

**Dossier zur Nutzenbewertung
gemäß § 35a SGB V**

Inebilizumab (Uplizna[®])

Amgen GmbH

Anhang 4-G zu Modul 4 B

*Behandlung von Erwachsenen mit aktiver
IgG4-assoziiertes Erkrankung*

Stand: 05.03.2026

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Modul 4 B, Anhang 4-G

1 Folgetherapien nach Abbruch der Prüfmedikation

Table 14-3.9.3.573. Concomitant Medication Used for IgG4-RD Disease Initiated After Treatment Discontinuation by Preferred Term During Randomized-controlled Period
(Subjects Discontinued During Randomized-controlled Period in Full Analysis Set)

ATC Level 4 Classification Preferred Term ^a (WHODrug GLOBALB3Mar20)	Placebo (N = 15) n (%)	Inebilizumab (N = 10) n (%)
Subjects with any concomitant medication used for igG4-RD disease	15 (100.0)	10 (100.0)
ALPHA-ADRENORECEPTOR ANTAGONISTS	0 (0.0)	1 (10.0)
TAMSULOSIN HYDROCHLORIDE	0 (0.0)	1 (10.0)
ANILIDES	0 (0.0)	1 (10.0)
PARACETAMOL	0 (0.0)	1 (10.0)
ANTICHOLINERGICS	0 (0.0)	1 (10.0)
ATROPINE SULFATE	0 (0.0)	1 (10.0)
CD20 (CLUSTERS OF DIFFERENTIATION 20) INHIBITORS	4 (26.7)	1 (10.0)
RITUXIMAB	4 (26.7)	1 (10.0)
CORTICOSTEROIDS, PLAIN	0 (0.0)	1 (10.0)
PREDNISOLONE SODIUM PHOSPHATE	0 (0.0)	1 (10.0)
GLUCOCORTICOIDS	15 (100.0)	10 (100.0)
MEPREDNISONE	1 (6.7)	0 (0.0)
METHYLPREDNISOLONE	4 (26.7)	0 (0.0)
PREDNISOLONE	2 (13.3)	3 (30.0)
PREDNISONE	9 (60.0)	6 (60.0)
PREDNISONE ACETATE	2 (13.3)	1 (10.0)
OTHER IMMUNOSUPPRESSANTS	1 (6.7)	1 (10.0)
AZATHIOPRINE	1 (6.7)	1 (10.0)
SELECTIVE IMMUNOSUPPRESSANTS	3 (20.0)	0 (0.0)
MYCOPHENOLATE MOFETIL	2 (13.3)	0 (0.0)
MYCOPHENOLATE SODIUM	1 (6.7)	0 (0.0)
SYMPATHOMIMETICS EXCL. ANTIGLAUCOMA PREPARATIONS	0 (0.0)	1 (10.0)
PHENYLEPHRINE	0 (0.0)	1 (10.0)
TESTOSTERONE-5-ALPHA REDUCTASE INHIBITORS	0 (0.0)	1 (10.0)
FINASTERIDE	0 (0.0)	1 (10.0)

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^a Subjects are counted once for each preferred term regardless of the frequency of medication usage.

Program:

/userdata/stat/amg335/igg4rd/20230068/analysis/germany_submission/tables/t-cm-igg4-disc-pt-rcp.sas

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csradam.adsl, csradam.adcm

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

2 IgG4-RD-Krankheitsaktivität

2.1 PhGA VAS (MMRM und deskriptive Auswertung)

Amgen: Final
 Inebilizumab, Protocol: VIB0551.P3.S2
 Study population
 Datacut: 09APR2024
 Between Treatment Comparison (Mixed Effects Model) of Change from Baseline for Physician Global Assessment of Disease Activity (VAS)
 Full Analysis Set

Visit	Inebilizumab (N=68)		Placebo (N=67)		Difference of		Hedges'g (95% CI) [2]	p-Value
	N[1]	LSMean (SE)	N[1]	LSMean (SE)	LSMeans (95% CI)	p-Value		
Week 2		-7.42 (1.96)		-8.62 (1.95)				
Week 4		-14.20 (1.77)		-13.75 (1.77)				
Week 8		-16.18 (2.04)		-13.35 (2.05)				
Week 12		-15.64 (2.40)		-8.38 (2.44)				
Week 16		-16.80 (2.25)		-9.92 (2.27)				
Week 20		-16.19 (2.40)		-9.73 (2.40)				
Week 26		-18.53 (2.45)		-9.53 (2.41)				
Week 30		-17.84 (2.59)		-12.02 (2.61)				
Week 34		-18.14 (2.98)		-6.81 (3.01)				
Week 38		-17.61 (2.58)		-12.09 (2.60)				
Week 42		-19.04 (2.32)		-14.64 (2.31)				
Week 46		-20.87 (2.22)		-15.05 (2.22)				
Week 52	68	-19.54 (2.13)	67	-16.46 (2.17)	-3.09 (-9.12, 2.95)	0.3124	-0.17 (-0.51, 0.16)	0.3136

Analysis based on repeated measures mixed-effects model with treatment, time, treatment-by-time, baseline value and stratification factor 'First or subsequent IgG4-RD manifestation' as covariates.
 Analysis based on restricted maximum likelihood (REML) using unstructured covariance matrix.

[1] N displays number of subjects included in the mixed-effects model.

[2] An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges'g.

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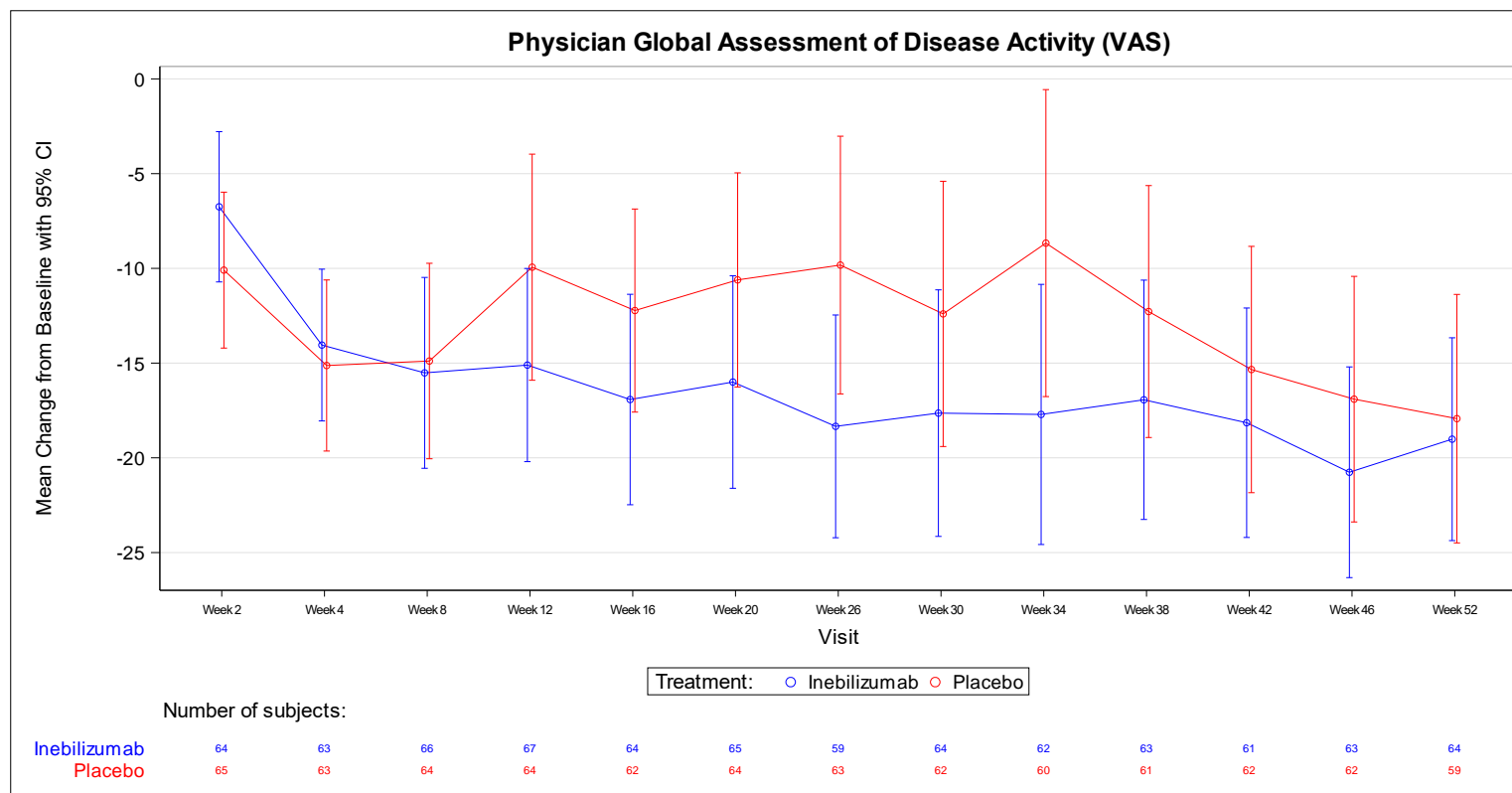
Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Amgen: Final
 Inebilizumab, Protocol: VIB0551.P3.S2
 Study population
 Datacut: 09APR2024
 Observed Means and Change from Baseline for Physician Global Assessment of Disease Activity (VAS)
 Full Analysis Set

Visit	Inebilizumab (N=68)				Placebo (N=67)			
	Observed Means		Change from Baseline		Observed Means		Change from Baseline	
	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)
Baseline	68	29.3 (22.08)			67	32.3 (24.54)		
Week 2	64	22.6 (21.50)	64	-6.8 (15.88)	65	22.9 (23.76)	65	-10.1 (16.60)
Week 4	63	15.6 (17.10)	63	-14.0 (15.90)	63	17.7 (22.00)	63	-15.1 (17.93)
Week 8	66	14.0 (16.60)	66	-15.5 (20.49)	64	17.8 (22.49)	64	-14.9 (20.65)
Week 12	67	14.5 (18.88)	67	-15.1 (20.90)	64	23.3 (27.29)	64	-9.9 (23.89)
Week 16	64	12.4 (15.61)	64	-16.9 (22.23)	62	21.3 (25.89)	62	-12.2 (21.10)
Week 20	65	13.5 (17.71)	65	-16.0 (22.63)	64	21.8 (26.00)	64	-10.6 (22.62)
Week 26	59	11.4 (15.47)	59	-18.3 (22.56)	63	21.9 (24.48)	63	-9.8 (27.01)
Week 30	64	12.1 (19.32)	64	-17.6 (26.05)	62	19.0 (22.34)	62	-12.4 (27.56)
Week 34	62	12.1 (19.20)	62	-17.7 (27.03)	60	24.0 (28.02)	60	-8.7 (31.36)
Week 38	63	12.6 (19.69)	63	-16.9 (25.08)	61	19.0 (23.27)	61	-12.3 (25.96)
Week 42	61	10.9 (15.92)	61	-18.1 (23.64)	62	16.2 (20.50)	62	-15.3 (25.60)
Week 46	63	9.0 (14.18)	63	-20.8 (22.08)	62	15.5 (20.17)	62	-16.9 (25.52)
Week 52	64	10.7 (15.38)	64	-19.0 (21.43)	59	14.2 (16.29)	59	-17.9 (25.16)

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Amgen: Final
 Inebilizumab, Protocol: VIB0551.P3.S2
 Study population
 Datacut: 09APR2024
 Graphical Summary of Change from Baseline for Physician Global Assessment of Disease Activity (VAS)
 Full Analysis Set



95% CIs are not drawn for visits with number of subjects < 10.

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

2.2 PGA VAS (MMRM und deskriptive Auswertung)

Amgen: Final
 Inebilizumab, Protocol: VIB0551.P3.S2
 Study population
 Dataset: 09APR2024
 Between Treatment Comparison (Mixed Effects Model) of Change from Baseline for Patient Global Assessment Of Disease Activity (VAS)
 Full Analysis Set

Visit	Inebilizumab (N=68)		Placebo (N=67)		Difference of		Hedges'g (95% CI) [2]	p-Value
	N[1]	LSMean (SE)	N[1]	LSMean (SE)	LSMeans (95% CI)	p-Value		
Week 2		0.89 (1.85)		-0.19 (1.83)				
Week 4		0.78 (2.02)		-0.26 (2.00)				
Week 8		-2.49 (2.36)		-2.84 (2.34)				
Week 12		-4.39 (2.85)		-9.51 (2.87)				
Week 16		-2.86 (2.59)		-3.75 (2.65)				
Week 20		-2.22 (2.71)		-1.72 (2.73)				
Week 26		-0.32 (2.54)		-3.85 (2.51)				
Week 30		-0.16 (2.61)		-2.37 (2.62)				
Week 34		-1.13 (2.91)		-4.35 (2.89)				
Week 38		-0.95 (2.81)		-2.64 (2.83)				
Week 42		-1.04 (2.69)		-2.54 (2.69)				
Week 46		3.07 (2.51)		-5.31 (2.50)				
Week 52	68	1.77 (2.33)	67	-1.37 (2.34)	3.14 (-3.38, 9.67)	0.3423	0.16 (-0.17, 0.50)	0.3443

Analysis based on repeated measures mixed-effects model with treatment, time, treatment-by-time, baseline value and stratification factor 'First or subsequent IgG4-RD manifestation' as covariates.

Analysis based on restricted maximum likelihood (REML) using unstructured covariance matrix.

[1] N displays number of subjects included in the mixed-effects model.

[2] An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges'g.

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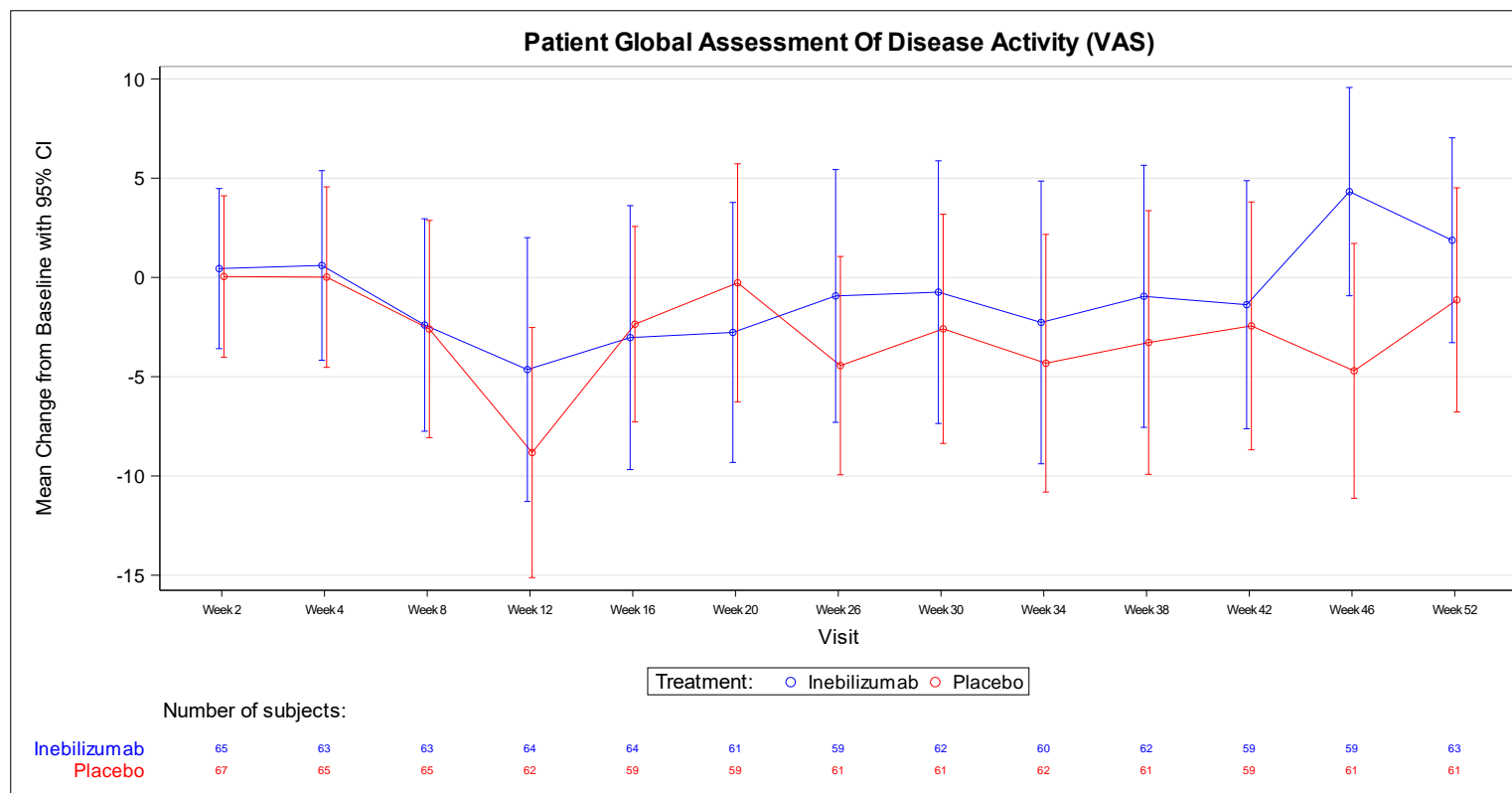
Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Amgen: Final
 Inebilizumab, Protocol: VIB0551.P3.S2
 Study population
 Datcut: 09APR2024
 Observed Means and Change from Baseline for Patient Global Assessment Of Disease Activity (VAS)
 Full Analysis Set

Visit	Inebilizumab (N=68)				Placebo (N=67)			
	Observed Means		Change From Baseline		Observed Means		Change from Baseline	
	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)
Baseline	68	71.1 (21.56)			67	69.7 (21.78)		
Week 2	65	71.2 (20.06)	65	0.4 (16.27)	67	69.7 (21.19)	67	0.0 (16.68)
Week 4	63	71.2 (20.94)	63	0.6 (18.96)	65	69.2 (19.98)	65	0.0 (18.34)
Week 8	63	68.4 (20.52)	63	-2.4 (21.25)	65	66.6 (23.33)	65	-2.6 (22.08)
Week 12	64	65.9 (25.02)	64	-4.6 (26.60)	62	60.7 (25.11)	62	-8.8 (24.81)
Week 16	64	67.4 (24.99)	64	-3.0 (26.62)	59	67.4 (21.45)	59	-2.4 (18.89)
Week 20	61	68.5 (24.44)	61	-2.8 (25.57)	59	69.4 (23.57)	59	-0.3 (23.00)
Week 26	59	69.7 (21.49)	59	-0.9 (24.43)	61	66.5 (21.71)	61	-4.4 (21.47)
Week 30	62	70.4 (23.58)	62	-0.7 (26.05)	61	67.6 (20.57)	61	-2.6 (22.53)
Week 34	60	68.7 (24.00)	60	-2.3 (27.57)	62	65.9 (23.71)	62	-4.3 (25.56)
Week 38	62	68.6 (23.48)	62	-1.0 (26.00)	61	67.2 (22.52)	61	-3.3 (25.93)
Week 42	59	69.5 (23.25)	59	-1.4 (23.98)	59	67.5 (22.21)	59	-2.4 (23.96)
Week 46	59	73.2 (20.10)	59	4.3 (20.13)	61	65.5 (23.70)	61	-4.7 (25.06)
Week 52	63	71.3 (20.66)	63	1.9 (20.48)	61	69.5 (21.62)	61	-1.1 (22.04)

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Amgen: Final
 Inebilizumab, Protocol: VIB0551.P3.S2
 Study population
 Datacut: 09APR2024
 Graphical Summary of Change from Baseline for Patient Global Assessment Of Disease Activity (VAS)
 Full Analysis Set



95% CIs are not drawn for visits with number of subjects < 10.

3 Fatigue

3.1 FACIT-Fatigue (MMRM und deskriptive Auswertung)

Amgen: Final
 Inebilizumab, Protocol: VIB0551.P3.S2
 Study population
 Datacut: 09APR2024
 Between Treatment Comparison (Mixed Effects Model) of Change from Baseline for Total FACIT-Fatigue Score
 Full Analysis Set

Visit	Inebilizumab (N=68)		Placebo (N=67)		Difference of		Hedges'g (95% CI) [2]	p-Value
	N[1]	LSMean (SE)	N[1]	LSMean (SE)	LSMeans (95% CI)	p-Value		
Week 2		-1.09 (0.58)		-1.53 (0.58)				
Week 4		-0.42 (0.54)		-0.49 (0.54)				
Week 8		-0.12 (0.72)		-0.56 (0.73)				
Week 12		1.57 (0.80)		0.96 (0.81)				
Week 16		1.20 (0.81)		-0.37 (0.83)				
Week 20		1.97 (0.77)		-0.62 (0.79)				
Week 26		0.51 (0.78)		0.97 (0.78)				
Week 30		0.89 (0.81)		0.47 (0.81)				
Week 34		0.29 (0.77)		-0.34 (0.77)				
Week 38		0.24 (0.79)		0.16 (0.80)				
Week 42		0.04 (0.80)		0.62 (0.80)				
Week 46		-0.03 (0.81)		0.92 (0.82)				
Week 52	68	-0.78 (0.72)	67	-0.54 (0.74)	-0.24 (-2.29, 1.81)	0.8162	-0.04 (-0.38, 0.30)	0.8167

Analysis based on repeated measures mixed-effects model with treatment, time, treatment-by-time, baseline value and stratification factor 'First or subsequent IgG4-RD manifestation' as covariates.
 Analysis based on restricted maximum likelihood (REML) using unstructured covariance matrix.

[1] N displays number of subjects included in the mixed-effects model.

[2] An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges'g.

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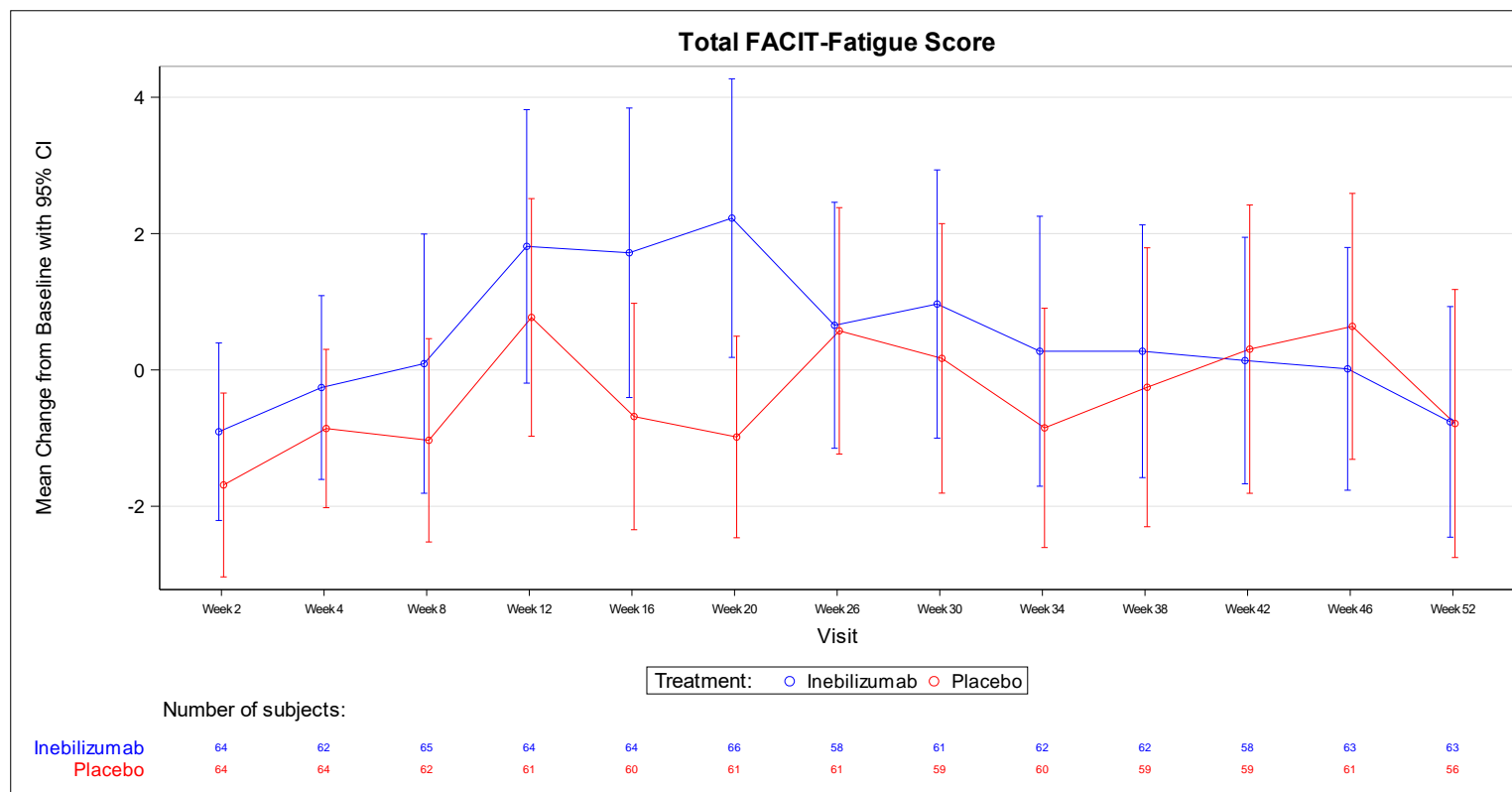
Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Amgen: Final
 Inebilizumab, Protocol: VIB0551.P3.S2
 Study population
 Datcut: 09APR2024
 Observed Means and Change from Baseline for Total FACIT-Fatigue Score
 Full Analysis Set

Visit	Inebilizumab (N=68)				Placebo (N=67)			
	Observed Means		Change From Baseline		Observed Means		Change from Baseline	
	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)
Baseline	68	12.1 (7.02)			67	13.7 (8.73)		
Week 2	64	11.5 (6.38)	64	-0.9 (5.21)	64	12.0 (7.61)	64	-1.7 (5.40)
Week 4	62	12.2 (5.80)	62	-0.3 (5.31)	64	12.9 (7.89)	64	-0.9 (4.65)
Week 8	65	12.4 (6.06)	65	0.1 (7.67)	62	12.8 (8.26)	62	-1.0 (5.87)
Week 12	64	14.1 (7.01)	64	1.8 (8.03)	61	14.1 (8.06)	61	0.8 (6.81)
Week 16	64	13.7 (7.24)	64	1.7 (8.50)	60	13.2 (8.01)	60	-0.7 (6.43)
Week 20	66	14.5 (6.95)	66	2.2 (8.31)	61	12.7 (8.06)	61	-1.0 (5.77)
Week 26	58	13.1 (6.82)	58	0.7 (6.86)	61	13.9 (8.52)	61	0.6 (7.06)
Week 30	61	13.4 (6.88)	61	1.0 (7.68)	59	13.6 (7.56)	59	0.2 (7.58)
Week 34	62	12.6 (6.81)	62	0.3 (7.80)	60	12.2 (5.93)	60	-0.9 (6.79)
Week 38	62	12.7 (6.52)	62	0.3 (7.30)	59	13.2 (7.65)	59	-0.3 (7.85)
Week 42	58	12.4 (5.96)	58	0.1 (6.88)	59	13.4 (7.65)	59	0.3 (8.11)
Week 46	63	12.1 (5.81)	63	0.0 (7.07)	61	13.9 (8.54)	61	0.6 (7.62)
Week 52	63	11.4 (5.66)	63	-0.8 (6.72)	56	12.2 (6.25)	56	-0.8 (7.34)

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Amgen: Final
 Inebilizumab, Protocol: VIB0551.P3.S2
 Study population
 Datacut: 09APR2024
 Graphical Summary of Change from Baseline for Total FACIT-Fatigue Score
 Full Analysis Set



95% CIs are not drawn for visits with number of subjects < 10.

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

4 Gesundheitsbezogene Lebensqualität: SF-36

4.1 PCS und MCS (MMRM und deskriptive Auswertung)

Amgen: Final
 Inebilizumab, Protocol: VIB0551.P3.S2
 Study population
 Datacut: 09APR2024
 Between Treatment Comparison (Mixed Effects Model) of Change from Baseline for Physical Component Score
 Full Analysis Set

Visit	Inebilizumab (N=68)		Placebo (N=67)		Difference of		Hedges'g (95% CI) [2]	p-Value
	N[1]	LSMean (SE)	N[1]	LSMean (SE)	LSMeans (95% CI)	p-Value		
Week 2		0.58 (0.51)		-0.51 (0.51)				
Week 4		-0.21 (0.67)		-1.16 (0.66)				
Week 8		0.06 (0.72)		-0.80 (0.73)				
Week 12		-2.00 (0.86)		-2.59 (0.87)				
Week 16		-2.04 (0.86)		-1.85 (0.88)				
Week 20		-1.87 (0.88)		-2.74 (0.90)				
Week 26		-1.05 (0.81)		-2.20 (0.80)				
Week 30		-0.94 (0.79)		-2.75 (0.79)				
Week 34		-0.38 (0.79)		-2.68 (0.80)				
Week 38		-0.82 (0.75)		-2.24 (0.76)				
Week 42		-0.82 (0.79)		-2.65 (0.80)				
Week 46		-0.40 (0.83)		-2.84 (0.84)				
Week 52	68	-0.55 (0.87)	67	-2.75 (0.88)	2.21 (-0.25, 4.66)	0.0773	0.30 (-0.03, 0.64)	0.0783

Analysis based on repeated measures mixed-effects model with treatment, time, treatment-by-time, baseline value and stratification factor 'First or subsequent IgG4-RD manifestation' as covariates.

Analysis based on restricted maximum likelihood (REML) using unstructured covariance matrix.

[1] N displays number of subjects included in the mixed-effects model.

[2] An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges'g.

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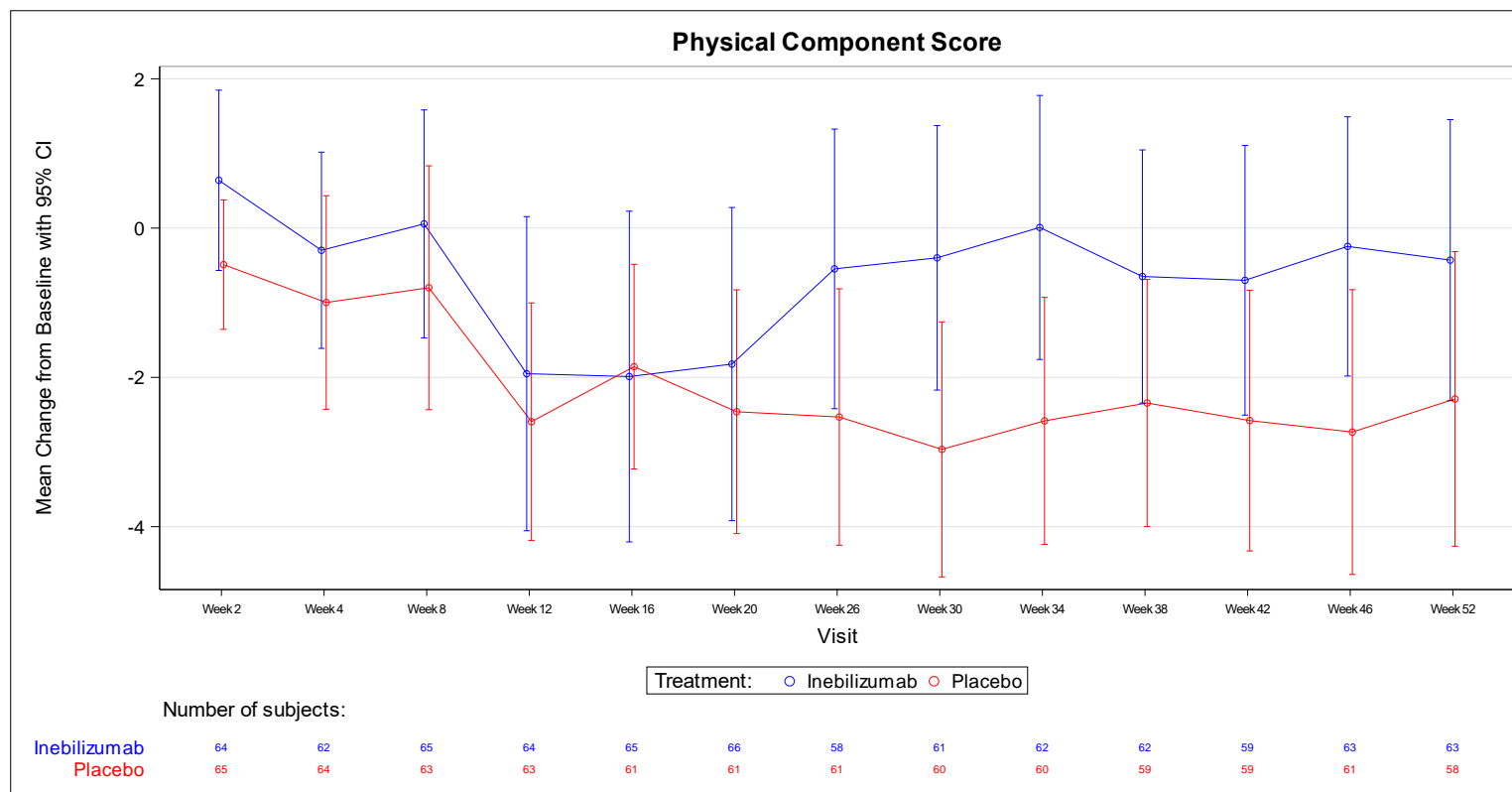
Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Amgen: Final
 Inebilizumab, Protocol: VIB0551.P3.S2
 Study population
 Datcut: 09APR2024
 Observed Means and Change from Baseline for Physical Component Score
 Full Analysis Set

Visit	Inebilizumab (N=68)				Placebo (N=67)			
	Observed Means		Change From Baseline		Observed Means		Change from Baseline	
	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)
Baseline	68	51.3 (7.93)			67	51.2 (7.35)		
Week 2	64	51.7 (6.73)	64	0.6 (4.84)	65	50.6 (8.58)	65	-0.5 (3.50)
Week 4	62	50.9 (7.61)	62	-0.3 (5.18)	64	50.3 (8.53)	64	-1.0 (5.73)
Week 8	65	51.3 (8.06)	65	0.1 (6.16)	63	50.3 (7.83)	63	-0.8 (6.49)
Week 12	64	49.3 (9.01)	64	-2.0 (8.42)	63	48.8 (8.03)	63	-2.6 (6.32)
Week 16	65	49.3 (9.15)	65	-2.0 (8.94)	61	49.5 (7.82)	61	-1.9 (5.35)
Week 20	66	49.3 (8.80)	66	-1.8 (8.53)	61	48.7 (8.81)	61	-2.5 (6.37)
Week 26	58	50.1 (7.53)	58	-0.5 (7.12)	61	49.2 (7.94)	61	-2.5 (6.71)
Week 30	61	50.3 (7.70)	61	-0.4 (6.92)	60	48.5 (8.16)	60	-3.0 (6.61)
Week 34	62	50.7 (7.93)	62	0.0 (6.96)	60	49.1 (7.55)	60	-2.6 (6.40)
Week 38	62	50.1 (8.44)	62	-0.6 (6.68)	59	49.0 (7.37)	59	-2.3 (6.35)
Week 42	59	50.6 (7.95)	59	-0.7 (6.93)	59	49.1 (7.64)	59	-2.6 (6.70)
Week 46	63	50.9 (7.73)	63	-0.2 (6.89)	61	48.8 (7.99)	61	-2.7 (7.45)
Week 52	63	50.6 (7.67)	63	-0.4 (7.48)	58	49.3 (7.70)	58	-2.3 (7.50)

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Amgen: Final
 Inebilizumab, Protocol: VIB0551.P3.S2
 Study population
 Datacut: 09APR2024
 Graphical Summary of Change from Baseline for Physical Component Score
 Full Analysis Set



95% CIs are not drawn for visits with number of subjects < 10.

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Amgen: Final
 Inebilizumab, Protocol: VIB0551.P3.S2
 Study population
 Datacut: 09APR2024
 Between Treatment Comparison (Mixed Effects Model) of Change from Baseline for Mental Component Score
 Full Analysis Set

Visit	Inebilizumab (N=68)		Placebo (N=67)		Difference of		Hedges'g (95% CI) [2]	p-Value
	N[1]	LSMean (SE)	N[1]	LSMean (SE)	LSMeans (95% CI)	p-Value		
Week 2		0.59 (0.69)		2.00 (0.69)				
Week 4		0.64 (0.72)		0.43 (0.72)				
Week 8		0.27 (0.78)		1.03 (0.79)				
Week 12		-0.86 (0.80)		-0.47 (0.81)				
Week 16		-0.07 (0.77)		1.13 (0.78)				
Week 20		-1.33 (0.88)		0.92 (0.90)				
Week 26		-0.14 (0.99)		-0.39 (0.97)				
Week 30		0.25 (0.90)		0.12 (0.91)				
Week 34		-0.38 (0.93)		0.47 (0.94)				
Week 38		0.10 (0.91)		0.92 (0.92)				
Week 42		0.23 (0.98)		0.72 (0.98)				
Week 46		0.44 (0.94)		-0.37 (0.95)				
Week 52	68	0.05 (0.97)	67	-0.36 (0.99)	0.41 (-2.32, 3.15)	0.7662	0.05 (-0.29, 0.39)	0.7670

Analysis based on repeated measures mixed-effects model with treatment, time, treatment-by-time, baseline value and stratification factor 'First or subsequent IgG4-RD manifestation' as covariates.

Analysis based on restricted maximum likelihood (REML) using unstructured covariance matrix.

[1] N displays number of subjects included in the mixed-effects model.

[2] An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges'g.

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Date of Table Generation: 07JAN2026

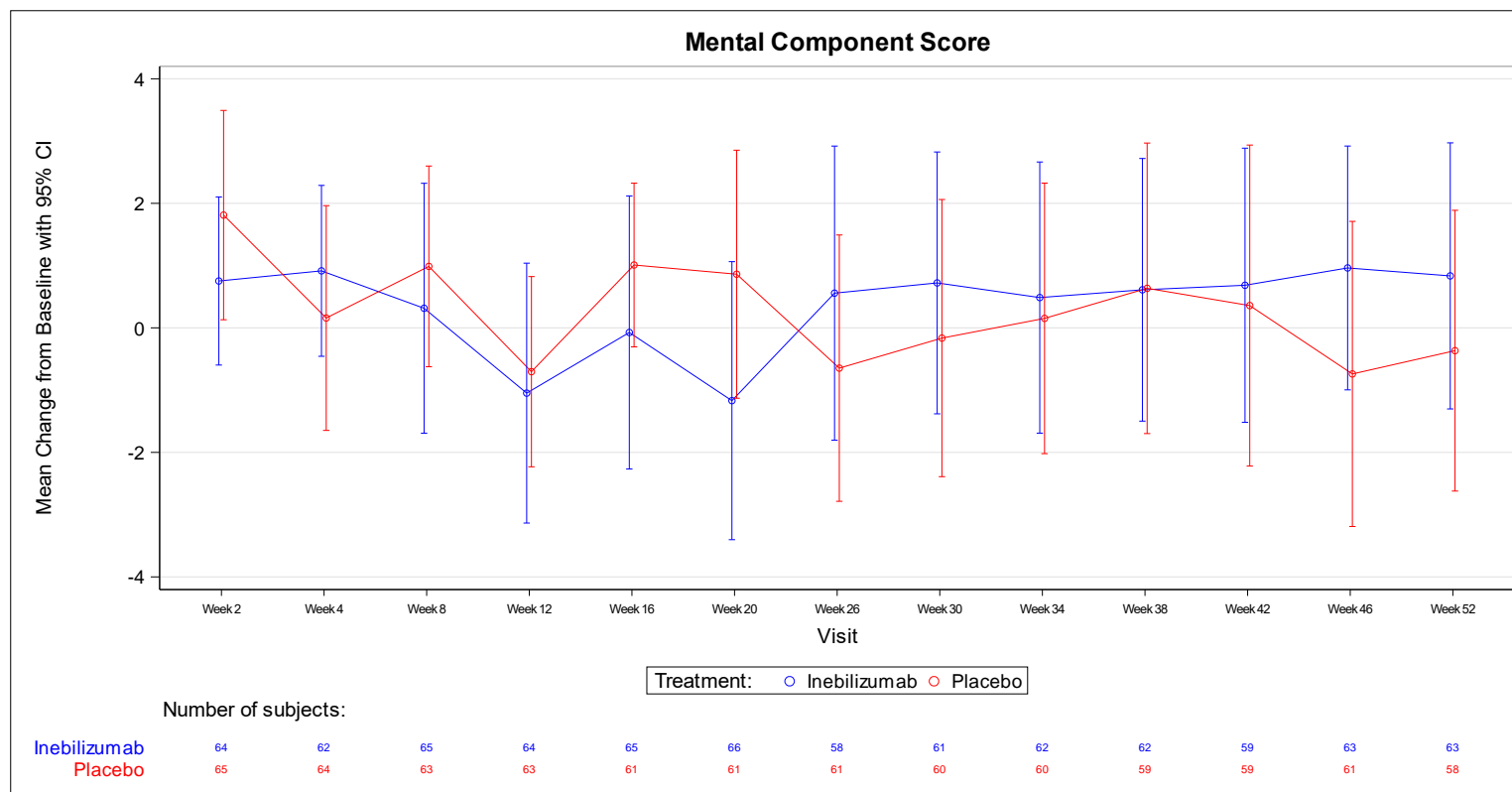
Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Amgen: Final
 Inebilizumab, Protocol: VIB0551.P3.S2
 Study population
 Datacut: 09APR2024
 Observed Means and Change from Baseline for Mental Component Score
 Full Analysis Set

Visit	Inebilizumab (N=68)				Placebo (N=67)			
	Observed Means		Change From Baseline		Observed Means		Change from Baseline	
	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)
Baseline	68	48.2 (9.22)			67	49.0 (10.07)		
Week 2	64	48.7 (8.56)	64	0.8 (5.40)	65	50.6 (9.29)	65	1.8 (6.78)
Week 4	62	48.5 (7.99)	62	0.9 (5.40)	64	49.3 (9.58)	64	0.2 (7.23)
Week 8	65	48.3 (8.86)	65	0.3 (8.10)	63	49.8 (8.46)	63	1.0 (6.40)
Week 12	64	47.3 (8.87)	64	-1.0 (8.36)	63	48.3 (8.90)	63	-0.7 (6.07)
Week 16	65	47.9 (8.48)	65	-0.1 (8.85)	61	49.6 (8.53)	61	1.0 (5.13)
Week 20	66	46.8 (8.50)	66	-1.2 (9.08)	61	49.9 (8.81)	61	0.9 (7.78)
Week 26	58	48.3 (9.09)	58	0.6 (8.98)	61	49.1 (9.47)	61	-0.6 (8.35)
Week 30	61	48.5 (9.01)	61	0.7 (8.21)	60	49.4 (8.56)	60	-0.2 (8.62)
Week 34	62	48.1 (8.27)	62	0.5 (8.57)	60	49.9 (9.14)	60	0.2 (8.41)
Week 38	62	48.5 (7.47)	62	0.6 (8.31)	59	50.1 (9.15)	59	0.6 (8.95)
Week 42	59	48.5 (8.45)	59	0.7 (8.45)	59	49.6 (9.53)	59	0.4 (9.89)
Week 46	63	48.6 (7.89)	63	1.0 (7.77)	61	48.5 (9.89)	61	-0.7 (9.57)
Week 52	63	48.4 (9.23)	63	0.8 (8.48)	58	49.0 (9.21)	58	-0.4 (8.57)

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Amgen: Final
 Inebilizumab, Protocol: VIB0551.P3.S2
 Study population
 Datacut: 09APR2024
 Graphical Summary of Change from Baseline for Mental Component Score
 Full Analysis Set



95% CIs are not drawn for visits with number of subjects < 10.

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

4.2 Einzelkomponenten (MMRM und deskriptive Auswertung)

Amgen: Final
 Inebilizumab, Protocol: VIB0551.P3.S2
 Study population
 Dataset: 09APR2024
 Between Treatment Comparison (Mixed Effects Model) of Change from Baseline for Physical Functioning
 Full Analysis Set

Visit	Inebilizumab (N=68)		Placebo (N=67)		Difference of		Hedges'g (95% CI) [2]	p-Value
	N[1]	LSMean (SE)	N[1]	LSMean (SE)	LSMeans (95% CI)	p-Value		
Week 2		0.70 (0.51)		0.07 (0.51)				
Week 4		0.31 (0.61)		-0.14 (0.60)				
Week 8		0.46 (0.72)		0.36 (0.72)				
Week 12		-0.05 (0.85)		-0.56 (0.86)				
Week 16		-1.27 (0.82)		-0.30 (0.84)				
Week 20		-0.97 (0.86)		-1.03 (0.88)				
Week 26		-0.75 (0.92)		-0.99 (0.91)				
Week 30		-0.45 (0.80)		-1.18 (0.80)				
Week 34		0.13 (0.80)		-0.93 (0.80)				
Week 38		-0.31 (0.79)		-0.60 (0.79)				
Week 42		-0.70 (0.87)		-1.08 (0.87)				
Week 46		-0.36 (0.86)		-1.32 (0.86)				
Week 52	68	-0.00 (0.81)	67	-1.35 (0.83)	1.35 (-0.95, 3.64)	0.2478	0.20 (-0.14, 0.54)	0.2495

Analysis based on repeated measures mixed-effects model with treatment, time, treatment-by-time, baseline value and stratification factor 'First or subsequent IgG4-RD manifestation' as covariates.
 Analysis based on restricted maximum likelihood (REML) using unstructured covariance matrix.

