Eigene Vorlage

Dossier zur Nutzenbewertung gemäß § 35a SGB V

Mepolizumab (Nucala) – EGPA

GlaxoSmithKline GmbH & Co. KG

Separater Anhang 4-G zu Modul 4B

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Protocol: MEA115921
Population: Intent-to-Treat

Table 2.67
Summary of BVAS Total Score at Each Visit

Timepoint			Placebo (N=68)	Mepolizumab 300 mg SC (N=68)
Baseline	BVAS Total Score	n	68	68
		Mean	3.51	3.06
		SD	4.410	4.998
		Median	2.00	1.00
		Min	0.0	0.0
		Max	19.0	22.0
Week 4	BVAS Total Score	n	68	68
		Mean	2.53	2.49
		SD	4.311	4.808
		Median	1.00	0.00
		Min	0.0	0.0
		Max	24.0	22.0
	BVAS Total Score Change from Baseline	n	68	68
		Mean	-0.99	-0.57
		SD	3.547	3.044
		Median	0.00	0.00
		Min	-13.0	-13.0
		Max	8.0	6.0

PPD

Protocol: MEA115921
Population: Intent-to-Treat

Table 2.67
Summary of BVAS Total Score at Each Visit

Timepoint			Placebo (N=68)	Mepolizumab 300 mg SC (N=68)
Week 8	BVAS Total Score	n	67	68
		Mean	2.42	1.38
		SD	4.120	3.134
		Median	0.00	0.00
		Min	0.0	0.0
		Max	21.0	18.0
	BVAS Total Score Change from Baseline	n	67	68
		Mean	-1.03	-1.68
		SD	4.141	4.504
		Median	0.00	0.00
		Min	-13.0	-22.0
		Max	13.0	8.0
Week 12	BVAS Total Score	n	66	68
		Mean	2.21	2.04
		SD	3.711	4.839
		Median	0.00	0.00
		Min	0.0	0.0
		Max	18.0	28.0
	BVAS Total Score Change from Baseline	n	66	68
		Mean	-1.11	-1.01
		SD	4.400	4.799
		Median	-1.00	0.00
		Min	-11.0	-18.0
		Max	18.0	18.0

PPD

Protocol: MEA115921
Population: Intent-to-Treat

Table 2.67
Summary of BVAS Total Score at Each Visit

Timepoint			Placebo (N=68)	Mepolizumab 300 mg SC (N=68)
Week 16	BVAS Total Score	n	64	67
		Mean	3.02	1.57
		SD	3.990	3.913
		Median	2.00	0.00
		Min	0.0	0.0
		Max	19.0	19.0
	BVAS Total Score Change from Baseline	n	64	67
		Mean	-0.28	-1.36
		SD	3.978	4.611
		Median	0.00	0.00
		Min	-11.0	-18.0
		Max	10.0	11.0
Week 20	BVAS Total Score	n	63	68
		Mean	2.24	1.62
		SD	3.171	3.883
		Median	1.00	0.00
		Min	0.0	0.0
		Max	12.0	18.0
	BVAS Total Score Change from Baseline	n	63	68
		Mean	-1.02	-1.44
		SD	4.098	4.814
		Median	-1.00	0.00
		Min	-13.0	-21.0
		Max	10.0	11.0

PPD

Protocol: MEA115921
Population: Intent-to-Treat

Table 2.67
Summary of BVAS Total Score at Each Visit

Timepoint			Placebo (N=68)	Mepolizumab 300 mg SC (N=68)
Week 24	BVAS Total Score	n	63	67
		Mean	1.94	1.58
		SD	3.364	3.615
		Median	0.00	0.00
		Min	0.0	0.0
		Max	16.0	19.0
	BVAS Total Score Change from Baseline	n	63	67
		Mean	-1.19	-1.49
		SD	3.645	5.046
		Median	-1.00	0.00
		Min	-11.0	-21.0
		Max	13.0	12.0
Week 28	BVAS Total Score	n	63	67
		Mean	2.54	2.06
		SD	3.378	4.203
		Median	2.00	0.00
		Min	0.0	0.0
		Max	16.0	17.0
	BVAS Total Score Change from Baseline	n	63	67
		Mean	-0.59	-1.01
		SD	3.749	5.381
		Median	0.00	0.00
		Min	-13.0	-18.0
		Max	9.0	16.0

PPD

Protocol: MEA115921
Population: Intent-to-Treat

Table 2.67
Summary of BVAS Total Score at Each Visit

Timepoint			Placebo (N=68)	Mepolizumab 300 mg SC (N=68)
Week 32	BVAS Total Score	n	61	67
		Mean	2.07	1.93
		SD	2.839	3.909
		Median	1.00	0.00
		Min	0.0	0.0
		Max	11.0	17.0
	BVAS Total Score Change from Baseline	n	61	67
		Mean	-1.03	-1.15
		SD	4.450	4.510
		Median	0.00	0.00
		Min	-14.0	-18.0
		Max	10.0	7.0
Week 36	BVAS Total Score	n	62	67
		Mean	1.65	2.15
		SD	2.497	4.297
		Median	0.00	0.00
		Min	0.0	0.0
		Max	9.0	22.0
	BVAS Total Score Change from Baseline	n	62	67
		Mean	-1.53	-0.93
		SD	3.732	4.720
		Median	-1.00	0.00
		Min	-16.0	-18.0
		Max	5.0	14.0

PPD

Protocol: MEA115921
Population: Intent-to-Treat

Table 2.67
Summary of BVAS Total Score at Each Visit

Timepoint			Placebo (N=68)	Mepolizumab 300 mg SC (N=68)
Week 40	BVAS Total Score	n	62	66
		Mean	1.65	1.82
		SD	2.937	4.173
		Median	0.00	0.00
		Min	0.0	0.0
		Max	13.0	22.0
	BVAS Total Score Change from Baseline	n	62	66
		Mean	-1.53	-1.30
		SD	4.397	5.544
		Median	-1.00	0.00
		Min	-18.0	-19.0
		Max	8.0	15.0
Week 44	BVAS Total Score	n	61	66
		Mean	2.30	2.38
		SD	3.779	4.845
		Median	0.00	0.00
		Min	0.0	0.0
		Max	18.0	22.0
	BVAS Total Score Change from Baseline	n	61	66
		Mean	-0.93	-0.74
		SD	3.763	5.850
		Median	-1.00	0.00
		Min	-13.0	-20.0
		Max	11.0	17.0

PPD

Protocol: MEA115921
Population: Intent-to-Treat

Table 2.67
Summary of BVAS Total Score at Each Visit

Timepoint			Placebo (N=68)	Mepolizumab 300 mg SC (N=68)
Week 48	BVAS Total Score	n	61	64
		Mean	2.11	1.81
		SD	3.210	3.741
		Median	0.00	0.00
		Min	0.0	0.0
		Max	17.0	23.0
	BVAS Total Score Change from Baseline	n	61	64
		Mean	-1.11	-1.20
		SD	4.367	5.210
		Median	-1.00	0.00
		Min	-15.0	-21.0
		Max	17.0	15.0
Week 52	BVAS Total Score	n	60	65
		Mean	1.97	2.22
		SD	2.923	3.524
		Median	0.50	0.00
		Min	0.0	0.0
		Max	13.0	18.0
	BVAS Total Score Change from Baseline	n	60	65
		Mean	-1.32	-0.94
		SD	3.916	4.863
		Median	0.00	0.00
		Min	-16.0	-18.0
		Max	6.0	13.0

PPD

Protocol: MEA115921
Population: Intent-to-Treat

Table 2.67
Summary of BVAS Total Score at Each Visit

Timepoint			Placebo (N=68)	Mepolizumab 300 mg SC (N=68)
Week 56	BVAS Total Score	n	62	63
		Mean	1.89	1.79
		SD	3.095	3.469
		Median	0.00	0.00
		Min	0.0	0.0
		Max	14.0	16.0
	BVAS Total Score Change from Baseline	n	62	63
		Mean	-1.29	-1.14
		SD	4.411	5.483
		Median	-0.50	0.00
		Min	-18.0	-22.0
		Max	11.0	10.0
Week 60	BVAS Total Score	n	61	65
		Mean	1.51	2.52
		SD	2.656	4.647
		Median	0.00	0.00
		Min	0.0	0.0
		Max	14.0	23.0
	BVAS Total Score Change from Baseline	n	61	65
		Mean	-1.70	-0.63
		SD	4.201	6.115
		Median	-1.00	0.00
		Min	-17.0	-21.0
		Max	7.0	15.0

PPD

Protocol: MEA115921
Population: Intent-to-Treat

Table 2.68
Analysis of Change from Baseline in BVAS

Visit: Week 4

	Placebo (N=68)	Mepolizumab 300 mg SC (N=68)
n	68	68
LS Mean (SE)	2.14 (0.461)	2.40 (0.462)
LS Mean Change (SE)	-1.02 (0.461)	-0.76 (0.462)
Comparison: Mepolizumab vs. Placebo		
Difference		0.26
95% Confidence Interval		(-0.78,1.31)
p-value		0.620

Analysis performed using mixed model repeated measures with terms for treatment group, baseline prednisolone/prednisone daily dose, baseline BVAS score, region, visit,visit by baseline BVAS and visit by treatment group.

PPD

Protocol: MEA115921
Population: Intent-to-Treat

Table 2.68
Analysis of Change from Baseline in BVAS

Visit: Week 8

	Placebo (N=68)	Mepolizumab 300 mg SC (N=68)
n	67	68
LS Mean (SE)	2.15 (0.472)	1.26 (0.471)
LS Mean Change (SE)	-1.01 (0.472)	-1.90 (0.471)
Comparison: Mepolizumab vs. Placebo		
Difference		-0.89
95% Confidence Interval		(-1.97,0.19)
p-value		0.105

Analysis performed using mixed model repeated measures with terms for treatment group, baseline prednisolone/prednisone daily dose, baseline BVAS score, region, visit,visit by baseline BVAS and visit by treatment group.

PPD

Protocol: MEA115921
Population: Intent-to-Treat

Table 2.68
Analysis of Change from Baseline in BVAS

Visit: Week 12

	Placebo (N=68)	Mepolizumab 300 mg SC (N=68)
n	66	68
LS Mean (SE)	2.12 (0.552)	1.93 (0.548)
LS Mean Change (SE)	-1.03 (0.552)	-1.23 (0.548)
Comparison: Mepolizumab vs. Placebo		
Difference		-0.19
95% Confidence Interval		(-1.53,1.15)
p-value		0.777

Analysis performed using mixed model repeated measures with terms for treatment group, baseline prednisolone/prednisone daily dose, baseline BVAS score, region, visit,visit by baseline BVAS and visit by treatment group.

PPD

Protocol: MEA115921
Population: Intent-to-Treat

Table 2.68
Analysis of Change from Baseline in BVAS

Visit: Week 16

	Placebo (N=68)	Mepolizumab 300 mg SC (N=68)
n	64	67
LS Mean (SE)	2.87 (0.505)	1.52 (0.500)
LS Mean Change (SE)	-0.29 (0.505)	-1.64 (0.500)
Comparison: Mepolizumab vs. Placebo		
Difference		-1.35
95% Confidence Interval		(-2.53,-0.17)
p-value		0.026

Analysis performed using mixed model repeated measures with terms for treatment group, baseline prednisolone/prednisone daily dose, baseline BVAS score, region, visit,visit by baseline BVAS and visit by treatment group.

PPD

Protocol: MEA115921
Population: Intent-to-Treat

Table 2.68
Analysis of Change from Baseline in BVAS

Visit: Week 20

	Placebo (N=68)	Mepolizumab 300 mg SC (N=68)
n	63	68
LS Mean (SE)	2.21 (0.487)	1.49 (0.481)
LS Mean Change (SE)	-0.95 (0.487)	-1.66 (0.481)
Comparison: Mepolizumab vs. Placebo		
Difference		-0.71
95% Confidence Interval		(-1.83,0.41)
p-value		0.212

Analysis performed using mixed model repeated measures with terms for treatment group, baseline prednisolone/prednisone daily dose, baseline BVAS score, region, visit,visit by baseline BVAS and visit by treatment group.

PPD

Protocol: MEA115921
Population: Intent-to-Treat

Table 2.68
Analysis of Change from Baseline in BVAS

Visit: Week 24

	Placebo (N=68)	Mepolizumab 300 mg SC (N=68)
n	63	67
LS Mean (SE)	1.93 (0.481)	1.45 (0.475)
LS Mean Change (SE)	-1.23 (0.481)	-1.71 (0.475)
Comparison: Mepolizumab vs. Placebo		
Difference		-0.48
95% Confidence Interval		(-1.58,0.63)
p-value		0.394

Analysis performed using mixed model repeated measures with terms for treatment group, baseline prednisolone/prednisone daily dose, baseline BVAS score, region, visit,visit by baseline BVAS and visit by treatment group.

PPD

Protocol: MEA115921
Population: Intent-to-Treat

Table 2.68
Analysis of Change from Baseline in BVAS

Visit: Week 28

	Placebo (N=68)	Mepolizumab 300 mg SC (N=68)
n	63	67
LS Mean (SE)	2.51 (0.518)	1.93 (0.511)
LS Mean Change (SE)	-0.65 (0.518)	-1.23 (0.511)
Comparison: Mepolizumab vs. Placebo		
Difference		-0.58
95% Confidence Interval		(-1.80,0.64)
p-value		0.350

Analysis performed using mixed model repeated measures with terms for treatment group, baseline prednisolone/prednisone daily dose, baseline BVAS score, region, visit,visit by baseline BVAS and visit by treatment group.

PPD

Protocol: MEA115921
Population: Intent-to-Treat

Table 2.68
Analysis of Change from Baseline in BVAS

Visit: Week 32

	Placebo (N=68)	Mepolizumab 300 mg SC (N=68)
n	61	67
LS Mean (SE)	2.02 (0.478)	1.79 (0.469)
LS Mean Change (SE)	-1.13 (0.478)	-1.37 (0.469)
Comparison: Mepolizumab vs. Placebo		
Difference		-0.24
95% Confidence Interval		(-1.32,0.85)
p-value		0.669

Analysis performed using mixed model repeated measures with terms for treatment group, baseline prednisolone/prednisone daily dose, baseline BVAS score, region, visit,visit by baseline BVAS and visit by treatment group.

PPD

Protocol: MEA115921
Population: Intent-to-Treat

Table 2.68
Analysis of Change from Baseline in BVAS

Visit: Week 36

	Placebo (N=68)	Mepolizumab 300 mg SC (N=68)
n	62	67
LS Mean (SE)	1.71 (0.483)	2.01 (0.475)
LS Mean Change (SE)	-1.45 (0.483)	-1.14 (0.475)
Comparison: Mepolizumab vs. Placebo		
Difference		0.31
95% Confidence Interval		(-0.80,1.41)
p-value		0.584

Analysis performed using mixed model repeated measures with terms for treatment group, baseline prednisolone/prednisone daily dose, baseline BVAS score, region, visit,visit by baseline BVAS and visit by treatment group.

PPD

Protocol: MEA115921
Population: Intent-to-Treat

Table 2.68
Analysis of Change from Baseline in BVAS

Visit: Week 40

	Placebo (N=68)	Mepolizumab 300 mg SC (N=68)
n	62	66
LS Mean (SE)	1.76 (0.522)	1.67 (0.514)
LS Mean Change (SE)	-1.40 (0.522)	-1.49 (0.514)
Comparison: Mepolizumab vs. Placebo		
Difference		-0.08
95% Confidence Interval		(-1.32,1.15)
p-value		0.892

Analysis performed using mixed model repeated measures with terms for treatment group, baseline prednisolone/prednisone daily dose, baseline BVAS score, region, visit,visit by baseline BVAS and visit by treatment group.

PPD

Protocol: MEA115921
Population: Intent-to-Treat

Table 2.68
Analysis of Change from Baseline in BVAS

Visit: Week 44

	Placebo (N=68)	Mepolizumab 300 mg SC (N=68)
n	61	66
LS Mean (SE)	2.44 (0.584)	2.25 (0.572)
LS Mean Change (SE)	-0.72 (0.584)	-0.91 (0.572)
Comparison: Mepolizumab vs. Placebo		
Difference		-0.19
95% Confidence Interval		(-1.61,1.24)
p-value		0.796

Analysis performed using mixed model repeated measures with terms for treatment group, baseline prednisolone/prednisone daily dose, baseline BVAS score, region, visit,visit by baseline BVAS and visit by treatment group.

PPD

Protocol: MEA115921
Population: Intent-to-Treat

Table 2.68
Analysis of Change from Baseline in BVAS

Visit: Week 48

	Placebo (N=68)	Mepolizumab 300 mg SC (N=68)
n	61	64
LS Mean (SE)	2.19 (0.507)	1.77 (0.501)
LS Mean Change (SE)	-0.97 (0.507)	-1.39 (0.501)
Comparison: Mepolizumab vs. Placebo		
Difference		-0.42
95% Confidence Interval		(-1.61,0.78)
p-value		0.491

Analysis performed using mixed model repeated measures with terms for treatment group, baseline prednisolone/prednisone daily dose, baseline BVAS score, region, visit,visit by baseline BVAS and visit by treatment group.

PPD

Protocol: MEA115921
Population: Intent-to-Treat

Table 2.68
Analysis of Change from Baseline in BVAS

Visit: Week 52

	Placebo (N=68)	Mepolizumab 300 mg SC (N=68)
n	60	65
LS Mean (SE)	1.97 (0.474)	2.05 (0.466)
LS Mean Change (SE)	-1.18 (0.474)	-1.11 (0.466)
Comparison: Mepolizumab vs. Placebo		
Difference		0.07
95% Confidence Interval		(-1.00,1.15)
p-value		0.895

Analysis performed using mixed model repeated measures with terms for treatment group, baseline prednisolone/prednisone daily dose, baseline BVAS score, region, visit,visit by baseline BVAS and visit by treatment group.

PPD

Protocol: MEA115921
Population: Intent-to-Treat

Table 2.73
Analysis of Change from Baseline in ACQ-6

Visit: Weeks 1-4

	Placebo (N=68)	Mepolizumab 300 mg SC (N=68)
n	65	68
LS Mean (SE)	1.31 (0.089)	1.06 (0.089)
LS Mean Change (SE)	-0.09 (0.089)	-0.34 (0.089)
Comparison: Mepolizumab vs. Placebo		
Difference		-0.25
95% Confidence Interval		(-0.43,-0.06)
p-value		0.008

Note: Analysis performed using mixed model repeated measures with terms for treatment group, baseline prednisolone/prednisone daily dose, baseline BVAS score, region, baseline ACQ-6, visit, visit by baseline ACQ-6 and visit by treatment group.

PPD

Protocol: MEA115921
Population: Intent-to-Treat

Table 2.73
Analysis of Change from Baseline in ACQ-6

Visit: Weeks 5-8

	Placebo (N=68)	Mepolizumab 300 mg SC (N=68)
n	68	67
LS Mean (SE)	1.26 (0.097)	0.96 (0.098)
LS Mean Change (SE)	-0.14 (0.097)	-0.44 (0.098)
Comparison: Mepolizumab vs. Placebo		
Difference		-0.30
95% Confidence Interval		(-0.51,-0.09)
p-value		0.005

Note: Analysis performed using mixed model repeated measures with terms for treatment group, baseline prednisolone/prednisone daily dose, baseline BVAS score, region, baseline ACQ-6, visit, visit by baseline ACQ-6 and visit by treatment group.

PPD

Protocol: MEA115921
Population: Intent-to-Treat

Table 2.73
Analysis of Change from Baseline in ACQ-6

Visit: Weeks 9-12

	Placebo (N=68)	Mepolizumab 300 mg SC (N=68)
n	66	68
LS Mean (SE)	1.38 (0.101)	0.84 (0.101)
LS Mean Change (SE)	-0.02 (0.101)	-0.57 (0.101)
Comparison: Mepolizumab vs. Placebo		
Difference		-0.55
95% Confidence Interval		(-0.77,-0.32)
p-value		<0.001

Note: Analysis performed using mixed model repeated measures with terms for treatment group, baseline prednisolone/prednisone daily dose, baseline BVAS score, region, baseline ACQ-6, visit, visit by baseline ACQ-6 and visit by treatment group.

PPD

Protocol: MEA115921
Population: Intent-to-Treat

Table 2.73
Analysis of Change from Baseline in ACQ-6

Visit: Weeks 13-16

	Placebo (N=68)	Mepolizumab 300 mg SC (N=68)
n	65	66
LS Mean (SE)	1.25 (0.102)	0.87 (0.102)
LS Mean Change (SE)	-0.15 (0.102)	-0.53 (0.102)
Comparison: Mepolizumab vs. Placebo		
Difference		-0.38
95% Confidence Interval		(-0.61,-0.16)
p-value		0.001

Note: Analysis performed using mixed model repeated measures with terms for treatment group, baseline prednisolone/prednisone daily dose, baseline BVAS score, region, baseline ACQ-6, visit, visit by baseline ACQ-6 and visit by treatment group.

PPD

Protocol: MEA115921
Population: Intent-to-Treat

Table 2.73
Analysis of Change from Baseline in ACQ-6

Visit: Weeks 17-20

	Placebo (N=68)	Mepolizumab 300 mg SC (N=68)
n	65	68
LS Mean (SE)	1.26 (0.098)	0.87 (0.098)
LS Mean Change (SE)	-0.14 (0.098)	-0.53 (0.098)
Comparison: Mepolizumab vs. Placebo		
Difference		-0.39
95% Confidence Interval		(-0.61,-0.18)
p-value		<0.001

Note: Analysis performed using mixed model repeated measures with terms for treatment group, baseline prednisolone/prednisone daily dose, baseline BVAS score, region, baseline ACQ-6, visit, visit by baseline ACQ-6 and visit by treatment group.

PPD

Protocol: MEA115921
Population: Intent-to-Treat

Table 2.73
Analysis of Change from Baseline in ACQ-6

Visit: Weeks 21-24

	Placebo (N=68)	Mepolizumab 300 mg SC (N=68)
n	63	66
LS Mean (SE)	1.24 (0.106)	0.87 (0.105)
LS Mean Change (SE)	-0.16 (0.106)	-0.53 (0.105)
Comparison: Mepolizumab vs. Placebo		
Difference		-0.37
95% Confidence Interval		(-0.61,-0.13)
p-value		0.003

Note: Analysis performed using mixed model repeated measures with terms for treatment group, baseline prednisolone/prednisone daily dose, baseline BVAS score, region, baseline ACQ-6, visit, visit by baseline ACQ-6 and visit by treatment group.

PPD

Protocol: MEA115921
Population: Intent-to-Treat

Table 2.73
Analysis of Change from Baseline in ACQ-6

Visit: Weeks 25-28

	Placebo (N=68)	Mepolizumab 300 mg SC (N=68)
n	63	67
LS Mean (SE)	1.43 (0.115)	0.93 (0.114)
LS Mean Change (SE)	0.03 (0.115)	-0.47 (0.114)
Comparison: Mepolizumab vs. Placebo		
Difference		-0.49
95% Confidence Interval		(-0.76,-0.22)
p-value		<0.001

Note: Analysis performed using mixed model repeated measures with terms for treatment group, baseline prednisolone/prednisone daily dose, baseline BVAS score, region, baseline ACQ-6, visit, visit by baseline ACQ-6 and visit by treatment group.

PPD

Protocol: MEA115921
Population: Intent-to-Treat

Table 2.73
Analysis of Change from Baseline in ACQ-6

Visit: Weeks 29-32

	Placebo (N=68)	Mepolizumab 300 mg SC (N=68)
n	62	66
LS Mean (SE)	1.26 (0.109)	0.92 (0.108)
LS Mean Change (SE)	-0.14 (0.109)	-0.48 (0.108)
Comparison: Mepolizumab vs. Placebo		
Difference		-0.33
95% Confidence Interval		(-0.58,-0.08)
p-value		0.009

Note: Analysis performed using mixed model repeated measures with terms for treatment group, baseline prednisolone/prednisone daily dose, baseline BVAS score, region, baseline ACQ-6, visit, visit by baseline ACQ-6 and visit by treatment group.

PPD

Protocol: MEA115921
Population: Intent-to-Treat

Table 2.73
Analysis of Change from Baseline in ACQ-6

Visit: Weeks 33-36

	Placebo (N=68)	Mepolizumab 300 mg SC (N=68)
n	61	64
LS Mean (SE)	1.23 (0.106)	0.88 (0.105)
LS Mean Change (SE)	-0.17 (0.106)	-0.52 (0.105)
Comparison: Mepolizumab vs. Placebo		
Difference		-0.35
95% Confidence Interval		(-0.59,-0.11)
p-value		0.005

Note: Analysis performed using mixed model repeated measures with terms for treatment group, baseline prednisolone/prednisone daily dose, baseline BVAS score, region, baseline ACQ-6, visit, visit by baseline ACQ-6 and visit by treatment group.

PPD

Protocol: MEA115921
Population: Intent-to-Treat

Table 2.73
Analysis of Change from Baseline in ACQ-6

Visit: Weeks 37-40

	Placebo (N=68)	Mepolizumab 300 mg SC (N=68)
n	54	57
LS Mean (SE)	1.33 (0.114)	0.91 (0.113)
LS Mean Change (SE)	-0.07 (0.114)	-0.49 (0.113)
Comparison: Mepolizumab vs. Placebo		
Difference		-0.42
95% Confidence Interval		(-0.69,-0.15)
p-value		0.002

Note: Analysis performed using mixed model repeated measures with terms for treatment group, baseline prednisolone/prednisone daily dose, baseline BVAS score, region, baseline ACQ-6, visit, visit by baseline ACQ-6 and visit by treatment group.

PPD

Protocol: MEA115921
Population: Intent-to-Treat

Table 2.73
Analysis of Change from Baseline in ACQ-6

Visit: Weeks 41-44

	Placebo (N=68)	Mepolizumab 300 mg SC (N=68)
n	53	55
LS Mean (SE)	1.30 (0.121)	0.97 (0.120)
LS Mean Change (SE)	-0.10 (0.121)	-0.43 (0.120)
Comparison: Mepolizumab vs. Placebo		
Difference		-0.32
95% Confidence Interval		(-0.61,-0.03)
p-value		0.029

Note: Analysis performed using mixed model repeated measures with terms for treatment group, baseline prednisolone/prednisone daily dose, baseline BVAS score, region, baseline ACQ-6, visit, visit by baseline ACQ-6 and visit by treatment group.

PPD

Protocol: MEA115921
Population: Intent-to-Treat

Table 2.73
Analysis of Change from Baseline in ACQ-6

Visit: Weeks 45-48

	Placebo (N=68)	Mepolizumab 300 mg SC (N=68)
n	50	52
LS Mean (SE)	1.21 (0.122)	1.00 (0.121)
LS Mean Change (SE)	-0.19 (0.122)	-0.40 (0.121)
Comparison: Mepolizumab vs. Placebo		
Difference		-0.21
95% Confidence Interval		(-0.50,0.08)
p-value		0.157

Note: Analysis performed using mixed model repeated measures with terms for treatment group, baseline prednisolone/prednisone daily dose, baseline BVAS score, region, baseline ACQ-6, visit, visit by baseline ACQ-6 and visit by treatment group.

PPD

Protocol: MEA115921
Population: Intent-to-Treat

Table 2.73
Analysis of Change from Baseline in ACQ-6

Visit: Weeks 49-52

	Placebo (N=68)	Mepolizumab 300 mg SC (N=68)
n	47	49
LS Mean (SE)	1.23 (0.110)	0.93 (0.110)
LS Mean Change (SE)	-0.17 (0.110)	-0.47 (0.110)
Comparison: Mepolizumab vs. Placebo		
Difference		-0.30
95% Confidence Interval		(-0.55,-0.04)
p-value		0.024

Note: Analysis performed using mixed model repeated measures with terms for treatment group, baseline prednisolone/prednisone daily dose, baseline BVAS score, region, baseline ACQ-6, visit, visit by baseline ACQ-6 and visit by treatment group.

PPD

Protocol: MEA115921
Population: Intent-to-Treat

Table 2.80
Summary of SNOT-22 Questionnaire Data at Each Visit

Time Point			Placebo (N=68)	Mepolizumab 300 mg SC (N=68)
Baseline	SNOT-22	n	68	68
		Mean	33.57	34.82
		SD	19.025	20.973
		Median	30.00	33.00
		Min.	3.0	1.0
		Max.	82.0	93.0
Week 12	SNOT-22	n	67	68
		Mean	31.89	26.71
		SD	18.188	17.443
		Median	32.00	24.50
		Min.	3.0	0.0
		Max.	79.0	66.0
	SNOT-22 Change from Baseline	n	67	68
		Mean	-1.54	-8.12
		SD	14.361	17.393
		Median	-2.00	-7.50
		Min.	-46.0	-80.0
		Max.	47.4	36.0

PPD

Protocol: MEA115921
Population: Intent-to-Treat

Table 2.80
Summary of SNOT-22 Questionnaire Data at Each Visit

Time Point			Placebo (N=68)	Mepolizumab 300 mg SC (N=68)
Week 24	SNOT-22	n	64	67
		Mean	32.78	27.69
		SD	17.599	17.648
		Median	30.00	25.00
		Min.	0.0	1.0
		Max.	81.0	69.0
	SNOT-22 Change from Baseline	n	64	67
		Mean	-1.15	-7.06
		SD	15.042	18.067
		Median	1.00	-7.00
		Min.	-39.0	-59.0
		Max.	43.0	49.0
Week 36	SNOT-22	n	62	67
		Mean	35.00	31.73
		SD	20.250	17.849
		Median	33.00	30.00
		Min.	2.0	0.0
		Max.	77.0	65.0
	SNOT-22 Change from Baseline	n	62	67
		Mean	0.39	-3.36
		SD	12.282	16.292
		Median	1.00	-2.00
		Min.	-27.0	-44.0
		Max.	31.0	27.0

PPD

Protocol: MEA115921
Population: Intent-to-Treat

Table 2.80
Summary of SNOT-22 Questionnaire Data at Each Visit

Time Point			Placebo (N=68)	Mepolizumab 300 mg SC (N=68)
Week 52	SNOT-22	n	61	65
		Mean	34.21	29.29
		SD	19.678	18.238
		Median	33.00	25.00
		Min.	0.0	1.0
		Max.	78.0	70.0
	SNOT-22 Change from Baseline	n	61	65
		Mean	-0.26	-4.85
		SD	13.413	17.353
		Median	0.00	-3.00
		Min.	-42.0	-45.0
		Max.	28.0	39.0

PPD

Protocol: MEA115921
Population: Intent-to-Treat

Table 2.81
Analysis of Change from Baseline in SNOT-22 Questionnaire Data

Visit: Week 12

	Placebo (N=68)	Mepolizumab 300 mg SC (N=68)
n	68	68
LS Mean (SE)	29.76 (2.128)	24.09 (2.115)
LS Mean Change (SE)	-4.65 (2.128)	-10.32 (2.115)
Comparison: Mepolizumab vs. Placebo		
Difference		-5.67
95% Confidence Interval		(-10.30,-1.03)
p-value		0.017

Note: Analysis performed using mixed model repeated measures with terms for treatment group,baseline prednisolone/prednisone daily dose, baseline BVAS score, region, baseline SNOT-22, visit, visit by baseline SNOT-22 and visit by treatment group.

PPD

Protocol: MEA115921
Population: Intent-to-Treat

Table 2.81
Analysis of Change from Baseline in SNOT-22 Questionnaire Data

Visit: Week 24

	Placebo (N=68)	Mepolizumab 300 mg SC (N=68)
n	68	68
LS Mean (SE)	30.50 (2.169)	25.14 (2.143)
LS Mean Change (SE)	-3.91 (2.169)	-9.27 (2.143)
Comparison: Mepolizumab vs. Placebo		
Difference		-5.36
95% Confidence Interval		(-10.13,-0.59)
p-value		0.028

Note: Analysis performed using mixed model repeated measures with terms for treatment group,baseline prednisolone/prednisone daily dose, baseline BVAS score, region, baseline SNOT-22, visit, visit by baseline SNOT-22 and visit by treatment group.

PPD

Protocol: MEA115921
Population: Intent-to-Treat

Table 2.81
Analysis of Change from Baseline in SNOT-22 Questionnaire Data

Visit: Week 36

	Placebo (N=68)	Mepolizumab 300 mg SC (N=68)
n	68	68
LS Mean (SE)	32.66 (2.089)	28.79 (2.058)
LS Mean Change (SE)	-1.75 (2.089)	-5.62 (2.058)
Comparison: Mepolizumab vs. Placebo		
Difference		-3.87
95% Confidence Interval		(-8.35,0.61)
p-value		0.090

Note: Analysis performed using mixed model repeated measures with terms for treatment group,baseline prednisolone/prednisone daily dose, baseline BVAS score, region, baseline SNOT-22, visit, visit by baseline SNOT-22 and visit by treatment group.

PPD

Protocol: MEA115921
Population: Intent-to-Treat

Table 2.81
Analysis of Change from Baseline in SNOT-22 Questionnaire Data

Visit: Week 52

	Placebo (N=68)	Mepolizumab 300 mg SC (N=68)
n	68	68
LS Mean (SE)	31.60 (2.185)	26.93 (2.152)
LS Mean Change (SE)	-2.81 (2.185)	-7.48 (2.152)
Comparison: Mepolizumab vs. Placebo		
Difference		-4.68
95% Confidence Interval		(-9.50,0.15)
p-value		0.057

Note: Analysis performed using mixed model repeated measures with terms for treatment group,baseline prednisolone/prednisone daily dose, baseline BVAS score, region, baseline SNOT-22, visit, visit by baseline SNOT-22 and visit by treatment group.

PPD

Protocol: MEA115921
Population: Intent-to-Treat

Table 2.91
Analysis of Change from Baseline in SNOT-22 Domain Scores: Nasal
(Mixed Model Repeated Measures)

Visit: Week 12

	Placebo (N=68)	Mepolizumab 300 mg SC (N=68)
n [1]	68	68
n [2]	67	68
LS Mean (SE)	11.75 (0.699)	9.90 (0.694)
LS Mean Change (SE)	-0.07 (0.699)	-1.92 (0.694)
Mepolizumab 300 mg SC vs Placebo		
Difference (Mepo - Placebo)		-1.85
95% CI		(-3.80, 0.10)
p-value		0.063
Corrected Hedges g [3]		-0.32
95% CI		(-0.66, 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] Derived from LS means and associated SE.
Note: Analysis performed using mixed model repeated measures with covariates of baseline SNOT-22, baseline prednisolone/prednisone daily dose, baseline BVAS score, region (EU vs. RoW), treatment and visit, plus interaction terms for visit-by-baseline and visit-by-treatment group. LS mean estimates are weighted according to the observed proportion of each categorical covariate in the study data.
PPD

Population: Intent-to-Treat

Table 2.91
Analysis of Change from Baseline in SNOT-22 Domain Scores: Nasal
(Mixed Model Repeated Measures)

Visit: Week 24

	Placebo (N=68)	Mepolizumab 300 mg SC (N=68)
n [1]	68	68
n [2]	64	67
LS Mean (SE)	12.52 (0.770)	10.79 (0.755)
LS Mean Change (SE)	0.70 (0.770)	-1.03 (0.755)
Mepolizumab 300 mg SC vs Placebo		
Difference (Mepo - Placebo)		-1.73
95% CI		(-3.86, 0.41)
p-value		0.111
Corrected Hedges g [3]		-0.28
95% CI		(-0.62, 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] Derived from LS means and associated SE.
Note: Analysis performed using mixed model repeated measures with covariates of baseline SNOT-22, baseline prednisolone/prednisone daily dose, baseline BVAS score, region (EU vs. RoW), treatment and visit, plus interaction terms for visit-by-baseline and visit-by-treatment group. LS mean estimates are weighted according to the observed proportion of each categorical covariate in the study data.

Population: Intent-to-Treat

Table 2.91
Analysis of Change from Baseline in SNOT-22 Domain Scores: Nasal
(Mixed Model Repeated Measures)

Visit: Week 36

	Placebo (N=68)	Mepolizumab 300 mg SC (N=68)
n [1]	68	68
n [2]	62	67
LS Mean (SE)	13.60 (0.744)	11.46 (0.720)
LS Mean Change (SE)	1.78 (0.744)	-0.36 (0.720)
Mepolizumab 300 mg SC vs Placebo		
Difference (Mepo - Placebo)		-2.14
95% CI		(-4.19, -0.09)
p-value		0.041
Corrected Hedges g [3]		-0.36
95% CI		(-0.71, -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] Derived from LS means and associated SE.
Note: Analysis performed using mixed model repeated measures with covariates of baseline SNOT-22, baseline prednisolone/prednisone daily dose, baseline BVAS score, region (EU vs. RoW), treatment and visit, plus interaction terms for visit-by-baseline and visit-by-treatment group. LS mean estimates are weighted according to the observed proportion of each categorical covariate in the study data.
PPD

Population: Intent-to-Treat

Table 2.91
Analysis of Change from Baseline in SNOT-22 Domain Scores: Nasal
(Mixed Model Repeated Measures)

Visit: Week 52

	Placebo (N=68)	Mepolizumab 300 mg SC (N=68)
n [1]	68	68
n [2]	61	65
LS Mean (SE)	13.08 (0.762)	10.77 (0.740)
LS Mean Change (SE)	1.26 (0.762)	-1.05 (0.740)
Mepolizumab 300 mg SC vs Placebo		
Difference (Mepo - Placebo)		-2.31
95% CI		(-4.41, -0.21)
p-value		0.032
Corrected Hedges g [3]		-0.39
95% CI		(-0.74, -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] Derived from LS means and associated SE.
Note: Analysis performed using mixed model repeated measures with covariates of baseline SNOT-22, baseline prednisolone/prednisone daily dose, baseline BVAS score, region (EU vs. RoW), treatment and visit, plus interaction terms for visit-by-baseline and visit-by-treatment group. LS mean estimates are weighted according to the observed proportion of each categorical covariate in the study data.

Population: Intent-to-Treat

Table 2.92
Analysis of Change from Baseline in SNOT-22 Domain Scores: Ear
(Mixed Model Repeated Measures)

Visit: Week 12

	Placebo (N=68)	Mepolizumab 300 mg SC (N=68)
n [1]	68	68
n [2]	67	68
LS Mean (SE)	2.75 (0.306)	2.09 (0.304)
LS Mean Change (SE)	0.14 (0.306)	-0.52 (0.304)
Mepolizumab 300 mg SC vs Placebo		
Difference (Mepo - Placebo)		-0.66
95% CI		(-1.51, 0.19)
p-value		0.129
Corrected Hedges g [3]		-0.26
95% CI		(-0.60, 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] Derived from LS means and associated SE.
Note: Analysis performed using mixed model repeated measures with covariates of baseline SNOT-22, baseline prednisolone/prednisone daily dose, baseline BVAS score, region (EU vs. RoW), treatment and visit, plus interaction terms for visit-by-baseline and visit-by-treatment group. LS mean estimates are weighted according to the observed proportion of each categorical covariate in the study data.

Table 2.92
Analysis of Change from Baseline in SNOT-22 Domain Scores: Ear
(Mixed Model Repeated Measures)

Visit: Week 24

	Placebo (N=68)	Mepolizumab 300 mg SC (N=68)
n [1]	68	68
n [2]	64	67
LS Mean (SE)	2.89 (0.309)	1.88 (0.303)
LS Mean Change (SE)	0.29 (0.309)	-0.72 (0.303)
Mepolizumab 300 mg SC vs Placebo		
Difference (Mepo - Placebo)		-1.01
95% CI		(-1.87, -0.15)
p-value		0.021
Corrected Hedges g [3]		-0.41
95% CI		(-0.75, -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] Derived from LS means and associated SE.
Note: Analysis performed using mixed model repeated measures with covariates of baseline SNOT-22, baseline prednisolone/prednisone daily dose, baseline BVAS score, region (EU vs. RoW), treatment and visit, plus interaction terms for visit-by-baseline and visit-by-treatment group. LS mean estimates are weighted according to the observed proportion of each categorical covariate in the study data.

Protocol: MEA115921
Population: Intent-to-Treat

Table 2.92
Analysis of Change from Baseline in SNOT-22 Domain Scores: Ear
(Mixed Model Repeated Measures)

Visit: Week 36

	Placebo (N=68)	Mepolizumab 300 mg SC (N=68)
n [1]	68	68
n [2]	62	67
LS Mean (SE)	3.42 (0.349)	2.12 (0.337)
LS Mean Change (SE)	0.82 (0.349)	-0.48 (0.337)
Mepolizumab 300 mg SC vs Placebo		
Difference (Mepo - Placebo)		-1.30
95% CI		(-2.26, -0.34)
p-value		0.008
Corrected Hedges g [3]		-0.47
95% CI		(-0.82, -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] Derived from LS means and associated SE.
Note: Analysis performed using mixed model repeated measures with covariates of baseline SNOT-22, baseline prednisolone/prednisone daily dose, baseline BVAS score, region (EU vs. RoW), treatment and visit, plus interaction terms for visit-by-baseline and visit-by-treatment group. LS mean estimates are weighted according to the observed proportion of each categorical covariate in the study data.
PPD

Table 2.92
Analysis of Change from Baseline in SNOT-22 Domain Scores: Ear
(Mixed Model Repeated Measures)

Visit: Week 52

	Placebo (N=68)	Mepolizumab 300 mg SC (N=68)
n [1]	68	68
n [2]	61	65
LS Mean (SE)	2.67 (0.292)	2.03 (0.284)
LS Mean Change (SE)	0.07 (0.292)	-0.57 (0.284)
Mepolizumab 300 mg SC vs Placebo		
Difference (Mepo - Placebo)		-0.64
95% CI		(-1.45, 0.17)
p-value		0.118
Corrected Hedges g [3]		-0.28
95% CI		(-0.63, 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] Derived from LS means and associated SE.
Note: Analysis performed using mixed model repeated measures with covariates of baseline SNOT-22, baseline prednisolone/prednisone daily dose, baseline BVAS score, region (EU vs. RoW), treatment and visit, plus interaction terms for visit-by-baseline and visit-by-treatment group. LS mean estimates are weighted according to the observed proportion of each categorical covariate in the study data.

Protocol: MEA115921
Population: Intent-to-Treat

Table 2.93
Analysis of Change from Baseline in SNOT-22 Domain Scores: Sleep
(Mixed Model Repeated Measures)

Visit: Week 12

	Placebo (N=68)	Mepolizumab 300 mg SC (N=68)
n [1]	68	68
n [2]	67	68
LS Mean (SE)	6.93 (0.407)	5.72 (0.404)
LS Mean Change (SE)	-0.70 (0.407)	-1.91 (0.404)
Mepolizumab 300 mg SC vs Placebo		
Difference (Mepo - Placebo)		-1.21
95% CI		(-2.35, -0.08)
p-value		0.036
Corrected Hedges g [3]		-0.36
95% CI		(-0.70, -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] Derived from LS means and associated SE.
Note: Analysis performed using mixed model repeated measures with covariates of baseline SNOT-22, baseline prednisolone/prednisone daily dose, baseline BVAS score, region (EU vs. RoW), treatment and visit, plus interaction terms for visit-by-baseline and visit-by-treatment group. LS mean estimates are weighted according to the observed proportion of each categorical covariate in the study data.
PPD

Protocol: MEA115921
Population: Intent-to-Treat

Table 2.93
Analysis of Change from Baseline in SNOT-22 Domain Scores: Sleep
(Mixed Model Repeated Measures)

Visit: Week 24

	Placebo (N=68)	Mepolizumab 300 mg SC (N=68)
n [1]	68	68
n [2]	64	67
LS Mean (SE)	6.84 (0.477)	5.46 (0.467)
LS Mean Change (SE)	-0.78 (0.477)	-2.17 (0.467)
Mepolizumab 300 mg SC vs Placebo		
Difference (Mepo - Placebo)		-1.39
95% CI		(-2.71, -0.07)
p-value		0.040
Corrected Hedges g [3]		-0.36
95% CI		(-0.71, -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] Derived from LS means and associated SE.
Note: Analysis performed using mixed model repeated measures with covariates of baseline SNOT-22, baseline prednisolone/prednisone daily dose, baseline BVAS score, region (EU vs. RoW), treatment and visit, plus interaction terms for visit-by-baseline and visit-by-treatment group. LS mean estimates are weighted according to the observed proportion of each categorical covariate in the study data.
PPD

Protocol: MEA115921
Population: Intent-to-Treat

Table 2.93
Analysis of Change from Baseline in SNOT-22 Domain Scores: Sleep
(Mixed Model Repeated Measures)

Visit: Week 36

	Placebo (N=68)	Mepolizumab 300 mg SC (N=68)
n [1]	68	68
n [2]	62	67
LS Mean (SE)	6.76 (0.470)	6.90 (0.456)
LS Mean Change (SE)	-0.87 (0.470)	-0.73 (0.456)
Mepolizumab 300 mg SC vs Placebo		
Difference (Mepo - Placebo)		0.14
95% CI		(-1.15, 1.44)
p-value		0.827
Corrected Hedges g [3]		0.04
95% CI		(-0.31, 0.38)

[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] Derived from LS means and associated SE.
Note: Analysis performed using mixed model repeated measures with covariates of baseline SNOT-22, baseline prednisolone/prednisone daily dose, baseline BVAS score, region (EU vs. RoW), treatment and visit, plus interaction terms for visit-by-baseline and visit-by-treatment group. LS mean estimates are weighted according to the observed proportion of each categorical covariate in the study data.

Table 2.93
Analysis of Change from Baseline in SNOT-22 Domain Scores: Sleep
(Mixed Model Repeated Measures)

Visit: Week 52

	Placebo (N=68)	Mepolizumab 300 mg SC (N=68)
n [1]	68	68
n [2]	61	65
LS Mean (SE)	7.21 (0.502)	6.28 (0.487)
LS Mean Change (SE)	-0.42 (0.502)	-1.34 (0.487)
Mepolizumab 300 mg SC vs Placebo		
Difference (Mepo - Placebo)		-0.93
95% CI		(-2.31, 0.46)
p-value		0.188
Corrected Hedges g [3]		-0.23
95% CI		(-0.59, 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] Derived from LS means and associated SE.
Note: Analysis performed using mixed model repeated measures with covariates of baseline SNOT-22, baseline prednisolone/prednisone daily dose, baseline BVAS score, region (EU vs. RoW), treatment and visit, plus interaction terms for visit-by-baseline and visit-by-treatment group. LS mean estimates are weighted according to the observed proportion of each categorical covariate in the study data.

Protocol: MEA115921
Population: Intent-to-Treat

Table 2.94
Analysis of Change from Baseline in SNOT-22 Domain Scores: General Symptoms
(Mixed Model Repeated Measures)

Visit: Week 12

	Placebo (N=68)	Mepolizumab 300 mg SC (N=68)
n [1]	68	68
n [2]	67	68
LS Mean (SE)	8.03 (0.450)	6.43 (0.447)
LS Mean Change (SE)	-0.99 (0.450)	-2.59 (0.447)
Mepolizumab 300 mg SC vs Placebo		
Difference (Mepo - Placebo)		-1.60
95% CI		(-2.85, -0.34)
p-value		0.013
Corrected Hedges g [3]		-0.43
95% CI		(-0.77, -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] Derived from LS means and associated SE.
Note: Analysis performed using mixed model repeated measures with covariates of baseline SNOT-22, baseline prednisolone/prednisone daily dose, baseline BVAS score, region (EU vs. RoW), treatment and visit, plus interaction terms for visit-by-baseline and visit-by-treatment group. LS mean estimates are weighted according to the observed proportion of each categorical covariate in the study data.
PPD

Population: Intent-to-Treat

Table 2.94
Analysis of Change from Baseline in SNOT-22 Domain Scores: General Symptoms
(Mixed Model Repeated Measures)

Visit: Week 24

	Placebo (N=68)	Mepolizumab 300 mg SC (N=68)
n [1]	68	68
n [2]	64	67
LS Mean (SE)	7.97 (0.488)	6.95 (0.479)
LS Mean Change (SE)	-1.05 (0.488)	-2.07 (0.479)
Mepolizumab 300 mg SC vs Placebo		
Difference (Mepo - Placebo)		-1.02
95% CI		(-2.38, 0.33)
p-value		0.138
Corrected Hedges g [3]		-0.26
95% CI		(-0.60, 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] Derived from LS means and associated SE.
Note: Analysis performed using mixed model repeated measures with covariates of baseline SNOT-22, baseline prednisolone/prednisone daily dose, baseline BVAS score, region (EU vs. RoW), treatment and visit, plus interaction terms for visit-by-baseline and visit-by-treatment group. LS mean estimates are weighted according to the observed proportion of each categorical covariate in the study data.

Protocol: MEA115921
Population: Intent-to-Treat

Table 2.94
Analysis of Change from Baseline in SNOT-22 Domain Scores: General Symptoms
(Mixed Model Repeated Measures)

Visit: Week 36

	Placebo (N=68)	Mepolizumab 300 mg SC (N=68)
n [1]	68	68
n [2]	62	67
LS Mean (SE)	8.23 (0.427)	7.80 (0.415)
LS Mean Change (SE)	-0.79 (0.427)	-1.22 (0.415)
Mepolizumab 300 mg SC vs Placebo		
Difference (Mepo - Placebo)		-0.43
95% CI		(-1.60, 0.75)
p-value		0.475
Corrected Hedges g [3]		-0.13
95% CI		(-0.47, 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] Derived from LS means and associated SE.
Note: Analysis performed using mixed model repeated measures with covariates of baseline SNOT-22, baseline prednisolone/prednisone daily dose, baseline BVAS score, region (EU vs. RoW), treatment and visit, plus interaction terms for visit-by-baseline and visit-by-treatment group. LS mean estimates are weighted according to the observed proportion of each categorical covariate in the study data.
PPD

Population: Intent-to-Treat

Table 2.94
Analysis of Change from Baseline in SNOT-22 Domain Scores: General Symptoms
(Mixed Model Repeated Measures)

Visit: Week 52

	Placebo (N=68)	Mepolizumab 300 mg SC (N=68)
n [1]	68	68
n [2]	61	65
LS Mean (SE)	8.37 (0.486)	7.52 (0.472)
LS Mean Change (SE)	-0.65 (0.486)	-1.50 (0.472)
Mepolizumab 300 mg SC vs Placebo		
Difference (Mepo - Placebo)		-0.85
95% CI		(-2.19, 0.50)
p-value		0.215
Corrected Hedges g [3]		-0.22
95% CI		(-0.57, 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] Derived from LS means and associated SE.
Note: Analysis performed using mixed model repeated measures with covariates of baseline SNOT-22, baseline prednisolone/prednisone daily dose, baseline BVAS score, region (EU vs. RoW), treatment and visit, plus interaction terms for visit-by-baseline and visit-by-treatment group. LS mean estimates are weighted according to the observed proportion of each categorical covariate in the study data.

Protocol: MEA115921
Population: Intent-to-Treat

Table 2.95
Analysis of Change from Baseline in SNOT-22 Domain Scores: Emotional Consequences
(Mixed Model Repeated Measures)

Visit: Week 12

	Placebo (N=68)	Mepolizumab 300 mg SC (N=68)
n [1]	68	68
n [2]	67	68
LS Mean (SE)	2.63 (0.269)	2.39 (0.267)
LS Mean Change (SE)	-0.70 (0.269)	-0.94 (0.267)
Mepolizumab 300 mg SC vs Placebo		
Difference (Mepo - Placebo)		-0.24
95% CI		(-0.99, 0.51)
p-value		0.534
Corrected Hedges g [3]		-0.11
95% CI		(-0.44, 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] Derived from LS means and associated SE.
Note: Analysis performed using mixed model repeated measures with covariates of baseline SNOT-22, baseline prednisolone/prednisone daily dose, baseline BVAS score, region (EU vs. RoW), treatment and visit, plus interaction terms for visit-by-baseline and visit-by-treatment group. LS mean estimates are weighted according to the observed proportion of each categorical covariate in the study data.
PPD

Population: Intent-to-Treat

Table 2.95
Analysis of Change from Baseline in SNOT-22 Domain Scores: Emotional Consequences
(Mixed Model Repeated Measures)

Visit: Week 24

	Placebo (N=68)	Mepolizumab 300 mg SC (N=68)
n [1]	68	68
n [2]	64	67
LS Mean (SE)	2.69 (0.259)	2.56 (0.254)
LS Mean Change (SE)	-0.65 (0.259)	-0.77 (0.254)
Mepolizumab 300 mg SC vs Placebo		
Difference (Mepo - Placebo)		-0.12
95% CI		(-0.84, 0.59)
p-value		0.732
Corrected Hedges g [3]		-0.06
95% CI		(-0.40, 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] Derived from LS means and associated SE.
Note: Analysis performed using mixed model repeated measures with covariates of baseline SNOT-22, baseline prednisolone/prednisone daily dose, baseline BVAS score, region (EU vs. RoW), treatment and visit, plus interaction terms for visit-by-baseline and visit-by-treatment group. LS mean estimates are weighted according to the observed proportion of each categorical covariate in the study data.
PPD

Protocol: MEA115921
Population: Intent-to-Treat

Table 2.95
Analysis of Change from Baseline in SNOT-22 Domain Scores: Emotional Consequences
(Mixed Model Repeated Measures)

Visit: Week 36

	Placebo (N=68)	Mepolizumab 300 mg SC (N=68)
n [1]	68	68
n [2]	62	67
LS Mean (SE)	2.94 (0.311)	2.98 (0.301)
LS Mean Change (SE)	-0.39 (0.311)	-0.35 (0.301)
Mepolizumab 300 mg SC vs Placebo		
Difference (Mepo - Placebo)		0.04
95% CI		(-0.82, 0.89)
p-value		0.930
Corrected Hedges g [3]		0.02
95% CI		(-0.33, 0.36)

[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] Derived from LS means and associated SE.
Note: Analysis performed using mixed model repeated measures with covariates of baseline SNOT-22, baseline prednisolone/prednisone daily dose, baseline BVAS score, region (EU vs. RoW), treatment and visit, plus interaction terms for visit-by-baseline and visit-by-treatment group. LS mean estimates are weighted according to the observed proportion of each categorical covariate in the study data.
PPD

Population: Intent-to-Treat

Table 2.95
Analysis of Change from Baseline in SNOT-22 Domain Scores: Emotional Consequences
(Mixed Model Repeated Measures)

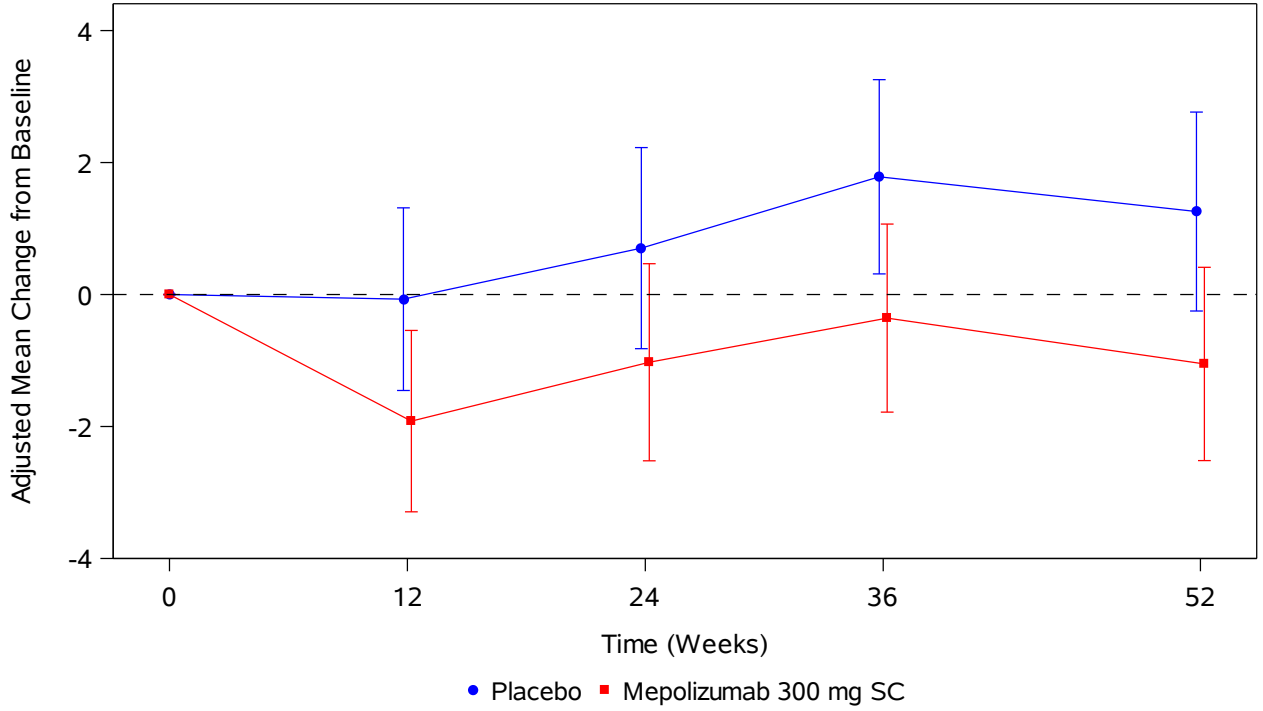
Visit: Week 52

	Placebo (N=68)	Mepolizumab 300 mg SC (N=68)
n [1]	68	68
n [2]	61	65
LS Mean (SE)	2.74 (0.293)	2.71 (0.284)
LS Mean Change (SE)	-0.59 (0.293)	-0.62 (0.284)
Mepolizumab 300 mg SC vs Placebo		
Difference (Mepo - Placebo)		-0.03
95% CI		(-0.84, 0.78)
p-value		0.942
Corrected Hedges g [3]		-0.01
95% CI		(-0.36, 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] Derived from LS means and associated SE.
Note: Analysis performed using mixed model repeated measures with covariates of baseline SNOT-22, baseline prednisolone/prednisone daily dose, baseline BVAS score, region (EU vs. RoW), treatment and visit, plus interaction terms for visit-by-baseline and visit-by-treatment group. LS mean estimates are weighted according to the observed proportion of each categorical covariate in the study data.

Protocol: MEA115921
Population: Intent-to-Treat

Figure 2.2
Change from Baseline in SNOT-22 Domain Scores: Nasal
(Mixed Model Repeated Measures)



Note: Vertical bars represent 95% confidence intervals.

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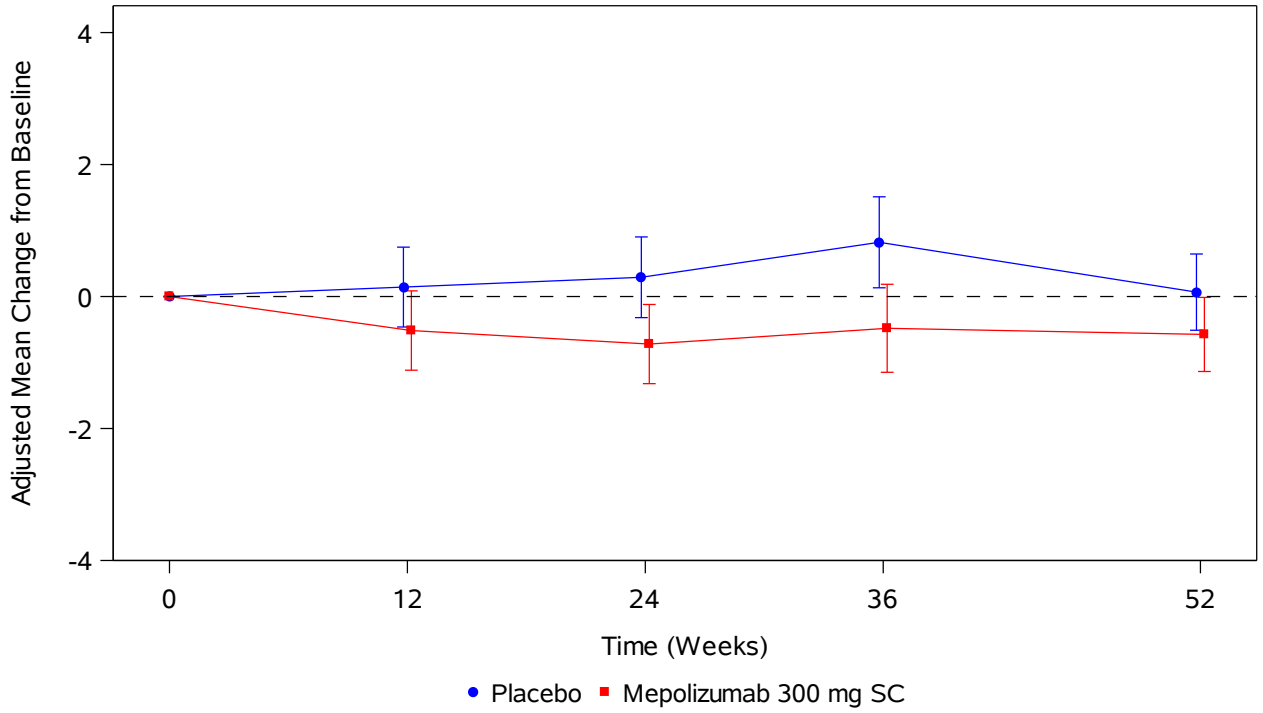
Protocol: MEA115921
Population: Intent-to-Treat

Figure 2.3
Change from Baseline in SNOT-22 Domain Scores: Ear
(Mixed Model Repeated Measures)

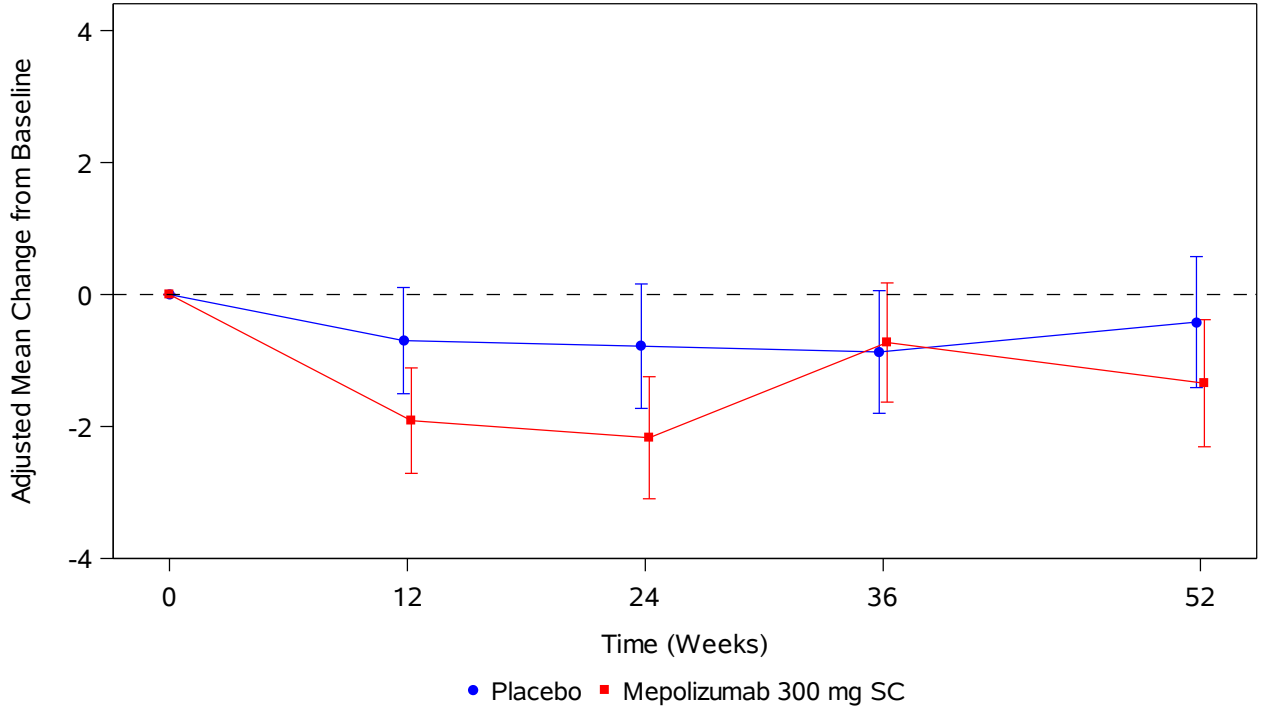


Note: Vertical bars represent 95% confidence intervals.

PPD

Protocol: MEA115921
Population: Intent-to-Treat

Figure 2.4
Change from Baseline in SNOT-22 Domain Scores: Sleep
(Mixed Model Repeated Measures)

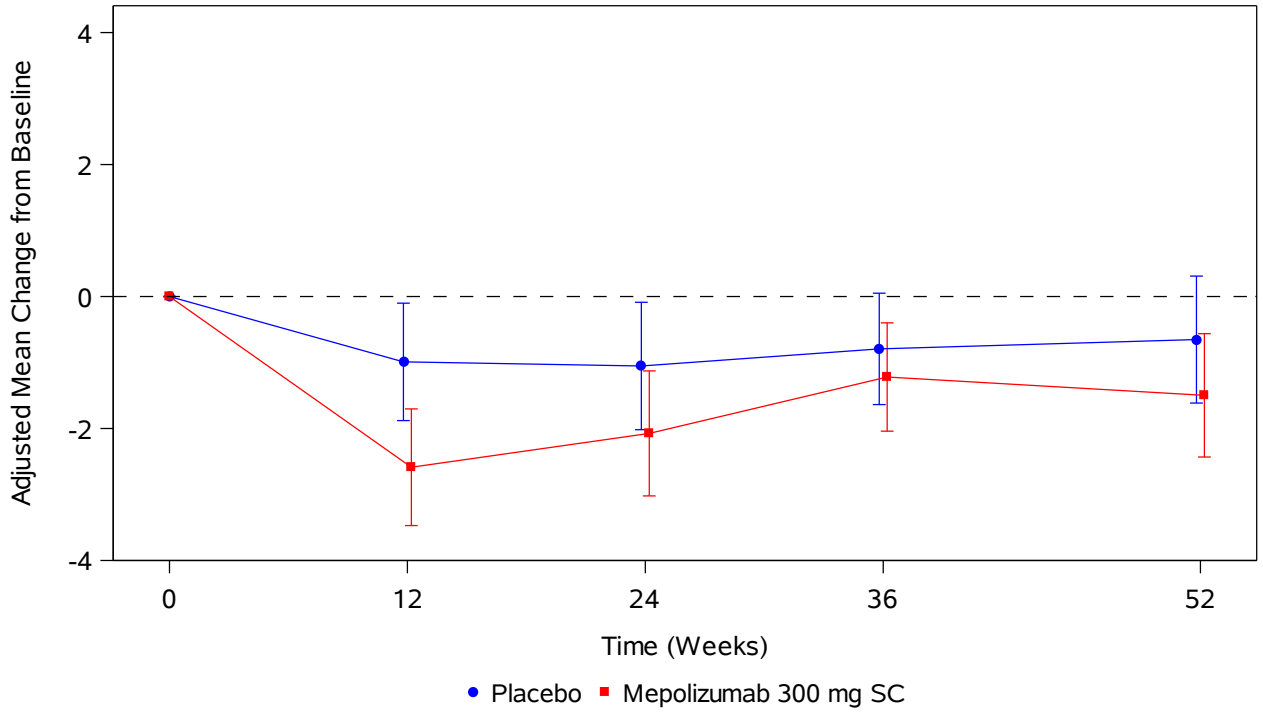


Note: Vertical bars represent 95% confidence intervals.

PPD

Protocol: MEA115921
Population: Intent-to-Treat

Figure 2.5
Change from Baseline in SNOT-22 Domain Scores: General Symptoms
(Mixed Model Repeated Measures)

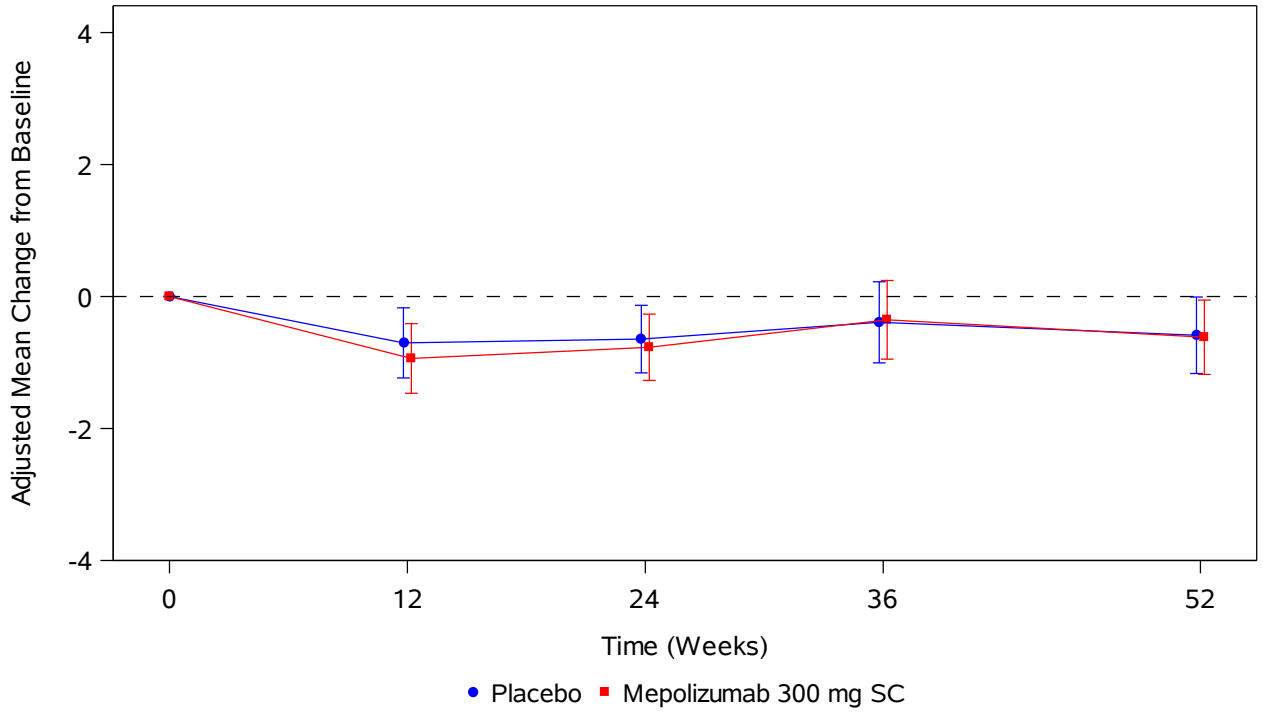


Note: Vertical bars represent 95% confidence intervals.

PPD

Protocol: MEA115921
Population: Intent-to-Treat

Figure 2.6
Change from Baseline in SNOT-22 Domain Scores: Emotional Consequences
(Mixed Model Repeated Measures)



Note: Vertical bars represent 95% confidence intervals.

PPD

Protocol: MEA115921
Population: Intent-to-Treat

Table 2.82
Summary of Sino-Nasal Questionnaire Data

Visit	Question	Responses	Placebo (N=68)		Mepolizumab 300 mg SC (N=68)	
Screening	Blockage/Congestion of Nose	n	64		68	
		None	12	(18%)	5	(7%)
		Mild	20	(29%)	29	(43%)
		Moderate	23	(34%)	20	(29%)
		Severe	5	(7%)	12	(18%)
		Very Severe	4	(6%)	2	(3%)
	Facial Pain/Pressure	n	64		68	
		None	27	(40%)	40	(59%)
		Mild	21	(31%)	12	(18%)
		Moderate	11	(16%)	13	(19%)
		Severe	3	(4%)	3	(4%)
		Very Severe	2	(3%)	0	
	Loss/Reduction of Taste/Smell	n	64		68	
		None	19	(28%)	21	(31%)
		Mild	15	(22%)	22	(32%)
		Moderate	18	(26%)	15	(22%)
		Severe	6	(9%)	5	(7%)
		Very Severe	6	(9%)	5	(7%)

Note: Questionnaire was administered every week. Values summarised are the highest (i.e. worst) responses within each reporting period.

