
Respiratory, thoracic and mediastinal disorders	120 (30%)	109 (27%)	0.87 (0.64,1.18)	0.90 (0.73,1.13)	-0.03 (-0.09,0.03)	0.390
Chronic obstructive pulmonary disease	62 (15%)	49 (12%)	0.76 (0.51,1.13)	0.79 (0.56,1.11)	-0.03 (-0.08,0.01)	0.185
Dyspnoea	20 (5%)	20 (5%)	0.99 (0.53,1.88)	1.00 (0.54,1.82)	0.00 (-0.03,0.03)	>0.999
Cough	14 (3%)	13 (3%)	0.92 (0.43,1.99)	0.92 (0.44,1.94)	0.00 (-0.03,0.02)	0.848
Musculoskeletal and connective tissue disorders	73 (18%)	76 (19%)	1.04 (0.73,1.49)	1.04 (0.78,1.38)	0.01 (-0.05,0.06)	0.856
Back pain	23 (6%)	26 (6%)	1.13 (0.64,2.02)	1.12 (0.65,1.94)	0.01 (-0.03,0.04)	0.768
Arthralgia	16 (4%)	22 (5%)	1.39 (0.72,2.69)	1.37 (0.73,2.57)	0.01 (-0.01,0.04)	0.406
Osteoarthritis	7 (2%)	10 (2%)	1.43 (0.54,3.80)	1.42 (0.55,3.70)	0.01 (-0.01,0.03)	0.625
Pain in extremity	6 (1%)	11 (3%)	1.85 (0.68,5.04)	1.82 (0.68,4.89)	0.01 (-0.01,0.03)	0.327

[1] For individual studies, the estimates are from frequency tables. In meta-analysis, odds ratio is from logistic regression and relative risk is from the poisson regression model with treatment and study as the covariates.
[2] For individual studies, p-value is from the Fisher’s exact test and for meta-analysis p-value is based on the poisson regression model.
Note: Asymptotic 95% CI’s are reported.
Note: Includes all SOC and PT which meet the given criteria in any treatment arm. If SOC meets the criteria but none of its PT meets the criteria then only the SOC is displayed.
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Population: Modified Intent-to-Treat Population with Eosinophils 300 cells/uL or More

Table 311.2
Summary and Analysis of On-Treatment Adverse Events
Occurring in >=10% of patients or in >=10 and >=1% of patients by SOC and PT:
Individual Studies and Meta-Analysis

Study: 208657

System Organ Class/Preferred Term	PBO	100 SC	Odds Ratio (95% CI) [1]	Relative Risk (95% CI) [1]	Risk Difference (95% CI) [1]	p-value [2]
Gastrointestinal disorders	56 (14%)	72 (18%)	1.34 (0.92,1.96)	1.28 (0.93,1.76)	0.04 (-0.01,0.09)	0.148
Diarrhoea	12 (3%)	22 (5%)	1.87 (0.91,3.84)	1.82 (0.92,3.64)	0.02 (0.00,0.05)	0.114
Nervous system disorders	67 (17%)	58 (14%)	0.84 (0.57,1.23)	0.86 (0.62,1.19)	-0.02 (-0.07,0.03)	0.382
Headache	27 (7%)	31 (8%)	1.15 (0.68,1.97)	1.14 (0.69,1.88)	0.01 (-0.03,0.05)	0.683
Dizziness	11 (3%)	9 (2%)	0.81 (0.33,1.98)	0.81 (0.34,1.94)	-0.01 (-0.03,0.02)	0.659
General disorders and administration site conditions	46 (11%)	52 (13%)	1.14 (0.75,1.75)	1.12 (0.78,1.63)	0.01 (-0.03,0.06)	0.590
Pyrexia	9 (2%)	12 (3%)	1.34 (0.56,3.21)	1.33 (0.57,3.11)	0.01 (-0.01,0.03)	0.659
Oedema peripheral	7 (2%)	10 (2%)	1.43 (0.54,3.80)	1.42 (0.55,3.70)	0.01 (-0.01,0.03)	0.625
Vascular disorders	43 (11%)	39 (10%)	0.89 (0.56,1.41)	0.90 (0.60,1.36)	-0.01 (-0.05,0.03)	0.643
Hypertension	27 (7%)	17 (4%)	0.61 (0.33,1.14)	0.63 (0.35,1.13)	-0.03 (-0.06,0.01)	0.124

[1] For individual studies, the estimates are from frequency tables. In meta-analysis, odds ratio is from logistic regression and relative risk is from the poisson regression model with treatment and study as the covariates.
[2] For individual studies, p-value is from the Fisher’s exact test and for meta-analysis p-value is based on the poisson regression model.
Note: Asymptotic 95% CI’s are reported.
Note: Includes all SOC and PT which meet the given criteria in any treatment arm. If SOC meets the criteria but none of its PT meets the criteria then only the SOC is displayed.
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Population: Modified Intent-to-Treat Population with Eosinophils 300 cells/uL or More

Table 311.2
Summary and Analysis of On-Treatment Adverse Events
Occurring in >=10% of patients or in >=10 and >=1% of patients by SOC and PT:
Individual Studies and Meta-Analysis

Study: 208657

System Organ Class/Preferred Term	PBO	100 SC	Odds Ratio (95% CI) [1]	Relative Risk (95% CI) [1]	Risk Difference (95% CI) [1]	p-value [2]
Cardiac disorders	44 (11%)	31 (8%)	0.68 (0.42,1.09)	0.70 (0.45,1.09)	-0.03 (-0.07,0.01)	0.116
Metabolism and nutrition disorders	34 (8%)	40 (10%)	1.19 (0.74,1.92)	1.17 (0.76,1.81)	0.01 (-0.03,0.05)	0.542
Injury, poisoning and procedural complications	31 (8%)	32 (8%)	1.03 (0.62,1.72)	1.03 (0.64,1.65)	0.00 (-0.04,0.04)	>0.999
Investigations	36 (9%)	22 (5%)	0.59 (0.34,1.01)	0.61 (0.36,1.01)	-0.04 (-0.07,0.00)	0.057
Skin and subcutaneous tissue disorders	22 (5%)	27 (7%)	1.24 (0.69,2.21)	1.22 (0.71,2.11)	0.01 (-0.02,0.05)	0.556

[1] For individual studies, the estimates are from frequency tables. In meta-analysis, odds ratio is from logistic regression and relative risk is from the poisson regression model with treatment and study as the covariates.
[2] For individual studies, p-value is from the Fisher’s exact test and for meta-analysis p-value is based on the poisson regression model.
Note: Asymptotic 95% CI’s are reported.
Note: Includes all SOC and PT which meet the given criteria in any treatment arm. If SOC meets the criteria but none of its PT meets the criteria then only the SOC is displayed.
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Population: Modified Intent-to-Treat Population with Eosinophils 300 cells/uL or More

Table 311.2
Summary and Analysis of On-Treatment Adverse Events
Occurring in >=10% of patients or in >=10 and >=1% of patients by SOC and PT:
Individual Studies and Meta-Analysis

Study: 208657

System Organ Class/Preferred Term	PBO	100 SC	Odds Ratio (95% CI) [1]	Relative Risk (95% CI) [1]	Risk Difference (95% CI) [1]	p-value [2]
Renal and urinary disorders	23 (6%)	16 (4%)	0.68 (0.35,1.31)	0.69 (0.37,1.29)	-0.02 (-0.05,0.01)	0.255
Eye disorders	20 (5%)	12 (3%)	0.58 (0.28,1.21)	0.60 (0.30,1.20)	-0.02 (-0.05,0.01)	0.154
Psychiatric disorders	13 (3%)	16 (4%)	1.23 (0.59,2.60)	1.22 (0.60,2.51)	0.01 (-0.02,0.03)	0.706
Blood and lymphatic system disorders	14 (3%)	12 (3%)	0.85 (0.39,1.86)	0.85 (0.40,1.82)	-0.01 (-0.03,0.02)	0.696
Hepatobiliary disorders	14 (3%)	12 (3%)	0.85 (0.39,1.86)	0.85 (0.40,1.82)	-0.01 (-0.03,0.02)	0.696

[1] For individual studies, the estimates are from frequency tables. In meta-analysis, odds ratio is from logistic regression and relative risk is from the poisson regression model with treatment and study as the covariates.
[2] For individual studies, p-value is from the Fisher’s exact test and for meta-analysis p-value is based on the poisson regression model.
Note: Asymptotic 95% CI’s are reported.
Note: Includes all SOC and PT which meet the given criteria in any treatment arm. If SOC meets the criteria but none of its PT meets the criteria then only the SOC is displayed.

Population: Modified Intent-to-Treat Population with Eosinophils 300 cells/uL or More

Table 311.2
Summary and Analysis of On-Treatment Adverse Events
Occurring in >=10% of patients or in >=10 and >=1% of patients by SOC and PT:
Individual Studies and Meta-Analysis

Study: 208657

System Organ Class/Preferred Term	PBO	100 SC	Odds Ratio (95% CI) [1]	Relative Risk (95% CI) [1]	Risk Difference (95% CI) [1]	p-value [2]
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	17 (4%)	9 (2%)	0.52 (0.23,1.17)	0.53 (0.24,1.17)	-0.02 (-0.04,0.00)	0.115

[1] For individual studies, the estimates are from frequency tables. In meta-analysis, odds ratio is from logistic regression and relative risk is from the poisson regression model with treatment and study as the covariates.
[2] For individual studies, p-value is from the Fisher’s exact test and for meta-analysis p-value is based on the poisson regression model.
Note: Asymptotic 95% CI’s are reported.
Note: Includes all SOC and PT which meet the given criteria in any treatment arm. If SOC meets the criteria but none of its PT meets the criteria then only the SOC is displayed.
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Population: Modified Intent-to-Treat Population with Eosinophils 300 cells/uL or More

Table 311.2
Summary and Analysis of On-Treatment Adverse Events
Occurring in >=10% of patients or in >=10 and >=1% of patients by SOC and PT:
Individual Studies and Meta-Analysis

Study: MEA117113

System Organ Class/Preferred Term	PBO	100 SC	Odds Ratio (95% CI) [1]	Relative Risk (95% CI) [1]	Risk Difference (95% CI) [1]	p-value [2]
Number of subjects (N)	87	83				
ANY EVENT	71 (82%)	72 (87%)	1.48 (0.64,3.40)	1.06 (0.93,1.21)	0.05 (-0.06,0.16)	0.406
Infections and infestations	52 (60%)	45 (54%)	0.80 (0.43,1.46)	0.91 (0.70,1.18)	-0.06 (-0.20,0.09)	0.536
Nasopharyngitis	17 (20%)	16 (19%)	0.98 (0.46,2.10)	0.99 (0.53,1.82)	0.00 (-0.12,0.12)	>0.999
Pneumonia	9 (10%)	12 (14%)	1.46 (0.58,3.68)	1.40 (0.62,3.14)	0.04 (-0.06,0.14)	0.488
Upper respiratory tract infection	11 (13%)	6 (7%)	0.54 (0.19,1.53)	0.57 (0.22,1.48)	-0.05 (-0.14,0.04)	0.309
Respiratory, thoracic and mediastinal disorders	21 (24%)	29 (35%)	1.69 (0.87,3.29)	1.45 (0.90,2.33)	0.11 (-0.03,0.24)	0.133

[1] For individual studies, the estimates are from frequency tables. In meta-analysis, odds ratio is from logistic regression and relative risk is from the poisson regression model with treatment and study as the covariates.
[2] For individual studies, p-value is from the Fisher’s exact test and for meta-analysis p-value is based on the poisson regression model.
Note: Asymptotic 95% CI’s are reported.
Note: Includes all SOC and PT which meet the given criteria in any treatment arm. If SOC meets the criteria but none of its PT meets the criteria then only the SOC is displayed.
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Population: Modified Intent-to-Treat Population with Eosinophils 300 cells/uL or More

Table 311.2
Summary and Analysis of On-Treatment Adverse Events
Occurring in >=10% of patients or in >=10 and >=1% of patients by SOC and PT:
Individual Studies and Meta-Analysis

Study: MEA117113

System Organ Class/Preferred Term	PBO	100 SC	Odds Ratio (95% CI) [1]	Relative Risk (95% CI) [1]	Risk Difference (95% CI) [1]	p-value [2]
Chronic obstructive pulmonary disease	13 (15%)	11 (13%)	0.87 (0.37,2.07)	0.89 (0.42,1.87)	-0.02 (-0.12,0.09)	0.827
Gastrointestinal disorders	20 (23%)	19 (23%)	0.99 (0.49,2.03)	1.00 (0.57,1.73)	0.00 (-0.13,0.13)	>0.999
Musculoskeletal and connective tissue disorders	16 (18%)	20 (24%)	1.41 (0.67,2.95)	1.31 (0.73,2.35)	0.06 (-0.07,0.18)	0.453
General disorders and administration site conditions	12 (14%)	17 (20%)	1.61 (0.72,3.62)	1.48 (0.76,2.92)	0.07 (-0.05,0.18)	0.309
Nervous system disorders	9 (10%)	20 (24%)	2.75 (1.17,6.46)	2.33 (1.13,4.82)	0.14 (0.03,0.25)	0.024
Headache	5 (6%)	15 (18%)	3.62 (1.25,10.46)	3.14 (1.20,8.27)	0.12 (0.03,0.22)	0.016

[1] For individual studies, the estimates are from frequency tables. In meta-analysis, odds ratio is from logistic regression and relative risk is from the poisson regression model with treatment and study as the covariates.
[2] For individual studies, p-value is from the Fisher’s exact test and for meta-analysis p-value is based on the poisson regression model.
Note: Asymptotic 95% CI’s are reported.
Note: Includes all SOC and PT which meet the given criteria in any treatment arm. If SOC meets the criteria but none of its PT meets the criteria then only the SOC is displayed.
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Population: Modified Intent-to-Treat Population with Eosinophils 300 cells/uL or More

Table 311.2

Summary and Analysis of On-Treatment Adverse Events

Occurring in >=10% of patients or in >=10 and >=1% of patients by SOC and PT:

Individual Studies and Meta-Analysis

Study: MEA117113

System Organ Class/Preferred Term	PBO	100 SC	Odds Ratio (95% CI) [1]	Relative Risk (95% CI) [1]	Risk Difference (95% CI) [1]	p-value [2]
Investigations	9 (10%)	11 (13%)	1.32 (0.52,3.38)	1.28 (0.56,2.93)	0.03 (-0.07,0.13)	0.637

[1] For individual studies, the estimates are from frequency tables. In meta-analysis, odds ratio is from logistic regression and relative risk is from the poisson regression model with treatment and study as the covariates.
[2] For individual studies, p-value is from the Fisher’s exact test and for meta-analysis p-value is based on the poisson regression model.
Note: Asymptotic 95% CI’s are reported.
Note: Includes all SOC and PT which meet the given criteria in any treatment arm. If SOC meets the criteria but none of its PT meets the criteria then only the SOC is displayed.
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Population: Modified Intent-to-Treat Population with Eosinophils 300 cells/uL or More

Table 311.2
Summary and Analysis of On-Treatment Adverse Events
Occurring in >=10% of patients or in >=10 and >=1% of patients by SOC and PT:
Individual Studies and Meta-Analysis

Study: MEA117106

System Organ Class/Preferred Term	PBO	100 SC	Odds Ratio (95% CI) [1]	Relative Risk (95% CI) [1]	Risk Difference (95% CI) [1]	p-value [2]
Number of subjects (N)	90	82				
ANY EVENT	72 (80%)	66 (80%)	1.03 (0.49,2.19)	1.01 (0.87,1.17)	0.00 (-0.11,0.12)	>0.999
Infections and infestations	45 (50%)	34 (41%)	0.71 (0.39,1.29)	0.83 (0.60,1.15)	-0.09 (-0.23,0.06)	0.286
Nasopharyngitis	12 (13%)	10 (12%)	0.90 (0.37,2.22)	0.91 (0.42,2.00)	-0.01 (-0.11,0.09)	>0.999
Pneumonia	11 (12%)	6 (7%)	0.57 (0.20,1.61)	0.60 (0.23,1.55)	-0.05 (-0.14,0.04)	0.317
Respiratory, thoracic and mediastinal disorders	31 (34%)	31 (38%)	1.16 (0.62,2.16)	1.10 (0.74,1.63)	0.03 (-0.11,0.18)	0.751
Chronic obstructive pulmonary disease	18 (20%)	12 (15%)	0.69 (0.31,1.53)	0.73 (0.38,1.42)	-0.05 (-0.17,0.06)	0.423

[1] For individual studies, the estimates are from frequency tables. In meta-analysis, odds ratio is from logistic regression and relative risk is from the poisson regression model with treatment and study as the covariates.
[2] For individual studies, p-value is from the Fisher’s exact test and for meta-analysis p-value is based on the poisson regression model.
Note: Asymptotic 95% CI’s are reported.
Note: Includes all SOC and PT which meet the given criteria in any treatment arm. If SOC meets the criteria but none of its PT meets the criteria then only the SOC is displayed.
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Population: Modified Intent-to-Treat Population with Eosinophils 300 cells/uL or More

Table 311.2
Summary and Analysis of On-Treatment Adverse Events
Occurring in >=10% of patients or in >=10 and >=1% of patients by SOC and PT:
Individual Studies and Meta-Analysis

Study: MEA117106

System Organ Class/Preferred Term	PBO	100 SC	Odds Ratio (95% CI) [1]	Relative Risk (95% CI) [1]	Risk Difference (95% CI) [1]	p-value [2]
Musculoskeletal and connective tissue disorders	17 (19%)	23 (28%)	1.67 (0.82,3.42)	1.48 (0.86,2.58)	0.09 (-0.03,0.22)	0.206
Back pain	9 (10%)	6 (7%)	0.71 (0.24,2.09)	0.73 (0.27,1.97)	-0.03 (-0.11,0.06)	0.597
Gastrointestinal disorders	14 (16%)	19 (23%)	1.64 (0.76,3.52)	1.49 (0.80,2.77)	0.08 (-0.04,0.19)	0.246
General disorders and administration site conditions	17 (19%)	13 (16%)	0.81 (0.37,1.79)	0.84 (0.44,1.62)	-0.03 (-0.14,0.08)	0.689
Nervous system disorders	19 (21%)	10 (12%)	0.52 (0.23,1.19)	0.58 (0.29,1.17)	-0.09 (-0.20,0.02)	0.154
Headache	12 (13%)	9 (11%)	0.80 (0.32,2.01)	0.82 (0.37,1.85)	-0.02 (-0.12,0.07)	0.816

[1] For individual studies, the estimates are from frequency tables. In meta-analysis, odds ratio is from logistic regression and relative risk is from the poisson regression model with treatment and study as the covariates.
[2] For individual studies, p-value is from the Fisher’s exact test and for meta-analysis p-value is based on the poisson regression model.
Note: Asymptotic 95% CI’s are reported.
Note: Includes all SOC and PT which meet the given criteria in any treatment arm. If SOC meets the criteria but none of its PT meets the criteria then only the SOC is displayed.
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Population: Modified Intent-to-Treat Population with Eosinophils 300 cells/uL or More

Table 311.2
Summary and Analysis of On-Treatment Adverse Events
Occurring in >=10% of patients or in >=10 and >=1% of patients by SOC and PT:
Individual Studies and Meta-Analysis

Study: MEA117106

System Organ Class/Preferred Term	PBO	100 SC	Odds Ratio (95% CI) [1]	Relative Risk (95% CI) [1]	Risk Difference (95% CI) [1]	p-value [2]
Injury, poisoning and procedural complications	13 (14%)	7 (9%)	0.55 (0.21,1.46)	0.59 (0.25,1.41)	-0.06 (-0.15,0.04)	0.245
Skin and subcutaneous tissue disorders	10 (11%)	10 (12%)	1.11 (0.44,2.82)	1.10 (0.48,2.50)	0.01 (-0.09,0.11)	>0.999
Metabolism and nutrition disorders	10 (11%)	4 (5%)	0.41 (0.12,1.36)	0.44 (0.14,1.35)	-0.06 (-0.14,0.02)	0.168

[1] For individual studies, the estimates are from frequency tables. In meta-analysis, odds ratio is from logistic regression and relative risk is from the poisson regression model with treatment and study as the covariates.
[2] For individual studies, p-value is from the Fisher’s exact test and for meta-analysis p-value is based on the poisson regression model.
Note: Asymptotic 95% CI’s are reported.
Note: Includes all SOC and PT which meet the given criteria in any treatment arm. If SOC meets the criteria but none of its PT meets the criteria then only the SOC is displayed.
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Population: Modified Intent-to-Treat Population with Eosinophils 300 cells/uL or More

Table 311.2
Summary and Analysis of On-Treatment Adverse Events
Occurring in >=10% of patients or in >=10 and >=1% of patients by SOC and PT:
Individual Studies and Meta-Analysis

Study: 208657 + MEA117113 + MEA117106

System Organ Class/Preferred Term	PBO	100 SC	Odds Ratio (95% CI) [1]	Relative Risk (95% CI) [1]	Risk Difference (95% CI) [1]	p-value [2]
Number of subjects (N)	578	568				
ANY EVENT	450 (78%)	437 (77%)	0.95 (0.72,1.26)	0.99 (0.87,1.13)	-0.01 (-0.11,0.09)	0.874
Infections and infestations	269 (47%)	269 (47%)	1.04 (0.82,1.31)	1.02 (0.86,1.21)	0.01 (-0.07,0.09)	0.828
Nasopharyngitis	61 (11%)	67 (12%)	1.15 (0.79,1.66)	1.13 (0.80,1.59)	0.02 (-0.02,0.05)	0.501
COVID-19	49 (8%)	50 (9%)	Non-Est.	Non-Est.	Non-Est.	Non-Est.
Pneumonia	47 (8%)	48 (8%)	1.05 (0.69,1.60)	1.05 (0.70,1.56)	0.00 (-0.03,0.04)	0.826
Upper respiratory tract infection	31 (5%)	33 (6%)	1.08 (0.65,1.80)	1.08 (0.66,1.76)	Non-Est.	0.767
Influenza	29 (5%)	22 (4%)	0.76 (0.43,1.34)	0.77 (0.44,1.34)	-0.01 (-0.04,0.01)	0.357
Urinary tract infection	14 (2%)	24 (4%)	1.78 (0.91,3.48)	1.75 (0.90,3.38)	0.02 (0.00,0.04)	0.098
Bronchitis	20 (3%)	11 (2%)	0.55 (0.26,1.17)	0.56 (0.27,1.17)	-0.01 (-0.03,0.01)	0.126
Sinusitis	12 (2%)	16 (3%)	1.38 (0.65,2.95)	1.37 (0.65,2.90)	0.01 (-0.01,0.02)	0.410
Rhinitis	10 (2%)	11 (2%)	1.13 (0.48,2.68)	1.13 (0.48,2.65)	0.00 (-0.02,0.02)	0.785

[1] For individual studies, the estimates are from frequency tables. In meta-analysis, odds ratio is from logistic regression and relative risk is from the poisson regression model with treatment and study as the covariates.
[2] For individual studies, p-value is from the Fisher’s exact test and for meta-analysis p-value is based on the poisson regression model.
Note: Asymptotic 95% CI’s are reported.
Note: Includes all SOC and PT which meet the given criteria in any treatment arm. If SOC meets the criteria but none of its PT meets the criteria then only the SOC is displayed.
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Population: Modified Intent-to-Treat Population with Eosinophils 300 cells/uL or More

Table 311.2
Summary and Analysis of On-Treatment Adverse Events
Occurring in >=10% of patients or in >=10 and >=1% of patients by SOC and PT:
Individual Studies and Meta-Analysis

Study: 208657 + MEA117113 + MEA117106

System Organ Class/Preferred Term	PBO	100 SC	Odds Ratio (95% CI) [1]	Relative Risk (95% CI) [1]	Risk Difference (95% CI) [1]	p-value [2]
Lower respiratory tract infection	10 (2%)	9 (2%)	0.91 (0.37,2.26)	0.91 (0.37,2.25)	0.00 (-0.02,0.01)	0.846
Pharyngitis	12 (2%)	7 (1%)	0.60 (0.23,1.53)	0.60 (0.24,1.54)	0.00 (-0.02,0.01)	0.291
Respiratory, thoracic and mediastinal disorders	172 (30%)	169 (30%)	1.00 (0.78,1.29)	1.00 (0.81,1.24)	0.00 (-0.06,0.06)	0.979
Chronic obstructive pulmonary disease	93 (16%)	72 (13%)	0.76 (0.54,1.06)	0.79 (0.58,1.07)	-0.03 (-0.08,0.01)	0.134
Dyspnoea	26 (4%)	28 (5%)	1.10 (0.64,1.90)	1.09 (0.64,1.87)	0.00 (-0.02,0.03)	0.743
Cough	18 (3%)	23 (4%)	1.31 (0.70,2.47)	1.30 (0.70,2.41)	0.01 (-0.01,0.03)	0.403
Oropharyngeal pain	7 (1%)	20 (4%)	3.10 (1.29,7.42)	2.98 (1.26,7.06)	0.02 (0.00,0.04)	0.013

[1] For individual studies, the estimates are from frequency tables. In meta-analysis, odds ratio is from logistic regression and relative risk is from the poisson regression model with treatment and study as the covariates.
[2] For individual studies, p-value is from the Fisher’s exact test and for meta-analysis p-value is based on the poisson regression model.
Note: Asymptotic 95% CI’s are reported.
Note: Includes all SOC and PT which meet the given criteria in any treatment arm. If SOC meets the criteria but none of its PT meets the criteria then only the SOC is displayed.
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Population: Modified Intent-to-Treat Population with Eosinophils 300 cells/uL or More

Table 311.2
Summary and Analysis of On-Treatment Adverse Events
Occurring in >=10% of patients or in >=10 and >=1% of patients by SOC and PT:
Individual Studies and Meta-Analysis

Study: 208657 + MEA117113 + MEA117106

System Organ Class/Preferred Term	PBO	100 SC	Odds Ratio (95% CI) [1]	Relative Risk (95% CI) [1]	Risk Difference (95% CI) [1]	p-value [2]
Musculoskeletal and connective tissue disorders	106 (18%)	119 (21%)	1.19 (0.89,1.59)	1.15 (0.88,1.49)	0.02 (-0.03,0.08)	0.307
Back pain	36 (6%)	38 (7%)	1.08 (0.68,1.74)	1.08 (0.68,1.70)	0.01 (-0.02,0.04)	0.744
Arthralgia	19 (3%)	30 (5%)	1.63 (0.91,2.94)	1.60 (0.90,2.84)	0.02 (0.00,0.05)	0.110
Pain in extremity	13 (2%)	16 (3%)	1.27 (0.60,2.67)	1.26 (0.61,2.62)	0.01 (-0.01,0.03)	0.535
Osteoarthritis	8 (1%)	13 (2%)	1.66 (0.68,4.03)	1.64 (0.68,3.96)	Non-Est.	0.271
Gastrointestinal disorders	90 (16%)	110 (19%)	1.31 (0.96,1.78)	1.25 (0.95,1.65)	0.04 (-0.01,0.09)	0.119
Diarrhoea	21 (4%)	31 (5%)	1.53 (0.87,2.71)	1.50 (0.86,2.61)	0.02 (0.00,0.05)	0.150
Nausea	12 (2%)	12 (2%)	1.04 (0.46,2.34)	1.04 (0.47,2.31)	0.00 (-0.02,0.01)	0.929
Constipation	8 (1%)	13 (2%)	1.67 (0.69,4.08)	1.66 (0.69,4.00)	0.01 (-0.01,0.02)	0.262
Nervous system disorders	95 (16%)	88 (15%)	0.93 (0.68,1.28)	0.94 (0.71,1.26)	-0.01 (-0.06,0.04)	0.697
Headache	44 (8%)	55 (10%)	1.32 (0.87,2.00)	1.28 (0.86,1.91)	0.02 (-0.02,0.05)	0.218
Dizziness	15 (3%)	13 (2%)	0.88 (0.41,1.86)	0.88 (0.42,1.85)	0.00 (-0.02,0.01)	0.735

[1] For individual studies, the estimates are from frequency tables. In meta-analysis, odds ratio is from logistic regression and relative risk is from the poisson regression model with treatment and study as the covariates.
[2] For individual studies, p-value is from the Fisher’s exact test and for meta-analysis p-value is based on the poisson regression model.
Note: Asymptotic 95% CI’s are reported.
Note: Includes all SOC and PT which meet the given criteria in any treatment arm. If SOC meets the criteria but none of its PT meets the criteria then only the SOC is displayed.
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Population: Modified Intent-to-Treat Population with Eosinophils 300 cells/uL or More

Table 311.2
Summary and Analysis of On-Treatment Adverse Events
Occurring in >=10% of patients or in >=10 and >=1% of patients by SOC and PT:
Individual Studies and Meta-Analysis

Study: 208657 + MEA117113 + MEA117106

System Organ Class/Preferred Term	PBO	100 SC	Odds Ratio (95% CI) [1]	Relative Risk (95% CI) [1]	Risk Difference (95% CI) [1]	p-value [2]
General disorders and administration site conditions	75 (13%)	82 (14%)	1.14 (0.81,1.60)	1.12 (0.82,1.53)	0.02 (-0.03,0.06)	0.481
Pyrexia	16 (3%)	17 (3%)	1.09 (0.54,2.18)	1.08 (0.55,2.15)	0.00 (-0.02,0.02)	0.815
Oedema peripheral	9 (2%)	13 (2%)	1.47 (0.62,3.47)	1.46 (0.62,3.42)	0.01 (-0.01,0.03)	0.383
Non-cardiac chest pain	10 (2%)	11 (2%)	1.14 (0.48,2.72)	1.14 (0.48,2.67)	0.00 (-0.01,0.01)	0.772
Vascular disorders	51 (9%)	49 (9%)	0.97 (0.64,1.46)	0.97 (0.65,1.43)	0.00 (-0.03,0.04)	0.877
Hypertension	31 (5%)	24 (4%)	0.77 (0.45,1.34)	0.78 (0.46,1.33)	0.00 (-0.03,0.03)	0.369
Injury, poisoning and procedural complications	52 (9%)	47 (8%)	0.92 (0.61,1.39)	0.93 (0.62,1.37)	0.00 (-0.04,0.03)	0.699

[1] For individual studies, the estimates are from frequency tables. In meta-analysis, odds ratio is from logistic regression and relative risk is from the poisson regression model with treatment and study as the covariates.
[2] For individual studies, p-value is from the Fisher’s exact test and for meta-analysis p-value is based on the poisson regression model.
Note: Asymptotic 95% CI’s are reported.
Note: Includes all SOC and PT which meet the given criteria in any treatment arm. If SOC meets the criteria but none of its PT meets the criteria then only the SOC is displayed.
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Population: Modified Intent-to-Treat Population with Eosinophils 300 cells/uL or More

Table 311.2
Summary and Analysis of On-Treatment Adverse Events
Occurring in >=10% of patients or in >=10 and >=1% of patients by SOC and PT:
Individual Studies and Meta-Analysis

Study: 208657 + MEA117113 + MEA117106

System Organ Class/Preferred Term	PBO	100 SC	Odds Ratio (95% CI) [1]	Relative Risk (95% CI) [1]	Risk Difference (95% CI) [1]	p-value [2]
Cardiac disorders	57 (10%)	41 (7%)	0.71 (0.46,1.08)	0.73 (0.49,1.09)	-0.03 (-0.06,0.00)	0.125
Atrial fibrillation	10 (2%)	5 (<1%)	0.50 (0.17,1.48)	0.51 (0.17,1.48)	Non-Est.	0.214
Metabolism and nutrition disorders	46 (8%)	51 (9%)	1.14 (0.75,1.73)	1.12 (0.75,1.68)	0.01 (-0.02,0.05)	0.565
Investigations	49 (8%)	38 (7%)	0.77 (0.50,1.20)	0.79 (0.52,1.21)	-0.02 (-0.05,0.01)	0.273
Skin and subcutaneous tissue disorders	38 (7%)	44 (8%)	1.21 (0.77,1.90)	1.19 (0.77,1.84)	0.01 (-0.02,0.04)	0.433
Renal and urinary disorders	29 (5%)	24 (4%)	0.83 (0.48,1.45)	0.84 (0.49,1.44)	-0.01 (-0.03,0.02)	0.530

[1] For individual studies, the estimates are from frequency tables. In meta-analysis, odds ratio is from logistic regression and relative risk is from the poisson regression model with treatment and study as the covariates.
[2] For individual studies, p-value is from the Fisher’s exact test and for meta-analysis p-value is based on the poisson regression model.
Note: Asymptotic 95% CI’s are reported.
Note: Includes all SOC and PT which meet the given criteria in any treatment arm. If SOC meets the criteria but none of its PT meets the criteria then only the SOC is displayed.
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Population: Modified Intent-to-Treat Population with Eosinophils 300 cells/uL or More

Table 311.2
Summary and Analysis of On-Treatment Adverse Events
Occurring in >=10% of patients or in >=10 and >=1% of patients by SOC and PT:
Individual Studies and Meta-Analysis

Study: 208657 + MEA117113 + MEA117106

System Organ Class/Preferred Term	PBO	100 SC	Odds Ratio (95% CI) [1]	Relative Risk (95% CI) [1]	Risk Difference (95% CI) [1]	p-value [2]
Psychiatric disorders	24 (4%)	27 (5%)	1.17 (0.66,2.05)	1.16 (0.67,2.01)	0.01 (-0.02,0.03)	0.601
Anxiety	9 (2%)	13 (2%)	1.49 (0.63,3.52)	1.48 (0.63,3.46)	0.01 (-0.01,0.02)	0.366
Eye disorders	27 (5%)	18 (3%)	0.67 (0.36,1.23)	0.68 (0.37,1.23)	-0.01 (-0.04,0.01)	0.202
Cataract	13 (2%)	10 (2%)	0.78 (0.34,1.80)	0.79 (0.35,1.80)	0.00 (-0.02,0.01)	0.570
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	22 (4%)	17 (3%)	0.78 (0.41,1.49)	0.79 (0.42,1.49)	-0.01 (-0.03,0.01)	0.465
Blood and lymphatic system disorders	18 (3%)	16 (3%)	0.90 (0.45,1.78)	0.90 (0.46,1.77)	0.00 (-0.02,0.02)	0.760
Anaemia	8 (1%)	11 (2%)	1.41 (0.56,3.53)	1.40 (0.56,3.48)	Non-Est.	0.469

[1] For individual studies, the estimates are from frequency tables. In meta-analysis, odds ratio is from logistic regression and relative risk is from the poisson regression model with treatment and study as the covariates.
[2] For individual studies, p-value is from the Fisher’s exact test and for meta-analysis p-value is based on the poisson regression model.
Note: Asymptotic 95% CI’s are reported.
Note: Includes all SOC and PT which meet the given criteria in any treatment arm. If SOC meets the criteria but none of its PT meets the criteria then only the SOC is displayed.
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Population: Modified Intent-to-Treat Population with Eosinophils 300 cells/uL or More

Table 311.2
Summary and Analysis of On-Treatment Adverse Events
Occurring in >=10% of patients or in >=10 and >=1% of patients by SOC and PT:
Individual Studies and Meta-Analysis

Study: 208657 + MEA117113 + MEA117106

System Organ Class/Preferred Term	PBO	100 SC	Odds Ratio (95% CI) [1]	Relative Risk (95% CI) [1]	Risk Difference (95% CI) [1]	p-value [2]
Hepatobiliary disorders	17 (3%)	13 (2%)	0.76 (0.37,1.59)	0.77 (0.37,1.58)	0.00 (-0.03,0.02)	0.478
Ear and labyrinth disorders	10 (2%)	14 (2%)	1.46 (0.64,3.31)	1.44 (0.64,3.25)	0.00 (-0.01,0.02)	0.376
Reproductive system and breast disorders	12 (2%)	10 (2%)	0.84 (0.36,1.96)	0.84 (0.36,1.95)	0.00 (-0.02,0.01)	0.694
Immune system disorders	13 (2%)	6 (1%)	0.47 (0.18,1.24)	0.47 (0.18,1.25)	Non-Est.	0.131

[1] For individual studies, the estimates are from frequency tables. In meta-analysis, odds ratio is from logistic regression and relative risk is from the poisson regression model with treatment and study as the covariates.
[2] For individual studies, p-value is from the Fisher’s exact test and for meta-analysis p-value is based on the poisson regression model.
Note: Asymptotic 95% CI’s are reported.
Note: Includes all SOC and PT which meet the given criteria in any treatment arm. If SOC meets the criteria but none of its PT meets the criteria then only the SOC is displayed.
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Population: Modified Intent-to-Treat Population with Eosinophils 300 cells/uL or More

Table 311.3

Analysis of On-Treatment Adverse Events

Occurring in >=10% of patients or in >=10 and >=1% of patients by SOC and PT:

Meta-Analysis: p-values for Interaction Effect

Study: 208657 + MEA117113 + MEA117106

System Organ Class/Preferred Term	p-value for study*treatment interaction [1]
ANY EVENT	0.879
Infections and infestations	0.433
Nasopharyngitis	0.720
COVID-19	Non-Est.
Pneumonia	0.419
Upper respiratory tract infection	0.097
Influenza	0.264
Urinary tract infection	0.330
Bronchitis	0.642
Sinusitis	0.843
Rhinitis	0.086
Lower respiratory tract infection	0.898
Pharyngitis	0.067
Respiratory, thoracic and mediastinal disorders	0.300
Chronic obstructive pulmonary disease	0.941
Dyspnoea	0.228
Cough	0.257
Oropharyngeal pain	0.114
Musculoskeletal and connective tissue disorders	0.549
Back pain	0.631
Arthralgia	0.538

[1] From the poisson regression model with covariates of treatment group, study and with an additional covariate of study*treatment interaction.

Note: Includes all SOC and PT which meet the given criteria in any treatment arm. If SOC meets the criteria but none of its PT meets the criteria then only the SOC is displayed.

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Population: Modified Intent-to-Treat Population with Eosinophils 300 cells/uL or More

Table 311.3
Analysis of On-Treatment Adverse Events
Occurring in >=10% of patients or in >=10 and >=1% of patients by SOC and PT:
Meta-Analysis: p-values for Interaction Effect

Study: 208657 + MEA117113 + MEA117106

System Organ Class/Preferred Term	p-value for study*treatment interaction [1]
Pain in extremity	0.231
Osteoarthritis	0.328
Gastrointestinal disorders	0.681
Diarrhoea	0.166
Nausea	0.628
Constipation	0.721
Nervous system disorders	0.025
Headache	0.099
Dizziness	0.741
General disorders and administration site conditions	0.553
Pyrexia	0.331
Oedema peripheral	0.224
Non-cardiac chest pain	0.728
Vascular disorders	0.258
Hypertension	0.026
Injury, poisoning and procedural complications	0.554
Cardiac disorders	0.560
Atrial fibrillation	0.583

[1] From the poisson regression model with covariates of treatment group, study and with an additional covariate of study*treatment interaction.
Note: Includes all SOC and PT which meet the given criteria in any treatment arm. If SOC meets the criteria but none of its PT meets the criteria then only the SOC is displayed.
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Population: Modified Intent-to-Treat Population with Eosinophils 300 cells/uL or More

Table 311.3
Analysis of On-Treatment Adverse Events
Occurring in >=10% of patients or in >=10 and >=1% of patients by SOC and PT:
Meta-Analysis: p-values for Interaction Effect

Study: 208657 + MEA117113 + MEA117106

System Organ Class/Preferred Term	p-value for study*treatment interaction [1]
Metabolism and nutrition disorders	0.067
Investigations	0.247
Skin and subcutaneous tissue disorders	0.979
Renal and urinary disorders	0.429
Psychiatric disorders	0.442
Anxiety	0.666
Eye disorders	0.792
Cataract	0.671
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	0.228
Blood and lymphatic system disorders	0.323
Anaemia	0.343
Hepatobiliary disorders	0.084
Ear and labyrinth disorders	0.545

[1] From the poisson regression model with covariates of treatment group, study and with an additional covariate of study*treatment interaction.
Note: Includes all SOC and PT which meet the given criteria in any treatment arm. If SOC meets the criteria but none of its PT meets the criteria then only the SOC is displayed.
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Population: Modified Intent-to-Treat Population with Eosinophils 300 cells/uL or More

Table 311.3

Analysis of On-Treatment Adverse Events

Occurring in >=10% of patients or in >=10 and >=1% of patients by SOC and PT:

Meta-Analysis: p-values for Interaction Effect

Study: 208657 + MEA117113 + MEA117106

System Organ Class/Preferred Term	p-value for study*treatment interaction [1]
Reproductive system and breast disorders	0.947
Immune system disorders	0.424

[1] From the poisson regression model with covariates of treatment group, study and with an additional covariate of study*treatment interaction.

Note: Includes all SOC and PT which meet the given criteria in any treatment arm. If SOC meets the criteria but none of its PT meets the criteria then only the SOC is displayed.

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Population: Modified Intent-to-Treat Population with Eosinophils 300 cells/uL or More

Table 311.4

Summary and Analysis of On-Treatment Adverse Events without Disease-Related Events Occurring in >=10% of patients or in >=10 and >=1% of patients by SOC and PT: Individual Studies and Meta-Analysis

Study: 208657

System Organ Class/Preferred Term	PBO	100 SC	Odds Ratio (95% CI) [1]	Relative Risk (95% CI) [1]	Risk Difference (95% CI) [1]	p-value [2]
Number of subjects (N)	401	403				
ANY EVENT	296 (74%)	297 (74%)	0.99 (0.73,1.36)	1.00 (0.92,1.08)	0.00 (-0.06,0.06)	>0.999
Infections and infestations	167 (42%)	186 (46%)	1.20 (0.91,1.59)	1.11 (0.95,1.30)	0.05 (-0.02,0.11)	0.202
COVID-19	49 (12%)	50 (12%)	1.02 (0.67,1.55)	1.02 (0.70,1.47)	0.00 (-0.04,0.05)	>0.999
Nasopharyngitis	32 (8%)	41 (10%)	1.31 (0.80,2.12)	1.27 (0.82,1.98)	0.02 (-0.02,0.06)	0.326
Pneumonia	27 (7%)	30 (7%)	1.11 (0.65,1.91)	1.11 (0.67,1.83)	0.01 (-0.03,0.04)	0.784
Upper respiratory tract infection	20 (5%)	25 (6%)	1.26 (0.69,2.31)	1.24 (0.70,2.20)	0.01 (-0.02,0.04)	0.540
Influenza	19 (5%)	19 (5%)	0.99 (0.52,1.91)	1.00 (0.53,1.85)	0.00 (-0.03,0.03)	>0.999
Urinary tract infection	7 (2%)	18 (4%)	2.63 (1.09,6.37)	2.56 (1.08,6.06)	0.03 (0.00,0.05)	0.040

[1] For individual studies, the estimates are from frequency tables. In meta-analysis, odds ratio is from logistic regression and relative risk is from the poisson regression model with treatment and study as the covariates.
[2] For individual studies, p-value is from the Fisher’s exact test and for meta-analysis p-value is based on the poisson regression model.
Note: Asymptotic 95% CI’s are reported.
Note: Includes all SOC and PT which meet the given criteria in any treatment arm. If SOC meets the criteria but none of its PT meets the criteria then only the SOC is displayed.
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Population: Modified Intent-to-Treat Population with Eosinophils 300 cells/uL or More

Table 311.4
Summary and Analysis of On-Treatment Adverse Events without Disease-Related Events
Occurring in >=10% of patients or in >=10 and >=1% of patients by SOC and PT:
Individual Studies and Meta-Analysis

Study: 208657

System Organ Class/Preferred Term	PBO	100 SC	Odds Ratio (95% CI) [1]	Relative Risk (95% CI) [1]	Risk Difference (95% CI) [1]	p-value [2]
Respiratory, thoracic and mediastinal disorders	77 (19%)	75 (19%)	0.96 (0.68,1.37)	0.97 (0.73,1.29)	-0.01 (-0.06,0.05)	0.857
Dyspnoea	20 (5%)	20 (5%)	0.99 (0.53,1.88)	1.00 (0.54,1.82)	0.00 (-0.03,0.03)	>0.999
Cough	14 (3%)	13 (3%)	0.92 (0.43,1.99)	0.92 (0.44,1.94)	0.00 (-0.03,0.02)	0.848
Musculoskeletal and connective tissue disorders	73 (18%)	76 (19%)	1.04 (0.73,1.49)	1.04 (0.78,1.38)	0.01 (-0.05,0.06)	0.856
Back pain	23 (6%)	26 (6%)	1.13 (0.64,2.02)	1.12 (0.65,1.94)	0.01 (-0.03,0.04)	0.768
Arthralgia	16 (4%)	22 (5%)	1.39 (0.72,2.69)	1.37 (0.73,2.57)	0.01 (-0.01,0.04)	0.406
Osteoarthritis	7 (2%)	10 (2%)	1.43 (0.54,3.80)	1.42 (0.55,3.70)	0.01 (-0.01,0.03)	0.625
Pain in extremity	6 (1%)	11 (3%)	1.85 (0.68,5.04)	1.82 (0.68,4.89)	0.01 (-0.01,0.03)	0.327
Gastrointestinal disorders	56 (14%)	72 (18%)	1.34 (0.92,1.96)	1.28 (0.93,1.76)	0.04 (-0.01,0.09)	0.148
Diarrhoea	12 (3%)	22 (5%)	1.87 (0.91,3.84)	1.82 (0.92,3.64)	0.02 (0.00,0.05)	0.114

[1] For individual studies, the estimates are from frequency tables. In meta-analysis, odds ratio is from logistic regression and relative risk is from the poisson regression model with treatment and study as the covariates.
[2] For individual studies, p-value is from the Fisher’s exact test and for meta-analysis p-value is based on the poisson regression model.
Note: Asymptotic 95% CI’s are reported.
Note: Includes all SOC and PT which meet the given criteria in any treatment arm. If SOC meets the criteria but none of its PT meets the criteria then only the SOC is displayed.

Population: Modified Intent-to-Treat Population with Eosinophils 300 cells/uL or More

Table 311.4
Summary and Analysis of On-Treatment Adverse Events without Disease-Related Events
Occurring in >=10% of patients or in >=10 and >=1% of patients by SOC and PT:
Individual Studies and Meta-Analysis

Study: 208657

System Organ Class/Preferred Term	PBO	100 SC	Odds Ratio (95% CI) [1]	Relative Risk (95% CI) [1]	Risk Difference (95% CI) [1]	p-value [2]
Nervous system disorders	67 (17%)	58 (14%)	0.84 (0.57,1.23)	0.86 (0.62,1.19)	-0.02 (-0.07,0.03)	0.382
Headache	27 (7%)	31 (8%)	1.15 (0.68,1.97)	1.14 (0.69,1.88)	0.01 (-0.03,0.05)	0.683
Dizziness	11 (3%)	9 (2%)	0.81 (0.33,1.98)	0.81 (0.34,1.94)	-0.01 (-0.03,0.02)	0.659
General disorders and administration site conditions	46 (11%)	52 (13%)	1.14 (0.75,1.75)	1.12 (0.78,1.63)	0.01 (-0.03,0.06)	0.590
Pyrexia	9 (2%)	12 (3%)	1.34 (0.56,3.21)	1.33 (0.57,3.11)	0.01 (-0.01,0.03)	0.659
Oedema peripheral	7 (2%)	10 (2%)	1.43 (0.54,3.80)	1.42 (0.55,3.70)	0.01 (-0.01,0.03)	0.625
Vascular disorders	43 (11%)	39 (10%)	0.89 (0.56,1.41)	0.90 (0.60,1.36)	-0.01 (-0.05,0.03)	0.643
Hypertension	27 (7%)	17 (4%)	0.61 (0.33,1.14)	0.63 (0.35,1.13)	-0.03 (-0.06,0.01)	0.124
Cardiac disorders	44 (11%)	31 (8%)	0.68 (0.42,1.09)	0.70 (0.45,1.09)	-0.03 (-0.07,0.01)	0.116

[1] For individual studies, the estimates are from frequency tables. In meta-analysis, odds ratio is from logistic regression and relative risk is from the poisson regression model with treatment and study as the covariates.
[2] For individual studies, p-value is from the Fisher’s exact test and for meta-analysis p-value is based on the poisson regression model.
Note: Asymptotic 95% CI’s are reported.
Note: Includes all SOC and PT which meet the given criteria in any treatment arm. If SOC meets the criteria but none of its PT meets the criteria then only the SOC is displayed.

Population: Modified Intent-to-Treat Population with Eosinophils 300 cells/uL or More

Table 311.4
Summary and Analysis of On-Treatment Adverse Events without Disease-Related Events
Occurring in >=10% of patients or in >=10 and >=1% of patients by SOC and PT:
Individual Studies and Meta-Analysis

Study: 208657

System Organ Class/Preferred Term	PBO	100 SC	Odds Ratio (95% CI) [1]	Relative Risk (95% CI) [1]	Risk Difference (95% CI) [1]	p-value [2]
Metabolism and nutrition disorders	34 (8%)	40 (10%)	1.19 (0.74,1.92)	1.17 (0.76,1.81)	0.01 (-0.03,0.05)	0.542
Injury, poisoning and procedural complications	31 (8%)	32 (8%)	1.03 (0.62,1.72)	1.03 (0.64,1.65)	0.00 (-0.04,0.04)	>0.999
Investigations	36 (9%)	22 (5%)	0.59 (0.34,1.01)	0.61 (0.36,1.01)	-0.04 (-0.07,0.00)	0.057
Skin and subcutaneous tissue disorders	22 (5%)	27 (7%)	1.24 (0.69,2.21)	1.22 (0.71,2.11)	0.01 (-0.02,0.05)	0.556
Renal and urinary disorders	23 (6%)	16 (4%)	0.68 (0.35,1.31)	0.69 (0.37,1.29)	-0.02 (-0.05,0.01)	0.255
Eye disorders	20 (5%)	12 (3%)	0.58 (0.28,1.21)	0.60 (0.30,1.20)	-0.02 (-0.05,0.01)	0.154

[1] For individual studies, the estimates are from frequency tables. In meta-analysis, odds ratio is from logistic regression and relative risk is from the poisson regression model with treatment and study as the covariates.
[2] For individual studies, p-value is from the Fisher’s exact test and for meta-analysis p-value is based on the poisson regression model.
Note: Asymptotic 95% CI’s are reported.
Note: Includes all SOC and PT which meet the given criteria in any treatment arm. If SOC meets the criteria but none of its PT meets the criteria then only the SOC is displayed.

Population: Modified Intent-to-Treat Population with Eosinophils 300 cells/uL or More

Table 311.4

Summary and Analysis of On-Treatment Adverse Events without Disease-Related Events Occurring in >=10% of patients or in >=10 and >=1% of patients by SOC and PT: Individual Studies and Meta-Analysis

Study: 208657

System Organ Class/Preferred Term	PBO	100 SC	Odds Ratio (95% CI) [1]	Relative Risk (95% CI) [1]	Risk Difference (95% CI) [1]	p-value [2]
Psychiatric disorders	13 (3%)	16 (4%)	1.23 (0.59,2.60)	1.22 (0.60,2.51)	0.01 (-0.02,0.03)	0.706
Blood and lymphatic system disorders	14 (3%)	12 (3%)	0.85 (0.39,1.86)	0.85 (0.40,1.82)	-0.01 (-0.03,0.02)	0.696
Hepatobiliary disorders	14 (3%)	12 (3%)	0.85 (0.39,1.86)	0.85 (0.40,1.82)	-0.01 (-0.03,0.02)	0.696
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	17 (4%)	9 (2%)	0.52 (0.23,1.17)	0.53 (0.24,1.17)	-0.02 (-0.04,0.00)	0.115

[1] For individual studies, the estimates are from frequency tables. In meta-analysis, odds ratio is from logistic regression and relative risk is from the poisson regression model with treatment and study as the covariates.
[2] For individual studies, p-value is from the Fisher’s exact test and for meta-analysis p-value is based on the poisson regression model.
Note: Asymptotic 95% CI’s are reported.
Note: Includes all SOC and PT which meet the given criteria in any treatment arm. If SOC meets the criteria but none of its PT meets the criteria then only the SOC is displayed.

Population: Modified Intent-to-Treat Population with Eosinophils 300 cells/uL or More

Table 311.4
Summary and Analysis of On-Treatment Adverse Events without Disease-Related Events
Occurring in >=10% of patients or in >=10 and >=1% of patients by SOC and PT:
Individual Studies and Meta-Analysis

Study: MEA117113

System Organ Class/Preferred Term	PBO	100 SC	Odds Ratio (95% CI) [1]	Relative Risk (95% CI) [1]	Risk Difference (95% CI) [1]	p-value [2]
Number of subjects (N)	87	83				
ANY EVENT	69 (79%)	72 (87%)	1.71 (0.75,3.88)	1.09 (0.95,1.25)	0.07 (-0.04,0.19)	0.225
Infections and infestations	50 (57%)	45 (54%)	0.88 (0.48,1.61)	0.94 (0.72,1.23)	-0.03 (-0.18,0.12)	0.758
Nasopharyngitis	17 (20%)	16 (19%)	0.98 (0.46,2.10)	0.99 (0.53,1.82)	0.00 (-0.12,0.12)	>0.999
Pneumonia	9 (10%)	12 (14%)	1.46 (0.58,3.68)	1.40 (0.62,3.14)	0.04 (-0.06,0.14)	0.488
Upper respiratory tract infection	11 (13%)	6 (7%)	0.54 (0.19,1.53)	0.57 (0.22,1.48)	-0.05 (-0.14,0.04)	0.309
Gastrointestinal disorders	20 (23%)	19 (23%)	0.99 (0.49,2.03)	1.00 (0.57,1.73)	0.00 (-0.13,0.13)	>0.999
Respiratory, thoracic and mediastinal disorders	12 (14%)	25 (30%)	2.69 (1.25,5.81)	2.18 (1.18,4.06)	0.16 (0.04,0.29)	0.015

[1] For individual studies, the estimates are from frequency tables. In meta-analysis, odds ratio is from logistic regression and relative risk is from the poisson regression model with treatment and study as the covariates.
[2] For individual studies, p-value is from the Fisher’s exact test and for meta-analysis p-value is based on the poisson regression model.
Note: Asymptotic 95% CI’s are reported.
Note: Includes all SOC and PT which meet the given criteria in any treatment arm. If SOC meets the criteria but none of its PT meets the criteria then only the SOC is displayed.

Population: Modified Intent-to-Treat Population with Eosinophils 300 cells/uL or More

Table 311.4
Summary and Analysis of On-Treatment Adverse Events without Disease-Related Events
Occurring in >=10% of patients or in >=10 and >=1% of patients by SOC and PT:
Individual Studies and Meta-Analysis

Study: MEA117113

System Organ Class/Preferred Term	PBO	100 SC	Odds Ratio (95% CI) [1]	Relative Risk (95% CI) [1]	Risk Difference (95% CI) [1]	p-value [2]
Musculoskeletal and connective tissue disorders	16 (18%)	20 (24%)	1.41 (0.67,2.95)	1.31 (0.73,2.35)	0.06 (-0.07,0.18)	0.453
General disorders and administration site conditions	12 (14%)	17 (20%)	1.61 (0.72,3.62)	1.48 (0.76,2.92)	0.07 (-0.05,0.18)	0.309
Nervous system disorders	9 (10%)	20 (24%)	2.75 (1.17,6.46)	2.33 (1.13,4.82)	0.14 (0.03,0.25)	0.024
Headache	5 (6%)	15 (18%)	3.62 (1.25,10.46)	3.14 (1.20,8.27)	0.12 (0.03,0.22)	0.016
Investigations	9 (10%)	11 (13%)	1.32 (0.52,3.38)	1.28 (0.56,2.93)	0.03 (-0.07,0.13)	0.637

[1] For individual studies, the estimates are from frequency tables. In meta-analysis, odds ratio is from logistic regression and relative risk is from the poisson regression model with treatment and study as the covariates.
[2] For individual studies, p-value is from the Fisher’s exact test and for meta-analysis p-value is based on the poisson regression model.
Note: Asymptotic 95% CI’s are reported.
Note: Includes all SOC and PT which meet the given criteria in any treatment arm. If SOC meets the criteria but none of its PT meets the criteria then only the SOC is displayed.

Population: Modified Intent-to-Treat Population with Eosinophils 300 cells/uL or More

Table 311.4
Summary and Analysis of On-Treatment Adverse Events without Disease-Related Events
Occurring in >=10% of patients or in >=10 and >=1% of patients by SOC and PT:
Individual Studies and Meta-Analysis

Study: MEA117106

System Organ Class/Preferred Term	PBO	100 SC	Odds Ratio (95% CI) [1]	Relative Risk (95% CI) [1]	Risk Difference (95% CI) [1]	p-value [2]
Number of subjects (N)	90	82				
ANY EVENT	69 (77%)	62 (76%)	0.94 (0.47,1.90)	0.99 (0.83,1.17)	-0.01 (-0.14,0.12)	>0.999
Infections and infestations	44 (49%)	34 (41%)	0.74 (0.41,1.35)	0.85 (0.61,1.18)	-0.07 (-0.22,0.07)	0.360
Nasopharyngitis	12 (13%)	10 (12%)	0.90 (0.37,2.22)	0.91 (0.42,2.00)	-0.01 (-0.11,0.09)	>0.999
Pneumonia	11 (12%)	6 (7%)	0.57 (0.20,1.61)	0.60 (0.23,1.55)	-0.05 (-0.14,0.04)	0.317
Musculoskeletal and connective tissue disorders	17 (19%)	23 (28%)	1.67 (0.82,3.42)	1.48 (0.86,2.58)	0.09 (-0.03,0.22)	0.206
Back pain	9 (10%)	6 (7%)	0.71 (0.24,2.09)	0.73 (0.27,1.97)	-0.03 (-0.11,0.06)	0.597
Respiratory, thoracic and mediastinal disorders	15 (17%)	24 (29%)	2.07 (1.00,4.30)	1.76 (0.99,3.11)	0.13 (0.00,0.25)	0.068

[1] For individual studies, the estimates are from frequency tables. In meta-analysis, odds ratio is from logistic regression and relative risk is from the poisson regression model with treatment and study as the covariates.
[2] For individual studies, p-value is from the Fisher’s exact test and for meta-analysis p-value is based on the poisson regression model.
Note: Asymptotic 95% CI’s are reported.
Note: Includes all SOC and PT which meet the given criteria in any treatment arm. If SOC meets the criteria but none of its PT meets the criteria then only the SOC is displayed.

Population: Modified Intent-to-Treat Population with Eosinophils 300 cells/uL or More

Table 311.4
Summary and Analysis of On-Treatment Adverse Events without Disease-Related Events
Occurring in >=10% of patients or in >=10 and >=1% of patients by SOC and PT:
Individual Studies and Meta-Analysis

Study: MEA117106

System Organ Class/Preferred Term	PBO	100 SC	Odds Ratio (95% CI) [1]	Relative Risk (95% CI) [1]	Risk Difference (95% CI) [1]	p-value [2]
Gastrointestinal disorders	14 (16%)	19 (23%)	1.64 (0.76,3.52)	1.49 (0.80,2.77)	0.08 (-0.04,0.19)	0.246
General disorders and administration site conditions	17 (19%)	13 (16%)	0.81 (0.37,1.79)	0.84 (0.44,1.62)	-0.03 (-0.14,0.08)	0.689
Nervous system disorders	19 (21%)	10 (12%)	0.52 (0.23,1.19)	0.58 (0.29,1.17)	-0.09 (-0.20,0.02)	0.154
Headache	12 (13%)	9 (11%)	0.80 (0.32,2.01)	0.82 (0.37,1.85)	-0.02 (-0.12,0.07)	0.816
Injury, poisoning and procedural complications	13 (14%)	7 (9%)	0.55 (0.21,1.46)	0.59 (0.25,1.41)	-0.06 (-0.15,0.04)	0.245
Skin and subcutaneous tissue disorders	10 (11%)	10 (12%)	1.11 (0.44,2.82)	1.10 (0.48,2.50)	0.01 (-0.09,0.11)	>0.999

[1] For individual studies, the estimates are from frequency tables. In meta-analysis, odds ratio is from logistic regression and relative risk is from the poisson regression model with treatment and study as the covariates.
[2] For individual studies, p-value is from the Fisher’s exact test and for meta-analysis p-value is based on the poisson regression model.
Note: Asymptotic 95% CI’s are reported.
Note: Includes all SOC and PT which meet the given criteria in any treatment arm. If SOC meets the criteria but none of its PT meets the criteria then only the SOC is displayed.
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Population: Modified Intent-to-Treat Population with Eosinophils 300 cells/uL or More

Table 311.4

Summary and Analysis of On-Treatment Adverse Events without Disease-Related Events Occurring in >=10% of patients or in >=10 and >=1% of patients by SOC and PT: Individual Studies and Meta-Analysis

Study: MEA117106

System Organ Class/Preferred Term	PBO	100 SC	Odds Ratio (95% CI) [1]	Relative Risk (95% CI) [1]	Risk Difference (95% CI) [1]	p-value [2]
Metabolism and nutrition disorders	10 (11%)	4 (5%)	0.41 (0.12,1.36)	0.44 (0.14,1.35)	-0.06 (-0.14,0.02)	0.168

[1] For individual studies, the estimates are from frequency tables. In meta-analysis, odds ratio is from logistic regression and relative risk is from the poisson regression model with treatment and study as the covariates.
[2] For individual studies, p-value is from the Fisher’s exact test and for meta-analysis p-value is based on the poisson regression model.
Note: Asymptotic 95% CI’s are reported.
Note: Includes all SOC and PT which meet the given criteria in any treatment arm. If SOC meets the criteria but none of its PT meets the criteria then only the SOC is displayed.

Population: Modified Intent-to-Treat Population with Eosinophils 300 cells/uL or More

Table 311.4
Summary and Analysis of On-Treatment Adverse Events without Disease-Related Events
Occurring in >=10% of patients or in >=10 and >=1% of patients by SOC and PT:
Individual Studies and Meta-Analysis

Study: 208657 + MEA117113 + MEA117106

System Organ Class/Preferred Term	PBO	100 SC	Odds Ratio (95% CI) [1]	Relative Risk (95% CI) [1]	Risk Difference (95% CI) [1]	p-value [2]
Number of subjects (N)	578	568				
ANY EVENT	434 (75%)	431 (76%)	1.05 (0.80,1.37)	1.01 (0.89,1.16)	0.01 (-0.09,0.11)	0.867
Infections and infestations	261 (45%)	265 (47%)	1.07 (0.84,1.35)	1.03 (0.87,1.23)	0.02 (-0.06,0.10)	0.696
Nasopharyngitis	61 (11%)	67 (12%)	1.15 (0.79,1.66)	1.13 (0.80,1.59)	0.02 (-0.02,0.05)	0.501
COVID-19	49 (8%)	50 (9%)	Non-Est.	Non-Est.	Non-Est.	Non-Est.
Pneumonia	47 (8%)	48 (8%)	1.05 (0.69,1.60)	1.05 (0.70,1.56)	0.00 (-0.03,0.04)	0.826
Upper respiratory tract infection	31 (5%)	33 (6%)	1.08 (0.65,1.80)	1.08 (0.66,1.76)	Non-Est.	0.767
Influenza	29 (5%)	22 (4%)	0.76 (0.43,1.34)	0.77 (0.44,1.34)	-0.01 (-0.04,0.01)	0.357
Urinary tract infection	14 (2%)	24 (4%)	1.78 (0.91,3.48)	1.75 (0.90,3.38)	0.02 (0.00,0.04)	0.098
Sinusitis	12 (2%)	16 (3%)	1.38 (0.65,2.95)	1.37 (0.65,2.90)	0.01 (-0.01,0.02)	0.410
Rhinitis	10 (2%)	11 (2%)	1.13 (0.48,2.68)	1.13 (0.48,2.65)	0.00 (-0.02,0.02)	0.785

[1] For individual studies, the estimates are from frequency tables. In meta-analysis, odds ratio is from logistic regression and relative risk is from the poisson regression model with treatment and study as the covariates.
[2] For individual studies, p-value is from the Fisher’s exact test and for meta-analysis p-value is based on the poisson regression model.
Note: Asymptotic 95% CI’s are reported.
Note: Includes all SOC and PT which meet the given criteria in any treatment arm. If SOC meets the criteria but none of its PT meets the criteria then only the SOC is displayed.
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Population: Modified Intent-to-Treat Population with Eosinophils 300 cells/uL or More

Table 311.4
Summary and Analysis of On-Treatment Adverse Events without Disease-Related Events
Occurring in >=10% of patients or in >=10 and >=1% of patients by SOC and PT:
Individual Studies and Meta-Analysis

Study: 208657 + MEA117113 + MEA117106

System Organ Class/Preferred Term	PBO	100 SC	Odds Ratio (95% CI) [1]	Relative Risk (95% CI) [1]	Risk Difference (95% CI) [1]	p-value [2]
Lower respiratory tract infection	10 (2%)	9 (2%)	0.91 (0.37,2.26)	0.91 (0.37,2.25)	0.00 (-0.02,0.01)	0.846
Pharyngitis	12 (2%)	7 (1%)	0.60 (0.23,1.53)	0.60 (0.24,1.54)	0.00 (-0.02,0.01)	0.291
Respiratory, thoracic and mediastinal disorders	104 (18%)	124 (22%)	1.28 (0.95,1.71)	1.22 (0.94,1.58)	0.03 (-0.02,0.09)	0.141
Dyspnoea	26 (4%)	28 (5%)	1.10 (0.64,1.90)	1.09 (0.64,1.87)	0.00 (-0.02,0.03)	0.743
Cough	18 (3%)	23 (4%)	1.31 (0.70,2.47)	1.30 (0.70,2.41)	0.01 (-0.01,0.03)	0.403
Oropharyngeal pain	7 (1%)	20 (4%)	3.10 (1.29,7.42)	2.98 (1.26,7.06)	0.02 (0.00,0.04)	0.013
Musculoskeletal and connective tissue disorders	106 (18%)	119 (21%)	1.19 (0.89,1.59)	1.15 (0.88,1.49)	0.02 (-0.03,0.08)	0.307
Back pain	36 (6%)	38 (7%)	1.08 (0.68,1.74)	1.08 (0.68,1.70)	0.01 (-0.02,0.04)	0.744
Arthralgia	19 (3%)	30 (5%)	1.63 (0.91,2.94)	1.60 (0.90,2.84)	0.02 (0.00,0.05)	0.110

[1] For individual studies, the estimates are from frequency tables. In meta-analysis, odds ratio is from logistic regression and relative risk is from the poisson regression model with treatment and study as the covariates.
[2] For individual studies, p-value is from the Fisher’s exact test and for meta-analysis p-value is based on the poisson regression model.
Note: Asymptotic 95% CI’s are reported.
Note: Includes all SOC and PT which meet the given criteria in any treatment arm. If SOC meets the criteria but none of its PT meets the criteria then only the SOC is displayed.

Population: Modified Intent-to-Treat Population with Eosinophils 300 cells/uL or More

Table 311.4
Summary and Analysis of On-Treatment Adverse Events without Disease-Related Events
Occurring in >=10% of patients or in >=10 and >=1% of patients by SOC and PT:
Individual Studies and Meta-Analysis

Study: 208657 + MEA117113 + MEA117106

System Organ Class/Preferred Term	PBO	100 SC	Odds Ratio (95% CI) [1]	Relative Risk (95% CI) [1]	Risk Difference (95% CI) [1]	p-value [2]
Pain in extremity	13 (2%)	16 (3%)	1.27 (0.60,2.67)	1.26 (0.61,2.62)	0.01 (-0.01,0.03)	0.535
Osteoarthritis	8 (1%)	13 (2%)	1.66 (0.68,4.03)	1.64 (0.68,3.96)	Non-Est.	0.271
Gastrointestinal disorders	90 (16%)	110 (19%)	1.31 (0.96,1.78)	1.25 (0.95,1.65)	0.04 (-0.01,0.09)	0.119
Diarrhoea	21 (4%)	31 (5%)	1.53 (0.87,2.71)	1.50 (0.86,2.61)	0.02 (0.00,0.05)	0.150
Nausea	12 (2%)	12 (2%)	1.04 (0.46,2.34)	1.04 (0.47,2.31)	0.00 (-0.02,0.01)	0.929
Constipation	8 (1%)	13 (2%)	1.67 (0.69,4.08)	1.66 (0.69,4.00)	0.01 (-0.01,0.02)	0.262
Nervous system disorders	95 (16%)	88 (15%)	0.93 (0.68,1.28)	0.94 (0.71,1.26)	-0.01 (-0.06,0.04)	0.697
Headache	44 (8%)	55 (10%)	1.32 (0.87,2.00)	1.28 (0.86,1.91)	0.02 (-0.02,0.05)	0.218
Dizziness	15 (3%)	13 (2%)	0.88 (0.41,1.86)	0.88 (0.42,1.85)	0.00 (-0.02,0.01)	0.735
General disorders and administration site conditions	75 (13%)	82 (14%)	1.14 (0.81,1.60)	1.12 (0.82,1.53)	0.02 (-0.03,0.06)	0.481
Pyrexia	16 (3%)	17 (3%)	1.09 (0.54,2.18)	1.08 (0.55,2.15)	0.00 (-0.02,0.02)	0.815

[1] For individual studies, the estimates are from frequency tables. In meta-analysis, odds ratio is from logistic regression and relative risk is from the poisson regression model with treatment and study as the covariates.
[2] For individual studies, p-value is from the Fisher’s exact test and for meta-analysis p-value is based on the poisson regression model.
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Note: Includes all SOC and PT which meet the given criteria in any treatment arm. If SOC meets the criteria but none of its PT meets the criteria then only the SOC is displayed.

Population: Modified Intent-to-Treat Population with Eosinophils 300 cells/uL or More

Table 311.4
Summary and Analysis of On-Treatment Adverse Events without Disease-Related Events
Occurring in >=10% of patients or in >=10 and >=1% of patients by SOC and PT:
Individual Studies and Meta-Analysis

Study: 208657 + MEA117113 + MEA117106

System Organ Class/Preferred Term	PBO	100 SC	Odds Ratio (95% CI) [1]	Relative Risk (95% CI) [1]	Risk Difference (95% CI) [1]	p-value [2]
Oedema peripheral	9 (2%)	13 (2%)	1.47 (0.62,3.47)	1.46 (0.62,3.42)	0.01 (-0.01,0.03)	0.383
Non-cardiac chest pain	10 (2%)	11 (2%)	1.14 (0.48,2.72)	1.14 (0.48,2.67)	0.00 (-0.01,0.01)	0.772
Vascular disorders	51 (9%)	49 (9%)	0.97 (0.64,1.46)	0.97 (0.65,1.43)	0.00 (-0.03,0.04)	0.877
Hypertension	31 (5%)	24 (4%)	0.77 (0.45,1.34)	0.78 (0.46,1.33)	0.00 (-0.03,0.03)	0.369
Injury, poisoning and procedural complications	52 (9%)	47 (8%)	0.92 (0.61,1.39)	0.93 (0.62,1.37)	0.00 (-0.04,0.03)	0.699
Cardiac disorders	57 (10%)	41 (7%)	0.71 (0.46,1.08)	0.73 (0.49,1.09)	-0.03 (-0.06,0.00)	0.125
Atrial fibrillation	10 (2%)	5 (<1%)	0.50 (0.17,1.48)	0.51 (0.17,1.48)	Non-Est.	0.214

[1] For individual studies, the estimates are from frequency tables. In meta-analysis, odds ratio is from logistic regression and relative risk is from the poisson regression model with treatment and study as the covariates.
[2] For individual studies, p-value is from the Fisher’s exact test and for meta-analysis p-value is based on the poisson regression model.
Note: Asymptotic 95% CI’s are reported.
Note: Includes all SOC and PT which meet the given criteria in any treatment arm. If SOC meets the criteria but none of its PT meets the criteria then only the SOC is displayed.

Population: Modified Intent-to-Treat Population with Eosinophils 300 cells/uL or More

Table 311.4
Summary and Analysis of On-Treatment Adverse Events without Disease-Related Events
Occurring in >=10% of patients or in >=10 and >=1% of patients by SOC and PT:
Individual Studies and Meta-Analysis

Study: 208657 + MEA117113 + MEA117106

System Organ Class/Preferred Term	PBO	100 SC	Odds Ratio (95% CI) [1]	Relative Risk (95% CI) [1]	Risk Difference (95% CI) [1]	p-value [2]
Metabolism and nutrition disorders	46 (8%)	51 (9%)	1.14 (0.75,1.73)	1.12 (0.75,1.68)	0.01 (-0.02,0.05)	0.565
Investigations	49 (8%)	38 (7%)	0.77 (0.50,1.20)	0.79 (0.52,1.21)	-0.02 (-0.05,0.01)	0.273
Skin and subcutaneous tissue disorders	38 (7%)	44 (8%)	1.21 (0.77,1.90)	1.19 (0.77,1.84)	0.01 (-0.02,0.04)	0.433
Renal and urinary disorders	29 (5%)	24 (4%)	0.83 (0.48,1.45)	0.84 (0.49,1.44)	-0.01 (-0.03,0.02)	0.530
Psychiatric disorders	24 (4%)	27 (5%)	1.17 (0.66,2.05)	1.16 (0.67,2.01)	0.01 (-0.02,0.03)	0.601
Anxiety	9 (2%)	13 (2%)	1.49 (0.63,3.52)	1.48 (0.63,3.46)	0.01 (-0.01,0.02)	0.366
Eye disorders	27 (5%)	18 (3%)	0.67 (0.36,1.23)	0.68 (0.37,1.23)	-0.01 (-0.04,0.01)	0.202
Cataract	13 (2%)	10 (2%)	0.78 (0.34,1.80)	0.79 (0.35,1.80)	0.00 (-0.02,0.01)	0.570

[1] For individual studies, the estimates are from frequency tables. In meta-analysis, odds ratio is from logistic regression and relative risk is from the poisson regression model with treatment and study as the covariates.
[2] For individual studies, p-value is from the Fisher’s exact test and for meta-analysis p-value is based on the poisson regression model.
Note: Asymptotic 95% CI’s are reported.
Note: Includes all SOC and PT which meet the given criteria in any treatment arm. If SOC meets the criteria but none of its PT meets the criteria then only the SOC is displayed.

Population: Modified Intent-to-Treat Population with Eosinophils 300 cells/uL or More

Table 311.4

Summary and Analysis of On-Treatment Adverse Events without Disease-Related Events Occurring in >=10% of patients or in >=10 and >=1% of patients by SOC and PT: Individual Studies and Meta-Analysis

Study: 208657 + MEA117113 + MEA117106

System Organ Class/Preferred Term	PBO	100 SC	Odds Ratio (95% CI) [1]	Relative Risk (95% CI) [1]	Risk Difference (95% CI) [1]	p-value [2]
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	22 (4%)	17 (3%)	0.78 (0.41,1.49)	0.79 (0.42,1.49)	-0.01 (-0.03,0.01)	0.465
Blood and lymphatic system disorders	18 (3%)	16 (3%)	0.90 (0.45,1.78)	0.90 (0.46,1.77)	0.00 (-0.02,0.02)	0.760
Anaemia	8 (1%)	11 (2%)	1.41 (0.56,3.53)	1.40 (0.56,3.48)	Non-Est.	0.469
Hepatobiliary disorders	17 (3%)	13 (2%)	0.76 (0.37,1.59)	0.77 (0.37,1.58)	0.00 (-0.03,0.02)	0.478
Ear and labyrinth disorders	10 (2%)	14 (2%)	1.46 (0.64,3.31)	1.44 (0.64,3.25)	0.00 (-0.01,0.02)	0.376

[1] For individual studies, the estimates are from frequency tables. In meta-analysis, odds ratio is from logistic regression and relative risk is from the poisson regression model with treatment and study as the covariates.
[2] For individual studies, p-value is from the Fisher’s exact test and for meta-analysis p-value is based on the poisson regression model.
Note: Asymptotic 95% CI’s are reported.
Note: Includes all SOC and PT which meet the given criteria in any treatment arm. If SOC meets the criteria but none of its PT meets the criteria then only the SOC is displayed.
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Population: Modified Intent-to-Treat Population with Eosinophils 300 cells/uL or More

Table 311.4

Summary and Analysis of On-Treatment Adverse Events without Disease-Related Events Occurring in >=10% of patients or in >=10 and >=1% of patients by SOC and PT: Individual Studies and Meta-Analysis

Study: 208657 + MEA117113 + MEA117106

System Organ Class/Preferred Term	PBO	100 SC	Odds Ratio (95% CI) [1]	Relative Risk (95% CI) [1]	Risk Difference (95% CI) [1]	p-value [2]
Reproductive system and breast disorders	12 (2%)	10 (2%)	0.84 (0.36,1.96)	0.84 (0.36,1.95)	0.00 (-0.02,0.01)	0.694
Immune system disorders	13 (2%)	6 (1%)	0.47 (0.18,1.24)	0.47 (0.18,1.25)	Non-Est.	0.131

[1] For individual studies, the estimates are from frequency tables. In meta-analysis, odds ratio is from logistic regression and relative risk is from the poisson regression model with treatment and study as the covariates.
[2] For individual studies, p-value is from the Fisher’s exact test and for meta-analysis p-value is based on the poisson regression model.
Note: Asymptotic 95% CI’s are reported.
Note: Includes all SOC and PT which meet the given criteria in any treatment arm. If SOC meets the criteria but none of its PT meets the criteria then only the SOC is displayed.

Population: Modified Intent-to-Treat Population with Eosinophils 300 cells/uL or More

Table 311.5

Analysis of On-Treatment Adverse Events without Disease-Related Events
Occurring in >=10% of patients or in >=10 and >=1% of patients by SOC and PT:
Meta-Analysis: p-values for Interaction Effect

Study: 208657 + MEA117113 + MEA117106

System Organ Class/Preferred Term	p-value for study*treatment interaction [1]
ANY EVENT	0.878
Infections and infestations	0.502
Nasopharyngitis	0.720
COVID-19	Non-Est.
Pneumonia	0.419
Upper respiratory tract infection	0.097
Influenza	0.264
Urinary tract infection	0.330
Sinusitis	0.843
Rhinitis	0.086
Lower respiratory tract infection	0.898
Pharyngitis	0.067
Respiratory, thoracic and mediastinal disorders	0.046
Dyspnoea	0.228
Cough	0.257
Oropharyngeal pain	0.114
Musculoskeletal and connective tissue disorders	0.549
Back pain	0.631
Arthralgia	0.538
Pain in extremity	0.231
Osteoarthritis	0.328

[1] From the poisson regression model with covariates of treatment group, study and with an additional covariate of study*treatment interaction.
Note: Includes all SOC and PT which meet the given criteria in any treatment arm. If SOC meets the criteria but none of its PT meets the criteria then only the SOC is displayed.
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Population: Modified Intent-to-Treat Population with Eosinophils 300 cells/uL or More

Table 311.5
Analysis of On-Treatment Adverse Events without Disease-Related Events
Occurring in >=10% of patients or in >=10 and >=1% of patients by SOC and PT:
Meta-Analysis: p-values for Interaction Effect

Study: 208657 + MEA117113 + MEA117106

System Organ Class/Preferred Term	p-value for study*treatment interaction [1]
Gastrointestinal disorders	0.681
Diarrhoea	0.166
Nausea	0.628
Constipation	0.721
Nervous system disorders	0.025
Headache	0.099
Dizziness	0.741
General disorders and administration site conditions	0.553
Pyrexia	0.331
Oedema peripheral	0.224
Non-cardiac chest pain	0.728
Vascular disorders	0.258
Hypertension	0.026
Injury, poisoning and procedural complications	0.554
Cardiac disorders	0.560
Atrial fibrillation	0.583
Metabolism and nutrition disorders	0.067

[1] From the poisson regression model with covariates of treatment group, study and with an additional covariate of study*treatment interaction.
Note: Includes all SOC and PT which meet the given criteria in any treatment arm. If SOC meets the criteria but none of its PT meets the criteria then only the SOC is displayed.
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Population: Modified Intent-to-Treat Population with Eosinophils 300 cells/uL or More

Table 311.5

Analysis of On-Treatment Adverse Events without Disease-Related Events
Occurring in >=10% of patients or in >=10 and >=1% of patients by SOC and PT:
Meta-Analysis: p-values for Interaction Effect

Study: 208657 + MEA117113 + MEA117106

System Organ Class/Preferred Term	p-value for study*treatment interaction [1]
Investigations	0.247
Skin and subcutaneous tissue disorders	0.979
Renal and urinary disorders	0.429
Psychiatric disorders	0.442
Anxiety	0.666
Eye disorders	0.792
Cataract	0.671
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	0.228
Blood and lymphatic system disorders	0.323
Anaemia	0.343
Hepatobiliary disorders	0.084
Ear and labyrinth disorders	0.545
Reproductive system and breast disorders	0.947

[1] From the poisson regression model with covariates of treatment group, study and with an additional covariate of study*treatment interaction.
Note: Includes all SOC and PT which meet the given criteria in any treatment arm. If SOC meets the criteria but none of its PT meets the criteria then only the SOC is displayed.
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Population: Modified Intent-to-Treat Population with Eosinophils 300 cells/uL or More

Table 311.5
Analysis of On-Treatment Adverse Events without Disease-Related Events
Occurring in >=10% of patients or in >=10 and >=1% of patients by SOC and PT:
Meta-Analysis: p-values for Interaction Effect

Study: 208657 + MEA117113 + MEA117106

System Organ Class/Preferred Term	p-value for study*treatment interaction [1]
Immune system disorders	0.424

[1] From the poisson regression model with covariates of treatment group, study and with an additional covariate of study*treatment interaction.
Note: Includes all SOC and PT which meet the given criteria in any treatment arm. If SOC meets the criteria but none of its PT meets the criteria then only the SOC is displayed.
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Population: Modified Intent-to-Treat Population with Eosinophils 300 cells/uL or More

Table 311.6

Summary and Analysis of Serious On-Treatment Adverse Events
Occurring in >=5% of patients or in >=10 and >=1% of patients by SOC and PT:
Individual Studies and Meta-Analysis

Study: 208657

System Organ Class/Preferred Term	PBO	100 SC	Odds Ratio (95% CI) [1]	Relative Risk (95% CI) [1]	Risk Difference (95% CI) [1]	p-value [2]
Number of subjects (N)	401	403				
ANY EVENT	112 (28%)	99 (25%)	0.84 (0.61,1.15)	0.88 (0.70,1.11)	-0.03 (-0.09,0.03)	0.298
Respiratory, thoracic and mediastinal disorders	62 (15%)	55 (14%)	0.86 (0.58,1.28)	0.88 (0.63,1.23)	-0.02 (-0.07,0.03)	0.485
Chronic obstructive pulmonary disease	55 (14%)	46 (11%)	0.81 (0.53,1.23)	0.83 (0.58,1.20)	-0.02 (-0.07,0.02)	0.340
Infections and infestations	31 (8%)	32 (8%)	1.03 (0.62,1.72)	1.03 (0.64,1.65)	0.00 (-0.04,0.04)	>0.999
Pneumonia	14 (3%)	14 (3%)	0.99 (0.47,2.11)	1.00 (0.48,2.06)	0.00 (-0.03,0.03)	>0.999
Cardiac disorders	16 (4%)	13 (3%)	0.80 (0.38,1.69)	0.81 (0.39,1.66)	-0.01 (-0.03,0.02)	0.577

[1] For individual studies, the estimates are from frequency tables. In meta-analysis, odds ratio is from logistic regression and relative risk is from the poisson regression model with treatment and study as the covariates.
[2] For individual studies, p-value is from the Fisher’s exact test and for meta-analysis p-value is based on the poisson regression model.
Note: Asymptotic 95% CI’s are reported.
Note: Includes all SOC and PT which meet the given criteria in any treatment arm. If SOC meets the criteria but none of its PT meets the criteria then only the SOC is displayed.

Population: Modified Intent-to-Treat Population with Eosinophils 300 cells/uL or More

Table 311.6

Summary and Analysis of Serious On-Treatment Adverse Events
Occurring in >=5% of patients or in >=10 and >=1% of patients by SOC and PT:
Individual Studies and Meta-Analysis

Study: 208657

System Organ Class/Preferred Term	PBO	100 SC	Odds Ratio (95% CI) [1]	Relative Risk (95% CI) [1]	Risk Difference (95% CI) [1]	p-value [2]
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	12 (3%)	8 (2%)	0.66 (0.27,1.62)	0.66 (0.27,1.61)	-0.01 (-0.03,0.01)	0.376

[1] For individual studies, the estimates are from frequency tables. In meta-analysis, odds ratio is from logistic regression and relative risk is from the poisson regression model with treatment and study as the covariates.
[2] For individual studies, p-value is from the Fisher’s exact test and for meta-analysis p-value is based on the poisson regression model.
Note: Asymptotic 95% CI’s are reported.
Note: Includes all SOC and PT which meet the given criteria in any treatment arm. If SOC meets the criteria but none of its PT meets the criteria then only the SOC is displayed.

Population: Modified Intent-to-Treat Population with Eosinophils 300 cells/uL or More

Table 311.6
Summary and Analysis of Serious On-Treatment Adverse Events
Occurring in >=5% of patients or in >=10 and >=1% of patients by SOC and PT:
Individual Studies and Meta-Analysis

Study: MEA117113

System Organ Class/Preferred Term	PBO	100 SC	Odds Ratio (95% CI) [1]	Relative Risk (95% CI) [1]	Risk Difference (95% CI) [1]	p-value [2]
Number of subjects (N)	87	83				
ANY EVENT	23 (26%)	17 (20%)	0.72 (0.35,1.47)	0.77 (0.45,1.34)	-0.06 (-0.19,0.07)	0.373
Respiratory, thoracic and mediastinal disorders	13 (15%)	9 (11%)	0.69 (0.28,1.72)	0.73 (0.33,1.61)	-0.04 (-0.14,0.06)	0.497
Chronic obstructive pulmonary disease	13 (15%)	8 (10%)	0.61 (0.24,1.55)	0.65 (0.28,1.48)	-0.05 (-0.15,0.05)	0.355
Infections and infestations	9 (10%)	9 (11%)	1.05 (0.40,2.80)	1.05 (0.44,2.51)	0.00 (-0.09,0.10)	>0.999
Pneumonia	6 (7%)	6 (7%)	1.05 (0.33,3.40)	1.05 (0.35,3.12)	0.00 (-0.07,0.08)	>0.999

[1] For individual studies, the estimates are from frequency tables. In meta-analysis, odds ratio is from logistic regression and relative risk is from the poisson regression model with treatment and study as the covariates.
[2] For individual studies, p-value is from the Fisher’s exact test and for meta-analysis p-value is based on the poisson regression model.
Note: Asymptotic 95% CI’s are reported.
Note: Includes all SOC and PT which meet the given criteria in any treatment arm. If SOC meets the criteria but none of its PT meets the criteria then only the SOC is displayed.
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Population: Modified Intent-to-Treat Population with Eosinophils 300 cells/uL or More

Table 311.6
Summary and Analysis of Serious On-Treatment Adverse Events
Occurring in >=5% of patients or in >=10 and >=1% of patients by SOC and PT:
Individual Studies and Meta-Analysis

Study: MEA117106

System Organ Class/Preferred Term	PBO	100 SC	Odds Ratio (95% CI) [1]	Relative Risk (95% CI) [1]	Risk Difference (95% CI) [1]	p-value [2]
Number of subjects (N)	90	82				
ANY EVENT	28 (31%)	17 (21%)	0.58 (0.29,1.16)	0.67 (0.39,1.12)	-0.10 (-0.23,0.03)	0.164
Respiratory, thoracic and mediastinal disorders	18 (20%)	11 (13%)	0.62 (0.27,1.41)	0.67 (0.34,1.33)	-0.07 (-0.18,0.04)	0.309
Chronic obstructive pulmonary disease	16 (18%)	9 (11%)	0.57 (0.24,1.37)	0.62 (0.29,1.32)	-0.07 (-0.17,0.04)	0.279
Infections and infestations	10 (11%)	6 (7%)	0.63 (0.22,1.82)	0.66 (0.25,1.73)	-0.04 (-0.12,0.05)	0.441
Pneumonia	5 (6%)	5 (6%)	1.10 (0.31,3.96)	1.10 (0.33,3.65)	0.01 (-0.06,0.08)	>0.999

[1] For individual studies, the estimates are from frequency tables. In meta-analysis, odds ratio is from logistic regression and relative risk is from the poisson regression model with treatment and study as the covariates.
[2] For individual studies, p-value is from the Fisher’s exact test and for meta-analysis p-value is based on the poisson regression model.
Note: Asymptotic 95% CI’s are reported.
Note: Includes all SOC and PT which meet the given criteria in any treatment arm. If SOC meets the criteria but none of its PT meets the criteria then only the SOC is displayed.

Population: Modified Intent-to-Treat Population with Eosinophils 300 cells/uL or More

Table 311.6

Summary and Analysis of Serious On-Treatment Adverse Events
Occurring in >=5% of patients or in >=10 and >=1% of patients by SOC and PT:
Individual Studies and Meta-Analysis

Study: 208657 + MEA117113 + MEA117106

System Organ Class/Preferred Term	PBO	100 SC	Odds Ratio (95% CI) [1]	Relative Risk (95% CI) [1]	Risk Difference (95% CI) [1]	p-value [2]
Number of subjects (N)	578	568				
ANY EVENT	163 (28%)	133 (23%)	0.78 (0.60,1.01)	0.83 (0.66,1.04)	-0.05 (-0.11,0.01)	0.111
Respiratory, thoracic and mediastinal disorders	93 (16%)	75 (13%)	0.79 (0.57,1.10)	0.82 (0.61,1.11)	-0.03 (-0.07,0.02)	0.206
Chronic obstructive pulmonary disease	84 (15%)	63 (11%)	0.73 (0.52,1.04)	0.76 (0.55,1.06)	-0.03 (-0.08,0.01)	0.108
Infections and infestations	50 (9%)	47 (8%)	0.96 (0.63,1.45)	0.96 (0.64,1.43)	0.00 (-0.04,0.03)	0.840
Pneumonia	25 (4%)	25 (4%)	1.03 (0.58,1.82)	1.03 (0.59,1.79)	0.00 (-0.02,0.02)	0.924
Cardiac disorders	23 (4%)	15 (3%)	0.65 (0.34,1.26)	0.66 (0.35,1.27)	Non-Est.	0.214

[1] For individual studies, the estimates are from frequency tables. In meta-analysis, odds ratio is from logistic regression and relative risk is from the poisson regression model with treatment and study as the covariates.
[2] For individual studies, p-value is from the Fisher’s exact test and for meta-analysis p-value is based on the poisson regression model.
Note: Asymptotic 95% CI’s are reported.
Note: Includes all SOC and PT which meet the given criteria in any treatment arm. If SOC meets the criteria but none of its PT meets the criteria then only the SOC is displayed.
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Population: Modified Intent-to-Treat Population with Eosinophils 300 cells/uL or More

Table 311.6

Summary and Analysis of Serious On-Treatment Adverse Events
Occurring in >=5% of patients or in >=10 and >=1% of patients by SOC and PT:
Individual Studies and Meta-Analysis

Study: 208657 + MEA117113 + MEA117106

System Organ Class/Preferred Term	PBO	100 SC	Odds Ratio (95% CI) [1]	Relative Risk (95% CI) [1]	Risk Difference (95% CI) [1]	p-value [2]
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	14 (2%)	11 (2%)	0.79 (0.35,1.75)	0.79 (0.36,1.75)	0.00 (-0.02,0.02)	0.565

[1] For individual studies, the estimates are from frequency tables. In meta-analysis, odds ratio is from logistic regression and relative risk is from the poisson regression model with treatment and study as the covariates.
[2] For individual studies, p-value is from the Fisher’s exact test and for meta-analysis p-value is based on the poisson regression model.
Note: Asymptotic 95% CI’s are reported.
Note: Includes all SOC and PT which meet the given criteria in any treatment arm. If SOC meets the criteria but none of its PT meets the criteria then only the SOC is displayed.

Population: Modified Intent-to-Treat Population with Eosinophils 300 cells/uL or More

Table 311.7
Analysis of Serious On-Treatment Adverse Events
Occurring in >=5% of patients or in >=10 and >=1% of patients by SOC and PT:
Meta-Analysis: p-values for Interaction Effect

Study: 208657 + MEA117113 + MEA117106

System Organ Class/Preferred Term	p-value for study*treatment interaction [1]
ANY EVENT	0.691
Respiratory, thoracic and mediastinal disorders	0.773
Chronic obstructive pulmonary disease	0.744
Infections and infestations	0.722
Pneumonia	0.991
Cardiac disorders	0.196
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	0.154

[1] From the poisson regression model with covariates of treatment group, study and with an additional covariate of study*treatment interaction.
Note: Includes all SOC and PT which meet the given criteria in any treatment arm. If SOC meets the criteria but none of its PT meets the criteria then only the SOC is displayed.
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Population: Modified Intent-to-Treat Population with Eosinophils 300 cells/uL or More

Table 311.8
Summary and Analysis of Serious On-Treatment Adverse Events without Disease Related Events
Occurring in >=5% of patients or in >=10 and >=1% of patients by SOC and PT:
Individual Studies and Meta-Analysis

Study: 208657

System Organ Class/Preferred Term	PBO	100 SC	Odds Ratio (95% CI) [1]	Relative Risk (95% CI) [1]	Risk Difference (95% CI) [1]	p-value [2]
Number of subjects (N)	401	403				
ANY EVENT	81 (20%)	75 (19%)	0.90 (0.64,1.28)	0.92 (0.69,1.22)	-0.02 (-0.07,0.04)	0.593
Infections and infestations	31 (8%)	32 (8%)	1.03 (0.62,1.72)	1.03 (0.64,1.65)	0.00 (-0.04,0.04)	>0.999
Pneumonia	14 (3%)	14 (3%)	0.99 (0.47,2.11)	1.00 (0.48,2.06)	0.00 (-0.03,0.03)	>0.999
Cardiac disorders	16 (4%)	13 (3%)	0.80 (0.38,1.69)	0.81 (0.39,1.66)	-0.01 (-0.03,0.02)	0.577
Respiratory, thoracic and mediastinal disorders	11 (3%)	13 (3%)	1.18 (0.52,2.67)	1.18 (0.53,2.59)	0.00 (-0.02,0.03)	0.836

[1] For individual studies, the estimates are from frequency tables. In meta-analysis, odds ratio is from logistic regression and relative risk is from the poisson regression model with treatment and study as the covariates.
[2] For individual studies, p-value is from the Fisher’s exact test and for meta-analysis p-value is based on the poisson regression model.
Note: Asymptotic 95% CI’s are reported.
Note: Includes all SOC and PT which meet the given criteria in any treatment arm. If SOC meets the criteria but none of its PT meets the criteria then only the SOC is displayed.

Population: Modified Intent-to-Treat Population with Eosinophils 300 cells/uL or More

Table 311.8

Summary and Analysis of Serious On-Treatment Adverse Events without Disease Related Events Occurring in >=5% of patients or in >=10 and >=1% of patients by SOC and PT: Individual Studies and Meta-Analysis

Study: 208657

System Organ Class/Preferred Term	PBO	100 SC	Odds Ratio (95% CI) [1]	Relative Risk (95% CI) [1]	Risk Difference (95% CI) [1]	p-value [2]
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	12 (3%)	8 (2%)	0.66 (0.27,1.62)	0.66 (0.27,1.61)	-0.01 (-0.03,0.01)	0.376

[1] For individual studies, the estimates are from frequency tables. In meta-analysis, odds ratio is from logistic regression and relative risk is from the poisson regression model with treatment and study as the covariates.
[2] For individual studies, p-value is from the Fisher’s exact test and for meta-analysis p-value is based on the poisson regression model.
Note: Asymptotic 95% CI’s are reported.
Note: Includes all SOC and PT which meet the given criteria in any treatment arm. If SOC meets the criteria but none of its PT meets the criteria then only the SOC is displayed.

Population: Modified Intent-to-Treat Population with Eosinophils 300 cells/uL or More

Table 311.8
Summary and Analysis of Serious On-Treatment Adverse Events without Disease Related Events
Occurring in >=5% of patients or in >=10 and >=1% of patients by SOC and PT:
Individual Studies and Meta-Analysis

Study: MEA117113

System Organ Class/Preferred Term	PBO	100 SC	Odds Ratio (95% CI) [1]	Relative Risk (95% CI) [1]	Risk Difference (95% CI) [1]	p-value [2]
Number of subjects (N)	87	83				
ANY EVENT	17 (20%)	15 (18%)	0.91 (0.42,1.96)	0.92 (0.49,1.73)	-0.01 (-0.13,0.10)	0.846
Infections and infestations	9 (10%)	9 (11%)	1.05 (0.40,2.80)	1.05 (0.44,2.51)	0.00 (-0.09,0.10)	>0.999
Pneumonia	6 (7%)	6 (7%)	1.05 (0.33,3.40)	1.05 (0.35,3.12)	0.00 (-0.07,0.08)	>0.999

[1] For individual studies, the estimates are from frequency tables. In meta-analysis, odds ratio is from logistic regression and relative risk is from the poisson regression model with treatment and study as the covariates.
[2] For individual studies, p-value is from the Fisher’s exact test and for meta-analysis p-value is based on the poisson regression model.
Note: Asymptotic 95% CI’s are reported.
Note: Includes all SOC and PT which meet the given criteria in any treatment arm. If SOC meets the criteria but none of its PT meets the criteria then only the SOC is displayed.

Population: Modified Intent-to-Treat Population with Eosinophils 300 cells/uL or More

Table 311.8

Summary and Analysis of Serious On-Treatment Adverse Events without Disease Related Events Occurring in >=5% of patients or in >=10 and >=1% of patients by SOC and PT: Individual Studies and Meta-Analysis

Study: MEA117106

System Organ Class/Preferred Term	PBO	100 SC	Odds Ratio (95% CI) [1]	Relative Risk (95% CI) [1]	Risk Difference (95% CI) [1]	p-value [2]
Number of subjects (N)	90	82				
ANY EVENT	18 (20%)	12 (15%)	0.69 (0.31,1.53)	0.73 (0.38,1.42)	-0.05 (-0.17,0.06)	0.423
Infections and infestations	9 (10%)	6 (7%)	0.71 (0.24,2.09)	0.73 (0.27,1.97)	-0.03 (-0.11,0.06)	0.597
Pneumonia	5 (6%)	5 (6%)	1.10 (0.31,3.96)	1.10 (0.33,3.65)	0.01 (-0.06,0.08)	>0.999

[1] For individual studies, the estimates are from frequency tables. In meta-analysis, odds ratio is from logistic regression and relative risk is from the poisson regression model with treatment and study as the covariates.
[2] For individual studies, p-value is from the Fisher’s exact test and for meta-analysis p-value is based on the poisson regression model.
Note: Asymptotic 95% CI’s are reported.
Note: Includes all SOC and PT which meet the given criteria in any treatment arm. If SOC meets the criteria but none of its PT meets the criteria then only the SOC is displayed.

Population: Modified Intent-to-Treat Population with Eosinophils 300 cells/uL or More

Table 311.8

Summary and Analysis of Serious On-Treatment Adverse Events without Disease Related Events Occurring in >=5% of patients or in >=10 and >=1% of patients by SOC and PT: Individual Studies and Meta-Analysis

Study: 208657 + MEA117113 + MEA117106

System Organ Class/Preferred Term	PBO	100 SC	Odds Ratio (95% CI) [1]	Relative Risk (95% CI) [1]	Risk Difference (95% CI) [1]	p-value [2]
Number of subjects (N)	578	568				
ANY EVENT	116 (20%)	102 (18%)	0.87 (0.65,1.17)	0.89 (0.68,1.17)	-0.02 (-0.07,0.03)	0.408
Infections and infestations	49 (8%)	47 (8%)	0.98 (0.64,1.48)	0.98 (0.66,1.46)	0.00 (-0.04,0.03)	0.916
Pneumonia	25 (4%)	25 (4%)	1.03 (0.58,1.82)	1.03 (0.59,1.79)	0.00 (-0.02,0.02)	0.924
Cardiac disorders	23 (4%)	15 (3%)	0.65 (0.34,1.26)	0.66 (0.35,1.27)	Non-Est.	0.214
Respiratory, thoracic and mediastinal disorders	14 (2%)	20 (4%)	1.47 (0.74,2.94)	1.46 (0.74,2.88)	0.01 (-0.01,0.03)	0.282

[1] For individual studies, the estimates are from frequency tables. In meta-analysis, odds ratio is from logistic regression and relative risk is from the poisson regression model with treatment and study as the covariates.
[2] For individual studies, p-value is from the Fisher’s exact test and for meta-analysis p-value is based on the poisson regression model.
Note: Asymptotic 95% CI’s are reported.
Note: Includes all SOC and PT which meet the given criteria in any treatment arm. If SOC meets the criteria but none of its PT meets the criteria then only the SOC is displayed.

Population: Modified Intent-to-Treat Population with Eosinophils 300 cells/uL or More

Table 311.8

Summary and Analysis of Serious On-Treatment Adverse Events without Disease Related Events Occurring in >=5% of patients or in >=10 and >=1% of patients by SOC and PT: Individual Studies and Meta-Analysis

Study: 208657 + MEA117113 + MEA117106

System Organ Class/Preferred Term	PBO	100 SC	Odds Ratio (95% CI) [1]	Relative Risk (95% CI) [1]	Risk Difference (95% CI) [1]	p-value [2]
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	14 (2%)	11 (2%)	0.79 (0.35,1.75)	0.79 (0.36,1.75)	0.00 (-0.02,0.02)	0.565

[1] For individual studies, the estimates are from frequency tables. In meta-analysis, odds ratio is from logistic regression and relative risk is from the poisson regression model with treatment and study as the covariates.
[2] For individual studies, p-value is from the Fisher’s exact test and for meta-analysis p-value is based on the poisson regression model.
Note: Asymptotic 95% CI’s are reported.
Note: Includes all SOC and PT which meet the given criteria in any treatment arm. If SOC meets the criteria but none of its PT meets the criteria then only the SOC is displayed.

Population: Modified Intent-to-Treat Population with Eosinophils 300 cells/uL or More

Table 311.9

Analysis of Serious On-Treatment Adverse Events without Disease Related Events Occurring in >=5% of patients or in >=10 and >=1% of patients by SOC and PT: Meta-Analysis: p-values for Interaction Effect

Study: 208657 + MEA117113 + MEA117106

System Organ Class/Preferred Term	p-value for study*treatment interaction [1]
ANY EVENT	0.846
Infections and infestations	0.833
Pneumonia	0.991
Cardiac disorders	0.196
Respiratory, thoracic and mediastinal disorders	0.607
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	0.154

[1] From the poisson regression model with covariates of treatment group, study and with an additional covariate of study*treatment interaction.
Note: Includes all SOC and PT which meet the given criteria in any treatment arm. If SOC meets the criteria but none of its PT meets the criteria then only the SOC is displayed.
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Population: Modified Intent-to-Treat Population with Eosinophils 300 cells/uL or More

Table 311.10

Summary and Analysis of On-Treatment Adverse Events of Special Interest: Individual Studies and Meta-Analysis

Study: 208657

	PBO	100 SC	Odds Ratio (95% CI) [1]	Relative Risk (95% CI) [1]	Risk Difference (95% CI) [1]	p-value [2]
Number of subjects (N)	401	403				
Risks						
Serious Adverse Events	112 (28%)	99 (25%)	0.84 (0.61,1.15)	0.88 (0.70,1.11)	-0.03 (-0.09,0.03)	0.298
Systemic Reactions	5 (1%)	5 (1%)	0.99 (0.29,3.46)	1.00 (0.29,3.41)	0.00 (-0.02,0.02)	>0.999
Hypersensitivity Reactions	0	0				
Non-allergic Reactions	0	0				
Anaphylaxis	0	0				
Local Site Reactions	3 (<1%)	2 (<1%)	0.66 (0.11,3.98)	0.66 (0.11,3.95)	0.00 (-0.01,0.01)	0.686

[1] For individual studies, the estimates are based on frequency tables. For meta-analysis odds ratio is based on logistic regression and relative risk is based on the poisson regression model with treatment and study as the covariates.
[2] For individual studies, p-value is based on the Fisher's exact test and for meta-analysis p-value is based on the poisson regression model for comparing the relative risks.
Note: Asymptotic 95% CI's are reported.
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Population: Modified Intent-to-Treat Population with Eosinophils 300 cells/uL or More

Table 311.10
Summary and Analysis of On-Treatment Adverse Events of Special Interest:
Individual Studies and Meta-Analysis

Study: 208657

	PBO	100 SC	Odds Ratio (95% CI) [1]	Relative Risk (95% CI) [1]	Risk Difference (95% CI) [1]	p-value [2]
All Infections	172 (43%)	190 (47%)	1.19 (0.90,1.57)	1.10 (0.94,1.28)	0.04 (-0.03,0.11)	0.229
Serious Infections	31 (8%)	32 (8%)	1.03 (0.62,1.72)	1.03 (0.64,1.65)	0.00 (-0.04,0.04)	>0.999
Potential Opportunistic Infections	7 (2%)	4 (<1%)	0.56 (0.16,1.94)	0.57 (0.17,1.93)	-0.01 (-0.02,0.01)	0.383
Neoplasms	17 (4%)	9 (2%)	0.52 (0.23,1.17)	0.53 (0.24,1.17)	-0.02 (-0.04,0.00)	0.115
Malignancies	13 (3%)	8 (2%)	0.60 (0.25,1.47)	0.61 (0.26,1.46)	-0.01 (-0.03,0.01)	0.279
Cardiac Disorders	44 (11%)	31 (8%)	0.68 (0.42,1.09)	0.70 (0.45,1.09)	-0.03 (-0.07,0.01)	0.116
Serious Cardiac Disorders	16 (4%)	13 (3%)	0.80 (0.38,1.69)	0.81 (0.39,1.66)	-0.01 (-0.03,0.02)	0.577
Serious CVT Events	29 (7%)	20 (5%)	0.67 (0.37,1.21)	0.69 (0.39,1.19)	-0.02 (-0.06,0.01)	0.188

[1] For individual studies, the estimates are based on frequency tables. For meta-analysis odds ratio is based on logistic regression and relative risk is based on the poisson regression model with treatment and study as the covariates.
[2] For individual studies, p-value is based on the Fisher's exact test and for meta-analysis p-value is based on the poisson regression model for comparing the relative risks.
Note: Asymptotic 95% CI's are reported.
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Population: Modified Intent-to-Treat Population with Eosinophils 300 cells/uL or More

Table 311.10

Summary and Analysis of On-Treatment Adverse Events of Special Interest: Individual Studies and Meta-Analysis

Study: 208657

	PBO	100 SC	Odds Ratio (95% CI) [1]	Relative Risk (95% CI) [1]	Risk Difference (95% CI) [1]	p-value [2]
Serious Ischemic Events	15 (4%)	6 (1%)	0.39 (0.15,1.01)	0.40 (0.16,1.02)	-0.02 (-0.04,0.00)	0.049

[1] For individual studies, the estimates are based on frequency tables. For meta-analysis odds ratio is based on logistic regression and relative risk is based on the poisson regression model with treatment and study as the covariates.
[2] For individual studies, p-value is based on the Fisher's exact test and for meta-analysis p-value is based on the poisson regression model for comparing the relative risks.
Note: Asymptotic 95% CI's are reported.
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Population: Modified Intent-to-Treat Population with Eosinophils 300 cells/uL or More

Table 311.10

Summary and Analysis of On-Treatment Adverse Events of Special Interest: Individual Studies and Meta-Analysis

Study: MEA117113

	PBO	100 SC	Odds Ratio (95% CI) [1]	Relative Risk (95% CI) [1]	Risk Difference (95% CI) [1]	p-value [2]
Number of subjects (N)	87	83				
Risks						
Serious Adverse Events	23 (26%)	17 (20%)	0.72 (0.35,1.47)	0.77 (0.45,1.34)	-0.06 (-0.19,0.07)	0.373
Systemic Reactions	0	0				
Hypersensitivity Reactions	0	0				
Non-allergic Reactions	0	0				
Anaphylaxis	0	0				
Local Site Reactions	2 (2%)	2 (2%)	1.05 (0.14,7.63)	1.05 (0.15,7.27)	0.00 (-0.04,0.05)	>0.999

[1] For individual studies, the estimates are based on frequency tables. For meta-analysis odds ratio is based on logistic regression and relative risk is based on the poisson regression model with treatment and study as the covariates.
[2] For individual studies, p-value is based on the Fisher's exact test and for meta-analysis p-value is based on the poisson regression model for comparing the relative risks.
Note: Asymptotic 95% CI's are reported.
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Population: Modified Intent-to-Treat Population with Eosinophils 300 cells/uL or More

Table 311.10
Summary and Analysis of On-Treatment Adverse Events of Special Interest:
Individual Studies and Meta-Analysis

Study: MEA117113

	PBO	100 SC	Odds Ratio (95% CI) [1]	Relative Risk (95% CI) [1]	Risk Difference (95% CI) [1]	p-value [2]
All Infections	52 (60%)	45 (54%)	0.80 (0.43,1.46)	0.91 (0.70,1.18)	-0.06 (-0.20,0.09)	0.536
Serious Infections	9 (10%)	9 (11%)	1.05 (0.40,2.80)	1.05 (0.44,2.51)	0.00 (-0.09,0.10)	>0.999
Potential Opportunistic Infections	2 (2%)	2 (2%)	1.05 (0.14,7.63)	1.05 (0.15,7.27)	0.00 (-0.04,0.05)	>0.999
Neoplasms	2 (2%)	3 (4%)	1.59 (0.26,9.79)	1.57 (0.27,9.17)	0.01 (-0.04,0.06)	0.677
Malignancies	2 (2%)	1 (1%)	0.52 (0.05,5.83)	0.52 (0.05,5.67)	-0.01 (-0.05,0.03)	>0.999
Cardiac Disorders	5 (6%)	2 (2%)	0.40 (0.08,2.15)	0.42 (0.08,2.10)	-0.03 (-0.09,0.03)	0.444
Serious Cardiac Disorders	3 (3%)	0				
Serious CVT Events	3 (3%)	0				

[1] For individual studies, the estimates are based on frequency tables. For meta-analysis odds ratio is based on logistic regression and relative risk is based on the poisson regression model with treatment and study as the covariates.
[2] For individual studies, p-value is based on the Fisher's exact test and for meta-analysis p-value is based on the poisson regression model for comparing the relative risks.
Note: Asymptotic 95% CI's are reported.
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Population: Modified Intent-to-Treat Population with Eosinophils 300 cells/uL or More

Table 311.10

Summary and Analysis of On-Treatment Adverse Events of Special Interest: Individual Studies and Meta-Analysis

Study: MEA117113

	PBO	100 SC	Odds Ratio (95% CI) [1]	Relative Risk (95% CI) [1]	Risk Difference (95% CI) [1]	p-value [2]
Serious Ischemic Events	1 (1%)	0				

[1] For individual studies, the estimates are based on frequency tables. For meta-analysis odds ratio is based on logistic regression and relative risk is based on the poisson regression model with treatment and study as the covariates.
[2] For individual studies, p-value is based on the Fisher's exact test and for meta-analysis p-value is based on the poisson regression model for comparing the relative risks.
Note: Asymptotic 95% CI's are reported.
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Population: Modified Intent-to-Treat Population with Eosinophils 300 cells/uL or More

Table 311.10

Summary and Analysis of On-Treatment Adverse Events of Special Interest: Individual Studies and Meta-Analysis

Study: MEA117106

	PBO	100 SC	Odds Ratio (95% CI) [1]	Relative Risk (95% CI) [1]	Risk Difference (95% CI) [1]	p-value [2]
Number of subjects (N)	90	82				
Risks						
Serious Adverse Events	28 (31%)	17 (21%)	0.58 (0.29,1.16)	0.67 (0.39,1.12)	-0.10 (-0.23,0.03)	0.164
Systemic Reactions	2 (2%)	2 (2%)	1.10 (0.15,7.99)	1.10 (0.16,7.61)	0.00 (-0.04,0.05)	>0.999
Hypersensitivity Reactions	0	0				
Non-allergic Reactions	0	0				
Anaphylaxis	0	0				
Local Site Reactions	1 (1%)	3 (4%)	3.38 (0.34,33.15)	3.29 (0.35,31.03)	0.03 (-0.02,0.07)	0.349

[1] For individual studies, the estimates are based on frequency tables. For meta-analysis odds ratio is based on logistic regression and relative risk is based on the poisson regression model with treatment and study as the covariates.
[2] For individual studies, p-value is based on the Fisher's exact test and for meta-analysis p-value is based on the poisson regression model for comparing the relative risks.
Note: Asymptotic 95% CI's are reported.
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Population: Modified Intent-to-Treat Population with Eosinophils 300 cells/uL or More

Table 311.10
Summary and Analysis of On-Treatment Adverse Events of Special Interest:
Individual Studies and Meta-Analysis

Study: MEA117106

	PBO	100 SC	Odds Ratio (95% CI) [1]	Relative Risk (95% CI) [1]	Risk Difference (95% CI) [1]	p-value [2]
All Infections	45 (50%)	34 (41%)	0.71 (0.39,1.29)	0.83 (0.60,1.15)	-0.09 (-0.23,0.06)	0.286
Serious Infections	10 (11%)	6 (7%)	0.63 (0.22,1.82)	0.66 (0.25,1.73)	-0.04 (-0.12,0.05)	0.441
Potential Opportunistic Infections	2 (2%)	1 (1%)	0.54 (0.05,6.10)	0.55 (0.05,5.94)	-0.01 (-0.05,0.03)	>0.999
Neoplasms	3 (3%)	5 (6%)	1.88 (0.44,8.14)	1.83 (0.45,7.42)	0.03 (-0.04,0.09)	0.481
Malignancies	2 (2%)	3 (4%)	1.67 (0.27,10.26)	1.65 (0.28,9.61)	0.01 (-0.04,0.07)	0.670
Cardiac Disorders	8 (9%)	8 (10%)	1.11 (0.40,3.10)	1.10 (0.43,2.79)	0.01 (-0.08,0.10)	>0.999
Serious Cardiac Disorders	4 (4%)	2 (2%)	0.54 (0.10,3.02)	0.55 (0.10,2.92)	-0.02 (-0.07,0.03)	0.684
Serious CVT Events	5 (6%)	2 (2%)	0.43 (0.08,2.25)	0.44 (0.09,2.20)	-0.03 (-0.09,0.03)	0.447

[1] For individual studies, the estimates are based on frequency tables. For meta-analysis odds ratio is based on logistic regression and relative risk is based on the poisson regression model with treatment and study as the covariates.
[2] For individual studies, p-value is based on the Fisher's exact test and for meta-analysis p-value is based on the poisson regression model for comparing the relative risks.
Note: Asymptotic 95% CI's are reported.
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Population: Modified Intent-to-Treat Population with Eosinophils 300 cells/uL or More

Table 311.10

Summary and Analysis of On-Treatment Adverse Events of Special Interest:
Individual Studies and Meta-Analysis

Study: MEA117106

	PBO	100 SC	Odds Ratio (95% CI) [1]	Relative Risk (95% CI) [1]	Risk Difference (95% CI) [1]	p-value [2]
Serious Ischemic Events	1 (1%)	0				

[1] For individual studies, the estimates are based on frequency tables. For meta-analysis odds ratio is based on logistic regression and relative risk is based on the poisson regression model with treatment and study as the covariates.
[2] For individual studies, p-value is based on the Fisher's exact test and for meta-analysis p-value is based on the poisson regression model for comparing the relative risks.
Note: Asymptotic 95% CI's are reported.
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Population: Modified Intent-to-Treat Population with Eosinophils 300 cells/uL or More

Table 311.10

Summary and Analysis of On-Treatment Adverse Events of Special Interest: Individual Studies and Meta-Analysis

Study: 208657 + MEA117113 + MEA117106

	PBO	100 SC	Odds Ratio (95% CI) [1]	Relative Risk (95% CI) [1]	Risk Difference (95% CI) [1]	p-value [2]
Number of subjects (N)	578	568				
Risks						
Serious Adverse Events	163(28%)	133(23%)	0.78 (0.60,1.01)	0.83 (0.66,1.04)	-0.05 (-0.11,0.01)	0.111
Systemic Reactions	7(1%)	7(1%)	Non-Est.	1.02 (0.36,2.92)	Non-Est.	0.966
Hypersensitivity Reactions	0	0				
Non-allergic Reactions	0	0				
Anaphylaxis	0	0				
Local Site Reactions	6(1%)	7(1%)	1.22 (0.41,3.66)	1.22 (0.41,3.62)	0.00 (-0.01,0.01)	0.726

[1] For individual studies, the estimates are based on frequency tables. For meta-analysis odds ratio is based on logistic regression and relative risk is based on the poisson regression model with treatment and study as the covariates.
[2] For individual studies, p-value is based on the Fisher's exact test and for meta-analysis p-value is based on the poisson regression model for comparing the relative risks.
Note: Asymptotic 95% CI's are reported.
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Population: Modified Intent-to-Treat Population with Eosinophils 300 cells/uL or More

Table 311.10

Summary and Analysis of On-Treatment Adverse Events of Special Interest: Individual Studies and Meta-Analysis

Study: 208657 + MEA117113 + MEA117106

	PBO	100 SC	Odds Ratio (95% CI) [1]	Relative Risk (95% CI) [1]	Risk Difference (95% CI) [1]	p-value [2]
All Infections	269(47%)	269(47%)	1.04 (0.82,1.31)	1.02 (0.86,1.21)	0.01 (-0.07,0.09)	0.828
Serious Infections	50(9%)	47(8%)	0.96 (0.63,1.45)	0.96 (0.64,1.43)	0.00 (-0.04,0.03)	0.840
Potential Opportunistic Infections	11(2%)	7(1%)	0.65 (0.25,1.68)	0.65 (0.25,1.68)	-0.01 (-0.02,0.01)	0.375
Neoplasms	22(4%)	17(3%)	0.78 (0.41,1.49)	0.79 (0.42,1.49)	-0.01 (-0.03,0.01)	0.465
Malignancies	17(3%)	12(2%)	0.71 (0.34,1.50)	0.72 (0.34,1.50)	-0.01 (-0.03,0.01)	0.380
Cardiac Disorders	57(10%)	41(7%)	0.71 (0.46,1.08)	0.73 (0.49,1.09)	-0.03 (-0.06,0.00)	0.125
Serious Cardiac Disorders	23(4%)	15(3%)	0.65 (0.34,1.26)	0.66 (0.35,1.27)	Non-Est.	0.214
Serious CVT Events	37(6%)	22(4%)	0.58 (0.34,1.00)	0.60 (0.35,1.02)	Non-Est.	0.058

[1] For individual studies, the estimates are based on frequency tables. For meta-analysis odds ratio is based on logistic regression and relative risk is based on the poisson regression model with treatment and study as the covariates.
[2] For individual studies, p-value is based on the Fisher's exact test and for meta-analysis p-value is based on the poisson regression model for comparing the relative risks.
Note: Asymptotic 95% CI's are reported.

Population: Modified Intent-to-Treat Population with Eosinophils 300 cells/uL or More

Table 311.10

Summary and Analysis of On-Treatment Adverse Events of Special Interest:
Individual Studies and Meta-Analysis

Study: 208657 + MEA117113 + MEA117106

	PBO	100 SC	Odds Ratio (95% CI) [1]	Relative Risk (95% CI) [1]	Risk Difference (95% CI) [1]	p-value [2]
Serious Ischemic Events	17(3%)	6(1%)	0.35 (0.13,0.88)	0.35 (0.14,0.90)	Non-Est.	0.029

[1] For individual studies, the estimates are based on frequency tables. For meta-analysis odds ratio is based on logistic regression and relative risk is based on the poisson regression model with treatment and study as the covariates.
[2] For individual studies, p-value is based on the Fisher's exact test and for meta-analysis p-value is based on the poisson regression model for comparing the relative risks.
Note: Asymptotic 95% CI's are reported.
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Population: Modified Intent-to-Treat Population with Eosinophils 300 cells/uL or More

Table 311.11
Analysis of On-Treatment Adverse Events
Meta-Analysis: p-values for Interaction Effect

Study: 208657 + MEA117113 + MEA117106

	p-value for study*treatment interaction [1]
Risks	
Serious Adverse Events	0.691
Systemic Reactions	0.997
Local Site Reactions	0.516
All Infections	0.433
Serious Infections	0.722
Potential Opportunistic Infections	0.865
Neoplasms	0.228
Malignancies	0.594
Cardiac Disorders	0.560
Serious Cardiac Disorders	0.196
Serious CVT Events	0.216
Serious Ischemic Events	0.550

[1] From the poisson regression model with covariates of treatment group, study and with an additional covariate of study*treatment interaction.
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Population: Modified Intent-to-Treat Population with Eosinophils 300 cells/uL or More

Table 311.12

Summary and Analysis of On-Treatment Serious Adverse Events of Special Interest: Individual Studies and Meta-Analysis

Study: 208657

	PBO	100 SC	Odds Ratio (95% CI) [1]	Relative Risk (95% CI) [1]	Risk Difference (95% CI) [1]	p-value [2]
Number of subjects (N)	401	403				
Risks						
Serious Adverse Events	112 (28%)	99 (25%)	0.84 (0.61,1.15)	0.88 (0.70,1.11)	-0.03 (-0.09,0.03)	0.298
Systemic Reactions	0	0				
Hypersensitivity Reactions	0	0				
Non-allergic Reactions	0	0				
Anaphylaxis	0	0				
Local Site Reactions	0	0				

[1] For individual studies, the estimates are based on frequency tables. For meta-analysis odds ratio is based on logistic regression and relative risk is based on the poisson regression model with treatment and study as the covariates.
[2] For individual studies, p-value is based on the Fisher's exact test and for meta-analysis p-value is based on the poisson regression model for comparing the relative risks.
Note: Asymptotic 95% CI's are reported.
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Population: Modified Intent-to-Treat Population with Eosinophils 300 cells/uL or More

Table 311.12
Summary and Analysis of On-Treatment Serious Adverse Events of Special Interest:
Individual Studies and Meta-Analysis

Study: 208657

	PBO	100 SC	Odds Ratio (95% CI) [1]	Relative Risk (95% CI) [1]	Risk Difference (95% CI) [1]	p-value [2]
All Infections	31 (8%)	32 (8%)	1.03 (0.62,1.72)	1.03 (0.64,1.65)	0.00 (-0.04,0.04)	>0.999
Serious Infections	31 (8%)	32 (8%)	1.03 (0.62,1.72)	1.03 (0.64,1.65)	0.00 (-0.04,0.04)	>0.999
Potential Opportunistic Infections	1 (<1%)	1 (<1%)	1.00 (0.06,15.96)	1.00 (0.06,15.85)	0.00 (-0.01,0.01)	>0.999
Neoplasms	12 (3%)	8 (2%)	0.66 (0.27,1.62)	0.66 (0.27,1.61)	-0.01 (-0.03,0.01)	0.376
Malignancies	11 (3%)	8 (2%)	0.72 (0.29,1.80)	0.72 (0.29,1.78)	-0.01 (-0.03,0.01)	0.497
Cardiac Disorders	16 (4%)	13 (3%)	0.80 (0.38,1.69)	0.81 (0.39,1.66)	-0.01 (-0.03,0.02)	0.577
Serious Cardiac Disorders	16 (4%)	13 (3%)	0.80 (0.38,1.69)	0.81 (0.39,1.66)	-0.01 (-0.03,0.02)	0.577
Serious CVT Events	29 (7%)	20 (5%)	0.67 (0.37,1.21)	0.69 (0.39,1.19)	-0.02 (-0.06,0.01)	0.188

[1] For individual studies, the estimates are based on frequency tables. For meta-analysis odds ratio is based on logistic regression and relative risk is based on the poisson regression model with treatment and study as the covariates.
[2] For individual studies, p-value is based on the Fisher's exact test and for meta-analysis p-value is based on the poisson regression model for comparing the relative risks.
Note: Asymptotic 95% CI's are reported.

Population: Modified Intent-to-Treat Population with Eosinophils 300 cells/uL or More

Table 311.12

Summary and Analysis of On-Treatment Serious Adverse Events of Special Interest: Individual Studies and Meta-Analysis

Study: 208657

	PBO	100 SC	Odds Ratio (95% CI) [1]	Relative Risk (95% CI) [1]	Risk Difference (95% CI) [1]	p-value [2]
Serious Ischemic Events	15 (4%)	6 (1%)	0.39 (0.15,1.01)	0.40 (0.16,1.02)	-0.02 (-0.04,0.00)	0.049

[1] For individual studies, the estimates are based on frequency tables. For meta-analysis odds ratio is based on logistic regression and relative risk is based on the poisson regression model with treatment and study as the covariates.
[2] For individual studies, p-value is based on the Fisher's exact test and for meta-analysis p-value is based on the poisson regression model for comparing the relative risks.
Note: Asymptotic 95% CI's are reported.

Population: Modified Intent-to-Treat Population with Eosinophils 300 cells/uL or More

Table 311.12

Summary and Analysis of On-Treatment Serious Adverse Events of Special Interest: Individual Studies and Meta-Analysis

Study: MEA117113

	PBO	100 SC	Odds Ratio (95% CI) [1]	Relative Risk (95% CI) [1]	Risk Difference (95% CI) [1]	p-value [2]
Number of subjects (N)	87	83				
Risks						
Serious Adverse Events	23 (26%)	17 (20%)	0.72 (0.35,1.47)	0.77 (0.45,1.34)	-0.06 (-0.19,0.07)	0.373
Systemic Reactions	0	0				
Hypersensitivity Reactions	0	0				
Non-allergic Reactions	0	0				
Anaphylaxis	0	0				
Local Site Reactions	0	0				

[1] For individual studies, the estimates are based on frequency tables. For meta-analysis odds ratio is based on logistic regression and relative risk is based on the poisson regression model with treatment and study as the covariates.
[2] For individual studies, p-value is based on the Fisher's exact test and for meta-analysis p-value is based on the poisson regression model for comparing the relative risks.
Note: Asymptotic 95% CI's are reported.
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Population: Modified Intent-to-Treat Population with Eosinophils 300 cells/uL or More

Table 311.12
Summary and Analysis of On-Treatment Serious Adverse Events of Special Interest:
Individual Studies and Meta-Analysis

Study: MEA117113

	PBO	100 SC	Odds Ratio (95% CI) [1]	Relative Risk (95% CI) [1]	Risk Difference (95% CI) [1]	p-value [2]
All Infections	9 (10%)	9 (11%)	1.05 (0.40,2.80)	1.05 (0.44,2.51)	0.00 (-0.09,0.10)	>0.999
Serious Infections	9 (10%)	9 (11%)	1.05 (0.40,2.80)	1.05 (0.44,2.51)	0.00 (-0.09,0.10)	>0.999
Potential Opportunistic Infections	0	0				
Neoplasms	2 (2%)	1 (1%)	0.52 (0.05,5.83)	0.52 (0.05,5.67)	-0.01 (-0.05,0.03)	>0.999
Malignancies	2 (2%)	1 (1%)	0.52 (0.05,5.83)	0.52 (0.05,5.67)	-0.01 (-0.05,0.03)	>0.999
Cardiac Disorders	3 (3%)	0				
Serious Cardiac Disorders	3 (3%)	0				
Serious CVT Events	3 (3%)	0				

[1] For individual studies, the estimates are based on frequency tables. For meta-analysis odds ratio is based on logistic regression and relative risk is based on the poisson regression model with treatment and study as the covariates.
[2] For individual studies, p-value is based on the Fisher's exact test and for meta-analysis p-value is based on the poisson regression model for comparing the relative risks.
Note: Asymptotic 95% CI's are reported.
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Population: Modified Intent-to-Treat Population with Eosinophils 300 cells/uL or More

Table 311.12

Summary and Analysis of On-Treatment Serious Adverse Events of Special Interest: Individual Studies and Meta-Analysis

Study: MEA117113

	PBO	100 SC	Odds Ratio (95% CI) [1]	Relative Risk (95% CI) [1]	Risk Difference (95% CI) [1]	p-value [2]
Serious Ischemic Events	1 (1%)	0				

[1] For individual studies, the estimates are based on frequency tables. For meta-analysis odds ratio is based on logistic regression and relative risk is based on the poisson regression model with treatment and study as the covariates.
[2] For individual studies, p-value is based on the Fisher's exact test and for meta-analysis p-value is based on the poisson regression model for comparing the relative risks.
Note: Asymptotic 95% CI's are reported.
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Population: Modified Intent-to-Treat Population with Eosinophils 300 cells/uL or More

Table 311.12

Summary and Analysis of On-Treatment Serious Adverse Events of Special Interest: Individual Studies and Meta-Analysis

Study: MEA117106

	PBO	100 SC	Odds Ratio (95% CI) [1]	Relative Risk (95% CI) [1]	Risk Difference (95% CI) [1]	p-value [2]
Number of subjects (N)	90	82				
Risks						
Serious Adverse Events	28 (31%)	17 (21%)	0.58 (0.29,1.16)	0.67 (0.39,1.12)	-0.10 (-0.23,0.03)	0.164
Systemic Reactions	0	0				
Hypersensitivity Reactions	0	0				
Non-allergic Reactions	0	0				
Anaphylaxis	0	0				
Local Site Reactions	0	0				

[1] For individual studies, the estimates are based on frequency tables. For meta-analysis odds ratio is based on logistic regression and relative risk is based on the poisson regression model with treatment and study as the covariates.
[2] For individual studies, p-value is based on the Fisher's exact test and for meta-analysis p-value is based on the poisson regression model for comparing the relative risks.
Note: Asymptotic 95% CI's are reported.
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Population: Modified Intent-to-Treat Population with Eosinophils 300 cells/uL or More

Table 311.12
Summary and Analysis of On-Treatment Serious Adverse Events of Special Interest:
Individual Studies and Meta-Analysis

Study: MEA117106

	PBO	100 SC	Odds Ratio (95% CI) [1]	Relative Risk (95% CI) [1]	Risk Difference (95% CI) [1]	p-value [2]
All Infections	10 (11%)	6 (7%)	0.63 (0.22,1.82)	0.66 (0.25,1.73)	-0.04 (-0.12,0.05)	0.441
Serious Infections	10 (11%)	6 (7%)	0.63 (0.22,1.82)	0.66 (0.25,1.73)	-0.04 (-0.12,0.05)	0.441
Potential Opportunistic Infections	0	0				
Neoplasms	0	2 (2%)				
Malignancies	0	2 (2%)				
Cardiac Disorders	4 (4%)	2 (2%)	0.54 (0.10,3.02)	0.55 (0.10,2.92)	-0.02 (-0.07,0.03)	0.684
Serious Cardiac Disorders	4 (4%)	2 (2%)	0.54 (0.10,3.02)	0.55 (0.10,2.92)	-0.02 (-0.07,0.03)	0.684
Serious CVT Events	5 (6%)	2 (2%)	0.43 (0.08,2.25)	0.44 (0.09,2.20)	-0.03 (-0.09,0.03)	0.447

[1] For individual studies, the estimates are based on frequency tables. For meta-analysis odds ratio is based on logistic regression and relative risk is based on the poisson regression model with treatment and study as the covariates.
[2] For individual studies, p-value is based on the Fisher's exact test and for meta-analysis p-value is based on the poisson regression model for comparing the relative risks.
Note: Asymptotic 95% CI's are reported.
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Population: Modified Intent-to-Treat Population with Eosinophils 300 cells/uL or More

Table 311.12

Summary and Analysis of On-Treatment Serious Adverse Events of Special Interest: Individual Studies and Meta-Analysis

Study: MEA117106

	PBO	100 SC	Odds Ratio (95% CI) [1]	Relative Risk (95% CI) [1]	Risk Difference (95% CI) [1]	p-value [2]
Serious Ischemic Events	1 (1%)	0				

[1] For individual studies, the estimates are based on frequency tables. For meta-analysis odds ratio is based on logistic regression and relative risk is based on the poisson regression model with treatment and study as the covariates.
[2] For individual studies, p-value is based on the Fisher's exact test and for meta-analysis p-value is based on the poisson regression model for comparing the relative risks.
Note: Asymptotic 95% CI's are reported.
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Population: Modified Intent-to-Treat Population with Eosinophils 300 cells/uL or More

Table 311.12

Summary and Analysis of On-Treatment Serious Adverse Events of Special Interest: Individual Studies and Meta-Analysis

Study: 208657 + MEA117113 + MEA117106

	PBO	100 SC	Odds Ratio (95% CI) [1]	Relative Risk (95% CI) [1]	Risk Difference (95% CI) [1]	p-value [2]
Number of subjects (N)	578	568				
Risks						
Serious Adverse Events	163(28%)	133(23%)	0.78 (0.60,1.01)	0.83 (0.66,1.04)	-0.05 (-0.11,0.01)	0.111
Systemic Reactions	0	0				
Hypersensitivity Reactions	0	0				
Non-allergic Reactions	0	0				
Anaphylaxis	0	0				
Local Site Reactions	0	0				

[1] For individual studies, the estimates are based on frequency tables. For meta-analysis odds ratio is based on logistic regression and relative risk is based on the poisson regression model with treatment and study as the covariates.
[2] For individual studies, p-value is based on the Fisher's exact test and for meta-analysis p-value is based on the poisson regression model for comparing the relative risks.
Note: Asymptotic 95% CI's are reported.
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Population: Modified Intent-to-Treat Population with Eosinophils 300 cells/uL or More

Table 311.12

Summary and Analysis of On-Treatment Serious Adverse Events of Special Interest: Individual Studies and Meta-Analysis

Study: 208657 + MEA117113 + MEA117106

	PBO	100 SC	Odds Ratio (95% CI) [1]	Relative Risk (95% CI) [1]	Risk Difference (95% CI) [1]	p-value [2]
All Infections	50(9%)	47(8%)	0.96 (0.63,1.45)	0.96 (0.64,1.43)	0.00 (-0.04,0.03)	0.840
Serious Infections	50(9%)	47(8%)	0.96 (0.63,1.45)	0.96 (0.64,1.43)	0.00 (-0.04,0.03)	0.840
Potential Opportunistic Infections	1(<1%)	1(<1%)	Non-Est.	1.00 (0.06,15.91)	Non-Est.	0.998
Neoplasms	14(2%)	11(2%)	0.79 (0.35,1.75)	0.79 (0.36,1.75)	0.00 (-0.02,0.02)	0.565
Malignancies	13(2%)	11(2%)	0.85 (0.38,1.92)	0.85 (0.38,1.91)	0.00 (-0.02,0.02)	0.701
Cardiac Disorders	23(4%)	15(3%)	0.65 (0.34,1.26)	0.66 (0.35,1.27)	Non-Est.	0.214
Serious Cardiac Disorders	23(4%)	15(3%)	0.65 (0.34,1.26)	0.66 (0.35,1.27)	Non-Est.	0.214
Serious CVT Events	37(6%)	22(4%)	0.58 (0.34,1.00)	0.60 (0.35,1.02)	Non-Est.	0.058

[1] For individual studies, the estimates are based on frequency tables. For meta-analysis odds ratio is based on logistic regression and relative risk is based on the poisson regression model with treatment and study as the covariates.
[2] For individual studies, p-value is based on the Fisher's exact test and for meta-analysis p-value is based on the poisson regression model for comparing the relative risks.
Note: Asymptotic 95% CI's are reported.
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Population: Modified Intent-to-Treat Population with Eosinophils 300 cells/uL or More

Table 311.12

Summary and Analysis of On-Treatment Serious Adverse Events of Special Interest: Individual Studies and Meta-Analysis

Study: 208657 + MEA117113 + MEA117106

	PBO	100 SC	Odds Ratio (95% CI) [1]	Relative Risk (95% CI) [1]	Risk Difference (95% CI) [1]	p-value [2]
Serious Ischemic Events	17(3%)	6(1%)	0.35 (0.13,0.88)	0.35 (0.14,0.90)	Non-Est.	0.029

[1] For individual studies, the estimates are based on frequency tables. For meta-analysis odds ratio is based on logistic regression and relative risk is based on the poisson regression model with treatment and study as the covariates.
[2] For individual studies, p-value is based on the Fisher's exact test and for meta-analysis p-value is based on the poisson regression model for comparing the relative risks.
Note: Asymptotic 95% CI's are reported.
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Population: Modified Intent-to-Treat Population with Eosinophils 300 cells/uL or More

Table 311.13
Analysis of On-Treatment Serious Adverse Events
Meta-Analysis: p-values for Interaction Effect

Study: 208657 + MEA117113 + MEA117106

	p-value for study*treatment interaction [1]
Risks	
Serious Adverse Events	0.691
All Infections	0.722
Serious Infections	0.722
Potential Opportunistic Infections	Non-Est.
Neoplasms	0.154
Malignancies	0.166
Cardiac Disorders	0.196
Serious Cardiac Disorders	0.196
Serious CVT Events	0.216
Serious Ischemic Events	0.550

[1] From the poisson regression model with covariates of treatment group, study and with an additional covariate of study*treatment interaction.
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Population: Modified Intent-to-Treat Population with Eosinophils 300 cells/uL or More

Table 311.14

Summary and Analysis of On-Treatment Adverse Events Leading to Study Drug Withdrawal by SOC and PT: Individual Studies and Meta-Analysis

Study: 208657

System Organ Class/Preferred Term	PBO	100 SC	Odds Ratio (95% CI) [1]	Relative Risk (95% CI) [1]	Risk Difference (95% CI) [1]	p-value [2]
Number of subjects (N)	401	403				
ANY EVENT	17 (4%)	12 (3%)	0.69 (0.33,1.47)	0.70 (0.34,1.45)	-0.01 (-0.04,0.01)	0.352
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	7 (2%)	4 (<1%)	0.56 (0.16,1.94)	0.57 (0.17,1.93)	-0.01 (-0.02,0.01)	0.383
Lung neoplasm malignant	1 (<1%)	2 (<1%)				

[1] For individual studies, the estimates are from frequency tables. In meta-analysis, odds ratio is from logistic regression and relative risk is from the poisson regression model with treatment and study as the covariates.
[2] For individual studies, p-value is from the Fisher’s exact test and for meta-analysis p-value is based on the poisson regression model.
Note: Asymptotic 95% CI’s are reported.
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Population: Modified Intent-to-Treat Population with Eosinophils 300 cells/uL or More

Table 311.14

Summary and Analysis of On-Treatment Adverse Events Leading to Study Drug Withdrawal by SOC and PT: Individual Studies and Meta-Analysis

Study: 208657

System Organ Class/Preferred Term	PBO	100 SC	Odds Ratio (95% CI) [1]	Relative Risk (95% CI) [1]	Risk Difference (95% CI) [1]	p-value [2]
Breast cancer	1 (<1%)	0				
Bronchial carcinoma	1 (<1%)	0				
Colorectal cancer	1 (<1%)	0				
Lung neoplasm	0	1 (<1%)				
Lung adenocarcinoma	1 (<1%)	0				
Lung adenocarcinoma stage I	1 (<1%)	0				
Small cell lung cancer metastatic	1 (<1%)	0				
Small cell carcinoma	0	1 (<1%)				
Cardiac disorders	1 (<1%)	2 (<1%)	2.00 (0.18,22.09)	1.99 (0.18,21.86)	0.00 (-0.01,0.01)	>0.999
Cardiac arrest	0	2 (<1%)				
Stress cardiomyopathy	1 (<1%)	0				

[1] For individual studies, the estimates are from frequency tables. In meta-analysis, odds ratio is from logistic regression and relative risk is from the poisson regression model with treatment and study as the covariates.
[2] For individual studies, p-value is from the Fisher’s exact test and for meta-analysis p-value is based on the poisson regression model.
Note: Asymptotic 95% CI’s are reported.
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Population: Modified Intent-to-Treat Population with Eosinophils 300 cells/uL or More

Table 311.14

Summary and Analysis of On-Treatment Adverse Events Leading to Study Drug Withdrawal by SOC and PT: Individual Studies and Meta-Analysis

Study: 208657

System Organ Class/Preferred Term	PBO	100 SC	Odds Ratio (95% CI) [1]	Relative Risk (95% CI) [1]	Risk Difference (95% CI) [1]	p-value [2]
Infections and infestations	2 (<1%)	1 (<1%)	0.50 (0.04,5.49)	0.50 (0.05,5.46)	0.00 (-0.01,0.01)	0.624
COVID-19	0	1 (<1%)				
Pulmonary tuberculosis	1 (<1%)	0				
Scrotal abscess	1 (<1%)	0				
Investigations	2 (<1%)	1 (<1%)	0.50 (0.04,5.49)	0.50 (0.05,5.46)	0.00 (-0.01,0.01)	0.624
Alanine aminotransferase increased	2 (<1%)	0				
Mycobacterium tuberculosis complex test negative	0	1 (<1%)				
Nervous system disorders	1 (<1%)	2 (<1%)	2.00 (0.18,22.09)	1.99 (0.18,21.86)	0.00 (-0.01,0.01)	>0.999
Cerebrovascular accident	0	1 (<1%)				
Headache	1 (<1%)	0				
Ischaemic stroke	0	1 (<1%)				

[1] For individual studies, the estimates are from frequency tables. In meta-analysis, odds ratio is from logistic regression and relative risk is from the poisson regression model with treatment and study as the covariates.
[2] For individual studies, p-value is from the Fisher’s exact test and for meta-analysis p-value is based on the poisson regression model.
Note: Asymptotic 95% CI’s are reported.
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Population: Modified Intent-to-Treat Population with Eosinophils 300 cells/uL or More

Table 311.14

Summary and Analysis of On-Treatment Adverse Events Leading to Study Drug Withdrawal by SOC and PT: Individual Studies and Meta-Analysis

Study: 208657

System Organ Class/Preferred Term	PBO	100 SC	Odds Ratio (95% CI) [1]	Relative Risk (95% CI) [1]	Risk Difference (95% CI) [1]	p-value [2]
Musculoskeletal and connective tissue disorders	2 (<1%)	0				
Myalgia	1 (<1%)	0				
Rhabdomyolysis	1 (<1%)	0				
Injury, poisoning and procedural complications	0	1 (<1%)				
Procedural pneumothorax	0	1 (<1%)				
Psychiatric disorders	0	1 (<1%)				
Anxiety	0	1 (<1%)				
Renal and urinary disorders	1 (<1%)	0				
Renal impairment	1 (<1%)	0				

[1] For individual studies, the estimates are from frequency tables. In meta-analysis, odds ratio is from logistic regression and relative risk is from the poisson regression model with treatment and study as the covariates.
[2] For individual studies, p-value is from the Fisher’s exact test and for meta-analysis p-value is based on the poisson regression model.
Note: Asymptotic 95% CI’s are reported.
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Population: Modified Intent-to-Treat Population with Eosinophils 300 cells/uL or More

Table 311.14

Summary and Analysis of On-Treatment Adverse Events Leading to Study Drug Withdrawal by SOC and PT: Individual Studies and Meta-Analysis

Study: 208657

System Organ Class/Preferred Term	PBO	100 SC	Odds Ratio (95% CI) [1]	Relative Risk (95% CI) [1]	Risk Difference (95% CI) [1]	p-value [2]
Respiratory, thoracic and mediastinal disorders	1 (<1%)	0				
Chronic obstructive pulmonary disease	1 (<1%)	0				

[1] For individual studies, the estimates are from frequency tables. In meta-analysis, odds ratio is from logistic regression and relative risk is from the poisson regression model with treatment and study as the covariates.
[2] For individual studies, p-value is from the Fisher’s exact test and for meta-analysis p-value is based on the poisson regression model.
Note: Asymptotic 95% CI’s are reported.
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Population: Modified Intent-to-Treat Population with Eosinophils 300 cells/uL or More

Table 311.14

Summary and Analysis of On-Treatment Adverse Events Leading to Study Drug Withdrawal by SOC and PT: Individual Studies and Meta-Analysis

Study: MEA117113

System Organ Class/Preferred Term	PBO	100 SC	Odds Ratio (95% CI) [1]	Relative Risk (95% CI) [1]	Risk Difference (95% CI) [1]	p-value [2]
Number of subjects (N)	87	83				
ANY EVENT	13 (15%)	1 (1%)	0.07 (0.01,0.54)	0.08 (0.01,0.60)	-0.14 (-0.22,-0.06)	0.001
Respiratory, thoracic and mediastinal disorders	4 (5%)	0				
Chronic obstructive pulmonary disease	3 (3%)	0				
Pneumothorax spontaneous	1 (1%)	0				
Infections and infestations	3 (3%)	0				
Osteomyelitis	1 (1%)	0				
Pharyngitis	1 (1%)	0				
Pneumonia	1 (1%)	0				

[1] For individual studies, the estimates are from frequency tables. In meta-analysis, odds ratio is from logistic regression and relative risk is from the poisson regression model with treatment and study as the covariates.
[2] For individual studies, p-value is from the Fisher’s exact test and for meta-analysis p-value is based on the poisson regression model.
Note: Asymptotic 95% CI’s are reported.
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Population: Modified Intent-to-Treat Population with Eosinophils 300 cells/uL or More

Table 311.14

Summary and Analysis of On-Treatment Adverse Events Leading to Study Drug Withdrawal by SOC and PT: Individual Studies and Meta-Analysis

Study: MEA117113

System Organ Class/Preferred Term	PBO	100 SC	Odds Ratio (95% CI) [1]	Relative Risk (95% CI) [1]	Risk Difference (95% CI) [1]	p-value [2]
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	2 (2%)	1 (1%)	0.52 (0.05,5.83)	0.52 (0.05,5.67)	-0.01 (-0.05,0.03)	>0.999
Adenocarcinoma of colon	1 (1%)	0				
Lung neoplasm malignant	0	1 (1%)				
Prostate cancer	1 (1%)	0				
Cardiac disorders	2 (2%)	0				
Acute myocardial infarction	1 (1%)	0				
Cardiac arrest	1 (1%)	0				
Gastrointestinal disorders	1 (1%)	0				
Gastrointestinal haemorrhage	1 (1%)	0				

[1] For individual studies, the estimates are from frequency tables. In meta-analysis, odds ratio is from logistic regression and relative risk is from the poisson regression model with treatment and study as the covariates.
[2] For individual studies, p-value is from the Fisher’s exact test and for meta-analysis p-value is based on the poisson regression model.
Note: Asymptotic 95% CI’s are reported.
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Population: Modified Intent-to-Treat Population with Eosinophils 300 cells/uL or More

Table 311.14

Summary and Analysis of On-Treatment Adverse Events Leading to Study Drug Withdrawal by SOC and PT: Individual Studies and Meta-Analysis

Study: MEA117113

System Organ Class/Preferred Term	PBO	100 SC	Odds Ratio (95% CI) [1]	Relative Risk (95% CI) [1]	Risk Difference (95% CI) [1]	p-value [2]
Nervous system disorders	1 (1%)	0				
Peripheral sensorimotor neuropathy	1 (1%)	0				
Skin and subcutaneous tissue disorders	1 (1%)	0				
Eczema	1 (1%)	0				

[1] For individual studies, the estimates are from frequency tables. In meta-analysis, odds ratio is from logistic regression and relative risk is from the poisson regression model with treatment and study as the covariates.
[2] For individual studies, p-value is from the Fisher’s exact test and for meta-analysis p-value is based on the poisson regression model.
Note: Asymptotic 95% CI’s are reported.

Population: Modified Intent-to-Treat Population with Eosinophils 300 cells/uL or More

Table 311.14

Summary and Analysis of On-Treatment Adverse Events Leading to Study Drug Withdrawal by SOC and PT: Individual Studies and Meta-Analysis

Study: MEA117106

System Organ Class/Preferred Term	PBO		100 SC		Odds Ratio (95% CI) [1]		Relative Risk (95% CI) [1]		Risk Difference (95% CI) [1]		p-value [2]
Number of subjects (N)	90		82								
ANY EVENT	5	(6%)	2	(2%)	0.43	(0.08,2.25)	0.44	(0.09,2.20)	-0.03	(-0.09,0.03)	0.447
Cardiac disorders	3	(3%)	0								
Bundle branch block right	1	(1%)	0								
Cardiac failure chronic	1	(1%)	0								
Myocardial infarction	1	(1%)	0								
Gastrointestinal disorders	1	(1%)	0								
Abdominal discomfort	1	(1%)	0								
Nausea	1	(1%)	0								

[1] For individual studies, the estimates are from frequency tables. In meta-analysis, odds ratio is from logistic regression and relative risk is from the poisson regression model with treatment and study as the covariates.
[2] For individual studies, p-value is from the Fisher’s exact test and for meta-analysis p-value is based on the poisson regression model.
Note: Asymptotic 95% CI’s are reported.
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Population: Modified Intent-to-Treat Population with Eosinophils 300 cells/uL or More

Table 311.14

Summary and Analysis of On-Treatment Adverse Events Leading to Study Drug Withdrawal by SOC and PT: Individual Studies and Meta-Analysis

Study: MEA117106

System Organ Class/Preferred Term	PBO	100 SC	Odds Ratio (95% CI) [1]	Relative Risk (95% CI) [1]	Risk Difference (95% CI) [1]	p-value [2]
Injury, poisoning and procedural complications	1 (1%)	0				
Respiratory fume inhalation disorder	1 (1%)	0				
Metabolism and nutrition disorders	1 (1%)	0				
Decreased appetite	1 (1%)	0				
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	0	1 (1%)				
Breast cancer	0	1 (1%)				

[1] For individual studies, the estimates are from frequency tables. In meta-analysis, odds ratio is from logistic regression and relative risk is from the poisson regression model with treatment and study as the covariates.
[2] For individual studies, p-value is from the Fisher’s exact test and for meta-analysis p-value is based on the poisson regression model.
Note: Asymptotic 95% CI’s are reported.
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Population: Modified Intent-to-Treat Population with Eosinophils 300 cells/uL or More

Table 311.14

Summary and Analysis of On-Treatment Adverse Events Leading to Study Drug Withdrawal by SOC and PT: Individual Studies and Meta-Analysis

Study: MEA117106

System Organ Class/Preferred Term	PBO	100 SC	Odds Ratio (95% CI) [1]	Relative Risk (95% CI) [1]	Risk Difference (95% CI) [1]	p-value [2]
Nervous system disorders	1 (1%)	0				
Brain fog	1 (1%)	0				
Headache	1 (1%)	0				
Respiratory, thoracic and mediastinal disorders	0	1 (1%)				
Chronic obstructive pulmonary disease	0	1 (1%)				

[1] For individual studies, the estimates are from frequency tables. In meta-analysis, odds ratio is from logistic regression and relative risk is from the poisson regression model with treatment and study as the covariates.
[2] For individual studies, p-value is from the Fisher’s exact test and for meta-analysis p-value is based on the poisson regression model.
Note: Asymptotic 95% CI’s are reported.

Population: Modified Intent-to-Treat Population with Eosinophils 300 cells/uL or More

Table 311.14

Summary and Analysis of On-Treatment Adverse Events Leading to Study Drug Withdrawal by SOC and PT: Individual Studies and Meta-Analysis

Study: 208657 + MEA117113 + MEA117106

System Organ Class/Preferred Term	PBO	100 SC	Odds Ratio (95% CI) [1]	Relative Risk (95% CI) [1]	Risk Difference (95% CI) [1]	p-value [2]
Number of subjects (N)	578	568				
ANY EVENT	35 (6%)	15 (3%)	0.42 (0.23,0.78)	0.44 (0.24,0.80)	-0.03 (-0.05,0.00)	0.008
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	9 (2%)	6 (1%)	0.67 (0.24,1.90)	0.67 (0.24,1.90)	0.00 (-0.02,0.01)	0.456
Lung neoplasm malignant	1 (<1%)	3 (<1%)				
Breast cancer	1 (<1%)	1 (<1%)				

[1] For individual studies, the estimates are from frequency tables. In meta-analysis, odds ratio is from logistic regression and relative risk is from the poisson regression model with treatment and study as the covariates.
[2] For individual studies, p-value is from the Fisher’s exact test and for meta-analysis p-value is based on the poisson regression model.
Note: Asymptotic 95% CI’s are reported.
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Population: Modified Intent-to-Treat Population with Eosinophils 300 cells/uL or More

Table 311.14

Summary and Analysis of On-Treatment Adverse Events Leading to Study Drug Withdrawal by SOC and PT: Individual Studies and Meta-Analysis

Study: 208657 + MEA117113 + MEA117106

System Organ Class/Preferred Term	PBO	100 SC	Odds Ratio (95% CI) [1]	Relative Risk (95% CI) [1]	Risk Difference (95% CI) [1]	p-value [2]
Adenocarcinoma of colon	1 (<1%)	0				
Bronchial carcinoma	1 (<1%)	0				
Colorectal cancer	1 (<1%)	0				
Lung neoplasm	0	1 (<1%)				
Lung adenocarcinoma	1 (<1%)	0				
Lung adenocarcinoma stage I	1 (<1%)	0				
Prostate cancer	1 (<1%)	0				
Small cell lung cancer metastatic	1 (<1%)	0				
Small cell carcinoma	0	1 (<1%)				
Cardiac disorders	6 (1%)	2 (<1%)	0.34 (0.07,1.72)	0.35 (0.07,1.73)	0.00 (-0.01,0.01)	0.197
Cardiac arrest	1 (<1%)	2 (<1%)				

[1] For individual studies, the estimates are from frequency tables. In meta-analysis, odds ratio is from logistic regression and relative risk is from the poisson regression model with treatment and study as the covariates.
[2] For individual studies, p-value is from the Fisher’s exact test and for meta-analysis p-value is based on the poisson regression model.
Note: Asymptotic 95% CI’s are reported.

Population: Modified Intent-to-Treat Population with Eosinophils 300 cells/uL or More

Table 311.14

Summary and Analysis of On-Treatment Adverse Events Leading to Study Drug Withdrawal by SOC and PT: Individual Studies and Meta-Analysis

Study: 208657 + MEA117113 + MEA117106

System Organ Class/Preferred Term	PBO	100 SC	Odds Ratio (95% CI) [1]	Relative Risk (95% CI) [1]	Risk Difference (95% CI) [1]	p-value [2]
Acute myocardial infarction	1 (<1%)	0				
Bundle branch block right	1 (<1%)	0				
Cardiac failure chronic	1 (<1%)	0				
Myocardial infarction	1 (<1%)	0				
Stress cardiomyopathy	1 (<1%)	0				
Infections and infestations	5 (<1%)	1 (<1%)	Non-Est.	0.20 (0.02,1.75)	Non-Est.	0.148
COVID-19	0	1 (<1%)				
Osteomyelitis	1 (<1%)	0				
Pharyngitis	1 (<1%)	0				
Pneumonia	1 (<1%)	0				
Pulmonary tuberculosis	1 (<1%)	0				
Scrotal abscess	1 (<1%)	0				

[1] For individual studies, the estimates are from frequency tables. In meta-analysis, odds ratio is from logistic regression and relative risk is from the poisson regression model with treatment and study as the covariates.
[2] For individual studies, p-value is from the Fisher’s exact test and for meta-analysis p-value is based on the poisson regression model.
Note: Asymptotic 95% CI’s are reported.
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Population: Modified Intent-to-Treat Population with Eosinophils 300 cells/uL or More

Table 311.14

Summary and Analysis of On-Treatment Adverse Events Leading to Study Drug Withdrawal by SOC and PT: Individual Studies and Meta-Analysis

Study: 208657 + MEA117113 + MEA117106

System Organ Class/Preferred Term	PBO	100 SC	Odds Ratio (95% CI) [1]	Relative Risk (95% CI) [1]	Risk Difference (95% CI) [1]	p-value [2]
Respiratory, thoracic and mediastinal disorders	5 (<1%)	1 (<1%)	0.20 (0.02,1.77)	0.21 (0.02,1.79)	Non-Est.	0.154
Chronic obstructive pulmonary disease	4 (<1%)	1 (<1%)				
Pneumothorax spontaneous	1 (<1%)	0				
Nervous system disorders	3 (<1%)	2 (<1%)	0.68 (0.11,4.10)	0.68 (0.11,4.09)	0.00 (-0.01,0.01)	0.677
Headache	2 (<1%)	0				
Brain fog	1 (<1%)	0				
Cerebrovascular accident	0	1 (<1%)				
Ischaemic stroke	0	1 (<1%)				
Peripheral sensorimotor neuropathy	1 (<1%)	0				

[1] For individual studies, the estimates are from frequency tables. In meta-analysis, odds ratio is from logistic regression and relative risk is from the poisson regression model with treatment and study as the covariates.
[2] For individual studies, p-value is from the Fisher’s exact test and for meta-analysis p-value is based on the poisson regression model.
Note: Asymptotic 95% CI’s are reported.
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Population: Modified Intent-to-Treat Population with Eosinophils 300 cells/uL or More

Table 311.14

Summary and Analysis of On-Treatment Adverse Events Leading to Study Drug Withdrawal by SOC and PT: Individual Studies and Meta-Analysis

Study: 208657 + MEA117113 + MEA117106

System Organ Class/Preferred Term	PBO	100 SC	Odds Ratio (95% CI) [1]	Relative Risk (95% CI) [1]	Risk Difference (95% CI) [1]	p-value [2]
Investigations	2 (<1%)	1 (<1%)	Non-Est.	0.50 (0.05,5.49)	Non-Est.	0.569
Alanine aminotransferase increased	2 (<1%)	0				
Mycobacterium tuberculosis complex test negative	0	1 (<1%)				
Gastrointestinal disorders	2 (<1%)	0	Non-Est.	0.00 (0.00,Non-Est.)	Non-Est.	>0.999
Abdominal discomfort	1 (<1%)	0				
Gastrointestinal haemorrhage	1 (<1%)	0				
Nausea	1 (<1%)	0				
Injury, poisoning and procedural complications	1 (<1%)	1 (<1%)	Non-Est.	1.05 (0.07,16.72)	Non-Est.	0.976

[1] For individual studies, the estimates are from frequency tables. In meta-analysis, odds ratio is from logistic regression and relative risk is from the poisson regression model with treatment and study as the covariates.
[2] For individual studies, p-value is from the Fisher’s exact test and for meta-analysis p-value is based on the poisson regression model.
Note: Asymptotic 95% CI’s are reported.
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Population: Modified Intent-to-Treat Population with Eosinophils 300 cells/uL or More

Table 311.14

Summary and Analysis of On-Treatment Adverse Events Leading to Study Drug Withdrawal by SOC and PT: Individual Studies and Meta-Analysis

Study: 208657 + MEA117113 + MEA117106

System Organ Class/Preferred Term	PBO	100 SC	Odds Ratio (95% CI) [1]	Relative Risk (95% CI) [1]	Risk Difference (95% CI) [1]	p-value [2]
Procedural pneumothorax	0	1 (<1%)				
Respiratory fume inhalation disorder	1 (<1%)	0				
Musculoskeletal and connective tissue disorders	2 (<1%)	0	Non-Est.	Non-Est.	Non-Est.	Non-Est.
Myalgia	1 (<1%)	0				
Rhabdomyolysis	1 (<1%)	0				
Metabolism and nutrition disorders	1 (<1%)	0	Non-Est.	Non-Est.	Non-Est.	Non-Est.
Decreased appetite	1 (<1%)	0				
Psychiatric disorders	0	1 (<1%)	Non-Est.	Non-Est.	Non-Est.	Non-Est.
Anxiety	0	1 (<1%)				

[1] For individual studies, the estimates are from frequency tables. In meta-analysis, odds ratio is from logistic regression and relative risk is from the poisson regression model with treatment and study as the covariates.
[2] For individual studies, p-value is from the Fisher’s exact test and for meta-analysis p-value is based on the poisson regression model.
Note: Asymptotic 95% CI’s are reported.

Population: Modified Intent-to-Treat Population with Eosinophils 300 cells/uL or More

Table 311.14

Summary and Analysis of On-Treatment Adverse Events Leading to Study Drug Withdrawal by SOC and PT: Individual Studies and Meta-Analysis

Study: 208657 + MEA117113 + MEA117106

System Organ Class/Preferred Term	PBO	100 SC	Odds Ratio (95% CI) [1]	Relative Risk (95% CI) [1]	Risk Difference (95% CI) [1]	p-value [2]
Renal and urinary disorders	1 (<1%)	0	Non-Est.	Non-Est.	Non-Est.	Non-Est.
Renal impairment	1 (<1%)	0				
Skin and subcutaneous tissue disorders	1 (<1%)	0	Non-Est.	Non-Est.	Non-Est.	Non-Est.
Eczema	1 (<1%)	0				

[1] For individual studies, the estimates are from frequency tables. In meta-analysis, odds ratio is from logistic regression and relative risk is from the poisson regression model with treatment and study as the covariates.
[2] For individual studies, p-value is from the Fisher’s exact test and for meta-analysis p-value is based on the poisson regression model.
Note: Asymptotic 95% CI’s are reported.
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Population: Modified Intent-to-Treat Population with Eosinophils 300 cells/uL or More

Table 311.15

Analysis of On-Treatment Adverse Events Leading to Study Drug Withdrawal
by SOC and PT: Meta-Analysis: p-values for Interaction Effect

Study: 208657 + MEA117113 + MEA117106

System Organ Class/Preferred Term	p-value for study*treatment interaction [1]
ANY EVENT	0.055
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	0.359
Cardiac disorders	0.083
Infections and infestations	Non-Est.
Respiratory, thoracic and mediastinal disorders	Non-Est.
Nervous system disorders	0.248
Investigations	Non-Est.
Gastrointestinal disorders	Non-Est.
Injury, poisoning and procedural complications	Non-Est.
Musculoskeletal and connective tissue disorders	Non-Est.
Metabolism and nutrition disorders	Non-Est.
Psychiatric disorders	Non-Est.
Renal and urinary disorders	Non-Est.

[1] From the poisson regression model with covariates of treatment group, study and with an additional covariate of study*treatment interaction.

Population: Modified Intent-to-Treat Population with Eosinophils 300 cells/uL or More

Table 311.15

Analysis of On-Treatment Adverse Events Leading to Study Drug Withdrawal
by SOC and PT: Meta-Analysis: p-values for Interaction Effect

Study: 208657 + MEA117113 + MEA117106

System Organ Class/Preferred Term	p-value for study*treatment interaction [1]
Skin and subcutaneous tissue disorders	Non-Est.

[1] From the poisson regression model with covariates of treatment group, study and with an additional covariate of study*treatment interaction.

Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Table 311.16

Summary and Analysis of Deaths: Individual Studies and Meta-Analysis

Study: 208657

	PBO (N=401)	100 SC (N=403)
Subject Status		
Dead	11 (3%)	11 (3%)
Alive at last contact, follow-up ended	390 (97%)	392 (97%)
Primary Cause of Death		
Cardiac arrhythmia	0	0
Haemorrhage	1 (<1%)	1 (<1%)
Heart failure	1 (<1%)	1 (<1%)
Myocardial infarction	1 (<1%)	0
Other Cardiovascular Cause	1 (<1%)	1 (<1%)
Cancer	2 (<1%)	0
Disease under study	2 (<1%)	0
Other cancer	0	0
Pulmonary embolism (PE)	0	0
Sepsis	0	0
Stroke	0	0
Suicide	0	0
Trauma	0	0
Other Non-cardiovascular Cause	5 (1%)	8 (2%)
Time from Last Dose to Death		
<=30 days	7 (2%)	7 (2%)
>30 days	4 (<1%)	4 (<1%)

[1] For individual studies, estimates are from frequency tables and p-value from Fisher’s exact test.
[2] Analysis used a logistic regression model with covariates treatment group and study.
[3] Analysis used poisson regression model with covariates treatment group and study, risk reduction uses identity link.
[4] Analysis model as in footnote [3] with an additional covariate of study*treatment interaction.
Note: Asymptotic 95% CI’s are reported.
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Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Table 311.16

Summary and Analysis of Deaths: Individual Studies and Meta-Analysis

Study: 208657

	PBO (N=401)	100 SC (N=403)
Odds Ratio to Placebo [1]		0.99
95% CI		(0.43,2.32)
Relative Risk [1]		1.00
95% CI		(0.44,2.27)
p-value		>0.999
Absolute Risk Reduction [1]		0.00
95% CI		(-0.02,0.02)

[1] For individual studies, estimates are from frequency tables and p-value from Fisher’s exact test.
[2] Analysis used a logistic regression model with covariates treatment group and study.
[3] Analysis used poisson regression model with covariates treatment group and study, risk reduction uses identity link.
[4] Analysis model as in footnote [3] with an additional covariate of study*treatment interaction.
Note: Asymptotic 95% CI’s are reported.
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Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Table 311.16

Summary and Analysis of Deaths: Individual Studies and Meta-Analysis

Study: MEA117113

	PBO (N=401)	100 SC (N=403)
Subject Status		
Dead	5 (6%)	2 (2%)
Alive at last contact, follow-up ended	82 (94%)	81 (98%)
Primary Cause of Death		
Cardiac arrhythmia	0	0
Haemorrhage	1 (1%)	0
Heart failure	0	0
Myocardial infarction	0	0
Other Cardiovascular Cause	0	0
Cancer	0	2 (2%)
Disease under study	0	0
Other cancer	0	2 (2%)
Pulmonary embolism (PE)	0	0
Sepsis	1 (1%)	0
Stroke	1 (1%)	0
Suicide	0	0
Trauma	0	0
Other Non-cardiovascular Cause	2 (2%)	0
Time from Last Dose to Death		
<=30 days	3 (3%)	1 (1%)
>30 days	2 (2%)	1 (1%)

[1] For individual studies, estimates are from frequency tables and p-value from Fisher’s exact test.
[2] Analysis used a logistic regression model with covariates treatment group and study.
[3] Analysis used poisson regression model with covariates treatment group and study, risk reduction uses identity link.
[4] Analysis model as in footnote [3] with an additional covariate of study*treatment interaction.
Note: Asymptotic 95% CI’s are reported.
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Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Table 311.16

Summary and Analysis of Deaths: Individual Studies and Meta-Analysis

Study: MEA117113

	PBO (N=401)	100 SC (N=403)
Odds Ratio to Placebo [1]		0.40
95% CI		(0.08,2.15)
Relative Risk [1]		0.42
95% CI		(0.08,2.10)
p-value		0.444
Absolute Risk Reduction [1]		-0.03
95% CI		(-0.09,0.03)

[1] For individual studies, estimates are from frequency tables and p-value from Fisher’s exact test.
[2] Analysis used a logistic regression model with covariates treatment group and study.
[3] Analysis used poisson regression model with covariates treatment group and study, risk reduction uses identity link.
[4] Analysis model as in footnote [3] with an additional covariate of study*treatment interaction.
Note: Asymptotic 95% CI’s are reported.
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Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Table 311.16

Summary and Analysis of Deaths: Individual Studies and Meta-Analysis

Study: MEA117106

	PBO (N=401)	100 SC (N=403)
Subject Status		
Dead	2 (2%)	1 (1%)
Alive at last contact, follow-up ended	88 (98%)	81 (99%)
Primary Cause of Death		
Cardiac arrhythmia	0	0
Haemorrhage	0	0
Heart failure	0	0
Myocardial infarction	0	0
Other Cardiovascular Cause	0	0
Cancer	1 (1%)	0
Disease under study	0	0
Other cancer	1 (1%)	0
Pulmonary embolism (PE)	0	0
Sepsis	0	0
Stroke	0	0
Suicide	0	0
Trauma	0	0
Other Non-cardiovascular Cause	1 (1%)	1 (1%)
Time from Last Dose to Death		
<=30 days	1 (1%)	0
>30 days	1 (1%)	1 (1%)

[1] For individual studies, estimates are from frequency tables and p-value from Fisher’s exact test.
[2] Analysis used a logistic regression model with covariates treatment group and study.
[3] Analysis used poisson regression model with covariates treatment group and study, risk reduction uses identity link.
[4] Analysis model as in footnote [3] with an additional covariate of study*treatment interaction.
Note: Asymptotic 95% CI’s are reported.
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Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Table 311.16

Summary and Analysis of Deaths: Individual Studies and Meta-Analysis

Study: MEA117106

	PBO (N=401)	100 SC (N=403)
Odds Ratio to Placebo [1]		0.54
95% CI		(0.05,6.10)
Relative Risk [1]		0.55
95% CI		(0.05,5.94)
p-value		>0.999
Absolute Risk Reduction [1]		-0.01
95% CI		(-0.05,0.03)

[1] For individual studies, estimates are from frequency tables and p-value from Fisher’s exact test.
[2] Analysis used a logistic regression model with covariates treatment group and study.
[3] Analysis used poisson regression model with covariates treatment group and study, risk reduction uses identity link.
[4] Analysis model as in footnote [3] with an additional covariate of study*treatment interaction.
Note: Asymptotic 95% CI’s are reported.
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Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Table 311.16

Summary and Analysis of Deaths: Individual Studies and Meta-Analysis

Study: 208657 + MEA117113 + MEA117106

	PBO (N=401)	100 SC (N=403)
Subject Status		
Dead	18 (3%)	14 (2%)
Alive at last contact, follow-up ended	560 (97%)	554 (98%)
Primary Cause of Death		
Cardiac arrhythmia	0	0
Haemorrhage	2 (<1%)	1 (<1%)
Heart failure	1 (<1%)	1 (<1%)
Myocardial infarction	1 (<1%)	0
Other Cardiovascular Cause	1 (<1%)	1 (<1%)
Cancer	3 (<1%)	2 (<1%)
Disease under study	2 (<1%)	0
Other cancer	1 (<1%)	2 (<1%)
Pulmonary embolism (PE)	0	0
Sepsis	1 (<1%)	0
Stroke	1 (<1%)	0
Suicide	0	0
Trauma	0	0
Other Non-cardiovascular Cause	8 (1%)	9 (2%)
Time from Last Dose to Death		
<=30 days	11 (2%)	8 (1%)
>30 days	7 (1%)	6 (1%)

[1] For individual studies, estimates are from frequency tables and p-value from Fisher’s exact test.
[2] Analysis used a logistic regression model with covariates treatment group and study.
[3] Analysis used poisson regression model with covariates treatment group and study, risk reduction uses identity link.
[4] Analysis model as in footnote [3] with an additional covariate of study*treatment interaction.
Note: Asymptotic 95% CI’s are reported.
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Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Table 311.16

Summary and Analysis of Deaths: Individual Studies and Meta-Analysis

Study: 208657 + MEA117113 + MEA117106

	PBO (N=401)	100 SC (N=403)
Odds Ratio to Placebo [2]		0.78
95% CI		(0.39,1.59)
Relative Risk [3]		0.79
95% CI		(0.39,1.59)
p-value		0.509
Absolute Risk Reduction [3]		-0.01
95% CI		(-0.02,0.01)
p-value for study*treatment interaction [4]		0.606

[1] For individual studies, estimates are from frequency tables and p-value from Fisher’s exact test.
[2] Analysis used a logistic regression model with covariates treatment group and study.
[3] Analysis used poisson regression model with covariates treatment group and study, risk reduction uses identity link.
[4] Analysis model as in footnote [3] with an additional covariate of study*treatment interaction.
Note: Asymptotic 95% CI’s are reported.
/mnt/code/postcsr_01/prod/tfls/t_s_death.sas 17JUL2025 17:18

Population: Modified Intent-to-Treat Population with Eosinophils 300 cells/uL or More

Table 311.17

Summary and Analysis of On-Treatment Adverse Events Leading to Withdrawal from Study by SOC and PT: Individual Studies and Meta-Analysis

Study: 208657

System Organ Class/Preferred Term	PBO	100 SC	Odds Ratio (95% CI) [1]	Relative Risk (95% CI) [1]	Risk Difference (95% CI) [1]	p-value [2]
Number of subjects (N)	401	403				
ANY EVENT	13 (3%)	13 (3%)	0.99 (0.46,2.17)	1.00 (0.47,2.12)	0.00 (-0.02,0.02)	>0.999
Infections and infestations	2 (<1%)	3 (<1%)	1.50 (0.25,9.00)	1.49 (0.25,8.88)	0.00 (-0.01,0.01)	>0.999
COVID-19	0	3 (<1%)				
Infective exacerbation of chronic obstructive airways disease	1 (<1%)	0				
Scrotal abscess	1 (<1%)	0				
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	4 (<1%)	1 (<1%)	0.25 (0.03,2.22)	0.25 (0.03,2.22)	-0.01 (-0.02,0.00)	0.216

[1] For individual studies, the estimates are from frequency tables. In meta-analysis, odds ratio is from logistic regression and relative risk is from the poisson regression model with treatment and study as the covariates.
[2] For individual studies, p-value is from the Fisher’s exact test and for meta-analysis p-value is based on the poisson regression model.
Note: Asymptotic 95% CI’s are reported.
/mnt/code/postcsr_01/prod/tfls/t_s_ae_onae_wd_gm.sas 17JUL2025 17:19

Population: Modified Intent-to-Treat Population with Eosinophils 300 cells/uL or More

Table 311.17

Summary and Analysis of On-Treatment Adverse Events Leading to Withdrawal from Study by SOC and PT: Individual Studies and Meta-Analysis

Study: 208657

System Organ Class/Preferred Term	PBO	100 SC	Odds Ratio (95% CI) [1]	Relative Risk (95% CI) [1]	Risk Difference (95% CI) [1]	p-value [2]
Bronchial carcinoma	1 (<1%)	0				
Lung neoplasm malignant	1 (<1%)	0				
Lung adenocarcinoma	1 (<1%)	0				
Small cell lung cancer metastatic	1 (<1%)	0				
Small cell carcinoma	0	1 (<1%)				
Respiratory, thoracic and mediastinal disorders	3 (<1%)	2 (<1%)	0.66 (0.11,3.98)	0.66 (0.11,3.95)	0.00 (-0.01,0.01)	0.686
Chronic obstructive pulmonary disease	2 (<1%)	1 (<1%)				
Haemoptysis	0	1 (<1%)				
Pulmonary oedema	1 (<1%)	0				

[1] For individual studies, the estimates are from frequency tables. In meta-analysis, odds ratio is from logistic regression and relative risk is from the poisson regression model with treatment and study as the covariates.
[2] For individual studies, p-value is from the Fisher’s exact test and for meta-analysis p-value is based on the poisson regression model.
Note: Asymptotic 95% CI’s are reported.

Population: Modified Intent-to-Treat Population with Eosinophils 300 cells/uL or More

Table 311.17

Summary and Analysis of On-Treatment Adverse Events Leading to Withdrawal from Study by SOC and PT: Individual Studies and Meta-Analysis

Study: 208657

System Organ Class/Preferred Term	PBO	100 SC	Odds Ratio (95% CI) [1]	Relative Risk (95% CI) [1]	Risk Difference (95% CI) [1]	p-value [2]
Cardiac disorders	1 (<1%)	3 (<1%)	3.00 (0.31,28.96)	2.99 (0.31,28.58)	0.00 (0.00,0.01)	0.624
Cardiac arrest	0	3 (<1%)				
Acute myocardial infarction	1 (<1%)	0				
General disorders and administration site conditions	0	2 (<1%)				
Death	0	2 (<1%)				
Vascular disorders	2 (<1%)	0				
Aortic aneurysm rupture	1 (<1%)	0				
Circulatory collapse	1 (<1%)	0				
Musculoskeletal and connective tissue disorders	1 (<1%)	0				

[1] For individual studies, the estimates are from frequency tables. In meta-analysis, odds ratio is from logistic regression and relative risk is from the poisson regression model with treatment and study as the covariates.
[2] For individual studies, p-value is from the Fisher’s exact test and for meta-analysis p-value is based on the poisson regression model.
Note: Asymptotic 95% CI’s are reported.
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Population: Modified Intent-to-Treat Population with Eosinophils 300 cells/uL or More

Table 311.17

Summary and Analysis of On-Treatment Adverse Events Leading to Withdrawal from Study by SOC and PT: Individual Studies and Meta-Analysis

Study: 208657

System Organ Class/Preferred Term	PBO	100 SC	Odds Ratio (95% CI) [1]	Relative Risk (95% CI) [1]	Risk Difference (95% CI) [1]	p-value [2]
Rhabdomyolysis	1 (<1%)	0				
Nervous system disorders	0	1 (<1%)				
Cerebrovascular accident	0	1 (<1%)				
Psychiatric disorders	0	1 (<1%)				
Anxiety	0	1 (<1%)				

[1] For individual studies, the estimates are from frequency tables. In meta-analysis, odds ratio is from logistic regression and relative risk is from the poisson regression model with treatment and study as the covariates.
[2] For individual studies, p-value is from the Fisher’s exact test and for meta-analysis p-value is based on the poisson regression model.
Note: Asymptotic 95% CI’s are reported.
/mnt/code/postcsr_01/prod/tfls/t_s_ae_onae_wd_gm.sas 17JUL2025 17:19

Population: Modified Intent-to-Treat Population with Eosinophils 300 cells/uL or More

Table 311.17

Summary and Analysis of On-Treatment Adverse Events Leading to Withdrawal from Study by SOC and PT: Individual Studies and Meta-Analysis

Study: MEA117113

System Organ Class/Preferred Term	PBO	100 SC	Odds Ratio (95% CI) [1]	Relative Risk (95% CI) [1]	Risk Difference (95% CI) [1]	p-value [2]
Number of subjects (N)	87	83				
ANY EVENT	8 (9%)	1 (1%)	0.12 (0.01,0.99)	0.13 (0.02,1.02)	-0.08 (-0.15,-0.01)	0.035
Respiratory, thoracic and mediastinal disorders	3 (3%)	0				
Chronic obstructive pulmonary disease	2 (2%)	0				
Pneumothorax spontaneous	1 (1%)	0				
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	1 (1%)	1 (1%)	1.05 (0.06,17.05)	1.05 (0.07,16.49)	0.00 (-0.03,0.03)	>0.999

[1] For individual studies, the estimates are from frequency tables. In meta-analysis, odds ratio is from logistic regression and relative risk is from the poisson regression model with treatment and study as the covariates.
[2] For individual studies, p-value is from the Fisher’s exact test and for meta-analysis p-value is based on the poisson regression model.
Note: Asymptotic 95% CI’s are reported.

Population: Modified Intent-to-Treat Population with Eosinophils 300 cells/uL or More

Table 311.17

Summary and Analysis of On-Treatment Adverse Events Leading to Withdrawal from Study by SOC and PT: Individual Studies and Meta-Analysis

Study: MEA117113

System Organ Class/Preferred Term	PBO	100 SC	Odds Ratio (95% CI) [1]	Relative Risk (95% CI) [1]	Risk Difference (95% CI) [1]	p-value [2]
Adenocarcinoma of colon	1 (1%)	0				
Lung neoplasm malignant	0	1 (1%)				
Cardiac disorders	1 (1%)	0				
Cardiac arrest	1 (1%)	0				
Gastrointestinal disorders	1 (1%)	0				
Gastrointestinal haemorrhage	1 (1%)	0				
Infections and infestations	1 (1%)	0				
Pharyngitis	1 (1%)	0				
Nervous system disorders	1 (1%)	0				
Peripheral sensorimotor neuropathy	1 (1%)	0				

[1] For individual studies, the estimates are from frequency tables. In meta-analysis, odds ratio is from logistic regression and relative risk is from the poisson regression model with treatment and study as the covariates.
[2] For individual studies, p-value is from the Fisher’s exact test and for meta-analysis p-value is based on the poisson regression model.
Note: Asymptotic 95% CI’s are reported.

Population: Modified Intent-to-Treat Population with Eosinophils 300 cells/uL or More

Table 311.17

Summary and Analysis of On-Treatment Adverse Events Leading to Withdrawal from Study by SOC and PT: Individual Studies and Meta-Analysis

Study: MEA117106

System Organ Class/Preferred Term	PBO	100 SC	Odds Ratio (95% CI) [1]	Relative Risk (95% CI) [1]	Risk Difference (95% CI) [1]	p-value [2]
Number of subjects (N)	90	82				
ANY EVENT	1 (1%)	1 (1%)	1.10 (0.07,17.86)	1.10 (0.07,17.27)	0.00 (-0.03,0.03)	>0.999
Injury, poisoning and procedural complications	1 (1%)	0				
Respiratory fume inhalation disorder	1 (1%)	0				
Respiratory, thoracic and mediastinal disorders	0	1 (1%)				
Chronic obstructive pulmonary disease	0	1 (1%)				

[1] For individual studies, the estimates are from frequency tables. In meta-analysis, odds ratio is from logistic regression and relative risk is from the poisson regression model with treatment and study as the covariates.
[2] For individual studies, p-value is from the Fisher’s exact test and for meta-analysis p-value is based on the poisson regression model.
Note: Asymptotic 95% CI’s are reported.
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Population: Modified Intent-to-Treat Population with Eosinophils 300 cells/uL or More

Table 311.17

Summary and Analysis of On-Treatment Adverse Events Leading to Withdrawal from Study by SOC and PT: Individual Studies and Meta-Analysis

Study: 208657 + MEA117113 + MEA117106

System Organ Class/Preferred Term	PBO	100 SC	Odds Ratio (95% CI) [1]	Relative Risk (95% CI) [1]	Risk Difference (95% CI) [1]	p-value [2]
Number of subjects (N)	578	568				
ANY EVENT	22 (4%)	15 (3%)	0.68 (0.35,1.33)	0.69 (0.36,1.33)	-0.01 (-0.03,0.01)	0.270
Respiratory, thoracic and mediastinal disorders	6 (1%)	3 (<1%)	0.51 (0.13,2.05)	0.51 (0.13,2.05)	0.00 (-0.01,0.01)	0.344
Chronic obstructive pulmonary disease	4 (<1%)	2 (<1%)				
Haemoptysis	0	1 (<1%)				
Pneumothorax spontaneous	1 (<1%)	0				
Pulmonary oedema	1 (<1%)	0				

[1] For individual studies, the estimates are from frequency tables. In meta-analysis, odds ratio is from logistic regression and relative risk is from the poisson regression model with treatment and study as the covariates.
[2] For individual studies, p-value is from the Fisher’s exact test and for meta-analysis p-value is based on the poisson regression model.
Note: Asymptotic 95% CI’s are reported.
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Population: Modified Intent-to-Treat Population with Eosinophils 300 cells/uL or More

Table 311.17

Summary and Analysis of On-Treatment Adverse Events Leading to Withdrawal from Study by SOC and PT: Individual Studies and Meta-Analysis

Study: 208657 + MEA117113 + MEA117106

System Organ Class/Preferred Term	PBO	100 SC	Odds Ratio (95% CI) [1]	Relative Risk (95% CI) [1]	Risk Difference (95% CI) [1]	p-value [2]
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	5 (<1%)	2 (<1%)	Non-Est.	0.40 (0.08,2.08)	Non-Est.	0.279
Lung neoplasm malignant	1 (<1%)	1 (<1%)				
Adenocarcinoma of colon	1 (<1%)	0				
Bronchial carcinoma	1 (<1%)	0				
Lung adenocarcinoma	1 (<1%)	0				
Small cell lung cancer metastatic	1 (<1%)	0				
Small cell carcinoma	0	1 (<1%)				
Infections and infestations	3 (<1%)	3 (<1%)	Non-Est.	1.00 (0.20,4.97)	Non-Est.	0.997
COVID-19	0	3 (<1%)				

[1] For individual studies, the estimates are from frequency tables. In meta-analysis, odds ratio is from logistic regression and relative risk is from the poisson regression model with treatment and study as the covariates.
[2] For individual studies, p-value is from the Fisher’s exact test and for meta-analysis p-value is based on the poisson regression model.
Note: Asymptotic 95% CI’s are reported.
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Population: Modified Intent-to-Treat Population with Eosinophils 300 cells/uL or More

Table 311.17

Summary and Analysis of On-Treatment Adverse Events Leading to Withdrawal from Study by SOC and PT: Individual Studies and Meta-Analysis

Study: 208657 + MEA117113 + MEA117106

System Organ Class/Preferred Term	PBO	100 SC	Odds Ratio (95% CI) [1]	Relative Risk (95% CI) [1]	Risk Difference (95% CI) [1]	p-value [2]
Infective exacerbation of chronic obstructive airways disease	1 (<1%)	0				
Pharyngitis	1 (<1%)	0				
Scrotal abscess	1 (<1%)	0				
Cardiac disorders	2 (<1%)	3 (<1%)	Non-Est.	1.51 (0.25,9.03)	Non-Est.	0.653
Cardiac arrest	1 (<1%)	3 (<1%)				
Acute myocardial infarction	1 (<1%)	0				
General disorders and administration site conditions	0	2 (<1%)	Non-Est.	Non-Est.	Non-Est.	Non-Est.
Death	0	2 (<1%)				
Nervous system disorders	1 (<1%)	1 (<1%)	Non-Est.	1.02 (0.06,16.33)	Non-Est.	0.989

[1] For individual studies, the estimates are from frequency tables. In meta-analysis, odds ratio is from logistic regression and relative risk is from the poisson regression model with treatment and study as the covariates.
[2] For individual studies, p-value is from the Fisher’s exact test and for meta-analysis p-value is based on the poisson regression model.
Note: Asymptotic 95% CI’s are reported.

Population: Modified Intent-to-Treat Population with Eosinophils 300 cells/uL or More

Table 311.17

Summary and Analysis of On-Treatment Adverse Events Leading to Withdrawal from Study by SOC and PT: Individual Studies and Meta-Analysis

Study: 208657 + MEA117113 + MEA117106

System Organ Class/Preferred Term	PBO	100 SC	Odds Ratio (95% CI) [1]	Relative Risk (95% CI) [1]	Risk Difference (95% CI) [1]	p-value [2]
Cerebrovascular accident	0	1 (<1%)				
Peripheral sensorimotor neuropathy	1 (<1%)	0				
Vascular disorders	2 (<1%)	0	Non-Est.	Non-Est.	Non-Est.	Non-Est.
Aortic aneurysm rupture	1 (<1%)	0				
Circulatory collapse	1 (<1%)	0				
Gastrointestinal disorders	1 (<1%)	0	Non-Est.	Non-Est.	Non-Est.	Non-Est.
Gastrointestinal haemorrhage	1 (<1%)	0				
Injury, poisoning and procedural complications	1 (<1%)	0	Non-Est.	Non-Est.	Non-Est.	Non-Est.