[1] N displays number of subjects included in the mixed-effects model.

[2] An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges'g.

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Date of Table Generation: 07JAN2026

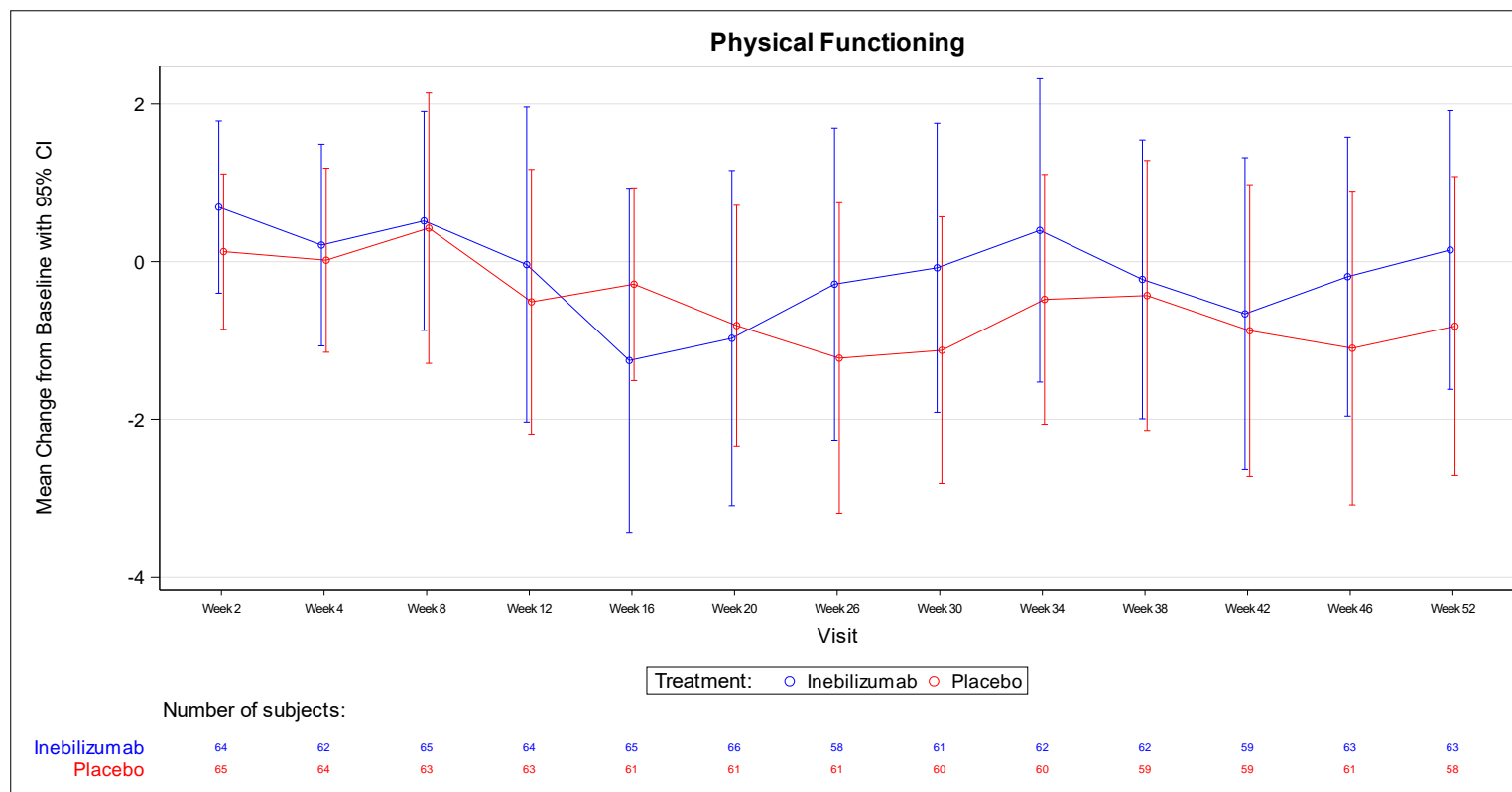
Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Amgen: Final
 Inebilizumab, Protocol: VIB0551.P3.S2
 Study population
 Datcut: 09APR2024
 Observed Means and Change from Baseline for Physical Functioning
 Full Analysis Set

Visit	Inebilizumab (N=68)				Placebo (N=67)			
	Observed Means		Change From Baseline		Observed Means		Change from Baseline	
	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)
Baseline	68	51.6 (8.11)			67	51.1 (7.94)		
Week 2	64	52.2 (7.00)	64	0.7 (4.37)	65	51.1 (9.19)	65	0.1 (3.97)
Week 4	62	51.7 (8.64)	62	0.2 (5.04)	64	51.2 (8.70)	64	0.0 (4.67)
Week 8	65	51.9 (7.83)	65	0.5 (5.60)	63	51.2 (8.92)	63	0.4 (6.81)
Week 12	64	51.5 (8.18)	64	-0.0 (8.00)	63	50.7 (8.44)	63	-0.5 (6.67)
Week 16	65	50.3 (8.34)	65	-1.3 (8.82)	61	50.8 (8.28)	61	-0.3 (4.77)
Week 20	66	50.4 (8.25)	66	-1.0 (8.66)	61	50.3 (8.77)	61	-0.8 (5.96)
Week 26	58	50.7 (7.61)	58	-0.3 (7.53)	61	50.4 (8.91)	61	-1.2 (7.70)
Week 30	61	51.0 (7.27)	61	-0.1 (7.16)	60	50.0 (8.28)	60	-1.1 (6.56)
Week 34	62	51.5 (7.07)	62	0.4 (7.58)	60	50.9 (7.51)	60	-0.5 (6.13)
Week 38	62	51.1 (7.72)	62	-0.2 (6.96)	59	50.5 (8.12)	59	-0.4 (6.57)
Week 42	59	51.1 (8.11)	59	-0.7 (7.60)	59	50.4 (7.87)	59	-0.9 (7.11)
Week 46	63	51.2 (7.40)	63	-0.2 (7.02)	61	50.3 (8.17)	61	-1.1 (7.78)
Week 52	63	51.4 (6.81)	63	0.1 (7.02)	58	50.5 (8.18)	58	-0.8 (7.22)

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Amgen: Final
 Inebilizumab, Protocol: VIB0551.P3.S2
 Study population
 Datacut: 09APR2024
 Graphical Summary of Change from Baseline for Physical Functioning
 Full Analysis Set



95% CIs are not drawn for visits with number of subjects < 10.

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Amgen: Final
 Inebilizumab, Protocol: VIB0551.P3.S2
 Study population
 Datacut: 09APR2024
 Between Treatment Comparison (Mixed Effects Model) of Change from Baseline for Role Physical
 Full Analysis Set

Visit	Inebilizumab (N=68)		Placebo (N=67)		Difference of		Hedges'g (95% CI) [2]	p-Value
	N[1]	LSMean (SE)	N[1]	LSMean (SE)	LSMeans (95% CI)	p-Value		
Week 2		0.86 (0.60)		0.52 (0.60)				
Week 4		0.79 (0.76)		-0.52 (0.75)				
Week 8		0.52 (0.73)		-0.27 (0.74)				
Week 12		-1.50 (0.91)		-1.66 (0.92)				
Week 16		-0.41 (0.85)		-0.66 (0.87)				
Week 20		-0.88 (0.88)		-0.94 (0.90)				
Week 26		-0.16 (0.82)		-1.73 (0.81)				
Week 30		0.19 (0.82)		-1.68 (0.82)				
Week 34		0.60 (0.76)		-1.03 (0.76)				
Week 38		0.71 (0.75)		-0.30 (0.76)				
Week 42		1.12 (0.80)		-1.79 (0.80)				
Week 46		1.31 (0.84)		-1.09 (0.84)				
Week 52	68	0.87 (0.79)	67	-1.67 (0.81)	2.54 (0.29, 4.79)	0.0271	0.38 (0.04, 0.72)	0.0276

Analysis based on repeated measures mixed-effects model with treatment, time, treatment-by-time, baseline value and stratification factor 'First or subsequent IgG4-RD manifestation' as covariates.

Analysis based on restricted maximum likelihood (REML) using unstructured covariance matrix.

[1] N displays number of subjects included in the mixed-effects model.

[2] An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges'g.

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Date of Table Generation: 07JAN2026

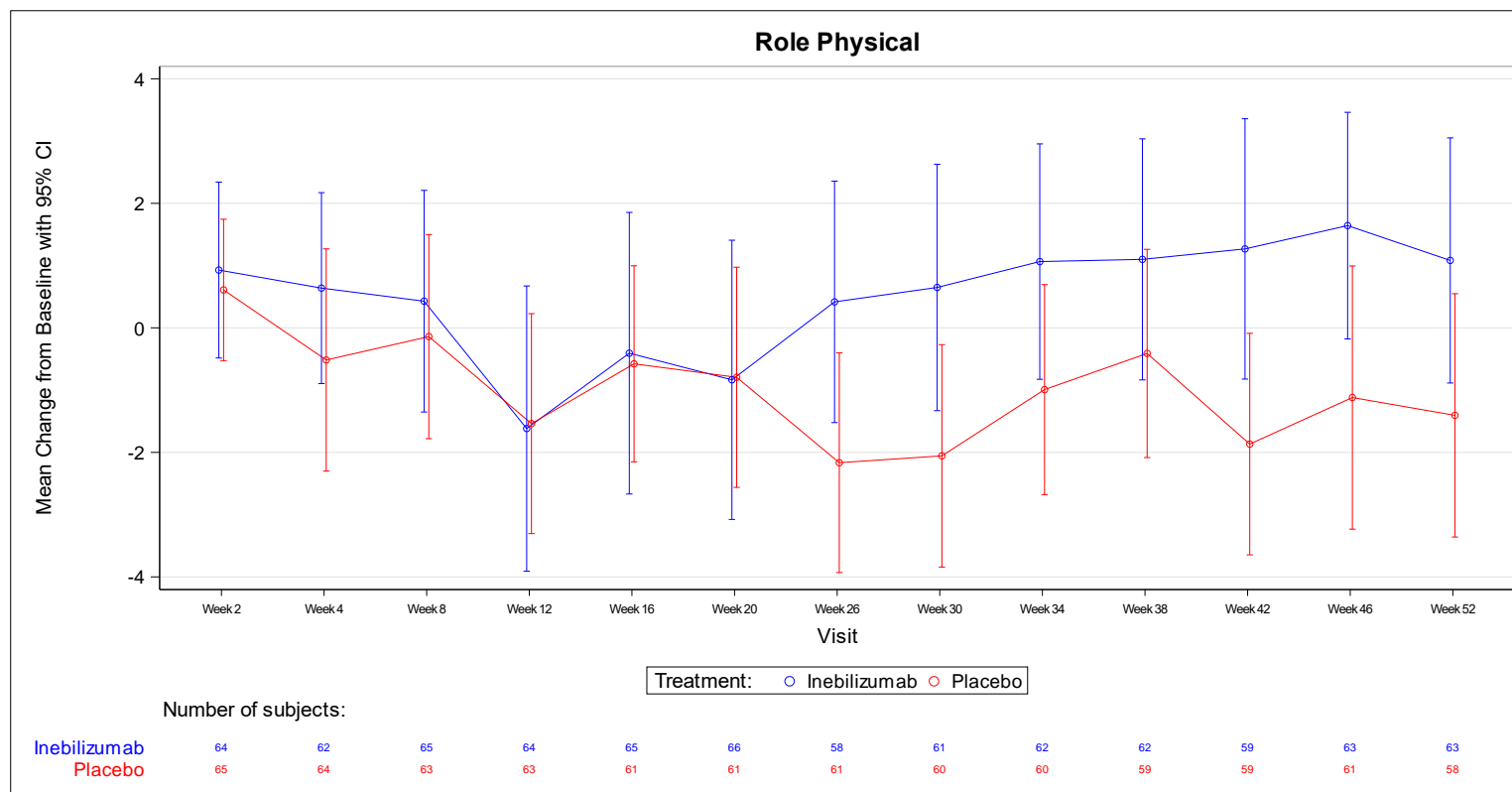
Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Amgen: Final
 Inebilizumab, Protocol: VIB0551.P3.S2
 Study population
 Datacut: 09APR2024
 Observed Means and Change from Baseline for Role Physical
 Full Analysis Set

Visit	Inebilizumab (N=68)				Placebo (N=67)			
	Observed Means		Change From Baseline		Observed Means		Change from Baseline	
	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)
Baseline	68	49.1 (8.92)			67	49.0 (9.79)		
Week 2	64	49.9 (7.90)	64	0.9 (5.66)	65	49.3 (9.62)	65	0.6 (4.58)
Week 4	62	49.7 (7.60)	62	0.6 (6.04)	64	48.5 (10.13)	64	-0.5 (7.15)
Week 8	65	49.6 (7.48)	65	0.4 (7.18)	63	48.6 (9.30)	63	-0.1 (6.51)
Week 12	64	47.6 (9.04)	64	-1.6 (9.17)	63	47.5 (9.18)	63	-1.5 (7.01)
Week 16	65	48.6 (8.72)	65	-0.4 (9.13)	61	48.2 (8.92)	61	-0.6 (6.15)
Week 20	66	48.0 (8.45)	66	-0.8 (9.12)	61	48.2 (9.22)	61	-0.8 (6.90)
Week 26	58	49.1 (7.30)	58	0.4 (7.37)	61	47.6 (9.63)	61	-2.2 (6.89)
Week 30	61	49.2 (7.58)	61	0.6 (7.73)	60	47.5 (9.10)	60	-2.1 (6.91)
Week 34	62	49.6 (7.60)	62	1.1 (7.45)	60	48.6 (7.76)	60	-1.0 (6.53)
Week 38	62	49.6 (7.52)	62	1.1 (7.62)	59	48.8 (8.26)	59	-0.4 (6.42)
Week 42	59	50.4 (6.88)	59	1.3 (8.02)	59	47.5 (8.71)	59	-1.9 (6.83)
Week 46	63	50.4 (6.73)	63	1.6 (7.23)	61	48.2 (8.82)	61	-1.1 (8.25)
Week 52	63	49.9 (6.64)	63	1.1 (7.82)	58	48.1 (8.17)	58	-1.4 (7.43)

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Amgen: Final
 Inebilizumab, Protocol: VIB0551.P3.S2
 Study population
 Datacut: 09APR2024
 Graphical Summary of Change from Baseline for Role Physical
 Full Analysis Set



95% CIs are not drawn for visits with number of subjects < 10.

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Amgen: Final
 Inebilizumab, Protocol: VIB0551.P3.S2
 Study population
 Datacut: 09APR2024
 Between Treatment Comparison (Mixed Effects Model) of Change from Baseline for Bodily Pain
 Full Analysis Set

Visit	Inebilizumab (N=68)		Placebo (N=67)		Difference of		Hedges'g (95% CI) [2]	p-Value
	N[1]	LSMean (SE)	N[1]	LSMean (SE)	LSMeans (95% CI)	p-Value		
Week 2		0.95 (0.79)		0.25 (0.78)				
Week 4		-0.97 (0.85)		-0.56 (0.84)				
Week 8		-0.28 (1.02)		-0.90 (1.04)				
Week 12		-3.37 (1.01)		-3.82 (1.03)				
Week 16		-3.25 (1.06)		-1.65 (1.09)				
Week 20		-3.48 (1.14)		-3.25 (1.17)				
Week 26		-1.20 (0.96)		-2.32 (0.94)				
Week 30		-1.48 (0.91)		-2.98 (0.92)				
Week 34		-1.45 (1.09)		-3.52 (1.10)				
Week 38		-1.46 (0.94)		-2.73 (0.95)				
Week 42		-2.05 (0.96)		-1.76 (0.96)				
Week 46		-1.37 (0.98)		-3.46 (0.99)				
Week 52	68	-1.92 (1.14)	67	-2.89 (1.17)	0.96 (-2.27, 4.20)	0.5556	0.10 (-0.24, 0.44)	0.5571

Analysis based on repeated measures mixed-effects model with treatment, time, treatment-by-time, baseline value and stratification factor 'First or subsequent IgG4-RD manifestation' as covariates.

Analysis based on restricted maximum likelihood (REML) using unstructured covariance matrix.

[1] N displays number of subjects included in the mixed-effects model.

[2] An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges'g.

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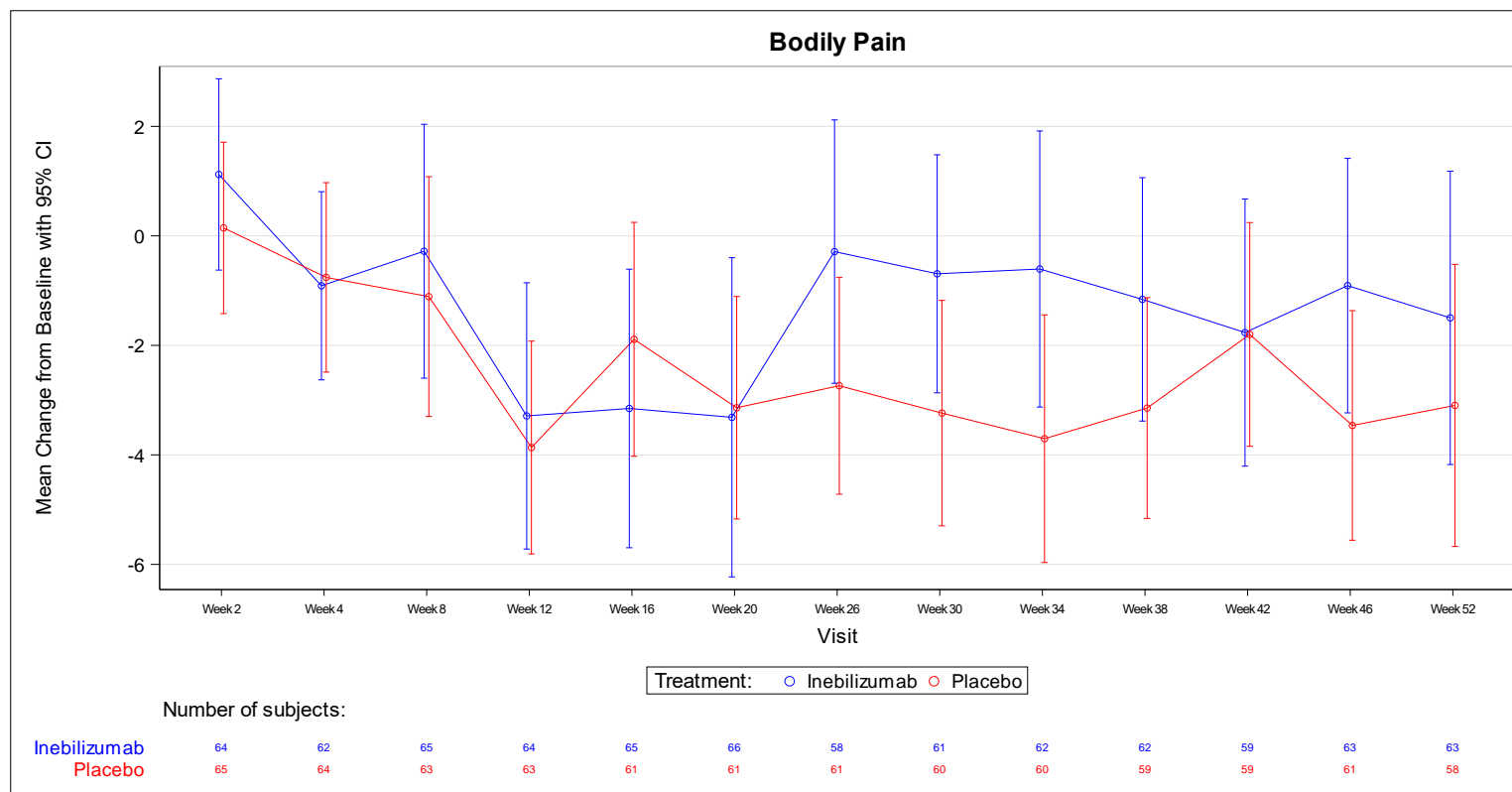
Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Amgen: Final
 Inebilizumab, Protocol: VIB0551.P3.S2
 Study population
 Datacut: 09APR2024
 Observed Means and Change from Baseline for Bodily Pain
 Full Analysis Set

Visit	Inebilizumab (N=68)				Placebo (N=67)			
	Observed Means		Change From Baseline		Observed Means		Change from Baseline	
	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)
Baseline	68	52.3 (8.43)			67	53.0 (9.22)		
Week 2	64	53.0 (8.63)	64	1.1 (6.99)	65	52.9 (9.12)	65	0.1 (6.32)
Week 4	62	51.0 (9.06)	62	-0.9 (6.77)	64	52.4 (9.93)	64	-0.8 (6.93)
Week 8	65	52.0 (9.75)	65	-0.3 (9.36)	63	51.7 (9.10)	63	-1.1 (8.70)
Week 12	64	49.0 (9.92)	64	-3.3 (9.74)	63	49.0 (10.03)	63	-3.9 (7.72)
Week 16	65	49.0 (10.33)	65	-3.2 (10.27)	61	50.9 (9.35)	61	-1.9 (8.34)
Week 20	66	48.7 (10.54)	66	-3.3 (11.86)	61	49.6 (9.61)	61	-3.1 (7.93)
Week 26	58	51.1 (8.15)	58	-0.3 (9.15)	61	51.0 (8.51)	61	-2.7 (7.74)
Week 30	61	50.7 (8.16)	61	-0.7 (8.49)	60	50.3 (8.81)	60	-3.2 (7.97)
Week 34	62	50.9 (8.96)	62	-0.6 (9.93)	60	49.8 (10.25)	60	-3.7 (8.75)
Week 38	62	50.4 (9.75)	62	-1.2 (8.75)	59	50.3 (8.65)	59	-3.1 (7.74)
Week 42	59	50.2 (8.44)	59	-1.8 (9.36)	59	51.4 (9.23)	59	-1.8 (7.84)
Week 46	63	50.9 (8.95)	63	-0.9 (9.23)	61	49.6 (9.45)	61	-3.5 (8.19)
Week 52	63	50.3 (9.29)	63	-1.5 (10.64)	58	50.3 (9.77)	58	-3.1 (9.80)

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Amgen: Final
 Inebilizumab, Protocol: VIB0551.P3.S2
 Study population
 Datacut: 09APR2024
 Graphical Summary of Change from Baseline for Bodily Pain
 Full Analysis Set



95% CIs are not drawn for visits with number of subjects < 10.

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Amgen: Final
 Inebilizumab, Protocol: VIB0551.P3.S2
 Study population
 Datacut: 09APR2024
 Between Treatment Comparison (Mixed Effects Model) of Change from Baseline for General Health
 Full Analysis Set

Visit	Inebilizumab (N=68)		Placebo (N=67)		Difference of		Hedges'g (95% CI) [2]	p-Value
	N[1]	LSMean (SE)	N[1]	LSMean (SE)	LSMeans (95% CI)	p-Value		
Week 2		0.60 (0.57)		-0.34 (0.57)				
Week 4		0.22 (0.62)		-0.81 (0.61)				
Week 8		0.51 (0.70)		-0.41 (0.71)				
Week 12		-1.64 (0.81)		-2.41 (0.82)				
Week 16		-1.22 (0.84)		-1.71 (0.86)				
Week 20		-1.26 (0.90)		-2.13 (0.92)				
Week 26		-1.05 (0.81)		-1.83 (0.80)				
Week 30		-0.70 (0.82)		-2.33 (0.82)				
Week 34		-0.52 (0.81)		-2.29 (0.81)				
Week 38		-1.12 (0.85)		-2.25 (0.86)				
Week 42		-0.56 (0.89)		-2.62 (0.89)				
Week 46		-0.38 (0.89)		-2.94 (0.89)				
Week 52	68	-0.24 (0.88)	67	-2.67 (0.89)	2.43 (-0.06, 4.91)	0.0554	0.33 (-0.01, 0.67)	0.0561

Analysis based on repeated measures mixed-effects model with treatment, time, treatment-by-time, baseline value and stratification factor 'First or subsequent IgG4-RD manifestation' as covariates.

Analysis based on restricted maximum likelihood (REML) using unstructured covariance matrix.

[1] N displays number of subjects included in the mixed-effects model.

[2] An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges'g.

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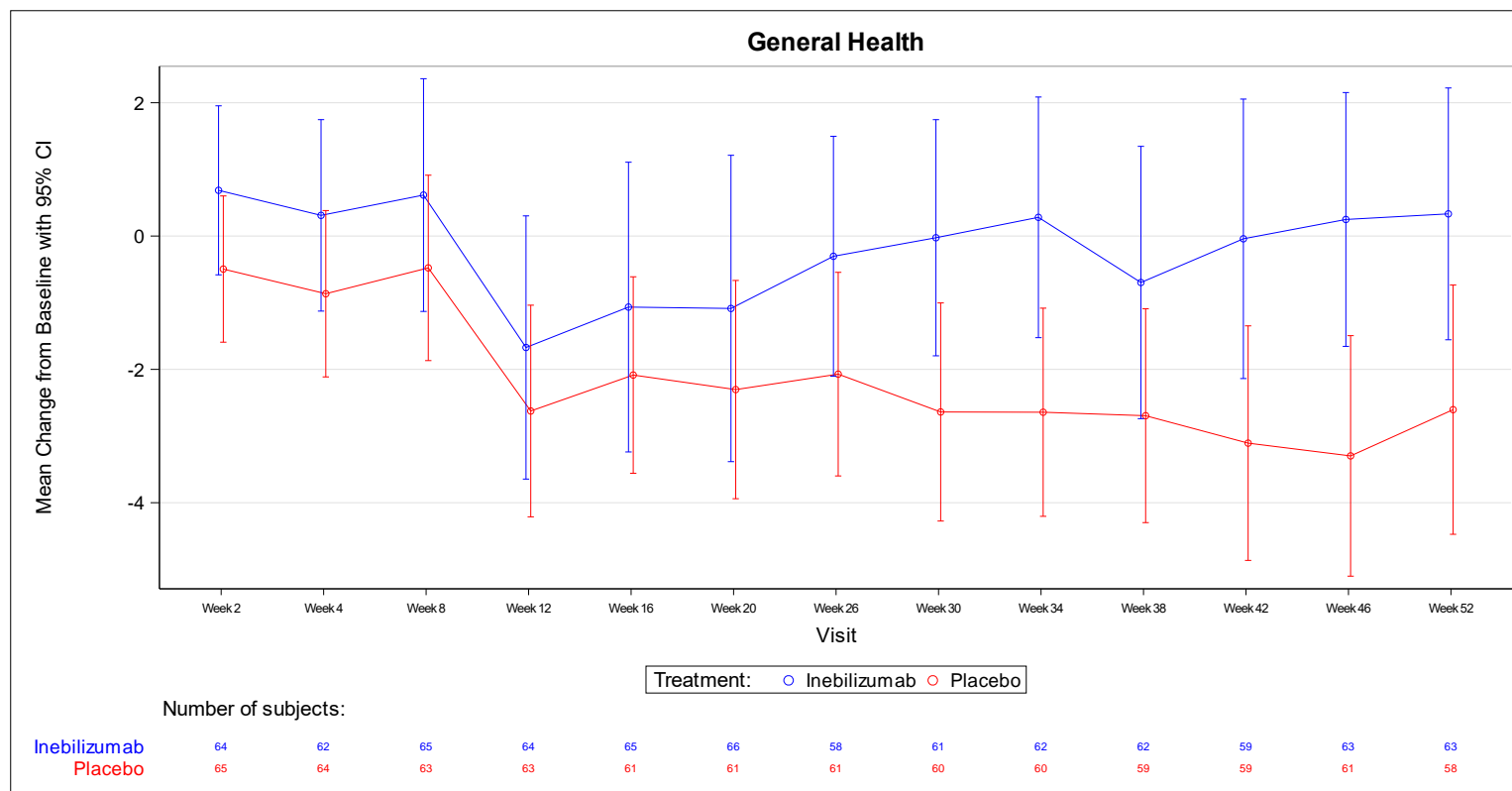
Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Amgen: Final
 Inebilizumab, Protocol: VIB0551.P3.S2
 Study population
 Datacut: 09APR2024
 Observed Means and Change from Baseline for General Health
 Full Analysis Set

Visit	Inebilizumab (N=68)				Placebo (N=67)			
	Observed Means		Change From Baseline		Observed Means		Change from Baseline	
	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)
Baseline	68	46.7 (8.78)			67	47.8 (8.73)		
Week 2	64	47.2 (7.85)	64	0.7 (5.07)	65	47.3 (9.36)	65	-0.5 (4.43)
Week 4	62	46.8 (7.64)	62	0.3 (5.65)	64	47.0 (8.96)	64	-0.9 (5.00)
Week 8	65	47.3 (8.14)	65	0.6 (7.04)	63	47.4 (8.28)	63	-0.5 (5.52)
Week 12	64	45.0 (8.76)	64	-1.7 (7.90)	63	45.5 (9.29)	63	-2.6 (6.30)
Week 16	65	45.6 (8.91)	65	-1.1 (8.77)	61	46.0 (9.24)	61	-2.1 (5.75)
Week 20	66	45.4 (9.30)	66	-1.1 (9.35)	61	45.7 (8.96)	61	-2.3 (6.39)
Week 26	58	46.1 (8.78)	58	-0.3 (6.84)	61	46.3 (8.96)	61	-2.1 (5.96)
Week 30	61	46.2 (8.87)	61	-0.0 (6.92)	60	45.6 (8.74)	60	-2.6 (6.33)
Week 34	62	46.3 (9.04)	62	0.3 (7.11)	60	45.9 (8.38)	60	-2.6 (6.04)
Week 38	62	45.6 (9.29)	62	-0.7 (8.04)	59	45.5 (8.58)	59	-2.7 (6.15)
Week 42	59	46.4 (9.09)	59	-0.0 (8.04)	59	45.5 (9.27)	59	-3.1 (6.75)
Week 46	63	46.5 (9.05)	63	0.2 (7.56)	61	45.2 (9.73)	61	-3.3 (7.04)
Week 52	63	46.6 (8.78)	63	0.3 (7.50)	58	45.8 (8.99)	58	-2.6 (7.11)

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Amgen: Final
 Inebilizumab, Protocol: VIB0551.P3.S2
 Study population
 Datacut: 09APR2024
 Graphical Summary of Change from Baseline for General Health
 Full Analysis Set



95% CIs are not drawn for visits with number of subjects < 10.

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Amgen: Final
 Inebilizumab, Protocol: VIB0551.P3.S2
 Study population
 Datacut: 09APR2024
 Between Treatment Comparison (Mixed Effects Model) of Change from Baseline for Vitality
 Full Analysis Set

Visit	Inebilizumab (N=68)		Placebo (N=67)		Difference of		Hedges'g (95% CI) [2]	p-Value
	N[1]	LSMean (SE)	N[1]	LSMean (SE)	LSMeans (95% CI)	p-Value		
Week 2		-0.81 (0.59)		0.63 (0.58)				
Week 4		-0.54 (0.77)		-1.29 (0.76)				
Week 8		-1.36 (0.92)		-0.60 (0.93)				
Week 12		-3.10 (1.03)		-2.80 (1.04)				
Week 16		-2.18 (0.93)		-0.73 (0.95)				
Week 20		-2.65 (0.96)		-1.30 (0.98)				
Week 26		-1.02 (0.97)		-1.79 (0.97)				
Week 30		-0.70 (1.01)		-2.32 (1.01)				
Week 34		-1.55 (1.00)		-1.84 (1.01)				
Week 38		-1.02 (1.01)		-1.34 (1.02)				
Week 42		-1.13 (1.02)		-1.97 (1.03)				
Week 46		-0.60 (0.98)		-2.92 (0.99)				
Week 52	68	-1.22 (0.93)	67	-1.66 (0.94)	0.44 (-2.17, 3.05)	0.7393	0.06 (-0.28, 0.39)	0.7402

Analysis based on repeated measures mixed-effects model with treatment, time, treatment-by-time, baseline value and stratification factor 'First or subsequent IgG4-RD manifestation' as covariates.

Analysis based on restricted maximum likelihood (REML) using unstructured covariance matrix.

[1] N displays number of subjects included in the mixed-effects model.

[2] An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges'g.

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Date of Table Generation: 07JAN2026

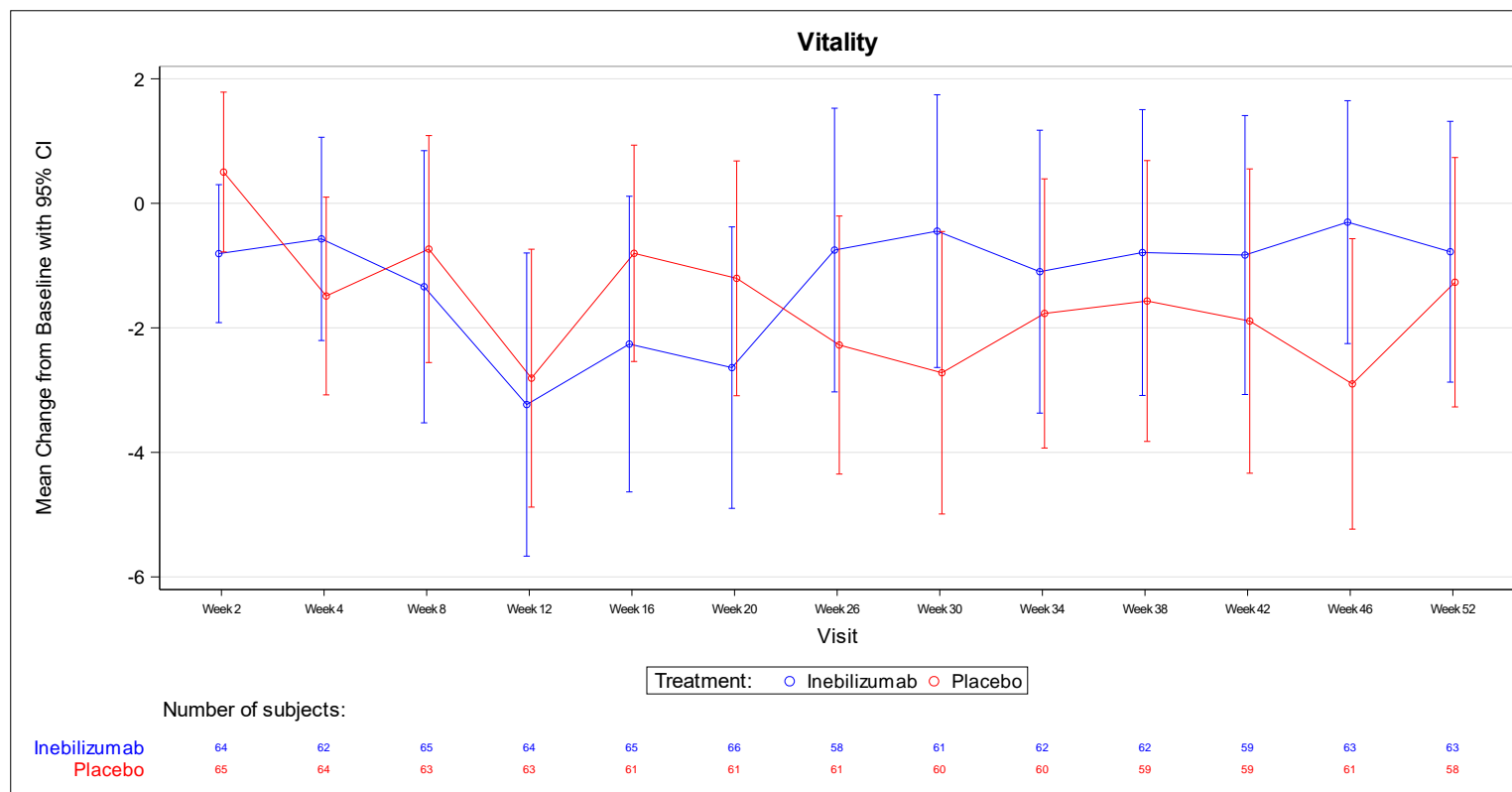
Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Amgen: Final
 Inebilizumab, Protocol: VIB0551.P3.S2
 Study population
 Datacut: 09APR2024
 Observed Means and Change from Baseline for Vitality
 Full Analysis Set

Visit	Inebilizumab (N=68)				Placebo (N=67)			
	Observed Means		Change From Baseline		Observed Means		Change from Baseline	
	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)
Baseline	68	52.5 (8.61)			67	52.9 (8.59)		
Week 2	64	51.3 (8.44)	64	-0.8 (4.44)	65	53.2 (8.95)	65	0.5 (5.18)
Week 4	62	51.2 (8.47)	62	-0.6 (6.43)	64	51.5 (9.51)	64	-1.5 (6.36)
Week 8	65	50.8 (8.03)	65	-1.3 (8.82)	63	52.1 (9.17)	63	-0.7 (7.24)
Week 12	64	49.1 (9.52)	64	-3.2 (9.75)	63	50.3 (8.80)	63	-2.8 (8.22)
Week 16	65	50.2 (7.86)	65	-2.3 (9.58)	61	52.1 (8.12)	61	-0.8 (6.78)
Week 20	66	49.4 (8.75)	66	-2.6 (9.20)	61	51.8 (8.65)	61	-1.2 (7.36)
Week 26	58	51.1 (8.34)	58	-0.8 (8.66)	61	51.2 (9.67)	61	-2.3 (8.09)
Week 30	61	51.4 (8.97)	61	-0.4 (8.55)	60	50.7 (9.64)	60	-2.7 (8.78)
Week 34	62	50.6 (8.44)	62	-1.1 (8.95)	60	51.6 (8.76)	60	-1.8 (8.37)
Week 38	62	50.9 (8.28)	62	-0.8 (9.04)	59	51.9 (9.41)	59	-1.6 (8.66)
Week 42	59	51.2 (7.90)	59	-0.8 (8.60)	59	51.3 (9.36)	59	-1.9 (9.38)
Week 46	63	51.8 (7.39)	63	-0.3 (7.75)	61	50.2 (9.69)	61	-2.9 (9.11)
Week 52	63	50.9 (8.52)	63	-0.8 (8.32)	58	52.0 (7.77)	58	-1.3 (7.62)

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Amgen: Final
 Inebilizumab, Protocol: VIB0551.P3.S2
 Study population
 Datacut: 09APR2024
 Graphical Summary of Change from Baseline for Vitality
 Full Analysis Set



95% CIs are not drawn for visits with number of subjects < 10.

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Amgen: Final
 Inebilizumab, Protocol: VIB0551.P3.S2
 Study population
 Datacut: 09APR2024
 Between Treatment Comparison (Mixed Effects Model) of Change from Baseline for Social Function
 Full Analysis Set

Visit	Inebilizumab (N=68)		Placebo (N=67)		Difference of		Hedges'g (95% CI) [2]	p-Value
	N[1]	LSMean (SE)	N[1]	LSMean (SE)	LSMeans (95% CI)	p-Value		
Week 2		0.71 (0.70)		0.87 (0.70)				
Week 4		0.57 (0.79)		-1.62 (0.78)				
Week 8		0.08 (0.84)		0.22 (0.85)				
Week 12		-1.84 (1.06)		-1.83 (1.07)				
Week 16		-0.66 (0.86)		-0.03 (0.88)				
Week 20		-2.47 (0.93)		-0.09 (0.96)				
Week 26		-1.40 (0.90)		-1.95 (0.89)				
Week 30		-0.41 (0.83)		-1.55 (0.84)				
Week 34		-0.26 (0.87)		-1.47 (0.88)				
Week 38		-0.68 (0.90)		-0.88 (0.91)				
Week 42		0.27 (0.93)		-0.83 (0.93)				
Week 46		-0.28 (0.97)		-2.08 (0.98)				
Week 52	68	-0.44 (0.98)	67	-1.54 (1.00)	1.10 (-1.67, 3.87)	0.4317	0.13 (-0.20, 0.47)	0.4335

Analysis based on repeated measures mixed-effects model with treatment, time, treatment-by-time, baseline value and stratification factor 'First or subsequent IgG4-RD manifestation' as covariates.

Analysis based on restricted maximum likelihood (REML) using unstructured covariance matrix.

[1] N displays number of subjects included in the mixed-effects model.

[2] An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges'g.

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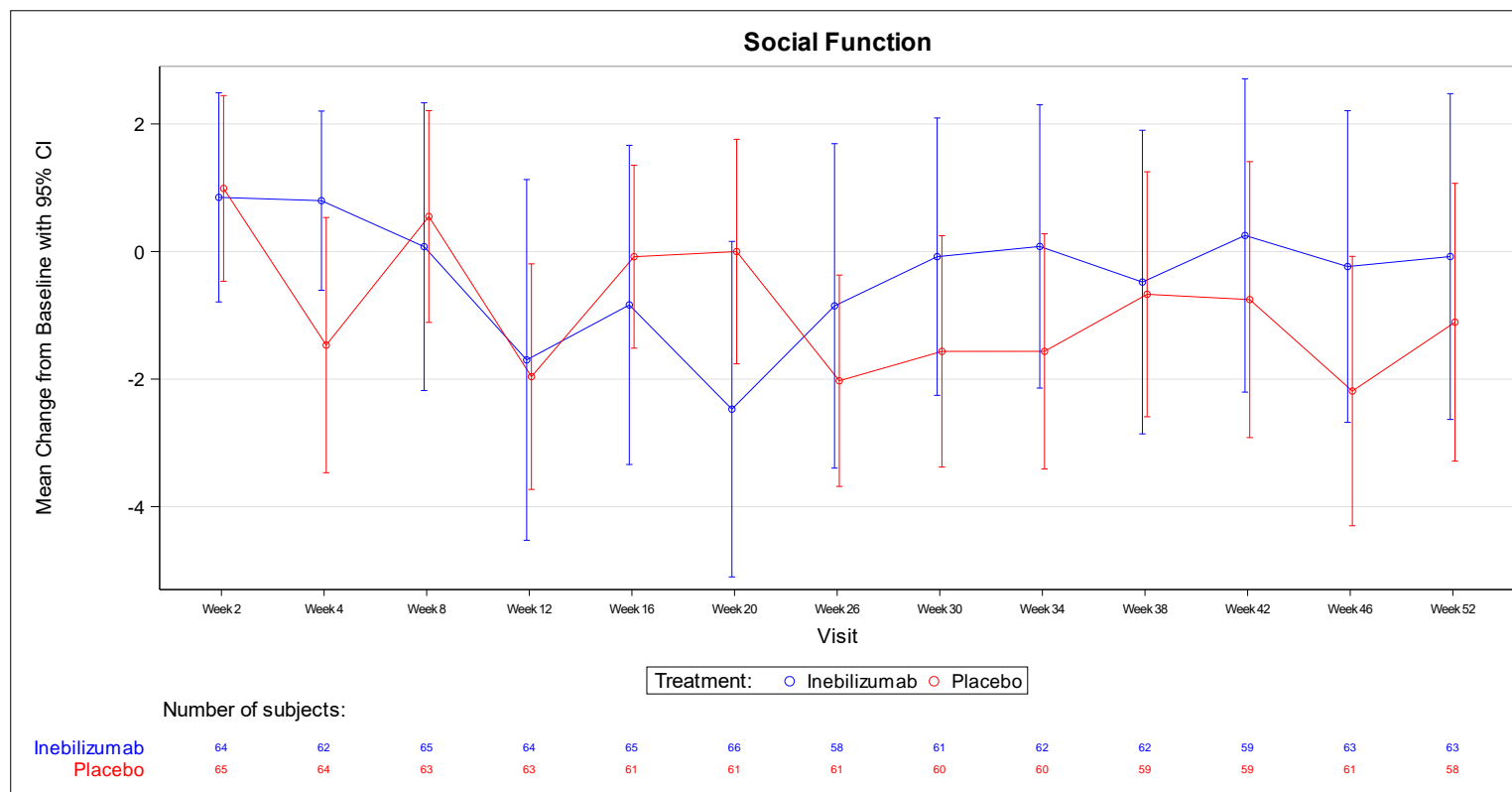
Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Amgen: Final
 Inebilizumab, Protocol: VIB0551.P3.S2
 Study population
 Datcut: 09APR2024
 Observed Means and Change from Baseline for Social Function
 Full Analysis Set

Visit	Inebilizumab (N=68)				Placebo (N=67)			
	Observed Means		Change From Baseline		Observed Means		Change from Baseline	
	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)
Baseline	68	50.7 (8.40)			67	50.3 (9.39)		
Week 2	64	51.3 (7.11)	64	0.8 (6.56)	65	51.2 (9.43)	65	1.0 (5.87)
Week 4	62	51.2 (7.83)	62	0.8 (5.53)	64	48.9 (9.56)	64	-1.5 (8.01)
Week 8	65	50.7 (7.80)	65	0.1 (9.10)	63	50.6 (8.91)	63	0.5 (6.59)
Week 12	64	49.0 (8.89)	64	-1.7 (11.32)	63	48.6 (9.81)	63	-2.0 (7.02)
Week 16	65	50.0 (7.93)	65	-0.8 (10.10)	61	50.3 (8.30)	61	-0.1 (5.60)
Week 20	66	48.2 (8.61)	66	-2.5 (10.70)	61	50.5 (7.86)	61	-0.0 (6.87)
Week 26	58	49.3 (7.76)	58	-0.9 (9.67)	61	49.0 (8.59)	61	-2.0 (6.47)
Week 30	61	50.3 (7.58)	61	-0.1 (8.49)	60	49.2 (8.27)	60	-1.6 (7.02)
Week 34	62	50.4 (7.72)	62	0.1 (8.74)	60	49.7 (8.45)	60	-1.6 (7.14)
Week 38	62	50.0 (7.65)	62	-0.5 (9.37)	59	50.0 (8.61)	59	-0.7 (7.37)
Week 42	59	51.1 (7.31)	59	0.3 (9.42)	59	50.0 (8.40)	59	-0.8 (8.30)
Week 46	63	50.5 (7.75)	63	-0.2 (9.70)	61	48.7 (8.76)	61	-2.2 (8.25)
Week 52	63	50.5 (7.60)	63	-0.1 (10.14)	58	49.8 (8.02)	58	-1.1 (8.28)

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Amgen: Final
 Inebilizumab, Protocol: VIB0551.P3.S2
 Study population
 Datacut: 09APR2024
 Graphical Summary of Change from Baseline for Social Function
 Full Analysis Set



95% CIs are not drawn for visits with number of subjects < 10.