PPD

Protocol: MEA115921
Population: Intent-to-Treat

Table 2.82
Summary of Sino-Nasal Questionnaire Data

Visit	Question	Responses	Placebo (N=68)		Mepolizumab 300 mg SC (N=68)	
Screening	Post-nasal Discharge	n	64		68	
		None	15	(22%)	18	(26%)
		Mild	17	(25%)	23	(34%)
		Moderate	28	(41%)	17	(25%)
		Severe	2	(3%)	9	(13%)
		Very Severe	2	(3%)	1	(1%)
	Runny Nose	n	64		68	
		None	14	(21%)	21	(31%)
		Mild	25	(37%)	25	(37%)
		Moderate	21	(31%)	17	(25%)
		Severe	2	(3%)	4	(6%)
		Very Severe	2	(3%)	1	(1%)
Baseline	Blockage/Congestion of Nose	n	49		50	
		None	14	(21%)	6	(9%)
		Mild	13	(19%)	24	(35%)
		Moderate	11	(16%)	12	(18%)
		Severe	7	(10%)	7	(10%)
		Very Severe	4	(6%)	1	(1%)
	Facial Pain/Pressure	n	49		50	
		None	23	(34%)	34	(50%)
		Mild	14	(21%)	6	(9%)
		Moderate	9	(13%)	10	(15%)
		Severe	1	(1%)	0	
		Very Severe	2	(3%)	0	

Note: Questionnaire was administered every week. Values summarised are the highest (i.e. worst) responses within each reporting period.

PPD

Protocol: MEA115921
Population: Intent-to-Treat

Table 2.82
Summary of Sino-Nasal Questionnaire Data

Visit	Question	Responses	Placebo (N=68)		Mepolizumab 300 mg SC (N=68)	
Baseline	Loss/Reduction of Taste/Smell	n	49		50	
		None	16	(24%)	17	(25%)
		Mild	15	(22%)	19	(28%)
		Moderate	9	(13%)	6	(9%)
		Severe	4	(6%)	4	(6%)
		Very Severe	5	(7%)	4	(6%)
	Post-nasal Discharge	n	49		50	
		None	13	(19%)	12	(18%)
		Mild	17	(25%)	23	(34%)
		Moderate	13	(19%)	13	(19%)
		Severe	3	(4%)	2	(3%)
		Very Severe	3	(4%)	0	
	Runny Nose	n	49		50	
		None	15	(22%)	17	(25%)
		Mild	22	(32%)	21	(31%)
		Moderate	9	(13%)	9	(13%)
		Severe	1	(1%)	3	(4%)
		Very Severe	2	(3%)	0	
Weeks 1-4	Blockage/Congestion of Nose	n	65		67	
		None	8	(12%)	11	(16%)
		Mild	17	(25%)	27	(40%)
		Moderate	27	(40%)	24	(35%)
		Severe	9	(13%)	4	(6%)
		Very Severe	4	(6%)	1	(1%)

Note: Questionnaire was administered every week. Values summarised are the highest (i.e. worst) responses within each reporting period.

PPD

Protocol: MEA115921
Population: Intent-to-Treat

Table 2.82
Summary of Sino-Nasal Questionnaire Data

Visit	Question	Responses	Placebo (N=68)		Mepolizumab 300 mg SC (N=68)	
Weeks 1-4	Facial Pain/Pressure	n	65		67	
		None	25	(37%)	36	(53%)
		Mild	17	(25%)	15	(22%)
		Moderate	21	(31%)	15	(22%)
		Severe	0		1	(1%)
		Very Severe	2	(3%)	0	
	Loss/Reduction of Taste/Smell	n	65		67	
		None	19	(28%)	18	(26%)
		Mild	16	(24%)	28	(41%)
		Moderate	15	(22%)	10	(15%)
		Severe	7	(10%)	6	(9%)
		Very Severe	8	(12%)	5	(7%)
	Post-nasal Discharge	n	65		67	
		None	10	(15%)	13	(19%)
		Mild	23	(34%)	27	(40%)
		Moderate	23	(34%)	21	(31%)
		Severe	8	(12%)	6	(9%)
		Very Severe	1	(1%)	0	
	Runny Nose	n	65		67	
		None	9	(13%)	20	(29%)
		Mild	31	(46%)	31	(46%)
		Moderate	19	(28%)	13	(19%)
		Severe	4	(6%)	3	(4%)
		Very Severe	2	(3%)	0	

Note: Questionnaire was administered every week. Values summarised are the highest (i.e. worst) responses within each reporting period.

PPD

Protocol: MEA115921
Population: Intent-to-Treat

Table 2.82
Summary of Sino-Nasal Questionnaire Data

Visit	Question	Responses	Placebo (N=68)		Mepolizumab 300 mg SC (N=68)	
Weeks 5-8	Blockage/Congestion of Nose	n	68		66	
		None	13	(19%)	12	(18%)
		Mild	15	(22%)	27	(40%)
		Moderate	26	(38%)	21	(31%)
		Severe	10	(15%)	5	(7%)
		Very Severe	4	(6%)	1	(1%)
	Facial Pain/Pressure	n	68		66	
		None	25	(37%)	33	(49%)
		Mild	22	(32%)	18	(26%)
		Moderate	14	(21%)	13	(19%)
		Severe	6	(9%)	2	(3%)
		Very Severe	1	(1%)	0	
	Loss/Reduction of Taste/Smell	n	68		66	
		None	18	(26%)	26	(38%)
		Mild	24	(35%)	23	(34%)
		Moderate	12	(18%)	11	(16%)
		Severe	8	(12%)	2	(3%)
		Very Severe	6	(9%)	4	(6%)

Note: Questionnaire was administered every week. Values summarised are the highest (i.e. worst) responses within each reporting period.

PPD

Protocol: MEA115921
Population: Intent-to-Treat

Table 2.82
Summary of Sino-Nasal Questionnaire Data

Visit	Question	Responses	Placebo (N=68)		Mepolizumab 300 mg SC (N=68)	
Weeks 5-8	Post-nasal Discharge	n	68		66	
		None	8	(12%)	19	(28%)
		Mild	28	(41%)	22	(32%)
		Moderate	21	(31%)	19	(28%)
		Severe	10	(15%)	6	(9%)
		Very Severe	1	(1%)	0	
	Runny Nose	n	68		66	
		None	15	(22%)	19	(28%)
		Mild	23	(34%)	30	(44%)
		Moderate	20	(29%)	14	(21%)
		Severe	9	(13%)	3	(4%)
		Very Severe	1	(1%)	0	
Weeks 9-12	Blockage/Congestion of Nose	n	64		67	
		None	9	(13%)	8	(12%)
		Mild	20	(29%)	33	(49%)
		Moderate	26	(38%)	20	(29%)
		Severe	8	(12%)	4	(6%)
		Very Severe	1	(1%)	2	(3%)
	Facial Pain/Pressure	n	64		67	
		None	26	(38%)	35	(51%)
		Mild	19	(28%)	19	(28%)
		Moderate	15	(22%)	12	(18%)
		Severe	3	(4%)	1	(1%)
		Very Severe	1	(1%)	0	

Note: Questionnaire was administered every week. Values summarised are the highest (i.e. worst) responses within each reporting period.

PPD

Protocol: MEA115921
Population: Intent-to-Treat

Table 2.82
Summary of Sino-Nasal Questionnaire Data

Visit	Question	Responses	Placebo (N=68)		Mepolizumab 300 mg SC (N=68)	
Weeks 9-12	Loss/Reduction of Taste/Smell	n	64		67	
		None	17	(25%)	27	(40%)
		Mild	20	(29%)	20	(29%)
		Moderate	9	(13%)	11	(16%)
		Severe	12	(18%)	5	(7%)
		Very Severe	6	(9%)	4	(6%)
	Post-nasal Discharge	n	64		67	
		None	9	(13%)	15	(22%)
		Mild	22	(32%)	31	(46%)
		Moderate	23	(34%)	15	(22%)
		Severe	8	(12%)	4	(6%)
		Very Severe	2	(3%)	2	(3%)
	Runny Nose	n	64		67	
		None	6	(9%)	21	(31%)
		Mild	32	(47%)	30	(44%)
		Moderate	16	(24%)	12	(18%)
		Severe	9	(13%)	3	(4%)
		Very Severe	1	(1%)	1	(1%)
Weeks 13-16	Blockage/Congestion of Nose	n	64		66	
		None	5	(7%)	11	(16%)
		Mild	26	(38%)	27	(40%)
		Moderate	24	(35%)	15	(22%)
		Severe	6	(9%)	11	(16%)
		Very Severe	3	(4%)	2	(3%)

Note: Questionnaire was administered every week. Values summarised are the highest (i.e. worst) responses within each reporting period.

PPD

Protocol: MEA115921
Population: Intent-to-Treat

Table 2.82
Summary of Sino-Nasal Questionnaire Data

Visit	Question	Responses	Placebo (N=68)	Mepolizumab 300 mg SC (N=68)
Weeks 13-16	Facial Pain/Pressure	n	64	66
		None	26 (38%)	35 (51%)
		Mild	18 (26%)	17 (25%)
		Moderate	16 (24%)	13 (19%)
		Severe	2 (3%)	1 (1%)
		Very Severe	2 (3%)	0
	Loss/Reduction of Taste/Smell	n	64	66
		None	13 (19%)	21 (31%)
		Mild	23 (34%)	20 (29%)
		Moderate	15 (22%)	13 (19%)
		Severe	6 (9%)	8 (12%)
		Very Severe	7 (10%)	4 (6%)
	Post-nasal Discharge	n	64	66
		None	6 (9%)	17 (25%)
		Mild	25 (37%)	28 (41%)
		Moderate	27 (40%)	14 (21%)
		Severe	5 (7%)	5 (7%)
		Very Severe	1 (1%)	2 (3%)
	Runny Nose	n	64	66
		None	7 (10%)	19 (28%)
		Mild	35 (51%)	31 (46%)
		Moderate	16 (24%)	12 (18%)
		Severe	6 (9%)	4 (6%)
		Very Severe	0	0

Note: Questionnaire was administered every week. Values summarised are the highest (i.e. worst) responses within each reporting period.

PPD

Protocol: MEA115921
Population: Intent-to-Treat

Table 2.82
Summary of Sino-Nasal Questionnaire Data

Visit	Question	Responses	Placebo (N=68)		Mepolizumab 300 mg SC (N=68)	
Weeks 17-20	Blockage/Congestion of Nose	n	65		67	
		None	9	(13%)	14	(21%)
		Mild	18	(26%)	23	(34%)
		Moderate	27	(40%)	18	(26%)
		Severe	8	(12%)	9	(13%)
		Very Severe	3	(4%)	3	(4%)
	Facial Pain/Pressure	n	65		67	
		None	25	(37%)	36	(53%)
		Mild	20	(29%)	15	(22%)
		Moderate	14	(21%)	12	(18%)
		Severe	5	(7%)	3	(4%)
		Very Severe	1	(1%)	1	(1%)
	Loss/Reduction of Taste/Smell	n	65		67	
		None	14	(21%)	19	(28%)
		Mild	15	(22%)	24	(35%)
		Moderate	22	(32%)	9	(13%)
		Severe	7	(10%)	10	(15%)
		Very Severe	7	(10%)	5	(7%)

Note: Questionnaire was administered every week. Values summarised are the highest (i.e. worst) responses within each reporting period.

PPD

Protocol: MEA115921
Population: Intent-to-Treat

Table 2.82
Summary of Sino-Nasal Questionnaire Data

Visit	Question	Responses	Placebo (N=68)		Mepolizumab 300 mg SC (N=68)	
Weeks 17-20	Post-nasal Discharge	n	65		67	
		None	12	(18%)	20	(29%)
		Mild	20	(29%)	21	(31%)
		Moderate	23	(34%)	16	(24%)
		Severe	8	(12%)	9	(13%)
		Very Severe	2	(3%)	1	(1%)
	Runny Nose	n	65		67	
		None	14	(21%)	18	(26%)
		Mild	25	(37%)	25	(37%)
		Moderate	18	(26%)	19	(28%)
		Severe	7	(10%)	5	(7%)
		Very Severe	1	(1%)	0	
Weeks 21-24	Blockage/Congestion of Nose	n	63		66	
		None	9	(13%)	9	(13%)
		Mild	20	(29%)	22	(32%)
		Moderate	19	(28%)	23	(34%)
		Severe	13	(19%)	9	(13%)
		Very Severe	2	(3%)	3	(4%)
	Facial Pain/Pressure	n	63		66	
		None	24	(35%)	33	(49%)
		Mild	23	(34%)	21	(31%)
		Moderate	10	(15%)	9	(13%)
		Severe	4	(6%)	3	(4%)
		Very Severe	2	(3%)	0	

Note: Questionnaire was administered every week. Values summarised are the highest (i.e. worst) responses within each reporting period.

PPD

Protocol: MEA115921
Population: Intent-to-Treat

Table 2.82
Summary of Sino-Nasal Questionnaire Data

Visit	Question	Responses	Placebo (N=68)		Mepolizumab 300 mg SC (N=68)	
Weeks 21-24	Loss/Reduction of Taste/Smell	n	63		66	
		None	14	(21%)	21	(31%)
		Mild	19	(28%)	21	(31%)
		Moderate	15	(22%)	8	(12%)
		Severe	7	(10%)	13	(19%)
		Very Severe	8	(12%)	3	(4%)
	Post-nasal Discharge	n	63		66	
		None	11	(16%)	19	(28%)
		Mild	22	(32%)	20	(29%)
		Moderate	22	(32%)	18	(26%)
		Severe	6	(9%)	9	(13%)
		Very Severe	2	(3%)	0	
	Runny Nose	n	63		66	
		None	11	(16%)	19	(28%)
		Mild	28	(41%)	26	(38%)
		Moderate	19	(28%)	15	(22%)
		Severe	4	(6%)	6	(9%)
		Very Severe	1	(1%)	0	
Weeks 25-28	Blockage/Congestion of Nose	n	63		66	
		None	5	(7%)	9	(13%)
		Mild	19	(28%)	24	(35%)
		Moderate	25	(37%)	25	(37%)
		Severe	9	(13%)	6	(9%)
		Very Severe	5	(7%)	2	(3%)

Note: Questionnaire was administered every week. Values summarised are the highest (i.e. worst) responses within each reporting period.

PPD

Protocol: MEA115921
Population: Intent-to-Treat

Table 2.82
Summary of Sino-Nasal Questionnaire Data

Visit	Question	Responses	Placebo (N=68)		Mepolizumab 300 mg SC (N=68)	
Weeks 25-28	Facial Pain/Pressure	n	63		66	
		None	21	(31%)	33	(49%)
		Mild	18	(26%)	20	(29%)
		Moderate	16	(24%)	9	(13%)
		Severe	3	(4%)	3	(4%)
		Very Severe	5	(7%)	1	(1%)
	Loss/Reduction of Taste/Smell	n	63		66	
		None	12	(18%)	21	(31%)
		Mild	19	(28%)	20	(29%)
		Moderate	12	(18%)	12	(18%)
		Severe	11	(16%)	8	(12%)
		Very Severe	9	(13%)	5	(7%)
	Post-nasal Discharge	n	63		66	
		None	10	(15%)	16	(24%)
		Mild	20	(29%)	25	(37%)
		Moderate	19	(28%)	17	(25%)
		Severe	11	(16%)	7	(10%)
		Very Severe	3	(4%)	1	(1%)
	Runny Nose	n	63		66	
		None	13	(19%)	18	(26%)
		Mild	23	(34%)	29	(43%)
		Moderate	16	(24%)	16	(24%)
		Severe	9	(13%)	2	(3%)
		Very Severe	2	(3%)	1	(1%)

Note: Questionnaire was administered every week. Values summarised are the highest (i.e. worst) responses within each reporting period.

PPD

Protocol: MEA115921
Population: Intent-to-Treat

Table 2.82
Summary of Sino-Nasal Questionnaire Data

Visit	Question	Responses	Placebo (N=68)		Mepolizumab 300 mg SC (N=68)	
Weeks 29-32	Blockage/Congestion of Nose	n	62		66	
		None	5	(7%)	11	(16%)
		Mild	23	(34%)	16	(24%)
		Moderate	18	(26%)	27	(40%)
		Severe	12	(18%)	11	(16%)
		Very Severe	4	(6%)	1	(1%)
	Facial Pain/Pressure	n	62		66	
		None	21	(31%)	35	(51%)
		Mild	21	(31%)	17	(25%)
		Moderate	11	(16%)	10	(15%)
		Severe	6	(9%)	4	(6%)
		Very Severe	3	(4%)	0	
	Loss/Reduction of Taste/Smell	n	62		66	
		None	12	(18%)	17	(25%)
		Mild	19	(28%)	26	(38%)
		Moderate	14	(21%)	10	(15%)
		Severe	7	(10%)	9	(13%)
		Very Severe	10	(15%)	4	(6%)

Note: Questionnaire was administered every week. Values summarised are the highest (i.e. worst) responses within each reporting period.

PPD

Protocol: MEA115921
Population: Intent-to-Treat

Table 2.82
Summary of Sino-Nasal Questionnaire Data

Visit	Question	Responses	Placebo (N=68)		Mepolizumab 300 mg SC (N=68)	
Weeks 29-32	Post-nasal Discharge	n	62		66	
		None	7	(10%)	16	(24%)
		Mild	22	(32%)	27	(40%)
		Moderate	22	(32%)	17	(25%)
		Severe	10	(15%)	6	(9%)
		Very Severe	1	(1%)	0	
	Runny Nose	n	62		66	
		None	10	(15%)	20	(29%)
		Mild	24	(35%)	26	(38%)
		Moderate	16	(24%)	19	(28%)
		Severe	11	(16%)	1	(1%)
		Very Severe	1	(1%)	0	
Weeks 33-36	Blockage/Congestion of Nose	n	61		64	
		None	7	(10%)	10	(15%)
		Mild	20	(29%)	25	(37%)
		Moderate	21	(31%)	19	(28%)
		Severe	8	(12%)	9	(13%)
		Very Severe	5	(7%)	1	(1%)
	Facial Pain/Pressure	n	61		64	
		None	23	(34%)	34	(50%)
		Mild	21	(31%)	17	(25%)
		Moderate	10	(15%)	10	(15%)
		Severe	4	(6%)	3	(4%)
		Very Severe	3	(4%)	0	

Note: Questionnaire was administered every week. Values summarised are the highest (i.e. worst) responses within each reporting period.

PPD

Protocol: MEA115921
Population: Intent-to-Treat

Table 2.82
Summary of Sino-Nasal Questionnaire Data

Visit	Question	Responses	Placebo (N=68)		Mepolizumab 300 mg SC (N=68)	
Weeks 33-36	Loss/Reduction of Taste/Smell	n	61		64	
		None	12	(18%)	19	(28%)
		Mild	18	(26%)	21	(31%)
		Moderate	18	(26%)	14	(21%)
		Severe	4	(6%)	8	(12%)
		Very Severe	9	(13%)	2	(3%)
	Post-nasal Discharge	n	61		64	
		None	10	(15%)	19	(28%)
		Mild	19	(28%)	24	(35%)
		Moderate	20	(29%)	17	(25%)
		Severe	10	(15%)	4	(6%)
		Very Severe	2	(3%)	0	
	Runny Nose	n	61		64	
		None	9	(13%)	16	(24%)
		Mild	25	(37%)	30	(44%)
		Moderate	17	(25%)	16	(24%)
		Severe	7	(10%)	2	(3%)
		Very Severe	3	(4%)	0	
Weeks 37-40	Blockage/Congestion of Nose	n	54		57	
		None	5	(7%)	9	(13%)
		Mild	20	(29%)	26	(38%)
		Moderate	16	(24%)	10	(15%)
		Severe	10	(15%)	11	(16%)
		Very Severe	3	(4%)	1	(1%)

Note: Questionnaire was administered every week. Values summarised are the highest (i.e. worst) responses within each reporting period.

PPD

Protocol: MEA115921
Population: Intent-to-Treat

Table 2.82
Summary of Sino-Nasal Questionnaire Data

Visit	Question	Responses	Placebo (N=68)		Mepolizumab 300 mg SC (N=68)	
Weeks 37-40	Facial Pain/Pressure	n	54		57	
		None	20	(29%)	28	(41%)
		Mild	13	(19%)	21	(31%)
		Moderate	14	(21%)	6	(9%)
		Severe	6	(9%)	1	(1%)
		Very Severe	1	(1%)	1	(1%)
	Loss/Reduction of Taste/Smell	n	54		57	
		None	10	(15%)	16	(24%)
		Mild	15	(22%)	21	(31%)
		Moderate	16	(24%)	9	(13%)
		Severe	6	(9%)	9	(13%)
		Very Severe	7	(10%)	2	(3%)
	Post-nasal Discharge	n	54		57	
		None	7	(10%)	16	(24%)
		Mild	19	(28%)	18	(26%)
		Moderate	20	(29%)	20	(29%)
		Severe	7	(10%)	3	(4%)
		Very Severe	1	(1%)	0	
	Runny Nose	n	54		57	
		None	10	(15%)	14	(21%)
		Mild	19	(28%)	26	(38%)
		Moderate	19	(28%)	14	(21%)
		Severe	4	(6%)	3	(4%)
		Very Severe	2	(3%)	0	

Note: Questionnaire was administered every week. Values summarised are the highest (i.e. worst) responses within each reporting period.

PPD

Protocol: MEA115921
Population: Intent-to-Treat

Table 2.82
Summary of Sino-Nasal Questionnaire Data

Visit	Question	Responses	Placebo (N=68)		Mepolizumab 300 mg SC (N=68)	
Weeks 41-44	Blockage/Congestion of Nose	n	52		55	
		None	6	(9%)	6	(9%)
		Mild	16	(24%)	23	(34%)
		Moderate	23	(34%)	15	(22%)
		Severe	5	(7%)	10	(15%)
		Very Severe	2	(3%)	1	(1%)
	Facial Pain/Pressure	n	52		55	
		None	18	(26%)	28	(41%)
		Mild	18	(26%)	17	(25%)
		Moderate	12	(18%)	8	(12%)
		Severe	4	(6%)	2	(3%)
		Very Severe	0		0	
	Loss/Reduction of Taste/Smell	n	52		55	
		None	6	(9%)	17	(25%)
		Mild	17	(25%)	18	(26%)
		Moderate	18	(26%)	10	(15%)
		Severe	4	(6%)	7	(10%)
		Very Severe	7	(10%)	3	(4%)

Note: Questionnaire was administered every week. Values summarised are the highest (i.e. worst) responses within each reporting period.

PPD

Protocol: MEA115921
Population: Intent-to-Treat

Table 2.82
Summary of Sino-Nasal Questionnaire Data

Visit	Question	Responses	Placebo (N=68)		Mepolizumab 300 mg SC (N=68)	
Weeks 41-44	Post-nasal Discharge	n	52		55	
		None	8	(12%)	15	(22%)
		Mild	13	(19%)	17	(25%)
		Moderate	21	(31%)	20	(29%)
		Severe	10	(15%)	3	(4%)
		Very Severe	0		0	
	Runny Nose	n	52		55	
		None	7	(10%)	12	(18%)
		Mild	20	(29%)	28	(41%)
		Moderate	18	(26%)	10	(15%)
		Severe	6	(9%)	4	(6%)
		Very Severe	1	(1%)	1	(1%)
Weeks 45-48	Blockage/Congestion of Nose	n	49		52	
		None	8	(12%)	10	(15%)
		Mild	13	(19%)	18	(26%)
		Moderate	18	(26%)	15	(22%)
		Severe	5	(7%)	9	(13%)
		Very Severe	5	(7%)	0	
	Facial Pain/Pressure	n	49		52	
		None	19	(28%)	30	(44%)
		Mild	17	(25%)	12	(18%)
		Moderate	5	(7%)	7	(10%)
		Severe	6	(9%)	3	(4%)
		Very Severe	2	(3%)	0	

Note: Questionnaire was administered every week. Values summarised are the highest (i.e. worst) responses within each reporting period.

PPD

Protocol: MEA115921
Population: Intent-to-Treat

Table 2.82
Summary of Sino-Nasal Questionnaire Data

Visit	Question	Responses	Placebo (N=68)		Mepolizumab 300 mg SC (N=68)	
Weeks 45-48	Loss/Reduction of Taste/Smell	n	49		52	
		None	9	(13%)	15	(22%)
		Mild	17	(25%)	17	(25%)
		Moderate	11	(16%)	12	(18%)
		Severe	5	(7%)	6	(9%)
		Very Severe	7	(10%)	2	(3%)
	Post-nasal Discharge	n	49		52	
		None	8	(12%)	14	(21%)
		Mild	15	(22%)	22	(32%)
		Moderate	16	(24%)	11	(16%)
		Severe	6	(9%)	5	(7%)
		Very Severe	4	(6%)	0	
	Runny Nose	n	49		52	
		None	11	(16%)	15	(22%)
		Mild	16	(24%)	20	(29%)
		Moderate	14	(21%)	12	(18%)
		Severe	5	(7%)	5	(7%)
		Very Severe	3	(4%)	0	
Weeks 49-52	Blockage/Congestion of Nose	n	47		49	
		None	7	(10%)	8	(12%)
		Mild	10	(15%)	19	(28%)
		Moderate	17	(25%)	10	(15%)
		Severe	10	(15%)	11	(16%)
		Very Severe	3	(4%)	1	(1%)

Note: Questionnaire was administered every week. Values summarised are the highest (i.e. worst) responses within each reporting period.

PPD

Protocol: MEA115921
Population: Intent-to-Treat

Table 2.82
Summary of Sino-Nasal Questionnaire Data

Visit	Question	Responses	Placebo (N=68)	Mepolizumab 300 mg SC (N=68)
Weeks 49-52	Facial Pain/Pressure	n	47	49
		None	20 (29%)	27 (40%)
		Mild	8 (12%)	11 (16%)
		Moderate	9 (13%)	6 (9%)
		Severe	10 (15%)	5 (7%)
		Very Severe	0	0
	Loss/Reduction of Taste/Smell	n	47	49
		None	8 (12%)	16 (24%)
		Mild	12 (18%)	17 (25%)
		Moderate	13 (19%)	5 (7%)
		Severe	6 (9%)	9 (13%)
		Very Severe	8 (12%)	2 (3%)
	Post-nasal Discharge	n	47	49
		None	8 (12%)	18 (26%)
		Mild	11 (16%)	18 (26%)
		Moderate	17 (25%)	9 (13%)
		Severe	9 (13%)	4 (6%)
		Very Severe	2 (3%)	0
	Runny Nose	n	47	49
		None	9 (13%)	19 (28%)
		Mild	17 (25%)	16 (24%)
		Moderate	13 (19%)	12 (18%)
		Severe	6 (9%)	2 (3%)
		Very Severe	2 (3%)	0

Note: Questionnaire was administered every week. Values summarised are the highest (i.e. worst) responses within each reporting period.

PPD

Protocol: MEA115921
Population: Intent-to-Treat

Table 2.82
Summary of Sino-Nasal Questionnaire Data

Visit	Question	Responses	Placebo (N=68)		Mepolizumab 300 mg SC (N=68)	
Weeks 53-56	Blockage/Congestion of Nose	n	43		45	
		None	6	(9%)	7	(10%)
		Mild	15	(22%)	20	(29%)
		Moderate	14	(21%)	13	(19%)
		Severe	5	(7%)	4	(6%)
		Very Severe	3	(4%)	1	(1%)
	Facial Pain/Pressure	n	43		45	
		None	19	(28%)	26	(38%)
		Mild	12	(18%)	10	(15%)
		Moderate	6	(9%)	7	(10%)
		Severe	5	(7%)	2	(3%)
		Very Severe	1	(1%)	0	
	Loss/Reduction of Taste/Smell	n	43		45	
		None	9	(13%)	14	(21%)
		Mild	10	(15%)	14	(21%)
		Moderate	13	(19%)	8	(12%)
		Severe	5	(7%)	6	(9%)
		Very Severe	6	(9%)	3	(4%)

Note: Questionnaire was administered every week. Values summarised are the highest (i.e. worst) responses within each reporting period.

PPD

Protocol: MEA115921
Population: Intent-to-Treat

Table 2.82
Summary of Sino-Nasal Questionnaire Data

Visit	Question	Responses	Placebo (N=68)		Mepolizumab 300 mg SC (N=68)	
Weeks 53-56	Post-nasal Discharge	n	43		45	
		None	6	(9%)	13	(19%)
		Mild	14	(21%)	19	(28%)
		Moderate	17	(25%)	8	(12%)
		Severe	4	(6%)	4	(6%)
		Very Severe	2	(3%)	1	(1%)
	Runny Nose	n	43		45	
		None	8	(12%)	14	(21%)
		Mild	14	(21%)	17	(25%)
		Moderate	14	(21%)	10	(15%)
		Severe	6	(9%)	3	(4%)
		Very Severe	1	(1%)	1	(1%)
Weeks 57-60	Blockage/Congestion of Nose	n	41		44	
		None	6	(9%)	8	(12%)
		Mild	14	(21%)	19	(28%)
		Moderate	13	(19%)	9	(13%)
		Severe	4	(6%)	7	(10%)
		Very Severe	4	(6%)	1	(1%)
	Facial Pain/Pressure	n	41		44	
		None	15	(22%)	26	(38%)
		Mild	12	(18%)	9	(13%)
		Moderate	7	(10%)	5	(7%)
		Severe	6	(9%)	2	(3%)
		Very Severe	1	(1%)	2	(3%)

Note: Questionnaire was administered every week. Values summarised are the highest (i.e. worst) responses within each reporting period.

PPD

Protocol: MEA115921
Population: Intent-to-Treat

Table 2.82
Summary of Sino-Nasal Questionnaire Data

Visit	Question	Responses	Placebo (N=68)		Mepolizumab 300 mg SC (N=68)	
Weeks 57-60	Loss/Reduction of Taste/Smell	n	41		44	
		None	8	(12%)	16	(24%)
		Mild	10	(15%)	9	(13%)
		Moderate	12	(18%)	9	(13%)
		Severe	6	(9%)	8	(12%)
		Very Severe	5	(7%)	2	(3%)
	Post-nasal Discharge	n	41		44	
		None	6	(9%)	12	(18%)
		Mild	12	(18%)	16	(24%)
		Moderate	15	(22%)	10	(15%)
		Severe	6	(9%)	6	(9%)
		Very Severe	2	(3%)	0	
	Runny Nose	n	41		44	
		None	9	(13%)	13	(19%)
		Mild	16	(24%)	18	(26%)
		Moderate	8	(12%)	9	(13%)
		Severe	5	(7%)	4	(6%)
		Very Severe	3	(4%)	0	

Note: Questionnaire was administered every week. Values summarised are the highest (i.e. worst) responses within each reporting period.

PPD

Protocol: MEA115921
Population: Intent-to-Treat

Table 4.2
SF-36 Healthy Survey Overall Component Scores(Observed and Change from Baseline) by Visit

Component Score: Physical Component Summary (PCS) Score

Timepoint			Placebo (N=68)	Mepolizumab 300 mg SC (N=68)
Baseline	Total Score	n	68	67
		Mean	40.97	40.88
		SD	9.792	11.333
		Median	43.08	42.29
		Min	18.6	16.0
		Max	58.7	66.2
Week 12	Total Score	n	66	67
		Mean	42.51	43.74
		SD	8.864	10.226
		Median	44.11	45.72
		Min	19.6	24.1
		Max	58.6	60.2
	Total Score Change from Baseline	n	66	66
		Mean	1.54	2.66
		SD	6.550	5.991
		Median	1.41	2.12
		Min	-13.1	-12.1
		Max	14.3	19.5

PPD

Protocol: MEA115921
Population: Intent-to-Treat

Table 4.2
SF-36 Healthy Survey Overall Component Scores(Observed and Change from Baseline) by Visit

Component Score: Physical Component Summary (PCS) Score

Timepoint			Placebo (N=68)	Mepolizumab 300 mg SC (N=68)
Week 24	Total Score	n	64	67
		Mean	42.46	43.54
		SD	8.893	10.273
		Median	43.62	44.57
		Min	18.5	21.0
		Max	59.9	59.1
	Total Score Change from Baseline	n	64	66
		Mean	1.45	2.83
		SD	7.286	7.166
		Median	0.55	2.41
		Min	-13.7	-16.2
		Max	19.0	24.8
Week 36	Total Score	n	62	66
		Mean	42.41	42.78
		SD	8.312	10.384
		Median	42.43	44.73
		Min	21.5	18.1
		Max	57.5	59.9
	Total Score Change from Baseline	n	62	65
		Mean	1.17	1.87
		SD	6.694	6.415
		Median	0.08	1.35
		Min	-12.8	-10.9
		Max	23.1	23.3

PPD

Protocol: MEA115921
Population: Intent-to-Treat

Table 4.2
SF-36 Healthy Survey Overall Component Scores(Observed and Change from Baseline) by Visit

Component Score: Physical Component Summary (PCS) Score

Timepoint			Placebo (N=68)	Mepolizumab 300 mg SC (N=68)
Week 52	Total Score	n	61	64
		Mean	42.95	43.27
		SD	8.917	9.339
		Median	44.75	44.98
		Min	24.5	20.9
		Max	61.1	62.3
	Total Score Change from Baseline	n	61	63
		Mean	1.57	1.92
		SD	7.040	6.593
		Median	1.13	2.40
		Min	-15.1	-17.8
		Max	22.6	16.0

PPD

Population: Intent-to-Treat

Table 7.18
Analysis of Change from Baseline in SF-36 Physical Component Summary Score
(Mixed Model Repeated Measures)

Visit: Week 12

	Placebo (N=68)	Mepolizumab 300 mg SC (N=68)
n [1]	68	67
n [2]	66	66
LS Mean (SE)	42.73 (0.696)	43.78 (0.698)
LS Mean Change (SE)	1.63 (0.696)	2.67 (0.698)
Mepolizumab 300 mg SC vs Placebo		
Difference (Mepo - Placebo)		1.05
95% CI		(-0.90, 3.00)
p-value		0.290
Corrected Hedges g [3]		0.18
95% CI		(-0.16, 0.53)

[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] Derived from LS means and associated SE.
Note: Analysis performed using mixed model repeated measures with covariates of baseline Physical Component Summary score, baseline prednisolone/prednisone daily dose, region (EU vs. RoW), treatment and visit, plus interaction terms for visit-by-baseline and visit-by-treatment group. LS mean estimates are weighted according to the observed proportions of each categorical covariate in the study data.

PPD

Population: Intent-to-Treat

Table 7.18
Analysis of Change from Baseline in SF-36 Physical Component Summary Score
(Mixed Model Repeated Measures)

Visit: Week 24

	Placebo (N=68)	Mepolizumab 300 mg SC (N=68)
n [1]	68	67
n [2]	64	66
LS Mean (SE)	42.49 (0.796)	43.80 (0.790)
LS Mean Change (SE)	1.38 (0.796)	2.70 (0.790)
Mepolizumab 300 mg SC vs Placebo		
Difference (Mepo - Placebo)		1.32
95% CI		(-0.90, 3.53)
p-value		0.243
Corrected Hedges g [3]		0.20
95% CI		(-0.14, 0.55)

[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] Derived from LS means and associated SE.
Note: Analysis performed using mixed model repeated measures with covariates of baseline Physical Component Summary score, baseline prednisolone/prednisone daily dose, region (EU vs. RoW), treatment and visit, plus interaction terms for visit-by-baseline and visit-by-treatment group. LS mean estimates are weighted according to the observed proportions of each categorical covariate in the study data.

PPD

Protocol: MEA115921
Population: Intent-to-Treat

Table 7.18
Analysis of Change from Baseline in SF-36 Physical Component Summary Score
(Mixed Model Repeated Measures)

Visit: Week 36

	Placebo (N=68)	Mepolizumab 300 mg SC (N=68)
n [1]	68	67
n [2]	62	65
LS Mean (SE)	42.20 (0.737)	42.86 (0.724)
LS Mean Change (SE)	1.09 (0.737)	1.75 (0.724)
Mepolizumab 300 mg SC vs Placebo		
Difference (Mepo - Placebo)		0.66
95% CI		(-1.39, 2.70)
p-value		0.525
Corrected Hedges g [3]		0.11
95% CI		(-0.24, 0.46)

[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] Derived from LS means and associated SE.
Note: Analysis performed using mixed model repeated measures with covariates of baseline Physical Component Summary score, baseline prednisolone/prednisone daily dose, region (EU vs. RoW), treatment and visit, plus interaction terms for visit-by-baseline and visit-by-treatment group. LS mean estimates are weighted according to the observed proportions of each categorical covariate in the study data.

PPD

Population: Intent-to-Treat

Table 7.18
Analysis of Change from Baseline in SF-36 Physical Component Summary Score
(Mixed Model Repeated Measures)

Visit: Week 52

	Placebo (N=68)	Mepolizumab 300 mg SC (N=68)
n [1]	68	67
n [2]	61	63
LS Mean (SE)	42.71 (0.754)	43.16 (0.743)
LS Mean Change (SE)	1.60 (0.754)	2.06 (0.743)
Mepolizumab 300 mg SC vs Placebo		
Difference (Mepo - Placebo)		0.46
95% CI		(-1.64, 2.55)
p-value		0.667
Corrected Hedges g [3]		0.08
95% CI		(-0.28, 0.43)

[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] Derived from LS means and associated SE.
Note: Analysis performed using mixed model repeated measures with covariates of baseline Physical Component Summary score, baseline prednisolone/prednisone daily dose, region (EU vs. RoW), treatment and visit, plus interaction terms for visit-by-baseline and visit-by-treatment group. LS mean estimates are weighted according to the observed proportions of each categorical covariate in the study data.

PPD

Protocol: MEA115921
Population: Intent-to-Treat

Table 4.2
SF-36 Healthy Survey Overall Component Scores(Observed and Change from Baseline) by Visit

Component Score: Mental Component Summary (MCS) Score

Timepoint			Placebo (N=68)	Mepolizumab 300 mg SC (N=68)
Baseline	Total Score	n	68	67
		Mean	50.23	48.57
		SD	10.221	10.468
		Median	52.08	51.55
		Min	24.8	24.8
		Max	67.9	67.4
Week 12	Total Score	n	66	67
		Mean	50.38	50.19
		SD	10.121	9.153
		Median	54.24	52.29
		Min	20.7	22.8
		Max	68.7	63.0
	Total Score Change from Baseline	n	66	66
		Mean	0.25	1.79
		SD	5.038	8.327
		Median	0.55	1.10
		Min	-11.0	-23.1
		Max	17.9	16.6

PPD

Protocol: MEA115921
Population: Intent-to-Treat

Table 4.2
SF-36 Healthy Survey Overall Component Scores(Observed and Change from Baseline) by Visit

Component Score: Mental Component Summary (MCS) Score

Timepoint			Placebo (N=68)	Mepolizumab 300 mg SC (N=68)
Week 24	Total Score	n	64	67
		Mean	50.13	50.31
		SD	9.674	8.200
		Median	51.86	51.48
		Min	17.2	27.2
		Max	62.8	63.7
	Total Score Change from Baseline	n	64	66
		Mean	-0.08	1.59
		SD	5.549	8.331
		Median	-0.50	-0.18
		Min	-11.9	-16.7
		Max	12.9	23.9
Week 36	Total Score	n	62	66
		Mean	49.71	50.06
		SD	11.019	8.872
		Median	53.16	51.98
		Min	16.8	27.4
		Max	67.7	64.0
	Total Score Change from Baseline	n	62	65
		Mean	-0.40	1.47
		SD	6.669	8.147
		Median	0.08	1.64
		Min	-21.8	-16.2
		Max	15.1	20.4

PPD

Protocol: MEA115921
Population: Intent-to-Treat

Table 4.2
SF-36 Healthy Survey Overall Component Scores(Observed and Change from Baseline) by Visit

Component Score: Mental Component Summary (MCS) Score

Timepoint			Placebo (N=68)	Mepolizumab 300 mg SC (N=68)
Week 52	Total Score	n	61	64
		Mean	50.73	48.69
		SD	10.812	9.318
		Median	54.01	50.02
		Min	16.1	17.7
		Max	63.5	63.3
	Total Score Change from Baseline	n	61	63
		Mean	0.57	0.05
		SD	7.005	8.916
		Median	-0.59	-0.40
		Min	-17.4	-17.7
		Max	19.9	26.1

PPD

Protocol: MEA115921
Population: Intent-to-Treat

Table 7.9
Analysis of Change from Baseline in SF-36 Mental Component Summary Score
(Mixed Model Repeated Measures)

Visit: Week 12

	Placebo (N=68)	Mepolizumab 300 mg SC (N=68)
n [1]	68	67
n [2]	66	66
LS Mean (SE)	49.83 (0.768)	50.85 (0.770)
LS Mean Change (SE)	0.48 (0.768)	1.50 (0.770)
Mepolizumab 300 mg SC vs Placebo		
Difference (Mepo - Placebo)		1.03
95% CI		(-1.13, 3.18)
p-value		0.348
Corrected Hedges g [3]		0.16
95% CI		(-0.18, 0.51)

[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] Derived from LS means and associated SE.
Note: Analysis performed using mixed model repeated measures with covariates of baseline Mental Component Summary score, baseline prednisolone/prednisone daily dose, region (EU vs. RoW), treatment and visit, plus interaction terms for visit-by-baseline and visit-by-treatment group. LS mean estimates are weighted according to the observed proportions of each categorical covariate in the study data.

PPD

Protocol: MEA115921
Population: Intent-to-Treat

Table 7.9
Analysis of Change from Baseline in SF-36 Mental Component Summary Score
(Mixed Model Repeated Measures)

Visit: Week 24

	Placebo (N=68)	Mepolizumab 300 mg SC (N=68)
n [1]	68	67
n [2]	64	66
LS Mean (SE)	49.60 (0.745)	50.63 (0.736)
LS Mean Change (SE)	0.25 (0.745)	1.28 (0.736)
Mepolizumab 300 mg SC vs Placebo		
Difference (Mepo - Placebo)		1.04
95% CI		(-1.04, 3.11)
p-value		0.325
Corrected Hedges g [3]		0.17
95% CI		(-0.17, 0.52)

[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] Derived from LS means and associated SE.
Note: Analysis performed using mixed model repeated measures with covariates of baseline Mental Component Summary score, baseline prednisolone/prednisone daily dose, region (EU vs. RoW), treatment and visit, plus interaction terms for visit-by-baseline and visit-by-treatment group. LS mean estimates are weighted according to the observed proportions of each categorical covariate in the study data.

PPD

Protocol: MEA115921
Population: Intent-to-Treat

Table 7.9
Analysis of Change from Baseline in SF-36 Mental Component Summary Score
(Mixed Model Repeated Measures)

Visit: Week 36

	Placebo (N=68)	Mepolizumab 300 mg SC (N=68)
n [1]	68	67
n [2]	62	65
LS Mean (SE)	49.30 (0.877)	50.57 (0.859)
LS Mean Change (SE)	-0.04 (0.877)	1.23 (0.859)
Mepolizumab 300 mg SC vs Placebo		
Difference (Mepo - Placebo)		1.27
95% CI		(-1.16, 3.70)
p-value		0.304
Corrected Hedges g [3]		0.18
95% CI		(-0.17, 0.53)

[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] Derived from LS means and associated SE.
Note: Analysis performed using mixed model repeated measures with covariates of baseline Mental Component Summary score, baseline prednisolone/prednisone daily dose, region (EU vs. RoW), treatment and visit, plus interaction terms for visit-by-baseline and visit-by-treatment group. LS mean estimates are weighted according to the observed proportions of each categorical covariate in the study data.

PPD

Population: Intent-to-Treat

Table 7.9
Analysis of Change from Baseline in SF-36 Mental Component Summary Score
(Mixed Model Repeated Measures)

Visit: Week 52

	Placebo (N=68)	Mepolizumab 300 mg SC (N=68)
n [1]	68	67
n [2]	61	63
LS Mean (SE)	50.37 (0.936)	49.12 (0.920)
LS Mean Change (SE)	1.02 (0.936)	-0.23 (0.920)
Mepolizumab 300 mg SC vs Placebo		
Difference (Mepo - Placebo)		-1.25
95% CI		(-3.85, 1.35)
p-value		0.344
Corrected Hedges g [3]		-0.17
95% CI		(-0.52, 0.18)

[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] Derived from LS means and associated SE.
Note: Analysis performed using mixed model repeated measures with covariates of baseline Mental Component Summary score, baseline prednisolone/prednisone daily dose, region (EU vs. RoW), treatment and visit, plus interaction terms for visit-by-baseline and visit-by-treatment group. LS mean estimates are weighted according to the observed proportions of each categorical covariate in the study data.

PPD

Protocol: MEA115921
Population: Intent-to-Treat

Table 4.1
SF-36 Healthy Survey Domain Scores(Observed and Change from Baseline) by Visit

Domain: Bodily Pain(0-100 score)

Timepoint			Placebo (N=68)	Mepolizumab 300 mg SC (N=68)
Baseline	Total Score	n	68	67
		Mean	66.87	65.81
		SD	27.872	27.855
		Median	74.00	74.00
		Min	0.0	0.0
		Max	100.0	100.0
Week 12	Total Score	n	67	68
		Mean	66.54	69.93
		SD	25.109	26.854
		Median	72.00	74.00
		Min	21.0	0.0
		Max	100.0	100.0
	Total Score Change from Baseline	n	67	67
		Mean	-0.72	4.55
		SD	24.809	20.710
		Median	0.00	0.00
		Min	-69.0	-62.0
		Max	48.0	78.0

PPD

Protocol: MEA115921
Population: Intent-to-Treat

Table 4.1
SF-36 Healthy Survey Domain Scores(Observed and Change from Baseline) by Visit

Domain: Bodily Pain(0-100 score)

Timepoint			Placebo (N=68)	Mepolizumab 300 mg SC (N=68)
Week 24	Total Score	n	64	67
		Mean	65.23	65.43
		SD	26.432	26.079
		Median	68.00	62.00
		Min	0.0	0.0
		Max	100.0	100.0
	Total Score Change from Baseline	n	64	66
		Mean	-1.84	-0.03
		SD	26.237	24.402
		Median	0.00	0.00
		Min	-100.0	-59.0
		Max	53.0	61.0
Week 36	Total Score	n	62	66
		Mean	63.05	67.26
		SD	28.414	25.221
		Median	62.00	73.00
		Min	0.0	0.0
		Max	100.0	100.0
	Total Score Change from Baseline	n	62	65
		Mean	-4.71	1.54
		SD	23.373	22.397
		Median	0.00	0.00
		Min	-74.0	-52.0
		Max	69.0	62.0

Protocol: MEA115921
Population: Intent-to-Treat

Table 4.1
SF-36 Healthy Survey Domain Scores(Observed and Change from Baseline) by Visit

Domain: Bodily Pain(0-100 score)

Timepoint			Placebo (N=68)	Mepolizumab 300 mg SC (N=68)
Week 52	Total Score	n	61	65
		Mean	68.16	64.18
		SD	26.274	26.321
		Median	72.00	62.00
		Min	10.0	0.0
		Max	100.0	100.0
	Total Score Change from Baseline	n	61	64
		Mean	-0.03	-1.80
		SD	23.223	19.229
		Median	0.00	0.00
		Min	-62.0	-49.0
		Max	69.0	64.0

PPD

Protocol: MEA115921
Population: Intent-to-Treat

Table 4.1
SF-36 Healthy Survey Domain Scores(Observed and Change from Baseline) by Visit

Domain: Bodily Pain(norm-based score)

Timepoint			Placebo (N=68)	Mepolizumab 300 mg SC (N=68)
Baseline	Total Score	n	68	67
		Mean	48.64	48.21
		SD	11.238	11.231
		Median	51.51	51.51
		Min	21.7	21.7
		Max	62.0	62.0
Week 12	Total Score	n	67	68
		Mean	48.51	49.87
		SD	10.124	10.828
		Median	50.71	51.51
		Min	30.1	21.7
		Max	62.0	62.0
	Total Score Change from Baseline	n	67	67
		Mean	-0.29	1.84
		SD	10.003	8.350
		Median	0.00	0.00
		Min	-27.8	-25.0
		Max	19.4	31.5

PPD

Protocol: MEA115921
Population: Intent-to-Treat

Table 4.1
SF-36 Healthy Survey Domain Scores(Observed and Change from Baseline) by Visit

Domain: Bodily Pain(norm-based score)

Timepoint			Placebo (N=68)	Mepolizumab 300 mg SC (N=68)
Week 24	Total Score	n	64	67
		Mean	47.98	48.06
		SD	10.658	10.515
		Median	49.10	46.68
		Min	21.7	21.7
		Max	62.0	62.0
	Total Score Change from Baseline	n	64	66
		Mean	-0.74	-0.01
		SD	10.578	9.839
		Median	0.00	0.00
		Min	-40.3	-23.8
		Max	21.4	24.6
Week 36	Total Score	n	62	66
		Mean	47.10	48.80
		SD	11.457	10.170
		Median	46.68	51.11
		Min	21.7	21.7
		Max	62.0	62.0
	Total Score Change from Baseline	n	62	65
		Mean	-1.90	0.62
		SD	9.424	9.031
		Median	0.00	0.00
		Min	-29.8	-21.0
		Max	27.8	25.0

PPD

Protocol: MEA115921
Population: Intent-to-Treat

Table 4.1
SF-36 Healthy Survey Domain Scores(Observed and Change from Baseline) by Visit

Domain: Bodily Pain(norm-based score)

Timepoint			Placebo (N=68)	Mepolizumab 300 mg SC (N=68)
Week 52	Total Score	n	61	65
		Mean	49.16	47.56
		SD	10.594	10.613
		Median	50.71	46.68
		Min	25.7	21.7
		Max	62.0	62.0
	Total Score Change from Baseline	n	61	64
		Mean	-0.01	-0.72
		SD	9.363	7.753
		Median	0.00	0.00
		Min	-25.0	-19.8
		Max	27.8	25.8

PPD

Protocol: MEA115921
Population: Intent-to-Treat

Table 4.1
SF-36 Healthy Survey Domain Scores(Observed and Change from Baseline) by Visit

Domain: General Health(0-100 score)

Timepoint			Placebo (N=68)	Mepolizumab 300 mg SC (N=68)
Baseline	Total Score	n	68	67
		Mean	35.54	36.49
		SD	20.944	20.527
		Median	32.00	35.00
		Min	0.0	0.0
		Max	92.0	97.0
Week 12	Total Score	n	68	68
		Mean	38.60	43.97
		SD	21.059	21.043
		Median	36.00	42.00
		Min	5.0	0.0
		Max	85.0	97.0
	Total Score Change from Baseline	n	68	67
		Mean	3.06	7.51
		SD	11.689	12.608
		Median	4.00	5.00
		Min	-25.0	-22.0
		Max	45.0	37.0

PPD

Protocol: MEA115921
Population: Intent-to-Treat

Table 4.1
SF-36 Healthy Survey Domain Scores(Observed and Change from Baseline) by Visit

Domain: General Health(0-100 score)

Timepoint			Placebo (N=68)	Mepolizumab 300 mg SC (N=68)
Week 24	Total Score	n	64	67
		Mean	38.92	45.25
		SD	21.363	20.884
		Median	35.00	42.00
		Min	5.0	5.0
		Max	82.0	100.0
	Total Score Change from Baseline	n	64	66
		Mean	3.14	8.71
		SD	15.988	14.623
		Median	3.00	10.00
		Min	-30.0	-17.0
		Max	47.0	62.0
Week 36	Total Score	n	62	67
		Mean	38.65	43.21
		SD	21.728	21.021
		Median	35.00	37.00
		Min	0.0	10.0
		Max	95.0	100.0
	Total Score Change from Baseline	n	62	66
		Mean	2.50	6.56
		SD	16.998	14.023
		Median	0.00	5.00
		Min	-45.0	-32.0
		Max	52.0	47.0

PPD

Protocol: MEA115921
Population: Intent-to-Treat

Table 4.1
SF-36 Healthy Survey Domain Scores(Observed and Change from Baseline) by Visit

Domain: General Health(0-100 score)

Timepoint			Placebo (N=68)	Mepolizumab 300 mg SC (N=68)
Week 52	Total Score	n	61	65
		Mean	39.62	42.63
		SD	21.791	21.483
		Median	37.00	42.00
		Min	5.0	5.0
		Max	87.0	100.0
	Total Score Change from Baseline	n	61	64
		Mean	3.62	6.00
		SD	15.191	14.083
		Median	0.00	5.00
		Min	-27.0	-27.0
		Max	47.0	35.0

PPD

Protocol: MEA115921
Population: Intent-to-Treat

Table 4.1
SF-36 Healthy Survey Domain Scores(Observed and Change from Baseline) by Visit

Domain: General Health(norm-based score)

Timepoint			Placebo (N=68)	Mepolizumab 300 mg SC (N=68)
Baseline	Total Score	n	68	67
		Mean	35.85	36.30
		SD	9.958	9.760
		Median	34.17	35.59
		Min	19.0	19.0
		Max	62.7	65.1
Week 12	Total Score	n	68	68
		Mean	37.31	39.86
		SD	10.013	10.005
		Median	36.07	38.92
		Min	21.3	19.0
		Max	59.4	65.1
	Total Score Change from Baseline	n	68	67
		Mean	1.45	3.57
		SD	5.558	5.995
		Median	1.90	2.38
		Min	-11.9	-10.5
		Max	21.4	17.6

PPD

Protocol: MEA115921
Population: Intent-to-Treat

Table 4.1
SF-36 Healthy Survey Domain Scores(Observed and Change from Baseline) by Visit

Domain: General Health(norm-based score)

Timepoint			Placebo (N=68)	Mepolizumab 300 mg SC (N=68)
Week 24	Total Score	n	64	67
		Mean	37.46	40.47
		SD	10.157	9.930
		Median	35.59	38.92
		Min	21.3	21.3
		Max	57.9	66.5
	Total Score Change from Baseline	n	64	66
		Mean	1.49	4.14
		SD	7.602	6.954
		Median	1.43	4.76
		Min	-14.3	-8.1
		Max	22.3	29.5
Week 36	Total Score	n	62	67
		Mean	37.33	39.50
		SD	10.331	9.996
		Median	35.59	36.54
		Min	19.0	23.7
		Max	64.1	66.5
	Total Score Change from Baseline	n	62	66
		Mean	1.19	3.12
		SD	8.083	6.668
		Median	0.00	2.38
		Min	-21.4	-15.2
		Max	24.7	22.4

Protocol: MEA115921
Population: Intent-to-Treat

Table 4.1
SF-36 Healthy Survey Domain Scores(Observed and Change from Baseline) by Visit

Domain: General Health(norm-based score)

Timepoint			Placebo (N=68)	Mepolizumab 300 mg SC (N=68)
Week 52	Total Score	n	61	65
		Mean	37.79	39.22
		SD	10.361	10.215
		Median	36.54	38.92
		Min	21.3	21.3
		Max	60.3	66.5
	Total Score Change from Baseline	n	61	64
		Mean	1.72	2.85
		SD	7.223	6.695
		Median	0.00	2.38
		Min	-12.8	-12.8
		Max	22.3	16.6

PPD

Protocol: MEA115921
Population: Intent-to-Treat

Table 4.1
SF-36 Healthy Survey Domain Scores(Observed and Change from Baseline) by Visit

Domain: Mental Health(0-100 score)

Timepoint			Placebo (N=68)	Mepolizumab 300 mg SC (N=68)
Baseline	Total Score	n	68	67
		Mean	72.50	72.31
		SD	19.365	17.781
		Median	75.00	75.00
		Min	20.0	25.0
		Max	100.0	100.0
Week 12	Total Score	n	67	67
		Mean	73.28	74.48
		SD	19.040	17.519
		Median	75.00	80.00
		Min	25.0	25.0
		Max	100.0	100.0
	Total Score Change from Baseline	n	67	66
		Mean	1.04	2.35
		SD	10.096	14.148
		Median	0.00	5.00
		Min	-15.0	-45.0
		Max	45.0	45.0

PPD

Protocol: MEA115921
Population: Intent-to-Treat

Table 4.1
SF-36 Healthy Survey Domain Scores(Observed and Change from Baseline) by Visit

Domain: Mental Health(0-100 score)

Timepoint			Placebo (N=68)	Mepolizumab 300 mg SC (N=68)
Week 24	Total Score	n	64	67
		Mean	74.84	75.07
		SD	17.705	16.663
		Median	80.00	80.00
		Min	25.0	20.0
		Max	100.0	100.0
	Total Score Change from Baseline	n	64	66
		Mean	1.88	2.58
		SD	10.856	12.897
		Median	0.00	0.00
		Min	-20.0	-25.0
		Max	35.0	40.0
Week 36	Total Score	n	62	66
		Mean	72.26	73.48
		SD	21.188	17.275
		Median	80.00	80.00
		Min	15.0	20.0
		Max	100.0	100.0
	Total Score Change from Baseline	n	62	65
		Mean	-0.73	1.31
		SD	13.515	13.672
		Median	0.00	0.00
		Min	-40.0	-30.0
		Max	35.0	40.0

Protocol: MEA115921
Population: Intent-to-Treat

Table 4.1
SF-36 Healthy Survey Domain Scores(Observed and Change from Baseline) by Visit

Domain: Mental Health(0-100 score)

Timepoint			Placebo (N=68)	Mepolizumab 300 mg SC (N=68)
Week 52	Total Score	n	61	64
		Mean	74.92	73.91
		SD	19.203	17.604
		Median	80.00	80.00
		Min	10.0	10.0
		Max	100.0	100.0
	Total Score Change from Baseline	n	61	63
		Mean	1.64	1.43
		SD	13.188	13.632
		Median	0.00	0.00
		Min	-30.0	-25.0
		Max	45.0	40.0

PPD

Protocol: MEA115921
Population: Intent-to-Treat

Table 4.1
SF-36 Healthy Survey Domain Scores(Observed and Change from Baseline) by Visit

Domain: Mental Health(norm-based score)

Timepoint			Placebo (N=68)	Mepolizumab 300 mg SC (N=68)
Baseline	Total Score	n	68	67
		Mean	49.56	49.46
		SD	10.133	9.303
		Median	50.87	50.87
		Min	22.1	24.7
		Max	64.0	64.0
Week 12	Total Score	n	67	67
		Mean	49.97	50.60
		SD	9.963	9.166
		Median	50.87	53.48
		Min	24.7	24.7
		Max	64.0	64.0
	Total Score Change from Baseline	n	67	66
		Mean	0.55	1.23
		SD	5.283	7.402
		Median	0.00	2.61
		Min	-7.9	-23.5
		Max	23.5	23.6

Protocol: MEA115921
Population: Intent-to-Treat

Table 4.1
SF-36 Healthy Survey Domain Scores(Observed and Change from Baseline) by Visit

Domain: Mental Health(norm-based score)

Timepoint			Placebo (N=68)	Mepolizumab 300 mg SC (N=68)
Week 24	Total Score	n	64	67
		Mean	50.79	50.91
		SD	9.264	8.718
		Median	53.48	53.48
		Min	24.7	22.1
		Max	64.0	64.0
	Total Score Change from Baseline	n	64	66
		Mean	0.98	1.35
		SD	5.680	6.748
		Median	0.00	0.00
		Min	-10.5	-13.1
		Max	18.3	20.9
Week 36	Total Score	n	62	66
		Mean	49.43	50.08
		SD	11.086	9.039
		Median	53.48	53.48
		Min	19.5	22.1
		Max	64.0	64.0
	Total Score Change from Baseline	n	62	65
		Mean	-0.38	0.68
		SD	7.072	7.154
		Median	0.00	0.00
		Min	-20.9	-15.7
		Max	18.3	20.9

PPD

Protocol: MEA115921
Population: Intent-to-Treat

Table 4.1
SF-36 Healthy Survey Domain Scores(Observed and Change from Baseline) by Visit

Domain: Mental Health(norm-based score)

Timepoint			Placebo (N=68)	Mepolizumab 300 mg SC (N=68)
Week 52	Total Score	n	61	64
		Mean	50.83	50.30
		SD	10.048	9.210
		Median	53.48	53.48
		Min	16.9	16.9
		Max	64.0	64.0
	Total Score Change from Baseline	n	61	63
		Mean	0.86	0.75
		SD	6.901	7.132
		Median	0.00	0.00
		Min	-15.7	-13.1
		Max	23.6	20.9

PPD

Protocol: MEA115921
Population: Intent-to-Treat

Table 4.1
SF-36 Healthy Survey Domain Scores(Observed and Change from Baseline) by Visit

Domain: Physical Functioning(0-100 score)

Timepoint			Placebo (N=68)	Mepolizumab 300 mg SC (N=68)
Baseline	Total Score	n	68	67
		Mean	64.12	62.09
		SD	25.900	25.601
		Median	65.01	65.01
		Min	5.0	10.0
		Max	100.0	100.0
Week 12	Total Score	n	68	68
		Mean	66.98	68.42
		SD	23.612	24.824
		Median	75.00	71.42
		Min	5.0	0.0
		Max	100.0	100.0
	Total Score Change from Baseline	n	68	67
		Mean	2.87	6.39
		SD	18.351	17.339
		Median	0.00	5.00
		Min	-65.0	-70.0
		Max	50.0	62.8

PPD

Protocol: MEA115921
Population: Intent-to-Treat

Table 4.1
SF-36 Healthy Survey Domain Scores(Observed and Change from Baseline) by Visit

Domain: Physical Functioning(0-100 score)

Timepoint			Placebo (N=68)	Mepolizumab 300 mg SC (N=68)
Week 24	Total Score	n	64	67
		Mean	68.20	70.04
		SD	23.844	24.451
		Median	70.00	75.00
		Min	5.0	15.0
		Max	100.0	100.0
	Total Score Change from Baseline	n	64	66
		Mean	3.83	8.52
		SD	21.264	15.651
		Median	0.00	5.00
		Min	-70.0	-25.0
		Max	70.0	45.0
Week 36	Total Score	n	62	67
		Mean	68.79	66.65
		SD	23.200	25.978
		Median	70.00	70.00
		Min	5.0	5.0
		Max	100.0	100.0
	Total Score Change from Baseline	n	62	66
		Mean	4.11	4.63
		SD	13.924	18.938
		Median	2.49	5.00
		Min	-25.0	-55.0
		Max	50.0	40.0

PPD

Protocol: MEA115921
Population: Intent-to-Treat

Table 4.1
SF-36 Healthy Survey Domain Scores(Observed and Change from Baseline) by Visit

Domain: Physical Functioning(0-100 score)

Timepoint			Placebo (N=68)	Mepolizumab 300 mg SC (N=68)
Week 52	Total Score	n	61	65
		Mean	68.69	70.13
		SD	24.763	22.617
		Median	75.00	75.00
		Min	10.0	20.0
		Max	100.0	100.0
	Total Score Change from Baseline	n	61	64
		Mean	3.77	7.40
		SD	16.141	15.318
		Median	0.00	5.00
		Min	-30.0	-15.0
		Max	55.0	52.2

PPD

Protocol: MEA115921
Population: Intent-to-Treat

Table 4.1
SF-36 Healthy Survey Domain Scores(Observed and Change from Baseline) by Visit

Domain: Physical Functioning(norm-based score)

Timepoint			Placebo (N=68)	Mepolizumab 300 mg SC (N=68)
Baseline	Total Score	n	68	67
		Mean	43.81	43.03
		SD	9.914	9.800
		Median	44.15	44.15
		Min	21.2	23.1
		Max	57.5	57.5
Week 12	Total Score	n	68	68
		Mean	44.90	45.45
		SD	9.038	9.502
		Median	47.97	46.60
		Min	21.2	19.3
		Max	57.5	57.5
	Total Score Change from Baseline	n	68	67
		Mean	1.10	2.44
		SD	7.024	6.637
		Median	0.00	1.92
		Min	-24.9	-26.8
		Max	19.1	24.1

PPD

Protocol: MEA115921
Population: Intent-to-Treat

Table 4.1
SF-36 Healthy Survey Domain Scores(Observed and Change from Baseline) by Visit

Domain: Physical Functioning(norm-based score)

Timepoint			Placebo (N=68)	Mepolizumab 300 mg SC (N=68)
Week 24	Total Score	n	64	67
		Mean	45.37	46.07
		SD	9.126	9.359
		Median	46.06	47.97
		Min	21.2	25.0
		Max	57.5	57.5
	Total Score Change from Baseline	n	64	66
		Mean	1.47	3.26
		SD	8.139	5.990
		Median	0.00	1.91
		Min	-26.8	-9.6
		Max	26.8	17.2
Week 36	Total Score	n	62	67
		Mean	45.59	44.78
		SD	8.880	9.943
		Median	46.06	46.06
		Min	21.2	21.2
		Max	57.5	57.5
	Total Score Change from Baseline	n	62	66
		Mean	1.57	1.77
		SD	5.329	7.249
		Median	0.95	1.91
		Min	-9.6	-21.1
		Max	19.1	15.3

Protocol: MEA115921
Population: Intent-to-Treat

Table 4.1
SF-36 Healthy Survey Domain Scores(Observed and Change from Baseline) by Visit

Domain: Physical Functioning(norm-based score)

Timepoint			Placebo (N=68)	Mepolizumab 300 mg SC (N=68)
Week 52	Total Score	n	61	65
		Mean	45.56	46.11
		SD	9.479	8.657
		Median	47.97	47.97
		Min	23.1	26.9
		Max	57.5	57.5
	Total Score Change from Baseline	n	61	64
		Mean	1.44	2.83
		SD	6.178	5.863
		Median	0.00	1.91
		Min	-11.5	-5.7
		Max	21.1	20.0

PPD

Protocol: MEA115921
Population: Intent-to-Treat

Table 4.1
SF-36 Healthy Survey Domain Scores(Observed and Change from Baseline) by Visit

Domain: Role Emotional(0-100 score)

Timepoint			Placebo (N=68)	Mepolizumab 300 mg SC (N=68)
Baseline	Total Score	n	68	67
		Mean	83.33	77.86
		SD	21.258	24.556
		Median	91.67	91.67
		Min	25.0	25.0
		Max	100.0	100.0
Week 12	Total Score	n	67	68
		Mean	84.08	83.82
		SD	21.602	21.543
		Median	100.00	91.67
		Min	25.0	16.7
		Max	100.0	100.0
	Total Score Change from Baseline	n	67	67
		Mean	0.75	6.09
		SD	18.449	22.825
		Median	0.00	0.00
		Min	-66.7	-58.3
		Max	41.7	58.3

PPD

Protocol: MEA115921
Population: Intent-to-Treat

Table 4.1
SF-36 Healthy Survey Domain Scores(Observed and Change from Baseline) by Visit

Domain: Role Emotional(0-100 score)

Timepoint			Placebo (N=68)	Mepolizumab 300 mg SC (N=68)
Week 24	Total Score	n	64	67
		Mean	82.16	84.08
		SD	22.560	18.449
		Median	91.67	91.67
		Min	0.0	33.3
		Max	100.0	100.0
	Total Score Change from Baseline	n	64	66
		Mean	-0.78	6.19
		SD	21.959	21.399
		Median	0.00	0.00
		Min	-91.7	-41.7
		Max	58.3	50.0
Week 36	Total Score	n	62	66
		Mean	82.80	83.96
		SD	24.511	19.845
		Median	100.00	91.67
		Min	0.0	8.3
		Max	100.0	100.0
	Total Score Change from Baseline	n	62	65
		Mean	-0.40	5.64
		SD	18.322	21.046
		Median	0.00	0.00
		Min	-41.7	-58.3
		Max	75.0	50.0

PPD

Protocol: MEA115921
Population: Intent-to-Treat

Table 4.1
SF-36 Healthy Survey Domain Scores(Observed and Change from Baseline) by Visit

Domain: Role Emotional(0-100 score)

Timepoint			Placebo (N=68)	Mepolizumab 300 mg SC (N=68)
Week 52	Total Score	n	61	65
		Mean	82.10	77.44
		SD	25.902	22.328
		Median	100.00	83.33
		Min	8.3	16.7
		Max	100.0	100.0
	Total Score Change from Baseline	n	61	64
		Mean	-0.82	-1.04
		SD	19.762	23.687
		Median	0.00	0.00
		Min	-50.0	-66.7
		Max	75.0	50.0

PPD

Protocol: MEA115921
Population: Intent-to-Treat

Table 4.1
SF-36 Healthy Survey Domain Scores(Observed and Change from Baseline) by Visit

Domain: Role Emotional(norm-based score)

Timepoint			Placebo (N=68)	Mepolizumab 300 mg SC (N=68)
Baseline	Total Score	n	68	67
		Mean	49.21	46.92
		SD	8.883	10.260
		Median	52.69	52.69
		Min	24.8	24.8
		Max	56.2	56.2
Week 12	Total Score	n	67	68
		Mean	49.52	49.41
		SD	9.026	9.002
		Median	56.17	52.69
		Min	24.8	21.4
		Max	56.2	56.2
	Total Score Change from Baseline	n	67	67
		Mean	0.31	2.55
		SD	7.709	9.537
		Median	0.00	0.00
		Min	-27.9	-24.4
		Max	17.4	24.4

PPD

Protocol: MEA115921
Population: Intent-to-Treat

Table 4.1
SF-36 Healthy Survey Domain Scores(Observed and Change from Baseline) by Visit

Domain: Role Emotional(norm-based score)

Timepoint			Placebo (N=68)	Mepolizumab 300 mg SC (N=68)
Week 24	Total Score	n	64	67
		Mean	48.72	49.52
		SD	9.427	7.709
		Median	52.69	52.69
		Min	14.4	28.3
		Max	56.2	56.2
	Total Score Change from Baseline	n	64	66
		Mean	-0.33	2.58
		SD	9.176	8.941
		Median	0.00	0.00
		Min	-38.3	-17.4
		Max	24.4	20.9
Week 36	Total Score	n	62	66
		Mean	48.98	49.47
		SD	10.242	8.292
		Median	56.17	52.69
		Min	14.4	17.9
		Max	56.2	56.2
	Total Score Change from Baseline	n	62	65
		Mean	-0.17	2.36
		SD	7.656	8.794
		Median	0.00	0.00
		Min	-17.4	-24.4
		Max	31.3	20.9

PPD

Protocol: MEA115921
Population: Intent-to-Treat

Table 4.1
SF-36 Healthy Survey Domain Scores(Observed and Change from Baseline) by Visit

Domain: Role Emotional(norm-based score)

Timepoint			Placebo (N=68)	Mepolizumab 300 mg SC (N=68)
Week 52	Total Score	n	61	65
		Mean	48.69	46.74
		SD	10.823	9.330
		Median	56.17	49.20
		Min	17.9	21.4
		Max	56.2	56.2
	Total Score Change from Baseline	n	61	64
		Mean	-0.34	-0.44
		SD	8.258	9.897
		Median	0.00	0.00
		Min	-20.9	-27.9
		Max	31.3	20.9

PPD

Protocol: MEA115921
Population: Intent-to-Treat

Table 4.1
SF-36 Healthy Survey Domain Scores(Observed and Change from Baseline) by Visit

Domain: Role Physical(0-100 score)

Timepoint			Placebo (N=68)	Mepolizumab 300 mg SC (N=68)
Baseline	Total Score	n	68	67
		Mean	59.38	57.93
		SD	30.590	32.157
		Median	68.75	56.25
		Min	0.0	0.0
		Max	100.0	100.0
Week 12	Total Score	n	68	68
		Mean	66.18	64.61
		SD	27.087	30.706
		Median	75.00	75.00
		Min	0.0	0.0
		Max	100.0	100.0
	Total Score Change from Baseline	n	68	67
		Mean	6.80	7.00
		SD	22.567	23.600
		Median	6.25	0.00
		Min	-56.3	-75.0
		Max	75.0	81.3