[1] For individual studies, the estimates are from frequency tables. In meta-analysis, odds ratio is from logistic regression and relative risk is from the poisson regression model with treatment and study as the covariates.
[2] For individual studies, p-value is from the Fisher’s exact test and for meta-analysis p-value is based on the poisson regression model.
Note: Asymptotic 95% CI’s are reported.
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Population: Modified Intent-to-Treat Population with Eosinophils 300 cells/uL or More

Table 311.17

Summary and Analysis of On-Treatment Adverse Events Leading to Withdrawal from Study by SOC and PT: Individual Studies and Meta-Analysis

Study: 208657 + MEA117113 + MEA117106

System Organ Class/Preferred Term	PBO	100 SC	Odds Ratio (95% CI) [1]	Relative Risk (95% CI) [1]	Risk Difference (95% CI) [1]	p-value [2]
Respiratory fume inhalation disorder	1 (<1%)	0				
Musculoskeletal and connective tissue disorders	1 (<1%)	0	Non-Est.	Non-Est.	Non-Est.	Non-Est.
Rhabdomyolysis	1 (<1%)	0				
Psychiatric disorders	0	1 (<1%)	Non-Est.	Non-Est.	Non-Est.	Non-Est.
Anxiety	0	1 (<1%)				

[1] For individual studies, the estimates are from frequency tables. In meta-analysis, odds ratio is from logistic regression and relative risk is from the poisson regression model with treatment and study as the covariates.
[2] For individual studies, p-value is from the Fisher’s exact test and for meta-analysis p-value is based on the poisson regression model.
Note: Asymptotic 95% CI’s are reported.

Population: Modified Intent-to-Treat Population with Eosinophils 300 cells/uL or More

Table 311.18

Analysis of On-Treatment Adverse Events Leading to Study Drug Withdrawal by SOC and PT: Meta-Analysis: p-values for Interaction Effect

Study: 208657 + MEA117113 + MEA117106

System Organ Class/Preferred Term	p-value for study*treatment interaction [1]
ANY EVENT	0.099
Respiratory, thoracic and mediastinal disorders	0.093
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	0.725
Infections and infestations	Non-Est.
Cardiac disorders	Non-Est.
General disorders and administration site conditions	Non-Est.
Nervous system disorders	Non-Est.
Vascular disorders	Non-Est.
Gastrointestinal disorders	Non-Est.
Injury, poisoning and procedural complications	Non-Est.
Musculoskeletal and connective tissue disorders	Non-Est.
Psychiatric disorders	Non-Est.

[1] From the poisson regression model with covariates of treatment group, study and with an additional covariate of study*treatment interaction.

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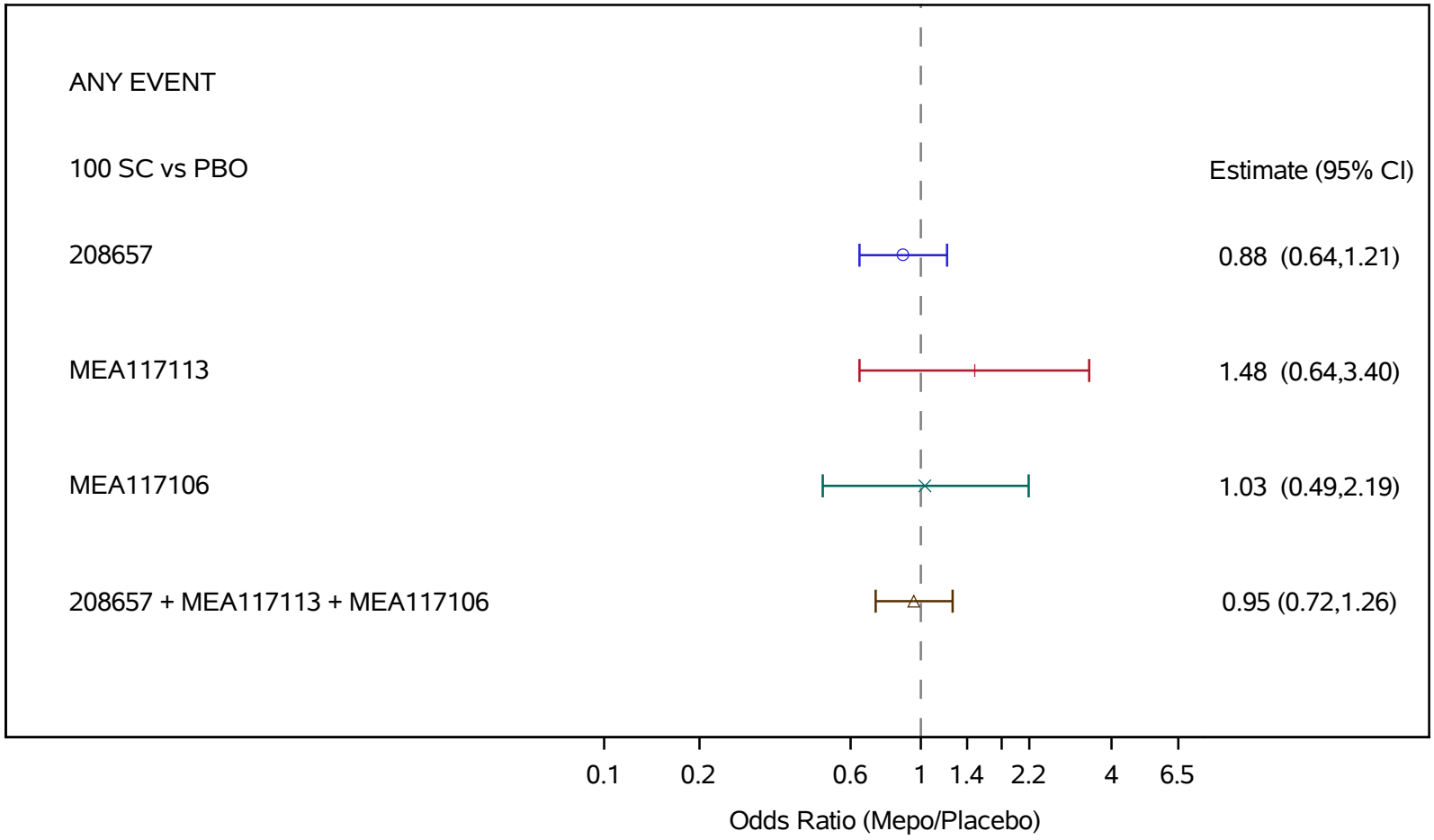
Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Figure 311.1

Forest Plot of Odds ratio for On-Treatment Adverse Events Occurring in >=10% of patients or in >=10 and >=1% of patients by SOC and PT: Individual Studies and Meta-Analysis

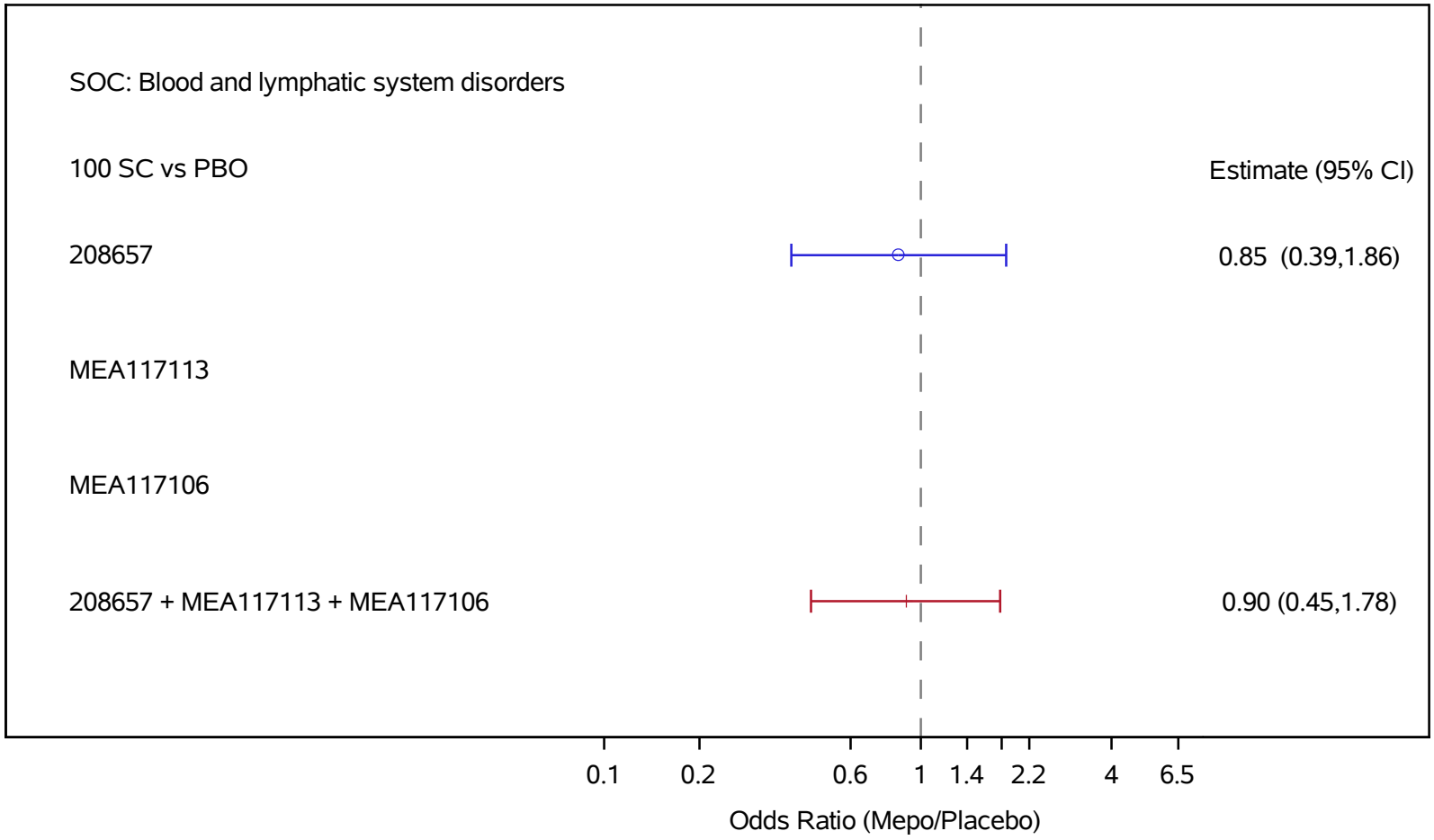


Horizontal bars indicate 95% confidence intervals for the Mepo/Placebo ratio.

Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Figure 311.1

Forest Plot of Odds ratio for On-Treatment Adverse Events Occurring in >=10% of patients or in >=10 and >=1% of patients by SOC and PT: Individual Studies and Meta-Analysis

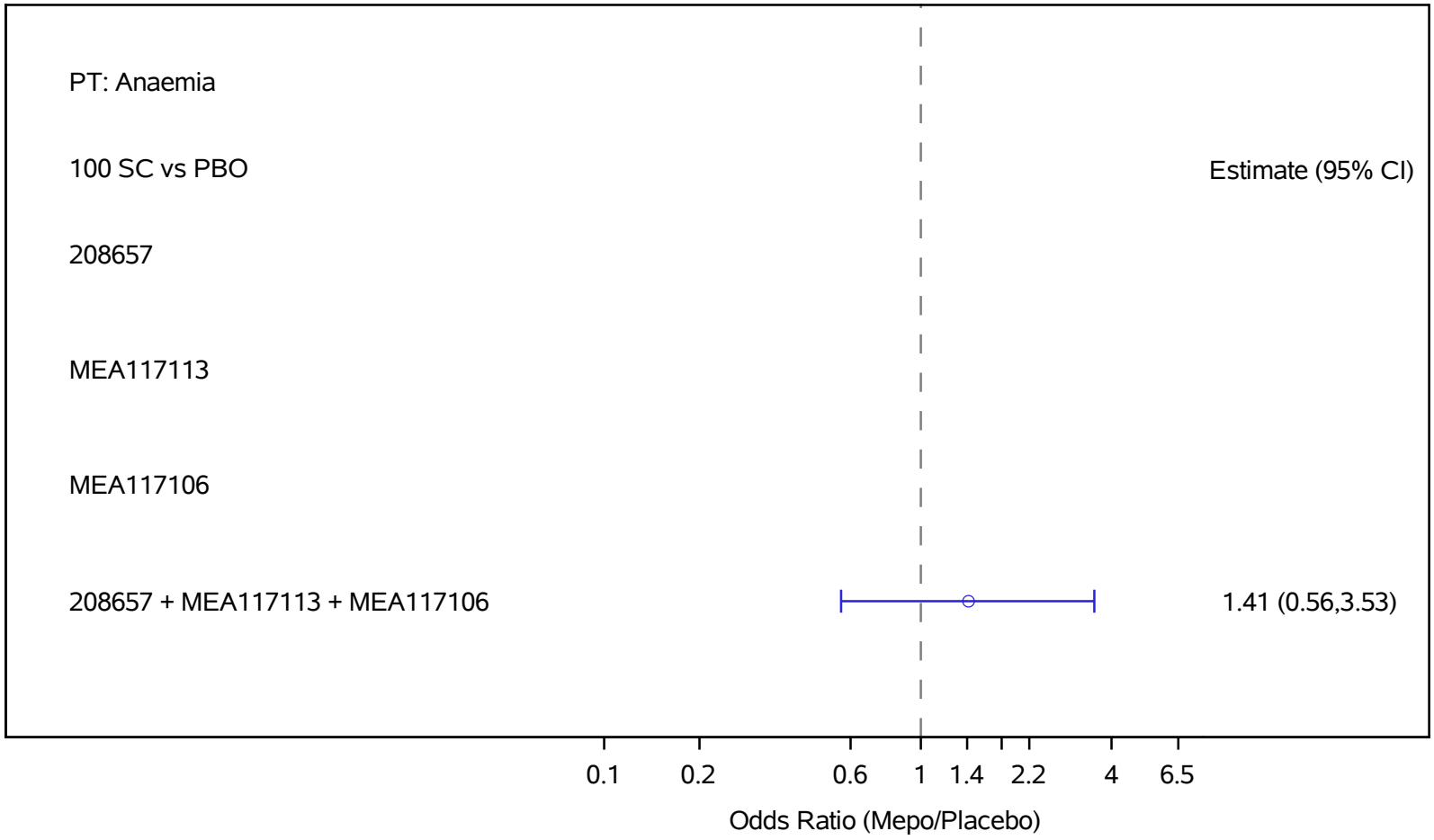


Horizontal bars indicate 95% confidence intervals for the Mepo/Placebo ratio.

Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Figure 311.1

Forest Plot of Odds ratio for On-Treatment Adverse Events Occurring in >=10% of patients or in >=10 and >=1% of patients by SOC and PT: Individual Studies and Meta-Analysis

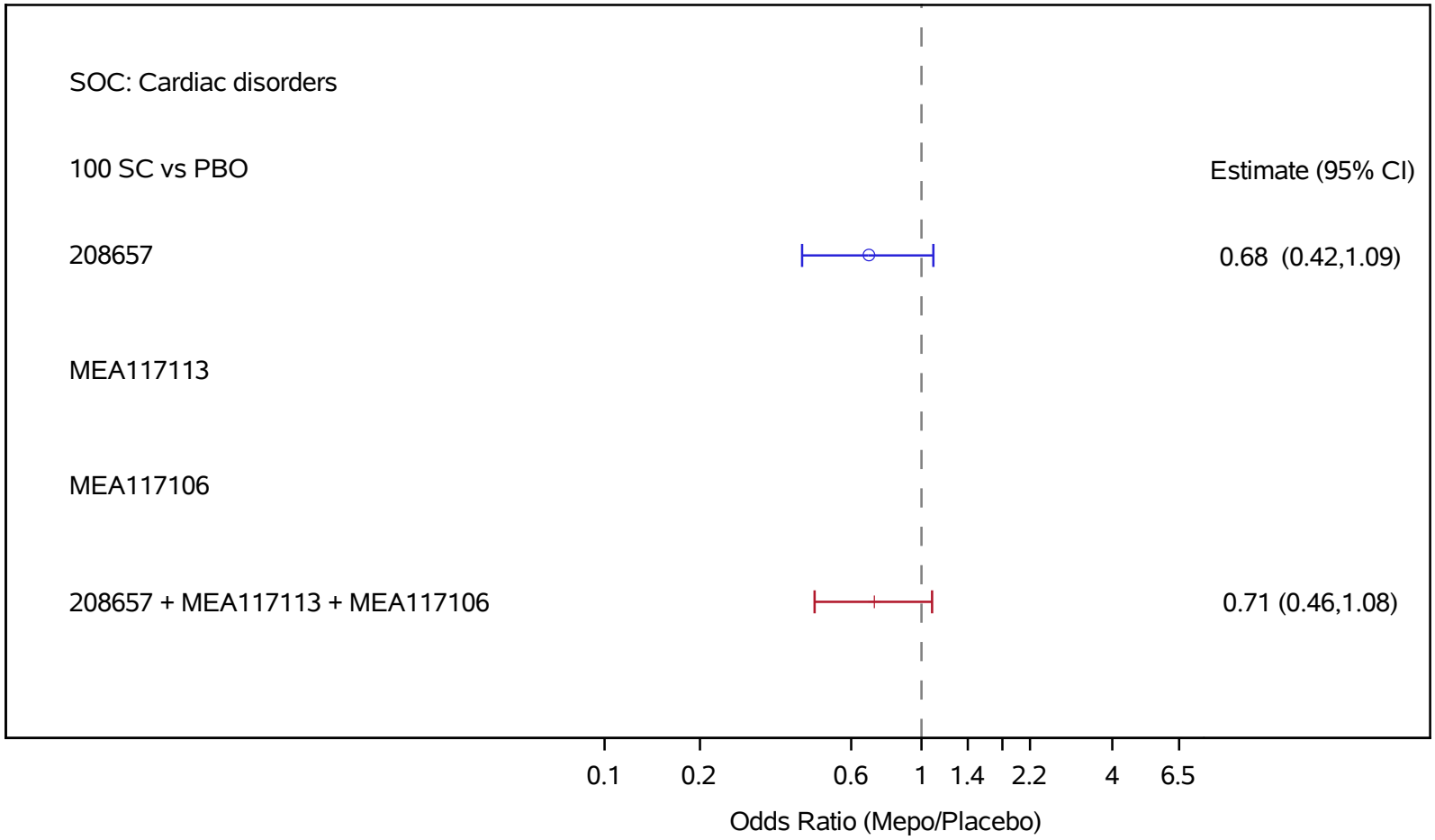


Horizontal bars indicate 95% confidence intervals for the Mepo/Placebo ratio.

Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Figure 311.1

Forest Plot of Odds ratio for On-Treatment Adverse Events Occurring in >=10% of patients or in >=10 and >=1% of patients by SOC and PT: Individual Studies and Meta-Analysis

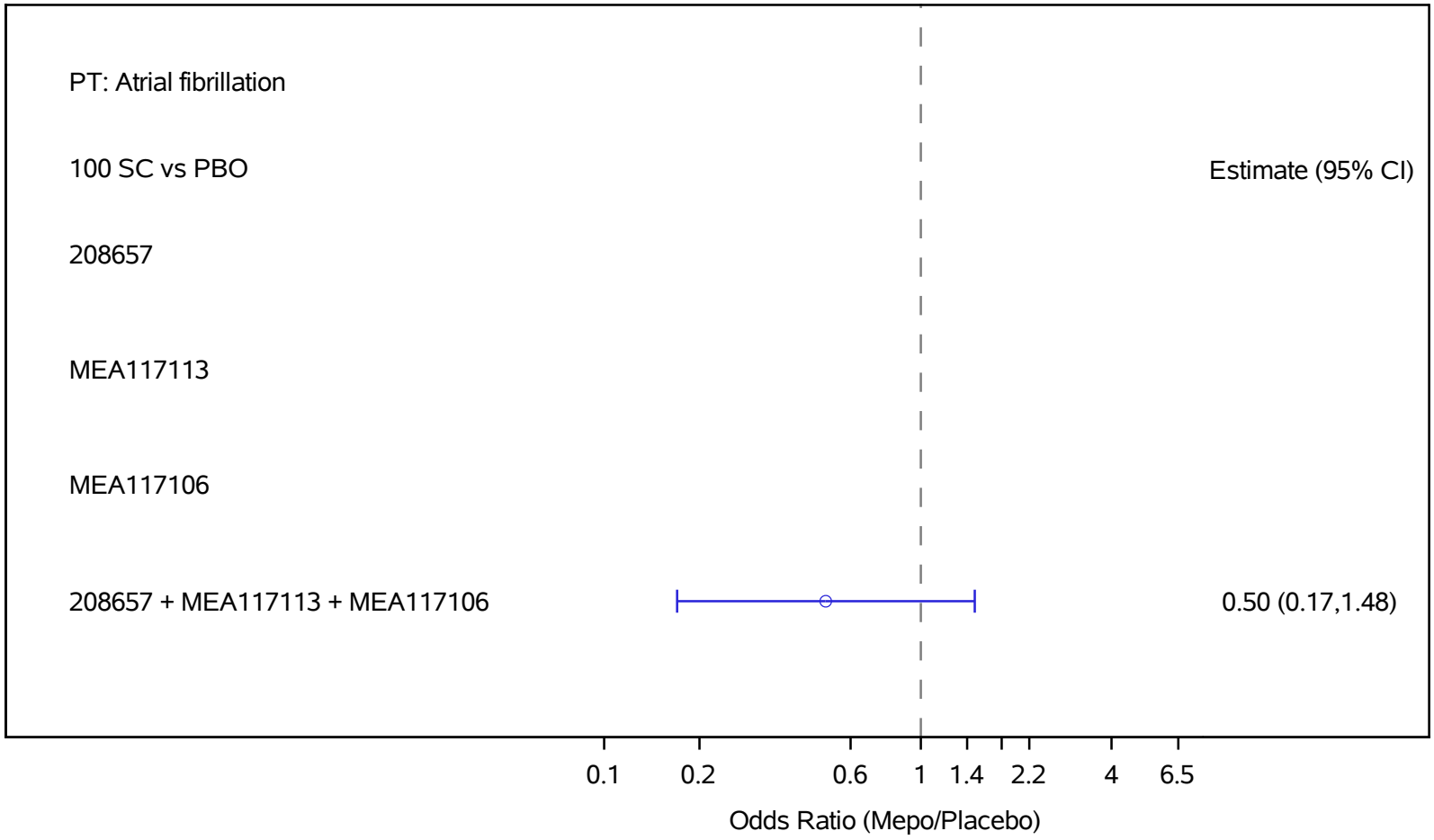


Horizontal bars indicate 95% confidence intervals for the Mepo/Placebo ratio.

Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Figure 311.1

Forest Plot of Odds ratio for On-Treatment Adverse Events Occurring in >=10% of patients or in >=10 and >=1% of patients by SOC and PT: Individual Studies and Meta-Analysis

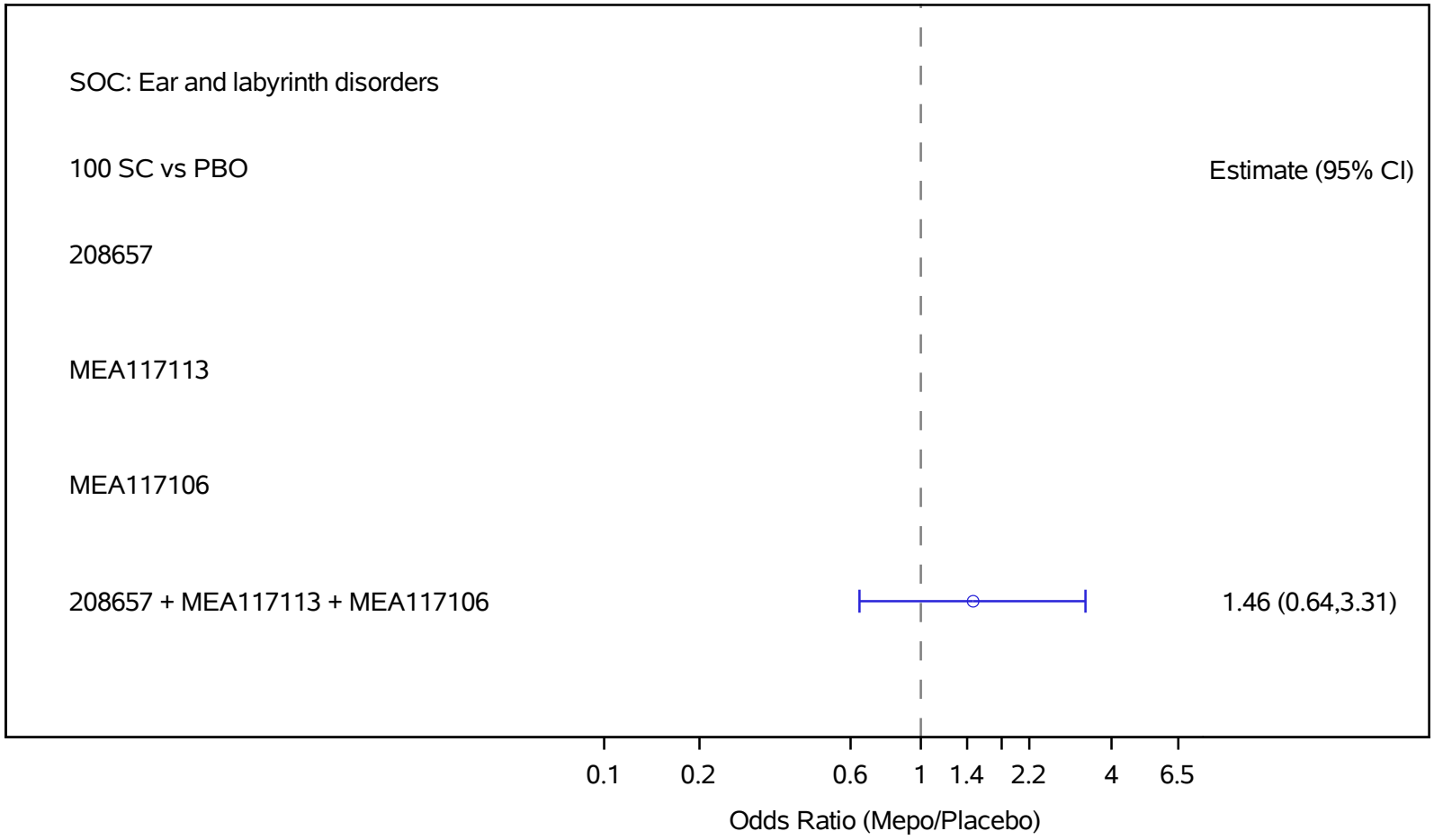


Horizontal bars indicate 95% confidence intervals for the Mepo/Placebo ratio.

Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Figure 311.1

Forest Plot of Odds ratio for On-Treatment Adverse Events Occurring in >=10% of patients or in >=10 and >=1% of patients by SOC and PT: Individual Studies and Meta-Analysis

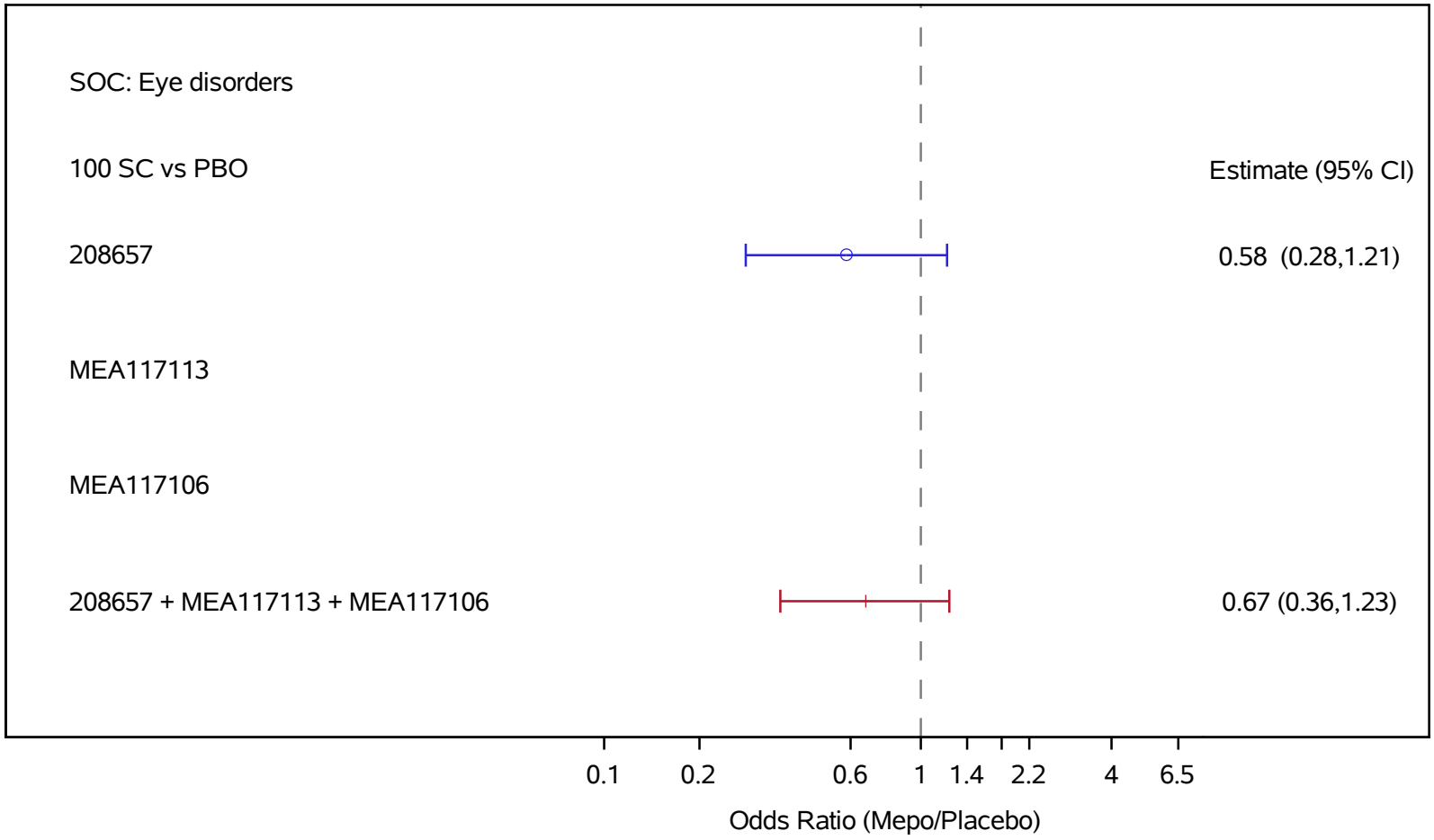


Horizontal bars indicate 95% confidence intervals for the Mepo/Placebo ratio.

Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Figure 311.1

Forest Plot of Odds ratio for On-Treatment Adverse Events Occurring in >=10% of patients or in >=10 and >=1% of patients by SOC and PT: Individual Studies and Meta-Analysis

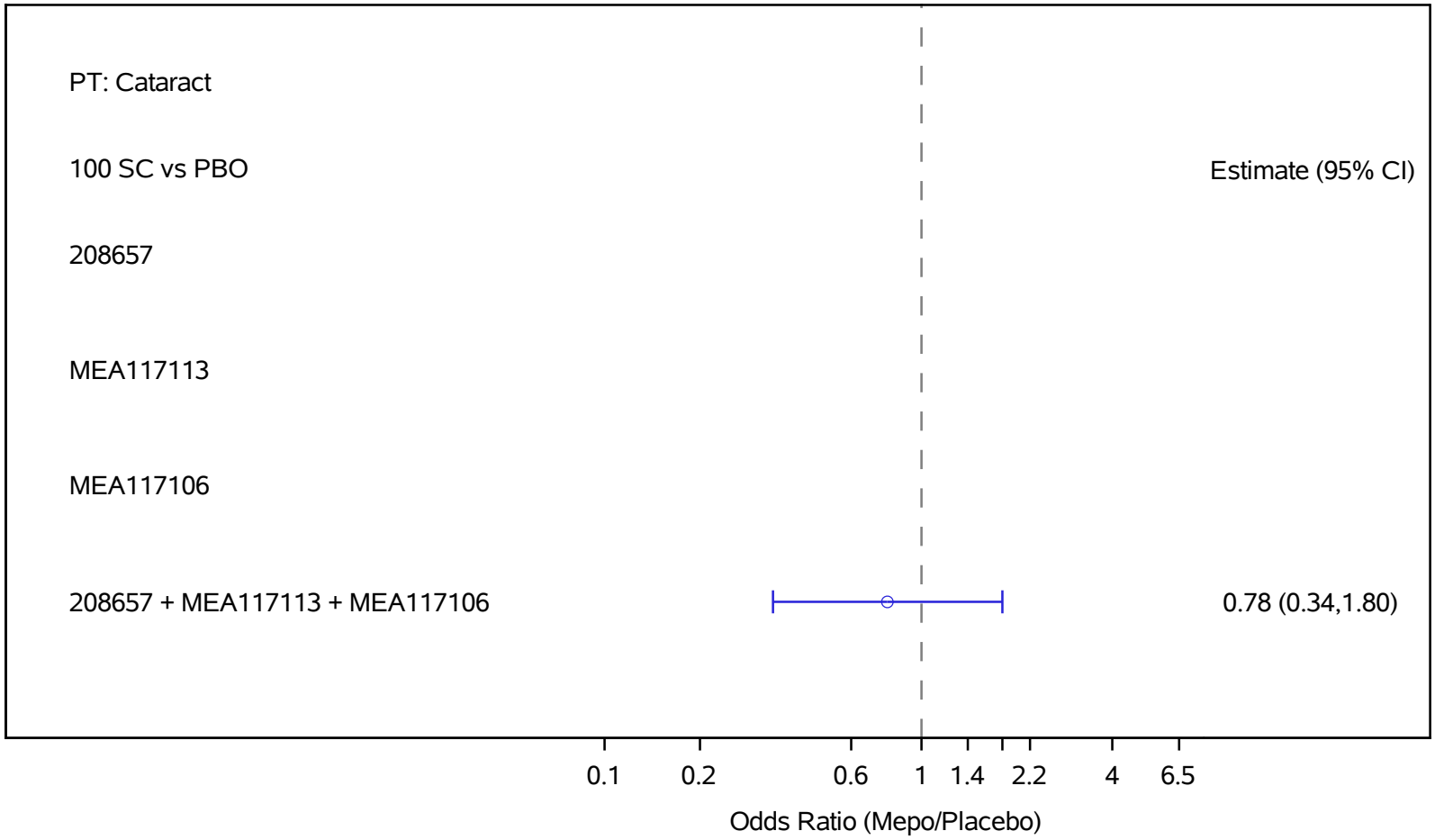


Horizontal bars indicate 95% confidence intervals for the Mepo/Placebo ratio.

Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Figure 311.1

Forest Plot of Odds ratio for On-Treatment Adverse Events Occurring in >=10% of patients or in >=10 and >=1% of patients by SOC and PT: Individual Studies and Meta-Analysis

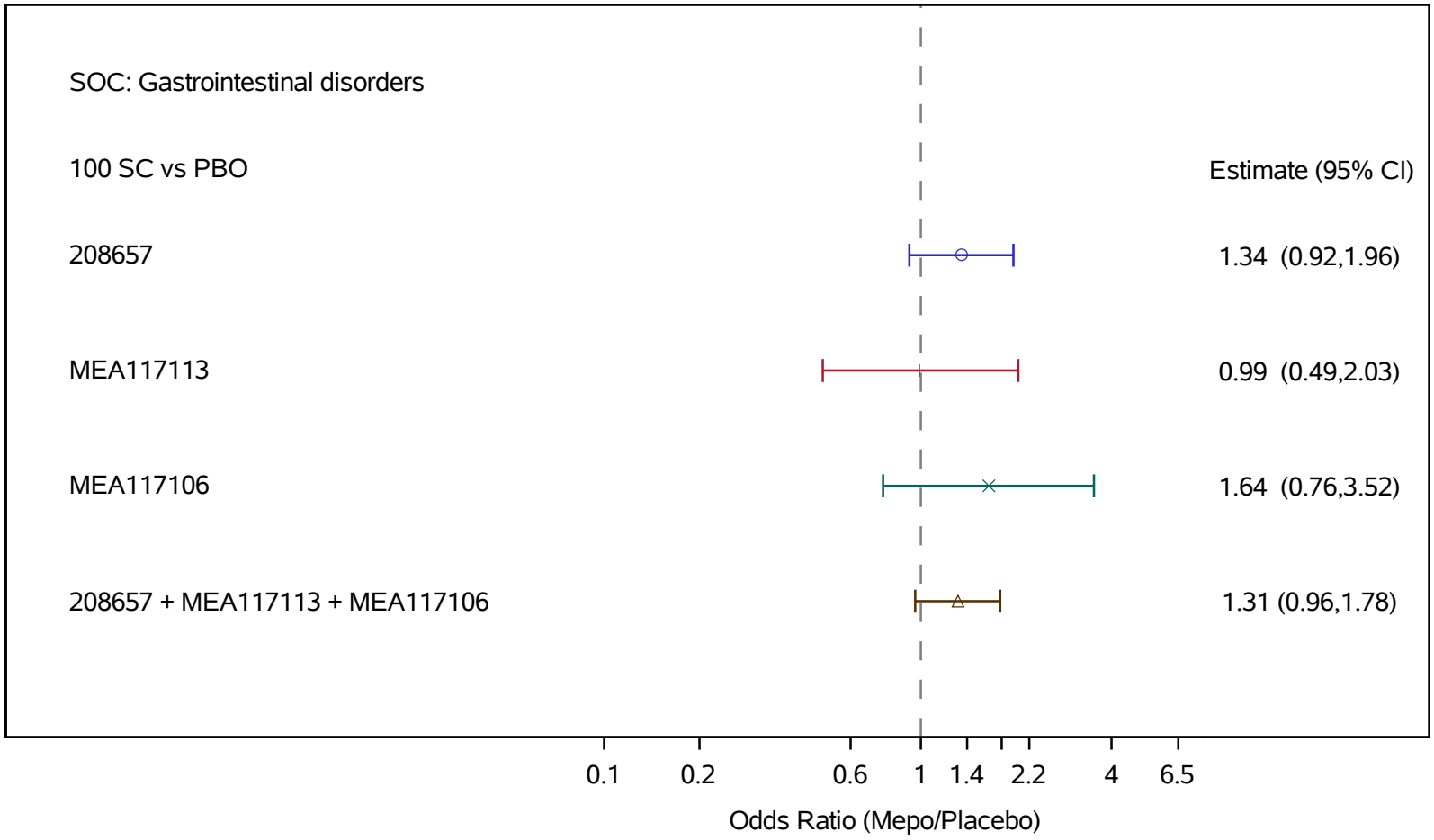


Horizontal bars indicate 95% confidence intervals for the Mepo/Placebo ratio.

Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Figure 311.1

Forest Plot of Odds ratio for On-Treatment Adverse Events Occurring in >=10% of patients or in >=10 and >=1% of patients by SOC and PT: Individual Studies and Meta-Analysis

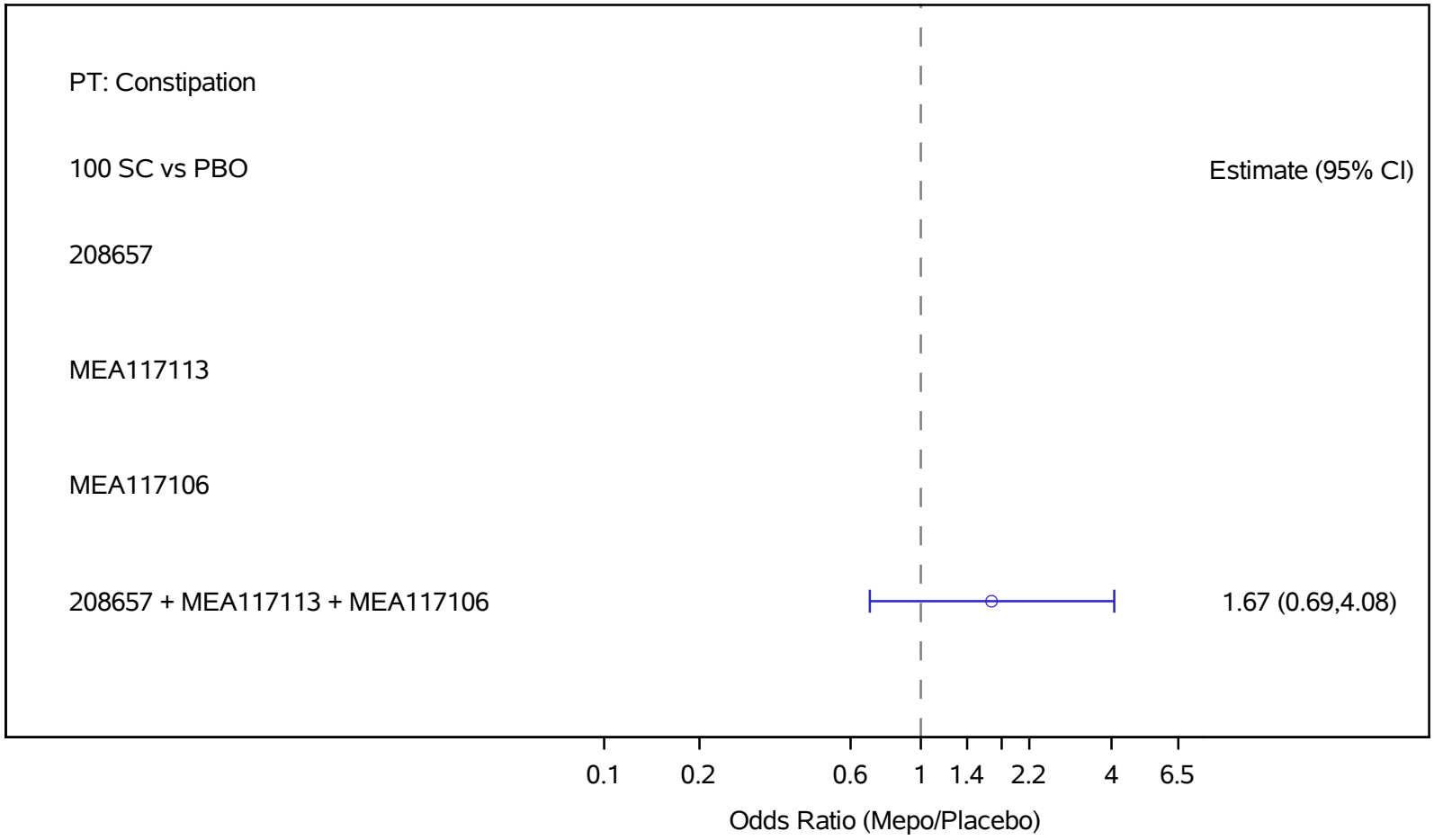


Horizontal bars indicate 95% confidence intervals for the Mepo/Placebo ratio.

Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Figure 311.1

Forest Plot of Odds ratio for On-Treatment Adverse Events Occurring in >=10% of patients or in >=10 and >=1% of patients by SOC and PT: Individual Studies and Meta-Analysis

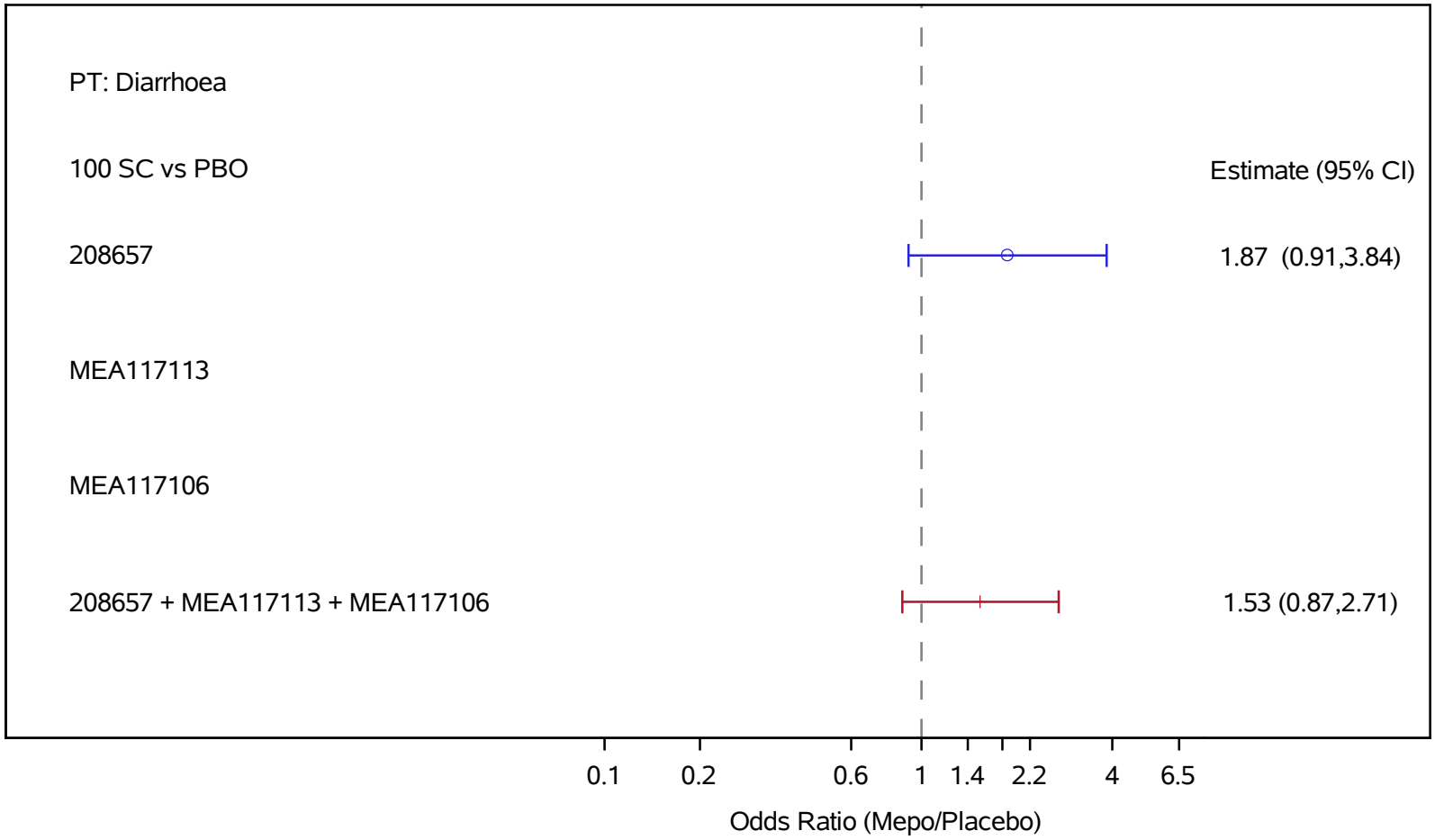


Horizontal bars indicate 95% confidence intervals for the Mepo/Placebo ratio.

Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Figure 311.1

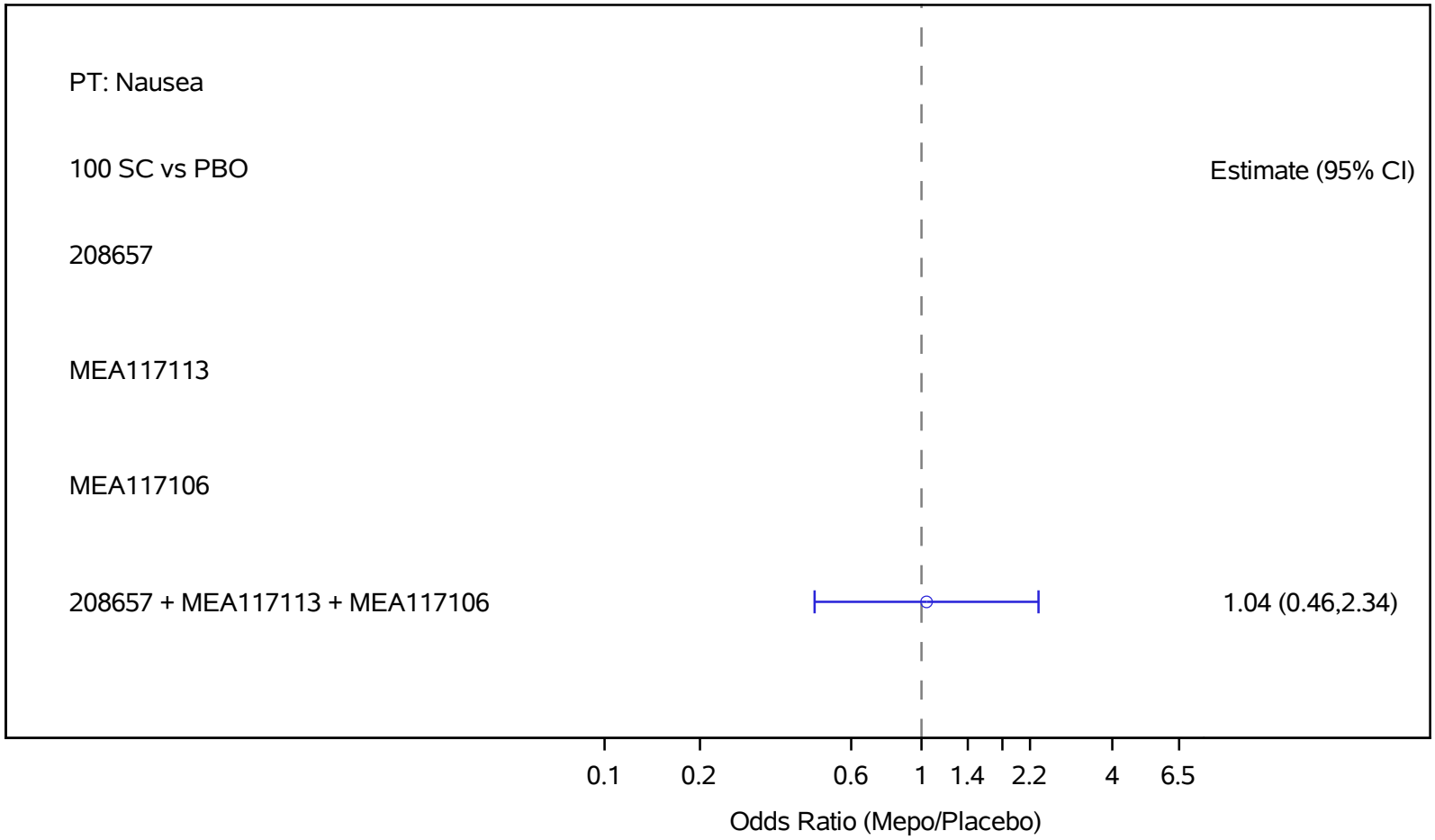
Forest Plot of Odds ratio for On-Treatment Adverse Events Occurring in >=10% of patients or in >=10 and >=1% of patients by SOC and PT: Individual Studies and Meta-Analysis



Horizontal bars indicate 95% confidence intervals for the Mepo/Placebo ratio.

Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Figure 311.1
Forest Plot of Odds ratio for On-Treatment Adverse Events Occurring in >=10% of patients or in >=10 and >=1% of patients by SOC and PT: Individual Studies and Meta-Analysis



Horizontal bars indicate 95% confidence intervals for the Mepo/Placebo ratio.
/mnt/code/postcsr_01/prod/tfls/f_s_ae_onae_or.sas 17JUL2025 18:09

Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

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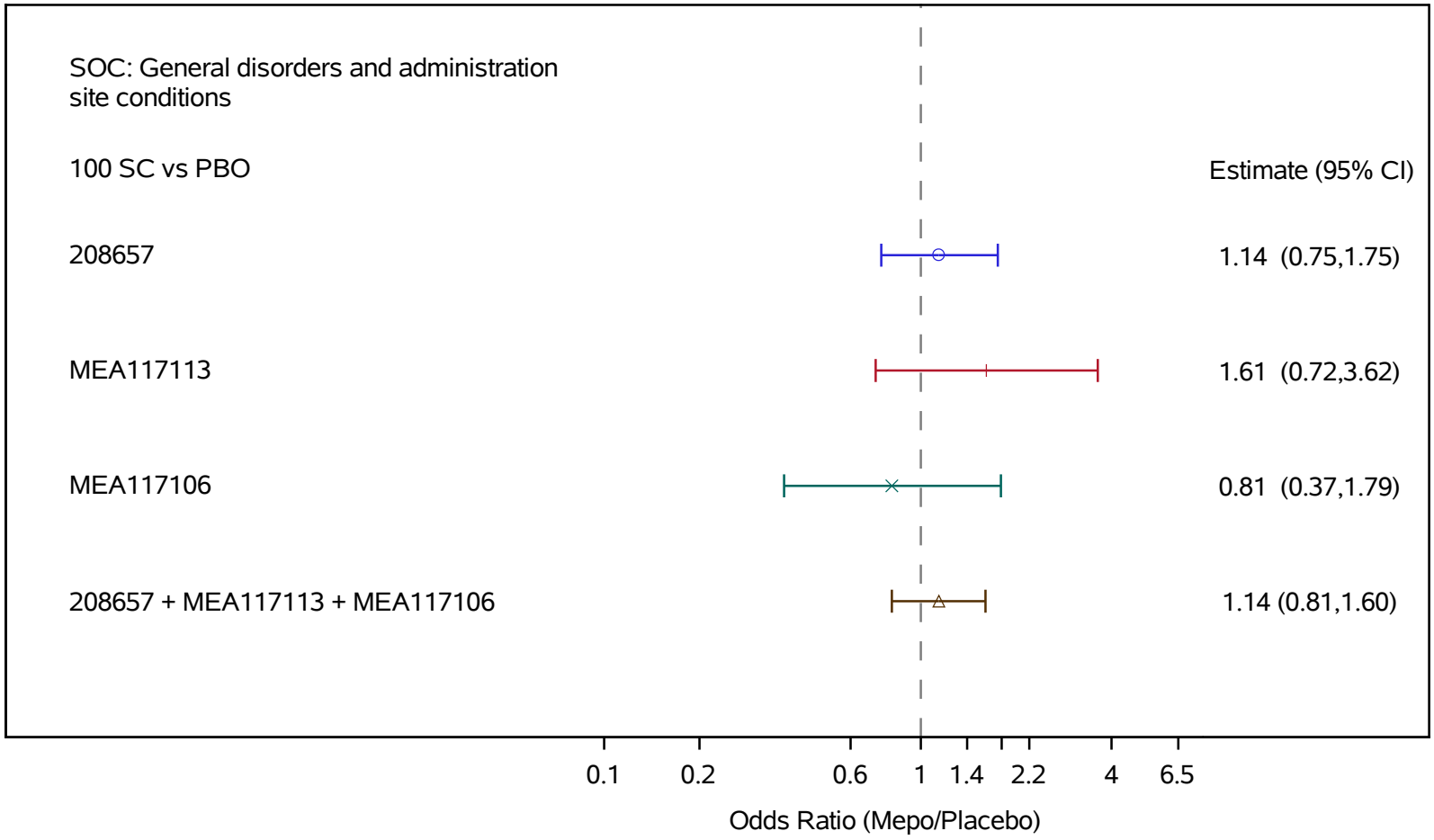

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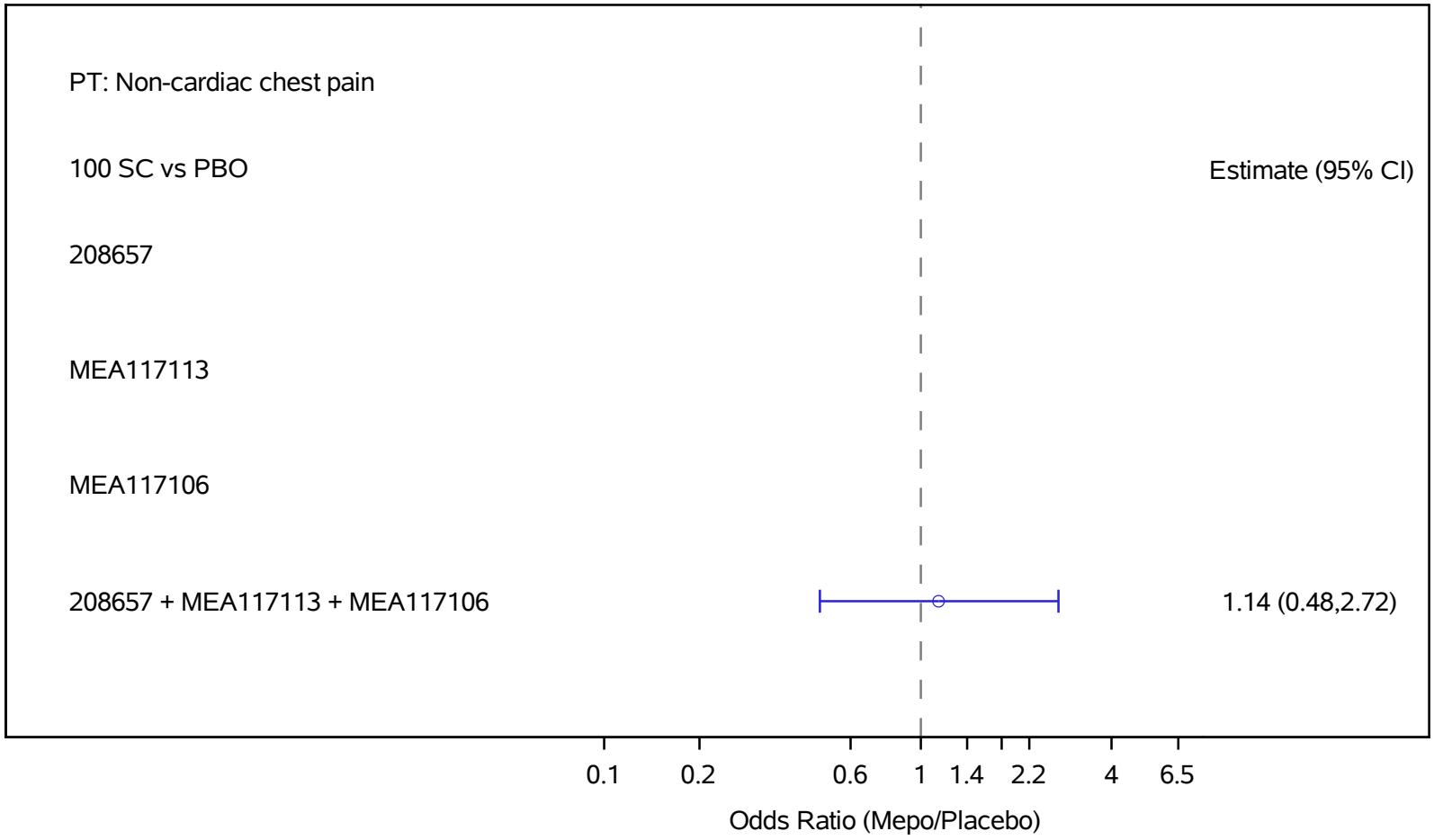

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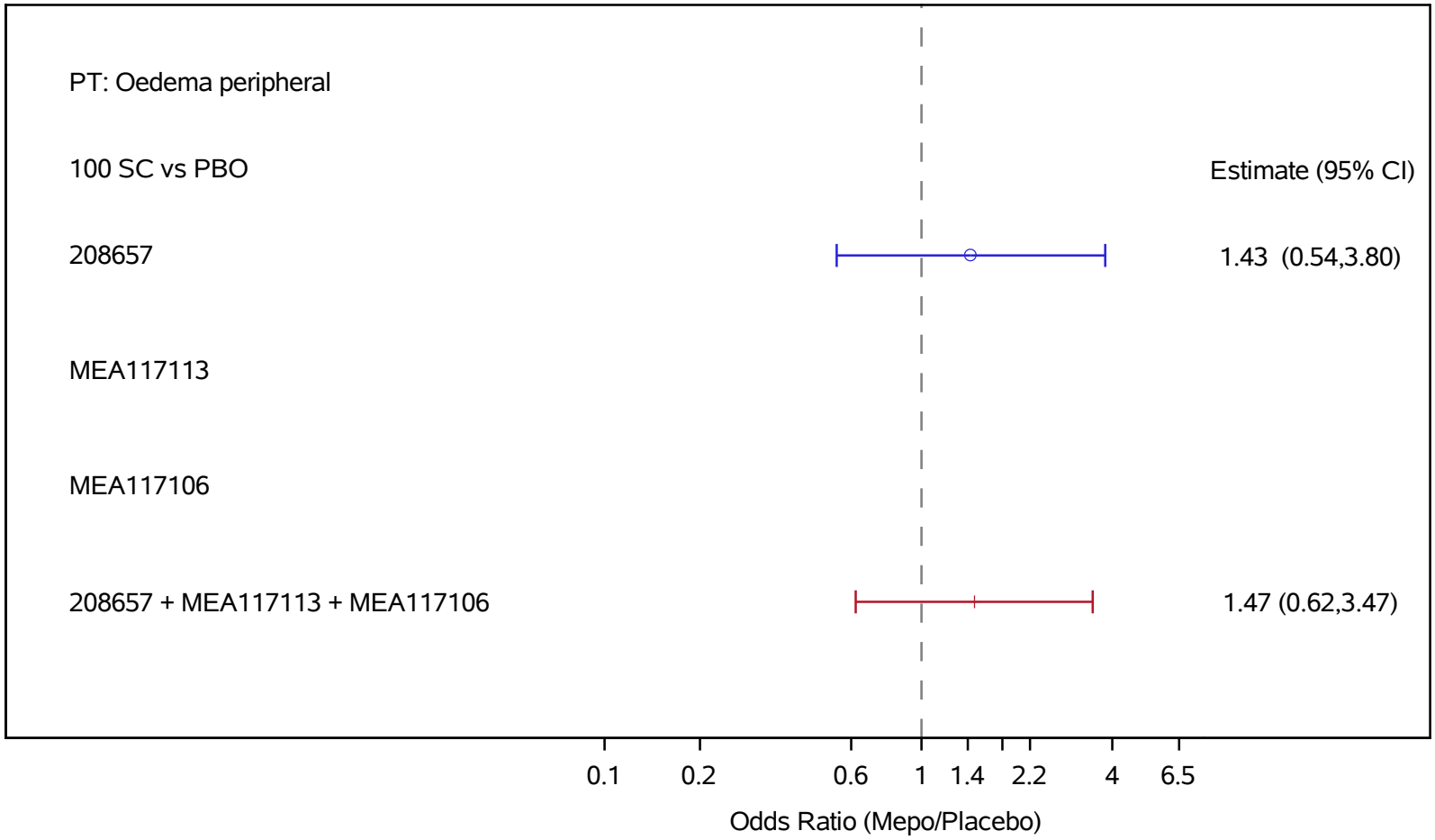

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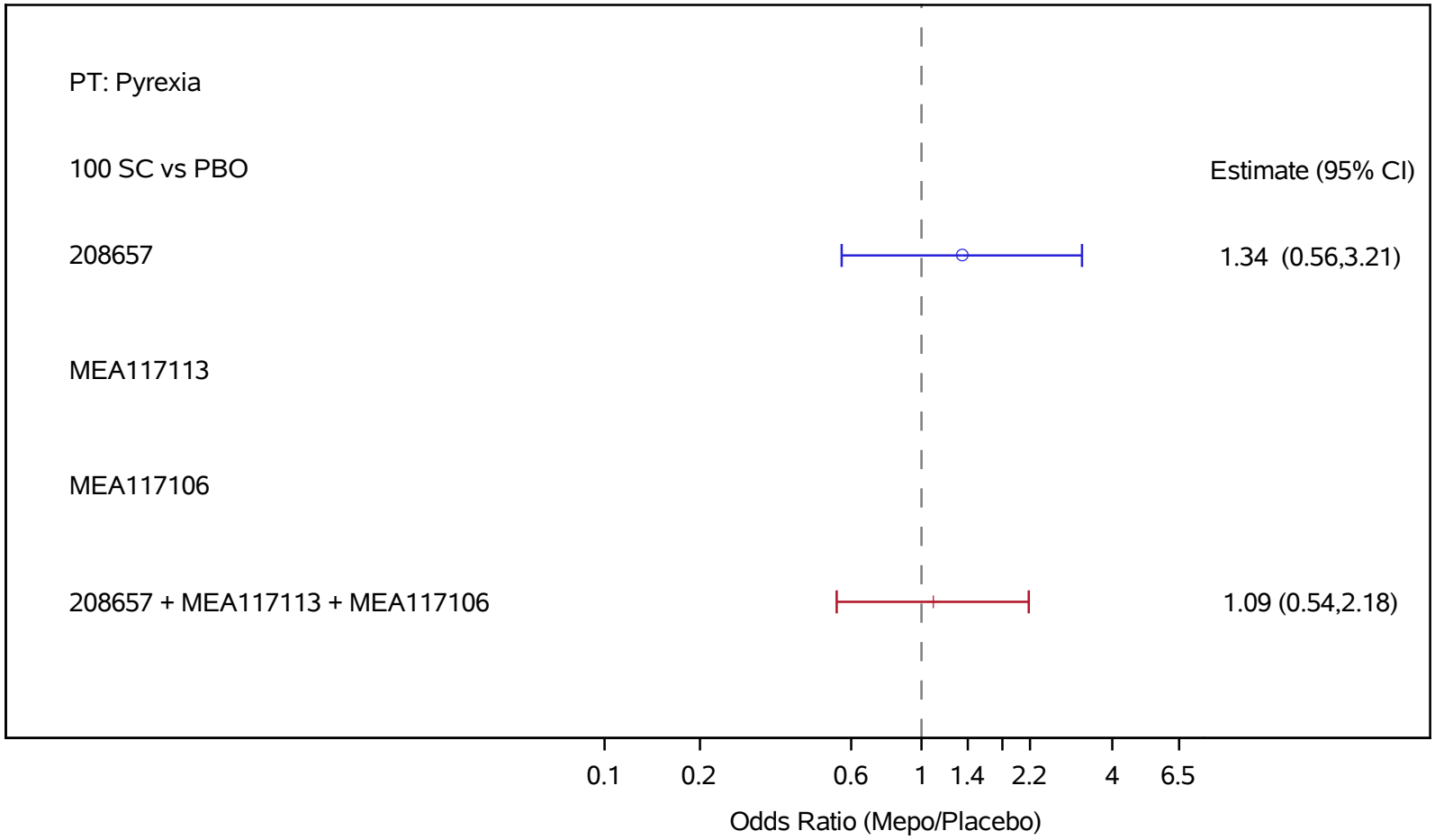

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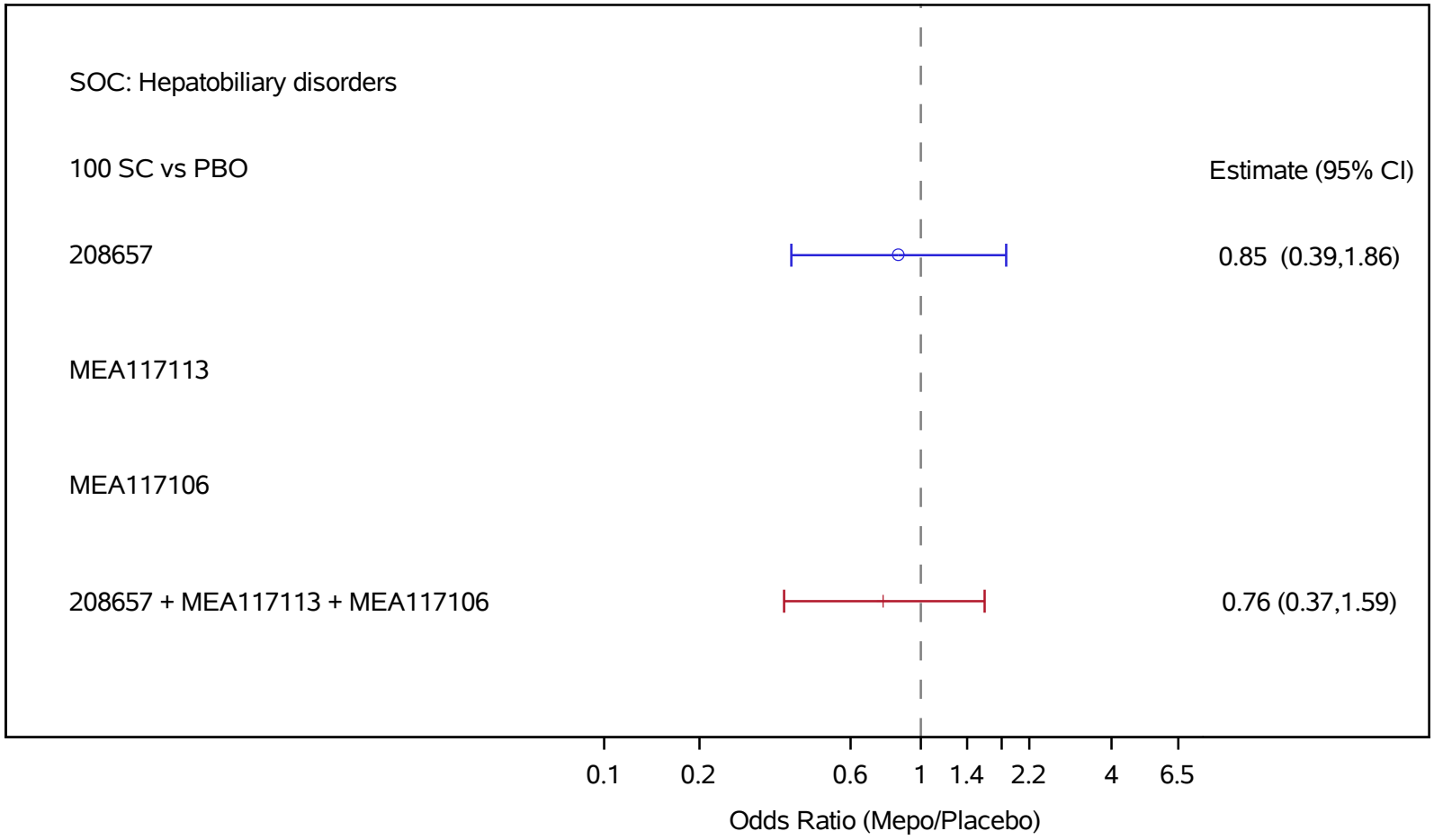

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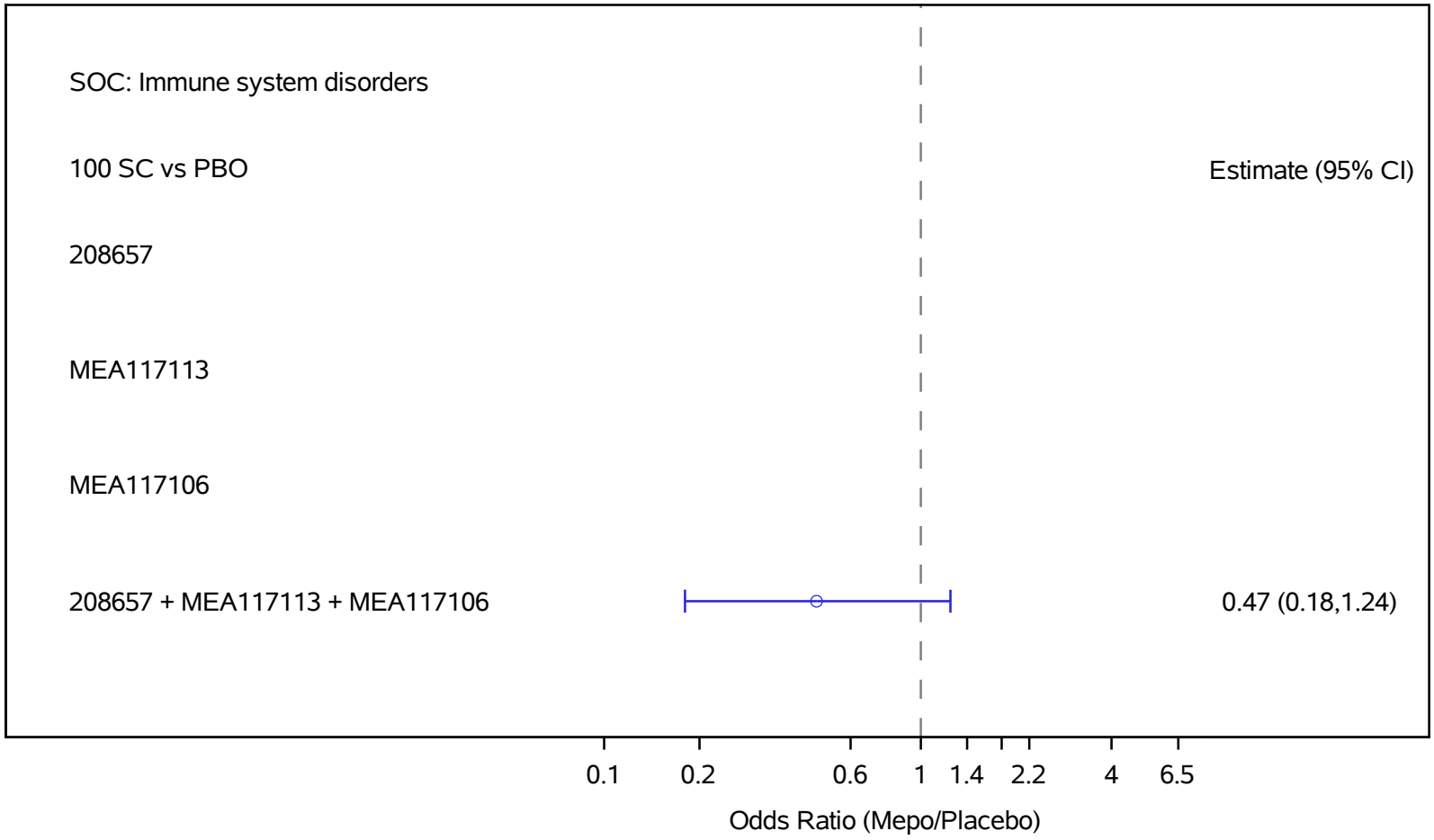

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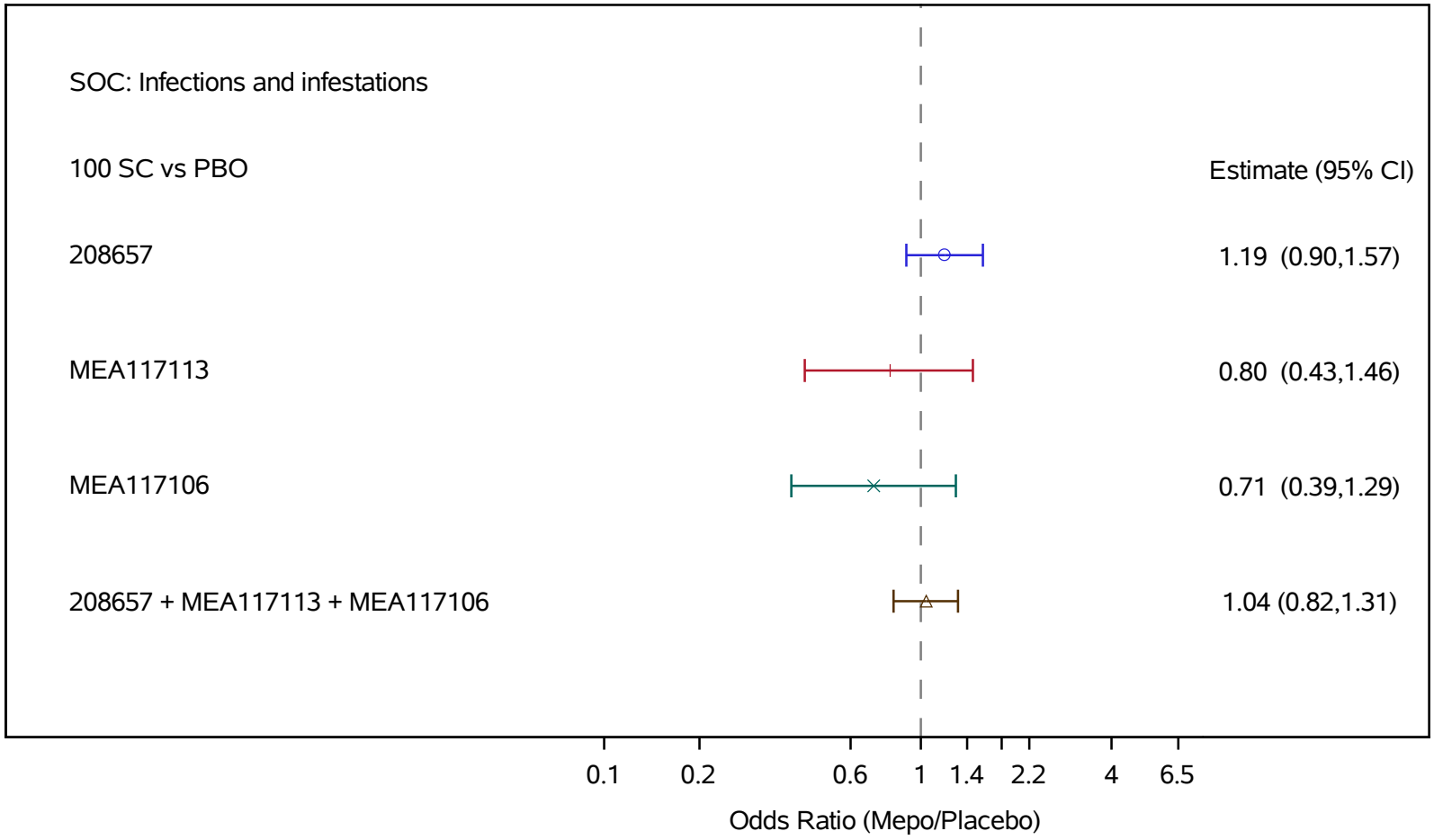

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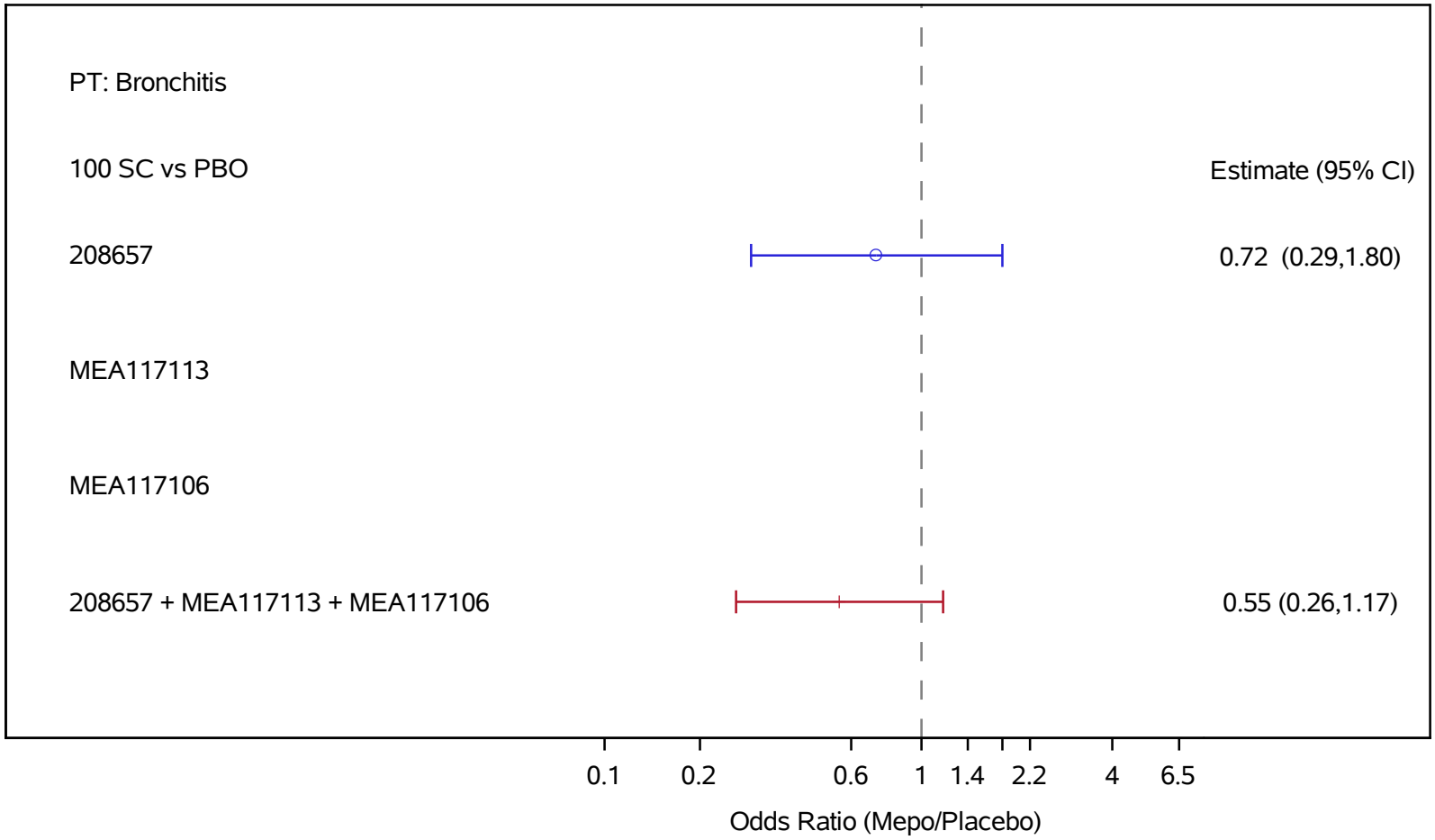

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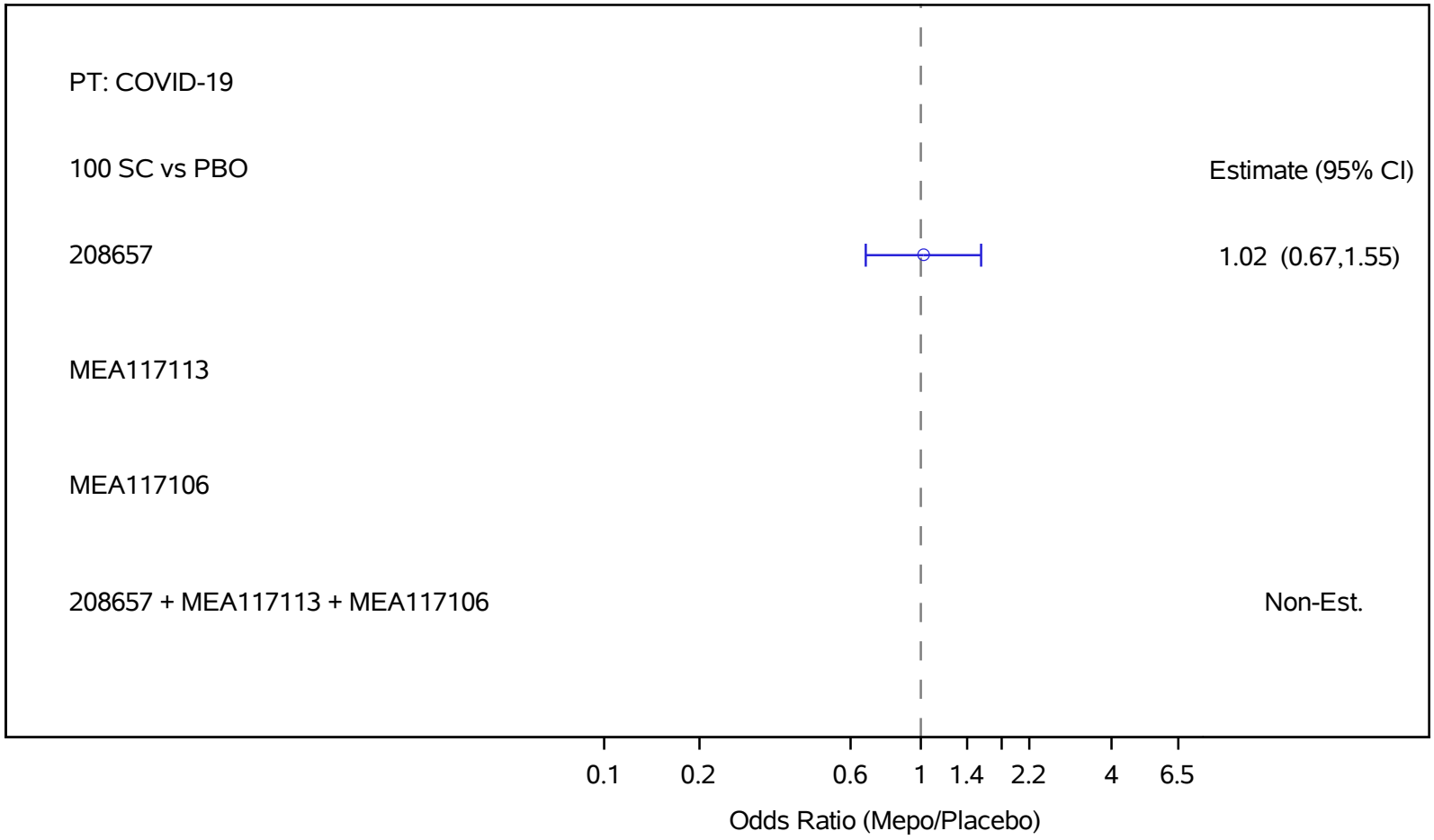

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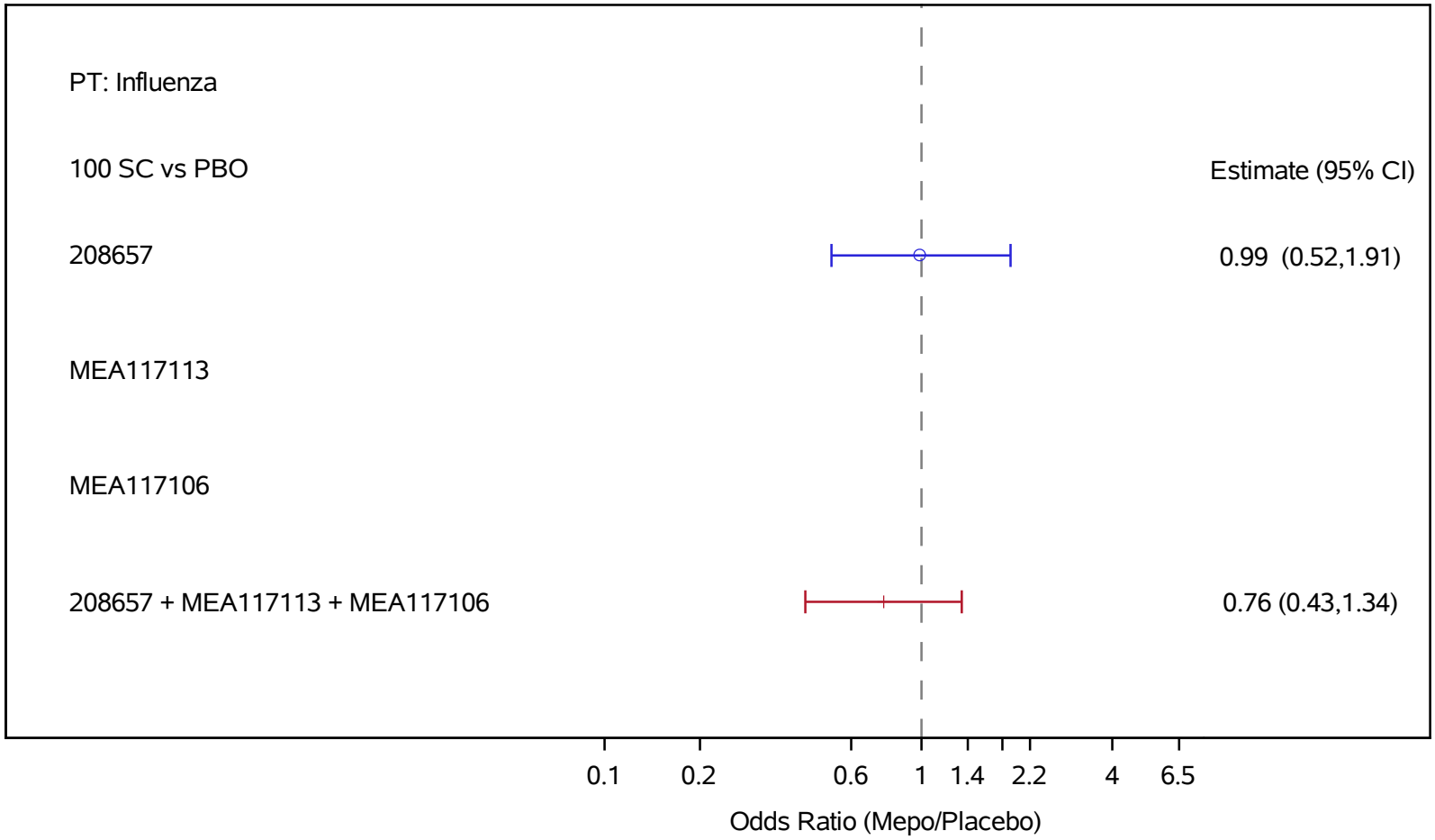

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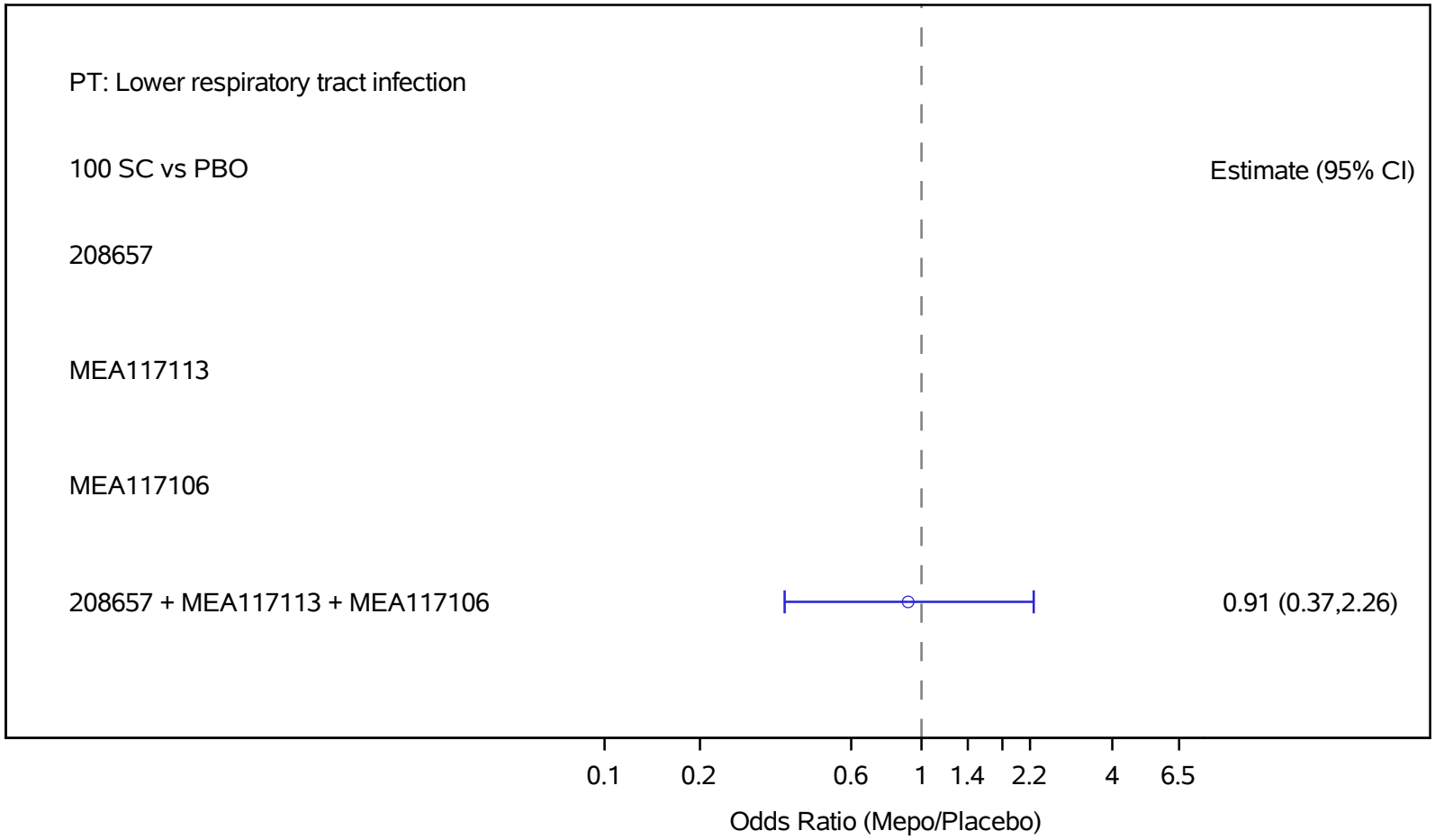

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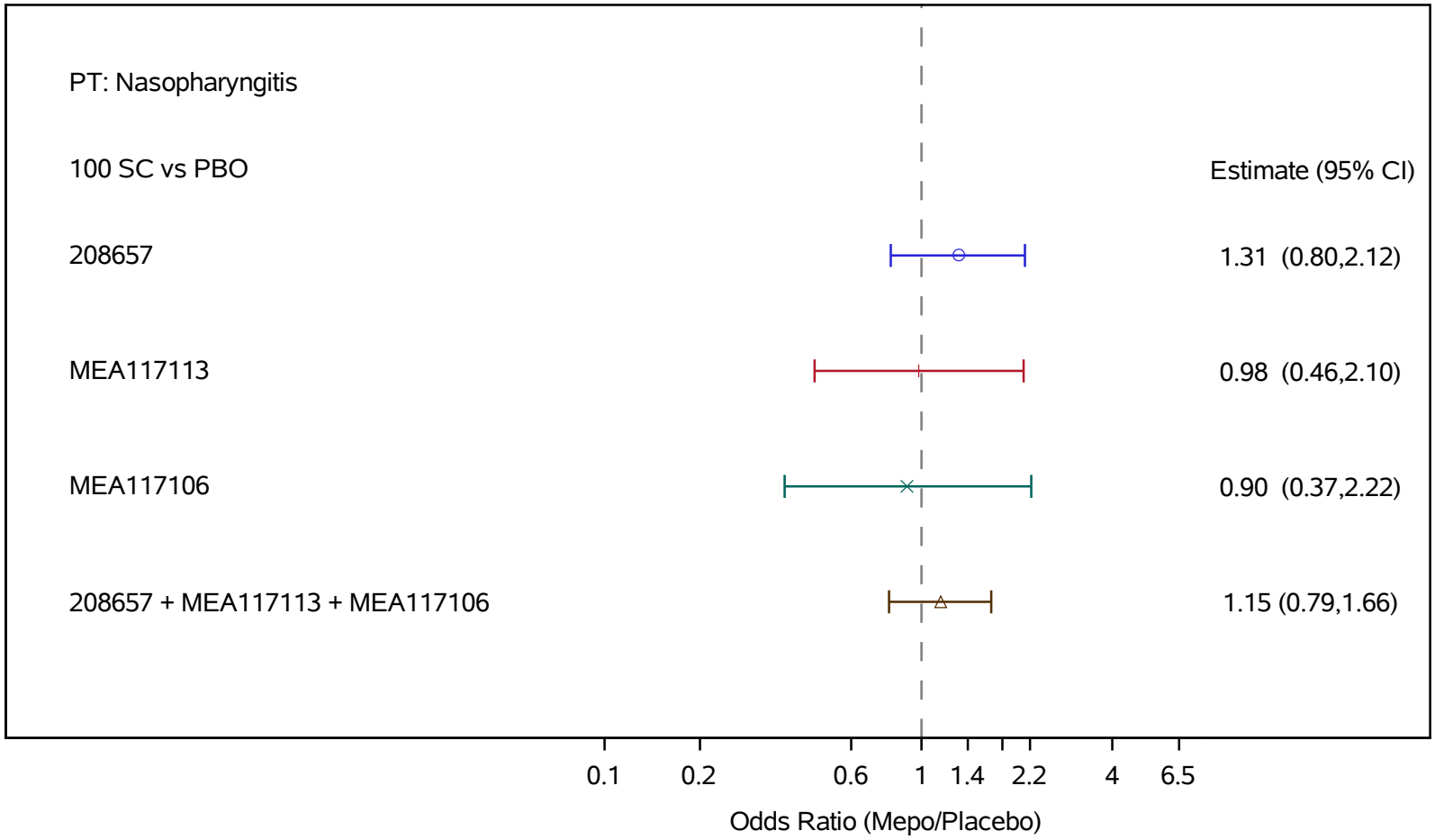

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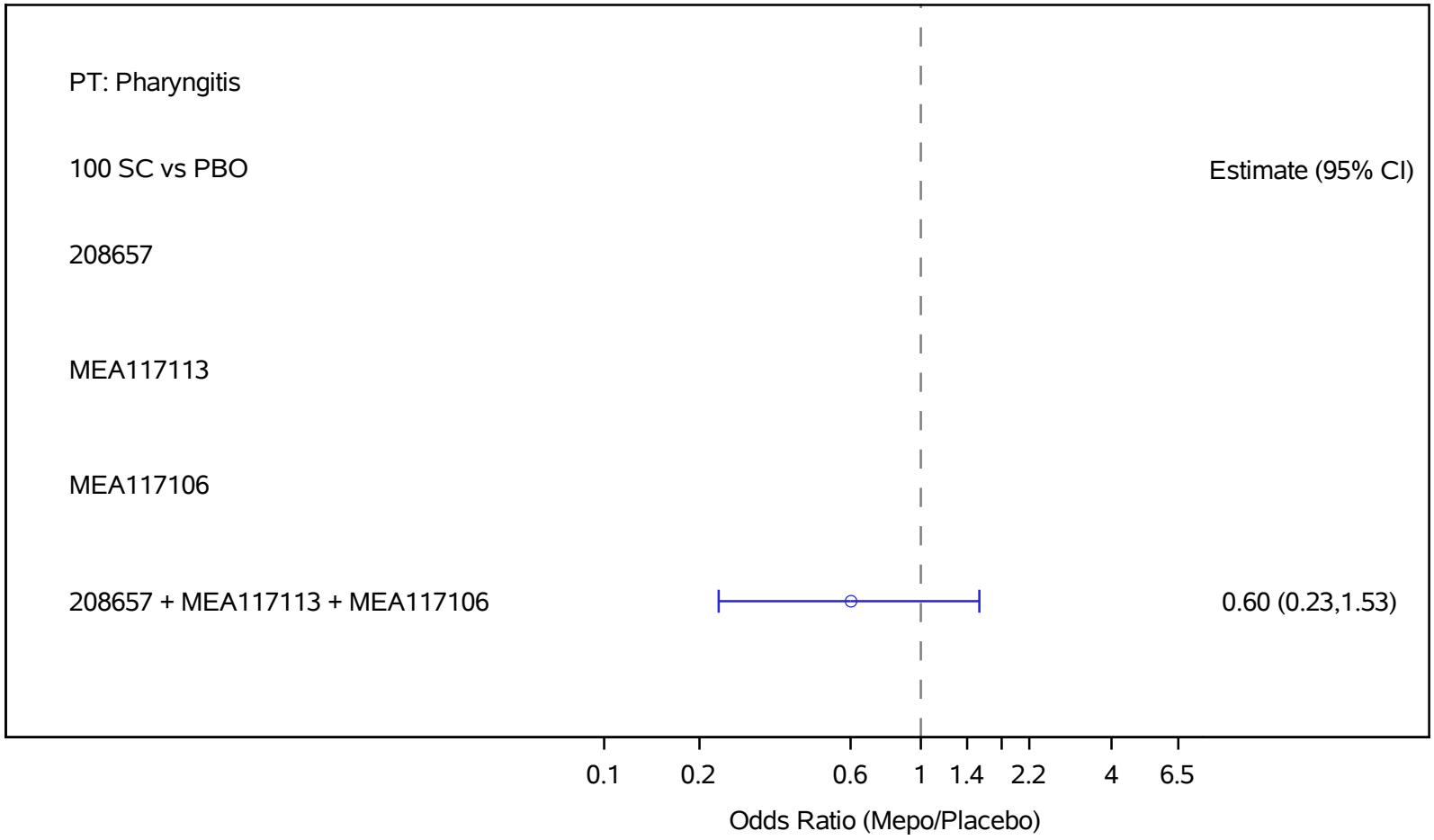

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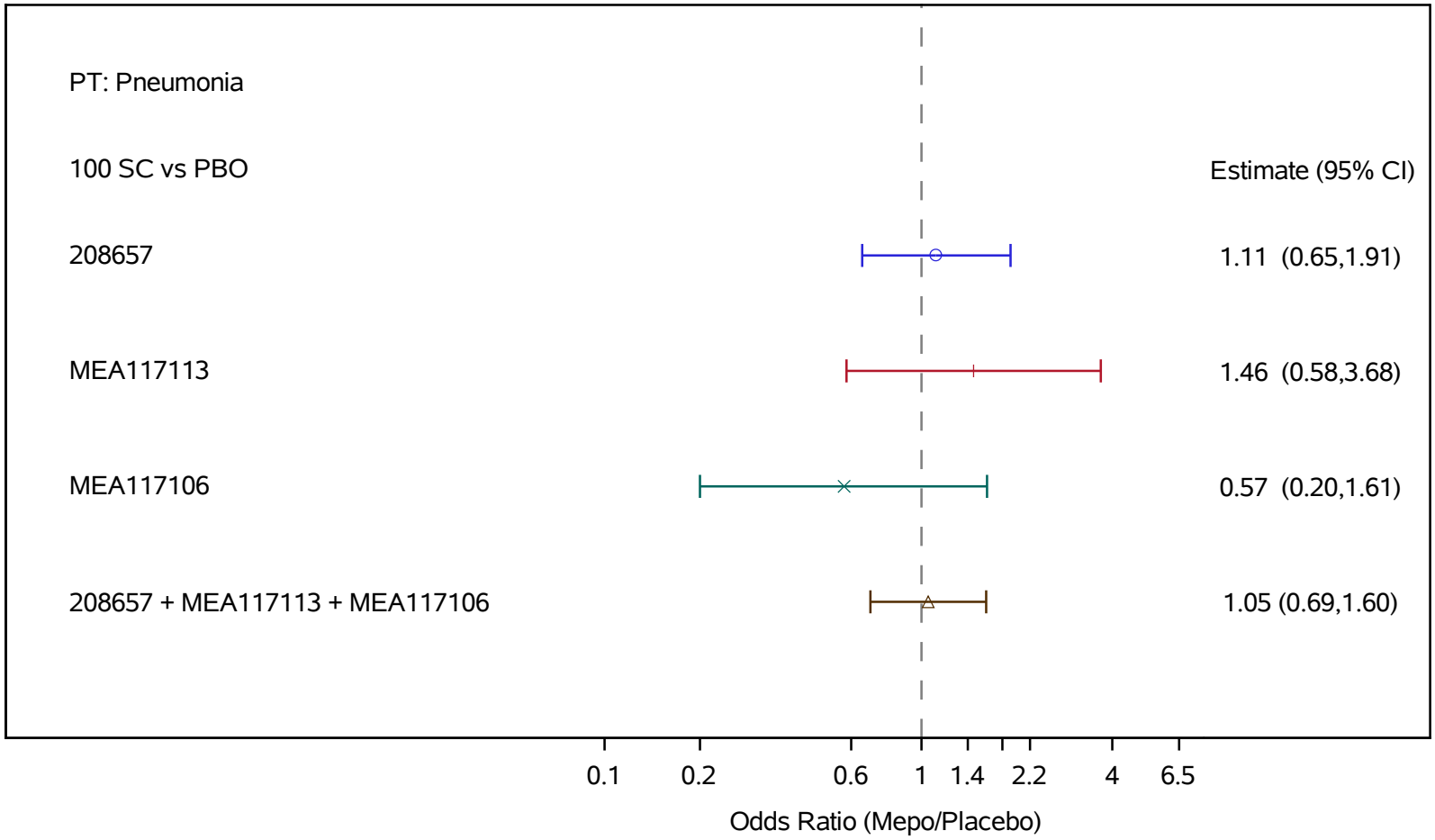

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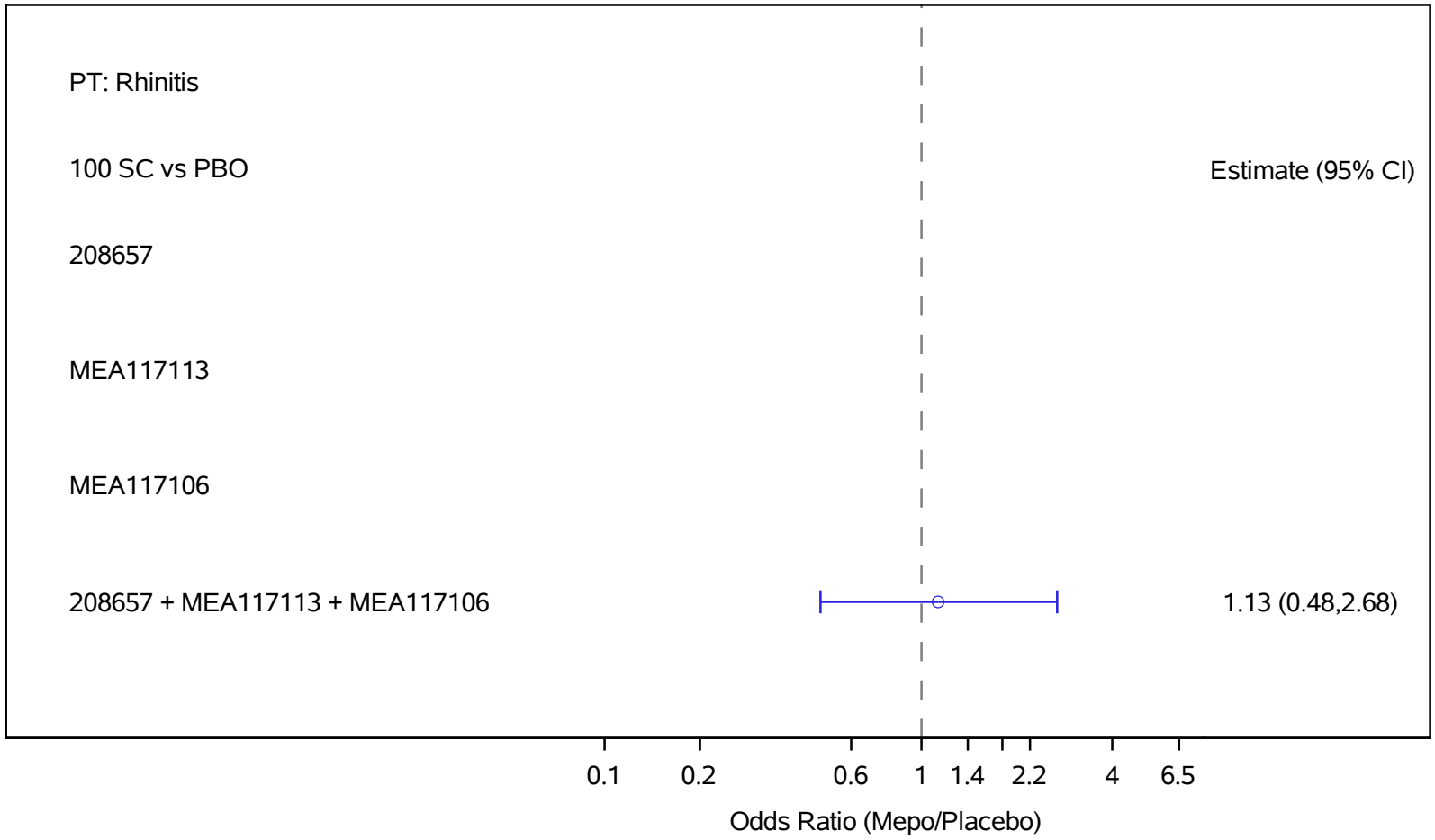

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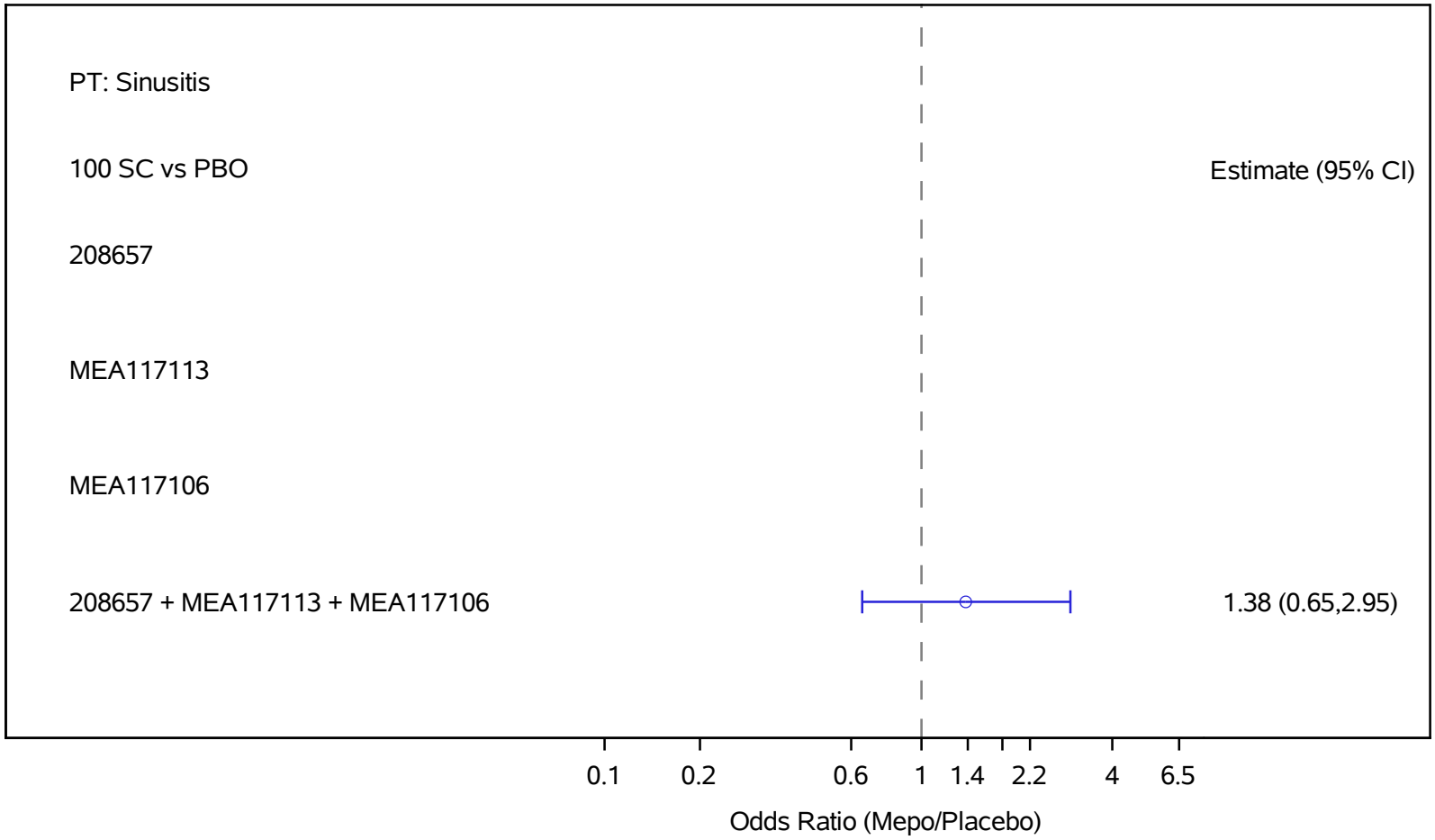

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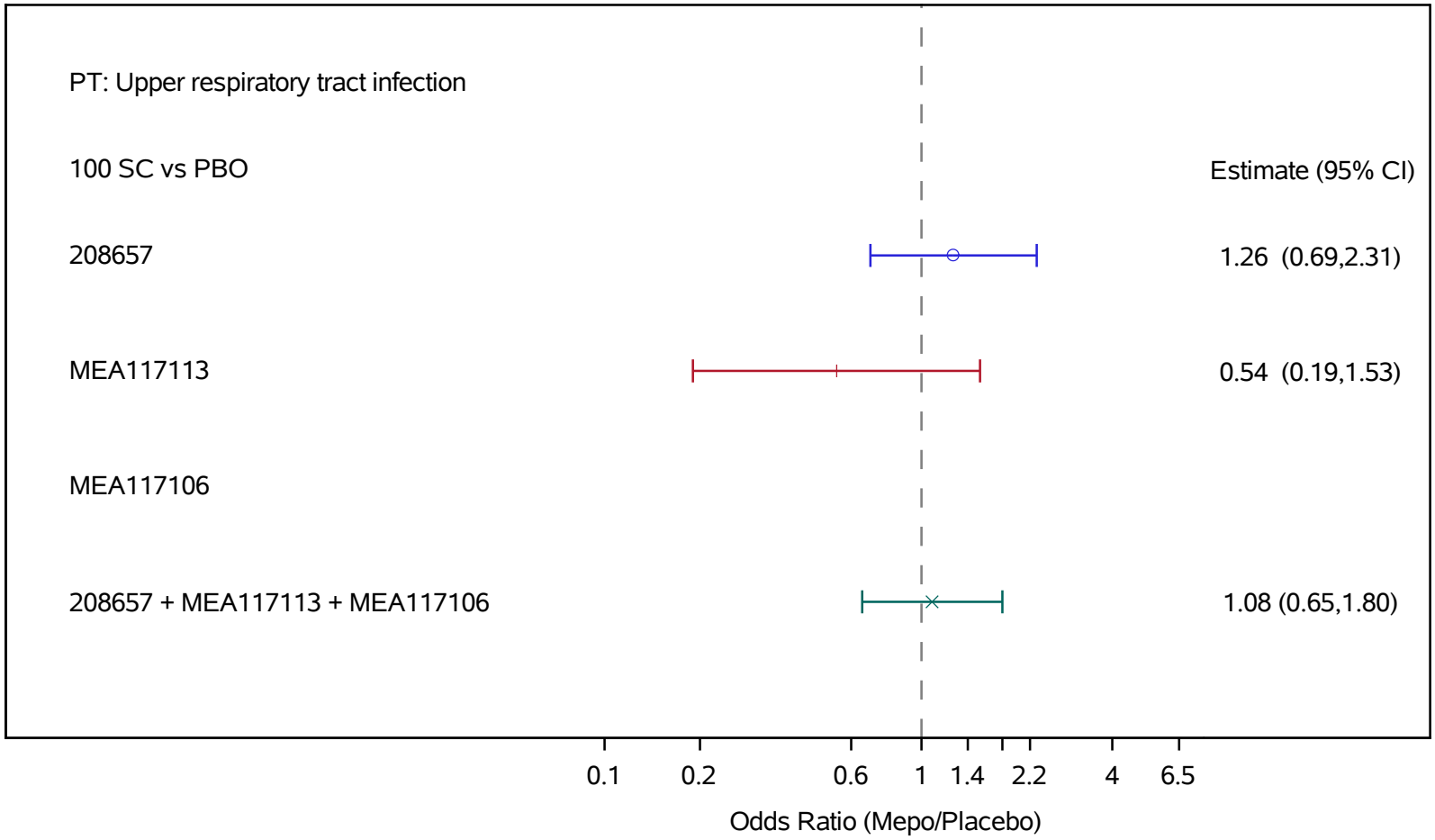

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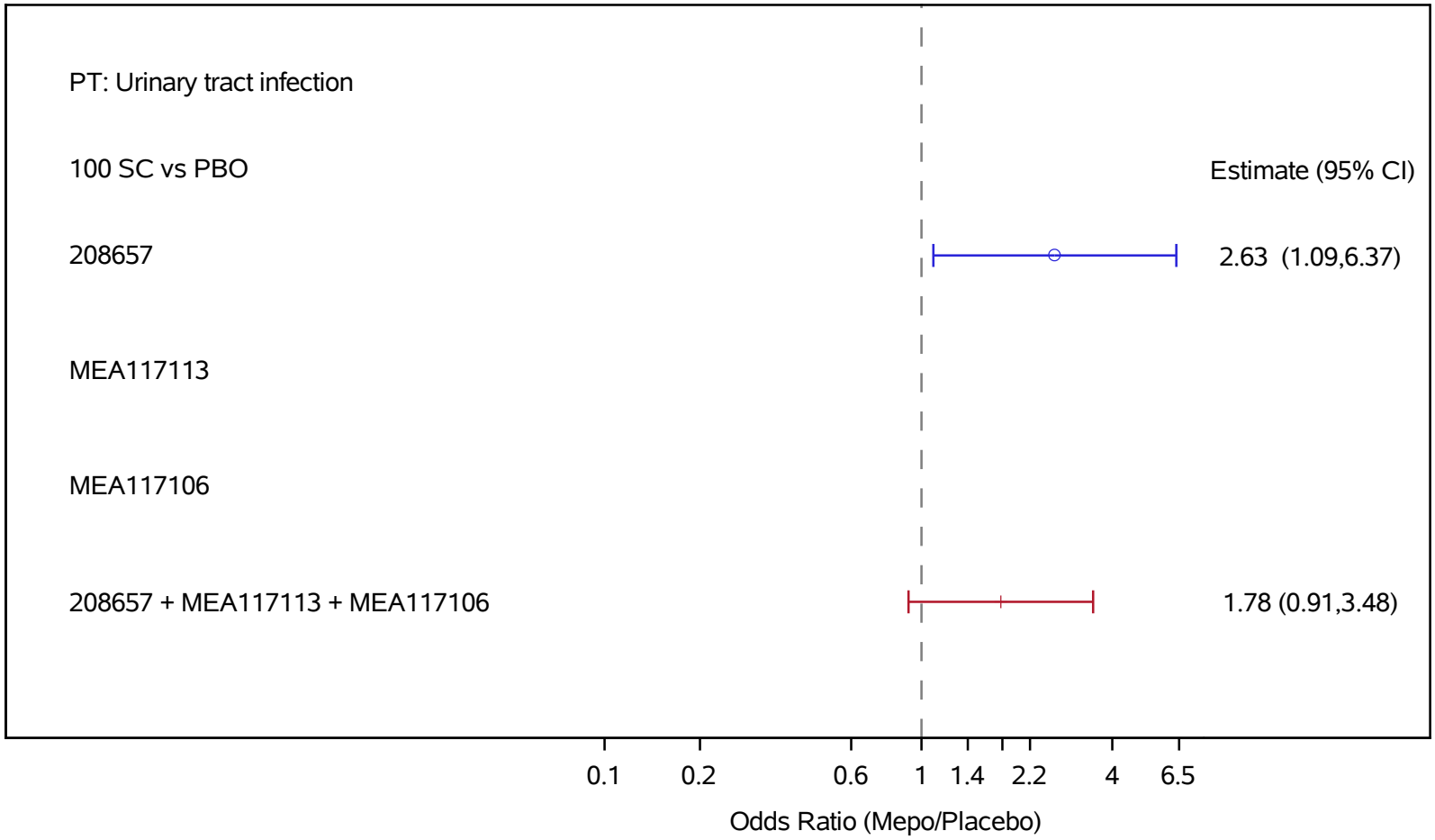

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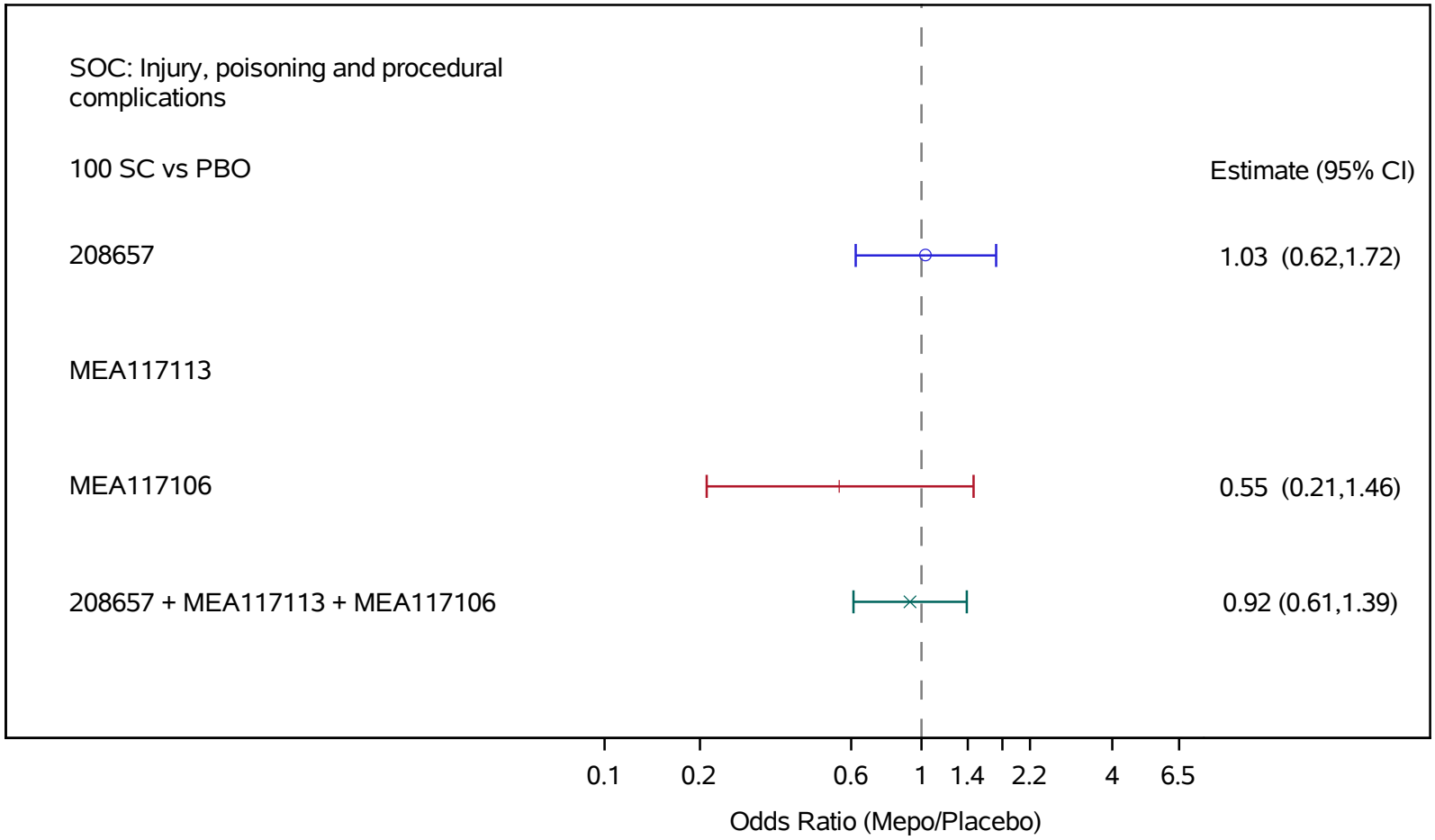

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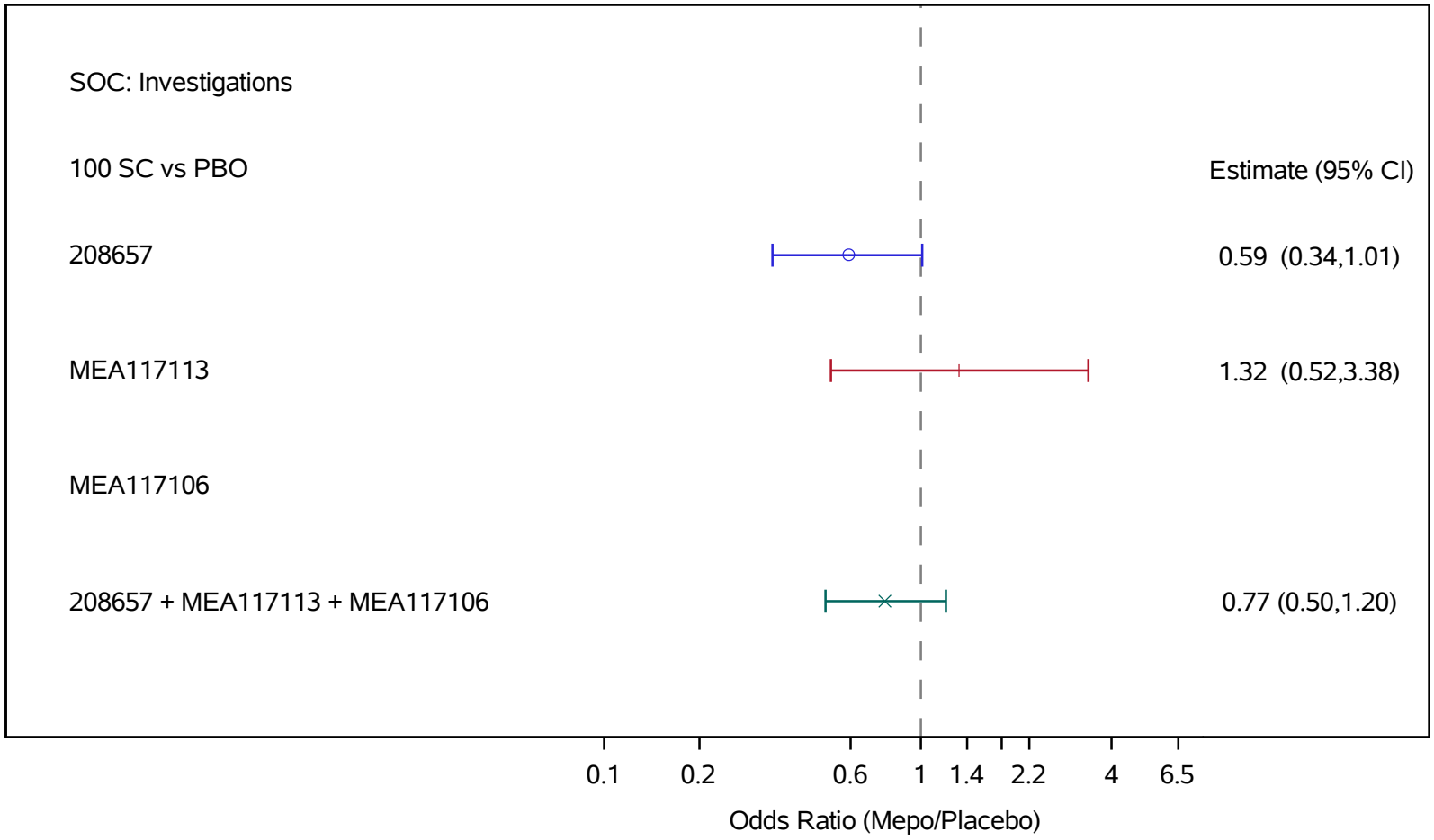

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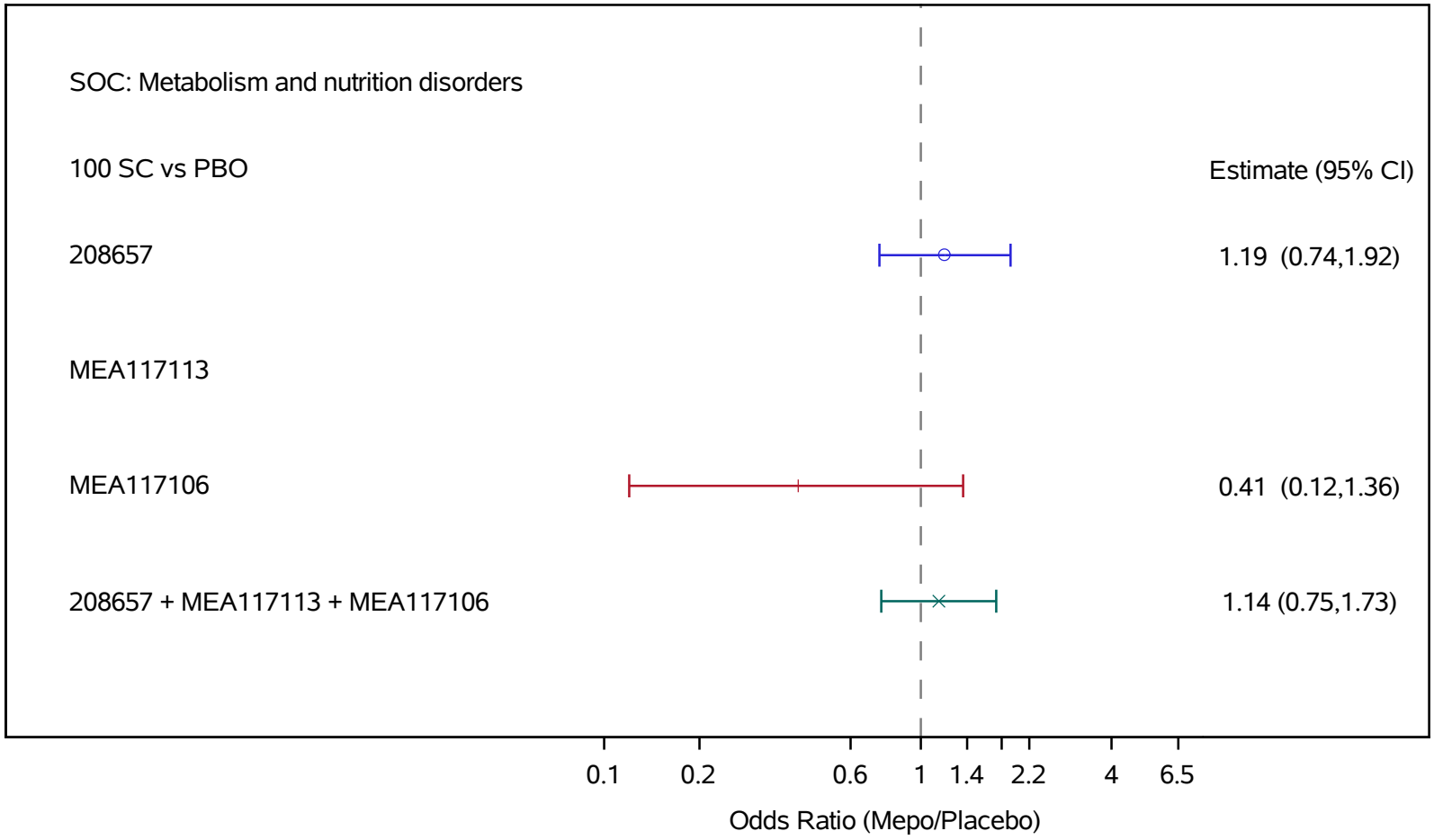

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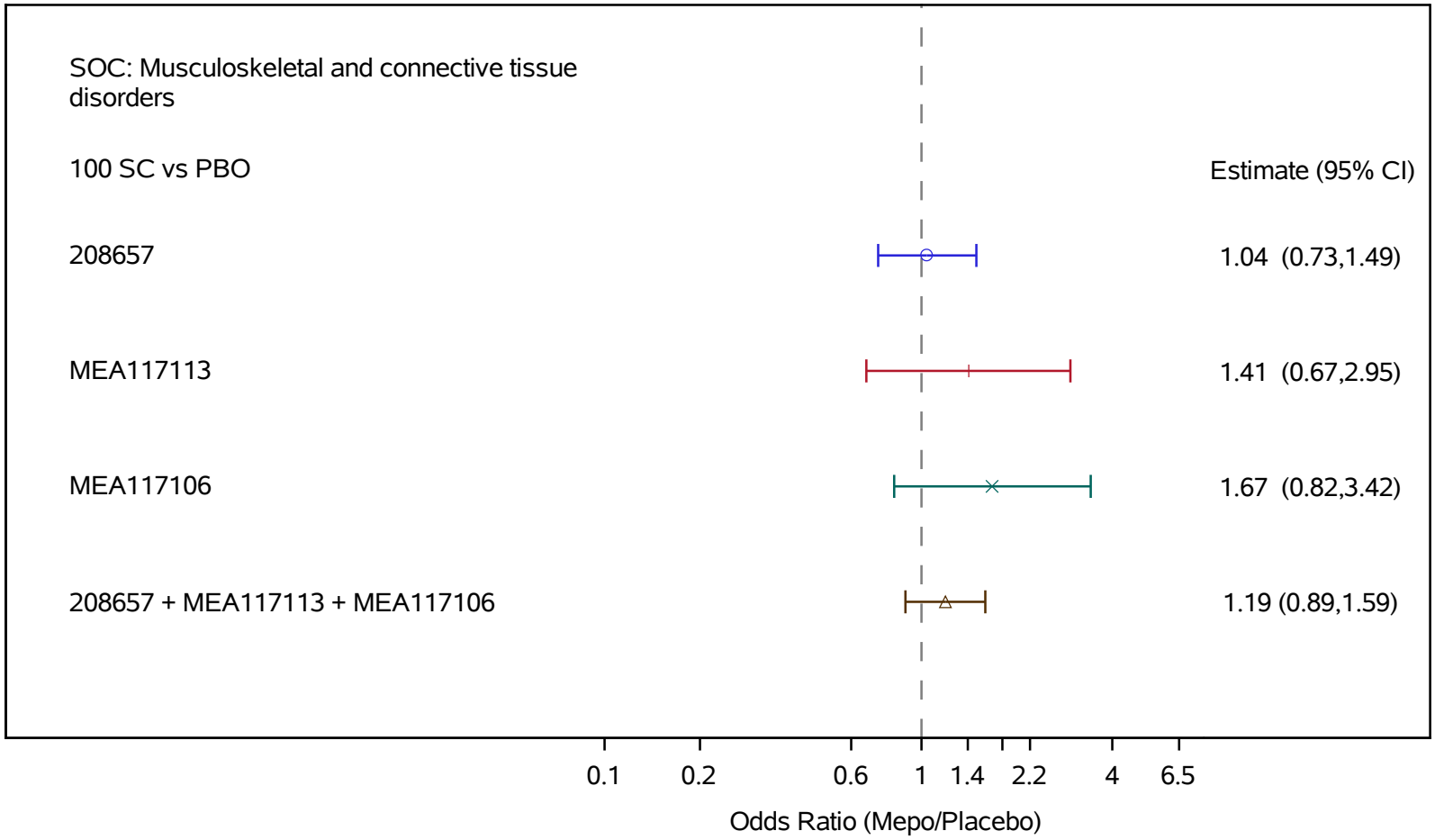

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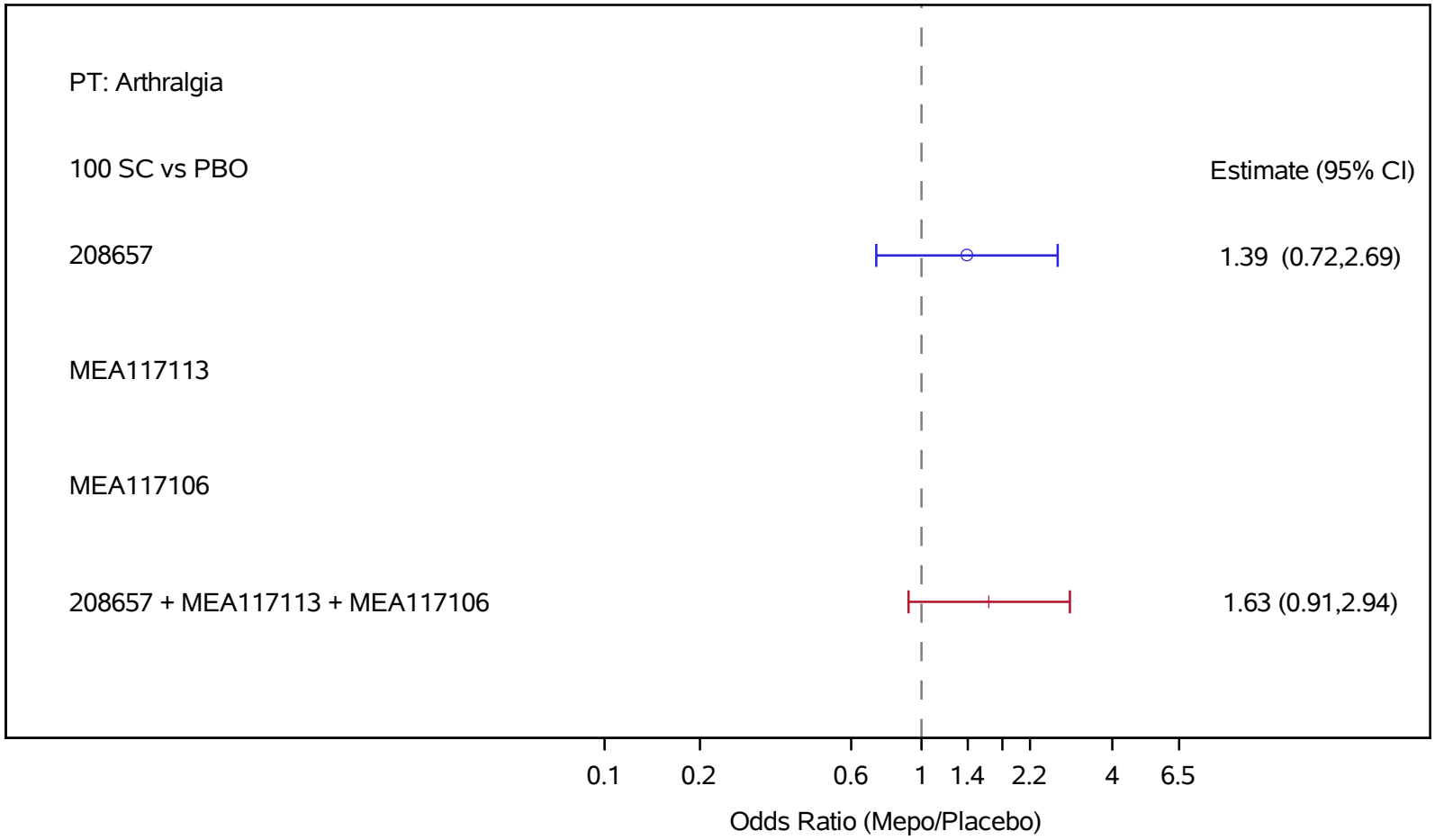

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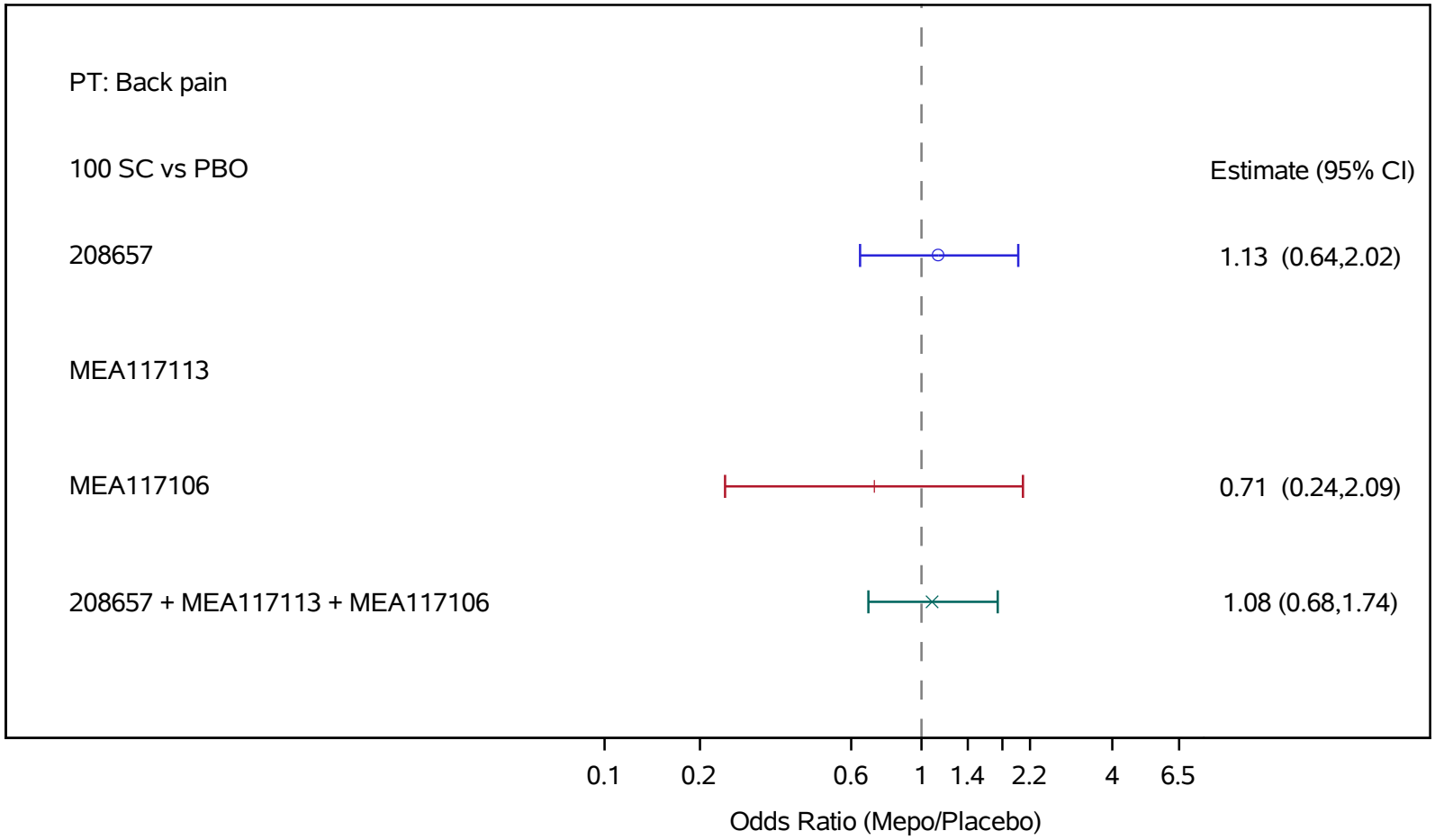

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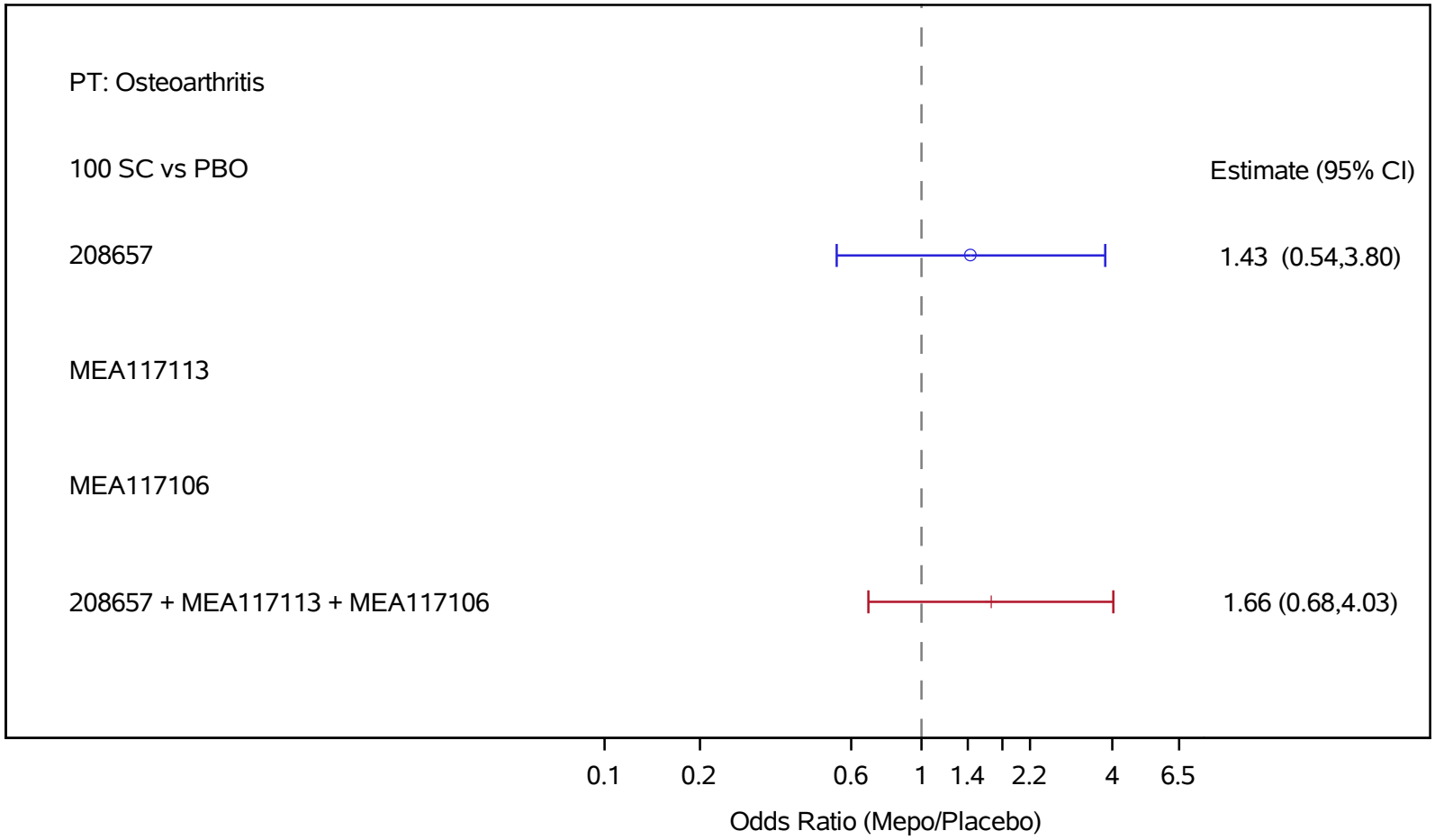

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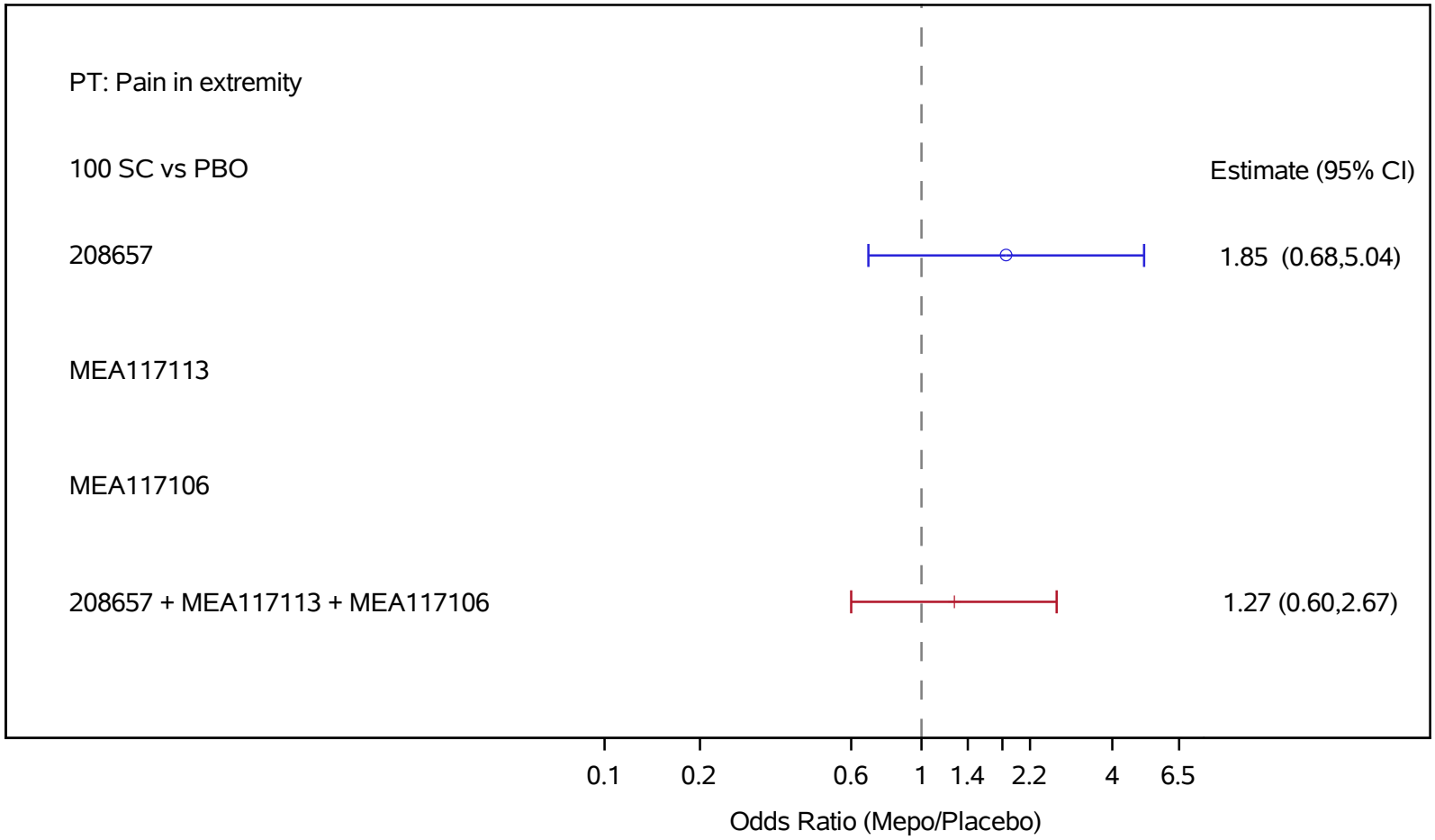

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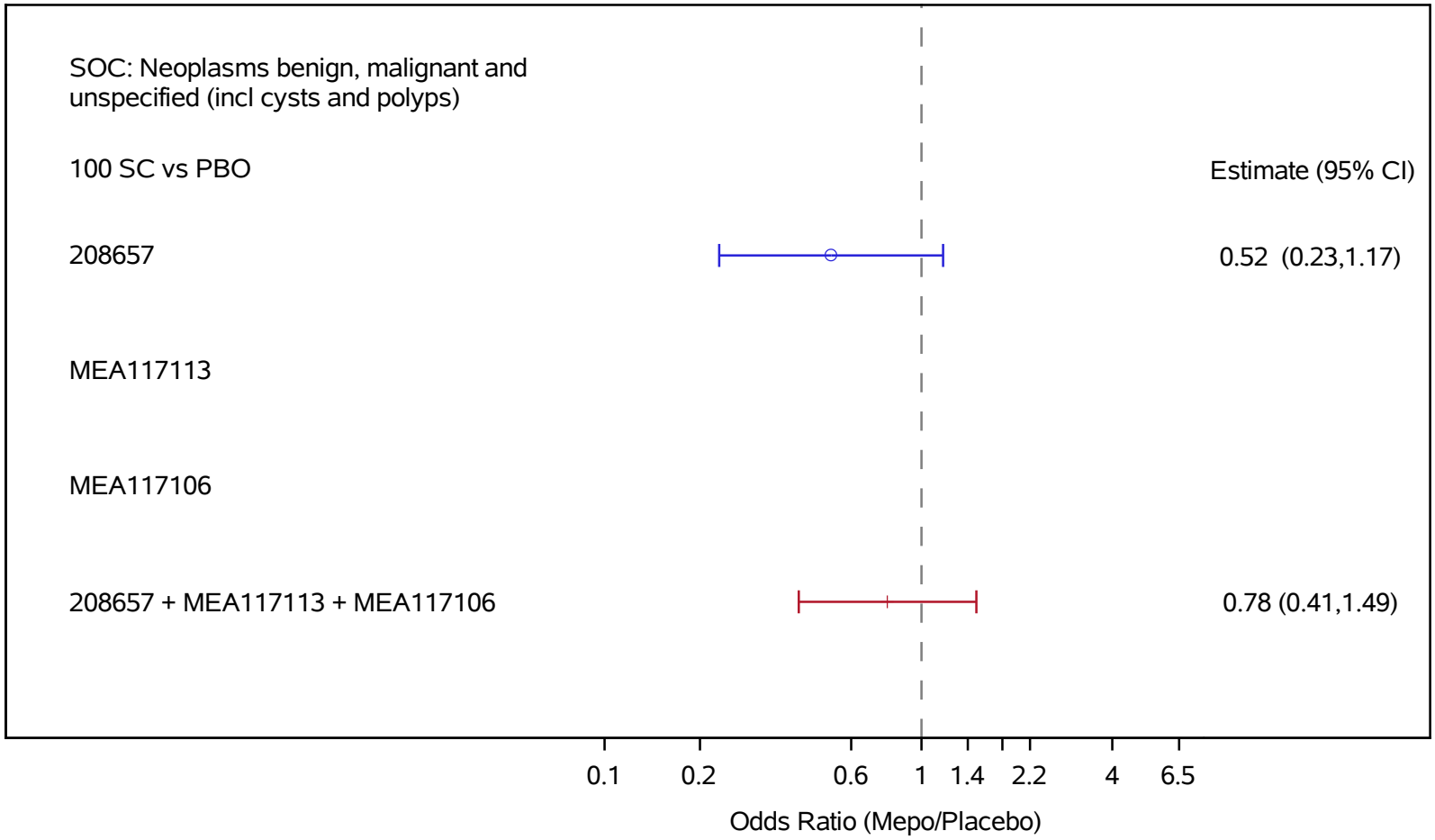

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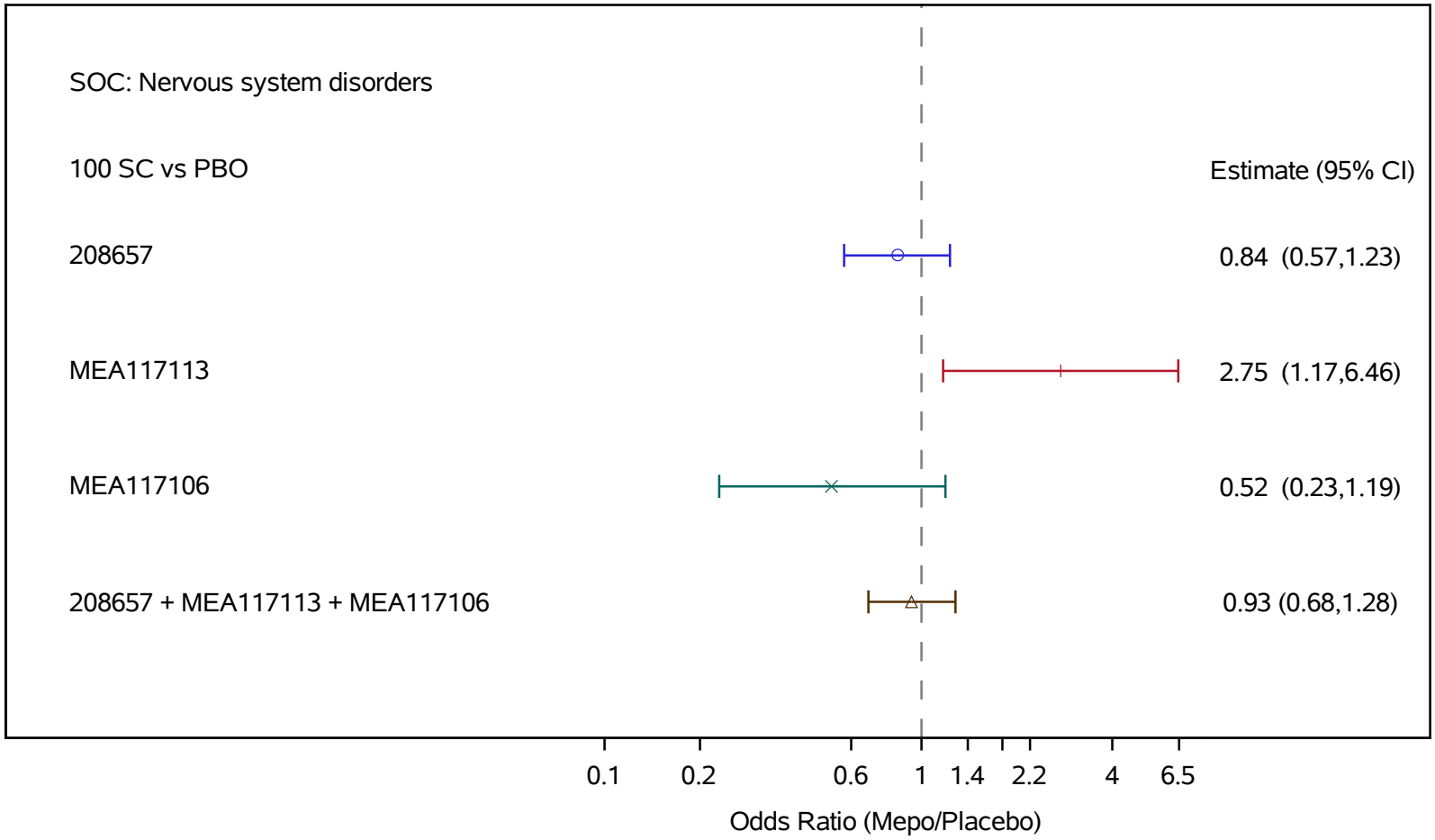

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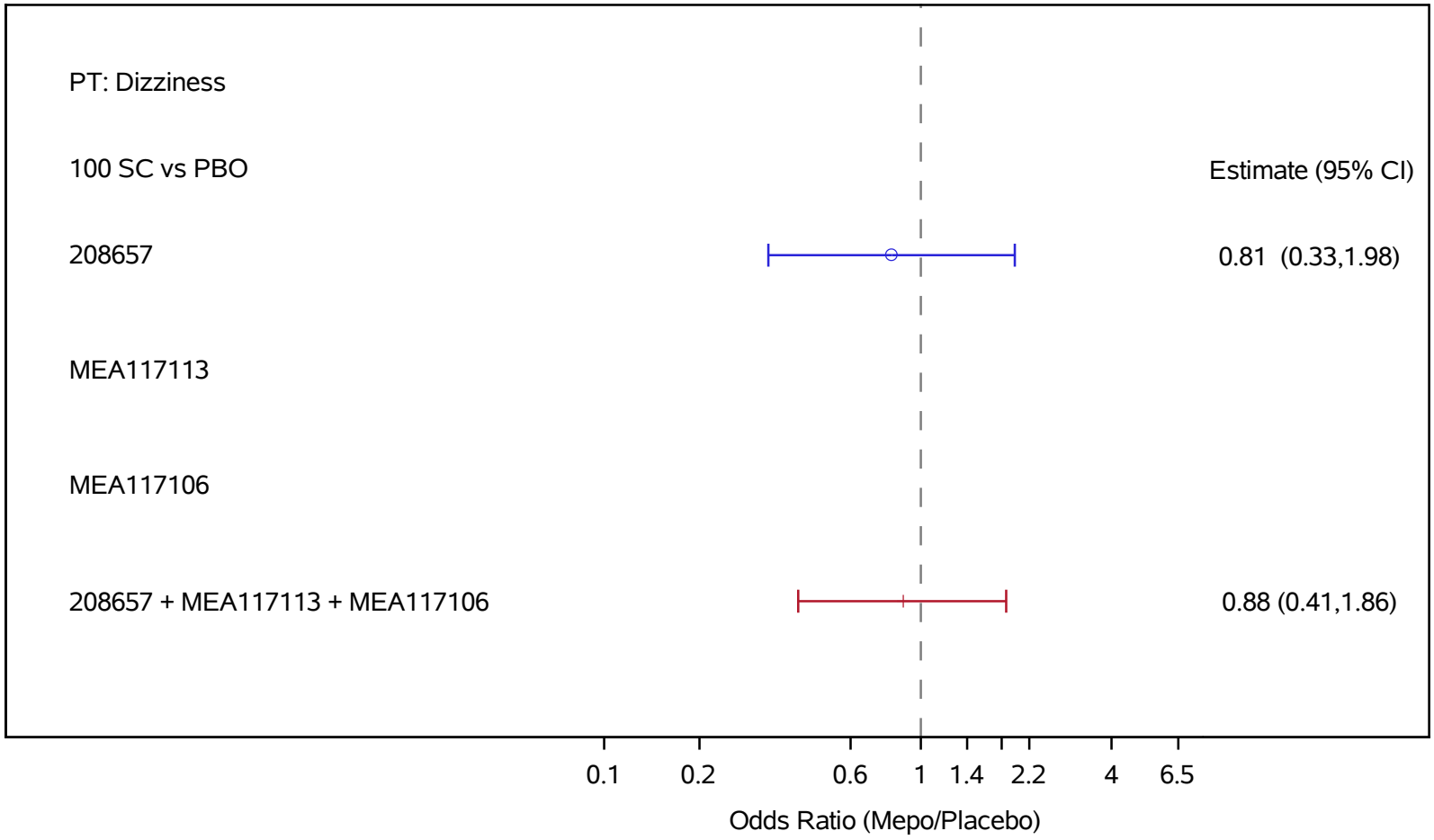

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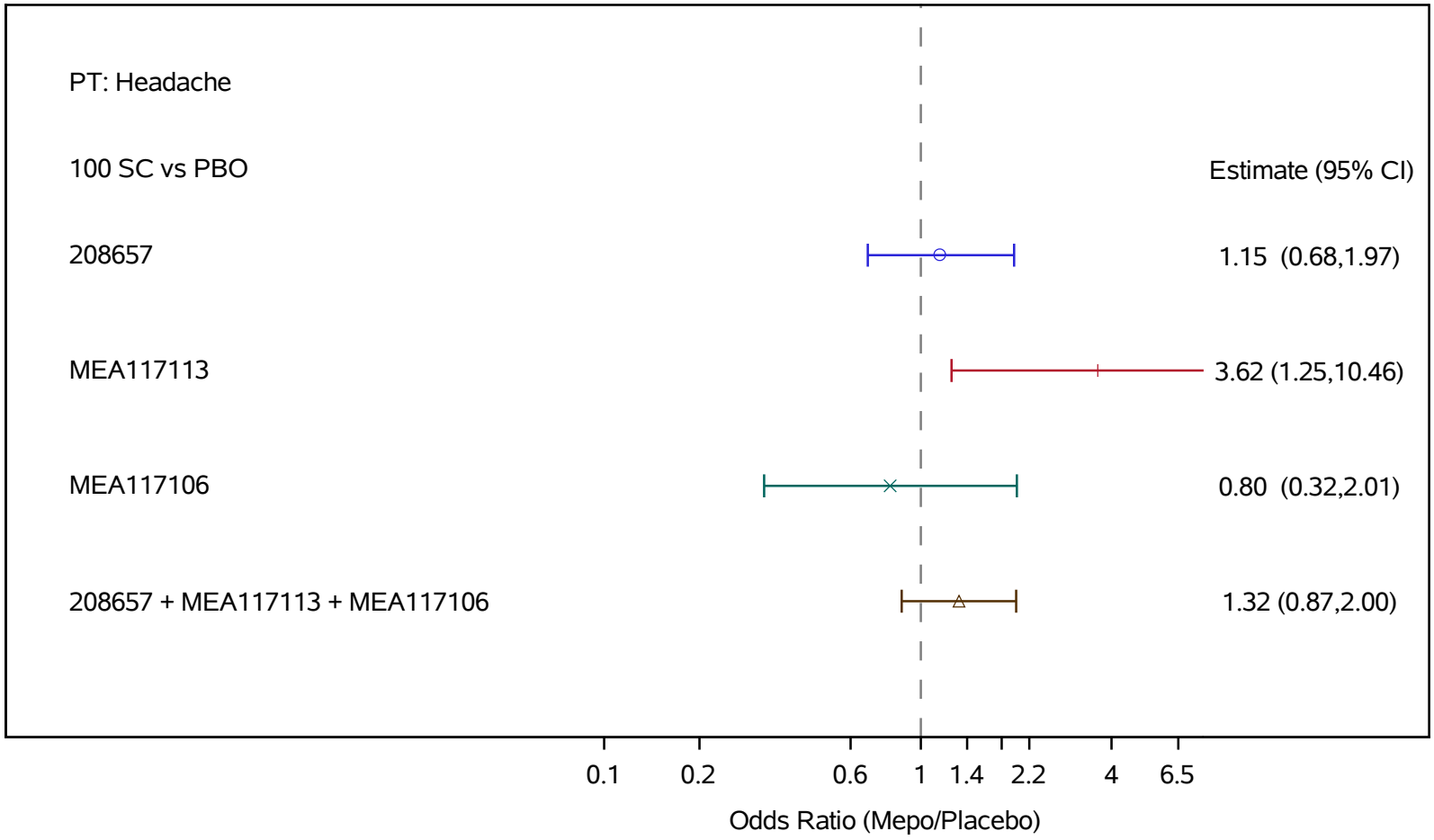

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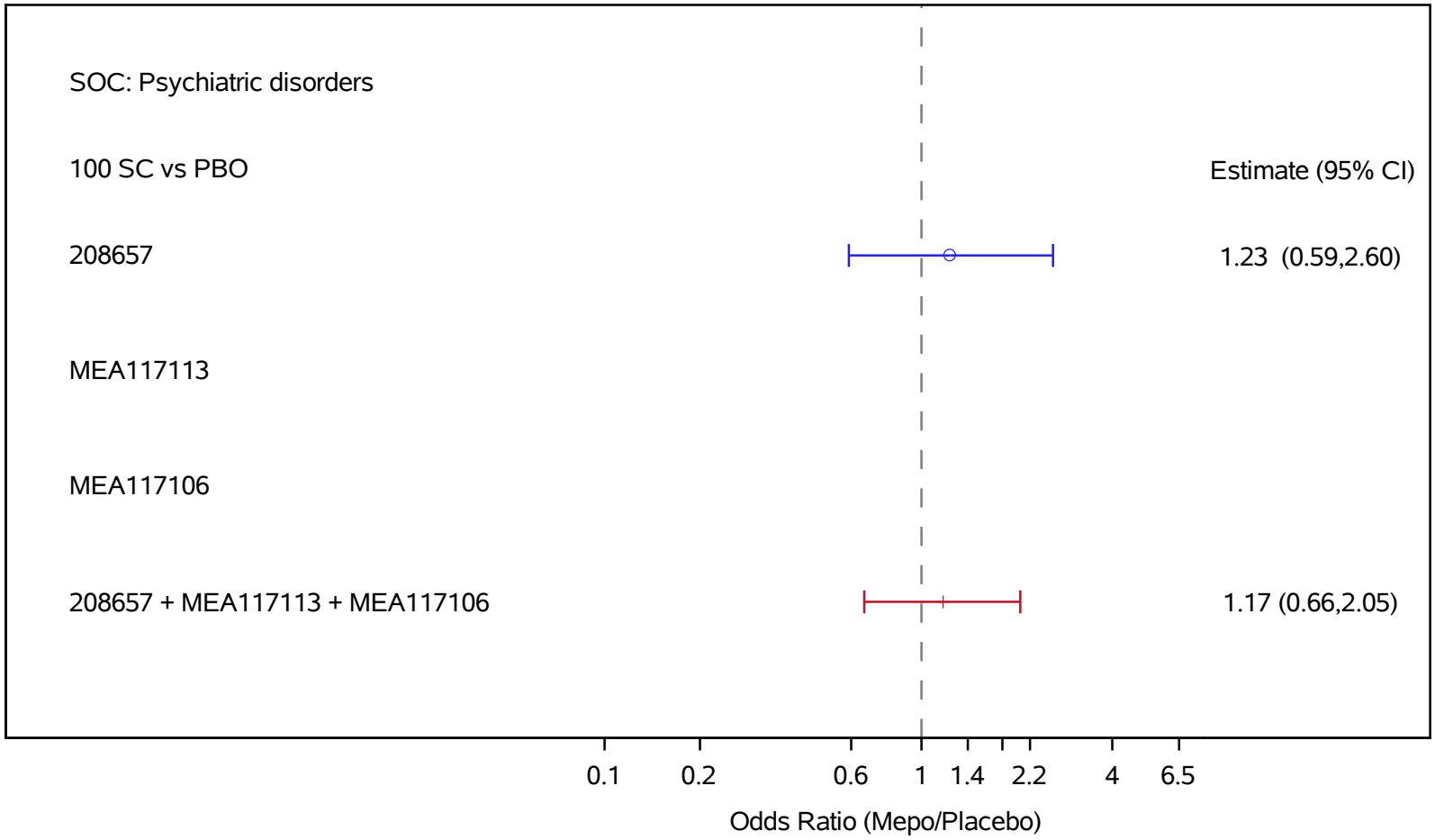

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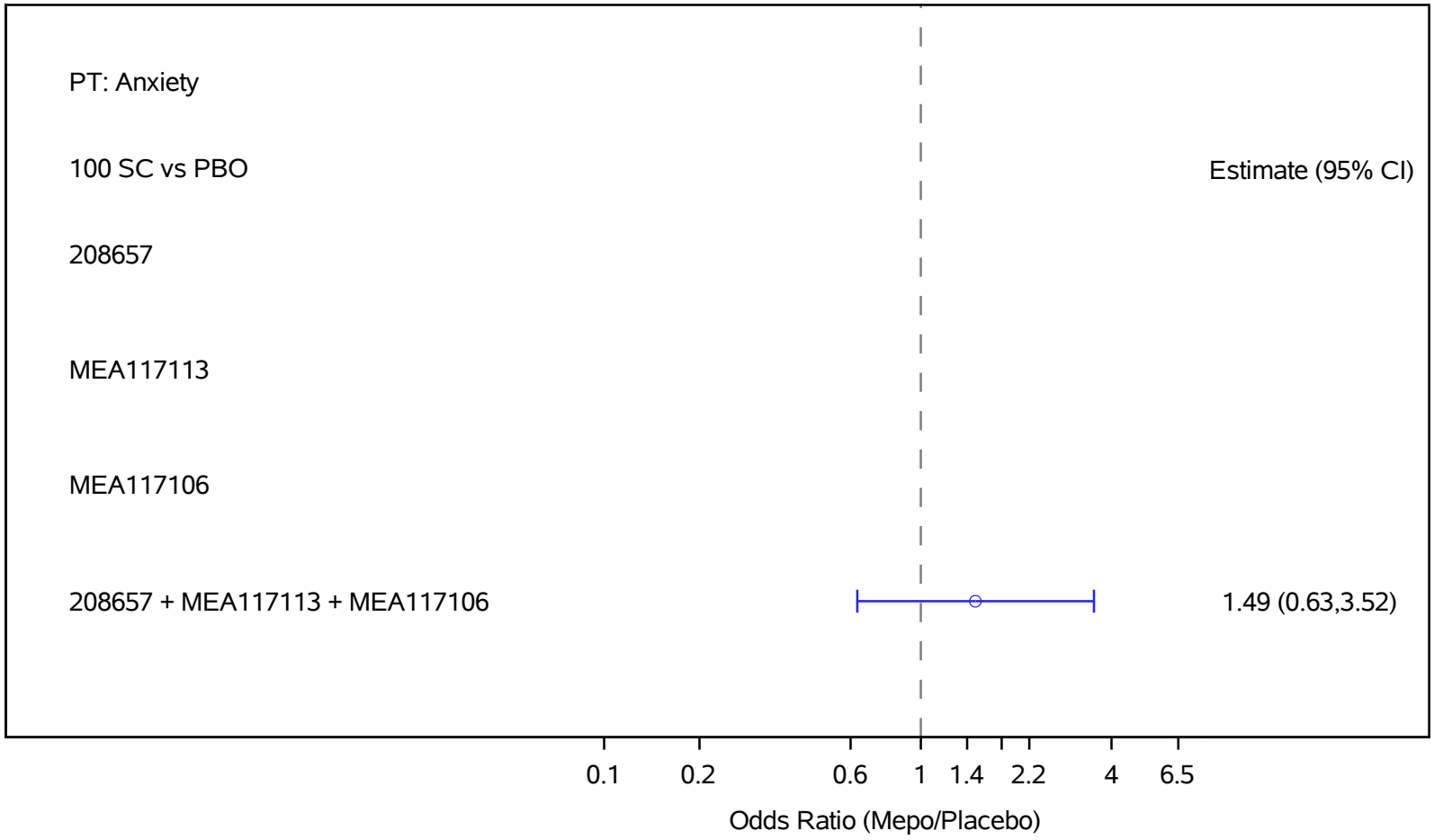

Horizontal bars indicate 95% confidence intervals for the Mepo/Placebo ratio.

Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

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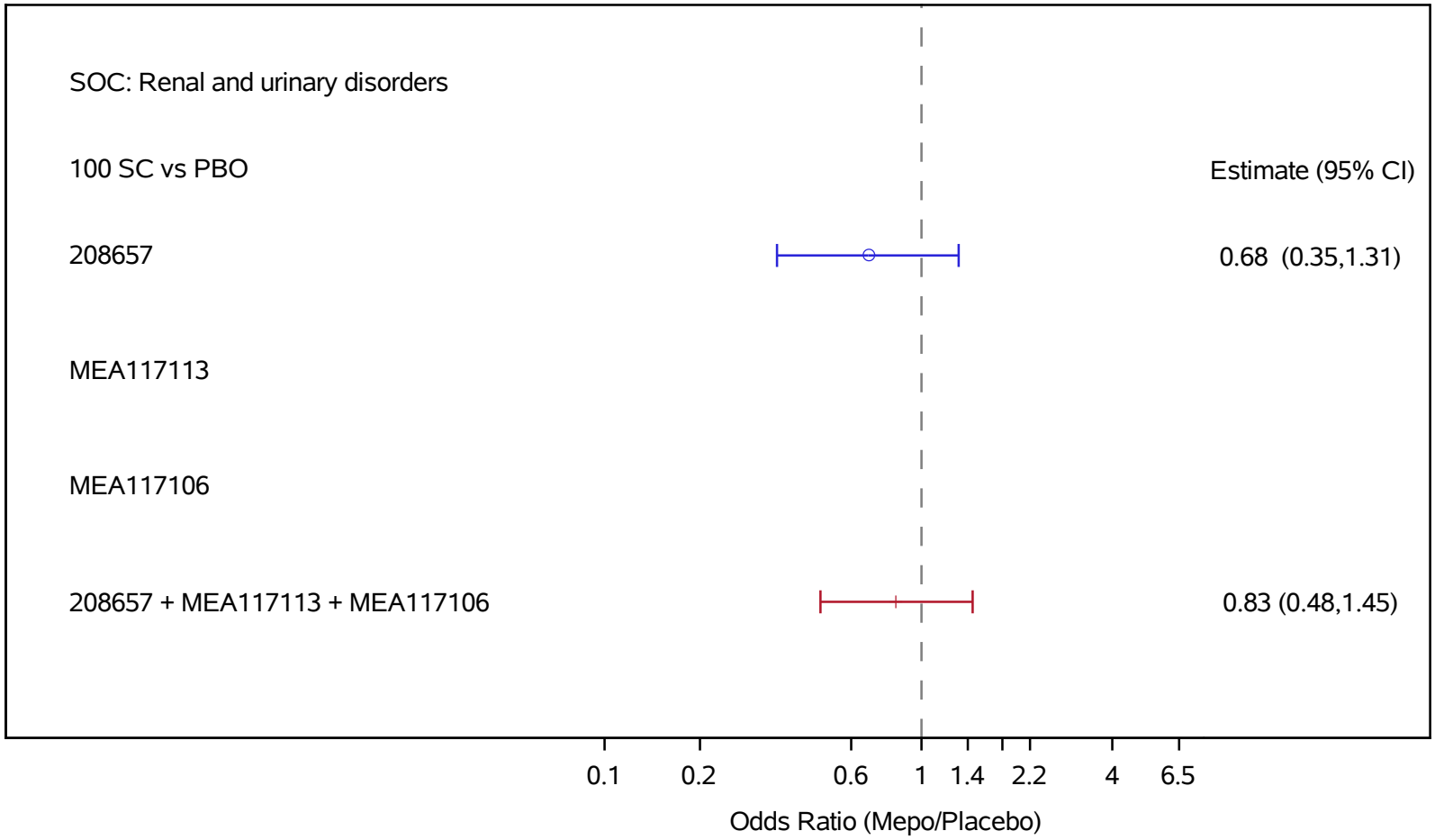

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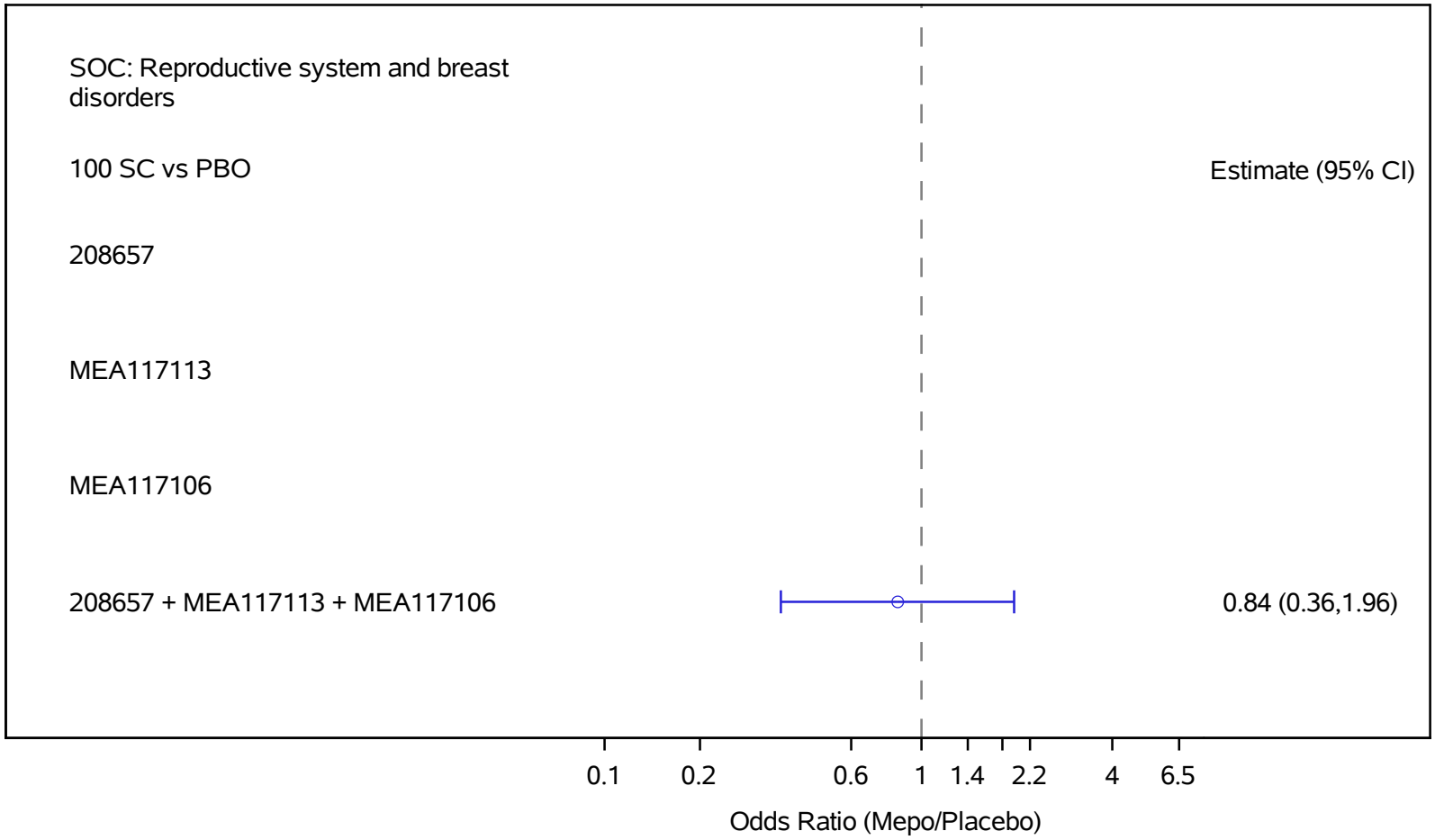

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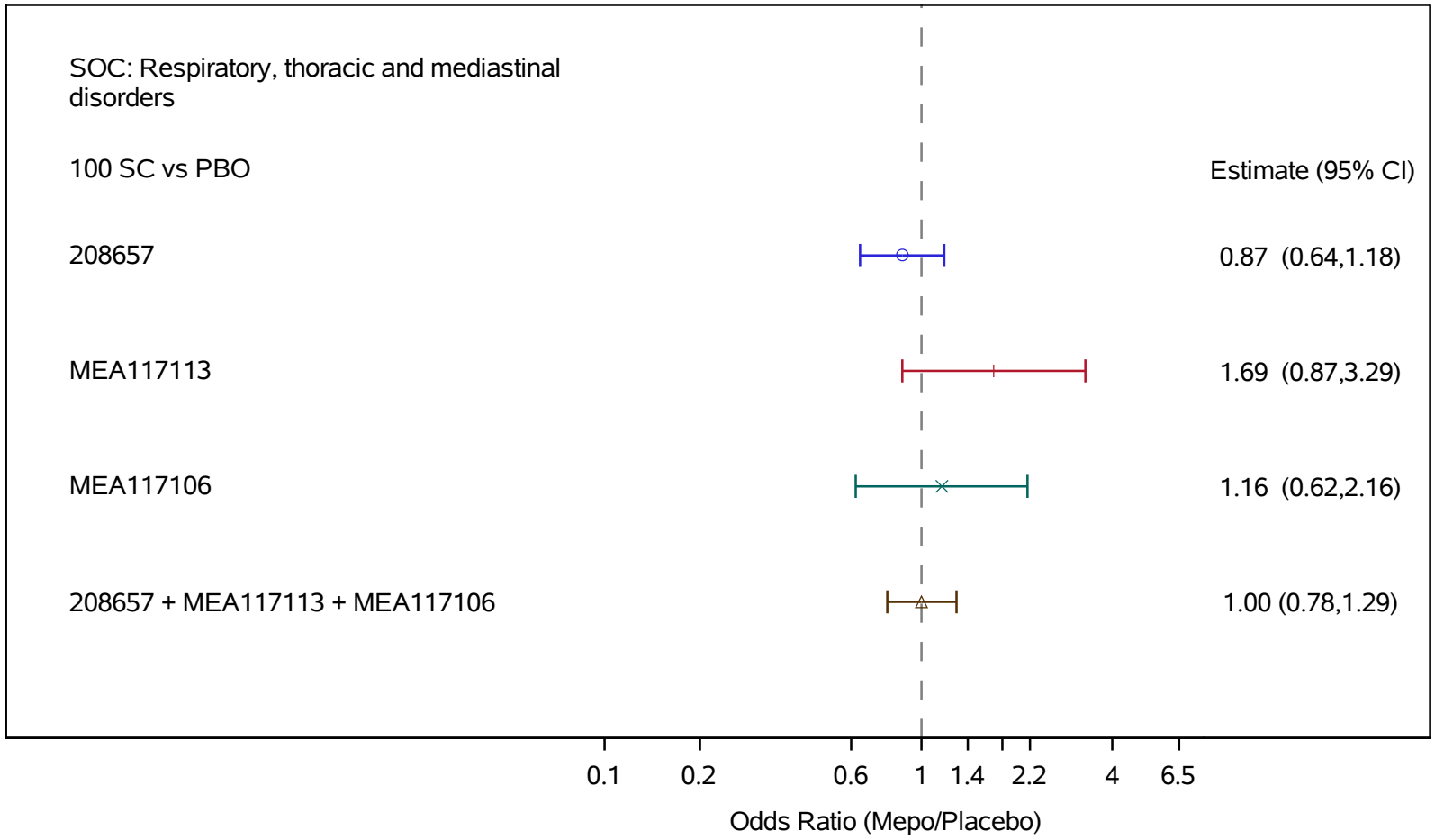

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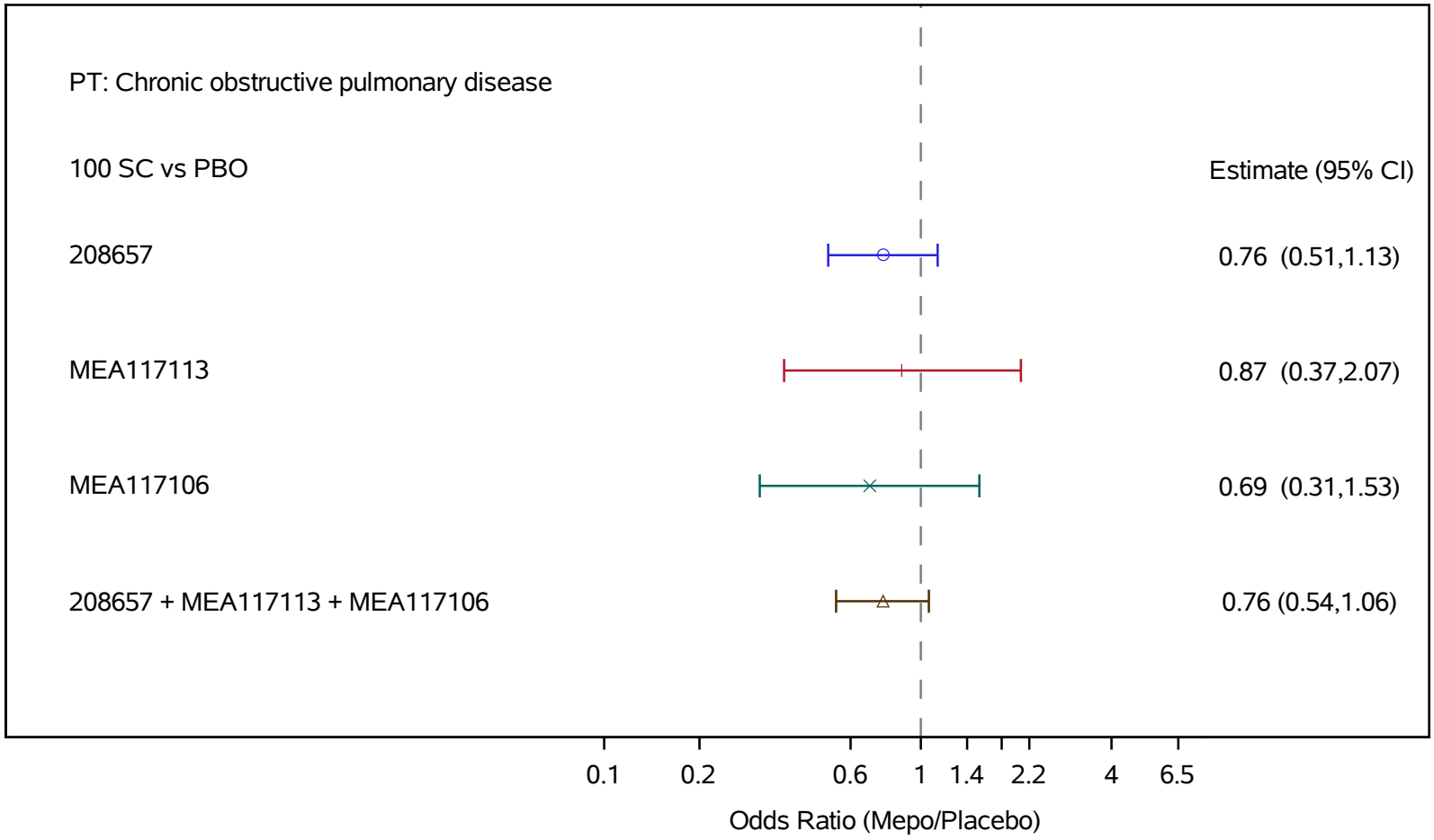

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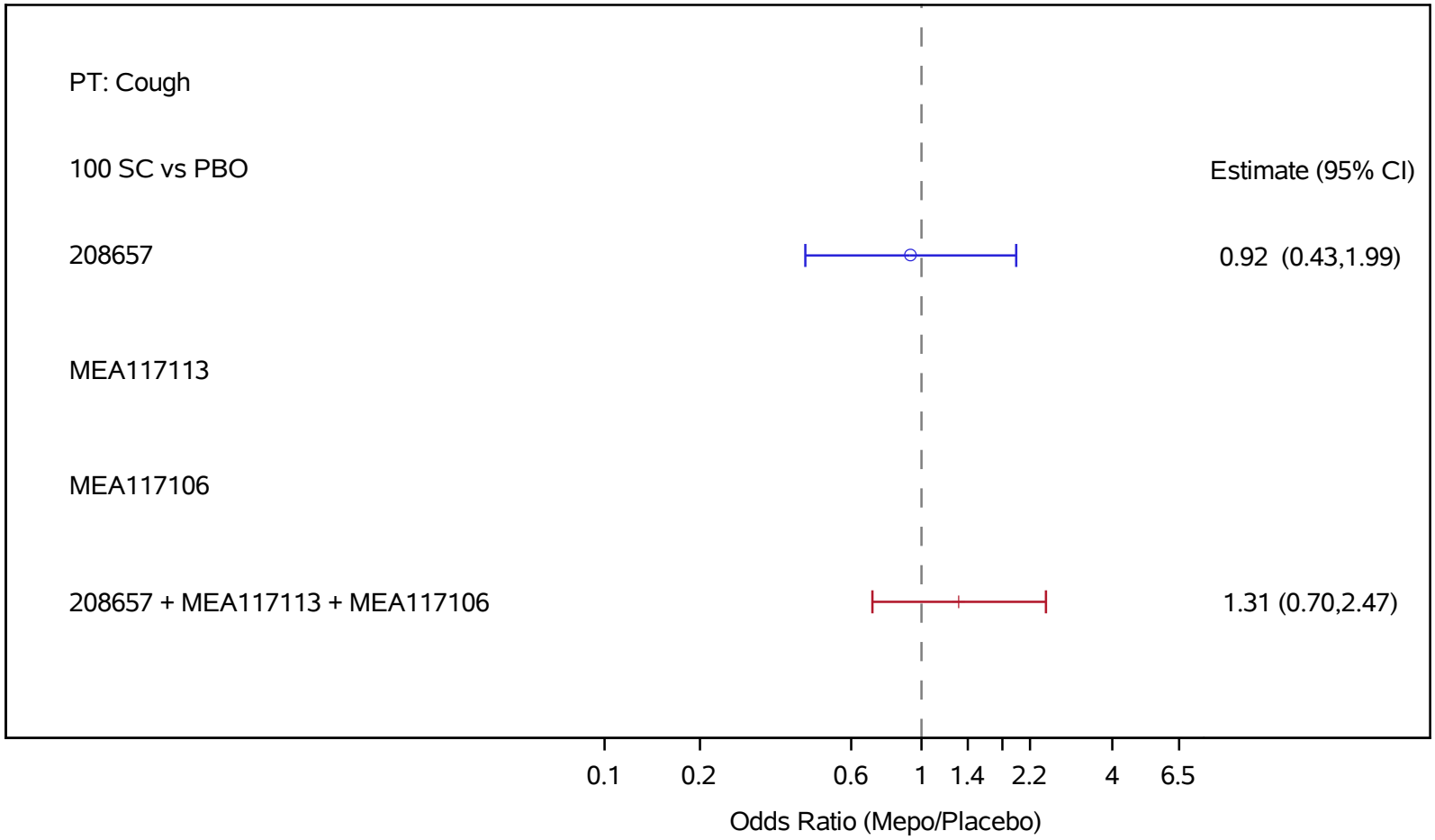

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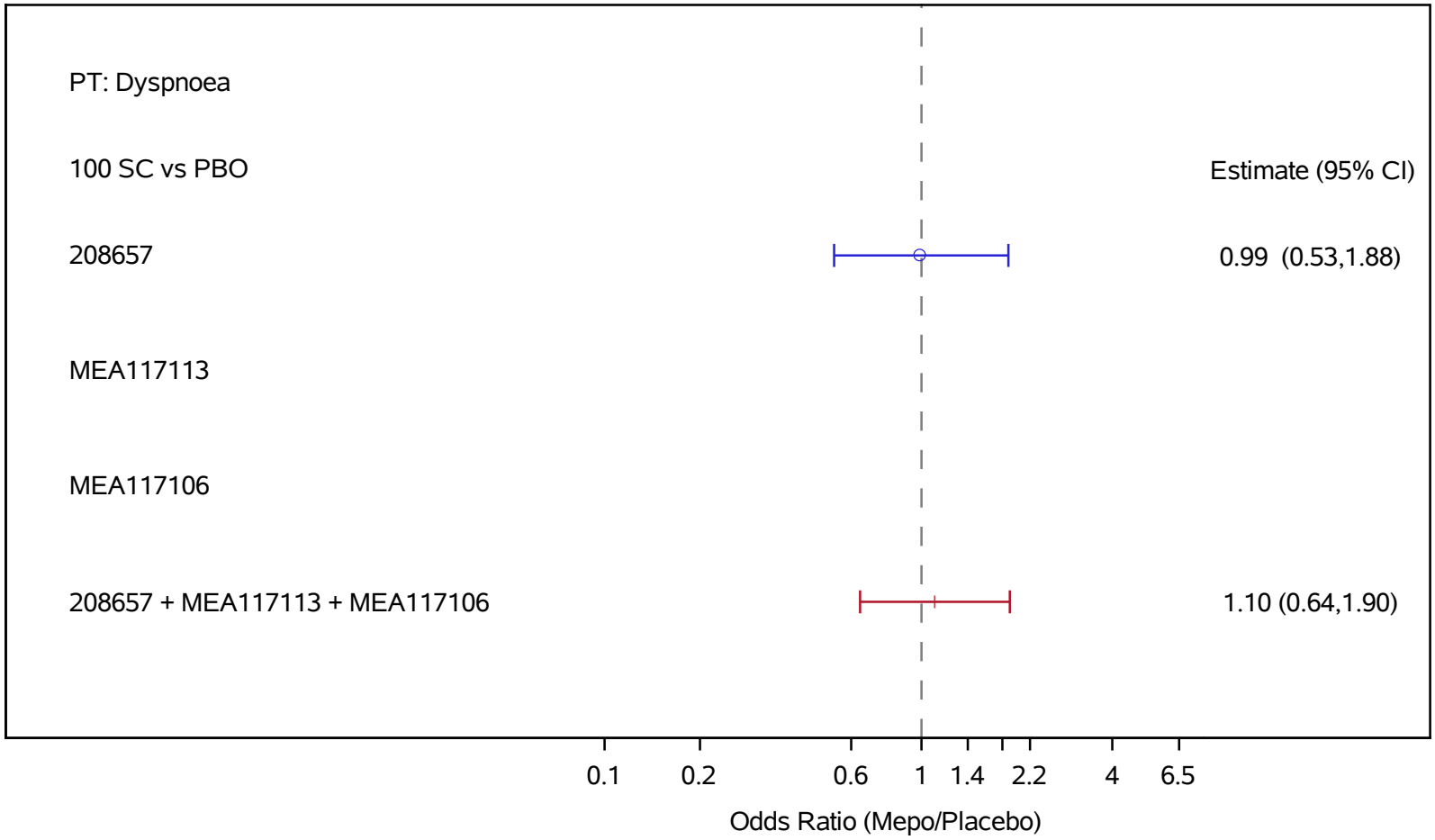

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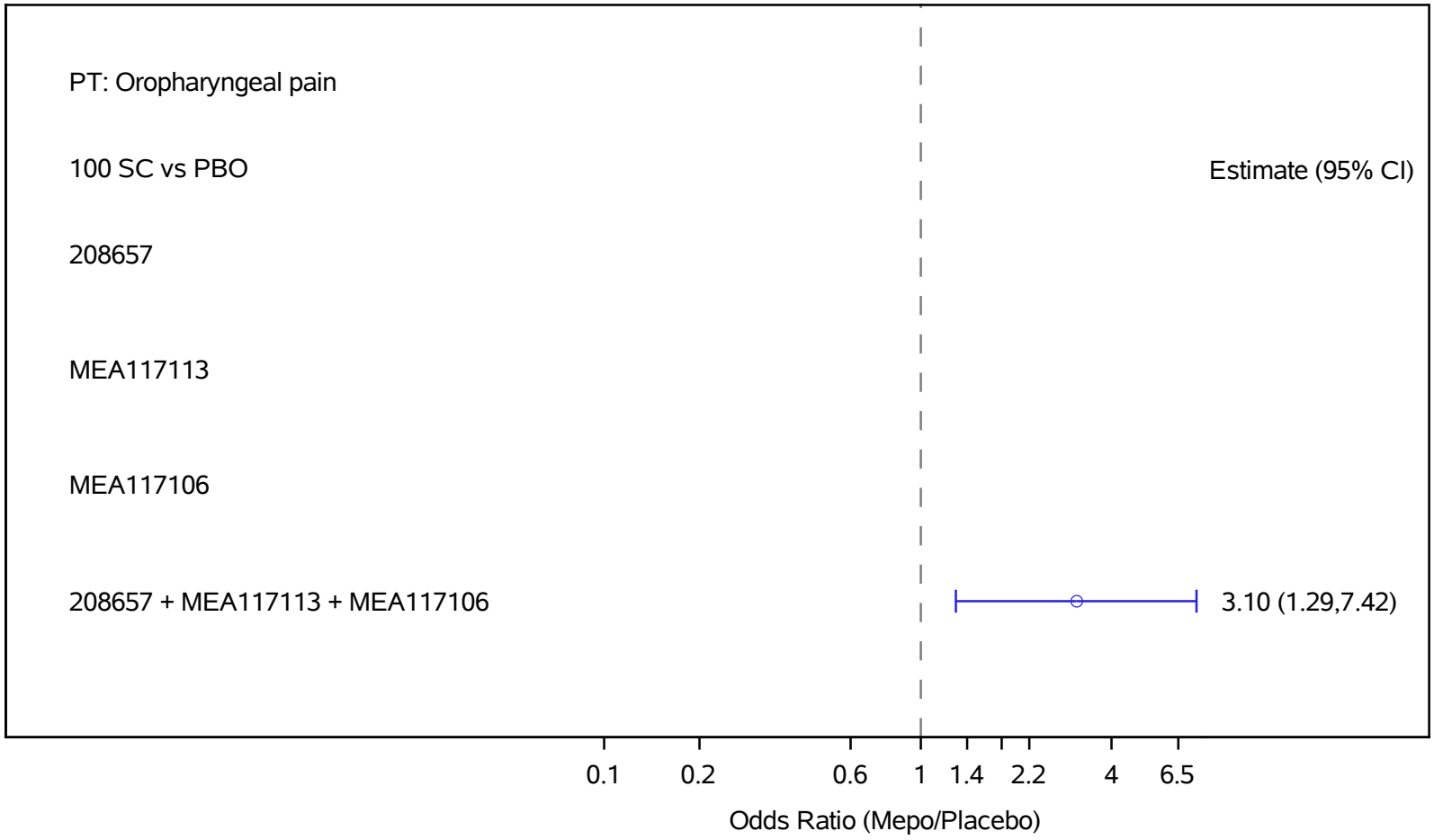

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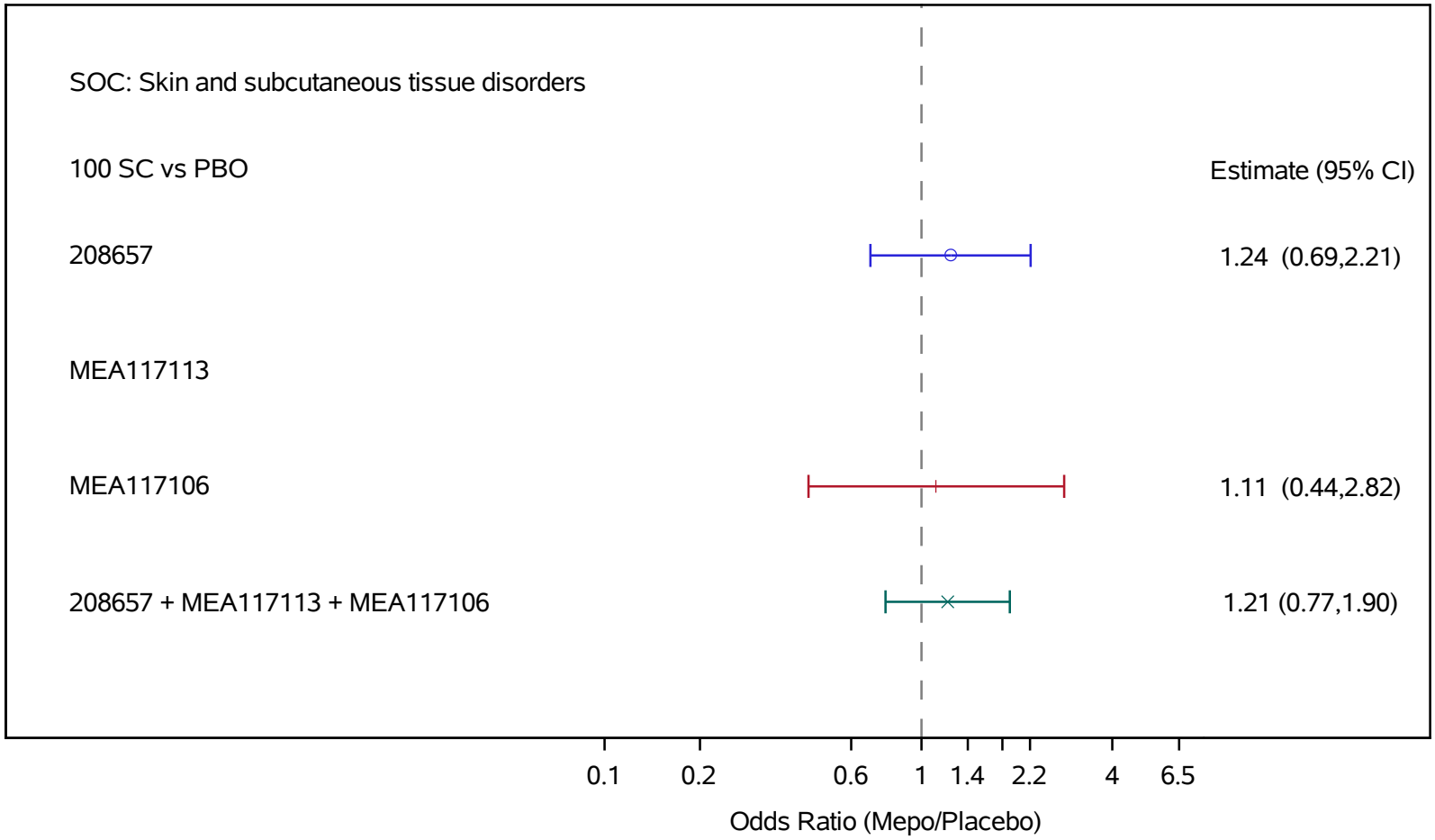

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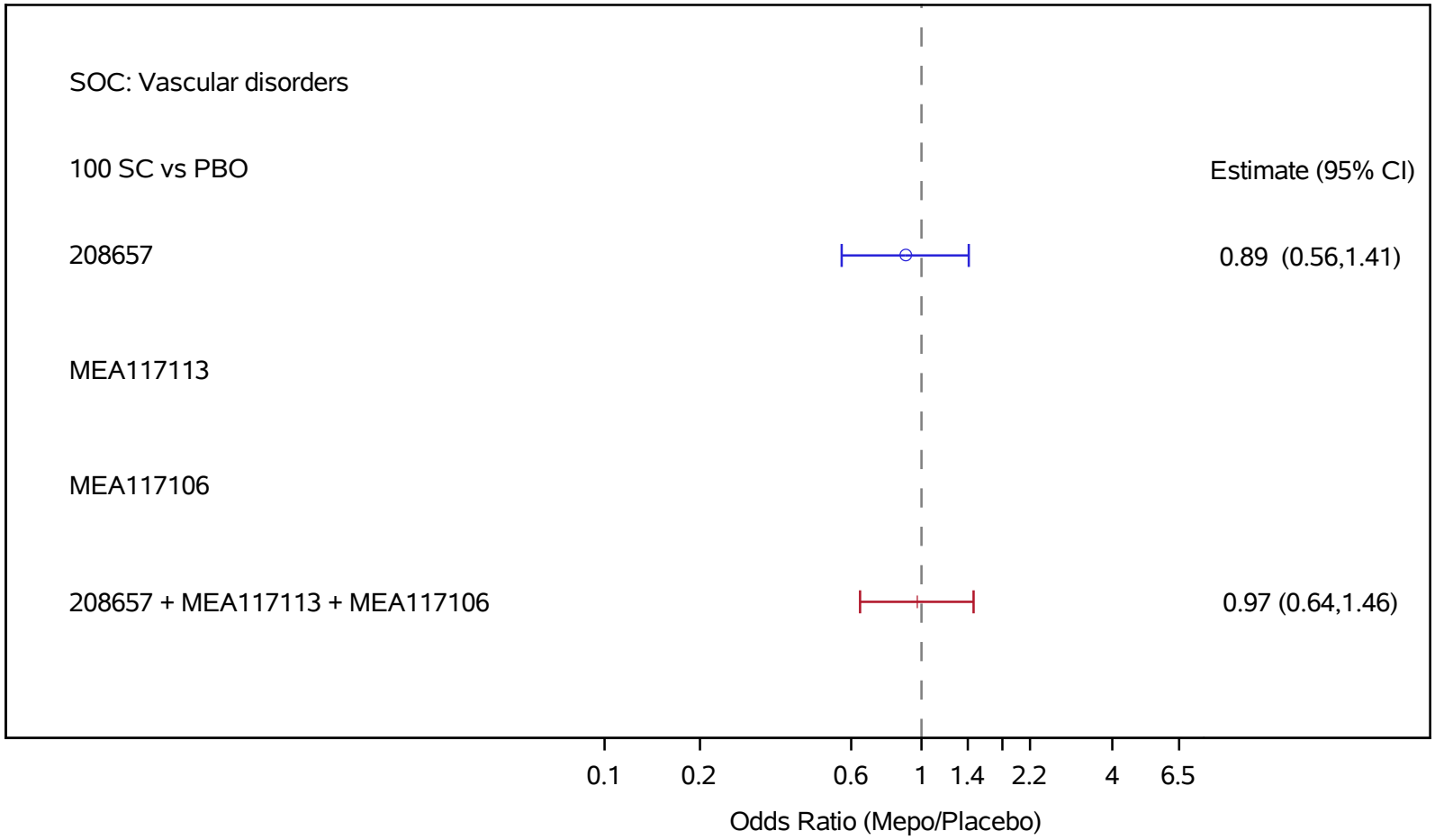

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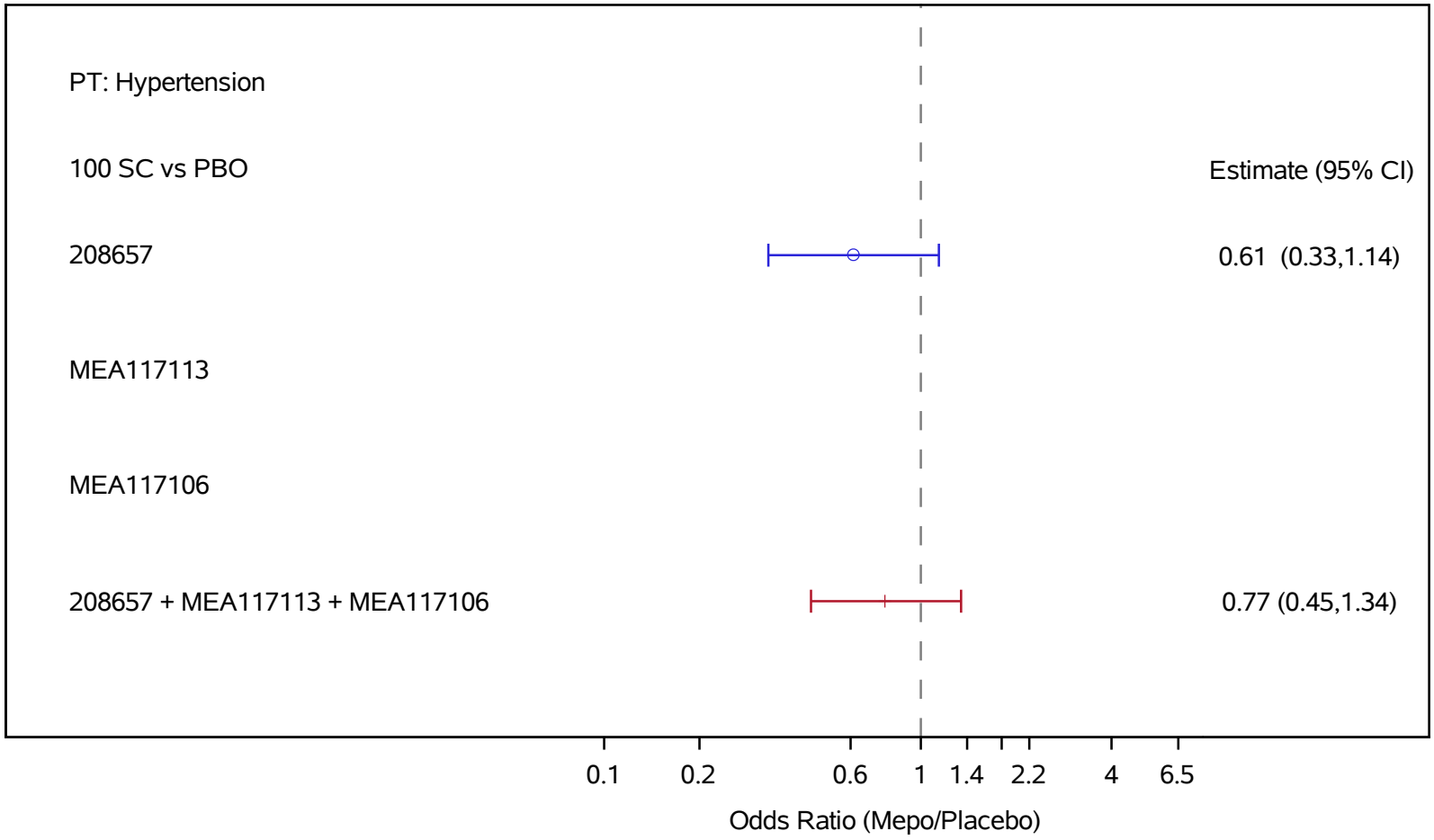

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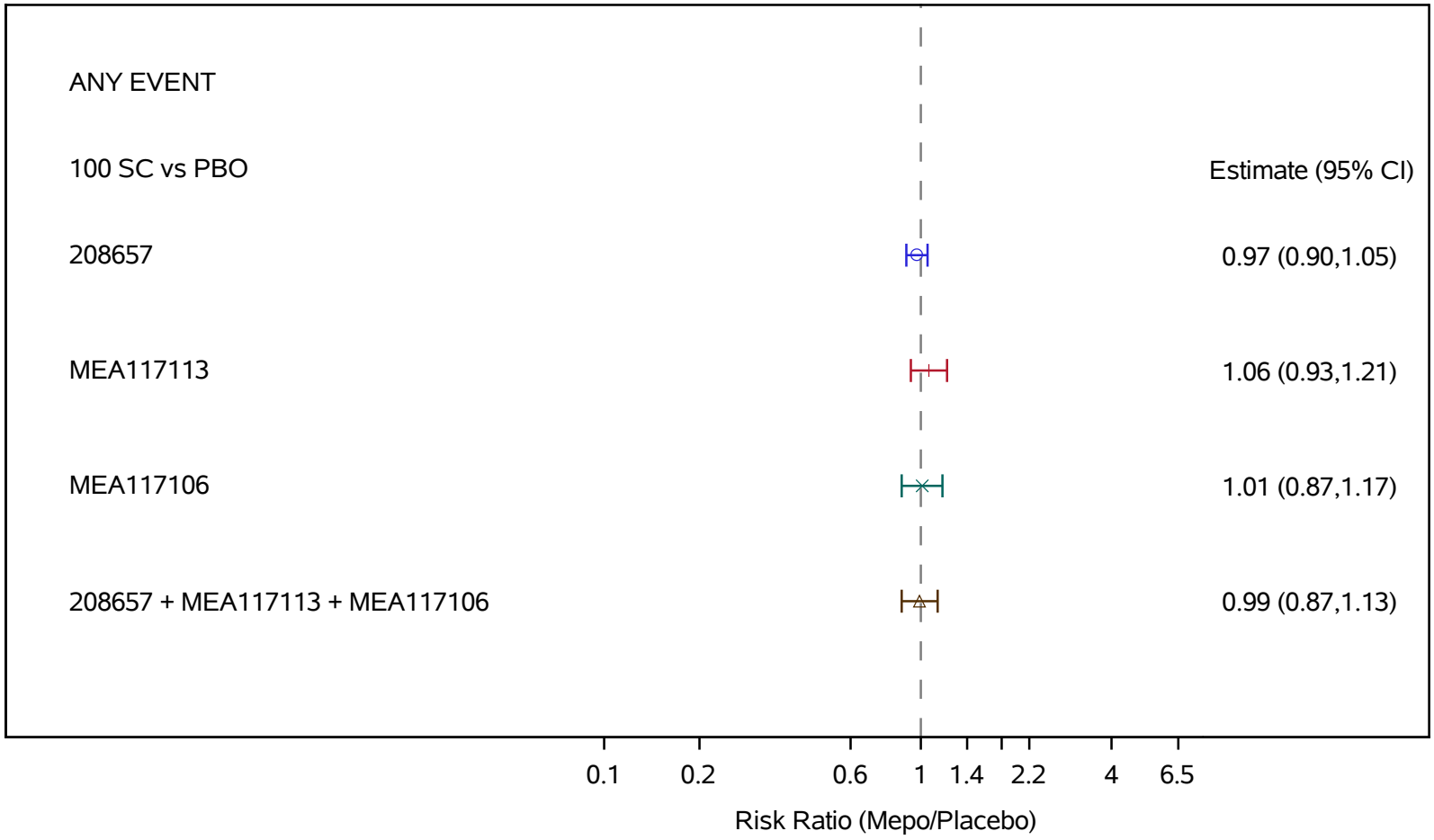

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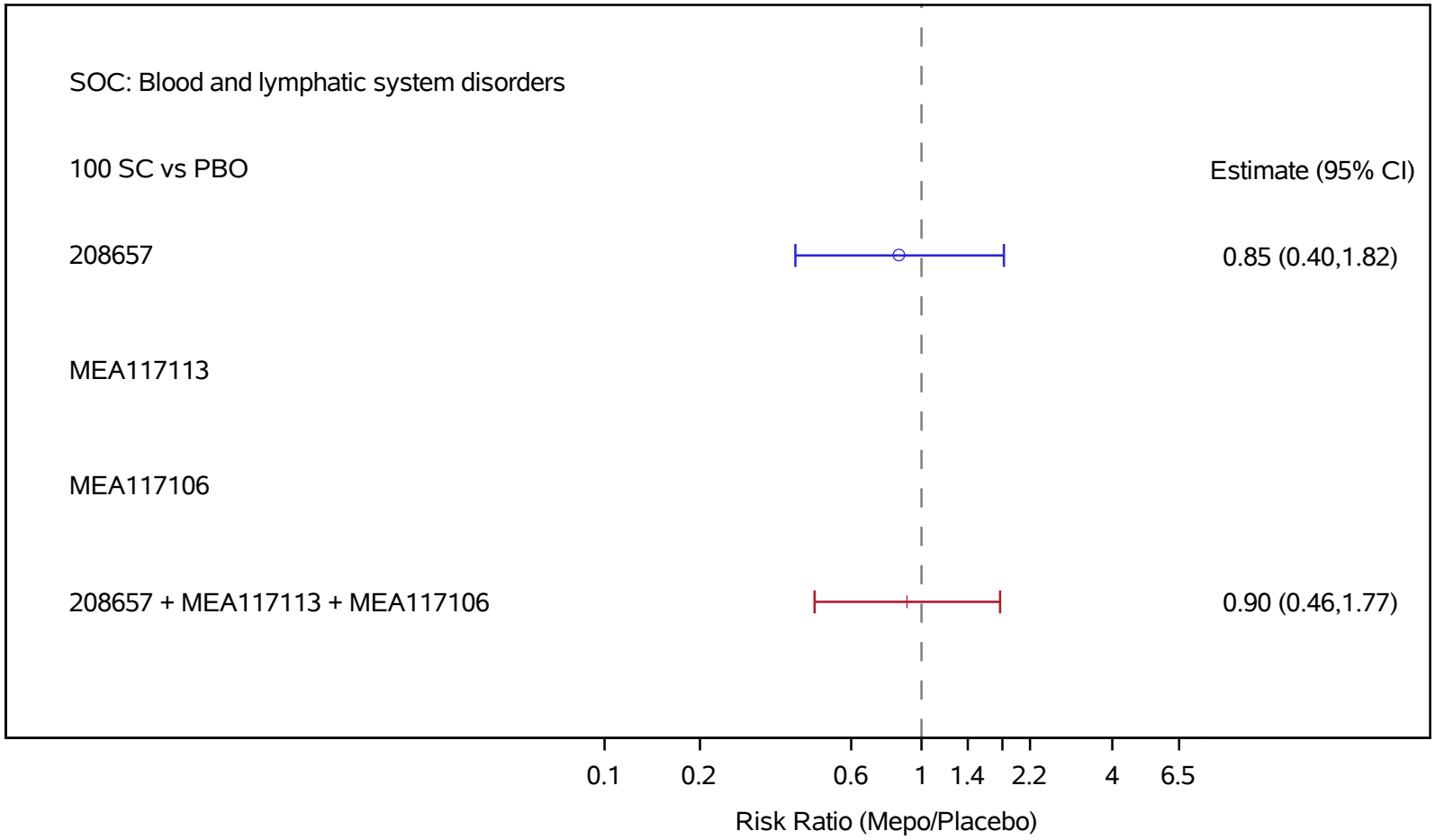

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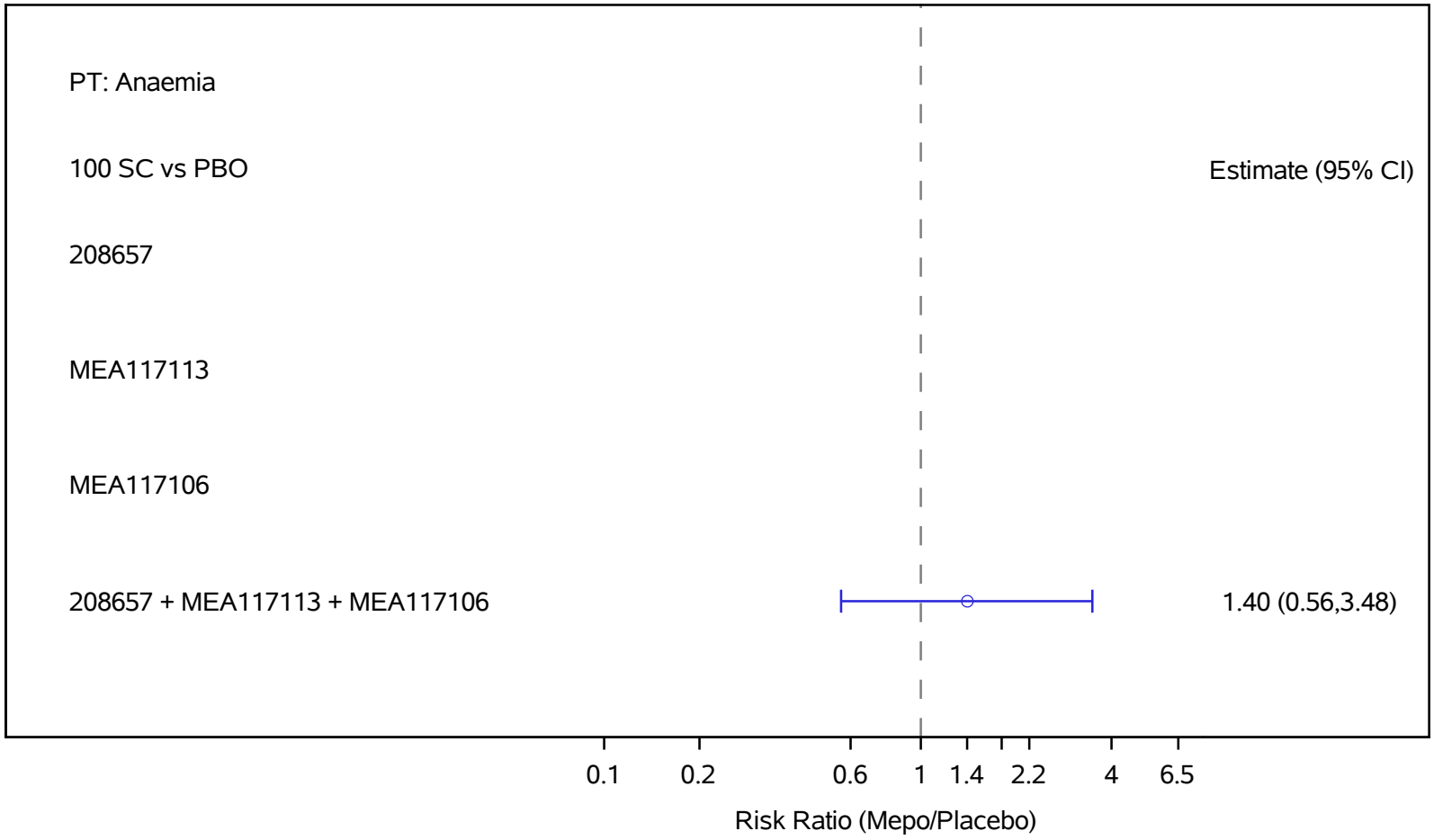

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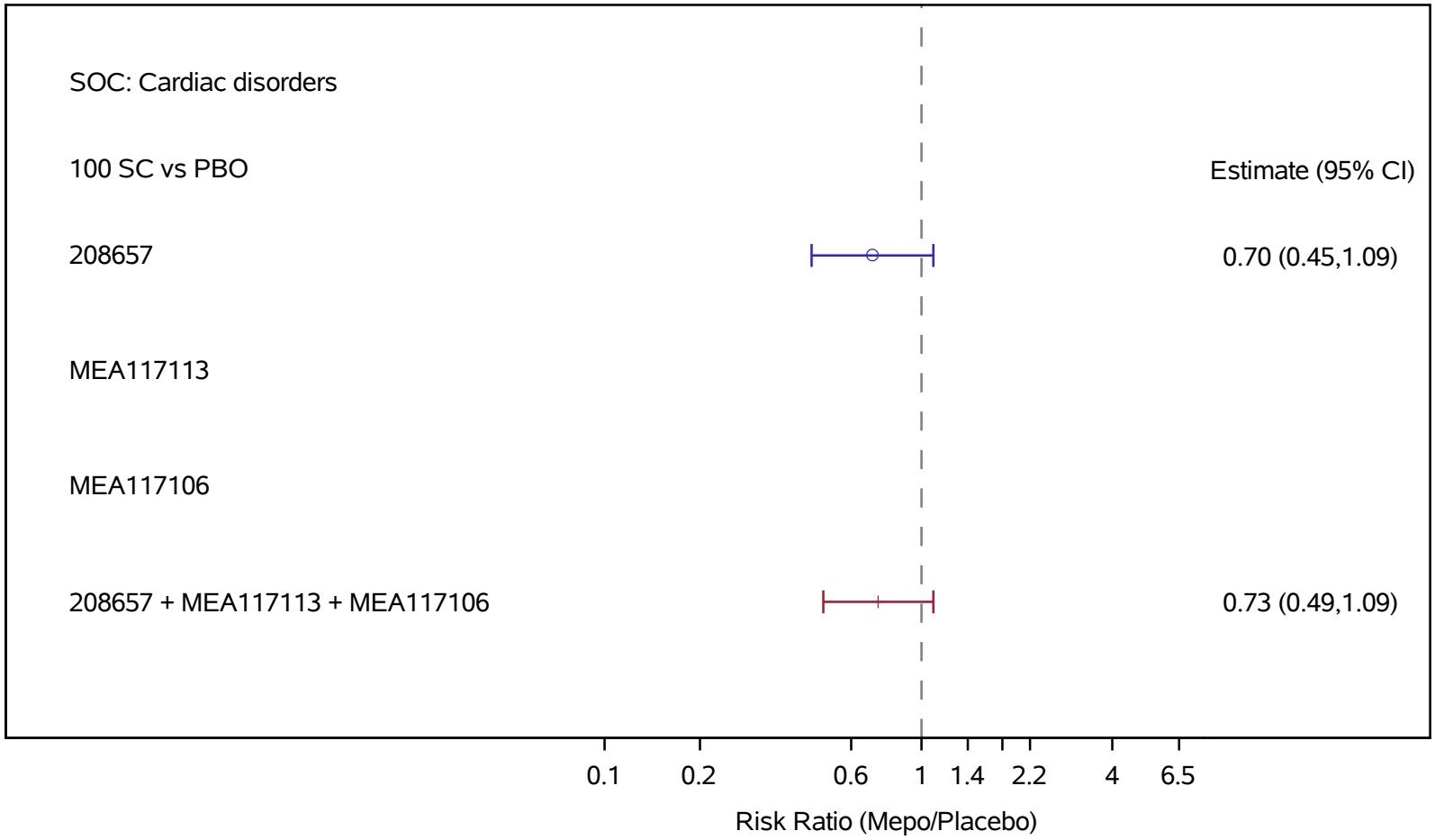

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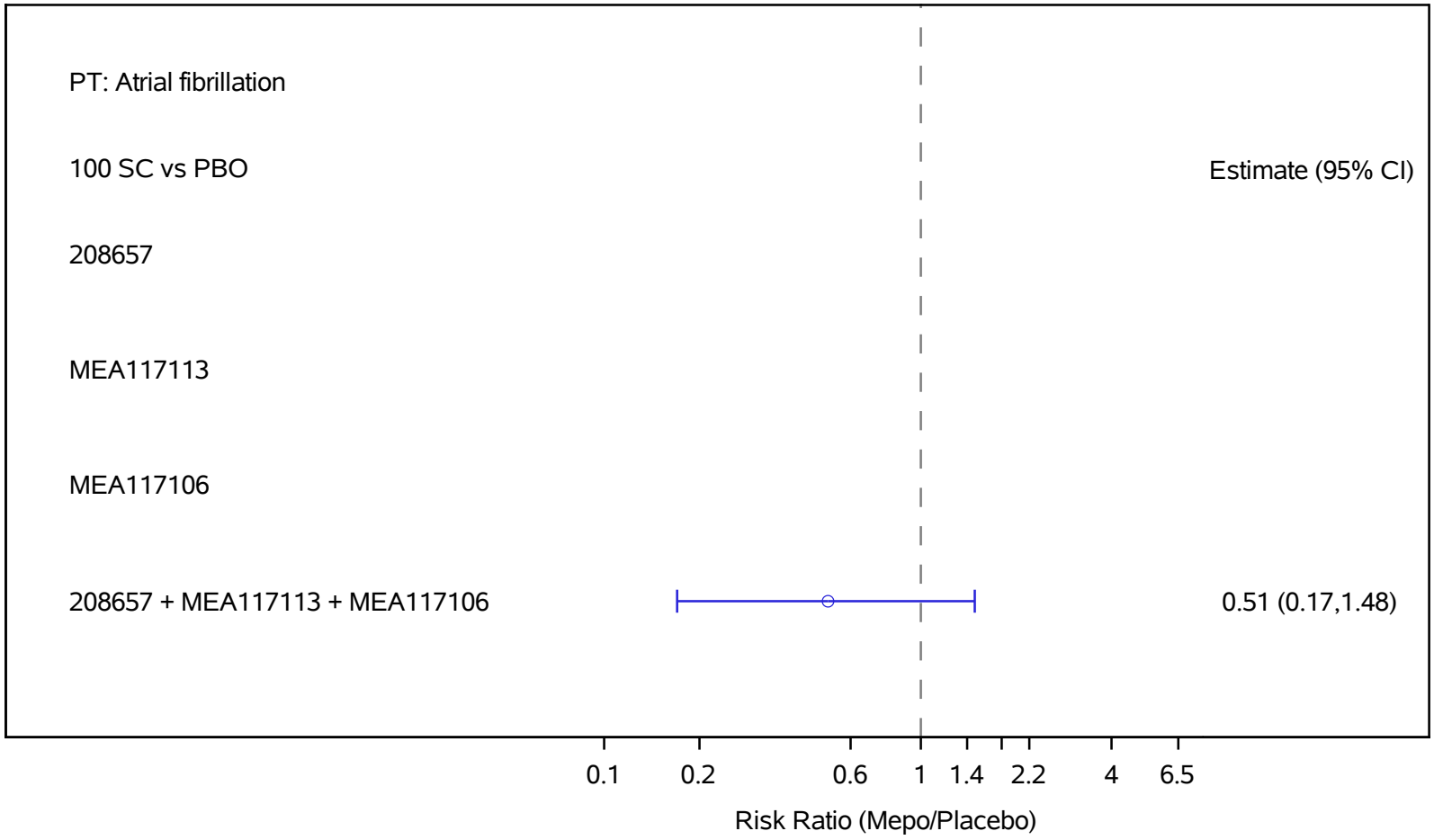

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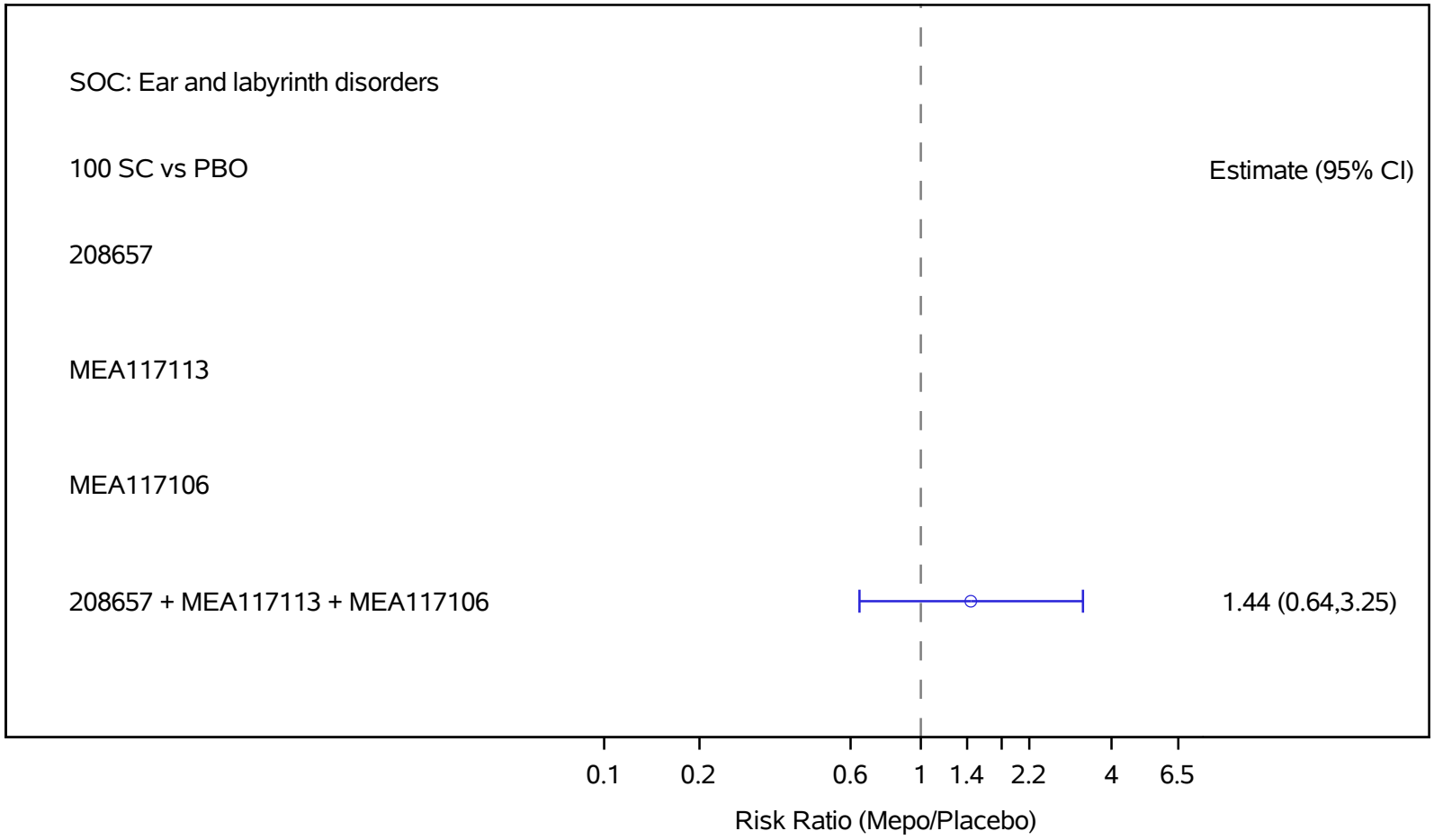

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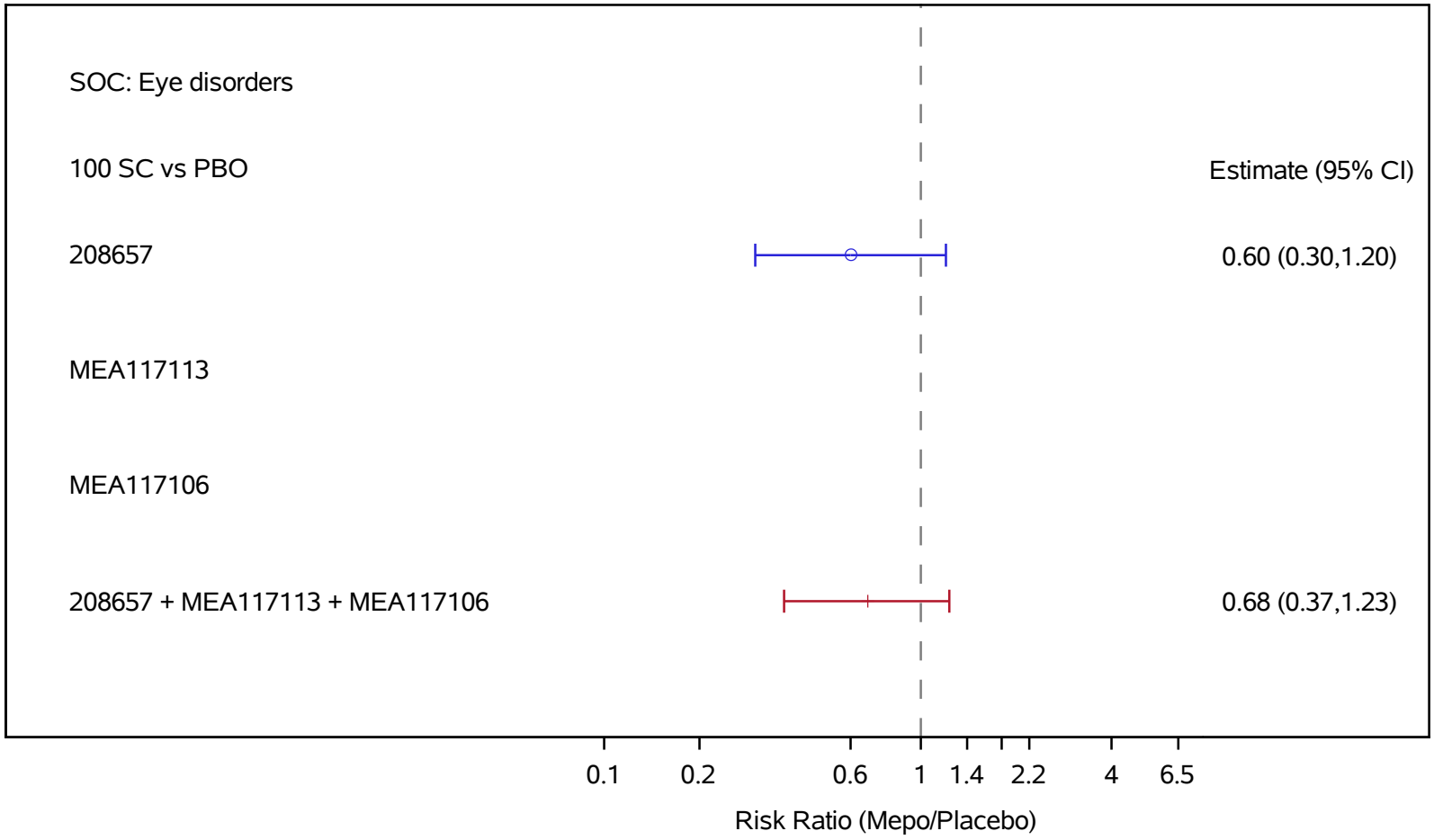

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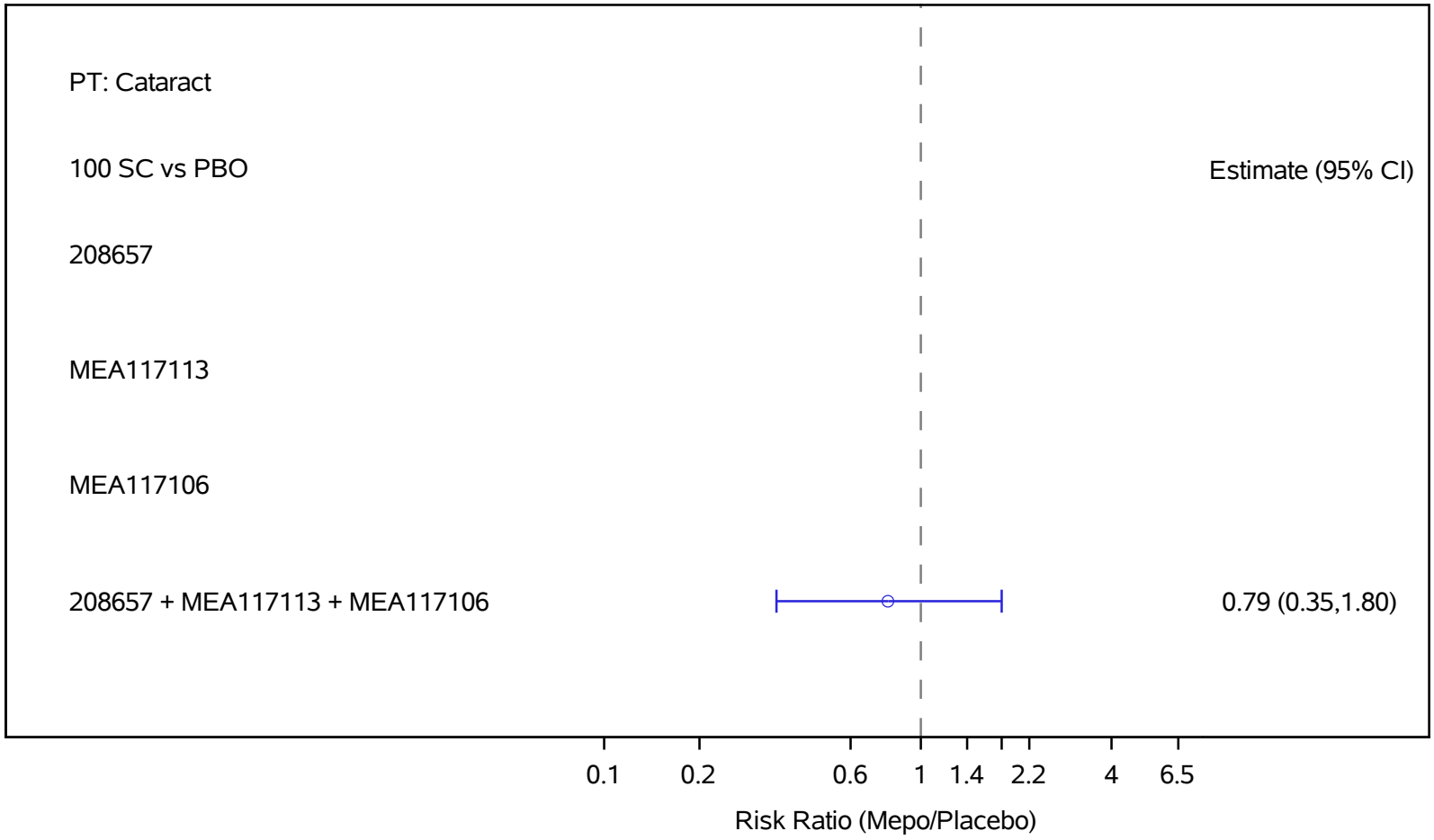

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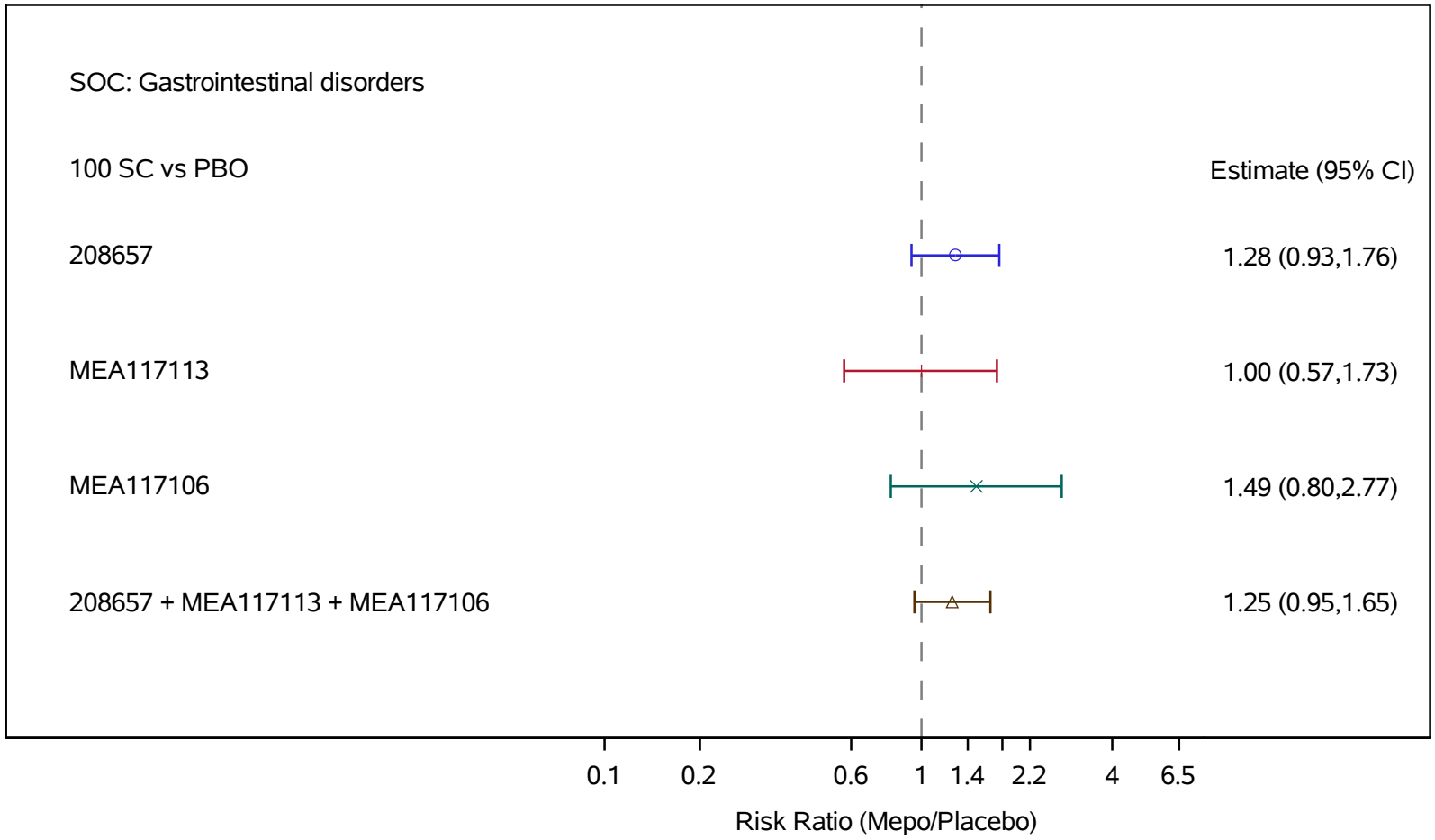

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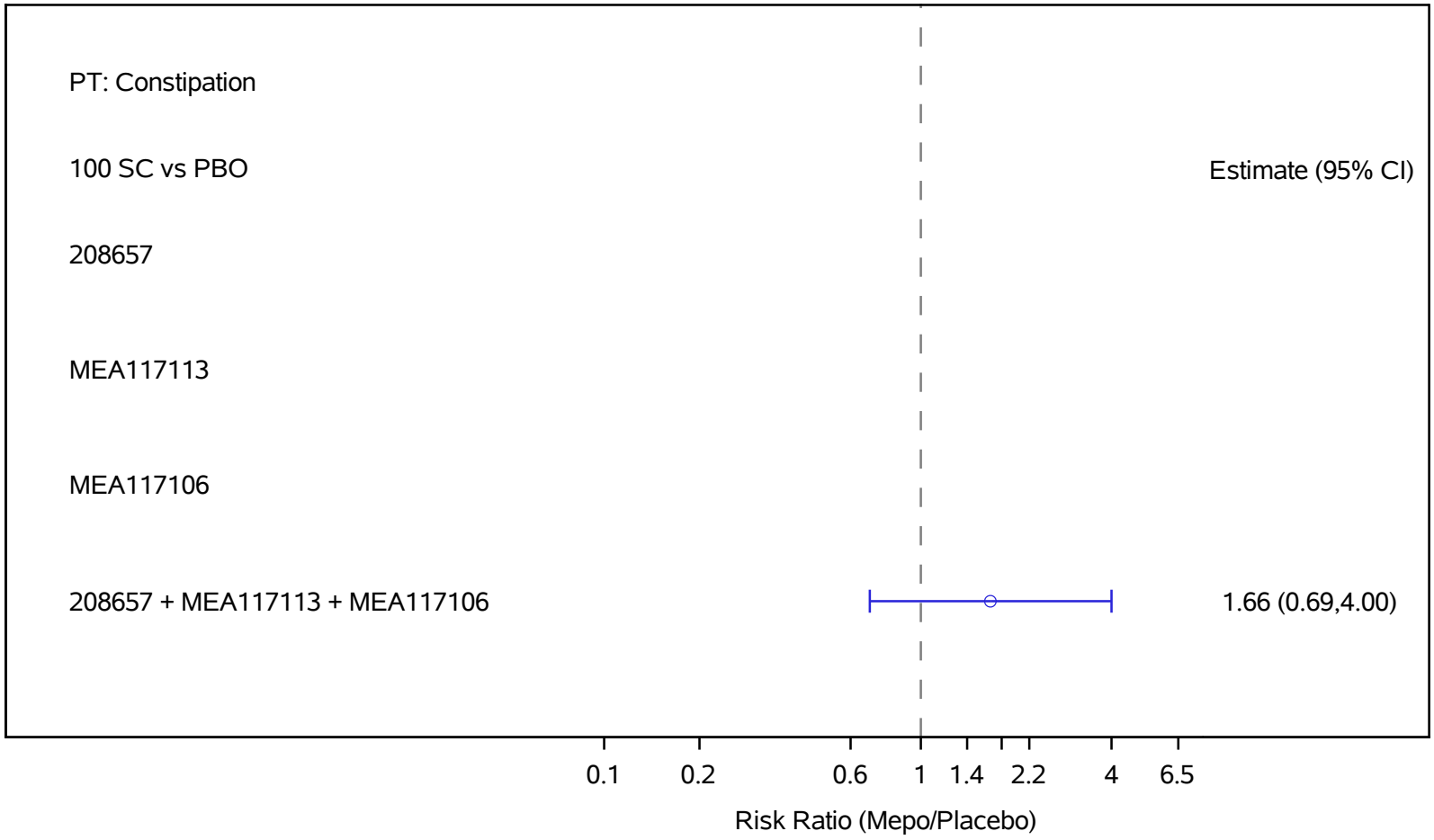

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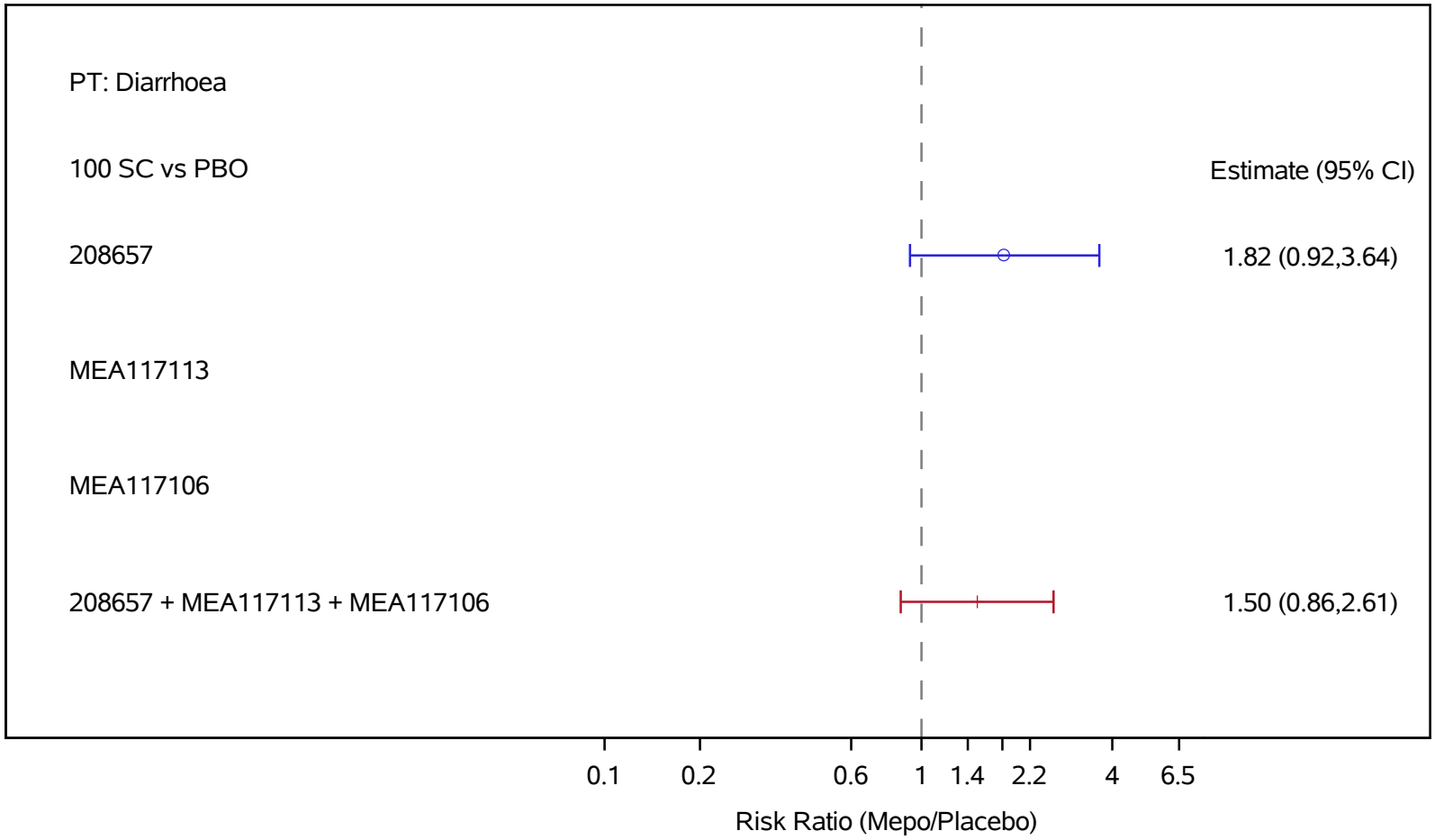

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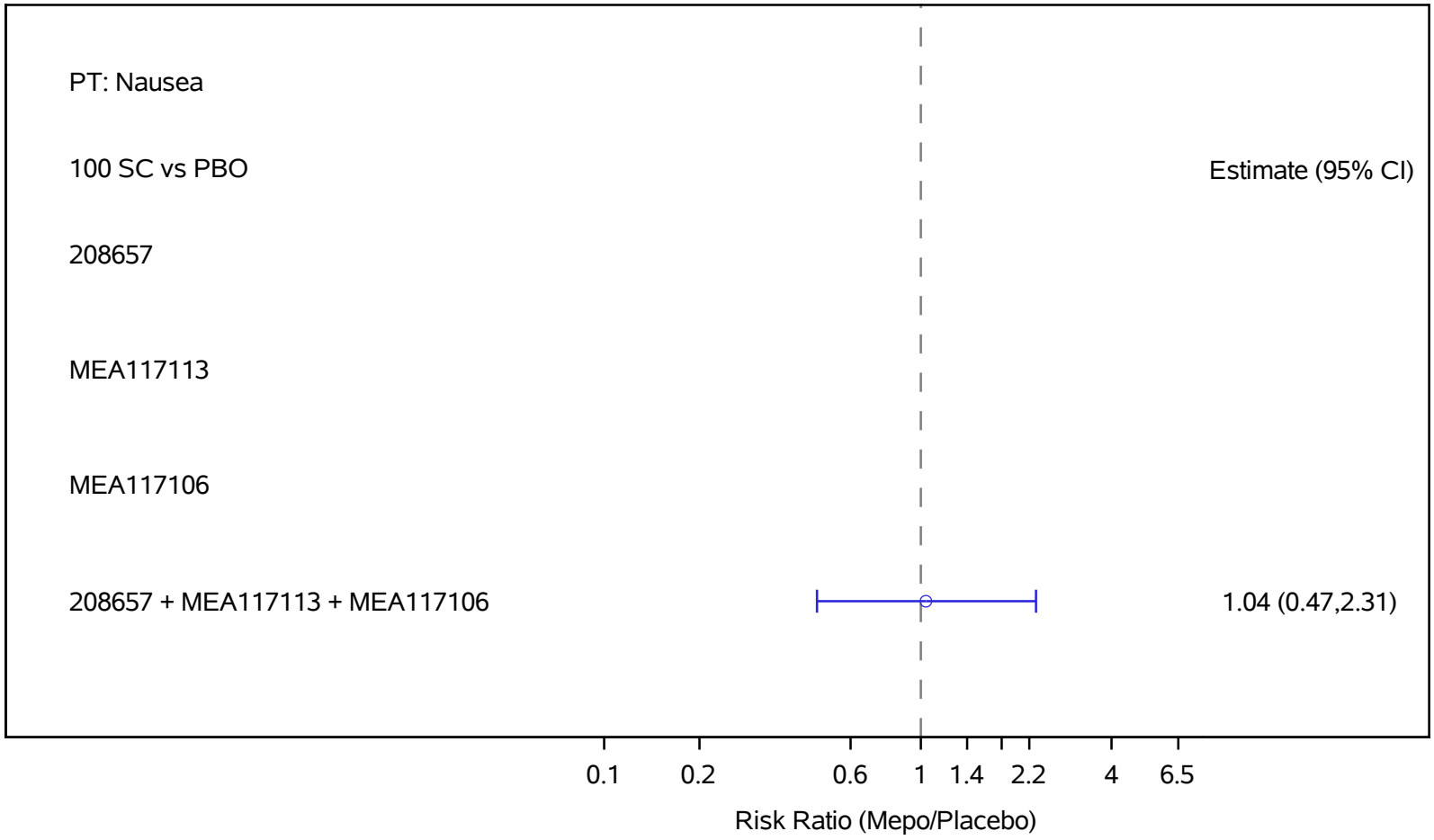

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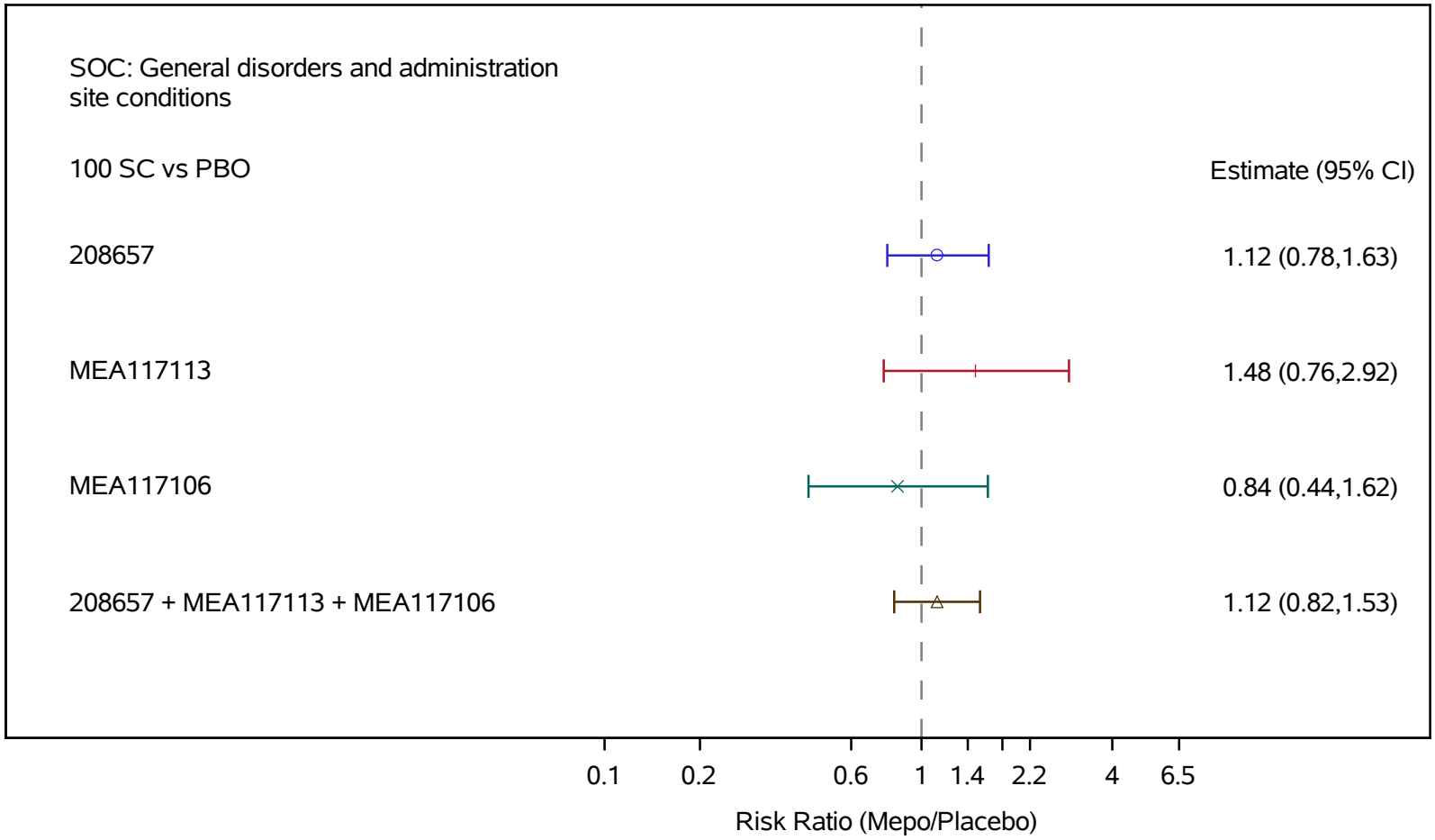

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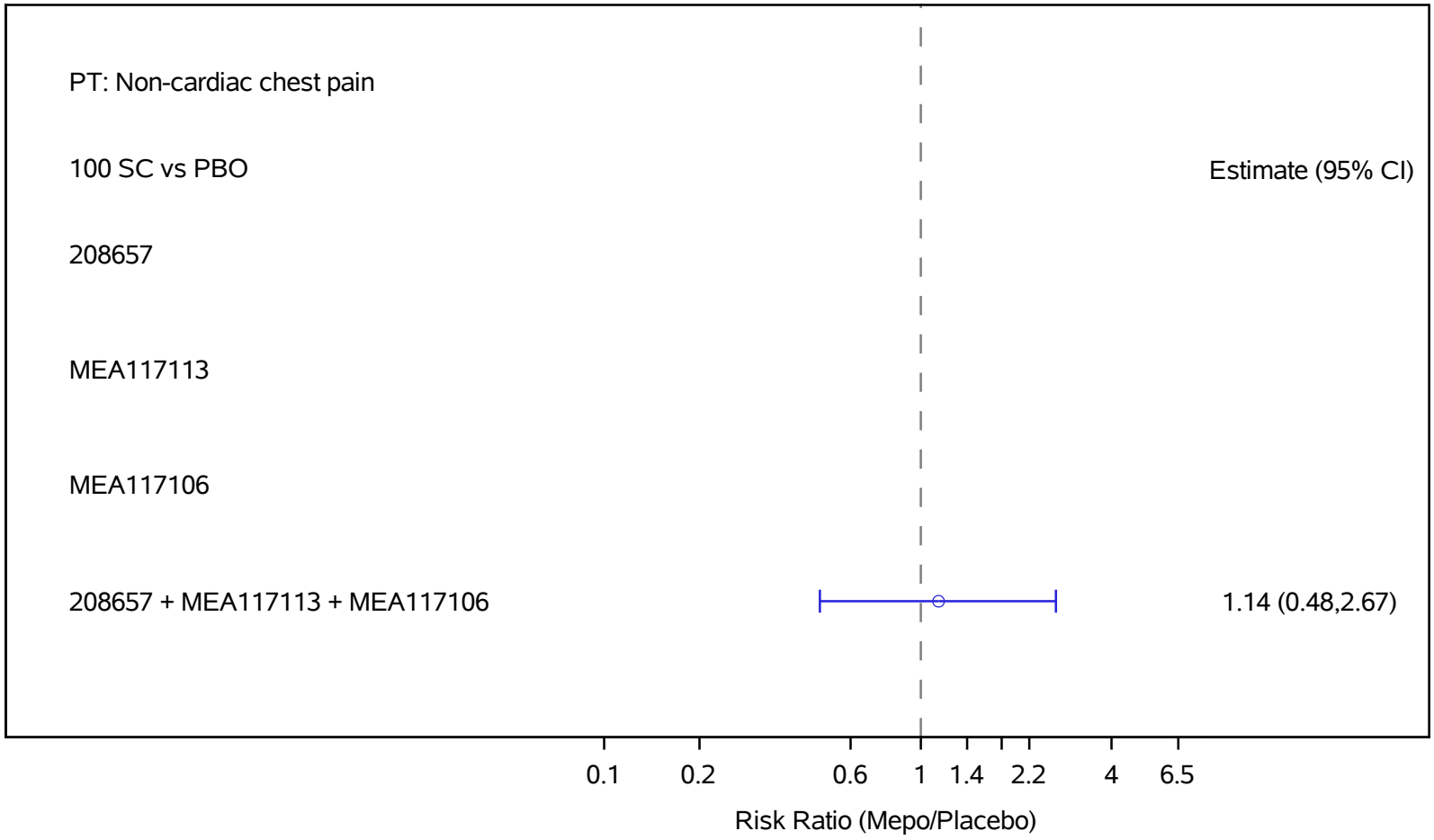

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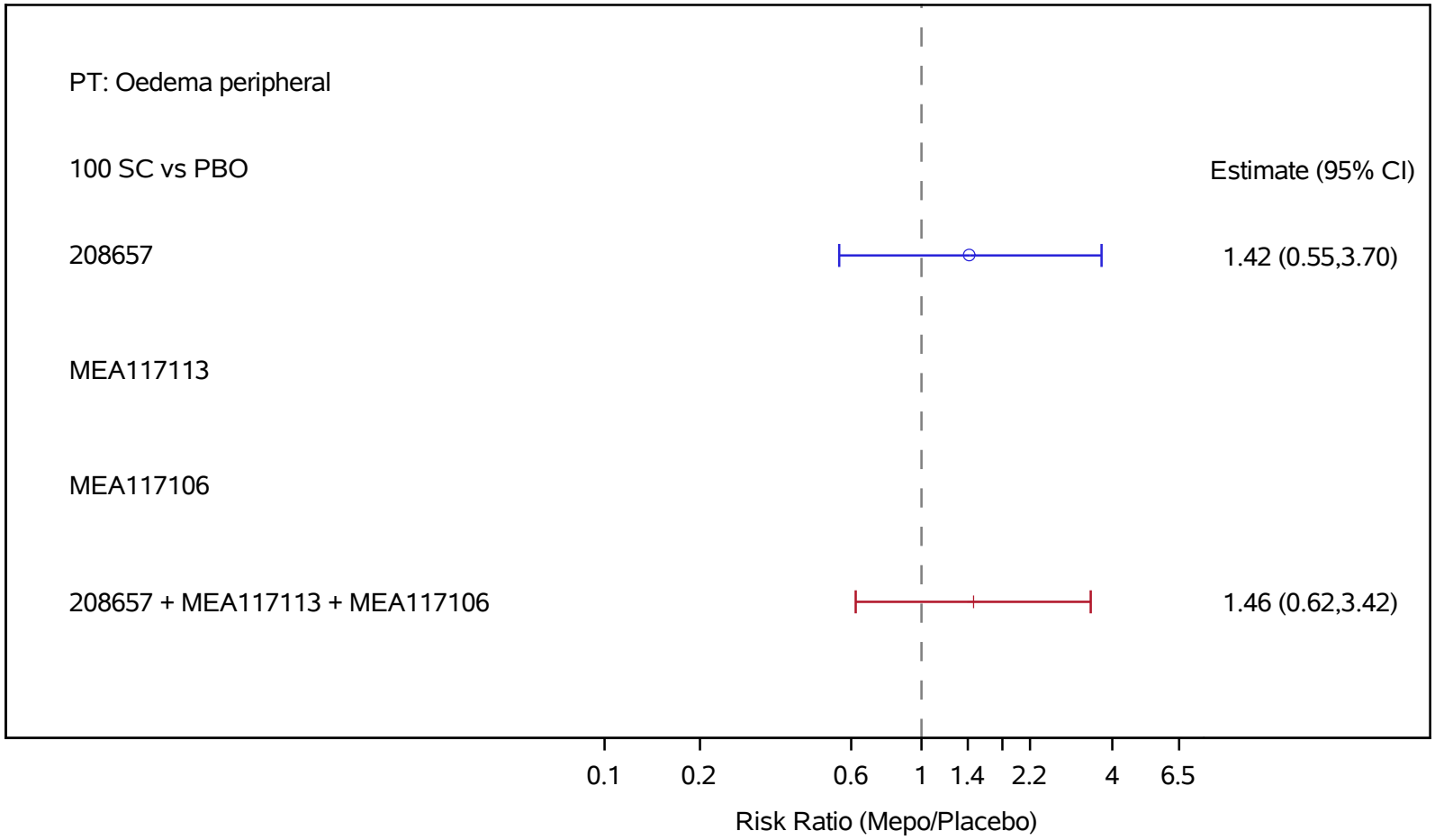

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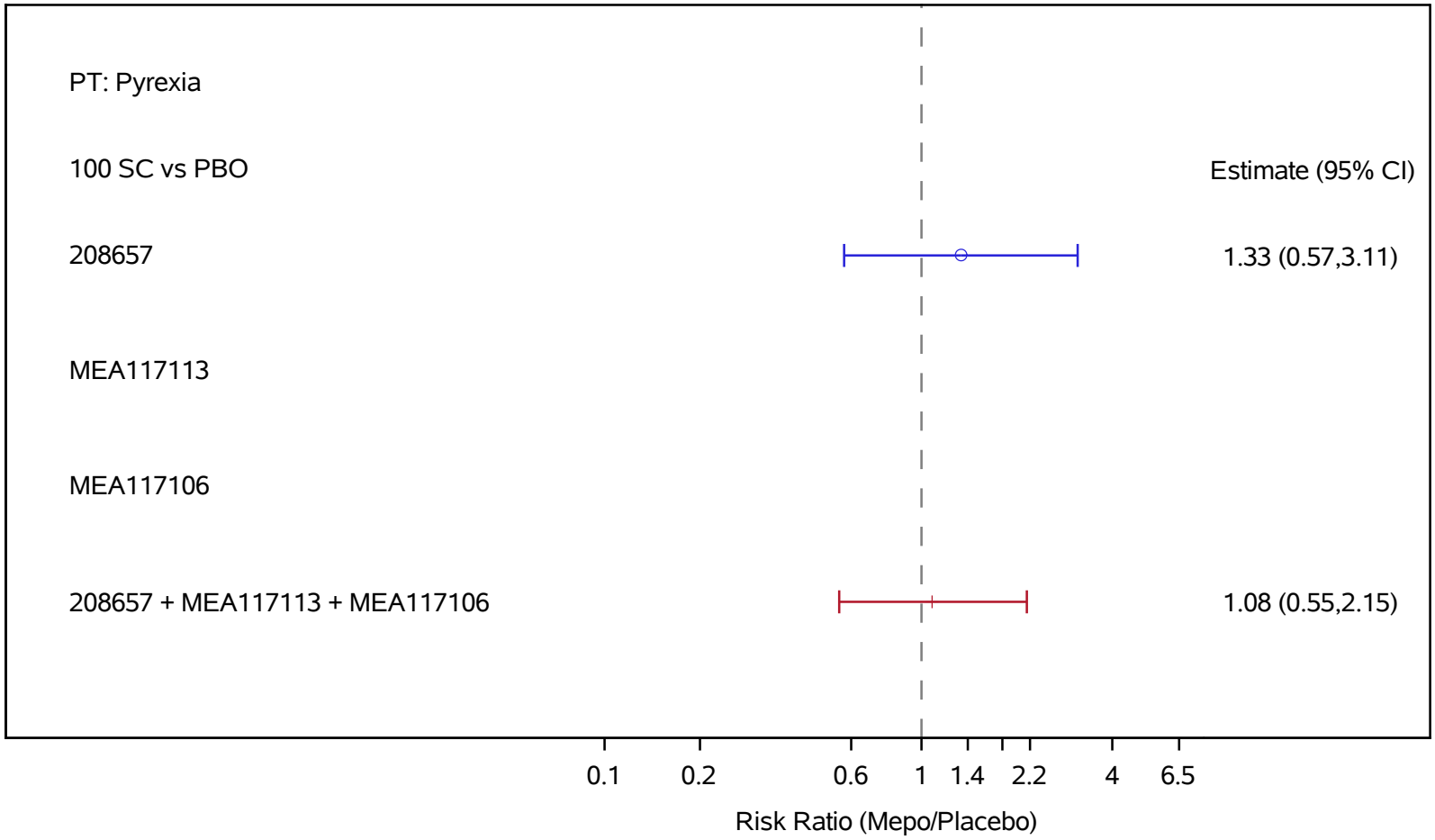

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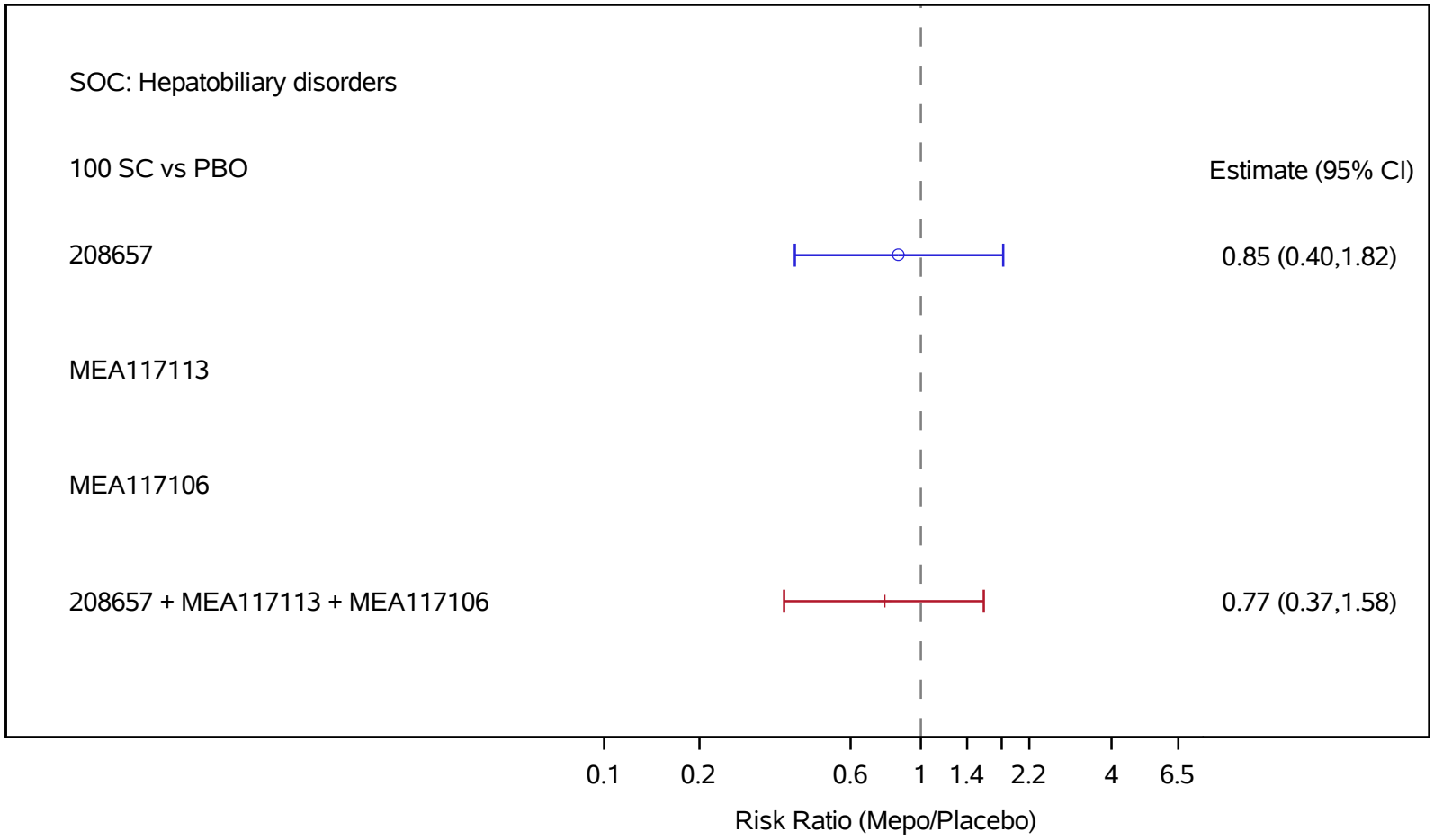

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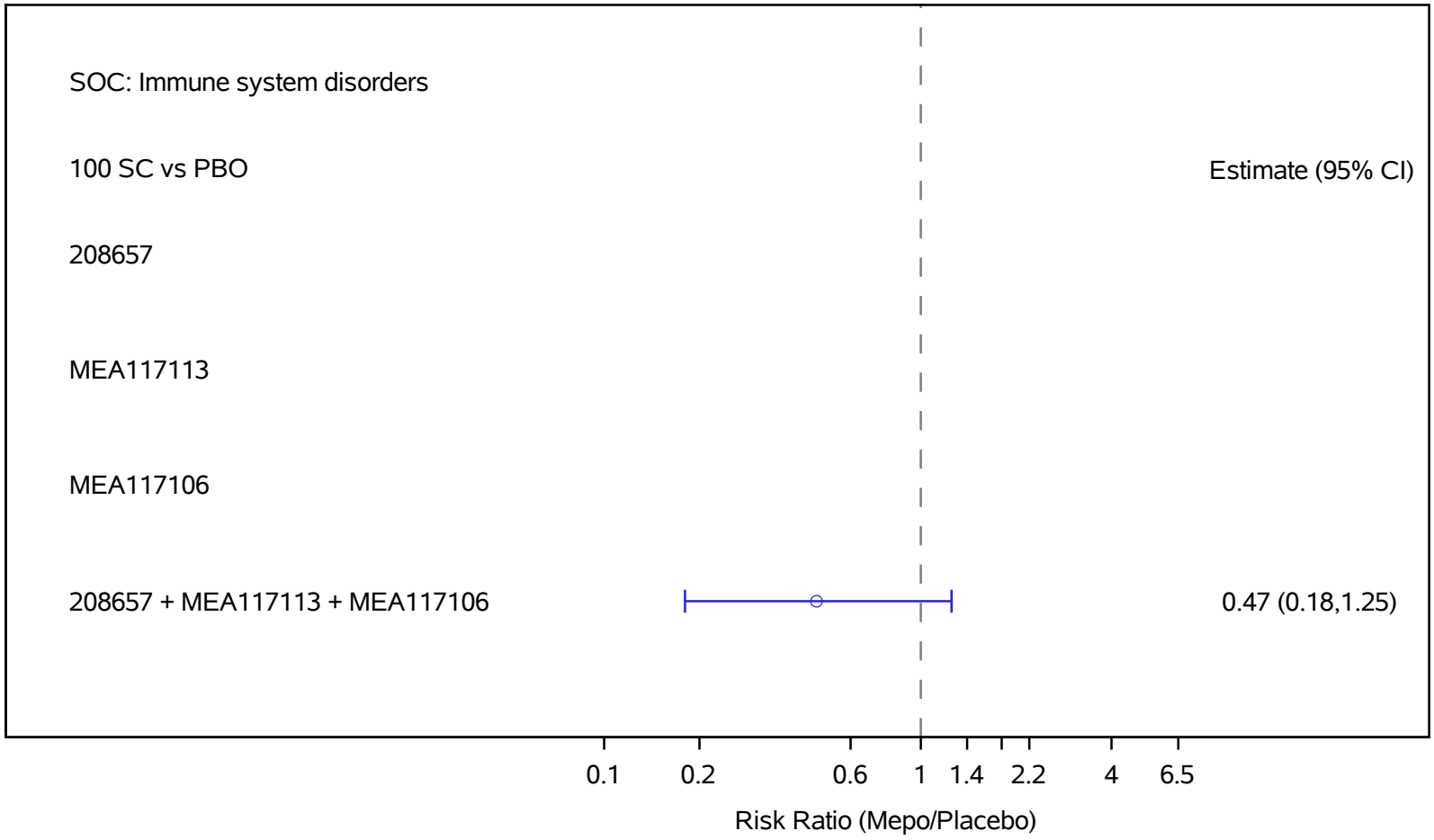

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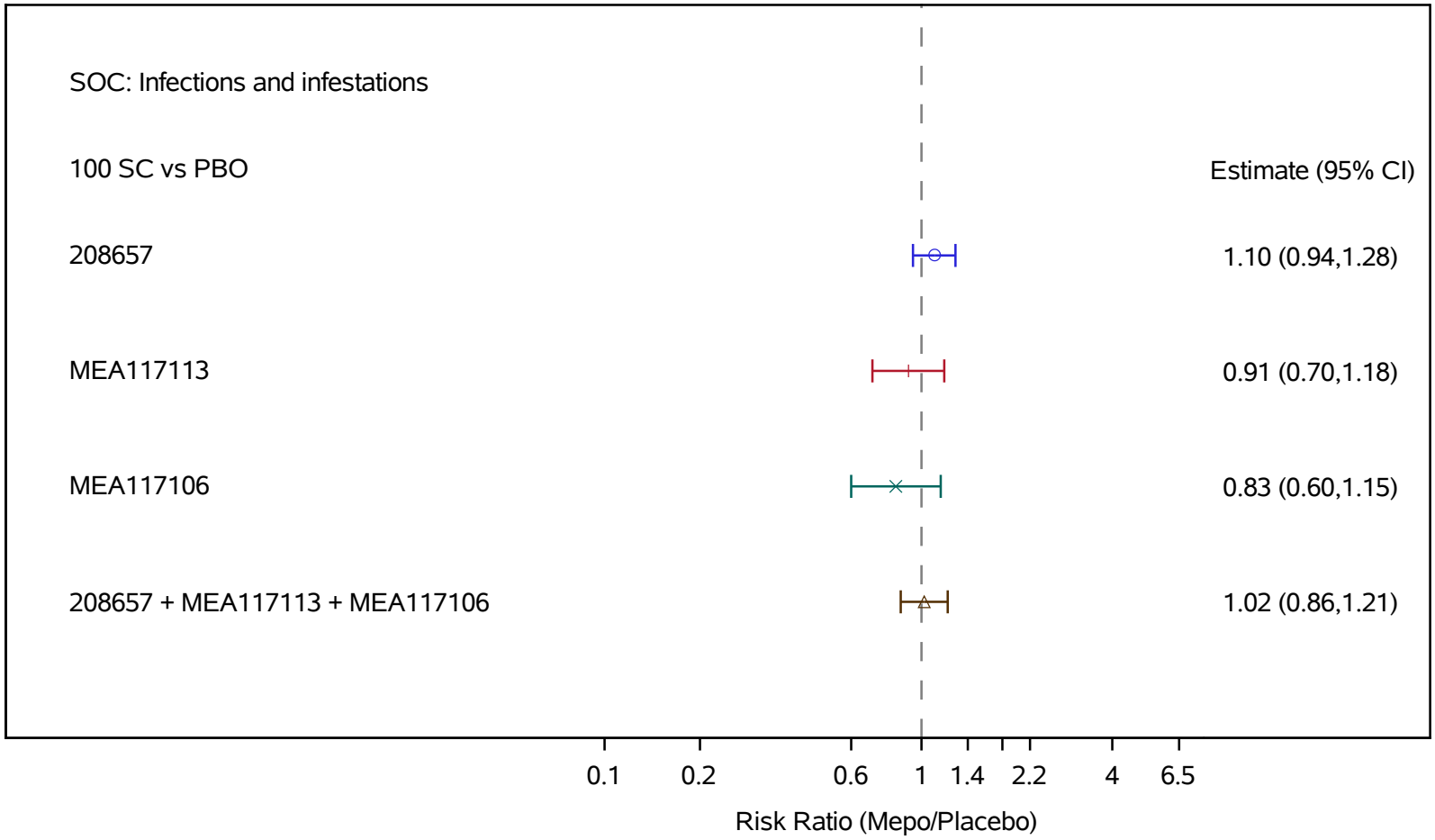

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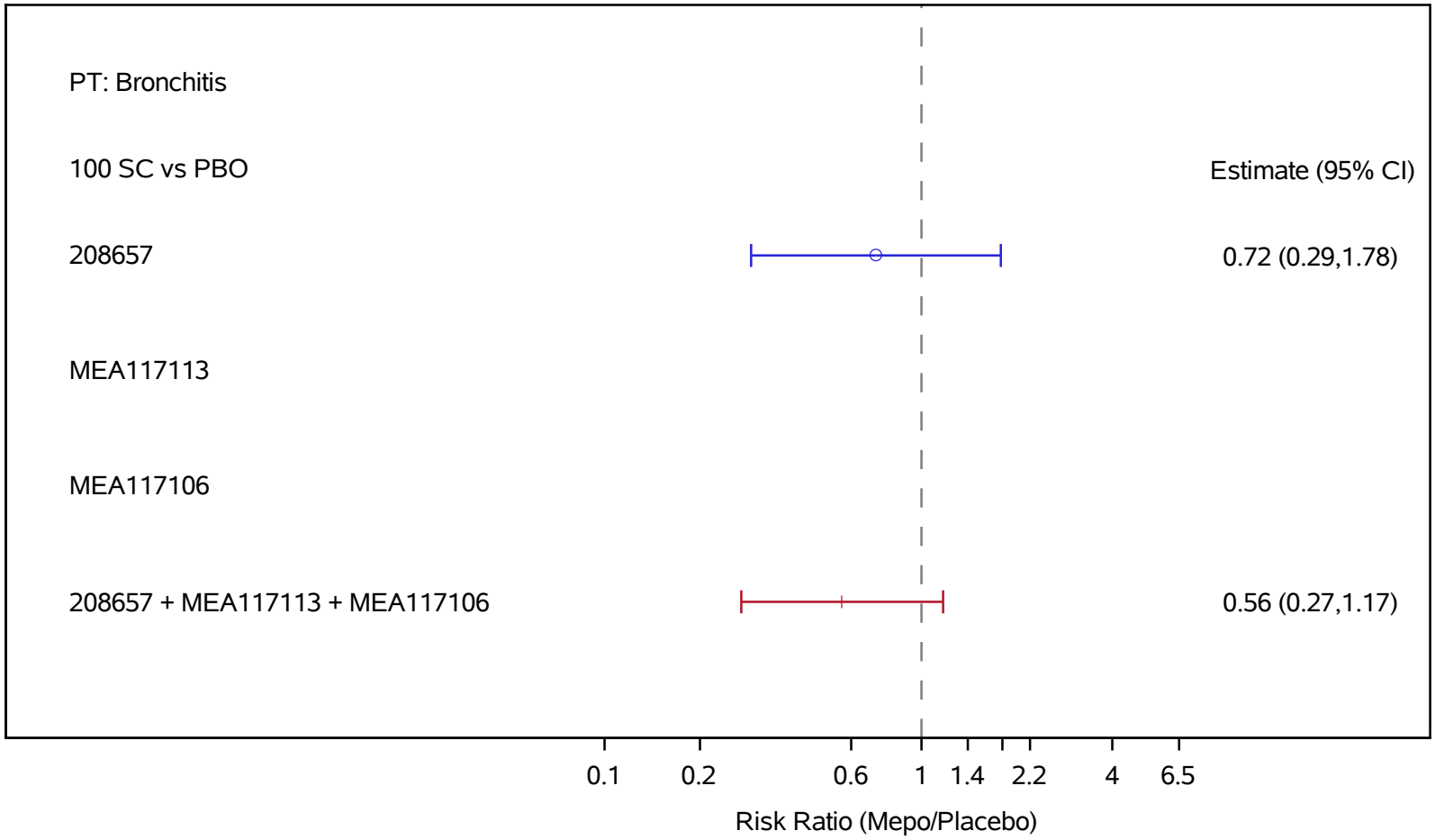

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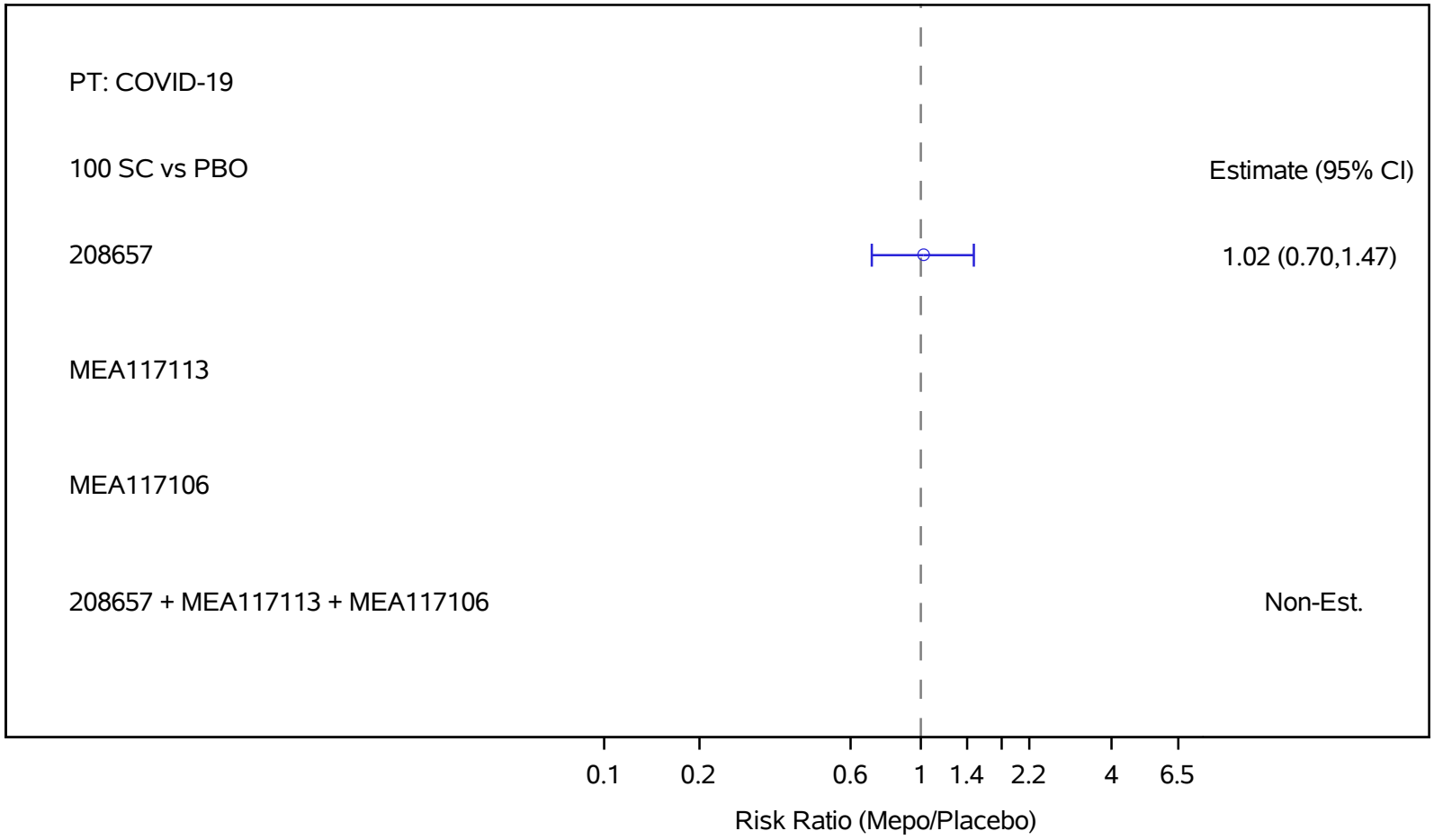

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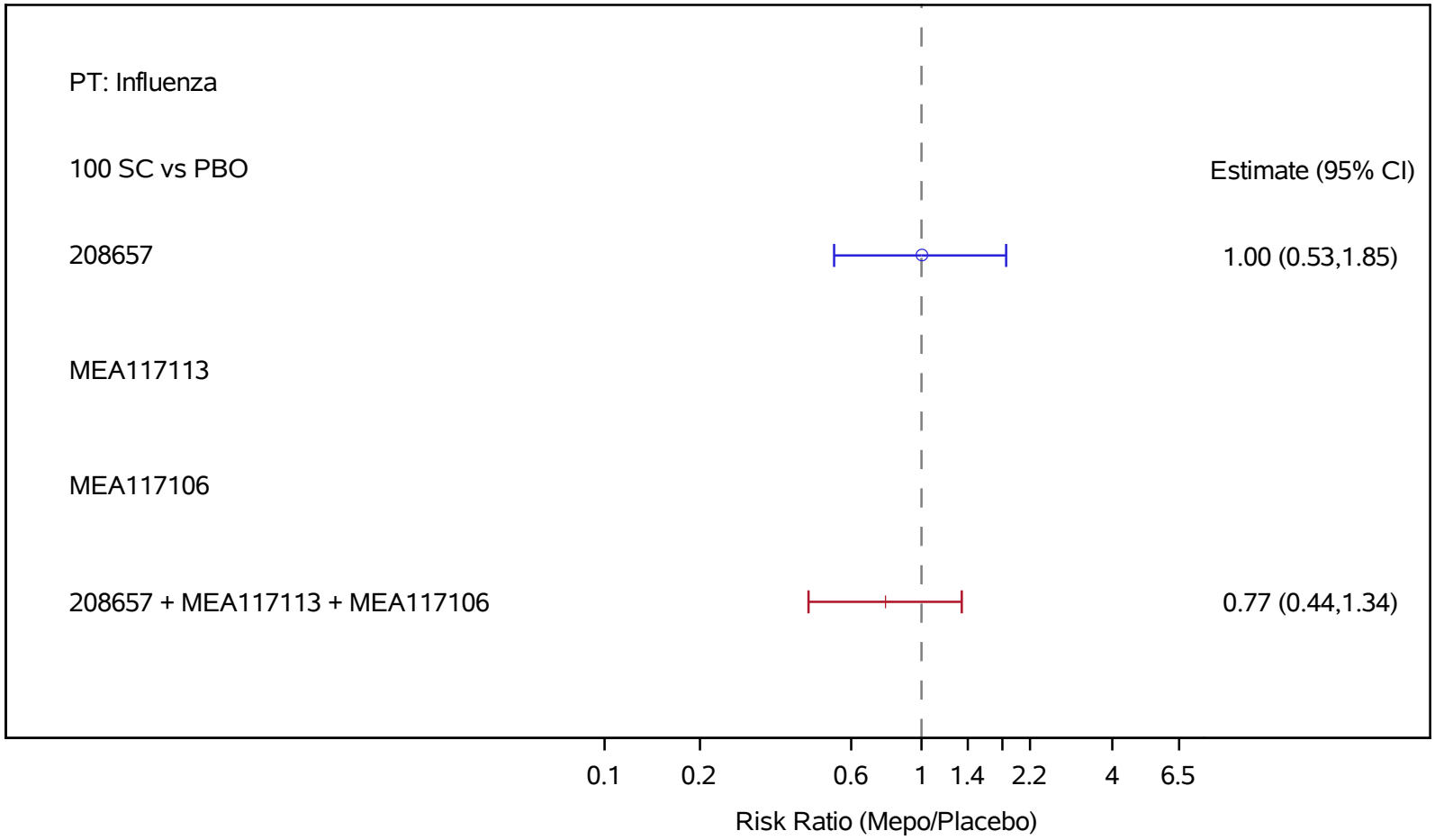

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Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

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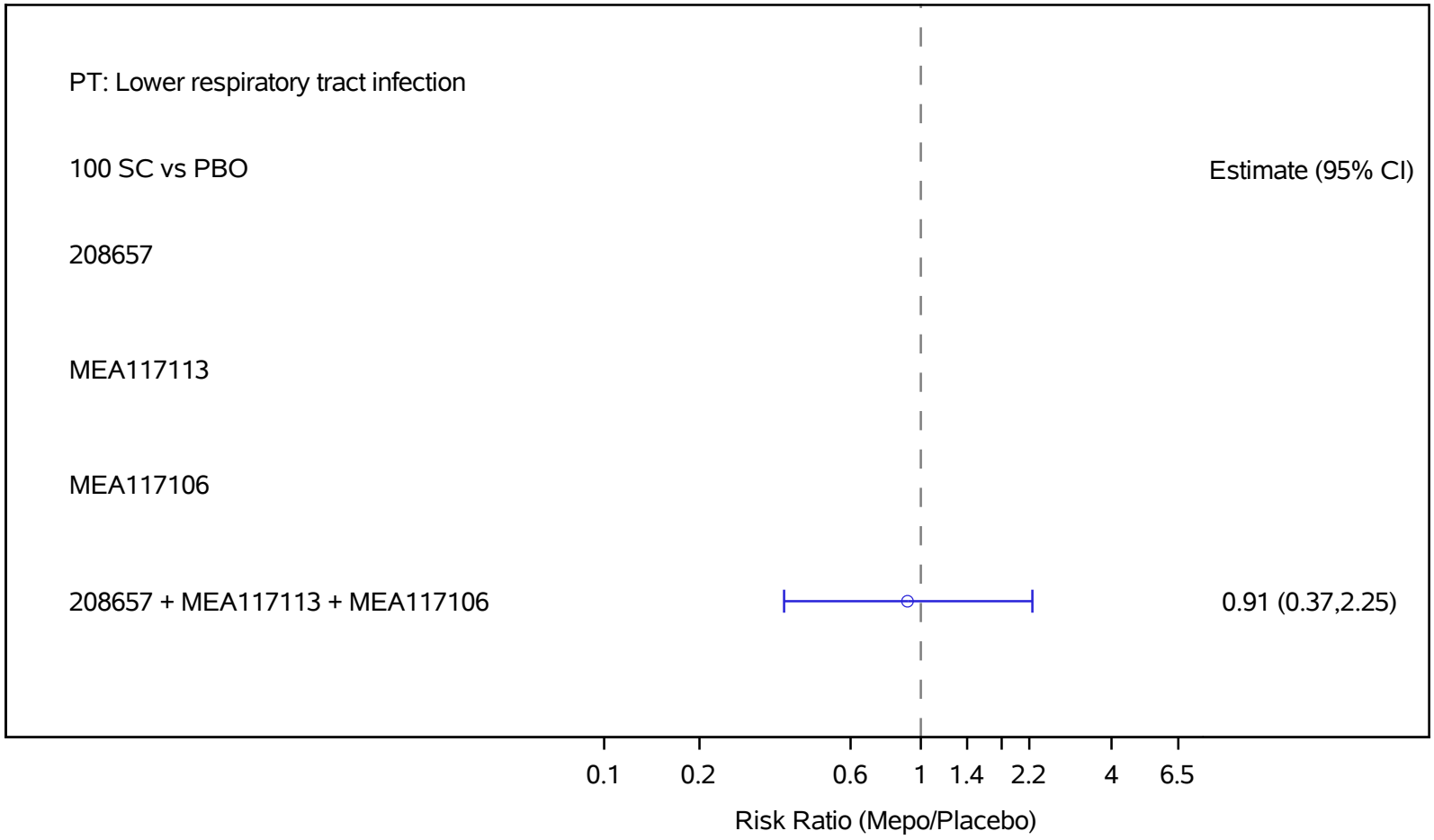
Forest Plot of Relative Risk for On-Treatment Adverse Events Occurring in >=10% of patients or in >=10 and >=1% of patients by SOC and PT: Individual Studies and Meta-Analysis

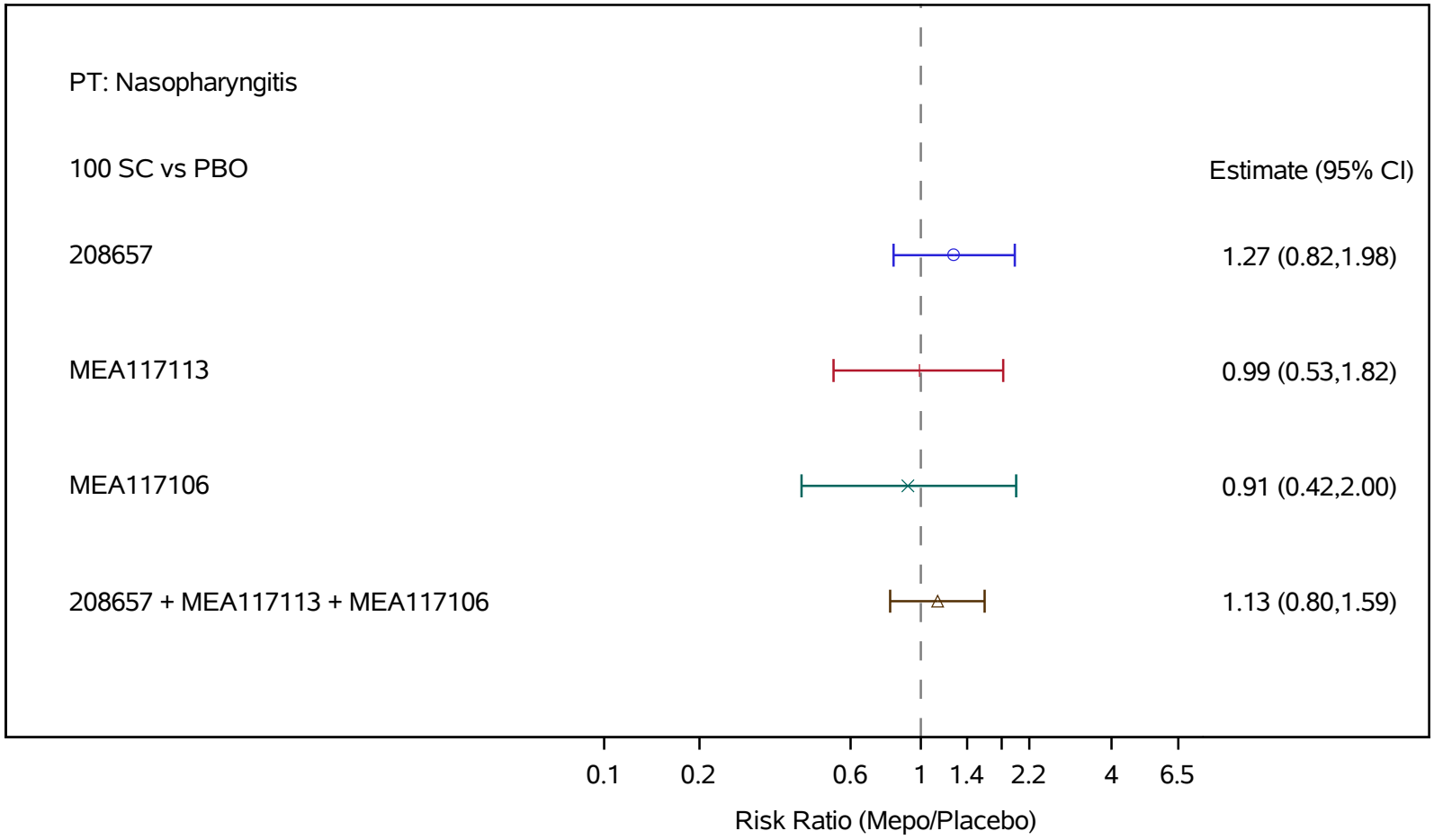


Horizontal bars indicate 95% confidence intervals for the Mepo/Placebo ratio.

Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Figure 311.2

Forest Plot of Relative Risk for On-Treatment Adverse Events Occurring in >=10% of patients or in >=10 and >=1% of patients by SOC and PT: Individual Studies and Meta-Analysis

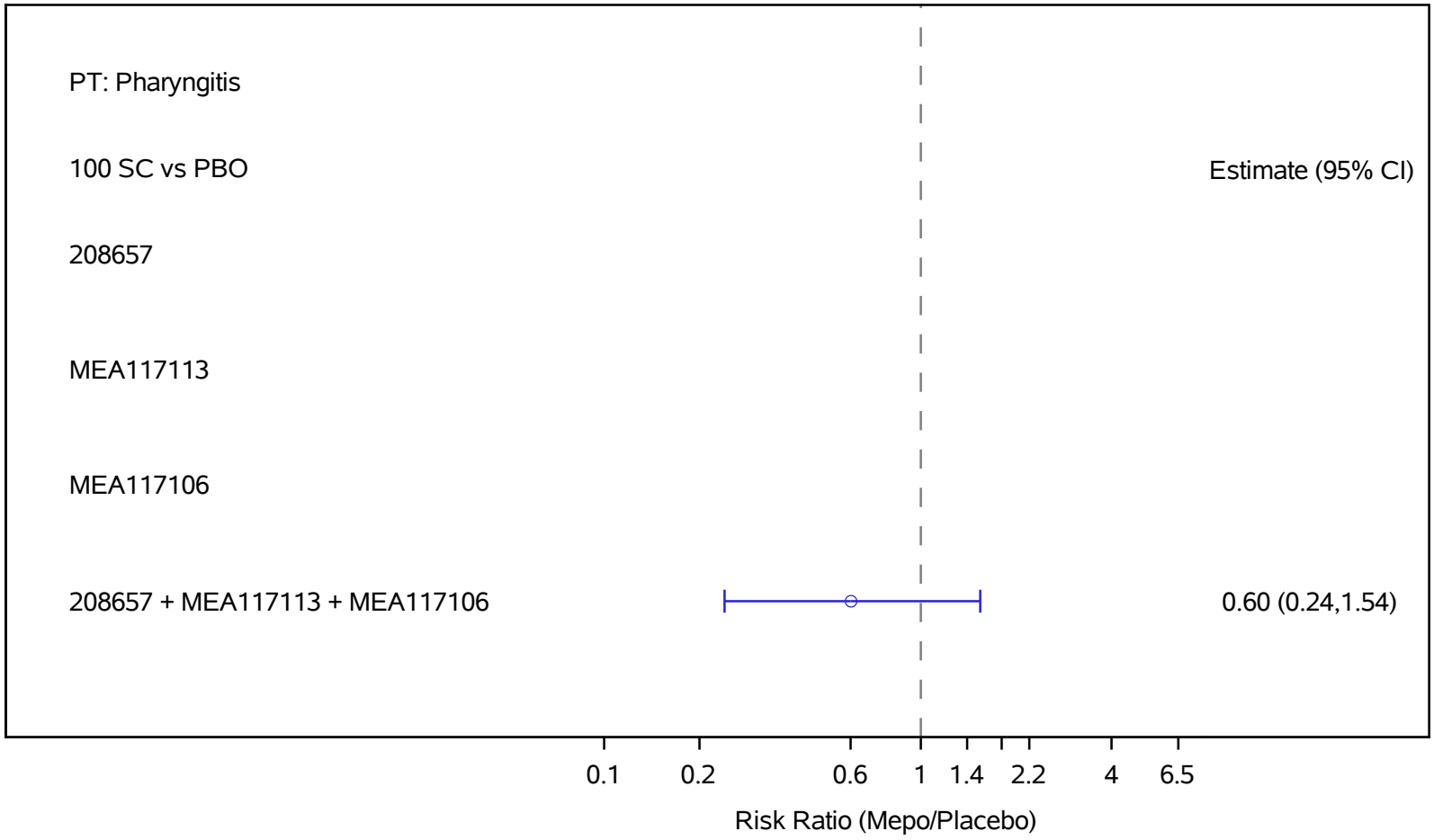


Horizontal bars indicate 95% confidence intervals for the Mepo/Placebo ratio.

Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Figure 311.2

Forest Plot of Relative Risk for On-Treatment Adverse Events Occurring in >=10% of patients or in >=10 and >=1% of patients by SOC and PT: Individual Studies and Meta-Analysis

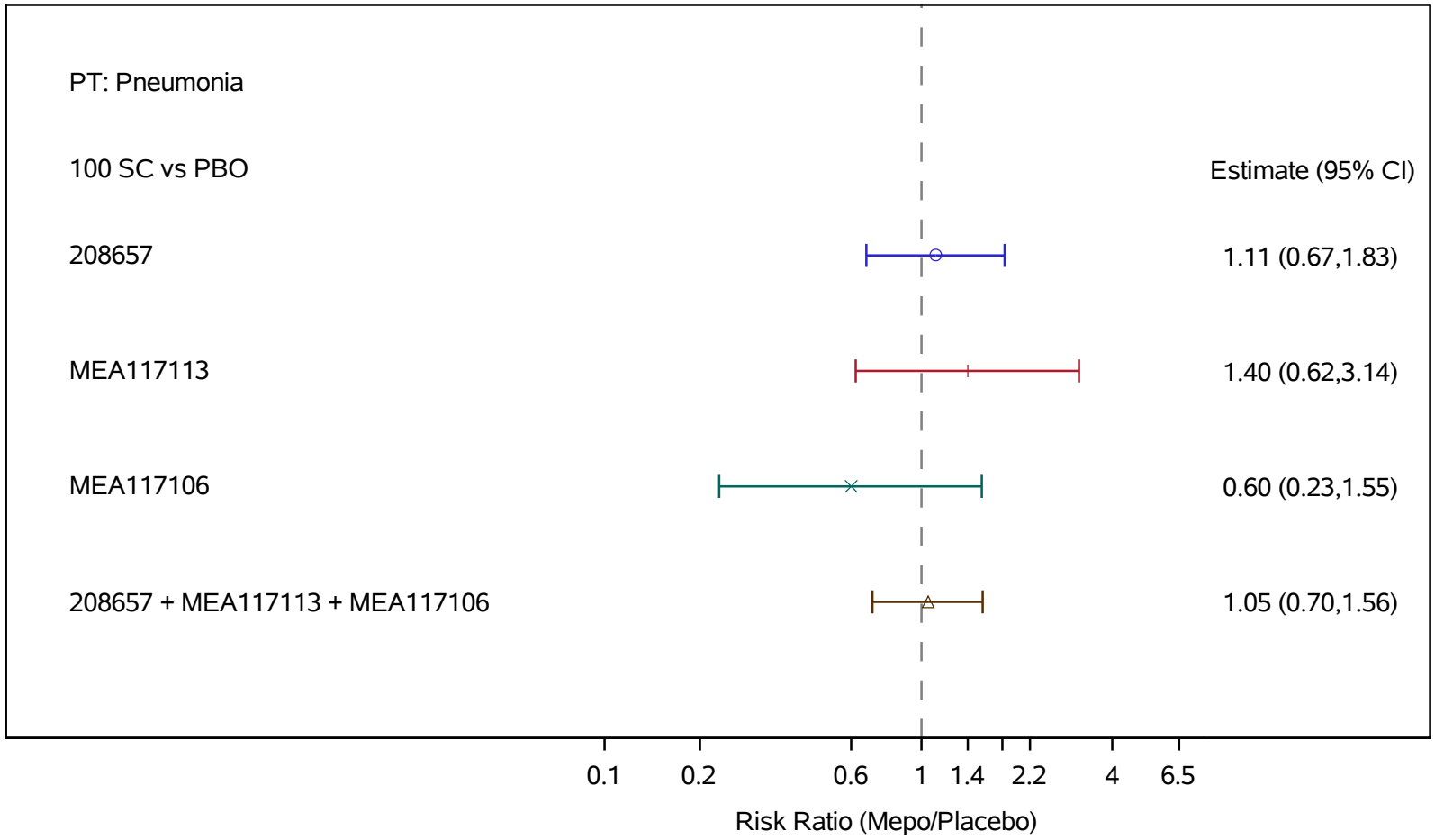


Horizontal bars indicate 95% confidence intervals for the Mepo/Placebo ratio.

Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Figure 311.2

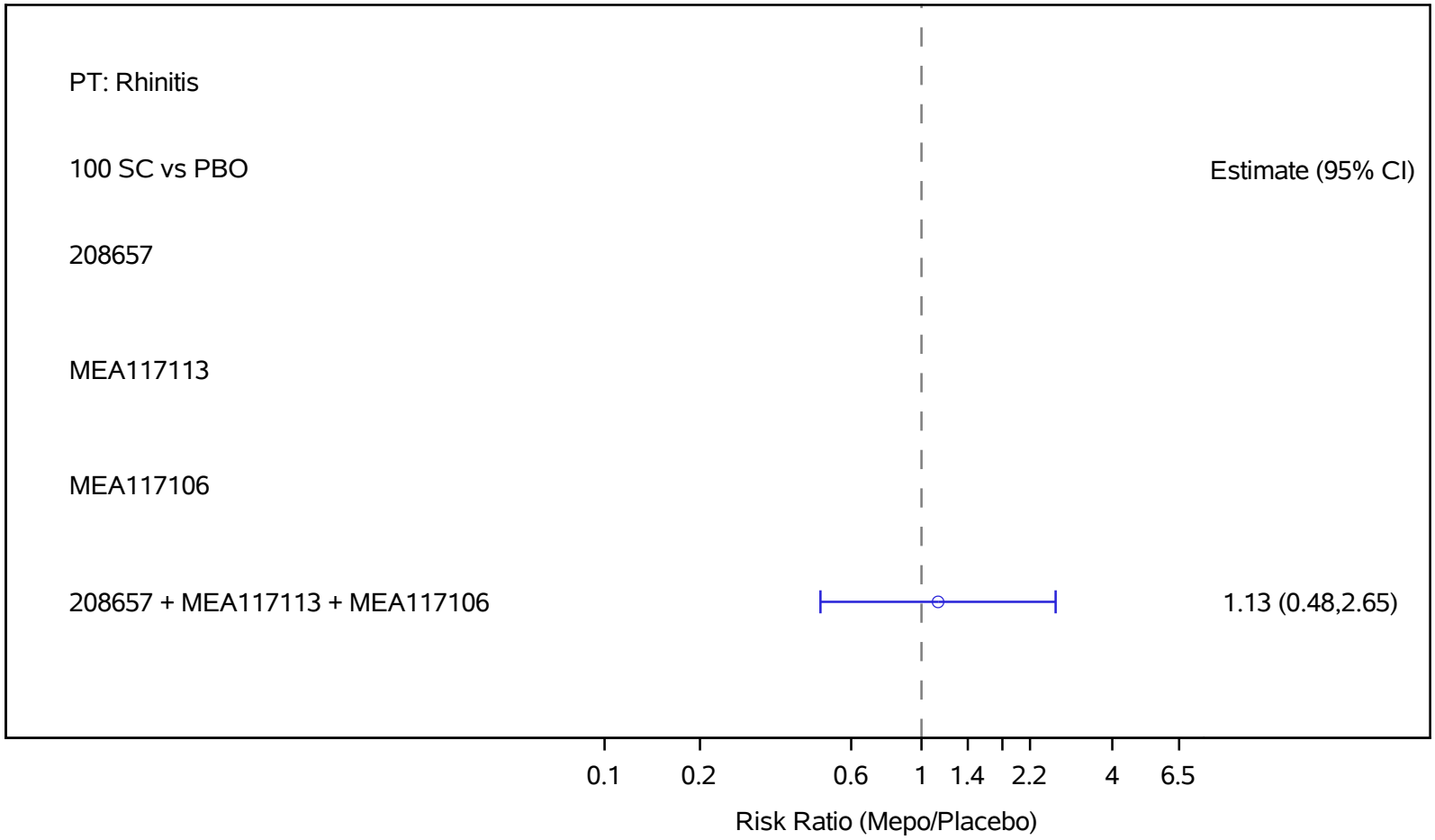
Forest Plot of Relative Risk for On-Treatment Adverse Events Occurring in >=10% of patients or in >=10 and >=1% of patients by SOC and PT: Individual Studies and Meta-Analysis



Horizontal bars indicate 95% confidence intervals for the Mepo/Placebo ratio.

Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Figure 311.2
Forest Plot of Relative Risk for On-Treatment Adverse Events Occurring in >=10% of patients or in >=10 and >=1% of patients by SOC and PT: Individual Studies and Meta-Analysis

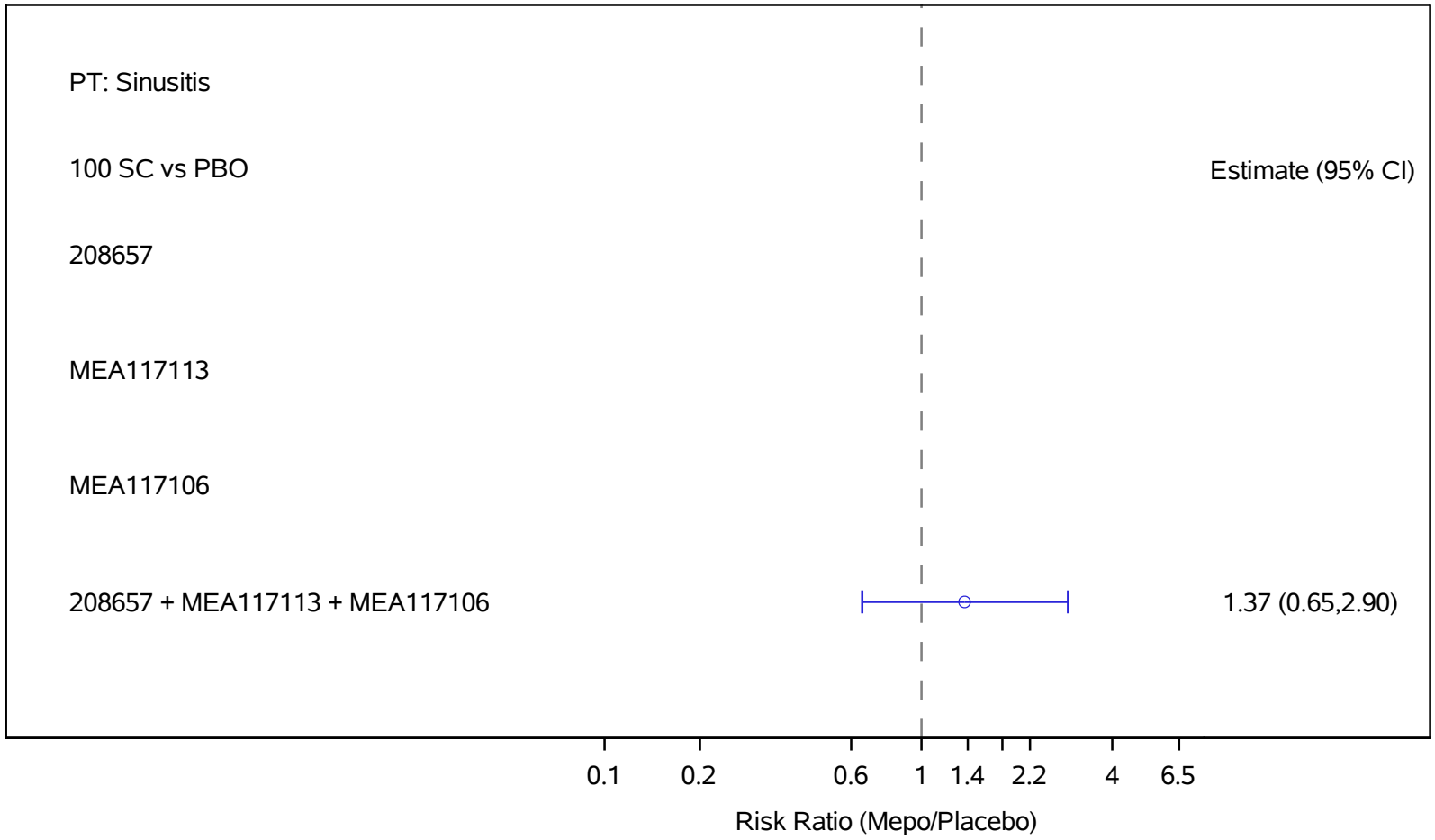


Horizontal bars indicate 95% confidence intervals for the Mepo/Placebo ratio.
/mnt/code/postcsr_01/prod/tfls/f_s_ae_onae_rr.sas 17JUL2025 18:09

Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Figure 311.2

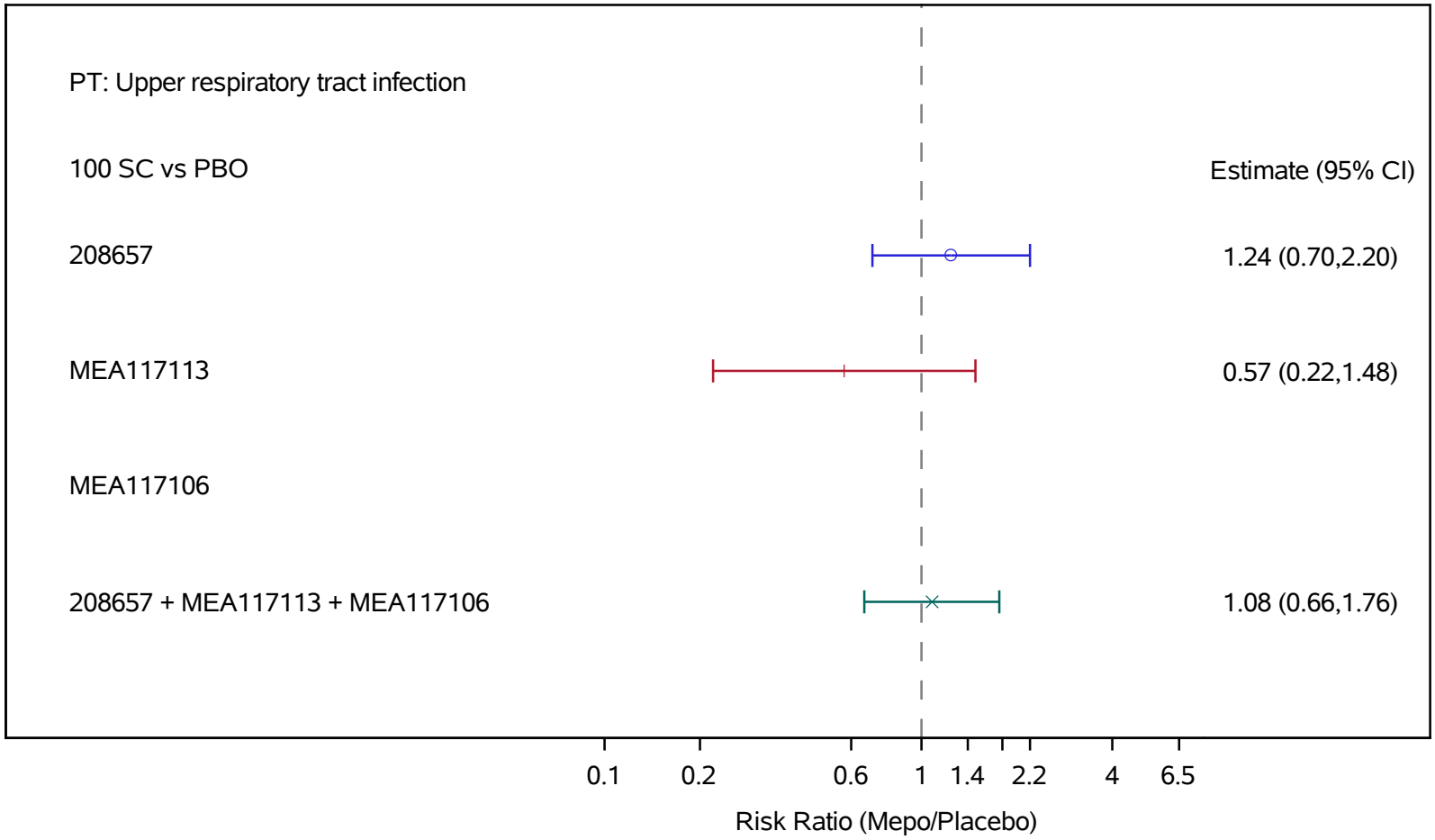
Forest Plot of Relative Risk for On-Treatment Adverse Events Occurring in >=10% of patients or in >=10 and >=1% of patients by SOC and PT: Individual Studies and Meta-Analysis



Horizontal bars indicate 95% confidence intervals for the Mepo/Placebo ratio.

Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Figure 311.2
Forest Plot of Relative Risk for On-Treatment Adverse Events Occurring in >=10% of patients or in >=10 and >=1% of patients by SOC and PT: Individual Studies and Meta-Analysis

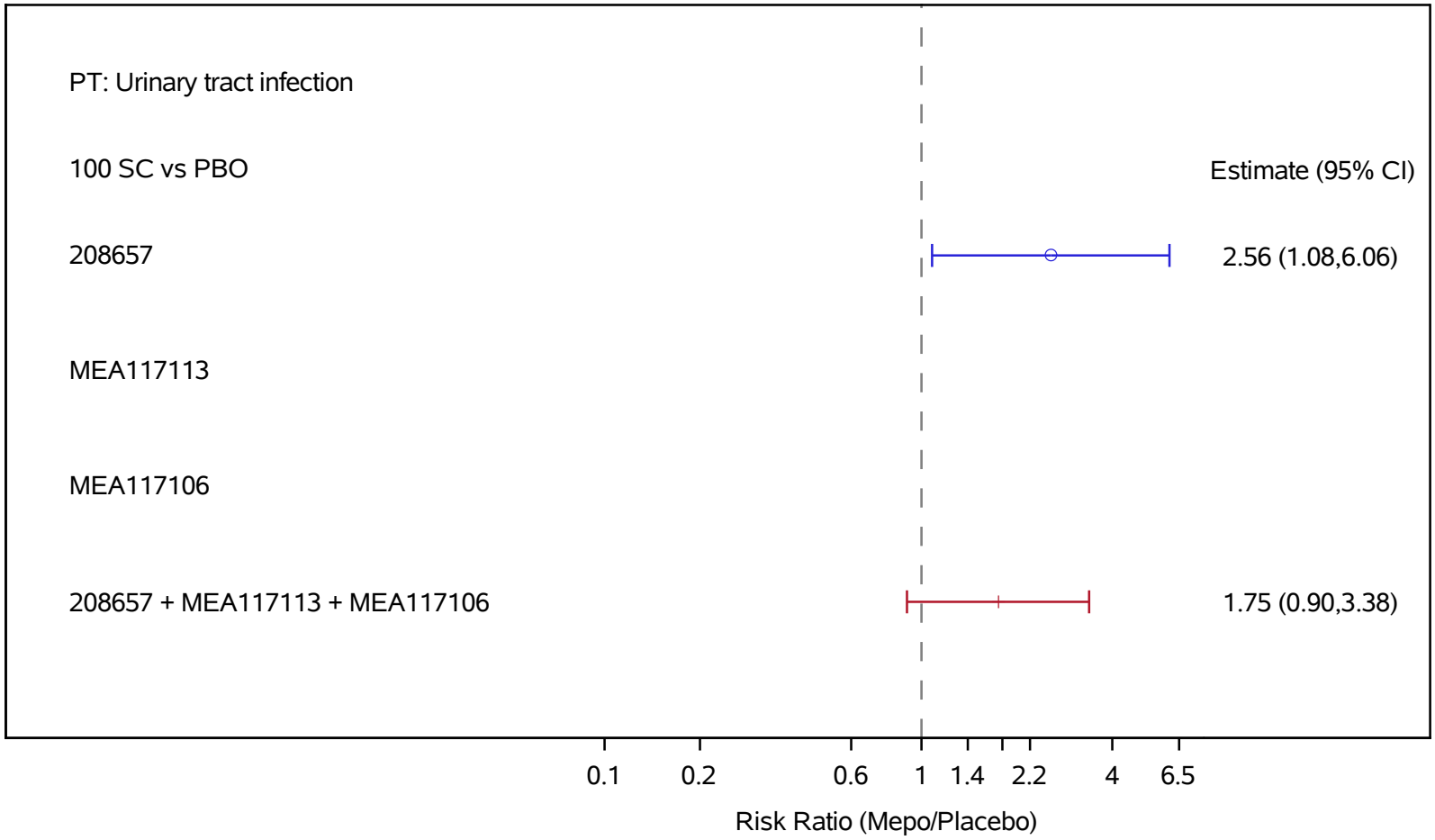


Horizontal bars indicate 95% confidence intervals for the Mepo/Placebo ratio.
/mnt/code/postcsr_01/prod/tfls/f_s_ae_onae_rr.sas 17JUL2025 18:09

Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Figure 311.2

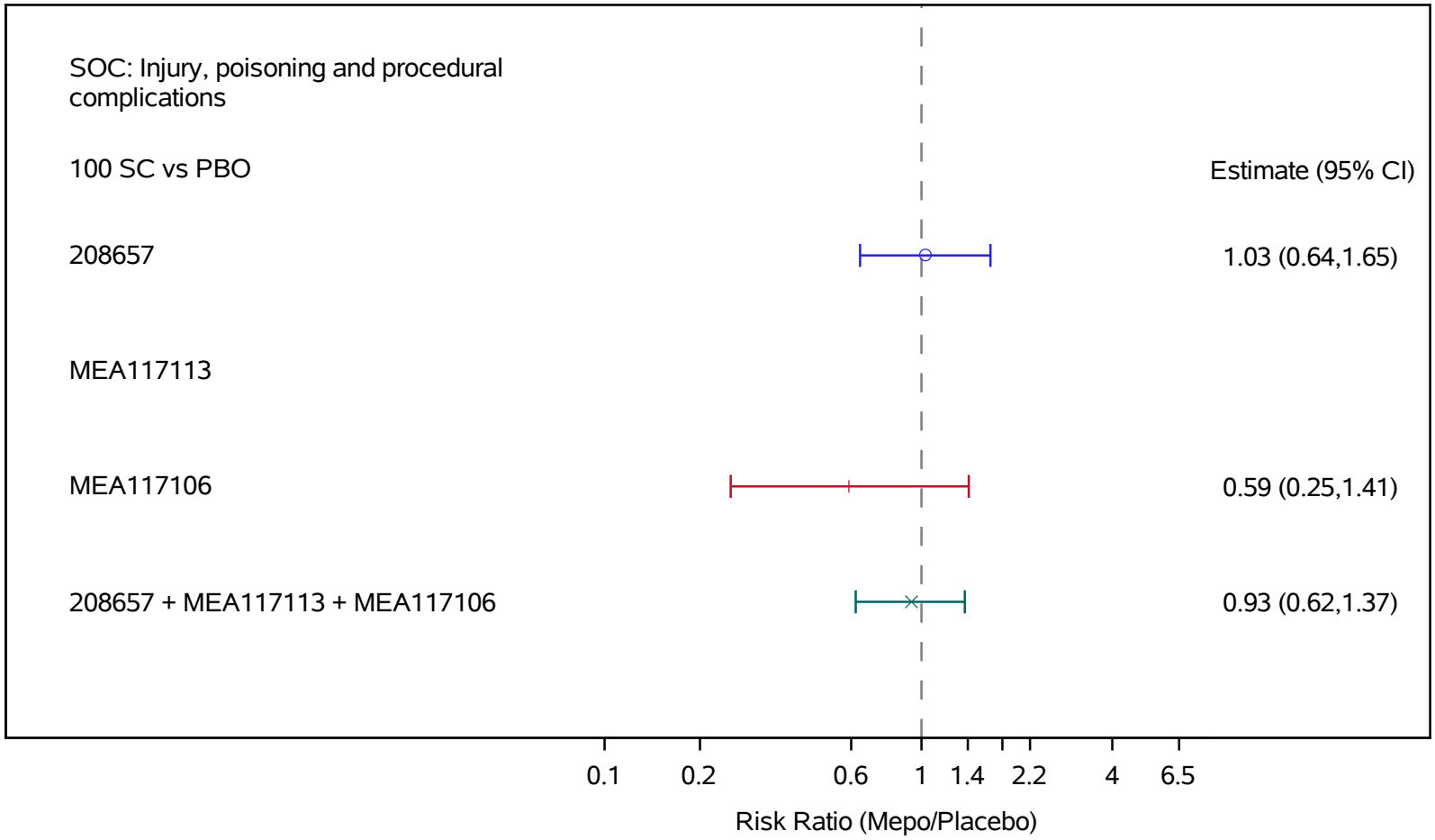
Forest Plot of Relative Risk for On-Treatment Adverse Events Occurring in >=10% of patients or in >=10 and >=1% of patients by SOC and PT: Individual Studies and Meta-Analysis



Horizontal bars indicate 95% confidence intervals for the Mepo/Placebo ratio.

Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Figure 311.2
Forest Plot of Relative Risk for On-Treatment Adverse Events Occurring in >=10% of patients or in >=10 and >=1% of patients by SOC and PT: Individual Studies and Meta-Analysis

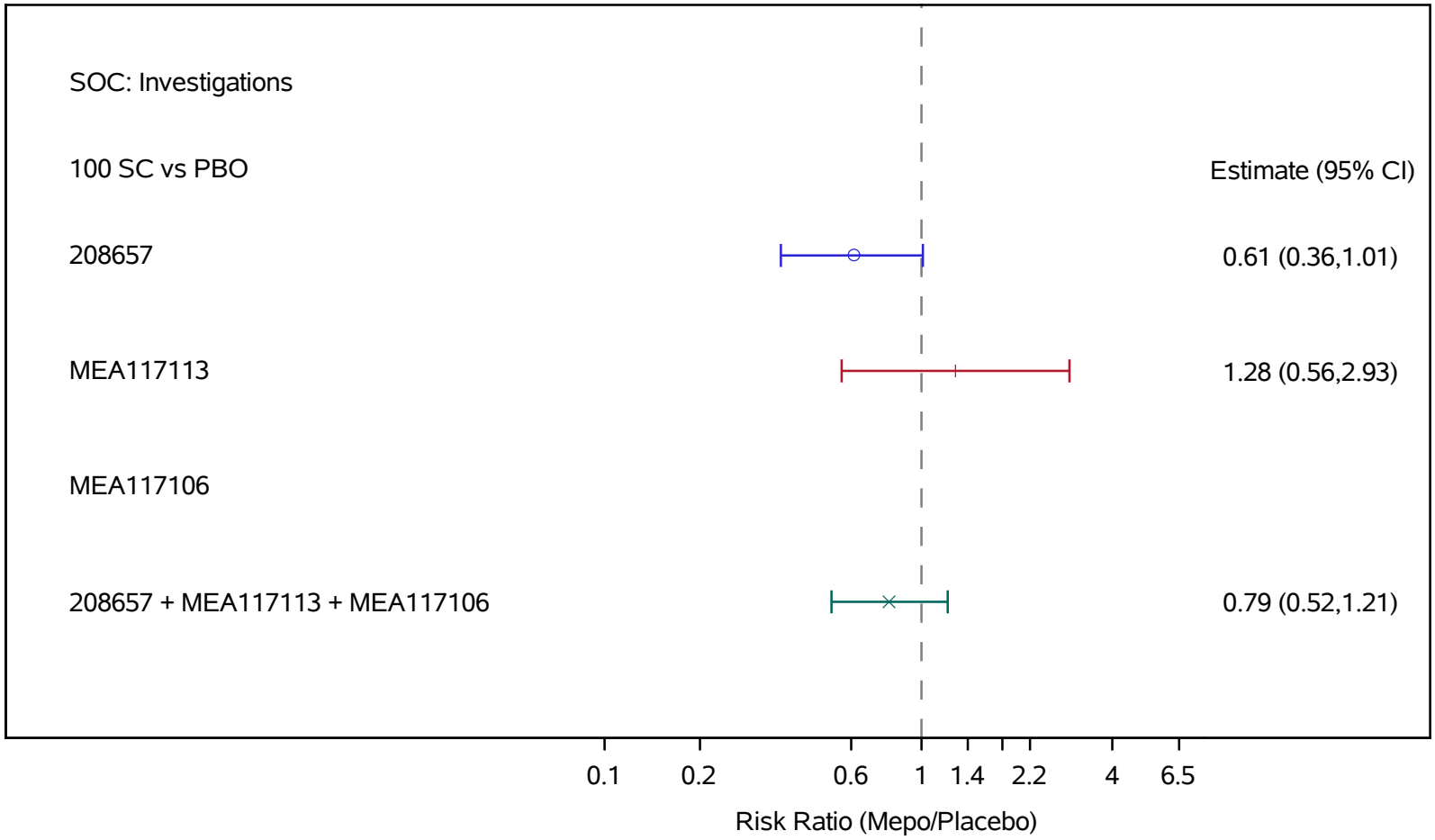


Horizontal bars indicate 95% confidence intervals for the Mepo/Placebo ratio.
/mnt/code/postcsr_01/prod/tfls/f_s_ae_onae_rr.sas 17JUL2025 18:09

Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Figure 311.2

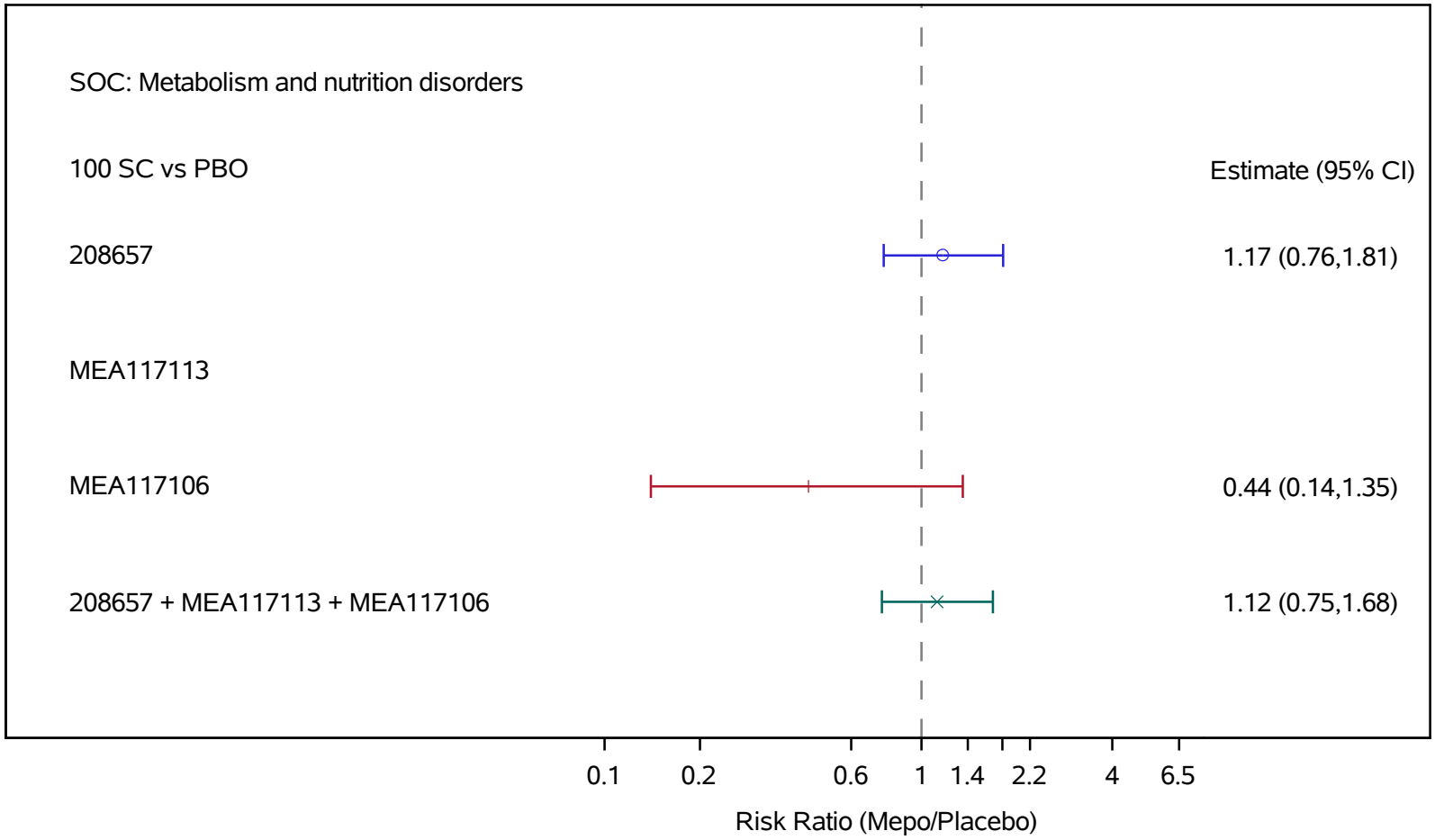
Forest Plot of Relative Risk for On-Treatment Adverse Events Occurring in >=10% of patients or in >=10 and >=1% of patients by SOC and PT: Individual Studies and Meta-Analysis



Horizontal bars indicate 95% confidence intervals for the Mepo/Placebo ratio.

Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Figure 311.2
Forest Plot of Relative Risk for On-Treatment Adverse Events Occurring in >=10% of patients or in >=10 and >=1% of patients by SOC and PT: Individual Studies and Meta-Analysis

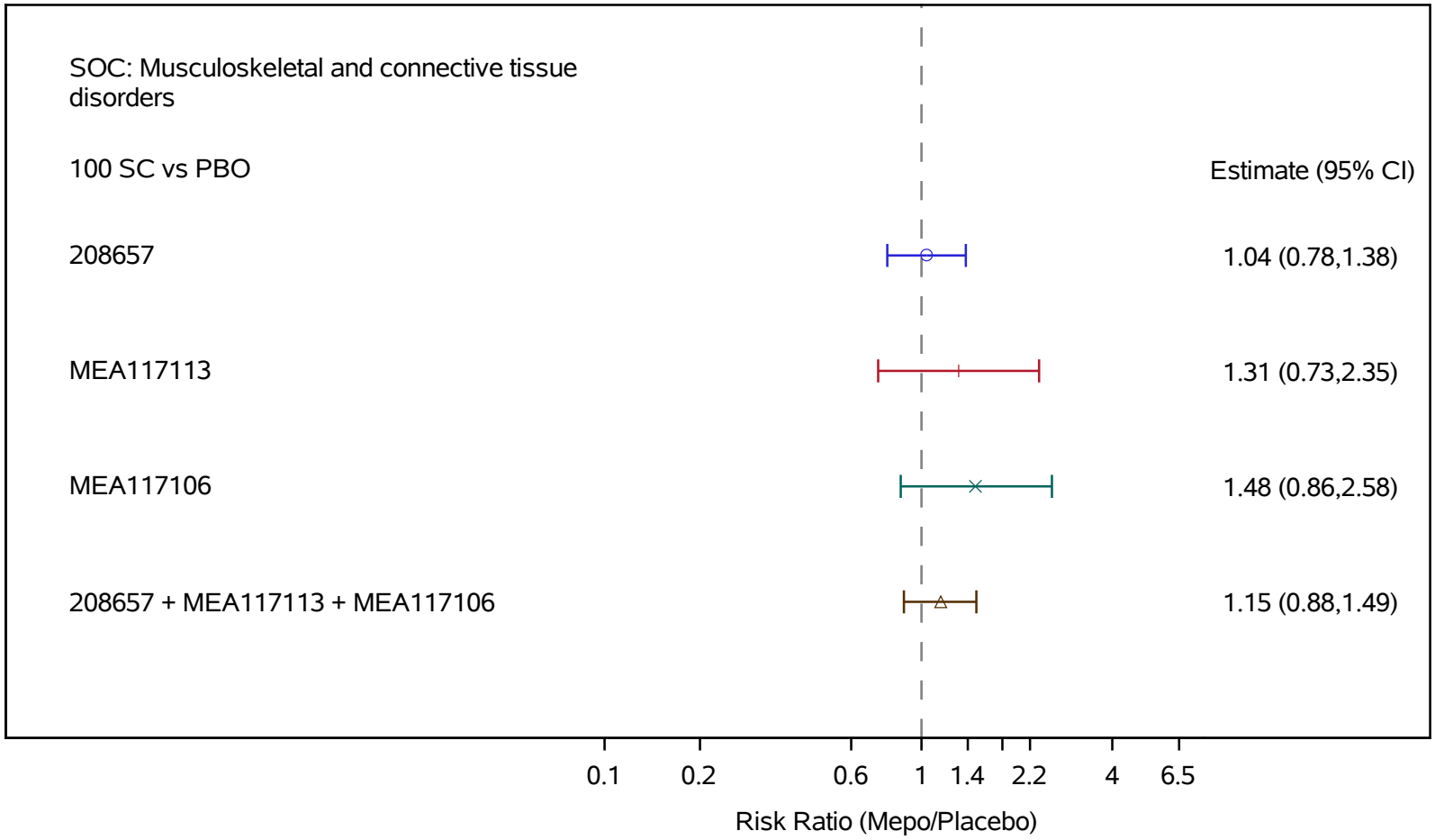


Horizontal bars indicate 95% confidence intervals for the Mepo/Placebo ratio.
/mnt/code/postcsr_01/prod/tfls/f_s_ae_onae_rr.sas 17JUL2025 18:09

Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Figure 311.2

Forest Plot of Relative Risk for On-Treatment Adverse Events Occurring in >=10% of patients or in >=10 and >=1% of patients by SOC and PT: Individual Studies and Meta-Analysis

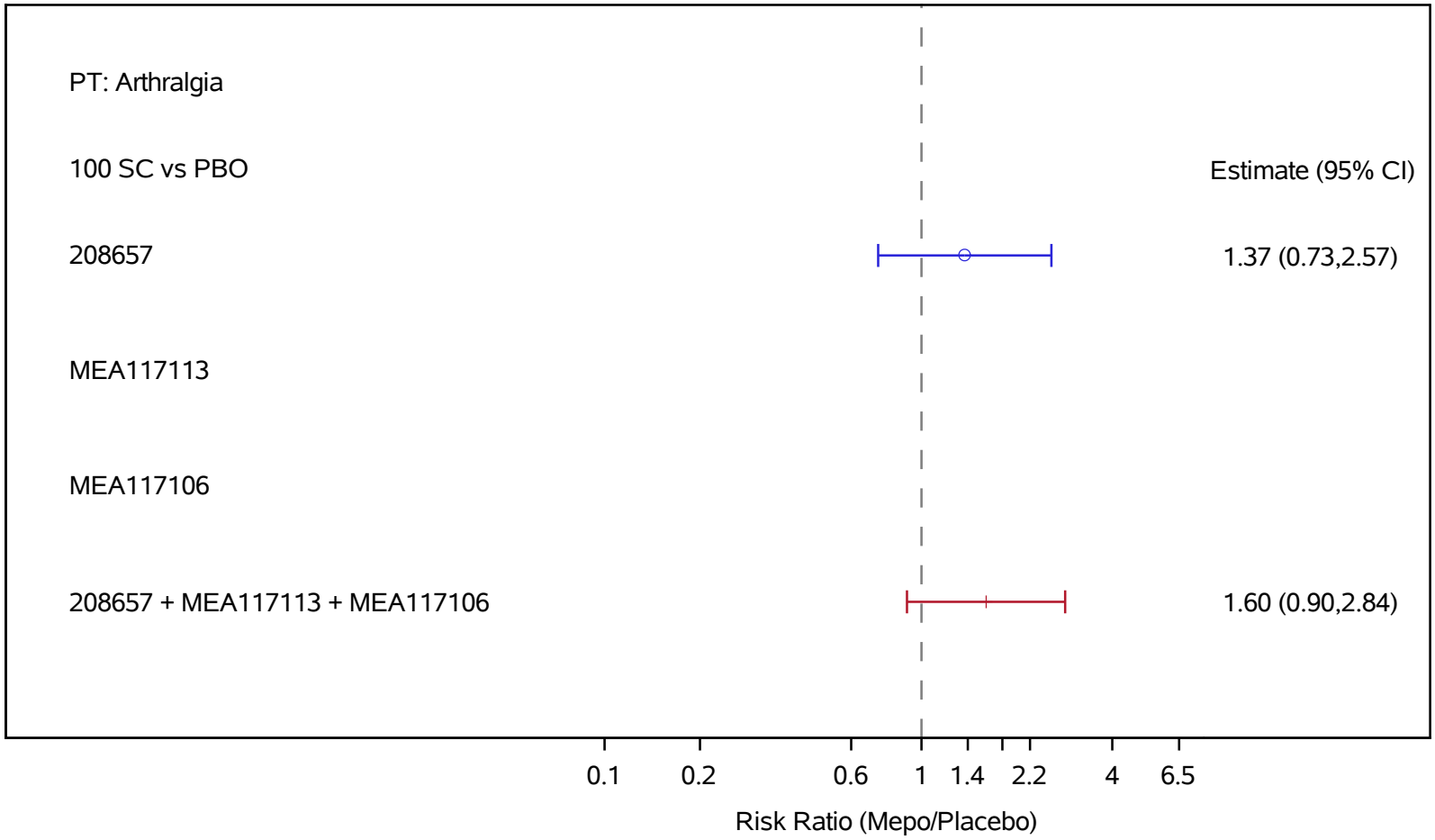


Horizontal bars indicate 95% confidence intervals for the Mepo/Placebo ratio.

Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Figure 311.2

Forest Plot of Relative Risk for On-Treatment Adverse Events Occurring in >=10% of patients or in >=10 and >=1% of patients by SOC and PT: Individual Studies and Meta-Analysis

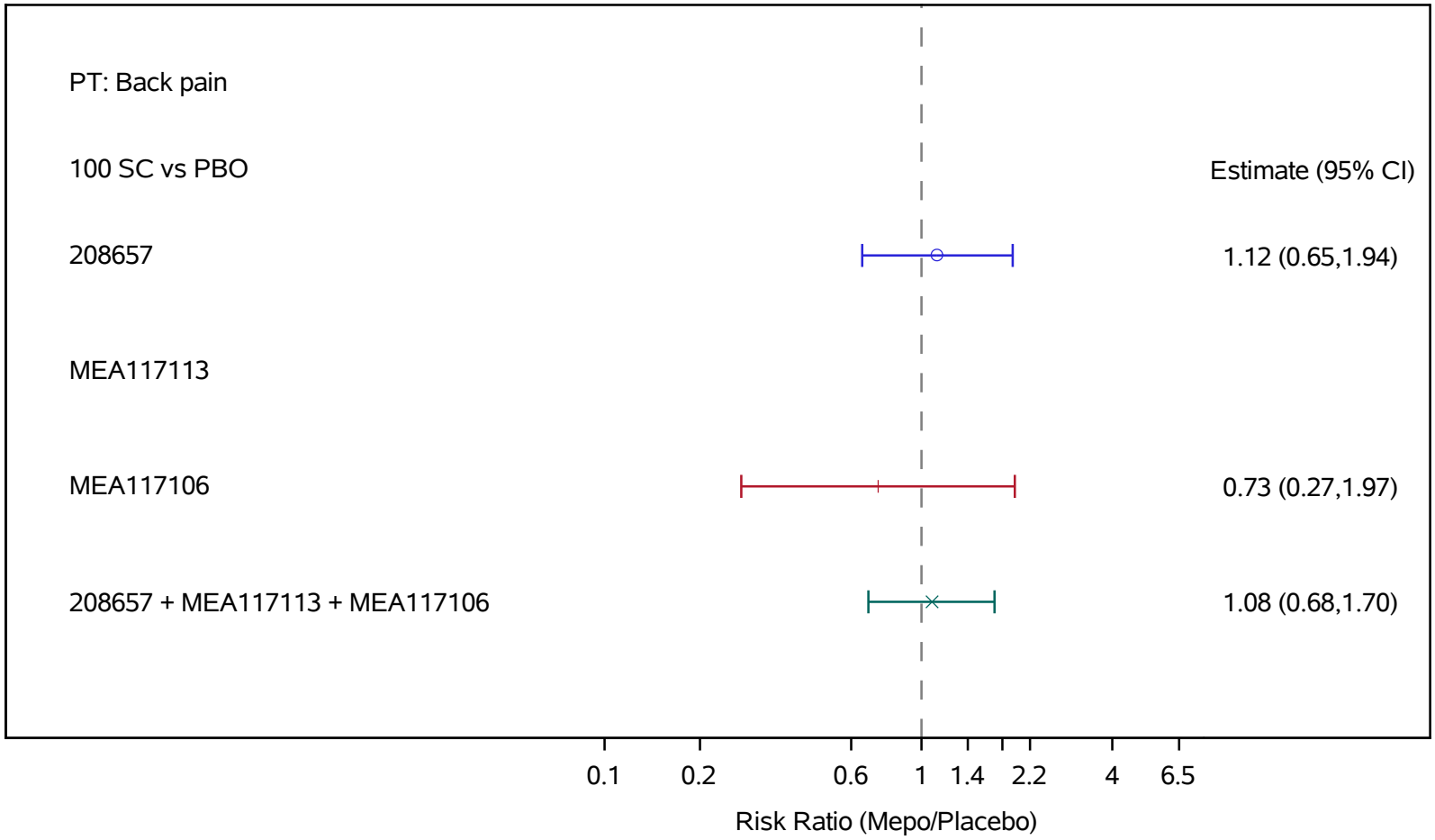


Horizontal bars indicate 95% confidence intervals for the Mepo/Placebo ratio.

Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Figure 311.2

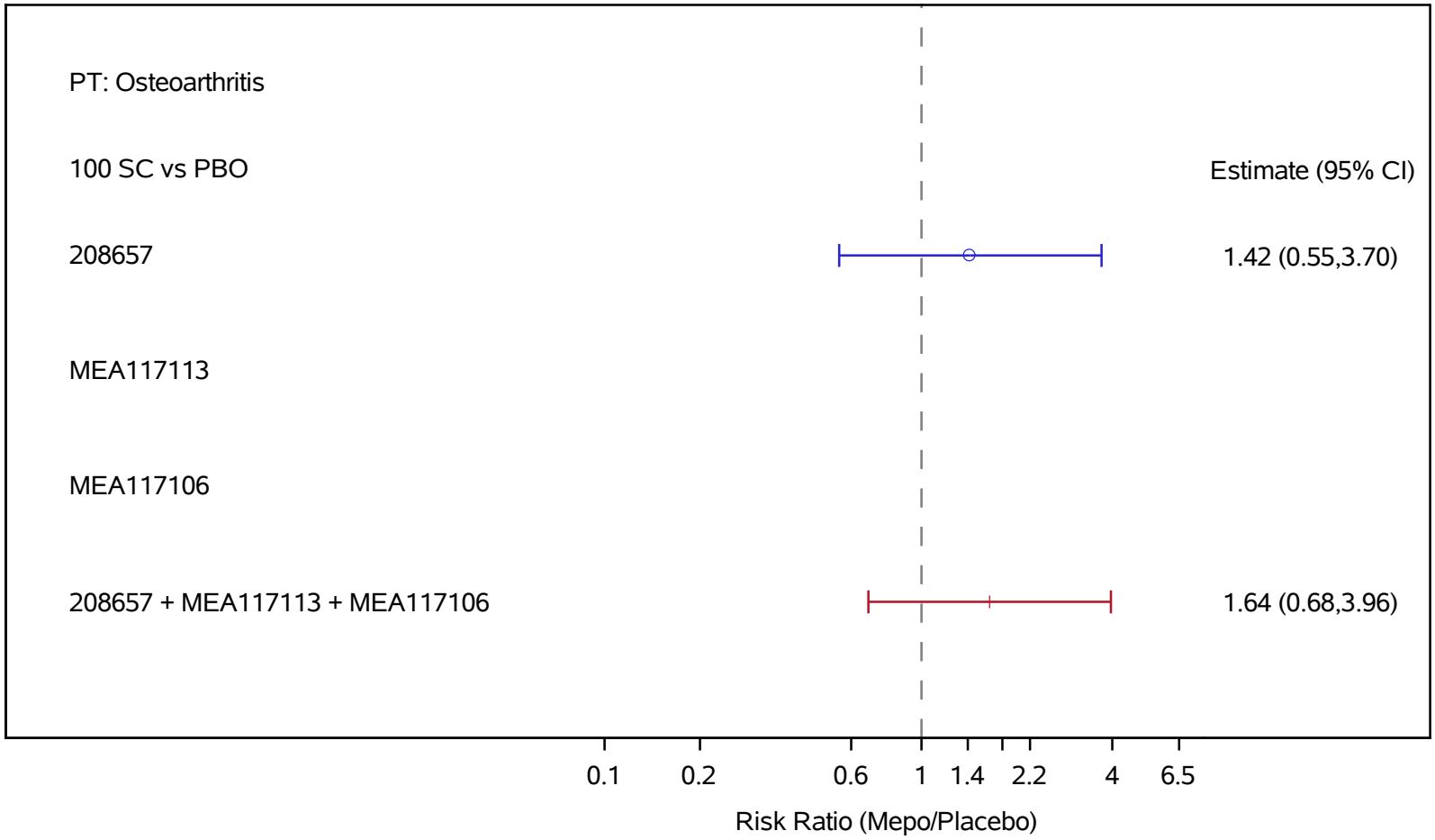
Forest Plot of Relative Risk for On-Treatment Adverse Events Occurring in >=10% of patients or in >=10 and >=1% of patients by SOC and PT: Individual Studies and Meta-Analysis



Horizontal bars indicate 95% confidence intervals for the Mepo/Placebo ratio.

Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Figure 311.2
Forest Plot of Relative Risk for On-Treatment Adverse Events Occurring in >=10% of patients or in >=10 and >=1% of patients by SOC and PT: Individual Studies and Meta-Analysis

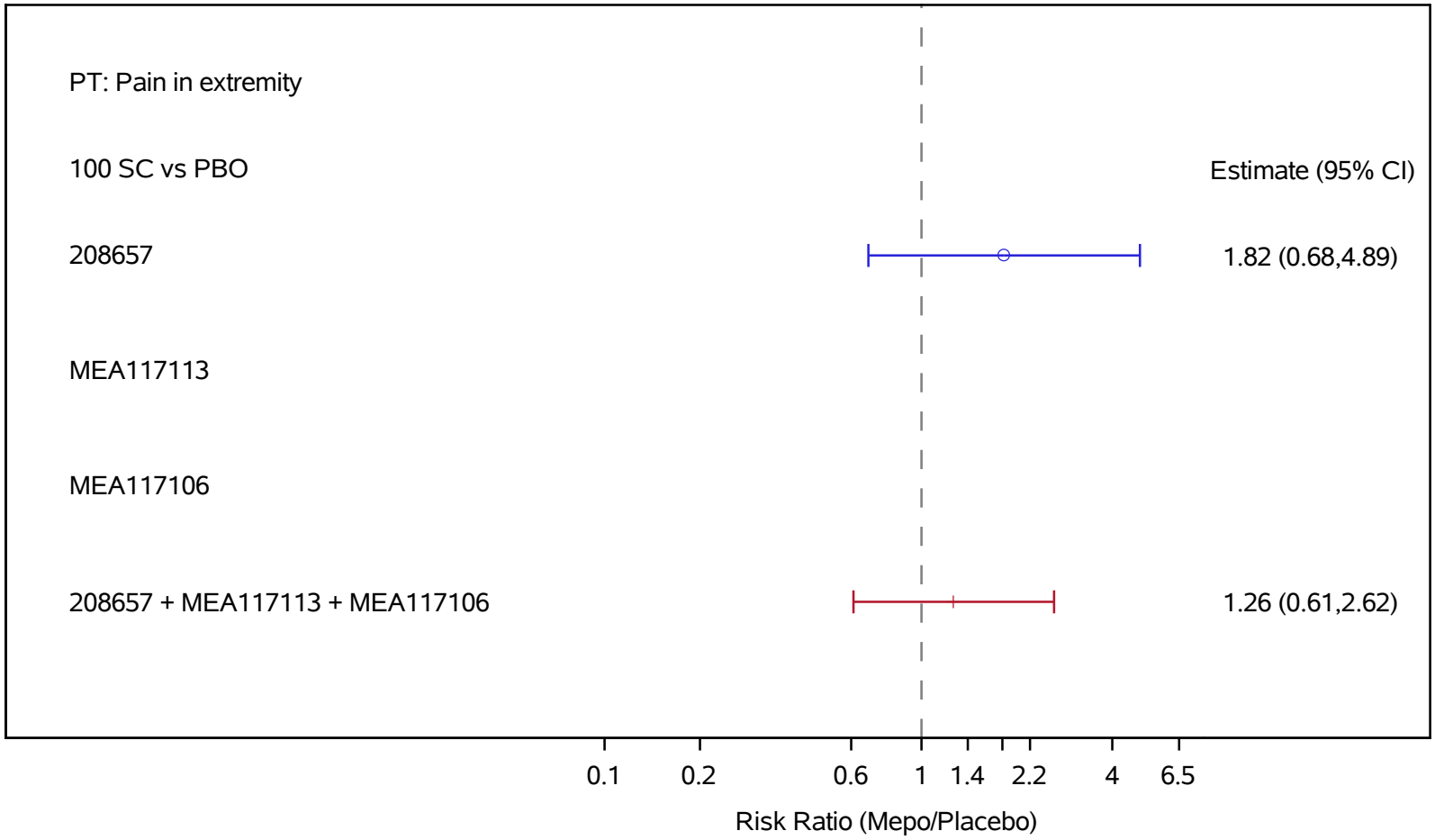


Horizontal bars indicate 95% confidence intervals for the Mepo/Placebo ratio.
/mnt/code/postcsr_01/prod/tfls/f_s_ae_onae_rr.sas 17JUL2025 18:09

Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Figure 311.2

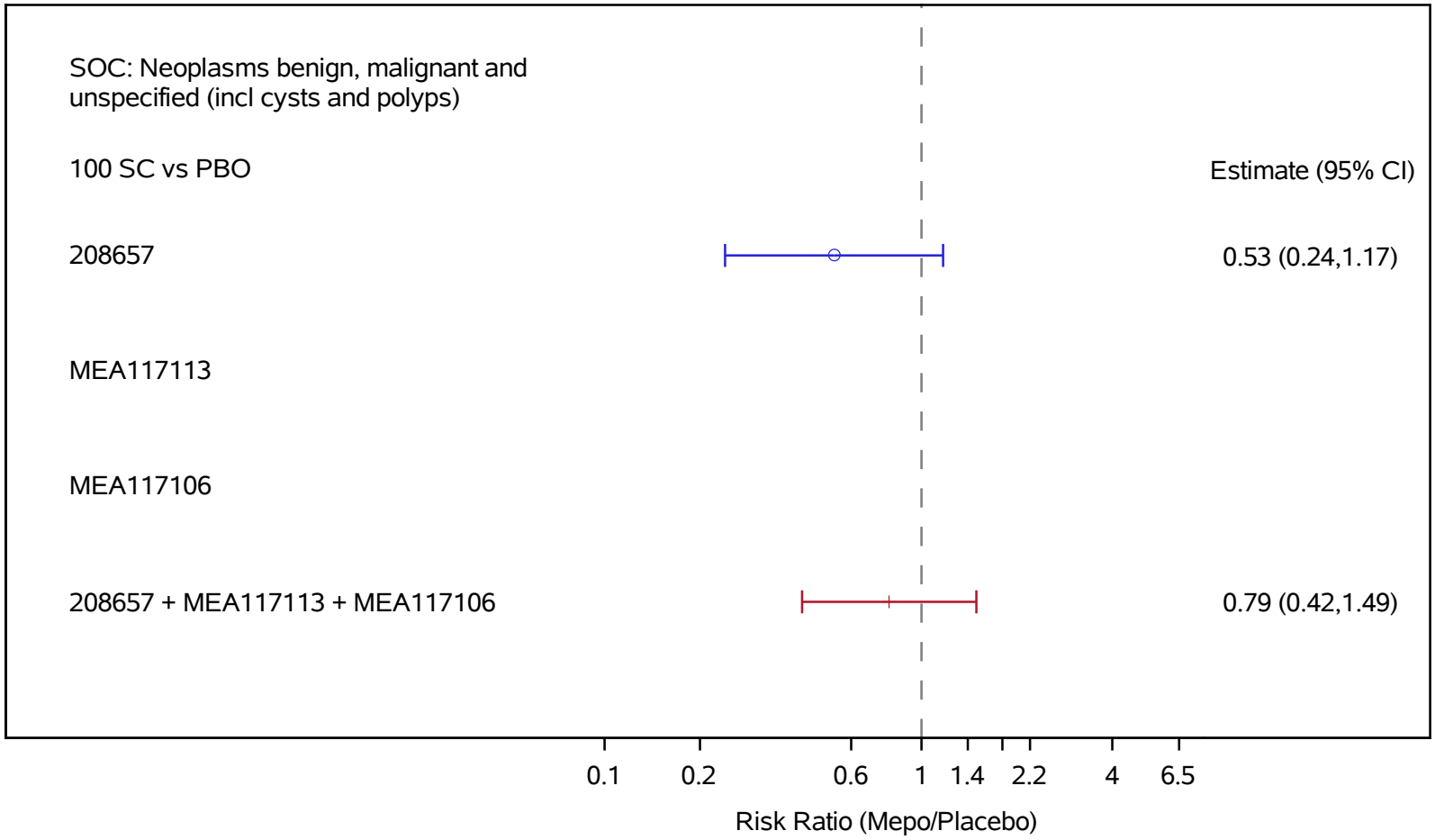
Forest Plot of Relative Risk for On-Treatment Adverse Events Occurring in >=10% of patients or in >=10 and >=1% of patients by SOC and PT: Individual Studies and Meta-Analysis



Horizontal bars indicate 95% confidence intervals for the Mepo/Placebo ratio.

Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Figure 311.2
Forest Plot of Relative Risk for On-Treatment Adverse Events Occurring in >=10% of patients or in >=10 and >=1% of patients by SOC and PT: Individual Studies and Meta-Analysis

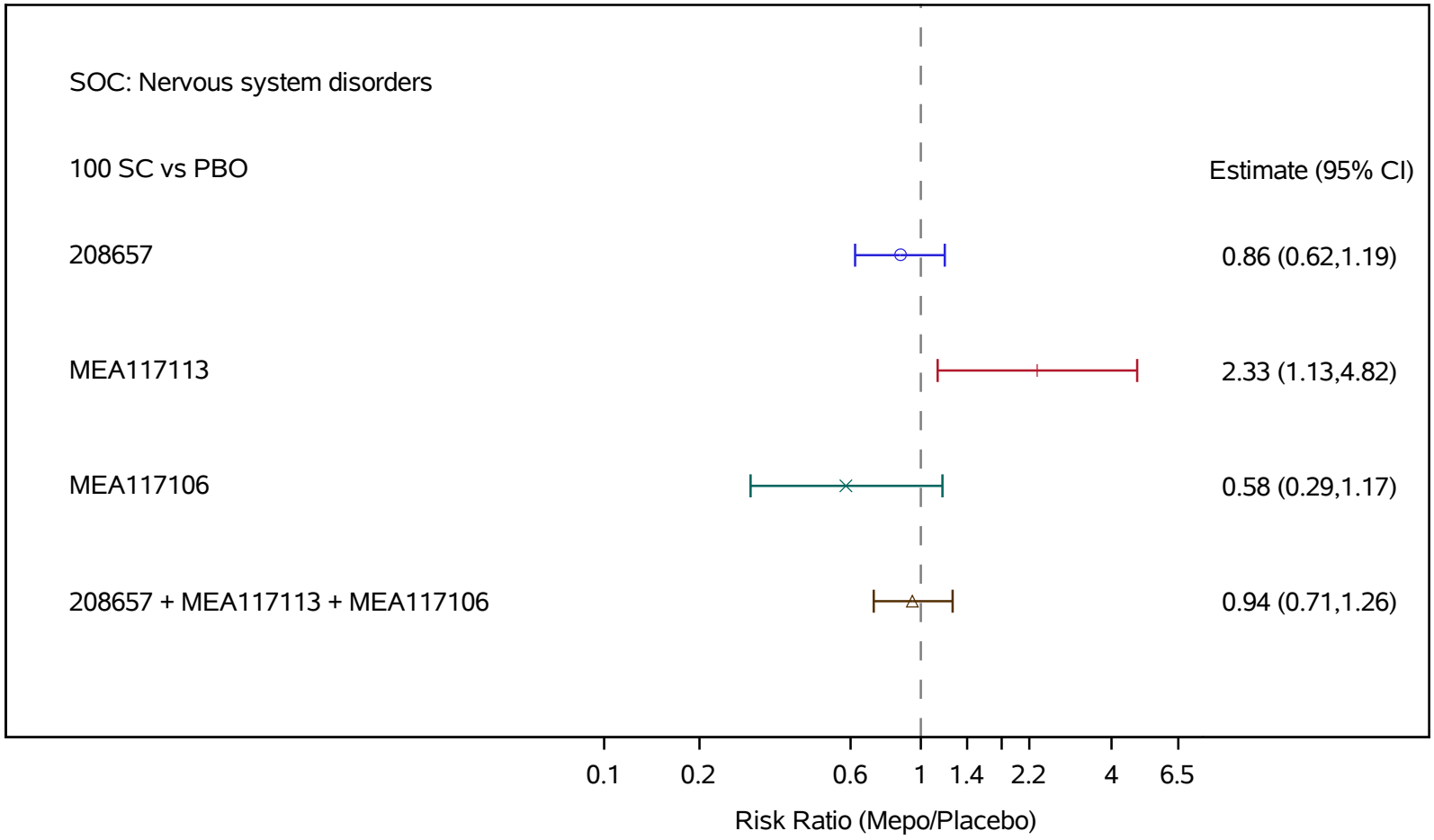


Horizontal bars indicate 95% confidence intervals for the Mepo/Placebo ratio.
/mnt/code/postcsr_01/prod/tfls/f_s_ae_onae_rr.sas 17JUL2025 18:09

Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Figure 311.2

Forest Plot of Relative Risk for On-Treatment Adverse Events Occurring in >=10% of patients or in >=10 and >=1% of patients by SOC and PT: Individual Studies and Meta-Analysis



Horizontal bars indicate 95% confidence intervals for the Mepo/Placebo ratio.

Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

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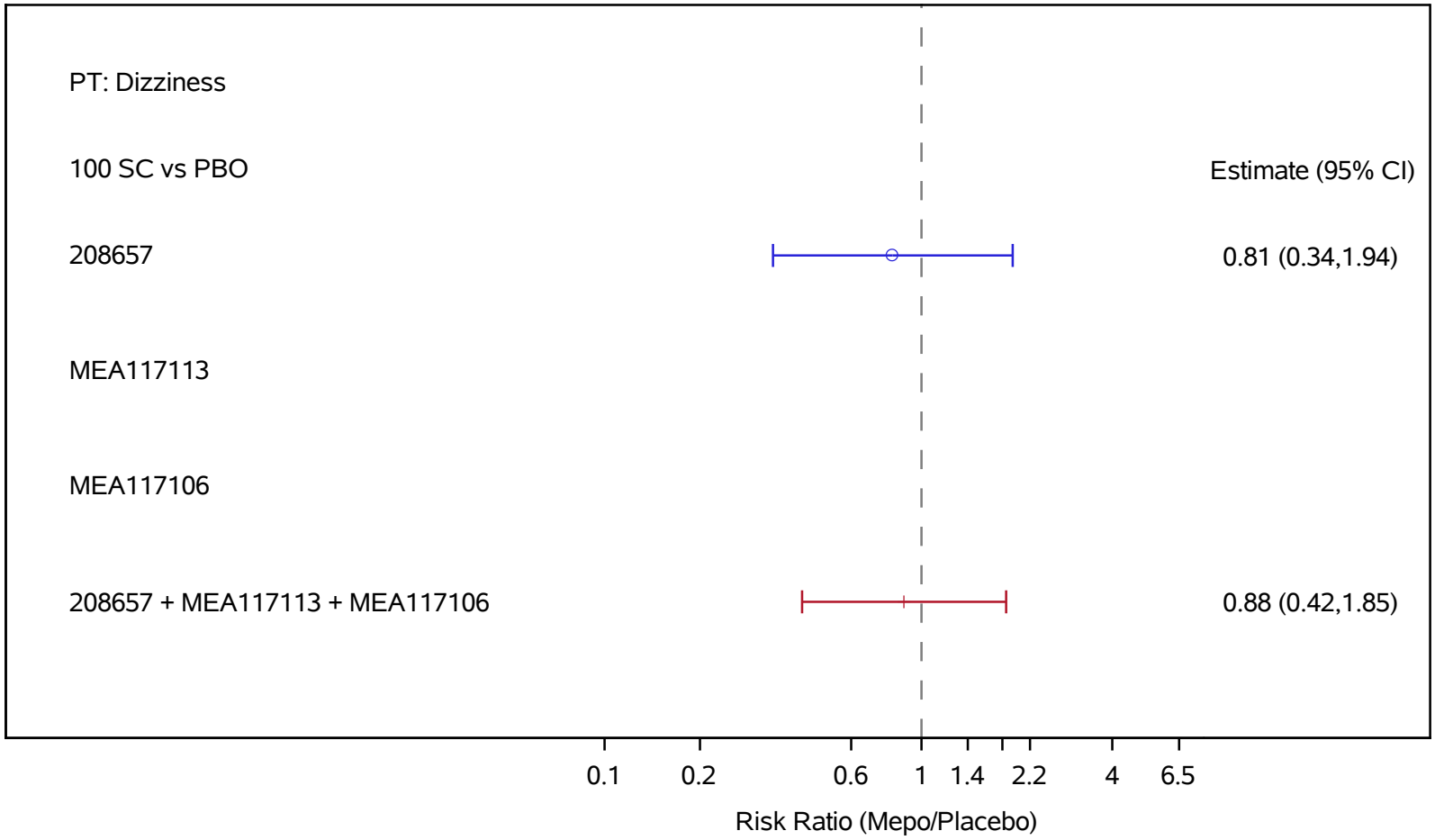
Forest Plot of Relative Risk for On-Treatment Adverse Events Occurring in >=10% of patients or in >=10 and >=1% of patients by SOC and PT: Individual Studies and Meta-Analysis

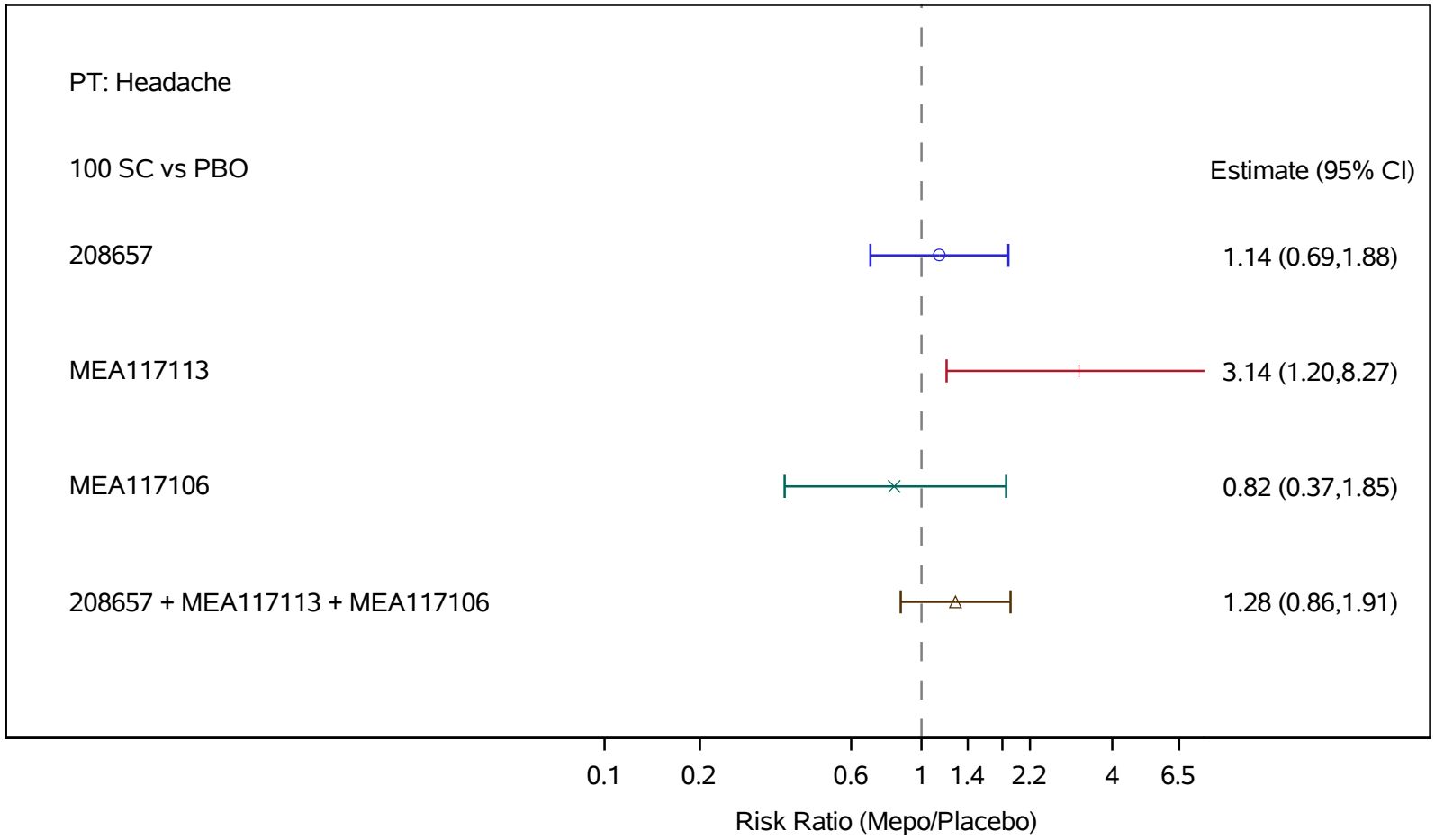


Horizontal bars indicate 95% confidence intervals for the Mepo/Placebo ratio.

Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Figure 311.2

Forest Plot of Relative Risk for On-Treatment Adverse Events Occurring in >=10% of patients or in >=10 and >=1% of patients by SOC and PT: Individual Studies and Meta-Analysis



Horizontal bars indicate 95% confidence intervals for the Mepo/Placebo ratio.

Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

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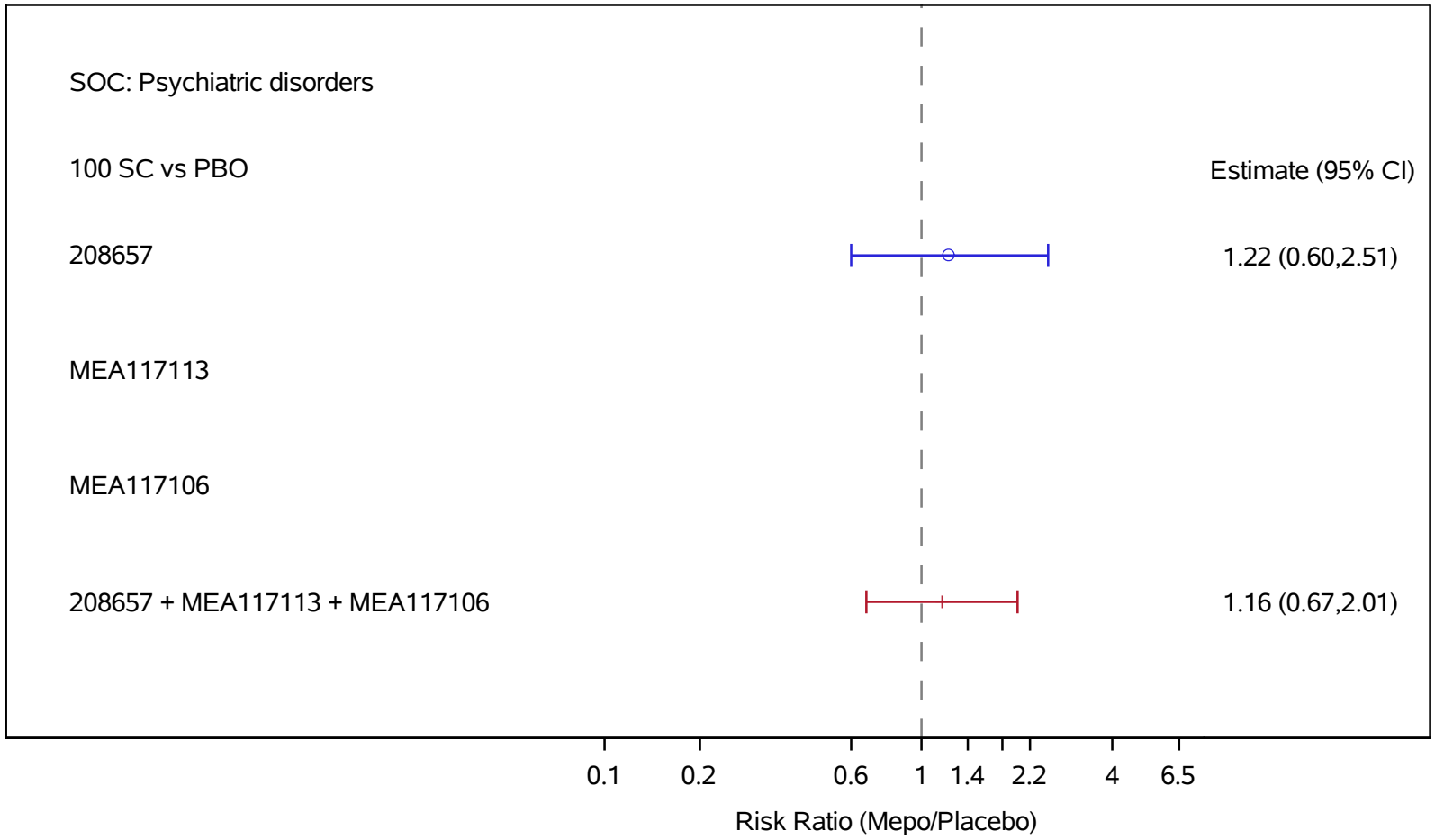
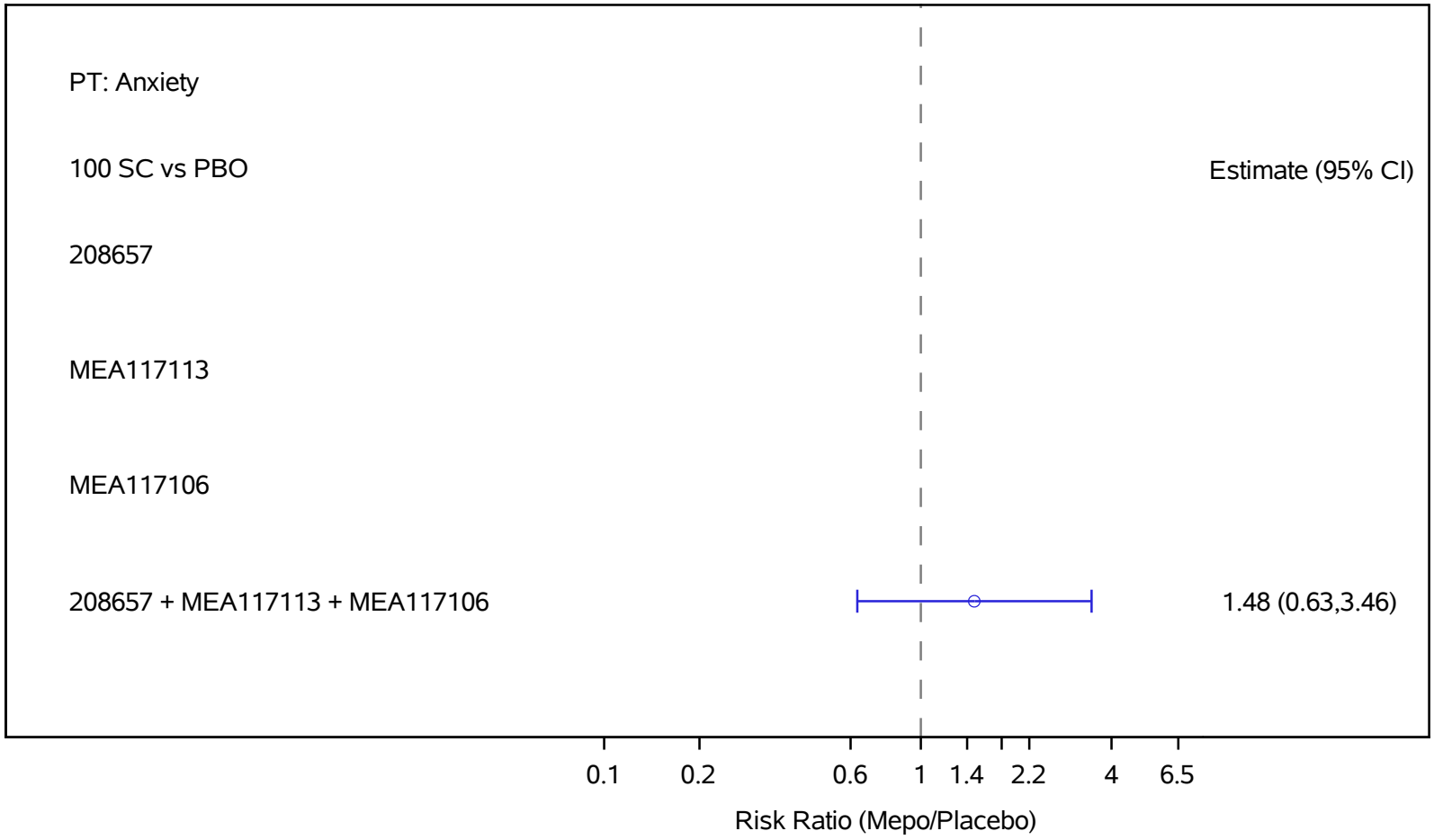
Forest Plot of Relative Risk for On-Treatment Adverse Events Occurring in >=10% of patients or in >=10 and >=1% of patients by SOC and PT: Individual Studies and Meta-Analysis



Horizontal bars indicate 95% confidence intervals for the Mepo/Placebo ratio.
/mnt/code/postcsr_01/prod/tfls/f_s_ae_onae_rr.sas 17JUL2025 18:09

Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Figure 311.2
Forest Plot of Relative Risk for On-Treatment Adverse Events Occurring in >=10% of patients or in >=10 and >=1% of patients by SOC and PT: Individual Studies and Meta-Analysis



Horizontal bars indicate 95% confidence intervals for the Mepo/Placebo ratio.
/mnt/code/postcsr_01/prod/tfls/f_s_ae_onae_rr.sas 17JUL2025 18:09

Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

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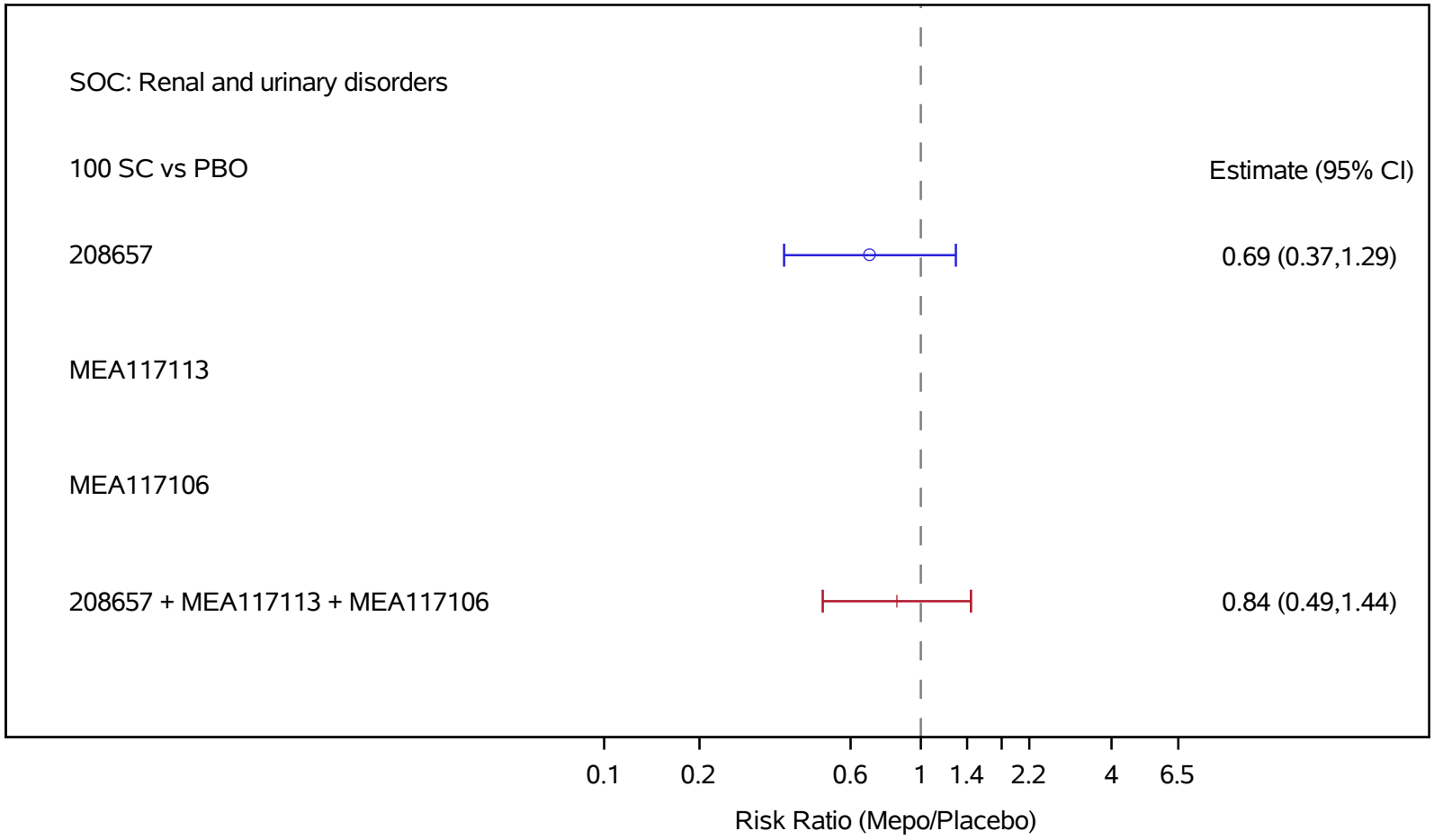

Horizontal bars indicate 95% confidence intervals for the Mepo/Placebo ratio.

Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

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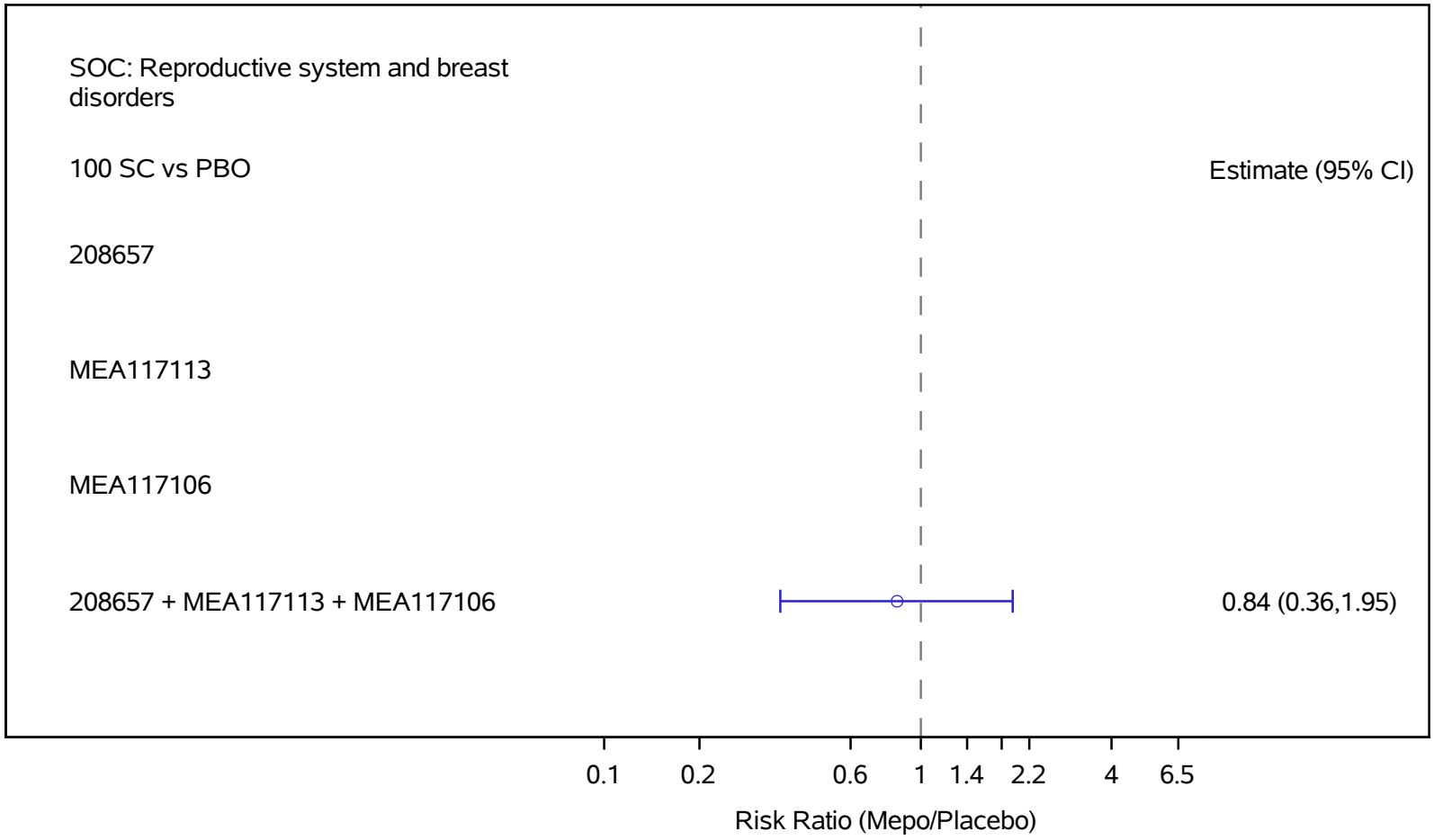
Forest Plot of Relative Risk for On-Treatment Adverse Events Occurring in >=10% of patients or in >=10 and >=1% of patients by SOC and PT: Individual Studies and Meta-Analysis

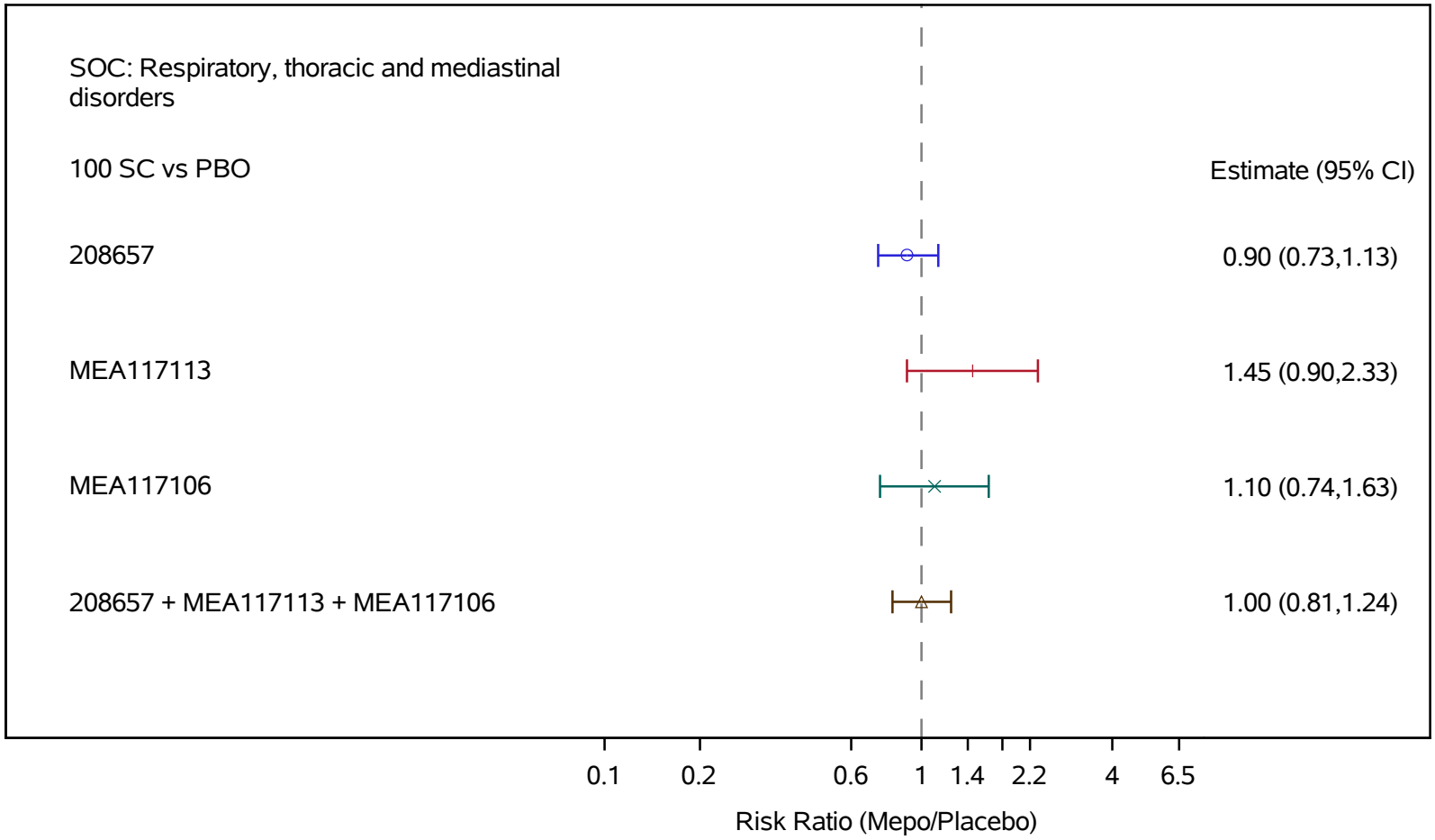


Horizontal bars indicate 95% confidence intervals for the Mepo/Placebo ratio.
/mnt/code/postcsr_01/prod/tfls/f_s_ae_onae_rr.sas 17JUL2025 18:09

Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Figure 311.2

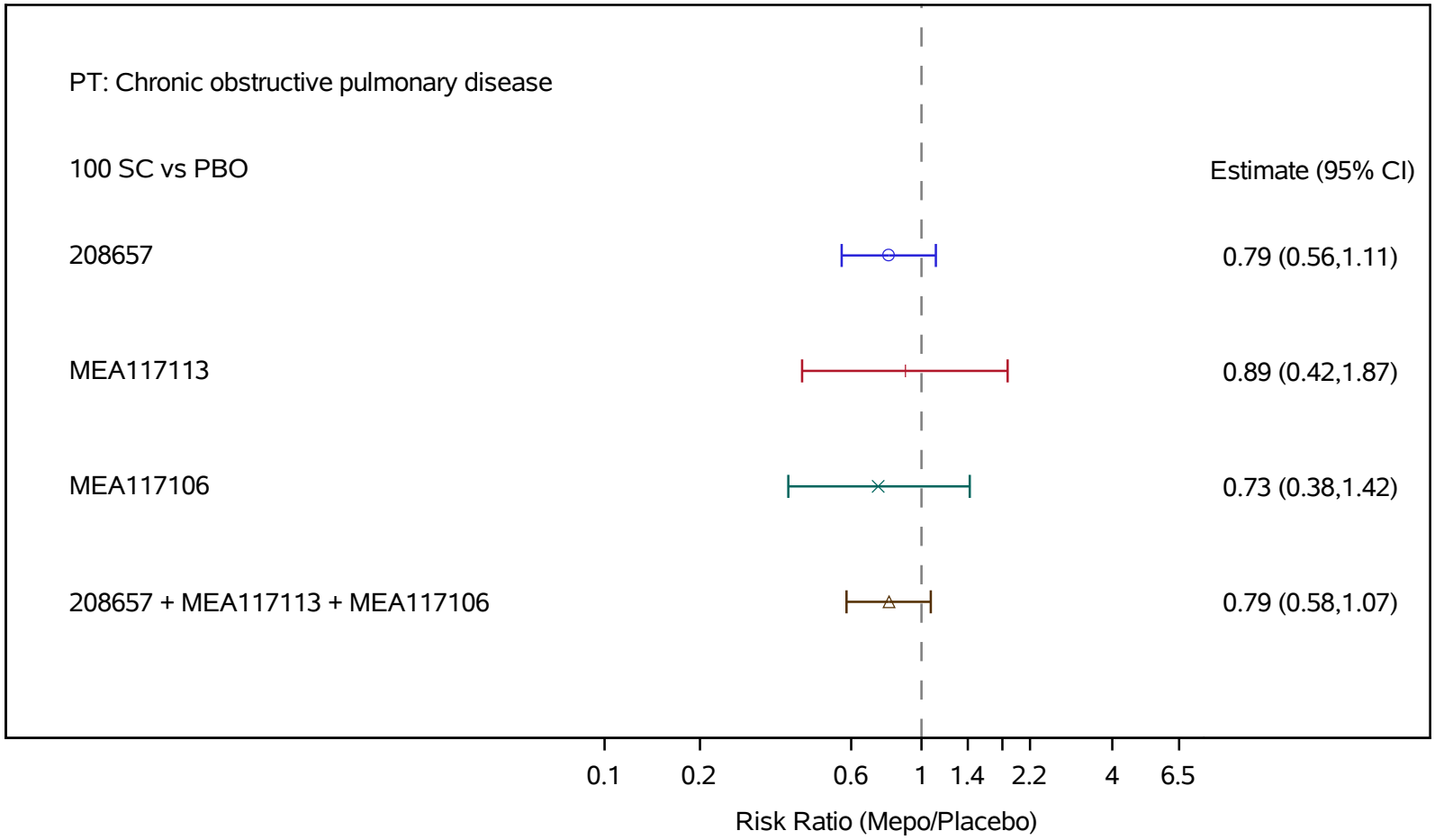
Forest Plot of Relative Risk for On-Treatment Adverse Events Occurring in >=10% of patients or in >=10 and >=1% of patients by SOC and PT: Individual Studies and Meta-Analysis



Horizontal bars indicate 95% confidence intervals for the Mepo/Placebo ratio.

Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Figure 311.2
Forest Plot of Relative Risk for On-Treatment Adverse Events Occurring in >=10% of patients or in >=10 and >=1% of patients by SOC and PT: Individual Studies and Meta-Analysis

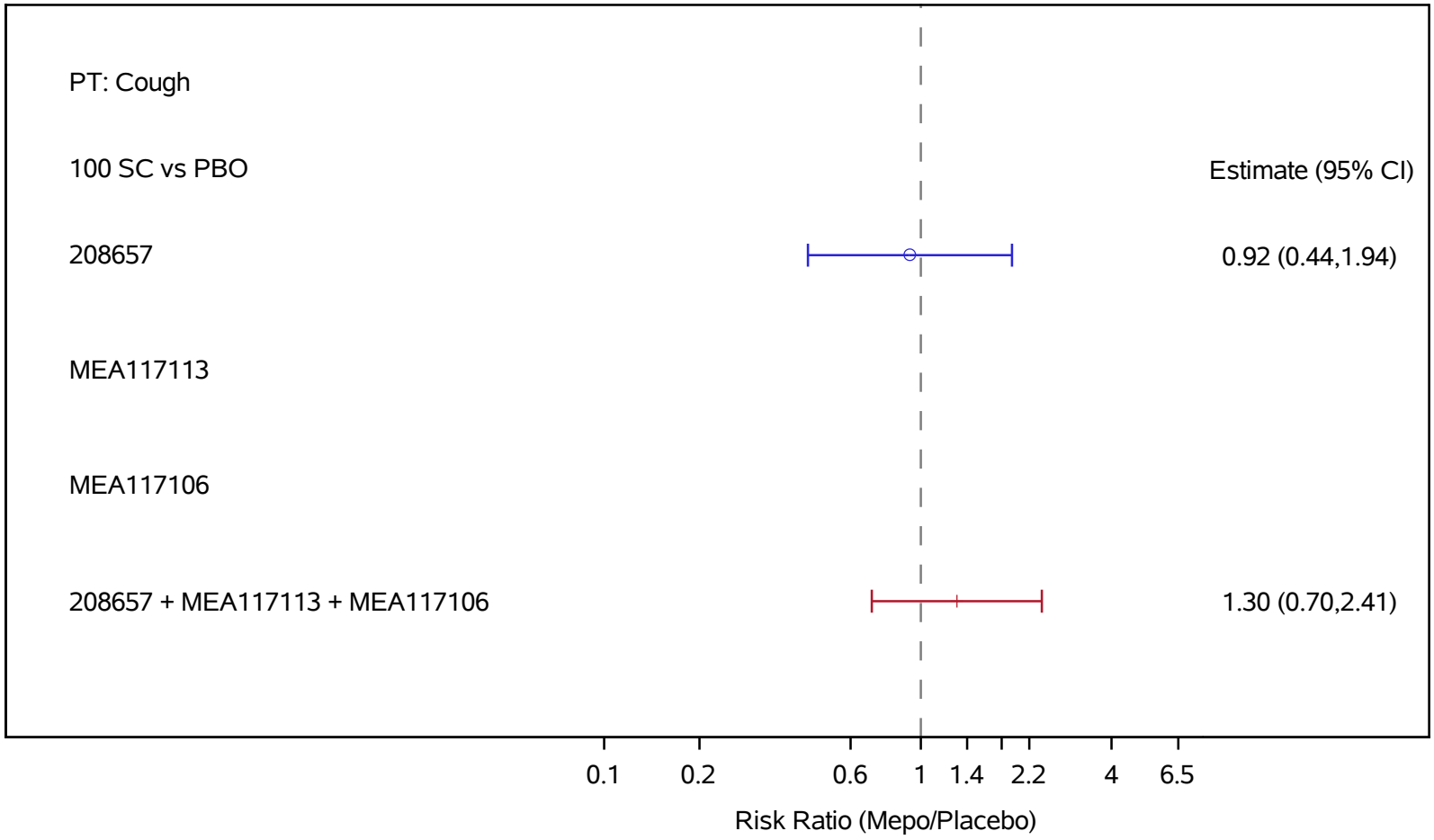


Horizontal bars indicate 95% confidence intervals for the Mepo/Placebo ratio.
/mnt/code/postcsr_01/prod/tfls/f_s_ae_onae_rr.sas 17JUL2025 18:09

Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Figure 311.2

Forest Plot of Relative Risk for On-Treatment Adverse Events Occurring in >=10% of patients or in >=10 and >=1% of patients by SOC and PT: Individual Studies and Meta-Analysis

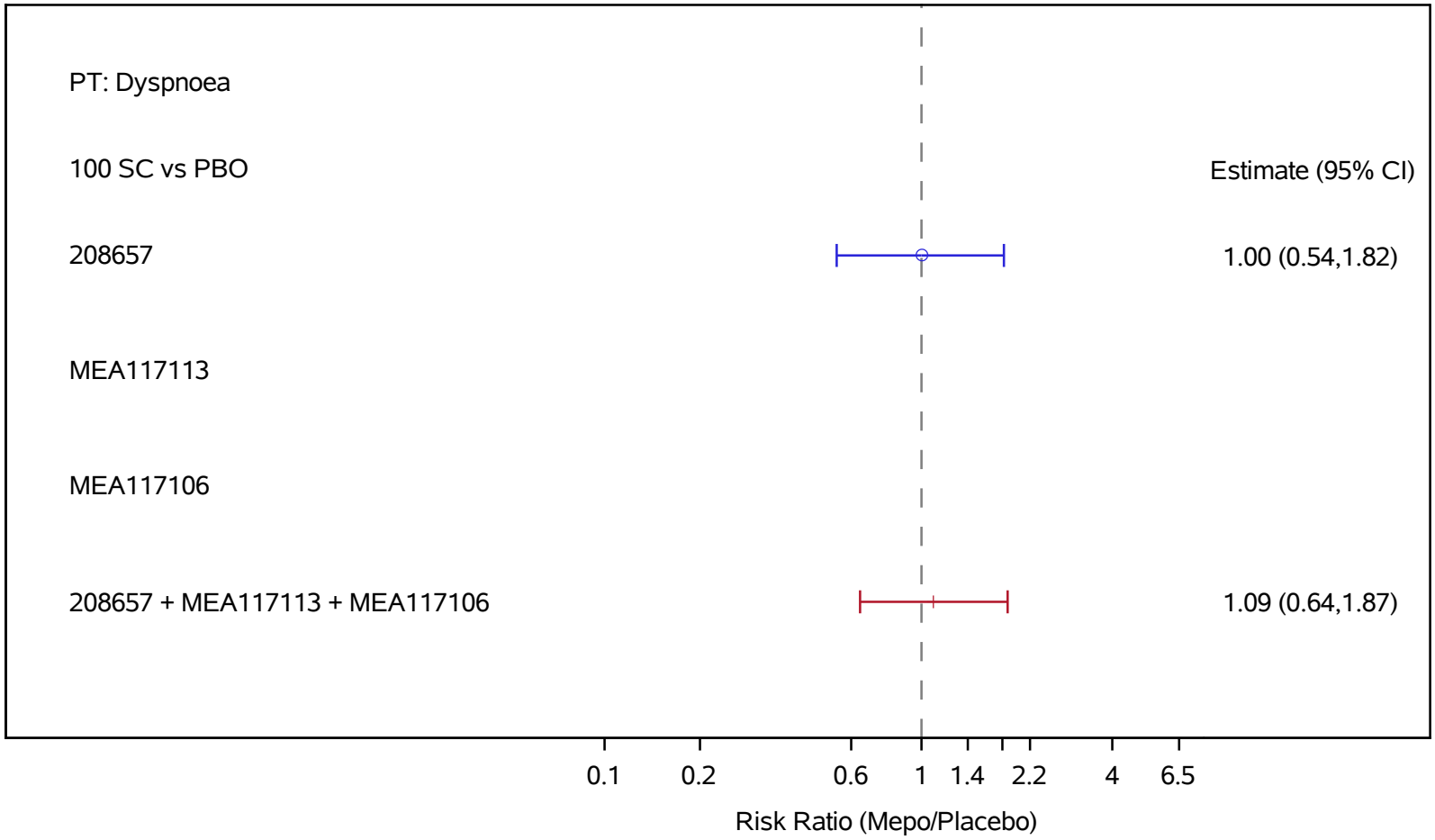


Horizontal bars indicate 95% confidence intervals for the Mepo/Placebo ratio.

Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Figure 311.2

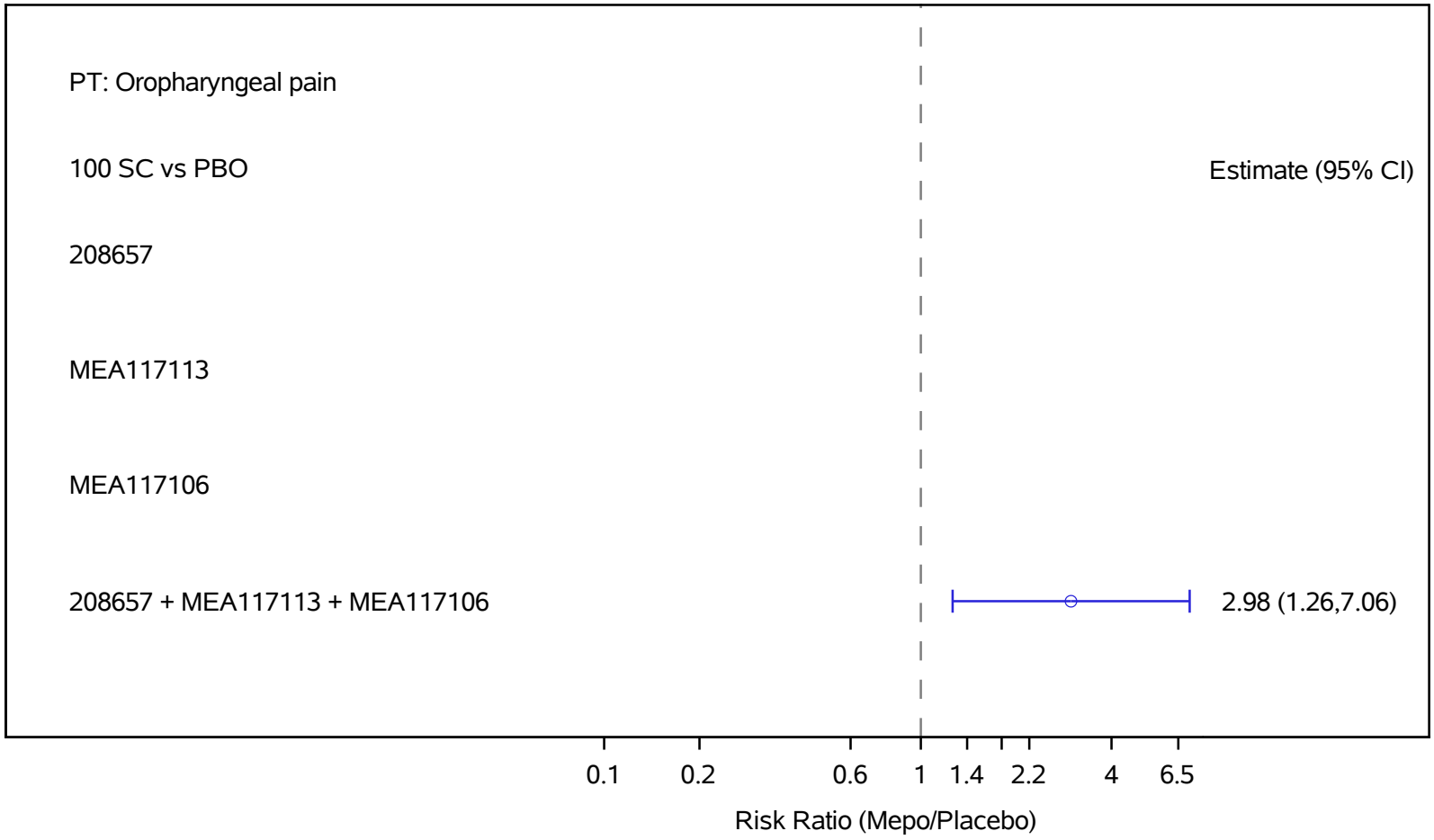
Forest Plot of Relative Risk for On-Treatment Adverse Events Occurring in >=10% of patients or in >=10 and >=1% of patients by SOC and PT: Individual Studies and Meta-Analysis



Horizontal bars indicate 95% confidence intervals for the Mepo/Placebo ratio.

Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

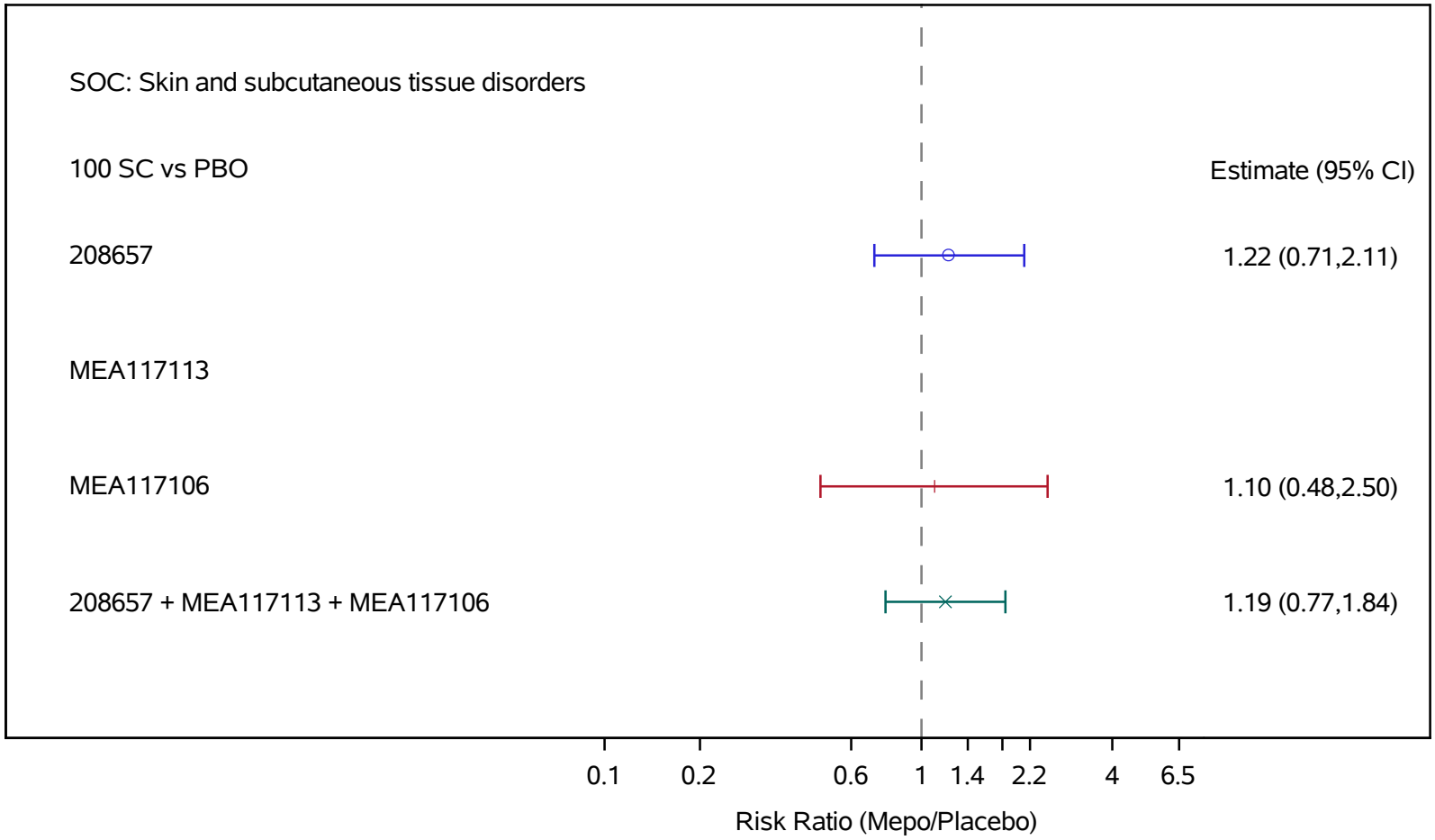
Figure 311.2
Forest Plot of Relative Risk for On-Treatment Adverse Events Occurring in >=10% of patients or in >=10 and >=1% of patients by SOC and PT: Individual Studies and Meta-Analysis



Horizontal bars indicate 95% confidence intervals for the Mepo/Placebo ratio.
/mnt/code/postcsr_01/prod/tfls/f_s_ae_onae_rr.sas 17JUL2025 18:09

Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Figure 311.2
Forest Plot of Relative Risk for On-Treatment Adverse Events Occurring in >=10% of patients or in >=10 and >=1% of patients by SOC and PT: Individual Studies and Meta-Analysis

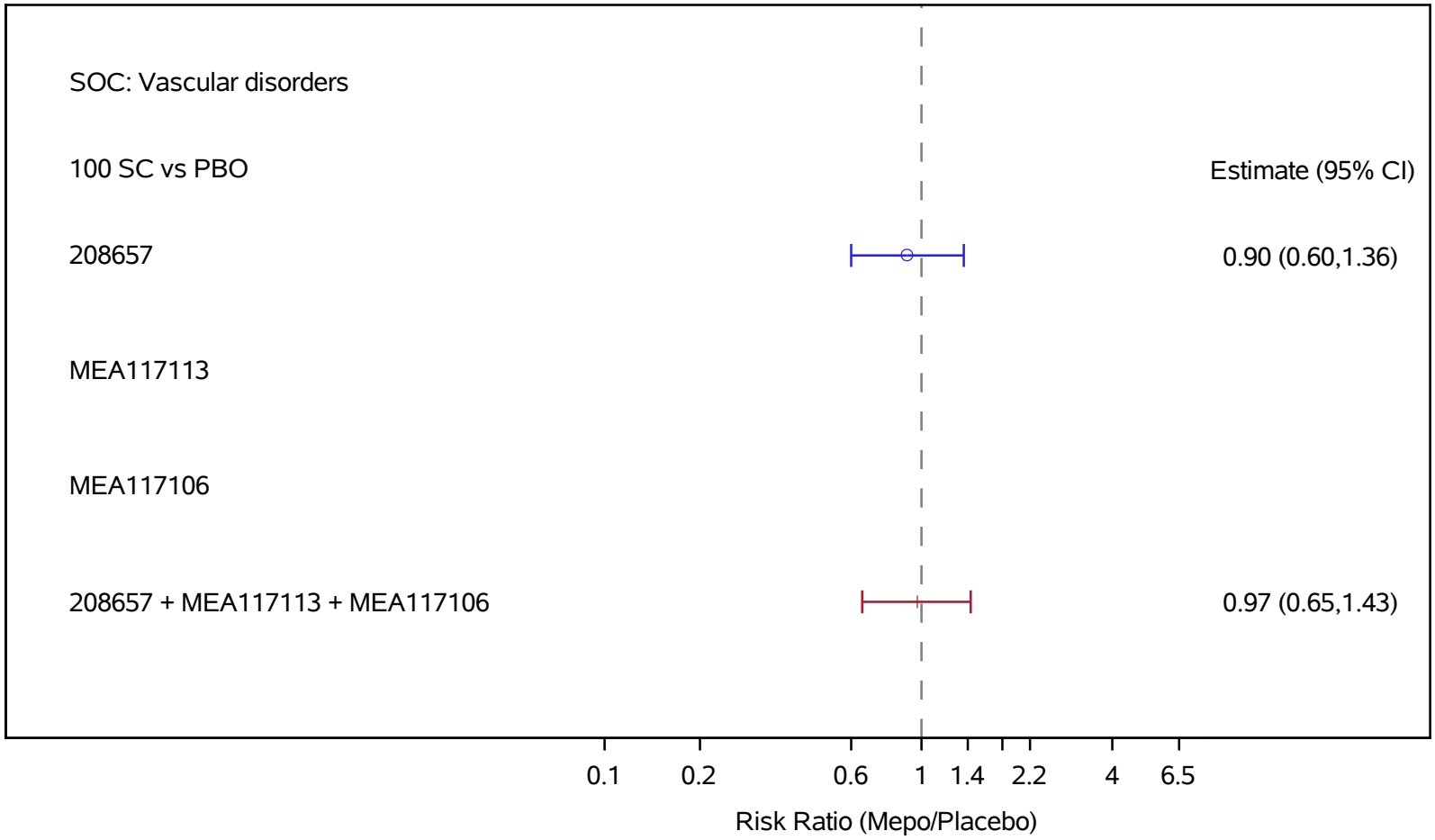


Horizontal bars indicate 95% confidence intervals for the Mepo/Placebo ratio.
/mnt/code/postcsr_01/prod/tfls/f_s_ae_onae_rr.sas 17JUL2025 18:09

Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Figure 311.2

Forest Plot of Relative Risk for On-Treatment Adverse Events Occurring in >=10% of patients or in >=10 and >=1% of patients by SOC and PT: Individual Studies and Meta-Analysis

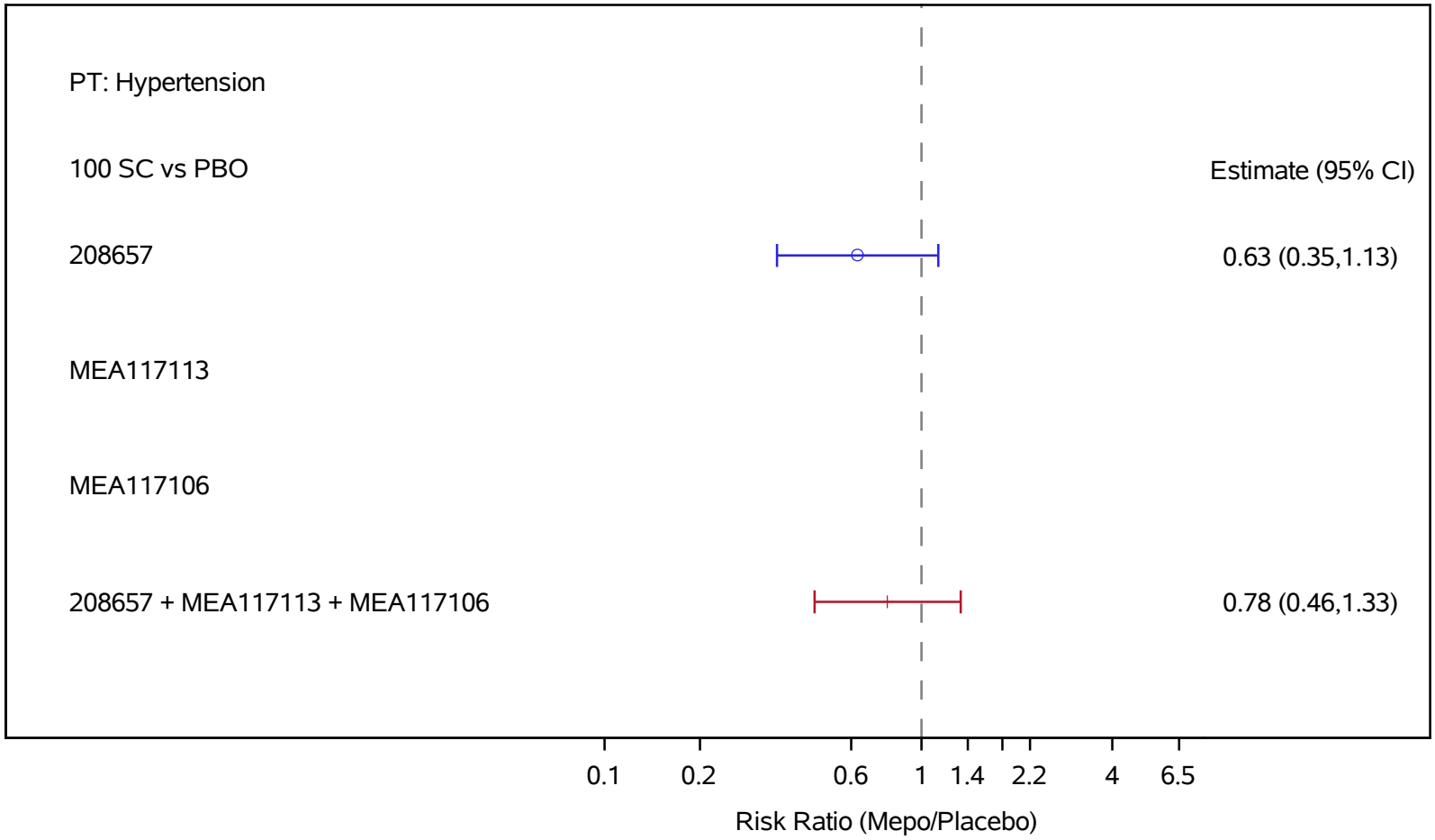


Horizontal bars indicate 95% confidence intervals for the Mepo/Placebo ratio.

Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Figure 311.2

Forest Plot of Relative Risk for On-Treatment Adverse Events Occurring in >=10% of patients or in >=10 and >=1% of patients by SOC and PT: Individual Studies and Meta-Analysis

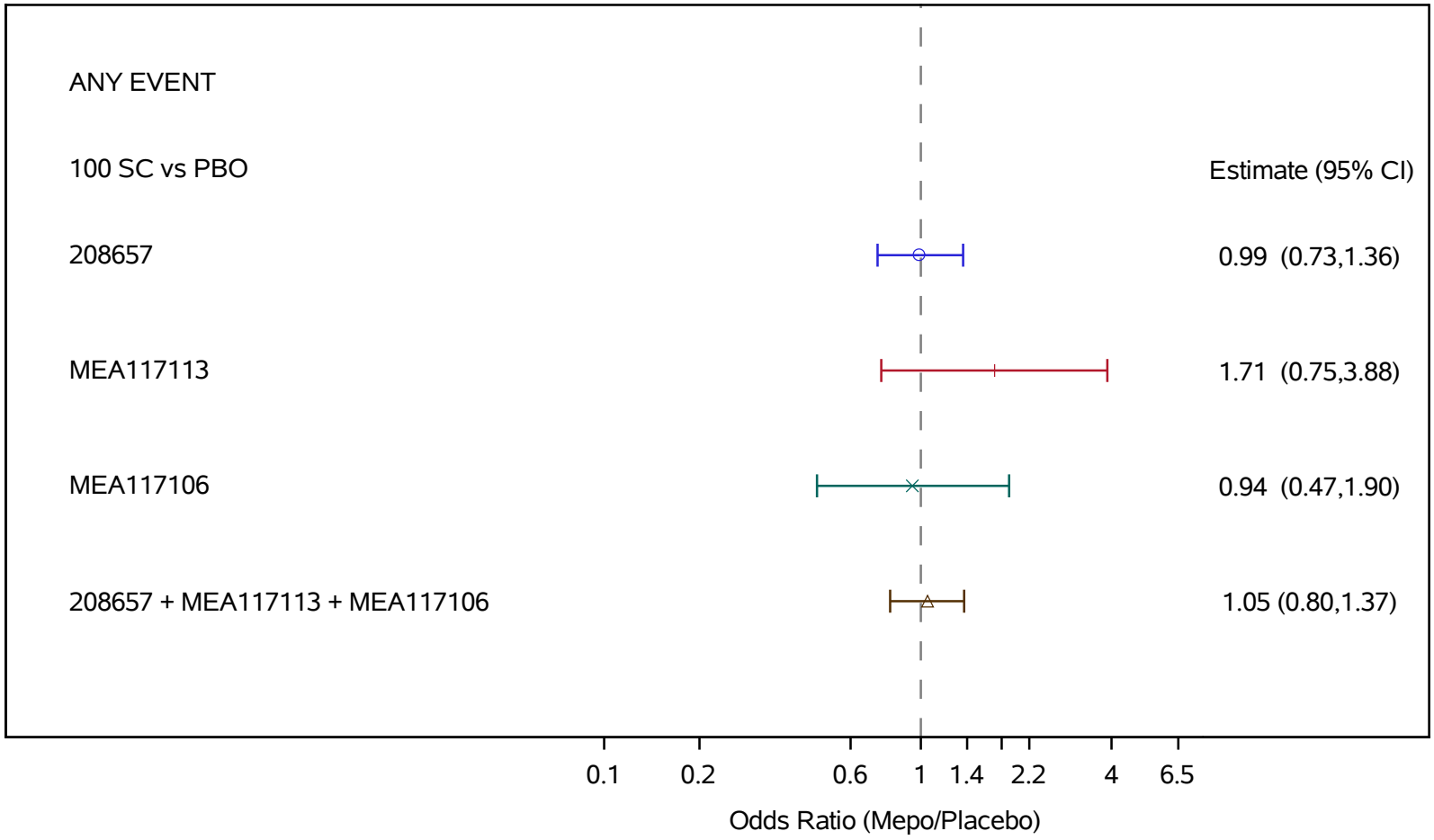


Horizontal bars indicate 95% confidence intervals for the Mepo/Placebo ratio.

Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Figure 311.3

Forest Plot of Odds ratio for On-Treatment Adverse Events without Disease-Related Events Occurring in >=10% of patients or in >=10 and >=1% of patients by SOC and PT: Individual Studies and Meta-Analysis



Horizontal bars indicate 95% confidence intervals for the Mepo/Placebo ratio.

Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

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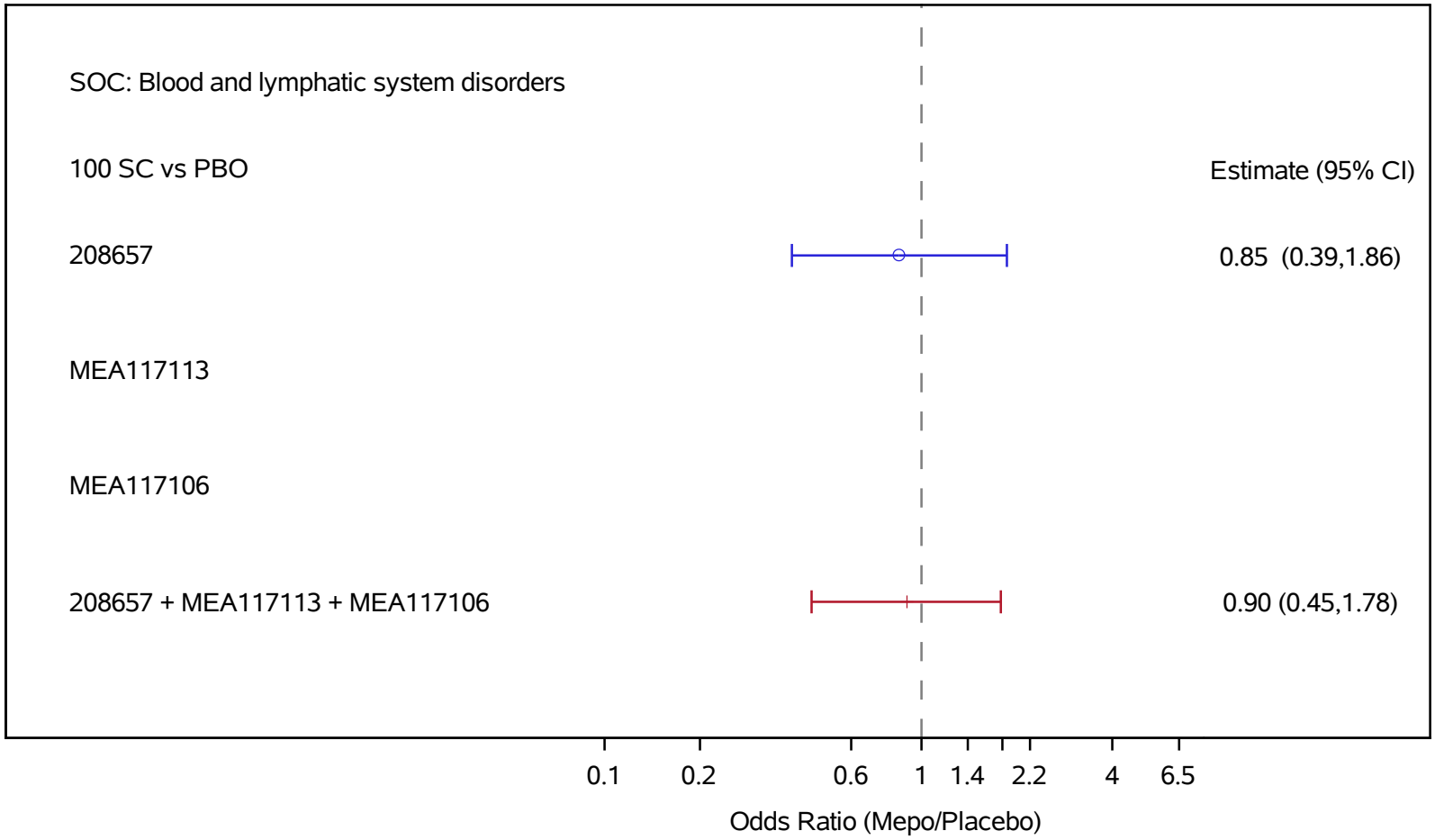

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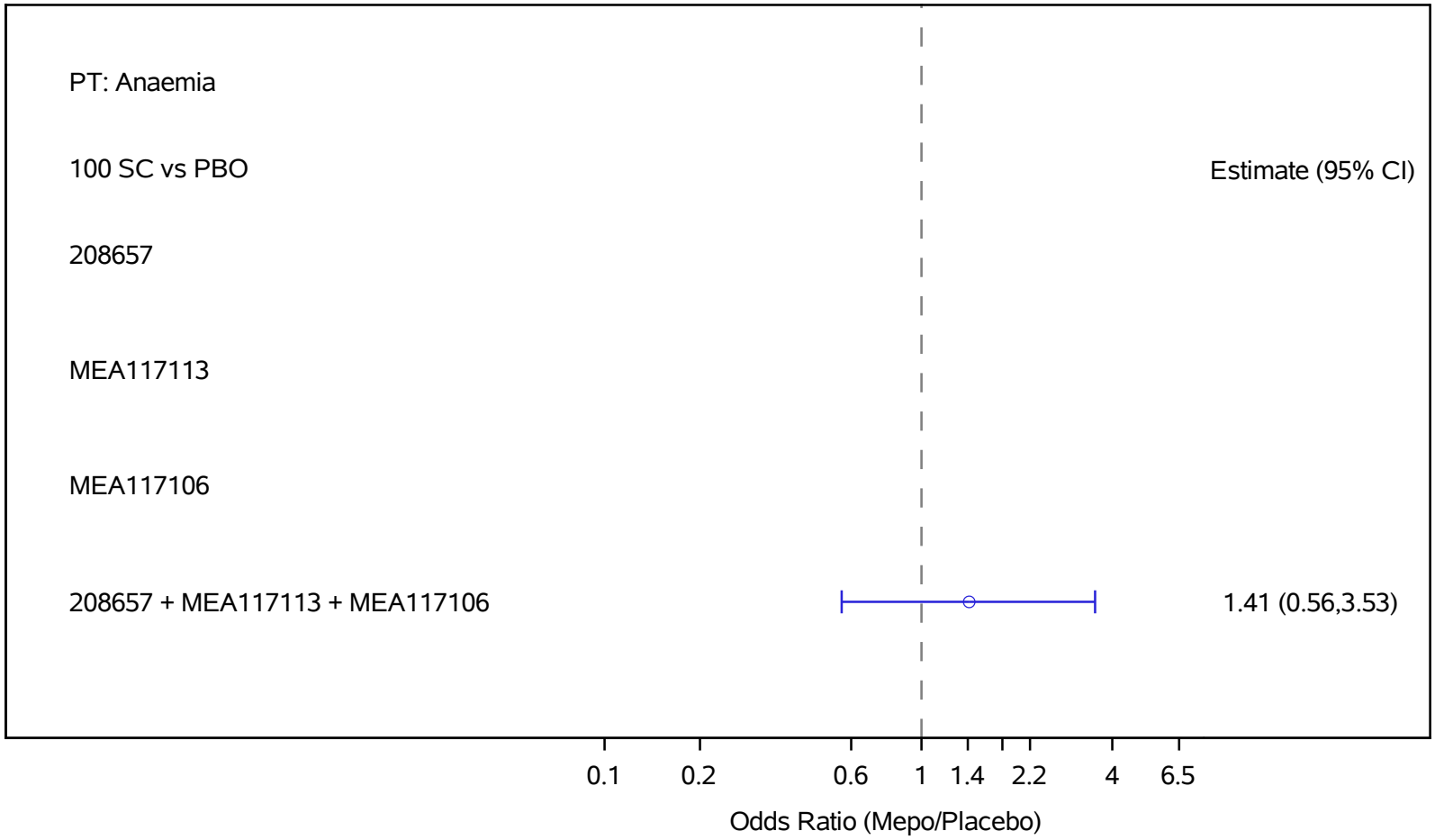

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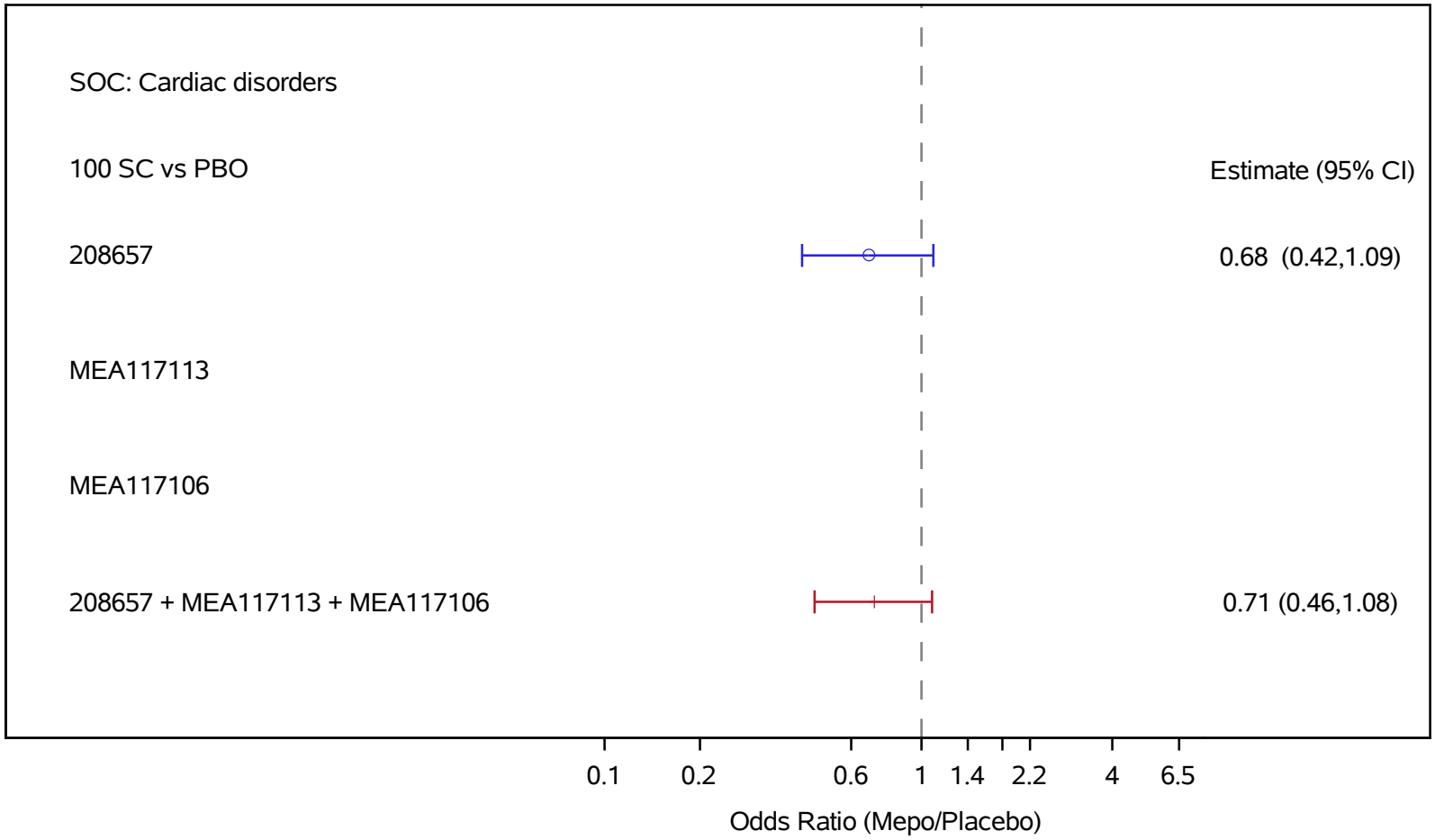

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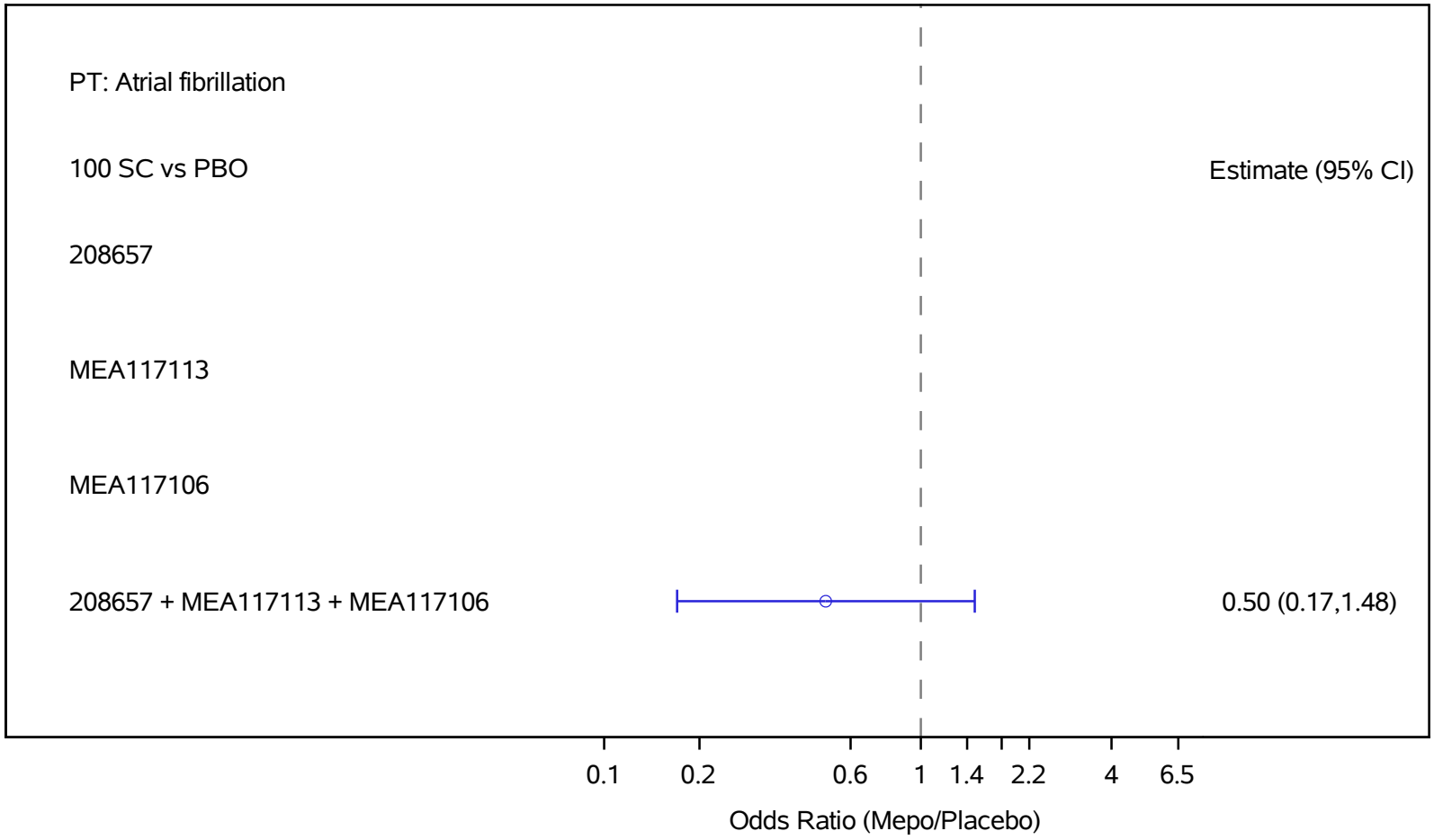

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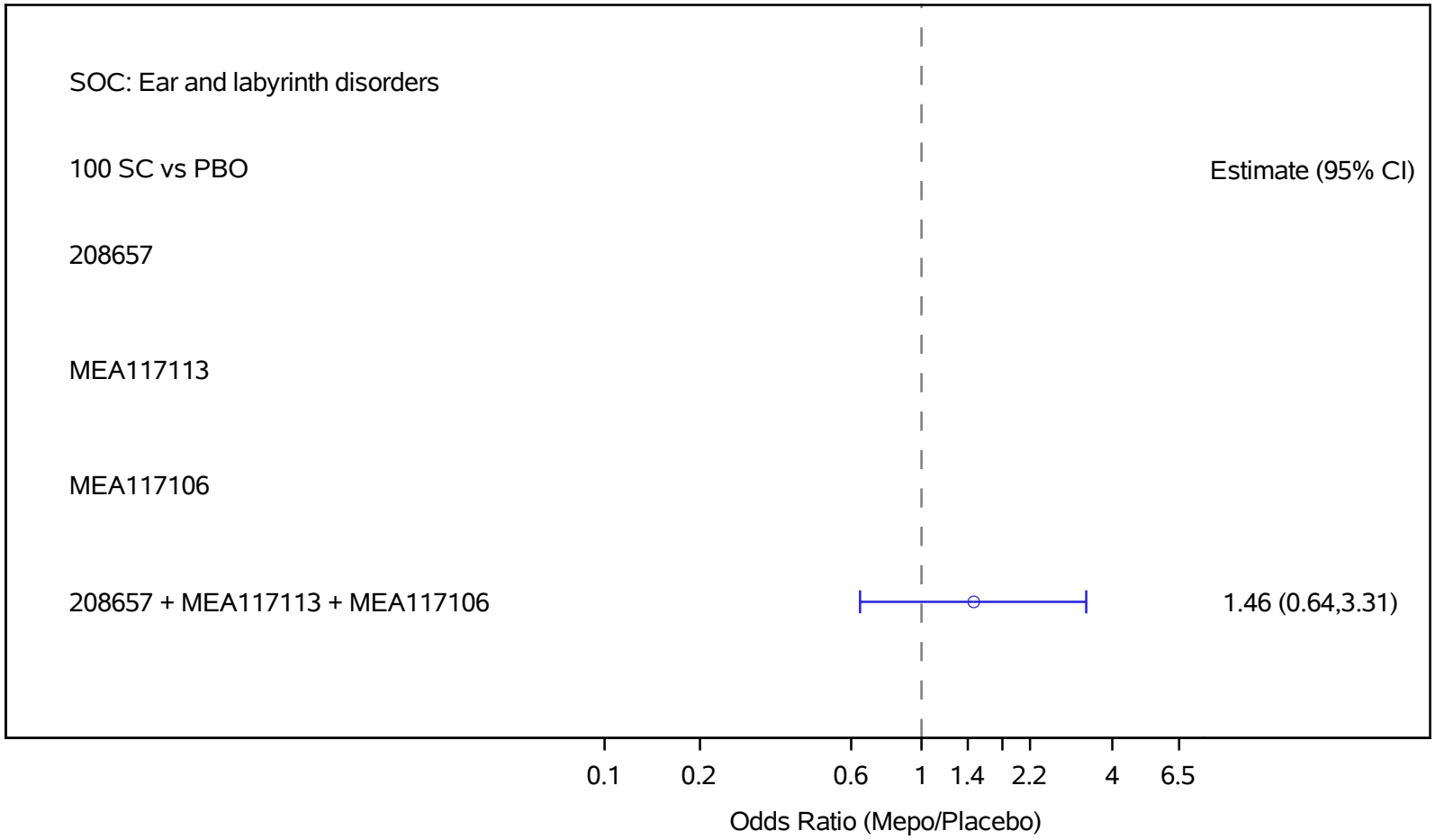

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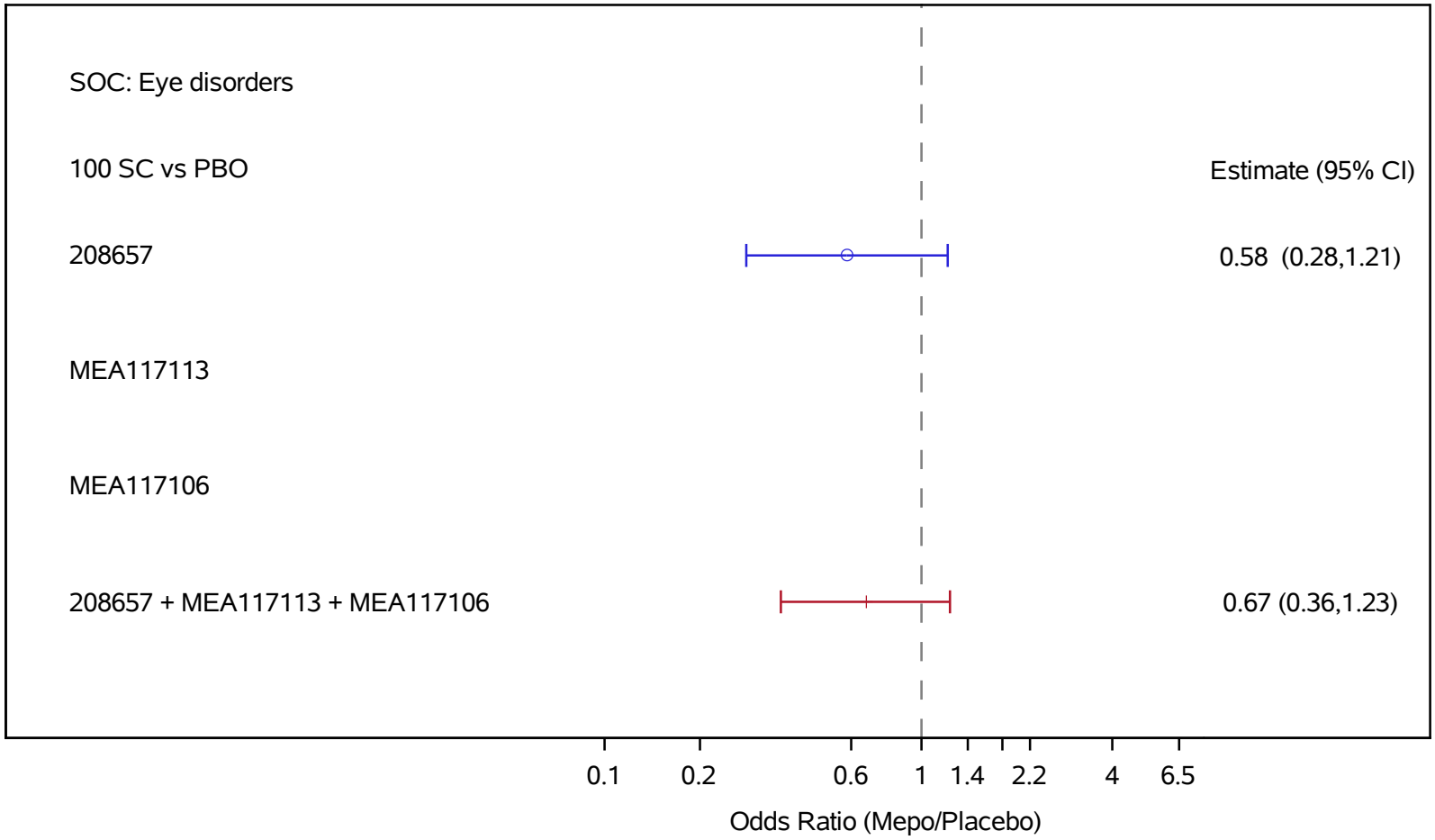

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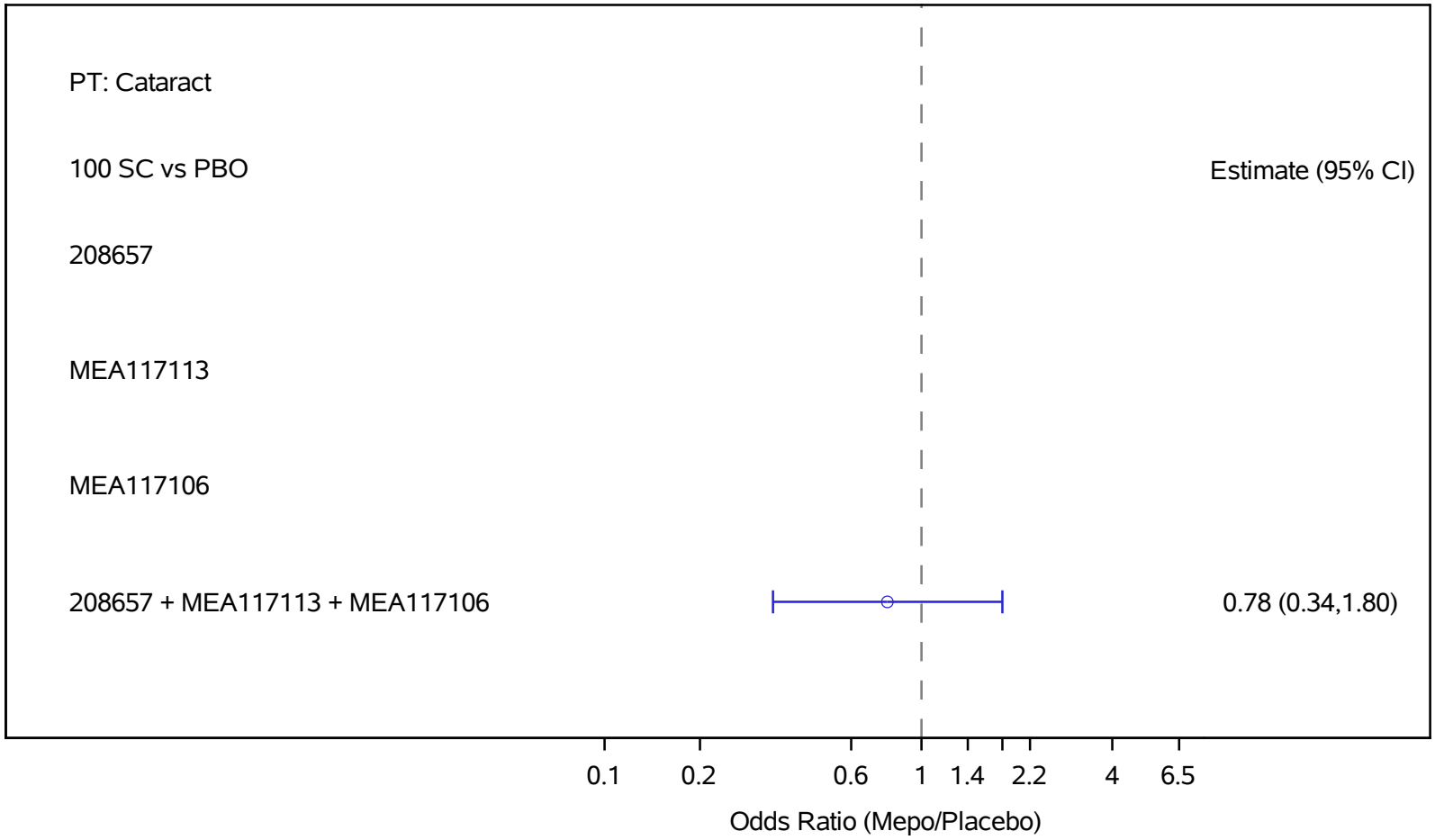

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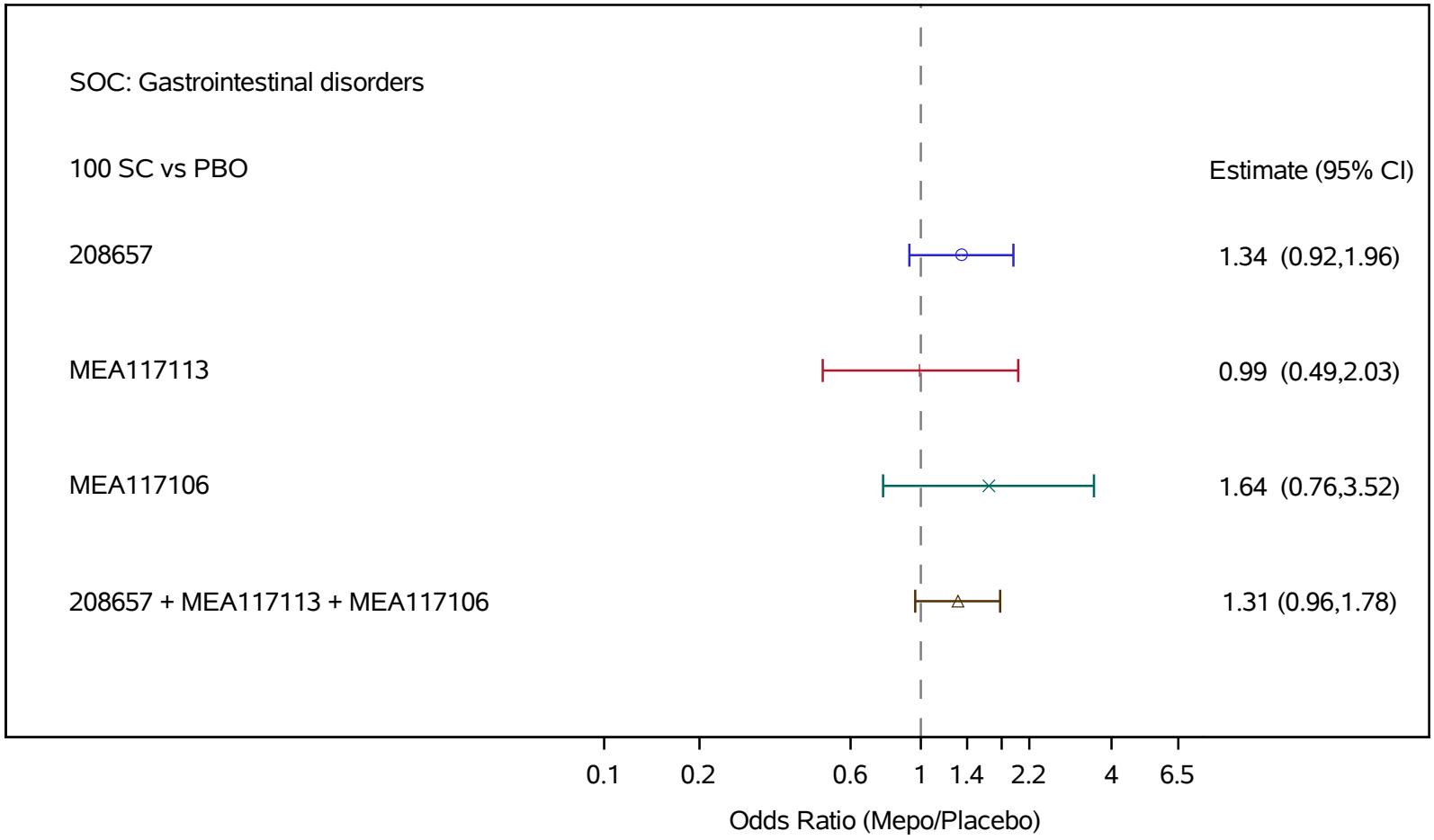

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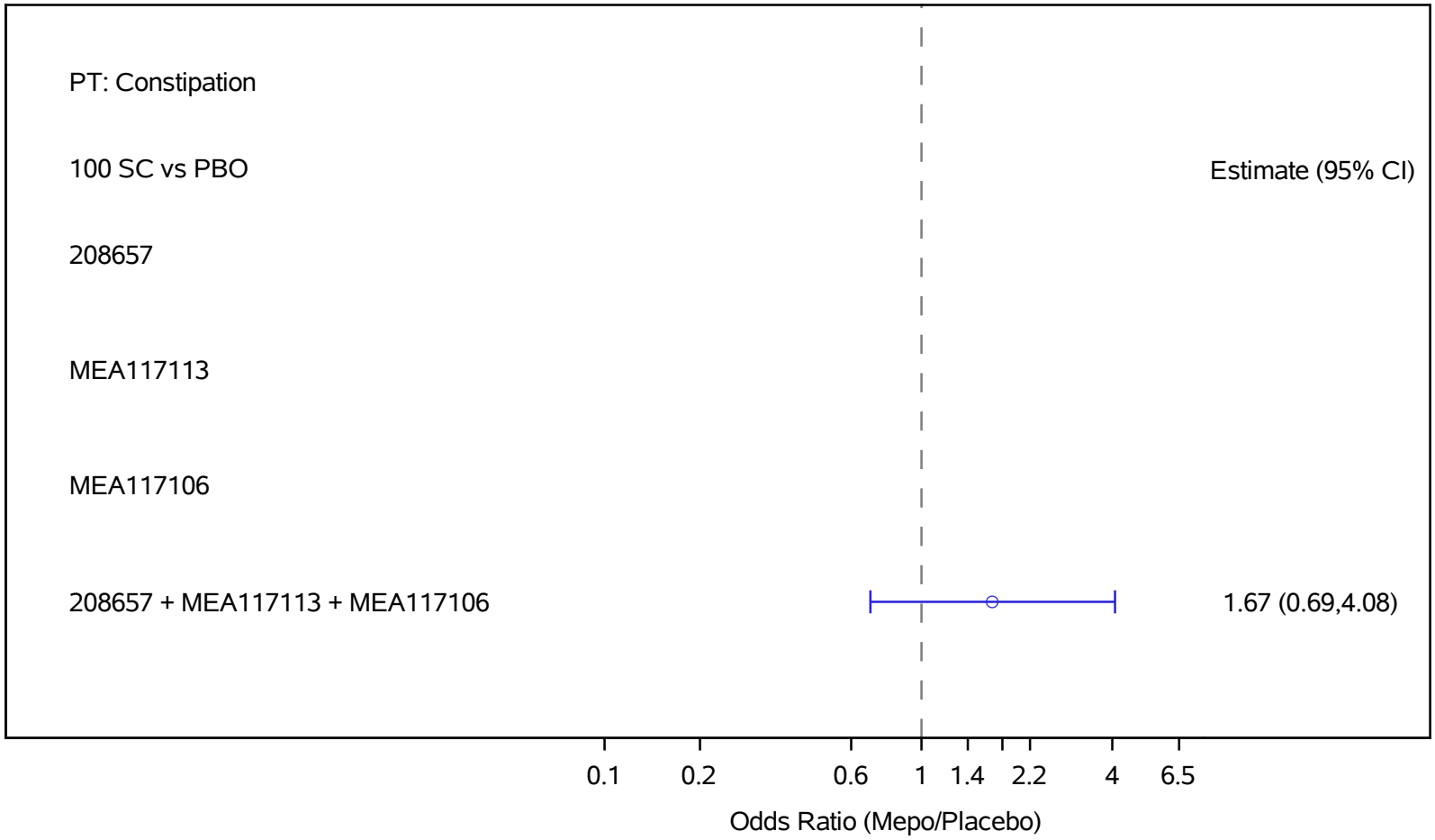

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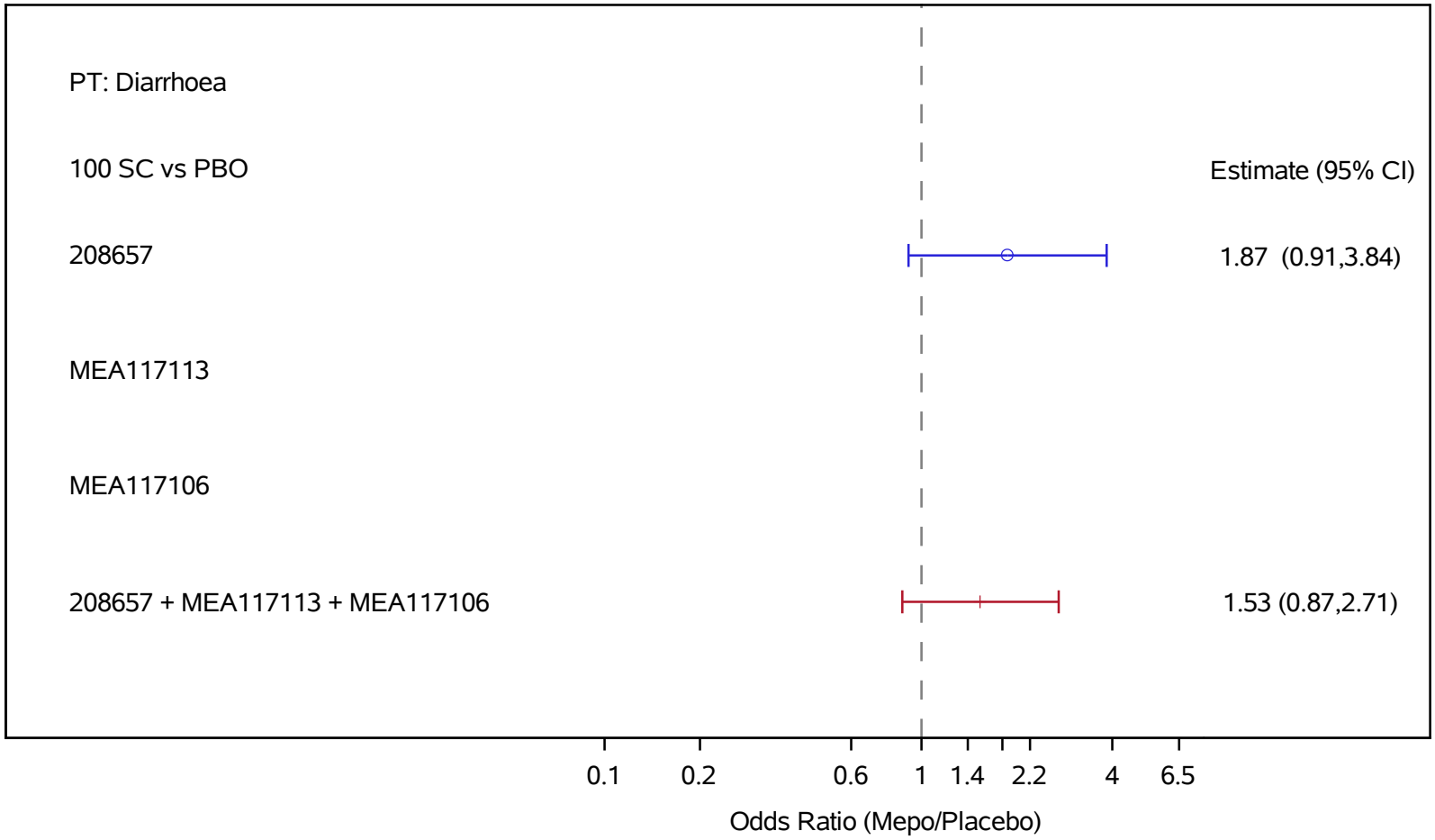

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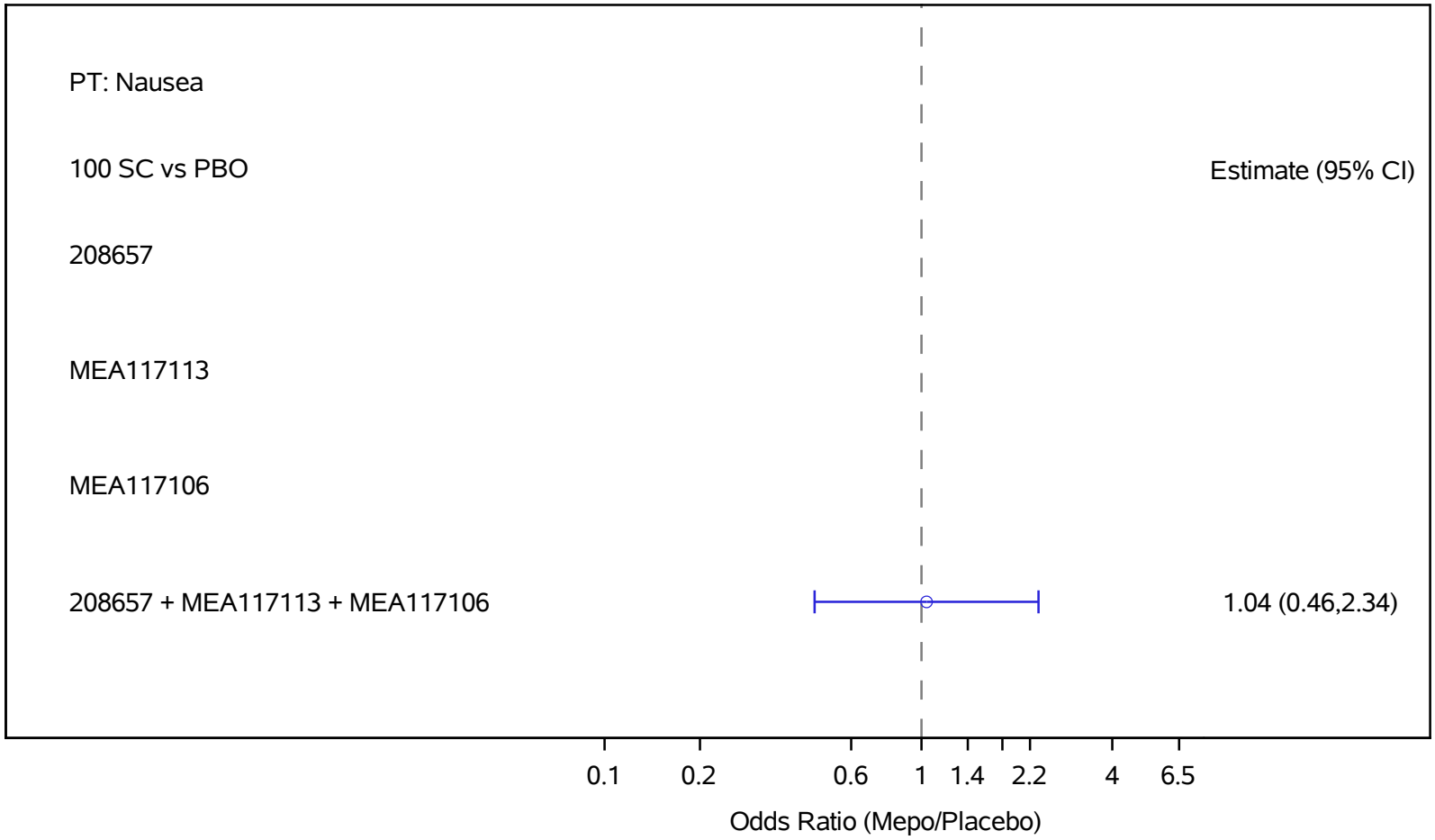

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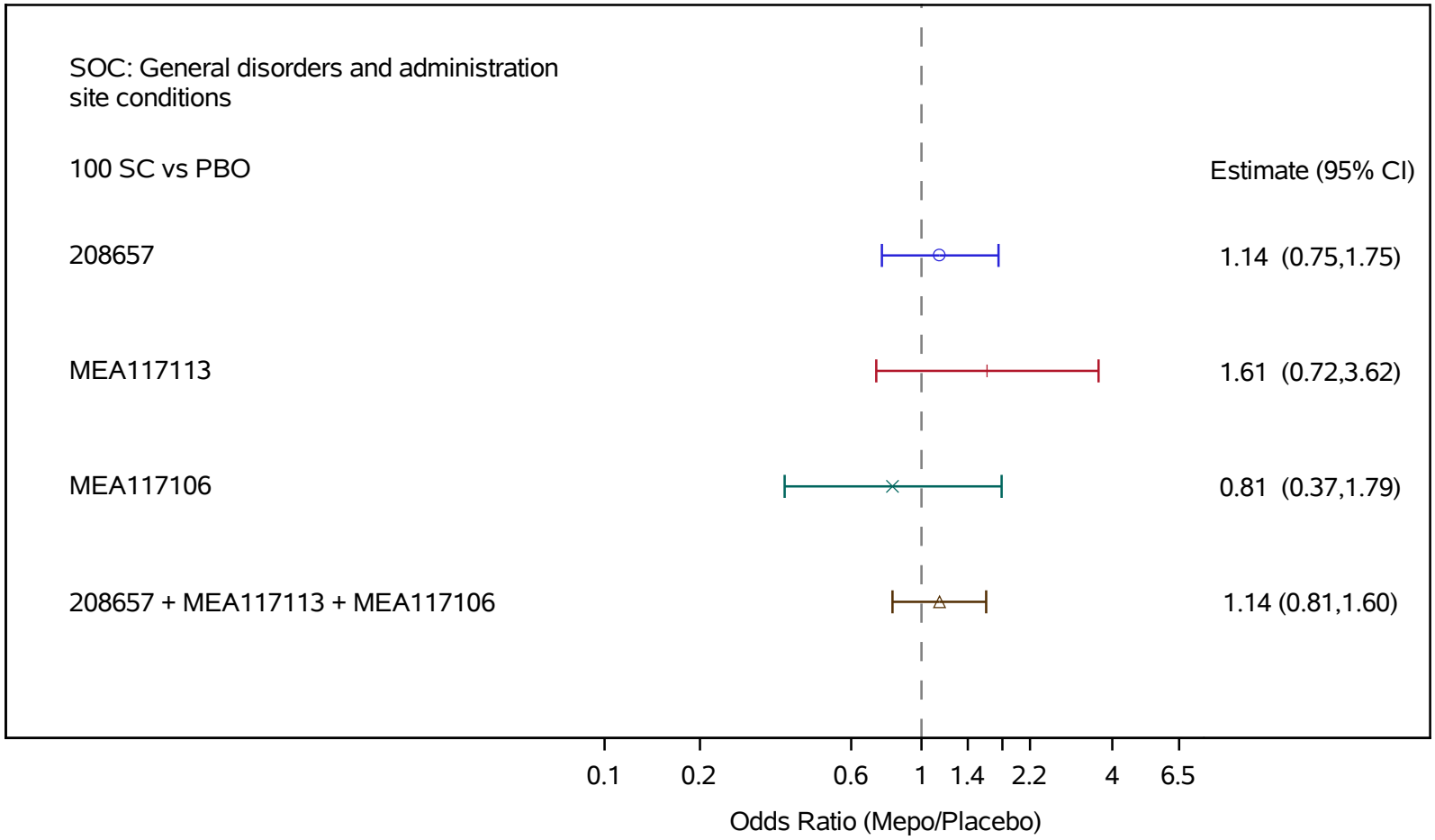

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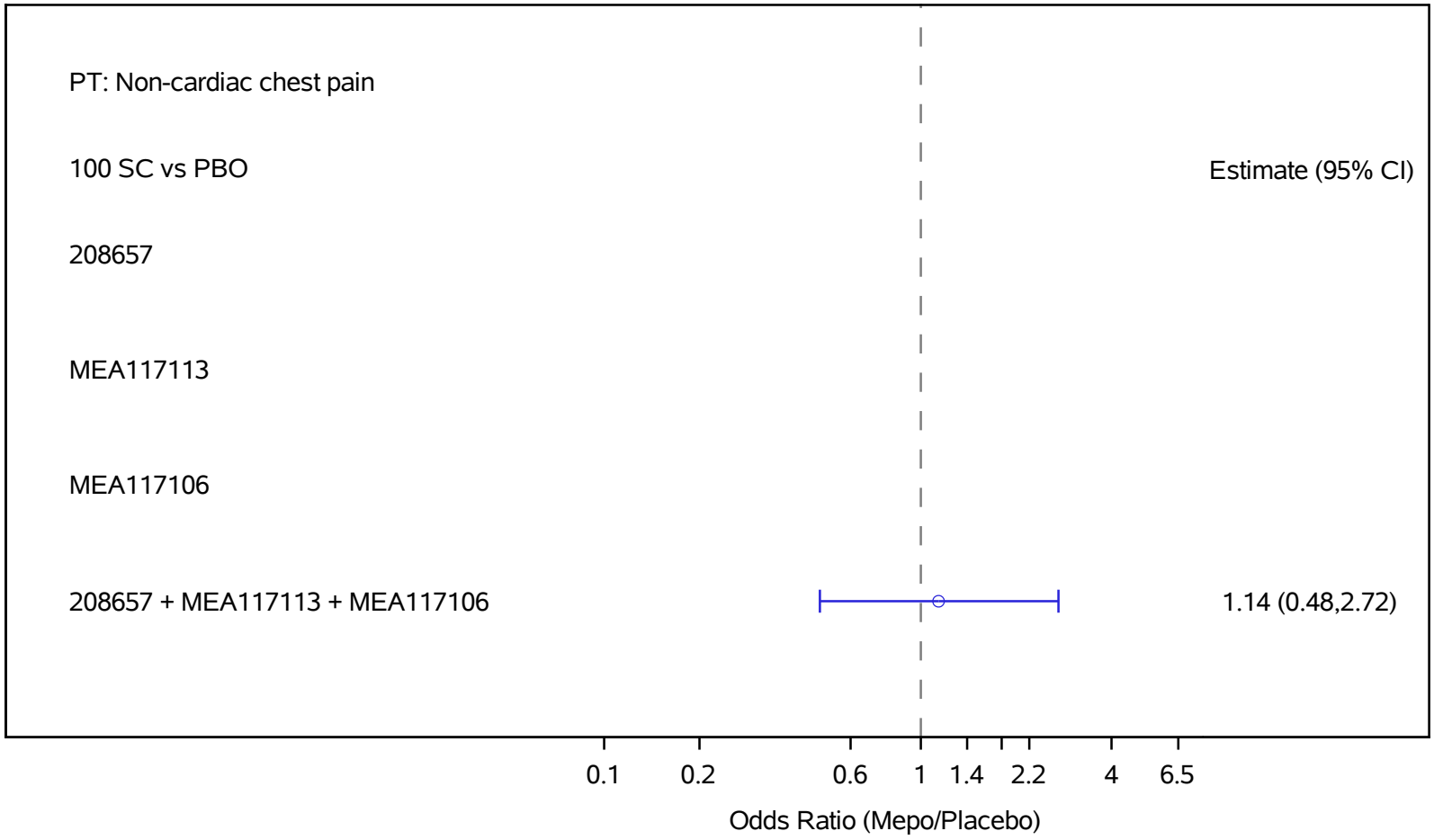

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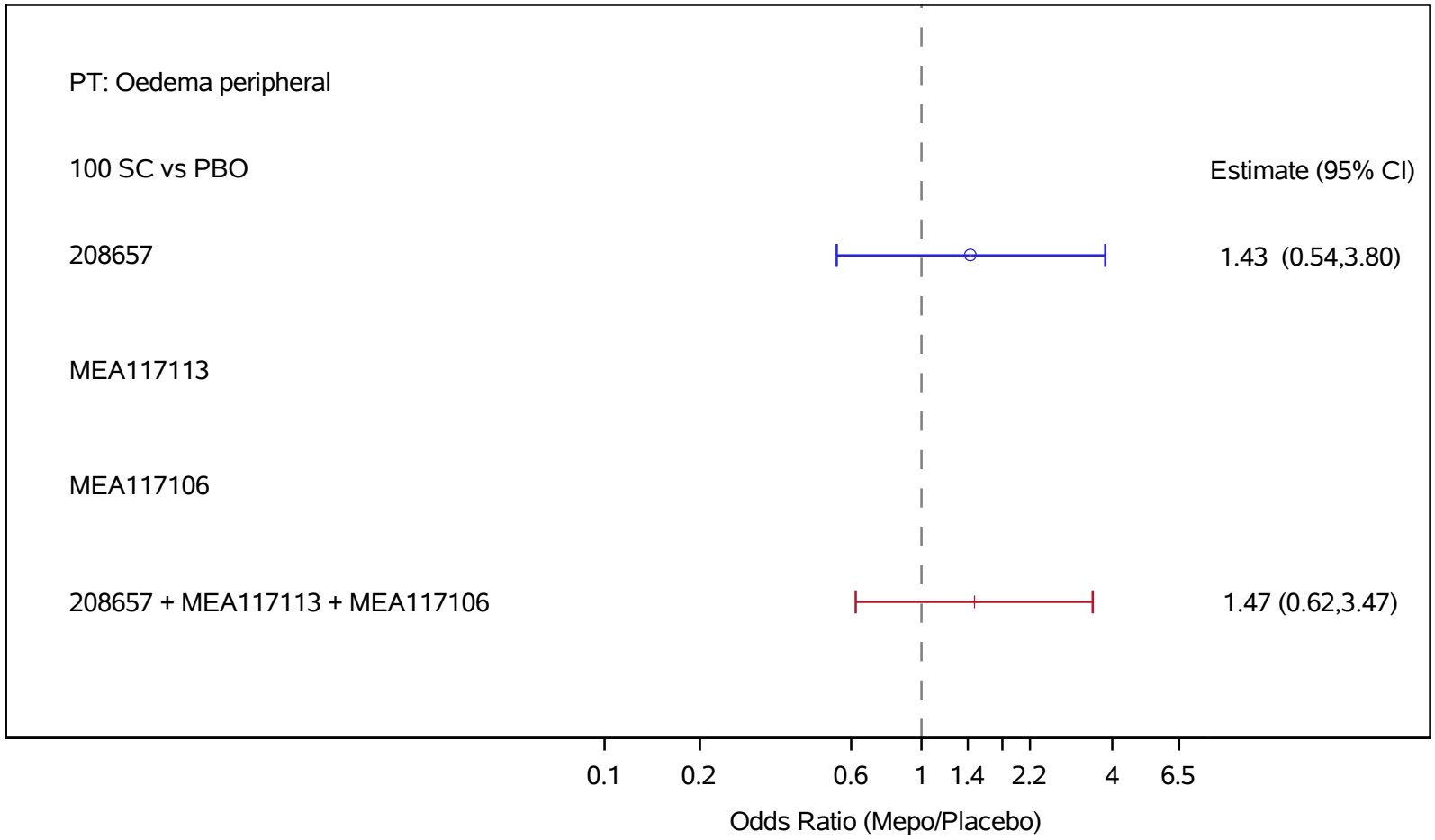

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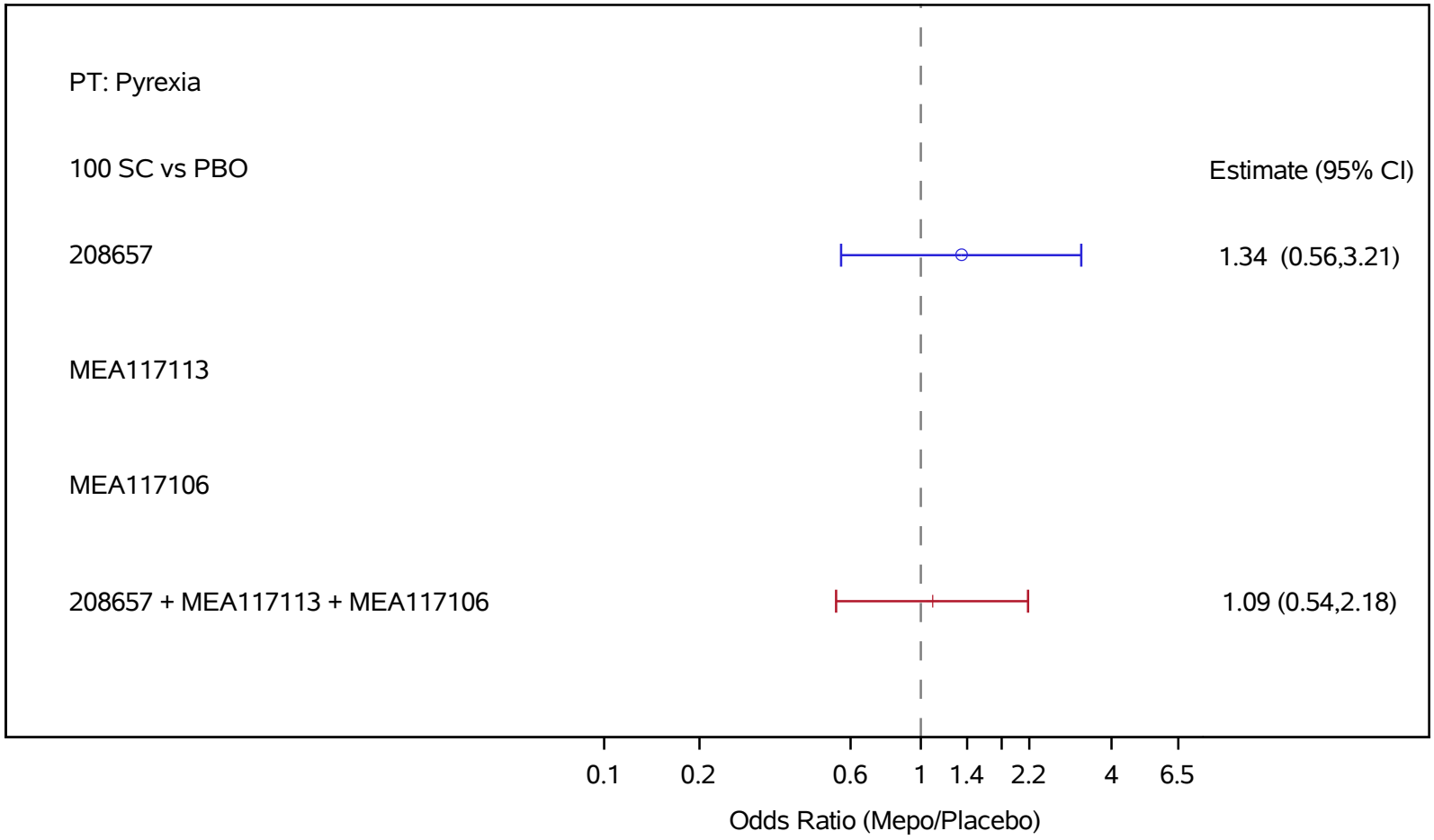

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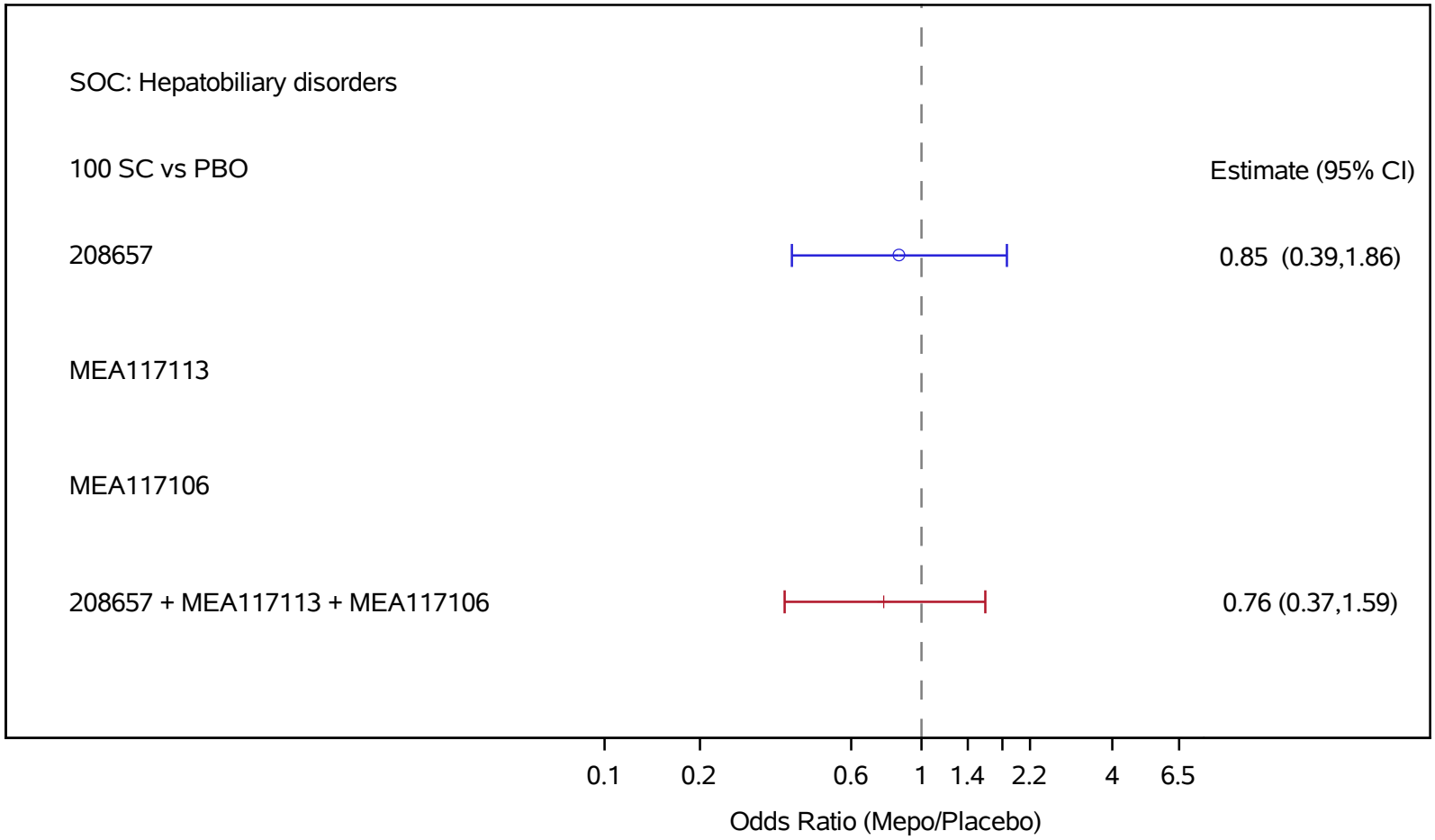

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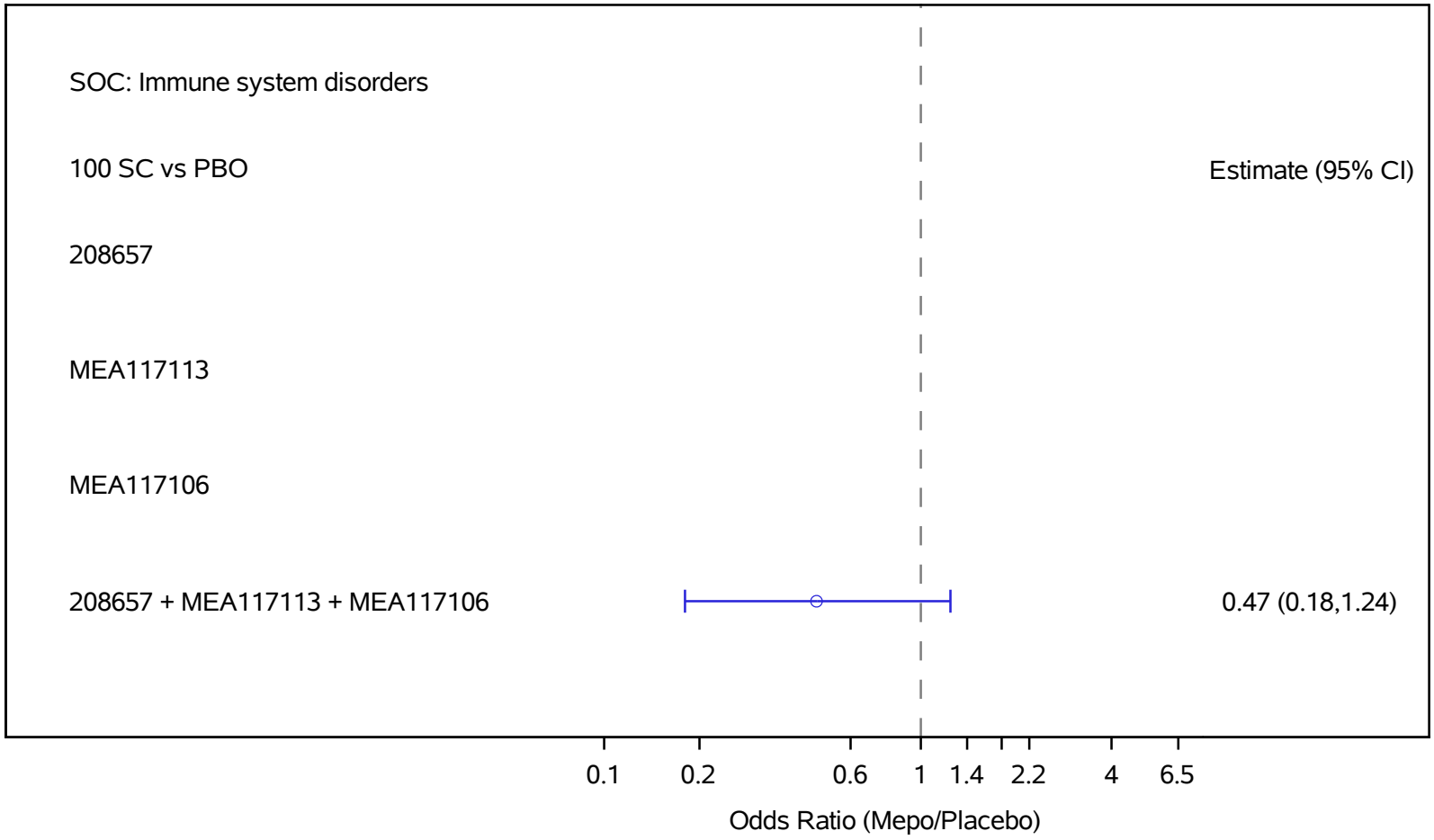

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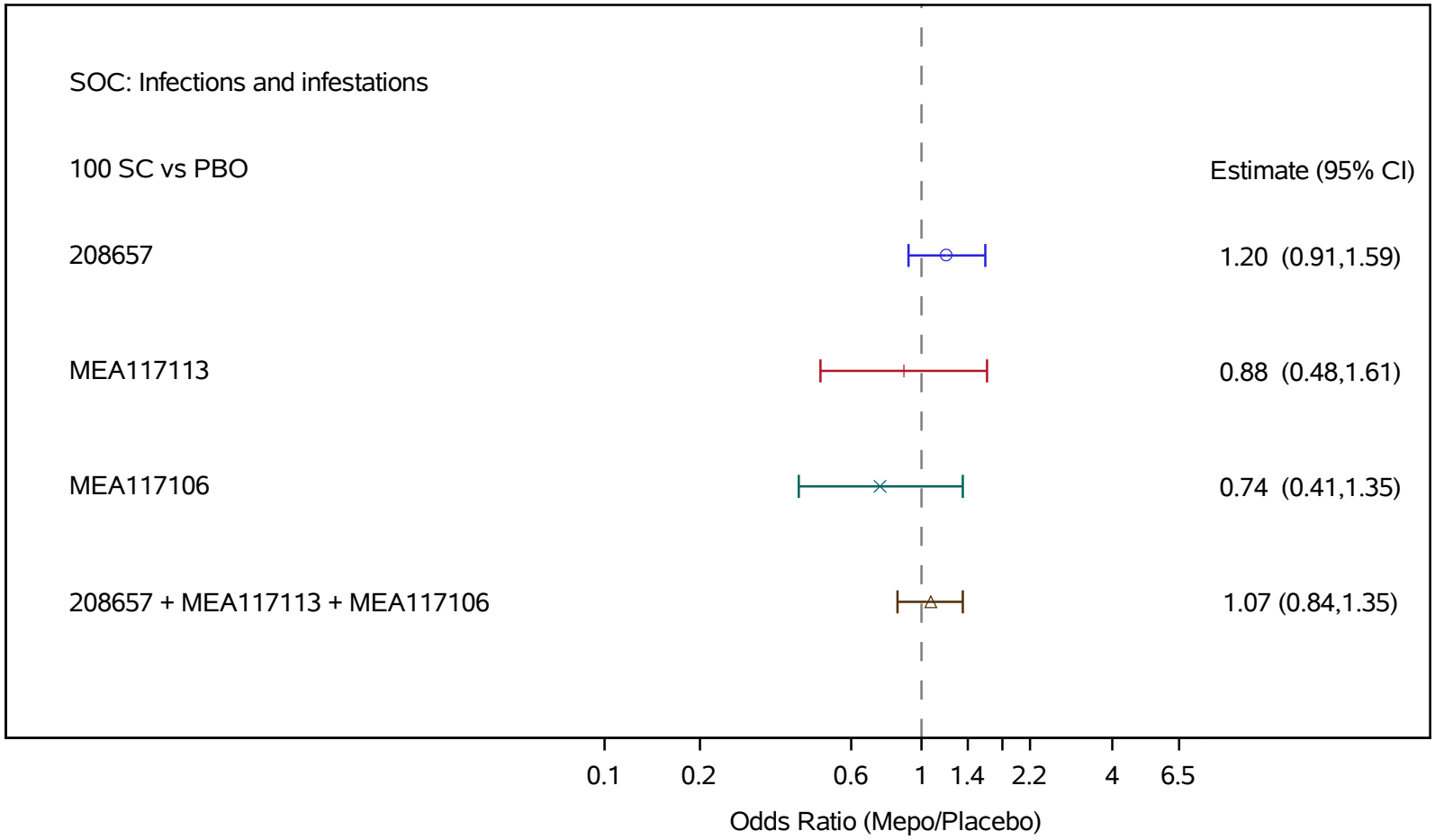

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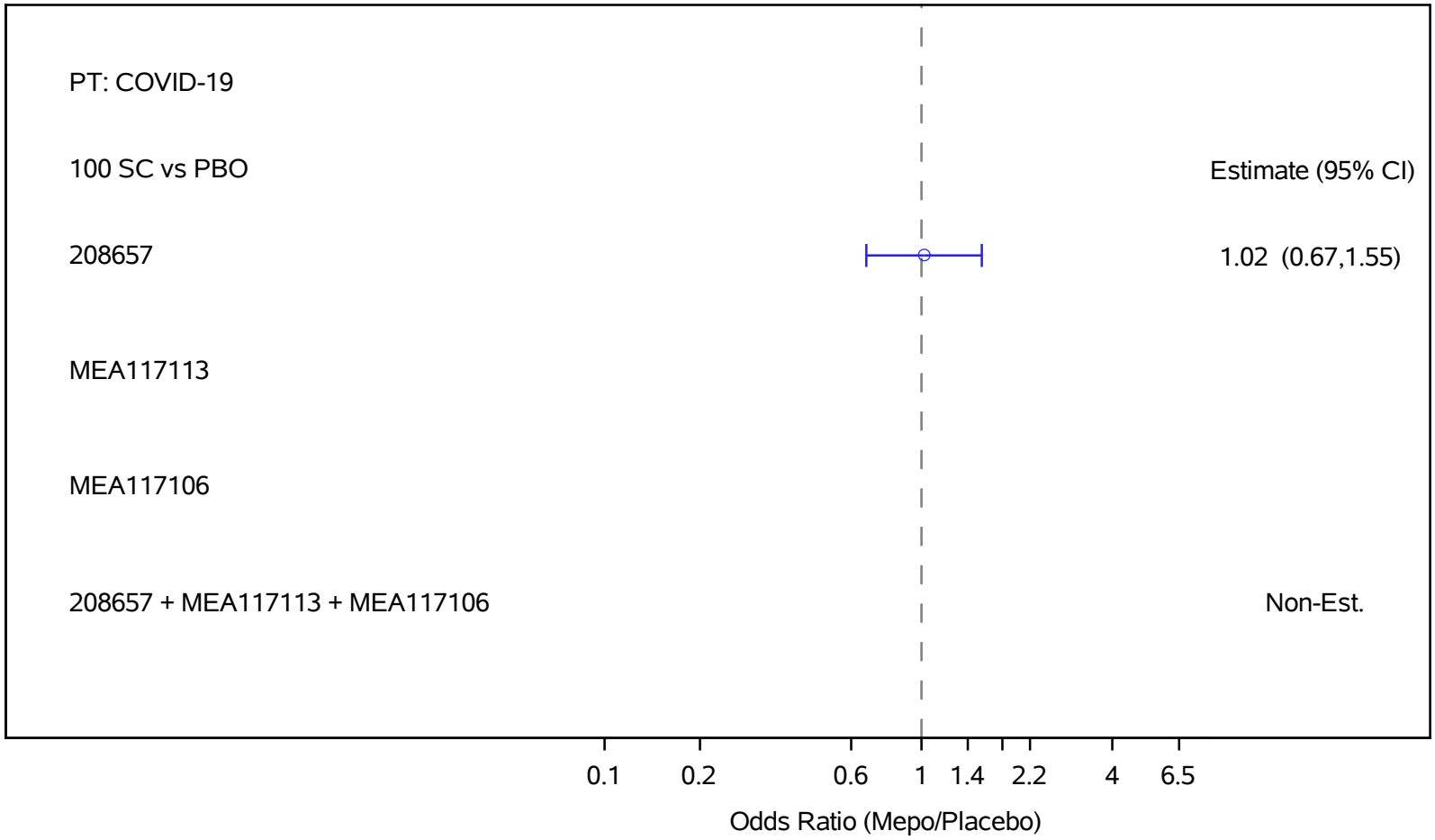

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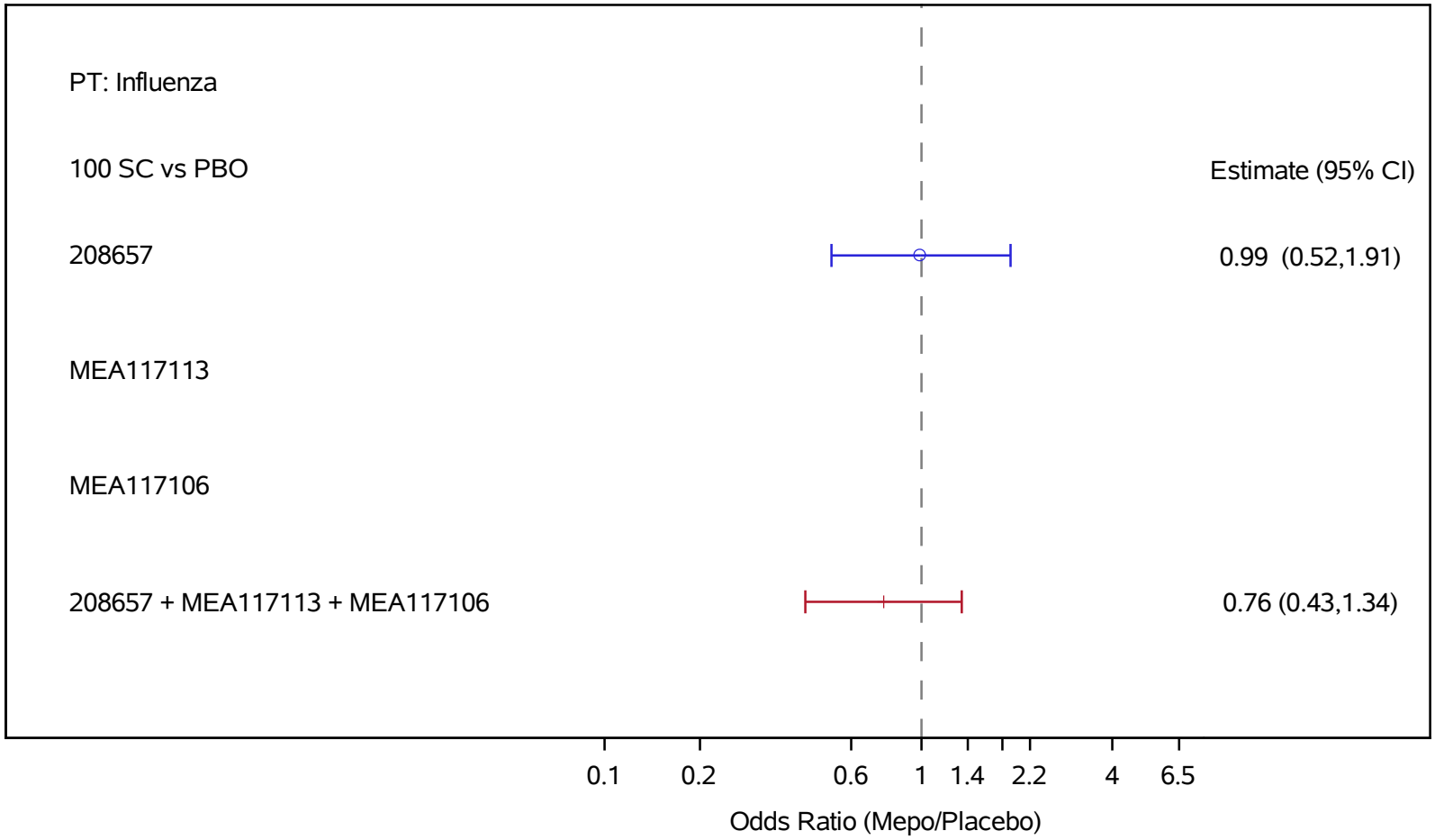

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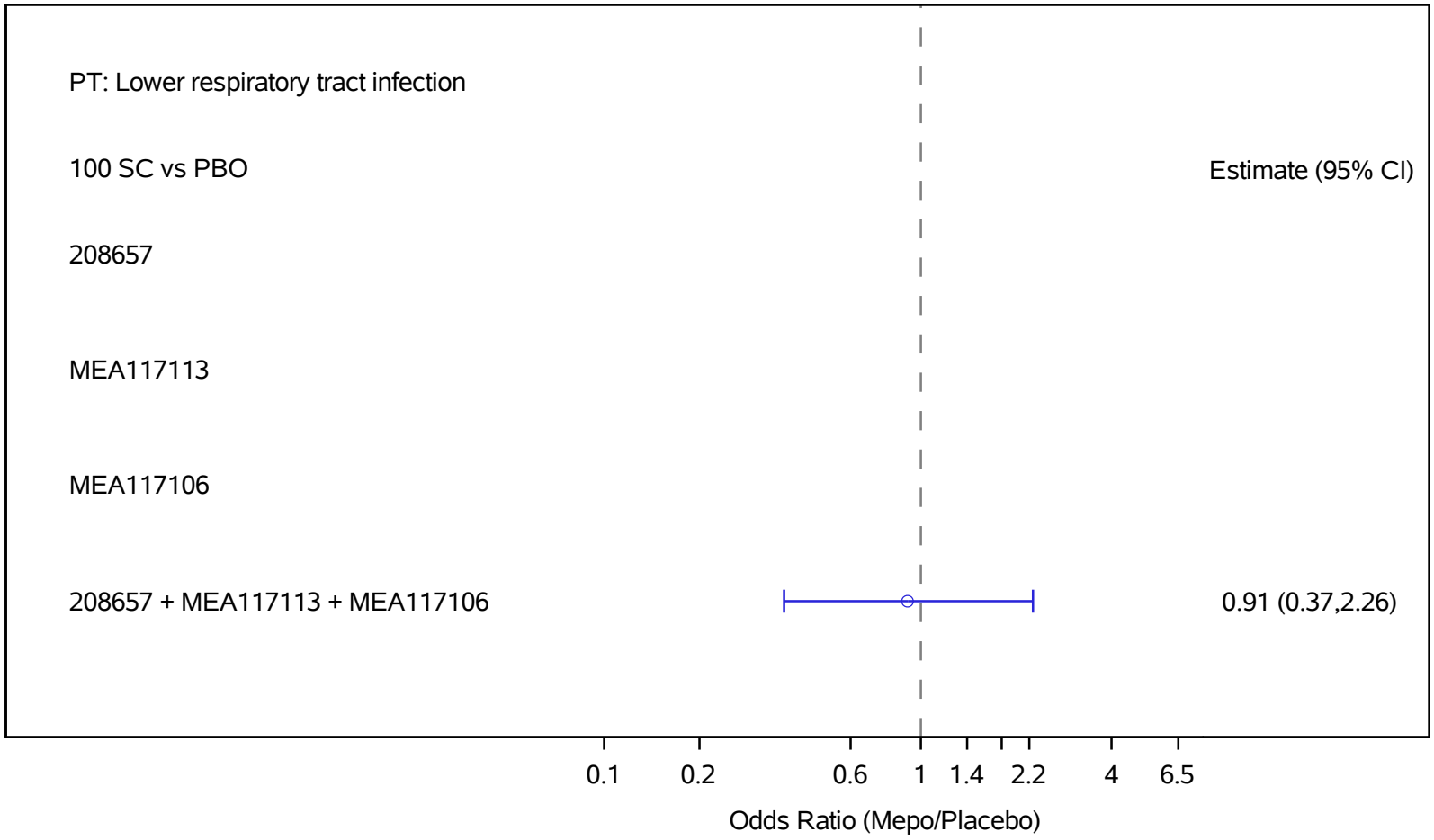

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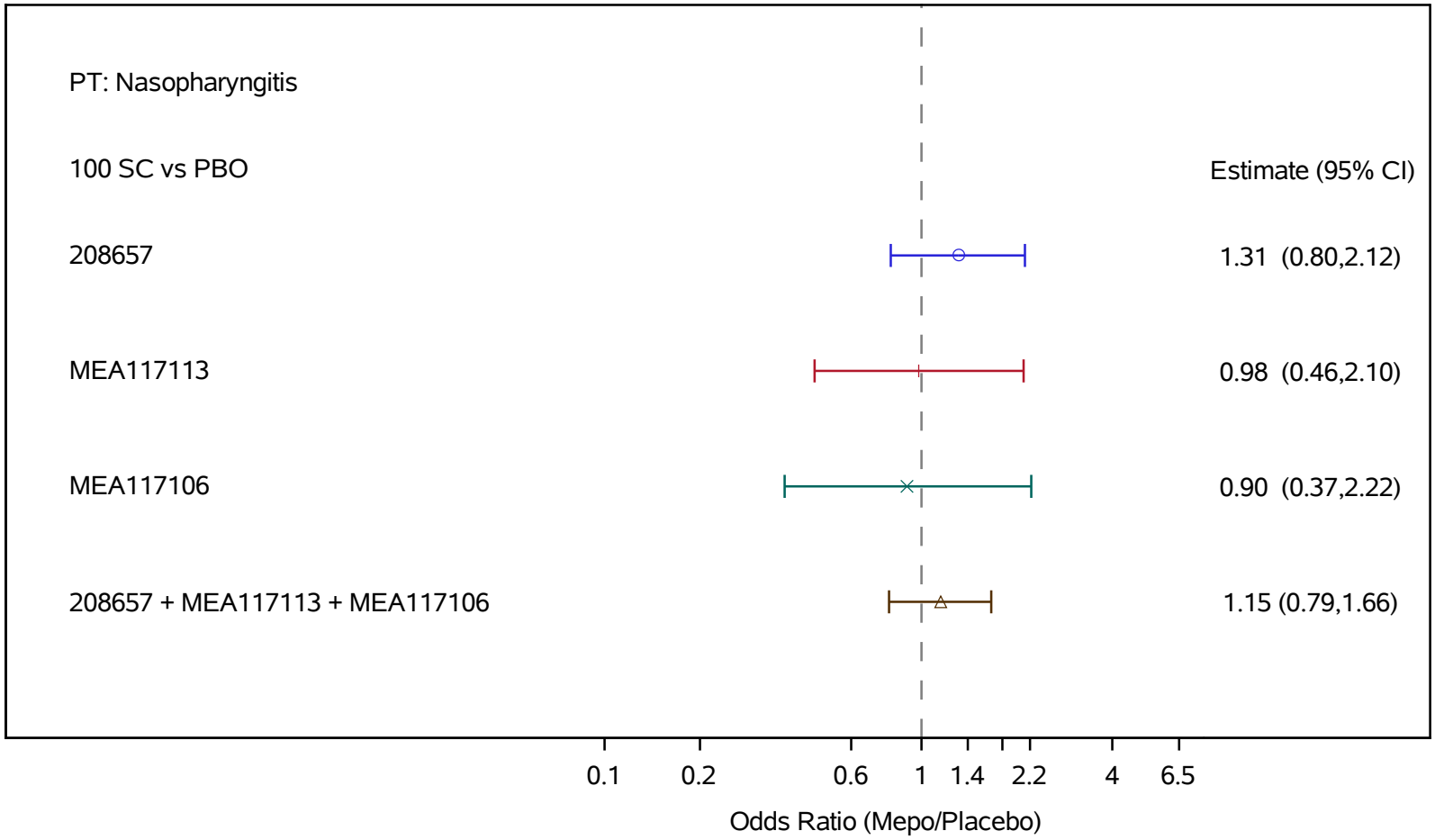

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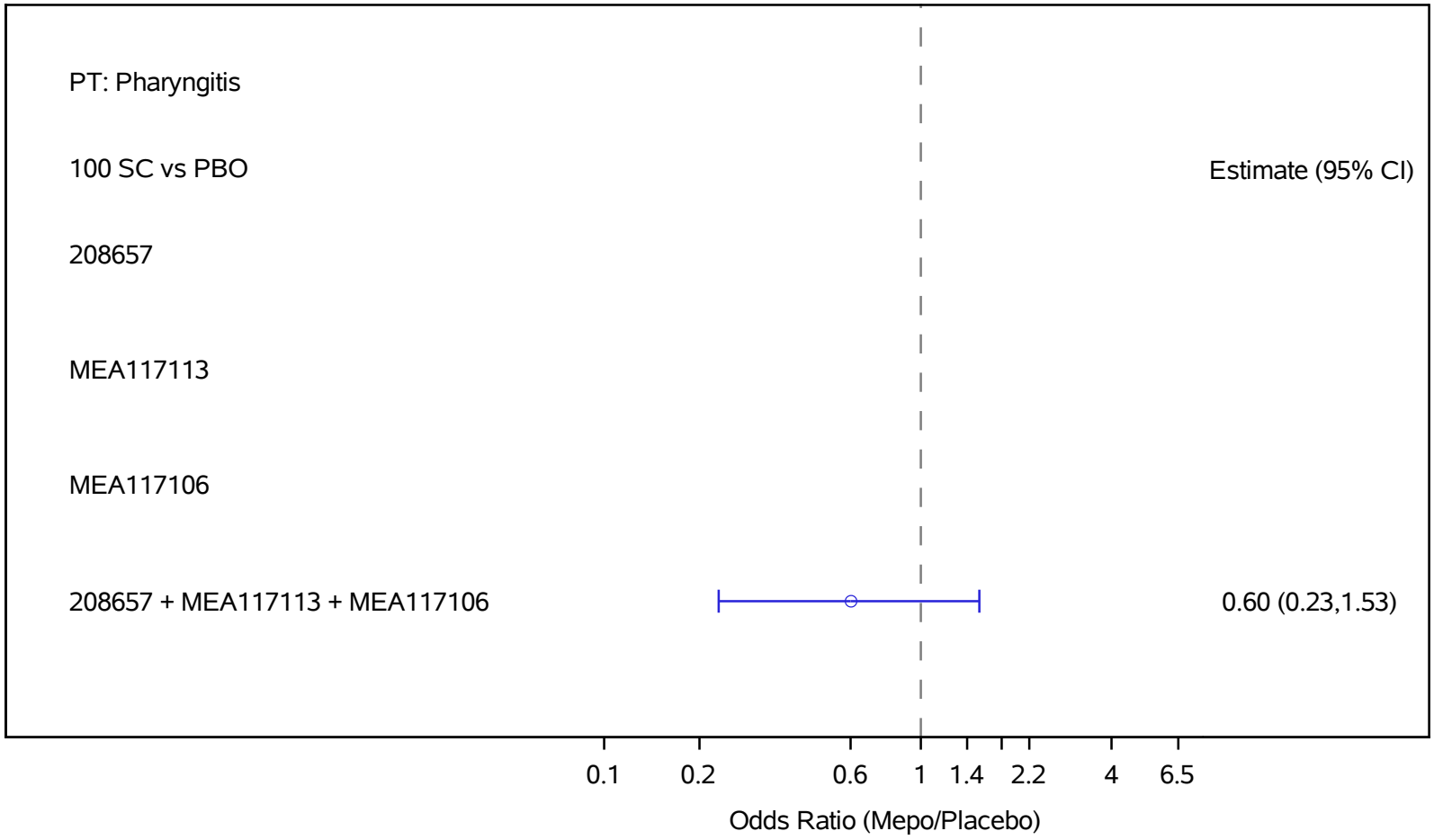

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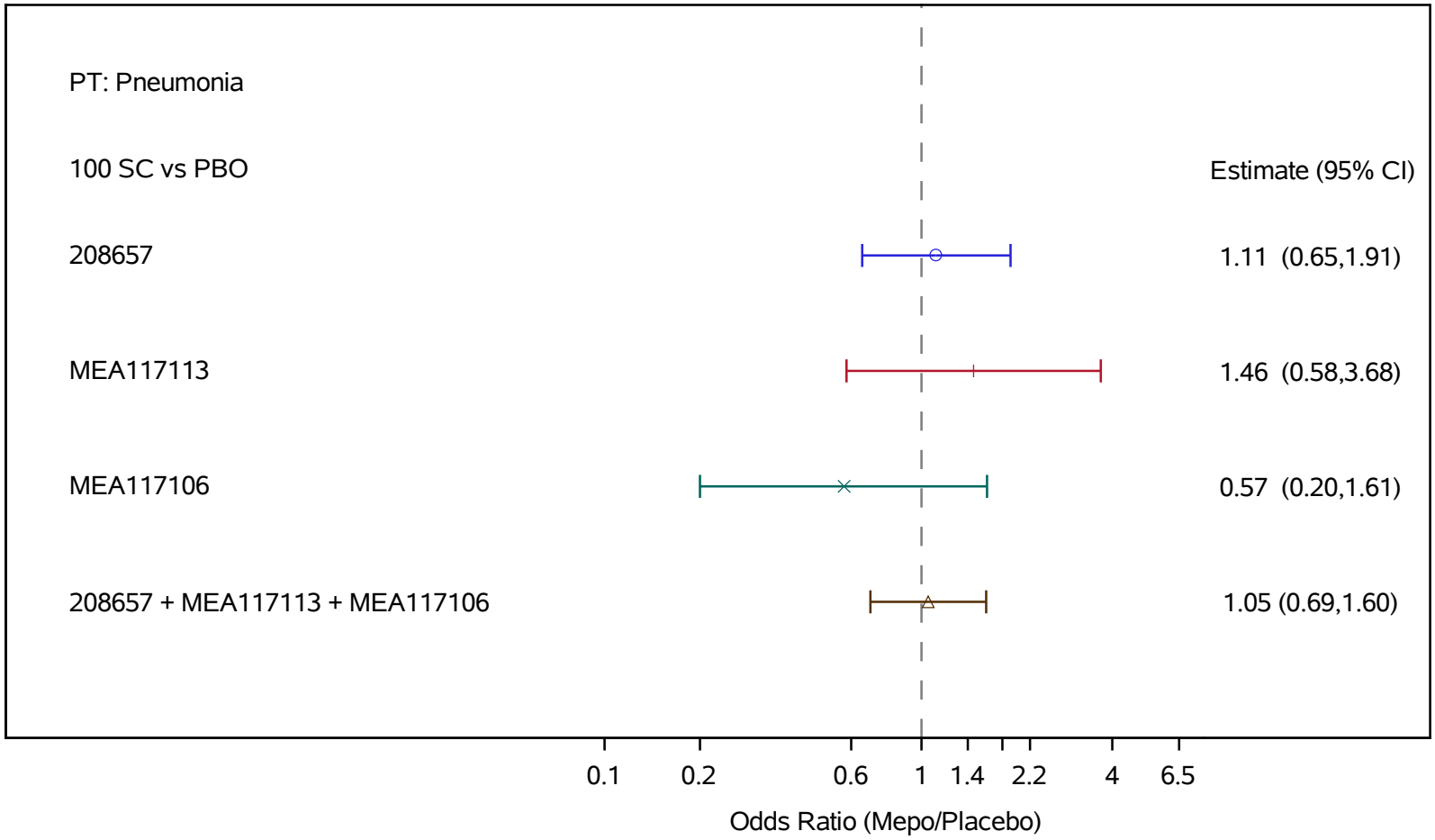

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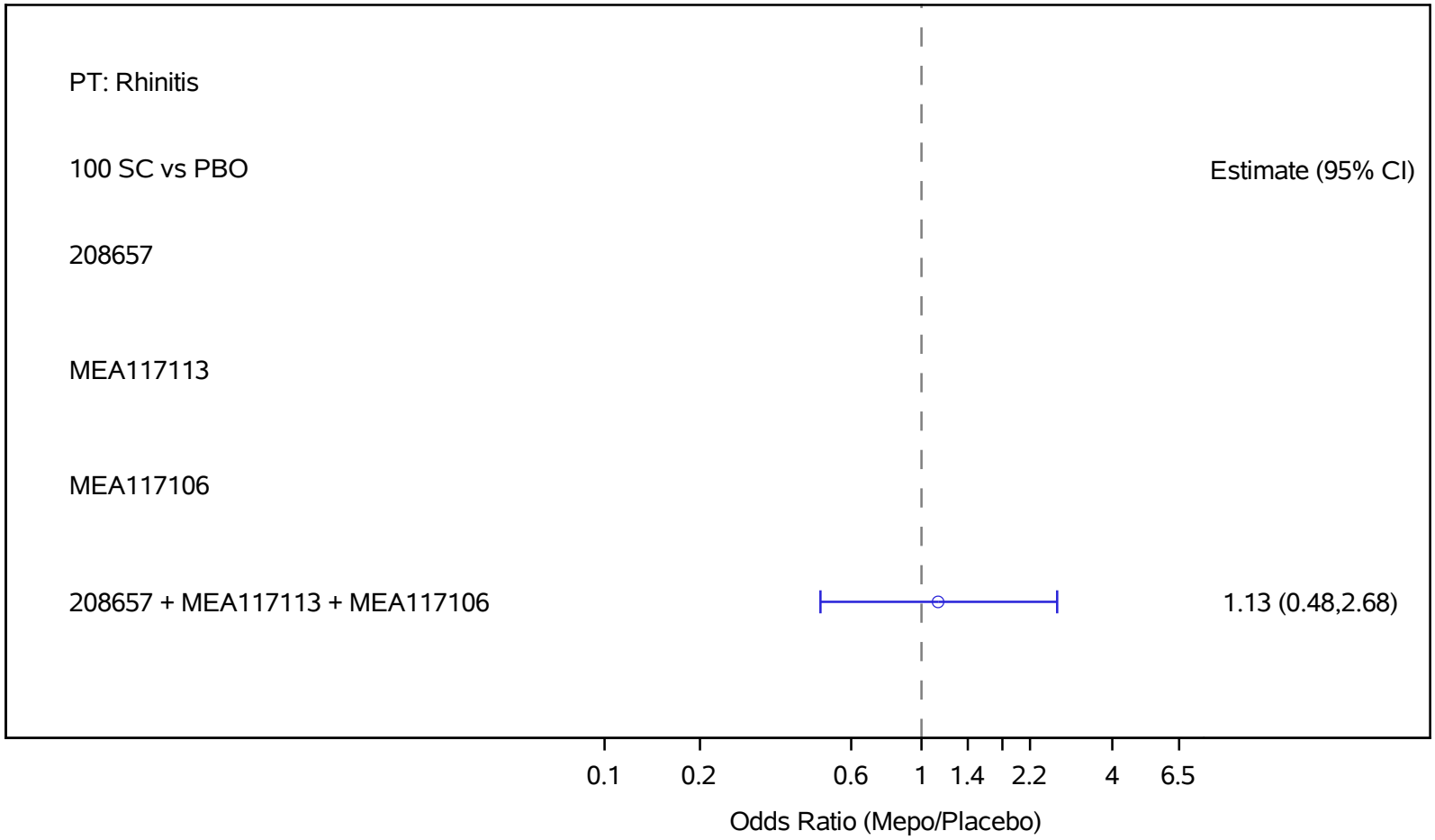

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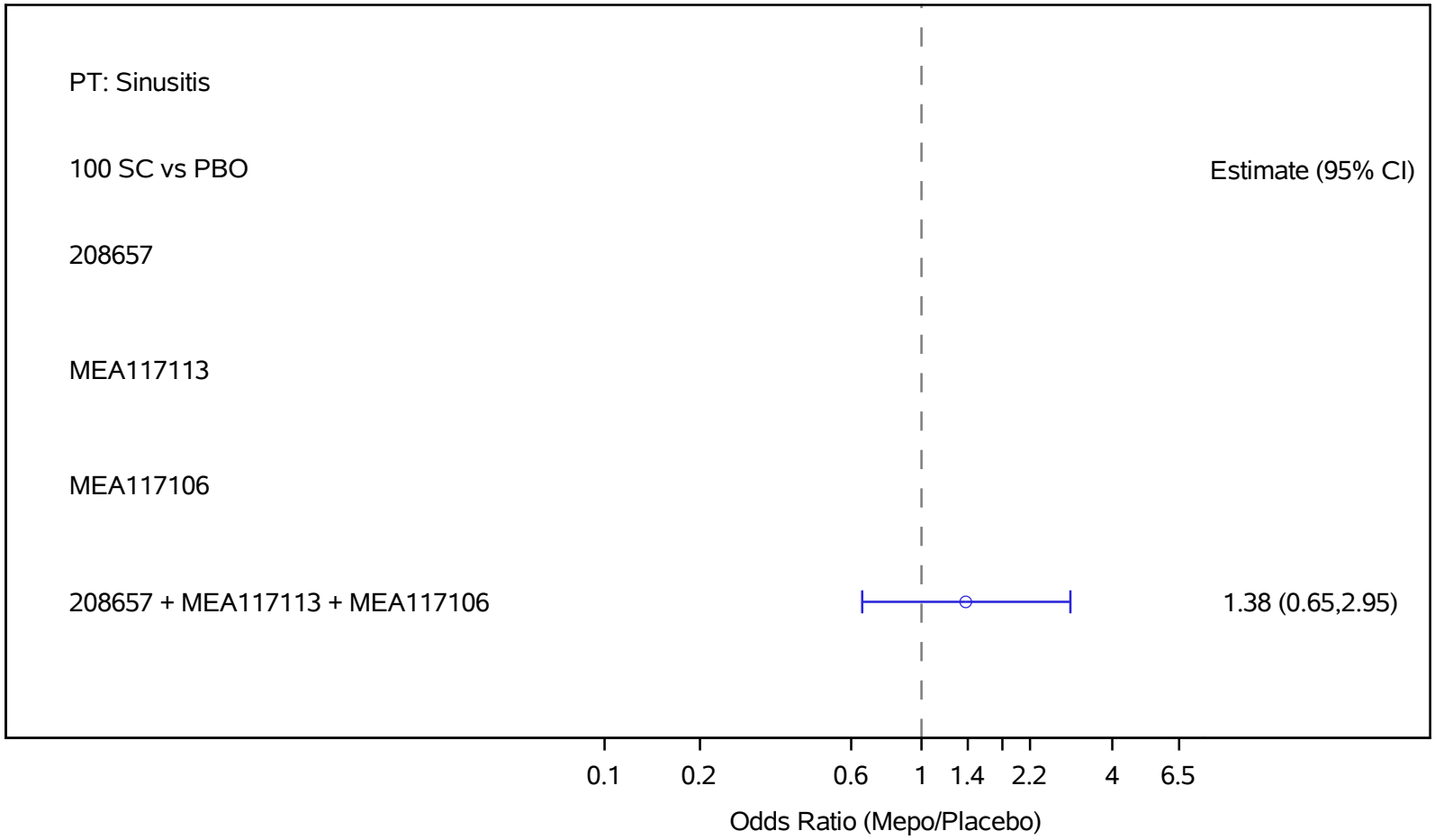

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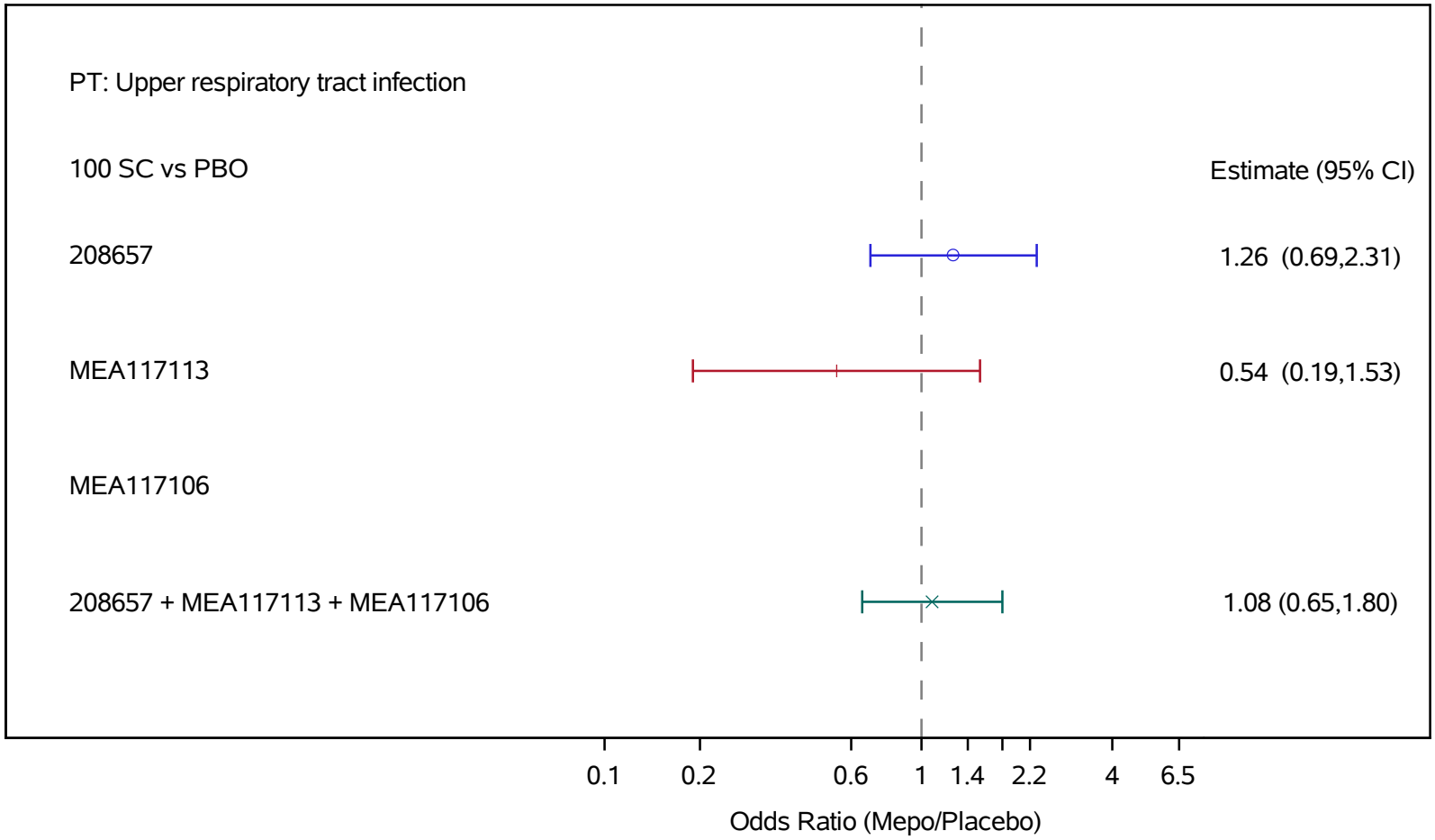

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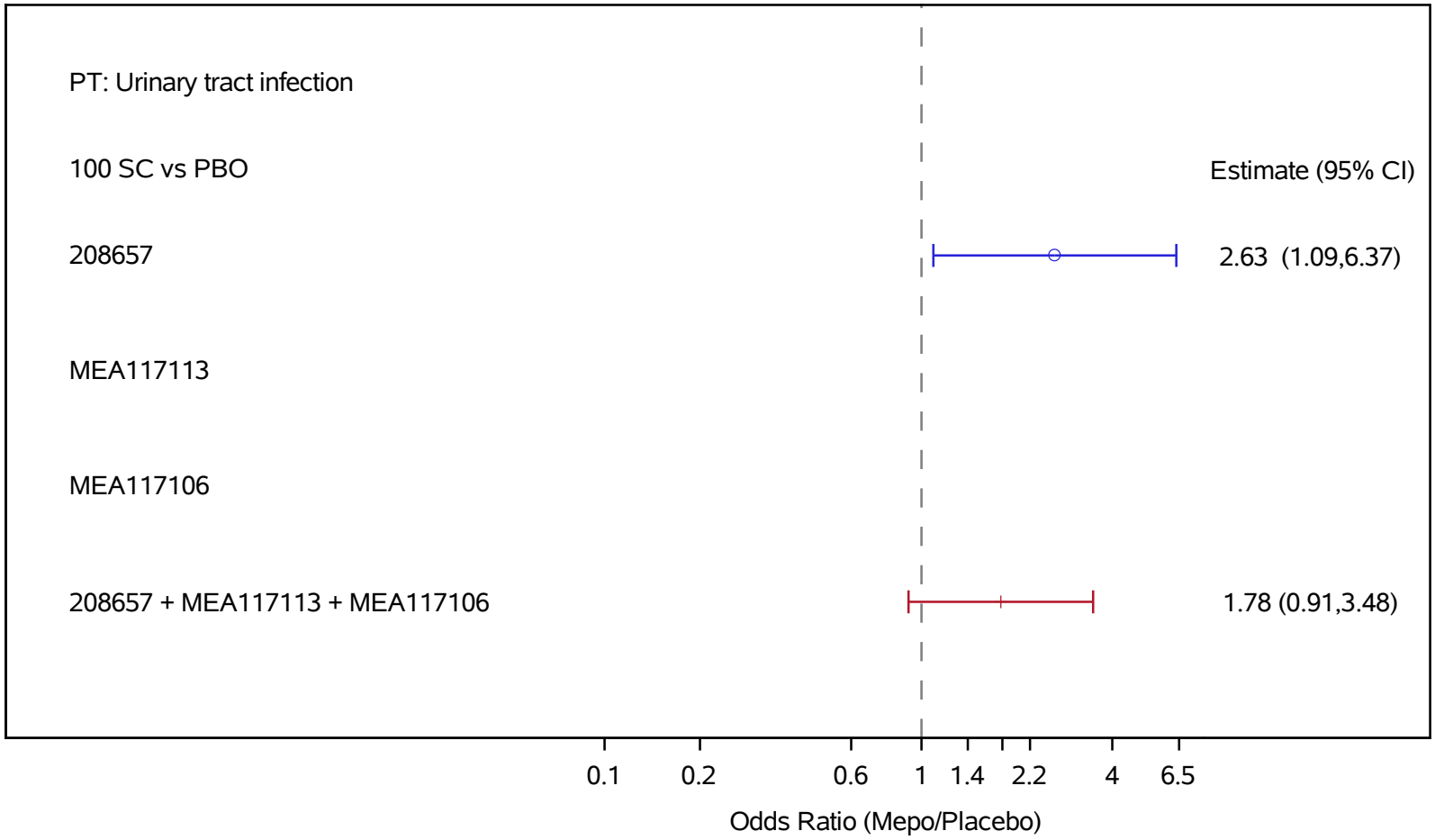

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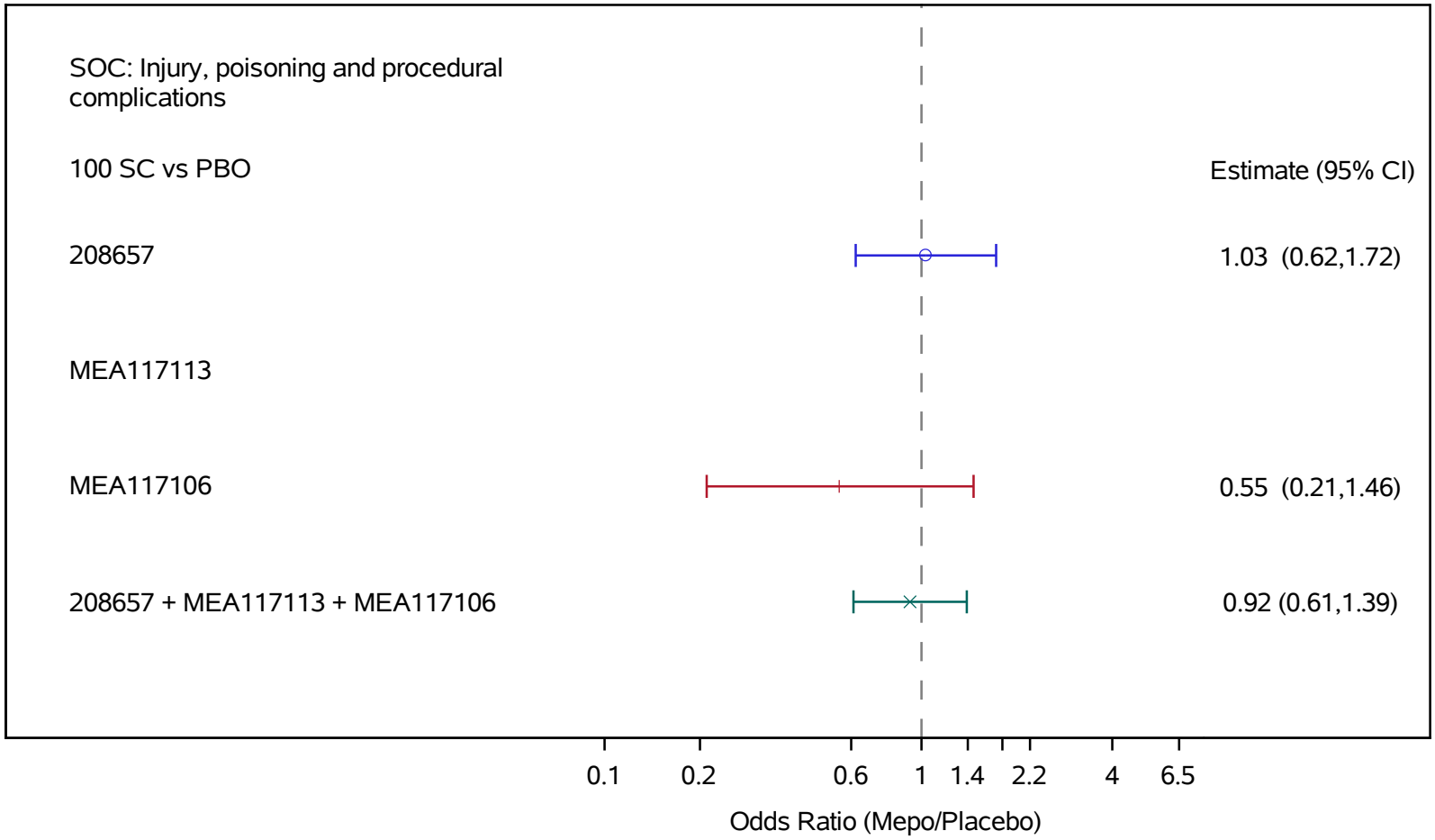

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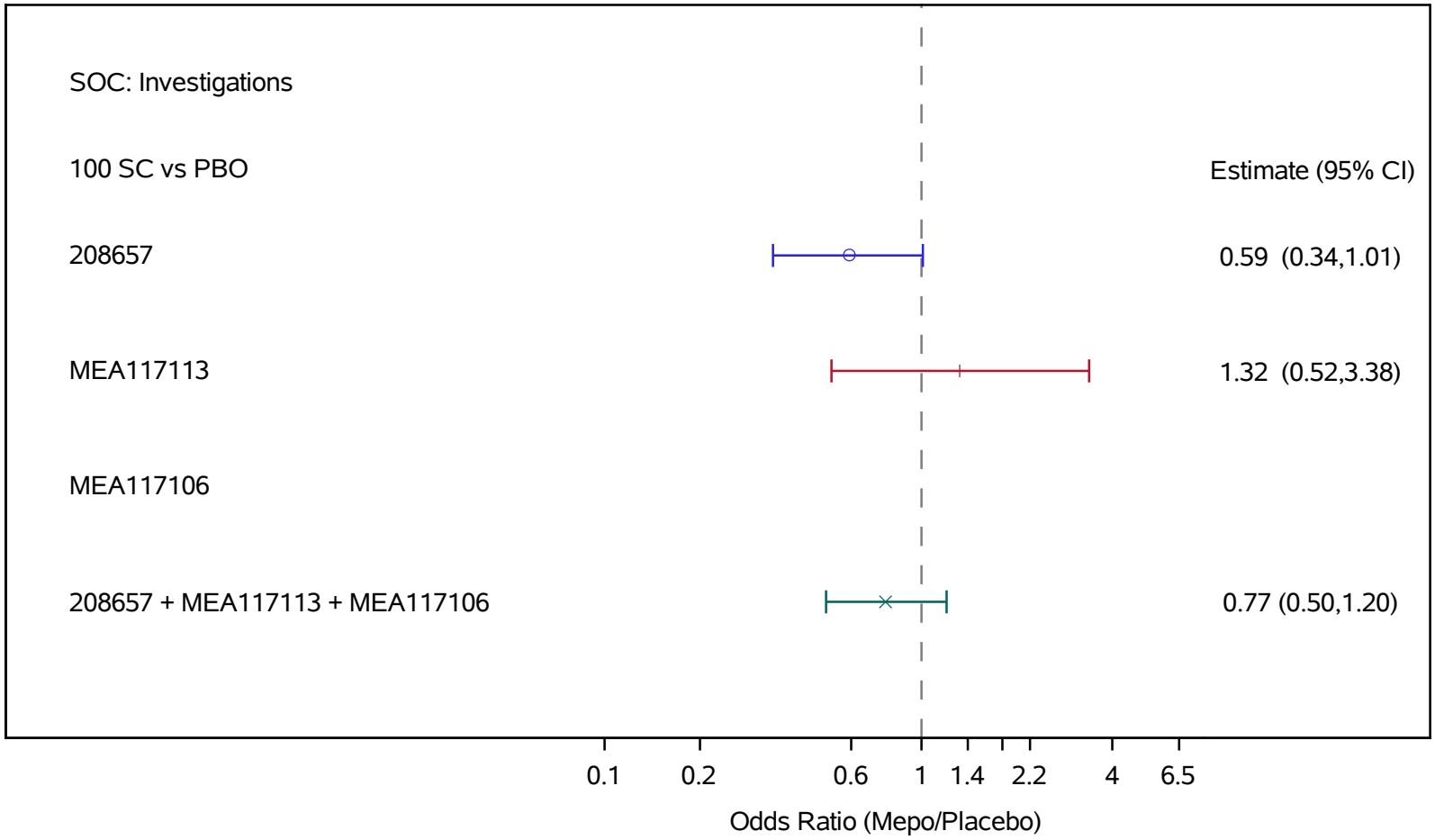

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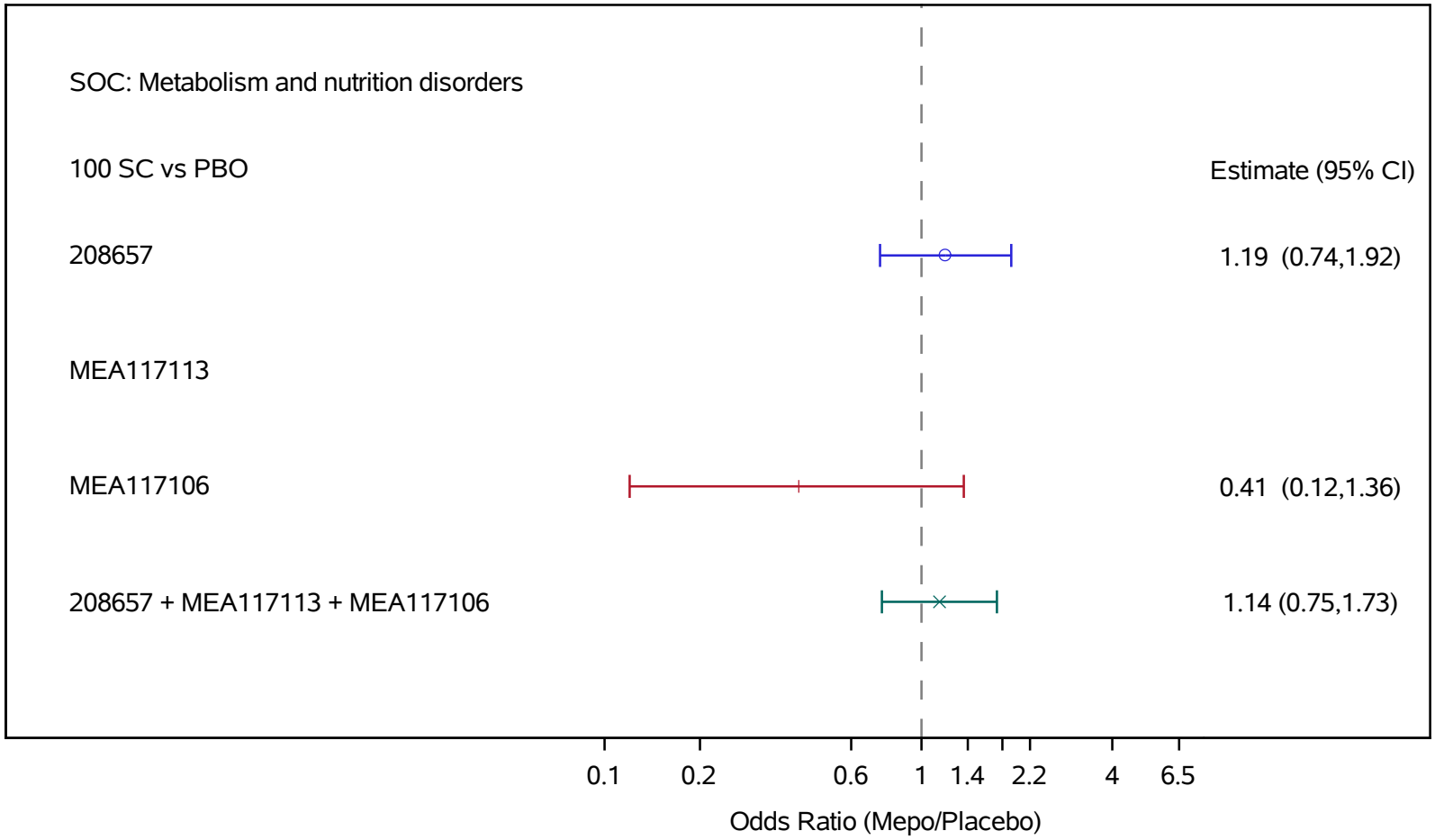

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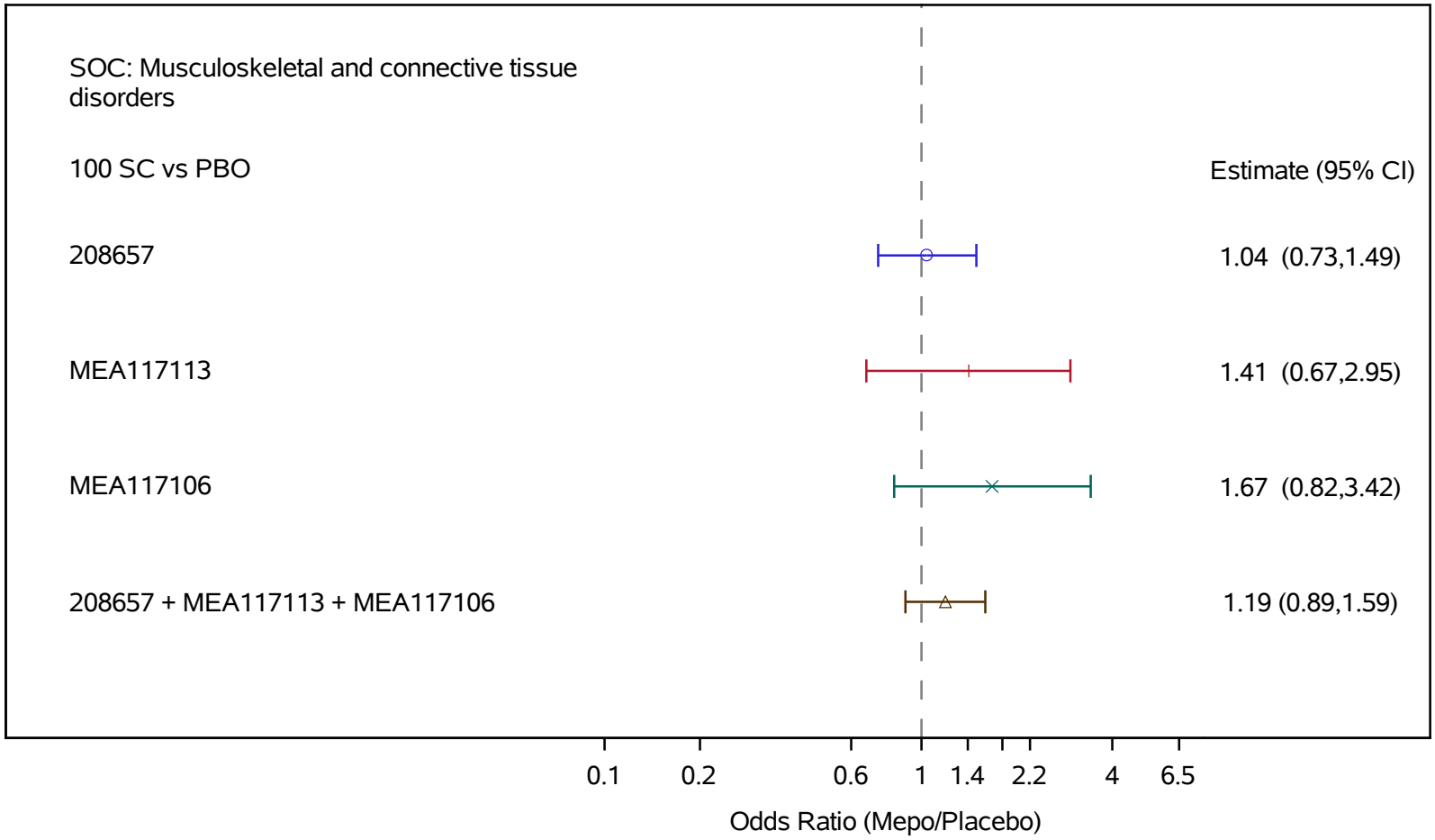

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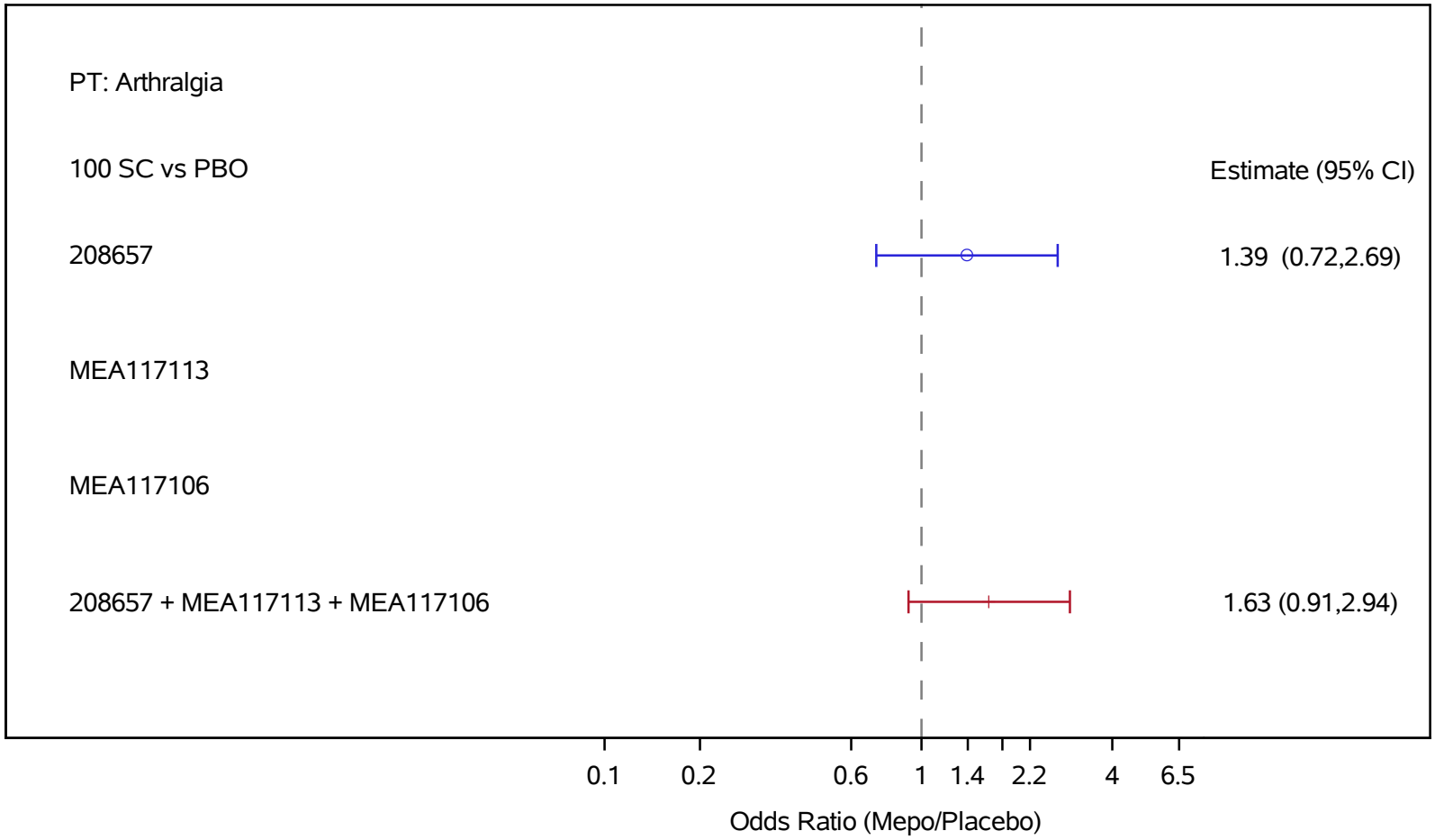

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Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

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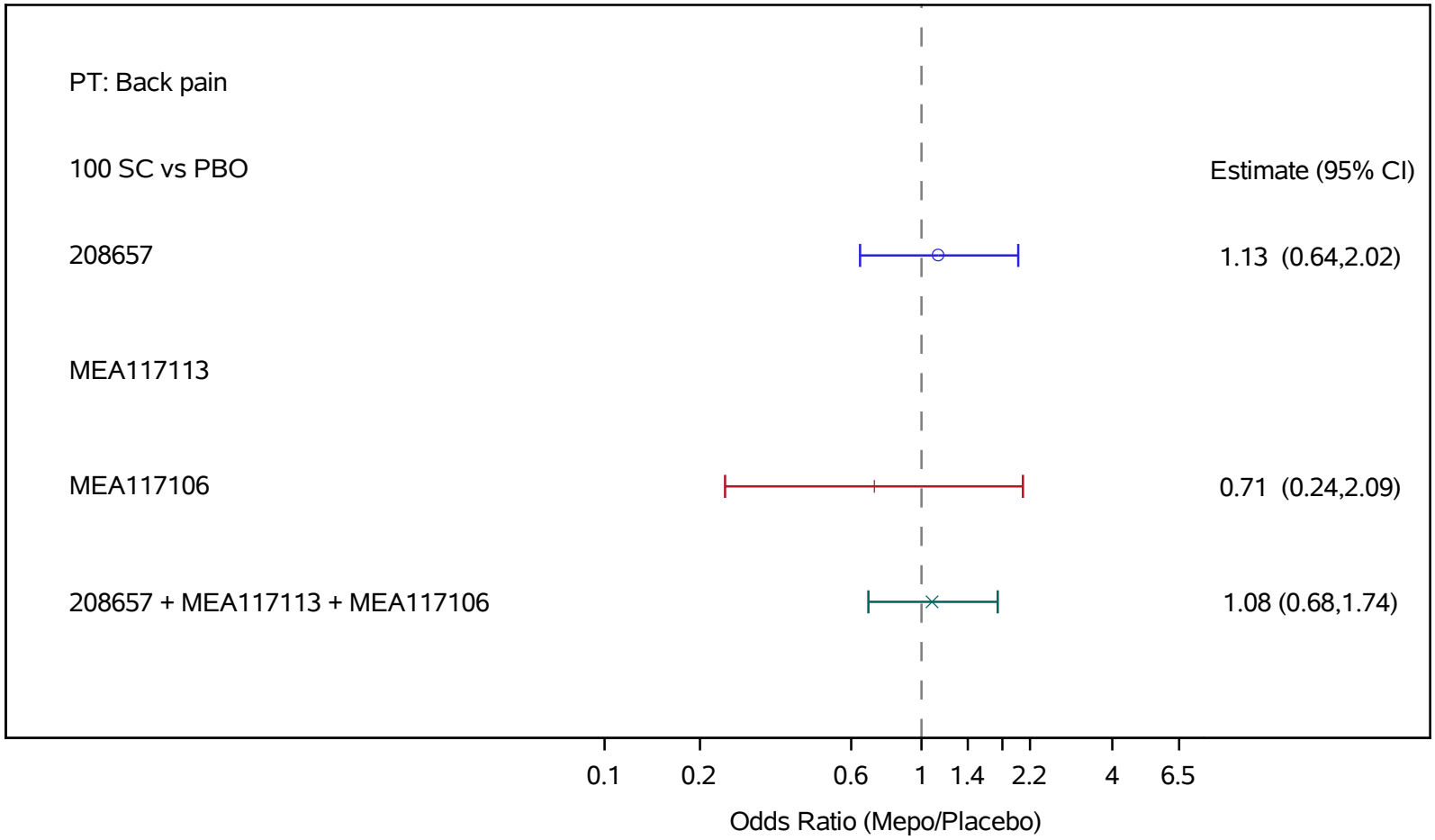
Forest Plot of Odds ratio for On-Treatment Adverse Events without Disease-Related Events Occurring in >=10% of patients or in >=10 and >=1% of patients by SOC and PT: Individual Studies and Meta-Analysis



Horizontal bars indicate 95% confidence intervals for the Mepo/Placebo ratio.