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Amgen: Final
 Inebilizumab, Protocol: VIB0551.P3.S2
 Study population
 Datacut: 09APR2024
 Between Treatment Comparison (Mixed Effects Model) of Change from Baseline for Role Emotional
 Full Analysis Set

Visit	Inebilizumab (N=68)		Placebo (N=67)		Difference of		Hedges'g (95% CI) [2]	p-Value
	N[1]	LSMean (SE)	N[1]	LSMean (SE)	LSMeans (95% CI)	p-Value		
Week 2		1.73 (0.77)		2.12 (0.77)				
Week 4		0.87 (0.79)		1.57 (0.78)				
Week 8		1.76 (0.79)		1.90 (0.80)				
Week 12		0.48 (0.85)		0.40 (0.86)				
Week 16		0.53 (0.85)		0.88 (0.87)				
Week 20		-0.76 (0.92)		0.97 (0.94)				
Week 26		0.39 (1.04)		-0.29 (1.03)				
Week 30		0.95 (0.90)		0.09 (0.90)				
Week 34		0.32 (1.00)		0.95 (1.01)				
Week 38		0.29 (1.02)		1.27 (1.03)				
Week 42		0.54 (0.92)		0.82 (0.93)				
Week 46		0.68 (0.94)		0.71 (0.95)				
Week 52	68	0.98 (0.99)	67	-0.56 (1.01)	1.55 (-1.25, 4.34)	0.2759	0.19 (-0.15, 0.53)	0.2775

Analysis based on repeated measures mixed-effects model with treatment, time, treatment-by-time, baseline value and stratification factor 'First or subsequent IgG4-RD manifestation' as covariates.

Analysis based on restricted maximum likelihood (REML) using unstructured covariance matrix.

[1] N displays number of subjects included in the mixed-effects model.

[2] An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges'g.

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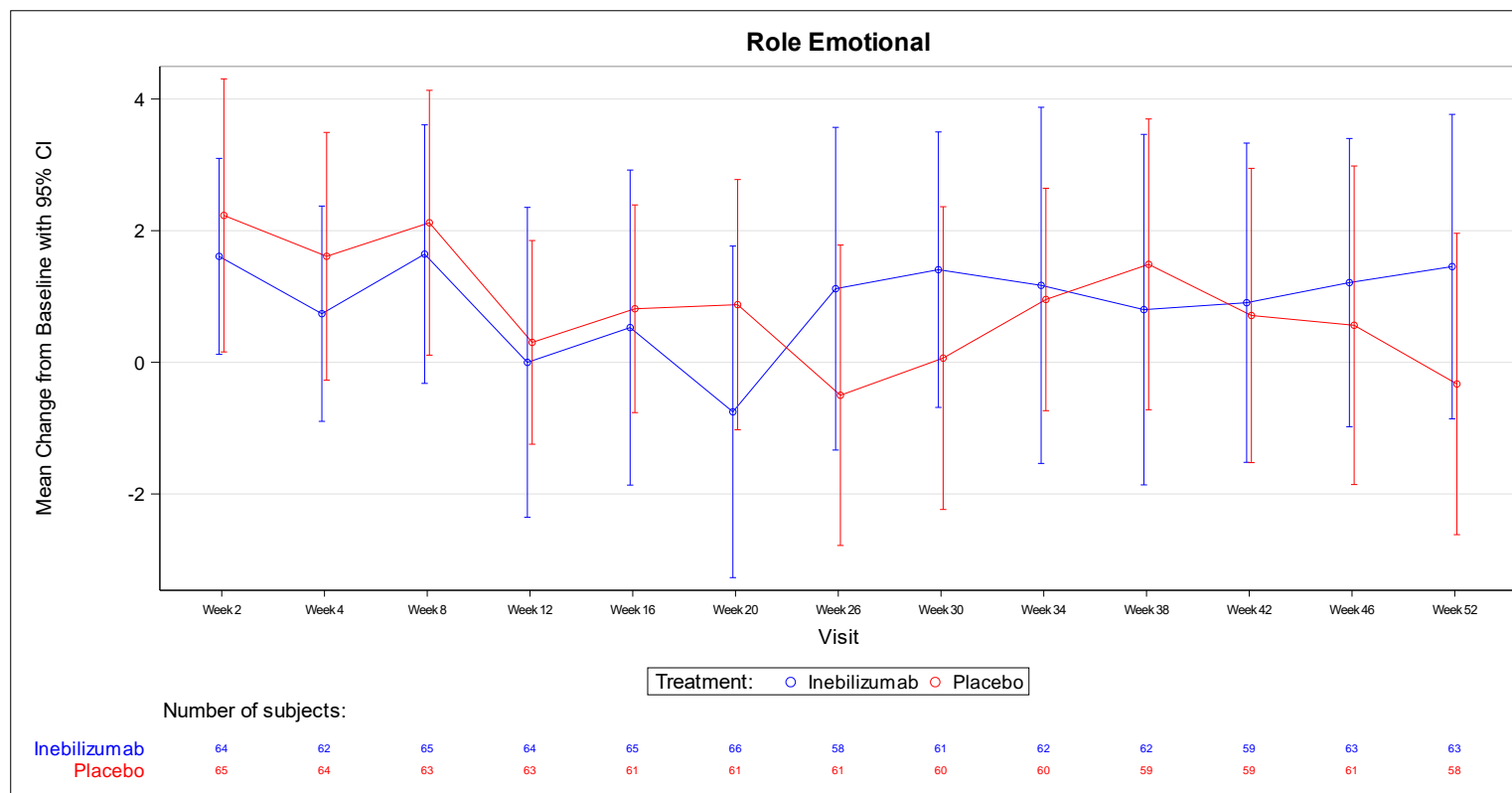
Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Amgen: Final
 Inebilizumab, Protocol: VIB0551.P3.S2
 Study population
 Datacut: 09APR2024
 Observed Means and Change from Baseline for Role Emotional
 Full Analysis Set

Visit	Inebilizumab (N=68)				Placebo (N=67)			
	Observed Means		Change From Baseline		Observed Means		Change from Baseline	
	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)
Baseline	68	47.7 (9.89)			67	47.4 (12.61)		
Week 2	64	49.4 (8.61)	64	1.6 (5.96)	65	49.4 (10.89)	65	2.2 (8.37)
Week 4	62	48.3 (8.86)	62	0.7 (6.44)	64	49.2 (11.28)	64	1.6 (7.54)
Week 8	65	49.3 (8.19)	65	1.6 (7.93)	63	49.2 (10.23)	63	2.1 (7.99)
Week 12	64	48.1 (8.70)	64	-0.0 (9.42)	63	47.8 (10.84)	63	0.3 (6.14)
Week 16	65	47.8 (8.83)	65	0.5 (9.66)	61	48.0 (10.95)	61	0.8 (6.16)
Week 20	66	46.7 (8.99)	66	-0.8 (10.25)	61	48.3 (10.30)	61	0.9 (7.42)
Week 26	58	48.4 (9.09)	58	1.1 (9.32)	61	48.1 (10.32)	61	-0.5 (8.91)
Week 30	61	48.6 (8.32)	61	1.4 (8.17)	60	48.3 (9.81)	60	0.1 (8.90)
Week 34	62	48.3 (8.67)	62	1.2 (10.65)	60	49.5 (9.22)	60	1.0 (6.54)
Week 38	62	48.2 (9.36)	62	0.8 (10.48)	59	49.4 (9.15)	59	1.5 (8.48)
Week 42	59	48.3 (8.00)	59	0.9 (9.31)	59	48.5 (9.28)	59	0.7 (8.58)
Week 46	63	48.2 (7.60)	63	1.2 (8.69)	61	48.5 (10.16)	61	0.6 (9.45)
Week 52	63	48.7 (9.03)	63	1.5 (9.18)	58	47.5 (10.19)	58	-0.3 (8.71)

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Amgen: Final
 Inebilizumab, Protocol: VIB0551.P3.S2
 Study population
 Datacut: 09APR2024
 Graphical Summary of Change from Baseline for Role Emotional
 Full Analysis Set



95% CIs are not drawn for visits with number of subjects < 10.

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Amgen: Final
 Inebilizumab, Protocol: VIB0551.P3.S2
 Study population
 Datacut: 09APR2024
 Between Treatment Comparison (Mixed Effects Model) of Change from Baseline for Mental Health
 Full Analysis Set

Visit	Inebilizumab (N=68)		Placebo (N=67)		Difference of		Hedges'g (95% CI) [2]	p-Value
	N[1]	LSMean (SE)	N[1]	LSMean (SE)	LSMeans (95% CI)	p-Value		
Week 2		0.53 (0.72)		1.59 (0.72)				
Week 4		0.59 (0.75)		0.53 (0.74)				
Week 8		-0.19 (0.82)		0.36 (0.83)				
Week 12		-0.94 (0.83)		-0.43 (0.83)				
Week 16		-0.64 (0.77)		1.35 (0.79)				
Week 20		-0.84 (0.92)		0.49 (0.94)				
Week 26		-0.08 (0.97)		-0.20 (0.96)				
Week 30		-0.19 (0.93)		0.28 (0.94)				
Week 34		-0.22 (0.89)		0.10 (0.90)				
Week 38		0.54 (0.89)		0.51 (0.90)				
Week 42		-0.11 (0.95)		0.51 (0.96)				
Week 46		0.54 (0.91)		-0.61 (0.92)				
Week 52	68	-0.08 (0.94)	67	-0.15 (0.96)	0.07 (-2.60, 2.74)	0.9567	0.01 (-0.33, 0.35)	0.9568

Analysis based on repeated measures mixed-effects model with treatment, time, treatment-by-time, baseline value and stratification factor 'First or subsequent IgG4-RD manifestation' as covariates.

Analysis based on restricted maximum likelihood (REML) using unstructured covariance matrix.

[1] N displays number of subjects included in the mixed-effects model.

[2] An approximate standard deviation was calculated for each arm based on the standard error of the LS mean to obtain the pooled standard deviation for Hedges'g.

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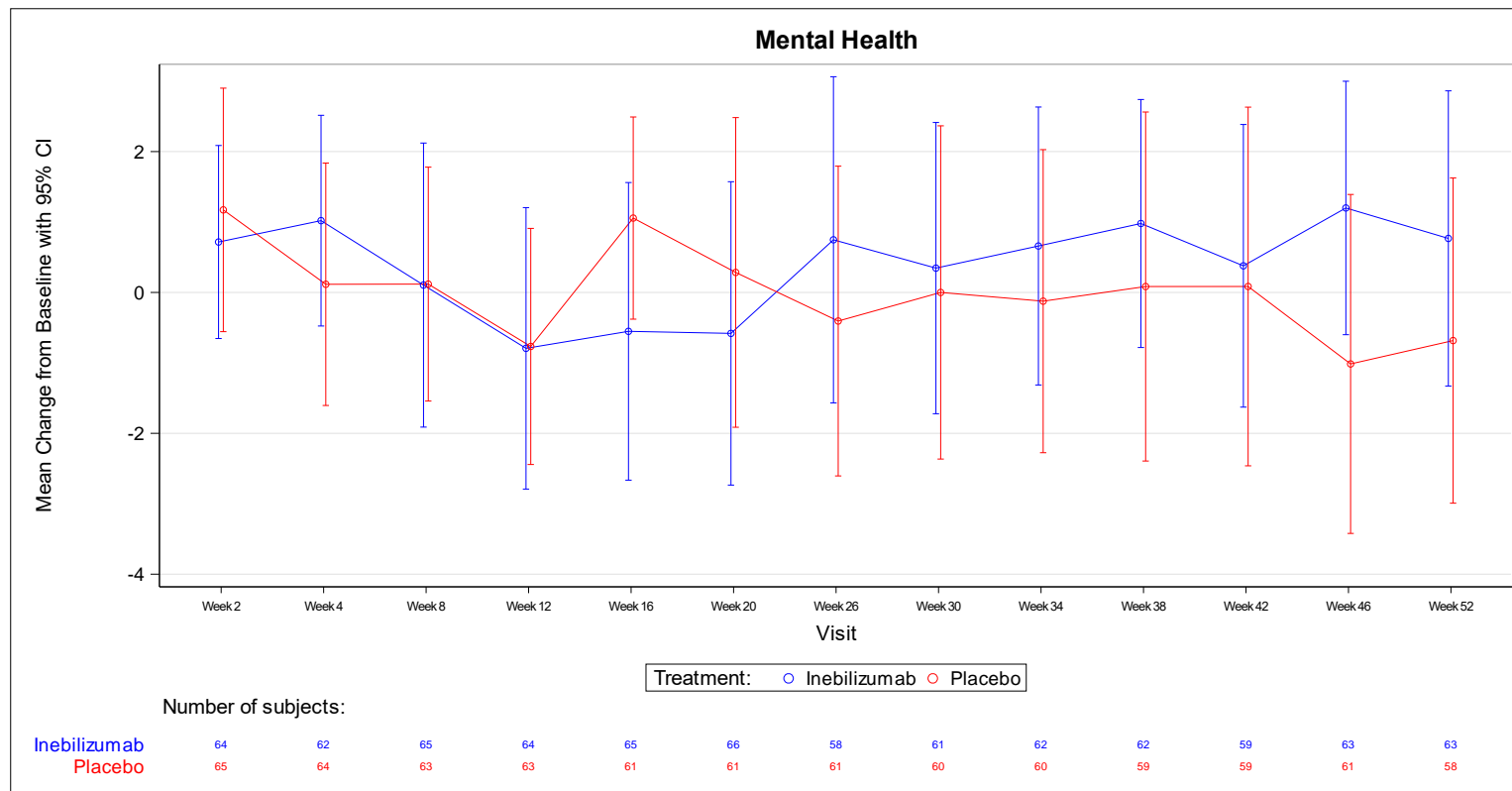
Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Amgen: Final
 Inebilizumab, Protocol: VIB0551.P3.S2
 Study population
 Datacut: 09APR2024
 Observed Means and Change from Baseline for Mental Health
 Full Analysis Set

Visit	Inebilizumab (N=68)				Placebo (N=67)			
	Observed Means		Change From Baseline		Observed Means		Change from Baseline	
	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)
Baseline	68	47.8 (8.71)			67	49.4 (9.73)		
Week 2	64	48.2 (8.37)	64	0.7 (5.49)	65	50.5 (9.42)	65	1.2 (6.98)
Week 4	62	48.0 (7.86)	62	1.0 (5.89)	64	49.7 (9.77)	64	0.1 (6.89)
Week 8	65	47.5 (9.08)	65	0.1 (8.14)	63	49.5 (8.66)	63	0.1 (6.59)
Week 12	64	46.8 (9.25)	64	-0.8 (8.00)	63	48.4 (8.97)	63	-0.8 (6.66)
Week 16	65	46.9 (8.58)	65	-0.6 (8.53)	61	49.9 (8.06)	61	1.1 (5.60)
Week 20	66	46.9 (8.62)	66	-0.6 (8.76)	61	49.6 (8.95)	61	0.3 (8.58)
Week 26	58	48.0 (8.99)	58	0.7 (8.81)	61	49.5 (8.96)	61	-0.4 (8.59)
Week 30	61	47.6 (9.02)	61	0.3 (8.07)	60	49.8 (8.37)	60	0.0 (9.16)
Week 34	62	47.7 (7.98)	62	0.7 (7.77)	60	49.5 (9.44)	60	-0.1 (8.33)
Week 38	62	48.4 (7.37)	62	1.0 (6.93)	59	49.8 (9.18)	59	0.1 (9.51)
Week 42	59	47.7 (8.17)	59	0.4 (7.70)	59	49.5 (9.34)	59	0.1 (9.77)
Week 46	63	48.3 (7.96)	63	1.2 (7.14)	61	48.4 (9.69)	61	-1.0 (9.39)
Week 52	63	47.8 (8.67)	63	0.8 (8.32)	58	49.1 (8.64)	58	-0.7 (8.78)

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Amgen: Final
 Inebilizumab, Protocol: VIB0551.P3.S2
 Study population
 Datacut: 09APR2024
 Graphical Summary of Change from Baseline for Mental Health
 Full Analysis Set



95% CIs are not drawn for visits with number of subjects < 10.

4.3 Einzelkomponenten (Responderanalysen von 15 % der Skalenbreite)

Amgen: Final
 Inebilizumab, Protocol: VIB0551.P3.S2
 Study population
 Datacut: 09APR2024
 Improvement in Physical Functioning by ≥ 5.8 points (=increase by ≥ 5.8 points)
 Full Analysis Set
 Week 52

	Inebilizumab (N=68)	Placebo (N=67)
Number of subjects with events, n (%)	8 (11.8)	5 (7.5)
Number of imputed subjects [1]	5	9
Adjusted analysis Inebilizumab vs. Placebo [2]		
Relative Risk (95% CI) [3a]	1.56 (0.56, 4.31)	
p-value	0.3945	
Odds Ratio (95% CI) [3b]	1.71 (0.50, 5.83)	
p-value	0.3912	
Risk Difference (95% CI) [3c]	NA [4]	
p-value		

[1] Non-responder imputation
 [2] Based on a generalized model with treatment and stratification factor 'First or subsequent IgG4-RD manifestation' as covariates.
 [3a] Link function: log
 [3b] Link function: logit
 [3c] Link function: identity
 [4] The convergence is questionable so no estimates are given.

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Amgen: Final
 Inebilizumab, Protocol: VIB0551.P3.S2
 Study population
 Datacut: 09APR2024
 Improvement in Role Physical by >= 5.3 points (=increase by >= 5.3 points)
 Full Analysis Set
 Week 52

	Inebilizumab (N=68)	Placebo (N=67)
Number of subjects with events, n (%)	13 (19.1)	10 (14.9)
Number of imputed subjects [1]	5	9
Adjusted analysis Inebilizumab vs. Placebo [2]		
Relative Risk (95% CI) [3a]	1.27 (0.61, 2.68)	
p-value	0.5242	
Odds Ratio (95% CI) [3b]	1.35 (0.54, 3.36)	
p-value	0.5211	
Risk Difference (95% CI) [3c]	3.90 (-8.22, 16.03)	
p-value	0.5281	

[1] Non-responder imputation
 [2] Based on a generalized model with treatment and stratification factor 'First or subsequent IgG4-RD manifestation' as covariates.
 [3a] Link function: log
 [3b] Link function: logit
 [3c] Link function: identity
 [4] The convergence is questionable so no estimates are given.

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Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Amgen: Final
 Inebilizumab, Protocol: VIB0551.P3.S2
 Study population
 Datacut: 09APR2024
 Improvement in Bodily Pain by >= 5.9 points (=increase by >= 5.9 points)
 Full Analysis Set
 Week 52

	Inebilizumab (N=68)	Placebo (N=67)
Number of subjects with events, n (%)	18 (26.5)	9 (13.4)
Number of imputed subjects [1]	5	9
Adjusted analysis Inebilizumab vs. Placebo [2]		
Relative Risk (95% CI) [3a]	1.94 (0.94, 3.99)	
p-value	0.0741	
Odds Ratio (95% CI) [3b]	2.33 (0.96, 5.66)	
p-value	0.0623	
Risk Difference (95% CI) [3c]	14.04 (1.14, 26.95)	
p-value	0.0330	

[1] Non-responder imputation
 [2] Based on a generalized model with treatment and stratification factor 'First or subsequent IgG4-RD manifestation' as covariates.
 [3a] Link function: log
 [3b] Link function: logit
 [3c] Link function: identity
 [4] The convergence is questionable so no estimates are given.

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Date of Table Generation: 07JAN2026

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Amgen: Final
 Inebilizumab, Protocol: VIB0551.P3.S2
 Study population
 Datacut: 09APR2024
 Improvement in General Health by ≥ 6.6 points (=increase by ≥ 6.6 points)
 Full Analysis Set
 Week 52

	Inebilizumab (N=68)	Placebo (N=67)
Number of subjects with events, n (%)	11 (16.2)	3 (4.5)
Number of imputed subjects [1]	5	9
Adjusted analysis Inebilizumab vs. Placebo [2]		
Relative Risk (95% CI) [3a]	3.61 (1.06, 12.28)	
p-value	0.0402	
Odds Ratio (95% CI) [3b]	4.17 (1.10, 15.82)	
p-value	0.0357	
Risk Difference (95% CI) [3c]	10.61 (0.26, 20.95)	
p-value	0.0445	

[1] Non-responder imputation
 [2] Based on a generalized model with treatment and stratification factor 'First or subsequent IgG4-RD manifestation' as covariates.
 [3a] Link function: log
 [3b] Link function: logit
 [3c] Link function: identity
 [4] The convergence is questionable so no estimates are given.

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Date of Table Generation: 07JAN2026

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Amgen: Final
 Inebilizumab, Protocol: VIB0551.P3.S2
 Study population
 Datacut: 09APR2024
 Improvement in Vitality by >= 6.5 points (=increase by >= 6.5 points)
 Full Analysis Set
 Week 52

	Inebilizumab (N=68)	Placebo (N=67)
Number of subjects with events, n (%)	6 (8.8)	5 (7.5)
Number of imputed subjects [1]	5	9
Adjusted analysis Inebilizumab vs. Placebo [2]		
Relative Risk (95% CI) [3a]	1.20 (0.38, 3.73)	
p-value	0.7570	
Odds Ratio (95% CI) [3b]	1.20 (0.35, 4.14)	
p-value	0.7759	
Risk Difference (95% CI) [3c]	0.05 (-10.01, 10.10)	
p-value	0.9926	

[1] Non-responder imputation
 [2] Based on a generalized model with treatment and stratification factor 'First or subsequent IgG4-RD manifestation' as covariates.
 [3a] Link function: log
 [3b] Link function: logit
 [3c] Link function: identity
 [4] The convergence is questionable so no estimates are given.

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Date of Table Generation: 07JAN2026

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Amgen: Final
 Inebilizumab, Protocol: VIB0551.P3.S2
 Study population
 Datacut: 09APR2024
 Improvement in Social Function by >= 5.9 points (=increase by >= 5.9 points)
 Full Analysis Set
 Week 52

	Inebilizumab (N=68)	Placebo (N=67)
Number of subjects with events, n (%)	13 (19.1)	6 (9.0)
Number of imputed subjects [1]	5	9
Adjusted analysis Inebilizumab vs. Placebo [2]		
Relative Risk (95% CI) [3a]	2.12 (0.88, 5.12)	
p-value	0.0948	
Odds Ratio (95% CI) [3b]	2.51 (0.87, 7.28)	
p-value	0.0898	
Risk Difference (95% CI) [3c]	6.69 (-3.90, 17.28)	
p-value	0.2158	

[1] Non-responder imputation
 [2] Based on a generalized model with treatment and stratification factor 'First or subsequent IgG4-RD manifestation' as covariates.
 [3a] Link function: log
 [3b] Link function: logit
 [3c] Link function: identity
 [4] The convergence is questionable so no estimates are given.

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Date of Table Generation: 07JAN2026

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Amgen: Final
 Inebilizumab, Protocol: VIB0551.P3.S2
 Study population
 Datacut: 09APR2024
 Improvement in Role Emotional by >= 6.9 points (=increase by >= 6.9 points)
 Full Analysis Set
 Week 52

	Inebilizumab (N=68)	Placebo (N=67)
Number of subjects with events, n (%)	19 (27.9)	8 (11.9)
Number of imputed subjects [1]	5	9
Adjusted analysis Inebilizumab vs. Placebo [2]		
Relative Risk (95% CI) [3a]	2.30 (1.12, 4.74)	
p-value	0.0236	
Odds Ratio (95% CI) [3b]	3.17 (1.22, 8.24)	
p-value	0.0183	
Risk Difference (95% CI) [3c]	11.41 (-0.76, 23.59)	
p-value	0.0662	

[1] Non-responder imputation
 [2] Based on a generalized model with treatment and stratification factor 'First or subsequent IgG4-RD manifestation' as covariates.
 [3a] Link function: log
 [3b] Link function: logit
 [3c] Link function: identity
 [4] The convergence is questionable so no estimates are given.

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Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

Amgen: Final
 Inebilizumab, Protocol: VIB0551.P3.S2
 Study population
 Datacut: 09APR2024
 Improvement in Mental Health by >= 7.4 points (=increase by >= 7.4 points)
 Full Analysis Set
 Week 52

	Inebilizumab (N=68)	Placebo (N=67)
Number of subjects with events, n (%)	12 (17.6)	13 (19.4)
Number of imputed subjects [1]	5	9
Adjusted analysis Inebilizumab vs. Placebo [2]		
Relative Risk (95% CI) [3a]	0.94 (0.47, 1.89)	
p-value	0.8602	
Odds Ratio (95% CI) [3b]	0.88 (0.37, 2.12)	
p-value	0.7829	
Risk Difference (95% CI) [3c]	-4.49 (-17.31, 8.33)	
p-value	0.4923	

[1] Non-responder imputation
 [2] Based on a generalized model with treatment and stratification factor 'First or subsequent IgG4-RD manifestation' as covariates.
 [3a] Link function: log
 [3b] Link function: logit
 [3c] Link function: identity
 [4] The convergence is questionable so no estimates are given.

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Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

5 Subgruppenanalysen

5.1 IgG4-RD-Krankheitsschübe

5.1.1 Zeit bis zum ersten behandelten und durch ein AC bestimmten IgG4-RD-Schub

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Table 14.2.2.1
 Subgroup Analysis Of Time (days) To The First Treated And AC-Determined IgG4-RD Flare (Randomized-Controlled Period)
 Full Analysis Set

Subgroup		Placebo N = 67	Inebilizumab N = 68
Age - < 65	Number of subjects with an IgG4-RD flare	30 (65.2%)	6 (12.8%)
	Number of censored subjects	16 (34.8%)	41 (87.2%)
	Median time to flare ^a	243.0	NA
	95% CI ^a	(180.0, 310.0)	(371.0, NA)
	Hazard ratio ^b		0.1
	95% CI ^b		(0.1, 0.3)
Age - >= 65	Number of subjects with an IgG4-RD flare	10 (47.6%)	1 (4.8%)
	Number of censored subjects	11 (52.4%)	20 (95.2%)
	Median time to flare ^a	NA	NA
	95% CI ^a	(117.0, NA)	(NA, NA)
	Hazard ratio ^b		0.1
	95% CI ^b		(0.0, 0.7)
Age interaction with treatment	P-value		0.0205
			0.6252

^a Based on Kaplan-Meier method.
^b Based on Cox regression method, with Placebo as the reference group.
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Table 14.2.2.1
Subgroup Analysis Of Time (days) To The First Treated And AC-Determined IgG4-RD Flare (Randomized-Controlled Period)
Full Analysis Set

Subgroup		Placebo N = 67	Inebilizumab N = 68
Sex - Female	Number of subjects with an IgG4-RD flare	10 (55.6%)	3 (10.3%)
	Number of censored subjects	8 (44.4%)	26 (89.7%)
	Median time to flare ^a	250.0	NA
	95% CI ^a	(191.0, NA)	(NA, NA)
	Hazard ratio ^b		0.2
	95% CI ^b		(0.0, 0.6)
Sex - Male	Number of subjects with an IgG4-RD flare	30 (61.2%)	4 (10.3%)
	Number of censored subjects	19 (38.8%)	35 (89.7%)
	Median time to flare ^a	246.0	NA
	95% CI ^a	(142.0, NA)	(371.0, NA)
	Hazard ratio ^b		0.1
	95% CI ^b		(0.0, 0.3)
Sex interaction with treatment	P-value		0.7423

^a Based on Kaplan-Meier method.

^b Based on Cox regression method, with Placebo as the reference group.

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Table 14.2.2.1
Subgroup Analysis Of Time (days) To The First Treated And AC-Determined IgG4-RD Flare (Randomized-Controlled Period)
Full Analysis Set

Subgroup		Placebo N = 67	Inebilizumab N = 68
Baseline serum IgG4 concentrations - < Median	Number of subjects with an IgG4-RD flare	14 (48.3%)	3 (10.0%)
	Number of censored subjects	15 (51.7%)	27 (90.0%)
	Median time to flare ^a	NA	NA
	95% CI ^a	(133.0, NA)	(NA, NA)
	Hazard ratio ^b		0.2
	95% CI ^b		(0.1, 0.6)
Baseline serum IgG4 concentrations - >= Median	Number of subjects with an IgG4-RD flare	24 (77.4%)	3 (10.3%)
	Number of censored subjects	7 (22.6%)	26 (89.7%)
	Median time to flare ^a	232.0	NA
	95% CI ^a	(141.0, 247.0)	(NA, NA)
	Hazard ratio ^b		0.1
	95% CI ^b		(0.0, 0.3)
Baseline serum IgG4 concentrations interaction with treatment	P-value		0.4882

^a Based on Kaplan-Meier method.

^b Based on Cox regression method, with Placebo as the reference group.

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Table 14.2.2.1
Subgroup Analysis Of Time (days) To The First Treated And AC-Determined IgG4-RD Flare (Randomized-Controlled Period)
Full Analysis Set

Subgroup		Placebo N = 67	Inebilizumab N = 68
First or subsequent IgG4-RD manifestation - First Manifestation of IgG4-RD	Number of subjects with an IgG4-RD flare	17 (54.8%)	1 (3.2%)
	Number of censored subjects	14 (45.2%)	30 (96.8%)
	Median time to flare ^a	240.0	NA
	95% CI ^a	(142.0, NA)	(NA, NA)
	Hazard ratio ^b		0.0
	95% CI ^b		(0.0, 0.3)
	P-value ^b		0.0026
First or subsequent IgG4-RD manifestation - Subsequent Manifestation of IgG4-RD	Number of subjects with an IgG4-RD flare	23 (63.9%)	6 (16.2%)
	Number of censored subjects	13 (36.1%)	31 (83.8%)
	Median time to flare ^a	246.5	NA
	95% CI ^a	(140.0, NA)	(371.0, NA)
	Hazard ratio ^b		0.2
	95% CI ^b		(0.1, 0.4)
	P-value ^b		0.0002
First or subsequent IgG4-RD manifestation interaction with treatment	P-value		0.1882

^a Based on Kaplan-Meier method.

^b Based on Cox regression method, with Placebo as the reference group.

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Table 14.2.2.1
Subgroup Analysis Of Time (days) To The First Treated And AC-Determined IgG4-RD Flare (Randomized-Controlled Period)
Full Analysis Set

Subgroup		Placebo N = 67	Inebilizumab N = 68
Region 1 - US	Number of subjects with an IgG4-RD flare	9 (64.3%)	3 (42.9%)
	Number of censored subjects	5 (35.7%)	4 (57.1%)
	Median time to flare ^a	268.5	360.0
	95% CI ^a	(89.0, NA)	(16.0, NA)
	Hazard ratio ^b		0.6
	95% CI ^b		(0.1, 2.1)
	P-value ^b		0.3761
Region 1 - Non-US	Number of subjects with an IgG4-RD flare	31 (58.5%)	4 (6.6%)
	Number of censored subjects	22 (41.5%)	57 (93.4%)
	Median time to flare ^a	246.0	NA
	95% CI ^a	(143.0, NA)	(371.0, NA)
	Hazard ratio ^b		0.1
	95% CI ^b		(0.0, 0.2)
	P-value ^b		<.0001
Region 1 interaction with treatment	P-value		0.0149

^a Based on Kaplan-Meier method.

^b Based on Cox regression method, with Placebo as the reference group.

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Table 14.2.2.1
Subgroup Analysis Of Time (days) To The First Treated And AC-Determined IgG4-RD Flare (Randomized-Controlled Period)
Full Analysis Set

Subgroup		Placebo N = 67	Inebilizumab N = 68
Region 2 - EU	Number of subjects with an IgG4-RD flare	15 (57.7%)	2 (10.0%)
	Number of censored subjects	11 (42.3%)	18 (90.0%)
	Median time to flare ^a	253.5	NA
	95% CI ^a	(140.0, NA)	(NA, NA)
	Hazard ratio ^b		0.1
	95% CI ^b		(0.0, 0.7)
	P-value ^b		0.0117
Region 2 - Non-EU	Number of subjects with an IgG4-RD flare	25 (61.0%)	5 (10.4%)
	Number of censored subjects	16 (39.0%)	43 (89.6%)
	Median time to flare ^a	237.0	NA
	95% CI ^a	(180.0, NA)	(371.0, NA)
	Hazard ratio ^b		0.1
	95% CI ^b		(0.0, 0.3)
	P-value ^b		<.0001
Region 2 interaction with treatment	P-value		0.9387

^a Based on Kaplan-Meier method.

^b Based on Cox regression method, with Placebo as the reference group.

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Table 14.2.2.1
Subgroup Analysis Of Time (days) To The First Treated And AC-Determined IgG4-RD Flare (Randomized-Controlled Period)
Full Analysis Set

Subgroup		Placebo N = 67	Inebilizumab N = 68
Region 3 - Asia	Number of subjects with an IgG4-RD flare	9 (50.0%)	1 (2.9%)
	Number of censored subjects	9 (50.0%)	33 (97.1%)
	Median time to flare ^a	NA	NA
	95% CI ^a	(142.0, NA)	(371.0, NA)
	Hazard ratio ^b		0.0
	95% CI ^b		(0.0, 0.2)
	P-value ^b		0.0009
Region 3 - Non-Asia	Number of subjects with an IgG4-RD flare	31 (63.3%)	6 (17.6%)
	Number of censored subjects	18 (36.7%)	28 (82.4%)
	Median time to flare ^a	237.0	NA
	95% CI ^a	(143.0, 310.0)	(NA, NA)
	Hazard ratio ^b		0.2
	95% CI ^b		(0.1, 0.5)
	P-value ^b		0.0007
Region 3 interaction with treatment	P-value		0.1638

^a Based on Kaplan-Meier method.

^b Based on Cox regression method, with Placebo as the reference group.

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Table 14.2.2.1
Subgroup Analysis Of Time (days) To The First Treated And AC-Determined IgG4-RD Flare (Randomized-Controlled Period)
Full Analysis Set

Subgroup		Placebo N = 67	Inebilizumab N = 68
Region 4 - Japan	Number of subjects with an IgG4-RD flare	4 (57.1%)	0
	Number of censored subjects	3 (42.9%)	20 (100%)
	Median time to flare ^a	246.0	NA
	95% CI ^a	(65.0, NA)	(NA, NA)
	Hazard ratio ^b		0.0
	95% CI ^b		(0.0, NA)
Region 4 - Non-Japan	Number of subjects with an IgG4-RD flare	36 (60.0%)	7 (14.6%)
	Number of censored subjects	24 (40.0%)	41 (85.4%)
	Median time to flare ^a	241.5	NA
	95% CI ^a	(180.0, NA)	(371.0, NA)
	Hazard ratio ^b		0.2
	95% CI ^b		(0.1, 0.4)
Region 4 interaction with treatment	P-value ^b		<.0001
	P-value		0.9851

^a Based on Kaplan-Meier method.

^b Based on Cox regression method, with Placebo as the reference group.

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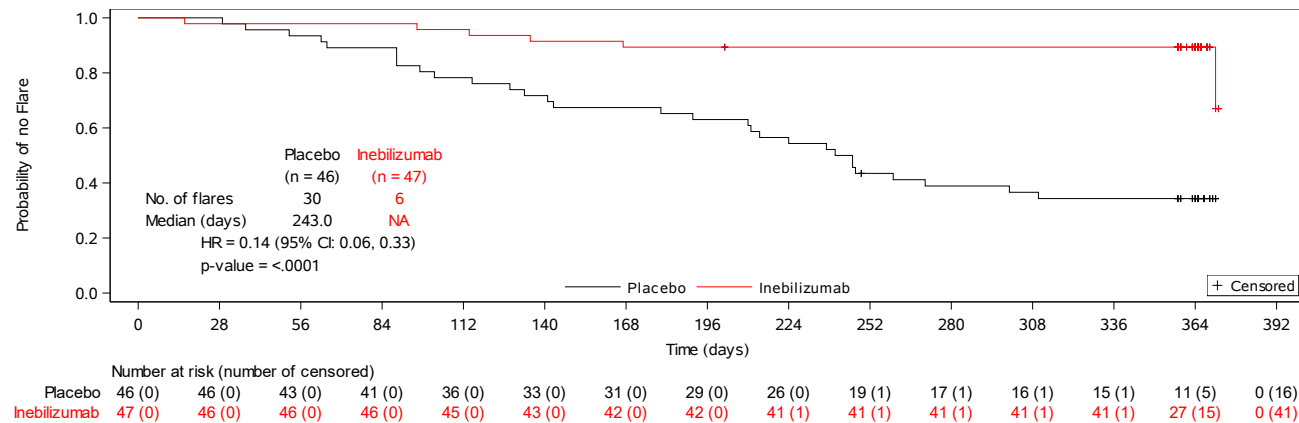
Data Extract: 29MAY2024



5.1.2 Kaplan-Meier-Kurven für Zeit bis zum ersten behandelten und durch ein AC bestimmten IgG4-RD-Schub

Figure 14-2.5.1.581. Subgroup Analysis: Kaplan Meier Plot for Time to First Treated and AC-determined IgG4 Flare During Randomized-controlled Period (Full Analysis Set)

Subgroup = Age - < 65 years



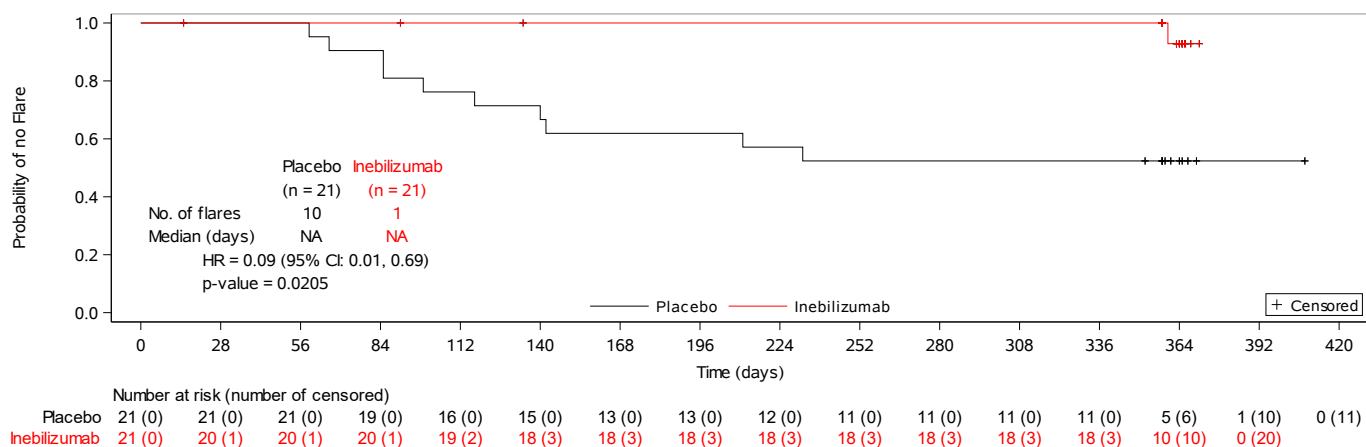
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Subjects who do not complete the randomized-controlled period and who have not had a treated and AC-determined IgG4 flare during the randomized-controlled period will be censored at the time of discontinuation.

Program: /userdata/stat/amg335/igg4rd/20230068/analysis/germany_submission/figures/f-km-taf-rcp-sub.sas
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Figure 14-2.5.1.581. Subgroup Analysis: Kaplan Meier Plot for Time to First Treated and AC-determined IgG4 Flare During Randomized-controlled Period (Full Analysis Set)

Subgroup = Age - ≥ 65 years



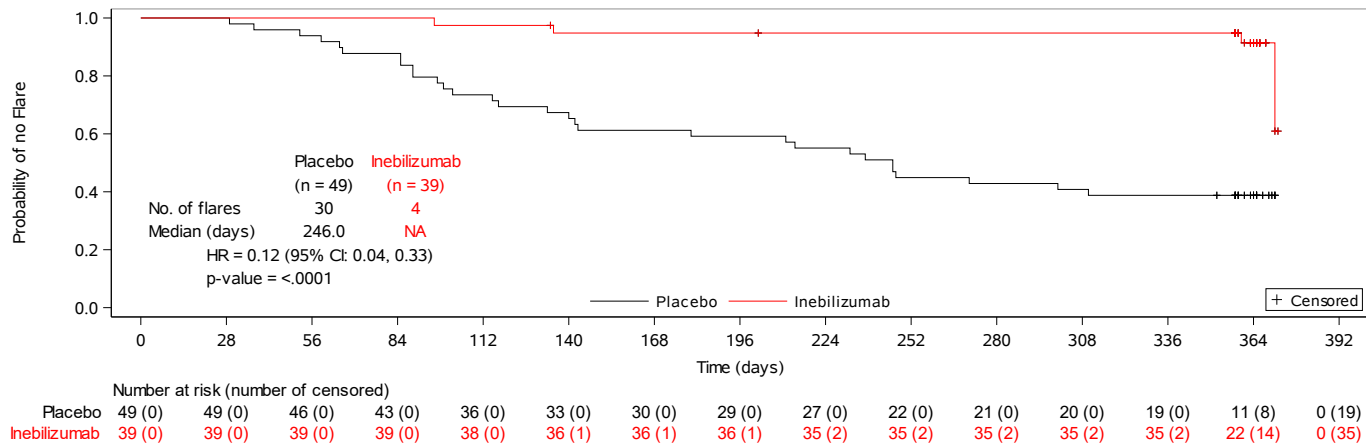
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Subjects who do not complete the randomized-controlled period and who have not had a treated and AC-determined IgG4 flare during the randomized-controlled period will be censored at the time of discontinuation.