PPD

Protocol: MEA115921
Population: Intent-to-Treat

Table 4.1
SF-36 Healthy Survey Domain Scores(Observed and Change from Baseline) by Visit

Domain: Role Physical(0-100 score)

Timepoint			Placebo (N=68)	Mepolizumab 300 mg SC (N=68)
Week 24	Total Score	n	64	67
		Mean	65.72	67.16
		SD	26.957	27.488
		Median	71.88	75.00
		Min	0.0	0.0
		Max	100.0	100.0
	Total Score Change from Baseline	n	64	66
		Mean	6.54	9.38
		SD	23.895	26.317
		Median	0.00	6.25
		Min	-56.3	-100.0
		Max	87.5	75.0
Week 36	Total Score	n	62	66
		Mean	65.22	63.26
		SD	29.350	30.273
		Median	71.88	68.75
		Min	0.0	0.0
		Max	100.0	100.0
	Total Score Change from Baseline	n	62	65
		Mean	5.44	5.38
		SD	26.768	22.149
		Median	6.25	6.25
		Min	-68.8	-75.0
		Max	75.0	75.0

Protocol: MEA115921
Population: Intent-to-Treat

Table 4.1
SF-36 Healthy Survey Domain Scores(Observed and Change from Baseline) by Visit

Domain: Role Physical(0-100 score)

Timepoint			Placebo (N=68)	Mepolizumab 300 mg SC (N=68)
Week 52	Total Score	n	61	65
		Mean	65.37	61.63
		SD	28.173	27.240
		Median	68.75	62.50
		Min	0.0	6.3
		Max	100.0	100.0
	Total Score Change from Baseline	n	61	64
		Mean	5.02	2.93
		SD	25.254	24.599
		Median	0.00	6.25
		Min	-62.5	-87.5
		Max	87.5	62.5

PPD

Protocol: MEA115921
Population: Intent-to-Treat

Table 4.1
SF-36 Healthy Survey Domain Scores(Observed and Change from Baseline) by Visit

Domain: Role Physical(norm-based score)

Timepoint			Placebo (N=68)	Mepolizumab 300 mg SC (N=68)
Baseline	Total Score	n	68	67
		Mean	42.56	42.04
		SD	10.991	11.554
		Median	45.93	41.44
		Min	21.2	21.2
		Max	57.2	57.2
Week 12	Total Score	n	68	68
		Mean	45.00	44.44
		SD	9.732	11.033
		Median	48.17	48.17
		Min	21.2	21.2
		Max	57.2	57.2
	Total Score Change from Baseline	n	68	67
		Mean	2.44	2.51
		SD	8.108	8.479
		Median	2.25	0.00
		Min	-20.2	-27.0
		Max	26.9	29.2

PPD

Protocol: MEA115921
Population: Intent-to-Treat

Table 4.1
SF-36 Healthy Survey Domain Scores(Observed and Change from Baseline) by Visit

Domain: Role Physical(norm-based score)

Timepoint			Placebo (N=68)	Mepolizumab 300 mg SC (N=68)
Week 24	Total Score	n	64	67
		Mean	44.84	45.36
		SD	9.685	9.877
		Median	47.05	48.17
		Min	21.2	21.2
		Max	57.2	57.2
	Total Score Change from Baseline	n	64	66
		Mean	2.35	3.37
		SD	8.585	9.455
		Median	0.00	2.25
		Min	-20.2	-35.9
		Max	31.4	26.9
Week 36	Total Score	n	62	66
		Mean	44.66	43.96
		SD	10.545	10.877
		Median	47.05	45.93
		Min	21.2	21.2
		Max	57.2	57.2
	Total Score Change from Baseline	n	62	65
		Mean	1.96	1.93
		SD	9.617	7.958
		Median	2.25	2.24
		Min	-24.7	-27.0
		Max	27.0	26.9

PPD

Protocol: MEA115921
Population: Intent-to-Treat

Table 4.1
SF-36 Healthy Survey Domain Scores(Observed and Change from Baseline) by Visit

Domain: Role Physical(norm-based score)

Timepoint			Placebo (N=68)	Mepolizumab 300 mg SC (N=68)
Week 52	Total Score	n	61	65
		Mean	44.71	43.37
		SD	10.122	9.787
		Median	45.93	43.68
		Min	21.2	23.5
		Max	57.2	57.2
	Total Score Change from Baseline	n	61	64
		Mean	1.80	1.05
		SD	9.074	8.837
		Median	0.00	2.25
		Min	-22.5	-31.4
		Max	31.4	22.5

PPD

Protocol: MEA115921
Population: Intent-to-Treat

Table 4.1
SF-36 Healthy Survey Domain Scores(Observed and Change from Baseline) by Visit

Domain: Social Functioning(0-100 score)

Timepoint			Placebo (N=68)	Mepolizumab 300 mg SC (N=68)
Baseline	Total Score	n	68	67
		Mean	72.43	66.23
		SD	28.205	27.266
		Median	75.00	62.50
		Min	0.0	0.0
		Max	100.0	100.0
Week 12	Total Score	n	67	68
		Mean	74.63	74.63
		SD	25.092	24.046
		Median	75.00	75.00
		Min	0.0	12.5
		Max	100.0	100.0
	Total Score Change from Baseline	n	67	67
		Mean	1.68	8.58
		SD	20.049	24.153
		Median	0.00	0.00
		Min	-50.0	-37.5
		Max	50.0	75.0

PPD

Protocol: MEA115921
Population: Intent-to-Treat

Table 4.1
SF-36 Healthy Survey Domain Scores(Observed and Change from Baseline) by Visit

Domain: Social Functioning(0-100 score)

Timepoint			Placebo (N=68)	Mepolizumab 300 mg SC (N=68)
Week 24	Total Score	n	64	67
		Mean	72.27	72.57
		SD	26.113	25.023
		Median	75.00	75.00
		Min	0.0	12.5
		Max	100.0	100.0
	Total Score Change from Baseline	n	64	66
		Mean	0.00	6.25
		SD	20.534	26.243
		Median	0.00	0.00
		Min	-50.0	-62.5
		Max	50.0	100.0
Week 36	Total Score	n	62	66
		Mean	73.99	70.45
		SD	24.825	26.003
		Median	75.00	75.00
		Min	0.0	0.0
		Max	100.0	100.0
	Total Score Change from Baseline	n	62	65
		Mean	1.61	4.42
		SD	19.665	27.549
		Median	0.00	0.00
		Min	-50.0	-50.0
		Max	50.0	75.0

PPD

Protocol: MEA115921
Population: Intent-to-Treat

Table 4.1
SF-36 Healthy Survey Domain Scores(Observed and Change from Baseline) by Visit

Domain: Social Functioning(0-100 score)

Timepoint			Placebo (N=68)	Mepolizumab 300 mg SC (N=68)
Week 52	Total Score	n	61	65
		Mean	77.87	71.54
		SD	26.060	25.912
		Median	87.50	75.00
		Min	0.0	12.5
		Max	100.0	100.0
	Total Score Change from Baseline	n	61	64
		Mean	5.33	4.69
		SD	20.598	26.305
		Median	0.00	0.00
		Min	-37.5	-62.5
		Max	62.5	75.0

PPD

Protocol: MEA115921
Population: Intent-to-Treat

Table 4.1
SF-36 Healthy Survey Domain Scores(Observed and Change from Baseline) by Visit

Domain: Social Functioning(norm-based score)

Timepoint			Placebo (N=68)	Mepolizumab 300 mg SC (N=68)
Baseline	Total Score	n	68	67
		Mean	46.28	43.80
		SD	11.312	10.935
		Median	47.31	42.30
		Min	17.2	17.2
		Max	57.3	57.3
Week 12	Total Score	n	67	68
		Mean	47.16	47.17
		SD	10.064	9.644
		Median	47.31	47.31
		Min	17.2	22.3
		Max	57.3	57.3
	Total Score Change from Baseline	n	67	67
		Mean	0.67	3.44
		SD	8.041	9.687
		Median	0.00	0.00
		Min	-20.1	-15.0
		Max	20.1	30.1

PPD

Protocol: MEA115921
Population: Intent-to-Treat

Table 4.1
SF-36 Healthy Survey Domain Scores(Observed and Change from Baseline) by Visit

Domain: Social Functioning(norm-based score)

Timepoint			Placebo (N=68)	Mepolizumab 300 mg SC (N=68)
Week 24	Total Score	n	64	67
		Mean	46.22	46.34
		SD	10.473	10.035
		Median	47.31	47.31
		Min	17.2	22.3
		Max	57.3	57.3
	Total Score Change from Baseline	n	64	66
		Mean	0.00	2.51
		SD	8.235	10.525
		Median	0.00	0.00
		Min	-20.1	-25.1
		Max	20.1	40.1
Week 36	Total Score	n	62	66
		Mean	46.91	45.49
		SD	9.957	10.429
		Median	47.31	47.31
		Min	17.2	17.2
		Max	57.3	57.3
	Total Score Change from Baseline	n	62	65
		Mean	0.65	1.77
		SD	7.886	11.049
		Median	0.00	0.00
		Min	-20.1	-20.1
		Max	20.1	30.1

Protocol: MEA115921
Population: Intent-to-Treat

Table 4.1
SF-36 Healthy Survey Domain Scores(Observed and Change from Baseline) by Visit

Domain: Social Functioning(norm-based score)

Timepoint			Placebo (N=68)	Mepolizumab 300 mg SC (N=68)
Week 52	Total Score	n	61	65
		Mean	48.46	45.92
		SD	10.452	10.392
		Median	52.33	47.31
		Min	17.2	22.3
		Max	57.3	57.3
	Total Score Change from Baseline	n	61	64
		Mean	2.14	1.88
		SD	8.261	10.550
		Median	0.00	0.00
		Min	-15.0	-25.1
		Max	25.1	30.1

PPD

Protocol: MEA115921
Population: Intent-to-Treat

Table 4.1
SF-36 Healthy Survey Domain Scores(Observed and Change from Baseline) by Visit

Domain: Vitality(0-100 score)

Timepoint			Placebo (N=68)	Mepolizumab 300 mg SC (N=68)
Baseline	Total Score	n	68	67
		Mean	48.90	46.83
		SD	21.378	21.851
		Median	50.00	43.75
		Min	0.0	6.3
		Max	81.3	87.5
Week 12	Total Score	n	67	67
		Mean	50.47	49.07
		SD	21.162	21.020
		Median	56.25	50.00
		Min	0.0	0.0
		Max	87.5	87.5
	Total Score Change from Baseline	n	67	66
		Mean	1.68	2.27
		SD	13.217	15.057
		Median	0.00	0.00
		Min	-25.0	-31.3
		Max	37.5	50.0

PPD

Protocol: MEA115921
Population: Intent-to-Treat

Table 4.1
SF-36 Healthy Survey Domain Scores(Observed and Change from Baseline) by Visit

Domain: Vitality(0-100 score)

Timepoint			Placebo (N=68)	Mepolizumab 300 mg SC (N=68)
Week 24	Total Score	n	64	67
		Mean	50.10	50.28
		SD	21.114	19.717
		Median	56.25	50.00
		Min	0.0	6.3
		Max	81.3	100.0
	Total Score Change from Baseline	n	64	66
		Mean	1.46	3.31
		SD	16.879	16.992
		Median	0.00	6.25
		Min	-37.5	-37.5
		Max	62.5	50.0
Week 36	Total Score	n	62	66
		Mean	49.03	50.47
		SD	21.402	20.284
		Median	56.25	56.25
		Min	0.0	6.3
		Max	87.5	100.0
	Total Score Change from Baseline	n	62	65
		Mean	1.04	3.65
		SD	14.894	15.185
		Median	0.00	0.00
		Min	-31.3	-25.0
		Max	37.5	43.8

Protocol: MEA115921
Population: Intent-to-Treat

Table 4.1
SF-36 Healthy Survey Domain Scores(Observed and Change from Baseline) by Visit

Domain: Vitality(0-100 score)

Timepoint			Placebo (N=68)	Mepolizumab 300 mg SC (N=68)
Week 52	Total Score	n	61	64
		Mean	51.33	48.73
		SD	23.444	20.173
		Median	56.25	53.13
		Min	0.0	0.0
		Max	87.5	100.0
	Total Score Change from Baseline	n	61	63
		Mean	2.77	1.39
		SD	17.174	15.450
		Median	0.00	0.00
		Min	-31.3	-25.0
		Max	62.5	50.0

PPD

Protocol: MEA115921
Population: Intent-to-Treat

Table 4.1
SF-36 Healthy Survey Domain Scores(Observed and Change from Baseline) by Visit

Domain: Vitality(norm-based score)

Timepoint			Placebo (N=68)	Mepolizumab 300 mg SC (N=68)
Baseline	Total Score	n	68	67
		Mean	46.13	45.15
		SD	10.162	10.387
		Median	46.66	43.69
		Min	22.9	25.9
		Max	61.5	64.5
Week 12	Total Score	n	67	67
		Mean	46.88	46.21
		SD	10.059	9.992
		Median	49.63	46.66
		Min	22.9	22.9
		Max	64.5	64.5
	Total Score Change from Baseline	n	67	66
		Mean	0.80	1.08
		SD	6.282	7.159
		Median	0.00	0.00
		Min	-11.9	-14.9
		Max	17.8	23.8

PPD

Protocol: MEA115921
Population: Intent-to-Treat

Table 4.1
SF-36 Healthy Survey Domain Scores(Observed and Change from Baseline) by Visit

Domain: Vitality(norm-based score)

Timepoint			Placebo (N=68)	Mepolizumab 300 mg SC (N=68)
Week 24	Total Score	n	64	67
		Mean	46.70	46.79
		SD	10.037	9.372
		Median	49.63	46.66
		Min	22.9	25.9
		Max	61.5	70.4
	Total Score Change from Baseline	n	64	66
		Mean	0.70	1.58
		SD	8.023	8.077
		Median	0.00	2.97
		Min	-17.8	-17.8
		Max	29.7	23.8
Week 36	Total Score	n	62	66
		Mean	46.20	46.88
		SD	10.173	9.642
		Median	49.63	49.63
		Min	22.9	25.9
		Max	64.5	70.4
	Total Score Change from Baseline	n	62	65
		Mean	0.50	1.74
		SD	7.079	7.219
		Median	0.00	0.00
		Min	-14.9	-11.9
		Max	17.8	20.8

PPD

Protocol: MEA115921
Population: Intent-to-Treat

Table 4.1
SF-36 Healthy Survey Domain Scores(Observed and Change from Baseline) by Visit

Domain: Vitality(norm-based score)

Timepoint			Placebo (N=68)	Mepolizumab 300 mg SC (N=68)
Week 52	Total Score	n	61	64
		Mean	47.29	46.05
		SD	11.144	9.590
		Median	49.63	48.15
		Min	22.9	22.9
		Max	64.5	70.4
	Total Score Change from Baseline	n	61	63
		Mean	1.32	0.66
		SD	8.163	7.345
		Median	0.00	0.00
		Min	-14.9	-11.9
		Max	29.7	23.8

PPD

Protocol: MEA115921
Population: Intent-to-Treat

Table 7.1
Analysis of Change from Baseline in SF-36 Domain Score (0-100 score):
Bodily Pain
(Mixed Model Repeated Measures)

Visit: Week 12

	Placebo (N=68)	Mepolizumab 300 mg SC (N=68)
n [1]	68	67
n [2]	67	67
LS Mean (SE)	66.32 (2.445)	70.94 (2.451)
LS Mean Change (SE)	-0.43 (2.445)	4.18 (2.451)
Mepolizumab 300 mg SC vs Placebo		
Difference (Mepo - Placebo)		4.61
95% CI		(-2.23, 11.46)
p-value		0.185
Corrected Hedges g [3]		0.23
95% CI		(-0.11, 0.57)

[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] Derived from LS means and associated SE.
Note: Analysis performed using mixed model repeated measures with covariates of baseline bodily pain score, baseline prednisolone/prednisone daily dose, region (EU vs. RoW), treatment and visit, plus interaction terms for visit-by-baseline and visit-by-treatment group. LS mean estimates are weighted according to the observed proportions of each categorical covariate in the study data.

PPD

Population: Intent-to-Treat

Table 7.1
Analysis of Change from Baseline in SF-36 Domain Score (0-100 score):
Bodily Pain
(Mixed Model Repeated Measures)

Visit: Week 24

	Placebo (N=68)	Mepolizumab 300 mg SC (N=68)
n [1]	68	67
n [2]	64	66
LS Mean (SE)	65.10 (2.702)	66.31 (2.679)
LS Mean Change (SE)	-1.66 (2.702)	-0.45 (2.679)
Mepolizumab 300 mg SC vs Placebo		
Difference (Mepo - Placebo)		1.21
95% CI		(-6.32, 8.74)
p-value		0.751
Corrected Hedges g [3]		0.06
95% CI		(-0.29, 0.40)

[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] Derived from LS means and associated SE.
Note: Analysis performed using mixed model repeated measures with covariates of baseline bodily pain score, baseline prednisolone/prednisone daily dose, region (EU vs. RoW), treatment and visit, plus interaction terms for visit-by-baseline and visit-by-treatment group. LS mean estimates are weighted according to the observed proportions of each categorical covariate in the study data.

PPD

Population: Intent-to-Treat

Table 7.1
Analysis of Change from Baseline in SF-36 Domain Score (0-100 score): Bodily Pain
(Mixed Model Repeated Measures)

Visit: Week 36

	Placebo (N=68)	Mepolizumab 300 mg SC (N=68)
n [1]	68	67
n [2]	62	65
LS Mean (SE)	62.29 (2.583)	68.01 (2.528)
LS Mean Change (SE)	-4.47 (2.583)	1.26 (2.528)
Mepolizumab 300 mg SC vs Placebo		
Difference (Mepo - Placebo)		5.72
95% CI		(-1.43, 12.88)
p-value		0.116
Corrected Hedges g [3]		0.28
95% CI		(-0.07, 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] Derived from LS means and associated SE.
Note: Analysis performed using mixed model repeated measures with covariates of baseline bodily pain score, baseline prednisolone/prednisone daily dose, region (EU vs. RoW), treatment and visit, plus interaction terms for visit-by-baseline and visit-by-treatment group. LS mean estimates are weighted according to the observed proportions of each categorical covariate in the study data.

PPD

Protocol: MEA115921
Population: Intent-to-Treat

Table 7.1
Analysis of Change from Baseline in SF-36 Domain Score (0-100 score): Bodily Pain
(Mixed Model Repeated Measures)

Visit: Week 52

	Placebo (N=68)	Mepolizumab 300 mg SC (N=68)
n [1]	68	67
n [2]	61	64
LS Mean (SE)	67.29 (2.418)	64.62 (2.368)
LS Mean Change (SE)	0.53 (2.418)	-2.14 (2.368)
Mepolizumab 300 mg SC vs Placebo		
Difference (Mepo - Placebo)		-2.67
95% CI		(-9.37, 4.04)
p-value		0.432
Corrected Hedges g [3]		-0.14
95% CI		(-0.49, 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] Derived from LS means and associated SE.
Note: Analysis performed using mixed model repeated measures with covariates of baseline bodily pain score, baseline prednisolone/prednisone daily dose, region (EU vs. RoW), treatment and visit, plus interaction terms for visit-by-baseline and visit-by-treatment group. LS mean estimates are weighted according to the observed proportions of each categorical covariate in the study data.

PPD

Protocol: MEA115921
Population: Intent-to-Treat

Table 7.2
Analysis of Change from Baseline in SF-36 Domain Score (0-100 score):
General Health
(Mixed Model Repeated Measures)

Visit: Week 12

	Placebo (N=68)	Mepolizumab 300 mg SC (N=68)
n [1]	68	67
n [2]	68	67
LS Mean (SE)	39.18 (1.438)	43.77 (1.449)
LS Mean Change (SE)	2.96 (1.438)	7.55 (1.449)
Mepolizumab 300 mg SC vs Placebo		
Difference (Mepo - Placebo)		4.59
95% CI		(0.55, 8.63)
p-value		0.026
Corrected Hedges g [3]		0.38
95% CI		(0.04, 0.73)

[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] Derived from LS means and associated SE.
Note: Analysis performed using mixed model repeated measures with covariates of baseline general health score, baseline prednisolone/prednisone daily dose, region (EU vs. RoW), treatment and visit, plus interaction terms for visit-by-baseline and visit-by-treatment group. LS mean estimates are weighted according to the observed proportions of each categorical covariate in the study data.

PPD

Protocol: MEA115921
Population: Intent-to-Treat

Table 7.2
Analysis of Change from Baseline in SF-36 Domain Score (0-100 score):
General Health
(Mixed Model Repeated Measures)

Visit: Week 24

	Placebo (N=68)	Mepolizumab 300 mg SC (N=68)
n [1]	68	67
n [2]	64	66
LS Mean (SE)	39.06 (1.793)	45.00 (1.776)
LS Mean Change (SE)	2.84 (1.793)	8.78 (1.776)
Mepolizumab 300 mg SC vs Placebo		
Difference (Mepo - Placebo)		5.94
95% CI		(0.95, 10.93)
p-value		0.020
Corrected Hedges g [3]		0.41
95% CI		(0.06, 0.76)

[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] Derived from LS means and associated SE.
Note: Analysis performed using mixed model repeated measures with covariates of baseline general health score, baseline prednisolone/prednisone daily dose, region (EU vs. RoW), treatment and visit, plus interaction terms for visit-by-baseline and visit-by-treatment group. LS mean estimates are weighted according to the observed proportions of each categorical covariate in the study data.

PPD

Population: Intent-to-Treat

Table 7.2
Analysis of Change from Baseline in SF-36 Domain Score (0-100 score):
General Health
(Mixed Model Repeated Measures)

Visit: Week 36

	Placebo (N=68)	Mepolizumab 300 mg SC (N=68)
n [1]	68	67
n [2]	62	66
LS Mean (SE)	38.83 (1.840)	42.85 (1.803)
LS Mean Change (SE)	2.60 (1.840)	6.62 (1.803)
Mepolizumab 300 mg SC vs Placebo		
Difference (Mepo - Placebo)		4.02
95% CI		(-1.08, 9.12)
p-value		0.121
Corrected Hedges g [3]		0.27
95% CI		(-0.07, 0.62)

[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] Derived from LS means and associated SE.
Note: Analysis performed using mixed model repeated measures with covariates of baseline general health score, baseline prednisolone/prednisone daily dose, region (EU vs. RoW), treatment and visit, plus interaction terms for visit-by-baseline and visit-by-treatment group. LS mean estimates are weighted according to the observed proportions of each categorical covariate in the study data.

PPD

Population: Intent-to-Treat

Table 7.2
Analysis of Change from Baseline in SF-36 Domain Score (0-100 score):
General Health
(Mixed Model Repeated Measures)

Visit: Week 52

	Placebo (N=68)	Mepolizumab 300 mg SC (N=68)
n [1]	68	67
n [2]	61	64
LS Mean (SE)	39.77 (1.756)	42.11 (1.729)
LS Mean Change (SE)	3.55 (1.756)	5.89 (1.729)
Mepolizumab 300 mg SC vs Placebo		
Difference (Mepo - Placebo)		2.34
95% CI		(-2.54, 7.22)
p-value		0.345
Corrected Hedges g [3]		0.17
95% CI		(-0.18, 0.52)

[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] Derived from LS means and associated SE.
Note: Analysis performed using mixed model repeated measures with covariates of baseline general health score, baseline prednisolone/prednisone daily dose, region (EU vs. RoW), treatment and visit, plus interaction terms for visit-by-baseline and visit-by-treatment group. LS mean estimates are weighted according to the observed proportions of each categorical covariate in the study data.

PPD

Protocol: MEA115921
Population: Intent-to-Treat

Table 7.3
Analysis of Change from Baseline in SF-36 Domain Score (0-100 score): Mental Health
(Mixed Model Repeated Measures)

Visit: Week 12

	Placebo (N=68)	Mepolizumab 300 mg SC (N=68)
n [1]	68	67
n [2]	67	66
LS Mean (SE)	73.56 (1.408)	74.86 (1.418)
LS Mean Change (SE)	0.97 (1.408)	2.27 (1.418)
Mepolizumab 300 mg SC vs Placebo		
Difference (Mepo - Placebo)		1.30
95% CI		(-2.65, 5.25)
p-value		0.517
Corrected Hedges g [3]		0.11
95% CI		(-0.23, 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] Derived from LS means and associated SE.
Note: Analysis performed using mixed model repeated measures with covariates of baseline mental health score, baseline prednisolone/prednisone daily dose, region (EU vs. RoW), treatment and visit, plus interaction terms for visit-by-baseline and visit-by-treatment group. LS mean estimates are weighted according to the observed proportions of each categorical covariate in the study data.

PPD

Population: Intent-to-Treat

Table 7.3
Analysis of Change from Baseline in SF-36 Domain Score (0-100 score): Mental Health
(Mixed Model Repeated Measures)

Visit: Week 24

	Placebo (N=68)	Mepolizumab 300 mg SC (N=68)
n [1]	68	67
n [2]	64	66
LS Mean (SE)	74.63 (1.348)	75.07 (1.330)
LS Mean Change (SE)	2.04 (1.348)	2.48 (1.330)
Mepolizumab 300 mg SC vs Placebo		
Difference (Mepo - Placebo)		0.44
95% CI		(-3.31, 4.19)
p-value		0.816
Corrected Hedges g [3]		0.04
95% CI		(-0.30, 0.38)

[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] Derived from LS means and associated SE.
Note: Analysis performed using mixed model repeated measures with covariates of baseline mental health score, baseline prednisolone/prednisone daily dose, region (EU vs. RoW), treatment and visit, plus interaction terms for visit-by-baseline and visit-by-treatment group. LS mean estimates are weighted according to the observed proportions of each categorical covariate in the study data.

PPD

Protocol: MEA115921
Population: Intent-to-Treat

Table 7.3
Analysis of Change from Baseline in SF-36 Domain Score (0-100 score): Mental Health
(Mixed Model Repeated Measures)

Visit: Week 36

	Placebo (N=68)	Mepolizumab 300 mg SC (N=68)
n [1]	68	67
n [2]	62	65
LS Mean (SE)	72.28 (1.641)	73.78 (1.607)
LS Mean Change (SE)	-0.31 (1.641)	1.19 (1.607)
Mepolizumab 300 mg SC vs Placebo		
Difference (Mepo - Placebo)		1.50
95% CI		(-3.05, 6.05)
p-value		0.515
Corrected Hedges g [3]		0.12
95% CI		(-0.23, 0.46)

[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] Derived from LS means and associated SE.
Note: Analysis performed using mixed model repeated measures with covariates of baseline mental health score, baseline prednisolone/prednisone daily dose, region (EU vs. RoW), treatment and visit, plus interaction terms for visit-by-baseline and visit-by-treatment group. LS mean estimates are weighted according to the observed proportions of each categorical covariate in the study data.

PPD

Population: Intent-to-Treat

Table 7.3
Analysis of Change from Baseline in SF-36 Domain Score (0-100 score): Mental Health
(Mixed Model Repeated Measures)

Visit: Week 52

	Placebo (N=68)	Mepolizumab 300 mg SC (N=68)
n [1]	68	67
n [2]	61	63
LS Mean (SE)	75.03 (1.586)	73.98 (1.559)
LS Mean Change (SE)	2.44 (1.586)	1.39 (1.559)
Mepolizumab 300 mg SC vs Placebo		
Difference (Mepo - Placebo)		-1.05
95% CI		(-5.45, 3.35)
p-value		0.638
Corrected Hedges g [3]		-0.08
95% CI		(-0.44, 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] Derived from LS means and associated SE.
Note: Analysis performed using mixed model repeated measures with covariates of baseline mental health score, baseline prednisolone/prednisone daily dose, region (EU vs. RoW), treatment and visit, plus interaction terms for visit-by-baseline and visit-by-treatment group. LS mean estimates are weighted according to the observed proportions of each categorical covariate in the study data.

PPD

Population: Intent-to-Treat

Table 7.4
Analysis of Change from Baseline in SF-36 Domain Score (0-100 score): Physical Functioning
(Mixed Model Repeated Measures)

Visit: Week 12

	Placebo (N=68)	Mepolizumab 300 mg SC (N=68)
n [1]	68	67
n [2]	68	67
LS Mean (SE)	66.39 (1.974)	69.34 (1.990)
LS Mean Change (SE)	3.11 (1.974)	6.06 (1.990)
Mepolizumab 300 mg SC vs Placebo		
Difference (Mepo - Placebo)		2.95
95% CI		(-2.60, 8.49)
p-value		0.295
Corrected Hedges g [3]		0.18
95% CI		(-0.16, 0.52)

[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] Derived from LS means and associated SE.
Note: Analysis performed using mixed model repeated measures with covariates of baseline physical functioning score, baseline prednisolone/prednisone daily dose, region (EU vs. RoW), treatment and visit, plus interaction terms for visit-by-baseline and visit-by-treatment group. LS mean estimates are weighted according to the observed proportions of each categorical covariate in the study data.

PPD

Population: Intent-to-Treat

Table 7.4
Analysis of Change from Baseline in SF-36 Domain Score (0-100 score): Physical Functioning
(Mixed Model Repeated Measures)

Visit: Week 24

	Placebo (N=68)	Mepolizumab 300 mg SC (N=68)
n [1]	68	67
n [2]	64	66
LS Mean (SE)	67.25 (2.087)	71.23 (2.069)
LS Mean Change (SE)	3.97 (2.087)	7.95 (2.069)
Mepolizumab 300 mg SC vs Placebo		
Difference (Mepo - Placebo)		3.98
95% CI		(-1.83, 9.80)
p-value		0.178
Corrected Hedges g [3]		0.24
95% CI		(-0.11, 0.58)

[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] Derived from LS means and associated SE.
Note: Analysis performed using mixed model repeated measures with covariates of baseline physical functioning score, baseline prednisolone/prednisone daily dose, region (EU vs. RoW), treatment and visit, plus interaction terms for visit-by-baseline and visit-by-treatment group. LS mean estimates are weighted according to the observed proportions of each categorical covariate in the study data.

PPD

Protocol: MEA115921
Population: Intent-to-Treat

Table 7.4
Analysis of Change from Baseline in SF-36 Domain Score (0-100 score):
Physical Functioning
(Mixed Model Repeated Measures)

Visit: Week 36

	Placebo (N=68)	Mepolizumab 300 mg SC (N=68)
n [1]	68	67
n [2]	62	66
LS Mean (SE)	67.45 (1.976)	67.68 (1.926)
LS Mean Change (SE)	4.17 (1.976)	4.40 (1.926)
Mepolizumab 300 mg SC vs Placebo		
Difference (Mepo - Placebo)		0.23
95% CI		(-5.24, 5.69)
p-value		0.934
Corrected Hedges g [3]		0.01
95% CI		(-0.33, 0.36)

[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] Derived from LS means and associated SE.
Note: Analysis performed using mixed model repeated measures with covariates of baseline physical functioning score, baseline prednisolone/prednisone daily dose, region (EU vs. RoW), treatment and visit, plus interaction terms for visit-by-baseline and visit-by-treatment group. LS mean estimates are weighted according to the observed proportions of each categorical covariate in the study data.

PPD

Protocol: MEA115921
Population: Intent-to-Treat

Table 7.4
Analysis of Change from Baseline in SF-36 Domain Score (0-100 score): Physical Functioning
(Mixed Model Repeated Measures)

Visit: Week 52

	Placebo (N=68)	Mepolizumab 300 mg SC (N=68)
n [1]	68	67
n [2]	61	64
LS Mean (SE)	67.12 (1.838)	70.84 (1.803)
LS Mean Change (SE)	3.84 (1.838)	7.56 (1.803)
Mepolizumab 300 mg SC vs Placebo		
Difference (Mepo - Placebo)		3.73
95% CI		(-1.37, 8.83)
p-value		0.151
Corrected Hedges g [3]		0.26
95% CI		(-0.09, 0.61)

[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] Derived from LS means and associated SE.
Note: Analysis performed using mixed model repeated measures with covariates of baseline physical functioning score, baseline prednisolone/prednisone daily dose, region (EU vs. RoW), treatment and visit, plus interaction terms for visit-by-baseline and visit-by-treatment group. LS mean estimates are weighted according to the observed proportions of each categorical covariate in the study data.

PPD

Population: Intent-to-Treat

Table 7.5
Analysis of Change from Baseline in SF-36 Domain Score (0-100 score):
Role Emotional
(Mixed Model Repeated Measures)

Visit: Week 12

	Placebo (N=68)	Mepolizumab 300 mg SC (N=68)
n [1]	68	67
n [2]	67	67
LS Mean (SE)	82.45 (2.144)	85.17 (2.150)
LS Mean Change (SE)	1.88 (2.144)	4.60 (2.150)
Mepolizumab 300 mg SC vs Placebo		
Difference (Mepo - Placebo)		2.73
95% CI		(-3.30, 8.76)
p-value		0.372
Corrected Hedges g [3]		0.15
95% CI		(-0.18, 0.49)

[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] Derived from LS means and associated SE.
Note: Analysis performed using mixed model repeated measures with covariates of baseline role emotional score, baseline prednisolone/prednisone daily dose, region (EU vs. RoW), treatment and visit, plus interaction terms for visit-by-baseline and visit-by-treatment group. LS mean estimates are weighted according to the observed proportions of each categorical covariate in the study data.

PPD

Population: Intent-to-Treat

Table 7.5
Analysis of Change from Baseline in SF-36 Domain Score (0-100 score):
Role Emotional
(Mixed Model Repeated Measures)

Visit: Week 24

	Placebo (N=68)	Mepolizumab 300 mg SC (N=68)
n [1]	68	67
n [2]	64	66
LS Mean (SE)	81.12 (2.136)	85.09 (2.117)
LS Mean Change (SE)	0.54 (2.136)	4.52 (2.117)
Mepolizumab 300 mg SC vs Placebo		
Difference (Mepo - Placebo)		3.98
95% CI		(-1.99, 9.95)
p-value		0.190
Corrected Hedges g [3]		0.23
95% CI		(-0.11, 0.58)

[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] Derived from LS means and associated SE.
Note: Analysis performed using mixed model repeated measures with covariates of baseline role emotional score, baseline prednisolone/prednisone daily dose, region (EU vs. RoW), treatment and visit, plus interaction terms for visit-by-baseline and visit-by-treatment group. LS mean estimates are weighted according to the observed proportions of each categorical covariate in the study data.

PPD

Protocol: MEA115921
Population: Intent-to-Treat

Table 7.5
Analysis of Change from Baseline in SF-36 Domain Score (0-100 score):
Role Emotional
(Mixed Model Repeated Measures)

Visit: Week 36

	Placebo (N=68)	Mepolizumab 300 mg SC (N=68)
n [1]	68	67
n [2]	62	65
LS Mean (SE)	81.44 (2.259)	85.12 (2.211)
LS Mean Change (SE)	0.87 (2.259)	4.55 (2.211)
Mepolizumab 300 mg SC vs Placebo		
Difference (Mepo - Placebo)		3.68
95% CI		(-2.61, 9.96)
p-value		0.249
Corrected Hedges g [3]		0.21
95% CI		(-0.14, 0.55)

[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] Derived from LS means and associated SE.
Note: Analysis performed using mixed model repeated measures with covariates of baseline role emotional score, baseline prednisolone/prednisone daily dose, region (EU vs. RoW), treatment and visit, plus interaction terms for visit-by-baseline and visit-by-treatment group. LS mean estimates are weighted according to the observed proportions of each categorical covariate in the study data.

PPD

Table 7.5
Analysis of Change from Baseline in SF-36 Domain Score (0-100 score):
Role Emotional
(Mixed Model Repeated Measures)

Visit: Week 52

	Placebo (N=68)	Mepolizumab 300 mg SC (N=68)
n [1]	68	67
n [2]	61	64
LS Mean (SE)	80.95 (2.511)	78.39 (2.458)
LS Mean Change (SE)	0.38 (2.511)	-2.18 (2.458)
Mepolizumab 300 mg SC vs Placebo		
Difference (Mepo - Placebo)		-2.56
95% CI		(-9.54, 4.42)
p-value		0.469
Corrected Hedges g [3]		-0.13
95% CI		(-0.48, 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] Derived from LS means and associated SE.
Note: Analysis performed using mixed model repeated measures with covariates of baseline role emotional score, baseline prednisolone/prednisone daily dose, region (EU vs. RoW), treatment and visit, plus interaction terms for visit-by-baseline and visit-by-treatment group. LS mean estimates are weighted according to the observed proportions of each categorical covariate in the study data.

PPD

Protocol: MEA115921
Population: Intent-to-Treat

Table 7.6
Analysis of Change from Baseline in SF-36 Domain Score (0-100 score):
Role Physical
(Mixed Model Repeated Measures)

Visit: Week 12

	Placebo (N=68)	Mepolizumab 300 mg SC (N=68)
n [1]	68	67
n [2]	68	67
LS Mean (SE)	65.84 (2.487)	65.50 (2.507)
LS Mean Change (SE)	6.98 (2.487)	6.64 (2.507)
Mepolizumab 300 mg SC vs Placebo		
Difference (Mepo - Placebo)		-0.34
95% CI		(-7.33, 6.64)
p-value		0.923
Corrected Hedges g [3]		-0.02
95% CI		(-0.35, 0.32)

[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] Derived from LS means and associated SE.
Note: Analysis performed using mixed model repeated measures with covariates of baseline role physical score, baseline prednisolone/prednisone daily dose, region (EU vs. RoW), treatment and visit, plus interaction terms for visit-by-baseline and visit-by-treatment group. LS mean estimates are weighted according to the observed proportions of each categorical covariate in the study data.

PPD

Population: Intent-to-Treat

Table 7.6
Analysis of Change from Baseline in SF-36 Domain Score (0-100 score):
Role Physical
(Mixed Model Repeated Measures)

Visit: Week 24

	Placebo (N=68)	Mepolizumab 300 mg SC (N=68)
n [1]	68	67
n [2]	64	66
LS Mean (SE)	65.74 (2.643)	67.61 (2.621)
LS Mean Change (SE)	6.88 (2.643)	8.75 (2.621)
Mepolizumab 300 mg SC vs Placebo		
Difference (Mepo - Placebo)		1.87
95% CI		(-5.50, 9.23)
p-value		0.617
Corrected Hedges g [3]		0.09
95% CI		(-0.26, 0.43)

[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] Derived from LS means and associated SE.
Note: Analysis performed using mixed model repeated measures with covariates of baseline role physical score, baseline prednisolone/prednisone daily dose, region (EU vs. RoW), treatment and visit, plus interaction terms for visit-by-baseline and visit-by-treatment group. LS mean estimates are weighted according to the observed proportions of each categorical covariate in the study data.

PPD

Protocol: MEA115921
Population: Intent-to-Treat

Table 7.6
Analysis of Change from Baseline in SF-36 Domain Score (0-100 score): Role Physical
(Mixed Model Repeated Measures)

Visit: Week 36

	Placebo (N=68)	Mepolizumab 300 mg SC (N=68)
n [1]	68	67
n [2]	62	65
LS Mean (SE)	64.48 (2.784)	63.49 (2.733)
LS Mean Change (SE)	5.62 (2.784)	4.63 (2.733)
Mepolizumab 300 mg SC vs Placebo		
Difference (Mepo - Placebo)		-0.99
95% CI		(-8.72, 6.73)
p-value		0.800
Corrected Hedges g [3]		-0.04
95% CI		(-0.39, 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] Derived from LS means and associated SE.
Note: Analysis performed using mixed model repeated measures with covariates of baseline role physical score, baseline prednisolone/prednisone daily dose, region (EU vs. RoW), treatment and visit, plus interaction terms for visit-by-baseline and visit-by-treatment group. LS mean estimates are weighted according to the observed proportions of each categorical covariate in the study data.

PPD

Table 7.6
Analysis of Change from Baseline in SF-36 Domain Score (0-100 score):
Role Physical
(Mixed Model Repeated Measures)

Visit: Week 52

	Placebo (N=68)	Mepolizumab 300 mg SC (N=68)
n [1]	68	67
n [2]	61	64
LS Mean (SE)	64.73 (2.709)	61.57 (2.655)
LS Mean Change (SE)	5.86 (2.709)	2.70 (2.655)
Mepolizumab 300 mg SC vs Placebo		
Difference (Mepo - Placebo)		-3.16
95% CI		(-10.67, 4.35)
p-value		0.407
Corrected Hedges g [3]		-0.15
95% CI		(-0.50, 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] Derived from LS means and associated SE.
Note: Analysis performed using mixed model repeated measures with covariates of baseline role physical score, baseline prednisolone/prednisone daily dose, region (EU vs. RoW), treatment and visit, plus interaction terms for visit-by-baseline and visit-by-treatment group. LS mean estimates are weighted according to the observed proportions of each categorical covariate in the study data.

PPD

Protocol: MEA115921
Population: Intent-to-Treat

Table 7.7
Analysis of Change from Baseline in SF-36 Domain Score (0-100 score): Social Functioning
(Mixed Model Repeated Measures)

Visit: Week 12

	Placebo (N=68)	Mepolizumab 300 mg SC (N=68)
n [1]	68	67
n [2]	67	67
LS Mean (SE)	72.49 (2.321)	76.59 (2.325)
LS Mean Change (SE)	3.11 (2.321)	7.21 (2.325)
Mepolizumab 300 mg SC vs Placebo		
Difference (Mepo - Placebo)		4.10
95% CI		(-2.43, 10.62)
p-value		0.217
Corrected Hedges g [3]		0.21
95% CI		(-0.13, 0.55)

[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] Derived from LS means and associated SE.
Note: Analysis performed using mixed model repeated measures with covariates of baseline social functioning score, baseline prednisolone/prednisone daily dose, region (EU vs. RoW), treatment and visit, plus interaction terms for visit-by-baseline and visit-by-treatment group. LS mean estimates are weighted according to the observed proportions of each categorical covariate in the study data.

PPD

Protocol: MEA115921
Population: Intent-to-Treat

Table 7.7
Analysis of Change from Baseline in SF-36 Domain Score (0-100 score): Social Functioning
(Mixed Model Repeated Measures)

Visit: Week 24

	Placebo (N=68)	Mepolizumab 300 mg SC (N=68)
n [1]	68	67
n [2]	64	66
LS Mean (SE)	70.89 (2.530)	74.06 (2.505)
LS Mean Change (SE)	1.51 (2.530)	4.68 (2.505)
Mepolizumab 300 mg SC vs Placebo		
Difference (Mepo - Placebo)		3.17
95% CI		(-3.90, 10.24)
p-value		0.377
Corrected Hedges g [3]		0.16
95% CI		(-0.19, 0.50)

[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] Derived from LS means and associated SE.
Note: Analysis performed using mixed model repeated measures with covariates of baseline social functioning score, baseline prednisolone/prednisone daily dose, region (EU vs. RoW), treatment and visit, plus interaction terms for visit-by-baseline and visit-by-treatment group. LS mean estimates are weighted according to the observed proportions of each categorical covariate in the study data.

PPD

Population: Intent-to-Treat

Table 7.7
Analysis of Change from Baseline in SF-36 Domain Score (0-100 score): Social Functioning
(Mixed Model Repeated Measures)

Visit: Week 36

	Placebo (N=68)	Mepolizumab 300 mg SC (N=68)
n [1]	68	67
n [2]	62	65
LS Mean (SE)	72.26 (2.605)	72.08 (2.557)
LS Mean Change (SE)	2.88 (2.605)	2.70 (2.557)
Mepolizumab 300 mg SC vs Placebo		
Difference (Mepo - Placebo)		-0.18
95% CI		(-7.43, 7.07)
p-value		0.961
Corrected Hedges g [3]		-0.01
95% CI		(-0.36, 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] Derived from LS means and associated SE.
Note: Analysis performed using mixed model repeated measures with covariates of baseline social functioning score, baseline prednisolone/prednisone daily dose, region (EU vs. RoW), treatment and visit, plus interaction terms for visit-by-baseline and visit-by-treatment group. LS mean estimates are weighted according to the observed proportions of each categorical covariate in the study data.

PPD

Protocol: MEA115921
Population: Intent-to-Treat

Table 7.7
Analysis of Change from Baseline in SF-36 Domain Score (0-100 score): Social Functioning
(Mixed Model Repeated Measures)

Visit: Week 52

	Placebo (N=68)	Mepolizumab 300 mg SC (N=68)
n [1]	68	67
n [2]	61	64
LS Mean (SE)	76.07 (2.640)	72.84 (2.583)
LS Mean Change (SE)	6.69 (2.640)	3.47 (2.583)
Mepolizumab 300 mg SC vs Placebo		
Difference (Mepo - Placebo)		-3.23
95% CI		(-10.56, 4.11)
p-value		0.386
Corrected Hedges g [3]		-0.16
95% CI		(-0.51, 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] Derived from LS means and associated SE.
Note: Analysis performed using mixed model repeated measures with covariates of baseline social functioning score, baseline prednisolone/prednisone daily dose, region (EU vs. RoW), treatment and visit, plus interaction terms for visit-by-baseline and visit-by-treatment group. LS mean estimates are weighted according to the observed proportions of each categorical covariate in the study data.

PPD

Protocol: MEA115921
Population: Intent-to-Treat

Table 7.8
Analysis of Change from Baseline in SF-36 Domain Score (0-100 score): Vitality
(Mixed Model Repeated Measures)

Visit: Week 12

	Placebo (N=68)	Mepolizumab 300 mg SC (N=68)
n [1]	68	67
n [2]	67	66
LS Mean (SE)	49.78 (1.625)	49.71 (1.637)
LS Mean Change (SE)	2.06 (1.625)	2.00 (1.637)
Mepolizumab 300 mg SC vs Placebo		
Difference (Mepo - Placebo)		-0.06
95% CI		(-4.63, 4.50)
p-value		0.978
Corrected Hedges g [3]		0.00
95% CI		(-0.34, 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] Derived from LS means and associated SE.
Note: Analysis performed using mixed model repeated measures with covariates of baseline vitality score, baseline prednisolone/prednisone daily dose, region (EU vs. RoW), treatment and visit, plus interaction terms for visit-by-baseline and visit-by-treatment group. LS mean estimates are weighted according to the observed proportions of each categorical covariate in the study data.

PPD

Population: Intent-to-Treat

Table 7.8
Analysis of Change from Baseline in SF-36 Domain Score (0-100 score): Vitality
(Mixed Model Repeated Measures)

Visit: Week 24

	Placebo (N=68)	Mepolizumab 300 mg SC (N=68)
n [1]	68	67
n [2]	64	66
LS Mean (SE)	49.47 (1.893)	50.66 (1.867)
LS Mean Change (SE)	1.76 (1.893)	2.95 (1.867)
Mepolizumab 300 mg SC vs Placebo		
Difference (Mepo - Placebo)		1.19
95% CI		(-4.07, 6.45)
p-value		0.656
Corrected Hedges g [3]		0.08
95% CI		(-0.27, 0.42)

[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] Derived from LS means and associated SE.
Note: Analysis performed using mixed model repeated measures with covariates of baseline vitality score, baseline prednisolone/prednisone daily dose, region (EU vs. RoW), treatment and visit, plus interaction terms for visit-by-baseline and visit-by-treatment group. LS mean estimates are weighted according to the observed proportions of each categorical covariate in the study data.

PPD

Population: Intent-to-Treat

Table 7.8
Analysis of Change from Baseline in SF-36 Domain Score (0-100 score): Vitality
(Mixed Model Repeated Measures)

Visit: Week 36

	Placebo (N=68)	Mepolizumab 300 mg SC (N=68)
n [1]	68	67
n [2]	62	65
LS Mean (SE)	48.77 (1.761)	51.17 (1.725)
LS Mean Change (SE)	1.06 (1.761)	3.46 (1.725)
Mepolizumab 300 mg SC vs Placebo		
Difference (Mepo - Placebo)		2.40
95% CI		(-2.48, 7.28)
p-value		0.332
Corrected Hedges g [3]		0.17
95% CI		(-0.18, 0.52)

[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] Derived from LS means and associated SE.
Note: Analysis performed using mixed model repeated measures with covariates of baseline vitality score, baseline prednisolone/prednisone daily dose, region (EU vs. RoW), treatment and visit, plus interaction terms for visit-by-baseline and visit-by-treatment group. LS mean estimates are weighted according to the observed proportions of each categorical covariate in the study data.

PPD

Protocol: MEA115921
Population: Intent-to-Treat

Table 7.8
Analysis of Change from Baseline in SF-36 Domain Score (0-100 score): Vitality
(Mixed Model Repeated Measures)

Visit: Week 52

	Placebo (N=68)	Mepolizumab 300 mg SC (N=68)
n [1]	68	67
n [2]	61	63
LS Mean (SE)	50.76 (1.959)	49.03 (1.926)
LS Mean Change (SE)	3.05 (1.959)	1.32 (1.926)
Mepolizumab 300 mg SC vs Placebo		
Difference (Mepo - Placebo)		-1.73
95% CI		(-7.17, 3.71)
p-value		0.530
Corrected Hedges g [3]		-0.11
95% CI		(-0.46, 0.24)

[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] Derived from LS means and associated SE.
Note: Analysis performed using mixed model repeated measures with covariates of baseline vitality score, baseline prednisolone/prednisone daily dose, region (EU vs. RoW), treatment and visit, plus interaction terms for visit-by-baseline and visit-by-treatment group. LS mean estimates are weighted according to the observed proportions of each categorical covariate in the study data.

PPD

Protocol: MEA115921
Population: Intent-to-Treat

Table 4.3
Summary of Change from Baseline in Work Productivity and Activity Impairment (WPAI) Questionnaire

Visit: Baseline

		Placebo (N=68)	Mepolizumab 300 mg SC (N=68)
Percent work time missed due to health	n	43	35
	Mean	9.1	13.3
	SD	24.76	28.50
	Median	0.0	0.0
	Min.	0	0
	Max.	100	100
Percent impairment while working due to health	n	38	31
	Mean	20.8	23.2
	SD	18.80	26.25
	Median	20.0	20.0
	Min.	0	0
	Max.	90	80
Percent overall work impairment due to health	n	38	31
	Mean	23.0	26.7
	SD	20.38	31.08
	Median	20.0	20.0
	Min.	0	0
	Max.	98	95
Percent activity impairment due to health	n	67	68
	Mean	39.6	36.8
	SD	28.68	29.14
	Median	40.0	30.0
	Min.	0	0
	Max.	90	90

Protocol: MEA115921
Population: Intent-to-Treat

Table 4.3
Summary of Change from Baseline in Work Productivity and Activity Impairment (WPAI) Questionnaire

Visit: Week 12

		Placebo (N=68)	Mepolizumab 300 mg SC (N=68)
Percent work time missed due to health	n	44	34
	Mean	7.9	8.7
	SD	21.74	22.89
	Median	0.0	0.0
	Min.	0	0
	Max.	100	100
Work time missed due to health Change from Baseline (%)	n	42	32
	Mean	-3.5	-3.2
	SD	21.45	8.89
	Median	0.0	0.0
	Min.	-100	-38
	Max.	25	9
Percent impairment while working due to health	n	38	30
	Mean	29.2	24.0
	SD	26.65	26.08
	Median	25.0	20.0
	Min.	0	0
	Max.	80	80
Impairment while working due to health Change from Baseline (%)	n	34	27
	Mean	8.8	-1.5
	SD	21.43	18.34
	Median	0.0	0.0
	Min.	-20	-40
	Max.	70	50

Protocol: MEA115921
Population: Intent-to-Treat

Table 4.3
Summary of Change from Baseline in Work Productivity and Activity Impairment (WPAI) Questionnaire

Visit: Week 12

		Placebo (N=68)	Mepolizumab 300 mg SC (N=68)
Percent overall work impairment due to health	n	38	30
	Mean	31.2	26.4
	SD	27.78	29.34
	Median	29.4	20.0
	Min.	0	0
	Max.	84	94
Overall work impairment due to health Change from Baseline (%)	n	34	27
	Mean	8.6	-3.4
	SD	22.96	17.57
	Median	0.0	0.0
	Min.	-30	-48
	Max.	71	50
Percent activity impairment due to health	n	68	66
	Mean	39.9	33.6
	SD	30.35	28.21
	Median	30.0	30.0
	Min.	0	0
	Max.	100	90
Activity impairment due to health Change from Baseline (%)	n	67	66
	Mean	0.1	-2.9
	SD	24.34	19.83
	Median	0.0	0.0
	Min.	-90	-50
	Max.	50	50

PPD

Protocol: MEA115921
Population: Intent-to-Treat

Table 4.3
Summary of Change from Baseline in Work Productivity and Activity Impairment (WPAI) Questionnaire

Visit: Week 24

		Placebo (N=68)	Mepolizumab 300 mg SC (N=68)
Percent work time missed due to health	n	42	32
	Mean	6.3	1.7
	SD	21.97	7.17
	Median	0.0	0.0
	Min.	0	0
	Max.	100	38
Work time missed due to health Change from Baseline (%)	n	41	31
	Mean	-3.1	-3.2
	SD	26.01	10.06
	Median	0.0	0.0
	Min.	-100	-33
	Max.	100	17
Percent impairment while working due to health	n	37	31
	Mean	22.4	17.1
	SD	21.14	20.20
	Median	20.0	10.0
	Min.	0	0
	Max.	80	70
Impairment while working due to health Change from Baseline (%)	n	33	29
	Mean	2.1	-1.7
	SD	21.62	24.65
	Median	0.0	0.0
	Min.	-60	-60
	Max.	50	60

PPD

Protocol: MEA115921
Population: Intent-to-Treat

Table 4.3
Summary of Change from Baseline in Work Productivity and Activity Impairment (WPAI) Questionnaire

Visit: Week 24

		Placebo (N=68)	Mepolizumab 300 mg SC (N=68)
Percent overall work impairment due to health	n	37	31
	Mean	23.5	18.1
	SD	21.65	21.40
	Median	20.0	10.0
	Min.	0	0
	Max.	80	75
Overall work impairment due to health Change from Baseline (%)	n	33	29
	Mean	0.4	-3.6
	SD	22.70	25.32
	Median	0.0	0.0
	Min.	-63	-64
	Max.	50	60
Percent activity impairment due to health	n	64	67
	Mean	37.0	29.9
	SD	26.65	26.37
	Median	30.0	20.0
	Min.	0	0
	Max.	100	90
Activity impairment due to health Change from Baseline (%)	n	63	67
	Mean	-2.9	-7.0
	SD	24.26	25.11
	Median	0.0	0.0
	Min.	-60	-70
	Max.	60	60

PPD

Protocol: MEA115921
Population: Intent-to-Treat

Table 4.3
Summary of Change from Baseline in Work Productivity and Activity Impairment (WPAI) Questionnaire

Visit: Week 36

		Placebo (N=68)	Mepolizumab 300 mg SC (N=68)
Percent work time missed due to health	n	42	36
	Mean	7.9	8.0
	SD	19.56	23.88
	Median	0.0	0.0
	Min.	0	0
	Max.	100	100
Work time missed due to health Change from Baseline (%)	n	40	32
	Mean	-1.5	-2.9
	SD	33.69	27.09
	Median	0.0	0.0
	Min.	-100	-100
	Max.	100	100
Percent impairment while working due to health	n	40	33
	Mean	26.8	22.7
	SD	24.43	20.66
	Median	20.0	20.0
	Min.	0	0
	Max.	80	70
Impairment while working due to health Change from Baseline (%)	n	34	26
	Mean	5.9	3.1
	SD	19.71	24.13
	Median	0.0	0.0
	Min.	-40	-40
	Max.	50	70

PPD

Protocol: MEA115921
Population: Intent-to-Treat

Table 4.3
Summary of Change from Baseline in Work Productivity and Activity Impairment (WPAI) Questionnaire

Visit: Week 36

		Placebo (N=68)	Mepolizumab 300 mg SC (N=68)
Percent overall work impairment due to health	n	40	33
	Mean	28.9	24.0
	SD	27.05	22.52
	Median	20.0	20.0
	Min.	0	0
	Max.	89	75
Overall work impairment due to health Change from Baseline (%)	n	34	26
	Mean	5.6	0.9
	SD	22.99	25.46
	Median	0.0	0.0
	Min.	-44	-48
	Max.	69	72
Percent activity impairment due to health	n	62	66
	Mean	39.2	34.1
	SD	28.42	26.43
	Median	40.0	30.0
	Min.	0	0
	Max.	100	100
Activity impairment due to health Change from Baseline (%)	n	61	66
	Mean	0.8	-2.3
	SD	27.65	24.73
	Median	0.0	0.0
	Min.	-60	-50
	Max.	100	70

PPD

Protocol: MEA115921
Population: Intent-to-Treat

Table 4.3
Summary of Change from Baseline in Work Productivity and Activity Impairment (WPAI) Questionnaire

Visit: Week 52

		Placebo (N=68)	Mepolizumab 300 mg SC (N=68)
Percent work time missed due to health	n	40	35
	Mean	8.4	8.9
	SD	20.10	24.36
	Median	0.0	0.0
	Min.	0	0
	Max.	100	100
Work time missed due to health Change from Baseline (%)	n	39	31
	Mean	-0.6	1.4
	SD	25.54	16.80
	Median	0.0	0.0
	Min.	-100	-38
	Max.	62	67
Percent impairment while working due to health	n	35	32
	Mean	19.7	18.1
	SD	18.23	19.75
	Median	20.0	10.0
	Min.	0	0
	Max.	70	80
Impairment while working due to health Change from Baseline (%)	n	31	26
	Mean	-1.9	-3.1
	SD	21.82	24.78
	Median	0.0	0.0
	Min.	-80	-60
	Max.	40	60

PPD

Protocol: MEA115921
Population: Intent-to-Treat

Table 4.3
Summary of Change from Baseline in Work Productivity and Activity Impairment (WPAI) Questionnaire

Visit: Week 52

		Placebo (N=68)	Mepolizumab 300 mg SC (N=68)
Percent overall work impairment due to health	n	35	32
	Mean	22.9	20.6
	SD	22.65	21.65
	Median	20.0	15.0
	Min.	0	0
	Max.	81	80
Overall work impairment due to health Change from Baseline (%)	n	31	26
	Mean	-0.6	-2.0
	SD	27.13	28.31
	Median	0.0	0.0
	Min.	-88	-68
	Max.	51	60
Percent activity impairment due to health	n	56	65
	Mean	28.9	34.9
	SD	26.54	25.01
	Median	20.0	30.0
	Min.	0	0
	Max.	90	80
Activity impairment due to health Change from Baseline (%)	n	56	65
	Mean	-8.0	-0.8
	SD	21.61	24.19
	Median	-5.0	0.0
	Min.	-60	-50
	Max.	40	70

PPD

Protocol: MEA115921
Population: Intent-to-Treat

Table 7.35
Analysis of Change from Baseline in Work Productivity and Activity Impairment Questionnaire (WPAI): Work Time Missed Due to Health (%)
(Mixed Model Repeated Measures)

Visit: Week 12

	Placebo (N=68)	Mepolizumab 300 mg SC (N=68)
n [1]	43	35
n [2]	42	32
LS Mean (SE)	5.85 (2.109)	7.14 (2.407)
LS Mean Change (SE)	-3.29 (2.109)	-2.00 (2.407)
Mepolizumab 300 mg SC vs Placebo		
Difference (Mepo - Placebo)		1.29
95% CI		(-5.09, 7.67)
p-value		0.688
Corrected Hedges g [3]		0.09
95% CI		(-0.37, 0.55)

[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] Derived from LS means and associated SE.
Note: Analysis performed using mixed model repeated measures with covariates of baseline, baseline prednisolone/prednisone daily dose, region (EU vs. RoW), treatment and visit, plus interaction terms for visit-by-baseline and visit-by-treatment group. LS mean estimates are weighted according to the observed proportions of each categorical covariate in the study data.

PPD

Table 7.35
Analysis of Change from Baseline in Work Productivity and Activity Impairment Questionnaire (WPAI): Work Time Missed Due to Health (%)
(Mixed Model Repeated Measures)

Visit: Week 24

	Placebo (N=68)	Mepolizumab 300 mg SC (N=68)
n [1]	43	35
n [2]	41	31
LS Mean (SE)	6.25 (2.475)	2.61 (2.865)
LS Mean Change (SE)	-2.88 (2.475)	-6.52 (2.865)
Mepolizumab 300 mg SC vs Placebo		
Difference (Mepo - Placebo)		-3.64
95% CI		(-11.21, 3.92)
p-value		0.340
Corrected Hedges g [3]		-0.23
95% CI		(-0.69, 0.24)

[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] Derived from LS means and associated SE.
Note: Analysis performed using mixed model repeated measures with covariates of baseline, baseline prednisolone/prednisone daily dose, region (EU vs. RoW), treatment and visit, plus interaction terms for visit-by-baseline and visit-by-treatment group. LS mean estimates are weighted according to the observed proportions of each categorical covariate in the study data.

PPD

Table 7.35
Analysis of Change from Baseline in Work Productivity and Activity Impairment Questionnaire (WPAI): Work Time Missed Due to Health (%)
(Mixed Model Repeated Measures)

Visit: Week 36

	Placebo (N=68)	Mepolizumab 300 mg SC (N=68)
n [1]	43	35
n [2]	40	32
LS Mean (SE)	8.15 (3.481)	7.70 (3.899)
LS Mean Change (SE)	-0.98 (3.481)	-1.44 (3.899)
Mepolizumab 300 mg SC vs Placebo		
Difference (Mepo - Placebo)		-0.46
95% CI		(-10.88, 9.96)
p-value		0.930
Corrected Hedges g [3]		-0.02
95% CI		(-0.49, 0.44)

[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] Derived from LS means and associated SE.
Note: Analysis performed using mixed model repeated measures with covariates of baseline, baseline prednisolone/prednisone daily dose, region (EU vs. RoW), treatment and visit, plus interaction terms for visit-by-baseline and visit-by-treatment group. LS mean estimates are weighted according to the observed proportions of each categorical covariate in the study data.

PPD

Protocol: MEA115921
Population: Intent-to-Treat

Table 7.35
Analysis of Change from Baseline in Work Productivity and Activity Impairment Questionnaire (WPAI): Work Time Missed Due to Health (%)
(Mixed Model Repeated Measures)

Visit: Week 52

	Placebo (N=68)	Mepolizumab 300 mg SC (N=68)
n [1]	43	35
n [2]	39	31
LS Mean (SE)	8.38 (3.029)	10.72 (3.406)
LS Mean Change (SE)	-0.76 (3.029)	1.59 (3.406)
Mepolizumab 300 mg SC vs Placebo		
Difference (Mepo - Placebo)		2.35
95% CI		(-6.75, 11.44)
p-value		0.608
Corrected Hedges g [3]		0.12
95% CI		(-0.35, 0.59)

[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] Derived from LS means and associated SE.
Note: Analysis performed using mixed model repeated measures with covariates of baseline, baseline prednisolone/prednisone daily dose, region (EU vs. RoW), treatment and visit, plus interaction terms for visit-by-baseline and visit-by-treatment group. LS mean estimates are weighted according to the observed proportions of each categorical covariate in the study data.

PPD

Protocol: MEA115921
Population: Intent-to-Treat

Table 7.42
Analysis of Change from Baseline in Work Productivity and Activity Impairment Questionnaire (WPAI): Impairment While Working Due to Health (%)
(Mixed Model Repeated Measures)

Visit: Week 12

	Placebo (N=68)	Mepolizumab 300 mg SC (N=68)
n [1]	38	31
n [2]	34	27
LS Mean (SE)	27.70 (3.381)	19.03 (3.809)
LS Mean Change (SE)	7.41 (3.381)	-1.26 (3.809)
Mepolizumab 300 mg SC vs Placebo		
Difference (Mepo - Placebo)		-8.67
95% CI		(-18.92, 1.58)
p-value		0.096
Corrected Hedges g [3]		-0.43
95% CI		(-0.94, 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] Derived from LS means and associated SE.
Note: Analysis performed using mixed model repeated measures with covariates of baseline, baseline prednisolone/prednisone daily dose, region (EU vs. RoW), treatment and visit, plus interaction terms for visit-by-baseline and visit-by-treatment group. LS mean estimates are weighted according to the observed proportions of each categorical covariate in the study data.

PPD

Population: Intent-to-Treat

Table 7.42
Analysis of Change from Baseline in Work Productivity and Activity Impairment Questionnaire (WPAI): Impairment While Working Due to Health (%)
(Mixed Model Repeated Measures)

Visit: Week 24

	Placebo (N=68)	Mepolizumab 300 mg SC (N=68)
n [1]	38	31
n [2]	33	29
LS Mean (SE)	23.77 (3.308)	17.36 (3.562)
LS Mean Change (SE)	3.48 (3.308)	-2.93 (3.562)
Mepolizumab 300 mg SC vs Placebo		
Difference (Mepo - Placebo)		-6.40
95% CI		(-16.14, 3.33)
p-value		0.193
Corrected Hedges g [3]		-0.33
95% CI		(-0.83, 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] Derived from LS means and associated SE.
Note: Analysis performed using mixed model repeated measures with covariates of baseline, baseline prednisolone/prednisone daily dose, region (EU vs. RoW), treatment and visit, plus interaction terms for visit-by-baseline and visit-by-treatment group. LS mean estimates are weighted according to the observed proportions of each categorical covariate in the study data.

PPD

Population: Intent-to-Treat

Table 7.42
Analysis of Change from Baseline in Work Productivity and Activity Impairment Questionnaire (WPAI): Impairment While Working Due to Health (%)
(Mixed Model Repeated Measures)

Visit: Week 36

	Placebo (N=68)	Mepolizumab 300 mg SC (N=68)
n [1]	38	31
n [2]	34	26
LS Mean (SE)	27.59 (3.303)	21.66 (3.751)
LS Mean Change (SE)	7.30 (3.303)	1.37 (3.751)
Mepolizumab 300 mg SC vs Placebo		
Difference (Mepo - Placebo)		-5.94
95% CI		(-15.96, 4.08)
p-value		0.241
Corrected Hedges g [3]		-0.31
95% CI		(-0.82, 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] Derived from LS means and associated SE.
Note: Analysis performed using mixed model repeated measures with covariates of baseline, baseline prednisolone/prednisone daily dose, region (EU vs. RoW), treatment and visit, plus interaction terms for visit-by-baseline and visit-by-treatment group. LS mean estimates are weighted according to the observed proportions of each categorical covariate in the study data.

PPD

Population: Intent-to-Treat

Table 7.42
Analysis of Change from Baseline in Work Productivity and Activity Impairment Questionnaire (WPAI): Impairment While Working Due to Health (%)
(Mixed Model Repeated Measures)

Visit: Week 52

	Placebo (N=68)	Mepolizumab 300 mg SC (N=68)
n [1]	38	31
n [2]	31	26
LS Mean (SE)	19.61 (3.022)	18.05 (3.308)
LS Mean Change (SE)	-0.68 (3.022)	-2.24 (3.308)
Mepolizumab 300 mg SC vs Placebo		
Difference (Mepo - Placebo)		-1.57
95% CI		(-10.56, 7.43)
p-value		0.728
Corrected Hedges g [3]		-0.09
95% CI		(-0.61, 0.43)

[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] Derived from LS means and associated SE.
Note: Analysis performed using mixed model repeated measures with covariates of baseline, baseline prednisolone/prednisone daily dose, region (EU vs. RoW), treatment and visit, plus interaction terms for visit-by-baseline and visit-by-treatment group. LS mean estimates are weighted according to the observed proportions of each categorical covariate in the study data.

PPD

Protocol: MEA115921
Population: Intent-to-Treat

Table 7.49
Analysis of Change from Baseline in Work Productivity and Activity Impairment Questionnaire (WPAI): Overall Work Impairment Due to Health (%)
(Mixed Model Repeated Measures)

Visit: Week 12

	Placebo (N=68)	Mepolizumab 300 mg SC (N=68)
n [1]	38	31
n [2]	34	27
LS Mean (SE)	30.13 (3.469)	20.23 (3.924)
LS Mean Change (SE)	7.33 (3.469)	-2.57 (3.924)
Mepolizumab 300 mg SC vs Placebo		
Difference (Mepo - Placebo)		-9.90
95% CI		(-20.45, 0.66)
p-value		0.066
Corrected Hedges g [3]		-0.48
95% CI		(-0.99, 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] Derived from LS means and associated SE.
Note: Analysis performed using mixed model repeated measures with covariates of baseline, baseline prednisolone/prednisone daily dose, region (EU vs. RoW), treatment and visit, plus interaction terms for visit-by-baseline and visit-by-treatment group. LS mean estimates are weighted according to the observed proportions of each categorical covariate in the study data.

Protocol: MEA115921
Population: Intent-to-Treat

Table 7.49
Analysis of Change from Baseline in Work Productivity and Activity Impairment Questionnaire (WPAI): Overall Work Impairment Due to Health (%)
(Mixed Model Repeated Measures)

Visit: Week 24

	Placebo (N=68)	Mepolizumab 300 mg SC (N=68)
n [1]	38	31
n [2]	33	29
LS Mean (SE)	24.48 (3.268)	18.31 (3.513)
LS Mean Change (SE)	1.68 (3.268)	-4.49 (3.513)
Mepolizumab 300 mg SC vs Placebo		
Difference (Mepo - Placebo)		-6.17
95% CI		(-15.79, 3.44)
p-value		0.204
Corrected Hedges g [3]		-0.32
95% CI		(-0.83, 0.18)

[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] Derived from LS means and associated SE.
Note: Analysis performed using mixed model repeated measures with covariates of baseline, baseline prednisolone/prednisone daily dose, region (EU vs. RoW), treatment and visit, plus interaction terms for visit-by-baseline and visit-by-treatment group. LS mean estimates are weighted according to the observed proportions of each categorical covariate in the study data.

PPD

Protocol: MEA115921
Population: Intent-to-Treat

Table 7.49
Analysis of Change from Baseline in Work Productivity and Activity Impairment Questionnaire (WPAI): Overall Work Impairment Due to Health (%)
(Mixed Model Repeated Measures)

Visit: Week 36

	Placebo (N=68)	Mepolizumab 300 mg SC (N=68)
n [1]	38	31
n [2]	34	26
LS Mean (SE)	29.82 (3.627)	22.33 (4.120)
LS Mean Change (SE)	7.02 (3.627)	-0.47 (4.120)
Mepolizumab 300 mg SC vs Placebo		
Difference (Mepo - Placebo)		-7.49
95% CI		(-18.49, 3.51)
p-value		0.178
Corrected Hedges g [3]		-0.35
95% CI		(-0.87, 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] Derived from LS means and associated SE.
Note: Analysis performed using mixed model repeated measures with covariates of baseline, baseline prednisolone/prednisone daily dose, region (EU vs. RoW), treatment and visit, plus interaction terms for visit-by-baseline and visit-by-treatment group. LS mean estimates are weighted according to the observed proportions of each categorical covariate in the study data.

PPD

Protocol: MEA115921
Population: Intent-to-Treat

Table 7.49
Analysis of Change from Baseline in Work Productivity and Activity Impairment Questionnaire (WPAI): Overall Work Impairment Due to Health (%)
(Mixed Model Repeated Measures)

Visit: Week 52

	Placebo (N=68)	Mepolizumab 300 mg SC (N=68)
n [1]	38	31
n [2]	31	26
LS Mean (SE)	22.63 (3.610)	20.71 (3.953)
LS Mean Change (SE)	-0.17 (3.610)	-2.09 (3.953)
Mepolizumab 300 mg SC vs Placebo		
Difference (Mepo - Placebo)		-1.92
95% CI		(-12.67, 8.83)
p-value		0.722
Corrected Hedges g [3]		-0.09
95% CI		(-0.62, 0.43)

[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] Derived from LS means and associated SE.
Note: Analysis performed using mixed model repeated measures with covariates of baseline, baseline prednisolone/prednisone daily dose, region (EU vs. RoW), treatment and visit, plus interaction terms for visit-by-baseline and visit-by-treatment group. LS mean estimates are weighted according to the observed proportions of each categorical covariate in the study data.