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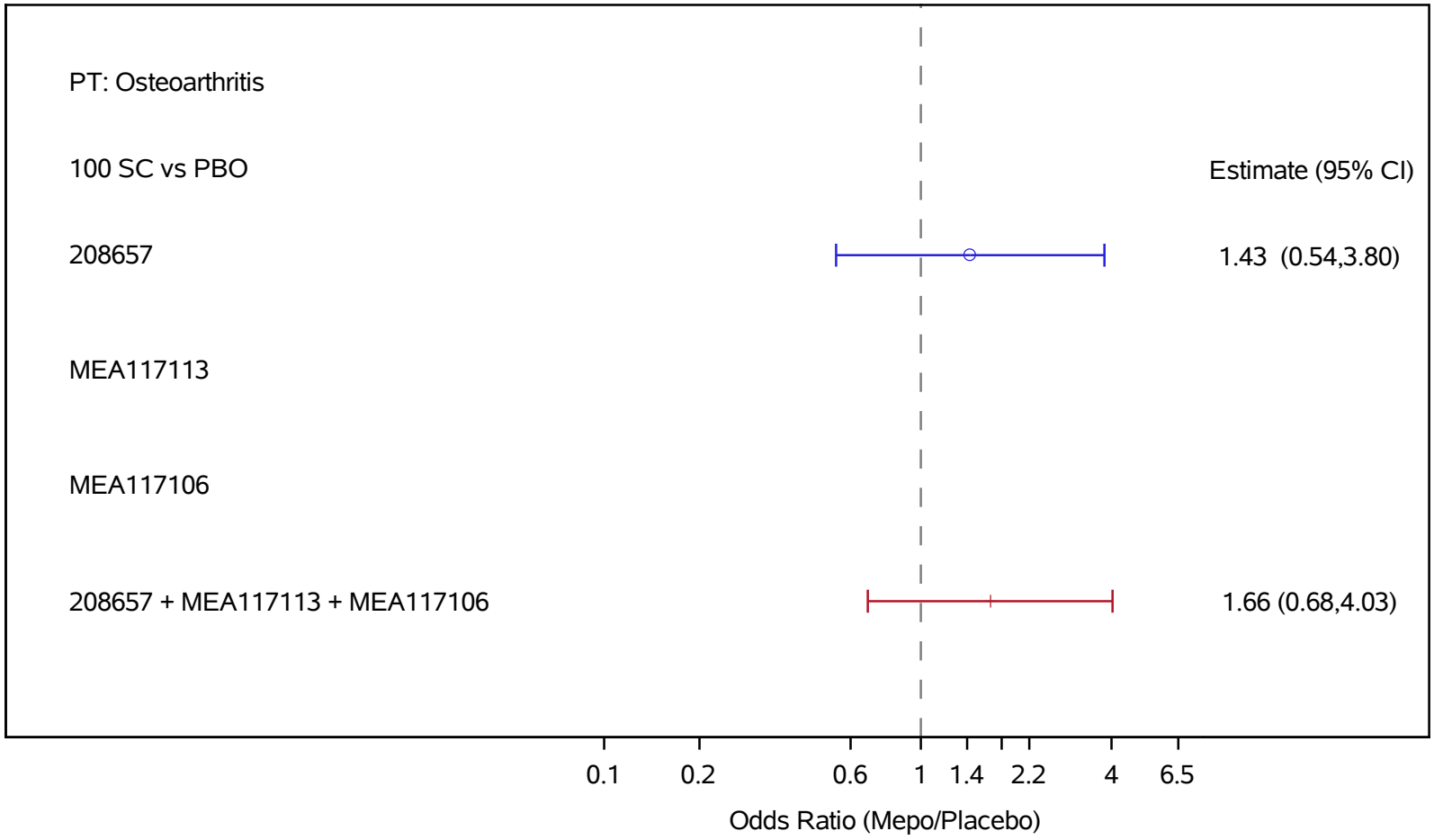

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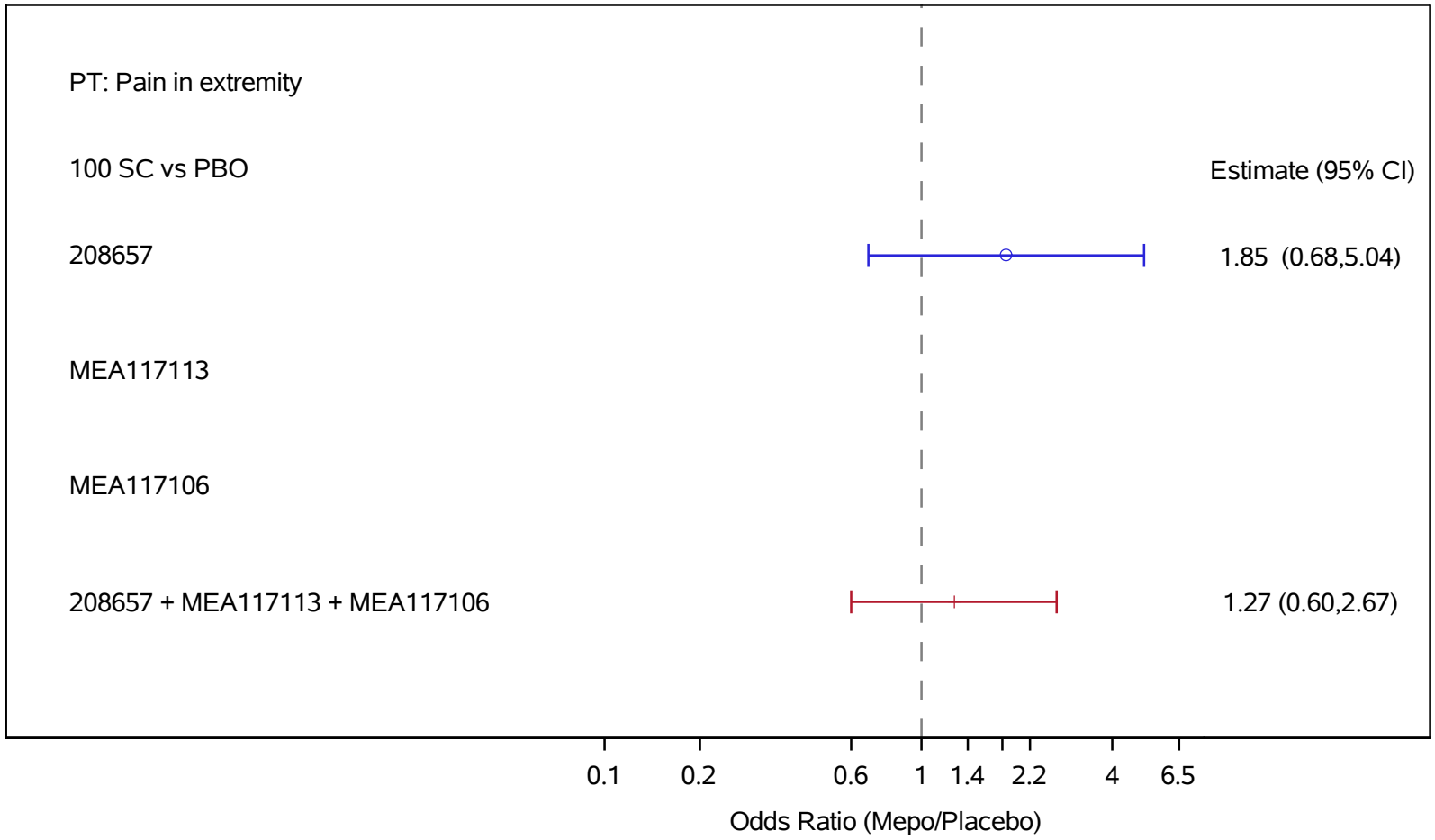

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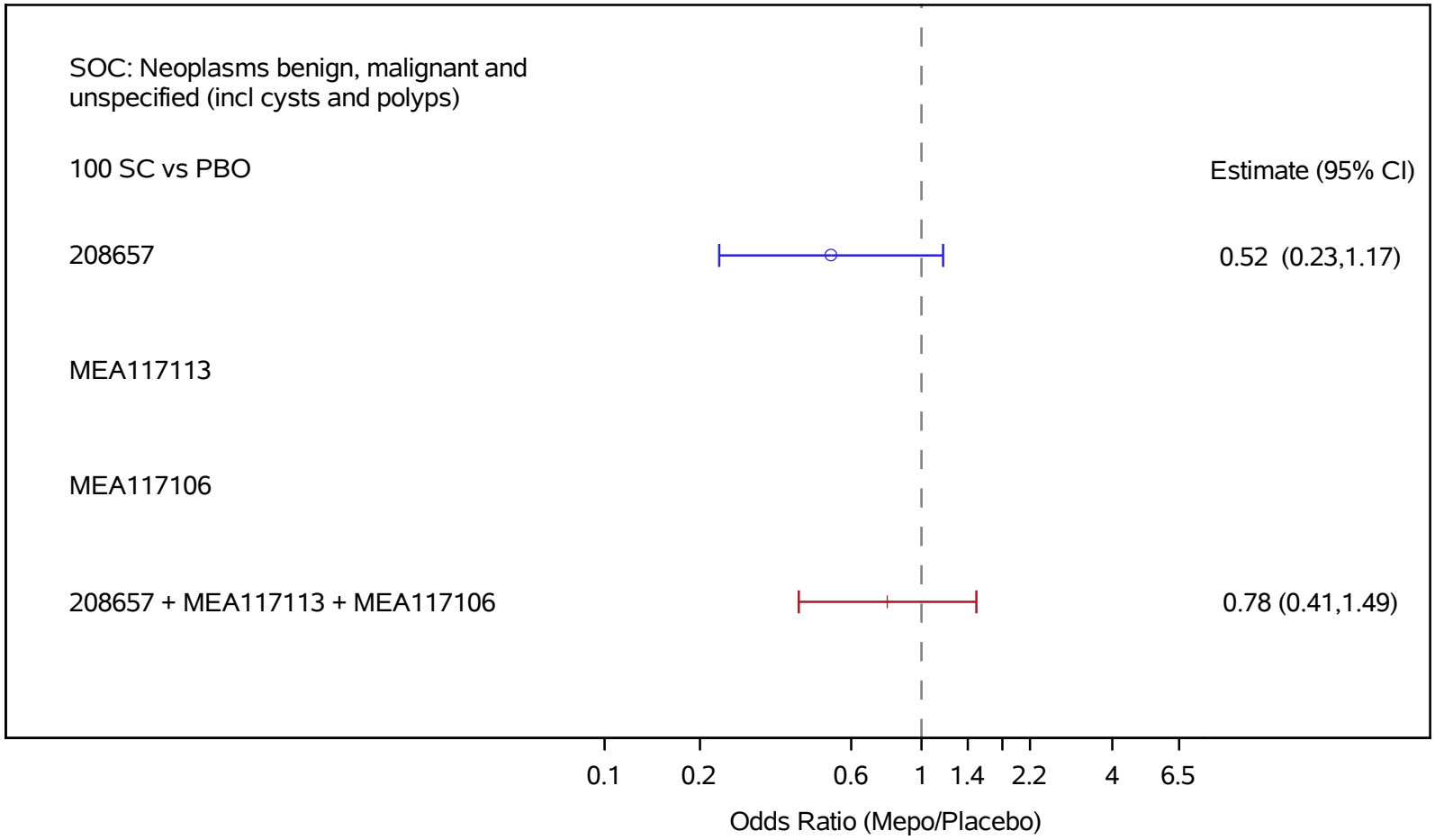

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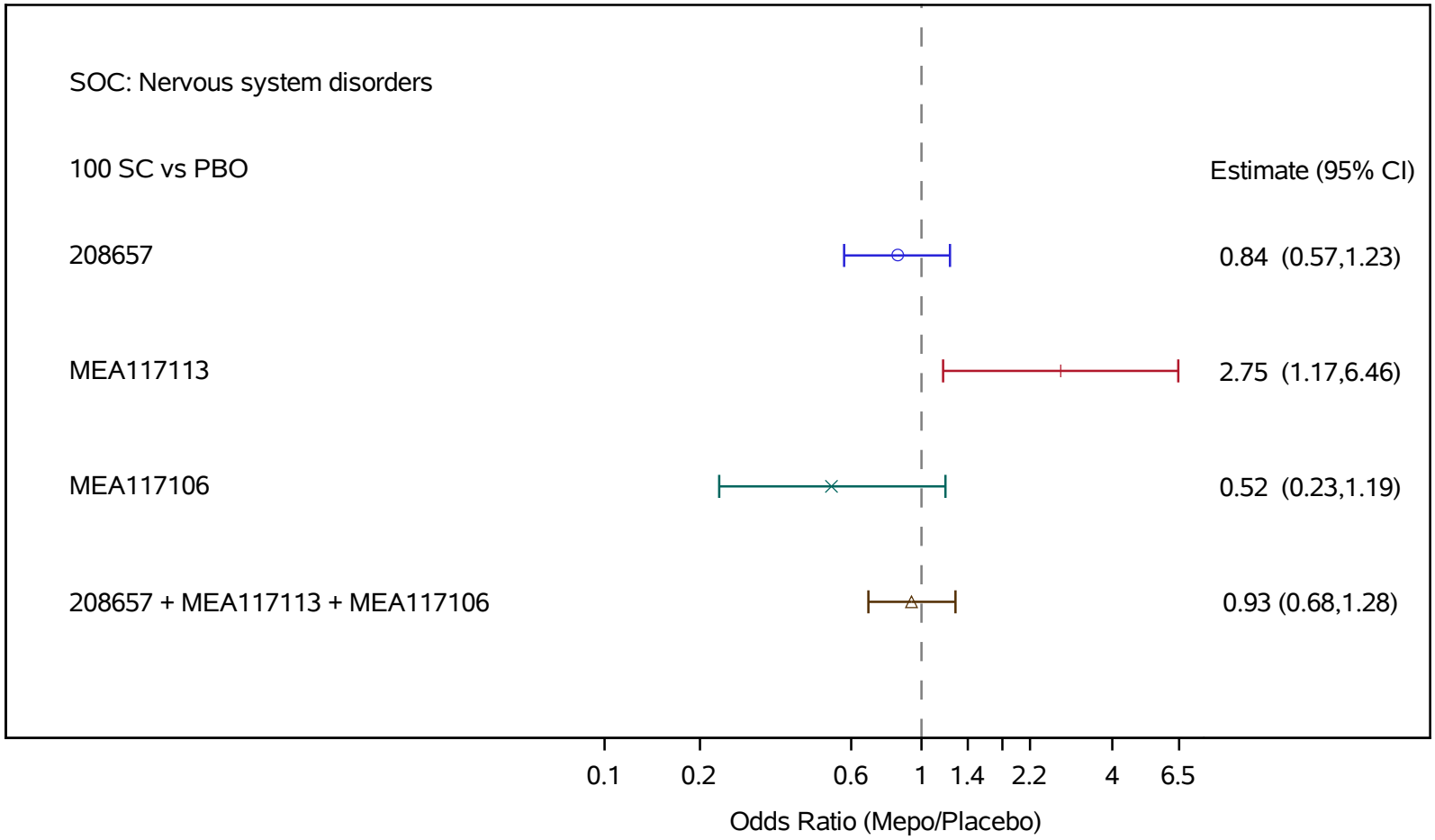

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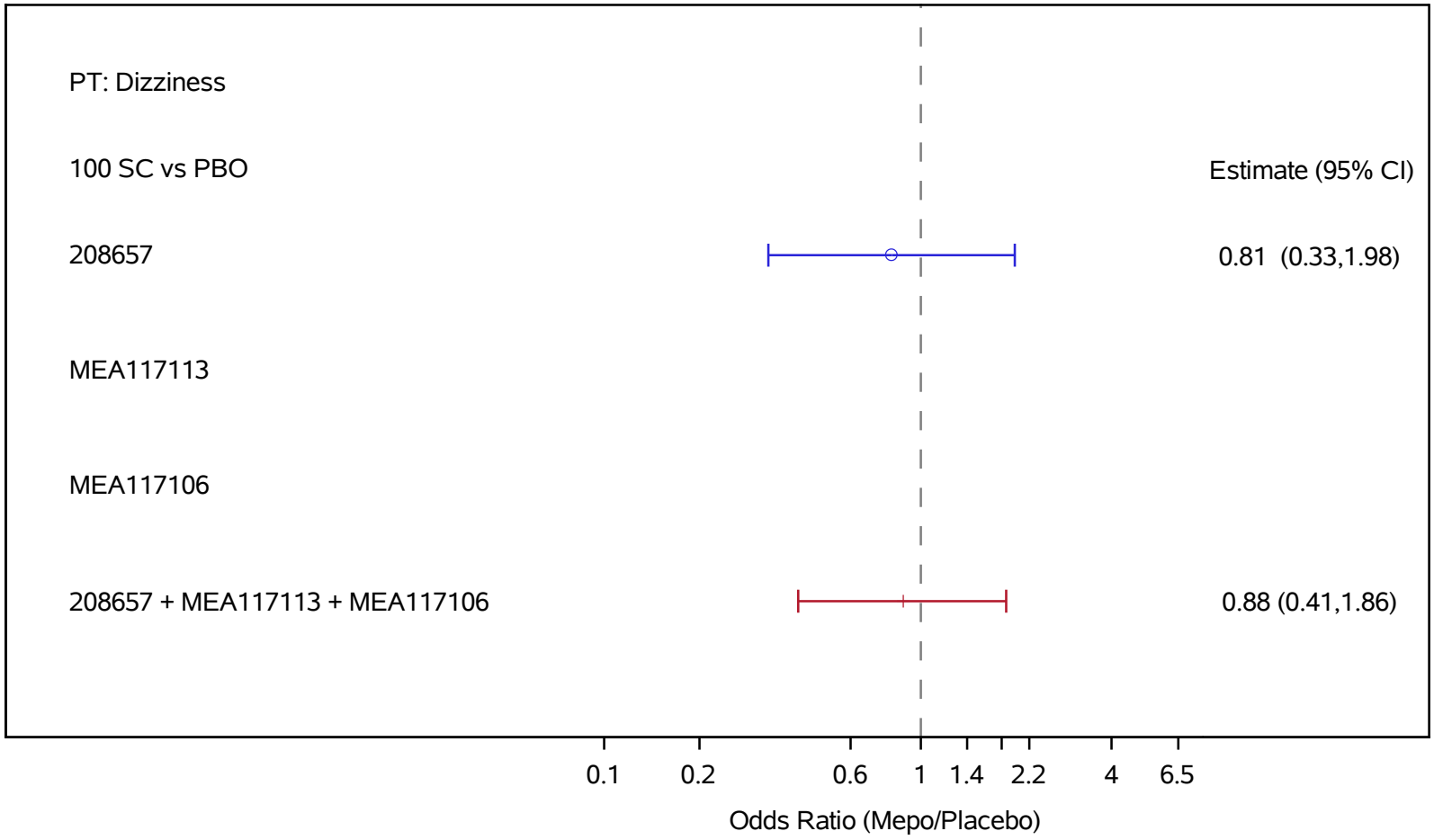

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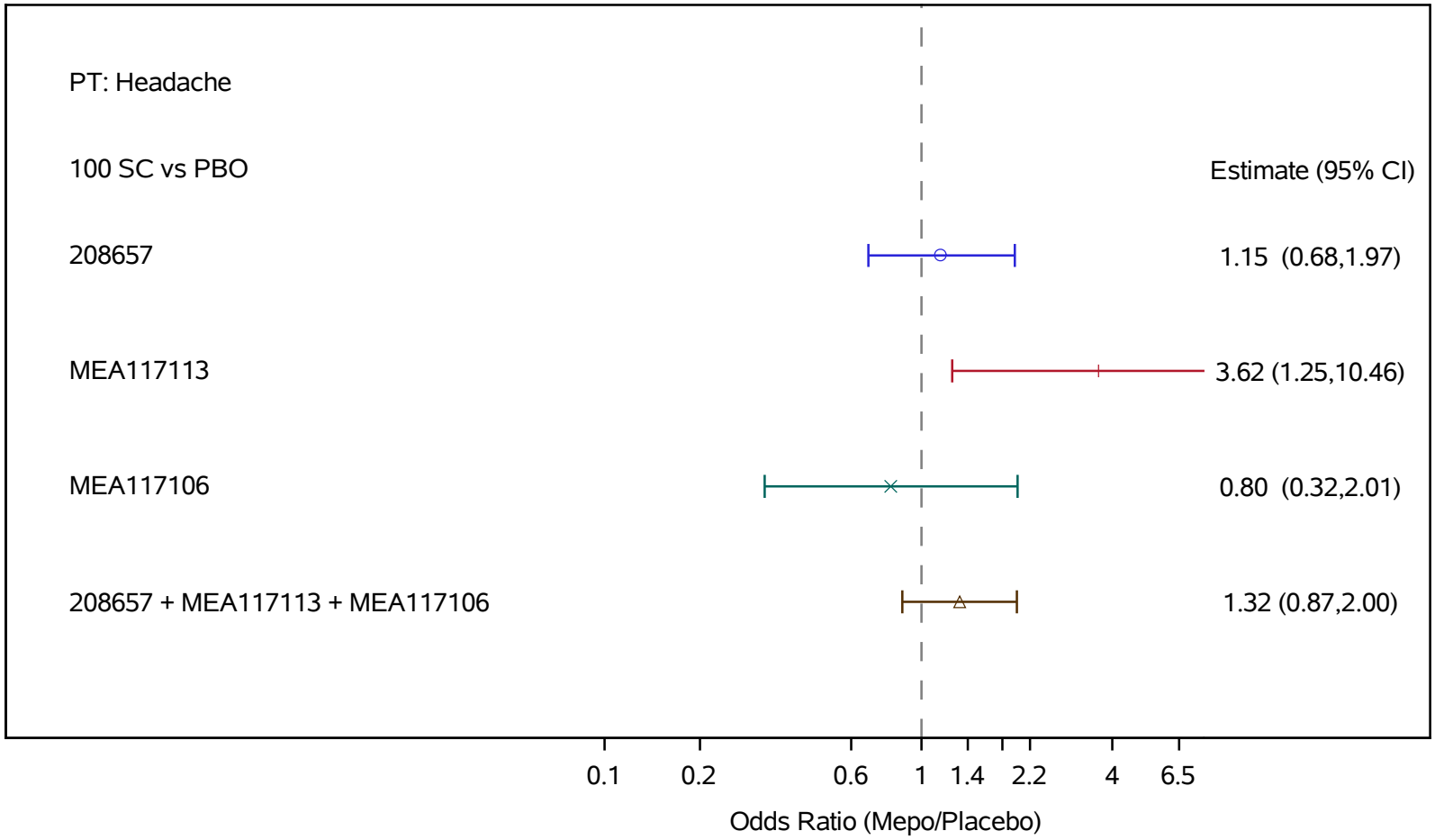

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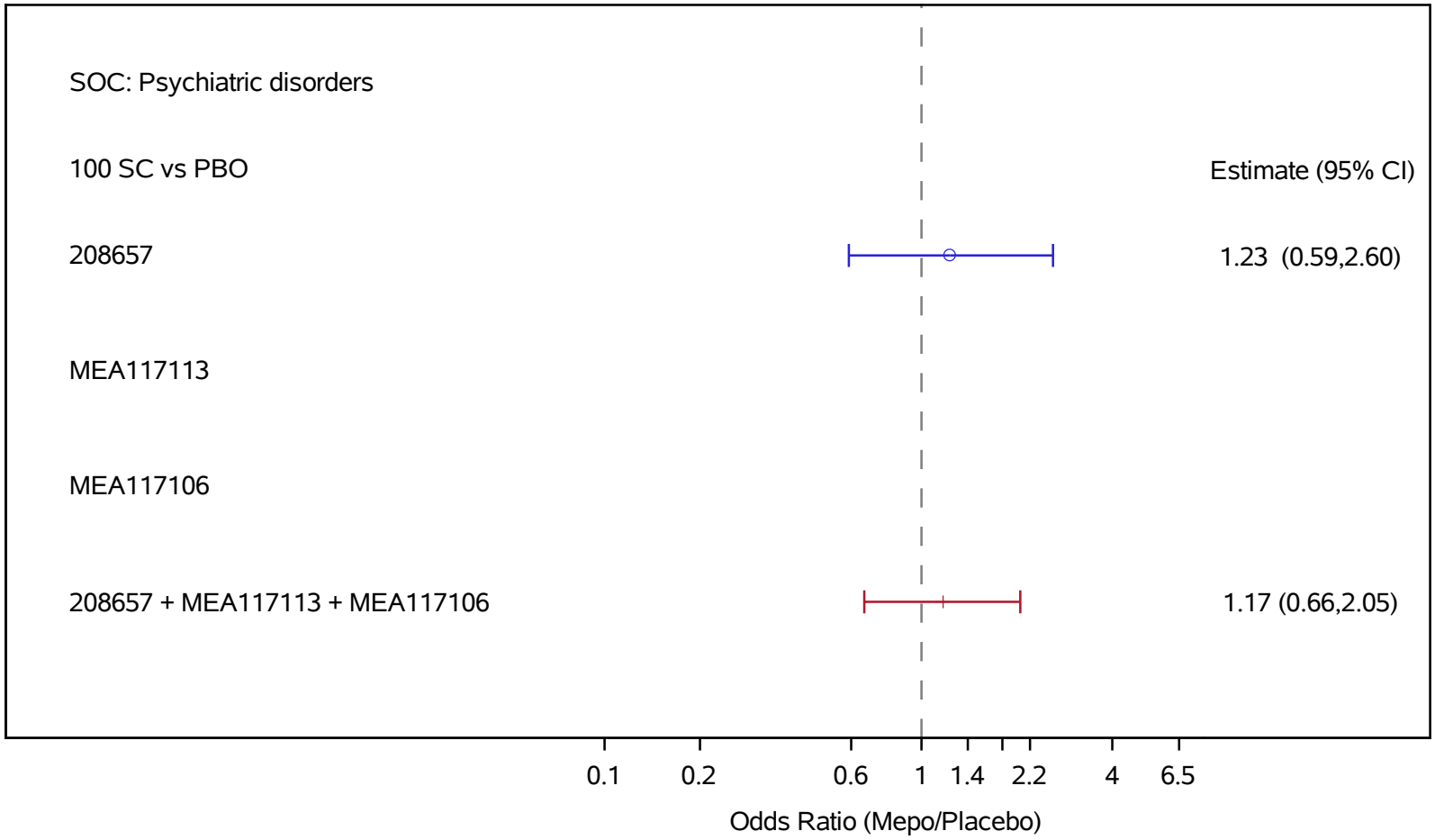

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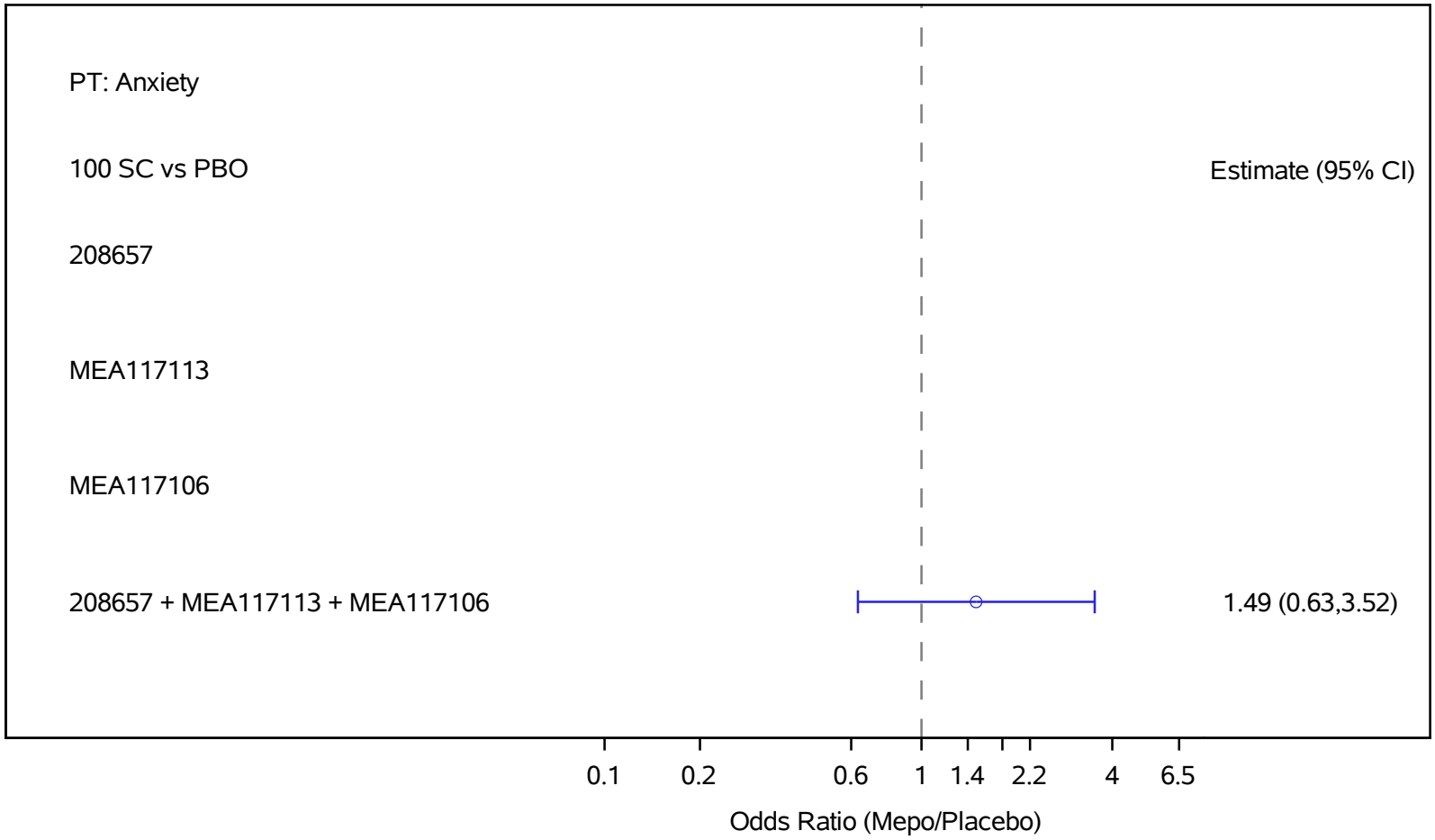

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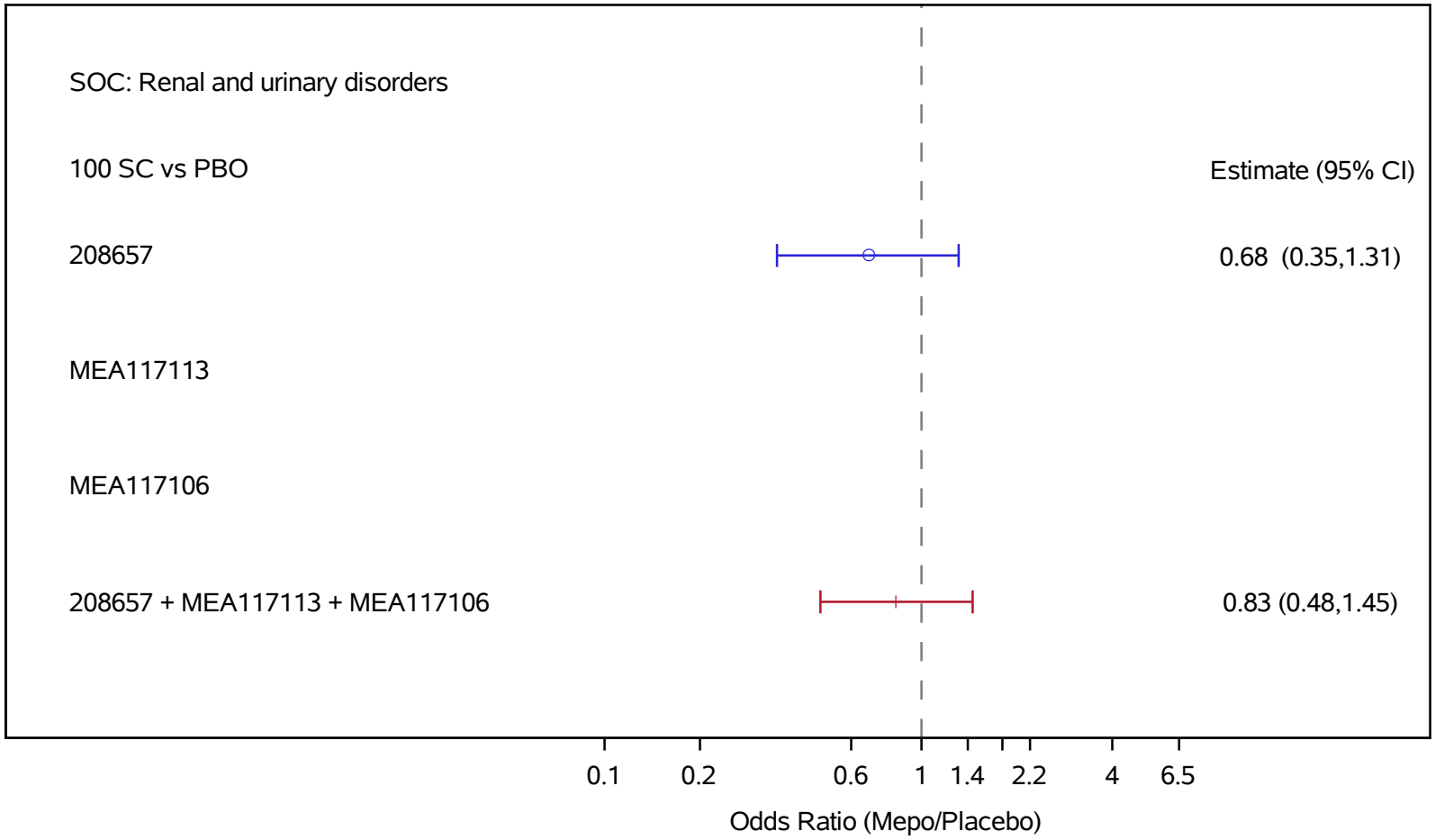

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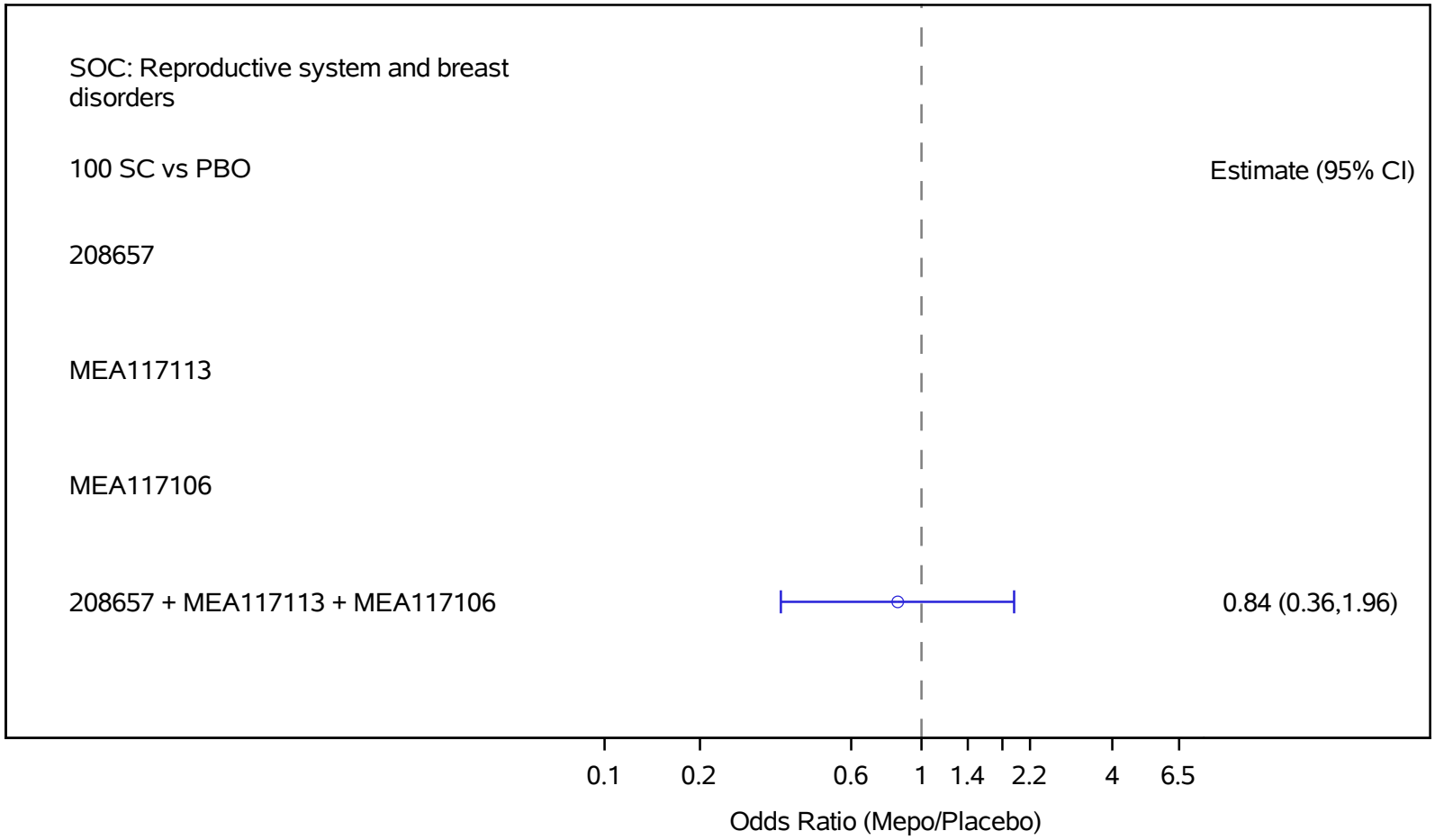

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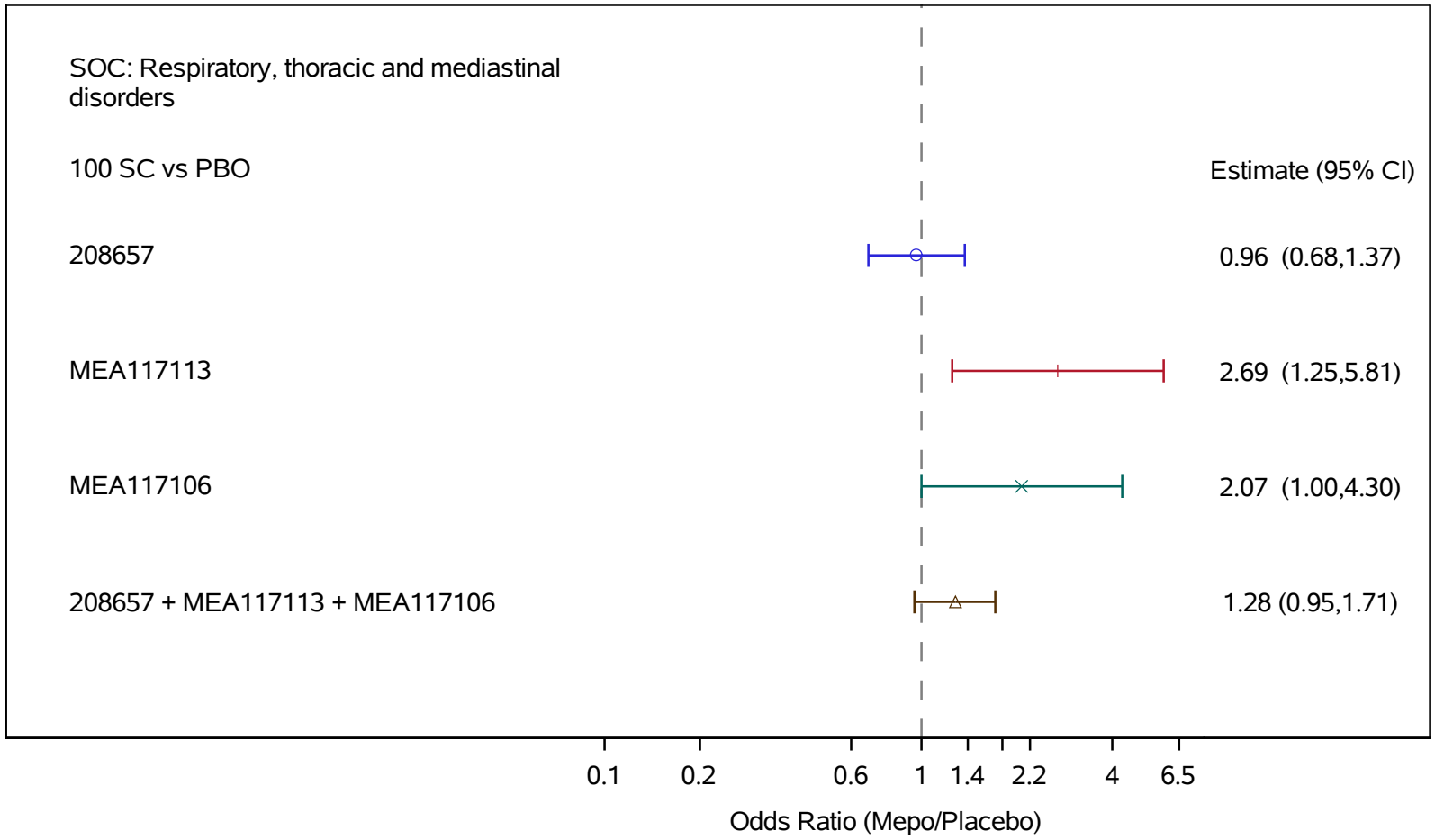

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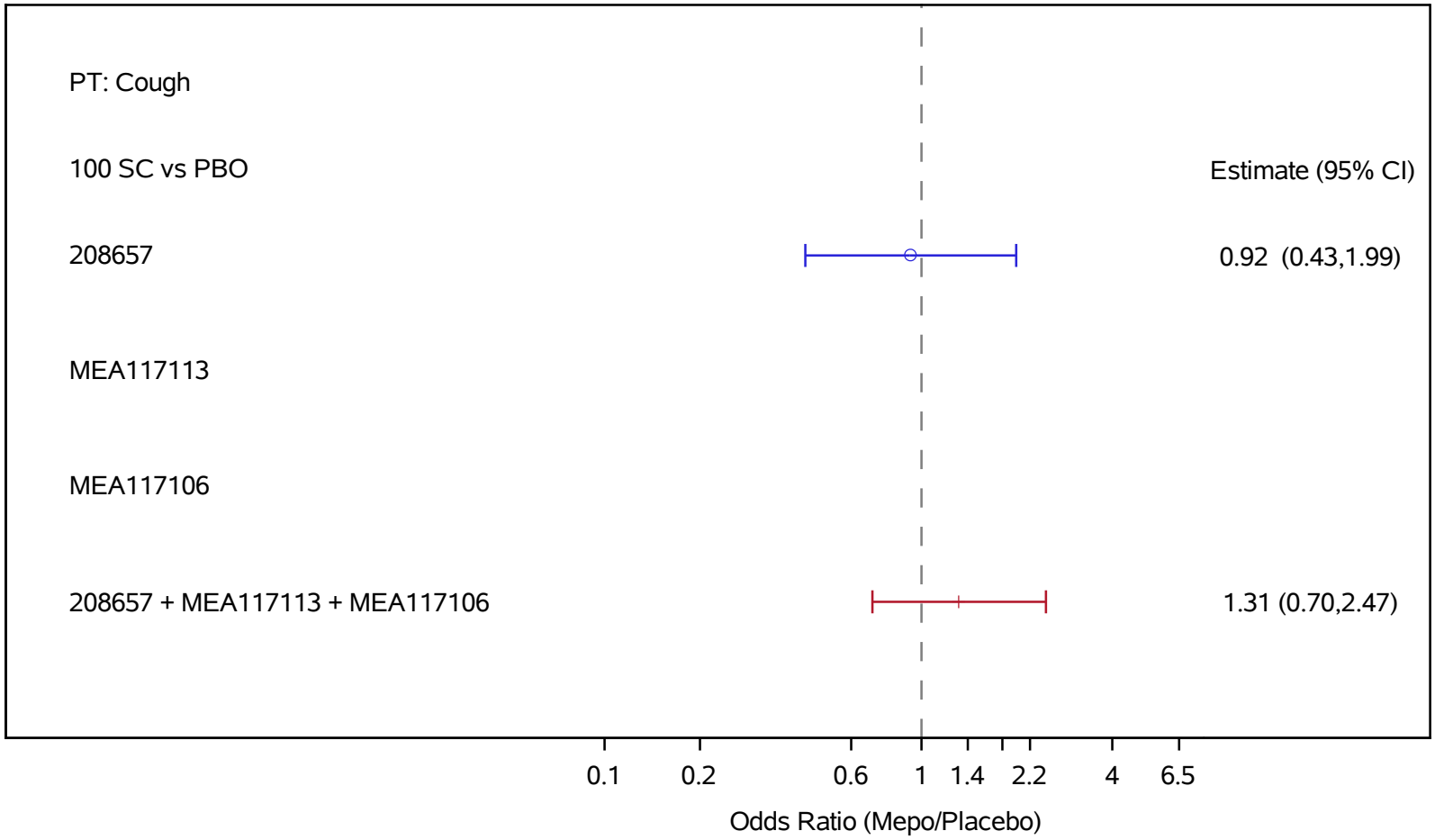

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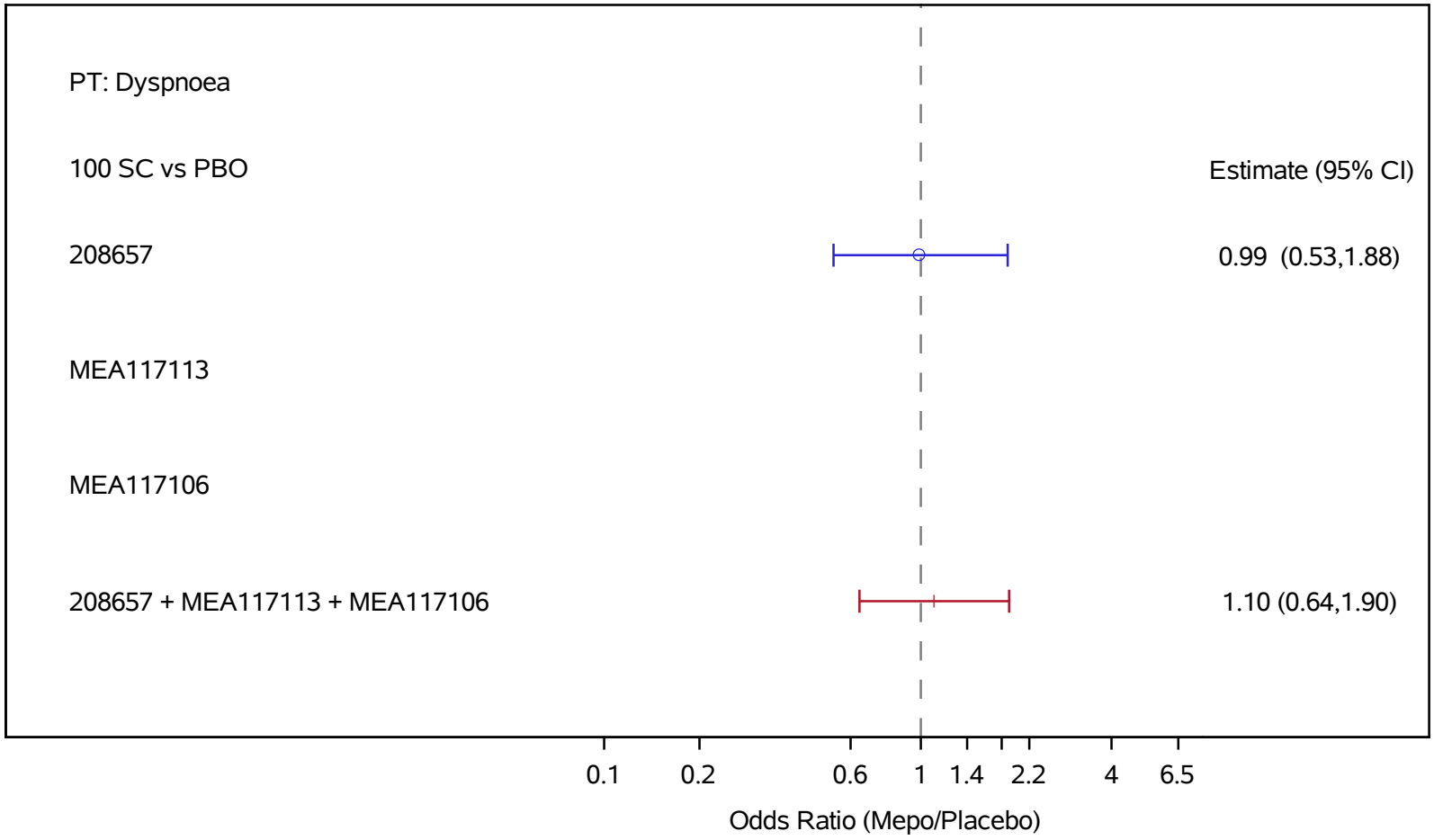

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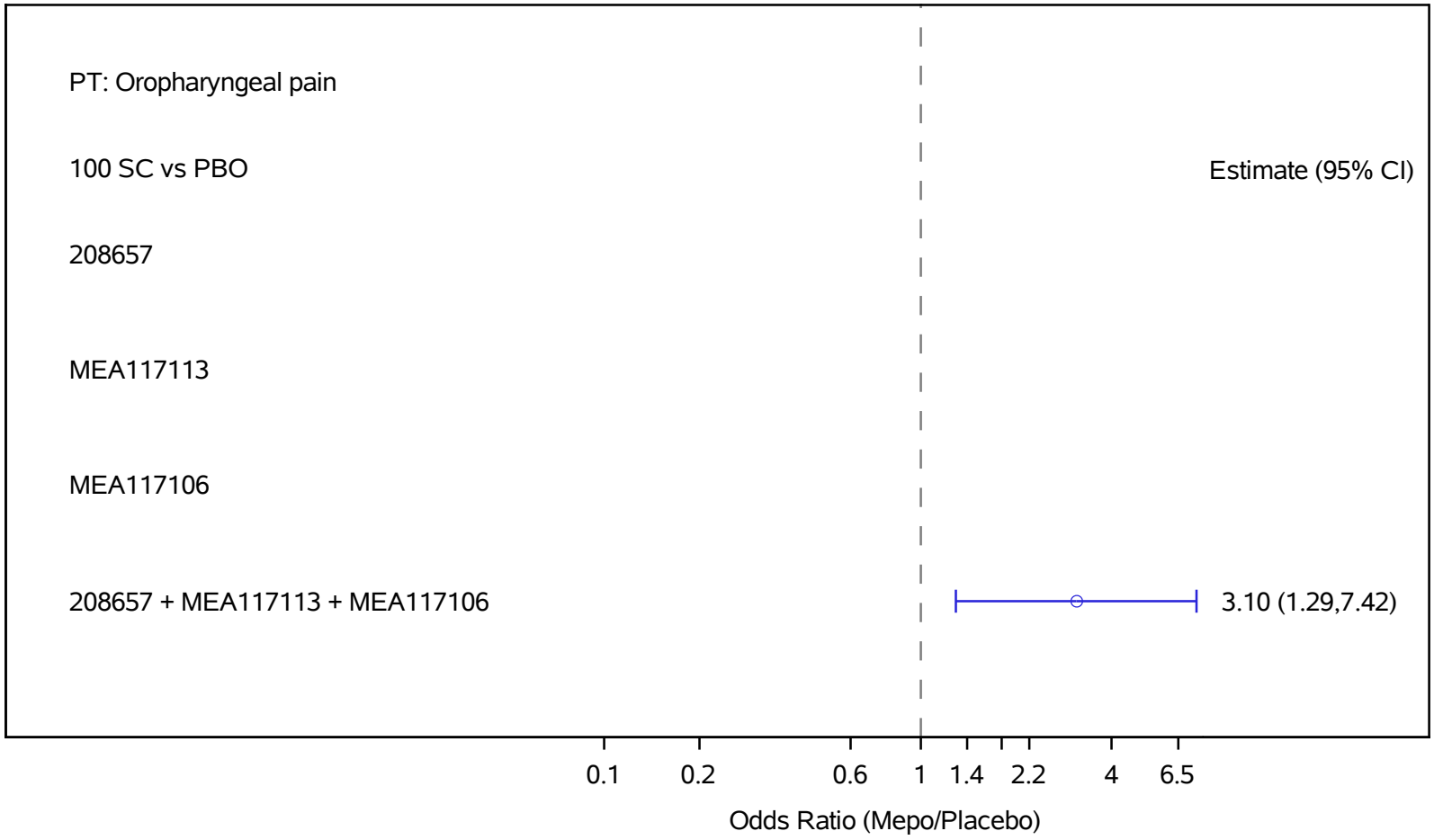

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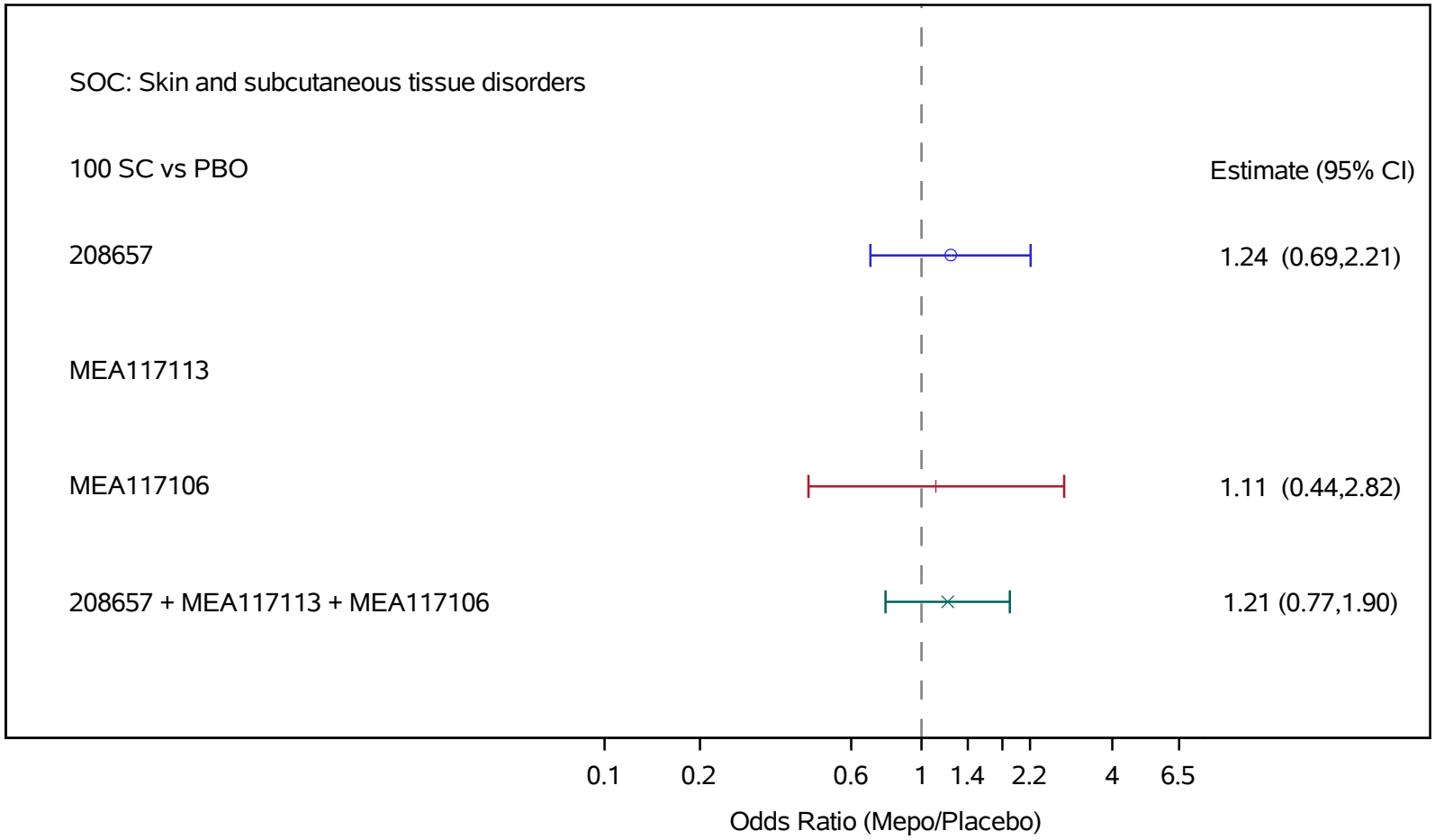

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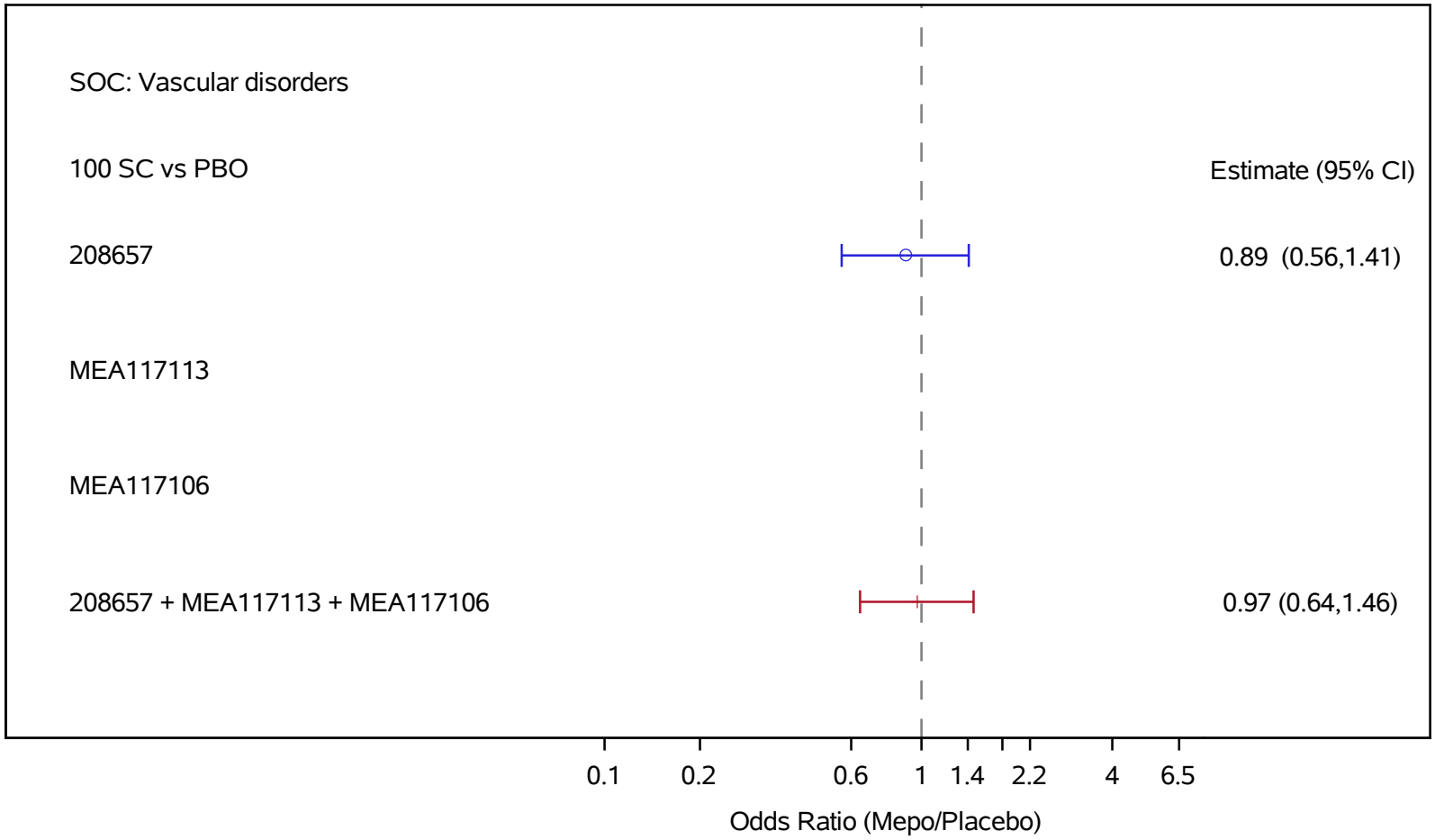

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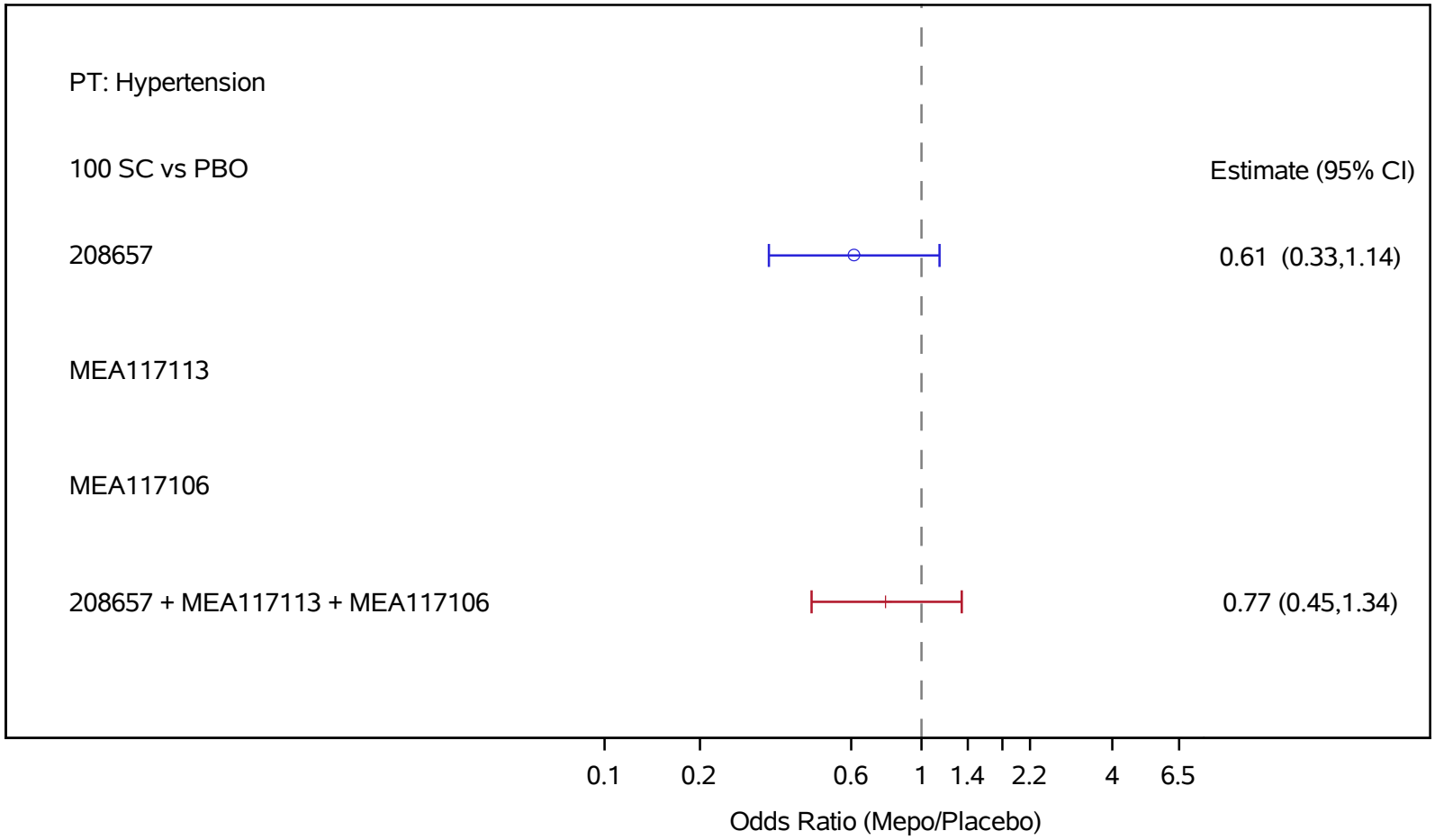

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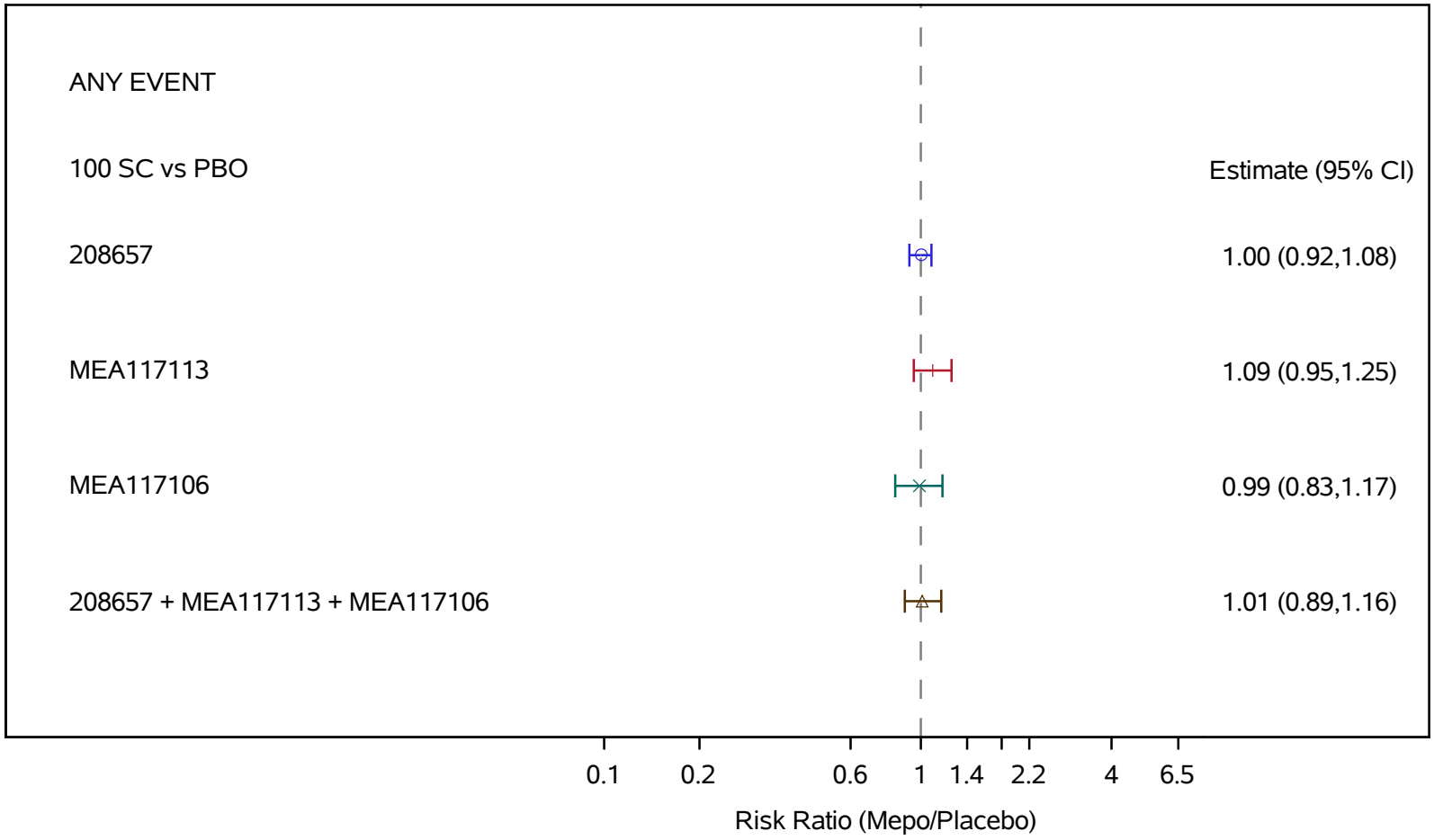

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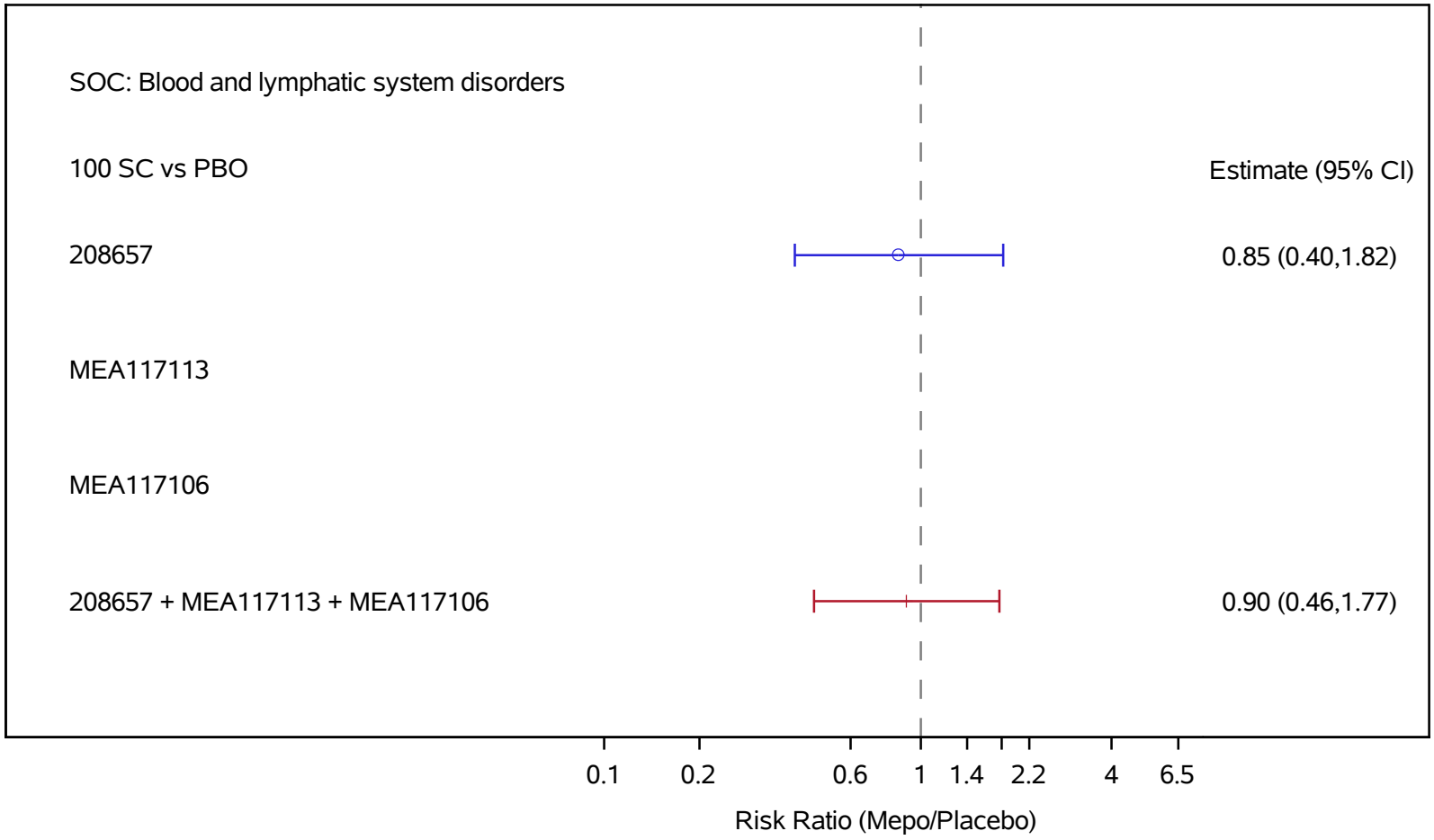

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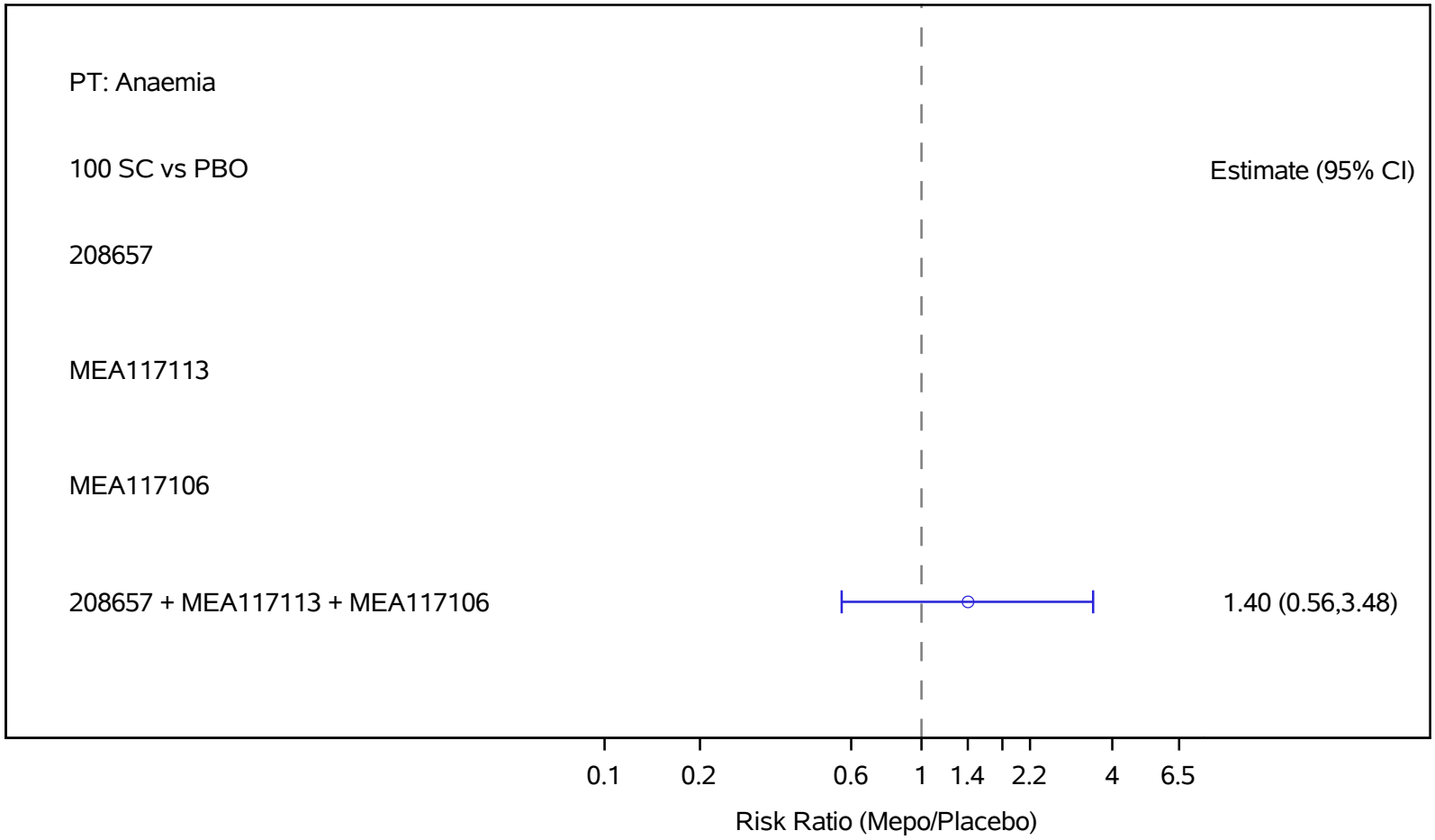

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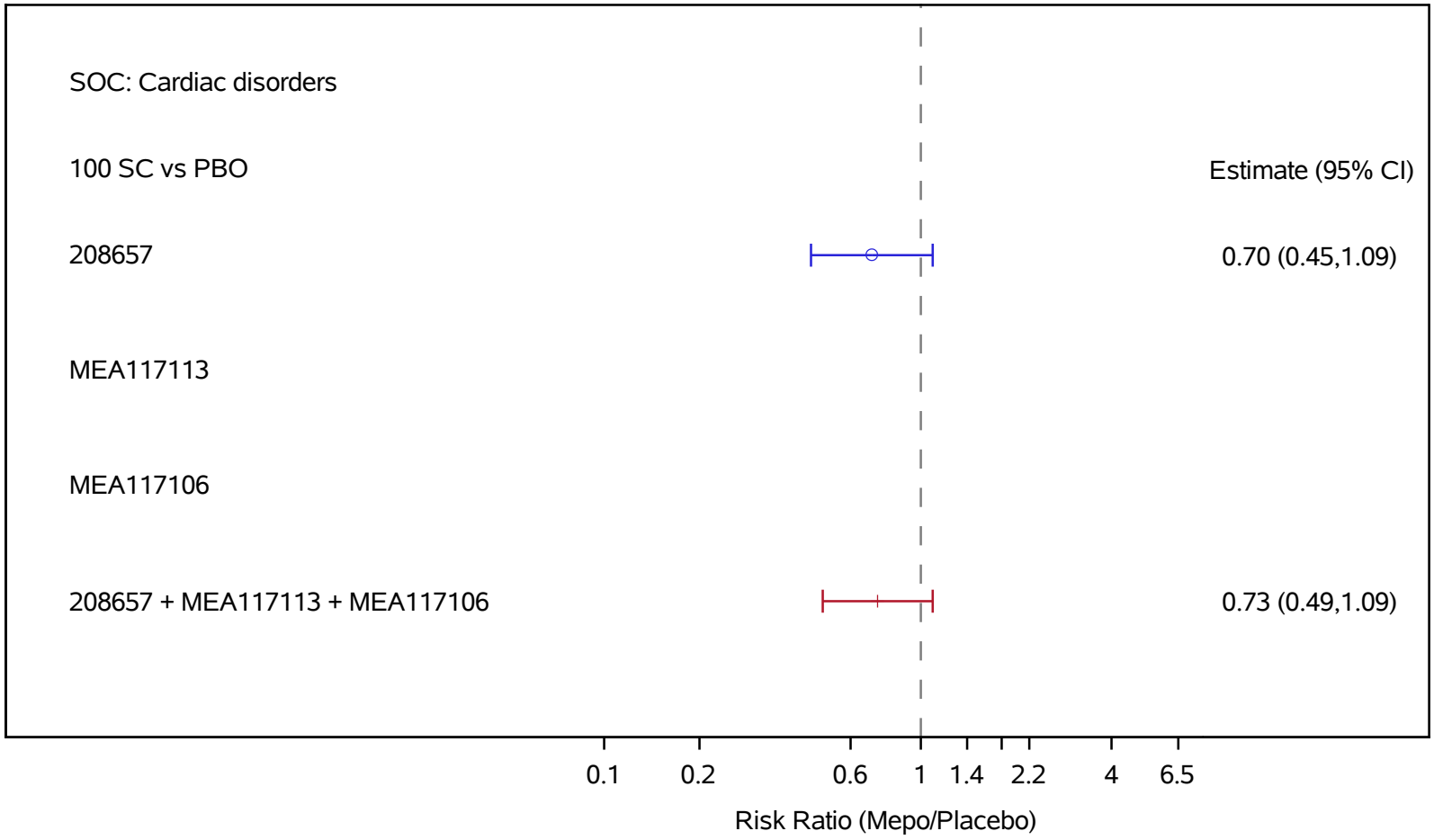

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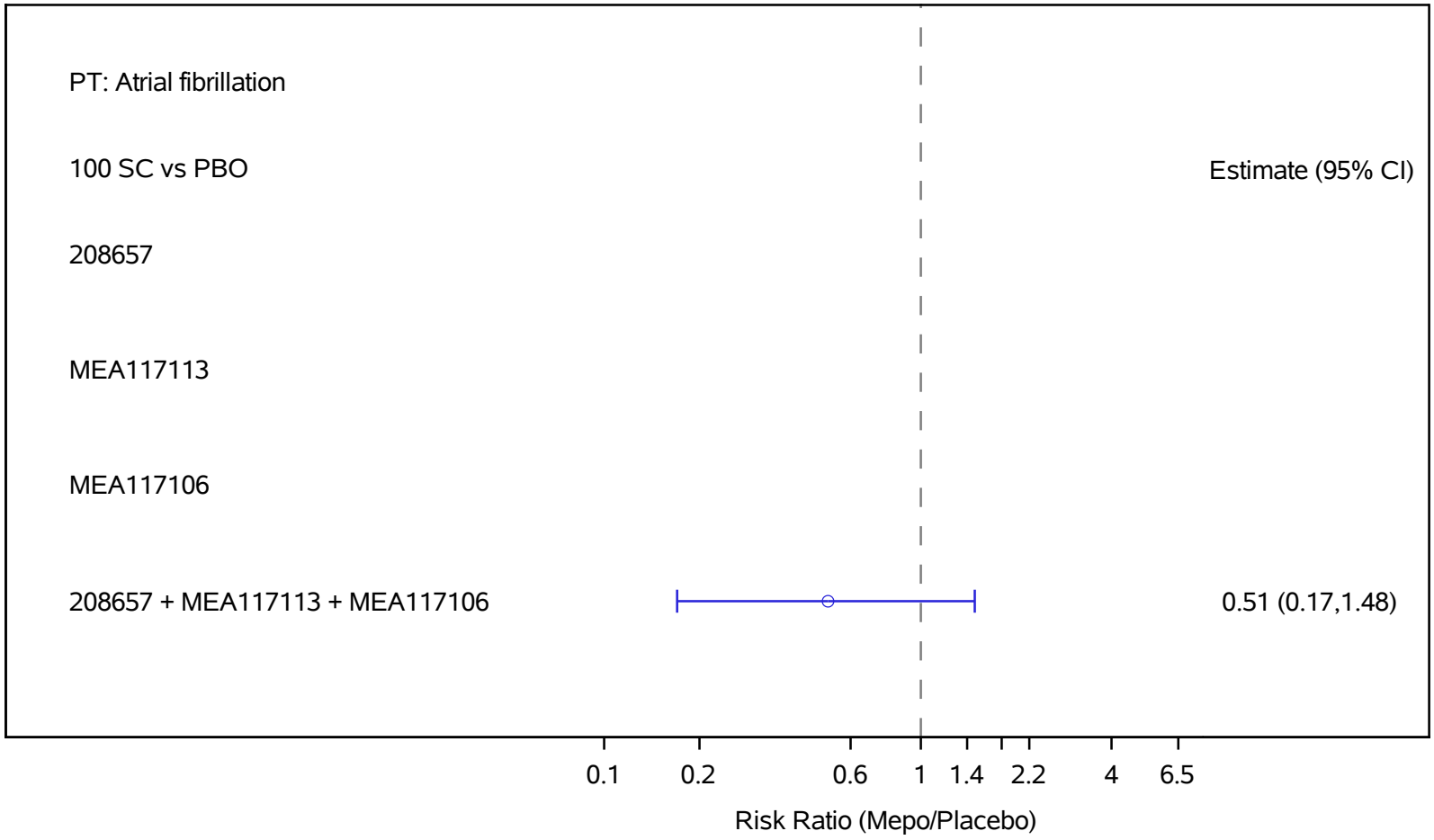

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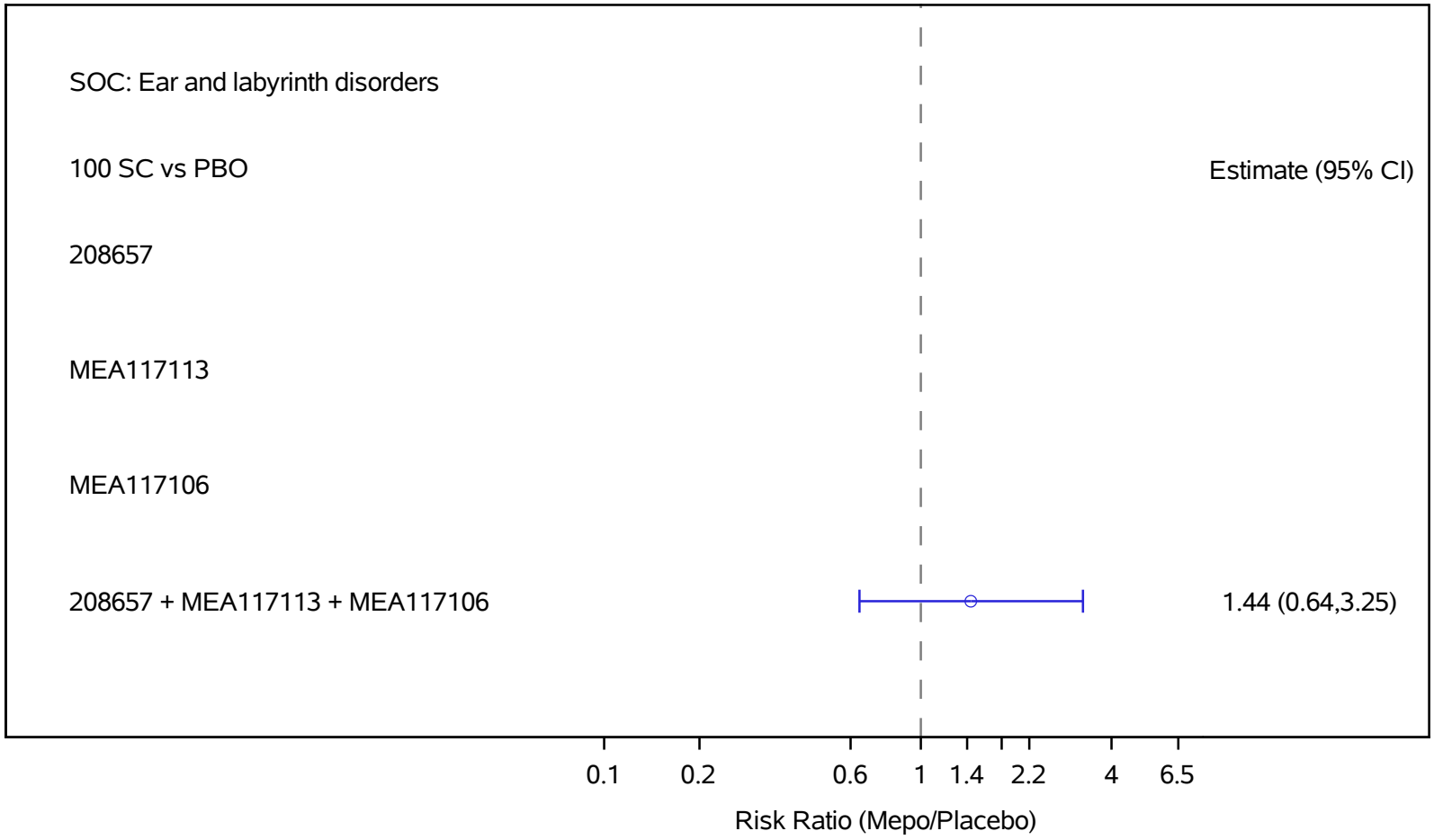

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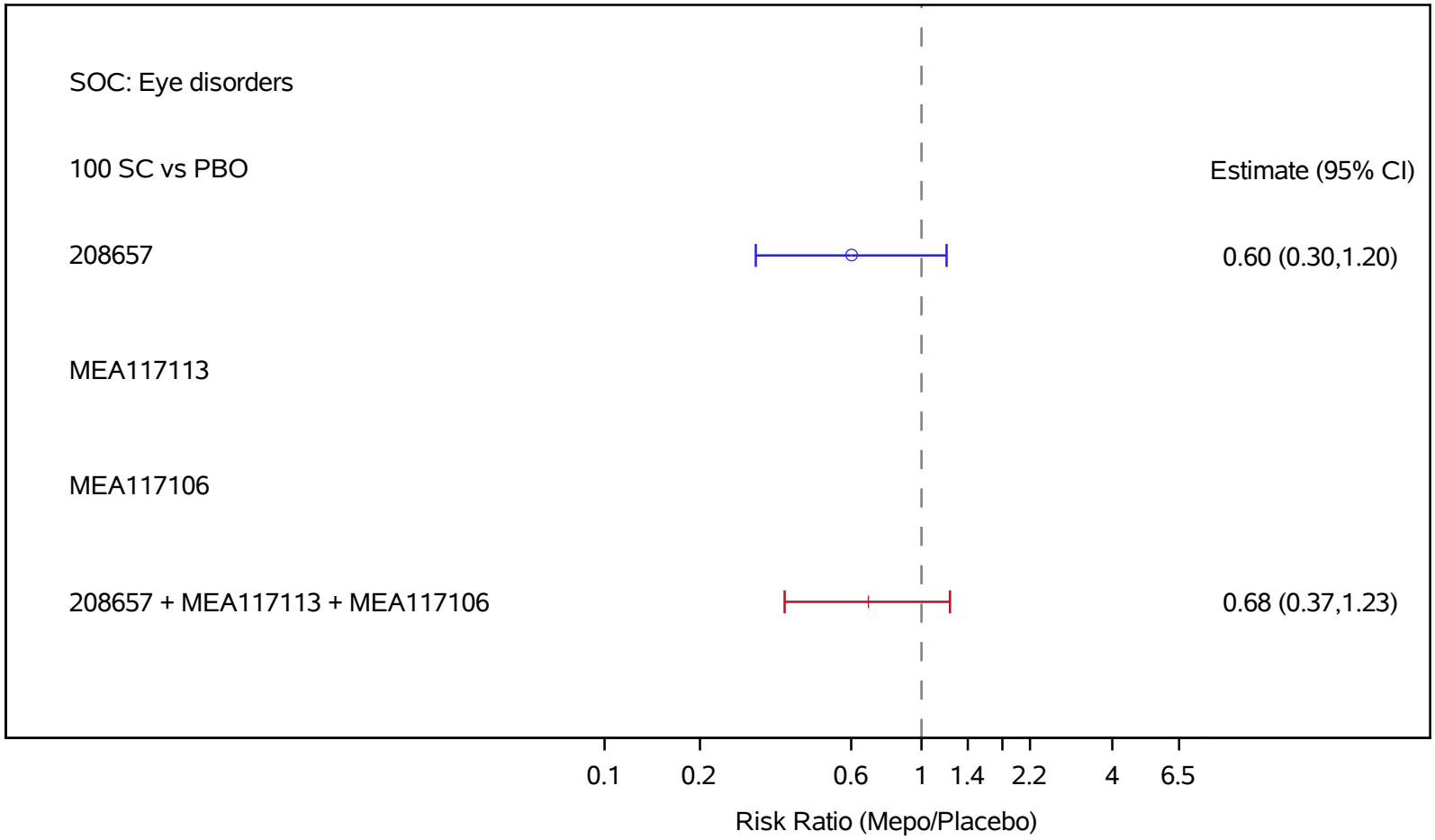

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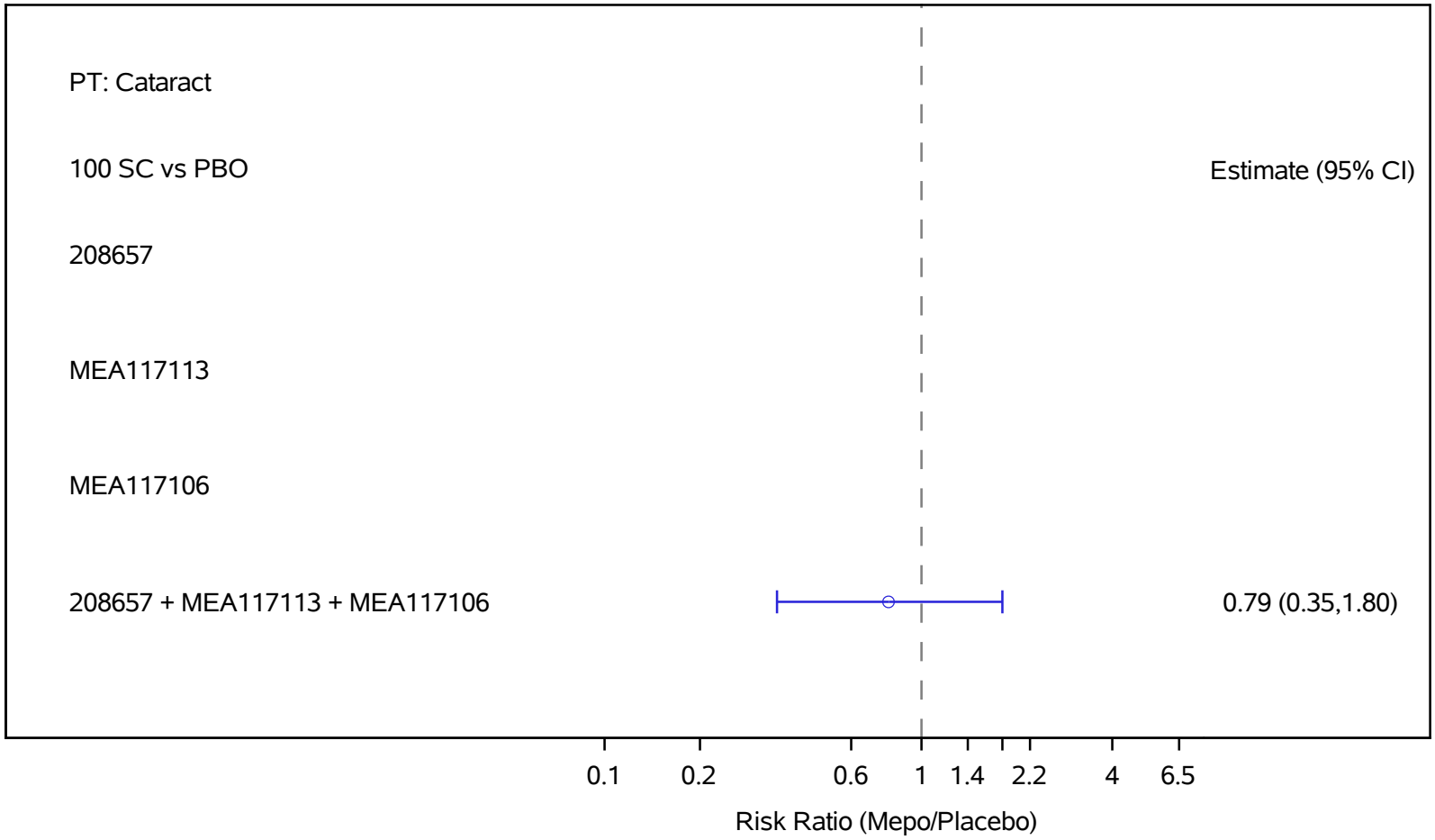

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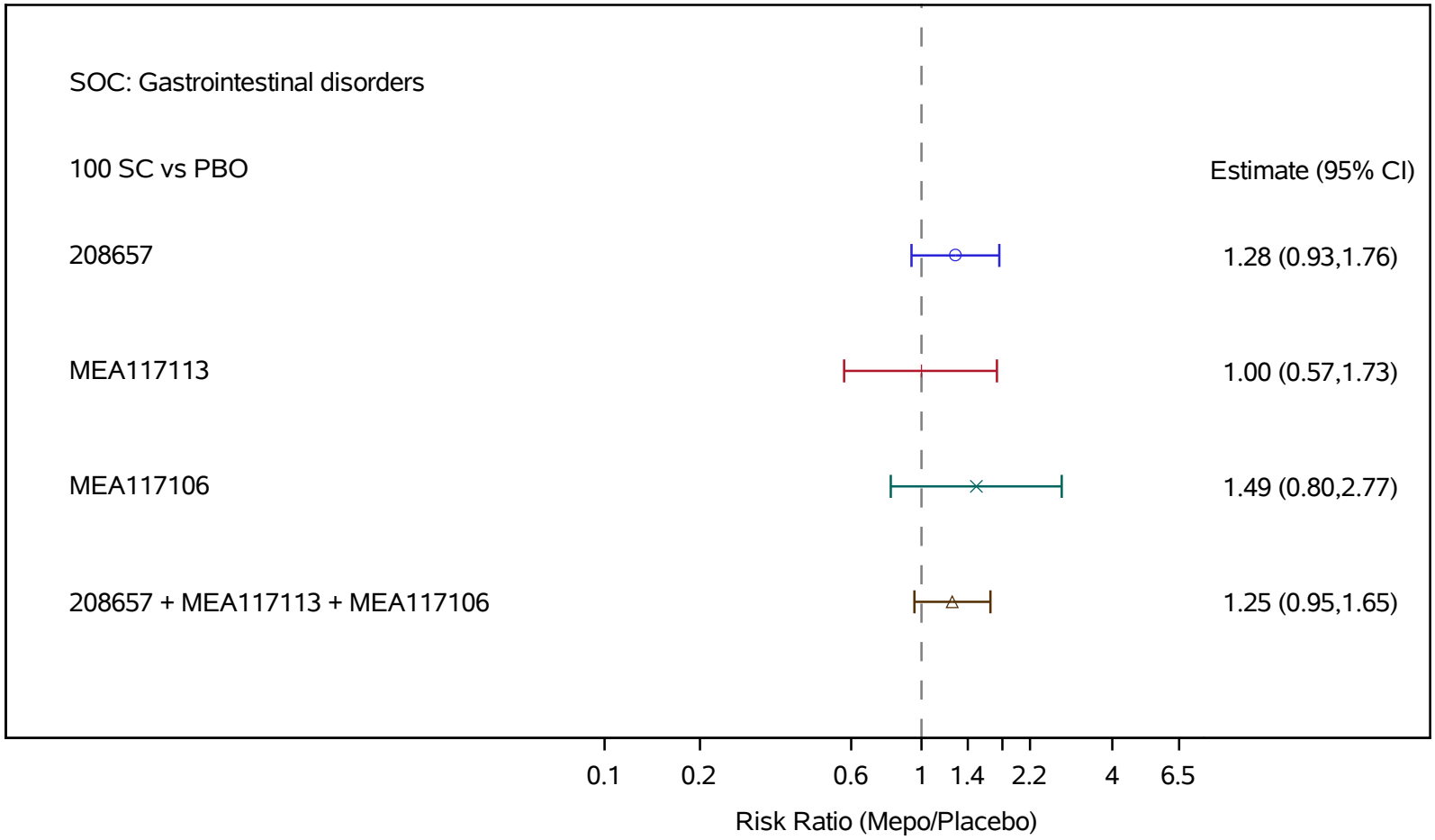

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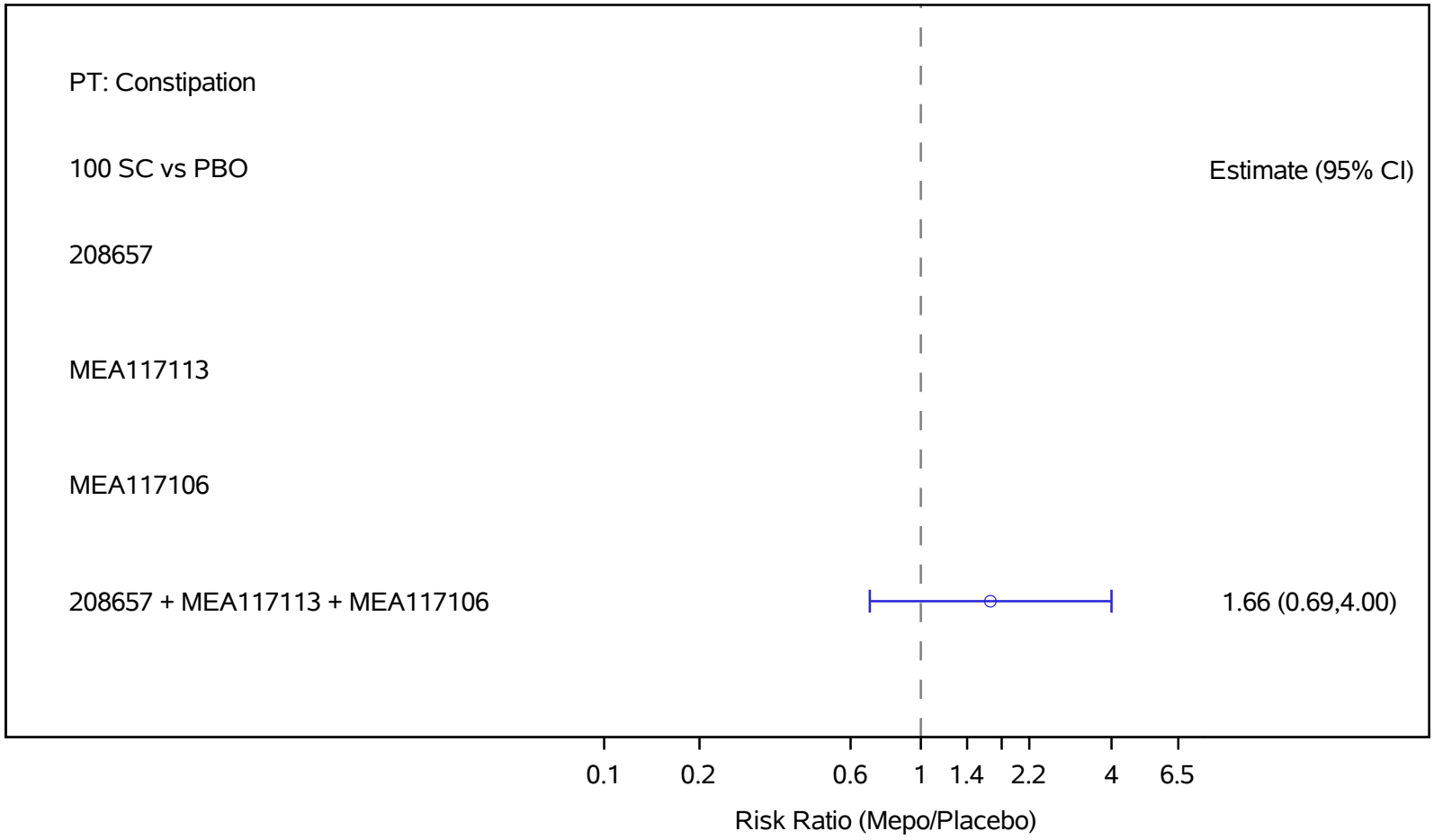

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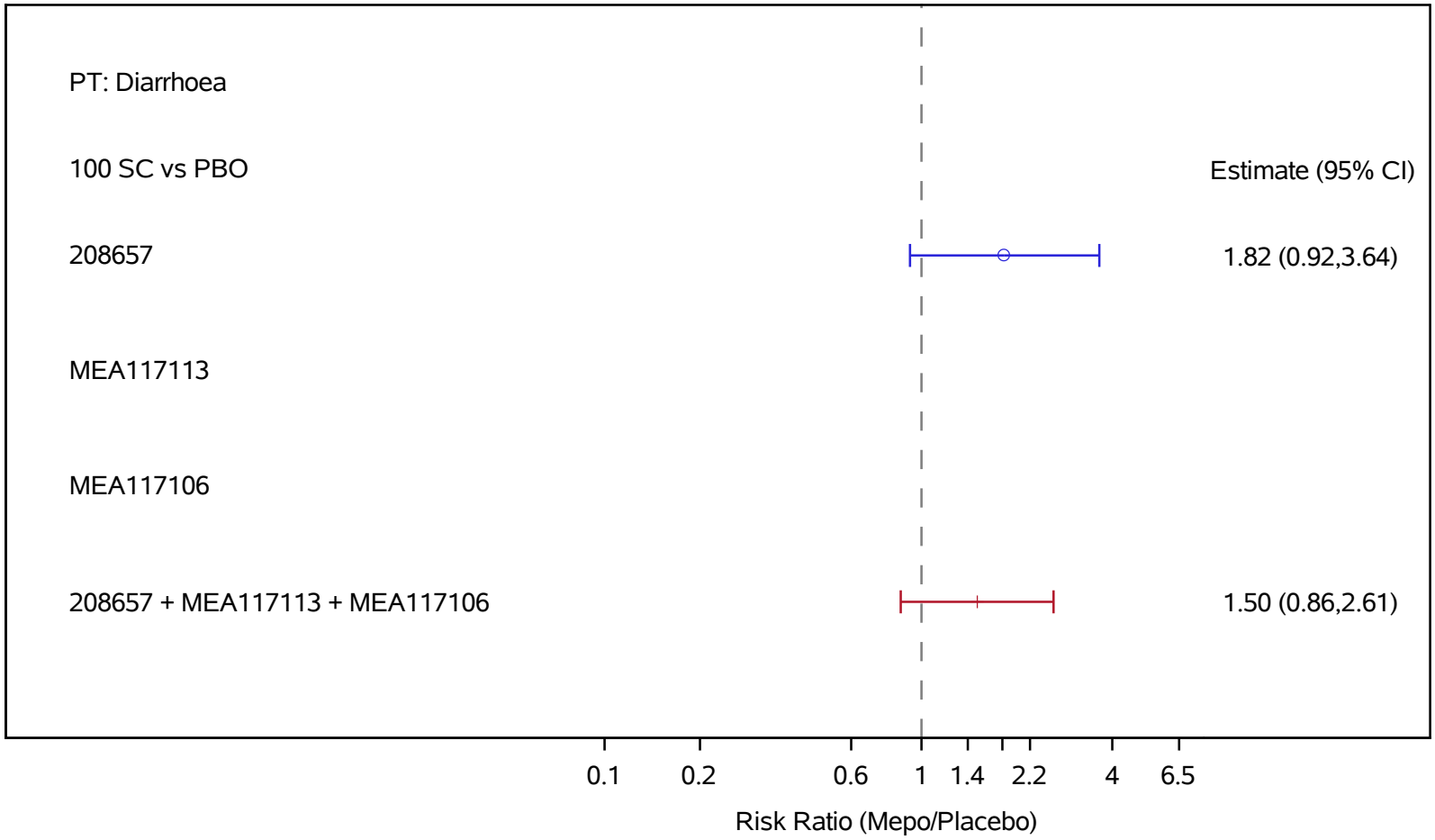

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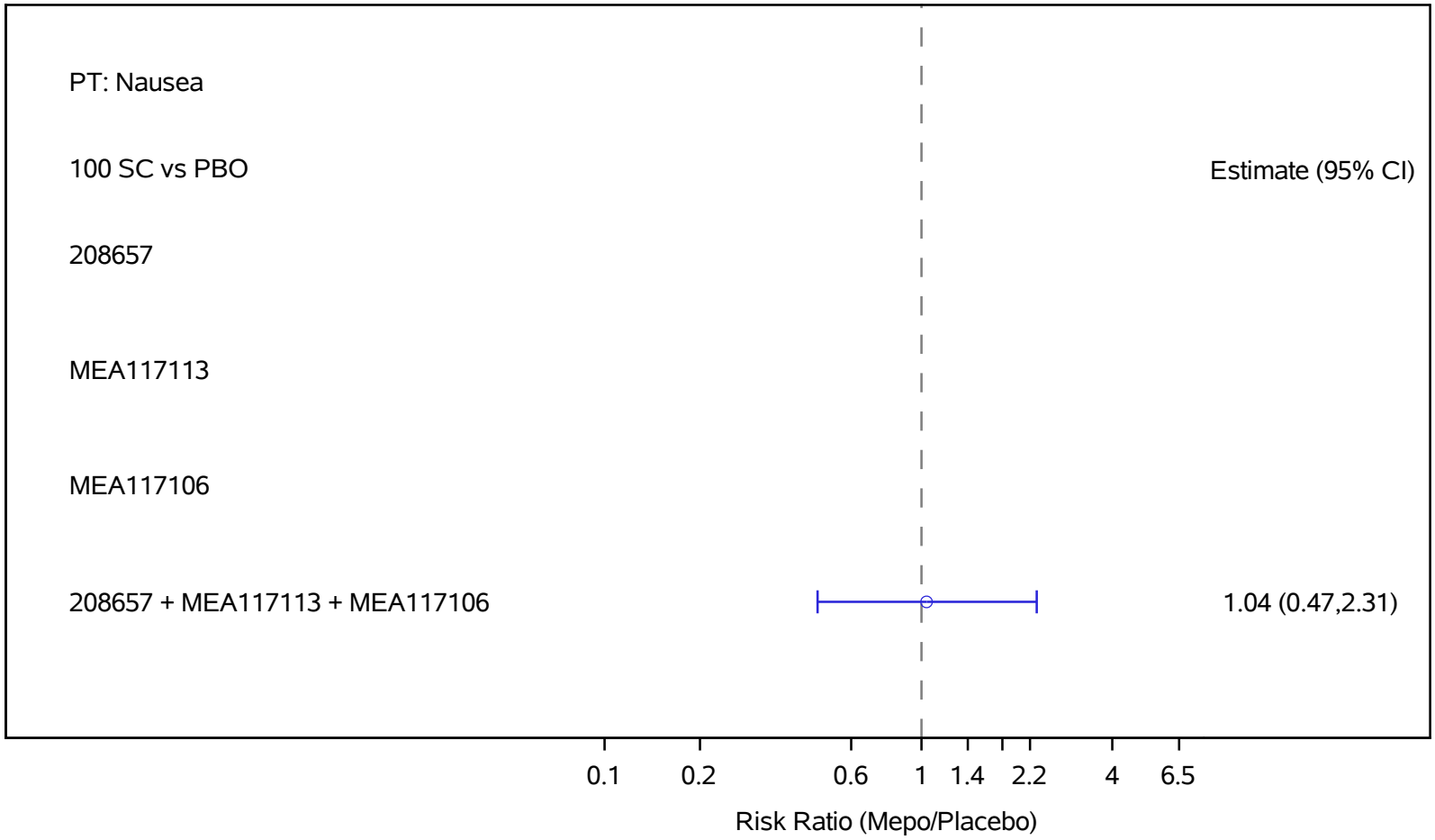

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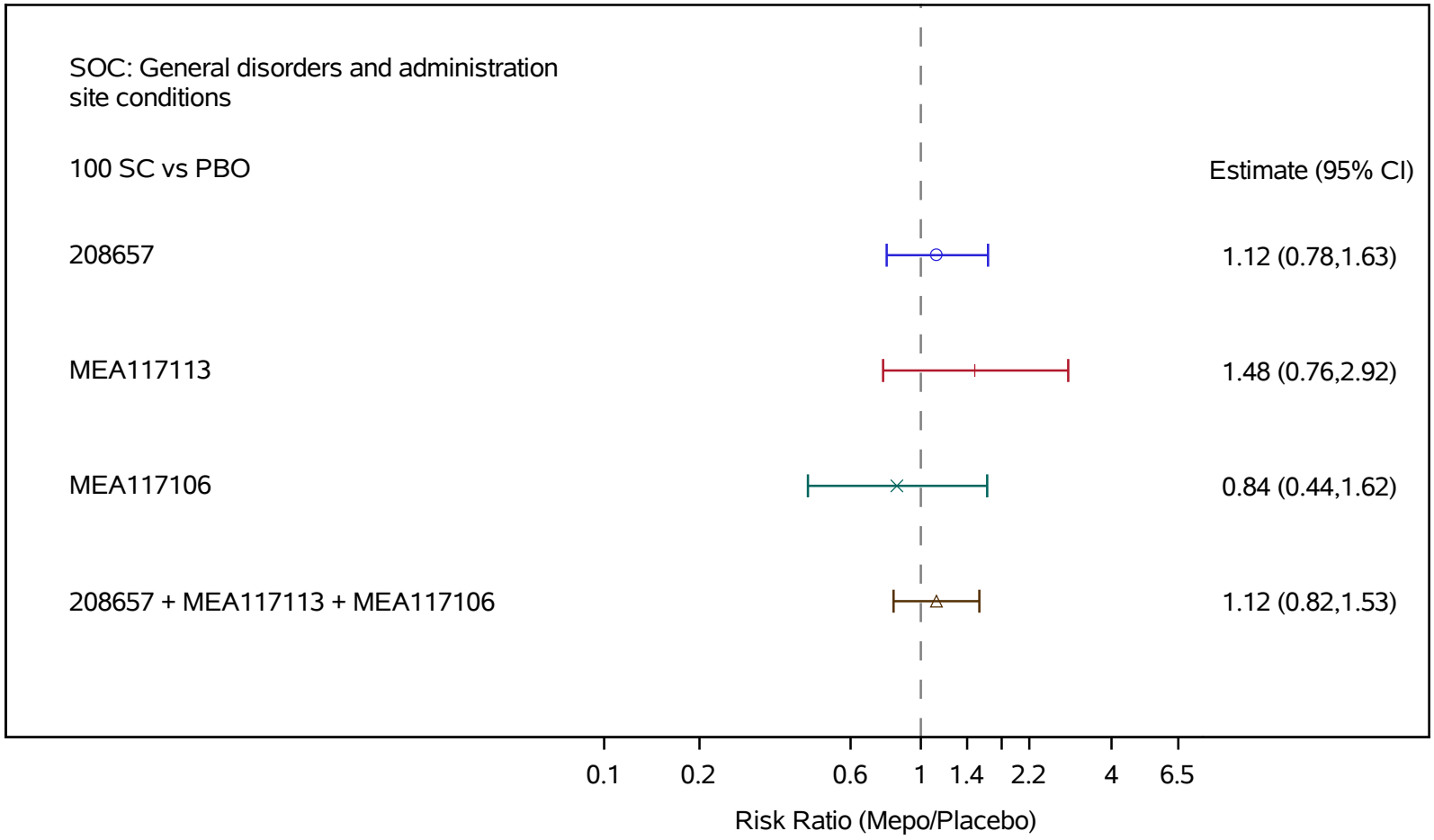

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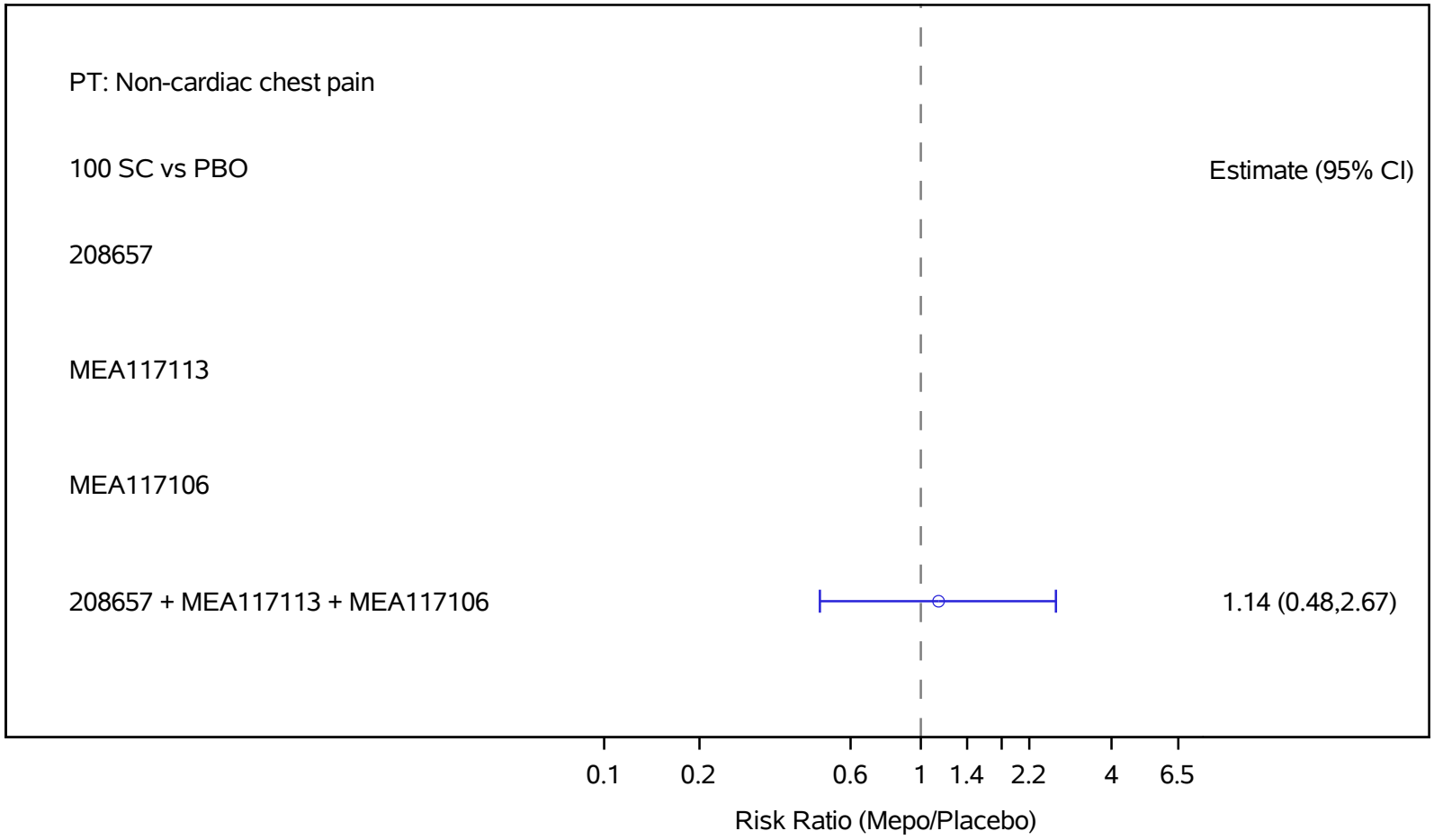

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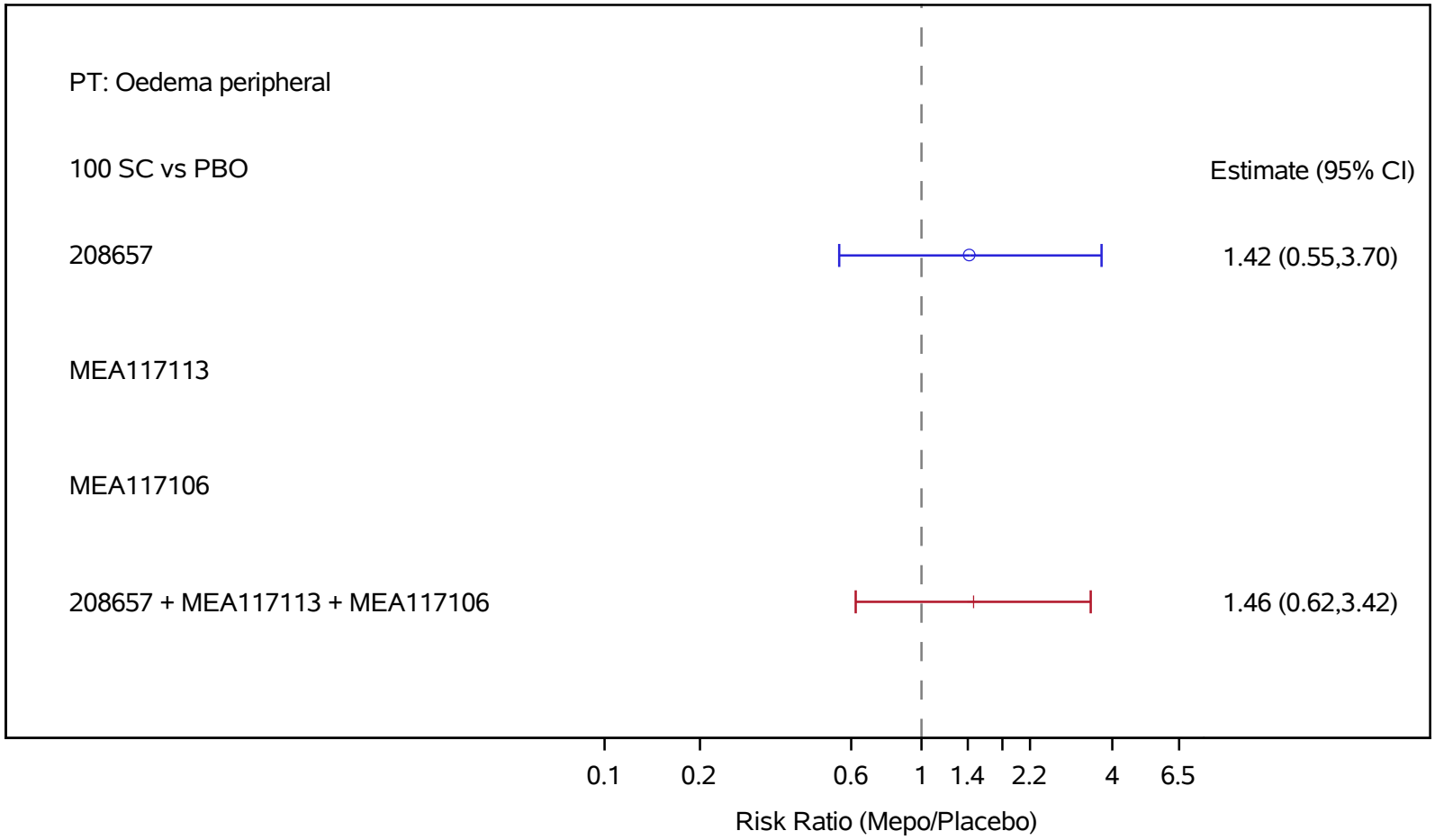

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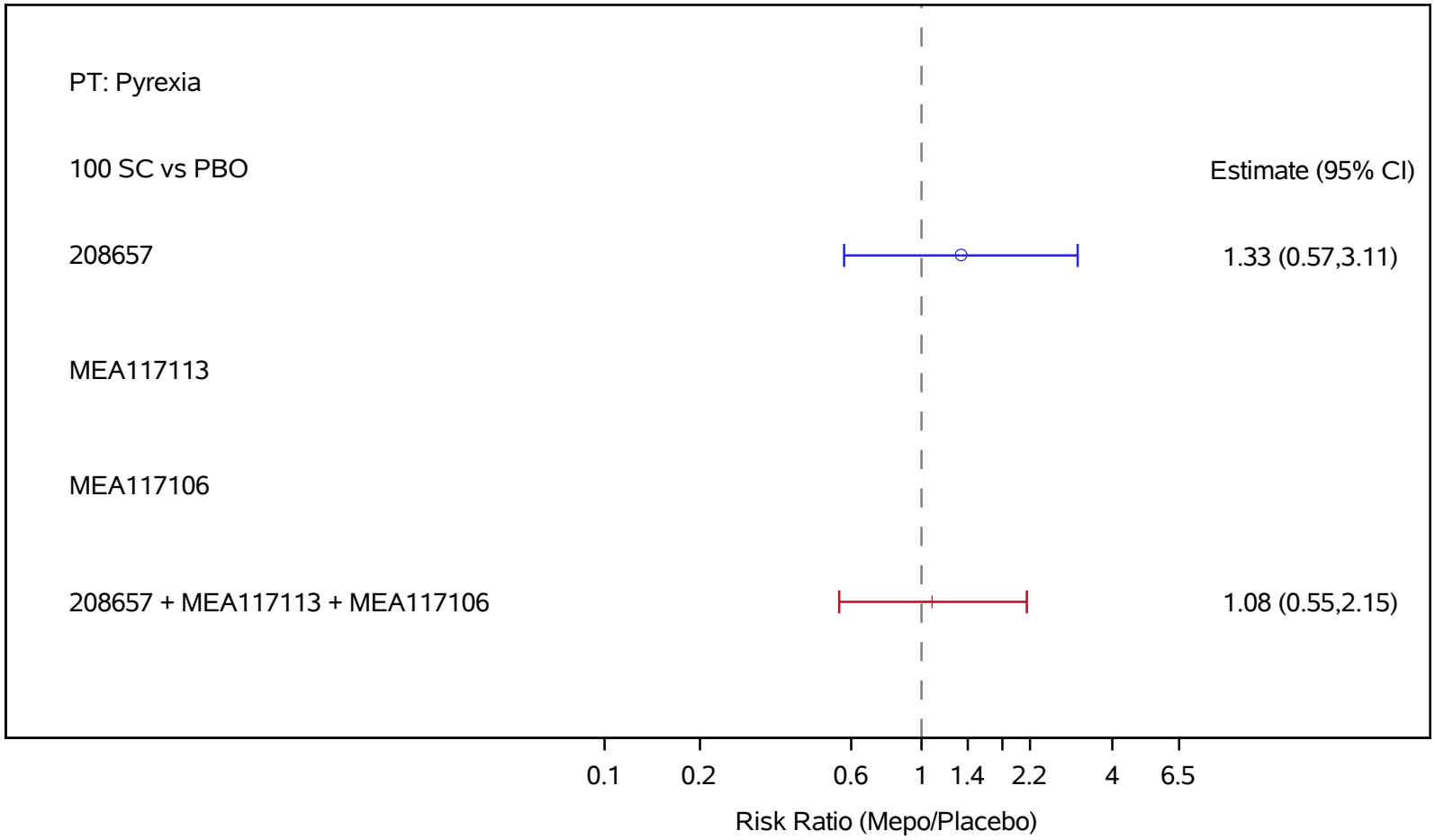

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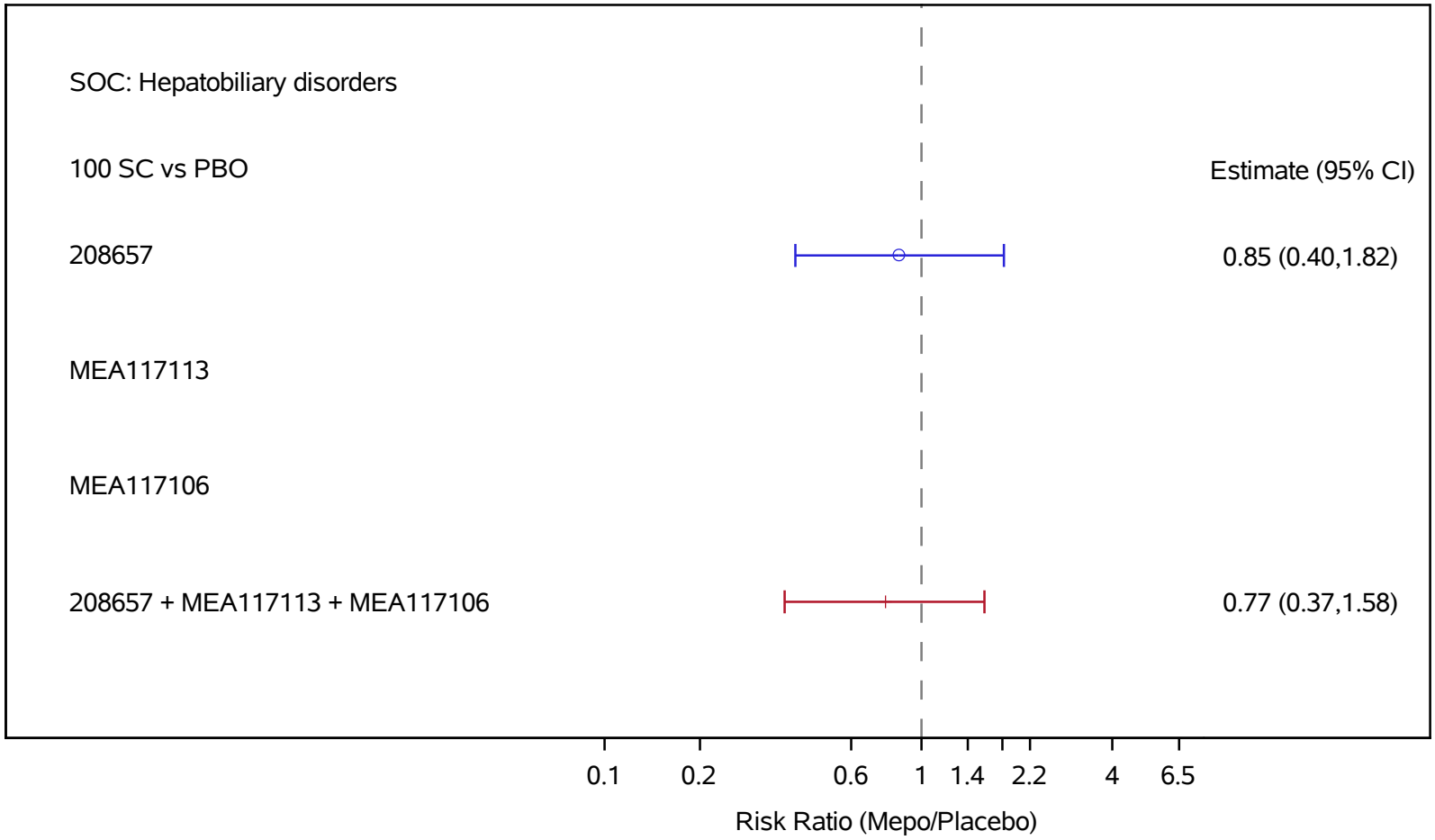
Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Figure 311.4

Forest Plot of Relative Risk for On-Treatment Adverse Events without Disease-Related Events Occurring in >=10% of patients or in >=10 and >=1% of patients by SOC and PT: Individual Studies and Meta-Analysis



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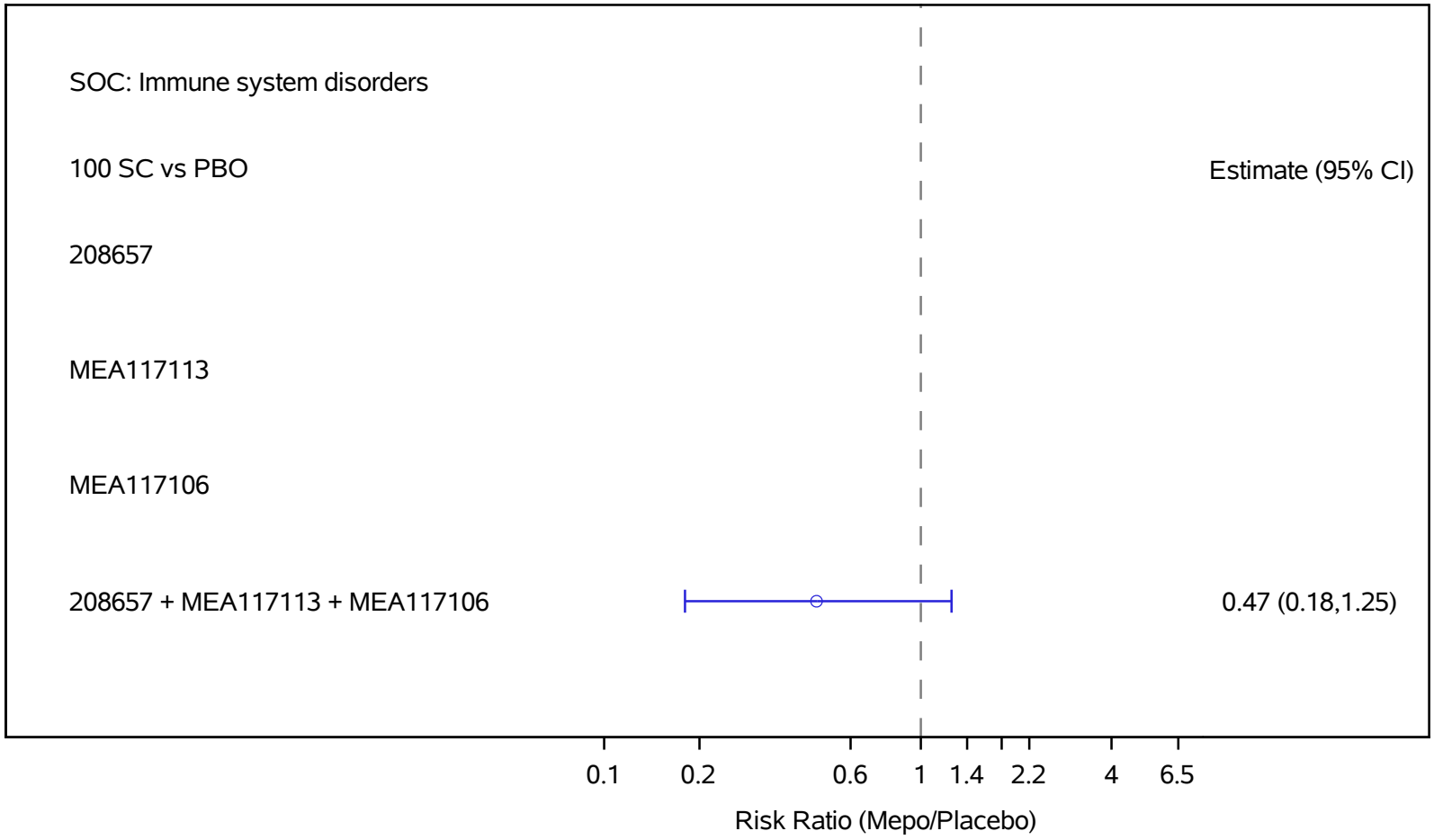

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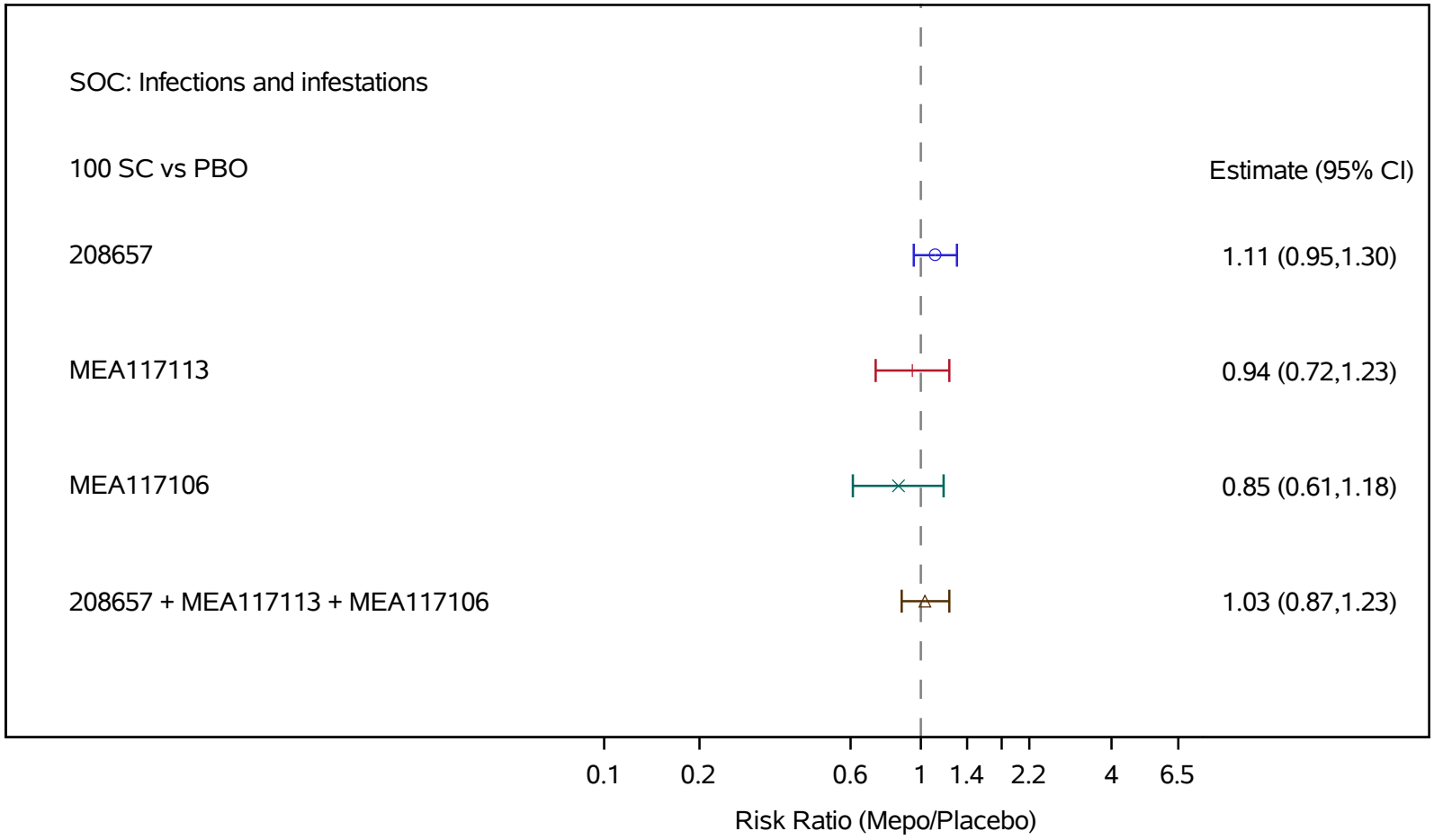

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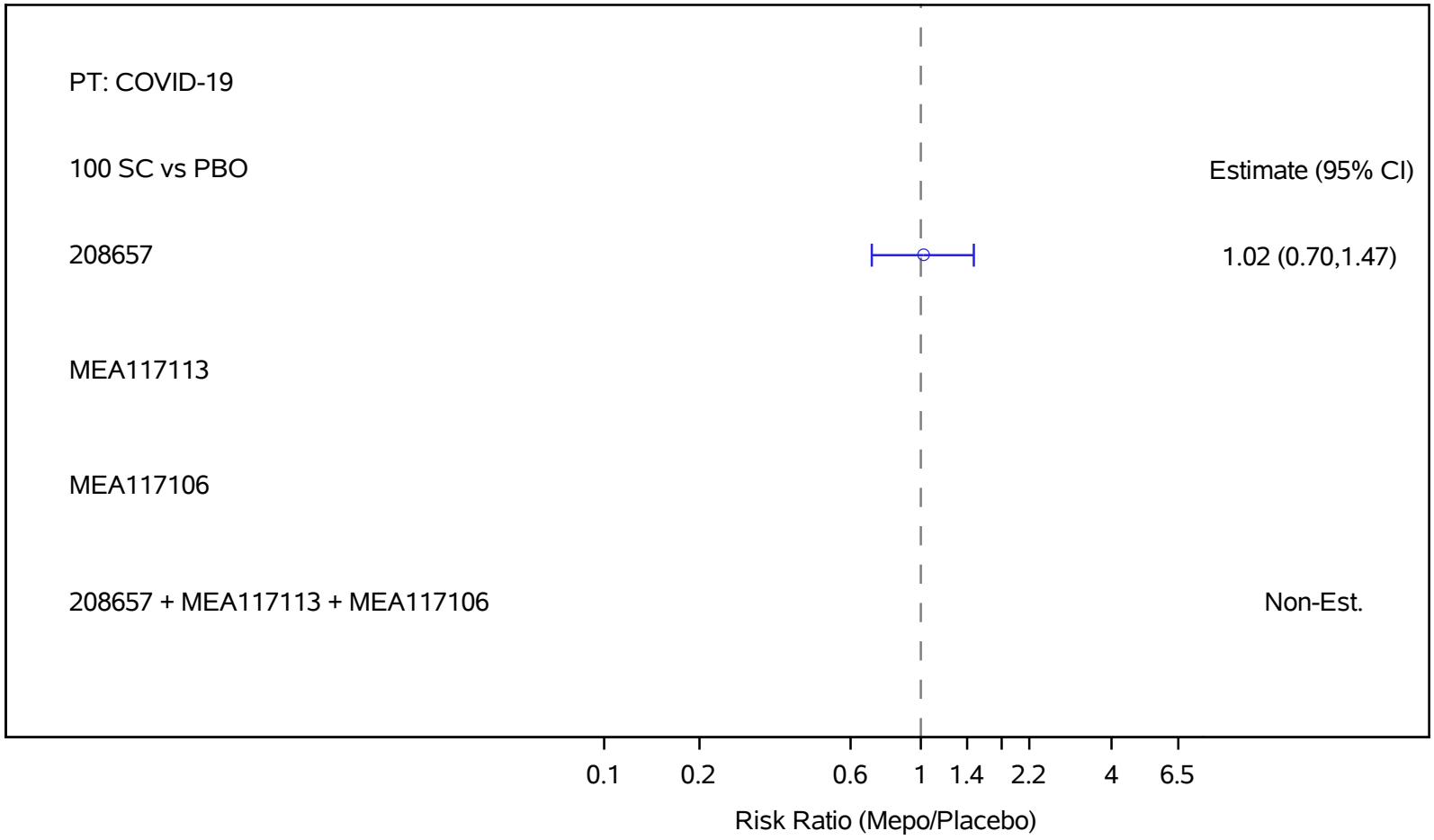

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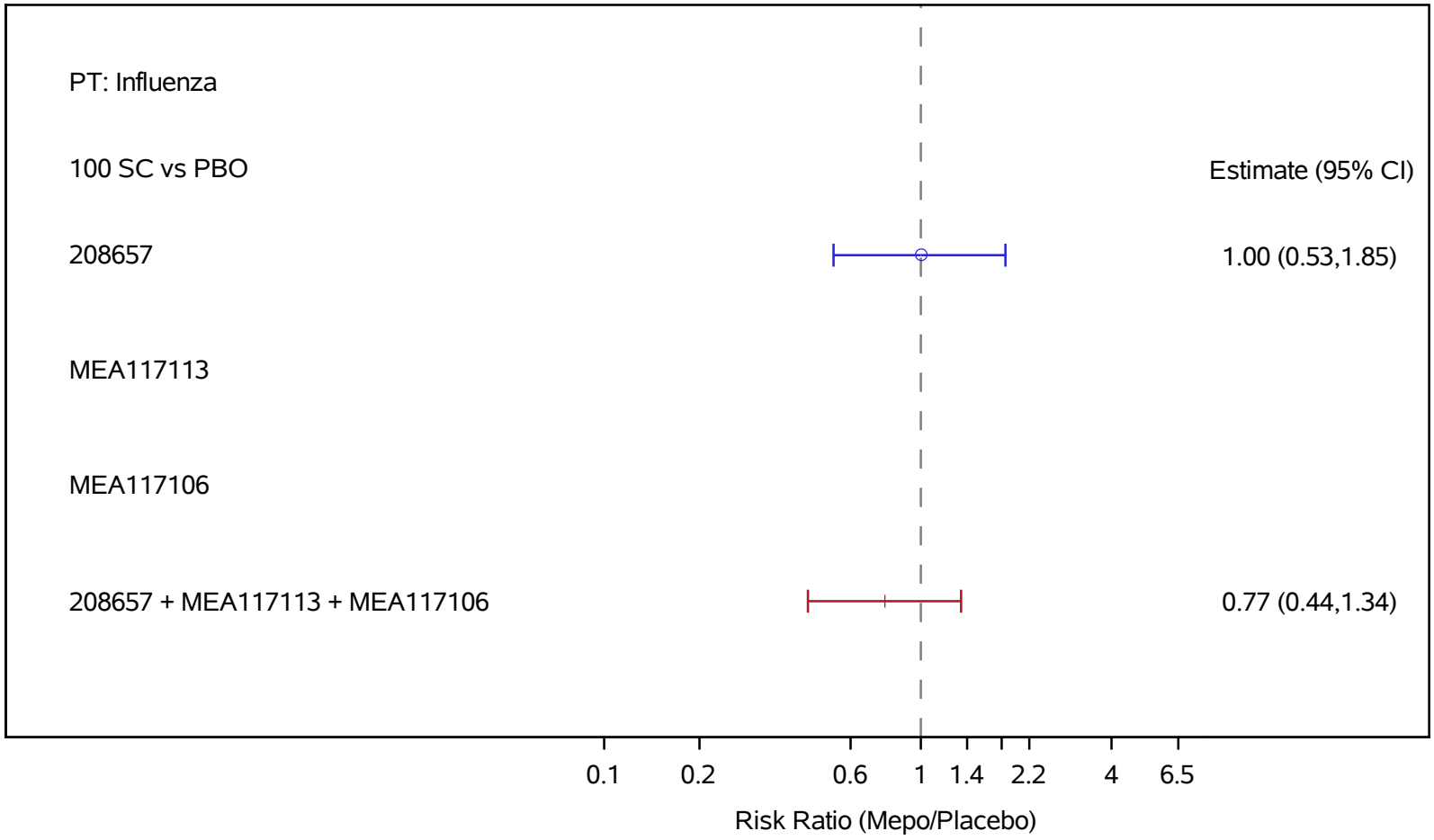

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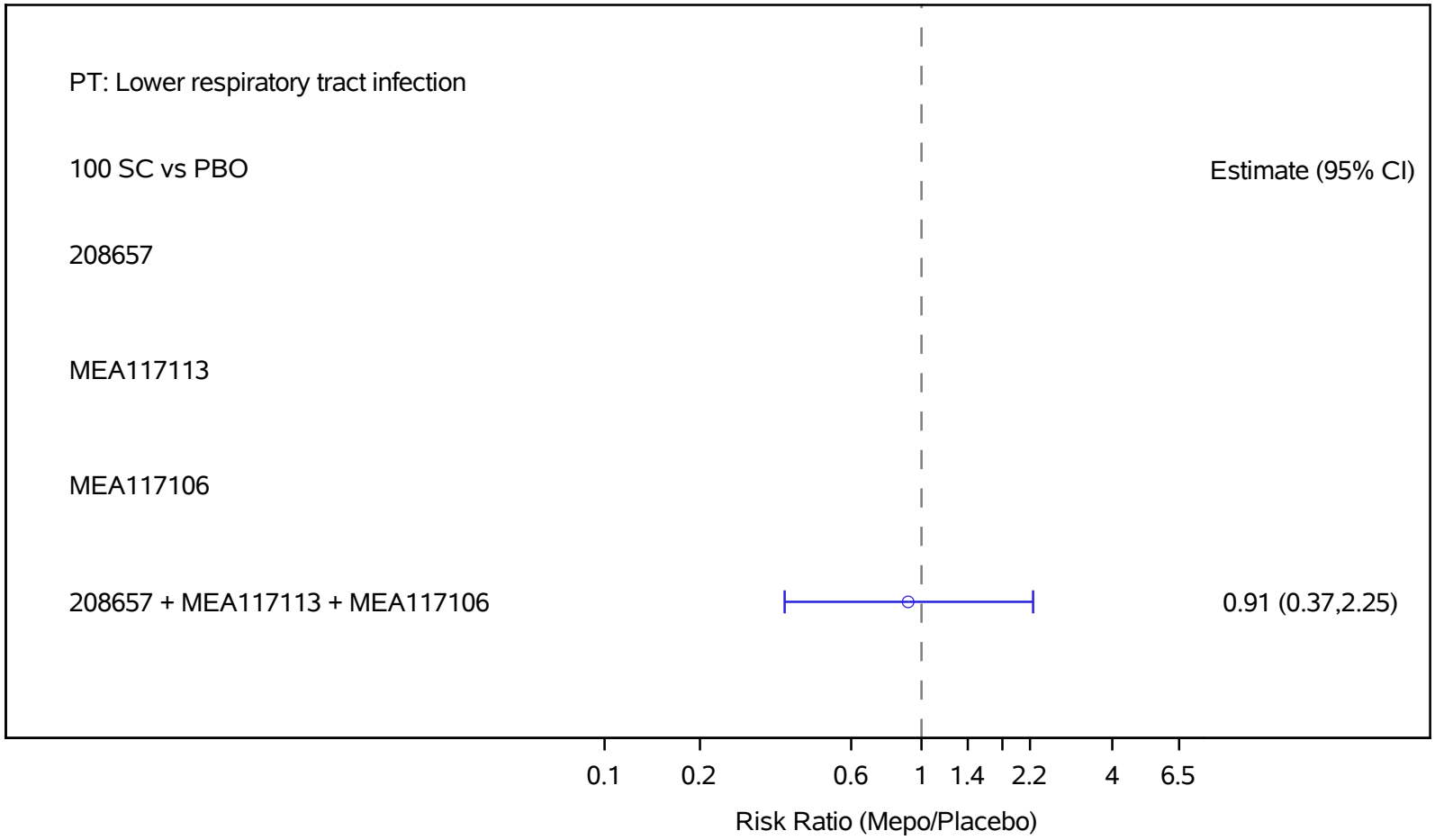

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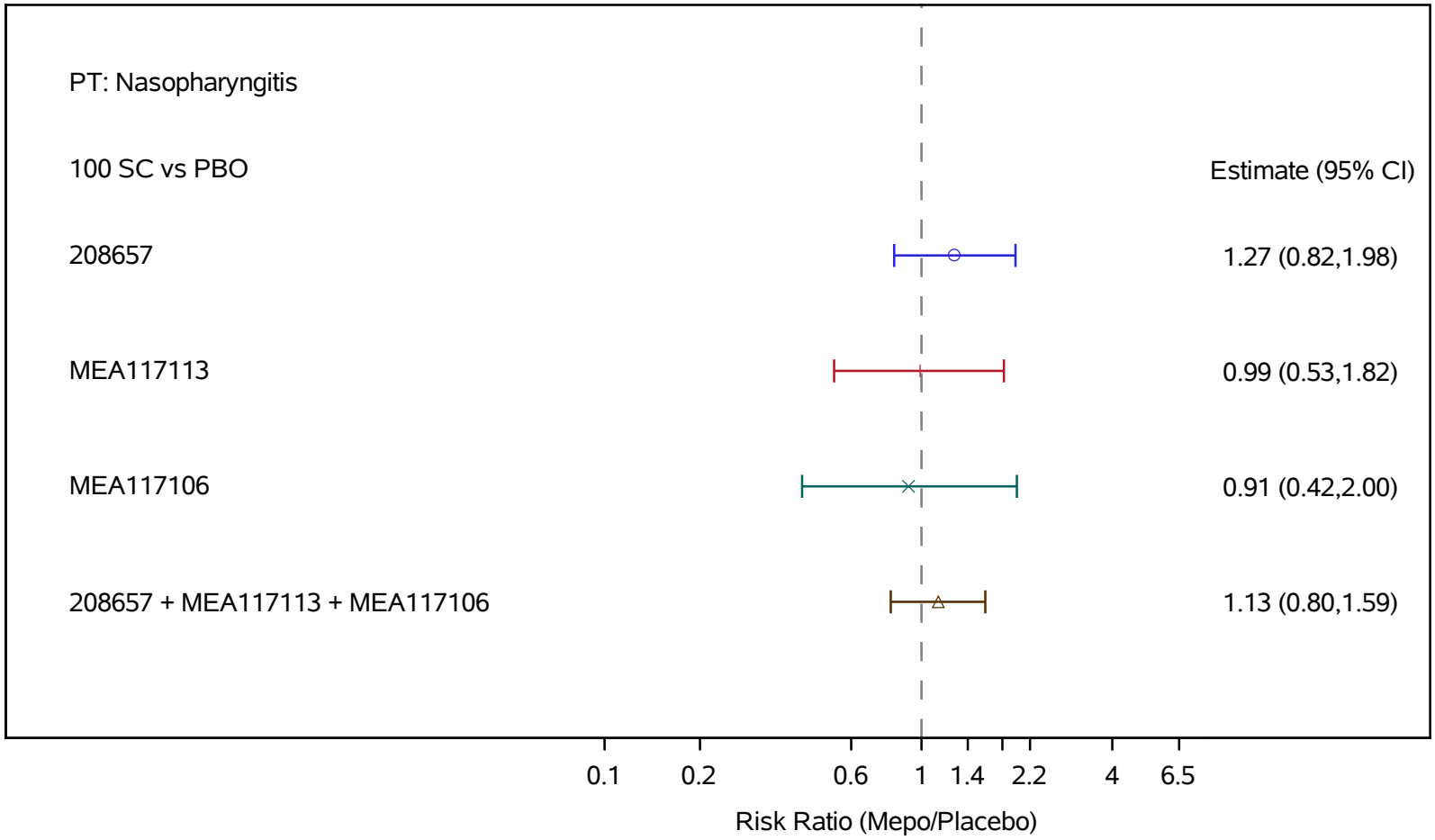

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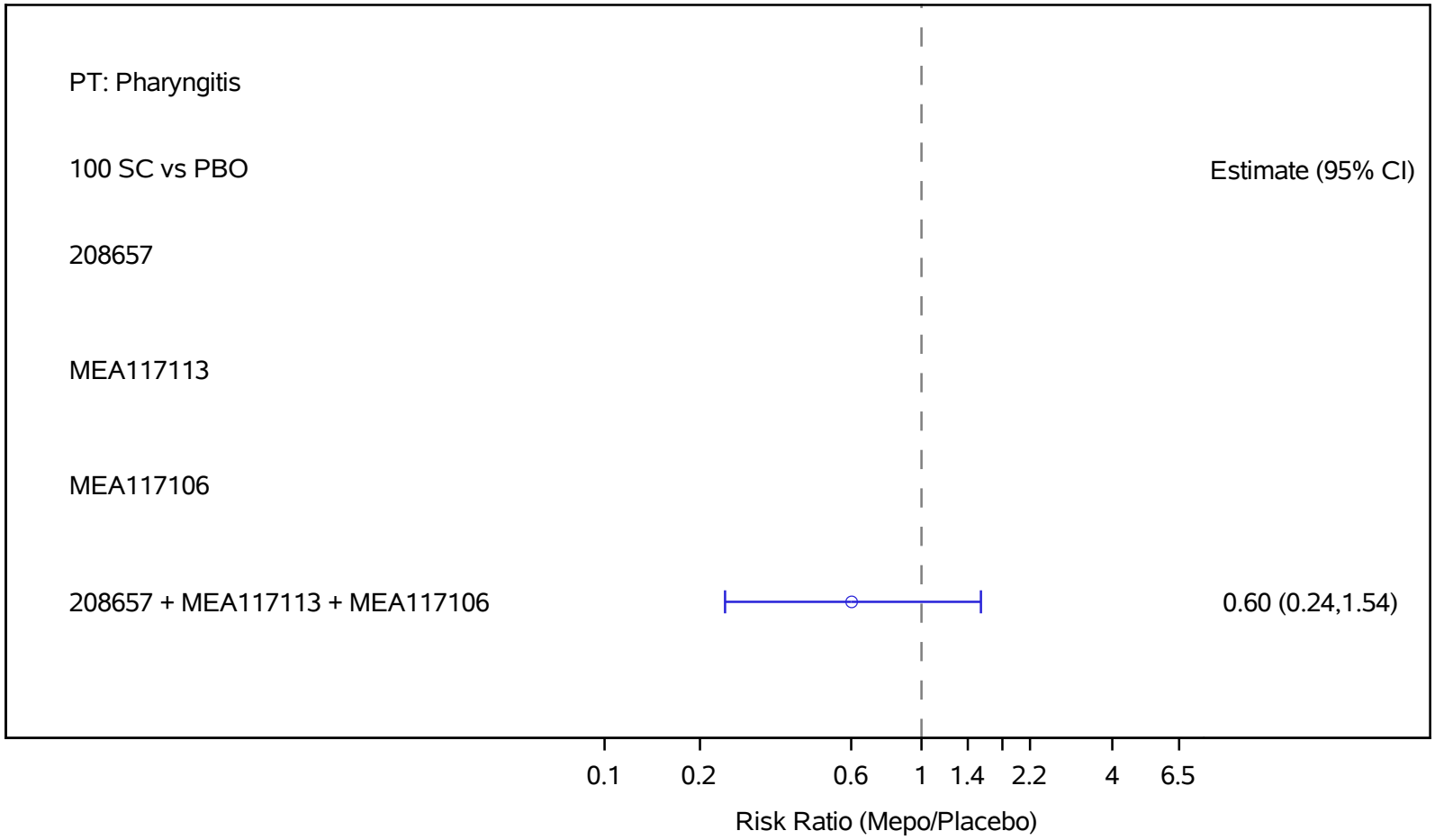

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Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

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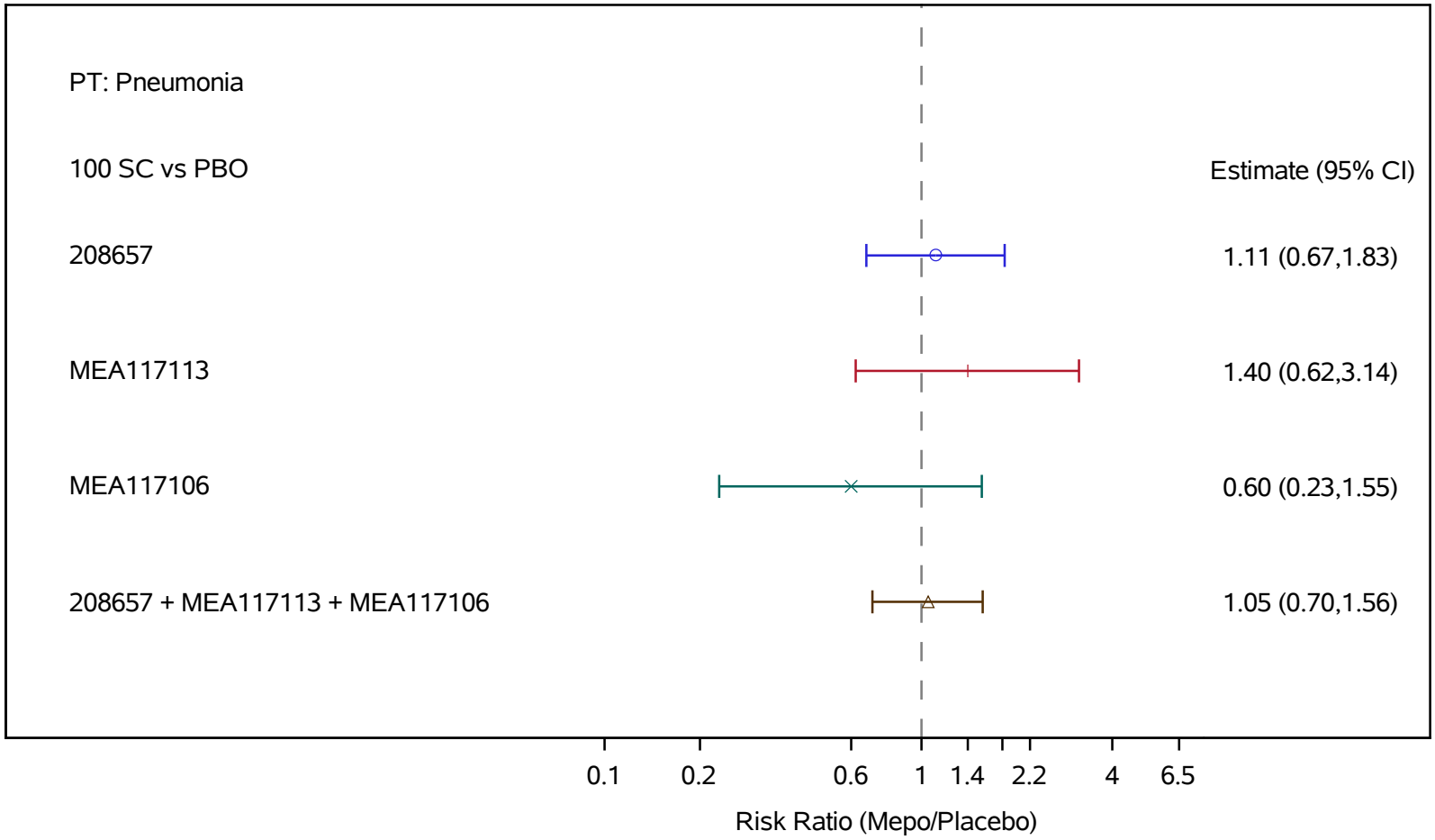

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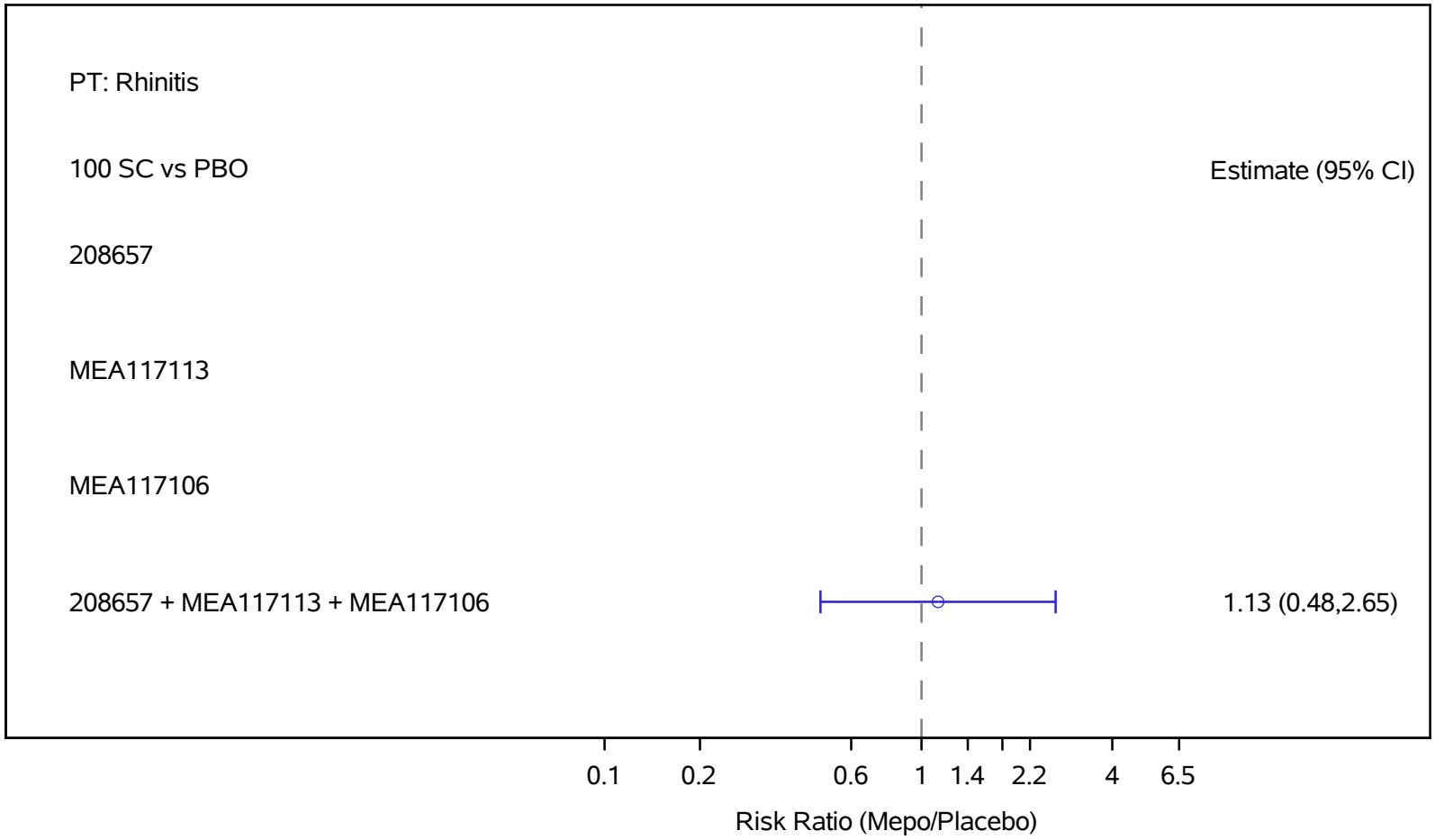

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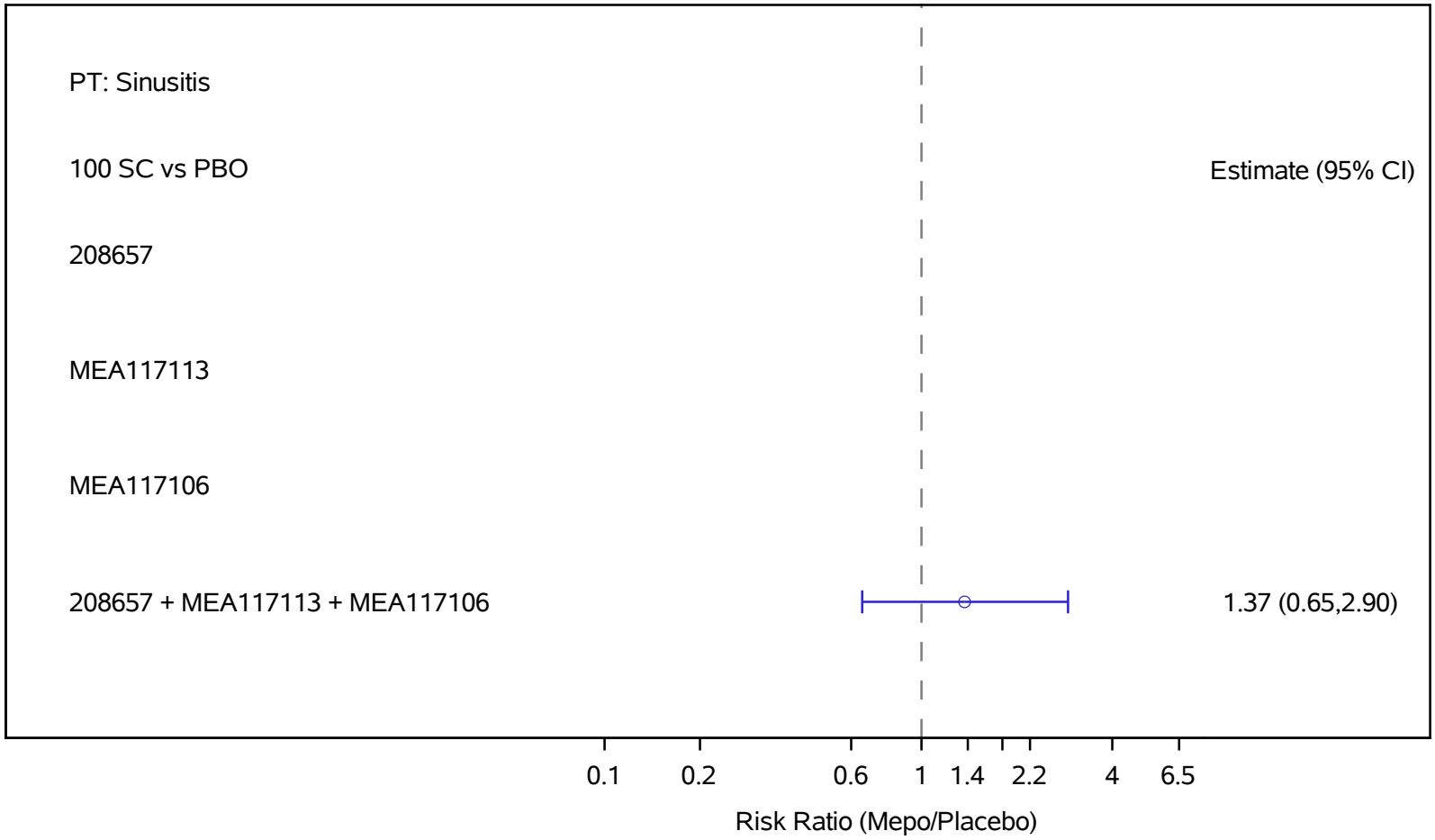

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Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

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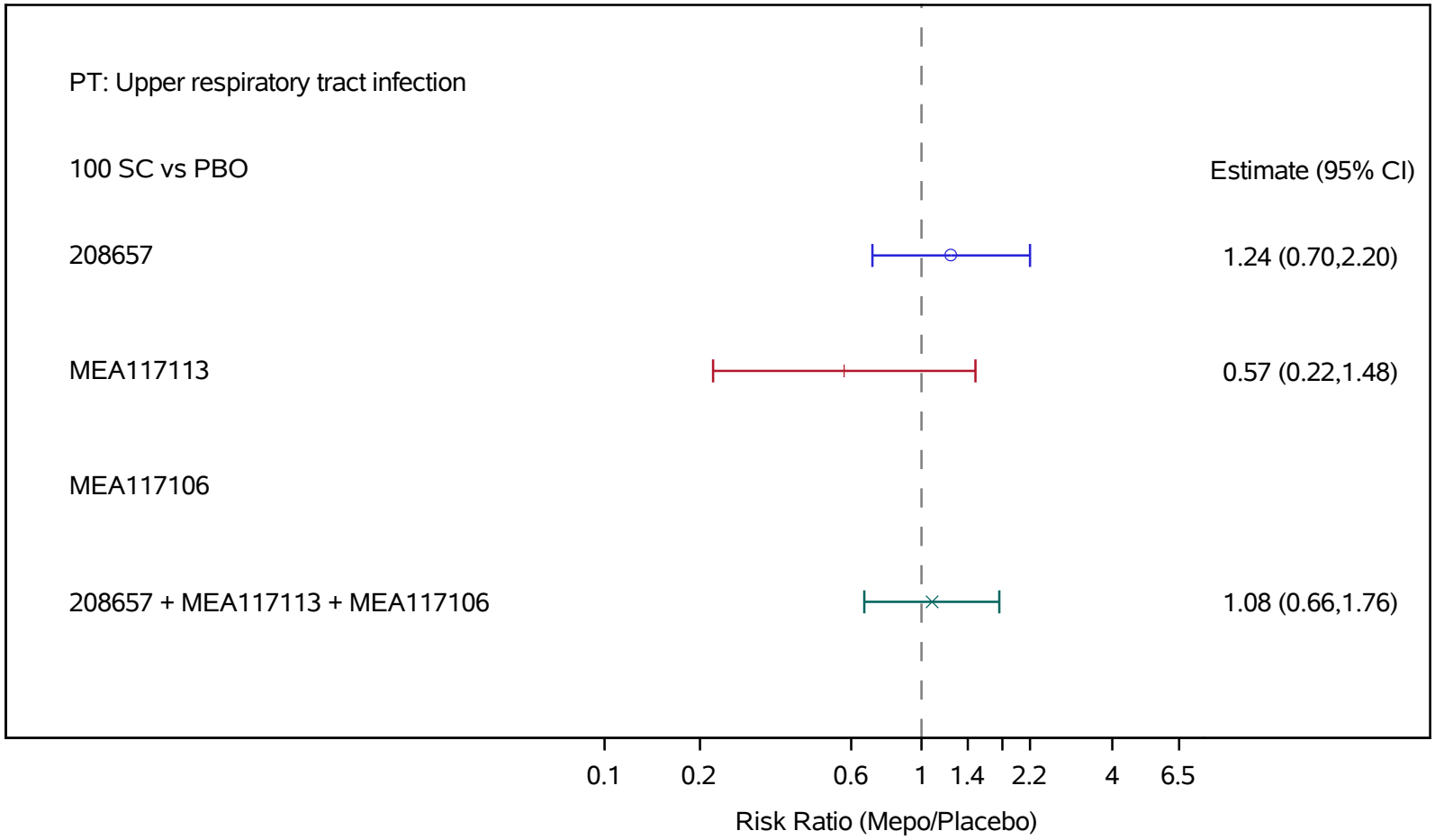

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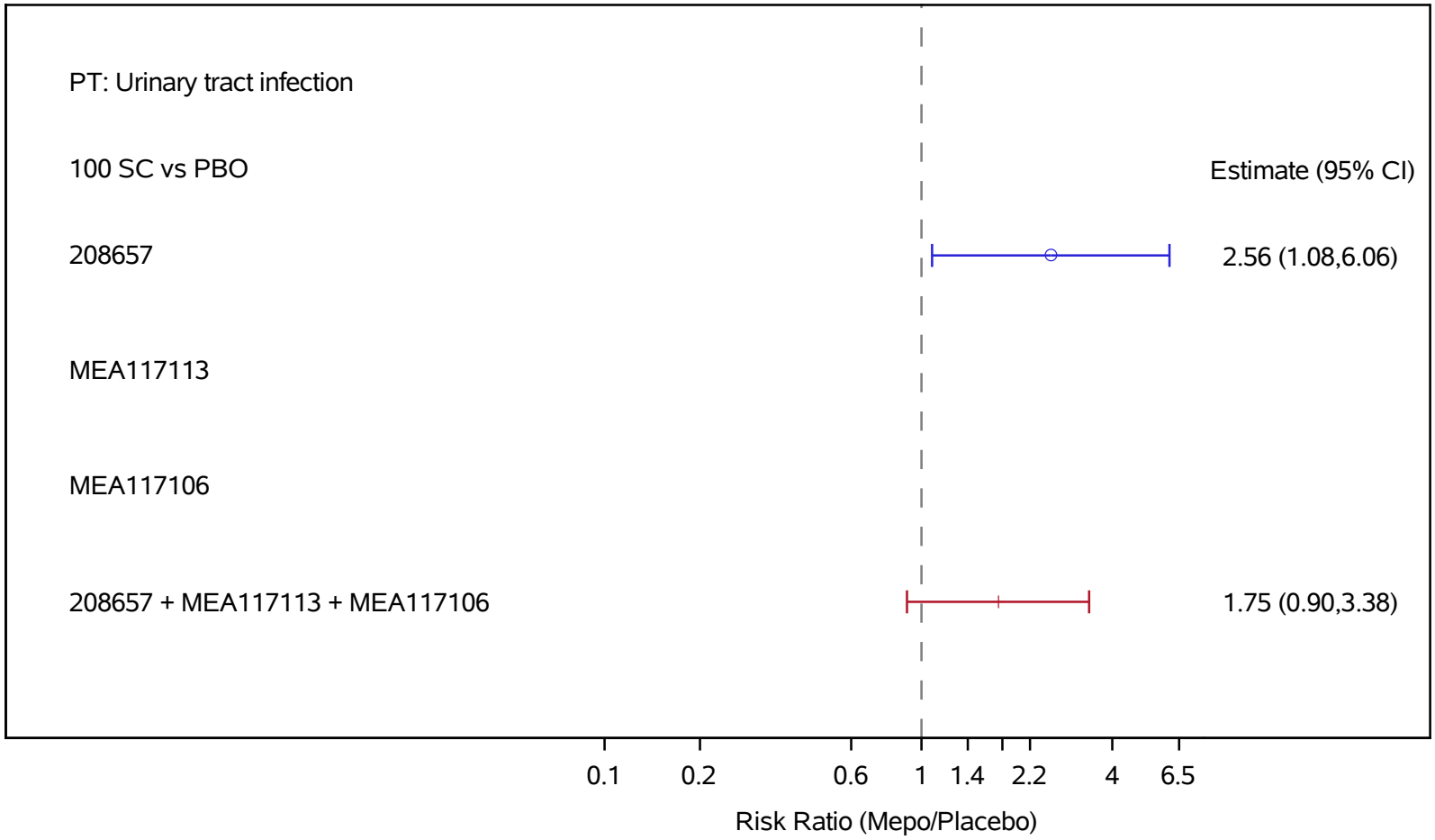

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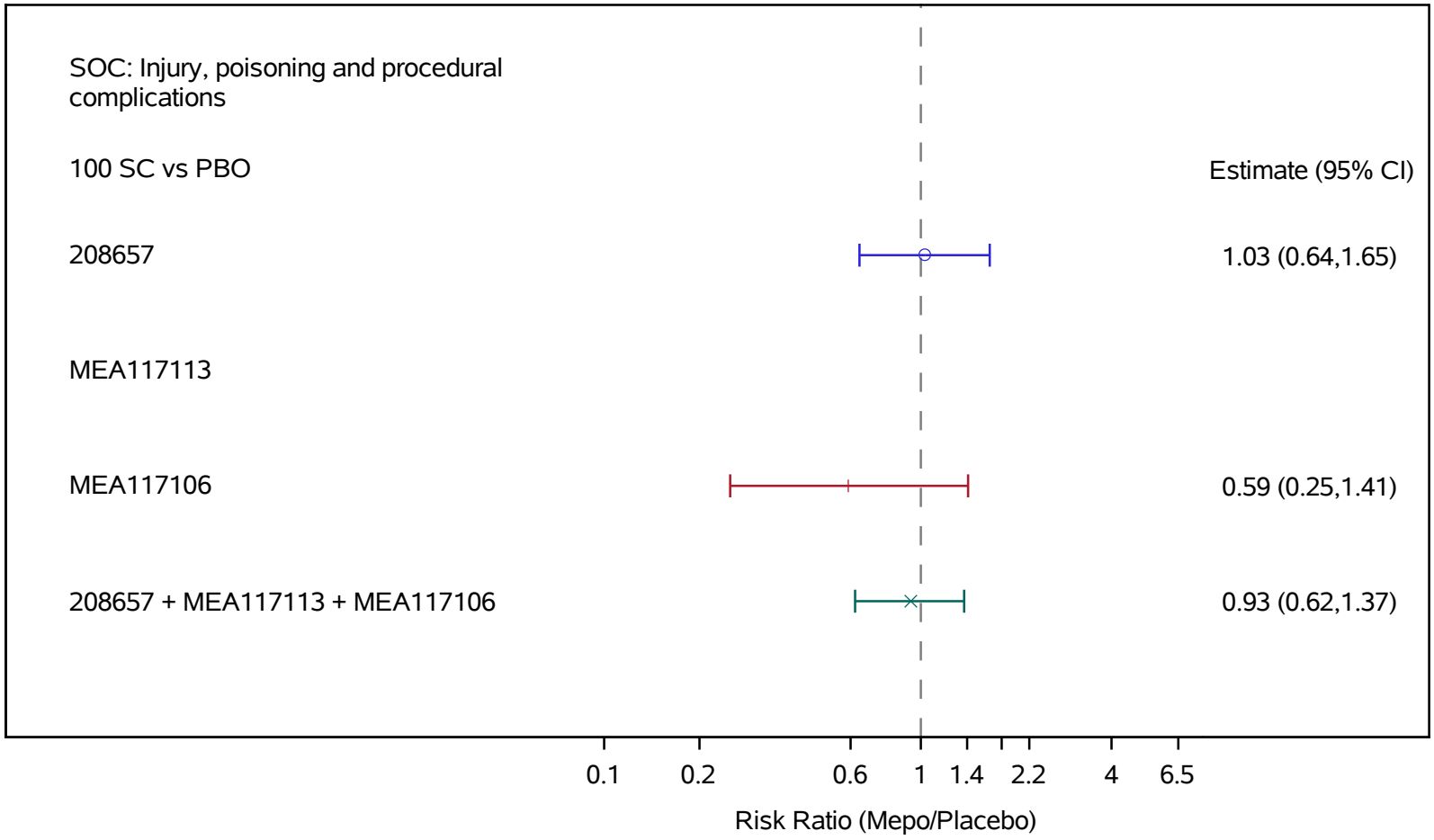

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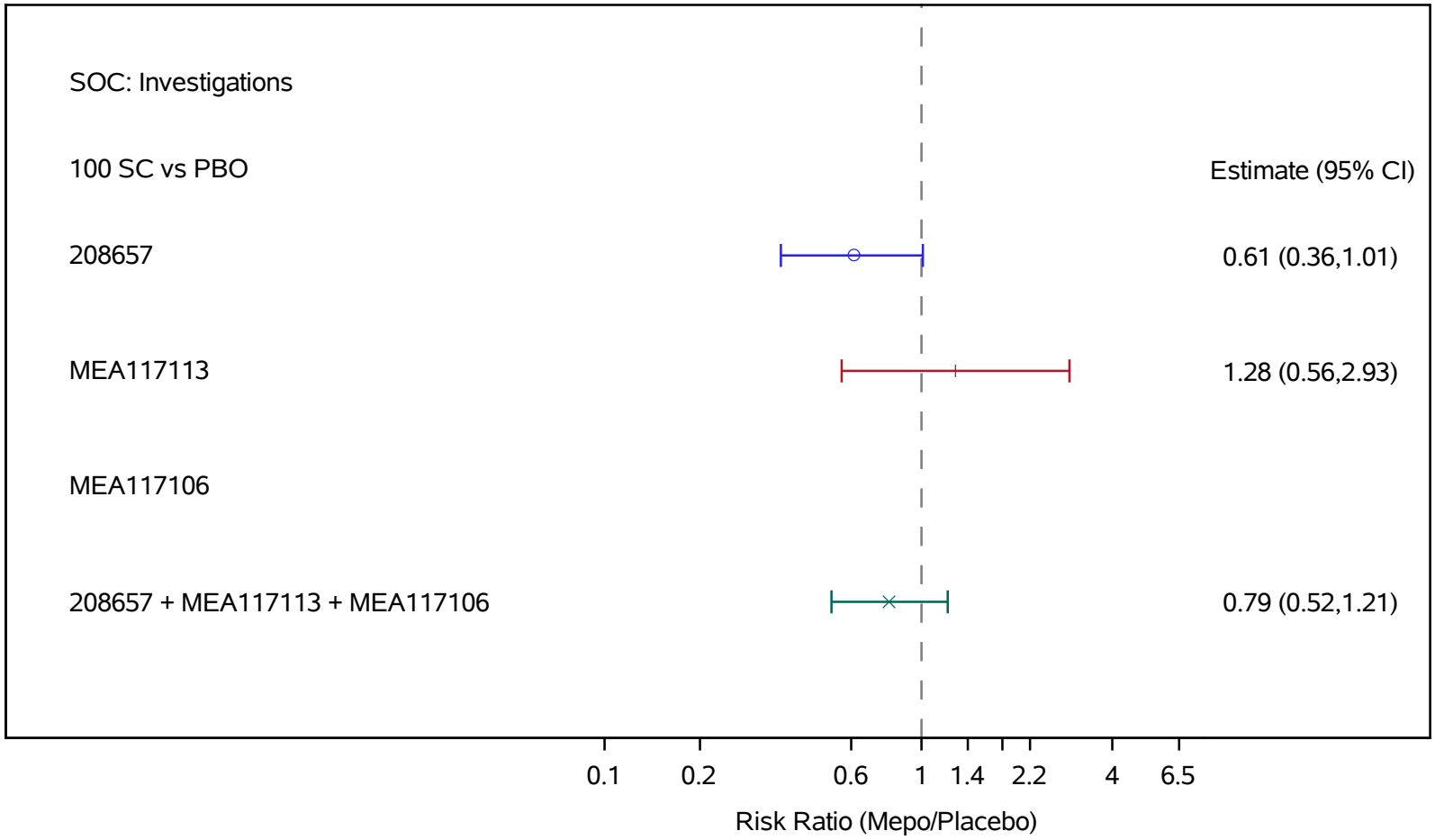

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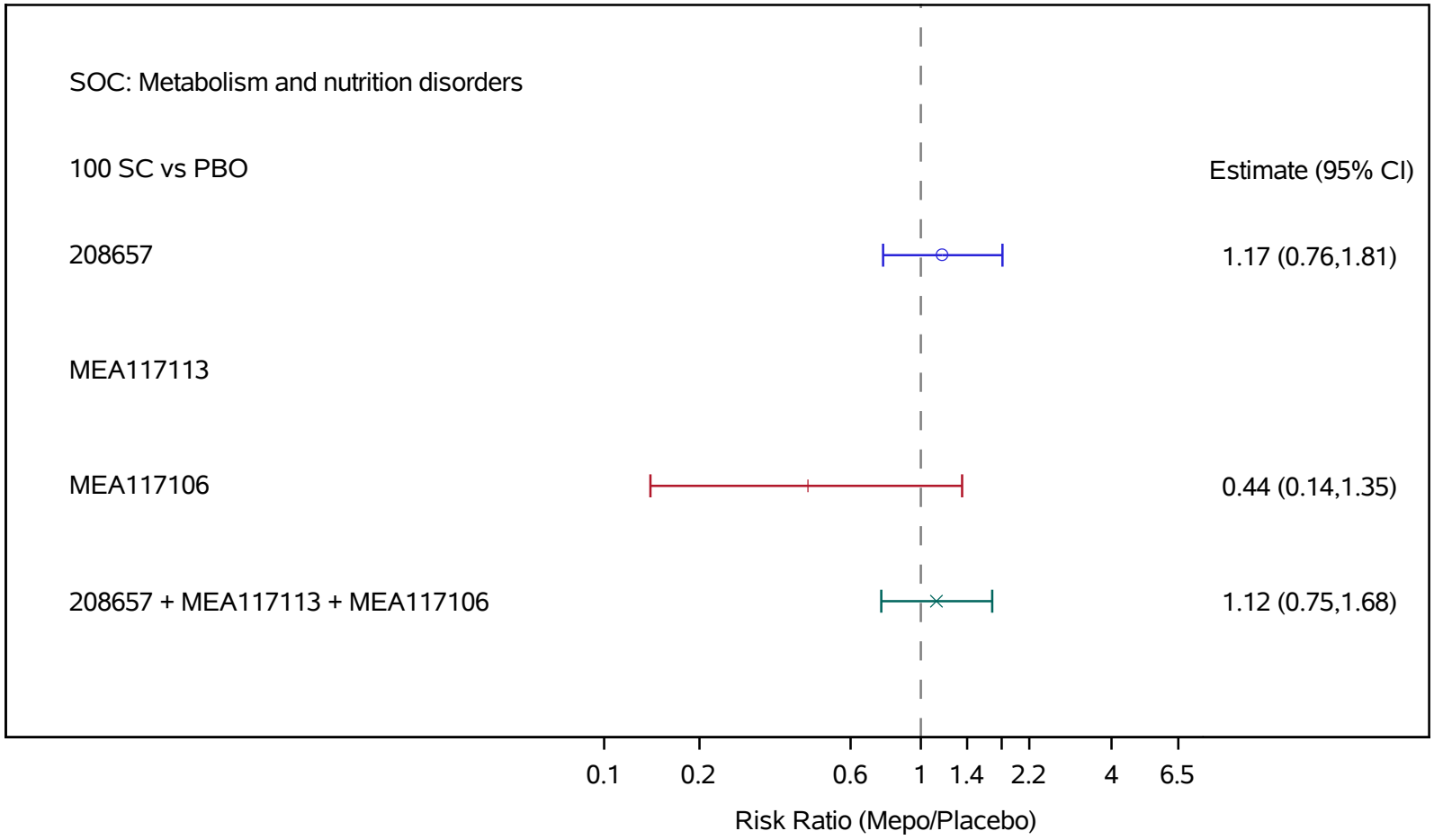

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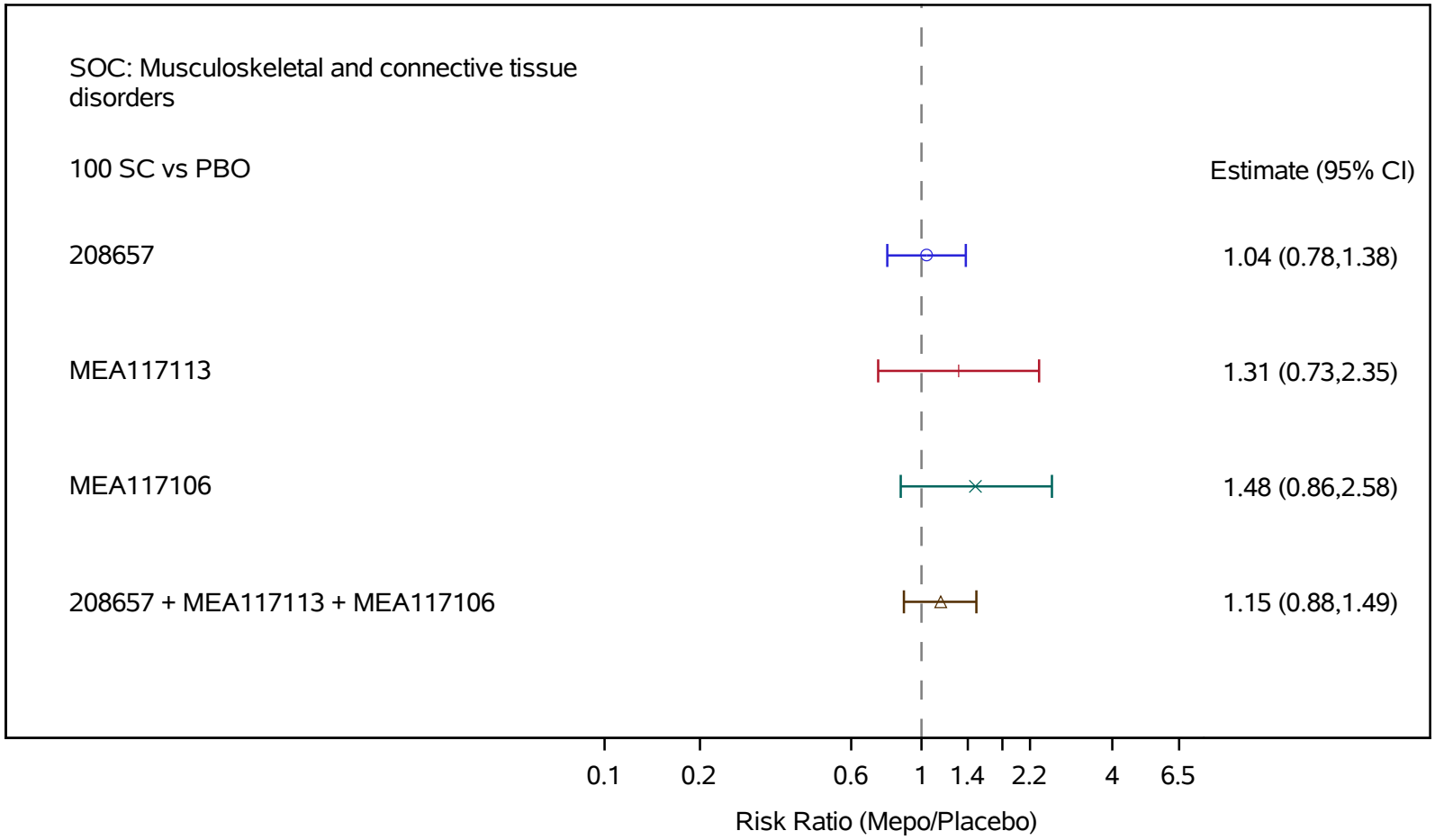