Program: /userdata/stat/amg335/igg4rd/20230068/analysis/germany_submission/figures/f-km-taf-rcp-sub.sas
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Figure 14-2.5.1.581. Subgroup Analysis: Kaplan Meier Plot for Time to First Treated and AC-determined IgG4 Flare During Randomized-controlled Period (Full Analysis Set)

Subgroup = Sex - Male



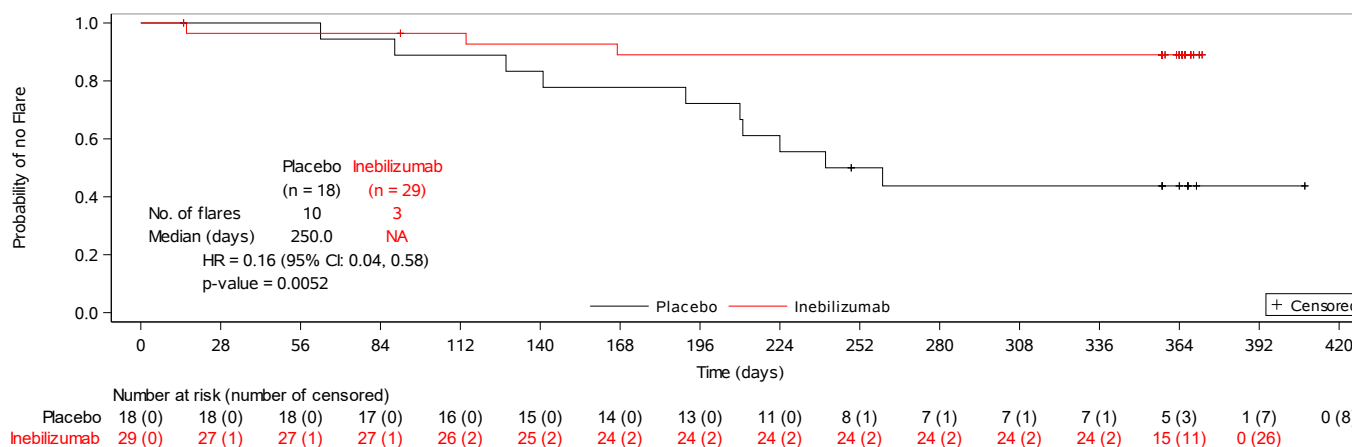
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Subjects who do not complete the randomized-controlled period and who have not had a treated and AC-determined IgG4 flare during the randomized-controlled period will be censored at the time of discontinuation.

Program: /userdata/stat/amg335/igg4rd/20230068/analysis/germany_submission/figures/f-km-taf-rcp-sub.sas
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Figure 14-2.5.1.581. Subgroup Analysis: Kaplan Meier Plot for Time to First Treated and AC-determined IgG4 Flare During Randomized-controlled Period (Full Analysis Set)

Subgroup = Sex - Female



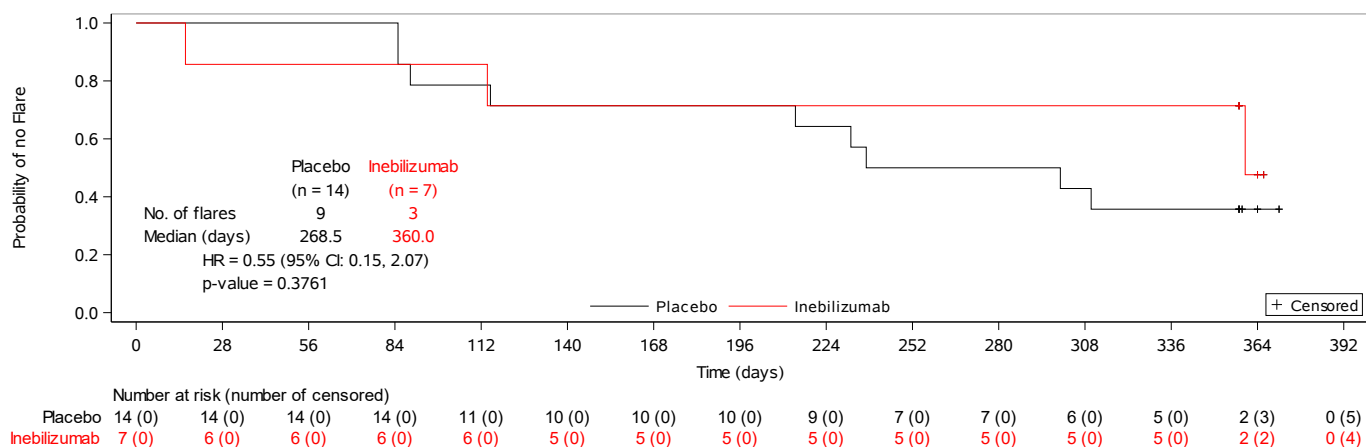
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Subjects who do not complete the randomized-controlled period and who have not had a treated and AC-determined IgG4 flare during the randomized-controlled period will be censored at the time of discontinuation.

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Figure 14-2.5.1.581. Subgroup Analysis: Kaplan Meier Plot for Time to First Treated and AC-determined IgG4 Flare During Randomized-controlled Period (Full Analysis Set)

Subgroup = Region - US



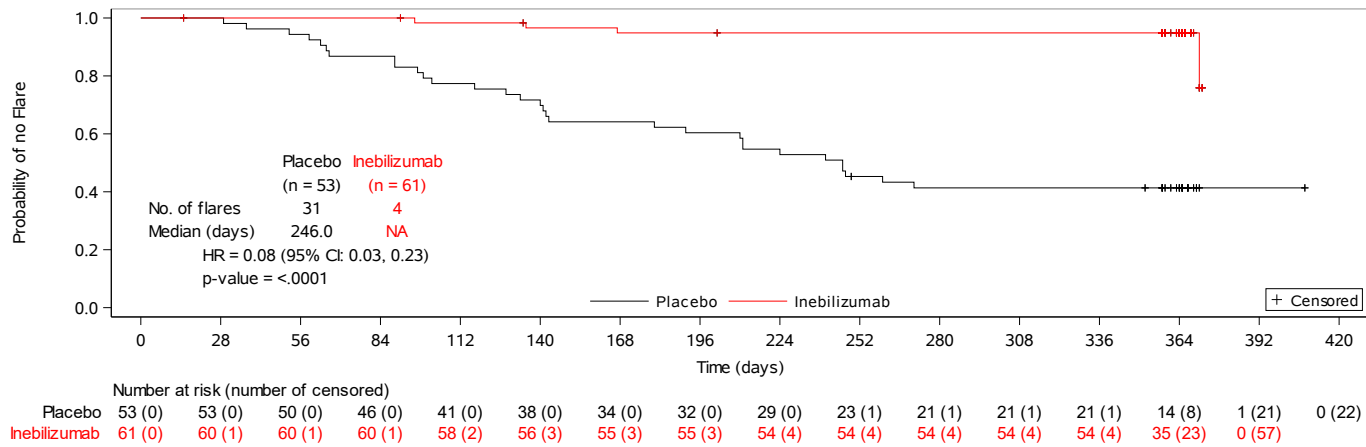
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Subjects who do not complete the randomized-controlled period and who have not had a treated and AC-determined IgG4 flare during the randomized-controlled period will be censored at the time of discontinuation.

Program: /userdata/stat/amg335/igg4rd/20230068/analysis/germany_submission/figures/f-km-taf-rcp-sub.sas
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Figure 14-2.5.1.581. Subgroup Analysis: Kaplan Meier Plot for Time to First Treated and AC-determined IgG4 Flare During Randomized-controlled Period (Full Analysis Set)

Subgroup = Region - Non-US



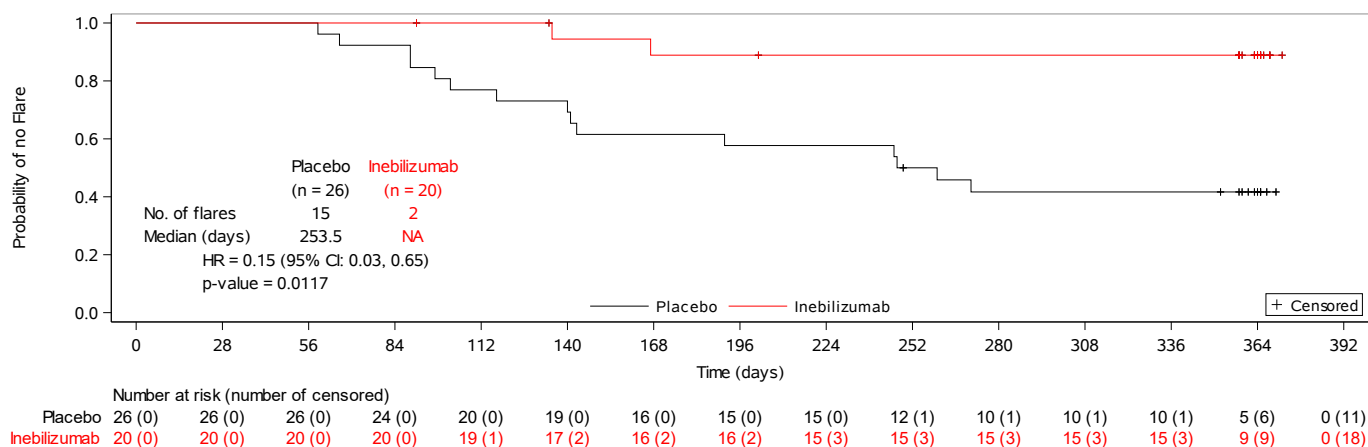
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Subjects who do not complete the randomized-controlled period and who have not had a treated and AC-determined IgG4 flare during the randomized-controlled period will be censored at the time of discontinuation.

Program: /userdata/stat/amg335/igg4rd/20230068/analysis/germany_submission/figures/f-km-taf-rcp-sub.sas
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Figure 14-2.5.1.581. Subgroup Analysis: Kaplan Meier Plot for Time to First Treated and AC-determined IgG4 Flare During Randomized-controlled Period (Full Analysis Set)

Subgroup = Region - EU



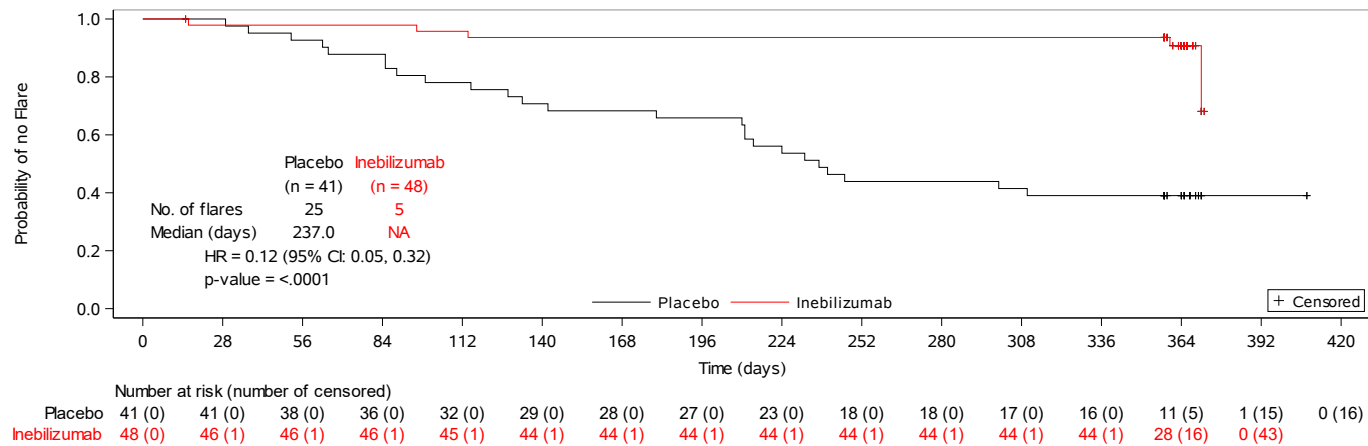
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Subjects who do not complete the randomized-controlled period and who have not had a treated and AC-determined IgG4 flare during the randomized-controlled period will be censored at the time of discontinuation.

Program: /userdata/stat/amg335/igg4rd/20230068/analysis/germany_submission/figures/f-km-taf-rcp-sub.sas
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Figure 14-2.5.1.581. Subgroup Analysis: Kaplan Meier Plot for Time to First Treated and AC-determined IgG4 Flare During Randomized-controlled Period (Full Analysis Set)

Subgroup = Region - Non-EU



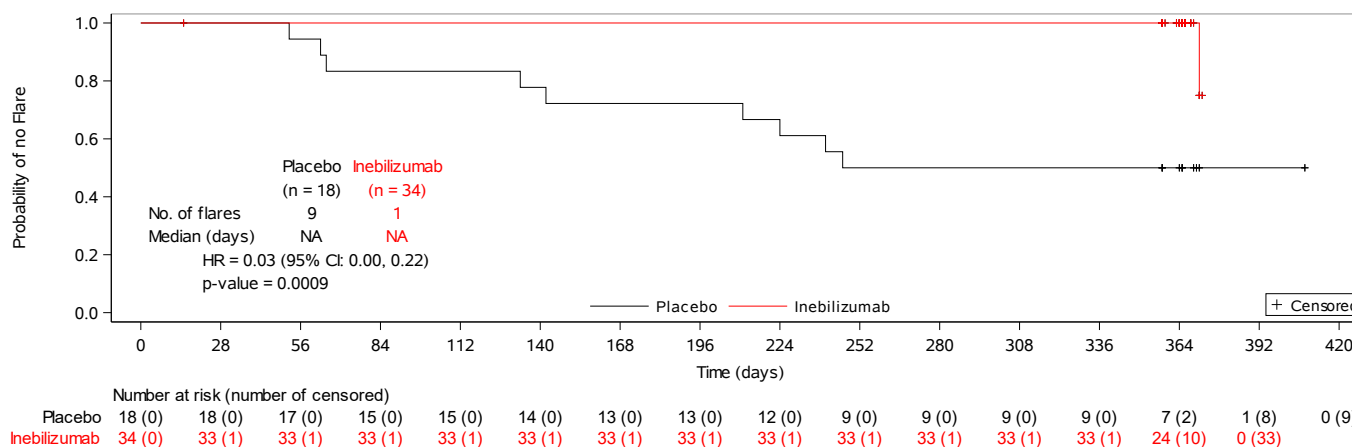
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Subjects who do not complete the randomized-controlled period and who have not had a treated and AC-determined IgG4 flare during the randomized-controlled period will be censored at the time of discontinuation.

Program: /userdata/stat/amg335/igg4rd/20230068/analysis/germany_submission/figures/f-km-taf-rcp-sub.sas
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Figure 14-2.5.1.581. Subgroup Analysis: Kaplan Meier Plot for Time to First Treated and AC-determined IgG4 Flare During Randomized-controlled Period (Full Analysis Set)

Subgroup = Region - Asia



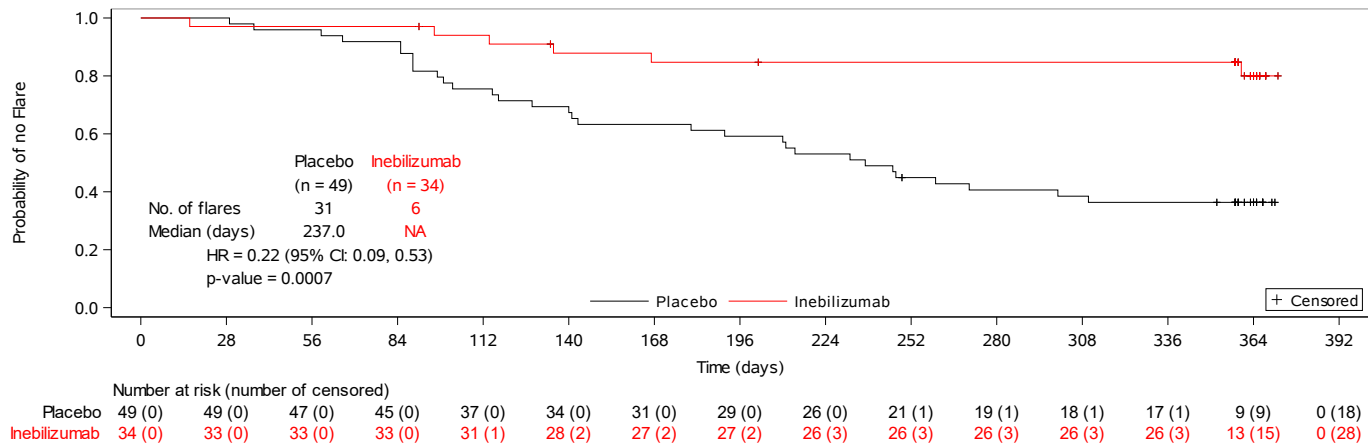
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Subjects who do not complete the randomized-controlled period and who have not had a treated and AC-determined IgG4 flare during the randomized-controlled period will be censored at the time of discontinuation.

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Figure 14-2.5.1.581. Subgroup Analysis: Kaplan Meier Plot for Time to First Treated and AC-determined IgG4 Flare During Randomized-controlled Period (Full Analysis Set)

Subgroup = Region - Non-Asia



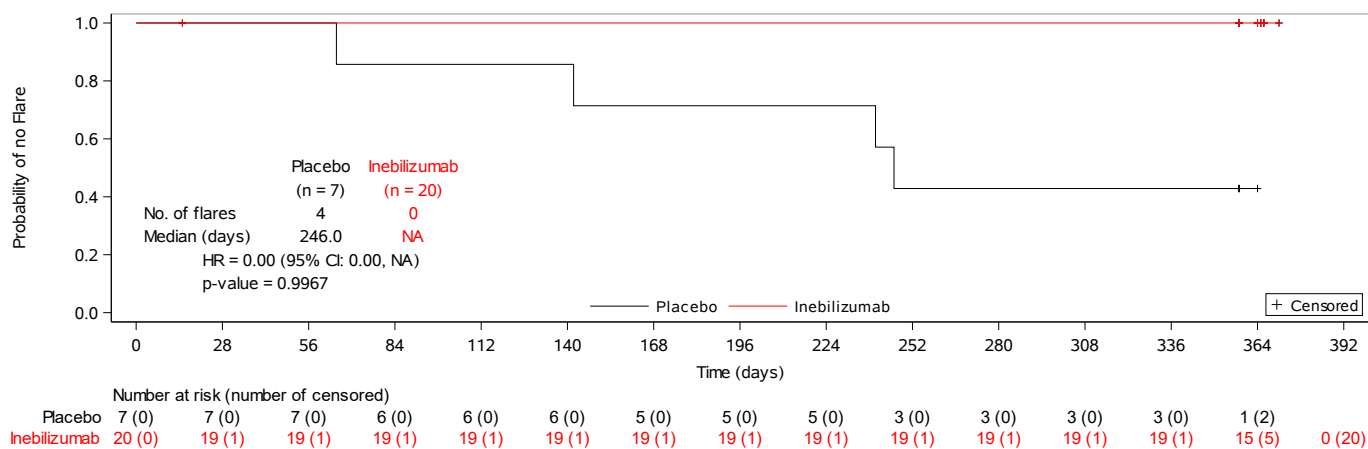
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Subjects who do not complete the randomized-controlled period and who have not had a treated and AC-determined IgG4 flare during the randomized-controlled period will be censored at the time of discontinuation.

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Figure 14-2.5.1.581. Subgroup Analysis: Kaplan Meier Plot for Time to First Treated and AC-determined IgG4 Flare During Randomized-controlled Period (Full Analysis Set)

Subgroup = Region - Japan



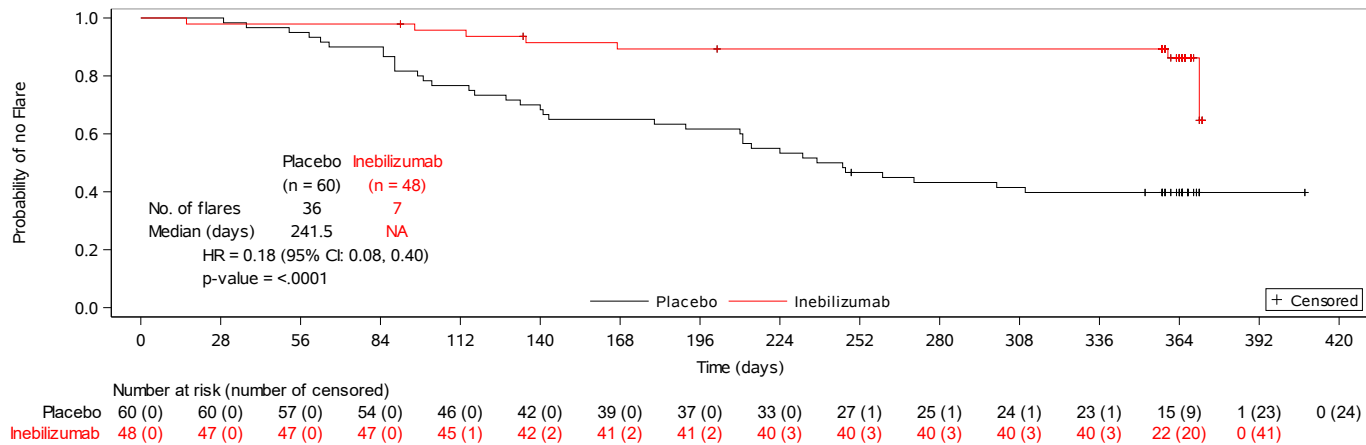
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Subjects who do not complete the randomized-controlled period and who have not had a treated and AC-determined IgG4 flare during the randomized-controlled period will be censored at the time of discontinuation.

Program: /userdata/stat/amg335/igg4rd/20230068/analysis/germany_submission/figures/f-km-taf-rcp-sub.sas
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Figure 14-2.5.1.581. Subgroup Analysis: Kaplan Meier Plot for Time to First Treated and AC-determined IgG4 Flare During Randomized-controlled Period (Full Analysis Set)

Subgroup = Region - Non-Japan



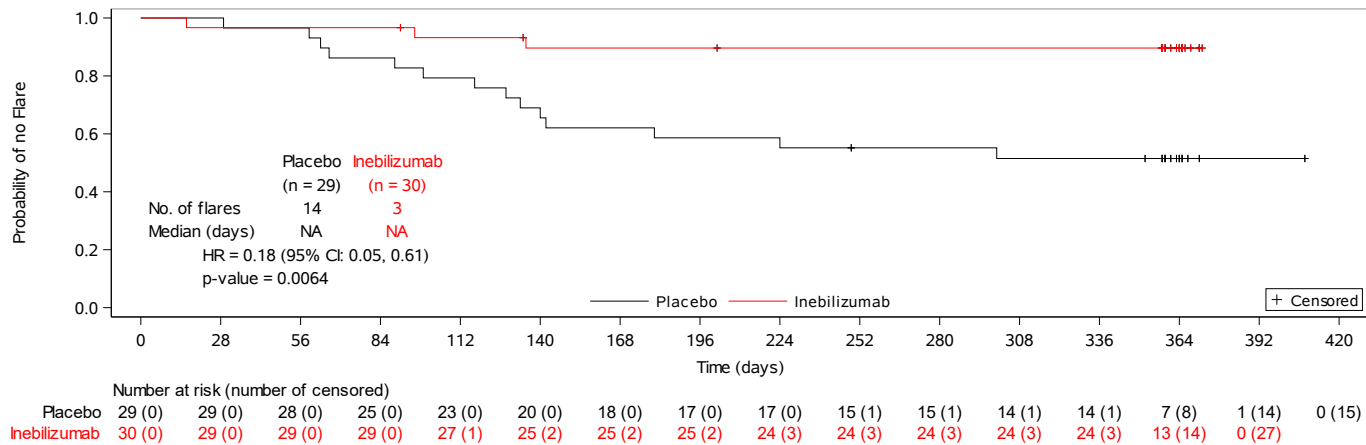
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Subjects who do not complete the randomized-controlled period and who have not had a treated and AC-determined IgG4 flare during the randomized-controlled period will be censored at the time of discontinuation.

Program: /userdata/stat/amg335/igg4rd/20230068/analysis/germany_submission/figures/f-km-taf-rcp-sub.sas
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Figure 14-2.5.1.581. Subgroup Analysis: Kaplan Meier Plot for Time to First Treated and AC-determined IgG4 Flare During Randomized-controlled Period (Full Analysis Set)

Subgroup = Serum IgG4 concentrations at baseline - < Median



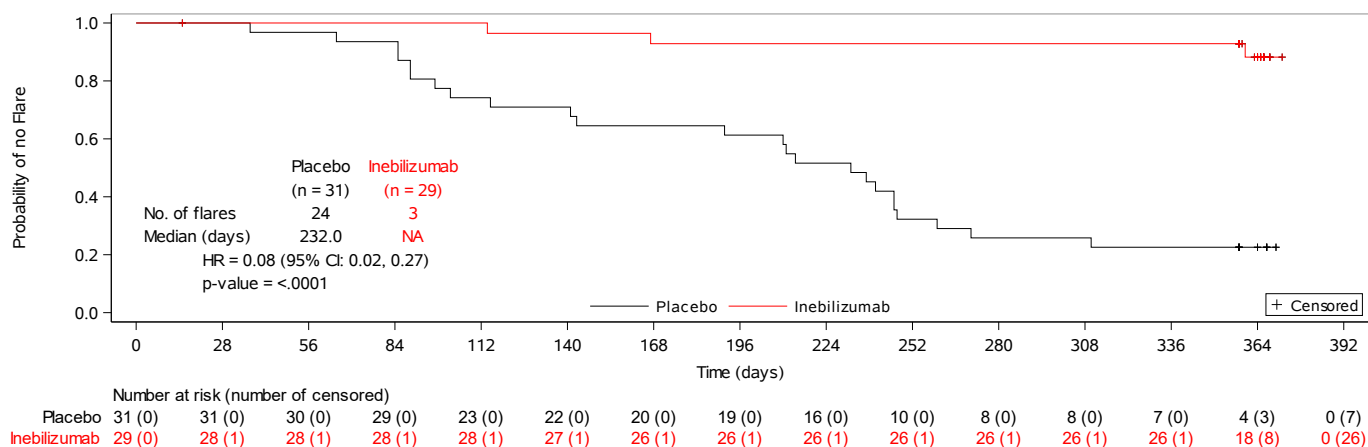
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Subjects who do not complete the randomized-controlled period and who have not had a treated and AC-determined IgG4 flare during the randomized-controlled period will be censored at the time of discontinuation.

Program: /userdata/stat/amg335/igg4rd/20230068/analysis/germany_submission/figures/f-km-taf-rcp-sub.sas
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Figure 14-2.5.1.581. Subgroup Analysis: Kaplan Meier Plot for Time to First Treated and AC-determined IgG4 Flare During Randomized-controlled Period (Full Analysis Set)

Subgroup = Serum IgG4 concentrations at baseline - \geq Median



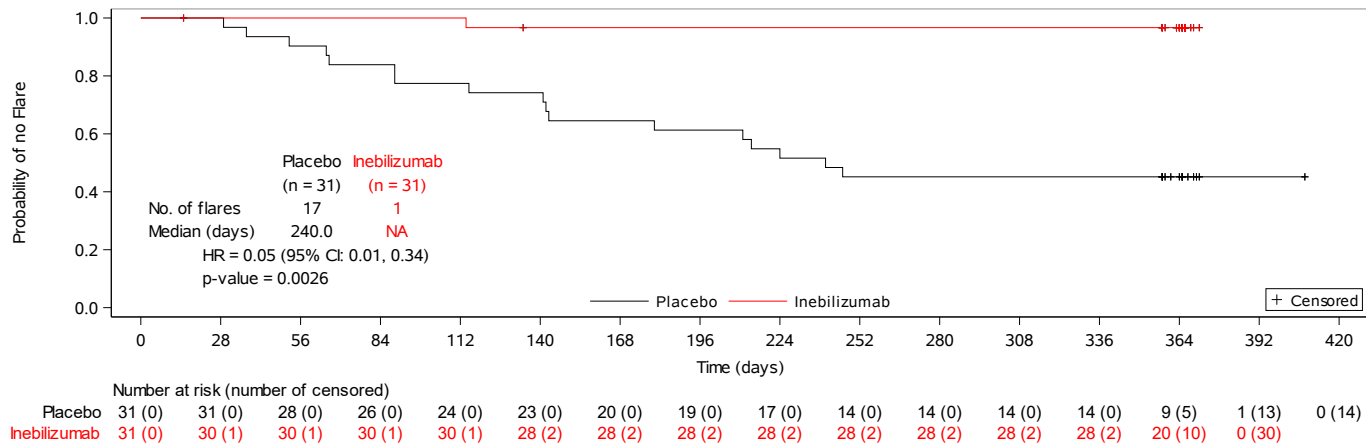
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Subjects who do not complete the randomized-controlled period and who have not had a treated and AC-determined IgG4 flare during the randomized-controlled period will be censored at the time of discontinuation.

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Figure 14-2.5.1.581. Subgroup Analysis: Kaplan Meier Plot for Time to First Treated and AC-determined IgG4 Flare During Randomized-controlled Period (Full Analysis Set)

Subgroup = First or subsequent IgG4-RD manifestation - Newly diagnosed



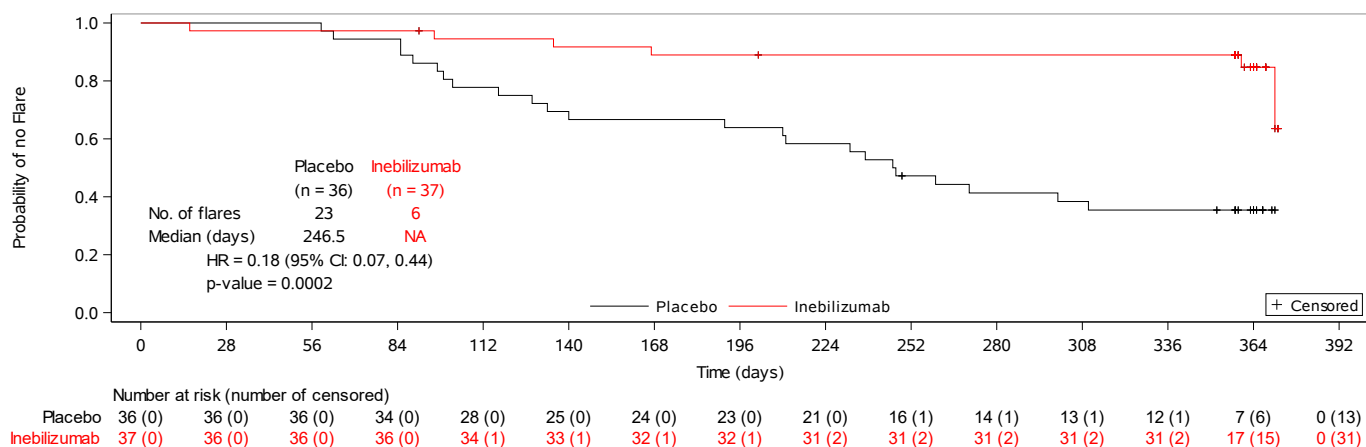
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Subjects who do not complete the randomized-controlled period and who have not had a treated and AC-determined IgG4 flare during the randomized-controlled period will be censored at the time of discontinuation.

Program: /userdata/stat/amg335/igg4rd/20230068/analysis/germany_submission/figures/f-km-taf-rcp-sub.sas
 Output: f14-02-005-001-581-km-taf-rcp-sub.rtf (Date Generated: 08JAN26:20:00:45) Source: csradam.adsl, csradam.adtte, csradam.adeff

Figure 14-2.5.1.581. Subgroup Analysis: Kaplan Meier Plot for Time to First Treated and AC-determined IgG4 Flare During Randomized-controlled Period (Full Analysis Set)

Subgroup = First or subsequent IgG4-RD manifestation - Recurrent



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Subjects who do not complete the randomized-controlled period and who have not had a treated and AC-determined IgG4 flare during the randomized-controlled period will be censored at the time of discontinuation.

Program: /userdata/stat/amg335/igg4rd/20230068/analysis/germany_submission/figures/f-km-taf-rcp-sub.sas
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5.1.3 Jährliche Schubrate für behandelte und durch ein AC bestimmte IgG4-RD-Schübe

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Table 14.2.2.2
 Subgroup Analysis Of Annualized Flare Rate For Treated And AC-Determined IgG4-RD Flares (Randomized-Controlled Period)
 Full Analysis Set

Subgroup		Placebo N = 67	Inebilizumab N = 68
Age - < 65	Annualized flare rate ^a	0.73	0.12
	95% CI of annualized flare rate ^a	(0.52, 1.02)	(0.05, 0.26)
	Rate ratio ^a		0.16
	95% CI of rate ratio ^a		(0.07, 0.39)
	P-value ^a		<.0001
Age - >= 65	Annualized flare rate ^a	0.65	0.05
	95% CI of annualized flare rate ^a	(0.37, 1.15)	(0.01, 0.37)
	Rate ratio ^a		0.08
	95% CI of rate ratio ^a		(0.01, 0.61)
	P-value ^a		0.0149
Age interaction with treatment	P-value		0.5215

^a Estimated from the negative binomial regression.
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Table 14.2.2.2
Subgroup Analysis Of Annualized Flare Rate For Treated And AC-Determined IgG4-RD Flares (Randomized-Controlled Period)
Full Analysis Set

Subgroup		Placebo N = 67	Inebilizumab N = 68
Sex - Female	Annualized flare rate ^a	0.57	0.10
	95% CI of annualized flare rate ^a	(0.30, 1.09)	(0.03, 0.30)
	Rate ratio ^a		0.17
	95% CI of rate ratio ^a		(0.05, 0.60)
Sex - Male	Annualized flare rate ^a	0.75	0.10
	95% CI of annualized flare rate ^a	(0.54, 1.03)	(0.04, 0.26)
	Rate ratio ^a		0.13
	95% CI of rate ratio ^a		(0.05, 0.37)
Sex interaction with treatment	P-value ^a		0.0001
	P-value		0.7865

^a Estimated from the negative binomial regression.
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Table 14.2.2.2
Subgroup Analysis Of Annualized Flare Rate For Treated And AC-Determined IgG4-RD Flares (Randomized-Controlled Period)
Full Analysis Set

Subgroup		Placebo N = 67	Inebilizumab N = 68
Baseline serum IgG4 concentrations - < Median	Annualized flare rate ^a	0.63	0.10
	95% CI of annualized flare rate ^a	(0.39, 1.01)	(0.03, 0.32)
	Rate ratio ^a		0.17
	95% CI of rate ratio ^a		(0.05, 0.56)
	P-value ^a		0.0040
Baseline serum IgG4 concentrations - >= Median	Annualized flare rate ^a	0.90	0.10
	95% CI of annualized flare rate ^a	(0.62, 1.31)	(0.03, 0.31)
	Rate ratio ^a		0.11
	95% CI of rate ratio ^a		(0.03, 0.37)
	P-value ^a		0.0003
Baseline serum IgG4 concentrations interaction with treatment	P-value		0.6471

^a Estimated from the negative binomial regression.
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Table 14.2.2.2
Subgroup Analysis Of Annualized Flare Rate For Treated And AC-Determined IgG4-RD Flares (Randomized-Controlled Period)
Full Analysis Set

Subgroup	Placebo N = 67	Inebilizumab N = 68
First or subsequent IgG4-RD manifestation - First Manifestation Annualized flare rate ^a of IgG4-RD	0.64	0.03
95% CI of annualized flare rate ^a	(0.42, 0.99)	(0.00, 0.23)
Rate ratio ^a		NA
95% CI of rate ratio ^a		NA
P-value ^a		NA
First or subsequent IgG4-RD manifestation - Subsequent Manifestation of IgG4-RD	0.79	0.16
95% CI of annualized flare rate ^a	(0.55, 1.15)	(0.07, 0.36)
Rate ratio ^a		0.20
95% CI of rate ratio ^a		(0.08, 0.49)
P-value ^a		0.0004
First or subsequent IgG4-RD manifestation interaction with treatment	P-value	0.2111

^a Estimated from the negative binomial regression.
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Table 14.2.2.2
Subgroup Analysis Of Annualized Flare Rate For Treated And AC-Determined IgG4-RD Flares (Randomized-Controlled Period)
Full Analysis Set

Subgroup		Placebo N = 67	Inebilizumab N = 68
Region 1 - US	Annualized flare rate ^a	0.65	0.39
	95% CI of annualized flare rate ^a	(0.32, 1.34)	(0.12, 1.26)
	Rate ratio ^a		0.59
	95% CI of rate ratio ^a		(0.16, 2.15)
Region 1 - Non-US	Annualized flare rate ^a	0.72	0.06
	95% CI of annualized flare rate ^a	(0.53, 0.99)	(0.02, 0.17)
	Rate ratio ^a		0.09
	95% CI of rate ratio ^a		(0.03, 0.25)
Region 1 interaction with treatment	P-value ^a		<.0001
	P-value		0.0242

^a Estimated from the negative binomial regression.
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Table 14.2.2.2
Subgroup Analysis Of Annualized Flare Rate For Treated And AC-Determined IgG4-RD Flares (Randomized-Controlled Period)
Full Analysis Set

Subgroup		Placebo N = 67	Inebilizumab N = 68
Region 2 - EU	Annualized flare rate ^a	0.85	0.12
	95% CI of annualized flare rate ^a	(0.55, 1.31)	(0.03, 0.49)
	Rate ratio ^a		0.14
	95% CI of rate ratio ^a		(0.03, 0.61)
	P-value ^a		0.0087
Region 2 - Non-EU	Annualized flare rate ^a	0.66	0.10
	95% CI of annualized flare rate ^a	(0.45, 0.96)	(0.04, 0.24)
	Rate ratio ^a		0.15
	95% CI of rate ratio ^a		(0.06, 0.39)
	P-value ^a		0.0001
Region 2 interaction with treatment	P-value		0.8058

^a Estimated from the negative binomial regression.
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Table 14.2.2.1
Subgroup Analysis Of Time (days) To The First Treated And AC-Determined IgG4-RD Flare (Randomized-Controlled Period)
Full Analysis Set

Subgroup		Placebo N = 67	Inebilizumab N = 68
Region 3 - Asia	Number of subjects with an IgG4-RD flare	9 (50.0%)	1 (2.9%)
	Number of censored subjects	9 (50.0%)	33 (97.1%)
	Median time to flare ^a	NA	NA
	95% CI ^a	(142.0, NA)	(371.0, NA)
	Hazard ratio ^b		0.0
	95% CI ^b		(0.0, 0.2)
	P-value ^b		0.0009
Region 3 - Non-Asia	Number of subjects with an IgG4-RD flare	31 (63.3%)	6 (17.6%)
	Number of censored subjects	18 (36.7%)	28 (82.4%)
	Median time to flare ^a	237.0	NA
	95% CI ^a	(143.0, 310.0)	(NA, NA)
	Hazard ratio ^b		0.2
	95% CI ^b		(0.1, 0.5)
	P-value ^b		0.0007
Region 3 interaction with treatment	P-value		0.1638

^a Based on Kaplan-Meier method.

^b Based on Cox regression method, with Placebo as the reference group.

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Table 14.2.2.1
Subgroup Analysis Of Time (days) To The First Treated And AC-Determined IgG4-RD Flare (Randomized-Controlled Period)
Full Analysis Set

Subgroup		Placebo N = 67	Inebilizumab N = 68
Region 4 - Japan	Number of subjects with an IgG4-RD flare	4 (57.1%)	0
	Number of censored subjects	3 (42.9%)	20 (100%)
	Median time to flare ^a	246.0	NA
	95% CI ^a	(65.0, NA)	(NA, NA)
	Hazard ratio ^b		0.0
	95% CI ^b		(0.0, NA)
	P-value ^b		0.9967
Region 4 - Non-Japan	Number of subjects with an IgG4-RD flare	36 (60.0%)	7 (14.6%)
	Number of censored subjects	24 (40.0%)	41 (85.4%)
	Median time to flare ^a	241.5	NA
	95% CI ^a	(180.0, NA)	(371.0, NA)
	Hazard ratio ^b		0.2
	95% CI ^b		(0.1, 0.4)
	P-value ^b		<.0001
Region 4 interaction with treatment	P-value		0.9851

^a Based on Kaplan-Meier method.

^b Based on Cox regression method, with Placebo as the reference group.