PPD

Protocol: MEA115921
Population: Intent-to-Treat

Table 7.56
Analysis of Change from Baseline in Work Productivity and Activity Impairment Questionnaire (WPAI): Activity Impairment Due to Health (%)
(Mixed Model Repeated Measures)

Visit: Week 12

	Placebo (N=68)	Mepolizumab 300 mg SC (N=68)
n [1]	67	68
n [2]	67	66
LS Mean (SE)	38.30 (2.505)	34.55 (2.522)
LS Mean Change (SE)	0.81 (2.505)	-2.95 (2.522)
Mepolizumab 300 mg SC vs Placebo		
Difference (Mepo - Placebo)		-3.75
95% CI		(-10.79, 3.28)
p-value		0.293
Corrected Hedges g [3]		-0.18
95% CI		(-0.52, 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] Derived from LS means and associated SE.
Note: Analysis performed using mixed model repeated measures with covariates of baseline, baseline prednisolone/prednisone daily dose, region (EU vs. RoW), treatment and visit, plus interaction terms for visit-by-baseline and visit-by-treatment group. LS mean estimates are weighted according to the observed proportions of each categorical covariate in the study data.

PPD

Population: Intent-to-Treat

Table 7.56
Analysis of Change from Baseline in Work Productivity and Activity Impairment Questionnaire (WPAI): Activity Impairment Due to Health (%)
(Mixed Model Repeated Measures)

Visit: Week 24

	Placebo (N=68)	Mepolizumab 300 mg SC (N=68)
n [1]	67	68
n [2]	63	67
LS Mean (SE)	35.67 (2.704)	30.56 (2.619)
LS Mean Change (SE)	-1.83 (2.704)	-6.94 (2.619)
Mepolizumab 300 mg SC vs Placebo		
Difference (Mepo - Placebo)		-5.11
95% CI		(-12.56, 2.34)
p-value		0.177
Corrected Hedges g [3]		-0.24
95% CI		(-0.58, 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] Derived from LS means and associated SE.
Note: Analysis performed using mixed model repeated measures with covariates of baseline, baseline prednisolone/prednisone daily dose, region (EU vs. RoW), treatment and visit, plus interaction terms for visit-by-baseline and visit-by-treatment group. LS mean estimates are weighted according to the observed proportions of each categorical covariate in the study data.

PPD

Protocol: MEA115921
Population: Intent-to-Treat

Table 7.56
Analysis of Change from Baseline in Work Productivity and Activity Impairment Questionnaire (WPAI): Activity Impairment Due to Health (%)
(Mixed Model Repeated Measures)

Visit: Week 36

	Placebo (N=68)	Mepolizumab 300 mg SC (N=68)
n [1]	67	68
n [2]	61	66
LS Mean (SE)	39.13 (2.912)	34.83 (2.803)
LS Mean Change (SE)	1.63 (2.912)	-2.67 (2.803)
Mepolizumab 300 mg SC vs Placebo		
Difference (Mepo - Placebo)		-4.30
95% CI		(-12.31, 3.70)
p-value		0.290
Corrected Hedges g [3]		-0.19
95% CI		(-0.54, 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] Derived from LS means and associated SE.
Note: Analysis performed using mixed model repeated measures with covariates of baseline, baseline prednisolone/prednisone daily dose, region (EU vs. RoW), treatment and visit, plus interaction terms for visit-by-baseline and visit-by-treatment group. LS mean estimates are weighted according to the observed proportions of each categorical covariate in the study data.

PPD

Protocol: MEA115921
Population: Intent-to-Treat

Table 7.56
Analysis of Change from Baseline in Work Productivity and Activity Impairment Questionnaire (WPAI): Activity Impairment Due to Health (%)
(Mixed Model Repeated Measures)

Visit: Week 52

	Placebo (N=68)	Mepolizumab 300 mg SC (N=68)
n [1]	67	68
n [2]	56	65
LS Mean (SE)	30.22 (2.612)	35.95 (2.438)
LS Mean Change (SE)	-7.28 (2.612)	-1.54 (2.438)
Mepolizumab 300 mg SC vs Placebo		
Difference (Mepo - Placebo)		5.74
95% CI		(-1.34, 12.81)
p-value		0.111
Corrected Hedges g [3]		0.29
95% CI		(-0.07, 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] Derived from LS means and associated SE.
Note: Analysis performed using mixed model repeated measures with covariates of baseline, baseline prednisolone/prednisone daily dose, region (EU vs. RoW), treatment and visit, plus interaction terms for visit-by-baseline and visit-by-treatment group. LS mean estimates are weighted according to the observed proportions of each categorical covariate in the study data.

PPD

Protocol: MEA115921
Population: Intent-to-Treat

Table 2.3
Analysis of Accrued Duration of Remission (BVAS=0 and Prednisolone/prednisone Dose <=4 mg/day) by Age

Age: <50 Years

		Placebo (N=68)	Mepolizumab 300 mg SC (N=68)
Duration of Remission [1]	n	33	31
	0	26 (79%)	12 (39%)
	>0 to <12 weeks	5 (15%)	6 (19%)
	12 to <24 weeks	2 (6%)	4 (13%)
	24 to <36 weeks	0	4 (13%)
	>=36 weeks	0	5 (16%)
Comparison: Placebo/ Mepolizumab [2]			
Odds Ratio			0.12
95% Confidence Interval			(0.04, 0.38)
p-value			<0.001

[1] Accrued number of weeks where remission achieved over the 52 week study period.
[2] Based on a proportional odds model with covariates: treatment group, baseline prednisolone/prednisone daily dose, baseline BVAS score and region (defined as EU vs RoW). An odds ratio <1 represents a benefit of mepolizumab compared to placebo.

PPD

Protocol: MEA115921
Population: Intent-to-Treat

Table 2.3
Analysis of Accrued Duration of Remission (BVAS=0 and Prednisolone/prednisone Dose <=4 mg/day) by Age

Age: >=50 Years

		Placebo (N=68)	Mepolizumab 300 mg SC (N=68)
Duration of Remission [1]	n	35	37
	0	29 (83%)	20 (54%)
	>0 to <12 weeks	3 (9%)	2 (5%)
	12 to <24 weeks	1 (3%)	5 (14%)
	24 to <36 weeks	0	6 (16%)
	>=36 weeks	2 (6%)	4 (11%)
Comparison: Placebo/ Mepolizumab [2]			
Odds Ratio			0.22
95% Confidence Interval			(0.07, 0.69)
p-value			0.010

[1] Accrued number of weeks where remission achieved over the 52 week study period.
[2] Based on a proportional odds model with covariates: treatment group, baseline prednisolone/prednisone daily dose, baseline BVAS score and region (defined as EU vs RoW). An odds ratio <1 represents a benefit of mepolizumab compared to placebo.

PPD

Protocol: MEA115921
Population: Intent-to-Treat

Table 2.4
Analysis of Accrued Duration of Remission (BVAS=0 and Prednisolone/prednisone Dose <=4 mg/day) by Gender

Gender: Female

		Placebo (N=68)	Mepolizumab 300 mg SC (N=68)
Duration of Remission [1]	n	38	42
	0	33 (87%)	19 (45%)
	>0 to <12 weeks	3 (8%)	5 (12%)
	12 to <24 weeks	2 (5%)	5 (12%)
	24 to <36 weeks	0	6 (14%)
	>=36 weeks	0	7 (17%)
Comparison: Placebo/ Mepolizumab [2]			
Odds Ratio			0.10
95% Confidence Interval			(0.03, 0.33)
p-value			<0.001

[1] Accrued number of weeks where remission achieved over the 52 week study period.
[2] Based on a proportional odds model with covariates: treatment group, baseline prednisolone/prednisone daily dose, baseline BVAS score and region (defined as EU vs RoW). An odds ratio <1 represents a benefit of mepolizumab compared to placebo.

PPD

Population: Intent-to-Treat

Table 2.4
Analysis of Accrued Duration of Remission (BVAS=0 and Prednisolone/prednisone Dose <=4 mg/day) by Gender

Gender: Male

		Placebo (N=68)	Mepolizumab 300 mg SC (N=68)
Duration of Remission [1]	n	30	26
	0	22 (73%)	13 (50%)
	>0 to <12 weeks	5 (17%)	3 (12%)
	12 to <24 weeks	1 (3%)	4 (15%)
	24 to <36 weeks	0	4 (15%)
	>=36 weeks	2 (7%)	2 (8%)
Comparison: Placebo/ Mepolizumab [2]			
Odds Ratio			0.24
95% Confidence Interval			(0.07, 0.76)
p-value			0.016

[1] Accrued number of weeks where remission achieved over the 52 week study period.
[2] Based on a proportional odds model with covariates: treatment group, baseline prednisolone/prednisone daily dose, baseline BVAS score and region (defined as EU vs RoW). An odds ratio <1 represents a benefit of mepolizumab compared to placebo.

PPD

Protocol: MEA115921
Population: Intent-to-Treat

Table 2.5
Analysis of Accrued Duration of Remission (BVAS=0 and Prednisolone/prednisone Dose <=4 mg/day) by Region

Region: Europe

		Placebo (N=68)	Mepolizumab 300 mg SC (N=68)
Duration of Remission [1]	n	33	32
	0	25 (76%)	12 (38%)
	>0 to <12 weeks	4 (12%)	3 (9%)
	12 to <24 weeks	3 (9%)	7 (22%)
	24 to <36 weeks	0	6 (19%)
	>=36 weeks	1 (3%)	4 (13%)
Comparison: Placebo/ Mepolizumab [2]			
Odds Ratio			0.20
95% Confidence Interval			(0.07, 0.58)
p-value			0.003

[1] Accrued number of weeks where remission achieved over the 52 week study period.
[2] Based on a proportional odds model with covariates: treatment group, baseline prednisolone/prednisone daily dose and baseline BVAS score. An odds ratio <1 represents a benefit of mepolizumab compared to placebo.

PPD

Protocol: MEA115921
Population: Intent-to-Treat

Table 2.5
Analysis of Accrued Duration of Remission (BVAS=0 and Prednisolone/prednisone Dose <=4 mg/day) by Region

Region: Rest of World

		Placebo (N=68)	Mepolizumab 300 mg SC (N=68)
Duration of Remission [1]	n	35	36
	0	30 (86%)	20 (56%)
	>0 to <12 weeks	4 (11%)	5 (14%)
	12 to <24 weeks	0	2 (6%)
	24 to <36 weeks	0	4 (11%)
	>=36 weeks	1 (3%)	5 (14%)
Comparison: Placebo/ Mepolizumab [2]			
Odds Ratio			0.13
95% Confidence Interval			(0.04, 0.43)
p-value			<0.001

[1] Accrued number of weeks where remission achieved over the 52 week study period.
[2] Based on a proportional odds model with covariates: treatment group, baseline prednisolone/prednisone daily dose and baseline BVAS score. An odds ratio <1 represents a benefit of mepolizumab compared to placebo.

PPD

Protocol: MEA115921
Population: Intent-to-Treat

Table 2.6
Analysis of Accrued Duration of Remission (BVAS=0 and Prednisolone/prednisone Dose <=4 mg/day) by Baseline Blood Eosinophils

Baseline blood eosinophils: <0.150 GI/L

		Placebo (N=68)	Mepolizumab 300 mg SC (N=68)
Duration of Remission [1]	n	28	29
	0	19 (68%)	18 (62%)
	>0 to <12 weeks	5 (18%)	2 (7%)
	12 to <24 weeks	2 (7%)	3 (10%)
	24 to <36 weeks	0	4 (14%)
	>=36 weeks	2 (7%)	2 (7%)
Comparison: Placebo/ Mepolizumab [2]			
Odds Ratio			1.01
95% Confidence Interval			(0.31, 3.27)
p-value			0.989

[1] Accrued number of weeks where remission achieved over the 52 week study period.
[2] Based on a proportional odds model with covariates: treatment group, baseline prednisolone/prednisone daily dose, baseline BVAS score and region (defined as EU vs RoW). An odds ratio <1 represents a benefit of mepolizumab compared to placebo.

PPD

Protocol: MEA115921
Population: Intent-to-Treat

Table 2.6
Analysis of Accrued Duration of Remission (BVAS=0 and Prednisolone/prednisone Dose <=4 mg/day) by Baseline Blood Eosinophils

Baseline blood eosinophils: >=0.150 GI/L

		Placebo (N=68)	Mepolizumab 300 mg SC (N=68)
Duration of Remission [1]	n	40	39
	0	36 (90%)	14 (36%)
	>0 to <12 weeks	3 (8%)	6 (15%)
	12 to <24 weeks	1 (3%)	6 (15%)
	24 to <36 weeks	0	6 (15%)
	>=36 weeks	0	7 (18%)
Comparison: Placebo/ Mepolizumab [2]			
Odds Ratio			0.03
95% Confidence Interval			(0.01, 0.13)
p-value			<0.001

[1] Accrued number of weeks where remission achieved over the 52 week study period.
[2] Based on a proportional odds model with covariates: treatment group, baseline prednisolone/prednisone daily dose, baseline BVAS score and region (defined as EU vs RoW). An odds ratio <1 represents a benefit of mepolizumab compared to placebo.

PPD

Protocol: MEA115921
Population: Intent-to-Treat

Table 2.7
Analysis of Accrued Duration of Remission (BVAS=0 and Prednisolone/prednisone Dose <=4 mg/day) by Duration of Disease

Duration of disease: <=4 years

		Placebo (N=68)	Mepolizumab 300 mg SC (N=68)
Duration of Remission [1]	n	32	34
	0	30 (94%)	17 (50%)
	>0 to <12 weeks	2 (6%)	6 (18%)
	12 to <24 weeks	0	3 (9%)
	24 to <36 weeks	0	4 (12%)
	>=36 weeks	0	4 (12%)
Comparison: Placebo/ Mepolizumab [2]			
Odds Ratio			0.06
95% Confidence Interval			(0.01, 0.29)
p-value			<0.001

[1] Accrued number of weeks where remission achieved over the 52 week study period.
[2] Based on a proportional odds model with covariates: treatment group, baseline prednisolone/prednisone daily dose, baseline BVAS score and region (defined as EU vs RoW). An odds ratio <1 represents a benefit of mepolizumab compared to placebo.

PPD

Population: Intent-to-Treat

Table 2.7
Analysis of Accrued Duration of Remission (BVAS=0 and Prednisolone/prednisone Dose <=4 mg/day) by Duration of Disease

Duration of disease: >4 years

		Placebo (N=68)	Mepolizumab 300 mg SC (N=68)
Duration of Remission [1]	n	36	34
	0	25 (69%)	15 (44%)
	>0 to <12 weeks	6 (17%)	2 (6%)
	12 to <24 weeks	3 (8%)	6 (18%)
	24 to <36 weeks	0	6 (18%)
	>=36 weeks	2 (6%)	5 (15%)
Comparison: Placebo/ Mepolizumab [2]			
Odds Ratio			0.24
95% Confidence Interval			(0.08, 0.66)
p-value			0.006

[1] Accrued number of weeks where remission achieved over the 52 week study period.
[2] Based on a proportional odds model with covariates: treatment group, baseline prednisolone/prednisone daily dose, baseline BVAS score and region (defined as EU vs RoW). An odds ratio <1 represents a benefit of mepolizumab compared to placebo.

PPD

Protocol: MEA115921
Population: Intent-to-Treat

Table 2.10
Analysis of Accrued Duration of Remission (BVAS=0 and Prednisolone/prednisone Dose <=7.5 mg/day) by Age

Age: <50 Years

		Placebo (N=68)	Mepolizumab 300 mg SC (N=68)
Duration of Remission [1]	n	33	31
	0	16 (48%)	4 (13%)
	>0 to <12 weeks	12 (36%)	9 (29%)
	12 to <24 weeks	0	3 (10%)
	24 to <36 weeks	3 (9%)	5 (16%)
	>=36 weeks	2 (6%)	10 (32%)
Comparison: Placebo/ Mepolizumab [2]			
Odds Ratio			0.12
95% Confidence Interval			(0.04, 0.36)
p-value			<0.001

[1] Accrued number of weeks where remission achieved over the 52 week study period.
[2] Based on a proportional odds model with covariates: treatment group, baseline prednisolone/prednisone daily dose, baseline BVAS score and region (defined as EU vs RoW). An odds ratio <1 represents a benefit of mepolizumab compared to placebo.

PPD

Protocol: MEA115921
Population: Intent-to-Treat

Table 2.10
Analysis of Accrued Duration of Remission (BVAS=0 and Prednisolone/prednisone Dose <=7.5 mg/day) by Age

Age: >=50 Years

		Placebo (N=68)	Mepolizumab 300 mg SC (N=68)
Duration of Remission [1]	n	35	37
	0	20 (57%)	11 (30%)
	>0 to <12 weeks	7 (20%)	6 (16%)
	12 to <24 weeks	0	4 (11%)
	24 to <36 weeks	4 (11%)	4 (11%)
	>=36 weeks	4 (11%)	12 (32%)
Comparison: Placebo/ Mepolizumab [2]			
Odds Ratio			0.24
95% Confidence Interval			(0.09, 0.67)
p-value			0.006

[1] Accrued number of weeks where remission achieved over the 52 week study period.
[2] Based on a proportional odds model with covariates: treatment group, baseline prednisolone/prednisone daily dose, baseline BVAS score and region (defined as EU vs RoW). An odds ratio <1 represents a benefit of mepolizumab compared to placebo.

PPD

Protocol: MEA115921
Population: Intent-to-Treat

Table 2.11
Analysis of Accrued Duration of Remission (BVAS=0 and Prednisolone/prednisone Dose <=7.5 mg/day) by Gender

Gender: Female

		Placebo (N=68)	Mepolizumab 300 mg SC (N=68)
Duration of Remission [1]	n	38	42
	0	21 (55%)	5 (12%)
	>0 to <12 weeks	10 (26%)	10 (24%)
	12 to <24 weeks	0	6 (14%)
	24 to <36 weeks	4 (11%)	4 (10%)
	>=36 weeks	3 (8%)	17 (40%)
Comparison: Placebo/ Mepolizumab [2]			
Odds Ratio			0.13
95% Confidence Interval			(0.05, 0.35)
p-value			<0.001

[1] Accrued number of weeks where remission achieved over the 52 week study period.
[2] Based on a proportional odds model with covariates: treatment group, baseline prednisolone/prednisone daily dose, baseline BVAS score and region (defined as EU vs RoW). An odds ratio <1 represents a benefit of mepolizumab compared to placebo.

PPD

Population: Intent-to-Treat

Table 2.11
Analysis of Accrued Duration of Remission (BVAS=0 and Prednisolone/prednisone Dose <=7.5 mg/day) by Gender

Gender: Male

		Placebo (N=68)	Mepolizumab 300 mg SC (N=68)
Duration of Remission [1]	n	30	26
	0	15 (50%)	10 (38%)
	>0 to <12 weeks	9 (30%)	5 (19%)
	12 to <24 weeks	0	1 (4%)
	24 to <36 weeks	3 (10%)	5 (19%)
	>=36 weeks	3 (10%)	5 (19%)
Comparison: Placebo/ Mepolizumab [2]			
Odds Ratio			0.35
95% Confidence Interval			(0.12, 1.02)
p-value			0.053

[1] Accrued number of weeks where remission achieved over the 52 week study period.
[2] Based on a proportional odds model with covariates: treatment group, baseline prednisolone/prednisone daily dose, baseline BVAS score and region (defined as EU vs RoW). An odds ratio <1 represents a benefit of mepolizumab compared to placebo.

PPD

Protocol: MEA115921
Population: Intent-to-Treat

Table 2.12
Analysis of Accrued Duration of Remission (BVAS=0 and Prednisolone/prednisone Dose <=7.5 mg/day) by Region

Region: Europe

		Placebo (N=68)	Mepolizumab 300 mg SC (N=68)
Duration of Remission [1]	n	33	32
	0	18 (55%)	3 (9%)
	>0 to <12 weeks	6 (18%)	4 (13%)
	12 to <24 weeks	0	5 (16%)
	24 to <36 weeks	4 (12%)	5 (16%)
	>=36 weeks	5 (15%)	15 (47%)
Comparison: Placebo/ Mepolizumab [2]			
Odds Ratio			0.18
95% Confidence Interval			(0.06, 0.48)
p-value			<0.001

[1] Accrued number of weeks where remission achieved over the 52 week study period.
[2] Based on a proportional odds model with covariates: treatment group, baseline prednisolone/prednisone daily dose and baseline BVAS score. An odds ratio <1 represents a benefit of mepolizumab compared to placebo.

PPD

Population: Intent-to-Treat

Table 2.12
Analysis of Accrued Duration of Remission (BVAS=0 and Prednisolone/prednisone Dose <=7.5 mg/day) by Region

Region: Rest of World

		Placebo (N=68)	Mepolizumab 300 mg SC (N=68)
Duration of Remission [1]	n	35	36
	0	18 (51%)	12 (33%)
	>0 to <12 weeks	13 (37%)	11 (31%)
	12 to <24 weeks	0	2 (6%)
	24 to <36 weeks	3 (9%)	4 (11%)
	>=36 weeks	1 (3%)	7 (19%)
Comparison: Placebo/ Mepolizumab [2]			
Odds Ratio			0.19
95% Confidence Interval			(0.07, 0.53)
p-value			0.001

[1] Accrued number of weeks where remission achieved over the 52 week study period.
[2] Based on a proportional odds model with covariates: treatment group, baseline prednisolone/prednisone daily dose and baseline BVAS score. An odds ratio <1 represents a benefit of mepolizumab compared to placebo.

PPD

Protocol: MEA115921
Population: Intent-to-Treat

Table 2.13
Analysis of Accrued Duration of Remission (BVAS=0 and Prednisolone/prednisone Dose <=7.5 mg/day)
by Baseline Blood Eosinophils

Baseline blood eosinophils: <0.150 GI/L

		Placebo (N=68)	Mepolizumab 300 mg SC (N=68)
Duration of Remission [1]	n	28	29
	0	14 (50%)	10 (34%)
	>0 to <12 weeks	9 (32%)	7 (24%)
	12 to <24 weeks	0	3 (10%)
	24 to <36 weeks	3 (11%)	2 (7%)
	>=36 weeks	2 (7%)	7 (24%)
Comparison: Placebo/ Mepolizumab [2]			
Odds Ratio			0.55
95% Confidence Interval			(0.19, 1.56)
p-value			0.262

[1] Accrued number of weeks where remission achieved over the 52 week study period.
[2] Based on a proportional odds model with covariates: treatment group, baseline prednisolone/prednisone daily dose, baseline BVAS score and region (defined as EU vs RoW). An odds ratio <1 represents a benefit of mepolizumab compared to placebo.

PPD

Population: Intent-to-Treat

Table 2.13
Analysis of Accrued Duration of Remission (BVAS=0 and Prednisolone/prednisone Dose <=7.5 mg/day) by Baseline Blood Eosinophils

Baseline blood eosinophils: >=0.150 GI/L

		Placebo (N=68)	Mepolizumab 300 mg SC (N=68)
Duration of Remission [1]	n	40	39
	0	22 (55%)	5 (13%)
	>0 to <12 weeks	10 (25%)	8 (21%)
	12 to <24 weeks	0	4 (10%)
	24 to <36 weeks	4 (10%)	7 (18%)
	>=36 weeks	4 (10%)	15 (38%)
Comparison: Placebo/ Mepolizumab [2]			
Odds Ratio			0.08
95% Confidence Interval			(0.03, 0.22)
p-value			<0.001

[1] Accrued number of weeks where remission achieved over the 52 week study period.
[2] Based on a proportional odds model with covariates: treatment group, baseline prednisolone/prednisone daily dose, baseline BVAS score and region (defined as EU vs RoW). An odds ratio <1 represents a benefit of mepolizumab compared to placebo.

PPD

Protocol: MEA115921
Population: Intent-to-Treat

Table 2.14
Analysis of Accrued Duration of Remission (BVAS=0 and Prednisolone/prednisone Dose <=7.5 mg/day) by Duration of Disease

Duration of disease: <=4 years

		Placebo (N=68)	Mepolizumab 300 mg SC (N=68)
Duration of Remission [1]	n	32	34
	0	18 (56%)	7 (21%)
	>0 to <12 weeks	11 (34%)	10 (29%)
	12 to <24 weeks	0	4 (12%)
	24 to <36 weeks	2 (6%)	3 (9%)
	>=36 weeks	1 (3%)	10 (29%)
Comparison: Placebo/ Mepolizumab [2]			
Odds Ratio			0.12
95% Confidence Interval			(0.04, 0.34)
p-value			<0.001

[1] Accrued number of weeks where remission achieved over the 52 week study period.
[2] Based on a proportional odds model with covariates: treatment group, baseline prednisolone/prednisone daily dose, baseline BVAS score and region (defined as EU vs RoW). An odds ratio <1 represents a benefit of mepolizumab compared to placebo.

PPD

Population: Intent-to-Treat

Table 2.14
Analysis of Accrued Duration of Remission (BVAS=0 and Prednisolone/prednisone Dose <=7.5 mg/day) by Duration of Disease

Duration of disease: >4 years

		Placebo (N=68)	Mepolizumab 300 mg SC (N=68)
Duration of Remission [1]	n	36	34
	0	18 (50%)	8 (24%)
	>0 to <12 weeks	8 (22%)	5 (15%)
	12 to <24 weeks	0	3 (9%)
	24 to <36 weeks	5 (14%)	6 (18%)
	>=36 weeks	5 (14%)	12 (35%)
Comparison: Placebo/ Mepolizumab [2]			
Odds Ratio			0.25
95% Confidence Interval			(0.09, 0.64)
p-value			0.004

[1] Accrued number of weeks where remission achieved over the 52 week study period.
[2] Based on a proportional odds model with covariates: treatment group, baseline prednisolone/prednisone daily dose, baseline BVAS score and region (defined as EU vs RoW). An odds ratio <1 represents a benefit of mepolizumab compared to placebo.

PPD

Protocol: MEA115921
Population: Intent-to-Treat

Table 2.18
Analysis of Subjects with Remission (BVAS = 0 and OCS dose <= 7.5 mg/day) at Weeks 36 and 48 by Age

Age: <50 Years

	Placebo (N=68)	Mepolizumab 300 mg SC (N=68)
n	33	31
Responder	3 (9%)	14 (45%)
Non-Responder	30 (91%)	17 (55%)
Comparison Mepolizumab 300 mg vs Placebo [1]		
Logistic regression [2]		
Inverse odds ratio (95% CI)		0.12 (0.03,0.59)
p-value		0.009
Inverse unadjusted odds ratio (95% CI) [3]		0.13 (0.02,0.54)
Inverse relative risk (95% CI) [4]		0.20 (0.03,0.61)
Risk difference (95% CI) [4]		-0.36 (-0.56,-0.13)
Fisher's Exact p-value (2-sided)		0.002

[1] Analysis compares the number of responders. Subjects with missing response are categorised as non-responders.
[2] Logistic regression analysis adjusted for baseline prednisolone/prednisone daily dose, baseline BVAS score and region (EU vs. RoW).
[3] Exact method.
[4] Exact unconditional CI calculated by inverting two separate one-sided tests based on the score statistic.
Note: Inverse odds ratio and inverse relative risk <1 and risk difference <0 indicate benefit for Mepolizumab over Placebo.

PPD

Protocol: MEA115921
Population: Intent-to-Treat

Table 2.18
Analysis of Subjects with Remission (BVAS = 0 and OCS dose <= 7.5 mg/day) at Weeks 36 and 48 by Age

Age: >=50 Years

	Placebo (N=68)	Mepolizumab 300 mg SC (N=68)
n	35	37
Responder	4 (11%)	14 (38%)
Non-Responder	31 (89%)	23 (62%)
Comparison Mepolizumab 300 mg vs Placebo [1]		
Logistic regression [2]		
Inverse odds ratio (95% CI)		0.16 (0.03,0.71)
p-value		0.016
Inverse unadjusted odds ratio (95% CI) [3]		0.22 (0.05,0.81)
Inverse relative risk (95% CI) [4]		0.30 (0.07,0.88)
Risk difference (95% CI) [4]		-0.26 (-0.45,-0.05)
Fisher's Exact p-value (2-sided)		0.014

[1] Analysis compares the number of responders. Subjects with missing response are categorised as non-responders.
[2] Logistic regression analysis adjusted for baseline prednisolone/prednisone daily dose, baseline BVAS score and region (EU vs. RoW).
[3] Exact method.
[4] Exact unconditional CI calculated by inverting two separate one-sided tests based on the score statistic.
Note: Inverse odds ratio and inverse relative risk <1 and risk difference <0 indicate benefit for Mepolizumab over Placebo.

PPD

Protocol: MEA115921
Population: Intent-to-Treat

Table 2.19
Analysis of Subjects with Remission (BVAS = 0 and OCS dose <= 7.5 mg/day) at Weeks 36 and 48 by Gender

Gender: Female

	Placebo (N=68)	Mepolizumab 300 mg SC (N=68)
n	38	42
Responder	4 (11%)	20 (48%)
Non-Responder	34 (89%)	22 (52%)
Comparison Mepolizumab 300 mg vs Placebo [1]		
Logistic regression [2]		
Inverse odds ratio (95% CI)		0.15 (0.04,0.57)
p-value		0.005
Inverse unadjusted odds ratio (95% CI) [3]		0.13 (0.03,0.47)
Inverse relative risk (95% CI) [4]		0.22 (0.05,0.57)
Risk difference (95% CI) [4]		-0.37 (-0.55,-0.15)
Fisher's Exact p-value (2-sided)		<0.001

[1] Analysis compares the number of responders. Subjects with missing response are categorised as non-responders.
[2] Logistic regression analysis adjusted for baseline prednisolone/prednisone daily dose, baseline BVAS score and region (EU vs. RoW).
[3] Exact method.
[4] Exact unconditional CI calculated by inverting two separate one-sided tests based on the score statistic.
Note: Inverse odds ratio and inverse relative risk <1 and risk difference <0 indicate benefit for Mepolizumab over Placebo.

PPD

Protocol: MEA115921
Population: Intent-to-Treat

Table 2.19
Analysis of Subjects with Remission (BVAS = 0 and OCS dose <= 7.5 mg/day) at Weeks 36 and 48 by Gender

Gender: Male

	Placebo (N=68)	Mepolizumab 300 mg SC (N=68)
n	30	26
Responder	3 (10%)	8 (31%)
Non-Responder	27 (90%)	18 (69%)
Comparison Mepolizumab 300 mg vs Placebo [1]		
Logistic regression [2]		
Inverse odds ratio (95% CI)		0.14 (0.03,0.74)
p-value		0.021
Inverse unadjusted odds ratio (95% CI) [3]		0.26 (0.04,1.25)
Inverse relative risk (95% CI) [4]		0.33 (0.06,1.03)
Risk difference (95% CI) [4]		-0.21 (-0.43,0.01)
Fisher's Exact p-value (2-sided)		0.090

[1] Analysis compares the number of responders. Subjects with missing response are categorised as non-responders.
[2] Logistic regression analysis adjusted for baseline prednisolone/prednisone daily dose, baseline BVAS score and region (EU vs. RoW).
[3] Exact method.
[4] Exact unconditional CI calculated by inverting two separate one-sided tests based on the score statistic.
Note: Inverse odds ratio and inverse relative risk <1 and risk difference <0 indicate benefit for Mepolizumab over Placebo.

PPD

Protocol: MEA115921
Population: Intent-to-Treat

Table 2.20
Analysis of Subjects with Remission (BVAS = 0 and OCS dose <= 7.5 mg/day) at Weeks 36 and 48 by Region

Region: Europe

	Placebo (N=68)	Mepolizumab 300 mg SC (N=68)
n	33	32
Responder	6 (18%)	18 (56%)
Non-Responder	27 (82%)	14 (44%)
Comparison Mepolizumab 300 mg vs Placebo [1]		
Logistic regression [2]		
Inverse odds ratio (95% CI)		0.20 (0.06,0.66)
p-value		0.008
Inverse unadjusted odds ratio (95% CI) [3]		0.18 (0.05,0.60)
Inverse relative risk (95% CI) [4]		0.32 (0.08,0.72)
Risk difference (95% CI) [4]		-0.38 (-0.59,-0.13)
Fisher's Exact p-value (2-sided)		0.002

[1] Analysis compares the number of responders. Subjects with missing response are categorised as non-responders.
[2] Logistic regression analysis adjusted for baseline prednisolone/prednisone daily dose and baseline BVAS score.
[3] Exact method.
[4] Exact unconditional CI calculated by inverting two separate one-sided tests based on the score statistic.
Note: Inverse odds ratio and inverse relative risk <1 and risk difference <0 indicate benefit for Mepolizumab over Placebo.

PPD

Table 2.20
Analysis of Subjects with Remission (BVAS = 0 and OCS dose <= 7.5 mg/day) at Weeks 36 and 48 by Region

Region: Rest of World

	Placebo (N=68)	Mepolizumab 300 mg SC (N=68)
n	35	36
Responder	1 (3%)	10 (28%)
Non-Responder	34 (97%)	26 (72%)
Comparison Mepolizumab 300 mg vs Placebo [1]		
Logistic regression [2]		
Inverse odds ratio (95% CI)		0.05 (0.01,0.49)
p-value		0.010
Inverse unadjusted odds ratio (95% CI) [3]		0.08 (<0.01,0.62)
Inverse relative risk (95% CI) [4]		0.10 (0.00,0.63)
Risk difference (95% CI) [4]		-0.25 (-0.42,-0.08)
Fisher's Exact p-value (2-sided)		0.006

[1] Analysis compares the number of responders. Subjects with missing response are categorised as non-responders.
[2] Logistic regression analysis adjusted for baseline prednisolone/prednisone daily dose and baseline BVAS score.
[3] Exact method.
[4] Exact unconditional CI calculated by inverting two separate one-sided tests based on the score statistic.
Note: Inverse odds ratio and inverse relative risk <1 and risk difference <0 indicate benefit for Mepolizumab over Placebo.

PPD

Protocol: MEA115921
Population: Intent-to-Treat

Table 2.21
Analysis of Subjects with Remission (BVAS = 0 and OCS dose <= 7.5 mg/day) at Weeks 36 and 48 by Baseline Blood Eosinophils

Baseline blood eosinophils: <0.150 GI/L

	Placebo (N=68)	Mepolizumab 300 mg SC (N=68)
n	28	29
Responder	3 (11%)	8 (28%)
Non-Responder	25 (89%)	21 (72%)
Comparison Mepolizumab 300 mg vs Placebo [1]		
Logistic regression [2]		
Inverse odds ratio (95% CI)		0.36 (0.07,1.87)
p-value		0.226
Inverse unadjusted odds ratio (95% CI) [3]		0.32 (0.05,1.56)
Inverse relative risk (95% CI) [4]		0.39 (0.07,1.24)
Risk difference (95% CI) [4]		-0.17 (-0.39,0.05)
Fisher's Exact p-value (2-sided)		0.179

[1] Analysis compares the number of responders. Subjects with missing response are categorised as non-responders.
[2] Logistic regression analysis adjusted for baseline prednisolone/prednisone daily dose, baseline BVAS score and region (EU vs. RoW).
[3] Exact method.
[4] Exact unconditional CI calculated by inverting two separate one-sided tests based on the score statistic.
Note: Inverse odds ratio and inverse relative risk <1 and risk difference <0 indicate benefit for Mepolizumab over Placebo.

PPD

Protocol: MEA115921
Population: Intent-to-Treat

Table 2.21
Analysis of Subjects with Remission (BVAS = 0 and OCS dose <= 7.5 mg/day) at Weeks 36 and 48 by Baseline Blood Eosinophils

Baseline blood eosinophils: >=0.150 GI/L

	Placebo (N=68)	Mepolizumab 300 mg SC (N=68)	
n	40	39	
Responder	4 (10%)	20 (51%)	
Non-Responder	36 (90%)	19 (49%)	
Comparison Mepolizumab 300 mg vs Placebo [1]			
Logistic regression [2]			
Inverse odds ratio (95% CI)		0.08	(0.02,0.29)
p-value		<0.001	
Inverse unadjusted odds ratio (95% CI) [3]		0.11	(0.02,0.39)
Inverse relative risk (95% CI) [4]		0.20	(0.04,0.49)
Risk difference (95% CI) [4]		-0.41	(-0.59,-0.19)
Fisher's Exact p-value (2-sided)		<0.001	

[1] Analysis compares the number of responders. Subjects with missing response are categorised as non-responders.
[2] Logistic regression analysis adjusted for baseline prednisolone/prednisone daily dose, baseline BVAS score and region (EU vs. RoW).
[3] Exact method.
[4] Exact unconditional CI calculated by inverting two separate one-sided tests based on the score statistic.
Note: Inverse odds ratio and inverse relative risk <1 and risk difference <0 indicate benefit for Mepolizumab over Placebo.

PPD

Protocol: MEA115921
Population: Intent-to-Treat

Table 2.22
Analysis of Subjects with Remission (BVAS = 0 and OCS dose <= 7.5 mg/day) at Weeks 36 and 48 by Duration of Disease

Duration of disease: <=4 years

	Placebo (N=68)	Mepolizumab 300 mg SC (N=68)
n	32	34
Responder	2 (6%)	11 (32%)
Non-Responder	30 (94%)	23 (68%)
Comparison Mepolizumab 300 mg vs Placebo [1]		
Logistic regression [2]		
Inverse odds ratio (95% CI)		0.19 (0.03,1.06)
p-value		0.058
Inverse unadjusted odds ratio (95% CI) [3]		0.14 (0.01,0.75)
Inverse relative risk (95% CI) [4]		0.19 (0.02,0.79)
Risk difference (95% CI) [4]		-0.26 (-0.45,-0.07)
Fisher's Exact p-value (2-sided)		0.012

[1] Analysis compares the number of responders. Subjects with missing response are categorised as non-responders.
[2] Logistic regression analysis adjusted for baseline prednisolone/prednisone daily dose, baseline BVAS score and region (EU vs. RoW).
[3] Exact method.
[4] Exact unconditional CI calculated by inverting two separate one-sided tests based on the score statistic.
Note: Inverse odds ratio and inverse relative risk <1 and risk difference <0 indicate benefit for Mepolizumab over Placebo.

PPD

Protocol: MEA115921
Population: Intent-to-Treat

Table 2.22
Analysis of Subjects with Remission (BVAS = 0 and OCS dose <= 7.5 mg/day) at Weeks 36 and 48 by Duration of Disease

Duration of disease: >4 years

	Placebo (N=68)	Mepolizumab 300 mg SC (N=68)
n	36	34
Responder	5 (14%)	17 (50%)
Non-Responder	31 (86%)	17 (50%)
Comparison Mepolizumab 300 mg vs Placebo [1]		
Logistic regression [2]		
Inverse odds ratio (95% CI)		0.09 (0.02,0.37)
p-value		<0.001
Inverse unadjusted odds ratio (95% CI) [3]		0.17 (0.04,0.57)
Inverse relative risk (95% CI) [4]		0.28 (0.06,0.67)
Risk difference (95% CI) [4]		-0.36 (-0.56,-0.13)
Fisher's Exact p-value (2-sided)		0.002

[1] Analysis compares the number of responders. Subjects with missing response are categorised as non-responders.
[2] Logistic regression analysis adjusted for baseline prednisolone/prednisone daily dose, baseline BVAS score and region (EU vs. RoW).
[3] Exact method.
[4] Exact unconditional CI calculated by inverting two separate one-sided tests based on the score statistic.
Note: Inverse odds ratio and inverse relative risk <1 and risk difference <0 indicate benefit for Mepolizumab over Placebo.

PPD

Protocol: MEA115921
Population: Intent-to-Treat

Table 2.26
Analysis of Subjects with Remission (BVAS = 0 and OCS dose <= 7.5 mg/day) within the First 24 Weeks of the Study and then Remain in Remission for the Remainder of the Study Treatment Period by Age

Age: <50 Years

	Placebo (N=68)	Mepolizumab 300 mg SC (N=68)
n	33	31
Responder	0	7 (23%)
Non-Responder	33 (100%)	24 (77%)
Comparison Mepolizumab 300 mg vs Placebo [1]		
Logistic regression [2]		
Inverse odds ratio (95% CI)		<0.01 (<0.01,>999.99)
p-value		0.947
Inverse unadjusted odds ratio (95% CI) [3]		0.08 (<0.01,0.43)
Inverse relative risk (95% CI) [4]		0.00 (0.00,0.55)
Risk difference (95% CI) [4]		-0.23 (-0.41,-0.09)
Fisher's Exact p-value (2-sided)		0.004

[1] Analysis compares the number of responders. Subjects with missing response are categorised as non-responders.
[2] Logistic regression analysis adjusted for baseline prednisolone/prednisone daily dose, baseline BVAS score and region (EU vs. RoW).
[3] Exact method.
[4] Exact unconditional CI calculated by inverting two separate one-sided tests based on the score statistic.
Note: Inverse odds ratio and inverse relative risk <1 and risk difference <0 indicate benefit for Mepolizumab over Placebo.

PPD

Protocol: MEA115921
Population: Intent-to-Treat

Table 2.26
Analysis of Subjects with Remission (BVAS = 0 and OCS dose <= 7.5 mg/day) within the First 24 Weeks of the Study and then Remain in Remission for the Remainder of the Study Treatment Period by Age

Age: >=50 Years

	Placebo (N=68)	Mepolizumab 300 mg SC (N=68)
n	35	37
Responder	2 (6%)	9 (24%)
Non-Responder	33 (94%)	28 (76%)
Comparison Mepolizumab 300 mg vs Placebo [1]		
Logistic regression [2]		
Inverse odds ratio (95% CI)		0.17 (0.03,0.99)
p-value		0.049
Inverse unadjusted odds ratio (95% CI) [3]		0.19 (0.02,1.04)
Inverse relative risk (95% CI) [4]		0.23 (0.02,0.94)
Risk difference (95% CI) [4]		-0.19 (-0.36,-0.02)
Fisher's Exact p-value (2-sided)		0.047

[1] Analysis compares the number of responders. Subjects with missing response are categorised as non-responders.
[2] Logistic regression analysis adjusted for baseline prednisolone/prednisone daily dose, baseline BVAS score and region (EU vs. RoW).
[3] Exact method.
[4] Exact unconditional CI calculated by inverting two separate one-sided tests based on the score statistic.
Note: Inverse odds ratio and inverse relative risk <1 and risk difference <0 indicate benefit for Mepolizumab over Placebo.

PPD

Protocol: MEA115921
Population: Intent-to-Treat

Table 2.27
Analysis of Subjects with Remission (BVAS = 0 and OCS dose <= 7.5 mg/day) within the First 24 Weeks of the Study and then Remain in Remission for the Remainder of the Study Treatment Period by Gender

Gender: Female

	Placebo (N=68)	Mepolizumab 300 mg SC (N=68)
n	38	42
Responder	0	12 (29%)
Non-Responder	38 (100%)	30 (71%)
Comparison Mepolizumab 300 mg vs Placebo [1]		
Logistic regression [2]		
Inverse odds ratio (95% CI)		<0.01 (<0.01,>999.99)
p-value		0.935
Inverse unadjusted odds ratio (95% CI) [3]		0.05 (<0.01,0.25)
Inverse relative risk (95% CI) [4]		0.00 (0.00,0.34)
Risk difference (95% CI) [4]		-0.29 (-0.45,0.15)
Fisher's Exact p-value (2-sided)		<0.001

[1] Analysis compares the number of responders. Subjects with missing response are categorised as non-responders.
[2] Logistic regression analysis adjusted for baseline prednisolone/prednisone daily dose, baseline BVAS score and region (EU vs. RoW).
[3] Exact method.
[4] Exact unconditional CI calculated by inverting two separate one-sided tests based on the score statistic.
Note: Inverse odds ratio and inverse relative risk <1 and risk difference <0 indicate benefit for Mepolizumab over Placebo.

PPD

Population: Intent-to-Treat

Table 2.27
Analysis of Subjects with Remission (BVAS = 0 and OCS dose <= 7.5 mg/day) within the First 24 Weeks of the Study and then Remain in Remission for the Remainder of the Study Treatment Period by Gender

Gender: Male

	Placebo (N=68)	Mepolizumab 300 mg SC (N=68)
n	30	26
Responder	2 (7%)	4 (15%)
Non-Responder	28 (93%)	22 (85%)
Comparison Mepolizumab 300 mg vs Placebo [1]		
Logistic regression [2]		
Inverse odds ratio (95% CI)		0.29 (0.04,2.01)
p-value		0.209
Inverse unadjusted odds ratio (95% CI) [3]		0.40 (0.03,3.08)
Inverse relative risk (95% CI) [4]		0.43 (0.06,2.33)
Risk difference (95% CI) [4]		-0.09 (-0.29,0.09)
Fisher's Exact p-value (2-sided)		0.401

[1] Analysis compares the number of responders. Subjects with missing response are categorised as non-responders.
[2] Logistic regression analysis adjusted for baseline prednisolone/prednisone daily dose, baseline BVAS score and region (EU vs. RoW).
[3] Exact method.
[4] Exact unconditional CI calculated by inverting two separate one-sided tests based on the score statistic.
Note: Inverse odds ratio and inverse relative risk <1 and risk difference <0 indicate benefit for Mepolizumab over Placebo.

PPD

Protocol: MEA115921
Population: Intent-to-Treat

Table 2.28
Analysis of Subjects with Remission (BVAS = 0 and OCS dose <= 7.5 mg/day) within the First 24 Weeks of the Study and then Remain in Remission for the Remainder of the Study Treatment Period by Region

Region: Europe

	Placebo (N=68)	Mepolizumab 300 mg SC (N=68)
n	33	32
Responder	2 (6%)	9 (28%)
Non-Responder	31 (94%)	23 (72%)
Comparison Mepolizumab 300 mg vs Placebo [1]		
Logistic regression [2]		
Inverse odds ratio (95% CI)		0.19 (0.03,1.03)
p-value		0.054
Inverse unadjusted odds ratio (95% CI) [3]		0.17 (0.02,0.93)
Inverse relative risk (95% CI) [4]		0.22 (0.02,0.89)
Risk difference (95% CI) [4]		-0.22 (-0.41,-0.03)
Fisher's Exact p-value (2-sided)		0.023

[1] Analysis compares the number of responders. Subjects with missing response are categorised as non-responders.
[2] Logistic regression analysis adjusted for baseline prednisolone/prednisone daily dose and baseline BVAS score.
[3] Exact method.
[4] Exact unconditional CI calculated by inverting two separate one-sided tests based on the score statistic.
Note: Inverse odds ratio and inverse relative risk <1 and risk difference <0 indicate benefit for Mepolizumab over Placebo.

PPD

Protocol: MEA115921
Population: Intent-to-Treat

Table 2.28
Analysis of Subjects with Remission (BVAS = 0 and OCS dose <= 7.5 mg/day) within the First 24 Weeks of the Study and then Remain in Remission for the Remainder of the Study Treatment Period by Region

Region: Rest of World

	Placebo (N=68)	Mepolizumab 300 mg SC (N=68)
n	35	36
Responder	0	7 (19%)
Non-Responder	35 (100%)	29 (81%)
Comparison Mepolizumab 300 mg vs Placebo [1]		
Logistic regression [2]		
Inverse odds ratio (95% CI)		<0.01 (<0.01,>999.99)
p-value		0.944
Inverse unadjusted odds ratio (95% CI) [3]		0.09 (<0.01,0.49)
Inverse relative risk (95% CI) [4]		0.00 (0.00,0.61)
Risk difference (95% CI) [4]		-0.19 (-0.36,-0.07)
Fisher's Exact p-value (2-sided)		0.011

[1] Analysis compares the number of responders. Subjects with missing response are categorised as non-responders.
[2] Logistic regression analysis adjusted for baseline prednisolone/prednisone daily dose and baseline BVAS score.
[3] Exact method.
[4] Exact unconditional CI calculated by inverting two separate one-sided tests based on the score statistic.
Note: Inverse odds ratio and inverse relative risk <1 and risk difference <0 indicate benefit for Mepolizumab over Placebo.

PPD

Protocol: MEA115921
Population: Intent-to-Treat

Table 2.29
Analysis of Subjects with Remission (BVAS = 0 and OCS dose <= 7.5 mg/day) within the First 24 Weeks of the Study and then Remain in Remission for the Remainder of the Study Treatment Period by Baseline Blood Eosinophils

Baseline blood eosinophils: <0.150 GI/L

	Placebo (N=68)	Mepolizumab 300 mg SC (N=68)
n	28	29
Responder	1 (4%)	5 (17%)
Non-Responder	27 (96%)	24 (83%)
Comparison Mepolizumab 300 mg vs Placebo [1]		
Logistic regression [2]		
Inverse odds ratio (95% CI)		0.21 (0.02,2.30)
p-value		0.202
Inverse unadjusted odds ratio (95% CI) [3]		0.18 (<0.01,1.80)
Inverse relative risk (95% CI) [4]		0.21 (0.01,1.35)
Risk difference (95% CI) [4]		-0.14 (-0.33,0.04)
Fisher's Exact p-value (2-sided)		0.194

[1] Analysis compares the number of responders. Subjects with missing response are categorised as non-responders.
[2] Logistic regression analysis adjusted for baseline prednisolone/prednisone daily dose, baseline BVAS score and region (EU vs. RoW).
[3] Exact method.
[4] Exact unconditional CI calculated by inverting two separate one-sided tests based on the score statistic.
Note: Inverse odds ratio and inverse relative risk <1 and risk difference <0 indicate benefit for Mepolizumab over Placebo.

PPD

Protocol: MEA115921
Population: Intent-to-Treat

Table 2.29
Analysis of Subjects with Remission (BVAS = 0 and OCS dose <= 7.5 mg/day) within the First 24 Weeks of the Study and then Remain in Remission for the Remainder of the Study Treatment Period by Baseline Blood Eosinophils

Baseline blood eosinophils: >=0.150 GI/L

	Placebo (N=68)	Mepolizumab 300 mg SC (N=68)
n	40	39
Responder	1 (3%)	11 (28%)
Non-Responder	39 (98%)	28 (72%)
Comparison Mepolizumab 300 mg vs Placebo [1]		
Logistic regression [2]		
Inverse odds ratio (95% CI)		0.04 (<0.01,0.40)
p-value		0.006
Inverse unadjusted odds ratio (95% CI) [3]		0.07 (<0.01,0.51)
Inverse relative risk (95% CI) [4]		0.09 (0.00,0.54)
Risk difference (95% CI) [4]		-0.26 (-0.43,-0.10)
Fisher's Exact p-value (2-sided)		0.001

[1] Analysis compares the number of responders. Subjects with missing response are categorised as non-responders.
[2] Logistic regression analysis adjusted for baseline prednisolone/prednisone daily dose, baseline BVAS score and region (EU vs. RoW).
[3] Exact method.
[4] Exact unconditional CI calculated by inverting two separate one-sided tests based on the score statistic.
Note: Inverse odds ratio and inverse relative risk <1 and risk difference <0 indicate benefit for Mepolizumab over Placebo.

PPD

Protocol: MEA115921
Population: Intent-to-Treat

Table 2.30
Analysis of Subjects with Remission (BVAS = 0 and OCS dose <= 7.5 mg/day) within the First 24 Weeks of the Study and then Remain in Remission for the Remainder of the Study Treatment Period by Duration of Disease

Duration of disease: <=4 years

	Placebo (N=68)	Mepolizumab 300 mg SC (N=68)
n	32	34
Responder	0	7 (21%)
Non-Responder	32 (100%)	27 (79%)
Comparison Mepolizumab 300 mg vs Placebo [1]		
Logistic regression [2]		
Inverse odds ratio (95% CI)		<0.01 (<0.01,>999.99)
p-value		0.934
Inverse unadjusted odds ratio (95% CI) [3]		0.09 (<0.01,0.50)
Inverse relative risk (95% CI) [4]		0.00 (0.00,0.62)
Risk difference (95% CI) [4]		-0.21 (-0.38,-0.07)
Fisher's Exact p-value (2-sided)		0.011

[1] Analysis compares the number of responders. Subjects with missing response are categorised as non-responders.
[2] Logistic regression analysis adjusted for baseline prednisolone/prednisone daily dose, baseline BVAS score and region (EU vs. RoW).
[3] Exact method.
[4] Exact unconditional CI calculated by inverting two separate one-sided tests based on the score statistic.
Note: Inverse odds ratio and inverse relative risk <1 and risk difference <0 indicate benefit for Mepolizumab over Placebo.

PPD

Protocol: MEA115921
Population: Intent-to-Treat

Table 2.30
Analysis of Subjects with Remission (BVAS = 0 and OCS dose <= 7.5 mg/day) within the First 24 Weeks of the Study and then Remain in Remission for the Remainder of the Study Treatment Period by Duration of Disease

Duration of disease: >4 years

	Placebo (N=68)	Mepolizumab 300 mg SC (N=68)
n	36	34
Responder	2 (6%)	9 (26%)
Non-Responder	34 (94%)	25 (74%)
Comparison Mepolizumab 300 mg vs Placebo [1]		
Logistic regression [2]		
Inverse odds ratio (95% CI)		0.14 (0.03,0.75)
p-value		0.022
Inverse unadjusted odds ratio (95% CI) [3]		0.17 (0.02,0.91)
Inverse relative risk (95% CI) [4]		0.21 (0.02,0.88)
Risk difference (95% CI) [4]		-0.21 (-0.39,-0.03)
Fisher's Exact p-value (2-sided)		0.022

[1] Analysis compares the number of responders. Subjects with missing response are categorised as non-responders.
[2] Logistic regression analysis adjusted for baseline prednisolone/prednisone daily dose, baseline BVAS score and region (EU vs. RoW).
[3] Exact method.
[4] Exact unconditional CI calculated by inverting two separate one-sided tests based on the score statistic.
Note: Inverse odds ratio and inverse relative risk <1 and risk difference <0 indicate benefit for Mepolizumab over Placebo.

PPD

Protocol: MEA115921
Population: Intent-to-Treat

Table 2.34
Analysis of Subjects with Remission (BVAS = 0 and OCS dose <= 7.5 mg/day) at Week 52 by Age

Age: <50 Years

	Placebo (N=68)	Mepolizumab 300 mg SC (N=68)
n	33	31
Responder	5 (15%)	12 (39%)
Non-Responder	28 (85%)	19 (61%)
Comparison Mepolizumab 300 mg vs Placebo [1]		
Logistic regression [2]		
Inverse odds ratio (95% CI)		0.26 (0.07,0.96)
p-value		0.044
Inverse unadjusted odds ratio (95% CI) [3]		0.29 (0.07,1.06)
Inverse relative risk (95% CI) [4]		0.39 (0.09,0.96)
Risk difference (95% CI) [4]		-0.24 (-0.45,-0.01)
Fisher's Exact p-value (2-sided)		0.048

[1] Analysis compares the number of responders. Subjects with missing response are categorised as non-responders.
[2] Logistic regression analysis adjusted for baseline prednisolone/prednisone daily dose, baseline BVAS score and region (EU vs. RoW).
[3] Exact method.
[4] Exact unconditional CI calculated by inverting two separate one-sided tests based on the score statistic.
Note: Inverse odds ratio and inverse relative risk <1 and risk difference <0 indicate benefit for Mepolizumab over Placebo.

PPD

Protocol: MEA115921
Population: Intent-to-Treat

Table 2.34
Analysis of Subjects with Remission (BVAS = 0 and OCS dose <= 7.5 mg/day) at Week 52
by Age

Age: >=50 Years

	Placebo (N=68)	Mepolizumab 300 mg SC (N=68)
n	35	37
Responder	5 (14%)	14 (38%)
Non-Responder	30 (86%)	23 (62%)
Comparison Mepolizumab 300 mg vs Placebo [1]		
Logistic regression [2]		
Inverse odds ratio (95% CI)		0.23 (0.06,0.85)
p-value		0.028
Inverse unadjusted odds ratio (95% CI) [3]		0.28 (0.07,0.97)
Inverse relative risk (95% CI) [4]		0.38 (0.07,0.94)
Risk difference (95% CI) [4]		-0.24 (-0.43,-0.02)
Fisher's Exact p-value (2-sided)		0.033

[1] Analysis compares the number of responders. Subjects with missing response are categorised as non-responders.
[2] Logistic regression analysis adjusted for baseline prednisolone/prednisone daily dose, baseline BVAS score and region (EU vs. RoW).
[3] Exact method.
[4] Exact unconditional CI calculated by inverting two separate one-sided tests based on the score statistic.
Note: Inverse odds ratio and inverse relative risk <1 and risk difference <0 indicate benefit for Mepolizumab over Placebo.

PPD

Protocol: MEA115921
Population: Intent-to-Treat

Table 2.35
Analysis of Subjects with Remission (BVAS = 0 and OCS dose <= 7.5 mg/day) at Week 52
by Gender

Gender: Female

	Placebo (N=68)	Mepolizumab 300 mg SC (N=68)
n	38	42
Responder	3 (8%)	18 (43%)
Non-Responder	35 (92%)	24 (57%)
Comparison Mepolizumab 300 mg vs Placebo [1]		
Logistic regression [2]		
Inverse odds ratio (95% CI)		0.14 (0.04,0.56)
p-value		0.006
Inverse unadjusted odds ratio (95% CI) [3]		0.12 (0.02,0.47)
Inverse relative risk (95% CI) [4]		0.18 (0.03,0.54)
Risk difference (95% CI) [4]		-0.35 (-0.52,-0.13)
Fisher's Exact p-value (2-sided)		<0.001

[1] Analysis compares the number of responders. Subjects with missing response are categorised as non-responders.
[2] Logistic regression analysis adjusted for baseline prednisolone/prednisone daily dose, baseline BVAS score and region (EU vs. RoW).
[3] Exact method.
[4] Exact unconditional CI calculated by inverting two separate one-sided tests based on the score statistic.
Note: Inverse odds ratio and inverse relative risk <1 and risk difference <0 indicate benefit for Mepolizumab over Placebo.

PPD

Population: Intent-to-Treat

Table 2.35
Analysis of Subjects with Remission (BVAS = 0 and OCS dose <= 7.5 mg/day) at Week 52
by Gender

Gender: Male

	Placebo (N=68)	Mepolizumab 300 mg SC (N=68)
n	30	26
Responder	7 (23%)	8 (31%)
Non-Responder	23 (77%)	18 (69%)
Comparison Mepolizumab 300 mg vs Placebo [1]		
Logistic regression [2]		
Inverse odds ratio (95% CI)		0.54 (0.15,1.94)
p-value		0.344
Inverse unadjusted odds ratio (95% CI) [3]		0.69 (0.18,2.65)
Inverse relative risk (95% CI) [4]		0.76 (0.28,1.92)
Risk difference (95% CI) [4]		-0.07 (-0.32,0.17)
Fisher's Exact p-value (2-sided)		0.560

[1] Analysis compares the number of responders. Subjects with missing response are categorised as non-responders.
[2] Logistic regression analysis adjusted for baseline prednisolone/prednisone daily dose, baseline BVAS score and region (EU vs. RoW).
[3] Exact method.
[4] Exact unconditional CI calculated by inverting two separate one-sided tests based on the score statistic.
Note: Inverse odds ratio and inverse relative risk <1 and risk difference <0 indicate benefit for Mepolizumab over Placebo.

PPD

Protocol: MEA115921
Population: Intent-to-Treat

Table 2.36
Analysis of Subjects with Remission (BVAS = 0 and OCS dose <= 7.5 mg/day) at Week 52
by Region

Region: Europe

	Placebo (N=68)	Mepolizumab 300 mg SC (N=68)
n	33	32
Responder	7 (21%)	16 (50%)
Non-Responder	26 (79%)	16 (50%)
Comparison Mepolizumab 300 mg vs Placebo [1]		
Logistic regression [2]		
Inverse odds ratio (95% CI)		0.30 (0.10,0.92)
p-value		0.035
Inverse unadjusted odds ratio (95% CI) [3]		0.28 (0.08,0.89)
Inverse relative risk (95% CI) [4]		0.42 (0.17,0.90)
Risk difference (95% CI) [4]		-0.29 (-0.50,-0.05)
Fisher's Exact p-value (2-sided)		0.020

[1] Analysis compares the number of responders. Subjects with missing response are categorised as non-responders.
[2] Logistic regression analysis adjusted for baseline prednisolone/prednisone daily dose and baseline BVAS score.
[3] Exact method.
[4] Exact unconditional CI calculated by inverting two separate one-sided tests based on the score statistic.
Note: Inverse odds ratio and inverse relative risk <1 and risk difference <0 indicate benefit for Mepolizumab over Placebo.

PPD

Protocol: MEA115921
Population: Intent-to-Treat

Table 2.36
Analysis of Subjects with Remission (BVAS = 0 and OCS dose <= 7.5 mg/day) at Week 52
by Region

Region: Rest of World

	Placebo (N=68)	Mepolizumab 300 mg SC (N=68)
n	35	36
Responder	3 (9%)	10 (28%)
Non-Responder	32 (91%)	26 (72%)
Comparison Mepolizumab 300 mg vs Placebo [1]		
Logistic regression [2]		
Inverse odds ratio (95% CI)		0.16 (0.03,0.74)
p-value		0.019
Inverse unadjusted odds ratio (95% CI) [3]		0.25 (0.04,1.10)
Inverse relative risk (95% CI) [4]		0.31 (0.07,0.98)
Risk difference (95% CI) [4]		-0.19 (-0.38,-0.01)
Fisher's Exact p-value (2-sided)		0.063

[1] Analysis compares the number of responders. Subjects with missing response are categorised as non-responders.
[2] Logistic regression analysis adjusted for baseline prednisolone/prednisone daily dose and baseline BVAS score.
[3] Exact method.
[4] Exact unconditional CI calculated by inverting two separate one-sided tests based on the score statistic.
Note: Inverse odds ratio and inverse relative risk <1 and risk difference <0 indicate benefit for Mepolizumab over Placebo.

PPD

Protocol: MEA115921
Population: Intent-to-Treat

Table 2.37
Analysis of Subjects with Remission (BVAS = 0 and OCS dose <= 7.5 mg/day) at Week 52
by Baseline Blood Eosinophils

Baseline blood eosinophils: <0.150 GI/L

	Placebo (N=68)	Mepolizumab 300 mg SC (N=68)	
n	28	29	
Responder	4 (14%)	7 (24%)	
Non-Responder	24 (86%)	22 (76%)	
Comparison Mepolizumab 300 mg vs Placebo [1]			
Logistic regression [2]			
Inverse odds ratio (95% CI)			0.68 (0.15,3.05)
p-value			0.617
Inverse unadjusted odds ratio (95% CI) [3]			0.53 (0.10,2.43)
Inverse relative risk (95% CI) [4]			0.59 (0.13,1.81)
Risk difference (95% CI) [4]			-0.10 (-0.32,0.12)
Fisher's Exact p-value (2-sided)			0.504

[1] Analysis compares the number of responders. Subjects with missing response are categorised as non-responders.
[2] Logistic regression analysis adjusted for baseline prednisolone/prednisone daily dose, baseline BVAS score and region (EU vs. RoW).
[3] Exact method.
[4] Exact unconditional CI calculated by inverting two separate one-sided tests based on the score statistic.
Note: Inverse odds ratio and inverse relative risk <1 and risk difference <0 indicate benefit for Mepolizumab over Placebo.

PPD

Protocol: MEA115921
Population: Intent-to-Treat

Table 2.37
Analysis of Subjects with Remission (BVAS = 0 and OCS dose <= 7.5 mg/day) at Week 52
by Baseline Blood Eosinophils

Baseline blood eosinophils: >=0.150 GI/L

	Placebo (N=68)	Mepolizumab 300 mg SC (N=68)	
n	40	39	
Responder	6 (15%)	19 (49%)	
Non-Responder	34 (85%)	20 (51%)	
Comparison Mepolizumab 300 mg vs Placebo [1]			
Logistic regression [2]			
Inverse odds ratio (95% CI)			0.16 (0.05,0.50)
p-value			0.002
Inverse unadjusted odds ratio (95% CI) [3]			0.19 (0.05,0.60)
Inverse relative risk (95% CI) [4]			0.31 (0.07,0.69)
Risk difference (95% CI) [4]			-0.34 (-0.53,-0.11)
Fisher's Exact p-value (2-sided)			0.002

[1] Analysis compares the number of responders. Subjects with missing response are categorised as non-responders.
[2] Logistic regression analysis adjusted for baseline prednisolone/prednisone daily dose, baseline BVAS score and region (EU vs. RoW).
[3] Exact method.
[4] Exact unconditional CI calculated by inverting two separate one-sided tests based on the score statistic.
Note: Inverse odds ratio and inverse relative risk <1 and risk difference <0 indicate benefit for Mepolizumab over Placebo.

PPD

Protocol: MEA115921
Population: Intent-to-Treat

Table 2.38
Analysis of Subjects with Remission (BVAS = 0 and OCS dose <= 7.5 mg/day) at Week 52
by Duration of Disease

Duration of disease: <=4 years

	Placebo (N=68)	Mepolizumab 300 mg SC (N=68)	
n	32	34	
Responder	3 (9%)	12 (35%)	
Non-Responder	29 (91%)	22 (65%)	
Comparison Mepolizumab 300 mg vs Placebo [1]			
Logistic regression [2]			
Inverse odds ratio (95% CI)			0.21 (0.05,0.89)
p-value			0.034
Inverse unadjusted odds ratio (95% CI) [3]			0.19 (0.03,0.84)
Inverse relative risk (95% CI) [4]			0.27 (0.04,0.89)
Risk difference (95% CI) [4]			-0.26 (-0.45,-0.05)
Fisher's Exact p-value (2-sided)			0.018

[1] Analysis compares the number of responders. Subjects with missing response are categorised as non-responders.
[2] Logistic regression analysis adjusted for baseline prednisolone/prednisone daily dose, baseline BVAS score and region (EU vs. RoW).
[3] Exact method.
[4] Exact unconditional CI calculated by inverting two separate one-sided tests based on the score statistic.
Note: Inverse odds ratio and inverse relative risk <1 and risk difference <0 indicate benefit for Mepolizumab over Placebo.

PPD

Protocol: MEA115921
Population: Intent-to-Treat

Table 2.38
Analysis of Subjects with Remission (BVAS = 0 and OCS dose <= 7.5 mg/day) at Week 52
by Duration of Disease

Duration of disease: >4 years

	Placebo (N=68)	Mepolizumab 300 mg SC (N=68)	
n	36	34	
Responder	7 (19%)	14 (41%)	
Non-Responder	29 (81%)	20 (59%)	
Comparison Mepolizumab 300 mg vs Placebo [1]			
Logistic regression [2]			
Inverse odds ratio (95% CI)			0.28 (0.09,0.91)
p-value			0.035
Inverse unadjusted odds ratio (95% CI) [3]			0.35 (0.10,1.13)
Inverse relative risk (95% CI) [4]			0.47 (0.18,1.01)
Risk difference (95% CI) [4]			-0.22 (-0.43,0.00)
Fisher's Exact p-value (2-sided)			0.068

[1] Analysis compares the number of responders. Subjects with missing response are categorised as non-responders.
[2] Logistic regression analysis adjusted for baseline prednisolone/prednisone daily dose, baseline BVAS score and region (EU vs. RoW).
[3] Exact method.
[4] Exact unconditional CI calculated by inverting two separate one-sided tests based on the score statistic.
Note: Inverse odds ratio and inverse relative risk <1 and risk difference <0 indicate benefit for Mepolizumab over Placebo.

PPD

Protocol: MEA115921
Population: Intent-to-Treat

Table 2.42
Analysis of Time to First EGPA Relapse by Age

Age: <50 Years

	Placebo (N=68)	Mepolizumab 300 mg SC (N=68)
Number of Subjects Analysed		
n	33	31
Endpoint (event) [1]	26 (79%)	18 (58%)
Censored [2]	7 (21%)	13 (42%)
Adjusted Hazard Ratio [3]		
Estimate		0.41
95% CI		(0.21,0.81)
Wald Chi-Squared P-value		0.010
Stratified Log-Rank [4]		
p-value		0.064

[1] An event is a first EGPA relapse that occurred prior to study completion or premature withdrawal from the study.
[2] Subjects are censored if they complete study, or withdraw prematurely from the study, without experiencing the event.
[3] Analysis performed using a Cox Proportional Hazards Model with covariates of treatment group, baseline prednisolone/prednisone daily dose, baseline BVAS score and region (defined as EU vs. RoW). A hazard ratio <1 indicates a lower risk of EGPA relapse in the Mepolizumab group compared to the Placebo group.
[4] Stratified by baseline prednisolone/prednisone daily dose group(<10,>=10mg), baseline BVAS group(<6,>=6) and region (defined as EU vs. RoW).

PPD

Protocol: MEA115921
Population: Intent-to-Treat

Table 2.42
Analysis of Time to First EGPA Relapse by Age

Age: >=50 Years

	Placebo (N=68)	Mepolizumab 300 mg SC (N=68)
Number of Subjects Analysed		
n	35	37
Endpoint (event) [1]	30 (86%)	20 (54%)
Censored [2]	5 (14%)	17 (46%)
Adjusted Hazard Ratio [3]		
Estimate		0.30
95% CI		(0.16,0.55)
Wald Chi-Squared P-value		<0.001
Stratified Log-Rank [4]		
p-value		0.004

[1] An event is a first EGPA relapse that occurred prior to study completion or premature withdrawal from the study.
[2] Subjects are censored if they complete study, or withdraw prematurely from the study, without experiencing the event.
[3] Analysis performed using a Cox Proportional Hazards Model with covariates of treatment group, baseline prednisolone/prednisone daily dose, baseline BVAS score and region (defined as EU vs. RoW). A hazard ratio <1 indicates a lower risk of EGPA relapse in the Mepolizumab group compared to the Placebo group.
[4] Stratified by baseline prednisolone/prednisone daily dose group(<10,>=10mg), baseline BVAS group(<6,>=6) and region (defined as EU vs. RoW).

PPD

Protocol: MEA115921
Population: Intent-to-Treat

Table 2.43
Analysis of Time to First EGPA Relapse by Gender

Gender: Female

	Placebo (N=68)	Mepolizumab 300 mg SC (N=68)
Number of Subjects Analysed		
n	38	42
Endpoint (event) [1]	31 (82%)	24 (57%)
Censored [2]	7 (18%)	18 (43%)
Adjusted Hazard Ratio [3]		
Estimate		0.39
95% CI		(0.22,0.69)
Wald Chi-Squared P-value		0.001
Stratified Log-Rank [4]		
p-value		0.017

[1] An event is a first EGPA relapse that occurred prior to study completion or premature withdrawal from the study.
[2] Subjects are censored if they complete study, or withdraw prematurely from the study, without experiencing the event.
[3] Analysis performed using a Cox Proportional Hazards Model with covariates of treatment group, baseline prednisolone/prednisone daily dose, baseline BVAS score and region (defined as EU vs. RoW). A hazard ratio <1 indicates a lower risk of EGPA relapse in the Mepolizumab group compared to the Placebo group.
[4] Stratified by baseline prednisolone/prednisone daily dose group(<10,>=10mg), baseline BVAS group(<6,>=6) and region (defined as EU vs. RoW).

PPD

Protocol: MEA115921
Population: Intent-to-Treat

Table 2.43
Analysis of Time to First EGPA Relapse by Gender

Gender: Male

	Placebo (N=68)	Mepolizumab 300 mg SC (N=68)
Number of Subjects Analysed		
n	30	26
Endpoint (event) [1]	25 (83%)	14 (54%)
Censored [2]	5 (17%)	12 (46%)
Adjusted Hazard Ratio [3]		
Estimate		0.29
95% CI		(0.14,0.60)
Wald Chi-Squared P-value		<0.001
Stratified Log-Rank [4]		
p-value		0.002

[1] An event is a first EGPA relapse that occurred prior to study completion or premature withdrawal from the study.
[2] Subjects are censored if they complete study, or withdraw prematurely from the study, without experiencing the event.
[3] Analysis performed using a Cox Proportional Hazards Model with covariates of treatment group, baseline prednisolone/prednisone daily dose, baseline BVAS score and region (defined as EU vs. RoW). A hazard ratio <1 indicates a lower risk of EGPA relapse in the Mepolizumab group compared to the Placebo group.
[4] Stratified by baseline prednisolone/prednisone daily dose group(<10,>=10mg), baseline BVAS group(<6,>=6) and region (defined as EU vs. RoW).