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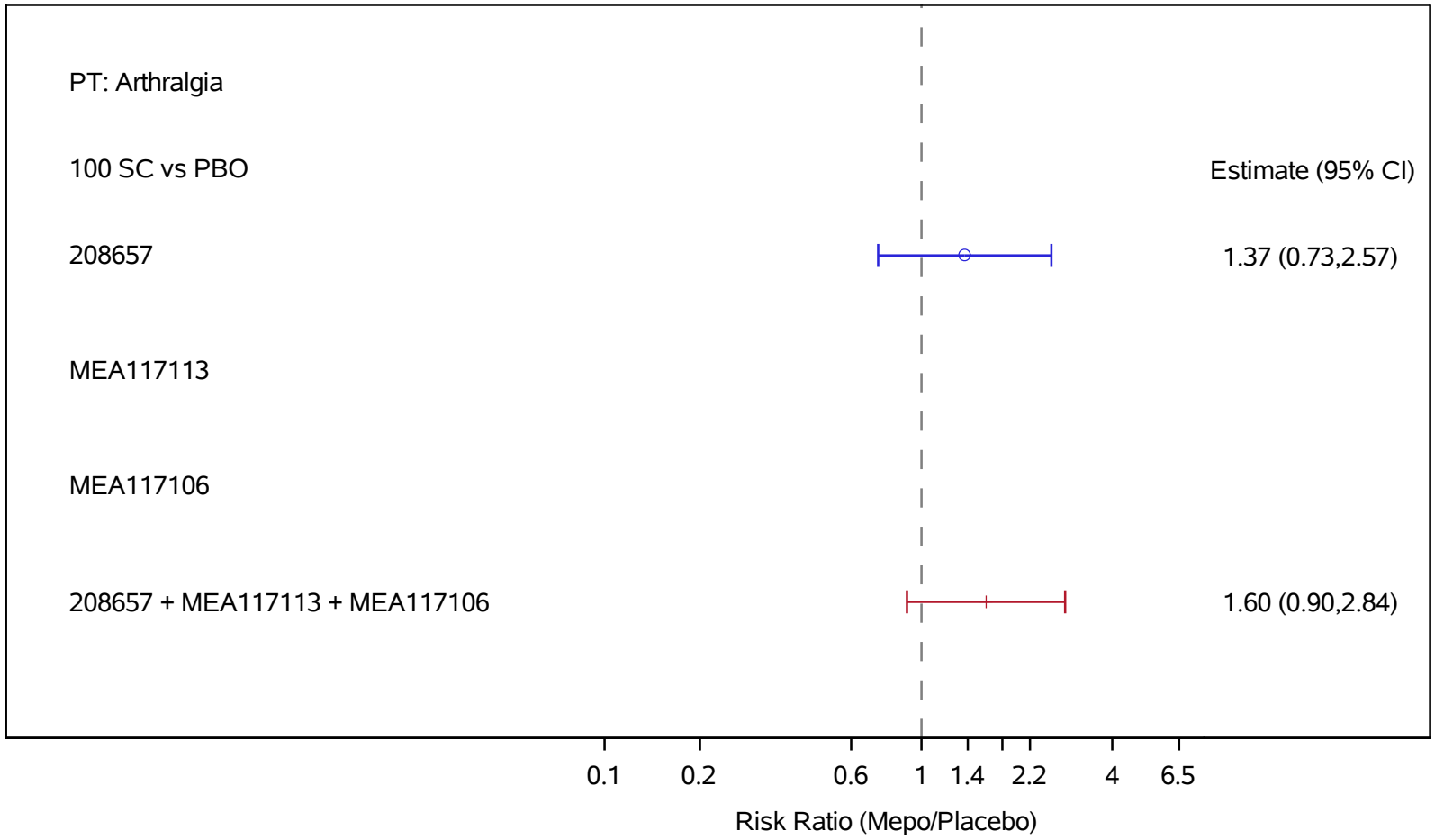

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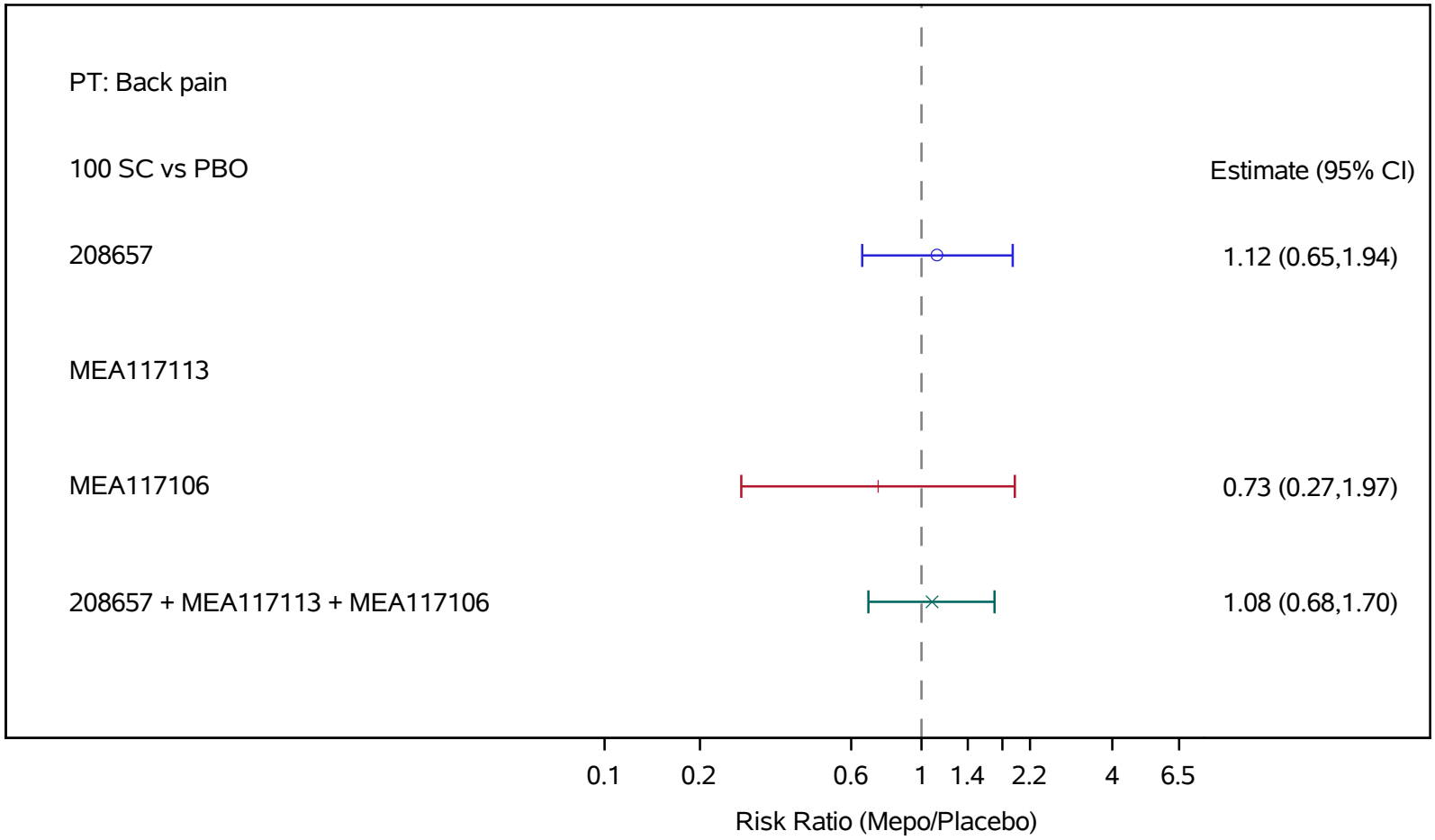

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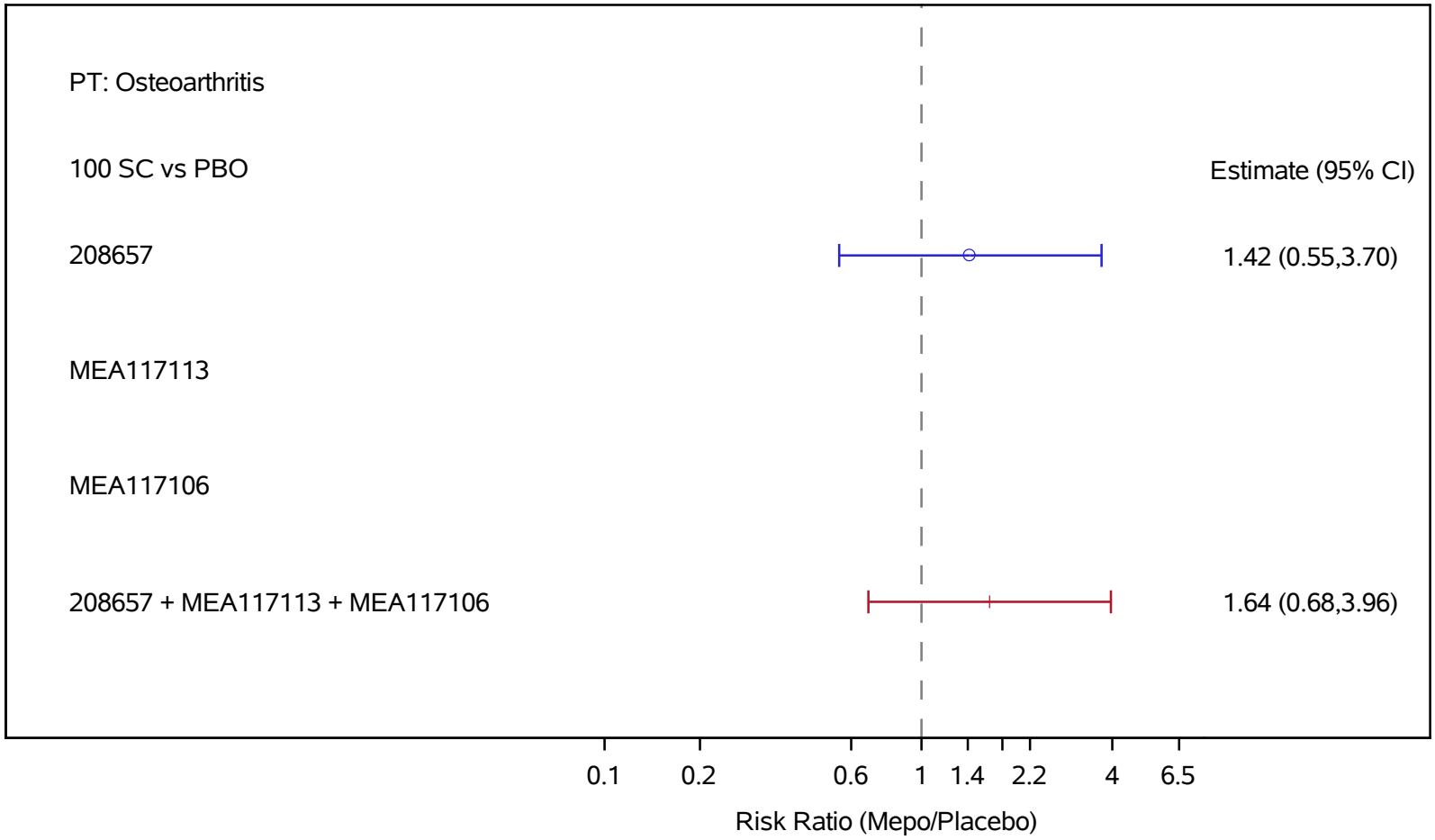

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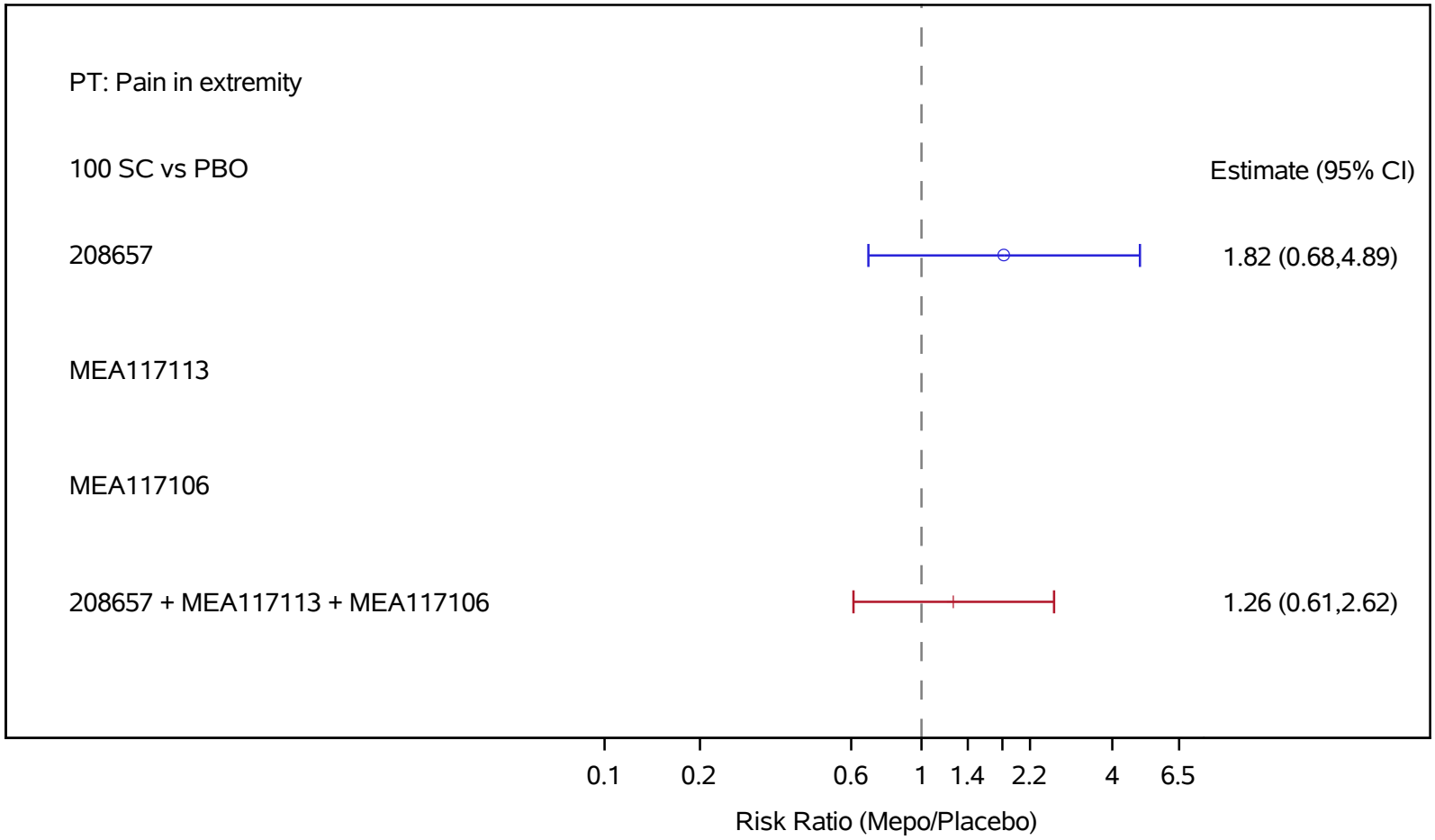

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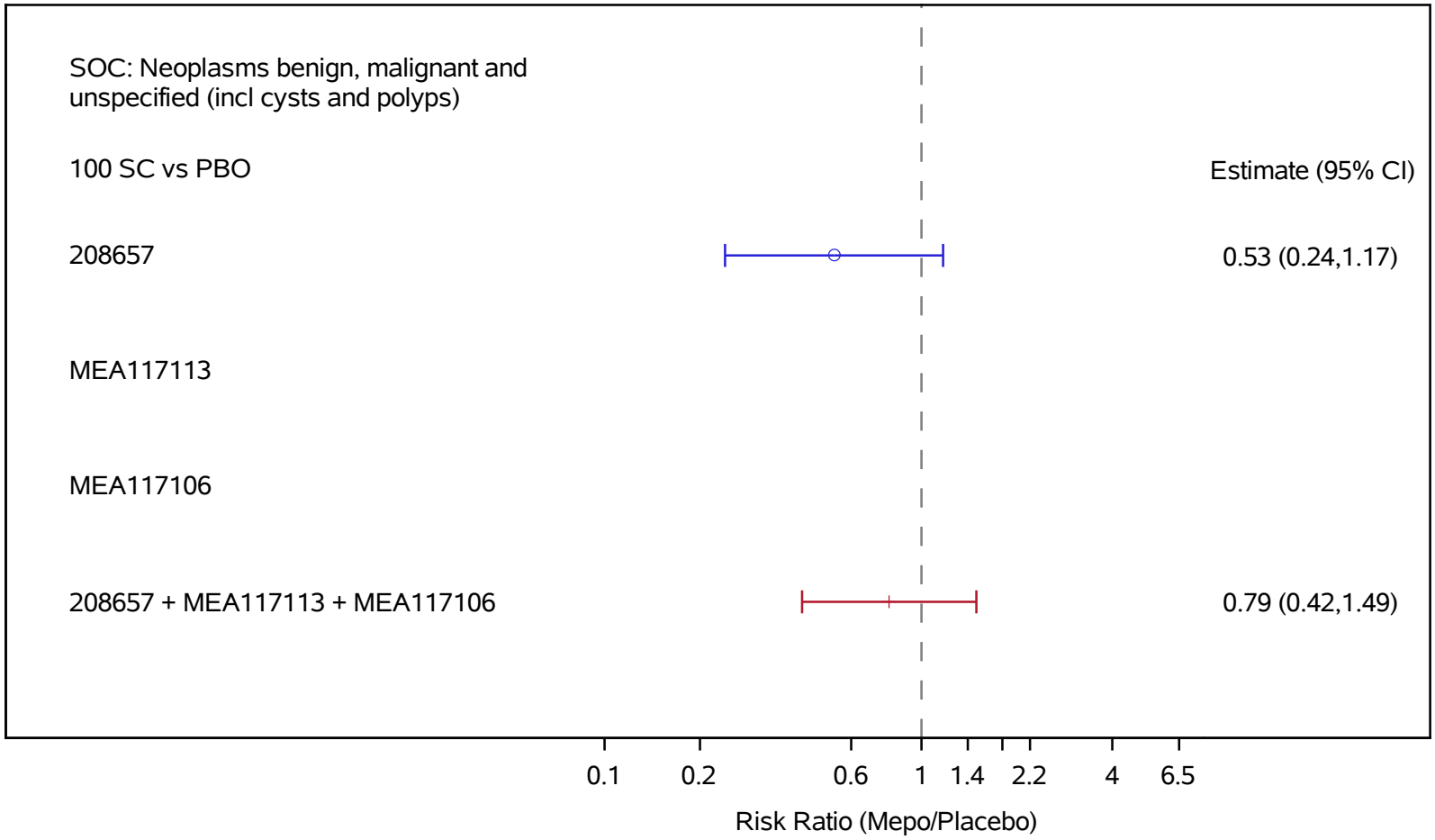

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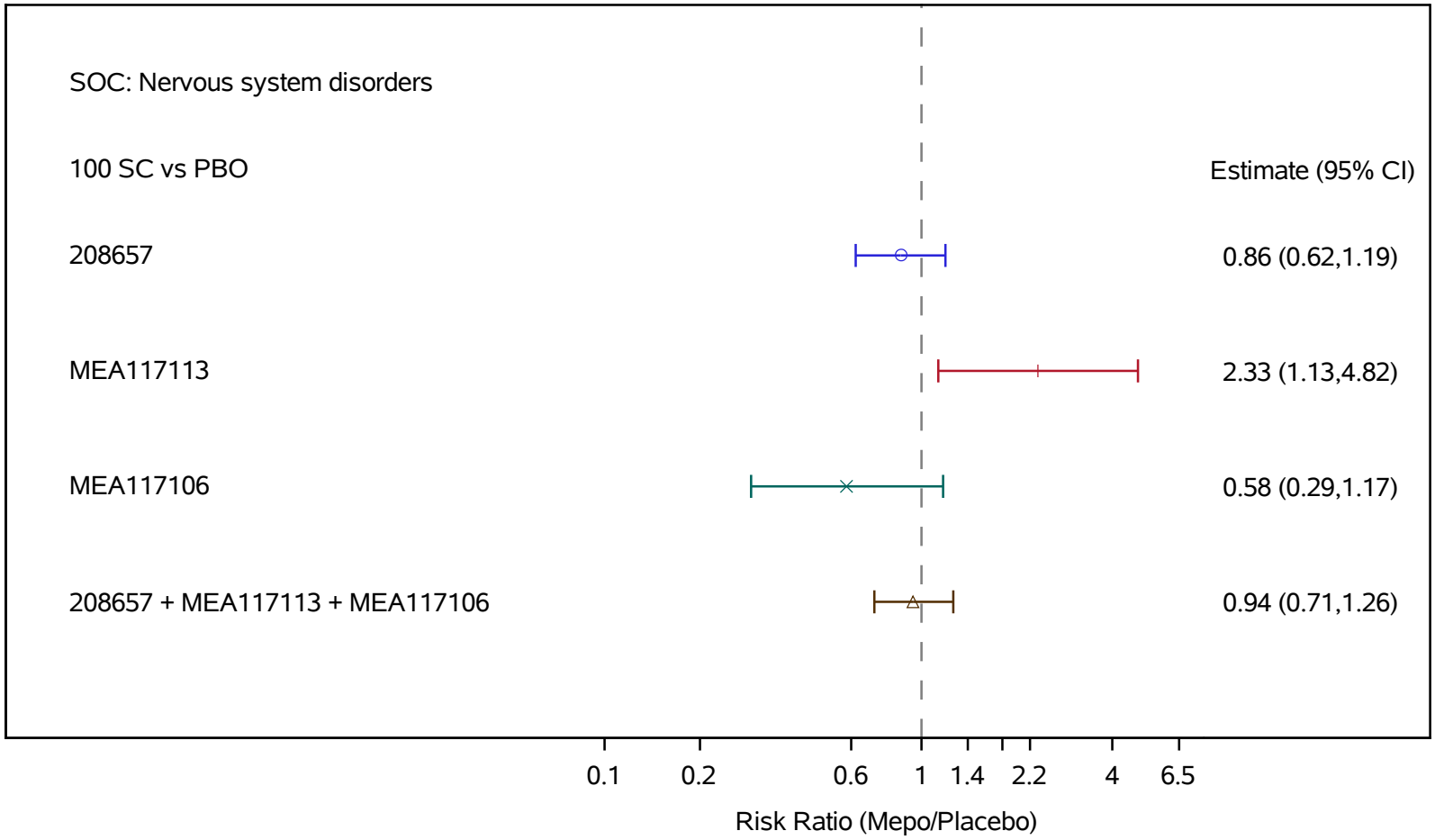

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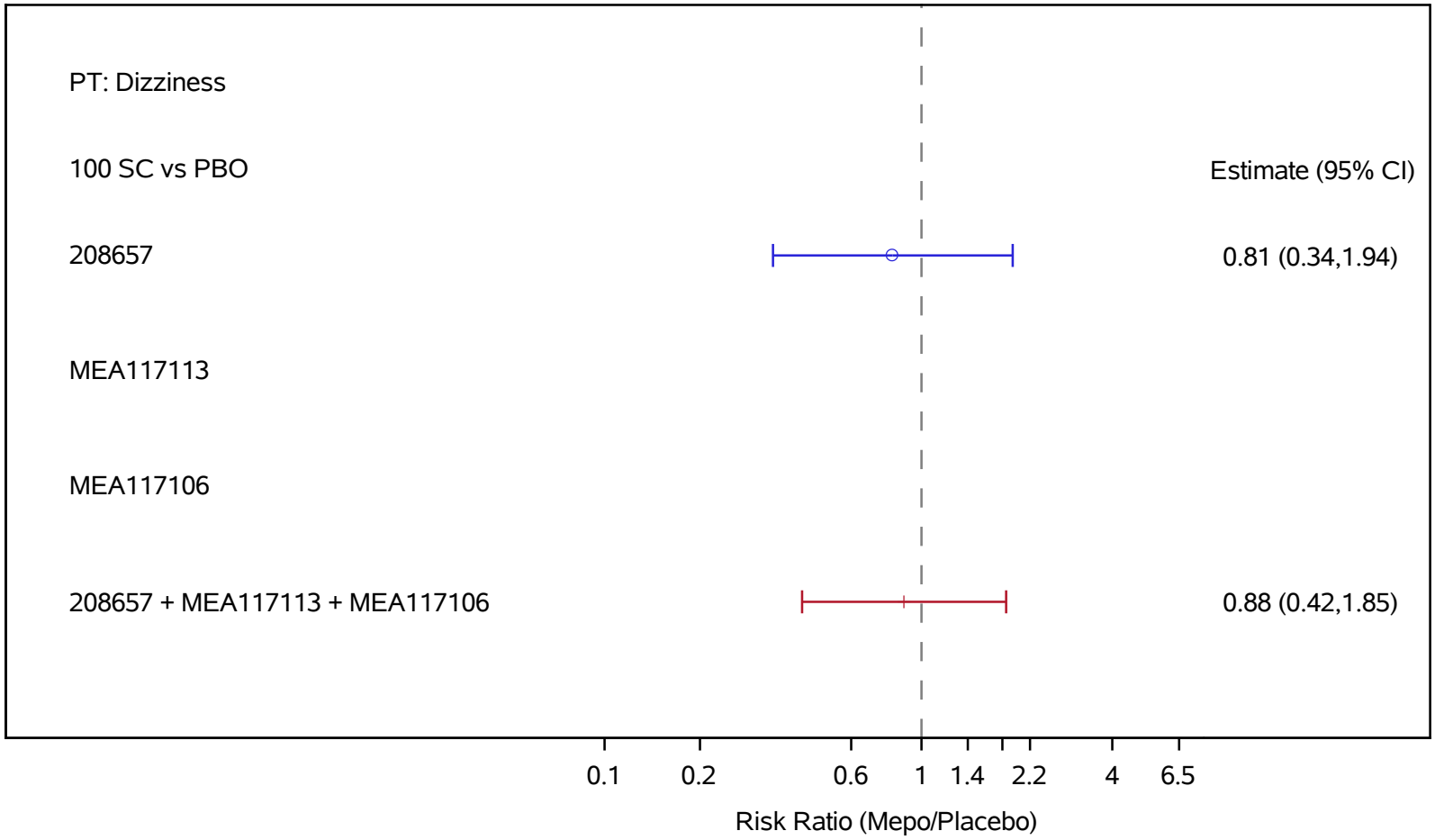

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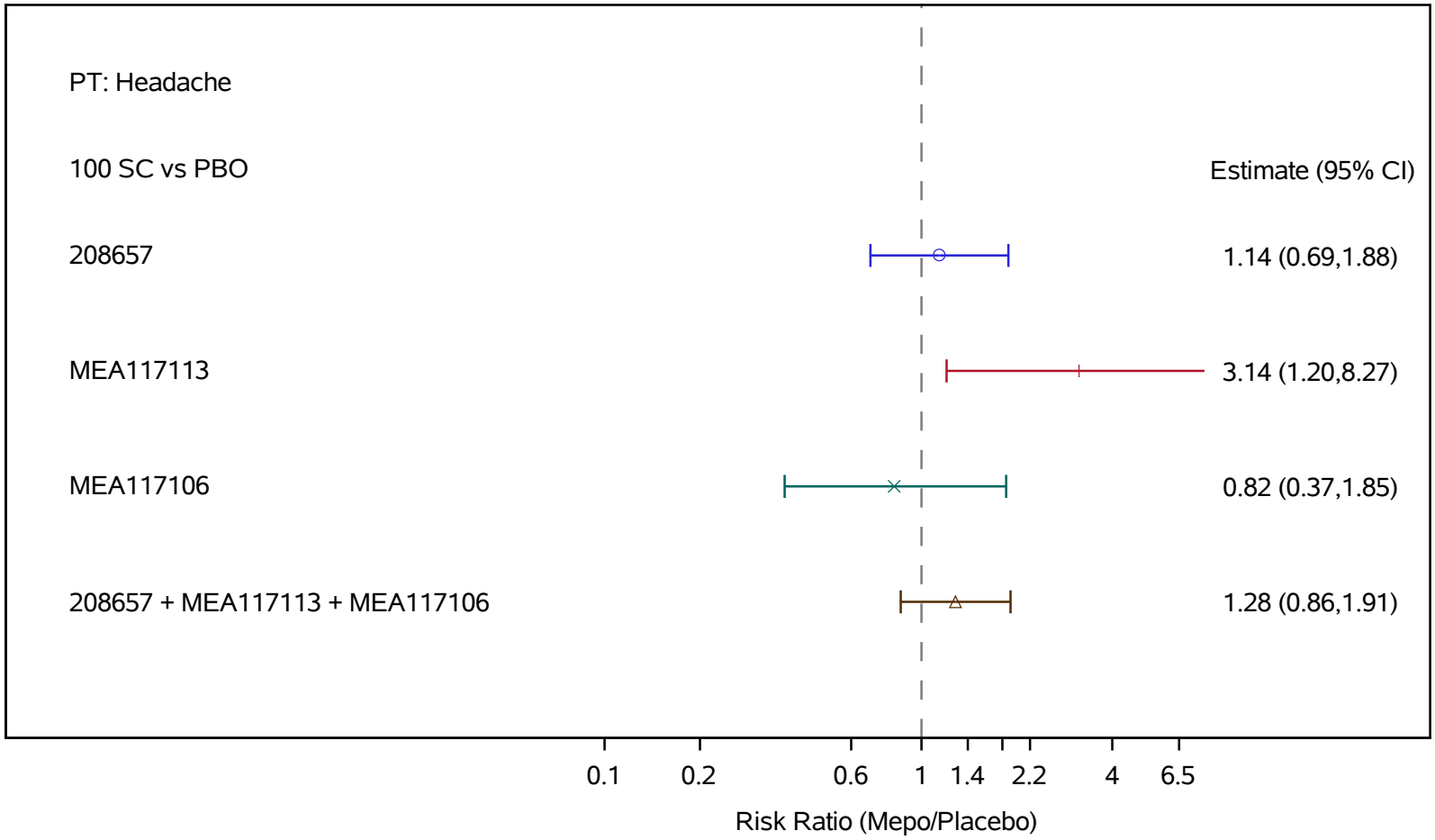

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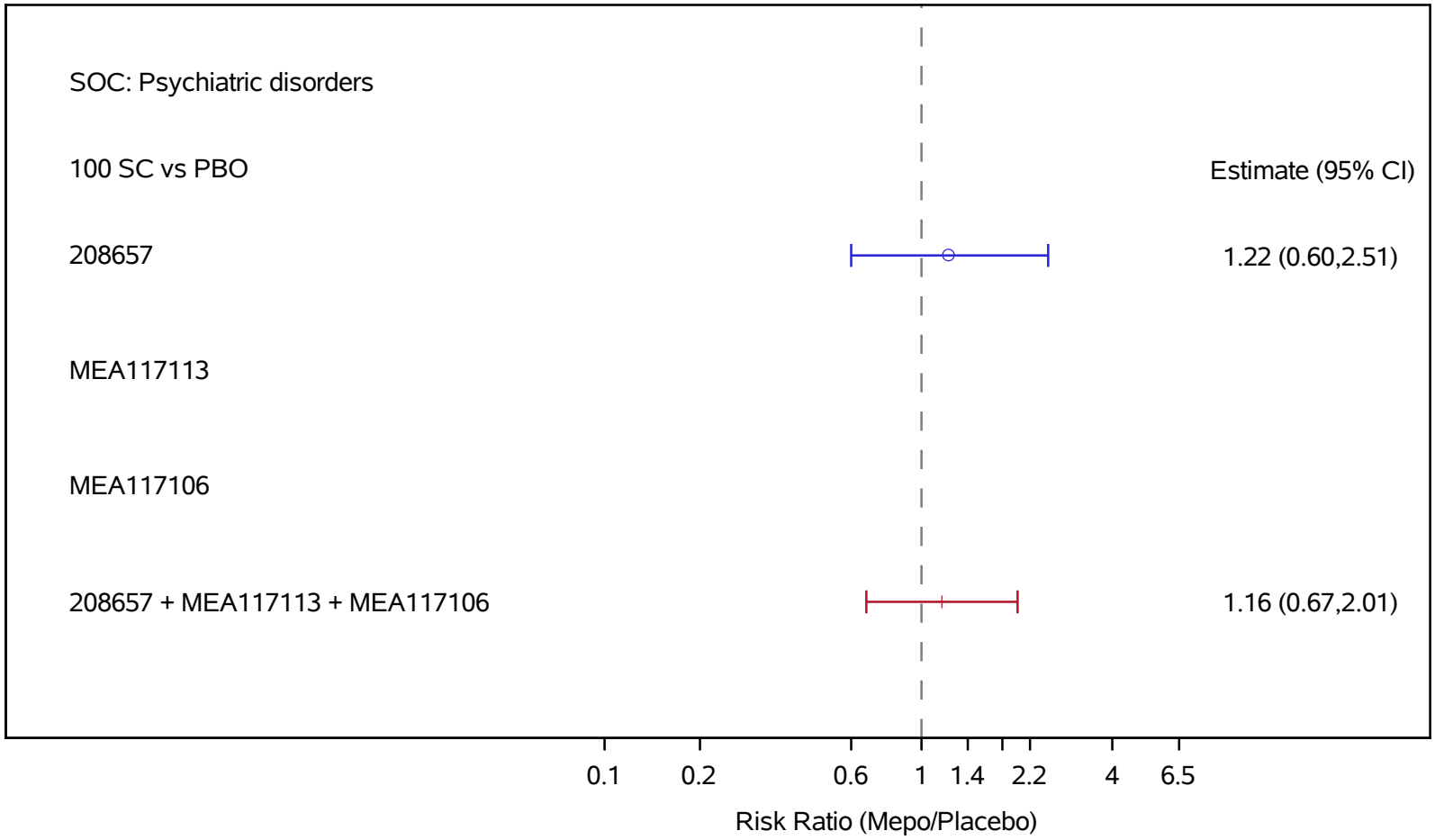

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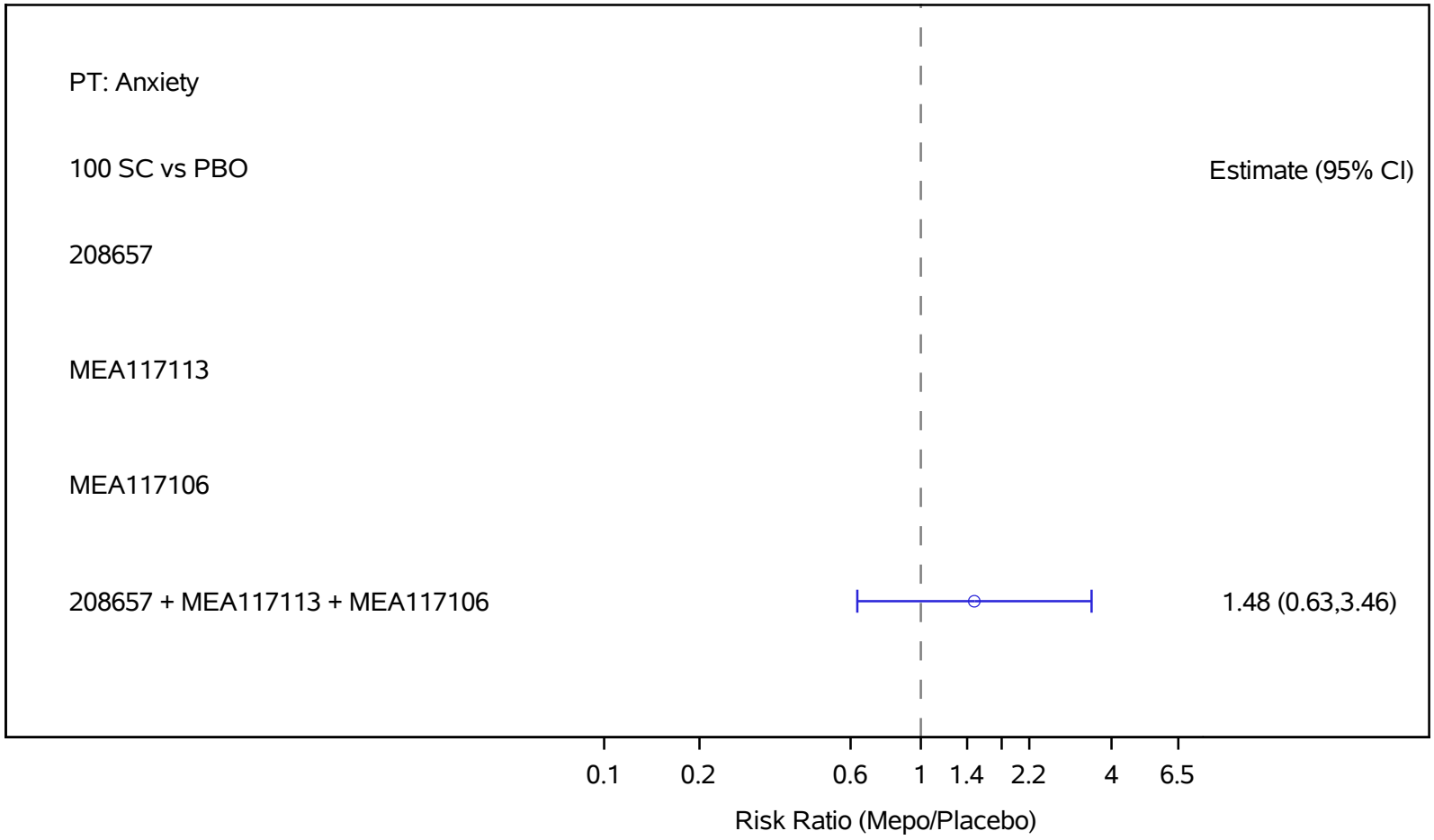

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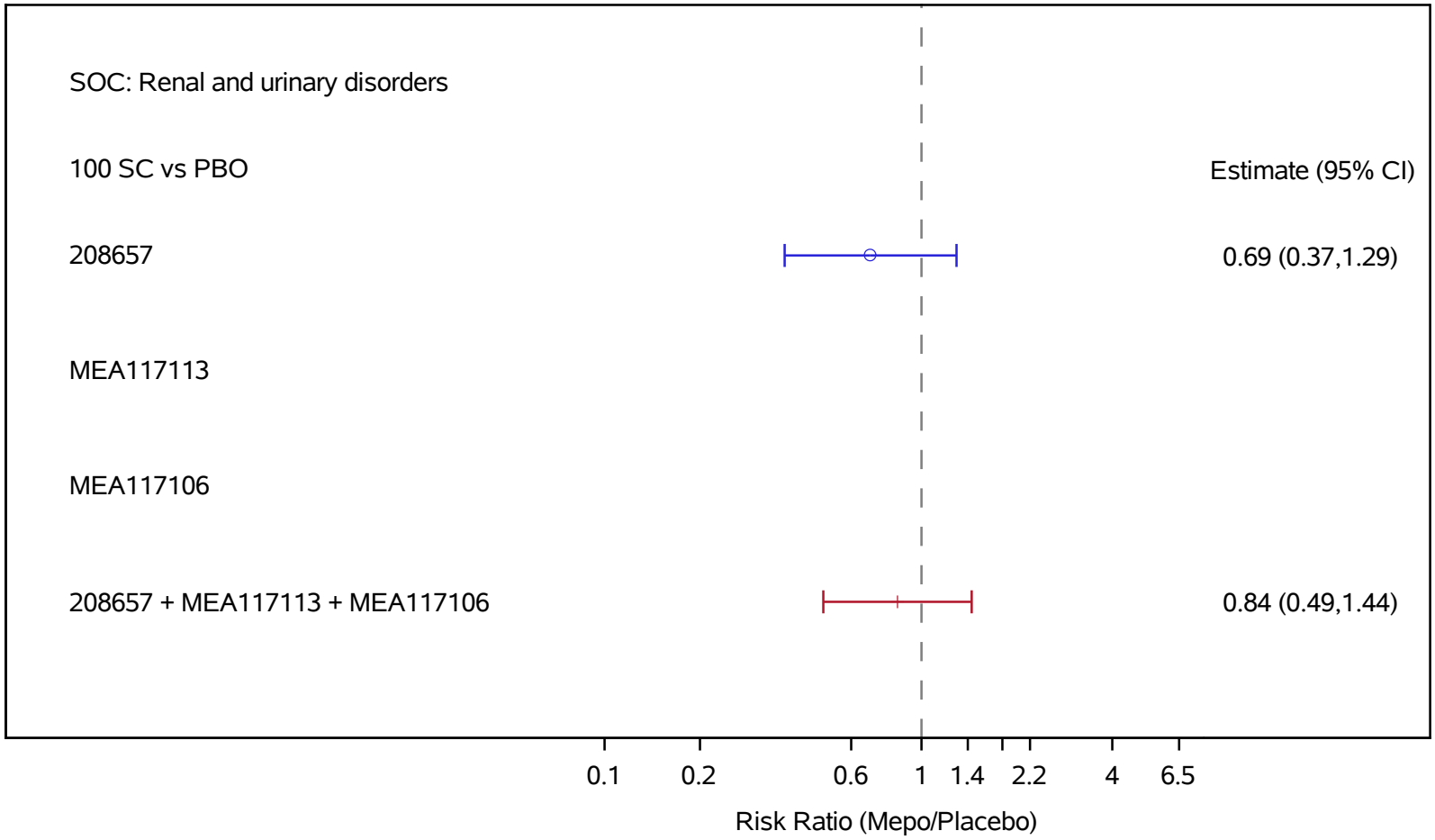

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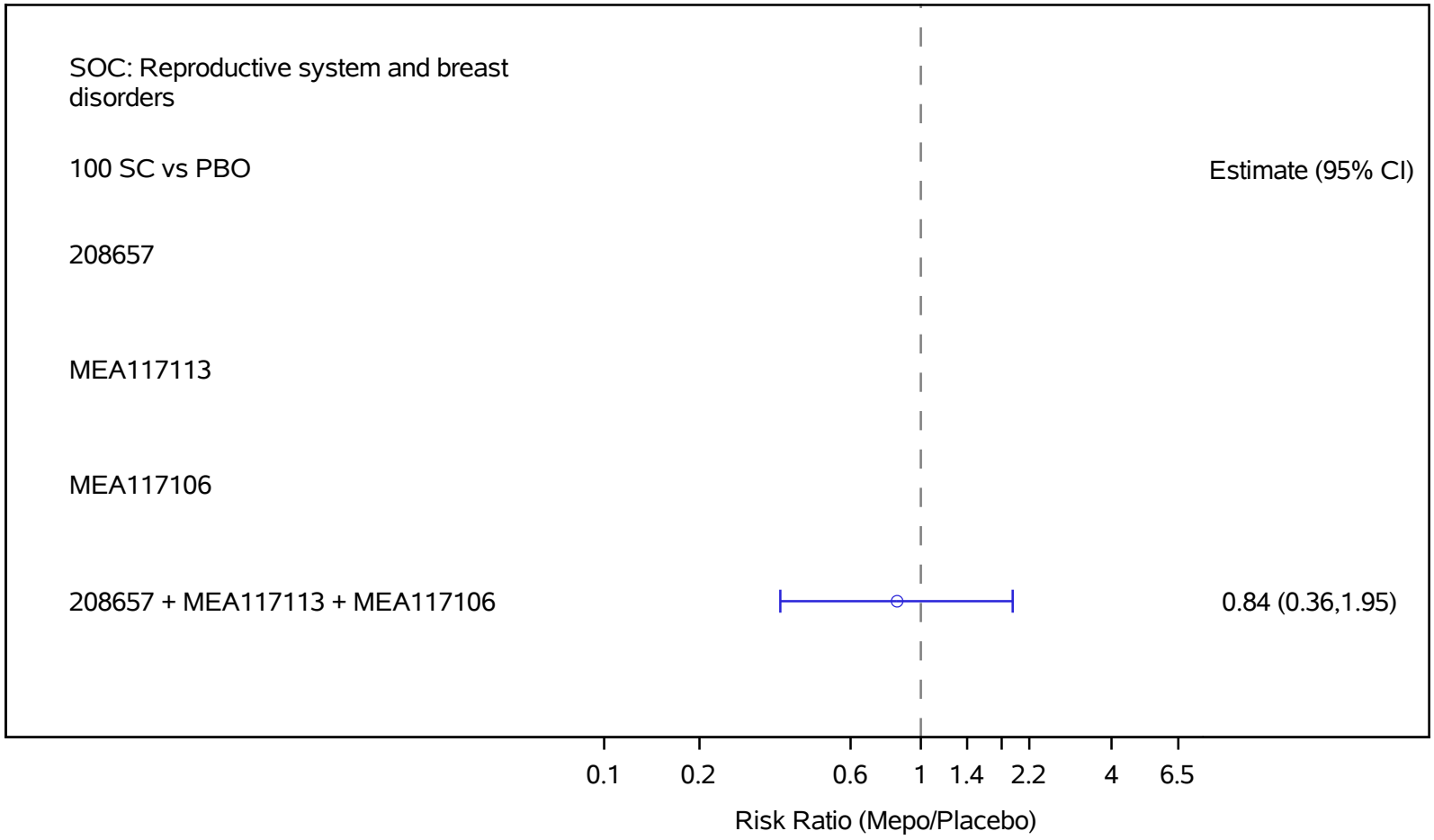

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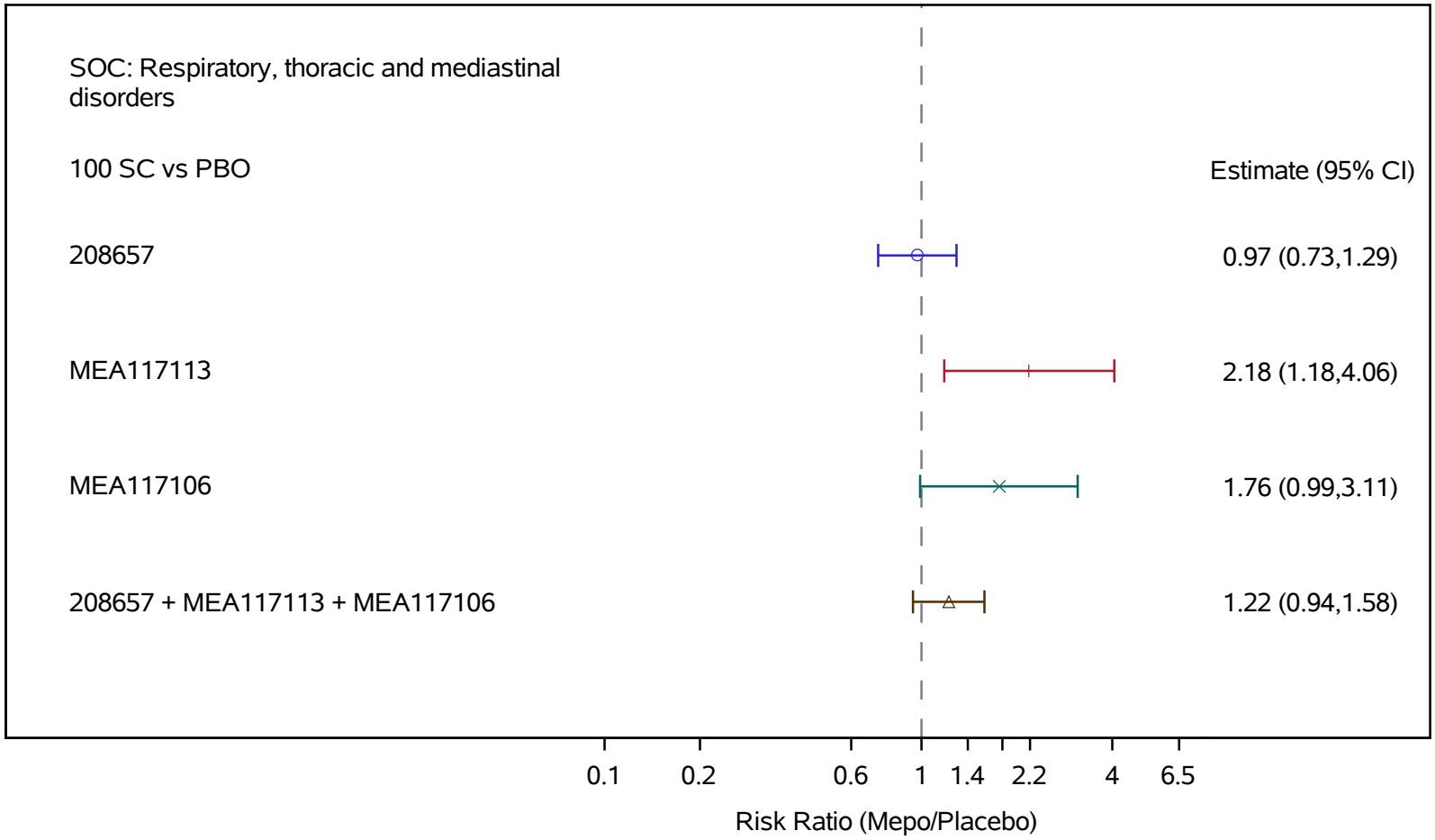

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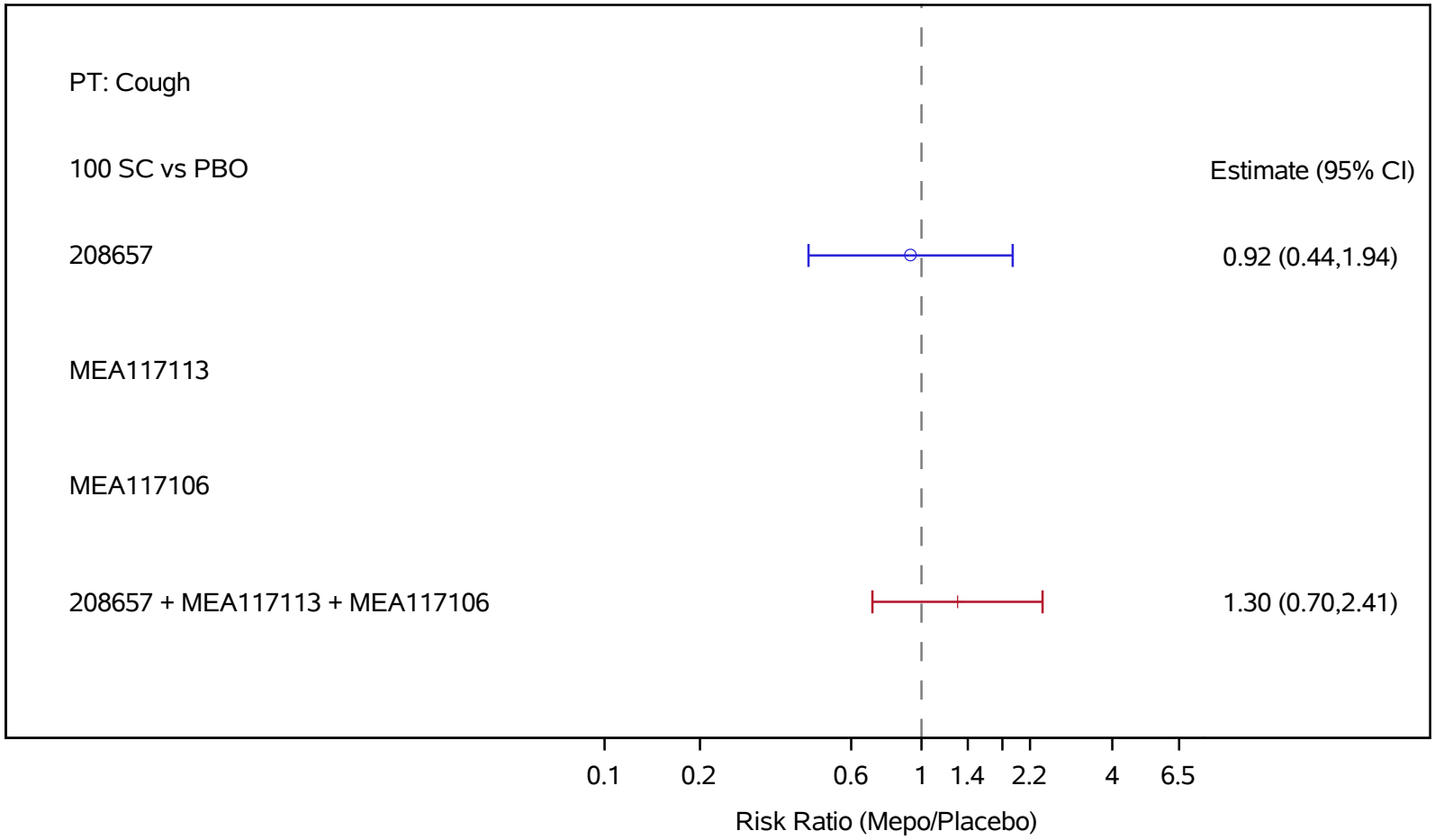

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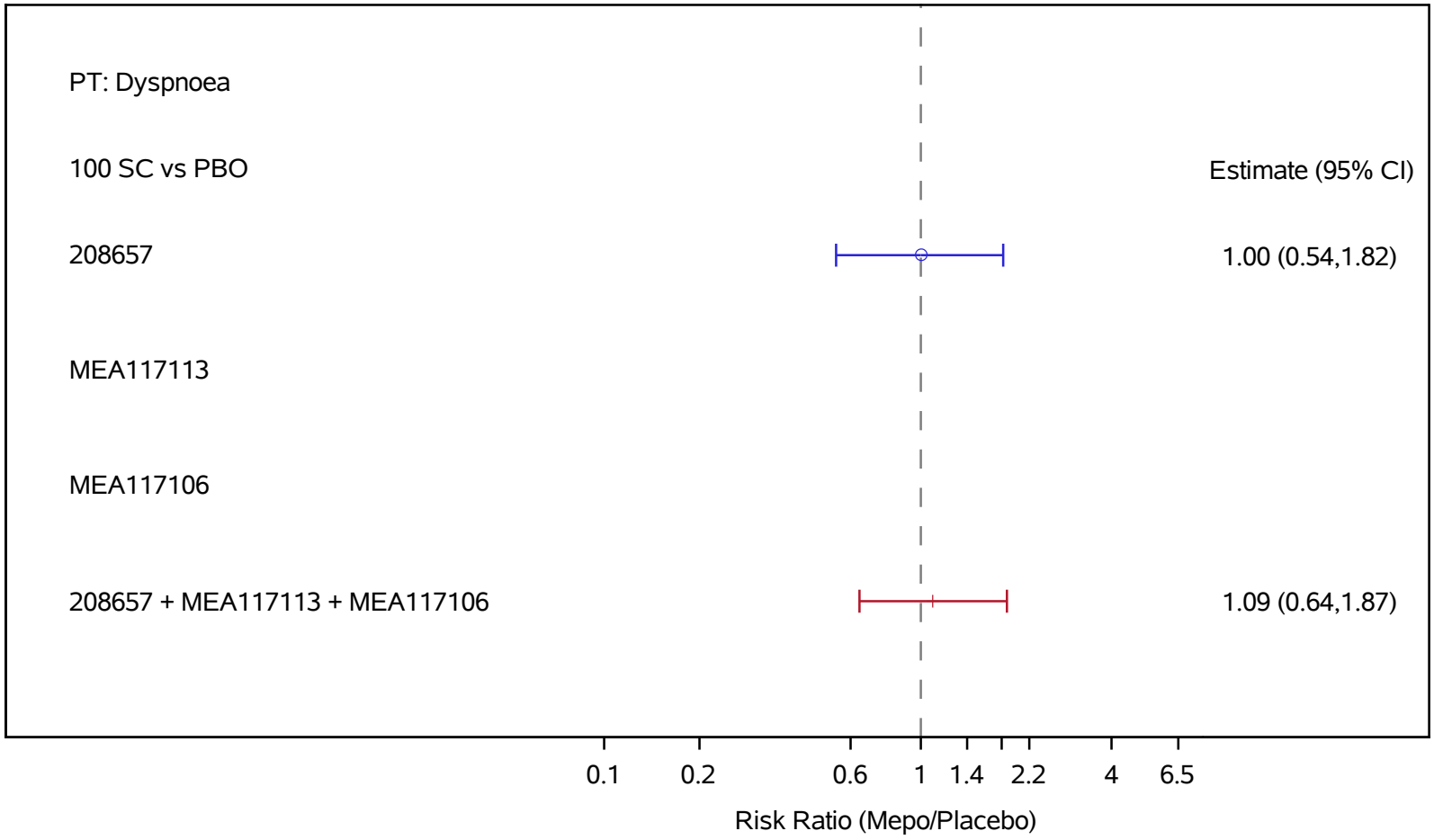

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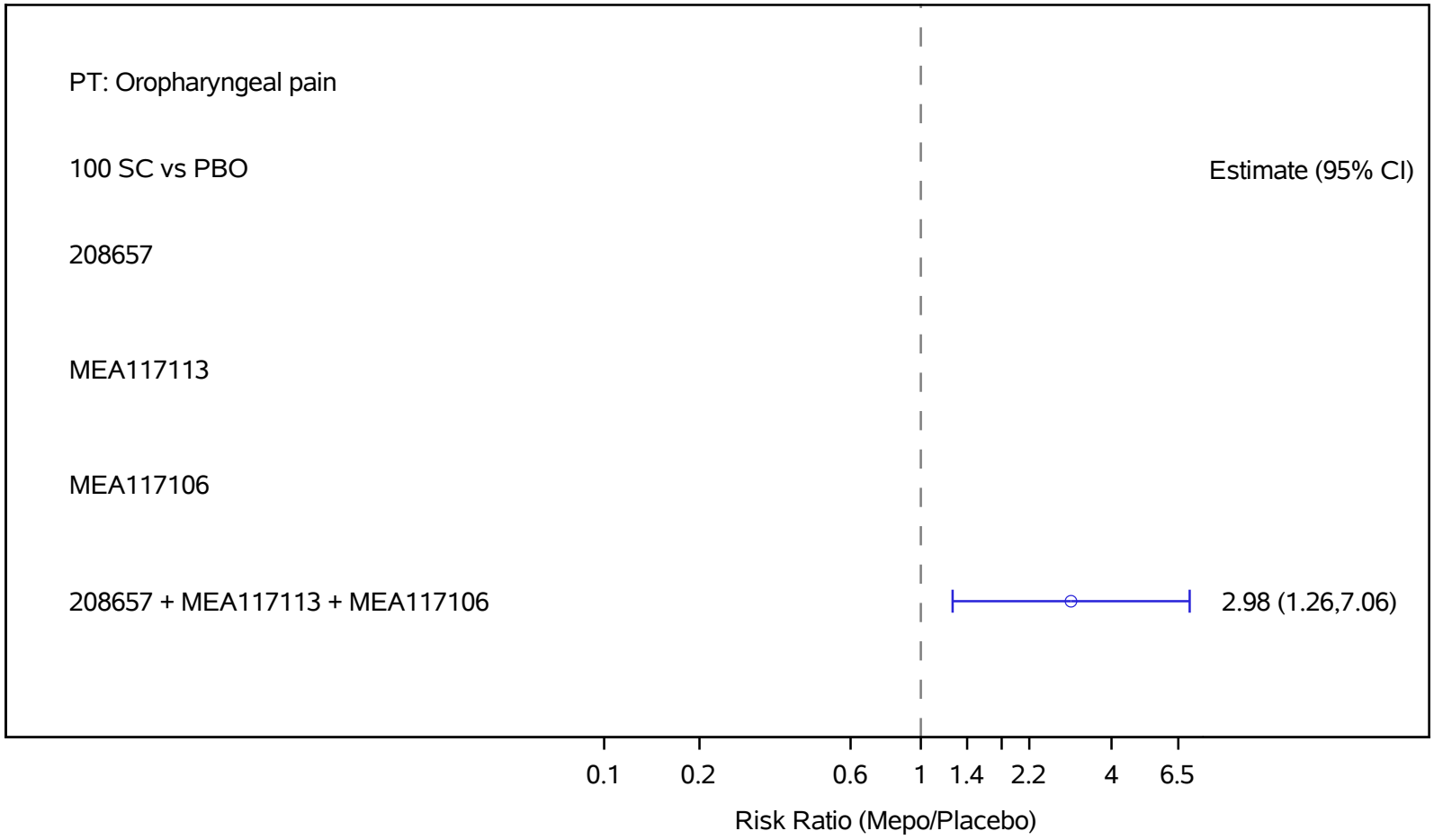

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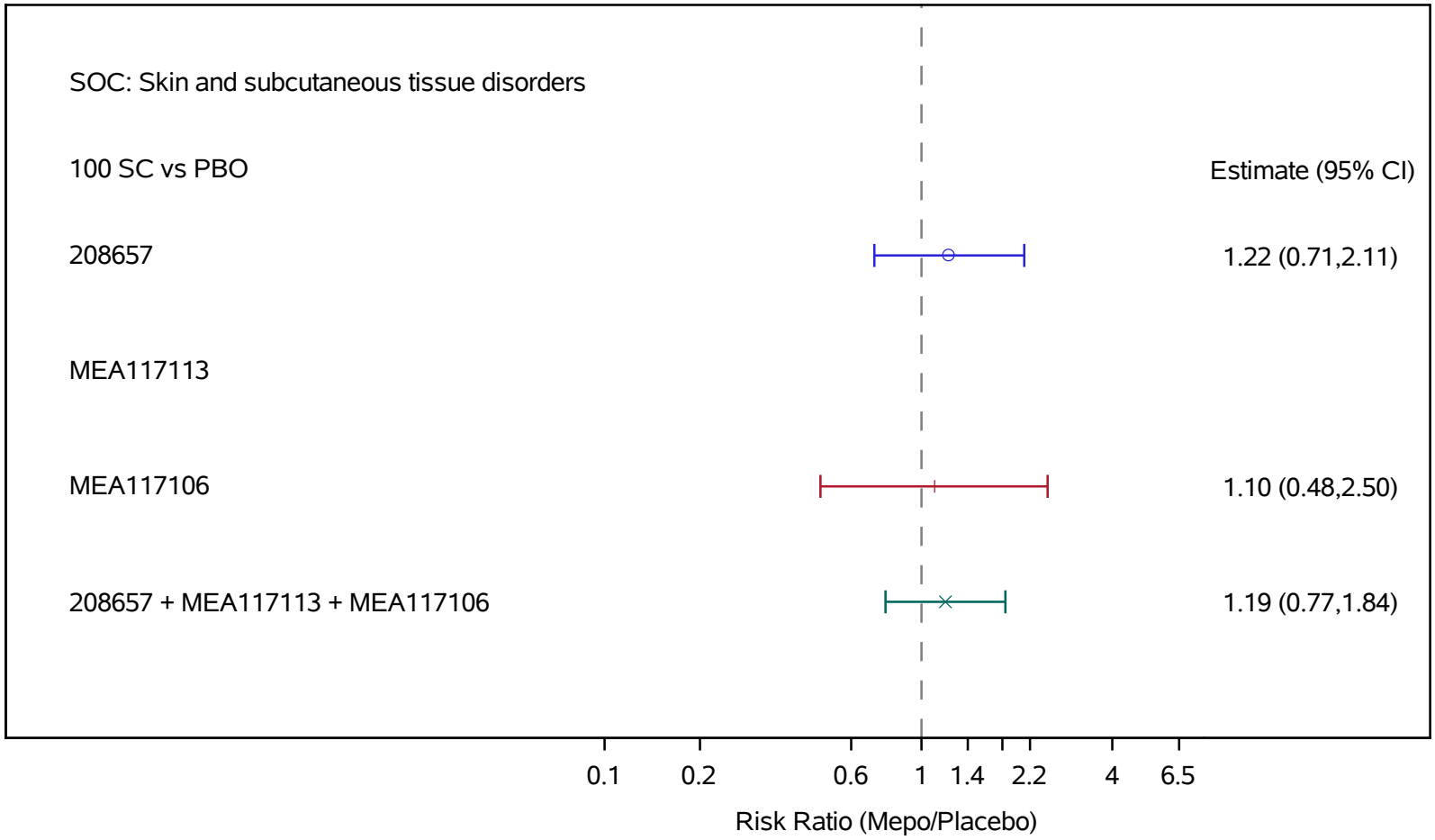
Forest Plot of Relative Risk for On-Treatment Adverse Events without Disease-Related Events Occurring in >=10% of patients or in >=10 and >=1% of patients by SOC and PT: Individual Studies and Meta-Analysis

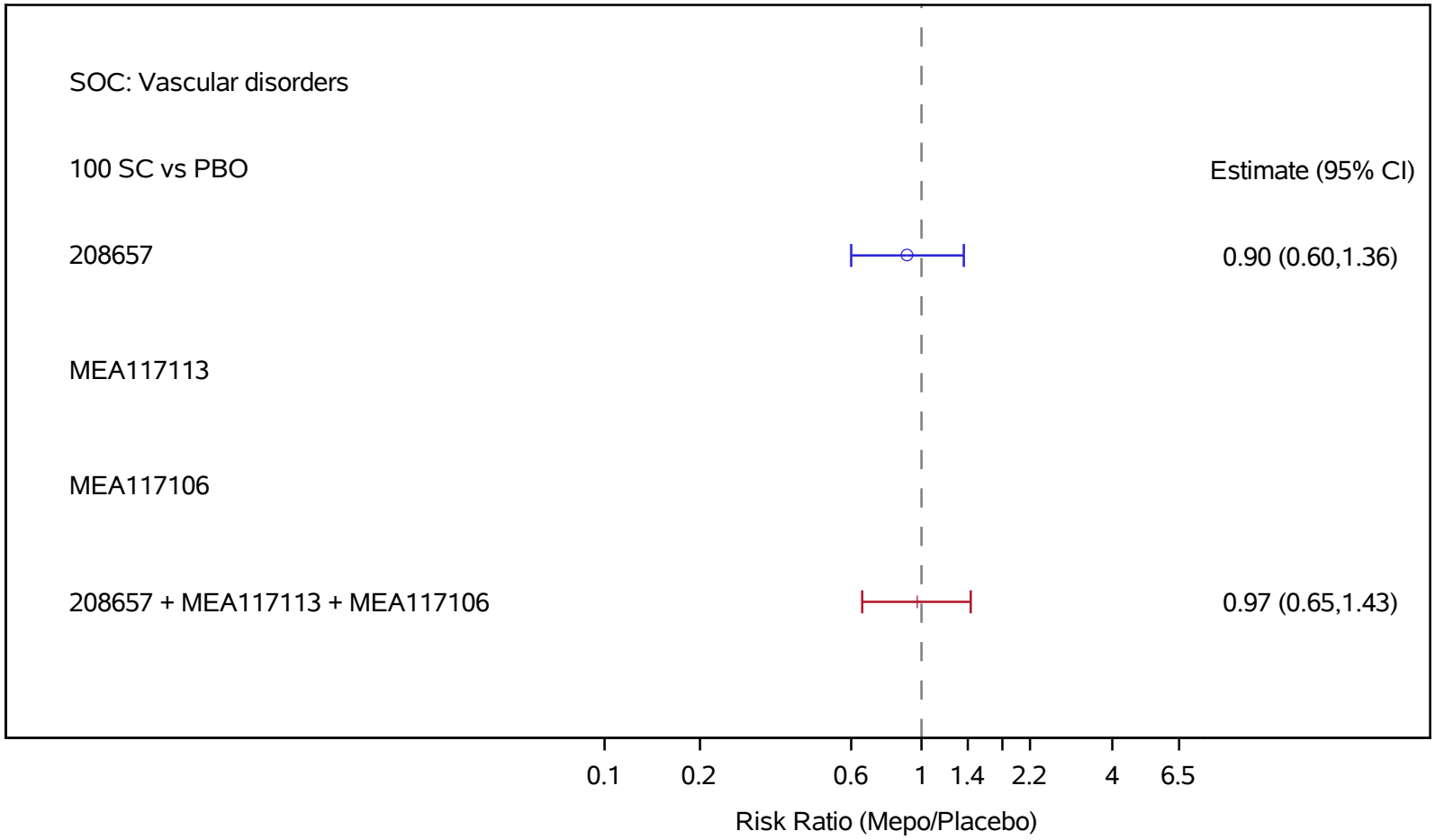


Horizontal bars indicate 95% confidence intervals for the Mepo/Placebo ratio.

Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Figure 311.4

Forest Plot of Relative Risk for On-Treatment Adverse Events without Disease-Related Events Occurring in >=10% of patients or in >=10 and >=1% of patients by SOC and PT: Individual Studies and Meta-Analysis

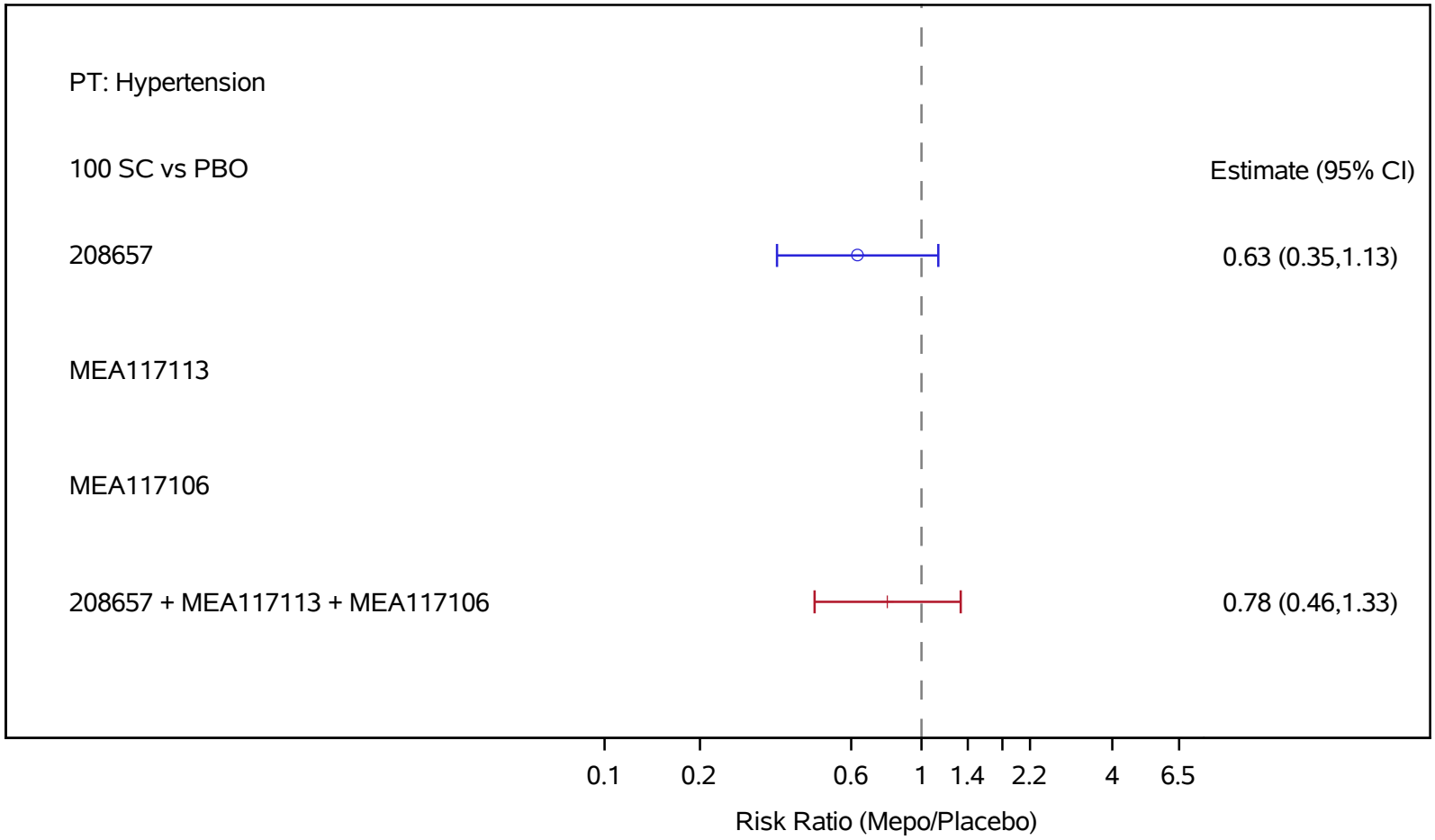


Horizontal bars indicate 95% confidence intervals for the Mepo/Placebo ratio.

Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Figure 311.4

Forest Plot of Relative Risk for On-Treatment Adverse Events without Disease-Related Events Occurring in >=10% of patients or in >=10 and >=1% of patients by SOC and PT: Individual Studies and Meta-Analysis

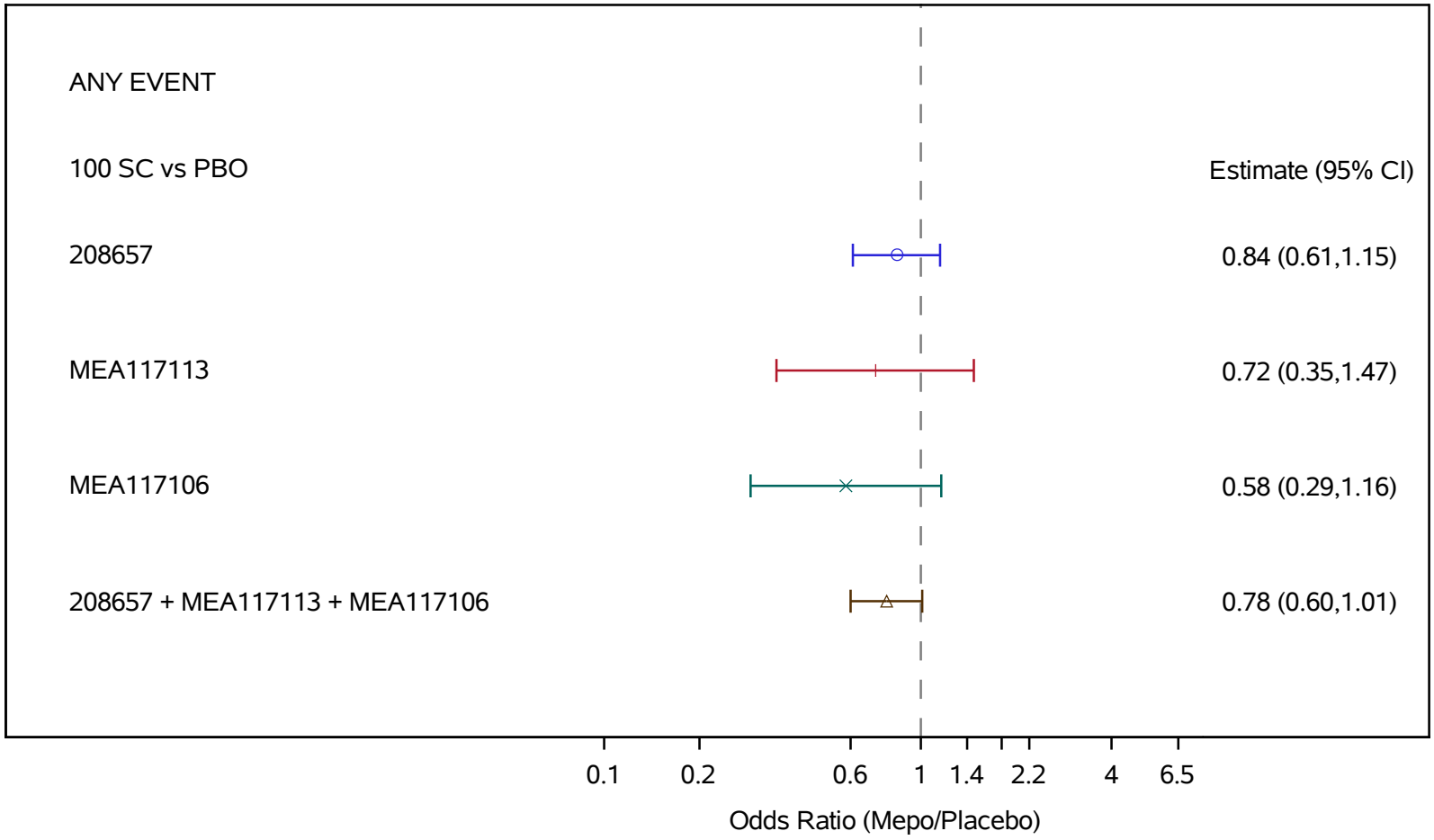


Horizontal bars indicate 95% confidence intervals for the Mepo/Placebo ratio.

Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Figure 311.5

Forest Plot of Odds ratio for Serious On-Treatment Adverse Events Occurring in >=5% of patients or in >=10 and >=1% of patients by SOC and PT: Individual Studies and Meta-Analysis

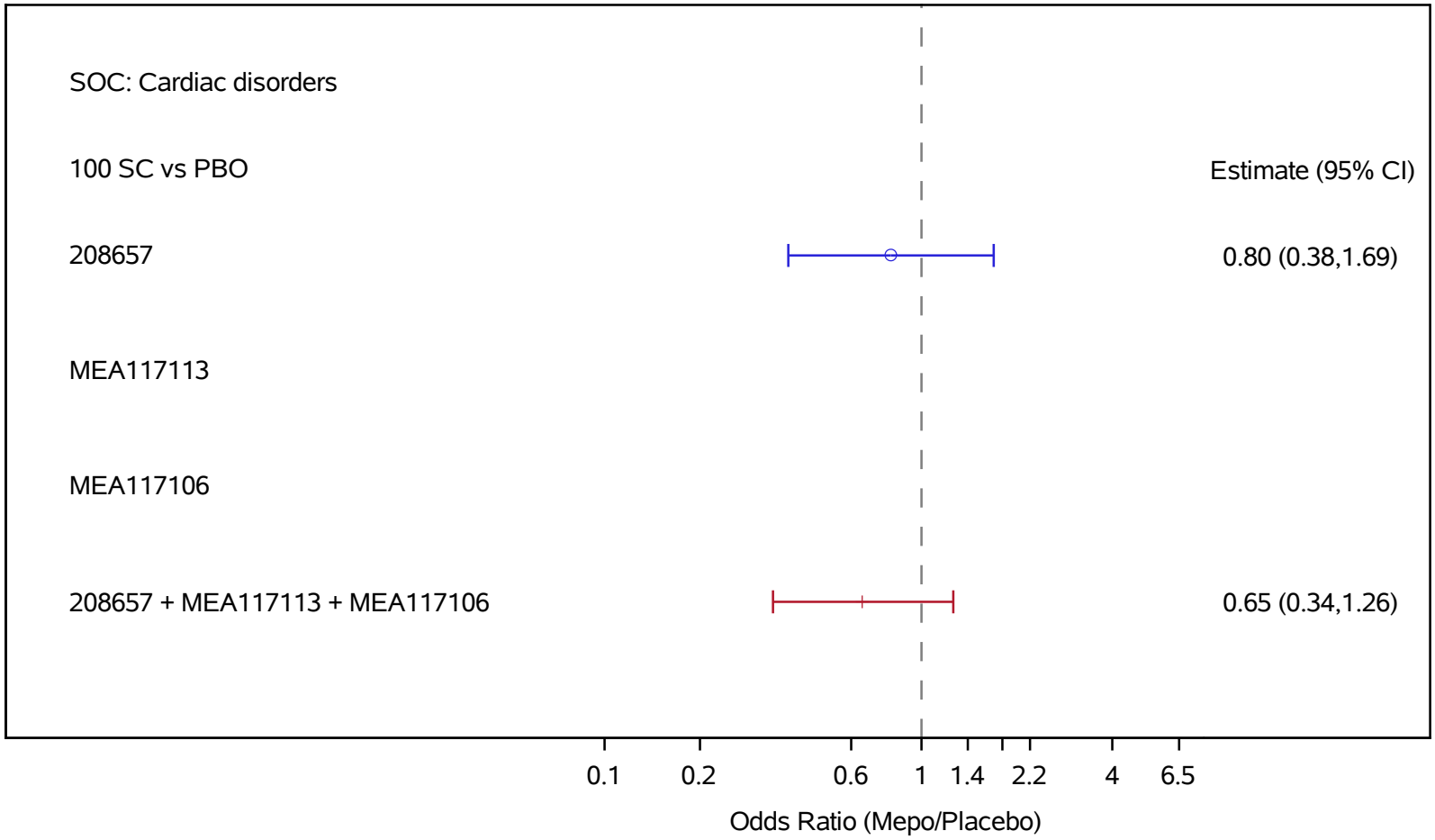


Horizontal bars indicate 95% confidence intervals for the Mepo/Placebo ratio.

Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Figure 311.5

Forest Plot of Odds ratio for Serious On-Treatment Adverse Events Occurring in >=5% of patients or in >=10 and >=1% of patients by SOC and PT: Individual Studies and Meta-Analysis

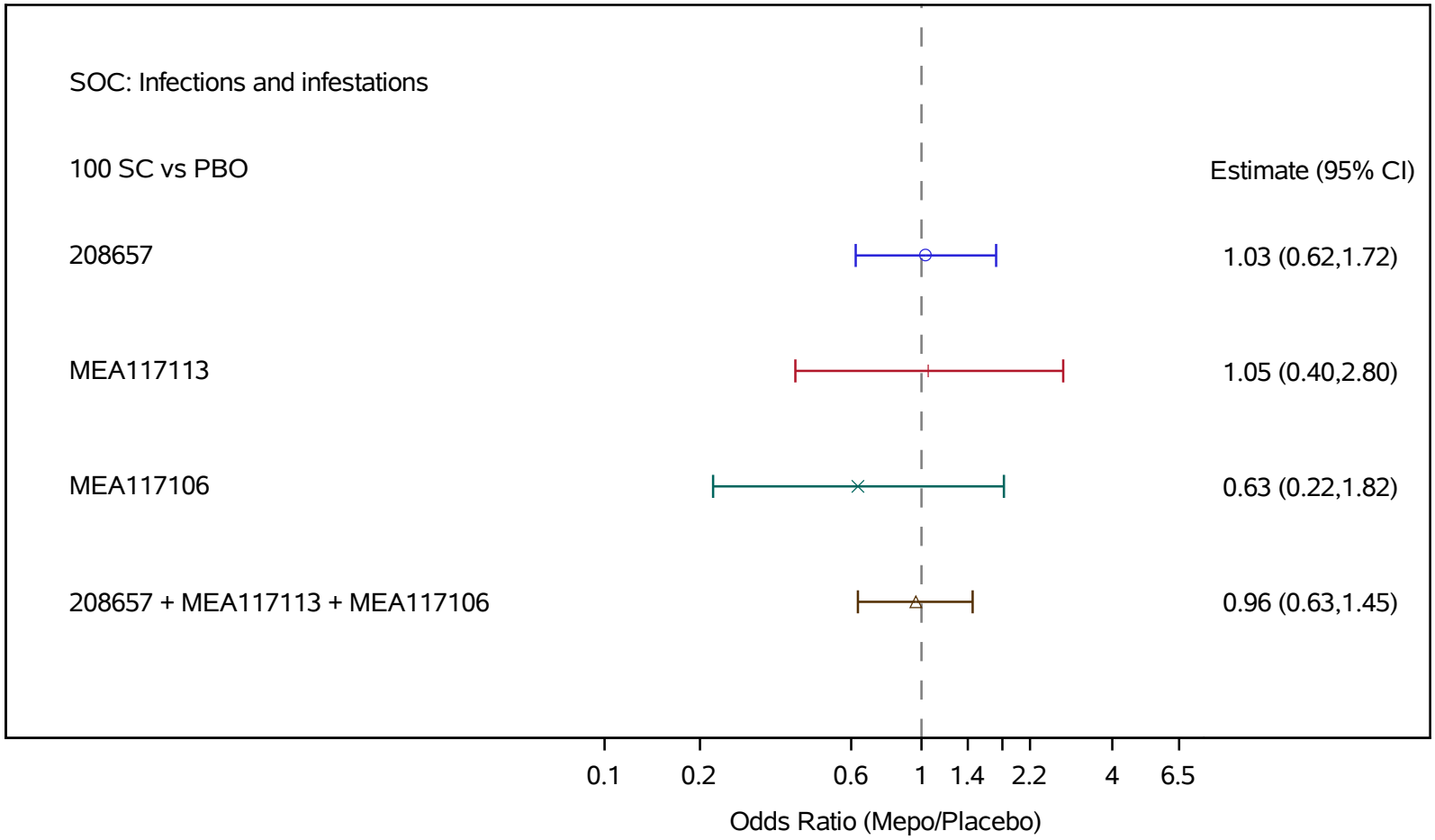


Horizontal bars indicate 95% confidence intervals for the Mepo/Placebo ratio.

Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Figure 311.5

Forest Plot of Odds ratio for Serious On-Treatment Adverse Events Occurring in >=5% of patients or in >=10 and >=1% of patients by SOC and PT: Individual Studies and Meta-Analysis

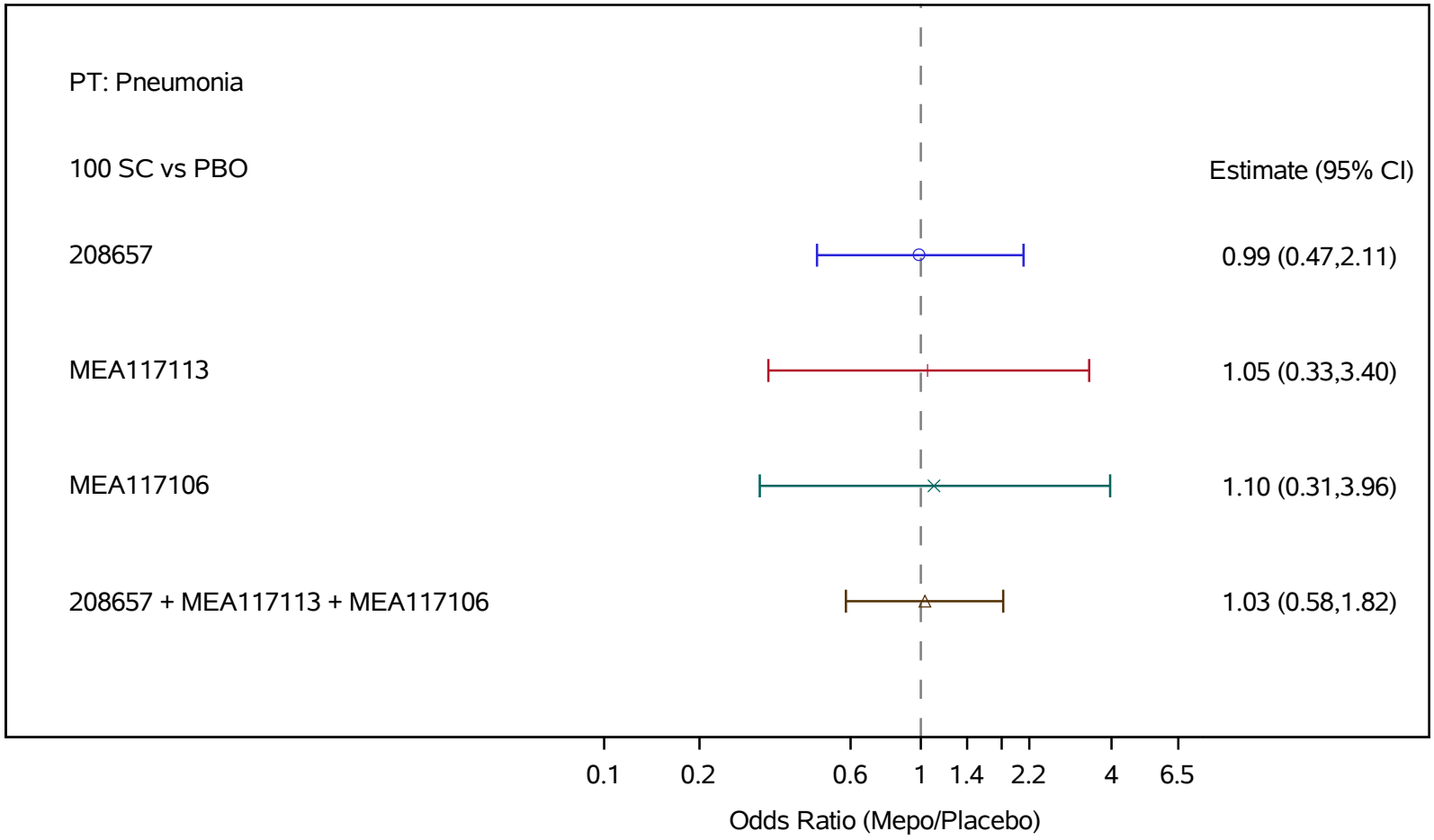


Horizontal bars indicate 95% confidence intervals for the Mepo/Placebo ratio.

Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Figure 311.5

Forest Plot of Odds ratio for Serious On-Treatment Adverse Events Occurring in >=5% of patients or in >=10 and >=1% of patients by SOC and PT: Individual Studies and Meta-Analysis

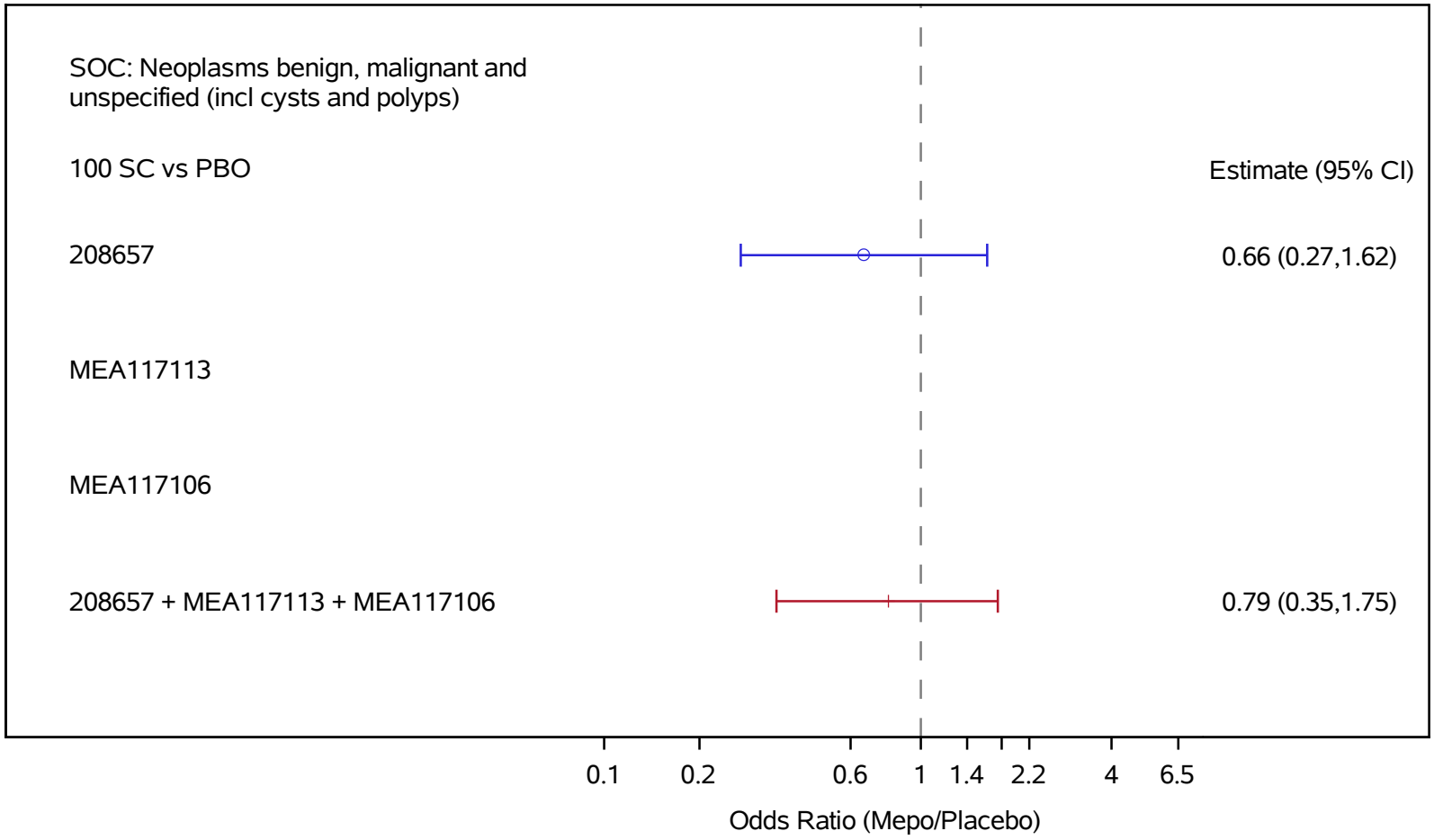


Horizontal bars indicate 95% confidence intervals for the Mepo/Placebo ratio.

Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Figure 311.5

Forest Plot of Odds ratio for Serious On-Treatment Adverse Events Occurring in >=5% of patients or in >=10 and >=1% of patients by SOC and PT: Individual Studies and Meta-Analysis

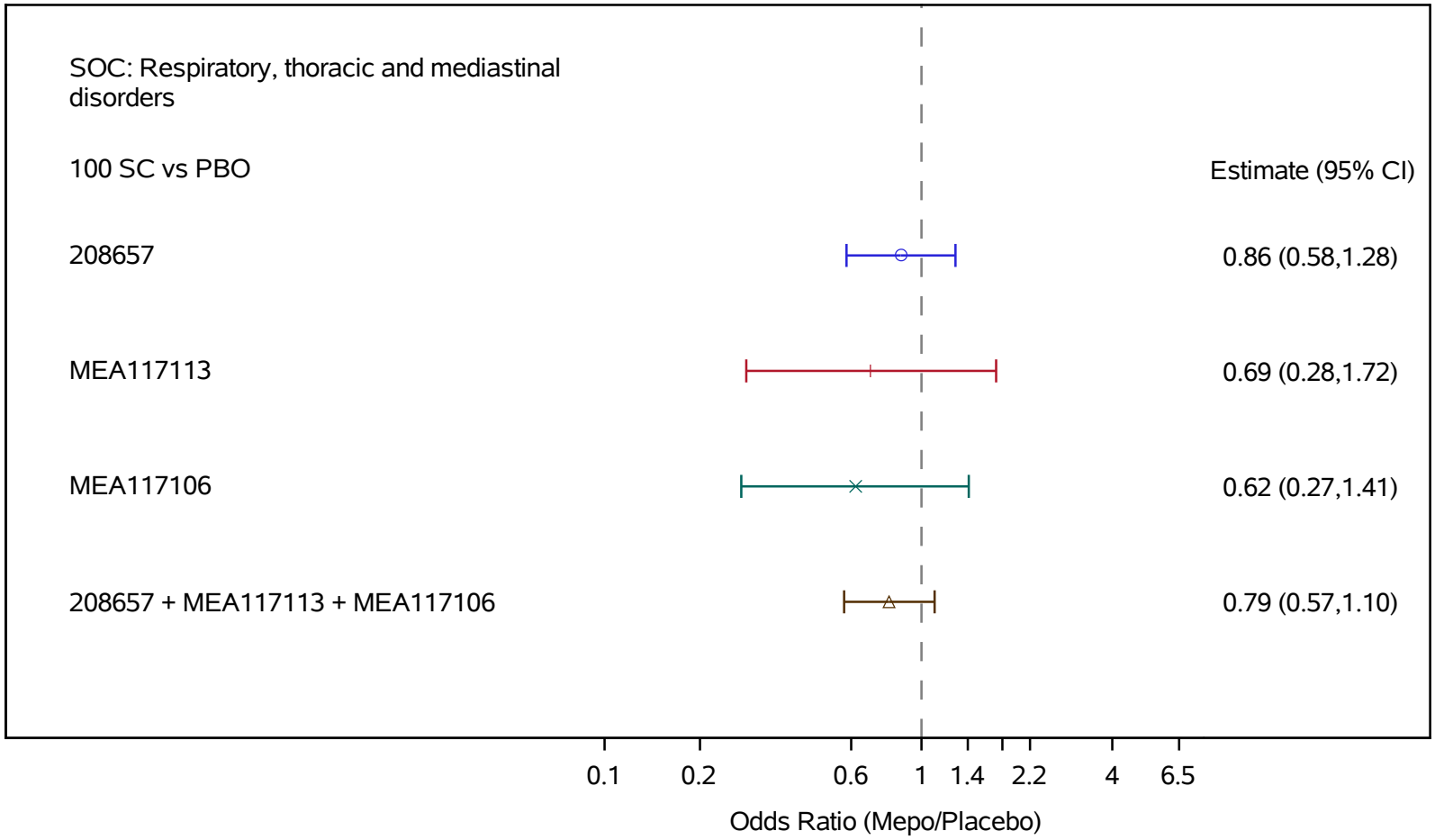


Horizontal bars indicate 95% confidence intervals for the Mepo/Placebo ratio.

Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Figure 311.5

Forest Plot of Odds ratio for Serious On-Treatment Adverse Events Occurring in >=5% of patients or in >=10 and >=1% of patients by SOC and PT: Individual Studies and Meta-Analysis

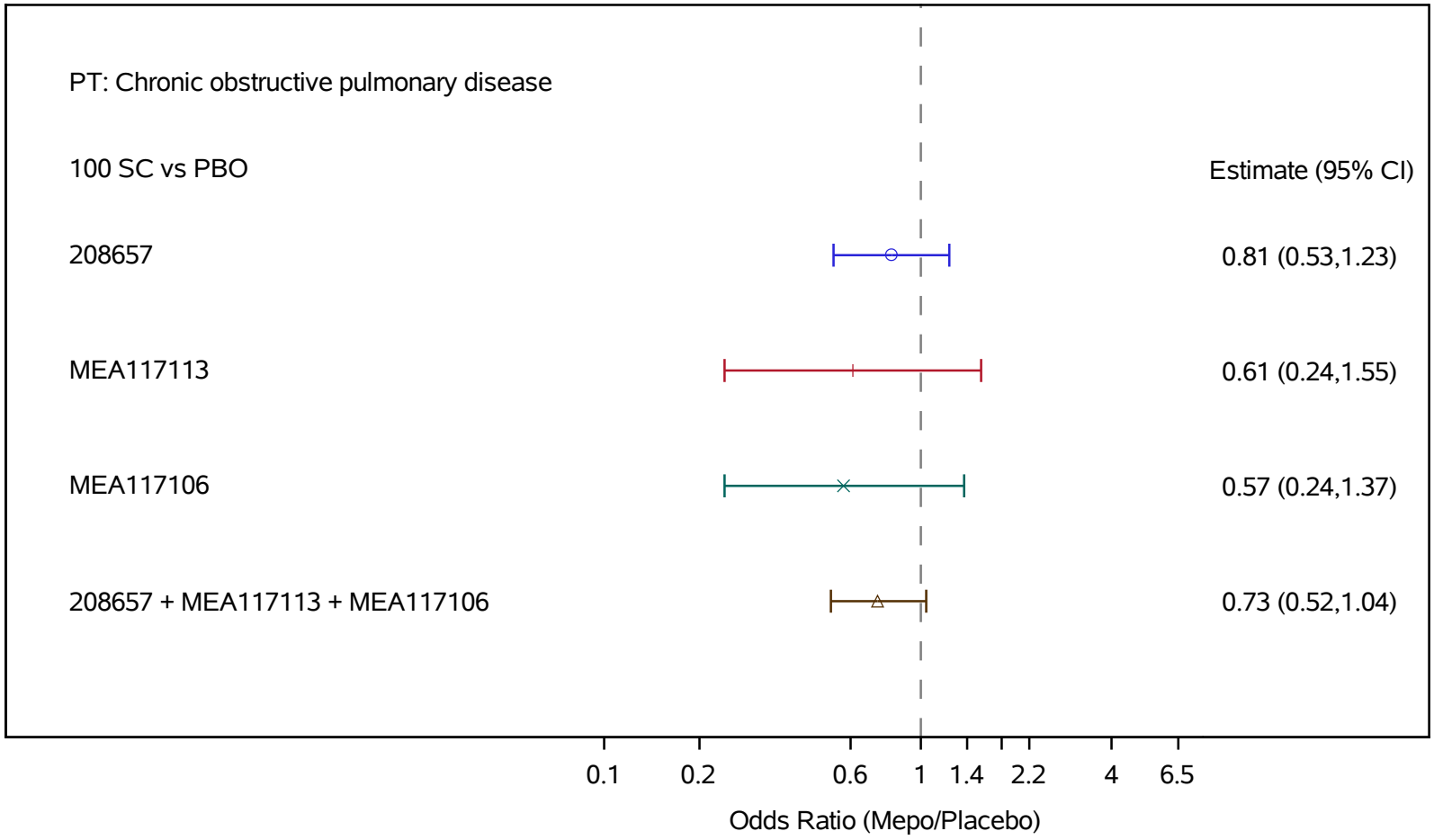


Horizontal bars indicate 95% confidence intervals for the Mepo/Placebo ratio.

Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Figure 311.5

Forest Plot of Odds ratio for Serious On-Treatment Adverse Events Occurring in >=5% of patients or in >=10 and >=1% of patients by SOC and PT: Individual Studies and Meta-Analysis

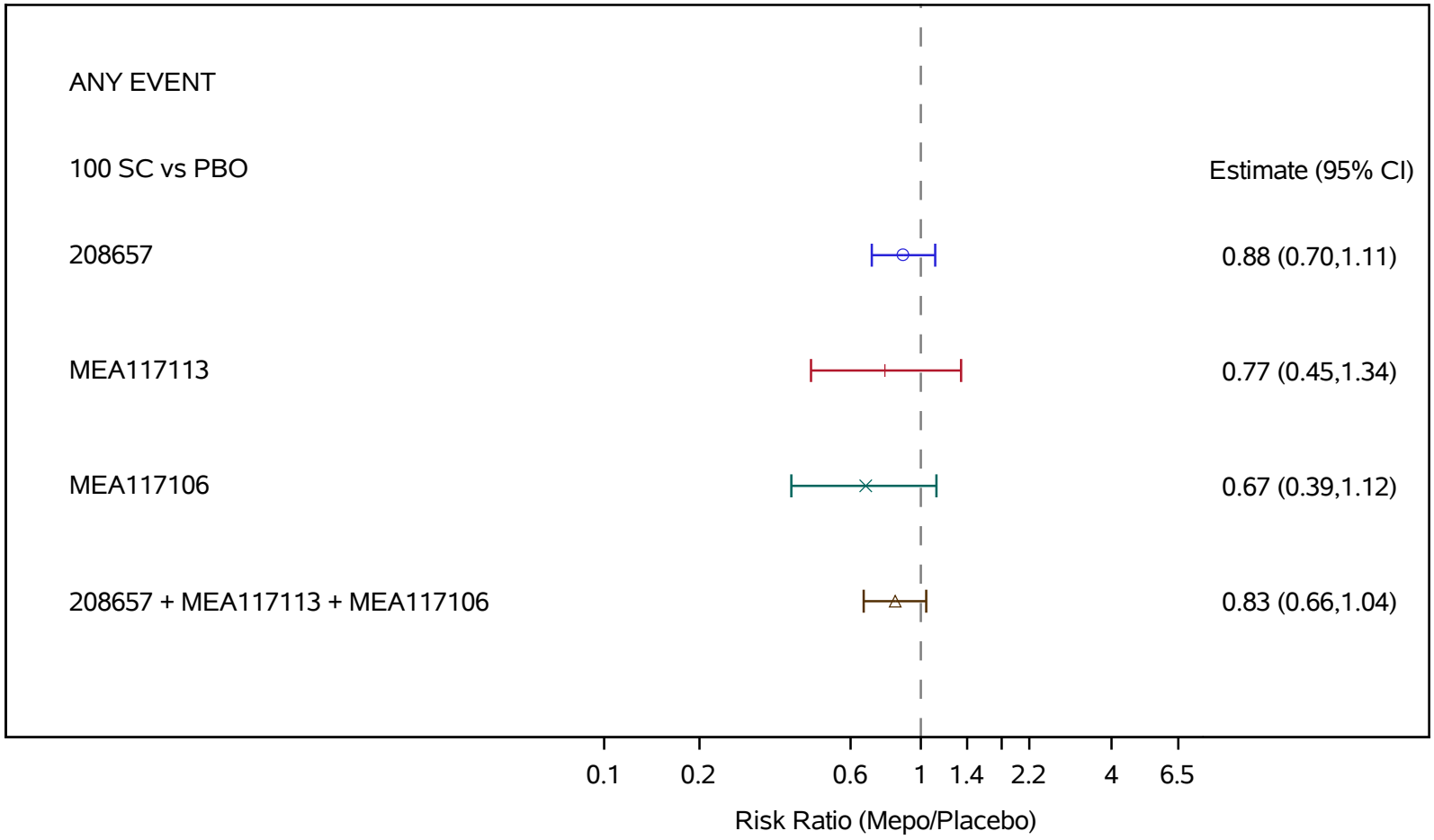


Horizontal bars indicate 95% confidence intervals for the Mepo/Placebo ratio.

Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Figure 311.6

Forest Plot of Relative Risk for Serious On-Treatment Adverse Events Occurring in >=5% of patients or in >=10 and >=1% of patients by SOC and PT: Individual Studies and Meta-Analysis

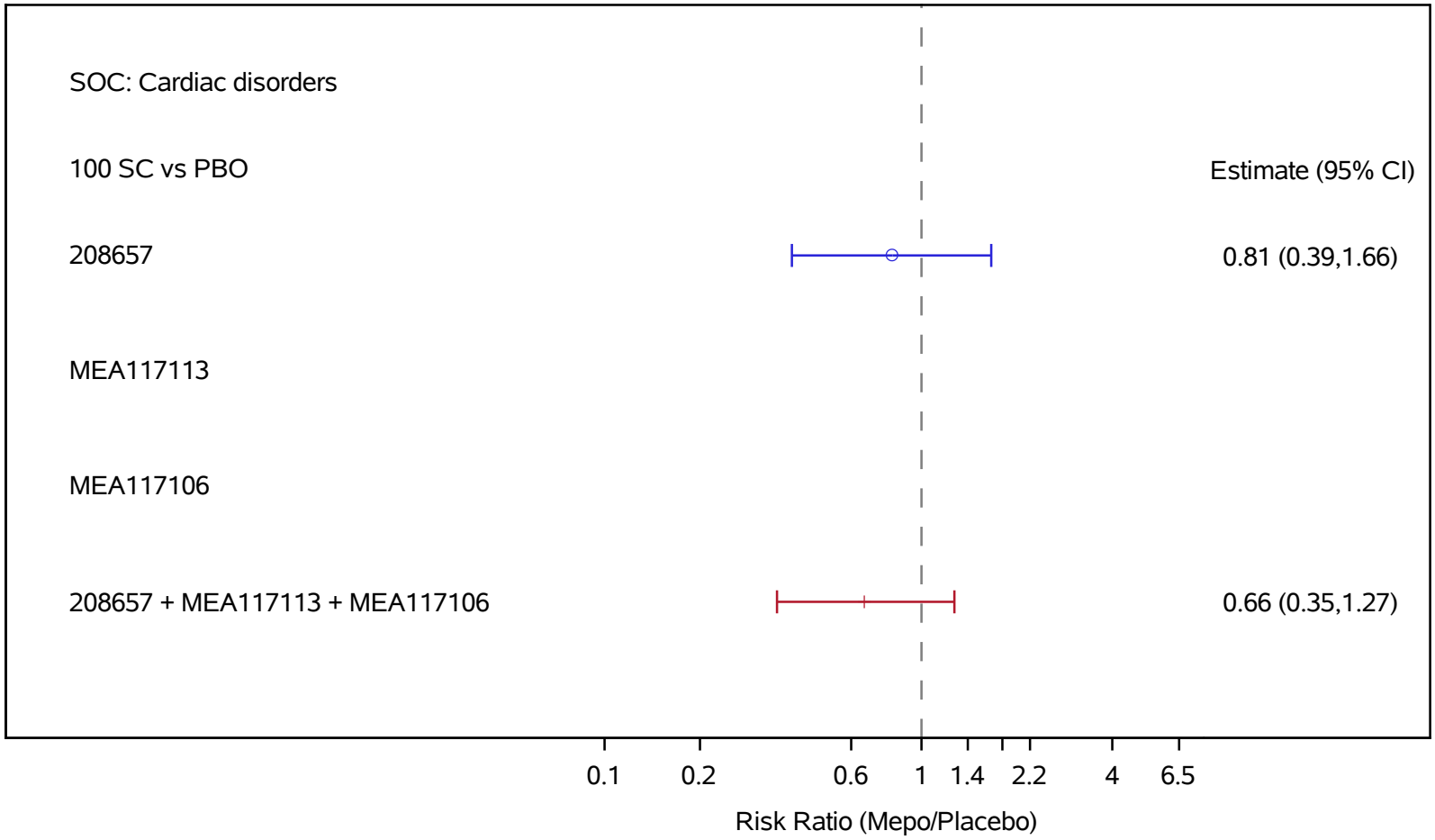


Horizontal bars indicate 95% confidence intervals for the Mepo/Placebo ratio.

Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Figure 311.6

Forest Plot of Relative Risk for Serious On-Treatment Adverse Events Occurring in >=5% of patients or in >=10 and >=1% of patients by SOC and PT: Individual Studies and Meta-Analysis

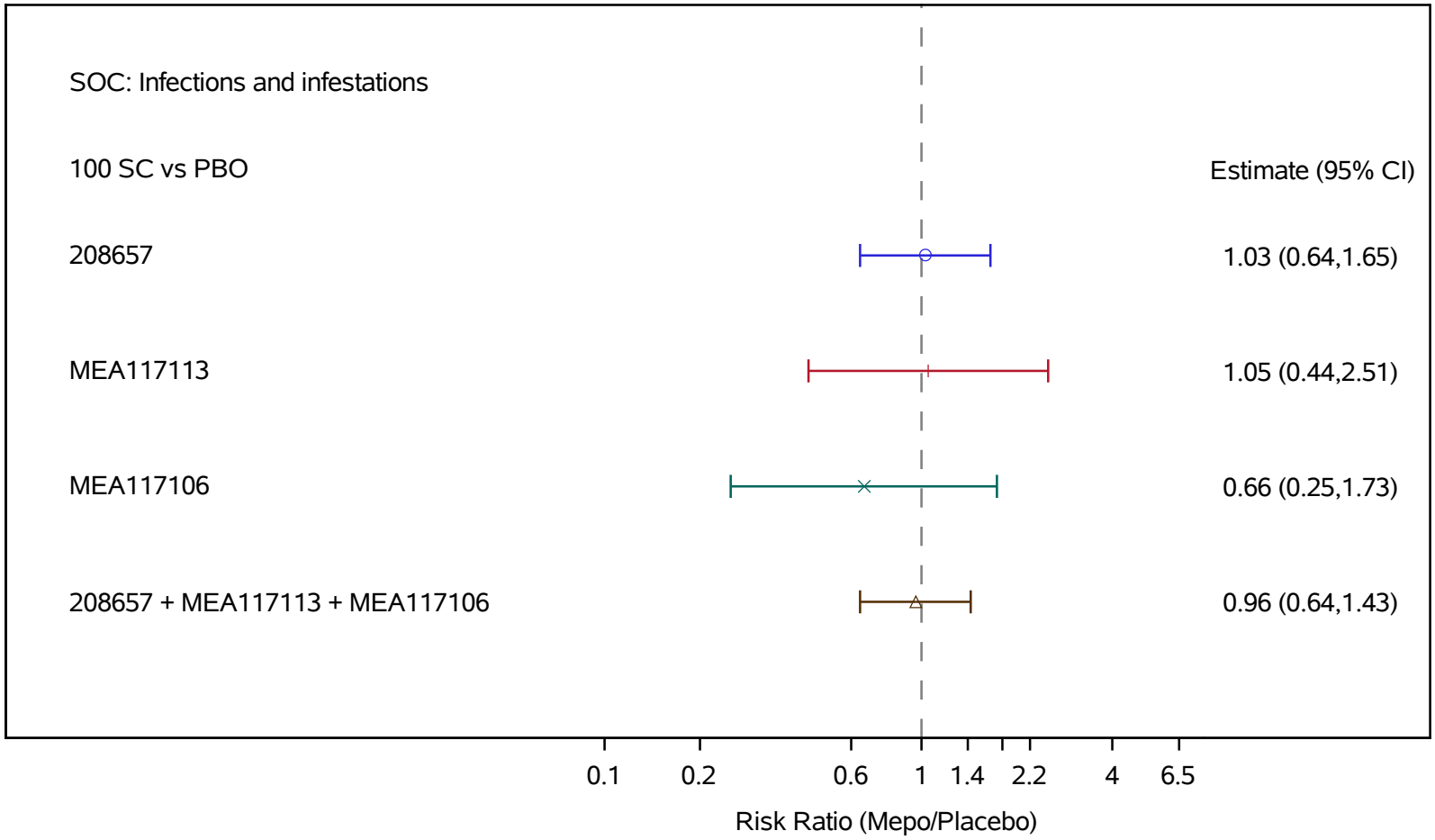


Horizontal bars indicate 95% confidence intervals for the Mepo/Placebo ratio.

Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Figure 311.6

Forest Plot of Relative Risk for Serious On-Treatment Adverse Events Occurring in >=5% of patients or in >=10 and >=1% of patients by SOC and PT: Individual Studies and Meta-Analysis



Horizontal bars indicate 95% confidence intervals for the Mepo/Placebo ratio.

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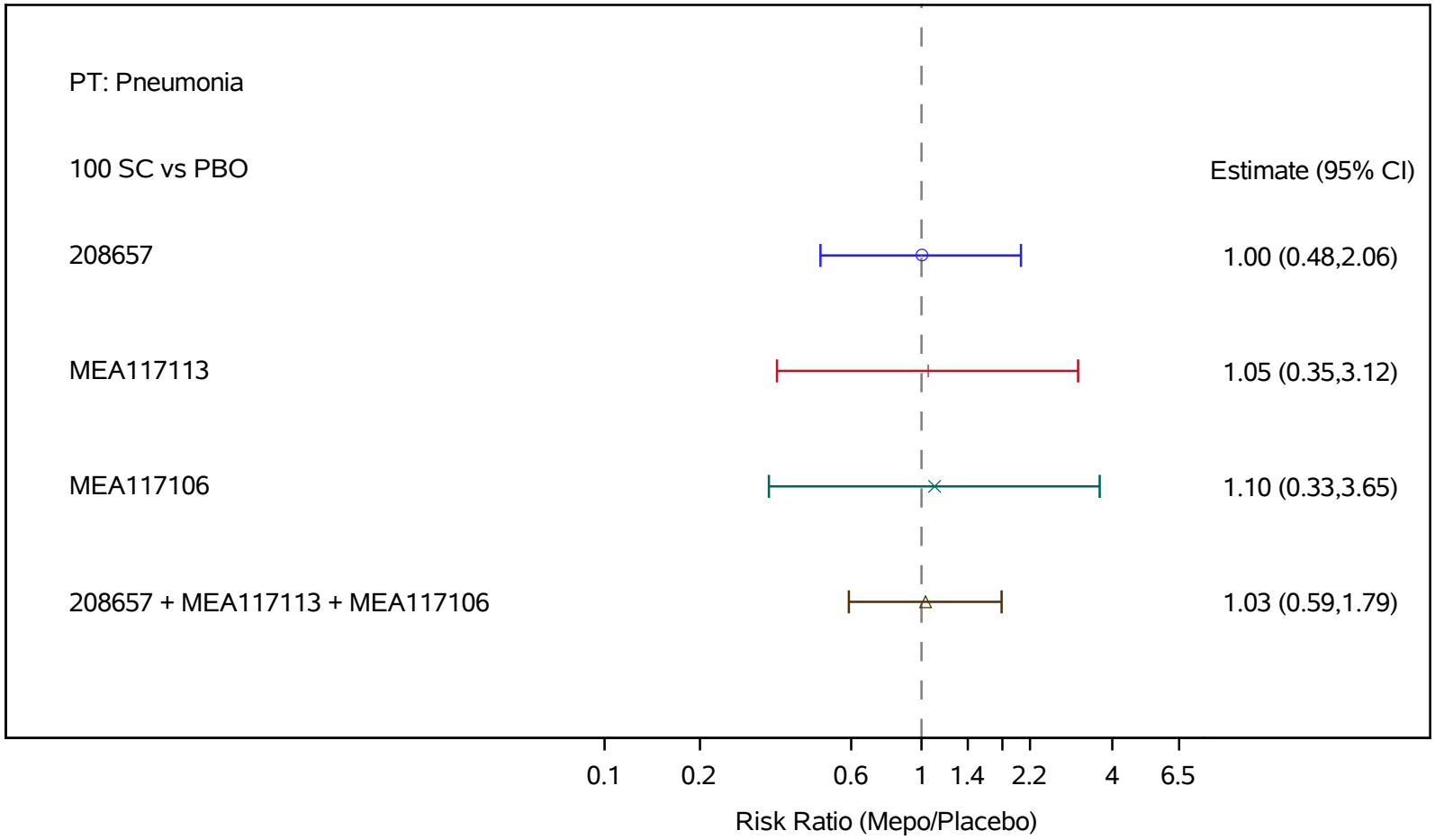
Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Figure 311.6

Forest Plot of Relative Risk for Serious On-Treatment Adverse Events Occurring in >=5% of patients or in >=10 and >=1% of patients by SOC and PT: Individual Studies and Meta-Analysis

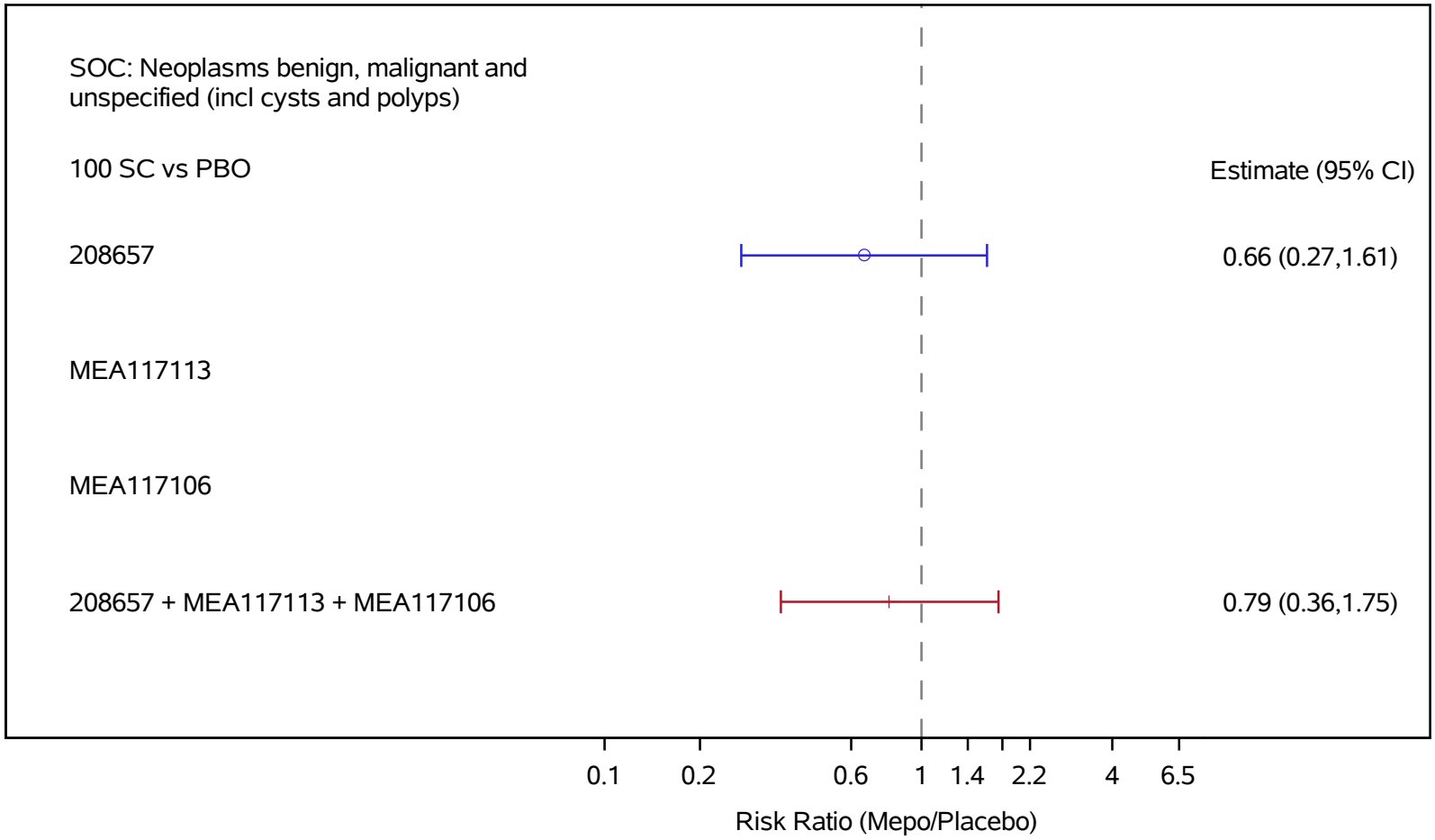


Horizontal bars indicate 95% confidence intervals for the Mepo/Placebo ratio.

Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Figure 311.6

Forest Plot of Relative Risk for Serious On-Treatment Adverse Events Occurring in >=5% of patients or in >=10 and >=1% of patients by SOC and PT: Individual Studies and Meta-Analysis

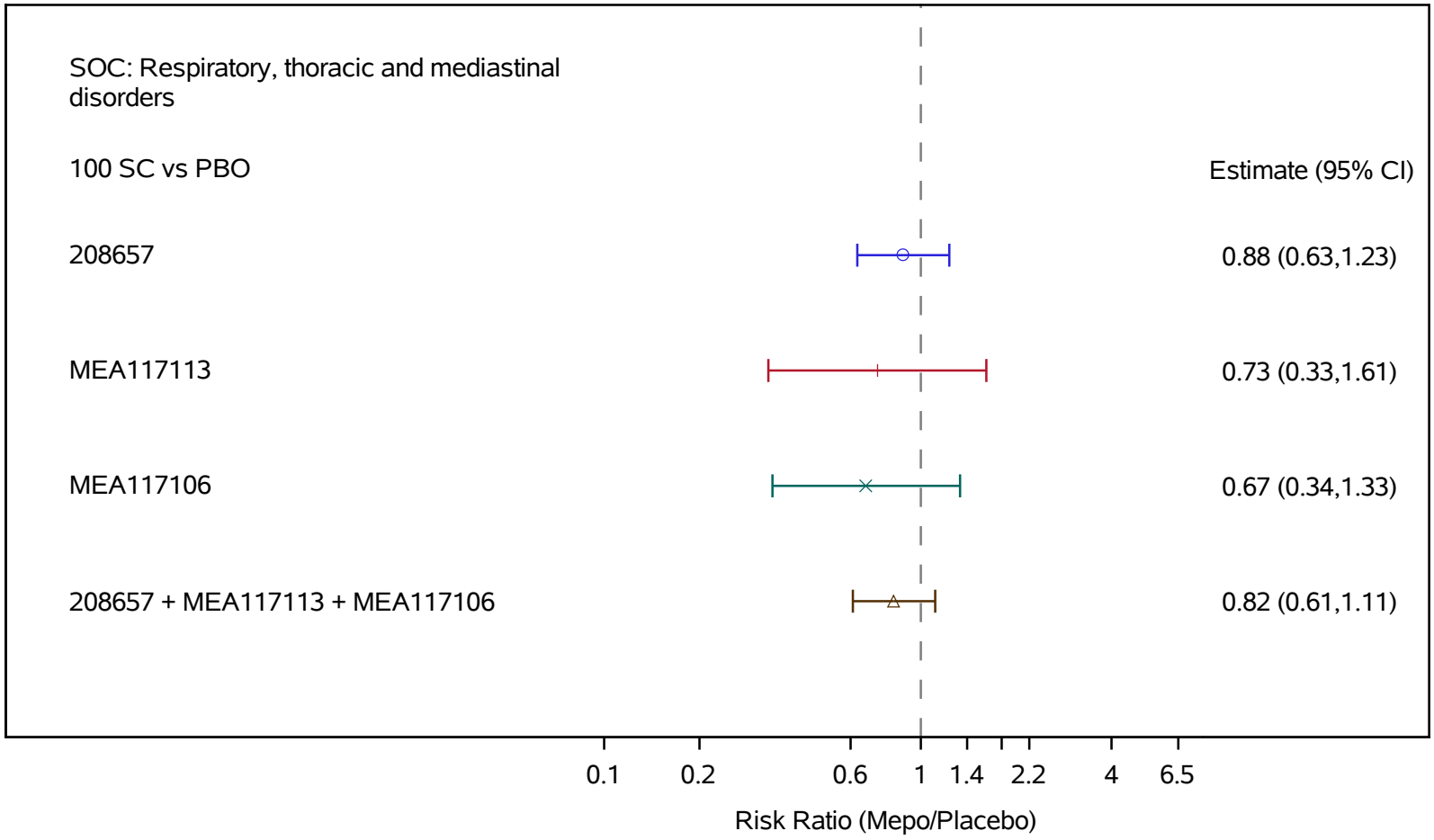


Horizontal bars indicate 95% confidence intervals for the Mepo/Placebo ratio.

Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Figure 311.6

Forest Plot of Relative Risk for Serious On-Treatment Adverse Events Occurring in >=5% of patients or in >=10 and >=1% of patients by SOC and PT: Individual Studies and Meta-Analysis

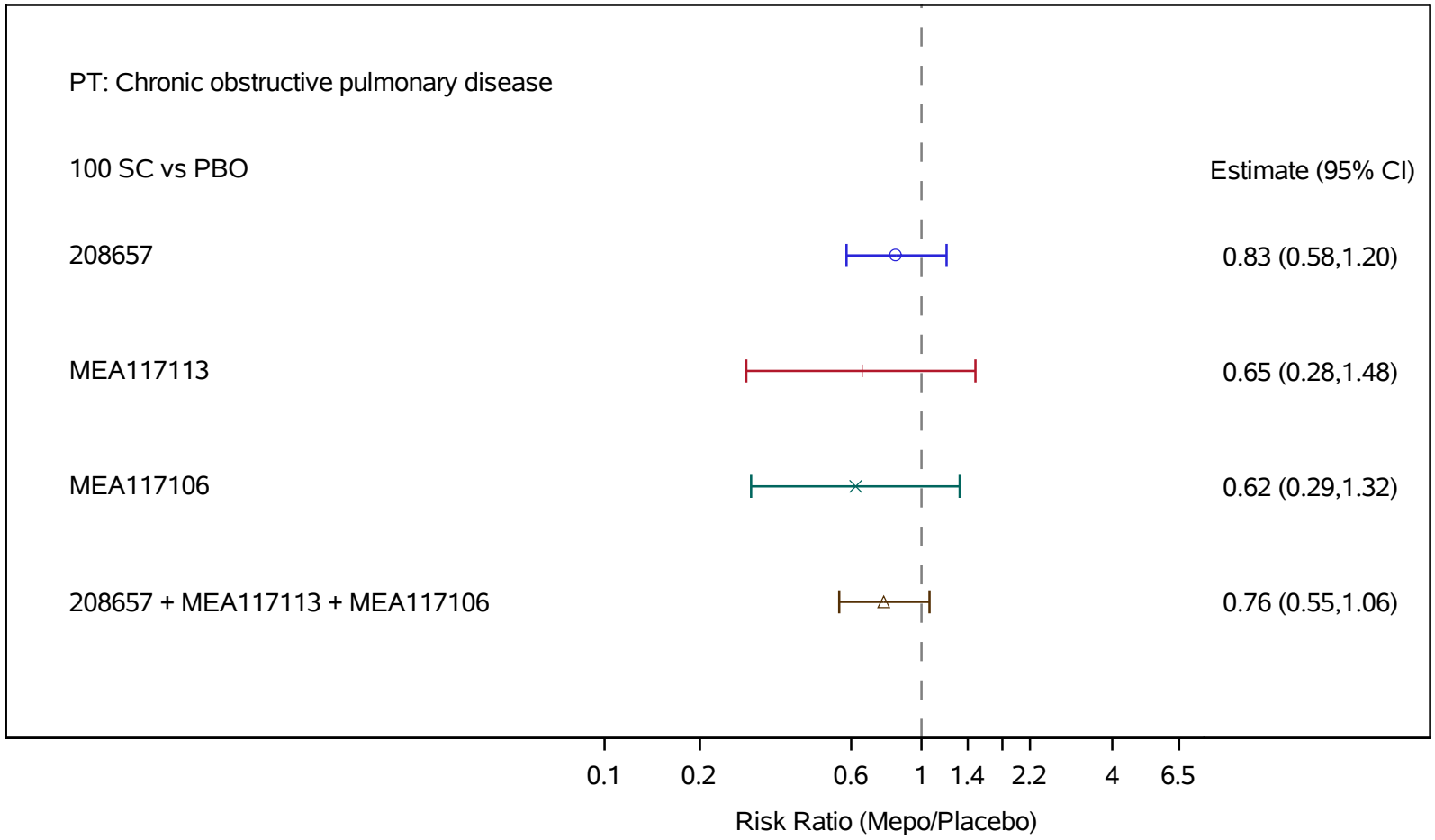


Horizontal bars indicate 95% confidence intervals for the Mepo/Placebo ratio.

Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Figure 311.6

Forest Plot of Relative Risk for Serious On-Treatment Adverse Events Occurring in >=5% of patients or in >=10 and >=1% of patients by SOC and PT: Individual Studies and Meta-Analysis

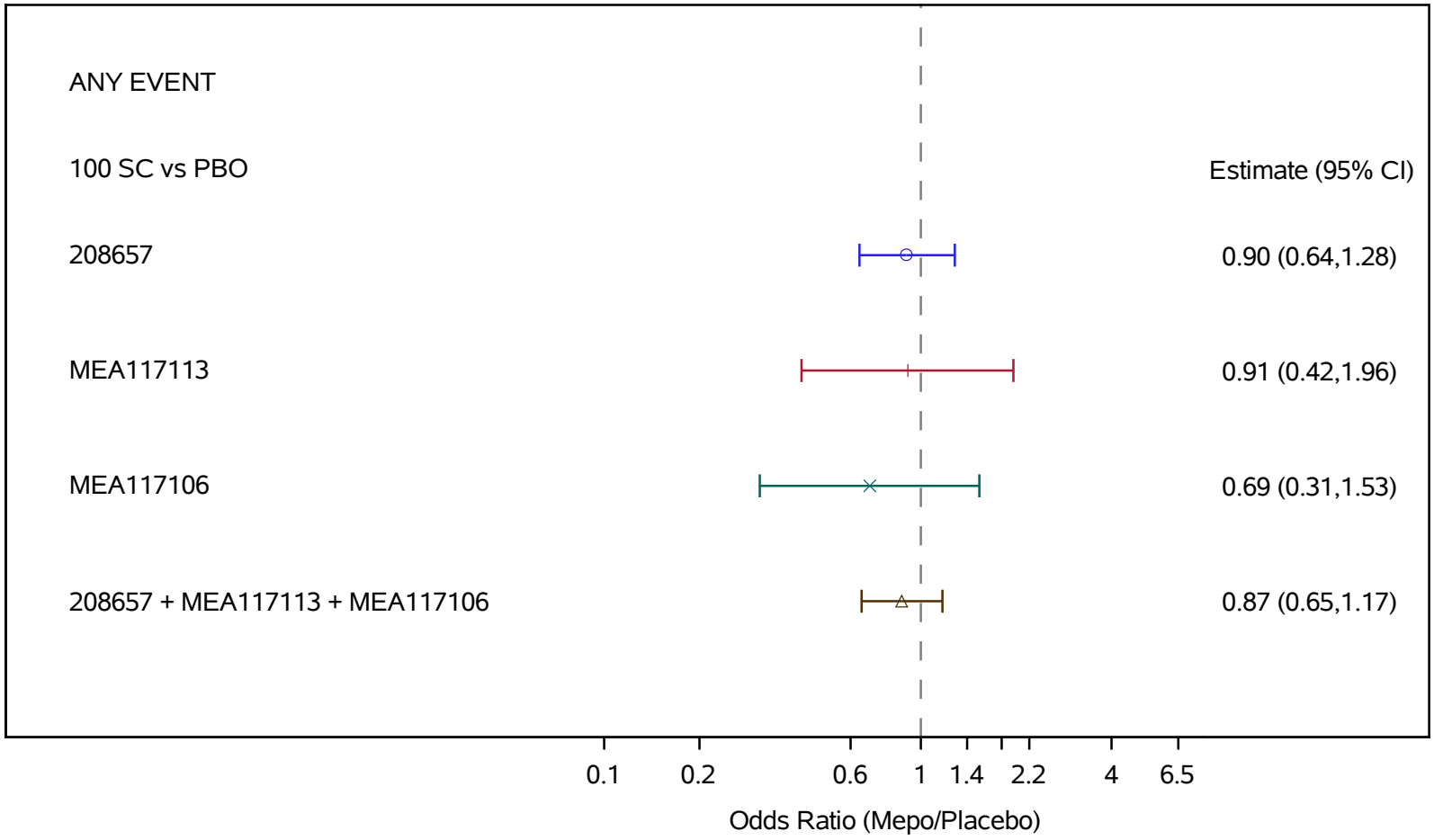


Horizontal bars indicate 95% confidence intervals for the Mepo/Placebo ratio.

Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Figure 311.7

Forest Plot of Odds ratio for Serious On-Treatment Adverse Events without disease Related Events Occurring in >=5% of patients or in >=10 and >=1% of patients by SOC and PT: Individual Studies and Meta-Analysis



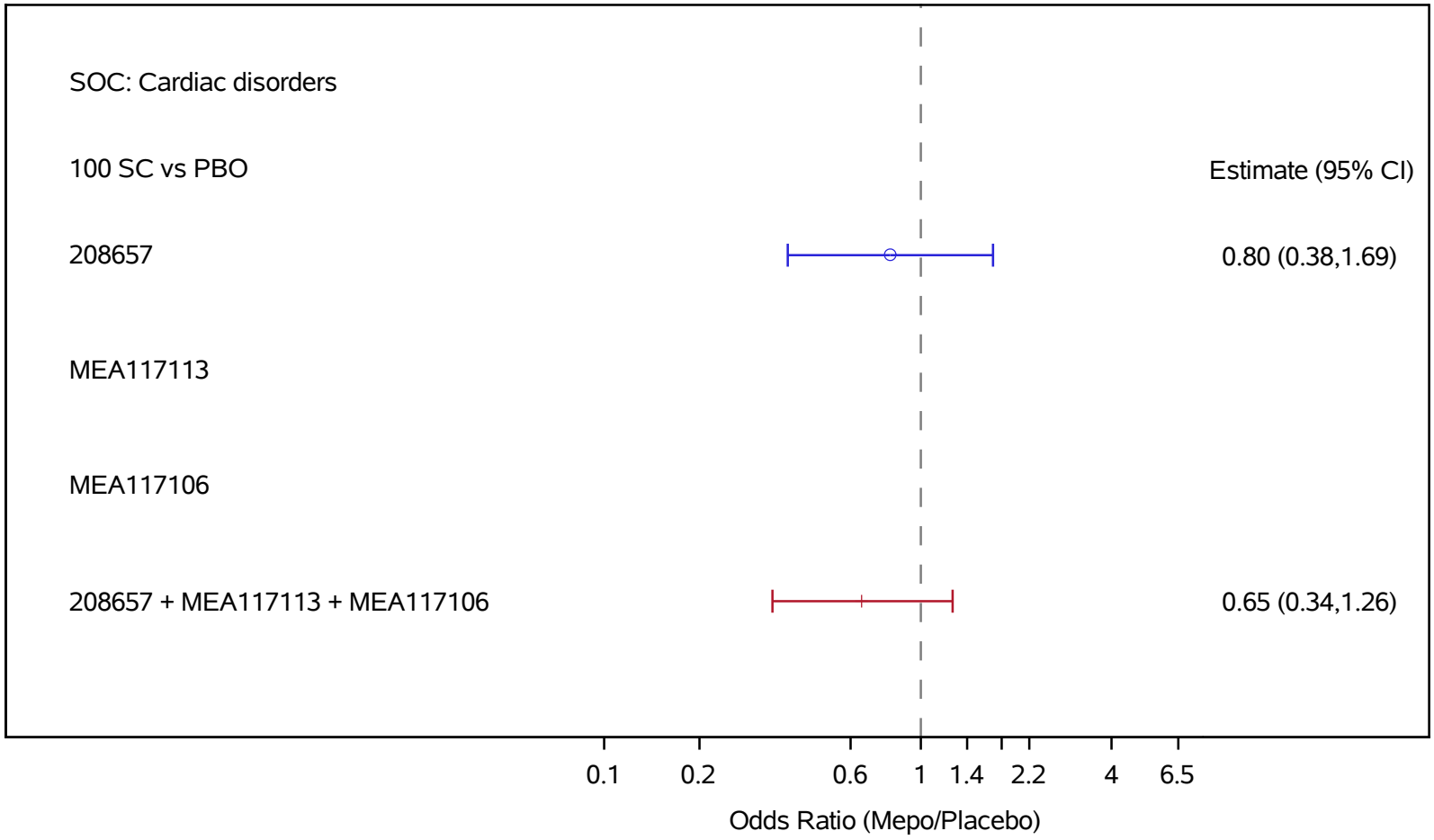
Horizontal bars indicate 95% confidence intervals for the Mepo/Placebo ratio.

/mnt/code/postcsr_01/prod/tfls/f_s_ae_onae_sae_dre_or.sas 17JUL2025 18:10

Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Figure 311.7

Forest Plot of Odds ratio for Serious On-Treatment Adverse Events without disease Related Events Occurring in >=5% of patients or in >=10 and >=1% of patients by SOC and PT: Individual Studies and Meta-Analysis

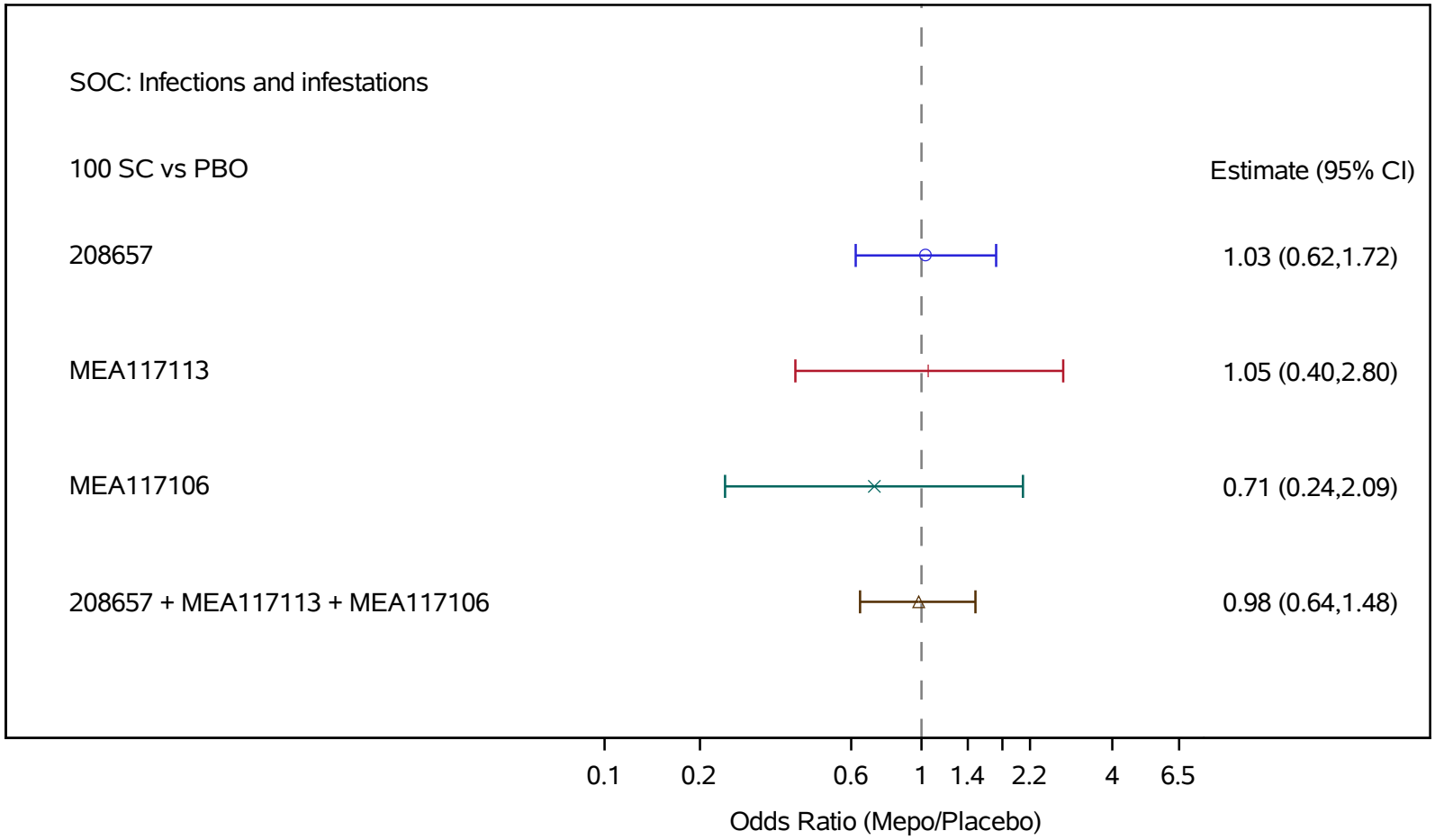


Horizontal bars indicate 95% confidence intervals for the Mepo/Placebo ratio.

Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Figure 311.7

Forest Plot of Odds ratio for Serious On-Treatment Adverse Events without disease Related Events Occurring in >=5% of patients or in >=10 and >=1% of patients by SOC and PT: Individual Studies and Meta-Analysis

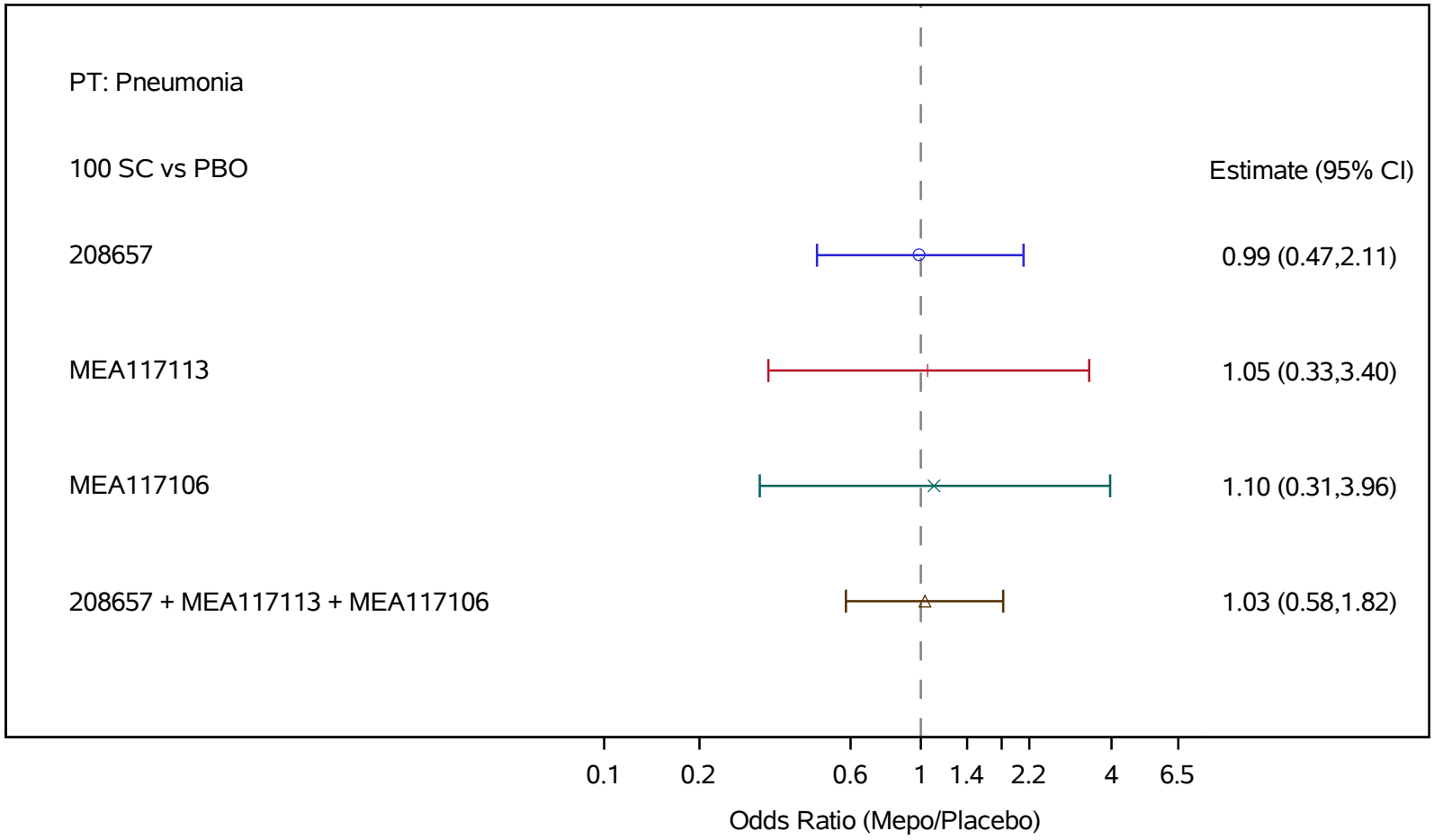


Horizontal bars indicate 95% confidence intervals for the Mepo/Placebo ratio.

Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Figure 311.7

Forest Plot of Odds ratio for Serious On-Treatment Adverse Events without disease Related Events Occurring in >=5% of patients or in >=10 and >=1% of patients by SOC and PT: Individual Studies and Meta-Analysis

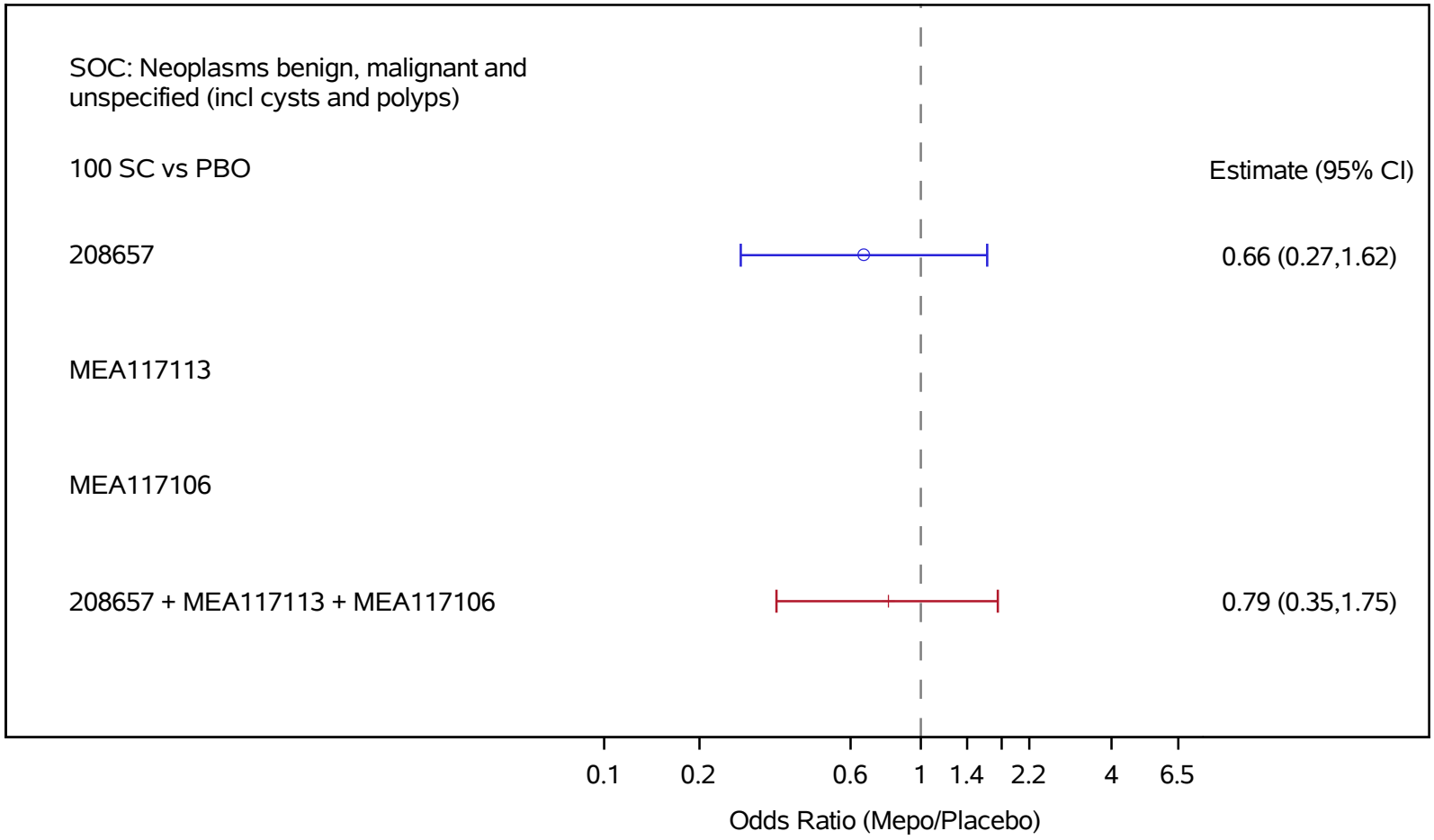


Horizontal bars indicate 95% confidence intervals for the Mepo/Placebo ratio.

Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Figure 311.7

Forest Plot of Odds ratio for Serious On-Treatment Adverse Events without disease Related Events Occurring in >=5% of patients or in >=10 and >=1% of patients by SOC and PT: Individual Studies and Meta-Analysis

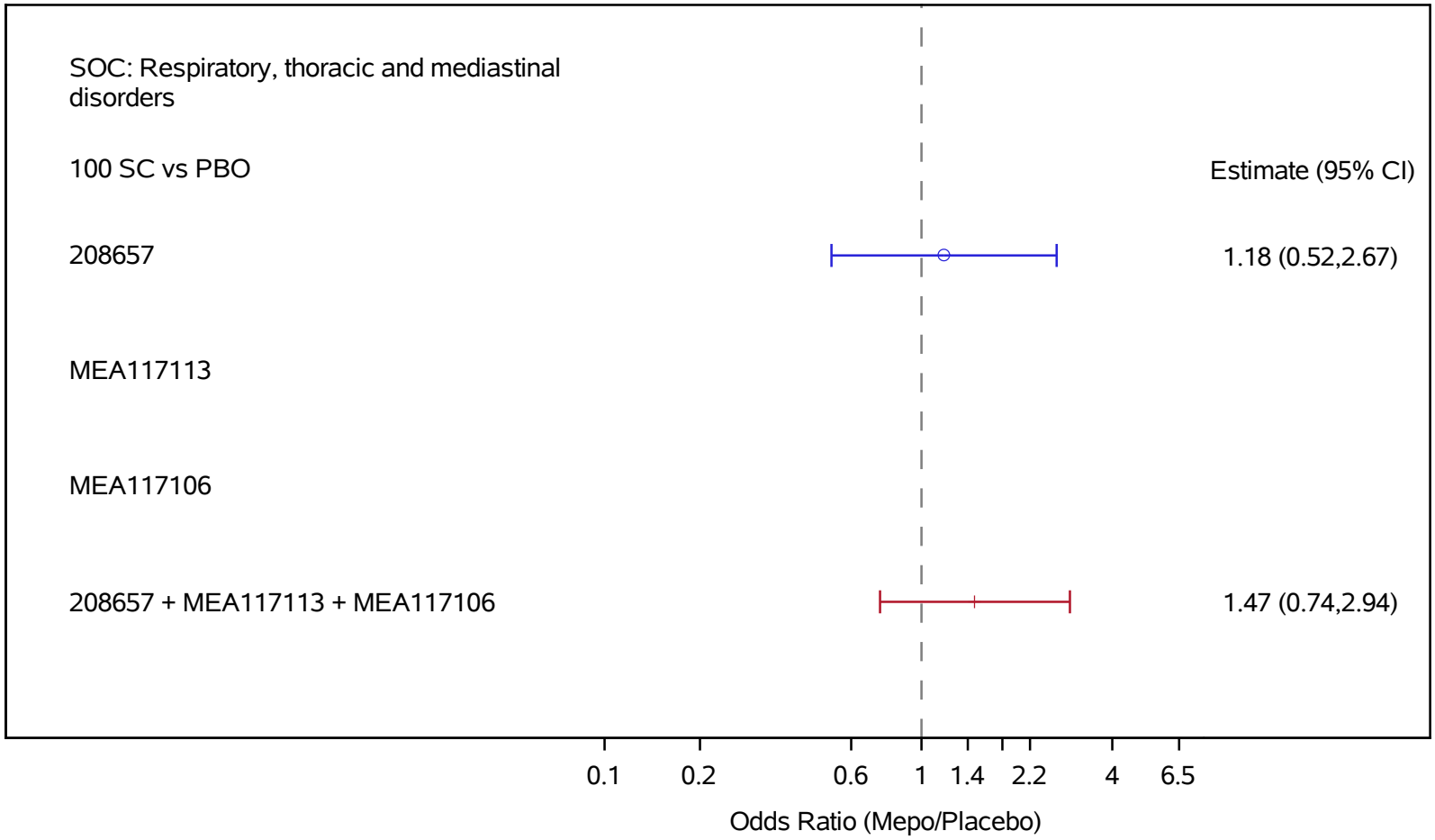


Horizontal bars indicate 95% confidence intervals for the Mepo/Placebo ratio.

Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Figure 311.7

Forest Plot of Odds ratio for Serious On-Treatment Adverse Events without disease Related Events Occurring in >=5% of patients or in >=10 and >=1% of patients by SOC and PT: Individual Studies and Meta-Analysis

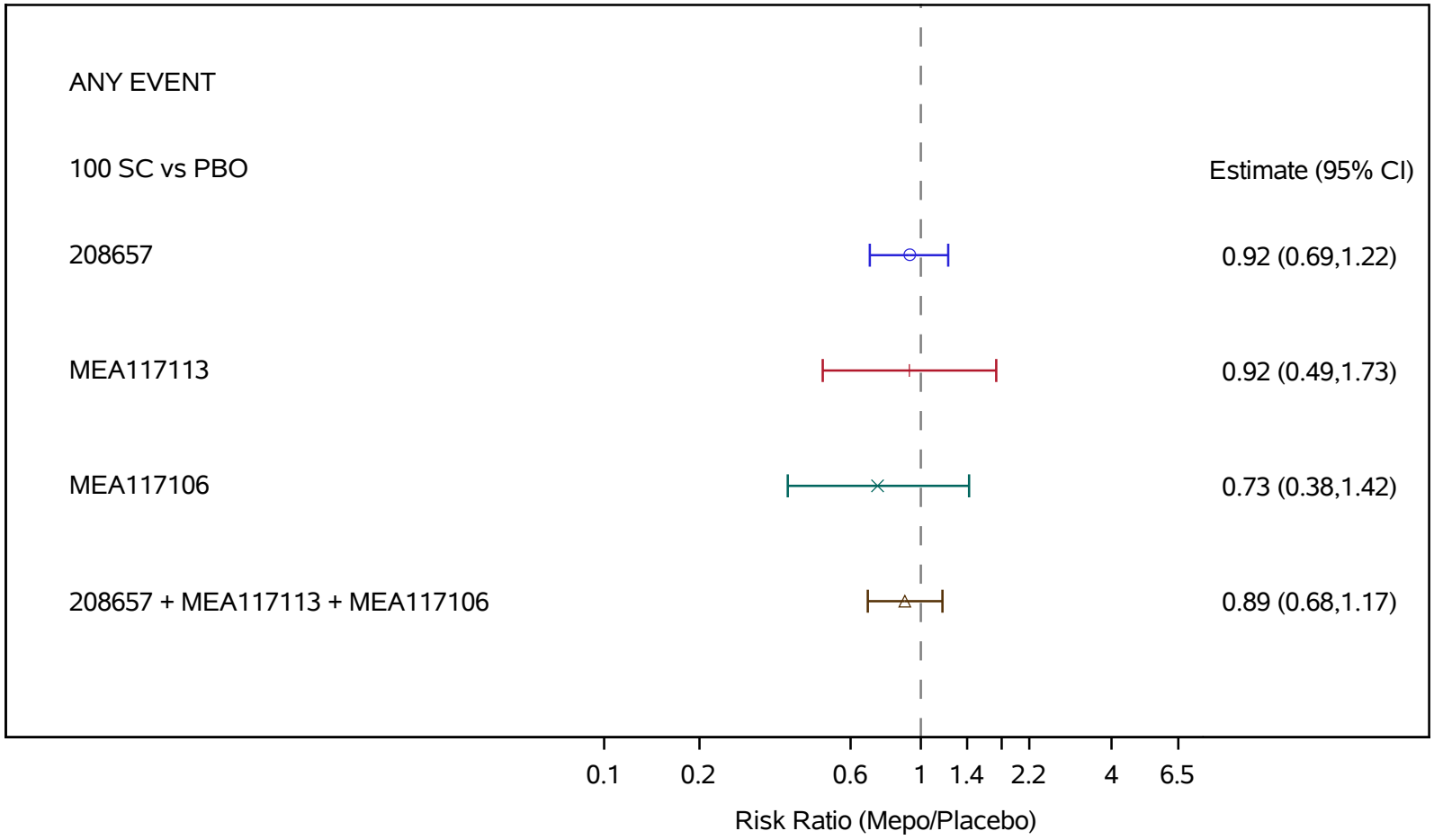


Horizontal bars indicate 95% confidence intervals for the Mepo/Placebo ratio.

Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Figure 311.8

Forest Plot of Relative Risk for Serious On-Treatment Adverse Events without disease Related Events Occurring in >=5% of patients or in >=10 and >=1% of patients by SOC and PT: Individual Studies and Meta-Analysis



Horizontal bars indicate 95% confidence intervals for the Mepo/Placebo ratio.

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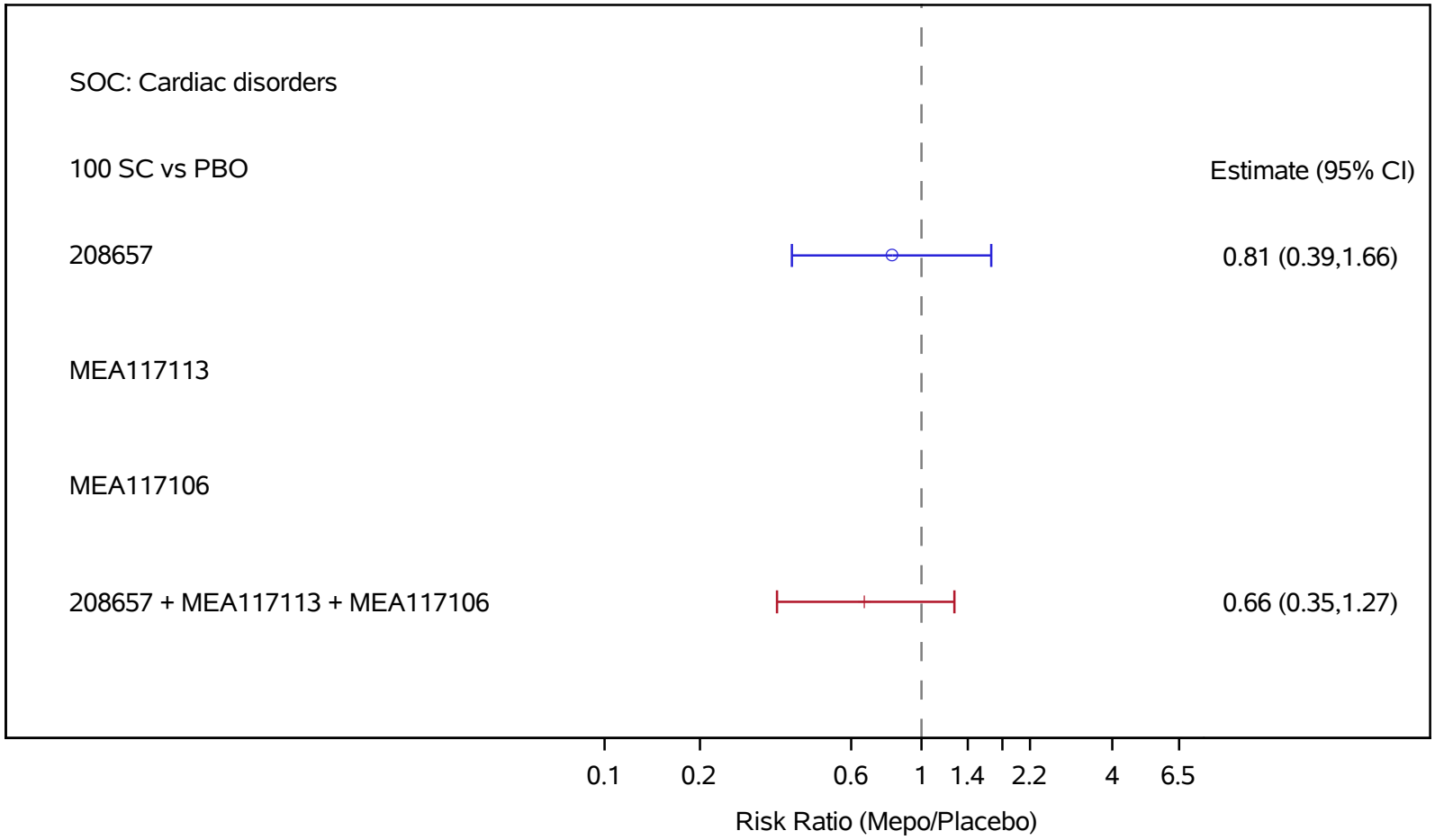
Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Figure 311.8

Forest Plot of Relative Risk for Serious On-Treatment Adverse Events without disease Related Events Occurring in >=5% of patients or in >=10 and >=1% of patients by SOC and PT: Individual Studies and Meta-Analysis

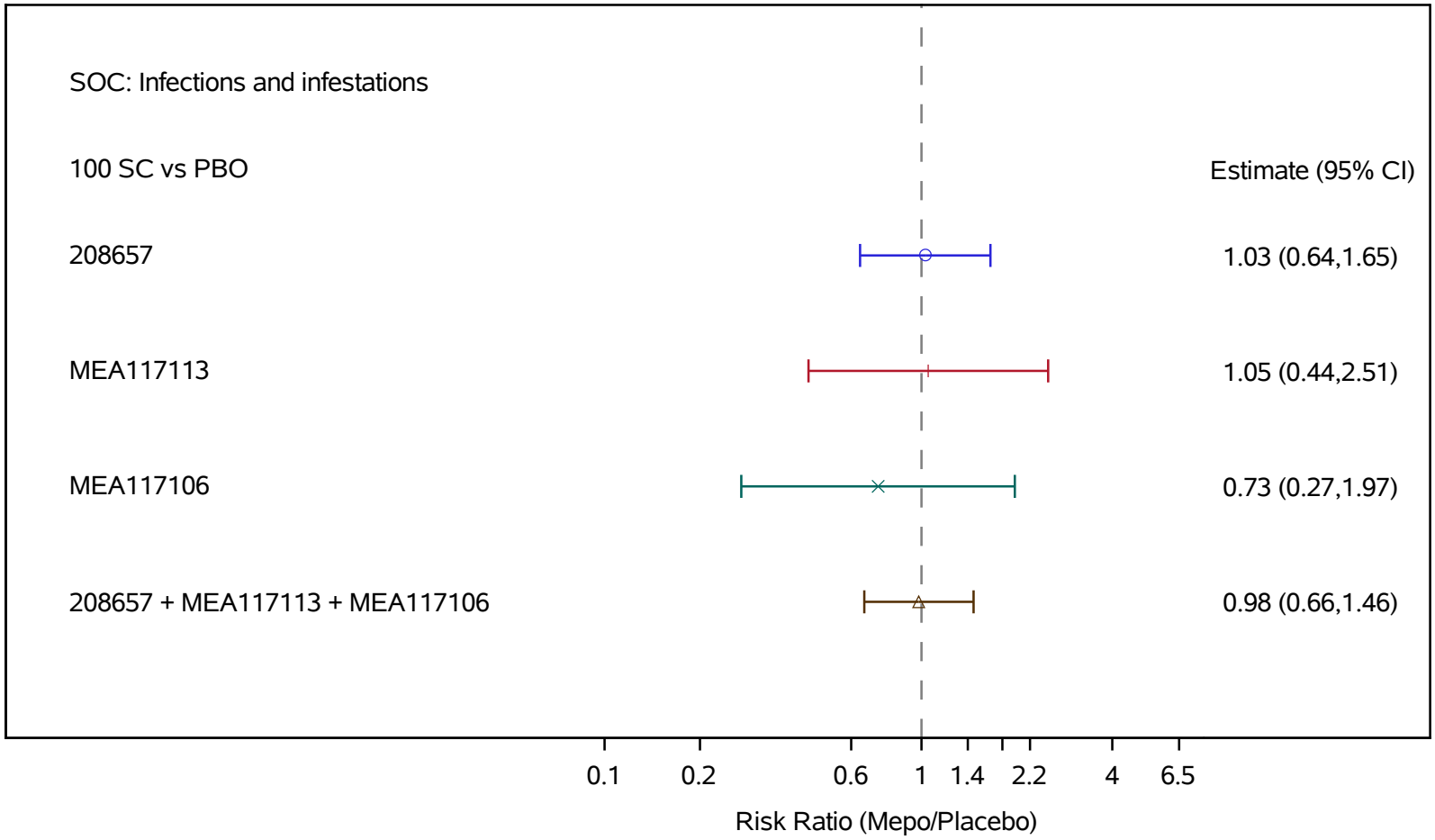


Horizontal bars indicate 95% confidence intervals for the Mepo/Placebo ratio.

Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Figure 311.8

Forest Plot of Relative Risk for Serious On-Treatment Adverse Events without disease Related Events Occurring in >=5% of patients or in >=10 and >=1% of patients by SOC and PT: Individual Studies and Meta-Analysis



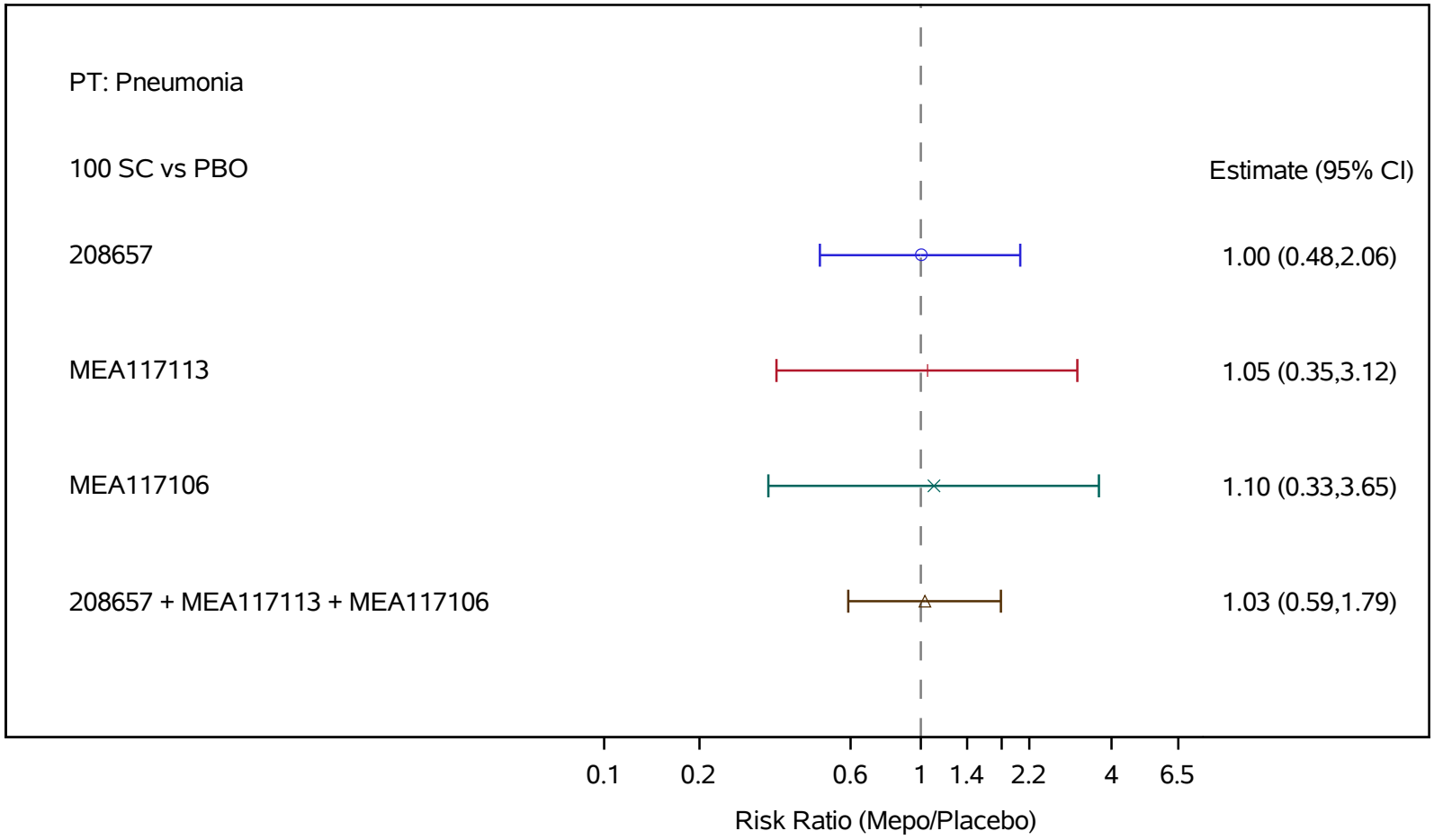
Horizontal bars indicate 95% confidence intervals for the Mepo/Placebo ratio.

/mnt/code/postcsr_01/prod/tfls/f_s_ae_onae_sae_dre_rr.sas 17JUL2025 18:10

Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Figure 311.8

Forest Plot of Relative Risk for Serious On-Treatment Adverse Events without disease Related Events Occurring in >=5% of patients or in >=10 and >=1% of patients by SOC and PT: Individual Studies and Meta-Analysis



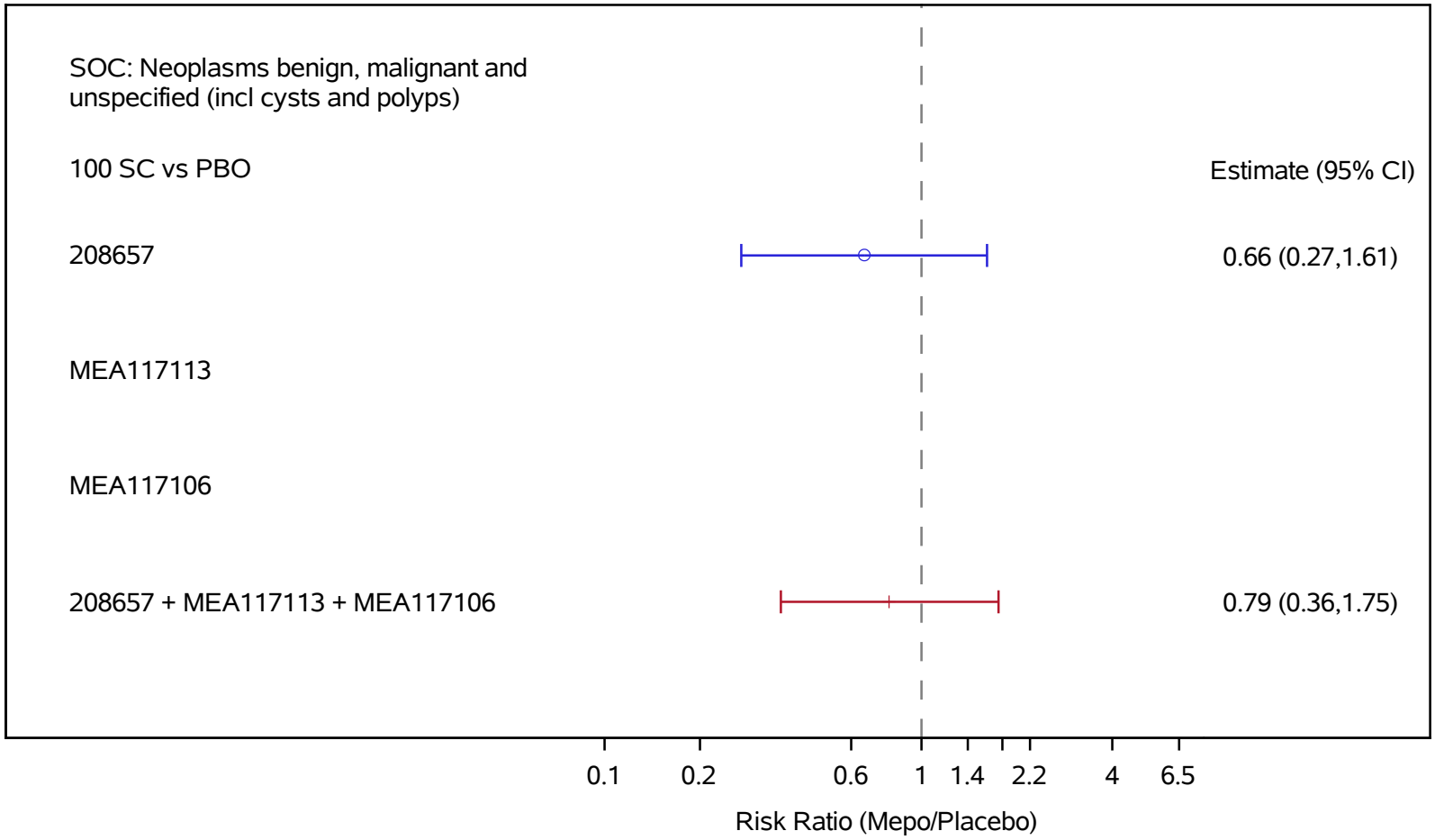
Horizontal bars indicate 95% confidence intervals for the Mepo/Placebo ratio.

/mnt/code/postcsr_01/prod/tfls/f_s_ae_onae_sae_dre_rr.sas 17JUL2025 18:10

Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Figure 311.8

Forest Plot of Relative Risk for Serious On-Treatment Adverse Events without disease Related Events Occurring in >=5% of patients or in >=10 and >=1% of patients by SOC and PT: Individual Studies and Meta-Analysis

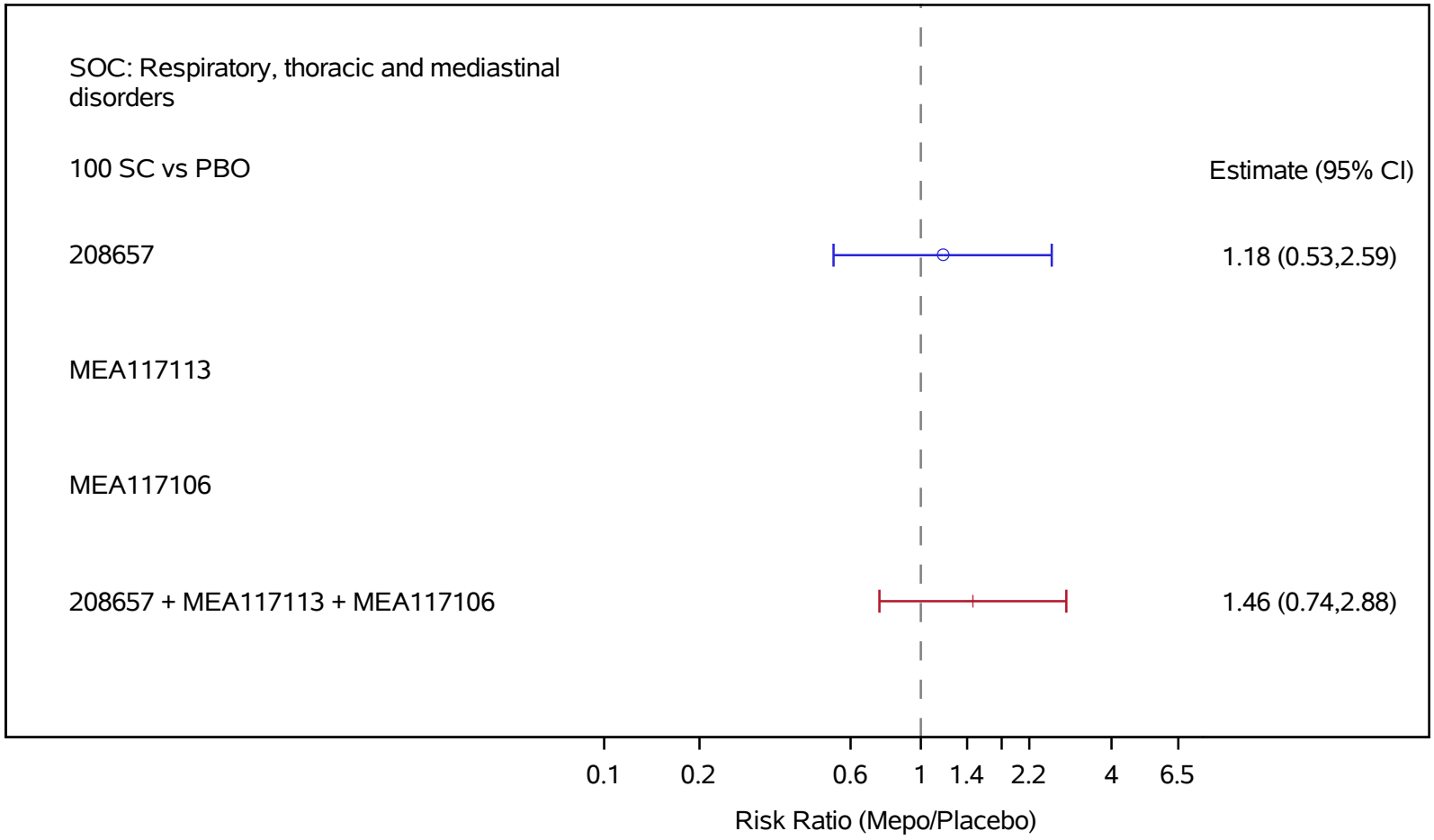


Horizontal bars indicate 95% confidence intervals for the Mepo/Placebo ratio.

Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Figure 311.8

Forest Plot of Relative Risk for Serious On-Treatment Adverse Events without disease Related Events Occurring in >=5% of patients or in >=10 and >=1% of patients by SOC and PT: Individual Studies and Meta-Analysis



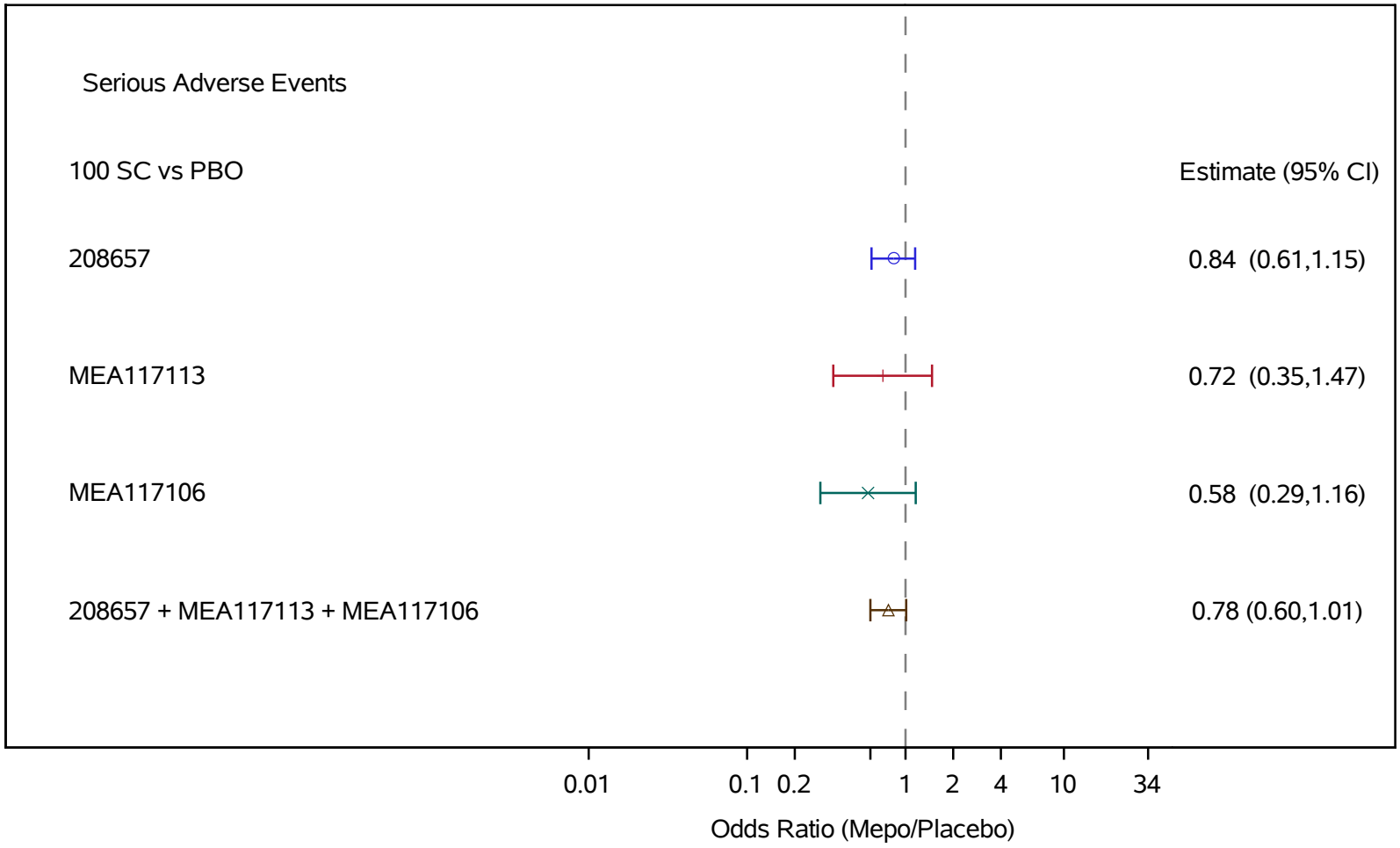
Horizontal bars indicate 95% confidence intervals for the Mepo/Placebo ratio.