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Data Extract: 29MAY2024



5.1.4 Jährliche Schubrate für durch ein AC bestimmte IgG4-RD-Schübe, unabhängig ihrer Behandlung

Table 14-2.2.581. Subgroup Analysis: Annualized Flare Rate for AC-determined IgG4-RD Flares, Whether or Not Treated During Randomized-controlled Period (Full Analysis Set)

Subgroup	Placebo N = 67	Inebilizumab N = 68
Age - < 65 years		
Number of AC-determined IgG4-RD flares, whether or not treated		
n	30	8
Mean	1.2	1.3
SD	0.4	0.5
Median	1.0	1.0
Q1, Q3	1.0, 1.0	1.0, 1.5
Min, Max	1, 2	1, 2
Annualized flare rate per subject		
n	46	47
Mean	0.82	0.20
SD	0.72	0.47
Median	0.94	0.00
Q1, Q3	0.00, 1.02	0.00, 0.00
Min, Max	0.0, 2.3	0.0, 2.0
Annualized flare rate ^a	0.78	0.20
95% CI of annualized flare rate ^a	(0.56, 1.08)	(0.11, 0.38)
Rate ratio ^a		0.26
95% CI of rate ratio ^a		(0.13, 0.52)
P-value ^a		0.0002

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 Output: t14-02-002-002-581-af-af-rcp-sub.rtf (Date Generated: 08JAN26:17:43:00) Source: csradam.adsl,
 csradam.adeff

Table 14-2.2.581. Subgroup Analysis: Annualized Flare Rate for AC-determined IgG4-RD Flares, Whether or Not Treated During Randomized-controlled Period (Full Analysis Set)

Subgroup		Placebo N = 67	Inebilizumab N = 68
Age - ≥ 65 years	Number of AC-determined IgG4-RD flares, whether or not treated		
	n	11	1
	Mean	1.5	1.0
	SD	0.7	NA
	Median	1.0	1.0
	Q1, Q3	1.0, 2.0	1.0, 1.0
	Min, Max	1, 3	1, 1
	Annualized flare rate per subject		
	n	21	21
	Mean	0.74	0.05
	SD	0.86	0.22
	Median	0.90	0.00
	Q1, Q3	0.00, 1.00	0.00, 0.00
	Min, Max	0.0, 2.8	0.0, 1.0
	Annualized flare rate ^a	0.68	0.05
	95% CI of annualized flare rate ^a	(0.40, 1.17)	(0.01, 0.36)
	Rate ratio ^a		0.07
	95% CI of rate ratio ^a		(0.01, 0.57)
	P-value ^a		0.0122
	Age interaction with treatment	P-value	

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Table 14-2.2.2.581. Subgroup Analysis: Annualized Flare Rate for AC-determined IgG4-RD Flares, Whether or Not Treated During Randomized-controlled Period (Full Analysis Set)

Subgroup	Placebo N = 67	Inebilizumab N = 68
Sex - Male		
Number of AC-determined IgG4-RD flares, whether or not treated		
n	31	5
Mean	1.3	1.0
SD	0.5	0.0
Median	1.0	1.0
Q1, Q3	1.0, 1.0	1.0, 1.0
Min, Max	1, 3	1, 1
Annualized flare rate per subject		
n	49	39
Mean	0.80	0.13
SD	0.74	0.33
Median	0.94	0.00
Q1, Q3	0.00, 1.00	0.00, 0.00
Min, Max	0.0, 2.8	0.0, 1.0
Annualized flare rate ^a	0.77	0.12
95% CI of annualized flare rate ^a	(0.56, 1.05)	(0.05, 0.30)
Rate ratio ^a		0.16
95% CI of rate ratio ^a		(0.06, 0.41)
P-value ^a		0.0001

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Table 14-2.2.581. Subgroup Analysis: Annualized Flare Rate for AC-determined IgG4-RD Flares, Whether or Not Treated During Randomized-controlled Period (Full Analysis Set)

Subgroup	Placebo N = 67	Inebilizumab N = 68
Sex - Female		
Number of AC-determined IgG4-RD flares, whether or not treated		
n	10	4
Mean	1.3	1.5
SD	0.5	0.6
Median	1.0	1.5
Q1, Q3	1.0, 2.0	1.0, 2.0
Min, Max	1, 2	1, 2
Annualized flare rate per subject		
n	18	29
Mean	0.79	0.19
SD	0.84	0.51
Median	0.93	0.00
Q1, Q3	0.00, 1.02	0.00, 0.00
Min, Max	0.0, 2.3	0.0, 2.0
Annualized flare rate ^a	0.72	0.20
95% CI of annualized flare rate ^a	(0.42, 1.26)	(0.09, 0.46)
Rate ratio ^a		0.28
95% CI of rate ratio ^a		(0.11, 0.74)
P-value ^a		0.0105
Sex interaction with treatment	P-value	0.4170

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Table 14-2.2.2.581. Subgroup Analysis: Annualized Flare Rate for AC-determined IgG4-RD Flares, Whether or Not Treated During Randomized-controlled Period (Full Analysis Set)

Subgroup	Placebo N = 67	Inebilizumab N = 68
Region - US		
Number of AC-determined IgG4-RD flares, whether or not treated		
n	9	3
Mean	1.1	1.3
SD	0.3	0.6
Median	1.0	1.0
Q1, Q3	1.0, 1.0	1.0, 2.0
Min, Max	1, 2	1, 2
Annualized flare rate per subject		
n	14	7
Mean	0.70	0.56
SD	0.61	0.78
Median	0.96	0.00
Q1, Q3	0.00, 1.01	0.00, 1.00
Min, Max	0.0, 2.0	0.0, 2.0
Annualized flare rate ^a	0.64	0.50
95% CI of annualized flare rate ^a	(0.31, 1.31)	(0.18, 1.42)
Rate ratio ^a		0.79
95% CI of rate ratio ^a		(0.25, 2.52)
P-value ^a		0.6887

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Table 14-2.2.581. Subgroup Analysis: Annualized Flare Rate for AC-determined IgG4-RD Flares, Whether or Not Treated During Randomized-controlled Period (Full Analysis Set)

Subgroup	Placebo N = 67	Inebilizumab N = 68
Region - Non-US		
Number of AC-determined IgG4-RD flares, whether or not treated		
n	32	6
Mean	1.3	1.2
SD	0.5	0.4
Median	1.0	1.0
Q1, Q3	1.0, 2.0	1.0, 1.0
Min, Max	1, 3	1, 2
Annualized flare rate per subject		
n	53	61
Mean	0.82	0.11
SD	0.80	0.33
Median	0.93	0.00
Q1, Q3	0.00, 1.02	0.00, 0.00
Min, Max	0.0, 2.8	0.0, 1.6
Annualized flare rate ^a	0.78	0.11
95% CI of annualized flare rate ^a	(0.58, 1.06)	(0.05, 0.24)
Rate ratio ^a		0.14
95% CI of rate ratio ^a		(0.07, 0.32)
P-value ^a		<.0001
Region (US vs. Non-US) interaction with treatment		P-value 0.0185

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Table 14-2.2.2.581. Subgroup Analysis: Annualized Flare Rate for AC-determined IgG4-RD Flares, Whether or Not Treated During Randomized-controlled Period (Full Analysis Set)

Subgroup	Placebo N = 67	Inebilizumab N = 68
Region - EU		
Number of AC-determined IgG4-RD flares, whether or not treated		
n	16	2
Mean	1.4	1.5
SD	0.6	0.7
Median	1.0	1.5
Q1, Q3	1.0, 2.0	1.0, 2.0
Min, Max	1, 3	1, 2
Annualized flare rate per subject		
n	26	20
Mean	0.91	0.13
SD	0.88	0.41
Median	0.94	0.00
Q1, Q3	0.00, 1.87	0.00, 0.00
Min, Max	0.0, 2.8	0.0, 1.6
Annualized flare rate ^a	0.93	0.18
95% CI of annualized flare rate ^a	(0.61, 1.41)	(0.06, 0.57)
Rate ratio ^a		0.19
95% CI of rate ratio ^a		(0.06, 0.65)
P-value ^a		0.0081

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Table 14-2.2.2.581. Subgroup Analysis: Annualized Flare Rate for AC-determined IgG4-RD Flares, Whether or Not Treated During Randomized-controlled Period (Full Analysis Set)

Subgroup	Placebo N = 67	Inebilizumab N = 68
Region - Non-EU		
Number of AC-determined IgG4-RD flares, whether or not treated		
n	25	7
Mean	1.2	1.1
SD	0.4	0.4
Median	1.0	1.0
Q1, Q3	1.0, 1.0	1.0, 1.0
Min, Max	1, 2	1, 2
Annualized flare rate per subject		
n	41	48
Mean	0.72	0.16
SD	0.68	0.42
Median	0.94	0.00
Q1, Q3	0.00, 1.01	0.00, 0.00
Min, Max	0.0, 2.3	0.0, 2.0
Annualized flare rate ^a	0.69	0.16
95% CI of annualized flare rate ^a	(0.48, 1.00)	(0.08, 0.33)
Rate ratio ^a		0.24
95% CI of rate ratio ^a		(0.11, 0.52)
P-value ^a		0.0003
Region (EU vs. Non-EU) interaction with treatment		P-value 0.6616

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Table 14-2.2.2.581. Subgroup Analysis: Annualized Flare Rate for AC-determined IgG4-RD Flares, Whether or Not Treated During Randomized-controlled Period (Full Analysis Set)

Subgroup	Placebo N = 67	Inebilizumab N = 68
Region - Asia		
Number of AC-determined IgG4-RD flares, whether or not treated		
n	9	3
Mean	1.1	1.0
SD	0.3	0.0
Median	1.0	1.0
Q1, Q3	1.0, 1.0	1.0, 1.0
Min, Max	1, 2	1, 1
Annualized flare rate per subject		
n	18	34
Mean	0.60	0.08
SD	0.71	0.27
Median	0.43	0.00
Q1, Q3	0.00, 0.96	0.00, 0.00
Min, Max	0.0, 2.3	0.0, 1.0
Annualized flare rate ^a	0.68	0.09
95% CI of annualized flare rate ^a	(0.34, 1.34)	(0.03, 0.29)
Rate ratio ^a		0.14
95% CI of rate ratio ^a		(0.04, 0.52)
P-value ^a		0.0033

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Table 14-2.2.2.581. Subgroup Analysis: Annualized Flare Rate for AC-determined IgG4-RD Flares, Whether or Not Treated During Randomized-controlled Period (Full Analysis Set)

Subgroup	Placebo N = 67	Inebilizumab N = 68
Region - Non-Asia		
Number of AC-determined IgG4-RD flares, whether or not treated		
n	32	6
Mean	1.3	1.3
SD	0.5	0.5
Median	1.0	1.0
Q1, Q3	1.0, 2.0	1.0, 2.0
Min, Max	1, 3	1, 2
Annualized flare rate per subject		
n	49	34
Mean	0.87	0.22
SD	0.78	0.51
Median	0.96	0.00
Q1, Q3	0.00, 1.02	0.00, 0.00
Min, Max	0.0, 2.8	0.0, 2.0
Annualized flare rate ^a	0.87	0.25
95% CI of annualized flare rate ^a	(0.63, 1.19)	(0.12, 0.50)
Rate ratio ^a		0.28
95% CI of rate ratio ^a		(0.13, 0.61)
P-value ^a		0.0012
Region (Asia vs. Non-Asia) interaction with treatment		0.4699

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Table 14-2.2.2.581. Subgroup Analysis: Annualized Flare Rate for AC-determined IgG4-RD Flares, Whether or Not Treated During Randomized-controlled Period (Full Analysis Set)

Subgroup	Placebo N = 67	Inebilizumab N = 68
Region - Japan		
Number of AC-determined IgG4-RD flares, whether or not treated		
n	4	1
Mean	1.3	1.0
SD	0.5	NA
Median	1.0	1.0
Q1, Q3	1.0, 1.5	1.0, 1.0
Min, Max	1, 2	1, 1
Annualized flare rate per subject		
n	7	20
Mean	0.68	0.05
SD	0.71	0.21
Median	0.92	0.00
Q1, Q3	0.00, 0.99	0.00, 0.00
Min, Max	0.0, 1.9	0.0, 0.9
Annualized flare rate ^a	0.69	0.05
95% CI of annualized flare rate ^a	(0.22, 2.19)	(0.01, 0.38)
Rate ratio ^a		0.07
95% CI of rate ratio ^a		(0.01, 0.63)
P-value ^a		0.0174

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Table 14-2.2.2.581. Subgroup Analysis: Annualized Flare Rate for AC-determined IgG4-RD Flares, Whether or Not Treated During Randomized-controlled Period (Full Analysis Set)

Subgroup	Placebo N = 67	Inebilizumab N = 68
Region - Non-Japan		
Number of AC-determined IgG4-RD flares, whether or not treated		
n	37	8
Mean	1.3	1.3
SD	0.5	0.5
Median	1.0	1.0
Q1, Q3	1.0, 1.0	1.0, 1.5
Min, Max	1, 3	1, 2
Annualized flare rate per subject		
n	60	48
Mean	0.81	0.20
SD	0.77	0.47
Median	0.94	0.00
Q1, Q3	0.00, 1.02	0.00, 0.00
Min, Max	0.0, 2.8	0.0, 2.0
Annualized flare rate ^a	0.76	0.20
95% CI of annualized flare rate ^a	(0.57, 1.02)	(0.11, 0.37)
Rate ratio ^a		0.26
95% CI of rate ratio ^a		(0.13, 0.52)
P-value ^a		0.0001
Region (Japan vs. Non-Japan) interaction with treatment	P-value	0.2565

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Table 14-2.2.2.581. Subgroup Analysis: Annualized Flare Rate for AC-determined IgG4-RD Flares, Whether or Not Treated During Randomized-controlled Period (Full Analysis Set)

Subgroup	Placebo N = 67	Inebilizumab N = 68
Serum IgG4 concentrations at baseline - < Median		
Number of AC-determined IgG4-RD flares, whether or not treated		
n	14	4
Mean	1.3	1.3
SD	0.6	0.5
Median	1.0	1.0
Q1, Q3	1.0, 1.0	1.0, 1.5
Min, Max	1, 3	1, 2
Annualized flare rate per subject		
n	29	30
Mean	0.65	0.16
SD	0.81	0.46
Median	0.00	0.00
Q1, Q3	0.00, 1.00	0.00, 0.00
Min, Max	0.0, 2.8	0.0, 2.0
Annualized flare rate ^a	0.63	0.17
95% CI of annualized flare rate ^a	(0.39, 1.01)	(0.07, 0.42)
Rate ratio ^a		NA
95% CI of rate ratio ^a		NA
P-value ^a		NA

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Table 14-2.2.581. Subgroup Analysis: Annualized Flare Rate for AC-determined IgG4-RD Flares, Whether or Not Treated During Randomized-controlled Period (Full Analysis Set)

Subgroup		Placebo N = 67	Inebilizumab N = 68
Serum IgG4 concentrations at baseline - ≥ Median	Number of AC-determined IgG4-RD flares, whether or not treated		
	n	25	4
	Mean	1.3	1.3
	SD	0.5	0.5
	Median	1.0	1.0
	Q1, Q3	1.0, 2.0	1.0, 1.5
	Min, Max	1, 2	1, 2
	Annualized flare rate per subject		
	n	31	29
	Mean	1.05	0.15
	SD	0.69	0.40
	Median	0.98	0.00
	Q1, Q3	0.92, 1.87	0.00, 0.00
	Min, Max	0.0, 2.1	0.0, 1.6
	Annualized flare rate ^a	1.01	0.17
	95% CI of annualized flare rate ^a	(0.71, 1.43)	(0.07, 0.41)
	Rate ratio ^a		0.17
95% CI of rate ratio ^a		(0.07, 0.43)	
P-value ^a		0.0002	
Serum IgG4 concentrations at baseline interaction with treatment	P-value		0.4689

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Table 14-2.2.2.581. Subgroup Analysis: Annualized Flare Rate for AC-determined IgG4-RD Flares, Whether or Not Treated During Randomized-controlled Period (Full Analysis Set)

Subgroup		Placebo N = 67	Inebilizumab N = 68
First or subsequent IgG4-RD manifestation - Newly diagnosed	Number of AC-determined IgG4-RD flares, whether or not treated		
	n	17	3
	Mean	1.4	1.0
	SD	0.6	0.0
	Median	1.0	1.0
	Q1, Q3	1.0, 2.0	1.0, 1.0
	Min, Max	1, 3	1, 1
	Annualized flare rate per subject		
	n	31	31
	Mean	0.72	0.09
	SD	0.78	0.28
	Median	0.92	0.00
	Q1, Q3	0.00, 0.99	0.00, 0.00
	Min, Max	0.0, 2.8	0.0, 0.9
	Annualized flare rate ^a	0.70	0.10
	95% CI of annualized flare rate ^a	(0.47, 1.06)	(0.03, 0.30)
Rate ratio ^a		NA	
95% CI of rate ratio ^a		NA	
P-value ^a		NA	

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Table 14-2.2.581. Subgroup Analysis: Annualized Flare Rate for AC-determined IgG4-RD Flares, Whether or Not Treated During Randomized-controlled Period (Full Analysis Set)

Subgroup		Placebo N = 67	Inebilizumab N = 68
First or subsequent IgG4-RD manifestation - Recurrent	Number of AC-determined IgG4-RD flares, whether or not treated		
	n	24	6
	Mean	1.2	1.3
	SD	0.4	0.5
	Median	1.0	1.0
	Q1, Q3	1.0, 1.0	1.0, 2.0
	Min, Max	1, 2	1, 2
	Annualized flare rate per subject		
	n	36	37
	Mean	0.86	0.20
	SD	0.75	0.50
	Median	0.95	0.00
	Q1, Q3	0.00, 1.02	0.00, 0.00
	Min, Max	0.0, 2.3	0.0, 2.0
	Annualized flare rate ^a	0.82	0.21
	95% CI of annualized flare rate ^a	(0.57, 1.18)	(0.11, 0.43)
	Rate ratio ^a		0.26
95% CI of rate ratio ^a		(0.12, 0.57)	
P-value ^a		0.0008	
First or subsequent IgG4-RD manifestation interaction with treatment	P-value		0.3798

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Footnotes defined on the last page of this output

Program: /userdata/stat/amg335/igg4rd/20230068/analysis/germany_submission/tables/t-af-af-rcp-sub.sas
Output: t14-02-002-002-581-af-af-rcp-sub.rtf (Date Generated: 08JAN26:17:43:00) Source: csradam.adsl, csradam.adeff

Table 14-2.2.2.581. Subgroup Analysis: Annualized Flare Rate for AC-determined IgG4-RD Flares, Whether or Not Treated During Randomized-controlled Period (Full Analysis Set)

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^a Estimated from negative binomial regression including treatment, stratification factor (first or subsequent IgG4-RD manifestation), and offset variable (the logarithm of the subject's corresponding follow-up time in years during randomized-controlled period).

Interaction p-value was obtained from negative binomial regression model including treatment, stratification factor (first or subsequent IgG4-RD manifestation), subgroup, treatment-by-subgroup interaction, and offset variable (the logarithm of the subject's corresponding follow-up time in years during randomized-controlled period). When the stratification factor was the subgroup, the corresponding stratification factor would not be included.

Program: /userdata/stat/amg335/igg4rd/20230068/analysis/germany_submission/tables/t-afr-af-rcp-sub.sas
Output: t14-02-002-002-581-afr-af-rcp-sub.rtf (Date Generated: 08JAN26:17:43:00) Source: csradam.adsl, csradam.adeff

5.1.5 Anteil der Patientinnen und Patienten, die zu Woche 52 eine schubfreie und kortikosteroidfreie Komplettremission erreichten**Table 14-2.2.4.581. Subgroup Analysis: The Proportion of Subjects Achieving Flare-free, Corticosteroid-free Complete Remission at Week 52 During Randomized-controlled Period (Full Analysis Set)**

Subgroup	Placebo N = 67		Inebilizumab N = 68			Treatment by Subgroup Interaction p-value
	Responder n / N1 (%)	Responder n / N1 (%)	Odds Ratio (95% CI) p-value	Risk Ratio (95% CI) p-value	Risk Difference (%) (95% CI) p-value	
Age						0.4033
< 65 years	9 / 46 (19.6)	28 / 47 (59.6)	6.50 (2.50, 16.90) 0.0001	3.07 (1.63, 5.75) 0.0005	41.55 (23.13, 59.97) <.0001	
≥ 65 years	6 / 21 (28.6)	12 / 21 (57.1)	3.75 (0.98, 14.28) 0.0531	2.11 (0.98, 4.55) 0.0563	31.10 (1.78, 60.41) 0.0376	
Sex						0.3146
Male	12 / 49 (24.5)	21 / 39 (53.8)	3.61 (1.46, 8.94) 0.0056	2.19 (1.24, 3.88) 0.0072	29.43 (9.66, 49.20) 0.0035	
Female	3 / 18 (16.7)	19 / 29 (65.5)	9.50 (2.21, 40.81) 0.0025	3.93 (1.35, 11.42) 0.0119	48.85 (24.44, 73.25) <.0001	

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N = Number of subjects in the analysis set; n = Number of responders; N1 = Number of subjects in each subgroup level

RCP = Randomized-controlled Period

Responder defined as the lack of evident disease activity at Week 52, no AC-determined flare during the RCP, and no corticosteroid treatment for flare or disease control except the required 8-week GC taper. Subjects who do not complete the RCP or miss IgG4-RD disease activity assessment at Week 52 will be treated as not achieving complete remission at Week 52.

Odds ratio and risk difference were obtained from a logistic regression model including for treatment, stratification factor (first or subsequent IgG4-RD manifestation).

Risk ratio was obtained from a log-binomial regression model including for treatment, stratification factor (first or subsequent IgG4-RD manifestation).

Interaction p-value was obtained from a log-binomial regression model including for treatment, stratification factor (first or subsequent IgG4-RD manifestation), subgroup, and treatment-by-subgroup interaction.

When the stratification factor was the subgroup, the corresponding stratification factor would not be included.

Program: /userdata/stat/amg335/igg4rd/20230068/analysis/germany_submission/tables/t-prop-cfcrw52-sub-rcp.sas

Output: t14-02-002-004-581-prop-cfcrw52-sub-rcp.rtf (Date Generated: 13JAN26:18:18:22) Source: csradam.adsl, csradam.adeff

Table 14-2.2.4.581. Subgroup Analysis: The Proportion of Subjects Achieving Flare-free, Corticosteroid-free Complete Remission at Week 52 During Randomized-controlled Period (Full Analysis Set)

Subgroup	Placebo N = 67		Inebilizumab N = 68			Treatment by Subgroup Interaction p-value
	Responder n / N1 (%)	Responder n / N1 (%)	Odds Ratio (95% CI) p-value	Risk Ratio (95% CI) p-value	Risk Difference (%) (95% CI) p-value	
Region						0.0430
US	5 / 14 (35.7)	2 / 7 (28.6)	0.71 (0.09, 5.35) 0.7375	0.83 (0.22, 3.11) 0.7790	-7.97 (-53.64, 37.70) 0.7323	
Non-US	10 / 53 (18.9)	38 / 61 (62.3)	7.10 (3.00, 16.80) <.0001	3.30 (1.83, 5.97) <.0001	43.41 (27.31, 59.51) <.0001	
Region						0.5730
EU	4 / 26 (15.4)	10 / 20 (50.0)	5.14 (1.28, 20.71) 0.0213	3.08 (1.12, 8.48) 0.0293	31.27 (4.12, 58.42) 0.0240	
Non-EU	11 / 41 (26.8)	30 / 48 (62.5)	4.54 (1.84, 11.22) 0.0011	2.33 (1.34, 4.05) 0.0026	35.63 (16.35, 54.90) 0.0003	

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N = Number of subjects in the analysis set; n = Number of responders; N1 = Number of subjects in each subgroup level

RCP = Randomized-controlled Period

Responder defined as the lack of evident disease activity at Week 52, no AC-determined flare during the RCP, and no corticosteroid treatment for flare or disease control except the required 8-week GC taper. Subjects who do not complete the RCP or miss IgG4-RD disease activity assessment at Week 52 will be treated as not achieving complete remission at Week 52.

Odds ratio and risk difference were obtained from a logistic regression model including for treatment, stratification factor (first or subsequent IgG4-RD manifestation).

Risk ratio was obtained from a log-binomial regression model including for treatment, stratification factor (first or subsequent IgG4-RD manifestation).

Interaction p-value was obtained from a log-binomial regression model including for treatment, stratification factor (first or subsequent IgG4-RD manifestation), subgroup, and treatment-by-subgroup interaction.

When the stratification factor was the subgroup, the corresponding stratification factor would not be included.

Program: /userdata/stat/amg335/igg4rd/20230068/analysis/germany_submission/tables/t-prop-cfcrw52-sub-rcp.sas

Output: t14-02-002-004-581-prop-cfcrw52-sub-rcp.rtf (Date Generated: 13JAN26:18:18:22) Source: csradam.adsl, csradam.adeff

Table 14-2.2.4.581. Subgroup Analysis: The Proportion of Subjects Achieving Flare-free, Corticosteroid-free Complete Remission at Week 52 During Randomized-controlled Period (Full Analysis Set)

Subgroup	Placebo N = 67	Inebilizumab N = 68			Treatment by Subgroup Interaction p-value
	Responder n / N1 (%)	Responder n / N1 (%)	Odds Ratio (95% CI) p-value	Risk Ratio (95% CI) p-value	
Region					0.8757
Asia	5 / 18 (27.8)	22 / 34 (64.7)	4.60 (1.31, 16.16) 0.0173	2.33 (1.07, 5.09) 0.0341	36.35 (9.47, 63.23) 0.0080
Non-Asia	10 / 49 (20.4)	18 / 34 (52.9)	4.39 (1.65, 11.67) 0.0030	2.61 (1.37, 4.96) 0.0035	32.57 (11.74, 53.41) 0.0022
Region					0.8055
Japan	1 / 7 (14.3)	10 / 20 (50.0)	5.75 (0.55, 60.53) 0.1450	3.37 (0.53, 21.39) 0.1970	38.90 (-2.56, 80.35) 0.0659
Non-Japan	14 / 60 (23.3)	30 / 48 (62.5)	5.99 (2.53, 14.20) <.0001	2.74 (1.66, 4.53) <.0001	41.38 (23.60, 59.15) <.0001

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N = Number of subjects in the analysis set; n = Number of responders; N1 = Number of subjects in each subgroup level

RCP = Randomized-controlled Period

Responder defined as the lack of evident disease activity at Week 52, no AC-determined flare during the RCP, and no corticosteroid treatment for flare or disease control except the required 8-week GC taper. Subjects who do not complete the RCP or miss IgG4-RD disease activity assessment at Week 52 will be treated as not achieving complete remission at Week 52.

Odds ratio and risk difference were obtained from a logistic regression model including for treatment, stratification factor (first or subsequent IgG4-RD manifestation).

Risk ratio was obtained from a log-binomial regression model including for treatment, stratification factor (first or subsequent IgG4-RD manifestation).

Interaction p-value was obtained from a log-binomial regression model including for treatment, stratification factor (first or subsequent IgG4-RD manifestation), subgroup, and treatment-by-subgroup interaction.

When the stratification factor was the subgroup, the corresponding stratification factor would not be included.

Program: /userdata/stat/amg335/igg4rd/20230068/analysis/germany_submission/tables/t-prop-cfcrw52-sub-rcp.sas

Output: t14-02-002-004-581-prop-cfcrw52-sub-rcp.rtf (Date Generated: 13JAN26:18:18:22) Source: csradam.adsl, csradam.adeff

Table 14-2.2.4.581. Subgroup Analysis: The Proportion of Subjects Achieving Flare-free, Corticosteroid-free Complete Remission at Week 52 During Randomized-controlled Period (Full Analysis Set)

Subgroup	Placebo N = 67	Inebilizumab N = 68				Treatment by Subgroup Interaction p-value
	Responder n / N1 (%)	Responder n / N1 (%)	Odds Ratio (95% CI) p-value	Risk Ratio (95% CI) p-value	Risk Difference (%) (95% CI) p-value	
Serum IgG4 concentrations at baseline						0.1213
< Median	9 / 29 (31.0)	20 / 30 (66.7)	4.46 (1.49, 13.33) 0.0075	2.14 (1.17, 3.90) 0.0133	35.64 (11.80, 59.48) 0.0034	
≥ Median	2 / 31 (6.5)	12 / 29 (41.4)	10.06 (2.00, 50.58) 0.0051	6.39 (1.55, 26.35) 0.0103	34.60 (14.59, 54.61) 0.0007	

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N = Number of subjects in the analysis set; n = Number of responders; N1 = Number of subjects in each subgroup level

RCP = Randomized-controlled Period

Responder defined as the lack of evident disease activity at Week 52, no AC-determined flare during the RCP, and no corticosteroid treatment for flare or disease control except the required 8-week GC taper. Subjects who do not complete the RCP or miss IgG4-RD disease activity assessment at Week 52 will be treated as not achieving complete remission at Week 52.

Odds ratio and risk difference were obtained from a logistic regression model including for treatment, stratification factor (first or subsequent IgG4-RD manifestation).

Risk ratio was obtained from a log-binomial regression model including for treatment, stratification factor (first or subsequent IgG4-RD manifestation).

Interaction p-value was obtained from a log-binomial regression model including for treatment, stratification factor (first or subsequent IgG4-RD manifestation), subgroup, and treatment-by-subgroup interaction.

When the stratification factor was the subgroup, the corresponding stratification factor would not be included.

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Output: t14-02-002-004-581-prop-cfcrw52-sub-rcp.rtf (Date Generated: 13JAN26:18:18:22) Source: csradam.adsl, csradam.adeff

Table 14-2.2.4.581. Subgroup Analysis: The Proportion of Subjects Achieving Flare-free, Corticosteroid-free Complete Remission at Week 52 During Randomized-controlled Period (Full Analysis Set)

Subgroup	Placebo N = 67	Inebilizumab N = 68				Treatment by Subgroup Interaction p-value
	Responder n / N1 (%)	Responder n / N1 (%)	Odds Ratio (95% CI) p-value	Risk Ratio (95% CI) p-value	Risk Difference (%) (95% CI) p-value	
First or subsequent IgG4-RD manifestation						0.5382
Newly diagnosed	8 / 31 (25.8)	18 / 31 (58.1)	3.98 (1.36, 11.67) 0.0118	2.25 (1.15, 4.39) 0.0173	32.26 (9.04, 55.47) 0.0065	
Recurrent	7 / 36 (19.4)	22 / 37 (59.5)	6.08 (2.12, 17.44) 0.0008	3.06 (1.49, 6.26) 0.0022	40.01 (19.58, 60.45) 0.0001	

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N = Number of subjects in the analysis set; n = Number of responders; N1 = Number of subjects in each subgroup level

RCP = Randomized-controlled Period

Responder defined as the lack of evident disease activity at Week 52, no AC-determined flare during the RCP, and no corticosteroid treatment for flare or disease control except the required 8-week GC taper. Subjects who do not complete the RCP or miss IgG4-RD disease activity assessment at Week 52 will be treated as not achieving complete remission at Week 52.

Odds ratio and risk difference were obtained from a logistic regression model including for treatment, stratification factor (first or subsequent IgG4-RD manifestation).

Risk ratio was obtained from a log-binomial regression model including for treatment, stratification factor (first or subsequent IgG4-RD manifestation).

Interaction p-value was obtained from a log-binomial regression model including for treatment, stratification factor (first or subsequent IgG4-RD manifestation), subgroup, and treatment-by-subgroup interaction.

When the stratification factor was the subgroup, the corresponding stratification factor would not be included.

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Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

5.1.6 Zeit bis zum Beginn der ersten Behandlung bei neuer oder sich verschlimmernder Krankheitsaktivität innerhalb der RCP, unabhängig von der Bestimmung eines Krankheitsschubs durch ein AC

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Table 14.2.2.5
 Subgroup Analysis Of Time (days) To Initiation Of First Treatment For IgG4-RD Within The RCP, Regardless Of AC Determination Of Flare (Randomized-Controlled Period)
 Full Analysis Set

Subgroup		Placebo N = 67	Inebilizumab N = 68
Age - < 65	Number of subjects with a IgG4-RD flare	31 (67.4%)	6 (12.8%)
	Number of censored subjects	15 (32.6%)	41 (87.2%)
	Median time to flare ^a	238.5	NA
	95% CI ^a	(141.0, 300.0)	(371.0, NA)
	Hazard ratio ^b		0.1
	95% CI ^b		(0.1, 0.3)
Age - >= 65	Number of subjects with a IgG4-RD flare	11 (52.4%)	1 (4.8%)
	Number of censored subjects	10 (47.6%)	20 (95.2%)
	Median time to flare ^a	232.0	NA
	95% CI ^a	(117.0, NA)	(NA, NA)
	Hazard ratio ^b		0.1
	95% CI ^b		(0.0, 0.6)
Age interaction with treatment	P-value		0.5708

^a Based on Kaplan-Meier method.

^b Based on Cox regression method, with Placebo as the reference group.

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Table 14.2.2.5
Subgroup Analysis Of Time (days) To Initiation Of First Treatment For IgG4-RD Within The RCP, Regardless Of AC Determination Of Flare (Randomized-Controlled Period)
Full Analysis Set

Subgroup		Placebo N = 67	Inebilizumab N = 68
Sex - Female	Number of subjects with a IgG4-RD flare	12 (66.7%)	3 (10.3%)
	Number of censored subjects	6 (33.3%)	26 (89.7%)
	Median time to flare ^a	220.5	NA
	95% CI ^a	(128.0, NA)	(NA, NA)
	Hazard ratio ^b		0.1
	95% CI ^b		(0.0, 0.4)
Sex - Male	Number of subjects with a IgG4-RD flare	30 (61.2%)	4 (10.3%)
	Number of censored subjects	19 (38.8%)	35 (89.7%)
	Median time to flare ^a	246.0	NA
	95% CI ^a	(142.0, NA)	(371.0, NA)
	Hazard ratio ^b		0.1
	95% CI ^b		(0.0, 0.3)
Sex interaction with treatment	P-value		0.9442

^a Based on Kaplan-Meier method.

^b Based on Cox regression method, with Placebo as the reference group.

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Table 14.2.2.5
Subgroup Analysis Of Time (days) To Initiation Of First Treatment For IgG4-RD Within The RCP, Regardless Of AC Determination Of Flare (Randomized-Controlled Period)
Full Analysis Set

Subgroup		Placebo N = 67	Inebilizumab N = 68
Baseline serum IgG4 concentrations - < Median	Number of subjects with a IgG4-RD flare	15 (51.7%)	3 (10.0%)
	Number of censored subjects	14 (48.3%)	27 (90.0%)
	Median time to flare ^a	300.0	NA
	95% CI ^a	(133.0, NA)	(NA, NA)
	Hazard ratio ^b		0.2
	95% CI ^b		(0.0, 0.6)
Baseline serum IgG4 concentrations - >= Median	Number of subjects with a IgG4-RD flare	25 (80.6%)	3 (10.3%)
	Number of censored subjects	6 (19.4%)	26 (89.7%)
	Median time to flare ^a	214.0	NA
	95% CI ^a	(102.0, 246.0)	(NA, NA)
	Hazard ratio ^b		0.1
	95% CI ^b		(0.0, 0.2)
Baseline serum IgG4 concentrations interaction with treatment	P-value		0.4641

^a Based on Kaplan-Meier method.
^b Based on Cox regression method, with Placebo as the reference group.
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Table 14.2.2.5
Subgroup Analysis Of Time (days) To Initiation Of First Treatment For IgG4-RD Within The RCP, Regardless Of AC Determination Of Flare (Randomized-Controlled Period)
Full Analysis Set

Subgroup		Placebo N = 67	Inebilizumab N = 68
First or subsequent IgG4-RD manifestation - First Manifestation of IgG4-RD	Number of subjects with a IgG4-RD flare	19 (61.3%)	1 (3.2%)
	Number of censored subjects	12 (38.7%)	30 (96.8%)
	Median time to flare ^a	217.0	NA
	95% CI ^a	(141.0, NA)	(NA, NA)
	Hazard ratio ^b		0.0
	95% CI ^b		(0.0, 0.3)
	P-value ^b		0.0015
First or subsequent IgG4-RD manifestation - Subsequent Manifestation of IgG4-RD	Number of subjects with a IgG4-RD flare	23 (63.9%)	6 (16.2%)
	Number of censored subjects	13 (36.1%)	31 (83.8%)
	Median time to flare ^a	246.5	NA
	95% CI ^a	(133.0, NA)	(371.0, NA)
	Hazard ratio ^b		0.2
	95% CI ^b		(0.1, 0.4)
	P-value ^b		0.0002
First or subsequent IgG4-RD manifestation interaction with treatment	P-value		0.1415

^a Based on Kaplan-Meier method.

^b Based on Cox regression method, with Placebo as the reference group.

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Table 14.2.2.5
Subgroup Analysis Of Time (days) To Initiation Of First Treatment For IgG4-RD Within The RCP, Regardless Of AC Determination Of Flare (Randomized-Controlled Period)
Full Analysis Set

Subgroup		Placebo N = 67	Inebilizumab N = 68
Region 1 - US	Number of subjects with a IgG4-RD flare	9 (64.3%)	3 (42.9%)
	Number of censored subjects	5 (35.7%)	4 (57.1%)
	Median time to flare ^a	268.5	360.0
	95% CI ^a	(89.0, NA)	(16.0, NA)
	Hazard ratio ^b		0.6
	95% CI ^b		(0.1, 2.1)
	P-value ^b		0.3761
Region 1 - Non-US	Number of subjects with a IgG4-RD flare	33 (62.3%)	4 (6.6%)
	Number of censored subjects	20 (37.7%)	57 (93.4%)
	Median time to flare ^a	224.0	NA
	95% CI ^a	(141.0, NA)	(371.0, NA)
	Hazard ratio ^b		0.1
	95% CI ^b		(0.0, 0.2)
	P-value ^b		<.0001
Region 1 interaction with treatment	P-value		0.0095

^a Based on Kaplan-Meier method.
^b Based on Cox regression method, with Placebo as the reference group.
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Table 14.2.2.5
Subgroup Analysis Of Time (days) To Initiation Of First Treatment For IgG4-RD Within The RCP, Regardless Of AC Determination Of Flare (Randomized-Controlled Period)
Full Analysis Set

Subgroup		Placebo N = 67	Inebilizumab N = 68
Region 2 - EU	Number of subjects with a IgG4-RD flare	15 (57.7%)	2 (10.0%)
	Number of censored subjects	11 (42.3%)	18 (90.0%)
	Median time to flare ^a	253.5	NA
	95% CI ^a	(140.0, NA)	(NA, NA)
	Hazard ratio ^b		0.1
	95% CI ^b		(0.0, 0.7)
Region 2 - Non-EU	Number of subjects with a IgG4-RD flare	27 (65.9%)	5 (10.4%)
	Number of censored subjects	14 (34.1%)	43 (89.6%)
	Median time to flare ^a	224.0	NA
	95% CI ^a	(133.0, 310.0)	(371.0, NA)
	Hazard ratio ^b		0.1
	95% CI ^b		(0.0, 0.3)
Region 2 interaction with treatment	P-value		0.8013

^a Based on Kaplan-Meier method.
^b Based on Cox regression method, with Placebo as the reference group.
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Table 14.2.2.5
Subgroup Analysis Of Time (days) To Initiation Of First Treatment For IgG4-RD Within The RCP, Regardless Of AC Determination Of Flare (Randomized-Controlled Period)
Full Analysis Set

Subgroup		Placebo N = 67	Inebilizumab N = 68
Region 3 - Asia	Number of subjects with a IgG4-RD flare	10 (55.6%)	1 (2.9%)
	Number of censored subjects	8 (44.4%)	33 (97.1%)
	Median time to flare ^a	243.0	NA
	95% CI ^a	(142.0, NA)	(371.0, NA)
	Hazard ratio ^b		0.0
	95% CI ^b		(0.0, 0.2)
	P-value ^b		0.0005
Region 3 - Non-Asia	Number of subjects with a IgG4-RD flare	32 (65.3%)	6 (17.6%)
	Number of censored subjects	17 (34.7%)	28 (82.4%)
	Median time to flare ^a	232.0	NA
	95% CI ^a	(140.0, 300.0)	(NA, NA)
	Hazard ratio ^b		0.2
	95% CI ^b		(0.1, 0.5)
	P-value ^b		0.0004
Region 3 interaction with treatment	P-value		0.1465

^a Based on Kaplan-Meier method.

^b Based on Cox regression method, with Placebo as the reference group.

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 Run Date: 27JUN2024 11:07

Table 14.2.2.5
Subgroup Analysis Of Time (days) To Initiation Of First Treatment For IgG4-RD Within The RCP, Regardless Of AC Determination Of Flare (Randomized-Controlled Period)
Full Analysis Set

Subgroup		Placebo N = 67	Inebilizumab N = 68
Region 4 - Japan	Number of subjects with a IgG4-RD flare	4 (57.1%)	0
	Number of censored subjects	3 (42.9%)	20 (100%)
	Median time to flare ^a	246.0	NA
	95% CI ^a	(65.0, NA)	(NA, NA)
	Hazard ratio ^b		0.0
	95% CI ^b		(0.0, NA)
Region 4 - Non-Japan	Number of subjects with a IgG4-RD flare	38 (63.3%)	7 (14.6%)
	Number of censored subjects	22 (36.7%)	41 (85.4%)
	Median time to flare ^a	228.0	NA
	95% CI ^a	(141.0, 310.0)	(371.0, NA)
	Hazard ratio ^b		0.2
	95% CI ^b		(0.1, 0.4)
Region 4 interaction with treatment	P-value ^b		<.0001
	P-value		0.9851

^a Based on Kaplan-Meier method.

^b Based on Cox regression method, with Placebo as the reference group.

G:\BPSApp\bps\workspace\UPLIZNA\3S2\CSR\Programs\ite_tf_sub_rep.sas

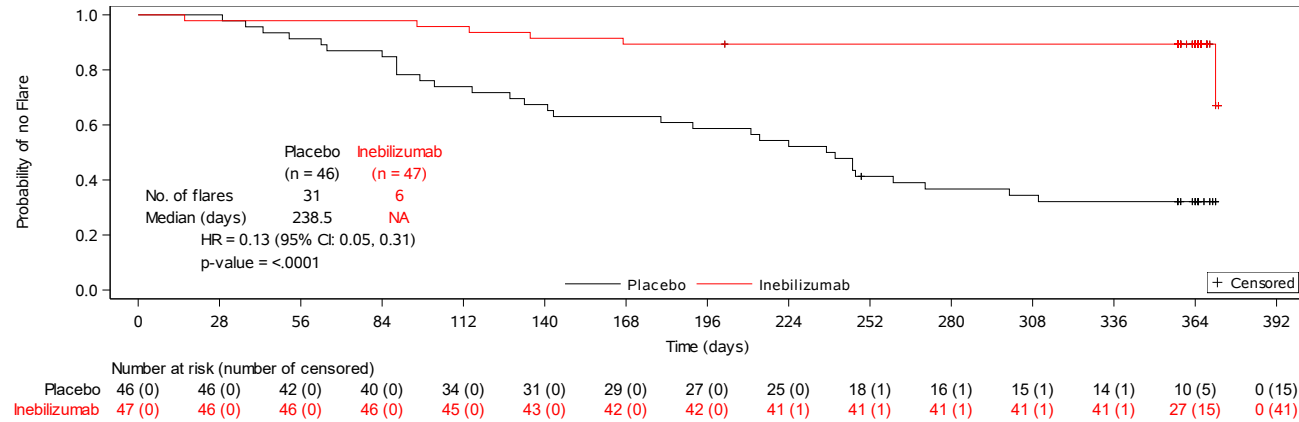
Data Extract: 29MAY2024



5.1.7 Kaplan-Meier-Kurven für Zeit bis zum Beginn der ersten Behandlung bei neuer oder sich verschlimmernder Krankheitsaktivität innerhalb der RCP, unabhängig von der Bestimmung eines Krankheitsschubs durch ein AC

Figure 14-2.5.2.581. Subgroup Analysis: Kaplan Meier Plot for Time to Initiation of First Treatment for IgG4-RD During Randomized-controlled Period (Full Analysis Set)

Subgroup = Age - < 65 years

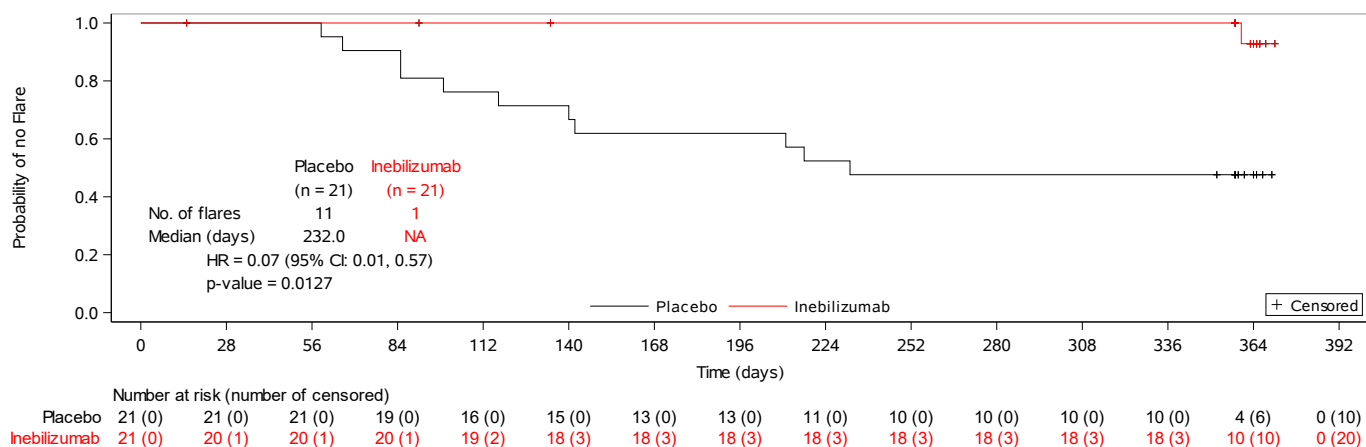


Subjects who do not complete the randomized-controlled period and who have not had a treated flare during the randomized-controlled period will be censored at the time of discontinuation.

Program: /userdata/stat/amg335/igg4rd/20230068/analysis/germany_submission/figures/f-km-tf-rcp-sub.sas
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Figure 14-2.5.2.581. Subgroup Analysis: Kaplan Meier Plot for Time to Initiation of First Treatment for IgG4-RD During Randomized-controlled Period (Full Analysis Set)

Subgroup = Age - ≥ 65 years



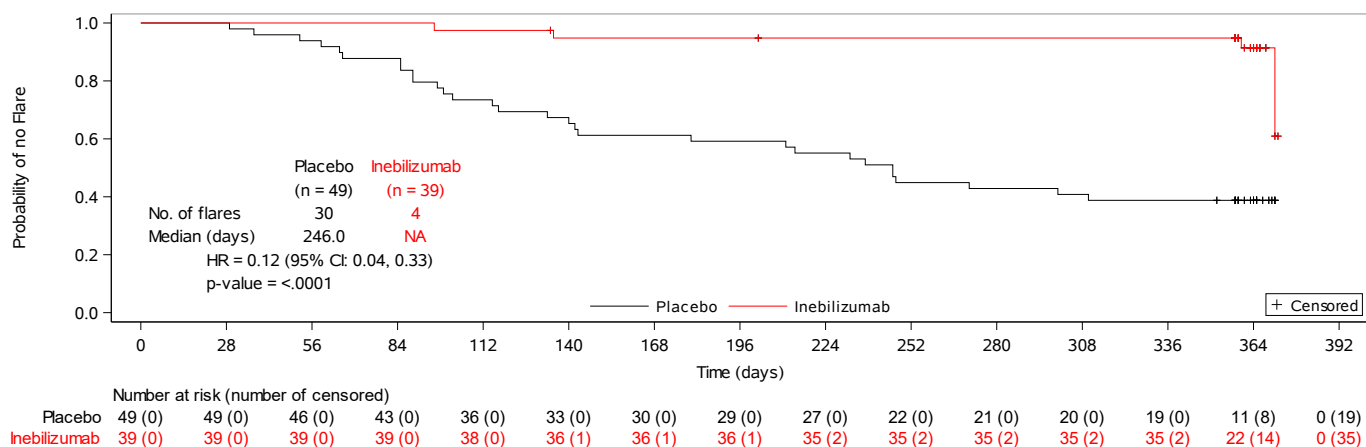
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Subjects who do not complete the randomized-controlled period and who have not had a treated flare during the randomized-controlled period will be censored at the time of discontinuation.

Program: /userdata/stat/amg335/igg4rd/20230068/analysis/germany_submission/figures/f-km-tf-rfp-sub.sas
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Figure 14-2.5.2.581. Subgroup Analysis: Kaplan Meier Plot for Time to Initiation of First Treatment for IgG4-RD During Randomized-controlled Period (Full Analysis Set)

Subgroup = Sex - Male



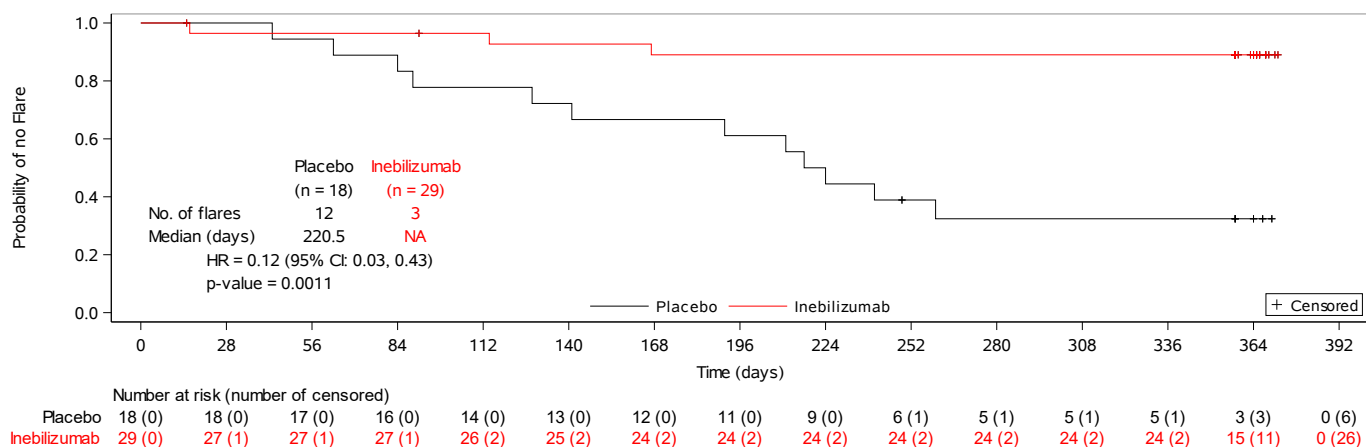
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Subjects who do not complete the randomized-controlled period and who have not had a treated flare during the randomized-controlled period will be censored at the time of discontinuation.