PPD

Protocol: MEA115921
Population: Intent-to-Treat

Table 2.44
Analysis of Time to First EGPA Relapse by Region

Region: Europe

	Placebo (N=68)	Mepolizumab 300 mg SC (N=68)
Number of Subjects Analysed		
n	33	32
Endpoint (event) [1]	23 (70%)	15 (47%)
Censored [2]	10 (30%)	17 (53%)
Adjusted Hazard Ratio [3]		
Estimate		0.47
95% CI		(0.24,0.94)
Wald Chi-Squared P-value		0.032
Stratified Log-Rank [4]		
p-value		0.022

[1] An event is a first EGPA relapse that occurred prior to study completion or premature withdrawal from the study.
[2] Subjects are censored if they complete study, or withdraw prematurely from the study, without experiencing the event.
[3] Analysis performed using a Cox Proportional Hazards Model with covariates of treatment group, baseline prednisolone/prednisone daily dose, baseline BVAS score. A hazard ratio <1 indicates a lower risk of EGPA relapse in the Mepolizumab group compared to the Placebo group.
[4] Stratified by baseline prednisolone/prednisone daily dose group(<10,>=10mg), baseline BVAS group(<6,>=6).

PPD

Protocol: MEA115921
Population: Intent-to-Treat

Table 2.44
Analysis of Time to First EGPA Relapse by Region

Region: Rest of World

	Placebo (N=68)	Mepolizumab 300 mg SC (N=68)
Number of Subjects Analysed		
n	35	36
Endpoint (event) [1]	33 (94%)	23 (64%)
Censored [2]	2 (6%)	13 (36%)
Adjusted Hazard Ratio [3]		
Estimate		0.28
95% CI		(0.16,0.50)
Wald Chi-Squared P-value		<0.001
Stratified Log-Rank [4]		
p-value		<0.001

[1] An event is a first EGPA relapse that occurred prior to study completion or premature withdrawal from the study.
[2] Subjects are censored if they complete study, or withdraw prematurely from the study, without experiencing the event.
[3] Analysis performed using a Cox Proportional Hazards Model with covariates of treatment group, baseline prednisolone/prednisone daily dose, baseline BVAS score. A hazard ratio <1 indicates a lower risk of EGPA relapse in the Mepolizumab group compared to the Placebo group.
[4] Stratified by baseline prednisolone/prednisone daily dose group(<10,>=10mg), baseline BVAS group(<6,>=6).

PPD

Protocol: MEA115921
Population: Intent-to-Treat

Table 2.45
Analysis of Time to First EGPA Relapse by Baseline Blood Eosinophils

Baseline blood eosinophils: <0.150 GI/L

	Placebo (N=68)	Mepolizumab 300 mg SC (N=68)
Number of Subjects Analysed		
n	28	29
Endpoint (event) [1]	23 (82%)	18 (62%)
Censored [2]	5 (18%)	11 (38%)
Adjusted Hazard Ratio [3]		
Estimate		0.44
95% CI		(0.23,0.86)
Wald Chi-Squared P-value		0.017
Stratified Log-Rank [4]		
p-value		0.025

[1] An event is a first EGPA relapse that occurred prior to study completion or premature withdrawal from the study.
[2] Subjects are censored if they complete study, or withdraw prematurely from the study, without experiencing the event.
[3] Analysis performed using a Cox Proportional Hazards Model with covariates of treatment group, baseline prednisolone/prednisone daily dose, baseline BVAS score and region (defined as EU vs. RoW). A hazard ratio <1 indicates a lower risk of EGPA relapse in the Mepolizumab group compared to the Placebo group.
[4] Stratified by baseline prednisolone/prednisone daily dose group(<10,>=10mg), baseline BVAS group(<6,>=6) and region (defined as EU vs. RoW).

PPD

Population: Intent-to-Treat

Table 2.45
Analysis of Time to First EGPA Relapse by Baseline Blood Eosinophils

Baseline blood eosinophils: >=0.150 GI/L

	Placebo (N=68)	Mepolizumab 300 mg SC (N=68)
Number of Subjects Analysed		
n	40	39
Endpoint (event) [1]	33 (83%)	20 (51%)
Censored [2]	7 (18%)	19 (49%)
Adjusted Hazard Ratio [3]		
Estimate		0.26
95% CI		(0.14,0.47)
Wald Chi-Squared P-value		<0.001
Stratified Log-Rank [4]		
p-value		<0.001

[1] An event is a first EGPA relapse that occurred prior to study completion or premature withdrawal from the study.
[2] Subjects are censored if they complete study, or withdraw prematurely from the study, without experiencing the event.
[3] Analysis performed using a Cox Proportional Hazards Model with covariates of treatment group, baseline prednisolone/prednisone daily dose, baseline BVAS score and region (defined as EU vs. RoW). A hazard ratio <1 indicates a lower risk of EGPA relapse in the Mepolizumab group compared to the Placebo group.
[4] Stratified by baseline prednisolone/prednisone daily dose group(<10,>=10mg), baseline BVAS group(<6,>=6) and region (defined as EU vs. RoW).

Protocol: MEA115921
Population: Intent-to-Treat

Table 2.46
Analysis of Time to First EGPA Relapse by Duration of Disease

Duration of disease: <=4 years

	Placebo (N=68)	Mepolizumab 300 mg SC (N=68)
Number of Subjects Analysed		
n	32	34
Endpoint (event) [1]	29 (91%)	21 (62%)
Censored [2]	3 (9%)	13 (38%)
Adjusted Hazard Ratio [3]		
Estimate		0.30
95% CI		(0.17,0.55)
Wald Chi-Squared P-value		<0.001
Stratified Log-Rank [4]		
p-value		<0.001

[1] An event is a first EGPA relapse that occurred prior to study completion or premature withdrawal from the study.
[2] Subjects are censored if they complete study, or withdraw prematurely from the study, without experiencing the event.
[3] Analysis performed using a Cox Proportional Hazards Model with covariates of treatment group, baseline prednisolone/prednisone daily dose, baseline BVAS score and region (defined as EU vs. RoW). A hazard ratio <1 indicates a lower risk of EGPA relapse in the Mepolizumab group compared to the Placebo group.
[4] Stratified by baseline prednisolone/prednisone daily dose group(<10,>=10mg), baseline BVAS group(<6,>=6) and region (defined as EU vs. RoW).

PPD

Protocol: MEA115921
Population: Intent-to-Treat

Table 2.46
Analysis of Time to First EGPA Relapse by Duration of Disease

Duration of disease: >4 years

	Placebo (N=68)	Mepolizumab 300 mg SC (N=68)
Number of Subjects Analysed		
n	36	34
Endpoint (event) [1]	27 (75%)	17 (50%)
Censored [2]	9 (25%)	17 (50%)
Adjusted Hazard Ratio [3]		
Estimate		0.36
95% CI		(0.19,0.68)
Wald Chi-Squared P-value		0.002
Stratified Log-Rank [4]		
p-value		0.005

[1] An event is a first EGPA relapse that occurred prior to study completion or premature withdrawal from the study.
[2] Subjects are censored if they complete study, or withdraw prematurely from the study, without experiencing the event.
[3] Analysis performed using a Cox Proportional Hazards Model with covariates of treatment group, baseline prednisolone/prednisone daily dose, baseline BVAS score and region (defined as EU vs. RoW). A hazard ratio <1 indicates a lower risk of EGPA relapse in the Mepolizumab group compared to the Placebo group.
[4] Stratified by baseline prednisolone/prednisone daily dose group(<10,>=10mg), baseline BVAS group(<6,>=6) and region (defined as EU vs. RoW).

PPD

Protocol: MEA115921
Population: Intent-to-Treat

Table 2.51
Analysis of Subjects with Daily OCS Dose = 0mg/day
During the Last 4 Weeks of the Study Treatment Period by Age

Age: <50 Years

	Placebo (N=68)	Mepolizumab 300 mg SC (N=68)
n	33	31
Responder	0	5 (16%)
Non-Responder	33 (100%)	26 (84%)
Comparison Mepolizumab 300 mg vs Placebo [1]		
Logistic regression [2]		
Inverse odds ratio (95% CI)		<0.01 (<0.01,>999.99)
p-value		0.955
Inverse unadjusted odds ratio (95% CI) [3]		0.12 (<0.01,0.71)
Inverse relative risk (95% CI) [4]		0.00 (0.00,0.87)
Risk difference (95% CI) [4]		-0.16 (-0.34,-0.04)
Fisher's Exact p-value (2-sided)		0.022

[1] Analysis compares the number of responders. Subjects with missing response are categorised as non-responders.
[2] Logistic regression analysis adjusted for baseline prednisolone/prednisone daily dose, baseline BVAS score and region (EU vs. RoW).
[3] Exact method.
[4] Exact unconditional CI calculated by inverting two separate one-sided tests based on the score statistic.
Note: Inverse odds ratio and inverse relative risk <1 and risk difference <0 indicate benefit for Mepolizumab over Placebo.

PPD

Table 2.51
Analysis of Subjects with Daily OCS Dose = 0mg/day
During the Last 4 Weeks of the Study Treatment Period by Age

Age: >=50 Years

	Placebo (N=68)	Mepolizumab 300 mg SC (N=68)
n	35	37
Responder	2 (6%)	7 (19%)
Non-Responder	33 (94%)	30 (81%)
Comparison Mepolizumab 300 mg vs Placebo [1]		
Logistic regression [2]		
Inverse odds ratio (95% CI)		0.02 (<0.01,0.39)
p-value		0.009
Inverse unadjusted odds ratio (95% CI) [3]		0.26 (0.02,1.53)
Inverse relative risk (95% CI) [4]		0.30 (0.03,1.23)
Risk difference (95% CI) [4]		-0.13 (-0.30,0.03)
Fisher's Exact p-value (2-sided)		0.153

[1] Analysis compares the number of responders. Subjects with missing response are categorised as non-responders.
[2] Logistic regression analysis adjusted for baseline prednisolone/prednisone daily dose, baseline BVAS score and region (EU vs. RoW).
[3] Exact method.
[4] Exact unconditional CI calculated by inverting two separate one-sided tests based on the score statistic.
Note: Inverse odds ratio and inverse relative risk <1 and risk difference <0 indicate benefit for Mepolizumab over Placebo.

PPD

Protocol: MEA115921
Population: Intent-to-Treat

Table 2.52
Analysis of Subjects with Daily OCS Dose = 0mg/day
During the Last 4 Weeks of the Study Treatment Period by Gender

Gender: Female

	Placebo (N=68)	Mepolizumab 300 mg SC (N=68)
n	38	42
Responder	1 (3%)	7 (17%)
Non-Responder	37 (97%)	35 (83%)
Comparison Mepolizumab 300 mg vs Placebo [1]		
Logistic regression [2]		
Inverse odds ratio (95% CI)		0.01 (<0.01,0.56)
p-value		0.024
Inverse unadjusted odds ratio (95% CI) [3]		0.14 (<0.01,1.16)
Inverse relative risk (95% CI) [4]		0.16 (0.01,0.98)
Risk difference (95% CI) [4]		-0.14 (-0.29,0.00)
Fisher's Exact p-value (2-sided)		0.059

[1] Analysis compares the number of responders. Subjects with missing response are categorised as non-responders.
[2] Logistic regression analysis adjusted for baseline prednisolone/prednisone daily dose, baseline BVAS score and region (EU vs. RoW).
[3] Exact method.
[4] Exact unconditional CI calculated by inverting two separate one-sided tests based on the score statistic.
Note: Inverse odds ratio and inverse relative risk <1 and risk difference <0 indicate benefit for Mepolizumab over Placebo.

PPD

Protocol: MEA115921
Population: Intent-to-Treat

Table 2.52
Analysis of Subjects with Daily OCS Dose = 0mg/day
During the Last 4 Weeks of the Study Treatment Period by Gender

Gender: Male

	Placebo (N=68)	Mepolizumab 300 mg SC (N=68)
n	30	26
Responder	1 (3%)	5 (19%)
Non-Responder	29 (97%)	21 (81%)
Comparison Mepolizumab 300 mg vs Placebo [1]		
Logistic regression [2]		
Inverse odds ratio (95% CI)		0.06 (<0.01,0.87)
p-value		0.039
Inverse unadjusted odds ratio (95% CI) [3]		0.15 (<0.01,1.48)
Inverse relative risk (95% CI) [4]		0.17 (0.01,1.13)
Risk difference (95% CI) [4]		-0.16 (-0.36,0.01)
Fisher's Exact p-value (2-sided)		0.086

[1] Analysis compares the number of responders. Subjects with missing response are categorised as non-responders.
[2] Logistic regression analysis adjusted for baseline prednisolone/prednisone daily dose, baseline BVAS score and region (EU vs. RoW).
[3] Exact method.
[4] Exact unconditional CI calculated by inverting two separate one-sided tests based on the score statistic.
Note: Inverse odds ratio and inverse relative risk <1 and risk difference <0 indicate benefit for Mepolizumab over Placebo.

PPD

Protocol: MEA115921
Population: Intent-to-Treat

Table 2.53
Analysis of Subjects with Daily OCS Dose = 0mg/day
During the Last 4 Weeks of the Study Treatment Period by Region

Region: Europe

	Placebo (N=68)	Mepolizumab 300 mg SC (N=68)
n	33	32
Responder	0	5 (16%)
Non-Responder	33 (100%)	27 (84%)
Comparison Mepolizumab 300 mg vs Placebo [1]		
Logistic regression [2]		
Inverse odds ratio (95% CI)		<0.01 (<0.01,>999.99)
p-value		0.953
Inverse unadjusted odds ratio (95% CI) [3]		0.13 (<0.01,0.74)
Inverse relative risk (95% CI) [4]		0.00 (0.00,0.87)
Risk difference (95% CI) [4]		-0.16 (-0.33,-0.03)
Fisher's Exact p-value (2-sided)		0.024

[1] Analysis compares the number of responders. Subjects with missing response are categorised as non-responders.
[2] Logistic regression analysis adjusted for baseline prednisolone/prednisone daily dose and baseline BVAS score.
[3] Exact method.
[4] Exact unconditional CI calculated by inverting two separate one-sided tests based on the score statistic.
Note: Inverse odds ratio and inverse relative risk <1 and risk difference <0 indicate benefit for Mepolizumab over Placebo.

PPD

Protocol: MEA115921
Population: Intent-to-Treat

Table 2.53
Analysis of Subjects with Daily OCS Dose = 0mg/day
During the Last 4 Weeks of the Study Treatment Period by Region

Region: Rest of World

	Placebo (N=68)	Mepolizumab 300 mg SC (N=68)
n	35	36
Responder	2 (6%)	7 (19%)
Non-Responder	33 (94%)	29 (81%)
Comparison Mepolizumab 300 mg vs Placebo [1]		
Logistic regression [2]		
Inverse odds ratio (95% CI)		0.10 (0.01,0.73)
p-value		0.024
Inverse unadjusted odds ratio (95% CI) [3]		0.26 (0.02,1.49)
Inverse relative risk (95% CI) [4]		0.29 (0.03,1.19)
Risk difference (95% CI) [4]		-0.14 (-0.31,0.02)
Fisher's Exact p-value (2-sided)		0.151

[1] Analysis compares the number of responders. Subjects with missing response are categorised as non-responders.
[2] Logistic regression analysis adjusted for baseline prednisolone/prednisone daily dose and baseline BVAS score.
[3] Exact method.
[4] Exact unconditional CI calculated by inverting two separate one-sided tests based on the score statistic.
Note: Inverse odds ratio and inverse relative risk <1 and risk difference <0 indicate benefit for Mepolizumab over Placebo.

PPD

Protocol: MEA115921
Population: Intent-to-Treat

Table 2.54
Analysis of Subjects with Daily OCS Dose = 0mg/day
During the Last 4 Weeks of the Study Treatment Period by Baseline Blood Eosinophils

Baseline blood eosinophils: <0.150 GI/L

	Placebo (N=68)	Mepolizumab 300 mg SC (N=68)
n	28	29
Responder	1 (4%)	4 (14%)
Non-Responder	27 (96%)	25 (86%)
Comparison Mepolizumab 300 mg vs Placebo [1]		
Logistic regression [2]		
Inverse odds ratio (95% CI)		0.19 (0.01,2.58)
p-value		0.213
Inverse unadjusted odds ratio (95% CI) [3]		0.24 (<0.01,2.61)
Inverse relative risk (95% CI) [4]		0.26 (0.01,1.80)
Risk difference (95% CI) [4]		-0.10 (-0.29,0.06)
Fisher's Exact p-value (2-sided)		0.352

[1] Analysis compares the number of responders. Subjects with missing response are categorised as non-responders.
[2] Logistic regression analysis adjusted for baseline prednisolone/prednisone daily dose, baseline BVAS score and region (EU vs. RoW).
[3] Exact method.
[4] Exact unconditional CI calculated by inverting two separate one-sided tests based on the score statistic.
Note: Inverse odds ratio and inverse relative risk <1 and risk difference <0 indicate benefit for Mepolizumab over Placebo.

PPD

Protocol: MEA115921
Population: Intent-to-Treat

Table 2.54
Analysis of Subjects with Daily OCS Dose = 0mg/day
During the Last 4 Weeks of the Study Treatment Period by Baseline Blood Eosinophils

Baseline blood eosinophils: >=0.150 GI/L

	Placebo (N=68)	Mepolizumab 300 mg SC (N=68)
n	40	39
Responder	1 (3%)	8 (21%)
Non-Responder	39 (98%)	31 (79%)
Comparison Mepolizumab 300 mg vs Placebo [1]		
Logistic regression [2]		
Inverse odds ratio (95% CI)		0.05 (<0.01,0.53)
p-value		0.013
Inverse unadjusted odds ratio (95% CI) [3]		0.10 (<0.01,0.83)
Inverse relative risk (95% CI) [4]		0.12 (0.00,0.87)
Risk difference (95% CI) [4]		-0.18 (-0.34,-0.04)
Fisher's Exact p-value (2-sided)		0.014

[1] Analysis compares the number of responders. Subjects with missing response are categorised as non-responders.
[2] Logistic regression analysis adjusted for baseline prednisolone/prednisone daily dose, baseline BVAS score and region (EU vs. RoW).
[3] Exact method.
[4] Exact unconditional CI calculated by inverting two separate one-sided tests based on the score statistic.
Note: Inverse odds ratio and inverse relative risk <1 and risk difference <0 indicate benefit for Mepolizumab over Placebo.

PPD

Protocol: MEA115921
Population: Intent-to-Treat

Table 2.55
Analysis of Subjects with Daily OCS Dose = 0mg/day
During the Last 4 Weeks of the Study Treatment Period by Duration of Disease

Duration of disease: <=4 years

	Placebo (N=68)	Mepolizumab 300 mg SC (N=68)
n	32	34
Responder	0	6 (18%)
Non-Responder	32 (100%)	28 (82%)
Comparison Mepolizumab 300 mg vs Placebo [1]		
Logistic regression [2]		
Inverse odds ratio (95% CI)		<0.01 (<0.01,>999.99)
p-value		0.901
Inverse unadjusted odds ratio (95% CI) [3]		0.11 (<0.01,0.62)
Inverse relative risk (95% CI) [4]		0.00 (0.00,0.86)
Risk difference (95% CI) [4]		-0.18 (-0.35,-0.05)
Fisher's Exact p-value (2-sided)		0.025

[1] Analysis compares the number of responders. Subjects with missing response are categorised as non-responders.
[2] Logistic regression analysis adjusted for baseline prednisolone/prednisone daily dose, baseline BVAS score and region (EU vs. RoW).
[3] Exact method.
[4] Exact unconditional CI calculated by inverting two separate one-sided tests based on the score statistic.
Note: Inverse odds ratio and inverse relative risk <1 and risk difference <0 indicate benefit for Mepolizumab over Placebo.

PPD

Protocol: MEA115921
Population: Intent-to-Treat

Table 2.55
Analysis of Subjects with Daily OCS Dose = 0mg/day
During the Last 4 Weeks of the Study Treatment Period by Duration of Disease

Duration of disease: >4 years

	Placebo (N=68)	Mepolizumab 300 mg SC (N=68)
n	36	34
Responder	2 (6%)	6 (18%)
Non-Responder	34 (94%)	28 (82%)
Comparison Mepolizumab 300 mg vs Placebo [1]		
Logistic regression [2]		
Inverse odds ratio (95% CI)		0.19 (0.03,1.21)
p-value		0.079
Inverse unadjusted odds ratio (95% CI) [3]		0.28 (0.03,1.72)
Inverse relative risk (95% CI) [4]		0.31 (0.03,1.40)
Risk difference (95% CI) [4]		-0.12 (-0.30,0.04)
Fisher's Exact p-value (2-sided)		0.145

[1] Analysis compares the number of responders. Subjects with missing response are categorised as non-responders.
[2] Logistic regression analysis adjusted for baseline prednisolone/prednisone daily dose, baseline BVAS score and region (EU vs. RoW).
[3] Exact method.
[4] Exact unconditional CI calculated by inverting two separate one-sided tests based on the score statistic.
Note: Inverse odds ratio and inverse relative risk <1 and risk difference <0 indicate benefit for Mepolizumab over Placebo.

PPD

Protocol: MEA115921
Population: Intent-to-Treat

Table 2.59
Analysis of Subjects with Daily OCS Dose <= 7.5mg/day
During the Last 4 Weeks of the Study Treatment Period by Age

Age: <50 Years

	Placebo (N=68)	Mepolizumab 300 mg SC (N=68)	
n	33	31	
Responder	11 (33%)	18 (58%)	
Non-Responder	22 (67%)	13 (42%)	
Comparison Mepolizumab 300 mg vs Placebo [1]			
Logistic regression [2]			
Inverse odds ratio (95% CI)			0.36 (0.11,1.10)
p-value			0.074
Inverse unadjusted odds ratio (95% CI) [3]			0.37 (0.12,1.12)
Inverse relative risk (95% CI) [4]			0.57 (0.30,1.02)
Risk difference (95% CI) [4]			-0.25 (-0.48,0.01)
Fisher's Exact p-value (2-sided)			0.078

[1] Analysis compares the number of responders. Subjects with missing response are categorised as non-responders.
[2] Logistic regression analysis adjusted for baseline prednisolone/prednisone daily dose, baseline BVAS score and region (EU vs. RoW).
[3] Exact method.
[4] Exact unconditional CI calculated by inverting two separate one-sided tests based on the score statistic.
Note: Inverse odds ratio and inverse relative risk <1 and risk difference <0 indicate benefit for Mepolizumab over Placebo.

PPD

Protocol: MEA115921
Population: Intent-to-Treat

Table 2.59
Analysis of Subjects with Daily OCS Dose <= 7.5mg/day
During the Last 4 Weeks of the Study Treatment Period by Age

Age: >=50 Years

	Placebo (N=68)	Mepolizumab 300 mg SC (N=68)	
n	35	37	
Responder	10 (29%)	20 (54%)	
Non-Responder	25 (71%)	17 (46%)	
Comparison Mepolizumab 300 mg vs Placebo [1]			
Logistic regression [2]			
Inverse odds ratio (95% CI)		0.33	(0.11,1.00)
p-value		0.049	
Inverse unadjusted odds ratio (95% CI) [3]		0.35	(0.11,1.00)
Inverse relative risk (95% CI) [4]		0.53	(0.25,0.97)
Risk difference (95% CI) [4]		-0.25	(-0.47,-0.02)
Fisher's Exact p-value (2-sided)		0.034	

[1] Analysis compares the number of responders. Subjects with missing response are categorised as non-responders.
[2] Logistic regression analysis adjusted for baseline prednisolone/prednisone daily dose, baseline BVAS score and region (EU vs. RoW).
[3] Exact method.
[4] Exact unconditional CI calculated by inverting two separate one-sided tests based on the score statistic.
Note: Inverse odds ratio and inverse relative risk <1 and risk difference <0 indicate benefit for Mepolizumab over Placebo.

PPD

Protocol: MEA115921
Population: Intent-to-Treat

Table 2.60
Analysis of Subjects with Daily OCS Dose <= 7.5mg/day
During the Last 4 Weeks of the Study Treatment Period by Gender

Gender: Female

	Placebo (N=68)	Mepolizumab 300 mg SC (N=68)
n	38	42
Responder	14 (37%)	27 (64%)
Non-Responder	24 (63%)	15 (36%)
Comparison Mepolizumab 300 mg vs Placebo [1]		
Logistic regression [2]		
Inverse odds ratio (95% CI)		0.33 (0.12,0.87)
p-value		0.026
Inverse unadjusted odds ratio (95% CI) [3]		0.33 (0.12,0.88)
Inverse relative risk (95% CI) [4]		0.57 (0.33,0.93)
Risk difference (95% CI) [4]		-0.27 (-0.48,-0.04)
Fisher's Exact p-value (2-sided)		0.025

[1] Analysis compares the number of responders. Subjects with missing response are categorised as non-responders.
[2] Logistic regression analysis adjusted for baseline prednisolone/prednisone daily dose, baseline BVAS score and region (EU vs. RoW).
[3] Exact method.
[4] Exact unconditional CI calculated by inverting two separate one-sided tests based on the score statistic.
Note: Inverse odds ratio and inverse relative risk <1 and risk difference <0 indicate benefit for Mepolizumab over Placebo.

PPD

Table 2.60
Analysis of Subjects with Daily OCS Dose <= 7.5mg/day
During the Last 4 Weeks of the Study Treatment Period by Gender

Gender: Male

	Placebo (N=68)	Mepolizumab 300 mg SC (N=68)
n	30	26
Responder	7 (23%)	11 (42%)
Non-Responder	23 (77%)	15 (58%)
Comparison Mepolizumab 300 mg vs Placebo [1]		
Logistic regression [2]		
Inverse odds ratio (95% CI)		0.36 (0.10,1.28)
p-value		0.113
Inverse unadjusted odds ratio (95% CI) [3]		0.42 (0.11,1.51)
Inverse relative risk (95% CI) [4]		0.55 (0.22,1.26)
Risk difference (95% CI) [4]		-0.19 (-0.44,0.07)
Fisher's Exact p-value (2-sided)		0.159

[1] Analysis compares the number of responders. Subjects with missing response are categorised as non-responders.
[2] Logistic regression analysis adjusted for baseline prednisolone/prednisone daily dose, baseline BVAS score and region (EU vs. RoW).
[3] Exact method.
[4] Exact unconditional CI calculated by inverting two separate one-sided tests based on the score statistic.
Note: Inverse odds ratio and inverse relative risk <1 and risk difference <0 indicate benefit for Mepolizumab over Placebo.

PPD

Protocol: MEA115921
Population: Intent-to-Treat

Table 2.61
Analysis of Subjects with Daily OCS Dose <= 7.5mg/day
During the Last 4 Weeks of the Study Treatment Period by Region

Region: Europe

	Placebo (N=68)	Mepolizumab 300 mg SC (N=68)	
n	33	32	
Responder	11 (33%)	21 (66%)	
Non-Responder	22 (67%)	11 (34%)	
Comparison Mepolizumab 300 mg vs Placebo [1]			
Logistic regression [2]			
Inverse odds ratio (95% CI)			0.28 (0.10,0.81)
p-value			0.019
Inverse unadjusted odds ratio (95% CI) [3]			0.27 (0.08,0.82)
Inverse relative risk (95% CI) [4]			0.51 (0.27,0.89)
Risk difference (95% CI) [4]			-0.32 (-0.54,-0.07)
Fisher's Exact p-value (2-sided)			0.013

[1] Analysis compares the number of responders. Subjects with missing response are categorised as non-responders.
[2] Logistic regression analysis adjusted for baseline prednisolone/prednisone daily dose and baseline BVAS score.
[3] Exact method.
[4] Exact unconditional CI calculated by inverting two separate one-sided tests based on the score statistic.
Note: Inverse odds ratio and inverse relative risk <1 and risk difference <0 indicate benefit for Mepolizumab over Placebo.

PPD

Table 2.61
Analysis of Subjects with Daily OCS Dose <= 7.5mg/day
During the Last 4 Weeks of the Study Treatment Period by Region

Region: Rest of World

	Placebo (N=68)	Mepolizumab 300 mg SC (N=68)	
n	35	36	
Responder	10 (29%)	17 (47%)	
Non-Responder	25 (71%)	19 (53%)	
Comparison Mepolizumab 300 mg vs Placebo [1]			
Logistic regression [2]			
Inverse odds ratio (95% CI)			0.22 (0.07,0.75)
p-value			0.015
Inverse unadjusted odds ratio (95% CI) [3]			0.45 (0.15,1.32)
Inverse relative risk (95% CI) [4]			0.61 (0.30,1.15)
Risk difference (95% CI) [4]			-0.19 (-0.40,0.04)
Fisher's Exact p-value (2-sided)			0.144

[1] Analysis compares the number of responders. Subjects with missing response are categorised as non-responders.
[2] Logistic regression analysis adjusted for baseline prednisolone/prednisone daily dose and baseline BVAS score.
[3] Exact method.
[4] Exact unconditional CI calculated by inverting two separate one-sided tests based on the score statistic.
Note: Inverse odds ratio and inverse relative risk <1 and risk difference <0 indicate benefit for Mepolizumab over Placebo.

PPD

Protocol: MEA115921
Population: Intent-to-Treat

Table 2.62
Analysis of Subjects with Daily OCS Dose <= 7.5mg/day
During the Last 4 Weeks of the Study Treatment Period by Baseline Blood Eosinophils

Baseline blood eosinophils: <0.150 GI/L

	Placebo (N=68)	Mepolizumab 300 mg SC (N=68)	
n	28	29	
Responder	8 (29%)	13 (45%)	
Non-Responder	20 (71%)	16 (55%)	
Comparison Mepolizumab 300 mg vs Placebo [1]			
Logistic regression [2]			
Inverse odds ratio (95% CI)			0.59 (0.17,2.05)
p-value			0.408
Inverse unadjusted odds ratio (95% CI) [3]			0.50 (0.14,1.68)
Inverse relative risk (95% CI) [4]			0.64 (0.28,1.30)
Risk difference (95% CI) [4]			-0.16 (-0.41,0.09)
Fisher's Exact p-value (2-sided)			0.274

[1] Analysis compares the number of responders. Subjects with missing response are categorised as non-responders.
[2] Logistic regression analysis adjusted for baseline prednisolone/prednisone daily dose, baseline BVAS score and region (EU vs. RoW).
[3] Exact method.
[4] Exact unconditional CI calculated by inverting two separate one-sided tests based on the score statistic.
Note: Inverse odds ratio and inverse relative risk <1 and risk difference <0 indicate benefit for Mepolizumab over Placebo.

PPD

Population: Intent-to-Treat

Table 2.62
Analysis of Subjects with Daily OCS Dose <= 7.5mg/day
During the Last 4 Weeks of the Study Treatment Period by Baseline Blood Eosinophils

Baseline blood eosinophils: >=0.150 GI/L

	Placebo (N=68)	Mepolizumab 300 mg SC (N=68)	
n	40	39	
Responder	13 (33%)	25 (64%)	
Non-Responder	27 (68%)	14 (36%)	
Comparison Mepolizumab 300 mg vs Placebo [1]			
Logistic regression [2]			
Inverse odds ratio (95% CI)		0.20	(0.07,0.57)
p-value		0.002	
Inverse unadjusted odds ratio (95% CI) [3]		0.27	(0.10,0.75)
Inverse relative risk (95% CI) [4]		0.51	(0.28,0.87)
Risk difference (95% CI) [4]		-0.32	(-0.52,-0.08)
Fisher's Exact p-value (2-sided)		0.007	

[1] Analysis compares the number of responders. Subjects with missing response are categorised as non-responders.
[2] Logistic regression analysis adjusted for baseline prednisolone/prednisone daily dose, baseline BVAS score and region (EU vs. RoW).
[3] Exact method.
[4] Exact unconditional CI calculated by inverting two separate one-sided tests based on the score statistic.
Note: Inverse odds ratio and inverse relative risk <1 and risk difference <0 indicate benefit for Mepolizumab over Placebo.

PPD

Protocol: MEA115921
Population: Intent-to-Treat

Table 2.63
Analysis of Subjects with Daily OCS Dose <= 7.5mg/day
During the Last 4 Weeks of the Study Treatment Period by Duration of Disease

Duration of disease: <=4 years

	Placebo (N=68)	Mepolizumab 300 mg SC (N=68)	
n	32	34	
Responder	8 (25%)	18 (53%)	
Non-Responder	24 (75%)	16 (47%)	
Comparison Mepolizumab 300 mg vs Placebo [1]			
Logistic regression [2]			
Inverse odds ratio (95% CI)			0.22 (0.06,0.74)
p-value			0.015
Inverse unadjusted odds ratio (95% CI) [3]			0.30 (0.09,0.94)
Inverse relative risk (95% CI) [4]			0.47 (0.20,0.94)
Risk difference (95% CI) [4]			-0.28 (-0.50,-0.03)
Fisher's Exact p-value (2-sided)			0.025

[1] Analysis compares the number of responders. Subjects with missing response are categorised as non-responders.
[2] Logistic regression analysis adjusted for baseline prednisolone/prednisone daily dose, baseline BVAS score and region (EU vs. RoW).
[3] Exact method.
[4] Exact unconditional CI calculated by inverting two separate one-sided tests based on the score statistic.
Note: Inverse odds ratio and inverse relative risk <1 and risk difference <0 indicate benefit for Mepolizumab over Placebo.

PPD

Protocol: MEA115921
Population: Intent-to-Treat

Table 2.63
Analysis of Subjects with Daily OCS Dose <= 7.5mg/day
During the Last 4 Weeks of the Study Treatment Period by Duration of Disease

Duration of disease: >4 years

	Placebo (N=68)	Mepolizumab 300 mg SC (N=68)	
n	36	34	
Responder	13 (36%)	20 (59%)	
Non-Responder	23 (64%)	14 (41%)	
Comparison Mepolizumab 300 mg vs Placebo [1]			
Logistic regression [2]			
Inverse odds ratio (95% CI)		0.35	(0.13,0.98)
p-value		0.045	
Inverse unadjusted odds ratio (95% CI) [3]		0.40	(0.13,1.15)
Inverse relative risk (95% CI) [4]		0.61	(0.32,1.03)
Risk difference (95% CI) [4]		-0.23	(-0.45,0.02)
Fisher's Exact p-value (2-sided)		0.093	

[1] Analysis compares the number of responders. Subjects with missing response are categorised as non-responders.
[2] Logistic regression analysis adjusted for baseline prednisolone/prednisone daily dose, baseline BVAS score and region (EU vs. RoW).
[3] Exact method.
[4] Exact unconditional CI calculated by inverting two separate one-sided tests based on the score statistic.
Note: Inverse odds ratio and inverse relative risk <1 and risk difference <0 indicate benefit for Mepolizumab over Placebo.

PPD

Protocol: MEA115921
Population: Intent-to-Treat

Table 2.67
Analysis of ACQ-6 Responders During Weeks 48-52 (Minimal Important Difference, Change <= -0.5) by Age

Age: <50 Years

	Placebo (N=68)	Mepolizumab 300 mg SC (N=68)
n	33	31
Responder	9 (27%)	7 (23%)
Non-Responder	24 (73%)	24 (77%)
Missing response	10 (30%)	10 (32%)
Comparison Mepolizumab 300 mg vs Placebo [1]		
Logistic regression [2]		
Inverse odds ratio (95% CI)		0.98 (0.25,3.83)
p-value		0.974
Inverse unadjusted odds ratio (95% CI) [3]		1.28 (0.36,4.77)
Inverse relative risk (95% CI) [4]		1.21 (0.48,3.10)
Risk difference (95% CI) [4]		0.05 (-0.17,0.26)
Fisher's Exact p-value (2-sided)		0.776

[1] Analysis compares the number of responders. Subjects with missing response are categorised as non-responders.
[2] Logistic regression analysis adjusted for baseline ACQ-6, baseline prednisolone/prednisone daily dose, baseline BVAS score and region (EU vs. RoW).
[3] Exact method.
[4] Exact unconditional CI calculated by inverting two separate one-sided tests based on the score statistic.
Note: Inverse odds ratio and inverse relative risk <1 and risk difference <0 indicate benefit for Mepolizumab over Placebo.

PPD

Protocol: MEA115921
Population: Intent-to-Treat

Table 2.67
Analysis of ACQ-6 Responders During Weeks 48-52 (Minimal Important Difference, Change <= -0.5) by Age

Age: >=50 Years

	Placebo (N=68)	Mepolizumab 300 mg SC (N=68)	
n	35	37	
Responder	5 (14%)	10 (27%)	
Non-Responder	30 (86%)	27 (73%)	
Missing response	11 (31%)	9 (24%)	
Comparison Mepolizumab 300 mg vs Placebo [1]			
Logistic regression [2]			
Inverse odds ratio (95% CI)		0.59	(0.13,2.60)
p-value		0.484	
Inverse unadjusted odds ratio (95% CI) [3]		0.45	(0.11,1.69)
Inverse relative risk (95% CI) [4]		0.53	(0.15,1.39)
Risk difference (95% CI) [4]		-0.13	(-0.32,0.07)
Fisher's Exact p-value (2-sided)		0.249	

[1] Analysis compares the number of responders. Subjects with missing response are categorised as non-responders.
[2] Logistic regression analysis adjusted for baseline ACQ-6, baseline prednisolone/prednisone daily dose, baseline BVAS score and region (EU vs. RoW).
[3] Exact method.
[4] Exact unconditional CI calculated by inverting two separate one-sided tests based on the score statistic.
Note: Inverse odds ratio and inverse relative risk <1 and risk difference <0 indicate benefit for Mepolizumab over Placebo.

PPD

Protocol: MEA115921
Population: Intent-to-Treat

Table 2.68
Analysis of ACQ-6 Responders During Weeks 48-52 (Minimal Important Difference, Change <= -0.5) by Gender

Gender: Female

	Placebo (N=68)	Mepolizumab 300 mg SC (N=68)
n	38	42
Responder	7 (18%)	14 (33%)
Non-Responder	31 (82%)	28 (67%)
Missing response	15 (39%)	8 (19%)
Comparison Mepolizumab 300 mg vs Placebo [1]		
Logistic regression [2]		
Inverse odds ratio (95% CI)		0.43 (0.14,1.34)
p-value		0.144
Inverse unadjusted odds ratio (95% CI) [3]		0.46 (0.14,1.42)
Inverse relative risk (95% CI) [4]		0.55 (0.20,1.20)
Risk difference (95% CI) [4]		-0.15 (-0.34,0.05)
Fisher's Exact p-value (2-sided)		0.203

[1] Analysis compares the number of responders. Subjects with missing response are categorised as non-responders.
[2] Logistic regression analysis adjusted for baseline ACQ-6, baseline prednisolone/prednisone daily dose, baseline BVAS score and region (EU vs. RoW).
[3] Exact method.
[4] Exact unconditional CI calculated by inverting two separate one-sided tests based on the score statistic.
Note: Inverse odds ratio and inverse relative risk <1 and risk difference <0 indicate benefit for Mepolizumab over Placebo.

PPD

Population: Intent-to-Treat

Table 2.68
Analysis of ACQ-6 Responders During Weeks 48-52 (Minimal Important Difference, Change <= -0.5) by Gender

Gender: Male

	Placebo (N=68)	Mepolizumab 300 mg SC (N=68)	
n	30	26	
Responder	7 (23%)	3 (12%)	
Non-Responder	23 (77%)	23 (88%)	
Missing response	6 (20%)	11 (42%)	
Comparison Mepolizumab 300 mg vs Placebo [1]			
Logistic regression [2]			
Inverse odds ratio (95% CI)		1.22	(0.19,7.78)
p-value		0.831	
Inverse unadjusted odds ratio (95% CI) [3]		2.30	(0.45,15.49)
Inverse relative risk (95% CI) [4]		2.02	(0.59,12.76)
Risk difference (95% CI) [4]		0.12	(-0.10,0.32)
Fisher's Exact p-value (2-sided)		0.310	

[1] Analysis compares the number of responders. Subjects with missing response are categorised as non-responders.
[2] Logistic regression analysis adjusted for baseline ACQ-6, baseline prednisolone/prednisone daily dose, baseline BVAS score and region (EU vs. RoW).
[3] Exact method.
[4] Exact unconditional CI calculated by inverting two separate one-sided tests based on the score statistic.
Note: Inverse odds ratio and inverse relative risk <1 and risk difference <0 indicate benefit for Mepolizumab over Placebo.

PPD

Protocol: MEA115921
Population: Intent-to-Treat

Table 2.69
Analysis of ACQ-6 Responders During Weeks 48-52 (Minimal Important Difference, Change <= -0.5) by Region

Region: Europe

	Placebo (N=68)	Mepolizumab 300 mg SC (N=68)
n	33	32
Responder	13 (39%)	10 (31%)
Non-Responder	20 (61%)	22 (69%)
Missing response	4 (12%)	4 (13%)
Comparison Mepolizumab 300 mg vs Placebo [1]		
Logistic regression [2]		
Inverse odds ratio (95% CI)		0.84 (0.25,2.78)
p-value		0.776
Inverse unadjusted odds ratio (95% CI) [3]		1.42 (0.46,4.53)
Inverse relative risk (95% CI) [4]		1.26 (0.63,2.81)
Risk difference (95% CI) [4]		0.08 (-0.16,0.31)
Fisher's Exact p-value (2-sided)		0.606

[1] Analysis compares the number of responders. Subjects with missing response are categorised as non-responders.
[2] Logistic regression analysis adjusted for baseline ACQ-6, baseline prednisolone/prednisone daily dose and baseline BVAS score.
[3] Exact method.
[4] Exact unconditional CI calculated by inverting two separate one-sided tests based on the score statistic.
Note: Inverse odds ratio and inverse relative risk <1 and risk difference <0 indicate benefit for Mepolizumab over Placebo.

PPD

Protocol: MEA115921
Population: Intent-to-Treat

Table 2.69
Analysis of ACQ-6 Responders During Weeks 48-52 (Minimal Important Difference, Change <= -0.5) by Region

Region: Rest of World

	Placebo (N=68)	Mepolizumab 300 mg SC (N=68)
n	35	36
Responder	1 (3%)	7 (19%)
Non-Responder	34 (97%)	29 (81%)
Missing response	17 (49%)	15 (42%)
Comparison Mepolizumab 300 mg vs Placebo [1]		
Logistic regression [2]		
Inverse odds ratio (95% CI)		0.14 (0.02,1.27)
p-value		0.081
Inverse unadjusted odds ratio (95% CI) [3]		0.12 (<0.01,1.06)
Inverse relative risk (95% CI) [4]		0.15 (0.01,0.95)
Risk difference (95% CI) [4]		-0.17 (-0.34,-0.02)
Fisher's Exact p-value (2-sided)		0.055

[1] Analysis compares the number of responders. Subjects with missing response are categorised as non-responders.
[2] Logistic regression analysis adjusted for baseline ACQ-6, baseline prednisolone/prednisone daily dose and baseline BVAS score.
[3] Exact method.
[4] Exact unconditional CI calculated by inverting two separate one-sided tests based on the score statistic.
Note: Inverse odds ratio and inverse relative risk <1 and risk difference <0 indicate benefit for Mepolizumab over Placebo.

PPD

Protocol: MEA115921
Population: Intent-to-Treat

Table 2.70
Analysis of ACQ-6 Responders During Weeks 48-52 (Minimal Important Difference, Change <= -0.5) by Baseline Blood Eosinophils

Baseline blood eosinophils: <0.150 GI/L

	Placebo (N=68)	Mepolizumab 300 mg SC (N=68)
n	28	29
Responder	6 (21%)	7 (24%)
Non-Responder	22 (79%)	22 (76%)
Missing response	12 (43%)	6 (21%)
Comparison Mepolizumab 300 mg vs Placebo [1]		
Logistic regression [2]		
Inverse odds ratio (95% CI)		0.75 (0.17,3.31)
p-value		0.702
Inverse unadjusted odds ratio (95% CI) [3]		0.86 (0.20,3.54)
Inverse relative risk (95% CI) [4]		0.89 (0.31,2.60)
Risk difference (95% CI) [4]		-0.03 (-0.25,0.20)
Fisher's Exact p-value (2-sided)		1.000

[1] Analysis compares the number of responders. Subjects with missing response are categorised as non-responders.
[2] Logistic regression analysis adjusted for baseline ACQ-6, baseline prednisolone/prednisone daily dose, baseline BVAS score and region (EU vs. RoW).
[3] Exact method.
[4] Exact unconditional CI calculated by inverting two separate one-sided tests based on the score statistic.
Note: Inverse odds ratio and inverse relative risk <1 and risk difference <0 indicate benefit for Mepolizumab over Placebo.

PPD

Protocol: MEA115921
Population: Intent-to-Treat

Table 2.70
Analysis of ACQ-6 Responders During Weeks 48-52 (Minimal Important Difference, Change <= -0.5) by Baseline Blood Eosinophils

Baseline blood eosinophils: >=0.150 GI/L

	Placebo (N=68)	Mepolizumab 300 mg SC (N=68)
n	40	39
Responder	8 (20%)	10 (26%)
Non-Responder	32 (80%)	29 (74%)
Missing response	9 (23%)	13 (33%)
Comparison Mepolizumab 300 mg vs Placebo [1]		
Logistic regression [2]		
Inverse odds ratio (95% CI)		0.48 (0.14,1.68)
p-value		0.249
Inverse unadjusted odds ratio (95% CI) [3]		0.73 (0.22,2.37)
Inverse relative risk (95% CI) [4]		0.78 (0.31,1.91)
Risk difference (95% CI) [4]		-0.06 (-0.25,0.14)
Fisher's Exact p-value (2-sided)		0.600

[1] Analysis compares the number of responders. Subjects with missing response are categorised as non-responders.
[2] Logistic regression analysis adjusted for baseline ACQ-6, baseline prednisolone/prednisone daily dose, baseline BVAS score and region (EU vs. RoW).
[3] Exact method.
[4] Exact unconditional CI calculated by inverting two separate one-sided tests based on the score statistic.
Note: Inverse odds ratio and inverse relative risk <1 and risk difference <0 indicate benefit for Mepolizumab over Placebo.

PPD

Protocol: MEA115921
Population: Intent-to-Treat

Table 2.71
Analysis of ACQ-6 Responders During Weeks 48-52 (Minimal Important Difference, Change <= -0.5) by Duration of Disease

Duration of disease: <=4 years

	Placebo (N=68)	Mepolizumab 300 mg SC (N=68)
n	32	34
Responder	5 (16%)	8 (24%)
Non-Responder	27 (84%)	26 (76%)
Missing response	10 (31%)	10 (29%)
Comparison Mepolizumab 300 mg vs Placebo [1]		
Logistic regression [2]		
Inverse odds ratio (95% CI)		0.56 (0.13,2.48)
p-value		0.446
Inverse unadjusted odds ratio (95% CI) [3]		0.61 (0.14,2.43)
Inverse relative risk (95% CI) [4]		0.66 (0.20,1.86)
Risk difference (95% CI) [4]		-0.08 (-0.28,0.12)
Fisher's Exact p-value (2-sided)		0.540

[1] Analysis compares the number of responders. Subjects with missing response are categorised as non-responders.
[2] Logistic regression analysis adjusted for baseline ACQ-6, baseline prednisolone/prednisone daily dose, baseline BVAS score and region (EU vs. RoW).
[3] Exact method.
[4] Exact unconditional CI calculated by inverting two separate one-sided tests based on the score statistic.
Note: Inverse odds ratio and inverse relative risk <1 and risk difference <0 indicate benefit for Mepolizumab over Placebo.

PPD

Protocol: MEA115921
Population: Intent-to-Treat

Table 2.71
Analysis of ACQ-6 Responders During Weeks 48-52 (Minimal Important Difference, Change <= -0.5) by Duration of Disease

Duration of disease: >4 years

	Placebo (N=68)	Mepolizumab 300 mg SC (N=68)
n	36	34
Responder	9 (25%)	9 (26%)
Non-Responder	27 (75%)	25 (74%)
Missing response	11 (31%)	9 (26%)
Comparison Mepolizumab 300 mg vs Placebo [1]		
Logistic regression [2]		
Inverse odds ratio (95% CI)		0.85 (0.24,3.02)
p-value		0.807
Inverse unadjusted odds ratio (95% CI) [3]		0.93 (0.28,3.11)
Inverse relative risk (95% CI) [4]		0.94 (0.39,2.32)
Risk difference (95% CI) [4]		-0.01 (-0.23,0.19)
Fisher's Exact p-value (2-sided)		1.000

[1] Analysis compares the number of responders. Subjects with missing response are categorised as non-responders.
[2] Logistic regression analysis adjusted for baseline ACQ-6, baseline prednisolone/prednisone daily dose, baseline BVAS score and region (EU vs. RoW).
[3] Exact method.
[4] Exact unconditional CI calculated by inverting two separate one-sided tests based on the score statistic.
Note: Inverse odds ratio and inverse relative risk <1 and risk difference <0 indicate benefit for Mepolizumab over Placebo.

PPD

Protocol: MEA115921
Population: Intent-to-Treat

Table 2.76
Analysis of SNOT-22 Responders (Minimal Important Difference, Change <= -8.9) at Week 52 by Age

Age: <50 Years

	Placebo (N=68)	Mepolizumab 300 mg SC (N=68)
n	33	31
Responder	8 (24%)	9 (29%)
Non-Responder	25 (76%)	22 (71%)
Missing response	3 (9%)	2 (6%)
Comparison Mepolizumab 300 mg vs Placebo [1]		
Logistic regression [2]		
Inverse odds ratio (95% CI)		0.58 (0.17,2.02)
p-value		0.394
Inverse unadjusted odds ratio (95% CI) [3]		0.79 (0.22,2.75)
Inverse relative risk (95% CI) [4]		0.84 (0.32,1.96)
Risk difference (95% CI) [4]		-0.05 (-0.27,0.17)
Fisher's Exact p-value (2-sided)		0.779

[1] Analysis compares the number of responders. Subjects with missing response are categorised as non-responders.
[2] Logistic regression analysis adjusted for baseline SNOT-22, baseline prednisolone/prednisone daily dose, baseline BVAS score and region (EU vs. RoW).
[3] Exact method.
[4] Exact unconditional CI calculated by inverting two separate one-sided tests based on the score statistic.
Note: Inverse odds ratio and inverse relative risk <1 and risk difference <0 indicate benefit for Mepolizumab over Placebo.

PPD

Population: Intent-to-Treat

Table 2.76
Analysis of SNOT-22 Responders (Minimal Important Difference, Change <= -8.9) at Week 52 by Age

Age: >=50 Years

	Placebo (N=68)	Mepolizumab 300 mg SC (N=68)
n	35	37
Responder	6 (17%)	17 (46%)
Non-Responder	29 (83%)	20 (54%)
Missing response	4 (11%)	1 (3%)
Comparison Mepolizumab 300 mg vs Placebo [1]		
Logistic regression [2]		
Inverse odds ratio (95% CI)		0.28 (0.07,1.06)
p-value		0.060
Inverse unadjusted odds ratio (95% CI) [3]		0.25 (0.07,0.80)
Inverse relative risk (95% CI) [4]		0.37 (0.10,0.88)
Risk difference (95% CI) [4]		-0.29 (-0.49,-0.07)
Fisher's Exact p-value (2-sided)		0.012

[1] Analysis compares the number of responders. Subjects with missing response are categorised as non-responders.
[2] Logistic regression analysis adjusted for baseline SNOT-22, baseline prednisolone/prednisone daily dose, baseline BVAS score and region (EU vs. RoW).
[3] Exact method.
[4] Exact unconditional CI calculated by inverting two separate one-sided tests based on the score statistic.
Note: Inverse odds ratio and inverse relative risk <1 and risk difference <0 indicate benefit for Mepolizumab over Placebo.

PPD

Protocol: MEA115921
Population: Intent-to-Treat

Table 2.77
Analysis of SNOT-22 Responders (Minimal Important Difference, Change <= -8.9) at Week 52
by Gender

Gender: Female

	Placebo (N=68)	Mepolizumab 300 mg SC (N=68)
n	38	42
Responder	7 (18%)	18 (43%)
Non-Responder	31 (82%)	24 (57%)
Missing response	6 (16%)	1 (2%)
Comparison Mepolizumab 300 mg vs Placebo [1]		
Logistic regression [2]		
Inverse odds ratio (95% CI)		0.26 (0.08,0.82)
p-value		0.022
Inverse unadjusted odds ratio (95% CI) [3]		0.31 (0.09,0.92)
Inverse relative risk (95% CI) [4]		0.43 (0.15,0.93)
Risk difference (95% CI) [4]		-0.24 (-0.44,-0.03)
Fisher's Exact p-value (2-sided)		0.029

[1] Analysis compares the number of responders. Subjects with missing response are categorised as non-responders.
[2] Logistic regression analysis adjusted for baseline SNOT-22, baseline prednisolone/prednisone daily dose, baseline BVAS score and region (EU vs. RoW).
[3] Exact method.
[4] Exact unconditional CI calculated by inverting two separate one-sided tests based on the score statistic.
Note: Inverse odds ratio and inverse relative risk <1 and risk difference <0 indicate benefit for Mepolizumab over Placebo.

PPD

Protocol: MEA115921
Population: Intent-to-Treat

Table 2.77
Analysis of SNOT-22 Responders (Minimal Important Difference, Change <= -8.9) at Week 52
by Gender

Gender: Male

	Placebo (N=68)	Mepolizumab 300 mg SC (N=68)
n	30	26
Responder	7 (23%)	8 (31%)
Non-Responder	23 (77%)	18 (69%)
Missing response	1 (3%)	2 (8%)
Comparison Mepolizumab 300 mg vs Placebo [1]		
Logistic regression [2]		
Inverse odds ratio (95% CI)		0.77 (0.18,3.29)
p-value		0.723
Inverse unadjusted odds ratio (95% CI) [3]		0.69 (0.18,2.65)
Inverse relative risk (95% CI) [4]		0.76 (0.28,1.92)
Risk difference (95% CI) [4]		-0.07 (-0.32,0.17)
Fisher's Exact p-value (2-sided)		0.560

[1] Analysis compares the number of responders. Subjects with missing response are categorised as non-responders.
[2] Logistic regression analysis adjusted for baseline SNOT-22, baseline prednisolone/prednisone daily dose, baseline BVAS score and region (EU vs. RoW).
[3] Exact method.
[4] Exact unconditional CI calculated by inverting two separate one-sided tests based on the score statistic.
Note: Inverse odds ratio and inverse relative risk <1 and risk difference <0 indicate benefit for Mepolizumab over Placebo.

PPD

Protocol: MEA115921
Population: Intent-to-Treat

Table 2.78
Analysis of SNOT-22 Responders (Minimal Important Difference, Change <= -8.9) at Week 52
by Region

Region: Europe

	Placebo (N=68)	Mepolizumab 300 mg SC (N=68)
n	33	32
Responder	9 (27%)	15 (47%)
Non-Responder	24 (73%)	17 (53%)
Missing response	0	1 (3%)
Comparison Mepolizumab 300 mg vs Placebo [1]		
Logistic regression [2]		
Inverse odds ratio (95% CI)		0.20 (0.06,0.73)
p-value		0.015
Inverse unadjusted odds ratio (95% CI) [3]		0.43 (0.13,1.34)
Inverse relative risk (95% CI) [4]		0.58 (0.28,1.14)
Risk difference (95% CI) [4]		-0.20 (-0.42,0.04)
Fisher's Exact p-value (2-sided)		0.127

[1] Analysis compares the number of responders. Subjects with missing response are categorised as non-responders.
[2] Logistic regression analysis adjusted for baseline SNOT-22, baseline prednisolone/prednisone daily dose and baseline BVAS score.
[3] Exact method.
[4] Exact unconditional CI calculated by inverting two separate one-sided tests based on the score statistic.
Note: Inverse odds ratio and inverse relative risk <1 and risk difference <0 indicate benefit for Mepolizumab over Placebo.

PPD

Table 2.78
Analysis of SNOT-22 Responders (Minimal Important Difference, Change <= -8.9) at Week 52 by Region

Region: Rest of World

	Placebo (N=68)	Mepolizumab 300 mg SC (N=68)
n	35	36
Responder	5 (14%)	11 (31%)
Non-Responder	30 (86%)	25 (69%)
Missing response	7 (20%)	2 (6%)
Comparison Mepolizumab 300 mg vs Placebo [1]		
Logistic regression [2]		
Inverse odds ratio (95% CI)		0.70 (0.17,2.87)
p-value		0.624
Inverse unadjusted odds ratio (95% CI) [3]		0.38 (0.09,1.40)
Inverse relative risk (95% CI) [4]		0.47 (0.12,1.17)
Risk difference (95% CI) [4]		-0.16 (-0.36,0.04)
Fisher's Exact p-value (2-sided)		0.155

[1] Analysis compares the number of responders. Subjects with missing response are categorised as non-responders.
[2] Logistic regression analysis adjusted for baseline SNOT-22, baseline prednisolone/prednisone daily dose and baseline BVAS score.
[3] Exact method.
[4] Exact unconditional CI calculated by inverting two separate one-sided tests based on the score statistic.
Note: Inverse odds ratio and inverse relative risk <1 and risk difference <0 indicate benefit for Mepolizumab over Placebo.

PPD

Protocol: MEA115921
Population: Intent-to-Treat

Table 2.79
Analysis of SNOT-22 Responders (Minimal Important Difference, Change <= -8.9) at Week 52
by Baseline Blood Eosinophils

Baseline blood eosinophils: <0.150 GI/L

	Placebo (N=68)	Mepolizumab 300 mg SC (N=68)
n	28	29
Responder	6 (21%)	12 (41%)
Non-Responder	22 (79%)	17 (59%)
Missing response	3 (11%)	2 (7%)
Comparison Mepolizumab 300 mg vs Placebo [1]		
Logistic regression [2]		
Inverse odds ratio (95% CI)		0.36 (0.09,1.52)
p-value		0.167
Inverse unadjusted odds ratio (95% CI) [3]		0.39 (0.10,1.42)
Inverse relative risk (95% CI) [4]		0.52 (0.18,1.17)
Risk difference (95% CI) [4]		-0.20 (-0.44,0.05)
Fisher's Exact p-value (2-sided)		0.155

[1] Analysis compares the number of responders. Subjects with missing response are categorised as non-responders.
[2] Logistic regression analysis adjusted for baseline SNOT-22, baseline prednisolone/prednisone daily dose, baseline BVAS score and region (EU vs. RoW).
[3] Exact method.
[4] Exact unconditional CI calculated by inverting two separate one-sided tests based on the score statistic.
Note: Inverse odds ratio and inverse relative risk <1 and risk difference <0 indicate benefit for Mepolizumab over Placebo.

PPD

Population: Intent-to-Treat

Table 2.79
Analysis of SNOT-22 Responders (Minimal Important Difference, Change <= -8.9) at Week 52
by Baseline Blood Eosinophils

Baseline blood eosinophils: >=0.150 GI/L

	Placebo (N=68)	Mepolizumab 300 mg SC (N=68)
n	40	39
Responder	8 (20%)	14 (36%)
Non-Responder	32 (80%)	25 (64%)
Missing response	4 (10%)	1 (3%)
Comparison Mepolizumab 300 mg vs Placebo [1]		
Logistic regression [2]		
Inverse odds ratio (95% CI)		0.37 (0.12,1.12)
p-value		0.078
Inverse unadjusted odds ratio (95% CI) [3]		0.45 (0.14,1.37)
Inverse relative risk (95% CI) [4]		0.56 (0.23,1.18)
Risk difference (95% CI) [4]		-0.16 (-0.36,0.04)
Fisher's Exact p-value (2-sided)		0.137

[1] Analysis compares the number of responders. Subjects with missing response are categorised as non-responders.
[2] Logistic regression analysis adjusted for baseline SNOT-22, baseline prednisolone/prednisone daily dose, baseline BVAS score and region (EU vs. RoW).
[3] Exact method.
[4] Exact unconditional CI calculated by inverting two separate one-sided tests based on the score statistic.
Note: Inverse odds ratio and inverse relative risk <1 and risk difference <0 indicate benefit for Mepolizumab over Placebo.

PPD

Protocol: MEA115921
Population: Intent-to-Treat

Table 2.80
Analysis of SNOT-22 Responders (Minimal Important Difference, Change <= -8.9) at Week 52
by Duration of Disease

Duration of disease: <=4 years

	Placebo (N=68)	Mepolizumab 300 mg SC (N=68)
n	32	34
Responder	5 (16%)	16 (47%)
Non-Responder	27 (84%)	18 (53%)
Missing response	4 (13%)	1 (3%)
Comparison Mepolizumab 300 mg vs Placebo [1]		
Logistic regression [2]		
Inverse odds ratio (95% CI)		0.15 (0.04,0.60)
p-value		0.007
Inverse unadjusted odds ratio (95% CI) [3]		0.21 (0.05,0.75)
Inverse relative risk (95% CI) [4]		0.33 (0.07,0.86)
Risk difference (95% CI) [4]		-0.31 (-0.52,-0.08)
Fisher's Exact p-value (2-sided)		0.008

[1] Analysis compares the number of responders. Subjects with missing response are categorised as non-responders.
[2] Logistic regression analysis adjusted for baseline SNOT-22, baseline prednisolone/prednisone daily dose, baseline BVAS score and region (EU vs. RoW).
[3] Exact method.
[4] Exact unconditional CI calculated by inverting two separate one-sided tests based on the score statistic.
Note: Inverse odds ratio and inverse relative risk <1 and risk difference <0 indicate benefit for Mepolizumab over Placebo.

PPD

Protocol: MEA115921
Population: Intent-to-Treat

Table 2.80
Analysis of SNOT-22 Responders (Minimal Important Difference, Change <= -8.9) at Week 52
by Duration of Disease

Duration of disease: >4 years

	Placebo (N=68)	Mepolizumab 300 mg SC (N=68)
n	36	34
Responder	9 (25%)	10 (29%)
Non-Responder	27 (75%)	24 (71%)
Missing response	3 (8%)	2 (6%)
Comparison Mepolizumab 300 mg vs Placebo [1]		
Logistic regression [2]		
Inverse odds ratio (95% CI)		0.77 (0.24,2.52)
p-value		0.671
Inverse unadjusted odds ratio (95% CI) [3]		0.80 (0.24,2.62)
Inverse relative risk (95% CI) [4]		0.85 (0.35,1.90)
Risk difference (95% CI) [4]		-0.04 (-0.26,0.17)
Fisher's Exact p-value (2-sided)		0.790

[1] Analysis compares the number of responders. Subjects with missing response are categorised as non-responders.
[2] Logistic regression analysis adjusted for baseline SNOT-22, baseline prednisolone/prednisone daily dose, baseline BVAS score and region (EU vs. RoW).
[3] Exact method.
[4] Exact unconditional CI calculated by inverting two separate one-sided tests based on the score statistic.
Note: Inverse odds ratio and inverse relative risk <1 and risk difference <0 indicate benefit for Mepolizumab over Placebo.

PPD

Protocol: MEA115921
Population: Intent-to-Treat

Table 2.84
Analysis of Sino-Nasal Questionnaire Data at Week 49-52 by Age

Symptom: Blockage/Congestion of Nose
Age: <50 Years

		Placebo (N=68)	Mepolizumab 300 mg SC (N=68)
Number of subjects in subgroup		33	31
Severity of symptom [1]	n	23	21
	None	3 (13%)	4 (19%)
	Mild	2 (9%)	8 (38%)
	Moderate	8 (35%)	4 (19%)
	Severe	8 (35%)	4 (19%)
	Very severe	2 (9%)	1 (5%)
Comparison: Placebo/ Mepolizumab [2]			
Inverse odds ratio			0.74
95% Confidence Interval			(0.22,2.54)
p-value			0.638

[1] Questionnaire was administered every week. Values summarised are the highest (i.e. worst) responses within each reporting period.
[2] Based on a proportional odds model with covariates: treatment group, baseline prednisolone/prednisone daily dose, baseline BVAS score and region (defined as EU vs RoW). An odds ratio <1 represents a benefit of mepolizumab compared to placebo.

PPD

Protocol: MEA115921
Population: Intent-to-Treat

Table 2.84
Analysis of Sino-Nasal Questionnaire Data at Week 49-52 by Age

Symptom: Blockage/Congestion of Nose
Age: >=50 Years

		Placebo (N=68)	Mepolizumab 300 mg SC (N=68)
Number of subjects in subgroup		35	37
Severity of symptom [1]	n	24	28
	None	4 (17%)	4 (14%)
	Mild	8 (33%)	11 (39%)
	Moderate	9 (38%)	6 (21%)
	Severe	2 (8%)	7 (25%)
	Very severe	1 (4%)	0
Comparison: Placebo/ Mepolizumab [2]			
Inverse odds ratio			0.84
95% Confidence Interval			(0.29,2.39)
p-value			0.745

[1] Questionnaire was administered every week. Values summarised are the highest (i.e. worst) responses within each reporting period.
[2] Based on a proportional odds model with covariates: treatment group, baseline prednisolone/prednisone daily dose, baseline BVAS score and region (defined as EU vs RoW). An odds ratio <1 represents a benefit of mepolizumab compared to placebo.

PPD

Table 2.84
Analysis of Sino-Nasal Questionnaire Data at Week 49-52 by Age

Symptom: Facial Pain/Pressure
Age: <50 Years

		Placebo (N=68)	Mepolizumab 300 mg SC (N=68)
Number of subjects in subgroup		33	31
Severity of symptom [1]	n	23	21
	None	8 (35%)	13 (62%)
	Mild	3 (13%)	4 (19%)
	Moderate	6 (26%)	2 (10%)
	Severe	6 (26%)	2 (10%)
	Very severe	0	0
Comparison: Placebo/ Mepolizumab [2]			
Inverse odds ratio			0.45
95% Confidence Interval			(0.13,1.65)
p-value			0.230

[1] Questionnaire was administered every week. Values summarised are the highest (i.e. worst) responses within each reporting period.
[2] Based on a proportional odds model with covariates: treatment group, baseline prednisolone/prednisone daily dose, baseline BVAS score and region (defined as EU vs RoW). An odds ratio <1 represents a benefit of mepolizumab compared to placebo.

PPD

Table 2.84
Analysis of Sino-Nasal Questionnaire Data at Week 49-52 by Age

Symptom: Facial Pain/Pressure
Age: >=50 Years

		Placebo (N=68)	Mepolizumab 300 mg SC (N=68)
Number of subjects in subgroup		35	37
Severity of symptom [1]	n	24	28
	None	12 (50%)	14 (50%)
	Mild	5 (21%)	7 (25%)
	Moderate	3 (13%)	4 (14%)
	Severe	4 (17%)	3 (11%)
	Very severe	0	0
Comparison: Placebo/ Mepolizumab [2]			
Inverse odds ratio			0.74
95% Confidence Interval			(0.25,2.18)
p-value			0.588

[1] Questionnaire was administered every week. Values summarised are the highest (i.e. worst) responses within each reporting period.
[2] Based on a proportional odds model with covariates: treatment group, baseline prednisolone/prednisone daily dose, baseline BVAS score and region (defined as EU vs RoW). An odds ratio <1 represents a benefit of mepolizumab compared to placebo.

PPD

Table 2.84
Analysis of Sino-Nasal Questionnaire Data at Week 49-52 by Age

Symptom: Loss/Reduction of Taste/Smell
Age: <50 Years

		Placebo (N=68)	Mepolizumab 300 mg SC (N=68)
Number of subjects in subgroup		33	31
Severity of symptom [1]	n	23	21
	None	2 (9%)	10 (48%)
	Mild	6 (26%)	6 (29%)
	Moderate	8 (35%)	1 (5%)
	Severe	3 (13%)	3 (14%)
	Very severe	4 (17%)	1 (5%)
Comparison: Placebo/ Mepolizumab [2]			
Inverse odds ratio			0.21
95% Confidence Interval			(0.06,0.78)
p-value			0.019

[1] Questionnaire was administered every week. Values summarised are the highest (i.e. worst) responses within each reporting period.
[2] Based on a proportional odds model with covariates: treatment group, baseline prednisolone/prednisone daily dose, baseline BVAS score and region (defined as EU vs RoW). An odds ratio <1 represents a benefit of mepolizumab compared to placebo.

PPD

Table 2.84
Analysis of Sino-Nasal Questionnaire Data at Week 49-52 by Age

Symptom: Loss/Reduction of Taste/Smell
Age: >=50 Years

		Placebo (N=68)	Mepolizumab 300 mg SC (N=68)
Number of subjects in subgroup		35	37
Severity of symptom [1]	n	24	28
	None	6 (25%)	6 (21%)
	Mild	6 (25%)	11 (39%)
	Moderate	5 (21%)	4 (14%)
	Severe	3 (13%)	6 (21%)
	Very severe	4 (17%)	1 (4%)
Comparison: Placebo/ Mepolizumab [2]			
Inverse odds ratio			0.48
95% Confidence Interval			(0.17,1.38)
p-value			0.176

[1] Questionnaire was administered every week. Values summarised are the highest (i.e. worst) responses within each reporting period.
[2] Based on a proportional odds model with covariates: treatment group, baseline prednisolone/prednisone daily dose, baseline BVAS score and region (defined as EU vs RoW). An odds ratio <1 represents a benefit of mepolizumab compared to placebo.

PPD

Table 2.84
Analysis of Sino-Nasal Questionnaire Data at Week 49-52 by Age

Symptom: Post-nasal Discharge
Age: <50 Years

		Placebo (N=68)	Mepolizumab 300 mg SC (N=68)
Number of subjects in subgroup		33	31
Severity of symptom [1]	n	23	21
	None	3 (13%)	8 (38%)
	Mild	4 (17%)	8 (38%)
	Moderate	9 (39%)	2 (10%)
	Severe	7 (30%)	3 (14%)
	Very severe	0	0
Comparison: Placebo/ Mepolizumab [2]			
Inverse odds ratio			0.31
95% Confidence Interval			(0.09,1.09)
p-value			0.068

[1] Questionnaire was administered every week. Values summarised are the highest (i.e. worst) responses within each reporting period.
[2] Based on a proportional odds model with covariates: treatment group, baseline prednisolone/prednisone daily dose, baseline BVAS score and region (defined as EU vs RoW). An odds ratio <1 represents a benefit of mepolizumab compared to placebo.

PPD

Population: Intent-to-Treat

Table 2.84
Analysis of Sino-Nasal Questionnaire Data at Week 49-52 by Age

Symptom: Post-nasal Discharge
Age: >=50 Years

		Placebo (N=68)	Mepolizumab 300 mg SC (N=68)
Number of subjects in subgroup		35	37
Severity of symptom [1]	n	24	28
	None	5 (21%)	10 (36%)
	Mild	7 (29%)	10 (36%)
	Moderate	8 (33%)	7 (25%)
	Severe	2 (8%)	1 (4%)
	Very severe	2 (8%)	0
Comparison: Placebo/ Mepolizumab [2]			
Inverse odds ratio			0.40
95% Confidence Interval			(0.14,1.17)
p-value			0.093

[1] Questionnaire was administered every week. Values summarised are the highest (i.e. worst) responses within each reporting period.
[2] Based on a proportional odds model with covariates: treatment group, baseline prednisolone/prednisone daily dose, baseline BVAS score and region (defined as EU vs RoW). An odds ratio <1 represents a benefit of mepolizumab compared to placebo.