/mnt/code/postcsr_01/prod/tfls/f_s_ae_onae_sae_dre_rr.sas 17JUL2025 18:10

Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Figure 311.9

Forest Plot of Odds ratio for On-Treatment Adverse Events of Special Interest: Individual Studies and Meta-Analysis



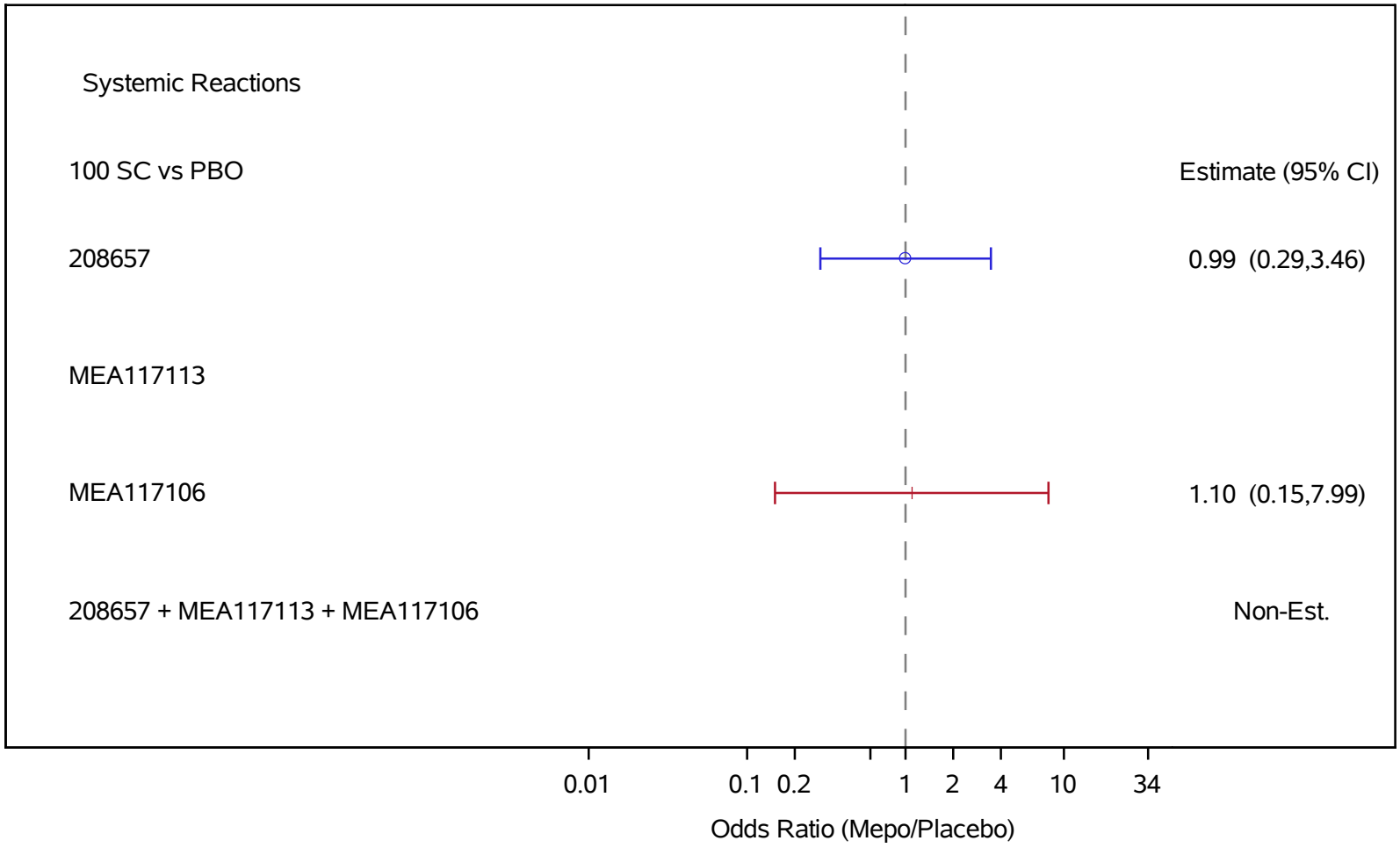
Horizontal bars indicate 95% confidence intervals for the Mepo/Placebo ratio.

/mnt/code/postcsr_01/prod/tfls/f_s_aesi_or.sas 17JUL2025 18:11

Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Figure 311.9

Forest Plot of Odds ratio for On-Treatment Adverse Events of Special Interest: Individual Studies and Meta-Analysis

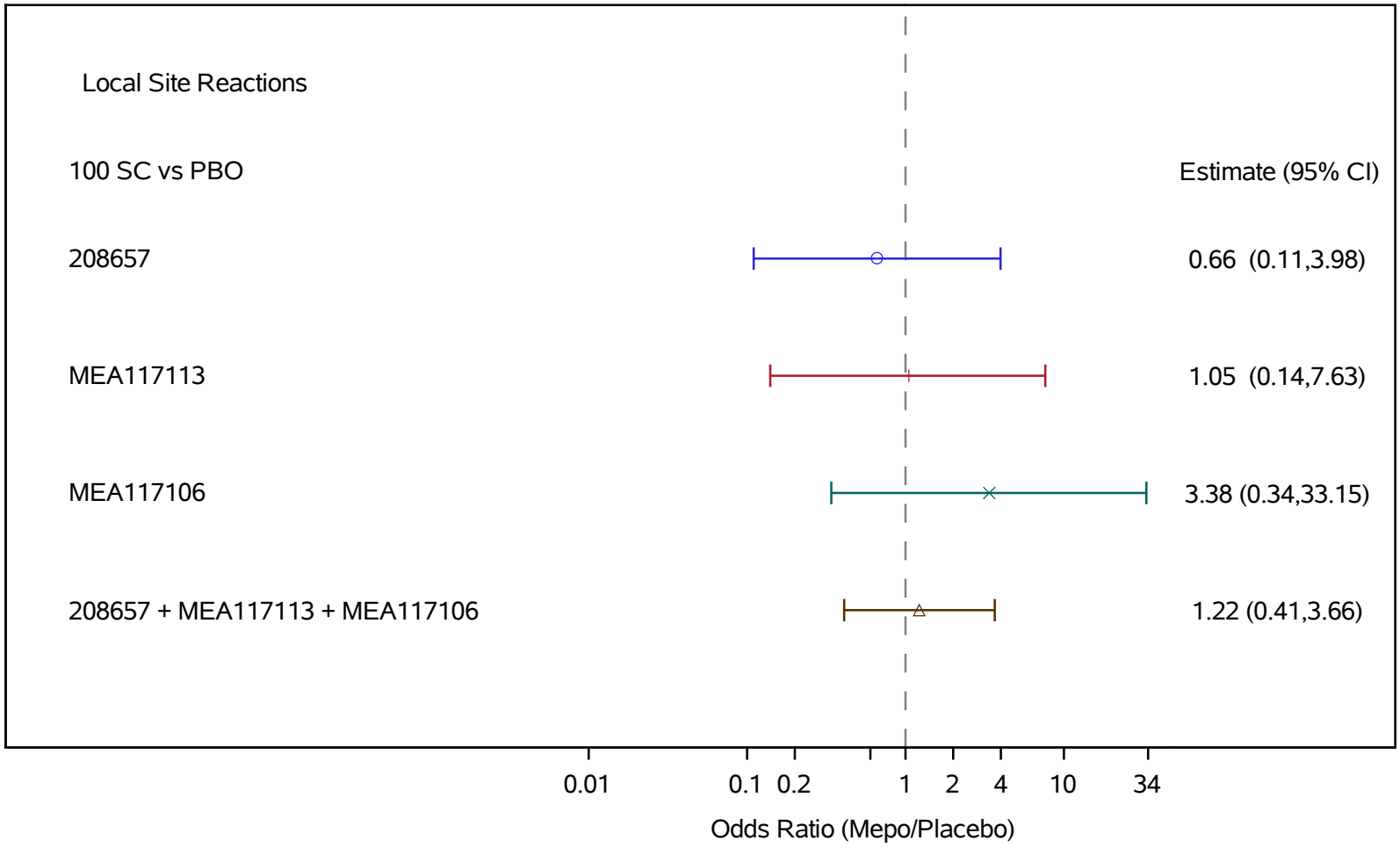


Horizontal bars indicate 95% confidence intervals for the Mepo/Placebo ratio.

Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Figure 311.9

Forest Plot of Odds ratio for On-Treatment Adverse Events of Special Interest: Individual Studies and Meta-Analysis

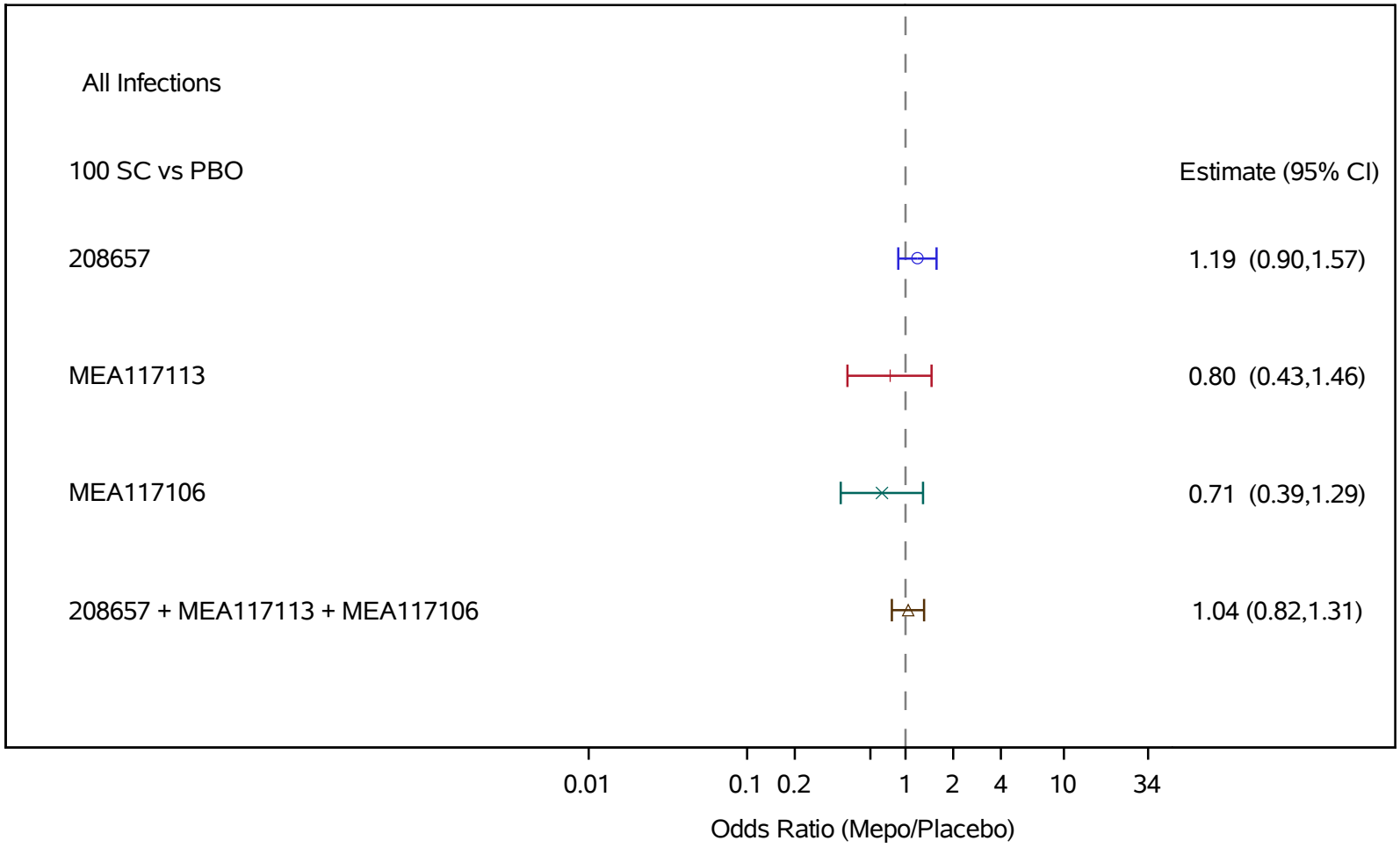


Horizontal bars indicate 95% confidence intervals for the Mepo/Placebo ratio.

Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Figure 311.9

Forest Plot of Odds ratio for On-Treatment Adverse Events of Special Interest: Individual Studies and Meta-Analysis

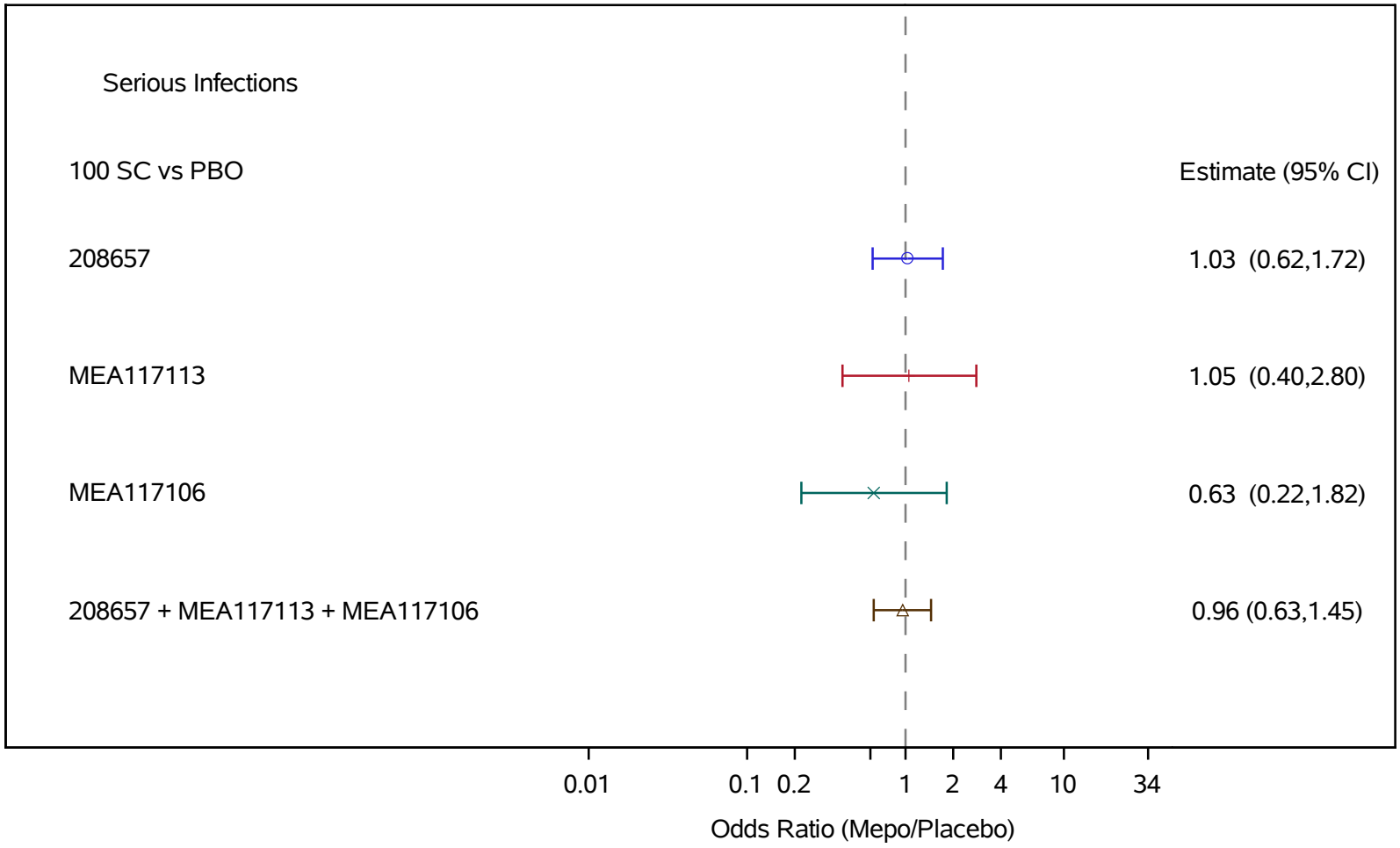


Horizontal bars indicate 95% confidence intervals for the Mepo/Placebo ratio.

Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Figure 311.9

Forest Plot of Odds ratio for On-Treatment Adverse Events of Special Interest: Individual Studies and Meta-Analysis



Horizontal bars indicate 95% confidence intervals for the Mepo/Placebo ratio.

Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

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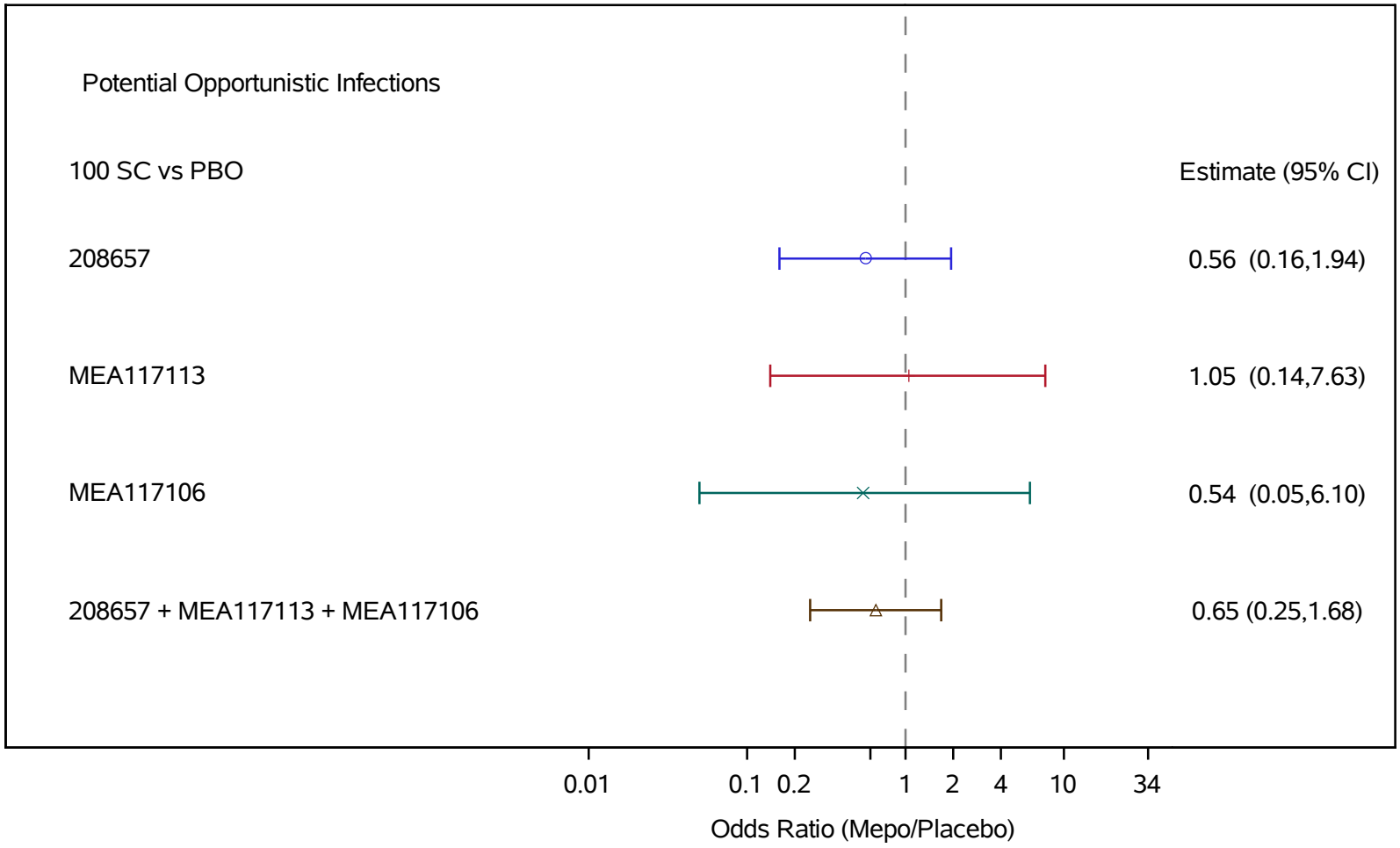

Horizontal bars indicate 95% confidence intervals for the Mepo/Placebo ratio.

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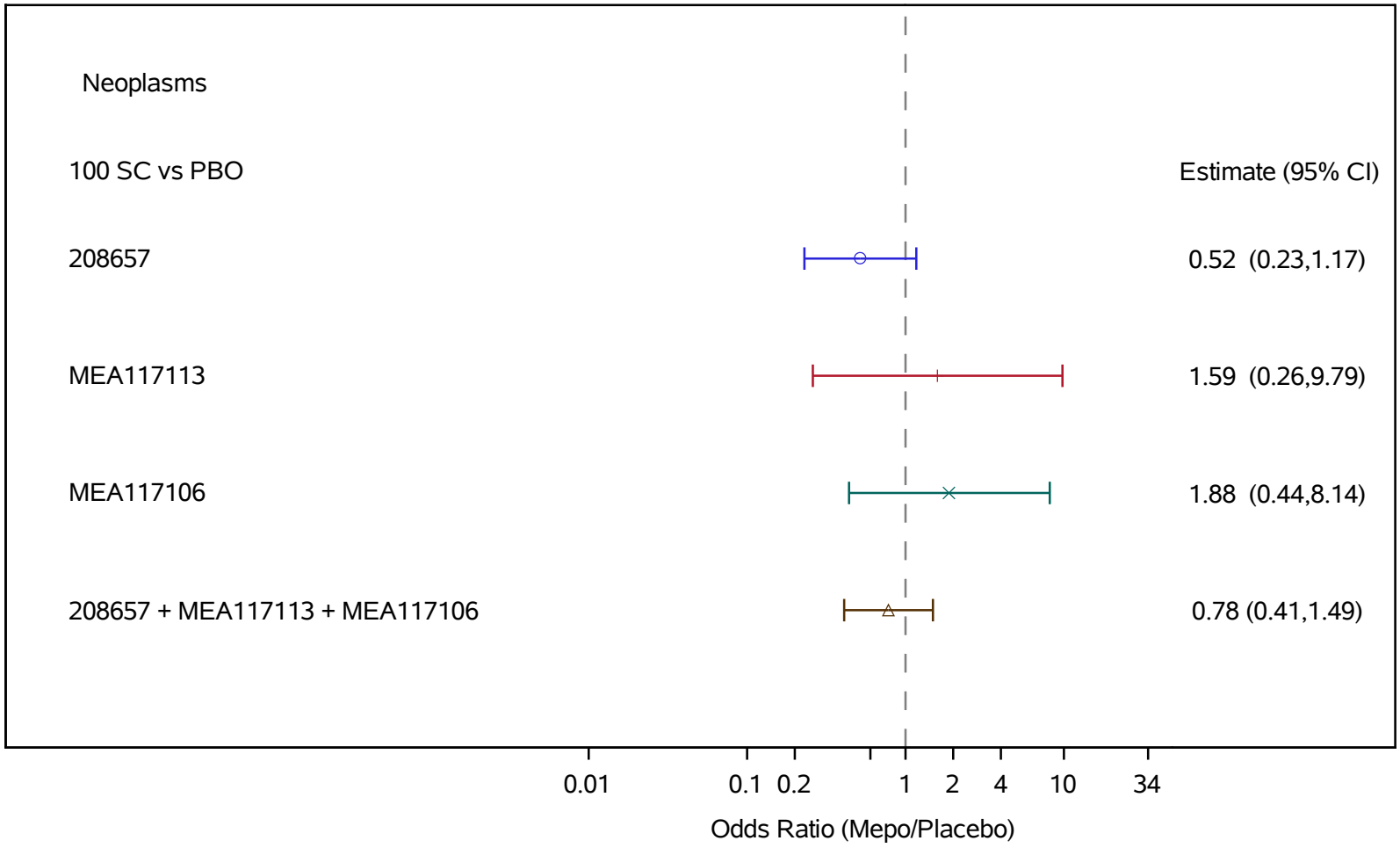

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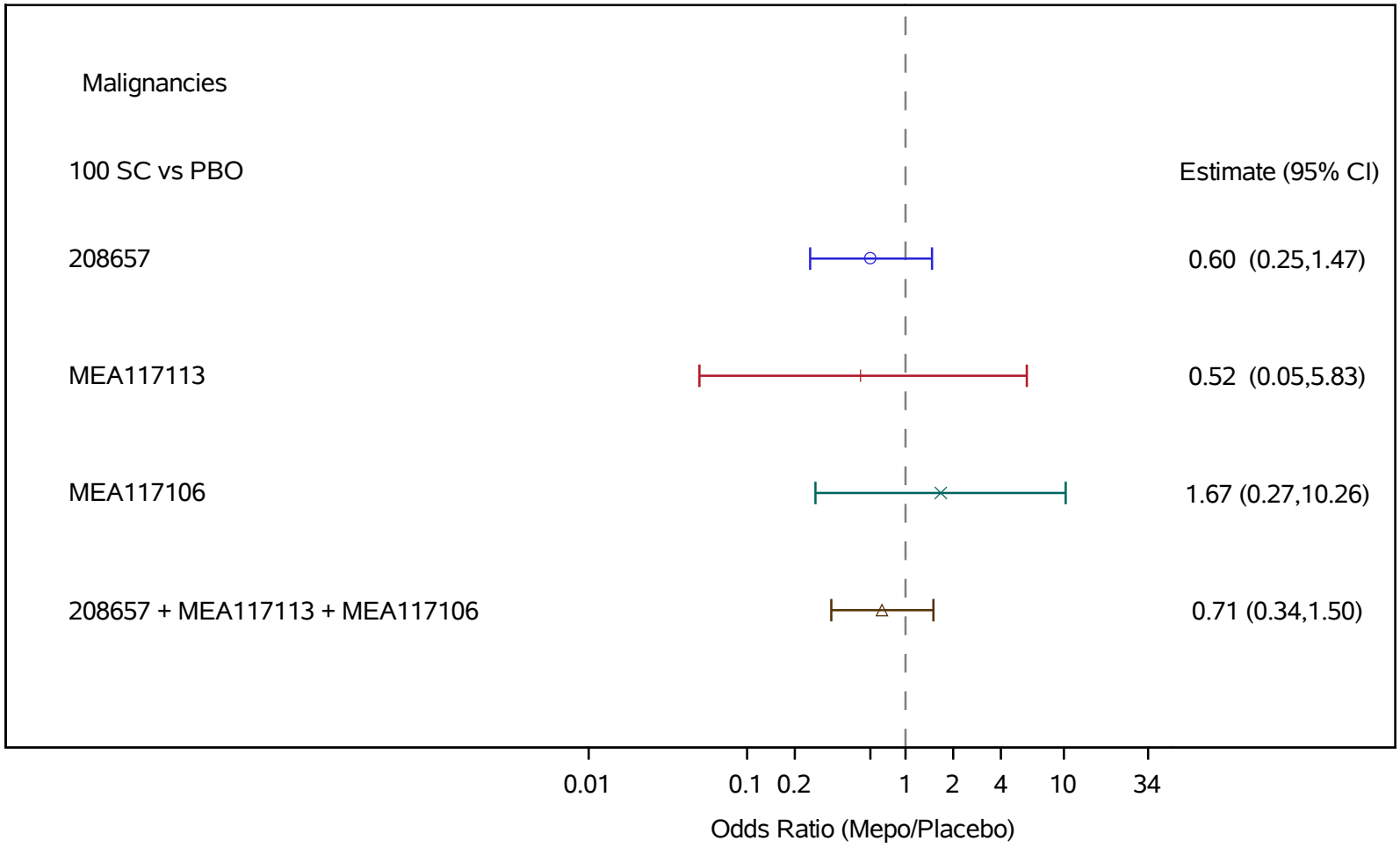

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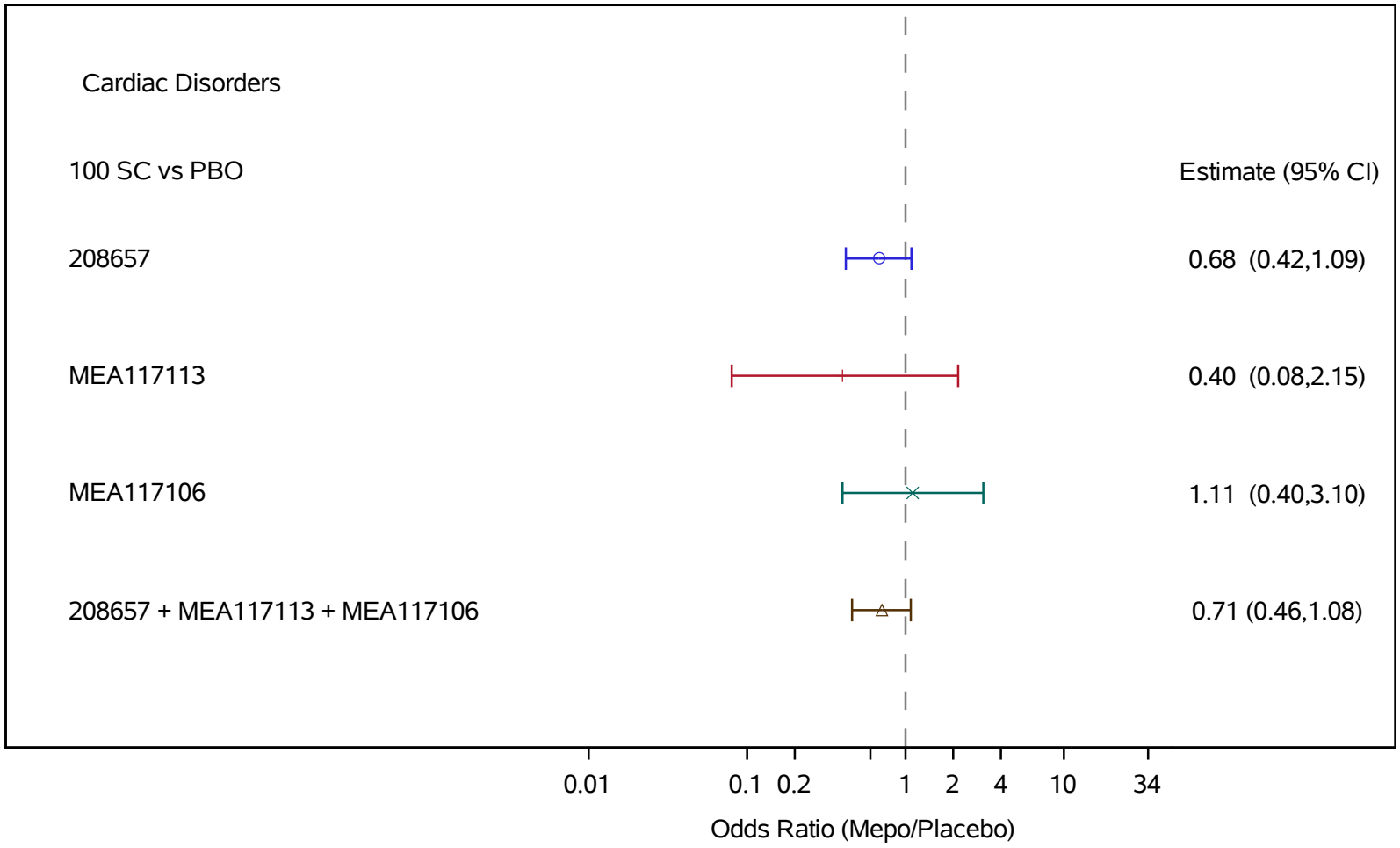

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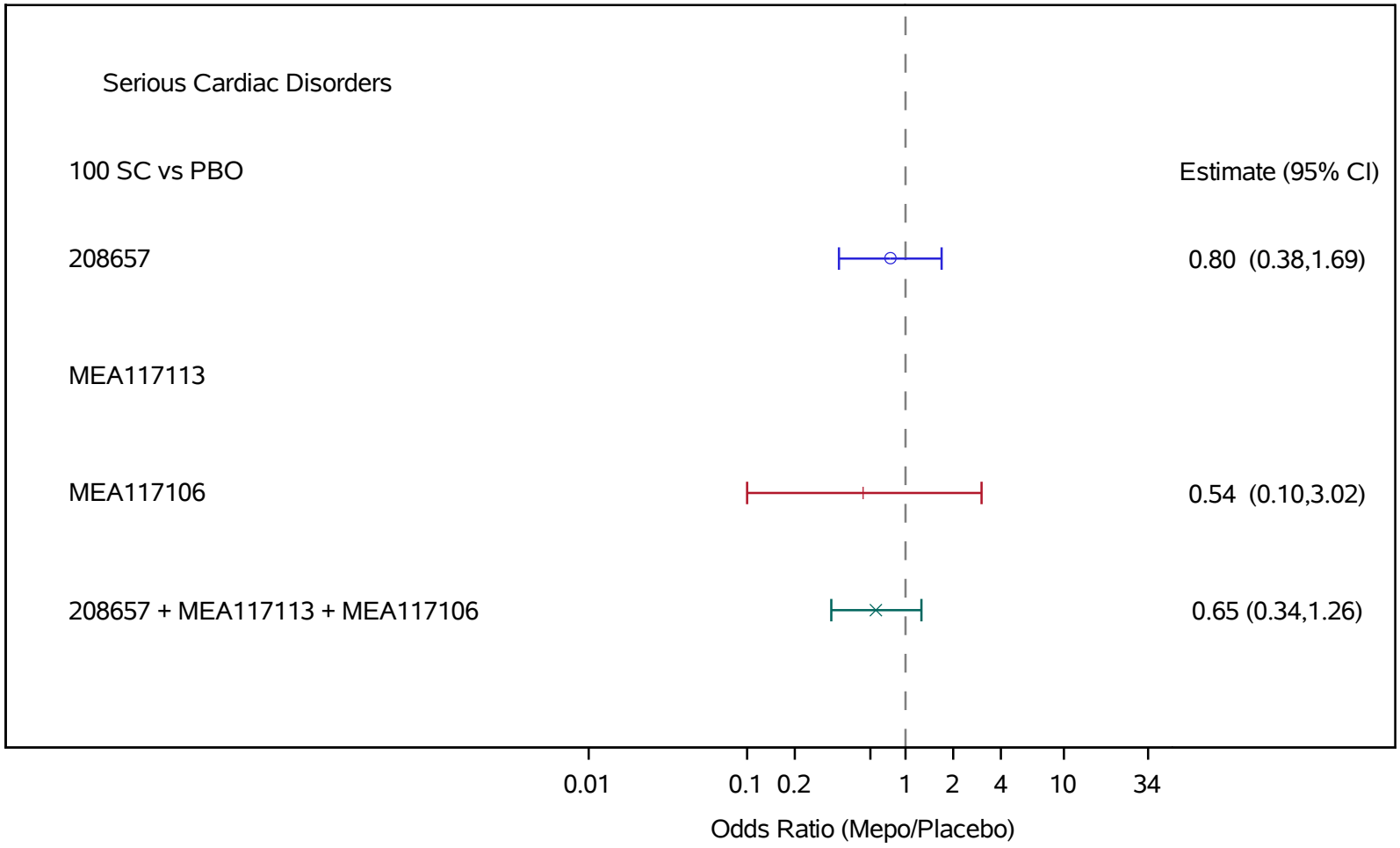

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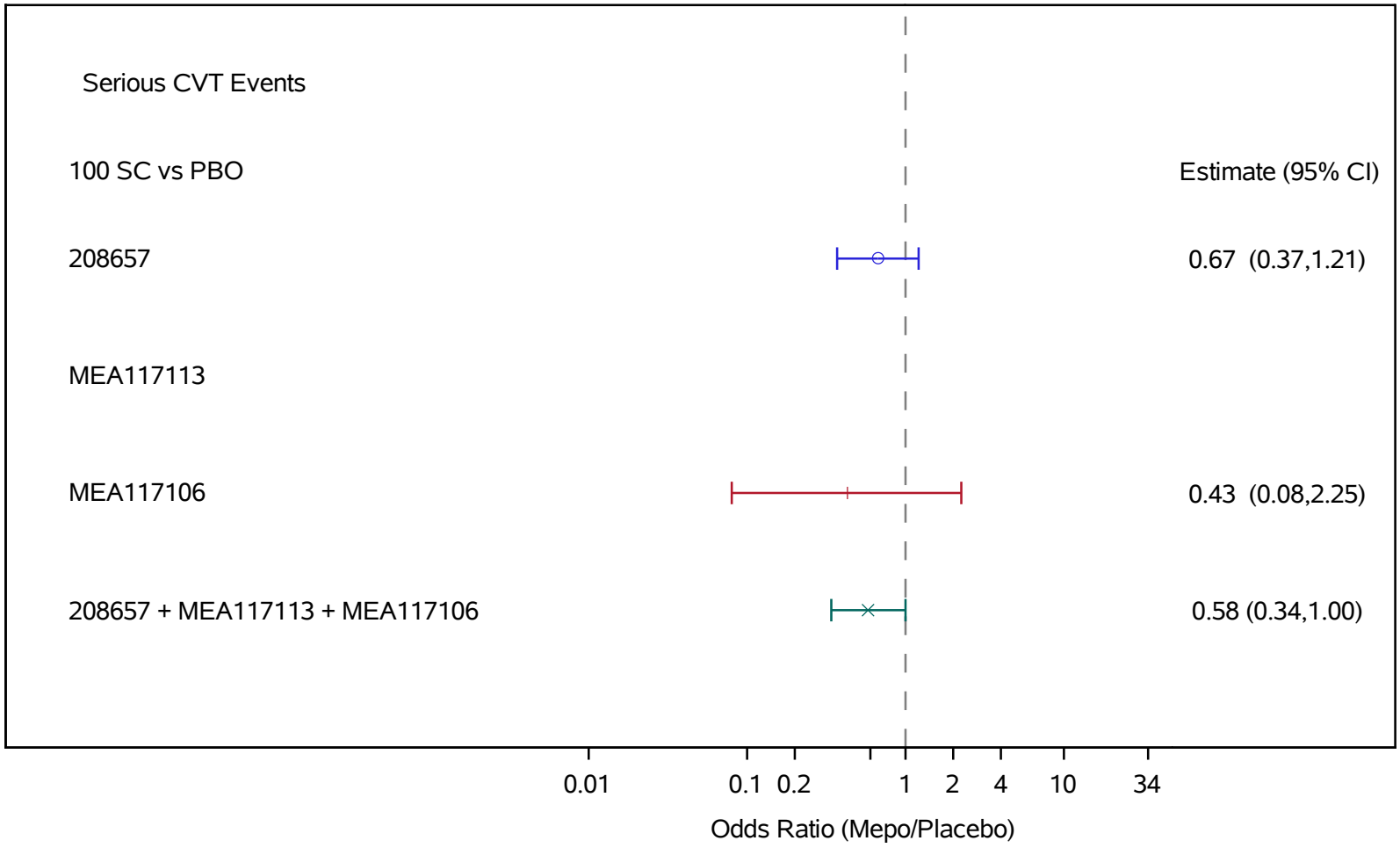

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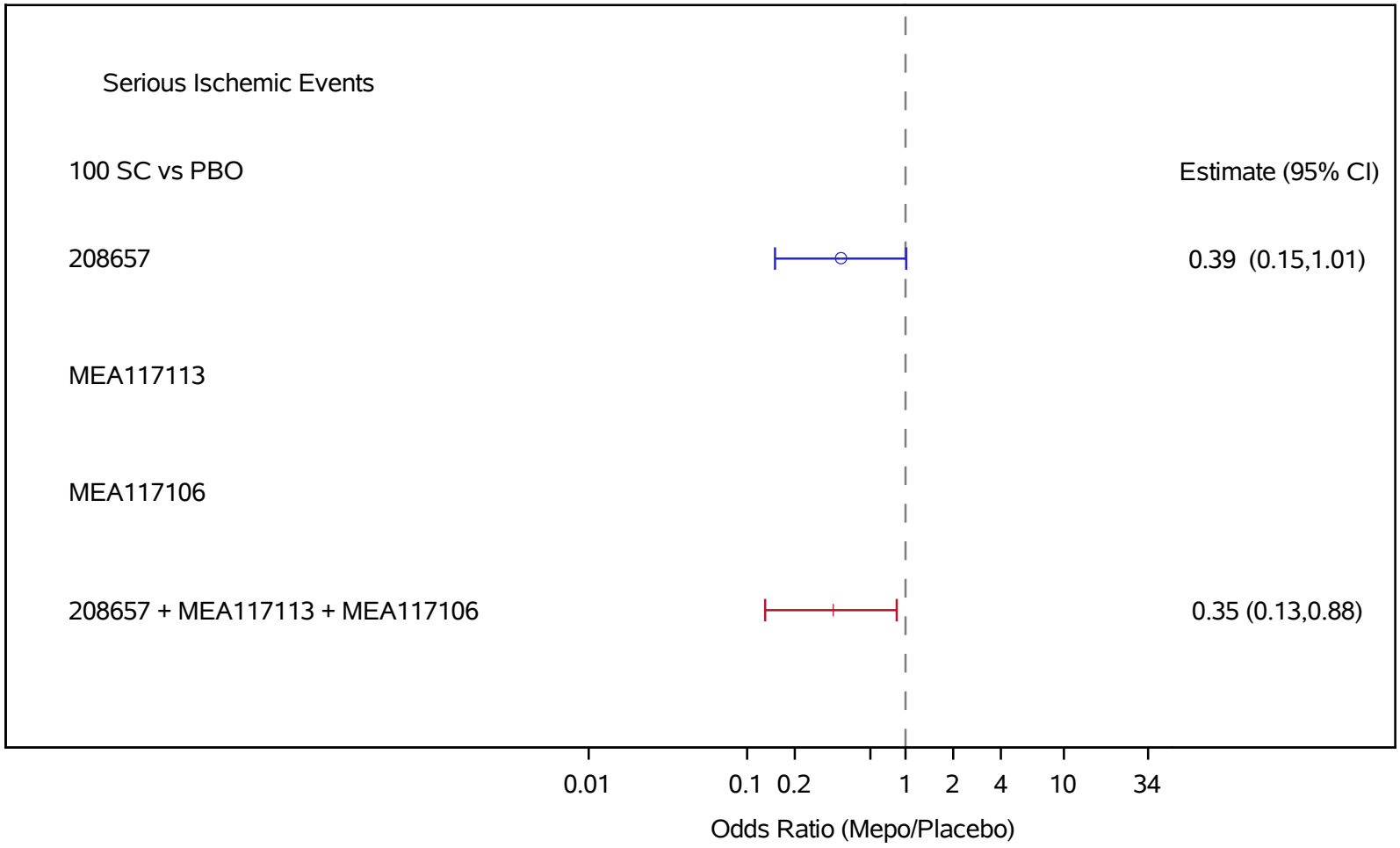
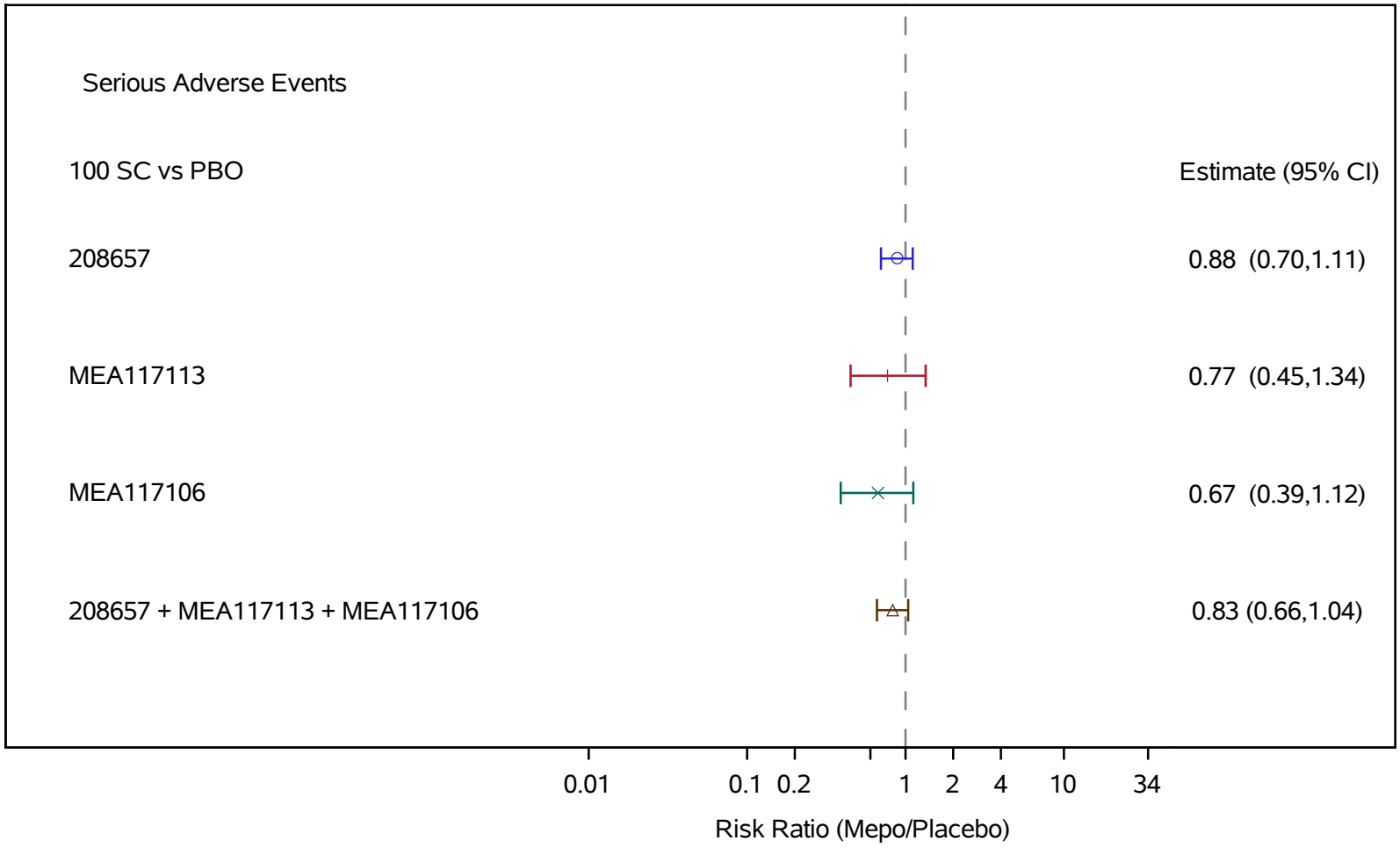


Horizontal bars indicate 95% confidence intervals for the Mepo/Placebo ratio.

Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Figure 311.10

Forest Plot of Relative Risk for On-Treatment Adverse Events of Special Interest: Individual Studies and Meta-Analysis



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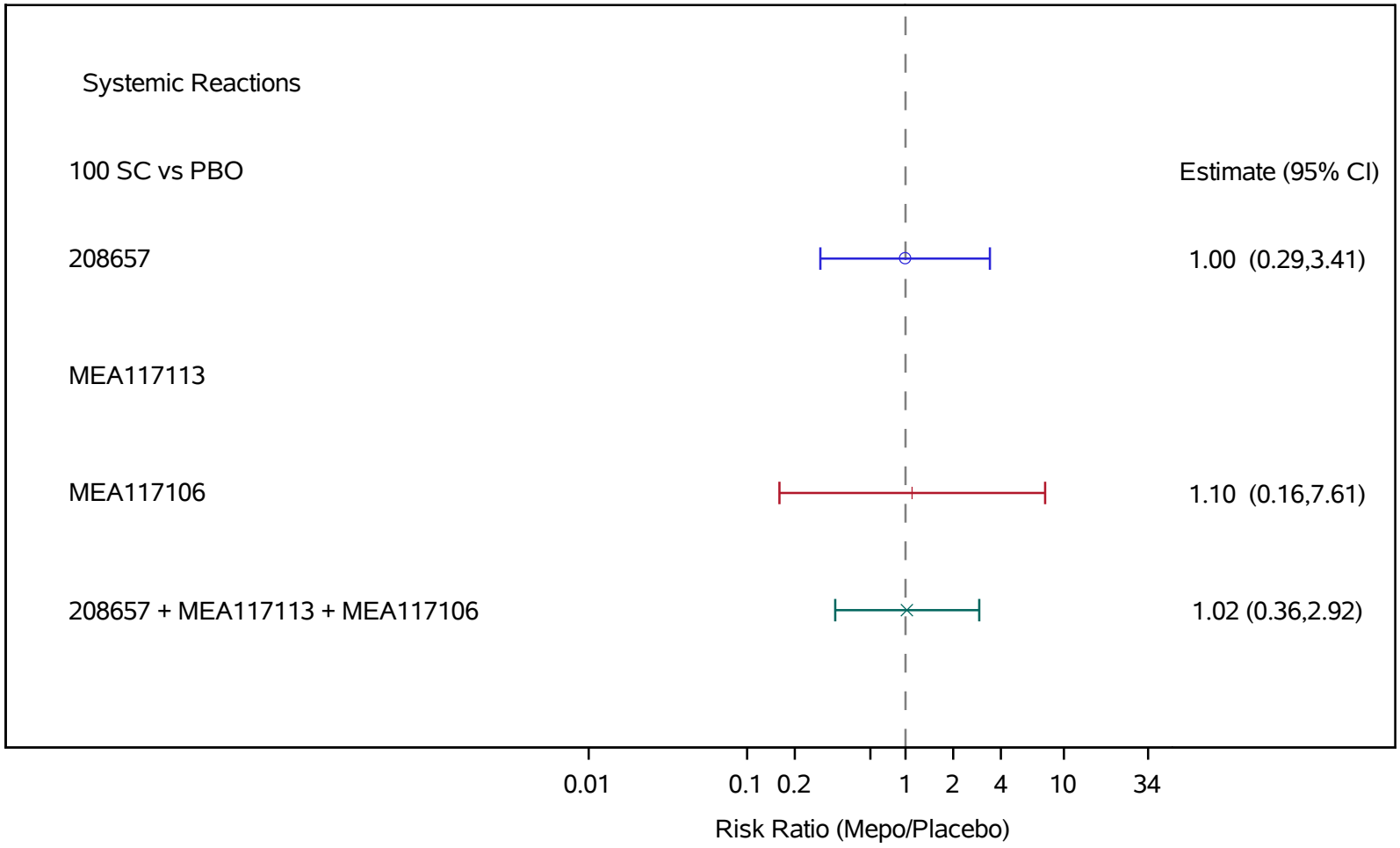

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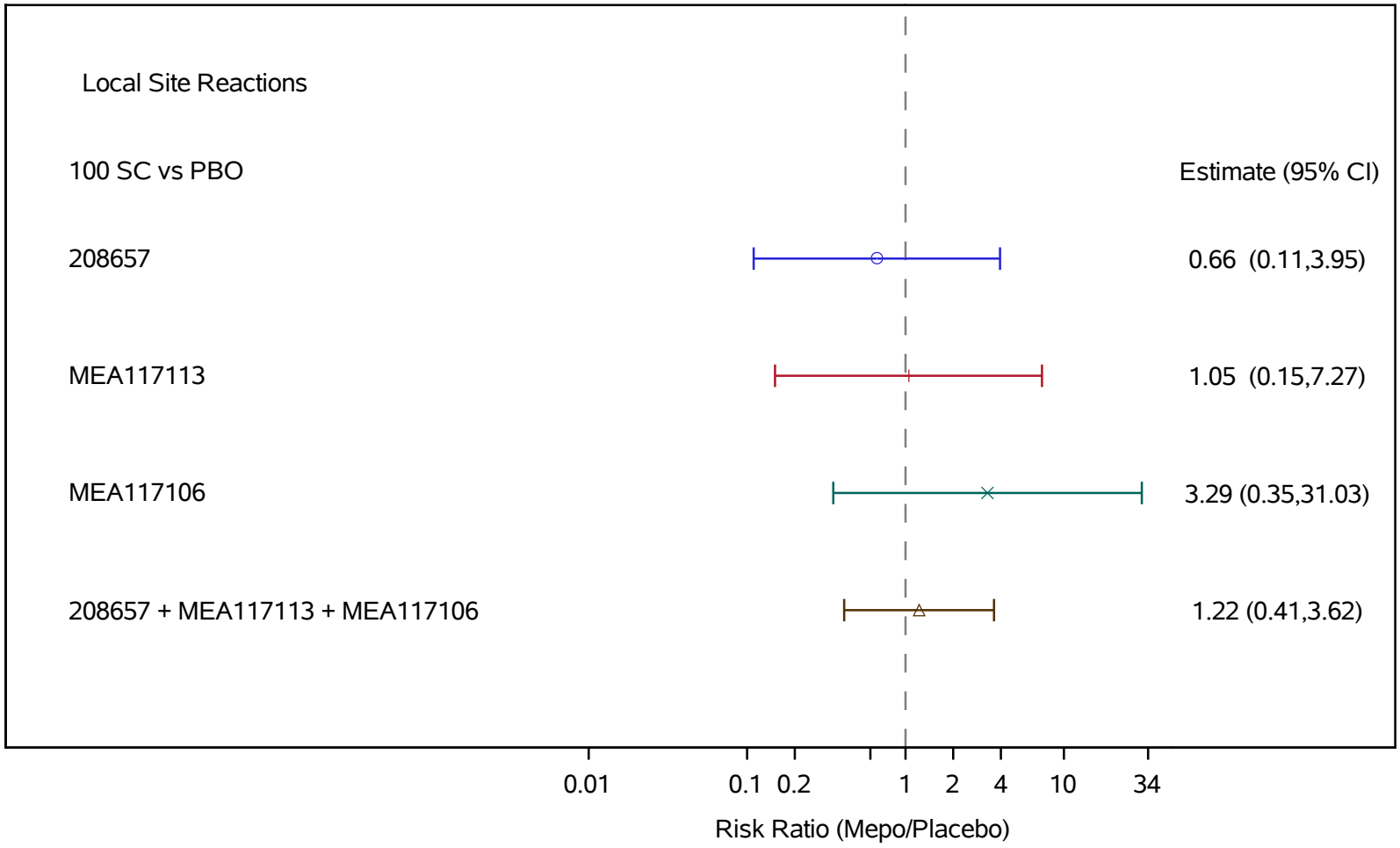

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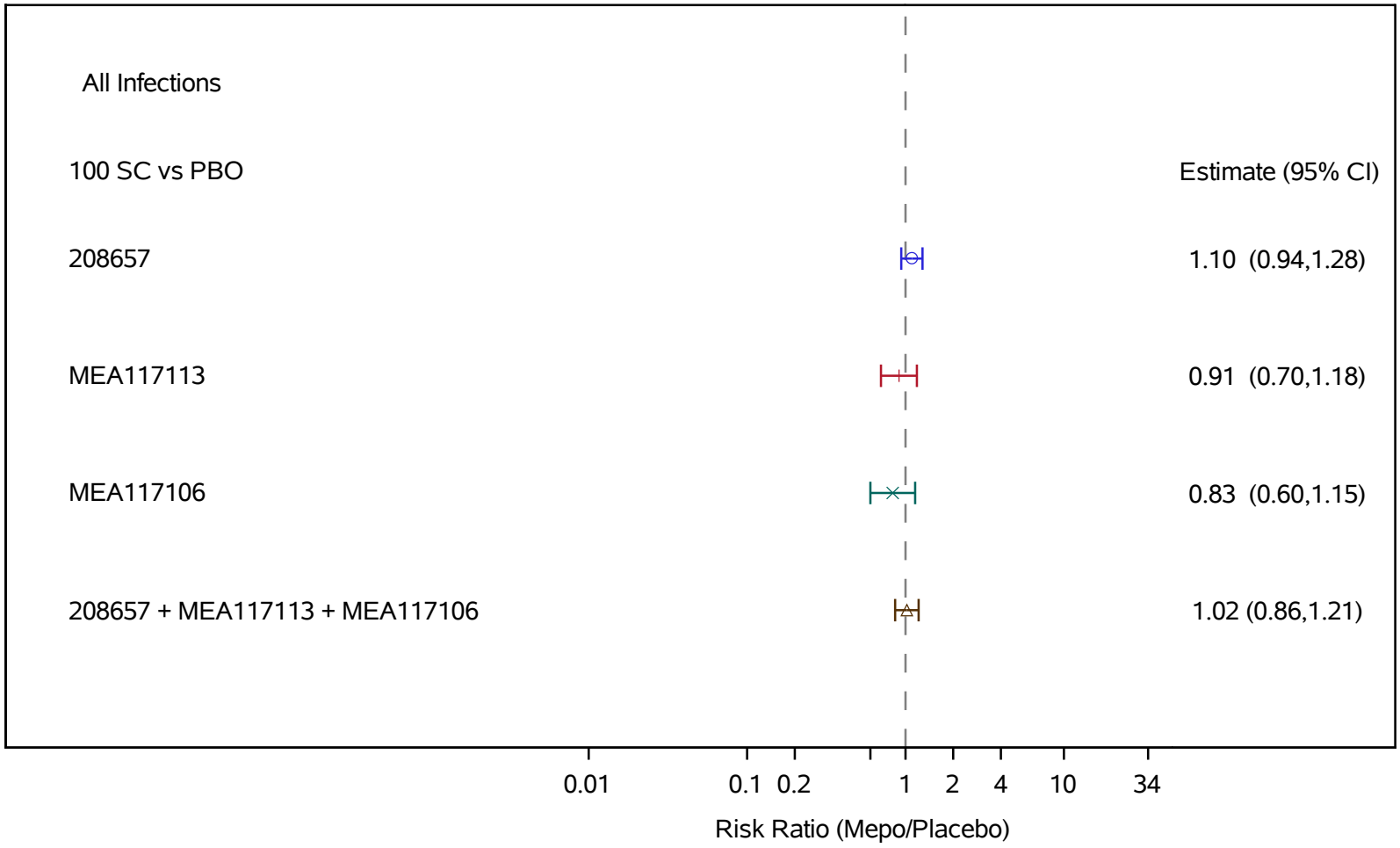

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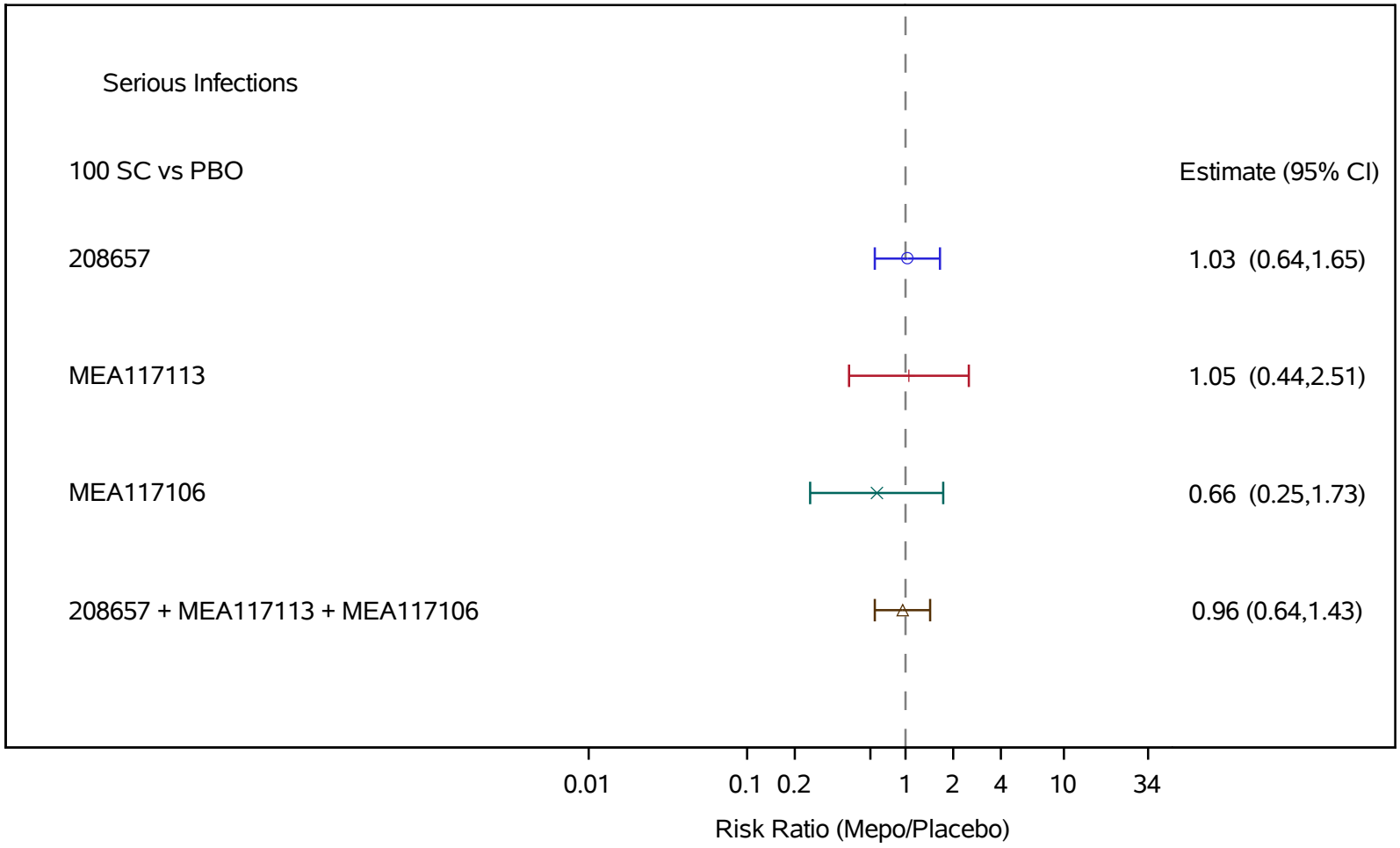

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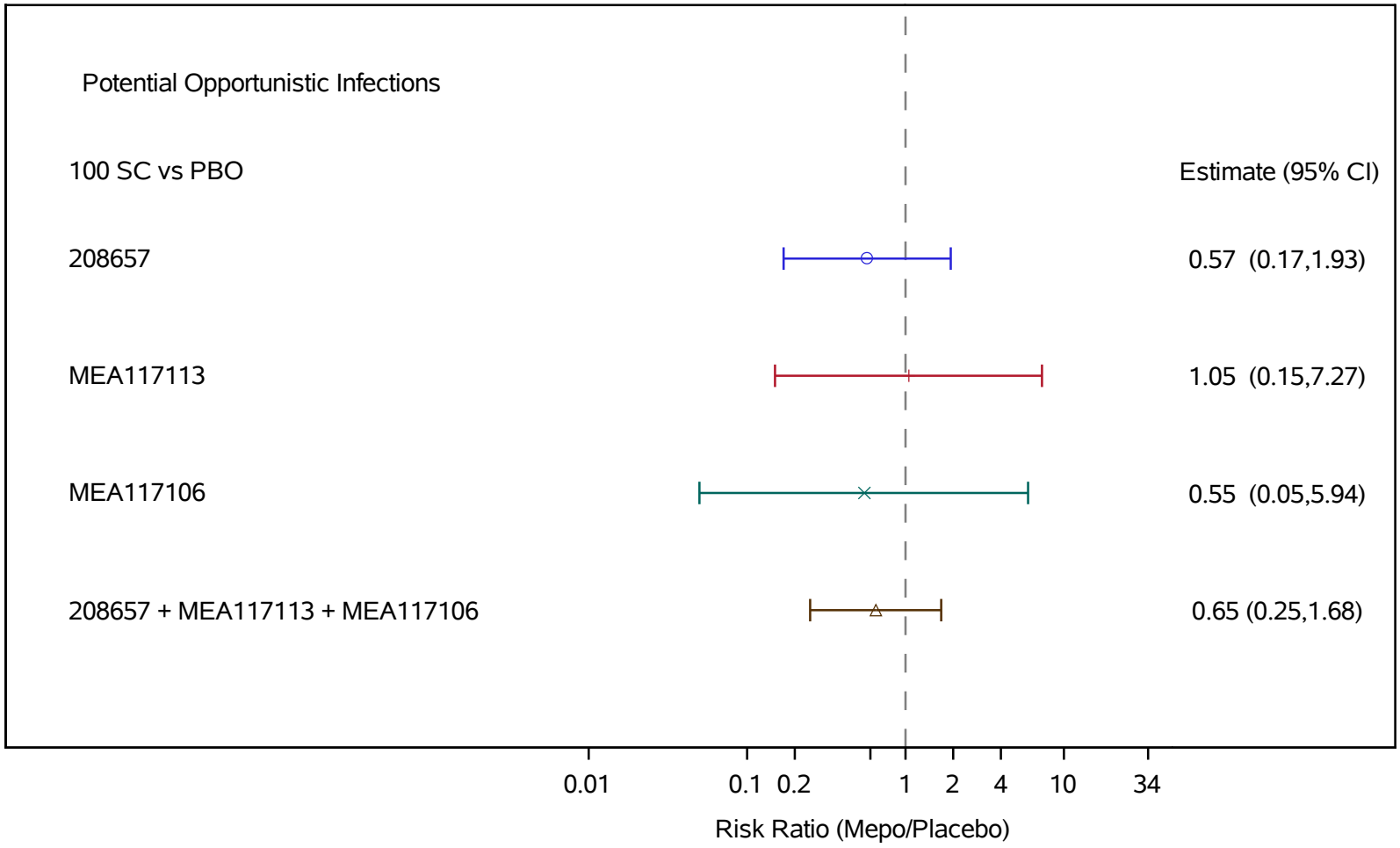

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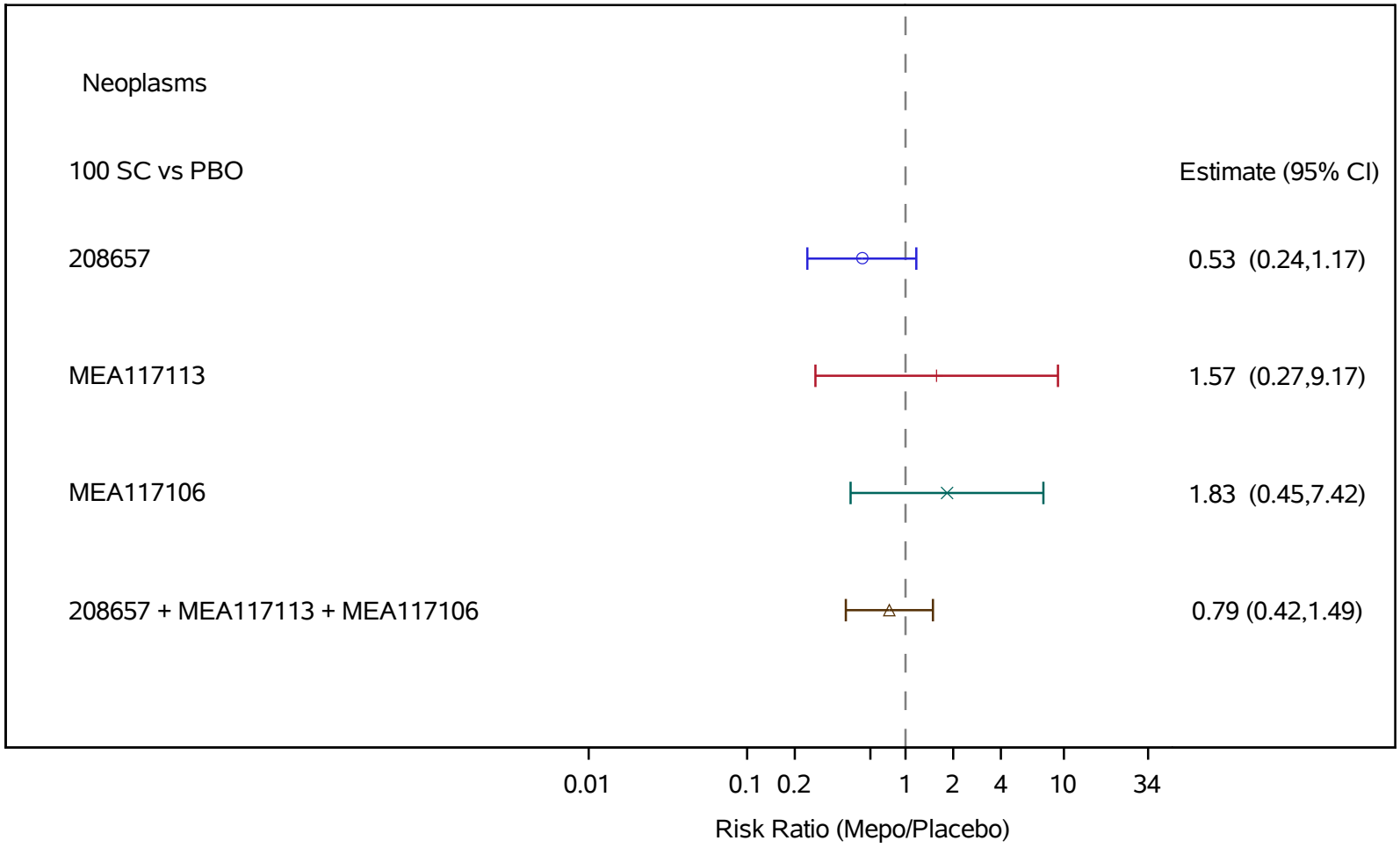

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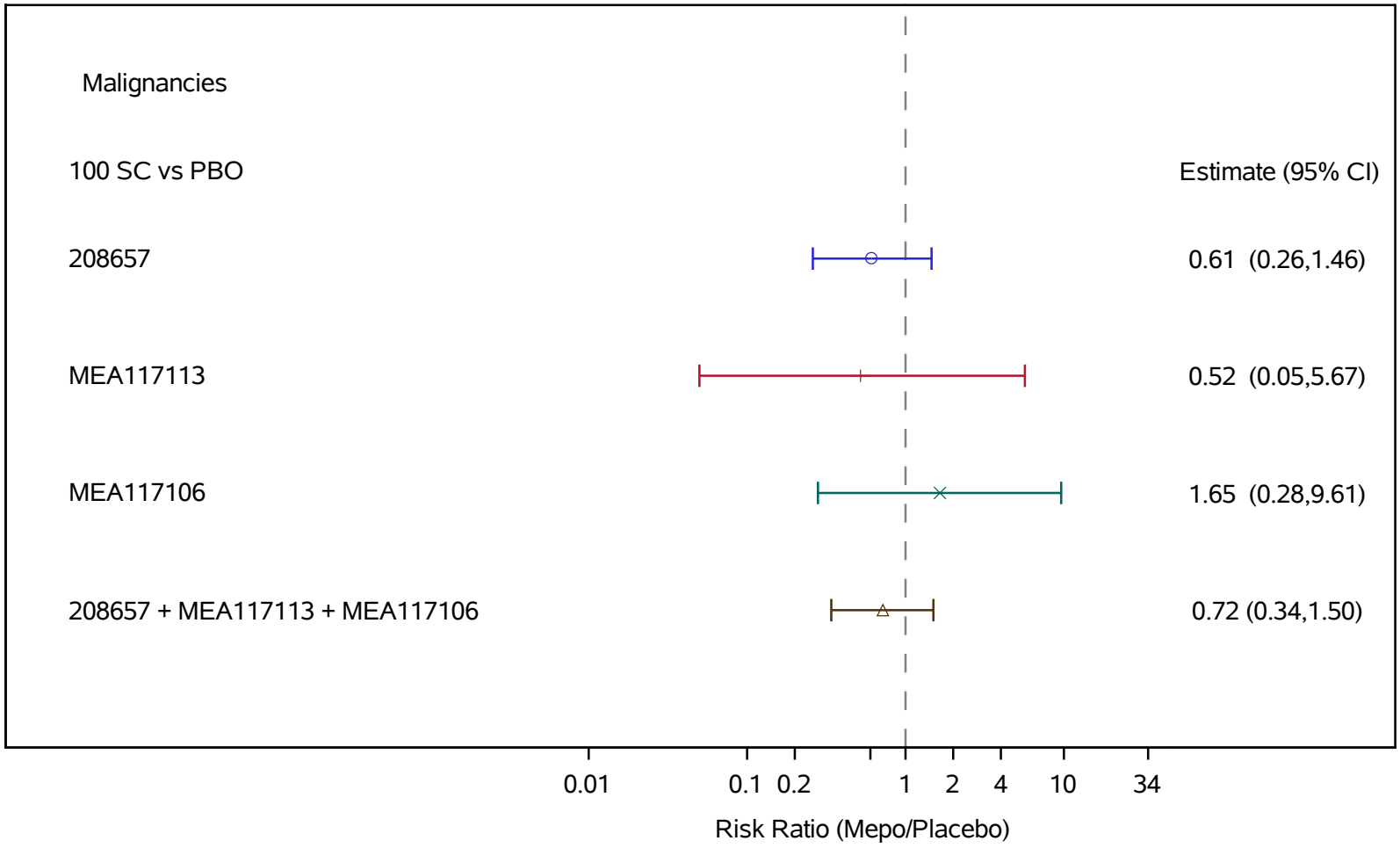

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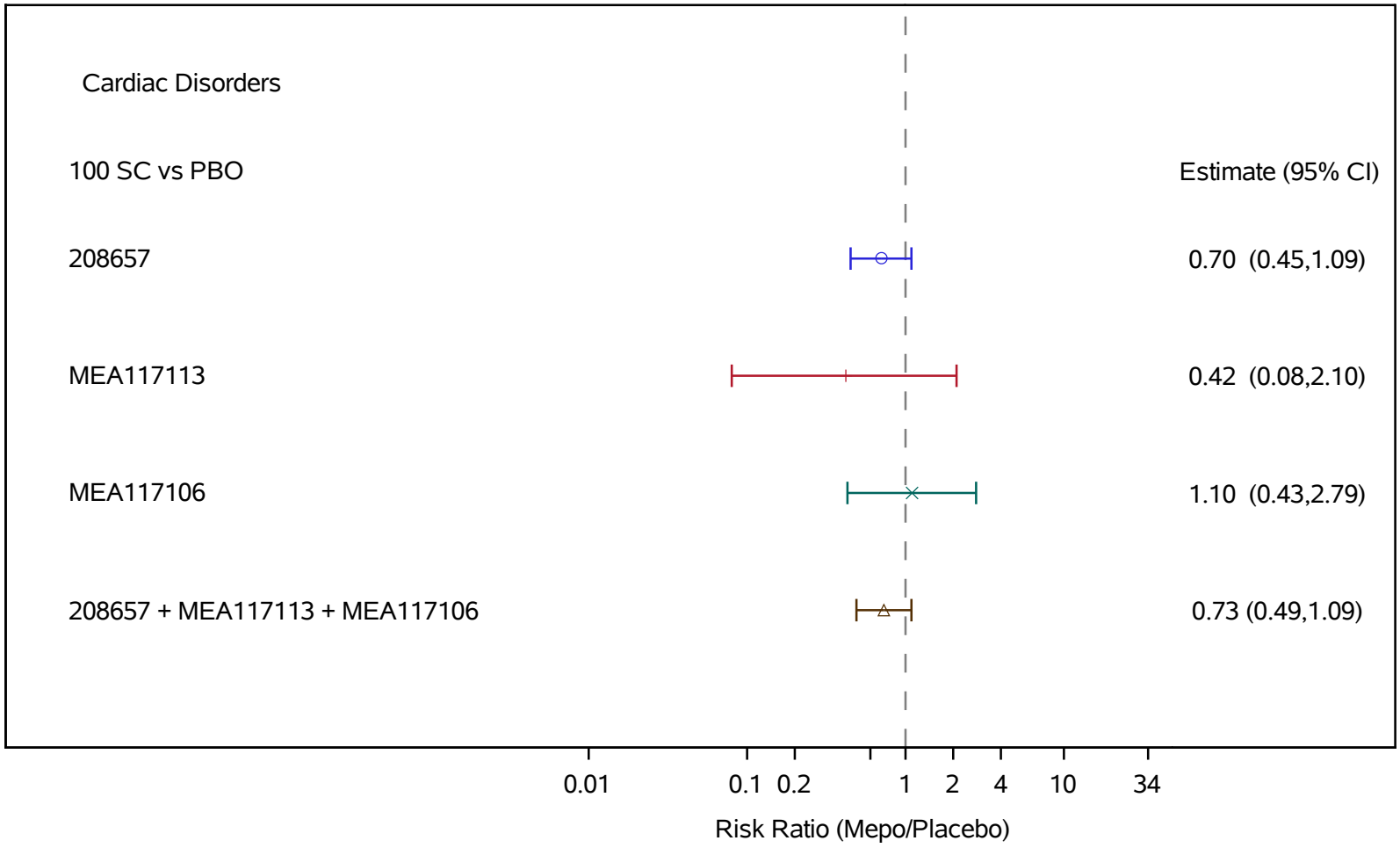

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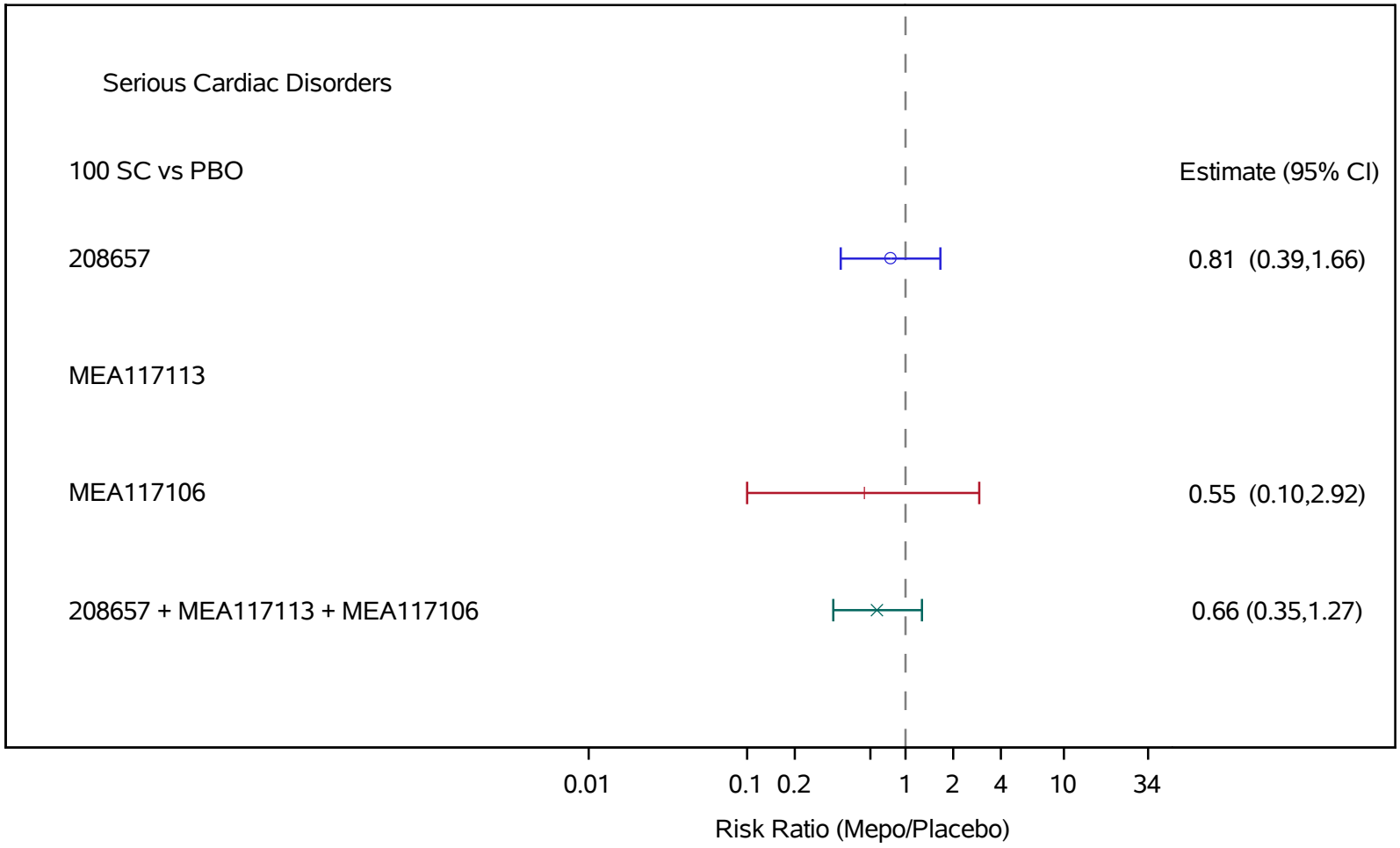

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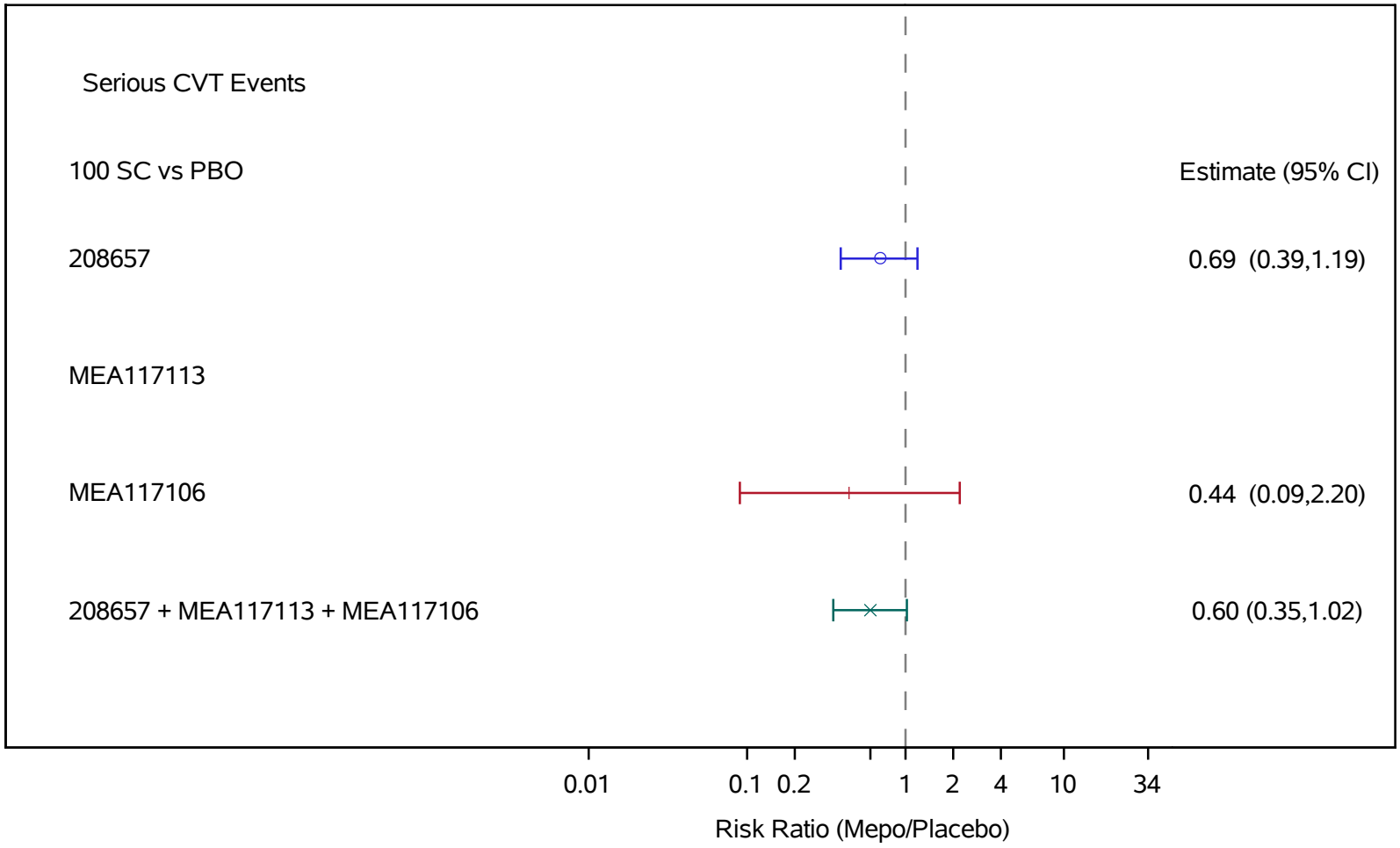

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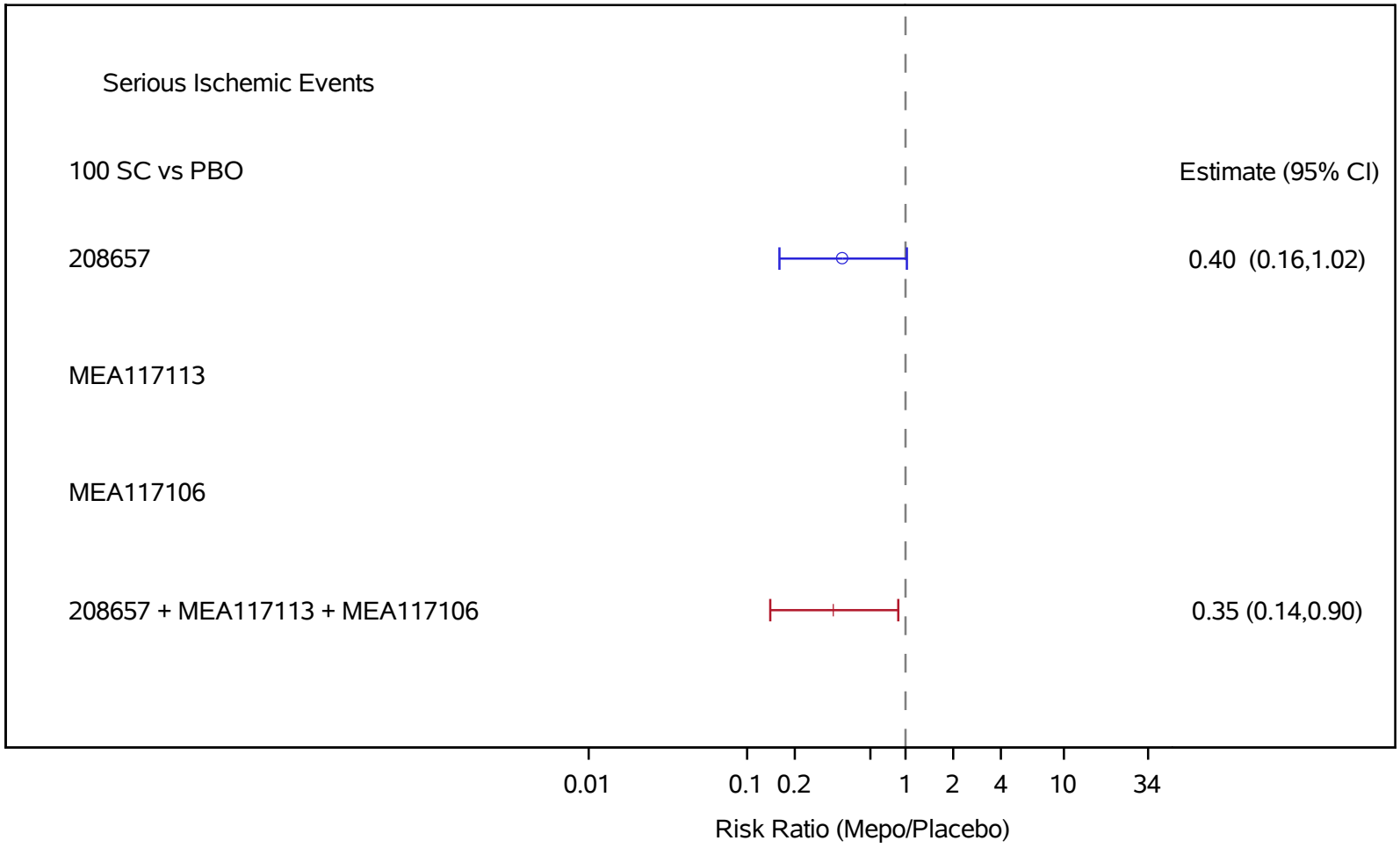

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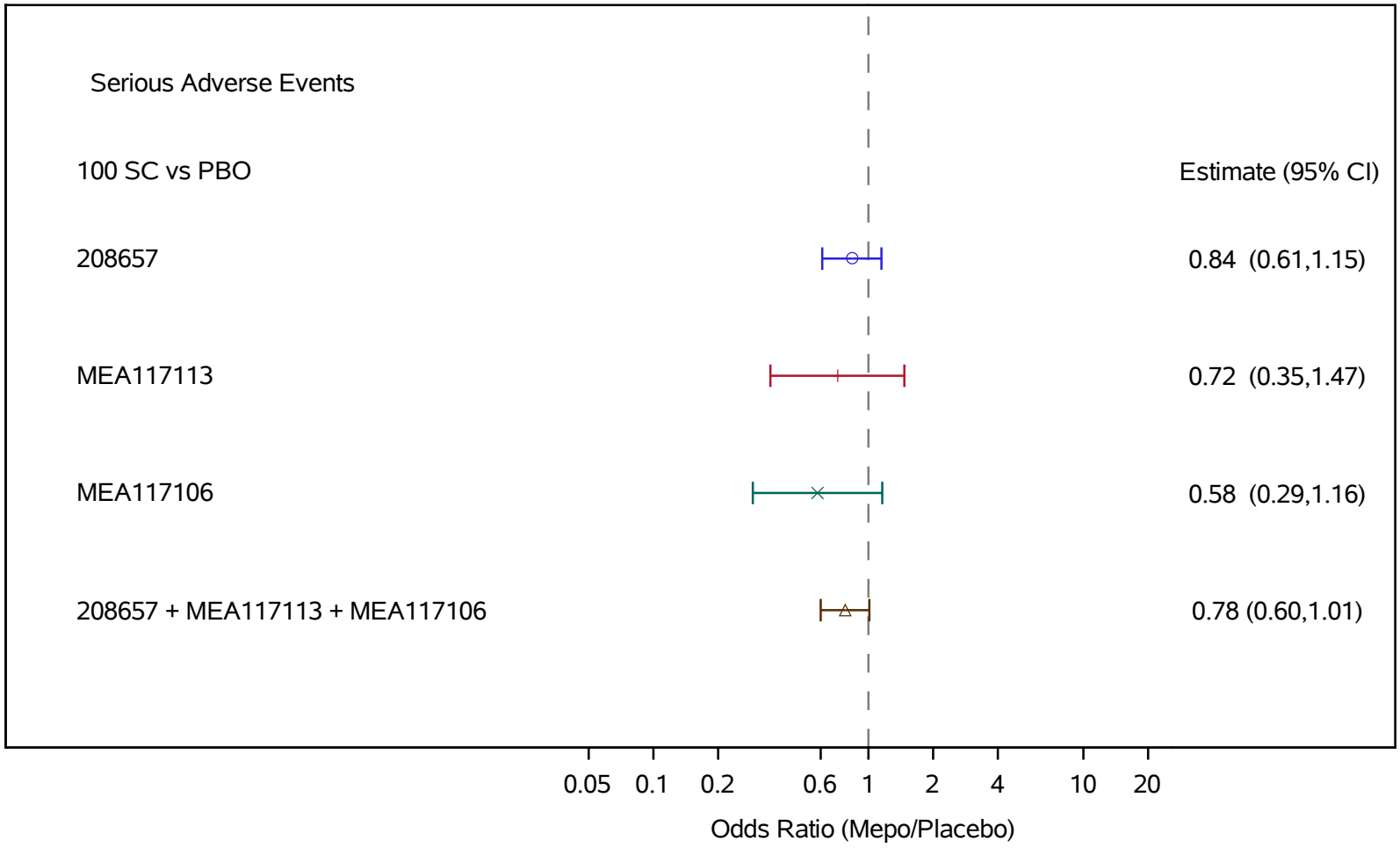

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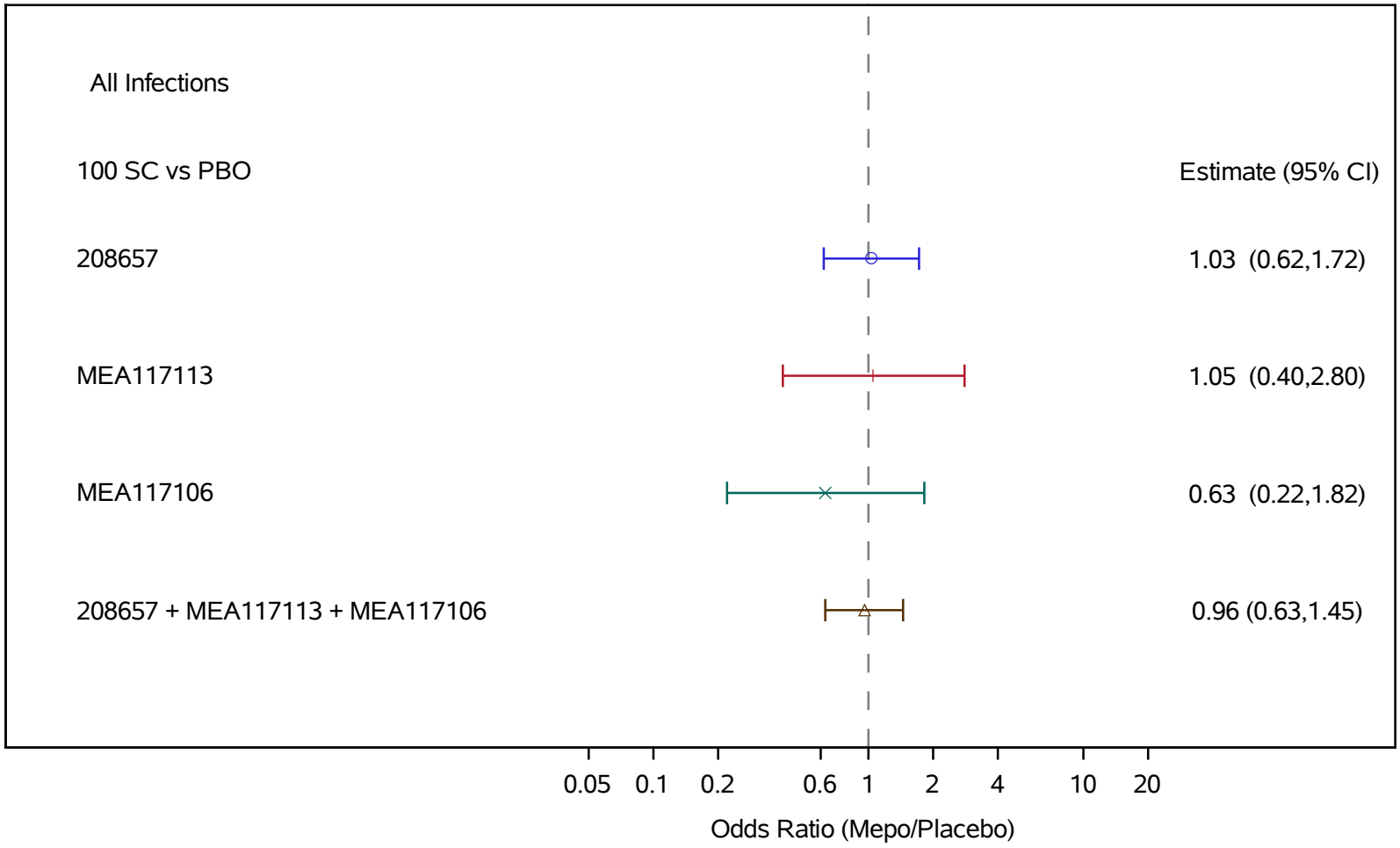

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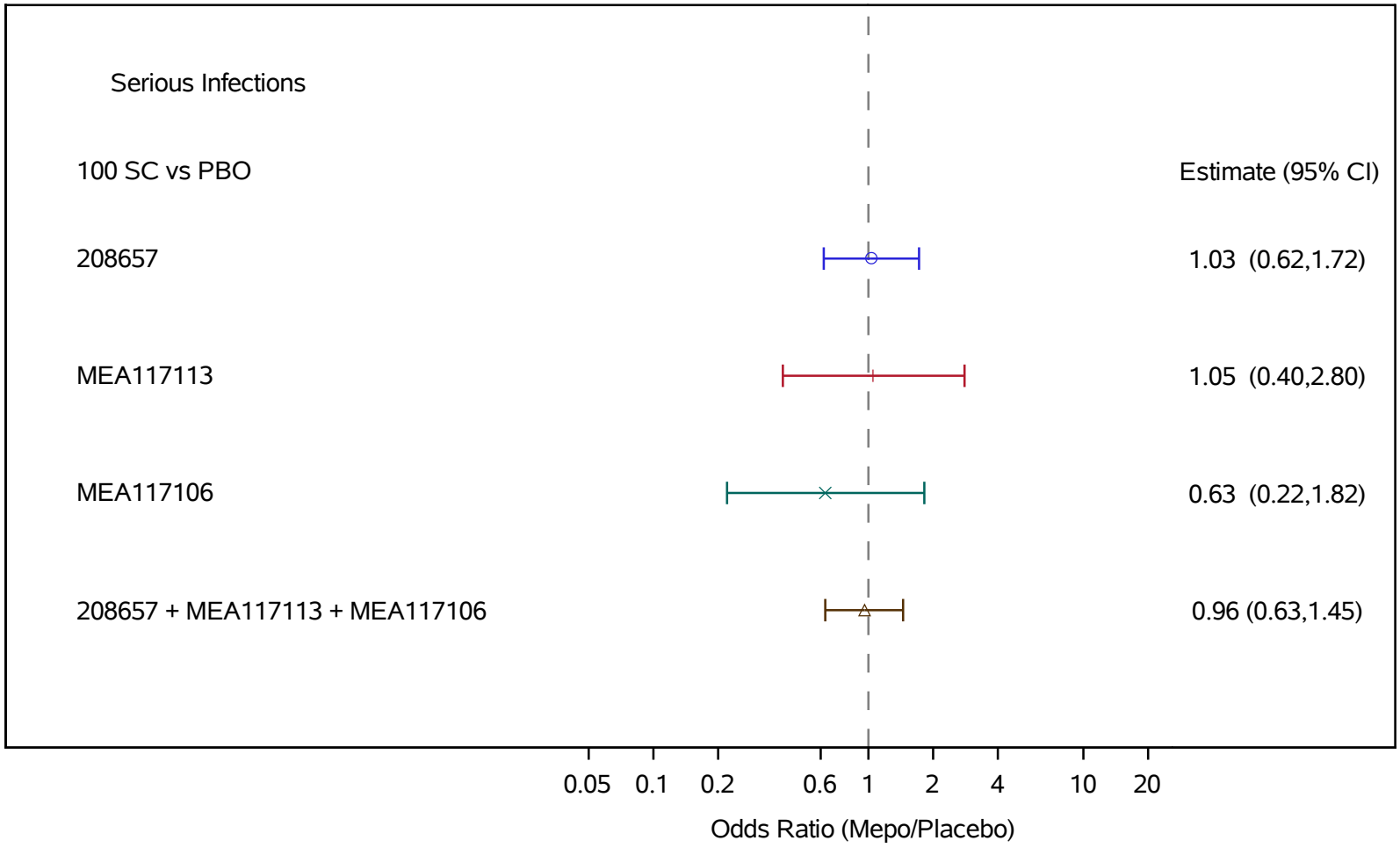

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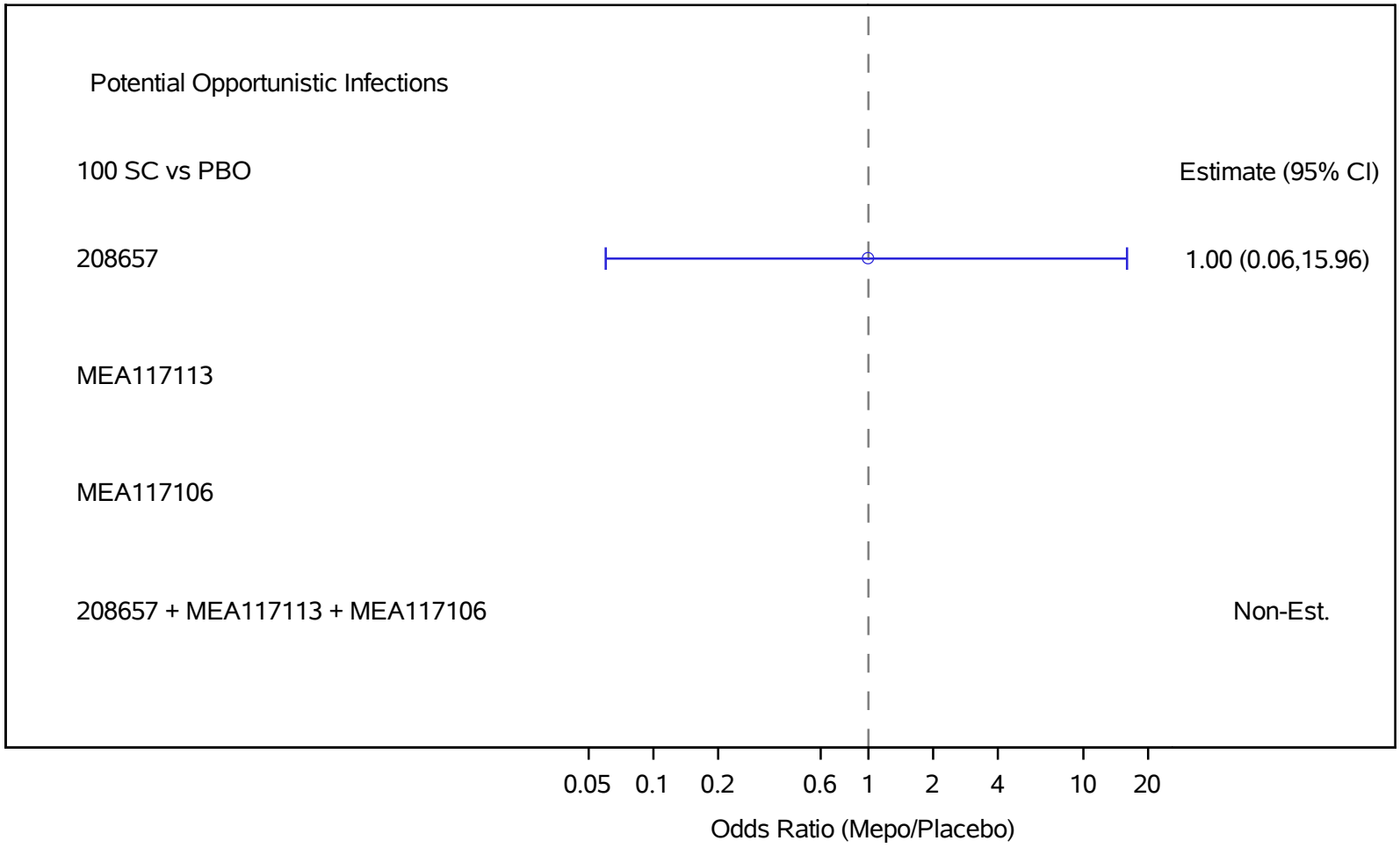

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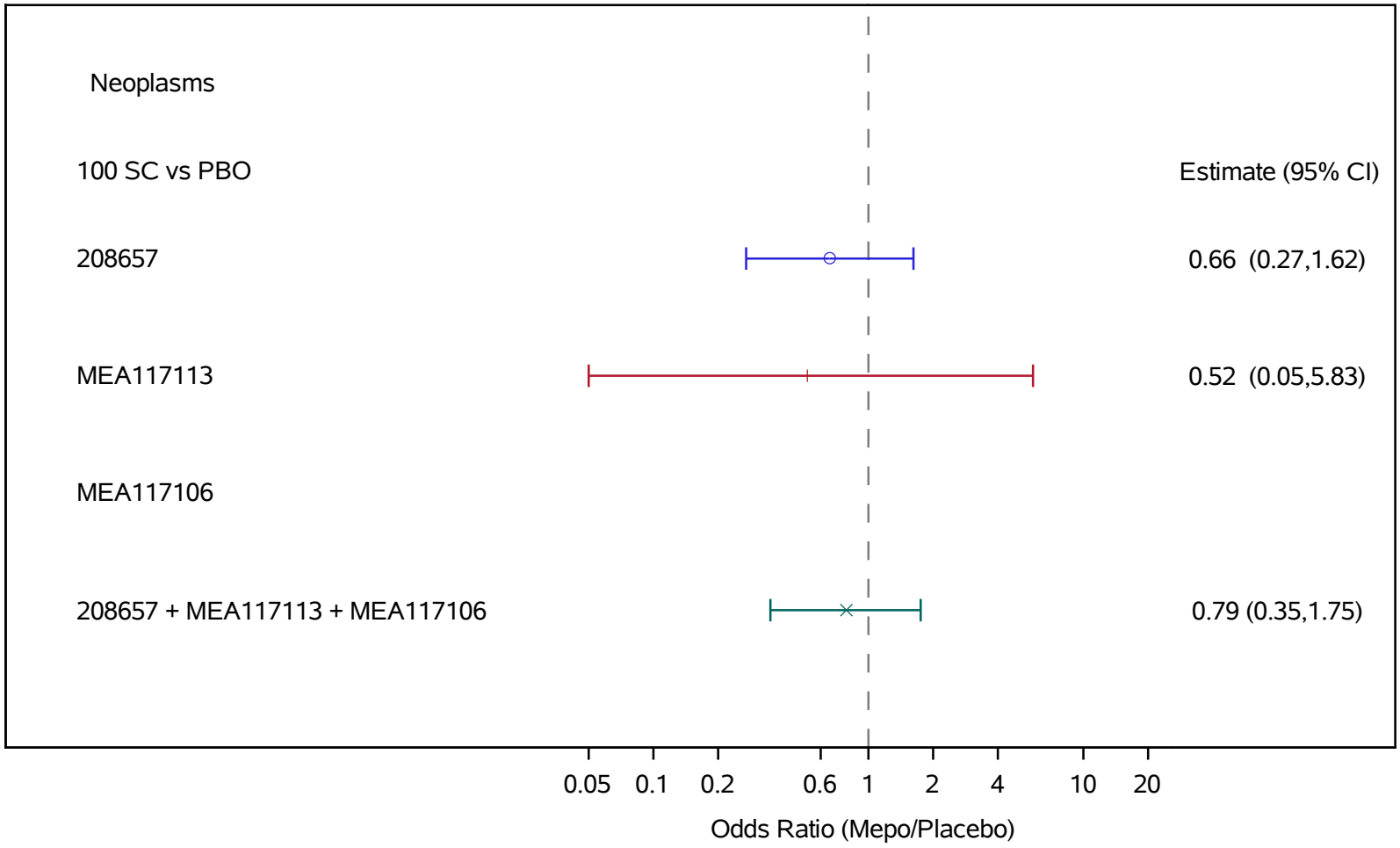

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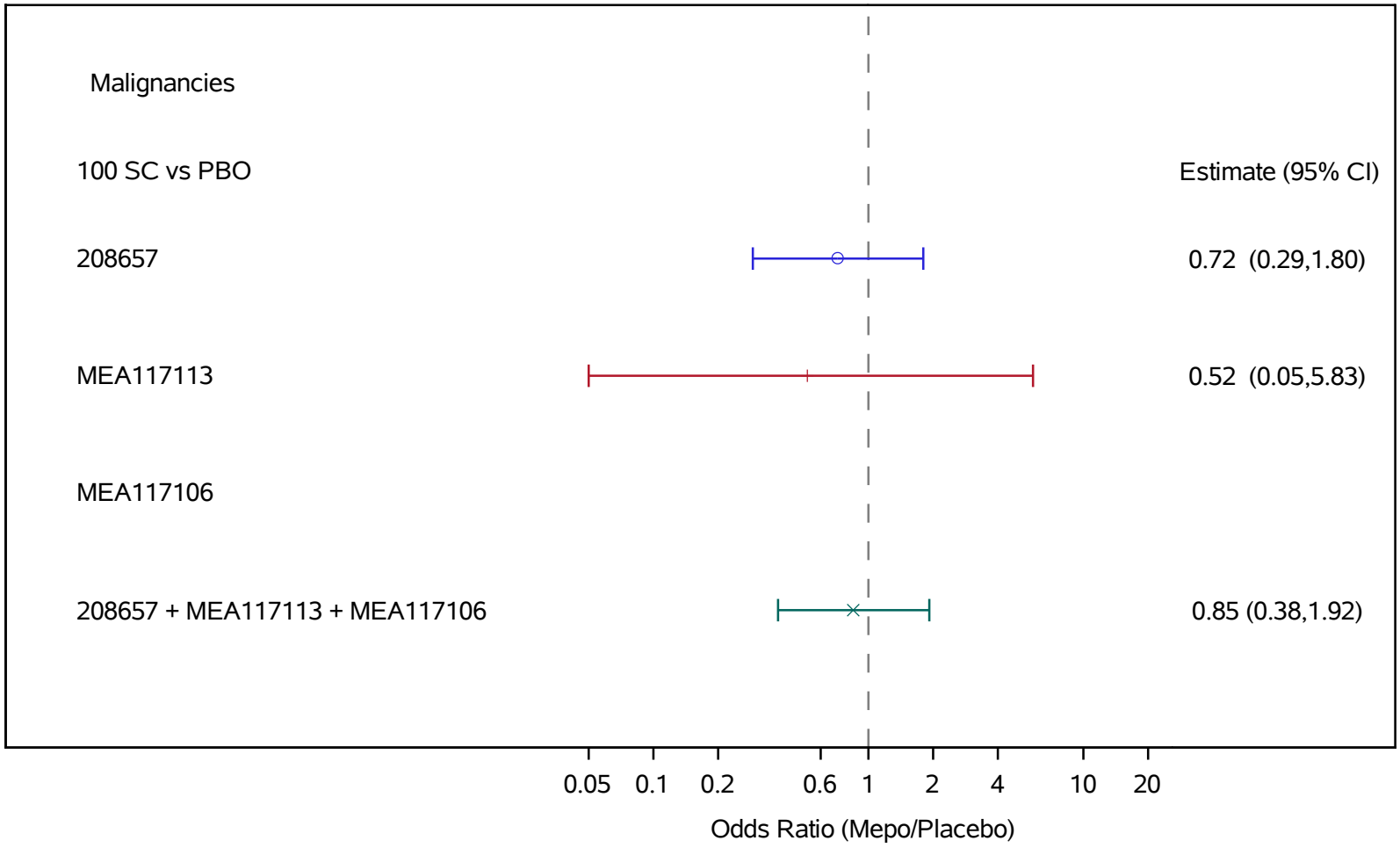

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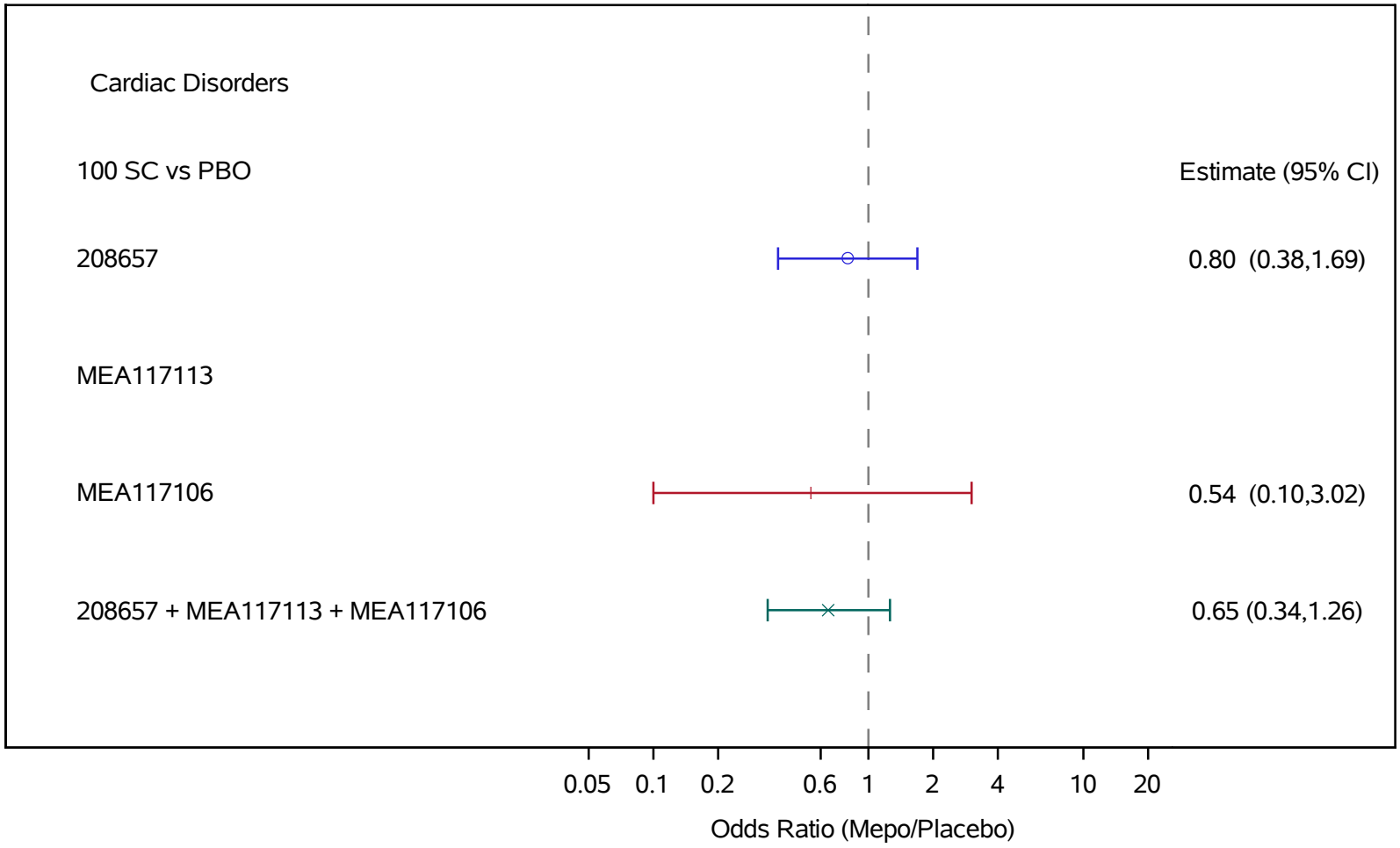

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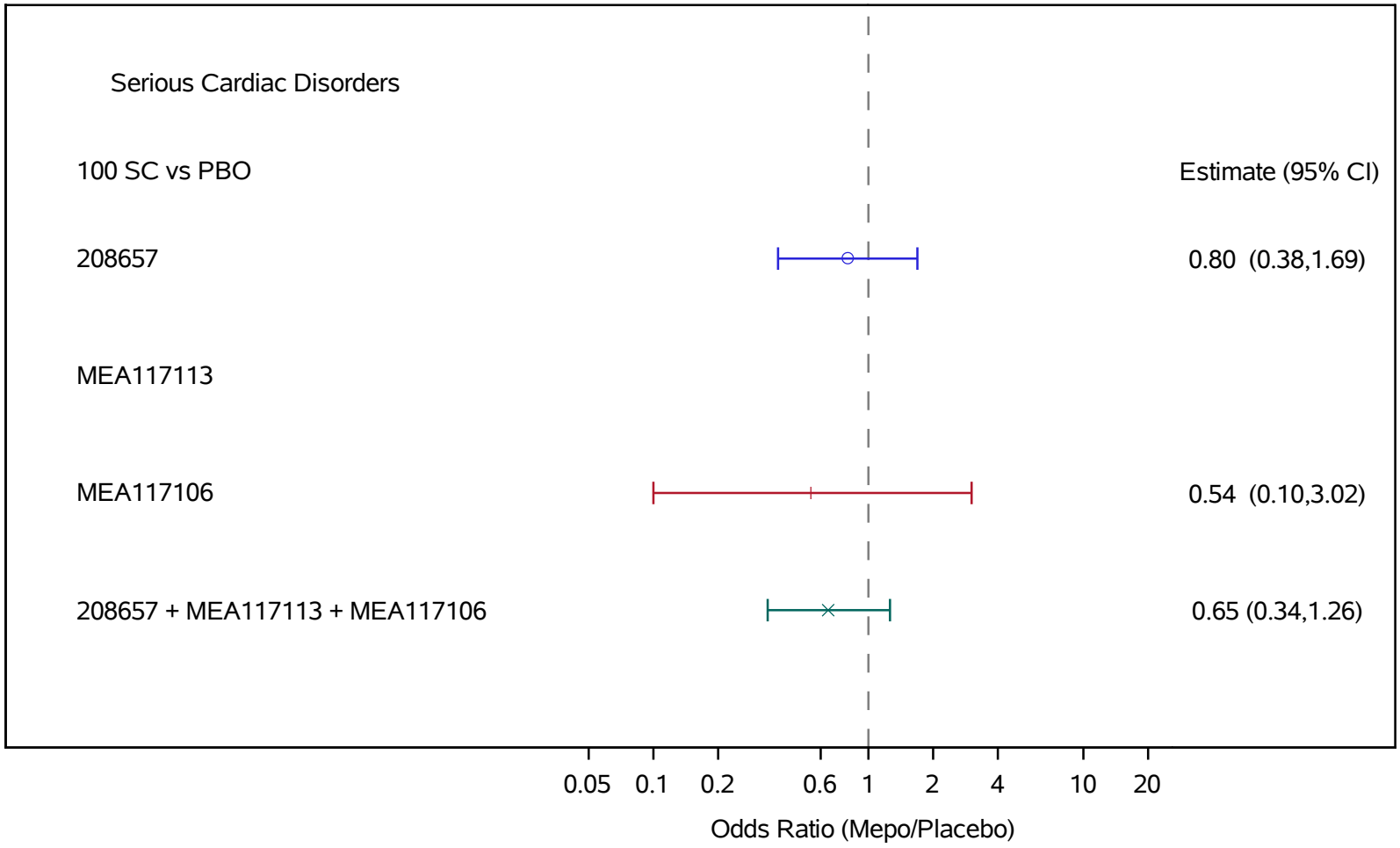

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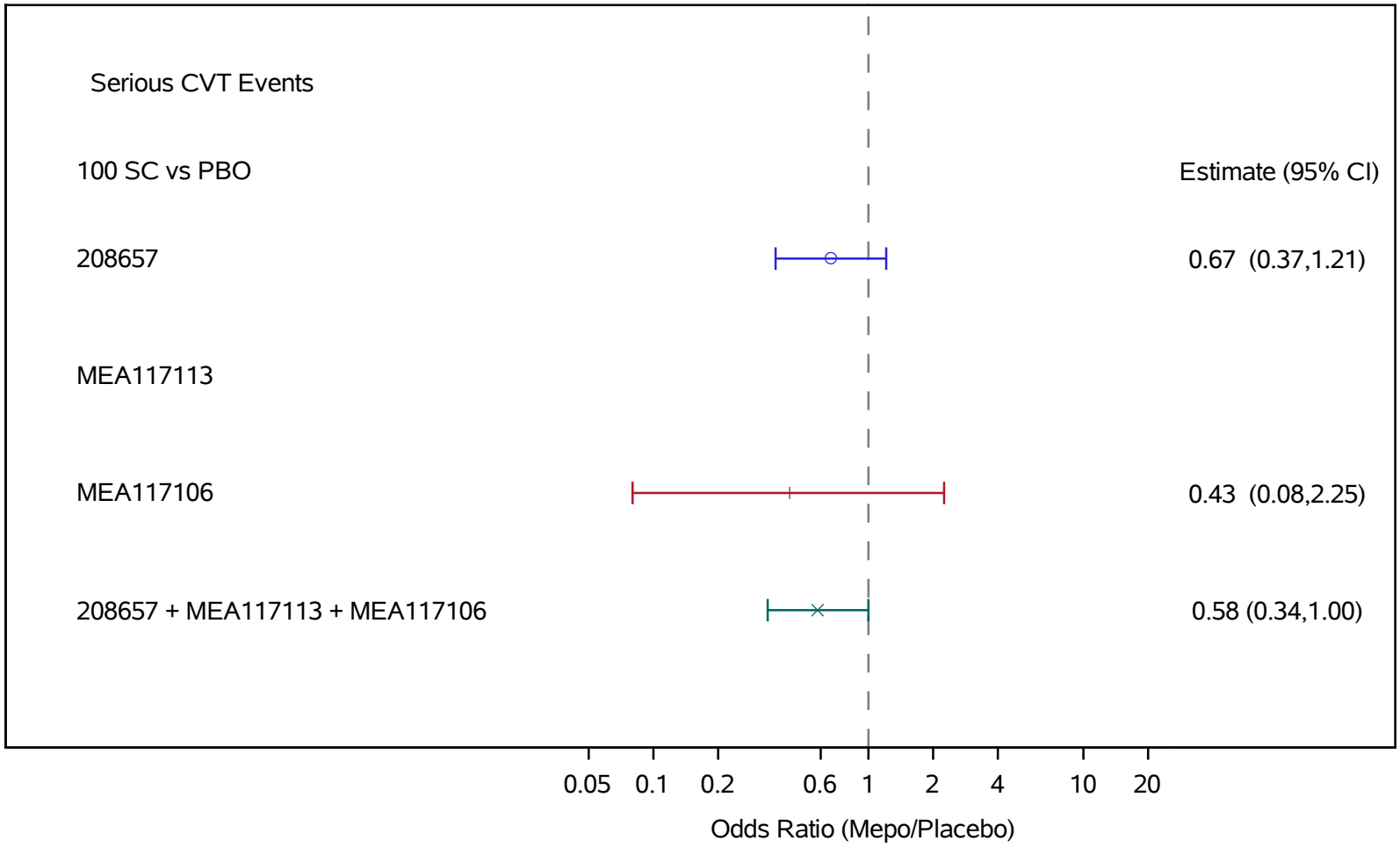

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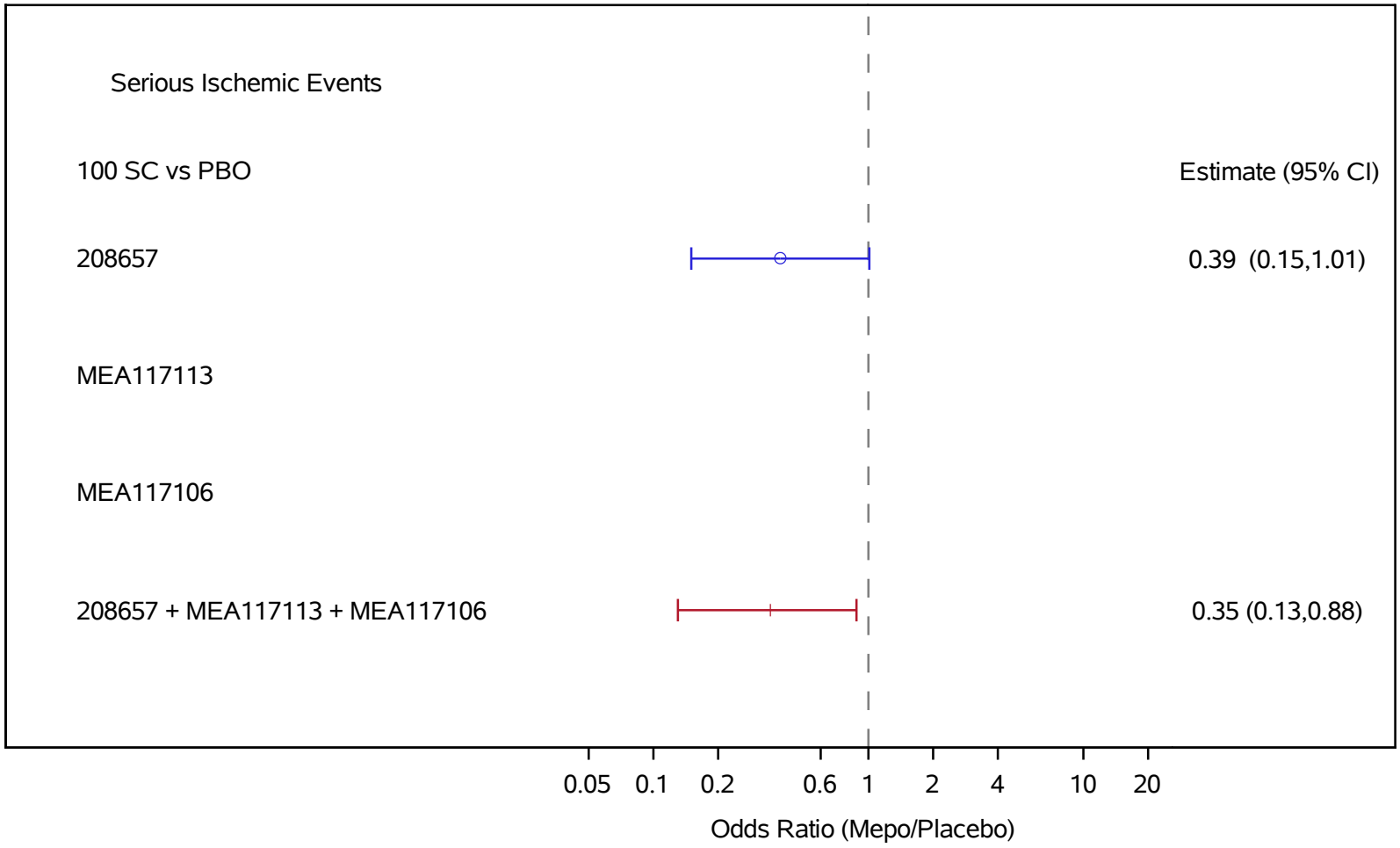

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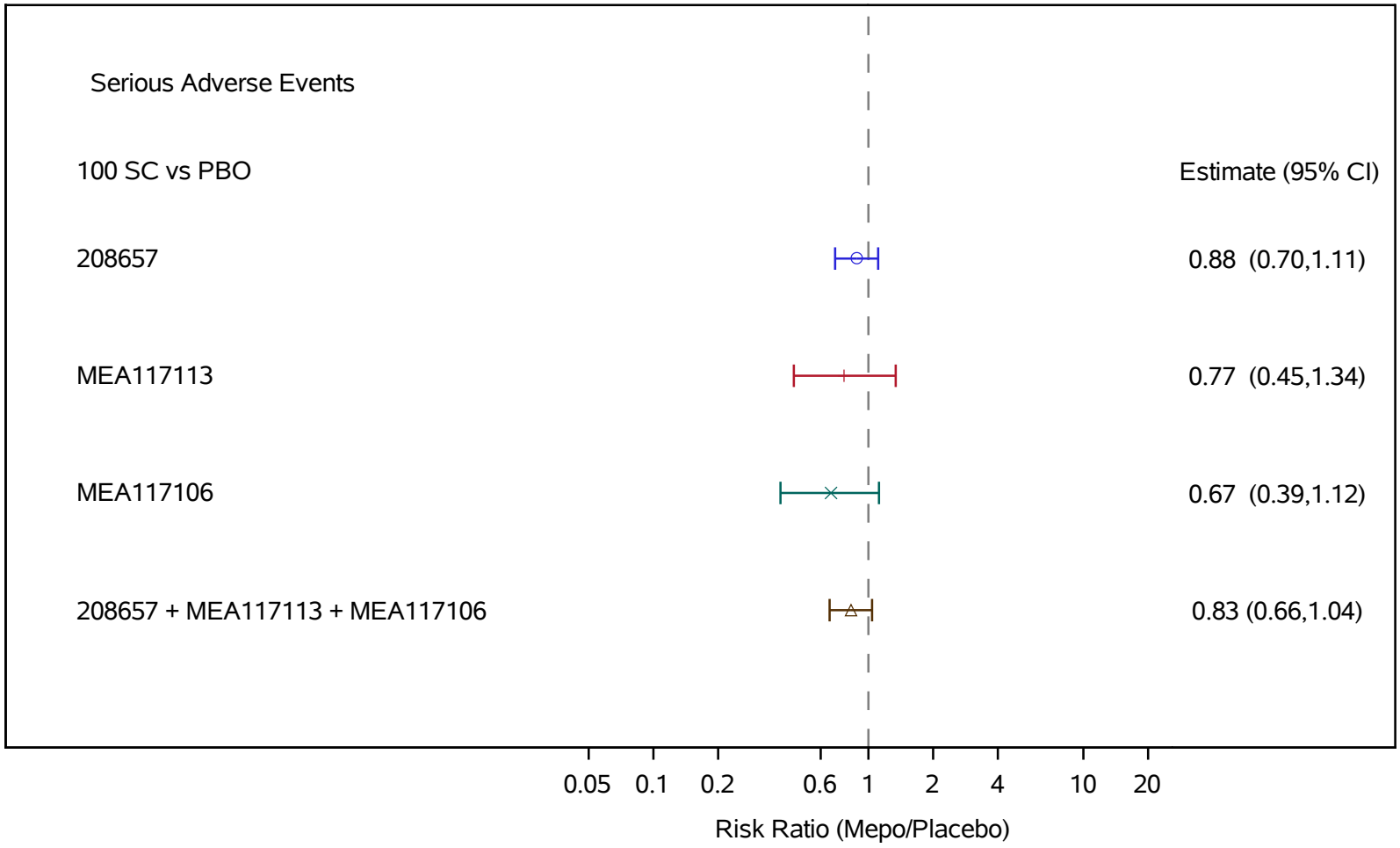
Figure 311.12

Forest Plot of Relative Risk for On-Treatment Serious Adverse Events of Special Interest: Individual Studies and Meta-Analysis



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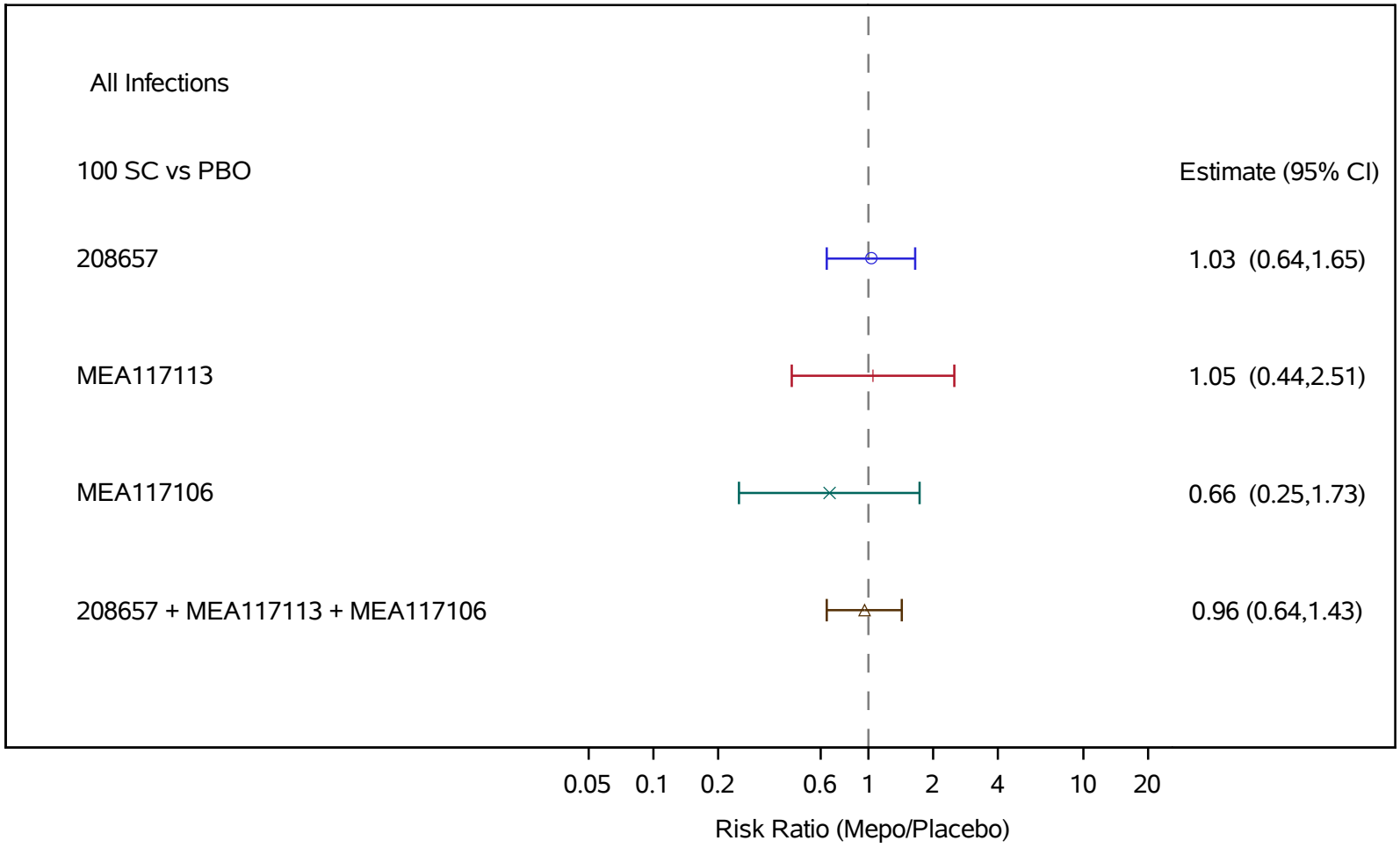

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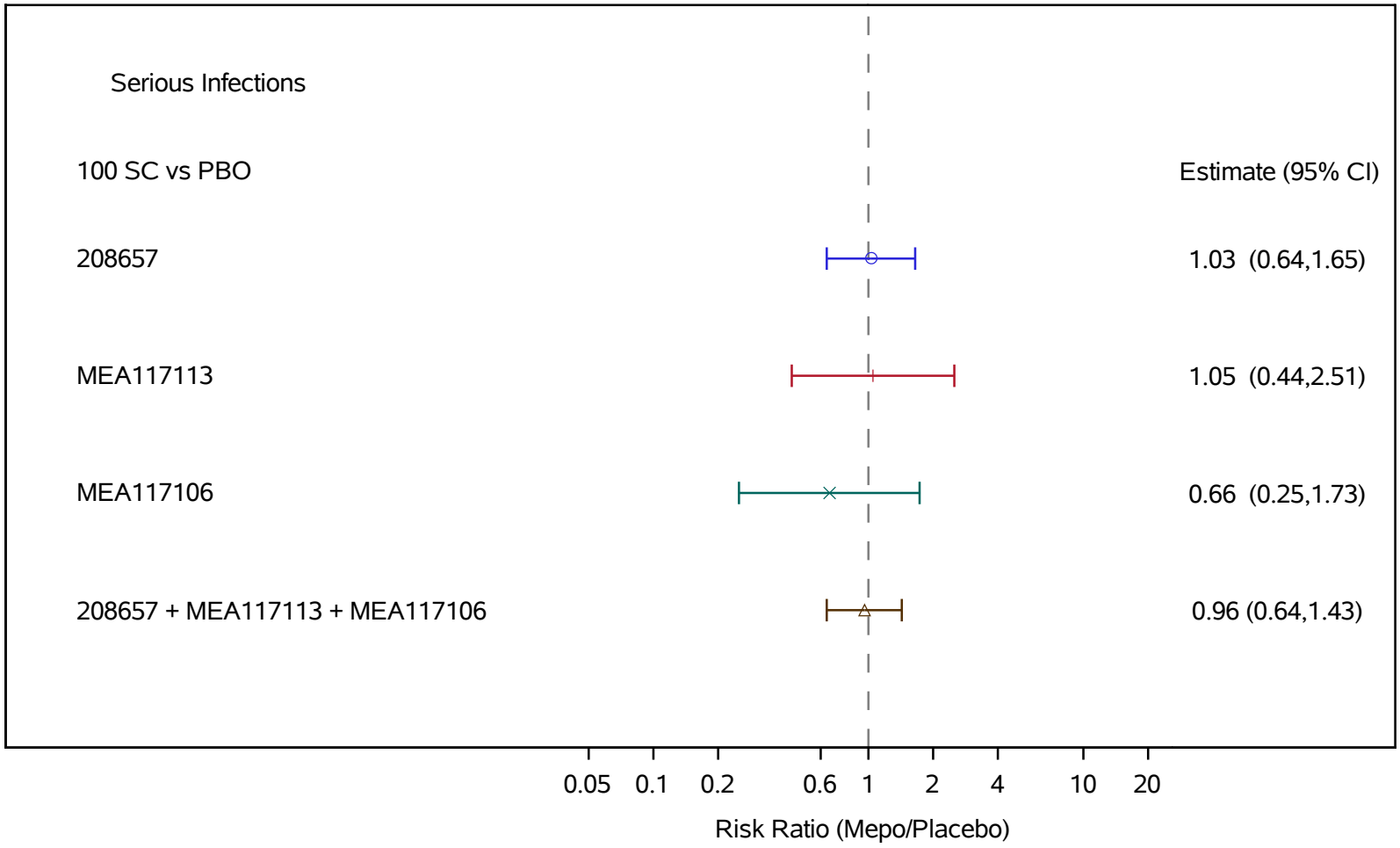

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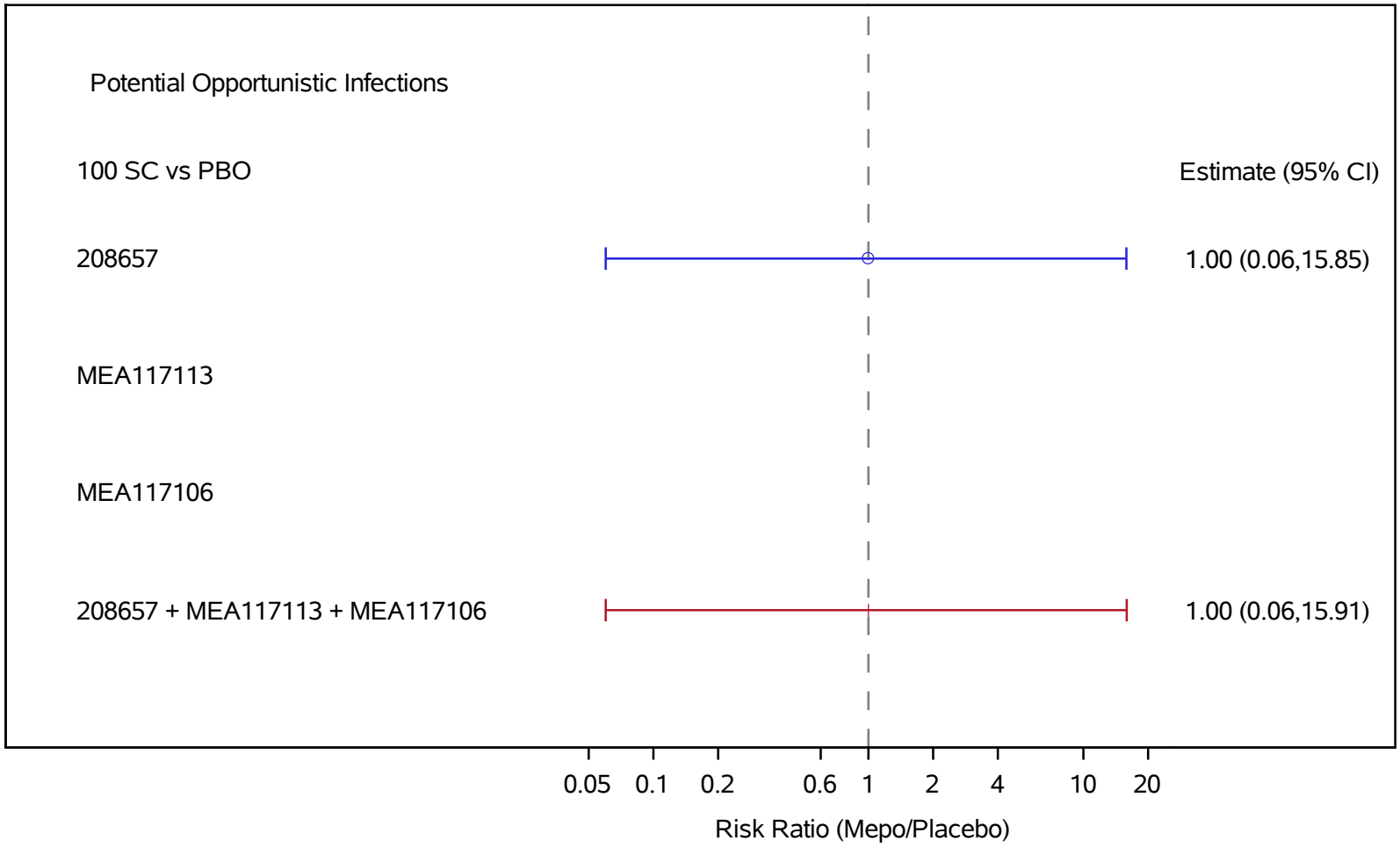

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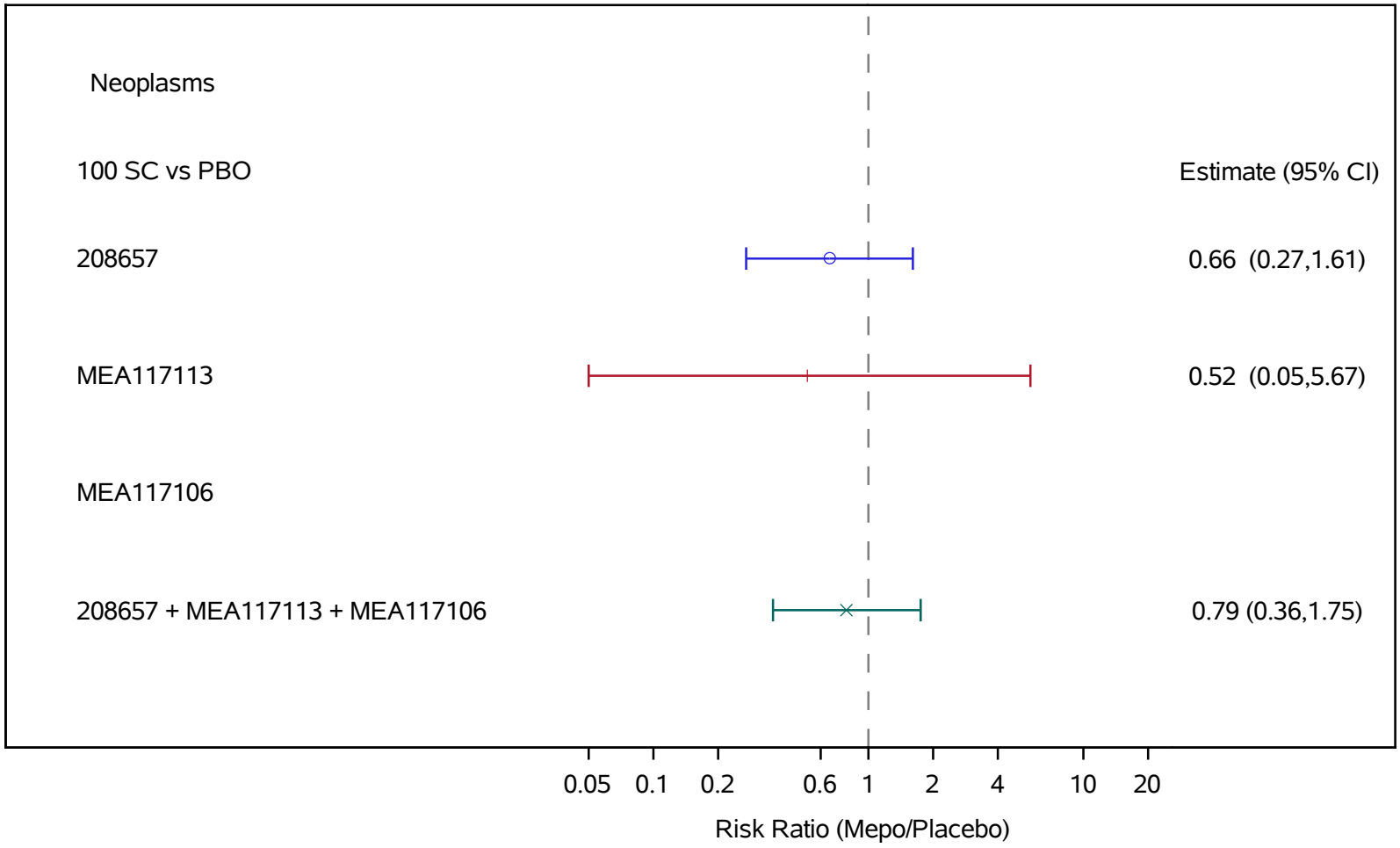

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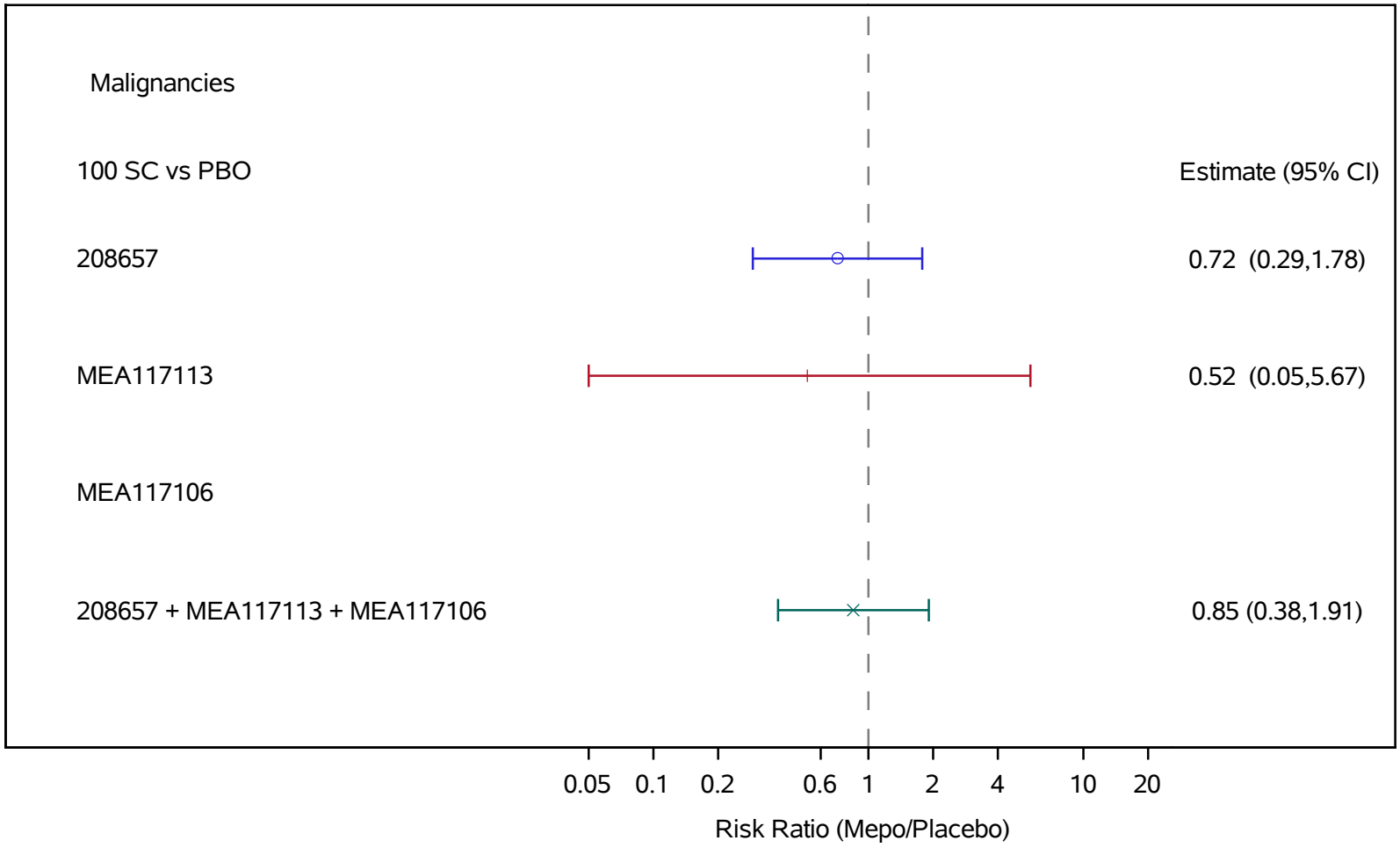
Forest Plot of Relative Risk for On-Treatment Serious Adverse Events of Special Interest: Individual Studies and Meta-Analysis



Horizontal bars indicate 95% confidence intervals for the Mepo/Placebo ratio.

Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

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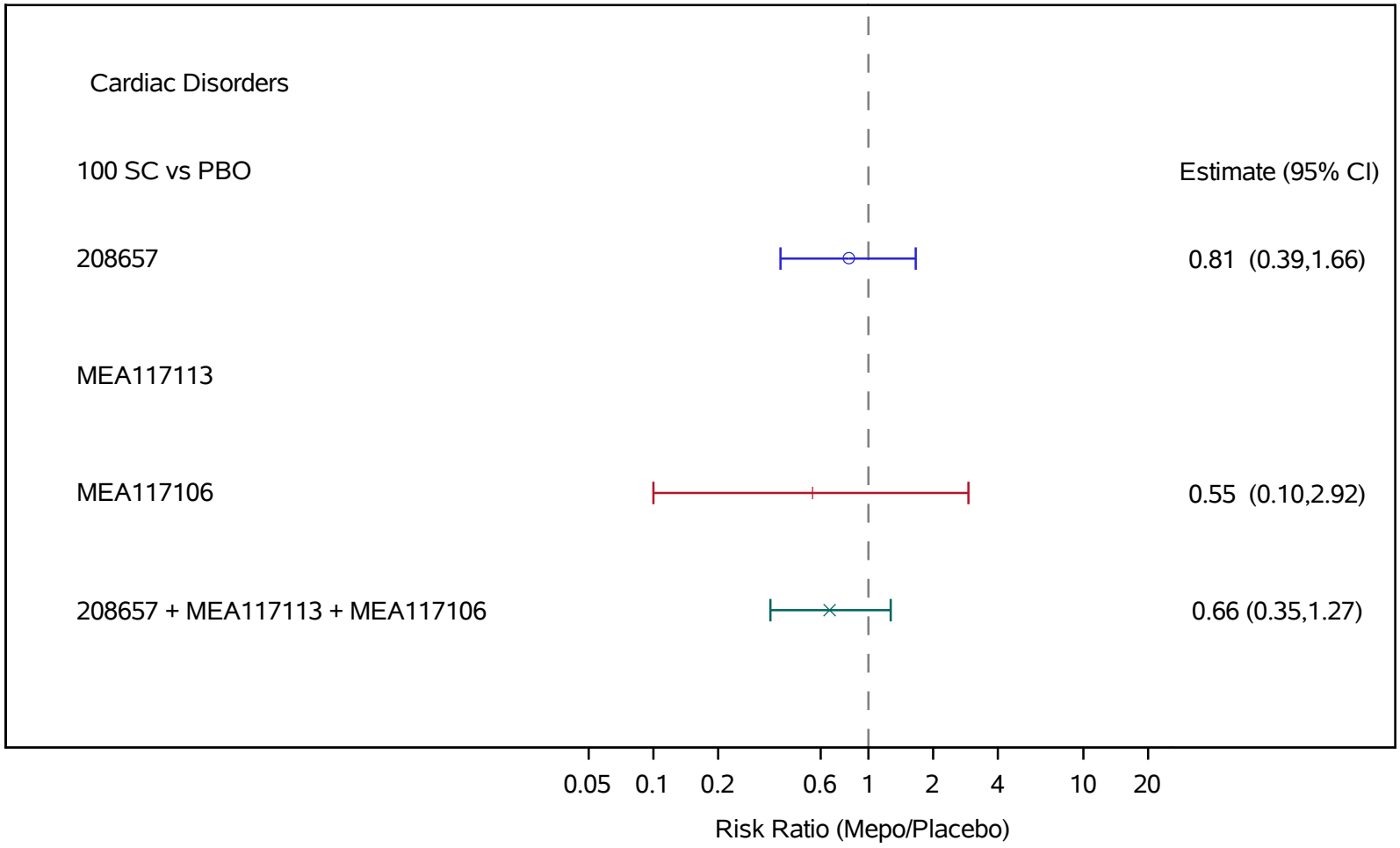

Horizontal bars indicate 95% confidence intervals for the Mepo/Placebo ratio.

/mnt/code/postcsr_01/prod/tfls/f_s_aesi_sae_rr.sas 17JUL2025 18:11

Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

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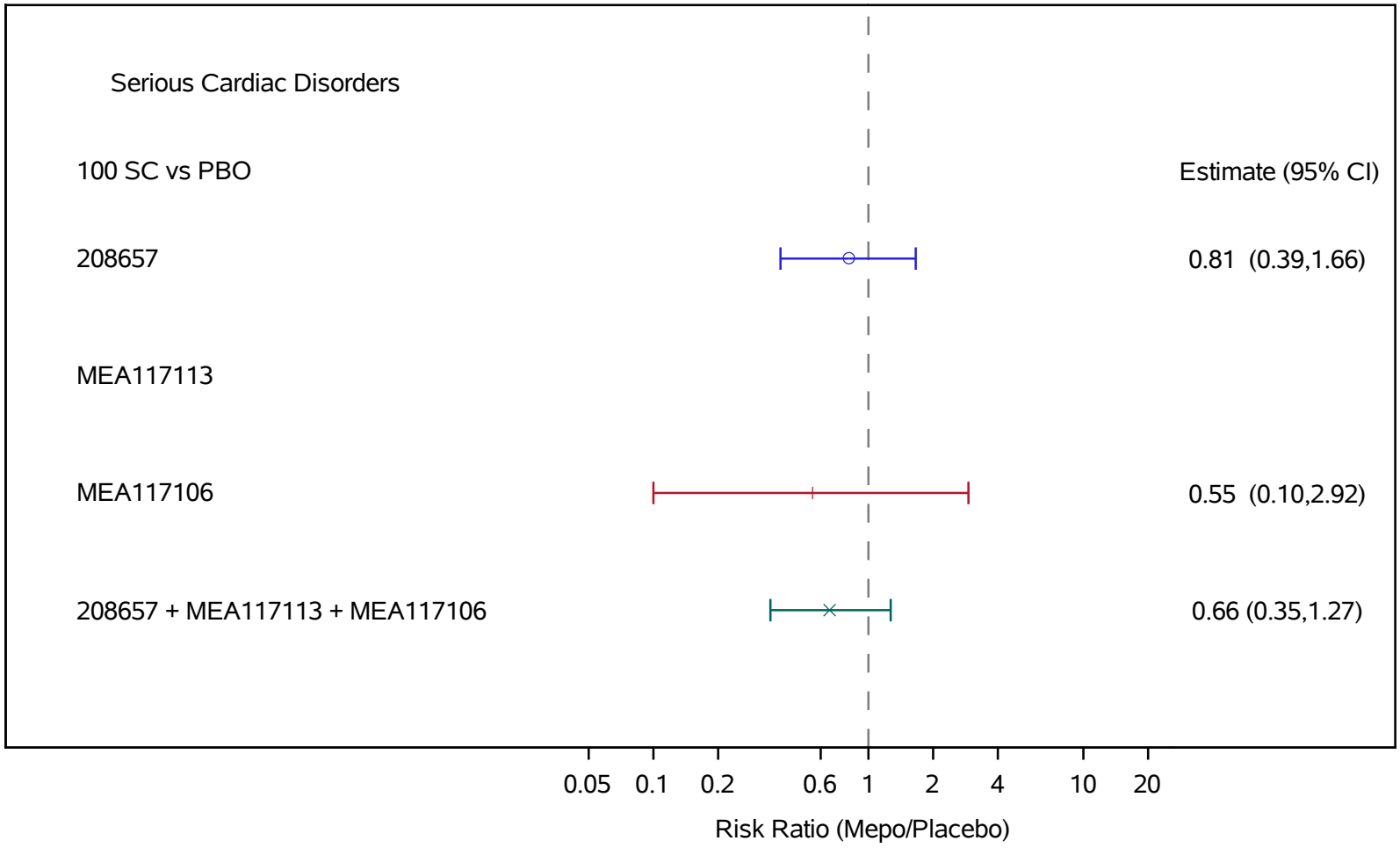

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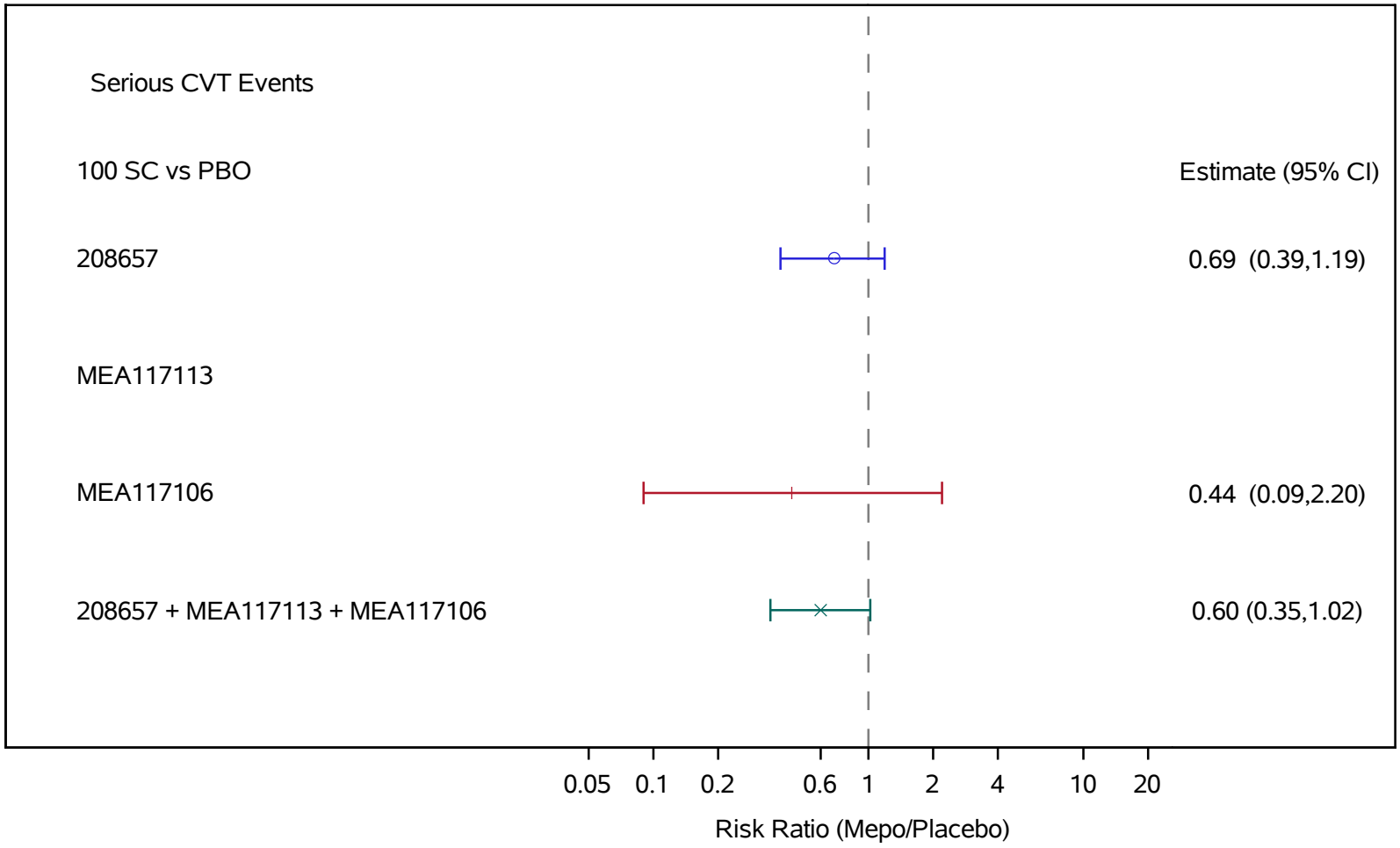

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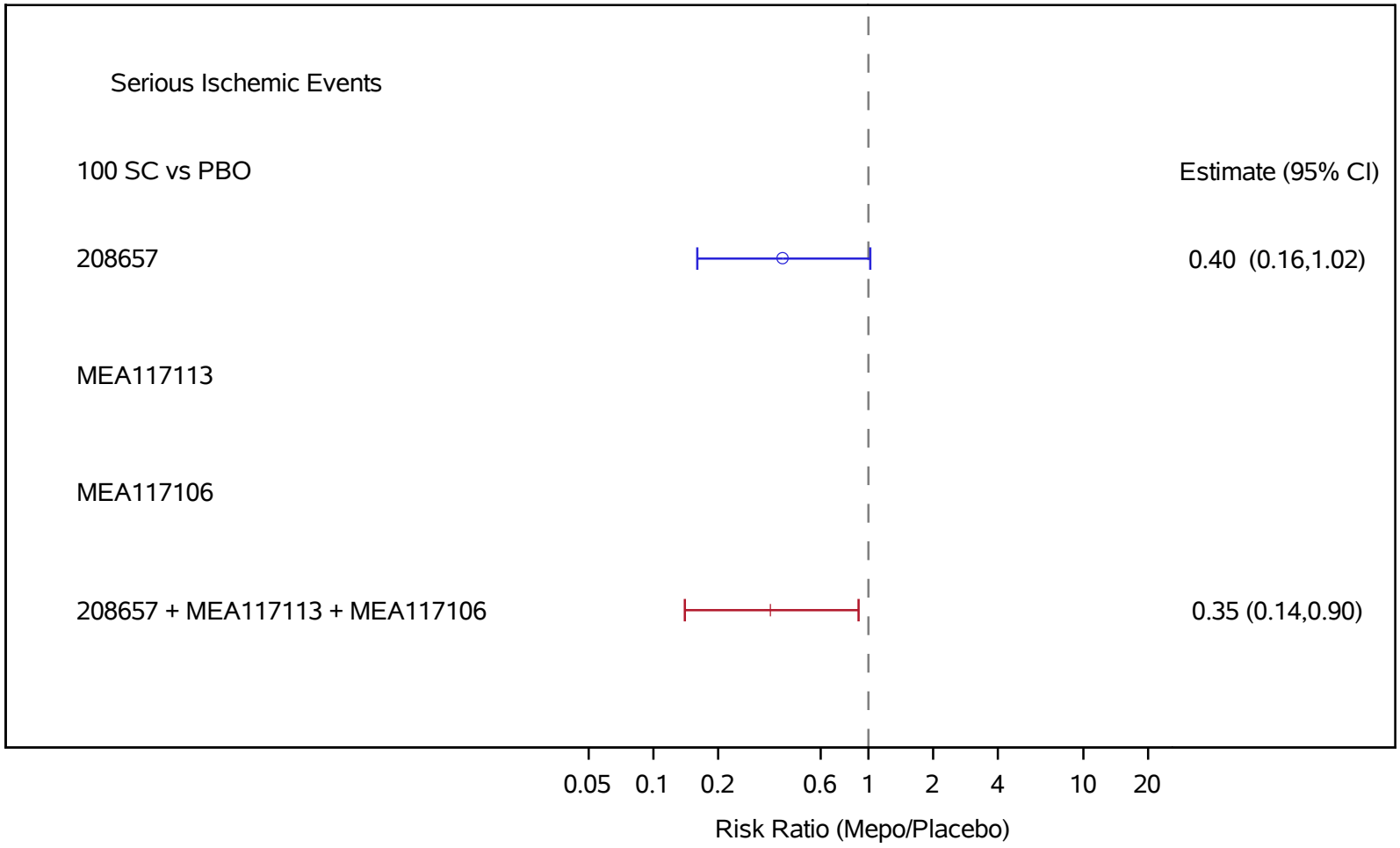

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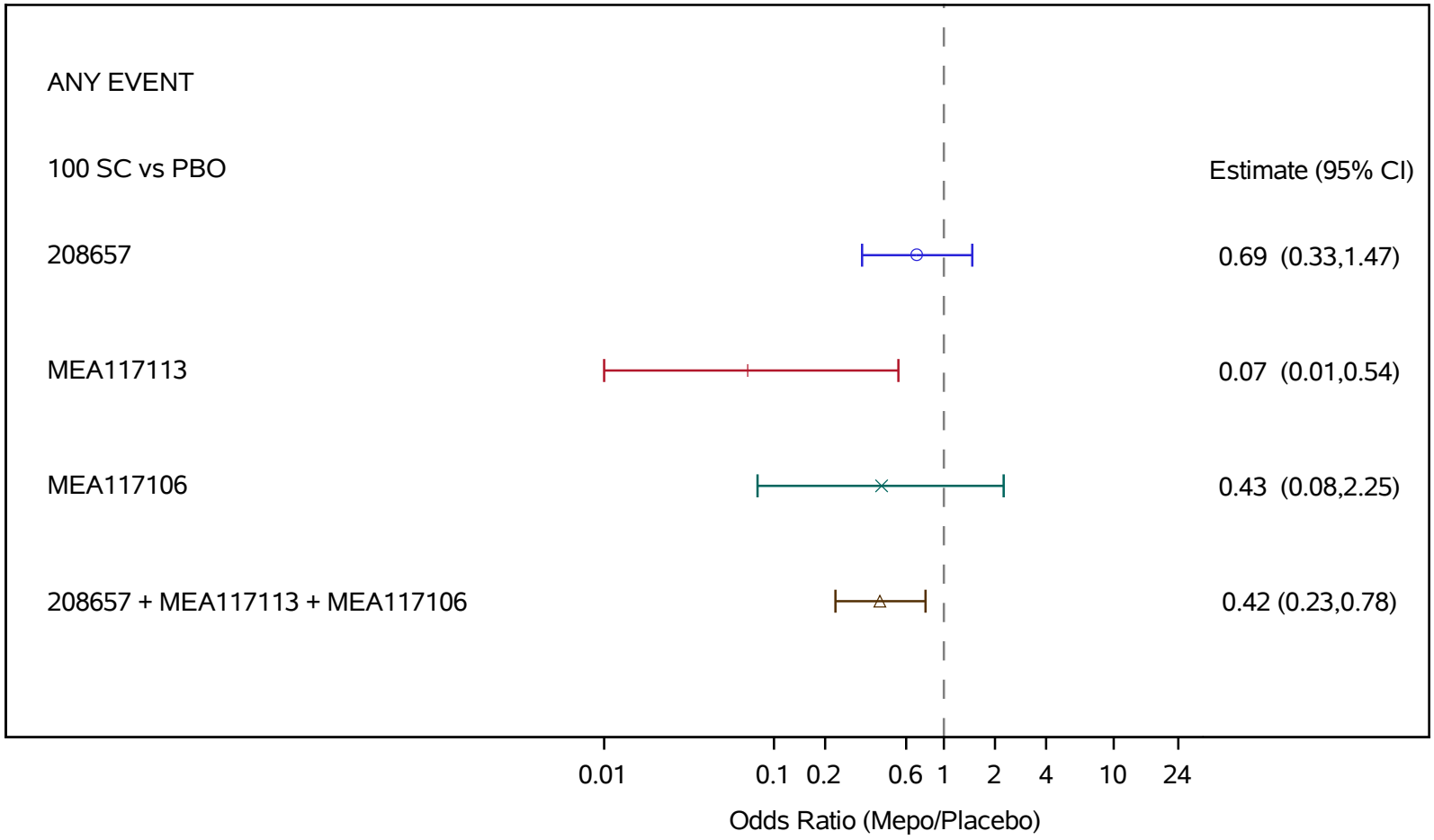
Figure 311.13

Forest Plot of Odds ratio for On-Treatment Adverse Events leading to study drug withdrawal by SOC and PT: Individual Studies and Meta-Analysis



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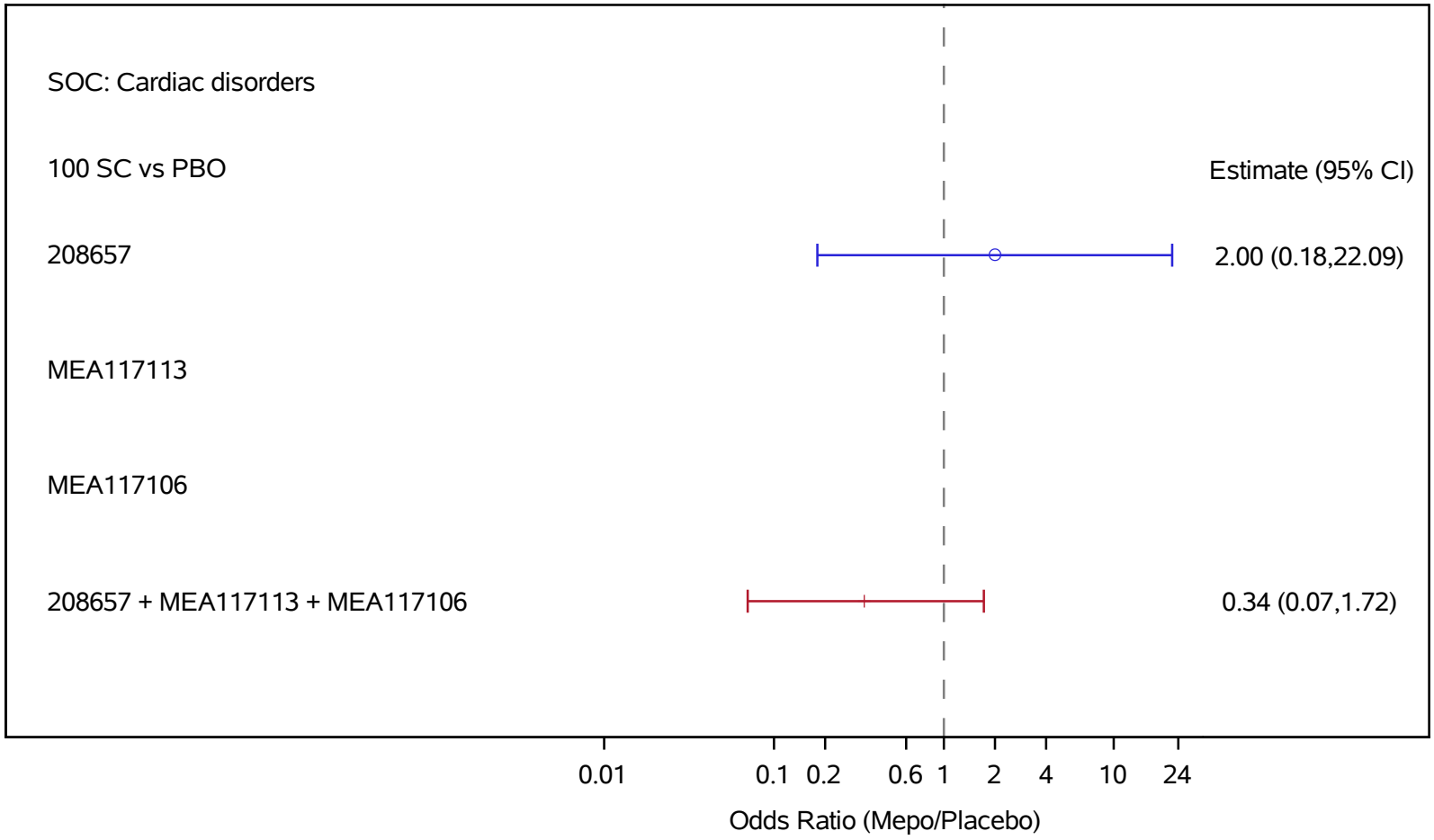
Forest Plot of Odds ratio for On-Treatment Adverse Events leading to study drug withdrawal by SOC and PT: Individual Studies and Meta-Analysis



Horizontal bars indicate 95% confidence intervals for the Mepo/Placebo ratio.