Program: /userdata/stat/amg335/igg4rd/20230068/analysis/germany_submission/figures/f-km-tf-rcp-sub.sas
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Figure 14-2.5.2.581. Subgroup Analysis: Kaplan Meier Plot for Time to Initiation of First Treatment for IgG4-RD During Randomized-controlled Period (Full Analysis Set)

Subgroup = Sex - Female



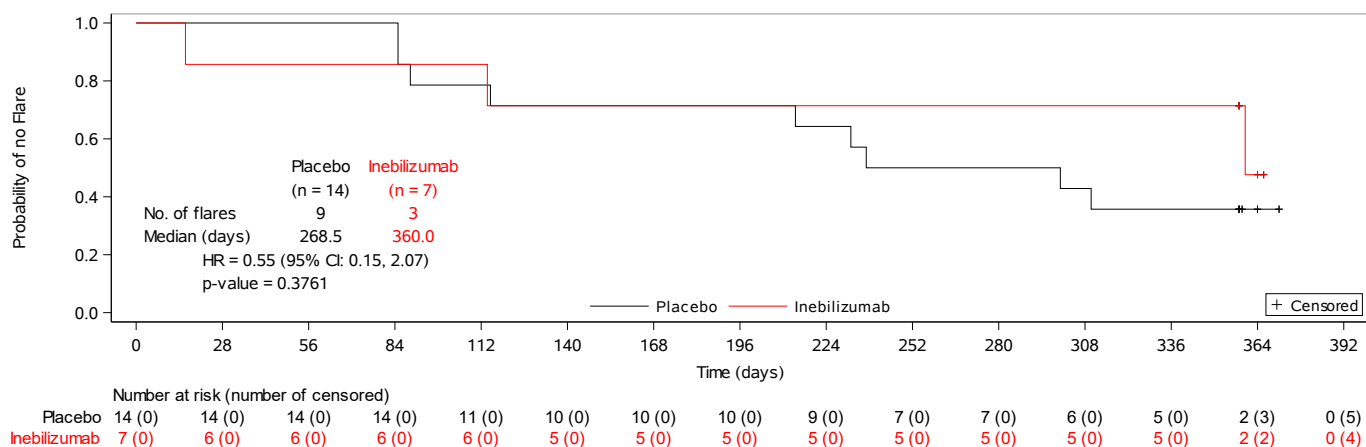
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Subjects who do not complete the randomized-controlled period and who have not had a treated flare during the randomized-controlled period will be censored at the time of discontinuation.

Program: /userdata/stat/amg335/igg4rd/20230068/analysis/germany_submission/figures/f-km-tf-rfp-sub.sas
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Figure 14-2.5.2.581. Subgroup Analysis: Kaplan Meier Plot for Time to Initiation of First Treatment for IgG4-RD During Randomized-controlled Period (Full Analysis Set)

Subgroup = Region - US



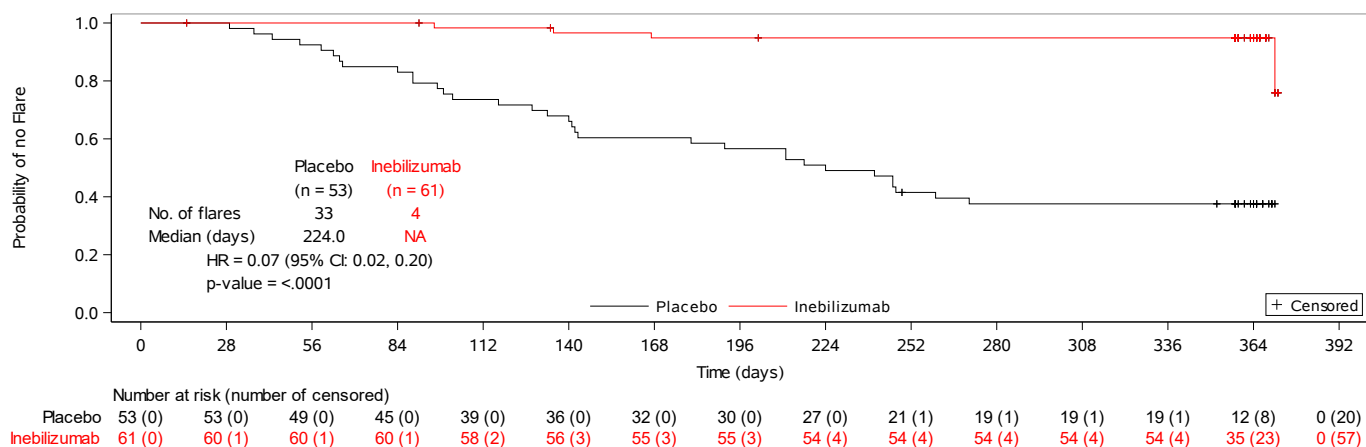
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Subjects who do not complete the randomized-controlled period and who have not had a treated flare during the randomized-controlled period will be censored at the time of discontinuation.

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Figure 14-2.5.2.581. Subgroup Analysis: Kaplan Meier Plot for Time to Initiation of First Treatment for IgG4-RD During Randomized-controlled Period (Full Analysis Set)

Subgroup = Region - Non-US



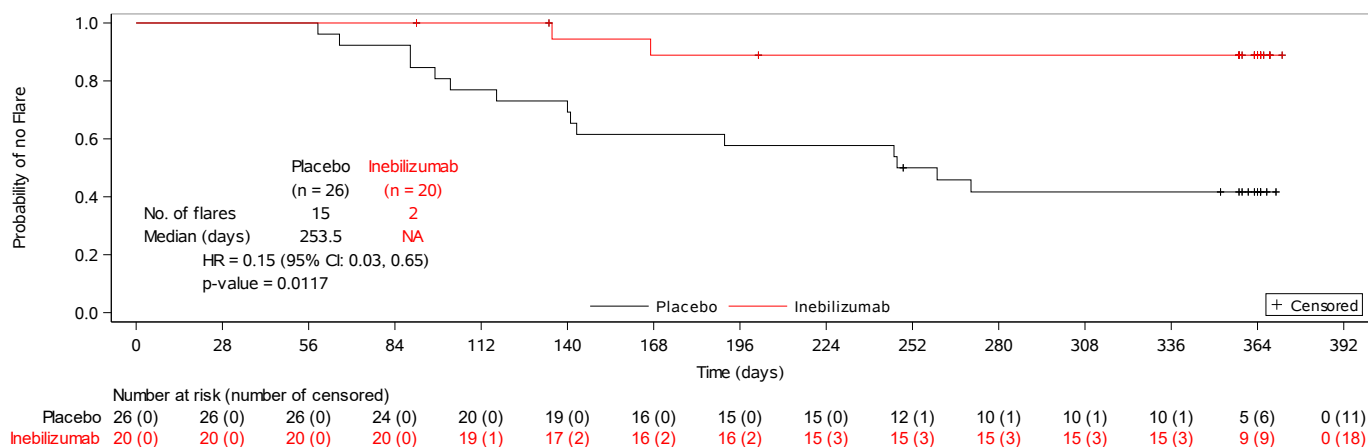
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Subjects who do not complete the randomized-controlled period and who have not had a treated flare during the randomized-controlled period will be censored at the time of discontinuation.

Program: /userdata/stat/amg335/igg4rd/20230068/analysis/germany_submission/figures/f-km-tf-rcp-sub.sas
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Figure 14-2.5.2.581. Subgroup Analysis: Kaplan Meier Plot for Time to Initiation of First Treatment for IgG4-RD During Randomized-controlled Period (Full Analysis Set)

Subgroup = Region - EU



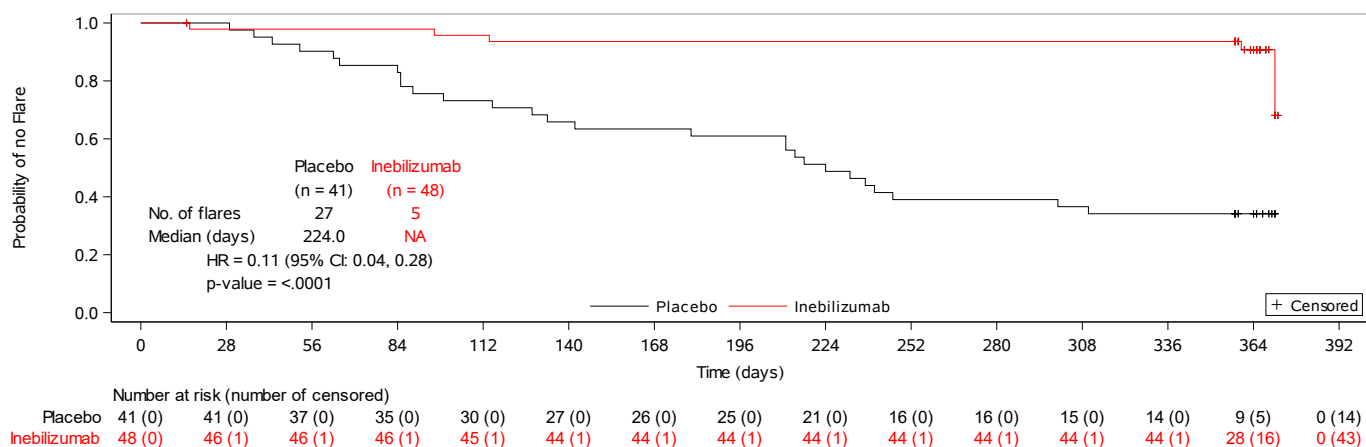
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Subjects who do not complete the randomized-controlled period and who have not had a treated flare during the randomized-controlled period will be censored at the time of discontinuation.

Program: /userdata/stat/amg335/igg4rd/20230068/analysis/germany_submission/figures/f-km-tf-rcp-sub.sas
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Figure 14-2.5.2.581. Subgroup Analysis: Kaplan Meier Plot for Time to Initiation of First Treatment for IgG4-RD During Randomized-controlled Period (Full Analysis Set)

Subgroup = Region - Non-EU



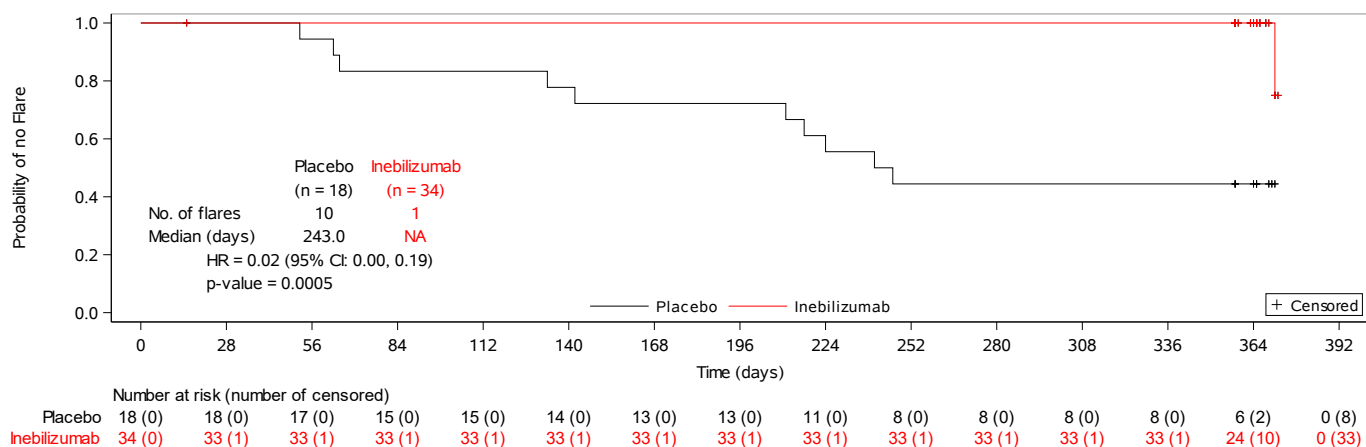
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Subjects who do not complete the randomized-controlled period and who have not had a treated flare during the randomized-controlled period will be censored at the time of discontinuation.

Program: /userdata/stat/amg335/igg4rd/20230068/analysis/germany_submission/figures/f-km-tf-rcp-sub.sas
 Output: f14-02-005-002-581-km-tf-rcp-sub.tf (Date Generated: 08JAN26:20:00:45) Source: csradam.adsl, csradam.adtte, csradam.adeff

Figure 14-2.5.2.581. Subgroup Analysis: Kaplan Meier Plot for Time to Initiation of First Treatment for IgG4-RD During Randomized-controlled Period (Full Analysis Set)

Subgroup = Region - Asia



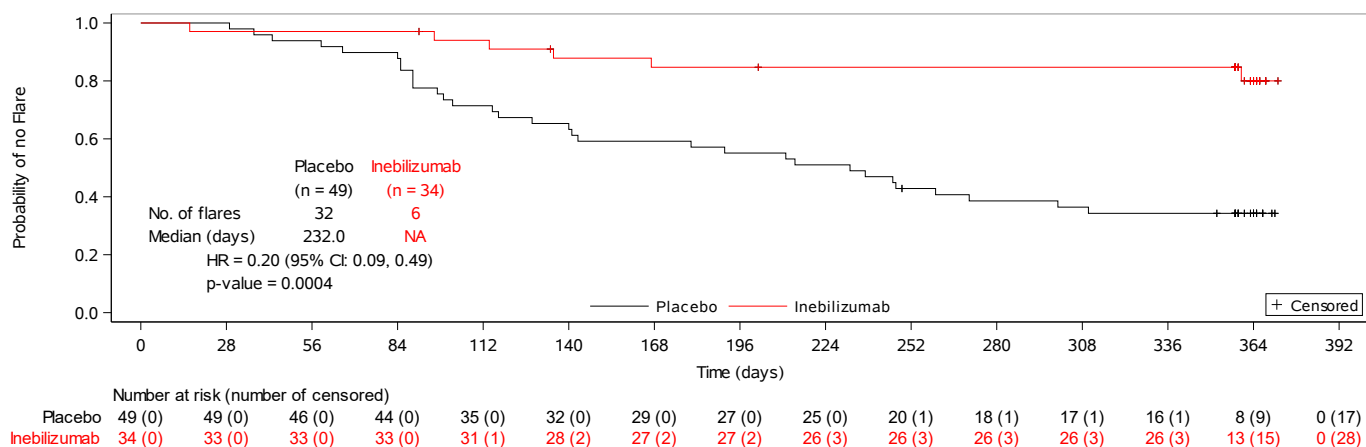
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Subjects who do not complete the randomized-controlled period and who have not had a treated flare during the randomized-controlled period will be censored at the time of discontinuation.

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Figure 14-2.5.2.581. Subgroup Analysis: Kaplan Meier Plot for Time to Initiation of First Treatment for IgG4-RD During Randomized-controlled Period (Full Analysis Set)

Subgroup = Region - Non-Asia



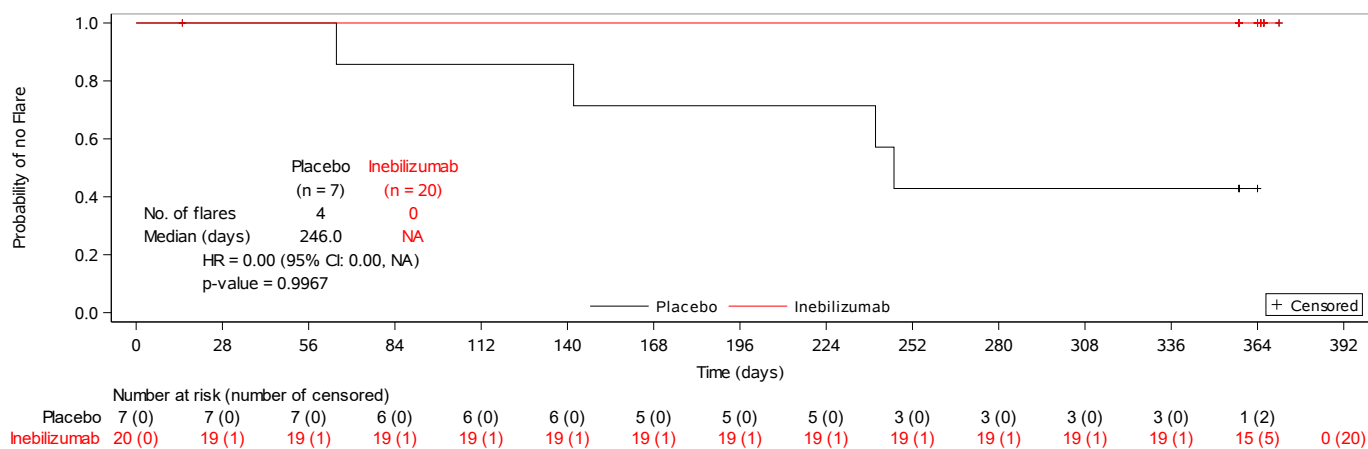
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Subjects who do not complete the randomized-controlled period and who have not had a treated flare during the randomized-controlled period will be censored at the time of discontinuation.

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Figure 14-2.5.2.581. Subgroup Analysis: Kaplan Meier Plot for Time to Initiation of First Treatment for IgG4-RD During Randomized-controlled Period (Full Analysis Set)

Subgroup = Region - Japan

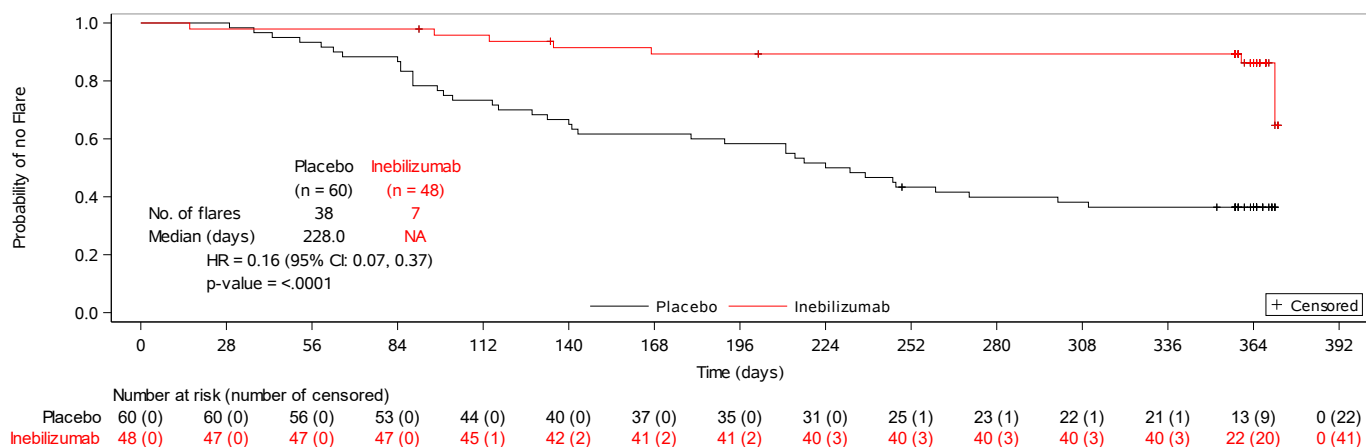


Subjects who do not complete the randomized-controlled period and who have not had a treated flare during the randomized-controlled period will be censored at the time of discontinuation.

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 Output: f14-02-005-002-581-km-tf-rcp-sub.tf (Date Generated: 08JAN26:20:00:46) Source: csradam.adsl, csradam.adtte, csradam.adeff

Figure 14-2.5.2.581. Subgroup Analysis: Kaplan Meier Plot for Time to Initiation of First Treatment for IgG4-RD During Randomized-controlled Period (Full Analysis Set)

Subgroup = Region - Non-Japan



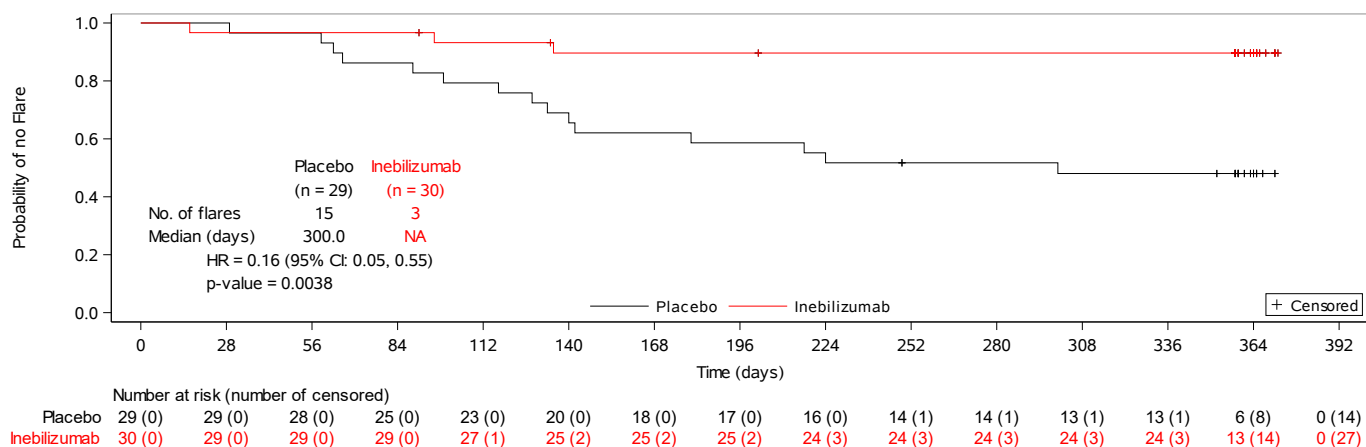
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Subjects who do not complete the randomized-controlled period and who have not had a treated flare during the randomized-controlled period will be censored at the time of discontinuation.

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 Output: f14-02-005-002-581-km-tf-rcp-sub.tf (Date Generated: 08JAN26:20:00:46) Source: csradam.adsl, csradam.adtte, csradam.adeff

Figure 14-2.5.2.581. Subgroup Analysis: Kaplan Meier Plot for Time to Initiation of First Treatment for IgG4-RD During Randomized-controlled Period (Full Analysis Set)

Subgroup = Serum IgG4 concentrations at baseline - < Median



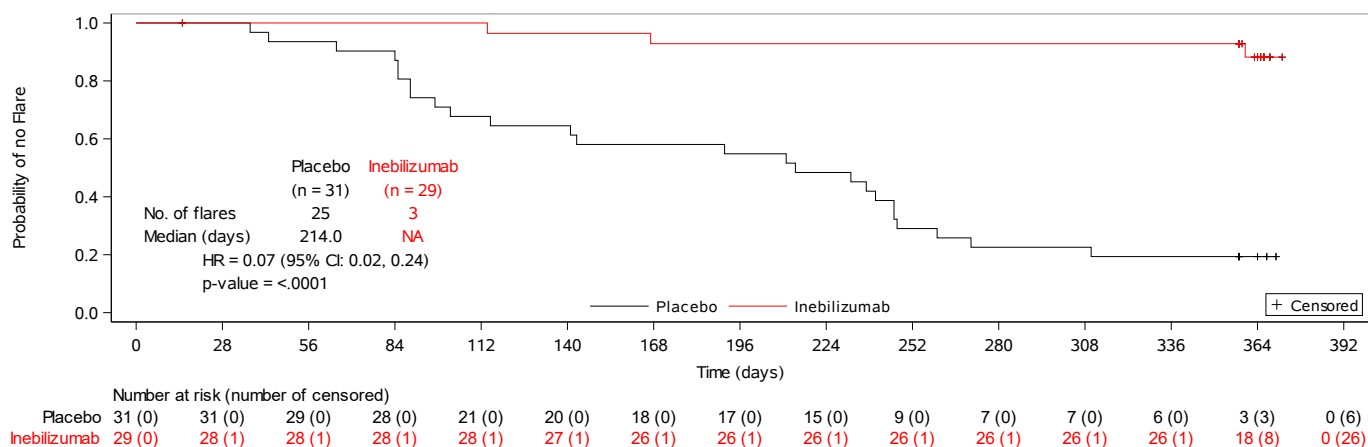
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Subjects who do not complete the randomized-controlled period and who have not had a treated flare during the randomized-controlled period will be censored at the time of discontinuation.

Program: /userdata/stat/amg335/igg4rd/20230068/analysis/germany_submission/figures/f-km-tf-rfp-sub.sas
 Output: f14-02-005-002-581-km-tf-rfp-sub.tf (Date Generated: 08JAN26:20:00:46) Source: csradam.adsl, csradam.adtte, csradam.adeff

Figure 14-2.5.2.581. Subgroup Analysis: Kaplan Meier Plot for Time to Initiation of First Treatment for IgG4-RD During Randomized-controlled Period (Full Analysis Set)

Subgroup = Serum IgG4 concentrations at baseline - \geq Median

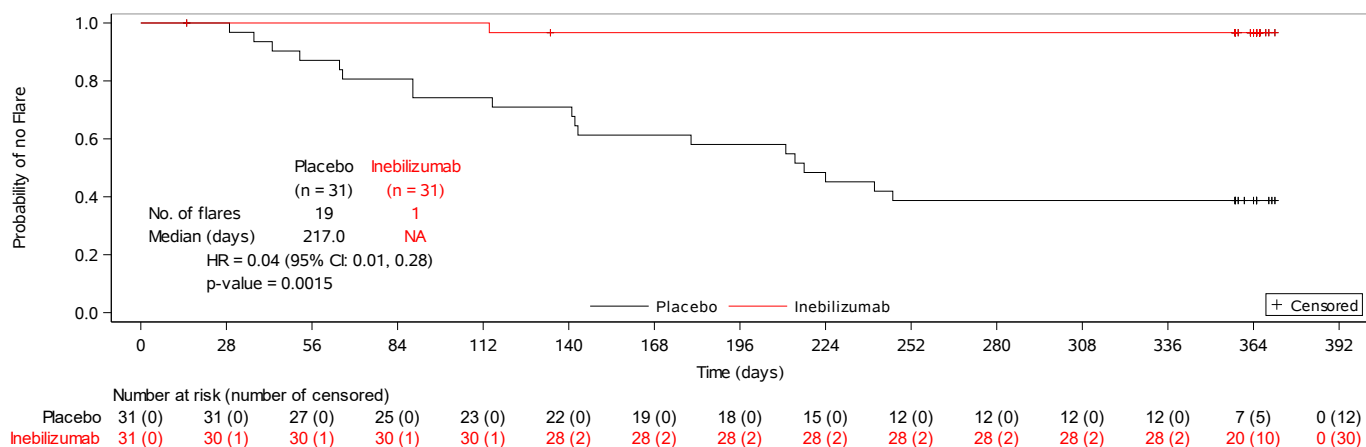


Subjects who do not complete the randomized-controlled period and who have not had a treated flare during the randomized-controlled period will be censored at the time of discontinuation.

Program: /userdata/stat/amg335/igg4rd/20230068/analysis/germany_submission/figures/f-km-tf-rcp-sub.sas
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Figure 14-2.5.2.581. Subgroup Analysis: Kaplan Meier Plot for Time to Initiation of First Treatment for IgG4-RD During Randomized-controlled Period (Full Analysis Set)

Subgroup = First or subsequent IgG4-RD manifestation - Newly diagnosed



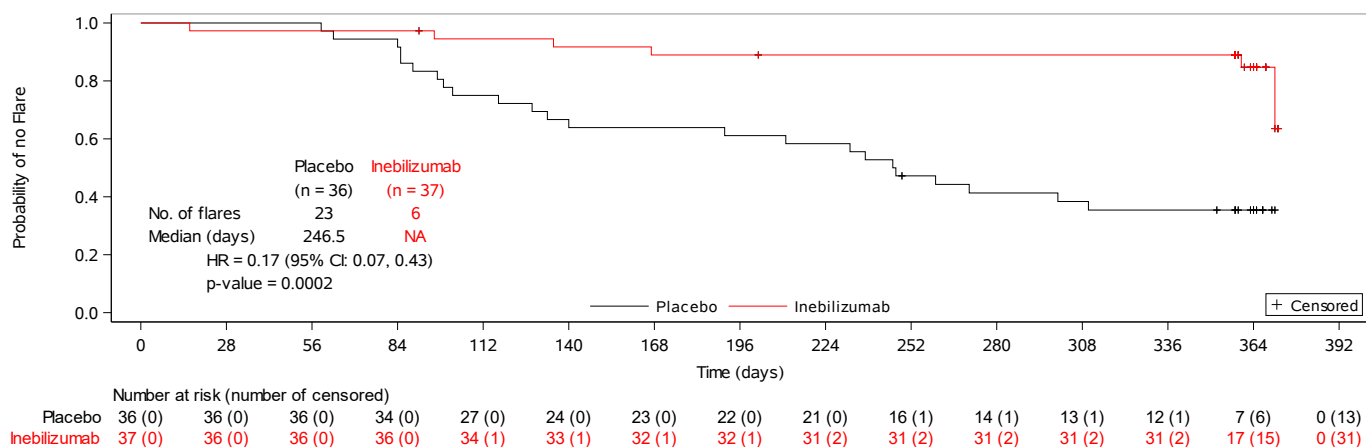
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Subjects who do not complete the randomized-controlled period and who have not had a treated flare during the randomized-controlled period will be censored at the time of discontinuation.

Program: /userdata/stat/amg335/igg4rd/20230068/analysis/germany_submission/figures/f-km-tf-rcp-sub.sas
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Figure 14-2.5.2.581. Subgroup Analysis: Kaplan Meier Plot for Time to Initiation of First Treatment for IgG4-RD During Randomized-controlled Period (Full Analysis Set)

Subgroup = First or subsequent IgG4-RD manifestation - Recurrent



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Subjects who do not complete the randomized-controlled period and who have not had a treated flare during the randomized-controlled period will be censored at the time of discontinuation.

Program: /userdata/stat/amg335/igg4rd/20230068/analysis/germany_submission/figures/f-km-tf-rcp-sub.sas
 Output: f14-02-005-002-581-km-tf-rcp-sub.tif (Date Generated: 08JAN26:20:00:47) Source: csradam.adsl, csradam.adtte, csradam.adeff

5.2 Glukokortikoid-Behandlung

5.2.1 Behandlung mit Glukokortikoiden bei IgG4-RD-Schüben oder zur Erhaltung (Gesamtdosierung)

Table 14-2.1.6.581. Subgroup Analysis: Glucocorticoid Use for IgG4-RD Flare or Maintenance During Randomized-controlled Period (Full Analysis Set)

Subgroup	All Subjects		Treatment by Subgroup Interaction p-value ^b
	Placebo N = 67	Inebilizumab N = 68	
Age			0.8589
< 65 years	Total GC use ^a (mg) per subject		
	n	46	47
	Mean	1433.09	163.64
	SD	1798.84	520.87
	Median	1140.00	0.00
	Q1, Q3	0.00, 1580.00	0.00, 0.00
	Min, Max	0.0, 9125.0	0.0, 2490.0
	Mean difference		-1269.45
	Hedges'g (95% CI)		-0.96 (-1.39, -0.53)
	LSMEAN (SE)	1433.09 (192.63)	206.05 (192.36)
	LSMEAN difference (SE)		-1227.04 (272.23)
	95% CI		-1767.87, -686.22
	p-value		<.0001
	LSM Hedges'g (95% CI)		-0.93 (-1.36, -0.51)
≥ 65 years	Total GC use ^a (mg) per subject		
	n	21	21
	Mean	1278.16	16.67
	SD	1581.71	76.38
	Median	459.40	0.00
	Q1, Q3	0.00, 2305.00	0.00, 0.00
	Min, Max	0.0, 4835.0	0.0, 350.0
	Mean difference		-1261.50
	Hedges'g (95% CI)		-1.13 (-1.78, -0.48)
	LSMEAN (SE)	1283.49 (251.03)	13.47 (248.72)
	LSMEAN difference (SE)		-1270.02 (356.43)
	95% CI		-1990.97, -549.07
	p-value		0.0010
	LSM Hedges'g (95% CI)		-1.10 (-1.75, -0.45)

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Footnotes defined on the last page of this output

Program: /userdata/stat/amg335/igg4rd/20230068/analysis/germany_submission/tables/t-gc-use1-rcp-sub.sas
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Table 14-2.1.6.581. Subgroup Analysis: Glucocorticoid Use for IgG4-RD Flare or Maintenance During Randomized-controlled Period (Full Analysis Set)

Subgroup	All Subjects		Treatment by Subgroup Interaction p-value ^b
	Placebo N = 67	Inebilizumab N = 68	
Sex			0.0989
Male	Total GC use ^a (mg) per subject		
	n	49	39
	Mean	1551.33	54.74
	SD	1915.88	242.12
	Median	1240.00	0.00
	Q1, Q3	0.00, 2437.50	0.00, 0.00
	Min, Max	0.0, 9125.0	0.0, 1260.0
	Mean difference		-1496.59
	Hedges'g (95% CI)		-1.04 (-1.49, -0.59)
	LSMEAN (SE)	1555.85 (204.48)	60.42 (229.21)
	LSMEAN difference (SE)		-1495.43 (307.12)
	95% CI		-2106.07, -884.78
	p-value		<.0001
	LSM Hedges'g (95% CI)		-1.04 (-1.49, -0.60)
Female	Total GC use ^a (mg) per subject		
	n	18	29
	Mean	930.46	203.66
	SD	930.89	606.92
	Median	1010.00	0.00
	Q1, Q3	0.00, 1290.00	0.00, 0.00
	Min, Max	0.0, 3215.0	0.0, 2490.0
	Mean difference		-726.81
	Hedges'g (95% CI)		-0.97 (-1.59, -0.35)
	LSMEAN (SE)	931.38 (179.56)	204.37 (141.43)
	LSMEAN difference (SE)		-727.01 (226.45)
	95% CI		-1183.40, -270.63
	p-value		0.0025
	LSM Hedges'g (95% CI)		-0.96 (-1.58, -0.34)

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Table 14-2.1.6.581. Subgroup Analysis: Glucocorticoid Use for IgG4-RD Flare or Maintenance During Randomized-controlled Period (Full Analysis Set)

Subgroup	All Subjects		Treatment by Subgroup Interaction p-value ^b
	Placebo N = 67	Inebilizumab N = 68	
Region			0.1205
US	Total GC use ^a (mg) per subject		
	n	14	7
	Mean	947.50	503.71
	SD	1062.32	957.19
	Median	875.00	0.00
	Q1, Q3	0.00, 1430.00	0.00, 1036.00
	Min, Max	0.0, 3755.0	0.0, 2490.0
	Mean difference		-443.79
	Hedges'g (95% CI)		-0.43 (-1.35, 0.49)
	LSMEAN (SE)	1018.68 (299.80)	574.89 (409.92)
	LSMEAN difference (SE)		-443.79 (484.22)
	95% CI		-1461.09, 573.52
	p-value		0.3715
	LSM Hedges'g (95% CI)		-0.42 (-1.34, 0.49)
Non-US	Total GC use ^a (mg) per subject		
	n	53	61
	Mean	1499.97	74.02
	SD	1849.86	322.85
	Median	1260.00	0.00
	Q1, Q3	0.00, 2437.50	0.00, 0.00
	Min, Max	0.0, 9125.0	0.0, 2030.0
	Mean difference		-1425.96
	Hedges'g (95% CI)		-1.11 (-1.51, -0.72)
	LSMEAN (SE)	1497.26 (175.83)	81.09 (163.98)
	LSMEAN difference (SE)		-1416.17 (240.48)
	95% CI		-1892.70, -939.63
	p-value		<.0001
	LSM Hedges'g (95% CI)		-1.11 (-1.50, -0.71)

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Footnotes defined on the last page of this output

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Table 14-2.1.6.581. Subgroup Analysis: Glucocorticoid Use for IgG4-RD Flare or Maintenance During Randomized-controlled Period (Full Analysis Set)

Subgroup	All Subjects		Treatment by Subgroup Interaction p-value ^b
	Placebo N = 67	Inebilizumab N = 68	
Region			0.5048
EU	Total GC use ^a (mg) per subject		
	n	26	20
	Mean	1271.58	162.50
	SD	1655.67	485.16
	Median	945.65	0.00
	Q1, Q3	0.00, 1575.00	0.00, 0.00
	Min, Max	0.0, 6215.0	0.0, 2030.0
	Mean difference		-1109.08
	Hedges'g (95% CI)		-0.86 (-1.47, -0.25)
	LSMEAN (SE)	1456.51 (256.08)	499.07 (315.07)
	LSMEAN difference (SE)		-957.43 (373.47)
	95% CI		-1710.62, -204.25
	p-value		0.0139
	LSM Hedges'g (95% CI)		-0.76 (-1.37, -0.16)
Non-EU	Total GC use ^a (mg) per subject		
	n	41	48
	Mean	1456.16	99.81
	SD	1781.30	422.32
	Median	1260.00	0.00
	Q1, Q3	0.00, 2305.00	0.00, 0.00
	Min, Max	0.0, 9125.0	0.0, 2490.0
	Mean difference		-1356.35
	Hedges'g (95% CI)		-1.09 (-1.53, -0.64)
	LSMEAN (SE)	1449.63 (196.39)	90.89 (182.26)
	LSMEAN difference (SE)		-1358.74 (266.56)
	95% CI		-1888.65, -828.83
	p-value		<.0001
	LSM Hedges'g (95% CI)		-1.08 (-1.53, -0.64)

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Program: /userdata/stat/amg335/igg4rd/20230068/analysis/germany_submission/tables/t-gc-use1-rcp-sub.sas
 Output: t14-02-001-006-581-gc-use1-rcp-sub.rtf (Date Generated: 09JAN26:00:19:52) Source: csradam.adsl, csradam.adeff

Table 14-2.1.6.581. Subgroup Analysis: Glucocorticoid Use for IgG4-RD Flare or Maintenance During Randomized-controlled Period (Full Analysis Set)

Subgroup	All Subjects		Treatment by Subgroup Interaction p-value ^b
	Placebo N = 67	Inebilizumab N = 68	
Region			0.5284
Asia	Total GC use ^a (mg) per subject		
	n	18	34
	Mean	1425.83	0.15
	SD	2256.95	0.86
	Median	666.25	0.00
	Q1, Q3	0.00, 2305.00	0.00, 0.00
	Min, Max	0.0, 9125.0	0.0, 5.0
	Mean difference		-1425.69
	Hedges'g (95% CI)		-1.08 (-1.69, -0.48)
	LSMEAN (SE)	1408.26 (344.51)	-10.71 (244.53)
	LSMEAN difference (SE)		-1418.97 (391.30)
	95% CI		-2205.31, -632.62
	p-value		0.0007
	LSM Hedges'g (95% CI)		-1.06 (-1.66, -0.45)
Non-Asia	Total GC use ^a (mg) per subject		
	n	49	34
	Mean	1369.36	236.35
	SD	1509.40	602.07
	Median	1240.00	0.00
	Q1, Q3	0.00, 1610.00	0.00, 0.00
	Min, Max	0.0, 6215.0	0.0, 2490.0
	Mean difference		-1133.00
	Hedges'g (95% CI)		-0.93 (-1.39, -0.47)
	LSMEAN (SE)	1492.50 (177.35)	445.14 (221.50)
	LSMEAN difference (SE)		-1047.36 (267.74)
	95% CI		-1580.18, -514.54
	p-value		0.0002
	LSM Hedges'g (95% CI)		-0.87 (-1.33, -0.42)

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Program: /userdata/stat/amg335/igg4rd/20230068/analysis/germany_submission/tables/t-gc-use1-rcp-sub.sas
Output: t14-02-001-006-581-gc-use1-rcp-sub.rtf (Date Generated: 09JAN26:00:19:52) Source: csradam.adsl, csradam.adeff

Table 14-2.1.6.581. Subgroup Analysis: Glucocorticoid Use for IgG4-RD Flare or Maintenance During Randomized-controlled Period (Full Analysis Set)

Subgroup	All Subjects		Treatment by Subgroup Interaction p-value ^b
	Placebo N = 67	Inebilizumab N = 68	
Region			0.7380
Japan	Total GC use ^a (mg) per subject		
	n	7	20
	Mean	1423.21	0.00
	SD	1546.22	0.00
	Median	1260.00	0.00
	Q1, Q3	0.00, 2437.50	0.00, 0.00
	Min, Max	0.0, 3960.0	0.0, 0.0
	Mean difference		-1423.21
	Hedges'g (95% CI)		-1.88 (-2.87, -0.88)
	LSMEAN (SE)	1501.84 (316.78)	55.04 (193.40)
	LSMEAN difference (SE)		-1446.80 (339.03)
	95% CI		-2146.53, -747.07
	p-value		0.0003
	LSM Hedges'g (95% CI)		-1.87 (-2.87, -0.88)
Non-Japan	Total GC use ^a (mg) per subject		
	n	60	48
	Mean	1380.02	167.52
	SD	1754.60	516.01
	Median	1027.50	0.00
	Q1, Q3	0.00, 1595.00	0.00, 0.00
	Min, Max	0.0, 9125.0	0.0, 2490.0
	Mean difference		-1212.50
	Hedges'g (95% CI)		-0.90 (-1.29, -0.50)
	LSMEAN (SE)	1420.77 (174.22)	249.03 (198.23)
	LSMEAN difference (SE)		-1171.74 (260.15)
	95% CI		-1687.56, -655.92
	p-value		<.0001
	LSM Hedges'g (95% CI)		-0.87 (-1.27, -0.48)

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Program: /userdata/stat/amg335/igg4rd/20230068/analysis/germany_submission/tables/t-gc-use1-rcp-sub.sas
Output: t14-02-001-006-581-gc-use1-rcp-sub.rtf (Date Generated: 09JAN26:00:19:52) Source: csradam.adsl, csradam.adeff

Table 14-2.1.6.581. Subgroup Analysis: Glucocorticoid Use for IgG4-RD Flare or Maintenance During Randomized-controlled Period (Full Analysis Set)

Subgroup	All Subjects		Treatment by Subgroup Interaction p-value ^b
	Placebo N = 67	Inebilizumab N = 68	
Serum IgG4 concentrations at baseline			0.0579
< Median	Total GC use ^a (mg) per subject		
	n	29	30
	Mean	1011.47	165.67
	SD	1400.17	520.07
	Median	459.40	0.00
	Q1, Q3	0.00, 1580.00	0.00, 0.00
	Min, Max	0.0, 4835.0	0.0, 2490.0
	Mean difference		-845.81
	Hedges'g (95% CI)		-0.81 (-1.34, -0.28)
	LSMEAN (SE)	1043.28 (200.78)	199.83 (198.36)
	LSMEAN difference (SE)		-843.45 (274.43)
	95% CI		-1393.20, -293.69
	p-value		0.0033
	LSM Hedges'g (95% CI)		-0.80 (-1.33, -0.27)
≥ Median	Total GC use ^a (mg) per subject		
	n	31	29
	Mean	1665.19	105.72
	SD	1454.10	417.05
	Median	1400.00	0.00
	Q1, Q3	980.00, 2437.50	0.00, 0.00
	Min, Max	0.0, 6215.0	0.0, 2030.0
	Mean difference		-1559.46
	Hedges'g (95% CI)		-1.44 (-2.00, -0.87)
	LSMEAN (SE)	1683.95 (193.84)	85.66 (200.44)
	LSMEAN difference (SE)		-1598.29 (279.54)
	95% CI		-2158.06, -1038.52
	p-value		<.0001
	LSM Hedges'g (95% CI)		-1.48 (-2.05, -0.91)

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Program: /userdata/stat/amg335/ig4rd/20230068/analysis/germany_submission/tables/t-gc-use1-rcp-sub.sas

Output: t14-02-001-006-581-gc-use1-rcp-sub.rtf (Date Generated: 09JAN26:00:19:52) Source: csradam.adsl, csradam.adeff

Table 14-2.1.6.581. Subgroup Analysis: Glucocorticoid Use for IgG4-RD Flare or Maintenance During Randomized-controlled Period (Full Analysis Set)

Subgroup	All Subjects		Treatment by Subgroup Interaction p-value ^b
	Placebo N = 67	Inebilizumab N = 68	
First or subsequent IgG4-RD manifestation			0.0283
Newly diagnosed	Total GC use ^a (mg) per subject		
	n	31	31
	Mean	1807.04	33.42
	SD	2175.24	186.07
	Median	1270.00	0.00
	Q1, Q3	0.00, 3197.50	0.00, 0.00
	Min, Max	0.0, 9125.0	0.0, 1036.0
	Mean difference		-1773.62
	Hedges'g (95% CI)		-1.15 (-1.69, -0.61)
	LSMEAN (SE)	1807.04 (277.26)	33.42 (277.26)
	LSMEAN difference (SE)		-1773.62 (392.11)
	95% CI		-2557.96, -989.28
	p-value		<.0001
	LSM Hedges'g (95% CI)		-1.15 (-1.69, -0.61)
Recurrent	Total GC use ^a (mg) per subject		
	n	36	37
	Mean	1020.70	189.32
	SD	1117.98	564.25
	Median	897.50	0.00
	Q1, Q3	0.00, 1470.00	0.00, 0.00
	Min, Max	0.0, 4835.0	0.0, 2490.0
	Mean difference		-831.38
	Hedges'g (95% CI)		-0.94 (-1.43, -0.46)
	LSMEAN (SE)	1020.70 (146.97)	189.32 (144.97)
	LSMEAN difference (SE)		-831.38 (206.43)
	95% CI		-1242.99, -419.76
	p-value		0.0001
	LSM Hedges'g (95% CI)		-0.94 (-1.43, -0.46)

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Program: /userdata/stat/amg335/ig4rd/20230068/analysis/germany_submission/tables/t-gc-use1-rcp-sub.sas

Output: t14-02-001-006-581-gc-use1-rcp-sub.rtf (Date Generated: 09JAN26:00:19:52) Source: csradam.adsl, csradam.adeff

Table 14-2.1.6.581. Subgroup Analysis: Glucocorticoid Use for IgG4-RD Flare or Maintenance During Randomized-controlled Period (Full Analysis Set)

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GC = Glucocorticoid

^a GC tapering per protocol excluded from the analysis. Unit is mg and dose is predisone or equivalent.^b Treatment by subgroup p-value for total GC use (mg) per subject.