PPD

Population: Intent-to-Treat

Table 2.84
Analysis of Sino-Nasal Questionnaire Data at Week 49-52 by Age

Symptom: Runny Nose
Age: <50 Years

		Placebo (N=68)	Mepolizumab 300 mg SC (N=68)
Number of subjects in subgroup		33	31
Severity of symptom [1]	n	23	21
	None	5 (22%)	9 (43%)
	Mild	6 (26%)	6 (29%)
	Moderate	8 (35%)	5 (24%)
	Severe	4 (17%)	1 (5%)
	Very severe	0	0
Comparison: Placebo/ Mepolizumab [2]			
Inverse odds ratio			0.55
95% Confidence Interval			(0.16,1.93)
p-value			0.353

[1] Questionnaire was administered every week. Values summarised are the highest (i.e. worst) responses within each reporting period.
[2] Based on a proportional odds model with covariates: treatment group, baseline prednisolone/prednisone daily dose, baseline BVAS score and region (defined as EU vs RoW). An odds ratio <1 represents a benefit of mepolizumab compared to placebo.

PPD

Table 2.84
Analysis of Sino-Nasal Questionnaire Data at Week 49-52 by Age

Symptom: Runny Nose
Age: >=50 Years

		Placebo (N=68)	Mepolizumab 300 mg SC (N=68)
Number of subjects in subgroup		35	37
Severity of symptom [1]	n	24	28
	None	4 (17%)	10 (36%)
	Mild	11 (46%)	10 (36%)
	Moderate	5 (21%)	7 (25%)
	Severe	2 (8%)	1 (4%)
	Very severe	2 (8%)	0
Comparison: Placebo/ Mepolizumab [2]			
Inverse odds ratio			0.35
95% Confidence Interval			(0.12,1.04)
p-value			0.060

[1] Questionnaire was administered every week. Values summarised are the highest (i.e. worst) responses within each reporting period.
[2] Based on a proportional odds model with covariates: treatment group, baseline prednisolone/prednisone daily dose, baseline BVAS score and region (defined as EU vs RoW). An odds ratio <1 represents a benefit of mepolizumab compared to placebo.

PPD

Protocol: MEA115921
Population: Intent-to-Treat

Table 2.85
Analysis of Sino-Nasal Questionnaire Data at Week 49-52 by Gender

Symptom: Blockage/Congestion of Nose
Gender: Female

		Placebo (N=68)	Mepolizumab 300 mg SC (N=68)
Number of subjects in subgroup		38	42
Severity of symptom [1]	n	23	34
	None	2 (9%)	5 (15%)
	Mild	5 (22%)	12 (35%)
	Moderate	10 (43%)	6 (18%)
	Severe	4 (17%)	10 (29%)
	Very severe	2 (9%)	1 (3%)
Comparison: Placebo/ Mepolizumab [2]			
Inverse odds ratio			0.79
95% Confidence Interval			(0.30,2.13)
p-value			0.646

[1] Questionnaire was administered every week. Values summarised are the highest (i.e. worst) responses within each reporting period.
[2] Based on a proportional odds model with covariates: treatment group, baseline prednisolone/prednisone daily dose, baseline BVAS score and region (defined as EU vs RoW). An odds ratio <1 represents a benefit of mepolizumab compared to placebo.

PPD

Protocol: MEA115921
Population: Intent-to-Treat

Table 2.85
Analysis of Sino-Nasal Questionnaire Data at Week 49-52 by Gender

Symptom: Blockage/Congestion of Nose
Gender: Male

		Placebo (N=68)	Mepolizumab 300 mg SC (N=68)
Number of subjects in subgroup		30	26
Severity of symptom [1]	n	24	15
	None	5 (21%)	3 (20%)
	Mild	5 (21%)	7 (47%)
	Moderate	7 (29%)	4 (27%)
	Severe	6 (25%)	1 (7%)
	Very severe	1 (4%)	0
Comparison: Placebo/ Mepolizumab [2]			
Inverse odds ratio			0.57
95% Confidence Interval			(0.17,1.95)
p-value			0.370

[1] Questionnaire was administered every week. Values summarised are the highest (i.e. worst) responses within each reporting period.
[2] Based on a proportional odds model with covariates: treatment group, baseline prednisolone/prednisone daily dose, baseline BVAS score and region (defined as EU vs RoW). An odds ratio <1 represents a benefit of mepolizumab compared to placebo.

PPD

Population: Intent-to-Treat

Table 2.85
Analysis of Sino-Nasal Questionnaire Data at Week 49-52 by Gender

Symptom: Facial Pain/Pressure
Gender: Female

		Placebo (N=68)	Mepolizumab 300 mg SC (N=68)
Number of subjects in subgroup		38	42
Severity of symptom [1]	n	23	34
	None	11 (48%)	19 (56%)
	Mild	3 (13%)	7 (21%)
	Moderate	4 (17%)	5 (15%)
	Severe	5 (22%)	3 (9%)
	Very severe	0	0
Comparison: Placebo/ Mepolizumab [2]			
Inverse odds ratio			0.63
95% Confidence Interval			(0.23,1.77)
p-value			0.384

[1] Questionnaire was administered every week. Values summarised are the highest (i.e. worst) responses within each reporting period.
[2] Based on a proportional odds model with covariates: treatment group, baseline prednisolone/prednisone daily dose, baseline BVAS score and region (defined as EU vs RoW). An odds ratio <1 represents a benefit of mepolizumab compared to placebo.

PPD

Population: Intent-to-Treat

Table 2.85
Analysis of Sino-Nasal Questionnaire Data at Week 49-52 by Gender

Symptom: Facial Pain/Pressure
Gender: Male

		Placebo (N=68)	Mepolizumab 300 mg SC (N=68)
Number of subjects in subgroup		30	26
Severity of symptom [1]	n	24	15
	None	9 (38%)	8 (53%)
	Mild	5 (21%)	4 (27%)
	Moderate	5 (21%)	1 (7%)
	Severe	5 (21%)	2 (13%)
	Very severe	0	0
Comparison: Placebo/ Mepolizumab [2]			
Inverse odds ratio			0.48
95% Confidence Interval			(0.13,1.71)
p-value			0.257

[1] Questionnaire was administered every week. Values summarised are the highest (i.e. worst) responses within each reporting period.
[2] Based on a proportional odds model with covariates: treatment group, baseline prednisolone/prednisone daily dose, baseline BVAS score and region (defined as EU vs RoW). An odds ratio <1 represents a benefit of mepolizumab compared to placebo.

PPD

Protocol: MEA115921
Population: Intent-to-Treat

Table 2.85
Analysis of Sino-Nasal Questionnaire Data at Week 49-52 by Gender

Symptom: Loss/Reduction of Taste/Smell
Gender: Female

		Placebo (N=68)	Mepolizumab 300 mg SC (N=68)
Number of subjects in subgroup		38	42
Severity of symptom [1]	n	23	34
	None	3 (13%)	10 (29%)
	Mild	7 (30%)	12 (35%)
	Moderate	7 (30%)	4 (12%)
	Severe	2 (9%)	7 (21%)
	Very severe	4 (17%)	1 (3%)
Comparison: Placebo/ Mepolizumab [2]			
Inverse odds ratio			0.42
95% Confidence Interval			(0.15,1.15)
p-value			0.091

[1] Questionnaire was administered every week. Values summarised are the highest (i.e. worst) responses within each reporting period.
[2] Based on a proportional odds model with covariates: treatment group, baseline prednisolone/prednisone daily dose, baseline BVAS score and region (defined as EU vs RoW). An odds ratio <1 represents a benefit of mepolizumab compared to placebo.

PPD

Population: Intent-to-Treat

Table 2.85
Analysis of Sino-Nasal Questionnaire Data at Week 49-52 by Gender

Symptom: Loss/Reduction of Taste/Smell
Gender: Male

		Placebo (N=68)	Mepolizumab 300 mg SC (N=68)
Number of subjects in subgroup		30	26
Severity of symptom [1]	n	24	15
	None	5 (21%)	6 (40%)
	Mild	5 (21%)	5 (33%)
	Moderate	6 (25%)	1 (7%)
	Severe	4 (17%)	2 (13%)
	Very severe	4 (17%)	1 (7%)
Comparison: Placebo/ Mepolizumab [2]			
Inverse odds ratio			0.33
95% Confidence Interval			(0.09,1.17)
p-value			0.085

[1] Questionnaire was administered every week. Values summarised are the highest (i.e. worst) responses within each reporting period.
[2] Based on a proportional odds model with covariates: treatment group, baseline prednisolone/prednisone daily dose, baseline BVAS score and region (defined as EU vs RoW). An odds ratio <1 represents a benefit of mepolizumab compared to placebo.

PPD

Population: Intent-to-Treat

Table 2.85
Analysis of Sino-Nasal Questionnaire Data at Week 49-52 by Gender

Symptom: Post-nasal Discharge
Gender: Female

		Placebo (N=68)	Mepolizumab 300 mg SC (N=68)
Number of subjects in subgroup		38	42
Severity of symptom [1]	n	23	34
	None	3 (13%)	12 (35%)
	Mild	5 (22%)	12 (35%)
	Moderate	10 (43%)	6 (18%)
	Severe	5 (22%)	4 (12%)
	Very severe	0	0
Comparison: Placebo/ Mepolizumab [2]			
Inverse odds ratio			0.33
95% Confidence Interval			(0.12,0.92)
p-value			0.034

[1] Questionnaire was administered every week. Values summarised are the highest (i.e. worst) responses within each reporting period.
[2] Based on a proportional odds model with covariates: treatment group, baseline prednisolone/prednisone daily dose, baseline BVAS score and region (defined as EU vs RoW). An odds ratio <1 represents a benefit of mepolizumab compared to placebo.

PPD

Population: Intent-to-Treat

Table 2.85
Analysis of Sino-Nasal Questionnaire Data at Week 49-52 by Gender

Symptom: Post-nasal Discharge
Gender: Male

		Placebo (N=68)	Mepolizumab 300 mg SC (N=68)
Number of subjects in subgroup		30	26
Severity of symptom [1]	n	24	15
	None	5 (21%)	6 (40%)
	Mild	6 (25%)	6 (40%)
	Moderate	7 (29%)	3 (20%)
	Severe	4 (17%)	0
	Very severe	2 (8%)	0
Comparison: Placebo/ Mepolizumab [2]			
Inverse odds ratio			0.33
95% Confidence Interval			(0.10,1.17)
p-value			0.086

[1] Questionnaire was administered every week. Values summarised are the highest (i.e. worst) responses within each reporting period.
[2] Based on a proportional odds model with covariates: treatment group, baseline prednisolone/prednisone daily dose, baseline BVAS score and region (defined as EU vs RoW). An odds ratio <1 represents a benefit of mepolizumab compared to placebo.

PPD

Protocol: MEA115921
Population: Intent-to-Treat

Table 2.85
Analysis of Sino-Nasal Questionnaire Data at Week 49-52 by Gender

Symptom: Runny Nose
Gender: Female

		Placebo (N=68)	Mepolizumab 300 mg SC (N=68)
Number of subjects in subgroup		38	42
Severity of symptom [1]	n	23	34
	None	5 (22%)	16 (47%)
	Mild	7 (30%)	8 (24%)
	Moderate	10 (43%)	8 (24%)
	Severe	1 (4%)	2 (6%)
	Very severe	0	0
Comparison: Placebo/ Mepolizumab [2]			
Inverse odds ratio			0.43
95% Confidence Interval			(0.15,1.20)
p-value			0.105

[1] Questionnaire was administered every week. Values summarised are the highest (i.e. worst) responses within each reporting period.
[2] Based on a proportional odds model with covariates: treatment group, baseline prednisolone/prednisone daily dose, baseline BVAS score and region (defined as EU vs RoW). An odds ratio <1 represents a benefit of mepolizumab compared to placebo.

PPD

Table 2.85
Analysis of Sino-Nasal Questionnaire Data at Week 49-52 by Gender

Symptom: Runny Nose
Gender: Male

		Placebo (N=68)	Mepolizumab 300 mg SC (N=68)
Number of subjects in subgroup		30	26
Severity of symptom [1]	n	24	15
	None	4 (17%)	3 (20%)
	Mild	10 (42%)	8 (53%)
	Moderate	3 (13%)	4 (27%)
	Severe	5 (21%)	0
	Very severe	2 (8%)	0
Comparison: Placebo/ Mepolizumab [2]			
Inverse odds ratio			0.54
95% Confidence Interval			(0.15,1.89)
p-value			0.333

[1] Questionnaire was administered every week. Values summarised are the highest (i.e. worst) responses within each reporting period.
[2] Based on a proportional odds model with covariates: treatment group, baseline prednisolone/prednisone daily dose, baseline BVAS score and region (defined as EU vs RoW). An odds ratio <1 represents a benefit of mepolizumab compared to placebo.

PPD

Protocol: MEA115921
Population: Intent-to-Treat

Table 2.86
Analysis of Sino-Nasal Questionnaire Data at Week 49-52 by Region

Symptom: Blockage/Congestion of Nose
Region: Europe

		Placebo (N=68)	Mepolizumab 300 mg SC (N=68)
Number of subjects in subgroup		33	32
Severity of symptom [1]	n	29	28
	None	0	3 (11%)
	Mild	6 (21%)	9 (32%)
	Moderate	13 (45%)	7 (25%)
	Severe	7 (24%)	8 (29%)
	Very severe	3 (10%)	1 (4%)
Comparison: Placebo/ Mepolizumab [2]			
Inverse odds ratio			0.48
95% Confidence Interval			(0.18,1.30)
p-value			0.150

[1] Questionnaire was administered every week. Values summarised are the highest (i.e. worst) responses within each reporting period.
[2] Based on a proportional odds model with covariates: treatment group, baseline prednisolone/prednisone daily dose and baseline BVAS score. An odds ratio <1 represents a benefit of mepolizumab compared to placebo.

PPD

Protocol: MEA115921
Population: Intent-to-Treat

Table 2.86
Analysis of Sino-Nasal Questionnaire Data at Week 49-52 by Region

Symptom: Blockage/Congestion of Nose
Region: Rest of World

		Placebo (N=68)	Mepolizumab 300 mg SC (N=68)
Number of subjects in subgroup		35	36
Severity of symptom [1]	n	18	21
	None	7 (39%)	5 (24%)
	Mild	4 (22%)	10 (48%)
	Moderate	4 (22%)	3 (14%)
	Severe	3 (17%)	3 (14%)
	Very severe	0	0
Comparison: Placebo/ Mepolizumab [2]			
Inverse odds ratio			1.26
95% Confidence Interval			(0.39,4.07)
p-value			0.695

[1] Questionnaire was administered every week. Values summarised are the highest (i.e. worst) responses within each reporting period.
[2] Based on a proportional odds model with covariates: treatment group, baseline prednisolone/prednisone daily dose and baseline BVAS score. An odds ratio <1 represents a benefit of mepolizumab compared to placebo.

PPD

Table 2.86
Analysis of Sino-Nasal Questionnaire Data at Week 49-52 by Region

Symptom: Facial Pain/Pressure
Region: Europe

		Placebo (N=68)	Mepolizumab 300 mg SC (N=68)
Number of subjects in subgroup		33	32
Severity of symptom [1]	n	29	28
	None	9 (31%)	17 (61%)
	Mild	4 (14%)	5 (18%)
	Moderate	7 (24%)	3 (11%)
	Severe	9 (31%)	3 (11%)
	Very severe	0	0
Comparison: Placebo/ Mepolizumab [2]			
Inverse odds ratio			0.24
95% Confidence Interval			(0.08,0.69)
p-value			0.008

[1] Questionnaire was administered every week. Values summarised are the highest (i.e. worst) responses within each reporting period.
[2] Based on a proportional odds model with covariates: treatment group, baseline prednisolone/prednisone daily dose and baseline BVAS score. An odds ratio <1 represents a benefit of mepolizumab compared to placebo.

PPD

Population: Intent-to-Treat

Table 2.86
Analysis of Sino-Nasal Questionnaire Data at Week 49-52 by Region

Symptom: Facial Pain/Pressure
Region: Rest of World

		Placebo (N=68)	Mepolizumab 300 mg SC (N=68)
Number of subjects in subgroup		35	36
Severity of symptom [1]	n	18	21
	None	11 (61%)	10 (48%)
	Mild	4 (22%)	6 (29%)
	Moderate	2 (11%)	3 (14%)
	Severe	1 (6%)	2 (10%)
	Very severe	0	0
Comparison: Placebo/ Mepolizumab [2]			
Inverse odds ratio			1.64
95% Confidence Interval			(0.47,5.72)
p-value			0.436

[1] Questionnaire was administered every week. Values summarised are the highest (i.e. worst) responses within each reporting period.
[2] Based on a proportional odds model with covariates: treatment group, baseline prednisolone/prednisone daily dose and baseline BVAS score. An odds ratio <1 represents a benefit of mepolizumab compared to placebo.

PPD

Population: Intent-to-Treat

Table 2.86
Analysis of Sino-Nasal Questionnaire Data at Week 49-52 by Region

Symptom: Loss/Reduction of Taste/Smell
Region: Europe

		Placebo (N=68)	Mepolizumab 300 mg SC (N=68)
Number of subjects in subgroup		33	32
Severity of symptom [1]	n	29	28
	None	3 (10%)	5 (18%)
	Mild	7 (24%)	11 (39%)
	Moderate	9 (31%)	4 (14%)
	Severe	4 (14%)	7 (25%)
	Very severe	6 (21%)	1 (4%)
Comparison: Placebo/ Mepolizumab [2]			
Inverse odds ratio			0.43
95% Confidence Interval			(0.16,1.15)
p-value			0.093

[1] Questionnaire was administered every week. Values summarised are the highest (i.e. worst) responses within each reporting period.
[2] Based on a proportional odds model with covariates: treatment group, baseline prednisolone/prednisone daily dose and baseline BVAS score. An odds ratio <1 represents a benefit of mepolizumab compared to placebo.

PPD

Population: Intent-to-Treat

Table 2.86
Analysis of Sino-Nasal Questionnaire Data at Week 49-52 by Region

Symptom: Loss/Reduction of Taste/Smell
Region: Rest of World

		Placebo (N=68)	Mepolizumab 300 mg SC (N=68)
Number of subjects in subgroup		35	36
Severity of symptom [1]	n	18	21
	None	5 (28%)	11 (52%)
	Mild	5 (28%)	6 (29%)
	Moderate	4 (22%)	1 (5%)
	Severe	2 (11%)	2 (10%)
	Very severe	2 (11%)	1 (5%)
Comparison: Placebo/ Mepolizumab [2]			
Inverse odds ratio			0.38
95% Confidence Interval			(0.11,1.26)
p-value			0.114

[1] Questionnaire was administered every week. Values summarised are the highest (i.e. worst) responses within each reporting period.
[2] Based on a proportional odds model with covariates: treatment group, baseline prednisolone/prednisone daily dose and baseline BVAS score. An odds ratio <1 represents a benefit of mepolizumab compared to placebo.

PPD

Protocol: MEA115921
Population: Intent-to-Treat

Table 2.86
Analysis of Sino-Nasal Questionnaire Data at Week 49-52 by Region

Symptom: Post-nasal Discharge
Region: Europe

		Placebo (N=68)	Mepolizumab 300 mg SC (N=68)
Number of subjects in subgroup		33	32
Severity of symptom [1]	n	29	28
	None	2 (7%)	11 (39%)
	Mild	5 (17%)	9 (32%)
	Moderate	13 (45%)	7 (25%)
	Severe	7 (24%)	1 (4%)
	Very severe	2 (7%)	0
Comparison: Placebo/ Mepolizumab [2]			
Inverse odds ratio			0.11
95% Confidence Interval			(0.04,0.35)
p-value			<0.001

[1] Questionnaire was administered every week. Values summarised are the highest (i.e. worst) responses within each reporting period.
[2] Based on a proportional odds model with covariates: treatment group, baseline prednisolone/prednisone daily dose and baseline BVAS score. An odds ratio <1 represents a benefit of mepolizumab compared to placebo.

PPD

Protocol: MEA115921
Population: Intent-to-Treat

Table 2.86
Analysis of Sino-Nasal Questionnaire Data at Week 49-52 by Region

Symptom: Post-nasal Discharge
Region: Rest of World

		Placebo (N=68)	Mepolizumab 300 mg SC (N=68)
Number of subjects in subgroup		35	36
Severity of symptom [1]	n	18	21
	None	6 (33%)	7 (33%)
	Mild	6 (33%)	9 (43%)
	Moderate	4 (22%)	2 (10%)
	Severe	2 (11%)	3 (14%)
	Very severe	0	0
Comparison: Placebo/ Mepolizumab [2]			
Inverse odds ratio			0.85
95% Confidence Interval			(0.26,2.78)
p-value			0.793

[1] Questionnaire was administered every week. Values summarised are the highest (i.e. worst) responses within each reporting period.
[2] Based on a proportional odds model with covariates: treatment group, baseline prednisolone/prednisone daily dose and baseline BVAS score. An odds ratio <1 represents a benefit of mepolizumab compared to placebo.

PPD

Protocol: MEA115921
Population: Intent-to-Treat

Table 2.86
Analysis of Sino-Nasal Questionnaire Data at Week 49-52 by Region

Symptom: Runny Nose
Region: Europe

		Placebo (N=68)	Mepolizumab 300 mg SC (N=68)
Number of subjects in subgroup		33	32
Severity of symptom [1]	n	29	28
	None	1 (3%)	8 (29%)
	Mild	12 (41%)	11 (39%)
	Moderate	9 (31%)	8 (29%)
	Severe	5 (17%)	1 (4%)
	Very severe	2 (7%)	0
Comparison: Placebo/ Mepolizumab [2]			
Inverse odds ratio			0.23
95% Confidence Interval			(0.08,0.67)
p-value			0.007

[1] Questionnaire was administered every week. Values summarised are the highest (i.e. worst) responses within each reporting period.
[2] Based on a proportional odds model with covariates: treatment group, baseline prednisolone/prednisone daily dose and baseline BVAS score. An odds ratio <1 represents a benefit of mepolizumab compared to placebo.

PPD

Table 2.86
Analysis of Sino-Nasal Questionnaire Data at Week 49-52 by Region

Symptom: Runny Nose
Region: Rest of World

		Placebo (N=68)	Mepolizumab 300 mg SC (N=68)
Number of subjects in subgroup		35	36
Severity of symptom [1]	n	18	21
	None	8 (44%)	11 (52%)
	Mild	5 (28%)	5 (24%)
	Moderate	4 (22%)	4 (19%)
	Severe	1 (6%)	1 (5%)
	Very severe	0	0
Comparison: Placebo/ Mepolizumab [2]			
Inverse odds ratio			0.69
95% Confidence Interval			(0.20,2.31)
p-value			0.543

[1] Questionnaire was administered every week. Values summarised are the highest (i.e. worst) responses within each reporting period.
[2] Based on a proportional odds model with covariates: treatment group, baseline prednisolone/prednisone daily dose and baseline BVAS score. An odds ratio <1 represents a benefit of mepolizumab compared to placebo.

PPD

Protocol: MEA115921
Population: Intent-to-Treat

Table 2.87
Analysis of Sino-Nasal Questionnaire Data at Week 49-52 by Baseline Eosinophil Count

Symptom: Blockage/Congestion of Nose
Baseline blood eosinophils: <0.150 GI/L

		Placebo (N=68)	Mepolizumab 300 mg SC (N=68)
Number of subjects in subgroup		28	29
Severity of symptom [1]	n	16	23
	None	3 (19%)	6 (26%)
	Mild	4 (25%)	8 (35%)
	Moderate	4 (25%)	6 (26%)
	Severe	4 (25%)	2 (9%)
	Very severe	1 (6%)	1 (4%)
Comparison: Placebo/ Mepolizumab [2]			
Inverse odds ratio			0.69
95% Confidence Interval			(0.20,2.35)
p-value			0.551

[1] Questionnaire was administered every week. Values summarised are the highest (i.e. worst) responses within each reporting period.
[2] Based on a proportional odds model with covariates: treatment group, baseline prednisolone/prednisone daily dose, baseline BVAS score and region (defined as EU vs RoW). An odds ratio <1 represents a benefit of mepolizumab compared to placebo.

PPD

Population: Intent-to-Treat

Table 2.87
Analysis of Sino-Nasal Questionnaire Data at Week 49-52 by Baseline Eosinophil Count

Symptom: Blockage/Congestion of Nose
Baseline blood eosinophils: >=0.150 GI/L

		Placebo (N=68)	Mepolizumab 300 mg SC (N=68)
Number of subjects in subgroup		40	39
Severity of symptom [1]	n	31	26
	None	4 (13%)	2 (8%)
	Mild	6 (19%)	11 (42%)
	Moderate	13 (42%)	4 (15%)
	Severe	6 (19%)	9 (35%)
	Very severe	2 (6%)	0
Comparison: Placebo/ Mepolizumab [2]			
Inverse odds ratio			0.92
95% Confidence Interval			(0.36,2.38)
p-value			0.867

[1] Questionnaire was administered every week. Values summarised are the highest (i.e. worst) responses within each reporting period.
[2] Based on a proportional odds model with covariates: treatment group, baseline prednisolone/prednisone daily dose, baseline BVAS score and region (defined as EU vs RoW). An odds ratio <1 represents a benefit of mepolizumab compared to placebo.

PPD

Population: Intent-to-Treat

Table 2.87
Analysis of Sino-Nasal Questionnaire Data at Week 49-52 by Baseline Eosinophil Count

Symptom: Facial Pain/Pressure
Baseline blood eosinophils: <0.150 GI/L

		Placebo (N=68)	Mepolizumab 300 mg SC (N=68)
Number of subjects in subgroup		28	29
Severity of symptom [1]	n	16	23
	None	9 (56%)	13 (57%)
	Mild	1 (6%)	6 (26%)
	Moderate	3 (19%)	2 (9%)
	Severe	3 (19%)	2 (9%)
	Very severe	0	0
Comparison: Placebo/ Mepolizumab [2]			
Inverse odds ratio			0.82
95% Confidence Interval			(0.21,3.19)
p-value			0.773

[1] Questionnaire was administered every week. Values summarised are the highest (i.e. worst) responses within each reporting period.
[2] Based on a proportional odds model with covariates: treatment group, baseline prednisolone/prednisone daily dose, baseline BVAS score and region (defined as EU vs RoW). An odds ratio <1 represents a benefit of mepolizumab compared to placebo.

PPD

Population: Intent-to-Treat

Table 2.87
Analysis of Sino-Nasal Questionnaire Data at Week 49-52 by Baseline Eosinophil Count

Symptom: Facial Pain/Pressure
Baseline blood eosinophils: >=0.150 GI/L

		Placebo (N=68)	Mepolizumab 300 mg SC (N=68)
Number of subjects in subgroup		40	39
Severity of symptom [1]	n	31	26
	None	11 (35%)	14 (54%)
	Mild	7 (23%)	5 (19%)
	Moderate	6 (19%)	4 (15%)
	Severe	7 (23%)	3 (12%)
	Very severe	0	0
Comparison: Placebo/ Mepolizumab [2]			
Inverse odds ratio			0.49
95% Confidence Interval			(0.18,1.31)
p-value			0.154

[1] Questionnaire was administered every week. Values summarised are the highest (i.e. worst) responses within each reporting period.
[2] Based on a proportional odds model with covariates: treatment group, baseline prednisolone/prednisone daily dose, baseline BVAS score and region (defined as EU vs RoW). An odds ratio <1 represents a benefit of mepolizumab compared to placebo.

PPD

Population: Intent-to-Treat

Table 2.87
Analysis of Sino-Nasal Questionnaire Data at Week 49-52 by Baseline Eosinophil Count

Symptom: Loss/Reduction of Taste/Smell
Baseline blood eosinophils: <0.150 GI/L

		Placebo (N=68)	Mepolizumab 300 mg SC (N=68)
Number of subjects in subgroup		28	29
Severity of symptom [1]	n	16	23
	None	6 (38%)	11 (48%)
	Mild	3 (19%)	7 (30%)
	Moderate	3 (19%)	3 (13%)
	Severe	2 (13%)	2 (9%)
	Very severe	2 (13%)	0
Comparison: Placebo/ Mepolizumab [2]			
Inverse odds ratio			0.44
95% Confidence Interval			(0.12,1.60)
p-value			0.214

[1] Questionnaire was administered every week. Values summarised are the highest (i.e. worst) responses within each reporting period.
[2] Based on a proportional odds model with covariates: treatment group, baseline prednisolone/prednisone daily dose, baseline BVAS score and region (defined as EU vs RoW). An odds ratio <1 represents a benefit of mepolizumab compared to placebo.

PPD

Population: Intent-to-Treat

Table 2.87
Analysis of Sino-Nasal Questionnaire Data at Week 49-52 by Baseline Eosinophil Count

Symptom: Loss/Reduction of Taste/Smell
Baseline blood eosinophils: >=0.150 GI/L

		Placebo (N=68)	Mepolizumab 300 mg SC (N=68)
Number of subjects in subgroup		40	39
Severity of symptom [1]	n	31	26
	None	2 (6%)	5 (19%)
	Mild	9 (29%)	10 (38%)
	Moderate	10 (32%)	2 (8%)
	Severe	4 (13%)	7 (27%)
	Very severe	6 (19%)	2 (8%)
Comparison: Placebo/ Mepolizumab [2]			
Inverse odds ratio			0.51
95% Confidence Interval			(0.19,1.32)
p-value			0.162

[1] Questionnaire was administered every week. Values summarised are the highest (i.e. worst) responses within each reporting period.
[2] Based on a proportional odds model with covariates: treatment group, baseline prednisolone/prednisone daily dose, baseline BVAS score and region (defined as EU vs RoW). An odds ratio <1 represents a benefit of mepolizumab compared to placebo.

PPD

Population: Intent-to-Treat

Table 2.87
Analysis of Sino-Nasal Questionnaire Data at Week 49-52 by Baseline Eosinophil Count

Symptom: Post-nasal Discharge
Baseline blood eosinophils: <0.150 GI/L

		Placebo (N=68)	Mepolizumab 300 mg SC (N=68)
Number of subjects in subgroup		28	29
Severity of symptom [1]	n	16	23
	None	3 (19%)	9 (39%)
	Mild	5 (31%)	9 (39%)
	Moderate	5 (31%)	4 (17%)
	Severe	2 (13%)	1 (4%)
	Very severe	1 (6%)	0
Comparison: Placebo/ Mepolizumab [2]			
Inverse odds ratio			0.38
95% Confidence Interval			(0.11,1.32)
p-value			0.128

[1] Questionnaire was administered every week. Values summarised are the highest (i.e. worst) responses within each reporting period.
[2] Based on a proportional odds model with covariates: treatment group, baseline prednisolone/prednisone daily dose, baseline BVAS score and region (defined as EU vs RoW). An odds ratio <1 represents a benefit of mepolizumab compared to placebo.

PPD

Population: Intent-to-Treat

Table 2.87
Analysis of Sino-Nasal Questionnaire Data at Week 49-52 by Baseline Eosinophil Count

Symptom: Post-nasal Discharge
Baseline blood eosinophils: >=0.150 GI/L

		Placebo (N=68)	Mepolizumab 300 mg SC (N=68)
Number of subjects in subgroup		40	39
Severity of symptom [1]	n	31	26
	None	5 (16%)	9 (35%)
	Mild	6 (19%)	9 (35%)
	Moderate	12 (39%)	5 (19%)
	Severe	7 (23%)	3 (12%)
	Very severe	1 (3%)	0
Comparison: Placebo/ Mepolizumab [2]			
Inverse odds ratio			0.31
95% Confidence Interval			(0.11,0.82)
p-value			0.019

[1] Questionnaire was administered every week. Values summarised are the highest (i.e. worst) responses within each reporting period.
[2] Based on a proportional odds model with covariates: treatment group, baseline prednisolone/prednisone daily dose, baseline BVAS score and region (defined as EU vs RoW). An odds ratio <1 represents a benefit of mepolizumab compared to placebo.

PPD

Population: Intent-to-Treat

Table 2.87
Analysis of Sino-Nasal Questionnaire Data at Week 49-52 by Baseline Eosinophil Count

Symptom: Runny Nose
Baseline blood eosinophils: <0.150 GI/L

		Placebo (N=68)	Mepolizumab 300 mg SC (N=68)
Number of subjects in subgroup		28	29
Severity of symptom [1]	n	16	23
	None	3 (19%)	12 (52%)
	Mild	9 (56%)	5 (22%)
	Moderate	1 (6%)	6 (26%)
	Severe	2 (13%)	0
	Very severe	1 (6%)	0
Comparison: Placebo/ Mepolizumab [2]			
Inverse odds ratio			0.54
95% Confidence Interval			(0.15,1.92)
p-value			0.339

[1] Questionnaire was administered every week. Values summarised are the highest (i.e. worst) responses within each reporting period.
[2] Based on a proportional odds model with covariates: treatment group, baseline prednisolone/prednisone daily dose, baseline BVAS score and region (defined as EU vs RoW). An odds ratio <1 represents a benefit of mepolizumab compared to placebo.

PPD

Population: Intent-to-Treat

Table 2.87
Analysis of Sino-Nasal Questionnaire Data at Week 49-52 by Baseline Eosinophil Count

Symptom: Runny Nose
Baseline blood eosinophils: >=0.150 GI/L

		Placebo (N=68)	Mepolizumab 300 mg SC (N=68)
Number of subjects in subgroup		40	39
Severity of symptom [1]	n	31	26
	None	6 (19%)	7 (27%)
	Mild	8 (26%)	11 (42%)
	Moderate	12 (39%)	6 (23%)
	Severe	4 (13%)	2 (8%)
	Very severe	1 (3%)	0
Comparison: Placebo/ Mepolizumab [2]			
Inverse odds ratio			0.43
95% Confidence Interval			(0.16,1.13)
p-value			0.087

[1] Questionnaire was administered every week. Values summarised are the highest (i.e. worst) responses within each reporting period.
[2] Based on a proportional odds model with covariates: treatment group, baseline prednisolone/prednisone daily dose, baseline BVAS score and region (defined as EU vs RoW). An odds ratio <1 represents a benefit of mepolizumab compared to placebo.

PPD

Protocol: MEA115921
Population: Intent-to-Treat

Table 2.88
Analysis of Sino-Nasal Questionnaire Data at Week 49-52 by Duration of Disease

Symptom: Blockage/Congestion of Nose
Duration of disease: <=4 years

		Placebo (N=68)	Mepolizumab 300 mg SC (N=68)
Number of subjects in subgroup		32	34
Severity of symptom [1]	n	22	24
	None	3 (14%)	2 (8%)
	Mild	4 (18%)	12 (50%)
	Moderate	9 (41%)	6 (25%)
	Severe	5 (23%)	4 (17%)
	Very severe	1 (5%)	0
Comparison: Placebo/ Mepolizumab [2]			
Inverse odds ratio			0.56
95% Confidence Interval			(0.18,1.74)
p-value			0.317

[1] Questionnaire was administered every week. Values summarised are the highest (i.e. worst) responses within each reporting period.
[2] Based on a proportional odds model with covariates: treatment group, baseline prednisolone/prednisone daily dose, baseline BVAS score and region (defined as EU vs RoW). An odds ratio <1 represents a benefit of mepolizumab compared to placebo.

PPD

Table 2.88
Analysis of Sino-Nasal Questionnaire Data at Week 49-52 by Duration of Disease

Symptom: Blockage/Congestion of Nose
Duration of disease: >4 years

		Placebo (N=68)	Mepolizumab 300 mg SC (N=68)
Number of subjects in subgroup		36	34
Severity of symptom [1]	n	25	25
	None	4 (16%)	6 (24%)
	Mild	6 (24%)	7 (28%)
	Moderate	8 (32%)	4 (16%)
	Severe	5 (20%)	7 (28%)
	Very severe	2 (8%)	1 (4%)
Comparison: Placebo/ Mepolizumab [2]			
Inverse odds ratio			1.08
95% Confidence Interval			(0.39,3.05)
p-value			0.879

[1] Questionnaire was administered every week. Values summarised are the highest (i.e. worst) responses within each reporting period.
[2] Based on a proportional odds model with covariates: treatment group, baseline prednisolone/prednisone daily dose, baseline BVAS score and region (defined as EU vs RoW). An odds ratio <1 represents a benefit of mepolizumab compared to placebo.

PPD

Population: Intent-to-Treat

Table 2.88
Analysis of Sino-Nasal Questionnaire Data at Week 49-52 by Duration of Disease

Symptom: Facial Pain/Pressure
Duration of disease: <=4 years

		Placebo (N=68)	Mepolizumab 300 mg SC (N=68)
Number of subjects in subgroup		32	34
Severity of symptom [1]	n	22	24
	None	8 (36%)	15 (63%)
	Mild	5 (23%)	6 (25%)
	Moderate	3 (14%)	2 (8%)
	Severe	6 (27%)	1 (4%)
	Very severe	0	0
Comparison: Placebo/ Mepolizumab [2]			
Inverse odds ratio			0.26
95% Confidence Interval			(0.08,0.87)
p-value			0.029

[1] Questionnaire was administered every week. Values summarised are the highest (i.e. worst) responses within each reporting period.
[2] Based on a proportional odds model with covariates: treatment group, baseline prednisolone/prednisone daily dose, baseline BVAS score and region (defined as EU vs RoW). An odds ratio <1 represents a benefit of mepolizumab compared to placebo.

PPD

Population: Intent-to-Treat

Table 2.88
Analysis of Sino-Nasal Questionnaire Data at Week 49-52 by Duration of Disease

Symptom: Facial Pain/Pressure
Duration of disease: >4 years

		Placebo (N=68)	Mepolizumab 300 mg SC (N=68)
Number of subjects in subgroup		36	34
Severity of symptom [1]	n	25	25
	None	12 (48%)	12 (48%)
	Mild	3 (12%)	5 (20%)
	Moderate	6 (24%)	4 (16%)
	Severe	4 (16%)	4 (16%)
	Very severe	0	0
Comparison: Placebo/ Mepolizumab [2]			
Inverse odds ratio			1.00
95% Confidence Interval			(0.34,2.92)
p-value			1.000

[1] Questionnaire was administered every week. Values summarised are the highest (i.e. worst) responses within each reporting period.
[2] Based on a proportional odds model with covariates: treatment group, baseline prednisolone/prednisone daily dose, baseline BVAS score and region (defined as EU vs RoW). An odds ratio <1 represents a benefit of mepolizumab compared to placebo.

PPD

Population: Intent-to-Treat

Table 2.88
Analysis of Sino-Nasal Questionnaire Data at Week 49-52 by Duration of Disease

Symptom: Loss/Reduction of Taste/Smell
Duration of disease: <=4 years

		Placebo (N=68)	Mepolizumab 300 mg SC (N=68)
Number of subjects in subgroup		32	34
Severity of symptom [1]	n	22	24
	None	2 (9%)	10 (42%)
	Mild	6 (27%)	9 (38%)
	Moderate	4 (18%)	1 (4%)
	Severe	4 (18%)	4 (17%)
	Very severe	6 (27%)	0
Comparison: Placebo/ Mepolizumab [2]			
Inverse odds ratio			0.09
95% Confidence Interval			(0.02,0.33)
p-value			<0.001

[1] Questionnaire was administered every week. Values summarised are the highest (i.e. worst) responses within each reporting period.
[2] Based on a proportional odds model with covariates: treatment group, baseline prednisolone/prednisone daily dose, baseline BVAS score and region (defined as EU vs RoW). An odds ratio <1 represents a benefit of mepolizumab compared to placebo.

PPD

Protocol: MEA115921
Population: Intent-to-Treat

Table 2.88
Analysis of Sino-Nasal Questionnaire Data at Week 49-52 by Duration of Disease

Symptom: Loss/Reduction of Taste/Smell
Duration of disease: >4 years

		Placebo (N=68)	Mepolizumab 300 mg SC (N=68)
Number of subjects in subgroup		36	34
Severity of symptom [1]	n	25	25
	None	6 (24%)	6 (24%)
	Mild	6 (24%)	8 (32%)
	Moderate	9 (36%)	4 (16%)
	Severe	2 (8%)	5 (20%)
	Very severe	2 (8%)	2 (8%)
Comparison: Placebo/ Mepolizumab [2]			
Inverse odds ratio			1.10
95% Confidence Interval			(0.39,3.08)
p-value			0.853

[1] Questionnaire was administered every week. Values summarised are the highest (i.e. worst) responses within each reporting period.
[2] Based on a proportional odds model with covariates: treatment group, baseline prednisolone/prednisone daily dose, baseline BVAS score and region (defined as EU vs RoW). An odds ratio <1 represents a benefit of mepolizumab compared to placebo.

PPD

Protocol: MEA115921
Population: Intent-to-Treat

Table 2.88
Analysis of Sino-Nasal Questionnaire Data at Week 49-52 by Duration of Disease

Symptom: Post-nasal Discharge
Duration of disease: <=4 years

		Placebo (N=68)	Mepolizumab 300 mg SC (N=68)
Number of subjects in subgroup		32	34
Severity of symptom [1]	n	22	24
	None	5 (23%)	10 (42%)
	Mild	5 (23%)	9 (38%)
	Moderate	8 (36%)	5 (21%)
	Severe	4 (18%)	0
	Very severe	0	0
Comparison: Placebo/ Mepolizumab [2]			
Inverse odds ratio			0.34
95% Confidence Interval			(0.11,1.07)
p-value			0.065

[1] Questionnaire was administered every week. Values summarised are the highest (i.e. worst) responses within each reporting period.
[2] Based on a proportional odds model with covariates: treatment group, baseline prednisolone/prednisone daily dose, baseline BVAS score and region (defined as EU vs RoW). An odds ratio <1 represents a benefit of mepolizumab compared to placebo.

PPD

Protocol: MEA115921
Population: Intent-to-Treat

Table 2.88
Analysis of Sino-Nasal Questionnaire Data at Week 49-52 by Duration of Disease

Symptom: Post-nasal Discharge
Duration of disease: >4 years

		Placebo (N=68)	Mepolizumab 300 mg SC (N=68)
Number of subjects in subgroup		36	34
Severity of symptom [1]	n	25	25
	None	3 (12%)	8 (32%)
	Mild	6 (24%)	9 (36%)
	Moderate	9 (36%)	4 (16%)
	Severe	5 (20%)	4 (16%)
	Very severe	2 (8%)	0
Comparison: Placebo/ Mepolizumab [2]			
Inverse odds ratio			0.38
95% Confidence Interval			(0.13,1.09)
p-value			0.071

[1] Questionnaire was administered every week. Values summarised are the highest (i.e. worst) responses within each reporting period.
[2] Based on a proportional odds model with covariates: treatment group, baseline prednisolone/prednisone daily dose, baseline BVAS score and region (defined as EU vs RoW). An odds ratio <1 represents a benefit of mepolizumab compared to placebo.

PPD

Population: Intent-to-Treat

Table 2.88
Analysis of Sino-Nasal Questionnaire Data at Week 49-52 by Duration of Disease

Symptom: Runny Nose
Duration of disease: <=4 years

		Placebo (N=68)	Mepolizumab 300 mg SC (N=68)
Number of subjects in subgroup		32	34
Severity of symptom [1]	n	22	24
	None	3 (14%)	11 (46%)
	Mild	8 (36%)	8 (33%)
	Moderate	7 (32%)	5 (21%)
	Severe	3 (14%)	0
	Very severe	1 (5%)	0
Comparison: Placebo/ Mepolizumab [2]			
Inverse odds ratio			0.18
95% Confidence Interval			(0.05,0.62)
p-value			0.007

[1] Questionnaire was administered every week. Values summarised are the highest (i.e. worst) responses within each reporting period.
[2] Based on a proportional odds model with covariates: treatment group, baseline prednisolone/prednisone daily dose, baseline BVAS score and region (defined as EU vs RoW). An odds ratio <1 represents a benefit of mepolizumab compared to placebo.

PPD

Population: Intent-to-Treat

Table 2.88
Analysis of Sino-Nasal Questionnaire Data at Week 49-52 by Duration of Disease

Symptom: Runny Nose
Duration of disease: >4 years

		Placebo (N=68)	Mepolizumab 300 mg SC (N=68)
Number of subjects in subgroup		36	34
Severity of symptom [1]	n	25	25
	None	6 (24%)	8 (32%)
	Mild	9 (36%)	8 (32%)
	Moderate	6 (24%)	7 (28%)
	Severe	3 (12%)	2 (8%)
	Very severe	1 (4%)	0
Comparison: Placebo/ Mepolizumab [2]			
Inverse odds ratio			0.94
95% Confidence Interval			(0.33,2.69)
p-value			0.907

[1] Questionnaire was administered every week. Values summarised are the highest (i.e. worst) responses within each reporting period.
[2] Based on a proportional odds model with covariates: treatment group, baseline prednisolone/prednisone daily dose, baseline BVAS score and region (defined as EU vs RoW). An odds ratio <1 represents a benefit of mepolizumab compared to placebo.

PPD

Protocol: MEA115921
Population: Intent-to-Treat

Table 7.20
Analysis of SF-36 Physical Component Score Responders (Minimal Important Difference, Change >= 5) at Week 52 by Age

Age: <50 Years

	Placebo (N=68)	Mepolizumab 300 mg SC (N=68)
n	33	30
Responder	8 (24%)	9 (30%)
Non-Responder	25 (76%)	21 (70%)
Missing response	3 (9%)	2 (7%)
Comparison Mepolizumab 300 mg vs Placebo [1]		
Logistic regression [2]		
Inverse odds ratio (95% CI)		0.79 (0.19,3.37)
p-value		0.755
Inverse unadjusted odds ratio (95% CI) [3]		0.75 (0.21,2.63)
Inverse relative risk (95% CI) [4]		0.81 (0.31,1.89)
Risk difference (95% CI) [4]		-0.06 (-0.28,0.17)
Fisher's Exact p-value (2-sided)		0.777

[1] Analysis compares the number of responders. Subjects with missing response are categorised as non-responders.
[2] Logistic regression analysis adjusted for baseline SF-36, baseline prednisolone/prednisone daily dose, baseline BVAS score and region (EU vs. RoW).
[3] Exact method. [4] Exact unconditional CI calculated by inverting two separate one-sided tests based on the score statistic.
Note: Inverse odds ratio and inverse relative risk <1 and risk difference <0 indicate benefit for Mepolizumab over Placebo.
Note: 1 Mepolizumab subject with missing baseline score is excluded from the analysis.

PPD

Protocol: MEA115921
Population: Intent-to-Treat

Table 7.20
Analysis of SF-36 Physical Component Score Responders (Minimal Important Difference, Change >= 5) at Week 52 by Age

Age: >=50 Years

	Placebo (N=68)	Mepolizumab 300 mg SC (N=68)
n	35	37
Responder	9 (26%)	9 (24%)
Non-Responder	26 (74%)	28 (76%)
Missing response	4 (11%)	2 (5%)
Comparison Mepolizumab 300 mg vs Placebo [1]		
Logistic regression [2]		
Inverse odds ratio (95% CI)		1.21 (0.39,3.80)
p-value		0.744
Inverse unadjusted odds ratio (95% CI) [3]		1.08 (0.32,3.60)
Inverse relative risk (95% CI) [4]		1.06 (0.43,2.60)
Risk difference (95% CI) [4]		0.01 (-0.19,0.22)
Fisher's Exact p-value (2-sided)		1.000

[1] Analysis compares the number of responders. Subjects with missing response are categorised as non-responders.
[2] Logistic regression analysis adjusted for baseline SF-36, baseline prednisolone/prednisone daily dose, baseline BVAS score and region (EU vs. RoW).
[3] Exact method. [4] Exact unconditional CI calculated by inverting two separate one-sided tests based on the score statistic.
Note: Inverse odds ratio and inverse relative risk <1 and risk difference <0 indicate benefit for Mepolizumab over Placebo.
Note: 1 Mepolizumab subject with missing baseline score is excluded from the analysis.

PPD

Protocol: MEA115921
Population: Intent-to-Treat

Table 7.21
Analysis of SF-36 Physical Component Score Responders (Minimal Important Difference, Change >= 5) at Week 52 by Gender

Gender: Female

	Placebo (N=68)	Mepolizumab 300 mg SC (N=68)
n	38	41
Responder	8 (21%)	13 (32%)
Non-Responder	30 (79%)	28 (68%)
Missing response	6 (16%)	2 (5%)
Comparison Mepolizumab 300 mg vs Placebo [1]		
Logistic regression [2]		
Inverse odds ratio (95% CI)		0.72 (0.23,2.27)
p-value		0.576
Inverse unadjusted odds ratio (95% CI) [3]		0.58 (0.18,1.77)
Inverse relative risk (95% CI) [4]		0.66 (0.27,1.43)
Risk difference (95% CI) [4]		-0.11 (-0.30,0.10)
Fisher's Exact p-value (2-sided)		0.318

[1] Analysis compares the number of responders. Subjects with missing response are categorised as non-responders.
[2] Logistic regression analysis adjusted for baseline SF-36, baseline prednisolone/prednisone daily dose, baseline BVAS score and region (EU vs. RoW).
[3] Exact method. [4] Exact unconditional CI calculated by inverting two separate one-sided tests based on the score statistic.
Note: Inverse odds ratio and inverse relative risk <1 and risk difference <0 indicate benefit for Mepolizumab over Placebo.
Note: 1 Mepolizumab subject with missing baseline score is excluded from the analysis.

PPD

Protocol: MEA115921
Population: Intent-to-Treat

Table 7.21
Analysis of SF-36 Physical Component Score Responders (Minimal Important Difference, Change >= 5) at Week 52 by Gender

Gender: Male

	Placebo (N=68)	Mepolizumab 300 mg SC (N=68)
n	30	26
Responder	9 (30%)	5 (19%)
Non-Responder	21 (70%)	21 (81%)
Missing response	1 (3%)	2 (8%)
Comparison Mepolizumab 300 mg vs Placebo [1]		
Logistic regression [2]		
Inverse odds ratio (95% CI)		1.79 (0.45,7.15)
p-value		0.409
Inverse unadjusted odds ratio (95% CI) [3]		1.78 (0.44,7.98)
Inverse relative risk (95% CI) [4]		1.56 (0.59,4.99)
Risk difference (95% CI) [4]		0.11 (-0.13,0.34)
Fisher's Exact p-value (2-sided)		0.537

[1] Analysis compares the number of responders. Subjects with missing response are categorised as non-responders.
[2] Logistic regression analysis adjusted for baseline SF-36, baseline prednisolone/prednisone daily dose, baseline BVAS score and region (EU vs. RoW).
[3] Exact method. [4] Exact unconditional CI calculated by inverting two separate one-sided tests based on the score statistic.
Note: Inverse odds ratio and inverse relative risk <1 and risk difference <0 indicate benefit for Mepolizumab over Placebo.
Note: 1 Mepolizumab subject with missing baseline score is excluded from the analysis.

PPD

Protocol: MEA115921
Population: Intent-to-Treat

Table 7.22
Analysis of SF-36 Physical Component Score Responders (Minimal Important Difference, Change >= 5) at Week 52 by Region

Region: Europe

	Placebo (N=68)	Mepolizumab 300 mg SC (N=68)
n	33	32
Responder	12 (36%)	6 (19%)
Non-Responder	21 (64%)	26 (81%)
Missing response	0	1 (3%)
Comparison Mepolizumab 300 mg vs Placebo [1]		
Logistic regression [2]		
Inverse odds ratio (95% CI)		2.04 (0.57,7.32)
p-value		0.273
Inverse unadjusted odds ratio (95% CI) [3]		2.44 (0.70,9.37)
Inverse relative risk (95% CI) [4]		1.94 (0.84,5.62)
Risk difference (95% CI) [4]		0.18 (-0.05,0.39)
Fisher's Exact p-value (2-sided)		0.166

[1] Analysis compares the number of responders. Subjects with missing response are categorised as non-responders.
[2] Logistic regression analysis adjusted for baseline SF-36, baseline prednisolone/prednisone daily dose and baseline BVAS score.
[3] Exact method. [4] Exact unconditional CI calculated by inverting two separate one-sided tests based on the score statistic.
Note: Inverse odds ratio and inverse relative risk <1 and risk difference <0 indicate benefit for Mepolizumab over Placebo.
Note: 1 Mepolizumab subject with missing baseline score is excluded from the analysis.

PPD

Protocol: MEA115921
Population: Intent-to-Treat

Table 7.22
Analysis of SF-36 Physical Component Score Responders (Minimal Important Difference, Change >= 5) at Week 52 by Region

Region: Rest of World

	Placebo (N=68)	Mepolizumab 300 mg SC (N=68)
n	35	35
Responder	5 (14%)	12 (34%)
Non-Responder	30 (86%)	23 (66%)
Missing response	7 (20%)	3 (9%)
Comparison Mepolizumab 300 mg vs Placebo [1]		
Logistic regression [2]		
Inverse odds ratio (95% CI)		0.36 (0.10,1.31)
p-value		0.121
Inverse unadjusted odds ratio (95% CI) [3]		0.32 (0.08,1.17)
Inverse relative risk (95% CI) [4]		0.42 (0.10,1.04)
Risk difference (95% CI) [4]		-0.20 (-0.40,0.00)
Fisher's Exact p-value (2-sided)		0.093

[1] Analysis compares the number of responders. Subjects with missing response are categorised as non-responders.
[2] Logistic regression analysis adjusted for baseline SF-36, baseline prednisolone/prednisone daily dose and baseline BVAS score.
[3] Exact method. [4] Exact unconditional CI calculated by inverting two separate one-sided tests based on the score statistic.
Note: Inverse odds ratio and inverse relative risk <1 and risk difference <0 indicate benefit for Mepolizumab over Placebo.
Note: 1 Mepolizumab subject with missing baseline score is excluded from the analysis.

PPD

Protocol: MEA115921
Population: Intent-to-Treat

Table 7.23
Analysis of SF-36 Physical Component Score Responders (Minimal Important Difference, Change >= 5) at Week 52 by Baseline Blood Eosinophils

Baseline blood eosinophils: <0.150 GI/L

	Placebo (N=68)	Mepolizumab 300 mg SC (N=68)
n	28	28
Responder	7 (25%)	6 (21%)
Non-Responder	21 (75%)	22 (79%)
Missing response	3 (11%)	2 (7%)
Comparison Mepolizumab 300 mg vs Placebo [1]		
Logistic regression [2]		
Inverse odds ratio (95% CI)		2.10 (0.38,11.50)
p-value		0.392
Inverse unadjusted odds ratio (95% CI) [3]		1.22 (0.29,5.19)
Inverse relative risk (95% CI) [4]		1.17 (0.40,3.29)
Risk difference (95% CI) [4]		0.04 (-0.21,0.27)
Fisher's Exact p-value (2-sided)		1.000

[1] Analysis compares the number of responders. Subjects with missing response are categorised as non-responders.
[2] Logistic regression analysis adjusted for baseline SF-36, baseline prednisolone/prednisone daily dose, baseline BVAS score and region (EU vs. RoW).
[3] Exact method. [4] Exact unconditional CI calculated by inverting two separate one-sided tests based on the score statistic.
Note: Inverse odds ratio and inverse relative risk <1 and risk difference <0 indicate benefit for Mepolizumab over Placebo.
Note: 1 Mepolizumab subject with missing baseline score is excluded from the analysis.

PPD

Protocol: MEA115921
Population: Intent-to-Treat

Table 7.23
Analysis of SF-36 Physical Component Score Responders (Minimal Important Difference, Change >= 5) at Week 52 by Baseline Blood Eosinophils

Baseline blood eosinophils: >=0.150 GI/L

	Placebo (N=68)	Mepolizumab 300 mg SC (N=68)
n	40	39
Responder	10 (25%)	12 (31%)
Non-Responder	30 (75%)	27 (69%)
Missing response	4 (10%)	2 (5%)
Comparison Mepolizumab 300 mg vs Placebo [1]		
Logistic regression [2]		
Inverse odds ratio (95% CI)		0.66 (0.22,1.98)
p-value		0.455
Inverse unadjusted odds ratio (95% CI) [3]		0.75 (0.25,2.25)
Inverse relative risk (95% CI) [4]		0.81 (0.36,1.73)
Risk difference (95% CI) [4]		-0.06 (-0.27,0.14)
Fisher's Exact p-value (2-sided)		0.622

[1] Analysis compares the number of responders. Subjects with missing response are categorised as non-responders.
[2] Logistic regression analysis adjusted for baseline SF-36, baseline prednisolone/prednisone daily dose, baseline BVAS score and region (EU vs. RoW).
[3] Exact method. [4] Exact unconditional CI calculated by inverting two separate one-sided tests based on the score statistic.
Note: Inverse odds ratio and inverse relative risk <1 and risk difference <0 indicate benefit for Mepolizumab over Placebo.
Note: 1 Mepolizumab subject with missing baseline score is excluded from the analysis.

PPD

Protocol: MEA115921
Population: Intent-to-Treat

Table 7.24
Analysis of SF-36 Physical Component Score Responders (Minimal Important Difference, Change >= 5) at Week 52 by Duration of Disease

Duration of disease: <=4 years

	Placebo (N=68)	Mepolizumab 300 mg SC (N=68)
n	32	33
Responder	3 (9%)	7 (21%)
Non-Responder	29 (91%)	26 (79%)
Missing response	4 (13%)	2 (6%)
Comparison Mepolizumab 300 mg vs Placebo [1]		
Logistic regression [2]		
Inverse odds ratio (95% CI)		0.41 (0.09,1.81)
p-value		0.240
Inverse unadjusted odds ratio (95% CI) [3]		0.39 (0.06,1.93)
Inverse relative risk (95% CI) [4]		0.44 (0.07,1.54)
Risk difference (95% CI) [4]		-0.12 (-0.31,0.07)
Fisher's Exact p-value (2-sided)		0.303

[1] Analysis compares the number of responders. Subjects with missing response are categorised as non-responders.
[2] Logistic regression analysis adjusted for baseline SF-36, baseline prednisolone/prednisone daily dose, baseline BVAS score and region (EU vs. RoW).
[3] Exact method. [4] Exact unconditional CI calculated by inverting two separate one-sided tests based on the score statistic.
Note: Inverse odds ratio and inverse relative risk <1 and risk difference <0 indicate benefit for Mepolizumab over Placebo.
Note: 1 Mepolizumab subject with missing baseline score is excluded from the analysis.

PPD

Protocol: MEA115921
Population: Intent-to-Treat

Table 7.24
Analysis of SF-36 Physical Component Score Responders (Minimal Important Difference, Change >= 5) at Week 52 by Duration of Disease

Duration of disease: >4 years

	Placebo (N=68)	Mepolizumab 300 mg SC (N=68)
n	36	34
Responder	14 (39%)	11 (32%)
Non-Responder	22 (61%)	23 (68%)
Missing response	3 (8%)	2 (6%)
Comparison Mepolizumab 300 mg vs Placebo [1]		
Logistic regression [2]		
Inverse odds ratio (95% CI)		1.74 (0.52,5.83)
p-value		0.369
Inverse unadjusted odds ratio (95% CI) [3]		1.33 (0.45,4.00)
Inverse relative risk (95% CI) [4]		1.20 (0.61,2.54)
Risk difference (95% CI) [4]		0.07 (-0.16,0.29)
Fisher's Exact p-value (2-sided)		0.624

[1] Analysis compares the number of responders. Subjects with missing response are categorised as non-responders.
[2] Logistic regression analysis adjusted for baseline SF-36, baseline prednisolone/prednisone daily dose, baseline BVAS score and region (EU vs. RoW).
[3] Exact method. [4] Exact unconditional CI calculated by inverting two separate one-sided tests based on the score statistic.
Note: Inverse odds ratio and inverse relative risk <1 and risk difference <0 indicate benefit for Mepolizumab over Placebo.
Note: 1 Mepolizumab subject with missing baseline score is excluded from the analysis.

PPD

Protocol: MEA115921
Population: Intent-to-Treat

Table 7.11
Analysis of SF-36 Mental Component Score Responders (Minimal Important Difference, Change >= 5) at Week 52 by Age

Age: <50 Years

	Placebo (N=68)	Mepolizumab 300 mg SC (N=68)
n	33	30
Responder	11 (33%)	4 (13%)
Non-Responder	22 (67%)	26 (87%)
Missing response	3 (9%)	2 (7%)
Comparison Mepolizumab 300 mg vs Placebo [1]		
Logistic regression [2]		
Inverse odds ratio (95% CI)		3.06 (0.71,13.30)
p-value		0.135
Inverse unadjusted odds ratio (95% CI) [3]		3.19 (0.80,15.73)
Inverse relative risk (95% CI) [4]		2.50 (0.93,13.41)
Risk difference (95% CI) [4]		0.20 (-0.02,0.41)
Fisher's Exact p-value (2-sided)		0.080

[1] Analysis compares the number of responders. Subjects with missing response are categorised as non-responders.
[2] Logistic regression analysis adjusted for baseline SF-36, baseline prednisolone/prednisone daily dose, baseline BVAS score and region (EU vs. RoW).
[3] Exact method. [4] Exact unconditional CI calculated by inverting two separate one-sided tests based on the score statistic.
Note: Inverse odds ratio and inverse relative risk <1 and risk difference <0 indicate benefit for Mepolizumab over Placebo.
Note: 1 Mepolizumab subject with missing baseline score is excluded from the analysis.

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Protocol: MEA115921
Population: Intent-to-Treat

Table 7.11
Analysis of SF-36 Mental Component Score Responders (Minimal Important Difference, Change >= 5) at Week 52 by Age

Age: >=50 Years

	Placebo (N=68)	Mepolizumab 300 mg SC (N=68)
n	35	37
Responder	4 (11%)	7 (19%)
Non-Responder	31 (89%)	30 (81%)
Missing response	4 (11%)	2 (5%)
Comparison Mepolizumab 300 mg vs Placebo [1]		
Logistic regression [2]		
Inverse odds ratio (95% CI)		1.21 (0.23,6.34)
p-value		0.824
Inverse unadjusted odds ratio (95% CI) [3]		0.56 (0.11,2.46)
Inverse relative risk (95% CI) [4]		0.60 (0.13,1.89)
Risk difference (95% CI) [4]		-0.07 (-0.25,0.11)
Fisher's Exact p-value (2-sided)		0.516

[1] Analysis compares the number of responders. Subjects with missing response are categorised as non-responders.
[2] Logistic regression analysis adjusted for baseline SF-36, baseline prednisolone/prednisone daily dose, baseline BVAS score and region (EU vs. RoW).
[3] Exact method. [4] Exact unconditional CI calculated by inverting two separate one-sided tests based on the score statistic.
Note: Inverse odds ratio and inverse relative risk <1 and risk difference <0 indicate benefit for Mepolizumab over Placebo.
Note: 1 Mepolizumab subject with missing baseline score is excluded from the analysis.

PPD

Protocol: MEA115921
Population: Intent-to-Treat

Table 7.12
Analysis of SF-36 Mental Component Score Responders (Minimal Important Difference, Change >= 5) at Week 52 by Gender

Gender: Female

	Placebo (N=68)	Mepolizumab 300 mg SC (N=68)
n	38	41
Responder	9 (24%)	6 (15%)
Non-Responder	29 (76%)	35 (85%)
Missing response	6 (16%)	2 (5%)
Comparison Mepolizumab 300 mg vs Placebo [1]		
Logistic regression [2]		
Inverse odds ratio (95% CI)		2.99 (0.75,11.82)
p-value		0.119
Inverse unadjusted odds ratio (95% CI) [3]		1.80 (0.50,6.91)
Inverse relative risk (95% CI) [4]		1.62 (0.63,4.59)
Risk difference (95% CI) [4]		0.09 (-0.10,0.27)
Fisher's Exact p-value (2-sided)		0.393

[1] Analysis compares the number of responders. Subjects with missing response are categorised as non-responders.
[2] Logistic regression analysis adjusted for baseline SF-36, baseline prednisolone/prednisone daily dose, baseline BVAS score and region (EU vs. RoW).
[3] Exact method. [4] Exact unconditional CI calculated by inverting two separate one-sided tests based on the score statistic.
Note: Inverse odds ratio and inverse relative risk <1 and risk difference <0 indicate benefit for Mepolizumab over Placebo.
Note: 1 Mepolizumab subject with missing baseline score is excluded from the analysis.

PPD

Protocol: MEA115921
Population: Intent-to-Treat

Table 7.12
Analysis of SF-36 Mental Component Score Responders (Minimal Important Difference, Change >= 5) at Week 52 by Gender

Gender: Male

	Placebo (N=68)	Mepolizumab 300 mg SC (N=68)
n	30	26
Responder	6 (20%)	5 (19%)
Non-Responder	24 (80%)	21 (81%)
Missing response	1 (3%)	2 (8%)
Comparison Mepolizumab 300 mg vs Placebo [1]		
Logistic regression [2]		
Inverse odds ratio (95% CI)		1.32 (0.26,6.76)
p-value		0.740
Inverse unadjusted odds ratio (95% CI) [3]		1.05 (0.23,5.03)
Inverse relative risk (95% CI) [4]		1.04 (0.32,3.41)
Risk difference (95% CI) [4]		0.01 (-0.22,0.22)
Fisher's Exact p-value (2-sided)		1.000

[1] Analysis compares the number of responders. Subjects with missing response are categorised as non-responders.
[2] Logistic regression analysis adjusted for baseline SF-36, baseline prednisolone/prednisone daily dose, baseline BVAS score and region (EU vs. RoW).
[3] Exact method. [4] Exact unconditional CI calculated by inverting two separate one-sided tests based on the score statistic.
Note: Inverse odds ratio and inverse relative risk <1 and risk difference <0 indicate benefit for Mepolizumab over Placebo.
Note: 1 Mepolizumab subject with missing baseline score is excluded from the analysis.

PPD

Protocol: MEA115921
Population: Intent-to-Treat

Table 7.13
Analysis of SF-36 Mental Component Score Responders (Minimal Important Difference, Change >= 5) at Week 52 by Region

Region: Europe

	Placebo (N=68)	Mepolizumab 300 mg SC (N=68)
n	33	32
Responder	10 (30%)	7 (22%)
Non-Responder	23 (70%)	25 (78%)
Missing response	0	1 (3%)
Comparison Mepolizumab 300 mg vs Placebo [1]		
Logistic regression [2]		
Inverse odds ratio (95% CI)		1.50 (0.40,5.58)
p-value		0.548
Inverse unadjusted odds ratio (95% CI) [3]		1.54 (0.44,5.65)
Inverse relative risk (95% CI) [4]		1.39 (0.60,3.44)
Risk difference (95% CI) [4]		0.08 (-0.14,0.30)
Fisher's Exact p-value (2-sided)		0.574

[1] Analysis compares the number of responders. Subjects with missing response are categorised as non-responders.
[2] Logistic regression analysis adjusted for baseline SF-36, baseline prednisolone/prednisone daily dose and baseline BVAS score.
[3] Exact method. [4] Exact unconditional CI calculated by inverting two separate one-sided tests based on the score statistic.
Note: Inverse odds ratio and inverse relative risk <1 and risk difference <0 indicate benefit for Mepolizumab over Placebo.
Note: 1 Mepolizumab subject with missing baseline score is excluded from the analysis.

PPD

Protocol: MEA115921
Population: Intent-to-Treat

Table 7.13
Analysis of SF-36 Mental Component Score Responders (Minimal Important Difference, Change >= 5) at Week 52 by Region

Region: Rest of World

	Placebo (N=68)	Mepolizumab 300 mg SC (N=68)
n	35	35
Responder	5 (14%)	4 (11%)
Non-Responder	30 (86%)	31 (89%)
Missing response	7 (20%)	3 (9%)
Comparison Mepolizumab 300 mg vs Placebo [1]		
Logistic regression [2]		
Inverse odds ratio (95% CI)		2.24 (0.45,11.08)
p-value		0.325
Inverse unadjusted odds ratio (95% CI) [3]		1.29 (0.25,7.14)
Inverse relative risk (95% CI) [4]		1.25 (0.31,5.11)
Risk difference (95% CI) [4]		0.03 (-0.14,0.20)
Fisher's Exact p-value (2-sided)		1.000

[1] Analysis compares the number of responders. Subjects with missing response are categorised as non-responders.
[2] Logistic regression analysis adjusted for baseline SF-36, baseline prednisolone/prednisone daily dose and baseline BVAS score.
[3] Exact method. [4] Exact unconditional CI calculated by inverting two separate one-sided tests based on the score statistic.
Note: Inverse odds ratio and inverse relative risk <1 and risk difference <0 indicate benefit for Mepolizumab over Placebo.
Note: 1 Mepolizumab subject with missing baseline score is excluded from the analysis.

PPD

Protocol: MEA115921
Population: Intent-to-Treat

Table 7.14
Analysis of SF-36 Mental Component Score Responders (Minimal Important Difference, Change >= 5) at Week 52 by Baseline Blood Eosinophils

Baseline blood eosinophils: <0.150 GI/L

	Placebo (N=68)	Mepolizumab 300 mg SC (N=68)
n	28	28
Responder	7 (25%)	4 (14%)
Non-Responder	21 (75%)	24 (86%)
Missing response	3 (11%)	2 (7%)
Comparison Mepolizumab 300 mg vs Placebo [1]		
Logistic regression [2]		
Inverse odds ratio (95% CI)		1.83 (0.30,11.17)
p-value		0.512
Inverse unadjusted odds ratio (95% CI) [3]		1.98 (0.43,10.55)
Inverse relative risk (95% CI) [4]		1.75 (0.57,7.95)
Risk difference (95% CI) [4]		0.11 (-0.11,0.33)
Fisher's Exact p-value (2-sided)		0.503

[1] Analysis compares the number of responders. Subjects with missing response are categorised as non-responders.
[2] Logistic regression analysis adjusted for baseline SF-36, baseline prednisolone/prednisone daily dose, baseline BVAS score and region (EU vs. RoW).
[3] Exact method. [4] Exact unconditional CI calculated by inverting two separate one-sided tests based on the score statistic.
Note: Inverse odds ratio and inverse relative risk <1 and risk difference <0 indicate benefit for Mepolizumab over Placebo.
Note: 1 Mepolizumab subject with missing baseline score is excluded from the analysis.

PPD

Protocol: MEA115921
Population: Intent-to-Treat

Table 7.14
Analysis of SF-36 Mental Component Score Responders (Minimal Important Difference, Change >= 5) at Week 52 by Baseline Blood Eosinophils

Baseline blood eosinophils: >=0.150 GI/L

	Placebo (N=68)	Mepolizumab 300 mg SC (N=68)
n	40	39
Responder	8 (20%)	7 (18%)
Non-Responder	32 (80%)	32 (82%)
Missing response	4 (10%)	2 (5%)
Comparison Mepolizumab 300 mg vs Placebo [1]		
Logistic regression [2]		
Inverse odds ratio (95% CI)		1.49 (0.42,5.31)
p-value		0.542
Inverse unadjusted odds ratio (95% CI) [3]		1.14 (0.32,4.18)
Inverse relative risk (95% CI) [4]		1.11 (0.41,3.12)
Risk difference (95% CI) [4]		0.02 (-0.17,0.20)
Fisher's Exact p-value (2-sided)		1.000

[1] Analysis compares the number of responders. Subjects with missing response are categorised as non-responders.
[2] Logistic regression analysis adjusted for baseline SF-36, baseline prednisolone/prednisone daily dose, baseline BVAS score and region (EU vs. RoW).
[3] Exact method. [4] Exact unconditional CI calculated by inverting two separate one-sided tests based on the score statistic.
Note: Inverse odds ratio and inverse relative risk <1 and risk difference <0 indicate benefit for Mepolizumab over Placebo.
Note: 1 Mepolizumab subject with missing baseline score is excluded from the analysis.