/mnt/code/postcsr_01/prod/tfls/f_s_ae_onae_ipd_or.sas 17JUL2025 18:13

Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

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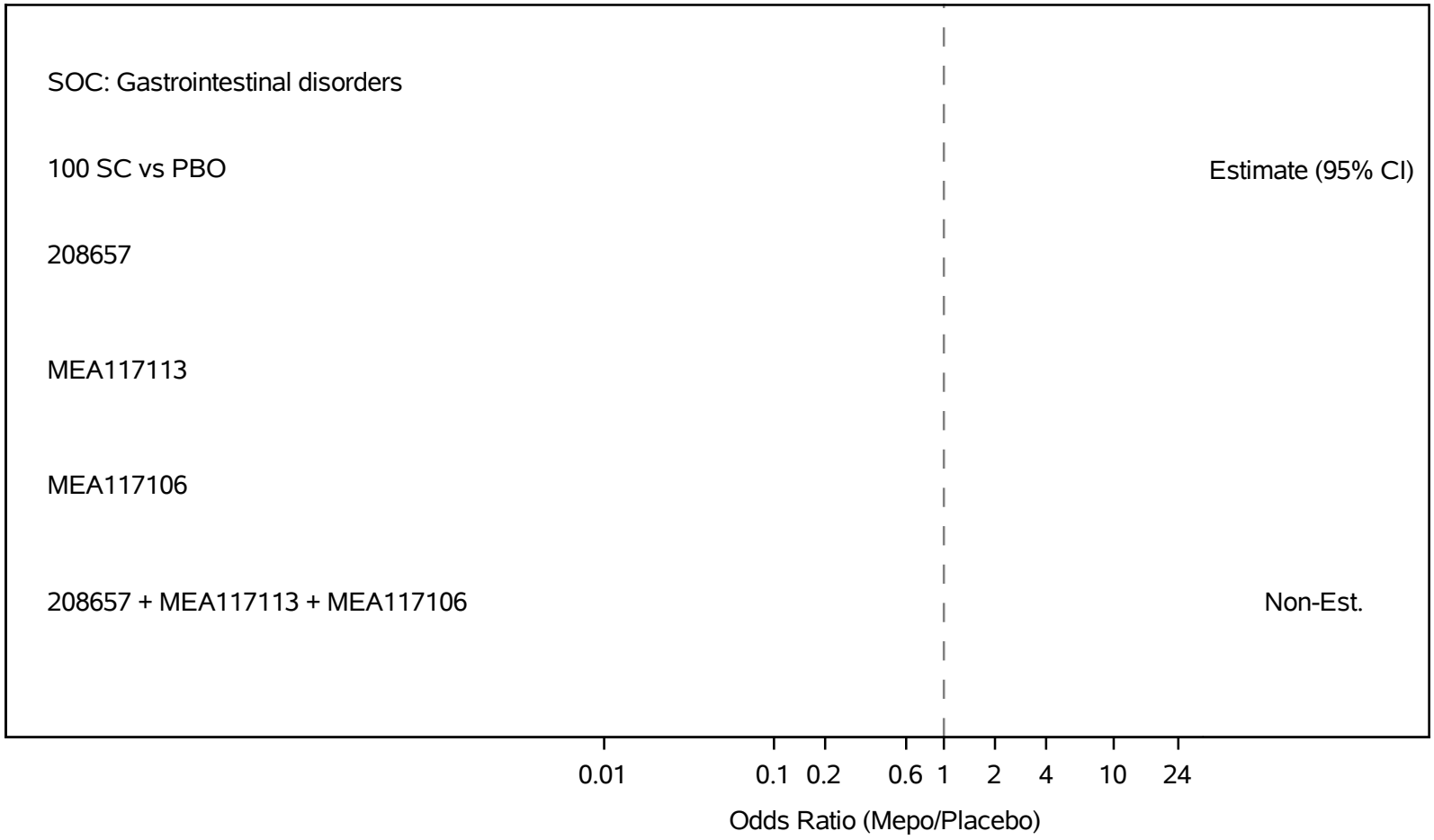
Forest Plot of Odds ratio for On-Treatment Adverse Events leading to study drug withdrawal by SOC and PT: Individual Studies and Meta-Analysis



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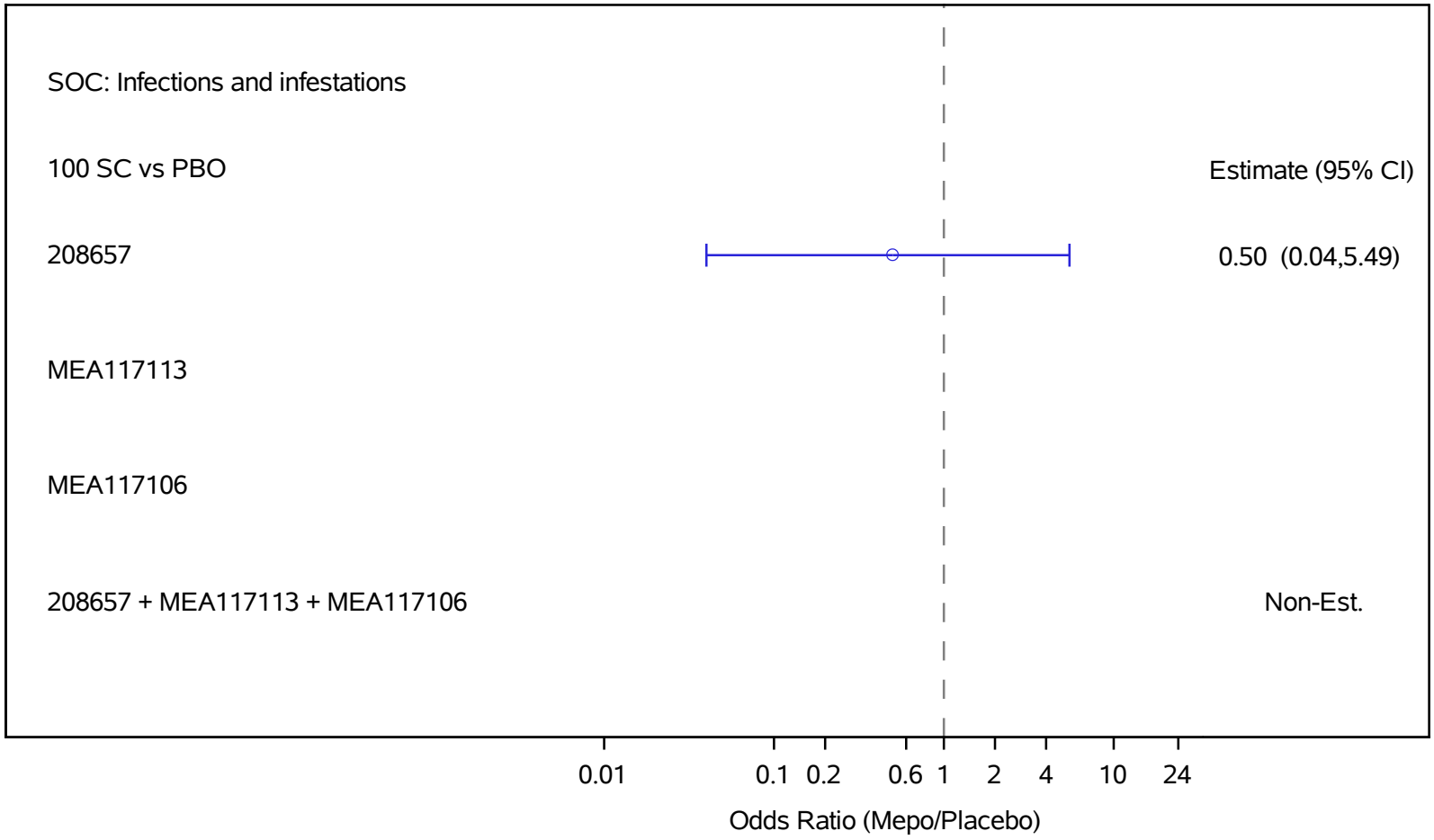

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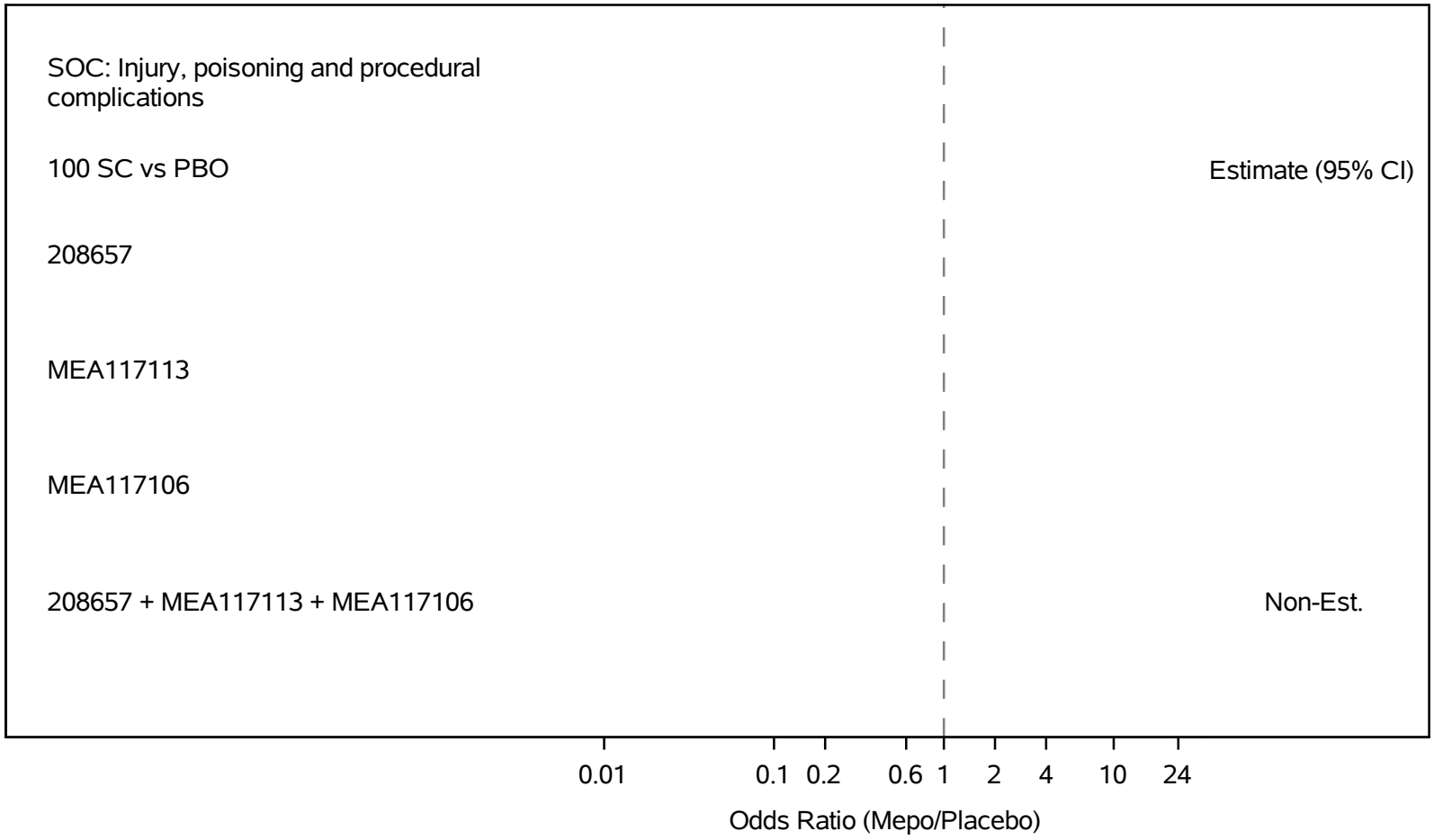

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/mnt/code/postcsr_01/prod/tfls/f_s_ae_onae_ipd_or.sas 17JUL2025 18:13

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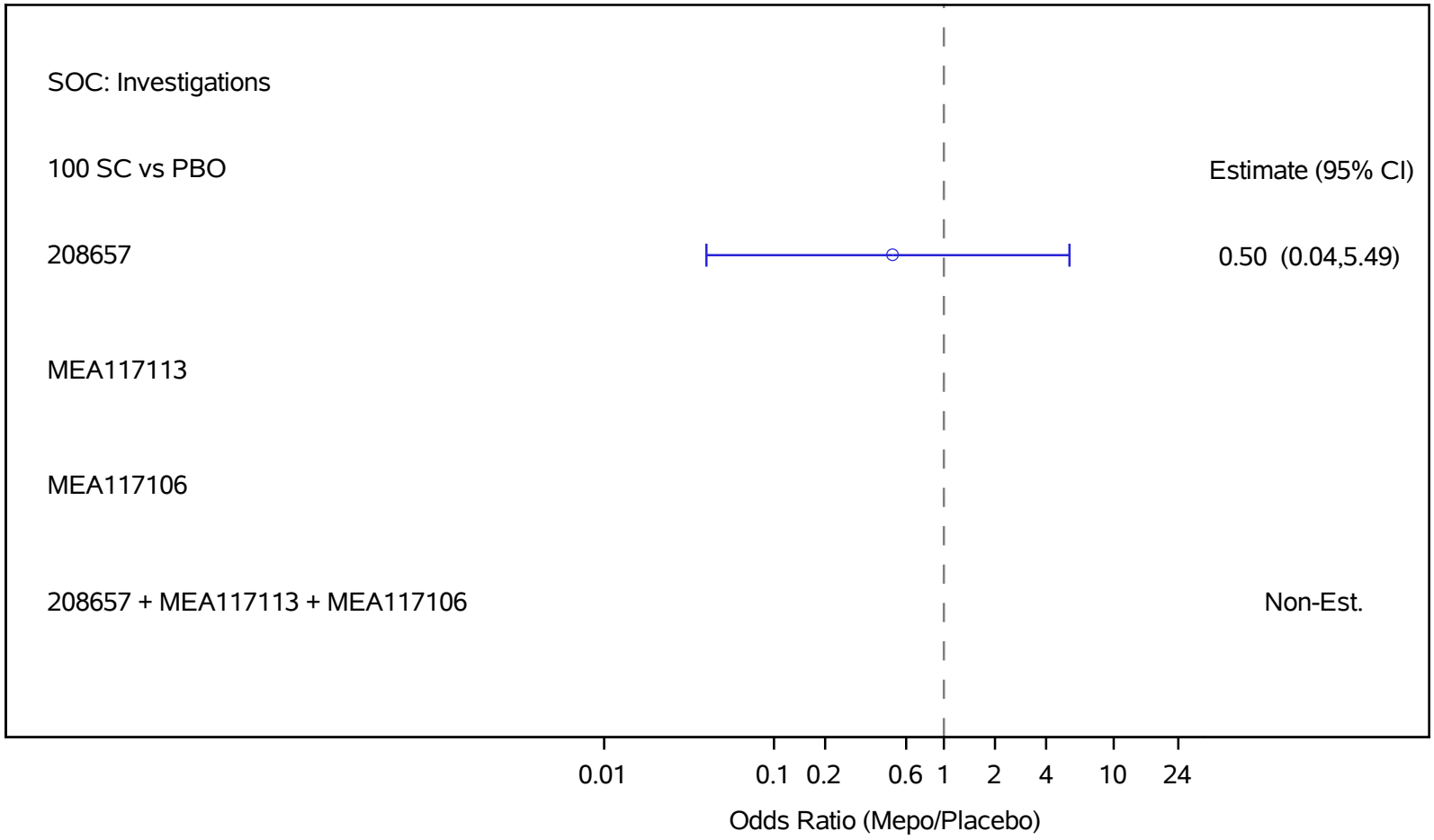

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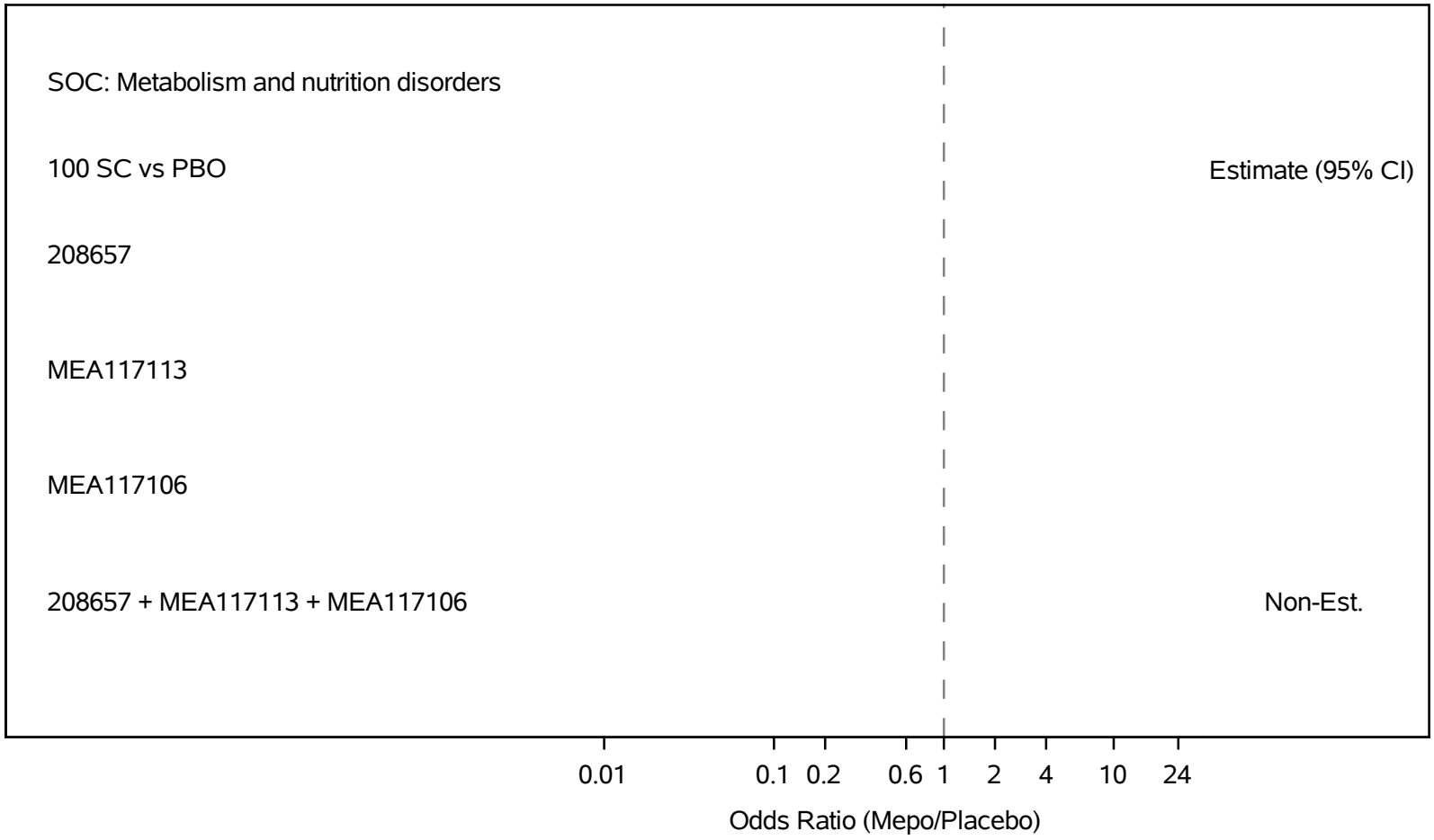

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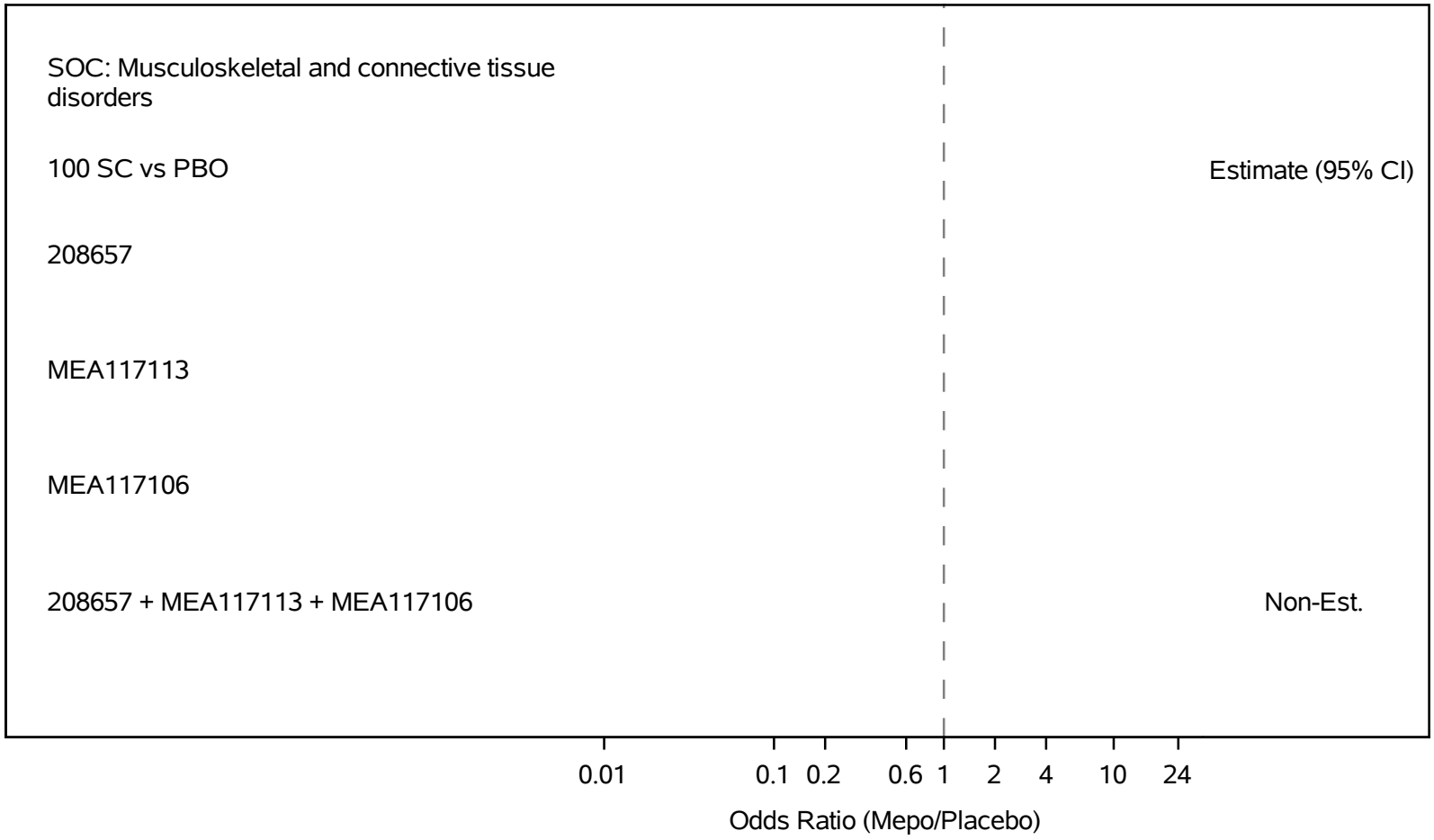

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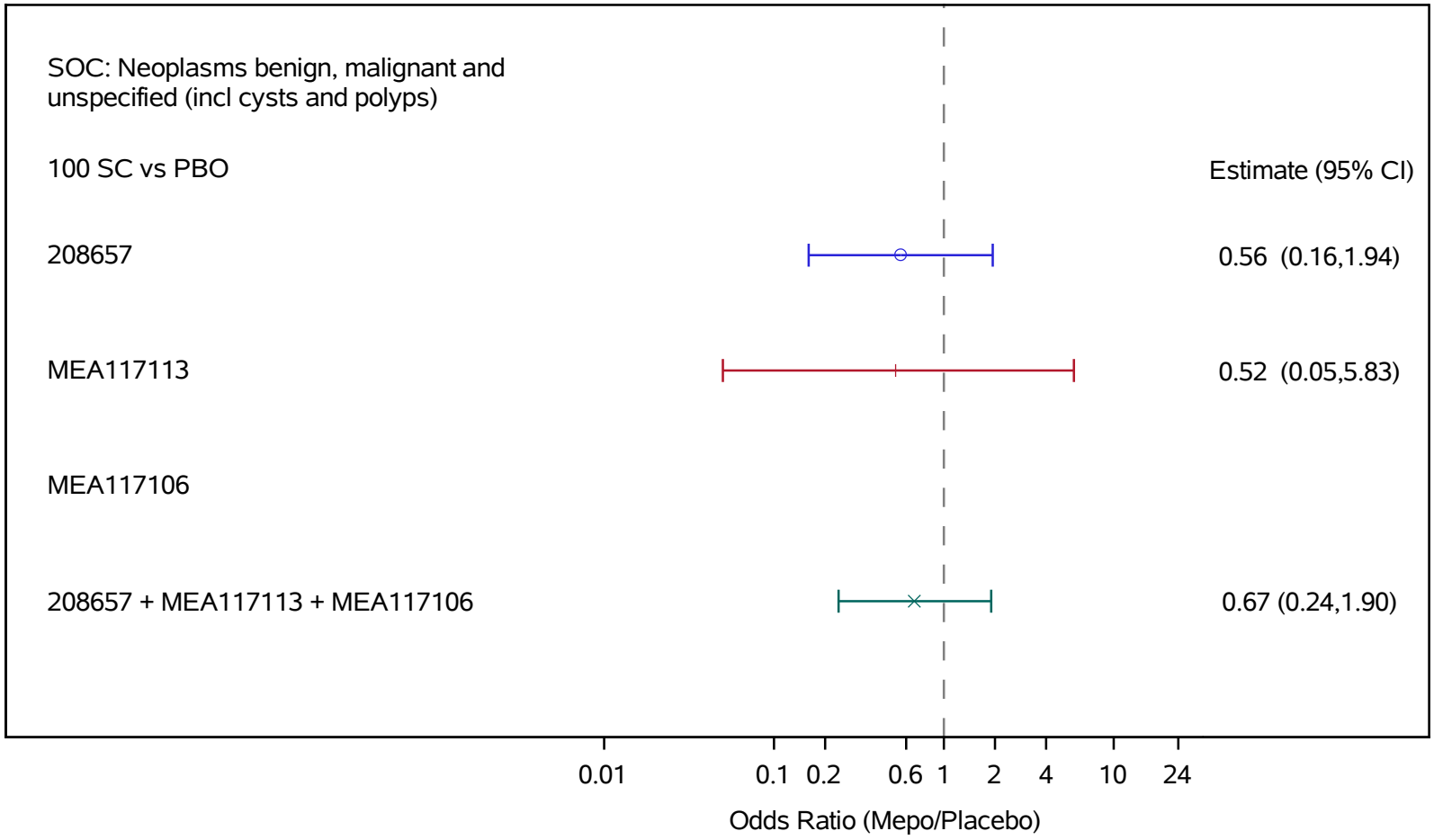

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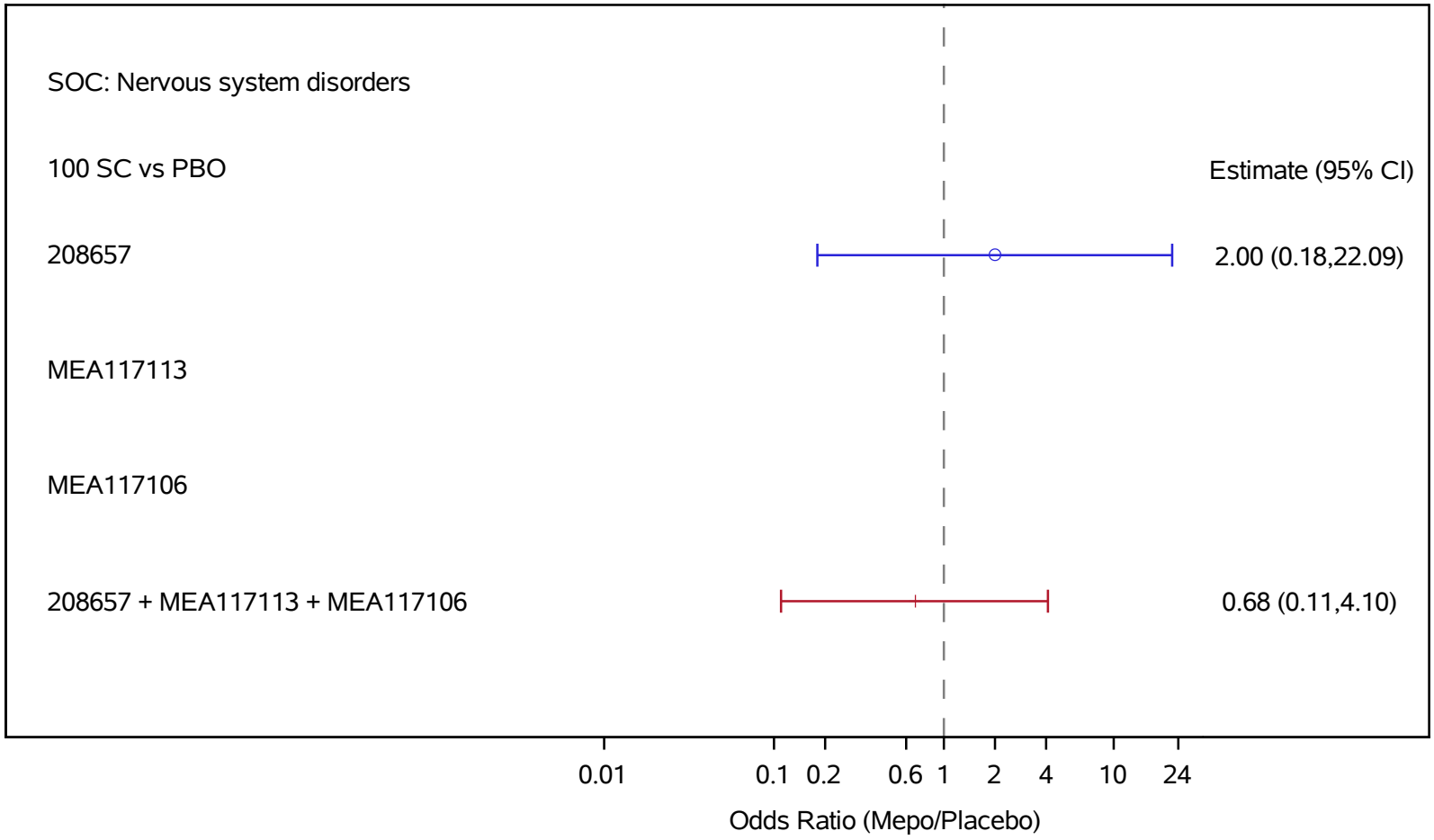

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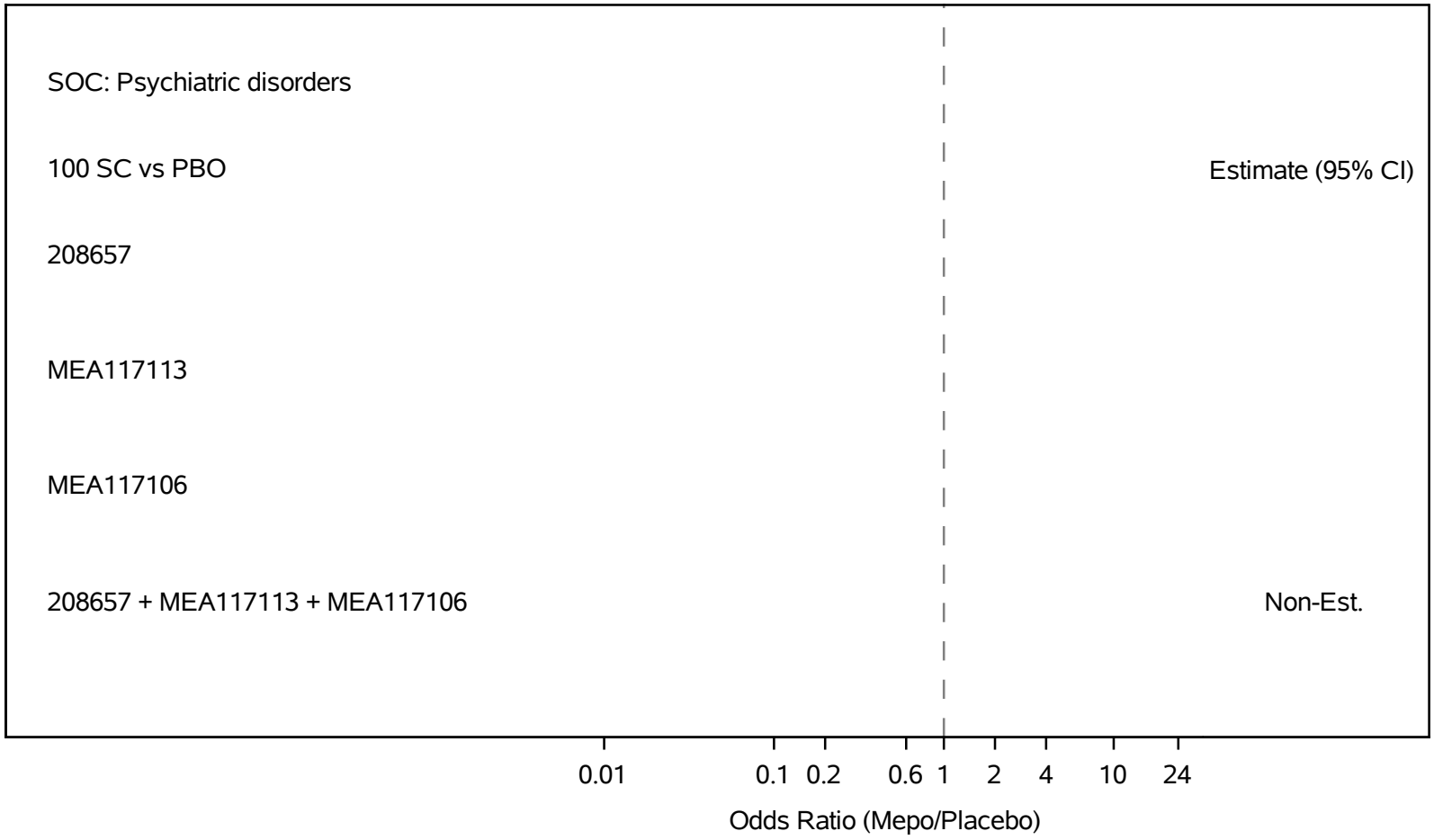

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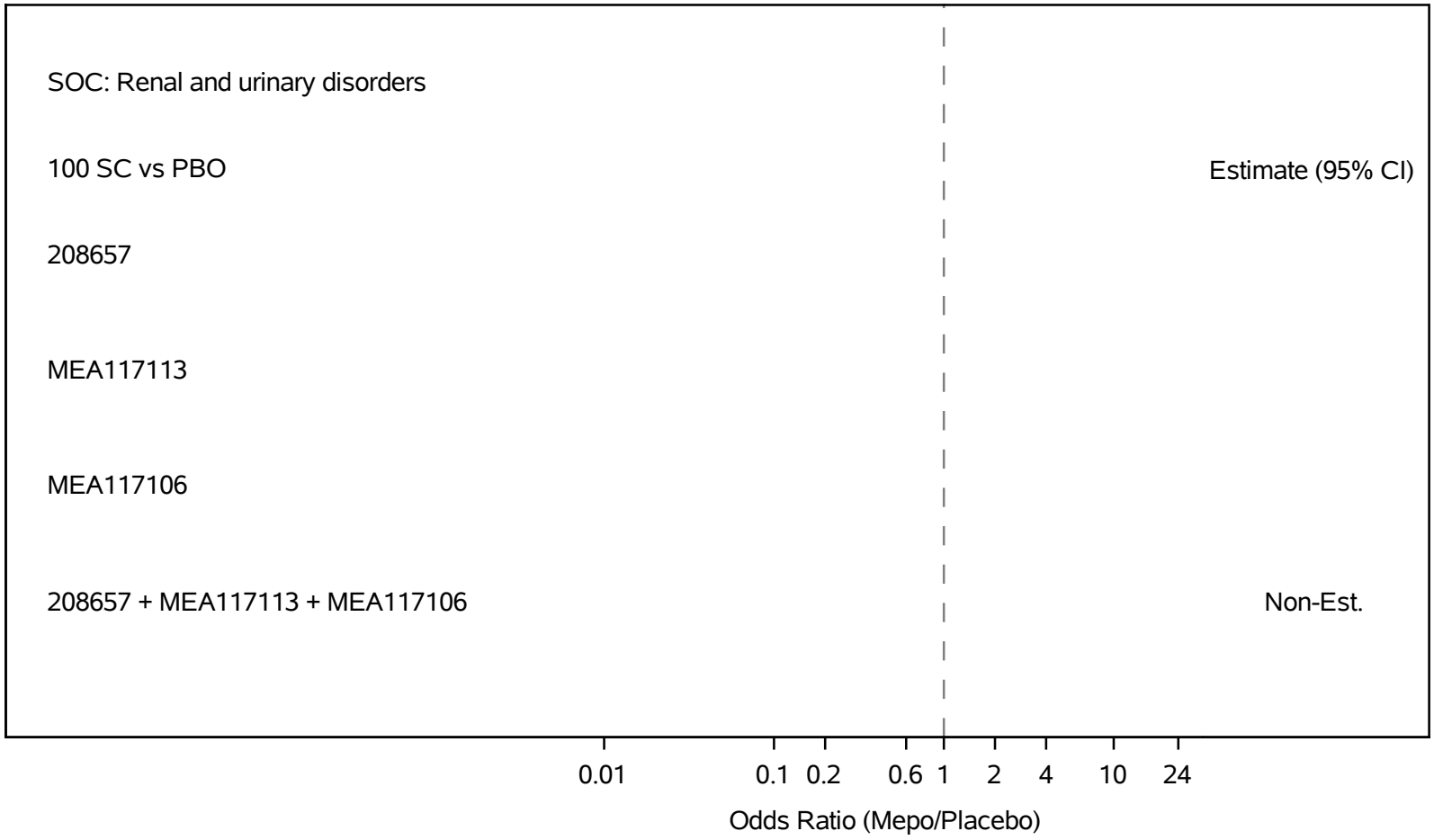

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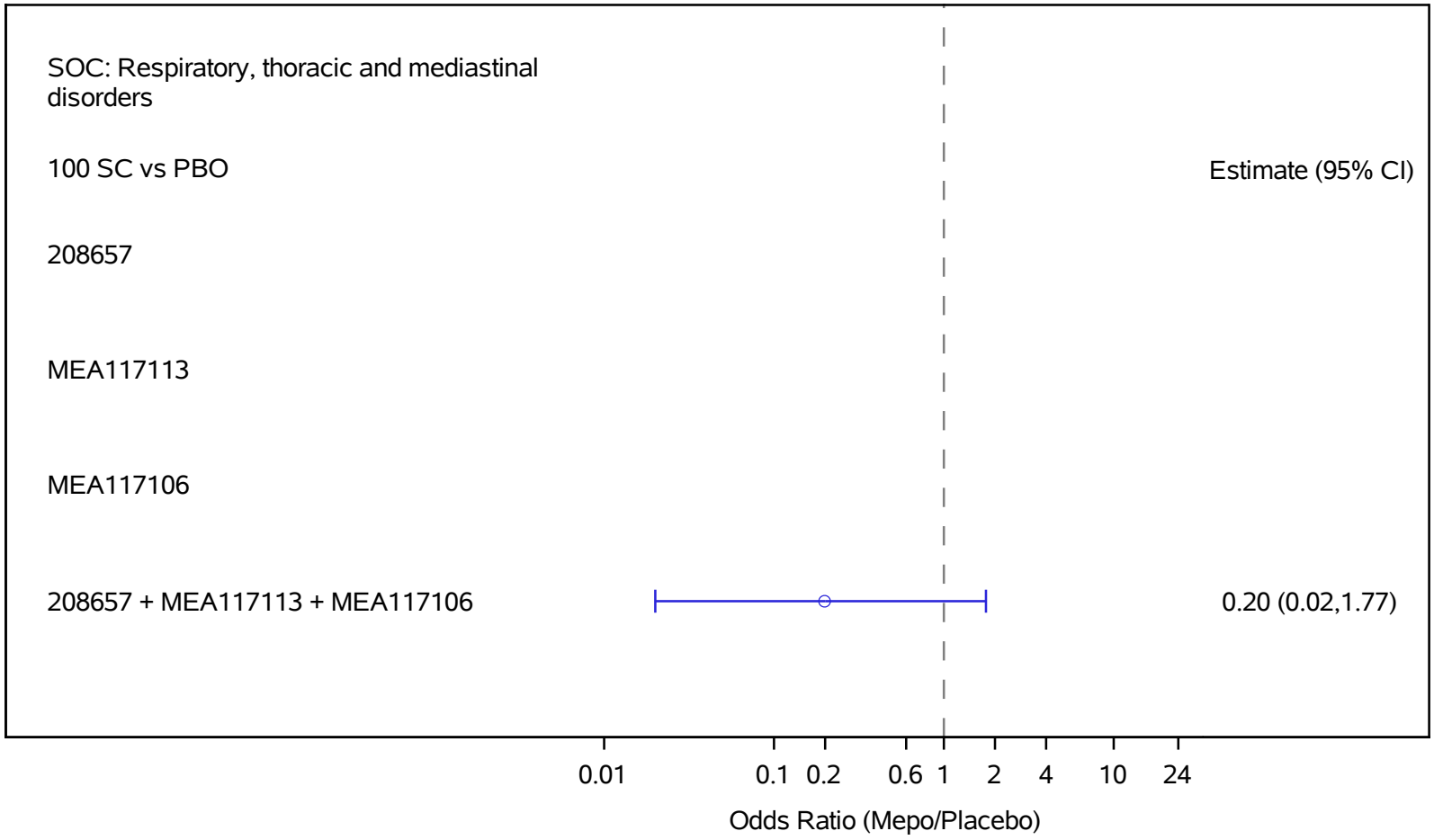

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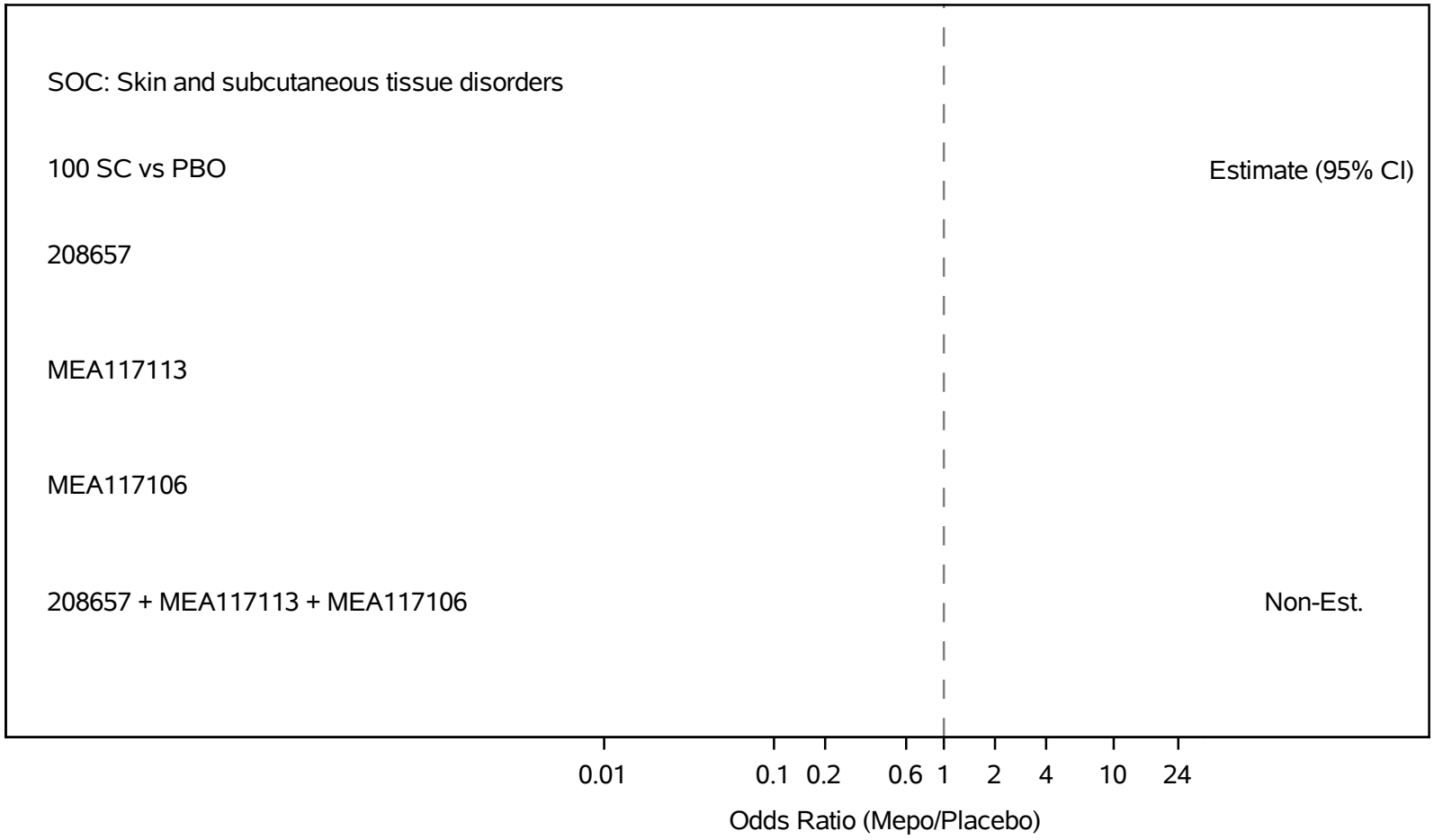

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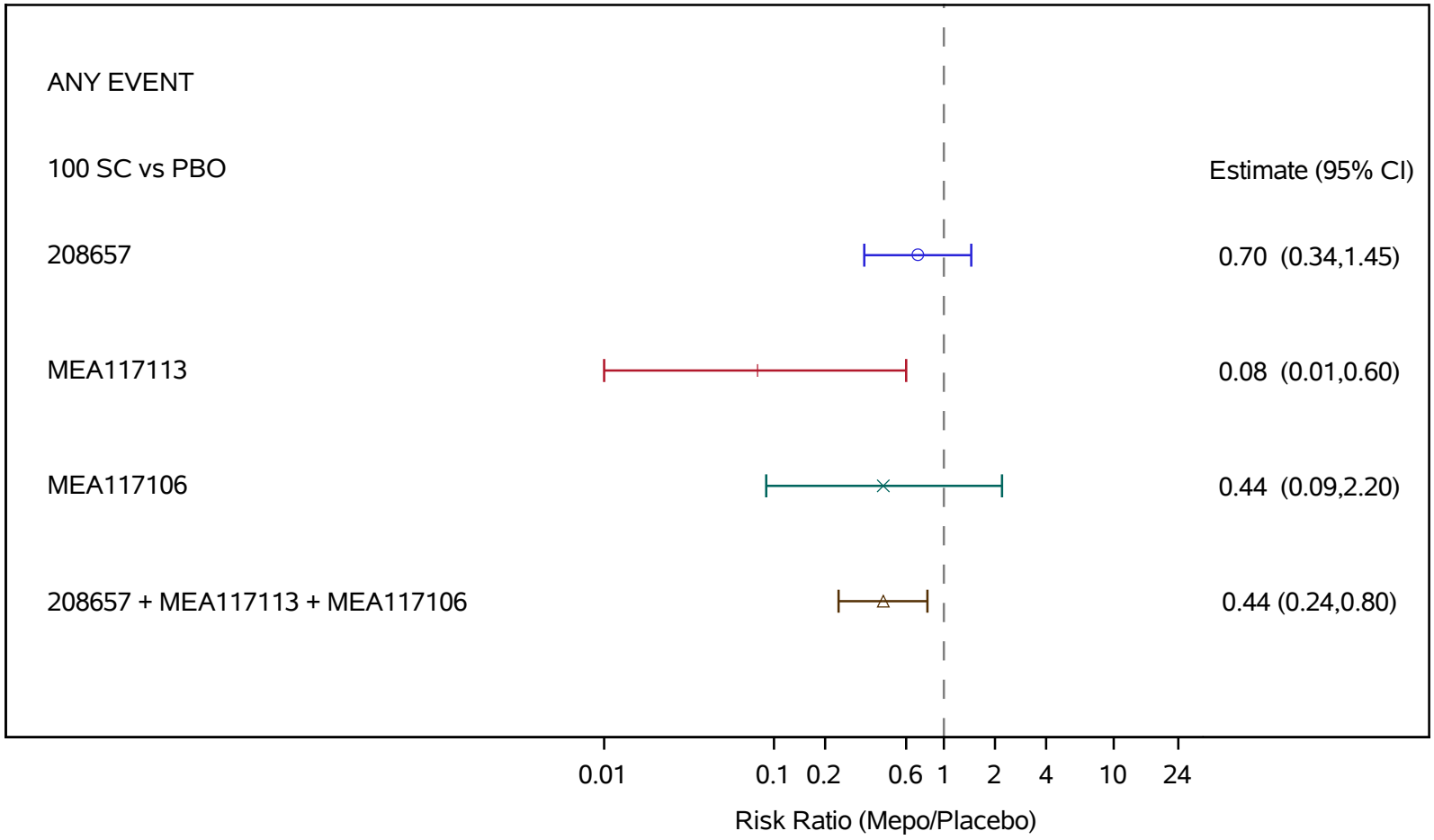

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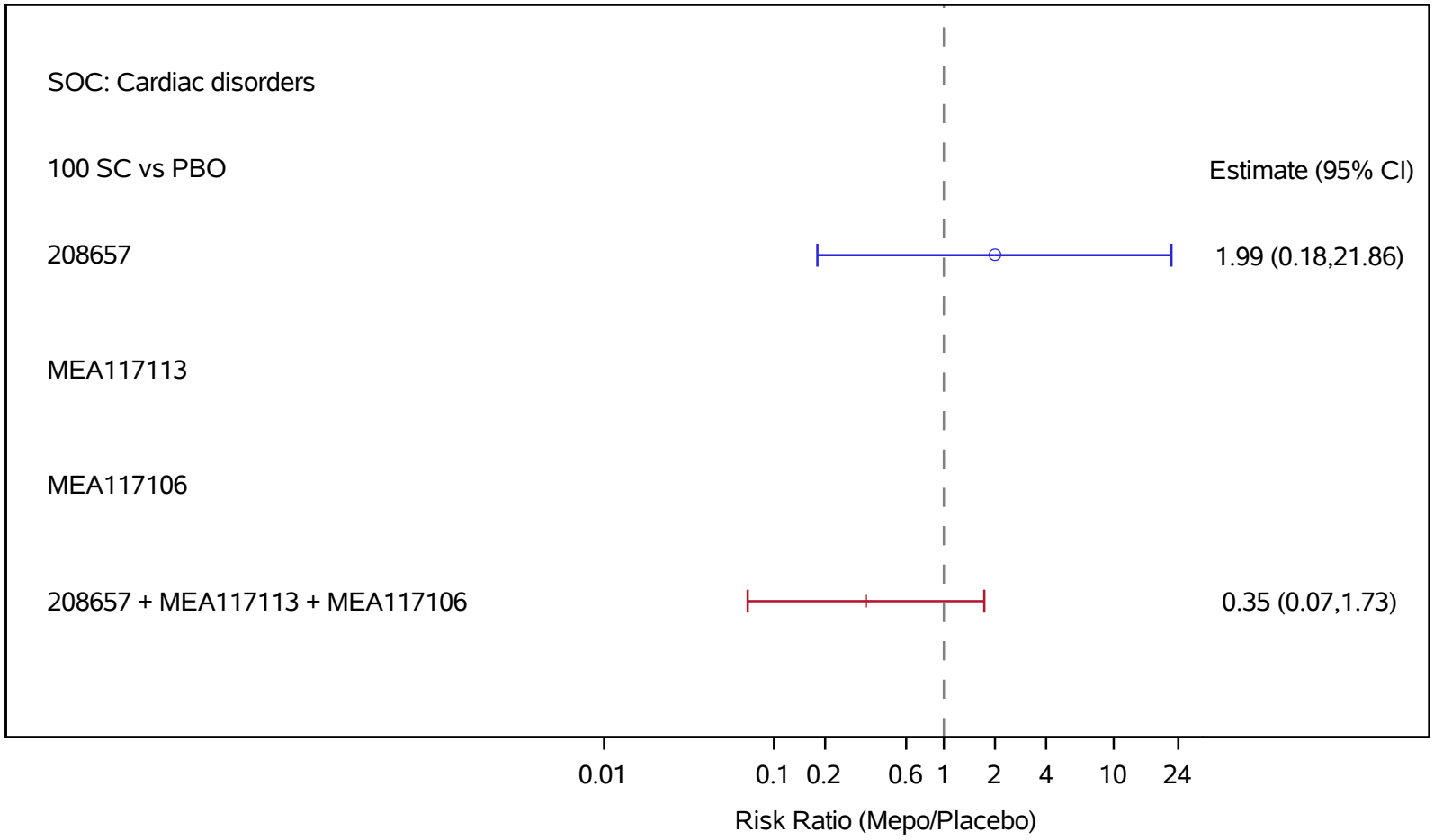

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/mnt/code/postcsr_01/prod/tfls/f_s_ae_onae_ipd_rr.sas 17JUL2025 18:12

Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

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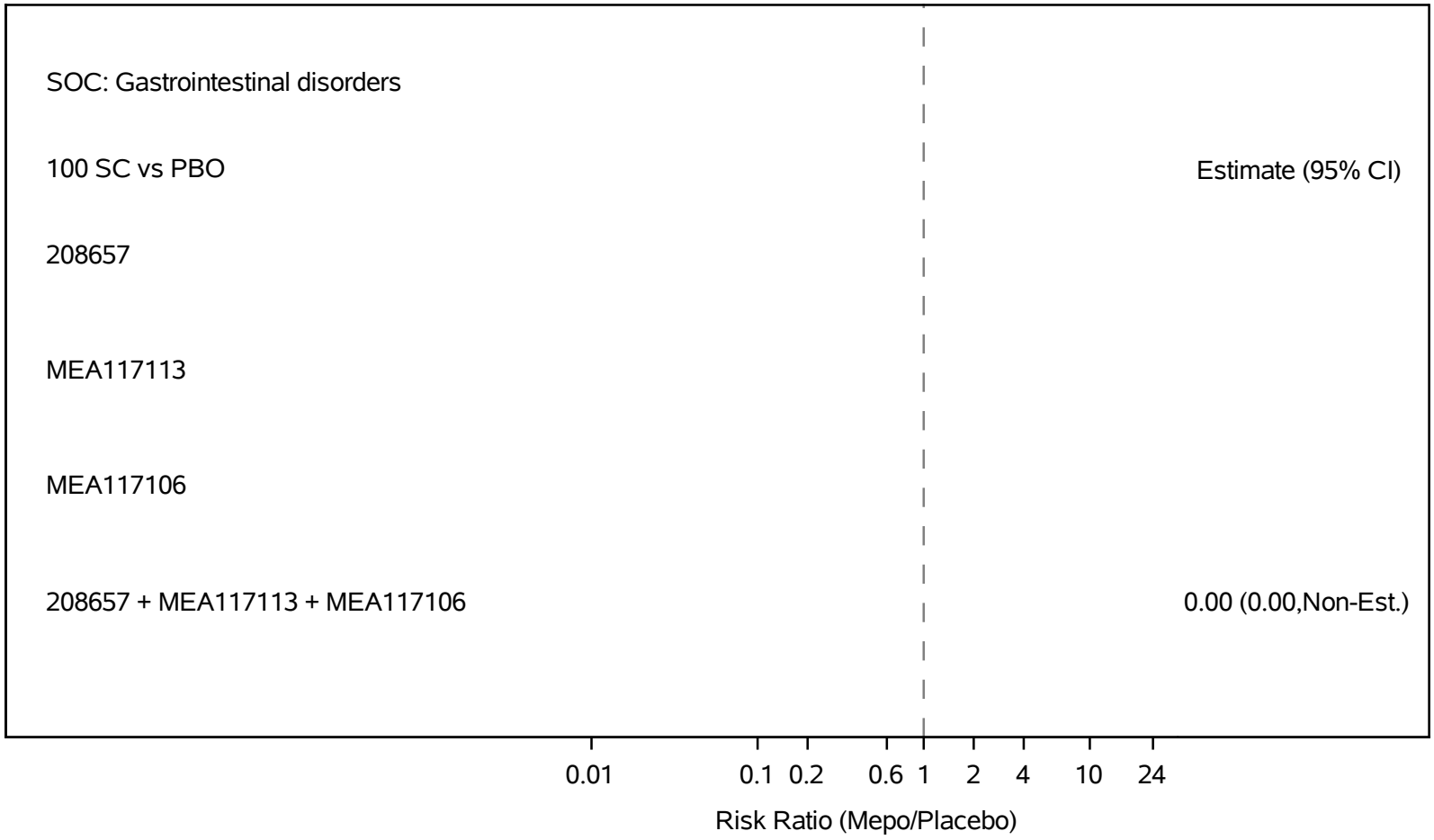
Forest Plot of Relative Risk for On-Treatment Adverse Events leading to study drug withdrawal by SOC and PT: Individual Studies and Meta-Analysis



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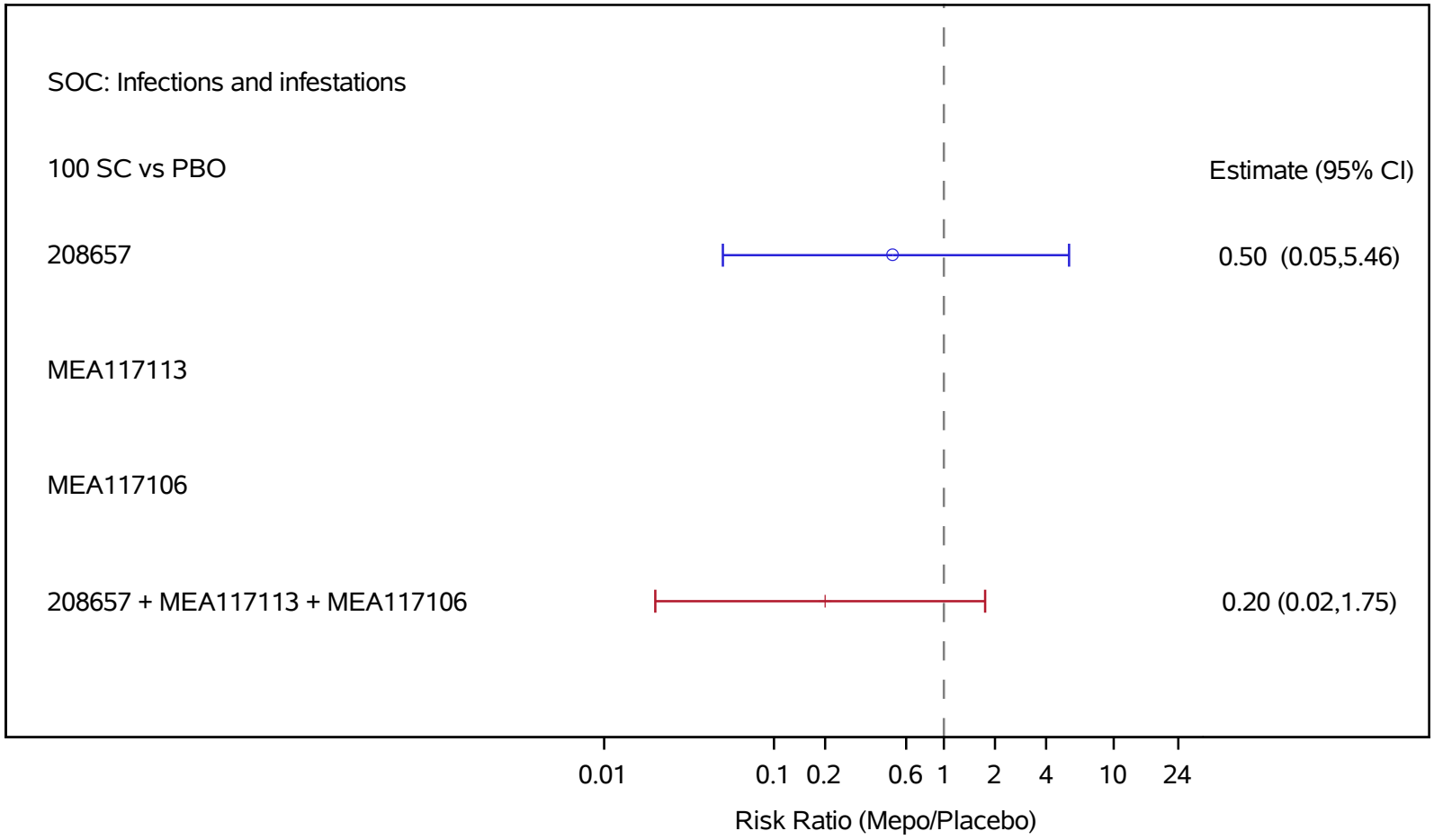

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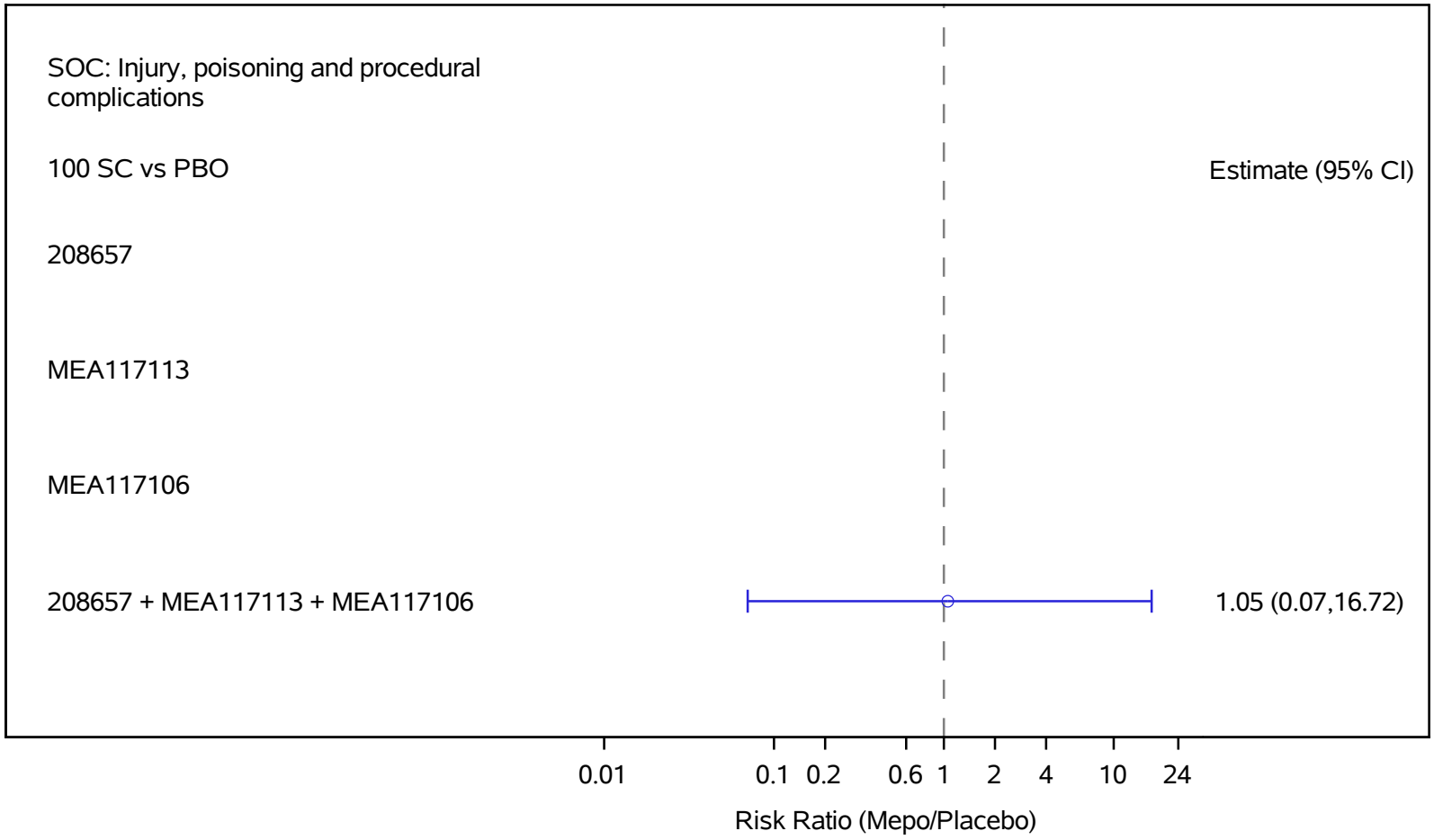

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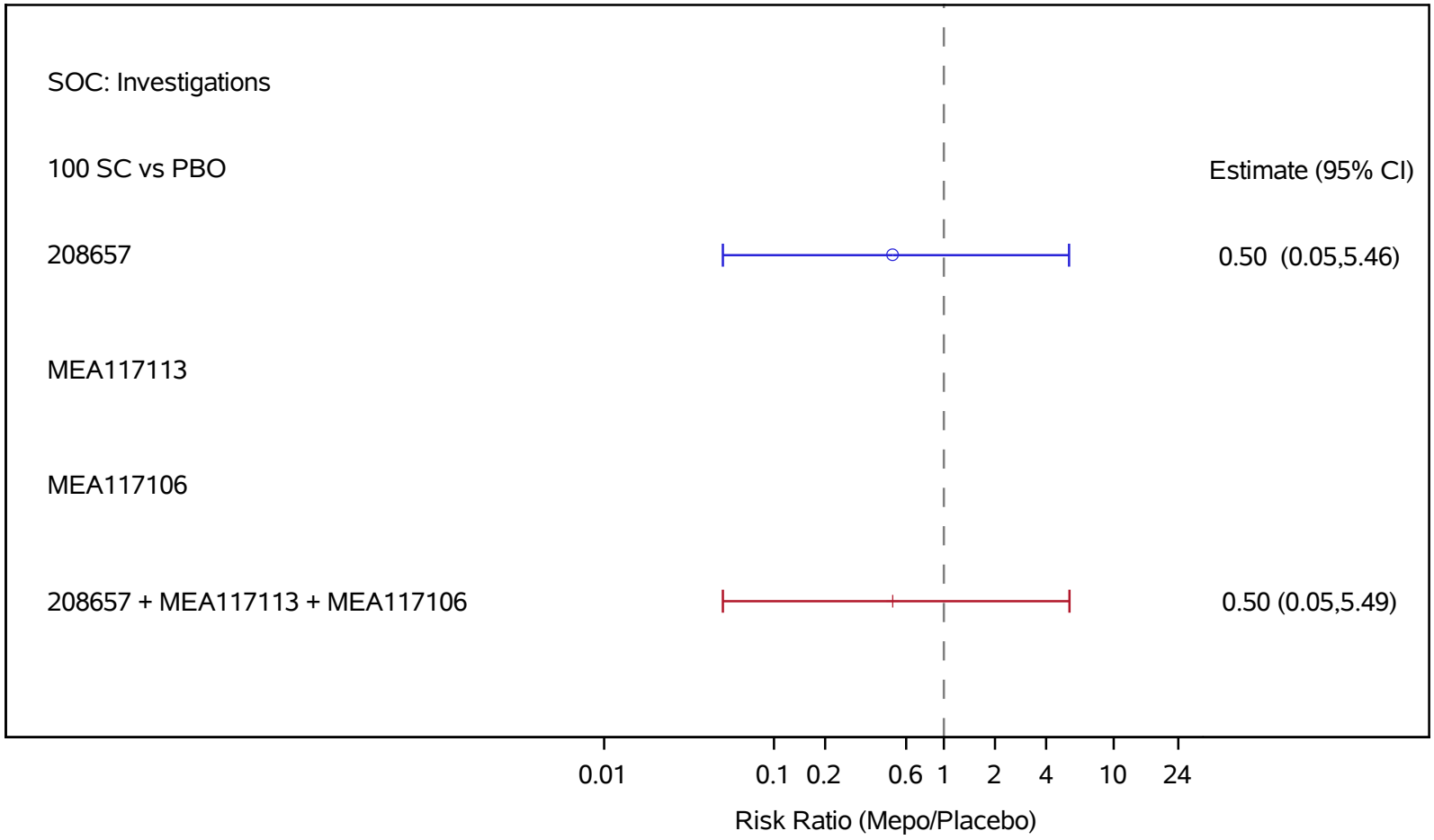

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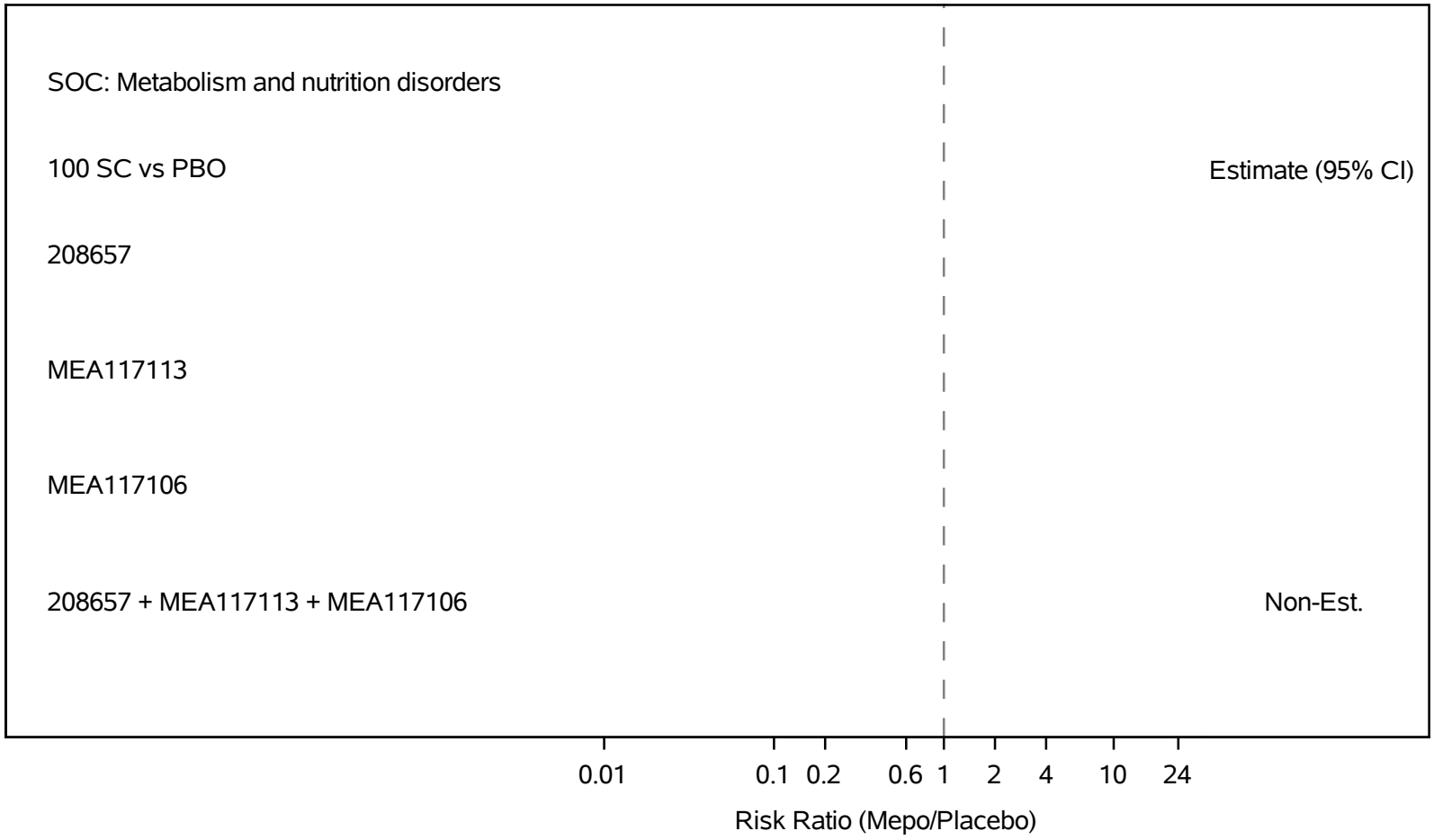

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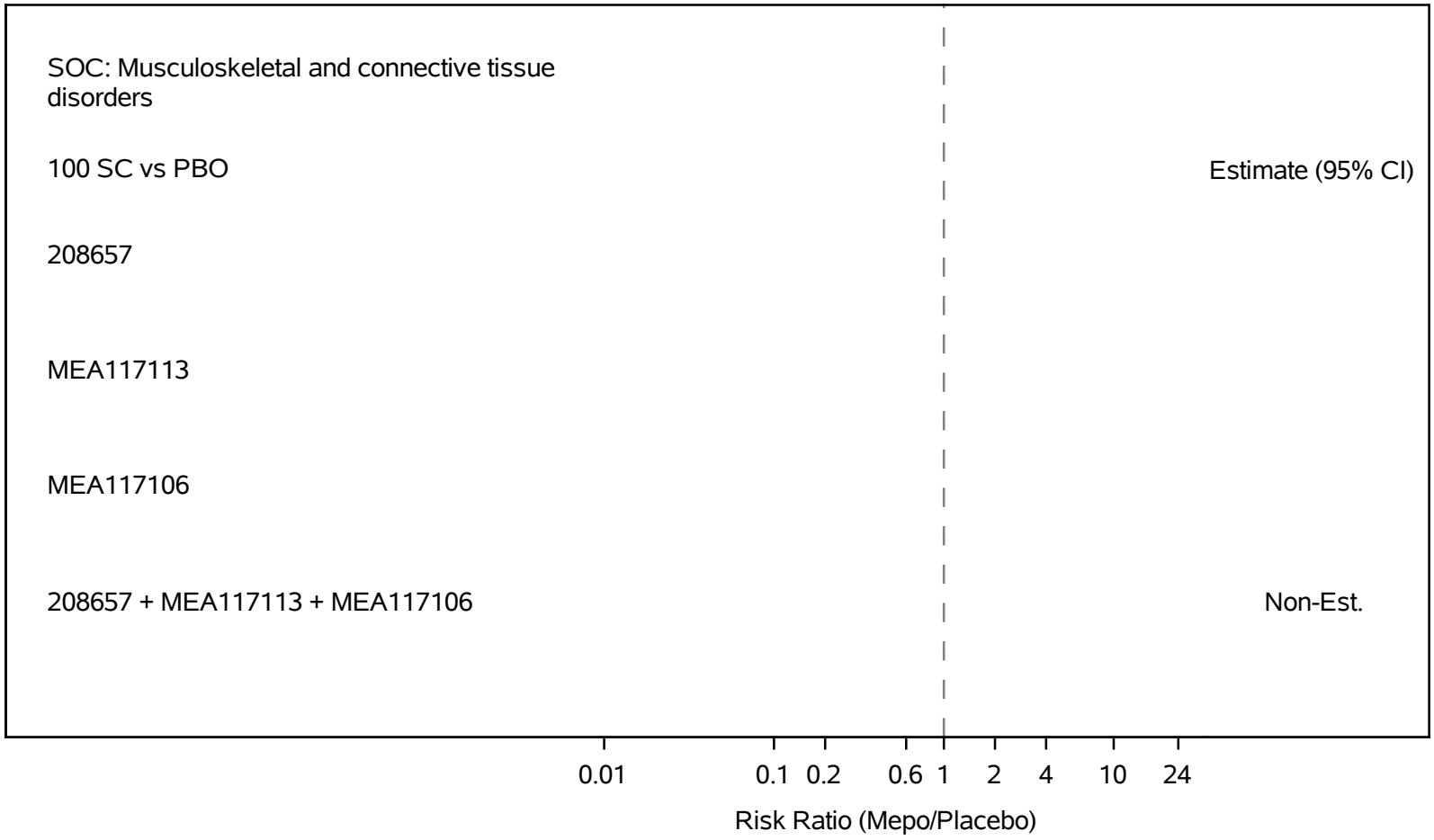

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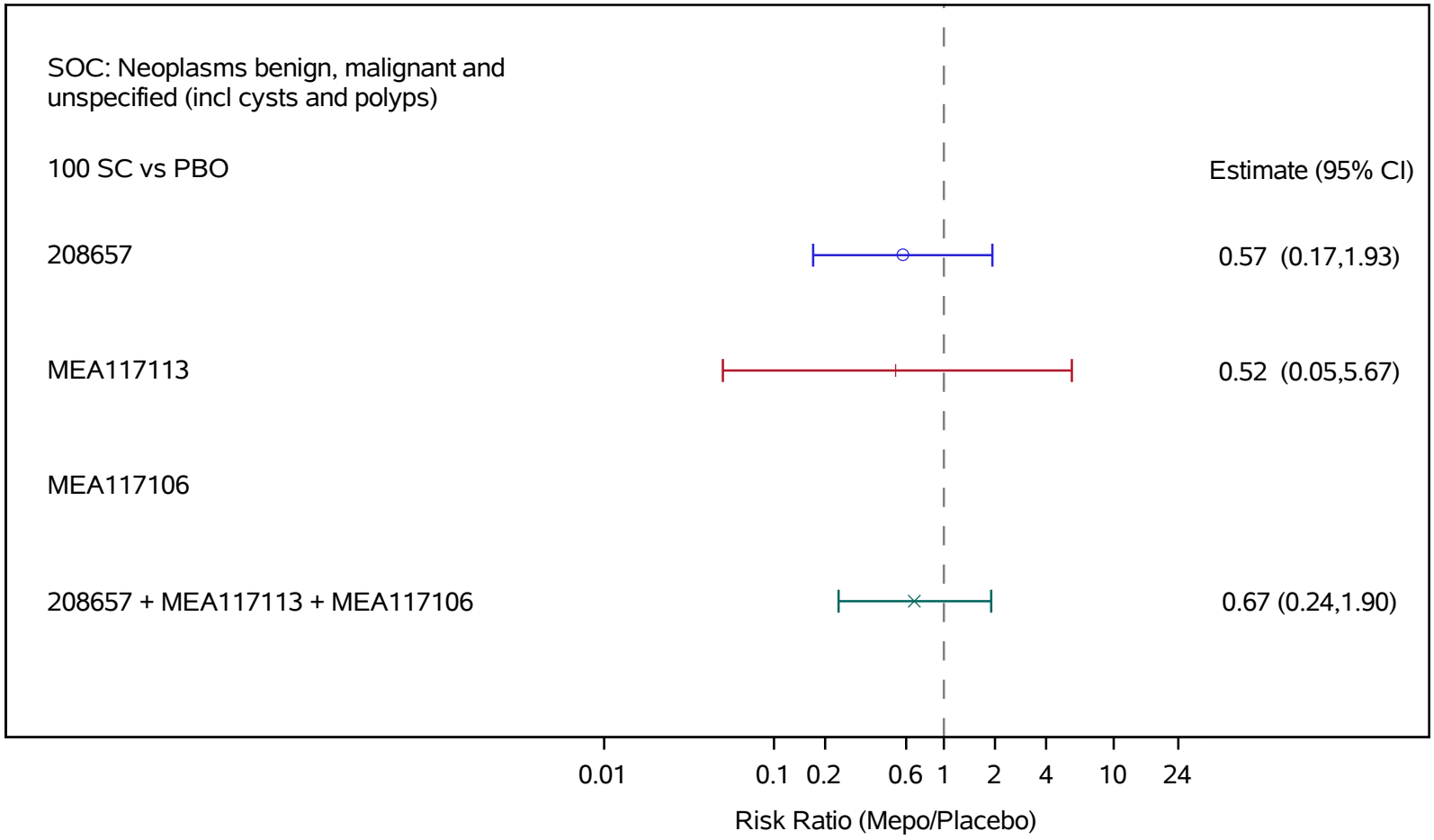

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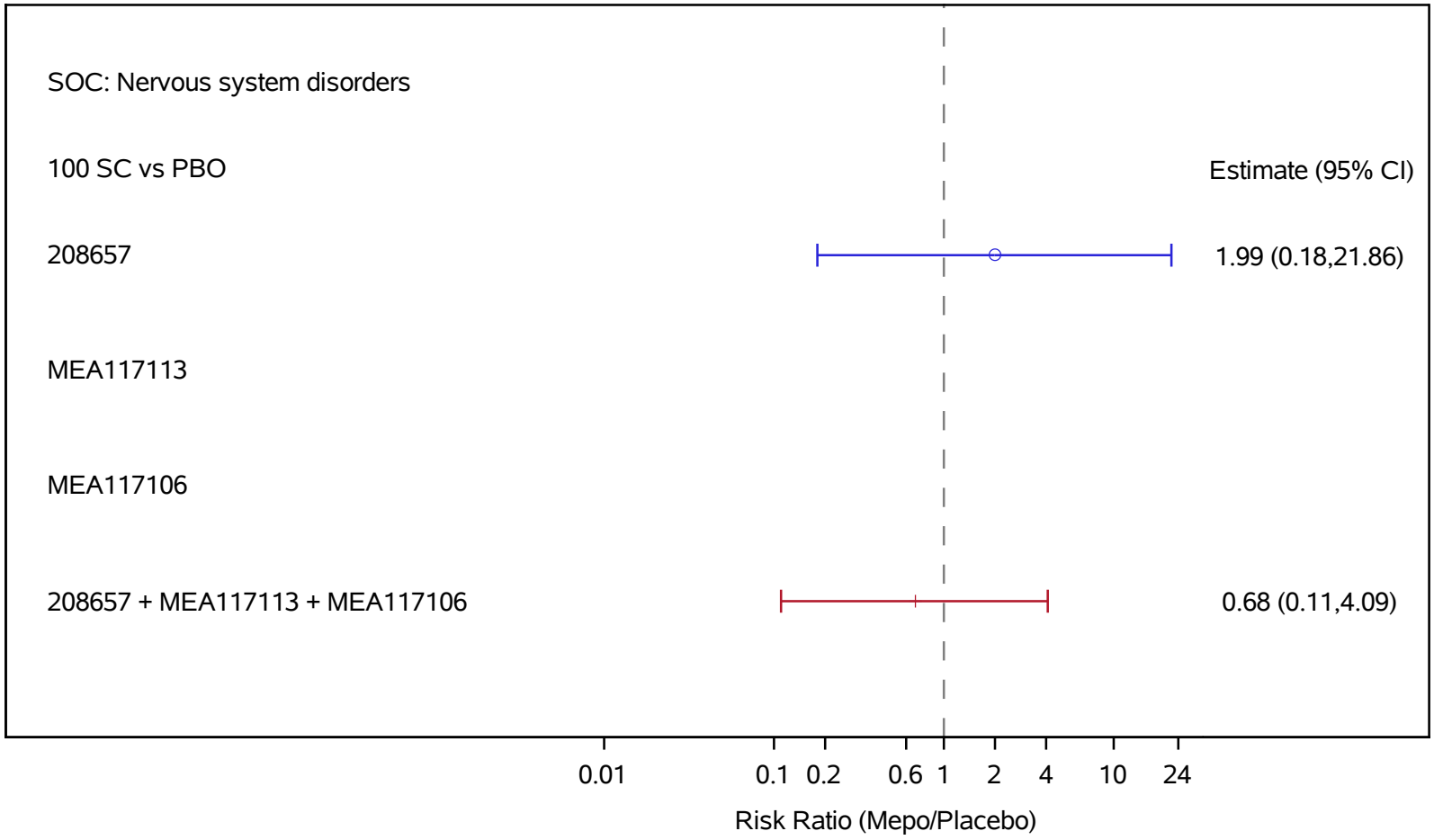

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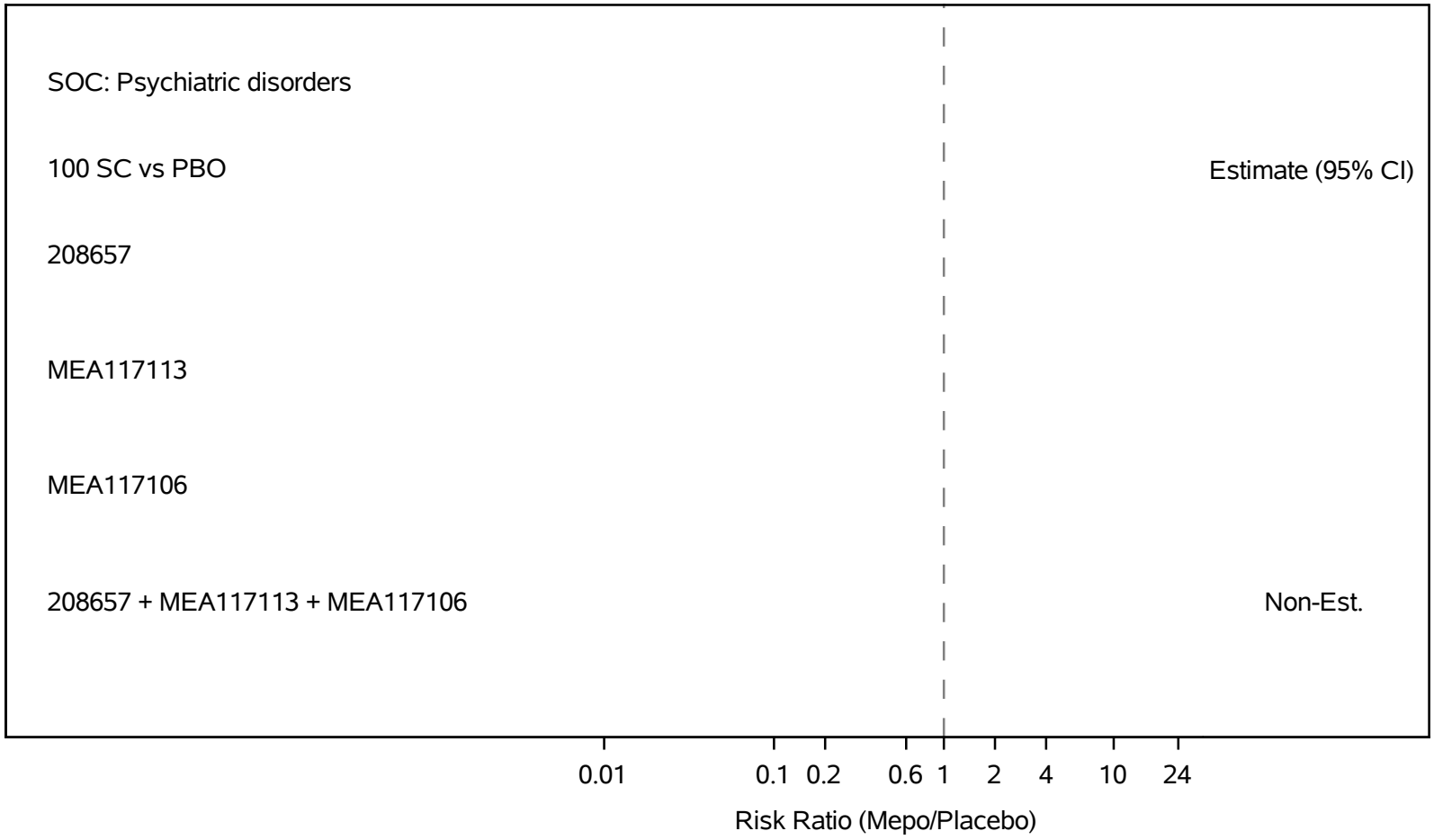

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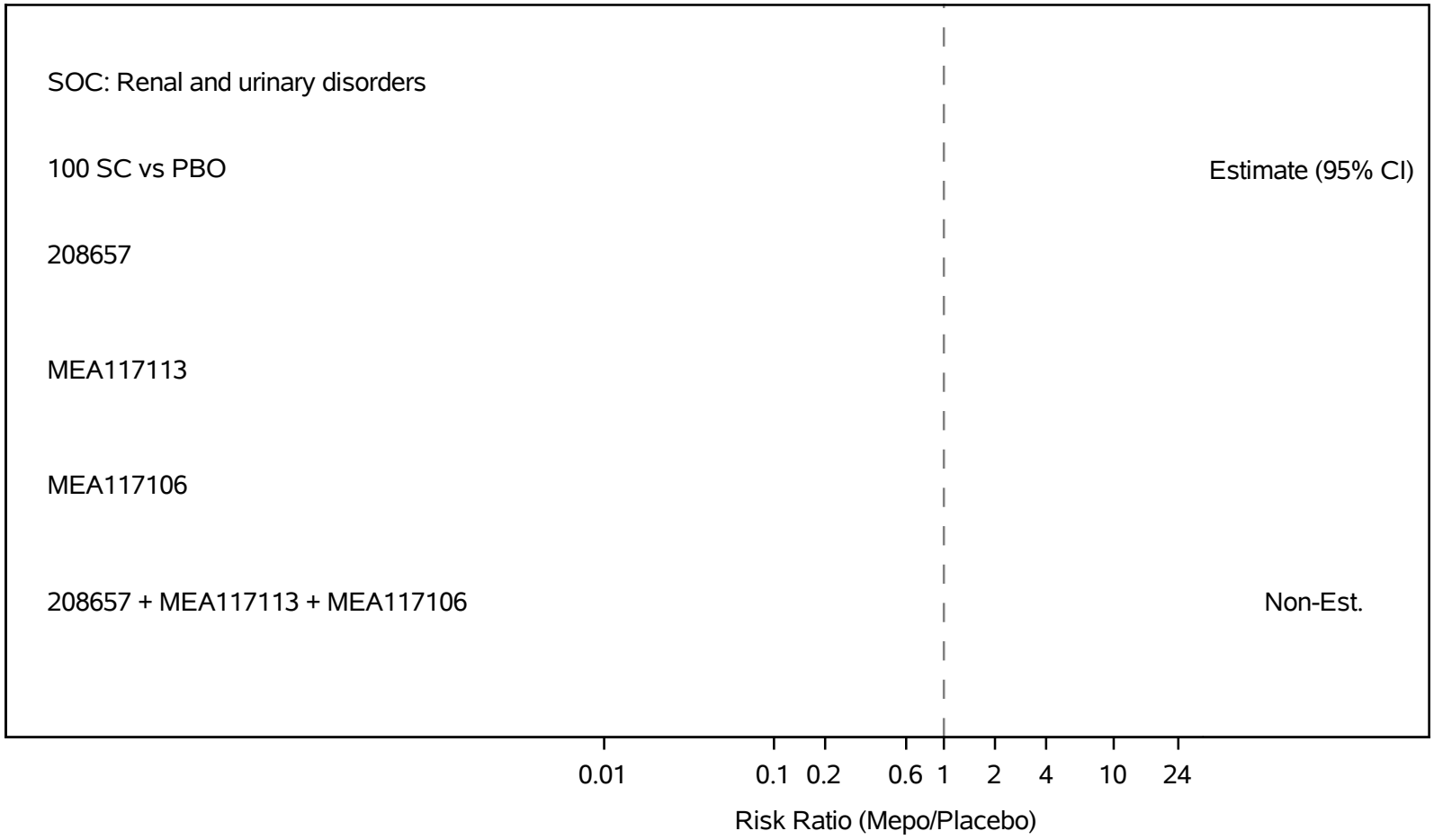

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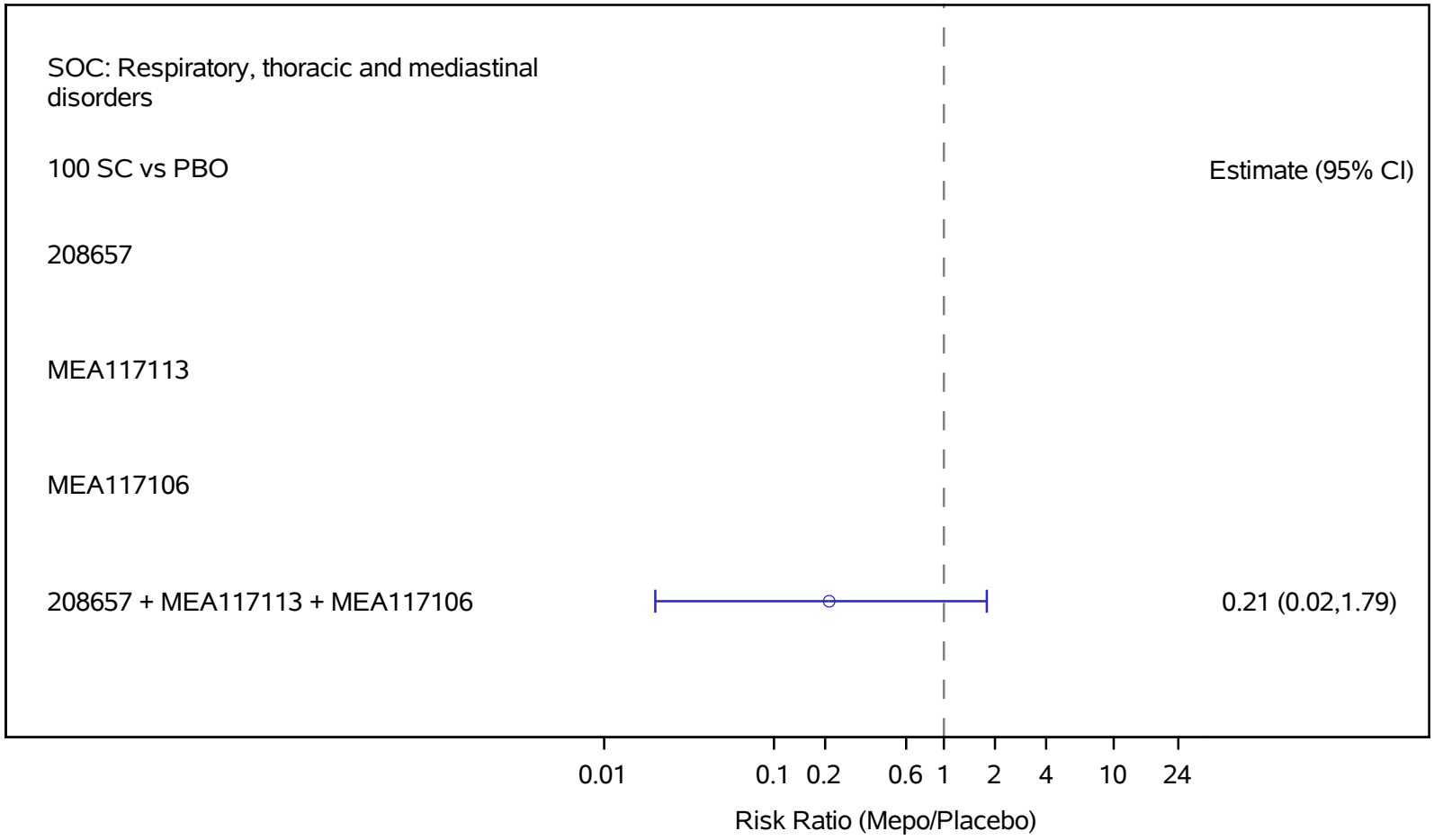

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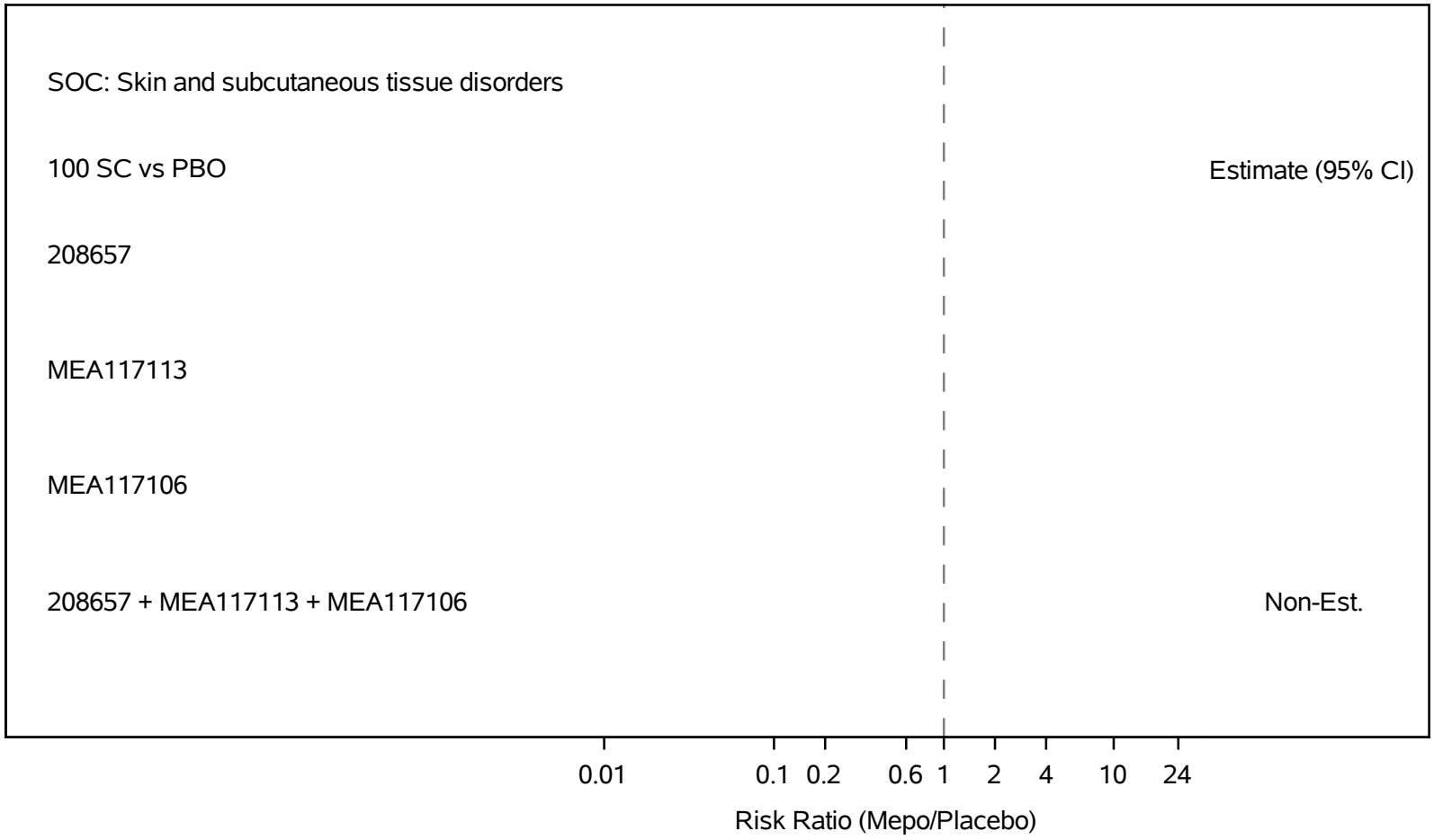
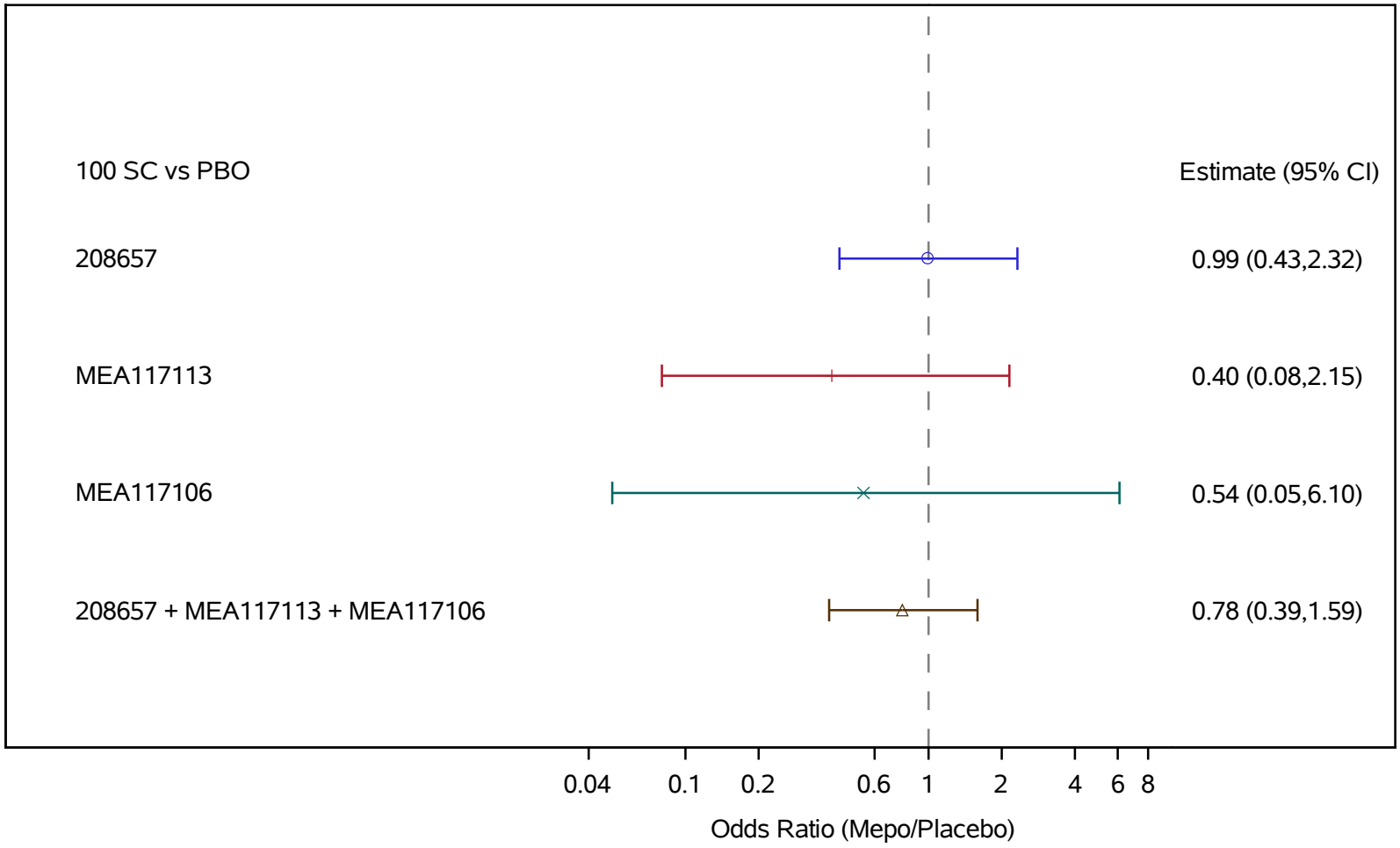


Horizontal bars indicate 95% confidence intervals for the Mepo/Placebo ratio.

Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Figure 311.15

Forest Plot of Odds ratio for Deaths: Individual Studies and Meta-Analysis



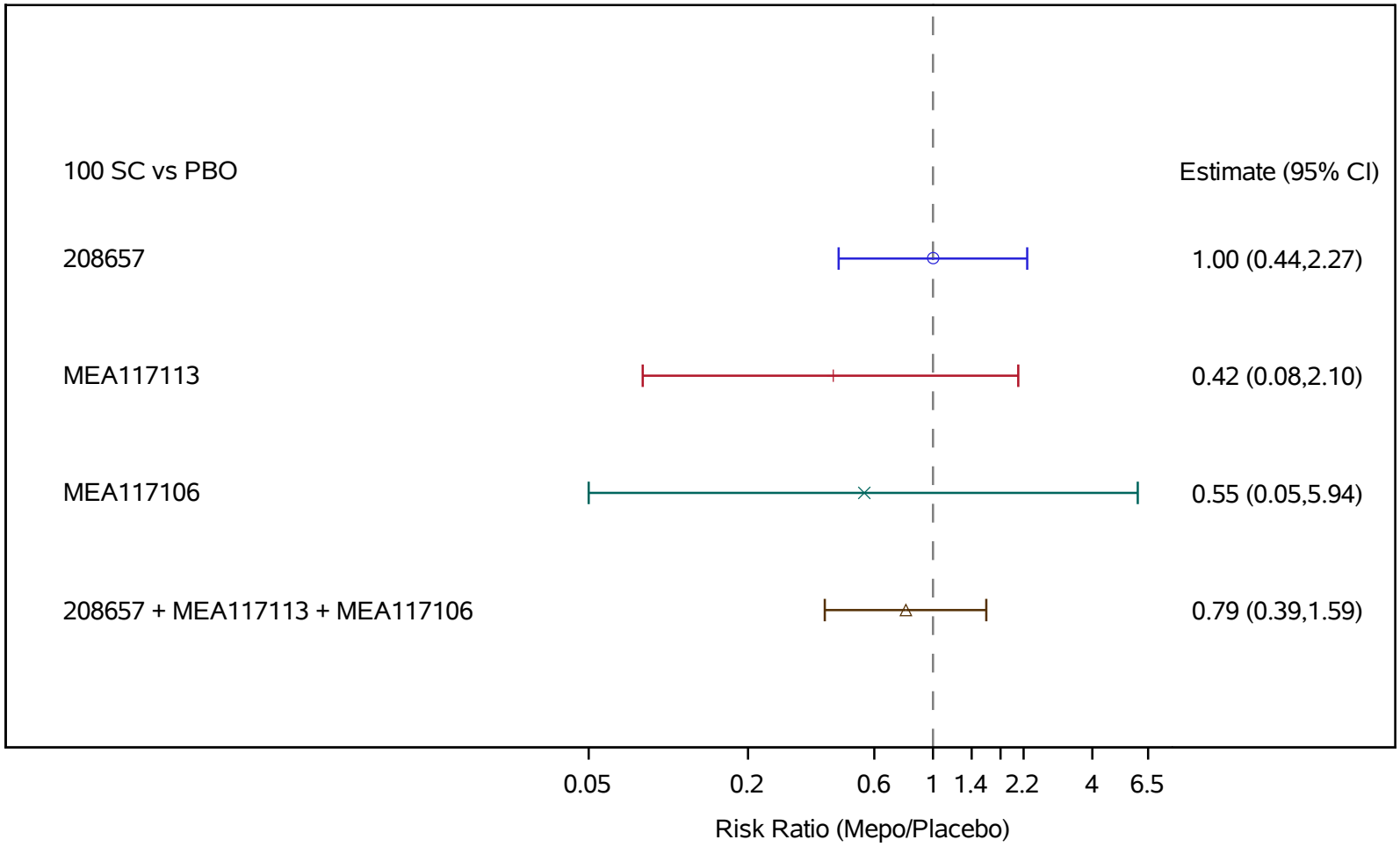
Horizontal bars indicate 95% confidence intervals for the Mepo/Placebo ratio.

/mnt/code/postcsr_01/prod/tfls/f_s_death_or.sas 17JUL2025 18:12

Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Figure 311.16

Forest Plot of Relative Risk for Deaths: Individual Studies and Meta-Analysis



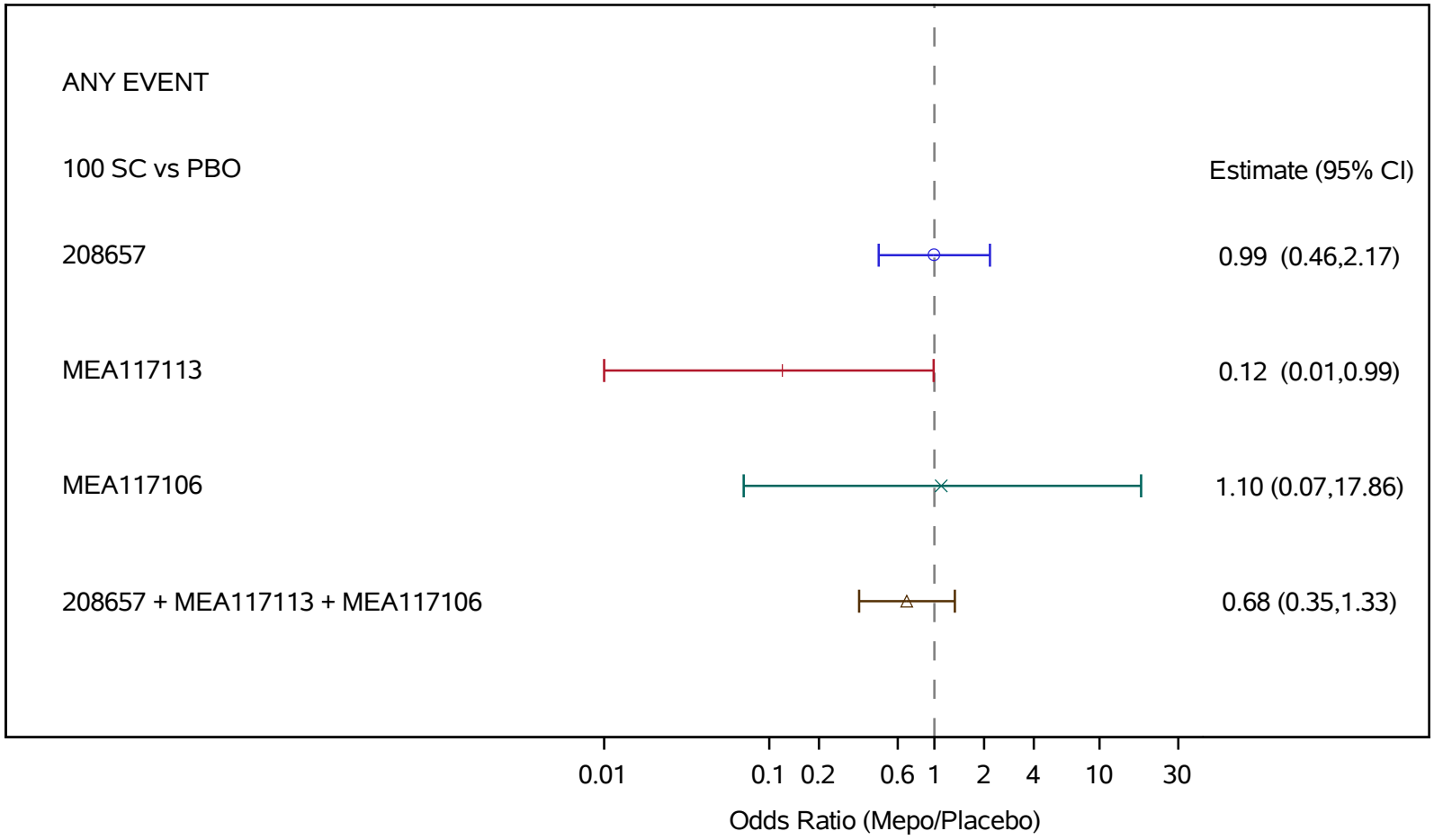
Horizontal bars indicate 95% confidence intervals for the Mepo/Placebo ratio.

/mnt/code/postcsr_01/prod/tfls/f_s_death_rr.sas 17JUL2025 18:12

Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Figure 311.17

Forest Plot of Odds ratio for On-Treatment Adverse Events leading to withdrawal from study by SOC and PT: Individual Studies and Meta-Analysis



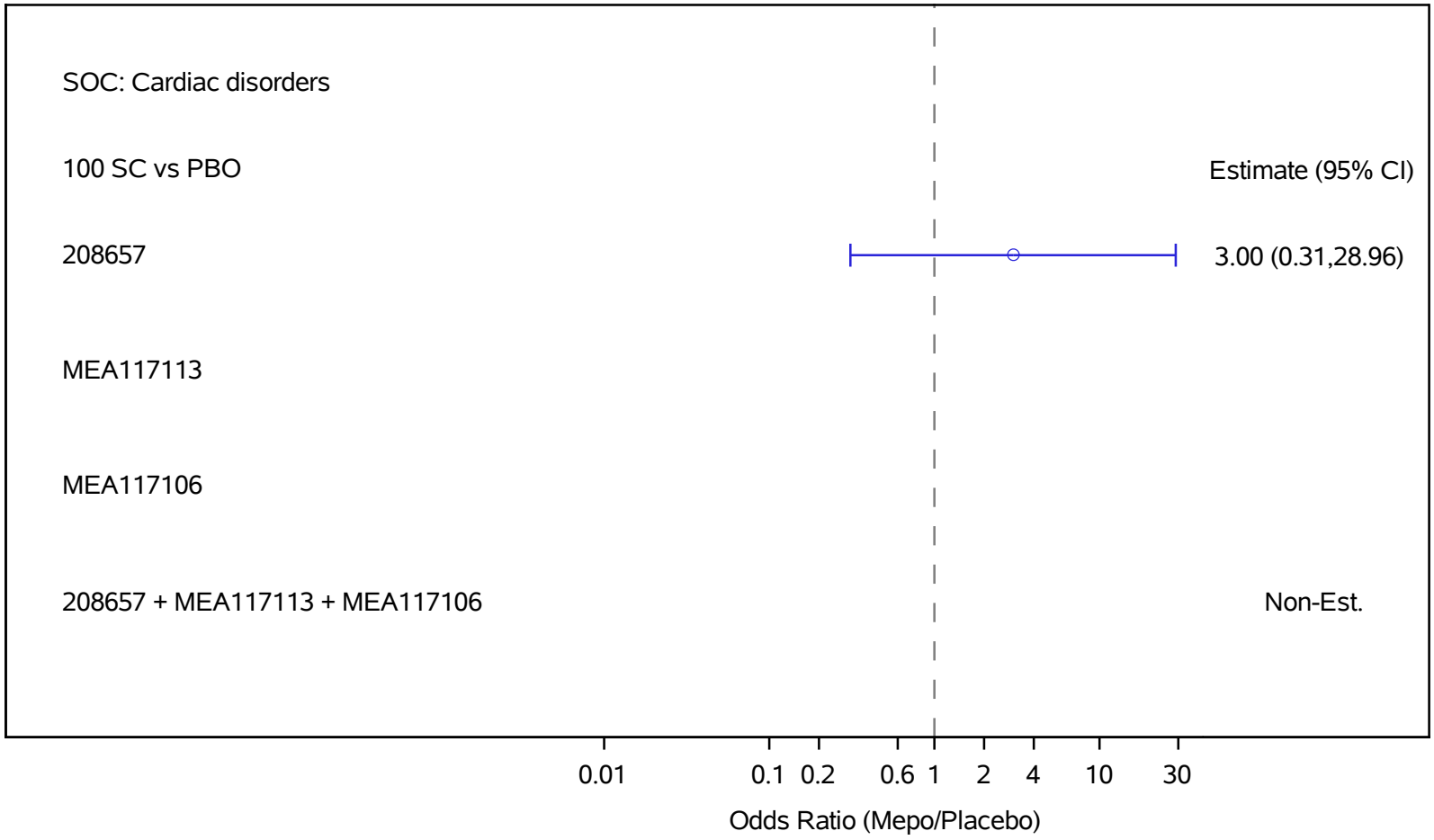
Horizontal bars indicate 95% confidence intervals for the Mepo/Placebo ratio.

/mnt/code/postcsr_01/prod/tfls/f_s_ae_onae_wd_or.sas 17JUL2025 18:13

Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Figure 311.17

Forest Plot of Odds ratio for On-Treatment Adverse Events leading to withdrawal from study by SOC and PT: Individual Studies and Meta-Analysis



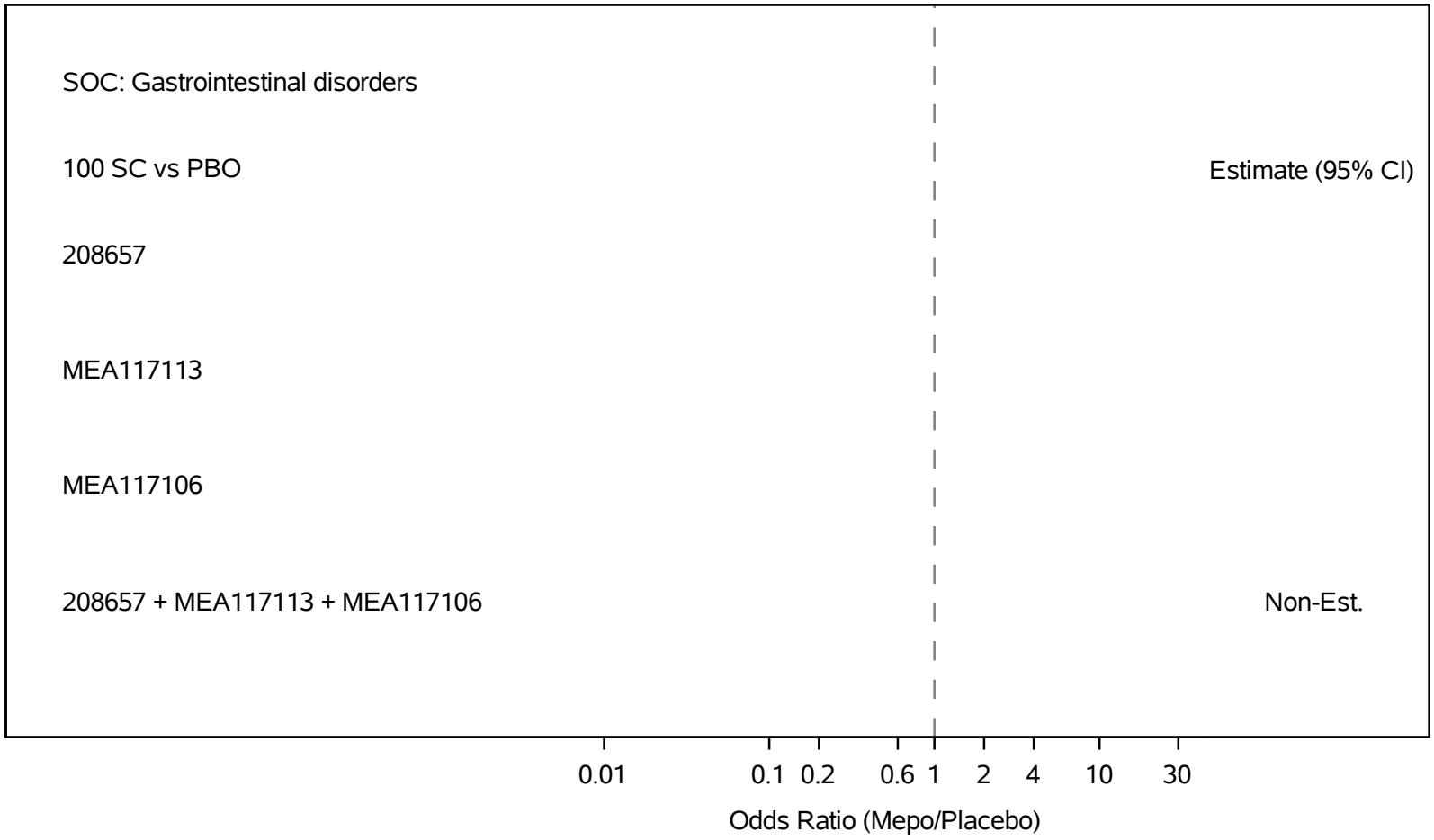
Horizontal bars indicate 95% confidence intervals for the Mepo/Placebo ratio.

/mnt/code/postcsr_01/prod/tfls/f_s_ae_onae_wd_or.sas 17JUL2025 18:13

Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Figure 311.17

Forest Plot of Odds ratio for On-Treatment Adverse Events leading to withdrawal from study by SOC and PT: Individual Studies and Meta-Analysis

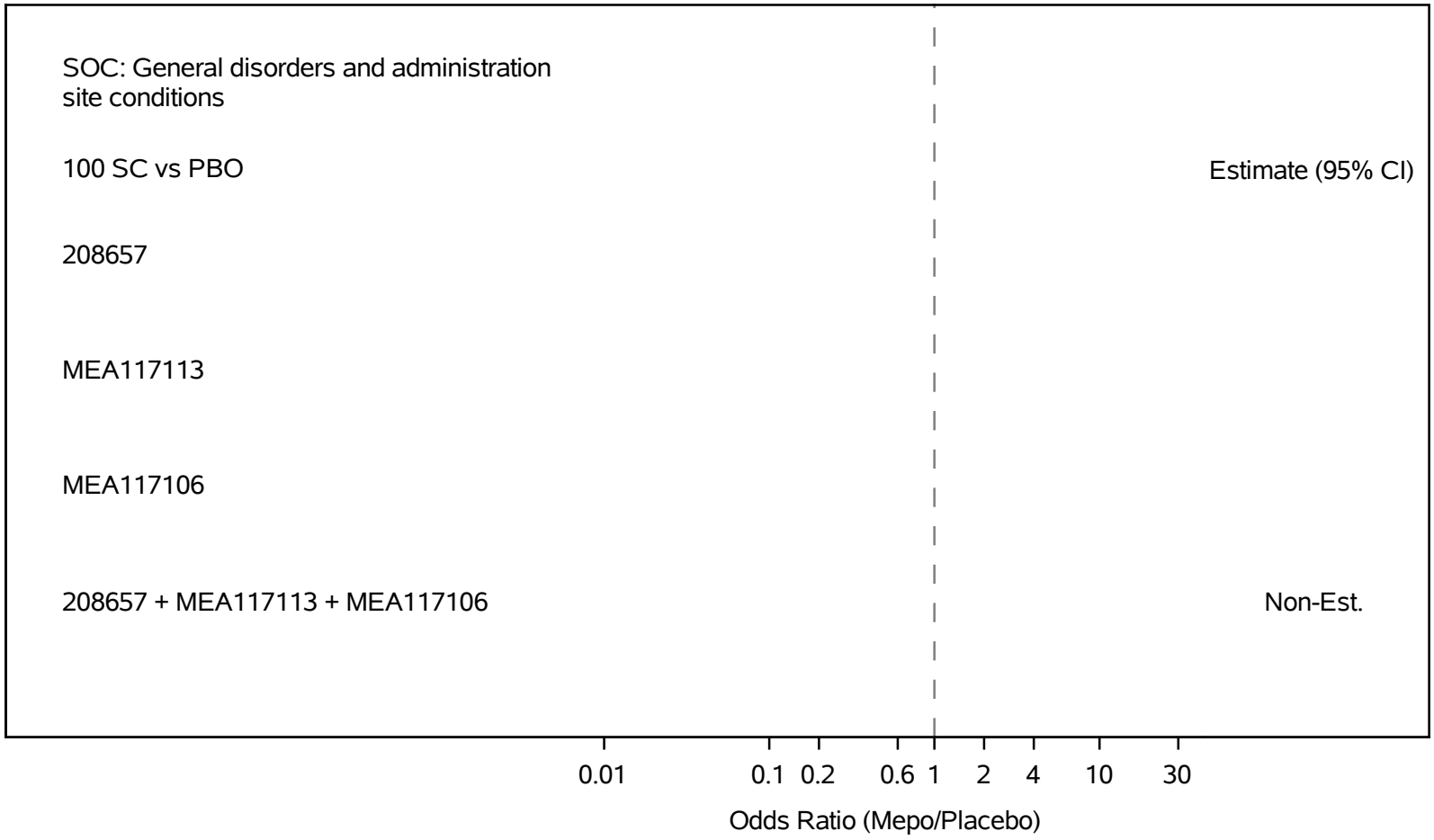


Horizontal bars indicate 95% confidence intervals for the Mepo/Placebo ratio.

Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Figure 311.17

Forest Plot of Odds ratio for On-Treatment Adverse Events leading to withdrawal from study by SOC and PT: Individual Studies and Meta-Analysis



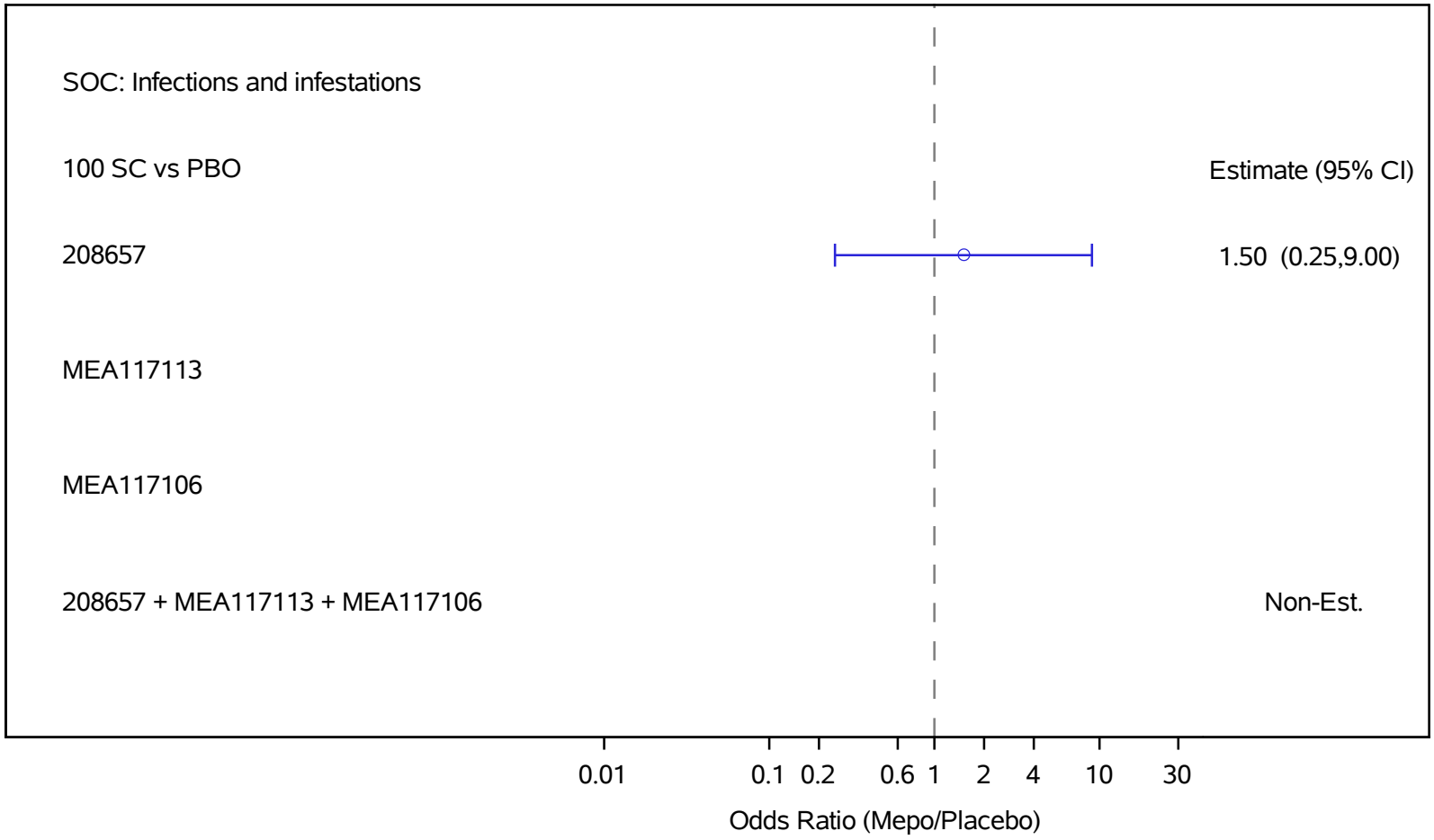
Horizontal bars indicate 95% confidence intervals for the Mepo/Placebo ratio.

/mnt/code/postcsr_01/prod/tfls/f_s_ae_onae_wd_or.sas 17JUL2025 18:13

Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Figure 311.17

Forest Plot of Odds ratio for On-Treatment Adverse Events leading to withdrawal from study by SOC and PT: Individual Studies and Meta-Analysis

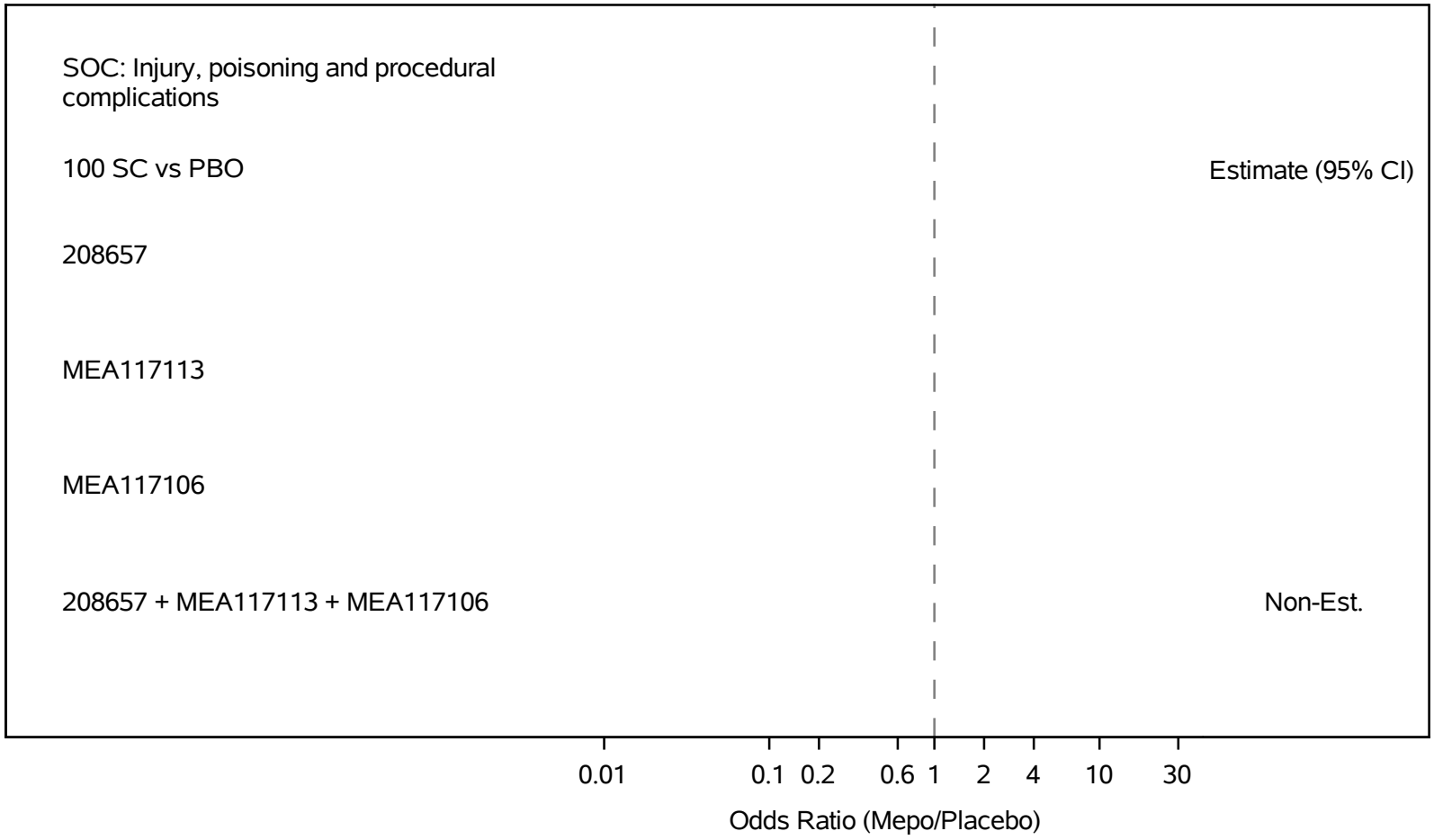


Horizontal bars indicate 95% confidence intervals for the Mepo/Placebo ratio.

Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Figure 311.17

Forest Plot of Odds ratio for On-Treatment Adverse Events leading to withdrawal from study by SOC and PT: Individual Studies and Meta-Analysis

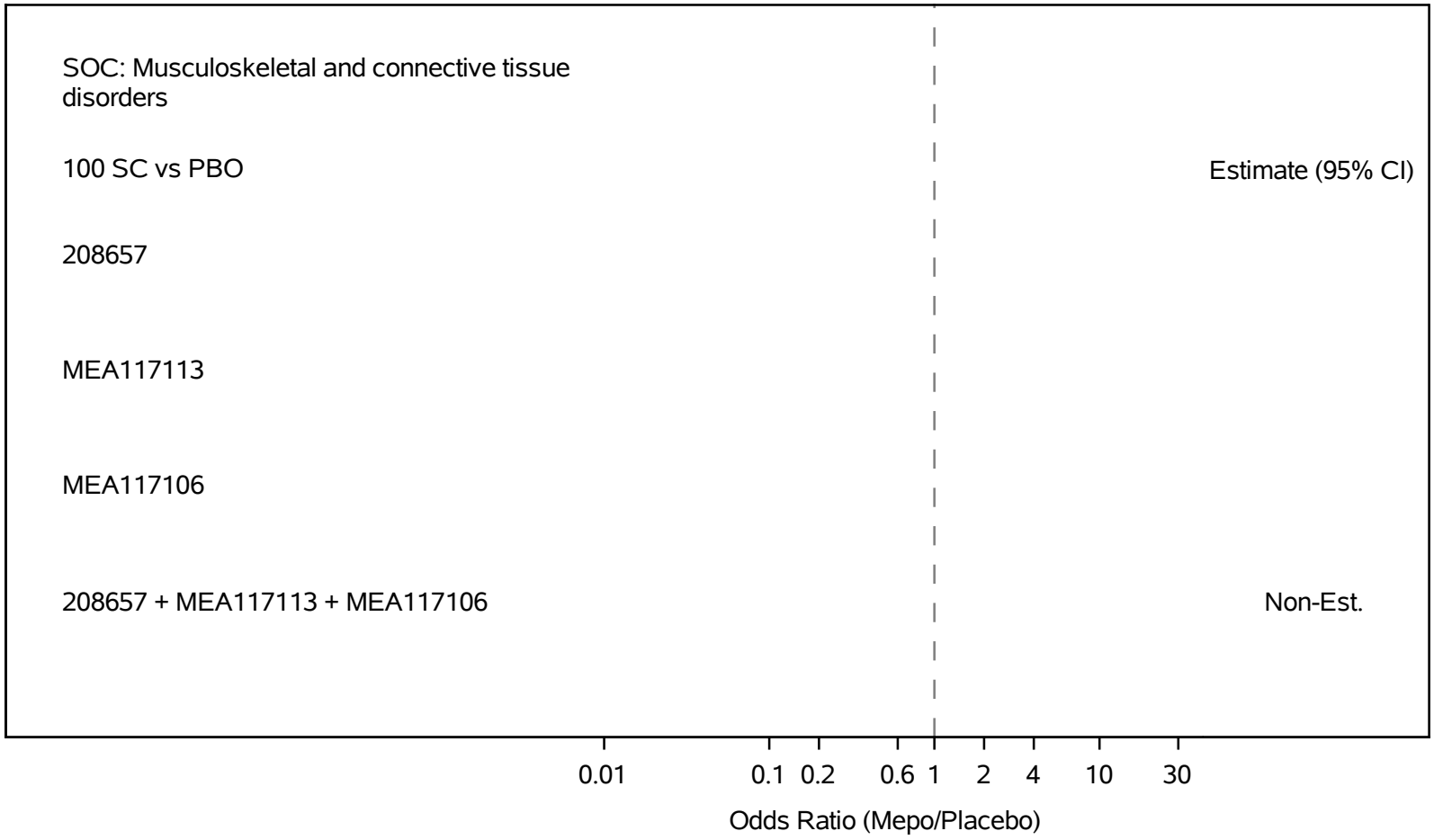


Horizontal bars indicate 95% confidence intervals for the Mepo/Placebo ratio.

Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Figure 311.17

Forest Plot of Odds ratio for On-Treatment Adverse Events leading to withdrawal from study by SOC and PT: Individual Studies and Meta-Analysis

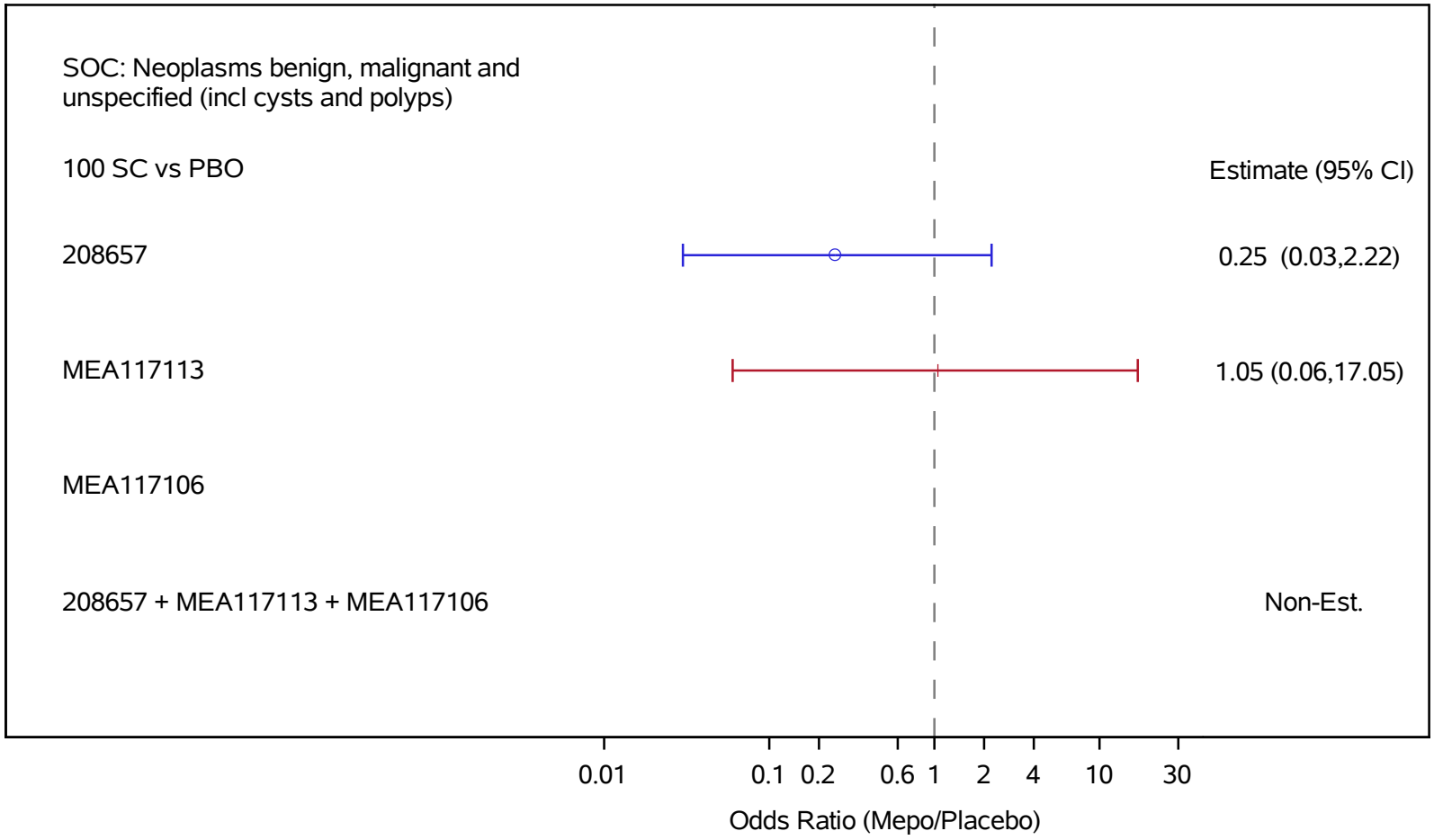


Horizontal bars indicate 95% confidence intervals for the Mepo/Placebo ratio.

Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Figure 311.17

Forest Plot of Odds ratio for On-Treatment Adverse Events leading to withdrawal from study by SOC and PT: Individual Studies and Meta-Analysis



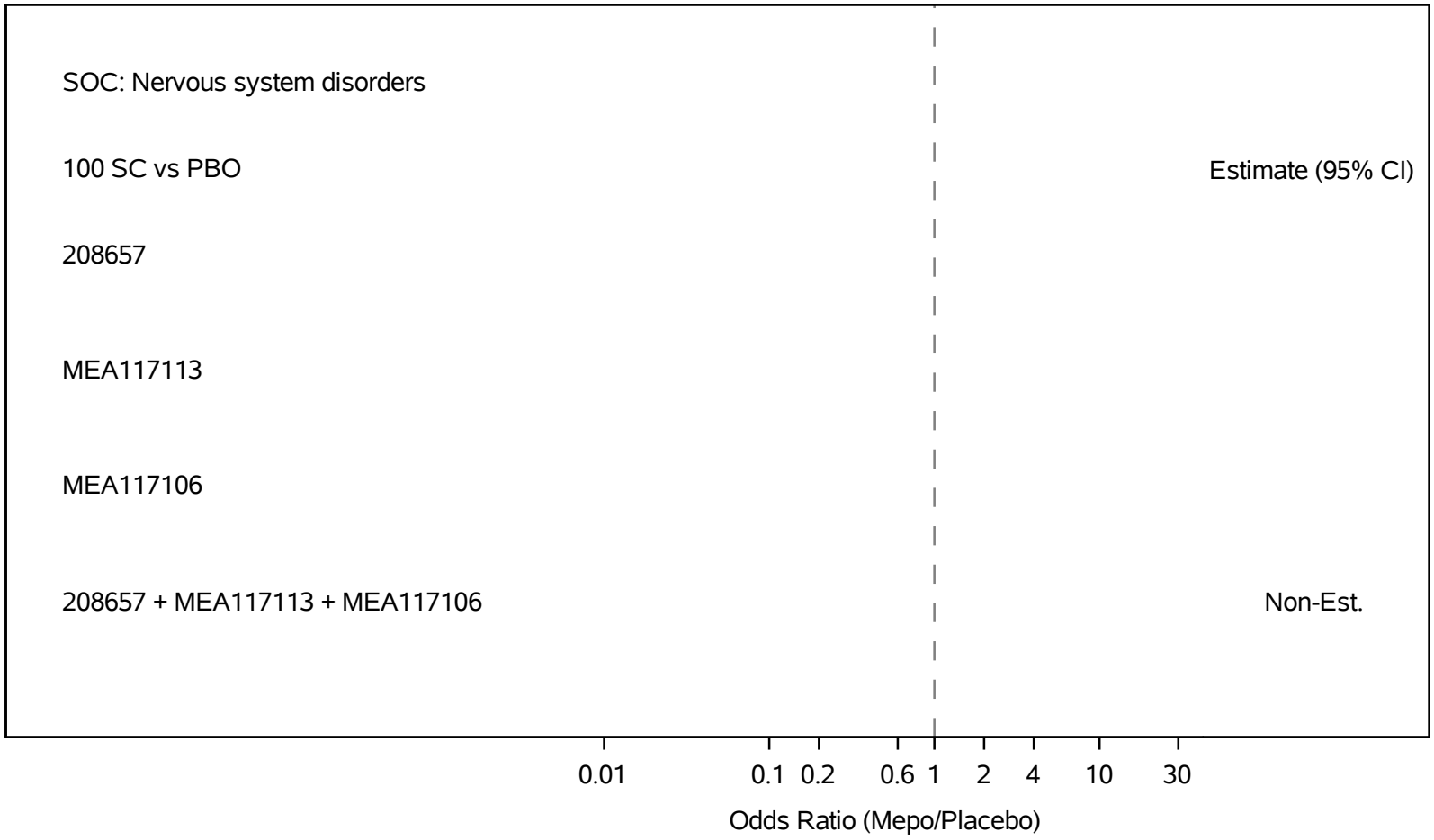
Horizontal bars indicate 95% confidence intervals for the Mepo/Placebo ratio.

/mnt/code/postcsr_01/prod/tfls/f_s_ae_onae_wd_or.sas 17JUL2025 18:13

Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Figure 311.17

Forest Plot of Odds ratio for On-Treatment Adverse Events leading to withdrawal from study by SOC and PT: Individual Studies and Meta-Analysis



Horizontal bars indicate 95% confidence intervals for the Mepo/Placebo ratio.

/mnt/code/postcsr_01/prod/tfls/f_s_ae_onae_wd_or.sas 17JUL2025 18:13

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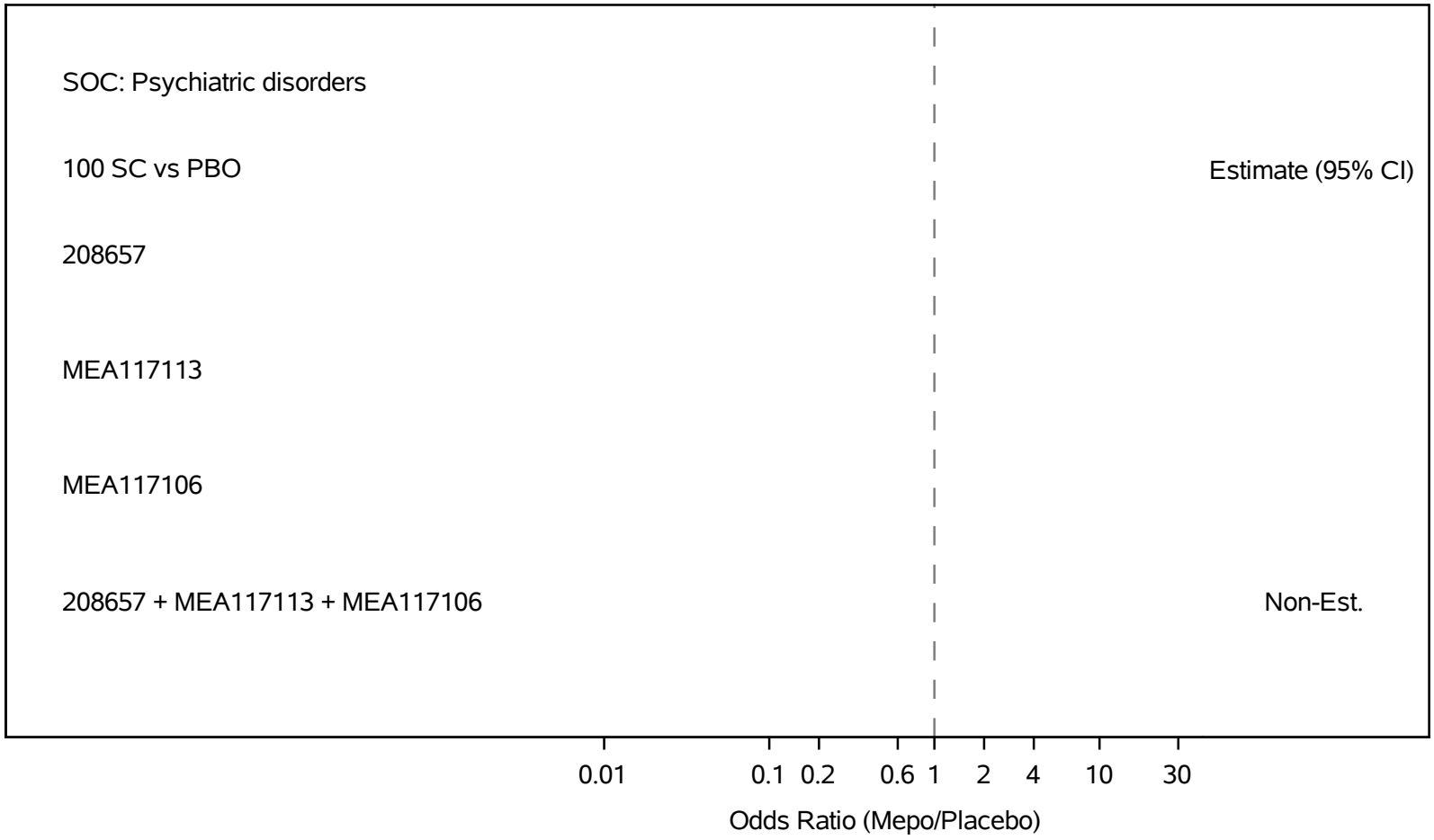
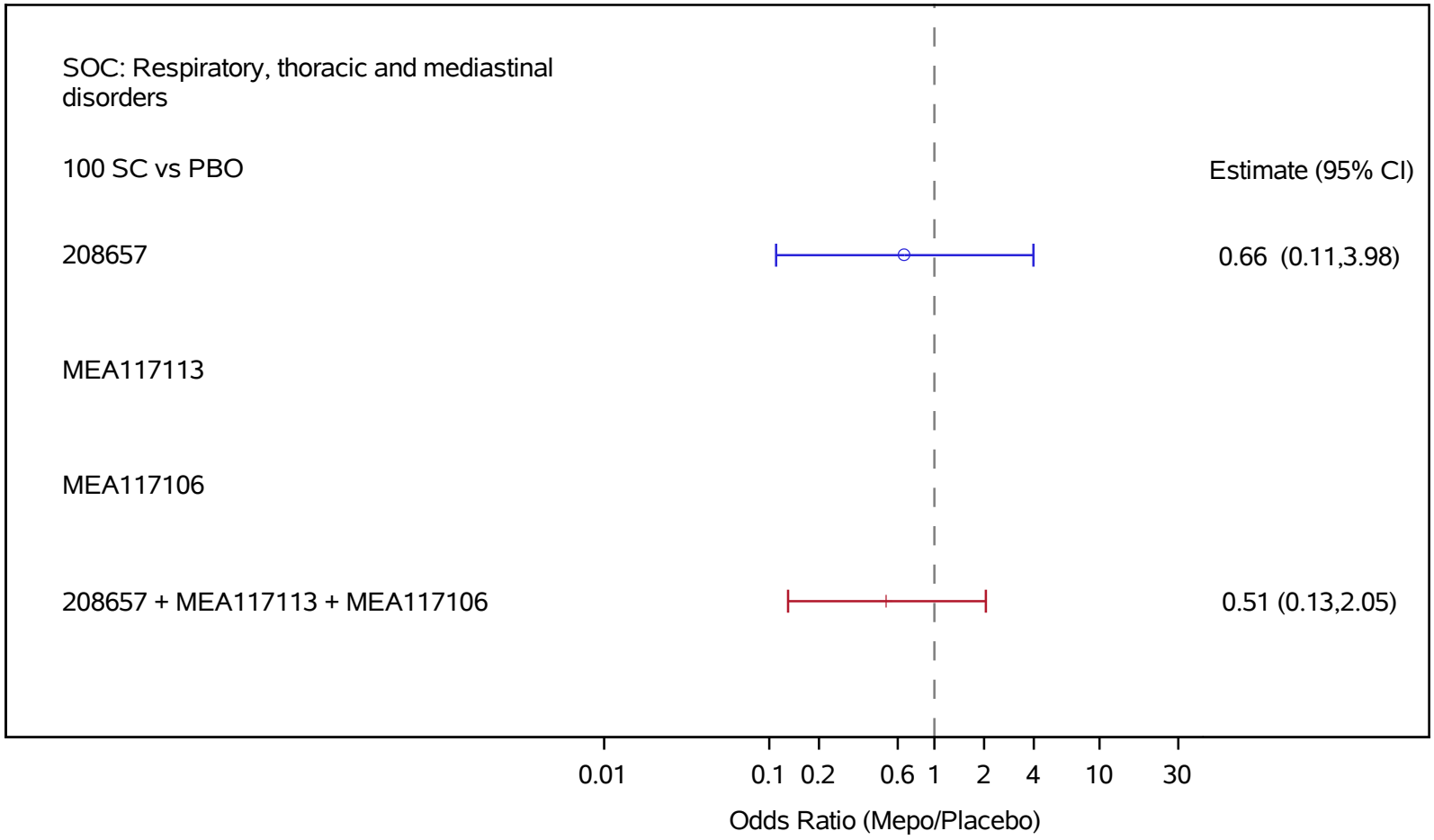


Horizontal bars indicate 95% confidence intervals for the Mepo/Placebo ratio.

Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Figure 311.17

Forest Plot of Odds ratio for On-Treatment Adverse Events leading to withdrawal from study by SOC and PT: Individual Studies and Meta-Analysis



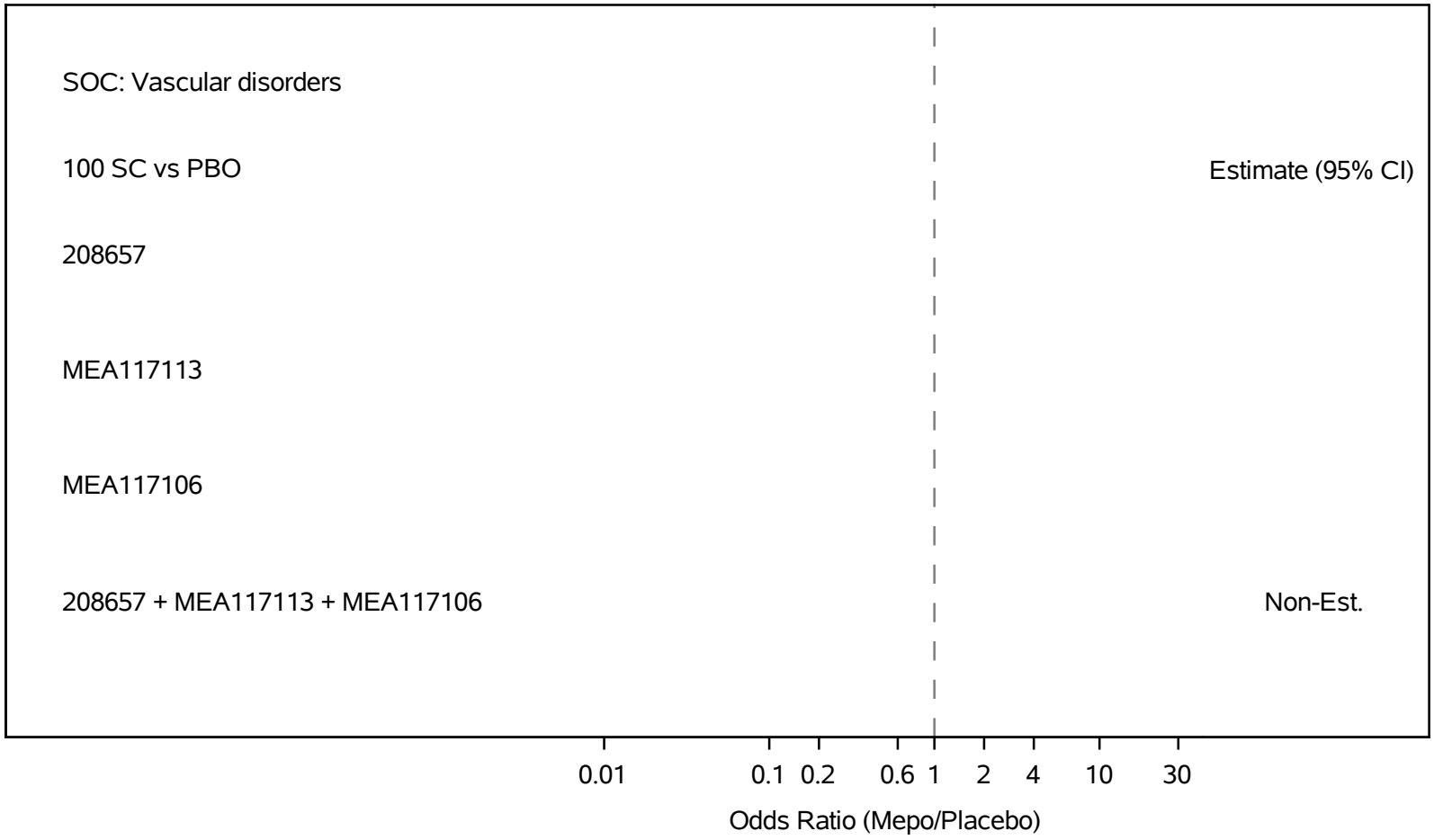
Horizontal bars indicate 95% confidence intervals for the Mepo/Placebo ratio.

/mnt/code/postcsr_01/prod/tfls/f_s_ae_onae_wd_or.sas 17JUL2025 18:13

Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Figure 311.17

Forest Plot of Odds ratio for On-Treatment Adverse Events leading to withdrawal from study by SOC and PT: Individual Studies and Meta-Analysis

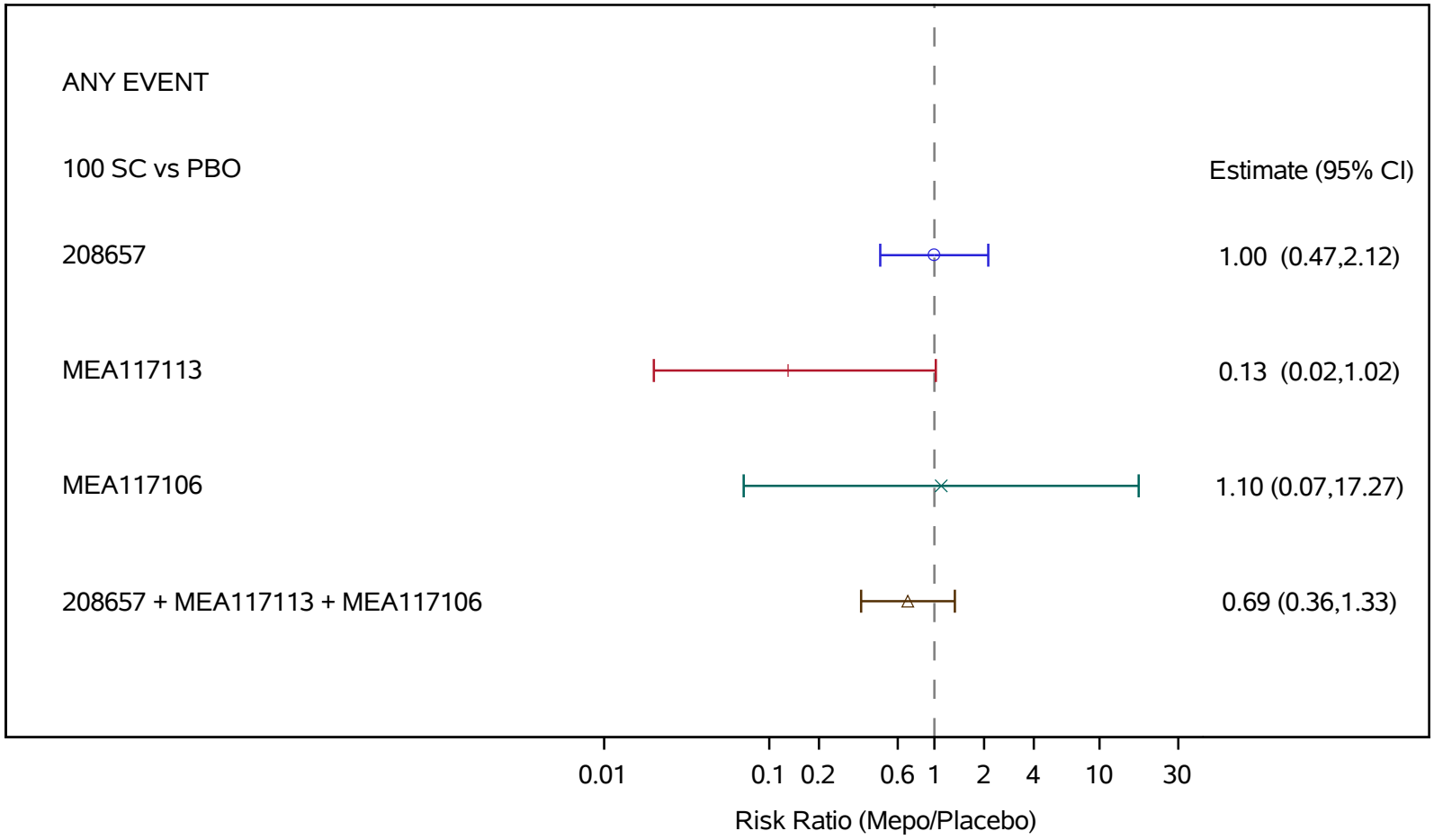


Horizontal bars indicate 95% confidence intervals for the Mepo/Placebo ratio.

Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Figure 311.18

Forest Plot of Relative Risk for On-Treatment Adverse Events leading to withdrawal from study by SOC and PT: Individual Studies and Meta-Analysis



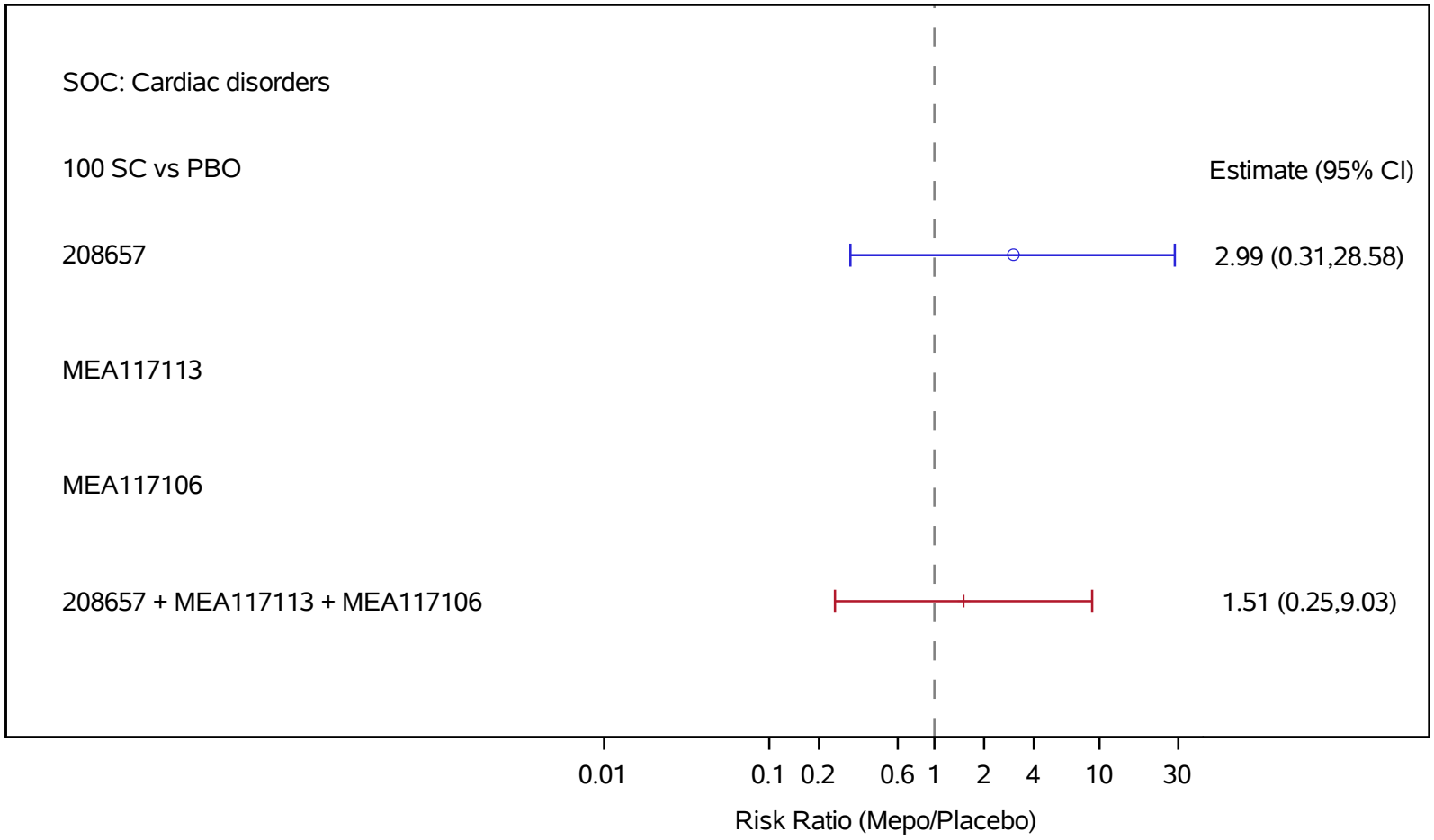
Horizontal bars indicate 95% confidence intervals for the Mepo/Placebo ratio.

/mnt/code/postcsr_01/prod/tfls/f_s_ae_onae_wd_rr.sas 17JUL2025 18:13

Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

Figure 311.18

Forest Plot of Relative Risk for On-Treatment Adverse Events leading to withdrawal from study by SOC and PT: Individual Studies and Meta-Analysis



Horizontal bars indicate 95% confidence intervals for the Mepo/Placebo ratio.

Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

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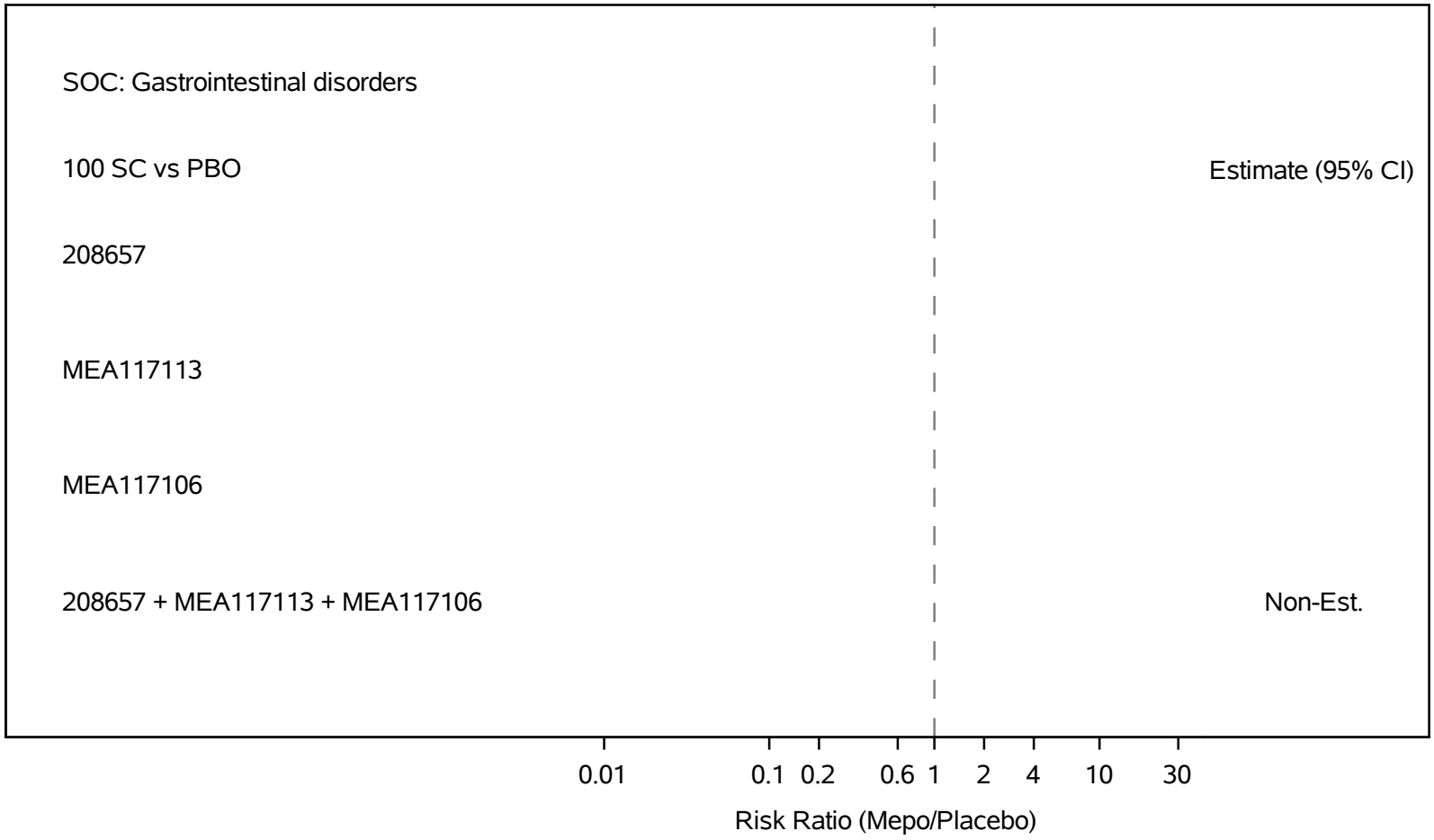

Horizontal bars indicate 95% confidence intervals for the Mepo/Placebo ratio.

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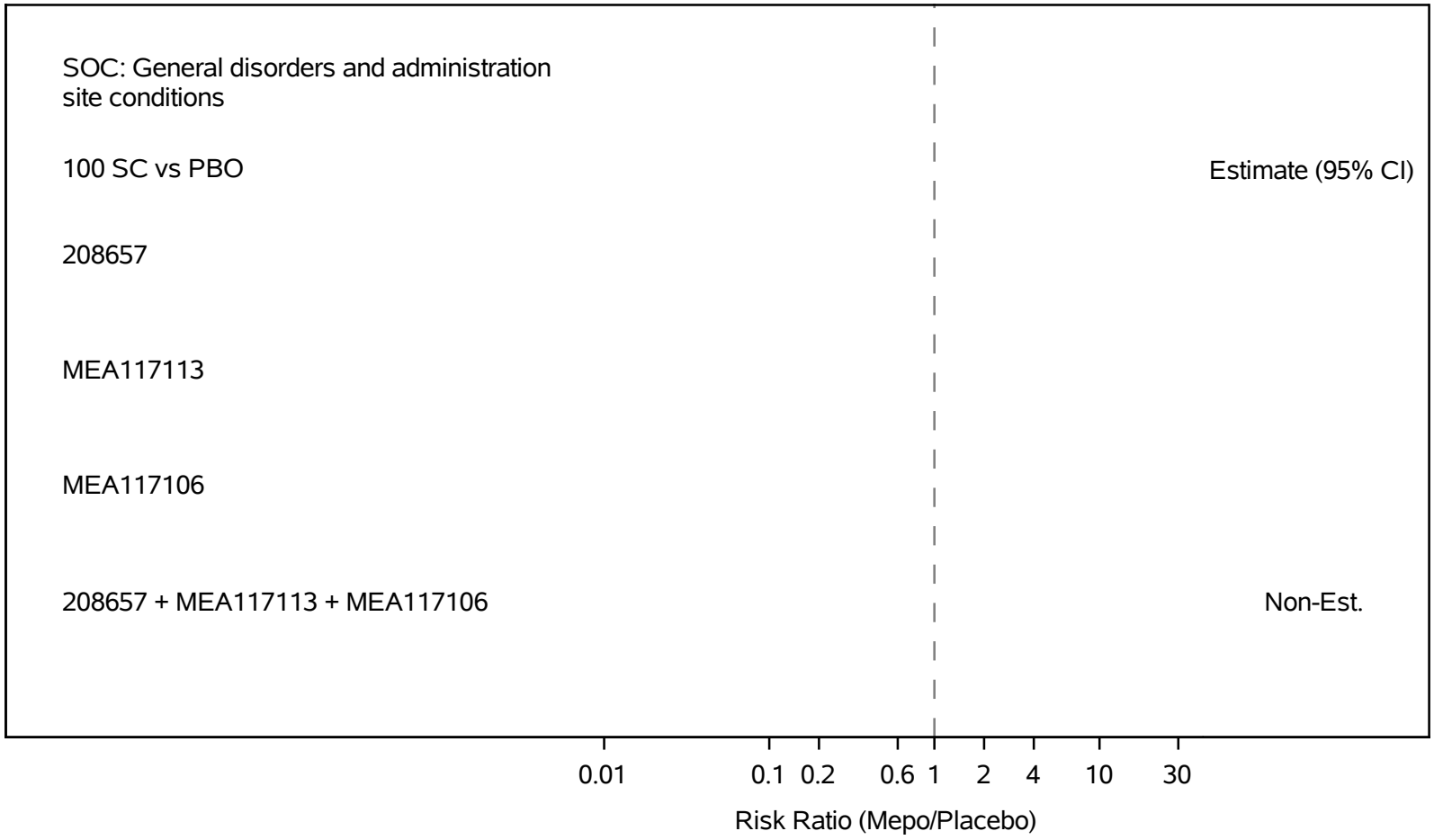

Horizontal bars indicate 95% confidence intervals for the Mepo/Placebo ratio.

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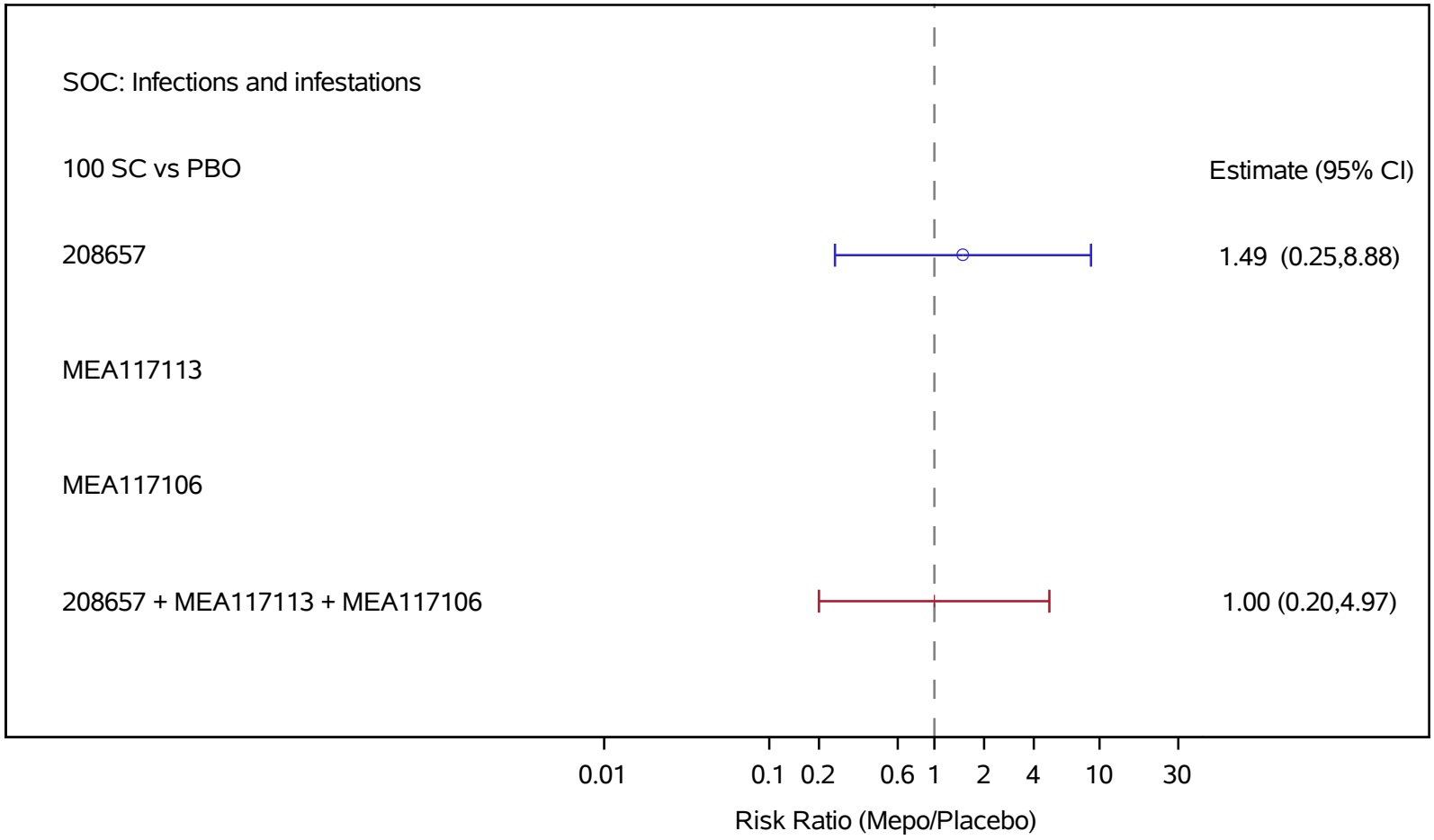

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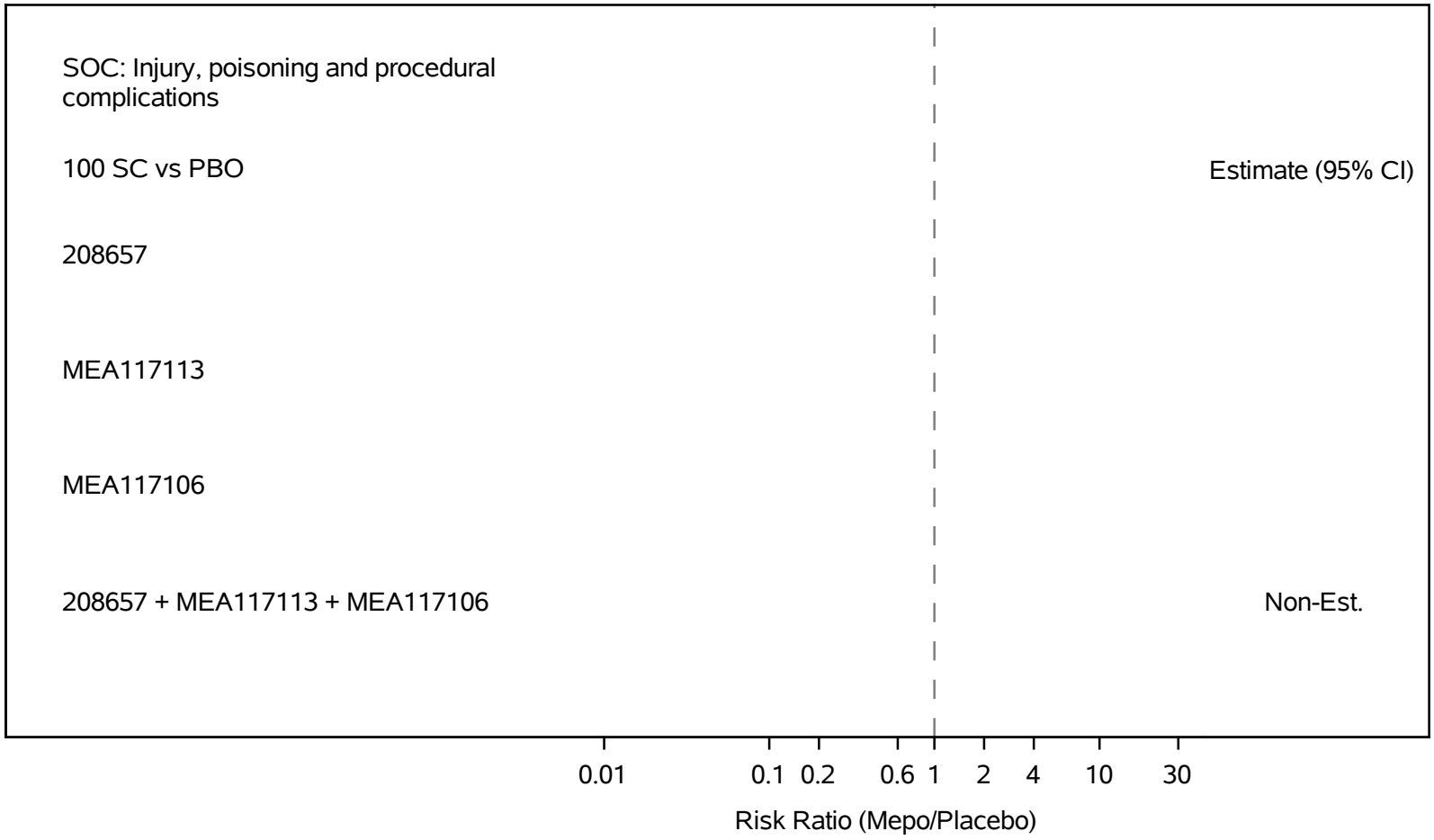

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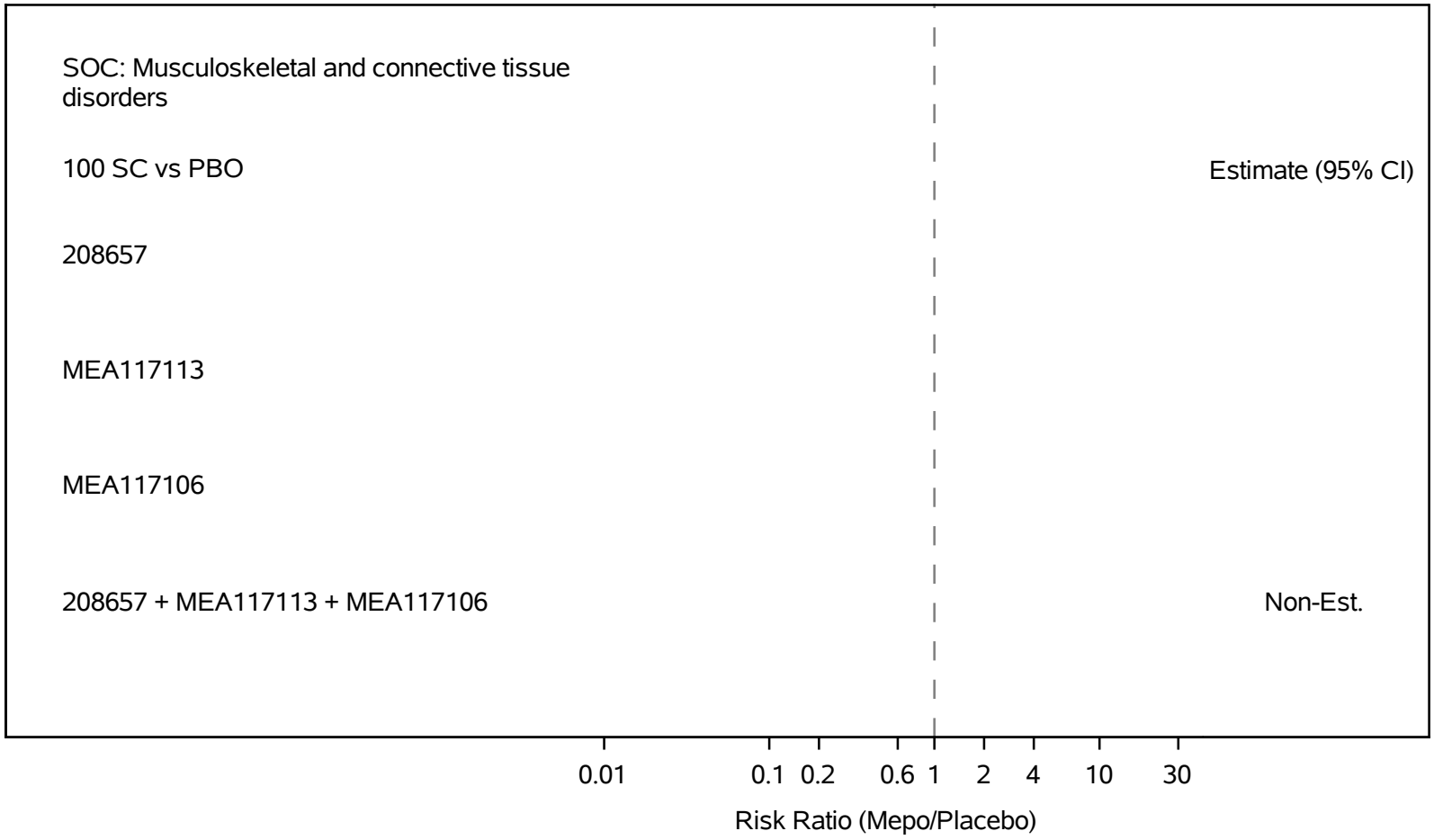

Horizontal bars indicate 95% confidence intervals for the Mepo/Placebo ratio.

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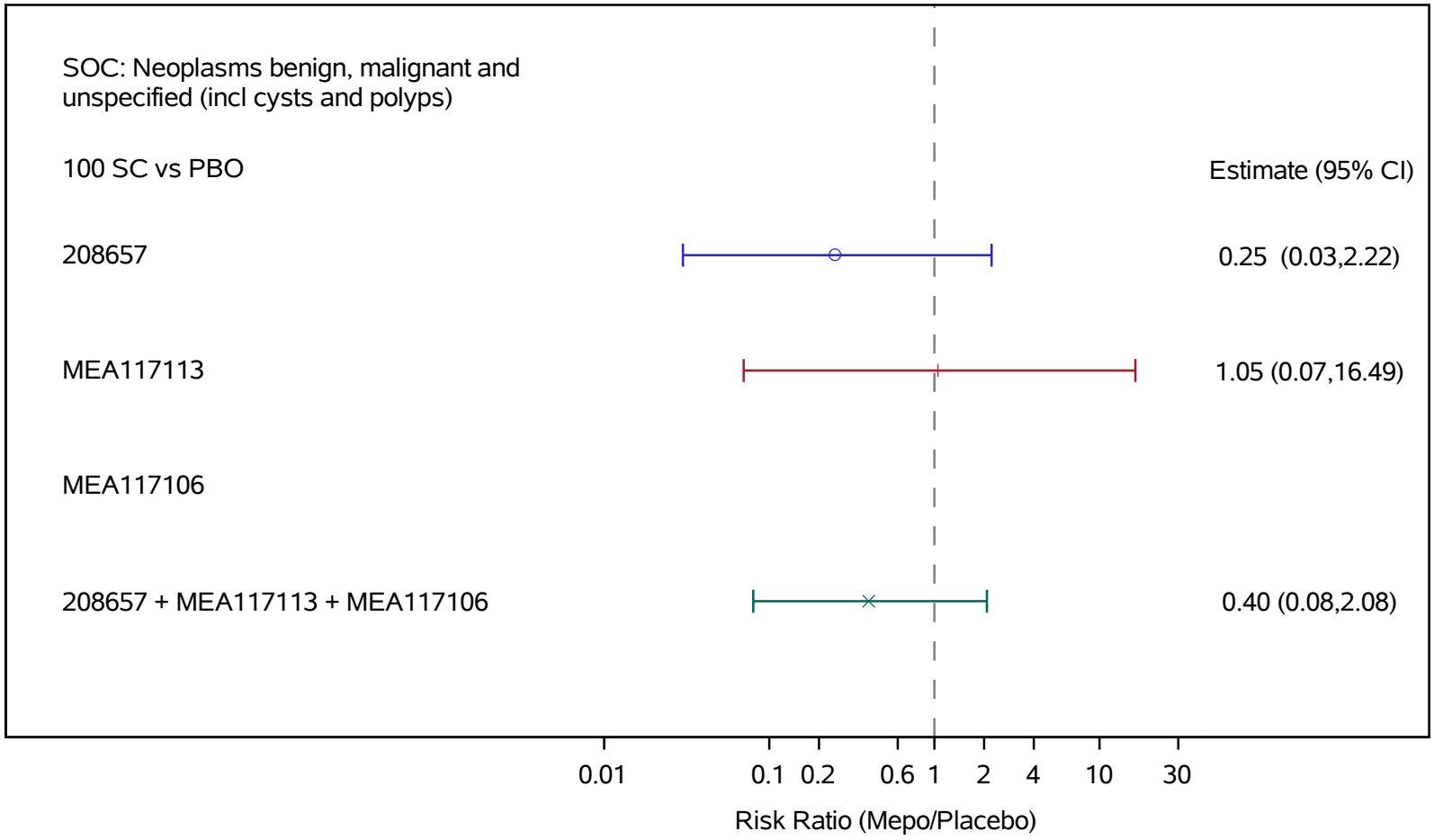
Forest Plot of Relative Risk for On-Treatment Adverse Events leading to withdrawal from study by SOC and PT: Individual Studies and Meta-Analysis



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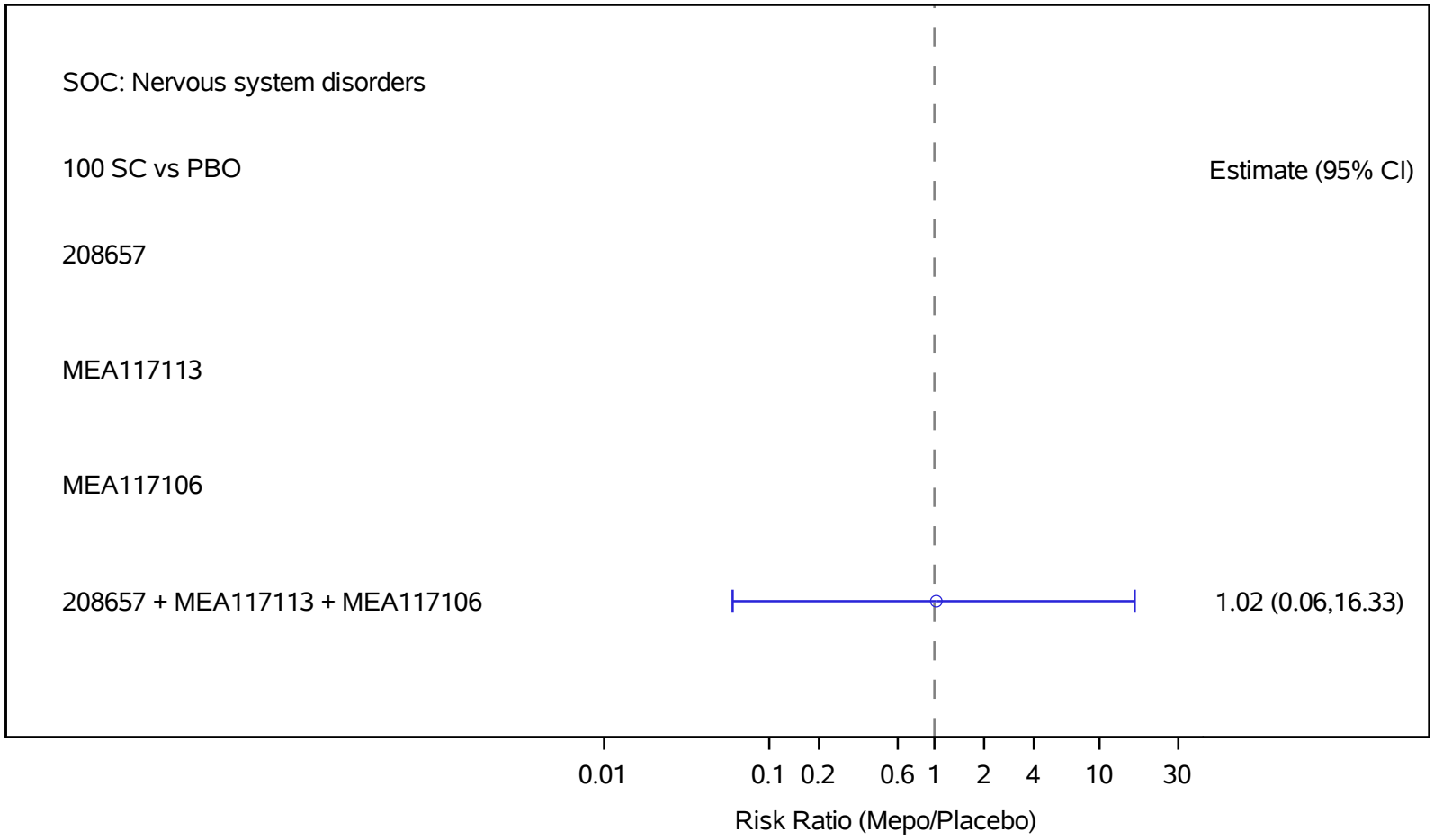

Horizontal bars indicate 95% confidence intervals for the Mepo/Placebo ratio.

Population: Modified Intent-To-Treat Population with Eosinophils 300 cells/uL or More

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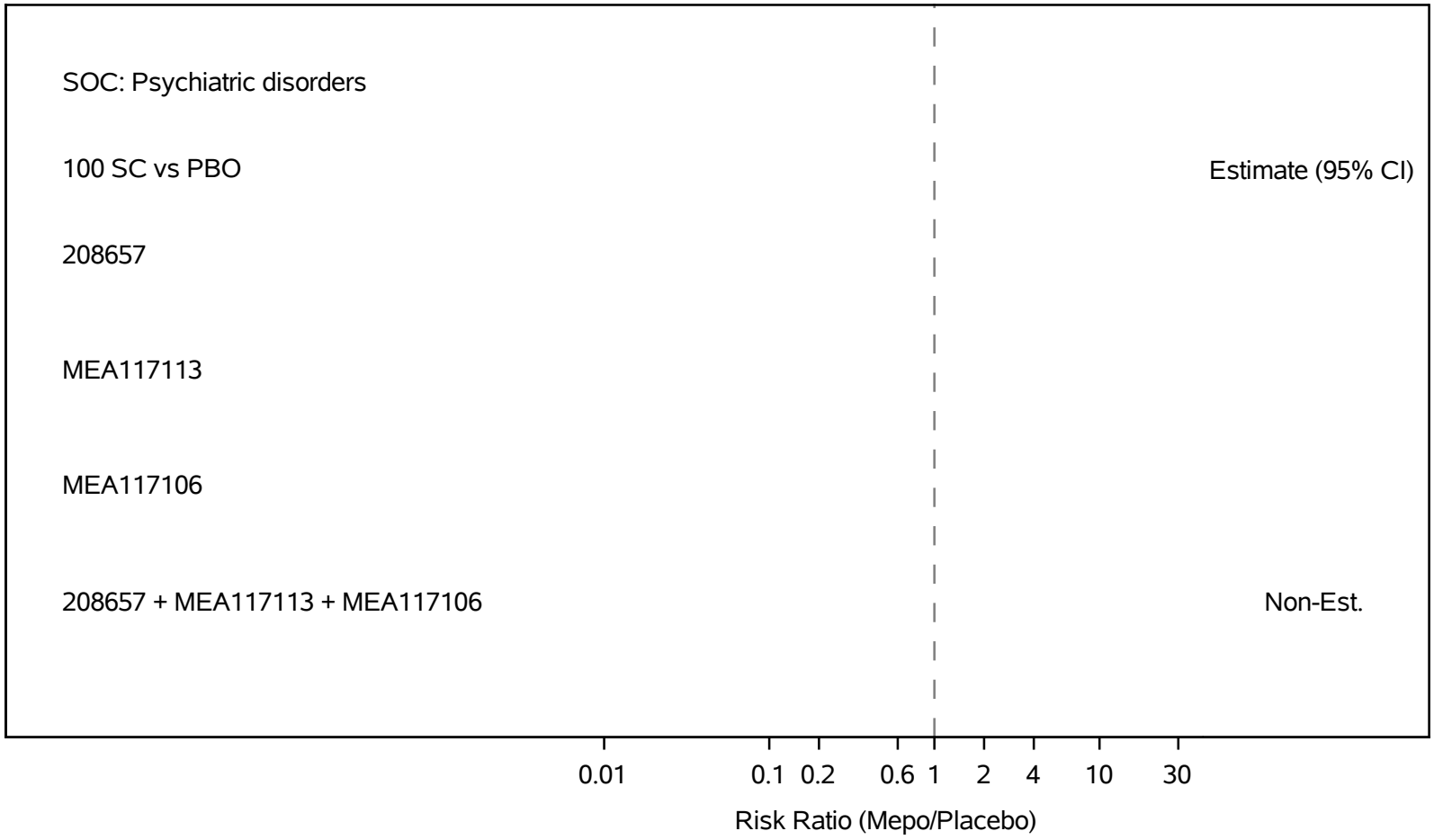
Forest Plot of Relative Risk for On-Treatment Adverse Events leading to withdrawal from study by SOC and PT: Individual Studies and Meta-Analysis



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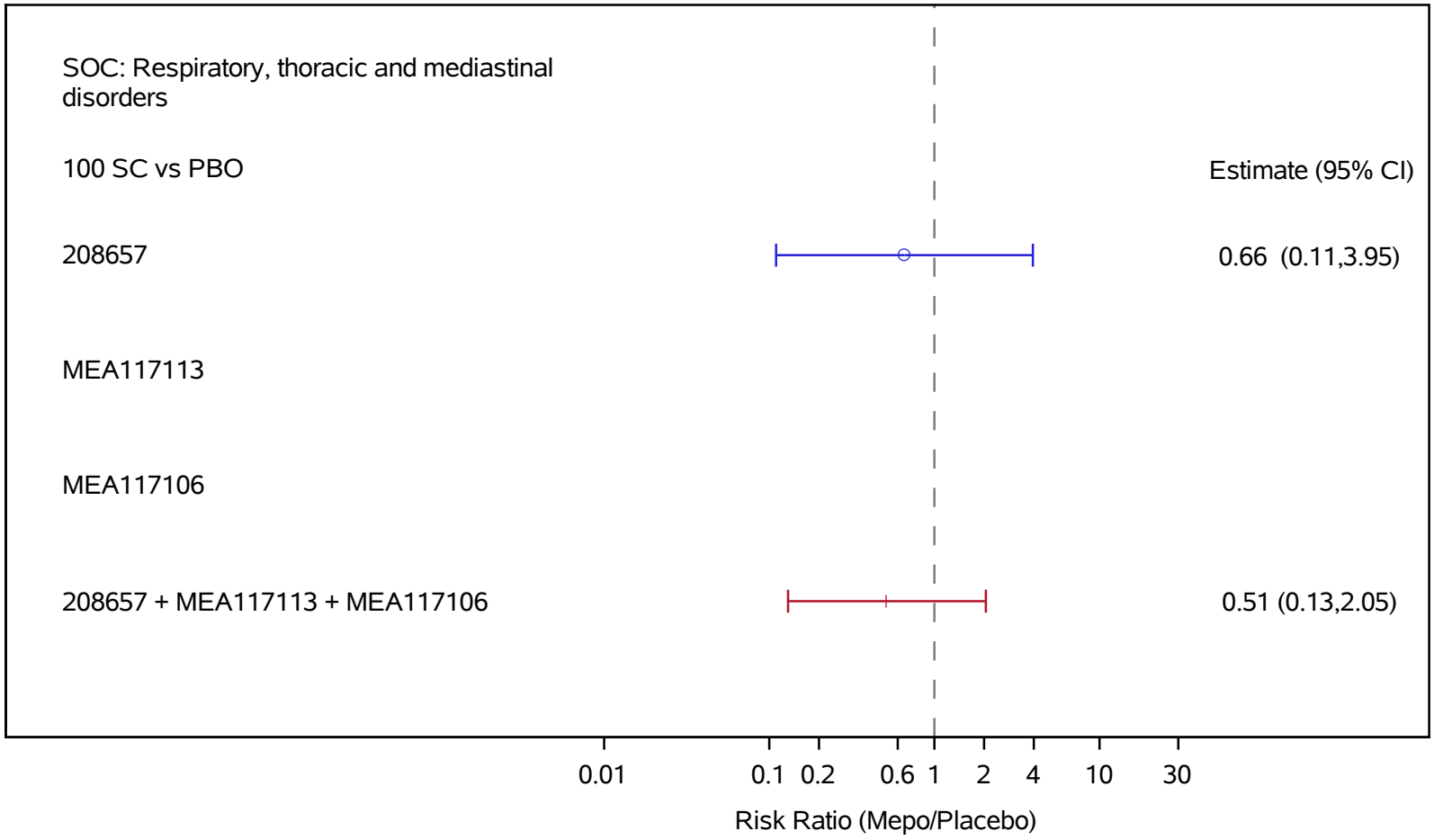

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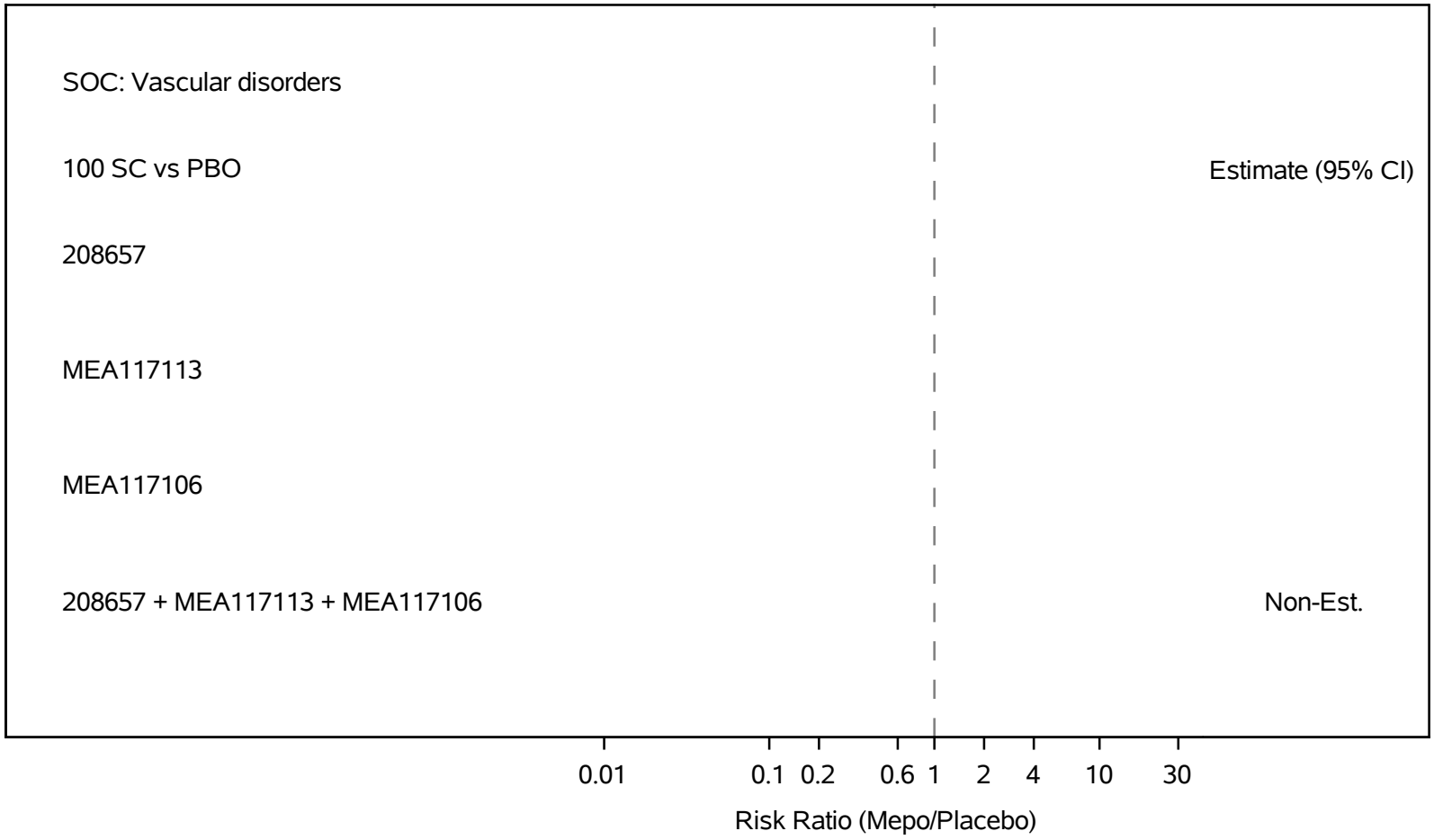

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