Analysis based on ANOVA model including treatment, stratification factor (first or subsequent IgG4-RD manifestation).

Interaction p-value was obtained from ANOVA model including treatment, stratification factor (first or subsequent IgG4-RD manifestation), subgroup, and treatment-by-subgroup interaction. When the stratification factor was the subgroup, the corresponding stratification factor would not be included.

The pooled standard deviation for Hedges'g was calculated using the standard deviations of the two group means.

The pooled standard deviation for LSM Hedges'g was derived from the standard error of the difference between two least squares means (LSMs).

The 95% CI for Hedges'g and LSM Hedges'g were computed based on the normal distribution.

*Program: /userdata/stat/amg335/igg4rd/20230068/analysis/germany_submission/tables/t-gc-use1-rcp-sub.sas**Output: t14-02-001-006-581-gc-use1-rcp-sub.rtf (Date Generated: 09JAN26:00:19:52) Source: csradam.adsl, csradam.adeff*

5.2.2 Jegliche Behandlung mit Glukokortikoiden (Gesamtdosierung)

Table 14-2.1.6.582. Subgroup Analysis: Glucocorticoid Use During Randomized-controlled Period (Full Analysis Set)

Subgroup	All Subjects		Treatment by Subgroup Interaction p-value ^b
	Placebo N = 67	Inebilizumab N = 68	
Age			0.4176
< 65 years	Total GC use ^a (mg) per subject		
	n		
	Mean		
	SD		
	Median		
	Q1, Q3		
	Min, Max		
	Mean difference		
	Hedges'g (95% CI)		
	LSMEAN (SE)		
	LSMEAN difference (SE)		
	95% CI		
	p-value		
	LSM Hedges'g (95% CI)		
≥ 65 years	Total GC use ^a (mg) per subject		
	n		
	Mean		
	SD		
	Median		
	Q1, Q3		
	Min, Max		
	Mean difference		
	Hedges'g (95% CI)		
	LSMEAN (SE)		
	LSMEAN difference (SE)		
	95% CI		
	p-value		
	LSM Hedges'g (95% CI)		

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Program: /userdata/stat/amg335/igg4rd/20230068/analysis/germany_submission/tables/t-gc-use2-rcp-sub.sas
Output: t14-02-001-006-582-gc-use2-rcp-sub.rtf (Date Generated: 09JAN26:00:19:53) Source: csradam.adsl, adam.adeff1

Table 14-2.1.6.582. Subgroup Analysis: Glucocorticoid Use During Randomized-controlled Period (Full Analysis Set)

Subgroup	All Subjects		Treatment by Subgroup Interaction p-value ^b
	Placebo N = 67	Inebilizumab N = 68	
Sex			0.6665
Male	Total GC use ^a (mg) per subject		
	n	49	39
	Mean	2636.71	1527.86
	SD	1875.33	2152.39
	Median	2090.00	1075.00
	Q1, Q3	1075.00, 3512.50	1075.00, 1180.00
	Min, Max	980.0, 10065.0	845.0, 14475.0
	Mean difference		-1108.84
	Hedges'g (95% CI)		-0.55 (-0.98, -0.13)
	LSMEAN (SE)	2643.14 (284.11)	1535.95 (318.47)
	LSMEAN difference (SE)		-1107.19 (426.72)
	95% CI		-1955.63, -258.76
	p-value		0.0112
	LSM Hedges'g (95% CI)		-0.56 (-0.99, -0.13)
Female	Total GC use ^a (mg) per subject		
	n	18	29
	Mean	2054.44	1223.00
	SD	867.70	640.19
	Median	1997.50	1075.00
	Q1, Q3	1188.80, 2412.00	1065.00, 1075.00
	Min, Max	1075.0, 4095.0	420.0, 3605.0
	Mean difference		-831.44
	Hedges'g (95% CI)		-1.13 (-1.76, -0.50)
	LSMEAN (SE)	2045.28 (176.50)	1215.89 (139.01)
	LSMEAN difference (SE)		-829.39 (222.59)
	95% CI		-1277.99, -380.78
	p-value		0.0006
	LSM Hedges'g (95% CI)		-1.12 (-1.75, -0.49)

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Program: /userdata/stat/amg335/igg4rd/20230068/analysis/germany_submission/tables/t-gc-use2-rcp-sub.sas
Output: t14-02-001-006-582-gc-use2-rcp-sub.rtf (Date Generated: 09JAN26:00:19:53) Source: csradam.adsl, adam.adeff1

Table 14-2.1.6.582. Subgroup Analysis: Glucocorticoid Use During Randomized-controlled Period (Full Analysis Set)

Subgroup	All Subjects		Treatment by Subgroup Interaction p-value ^b
	Placebo N = 67	Inebilizumab N = 68	
Region			0.3937
US	Total GC use ^a (mg) per subject		
	n	14	7
	Mean	2108.45	1632.79
	SD	1090.82	772.37
	Median	1935.00	1075.00
	Q1, Q3	1080.00, 2545.00	1075.00, 2177.00
	Min, Max	1075.0, 4850.0	1055.0, 3015.0
	Mean difference		-475.66
	Hedges'g (95% CI)		-0.48 (-1.39, 0.44)
	LSMEAN (SE)	2156.75 (293.14)	1681.08 (400.82)
	LSMEAN difference (SE)		-475.66 (473.47)
	95% CI		-1470.38, 519.05
	p-value		0.3284
	LSM Hedges'g (95% CI)		-0.47 (-1.38, 0.45)
Non-US	Total GC use ^a (mg) per subject		
	n	53	61
	Mean	2578.49	1370.89
	SD	1798.27	1756.22
	Median	2240.00	1075.00
	Q1, Q3	1145.00, 3455.80	1070.00, 1096.50
	Min, Max	980.0, 10065.0	420.0, 14475.0
	Mean difference		-1207.61
	Hedges'g (95% CI)		-0.68 (-1.06, -0.30)
	LSMEAN (SE)	2574.43 (243.21)	1381.48 (226.83)
	LSMEAN difference (SE)		-1192.95 (332.65)
	95% CI		-1852.11, -533.78
	p-value		0.0005
	LSM Hedges'g (95% CI)		-0.67 (-1.05, -0.30)

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Program: /userdata/stat/amg335/igg4rd/20230068/analysis/germany_submission/tables/t-gc-use2-rcp-sub.sas
Output: t14-02-001-006-582-gc-use2-rcp-sub.rtf (Date Generated: 09JAN26:00:19:53) Source: csradam.adsl, adam.adeff1

Table 14-2.1.6.582. Subgroup Analysis: Glucocorticoid Use During Randomized-controlled Period (Full Analysis Set)

Subgroup	All Subjects		Treatment by Subgroup Interaction p-value ^b
	Placebo N = 67	Inebilizumab N = 68	
Region			0.9794
EU	Total GC use ^a (mg) per subject		
	n	26	20
	Mean	2390.28	1231.46
	SD	1584.20	636.03
	Median	1910.65	1072.50
	Q1, Q3	1183.80, 2525.00	983.15, 1194.40
	Min, Max	980.0, 7262.5	625.0, 3605.0
	Mean difference		-1158.82
	Hedges'g (95% CI)		-0.92 (-1.53, -0.30)
	LSMEAN (SE)	2543.05 (255.69)	1509.50 (314.59)
	LSMEAN difference (SE)		-1033.55 (372.90)
	95% CI		-1785.59, -281.52
	p-value		0.0082
	LSM Hedges'g (95% CI)		-0.82 (-1.43, -0.22)
Non-EU	Total GC use ^a (mg) per subject		
	n	41	48
	Mean	2537.34	1467.18
	SD	1753.46	1960.23
	Median	2240.00	1075.00
	Q1, Q3	1075.00, 3382.50	1075.00, 1097.50
	Min, Max	1075.0, 10065.0	420.0, 14475.0
	Mean difference		-1070.17
	Hedges'g (95% CI)		-0.57 (-1.00, -0.15)
	LSMEAN (SE)	2521.60 (293.75)	1445.66 (272.60)
	LSMEAN difference (SE)		-1075.94 (398.70)
	95% CI		-1868.52, -283.36
	p-value		0.0084
	LSM Hedges'g (95% CI)		-0.57 (-1.00, -0.15)

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Program: /userdata/stat/amg335/igg4rd/20230068/analysis/germany_submission/tables/t-gc-use2-rcp-sub.sas
Output: t14-02-001-006-582-gc-use2-rcp-sub.rtf (Date Generated: 09JAN26:00:19:53) Source: csradam.adsl, adam.adeff1

Table 14-2.1.6.582. Subgroup Analysis: Glucocorticoid Use During Randomized-controlled Period (Full Analysis Set)

Subgroup	All Subjects		Treatment by Subgroup Interaction p-value ^b
	Placebo N = 67	Inebilizumab N = 68	
Region			0.7861
Asia	Total GC use ^a (mg) per subject		
	n	18	34
	Mean	2471.39	1474.12
	SD	2224.66	2303.61
	Median	1678.75	1075.00
	Q1, Q3	1075.00, 3380.00	1075.00, 1075.00
	Min, Max	1075.0, 10065.0	420.0, 14475.0
	Mean difference		-997.27
	Hedges'g (95% CI)		-0.44 (-1.02, 0.14)
	LSMEAN (SE)	2343.40 (594.56)	1395.06 (422.02)
	LSMEAN difference (SE)		-948.33 (675.31)
	95% CI		-2305.43, 408.76
	p-value		0.1665
	LSM Hedges'g (95% CI)		-0.41 (-0.99, 0.17)
Non-Asia	Total GC use ^a (mg) per subject		
	n	49	34
	Mean	2483.54	1321.58
	SD	1457.27	640.88
	Median	2245.00	1077.50
	Q1, Q3	1183.80, 3130.00	1055.00, 1235.00
	Min, Max	980.0, 7262.5	625.0, 3605.0
	Mean difference		-1161.96
	Hedges'g (95% CI)		-0.97 (-1.43, -0.51)
	LSMEAN (SE)	2581.19 (175.16)	1487.14 (218.77)
	LSMEAN difference (SE)		-1094.05 (264.44)
	95% CI		-1620.29, -567.80
	p-value		<.0001
	LSM Hedges'g (95% CI)		-0.92 (-1.38, -0.46)

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Program: /userdata/stat/amg335/igg4rd/20230068/analysis/germany_submission/tables/t-gc-use2-rcp-sub.sas
Output: t14-02-001-006-582-gc-use2-rcp-sub.rtf (Date Generated: 09JAN26:00:19:53) Source: csradam.adsl, adam.adeff1

Table 14-2.1.6.582. Subgroup Analysis: Glucocorticoid Use During Randomized-controlled Period (Full Analysis Set)

Subgroup	All Subjects		Treatment by Subgroup Interaction p-value ^b
	Placebo N = 67	Inebilizumab N = 68	
Region			0.6020
Japan	Total GC use ^a (mg) per subject		
	n	7	20
	Mean	2480.36	1092.50
	SD	1512.40	223.77
	Median	2335.00	1075.00
	Q1, Q3	1075.00, 3512.50	1075.00, 1077.50
	Min, Max	1075.0, 4910.0	420.0, 1775.0
	Mean difference		-1387.86
	Hedges'g (95% CI)		-1.81 (-2.80, -0.82)
	LSMEAN (SE)	2621.41 (314.92)	1191.24 (192.26)
	LSMEAN difference (SE)		-1430.17 (337.05)
	95% CI		-2125.81, -734.54
	p-value		0.0003
	LSM Hedges'g (95% CI)		-1.86 (-2.86, -0.87)
Non-Japan	Total GC use ^a (mg) per subject		
	n	60	48
	Mean	2480.27	1525.08
	SD	1709.13	1986.52
	Median	2080.00	1075.00
	Q1, Q3	1156.90, 3047.50	1055.65, 1150.00
	Min, Max	980.0, 10065.0	625.0, 14475.0
	Mean difference		-955.19
	Hedges'g (95% CI)		-0.52 (-0.91, -0.13)
	LSMEAN (SE)	2541.14 (235.71)	1646.82 (268.20)
	LSMEAN difference (SE)		-894.32 (351.97)
	95% CI		-1592.21, -196.42
	p-value		0.0125
	LSM Hedges'g (95% CI)		-0.49 (-0.88, -0.11)

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Program: /userdata/stat/amg335/igg4rd/20230068/analysis/germany_submission/tables/t-gc-use2-rcp-sub.sas
Output: t14-02-001-006-582-gc-use2-rcp-sub.rtf (Date Generated: 09JAN26:00:19:53) Source: csradam.adsl, adam.adeff1

Table 14-2.1.6.582. Subgroup Analysis: Glucocorticoid Use During Randomized-controlled Period (Full Analysis Set)

Subgroup	All Subjects		Treatment by Subgroup Interaction p-value ^b
	Placebo N = 67	Inebilizumab N = 68	
Serum IgG4 concentrations at baseline			0.0856
< Median	Total GC use ^a (mg) per subject		
	n	29	30
	Mean	2123.89	1230.92
	SD	1332.48	470.86
	Median	1755.00	1077.50
	Q1, Q3	1145.00, 2345.00	1075.00, 1208.80
	Min, Max	980.0, 5785.0	625.0, 3015.0
	Mean difference		-892.97
	Hedges'g (95% CI)		-0.90 (-1.44, -0.36)
	LSMEAN (SE)	2146.27 (190.31)	1254.96 (188.02)
	LSMEAN difference (SE)		-891.31 (260.13)
	95% CI		-1412.41, -370.21
	p-value		0.0012
	LSM Hedges'g (95% CI)		-0.89 (-1.43, -0.36)
≥ Median	Total GC use ^a (mg) per subject		
	n	31	29
	Mean	2755.02	1213.31
	SD	1429.98	562.71
	Median	2475.00	1075.00
	Q1, Q3	1732.50, 3455.80	1070.00, 1075.00
	Min, Max	1075.0, 7262.5	420.0, 3605.0
	Mean difference		-1541.71
	Hedges'g (95% CI)		-1.40 (-1.97, -0.84)
	LSMEAN (SE)	2764.91 (198.94)	1202.74 (205.72)
	LSMEAN difference (SE)		-1562.17 (286.89)
	95% CI		-2136.66, -987.67
	p-value		<.0001
	LSM Hedges'g (95% CI)		-1.41 (-1.97, -0.84)

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Footnotes defined on the last page of this output

Program: /userdata/stat/amg335/igg4rd/20230068/analysis/germany_submission/tables/t-gc-use2-rcp-sub.sas

Output: t14-02-001-006-582-gc-use2-rcp-sub.rtf (Date Generated: 09JAN26:00:19:53) Source: csradam.adsl, adam.adeff1

Table 14-2.1.6.582. Subgroup Analysis: Glucocorticoid Use During Randomized-controlled Period (Full Analysis Set)

Subgroup	All Subjects		Treatment by Subgroup Interaction p-value ^b
	Placebo N = 67	Inebilizumab N = 68	
First or subsequent IgG4-RD manifestation			0.4660
Newly diagnosed	Total GC use ^a (mg) per subject		
n	31	31	
Mean	2820.34	1512.00	
SD	2144.24	2417.93	
Median	2240.00	1075.00	
Q1, Q3	1075.00, 4095.00	1075.00, 1080.00	
Min, Max	1075.0, 10065.0	420.0, 14475.0	
Mean difference		-1308.34	
Hedges'g (95% CI)		-0.57 (-1.08, -0.06)	
LSMEAN (SE)	2820.34 (410.43)	1512.00 (410.43)	
LSMEAN difference (SE)		-1308.34 (580.44)	
95% CI		-2469.39, -147.29	
p-value		0.0279	
LSM Hedges'g (95% CI)		-0.57 (-1.08, -0.06)	
Recurrent	Total GC use ^a (mg) per subject		
n	36	37	
Mean	2187.45	1302.21	
SD	1088.46	599.38	
Median	2001.25	1075.00	
Q1, Q3	1181.90, 2717.50	1070.00, 1235.00	
Min, Max	980.0, 5785.0	625.0, 3605.0	
Mean difference		-885.24	
Hedges'g (95% CI)		-1.01 (-1.50, -0.52)	
LSMEAN (SE)	2187.45 (145.89)	1302.21 (143.90)	
LSMEAN difference (SE)		-885.24 (204.92)	
95% CI		-1293.83, -476.65	
p-value		<.0001	
LSM Hedges'g (95% CI)		-1.01 (-1.50, -0.52)	

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Footnotes defined on the last page of this output

Program: /userdata/stat/amg335/ig4rd/20230068/analysis/germany_submission/tables/t-gc-use2-rcp-sub.sas

Output: t14-02-001-006-582-gc-use2-rcp-sub.rtf (Date Generated: 09JAN26:00:19:53) Source: csradam.adsl, adam.adeff1

Table 14-2.1.6.582. Subgroup Analysis: Glucocorticoid Use During Randomized-controlled Period (Full Analysis Set)

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GC = Glucocorticoid

^a Non-systemic glucocorticoid excluded from the analysis. Unit is mg and dose is prednisone or equivalent.^b Treatment by subgroup p-value for total GC use (mg) per subject.

Analysis based on ANOVA model including treatment, stratification factor (first or subsequent IgG4-RD manifestation).

Interaction p-value was obtained from ANOVA model including treatment, stratification factor (first or subsequent IgG4-RD manifestation), subgroup, and treatment-by-subgroup interaction. When the stratification factor was the subgroup, the corresponding stratification factor would not be included.

The pooled standard deviation for Hedges'g was calculated using the standard deviations of the two group means.

The pooled standard deviation for LSM Hedges'g was derived from the standard error of the difference between two least squares means (LSMs).

The 95% CI for Hedges'g and LSM Hedges'g were computed based on the normal distribution.

*Program: /userdata/stat/amg335/igg4rd/20230068/analysis/germany_submission/tables/t-gc-use2-rcp-sub.sas**Output: t14-02-001-006-582-gc-use2-rcp-sub.rtf (Date Generated: 09JAN26:00:19:53) Source: csradam.adsl, adam.adeff1*

5.3 Hospitalisierung

5.3.1 Jährliche Hospitalisierungsrate

Table 14-2.2.582. Subgroup Analysis: Annualized Hospitalization Rate of Healthcare Resource Utilization During Randomized-controlled Period (Full Analysis Set)

Subgroup		Placebo N = 67	Inebilizumab N = 68
Age - < 65 years	Annualized hospitalization rate ^a	0.10	0.02
	95% CI of annualized hospitalization rate ^a	(0.04, 0.25)	(0.00, 0.15)
	Rate ratio ^a		NA
	95% CI of rate ratio ^a		NA
	P-value ^a		NA
Age - ≥ 65 years	Annualized hospitalization rate ^a	0.17	0.31
	95% CI of annualized hospitalization rate ^a	(0.04, 0.69)	(0.09, 1.05)
	Rate ratio ^a		1.77
	95% CI of rate ratio ^a		(0.28, 11.35)
	P-value ^a		0.5454
Age interaction with treatment	P-value		0.1335
Sex - Male	Annualized hospitalization rate ^a	0.13	0.06
	95% CI of annualized hospitalization rate ^a	(0.05, 0.38)	(0.01, 0.27)
	Rate ratio ^a		0.47
	95% CI of rate ratio ^a		(0.08, 2.83)
	P-value ^a		0.4115
Sex - Female	Annualized hospitalization rate ^a	0.09	0.10
	95% CI of annualized hospitalization rate ^a	(0.02, 0.49)	(0.03, 0.39)
	Rate ratio ^a		1.09
	95% CI of rate ratio ^a		(0.16, 7.39)
	P-value ^a		0.9332
Sex interaction with treatment	P-value		0.5520

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Footnotes defined on the last page of this output

Program: /userdata/stat/amg335/igg4rd/20230068/analysis/germany_submission/tables/t-hru-rfp-sub.sas
Output: t14-02-002-582-hru-rfp-sub.rtf (Date Generated: 08JAN26:18:05:52) Source: csradam.adsl,
csradam.adho

Table 14-2.2.2.582. Subgroup Analysis: Annualized Hospitalization Rate of Healthcare Resource Utilization During Randomized-controlled Period (Full Analysis Set)

Subgroup		Placebo N = 67	Inebilizumab N = 68
Region - US	Annualized hospitalization rate ^a	0.00	0.00
	95% CI of annualized hospitalization rate ^a	(0.00, NA)	(0.00, NA)
	Rate ratio ^a		NA
	95% CI of rate ratio ^a		NA
	P-value ^a		NA
Region - Non-US	Annualized hospitalization rate ^a	0.17	0.11
	95% CI of annualized hospitalization rate ^a	(0.07, 0.40)	(0.05, 0.28)
	Rate ratio ^a		0.68
	95% CI of rate ratio ^a		(0.20, 2.32)
	P-value ^a		0.5333
Region (US vs. Non-US) interaction with treatment	P-value		NA
Region - EU	Annualized hospitalization rate ^a	0.15	0.14
	95% CI of annualized hospitalization rate ^a	(0.04, 0.53)	(0.03, 0.64)
	Rate ratio ^a		0.90
	95% CI of rate ratio ^a		(0.19, 4.30)
	P-value ^a		0.8994
Region - Non-EU	Annualized hospitalization rate ^a	0.00	0.00
	95% CI of annualized hospitalization rate ^a	(0.00, 45358.47)	(0.00, 29053.39)
	Rate ratio ^a		NA
	95% CI of rate ratio ^a		NA
	P-value ^a		NA
Region (EU vs. Non-EU) interaction with treatment	P-value		0.6311

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Footnotes defined on the last page of this output

Program: /userdata/stat/amg335/igg4rd/20230068/analysis/germany_submission/tables/t-hru-rcp-sub.sas
Output: t14-02-002-582-hru-rcp-sub.rtf (Date Generated: 08JAN26:18:05:52) Source: csradam.adsl, csradam.adho

Table 14-2.2.2.582. Subgroup Analysis: Annualized Hospitalization Rate of Healthcare Resource Utilization During Randomized-controlled Period (Full Analysis Set)

Subgroup		Placebo N = 67	Inebilizumab N = 68
Region - Asia	Annualized hospitalization rate ^a	0.00	0.00
	95% CI of annualized hospitalization rate ^a	(0.00, 0.00)	(0.00, 0.00)
	Rate ratio ^a		0.50
	95% CI of rate ratio ^a		(0.07, 3.46)
	P-value ^a		0.4860
Region - Non-Asia	Annualized hospitalization rate ^a	0.08	0.07
	95% CI of annualized hospitalization rate ^a	(0.02, 0.28)	(0.02, 0.35)
	Rate ratio ^a		0.98
	95% CI of rate ratio ^a		(0.19, 4.95)
	P-value ^a		0.9766
Region (Asia vs. Non-Asia) interaction with treatment	P-value		0.4286
Region - Japan	Annualized hospitalization rate ^a	0.00	0.00
	95% CI of annualized hospitalization rate ^a	(0.00, 0.00)	(0.00, 0.00)
	Rate ratio ^a		0.64
	95% CI of rate ratio ^a		(0.04, 10.36)
	P-value ^a		0.7530
Region - Non-Japan	Annualized hospitalization rate ^a	0.11	0.07
	95% CI of annualized hospitalization rate ^a	(0.04, 0.27)	(0.02, 0.23)
	Rate ratio ^a		0.63
	95% CI of rate ratio ^a		(0.15, 2.69)
	P-value ^a		0.5369
Region (Japan vs. Non-Japan) interaction with treatment	P-value		0.8835

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Footnotes defined on the last page of this output

Program: /userdata/stat/amg335/igg4rd/20230068/analysis/germany_submission/tables/t-hru-rcp-sub.sas
Output: t14-02-002-582-hru-rcp-sub.rtf (Date Generated: 08JAN26:18:05:52) Source: csradam.adsl, csradam.adho

Table 14-2.2.2.582. Subgroup Analysis: Annualized Hospitalization Rate of Healthcare Resource Utilization During Randomized-controlled Period (Full Analysis Set)

Subgroup		Placebo N = 67	Inebilizumab N = 68
Serum IgG4 concentrations at baseline - < Median	Annualized hospitalization rate ^a	0.19	0.21
	95% CI of annualized hospitalization rate ^a	(0.05, 0.65)	(0.07, 0.68)
	Rate ratio ^a		1.13
	95% CI of rate ratio ^a		(0.21, 6.18)
	P-value ^a		0.8880
Serum IgG4 concentrations at baseline - ≥ Median	Annualized hospitalization rate ^a	0.10	0.03
	95% CI of annualized hospitalization rate ^a	(0.03, 0.30)	(0.00, 0.24)
	Rate ratio ^a		0.35
	95% CI of rate ratio ^a		(0.04, 3.37)
	P-value ^a		0.3625
Serum IgG4 concentrations at baseline interaction with treatment	P-value		0.4289
First or subsequent IgG4-RD manifestation - Newly diagnosed	Annualized hospitalization rate ^a	0.15	0.10
	95% CI of annualized hospitalization rate ^a	(0.05, 0.48)	(0.03, 0.38)
	Rate ratio ^a		0.64
	95% CI of rate ratio ^a		(0.11, 3.79)
	P-value ^a		0.6244
First or subsequent IgG4-RD manifestation - Recurrent	Annualized hospitalization rate ^a	0.12	0.11
	95% CI of annualized hospitalization rate ^a	(0.03, 0.41)	(0.03, 0.37)
	Rate ratio ^a		0.91
	95% CI of rate ratio ^a		(0.16, 5.29)
	P-value ^a		0.9151
First or subsequent IgG4-RD manifestation interaction with treatment	P-value		0.7839

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Program: /userdata/stat/amg335/igg4rd/20230068/analysis/germany_submission/tables/t-hru-rcp-sub.sas
 Output: t14-02-002-002-582-hru-rcp-sub.rtf (Date Generated: 08JAN26:18:05:52) Source: csradam.adsl, csradam.adho

Table 14-2.2.2.582. Subgroup Analysis: Annualized Hospitalization Rate of Healthcare Resource Utilization During Randomized-controlled Period (Full Analysis Set)

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^a Estimated from negative binomial regression including treatment, stratification factor (first or subsequent IgG4-RD manifestation), and offset variable (the logarithm of the subject's corresponding follow-up time in years during randomized-controlled period).

Interaction p-value was obtained from negative binomial regression model including treatment, stratification factor (first or subsequent IgG4-RD manifestation), subgroup, treatment-by-subgroup interaction, and offset variable (the logarithm of the subject's corresponding follow-up time in years during randomized-controlled period). When the stratification factor was the subgroup, the corresponding stratification factor would not be included.

Program: /userdata/stat/amg335/igg4rd/20230068/analysis/germany_submission/tables/t-hru-rcp-sub.sas
Output: t14-02-002-002-582-hru-rcp-sub.rtf (Date Generated: 08JAN26:18:05:52) Source: csradam.adsl, csradam.adho

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

5.4 IgG4-RD-Krankheitsaktivität

5.4.1 PhGA VAS (Responderanalysen von 15 % der Skalenbreite)

Amgen: Final
 Inebilizumab, Protocol: VIB0551.P3.S2
 Study population
 Datacut: 09APR2024
 Improvement in Physician Global Assessment of Disease Activity (VAS) by >= 15 points (=decrease by >= 15 points) - Subgroup analysis
 Full Analysis Set
 Week 52

Subgroup Level	Inebilizumab (N=68)				Placebo (N=67)				Adjusted analysis Inebilizumab vs. Placebo [1]		Adjusted Interaction p-Value [3]
	n/	N	(%)	NRI	n/	N	(%)	NRI	Relative Risk (95% CI) [2]	p-Value [2]	
Age											
< 65	19/	47	(40.4)	1	20/	46	(43.5)	5	0.90	(0.57, 1.43)	0.6641
>= 65	11/	21	(52.4)	3	9/	21	(42.9)	3	1.25	(0.66, 2.39)	0.4945
Sex											
Female	11/	29	(37.9)	2	6/	18	(33.3)	4	1.17	(0.53, 2.58)	0.6909
Male	19/	39	(48.7)	2	23/	49	(46.9)	4	1.03	(0.67, 1.58)	0.9027
Baseline serum IgG4 concentrations											
< Median	14/	30	(46.7)	3	16/	29	(55.2)	5	0.85	(0.51, 1.40)	0.5182
>= Median	12/	29	(41.4)	1	11/	31	(35.5)	3	1.22	(0.66, 2.25)	0.5294
First or subsequent IgG4-RD manifestation											
First Manifestation of IgG4-RD	11/	31	(35.5)	2	11/	31	(35.5)	3	1.00	(0.51, 1.96)	1.0000
Subsequent Manifestation of IgG4-RD	19/	37	(51.4)	2	18/	36	(50.0)	5	1.03	(0.65, 1.62)	0.9081
Region 1											
US	2/	7	(28.6)	0	6/	14	(42.9)	0	0.70	(0.20, 2.50)	0.5841
Non-US	28/	61	(45.9)	4	23/	53	(43.4)	8	1.05	(0.70, 1.57)	0.8173
Region 2											
EU	12/	20	(60.0)	3	14/	26	(53.8)	6	1.14	(0.69, 1.89)	0.6048
Non-EU	18/	48	(37.5)	1	15/	41	(36.6)	2	1.01	(0.60, 1.72)	0.9606
Region 3											
Asia	11/	34	(32.4)	1	4/	18	(22.2)	2	1.38	(0.51, 3.75)	0.5292
Non-Asia	19/	34	(55.9)	3	25/	49	(51.0)	6	1.09	(0.73, 1.65)	0.6669
Region 4											
Japan	5/	20	(25.0)	1	1/	7	(14.3)	0	1.00	(0.11, 9.23)	1.0000
Non-Japan	25/	48	(52.1)	3	28/	60	(46.7)	8	1.11	(0.75, 1.63)	0.6013

NRI: Non-responder imputation; NA: not applicable

[1] Based on a generalized model with treatment and stratification factor 'First or subsequent IgG4-RD manifestation' as covariates.

[2] Link function: log

[3] Based on a generalized model with treatment, subgroup, treatment by subgroup interaction and stratification factor 'First or subsequent IgG4-RD manifestation' as covariates.

[4] The convergence is questionable so no estimates are given.

Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.

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Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

5.4.2 PGA VAS (Responderanalysen von 15 % der Skalenbreite)

Amgen: Final
 Inebilizumab, Protocol: VIB0551.P3.S2
 Study population
 Datacut: 09APR2024
 Improvement in Patient Global Assessment Of Disease Activity (VAS) by >= 15 points (=decrease by >= 15 points) - Subgroup analysis
 Full Analysis Set
 Week 52

Subgroup Level	Inebilizumab (N=68)				Placebo (N=67)				Adjusted analysis Inebilizumab vs. Placebo [1]		Adjusted Interaction p-Value [3]
	n/ N	(%)	NRI		n/ N	(%)	NRI	Relative Risk (95% CI) [2]	p-Value [2]		
Age											
< 65	8/ 47	(17.0)	2		8/ 46	(17.4)	4	0.96 (0.39, 2.34)	0.9279		0.7315
>= 65	5/ 21	(23.8)	3		4/ 21	(19.0)	2	1.22 (0.38, 3.91)	0.7436		
Sex											
Female	4/ 29	(13.8)	3		3/ 18	(16.7)	4	0.85 (0.21, 3.33)	0.8098		0.6189
Male	9/ 39	(23.1)	2		9/ 49	(18.4)	2	1.26 (0.55, 2.87)	0.5839		
Baseline serum IgG4 concentrations											
< Median	7/ 30	(23.3)	4		3/ 29	(10.3)	4	2.23 (0.64, 7.81)	0.2097		0.1775
>= Median	6/ 29	(20.7)	1		8/ 31	(25.8)	2	0.80 (0.32, 2.03)	0.6426		
First or subsequent IgG4-RD manifestation											
First Manifestation of IgG4-RD	6/ 31	(19.4)	2		5/ 31	(16.1)	1	1.20 (0.41, 3.52)	0.7401		0.7737
Subsequent Manifestation of IgG4-RD	7/ 37	(18.9)	3		7/ 36	(19.4)	5	0.97 (0.38, 2.50)	0.9545		
Region 1											
US	0/ 7	(0.0)	0		5/ 14	(35.7)	0	NA			NA
Non-US	13/ 61	(21.3)	5		7/ 53	(13.2)	6	1.60 (0.69, 3.72)	0.2724		
Region 2											
EU	3/ 20	(15.0)	3		3/ 26	(11.5)	4	1.47 (0.32, 6.81)	0.6209		0.7544
Non-EU	10/ 48	(20.8)	2		9/ 41	(22.0)	2	0.95 (0.43, 2.11)	0.9078		
Region 3											
Asia	8/ 34	(23.5)	2		3/ 18	(16.7)	2	1.29 (0.39, 4.34)	0.6764		0.4743
Non-Asia	5/ 34	(14.7)	3		9/ 49	(18.4)	4	0.80 (0.29, 2.20)	0.6681		
Region 4											
Japan	8/ 20	(40.0)	1		2/ 7	(28.6)	0	1.00 (0.24, 4.20)	1.0000		0.4031
Non-Japan	5/ 48	(10.4)	4		10/ 60	(16.7)	6	0.62 (0.23, 1.68)	0.3442		

NRI: Non-responder imputation; NA: not applicable
 [1] Based on a generalized model with treatment and stratification factor 'First or subsequent IgG4-RD manifestation' as covariates.
 [2] Link function: log
 [3] Based on a generalized model with treatment, subgroup, treatment by subgroup interaction and stratification factor 'First or subsequent IgG4-RD manifestation' as covariates.
 [4] The convergence is questionable so no estimates are given.
 Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

5.5 Fatigue

5.5.1 FACIT-Fatigue (Responderanalysen von 15 % der Skalenbreite)

Amgen: Final
 Inebilizumab, Protocol: VIB0551.P3.S2
 Study population
 Datacut: 09APR2024
 Improvement in Total FACIT-Fatigue Score by >= 7.8 points (=increase by >= 7.8 points) - Subgroup analysis
 Full Analysis Set
 Week 52

Subgroup Level	Inebilizumab (N=68)				Placebo (N=67)				Adjusted analysis Inebilizumab vs. Placebo [1]		Adjusted Interaction p-Value [3]
	n/ N	(%)	NRI	n/ N	(%)	NRI	Relative Risk (95% CI) [2]	p-Value [2]			
Age											
< 65	4/ 47	(8.5)	2	5/ 46	(10.9)	7					
>= 65	3/ 21	(14.3)	3	1/ 21	(4.8)	4					
Sex											0.9991
Female	2/ 29	(6.9)	2	1/ 18	(5.6)	5	1.24 (0.12, 12.68)	0.8565			
Male	5/ 39	(12.8)	3	5/ 49	(10.2)	6	1.23 (0.39, 3.90)	0.7217			
Baseline serum IgG4 concentrations											
< Median	4/ 30	(13.3)	4	1/ 29	(3.4)	7					
>= Median	3/ 29	(10.3)	1	4/ 31	(12.9)	4					
First or subsequent IgG4-RD manifestation											
First Manifestation of IgG4-RD	4/ 31	(12.9)	2	4/ 31	(12.9)	2					
Subsequent Manifestation of IgG4-RD	3/ 37	(8.1)	3	2/ 36	(5.6)	9					
Region 1											NA
US	0/ 7	(0.0)	0	3/ 14	(21.4)	1	NA				
Non-US	7/ 61	(11.5)	5	3/ 53	(5.7)	10	2.05 (0.56, 7.53)	0.2773			
Region 2											
EU	2/ 20	(10.0)	3	2/ 26	(7.7)	8					
Non-EU	5/ 48	(10.4)	2	4/ 41	(9.8)	3					
Region 3											0.7920
Asia	2/ 34	(5.9)	1	1/ 18	(5.6)	2	1.25 (0.12, 12.62)	0.8500			
Non-Asia	5/ 34	(14.7)	4	5/ 49	(10.2)	9	1.66 (0.53, 5.17)	0.3853			
Region 4											NA
Japan	2/ 20	(10.0)	1	0/ 7	(0.0)	0	NA [4]				
Non-Japan	5/ 48	(10.4)	4	6/ 60	(10.0)	11	1.09 (0.36, 3.33)	0.8808			

NRI: Non-responder imputation; NA: not applicable

[1] Based on a generalized model with treatment and stratification factor 'First or subsequent IgG4-RD manifestation' as covariates.

[2] Link function: log

[3] Based on a generalized model with treatment, subgroup, treatment by subgroup interaction and stratification factor 'First or subsequent IgG4-RD manifestation' as covariates.

[4] The convergence is questionable so no estimates are given.

Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.

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Date of Table Generation: 07JAN2026

5.6 Gesundheitsbezogene Lebensqualität: SF-36

5.6.1 PCS (Responderanalysen von 15 % der Skalenbreite)

Amgen: Final
 Inebilizumab, Protocol: VIB0551.P3.S2
 Study population
 Datacut: 09APR2024
 Improvement in Physical Component Score by >= 9.7 points (=increase by >= 9.7 points) - Subgroup analysis
 Full Analysis Set
 Week 52

Subgroup Level	Inebilizumab (N=68)				Placebo (N=67)				Adjusted analysis Inebilizumab vs. Placebo [1]		Adjusted Interaction p-Value [3]
	n/	N	(%)	NRI	n/	N	(%)	NRI	Relative Risk (95% CI) [2]	p-Value [2]	
Age											
< 65	7/	47	(14.9)	2	1/	46	(2.2)	7			
>= 65	0/	21	(0.0)	3	0/	21	(0.0)	2			
Sex											
Female	5/	29	(17.2)	2	0/	18	(0.0)	4			
Male	2/	39	(5.1)	3	1/	49	(2.0)	5			
Baseline serum IgG4 concentrations											
< Median	4/	30	(13.3)	4	0/	29	(0.0)	5			
>= Median	3/	29	(10.3)	1	1/	31	(3.2)	4			
First or subsequent IgG4-RD manifestation											
First Manifestation of IgG4-RD	0/	31	(0.0)	2	0/	31	(0.0)	1			
Subsequent Manifestation of IgG4-RD	7/	37	(18.9)	3	1/	36	(2.8)	8			
Region 1											
US	1/	7	(14.3)	0	1/	14	(7.1)	1			
Non-US	6/	61	(9.8)	5	0/	53	(0.0)	8			
Region 2											
EU	4/	20	(20.0)	3	0/	26	(0.0)	7			
Non-EU	3/	48	(6.3)	2	1/	41	(2.4)	2			
Region 3											
Asia	1/	34	(2.9)	1	0/	18	(0.0)	1			
Non-Asia	6/	34	(17.6)	4	1/	49	(2.0)	8			
Region 4											
Japan	1/	20	(5.0)	1	0/	7	(0.0)	0			
Non-Japan	6/	48	(12.5)	4	1/	60	(1.7)	9			

NRI: Non-responder imputation; NA: not applicable

[1] Based on a generalized model with treatment and stratification factor 'First or subsequent IgG4-RD manifestation' as covariates.

[2] Link function: log

[3] Based on a generalized model with treatment, subgroup, treatment by subgroup interaction and stratification factor 'First or subsequent IgG4-RD manifestation' as covariates.

[4] The convergence is questionable so no estimates are given.

Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.

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Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

5.6.2 MCS (Responderanalysen von 15 % der Skalenbreite)

Amgen: Final
 Inebilizumab, Protocol: VIB0551.P3.S2
 Study population
 Datacut: 09APR2024
 Improvement in Mental Component Score by >= 9.6 points (=increase by >= 9.6 points) - Subgroup analysis
 Full Analysis Set
 Week 52

Subgroup Level	Inebilizumab (N=68)				Placebo (N=67)				Adjusted analysis Inebilizumab vs. Placebo [1]		Adjusted Interaction p-Value [3]
	n/ N	(%)	NRI		n/ N	(%)	NRI	Relative Risk (95% CI) [2]	p-Value [2]		
Age											
< 65	6/ 47	(12.8)	2		4/ 46	(8.7)	7	1.40 (0.43, 4.56)	0.5766		0.8071
>= 65	3/ 21	(14.3)	3		2/ 21	(9.5)	2	1.82 (0.35, 9.47)	0.4783		
Sex											
Female	5/ 29	(17.2)	2		2/ 18	(11.1)	4				
Male	4/ 39	(10.3)	3		4/ 49	(8.2)	5				
Baseline serum IgG4 concentrations											
< Median	4/ 30	(13.3)	4		2/ 29	(6.9)	5				
>= Median	3/ 29	(10.3)	1		3/ 31	(9.7)	4				
First or subsequent IgG4-RD manifestation											
First Manifestation of IgG4-RD	1/ 31	(3.2)	2		2/ 31	(6.5)	1	0.50 (0.05, 5.23)	0.5629		0.2877
Subsequent Manifestation of IgG4-RD	8/ 37	(21.6)	3		4/ 36	(11.1)	8	1.95 (0.64, 5.90)	0.2394		
Region 1											
US	2/ 7	(28.6)	0		1/ 14	(7.1)	1	NA [4]			0.2736
Non-US	7/ 61	(11.5)	5		5/ 53	(9.4)	8	1.17 (0.41, 3.37)	0.7712		
Region 2											
EU	4/ 20	(20.0)	3		2/ 26	(7.7)	7				
Non-EU	5/ 48	(10.4)	2		4/ 41	(9.8)	2				
Region 3											
Asia	3/ 34	(8.8)	1		1/ 18	(5.6)	1	1.41 (0.16, 12.44)	0.7596		0.9115
Non-Asia	6/ 34	(17.6)	4		5/ 49	(10.2)	8	1.58 (0.53, 4.72)	0.4106		
Region 4											
Japan	1/ 20	(5.0)	1		0/ 7	(0.0)	0	NA [4]			NA
Non-Japan	8/ 48	(16.7)	4		6/ 60	(10.0)	9	1.60 (0.60, 4.26)	0.3494		

NRI: Non-responder imputation; NA: not applicable
 [1] Based on a generalized model with treatment and stratification factor 'First or subsequent IgG4-RD manifestation' as covariates.
 [2] Link function: log
 [3] Based on a generalized model with treatment, subgroup, treatment by subgroup interaction and stratification factor 'First or subsequent IgG4-RD manifestation' as covariates.
 [4] The convergence is questionable so no estimates are given.
 Effect measures are calculated if each subgroup level comprises at least 10 patients and at least 10 events occurred in one of the subgroup levels.