PPD

Protocol: MEA115921
Population: Intent-to-Treat

Table 7.15
Analysis of SF-36 Mental Component Score Responders (Minimal Important Difference, Change >= 5) at Week 52 by Duration of Disease

Duration of disease: <=4 years

	Placebo (N=68)	Mepolizumab 300 mg SC (N=68)
n	32	33
Responder	9 (28%)	7 (21%)
Non-Responder	23 (72%)	26 (79%)
Missing response	4 (13%)	2 (6%)
Comparison Mepolizumab 300 mg vs Placebo [1]		
Logistic regression [2]		
Inverse odds ratio (95% CI)		2.11 (0.59,7.57)
p-value		0.250
Inverse unadjusted odds ratio (95% CI) [3]		1.45 (0.40,5.38)
Inverse relative risk (95% CI) [4]		1.33 (0.53,3.41)
Risk difference (95% CI) [4]		0.07 (-0.15,0.29)
Fisher's Exact p-value (2-sided)		0.574

[1] Analysis compares the number of responders. Subjects with missing response are categorised as non-responders.
[2] Logistic regression analysis adjusted for baseline SF-36, baseline prednisolone/prednisone daily dose, baseline BVAS score and region (EU vs. RoW).
[3] Exact method. [4] Exact unconditional CI calculated by inverting two separate one-sided tests based on the score statistic.
Note: Inverse odds ratio and inverse relative risk <1 and risk difference <0 indicate benefit for Mepolizumab over Placebo.
Note: 1 Mepolizumab subject with missing baseline score is excluded from the analysis.

PPD

Population: Intent-to-Treat

Table 7.15
Analysis of SF-36 Mental Component Score Responders (Minimal Important Difference, Change >= 5) at Week 52 by Duration of Disease

Duration of disease: >4 years

	Placebo (N=68)	Mepolizumab 300 mg SC (N=68)
n	36	34
Responder	6 (17%)	4 (12%)
Non-Responder	30 (83%)	30 (88%)
Missing response	3 (8%)	2 (6%)
Comparison Mepolizumab 300 mg vs Placebo [1]		
Logistic regression [2]		
Inverse odds ratio (95% CI)		1.48 (0.23,9.32)
p-value		0.677
Inverse unadjusted odds ratio (95% CI) [3]		1.49 (0.32,7.95)
Inverse relative risk (95% CI) [4]		1.42 (0.42,5.73)
Risk difference (95% CI) [4]		0.05 (-0.13,0.23)
Fisher's Exact p-value (2-sided)		0.736

[1] Analysis compares the number of responders. Subjects with missing response are categorised as non-responders.
[2] Logistic regression analysis adjusted for baseline SF-36, baseline prednisolone/prednisone daily dose, baseline BVAS score and region (EU vs. RoW).
[3] Exact method. [4] Exact unconditional CI calculated by inverting two separate one-sided tests based on the score statistic.
Note: Inverse odds ratio and inverse relative risk <1 and risk difference <0 indicate benefit for Mepolizumab over Placebo.
Note: 1 Mepolizumab subject with missing baseline score is excluded from the analysis.

PPD

Protocol: MEA115921
Population: Intent-to-Treat

Table 7.28
Subgroup Analysis of Subjects with at Least One Hospitalisation Day (ICU or General Ward) at Any Time Post Baseline by Age

Age: <50 Years

	Placebo (N=68)	Mepolizumab 300 mg SC (N=68)
n	22	27
Responder	4 (18%)	4 (15%)
Non-Responder	18 (82%)	23 (85%)
Comparison Mepolizumab 300 mg vs Placebo [1]		
Logistic regression [2]		
Odds ratio (95% CI)		1.20 (0.22,6.42)
p-value		0.835
Unadjusted odds ratio (95% CI) [3]		0.79 (0.13,4.85)
Relative risk (95% CI) [4]		0.81 (0.20,3.35)
Risk difference (95% CI) [4]		-0.03 (-0.27,0.19)
Fisher's Exact p-value (2-sided)		1.000

[1] Analysis compares the number of responders.
[2] Logistic regression analysis adjusted for baseline prednisolone/prednisone daily dose, baseline BVAS score and region (EU vs. RoW).
[3] Exact method.
[4] Exact unconditional CI calculated by inverting two separate one-sided tests based on the score statistic.
Note: Odds ratio and relative risk <1 and risk difference <0 indicate benefit for Mepolizumab over Placebo.

PPD

Table 7.28
Subgroup Analysis of Subjects with at Least One Hospitalisation Day (ICU or General Ward) at Any Time Post Baseline by Age

Age: >=50 Years

	Placebo (N=68)	Mepolizumab 300 mg SC (N=68)
n	32	29
Responder	6 (19%)	5 (17%)
Non-Responder	26 (81%)	24 (83%)
Comparison Mepolizumab 300 mg vs Placebo [1]		
Logistic regression [2]		
Odds ratio (95% CI)		0.77 (0.19,3.18)
p-value		0.717
Unadjusted odds ratio (95% CI) [3]		0.90 (0.19,4.09)
Relative risk (95% CI) [4]		0.92 (0.28,2.97)
Risk difference (95% CI) [4]		-0.02 (-0.22,0.19)
Fisher's Exact p-value (2-sided)		1.000

[1] Analysis compares the number of responders.
[2] Logistic regression analysis adjusted for baseline prednisolone/prednisone daily dose, baseline BVAS score and region (EU vs. RoW).
[3] Exact method.
[4] Exact unconditional CI calculated by inverting two separate one-sided tests based on the score statistic.
Note: Odds ratio and relative risk <1 and risk difference <0 indicate benefit for Mepolizumab over Placebo.

PPD

Protocol: MEA115921
Population: Intent-to-Treat

Table 7.29
Subgroup Analysis of Subjects with at Least One Hospitalisation Day (ICU or General Ward) at Any Time Post Baseline by Gender

Gender: Female

	Placebo (N=68)	Mepolizumab 300 mg SC (N=68)
n	31	34
Responder	6 (19%)	5 (15%)
Non-Responder	25 (81%)	29 (85%)
Comparison Mepolizumab 300 mg vs Placebo [1]		
Logistic regression [2]		
Odds ratio (95% CI)		0.80 (0.21,3.05)
p-value		0.748
Unadjusted odds ratio (95% CI) [3]		0.72 (0.15,3.23)
Relative risk (95% CI) [4]		0.76 (0.23,2.47)
Risk difference (95% CI) [4]		-0.05 (-0.24,0.15)
Fisher's Exact p-value (2-sided)		0.745

[1] Analysis compares the number of responders.
[2] Logistic regression analysis adjusted for baseline prednisolone/prednisone daily dose, baseline BVAS score and region (EU vs. RoW).
[3] Exact method.
[4] Exact unconditional CI calculated by inverting two separate one-sided tests based on the score statistic.
Note: Odds ratio and relative risk <1 and risk difference <0 indicate benefit for Mepolizumab over Placebo.

PPD

Population: Intent-to-Treat

Table 7.29
Subgroup Analysis of Subjects with at Least One Hospitalisation Day (ICU or General Ward) at Any Time Post Baseline by Gender

Gender: Male

	Placebo (N=68)	Mepolizumab 300 mg SC (N=68)
n	23	22
Responder	4 (17%)	4 (18%)
Non-Responder	19 (83%)	18 (82%)
Comparison Mepolizumab 300 mg vs Placebo [1]		
Logistic regression [2]		
Odds ratio (95% CI)		0.97 (0.16,5.74)
p-value		0.971
Unadjusted odds ratio (95% CI) [3]		1.05 (0.17,6.59)
Relative risk (95% CI) [4]		1.05 (0.26,4.27)
Risk difference (95% CI) [4]		0.01 (-0.24,0.25)
Fisher's Exact p-value (2-sided)		1.000

[1] Analysis compares the number of responders.
[2] Logistic regression analysis adjusted for baseline prednisolone/prednisone daily dose, baseline BVAS score and region (EU vs. RoW).
[3] Exact method.
[4] Exact unconditional CI calculated by inverting two separate one-sided tests based on the score statistic.
Note: Odds ratio and relative risk <1 and risk difference <0 indicate benefit for Mepolizumab over Placebo.

PPD

Protocol: MEA115921
Population: Intent-to-Treat

Table 7.30
Subgroup Analysis of Subjects with at Least One Hospitalisation Day (ICU or General Ward) at Any Time Post Baseline by Region

Region: Europe

	Placebo (N=68)	Mepolizumab 300 mg SC (N=68)	
n	22	22	
Responder	6 (27%)	2 (9%)	
Non-Responder	16 (73%)	20 (91%)	
Comparison Mepolizumab 300 mg vs Placebo [1]			
Logistic regression [2]			
Odds ratio (95% CI)			0.42 (0.07,2.71)
p-value			0.363
Unadjusted odds ratio (95% CI) [3]			0.27 (0.02,1.81)
Relative risk (95% CI) [4]			0.33 (0.03,1.41)
Risk difference (95% CI) [4]			-0.18 (-0.43,0.06)
Fisher's Exact p-value (2-sided)			0.240

[1] Analysis compares the number of responders.
[2] Logistic regression analysis adjusted for baseline prednisolone/prednisone daily dose and baseline BVAS score.
[3] Exact method.
[4] Exact unconditional CI calculated by inverting two separate one-sided tests based on the score statistic.
Note: Odds ratio and relative risk <1 and risk difference <0 indicate benefit for Mepolizumab over Placebo.

PPD

Table 7.30
Subgroup Analysis of Subjects with at Least One Hospitalisation Day (ICU or General Ward) at Any Time Post Baseline by Region

Region: Rest of World

	Placebo (N=68)	Mepolizumab 300 mg SC (N=68)
n	32	34
Responder	4 (13%)	7 (21%)
Non-Responder	28 (88%)	27 (79%)
Comparison Mepolizumab 300 mg vs Placebo [1]		
Logistic regression [2]		
Odds ratio (95% CI)		1.64 (0.41,6.59)
p-value		0.484
Unadjusted odds ratio (95% CI) [3]		1.80 (0.40,9.37)
Relative risk (95% CI) [4]		1.65 (0.53,7.76)
Risk difference (95% CI) [4]		0.08 (-0.11,0.28)
Fisher's Exact p-value (2-sided)		0.513

[1] Analysis compares the number of responders.
[2] Logistic regression analysis adjusted for baseline prednisolone/prednisone daily dose and baseline BVAS score.
[3] Exact method.
[4] Exact unconditional CI calculated by inverting two separate one-sided tests based on the score statistic.
Note: Odds ratio and relative risk <1 and risk difference <0 indicate benefit for Mepolizumab over Placebo.

PPD

Protocol: MEA115921
Population: Intent-to-Treat

Table 7.31
Subgroup Analysis of Subjects with at Least One Hospitalisation Day (ICU or General Ward) at Any Time Post Baseline by Baseline Blood Eosinophils

Baseline blood eosinophils: <0.150 GI/L

	Placebo (N=68)	Mepolizumab 300 mg SC (N=68)
n	23	24
Responder	2 (9%)	8 (33%)
Non-Responder	21 (91%)	16 (67%)
Comparison Mepolizumab 300 mg vs Placebo [1]		
Logistic regression [2]		
Odds ratio (95% CI)		10.15 (1.28,80.35)
p-value		0.028
Unadjusted odds ratio (95% CI) [3]		5.07 (0.85,55.47)
Relative risk (95% CI) [4]		3.83 (1.00,31.73)
Risk difference (95% CI) [4]		0.25 (0.00,0.48)
Fisher's Exact p-value (2-sided)		0.072

[1] Analysis compares the number of responders.
[2] Logistic regression analysis adjusted for baseline prednisolone/prednisone daily dose, baseline BVAS score and region (EU vs. RoW).
[3] Exact method.
[4] Exact unconditional CI calculated by inverting two separate one-sided tests based on the score statistic.
Note: Odds ratio and relative risk <1 and risk difference <0 indicate benefit for Mepolizumab over Placebo.

PPD

Population: Intent-to-Treat

Table 7.31
Subgroup Analysis of Subjects with at Least One Hospitalisation Day (ICU or General Ward) at Any Time Post Baseline by Baseline Blood Eosinophils

Baseline blood eosinophils: >=0.150 GI/L

	Placebo (N=68)	Mepolizumab 300 mg SC (N=68)
n	31	32
Responder	8 (26%)	1 (3%)
Non-Responder	23 (74%)	31 (97%)
Comparison Mepolizumab 300 mg vs Placebo [1]		
Logistic regression [2]		
Odds ratio (95% CI)		0.06 (0.01,0.71)
p-value		0.025
Unadjusted odds ratio (95% CI) [3]		0.10 (<0.01,0.80)
Relative risk (95% CI) [4]		0.12 (0.00,0.84)
Risk difference (95% CI) [4]		-0.23 (-0.42,-0.05)
Fisher's Exact p-value (2-sided)		0.013

[1] Analysis compares the number of responders.
[2] Logistic regression analysis adjusted for baseline prednisolone/prednisone daily dose, baseline BVAS score and region (EU vs. RoW).
[3] Exact method.
[4] Exact unconditional CI calculated by inverting two separate one-sided tests based on the score statistic.
Note: Odds ratio and relative risk <1 and risk difference <0 indicate benefit for Mepolizumab over Placebo.

PPD

Protocol: MEA115921
Population: Intent-to-Treat

Table 7.32
Subgroup Analysis of Subjects with at Least One Hospitalisation Day (ICU or General Ward) at Any Time Post Baseline by Duration of Disease

Duration of disease: <=4 years

	Placebo (N=68)	Mepolizumab 300 mg SC (N=68)
n	24	28
Responder	1 (4%)	1 (4%)
Non-Responder	23 (96%)	27 (96%)
Comparison Mepolizumab 300 mg vs Placebo [1]		
Logistic regression [2]		
Odds ratio (95% CI)		0.82 (0.04,16.99)
p-value		0.897
Unadjusted odds ratio (95% CI) [3]		0.85 (0.01,69.74)
Relative risk (95% CI) [4]		0.86 (0.03,28.42)
Risk difference (95% CI) [4]		-0.01 (-0.18,0.15)
Fisher's Exact p-value (2-sided)		1.000

[1] Analysis compares the number of responders.
[2] Logistic regression analysis adjusted for baseline prednisolone/prednisone daily dose, baseline BVAS score and region (EU vs. RoW).
[3] Exact method.
[4] Exact unconditional CI calculated by inverting two separate one-sided tests based on the score statistic.
Note: Odds ratio and relative risk <1 and risk difference <0 indicate benefit for Mepolizumab over Placebo.

PPD

Table 7.32
Subgroup Analysis of Subjects with at Least One Hospitalisation Day (ICU or General Ward) at Any Time Post Baseline by Duration of Disease

Duration of disease: >4 years

	Placebo (N=68)	Mepolizumab 300 mg SC (N=68)
n	30	28
Responder	9 (30%)	8 (29%)
Non-Responder	21 (70%)	20 (71%)
Comparison Mepolizumab 300 mg vs Placebo [1]		
Logistic regression [2]		
Odds ratio (95% CI)		0.90 (0.24,3.34)
p-value		0.879
Unadjusted odds ratio (95% CI) [3]		0.93 (0.26,3.35)
Relative risk (95% CI) [4]		0.95 (0.37,2.20)
Risk difference (95% CI) [4]		-0.01 (-0.25,0.24)
Fisher's Exact p-value (2-sided)		1.000

[1] Analysis compares the number of responders.
[2] Logistic regression analysis adjusted for baseline prednisolone/prednisone daily dose, baseline BVAS score and region (EU vs. RoW).
[3] Exact method.
[4] Exact unconditional CI calculated by inverting two separate one-sided tests based on the score statistic.
Note: Odds ratio and relative risk <1 and risk difference <0 indicate benefit for Mepolizumab over Placebo.

PPD

Population: Intent-to-Treat

Table 7.36
Subgroup Analysis of Change from Baseline in Work Productivity and Activity Impairment Questionnaire (WPAI) at Week 52: Work Time Missed Due to Health (%) by Age
(Mixed Model Repeated Measures)

Age: <50 Years

	Placebo (N=68)	Mepolizumab 300 mg SC (N=68)
Number of subjects in subgroup	33	31
n [1]	24	18
n [2]	22	17
LS Mean (SE)	8.51 (3.549)	5.06 (4.080)
LS Mean Change (SE)	1.33 (3.549)	-2.12 (4.080)
Mepolizumab 300 mg SC vs Placebo		
Difference (Mepo - Placebo)		-3.45
95% CI		(-14.48, 7.58)
p-value		0.530
Corrected Hedges g [3]		-0.20
95% CI		(-0.84, 0.43)

[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] Derived from LS means and associated SE.
Note: Analysis performed separately for each subgroup using mixed model repeated measures with covariates of baseline, baseline prednisolone/prednisone daily dose, region (EU vs. RoW), treatment and visit, plus interaction terms for visit-by-baseline and visit-by-treatment group.
LS mean estimates are weighted according to the observed proportion of each categorical covariate in the study data.

Population: Intent-to-Treat

Table 7.36
Subgroup Analysis of Change from Baseline in Work Productivity and Activity Impairment Questionnaire (WPAI) at Week 52: Work Time Missed Due to Health (%) by Age
(Mixed Model Repeated Measures)

Age: >=50 Years

	Placebo (N=68)	Mepolizumab 300 mg SC (N=68)
Number of subjects in subgroup	35	37
n [1]	19	17
n [2]	17	14
LS Mean (SE)	6.93 (5.649)	19.67 (6.310)
LS Mean Change (SE)	-4.57 (5.649)	8.17 (6.310)
Mepolizumab 300 mg SC vs Placebo		
Difference (Mepo - Placebo)		12.74
95% CI		(-4.81, 30.28)
p-value		0.148
Corrected Hedges g [3]		0.53
95% CI		(-0.19, 1.25)

[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] Derived from LS means and associated SE.
Note: Analysis performed separately for each subgroup using mixed model repeated measures with covariates of baseline, baseline prednisolone/prednisone daily dose, region (EU vs. RoW), treatment and visit, plus interaction terms for visit-by-baseline and visit-by-treatment group.
LS mean estimates are weighted according to the observed proportion of each categorical covariate in the study data.

Protocol: MEA115921
Population: Intent-to-Treat

Table 7.37
Subgroup Analysis of Change from Baseline in Work Productivity and Activity Impairment Questionnaire (WPAI) at Week 52: Work Time Missed Due to Health (%) by Gender
(Mixed Model Repeated Measures)

Gender: Female

	Placebo (N=68)	Mepolizumab 300 mg SC (N=68)
Number of subjects in subgroup	38	42
n [1]	23	17
n [2]	21	15
LS Mean (SE)	5.26 (3.008)	5.73 (3.641)
LS Mean Change (SE)	-2.87 (3.008)	-2.40 (3.641)
Mepolizumab 300 mg SC vs Placebo		
Difference (Mepo - Placebo)		0.47
95% CI		(-9.28, 10.23)
p-value		0.922
Corrected Hedges g [3]		0.03
95% CI		(-0.63, 0.70)

[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] Derived from LS means and associated SE.
Note: Analysis performed separately for each subgroup using mixed model repeated measures with covariates of baseline, baseline prednisolone/prednisone daily dose, region (EU vs. RoW), treatment and visit, plus interaction terms for visit-by-baseline and visit-by-treatment group.
LS mean estimates are weighted according to the observed proportion of each categorical covariate in the study data.

PPD

Population: Intent-to-Treat

Table 7.37
Subgroup Analysis of Change from Baseline in Work Productivity and Activity Impairment Questionnaire (WPAI) at Week 52: Work Time Missed Due to Health (%) by Gender
(Mixed Model Repeated Measures)

Gender: Male

	Placebo (N=68)	Mepolizumab 300 mg SC (N=68)
Number of subjects in subgroup	30	26
n [1]	20	18
n [2]	18	16
LS Mean (SE)	14.05 (5.847)	16.89 (6.231)
LS Mean Change (SE)	3.91 (5.847)	6.74 (6.231)
Mepolizumab 300 mg SC vs Placebo		
Difference (Mepo - Placebo)		2.84
95% CI		(-14.69, 20.36)
p-value		0.744
Corrected Hedges g [3]		0.11
95% CI		(-0.56, 0.79)

[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] Derived from LS means and associated SE.
Note: Analysis performed separately for each subgroup using mixed model repeated measures with covariates of baseline, baseline prednisolone/prednisone daily dose, region (EU vs. RoW), treatment and visit, plus interaction terms for visit-by-baseline and visit-by-treatment group.
LS mean estimates are weighted according to the observed proportion of each categorical covariate in the study data.

Population: Intent-to-Treat

Table 7.38
Subgroup Analysis of Change from Baseline in Work Productivity and Activity Impairment Questionnaire (WPAI) at Week 52: Work Time Missed Due to Health (%) by Region
(Mixed Model Repeated Measures)

Region: Europe

	Placebo (N=68)	Mepolizumab 300 mg SC (N=68)
Number of subjects in subgroup	33	32
n [1]	18	17
n [2]	17	15
LS Mean (SE)	12.04 (5.671)	15.33 (6.047)
LS Mean Change (SE)	-2.89 (5.671)	0.40 (6.047)
Mepolizumab 300 mg SC vs Placebo		
Difference (Mepo - Placebo)		3.29
95% CI		(-13.83, 20.40)
p-value		0.698
Corrected Hedges g [3]		0.14
95% CI		(-0.56, 0.83)

[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] Derived from LS means and associated SE.
Note: Analysis performed separately for each subgroup using mixed model repeated measures with covariates of baseline, baseline prednisolone/prednisone daily dose, treatment and visit, plus interaction terms for visit-by-baseline and visit-by-treatment group.
LS mean estimates are weighted according to the observed proportion of each categorical covariate in the study data.

Protocol: MEA115921
Population: Intent-to-Treat

Table 7.38
Subgroup Analysis of Change from Baseline in Work Productivity and Activity Impairment Questionnaire (WPAI) at Week 52: Work Time Missed Due to Health (%) by Region
(Mixed Model Repeated Measures)

Region: Rest of World

	Placebo (N=68)	Mepolizumab 300 mg SC (N=68)
Number of subjects in subgroup	35	36
n [1]	25	18
n [2]	22	16
LS Mean (SE)	3.96 (3.734)	6.04 (4.285)
LS Mean Change (SE)	-0.34 (3.734)	1.75 (4.285)
Mepolizumab 300 mg SC vs Placebo		
Difference (Mepo - Placebo)		2.09
95% CI		(-10.08, 14.25)
p-value		0.726
Corrected Hedges g [3]		0.12
95% CI		(-0.53, 0.76)

[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] Derived from LS means and associated SE.
Note: Analysis performed separately for each subgroup using mixed model repeated measures with covariates of baseline, baseline prednisolone/prednisone daily dose, treatment and visit, plus interaction terms for visit-by-baseline and visit-by-treatment group.
LS mean estimates are weighted according to the observed proportion of each categorical covariate in the study data.

Protocol: MEA115921
Population: Intent-to-Treat

Table 7.39
Subgroup Analysis of Change from Baseline in Work Productivity and Activity Impairment Questionnaire (WPAI) at Week 52: Work Time Missed Due to Health (%) by Duration of Disease
(Mixed Model Repeated Measures)

Duration of disease: <=4 years

	Placebo (N=68)	Mepolizumab 300 mg SC (N=68)
Number of subjects in subgroup	32	34
n [1]	27	20
n [2]	23	18
LS Mean (SE)	5.67 (2.153)	2.43 (2.368)
LS Mean Change (SE)	0.38 (2.153)	-2.86 (2.368)
Mepolizumab 300 mg SC vs Placebo		
Difference (Mepo - Placebo)		-3.24
95% CI		(-9.73, 3.24)
p-value		0.317
Corrected Hedges g [3]		-0.31
95% CI		(-0.93, 0.31)

[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] Derived from LS means and associated SE.
Note: Analysis performed separately for each subgroup using mixed model repeated measures with covariates of baseline, baseline prednisolone/prednisone daily dose, region (EU vs. RoW), treatment and visit, plus interaction terms for visit-by-baseline and visit-by-treatment group.
LS mean estimates are weighted according to the observed proportion of each categorical covariate in the study data.

Population: Intent-to-Treat

Table 7.39
Subgroup Analysis of Change from Baseline in Work Productivity and Activity Impairment Questionnaire (WPAI) at Week 52: Work Time Missed Due to Health (%) by Duration of Disease
(Mixed Model Repeated Measures)

Duration of disease: >4 years

	Placebo (N=68)	Mepolizumab 300 mg SC (N=68)
Number of subjects in subgroup	36	34
n [1]	16	15
n [2]	16	13
LS Mean (SE)	11.17 (6.788)	20.56 (7.475)
LS Mean Change (SE)	-3.58 (6.788)	5.81 (7.475)
Mepolizumab 300 mg SC vs Placebo		
Difference (Mepo - Placebo)		9.39
95% CI		(-11.45, 30.23)
p-value		0.363
Corrected Hedges g [3]		0.34
95% CI		(-0.40, 1.07)

[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] Derived from LS means and associated SE.
Note: Analysis performed separately for each subgroup using mixed model repeated measures with covariates of baseline, baseline prednisolone/prednisone daily dose, region (EU vs. RoW), treatment and visit, plus interaction terms for visit-by-baseline and visit-by-treatment group.
LS mean estimates are weighted according to the observed proportion of each categorical covariate in the study data.

Protocol: MEA115921
Population: Intent-to-Treat

Table 7.40
Subgroup Analysis of Change from Baseline in Work Productivity and Activity Impairment Questionnaire (WPAI) at Week 52: Work Time Missed Due to Health (%) by Baseline Blood Eosinophils (Mixed Model Repeated Measures)

Baseline blood eosinophils: <0.150 GI/L

	Placebo (N=68)	Mepolizumab 300 mg SC (N=68)
Number of subjects in subgroup	28	29
n [1]	20	17
n [2]	18	14
LS Mean (SE)	7.26 (5.011)	20.22 (5.629)
LS Mean Change (SE)	-2.97 (5.011)	9.99 (5.629)
Mepolizumab 300 mg SC vs Placebo		
Difference (Mepo - Placebo)		12.96
95% CI		(-2.49, 28.41)
p-value		0.097
Corrected Hedges g [3]		0.60
95% CI		(-0.12, 1.31)

[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] Derived from LS means and associated SE.
Note: Analysis performed separately for each subgroup using mixed model repeated measures with covariates of baseline, baseline prednisolone/prednisone daily dose, region (EU vs. RoW), treatment and visit, plus interaction terms for visit-by-baseline and visit-by-treatment group.
LS mean estimates are weighted according to the observed proportion of each categorical covariate in the study data.

Population: Intent-to-Treat

Table 7.40
Subgroup Analysis of Change from Baseline in Work Productivity and Activity Impairment Questionnaire (WPAI) at Week 52: Work Time Missed Due to Health (%) by Baseline Blood Eosinophils (Mixed Model Repeated Measures)

Baseline blood eosinophils: >=0.150 GI/L

	Placebo (N=68)	Mepolizumab 300 mg SC (N=68)
Number of subjects in subgroup	40	39
n [1]	23	18
n [2]	21	17
LS Mean (SE)	9.76 (3.528)	2.33 (4.002)
LS Mean Change (SE)	1.57 (3.528)	-5.85 (4.002)
Mepolizumab 300 mg SC vs Placebo		
Difference (Mepo - Placebo)		-7.42
95% CI		(-18.32, 3.48)
p-value		0.176
Corrected Hedges g [3]		-0.45
95% CI		(-1.09, 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] Derived from LS means and associated SE.
Note: Analysis performed separately for each subgroup using mixed model repeated measures with covariates of baseline, baseline prednisolone/prednisone daily dose, region (EU vs. RoW), treatment and visit, plus interaction terms for visit-by-baseline and visit-by-treatment group.
LS mean estimates are weighted according to the observed proportion of each categorical covariate in the study data.

Protocol: MEA115921
Population: Intent-to-Treat

Table 7.43
Subgroup Analysis of Change from Baseline in Work Productivity and Activity Impairment Questionnaire (WPAI) at Week 52: Impairment While Working Due to Health (%) by Age
(Mixed Model Repeated Measures)

Age: <50 Years

	Placebo (N=68)	Mepolizumab 300 mg SC (N=68)
Number of subjects in subgroup	33	31
n [1]	23	15
n [2]	19	14
LS Mean (SE)	21.42 (4.045)	15.08 (4.834)
LS Mean Change (SE)	0.81 (4.045)	-5.52 (4.834)
Mepolizumab 300 mg SC vs Placebo		
Difference (Mepo - Placebo)		-6.33
95% CI		(-19.27, 6.61)
p-value		0.324
Corrected Hedges g [3]		-0.35
95% CI		(-1.04, 0.35)

[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] Derived from LS means and associated SE.
Note: Analysis performed separately for each subgroup using mixed model repeated measures with covariates of baseline, baseline prednisolone/prednisone daily dose, region (EU vs. RoW), treatment and visit, plus interaction terms for visit-by-baseline and visit-by-treatment group.
LS mean estimates are weighted according to the observed proportion of each categorical covariate in the study data.

Protocol: MEA115921
Population: Intent-to-Treat

Table 7.43
Subgroup Analysis of Change from Baseline in Work Productivity and Activity Impairment Questionnaire (WPAI) at Week 52: Impairment While Working Due to Health (%) by Age
(Mixed Model Repeated Measures)

Age: >=50 Years

	Placebo (N=68)	Mepolizumab 300 mg SC (N=68)
Number of subjects in subgroup	35	37
n [1]	15	16
n [2]	12	12
LS Mean (SE)	17.00 (4.701)	22.68 (4.674)
LS Mean Change (SE)	-2.91 (4.701)	2.77 (4.674)
Mepolizumab 300 mg SC vs Placebo		
Difference (Mepo - Placebo)		5.67
95% CI		(-8.27, 19.62)
p-value		0.405
Corrected Hedges g [3]		0.34
95% CI		(-0.47, 1.14)

[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] Derived from LS means and associated SE.
Note: Analysis performed separately for each subgroup using mixed model repeated measures with covariates of baseline, baseline prednisolone/prednisone daily dose, region (EU vs. RoW), treatment and visit, plus interaction terms for visit-by-baseline and visit-by-treatment group.
LS mean estimates are weighted according to the observed proportion of each categorical covariate in the study data.

Protocol: MEA115921
Population: Intent-to-Treat

Table 7.44
Subgroup Analysis of Change from Baseline in Work Productivity and Activity Impairment Questionnaire (WPAI) at Week 52: Impairment While Working Due to Health (%) by Gender
(Mixed Model Repeated Measures)

Gender: Female

	Placebo (N=68)	Mepolizumab 300 mg SC (N=68)
Number of subjects in subgroup	38	42
n [1]	21	14
n [2]	17	13
LS Mean (SE)	18.38 (4.473)	19.87 (5.267)
LS Mean Change (SE)	-6.49 (4.473)	-5.00 (5.267)
Mepolizumab 300 mg SC vs Placebo		
Difference (Mepo - Placebo)		1.49
95% CI		(-12.94, 15.92)
p-value		0.834
Corrected Hedges g [3]		0.08
95% CI		(-0.64, 0.80)

[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] Derived from LS means and associated SE.
Note: Analysis performed separately for each subgroup using mixed model repeated measures with covariates of baseline, baseline prednisolone/prednisone daily dose, region (EU vs. RoW), treatment and visit, plus interaction terms for visit-by-baseline and visit-by-treatment group.
LS mean estimates are weighted according to the observed proportion of each categorical covariate in the study data.

Protocol: MEA115921
Population: Intent-to-Treat

Table 7.44
Subgroup Analysis of Change from Baseline in Work Productivity and Activity Impairment Questionnaire (WPAI) at Week 52: Impairment While Working Due to Health (%) by Gender
(Mixed Model Repeated Measures)

Gender: Male

	Placebo (N=68)	Mepolizumab 300 mg SC (N=68)
Number of subjects in subgroup	30	26
n [1]	17	17
n [2]	14	13
LS Mean (SE)	21.44 (3.978)	15.11 (4.098)
LS Mean Change (SE)	5.51 (3.978)	-0.82 (4.098)
Mepolizumab 300 mg SC vs Placebo		
Difference (Mepo - Placebo)		-6.33
95% CI		(-18.13, 5.48)
p-value		0.281
Corrected Hedges g [3]		-0.41
95% CI		(-1.18, 0.35)

[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] Derived from LS means and associated SE.
Note: Analysis performed separately for each subgroup using mixed model repeated measures with covariates of baseline, baseline prednisolone/prednisone daily dose, region (EU vs. RoW), treatment and visit, plus interaction terms for visit-by-baseline and visit-by-treatment group.
LS mean estimates are weighted according to the observed proportion of each categorical covariate in the study data.

Protocol: MEA115921
Population: Intent-to-Treat

Table 7.45
Subgroup Analysis of Change from Baseline in Work Productivity and Activity Impairment Questionnaire (WPAI) at Week 52: Impairment While Working Due to Health (%) by Region
(Mixed Model Repeated Measures)

Region: Europe

	Placebo (N=68)	Mepolizumab 300 mg SC (N=68)
Number of subjects in subgroup	33	32
n [1]	14	15
n [2]	12	13
LS Mean (SE)	23.40 (6.772)	24.83 (6.374)
LS Mean Change (SE)	0.75 (6.772)	2.19 (6.374)
Mepolizumab 300 mg SC vs Placebo		
Difference (Mepo - Placebo)		1.44
95% CI		(-18.88, 21.75)
p-value		0.885
Corrected Hedges g [3]		0.06
95% CI		(-0.72, 0.84)

[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] Derived from LS means and associated SE.
Note: Analysis performed separately for each subgroup using mixed model repeated measures with covariates of baseline, baseline prednisolone/prednisone daily dose, treatment and visit, plus interaction terms for visit-by-baseline and visit-by-treatment group.
LS mean estimates are weighted according to the observed proportion of each categorical covariate in the study data.

Population: Intent-to-Treat

Table 7.45
Subgroup Analysis of Change from Baseline in Work Productivity and Activity Impairment Questionnaire (WPAI) at Week 52: Impairment While Working Due to Health (%) by Region
(Mixed Model Repeated Measures)

Region: Rest of World

	Placebo (N=68)	Mepolizumab 300 mg SC (N=68)
Number of subjects in subgroup	35	36
n [1]	24	16
n [2]	19	13
LS Mean (SE)	14.00 (2.828)	13.08 (3.460)
LS Mean Change (SE)	-4.56 (2.828)	-5.47 (3.460)
Mepolizumab 300 mg SC vs Placebo		
Difference (Mepo - Placebo)		-0.92
95% CI		(-10.32, 8.49)
p-value		0.843
Corrected Hedges g [3]		-0.07
95% CI		(-0.78, 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] Derived from LS means and associated SE.
Note: Analysis performed separately for each subgroup using mixed model repeated measures with covariates of baseline, baseline prednisolone/prednisone daily dose, treatment and visit, plus interaction terms for visit-by-baseline and visit-by-treatment group.
LS mean estimates are weighted according to the observed proportion of each categorical covariate in the study data.

Population: Intent-to-Treat

Table 7.46
Subgroup Analysis of Change from Baseline in Work Productivity and Activity Impairment Questionnaire (WPAI) at Week 52: Impairment While Working Due to Health (%) by Duration of Disease
(Mixed Model Repeated Measures)

Duration of disease: <=4 years

	Placebo (N=68)	Mepolizumab 300 mg SC (N=68)
Number of subjects in subgroup	32	34
n [1]	25	19
n [2]	20	16
LS Mean (SE)	20.35 (3.916)	19.25 (4.494)
LS Mean Change (SE)	-0.05 (3.916)	-1.15 (4.494)
Mepolizumab 300 mg SC vs Placebo		
Difference (Mepo - Placebo)		-1.10
95% CI		(-13.48, 11.28)
p-value		0.857
Corrected Hedges g [3]		-0.06
95% CI		(-0.72, 0.60)

[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] Derived from LS means and associated SE.
Note: Analysis performed separately for each subgroup using mixed model repeated measures with covariates of baseline, baseline prednisolone/prednisone daily dose, region (EU vs. RoW), treatment and visit, plus interaction terms for visit-by-baseline and visit-by-treatment group.
LS mean estimates are weighted according to the observed proportion of each categorical covariate in the study data.

Population: Intent-to-Treat

Table 7.46
Subgroup Analysis of Change from Baseline in Work Productivity and Activity Impairment Questionnaire (WPAI) at Week 52: Impairment While Working Due to Health (%) by Duration of Disease
(Mixed Model Repeated Measures)

Duration of disease: >4 years

	Placebo (N=68)	Mepolizumab 300 mg SC (N=68)
Number of subjects in subgroup	36	34
n [1]	13	12
n [2]	11	10
LS Mean (SE)	18.41 (5.534)	17.26 (5.718)
LS Mean Change (SE)	-1.70 (5.534)	-2.86 (5.718)
Mepolizumab 300 mg SC vs Placebo		
Difference (Mepo - Placebo)		-1.15
95% CI		(-18.28, 15.97)
p-value		0.889
Corrected Hedges g [3]		-0.06
95% CI		(-0.92, 0.80)

[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] Derived from LS means and associated SE.
Note: Analysis performed separately for each subgroup using mixed model repeated measures with covariates of baseline, baseline prednisolone/prednisone daily dose, region (EU vs. RoW), treatment and visit, plus interaction terms for visit-by-baseline and visit-by-treatment group.
LS mean estimates are weighted according to the observed proportion of each categorical covariate in the study data.

Protocol: MEA115921
Population: Intent-to-Treat

Table 7.47
Subgroup Analysis of Change from Baseline in Work Productivity and Activity Impairment Questionnaire (WPAI) at Week 52: Impairment While Working Due to Health (%) by Baseline Blood Eosinophils
(Mixed Model Repeated Measures)

Baseline blood eosinophils: <0.150 GI/L

	Placebo (N=68)	Mepolizumab 300 mg SC (N=68)
Number of subjects in subgroup	28	29
n [1]	18	16
n [2]	14	12
LS Mean (SE)	21.22 (5.016)	26.83 (5.444)
LS Mean Change (SE)	2.10 (5.016)	7.70 (5.444)
Mepolizumab 300 mg SC vs Placebo		
Difference (Mepo - Placebo)		5.61
95% CI		(-9.73, 20.94)
p-value		0.459
Corrected Hedges g [3]		0.29
95% CI		(-0.49, 1.06)

[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] Derived from LS means and associated SE.
Note: Analysis performed separately for each subgroup using mixed model repeated measures with covariates of baseline, baseline prednisolone/prednisone daily dose, region (EU vs. RoW), treatment and visit, plus interaction terms for visit-by-baseline and visit-by-treatment group.
LS mean estimates are weighted according to the observed proportion of each categorical covariate in the study data.

Population: Intent-to-Treat

Table 7.47
Subgroup Analysis of Change from Baseline in Work Productivity and Activity Impairment Questionnaire (WPAI) at Week 52: Impairment While Working Due to Health (%) by Baseline Blood Eosinophils
(Mixed Model Repeated Measures)

Baseline blood eosinophils: >=0.150 GI/L

	Placebo (N=68)	Mepolizumab 300 mg SC (N=68)
Number of subjects in subgroup	40	39
n [1]	20	15
n [2]	17	14
LS Mean (SE)	18.35 (3.259)	10.96 (3.685)
LS Mean Change (SE)	-3.00 (3.259)	-10.39 (3.685)
Mepolizumab 300 mg SC vs Placebo		
Difference (Mepo - Placebo)		-7.40
95% CI		(-17.64, 2.85)
p-value		0.150
Corrected Hedges g [3]		-0.53
95% CI		(-1.25, 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] Derived from LS means and associated SE.
Note: Analysis performed separately for each subgroup using mixed model repeated measures with covariates of baseline, baseline prednisolone/prednisone daily dose, region (EU vs. RoW), treatment and visit, plus interaction terms for visit-by-baseline and visit-by-treatment group.
LS mean estimates are weighted according to the observed proportion of each categorical covariate in the study data.

Protocol: MEA115921
Population: Intent-to-Treat

Table 7.50
Subgroup Analysis of Change from Baseline in Work Productivity and Activity Impairment Questionnaire (WPAI) at Week 52: Overall Work Impairment Due to Health (%) by Age
(Mixed Model Repeated Measures)

Age: <50 Years

	Placebo (N=68)	Mepolizumab 300 mg SC (N=68)
Number of subjects in subgroup	33	31
n [1]	23	15
n [2]	19	14
LS Mean (SE)	25.93 (4.920)	14.78 (5.829)
LS Mean Change (SE)	3.04 (4.920)	-8.11 (5.829)
Mepolizumab 300 mg SC vs Placebo		
Difference (Mepo - Placebo)		-11.15
95% CI		(-26.78, 4.48)
p-value		0.155
Corrected Hedges g [3]		-0.50
95% CI		(-1.20, 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] Derived from LS means and associated SE.
Note: Analysis performed separately for each subgroup using mixed model repeated measures with covariates of baseline, baseline prednisolone/prednisone daily dose, region (EU vs. RoW), treatment and visit, plus interaction terms for visit-by-baseline and visit-by-treatment group.
LS mean estimates are weighted according to the observed proportion of each categorical covariate in the study data.

PPD

Population: Intent-to-Treat

Table 7.50
Subgroup Analysis of Change from Baseline in Work Productivity and Activity Impairment Questionnaire (WPAI) at Week 52: Overall Work Impairment Due to Health (%) by Age
(Mixed Model Repeated Measures)

Age: >=50 Years

	Placebo (N=68)	Mepolizumab 300 mg SC (N=68)
Number of subjects in subgroup	35	37
n [1]	15	16
n [2]	12	12
LS Mean (SE)	17.98 (5.374)	28.49 (5.392)
LS Mean Change (SE)	-4.71 (5.374)	5.79 (5.392)
Mepolizumab 300 mg SC vs Placebo		
Difference (Mepo - Placebo)		10.51
95% CI		(-5.51, 26.52)
p-value		0.186
Corrected Hedges g [3]		0.54
95% CI		(-0.27, 1.36)

[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] Derived from LS means and associated SE.
Note: Analysis performed separately for each subgroup using mixed model repeated measures with covariates of baseline, baseline prednisolone/prednisone daily dose, region (EU vs. RoW), treatment and visit, plus interaction terms for visit-by-baseline and visit-by-treatment group.
LS mean estimates are weighted according to the observed proportion of each categorical covariate in the study data.

Protocol: MEA115921
Population: Intent-to-Treat

Table 7.51
Subgroup Analysis of Change from Baseline in Work Productivity and Activity Impairment Questionnaire (WPAI) at Week 52: Overall Work Impairment Due to Health (%) by Gender
(Mixed Model Repeated Measures)

Gender: Female

	Placebo (N=68)	Mepolizumab 300 mg SC (N=68)
Number of subjects in subgroup	38	42
n [1]	21	14
n [2]	17	13
LS Mean (SE)	20.60 (4.768)	19.70 (5.600)
LS Mean Change (SE)	-6.04 (4.768)	-6.94 (5.600)
Mepolizumab 300 mg SC vs Placebo		
Difference (Mepo - Placebo)		-0.91
95% CI		(-16.25, 14.44)
p-value		0.904
Corrected Hedges g [3]		-0.04
95% CI		(-0.77, 0.68)

[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] Derived from LS means and associated SE.
Note: Analysis performed separately for each subgroup using mixed model repeated measures with covariates of baseline, baseline prednisolone/prednisone daily dose, region (EU vs. RoW), treatment and visit, plus interaction terms for visit-by-baseline and visit-by-treatment group.
LS mean estimates are weighted according to the observed proportion of each categorical covariate in the study data.

Protocol: MEA115921
Population: Intent-to-Treat

Table 7.51
Subgroup Analysis of Change from Baseline in Work Productivity and Activity Impairment Questionnaire (WPAI) at Week 52: Overall Work Impairment Due to Health (%) by Gender
(Mixed Model Repeated Measures)

Gender: Male

	Placebo (N=68)	Mepolizumab 300 mg SC (N=68)
Number of subjects in subgroup	30	26
n [1]	17	17
n [2]	14	13
LS Mean (SE)	25.74 (5.484)	19.92 (5.778)
LS Mean Change (SE)	6.60 (5.484)	0.77 (5.778)
Mepolizumab 300 mg SC vs Placebo		
Difference (Mepo - Placebo)		-5.82
95% CI		(-22.30, 10.66)
p-value		0.474
Corrected Hedges g [3]		-0.27
95% CI		(-1.03, 0.49)

[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] Derived from LS means and associated SE.
Note: Analysis performed separately for each subgroup using mixed model repeated measures with covariates of baseline, baseline prednisolone/prednisone daily dose, region (EU vs. RoW), treatment and visit, plus interaction terms for visit-by-baseline and visit-by-treatment group.
LS mean estimates are weighted according to the observed proportion of each categorical covariate in the study data.

Protocol: MEA115921
Population: Intent-to-Treat

Table 7.52
Subgroup Analysis of Change from Baseline in Work Productivity and Activity Impairment Questionnaire (WPAI) at Week 52: Overall Work Impairment Due to Health (%) by Region
(Mixed Model Repeated Measures)

Region: Europe

	Placebo (N=68)	Mepolizumab 300 mg SC (N=68)
Number of subjects in subgroup	33	32
n [1]	14	15
n [2]	12	13
LS Mean (SE)	31.57 (8.148)	25.20 (7.825)
LS Mean Change (SE)	6.25 (8.148)	-0.11 (7.825)
Mepolizumab 300 mg SC vs Placebo		
Difference (Mepo - Placebo)		-6.36
95% CI		(-31.45, 18.73)
p-value		0.606
Corrected Hedges g [3]		-0.22
95% CI		(-1.00, 0.57)

[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] Derived from LS means and associated SE.
Note: Analysis performed separately for each subgroup using mixed model repeated measures with covariates of baseline, baseline prednisolone/prednisone daily dose, treatment and visit, plus interaction terms for visit-by-baseline and visit-by-treatment group.
LS mean estimates are weighted according to the observed proportion of each categorical covariate in the study data.

PPD

Protocol: MEA115921
Population: Intent-to-Treat

Table 7.52
Subgroup Analysis of Change from Baseline in Work Productivity and Activity Impairment Questionnaire (WPAI) at Week 52: Overall Work Impairment Due to Health (%) by Region
(Mixed Model Repeated Measures)

Region: Rest of World

	Placebo (N=68)	Mepolizumab 300 mg SC (N=68)
Number of subjects in subgroup	35	36
n [1]	24	16
n [2]	19	13
LS Mean (SE)	15.51 (3.334)	15.74 (4.012)
LS Mean Change (SE)	-5.44 (3.334)	-5.21 (4.012)
Mepolizumab 300 mg SC vs Placebo		
Difference (Mepo - Placebo)		0.23
95% CI		(-10.78, 11.24)
p-value		0.966
Corrected Hedges g [3]		0.02
95% CI		(-0.69, 0.72)

[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] Derived from LS means and associated SE.
Note: Analysis performed separately for each subgroup using mixed model repeated measures with covariates of baseline, baseline prednisolone/prednisone daily dose, treatment and visit, plus interaction terms for visit-by-baseline and visit-by-treatment group.
LS mean estimates are weighted according to the observed proportion of each categorical covariate in the study data.

PPD

Population: Intent-to-Treat

Table 7.53
Subgroup Analysis of Change from Baseline in Work Productivity and Activity Impairment Questionnaire (WPAI) at Week 52: Overall Work Impairment Due to Health (%) by Duration of Disease
(Mixed Model Repeated Measures)

Duration of disease: <=4 years

	Placebo (N=68)	Mepolizumab 300 mg SC (N=68)
Number of subjects in subgroup	32	34
n [1]	25	19
n [2]	20	16
LS Mean (SE)	22.05 (4.379)	22.07 (4.955)
LS Mean Change (SE)	-1.49 (4.379)	-1.48 (4.955)
Mepolizumab 300 mg SC vs Placebo		
Difference (Mepo - Placebo)		0.01
95% CI		(-13.70, 13.73)
p-value		0.998
Corrected Hedges g [3]		0.00
95% CI		(-0.66, 0.66)

[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] Derived from LS means and associated SE.
Note: Analysis performed separately for each subgroup using mixed model repeated measures with covariates of baseline, baseline prednisolone/prednisone daily dose, region (EU vs. RoW), treatment and visit, plus interaction terms for visit-by-baseline and visit-by-treatment group.
LS mean estimates are weighted according to the observed proportion of each categorical covariate in the study data.

Population: Intent-to-Treat

Table 7.53
Subgroup Analysis of Change from Baseline in Work Productivity and Activity Impairment Questionnaire (WPAI) at Week 52: Overall Work Impairment Due to Health (%) by Duration of Disease
(Mixed Model Repeated Measures)

Duration of disease: >4 years

	Placebo (N=68)	Mepolizumab 300 mg SC (N=68)
Number of subjects in subgroup	36	34
n [1]	13	12
n [2]	11	10
LS Mean (SE)	24.59 (6.763)	18.00 (7.123)
LS Mean Change (SE)	3.05 (6.763)	-3.53 (7.123)
Mepolizumab 300 mg SC vs Placebo		
Difference (Mepo - Placebo)		-6.59
95% CI		(-27.56, 14.38)
p-value		0.521
Corrected Hedges g [3]		-0.28
95% CI		(-1.14, 0.58)

[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] Derived from LS means and associated SE.
Note: Analysis performed separately for each subgroup using mixed model repeated measures with covariates of baseline, baseline prednisolone/prednisone daily dose, region (EU vs. RoW), treatment and visit, plus interaction terms for visit-by-baseline and visit-by-treatment group.
LS mean estimates are weighted according to the observed proportion of each categorical covariate in the study data.

Protocol: MEA115921
Population: Intent-to-Treat

Table 7.54
Subgroup Analysis of Change from Baseline in Work Productivity and Activity Impairment Questionnaire (WPAI) at Week 52: Overall Work Impairment Due to Health (%) by Baseline Blood Eosinophils
(Mixed Model Repeated Measures)

Baseline blood eosinophils: <0.150 GI/L

	Placebo (N=68)	Mepolizumab 300 mg SC (N=68)
Number of subjects in subgroup	28	29
n [1]	18	16
n [2]	14	12
LS Mean (SE)	24.00 (5.721)	30.59 (6.223)
LS Mean Change (SE)	1.73 (5.721)	8.33 (6.223)
Mepolizumab 300 mg SC vs Placebo		
Difference (Mepo - Placebo)		6.59
95% CI		(-10.86, 24.04)
p-value		0.444
Corrected Hedges g [3]		0.30
95% CI		(-0.48, 1.07)

[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] Derived from LS means and associated SE.
Note: Analysis performed separately for each subgroup using mixed model repeated measures with covariates of baseline, baseline prednisolone/prednisone daily dose, region (EU vs. RoW), treatment and visit, plus interaction terms for visit-by-baseline and visit-by-treatment group.
LS mean estimates are weighted according to the observed proportion of each categorical covariate in the study data.

Population: Intent-to-Treat

Table 7.54
Subgroup Analysis of Change from Baseline in Work Productivity and Activity Impairment Questionnaire (WPAI) at Week 52: Overall Work Impairment Due to Health (%) by Baseline Blood Eosinophils
(Mixed Model Repeated Measures)

Baseline blood eosinophils: >=0.150 GI/L

	Placebo (N=68)	Mepolizumab 300 mg SC (N=68)
Number of subjects in subgroup	40	39
n [1]	20	15
n [2]	17	14
LS Mean (SE)	21.48 (4.228)	11.59 (4.712)
LS Mean Change (SE)	-1.80 (4.228)	-11.69 (4.712)
Mepolizumab 300 mg SC vs Placebo		
Difference (Mepo - Placebo)		-9.89
95% CI		(-22.94, 3.16)
p-value		0.132
Corrected Hedges g [3]		-0.55
95% CI		(-1.27, 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] Derived from LS means and associated SE.
Note: Analysis performed separately for each subgroup using mixed model repeated measures with covariates of baseline, baseline prednisolone/prednisone daily dose, region (EU vs. RoW), treatment and visit, plus interaction terms for visit-by-baseline and visit-by-treatment group.
LS mean estimates are weighted according to the observed proportion of each categorical covariate in the study data.

Protocol: MEA115921
Population: Intent-to-Treat

Table 7.57
Subgroup Analysis of Change from Baseline in Work Productivity and Activity Impairment Questionnaire (WPAI) at Week 52: Activity Impairment Due to Health (%) by Age
(Mixed Model Repeated Measures)

Age: <50 Years

	Placebo (N=68)	Mepolizumab 300 mg SC (N=68)
Number of subjects in subgroup	33	31
n [1]	33	31
n [2]	28	29
LS Mean (SE)	29.69 (3.514)	31.73 (3.477)
LS Mean Change (SE)	-9.24 (3.514)	-7.20 (3.477)
Mepolizumab 300 mg SC vs Placebo		
Difference (Mepo - Placebo)		2.04
95% CI		(-7.96, 12.03)
p-value		0.685
Corrected Hedges g [3]		0.11
95% CI		(-0.41, 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] Derived from LS means and associated SE.
Note: Analysis performed separately for each subgroup using mixed model repeated measures with covariates of baseline, baseline prednisolone/prednisone daily dose, region (EU vs. RoW), treatment and visit, plus interaction terms for visit-by-baseline and visit-by-treatment group.
LS mean estimates are weighted according to the observed proportion of each categorical covariate in the study data.

Population: Intent-to-Treat

Table 7.57
Subgroup Analysis of Change from Baseline in Work Productivity and Activity Impairment Questionnaire (WPAI) at Week 52: Activity Impairment Due to Health (%) by Age
(Mixed Model Repeated Measures)

Age: >=50 Years

	Placebo (N=68)	Mepolizumab 300 mg SC (N=68)
Number of subjects in subgroup	35	37
n [1]	34	37
n [2]	28	36
LS Mean (SE)	31.20 (3.926)	38.91 (3.489)
LS Mean Change (SE)	-4.99 (3.926)	2.72 (3.489)
Mepolizumab 300 mg SC vs Placebo		
Difference (Mepo - Placebo)		7.71
95% CI		(-2.85, 18.27)
p-value		0.149
Corrected Hedges g [3]		0.37
95% CI		(-0.13, 0.86)

[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] Derived from LS means and associated SE.
Note: Analysis performed separately for each subgroup using mixed model repeated measures with covariates of baseline, baseline prednisolone/prednisone daily dose, region (EU vs. RoW), treatment and visit, plus interaction terms for visit-by-baseline and visit-by-treatment group.
LS mean estimates are weighted according to the observed proportion of each categorical covariate in the study data.

Protocol: MEA115921
Population: Intent-to-Treat

Table 7.58
Subgroup Analysis of Change from Baseline in Work Productivity and Activity Impairment Questionnaire (WPAI) at Week 52: Activity Impairment Due to Health (%) by Gender
(Mixed Model Repeated Measures)

Gender: Female

	Placebo (N=68)	Mepolizumab 300 mg SC (N=68)
Number of subjects in subgroup	38	42
n [1]	38	42
n [2]	29	41
LS Mean (SE)	30.53 (4.028)	38.97 (3.409)
LS Mean Change (SE)	-12.46 (4.028)	-4.02 (3.409)
Mepolizumab 300 mg SC vs Placebo		
Difference (Mepo - Placebo)		8.44
95% CI		(-2.09, 18.98)
p-value		0.115
Corrected Hedges g [3]		0.38
95% CI		(-0.10, 0.86)

[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] Derived from LS means and associated SE.
Note: Analysis performed separately for each subgroup using mixed model repeated measures with covariates of baseline, baseline prednisolone/prednisone daily dose, region (EU vs. RoW), treatment and visit, plus interaction terms for visit-by-baseline and visit-by-treatment group.
LS mean estimates are weighted according to the observed proportion of each categorical covariate in the study data.

Population: Intent-to-Treat

Table 7.58
Subgroup Analysis of Change from Baseline in Work Productivity and Activity Impairment Questionnaire (WPAI) at Week 52: Activity Impairment Due to Health (%) by Gender
(Mixed Model Repeated Measures)

Gender: Male

	Placebo (N=68)	Mepolizumab 300 mg SC (N=68)
Number of subjects in subgroup	30	26
n [1]	29	26
n [2]	27	24
LS Mean (SE)	27.12 (2.704)	32.73 (2.869)
LS Mean Change (SE)	-2.50 (2.704)	3.12 (2.869)
Mepolizumab 300 mg SC vs Placebo		
Difference (Mepo - Placebo)		5.62
95% CI		(-2.38, 13.62)
p-value		0.165
Corrected Hedges g [3]		0.39
95% CI		(-0.16, 0.95)

[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] Derived from LS means and associated SE.
Note: Analysis performed separately for each subgroup using mixed model repeated measures with covariates of baseline, baseline prednisolone/prednisone daily dose, region (EU vs. RoW), treatment and visit, plus interaction terms for visit-by-baseline and visit-by-treatment group.
LS mean estimates are weighted according to the observed proportion of each categorical covariate in the study data.

Protocol: MEA115921
Population: Intent-to-Treat

Table 7.59
Subgroup Analysis of Change from Baseline in Work Productivity and Activity Impairment Questionnaire (WPAI) at Week 52: Activity Impairment Due to Health (%) by Region
(Mixed Model Repeated Measures)

Region: Europe

	Placebo (N=68)	Mepolizumab 300 mg SC (N=68)
Number of subjects in subgroup	33	32
n [1]	32	32
n [2]	29	31
LS Mean (SE)	35.60 (3.430)	41.95 (3.356)
LS Mean Change (SE)	-5.32 (3.430)	1.03 (3.356)
Mepolizumab 300 mg SC vs Placebo		
Difference (Mepo - Placebo)		6.35
95% CI		(-3.49, 16.19)
p-value		0.201
Corrected Hedges g [3]		0.34
95% CI		(-0.17, 0.85)

[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] Derived from LS means and associated SE.
Note: Analysis performed separately for each subgroup using mixed model repeated measures with covariates of baseline, baseline prednisolone/prednisone daily dose, treatment and visit, plus interaction terms for visit-by-baseline and visit-by-treatment group.
LS mean estimates are weighted according to the observed proportion of each categorical covariate in the study data.

PPD

Protocol: MEA115921
Population: Intent-to-Treat

Table 7.59
Subgroup Analysis of Change from Baseline in Work Productivity and Activity Impairment Questionnaire (WPAI) at Week 52: Activity Impairment Due to Health (%) by Region
(Mixed Model Repeated Measures)

Region: Rest of World

	Placebo (N=68)	Mepolizumab 300 mg SC (N=68)
Number of subjects in subgroup	35	36
n [1]	35	36
n [2]	27	34
LS Mean (SE)	21.69 (3.836)	33.26 (3.397)
LS Mean Change (SE)	-12.54 (3.836)	-0.98 (3.397)
Mepolizumab 300 mg SC vs Placebo		
Difference (Mepo - Placebo)		11.57
95% CI		(1.15, 21.98)
p-value		0.030
Corrected Hedges g [3]		0.57
95% CI		(0.06, 1.09)

[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] Derived from LS means and associated SE.
Note: Analysis performed separately for each subgroup using mixed model repeated measures with covariates of baseline, baseline prednisolone/prednisone daily dose, treatment and visit, plus interaction terms for visit-by-baseline and visit-by-treatment group.
LS mean estimates are weighted according to the observed proportion of each categorical covariate in the study data.

Protocol: MEA115921
Population: Intent-to-Treat

Table 7.60
Subgroup Analysis of Change from Baseline in Work Productivity and Activity Impairment Questionnaire (WPAI) at Week 52: Activity Impairment Due to Health (%) by Duration of Disease
(Mixed Model Repeated Measures)

Duration of disease: <=4 years

	Placebo (N=68)	Mepolizumab 300 mg SC (N=68)
Number of subjects in subgroup	32	34
n [1]	31	34
n [2]	27	33
LS Mean (SE)	32.58 (4.085)	32.58 (3.703)
LS Mean Change (SE)	-2.57 (4.085)	-2.56 (3.703)
Mepolizumab 300 mg SC vs Placebo		
Difference (Mepo - Placebo)		0.00
95% CI		(-11.05, 11.06)
p-value		>0.999
Corrected Hedges g [3]		0.00
95% CI		(-0.51, 0.51)

[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] Derived from LS means and associated SE.
Note: Analysis performed separately for each subgroup using mixed model repeated measures with covariates of baseline, baseline prednisolone/prednisone daily dose, region (EU vs. RoW), treatment and visit, plus interaction terms for visit-by-baseline and visit-by-treatment group.
LS mean estimates are weighted according to the observed proportion of each categorical covariate in the study data.

Population: Intent-to-Treat

Table 7.60
Subgroup Analysis of Change from Baseline in Work Productivity and Activity Impairment Questionnaire (WPAI) at Week 52: Activity Impairment Due to Health (%) by Duration of Disease
(Mixed Model Repeated Measures)

Duration of disease: >4 years

	Placebo (N=68)	Mepolizumab 300 mg SC (N=68)
Number of subjects in subgroup	36	34
n [1]	36	34
n [2]	29	32
LS Mean (SE)	28.51 (3.245)	39.62 (3.134)
LS Mean Change (SE)	-11.19 (3.245)	-0.08 (3.134)
Mepolizumab 300 mg SC vs Placebo		
Difference (Mepo - Placebo)		11.11
95% CI		(2.05, 20.17)
p-value		0.017
Corrected Hedges g [3]		0.62
95% CI		(0.11, 1.14)

[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] Derived from LS means and associated SE.
Note: Analysis performed separately for each subgroup using mixed model repeated measures with covariates of baseline, baseline prednisolone/prednisone daily dose, region (EU vs. RoW), treatment and visit, plus interaction terms for visit-by-baseline and visit-by-treatment group.
LS mean estimates are weighted according to the observed proportion of each categorical covariate in the study data.

PPD

Protocol: MEA115921
Population: Intent-to-Treat

Table 7.61
Subgroup Analysis of Change from Baseline in Work Productivity and Activity Impairment Questionnaire (WPAI) at Week 52: Activity Impairment Due to Health (%) by Baseline Blood Eosinophils
(Mixed Model Repeated Measures)

Baseline blood eosinophils: <0.150 GI/L

	Placebo (N=68)	Mepolizumab 300 mg SC (N=68)
Number of subjects in subgroup	28	29
n [1]	27	29
n [2]	24	27
LS Mean (SE)	24.50 (4.252)	35.70 (3.982)
LS Mean Change (SE)	-9.87 (4.252)	1.34 (3.982)
Mepolizumab 300 mg SC vs Placebo		
Difference (Mepo - Placebo)		11.20
95% CI		(-0.61, 23.01)
p-value		0.062
Corrected Hedges g [3]		0.53
95% CI		(-0.03, 1.09)

[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] Derived from LS means and associated SE.
Note: Analysis performed separately for each subgroup using mixed model repeated measures with covariates of baseline, baseline prednisolone/prednisone daily dose, region (EU vs. RoW), treatment and visit, plus interaction terms for visit-by-baseline and visit-by-treatment group.
LS mean estimates are weighted according to the observed proportion of each categorical covariate in the study data.

Protocol: MEA115921
Population: Intent-to-Treat

Table 7.61
Subgroup Analysis of Change from Baseline in Work Productivity and Activity Impairment Questionnaire (WPAI) at Week 52: Activity Impairment Due to Health (%) by Baseline Blood Eosinophils
(Mixed Model Repeated Measures)

Baseline blood eosinophils: >=0.150 GI/L

	Placebo (N=68)	Mepolizumab 300 mg SC (N=68)
Number of subjects in subgroup	40	39
n [1]	40	39
n [2]	32	38
LS Mean (SE)	34.73 (3.384)	36.01 (3.158)
LS Mean Change (SE)	-5.00 (3.384)	-3.72 (3.158)
Mepolizumab 300 mg SC vs Placebo		
Difference (Mepo - Placebo)		1.28
95% CI		(-8.04, 10.60)
p-value		0.784
Corrected Hedges g [3]		0.07
95% CI		(-0.40, 0.54)

[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] Derived from LS means and associated SE.
Note: Analysis performed separately for each subgroup using mixed model repeated measures with covariates of baseline, baseline prednisolone/prednisone daily dose, region (EU vs. RoW), treatment and visit, plus interaction terms for visit-by-baseline and visit-by-treatment group.
LS mean estimates are weighted according to the observed proportion of each categorical covariate in the study data.

Protocol: MEA115921
Population: Safety

Table 3.1
Summary and Analysis of Proportion of Subjects with On-Treatment Adverse Events Overall and by Subgroup

	Placebo (N=68)	Mepolizumab 300 mg SC (N=68)	Odds Ratio (Exact 95% CI)	Relative Risk (Exact 95% CI) [1]	Risk Difference (Exact 95% CI) [1]	p-value [2]
All Subjects	64 (94%)	66 (97%)	2.06 (0.28,23.43)	1.03 (0.94,1.14)	0.03 (-0.05,0.12)	0.680
Subgroups						
Age (Years)						
<50	30/32 (94%)	32/32 (>99%)	Inf (0.29,Inf)	1.07 (0.94,1.26)	0.06 (-0.05,0.21)	0.492
>=50	34/36 (94%)	34/36 (94%)	1.00 (0.07,14.53)	1.00 (0.85,1.17)	0.00 (-0.14,0.14)	>0.999
Gender						
Male	29/30 (97%)	24/26 (92%)	0.41 (0.01,8.53)	0.95 (0.76,1.14)	-0.04 (-0.22,0.11)	0.592
Female	35/38 (92%)	42/42 (>99%)	Inf (0.66,Inf)	1.09 (0.98,1.28)	0.08 (-0.01,0.21)	0.103
Region						
Europe	31/33 (94%)	31/32 (97%)	2.00 (0.10,121.74)	1.03 (0.88,1.23)	0.03 (-0.11,0.18)	>0.999
Rest of World	33/35 (94%)	35/36 (97%)	2.12 (0.10,128.66)	1.03 (0.90,1.20)	0.03 (-0.09,0.17)	0.614
Baseline Blood Eosinophils						
<0.150 GI/L	26/28 (93%)	28/29 (97%)	2.15 (0.10,131.53)	1.04 (0.88,1.27)	0.04 (-0.12,0.20)	0.611
>=0.150 GI/L	38/40 (95%)	38/39 (97%)	2.00 (0.10,121.05)	1.03 (0.90,1.18)	0.02 (-0.09,0.15)	>0.999
Duration of Disease (Years)						
<=4 years	30/32 (94%)	34/34 (>99%)	Inf (0.31,Inf)	1.07 (0.95,1.27)	0.06 (-0.05,0.21)	0.231
>4 years	34/36 (94%)	32/34 (94%)	0.94 (0.06,13.71)	1.00 (0.84,1.17)	0.00 (-0.15,0.13)	>0.999

Note: Information presented as number of subjects with event / number subjects in the subgroup.
[1] Exact unconditional CI calculated by inverting two separate one-sided tests based on the score statistic.
[2] 2-sided Fisher's Exact p-value.

PPD

Protocol: MEA115921
Population: Safety

Table 3.3
Summary and Analysis of Proportion of Subjects with On-Treatment Adverse Events
Occurring in >=10% of Patients or in >=10 and >=1% of Patients

System Organ Class/Preferred Term	Placebo (N=68)	Mepolizumab 300 mg SC (N=68)	Odds Ratio (Exact 95% CI)	Relative Risk (Exact 95% CI) [1]	Risk Difference (Exact 95% CI) [1]	p-value [2]
Infections and infestations	53 (78%)	57 (84%)	1.47 (0.57,3.86)	1.08 (0.90,1.30)	0.06 (-0.08,0.20)	0.514
Nasopharyngitis	16 (24%)	12 (18%)	0.70 (0.27,1.74)	0.75 (0.35,1.51)	-0.06 (-0.20,0.08)	0.525
Sinusitis	11 (16%)	14 (21%)	1.34 (0.51,3.58)	1.27 (0.61,2.90)	0.04 (-0.09,0.18)	0.659
Upper respiratory tract infection	11 (16%)	14 (21%)	1.34 (0.51,3.58)	1.27 (0.61,2.90)	0.04 (-0.09,0.18)	0.659
Bronchitis	9 (13%)	7 (10%)	0.75 (0.22,2.44)	0.78 (0.28,2.04)	-0.03 (-0.15,0.09)	0.791
Influenza	8 (12%)	7 (10%)	0.86 (0.25,2.91)	0.88 (0.31,2.52)	-0.01 (-0.13,0.10)	>0.999
Respiratory tract infection	8 (12%)	6 (9%)	0.73 (0.20,2.55)	0.75 (0.25,2.07)	-0.03 (-0.14,0.08)	0.779
Nervous system disorders	32 (47%)	38 (56%)	1.43 (0.69,2.96)	1.19 (0.85,1.68)	0.09 (-0.09,0.26)	0.391
Headache	12 (18%)	22 (32%)	2.23 (0.93,5.49)	1.83 (1.00,3.61)	0.15 (0.00,0.29)	0.074
General disorders and administration site conditions	28 (41%)	40 (59%)	2.04 (0.98,4.28)	1.43 (1.00,2.08)	0.18 (0.00,0.34)	0.059
Fatigue	10 (15%)	10 (15%)	1.00 (0.34,2.90)	1.00 (0.41,2.45)	0.00 (-0.13,0.13)	>0.999
Injection site reaction	7 (10%)	9 (13%)	1.33 (0.41,4.49)	1.29 (0.49,3.52)	0.03 (-0.09,0.15)	0.791
Pyrexia	8 (12%)	7 (10%)	0.86 (0.25,2.91)	0.88 (0.31,2.52)	-0.01 (-0.13,0.10)	>0.999

Note: Includes all SOC and PT which meet the given criteria in any treatment arm. If SOC meets the criteria but none of it's PT meets the criteria then only the SOC is displayed.
[1] Exact unconditional CI calculated by inverting two separate one-sided tests based on the score statistic.
[2] 2-sided Fisher's Exact p-value.

Protocol: MEA115921
Population: Safety

Table 3.3
Summary and Analysis of Proportion of Subjects with On-Treatment Adverse Events
Occurring in >=10% of Patients or in >=10 and >=1% of Patients

System Organ Class/Preferred Term	Placebo (N=68)	Mepolizumab 300 mg SC (N=68)	Odds Ratio (Exact 95% CI)	Relative Risk (Exact 95% CI) [1]	Risk Difference (Exact 95% CI) [1]	p-value [2]
Musculoskeletal and connective tissue disorders	30 (44%)	38 (56%)	1.60 (0.77,3.34)	1.27 (0.90,1.83)	0.12 (-0.06,0.29)	0.230
Arthralgia	12 (18%)	15 (22%)	1.32 (0.52,3.40)	1.25 (0.61,2.69)	0.04 (-0.09,0.18)	0.668
Back pain	6 (9%)	9 (13%)	1.58 (0.47,5.72)	1.50 (0.55,4.35)	0.04 (-0.07,0.16)	0.585
Myalgia	9 (13%)	6 (9%)	0.63 (0.17,2.15)	0.67 (0.23,1.81)	-0.04 (-0.16,0.07)	0.585
Neck pain	2 (3%)	8 (12%)	4.40 (0.82,43.71)	4.00 (0.97,33.39)	0.09 (0.00,0.19)	0.096
Gastrointestinal disorders	31 (46%)	34 (50%)	1.19 (0.58,2.47)	1.10 (0.76,1.61)	0.04 (-0.13,0.21)	0.731
Nausea	13 (19%)	11 (16%)	0.82 (0.30,2.17)	0.85 (0.37,1.81)	-0.03 (-0.16,0.10)	0.822
Diarrhoea	8 (12%)	12 (18%)	1.61 (0.55,4.88)	1.50 (0.64,3.62)	0.06 (-0.06,0.19)	0.468
Vomiting	4 (6%)	11 (16%)	3.09 (0.85,13.94)	2.75 (0.94,14.88)	0.10 (0.00,0.22)	0.098
Respiratory, thoracic and mediastinal disorders	28 (41%)	35 (51%)	1.52 (0.73,3.16)	1.25 (0.86,1.86)	0.10 (-0.07,0.27)	0.302
Asthma	11 (16%)	11 (16%)	1.00 (0.36,2.77)	1.00 (0.44,2.27)	0.00 (-0.13,0.13)	>0.999
Cough	8 (12%)	5 (7%)	0.60 (0.15,2.21)	0.63 (0.18,1.82)	-0.04 (-0.16,0.06)	0.561
Oropharyngeal pain	5 (7%)	8 (12%)	1.68 (0.45,6.88)	1.60 (0.55,5.52)	0.04 (-0.06,0.16)	0.561
Productive cough	7 (10%)	6 (9%)	0.84 (0.22,3.12)	0.86 (0.28,2.69)	-0.01 (-0.12,0.09)	>0.999

Note: Includes all SOC and PT which meet the given criteria in any treatment arm. If SOC meets the criteria but none of it's PT meets the criteria then only the SOC is displayed.
[1] Exact unconditional CI calculated by inverting two separate one-sided tests based on the score statistic.
[2] 2-sided Fisher's Exact p-value.

PPD

Protocol: MEA115921
Population: Safety

Table 3.3
Summary and Analysis of Proportion of Subjects with On-Treatment Adverse Events
Occurring in >=10% of Patients or in >=10 and >=1% of Patients

System Organ Class/Preferred Term	Placebo (N=68)	Mepolizumab 300 mg SC (N=68)	Odds Ratio (Exact 95% CI)	Relative Risk (Exact 95% CI) [1]	Risk Difference (Exact 95% CI) [1]	p-value [2]
Skin and subcutaneous tissue disorders	13 (19%)	30 (44%)	3.34 (1.46,7.87)	2.31 (1.30,4.35)	0.25 (0.08,0.40)	0.003
Rash	6 (9%)	9 (13%)	1.58 (0.47,5.72)	1.50 (0.55,4.35)	0.04 (-0.07,0.16)	0.585
Injury, poisoning and procedural complications	10 (15%)	22 (32%)	2.77 (1.12,7.20)	2.20 (1.06,4.79)	0.18 (0.03,0.32)	0.025
Investigations	11 (16%)	15 (22%)	1.47 (0.57,3.86)	1.36 (0.66,3.24)	0.06 (-0.08,0.20)	0.514
Eye disorders	9 (13%)	16 (24%)	2.02 (0.76,5.62)	1.78 (0.85,4.09)	0.10 (-0.03,0.24)	0.183
Ear and labyrinth disorders	10 (15%)	13 (19%)	1.37 (0.51,3.80)	1.30 (0.61,3.24)	0.04 (-0.09,0.18)	0.648
Vascular disorders	2 (3%)	9 (13%)	5.03 (0.98,49.21)	4.50 (1.05,51.72)	0.10 (0.01,0.21)	0.055

Note: Includes all SOC and PT which meet the given criteria in any treatment arm. If SOC meets the criteria but none of it's PT meets the criteria then only the SOC is displayed.
[1] Exact unconditional CI calculated by inverting two separate one-sided tests based on the score statistic.
[2] 2-sided Fisher's Exact p-value.

Protocol: MEA115921
Population: Safety

Table 3.4
Summary and Analysis of Proportion of Subjects with On-Treatment Adverse Events
Occurring in >=10% of Patients or in >=10 and >=1% of Patients by Subgroup

System Organ Class: Skin and subcutaneous tissue disorders

	Placebo (N=68)	Mepolizumab 300 mg SC (N=68)	Odds Ratio (Exact 95% CI)	Relative Risk (Exact 95% CI) [1]	Risk Difference (Exact 95% CI) [1]	p-value [2]
Subgroups						
Age (Years)						
<50	8/32 (25%)	19/32 (59%)	4.38 (1.35,14.76)	2.38 (1.16,5.77)	0.34 (0.10,0.56)	0.011
>=50	5/36 (14%)	11/36 (31%)	2.73 (0.74,11.24)	2.20 (0.88,8.77)	0.17 (-0.03,0.36)	0.155
Gender						
Male	5/30 (17%)	11/26 (42%)	3.67 (0.93,15.88)	2.54 (1.04,9.48)	0.26 (0.01,0.49)	0.043
Female	8/38 (21%)	19/42 (45%)	3.10 (1.05,9.60)	2.15 (1.05,5.29)	0.24 (0.02,0.44)	0.033
Region						
Europe	7/33 (21%)	13/32 (41%)	2.54 (0.76,8.96)	1.92 (0.88,4.70)	0.19 (-0.04,0.41)	0.112
Rest of World	6/35 (17%)	17/36 (47%)	4.32 (1.30,15.61)	2.75 (1.14,10.38)	0.30 (0.07,0.50)	0.011
Baseline Blood Eosinophils						
<0.150 GI/L	5/28 (18%)	14/29 (48%)	4.29 (1.13,18.09)	2.70 (1.11,13.91)	0.30 (0.05,0.53)	0.024
>=0.150 GI/L	8/40 (20%)	16/39 (41%)	2.78 (0.92,8.77)	2.05 (1.01,4.76)	0.21 (0.00,0.41)	0.053

Note: Includes all SOC and PT which meet the given criteria in any treatment arm and where Fisher's Exact p-value <0.05.
Note: Information presented as number of subjects with event / number subjects in the subgroup.
[1] Exact unconditional CI calculated by inverting two separate one-sided tests based on the score statistic.
[2] 2-sided Fisher's Exact p-value.

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Population: Safety

Table 3.4
Summary and Analysis of Proportion of Subjects with On-Treatment Adverse Events
Occurring in >=10% of Patients or in >=10 and >=1% of Patients by Subgroup

System Organ Class: Skin and subcutaneous tissue disorders

	Placebo (N=68)	Mepolizumab 300 mg SC (N=68)	Odds Ratio (Exact 95% CI)	Relative Risk (Exact 95% CI) [1]	Risk Difference (Exact 95% CI) [1]	p-value [2]
Duration of Disease (Years)						
<=4 years	5/32 (16%)	17/34 (50%)	5.40 (1.50,21.75)	3.20 (1.31,13.89)	0.34 (0.10,0.55)	0.004
>4 years	8/36 (22%)	13/34 (38%)	2.17 (0.68,7.16)	1.72 (0.81,4.05)	0.16 (-0.06,0.38)	0.194

Note: Includes all SOC and PT which meet the given criteria in any treatment arm and where Fisher's Exact p-value <0.05.
Note: Information presented as number of subjects with event / number subjects in the subgroup.
[1] Exact unconditional CI calculated by inverting two separate one-sided tests based on the score statistic.
[2] 2-sided Fisher's Exact p-value.

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Protocol: MEA115921
Population: Safety

Table 3.4
Summary and Analysis of Proportion of Subjects with On-Treatment Adverse Events
Occurring in >=10% of Patients or in >=10 and >=1% of Patients by Subgroup

System Organ Class: Injury, poisoning and procedural complications

	Placebo (N=68)	Mepolizumab 300 mg SC (N=68)	Odds Ratio (Exact 95% CI)	Relative Risk (Exact 95% CI) [1]	Risk Difference (Exact 95% CI) [1]	p-value [2]
Subgroups						
Age (Years)						
<50	4/32 (13%)	6/32 (19%)	1.62 (0.34,8.64)	1.50 (0.45,5.97)	0.06 (-0.13,0.26)	0.732
>=50	6/36 (17%)	16/36 (44%)	4.00 (1.20,14.45)	2.67 (1.14,9.47)	0.28 (0.06,0.48)	0.020
Gender						
Male	3/30 (10%)	8/26 (31%)	4.00 (0.80,25.91)	3.08 (0.97,17.06)	0.21 (-0.01,0.43)	0.090
Female	7/38 (18%)	14/42 (33%)	2.21 (0.70,7.41)	1.81 (0.83,4.93)	0.15 (-0.05,0.34)	0.203
Region						
Europe	3/33 (9%)	10/32 (31%)	4.55 (0.99,28.06)	3.44 (1.08,15.34)	0.22 (0.02,0.42)	0.033
Rest of World	7/35 (20%)	12/36 (33%)	2.00 (0.60,6.97)	1.67 (0.73,4.11)	0.13 (-0.08,0.34)	0.285
Baseline Blood Eosinophils						
<0.150 GI/L	5/28 (18%)	9/29 (31%)	2.07 (0.51,9.13)	1.74 (0.65,5.56)	0.13 (-0.10,0.36)	0.358
>=0.150 GI/L	5/40 (13%)	13/39 (33%)	3.50 (1.00,13.95)	2.67 (1.05,13.36)	0.21 (0.02,0.39)	0.034

Note: Includes all SOC and PT which meet the given criteria in any treatment arm and where Fisher's Exact p-value <0.05.
Note: Information presented as number of subjects with event / number subjects in the subgroup.
[1] Exact unconditional CI calculated by inverting two separate one-sided tests based on the score statistic.
[2] 2-sided Fisher's Exact p-value.

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Protocol: MEA115921
Population: Safety

Table 3.4
Summary and Analysis of Proportion of Subjects with On-Treatment Adverse Events
Occurring in >=10% of Patients or in >=10 and >=1% of Patients by Subgroup

System Organ Class: Injury, poisoning and procedural complications

	Placebo (N=68)	Mepolizumab 300 mg SC (N=68)	Odds Ratio (Exact 95% CI)	Relative Risk (Exact 95% CI) [1]	Risk Difference (Exact 95% CI) [1]	p-value [2]
Duration of Disease (Years)						
<=4 years	7/32 (22%)	9/34 (26%)	1.29 (0.36,4.74)	1.21 (0.48,3.11)	0.05 (-0.17,0.26)	0.777
>4 years	3/36 (8%)	13/34 (38%)	6.81 (1.56,40.54)	4.59 (1.44,35.18)	0.30 (0.09,0.49)	0.004

Note: Includes all SOC and PT which meet the given criteria in any treatment arm and where Fisher's Exact p-value <0.05.
Note: Information presented as number of subjects with event / number subjects in the subgroup.
[1] Exact unconditional CI calculated by inverting two separate one-sided tests based on the score statistic.
[2] 2-sided Fisher's Exact p-value.

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Protocol: MEA115921
Population: Safety

Table 3.8
Summary and Analysis of Proportion of Subjects with On-Treatment Non-Fatal Serious Adverse Events
Overall and by Subgroup

	Placebo (N=68)	Mepolizumab 300 mg SC (N=68)	Odds Ratio (Exact 95% CI)	Relative Risk (Exact 95% CI) [1]	Risk Difference (Exact 95% CI) [1]	p-value [2]
All Subjects	18 (26%)	11 (16%)	0.54 (0.21,1.34)	0.61 (0.29,1.19)	-0.10 (-0.25,0.04)	0.209
Subgroups						
Age (Years)						
<50	6/32 (19%)	5/32 (16%)	0.80 (0.17,3.61)	0.83 (0.25,2.70)	-0.03 (-0.23,0.17)	>0.999
>=50	12/36 (33%)	6/36 (17%)	0.40 (0.11,1.38)	0.50 (0.17,1.17)	-0.17 (-0.37,0.04)	0.173
Gender						
Male	7/30 (23%)	4/26 (15%)	0.60 (0.11,2.77)	0.66 (0.14,2.01)	-0.08 (-0.29,0.15)	0.517
Female	11/38 (29%)	7/42 (17%)	0.49 (0.14,1.62)	0.58 (0.22,1.35)	-0.12 (-0.31,0.07)	0.284
Region						
Europe	10/33 (30%)	4/32 (13%)	0.33 (0.07,1.35)	0.41 (0.07,1.13)	-0.18 (-0.38,0.03)	0.130
Rest of World	8/35 (23%)	7/36 (19%)	0.81 (0.22,2.98)	0.85 (0.31,2.25)	-0.03 (-0.23,0.17)	0.778
Baseline Blood Eosinophils						
<0.150 GI/L	7/28 (25%)	8/29 (28%)	1.14 (0.30,4.44)	1.10 (0.44,3.04)	0.03 (-0.22,0.26)	>0.999
>=0.150 GI/L	11/40 (28%)	3/39 (8%)	0.22 (0.04,0.95)	0.28 (0.05,0.93)	-0.20 (-0.37,-0.03)	0.037
Duration of Disease (Years)						
<=4 years	7/32 (22%)	2/34 (6%)	0.22 (0.02,1.34)	0.27 (0.03,1.08)	-0.16 (-0.35,0.02)	0.079
>4 years	11/36 (31%)	9/34 (26%)	0.82 (0.25,2.62)	0.87 (0.35,1.88)	-0.04 (-0.25,0.18)	0.794

Note: Information presented as number of subjects with event / number subjects in the subgroup.
[1] Exact unconditional CI calculated by inverting two separate one-sided tests based on the score statistic.
[2] 2-sided Fisher's Exact p-value.

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Protocol: MEA115921
Population: Safety

Table 3.6
Summary and Analysis of Proportion of Subjects with On-Treatment Adverse Events Leading to Permanent Discontinuation of Study Treatment/Study Withdrawal Overall and by Subgroup

	Placebo (N=68)	Mepolizumab 300 mg SC (N=68)	Odds Ratio (Exact 95% CI)	Relative Risk (Exact 95% CI) [1]	Risk Difference (Exact 95% CI) [1]	p-value [2]
All Subjects	1 (1%)	2 (3%)	2.03 (0.10,121.54)	2.00 (0.18,54.34)	0.01 (-0.06,0.09)	>0.999
Subgroups						
Age (Years)						
<50	0/32	1/32 (3%)	Inf (0.05,Inf)	Inf (0.07,Inf)	0.03 (-0.08,0.17)	>0.999
>=50	1/36 (3%)	1/36 (3%)	1.00 (0.01,80.71)	1.00 (0.03,33.24)	0.00 (-0.12,0.12)	>0.999
Gender						
Male	0/30	2/26 (8%)	Inf (0.34,Inf)	Inf (0.44,Inf)	0.08 (-0.05,0.25)	0.211
Female	1/38 (3%)	0/42	0.00 (0.00,17.19)	0.00 (0.00,13.16)	-0.03 (-0.14,0.06)	0.475
Region						
Europe	0/33	1/32 (3%)	Inf (0.05,Inf)	Inf (0.07,Inf)	0.03 (-0.08,0.16)	0.492
Rest of World	1/35 (3%)	1/36 (3%)	0.97 (0.01,78.47)	0.97 (0.03,32.32)	0.00 (-0.12,0.12)	>0.999
Baseline Blood Eosinophils						
<0.150 GI/L	0/28	1/29 (3%)	Inf (0.05,Inf)	Inf (0.07,Inf)	0.03 (-0.09,0.19)	>0.999
>=0.150 GI/L	1/40 (3%)	1/39 (3%)	1.03 (0.01,82.60)	1.03 (0.03,34.12)	0.00 (-0.11,0.12)	>0.999
Duration of Disease (Years)						
<=4 years	0/32	2/34 (6%)	Inf (0.27,Inf)	Inf (0.36,Inf)	0.06 (-0.06,0.20)	0.493
>4 years	1/36 (3%)	0/34	0.00 (0.00,20.12)	0.00 (0.00,15.36)	-0.03 (-0.15,0.08)	>0.999

Note: Information presented as number of subjects with event / number subjects in the subgroup.
[1] Exact unconditional CI calculated by inverting two separate one-sided tests based on the score statistic.
[2] 2-sided Fisher's Exact p-value.

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Protocol: MEA115921
Population: Safety

Table 3.14
Summary and Analysis of Proportion of Subjects with On-Treatment Serious Adverse Events and Adverse Events of Special Interest by Age

Age: <50 Years

	Placebo (N=68)	Mepolizumab 300 mg SC (N=68)	Odds Ratio (Exact 95% CI)	Relative Risk (Exact 95% CI) [7]	Risk Difference (Exact 95% CI) [7]	p-value [8]
Number of Subjects in Subgroup	32	32				
Risks						
Serious Adverse Events	6 (19%)	6 (19%)	1.00 (0.23,4.29)	1.00 (0.32,3.17)	0.00 (-0.20,0.20)	>0.999
Systemic Reactions[1]	0	2 (6%)	Inf (0.29,Inf)	Inf (0.38,Inf)	0.06 (-0.05,0.21)	0.492
Systemic Reactions (Hypersensitivity)[2]	0	2 (6%)	Inf (0.29,Inf)	Inf (0.38,Inf)	0.06 (-0.05,0.21)	0.492
Systemic Reactions (Non-Allergic) [2]	0	0				

Note: Only On-Treatment Adverse Events have been included in this table.
[1] Systemic Reactions & Local Injection Site Reactions were defined by the Investigator.
[2] Systemic Reactions (Non-Allergic) were defined based on preferred terms: Injection related reaction, Administration related reaction or Infusion related reaction. Systemic Reactions (Hypersensitivity) were defined based on preferred terms (all other terms).
[3] Infections obtained via the Infections and infestations System Organ Class.
[4] Neoplasms obtained via the Neoplasms System Organ Class.
[5] Cardiac disorders obtained via the Cardiac disorders System Organ Class.
[6] Identified by the Safety Review Team. [7] Score method, [8] 2-sided Fisher's Exact p-value.

PPD

Table 3.14
Summary and Analysis of Proportion of Subjects with On-Treatment Serious Adverse Events and Adverse Events of Special Interest by Age

Age: <50 Years

	Placebo (N=68)	Mepolizumab 300 mg SC (N=68)	Odds Ratio (Exact 95% CI)	Relative Risk (Exact 95% CI) [7]	Risk Difference (Exact 95% CI) [7]	p-value [8]
Local Injection Site Reactions[1]	8 (25%)	5 (16%)	0.56 (0.13,2.26)	0.63 (0.19,1.75)	-0.09 (-0.30,0.11)	0.536
Anaphylaxis	0	0				
All Infections[3]	27 (84%)	28 (88%)	1.30 (0.25,7.24)	1.04 (0.83,1.33)	0.03 (-0.16,0.23)	>0.999
Serious Infections	5 (16%)	1 (3%)	0.17 (0.00,1.74)	0.20 (0.01,1.33)	-0.13 (-0.30,0.03)	0.196
Opportunistic Infections[6]	0	3 (9%)	Inf (0.60,Inf)	Inf (0.70,Inf)	0.09 (-0.02,0.26)	0.238
Neoplasms[4]	1 (3%)	0	0.00 (0.00,19.00)	0.00 (0.00,14.49)	-0.03 (-0.17,0.08)	>0.999
Malignancies[6]	1 (3%)	0	0.00 (0.00,19.00)	0.00 (0.00,14.49)	-0.03 (-0.17,0.08)	>0.999
Cardiac Disorders[5]	2 (6%)	2 (6%)	1.00 (0.07,14.63)	1.00 (0.07,14.75)	0.00 (-0.15,0.15)	>0.999

Note: Only On-Treatment Adverse Events have been included in this table.
[1] Systemic Reactions & Local Injection Site Reactions were defined by the Investigator.
[2] Systemic Reactions (Non-Allergic) were defined based on preferred terms: Injection related reaction, Administration related reaction or Infusion related reaction. Systemic Reactions (Hypersensitivity) were defined based on preferred terms (all other terms).
[3] Infections obtained via the Infections and infestations System Organ Class.
[4] Neoplasms obtained via the Neoplasms System Organ Class.
[5] Cardiac disorders obtained via the Cardiac disorders System Organ Class.
[6] Identified by the Safety Review Team. [7] Score method, [8] 2-sided Fisher's Exact p-value.

PPD

Table 3.14
Summary and Analysis of Proportion of Subjects with On-Treatment Serious Adverse Events and Adverse Events of Special Interest by Age

Age: <50 Years

	Placebo (N=68)	Mepolizumab 300 mg SC (N=68)	Odds Ratio (Exact 95% CI)	Relative Risk (Exact 95% CI) [7]	Risk Difference (Exact 95% CI) [7]	p-value [8]
Serious Cardiac Disorders	0	1 (3%)	Inf (0.05,Inf)	Inf (0.07,Inf)	0.03 (-0.08,0.17)	>0.999
Serious Cardiac, Vascular & Thromboembolic events[6]	0	1 (3%)	Inf (0.05,Inf)	Inf (0.07,Inf)	0.03 (-0.08,0.17)	>0.999
Serious Ischemic Events[6]	0	0				

Note: Only On-Treatment Adverse Events have been included in this table.
[1] Systemic Reactions & Local Injection Site Reactions were defined by the Investigator.
[2] Systemic Reactions (Non-Allergic) were defined based on preferred terms: Injection related reaction, Administration related reaction or Infusion related reaction. Systemic Reactions (Hypersensitivity) were defined based on preferred terms (all other terms).
[3] Infections obtained via the Infections and infestations System Organ Class.
[4] Neoplasms obtained via the Neoplasms System Organ Class.
[5] Cardiac disorders obtained via the Cardiac disorders System Organ Class.
[6] Identified by the Safety Review Team. [7] Score method, [8] 2-sided Fisher's Exact p-value.

PPD

Table 3.14
Summary and Analysis of Proportion of Subjects with On-Treatment Serious Adverse Events and Adverse Events of Special Interest by Age

Age: >=50 Years

	Placebo (N=68)	Mepolizumab 300 mg SC (N=68)	Odds Ratio (Exact 95% CI)	Relative Risk (Exact 95% CI) [7]	Risk Difference (Exact 95% CI) [7]	p-value [8]
Number of Subjects in Subgroup	36	36				
Risks						
Serious Adverse Events	12 (33%)	6 (17%)	0.40 (0.11,1.38)	0.50 (0.17,1.17)	-0.17 (-0.37,0.04)	0.173
Systemic Reactions[1]	1 (3%)	2 (6%)	2.06 (0.10,124.88)	2.00 (0.18,54.26)	0.03 (-0.10,0.16)	>0.999
Systemic Reactions (Hypersensitivity)[2]	1 (3%)	1 (3%)	1.00 (0.01,80.71)	1.00 (0.03,33.24)	0.00 (-0.12,0.12)	>0.999
Systemic Reactions (Non-Allergic) [2]	0	1 (3%)	Inf (0.05,Inf)	Inf (0.07,Inf)	0.03 (-0.08,0.15)	>0.999

Note: Only On-Treatment Adverse Events have been included in this table.
[1] Systemic Reactions & Local Injection Site Reactions were defined by the Investigator.
[2] Systemic Reactions (Non-Allergic) were defined based on preferred terms: Injection related reaction, Administration related reaction or Infusion related reaction. Systemic Reactions (Hypersensitivity) were defined based on preferred terms (all other terms).
[3] Infections obtained via the Infections and infestations System Organ Class.
[4] Neoplasms obtained via the Neoplasms System Organ Class.
[5] Cardiac disorders obtained via the Cardiac disorders System Organ Class.
[6] Identified by the Safety Review Team. [7] Score method, [8] 2-sided Fisher's Exact p-value.

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Protocol: MEA115921
Population: Safety

Table 3.14
Summary and Analysis of Proportion of Subjects with On-Treatment Serious Adverse Events and Adverse Events of Special Interest by Age

Age: >=50 Years

	Placebo (N=68)	Mepolizumab 300 mg SC (N=68)	Odds Ratio (Exact 95% CI)	Relative Risk (Exact 95% CI) [7]	Risk Difference (Exact 95% CI) [7]	p-value [8]
Local Injection Site Reactions[1]	1 (3%)	5 (14%)	5.65 (0.57,274.46)	5.00 (0.74,126.69)	0.11 (-0.03,0.27)	0.199
Anaphylaxis	0	0				
All Infections[3]	26 (72%)	29 (81%)	1.59 (0.46,5.68)	1.12 (0.84,1.52)	0.08 (-0.12,0.29)	0.580
Serious Infections	5 (14%)	3 (8%)	0.56 (0.08,3.20)	0.60 (0.07,2.57)	-0.06 (-0.22,0.11)	0.710
Opportunistic Infections[6]	2 (6%)	2 (6%)	1.00 (0.07,14.53)	1.00 (0.07,14.77)	0.00 (-0.14,0.14)	>0.999
Neoplasms[4]	2 (6%)	1 (3%)	0.49 (0.01,9.83)	0.50 (0.02,5.43)	-0.03 (-0.16,0.10)	>0.999
Malignancies[6]	1 (3%)	0	0.00 (0.00,19.00)	0.00 (0.00,14.52)	-0.03 (-0.15,0.08)	>0.999
Cardiac Disorders[5]	4 (11%)	2 (6%)	0.47 (0.04,3.58)	0.50 (0.07,2.71)	-0.06 (-0.21,0.09)	0.674

Note: Only On-Treatment Adverse Events have been included in this table.
[1] Systemic Reactions & Local Injection Site Reactions were defined by the Investigator.
[2] Systemic Reactions (Non-Allergic) were defined based on preferred terms: Injection related reaction, Administration related reaction or Infusion related reaction. Systemic Reactions (Hypersensitivity) were defined based on preferred terms (all other terms).
[3] Infections obtained via the Infections and infestations System Organ Class.
[4] Neoplasms obtained via the Neoplasms System Organ Class.
[5] Cardiac disorders obtained via the Cardiac disorders System Organ Class.
[6] Identified by the Safety Review Team. [7] Score method, [8] 2-sided Fisher's Exact p-value.

PPD

Table 3.14
Summary and Analysis of Proportion of Subjects with On-Treatment Serious Adverse Events and Adverse Events of Special Interest by Age

Age: >=50 Years

	Placebo (N=68)	Mepolizumab 300 mg SC (N=68)	Odds Ratio (Exact 95% CI)	Relative Risk (Exact 95% CI) [7]	Risk Difference (Exact 95% CI) [7]	p-value [8]
Serious Cardiac Disorders	2 (6%)	0	0.00 (0.00,3.45)	0.00 (0.00,2.65)	-0.06 (-0.19,0.05)	0.493
Serious Cardiac, Vascular & Thromboembolic events[6]	2 (6%)	1 (3%)	0.49 (0.01,9.83)	0.50 (0.02,5.43)	-0.03 (-0.16,0.10)	>0.999
Serious Ischemic Events[6]	2 (6%)	1 (3%)	0.49 (0.01,9.83)	0.50 (0.02,5.43)	-0.03 (-0.16,0.10)	>0.999

Note: Only On-Treatment Adverse Events have been included in this table.
[1] Systemic Reactions & Local Injection Site Reactions were defined by the Investigator.
[2] Systemic Reactions (Non-Allergic) were defined based on preferred terms: Injection related reaction, Administration related reaction or Infusion related reaction. Systemic Reactions (Hypersensitivity) were defined based on preferred terms (all other terms).
[3] Infections obtained via the Infections and infestations System Organ Class.
[4] Neoplasms obtained via the Neoplasms System Organ Class.
[5] Cardiac disorders obtained via the Cardiac disorders System Organ Class.
[6] Identified by the Safety Review Team. [7] Score method, [8] 2-sided Fisher's Exact p-value.

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Protocol: MEA115921
Population: Safety

Table 3.15
Summary and Analysis of Proportion of Subjects with On-Treatment Serious Adverse Events and Adverse Events of Special Interest by Gender

Gender: Male

	Placebo (N=68)	Mepolizumab 300 mg SC (N=68)	Odds Ratio (Exact 95% CI)	Relative Risk (Exact 95% CI) [7]	Risk Difference (Exact 95% CI) [7]	p-value [8]
Number of Subjects in Subgroup	30	26				
Risks						
Serious Adverse Events	7 (23%)	5 (19%)	0.78 (0.17,3.40)	0.82 (0.27,2.32)	-0.04 (-0.26,0.19)	0.755
Systemic Reactions[1]	0	2 (8%)	Inf (0.34,Inf)	Inf (0.44,Inf)	0.08 (-0.05,0.25)	0.211
Systemic Reactions (Hypersensitivity)[2]	0	1 (4%)	Inf (0.06,Inf)	Inf (0.08,Inf)	0.04 (-0.08,0.20)	0.464
Systemic Reactions (Non-Allergic)[2]	0	1 (4%)	Inf (0.06,Inf)	Inf (0.08,Inf)	0.04 (-0.08,0.20)	0.464

Note: Only On-Treatment Adverse Events have been included in this table.
[1] Systemic Reactions & Local Injection Site Reactions were defined by the Investigator.
[2] Systemic Reactions (Non-Allergic) were defined based on preferred terms: Injection related reaction, Administration related reaction or Infusion related reaction. Systemic Reactions (Hypersensitivity) were defined based on preferred terms (all other terms).
[3] Infections obtained via the Infections and infestations System Organ Class.
[4] Neoplasms obtained via the Neoplasms System Organ Class.
[5] Cardiac disorders obtained via the Cardiac disorders System Organ Class.
[6] Identified by the Safety Review Team. [7] Score method, [8] 2-sided Fisher's Exact p-value.

PPD

Table 3.15
Summary and Analysis of Proportion of Subjects with On-Treatment Serious Adverse Events and Adverse Events of Special Interest by Gender

Gender: Male

	Placebo (N=68)	Mepolizumab 300 mg SC (N=68)	Odds Ratio (Exact 95% CI)	Relative Risk (Exact 95% CI) [7]	Risk Difference (Exact 95% CI) [7]	p-value [8]
Local Injection Site Reactions[1]	2 (7%)	2 (8%)	1.17 (0.08,17.19)	1.15 (0.08,16.95)	0.01 (-0.15,0.19)	>0.999
Anaphylaxis	0	0				
All Infections[3]	22 (73%)	20 (77%)	1.21 (0.30,5.03)	1.05 (0.75,1.49)	0.04 (-0.21,0.27)	>0.999
Serious Infections	2 (7%)	1 (4%)	0.56 (0.01,11.48)	0.58 (0.02,6.19)	-0.03 (-0.19,0.15)	>0.999
Opportunistic Infections[6]	1 (3%)	1 (4%)	1.16 (0.01,94.15)	1.15 (0.03,38.23)	0.01 (-0.15,0.17)	>0.999
Neoplasms[4]	2 (7%)	0	0.00 (0.00,3.98)	0.00 (0.00,3.02)	-0.07 (-0.22,0.07)	0.494
Malignancies[6]	2 (7%)	0	0.00 (0.00,3.98)	0.00 (0.00,3.02)	-0.07 (-0.22,0.07)	0.494
Cardiac Disorders[5]	2 (7%)	3 (12%)	1.83 (0.19,23.36)	1.73 (0.29,17.06)	0.05 (-0.12,0.25)	0.655

Note: Only On-Treatment Adverse Events have been included in this table.
[1] Systemic Reactions & Local Injection Site Reactions were defined by the Investigator.
[2] Systemic Reactions (Non-Allergic) were defined based on preferred terms: Injection related reaction, Administration related reaction or Infusion related reaction. Systemic Reactions (Hypersensitivity) were defined based on preferred terms (all other terms).
[3] Infections obtained via the Infections and infestations System Organ Class.
[4] Neoplasms obtained via the Neoplasms System Organ Class.
[5] Cardiac disorders obtained via the Cardiac disorders System Organ Class.
[6] Identified by the Safety Review Team. [7] Score method, [8] 2-sided Fisher's Exact p-value.

PPD

Table 3.15
Summary and Analysis of Proportion of Subjects with On-Treatment Serious Adverse Events and Adverse Events of Special Interest by Gender

Gender: Male

	Placebo (N=68)	Mepolizumab 300 mg SC (N=68)	Odds Ratio (Exact 95% CI)	Relative Risk (Exact 95% CI) [7]	Risk Difference (Exact 95% CI) [7]	p-value [8]
Serious Cardiac Disorders	0	1 (4%)	Inf (0.06,Inf)	Inf (0.08,Inf)	0.04 (-0.08,0.20)	0.464
Serious Cardiac, Vascular & Thromboembolic events[6]	0	1 (4%)	Inf (0.06,Inf)	Inf (0.08,Inf)	0.04 (-0.08,0.20)	0.464
Serious Ischemic Events[6]	0	0				

Note: Only On-Treatment Adverse Events have been included in this table.
[1] Systemic Reactions & Local Injection Site Reactions were defined by the Investigator.
[2] Systemic Reactions (Non-Allergic) were defined based on preferred terms: Injection related reaction, Administration related reaction or Infusion related reaction. Systemic Reactions (Hypersensitivity) were defined based on preferred terms (all other terms).
[3] Infections obtained via the Infections and infestations System Organ Class.
[4] Neoplasms obtained via the Neoplasms System Organ Class.
[5] Cardiac disorders obtained via the Cardiac disorders System Organ Class.
[6] Identified by the Safety Review Team. [7] Score method, [8] 2-sided Fisher's Exact p-value.

PPD

Table 3.15
Summary and Analysis of Proportion of Subjects with On-Treatment Serious Adverse Events and Adverse Events of Special Interest by Gender

Gender: Female

	Placebo (N=68)	Mepolizumab 300 mg SC (N=68)	Odds Ratio (Exact 95% CI)	Relative Risk (Exact 95% CI) [7]	Risk Difference (Exact 95% CI) [7]	p-value [8]
Number of Subjects in Subgroup	38	42				
Risks						
Serious Adverse Events	11 (29%)	7 (17%)	0.49 (0.14,1.62)	0.58 (0.22,1.35)	-0.12 (-0.31,0.07)	0.284
Systemic Reactions[1]	1 (3%)	2 (5%)	1.85 (0.09,112.05)	1.81 (0.17,49.11)	0.02 (-0.10,0.14)	>0.999
Systemic Reactions (Hypersensitivity)[2]	1 (3%)	2 (5%)	1.85 (0.09,112.05)	1.81 (0.17,49.11)	0.02 (-0.10,0.14)	>0.999
Systemic Reactions (Non-Allergic) [2]	0	0				

Note: Only On-Treatment Adverse Events have been included in this table.
[1] Systemic Reactions & Local Injection Site Reactions were defined by the Investigator.
[2] Systemic Reactions (Non-Allergic) were defined based on preferred terms: Injection related reaction, Administration related reaction or Infusion related reaction. Systemic Reactions (Hypersensitivity) were defined based on preferred terms (all other terms).
[3] Infections obtained via the Infections and infestations System Organ Class.
[4] Neoplasms obtained via the Neoplasms System Organ Class.
[5] Cardiac disorders obtained via the Cardiac disorders System Organ Class.
[6] Identified by the Safety Review Team. [7] Score method, [8] 2-sided Fisher's Exact p-value.

PPD

Table 3.15
Summary and Analysis of Proportion of Subjects with On-Treatment Serious Adverse Events and Adverse Events of Special Interest by Gender

Gender: Female

	Placebo (N=68)	Mepolizumab 300 mg SC (N=68)	Odds Ratio (Exact 95% CI)	Relative Risk (Exact 95% CI) [7]	Risk Difference (Exact 95% CI) [7]	p-value [8]
Local Injection Site Reactions[1]	7 (18%)	8 (19%)	1.04 (0.29,3.81)	1.03 (0.38,2.90)	0.01 (-0.18,0.19)	>0.999
Anaphylaxis	0	0				
All Infections[3]	31 (82%)	37 (88%)	1.67 (0.41,7.34)	1.08 (0.88,1.37)	0.07 (-0.10,0.24)	0.535
Serious Infections	8 (21%)	3 (7%)	0.29 (0.05,1.35)	0.34 (0.06,1.12)	-0.14 (-0.31,0.02)	0.105
Opportunistic Infections[6]	1 (3%)	4 (10%)	3.89 (0.36,196.89)	3.62 (0.51,91.57)	0.07 (-0.06,0.21)	0.362
Neoplasms[4]	1 (3%)	1 (2%)	0.90 (0.01,72.73)	0.90 (0.03,30.11)	0.00 (-0.12,0.11)	>0.999
Malignancies[6]	0	0				
Cardiac Disorders[5]	4 (11%)	1 (2%)	0.21 (0.00,2.26)	0.23 (0.01,1.60)	-0.08 (-0.23,0.04)	0.185

Note: Only On-Treatment Adverse Events have been included in this table.
[1] Systemic Reactions & Local Injection Site Reactions were defined by the Investigator.
[2] Systemic Reactions (Non-Allergic) were defined based on preferred terms: Injection related reaction, Administration related reaction or Infusion related reaction. Systemic Reactions (Hypersensitivity) were defined based on preferred terms (all other terms).
[3] Infections obtained via the Infections and infestations System Organ Class.
[4] Neoplasms obtained via the Neoplasms System Organ Class.
[5] Cardiac disorders obtained via the Cardiac disorders System Organ Class.
[6] Identified by the Safety Review Team. [7] Score method, [8] 2-sided Fisher's Exact p-value.

PPD

Population: Safety

Table 3.15
Summary and Analysis of Proportion of Subjects with On-Treatment Serious Adverse Events and Adverse Events of Special Interest by Gender

Gender: Female

	Placebo (N=68)	Mepolizumab 300 mg SC (N=68)	Odds Ratio (Exact 95% CI)	Relative Risk (Exact 95% CI) [7]	Risk Difference (Exact 95% CI) [7]	p-value [8]
Serious Cardiac Disorders	2 (5%)	0	0.00 (0.00,3.12)	0.00 (0.00,2.40)	-0.05 (-0.18,0.04)	0.222
Serious Cardiac, Vascular & Thromboembolic events[6]	2 (5%)	1 (2%)	0.44 (0.01,8.85)	0.45 (0.02,4.93)	-0.03 (-0.16,0.09)	0.602
Serious Ischemic Events[6]	2 (5%)	1 (2%)	0.44 (0.01,8.85)	0.45 (0.02,4.93)	-0.03 (-0.16,0.09)	0.602

Note: Only On-Treatment Adverse Events have been included in this table.
[1] Systemic Reactions & Local Injection Site Reactions were defined by the Investigator.
[2] Systemic Reactions (Non-Allergic) were defined based on preferred terms: Injection related reaction, Administration related reaction or Infusion related reaction. Systemic Reactions (Hypersensitivity) were defined based on preferred terms (all other terms).
[3] Infections obtained via the Infections and infestations System Organ Class.
[4] Neoplasms obtained via the Neoplasms System Organ Class.
[5] Cardiac disorders obtained via the Cardiac disorders System Organ Class.
[6] Identified by the Safety Review Team. [7] Score method, [8] 2-sided Fisher's Exact p-value.

Protocol: MEA115921
Population: Safety

Table 3.16
Summary and Analysis of Proportion of Subjects with On-Treatment Serious Adverse Events and Adverse Events of Special Interest by Region

Region: Europe

	Placebo (N=68)	Mepolizumab 300 mg SC (N=68)	Odds Ratio (Exact 95% CI)	Relative Risk (Exact 95% CI) [7]	Risk Difference (Exact 95% CI) [7]	p-value [8]
Number of Subjects in Subgroup	33	32				
Risks						
Serious Adverse Events	10 (30%)	4 (13%)	0.33 (0.07,1.35)	0.41 (0.07,1.13)	-0.18 (-0.38,0.03)	0.130
Systemic Reactions[1]	0	3 (9%)	Inf (0.62,Inf)	Inf (0.72,Inf)	0.09 (-0.03,0.25)	0.114
Systemic Reactions (Hypersensitivity)[2]	0	2 (6%)	Inf (0.30,Inf)	Inf (0.39,Inf)	0.06 (-0.05,0.21)	0.238
Systemic Reactions (Non-Allergic) [2]	0	1 (3%)	Inf (0.05,Inf)	Inf (0.07,Inf)	0.03 (-0.08,0.16)	0.492

Note: Only On-Treatment Adverse Events have been included in this table.
[1] Systemic Reactions & Local Injection Site Reactions were defined by the Investigator.
[2] Systemic Reactions (Non-Allergic) were defined based on preferred terms: Injection related reaction, Administration related reaction or Infusion related reaction. Systemic Reactions (Hypersensitivity) were defined based on preferred terms (all other terms).
[3] Infections obtained via the Infections and infestations System Organ Class.
[4] Neoplasms obtained via the Neoplasms System Organ Class.
[5] Cardiac disorders obtained via the Cardiac disorders System Organ Class.
[6] Identified by the Safety Review Team. [7] Score method, [8] 2-sided Fisher's Exact p-value.

PPD

Table 3.16
Summary and Analysis of Proportion of Subjects with On-Treatment Serious Adverse Events and Adverse Events of Special Interest by Region

Region: Europe

	Placebo (N=68)	Mepolizumab 300 mg SC (N=68)	Odds Ratio (Exact 95% CI)	Relative Risk (Exact 95% CI) [7]	Risk Difference (Exact 95% CI) [7]	p-value [8]
Local Injection Site Reactions[1]	6 (18%)	5 (16%)	0.83 (0.18,3.74)	0.86 (0.26,2.79)	-0.03 (-0.22,0.18)	>0.999
Anaphylaxis	0	0				
All Infections[3]	27 (82%)	29 (91%)	2.15 (0.40,14.43)	1.11 (0.89,1.43)	0.09 (-0.09,0.27)	0.475
Serious Infections	7 (21%)	2 (6%)	0.25 (0.02,1.48)	0.29 (0.03,1.18)	-0.15 (-0.33,0.03)	0.149
Opportunistic Infections[6]	0	1 (3%)	Inf (0.05,Inf)	Inf (0.07,Inf)	0.03 (-0.08,0.16)	0.492
Neoplasms[4]	3 (9%)	0	0.00 (0.00,1.73)	0.00 (0.00,1.47)	-0.09 (-0.24,0.03)	0.238
Malignancies[6]	2 (6%)	0	0.00 (0.00,3.56)	0.00 (0.00,2.72)	-0.06 (-0.21,0.06)	0.492
Cardiac Disorders[5]	2 (6%)	0	0.00 (0.00,3.56)	0.00 (0.00,2.72)	-0.06 (-0.21,0.06)	0.492

Note: Only On-Treatment Adverse Events have been included in this table.
[1] Systemic Reactions & Local Injection Site Reactions were defined by the Investigator.
[2] Systemic Reactions (Non-Allergic) were defined based on preferred terms: Injection related reaction, Administration related reaction or Infusion related reaction. Systemic Reactions (Hypersensitivity) were defined based on preferred terms (all other terms).
[3] Infections obtained via the Infections and infestations System Organ Class.
[4] Neoplasms obtained via the Neoplasms System Organ Class.
[5] Cardiac disorders obtained via the Cardiac disorders System Organ Class.
[6] Identified by the Safety Review Team. [7] Score method, [8] 2-sided Fisher's Exact p-value.

PPD

Table 3.16
Summary and Analysis of Proportion of Subjects with On-Treatment Serious Adverse Events and Adverse Events of Special Interest by Region

Region: Europe

	Placebo (N=68)	Mepolizumab 300 mg SC (N=68)	Odds Ratio (Exact 95% CI)	Relative Risk (Exact 95% CI) [7]	Risk Difference (Exact 95% CI) [7]	p-value [8]
Serious Cardiac Disorders	0	0				
Serious Cardiac, Vascular & Thromboembolic events[6]	0	1 (3%)	Inf (0.05,Inf)	Inf (0.07,Inf)	0.03 (-0.08,0.16)	0.492
Serious Ischemic Events[6]	0	1 (3%)	Inf (0.05,Inf)	Inf (0.07,Inf)	0.03 (-0.08,0.16)	0.492

Note: Only On-Treatment Adverse Events have been included in this table.
[1] Systemic Reactions & Local Injection Site Reactions were defined by the Investigator.
[2] Systemic Reactions (Non-Allergic) were defined based on preferred terms: Injection related reaction, Administration related reaction or Infusion related reaction. Systemic Reactions (Hypersensitivity) were defined based on preferred terms (all other terms).
[3] Infections obtained via the Infections and infestations System Organ Class.
[4] Neoplasms obtained via the Neoplasms System Organ Class.
[5] Cardiac disorders obtained via the Cardiac disorders System Organ Class.
[6] Identified by the Safety Review Team. [7] Score method, [8] 2-sided Fisher's Exact p-value.

PPD

Table 3.16
Summary and Analysis of Proportion of Subjects with On-Treatment Serious Adverse Events and Adverse Events of Special Interest by Region

Region: Rest of World

	Placebo (N=68)	Mepolizumab 300 mg SC (N=68)	Odds Ratio (Exact 95% CI)	Relative Risk (Exact 95% CI) [7]	Risk Difference (Exact 95% CI) [7]	p-value [8]
Number of Subjects in Subgroup	35	36				
Risks						
Serious Adverse Events	8 (23%)	8 (22%)	0.96 (0.27,3.42)	0.97 (0.37,2.57)	-0.01 (-0.21,0.20)	>0.999
Systemic Reactions[1]	1 (3%)	1 (3%)	0.97 (0.01,78.47)	0.97 (0.03,32.32)	0.00 (-0.12,0.12)	>0.999
Systemic Reactions (Hypersensitivity)[2]	1 (3%)	1 (3%)	0.97 (0.01,78.47)	0.97 (0.03,32.32)	0.00 (-0.12,0.12)	>0.999
Systemic Reactions (Non-Allergic) [2]	0	0				

Note: Only On-Treatment Adverse Events have been included in this table.
[1] Systemic Reactions & Local Injection Site Reactions were defined by the Investigator.
[2] Systemic Reactions (Non-Allergic) were defined based on preferred terms: Injection related reaction, Administration related reaction or Infusion related reaction. Systemic Reactions (Hypersensitivity) were defined based on preferred terms (all other terms).
[3] Infections obtained via the Infections and infestations System Organ Class.
[4] Neoplasms obtained via the Neoplasms System Organ Class.
[5] Cardiac disorders obtained via the Cardiac disorders System Organ Class.
[6] Identified by the Safety Review Team. [7] Score method, [8] 2-sided Fisher's Exact p-value.

PPD

Table 3.16
Summary and Analysis of Proportion of Subjects with On-Treatment Serious Adverse Events and Adverse Events of Special Interest by Region

Region: Rest of World

	Placebo (N=68)	Mepolizumab 300 mg SC (N=68)	Odds Ratio (Exact 95% CI)	Relative Risk (Exact 95% CI) [7]	Risk Difference (Exact 95% CI) [7]	p-value [8]
Local Injection Site Reactions[1]	3 (9%)	5 (14%)	1.72 (0.30,11.94)	1.62 (0.38,14.12)	0.05 (-0.11,0.23)	0.710
Anaphylaxis	0	0				
All Infections[3]	26 (74%)	28 (78%)	1.21 (0.35,4.20)	1.05 (0.79,1.43)	0.03 (-0.17,0.24)	0.786
Serious Infections	3 (9%)	2 (6%)	0.63 (0.05,5.89)	0.65 (0.07,3.86)	-0.03 (-0.18,0.12)	0.674
Opportunistic Infections[6]	2 (6%)	4 (11%)	2.06 (0.27,24.06)	1.94 (0.36,14.49)	0.05 (-0.09,0.21)	0.674
Neoplasms[4]	0	1 (3%)	Inf (0.05,Inf)	Inf (0.07,Inf)	0.03 (-0.08,0.15)	>0.999
Malignancies[6]	0	0				
Cardiac Disorders[5]	4 (11%)	4 (11%)	0.97 (0.16,5.70)	0.97 (0.23,4.11)	0.00 (-0.17,0.16)	>0.999

Note: Only On-Treatment Adverse Events have been included in this table.
[1] Systemic Reactions & Local Injection Site Reactions were defined by the Investigator.
[2] Systemic Reactions (Non-Allergic) were defined based on preferred terms: Injection related reaction, Administration related reaction or Infusion related reaction. Systemic Reactions (Hypersensitivity) were defined based on preferred terms (all other terms).
[3] Infections obtained via the Infections and infestations System Organ Class.
[4] Neoplasms obtained via the Neoplasms System Organ Class.
[5] Cardiac disorders obtained via the Cardiac disorders System Organ Class.
[6] Identified by the Safety Review Team. [7] Score method, [8] 2-sided Fisher's Exact p-value.

PPD

Table 3.16
Summary and Analysis of Proportion of Subjects with On-Treatment Serious Adverse Events and Adverse Events of Special Interest by Region

Region: Rest of World

	Placebo (N=68)	Mepolizumab 300 mg SC (N=68)	Odds Ratio (Exact 95% CI)	Relative Risk (Exact 95% CI) [7]	Risk Difference (Exact 95% CI) [7]	p-value [8]
Serious Cardiac Disorders	2 (6%)	1 (3%)	0.47 (0.01,9.55)	0.49 (0.02,5.27)	-0.03 (-0.17,0.09)	0.614
Serious Cardiac, Vascular & Thromboembolic events[6]	2 (6%)	1 (3%)	0.47 (0.01,9.55)	0.49 (0.02,5.27)	-0.03 (-0.17,0.09)	0.614
Serious Ischemic Events[6]	2 (6%)	0	0.00 (0.00,3.35)	0.00 (0.00,2.57)	-0.06 (-0.19,0.04)	0.239

Note: Only On-Treatment Adverse Events have been included in this table.
[1] Systemic Reactions & Local Injection Site Reactions were defined by the Investigator.
[2] Systemic Reactions (Non-Allergic) were defined based on preferred terms: Injection related reaction, Administration related reaction or Infusion related reaction. Systemic Reactions (Hypersensitivity) were defined based on preferred terms (all other terms).
[3] Infections obtained via the Infections and infestations System Organ Class.
[4] Neoplasms obtained via the Neoplasms System Organ Class.
[5] Cardiac disorders obtained via the Cardiac disorders System Organ Class.
[6] Identified by the Safety Review Team. [7] Score method, [8] 2-sided Fisher's Exact p-value.

PPD

Protocol: MEA115921
Population: Safety

Table 3.17
Summary and Analysis of Proportion of Subjects with On-Treatment Serious Adverse Events and Adverse Events of Special Interest by Duration of Disease

Duration of Disease: <=4 years

	Placebo (N=68)	Mepolizumab 300 mg SC (N=68)	Odds Ratio (Exact 95% CI)	Relative Risk (Exact 95% CI) [7]	Risk Difference (Exact 95% CI) [7]	p-value [8]
Number of Subjects in Subgroup	32	34				
Risks						
Serious Adverse Events	7 (22%)	3 (9%)	0.35 (0.05,1.74)	0.40 (0.06,1.41)	-0.13 (-0.32,0.05)	0.180
Systemic Reactions[1]	1 (3%)	1 (3%)	0.94 (0.01,76.09)	0.94 (0.03,31.27)	0.00 (-0.14,0.13)	>0.999
Systemic Reactions (Hypersensitivity)[2]	1 (3%)	1 (3%)	0.94 (0.01,76.09)	0.94 (0.03,31.27)	0.00 (-0.14,0.13)	>0.999
Systemic Reactions (Non-Allergic) [2]	0	0				

Note: Only On-Treatment Adverse Events have been included in this table.
[1] Systemic Reactions & Local Injection Site Reactions were defined by the Investigator.
[2] Systemic Reactions (Non-Allergic) were defined based on preferred terms: Injection related reaction, Administration related reaction or Infusion related reaction. Systemic Reactions (Hypersensitivity) were defined based on preferred terms (all other terms).
[3] Infections obtained via the Infections and infestations System Organ Class.
[4] Neoplasms obtained via the Neoplasms System Organ Class.
[5] Cardiac disorders obtained via the Cardiac disorders System Organ Class.
[6] Identified by the Safety Review Team. [7] Score method, [8] 2-sided Fisher's Exact p-value.

PPD

Table 3.17
Summary and Analysis of Proportion of Subjects with On-Treatment Serious Adverse Events and Adverse Events of Special Interest by Duration of Disease

Duration of Disease: <=4 years

	Placebo (N=68)	Mepolizumab 300 mg SC (N=68)	Odds Ratio (Exact 95% CI)	Relative Risk (Exact 95% CI) [7]	Risk Difference (Exact 95% CI) [7]	p-value [8]
Local Injection Site Reactions[1]	2 (6%)	6 (18%)	3.21 (0.51,34.56)	2.82 (0.64,31.28)	0.11 (-0.06,0.29)	0.260
Anaphylaxis	0	0				
All Infections[3]	24 (75%)	27 (79%)	1.29 (0.35,4.84)	1.06 (0.79,1.46)	0.04 (-0.17,0.25)	0.772
Serious Infections	2 (6%)	0	0.00 (0.00,3.24)	0.00 (0.00,2.49)	-0.06 (-0.21,0.05)	0.231
Opportunistic Infections[6]	0	2 (6%)	Inf (0.27,Inf)	Inf (0.36,Inf)	0.06 (-0.06,0.20)	0.493
Neoplasms[4]	3 (9%)	1 (3%)	0.29 (0.01,3.95)	0.31 (0.01,2.98)	-0.06 (-0.22,0.08)	0.348
Malignancies[6]	2 (6%)	0	0.00 (0.00,3.24)	0.00 (0.00,2.49)	-0.06 (-0.21,0.05)	0.231
Cardiac Disorders[5]	3 (9%)	4 (12%)	1.29 (0.20,9.54)	1.25 (0.28,8.59)	0.02 (-0.15,0.20)	>0.999

Note: Only On-Treatment Adverse Events have been included in this table.
[1] Systemic Reactions & Local Injection Site Reactions were defined by the Investigator.
[2] Systemic Reactions (Non-Allergic) were defined based on preferred terms: Injection related reaction, Administration related reaction or Infusion related reaction. Systemic Reactions (Hypersensitivity) were defined based on preferred terms (all other terms).
[3] Infections obtained via the Infections and infestations System Organ Class.
[4] Neoplasms obtained via the Neoplasms System Organ Class.
[5] Cardiac disorders obtained via the Cardiac disorders System Organ Class.
[6] Identified by the Safety Review Team. [7] Score method, [8] 2-sided Fisher's Exact p-value.

Table 3.17
Summary and Analysis of Proportion of Subjects with On-Treatment Serious Adverse Events and Adverse Events of Special Interest by Duration of Disease

Duration of Disease: <=4 years

	Placebo (N=68)	Mepolizumab 300 mg SC (N=68)	Odds Ratio (Exact 95% CI)	Relative Risk (Exact 95% CI) [7]	Risk Difference (Exact 95% CI) [7]	p-value [8]
Serious Cardiac Disorders	1 (3%)	1 (3%)	0.94 (0.01,76.09)	0.94 (0.03,31.27)	0.00 (-0.14,0.13)	>0.999
Serious Cardiac, Vascular & Thromboembolic events[6]	1 (3%)	1 (3%)	0.94 (0.01,76.09)	0.94 (0.03,31.27)	0.00 (-0.14,0.13)	>0.999
Serious Ischemic Events[6]	1 (3%)	0	0.00 (0.00,17.88)	0.00 (0.00,13.65)	-0.03 (-0.17,0.08)	0.485

Note: Only On-Treatment Adverse Events have been included in this table.
[1] Systemic Reactions & Local Injection Site Reactions were defined by the Investigator.
[2] Systemic Reactions (Non-Allergic) were defined based on preferred terms: Injection related reaction, Administration related reaction or Infusion related reaction. Systemic Reactions (Hypersensitivity) were defined based on preferred terms (all other terms).
[3] Infections obtained via the Infections and infestations System Organ Class.
[4] Neoplasms obtained via the Neoplasms System Organ Class.
[5] Cardiac disorders obtained via the Cardiac disorders System Organ Class.
[6] Identified by the Safety Review Team. [7] Score method, [8] 2-sided Fisher's Exact p-value.

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Table 3.17
Summary and Analysis of Proportion of Subjects with On-Treatment Serious Adverse Events and Adverse Events of Special Interest by Duration of Disease

Duration of Disease: >4 years

	Placebo (N=68)	Mepolizumab 300 mg SC (N=68)	Odds Ratio (Exact 95% CI)	Relative Risk (Exact 95% CI) [7]	Risk Difference (Exact 95% CI) [7]	p-value [8]
Number of Subjects in Subgroup	36	34				
Risks						
Serious Adverse Events	11 (31%)	9 (26%)	0.82 (0.25,2.62)	0.87 (0.35,1.88)	-0.04 (-0.25,0.18)	0.794
Systemic Reactions[1]	0	3 (9%)	Inf (0.63,Inf)	Inf (0.74,Inf)	0.09 (-0.02,0.24)	0.109
Systemic Reactions (Hypersensitivity)[2]	0	2 (6%)	Inf (0.31,Inf)	Inf (0.40,Inf)	0.06 (-0.05,0.20)	0.232
Systemic Reactions (Non-Allergic)[2]	0	1 (3%)	Inf (0.06,Inf)	Inf (0.07,Inf)	0.03 (-0.08,0.16)	0.486

Note: Only On-Treatment Adverse Events have been included in this table.
[1] Systemic Reactions & Local Injection Site Reactions were defined by the Investigator.
[2] Systemic Reactions (Non-Allergic) were defined based on preferred terms: Injection related reaction, Administration related reaction or Infusion related reaction. Systemic Reactions (Hypersensitivity) were defined based on preferred terms (all other terms).
[3] Infections obtained via the Infections and infestations System Organ Class.
[4] Neoplasms obtained via the Neoplasms System Organ Class.
[5] Cardiac disorders obtained via the Cardiac disorders System Organ Class.
[6] Identified by the Safety Review Team. [7] Score method, [8] 2-sided Fisher's Exact p-value.

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Table 3.17
Summary and Analysis of Proportion of Subjects with On-Treatment Serious Adverse Events and Adverse Events of Special Interest by Duration of Disease

Duration of Disease: >4 years

	Placebo (N=68)	Mepolizumab 300 mg SC (N=68)	Odds Ratio (Exact 95% CI)	Relative Risk (Exact 95% CI) [7]	Risk Difference (Exact 95% CI) [7]	p-value [8]
Local Injection Site Reactions[1]	7 (19%)	4 (12%)	0.55 (0.11,2.47)	0.61 (0.13,1.89)	-0.08 (-0.26,0.11)	0.515
Anaphylaxis	0	0				
All Infections[3]	29 (81%)	30 (88%)	1.81 (0.40,9.29)	1.10 (0.88,1.41)	0.08 (-0.11,0.26)	0.515
Serious Infections	8 (22%)	4 (12%)	0.47 (0.09,2.00)	0.53 (0.09,1.65)	-0.10 (-0.29,0.08)	0.345
Opportunistic Infections[6]	2 (6%)	3 (9%)	1.65 (0.17,20.77)	1.59 (0.27,15.73)	0.03 (-0.11,0.19)	0.669
Neoplasms[4]	0	0				
Malignancies[6]	0	0				
Cardiac Disorders[5]	3 (8%)	0	0.00 (0.00,1.78)	0.00 (0.00,1.52)	-0.08 (-0.22,0.03)	0.240

Note: Only On-Treatment Adverse Events have been included in this table.
[1] Systemic Reactions & Local Injection Site Reactions were defined by the Investigator.
[2] Systemic Reactions (Non-Allergic) were defined based on preferred terms: Injection related reaction, Administration related reaction or Infusion related reaction. Systemic Reactions (Hypersensitivity) were defined based on preferred terms (all other terms).
[3] Infections obtained via the Infections and infestations System Organ Class.
[4] Neoplasms obtained via the Neoplasms System Organ Class.
[5] Cardiac disorders obtained via the Cardiac disorders System Organ Class.
[6] Identified by the Safety Review Team. [7] Score method, [8] 2-sided Fisher's Exact p-value.

Table 3.17
Summary and Analysis of Proportion of Subjects with On-Treatment Serious Adverse Events and Adverse Events of Special Interest by Duration of Disease

Duration of Disease: >4 years

	Placebo (N=68)	Mepolizumab 300 mg SC (N=68)	Odds Ratio (Exact 95% CI)	Relative Risk (Exact 95% CI) [7]	Risk Difference (Exact 95% CI) [7]	p-value [8]
Serious Cardiac Disorders	1 (3%)	0	0.00 (0.00,20.12)	0.00 (0.00,15.36)	-0.03 (-0.15,0.08)	>0.999
Serious Cardiac, Vascular & Thromboembolic events[6]	1 (3%)	1 (3%)	1.06 (0.01,85.60)	1.06 (0.03,35.18)	0.00 (-0.12,0.13)	>0.999
Serious Ischemic Events[6]	1 (3%)	1 (3%)	1.06 (0.01,85.60)	1.06 (0.03,35.18)	0.00 (-0.12,0.13)	>0.999

Note: Only On-Treatment Adverse Events have been included in this table.
[1] Systemic Reactions & Local Injection Site Reactions were defined by the Investigator.
[2] Systemic Reactions (Non-Allergic) were defined based on preferred terms: Injection related reaction, Administration related reaction or Infusion related reaction. Systemic Reactions (Hypersensitivity) were defined based on preferred terms (all other terms).
[3] Infections obtained via the Infections and infestations System Organ Class.
[4] Neoplasms obtained via the Neoplasms System Organ Class.
[5] Cardiac disorders obtained via the Cardiac disorders System Organ Class.
[6] Identified by the Safety Review Team. [7] Score method, [8] 2-sided Fisher's Exact p-value.

PPD

Protocol: MEA115921
Population: Safety

Table 3.18
Summary and Analysis of Proportion of Subjects with On-Treatment Serious Adverse Events and Adverse Events of Special Interest by Baseline Blood Eosinophils

Baseline Blood Eosinophils: <0.150 GI/L

	Placebo (N=68)	Mepolizumab 300 mg SC (N=68)	Odds Ratio (Exact 95% CI)	Relative Risk (Exact 95% CI) [7]	Risk Difference (Exact 95% CI) [7]	p-value [8]
Number of Subjects in Subgroup	28	29				
Risks						
Serious Adverse Events	7 (25%)	9 (31%)	1.35 (0.36,5.14)	1.24 (0.50,3.16)	0.06 (-0.19,0.30)	0.770
Systemic Reactions[1]	0	2 (7%)	Inf (0.28,Inf)	Inf (0.37,Inf)	0.07 (-0.06,0.23)	0.491
Systemic Reactions (Hypersensitivity)[2]	0	2 (7%)	Inf (0.28,Inf)	Inf (0.37,Inf)	0.07 (-0.06,0.23)	0.491
Systemic Reactions (Non-Allergic) [2]	0	0				

Note: Only On-Treatment Adverse Events have been included in this table.
[1] Systemic Reactions & Local Injection Site Reactions were defined by the Investigator.
[2] Systemic Reactions (Non-Allergic) were defined based on preferred terms: Injection related reaction, Administration related reaction or Infusion related reaction. Systemic Reactions (Hypersensitivity) were defined based on preferred terms (all other terms).
[3] Infections obtained via the Infections and infestations System Organ Class.
[4] Neoplasms obtained via the Neoplasms System Organ Class.
[5] Cardiac disorders obtained via the Cardiac disorders System Organ Class.
[6] Identified by the Safety Review Team. [7] Score method, [8] 2-sided Fisher's Exact p-value.

PPD

Table 3.18
Summary and Analysis of Proportion of Subjects with On-Treatment Serious Adverse Events and Adverse Events of Special Interest by Baseline Blood Eosinophils

Baseline Blood Eosinophils: <0.150 GI/L

	Placebo (N=68)	Mepolizumab 300 mg SC (N=68)	Odds Ratio (Exact 95% CI)	Relative Risk (Exact 95% CI) [7]	Risk Difference (Exact 95% CI) [7]	p-value [8]
Local Injection Site Reactions[1]	4 (14%)	5 (17%)	1.25 (0.24,7.09)	1.21 (0.31,4.76)	0.03 (-0.19,0.24)	>0.999
Anaphylaxis	0	0				
All Infections[3]	20 (71%)	22 (76%)	1.26 (0.33,4.89)	1.06 (0.75,1.51)	0.04 (-0.19,0.29)	0.770
Serious Infections	2 (7%)	4 (14%)	2.08 (0.27,24.61)	1.93 (0.36,14.33)	0.07 (-0.12,0.25)	0.670
Opportunistic Infections[6]	2 (7%)	2 (7%)	0.96 (0.07,14.21)	0.97 (0.07,14.21)	0.00 (-0.18,0.16)	>0.999
Neoplasms[4]	1 (4%)	1 (3%)	0.96 (0.01,78.46)	0.97 (0.03,32.03)	0.00 (-0.15,0.15)	>0.999
Malignancies[6]	1 (4%)	0	0.00 (0.00,18.34)	0.00 (0.00,13.97)	-0.04 (-0.19,0.09)	0.491
Cardiac Disorders[5]	1 (4%)	2 (7%)	2.00 (0.10,122.29)	1.93 (0.18,52.35)	0.03 (-0.12,0.19)	>0.999

Note: Only On-Treatment Adverse Events have been included in this table.
[1] Systemic Reactions & Local Injection Site Reactions were defined by the Investigator.
[2] Systemic Reactions (Non-Allergic) were defined based on preferred terms: Injection related reaction, Administration related reaction or Infusion related reaction. Systemic Reactions (Hypersensitivity) were defined based on preferred terms (all other terms).
[3] Infections obtained via the Infections and infestations System Organ Class.
[4] Neoplasms obtained via the Neoplasms System Organ Class.
[5] Cardiac disorders obtained via the Cardiac disorders System Organ Class.
[6] Identified by the Safety Review Team. [7] Score method, [8] 2-sided Fisher's Exact p-value.

PPD

Table 3.18
Summary and Analysis of Proportion of Subjects with On-Treatment Serious Adverse Events and Adverse Events of Special Interest by Baseline Blood Eosinophils

Baseline Blood Eosinophils: <0.150 GI/L

	Placebo (N=68)	Mepolizumab 300 mg SC (N=68)	Odds Ratio (Exact 95% CI)	Relative Risk (Exact 95% CI) [7]	Risk Difference (Exact 95% CI) [7]	p-value [8]
Serious Cardiac Disorders	0	1 (3%)	Inf (0.05,Inf)	Inf (0.07,Inf)	0.03 (-0.09,0.19)	>0.999
Serious Cardiac, Vascular & Thromboembolic events[6]	0	2 (7%)	Inf (0.28,Inf)	Inf (0.37,Inf)	0.07 (-0.06,0.23)	0.491
Serious Ischemic Events[6]	0	1 (3%)	Inf (0.05,Inf)	Inf (0.07,Inf)	0.03 (-0.09,0.19)	>0.999

Note: Only On-Treatment Adverse Events have been included in this table.
[1] Systemic Reactions & Local Injection Site Reactions were defined by the Investigator.
[2] Systemic Reactions (Non-Allergic) were defined based on preferred terms: Injection related reaction, Administration related reaction or Infusion related reaction. Systemic Reactions (Hypersensitivity) were defined based on preferred terms (all other terms).
[3] Infections obtained via the Infections and infestations System Organ Class.
[4] Neoplasms obtained via the Neoplasms System Organ Class.
[5] Cardiac disorders obtained via the Cardiac disorders System Organ Class.
[6] Identified by the Safety Review Team. [7] Score method, [8] 2-sided Fisher's Exact p-value.

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Table 3.18
Summary and Analysis of Proportion of Subjects with On-Treatment Serious Adverse Events and Adverse Events of Special Interest by Baseline Blood Eosinophils

Baseline Blood Eosinophils: >=0.150 GI/L

	Placebo (N=68)	Mepolizumab 300 mg SC (N=68)	Odds Ratio (Exact 95% CI)	Relative Risk (Exact 95% CI) [7]	Risk Difference (Exact 95% CI) [7]	p-value [8]
Number of Subjects in Subgroup	40	39				
Risks						
Serious Adverse Events	11 (28%)	3 (8%)	0.22 (0.04,0.95)	0.28 (0.05,0.93)	-0.20 (-0.37,-0.03)	0.037
Systemic Reactions[1]	1 (3%)	2 (5%)	2.11 (0.10,127.51)	2.05 (0.19,55.66)	0.03 (-0.09,0.15)	0.615
Systemic Reactions (Hypersensitivity)[2]	1 (3%)	1 (3%)	1.03 (0.01,82.60)	1.03 (0.03,34.12)	0.00 (-0.11,0.12)	>0.999
Systemic Reactions (Non-Allergic) [2]	0	1 (3%)	Inf (0.05,Inf)	Inf (0.07,Inf)	0.03 (-0.07,0.14)	0.494

Note: Only On-Treatment Adverse Events have been included in this table.
[1] Systemic Reactions & Local Injection Site Reactions were defined by the Investigator.
[2] Systemic Reactions (Non-Allergic) were defined based on preferred terms: Injection related reaction, Administration related reaction or Infusion related reaction. Systemic Reactions (Hypersensitivity) were defined based on preferred terms (all other terms).
[3] Infections obtained via the Infections and infestations System Organ Class.
[4] Neoplasms obtained via the Neoplasms System Organ Class.
[5] Cardiac disorders obtained via the Cardiac disorders System Organ Class.
[6] Identified by the Safety Review Team. [7] Score method, [8] 2-sided Fisher's Exact p-value.

PPD

Table 3.18
Summary and Analysis of Proportion of Subjects with On-Treatment Serious Adverse Events and Adverse Events of Special Interest by Baseline Blood Eosinophils

Baseline Blood Eosinophils: >=0.150 GI/L

	Placebo (N=68)	Mepolizumab 300 mg SC (N=68)	Odds Ratio (Exact 95% CI)	Relative Risk (Exact 95% CI) [7]	Risk Difference (Exact 95% CI) [7]	p-value [8]
Local Injection Site Reactions[1]	5 (13%)	5 (13%)	1.03 (0.22,4.91)	1.03 (0.30,3.54)	0.00 (-0.16,0.17)	>0.999
Anaphylaxis	0	0				
All Infections[3]	33 (83%)	35 (90%)	1.86 (0.42,9.40)	1.09 (0.90,1.36)	0.07 (-0.09,0.24)	0.518
Serious Infections	8 (20%)	0	0.00 (0.00,0.41)	0.00 (0.00,0.50)	-0.20 (-0.36,-0.08)	0.005
Opportunistic Infections[6]	0	3 (8%)	Inf (0.61,Inf)	Inf (0.71,Inf)	0.08 (-0.02,0.21)	0.116
Neoplasms[4]	2 (5%)	0	0.00 (0.00,3.54)	0.00 (0.00,2.72)	-0.05 (-0.17,0.04)	0.494
Malignancies[6]	1 (3%)	0	0.00 (0.00,19.49)	0.00 (0.00,14.91)	-0.03 (-0.13,0.07)	>0.999
Cardiac Disorders[5]	5 (13%)	2 (5%)	0.38 (0.03,2.53)	0.41 (0.05,2.04)	-0.07 (-0.22,0.07)	0.432

Note: Only On-Treatment Adverse Events have been included in this table.
[1] Systemic Reactions & Local Injection Site Reactions were defined by the Investigator.
[2] Systemic Reactions (Non-Allergic) were defined based on preferred terms: Injection related reaction, Administration related reaction or Infusion related reaction. Systemic Reactions (Hypersensitivity) were defined based on preferred terms (all other terms).
[3] Infections obtained via the Infections and infestations System Organ Class.
[4] Neoplasms obtained via the Neoplasms System Organ Class.
[5] Cardiac disorders obtained via the Cardiac disorders System Organ Class.
[6] Identified by the Safety Review Team. [7] Score method, [8] 2-sided Fisher's Exact p-value.

PPD

Table 3.18
Summary and Analysis of Proportion of Subjects with On-Treatment Serious Adverse Events and Adverse Events of Special Interest by Baseline Blood Eosinophils

Baseline Blood Eosinophils: >=0.150 GI/L

	Placebo (N=68)	Mepolizumab 300 mg SC (N=68)	Odds Ratio (Exact 95% CI)	Relative Risk (Exact 95% CI) [7]	Risk Difference (Exact 95% CI) [7]	p-value [8]
Serious Cardiac Disorders	2 (5%)	0	0.00 (0.00,3.54)	0.00 (0.00,2.72)	-0.05 (-0.17,0.04)	0.494
Serious Cardiac, Vascular & Thromboembolic events[6]	2 (5%)	0	0.00 (0.00,3.54)	0.00 (0.00,2.72)	-0.05 (-0.17,0.04)	0.494
Serious Ischemic Events[6]	2 (5%)	0	0.00 (0.00,3.54)	0.00 (0.00,2.72)	-0.05 (-0.17,0.04)	0.494

Note: Only On-Treatment Adverse Events have been included in this table.
[1] Systemic Reactions & Local Injection Site Reactions were defined by the Investigator.
[2] Systemic Reactions (Non-Allergic) were defined based on preferred terms: Injection related reaction, Administration related reaction or Infusion related reaction. Systemic Reactions (Hypersensitivity) were defined based on preferred terms (all other terms).
[3] Infections obtained via the Infections and infestations System Organ Class.
[4] Neoplasms obtained via the Neoplasms System Organ Class.
[5] Cardiac disorders obtained via the Cardiac disorders System Organ Class.
[6] Identified by the Safety Review Team. [7] Score method, [8] 2-sided Fisher's Exact p-value.

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