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

5.7 Sicherheitsrelevante Endpunkte

5.7.1 Gesamtraten: UE

Table 14-3.1.2.1.581. Subgroup Analysis: Summary of Treatment-emergent Adverse Events During Randomized-controlled Period (Safety Analysis Set)

Subgroup			Inebilizumab vs. Placebo						p-value
	Placebo	Inebilizumab	Odds Ratio		Risk Ratio		Risk Difference (%)		
	N = 67 n / N1 (%)	N = 68 n / N1 (%)	Pt Est	(95% CI)	Pt Est	(95% CI)	Pt Est	(95% CI)	
Treatment-emergent adverse events									0.5884
Age									
< 65 years	45 / 46 (97.8)	46 / 47 (97.9)	1.02	(0.10, 10.08)	1.00	(0.91, 1.11)	0.05	(-9.18, 9.44)	1.0000
≥ 65 years	21 / 21 (100.0)	20 / 21 (95.2)	0.32	(0.03, 4.18)	0.95	(0.77, 1.15)	-4.55	(-22.99, 12.55)	1.0000
Sex									0.8429
Male	48 / 49 (98.0)	38 / 39 (97.4)	0.79	(0.08, 7.83)	0.99	(0.88, 1.09)	-0.52	(-11.35, 8.45)	1.0000
Female	18 / 18 (100.0)	28 / 29 (96.6)	0.51	(0.04, 6.73)	0.98	(0.83, 1.21)	-2.37	(-16.90, 16.46)	1.0000
Region									0.9271
US	13 / 14 (92.9)	6 / 7 (85.7)	0.46	(0.04, 5.18)	0.92	(0.52, 1.30)	-7.14	(-45.66, 20.92)	1.0000
Non-US	53 / 53 (100.0)	60 / 61 (98.4)	0.38	(0.03, 4.72)	0.98	(0.91, 1.07)	-1.49	(-9.02, 6.04)	1.0000

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IP = Investigational Product

N = Number of subjects in the analysis set; n = Number of subjects with observed data; N1 = Number of subjects in each subgroup level

^a Grade 1: Mild; Grade 2: Moderate; Grade 3: Severe; Grade 4: Life-threatening; Grade 5: Fatal^b Serious adverse event criteria: death, life-threatening, required inpatient hospitalization, prolongation of existing hospitalization, persistent or significant disability/incapacity, important medical event, congenital anomaly/birth defect (in the offspring of the subject).

95% CI for risk difference, risk ratio, and odds ratio was based on Miettinen-Nurminen (score) confidence limits without default bias correction factor; p-value was based on Fisher's exact test for association; interaction p-value was based on Zelen's exact test for equal odds ratios.

If Zero cell correction applied, 95% CI for risk difference, risk ratio, and odds ratio was based on the same confidence limits above after Zero cell correction; p-value was based on Fisher's exact test for association before Zero cell correction; interaction p-value was based on Breslow-Day test for homogeneity of odds ratios after Zero cell correction.

Program: /userdata/stat/amg335/ig4rd/20230068/analysis/germany_submission/tables/t-teaesum-rcp-sub.sas

Output: t14-03-001-002-001-581-teaesum-rcp-sub.rtf (Date Generated: 08JAN26:23:03:14) Source: csradam.adsl, csradam.adae

Table 14-3.1.2.1.581. Subgroup Analysis: Summary of Treatment-emergent Adverse Events During Randomized-controlled Period (Safety Analysis Set)

Subgroup			Inebilizumab vs. Placebo						p-value
	Placebo	Inebilizumab	Odds Ratio		Risk Ratio		Risk Difference (%)		
	N = 67 n / N1 (%)	N = 68 n / N1 (%)	Pt Est	(95% CI)	Pt Est	(95% CI)	Pt Est	(95% CI)	
Region									0.9004
EU	26 / 26 (100.0)	20 / 20 (100.0)	0.77	(0.04, 13.86)	0.99	(0.82, 1.16)	-0.53	(-17.60, 13.43)	NA
Non-EU	40 / 41 (97.6)	46 / 48 (95.8)	0.58	(0.07, 4.60)	0.98	(0.88, 1.10)	-1.73	(-11.89, 8.88)	1.0000
Region									0.9526
Asia	18 / 18 (100.0)	33 / 34 (97.1)	0.60	(0.05, 7.87)	0.98	(0.85, 1.21)	-1.65	(-14.47, 17.05)	1.0000
Non-Asia	48 / 49 (98.0)	33 / 34 (97.1)	0.69	(0.07, 6.81)	0.99	(0.87, 1.09)	-0.90	(-13.08, 8.15)	1.0000
Region									0.9696
Japan	7 / 7 (100.0)	19 / 20 (95.0)	0.87	(0.07, 12.32)	0.99	(0.78, 1.57)	-0.89	(-21.24, 34.09)	1.0000
Non-Japan	59 / 60 (98.3)	47 / 48 (97.9)	0.80	(0.08, 7.83)	1.00	(0.90, 1.08)	-0.42	(-9.39, 7.02)	1.0000

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95% CI for risk difference, risk ratio, and odds ratio was based on Miettinen-Nurminen (score) confidence limits without default bias correction factor; p-value was based on Fisher's exact test for association; interaction p-value was based on Zelen's exact test for equal odds ratios.

If Zero cell correction applied, 95% CI for risk difference, risk ratio, and odds ratio was based on the same confidence limits above after Zero cell correction; p-value was based on Fisher's exact test for association before Zero cell correction; interaction p-value was based on Breslow-Day test for homogeneity of odds ratios after Zero cell correction.

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Table 14-3.1.2.1.581. Subgroup Analysis: Summary of Treatment-emergent Adverse Events During Randomized-controlled Period (Safety Analysis Set)

Subgroup			Inebilizumab vs. Placebo						p-value
	Placebo	Inebilizumab	Odds Ratio		Risk Ratio		Risk Difference (%)		
	N = 67 n / N1 (%)	N = 68 n / N1 (%)	Pt Est	(95% CI)	Pt Est	(95% CI)	Pt Est	(95% CI)	
Serum IgG4 concentrations at baseline									0.5669
< Median	28 / 29 (96.6)	29 / 30 (96.7)	1.04	(0.10, 10.40)	1.00	(0.86, 1.17)	0.11	(-13.69, 14.28)	1.0000
≥ Median	31 / 31 (100.0)	28 / 29 (96.6)	0.30	(0.02, 3.88)	0.97	(0.82, 1.10)	-3.44	(-17.71, 8.89)	0.4833
First or subsequent IgG4-RD manifestation									0.5906
Newly diagnosed	31 / 31 (100.0)	30 / 31 (96.8)	0.32	(0.03, 4.14)	0.97	(0.83, 1.11)	-3.13	(-16.66, 9.15)	1.0000
Recurrent	35 / 36 (97.2)	36 / 37 (97.3)	1.03	(0.10, 10.23)	1.00	(0.88, 1.14)	0.08	(-11.39, 11.79)	1.0000

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95% CI for risk difference, risk ratio, and odds ratio was based on Miettinen-Nurminen (score) confidence limits without default bias correction factor; p-value was based on Fisher's exact test for association; interaction p-value was based on Zelen's exact test for equal odds ratios.

If Zero cell correction applied, 95% CI for risk difference, risk ratio, and odds ratio was based on the same confidence limits above after Zero cell correction; p-value was based on Fisher's exact test for association before Zero cell correction; interaction p-value was based on Breslow-Day test for homogeneity of odds ratios after Zero cell correction.

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5.7.2 Gesamtraten: Schwere UE (CTCAE Grad ≥ 3)

Table 14-3.1.2.1.581. Subgroup Analysis: Summary of Treatment-emergent Adverse Events During Randomized-controlled Period (Safety Analysis Set)

Subgroup	Placebo N = 67 n / N1 (%)	Inebilizumab N = 68 n / N1 (%)	Inebilizumab vs. Placebo						p-value
			Odds Ratio		Risk Ratio		Risk Difference (%)		
			Pt Est	(95% CI)	Pt Est	(95% CI)	Pt Est	(95% CI)	
Events of \geq grade 3 severity ^a									
Age									0.1475
< 65 years	6 / 46 (13.0)	5 / 47 (10.6)	0.79	(0.24, 2.66)	0.82	(0.28, 2.36)	-2.41	(-16.67, 11.57)	0.7586
\geq 65 years	2 / 21 (9.5)	7 / 21 (33.3)	4.75	(0.94, 23.03)	3.50	(0.96, 13.85)	23.81	(-1.10, 47.28)	0.1300
Sex									0.5633
Male	6 / 49 (12.2)	9 / 39 (23.1)	2.15	(0.71, 6.44)	1.88	(0.76, 4.72)	10.83	(-5.07, 27.86)	0.2545
Female	2 / 18 (11.1)	3 / 29 (10.3)	0.92	(0.16, 5.13)	0.93	(0.20, 4.41)	-0.77	(-23.95, 17.73)	1.0000
Region									0.5131
US	1 / 14 (7.1)	2 / 7 (28.6)	5.20	(0.53, 48.23)	4.00	(0.59, 27.49)	21.43	(-10.49, 58.72)	0.2474
Non-US	7 / 53 (13.2)	10 / 61 (16.4)	1.29	(0.47, 3.55)	1.24	(0.53, 2.97)	3.19	(-10.62, 16.51)	0.7932

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95% CI for risk difference, risk ratio, and odds ratio was based on Miettinen-Nurminen (score) confidence limits without default bias correction factor; p-value was based on Fisher's exact test for association; interaction p-value was based on Zelen's exact test for equal odds ratios.

If Zero cell correction applied, 95% CI for risk difference, risk ratio, and odds ratio was based on the same confidence limits above after Zero cell correction; p-value was based on Fisher's exact test for association before Zero cell correction; interaction p-value was based on Breslow-Day test for homogeneity of odds ratios after Zero cell correction.

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Table 14-3.1.2.1.581. Subgroup Analysis: Summary of Treatment-emergent Adverse Events During Randomized-controlled Period (Safety Analysis Set)

Subgroup			Inebilizumab vs. Placebo						p-value
	Placebo	Inebilizumab	Odds Ratio		Risk Ratio		Risk Difference (%)		
	N = 67 n / N1 (%)	N = 68 n / N1 (%)	Pt Est	(95% CI)	Pt Est	(95% CI)	Pt Est	(95% CI)	
Region									
EU	2 / 26 (7.7)	5 / 20 (25.0)	4.00	(0.77, 20.09)	3.25	(0.81, 13.57)	17.31	(-3.90, 40.62)	0.2127
Non-EU	6 / 41 (14.6)	7 / 48 (14.6)	1.00	(0.32, 3.11)	1.00	(0.38, 2.65)	-0.05	(-15.94, 15.02)	1.0000
Region									0.2684
Asia	3 / 18 (16.7)	4 / 34 (11.8)	0.67	(0.15, 3.02)	0.71	(0.20, 2.63)	-4.90	(-29.08, 13.93)	0.6818
Non-Asia	5 / 49 (10.2)	8 / 34 (23.5)	2.71	(0.83, 8.74)	2.31	(0.86, 6.23)	13.33	(-2.58, 31.22)	0.1290
Region									1.0000
Japan	1 / 7 (14.3)	3 / 20 (15.0)	1.06	(0.12, 8.57)	1.05	(0.19, 6.97)	0.71	(-38.67, 26.34)	1.0000
Non-Japan	7 / 60 (11.7)	9 / 48 (18.8)	1.75	(0.62, 4.94)	1.61	(0.66, 3.90)	7.08	(-6.51, 21.84)	0.4147

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95% CI for risk difference, risk ratio, and odds ratio was based on Miettinen-Nurminen (score) confidence limits without default bias correction factor; p-value was based on Fisher's exact test for association; interaction p-value was based on Zelen's exact test for equal odds ratios.

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Table 14-3.1.2.1.581. Subgroup Analysis: Summary of Treatment-emergent Adverse Events During Randomized-controlled Period (Safety Analysis Set)

Subgroup	Placebo		Inebilizumab		Inebilizumab vs. Placebo					p-value
	N = 67 n / N1 (%)	N = 68 n / N1 (%)	Odds Ratio		Risk Ratio		Risk Difference (%)			
			Pt Est	(95% CI)	Pt Est	(95% CI)	Pt Est	(95% CI)		
Serum IgG4 concentrations at baseline										0.6055
< Median	3 / 29 (10.3)	7 / 30 (23.3)	2.64	(0.65, 10.46)	2.26	(0.71, 7.50)	12.99	(-6.74, 32.56)	0.2990	
≥ Median	4 / 31 (12.9)	4 / 29 (13.8)	1.08	(0.26, 4.41)	1.07	(0.32, 3.61)	0.89	(-17.50, 19.81)	1.0000	
First or subsequent IgG4-RD manifestation										0.6216
Newly diagnosed	4 / 31 (12.9)	4 / 31 (12.9)	1.00	(0.25, 4.06)	1.00	(0.30, 3.39)	0.00	(-18.14, 18.14)	1.0000	
Recurrent	4 / 36 (11.1)	8 / 37 (21.6)	2.21	(0.63, 7.63)	1.95	(0.68, 5.70)	10.51	(-7.00, 28.03)	0.3447	

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If Zero cell correction applied, 95% CI for risk difference, risk ratio, and odds ratio was based on the same confidence limits above after Zero cell correction; p-value was based on Fisher's exact test for association before Zero cell correction; interaction p-value was based on Breslow-Day test for homogeneity of odds ratios after Zero cell correction.

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5.7.3 Gesamtraten: SUE

Table 14-3.1.2.1.581. Subgroup Analysis: Summary of Treatment-emergent Adverse Events During Randomized-controlled Period (Safety Analysis Set)

Subgroup	Placebo N = 67 n / N1 (%)	Inebilizumab N = 68 n / N1 (%)	Inebilizumab vs. Placebo						p-value
			Odds Ratio		Risk Ratio		Risk Difference (%)		
			Pt Est	(95% CI)	Pt Est	(95% CI)	Pt Est	(95% CI)	
Serious ^b events									
Age									
< 65 years	4 / 46 (8.7)	4 / 47 (8.5)	0.98	(0.25, 3.82)	0.98	(0.28, 3.40)	-0.19	(-13.09, 12.57)	1.0000
≥ 65 years	2 / 21 (9.5)	8 / 21 (38.1)	5.85	(1.17, 28.05)	4.00	(1.12, 15.56)	28.57	(3.05, 51.85)	0.0670
Sex									1.0000
Male	4 / 49 (8.2)	6 / 39 (15.4)	2.05	(0.57, 7.31)	1.88	(0.61, 5.87)	7.22	(-6.46, 22.73)	0.3280
Female	2 / 18 (11.1)	6 / 29 (20.7)	2.09	(0.41, 10.12)	1.86	(0.49, 7.63)	9.58	(-14.93, 29.98)	0.6918
Region									0.5735
US	1 / 14 (7.1)	2 / 7 (28.6)	5.20	(0.53, 48.23)	4.00	(0.59, 27.49)	21.43	(-10.49, 58.72)	0.2474
Non-US	5 / 53 (9.4)	10 / 61 (16.4)	1.88	(0.62, 5.65)	1.74	(0.67, 4.63)	6.96	(-6.02, 19.71)	0.4057

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95% CI for risk difference, risk ratio, and odds ratio was based on Miettinen-Nurminen (score) confidence limits without default bias correction factor; p-value was based on Fisher's exact test for association; interaction p-value was based on Zelen's exact test for equal odds ratios.

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Table 14-3.1.2.1.581. Subgroup Analysis: Summary of Treatment-emergent Adverse Events During Randomized-controlled Period (Safety Analysis Set)

Subgroup			Inebilizumab vs. Placebo						p-value
	Placebo	Inebilizumab	Odds Ratio		Risk Ratio		Risk Difference (%)		
	N = 67 n / N1 (%)	N = 68 n / N1 (%)	Pt Est	(95% CI)	Pt Est	(95% CI)	Pt Est	(95% CI)	
Region									
EU	3 / 26 (11.5)	5 / 20 (25.0)	2.56	(0.58, 11.20)	2.17	(0.64, 7.50)	13.46	(-8.93, 37.45)	0.2674
Non-EU	3 / 41 (7.3)	7 / 48 (14.6)	2.16	(0.56, 8.22)	1.99	(0.60, 6.78)	7.27	(-6.82, 21.13)	0.3312
Region									0.5284
Asia	2 / 18 (11.1)	4 / 34 (11.8)	1.07	(0.20, 5.51)	1.06	(0.25, 4.71)	0.65	(-22.55, 18.15)	1.0000
Non-Asia	4 / 49 (8.2)	8 / 34 (23.5)	3.46	(1.00, 11.89)	2.88	(1.00, 8.44)	15.37	(-0.02, 32.99)	0.0626
Region									0.6130
Japan	0 / 7 (0.0)	4 / 20 (20.0)	4.09	(0.32, 46.14)	3.43	(0.42, 34.94)	15.18	(-21.54, 38.37)	0.5453
Non-Japan	6 / 60 (10.0)	8 / 48 (16.7)	1.80	(0.60, 5.38)	1.67	(0.64, 4.33)	6.67	(-6.25, 20.92)	0.3907

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IP = Investigational Product

N = Number of subjects in the analysis set; n = Number of subjects with observed data; N1 = Number of subjects in each subgroup level

^a Grade 1: Mild; Grade 2: Moderate; Grade 3: Severe; Grade 4: Life-threatening; Grade 5: Fatal^b Serious adverse event criteria: death, life-threatening, required inpatient hospitalization, prolongation of existing hospitalization, persistent or significant disability/incapacity, important medical event, congenital anomaly/birth defect (in the offspring of the subject).

95% CI for risk difference, risk ratio, and odds ratio was based on Miettinen-Nurminen (score) confidence limits without default bias correction factor; p-value was based on Fisher's exact test for association; interaction p-value was based on Zelen's exact test for equal odds ratios.

If Zero cell correction applied, 95% CI for risk difference, risk ratio, and odds ratio was based on the same confidence limits above after Zero cell correction; p-value was based on Fisher's exact test for association before Zero cell correction; interaction p-value was based on Breslow-Day test for homogeneity of odds ratios after Zero cell correction.

Program: /userdata/stat/amg335/igg4rd/20230068/analysis/germany_submission/tables/t-teaesum-rcp-sub.sas

Output: t14-03-001-002-001-581-teaesum-rcp-sub.rtf (Date Generated: 08JAN26:23:03:14) Source: csradam.adsl, csradam.adae

Table 14-3.1.2.1.581. Subgroup Analysis: Summary of Treatment-emergent Adverse Events During Randomized-controlled Period (Safety Analysis Set)

Subgroup	Placebo		Inebilizumab		Inebilizumab vs. Placebo					p-value
	N = 67 n / N1 (%)	N = 68 n / N1 (%)	Odds Ratio		Risk Ratio		Risk Difference (%)			
			Pt Est	(95% CI)	Pt Est	(95% CI)	Pt Est	(95% CI)		
Serum IgG4 concentrations at baseline										1.0000
< Median	3 / 29 (10.3)	7 / 30 (23.3)	2.64	(0.65, 10.46)	2.26	(0.71, 7.50)	12.99	(-6.74, 32.56)	0.2990	
≥ Median	2 / 31 (6.5)	5 / 29 (17.2)	3.02	(0.61, 14.65)	2.67	(0.65, 11.37)	10.79	(-6.27, 29.24)	0.2472	
First or subsequent IgG4-RD manifestation										0.6130
Newly diagnosed	2 / 31 (6.5)	6 / 31 (19.4)	3.48	(0.72, 16.34)	3.00	(0.76, 12.41)	12.90	(-4.35, 31.01)	0.2554	
Recurrent	4 / 36 (11.1)	6 / 37 (16.2)	1.55	(0.42, 5.63)	1.46	(0.48, 4.52)	5.11	(-11.64, 21.92)	0.7355	

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IP = Investigational Product

N = Number of subjects in the analysis set; n = Number of subjects with observed data; N1 = Number of subjects in each subgroup level

^a Grade 1: Mild; Grade 2: Moderate; Grade 3: Severe; Grade 4: Life-threatening; Grade 5: Fatal^b Serious adverse event criteria: death, life-threatening, required inpatient hospitalization, prolongation of existing hospitalization, persistent or significant disability/incapacity, important medical event, congenital anomaly/birth defect (in the offspring of the subject).

95% CI for risk difference, risk ratio, and odds ratio was based on Miettinen-Nurminen (score) confidence limits without default bias correction factor; p-value was based on Fisher's exact test for association; interaction p-value was based on Zelen's exact test for equal odds ratios.

If Zero cell correction applied, 95% CI for risk difference, risk ratio, and odds ratio was based on the same confidence limits above after Zero cell correction; p-value was based on Fisher's exact test for association before Zero cell correction; interaction p-value was based on Breslow-Day test for homogeneity of odds ratios after Zero cell correction.

Program: /userdata/stat/amg335/igg4rd/20230068/analysis/germany_submission/tables/t-teaesum-rcp-sub.sas

Output: t14-03-001-002-001-581-teaesum-rcp-sub.rtf (Date Generated: 08JAN26:23:03:14) Source: csradam.adsl, csradam.adae

5.7.4 Gesamtraten: Therapieabbruch aufgrund von UE

Table 14-3.1.2.1.581. Subgroup Analysis: Summary of Treatment-emergent Adverse Events During Randomized-controlled Period (Safety Analysis Set)

Subgroup	Placebo N = 67 n / N1 (%)	Inebilizumab N = 68 n / N1 (%)	Inebilizumab vs. Placebo						p-value
			Odds Ratio		Risk Ratio		Risk Difference (%)		
			Pt Est	(95% CI)	Pt Est	(95% CI)	Pt Est	(95% CI)	
Events leading to discontinuation of IP									NA
Age									NA
< 65 years	2 / 46 (4.3)	2 / 47 (4.3)	NA	NA	NA	NA	NA	NA	NA
≥ 65 years	1 / 21 (4.8)	4 / 21 (19.0)	NA	NA	NA	NA	NA	NA	NA
Sex									NA
Male	2 / 49 (4.1)	4 / 39 (10.3)	NA	NA	NA	NA	NA	NA	NA
Female	1 / 18 (5.6)	2 / 29 (6.9)	NA	NA	NA	NA	NA	NA	NA
Region									NA
US	0 / 14 (0.0)	2 / 7 (28.6)	NA	NA	NA	NA	NA	NA	NA
Non-US	3 / 53 (5.7)	4 / 61 (6.6)	NA	NA	NA	NA	NA	NA	NA

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IP = Investigational Product

N = Number of subjects in the analysis set; n = Number of subjects with observed data; N1 = Number of subjects in each subgroup level

^a Grade 1: Mild; Grade 2: Moderate; Grade 3: Severe; Grade 4: Life-threatening; Grade 5: Fatal

^b Serious adverse event criteria: death, life-threatening, required inpatient hospitalization, prolongation of existing hospitalization, persistent or significant disability/incapacity, important medical event, congenital anomaly/birth defect (in the offspring of the subject).

95% CI for risk difference, risk ratio, and odds ratio was based on Miettinen-Nurminen (score) confidence limits without default bias correction factor; p-value was based on Fisher's exact test for association; interaction p-value was based on Zelen's exact test for equal odds ratios.

If Zero cell correction applied, 95% CI for risk difference, risk ratio, and odds ratio was based on the same confidence limits above after Zero cell correction; p-value was based on Fisher's exact test for association before Zero cell correction; interaction p-value was based on Breslow-Day test for homogeneity of odds ratios after Zero cell correction.

Program: /userdata/stat/amg335/igg4rd/20230068/analysis/germany_submission/tables/t-teaesum-rcp-sub.sas

Output: t14-03-001-002-001-581-teaesum-rcp-sub.rtf (Date Generated: 08JAN26:23:03:14) Source: csradam.adsl, csradam.adae

Table 14-3.1.2.1.581. Subgroup Analysis: Summary of Treatment-emergent Adverse Events During Randomized-controlled Period (Safety Analysis Set)

Subgroup			Inebilizumab vs. Placebo						p-value
	Placebo	Inebilizumab	Odds Ratio		Risk Ratio		Risk Difference (%)		
	N = 67 n / N1 (%)	N = 68 n / N1 (%)	Pt Est	(95% CI)	Pt Est	(95% CI)	Pt Est	(95% CI)	
Region									NA
EU	2 / 26 (7.7)	3 / 20 (15.0)	NA	NA	NA	NA	NA	NA	NA
Non-EU	1 / 41 (2.4)	3 / 48 (6.3)	NA	NA	NA	NA	NA	NA	NA
Region									NA
Asia	1 / 18 (5.6)	1 / 34 (2.9)	NA	NA	NA	NA	NA	NA	NA
Non-Asia	2 / 49 (4.1)	5 / 34 (14.7)	NA	NA	NA	NA	NA	NA	NA
Region									NA
Japan	1 / 7 (14.3)	0 / 20 (0.0)	NA	NA	NA	NA	NA	NA	NA
Non-Japan	2 / 60 (3.3)	6 / 48 (12.5)	NA	NA	NA	NA	NA	NA	NA

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IP = Investigational Product

N = Number of subjects in the analysis set; n = Number of subjects with observed data; N1 = Number of subjects in each subgroup level

^a Grade 1: Mild; Grade 2: Moderate; Grade 3: Severe; Grade 4: Life-threatening; Grade 5: Fatal^b Serious adverse event criteria: death, life-threatening, required inpatient hospitalization, prolongation of existing hospitalization, persistent or significant disability/incapacity, important medical event, congenital anomaly/birth defect (in the offspring of the subject).

95% CI for risk difference, risk ratio, and odds ratio was based on Miettinen-Nurminen (score) confidence limits without default bias correction factor; p-value was based on Fisher's exact test for association; interaction p-value was based on Zelen's exact test for equal odds ratios.

If Zero cell correction applied, 95% CI for risk difference, risk ratio, and odds ratio was based on the same confidence limits above after Zero cell correction; p-value was based on Fisher's exact test for association before Zero cell correction; interaction p-value was based on Breslow-Day test for homogeneity of odds ratios after Zero cell correction.

Program: /userdata/stat/amg335/igg4rd/20230068/analysis/germany_submission/tables/t-teaesum-rcp-sub.sas

Output: t14-03-001-002-001-581-teaesum-rcp-sub.rtf (Date Generated: 08JAN26:23:03:14) Source: csradam.adsl, csradam.adae

Table 14-3.1.2.1.581. Subgroup Analysis: Summary of Treatment-emergent Adverse Events During Randomized-controlled Period (Safety Analysis Set)

Subgroup			Inebilizumab vs. Placebo						p-value
	Placebo	Inebilizumab	Odds Ratio		Risk Ratio		Risk Difference (%)		
	N = 67 n / N1 (%)	N = 68 n / N1 (%)	Pt Est	(95% CI)	Pt Est	(95% CI)	Pt Est	(95% CI)	
Serum IgG4 concentrations at baseline									NA
< Median	1 / 29 (3.4)	4 / 30 (13.3)	NA	NA	NA	NA	NA	NA	NA
≥ Median	2 / 31 (6.5)	1 / 29 (3.4)	NA	NA	NA	NA	NA	NA	NA
First or subsequent IgG4-RD manifestation									NA
Newly diagnosed	3 / 31 (9.7)	2 / 31 (6.5)	NA	NA	NA	NA	NA	NA	NA
Recurrent	0 / 36 (0.0)	4 / 37 (10.8)	NA	NA	NA	NA	NA	NA	NA

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IP = Investigational Product

N = Number of subjects in the analysis set; n = Number of subjects with observed data; N1 = Number of subjects in each subgroup level

^a Grade 1: Mild; Grade 2: Moderate; Grade 3: Severe; Grade 4: Life-threatening; Grade 5: Fatal

^b Serious adverse event criteria: death, life-threatening, required inpatient hospitalization, prolongation of existing hospitalization, persistent or significant disability/incapacity, important medical event, congenital anomaly/birth defect (in the offspring of the subject).

95% CI for risk difference, risk ratio, and odds ratio was based on Miettinen-Nurminen (score) confidence limits without default bias correction factor; p-value was based on Fisher's exact test for association; interaction p-value was based on Zelen's exact test for equal odds ratios.

If Zero cell correction applied, 95% CI for risk difference, risk ratio, and odds ratio was based on the same confidence limits above after Zero cell correction; p-value was based on Fisher's exact test for association before Zero cell correction; interaction p-value was based on Breslow-Day test for homogeneity of odds ratios after Zero cell correction.

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Output: t14-03-001-002-001-581-teaesum-rcp-sub.rtf (Date Generated: 08JAN26:23:03:14) Source: csradam.adsl, csradam.adae

Medizinischer Nutzen, medizinischer Zusatznutzen, Patientengruppen mit therap. bedeutsamem Zusatznutzen

5.7.5 UE nach SOC/PT

Table 14-3.1.2.2.581. Subgroup Analysis: Treatment-emergent Adverse Events With Incidence \geq 10% in Either Group, or at Least 10 Subjects in Total and With Incidence \geq 1% in Either Group, by System Organ Class and Preferred Term During Randomized-controlled Period (Safety Analysis Set)

System Organ Class	Preferred Term	Subgroup	Placebo		Inebilizumab		Inebilizumab vs. Placebo				p-value	
			N = 67 n / N1 (%)	N = 68 n / N1 (%)	Pt Est	Odds Ratio (95% CI)	Pt Est	Risk Ratio (95% CI)	Pt Est	Risk Difference (%) (95% CI)		
Infections and infestations	Age										0.6874	
		< 65 years	25 / 46 (54.3)	34 / 47 (72.3)	2.20	(0.93, 5.16)	1.33	(0.97, 1.87)	17.99	(-1.59, 36.37)	0.0872	
		\geq 65 years	11 / 21 (52.4)	17 / 21 (81.0)	3.86	(1.00, 14.68)	1.55	(1.00, 2.58)	28.57	(0.06, 53.15)	0.1001	
	Sex											0.2599
		Male	24 / 49 (49.0)	30 / 39 (76.9)	3.47	(1.38, 8.69)	1.57	(1.13, 2.23)	27.94	(7.66, 45.73)	0.0088	
		Female	12 / 18 (66.7)	21 / 29 (72.4)	1.31	(0.38, 4.56)	1.09	(0.74, 1.72)	5.75	(-19.94, 33.00)	0.7488	
	Region											0.6112
		US	3 / 14 (21.4)	4 / 7 (57.1)	4.89	(0.75, 32.41)	2.67	(0.83, 8.49)	35.71	(-6.55, 69.20)	0.1564	
		Non-US	33 / 53 (62.3)	47 / 61 (77.0)	2.03	(0.91, 4.56)	1.24	(0.97, 1.62)	14.79	(-2.05, 31.27)	0.1026	
	Region											1.0000
EU		15 / 26 (57.7)	15 / 20 (75.0)	2.20	(0.63, 7.58)	1.30	(0.84, 2.02)	17.31	(-10.67, 41.96)	0.3496		
	Non-EU	21 / 41 (51.2)	36 / 48 (75.0)	2.86	(1.18, 6.93)	1.46	(1.06, 2.12)	23.78	(3.79, 42.33)	0.0269		

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N = Number of subjects in the analysis set; n = Number of subjects with observed data; N1 = Number of subjects in each subgroup level

Coded using MedDRA version 26.1

95% CI for risk difference, risk ratio, and odds ratio was based on Miettinen-Nurminen (score) confidence limits without default bias correction factor; p-value was based on Fisher's exact test for association; interaction p-value was based on Zelen's exact test for equal odds ratios.

Program: /userdata/stat/amg335/igg4rd/20230068/analysis/germany_submission/tables/t-teae-ge-rcp-sub.sas

Output: t14-03-001-002-002-581-teae-ge10-rcp-sub.rtf (Date Generated: 08JAN26:23:03:52) Source: csradam.adsl, csradam.adae

Table 14-3.1.2.2.581. Subgroup Analysis: Treatment-emergent Adverse Events With Incidence \geq 10% in Either Group, or at Least 10 Subjects in Total and With Incidence \geq 1% in Either Group, by System Organ Class and Preferred Term During Randomized-controlled Period (Safety Analysis Set)

System Organ Class Preferred Term	Subgroup			Inebilizumab vs. Placebo						
		Placebo N = 67 n / N1 (%)	Inebilizumab N = 68 n / N1 (%)	Odds Ratio		Risk Ratio		Risk Difference (%)		p-value
				Pt Est	(95% CI)	Pt Est	(95% CI)	Pt Est	(95% CI)	
	Region									0.4187
	Asia	13 / 18 (72.2)	26 / 34 (76.5)	1.25	(0.36, 4.44)	1.06	(0.77, 1.60)	4.25	(-18.92, 30.61)	0.7472
	Non-Asia	23 / 49 (46.9)	25 / 34 (73.5)	3.14	(1.23, 7.97)	1.57	(1.09, 2.28)	26.59	(5.10, 45.23)	0.0234
	Region									1.0000
	Japan	4 / 7 (57.1)	15 / 20 (75.0)	2.25	(0.41, 12.74)	1.31	(0.76, 3.08)	17.86	(-18.23, 54.92)	0.6334
	Non-Japan	32 / 60 (53.3)	36 / 48 (75.0)	2.63	(1.16, 5.94)	1.41	(1.06, 1.90)	21.67	(3.41, 38.26)	0.0274
	Serum IgG4 concentrations at baseline									0.4389
	< Median	12 / 29 (41.4)	18 / 30 (60.0)	2.13	(0.76, 5.94)	1.45	(0.87, 2.51)	18.62	(-6.84, 41.80)	0.1964
	\geq Median	18 / 31 (58.1)	25 / 29 (86.2)	4.51	(1.31, 15.32)	1.48	(1.08, 2.16)	28.14	(5.60, 48.35)	0.0220

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N = Number of subjects in the analysis set; n = Number of subjects with observed data; N1 = Number of subjects in each subgroup level

Coded using MedDRA version 26.1

95% CI for risk difference, risk ratio, and odds ratio was based on Miettinen-Nurminen (score) confidence limits without default bias correction factor; p-value was based on Fisher's exact test for association; interaction p-value was based on Zelen's exact test for equal odds ratios.

Program: /userdata/stat/amg335/igg4rd/20230068/analysis/germany_submission/tables/t-teae-ge-rcp-sub.sas

Output: t14-03-001-002-002-581-teae-ge10-rcp-sub.rtf (Date Generated: 08JAN26:23:03:52) Source: csradam.adsl, csradam.adae

Table 14-3.1.2.2.581. Subgroup Analysis: Treatment-emergent Adverse Events With Incidence ≥ 10% in Either Group, or at Least 10 Subjects in Total and With Incidence ≥ 1% in Either Group, by System Organ Class and Preferred Term During Randomized-controlled Period (Safety Analysis Set)

System Organ Class	Preferred Term	Subgroup	Placebo		Inebilizumab		Inebilizumab vs. Placebo			p-value	
			N = 67	N = 68	Odds Ratio		Risk Ratio		Risk Difference (%)		
			n / N1 (%)	n / N1 (%)	Pt Est	(95% CI)	Pt Est	(95% CI)	Pt Est	(95% CI)	
		First or subsequent IgG4-RD manifestation								1.0000	
		Newly diagnosed	17 / 31 (54.8)	23 / 31 (74.2)	2.37	(0.82, 6.79)	1.35	(0.93, 2.04)	19.35	(-4.49, 41.26)	0.1839
		Recurrent	19 / 36 (52.8)	28 / 37 (75.7)	2.78	(1.04, 7.43)	1.43	(1.01, 2.11)	22.90	(0.93, 42.97)	0.0524

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N = Number of subjects in the analysis set; n = Number of subjects with observed data; N1 = Number of subjects in each subgroup level

Coded using MedDRA version 26.1

95% CI for risk difference, risk ratio, and odds ratio was based on Miettinen-Nurminen (score) confidence limits without default bias correction factor; p-value was based on Fisher's exact test for association; interaction p-value was based on Zelen's exact test for equal odds ratios.

Program: /userdata/stat/amg335/igg4rd/20230068/analysis/germany_submission/tables/t-teae-ge-rcp-sub.sas

Output: t14-03-001-002-002-581-teae-ge10-rcp-sub.rtf (Date Generated: 08JAN26:23:03:52) Source: csradam.adsl, csradam.adae

Table 14-3.1.2.2.582. Subgroup Analysis: Treatment-emergent Adverse Events With Incidence ≥ 10% in Either Group, or at Least 10 Subjects in Total and With Incidence ≥ 1% in Either Group, by Preferred Term of Asthenia During Randomized-controlled Period (Safety Analysis Set)

Preferred Term	Subgroup	Inebilizumab vs. Placebo								p-value
		Placebo	Inebilizumab	Odds Ratio		Risk Ratio		Risk Difference (%)		
		N = 67 n / N1 (%)	N = 68 n / N1 (%)	Pt Est	(95% CI)	Pt Est	(95% CI)	Pt Est	(95% CI)	
Asthenia	Age									
	< 65 years	6 / 46 (13.0)	1 / 47 (2.1)	NA	NA	NA	NA	NA	NA	NA
	≥ 65 years	2 / 21 (9.5)	1 / 21 (4.8)	NA	NA	NA	NA	NA	NA	NA
	Sex									
	Male	7 / 49 (14.3)	1 / 39 (2.6)	NA	NA	NA	NA	NA	NA	NA
	Female	1 / 18 (5.6)	1 / 29 (3.4)	NA	NA	NA	NA	NA	NA	NA
	Region									
	US	0 / 14 (0.0)	0 / 7 (0.0)	NA	NA	NA	NA	NA	NA	NA
	Non-US	8 / 53 (15.1)	2 / 61 (3.3)	0.19	(0.04, 0.84)	0.22	(0.05, 0.86)	-11.82	(-24.24, -1.58)	0.0429
	Region									
	EU	4 / 26 (15.4)	2 / 20 (10.0)	NA	NA	NA	NA	NA	NA	NA
	Non-EU	4 / 41 (9.8)	0 / 48 (0.0)	NA	NA	NA	NA	NA	NA	NA

Page 1 of 3

N = Number of subjects in the analysis set; n = Number of subjects with observed data; N1 = Number of subjects in each subgroup level

Coded using MedDRA version 26.1

95% CI for risk difference, risk ratio, and odds ratio was based on Miettinen-Nurminen (score) confidence limits without default bias correction factor; p-value was based on Fisher's exact test for association; interaction p-value was based on Zelen's exact test for equal odds ratios.

Program: /userdata/stat/amg335/igg4rd/20230068/analysis/germany_submission/tables/t-teae-ge10-rcp-sub-asthenia.sas

Output: t14-03-001-002-002-582-teae-ge10-rcp-sub-asthenia.rtf (Date Generated: 08JAN26:23:03:34) Source: csradam.adsl, csradam.adae

Table 14-3.1.2.582. Subgroup Analysis: Treatment-emergent Adverse Events With Incidence $\geq 10\%$ in Either Group, or at Least 10 Subjects in Total and With Incidence $\geq 1\%$ in Either Group, by Preferred Term of Asthenia During Randomized-controlled Period (Safety Analysis Set)

Preferred Term	Subgroup	Inebilizumab vs. Placebo								p-value
		Placebo	Inebilizumab	Odds Ratio		Risk Ratio		Risk Difference (%)		
		N = 67 n / N1 (%)	N = 68 n / N1 (%)	Pt Est	(95% CI)	Pt Est	(95% CI)	Pt Est	(95% CI)	
	Region									NA
	Asia	1 / 18 (5.6)	0 / 34 (0.0)	NA	NA	NA	NA	NA	NA	NA
	Non-Asia	7 / 49 (14.3)	2 / 34 (5.9)	NA	NA	NA	NA	NA	NA	NA
	Region									NA
	Japan	0 / 7 (0.0)	0 / 20 (0.0)	NA	NA	NA	NA	NA	NA	NA
	Non-Japan	8 / 60 (13.3)	2 / 48 (4.2)	0.28	(0.06, 1.25)	0.31	(0.08, 1.22)	-9.17	(-20.72, 2.25)	0.1799
	Serum IgG4 concentrations at baseline									NA
	< Median	5 / 29 (17.2)	2 / 30 (6.7)	NA	NA	NA	NA	NA	NA	NA
	\geq Median	2 / 31 (6.5)	0 / 29 (0.0)	NA	NA	NA	NA	NA	NA	NA

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N = Number of subjects in the analysis set; n = Number of subjects with observed data; N1 = Number of subjects in each subgroup level

Coded using MedDRA version 26.1

95% CI for risk difference, risk ratio, and odds ratio was based on Miettinen-Nurminen (score) confidence limits without default bias correction factor; p-value was based on Fisher's exact test for association; interaction p-value was based on Zelen's exact test for equal odds ratios.

Program: /userdata/stat/amg335/igg4rd/20230068/analysis/germany_submission/tables/t-teae-ge10-rcp-sub-asthenia.sas

Output: t14-03-001-002-002-582-teae-ge10-rcp-sub-asthenia.rtf (Date Generated: 08JAN26:23:03:34) Source: csradam.adsl, csradam.adae

Table 14-3.1.2.2.582. Subgroup Analysis: Treatment-emergent Adverse Events With Incidence $\geq 10\%$ in Either Group, or at Least 10 Subjects in Total and With Incidence $\geq 1\%$ in Either Group, by Preferred Term of Asthenia During Randomized-controlled Period (Safety Analysis Set)

Preferred Term	Subgroup	Inebilizumab vs. Placebo								p-value
		Placebo	Inebilizumab	Odds Ratio		Risk Ratio		Risk Difference (%)		
		N = 67 n / N1 (%)	N = 68 n / N1 (%)	Pt Est	(95% CI)	Pt Est	(95% CI)	Pt Est	(95% CI)	
	First or subsequent IgG4-RD manifestation									NA
	Newly diagnosed	4 / 31 (12.9)	0 / 31 (0.0)	NA	NA	NA	NA	NA	NA	NA
	Recurrent	4 / 36 (11.1)	2 / 37 (5.4)	NA	NA	NA	NA	NA	NA	NA

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N = Number of subjects in the analysis set; n = Number of subjects with observed data; N1 = Number of subjects in each subgroup level

Coded using MedDRA version 26.1

95% CI for risk difference, risk ratio, and odds ratio was based on Miettinen-Nurminen (score) confidence limits without default bias correction factor; p-value was based on Fisher's exact test for association; interaction p-value was based on Zelen's exact test for equal odds ratios.

Program: /userdata/stat/amg335/igg4rd/20230068/analysis/germany_submission/tables/t-teae-ge10-rcp-sub-asthenia.sas

Output: t14-03-001-002-002-582-teae-ge10-rcp-sub-asthenia.rtf (Date Generated: 08JAN26:23:03:34) Source: csradam.adsl, csradam.adae

5.7.6 SUE nach SOC/PT

Table 14-3.1.3.1.581. Subgroup Analysis: Treatment-emergent Serious Adverse Events With Incidence ≥ 5% in Either Group, or at Least 10 Subjects in Total and With Incidence ≥ 1% in Either Group, by System Organ Class and Preferred Term During Randomized-controlled Period (Safety Analysis Set)

System Organ Class Preferred Term Subgroup		Placebo N = 67 n / N1 (%)	Inebilizumab N = 68 n / N1 (%)	Inebilizumab vs. Placebo						
				Odds Ratio		Risk Ratio		Risk Difference (%)		
				Pt Est	(95% CI)	Pt Est	(95% CI)	Pt Est	(95% CI)	p-value
--- No data to report ---										

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N = Number of subjects in the analysis set; n = Number of subjects with observed data; N1 = Number of subjects in each subgroup level

Coded using MedDRA version 26.1

Serious adverse event criteria: death, life-threatening, required inpatient hospitalization, prolongation of existing hospitalization, persistent or significant disability/incapacity, important medical event, congenital anomaly/birth defect (in the offspring of the subject).

95% CI for risk difference, risk ratio, and odds ratio was based on Miettinen-Nurminen (score) confidence limits without default bias correction factor; p-value was based on Fisher's exact test for association; interaction p-value was based on Zelen's exact test for equal odds ratios.

Program: /userdata/stat/amg335/igg4rd/20230068/analysis/germany_submission/tables/t-tesae-ge5-rcp-sub.sas

Output: t14-03-001-003-001-581-tesae-ge5-rcp-sub.rtf (Date Generated: 08JAN26:21:39:50) Source: csradam.adsl, csradam.adae

5.7.7 Schwere UE (CTCAE Grad ≥ 3) nach SOC/PT

Table 14-3.1.2.3.581. Subgroup Analysis: Treatment-emergent Adverse Events of ≥ Grade 3 Severity With Incidence ≥ 5% in Either Group, or at Least 10 Subjects in Total and With Incidence ≥ 1% in Either Group, by System Organ Class and Preferred Term During Randomized-controlled Period (Safety Analysis Set)

System Organ Class Preferred Term		Subgroup	Inebilizumab vs. Placebo							
			Placebo N = 67 n / N1 (%)	Inebilizumab N = 68 n / N1 (%)	Odds Ratio		Risk Ratio		Risk Difference (%)	
			Pt Est	Pt Est	(95% CI)	Pt Est	(95% CI)	Pt Est	(95% CI)	p-value
--- No data to report ---										

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N = Number of subjects in the analysis set; n = Number of subjects with observed data; N1 = Number of subjects in each subgroup level

Coded using MedDRA version 26.1

Grade 1: Mild; Grade 2: Moderate; Grade 3: Severe; Grade 4: Life-threatening; Grade 5: Fatal

95% CI for risk difference, risk ratio, and odds ratio was based on Miettinen-Nurminen (score) confidence limits without default bias correction factor; p-value was based on Fisher's exact test for association; interaction p-value was based on Zelen's exact test for equal odds ratios.

Program: /userdata/stat/amg335/igg4rd/20230068/analysis/germany_submission/tables/t-teae-ge-rcp-sub.sas

Output: t14-03-001-002-003-581-teae-gr3-ge5-rcp-sub.rtf (Date Generated: 08JAN26:23:03:54) Source: csradam.adsl, csradam.adae